PMcardio

Instructions for Use (IFU)

for PMcardio 2.6

v1.0 - English

January 2023

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Read the Instructions for Use before using PMcardio

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1. Introduction

PMcardio is an AI-powered clinical assistant in the form of a mobile application empowering non-cardiologist healthcare professionals with advanced cardiovascular diagnostic capabilities and ensuring optimal patient management in medical practice or clinic, hospital, or EMS environment. We lay an emphasis on great user experience, data security, and proven clinical value, to doctors and patients alike.

Although primary care physicians and other healthcare professionals are often the first point of contact for patients, they are usually not trained to precisely diagnose cardiovascular diseases from ECG recordings and treat them accordingly. Even in simple cases, patients often have to be referred to cardiologists, lengthening the time to diagnosis and optimal management and burdening the healthcare system.

PMcardio allows physicians and other healthcare workers to scan paper-based ECG recordings. The scans are then digitized and waveform signals are extracted from the photo. PMcardio automatically evaluates the digitized signals and provides a diagnosis and in-depth interpretation of the ECG within seconds. In the last step, the user fills out further symptom-based questions and the clinical assistant generates personalized, disease-specific management recommendations and indicates further diagnostic or treatment procedures.

Additionally, PMcardio streamlines the patient journey and seamlessly bridges non-cardiologists and other healthcare workers to cardiologists, allowing them to securely exchange and interact with the AI-powered ECG reports and patient parameters to establish an immediate and adequate diagnosis and treatment plan, saving valuable time and providing a superior patient treatment flow.

PMcardio offers maximum compatibility and aids users with digitizing and analyzing standard 12-lead electrocardiograms (including 12 lead resting ECG devices, or ECG devices in ambulances) either printed on paper or captured from a monitor.

2. Warnings

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

3. PMcardio must not be used with other ECG formats as indicated in the format selection menu in the app and the section Supported Formats in this document.

3. Cautions

1. Ensure a permanent broadband Internet connection at all times of using PMcardio.
2. Ensure that the system time and date of the phone are not set to the future.
3. Ensure that you are logged in before attempting to use the device.
4. Ensure a sufficient amount of credits or availability of organizational profile before usage.
5. Do clean the camera lens of the smartphone before use.
6. Ensure good lighting conditions when using PMcardio and set the flashlight to automatic mode.
7. Ensure the correct setting of the paper speed (mm/s) and the voltage gain (mm/mV).
8. Additional diagnostic investigations other than the ones suggested by the app may be necessary.
9. PMcardio only detects the diagnoses listed in the section Clinical Safety and Performance in this document. Other diagnoses that are not identified by PMcardio might nevertheless be present.
10. Complete ALL patient history questions, if more than one diagnosis is detected to ensure accurate patient management/treatment recommendations.
11. The report has 90 days lifetime, after that it is not possible to edit or share it anymore.
12. 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, or failure to update the application as instructed.
13. DO NOT use PMcardio for analyzing ECG recording of low quality.
14. DO NOT use PMcardio for analyzing ECGs of patients with an active pacemaker.
15. DO NOT use PMcardio for analyzing ECGs with flatlines (disconnected leads).
16. DO NOT use PMcardio for analyzing exercise stress test ECG recordings.
17. DO NOT use PMcardio for analyzing ambulatory/Holter ECG recordings.
18. DO NOT rely on the sharing functionality in time-critical situations.
19. The diagnostic confidence levels for each diagnosis shall be interpreted as follows:
    a. Low confidence: PMcardio is slightly more confident that the patient has the diagnosis than that the patient does not have it.
    b. Medium confidence: PMcardio is more confident that the patient has the diagnosis than that the patient does not have it.
    c. High confidence: PMcardio is confident that the patient has the diagnosis.
20. Selecting incorrect answers to anamnestic questions may result in under- or overdiagnosis or under- or overtreatment of a patient.
21. After ECG analysis, the app may incorrectly identify cardiovascular conditions.
22. 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.
23. The overall average values of the ECG intervals may be inaccurate for ECG recordings of low quality.
24. It is the user's responsibility to restrict access to the application for persons other than the logged-in user.
25. The user must give PMcardio access to their smartphone camera to create a report.
26. The user must give PMcardio access to their contacts to share and consult reports with your colleagues.
27. The user must give PMcardio access to their push-notifications to receive notifications and updates on reports that they shared with one or more other users.
28. The user must give PMcardio access to their push-notifications and deactivate "no disturb"-mode to get notified if another user shared a report with them.

4. Hardware requirements

PMcardio can be downloaded from the Apple App Store and Google Play Store and runs on both iPhones and Android Smartphones. A list is provided below of the minimum hardware requirements necessary to use PMcardio:

- iPhone 8 or newer, Android smartphones with more than 2 GB of RAM.
- PMcardio is currently compatible with the following operating systems: Android 9.0 or newer, and from iOS 13.0 or newer.
- The user must continuously update the device software. If older software is used, the user may only be able to use the services to a limited extent or not at all.
- PMcardio requires a permanent broadband Internet connection.

5. Medical Purpose

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

6. Indications for use, Contra-indications and exclusions, intended users and patients

6.1. Indications for use

The PMcardio mobile application is intended for use by qualified healthcare professionals, for the assessment of Electrocardiograms in subjects over 18 years of age. PMcardio should be used in a professional healthcare environments and its use should not be limited to a specific patient population.

Indications for use include patients presenting with common cardiovascular symptoms, such as Chest pain, Palpitations, Shortness of breath, Syncope. Additionally, PMcardio should 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.

6.2. Contra-indications and exclusions

The use of PMcardio is not recommended for the management of pediatric patients or patients under the age of 18, due to different normal ranges for electrocardiographic measurements. The use of PMcardio is not recommended for the analysis of stress test ECG recordings and Holter recordings. Furthermore, it is not recommended to use PMcardio for the assessment of other waveform data such as electroencephalograms (EEGs) depicting electrical activity of the brain, due to different features of the waveform. The PMcardio mobile application is not for use in life-supporting or sustaining systems or ECG monitor and Alarm devices. PMcardio mobile application interpretation results are not intended to be the sole means of diagnosis. It is offered to physicians and clinicians on an advisory basis in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.

6.3. Intended users

The PMcardio mobile application is intended to be used by the following users:

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

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

- Physicians
- Non-Physician Health Care Professionals

6.4. Characterization of Patients

PMcardio is intended to be used as a standard tool to analyze and interpret standard 12-lead electrocardiograms recorded by healthcare professionals and physicians for patients over 18 years of age. 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

Furthermore, PMcardio may be used for patients of any gender, patient comorbidities or risk factors, physical properties, or social and cultural background.

7. Setting up PMcardio for the first time

1. Download the PMcardio app from the App Store or Google Play Store.
   - Be sure to use a compatible iOS or Android device, meeting the requirements in the section Hardware Requirements.
2. Log in with your given credentials. (It is needed to register through powerfulmedical.com first.)
3. Follow the on-screen instructions.

First use only: Make sure to enable push notifications to receive notifications and updates if someone shares a report with you and sends messages to you.

If it is your first time using the PMcardio app, follow the on-screen tutorial of the application.
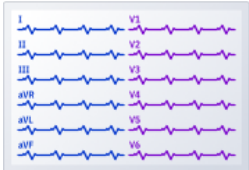
8. How to use PMcardio

Using PMcardio does not require any special training other than the initial tutorial as well as the instructions for use (this document).

8.1. ECG digitization

8.1.1. Supported ECG formats and layouts

PMcardio supports the analysis of the ECG formats below. You can change your preference at any time by clicking the "Change Format" button in the top right corner of the screen (see section 8.4. step 2 - 4). Make sure that the selected format matches the lead layout of the ECG in front of you.

ECG format	Lead layout
1 page, 6x2	

ECG format	Lead layout
1 page, 6x2, Rhythm lead	
1 page, 3x4	
1 page, 3x4, Rhythm lead	
1 page, 3x4, 2 rhythm leads	
1 page, 3x4, 3 rhythm leads	
1 page, 12x1	
2 pages, 6x1	
2 pages, 3x2	
4 pages, 3x1	

8.1.2. Digitization requirements

The following image formats of photos are supported:

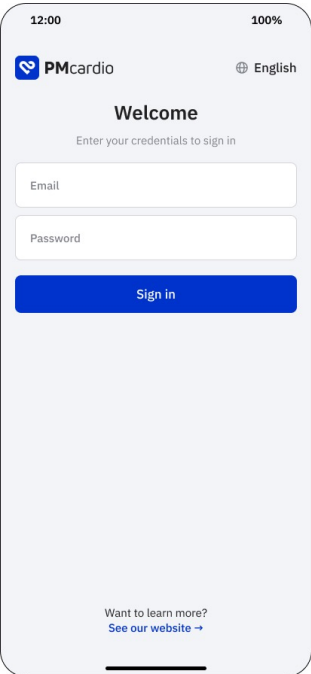- JPEG
- PNG

The ECG must meet the following requirements:

- ECG recording must contain a mm-grid
- the leads must be in a horizontal position on a photo
- all base-leads must be of equal length, and must not represent less than 2500 ms or more than 10000 ms
- all leads must be printed or displayed with the same voltage gain and paper speed across one ECG
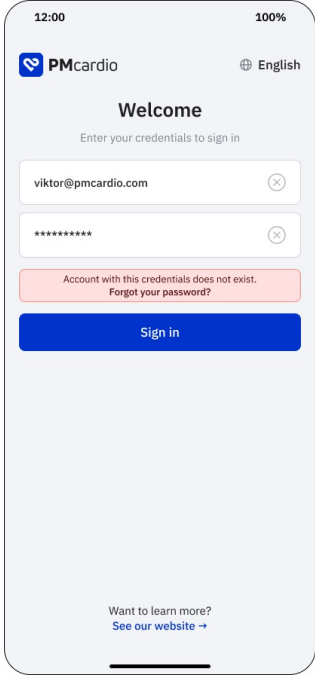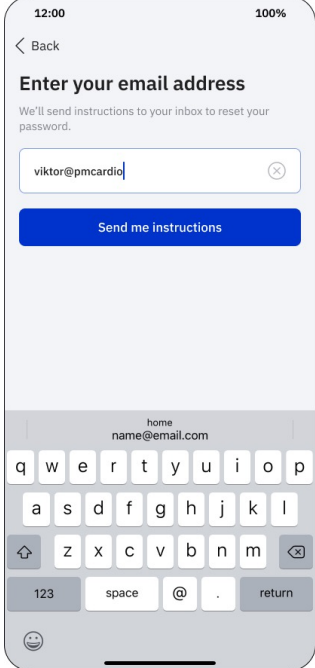
- the ECG must only include 12 leads that are related to one ECG, and no other measurements whatsoever, except the rhythm-leads
- all leads/signals must not have empty parts, i.e. they are printed from start to finish
- all leads/signals must have non-zero values, i.e. when a lead is not attached, diagnostics results might be affected
- ECG leads must be represented on a bright background, the grid color must be distinguishable from the background and the leads printed with a dark color

8.1.3. Unsupported ECG formats and characteristics

- Cabrera format
- ECG recording does not contain a grid
- grid is not present behind every recorded lead
- grid is partially missing (printer error, faded ink, damaged paper, gaps in the grid, among others) or barely visible
- grid has other granularity than 1 mm x 1 mm squares and has no/barely distinguishable lines forming 5 mm x 5 mm squares
- any of the leads is shorter than 2500 ms or longer than 10000 ms
- at least one lead has no activity measured or is missing
- leads are partially missing on the photo for more than 5 mm
- leads are barely visible
- leads are crossing other leads for more than 5mm
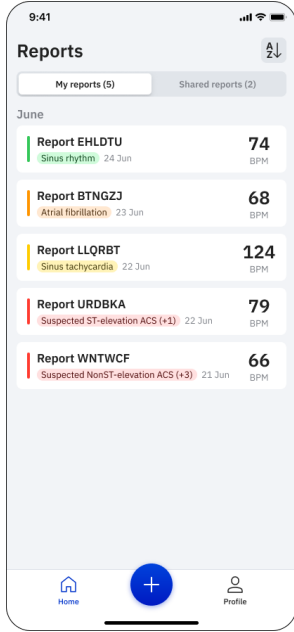- leads are not printed alongside the horizontal grid lines

8.2. Login

Step	Screen	Description
1. Sign in		Enter the e-mail address and password you have registered with. Press **"Sign in"** to proceed.

Step	Screen	Description
2. Wrong credentials		If the authentication fails, the screen will display a message indicating that you entered wrong credentials. Press the **"Forgot your password?** link, if you want to reset your password.
3. Forgotten password		Fill in the e-mail address to which the password reset instructions will be sent. Press the blue **"Send me instructions"** button to complete the action.

8.3. Home and profile screens

Step	Screen	Description

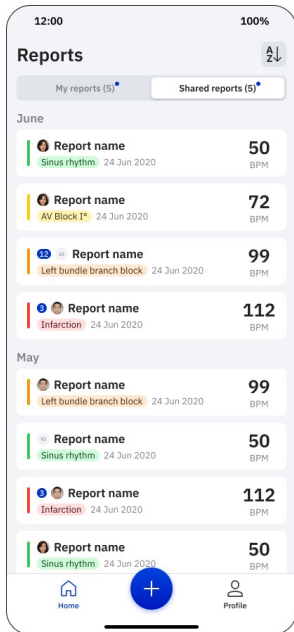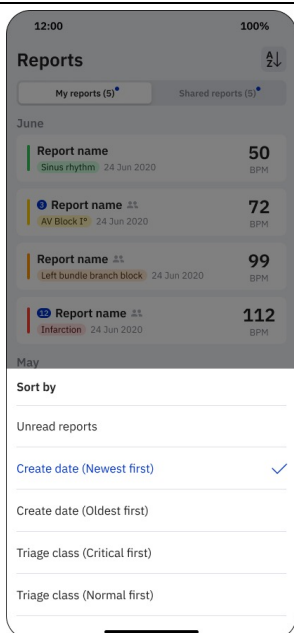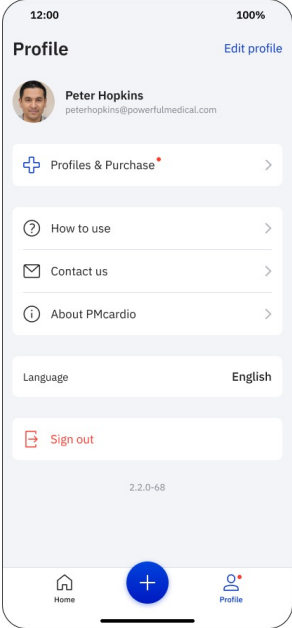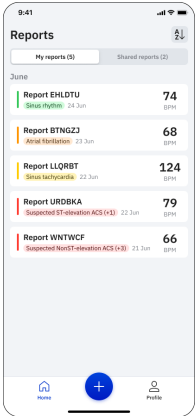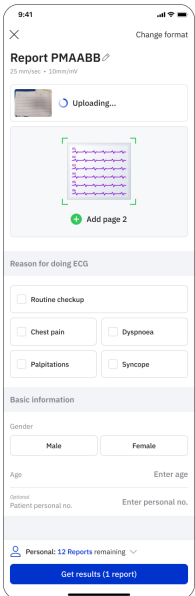| Step	Screen	Description
1. My reports		The **"My Reports"** tab on the Home screen is where all reports created by you are stored. Each report is marked with color representing the most severe diagnosis in report. The triage classes are following: - Acute (Red) - Subacute (Orange) - Abnormal (Yellow) - Normal (Green)
2. Shared reports		The **"Shared Reports"** tab on the Home screen is where all reports shared with you by other people are stored.
3. Sort reports		Press the ![icon] button in the top right corner to sort reports by Unread reports first, Date, or Triage class.
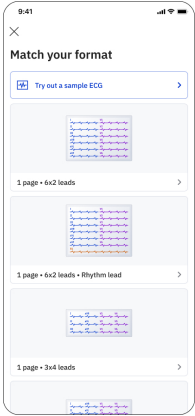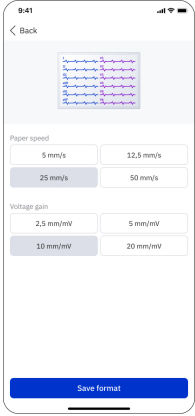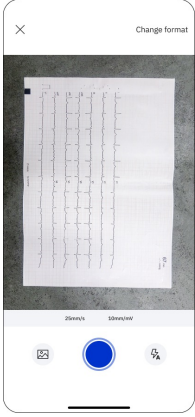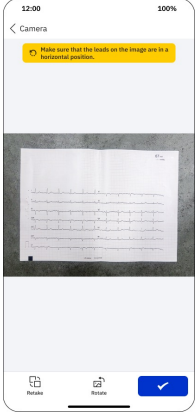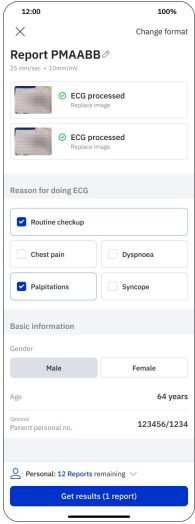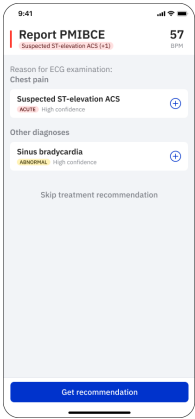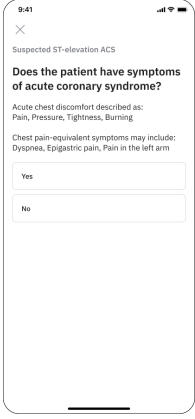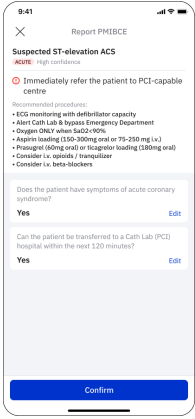
Step	Screen	Description
4. **Profile**		Press the 👤 **"Profile"** button at the bottom right to access the Profile screen.

8.4. ECG analysis

Step	Screen	Description
1. New report		Start the app and press the ⊕ button at the bottom middle to create a new report.
2. Add page(s)		Tap on ⊕ **"Add Page"** to open the camera window. If required, change the ECG format setting to match the format of the ECG that you want to analyze by tapping **"Change format"**.

Step	Screen	Description
3. Match your format		Select the drawing that matches the lead layout of the ECG you want to analyze. You can change your preference at any time by clicking the "Change Format" button in the top right corner during report creation. Note: There is also an option to try out a Sample ECG to see how the app works free of charge.
4. ECG settings		Select the correct paper speed and voltage gain that matches the settings of the ECG you want to analyze. Press **"Save format"** to continue.
5. Add an image		With the blue ⬤ capture button, take a picture of an ECG so all leads are visible or select an image from the gallery of the phone by pressing the 🖼 **Gallery** button. *First use only: Make sure to give PMcardio access to your camera.*
6. Rotation		If required, use the 🖼↺ **"Rotate"** button to rotate the image until the leads on the image area are in a horizontal position (see the screen). Press the ✔ to start uploading the ECG.

Step	Screen	Description
7. Add basic information		Fill in the reason for doing ECG, gender, and age. Make sure you have selected the correct profile under which you want to create the report and press the blue **"Get results"**. For additional information about the profile selection see the section *8.6. Institutions and purchasing*.
8. Get recommendation		Press the blue **"Get recommendation"** button to answer clinical questions of the most severe detected diagnosis. *Note: The recommendations are not available for the cardiac axis deviations.*
9. Answer the questions		Answer clinical questions to get a recommendation. If required, perform the immediate actions.
10. Answers summary		Review the answers and if required change the answer by pressing the **"Edit"** button. Press the blue **"Confirm"** button to get back to the report detail.

Step	Screen	Description
11. Report details		View the details of the report. Select the diagnosis to view recommendation details and answers to the clinical questions. Each diagnosis is marked with triage class representing severity of diagnosis. The triage classes are following: - Acute (Red) - Subacute (Orange) - Abnormal (Yellow) - Normal (Green) Select the **"Parameters"** to view all filled parameters. Select the **"Leads"** to view all digitized leads of the ECG. Press the ⬆ **"Export ECG"** button in the bottom menu to view the full PMcardio PDF Report with digitized ECG.
12. View PDF		View the PDF version of the report with all the important information. Press the ⬆ **Export** button to use the native sharing function of the phone (iOS and Android) or download PDF (iOS only). Press the **"Download"** button on Android phones to download a PDF file to the phone.
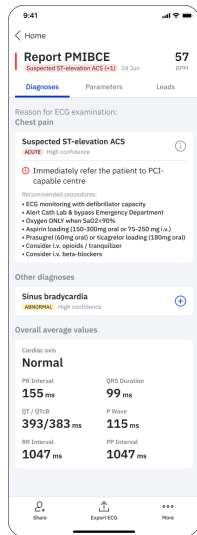
8.5. Sharing reports with colleagues

Step	Screen	Description
1. Open report		Start the app and open the report you want to share with your colleagues.
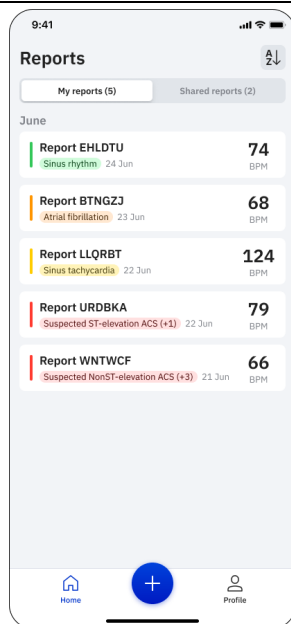
Step	Screen	Description

2. Sharing
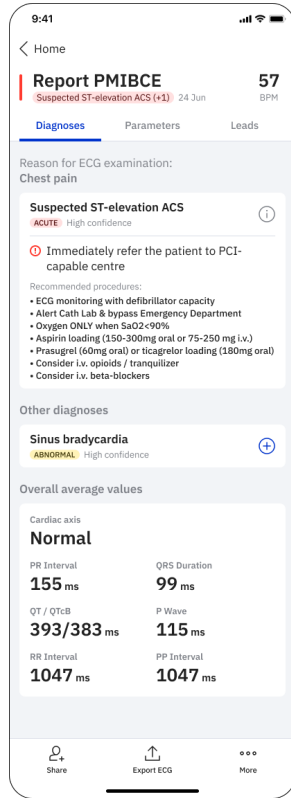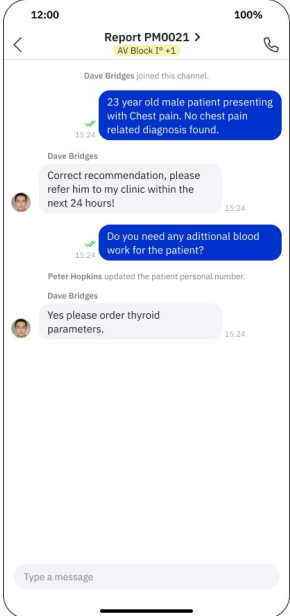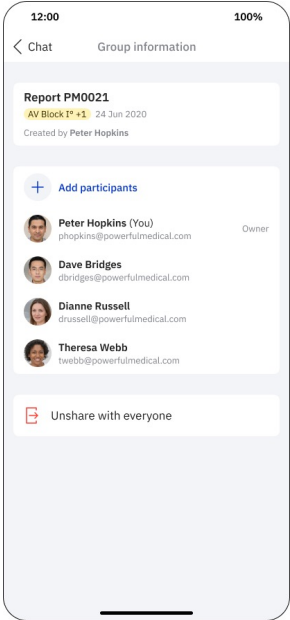
Press the 👤⁺ **"Share report"** button at the bottom left.

3. Select users
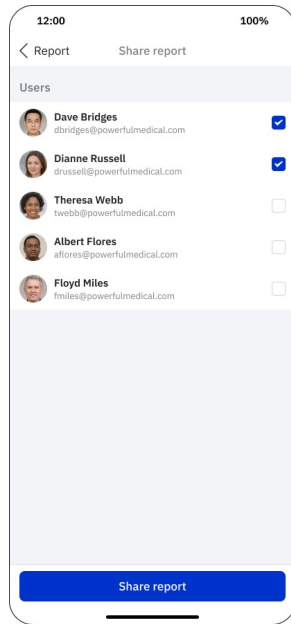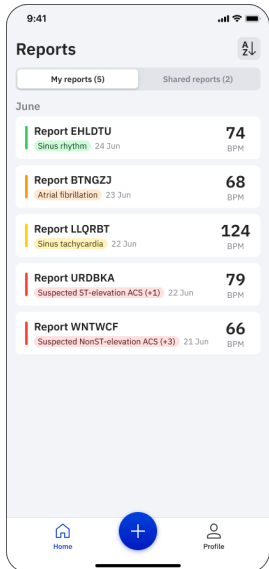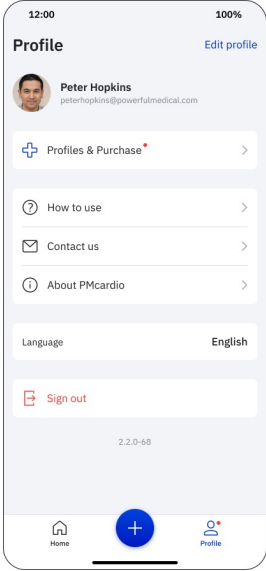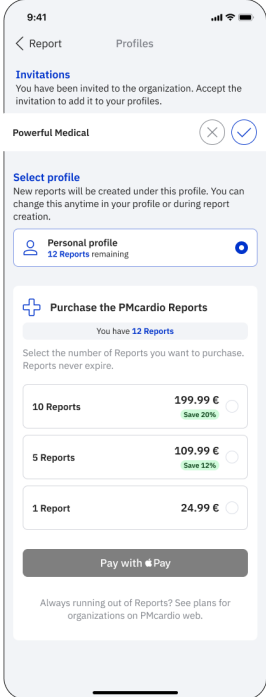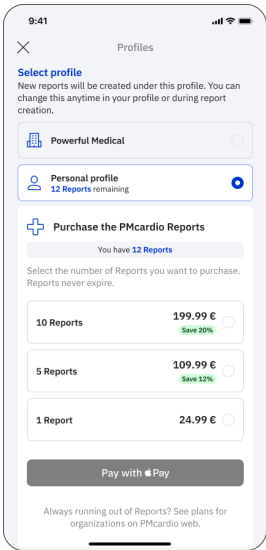
Select the users and press the blue **"Share report"** button.

First use only: PMcardio requires access to your contacts. The contacts in user's phone have to be stored in correct format - with international prefix (e. q. +421 for Slovakia or +44 for United Kingdom).

Step	Screen	Description
4. Chat securely		Chat securely with your colleagues! Select the name of the report to view details about the group.
5. Add/remove users		Press **"Add participants"** to add additional users to the chat. For removal, select the user you want to remove and press the option "Remove from group". Press **"Unshare with everyone"** to remove all users from the chat. They will no longer have access to your report.

8.6. Institutions and purchasing

Step	Screen	Description
1. Open profile		Start the app and press the 👤 **"Profile"** at the bottom right.

Step	Screen	Description
2. Profiles & Purchase		Press the **"Profiles & Purchase"** button. It is also possible to access this screen during the new report creation when you are selecting the profile under which is the new report created.
3. Invitations		Invitations to the institutions will be displayed here. Accept the invitation with the blue **"Check"** button or decline press the grey **"X"** button to decline it.
4. Profile selection		Select the profile under which you want to create new reports.

Step	Screen	Description
5. Purchase the PMcardio reports		With your personal profile selected, choose the number of reports you want to purchase. Press the dark **"Pay with Google Pay"** or **"Pay with Apple Pay"** button to open the confirmation window and then confirm the purchase.

8.7. Accessing help and support

8.7.1. Contacting Powerful Medical

Step	Screen	Description
1. Open profile		Start the app and press the 👤 **"Profile"** at the bottom right.

Step	Screen	Description
2. Contact us		Press the ✉ **"Contact us"** button.
3. Select a category		Select the category that suits your request best.
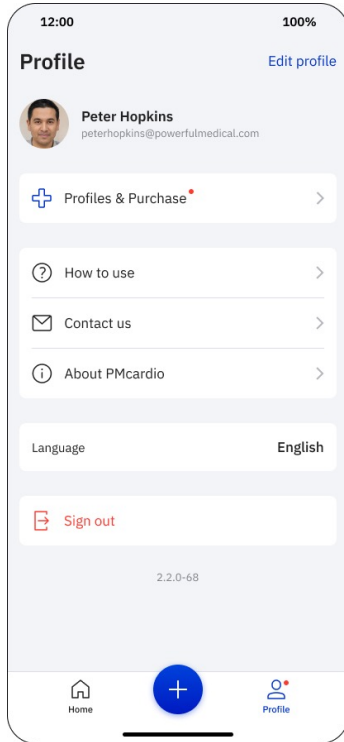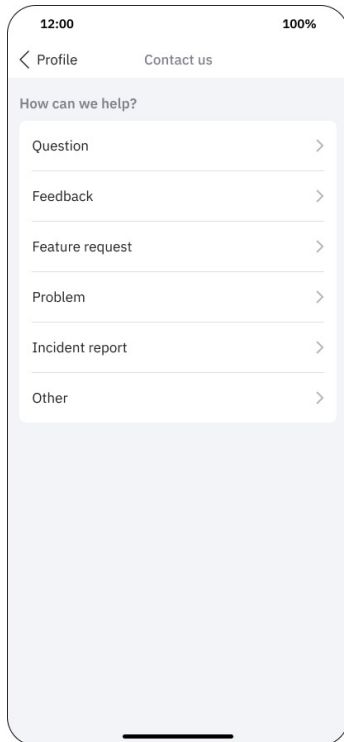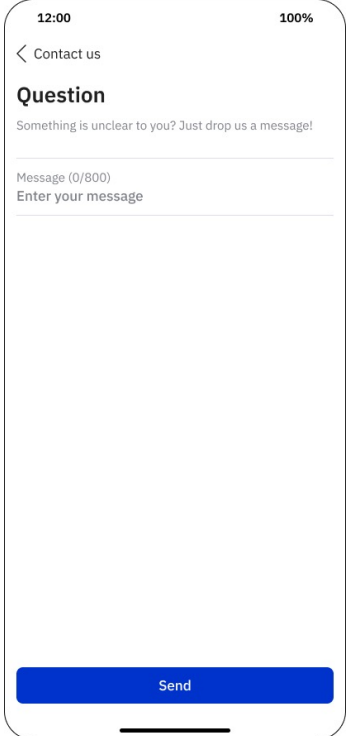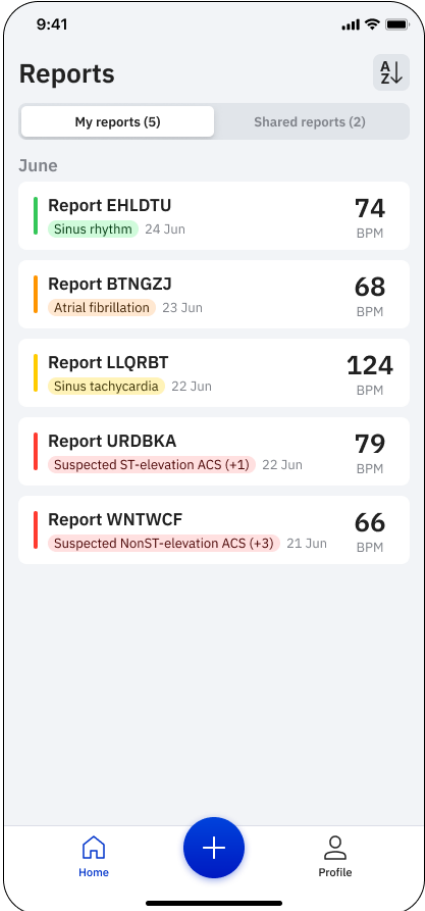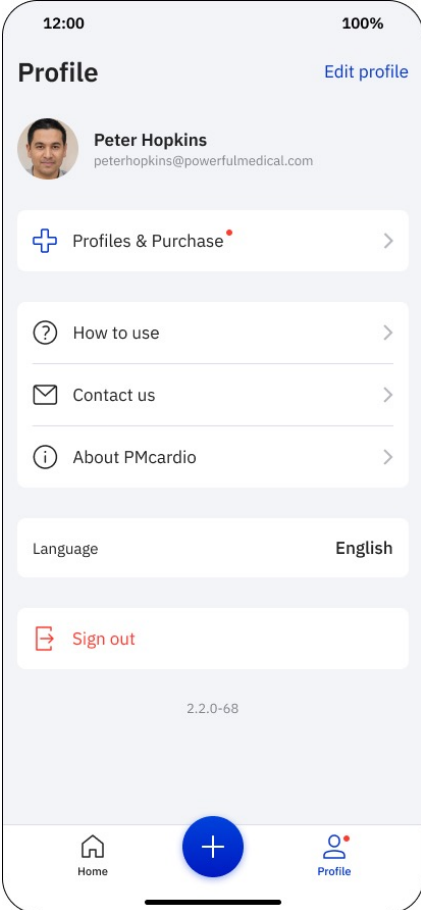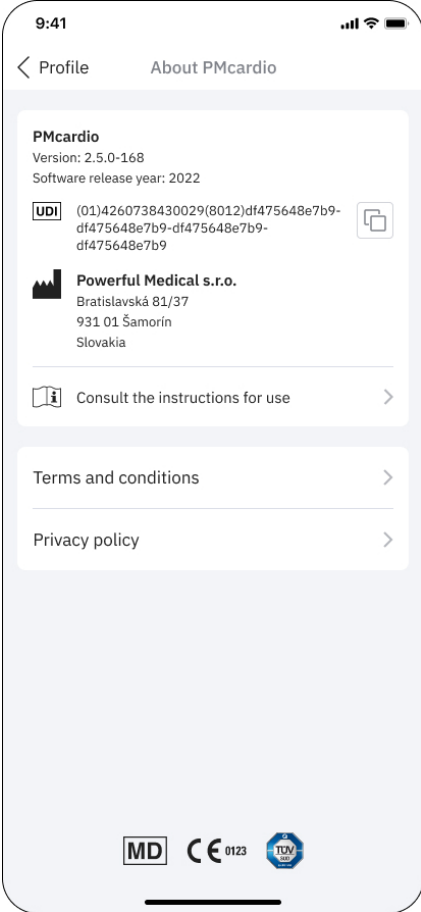
Step	Screen	Description
4. Write a message		Select the **"Enter your message"** field and type your message. Pred the blue **"Send"** button to send us the message. We will get back to you as soon as we can.

8.7.2. Accessing the instructions for use within PMcardio

Step	Screen	Description
1. Open profile		Start the app and press the ⚬ **"Profile"** at the bottom right.

Step	Screen	Description
2. About PMcardio		Press the (i) **"About PMcardio"** button.
3. Instructions for Use		Press the [book icon] **"Consult the instructions for use"** button to view the instructions for use, directly in PMcardio.

9. Supported Diagnoses, Clinical Safety, and Performance

A clinical evaluation report (CER) assessed the clinical performance, safety and benefit of the medical device software PMcardio manufactured by POWERFUL MEDICAL s.r.o. The PMcardio mobile application is intended to be used by qualified healthcare professionals, specifically in the primary care setting for the assessment of cardiovascular diseases using ECG data and disease specific patient history forms in subjects over 18 years of age. The PMcardio mobile application provides ECG signal digitization, processing, analysis and detection of 38 diagnostic categories consisting of rhythms, arrhythmias, heart blocks, infarctions and others. PMcardio is classified as a IIb device according to MDR Annex VIII.

In summary, the potential benefits for users and patients outweigh the potential risks. The risk-benefit ratio is positive if PMcardio is used in accordance with the intended purpose and the instructions for use of PMcardio. This clinical evaluation confirms that PMcardio complies with the general safety and performance requirements (GSPR) of the MDR.

As mentioned, PMcardio provides detection or classification of 38 diagnostic categories. The term classification means that the goal of the process is to attribute the correct label to each data instance (ECG); the process itself is known as the classifier, or classification algorithm. One crucial aspect naturally arises concerning the outcome of the classification process: how should the classifier performance be evaluated?

The previous IEC 60601-2-51 standard stated that manufacturers of ECG analysis programs and equipment should report the sensitivity, specificity, and positive predictive accuracy of the interpretive statements for each of the major diagnostic categories (see 60601-2-51(c) IEC 2003). However, for unclear reasons, these requirements for ECG interpretation (the old clause 50.102 in IEC 60601-2-51) have been completely removed from the updated IEC 60601-2-25:2011 standard. As such, this document will provide several statistical measures to report the diagnostic performance of PMcardio.

Several statistical rates are available to evaluate (binary) classifications and their confusion matrices. Despite being an essential trait in machine learning, no widespread consensus has been reached on a unified elective chosen measure yet. Accuracy and F1 score computed on confusion matrices have been (and still are) among the most popular adopted metrics in binary classification tasks. However, these statistical measures can dangerously show overoptimistic inflated results, especially on imbalanced datasets (2018 Dec 22. In: Kubben P, Dumontier M, Dekker A, editors. Fundamentals of Clinical Data Science [Internet]. Cham (CH): Springer; 2019. Chapter 8.).

To address this issue, we evaluated our results using a more reliable statistical metric that yields a high score only if the prediction performed well in all categories of the confusion matrix (true positives, false negatives, true negatives, and false positives), proportional to both the size of the positive elements and the size of the negative elements in the data set – the Matthews Correlation Coefficient (MCC) (Chicco and Jurman BMC Genomics (2020) 21:6 https://doi.org/10.1186/s12864-019-6413-7). In addition, for completeness, we also report the PPV, NPV, Specificity and Sensitivity for the 38 supported diagnoses.

To summarize, the following list of metrics is used for the evaluation of the performance:

Sensitivity

The ability of a test to correctly identify patients with a specified disease.

$$\text{TPR} = \frac{\text{TP}}{\text{P}} = \frac{\text{TP}}{\text{TP} + \text{FN}} = 1 - \text{FNR}$$

Specificity

The ability of a test to correctly identify people without a specified disease.

$$\text{TNR} = \frac{\text{TN}}{\text{N}} = \frac{\text{TN}}{\text{TN} + \text{FP}} = 1 - \text{FPR}$$

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.

$$\text{PPV} = \frac{\text{TP}}{\text{TP} + \text{FP}} = 1 - \text{FDR}$$

Negative Predictive Value (PPV)

The negative predictive value is the probability that following a negative test result, that individual will truly not have the specified disease.

$$\text{NPV} = \frac{\text{TN}}{\text{TN} + \text{FN}} = 1 - \text{FOR}$$

Matthews correlation coefficient (MCC)

A highly reliable statistical rate which produces a high score only if the prediction obtained good results in all of the four confusion matrix categories (true positives, false negatives, true negatives, and false positives), proportionally both to the size of positive elements and the size of negative elements in the dataset.

$$\text{MCC} = \frac{TP \times TN - FP \times FN}{\sqrt{(TP + FP)(TP + FN)(TN + FP)(TN + FN)}}$$

After the conversion of the diagnostic patterns to diagnoses, reporting the AUC metric is no longer possible since it cannot be calculated for boolean outputs that result from the combination of measurements and diagnostic patterns. Therefore, the reported performance metrics are PPV, NPV, Sensitivity, Specificity, and MCC. The metric is reported with the associated confidence intervals (CI) for each metric.

9.1. Supported diagnostic patterns detected by the AI-algorithms

Pattern	PPV - 2.5 s	NPV - 2.5 s	Sensitivity - 2.5 s	Specificity - 2.5 s	MCC - 2.5 s	F1 - 2.5 s	PPV - 5 s	NPV - 5 s	Sensitivity - 5 s	Specificity - 5 s	MCC - 5 s	F1 - 5 s
Sinus rhythm	0.912 (0.896-0.928)	0.995 (0.991-0.999)	0.99 (0.984-0.996)	0.952 (0.94-0.964)	0.924 (0.915-0.932)	0.949 (0.936-0.962)	0.93 (0.915-0.945)	0.992 (0.987-0.997)	0.985 (0.978-0.992)	0.962 (0.951-0.973)	0.934 (0.926-0.941)	0.956 (0.944-0.968)
Paced rhythm	0.976 (0.967-0.985)	0.963 (0.952-0.974)	0.876 (0.857-0.895)	0.993 (0.988-0.998)	0.903 (0.892-0.913)	0.923 (0.908-0.938)	0.97 (0.96-0.98)	0.98 (0.972-0.988)	0.935 (0.921-0.949)	0.991 (0.986-0.996)	0.938 (0.931-0.945)	0.952 (0.94-0.964)
Atrial fibrillation	0.903 (0.886-0.92)	0.995 (0.991-0.999)	0.974 (0.965-0.983)	0.979 (0.971-0.987)	0.925 (0.916-0.933)	0.937 (0.923-0.951)	0.984 (0.977-0.991)	0.993 (0.988-0.998)	0.964 (0.953-0.975)	0.997 (0.994-1.0)	0.969 (0.965-0.972)	0.974 (0.965-0.983)
Atrial flutter	0.973 (0.964-0.982)	0.986 (0.979-0.993)	0.912 (0.896-0.928)	0.996 (0.992-1.0)	0.933 (0.925-0.94)	0.942 (0.929-0.955)	0.975 (0.966-0.984)	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)
Other rhythm	0.918 (0.902-0.934)	0.978 (0.97-0.986)	0.842 (0.821-0.863)	0.989 (0.983-0.995)	0.863 (0.848-0.877)	0.879 (0.86-0.898)	0.92 (0.904-0.936)	0.98 (0.972-0.988)	0.863 (0.843-0.883)	0.989 (0.983-0.995)	0.876 (0.862-0.889)	0.89 (0.872-0.908)
Premature complex	0.994 (0.986-1.0)	0.88 (0.847-0.913)	0.864 (0.829-0.899)	0.995 (0.988-1.0)	0.866 (0.838-0.889)	0.924 (0.897-0.951)	0.994 (0.986-1.0)	0.958 (0.938-0.978)	0.957 (0.936-0.978)	0.995 (0.988-1.0)	0.952 (0.941-0.961)	0.975 (0.959-0.991)
2nd Degree AV Block, type Wenckebach	1.0 (1.0-1.0)	0.853 (0.822-0.884)	0.172 (0.139-0.205)	1.0 (1.0-1.0)	0.383 (0.306-0.455)	0.294 (0.254-0.334)	0.857 (0.826-0.888)	0.951 (0.932-0.97)	0.759 (0.722-0.796)	0.974 (0.96-0.988)	0.769 (0.731-0.802)	0.805 (0.77-0.84)
Higher degree AV blocks	0.729 (0.69-0.768)	0.9 (0.874-0.926)	0.843 (0.811-0.875)	0.818 (0.784-0.852)	0.645 (0.591-0.693)	0.782 (0.746-0.818)	0.892 (0.865-0.919)	0.851 (0.82-0.882)	0.714 (0.675-0.753)	0.95 (0.931-0.969)	0.702 (0.655-0.744)	0.793 (0.758-0.828)
Right Bundle Branch Block	0.942 (0.922-0.962)	1.0 (1.0-1.0)	1.0 (1.0-1.0)	0.969 (0.954-0.984)	0.956 (0.948-0.963)	0.97 (0.956-0.984)	0.902 (0.877-0.927)	0.991 (0.983-0.999)	0.983 (0.972-0.994)	0.947 (0.928-0.966)	0.912 (0.897-0.925)	0.941 (0.921-0.961)
Left Bundle Branch Block	0.989 (0.98-0.998)	0.986 (0.976-0.996)	0.974 (0.961-0.987)	0.994 (0.987-1.0)	0.971 (0.966-0.975)	0.981 (0.969-0.993)	0.989 (0.98-0.998)	0.972 (0.958-0.986)	0.947 (0.928-0.966)	0.994 (0.987-1.0)	0.951 (0.942-0.958)	0.968 (0.953-0.983)
Left Anterior Fascicular Block	0.944 (0.923-0.965)	0.94 (0.919-0.961)	0.871 (0.841-0.901)	0.975 (0.961-0.989)	0.865 (0.84-0.886)	0.906 (0.88-0.932)	0.953 (0.934-0.972)	0.957 (0.939-0.975)	0.91 (0.884-0.936)	0.978 (0.965-0.991)	0.899 (0.88-0.915)	0.931 (0.908-0.954)
Left Posterior Fascicular Block	0.963 (0.946-0.98)	0.981 (0.969-0.993)	0.963 (0.946-0.98)	0.981 (0.969-0.993)	0.944 (0.933-0.953)	0.963 (0.946-0.98)	0.958 (0.94-0.976)	0.928 (0.905-0.951)	0.852 (0.82-0.884)	0.981 (0.969-0.993)	0.859 (0.833-0.881)	0.902 (0.875-0.929)
Atrial enlargement	0.977 (0.962-0.992)	0.92 (0.894-0.946)	0.959 (0.94-0.978)	0.955 (0.935-0.975)	0.906 (0.887-0.922)	0.968 (0.951-0.985)	0.968 (0.951-0.985)	0.984 (0.972-0.996)	0.993 (0.985-1.0)	0.932 (0.907-0.957)	0.938 (0.925-0.949)	0.98 (0.966-0.994)
Suspected ventricular hypertrophy	0.933 (0.906-0.96)	0.98 (0.965-0.995)	0.982 (0.968-0.996)	0.924 (0.895-0.953)	0.91 (0.889-0.927)	0.957 (0.935-0.979)	0.933 (0.906-0.96)	0.967 (0.948-0.986)	0.971 (0.953-0.989)	0.924 (0.895-0.953)	0.897 (0.874-0.916)	0.951 (0.928-0.974)
ST-Elevation ACS	0.914 (0.886-0.942)	0.986 (0.974-0.998)	0.981 (0.967-0.995)	0.935 (0.911-0.959)	0.908 (0.889-0.924)	0.946 (0.924-0.968)	0.899 (0.869-0.929)	0.995 (0.988-1.0)	0.994 (0.986-1.0)	0.922 (0.895-0.949)	0.905 (0.885-0.921)	0.944 (0.921-0.967)
NonST-Elevation ACS	0.946 (0.924-0.968)	0.926 (0.9-0.952)	0.8 (0.76-0.84)	0.982 (0.969-0.995)	0.826 (0.792-0.855)	0.867 (0.833-0.901)	0.948 (0.926-0.97)	0.936 (0.912-0.96)	0.827 (0.79-0.864)	0.982 (0.969-0.995)	0.846 (0.815-0.872)	0.883 (0.851-0.915)
Extreme R-axis deviation	1.0 (1.0-1.0)	0.95 (0.925-0.975)	0.759 (0.711-0.807)	1.0 (1.0-1.0)	0.849 (0.814-0.878)	0.863 (0.824-0.902)	0.981 (0.966-0.996)	0.996 (0.989-1.0)	0.981 (0.966-0.996)	0.996 (0.989-1.0)	0.977 (0.971-0.982)	0.981 (0.966-0.996)

Pattern	PPV - 2.5 s	NPV - 2.5 s	Sensitivity - 2.5 s	Specificity - 2.5 s	MCC - 2.5 s	F1 - 2.5 s	PPV - 5 s	NPV - 5 s	Sensitivity - 5 s	Specificity - 5 s	MCC - 5 s	F1 - 5 s
Left R-axis deviation	0.935 (0.907-0.963)	0.916 (0.885-0.947)	0.791 (0.745-0.837)	0.976 (0.959-0.993)	0.808 (0.765-0.844)	0.857 (0.818-0.896)	0.986 (0.973-0.999)	0.921 (0.891-0.951)	0.802 (0.757-0.847)	0.995 (0.987-1.0)	0.851 (0.817-0.879)	0.885 (0.849-0.921)
Normal R-axis	0.82 (0.777-0.863)	0.983 (0.968-0.998)	0.971 (0.952-0.99)	0.889 (0.854-0.924)	0.831 (0.792-0.863)	0.889 (0.854-0.924)	0.823 (0.78-0.866)	0.994 (0.985-1.0)	0.99 (0.979-1.0)	0.889 (0.854-0.924)	0.848 (0.813-0.877)	0.899 (0.865-0.933)
Right R-axis deviation	0.823 (0.78-0.866)	0.988 (0.976-1.0)	0.944 (0.918-0.97)	0.956 (0.933-0.979)	0.854 (0.82-0.882)	0.879 (0.842-0.916)	0.98 (0.964-0.996)	0.98 (0.964-0.996)	0.907 (0.874-0.94)	0.996 (0.989-1.0)	0.931 (0.914-0.945)	0.942 (0.916-0.968)

9.2. Supported ECG measurements detected by the AI-algorithms

Measurement	Mean Difference (ms) - 2.5 s	Standard Deviation (ms) - 2.5 s	Evaluation - 2.5 s	Mean Difference (ms) - 5 s	Standard Deviation (ms) - 5 s	Evaluation - 5 s
PDuration	4.13	6.308	Pass	5.196	6.564	Pass
PRInterval	-2.63	6.903	Pass	-3.413	7.343	Pass
QRSDuration	1.587	5.678	Pass	1.707	6.179	Pass
QTInterval	-2.609	11.047	Pass	-4.076	10.705	Pass
RRInterval	0.228	13.651	Pass	-0.457	7.639	Pass

Measurement name	Definition
P Wave	`PDuration` if none of `afib_p`, `aflut_p`, `otherhy_p` Patterns predicted, otherwise `0`.
Heart Rate	`60000/RRInterval` if nonzero RRInterval, otherwise `0`.
PP Interval	`rr_interval` if none of `afib_p`, `aflut_p`, `otherhy_p`, `avblock2w_p`, `avblockhd_p` Patterns predicted, otherwise `0`.
QTc Time	`QTInterval / sqrt(RR interval in seconds)` (based on the Bazett formula (Bazett, H.C. (1920) An Analysis of the Time-Relations of Electrocardiograms. Heart, 7, 353-370.)).

9.3. Supported diagnoses based on a combination of the above

Diagnosis	Explanation
Sinus bradycardia	Sinus bradycardia diagnosis is a combination of the Sinus rhythm diagnostic pattern, and low heart rate prediction derived from the RRInterval measurement.
Sinus rhythm	Sinus rhythm diagnosis is a combination of the Sinus rhythm diagnostic pattern, and standard (not high or low) heart rate prediction derived from the RRInterval measurement.
Sinus tachycardia	Sinus tachycardia diagnosis is a combination of the Sinus rhythm diagnostic pattern, and high heart rate prediction derived from the RRInterval measurement.
Paced rhythm	Paced rhythm diagnosis is derived from the Paced rhythm diagnostic pattern.
Atrial fibrillation	Atrial fibrillation diagnosis is a combination of the Atrial fibrillation diagnostic pattern, and standard (not high or low) heart rate prediction derived from the RRInterval measurement.
Atrial fibrillation - rapid	Atrial fibrillation - rapid diagnosis is a combination of the Atrial fibrillation diagnostic pattern, and high heart rate prediction derived from the RRInterval measurement.
Atrial fibrillation - slow	Atrial fibrillation - slow diagnosis is a combination of the Atrial fibrillation diagnostic pattern, and low heart rate prediction derived from the RRInterval measurement.
Atrial flutter	Atrial flutter diagnosis is a combination of the Atrial flutter diagnostic pattern, and standard (not high or low) heart rate prediction derived from the RRInterval measurement.
Atrial flutter - rapid	Atrial flutter - rapid diagnosis is a combination of the Atrial flutter diagnostic pattern, and high heart rate prediction derived from the RRInterval measurement.
Atrial flutter - slow	Atrial flutter - slow diagnosis is a combination of the Atrial flutter diagnostic pattern, and low heart rate prediction derived from the RRInterval measurement.
Supraventricular tachycardia	Supraventricular tachycardia diagnosis is a combination of the Other rhythm (Ventricular/Junctional) diagnostic pattern, heart rate threshold derived from the RRInterval measurement, and QRSDuration threshold.

Diagnosis	Explanation
Suspected junctional rhythm	Suspected junctional rhythm diagnosis is a combination of the Other rhythm (Ventricular/Junctional) diagnostic pattern, standard (not high or low) heart rate derived from the RRInterval measurement, and QRSDuration threshold.
Suspected junctional bradycardia	Suspected junctional bradycardia diagnosis is a combination of the Other rhythm (Ventricular/Junctional) diagnostic pattern, low heart rate derived from the RRInterval measurement, and QRSDuration threshold.
Suspected accelerated junctional rhythm	Suspected accelerated junctional rhythm diagnosis is a combination of the Other rhythm (Ventricular/Junctional) diagnostic pattern, high heart rate derived from the RRInterval measurement, and QRSDuration threshold.
Wide QRS rhythm	Wide QRS rhythm diagnosis is a combination of the Other rhythm (Ventricular/Junctional) diagnostic pattern, standard (not high or low) heart rate derived from the RRInterval measurement, and QRSDuration threshold.
Idioventricular rhythm	Idioventricular rhythm diagnosis is a combination of the Other rhythm (Ventricular/Junctional) diagnostic pattern, low heart rate derived from the RRInterval measurement, and QRSDuration threshold.
Wide QRS tachycardia	Wide QRS tachycardia diagnosis is a combination of the Other rhythm (Ventricular/Junctional) diagnostic pattern, high heart rate derived from the RRInterval measurement, and QRSDuration threshold.
Premature complex	Premature complexes diagnosis is derived from the Premature complex diagnostic pattern.
1st degree AV block	1st degree AV block diagnosis is derived from the PRInterval measurement threshold.
2nd degree AV block, type Wenckebach	2nd degree AV block, type Wenckebach diagnosis is derived from the 2nd degree AV block, type Wenckebach diagnostic pattern.
Higher degree AV block	Higher degree AV block diagnosis is derived from the Higher degree AV block diagnostic pattern.
Complete right bundle branch block	Complete right bundle branch block diagnosis is derived from the Right Bundle Branch Block diagnostic pattern and QRSDuration measurement threshold.
Incomplete right bundle branch block	Incomplete right bundle branch block diagnosis is derived from the Right Bundle Branch Block diagnostic pattern and QRSDuration measurement threshold.
Complete left bundle branch block	Complete left bundle branch block diagnosis is derived from the Left Bundle Branch Block diagnostic pattern and QRSDuration measurement threshold.
Incomplete left bundle branch block	Incomplete left bundle branch block diagnosis is derived from the Left Bundle Branch Block diagnostic pattern and QRSDuration measurement threshold.
Nonspecific intraventricular conduction delay	Nonspecific intraventricular conduction delay diagnosis is derived from the QRSDuration measurement threshold.
Left anterior fascicular block	Left anterior fascicular block diagnosis is derived from the Left anterior fascicular block diagnostic pattern.
Left posterior fascicular block	Left posterior fascicular block diagnosis is derived from the Left posterior fascicular block diagnostic pattern.
Bifascicular block (RBBB + LAFB)	Bifascicular block (RBBB + LAFB) diagnosis is derived from the Right Bundle Branch Block diagnostic pattern, Left anterior fascicular block diagnostic pattern, and QRSDuration measurement threshold.
Bifascicular block (RBBB + LPFB)	Bifascicular block (RBBB + LAFB) diagnosis is derived from the Right Bundle Branch Block diagnostic pattern, Left posterior fascicular block diagnostic pattern, and QRSDuration measurement threshold.
Trifascicular block (RBBB + LAFB + AVBLOCK1)	Trifascicular block (RBBB + LAFB + AVBLOCK1) diagnosis is derived from the Right Bundle Branch Block diagnostic pattern, Left anterior fascicular block diagnostic pattern, PRInterval measurement threshold and QRSDuration measurement threshold.
Trifascicular block (RBBB + LPFB + AVBLOCK1)	Trifascicular block (RBBB + LPFB + AVBLOCK1) is derived from the Right Bundle Branch Block diagnostic pattern, Left posterior fascicular block diagnostic pattern, PRInterval measurement threshold and QRSDuration measurement threshold.
Suspected long QT syndrome	Suspected long QT syndrome diagnosis is derived from the QTInterval measurement threshold.
Suspected short QT syndrome	Suspected short QT syndrome diagnosis is derived from the QTInterval measurement threshold.
Suspected atrial enlargement	Suspected atrial enlargement diagnosis is derived from the Atrial enlargement diagnostic pattern and Sinus rhythm diagnostic pattern.
Suspected ventricular hypertrophy	Suspected ventricular hypertrophy diagnosis is derived from the Ventricular hypertrophy diagnostic pattern.
Suspected ST-elevation ACS	Suspected ST-elevation ACS diagnosis is derived from the ST-elevation ACS diagnostic pattern.

Diagnosis	Explanation
Suspected NonST-elevation ACS	Suspected NonST-elevation ACS diagnosis is derived from the NonST-elevation ACS diagnostic pattern.

9.4. Unsupported diagnoses by the AI-algorithms

- 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
- Any other not explicitly supported diagnosis

9.5. Clinical benefits of PMcardio

ID	Clinical Benefit
CB1	Patients receive prompt ECG diagnostic recommendations from a spectrum of 38 cardiac pathologies while in a primary or emergency care setting.
CB2	Patients receive diagnostic recommendations with a high degree of accuracy.
CB3	Patients receive improved ECG diagnostics at the primary care level.
CB4	Patients receive appropriate, guideline-compliant clinical management recommendations for diagnoses detected from their 12-lead ECG.
CB5	Patients receive an in-depth, analysis of their 12-lead ECGs in the context of their clinical symptoms.
CB6	Patients receive clinical management recommendations according to the most up-to-date clinical practice guidelines, already at the first point of contact.

10. Residual risks and undesirable side-effects

1. **Misclassification**: The detection and classification is related to confidence intervals, thus especially for low confidence intervals a misclassification or misinterpretation of the ECG, resulting in under- or overdiagnosis, might be possible.
2. **Loss of service**: PMcardio's services or parts of its functions may be interrupted or unavailable due to technical problems (e.g. cybersecurity attacks, system errors, connectivity issues), incorrect use or internet outages. An internet connection is required at all times. In case of time-critical decisions in an environment with poor connectivity, uploading an ECG report, analyzing, and consultation with other users may be delayed or even fail altogether.
3. **Wrong information provided by the user**: The answers requested by the anamnestic questions in the app are used to further narrow down the diagnosis and establish immediate patient management recommendations. Inadequate information provided by the user may result in inappropriate patient management recommendations.
4. **Wrong format or ECG settings selected**: The correct selection of the format and the respective settings of the ECG is crucial to allow for a correct analysis and diagnosis of the ECG. Selecting the wrong format may lead to erroneous output or a misinterpretation of the ECG recording.

11. Environmental specification

Use Environment	Lighting	Sound/Noise (ambient and intermittent)	Climate	Social environment, social interactions, work organization	Typical equipment used (in conjunction with the medical device)/Connectivity	Distractions and interruptions
Professional healthcare environment (practices of primary care physicians, internal medicine doctors, cardiologists and hospitals)	· Adequate lighting conditions preferred · If insufficient lighting would result in low quality images, the app will automatically activate the smartphone flashlight	· Ambient or intermittent due to colleagues and other patients being in adjacent rooms	· No restrictions or specifications regarding the climate	· Colleagues or other patients might be in adjacent rooms or on the corridor · Normal stress level (GP-environment) · Elevated stress level (Hospital-/EMS-environment)	· Stable wireless internet connection (Wi-Fi or cellular) · Available ECG printout or monitor that displays such · iOS and Android smartphone · 12-lead ECG recording in either digital form or paper-form	· Noises or chatter from other treatment rooms · Nurse or assistant entering the room · Other patients knocking on door or asking a question · Phone ringing · Environmental noises

12. Expected service life

The expected Service life of PMcardio is 3 years.

13. Updating and decommissioning PMcardio

PMcardio can be updated exclusively through the Apple App Store and Google Playstore. The user is informed about new updates, incl. new features, as well as service and security patches, and updates to the instruction for use via email. It is the responsibility of the user to keep the PMcardio application updated to the latest version.

To delete PMcardio, follow the respective instructions of your operating system (i.e. iOS or Android) to delete applications. In order to delete your account and all your data, please contact support@powerfulmedical.com.

14. Troubleshooting

| Problem	Solution
I'm unable to take a picture of an ECG. My camera is not working.	If you want to take pictures of the ECGs, you have to allow PMcardio to access the camera in your system settings.
I cannot see any contacts when I want to share a report.	If you want to see which of your contacts are using PMcardio and access sharing of the reports, you have to allow PMcardio to access your contacts in your system settings. Make sure the contacts in your phone are stored in required format with international prefix (e. q. +421 for Slovakia or +44 for United Kingdom).
My colleagues are sending me messages but I don't see the notifications.	If you want to see the notifications when someone messages or shares a report with you, you have to allow PMcardio to send you the Push notifications in your system settings.
I tried to digitize an ECG and I got a "Wrong format chosen" error.	If you get the "Wrong format" error 1. Make sure that the selected format matches the layout of the ECG in front of you and try again. 2. Make sure that the ECG on the picture is sharp and visible.
I tried to digitize an ECG and I got a "Digitized leads are too short" error.	If you get the "Digitized leads are too short" error, please try again and make sure that the lighting conditions are good and the ECG leads are fully visible and longer than 2500ms.
I tried to digitize an ECG and I got a "No ECG paper detected" error.	If you get the "No ECG paper detected" error, please try again and make sure that all edges of the ECG paper are visible and the photo is sharp.

Problem	Solution
I tried to digitize an ECG and I got a "Wrong rotation" error.	If you get the "Wrong rotation" error, please try again and make sure that the leads are in the horizontal position.
I tried to digitize an ECG and I got a "Leads missing parts" error.	If you get the "Leads missing parts" error, please try again and make sure that the lighting conditions are good and the ECG leads are fully visible.
I tried to digitize an ECG and I got a "Wrong lead number detected" error.	If you get the "Missing leads" error, please try again and make sure that you capture whole ECG with all leads.
I tried to digitize an ECG and I got a "Digitization failed" error.	If you get the "Digitization failed" error, please try to digitize the ECG again. If the problem persists, we probably don't support the format.
I can see gaps in the digitized signals in the exported PDF.	If you can see that some parts of the digitized signals are missing, please try to digitize the ECG again. If the problem persists, the quality of the signals may be too low.
I accidentally declined an invitation to the organization.	If you decline the invitation and want to get it again, you have to contact the responsible person for the organization and ask them to resend the invitation.
I tried to purchase credits and I got an "Oh no!" error.	If you get the "Oh no!" error, please try to purchase credits again. If the problem persists, please contact support@powerfulmedical.com.
I purchased credits and I got a "Pending purchase" information message.	If you get the "Pending purchase" information message, the purchase is not processed immediately and you have to wait. If the purchase is successful, you get the "PMcardio Report credits received" information message.
I purchased credits and I got a "Purchase failed" information message.	If you get the "Purchase failed" information message, please try to purchase credits again. If the problem persists, please contact support@powerfulmedical.com.
I need a printed version of the manual.	Contact support@powerfulmedical.com for a printed copy of this manual. We will provide a printed copy within 7 days at no additional costs.
Is the manual available in another language?	This manual is currently only available in English.

15. Reporting

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.

16. Labels

The following symbols are used in the labeling of PMcardio.

Symbol	Description
	Consult instructions for use
	Manufacturer of the medical device
CE 0123	European conformity mark
MD	Medical device
UDI	Unique device identifier

17. Information

Name of the medical device	PMcardio

Manufacturer of the medical device	POWERFUL MEDICAL s.r.o. Bratislavská 81/37, 931 01 Šamorín, Slovakia www.powerfulmedical.com
Version of the instructions for use	1.0
Corresponding version of the the medical device	2.6
Date of publication of Instructions for Use	January 2023
Basic-UDI-DI	426073843PMcardio0001H2
UDI-DI (iOS)	4260738430043
UDI-DI (Android)	4260738430050
CE Mark	CE 0123
Contact manufacturer	www.powerfulmedical.com support@powerfulmedical.com