PMcardio®
for Individuals

OMI AI ECG Model

Instructions for Use

Rev 1.0 - English

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Read the Instructions for Use before using OMI AI ECG Model

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1. Introduction

The OMI AI ECG Model is an artificial intelligence-based model providing an accurate diagnosis of STEMI and STEMI-equivalents in patients presenting with chest pain or symptoms equivalent to acute coronary syndrome. The device leverages deep learning algorithms trained on thousands of ECGs from patients with suspect acute coronary syndrome. The device is only intended to analyze ECG recordings generated from adults.

2. Warnings and precautions

2.1. Warnings

1. A negative interpretation result does not rule-out follow-up testing.
2. DO NOT use for analyzing other waveform data such as electroencephalograms (EEGs) depicting the electrical activity of the brain.
3. The device has not been tested for pediatric patients or patients under the age of 18.
4. Read instructions for use before using the device.

2.2. Precautions

1. The OMI AI ECG Model only detects the indications listed in the section 4.1. Supported ECG diagnoses in the instructions for use. Other indications that are not identified by OMI AI ECG Model might nevertheless be present.
2. A negative interpretation result does not guarantee that the patient is not experiencing a cardiovascular event, abnormal rhythm, or other health conditions when no serious diagnoses are detected.
3. Additional diagnostic investigations other than the ones suggested by the device may be necessary.
4. The OMI AI ECG Model does not detect all types of acute myocardial infarctions, it only detects myocardial infarction of a culprit artery with an occlusive or flow limiting lesion.
5. 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.
6. DO NOT use the OMI AI ECG Model for analyzing ECG recordings of low quality.
7. DO NOT use the OMI AI ECG Model for analyzing ECG recordings that do not satisfy the device's input requirements.
8. DO NOT use the OMI AI ECG Model for analyzing ECGs with flatlines (disconnected leads).
9. DO NOT use the OMI AI ECG Model for analyzing exercise stress test ECG recordings.
10. DO NOT use the OMI AI ECG Model for analyzing ambulatory/Holter ECG recordings.
11. The OMI AI ECG Model may incorrectly identify cardiovascular conditions.
12. The OMI AI ECG Model may have lower sensitivity in Black (African or African American) patients.
13. The OMI AI ECG Model may have lower sensitivity for ECGs with QRS duration ≥ 120ms.
14. The OMI AI ECG Model may have lower sensitivity for patients with Left Bundle Branch Block (LBBB).
15. Always ensure correct placements of the leads to avoid limb lead reversal.
16. The OMI AI ECG Model is not intended for the detection of chronic total occlusions as a culprit for present symptoms.

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 product provides diagnostic recommendations for patients aged 18 years and above.

3.2. Indications for use

The OMI AI ECG Model is designed to assist qualified healthcare professionals in interpreting 12-lead resting ECGs. The OMI AI ECG Model is intended for use by healthcare professionals trained in ECG interpretation in a professional healthcare environment such as a pre-hospital or in-hospital environment. The indications for use focus on the assessment of ECGs of adult patients presenting with symptoms of acute coronary syndrome for the presence of occlusion myocardial infarction (OMI). The OMI 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.

3.3. Contra-indications and exclusions

- The OMI AI ECG Model is not intended to be used for general ECG interpretation in patients without clinical suspicion of acute coronary syndrome.
- The use of OMI AI ECG Model is not intended to be used for pediatric patients (patients under the age of 18), due to different normal ranges for electrocardiographic measurements.
- The OMI AI ECG Model is not intended for the analysis of stress test ECG recordings and Holter recordings.
- The OMI AI ECG Model is not intended for the assessment of other waveform data such as electroencephalograms (EEGs) depicting electrical activity from the brain, due to different features of the waveform.
- The OMI AI ECG Model is not for use in life-supporting or sustaining systems or ECG monitors and Alarm devices.
- Interpretation results of the OMI AI ECG Model are not intended to be the sole means of diagnosis. It is offered to qualified healthcare professionals trained in ECG interpretation on an advisory basis in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.
- The OMI AI ECG Model is not intended for the detection of chronic total occlusions as a culprit for present symptoms.

3.4. Intended users

The device is intended to be used by qualified healthcare professionals trained in ECG interpretation.

3.5. Characterization of Patients

The device is designed to serve as a tool for analyzing ECGs of adult patients with acute coronary syndrome, recorded by healthcare professionals and/or physicians, in order to detect the presence of acute coronary

occlusion (occlusion myocardial infarction, OMI for short).

These patients will typically seek medical attention by calling an ambulance or presenting to the emergency department or consulting their general practitioner (GP).

The following types of adult patients can be considered:

- Patients with mild anginal symptoms or atypical symptoms (such as nausea, shortness of breath or sweating) presenting to the emergency department, ambulance (emergency medical services) or GP
- Patients with symptoms of acute coronary syndrome (such as chest pain) or equivalent symptoms presenting to the emergency department, ambulance (emergency medical services)or GP

The device can be used for patients with any sex, patient comorbidities or risk factors, physical properties or social and cultural background.

4. Supported Diagnoses, Clinical Safety, and Performance

4.1. Supported ECG diagnoses

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

Diagnosis
STEMI/STEMI equivalent detected
STEMI/STEMI equivalent not detected

4.2. Unsupported diagnoses by the AI-algorithms

The OMI AI ECG Model does not support any other indications than the indications listed in the 4.1. Supported ECG diagnoses section. Non-presence of these indications does not exclude the presence of the conditions that are not detected by the OMI AI ECG Model.

4.3. Clinical benefits of OMI AI ECG Model

ID	**Clinical Benefit**
CB1	Physician-determined necessity for early referral to cathlab is more accurately identified by the OMI AI model compared to the STEMI criteria.
CB2	Patients with OMI detected by the OMI AI model have on average a 3-hour shorter time to diagnosis compared to patients detected by STEMI criteria.
CB3	The OMI AI model reduced false negatives by 70% compared to the STEMI criteria.
CB4	The OMI AI model increased true positives by 145% compared to the STEMI criteria.

4.4. Device performance

Performance Testing Methods:

The performance testing methodology for the OMI AI ECG Model was constructed to evaluate the machine learning based algorithm's performance in detecting Occlusion Myocardial Infarction (OMI) and its operational robustness across a range of clinical scenarios. The validation dataset for final model validation was obtained from four geographically diverse sites, one of them in Europe and three geographically diverse sites in the United States. It includes 3,991 ECGs from 2,785 patients (age 62±14 years, 67% males, 28.9% of ECGs with OMI) cases with ground truth established by using invasive coronary angiography data and laboratory test results.

A primary analysis assessed the model's diagnostic capability through metrics that reflect its sensitivity and specificity on an individual ECG basis. This involved a detailed examination of the algorithm's interpretive accuracy on a granular level, focusing on each ECG record within the dataset to determine the algorithm's predictive success or failure against the established ground truth—which, in this context, was invasively confirmed coronary artery occlusion.

Various subgroup analyses were conducted to assess the algorithm's performance across distinct patient demographics, including age ranges, gender categories, and race and ethnicity. Additional subgroup assessments centered on the diversity of hardware and included an array of ECG devices from multiple manufacturers. Moreover, subgroup analyses were conducted across different clinical and electrocardiographic conditions, evaluating the algorithm's responsiveness to cardiac rhythm abnormalities and other heart-related variances anticipated in real-world settings. The testing extended to determining the robustness of the AI model against various types and levels of noise, and input variations representative of real-life signal quality issues encountered in clinical practice. These included, among others, muscle tremor interference, electrical noise, baseline wander, and signal truncation.

Each of these testing methods was vital in crafting a multidimensional landscape of performance evaluation, aimed at ensuring that the OMI AI ECG Model is tested to operate effectively across the complex spectrum of clinical conditions and patient populations.

Summary of Performance:

The performance validation testing demonstrated the OMI AI ECG Model provides accurate representation of key processing parameters under a range of clinically relevant perturbations associated with the intended use of the software. The validation dataset for final model validation was obtained from four geographically diverse sites, one of them in Europe and three geographically diverse sites in the United States. It includes 3,991 ECGs from 2,785 patients (age 62±14 years, 67% males, 28.9% of ECGs with OMI) cases with ground truth established by using invasive coronary angiography data and laboratory test results. The analysis passed with Sensitivity = 0.739 (0.701-0.776) and Specificity = 0.944 (0.933-0.955). The cases were split Male: ~68%, Female: ~32% with an age range of 18-95 years. Males constituted a predominant proportion of the cases, reflecting the general trend of higher coronary artery disease prevalence in males.

Subgroup analyses revealed the model's performance was consistent across ECG devices from different manufacturers, affirming its broad utility. Notably, within the electrocardiographic subgroups, the model effectively identified OMI across various rhythms and conduction disturbances. A reduced sensitivity of the OMI AI ECG Model was observed among black patients, those with QRS duration greater than 120 milliseconds, and patients presenting with left bundle branch block (LBBB). This is in line with expectations due to the complex nature of ECG interpretation within these groups. Hardware testing incorporated a range of 12-lead ECG machines spanning multiple manufacturers to ensure compatibility and reliability, and demonstrated robust performance across different ECG devices.

Overall, the AI model demonstrated high accuracy across the tested ECGs. Sensitivity was 0.739, while specificity was 0.944, showing discriminative power in distinguishing non-OMI ECGs. The prevalence-adjusted performance metrics confirmed these findings.

The table below summarizes the performance of the OMI AI ECG Model on all ECGs in the Validation Dataset, 95% confidence intervals are reported for each metric:

		Ref -	Ref +	Sensitivity	Specificity	PPV	NPV
OMI AI Model	+	158	851	0.739 (0.701-0.776)	0.944 (0.933-0.955)	0.843 (0.812-0.872)	0.899 (0.882-0.915)
	-	2681	301				

An explanation of the above performance metrics can be found below:

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 (PPV)	The negative predictive value is the probability that following a negative test result, that individual will truly not have the specified disease.	$\mathrm{NPV} = \frac{\mathrm{TN}}{\mathrm{TN}+\mathrm{FN}} = 1 - \mathrm{FOR}$

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 OMI 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

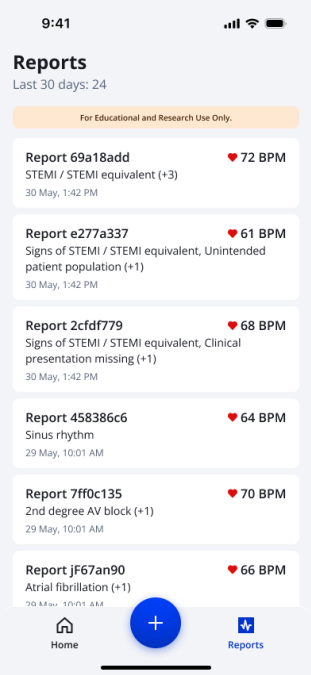

Figure 1: Reports list

1. Reports list

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

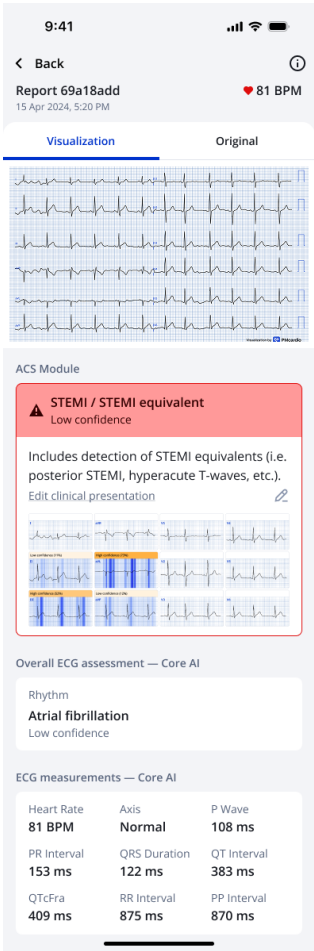

Figure 2: Report detail, success

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

Report detail screen contains the following 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 OMI AI ECG Model are displayed in the diagnosis area. In case the OMI AI ECG Model detected signs of STEMI or STEMI equivalent on the patient's ECG, it will display `STEMI/STEMI equivalent detected`. If the OMI AI ECG Model did not detect occlusion myocardial infarction on the patient's ECG, it will display `STEMI/STEMI equivalent not detected`.

   Further, in case of any error, no diagnostic output will be displayed. Instead, the respective error statement will be displayed in this area (see the section 6.3. Error messages for details).

3. **Waveform area**

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

6.2. View information about the OMI AI ECG Model

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

Figure 3: About screen

6.3. Error messages

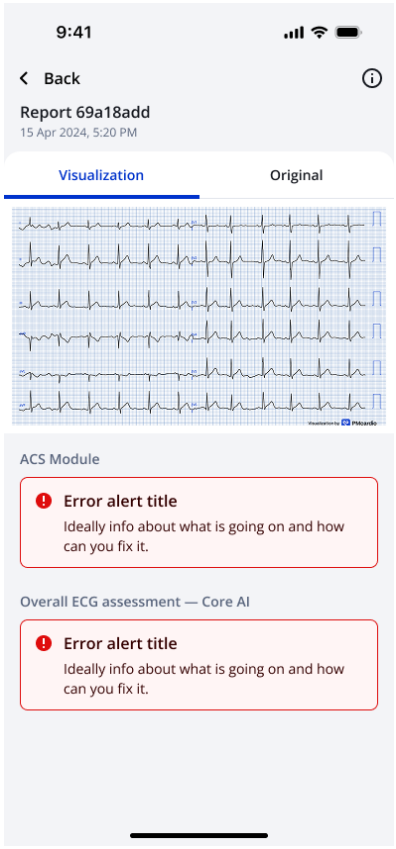

Figure 4: Report detail, error

If the processing of the ECG was unsuccessful, one of the error messages listed in the section 7.2. Unsuccessful ECG Analysis - Error messages will be displayed in the diagnosis area of the GUI.

7. Device output and follow-up

7.1. Successful ECG Analysis

If the processing of the ECG was successful, one of the OMI AI ECG Model will return one of the following outputs:

7.1.1. `STEMI/STEMI equivalent detected`

If the OMI AI ECG Model has identified signs suggestive of an occlusion myocardial infarction on the analyzed ECG, it will return the output `STEMI/STEMI equivalent detected`.

Occlusion Myocardial Infarction (OMI) is caused by the sudden blockage of a coronary artery, leading to a portion of the heart muscle being deprived of oxygen, resulting in dying (or loss of) cardiac tissue. For healthcare professionals, this output communicates a high likelihood that the patient is experiencing an acute coronary occlusion, requiring immediate attention.
If the ECG analysis returns `STEMI/STEMI equivalent detected`, the output should be used as follows:

- **Prioritize and Expedite Care**: An output indicating the presence of STEMI or STEMI-equivalent should prompt healthcare professionals to prioritize the patient for rapid assessment and treatment. Time is muscle in coronary occlusions, and prompt reperfusion therapy is key in saving heart muscle and improving outcomes.

- **Confirmation and Further Testing**: Healthcare professionals should use the output of the device as a decision-support tool rather than definitive diagnosis, even if the device suggests the presence of STEMI or STEMI-equivalent. Further confirmatory testing may be necessary, including but not limited to:

    - Coronary Angiography: This imaging test visualizes the coronary arteries and can confirm or exclude the presence and exact location of an occlusion.
    - Additional Imaging: Other imaging modalities like echocardiography may be used to assess the cardiac function and areas of impaired muscle movement.
    - Cardiac Biomarkers: Measuring serum levels of troponin, which are proteins released when heart muscle is injured, can support the diagnosis of myocardial infarction.
    - Serial ECGs: Performing additional ECGs can confirm ongoing ischemic changes and monitor for any evolution in the ECG pattern.

- **Immediate Management**: Depending on the resources at hand and the patient's clinical stability, immediate management may include preparing for an urgent percutaneous coronary intervention (PCI) to mechanically open the affected coronary artery, or pharmacologic thrombolysis (clot-busting drugs) if PCI is not available.

- **Protocol Adherence**: Health professionals should abide by the established protocols for the management of acute coronary syndrome. These protocols incorporate a combination of clinical evaluation, ECG interpretation, and lab findings to guide therapeutic decisions.

In summary, the output from the OMI AI ECG Model must be integrated into the clinical workflow with confirmatory diagnostics and treated with the urgency warranted by a potential acute coronary occlusion.

Note: The OMI 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.

7.1.2. `STEMI/STEMI equivalent not detected`

If the device has not found evidence suggestive of an occlusion myocardial infarction based on the ECG analysis, it returns `STEMI/STEMI equivalent not detected`. In other words, the AI tool has not detected the specific ECG changes that it associates with the acute blockage of a coronary artery.

If the ECG analysis returns `STEMI/STEMI equivalent not detected`, the output should be used as follows:

- **Clinical Integration**: The AI output should be interpreted within the broader clinical context and must always be interpreted in conjunction with the patient's symptoms, history, and risk factors for coronary artery disease in addition to the device's interpretation.

- **Further Assessment**: Despite the negative interpretation, healthcare professionals should remain vigilant. It is important to understand that the ECG is considered a rule-in test and not a rule-out test. If clinical suspicion remains high, additional assessments should be conducted, including but not limited to:

    - Repeat ECGs: To monitor for any evolving changes, as initial ECGs may not always show signs of myocardial infarction immediately after symptom onset.
    - Cardiac Biomarkers: Checking cardiac biomarkers like troponins may reveal myocardial injury not evident on the initial ECG.
    - Additional Imaging: Tests like echocardiography can identify wall motion abnormalities suggestive of ischemia or infarction without ECG changes.
    - Coronary Angiography: This imaging test visualizes the coronary arteries and can confirm or exclude the presence and exact location of an occlusion.

- **Alternative Diagnoses**: The HCP should consider other potential causes for the patient's symptoms that may not be due to OMI. These could include for example myocarditis, pericarditis, pulmonary embolism, or aortic dissection, among others.

- **Risk Stratification**: Based on the totality of clinical findings, the HCP must determine the appropriate care setting, whether it's safe discharge, observation, or further in-hospital evaluation.

In summary, if the ECG analysis of the OMI AI ECG Analysis concludes `STEMI/STEMI equivalent not detected`, the output is a data point to be considered only as part of a comprehensive evaluation. A negative interpretation result does not definitively rule out acute coronary syndromes and requires further testing, especially if clinical suspicion for myocardial infarction remains high based on the patient's overall presentation.

⚠ Warning: A negative interpretation result does not rule-out follow-up testing.

7.2. Unsuccessful ECG Analysis - Error messages

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. `Missing leads error`

    - Title: "*One or more leads missing.*"
    - Message: "*At least one of the following leads is missing 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.*"

    This error will be displayed if at least one of the required 12 leads was missing.

2. `Too many gaps in lead 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 the input ECG had too many missing values, i.e. if there were too many gaps in the leads.

3. `Low sampling frequency`

    - Title: "*Too low sampling frequency.*"
    - Message: "*One or more leads have a too low sampling frequency. All input leads must have a sampling frequency of at least 250Hz.*"

The minimum required sampling frequency of the input ECG recording must be 250Hz. The error will be displayed if the input ECG had a sampling frequency of less than 250Hz.

4. `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 was shorter than 2500 milliseconds.

5. `Leads too long error`
    - Title: "*Leads are too long.*"
    - Message: "*All input lead signals should have at most 20000 data points.*"

    This error will be displayed if any of the leads of the input ECG had more than 20000 data points.

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

    This error will be displayed in case an unexpected error occurred. For example, this could be due to unavailability of the OMI 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 OMI AI ECG Model:

Symbol	Description
	Consult instructions for use
	Manufacturer of the medical device
	European conformity mark
	Medical device
	Unique device identifier
	Swiss representative

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

11. Device input requirements

The OMI AI ECG Model has the following input requirements:

- **Compatible ECG manufacturers and devices:** The device is compatible with all FDA-cleared 12-lead ECG devices.
- **Sampling Frequency:** 250Hz or higher.
- **File size (MB):** The maximal acceptable file size is 20 MB.

12. Device and manufacturer information

Name of the medical device	OMI 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	1.0
Release year of the medical device	2024
Basic-UDI-DI	426073843PMcardio0002H4
UDI-DI	4260738430081
Contact manufacturer	www.powerfulmedical.com support@powerfulmedical.com
Swiss authorized representative	 Johner Medical Schweiz GmbH Tafelstattstrasse 13a, CH-6415 Arth, Switzerland