

# OMI AI ECG Model

Instructions For Use

Rev 1.0 - English

March 2026



Read the Instructions for Use before using OMI AI ECG Model

## Indications For Use

The OMI AI ECG Model is a stand-alone software device (SaMD) intended for the analysis of resting 12-lead ECGs of patients presenting with symptoms suspicious for acute coronary syndromes (chest pain or perceived anginal equivalent, such as, shortness of breath and epigastric pain) in the triage setting of such patients (e.g., ED or EMS). The OMI AI ECG Model identifies ECG patterns of Occlusive Myocardial Infarction (STEMI and STEMI equivalents) on 12-lead ECGs and is used by trained first-line healthcare professionals (non-cardiologists) to prioritize patients for specialist (cardiologist) evaluation. The Device is intended to be used in conjunction with the standard of care in ED and EMS settings for improved prioritization of patients with Occlusive Myocardial Infarction (STEMI or STEMI equivalent). A negative Model output does not exclude possible STEMI or other cardiac conditions, and the standard of care should not be modified as a consequence of a negative Model output. The device is not intended to replace a healthcare professional's ECG interpretation and a negative result from the OMI AI ECG Model should not override a healthcare professional's assessment that the ECG is consistent with Occlusive Myocardial Infarction (STEMI or STEMI equivalent). No therapeutic decisions should be made based solely on the OMI AI ECG Model output, and any positive Model finding should be reviewed by a qualified specialist (cardiologist). The device is intended for adults-only (18+).

## Description

The OMI AI ECG Model software analyzes 12-lead resting ECG data from adult patients using an artificial intelligence-based algorithm to detect ST-segment elevation myocardial infarction (STEMI) and STEMI equivalent (also known as “*Occlusive Myocardial Infarction – OMI*”) ECG patterns in patients presenting with a clinical suspicion of acute coronary syndrome.

The OMI AI ECG Model is a stand-alone software module that integrates with existing medical systems (e.g., electronic health record systems, hospital information systems, or other medical device platforms) and is an adjunctive decision support tool intended for healthcare professionals to help triage and prioritize patients presenting with a clinical suspicion for acute coronary syndromes for review by a cardiologist. The device is not intended to be the sole means of diagnosis, and no therapeutic decisions are made based solely on the OMI AI ECG Model output.

Note: A negative interpretation result does not rule-out follow-up testing. Also the OMI 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 the OMI AI ECG Model might nevertheless be present.

Note: The device has not been tested for pediatric patients or patients under the age of 18.

## Cautions

- A negative interpretation result does not rule-out follow-up testing.
- 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.
- The device output does not replace a full clinical evaluation of the patient and the output may not be sufficient as the sole basis for further therapeutic or diagnostic decisions.
- The OMI AI ECG Model does not detect all types of acute myocardial infarctions, it is only designed to detect myocardial infarction due to an acutely occlusive or flow limiting culprit lesion. The OMI AI ECG Model is not intended for the detection of chronic total occlusions.
- 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.
- DO NOT use the OMI AI ECG Model for analyzing ECG recordings of low quality or if it does not satisfy the device's input requirements. Low quality includes, but is not limited to, missing/disconnected leads, lead reversal, movement artifact, pulse tapping artifact, and any other feature lowering the quality of human ECG interpretation. As a rule of thumb, if any aspect of ECG quality prohibits the physician from being confident in their human interpretation, then the physician should not rely on the quality of the OMI AI ECG Model output.
- DO NOT use the OMI AI ECG Model for analyzing exercise stress test ECG recordings.
- DO NOT use the OMI AI ECG Model for analyzing ambulatory/Holter ECG recordings.
- The OMI AI ECG Model does not achieve 100% accuracy and may occasionally misidentify cardiovascular conditions. As with any medical device, experienced clinician judgment supersedes the Model in the event of disagreement.

## 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.

## Characterization of Patients

The device is designed to serve as a tool for analyzing ECGs of adult patients (18+) with symptoms potentially compatible with acute coronary syndrome, recorded by healthcare professionals and/or physicians, in order to detect the presence of Occlusive Myocardial Infarction (STEMI or STEMI equivalents).

These patients will typically seek medical attention by calling Emergency Medical Services (EMS) or presenting to the Emergency Department (ED).

The following types of adult patients can be considered:

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

## Characterization of Users

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

## Supported Diagnoses, Clinical Safety, and Performance

### Supported ECG diagnoses

Using the proprietary OMI AI ECG Model algorithm, the device is able to assist in the detection of ECG patterns of OMI (STEMI and STEMI equivalents) on 12-lead ECG.

Note: Occlusive Myocardial Infarction (ST-segment elevation myocardial infarction (STEMI) or its equivalent) 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.

### Unsupported diagnoses

The OMI AI ECG Model is specifically designed to detect Occlusive Myocardial Infarction (STEMI and STEMI equivalent) patterns. It does not support detection of other ECG abnormalities or conditions. Non-presence of Occlusive Myocardial Infarction (STEMI or STEMI equivalents) does not exclude the presence of conditions that are not detected by the OMI AI ECG Model. Absence of OMI (STEMI or equivalent) does not mean absence of acute myocardial infarction.

### 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.
- 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

## Device performance

The OMI AI ECG Model does not achieve 100% accuracy and may occasionally misidentify cardiovascular conditions. As with any medical device, experienced clinician judgment supersedes the device output in the event of disagreement.

In a clinical validation study, the performance of the OMI AI ECG Model was evaluated using standard diagnostic accuracy metrics derived from the confusion matrix. Ninety-five percent confidence intervals were estimated via bootstrap resampling. Model performance was compared against standard-of-care (SOC) triage. The OMI AI ECG Model demonstrated significantly higher sensitivity and statistically non-inferior specificity compared with SOC.

Performance was evaluated across predefined demographic and electrocardiographic subgroups. Consistent performance was observed across age, sex, race, geographic location, and ECG characteristics.

## Clinical benefits

| ID  | Clinical Benefit                                                                                  | Explanation                                                                                                                                                                                                                                                        |
|-----|---------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| CB1 | Support for identification of patients requiring further diagnostic evaluation for suspected OMI. | The OMI AI ECG Model demonstrated higher sensitivity compared to standard-of-care (SOC) triage determination, which may support healthcare professionals in identifying patients who may require further diagnostic assessment within standard clinical workflows. |
| CB2 | Reduction in missed OMI cases compared to STEMI criteria.                                         | The higher sensitivity of the model relative to SOC indicates a lower proportion of false negative classifications within the validation dataset, supporting a reduced likelihood of missed OMI cases when used as an adjunct to clinical assessment.              |
| CB3 | Increased identification of OMI cases relative to STEMI criteria.                                 | The model demonstrated a higher number of correctly identified OMI cases (true positives) compared to standard-of-care (SOC) triage determination, supporting its role in augmenting ECG-based triage decisions.                                                   |

| ID  | Clinical Benefit                                                           | Explanation                                                                                                                                                                                                                                                      |
|-----|----------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| CB4 | Support for timely clinical decision-making within existing care pathways. | The diagnostic performance characteristics of the model (higher sensitivity with non-inferior specificity: support its use as an adjunctive tool to assist clinical decision-making when interpreted alongside clinical context and other diagnostic information |

## Device output and Follow-up

The OMI AI ECG Model will return one of the following outputs:

- *STEMI/STEMI equivalent detected*
- *No signs of STEMI/STEMI equivalent detected*
- *Error*

| Output                                                                                                     | Definition                                                                                                        | Recommended Follow-Up Actions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>STEMI/STEMI equivalent detected</b><br>Emergent cardiology consult recommended.                         | The AI model identified signs suggestive of STEMI or STEMI equivalent occlusion myocardial infarction on the ECG. | <ul style="list-style-type: none"> <li>- <b>Prioritize and Expedite Care:</b> Immediate referral to cardiologist; treat as a time-sensitive emergency and prioritize the patient for immediate referral to a cardiologist for a full patient evaluation.</li> <li>- <b>Confirmation and Further Testing:</b> Use as an adjunctive tool, not a sole diagnosis. Consider: <ul style="list-style-type: none"> <li>- <b>Additional imaging</b> (e.g., echocardiography)</li> <li>- <b>Cardiac biomarkers</b> (troponins)</li> <li>- <b>Serial ECGs</b></li> <li>- <b>Coronary angiography</b></li> </ul> </li> <li>- <b>Protocol Adherence:</b> Follow established ACS protocols, integrating ECG with clinical findings.</li> </ul> <p><b>Summary:</b> 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.</p> <p><b>Note:</b> 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.</p> |
| <b>No signs of STEMI/STEMI equivalent detected -</b><br>Caution: A negative interpretation result does not | The AI model found no ECG evidence of occlusion myocardial infarction. The model has not detected                 | <ul style="list-style-type: none"> <li>- <b>Clinical Integration:</b> Interpret in broader clinical context of symptoms, history, and risk factors.</li> <li>- <b>Further Assessment:</b> Continue patient</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

| Output                      | Definition                                                                                                                                                                                                                                                             | Recommended Follow-Up Actions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| rule-out follow-up testing. | <p>specific ECG changes suggestive of acute coronary blockage.</p> <p><b>Note:</b> A negative interpretation result does not rule out acute myocardial infarction. A negative interpretation should not be used to justify decreased clinical suspicion or workup.</p> | <p>evaluation as clinically indicated, regardless of a negative AI model result. Consider:</p> <ul style="list-style-type: none"> <li>- Serial ECGs</li> <li>- Cardiac biomarkers (troponins)</li> <li>- Additional imaging (e.g., echocardiography)</li> <li>- Coronary angiography</li> </ul> <p>- <b>Alternative Diagnoses:</b> Evaluate for other conditions (myocarditis, pericarditis, PE, aortic dissection, GI causes, etc.).</p> <p>- <b>Risk Stratification:</b> Determine patient risk and appropriate disposition according to standard of care.</p> <p><b>Summary:</b> A negative output does not exclude ACS or AMI. Further testing required if suspicion remains.</p> |
| <b>"Error"</b>              | If the processing of the ECG was not successful, the OMI AI ECG Model returns an error.                                                                                                                                                                                | The ECG analysis was not successful and the OMI AI ECG Model returned an error. Please refer to section ' <i>Troubleshooting Guide - Common Errors and Resolution</i> ' for details.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

## Troubleshooting Guide - Common Errors and Resolutions

This section provides guidance on resolving issues that may arise while interfacing with the API. For connectivity or operational concerns, contact the support team specified by your organization or [support@powerfulmedical.com](mailto:support@powerfulmedical.com).

| Problem                                                                                                                                                                                                                                          | Possible solution                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>"Poor Signal quality"</b></p> <p>The error <i>"Poor Signal quality"</i> with the following message <i>"The provided leads have patterns of inadequate signal quality. Please ensure the input ECG is properly recorded."</i> is shown.</p> | <ul style="list-style-type: none"> <li>• Re-acquire ECG data using appropriate recording protocols.</li> <li>• Common errors detected on the ECG: <ul style="list-style-type: none"> <li>○ Missing signal values in leads.</li> <li>○ The signal is not continuous. The lead regions without missing values are shorter than 2.000 ms, e.g., 1 s.</li> <li>○ Make sure the diodes are correctly applied to the patient's body (focusing on connection quality as well as the placement location of the application).</li> <li>○ Certain ECG electrodes might be disconnected. Make sure all electrodes are correctly applied to the patient's body when recording the ECG.</li> </ul> </li> </ul> |
| <p><b>"Code 4XX"</b></p> <p>The error <i>"Code 4XX"</i> is shown, e.g., 422 or 413.</p>                                                                                                                                                          | Based on the setup made by the Medical Device Operator, these errors should be addressed by them - contact the Medical Device Operator with details of the request, including the input parameters and timestamps.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |

| Problem                                             | Possible solution                                                                                                                                                                                                          |
|-----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>"Code 500"</b><br>The error "Code 500" is shown. | <ul style="list-style-type: none"> <li>• Retry the operation.</li> <li>• If the issue persists, contact the Medical Device Operator with details of the request, including the input parameters and timestamps.</li> </ul> |
| Connectivity and Unresponsiveness                   | For any issues related to connectivity or API unresponsiveness, consult the Medical Device Operator. Ensure that network connectivity is stable.                                                                           |

## Device input requirements

The OMI AI ECG Model has the following input requirements:

- **Compatible ECG electrodes:** The device is compatible with standard 'wet' AG/AgCl electrodes with conductive gel/paste to record an ECG.
- **ECG recording duration:** Between 2.25 and 15 seconds.
- **ECG recording quality:** ECG recording contains all 12 leads of sufficient quality and presence of an actual ECG signal.
- **ECG recording sampling frequency:** 200Hz or higher, but no more than 2000Hz.
- **File size (MB):** The maximal acceptable file size is 20 MB.

## Symbols

The following symbols apply to the device:

| Symbol                                                                              | Description                          |
|-------------------------------------------------------------------------------------|--------------------------------------|
|  | Instructions for use                 |
|  | Manufacturer of the medical device   |
|  | Prescription use only (US only)      |
|  | Medical device                       |
|  | Unique device identifier             |
|  | (EU only) CE Mark                    |
|  | (if applicable) Swiss representative |

## Contact

If there are difficulties operating or integrating your source devices with the OMI AI ECG Model Software, or for additional support not specified in this document, contact the Powerful Medical support team at [support@powerfulmedical.com](mailto:support@powerfulmedical.com).

## Reporting according to the EU MDR

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](mailto:support@powerfulmedical.com).

## Printed version of the Instructions for Use

The user can contact the manufacturer at [support@powerfulmedical.com](mailto: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.

## Legal

OMI AI ECG Model™ is claimed as a trademark of Powerful Medical, Inc. © 2026 Powerful Medical, Inc. All rights reserved.

## Device and Manufacturer information

|                                                        |                                                                                                                                                                                                                                      |
|--------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Name of the medical device</b>                      | OMI AI ECG Model                                                                                                                                                                                                                     |
| <b>Manufacturer of the medical device</b>              | <br>POWERFUL MEDICAL s.r.o.<br>Karadžičova 8/A, 821 08 Bratislava, Slovakia<br><a href="http://www.powerfulmedical.com">www.powerfulmedical.com</a> |
| <b>Corresponding version of the medical device</b>     | 2.1                                                                                                                                                                                                                                  |
| <b>Release year of the medical device</b>              | 2026                                                                                                                                                                                                                                 |
| <b>Basic-UDI-DI</b>                                    | 426073843PMcardio0002H4                                                                                                                                                                                                              |
| <b>UDI-DI</b>                                          | 4260738430173                                                                                                                                                                                                                        |
| <b>Swiss authorized representative (if applicable)</b> | <div>CH REP</div><br>Johner Medical Schweiz GmbH<br>Tafelstattstrasse 13a, CH-6415 Arth, Switzerland                                                                                                                                 |