PMcardio®
for Individuals

Digitization AI ECG Model

User Manual

Rev 1.0 - English

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Please read this user manual before using the PMcardio Digitization AI ECG Model

Table of contents

- 1. Introduction
- 2. Important Use Information
- 3. How to use the Digitization AI ECG Model
  - 3.1. Digitize the photo
  - 3.2. View digitization result
  - 3.3. Supported layouts and characteristics
    - 3.3.1. Supported ECG layouts
    - 3.3.2. Supported characteristics
    - 3.3.3. Unsupported characteristics
  - 3.4. Error messages
- 4. Other information

1. Introduction

Powerful Medical's proprietary Digitization AI ECG Model is an artificial intelligence based technology for digitizing 12-lead ECG recordings from an image. The technology can be integrated into other healthcare IT solutions to build web, mobile or other types of applications.

2. Important Use Information

1. The Digitization AI ECG Model only works for digitizing 12-lead ECG recordings.
2. The Digitization AI ECG Model only works with ECG layouts as indicated in the section 'Supported ECG Layouts' in this document.
3. Read the user manual before using the device.
4. Do not use the Digitization AI ECG Model for analyzing ECG recordings from also smartwatches or ambulatory/holter devices.
5. Do not use the Digitization AI ECG Model for analyzing ECG recordings of low quality.
6. Do not use the Digitization AI ECG Model for analyzing ECGs of patients with an active pacemaker.
7. Do not use the Digitization AI ECG Model for analyzing ECG recordings that do not satisfy the device's input requirements.
8. Do not use the Digitization AI ECG Model for digitizing ECGs with flatlines (disconnected electrode(s)).
9. For correct ECG digitization, ensure the correct paper speed and voltage gain input settings.
10. 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.

3. How to use the Digitization AI ECG Model

3.1. Digitize the photo

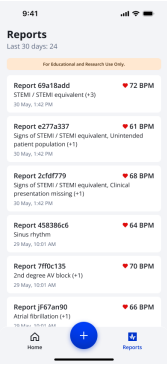


Figure 1: Reports list

1. New report

Press the blue + button to create a new report.

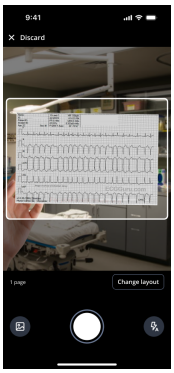


Figure 2: Camera screen

2. Upload image

Use camera view to take or upload the photo for digitization.

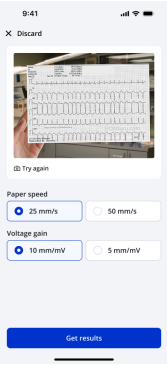


Figure 3: Image preview

3. Set additional parameters and digitize

The uploaded image can be removed by clicking on the *Try again* button. Set *Paper speed* and *Voltage gain* parameters. Press the *Get results* button to get the digitization result.

Table 1: Digitization workflow steps

3.2. View digitization result

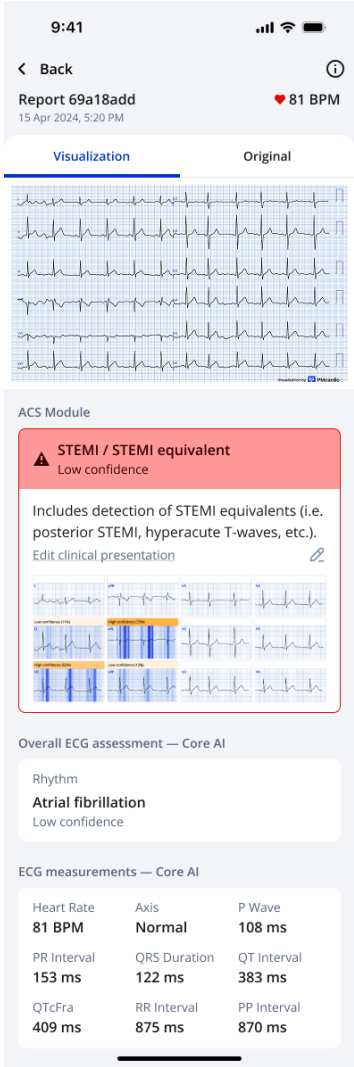


Figure 4: Report detail, success

Report details	Creation date and time and report name.
ECG visualization	Visualized ECG record in a standardized format. Applied input parameters (*Paper speed* and *Voltage gain*) are displayed at the bottom of the visualization.
Error message	In case the uploaded image does not meet the requirements (see section 5.3. Supported layouts and characteristics), the respective error message is displayed instead. The detailed list of error messages is in section 5.4. Error messages.

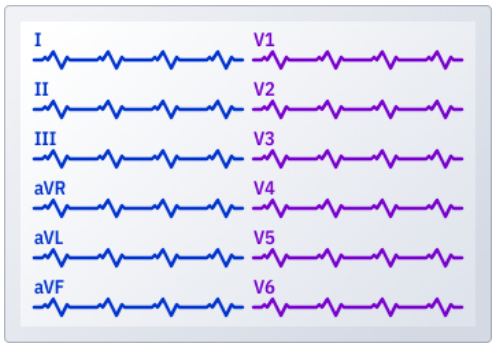
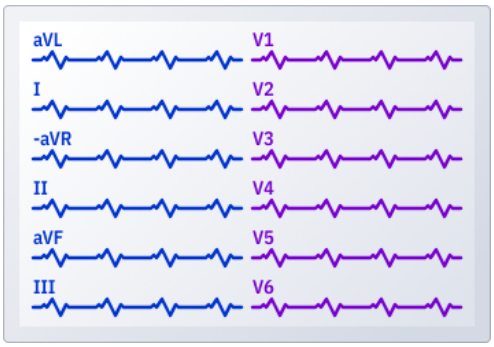
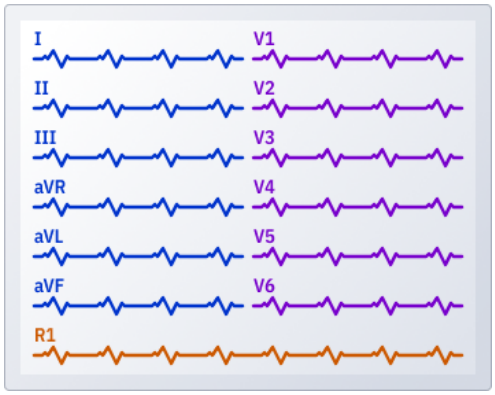
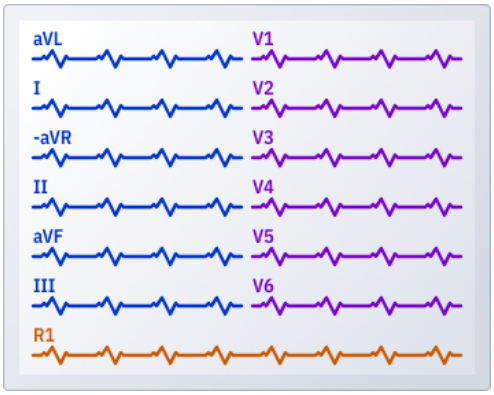
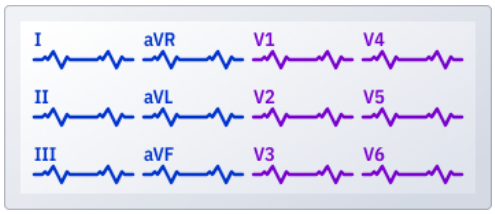
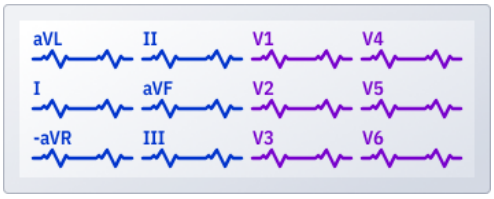
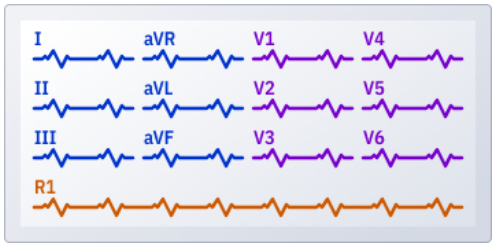
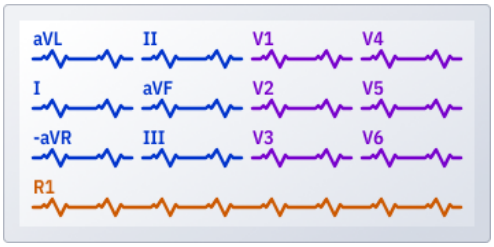
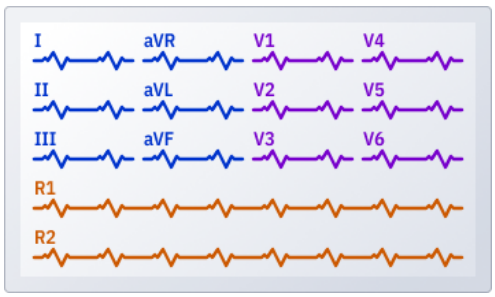
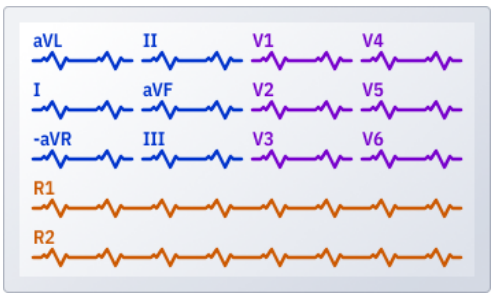
Table 2: Results screen components

3.3. Supported layouts and characteristics

3.3.1. Supported ECG layouts

The ECG layout refers to the lead layout on the ECG recording. The Digitization AI ECG Model only supports 12-lead ECGs. In addition to these 12 leads, specific ECG layouts can contain up to 3 rhythm leads.

The ECG layout indicates the lead order, number of rows, columns and rhythm leads as follows: [Lead order]_[Rows]x[Columns]_[Rhythm leads]. For example: `s_6x2_r1`. The pictograms show the layout and order of the leads. The Digitization AI ECG Model can digitize the following ECG layouts:

Layout	Standard presentation system preview	Cabrera presentation system preview
6x2_r0		
6x2_r1		
3x4_r0		
3x4_r1		
3x4_r2		

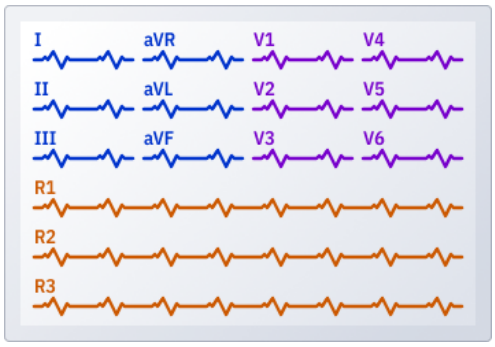
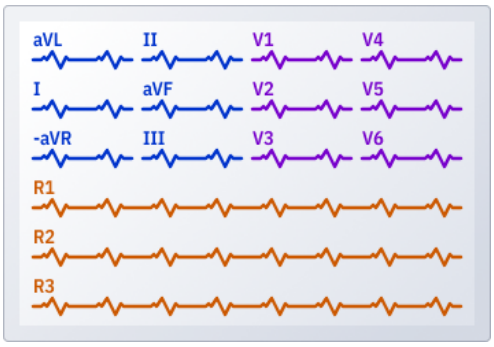
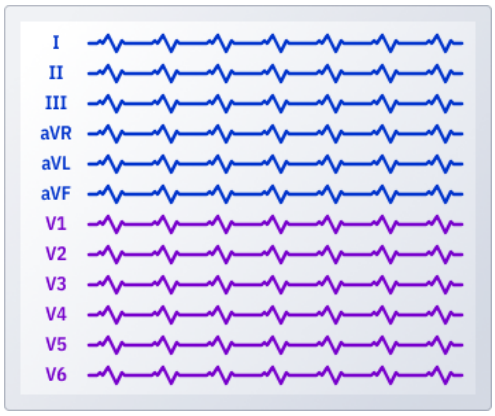
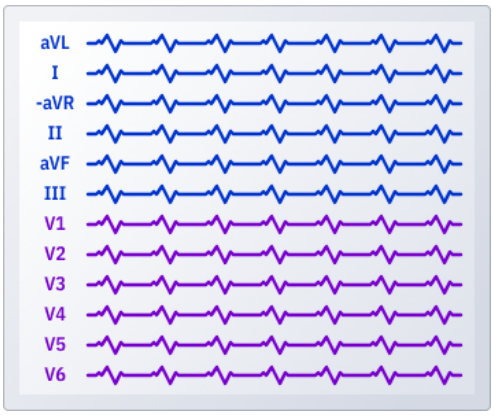
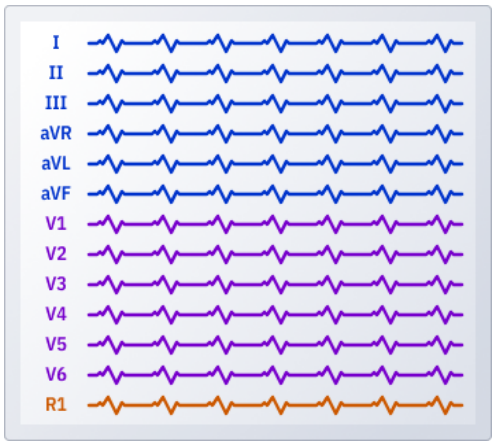
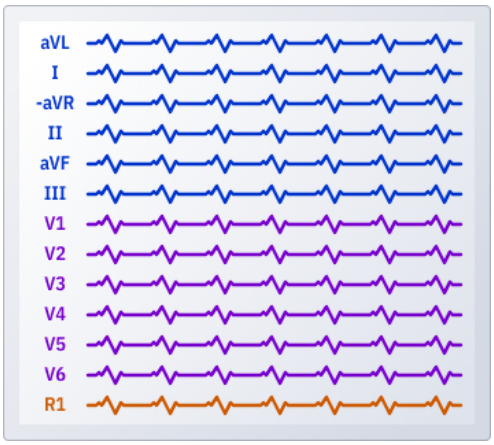
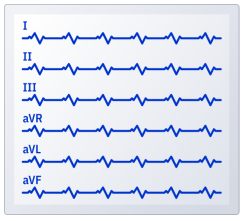
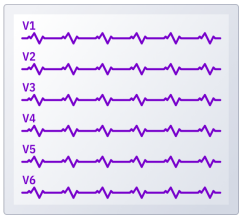
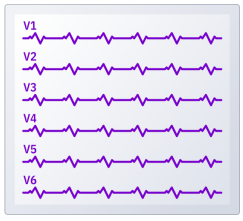
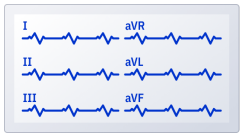
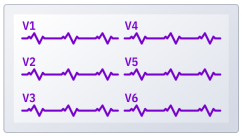
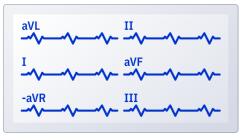
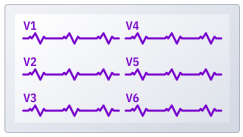
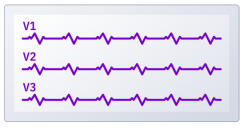
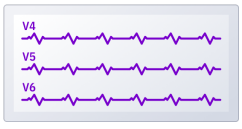
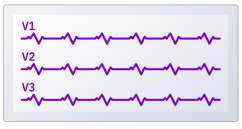
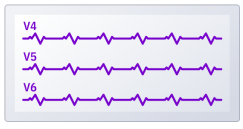
Layout	Standard presentation system preview	Cabrera presentation system preview
3x4_r3		
12x1_r0		
12x1_r1		
6x1_r0	 	
3x2_r0	 	 
3x1_r0	 	 

Table 3: Supported layouts

3.3.2. Supported characteristics

The submitted image must meet the following requirements:

- submitted image contains an ECG
- submitted image contains only one ECG (does not contain multiple ECGs)
- submitted image is in JPEG, PNG, or PDF format

The ECG must meet the following requirements:

- ECG recording must be one of the supported layouts
- ECG recording must contain a millimeter grid
- all base-leads must not represent less than 1500 ms
- all leads must be printed or displayed with the same voltage gain and paper speed across one ECG
- all leads must be printed on the grid and must have a sufficient area (5 mm in each direction) where the grid is visible
- the ECG must only include 12 base leads that are related to one ECG and no other lead-like objects whatsoever, except the rhythm leads
- all leads/signals must not have empty/missing 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, digitization results might be affected
- all leads/signals must be clearly distinguishable, and apart from minor regions (not more than 5 mm), must not intersect other leads
- ECG leads must be represented on a bright background, the grid color must be distinguishable from the background, and the leads must be printed with a dark color

3.3.3. Unsupported characteristics

- ECG recording does not contain a millimeter 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 1500 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 5 mm
- leads are not printed alongside the horizontal grid lines

3.4. Error messages

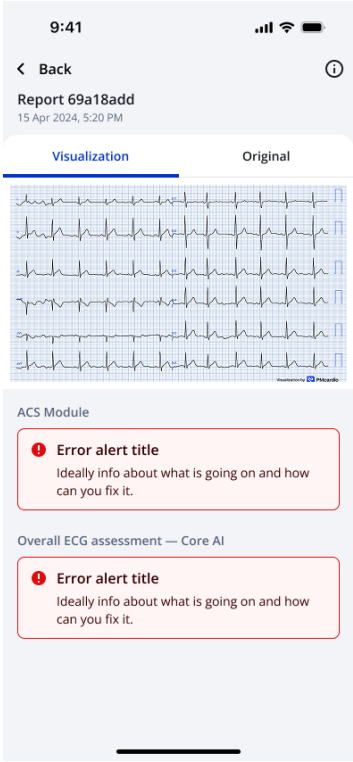


Figure 5: Report detail, error

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

1. `Input image too small error`
    - Title: "*Input image is too small.*"
    - Message: "*The minimum width and height of the image is 128 pixels.*"
2. `Uniform input image error`
    - Title: "*No objects detected.*"
    - Message: "*No objects can be detected on the image. Please ensure good lighting conditions and sharp image and try again.*"
3. `ECG photo too small error`
    - Title: "*ECG photo is too small.*"
    - Message: "*The longer side of the photo must be at least 12 cm (6 cm for multipage ECGs).*"
4. `Not enough points error`
    - Title: "*No ECG grid detected.*"
    - Message: "*No ECG paper was detected on the image. Please ensure good lighting conditions and sharp image and try again.*"
5. `Bad grid angle error`
    - Title: "*Low ECG grid quality.*"

- Message: "*Detected points do not seem to form a regular ECG grid. Please ensure good lighting conditions and sharp image and try again.*"

6. `Not enough squares error`
   - Title: "*Low ECG grid quality.*"
   - Message: "*Detected points do not seem to form a regular ECG grid. Please ensure good lighting conditions and sharp image and try again.*"
7. `Too many points error`
   - Title: "*Too many ECG grid points detected.*"
   - Message: "*Ensure that the small and large squares of the ECG grid are clearly distinguishable and try again.*"
8. `Wrong rotation error`
   - Title: "*Wrong image rotation.*"
   - Message: "*The image is incorrectly rotated. Please try again and make sure that the leads on the image are in a horizontal position.*"
9. `No leads error`
   - Title: "*No ECG leads detected.*"
   - Message: "*No leads were detected on the ECG grid. Please try again and make sure that ECG leads are clearly distinguishable.*"
10. `Unsupported layout error`
    - Title: "*Unsupported ECG layout detected.*"
    - Message: "*This ECG layout might not be supported. Please try again.*"
11. `Wrong layout error`
    - Title: "*Wrong ECG layout detected.*"
    - Message: "*Detected ECG layout does not match the selected one. Please try again.*"
12. `Wrong lead number error`
    - Title: "*Unusual number of leads.*"
    - Message: "*The leads in some lead columns could not be reliably found. Check if all leads are clearly visible.*"
13. `Leads too short error`
    - Title: "*Leads are too short.*"
    - Message: "*All ECG leads should have at least 1.5 seconds (1500 ms).*"
14. `Invalid input image error`
    - Title: "*Invalid image format.*"
    - Message: "*The image format is not supported. Ensure the image is JPEG, PNG, or PDF format and try again.*"

15. `Invalid input parameters error`
    - Title: "*Invalid input parameters.*"
    - Message: "*The input parameters are not supported. Check the input parameters and try again.*"
16. `Unexpected error`
    - Title: "*Unexpected error occurred.*"
    - Message: "*An unexpected error occurred. Please try again.*"

4. Other information

The Digitization AI ECG Model is developed by POWERFUL MEDICAL s.r.o. with registered seat at Karadžičova 8/A, 821 08 Bratislava, Slovakia. For further information, please visit www.powerfulmedical.com or contact us at support@powerfulmedical.com.

This document is applicable to version 3.2 of the Digitization AI ECG Model.