

Title: M-Cardia Instructions For Use

Document No: NASAN-D&D-D-012

# M-Cardia

### **USER MANUAL**

Software Version 1.0

Nasan Medical Electronics Pvt. Ltd.

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Hope you don't require service at all.

But incase you require,

Please contact: 09371039255

For any working days 9.30a.m to 6 p.m

Rev.0, Date:30-04-2025 1/35

Dear customer,

We take this opportunity to thank you once again for your patronage. We reiterate our commitment to live up to the confidence you have shown in us. Our continued endeavor is to exceed your expectation by offering you products that have optimum features and reliable, high quality performance backed by prompt technical support.

It is our pleasure to give you this user manual. Please study the same thoroughly before using the system.

Contact details:

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Website: www.nasanmedical.com

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### **Revision History**

The revision history of this document is summarized in the table below

Revision	Date	Comments
0	30APR2025	Initial release of the manual
1	30-05-2025	Updated System requirement

Rev.0, Date:30-04-2025



Not only 'Make in India' but 'Made in India'

# User manual for M-cardia

The complete Android based 12 Lead ECG Machine with measurements.

## 1. Introduction-

We thank you for purchasing our M-cardia, a portable ECG machine.

#### **Intended Use:**

M-cardia is a 12 lead resting, ECG machine with facility of Measurement and Interpretation. It connects to any android mobile through OTG USB Type C cable.

It is suitable on adult, paediatric.

#### Features:

- Display 12 lead, 10 second ECG on screen with medians next to each lead are displayed.
- Gain of ECG waveform (0.5, 1, 2) with standardization pulse.

- Facility to change long lead, QRS detection Lead, Amplify QRS.
- Automatic detection of P+ start, P+ end, P end, Q start, R Start, R end, S end, r' end, s' end, T Start, T End, U start, U end points on the median once.
- Facility to display and print interpretation
- \* Facility to review data
- Facility to change P+ start, P+ end, P end, Q start, R Start, R end, S end, r' end, s' end, T Start, T End, U start, U end points.
- \* Facility for link emergency
- \* Facility to print
  - Resting ECG report
  - o ECG with Measurement and Interpretation
  - o Medians with Measurement

# 2. System requirements-

- Android Mobile with android 13 and android 14
- Wi-Fi printer

#### Following is supported Wi-Fi printer

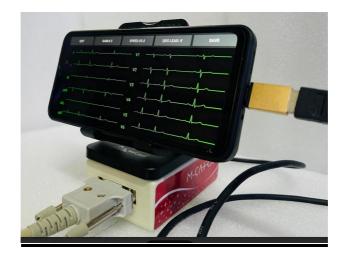
- Canon PIXMA TS307a
- HP DeskJet Ink Advantage2878

Download the printer service name as Mopria print service plug in with following steps click on play store-> search Mopria print service plugin-> click on install-> accept terms and conditions.



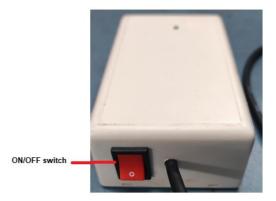
This 'Mopria print service enable printing from a mobile device to printers from different manufacturers or brands.

# 3. <u>Configuring</u> the <u>system</u>

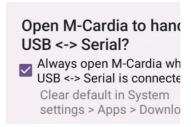


M-cardia

Install the M-cardia application from email. Connect the USB cable to Machine and OTG cable to USB and OTG cable to mobile. Switch ON by pressing ON/OFF switch button as shown below.



Click on check box "Open M-cardia to handle USB <-> Serial" and click on Ok button



After click , following Main Screen of the M-cardia will appear.



**1. Emergency:** When patient with emergency comes to the doctor/cardiologist, emergency ECG can be taken with emergency button.



Steps to take ECG in emergency condition

- > Click on emergency button.
- ➤ Wait for 10 seconds.
- ➤ Before the ECG data to save the Check the signal quality of the waveforms.

# Note- It is necessary to receive comments for printing the report.

- ➤ QRS lead can be changed with QRS button on screen.
- Change gain/ speed with buttons gain and speed respectively.
- 2. Patient- for regular checkup Or New: When patient comes for regular check up, and he is new patient. To check whether patient is new or existing, click on 'Patient' button on the following screen.



You can view patient list by clicking 'search' button. OR Enter details name, middle name, last name, mobile number and birth date to search the particular patient



If patient with same details is not registered, then message "No records found" will appear on screen.

# Note: Please enter complete details; it will help you search the particular patient.

For new patients, register patient by pressing button 'Register new'.

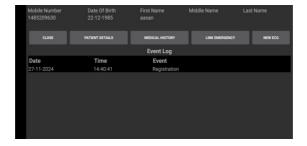


You can do registration by entering the personal patient details. Click on 'Update' button to register the patient.

If 'Short Details' checkbox from configuration is checked, then only mandatory fields will appear in the new registration window.

- On the Registration page, fill the following details and click on update button
  - 1. Name
  - 2. Middle name
  - 3. Last name
  - 4. Birth date- select date from calendar
  - 5. Age
  - 6. Gender- radio button
  - 7. Email
  - 8. Mobile 1
  - 9. Mobile2 if available
  - 10. Address- in two lines
  - 11. City
  - 12. Pin code
  - 13. State
  - 14. Country
  - 15. Occupation
  - 16. ID number- it can be any unique id number
  - 17. Insurance covered- checkbox
  - 18. Insurance provider ID

After registration following window will be displayed.



#### New ECG of new patient

- > Press "New ECG" button to take new ECG.
- You can see the ECG of patient on the acquisition screen where 12 leads are displayed in 6 channel formats as shown below.



> Save button will get enabled after 10 secs.

On this screen following buttons are present.

- > QRS lead- select lead for heart rate calculation
- Speed- to change the sweep speed
- Gain- to change the gain.

- > Exit- to exit from the acquisition screen
- When 'Save' button is pressed latest 10 sec patient's data is saved.

**Medical history: -** Enter medical history by clicking medical history button.



Click on save to save medical history.

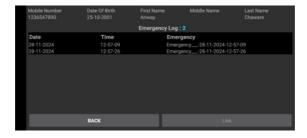
> 'Patient History updated' event will be displayed on event log page.

**Patient details:** - Patient details can be edited with patient details button. When patient details is pressed, the following screen will appear.



- After entering or editing details, click on update button to save the details
- 'Patient details updated' event will be displayed on event log page.

**Link Emergency:** List of emergencies are displayed on this screen. You can select the one and link to the patient with 'link' button.



Emergency tab will get disabled as per emergencies count is selected in configuration. To enable the emergency tab again, first link the emergencies to patients.

**Existing Patient for regular checkup: -** When a patient comes for regular check up and he is an existing patient, click on patient button on the following screen. The following screen will appear.

You can view patient list by clicking 'search' button. OR Enter details name, middle name, last name, mobile number and birth date to search for the patient



# Note: Please enter complete details; it will help you search the patient.

- After entering patient details, click on search button, this will provide you registered patient with the same details.
- When existing patient comes, this patient will be displayed in search result as shown below.
- Select the patient with 'select' button.
- After clicking on 'select', Patients event log will be displayed on screen.

- Then Doctor can take ECG of Patient. You can follow the steps given under heading "New Patient for regular checkup".
- When 'median' button is pressed following screen will appear

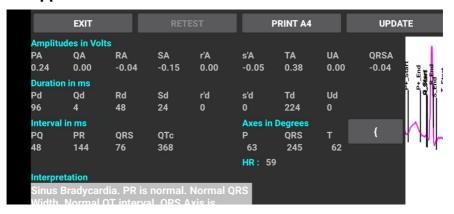


Fig. Median screen

Note: Median screen will display after pressing save button on acquisition screen if 'ECG screen' is not selected from configuration.

- Exit To exit from 'ECG' screen then main screen will be displayed.
- Print A4-To take printout on A4 paper
- Update It is used to save changes done for Measurement.
- ECG To view 'ECG' screen.

#### Displays following Measurement:

- Amplitude (in V) for selected Lead Amplitude of PA, QA, RA, SA, r'A, s'A, TA, UA, QRSA points in Volts
- Duration (in msec) Duration of Pd, Qd, Rd, Sd, r'd, s'd, Td, Ud points in ms
- Interval in msec
- Axis measurement- Axes of P, QRS and T in degree
- Heart rate

#### Displays following ECG interpretation

#### **Rhythm statements:**

Sinus Rhythm/ Junctional or NonSinus Rhythm suspected

/Sinus Bradycardia / Sinus Tachycardia

#### PR interval statements:

PR is normal / PR is long / PR is short

#### **QRS** interval statements:

Normal ORS Width / Wide ORS

#### **QT interval statements:**

Normal QT interval / QT Interval is prolonged / QT Interval - Little clinical significance

#### **QRS Axis statements:**

QRS Axis is normal / Right axis deviation / Left axis deviation / QRS Axis is indeterminate

#### T wave inversion:

Lead names of leads showing T wave inversion

#### Marker<sub>Button</sub> with << & >> spin button

Click on marker button and then Spin button <<&>> ,so that P+ start, P+ end , Q start, R Start, R end, S end , T Start, T End, points on median are shifted to left or right as per the spin button clicked. Accordingly check marking position are changing.

ш Lead name button to change the displayed median on interpretation screen.

Update To save changed values of P+ start, P+ end, P - end, Q start, R Start, R end, S end, T Start, T End, points for selected lead only. If changes are save using Update button, \*Edited Report\* appears on print out.

NOTE: When interpretation is edited in interpretation field, do not use 'Update' button to save the changes.

X Button, if you want original point position then press X button.

Adv button on Interpretation Screen to mark Q\_Start, S End, R Start, P+ End, T End, T Start, R End, P-End, R'End, U End, U Start and S'End points on median.

Nor button, Adv button text name is changed to 'Nor'.Only the O Start, S End, R Start, P+ End, T End, T Start, R End is seen on the median.

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# (Curly bracket) used to zoom the median screen as shown in figure.

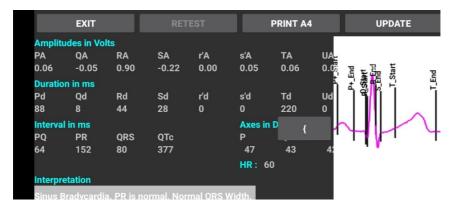


Fig.curly button

### Graph

Initially Grid, Graph or No Grid in interpretation is as per settings. You can change by using this button. When you press this button name on button changes, current condition is displayed by name on button.

Note: allows interpretation editing.

Tap on interpretation screen and edit as per requirement and edited interpretation is printed on thermal '\*Edited Report' text & A4 paper "Edited interpretation" will be displayed.

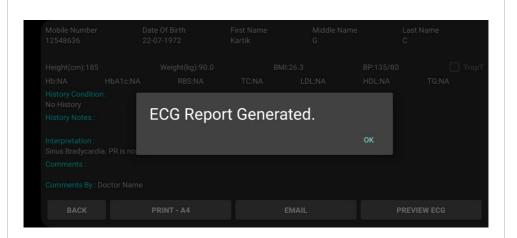
**3. Review tests:** You can see the log and status of the ECG in "Review tests" window. In review tests, log of ECGs is displayed on the review tests page.

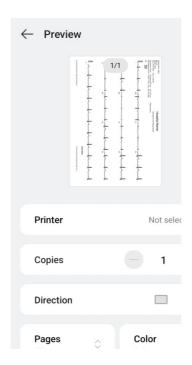


- Click on the patient's name and select the view report.
- You can view the report or check the status of the patient with date and time of the test and when ECG is taken.
- When View report is clicked, following screen will appear.

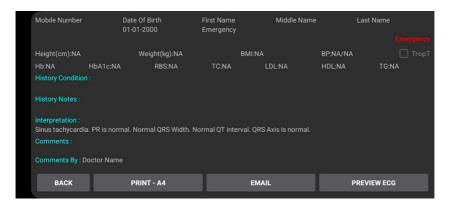


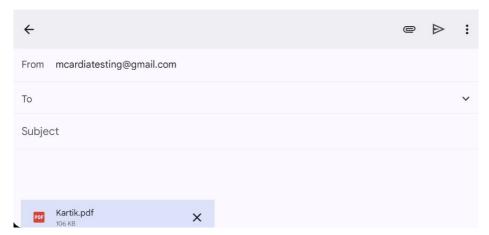
- Back: To go to the review test page.
- Print A4: To take A4 print, after pressing Print A4





#### • Email: To email PDF of ECG report



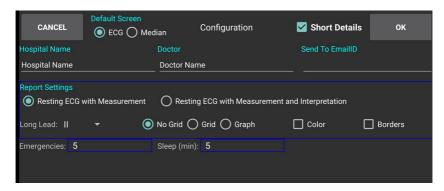


After pressing EMAIL above page is displayed

• **Preview ECG:** To preview the ECG report



### 4. Configuration:



- Default screen: radio button for ECG, Median, As per selection criteria after acquiring ECG screen will be displayed.
- Short details: When this checkbox is checked, then only mandatory fields will appear in the patient registration page.
- Hospital Name: Enter the hospital name which will be printed on report
- Doctor: Enter the doctor name which will be printed on report
- Send To Email ID Enter Receiver Email ID here.

#### Print Setting: Radio button for Report selection

- 1. Resting ECG with Measurement
- 2. Resting ECG with Measurement and Interpretation
- Long lead dropdown all leads are displayed in dropdown list.
   We can select any of the following lead to print as a long lead on A4 report.
   Lead name as I II III AvR AvL AvF V1 V2 V3 V4 V5 V6
- Radio button for No Grid, Grid, Graph for report printout.
- Check box for Color and Border selection for report
- Emergencies dropdown- select number of emergencies from 0 to 100.

- Sleep time drop down- Select sleep time for sleep mode. When the machine is ideal for time which is selected in sleep time, then after the selected minutes, machine will automatically get switched OFF. Sleep time 1, 2, 5, 10, 15, 20 and 30 min can be selected.
- Ok –To save and exit.
- Cancel –To exit without save.

#### Notes:-

Don't use the back button to exit the mobile application.



# **APPENDIX-A**

Note: This product should be used by trained person only.

### A. SYMBOL description

Symbol	Description
$\triangle$	Cautions indicate conditions
/!\	which may damage or
CAUTIONS:	malfunction of the device.
WARNINGS:	Warnings indicate a potential
	harmful condition that can
	possibly lead to injury or death.
Note:	Note:
	Alert the user to pertinent fact
	and conditions.
Mfg.Lic.No	Manufacturing license number
	Manufacturer symbol,
*	Medical Device
MAD	
	Type CF applied part
CN	Serial number
SN	

<b>*</b>	Keep dry
X	Dispose of in accordance with the requirements of your state
(3)	Instruction for use
NON STEDILE	Medical device that has not been subjected to a sterilization process.

### Classification of Applied parts

Applied part	Degree of protection
	against electric shock
Patient Cable 10 Lead	CF CF

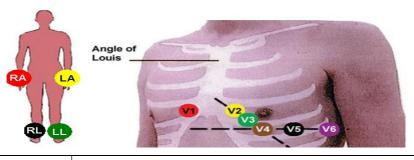
### **B.** Patient preparation -

Proper patient preparation is the most important factor in obtaining proper results. If electrodes are applied to an improperly prepared skin site, it-may result in excessive base line shift and artifacts while obtaining an ECG.

The skin at 6 chest leads and 4 limb leads sites has to be prepared.

### C. Electrode placement-

- Apply some jelly to the electrode site and thoroughly rub the site with gauze till it becomes slightly red. This removes the horny non-conducting layer of the epidermis enabling a good electric contact with the body fluids.
- Inspect both the limb clamp and Bulb electrodes to ensure that both are clean
- Ensure that the patient data cable and the lead wires are not twisted
- Apply a thin layer of electrolyte gel to the area of the skin where the electrode will be applied. The skin area covered by the electrolyte gel should not exceed the diameter of the electrode.
- The skin must be clean, dry and completely free of jelly for the electrodes to remain well in position till the end of ECG acquisition.



RA (Red)	Right Arm
LA (Yellow)	Left Arm
RL (Black)	Right Leg
LL (Green)	Left Leg
V1	Fourth inter coastal space to the right of sternum
V2	Fourth inter coastal space to the left sternum
V3	Directly between leads V2 &V4
V4	Fifth inter costal space at midclavicular Line
V5	Level with V4 at anterior axillary line
V6	Level with V5 at midaxillary line.

# CAUTION:

When applying the precordial electrodes, do not overlap the electrolyte gel of adjacent electrode sites. Overlapping electrolyte gel will cause interaction between electrode sites, and may result in distortion of the ECG signal

**WARNING:** Always clean and disinfect reusable electrodes before patient use. Failure to properly clean and disinfect reusable electrodes before patient use may cause infectious materials to be transferred between patients.

#### **WARNING:**

Always clean and disinfect the ECG machine after patient use. Wipe the external surface of machine with soft cloth.

### **CAUTION**



Refer servicing for equipment under warranty to NASAN authorized service personnel. Any attempt to repair equipment that is under warranty may void that warranty.

### CAUTION



Solder multilayer and surface mount circuit boards at your own risk! Improper methods of repairing these boards may damage boards even further.

# CAUTION

PROPER LEADWIRE CONNECTION — improper connection will cause inaccuracies in the ECG.

#### **D.** <u>Cleaning Instruction:</u>

To clean reusable electrodes and patient cable:

- a. prior to cleaning the patient data cable, inspect the patient data cable for any cracks or breaks in the cable insulation. If the integrity of the patient data cable is not assured, replace the patient data cable.
- b. Detach the rubber bulb from the metal cup by pulling. Wash the rubber bulb in warm water. Remove all electrolyte gel residue, check inside the rubber bulb to ensure that all residue is removed.
- c. Dampen a soft cloth with soapy water or with one of the disinfectants and clean the machine

**CAUTIONS**: Do not use strong solvents or abrasive cleaning materials. Do not use any of the following to clean the machine:

- Acetone
- Iodine-based cleaners
- Phenol-based cleaners
- Ethylene oxide sterilization
- Ammonia-based cleaners

The M-cardia machine, bulb and clamp electrode and patient data cable should not be autoclaved, ultrasonically cleaned, or immersed.

#### E. Specification

1. Dimension and Weight

Dimension (in mm) (L x B x H): 105X65X40 mm

Weight (in Kg) : 150gm

2. Environmental

Operating Temp : 0 °C to +50 °C

Operating & Storage : 0 to 95 % non-condensing

Humidity

3. Power supply

Input : USB powered

Power consumption : < 10 Watt

4. Performance

Display : color

Language : English

5. Acquisition

Frequency response : 0.05 Hz to 100 Hz with notch

at 50Hz

Filter : DSP

Input impedance :  $10 \text{ M}\Omega$ 

Time constant :>3.2 sec

A/D conversion : 12 bit

Noise :  $< 20\mu V_{p-p}$ 

Leakage current :  $< 10 \mu A$ 

Patient isolation : Optical isolation.

Gain : 5, 10 & 20 mm/mV selectable.

CMRR : > 120 dB

Sweep speed : 25.0 mm/S.

Accuracy of HR : +/- 2 BPM.

Sampling Frequency : 250 samples per second

simultaneous

#### F. Supplies and Accessories: List of Accessories

NOTE: Do not store any consumables after its expiry date.

Sr. No.	Material Name	Qty.	
1.	Patient Cable 10 Lead	1	Detachable
2.	M-cardia unit	1	-
3.	User manual	1	-
4.	ECG Bulb Electrode [Pack of 6Nos]	1	Detachable
5.	USB C type to USB OTG cable	1	Detachable
6.	Clip-On Electrode [Pack of 4Nos]	1	Detachable

#### Warning:

Use only the patient cable and accessories as supplied. Substitutions may cause the ECG machine to function improperly. If you wish to replace the accessories, then contact our Service personnel (Refer Service Information)

#### **G.** Maintenance

Material name	Recommended	Maintenance details	
	frequency	reference	
ECG Machine	weekly	Refer Appendix-A -	
		Warning point D	
		Cleaning Instruction	
Reusable Patient	After each patient	Refer Appendix-A	
cable	use	and point D <u>Cleaning</u>	
		<u>Instruction</u>	
Reusable Electrode	After each patient	Refer Appendix-A	
Cleaning	use	Warning and point D	
		Cleaning Instruction	

### H. Environmental protection

#### Disposal of the Equipment:

Then dispose of the device and supplies in accordance with your state regulations.



#### NOTE:

Disposal of the product: The product described in this user manual must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

### I. Servicing Information

Service life of machine is 7 years.

#### Warning:

Authorized personnel should only open this device as there are no user serviceable parts inside.

For servicing contact an authorized NASAN Medical Electronics Pvt. Ltd. Service Engineer.

#### Contact us:

All INDIA SERVICE (Mobile): 09371039255

Email address : <u>service@nasanmedical.com</u>

Website : <u>www.nasanmedical.com</u>