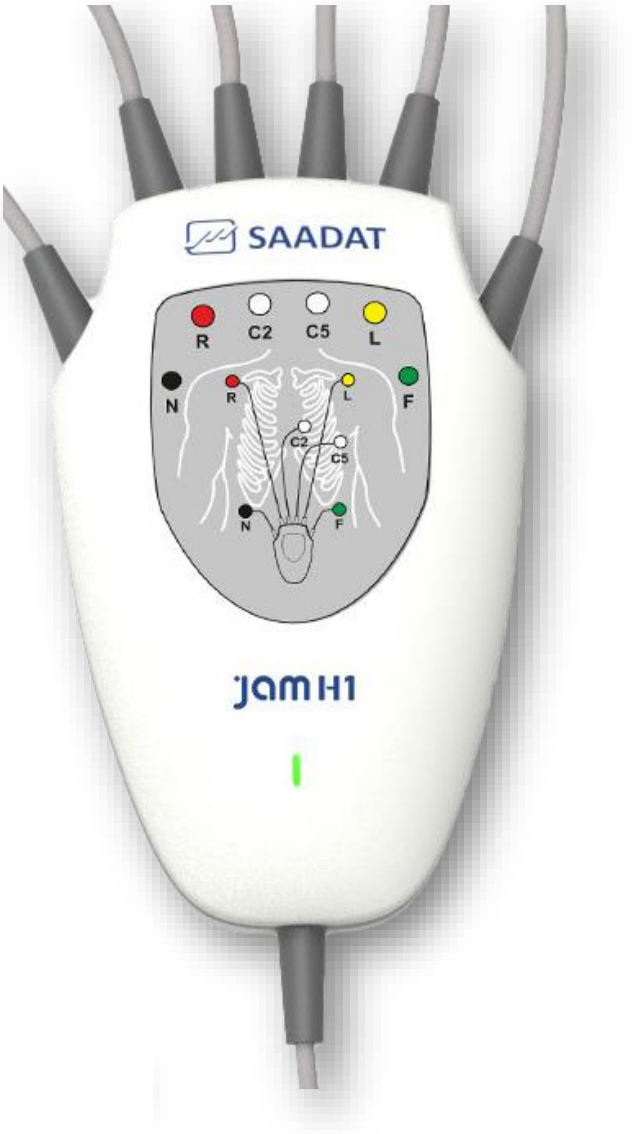
POOYANDEGAN RAH SAADAT Co.

Telecardiograph

JAM H1

Operator's Manual



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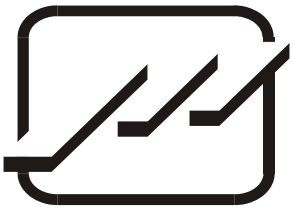

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Contents

About the operator’s manual

This manual is intended for JAM H1 telecardiograph device.

This manual is a part of the product and describes its proper and safe intended use to the patient and user. Observance of the manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

In order to use the equipment safely, it is necessary to follow the instructions in this manual. However, the instructions in this manual are in no way a substitute for medical patient care practices.

Indications used in this manual

Warning

The items listed in this indication, remark a warning to avoid any danger or injury to the patient, user or device.

Note

The items listed in this indication, contain additional recommendations and explanations for better use of the device.

Version of manual

This manual has a version number. The version number changes whenever the manual is updated.

The version information of this manual is as follows.

Code and Version	Issue date
D01179–V4	Apr 2024

- Read this manual carefully before patient use of the device.
- All illustrations in this manual are provided as examples only. They may not necessarily reflect your device setup or data displayed on your device.
- Pooyandegan Rah Saadat Co. reserves the right to make changes to this manual and describes improvements to the product at any time without notice obligation.

Symbols

1	Protected from objects greater than 12 millimeters. Protected from water spray less than 15 degrees from vertical.	**IP44**
2	Manufacturer address	
3	Refer to the operator's manual for complete information.	
4	This symbol indicates that the equipment shall be disposed of in an environmentally-friendly manner.	
5	Manufacture Date and name of manufacturer	 YYYY
6	Serial Number	SN
7	This symbol indicates that the equipment has a unique identifier.	UDI
8	This symbol indicates that the equipment is medical.	MD
9	CE sign & NB identification number	CE 2195
10	This symbol indicates that the device has CF type and Defibrillation Proof applied part according to IEC60601-1. The modules with this symbol contain a CF-Type isolated (Cardiac Float) patient applied part providing a high degree of protection against shock, and is usable during defibrillation.	
11	This symbol beside the patient connector indicates that a part of protection against effects of defibrillator is provided by the connected accessory to patient. Therefore, use only accessories approved by the manufacturer.	
12	European Community Representative	EC REP

Safety and general warnings

The following Warnings and Notes have to be obeyed to guaranty a safe operation of the device. The device is designed to comply with the international safety standard requirements for medical electrical equipment. This device has floating inputs and is isolated from power line.

Warning

- The device shall be used after carefully reading the entire operator's manual and in accordance with its instructions.
- The device users must be adequately trained to use the device.
- Any assembly, production, development, updating, modification or repair must be done by the company's authorized trained personnel.
- The device is intended to be used as a diagnostic assistance. The health care professional should seek a full capability ECG system for diagnostic purposes.
- The device is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.
- The results provided by JAM H1 are not to be used as the basis for beginning or changing therapeutic measures without an independent medical examination.
- Do not attempt to make a diagnosis on the basis of the results and analysis provided by JAM H1. Always check with your physician. Self-diagnosis may cause a deterioration of your state of health or medical condition.
- Results provided by JAM H1 reflect the moment of a recording. Your state of health may change rapidly. In case you notice a change in your state of health, contact a physician.
- JAM H1 serves the purpose of detecting new ischemia and arrhythmias of the heart. JAM H1 is not designed for continuous ECG monitoring, but merely evaluates a short time window of your heart's activity.
- Note that a physician may only receive your ECG recordings if you are actively linked to the physician through the JAM H1 database.

- Transmission of ECG data to the linked physician is not guaranteed. In addition, when your ECG data is received by your physician, this does not guarantee that they will look at the data or establish a diagnosis. It is recommended that you contact the physician you are linked to directly. This is especially important in the case of an emergency.
- The device is protected against effects of Defibrillator. Recovery time after defibrillation is 10 seconds. Do not touch the patient, bed, bedside or Jam H1 when using with a defibrillator.
- The device is protected against effects of Electro surgery unit. When using Electro surgery equipment, leads should be placed in the furthest possible distance from Electro surgery electrodes and its grounding plate to avoid burning.
- The device is intended for use in the electromagnetic environment specified in EMC appendix. It should be assured that the JAM H1 is used in the electromagnetic environment specified in this manual.
- The device function can be affected in presence of electromagnetic sources. It should be assured that nearby electrical equipment complies with EMC requirements.
- The device needs special precautions if it is placed close to a strong transmitter such as X-ray equipment, electrosurgical equipment, MRI devices, TV, AM/FM radios, police/fire stations, a HAM radio operator, or an airport. Their Signals could interfere with the device, which may result in dysfunction of this device or prevents the clear acquisition of signals by the device.
- Do not use the device with MRI equipment.
- Portable RF communications equipment including peripherals such as antenna cables and external antennas should be used no closer than 30 cm (12 inches) to any part of the device including cables specified by the manufacturer. Otherwise degradation of the performance of this equipment could result.
- To avoid device malfunction, liquids must not be allowed to enter the device. If liquids have entered the device, take it out of service and have it checked by a service technician before it is used again.

- Protect the device from moisture and liquids and extremely high/low temperatures. Also, protect the device from mechanical stress and do not expose it to direct sunlight, as this can cause the device to not function properly.
- .Do not use this device in the vicinity of flammable gases such as anesthetic gases due to the risk of explosion.
- The device is not intended to be used in oxygen saturated environments.
- To prevent the environment pollution, the device shall be disposed in accordance with national laws after their useful lives.
- Do not use the device for any other purpose other than the items listed in this manual. Doing so will void the device's warranty.

1. Introduction

General description

The JAM H1 (ECG) records ECG signal via six electrodes and facilitates the heart monitoring through detecting and analyzing the heart abnormalities. The data recorded by the mobile software will be sent to the server via the internet. After analysis of the heart signal, an interpretation report will be provided by the software that can be presented to a specialist.

Intended purpose

JAM H1 along with its mobile application is a medical electronic device intended to acquire, analyze, display, save and send ECG signals.

Indications

The JAM H1 (ECG) is indicated for recognizing cardiac disorders. This device helps cardiac patients to record ECG and send it to their physician in case of chest pain or heart attack symptoms and track momentary and transient disorders. In addition, clinicians could record and check ECG if needed.

Contraindications

Do not use the JAM H1 (ECG) for Open Heart Applications (Intra-cardiac Application).

Target population

Adults, pediatrics and neonates.

Intended user

- Healthcare providers
- Patients can use the device base on a doctor’s prescription.

Principle of operation

Acquisition of ECG signal via electrodes.

Performance characteristics

- Deriving 12 leads ECG using 6 wires
- Pace Detection and Rejection
- Defibrillator proof
- Filter to reject environmental noises
- Real-time transmission of data to Smart phone application via USB-type C cable
- Powered by connecting to the USB-type C mobile port
- No need to pay any fee for either downloading or updating our ECG app for smartphones
- Real-time receiving and displaying 12 lead ECG
- Storing the patient history in a cloud based secure server to access the patient data
- Running the Glasgow software to provide automated interpretation of ECG for heart health assessment
- Capable of transmitting the 12 lead ECG, parameters and interpretational reports to specialist's email through the Internet communications

Undesired side effects

Skin allergy when electrodes are attached.

Intended environment

- Clinical environment (hospital, ambulance)
- Home use based on a doctor’s prescription

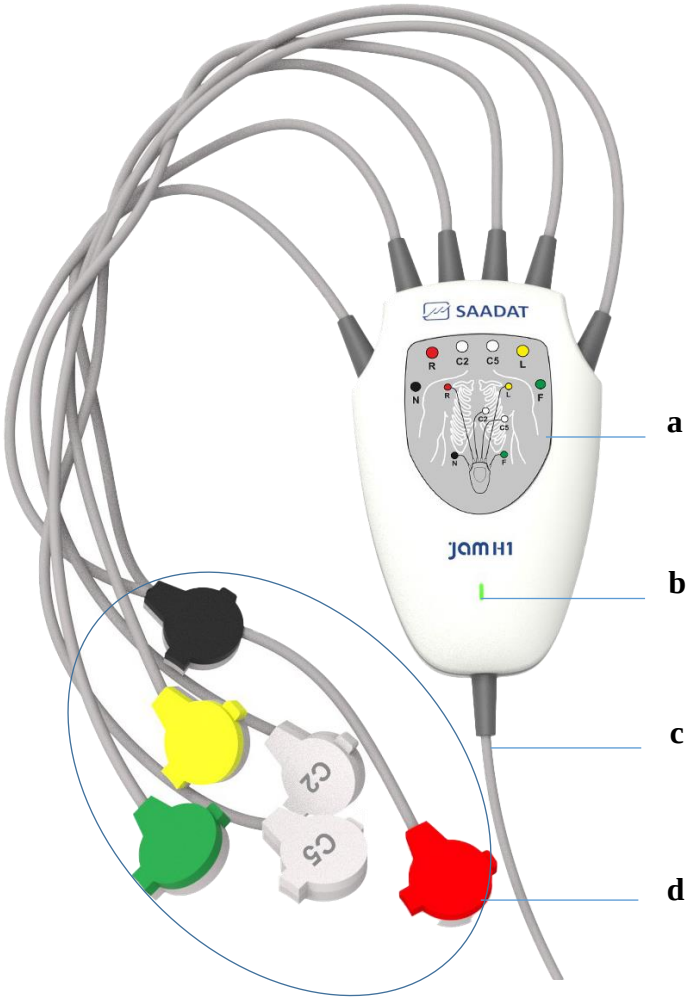
Note

- To access information about operating and storage and transport temperature and humidity, refer to technical specification chapter.

Components of the package

- Jam H1 device
- Disposable ECG chest leads
- Device Holder
- Quick reference

Device components



a. **Electrodes attachment guide**

b. **LED**: Turns on when connected to mobile phone and flashes according to heart rate

c. **USB-C cable**: Connects to mobile phone

d. **ECG lead wires**: Connect to chest leads

2. Installing mobile phone application

Scan the QR code printed at the back label of your device and the download page will be displayed automatically. Jam H1 application can also be installed by searching “JAM H1 heart signal analyser” in Bazaar app store. It can also be installed by clicking on the link below:

https://cafebazaar.ir/app/com.wearable.jamh1

After installation, Jam H1 application can executed. The application is automatically executed by connecting the device to your phone or tablet.

Note

- Jam H1 is not applicable without an Android mobile phone or tablet.

3. Electrodes attachment and mobile phone connection

Device hardware

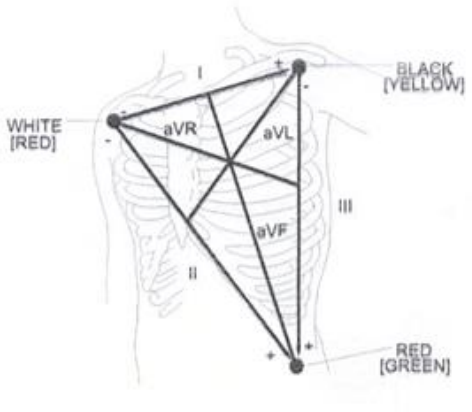
Introduction

The continuous function of the myocardium generates an electric potential that are sensed by ECG electrodes on the skin.

Through ECG acquisition you can see a continuous waveform of the patient's cardiac electric activity which enables physician to perform a precise assessment of patient current physiological condition. Proper connection of the ECG cable and electrodes can ensure accurate assessment. The device measures ECG signal by 6 ECG electrodes and then processes and amplifies this signal and displays it as ECG waveform on the mobile screen.

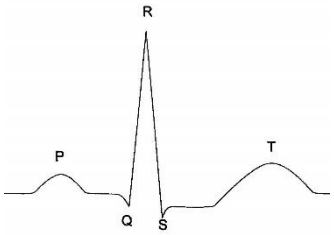
The ECG leads are as follows:

"I": L - R	**"aVR"**: R - $\frac{L+F}{2}$
"II": F - R	**"aVL"**: L - $\frac{R+F}{2}$
"III": F - L	**"aVF"**: F - $\frac{R+L}{2}$
"V2": C2 - $\frac{R+L+F}{3}$	**"V5"**: C5 - $\frac{R+L+F}{3}$



Normal QRS waveform

- Tall R-wave completely above or below the baseline.
- T -wave less than one-third of the R-wave height.
- P-wave smaller than the T -wave.

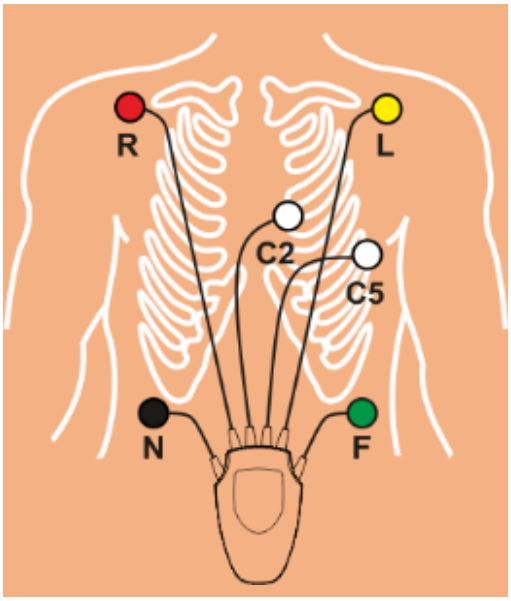


Electrodes attachment

Skin Preparation and attachment

The following is an instruction for skin preparation and should be followed for all electrode types.

- Choose flat, non-muscular areas to place electrodes.
- Make sure the skin area where the electrodes are to be placed is clean, dry, intact and free of powder, oil or lotion.
- If necessary, shave hair from skin at the chosen sites.
- Place chest leads on the proper place on the patient's body. If the chest lead has no conductive gel, apply some conductive gel on intended site of the skin.



Region	Color	Electrode
Near the right shoulder, directly below the clavicle.		Right Arm (R)
Near the left shoulder, directly below the clavicle		Left Arm (L)
On the left hypogastrium.		Left Leg (F)
On the right hypogastrium.		Right Leg (N)
On 4th intercostal space at the left sterna margin.		C2
On the left anterior axillary line		C5

- Attach the clips or snaps to the chest leads.
- Place the device in the holder and attach it to patient's clothes or belt.

Warning

- Check that all ECG electrodes are correctly attached to the patient.
- Make sure that ECG cable is not under tension during monitoring.
- Do not touch the patient, the device and bed during defibrillation.

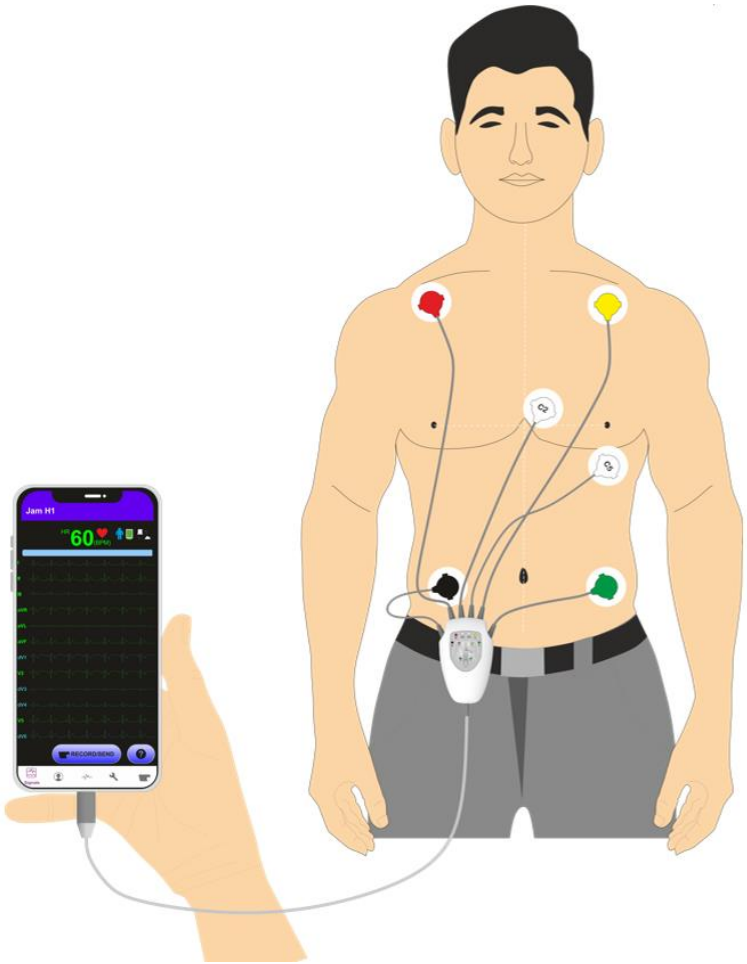
- ECG cable may be damaged if it is connected to the patient during defibrillation. The cables which have been connected to the patient during defibrillation should be checked functionally before being used again.

Some advice to reduce measurement errors

- Sit down calmly for at least 3 minutes before recording with Jam H1. Sitting with a straight back is ideal. Do not cough or talk during recording. Body movements could result in signal distortion and error in measurement and interpretation.
- Do not Record and send to server when device and patient are exposed to vibrations (in a moving vehicle, train or airplane).

Connecting the device to mobile phone

1. Attach the ECG electrodes to the patient body (according to patient preparation instructions).
2. Connect the device cable to Type-C connector of the mobile phone.
3. JAM H1 (ECG) application will automatically run.



Electrodes attachment and mobile connection

Note

- The power of the device is supplied by USB port of the mobile phone and a battery is not required.
- The LED on the ECG module will light up when powered by connecting to mobile, then it will blink proportional to the heart rate.
- When the device is connected for the first time, an auto execution window may pop up. Confirm auto execution of the app.
- Software name, version and date of issue are displayed at the beginning of app execution.

4. Working with the app

Features of the application

The ECG Analyzer application is designed to communicate with the JAM H1 (ECG) device and can connect to the device via USB-C cable and display ECG signal.

Language of the app

The application language is set according to mobile phone language, English or Persian.

Leads reconstruction

In order to make the patient more comfortable and reduce the workload of the clinical staff, Jam H1 records I, II, III, aVR, aVL, aVF, V2 and V5 leads using 6 electrodes and reconstructs V1, V3, V4 and V5 leads using smart algorithm and displays the estimation of them along with acquired leads.

Glasgow interpretation

Glasgow university ECG analysis algorithm, analyses ECG signal considering patient age and gender. Cardiac disorders such as infarctus, ischemia, bradycardia, tachycardia, arrhythmia and etc. can be detected by this algorithm.

10 seconds of recorded signals to the server and receive the sophisticated interpretation of ECG analyzed by Glasgow software.

Sending E-mail

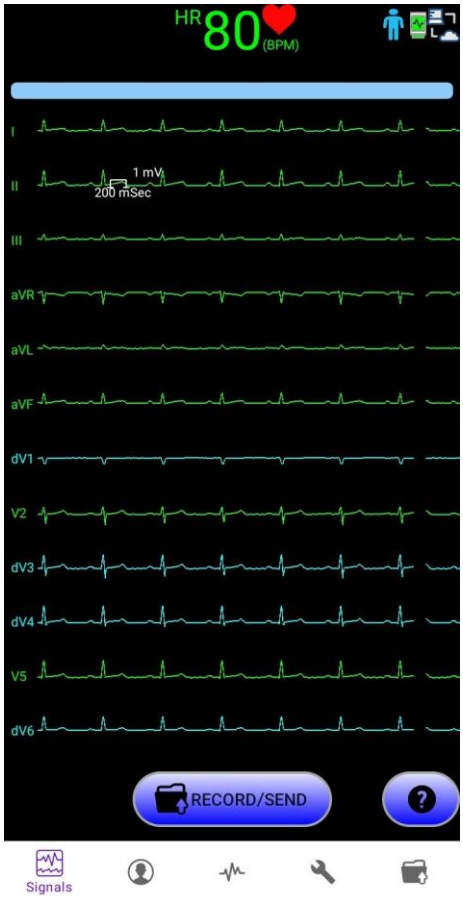
The application is capable of sending a PDF file containing patient information, ECG signal and Glasgow interpretation results to any user-predefined E-mail address.

Application menus

Menus of the application are available at the bottom menu bar:

Signals menu

- The software main page where the ECG signals are displayed. (Reconstructed leads are displayed in blue color). The lead name of each signal is displayed at the left side with the same color as the signal (beside the names of reconstructed leads, letter “d” is displayed, meaning it’s a derived lead). The application constructs 12 lead ECG using artificial intelligence algorithms.



The displayed icons in the main page are as following:

	This icon will appear if connection to the server is made and there is no request for data sending
	This icon will appear if the internet connection fails and there is request for data sending
	This icon will appear if the connection to the server is made and data are sent.
	If the connection between the mobile and the device is established, this icon will be shown in green. Otherwise, it is white.
	Neonate patient (below 3 years)
	Pediatric patient (male/female below 17 years)
	Adult patient (male/female above 17 years)
	Patient with undefined gender
	This icon will appear when PACE Detect is ON.
	Hear rate
	record and send key

Note

- Any reason that saturates the ECG circuit (such as discharge of the defibrillator device), will cause the signal to be displayed in the form of a flat line and display the Check Lead message, which usually returns to normal conditions in less than 5 seconds.

Status messages

The device messages including “Software performance” and “Module Connection” are displayed on top of the **signals** page. Status messages and their definitions are displayed.

	Status Message	Definition
Module Connection	No module: ECG	The module is not connected.
	ECG Check L	Lead wire L is not connected.
	ECG Check R	Lead wire R is not connected.
	ECG Check F	Lead wire F is not connected.
	ECG Check C2	Lead wire C2 is not connected.
	ECG Check C5	Lead wire C5 is not connected.
Software Performance	Start Record	Start data recording for 10 seconds
	Record complete	End of data recording
	Recording: --%	The percentage of the recording progress according to the progress bar
	Break Record	Disconnection of a lead wire during recording
	Send File OK	Successful data sending to the server
	File Remain: --	The number of files waiting to be sent to the server
	PDF Downloading	Downloading the PDF Report

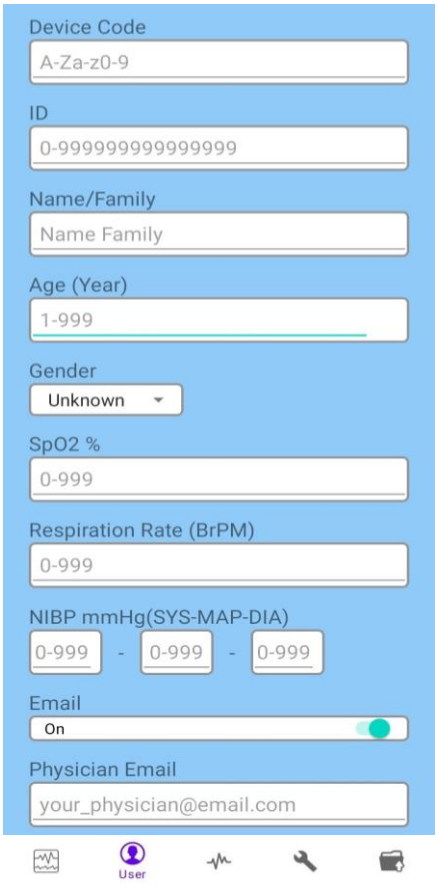
	PDF Downloaded	PDF report has been downloaded and ready to be checked.
	Start record fail	The recoding is impossible (due to the electrodes disconnection)
	Report summery	Summary of interpretation report (Normal ECG and etc.)

Note

- The results of the records interpretation will be displayed in yellow after receiving data from the server.
- Informative messages (e.g., Start Record, Send File OK and etc.) are displayed in white.
- In case of no internet connection, the number of records that are in the sending queue will be displayed in the status messages area as “File Remain: --”.
- Make sure that no VPN is active on the mobile phone.
- Beat volume can be adjusted by phone’s volume buttons.

User menu

- In this section, set user information:
  - Device code
  - ID
  - Name/Family
  - Age
  - Gender
  - SpO2: Oxygen saturation
  - Respiration Rate
  - NIBP: Non-invasive blood pressure
  - Physician E-mail

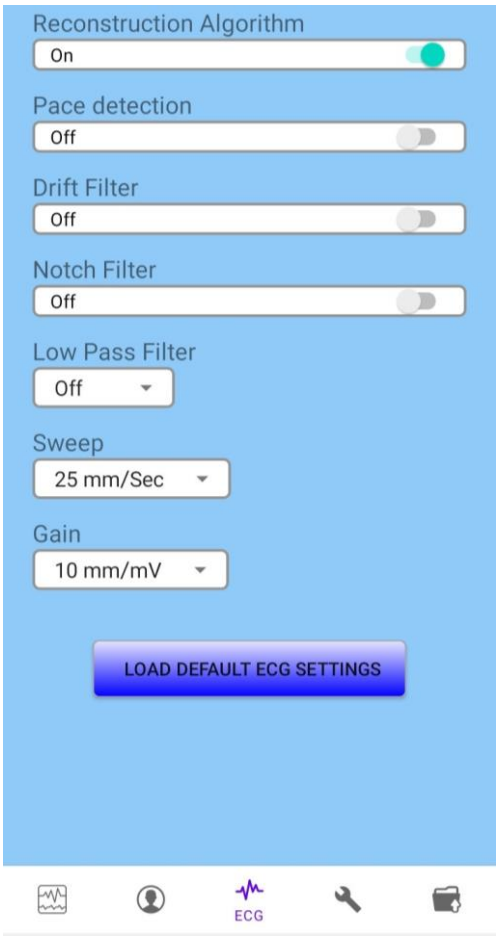


Note

- Toggle Physician E-mail on and enter the corresponding E-mail address to send recording results to your physician.

ECG menu

- In this section, ECG module settings are available:



  - **Reconstruction algorithm**: By activating this item, reconstructed leads are also displayed. Default: On

- **Pace detection**: By activating this item, pacemaker-generated signals that they will be ignored in determining heart rate.

  Default: Off

Warning

- For patients with pacemaker, **Pace detection** must be switched **ON**, otherwise, the pace pulses may affect HR counting and result in low precision of HR value. This option should be **OFF** for patients have no pacemaker.
- For the patients with pacemaker, the device may continue to count the pacemaker rate during occurrence of cardiac arrest or some arrhythmias. Do not rely entirely on monitor and keep the patients with pacemaker under close surveillance.

Note

- A vertical bar is displayed on the ECG waveform, where a pacemaker signal is detected.
- If the patient does not have a pacemaker, it may be desirable to turn the **pace detection OFF**, so that artifacts in the waveform will not be mistaken for a pacemaker signal.

- **Drift filter**: This filter reduces signal fluctuations (up and down signal reference line) that are mainly due to the patient's breathing and movement.

  Default: Off

- **Notch Filter**: The function of this filter is to eliminate the effects of mains noise on signals.

  Default: Off

- **Low Pass Filter**: Available options are Off and 35, 75, 120 Hz. This filter is used to remove muscle noise and high frequency noise. Using these filters make the heart signal smoother and cleaner.

  Default: Off

- **Sweep speed**: Available options are 25 mm/Sec and 50 mm/Sec.

  Default: 25 mm/Sec

- **Gain**: Available options are 5 mm/mV, 10 mm/mV and 20 mm/mV.
  Default: 10 mm/mV

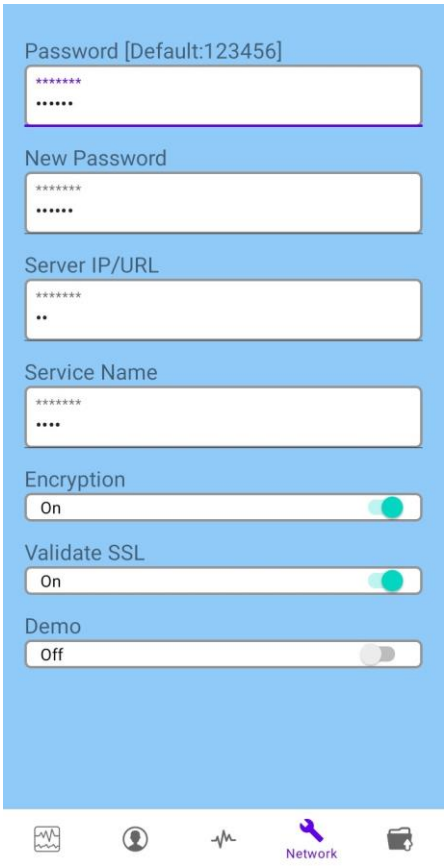
Note

- It should be noted that the gain and filter settings in the software will be applied at the stage of signal analysis and report PDF file creation and do not affect signal displaying on **signals** menu.
- Signal plotting on the main screen (Signals menu) is always done with Auto gain and sweep and cannot be changed.

Press **Load Default ECG Settings** to restore setting to defaults.

Network menu

- Type the default password to enter the network menu. In this section, the network settings can be done.



- **Password**: The default password is 123456.
- **New Password**: Enter the new password if you want to change the default one.
- **Server IP/URL**: By default, this value is set to the predefined server.
- **Service Name**: By default, this value is set to default service name.
- **Encryption**: This option must remain **On** in normal situation.
- **Validate SSL**: If an IP address is entered on **Server IP/URL** field, this option must be set to **Off**.
  If a URL is entered on **Server IP/URL** field, this option must be set to **On**.

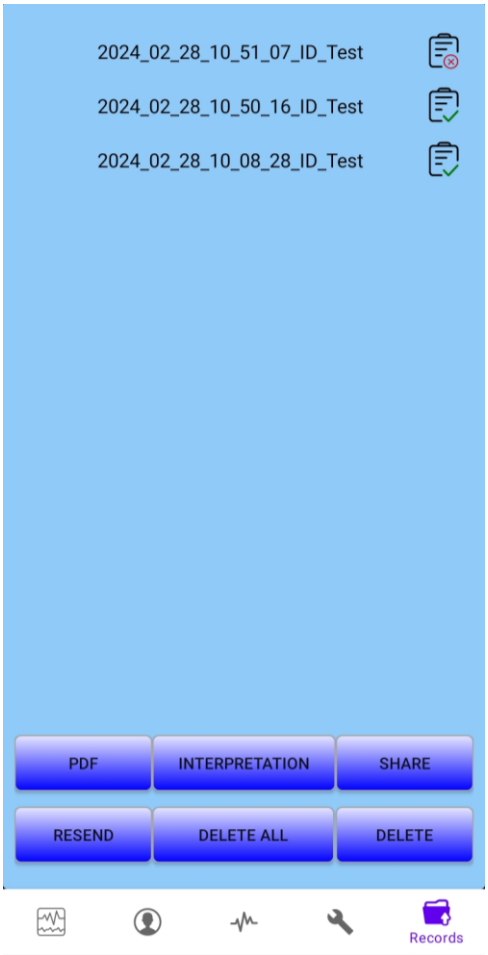
Note

- If the device is used in an ambulance, it is necessary to change the **Server IP/URL** and **Service Name**. If so, sending the signal to TC viewer app will be available. (Refer to TC viewer operator's manual if needed.)

Records menu

- All recorded data can be seen in this section. You can also view the signals, receive the report in PDF format and resend data through this page.

  - **PDF**: To receive and view PDF report.
  - **INTERPRETATION**: to view interpretation of the records.
  - **SHARE**: To share data and their report
  - **RESEND**: To resend the data records to the server.
  - **DELETE ALL**: To delete the whole archive.
  - **DELETE**: To delete the selected record.

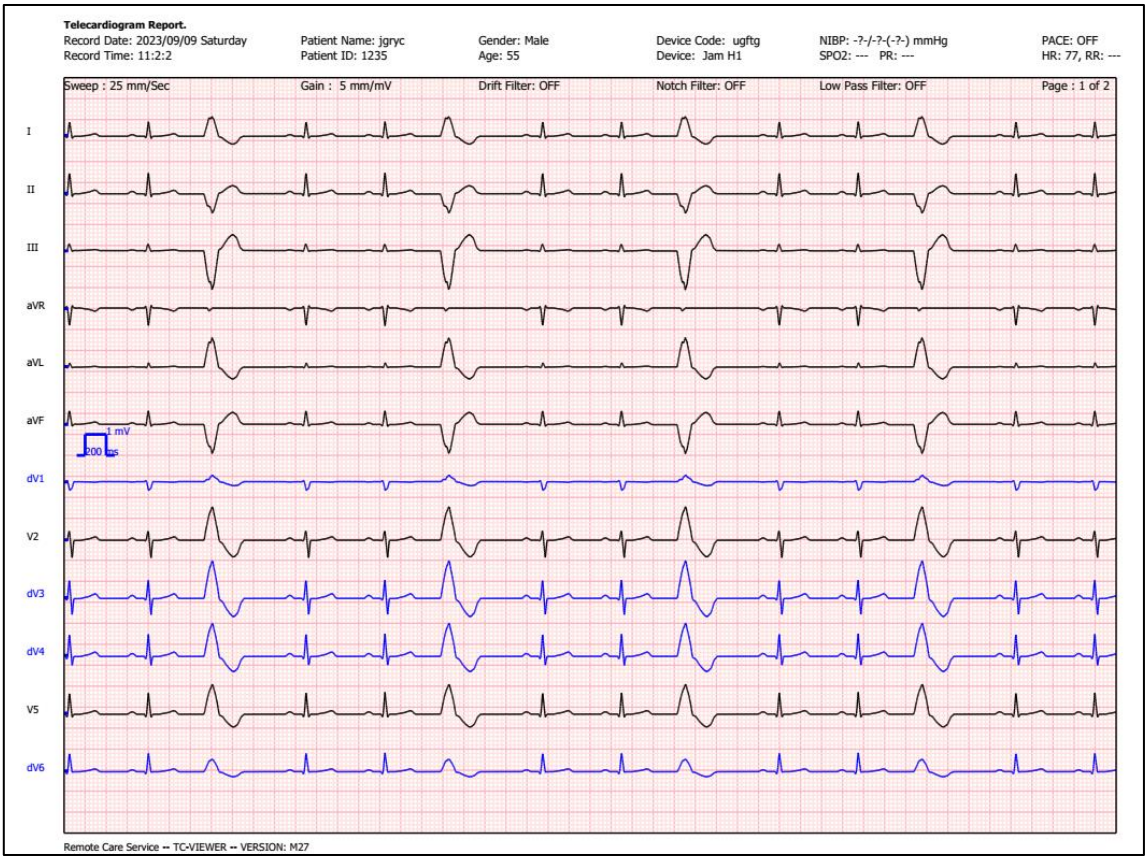


Note

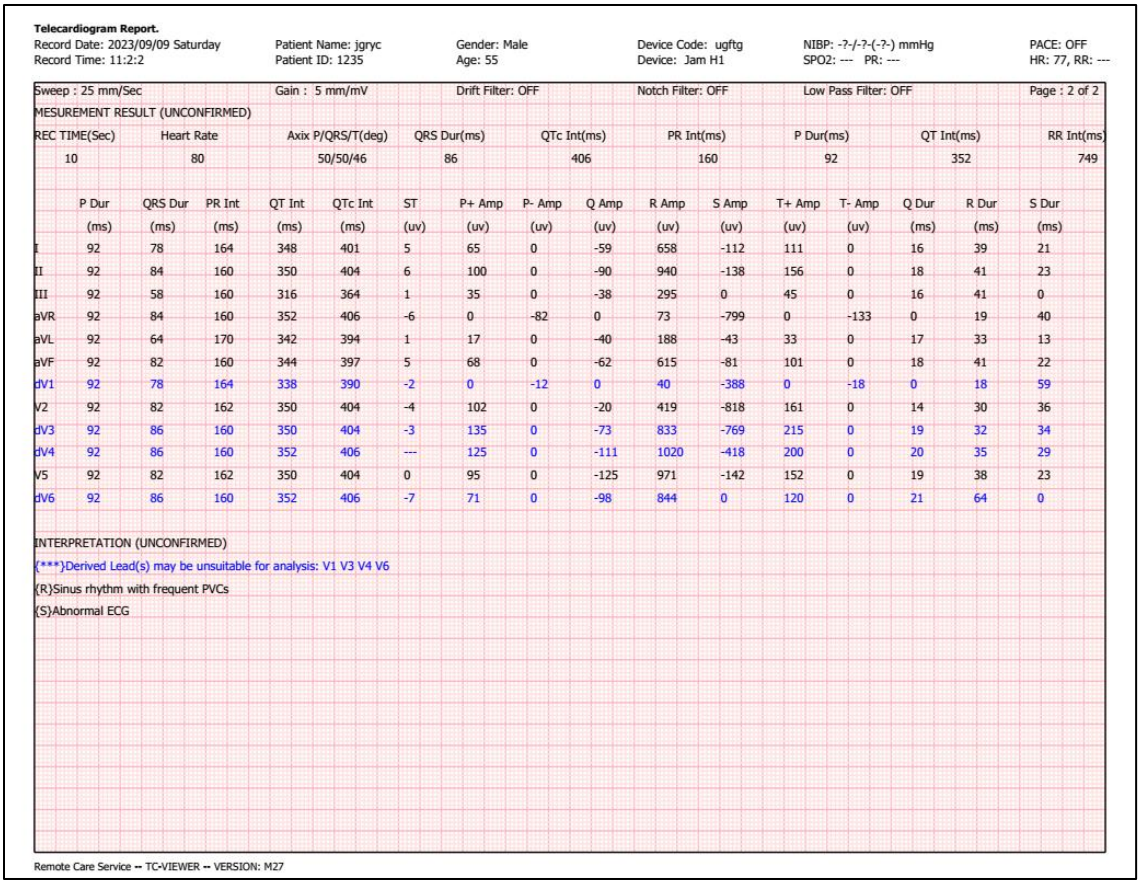
- A sign on the record indicates that the data has not been sent to the server, sending and viewing Glasgow interpretation and PDF file is not possible. The record is automatically sent as soon as connection is restored.

PDF

By pressing **PDF** button, a pdf file is generated in which patient information, leads signals and at the end Glasgow interpretation results are displayed.



First page of pdf output consists of patient information, settings and signals



Telecardiogram Report.

Record Date: 2023/09/09 Saturday | Patient Name: jgryc | Gender: Male | Device Code: ugftg | NIBP: -?-/-?-(-?-) mmHg | PACE: OFF
Record Time: 11:2:2 | Patient ID: 1235 | Age: 55 | Device: Jam H1 | SPO2: --- PR: --- | HR: 77, RR: ---

Sweep : 25 mm/Sec | Gain : 5 mm/mV | Drift Filter: OFF | Notch Filter: OFF | Low Pass Filter: OFF | Page : 2 of 2

MESUREMENT RESULT (UNCONFIRMED)

REC TIME(Sec)	Heart Rate	Axix P/QRS/T(deg)	QRS Dur(ms)	QTc Int(ms)	PR Int(ms)	P Dur(ms)	QT Int(ms)	RR Int(ms)
10	80	50/50/46	86	406	160	92	352	749

	P Dur (ms)	QRS Dur (ms)	PR Int (ms)	QT Int (ms)	QTc Int (ms)	ST (uv)	P+ Amp (uv)	P- Amp (uv)	Q Amp (uv)	R Amp (uv)	S Amp (uv)	T+ Amp (uv)	T- Amp (uv)	Q Dur (ms)	R Dur (ms)	S Dur (ms)
I	92	78	164	348	401	5	65	0	-59	658	-112	111	0	16	39	21
II	92	84	160	350	404	6	100	0	-90	940	-138	156	0	18	41	23
III	92	58	160	316	364	1	35	0	-38	295	0	45	0	16	41	0
aVR	92	84	160	352	406	-6	0	-82	0	73	-799	0	-133	0	19	40
aVL	92	64	170	342	394	1	17	0	-40	188	-43	33	0	17	33	13
aVF	92	82	160	344	397	5	68	0	-62	615	-81	101	0	18	41	22
dV1	92	78	164	338	390	-2	0	-12	0	40	-388	0	-18	0	18	59
V2	92	82	162	350	404	-4	102	0	-20	419	-818	161	0	14	30	36
dV3	92	86	160	350	404	-3	135	0	-73	833	-769	215	0	19	32	34
dV4	92	86	160	352	406	---	125	0	-111	1020	-418	200	0	20	35	29
V5	92	82	162	350	404	0	95	0	-125	971	-142	152	0	19	38	23
dV6	92	86	160	352	406	-7	71	0	-98	844	0	120	0	21	64	0

INTERPRETATION (UNCONFIRMED)

{***}Derived Lead(s) may be unsuitable for analysis: V1 V3 V4 V6

{R}Sinus rhythm with frequent PVCs

{S}Abnormal ECG

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Second page of pdf, Glasgow interpretation

5. Recording

1. Attach ECG electrodes to patient (According to **Electrodes attachment** section)
2. Connect USB-type C cable to your mobile phone.
3. Jam H1 application will be executed automatically (more details on **Connecting the device to mobile phone)**
4. Make sure the mobile phone or tablet is connected to the internet.
5. Press **Record/Send button**.
6. The device records 10 seconds of 12 lead ECG signal. The recorded signal with its Glasgow interpretation results are sent to physician's e-mail address as a pdf file and is also available on the **Records** menu.

Warning

- The device app is not a substitute for a physician's diagnosis.
- It's advised to immediately send the reports for a cardiologist to obtain necessary consultations and recommendations.

6. Care and cleaning (PM)

System Check

Before using the device:

- Check if there is any mechanical damage in the device and accessories.
- Check if all connectors and lead-wires are tightly connected.

Warning

- If you see any signs of damage or deterioration in the device and its accessories, do not use it, and if necessary, contact the After-Sales Services department.
- The overall check of the device, including the safety check, should be performed only by qualified personnel. All checks which need the device to be opened, or could affect the safety, should be performed by After- Sales Services department.
- If user does not follow a satisfactory maintenance schedule, the device may become inaccurate, and human health may be endangered.

Note

- It is recommended that the device is calibrated by manufacturer every year, but it has to be calibrated once every 2 years. The medical center can request the system calibration whenever the device accuracy is in doubt.
- The device lifetime is 10 years.
- Use only the substances approved by manufacturer and methods listed in this chapter to clean or disinfect your equipment.
- Manufacturer makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For a method to control infection, consult your hospital's Infection Control Officer or Epidemiologist. Also observe any local policies that apply within your hospital.

Cleaning and Disinfection

Warning

- Before cleaning the device, make sure that it is disconnected from the mobile phone.
- Sterilization with gas or autoclave may cause damage to the device, so it is not recommended for the device.
- Allow the device to dry completely before making connections.
- Do not use ETO gas to disinfect the device.

Note

1- The device should be kept away from dust.

2- Do not use detergents that contain ammonia or acetone.

3. Most detergents should be diluted during use.

4- Avoid sharp nails or tools to clean hard stains.

5- Be careful not to put detergent inside the system case.

6- Dry the remaining detergent.

External surfaces

In-between patients or as required, in order to clean the device, wipe it gently using a moist cloth and warm soapy water or mild detergent, and for disinfection, Alcohol 70%, Isopropyl alcohol or N-propanol are recommended.

ECG Cable

Use soft cloth moistened with mild soap liquid or cleaning agent containing 70% ethanol to clean the ECG cable. To avoid damaging the system, it is recommended that disinfection be performed according to the general hospital schedule. Disinfection facilities should be cleaned first.

Warning

- Do not immerse ECG cable completely in water, solvents, or cleaning solutions since it is not waterproof.
- Do not attempt to sterilize ECG cable by irradiation, steam, ethylene oxide or any other method.
- If you see any signs of damage or deterioration in the cable, do not use it and contact the After-Sales Services department.

Preventive Maintenance (PM)

To ensure that the device performs in the best condition, it shall be kept clean and all points related to its maintenance shall be observed. There is no repairable part in the device and all repairs shall be done by the manufacturer.

Storage

The storage environment shall be clean and dry. If possible, use the original packaging of the device.

Note

- If the device or equipment falls from a height and is damaged or is in the vicinity of high temperature and humidity, contact the company's After-Sales Services at the earliest opportunity to ensure the correct operation.
- Thoroughly clean the device before and after it is not used for a while.

Weekly check of the following items is recommended:	Monthly check of the following items is recommended:
1. Device cleanness 2. Visual inspection of the device (case, cables, connectors and etc.) in terms of mechanical damage	1. Calibration label (Sending the device to the manufacturer for calibration at the specified date). 2. Visual inspection of the device in terms of mechanical damage 3. Device cleanness

Preventive Maintenance (PM) Checklist

The preventive maintenance (PM) checklist #PL-F-24 should be completed by responsible individuals of healthcare center. It should be noted that PM checklist is only used to inspect the device function in a specific time and will not guarantee continuity of the device integrity.

SAADAT Co.					
Form No. : PL-F-24/0		**PM Form (JAM H1 (ECG))**			
State:	**City:**	**Medical center:**	**Ward:**		
Device model:	**Serial number:**	**Installation date:**	**Inspection date:**		
No.	**Test and Inspection Item**		**OK**	**NOK**	**N/A**
1	**Visual inspection**	**No damage or breakage in the case**			
		Cleaning and disinfection according to the user manual			
		ECG Cable			
2	**Module function and communication to the mobile phone**	**Indicator of the module connection on the mobile phone**			
		Correct display of the ECG signal on the mobile phone			
3	**Software**	**Pace detection**			
		Data communication (sending /receiving data to/from the server)			

Final decision: **Pass** □ **Fail**

Expert Recommendation:

Expert Name & Signature: Name & Signature of person in charge:

7. Troubleshooting

Repairing the internal parts of the device must be only done by trained and authorized personnel of After- Sales Services; otherwise, the manufacturer will not take any responsibility for any possible hazard to the patient and the device.

Troubleshooting guide is intended to help users to solve the device problems caused by misuse or any other reason. When you face any problem, please make sure that you have followed all procedure mentioned in “Correct Action” column before you contact with After- Sales Services.

Fault Symptoms	Possible Cause	Correct Action
NO ECG waveform	• ECG cable failure. • Improper placement of the leads and electrodes.	• Check the leads and electrodes. • Short-circuit all the leads. If the cable is ok, no error message will be displayed. • Call for service.
Noisy ECG waveform	• Loose connection of the electrodes.	• Check the electrodes and leads. • Check applied gel on the chest lead or change the chest lead, if necessary. • Make the other sources of noise such as other medical devices far from the device. • Call for service.
Vertical bars on ECG waveform	• If "PACE ON" is activated for patient without Pace marker, ECG signal will be received as PACE.	• Turn “Pace detection” OFF.

Fault Symptoms	Possible Cause	Correct Action
Unstable HR	• ECG signal is noisy and inappropriate.	• Check the leads and electrodes. • Set the patient age (Adult, Paediatric and Neonate) correctly. • Call for service.
No connection between the device and the mobile phone.	• The mobile setting does not allow access to the USB port. • Failure of the module hardware or USB connector.	• Check the module cable and connector. • Delete the application and reinstall it and allow access to the USB port and automatic software running. • Call for service.
The software fails to run/stops running		• Delete and reinstall the application. • Call for service.

8. Technical specifications

CLASSIFICATION	
Protection against electroshock	Class I, INTERNALLY POWERED MEE, Type CF (Based on IEC 60601-1).
Mode of operation	Continues operation equipment
Harmful Liquid Proof Degree	IP 44
Safety of anesthetic mixture	Not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
ECG	
Leads and wires	6 Wires Original Leads: I, II, III, V2, V5, aVR, aVF, aVL. Derived leads: V1, V3, V4 and V6.
Dynamic Range	±8 mv
Lead Off Current	< 90 nA
Gain	5, 10 mm/mV
Filters	Drift: 0.5 Hz Notch: 50 Hz Low pass: 35, 75, 120 Hz
CMRR	> 98 dB
Internal Noise	< 30 μV RTI
Input Impedance	> 5 MΩ
Heart Rate Range	15 - 300 BPM for adult
	15 - 350 BPM for pediatric/neonate
Accuracy	±1% or 2 BPM
Tall T-Wave	Reject up to 1.2 mV Amp
Pacer Detection/Rejection	Duration: 0.1 - 2 msec
	Amp: ±2 to ± 700 mV (Without over/undershoot)
	Reject from heart rate counter
	Re-insert into ECG to display on screen
	Ineffective pace rejection: HR:0, Pace: 60 HR:60, Pace:60 HR:30, Pace:80
	Beside rejection of atrial paces precede ventricular paces by 150 or 250 ms
Protection	Defibrillator and Electro surgery

Standards	IEC 60601-1, IEC 60601-1-2, EN 60601-2-25 , IEC 60601-1-11, EN ISO 10993-1
Software	Running the Glasgow software to provide automated measurement and interpretation of ECG (on server): * Acute MI/Ischemia * Extreme Tachycardia and Bradycardia * Significant Arrhythmia * Prolonged QTc Interval
	Displaying 12-lead ECG
	Communication with server to Send ECG data and patient information, and receive the interpretation report.
INPUT/OUTPUT	
USB- type C port	
GENERAL	
Power	Powered by connecting to the USB-type C mobile port.
Operation Method	Mobile application
Protection	Against Electro surgery and Defibrillator
Physical Specification	
Weight (approximately)	120 g
Dimension (mm)	102 × 64 × 26
Case Material	ABS
ENVIROMENT	
Temperature	Operating: 5 to 40 ◦C (41 ~ 104 ◦F)
	Storage & Transport: -25 to 60 ◦C (-13 ~ 140 ◦F)
Humidity	Operating: 20-90 % (Noncondensing) Storage & Transport: 10-95 % (Noncondensing)
Altitude	-200 to 3000 m

Appendix I. System default settings

ITEMS	SELECTION	DEFAULT
ECG Settings		
Reconstruction Algorithm	On, Off	On
PACE Detection	On, Off	Off
Drift filter	On, Off	Off
Notch filter	On, Off	Off
Low Pass filter	Off, 35Hz, 75Hz, 120Hz	Off
Sweep	25 mm/Sec, 50 mm/Sec	25 mm/Sec
Gain	5 mm/mV, 10 mm/mV, 20 mm/mV	10

Appendix II. EMC

Warning

- To prevent EMC effect on the device, it should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the equipment should be observed to verify correct performance in the configuration in which it will be used.

EMC Declaration for Jam H1 (ECG)

Guidance and manufacturer's declaration – JAM H1 emissions		
The JAM H1 is intended for use in the electromagnetic environment specified below. The customer or the user of the device, should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The JAM H1 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The JAM H1 (ECG) is suitable for use in all establishments.
Harmonic emissions IEC 61000-3-2	N.A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N.A	

Guidance and manufacturer's declaration – electromagnetic immunity			
The JAM H1 (ECG) is intended for use in the electromagnetic environment specified below. The customer or the user of the JAM H1 (ECG) should assure that it is used in such an environment.			
Immunity test	Port	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Enclosure	±8 kV contact ±2 kV, ± 4kV, ± 8kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	Patient coupling		
	Signal input/output parts	N.A	
Electrical fast transient/burst IEC 61000-4-4	Input a.c. power	N.A	
	Signal input/output parts	N.A	
Surge IEC 61000-4-5	Input a.c. power	N.A	
	Signal input/output parts	N.A	
Voltage dips, IEC 61000-4-11	Input a.c. power	N.A	
		N.A	
Voltage interruptions IEC 61000-4-11	Input a.c. power	N.A	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	Enclosure	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The JAM H1 (ECG) is intended for use in the electromagnetic environment specified below. The customer or the user of the JAM H1 (ECG) should assures that it is used in such an environment.			
Immunity test	Port	Compliance level	Electromagnetic environment – guidance
Conducted RF [a)] IEC 61000-4-6	Input a.c. power	N.A	
	PATIENT coupling	3 V [b)] 0,15 MHz – 80 MHz 6 V [b)] in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1kHz	
	Signal input/output parts	N.A	
Radiated RF IEC 61000-4-3	ENCLOSURE	10 V/m, 80 MHz - 2,7 GHz, 80% AM at 1 kHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	ENCLOSURE	Refer to the following table (table 9 of EN 60601-1-2: 2020)	
Proximity magnetic fields IEC 61000-4-39	ENCLOSURE	Refer to the following table (table 11 of EN 60601-1-2: 2020)	

a) The following apply:
– All PATIENT-COUPLED cables shall be tested, either individually or bundled
– PATIENT-COUPLED cables shall be tested using a current clamp unless a current clamp is not suitable. In cases were a current clamp is not suitable, an EM clamp shall be used.
– No intentional decoupling device shall be used between the injection point and the PATIENT COUPLING POINT in any case.
– Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
– Tubes that are intentionally filled with conductive liquids and intended to be connected to a PATIENT shall be considered to be PATIENT-COUPLED cables.
– If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
– The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

b) r.m.s., before modulation is applied.

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment				
Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	IMMUNITY TEST LEVEL (V/m)
385	380- 390	TETRA 400	Pulse modulation [b] 18 Hz	27
450	430- 470	GMRS 460, FRS 460	FM [C] ±5 KHz deviation 1 KHz sine	28
710	704- 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	9
745				
780				
810	800- 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	28
870				
930				
1720	1700- 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4 25; UMTS	Pulse modulation [b] 217 Hz	28
1845				
1970				
2450	2400- 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	28
5240	5100- 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	9
5500				
5785				

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields		
Test frequency	Modulation	Immunity Test Level (A/m)
30 kHz [a]	CW	8
134,2 kHz	Pulse modulation [b] 2,1 kHz	65 [c]
13,56 MHz	Pulse modulation [b] 50 kHz	7,5 [c]

a) This test is applicable only to ME Equipment and ME Systems intended for use in the home healthcare environment.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) r.m.s., before modulation is applied.