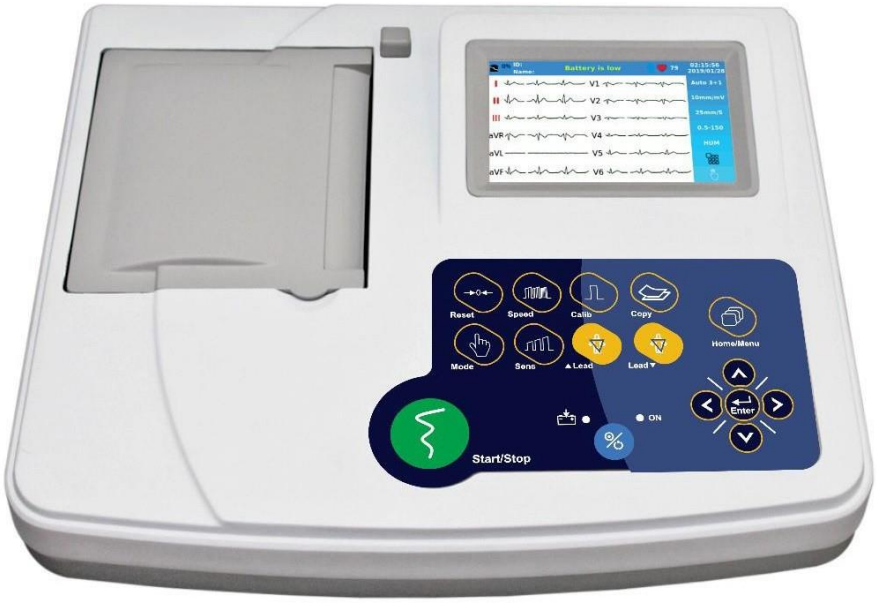
URUK Medical Equipment

User Manual

EM650
Electrocardiograph



D00012-V2

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Table of Contents

Manual Purpose

This manual provides the instructions necessary to operate Electrocardiograph device based on its intended use. Observance of this manual is a prerequisite for proper operation and ensures patient and operator safety. If you have any question about the device, please contact our customer service.

Intended Audience

This manual is provided for the clinical medical professionals. Clinical medical professionals are expected to have working knowledge of medical terminology and procedures as required for the device operation.

Version Information

This manual has a version number. The version number changes whenever the manual is revised due to software or technical specification changes. The version information of this manual is as follows:

Release date	Version number
Jan 2022	D00012-V1

Explanations of the used expressions in this Manual

A WARNING symbol advises against certain actions or situations that could result in personal injury or equipment damage.

A NOTE symbol provides useful information and recommendations about device function.

Explanations of the symbols in the Manual and device

Symbol	Definition
	Consult user manual of the monitor and pay attention to the warnings and cautions.
	The device is IEC60601-1 type CF (Defibrillation proof applied part) equipment. The units displaying this symbol provide an F-type isolated (floating) patient applied part with a high degree of protection against shock and is suitable to use with defibrillator simultaneously.
	For protection against defibrillator, use only manufacturer recommended accessories.
	The equipment shall be disposed of in an environmentally-friendly manner.
100-240 VAC 60VA 50/60 Hz	AC power supply
	3A fast fuse
USB	USB port
SD	SD port
S/N	Serial number
	Manufacture date
	Manufacturer information

Section 1- General Warnings

Please refer to this section for overall safety information.

General Warnings

⚠ **Warning** ⚠

Electrocardiograph system is intended to be used only by qualified medical staff.

⚠ **Warning** ⚠

Before use, carefully read this manual and directions for use of any accessories.

⚠ **Warning** ⚠

The electrocardiograph is intended for use only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

⚠ **Warning** ⚠

Do not use the electrocardiograph system during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The device may affect the MRI image, and the MRI unit may affect the accuracy of device measurements.

⚠ **Warning** ⚠

There could be hazard of electrical shock by opening the system casing. All servicing and future upgrading to this equipment must be carried out by personnel trained and authorized by manufacturer.

⚠ **Warning** ⚠

Always verify the beep sound when the system powers on. (For more information, please refer to section 8)

⚠ **Warning** ⚠

The operator must check that the system and accessories function safely and see that it is in proper working condition before being used (e.g. Date of the last calibration must be valid).

⚠ **Warning** ⚠

Do not use cellular phone in the vicinity of this system. High level of electromagnetic radiation emitted from such devices may result in strong interference with the electrocardiograph performance.

⚠ **Warning** ⚠

Do not touch the patient, bed or devices nearby during defibrillation.

⚠ **Warning** ⚠

When defibrillator is used, the signals may be disturbed for a few seconds, after which the device will continue to operate normally.

⚠ **Warning** ⚠

The physician shall consider all well-known side-effects when using the electrocardiograph.

⚠ **Warning** ⚠

To prevent the environment pollution, the device and accessories (e.g. battery) shall be disposed in accordance with national laws after their useful lives. Contact your municipality to check where you can safely dispose of old batteries.

⚠ **Warning** ⚠

Do not expose the system near any local heating item such as the direct radiation.

⚠ **Warning** ⚠

It is possible to increase leakage current when several systems as well as electrocardiograph are connected to the patient. ..simultaneously.

⚠ **Warning** ⚠

Electrocardiograph software is designed in a way that hazards arising from errors in the software programmed are minimized.

⚠ **Warning** ⚠

Do not connect items not specified as parts of the electrocardiograph system.

⚠ **Warning** ⚠

Equipment is not suitable for use in the presence of a flammable anaesthetic mixture.

⚠ **Warning** ⚠

To protect patient against the electrical shock hazards, the electrocardiograph device needs to be connected to grounded power receptacle.

⚠ **Warning** ⚠

Electrocardiograph needs to be installed and put into service according to the EMC information provided in the APPENDIX IV.

⚠ **Warning** ⚠

To prevent EMC effect on the electrocardiograph, it should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the system should be checked for normal operation in the configuration in which it will be used.

⚠ **Warning** ⚠

If any liquid is spilled on the system or accessories, immediately turn off the system and wipe up it by a soft cloth.

Section 2- System Configuration

Features:

EM650 is applicable to adult and neonatal patients and capable of:

_ Displaying 12-lead ECG waveform
_ Displaying Rhythm-lead waveform separately on the screen
_ 6-channel waveform recording
_ Data storage in internal and external memories
_ Displaying and recording stored data
_ Data transfer via USB
_ Programming software via USB
_ Supporting Linux operating system
_ Dividing space of the recorder paper based on the signal amplitude of different leads
_ Signal analysis and abnormality recognition (Measurement and interpretation)

Signal recovery accuracy:

With regard to maximum frequency bandwidth of 150 Hz and sampling rate of 1000 samples/s, the signal recovery accuracy of Dena Electrocardiograph complies with the requirements of IEC 60601-2-25 standard.

General

EM650 is a small, light-weight and portable Electrocardiograph device. It is equipped with a color TFT touch screen, recorder and built-in battery.

Environment:

Temperature:	
Working	5~ 40º C
Transport and Storage	-25 ~60º C
Humidity	20~90 %
Altitude	-200 to 3500m
Power Supply	100-240VAC, 50/60Hz 60 VA

Intended Use

EM650 is an advanced electrocardiograph which is designed to record electrical signals of the heart in six channels (10-wire) using a thermal printer with adjustable filter, gain, speed, and mode. This device is applicable to adults and neonates in all parts of the medical centre and used by healthcare professionals for diagnostic purposes.

System Description

Top Panel

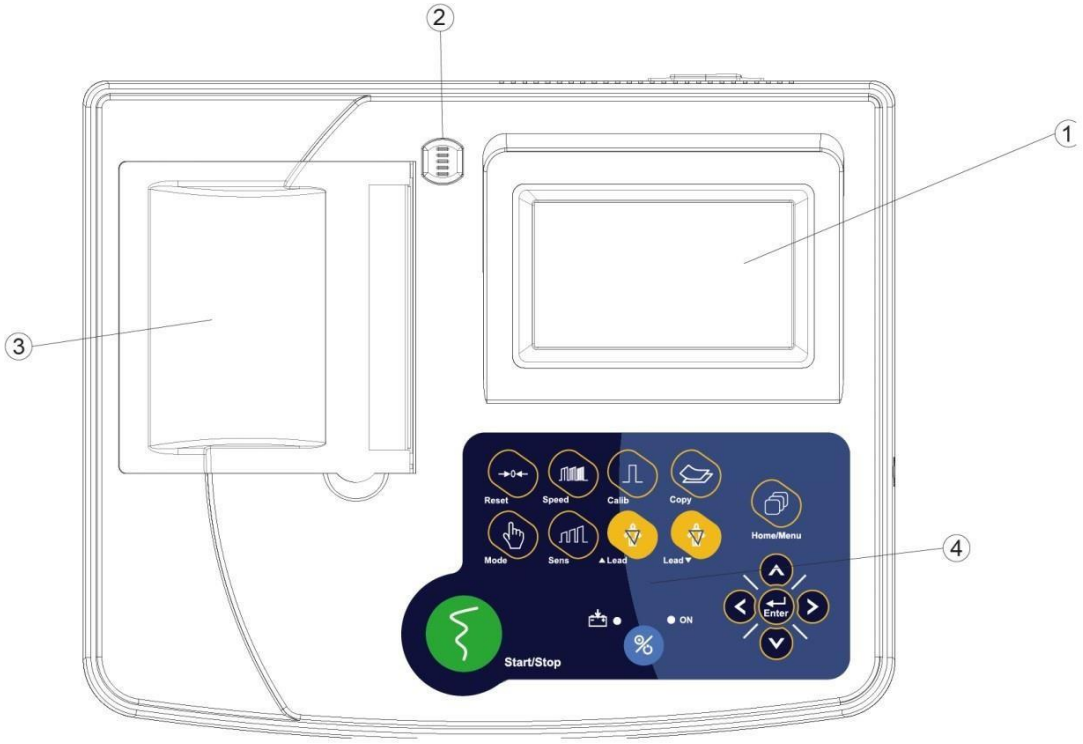


Figure 2-1 Top Panel

① Display Screen: ECG waveforms, patient information, messages, etc are displayed on the screen (See 1-1 for details).

② Recorder Release Button: to open the recorder door.

③ Recorder: to load recording paper and record ECG waveforms.

④ Control panel: to control the system operation (See 1-2 for details).

Display Screen

EM650 is equipped with a TFT color screen. All 12-lead ECG waveform, HR value, Patient name/ID, Date and Time, system operating status, error and informative messages are displayed on the screen. The screen is divided into four areas: informative and system error messages area (Figure 2-2-①), Header area (Figure 2-2-②), touch keys area (Figure 2-2-③), Waveform/ Menu area and lead error message area (Figure 2-2-④).

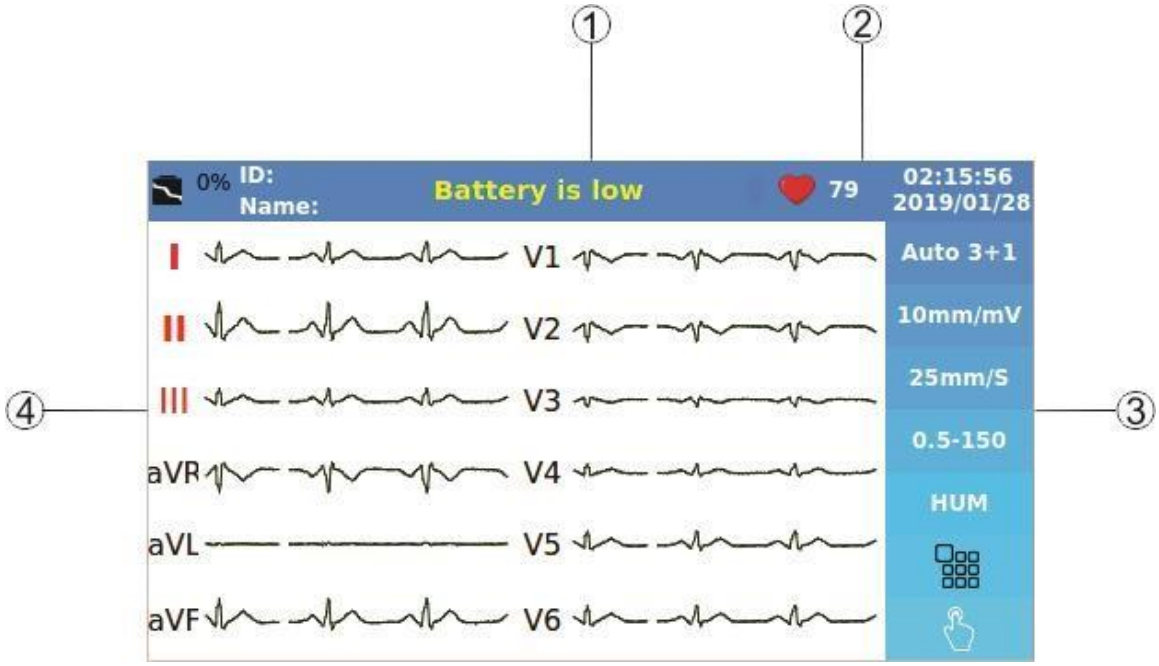


Figure 2-2 Display Screen

Header Area:

The Header Area is at the top of the screen. The heart rate, patient name/ ID, current date and time and system operating status are displayed in this area. This information is displayed on the screen during the system operation.

Symbol will appear in the Header Area only if the device runs on the battery.

The HR value is measured and updated per second.

Selecting each adjustable parameter from the main screen will call up a menu through which you can set the parameter.

Waveform/ Menu Area:

Rhythm-lead or 12-lead ECG waveforms are displayed on the screen and their arrangement can not be changed.

ECG lead type is displayed in Waveform Area.

Message Area:

The message area is divided into two parts:

1- Lead error message area:

All electrodes connection is checked regularly by the system and in case of improper connection, the related message will appear in this area in red (Figure 2-2-④).

2- Informative and system error messages area (Figure 2-2-①).

The system messages are displayed in white background and red text.

(Refer to Appendix III for the system messages).

Touch screen keys

The function of touch keys is the same as their corresponding hard keys on the control panel.

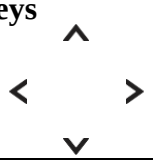
Refer to 1-2 (Control Panel) for details.

⚠ **Warning** ⚠

Do not touch the screen with sharp objects.

Control Panel

EM650 is designed in such a way that user can easily perform operations using some keys and touch screen.

① **Menu**	Press to access Main Menu.
② **Lead▲**	Press to select next lead(s).
③ **Copy**	Press to record the last saved data
④ **▼Lead**	Press to select previous lead (s).
⑤ **Calib**	Press to record a 1mv calibration signal.
⑥ **Speed**	Use to adjust the recording speed.
⑦ **Reset**	Use to reset Drift filter and restore signals quickly to the screen.
⑧ **Mode**	Use to select recording mode.
⑨ **Start/Stop**	Press to start/stop ECG recording.
⑩ **Sens**	Use to adjust the amplitude of ECG waveform on the screen and recording paper
⑪ 	Battery indicator
⑫ 	Press to turn on or off the device.
⑬ ON	On/Off indicator
⑭ **Arrow Keys** 	Use to scroll between menus.
⑮ **Enter**	Press to enter software menus or select menus options

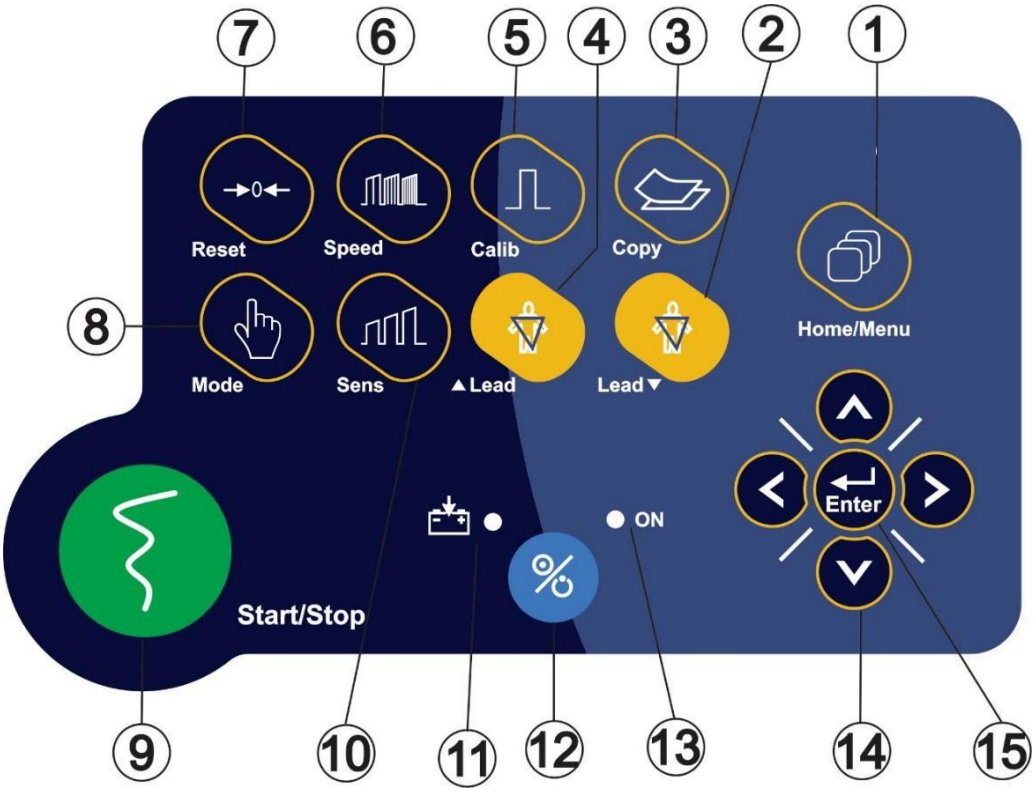


Figure 2-3 Control Panel

⚠ **Warning** ⚠

Before using the electrocardiograph, check function of all keys and make sure that it is in proper working order.

Indicators

The POWER switch (On/Off) is located on the control panel (⑫ in the figure 2-3). There are two indicators for power and battery on the control panel.

The green power indicator lights up when the device is powered on (⑬ in the figure 2-3).

The battery indicator illuminates green when the battery is fully charged; otherwise it is orange.

(⑪in the figure 2-3).

Bottom Panel

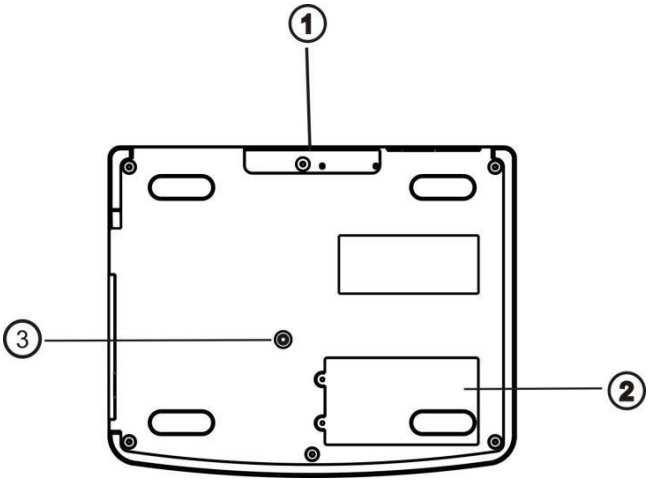


Figure 2-4 Bottom Panel

① Handhold: For transporting the device.

② Battery Compartment: For loading the battery.

③ 3A fast fuse

⚠ **Warning** ⚠

If the device is to be stored for a long period (more than 10 days), the fuse should be removed in order to prevent battery discharge.

Connectors

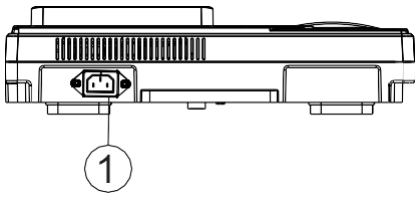


Figure 2-5 Rear Panel

① Power Supply: 100-240 VAC, 60 VA, 50/60 Hz

The following connectors are located at the right side of the device:

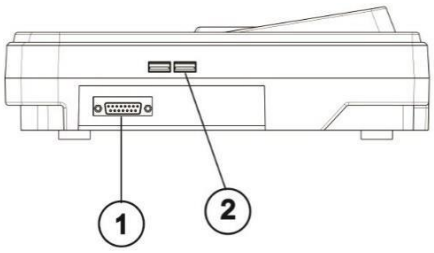


Figure 2-6 Side Panel

① Connector of ECG cable

③ USB port for data export and software update

Built-in Battery

The electrocardiograph is equipped with a rechargeable battery. The battery will charge automatically once you connect the system to the AC INPUT (whether the device is on or off). When the battery is fully discharged, it takes about 5 hours to charge it. The system can run on a fully-charged battery when the power cord is unplugged. Different types of the batteries used in the system and their charge time are specified in “Technical Specification” section.

⚠ **Warning** ⚠

If the battery is discharged in less than 1 hour, contact your after-sales service to replace it.

The icon  in the Header Area indicates the battery charge level. The table below illustrates the icon in different conditions.

Icon	Battery status
	The battery disconnection
	The battery is charging
	The device is plugged in
	25% charged
	25% charged,the device is plugged in
	50% charged
	50% charged, the device is plugged in
	75% charged
	75% charged, the device is plugged in
	100% charged
	100% charged,the device is plugged in

⚠ **Warning** ⚠

The electrocardiograph will turn off automatically if the battery power is too low. When the electric power is going out, the message "BATTERY LOW" will be displayed.

⚠ **Warning** ⚠

Use only the manufacturer recommended batteries

ECG Electrodes Connection

ECG cable consists of two parts: main cable that is connected to the device and lead wires that are connected to the patient.

⚠ **Warning** ⚠

Use only one type of electrode on the same patient to avoid variations in electrical impedance. It is recommended to use silver/silver chloride electrode. When dissimilar metals are used for different electrodes, the electrodes may cause large offset potentials due to polarization, which may be severe enough to prevent obtaining an ECG trace. Using dissimilar metals may also increase recovery time after defibrillation.

⚠ **Warning** ⚠

When you connect the cables and electrodes, make sure that no metal part is in contact with the safety ground. Verify that all ECG electrodes are correctly attached to the patient.

⚠ **Warning** ⚠

Interference from a non-grounded instrument near the patient and/or ESU (Electrosurgical Unit) interference can cause inaccuracy of ECG waveform.

⚠ **Warning** ⚠

Use only the manufacturer recommended ECG cable with internal resistance. Other ECG cables and leads may cause improper performance and/or provide inadequate protection during defibrillation.

⚠ **Warning** ⚠

When the device is used with electrocautery unit, please note the position of leads. In order to reduce the hazard of burns, the leads should be located away from the electrocautery pen and return electrode.

⚠ **Warning** ⚠

Use intact and clean electrodes only. Electrodes with damaged surface may cause ECG waveform

Connection of the Limb Electrodes

4 electrodes of 10 ECG electrodes are attached to the limbs. Reference lead is the electrode connected onto the right leg.

Before connecting electrodes:

1- Prepare the patient’s skin.

■ The skin is a poor conductor of electricity, therefore preparation of the patient's skin is important to facilitate good electrode contact to skin.

■ Wash sites thoroughly with soap and water.

2- Apply some gel on the skin of these sites.

3- Place the electrode on proper site of the patient body.

The limb electrodes of 12-lead ECG should be placed in the following sites:

- Left arm (LA)
- Right arm (RA)
- Left leg (LL)
- Right leg (RL)

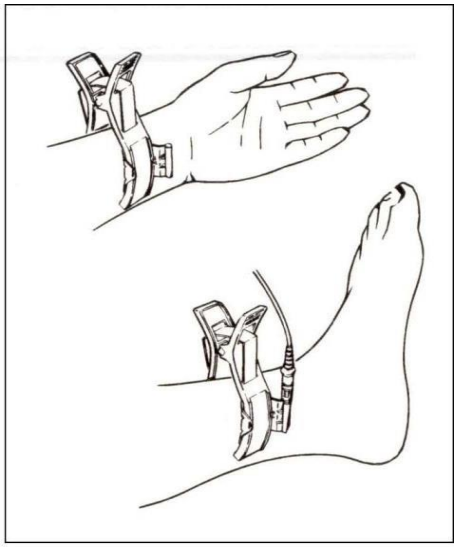


Figure 2-7 Connection of the Limb Electrodes

Connection of the Chest Electrodes

Before connecting electrodes:

1- Prepare the patient’s skin.

■ The skin is a poor conductor of electricity, therefore preparation of the patient's skin is important to facilitate good electrode contact to skin.

■ Shave hair from sites, if necessary.

■ Wash sites thoroughly with soap and water.

2- Apply some gel on the skin of these sites.

3- Place the chest electrode on proper site and press its suction bulb to attach it to the skin.

The chest electrodes of 12-lead ECG should be placed in the following sites:

- C1 (V1) : Fourth intercostal space at the right margin of the sternum
- C2 (V2) : Fourth intercostal space at the left margin of the sternum
- C3 (V3) : Midway between V2 and V4
- C4 (V4) : Fifth intercostal space at the left midclavicular line
- C5 (V5) : Left anterior axillary line at the horizontal level of V4
- C6 (V6) : Left midaxillary line at the horizontal level of V4

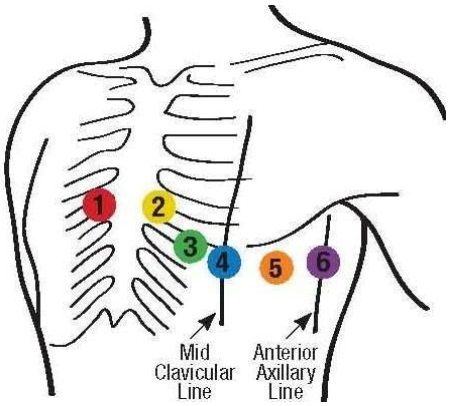


Figure 2-8 Connection of the Chest Electrodes

There are different labels and color codes for ECG electrodes according to IEC and AHA standards. Select ECG cable with regard to acceptable standard in your hospital.

IEC Standard:

Site for electrodes	Symbol for electrodes	Color code for electrodes
Right arm	R	Red
Left arm	L	Yellow
Right leg	N (RF)	Black
Left leg	F	Green
Chest	C1	White/ Red
	C2	White/Yellow
	C3	White/Green
	C4	White/Brown
	C5	White/ Black
	C6	White/ Violet

AHA Standard:

Site for electrodes	Symbol for electrodes	Color code for electrodes
Right arm	RA	White
Left arm	LA	Black
Right leg	RL	Green
Left leg	LL	Red
Chest	V1	Brown/Red
	V2	Brown/ Yellow
	V3	Brown/ Green
	V4	Brown/ Blue
	V5	Brown/ Orange
	V6	Brown/ Violet

Lead Placement Diagram

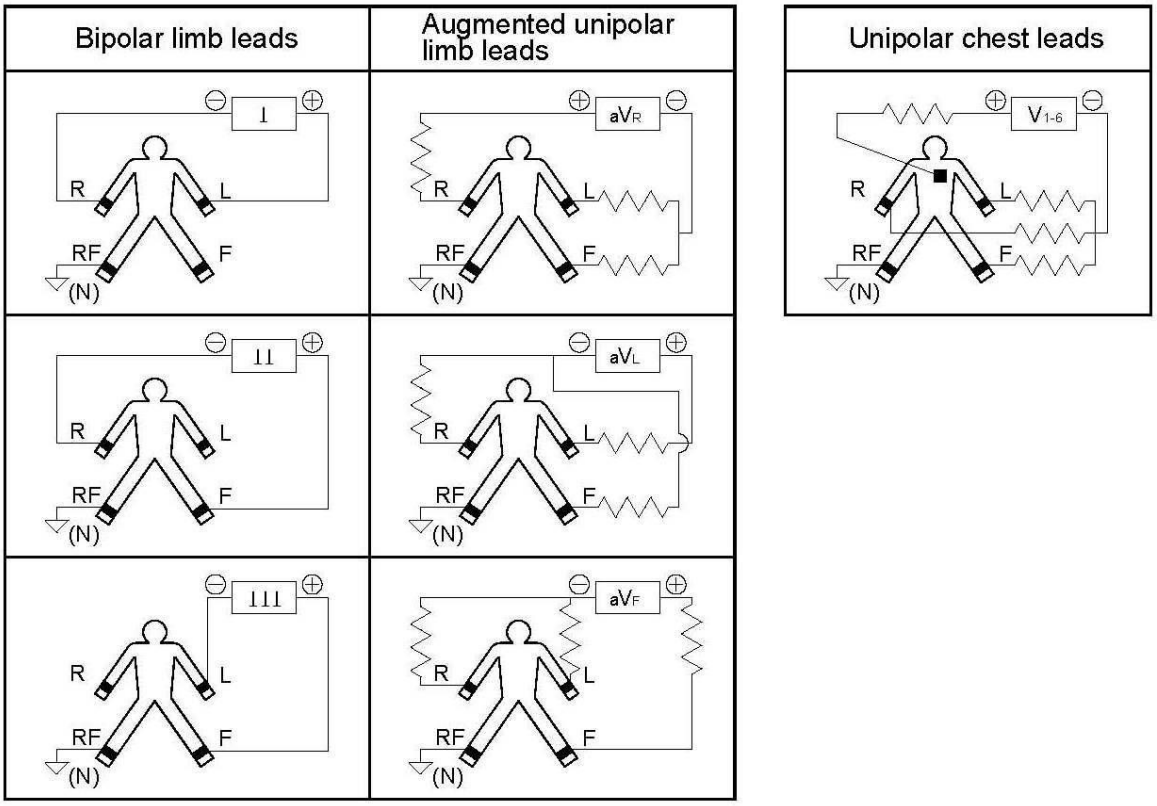


Figure 2-9 Lead placement diagram

Measurement

The purpose of measurement is ECG signal analysis, detection of onset and offset points of P, QRS, T waves and heart axis. They are useful parameters for physician diagnosis to interpret the signal.ECG parameters including QRS and P waves duration and PR, QT and QTc intervals are measured in millisecond. Also Heart Axis is same electrical axes of P, QRS and T waves which can be calculated. During measurement process, the signal of each 12-lead are analyzed separately.

EGC Parameters	Comment
P Duration	P-wave Onset to P-wave Offset
QRS Duration	Q-wave Onset to S wave Offset
PR Interval	P-wave Onset to Q wave Onset
QT Interval	Q-wave Onset to T wave Offset
QTc Interval	Normalized QT based on RR interval
P/QRS/T Axis	Heart Axis

Measurable parameters in a heart rate are determined in figure 2-10.

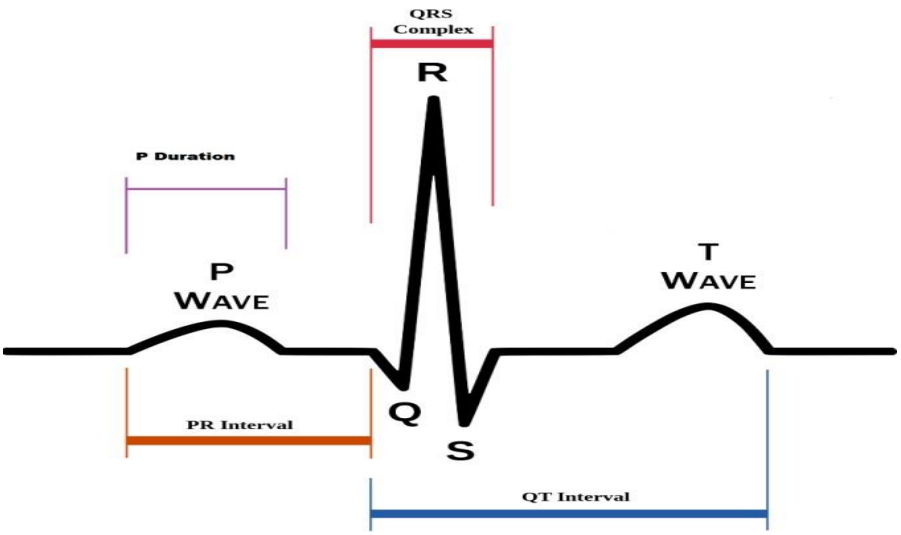
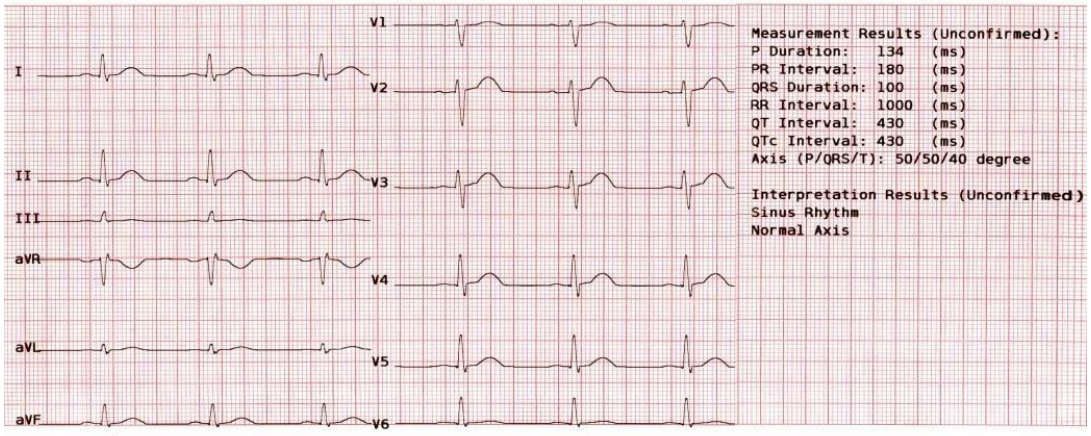


Figure 2-10 ECG Parameters including Duration and Intervals

The measurement results of ECG signal are recorded on the paper in two forms: (Figure 2-11).

- Global mode: general parameters of ECG signal including duration of P and QRS waves and interval of PR, QT, QTc and RR waves. Heart axes of P, QRS and T waves are also recorded on the paper. In addition to measurement results, up to six heart abnormalities detected in the signal measurement will be reported.

- Detail mode: all mentioned parameters in the Global mode are calculated for each lead and the results are recorded. Amplitude of P, Q, R, S and T waves as well as their interval and duration will be recorded in this mode. For example, P_amp of P wave is calculated in microvolt unit. ST parameter is also calculated in this unit. In addition, duration of Q, R and S waves is recorded for each lead. In Pattern column of the record, morphology of QRS complex is indicated for each lead. Lower-case letter in the Pattern means low amplitude and upper-case letter indicates high amplitude. For example, qRs indicates a complex with short Q and S waves and tall R wave. As Global mode, up to six abnormalities are recorded in priority.



Measurement Results (Unconfirmed):
Axis (P/QRS/T): 50/50/40 degree RR Interval: 1004 (ms)

Unit	P (ms)	QRS (ms)	PR (ms)	QT (ms)	QTc (ms)	ST (uV)	P_Amp (uV)	Q_Amp (uV)	R_Amp (uV)	S_Amp (uV)	T_Amp (uV)	Q_Dur (ms)	R_Dur (ms)	S_Dur (ms)	Pattern
Global	134	100	180	430	426										
I	128	98	176	428	424	10	96	-96	1038	-244	388	14	72	36	Rs
II	128	98	176	428	424	10	149	-114	1474	-267	477	14	62	34	QRS
III	128	98	176	426	422	0	54	--	481	-36	88	--	96	--	R
AVR	128	98	176	428	424	-10	-122	--	255	-1252	-432	--	--	--	--
AVL	128	96	176	428	424	0	21	--	313	-120	150	--	62	46	rs
AVF	128	98	176	426	422	10	101	-67	962	-149	283	14	78	32	Rs
V1	86	94	182	422	418	20	52	--	263	-1001	152	--	34	68	rS
V2	78	94	180	424	420	140	61	--	596	-1607	682	--	40	60	RS
V3	128	88	176	420	416	140	61	--	836	-1000	672	--	46	46	RS
V4	128	98	176	428	424	80	58	-71	1484	-529	561	18	50	36	RS
V5	128	98	176	426	422	10	52	-77	1517	-275	430	18	62	30	QRS
V6	128	98	176	424	420	10	48	-78	1254	-153	131	18	62	30	QRS

Interpretation Results (Unconfirmed):
Sinus Rhythm
Normal Axis

Figure 2-11Measurement Table

When the signal is saved and the measurement is enabled, the measured parameters table is recorded on the recorder paper while recording the relevant signal.

Time intervals calculation

The used method to measure the time intervals is based on analyzing 10-seconds of 12-leads ECG signals.

Notch filter (50/60 Hz) is used to remove the artifacts and improve the signal quality and a linear second order band-pass filter with the frequency band (0.8-18 Hz) is used to eliminate the AC interferencece. In the next step, R wave is detected and the different beats are separated based on its situation. R wave detection in Dena system was accomplished based on the well-known Pan-Tompkins algorithm and by using the signal of leads I, II, V3. Based on QRS complex situation and detecting the complex type, using windowing technique and calculating the signal slope, the exact situation of each wave and their onset and offset points will be determined. This process is implemented on all leads separately and in each step, the relevant outputs are saved. Finally, the best value for the start/end points of P, QRS and T waves is selected based on Multi-Lead-Selection algorithm.

The general block diagram of the used method to determine the time intervals is as follow.

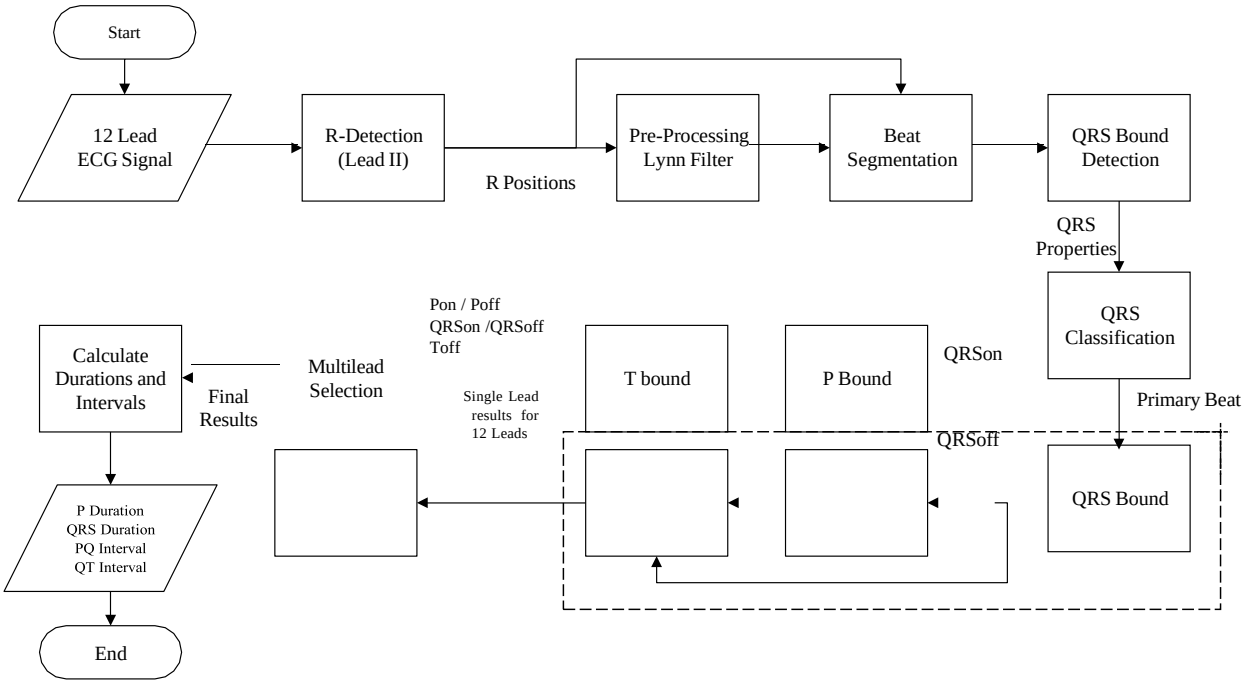


Figure 2-12 Block diagram of time interval calculation

Heart Axis calculation

The heart axis detection is one of the most important calculatory sections of electrocardiograph system. This parameter provides the helpful information for medical diagnosis. Heart axis is average of all electrical signals of the heart, in the other word it indicates the consequence vector of heart electrical activities. The electrical axis can be calculated for P, QRS and T waves. Among above axes, QRS axis is used clinically more and can be calculated simply. Leads I, II, and III or aVF, aVL and aVR can be used to calculate QRS axis. Each of these leads indicates electrical activity of heart in the specific direction. Axes corresponding with each lead are indicated in figure 2-13. Normal heart axis (as shown) is between -30 and +90 degrees.

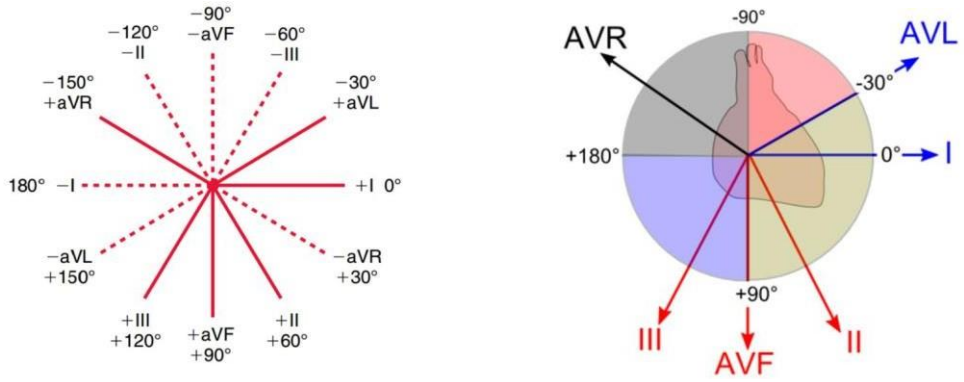


Figure 2-13 Angles of different leads for the heart axis diagnose

A common method among physician for heart axis calculation is iso-electric method. Iso-electric lead for QRS complex is a lead which the collection of Q, R and S complex amplitudes is near to zero. In this situation, the direction of heart axis will be perpendicular to direction of iso-electric vector. Any combination of 2 limb leads can be used to calculate the electrical axis of heart. Some ofwell-known equations to calculate the heart axes are provided in the following table.

Selected Leads	Equation
I and aVF	$\alpha = \tan^{-1}(2aVF/\sqrt{3}\,I)$
I and II	$\alpha = \tan^{-1}((2II - I)/\sqrt{3}\,I$
I and III	$\alpha = \tan^{-1}((I + 2III)/\sqrt{3}\,I$
II and III	$\alpha = \tan^{-1}\left(\frac{II + III}{\sqrt{3}\,(II - III)}\right)$

In these equations, “I” is the net amplitude of QRS complex in lead I and “II” is the net amplitude of QRS complex in lead II. So based on researches done, using the lead with the maximum net amplitude makes the results more accurate. In DENA electrocardiograph system, the combination of two leads with highest amplitude is used to calculate the heart axis according to the equations defined in the above table.

Section 3- Device Setting

General

Different software menus of the device will be explained in this section.

■ For date and time settings, please refer to **Setting/ Date &Time.**

■ For manufacturer information, please refer to **Menu/About.**

■ For recording setting, please refer to **Rec Setting** and **Print Mode.**

It is recommended that the device is set properly before recording.

Main Menu

EM650 has a flexible configuration which can be changed through Main Menu. You can access the Main Menu by pressing **Menu** key on the control panel or touching **Menu** on the screen (Figure 3-1).

Figure 3-1 Main Menu

Patient, **Archive**, **Print Mode**, **Rec Setting**, **Filters**, **User**, **Export**, **Network**, **About** and **Setting** options are available in the Main Menu.

Print Mode Menu

Select **Print Mode** from the Main Menu to access the below menu:

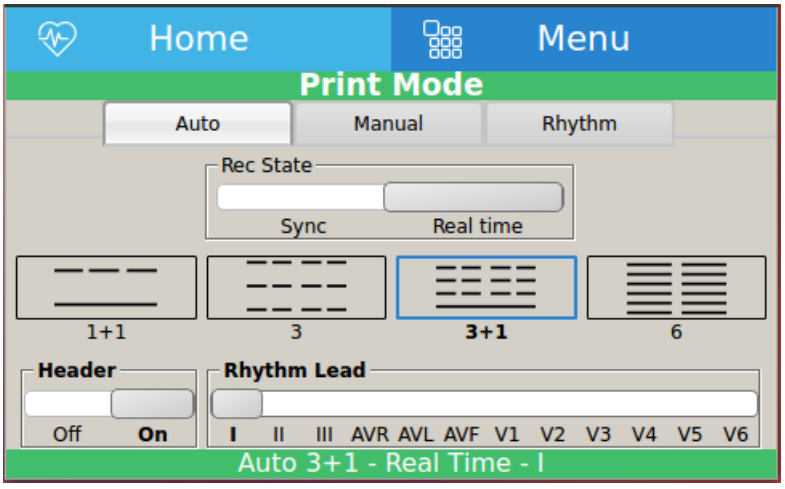


Figure 3-2 Print Mode Menu

The following items can be set through this menu:

- **Print Mode:** Available options are **Auto**, **Manual** and **Rhythm**.

Auto: Automatic modes of recording are 1+1, 3, 3+1 and 6.

Manual: Manual modes of recording are 1+1, 3, 3+1 and 6.

Rhythm: Available options for duration of Rhythm recording are 30, 60, 90, 120, 150 and 180.

For more information about different types of recording, please refer to section 6 (Recording Operation).

- **Rec State:** Available options for this item are **Real time** and **Sync**.

In the **Sync** mode, the signals of different leads are recorded simultaneously i.e. recording of all leads starts at the same time.

Sync recording can be performed only in Automatic and Periodic modes.

- **Rhythm lead**: if you select Auto 1+1, Auto 3+1, Manual 1+1, Manual 3+1 or Rhythm mode, **Rhythm Lead** will be enabled.
  The Rhythm lead can be one of I, II, III, aVL, aVR, aVF, V1, V2, V3, V4,V5 and V6 leads.

- **Header**: Select ON to print the signal and recording information on header of the recorder paper. Select OFF to print only signal on the paper (without any information).

Recorder Setting Menu

Select **Rec Setting** from the Main Menu to access the below menu:

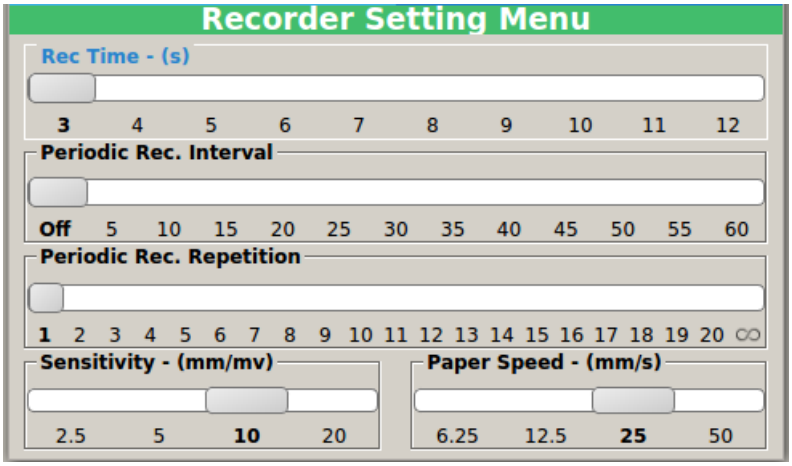


Figure 3-3 Recorder Setting Menu

The following items can be set through this menu:

- **Rec Time:** To set recording duration for different leads in Auto mode. It ranges from **3** to **12** seconds.
- **Periodic Rec. Interval**: To set time interval in periodic recording. Available options are **5-60** min and **Off**. If you select Off, periodic recording will be stopped.
- **Periodic Rec. Repetition**: Press to set repetition of recording. Available options are **1-20** and ∞.
- **Sensitivity**: To set amplitude of ECG waveform. Available options are 2.5, 5, 10 and 20 (mm/mV).
- **Paper Speed**: Press to set the recording speed. Available options are 6.25, 12.5, 25 and 50 (mm/sec).

Filters Menu

Select **Filters** from the Main Menu to access the below menu:

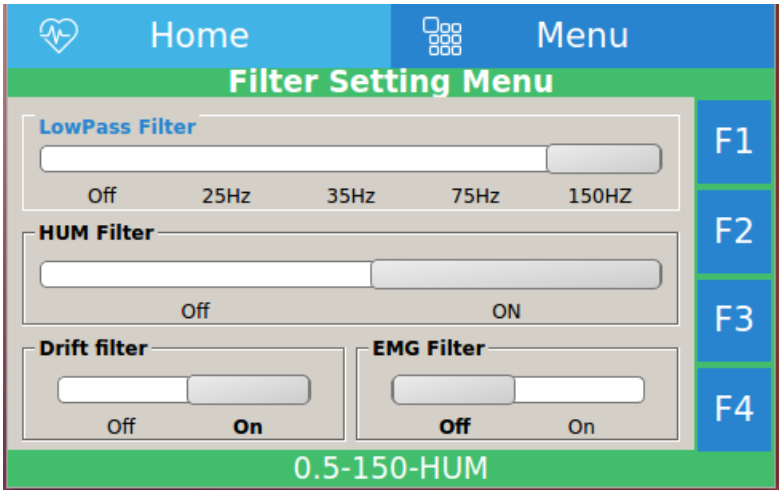


Figure 3-4 Filter Setting Menu

The following items can be set through this menu:

- **Lowpass Filter:** Press to toggle between **25**, **35**, **75**, **150** Hz and **Off**. This filter is used to remove muscle artifacts and high frequency noises, yet some of the signal details might be removed. -3dB cutoff frequency of these filters is 25 ± 2Hz, 35 ± 2 Hz, 75 ± 5 Hz and 150 ± 20Hz. The frequency of the selected filter is displayed on the screen. By selecting Off, you can disable the filter.
- **Frequency:** frequency of the selected filter is shown on the screen and header of the recorder paper. If you select Off, the frequency will not be recorded on the header.

⚠ **Warning** ⚠

During use of low-pass filter (25, 35, and 75Hz), you might lose some of useful details of the signal.

⚠ **Warning** ⚠

If EMG filter and 25 Hz or 35 Hz Lowpass filters are turned on simultaneously, significant changes in the ECG amplitude will occur. Thus when EMG filter is enabled, only 75 Hz or 150 Hz are available for Lowpass filter.

▪ **HUM Filter:** Press to toggle between **ON** and **OFF**. Select this filter with regard to your local AC frequency. If the HUM filter is turned on, the third harmonic in accordance with the selected frequency will be deleted. In other words, when the HUM filter is set to 50 Hz, the frequency of 150Hz as well as 50 Hz will be removed. If the frequency of 60 Hz is selected, the frequency of 180 Hz as well as 60 Hz will be eliminated. This aims to get more clear heart signal. The HUM filter will be set automatically according to local AC frequency.

If you set On this filter, "HUM" will appear on the screen.

▪ **Drift Filter:** Press to switch **ON** or **OFF**. This filter is used to reduce signal oscillations resulting from patient breathing and movement. -3dB cutoff frequency of this filter is about 0.6 Hz. Using this filter will remove the frequencies below the cutoff value from the ECG report. If the drift filter is switched off, the cutoff frequency of the device will be about 0.05Hz. If the drift filter is set On, "**0.5**" will be displayed. Otherwise "**0.05**" will appear on the screen.

0.5 filter is used to remove signal baseline oscillations and may interfere with the ST Segment analysis.

▪ **EMG Filter:** Press to toggle between **ON** and **OFF**. This filter is used to reject muscular noise. If EMG is set On, "+M" will be displayed on the screen and "EMG" will be recorded on the header.

EMG filter is a lowpass filter which varies based on time and the signal slope .The filter bandwidth varies from one sample to another sample proportional to the signal slope. The purpose of the EMG filter is to remove skeletal muscle artifact from the ECG baseline. The EMG filter will eliminate noise from the baseline, but it will not affect QRS complex components. The cut-off frequency of this filter increases to about 55Hz in areas where the signal slope is high and decreases to about 10Hz when the signal slope is low.

If the EMG filter is set On, "**EMG**" will be displayed on the screen.

To remove ECG signal noise, take the following steps:

1. At first remove any noise sources (for more details, please refer to Troubleshooting chapter)
2. If noise is not removed by taking the above action, set On the EMG filter.
3. If the signal is still noisy, set off the EMG filter and use the lowpass filter (25-35Hz).

4. It is necessary to mention, if the LowPass filters are used, the amplitude of the QRS complex will be reduced
5. If the EMG filter is enabled, the available LowPass filters will be Off, 75 Hz and 150 Hz.

After setting On the EMG filter, wait a few seconds to record.

⚠ **Warning** ⚠

The EMG filter is an adaptive, non-linear and time- variant low pass filter that is applied to ECG signals. Since EMG is a non-linear filter, user should be trained by a qualified person to use this filter.

In some cases, using the EMG filter may affect P, QRS and T waves.

⚠ **Warning** ⚠

Lowpass and non-linear EMG filter may decrease amplitude of 10 Hz and higher frequency signals for different morphologies of ECG signal.

⚠ **Warning** ⚠

The EMG filter is designed only for ECG signals. In case of other applications (e.g. calibration), turn off this filter.

In addition to the above filters, some filters with default settings (F1, F2, F3 and F4) are available in the system. These settings are shown in the below table that only F4 filter settings could be changed by user.

Filter	LowPass	HUM	Drift	EMG
F1	Off	On	On	On
F2	25	On	On	Off
F3	35	On	On	Off
F4	150	Off	Off	Off

About Menu

Select this item from the Main Menu to view product and manufacturer information in the menu.

Figure 3-5 About Menu

User Setting Menu

Select **User** from the Main Menu to access the below menu:

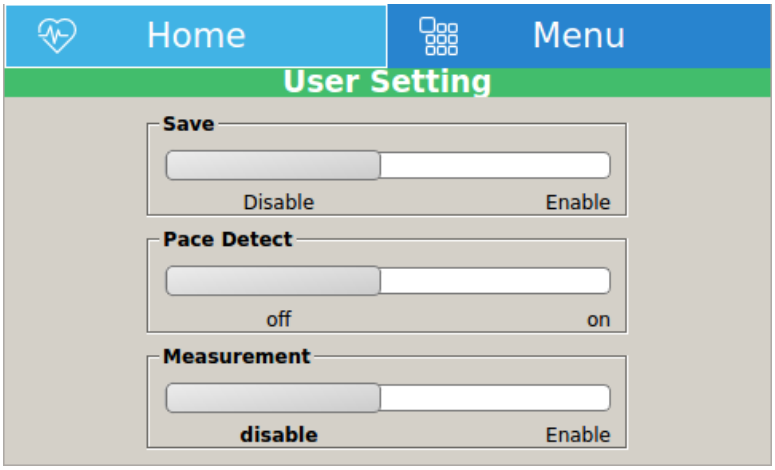


Figure 3-6 User Setting Menu

The following items can be set through this menu:

- **Save:** Enable this item to save patient data and signals of Auto and Rhythm modes.
- **Pace Detect:** Available options are Off and On. The electrocardiograph system detects and rejects pacemaker-generated signals from ECG signal, so that they will be ignored in determining heart rate.

If you select On for patients with pacemaker, detected pacemaker signals will be marked on the ECG waveform as a white vertical line.

⚠ **Warning** ⚠

For patients with pacemaker, the PACE DETECT function must be switched "ON", otherwise, the pacing impulse may be counted as normal QRS complex.

⚠ **Warning** ⚠

In patients with pacemaker, if the PACE DETECT function is "OFF", turn off the low pass (25Hz, 35Hz) and EMG filters to check pacemaker function.

⚠ **Warning** ⚠

ECG signal saturation occurs when the signal is not displayed or exceeds lower or upper limits of the display area.

Setting Menu

Select **Setting** from the Main Menu to access the below menu:

Figure 3-7 Setting Menu

The below parameters can be set through this menu:

- **Date/Time:** Press to open the below menu:

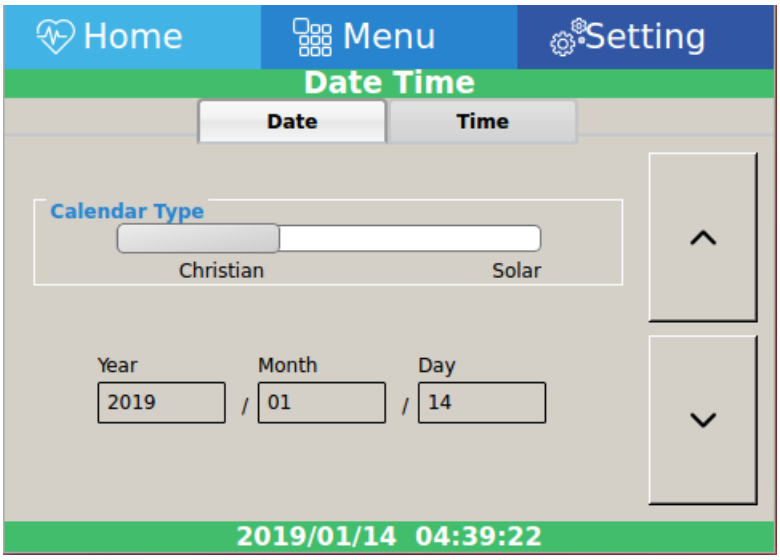


Figure 3-8 Date Setting Menu

- **Calendar Type:** Available options are **Solar** and **Christian**.
- **Date:** To set the date.
- **Time:** To set the time.

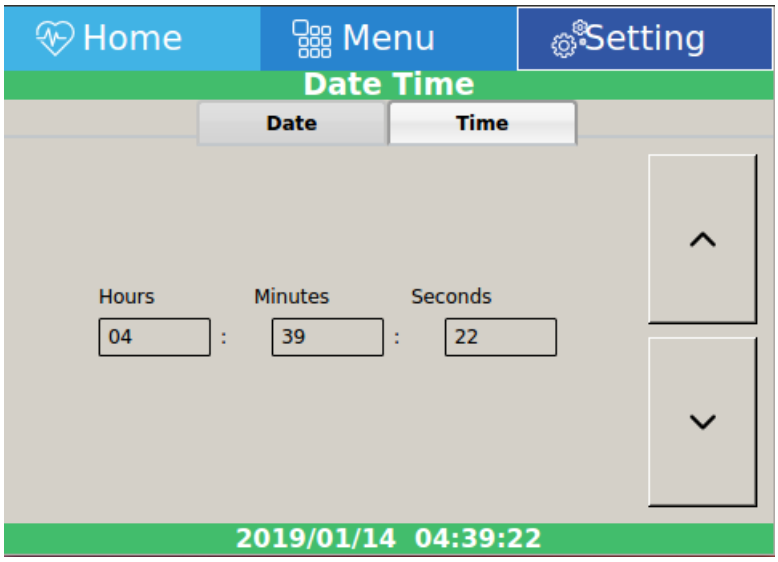


Figure 3-9 Time Setting Menu

■ **Hospital/Ward:** Select this item from the Setting Menu to enter hospital or ward name in the below window.

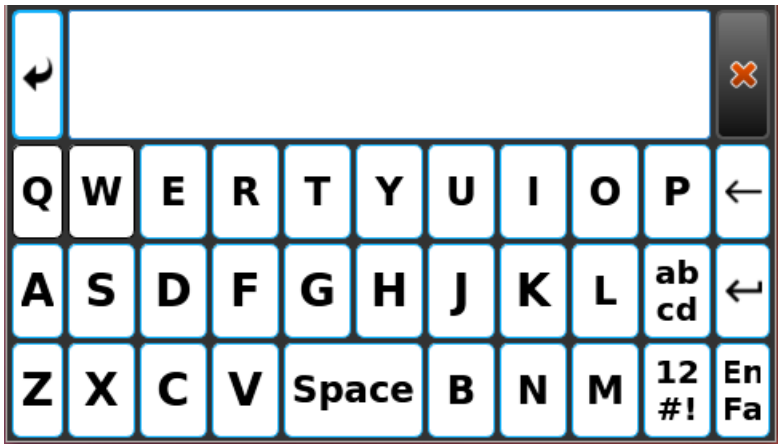


Figure 3-10 Hospital/Ward

- **Rec Test:** To test the recorder function.

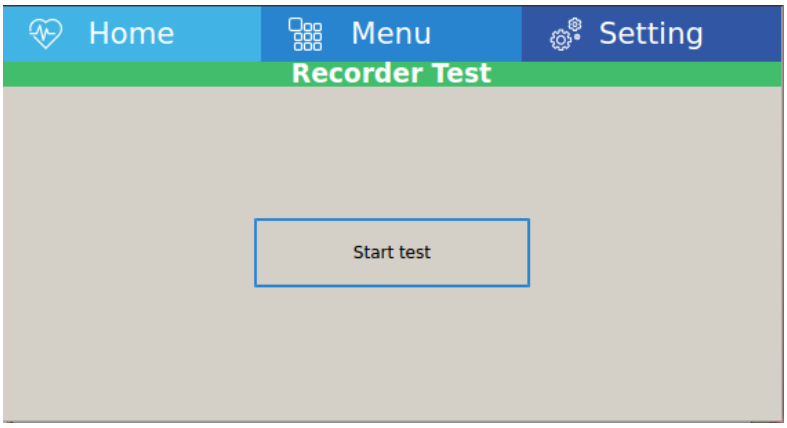


Figure 3-11 Recorder Test

- **Default:** To load factory default settings. Because of changing all your previous settings, the system will ask you to confirm this setting.

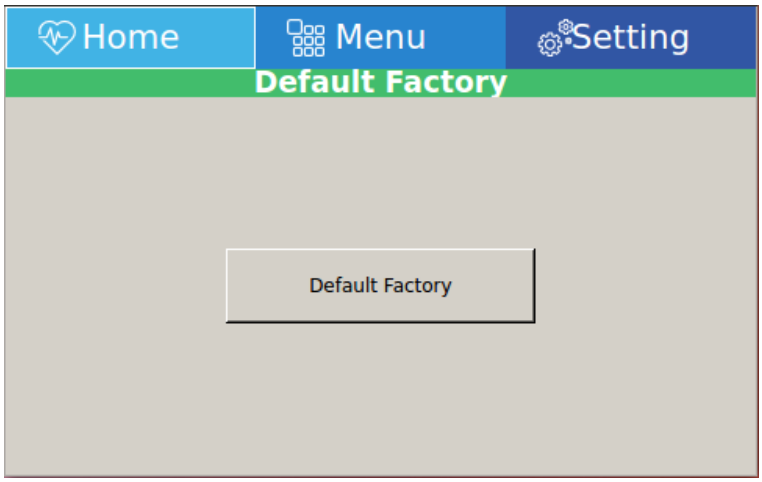


Figure 3-12 Default Factory

■ **Factory:** Select this item to access the below window.

Only manufacturer's authorized personnel have access to this window.

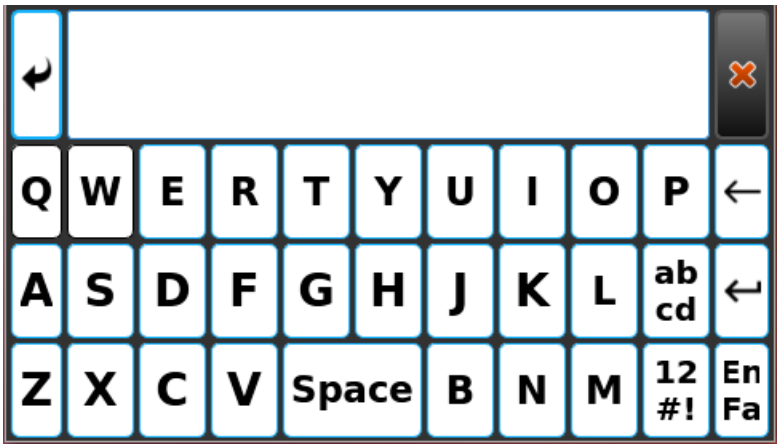


Figure 3-13 Factory

■ **Touch Sound:** To switch ON/OFF the sound of touch or hard keys.

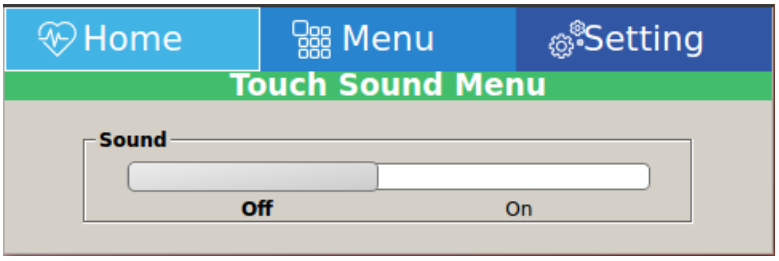


Figure 3-14 Touch Sound Menu

■ **Language:** Available options are **English** and **Persian**.

Figure 3-15 Language

Section 4-Patient Information

This section will explain how to manage the patient information.

⚠ **Warning** ⚠

Enter the patient information correctly, otherwise it may be confused with the information of other patients.

Touch **Patient** in the Main Menu, or select **Patient** using arrow keys and then press **Enter,** the **Patient Information Menu** will appear.

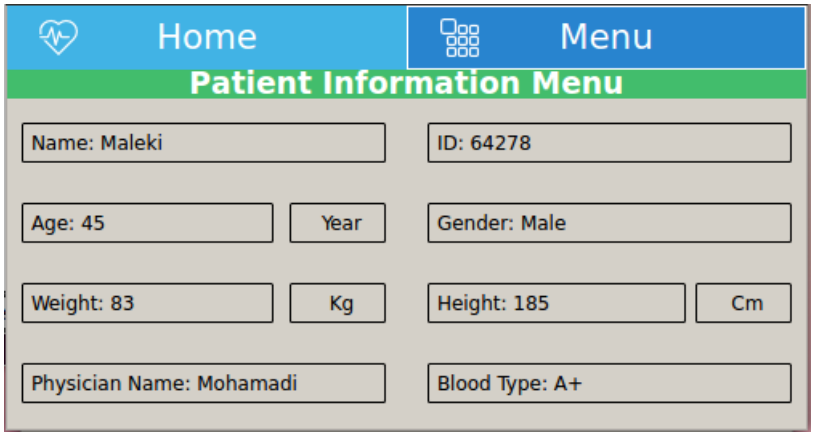


Figure 4-1 Patient Information Menu

Patient Data Entry

Selecting each field from the Patient Information Menu will call up a keyboard to enter data.

▪ **Name**

Enter the patient name and press **Save** to exit from this window (Figure 4-2). Up to 20 characters can be entered in this field.

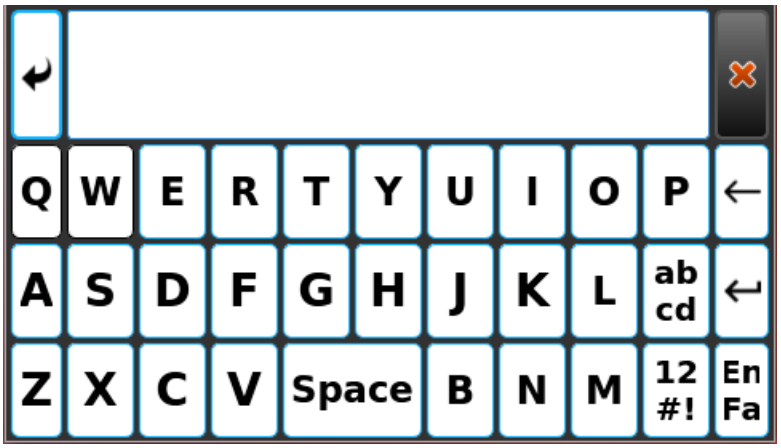


Figure 4-2 Name

Press **Cancel** to exit from this window and return to the previous menu.

- **Age**

Available options are **Years** and **Months**. Factory default setting is **Years.**

According to the selected option, the patient age can be entered in year or month.

Enter the patient age and press **Save** to exit from this window.

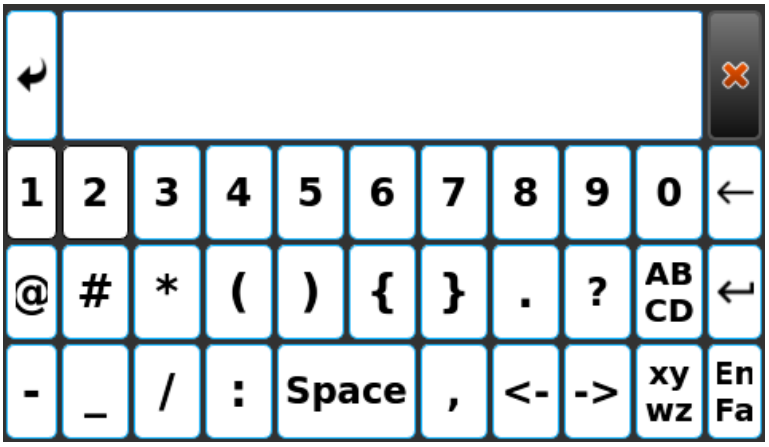


Figure 4-3 Age

Press **Cancel** to exit from this window and return to the previous menu.

- **Gender**

Available options are **Male** and **Female**. Factory default setting is **None.**

- **ID**

Enter the patient ID number and press **Save** to exit from this window. Up to 20 characters can be entered in this field.

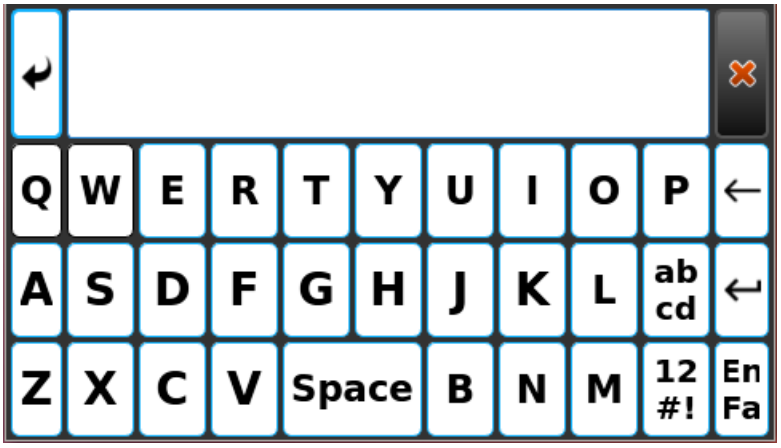


Figure 4-4 ID

Press **Cancel** to exit from this window and return to the previous menu.

- **Weight**

Available options are **Kg** and **lb**. Factory default setting is **Kg.**

Enter the patient weight and press **Save** to exit from this window.

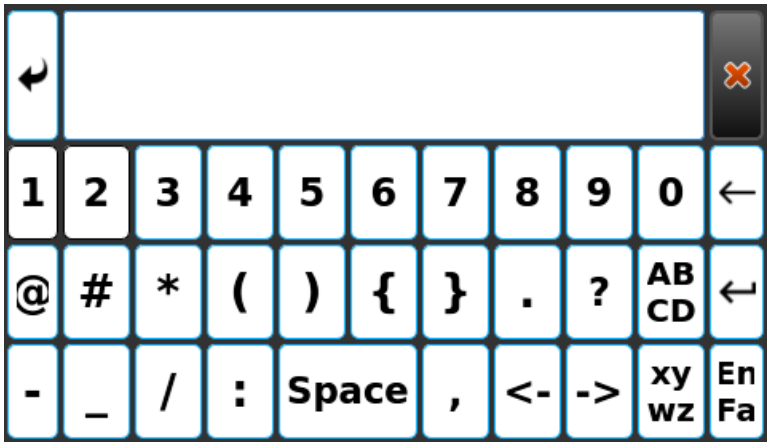


Figure 4-5 Weight

Press **Cancel** to exit from this window and return to the previous menu.

- **Height**

Available options are **Foot** and **cm**. Factory default setting is **cm.**

Enter the patient height and press **Save** to exit from this window.

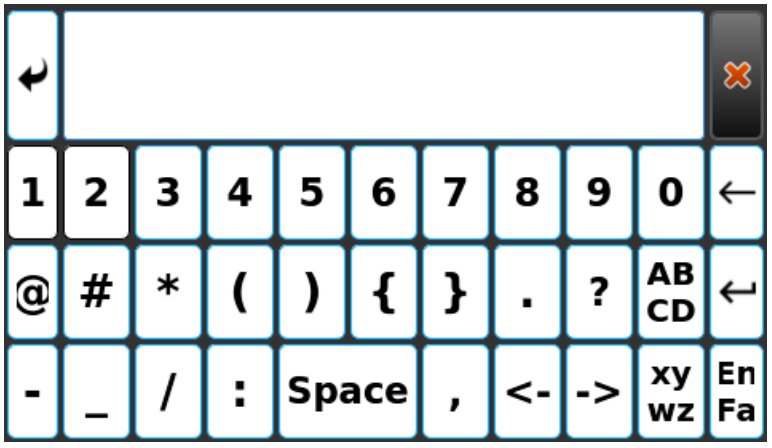


Figure 4-6 Height

Press **Cancel** to exit from this window and return to the previous menu.

- **Physician Name**

Enter the physician name and press **Save** to exit from this window. Up to 20 characters can be entered in this field.

Press **Cancel** to exit from this window and return to the previous menu.

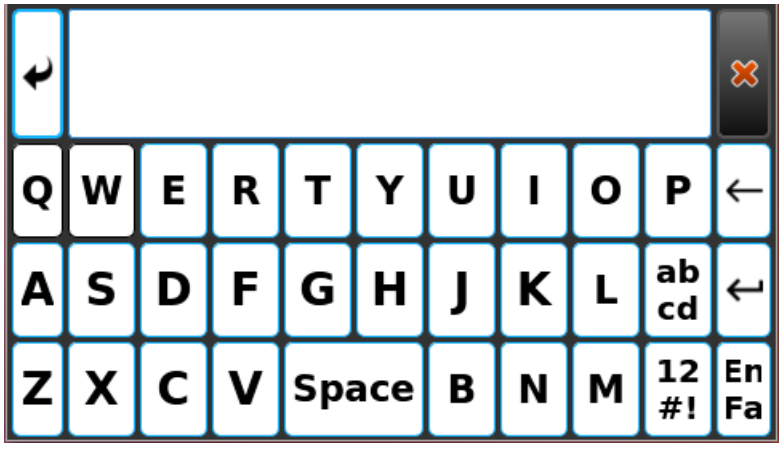


Figure 4-7 Physician Name

- **Blood Type**

Press to toggle between **A+**, **A-**, **B+**, **B-**, **AB+**, **AB-**, **O+**, **O-** and **Unknown**. Factory default setting is **Unknown.**

Note: Each time you exit from the Patient Information menu; a message will appear on the screen asking you whether to save changes or not.

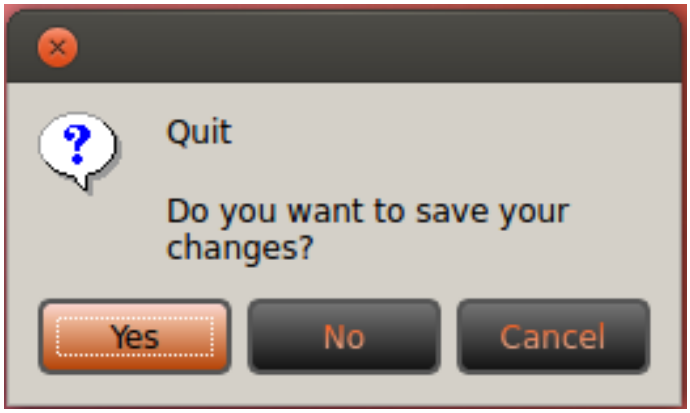


Figure 4-8 Confirmation Menu

Section 5- Data Management

General

All ECG recorded data in Auto modes will be automatically stored in the internal memory of the device for future reference.

Up to 5 records can be stored in the internal memory. When the memory is full the new data will overwrite the oldest data.

Archive Menu

Select **Archive** from the Main Menu to access the below menu.

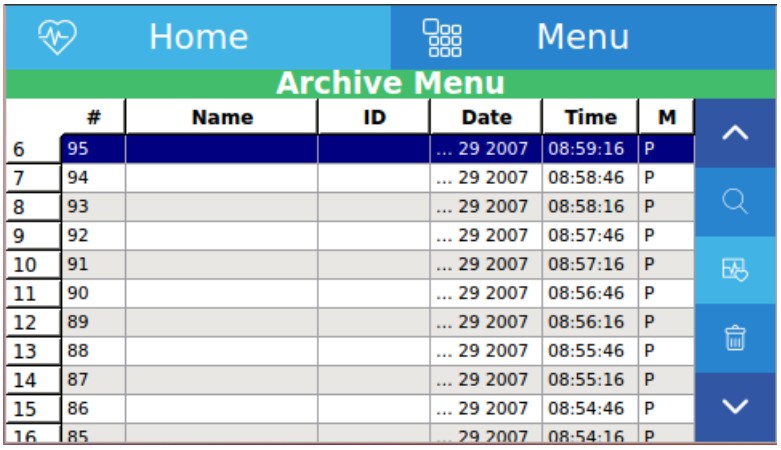


Figure 5-1 Archive Menu

Enable Save in the User Setting menu to save signals recorded in Auto and Rhythm modes. You can see the recorded signals in **Archive Menu**. If you disable the Save, no signal will be saved and displayed in this menu.

Each record in the **Archive Menu** contains the following information:

_ Assigned code by the system
_ Patient Name (if any)
_ Patient ID (if any)
_ Date and time of recording
_ Recording mode: "**R**" indicates Rhythm mode and "**P**" indicates Periodic mode. "**PR**" indicates both Rhythm and Periodic modes.

The last record is always displayed at the top of the list.

- Press. recordto move to the previous or next or
- Swipe up and down to access the previous and next pages.

- **Search:** Enter patient name/ID in on-screen keyboard and press Search to view all stored data for the patient.

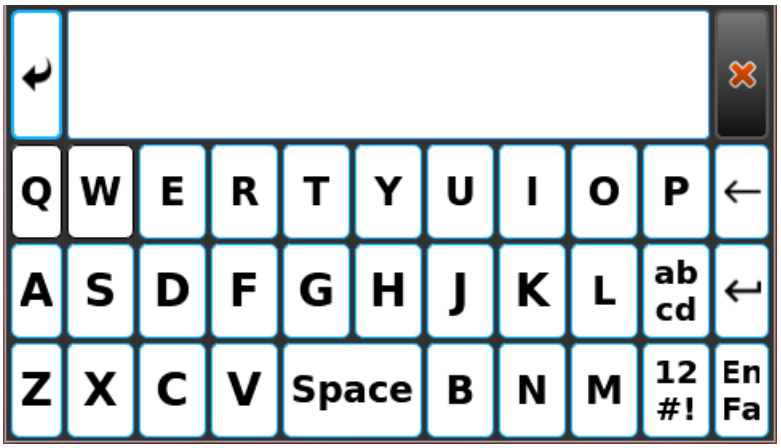


Figure 5-2 Keyboard

If your intended name/ID is not available or entered incorrectly, the below message will appear.

Figure 5-3 Message

- **Delete**

Press **Delete** to delete the highlighted record. An alert message (Are you sure you want to delete this file) will appear that asks you to confirm your selection. By selecting No, you will return to the Archive menu.

- **Review**

Press to observe the information of highlighted record. “Reviewing…” is displayed below the screen.

If you press the Review button while no data has been saved and the Archive window is blank, the message **“ECG Data not exists”** will appear.

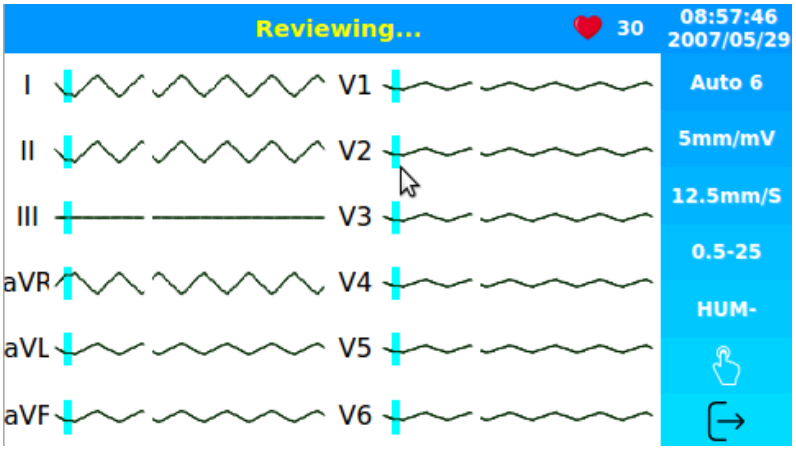


Figure 5-4 Review

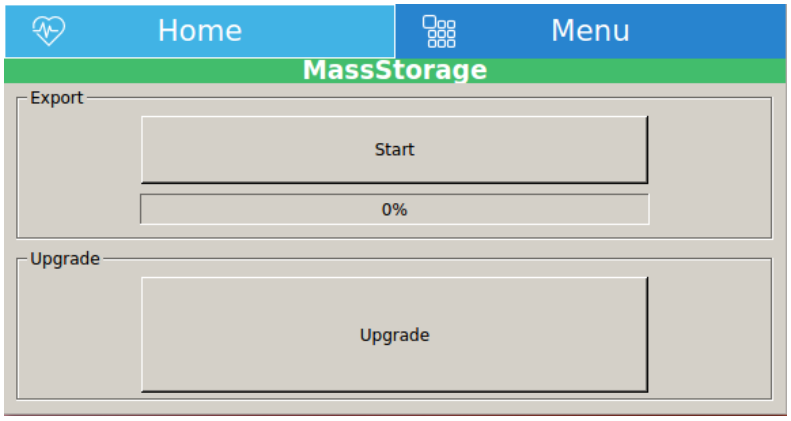
The following information are displayed in this window:
_ ECG waveforms
_ HR value
_ Speed, Gain and recording mode
_ Filter name
_ Patient name and ID
_ Date and time of recording

Press Start/Stop key to print the stored ECG signals in the same condition as the recording time.

Export Menu

Select **Export** from the Main Menu to access the below menu.

Figure 5-5 Export menu



- **Start**

Connect flash memory to the system and select **Start** to export all saved records in the system. When progress bar reaches 100%, data is exported completely.

Select **Start** while the flash memory is not connected to the system, the message “Mass Storage Not Exists” will appear.
If the export procedure is done successfully, “Exported successfully” will appear on the screen.

- **Upgrade**

This item is used by trained and authorized personnel of the manufacturer to upgrade the software to the latest version.

Section 6- Recording Operation

This section will explain recorder operation.

Please refer to section 2, “Rec Setting Menu” and “Print Mode”, for details on recording settings.

Signal recovery accuracy:

With regard to maximum frequency bandwidth of 150 Hz and sampling rate of 1000 samples/s, the signal recovery accuracy of Dena Electrocardiograph complies with IEC 60601-2-25 standard requirements.

General

EM650 electrocardiograph is equipped with URUK thermal recorder.

Features

- Optional recording speed (6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s)
- 6- channel waveform recording
- Real- time and Synchronic recording
- Periodic recording with adjustable time intervals
- Rhythm lead recording in six channels

Recording Type

Manual Recording

Press **Mode** key on the screen or the control panel to toggle between **Manual 1+1**, **Manual 3**, **Manual 3+1** and **Manual 6**.

Press the Start/Stop key on the control panel to start recording. The recording will continue until you press this key again.

Press **Lead▼** and **▲Lead** keys to switch lead (lead group) during the recording. Note that you can only record the selected lead (s).

■ Manual 1+1 **:** Select this mode and press **Lead▼** and **▲Lead** keys to choose between leads. Then press the Start/Stop key to start recording.

In the recording paper, the first waveform indicates the waveform of selected lead and the second one is the waveform of selected Rhythm lead.

■ Manual 3**:** Select this mode and press **Lead▼** and **▲Lead** keys to choose between lead groups. Then press the Start/Stop key to start recording.

■ Manual 3+1 **:** Select this mode and press **Lead▼** and **▲Lead** keys to choose between lead groups. Then press the Start/Stop key to start recording.

In the recording paper, the first three waveforms are the waveforms of selected lead groups and the last one is the waveform of Rhythm lead.

■ Manual 6 **:** Select this mode and press **Lead▼** and **▲Lead** keys to choose between lead groups. Then press the Start/Stop key to start recording.

Automatic Recording

Press **Mode** key on the screen or the control panel to toggle between **Auto 1+1**, **Auto 3**, **Auto 3+1** and **Auto 6**.

Press Start/Stop key on the control panel to start recording for 3-12 seconds (Refer to section 2 **"User Setting Menu"**).

It is not possible to toggle between different leads using **Lead▼** and **▲Lead** keys.

There are four modes in which only specific leads can be recorded:

Auto 1+1: lead I

Auto 3 and Auto 3+1: leads I, II, III

Auto 6: I, II, III, aVF, aVR, aVL

■ Auto 1+1 **:** Select this mode and press the Start/Stop key to start recording.

In the recording paper the first waveform indicates the waveform of selected lead and the second one is the waveform of Rhythm lead.

■ Auto 3**:** Select this mode and press the Start/Stop key to start recording.

■ Auto 3+1 **:** Select this mode and press the Start/Stop key to start recording.

In the recording paper the first three waveforms are the waveforms of selected leads and the last one is the waveform of Rhythm lead. The recording duration will be according to the “Rec Time”.

■ Auto 6 **:** Select this mode and press the Start/Stop key to start recording.

Rhythm Recording

Select **Rhythm** using the **Mode** key on the screen or control panel to see ECG waveform of the main lead in four traces. Press Start/Stop key to record according to "Length of Rhythm Rec" (Refer to section 2 **"User Setting Menu"**).

There are always six channels of recording in this mode.

Periodic Recording

To perform periodic recording:

1. Set On "Periodic Recording" and select your desired time interval (5-60 min).

2. Select number of recording repetitions. Available options are "infinite" and 1-20.

3. Select recording mode using Mode key.

(For more information about Periodic recording settings, refer to "User Setting Menu" in section 2)

You can also perform Automatic and Manual recordings during Periodic recording. For this purpose:

1. Select the recording mode.
2. Press the Start/Stop key.

After that recording in the selected mode is finished, Periodic recording will be started automatically.

Copy Mode

When the recording is finished, press **Copy** key to record the last stored data once more.

Only in Automatic and Periodic modes, stored data can be copied.

When the system is turned off and on, data cannot be copied.

Recorder Paper

Use only heat sensitive recording paper with 110 mm width.

⚠ **Warning** ⚠

Use only the manufacturer recommended record paper, otherwise the recording quality may be poor and the thermo-sensitive printhead may be damaged.

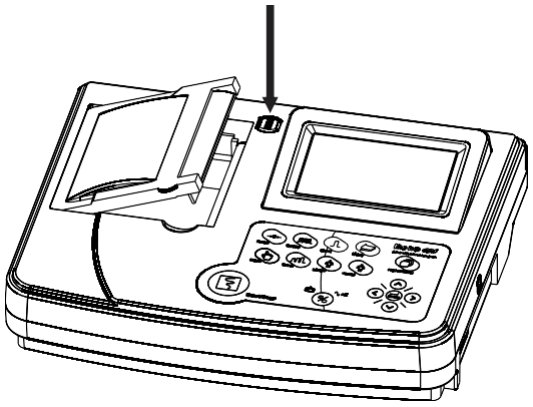
⚠ **Warning** ⚠

Do not touch the recorder head while recording and immediately after recording because it is so hot and may lead to personal injury including burns.

The paper space is divided based on the signal amplitude. An appropriate space is allocated to each lead regarding difference between maximum and minimum amplitudes of the lead and number of leads in each column. After connecting the ECG cable to the device, wait at least 4 seconds until the space division is done appropriately for leads (if the recording is carried out before 4 seconds, equal space will be allocated to all signals). The space division is conducted every 2 seconds in proportion to amplitude of online signals.

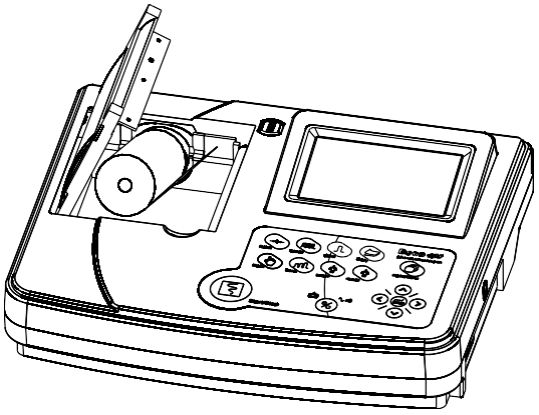
Paper loading

- Press the recorder release button as shown in the figure below.



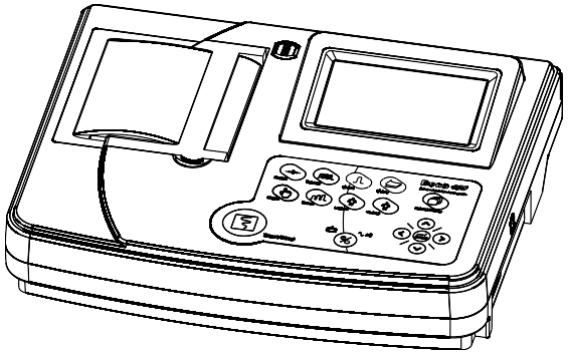
- Open the recorder door.

- Place the paper roll in the recorder and push it.



- Place the other side of the paper roll in the recorder.

■ Close the recorder door firmly.



⚠ **Warning** ⚠

Do not open the recorder door during recording. This can damage it.

The paper detector may not operate properly if covered with foreign matter. Therefore, if you find foreign matter on the sensor, remove it and clean the sensor.

⚠ **Warning** ⚠

During the recorder operation the record paper exits steadily. Pulling the paper will damage the recorder.

⚠ **Warning** ⚠

If the paper is jammed, open the recorder door and remove the paper. Do not pull the paper out by force.

Be careful when loading the paper in the recorder. Avoid damaging the thermo-sensitive printhead. Do not touch thermo-sensitive printhead.

It is recommended to use the paper with coloured marks intended to aware user that the paper is near to finish. Otherwise, user should ensure that sufficient paper has been fed to the recorder before recording.

The following information are printed on the recorder paper:

- Recording type (Auto, Manual, Periodic)
- Recording mode
- Date and time
- Patient information
- HR value
- Recording speed
- ECG lead, gain and filter
- Hospital/ward
- Physician name
- System model
- Software version

Recorder Cleaning

Accumulation of paper powder or foreign matter between the thermal head and platen roller reduces the print quality. Clean the head elements and platen roller surface using a cloth moistened with alcohol.Wait until the alcohol dries, then close the recorder door.

⚠ **Warning** ⚠

Do not clean the recorder immediately after recording because thermal head and its surrounding area are hot during and after recording.

Do not use sandpaper or other sharp objects for cleaning the recorder.

Section 7- Patient Safety

The electrocardiograph system is designed to comply with the international safety standards requirements for medical electrical equipment. This device has floating input (isolated electricity) and is protected against the effects of defibrillation. If correct electrodes are used in accordance with the manufacturer instructions, the display screen will recover within 10 seconds after defibrillation.

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 (Cardiac Float) and Defibrillation Proof applied part providing a high degree of protection against shock, and is usable during defibrillation.

⚠ **Warning** ⚠

Do not touch the patient, bed or instrument during defibrillation.

Follow the instructions below to ensure safety of the device installation.

The environment where the device will be used should be reasonably free from vibration, dust, corrosive or explosive gases, extremes of temperature and humidity.

The electrocardiograph system is designed to operate under ambient temperatures between 5º C and 40ºC. Ambient temperatures exceeding these limits could affect the accuracy of the device and cause damage to the electrical circuits.

Grounding the electrocardiograph

To protect the patient and hospital personnel, the electrocardiograph system must be grounded. The device is equipped with a detachable 3-wire cable which grounds the instrument to the power line ground (protective earth) when plugged into an appropriate 3-wire receptacle. If a 3-wire receptacle is not available, consult the hospital electricians. If there is any doubt regarding the integrity of the protective grounding wire, the equipment should run on the battery.

⚠ **Warning** ⚠

Possible explosion hazard if the device is used in the presence of flammable anesthetic agents.

Section 8- Getting Started

8-1 Open the package.

Open the package and take out the electrocardiograph and accessories carefully. Keep the package for possible future transportation or storage.

■ Check the device for any mechanical damage.

■ Check existence of accessories and contents according the following checklist:

Electrocardiograph device	1 unit
Patient cable	1 piece
Recorder thermosensitive paper	1 roll
Limb electrode (wrist electrode clamping)	Set of 4
Chest electrode (suction bulb)	Set of 6
Gel	1 packet
Power cable	1 piece
User manual	
Guarantee card	
Calibration certificate	

If there is any problem, contact the distributor immediately.

8-2 Connect the power cable to the device.

■ Make sure the AC power supply complies with the following specification:

100-240 VAC, 50 /60Hz.

■ Plug the power cable to the power supply socket of the device. Connect the other end of the power cable to a grounded power receptacle.

Make sure that the battery indicator lights. If it does not light, check your local power supply and power cable connection. If the problem still exists, contact the After -Sales Services department.

The battery needs to be charged after transportation or storage. If the power cable is not plugged in before turning on the device, the device may not work properly because of insufficient power. Connect the device to AC INPUT for about 24 hours while it is off.

8-3 Power on the electrocardiograph system.

Press Power key to turn on the electrocardiograph.

The battery must be recharged after a while to ensure adequate electricity reserve. To do so, you only connect the system to AC INPUT.

The system beeps every time it is powered on. If no beep sound is heard, the audio system eep sound, key/touch sound) may be faulty.

⚠ **Warning** ⚠

If any sign or error message is observed in the device that may be due to its failure, please do not use it on the patient.

8-4 Connect the patient sensor.

Connect all necessary accessories to patient and the electrocardiograph.

Section 9- Technical Specifications

CLASSIFICATION	
Protection against electroshock	Class I, Type CF Defibrillation proof (based on IEC 60601-1)
Mode of operation	Continues operation equipment
Harmful Liquid Proof Degree	Ordinary equipment, (without Liquid Proof)
Method of disinfection	Refer to chapter 10 for detail
Safety of anesthetic mixture	Not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
DISPLAY	
Display	TFT COLOR 480×272, 5”
Waveforms	12 Lead ECG/ Rhythm Lead
Numeric Parameters	HR
Operation Method	Membrane Keys and Touch
Displayed data	Waveforms, Patient information (Name and ID), Recording Speed, Operation Mode, Filter, HR Value Message
ECG	
Input Channel	Simultaneous acquisition of all 12 leads/ Rhythm Lead
Standard leads acquired	I, II, III, aVR, aVF, aVL, V1, V2, V3, V4, V5, V6
Sensitivity Selection	2.5, 5, 10, 20 mm/mV
Filters	Drift: on or off
	HUM: on or off
	Low pass: 25, 35, 150 HZ , Off
	EMG: on or off
Calibration	1 mV
Dynamic Range	±5 mV
Leakage Current	>10 µA
CMRR	> 98 dB
Time Constant	3.2 sec.
Frequency Response	0.05~150Hz
Pace	Detection & Rejection: 0.1~2 ms, ±2~±250 mV
Protection	Defibrillator
Standards	IEC 60601-2-25
ECG Storage	
Internal Memory	Up to 100 Records
Recorder	
Model	URUK Thermal Printer
Print Method	Thermal dot line printing
Dots per line	832 dots

Resolution	16 dots/mm (Horizontal)
	8 dots/mm (Vertical)
Printing Speed	6.25, 12.5, 25, 50 mm/s
Paper Width	110 mm
Print Width	104 mm
Printed data	12 Lead ECG Waveforms, HR Value, Patient Information, Hospital/ ward, system model, software version, date and time, paper speed, sensitivity, filter
Recording Mode	Manual, Periodic
Recording Format	Auto 1+1, Auto 3, Auto 3+1, Auto 6, Manual 1+1, Manual 3, Manual 3+1, Manual 6 and Rhythm
GENERAL	
Safety	Class I (Based on IEC60601-1)
Protection	Against Defibrillator
AC Power	100-240 VAC, 60 VA, 50/60 Hz
Internal Rechargeable Battery	Lithium Polymer, 11.1V, 4.3Ah Charge time: ~ 6 h Usage (New & Full Charged): ~ 8 h or Lithium-Ion, 11.1V, 3.35Ah Charge time: ~ 4 h Usage (New & Full Charged): ~ 5:30h or Lithium-Ion, 11.1V, 2.2Ah Charge time: ~ 5 h Usage (New & Full Charged): ~ 4:30 h
Dimension	290 mm (W)*70 mm (H)*350 mm (L)
Weight	2.5 Kg (with battery)

Section 10- Care and Cleaning (PM)

System Check

Before using the device,

■ Check if there is any mechanical damage in the system and accessories.

■ Check if the power cable and accessories are firmly connected.

■ Check if all the keys function correctly and are in proper condition.

If you find any damage in the electrocardiograph, stop using it on patient, and contact the biomedical engineer of the hospital or the manufacturer After Sales Service.

The overall check of the device, including the safety check, should be performed only by qualified personnel.

All checks which need the electrocardiograph to be opened or may affect the device safety should be performed by After Sales Service.

⚠ **Warning** ⚠

If users do not follow a satisfactory maintenance schedule, the device may become invalid, and human health may be endangered.

To ensure maximum battery life, let the electrocardiograph runs on the battery, at least once a month, until it turns itself off and then recharge the battery.

Cleaning

⚠ **Warning** ⚠

Before cleaning the electrocardiograph or the sensor, make sure that the equipment is switched off and disconnected from the power line.

The electrocardiograph system must be kept dust-free.
Regular cleaning of the device and the LCD screen is strongly recommended.

Please pay special attention to the following items:
1- Do not use strong solvents such as acetone or ammonia.
2- Most cleaning agents must be diluted before use.
3- Do not use rough material, such as steel wool, etc.
4- Do not let the cleaning agent enters into the chassis of the system.
5- Do not leave the cleaning agents on any part of the equipment.

The electrocardigraph and sensor surface can be cleaned with hospital-grade ethanol and dried with a clean cloth.

Please pay attention to the following guidelines for cleaning the accessories:

ECG Cable:

Use soft cloth moistened with mild soap liquid or cleaning agent containing 70% ethanol to clean the ECG cable.

Electrode (Clamp electrode, Chest electrode, Suction chest electrode) :
CLEANING / DISINFECTION : Cleaning and disinfecting detergents commonly suitable for surgical devices are suggested. These may be, for example, benzalkonium chloride-based products. Before using these cleaning products read carefully their instructions. After cleaning

wash with water. N.B. Do not use ultrasonic cleaners. Don't use removers, don't sterilize with steam. It possible to clean with ethyl alcool with concentration less than 10%.

Recorder:

Accumulation of paper powder or foreign matter on the thermal head and platen roller deteriorates the print quality. Clean the head elements and platen roller surface using a cloth moistened with alcohol. Wait until the alcohol dries then close the recorder door.

⚠ **Warning** ⚠

Do not clean the recorder immediately after recording because thermal head and its surrounding area are hot during and after recording.

Disinfection

Examples of disinfectants that can be used for the device are listed below:

- Alcohol 70%
- Isopropanol

To avoid damage to the equipment, disinfection should be performed according to the Hospital Maintenance Schedule.

- **Do not let the cleaning agent enter into the chassis of the system.**
- **Do not immerse any part of the system in water or cleaning solutions.**
- **Do not spill liquids on the system.**
- **Wipe up the system by a soft cloth after cleaning.**

⚠ **Warning** ⚠

Do not use ETO gas to disinfect the electrocardiograph.

The manufacturer does not accept any responsibility for effective control of infectious diseases using these chemical agents. Please contact infectious disease specialists in your hospital for more information.

Daily check of the following items is recommended:

1. Accessories intactness (no mechanical damage)
2. Accessories function

Weekly check of the following items is recommended:

1. The system cleanness
2. The system intactness (case, screen, keys, indicators, recorder door and release button)
3. The recorder function

Monthly check of the following items is recommended:

1. Calibration label (Send the system to the manufacturer for calibration on the predetermined date).
2. The system intactness (no mechanical damage)
3. The system cleanness
4. Keys and indicators function
5. Accessories intactness (no mechanical damage)
6. The recorder function

It is recommended that the system is calibrated by manufacturer every year, but it has to be calibrated once every 2 years. In addition, the system lifetime is 10 years.

The medical center can request the system calibration whenever the system accuracy is in doubt.

Preventive Maintenance (PM) Checklist

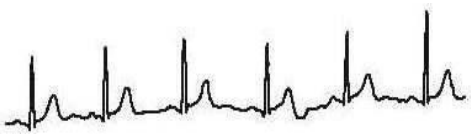
The preventive maintenance (PM) checklist should be completed by responsible individuals of healthcare center. It should be noted that PM checklist only is used to perform systematic inspection of the equipment and will not guarantee their correct function.

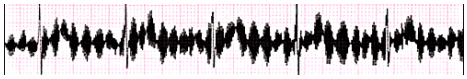
Section 11- Troubleshooting

Repairing the internal parts of the electrocardiograph must be only done by trained and authorized personnel of After Sale Service; 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 minor problems caused by incorrect use of the electrocardiograph or failure of accessories.

When you face any problem, please ensure that you have followed all actions mentioned in Solution column before you contact After- Sales Services.

Problem	Possible Cause	Solution
The device is not turned on		● Check AC power path. ● Call After- Sales Services.
The device is unable to run on the battery	● Battery is discharged. ● Faulty fuse	● Charge the battery for 5 hours. ● Check the battery fuse. ● Call After- Sales Services.
NO ECG waveform	● ECG cable connection failure ●Faulty ECG cable ●Improper placement of electrodes	● Check ECG cable connection. ● Short circuit all leads with each other. If ECG cable is ok, lead error message will not appear. ● Do not use old and faulty electrodes. ● Call After- Sales Services.
Inappropriate HR value	● Noisy and improper ECG signal	● Check leads and electrodes. ● Put the patient in a stable condition. ● Call After- Sales Services.
There is irregular up and down shifts in ECG waveform from baseline 	● Various electrodes are used together ● Loose connection of electrodes to lead wires ● Electrodes are placed on bony site of body. ● Unclean or sulfated electrodes ● Insufficient gel is applied to electrodes. ● Patient skin is not clean ● Abnormal patient breathing	● Check connection of electrodes to lead wires. ● Check proper placement of electrodes. ● Clean electrodes after each use. ● Apply sufficient gel. ● Clean patient skin by alcohol. ● Relax patient in a comfortable position. ● Press Reset key. ● If the problem still persists, use Drift filter.

Problem	Possible Cause	Solution
High frequencies and muscle artifacts make ECG signal noisy. (This may occur concurrently with AC noises) 	● Patient has stress or placed in an uncomfortable condition. ● Patient feels cold and starts shaking. ● Improper placement of patient hands and feet. ● Bed dimensions are not suitable for comfortable placement of patient hands and feet. ● Limb electrodes are attached tightly.	● Relax the patient. ● Check electrodes connection. ●If the problem persists, use Lowpass filter. ● If the problem still persists, take the following actions to reduce AC noise.
Noisy ECG signal due to AC power interferences 	● Electrodes are placed on bony site of the patient body. ● Unclean or sulfated electrodes ● Insufficient gel is applied. ● Contact with metal parts of bed, trolley, etc. ● Lead wires, patient cable or power cable fails to make connection. ● There are other electronic devices in the vicinity of the electrocardiograph. ● Improper ambient light for example using fluorescent lamp in the room which ECG record is taken. ● Incorrect HUM Filter is used. ● Improper Earth system	● Check electrodes and lead wires connection. ● Check that lead wires are not tangled. ● Check that the patient does not contact the metal parts. ● Check that patient cable and power cable have no contact. ● Check the selected HUM Filter. ● If the problem persists, unplug the power cable (the device runs on the battery). If the problem is solved, you can make sure that noise source is the device's power supply. ● If the problem still persists, noise source may be other devices, room or its earth system. Consequently this room is not suitable for ECG recording.

APPENDIX I- Accessories

General

This section lists the recommended accessories used for the electrocardiograph.

The accessories listed below are specified to be used for the electrocardiograph. Manufacturer does not take responsibility for any possible hazard to the patient or device if other accessories are used.

Accessories	Part #
• EKG Clamp electrodes, Adult, FIAB, Ref F9024SSC	P28042
• EKG Suction chest electrode, Adult , FIAB, Ref F9009SSC	P28043
• EKG Clamp electrodes, Pediatric, FIAB , Ref F9023SSC	P28047
• ECG Suction chest electrode, Pediatric-FIAB , Ref F9015SSC	P28048
• Electrocardiograph Cable,10wires, Banana Ends (URUK)	P28078
• ECG GEL	P28045
• Recorder Paper, 110mm , Roll	P28026

⚠ **Warning** ⚠

Use only the manufacturer recommended ECG cable. Other ECG cables and leads may cause improper device performance, patient injury and inadequate protection during defibrillation.

APPENDIX II- List of the System Parameters (Selections and Defaults)

ITEM	SELECTION	DEFAULT
Task bar Menu		
Recording Mode	Manual 1+1, Manual 3, Manual 3+1, Manual6, Auto 1+1, Auto 3, Auto 3+1, Auto 6, Rhythm	Auto 3
Sensitivity	2.5, 5, 10, 20 mm/mv	10
Paper Speed	6.25, 12.5, 25, 50 mm/s	25
Patient Information Menu		
Name		Blank
ID		Blank
Age	Years/Months	Years
Gender	Male/Female/None	None
Weight	Kg/lb.	Kg
Height	Cm/Foot	Cm
Physician Name		Blank
Blood Type	A+/A-/B+/B-/AB+/AB-/O+/O-/ Unknown	Unknown
Archive Menu		
Search	-	
Review	-	
Delete	-	
Page up	-	
Page Down	-	
Cursor up	-	
Cursor down	-	
Review		
Back	-	
Print Mode		
Print Modes	Auto, Manual, Rhythm	Auto
Auto		
Modes	1+1, 3, 3+1, 6	3
Rec State	Sync/ Real Time	Sync
Header	ON/ OFF	ON
Rhythm Lead	I, II, III, aVL, aVF, aVR, V1, V2, V3, V4, V5, V6	I

ITEM	SELECTION	DEFAULT
Manual		
Modes	1+1, 3, 3+1, 6	3
Header	ON/ OFF	ON
Rhythm Lead	I, II, III, aVL, aVF, aVR, V1, V2, V3, V4, V5, V6	I
Rhythm		
Length of Rhythm Recording	30, 60, 90, 120, 150, 180 Seconds	30
Header	ON/ OFF	ON
Rhythm Lead	I, II, III, aVL, aVF, aVR, V1, V2, V3, V4, V5, V6	I
Recorder Setting Menu		
Rec Time	3-12 Seconds, Interval=1(s)	3
Periodic Recording	Off, 5-60 Min, Interval=5	Off
Periodic Interval	1-20, Infinite, Interval=1	1
Sensitivity	2.5, 5, 10, 20	10
Paper Speed	6.25, 12.5, 25, 50	25
Filter Setting Menu		
Low Pass Filter	Off, 25, 35,75, 150 HZ	150
HUM Filter	ON/ OFF	ON
Drift Filter	ON/ OFF	ON
EMG Filter	ON/ OFF	OFF
F1	Low Pass Filter, HUM Filter, Drift Filter, EMG Filter	Low Pass Filter: Off HUM Filter: 50 Hz Drift Filter: On EMG Filter: On
F2	Low Pass Filter, HUM Filter, Drift Filter, EMG Filter	Low Pass Filter: 25 Hz HUM Filter: 50 Hz Drift Filter: On EMG Filter: Off
F3	Low Pass Filter, HUM Filter, Drift Filter, EMG Filter	Low Pass Filter: 35 Hz HUM Filter: 50 Hz Drift Filter: On EMG Filter: Off
F4	Low Pass Filter, HUM Filter, Drift Filter, EMG Filter	Low Pass Filter: 150 Hz HUM Filter: Off Drift Filter: Off EMG Filter: Off
User Setting Menu		
Save	Enable/ Disable	Disable
Pace Detect	ON/ OFF	OFF

ITEM	SELECTION	DEFAULT
Measurement	Enable/ Disable	Disable
Export Menu		
USB	-	
Close	-	
USB		
Cancel	-	
Network Menu		
About Menu		
Version	-	
Fax	-	
Website	-	
E-mail	-	
Tel	-	
Setting Menu		
Date & Time	Date, Time	
Hospital Ward	Ward	blank
Rec Test	Testing Recorder	
Default	Default Factory	
Factory	Demo, Company Name, Hardware Format, Calibration	
Touch Sound	Key Sound	
Language	English /Persian	English
Network	-	
Date & Time		
Date	Calendar Type (Christian, Solar) Year, Month, Day, Cursor up, Cursor down	-
Time	Hour, Minute, Second Cursor up, Cursor down	-
Factory		
Demo	ON/ OFF	OFF
Company Name	URUK	URUK
Touch Sound		
Key Sound	ON/ OFF	OFF

APPENDIX III -Error Messages

Message	Cause	Solution	Remarks
Leads Error Messages			
CHECK RA	Lead RA is not properly connected to patient.	Make sure that mentioned electrode is properly connected.	The message is displayed in red color on the screen.
CHECK LA	Lead LA is not properly connected to patient.	Make sure that mentioned electrode is properly connected.	The message is displayed in red color on the screen.
CHECK LL	Lead LL is not properly connected to patient.	Make sure that mentioned electrode is properly connected.	The message is displayed in red color on the screen.
CHECK C1	Improper connection of C1 electrode	Make sure that C1 electrode is properly connected to patient.	The message is displayed in red color on the screen.
CHECK C2	Improper connection of C2 electrode	Make sure that C2 electrode is properly connected to patient.	The message is displayed in red color on the screen.
CHECK C3	Improper connection of C3 electrode	Make sure that C3 electrode is properly connected to patient.	The message is displayed in red color on the screen.
CHECK C4	Improper connection of C4 electrode	Make sure that C4 electrode is properly connected to patient.	The message is displayed in red color on the screen.
CHECK C5	Improper connection of C5 electrode	Make sure that C5 electrode is properly connected to patient.	The message is displayed in red color on the screen.
CHECK C6	Improper connection of C6 electrode	Make sure that C6 electrode is properly connected to patient.	The message is displayed in red color on the screen.
System Messages			
Recorder Error Messages			
Rec. Hardware Error	Hardware error	Turn the system off and on. If the problem still exists, contact the manufacturer's After Sales Service.	The message blinks in yellow color on the screen.
Door Open	The recorder door is open.	Close the recorder door.	The message blinks in yellow color on the screen.
Paper Out	Paper roll is used up.	Insert a new paper roll into the recorder.	The message blinks in yellow color on the screen.
Head Hight Temp	The Print head is too hot.	Stop operation for a few minutes.	The message blinks in yellow color on the screen.

Message	Cause	Solution	Remarks
Head Hight Vol	The Print head voltage is high.	Turn the system off and on. If the problem still exists, contact the manufacturer's After Sales Service.	The message blinks in yellow color on the screen.
Head Low Vol	1- The print head voltage is low. 2- The battery voltage is low.	1- Turn the system off and on. 2- Make sure that the battery is sufficiently charged. If the problem still exists, contact the manufacturer's After Sales Service.	The message blinks in yellow color on the screen.
Time out Error	The recorder could not record.	Turn the system off and on. If the problem still exists, contact the manufacturer's After Sales Service.	The message blinks in yellow color on the screen.
Battery Error Messages			
Battery Low	Low battery voltage	Connect the power cable to the system.	The message blinks in yellow color on the screen.
Save & Copy Messages			
Rec's Saving Plz Wait	The system is saving data	Wait a few minutes to finish data saving	The message is displayed in yellow color and yellow box.
Data Acquisition	The system is loading saved file	Wait a few minutes to load the file	The message blinks in yellow color.
There's No Copy Rec	The last stored data could not be recorded after turning the system off and on	Avoid turning the system off and on when the Copy key is pressed.	The message is displayed in yellow color.

APPENDIX IV-EMC

⚠ **Warning** ⚠

Use only the recommended manufacturer accessory .Using the accessory other than in relevant chapter may cause to increase the EMISSION or decrease the IMMUNITY of system.

⚠ **Warning** ⚠

Measurements can be affected by mobile and RF communications equipment. It should be assured that the Electrocardiograph is used in the electromagnetic environment specified

⚠ **Warning** ⚠

To prevent EMC effect on the Electrocardiograph, the system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.

⚠ **Warning** ⚠

Do not use cellular phone in the vicinity of this equipment. High result in strong level of electromagnetic radiation emitted from such devices may interference with the Electrocardiograph performance.

Guidance and manufacturer's declaration – electromagnetic emissions		
The EM650 Electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the EM650 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The EM650 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 EM650 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The EM650 Electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the EM650 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 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%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (>60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T for 0.5 cycle 40% U_T for 5 cycles 70% U_T for 25 cycles <5% U_T for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EM650 requires continued operation, it is recommended that the ***EM650 Electrocardiograph*** be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	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 EM650 Electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the EM650 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ***EM650 Electrocardiograph***, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.17\sqrt{p}$ 150 kHz to 80 MHz $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted the oretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EM650 is used exceeds the applicable RF compliance level above, the EM650 should be observed to verify normal operation. If abnormal performance is observed, additional measures may necessary, such as reorienting or relocating the Electrocardiograph.

[b] Over the frequency range 150kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between Portable and mobile RF communications equipment and the Electrocardiograph

The EM650 Electrocardiograph is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EM650 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EM650 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

APPENDIX V- Detectable Abnormalities by Algorithm

Ventricular Hypertrophy

order	Arrhythmia	Criteria
1	**Left Ventricular Hypertrophy (LVH)**	**if both of the following criteria are satisfied:** * S amplitude in V1 + S amplitude in V5 > 3.5 mv * R amplitude > 1.1 mV in aVL
2	**Biventricular Hypertrophy (BVH)**	**if at least one of the following criteria is satisfied:** * R amplitude in V1, V2, V3, V5 and V6 > 3.5 mv AND QRS axis > 90˚ * LVH is the case already AND QRS axis > 90˚ * LVH is the case already AND S amplitude > $^1/_3$ × R amplitude in V5 and V6
3	**Right Ventricular Hypertrophy (RVH)**	**if at least one of the following criteria is satisfied:** * R amplitude > 0.7 mV in V1 * QR pattern in V1 * R amplitude > 0.5 mV in V1 AND R amplitude > S amplitude in V1 * R amplitude < S amplitude in V5 or V6 * S amplitude > 0.7 mV in V5 or V6 * S amplitude < 0.2 mV in V1 and R amplitude > 0.4 mV in V5 or V6 * QRS axis > 90˚

Ventricular Conduction Disturbances

4	**Complete Right Bundle Branch Block (RBBB)**	**For age[1] > 16:** **if all of the following criteria are satisfied:** * S duration > 40 mS in I and V6 * S duration > R duration in I and V6 * "Rsr" or "rsR" or "rSR" pattern in V1 or V2 **For age < 16:** **if the following criteria is satisfied:** * "Rsr" or "rsR" or "rSR" pattern in V1 or V2
5	**Complete Left Bundle Branch Block (LBBB)**	**if all of the following criteria are satisfied:** * QRS duration>120 mS (for 16<age) QRS duration>100 mS (for 4<age<16) QRS duration>90 mS (for age<4) in at least two leads out of I, V5, V6 or aVL. * Q amplitude < 0.1 mV in I, V5 and V6 * R amplitude is small in V1 and V2 AND followed by a big S wave
6	**Intraventricular Conduction Disturbances (IVCD)**	**if both of the following criteria are satisfied:** * RBBB or LBBB are not detected already. * QRS duration>110 mS in V1 or V2

7	**Incomplete Right Bundle Branch Block (IRBBB)**	**if both of the following criteria are satisfied:** * 110<QRS duration<120 mS (for 16<age) 90<QRS duration<100 mS (for 8<age<16) 86<QRS duration<90 mS (for age<8) in V1 or V2 * rSr pattern in V1
8	**Incomplete Left Bundle Branch Block (ILBBB)**	**if both of the following criteria are satisfied:** * 110<QRS duration<119 mS (for 16<age) 90<QRS duration<100 mS (for 8<age<16) 80<QRS duration<90 mS (for age<8) in V1 or V2 * LVH is not detected already
9	**Left Anterior Fascicular Block (LAFB)**	**if all of the following criteria are satisfied:** * -90° <QRSaxis< -45° * qR pattern in aVL * QRS duration < 120 mS in II
10	**Left Posterior Fascicular Block (LPFB)**	**if all of the following criteria are satisfied:** * 90° <QRSaxis< 180° * RS pattern in I and aVL * qR pattern in III and aVF
11	**Left Anterior Hemi Block (LAHB)**	**if all of the following criteria are satisfied:** * -90° <QRSaxis< -60° * R or qR pattern in both II and aVL * RS or QS pattern in both III and aVF
12	**Left Posterior Hemi Block (LPHB)**	**if all of the following criteria are satisfied:** * 120° <QRSaxis< 180° * QS pattern in I * QR pattern in III
		Heart Axis Abnormalities
13	**Left Axis Deviation (LAD)**	**if the following criteria is satisfied:** **For age[1] > 16:** * QRSaxis < -60° **For 5 < age < 8:** * QRSaxis < 0° **For age < 1:** * -90° < QRSaxis < 10°
14	**Moderate Left Axis Deviation (MLAD)**	**if the following criteria is satisfied:** **For age > 16:** * -45° < QRSaxis < -30°
15	**Marked Left Axis Deviation (MDLAD)**	**if the following criteria is satisfied:** **For age > 16:** * -90° < QRSaxis < -45°
16	**Moderate Right Axis Deviation (MRAD)**	**if the following criteria is satisfied:** **For age > 16:** * 90° < QRSaxis < 120°
17	**Marked Right Axis Deviation (MDRAD)**	**if the following criteria is satisfied:** **For age > 16:** * 120° < QRSaxis < 180°
18	**Right Axis Deviation**	**if the following criteria is satisfied:** **For 8 < age < 16:** * QRSaxis> 120°

	(RAD)	**<u>For 5 < age < 8</u>:** * QRSaxis> 140˚ **<u>For 1 < age < 5</u>:** * QRSaxis> 100˚ **<u>For age < 1</u>:** * QRSaxis> 120˚
19	**Normal Axis (NA)**	**if the following criteria is satisfied:** **<u>For age > 16</u>:** * −30˚ < QRSaxis < 90˚ **<u>For 8 < age < 16</u>:** * 0˚ < QRSaxis < 120˚ **<u>For 5 < age < 8</u>:** * 0˚ < QRSaxis < 140˚ **<u>For 1 < age < 5</u>:** * 5˚ < QRSaxis < 100˚ **<u>For age < 1</u>:** * 10˚ < QRSaxis < 120˚
		Atrioventricular Conduction Abnormalities
20	**First Degree Block (FDB)**	**if all of the following criteria are satisfied:** * distance between successive QRS peaks is regular * PR interval > 200 mS in II * QRS duration < 120 mS in II * successive QRS durations are almost equal
		Myocardial Infarction
21	**Acute Inferior Infarction (AII)**	**if both of the following criteria are satisfied in II, III and aVF:** * ST value > 0.3 mV * 5×Q amplitude > R amplitude <u>OR</u> QRS duration > 40 mS
22	**Inferior Infarction (II)**	**if all of the following criteria are satisfied in II, III and aVF:** * 3×Q amplitude > R amplitude * QRS duration > 40 mS * ST value > 0.15 mV <u>OR</u> T amplitude < 0
23	**Anterior Infarction (AI)**	**if all of the following criteria are satisfied in V1, V2, V3 and V4:** * 3×Q amplitude > R amplitude * QRS duration > 40 mS * ST value > 0.3 mV <u>OR</u> T amplitude < 0
24	**Anteroseptal Infarction (ASI)**	**if both of the following criteria are satisfied**: * AI is detected already * QS pattern in II (now , ASI will be reported instead of AI)
25	**Poor R Progression (PRP)**	**if one of the following criteria is satisfied**: * R amplitude < 0.2 mV in V2 and V3 <u>AND</u> R amplitude in V2 > R amplitude in V3 * R amplitude < 0.2 mV in V3 and V4 <u>AND</u> R amplitude in V3 > R amplitude in V4 * R amplitude < 0.2 mV in V4 and V5 <u>AND</u> R amplitude in V4 > R amplitude in V5 * R amplitude < 0.2 mV in V5 and V6 <u>AND</u> R amplitude in V5 > R amplitude in V6
26	**Abnormal Q Wave Adults**	**if one of the following criteria is satisfied <u>AND</u> age[1] > 18:** * Q amplitude > 0.15 mV in V2

	(AQWA)	* 3×Q amplitude > R amplitude in V2 * Q duration < 30 mS in at least one of I, II, V2, V3, V4, V5 or V6 leads OR Q duration > 45 mS in aVF
27	**Abnormal Q Wave Under 18 (AQWNA)**	**if one of the following criteria is satisfied AND age < 18:** * Q amplitude > 0.5 mV in I, II or aVF * Q amplitude exists in at least one of V1, V2 or V3 * Q amplitude > 0.5 mV AND 5×Q amplitude > R amplitude in at least one of V4, V5 or V6 leads
		Rhythm Abnormalities
28	**Sinus Rhythm (SINUS)**	**if both of the following criteria are satisfied:** * 60 < HeartRate < 100 * distance between successive QRS peaks is regular
29	**Bradycardia (BRADY)**	**if the following criteria are satisfied:** * heart Rate < 60
30	**Sinus Bradycardia (SBRADY)**	**if all of the following criteria are satisfied:** * 35 < Heart Rate < 50 * distance between successive QRS peaks is regular * P wave is positive in II AND negative in aVR
31	**Tachycardia (TACHY)**	**if the following criteria are satisfied:** * 100 < HeartRate
32	**Sinus Tachycardia (STACHY)**	**if all of the following criteria are satisfied:** * 100 < Heart Rate * distance between successive QRS peaks is regular * P wave is positive in II AND negative in aVR
33	**Narrow Regular Tachycardia (NRTACHY)**	**if all of the following criteria are satisfied:** * 100 < Heart Rate * distance between successive QRS peaks is regular * QRS duration < 120 mS in II
34	**Narrow Irregular Tachycardia (NIRTACHY)**	**if all of the following criteria are satisfied:** * 100 < Heart Rate * distance between successive QRS peaks is not regular * QRS duration < 120 mS in II
35	**Wide Regular Tachycardia (WRTACHY)**	**if all of the following criteria are satisfied:** * 100 < Heart Rate * distance between successive QRS peaks is regular * QRS duration > 120 mS in II
36	**Wide Irregular Tachycardia (WIRTACHY)**	**if all of the following criteria are satisfied:** * 100 < Heart Rate * distance between successive QRS peaks is not regular * QRS duration > 120 mS in II
37	**Premature Ventricular Contraction (PVC)**	**if all of the following criteria are satisfied:** * distance between successive QRS peaks is not regular * QRS duration > 120 mS in at least one of the beats of the reference lead * QRS duration in at least one of the beats of the reference lead has a considerable difference with the median of QRS durations of all beats in the same lead
		Unclassified Abnormalities
38	**Low Voltage Limb Leads (LVLIMB)**	**if the following criteria are satisfied:** * difference between highest and lowest point of QRS wave < 0.5 mV in all the limb leads (I,II,III,aVL,aVR and aVF)

39	**Low Voltage Chest Leads (LVCHEST)**	**if the following criteria are satisfied:** * difference between highest and lowest point of QRS wave < 1 mV in all the chest leads (V1,V2,V3,V4,V5 and V6)
40	**Possible Arm Leads Reversed (PALREVERS)**	**if the following criteria are satisfied:** * Lead I is completely inverted (negative P wave, QRS complex and T wave)
41	**Arm Leads Reversed (ALREVERS)**	**if all of the following criteria are satisfied:** * PALREVERS arrhythmia is already detected * P, QRS and T waves have positive amplitude * MDRAD arrhythmia is already detected (now , ALREVERS will be reported instead of PALREVERS)
42	**Very Large T Wave (Adults) (VLTA)**	**if all of the following criteria are satisfied:** * 18 < age[1] * T amplitude > 1.5 mV in more than two leads (except aVR) * none of the Myocardial Infarction arrhythmias have already been detected
43	**Very Large T Wave (under 18 years) (VLTNA)**	**if all of the following criteria are satisfied:** * 18 > age * T amplitude > 1.5 mV in more than two leads (except aVR)
44	**Long QT Interval (LQT)**	**if the following criteria is satisfied:** * QTcInterval > 480 in V2 and V3
45	**Short QT Interval (SQT)**	**if the following criteria is satisfied:** * QTcInterval < 350 in V2 and V3
46	**QT Prolongation (QTPROLONG)**	**if all of the following criteria are satisfied:** * Heart Rate < 80 * RBBB has not already been detected * QTcInterval > 480 in reference lead

Sinusoidal Amplitude:2 mv							
Filters\Frequency	**0.5 HZ (mm)**	**5 HZ (mm)**	**10 HZ (mm)**	**16 HZ (mm)**	**25 HZ (mm)**	**30 HZ (mm)**	**40 HZ (mm)**
0.05-150+ M	20	22	21	20	17.5	17	0
0.05-75+ M	20	21	20	18.5	17.5	17	0
0.05-35+ M	20	20	20	18.5	15	13	0

0.05-25+ M	20	20	19	17	12.5	9.5	0
0.5-150+ M	10	20	19.5	19	18	18	0.5
0.5-75+ M	10	20	19	19	18	19	0
0.5-35+ M	10	20	20	19	15.5	13.5	0
0.5-25+ M	10	19.5	19	17	12.5	9	0
0.05-150-H50+ M	20	20	20	18.5	17.5	16	0
0.05-75-H50+ M	20	20	20	19	17.5	16	0
0.05-35-H50+ M	20	20	20	19	15.5	14	0
0.05-25-H50+ M	20	19.5	19.5	16.5	12	9	0
0.5-150-H50+ M	9.5	20	20	19	17.5	16	0
0.5-75-H50+ M	9.5	19.5	20	19	18	17	0
0.5-35-H50+ M	10	19.5	19.5	18.5	15	12.5	0
0.5-25-H50+ M	10	19.5	19.5	16.5	12.5	9.5	0
Filters\Frequency	**45Hz (mm)**	**50 HZ (mm)**	**55 HZ (mm)**	**60 HZ (mm)**	**65 HZ (mm)**	**70 HZ (mm)**	**80 HZ (mm)**
0.05-150+ M	14	10.5	13	10	11	9	0
0.05-75+ M	13	13.5	13	10.5	10	9	1
0.05-35+ M	6	4	2.5	1	1	1	0
0.05-25+ M	0	0	0	0	1	0	0
0.5-150+ M	14	11.5	11	10	11	8.5	0
0.5-75+ M	12	12	12	10.5	9.5	8	0
0.5-35+ M	6	4	2.5	1.5	0.5	1	0
0.5-25+ M	0	0	0	1	0.5	1	0
0.05-150-H50+ M	12.5	0	7	11	11	9.5	0
0.05-75-H50+ M	11	0	12	11	9	8.5	0
0.05-35-H50+ M	6	0	2.5	1.5	1	1	0
0.05-25-H50+ M	0	0	0	0	1	0	0
0. 5-150-H50+ M	11.5	0	12	11	10	9	0
0. 5-75-H50+ M	11	0	12	10	9	8.5	0
0. 5-35-H50+ M	6	0.5	0	2	1	1	0
0. 5-25-H50+ M	0	0	0	0	1	1	0

Sinusoidal Amplitude:2 mv						
Filters\Frequency	**90 HZ (mm)**	**100 HZ (mm)**	**110 HZ (mm)**	**120 HZ (mm)**	**130 HZ (mm)**	**150 HZ (mm)**
0.05-150+ M	4.5	0	2	5	6	3

0.05-75+ M	2.5	0	0	0.5	4	2
0.05-35+ M	0	0	0	1	2	0
0.05-25+ M	0	0	0	0.5	2	0
0.5-150+ M	4.5	0	1	2	6	3
0.5-75+ M	2	0	0	2	4.5	2
0.5-35+ M	0.5	0	0	0	2	0
0.5-25+ M	0.5	0	0	0	2.5	0
0.05-150-H50+ M	5	0	1	0	5	0
0.05-75-H50+ M	1	0	0	1	4	0
0.05-35-H50+ M	0	0	0	0	2	0
0.05-25-H50+ M	0	0	0	0	2	0
0. 5-150-H50+ M	7	0	1	1	6	0
0. 5-75-H50+ M	2	0	0.5	0	4	0
0. 5-35-H50+ M	0	0	0	0.5	2	0
0. 5-25-H50+ M	0	0	0	0.5	1.5	0

For Amp:0.5 mv							
Filters\Frequency	**0.5 HZ (mm)**	**5 HZ (mm)**	**10 HZ (mm)**	**16 HZ (mm)**	**25 HZ (mm)**	**30 HZ (mm)**	**40 HZ (mm)**

0.05-150+ M	5	4.5	5	4.5	4.5	5	0
0.05-75+ M	5	5	5	5	4.5	4.5	0
0.05-35+ M	5	5	5	4.5	4	3.5	2
0.05-25+ M	5	5	4.5	4	3	2	0
0.5-150+ M	3	5	5.5	4.5	4.5	4.5	0
0.5-75+ M	2	5	4.5	5	5	4.5	0
0.5-35+ M	2	5	4.5	5	3.5	3	0
0.5-25+ M	2.5	5	5	4.5	3	2	0
0.05-150-H50+ M	4.5	5	5.5	5	4.5	3.5	3
0.05-75-H50+ M	5	5.5	4.5	4.5	4.5	4	3
0.05-35-H50+ M	5	5	5	4.5	4	3	0
0.05-25-H50+ M	5	5	5	4	3	2.5	0
0. 5-150-H50+ M	2.5	5	4.5	4.5	4	4	0
0. 5-75-H50+ M	3.5	5	4.5	4.5	5	4.5	0
0. 5-35-H50+ M	2.5	4.5	4.5	4.5	4	3.5	0
0. 5-25-H50+ M	2.5	4.5	4.5	4.5	3	2.5	0
Filters\Frequency	**45Hz (mm)**	**50 HZ (mm)**	**55 HZ (mm)**	**60 HZ (mm)**	**65 HZ (mm)**	**70 HZ (mm)**	**80 HZ (mm)**
0.05-150+ M	4	3	3	3	3	2.5	0
0.05-75+ M	5	2	3	3	2.5	3	1
0.05-35+ M	0	0	0	0	0	0	0
0.05-25+ M	0	0	0	0	0	0	0
0.5-150+ M	4.5	4	4	3.5	4	2	0
0.5-75+ M	4.5	4.5	3	3	3	2	0
0.5-35+ M	0	0	0	0	0	0	0
0.5-25+ M	0	0	0	0	0	0	0
0.05-150-H50+ M	0	0	3	3	3	3	0
0.05-75-H50+ M	0	0	3	2	1.5	1.5	1
0.05-35-H50+ M	1.5	0	0	0	0	0	0
0.05-25-H50+ M	0	0	0	0	0	0	0
0. 5-150-H50+ M	0	0	2	2.5	2	2	0
0. 5-75-H50+ M	0	0	2.5	2	1.5	2	0
0. 5-35-H50+ M	0	0	0	0	0.5	0	0
0. 5-25-H50+ M	0	0	0	0	0	0	0

Sinusoidal Amplitude:0.5 mv

Filters\Frequency	90 HZ (mm)	100 HZ (mm)	110 HZ (mm)	120 HZ (mm)	130 HZ (mm)	150 HZ (mm)
0.05-150+ M	0	1	1	0	1	1
0.05-75+ M	0	0	0	0	0	0
0.05-35+ M	0	0	0	0	0	0
0.05-25+ M	0	0	0	0	0	0
0.5-150+ M	0	2	0	0	0.5	1
0.5-75+ M	0	0	0	0	0.5	0
0.5-35+ M	0	0	0	0.5	0.5	0
0.5-25+ M	0	0	0	0	0	0
0.05-150-H50+ M	0	1	1	0	1	0
0.05-75-H50+ M	0	0	0	0	1	0
0.05-35-H50+ M	0	0	0	0	0	0
0.05-25-H50+ M	0	0	0	0	0	0
0. 5-150-H50+ M	0	0	1	0	0.5	0
0. 5-75-H50+ M	0	0.5	0.5	0	0.5	0
0. 5-35-H50+ M	0	0	0	0.5	0.5	0
0. 5-25-H50+ M	0	0	0	0	0.5	0

Change history

Rev	Date	Description	Created By	Confirmed By	Approved By
1			Mohsen	Shima	S.Mohammad
2	2023/04/16	European Authorized Representative was changed	Mohsen	Shima	S.Mohammad