SAADAT Co.

User Manual

Dena

Electrocardiograph

DENA 650 (Linux)

CE 2195

D00912-10

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Contents

Manual Purpose

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.

Explanations of the used expressions in this Manual

WARNING

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

NOTE

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

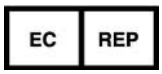
Version Information

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
Oct. 2021	D00912-V10

This version of the manual, is intended for DENA 650 electrocardiograph with software version 4(202.4.0.0) and later.

Symbols

Symbol	Definition
	Consult user manual of the device 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
	European community representative

Patient’s safety

Introduction

The DENA 650 electrocardiograph device 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.

Grounding

To protect the patient and hospital personnel, the electrocardiograph system must be grounded. The DENA 650 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

- DENA 650 is intended to be used only by qualified medical staff.
- Before use, carefully read this manual and directions for use of any accessories.
- DENA 650 is intended for use only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.
- 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.
- The operator must check that the DENA 650 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).
- Do not touch the patient, bed or devices nearby during defibrillation.
- When defibrillator is used, the signals may be disturbed for a few seconds, after which the device will continue to operate normally.
- For people who have a pacemaker, be sure to enable the pacemaker detection feature on the device.
- The physician shall consider all well-known side-effects when using DENA 650 .

- 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.
- Use disposable electrodes when using electroshock and electrosurgery with an electrocardiograph.
- Do not connect items not specified as parts of DENA 650 .
- Do not expose DENA 650 near any local heating item such as the direct radiation.
- It is possible to increase leakage current when touching the patient and connected devices, or when several systems as well as DENA 650 are connected to the patient simultaneously.
- Due to the possibility of explosion, the equipment is not suitable for use in the presence of a flammable anaesthetic mixture or in oxygen-rich places.
- To protect patient against the electrical shock hazards, DENA 650 needs to be connected to grounded power receptacle.
- If any liquid is spilled on the system or accessories, immediately turn off the system and wipe up it by a soft cloth. If water seeps into the device, it should be inspected by trained personnel before reuse.
- Electric and magnetic fields cause the device to malfunction. DENA 650 must be installed and serviced in accordance with the information in Appendix 3 Electro-magnetic compliance .
- Electrocardiograph needs to be installed and put into service according to the EMC information provided in the Appendix 3.
- To prevent EMC effect on DENA 650, 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.
- Do not use DENA 650 during X-ray and Magnetic Resonance imaging. Induced current could potentially cause burns and may affect the accuracy of DENA 650 measurements. DENA 650 may also adversely affect MRI and X-ray images.

NOTE

- Before connecting the device to the power supply, make sure that the voltage and frequency match the specifications of the device.
- The environment in which the device is used must be free from vibration, dust, corrosive and flammable gases, high temperature and humidity.
- The device is designed to work well at temperatures between 5 and 40 degrees Celsius. When the ambient temperature exceeds this range, it adversely affects the measurement accuracy of the device and may damage electrical circuits.
- DENA 650 software is designed to minimize the risk of software errors.
- Due to the frequency band up to 150 Hz and the sampling rate of 1000 sample/s, the accuracy of signal reconstruction in DENA 650 is in accordance with the requirements of IEC 60601-2-25 standard.

1) Introduction

Device description

DENA 650 (ECG Recorder) is one of the most important, safest, and simplest medical devices for measuring, displaying, storing, and recording cardiac signals to diagnose many heart diseases.

Intended use

DENA 650 can be used for adults, children and infants. This device is intended for trained medical staff in all medical centers that have complied with the requirements of the medical location, for diagnostic purposes.

Contraindications:

- DENA 650 is not intended for home or MRI use.
- DENA 650 is not a therapeutic device. The results provided by the device should be evaluated based on the patient's clinical condition and these results can not replace routine examinations.

Features

- Color display and touch screen
- Lightweight and portable
- Works with rechargeable batteries or AC power
- Recording and displaying 12-lead ECG waveform
- Displaying Rhythm-lead waveform separately on the screen
- Up to 6-channel waveform recording
- Adjustable filter, gain, paper speed and recording mode
- Data storage in internal and external memories
- Displaying and recording stored data
- Data transfer via USB
- Connection and online data transfer to PC
- Upgrading the software via USB
- Dividing the paper space according to the signal amplitudes
- Signal analysis and diagnosing cardiovascular abnormalities – Measurement and Interpretation
- Measurement of cardiac angles

Get started

1- Open the package and take out the DENA 650 and accessories carefully. Keep the package for possible future transportation or storage. If trolley is available, assemble it according to its instruction and place the electrocardiograph on it properly.

- Check the device for any mechanical damage.
- If there is any problem, contact the distributor immediately.

2- Connect the power cable to the device.

- Make sure the AC power supply complies with 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.

3- Power on the DENA 650.

- Press the Power key to turn on the electrocardiograph.

4- Connect the patient cable. Connect all necessary accessories to patient and the DENA 650.

⚠ WARNING

- If any sign or error message is observed in DENA 650 that may be due to its failure, please do not use it on the patient.

In the following, the different parts of this device will be explained.

Top panel

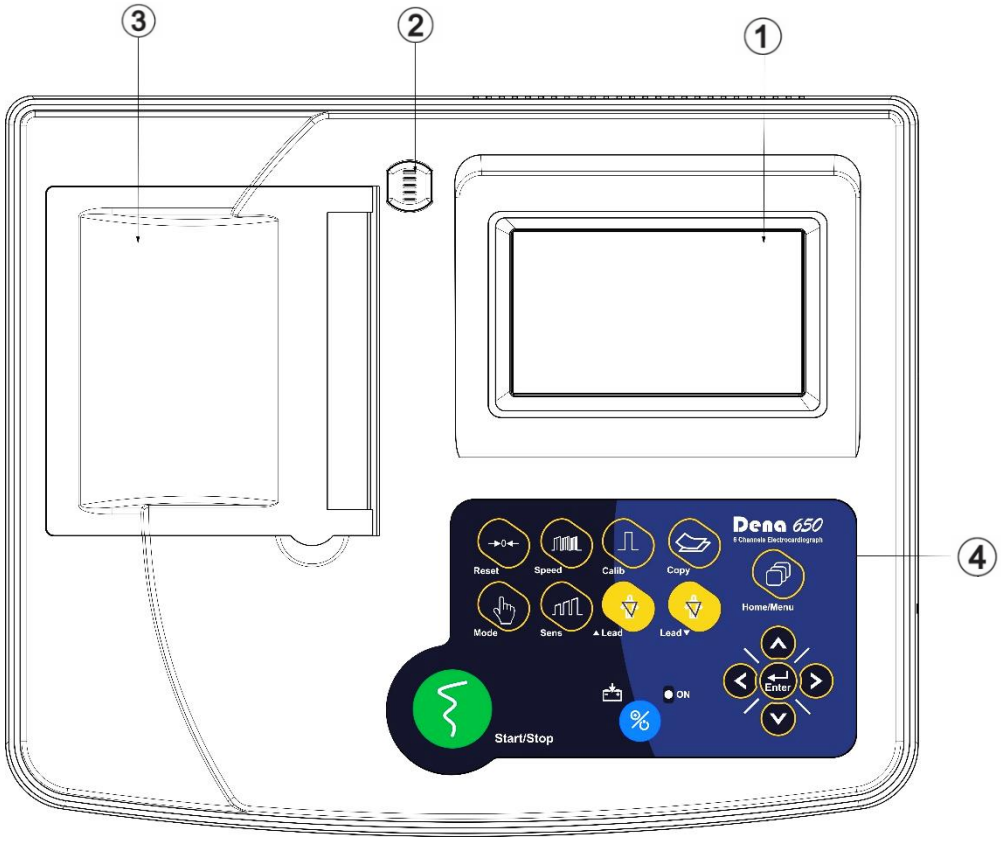


Figure 1-1 Top panel

① Display Screen: ECG waveforms, patient information, messages, etc. are displayed on the screen . (more information follows).
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. (more information follows).

Display screen

DENA 650 has a TFT color screen. The 12-wave ECG waveform, HR numerical value, patient name and ID, date and time, device status and system messages are displayed on this screen. The screen can be divided into three parts:

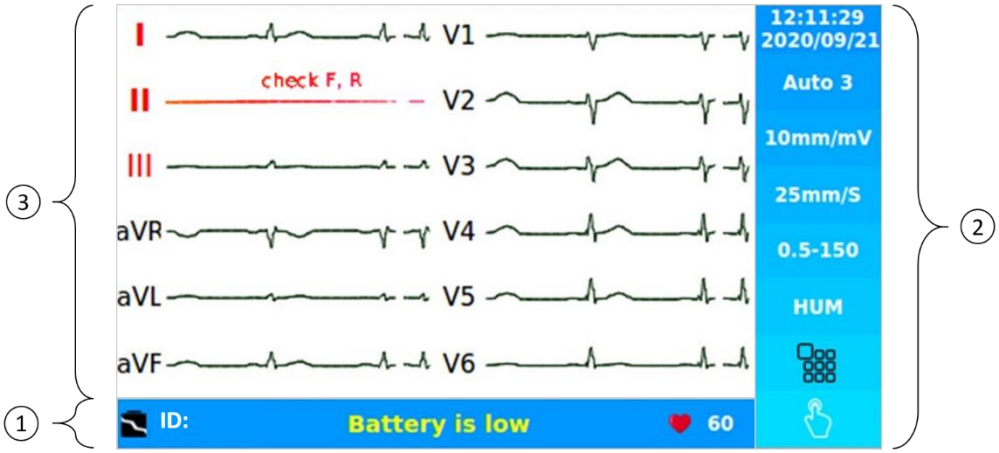


Figure 1-2 Display screen

Bottom Ribbon (figure 1-2-①),
Touch keys area (figure 1-2-②),
Waveform area and error messages area (figure 1-2-③).

Bottom Ribbon

The bottom of the screen is called Bottom Ribbon. The parameters displayed in this area include the numerical value of the HR, the patient's ID and operating conditions of the device. This information is always displayed on the screen when the device is on.
By enabling the PACS option, the below icons will be shown in this ribbon:

 This icon is displayed when PACS is enabled but the network connection has not yet been established.

 This icon indicates the connection of the network cable to the device.

 This icon is displayed when communicating with the PACS server.

If PACS is disabled, no icon will be displayed.
Depending on the condition of the battery during operation of the device, the corresponding symbol (such as ) is displayed.in this ribbon.
The HR value is measured and updated per second.

Device notifications and error messages are displayed in yellow in the middle of this area.
It should also be noted that by selecting the ID, you can more quickly refer to the relevant menu and make the necessary settings.

Touch keys

Time and Date are displayed at the top right corner of this section.
The function of each of the keys in this section is similar to the equivalent key function on the device keyboard.

During recording, or by touching the key  , the touch screen is locked and its icon is converted to  . At the end of the recording or by touching again, it will reset and the touch screen will be activated.
(more information follows).

Wave Form Area

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

ECG lead type is displayed in Waveform Area.

DENA 650 constantly checks the connection of the electrodes and, if it detects that the electrodes are not properly connected, displays a red message in the waveform area (such as lead II in Figure 1-2-③).

Control panel

DENA 650 is designed in such a way that user can easily perform operations using some keys and touch screen. Figure 1-3 illustrates these keys and indicators.

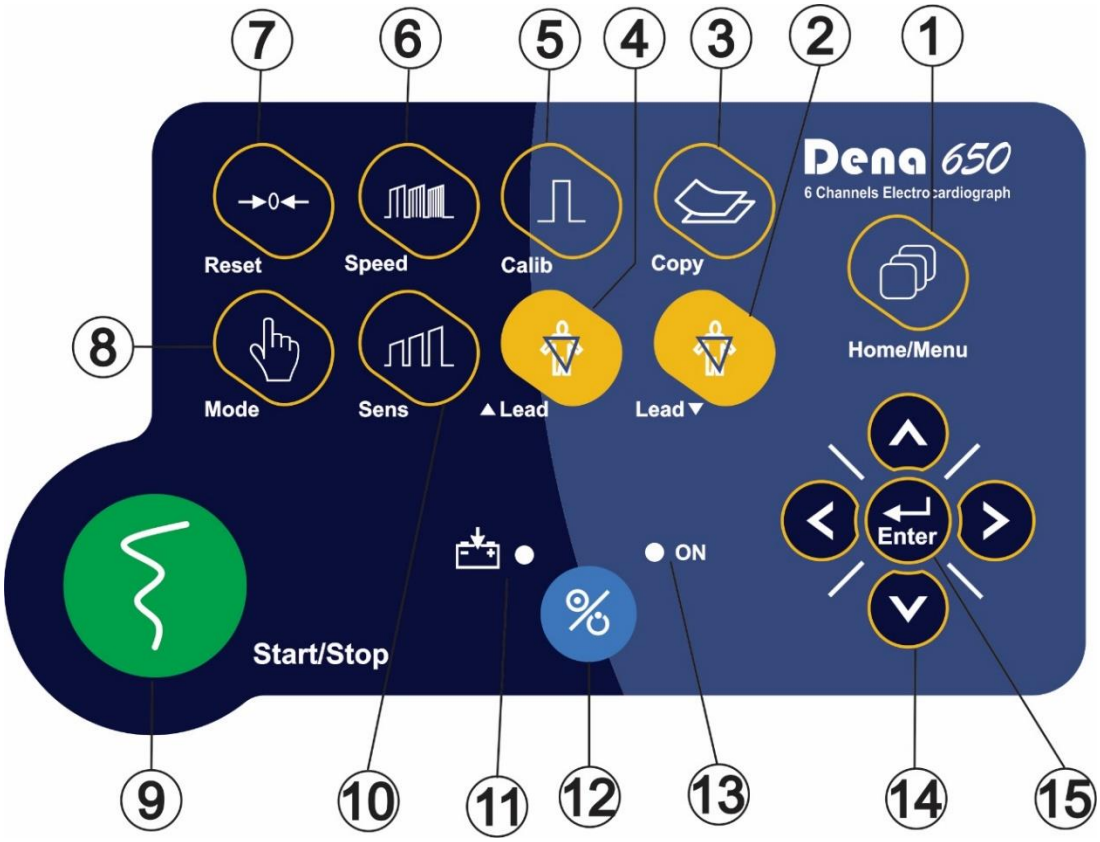
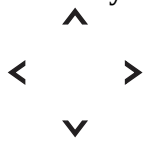


Figure 1-3 Control panel

Table 1-1 Control panel Items

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. (green if fully charged, and otherwise orange)
⑫ 	Press to turn on or off the device.
⑬ ON	On/Off indicator. (green)
⑭ **Arrow Keys** 	Use to scroll between menus.
⑮ **Enter**	Press to enter software menus or select menus options

⚠ WARNING

- Before using the DENA 650, check function of all keys and make sure that it is in proper working order.
- Do not use sharp objects to touch the screen.

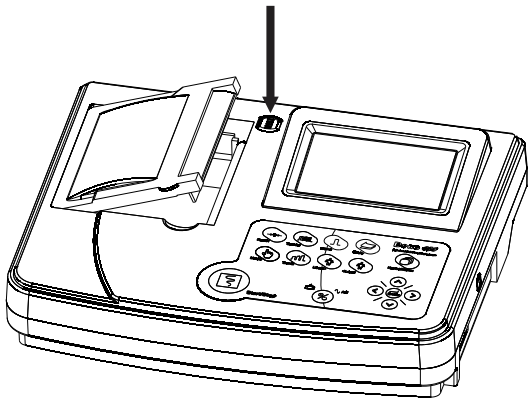
Recorder

⚠ WARNING

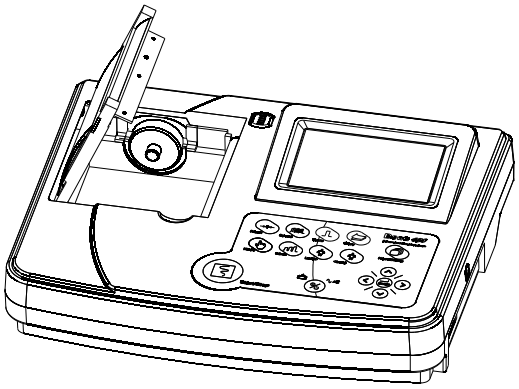
- Use only the manufacturer recommended record paper, otherwise the recording quality may be poor and the thermal head may be damaged.
- The thermal head and its surroundings are very hot during and immediately after recording, and touching it can cause injuries such as burns.

Paper loading

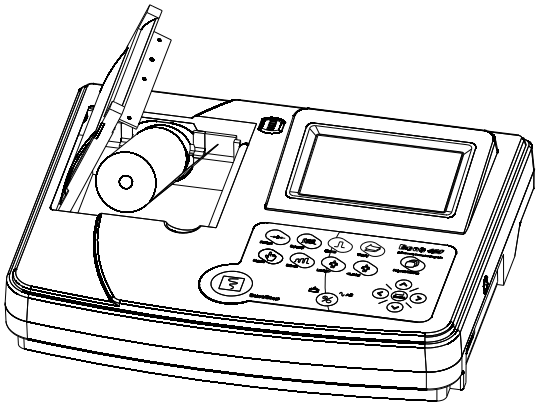
1- Press the recorder release button as shown in the figure below.



2- Open the recorder door.

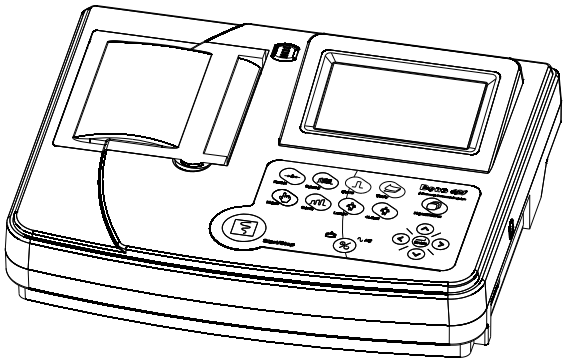


3- Place the paper roll inclined in the recorder and push it.



4- Place the other side of the paper roll in the recorder. Open the paper roll to leave some of it out of the recorder.

5- Close the recorder door firmly.



WARNING

- Do not open the recorder door during recording. This can damage it.
- During the recorder operation the record paper exits steadily. Pulling the paper will damage the recorder.
- If the paper is jammed, open the recorder door and remove the paper. Do not pull the paper out by force.

NOTE

- 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.
- Be careful when loading the paper in the recorder. Avoid damaging the thermosensitive print head. Do not touch thermosensitive print head.
- It is recommended to use the paper with colored 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.

Information printed on the recorder paper

- Recording type (Auto, Manual, Rhythm) and Status (Normal, Copy, Review, Periodic)
- Recording state (Real, Sync)
- Date and Time
- Patient information (Name, ID, Gender, Height, Weight, Blood type)
- HR value
- Rhythm lead
- Gain, Filter, Speed and Recording time
- Pacemaker status
- Measurement status
- Hospital/Ward and Physician name
- System model and Software version

NOTE

- The paper space is divided according to the size of the signals. It should be noted that after connecting the patient cable, it takes at least 4 seconds for these values to be calculated and the space to be divided proportionally between the leads.
- If the Drift filter is Off and there is DC offset in the signal, or if the patient has Pacemaker and the Pace option of the device is off, the paper space may not be devided properly.

Bottom panel

figure 1-4 shows the bottom panel:

① Handhold: For transporting the device.

② Battery Compartment: For loading the battery.

③ 3A fast fuse

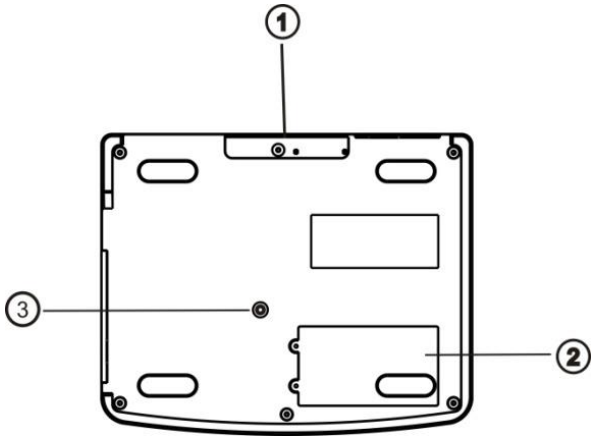


Figure 1-4 Bottom panel

Built-in Battery

DENA 650 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).

The charging and discharging time of the device can vary depending on the type of battery used (its types are described in the Technical specification chapter) and also the duration of use.

Table 1-2 shows the battery status in different conditions.

⚠ WARNING

- If the device is not to be used for a long time (more than 10 days), remove the fuse from the device to prevent full discharge of the battery.
- If the battery discharges in less than 1 hour, contact after-sales service to replace it.
- DENA 650 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.
- Use only the manufacturer recommended batteries. Other batteries may result in fire.

Table 1-2 Battery status icons

Battery stats	Icon
Battety disconnection	
Charging (below 20%)	
Pluged in and fully charged	
20-40% charged	
40-60% charged	
60-80% charged	
80-99% charged	
20-40% charged, charging	
40-60% charged, charging	
60-80% charged, charging	
80-99% charged, charging	

NOTE

- Make sure the battery indicator lights up. If the battery indicator does not light up, check the local power supply and power cord connection. If this problem persists, contact after-sales service.
- The battery needs to be charged after transport or storage. If in this case you turn on the device without connecting the power cable, the device can not be turned on due to insufficient charge, in this case, connect the device to the mains for a period of time according to the type of battery (by referring to the Technical specification).
- After working with the battery for a while, the battery needs to be recharged. To do this, just connect the device to AC mains.

Rear panel

figure 1-5 shows the rear panel.

① AC power input

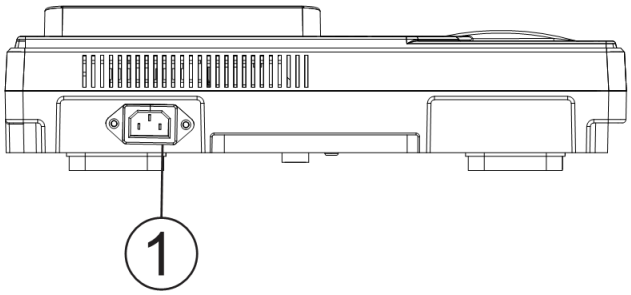


Figure 1-5 Rear panel

Side panel

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

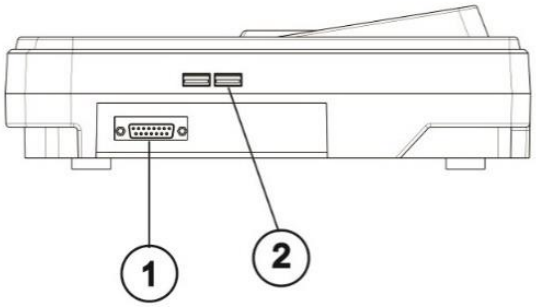


Figure 1-6 Side panel

① ECG cable connector

① USB port for data export and software update

2) System settings

General

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

- For date and time settings, please refer to **Menu→ Setting→ Date & Time**.
- For filter settings, please refer to **Menu→ Filters**.
- For recording setting, please refer to **Menu→ Rec Mode** and **Menu→ Rec Setting**.
- For manufacturer information, please refer to **Menu →About**.
- For setting the Measurement and Interpretation, Saving the signals and enabling/disabling the Pacemaker, please refer to **Menu→ User**.

NOTE

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

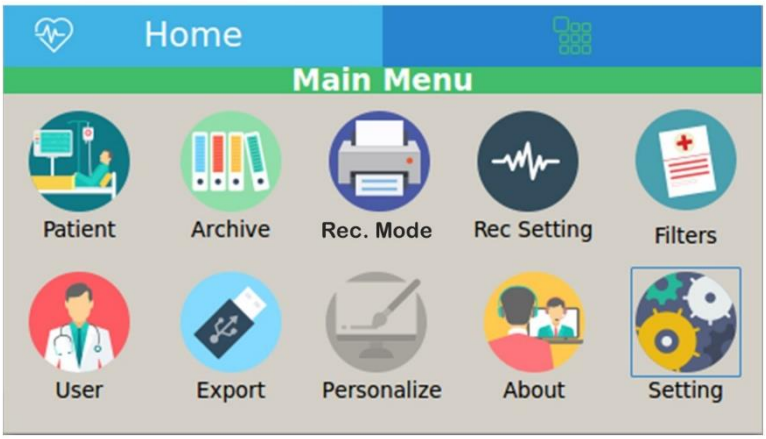


Figure 2-1 Main menu

DENA 650 has a flexible configuration that 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.

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

Recording Mode Menu

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

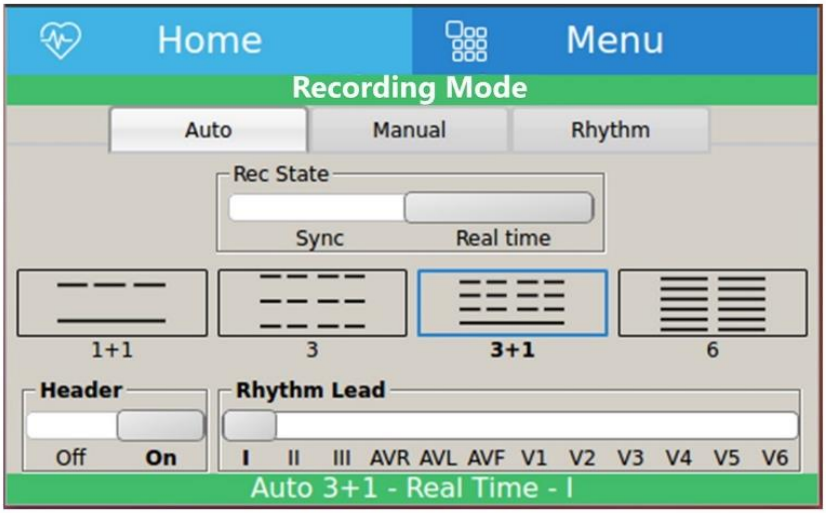


Figure 2-2 Rec mode menu

The following items can be set through this menu:

- Rec Type: available options are Auto, Manual and Rhythm.

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

- 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.
  In the Real time mode, at the moment of recording each signal, the signal received from the patient is used at the same time.

- 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 and selectable.

  The Rhythm lead can be one of I, II, III, aVR, aVL, 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).

NOTE

- For more information about Recording types, see the chapter Recording Operation.
- Sync recording can be performed only in Automatic modes.

Recorder Setting Menu

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

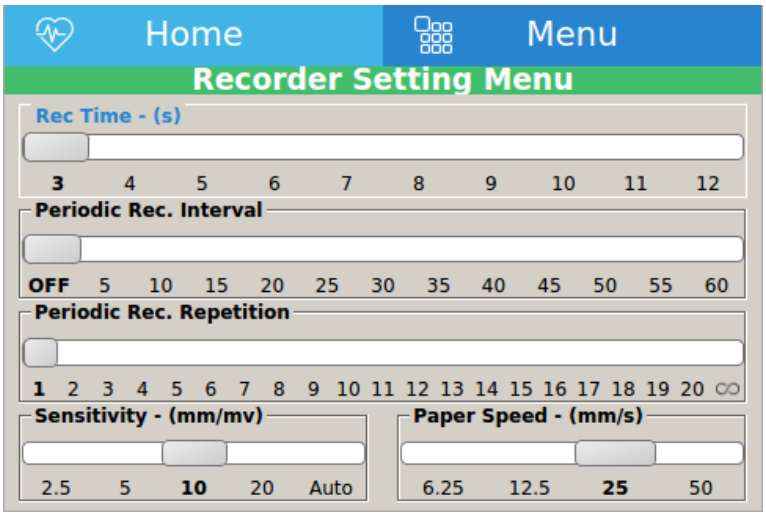


Figure 2-3 Recorder setting menu

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 in record & display screen. Available options are 2.5, 5, 10, 20 and Auto (mm/mV). By selecting Auto, the best option will be selected.
- Paper Speed: 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:

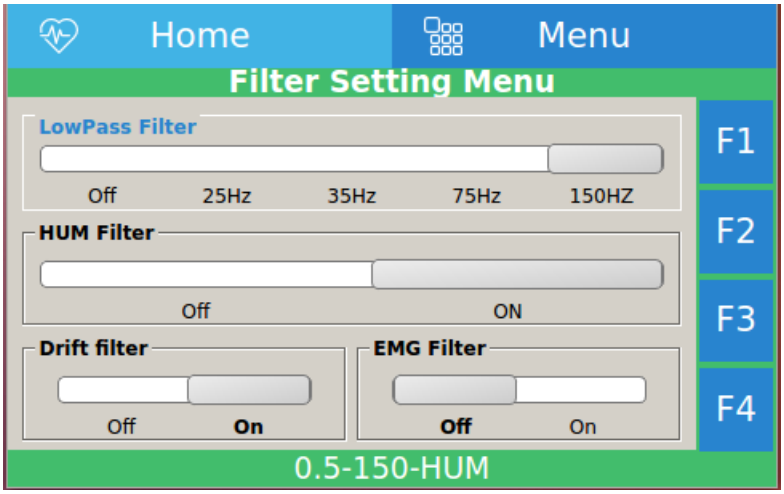


Figure 2-4 Filter setting menu

The following items can be set through this menu:

- LowPass Filter: available options are Off and 25, 35, 75, 150 Hz. This filter is used to remove muscle noise and high frequency noise. These filters make the heart signal smoother and cleaner. The selected filter type or frequency is displayed on the screen and in the record paper. If you select the Off option, this filter will be disabled.
- HUM Filter: available options are Off and On. The function of this filter is to eliminate the effects of local AC frequency on the signals. By selecting the On option, the phrase "HUM" will be inserted on the screen and the record paper, and if the Off option is selected, the phrase on the screen and the record paper will not be displayed.
  This filter is automatically adjusted according to the AC power frequency (50 or 60 Hz) if it is On
- Drift Filter: available options are On and Off. This filter reduces signal fluctuations (base line wandering) that are mainly due to the patient's breathing and movement. By setting Drift filter: On, the phrase "0.5" and otherwise "0.05" is displayed on the record screen and paper.
- EMG Filter: available options are On and Off. This filter is used to remove muscle noise. By setting On, the phrase EMG is displayed on the screen and in the record paper.

WARNING

- The use of 25, 35, and 75 Hz LowPass filters may reduce the amplitude of the cardiac signal and omit some useful signal details.
- If you turn on the HUM filter, in proportion to the selected frequency, its third harmonic will also be removed. In other words, if the local power frequency is 50 Hz, in addition to the 50 Hz frequency, the frequency of 150 HZ is also removed. If the power frequency of the local power is 60 Hz, in addition to the frequency of 60 Hz, the frequency of 180 is also removed. The reason for this is to make the heart signal clearer and smoother.
- If the EMG filter is turned on, only 75 or 150 Hz options for the low-pass filter are available. Because if the EMG filters and the 25 or 35 Hz low-pass filters are On at the same time, significant changes will be observed on the signal amplitude.
- The EMG filter is an adaptive, non-linear and time- variant filter that is applied to ECG signals. Since EMG is a non-linear filter, the 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.

NOTE

- After setting On the EMG filter, wait a few seconds before recording.
- Refer to the Troubleshooting and Error messages chapter to eliminate ECG signal noise.
- If the drift filter is inactive and the signals have offset, the signals may not be flush with the corresponding labels and the paper space may not be partitioned correctly.
- For LowPass filters, -3dB cut-off frequencies are at 150 ± 20 Hz, 75 ± 5 Hz, 35 ± 2 Hz and 25 ± 2 Hz, respectively.
- For Drift filter, -3dB cut-off frequency is at 0.5 ±0.1 Hz. If the drift filter is switched off, the cuto-ff frequency will be about 0.05Hz.
- The 0.5 Hz filter is used to remove signal baseline oscillations and may interfere with the ST Segment analysis.
- ECG signal saturation occurs when the signal is not displayed or exceeds lower or upper limits of the display area.
- For EMG filter, -3dB cut-off frequency increases to about 55Hz in areas where the signal slope is high and decreases to about 10Hz when the signal slope is low.

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.

Table 2-1 Default filters

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

User Setting Menu

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

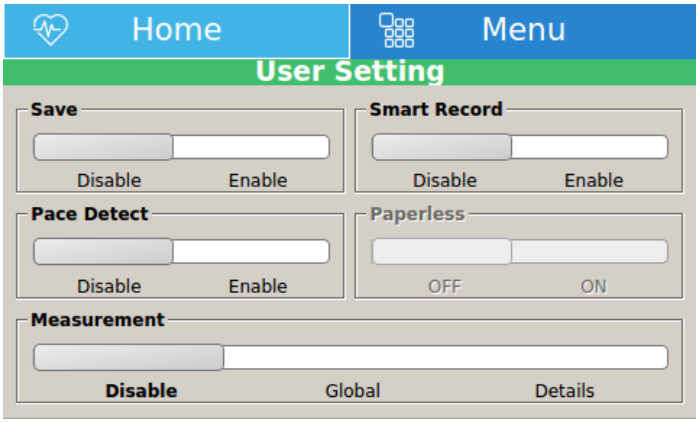


Figure 2-5 User setting

The following items can be set through this menu:

- Save: Enable this item to save patient data and signals in Auto and Rhythm modes.
- Smart Record: Enabling this option, the paper space will be divided according to the amplitude of signals in each group, in such a way that the maximum amplitude and the minimum interference are achieved. Disabling this option, the paper space will be evenly divided between the signals.
- Pace Detect: Available options are Off and On. DENA 650 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.
- Paperless: This option is currently inactive.
- Measurement: If you select Global or Details, a measurement table will be printed at the end of recording. For more information, refer to ECG analysis and measurement chapter.

⚠ WARNING

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

Setting Menu

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

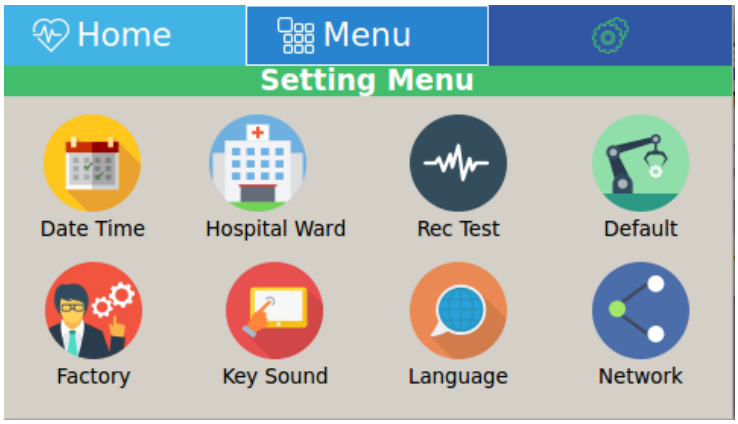


Figure 2-6 Setting menu

The below parameters can be set through this menu:

Date/Time: Press to open menus shown in figure 2-7 and 2-8.
The following parameters can be set in these menus:
Calendar Type: Available options are **Solar** and **Christian**.
Date: To set the date.
Time: To set the time.

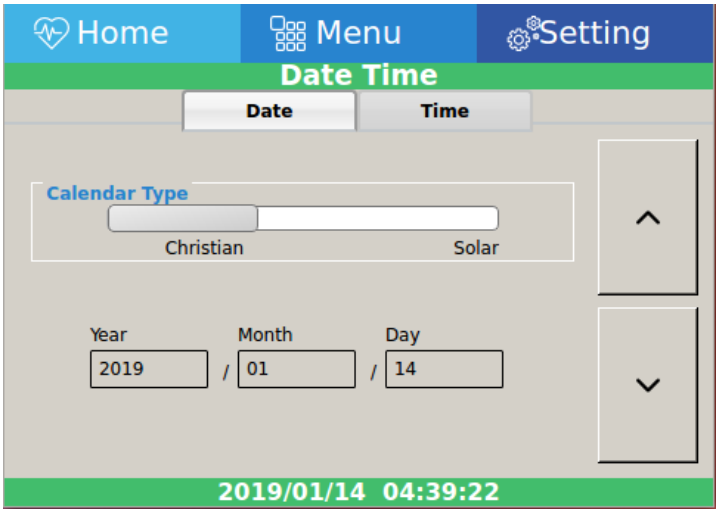


Figure 2-7 Date setting menu

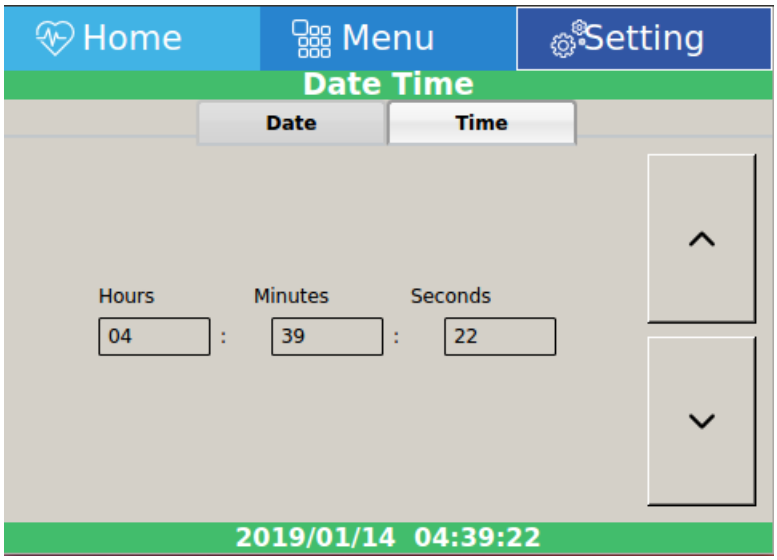
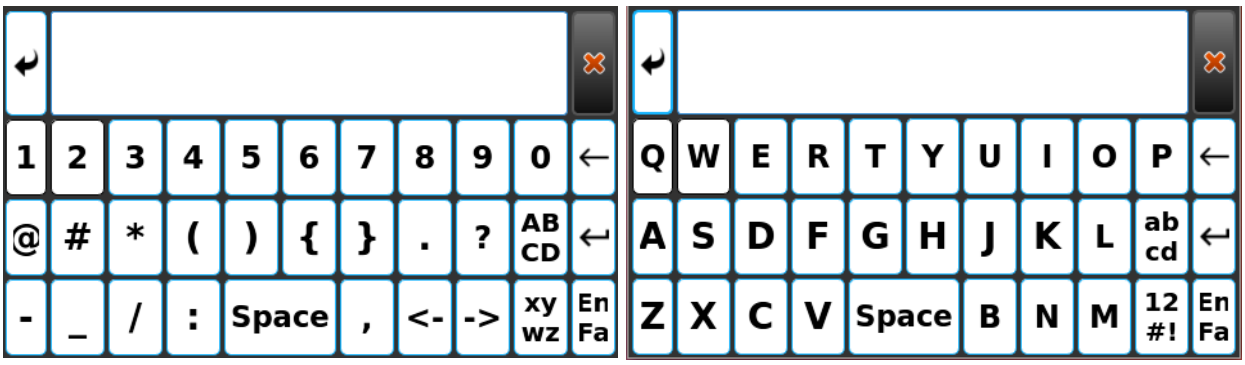


Figure 2-8 Time setting menu

Hospital/Ward: Select this item from the Setting Menu to open the virtual keyboard (figure 2-9) and enter hospital or ward name in the below window.



(a) (b)

Figure 2-9 Virtual keyboard (a) numbers and symbols, (b) characters

Rec Test: Used to test the recorder function. By selecting this option, the following menu is displayed, and the test is done by selecting Start Test

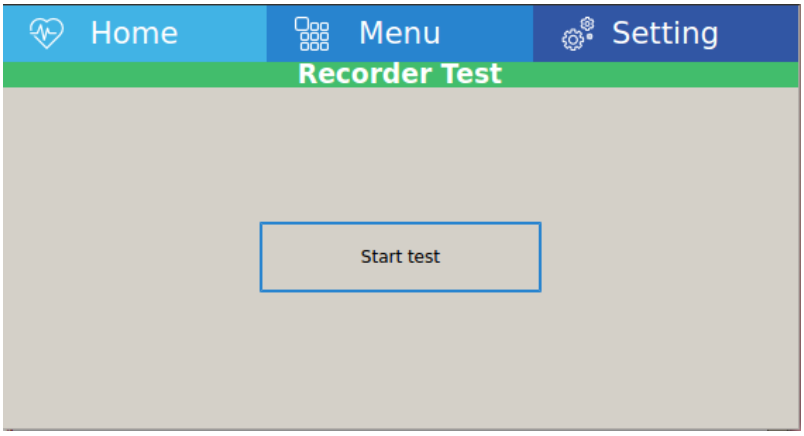


Figure 2-10 Recorder test

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

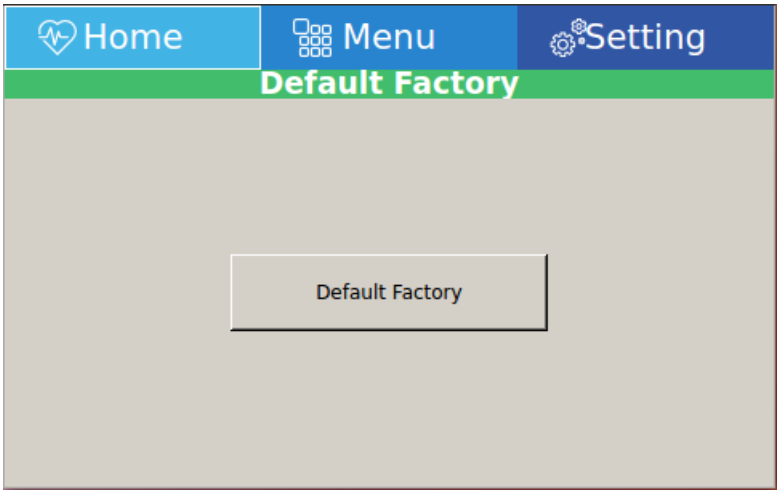


Figure 2-11 Default factory

Factory: Pressing this key opens the virtual keyboard window (Figure 2-9). Screen calibration settings, hardware settings and Demo mode activation will be done in this menu.
The operator does not have access to the options in this menu and only people approved by the manufacturer can apply the necessary settings in this menu.

Key Sound: To switch ON/OFF the sound of touch or hard keys.

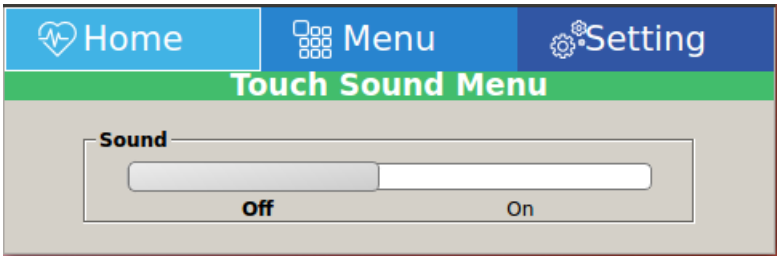


Figure 2-12 Touch sound menu

Language: Available options are **English** and **فارسی**. By selecting any language, all the device menus and entries on the screen change to the same language

Figure 2-13 Language menu

Network: selecting this option, the virtual key board (Figure 2-9) will be opened. The operator does not have access to the options in this menu and only people approved by the manufacturer can enter the necessary settings in this menu by entering the password. Network settings will be made in this menu. This menu consists of three sections: Device, PACS and NTP.

NOTE

- If there is no connection with NTP server, PACS data will not be sent and the message "NTP Error" will be displaye.
- To send the record to the PACS server, the patient ID must be entered correctly. If no ID is entered, a "Patient Error" message is displayed when sending information to the PACS server.
- If connected to a PACS server, each time you press the Start / Stop key, in addition to performing the record, the user will send it to the PACS server if approved.
- By pressing the Copy key, the information will be sent back to the PACS server.
- In both cases above, the message "Send Successful" is displayed if the submission is successful.

About

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

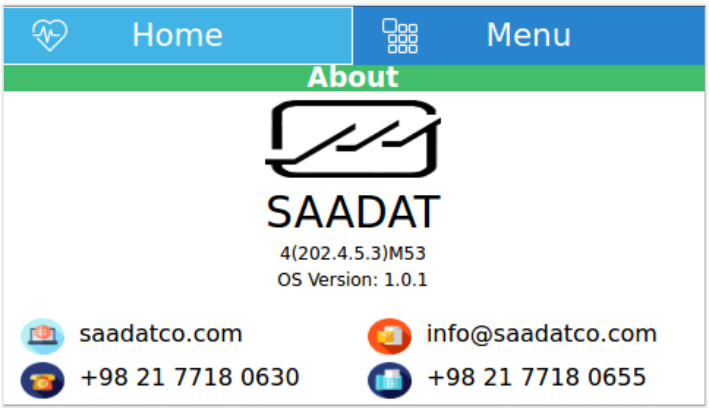


Figure 2-14 About

3) Patient information

Patient Data Entry

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

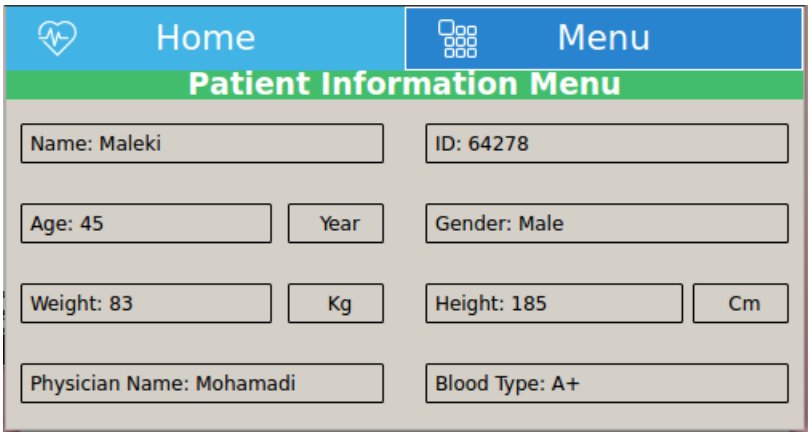


Figure 3-1 Patient information menu

To enter the patient information, select the Patient option. With each selection, a window corresponding to the desired option will open.

- Name: Select this field to enter the patient's name. This opens the virtual keyboard (Figure 2-9). After entering the name, by selecting the Save option, the patient's name is saved and you exit this menu. It should be noted that a maximum of 20 letters can be entered. By selecting the Cancel option, you will enter the previous menu.
- Age: Select this field to enter the patient's age. This opens the virtual keyboard (Figure 2-9). The default unit is Year. The other available option is Mounth. After entering the age, by selecting the Save option, the patient's age is saved and you exit this menu. By selecting the Cancel option, you will enter the previous menu.
- Gender: Select this field to enter the patient's gender. The default value is None and the available options are Female and Male.
- ID: Select this field to enter the patient's ID. This opens the virtual keyboard (Figure 2-9). After entering the ID, by selecting the Save option, the patient's ID is saved and you exit this menu. It should be noted that a maximum of 20 letters can be entered. By selecting the Cancel option, you will enter the previous menu.
- Weight: Select this field to enter the patient's weight. This opens the virtual keyboard (Figure 2-9). The default unit is Kg. The other available option is lb. After entering the weight, by selecting the Save option, the patient's weight is saved and you exit this menu. By selecting the Cancel option, you will enter the previous menu.
- Height: Select this field to enter the patient's height. This opens the virtual keyboard (Figure 2-9). The default unit is cm. The other available option is Foot. After entering the height, by selecting the Save option, the patient's height is saved and you exit this menu. By selecting the Cancel option, you will enter the previous menu.
- Physician Name: Select this field to enter the physician name. This opens the virtual keyboard (Figure 2-9). After entering the physician name, by selecting the Save option, the physician name is saved and you exit this menu. It should be noted that a maximum of 20 letters can be entered. By selecting the Cancel option, you will enter the previous menu.

- Blood Type: By default, the blood type is set to Unknown. Other options are A+, A-, B+, B-, AB+, AB-, O+ and O-.

⚠ WARNING

- Enter patient information correctly. Otherwise, the stored information may be mistaken for other patients' information.
- Information such as age and gender affect the accuracy of the results of the Measurement and Interpretation.

After any changes in Patient information menu, the following window will open to make sure about saving changes.

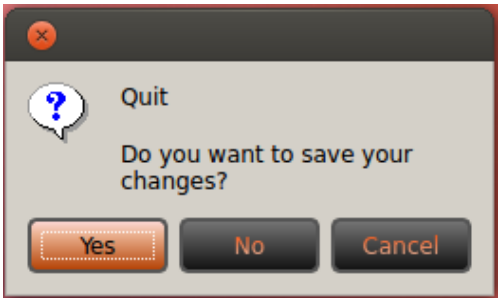


Figure 3-2 Save changes

4) Patient preparation

Actions Before Recording

Before recording the signal, pay attention to the following:

- Give the patient enough time to relax after lying on the bed.
- If necessary, shave the hair where the electrodes are placed on the patient's skin.
- The connection of the electrodes to the skin should be cleaned with alcohol or a solution of soap and water and then dried.
- Use enough gel.
- The ambient temperature should be appropriate and the patient should not suffer from cold and tremors.
- Make all necessary settings on the device before recording.
- During the recording, ask the patient to be as calm and immobile as possible, not to talk, and not to contract their muscles.
- At the beginning / end of recording, or at least at the end of each shift, the accessories, especially the suction chest electrodes and clamp, should be cleaned.

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. (figure 4-1).

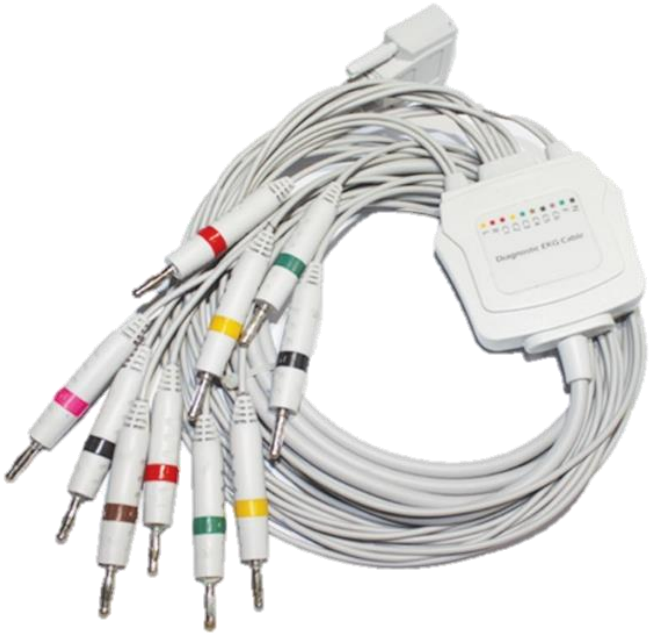


Figure 4-1 ECG cable

⚠ 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.
- Use intact and clean electrodes only. Electrodes with damaged surface may cause ECG waveform inaccuracy.
- Use only the manufacturer recommended ECG cable with internal resistance. Other ECG cables and leads may cause burns, improper performance and/or provide inadequate protection during defibrillation.
- 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.
- Interference from a non-grounded instrument near the patient and/or ESU (Electrosurgical Unit) interference can cause inaccuracy of ECG waveform.
- 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.

Connection of theLimb Electrodes

4 electrodes of 10 ECG electrodes are attached to the limbs.

The location of the limb electrodes for the 12-lead ECG is as follows:

- Left hand (L)
- Right hand (R)
- Left foot (F)
- Righ foot (N)

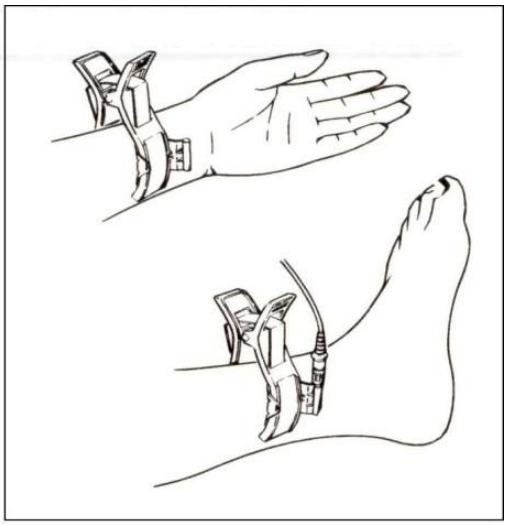


Figure 4-2 Connection of the Limb Electrodes

Connection of the Chest Electrodes

Press the suction bulb and place the chest electrode on proper site (Figure 4-3) and then release.

The location of the chest electrodes is as follows:

- 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 mid-axillary line at the horizontal level of V4

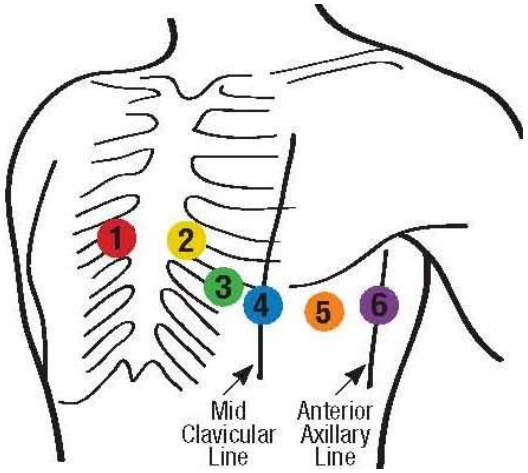


Figure 4-3 Connection of the Chest Electrodes

Detection of electrode disconnection

DENA 650 continuously monitors the connection status of the electrodes, and in the event of a disconnection, displays the relevant messages at the location of the signals on the screen (Figure 1-2).

- If any of the R, L, or F electrodes are disconnected, the messages Check R, Check L, and Check F are displayed.
- If any of the chest electrodes are disconnected, the message Check Cx is displayed (x from 1 to 6).
- If the N electrode is disconnected, one or more disconnection messages may be displayed.

NOTE

- Refer to Troubleshooting and Error messages chapter to view device messages.

Color codes and Labels of 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

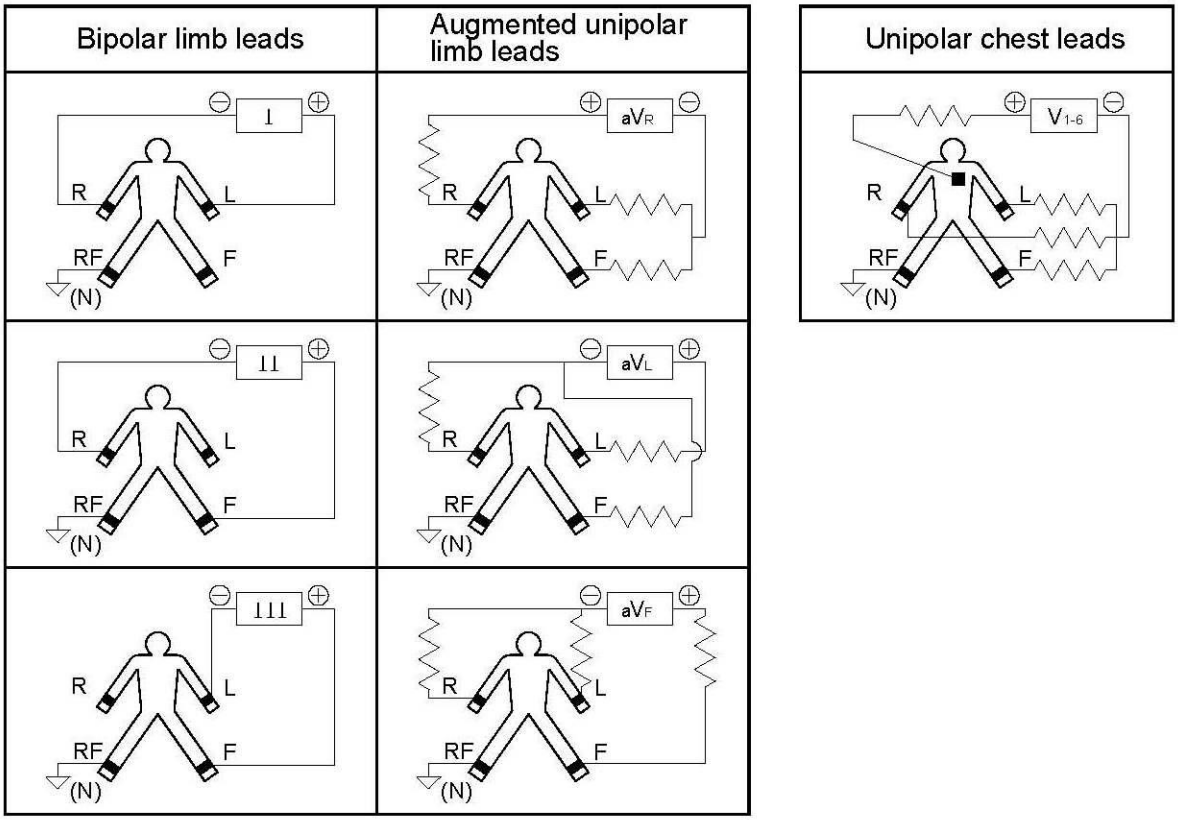


Figure 4-4 Lead placement digram

5) Recording Operation

NTOE

- See the System settings chapter to view the recording settings.

Recording Types

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:** In this mode, a selected lead and a Rhythm lead will be recorded.
  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:** In this mode, 3 selected leads will be recorded.
- **Manual 3+1:** In this mode, 3 selected leads and a Rhythm lead will be recorded.
  In the recording paper, the first 3 waveforms indicate the waveform of selected leads and the last one is the waveform of selected Rhythm lead.
- **Manual 6:** In this mode, 6 selected leads will be recorded.

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.

By pressing Start/Stop key on the control panel, recording starts and ends after 3 to 12 seconds based on selected option.
It is not possible to toggle between different leads using ▲**Lead** and **Lead**▼ keys.

- **Auto 1+1:** In this mode, a Rhythm lead will be recorded along with the other leads (individually).
  In the recording paper the first waveform indicates the selected lead and the second one is the waveform of Rhythm lead.
- **Auto 3:** In this mode, the leads will be recorded in groups of three.
- **Auto 3+1:** In this mode, a Rhythm lead will be recorded along with the other leads (in groups of three).
  In the recording paper the first three waveforms indicate the selected leads and the other one is the waveform of Rhythm lead.
- **Auto 6:** In this mode, the leads will be recorded in groups of six.

Rhythm Recording

Select **Rhythm** using the **Mode** key on the screen or control panel to see the ECG waveform of the Rhythm lead in four traces. Press Start/Stop key to record according to “Length of Rhythm Rec”.
In this mode, there are always six channels of recording on the paper.

NOTE

- In all Manual recording types, press **▲Lead** and **Lead▼** keys to switch lead (lead group) during the recording.
- In Manual recording types, after the recording starts, the recording stops just by pressing the "Start / Stop" key again.
- Copy key is used to retrieve the last record (except manual types). By turning the device on and off due to the lack of a previous record, the information cannot be copied.

Periodic Recording

To perform periodic recording:
1- Enter the “Recorder setting menu”, and select the desired time interval (5-60 min) for “Periodic Rec. Interval”.
2- Select number of recording repetitions. Available options are “infinite” and 1-20.
3- The recording type in this case is similar to other types of recording and is determined using the Print Mode menu.

NOTE

- In this case, the recording is always done according to the latest settings of the device.
- You can also perform Automatic, Manual and Rhythm recordings during Periodic recording. For this purpose:

  1- select the recording mode and desired settings.

  2- Press the Start/Stop key.

  After the recording in the selected mode is finished, Periodic recording will be continued automatically.
- If the device is set on Manual modes and the Periodic mode is active, the device records the equivalent Automatic mode. For example, the device considers the Manual 3+1 as Auto 3+1.
- It is possible to copy the stored information only in Auto and Rhythm modes (since recording in periodic mode is also done in automatic mode, it is also possible to copy in this mode).
- In all recording types and at any stage of recording, it ends by pressing the Start/Stop key.

6) ECG analysis and measurement

General information

In order to automatically analyze the ECG signal, the analysis and interpretation software of the University of Glasgow (The Glasgow Program) has been added to DENA 650. This software helps in more accurate diagnosis of the disease in two parts: Measurement and Interpretation. The Measurement section measures and reports the important parameters of the ECG signal and the Interpretation section uses the results of the Measurement section to diagnose the disease.
For best results, the physician must enter the patient's gender and age. It should be noted that the Glasgow software analyzes and interprets 10 seconds of the ECG signal.

Reported parameters in Global mode

In Global mode, reported signal specifications, are not dependent on individual ECG leads and are generally calculated for the ECG signal.

Table 6-1 Reported parameters in Global

ECG parameters	Description
P Duration [ms]	Time interval from the beginning to the end of the P wave
PR Interval [ms]	Time interval from the beginning of the P wave to the beginning of the Q wave
QRS Duration [ms]	Time interval from the beginning of the Q wave to the end of the S wave
RR Interval [ms]	Average time interval between two consecutive R peaks
QT Interval [ms]	Time interval from the beginning of the Q wave to the end of the T wave
QTc Interval [ms]	Normalized QT based on RR Intervals
T Duration [ms]	Time interval from the beginning to the end of the T wave
ST Duration [ms]	Time interval from the beginning to the end of the ST segment
P/QRS/T/ST Axis [degree]	Heart Axis

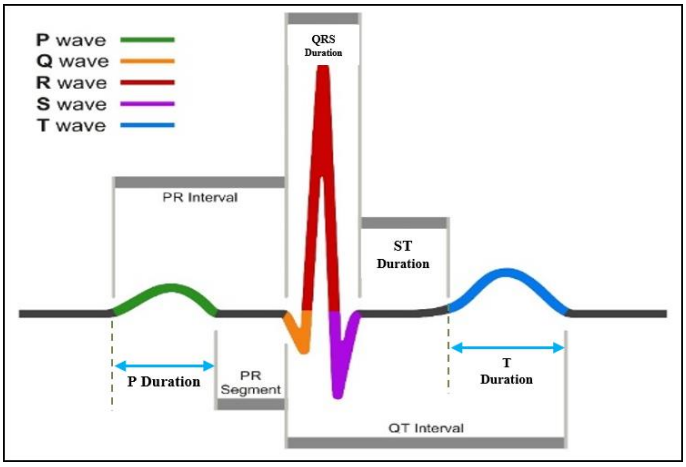


Figure 6-1 Signal parameters in Global

Heart Axis

The cardiac vector (Heart axis) is the average sum of the electrical forces inside the heart, or in other words, the angle of the result of the vector of the heart's electrical activity.
The electric vector can be calculated for P, QRS and T waves.
Among cardiac angles, the QRS axis has the most clinical use and is easily calculated. Leads I, II and III or aVF, aVL and aVR leads can be used to calculate the QRS axis. Each of these leads shows the electrical activity of the heart in a specific direction. The normal cardiac vector is in the range of -30 to +90 degrees. The following figure shows the angles corresponding to each lead.

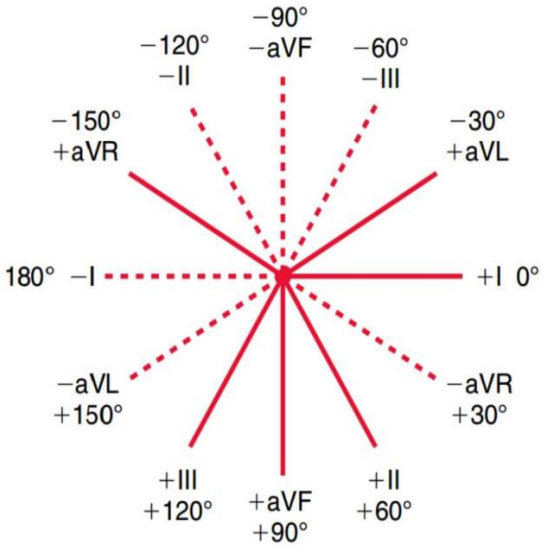


Figure 6-2 Heart angles related to different leads

QTc Parameter

The QT Interval is from the beginning of the QRS to the end of the T wave, which indicates the duration of ventricular depolarization and repolarization.
Since QT is affected by heart rate, it needs to be corrected and normalized to the heart rate (normalizing QT means eliminating its dependence on HR). For example, increasing HR reduces QT, and this dependence needs to be removed to make a diagnostic comparison with the normal range.
In order to normalize the QT parameter, the following equations are used:

$$QTc = \frac{QT}{\sqrt{RR}} \quad ، \quad RR = \frac{60}{HR}\ [sec]$$

Reported parameters in Details mode

In this mode, the details of 12 leads are reported in addition to the Global mode. These details are given in table 6-2.

Table 6-2 Reported parameters in Details

ECG parameters	Description
P Dur [ms]	Time interval from the beginning to the end of the P wave
QRS Dur [ms]	Time interval from the beginning of the Q wave to the end of the S wave
T Dur [ms]	Time interval from the beginning to the end of the T wave
ST Dur [ms]	Time interval from the beginning to the end of the ST segment
PR Int [ms]	Time interval from the beginning of the P wave to the end of the Q wave
QT Int [ms]	Time interval from the beginning of the Q wave to the end of the T wave
QTc Int [ms]	Normalized QT based on RR intervals
Q Dur [ms]	Time interval from the beginning to the end of the Q wave
R Dur [ms]	Time interval from the beginning to the end of the R wave
S Dur [ms]	Time interval from the beginning to the end of the S wave
R' Dur [ms]	Time interval from the beginning to the end of the secondary R wave
S' Dur [ms]	Time interval from the beginning to the end of the secondary S wave
P+ Amp [µV]	Amplitude of ascending edge of P wave
P- Amp [µV]	Amplitude of descending edge of P wave
Q Amp [µV]	Amplitude of Q wave
R Amp [µV]	Amplitude of R wave
S Amp [µV]	Amplitude of S wave
R' Amp [µV]	Amplitude of secondary Rwave
S' Amp [µV]	Amplitude of secondary S wave
P2P Amp [µV]	Amplitude of QRS complex
T+ Amp [µV]	Amplitude of ascending edge of T wave
T- Amp [µV]	Amplitude of descending edge of T wave
ST Amp [µV]	Amplitude of ST parameter
ST Mid Amp [µV]	Amplitude of ST parameter in the middle of ST segment
ST Slope [deg]	Slope of ST segment
P/QRS/T/ST Axis [degree]	Heart Axis

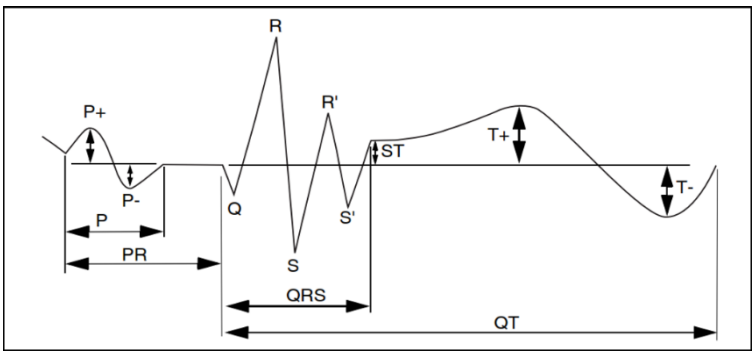


Figure 6-3 Signal parameters in Details

By selecting one of the two modes Global or Detail and recording the results, it will be printed as a table at the end of the record paper. The difference between Global and Detail modes is in the detailed expression of the ECG signal parameters (Measurement section) and the results of the Interpretation section are exactly the same in both cases.

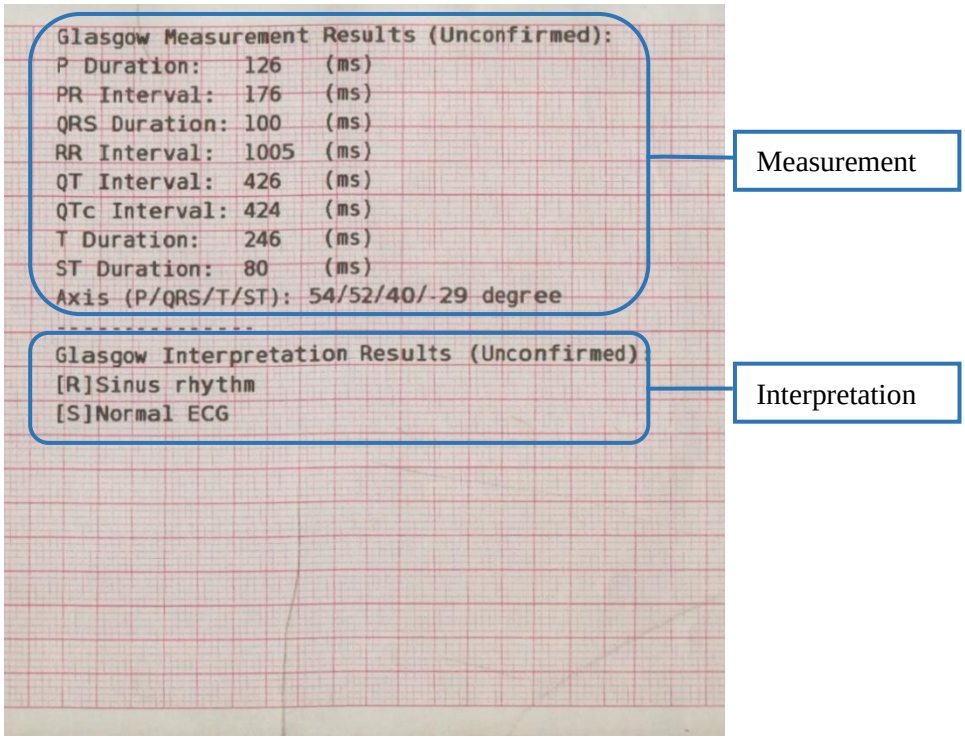


Figure 6-4 Reported parameters in Global

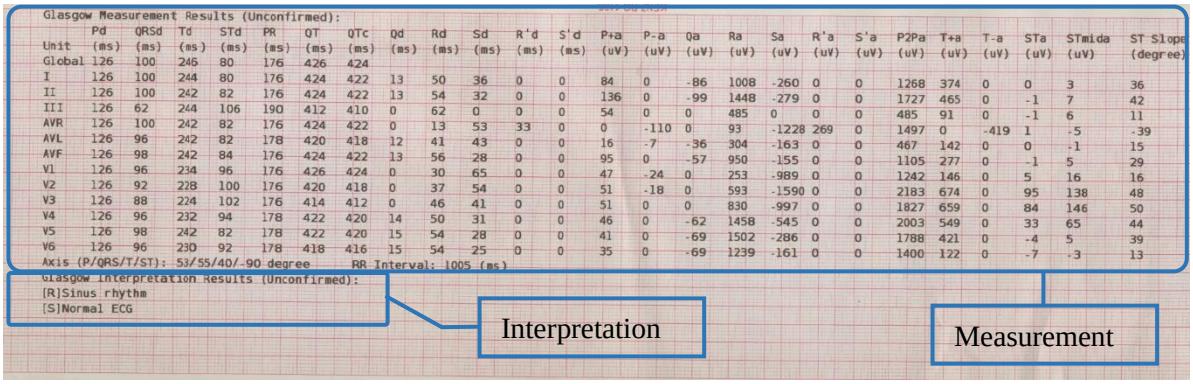


Figure 6-5 Reported parameters in Details

Each Interpretation phrase begins with a special letter that indicates the following:
{H}: Indicates the title of report and is written in first line.
{R}: Corresponds the rhythm interpretation.
{D}: Indicates the details of the signal analysis and identifies the diagnostic terms.
{S}: Shows a summary of the signal analysis status.

NOTE

- **The Measurement results are calculated using raw signal (unfiltered) recorded from the patient, and may differ slightly from the measurements made from the recorded signals.**
- The measurement table is printed at the end of recording, only in Automatic and Sync recording.
- The units for time parameters and amplitude parameters, are millisecond [ms] and microvolt [µV], respectively.
- Glasgow Analysis Software is merely a diagnostic aid software, and for treatment measures, it is essential that the specialist doctor make a definite statement about the patient's condition.
- The specific code of the expressions is reported according to the type of signal and the presence of cardiac abnormalities, and in some cases, not all of the codes mentioned in the interpretation results may be present. For example, if STEMI is detected, the corresponding expression is reported to the user with the code {H}, while for a normal signal, none of the expressions begin with the specific code {H}.
- For more information, refer to Appendix 4 The GLASGOW program.

7) Data management

General information

All ECG recorded data in Auto and Rhythm modes, as weel as Periodic recordings, will be stored in the internal memory of DENA 650 for future reference. For this purpose, the Save option in User settings menu should be Enable. In case of disabling the Save option no data is saved in the Archive.

Up to 100 records can be stored in the internal memory. When the memory is full the new data will overwrite the oldest data.

Transferring the saved data is possible through the Export menu using a flash memory.

NOTE

- Signal storage is always done as Sync.

Archive Menu

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

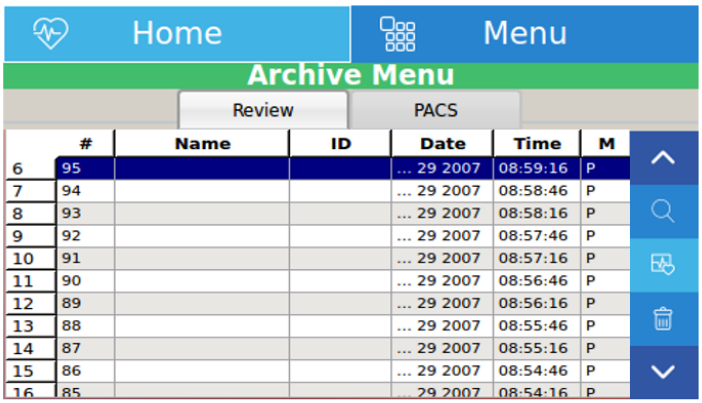


Figure 7-1 Archive menu

Entering the Archive menu displays the properties of all stored signals in two sections.
The following information about each saved record can be seen in the Review tab:

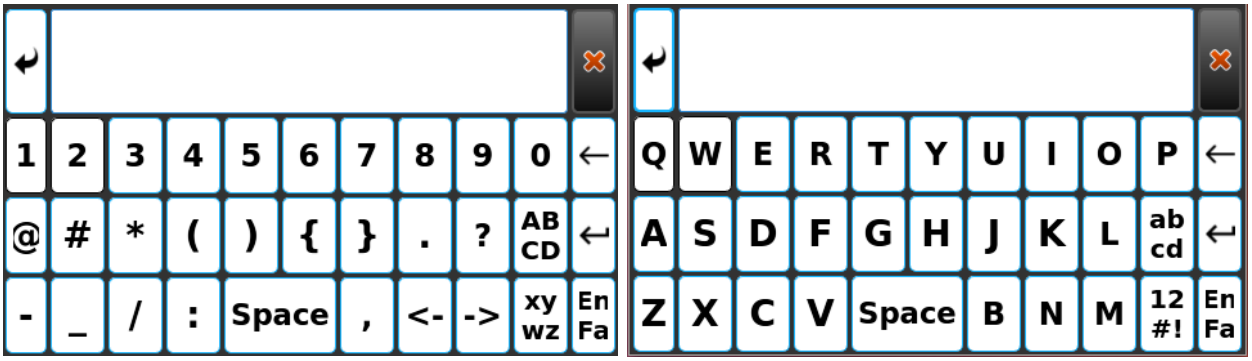
- Assigned code by the system
- Patient's name (if any)
- Patient's ID (if any)
- Date/Time of recording
- Recording mode: "**R**" indicates Rhythm mode and "**P**" indicates Periodic mode. "**PR**" indicates both Rhythm and Periodic modes.

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

Press or to move to the previous or next record

Swipe up and down to access the previous and next pages.

Search: Enter patient name/ID in on-screen keyboard (figure 7-2) and press Search to view all stored data for the patient.



(a) (b)

Figure 7-2 Virtual keyboard (a) numbers and symbols, (b) characters

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

Figure 7-3 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 Yes, the record will be deleted and by selecting No, you will return to the Archive menu.

Review: Press to observe the information of highlighted record. 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.

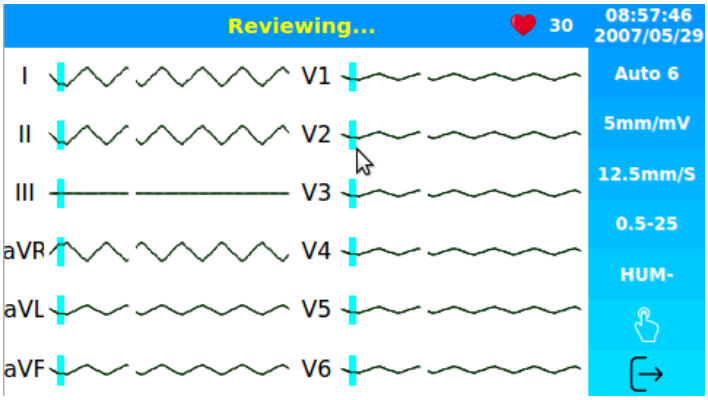


Figure 7-4 Review window

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

NOTE

- The information in this window is related to the recording time.
- Touch keys are disabled in this window. You can only return to the Archive menu with the key.
- The phrase "Reviewing…" appears in the top bar.
- Press Start/Stop key to print the stored ECG signals in the same condition as the recording time.

In the PACS tab, the user can select the saved records and if the connection to the server is established, send them by touching the button. If there is no connection, the records will be saved in this section and after establishing the connection, the user can send the desired items.

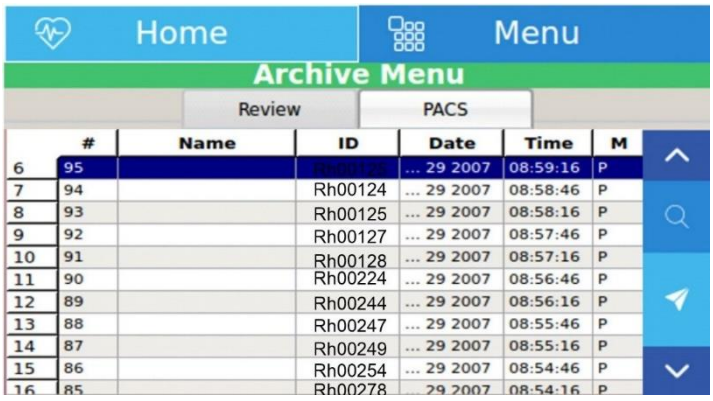


Figure 7-5 PACS window

NOTE

- Only records whose ID field has a value will be displayed in this window.
- To save the records that are recorded, the Save option in the User Settings menu must be Enabled.
- It is possible to select one or more records and send them at once in this menu.
- Pay attention to the notes inserted in the Export Menu section.

Export Menu

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

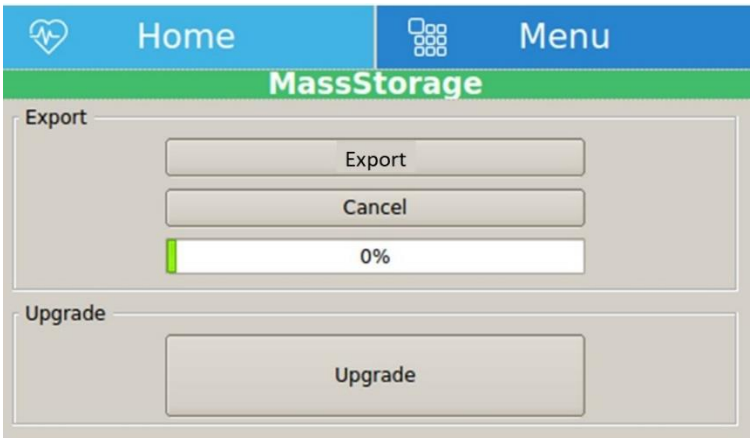


Figure 7-6 Export menu

Connect flash memory to the system and select Export button to export all saved records in the system.

When progress bar reaches 100%, data is exported completely.

By selecting Export while the flash memory is not connected to the system, the message “USB not detected!” will appear.

If the export procedure is done successfully, “Exported successfully” will appear on the screen.

NOTE

- It is necessary to exit from the Export menu, before ejecting the flash memory.
- This item is used by trained and authorized personnel of the manufacturer to upgrade the software to the latest version.
- PACS and NTP windows information will be reset by software updates, and re-settings must be performed under the supervision of a person approved by the manufacturer.

Online data transfer to PC

DENA 650 has the ability to transfer the information of the signals being drawn on the screen to a personal computer via a Device USB port. For this purpose, the request to install the said port must be notified to the manufacturer. After installing the port and installing the relevant software on the personal computer, by connecting the port to the computer via a USB cable, it is possible to transfer data online. When installing this software, a quick user guide and software installation guide and user guide will be delivered to the user. This software also has the ability to display files that have been transferred to flash memory via the Export option. After displaying the files, it is also possible to make a hard copy and save the transferred information to the personal computer.

Figure 7-7 ECG Viewer software

8) Care and Cleaning

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.

WARNING

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

NOTE

- To ensure maximum battery life, let the DENA 650 runs on the battery, at least once a month, until it turns itself off and then recharge the battery.
- If you find any damage in DENA 650, 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.

Maintenance

NOTE

- It is recommended that the device be calibrated once a year by the manufacturer, but calibration is mandatory every 2 years.
- The life of the device is 10 years.
- The hospital can also request a calibration whenever the accuracy of the device is in doubt.

It is recommended that the following be checked daily:

- Accessory physical health
- Accessory function

It is recommended that the following be checked weekly:

- Cleanliness of the device
- Physical health of the device (body, screen, keys, indicators, door and recorder key)
- Recorder performance

It is recommended to check the following on a monthly basis:

- Calibration label control (the device should be sent to the manufacturer on the date specified for calibration)
- Physical health of the device
- Cleanliness of the device
- Function of device keys and indicators
- Accessory physical health
- Recorder performance

Cleaning & Disinfection

Use only the substances approved by us and methods listed in this chapter to clean or disinfect your equipment.
Manufacturer makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's Infection Control Officer or Epidemiologist. See also any local policies that apply within your hospital.

WARNING

- Before cleaning the electrocardiograph or the accessories, make sure that the equipment is switched off and disconnected from the power line.
- Sterilization may cause damage to ECG device and is therefore not recommended for this device otherwise indicated in the instructions delivered with accessories or your hospital's maintenance schedule.
- If you see any signs of damage or deterioration in the device and its accessories, do not use it, and if necessary, contact the After-sales service.
- Allow the device to dry completely before making connections. Make sure all connections are secure before using the system.

NOTE

1- DENA 650 and accessories should be kept away from dust.
2- Do not use detergents that contain ammonia or acetone.
3- Most cleaning agents must be diluted before use.
4- Don't use rough or sharp material or your fingernail to remove stubborn stains.
5- Do not let the cleaning agent enters into the chassis of the system.
6- Do not leave the cleaning agents on any part of the equipment.

WARNING

- Do not use ETO gas to disinfect DENA 650.

External surfaces of the device

In-between patients and as required, wipe gently using a moist cloth and warm soapy water or mild detergent to clean the device and also recommended to use 70% alcohol or Isopropyl alcohol or N-propanol for its disinfection

Display screen

In-between patients and as required use clean and soft cloth with screen cleaner or mild soapy water and with Isopropyl alcohol may be used for cleaning and disinfection.

NOTE

- Take extra care when cleaning the screen of the monitor because it is more sensitive to rough cleaning methods than the housing.
- Avoid direct spray of a liquid on the screen.

Recorder

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

WARNING

- Do not clean the recorder immediately after recording due to overheating of the head and the surrounding environment.

Accessories

Refer to the accompanying instructions for cleaning, disinfecting, and sterilizing reusable accessories such as cables, leads, electrodes, etc.

Also, the trolley of the device (if any) should be cleaned and disinfected after each patient or, if necessary, using a soft, clean cloth soaked in soap and water and, if necessary, with isopropyl alcohol, and then wiped dryed with a cloth.

WARNING

- Do not immerse any part of the Dena electrocardiograph in any fluids.
- Disposable accessories shall not be sterilized or reused.
- To prevent environmental pollution, the disposal of single-use accessories shall be done in accordance with the policies of the hospital.

The following table summarizes the methods of cleaning, disinfecting and sterilizing the various parts of the device:

<table>
<tr><th>Device parts</th><th>Single-use</th><th>Cleaning</th><th>Disinfection</th><th>Sterilization</th></tr>
<tr><td>External surface of device</td><td>-</td><td rowspan="2">In-between patients and as required wipe gently using a moist cloth and warm soapy water or mild detergent.</td><td>In-between patients and as required use
■ Alcohol 70%
■ Isopropyl alcohol
■ N-propanol</td><td rowspan="4">To avoid extended damage to the equipment, sterilization is not recommended for this device, related products, accessories or supplies unless otherwise indicated in the Instructions for Use that accompany the accessories and supplies or when stipulated as necessary in the Hospital Maintenance Schedule.</td></tr>
<tr><td>Trolley</td><td>-</td><td rowspan="2">In-between patients and as required use
■ Isopropyl alcohol</td></tr>
<tr><td>Display screen</td><td>-</td><td>In-between patients and as required:
Clean and soft cloth with screen cleaner or mild soapy water</td></tr>
<tr><td>Recorder (printhead)</td><td>-</td><td>as required:
1.Gently wipe around the printhead using cotton swabs dampened with alcohol.

2.After the alcohol has completely been dried, reload the paper and close the recorder door.</td><td>use as required
■ Isopropyl alcohol</td></tr>
<tr><td>ECG Accessory
(Cables, lead wires, Electrodes)</td><td>disposable electrodes</td><td colspan="3">According to the instructions delivered with the reusable accessories
To clean, disinfect and sterilize reusable accessories, refer to the instructions delivered with them.</td></tr>
</table>

Preventive Maintenance (PM) checklist

The preventive maintenance (PM) checklist #PL-F-33 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.

Pooyandegan Rah Saadat Co.					
Form No. : PL-F-33-V1		**PM Form (DENA 650 Electrocardiograph)**			
State:	**City:**	**Healthcare center:**	**Ward:**		
Device model:	**Serial number:**	**Installation date:**	**Inspection date:**		
No.	**Test and Inspection Item**		**OK**	**Not OK**	**N/A**
1	**Visual inspection**	**No damage or breakage in the case**			
2		**Correct function of the touch screen**			
3		**Correct function of the keyboard**			
4		**Cleaning and disinfection according to the user manual**			
5	**Display screen**	**Correct display of Waveform area and information**			
6	**Battery**	**Unplugging the system (check the battery function)**			
7		**Periodic usage of the battery**			
8	**Saving date& time settings**				
9	**Saving system settings**				
10	**Accessories**	**Check ECG cable (clamps, leadwires, trunk)**			
11		**Check ECG clip clamp and suction bulb (visual and sulfation test)**			
12		**Cleaning and disinfection according to the user manual**			
13	**Recorder**	**Correct function of the recorder**			
14		**Appropriate size of the recorder paper**			
15		**Check the eject key function on the recorder door**			
16		**Check the paper holder**			
17		**Check the recorder thermal head**			
18		**Check the recorder error messages**			
19	**Review**	**Check Review window periodically**			
Final result: Pass □ Fail □					
Expert recommendation:					
Name and signature of person in charge: **Name and signature of expert:**					

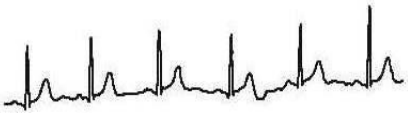
9) Troubleshooting and Error messages

Troubleshooting

Repairing the internal parts of DENA 650 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 DENA 650 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 to the device. ● Check ECG cable connection to the electrodes. ● Check ECG cable connection to the patient. ● 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 ● After connecting the electrodes and before recording, wait for a few moments.	● Check the leads and electrodes. ● Make sure the patient is relaxed and immobile. ● Pay attention to the following points (related to signal quality) ● 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 prepared. ● Abnormal patient breathing	●Use the same electrodes. ●Check connection of electrodes to lead wires. ● Check proper placement of electrodes. ● Clean electrodes after each use. ● Apply sufficient gel. ● perform actions before recording (Patient preparation chapter). ● Relax patient in a comfortable position. ● Press Reset key. ● If the problem still persists, use Drift filter.
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. ● Patient's limbs are not placed properly. ● Bed dimensions are not suitable for comfortable placement of patient hands and feet. ● Limb electrodes are attached tightly.	● Relax the patient. ● Warm the patient with a suitable blanket. ● Check electrodes connection. ●If the problem persists, use Lowpass or EMG 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. ● Improper HUM filter. ● Improper Earth system.	● Check electrodes and lead wires connection. ● Check that lead wires are not tangled or connected to ground. ● Check that the patient does not contact the metal parts. ● Check that patient cable and power cable have no contact. ● Turn on the HUM Filter. ● If the problem persists, unplug the power cable (the device runs on the battery). ● 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.

Error messages

Message	Cause	Solution	Remarks
Leads Error Messages			
CHECK R	Lead R 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 L	Lead L 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 F	Lead F 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	Recorder 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 or the paper is not exited from the recorder.	Check the paper placement or insert a new paper roll into the recorder.	The message blinks in yellow color on the screen.
Head High Temp	The Print head is too hot.	Stop operation for a few minutes.	The message blinks in yellow color on the screen.
Head High 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,	The message blinks in yellow color on the screen.

Message	Cause	Solution	Remarks
		contact the manufacturer's After Sales Service.	
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 please 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.

10) Technical specification

CLASSIFICATION	
Protection against electroshock	**Class I, Type CF , defibrillation-proof applied part**
Mode of operation	**Continuous operation equipment**
Harmful Liquid Proof Degree	**Ordinary equipment, (without Liquid Proof)**
Method of sterilization and disinfection	**Refer to Care and cleaning chapter for detail.**
Safety in presence 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, 5''**
Resolution	**480 × 272**
Waveforms	**12 Lead ECG/Rhythm Lead**
Numeric Parameters	**HR**
Operation Method	**Membrane Keys and Touch**
Displayed data	**Waveforms, Patinet Information (Name and ID), Data & Time, Recording Speed, Sensitivity, Operation Mode, Filter, HR Value, Message**
ECG	
Input Channel	**Simultaneous acquisition of all 12 leads/ Rhythm Lead**
Standard leads acquired	**I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6**
Sensitivity Selection	**2.5, 5, 10, 20 mm/mV , Auto**
Filters	**Drift: on or off**
	HUM: on or off
	Low pass: 25, 35, 75, 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	**0.05~150 Hz**
Pace	**Detection & Rejection: 0.1~2 ms, ±2~±250 mV** **Indication : 0.5~2 ms, ±2~±250 mV**
Protection	**Defibrillator**
Standards	**IEC 60601-2-25**

ECG Storage		
Internal Memory	**Up to 100 Records**	
Recorder		
Model	**SAADAT Thermal Printer**	
Print Method	**Thermal dot line printing**	
Dots per line	**832 dots**	
Resolution	**16 dots/mm (Horizontal) @ 25 mm/sec**	
	8 dots/mm (Vertical)	
Printing Speed	**6.25, 12.5, 25, 50 mm/s**	
Paper Width	**110mm**	
Print Width	**104mm**	
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	**Type**	**Auto, Manual, Rhythm**
	State	**Sync, Realtime**
	Format	**1+1, 3, 3+1, 6**
	Status	**Normal, Periodic, Copy, Review**
GENERAL		
Safety	**Class I (Based on IEC60601-1)**	
Protection	**Against Defibrillator**	
AC Power	**100-240 VAC, 60VA 50/60 Hz**	
Internal Rechargeable Battery	**Lithium Polymer, 11.1V, 4.3Ah** **Charge time: ~ 6 h** **Usage (New & Full Charged): ~ 8 h or 100 records** **or** **Lithium-Ion, 11.1V, 3.35Ah** **Charge time: ~ 5 h** **Usage (New & Full Charged): ~ 7 h or 80 records** **or** **Lithium-Ion, 11.1V, 2.2Ah** **Charge time: ~ 5 h** **Usage (New & Full Charged): ~ 5 h or 60 records**	
Dimension	**290mm (W) x 70mm (H) x 350mm (L)**	
Weight	**2.5 Kg (with battery)**	
Environment		
Temperature	**Operating: 5~40 °C**	
	Storage: -25~60 °C	
Humidity	**20~90 % (Non condensing)**	
Altitude	**-200~3500 m**	

Appendix 1: Accessories

⚠ WARNING

- The accessories listed below are specified to be used for DENA 650. Manufacturer does not take responsibility for any possible hazard to the patient or device if other accessories are used.
- Use only the manufacturer recommended ECG cable. Other ECG cables and leads may cause improper device performance, patient injury and inadequate protection during defibrillation.

Accessories

Accessories	Part #
Diagnostic EKG Cable,10 wires, Launch, Ref 60101010	P28041
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 (SAADAT)	P28078
ECG GEL	P28045
Recorder Paper, 110mm ,Roll	P28026
Trolley	P09248

Appendix 2: system parameters

ITEM	SELECTION	DEFAULT
Patient Information Menu		
Name		Blank
ID		Blank
Age	Year/Month	Year
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
Recording Mode		
Rec. Types	Auto, Manual, Rhythm	Auto
Rec. Status	Normal, Copy, Review, Periodic	Normal
Auto / Manual		
Formats	1+1, 3, 3+1, 6	6
Rec State (Auto)	Sync/ Real Time	Sync
Header	ON/ OFF	ON
Rhythm Lead	I, II, III, aVR, aVL, aVF, 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, aVR, aVL, aVF, 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, Auto	10
Paper Speed	6.25, 12.5, 25, 50	25
Filter Setting Menu		
LowPass 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: On Drift Filter: On EMG Filter: On

ITEM	SELECTION	DEFAULT
F2	Low Pass Filter, HUM Filter, Drift Filter, EMG Filter	Low Pass Filter: 25 Hz HUM Filter: On Drift Filter: On EMG Filter: Off
F3	Low Pass Filter, HUM Filter, Drift Filter, EMG Filter	Low Pass Filter: 35 Hz HUM Filter: On 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	Enable
Pace Detect	Enable/ Disable	Disable
Measurement	Global/Details/Disable	Disable
Smart Record	Enable/ Disable	Disable
Setting Menu		
Date & Time	Date, Time	
Hospital Ward	Ward	Blank
Rec Test	Testing Recorder	
Default	Default Factory	
Key & Touch Sound	ON/ OFF	OFF
Language	English /فارسی	English
Date & Time		
Date	Clender Type (Christian, Solar) Year, Month, Day, Cursor up, Cursor down	-
Time	Hour, Minute, Second Cursor up, Cursor down	-

Appendix 3: Electro-magnetic compliance

⚠ 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.
- Measurements can be affected by mobile and RF communications equipment. It should be assured that DENA 650 is used in the electromagnetic environment specified.
- To prevent EMC effect on DENA 650, 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.
- Do not use cellular phone in the vicinity of this equipment. High result in strong level of electromagnetic radiation emitted from such devices may interfere with DENA 650 performance.

Guidance and manufacturer's declaration – electromagnetic emissions		
The DENA 650 is intended for use in the electromagnetic environment specified below. The customer or the user of the DENA 650 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The DENA 650 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 DENA 650 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 DENA 650 electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the DENA 650 electrocardiograph should assure that it is used in such an environment.

Immunity test	Port	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Enclosure	±8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	electrocardiograph coupling		
	Signal input/output parts		
Electrical fast transient/burst IEC 61000-4-4	Input a.c. power	± 2 kV, 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
	Signal input/output parts	± 1 kV 100 kHz repetition frequency	
Surge IEC 61000-4-5	Input a.c. power	± 0,5 kV, ± 1 kV Line-to-line ± 0,5 kV, ± 1 kV, ± 2 kV Line-to-ground	Mains power quality should be that of a typical commercial or hospital environment.
	Signal input/output parts	± 2 kV Line-to ground	
Voltage dips, IEC 61000-4-11	Input a.c. power	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	
		0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	
Voltage interruptions IEC 61000-4-11	Input a.c. power	0 % U_T; 250/300 cycle	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	Enclosure	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The DENA 650 electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the DENA 650 electrocardiograph should assures that it is used in such an environment.			
Immunity test	**Port**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	Input a.c. power Electrocardiograph coupling Signal input/output parts	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 and 80 MHz 80 % AM at 1 kHz	
Radiated RF IEC 61000-4-3	ENCLOSURE	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	ENCLOSURE	Refer to the following table (table 9 of EN 60601-1-2: 2015)	

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment						
Test frequency (MHz)	**Band [a] (MHz)**	**[a] Service**	**[b] Modulation**	**Max power (W)**	**Distance (m)**	**IMMUNITY TEST LEVEL (V/m)**
385	380-390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM C) ±5 KHz deviation 1 KHz sine	2	0.3	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
810 870 930	800-960	GSM800/900, TETRA 800, iDEN 820, CDMA850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28

Appendix 4: The GLASGOW program

ATRIAL ABNORMALITIES

- Possible right atrial abnormality
- Consider left atrial abnormality
- Possible right atrial abnormality consistent with pulmonary disease
- Possible left atrial abnormality
- Possible biatrial enlargement

QRS AXIS DEVIATION

- Indeterminate axis
- Leftward axis
- Left axis deviation
- Marked left axis deviation
- QRS axis leftward for age
- Rightward axis
- Right axis deviation
- Marked right axis deviation
- Left anterior fascicular block
- Possible left anterior fascicular block
- Possible left posterior fascicular block
- Severe right axis deviation

CONDUCTION DEFECTS

- Left bundle branch block
- Incomplete LBBB
- Right bundle branch block
- RBBB with left anterior fascicular block
- RBBB with RAD - possible left posterior fascicular block
- IV conduction defect
- Incomplete RBBB
- rSr'(V1) - probable normal variant

WOLFF-PARKINSON-WHITE PATTERN

- WPW pattern – probable right posteroseptal accessory pathway
- WPW pattern – probable midseptal accessory pathway
- WPW pattern – probable anteroseptal accessory pathway
- WPW pattern – probable right anterolateral accessory pathway
- WPW pattern – probable right posterolateral accessory pathway
- WPW pattern – probable left anterolateral accessory pathway
- WPW pattern – probable left posteroseptal accessory pathway
- WPW pattern – probable left posterolateral accessory pathway

HYPERTROPHY

LEFT VENTRICULAR HYPERTROPHY

- Left ventricular hypertrophy
- Possible left ventricular hypertrophy
- Left ventricular hypertrophy, possible digitalis effect
- Possible left ventricular hypertrophy, possible digitalis effect
- Left ventricular hypertrophy by voltage only
- Borderline high QRS voltage – probable normal variant

RIGHT VENTRICULAR HYPERTROPHY

- Right ventricular hypertrophy
- Possible right ventricular hypertrophy
- Right ventricular hypertrophy, possible digitalis effect
- Possible right ventricular hypertrophy, possible digitalis effect

BIVENTRICULAR HYPERTROPHY

- Biventricular hypertrophy
- Possible biventricular hypertrophy

MYOCARDIAL INFARCTION

INFERIOR INFARCTION STATEMENTS

- *** INFERIOR INFARCT – POSSIBLY ACUTE ***
- Inferior infarct – age undetermined
- Possible inferior infarct – age undetermined
- Small inferior Q waves: infarct cannot be excluded
- Small inferior Q waves noted: probably normal ECG
- Abnormal Q waves of undetermined cause
- Inferior Q waves may be due to cardiomyopathy
- Q waves may be due to cardiomyopathy

LATERAL INFARCTION STATEMENTS

- *** LATERAL INFARCT – POSSIBLY ACUTE ***
- Lateral infarction – age undetermined
- Possible lateral infarction – age undetermined
- Small lateral Q waves noted: probably normal ECG
- Abnormal Q waves of undetermined cause
- Lateral Q waves may be due to cardiomyopathy
- Q waves may be due to cardiomyopathy

ANTEROSEPTAL MYOCARDIAL INFARCTION STATEMENTS

- *** ANTEROSEPTAL INFARCT – POSSIBLY ACUTE ***
- Anteroseptal infarct – age undetermined
- Possible anteroseptal infarct – age undetermined
- Cannot rule out anteroseptal infarct – age undetermined
- Abnormal Q waves of undetermined cause
- Anteroseptal QRS changes may be due to ventricular hypertrophy
- Anteroseptal QRS changes may be due to corrected transposition
- QRS changes may be due to LVH but cannot rule out anteroseptal infarct
- Poor R wave progression – cannot rule out anteroseptal infarct
- Poor R wave progression consistent with pulmonary disease
- Q waves may be due to cardiomyopathy

ANTERIOR MYOCARDIAL INFARCTION STATEMENT

- *** ANTERIOR INFARCT – POSSIBLY ACUTE ***
- Anterior infarct – age undetermined
- Possible anterior infarct – age undetermined
- Cannot rule out anterior infarct – age undetermined
- Abnormal Q waves of undetermined cause
- Anterior QRS changes may be due to ventricular hypertrophy
- Anterior QRS changes may be due to corrected transposition
- QRS changes V3/V4 may be due to LVH but cannot rule out anterior infarct
- Anterior QRS changes are probably related to pulmonary disease
- Poor R wave progression
- Q waves may be due to cardiomyopathy

SEPTAL INFARCTION STATEMENTS

- *** SEPTAL INFARCT – POSSIBLY ACUTE ***
- Cannot rule out septal infarct – age undetermined
- Q in V1/V2 may be normal variant but septal infarct cannot be excluded
- Q in V1/V2 may be due to lead placement error though septal infarct cannot be excluded
- Q in V1/V2 may be due to LVH though septal infarct cannot be excluded
- Abnormal Q waves of undetermined cause
- Septal QRS changes may be due to ventricular hypertrophy
- Septal QRS changes may be due to corrected transposition
- QRS changes in V2 probably due to LVH but cannot rule out septal infarct
- Poor R wave progression – cannot rule out septal infarct
- Poor R wave progression may be due to pulmonary disease
- Q waves may be due to cardiomyopathy

POSTERIOR MYOCARDIAL INFARCTION

- Possible posterior infarct – age undetermined
- Possible posterior extension of infarct
- Tall R V1/V2 probably reflect the infarct

ANTEROLATERAL MYOCARDIAL INFARCTION

- *** ANTEROLATERAL INFARCT – POSSIBLY ACUTE ***
- Anterolateral infarct – age undetermined
- Possible anterolateral infarct – age undetermined
- Abnormal Q waves of undetermined cause
- Q waves may be due to cardiomyopathy

EXTENSIVE MYOCARDIAL INFARCTION

- *** EXTENSIVE INFARCT – POSSIBLY ACUTE ***
- Extensive infarct – age undetermined
- Possible extensive infarct – age undetermined
- Abnormal Q waves of undetermined cause
- Q waves may be due to cardiomyopathy

ST ABNORMALITIES

- Inferior ST elevation
- Lateral ST elevation
- Anteroseptal ST elevation
- Anterior ST elevation
- Septal ST elevation
- Extensive ST elevation
- Anterolateral ST elevation
- Anteroseptal ST depression
- Marked anteroseptal ST depression
- Marked inferior ST depression
- Marked lateral ST depression

MISCELLANEOUS

LOW QRS VOLTAGES

- Low QRS voltages in limb leads
- Low QRS voltages in precordial leads
- Generalized low QRS voltages

TALL T WAVES

- Tall T waves – consider acute ischemia or hyperkalemia
- Tall T waves – consider hyperkalemia

CRITICAL VALUES

- Consider Acute STEMI
- Acute MI/Ischemia
- Extreme Tachycardia
- Extreme Bradycardia
- Significant Arrhythmia
- Prolonged QTc Interval

INTERVALS

- Short PR interval
- Prolonged QT interval
- Short QT interval

DOMINANT RHYTHM STATEMENTS

- Sinus rhythm
- Sinus tachycardia
- Sinus bradycardia
- Sinus arrhythmia
- Sinus tachycardia with sinus arrhythmia
- Sinus bradycardia with sinus arrhythmia
- Atrial tachycardia
- Atrial flutter
- Atrial fibrillation
- Junctional rhythm
- Accelerated junctional rhythm
- Junctional bradycardia
- Atrial pacing
- Ventricular pacing
- A-V sequential pacemaker
- Pacemaker rhythm
- Possible ectopic atrial rhythm
- Possible ectopic atrial tachycardia
- Possible ectopic atrial bradycardia
- Irregular ectopic atrial rhythm
- Irregular ectopic atrial tachycardia
- Irregular ectopic atrial bradycardia
- Probable atrial tachycardia
- Probable sinus tachycardia
- Probable supraventricular tachycardia
- Marked sinus bradycardia
- Probable atrial flutter
- Probable atrial fibrillation
- Probable junctional rhythm
- Probable accelerated junctional rhythm
- Probable ventricular tachycardia
- Wide QRS tachycardia
- Accelerated idioventricular rhythm
- Possible idioventricular rhythm
- Possible atrial flutter
- Possible junctional rhythm
- Possible accelerated junctional rhythm
- Possible junctional bradycardia
- A-V dissociation
- Undetermined rhythm
- Regular supraventricular rhythm
- Irregular supraventricular rhythm

SUPPLEMENTARY RHYTHM STATEMENTS

- with PVC(s)
- with frequent PVCs
- with multifocal PVCs
- with frequent multifocal PVCs
- with interpolated PVC(s)
- with multifocal interpolated PVCs
- with paroxysmal idioventricular rhythm
- with multifocal PVCs
- with multifocal interpolated PVCs
- with frequent multifocal PVCs
- with non-sustained ventricular tachycardia
- with intermittent conduction defect
- with rapid ventricular response
- with uncontrolled ventricular response
- with slow ventricular response
- with PACs
- with frequent PACs
- with 1st degree A-V block
- with borderline 1st degree A-V block
- with 2nd degree A-V block, Mobitz I (Wenckebach)
- with 2nd degree A-V block, Mobitz II
- with 2:1 A-V block
- with 3:1 A-V block
- with 4:1 A-V block
- with high degree A-V block
- with varying 2nd degree A-V block
- with complete A-V block
- with 2nd degree (Mobitz II) SA block
- with bigeminal PACs
- with bigeminal PVCs
- with fusion complexes
- or aberrant ventricular conduction
- Demand atrial pacing
- Demand pacing
- with aberrantly conducted supraventricular complexes
- with unclassified aberrant complexes
- with undetermined ectopic complexes with undetermined irregular