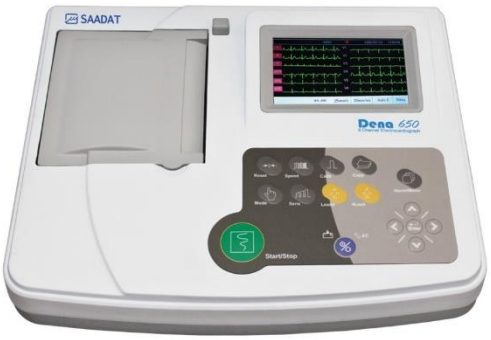
SAADAT Co.

User Manual

Dena

Electrocardiograph

Dena 650



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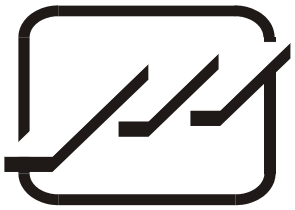

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Manual Purpose

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

Intended Audience

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

Version Information

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

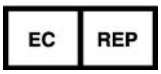
Release date	Version number
Aug 2022	D00150-V8.8

Explanations of the used expressions in this Manual

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

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

Explanations of the symbols in the Manual and device

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

Section 1- General Warnings

Please refer to this section for overall safety information.

1-1 General Warnings:

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

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

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

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

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 location of the device shall be such that when necessary, the plug of the device can be easily disconnected from the electrical outlet.

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

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

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

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.

The electrocardiograph and devices connected to it should form an equipotential body to ensure effective grounding.

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

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.

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

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

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

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

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

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

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

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

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

After the hardware reset, set the lowpass filter to 35Hz, if required.

To perform calibration and standard tests, all the filters must be off.

Section 2- System Configuration

Features:

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

- Displaying 12-lead ECG waveform
- Displaying Rhythm-lead waveform separately on the screen
- 6-channel waveform recording
- Data storage in internal and external memories
- Displaying and printing stored data

Signal recovery accuracy:

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

General

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

Environment:

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

Intended Use

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

System Description

1. Top Panel

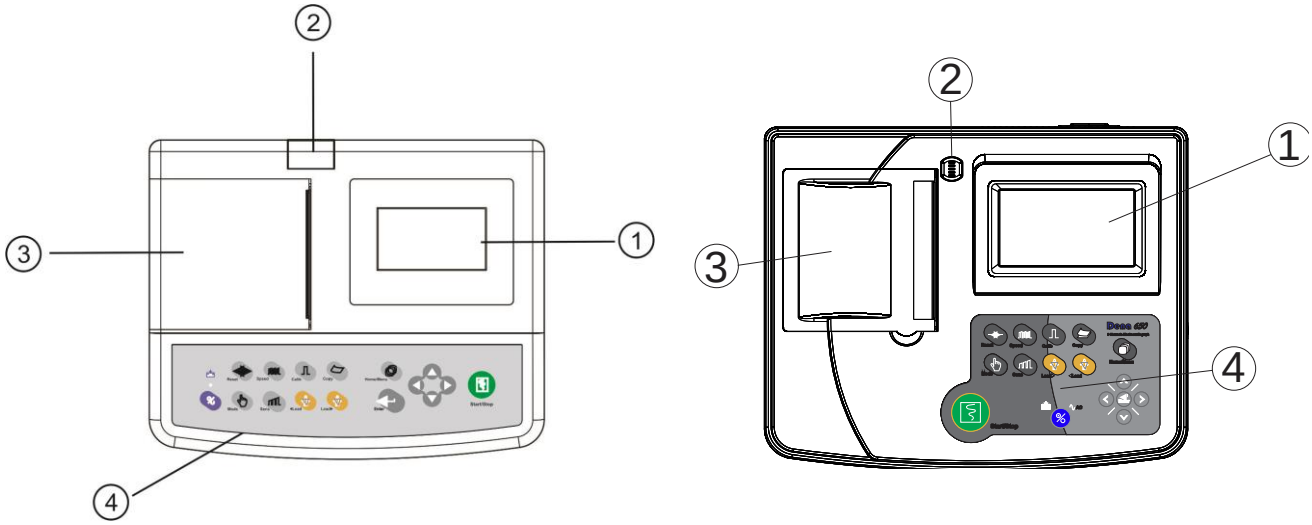


Figure 2-1 Top Panel

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

② Recorder Release Button: to open the recorder door.

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

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

1-1 Display Screen

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

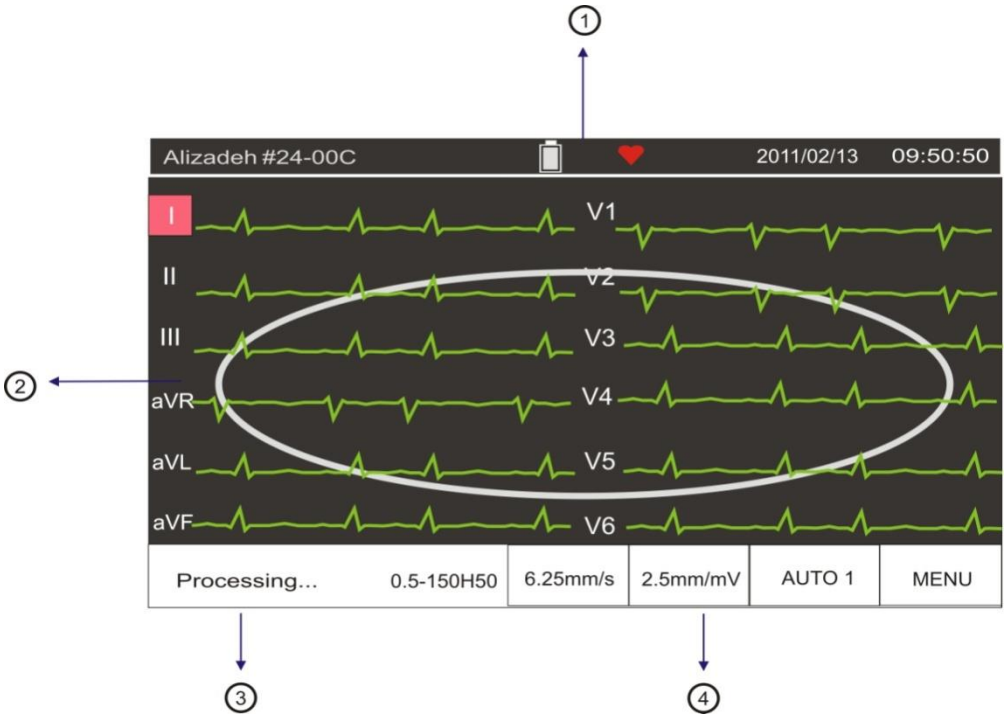


Figure 2-2 Display Screen

Header Area:

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

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

The HR value is measured and updated per second.

Waveform/ Menu Area:

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

ECG lead type is displayed in Waveform Area.

Message Area:

The message area is divided into two parts:

1- Lead error message area:

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

2- Informative and system error messages area (Figure 2-2-③).

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

(Refer to Appendix III for the system messages).

Touch screen keys

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

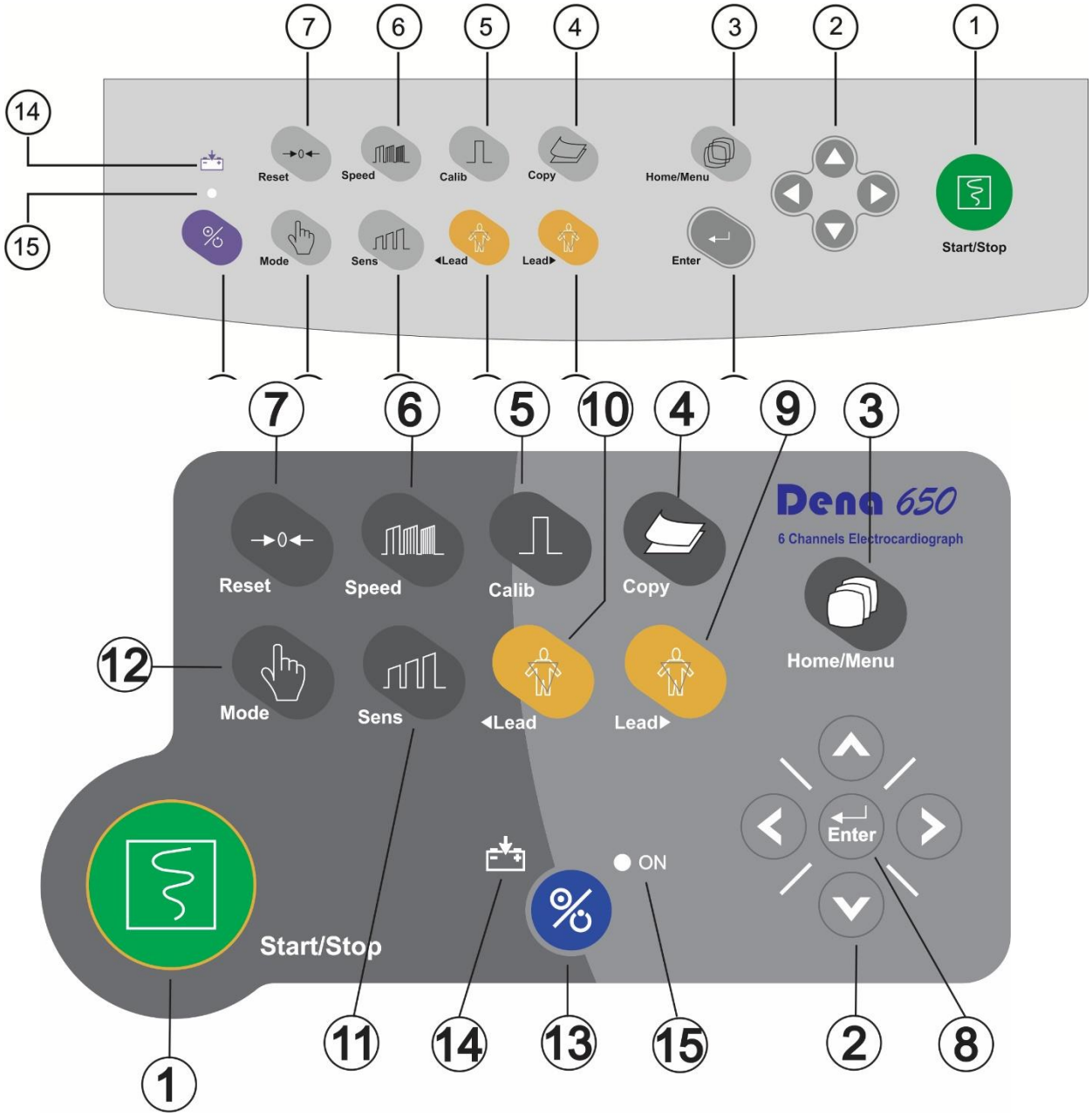
Refer to 1-2 (Control Panel) for details.

Do not touch the screen with sharp objects.

1-2 Control Panel

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

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


Reset
Speed
Calib
Copy
Home/Menu
Start/Stop
Mode
Sens
◂Lead
Lead▸
Enter
Dena 650
6 Channels Electrocardiograph
ON

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

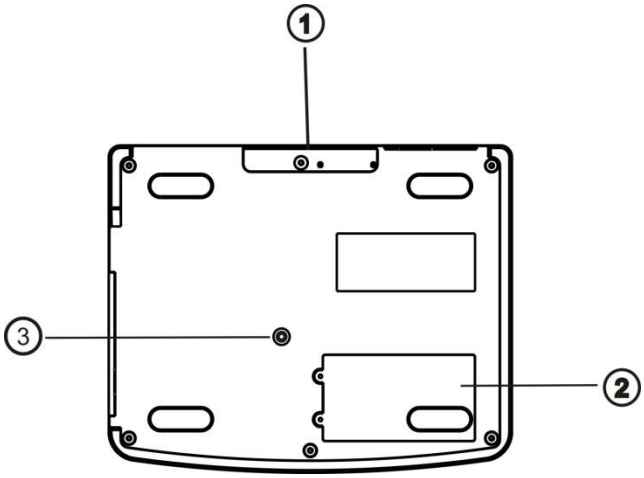
1-3 Indicators

The POWER switch (On/Off) is located on the control panel (⑬ in Figure 2-3). There are two indicators for power and battery on the control panel.

The green power indicator lights up when the device is powered on (⑮ in Figure 2-3).
The battery indicator illuminates green when the battery is fully charged otherwise it is orange.

(⑭ in Figure 2-3).

2. Bottom Panel



① Handhold: For transporting the device.

② Battery Compartment: For loading the battery.

③ 3A fast fuse

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

3. Connectors

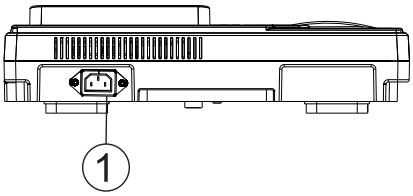
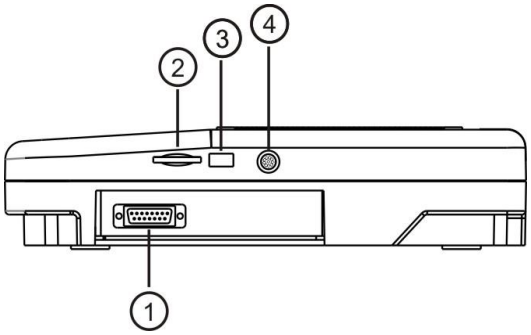


Figure 2-5 Rear Panel

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

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



① Connector of ECG cable

② Slot for SD card (Future capability)

③ USB port (Future capability)

④ Programmer connector: it should only be used by the manufacturer trained and authorized personnel.

4. Built-in Battery

Electrocardiograph is equipped with a rechargeable battery. The battery will charge automatically once you connect the system to the AC INPUT (whether the device is on or off). When the battery is fully discharged, it takes about 5 hours to charge it again. A fully-charged battery allows an operating time of minimum 8 hours. Refer to Technical Specification chapter for charge & recharge time of your own battery.

If for any reason, the charge of battery is less than what you need, contact your after-sales service to replace the battery.

Symbol  in the Header Area indicates the battery charge capacity, in which the yellow part represents the remaining battery charge. This symbol is only displayed when the AC INPUT is not plugged in.

The status of the battery charging is also shown by the battery indicator on the control panel. When the battery indicator is solid green, the battery is fully charged. Orange indicator means that the battery is being charged.

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

Use only the manufacturer recommended batteries. Other batteries may result in fire.

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.

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.

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.

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

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.

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

Connection of the Limb Electrodes

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

Before connecting electrodes:

1- Prepare the patient’s skin.

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

■ Wash sites thoroughly with soap and water.

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

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

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

- Left arm (LA)(L)
- Right arm(RA)®
- Left leg (LL)(F)
- Right leg (RL)(N)

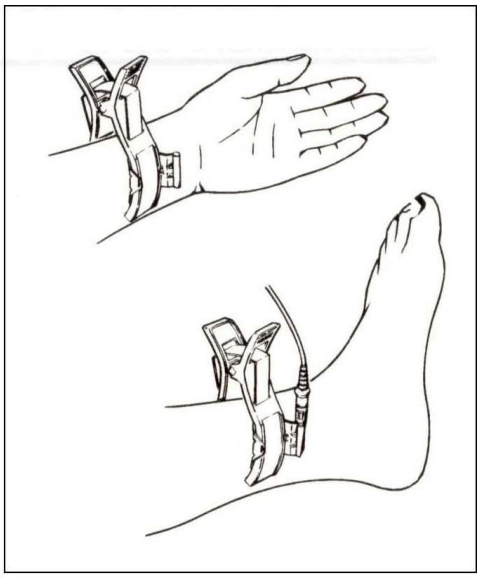


Figure 2-7 Connection of the Limb Electrodes

Connection of the Chest Electrodes

Before connecting electrodes:

1- Prepare the patient’s skin.

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

■ Shave hair from sites, if necessary.

■ Wash sites thoroughly with soap and water.

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

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

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

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

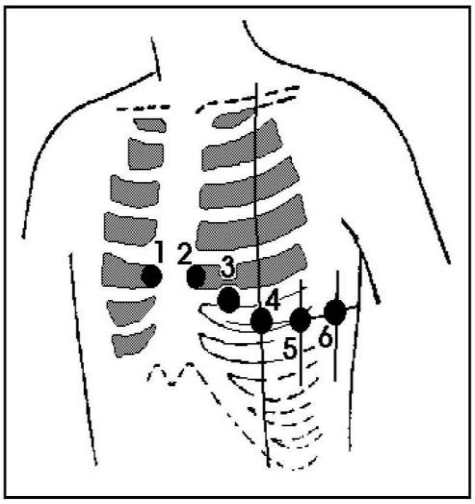


Figure 2-8 Connection of the Chest Electrodes

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

IEC Standard:

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

AHA Standard:

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

For SAADAT ECG cables, labels and color codes according to IEC standard is used.

Lead Placement Diagram

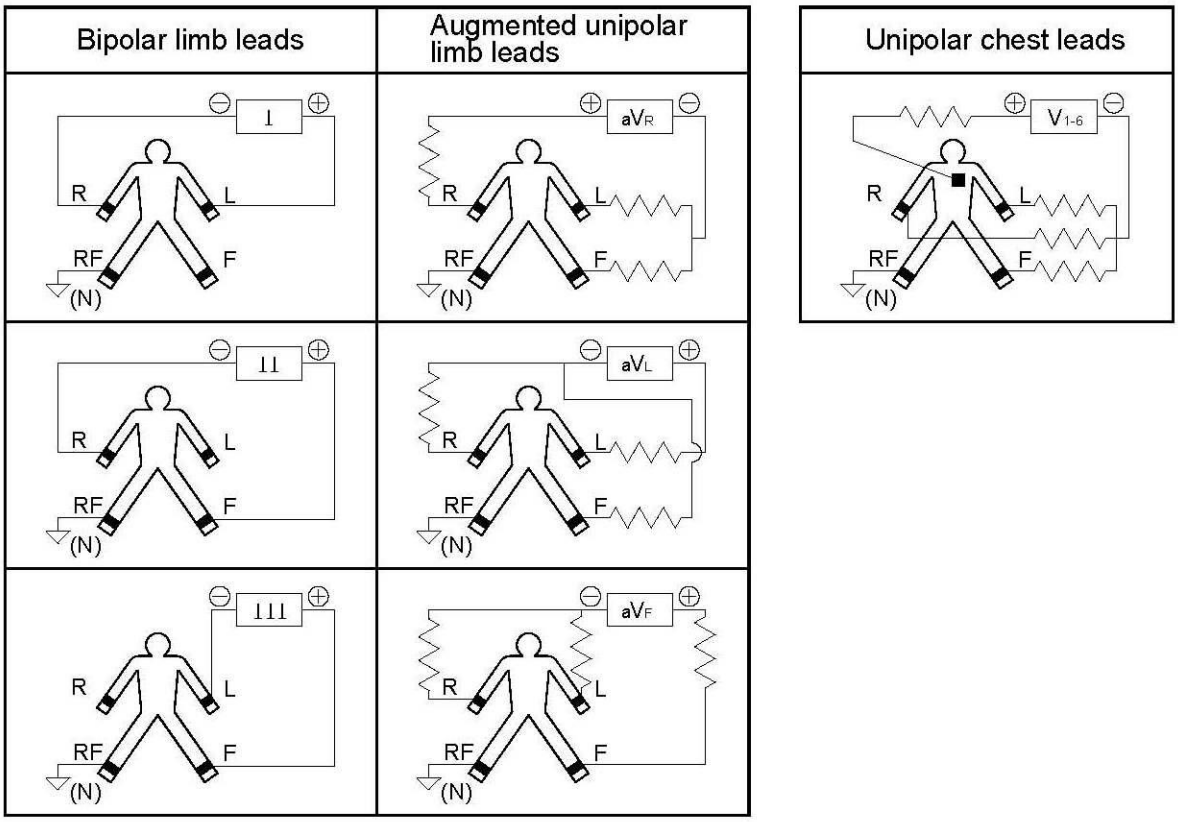


Figure 2-9 Lead placement diagram

Section 3- Device Setting

General

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

■ For date and time settings, please refer to **System setting/Time and Date.**

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

■ For recording setting, please refer to **User Setting.**

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

Main Menu

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

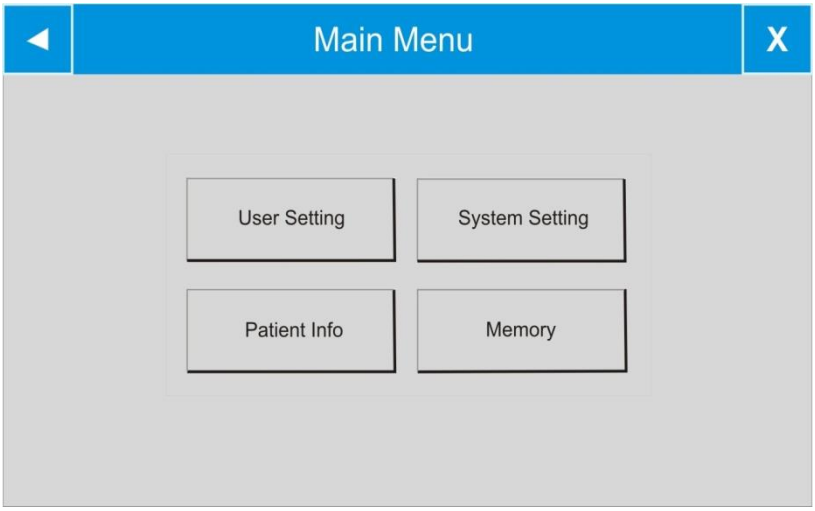


Figure 3-1 Main Menu

The Main menu consists of four options; “User Setting”, “System Setting”, “Patient Info” and “Memory”.

System Setting Menu

By pressing **System Setting** in the Main menu, you can access System Setting Menu (Figure 3-2).

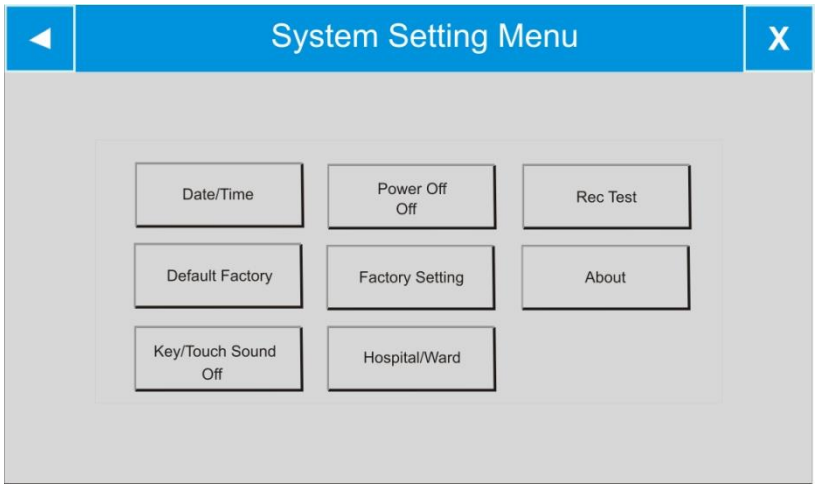


Figure 3-2 System Setting Menu

The following parameters can be set in this menu:

- **Date/Time**：To set date and time as shown in the figure below.

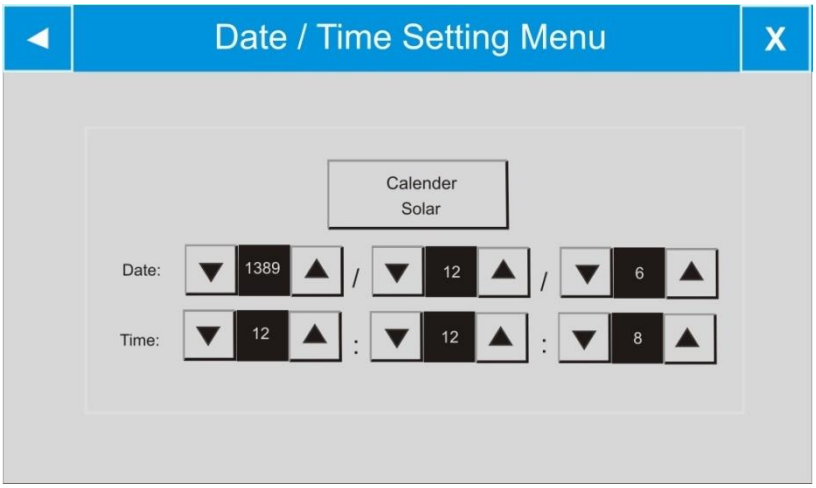


Figure 3-3 Date/Time Setting Menu

Calendar: Available options are **Solar** and **Christian.**
Date: To set the current date.
Time: To set the current time.
Power Off: To shut down the device automatically after 5-60 min. Select Off to disable this function.

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

- **Default Factory:** To load factory default settings. Because of changing all your previous settings, the system asks if you are sure to change all by this message (Figure 3-4).

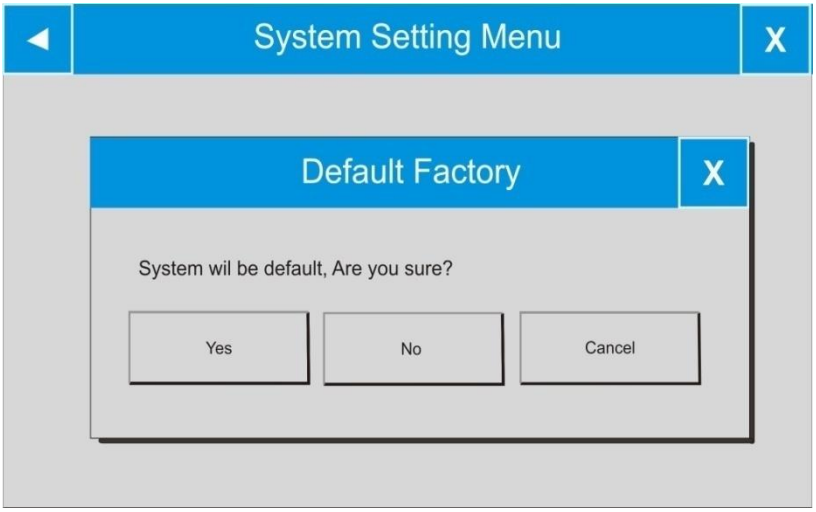


Figure 3-4 Default Factory

■ **Factory Setting:** By selecting this option, you can access the following window.

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

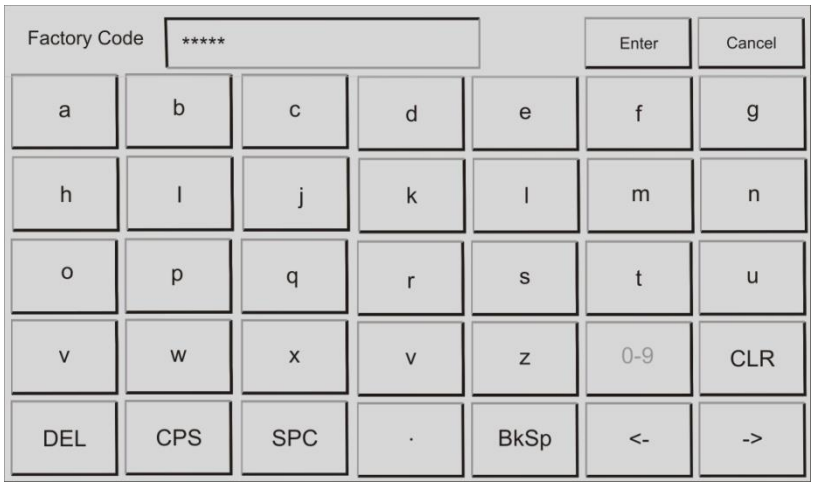


Figure 3-5 Factory Code

■ **About:** By selecting this option, you can view product and manufacturer information as shown in the figure below.

Figure 3-6 About Menu

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

▪ **Hospital/Ward:** By selecting this option, you can access the following window and enter hospital or ward name.

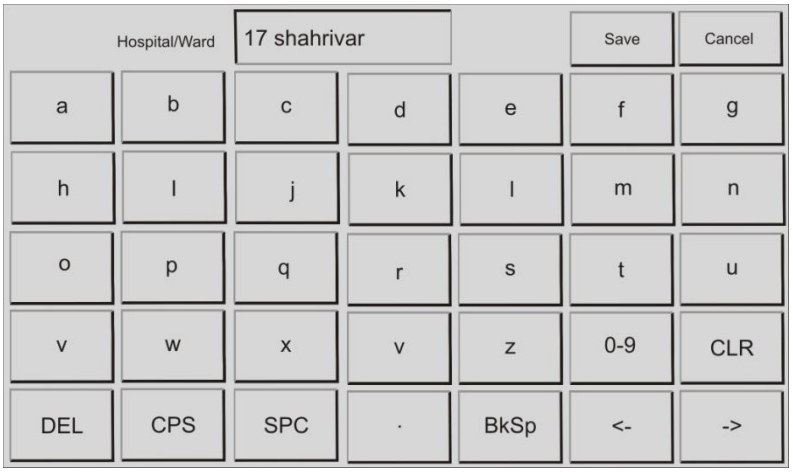


Figure 3-7 Hospital/Ward

User Setting Menu

By pressing **User Setting** in the Main menu, you can access **User Setting Menu** (Figure 3-8).

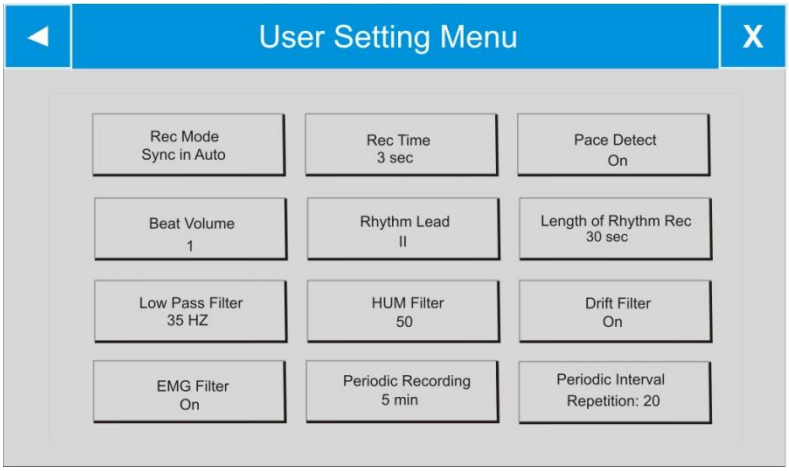


Figure 3-8 User Setting Menu

The following parameters can be set in this menu:

- **Rec Mode:** Available options are **Real Time** and **Sync in Auto**.

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

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

- **Rec Time:** Press to set recording duration for different leads in Auto mode. It ranges from **3** to **12** seconds.
- **Pace Detect:** Available options are Off and On. Electrocardiograph system detects and rejects pacemaker-generated signals from ECG signal so that they will be ignored in determining heart rate. If you select On for patients with pacemaker, detected pacemaker signals will be marked on the ECG waveform as a white vertical line.

> **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.

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

- **Beat Volume:** Available options are **1**, **2**, **3** and **off,** if the Beat Volume is "off", the heart rate volume is turned off.
- **Rhythm Lead:** The Rhythm lead can be one of the leads **I**, **II**, **III**, **aVL**, **aVR**, **aVF**, **V1**, **V2**, **V3**, **V4**, **V5** and **V6**.
- **Length of Rhythm Rec:** Press to set duration of Rhythm lead recording. Available options are **30**, **60**, **90**, **120**, **150** and **180** seconds.
- **Low Pass Filter:** Press to toggle between **25**, **35**, **75** and **150** Hz. This filter is used to remove muscle artifacts and high frequency noises, yet some of the signal details might be removed. The cutoff frequency of these filters is 25 ± 2Hz, 35 ± 2 Hz, 75 ± 7 Hz and 150 ± 20Hz. The frequency of the selected filter is displayed on the screen.

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

Due to the significant changes in the ECG amplitude, if 25 Hz or 35 Hz and EMG filter are turned on simultaneously, the available LowPass filters are Off, 75 Hz and 150 Hz.

- **HUM Filter:** Press to toggle between **50** Hz, **60** Hz and **Off.** Select this filter with regard to your local AC frequency. If the HUM filter is turned on, the third harmonic in accordance with the selected frequency will be deleted. In other words, when the HUM filter is set to 50 Hz, the frequency of 150Hz as well as 50 Hz will be removed. If the frequency of 60 Hz is selected, the frequency of 180 Hz will also be eliminated.

  When 50 Hz and 60 Hz are selected, "H50" and "H60" will be displayed respectively on the screen.

▪ **Drift Filter:** Press to switch **On** or **Off**. This filter is used to reduce signal oscillations. The cutoff frequency of this filter is 0.9 Hz. Using this filter will remove the frequencies below the cutoff value from the ECG report. If the drift filter is switched off, the cutoff frequency of the device will be about 0.05Hz. If the drift filter is set On, "**0.5**" will be displayed on the screen and otherwise "**0.05**".

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

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

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

If the EMG filter is set On, "**M**" and "**EMG**" will be displayed on the screen and recording paper and otherwise it will be blanked.

To remove ECG signal noise, take the following steps:

1. At first remove any noise sources (for more details, please refer to Troubleshooting chapter)
2. If after taking above action the noise is not rejected, set On EMG filter.
3. If the signal is still noisy, set off the EMG filter and use the lowpass filter (25-35Hz).
4. It is necessary to mention, if the LowPass filters are used, the amplitude of the QRS complex will be reduced
5. If the EMG filter is enable, the available LowPass filters are Off, 75 Hz and 150 Hz.

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

Using 25 Hz and EMG filters together may cause variation in the ECG signal amplitude.

Using the Drift and EMG filters together may change position of the pace spike.

Pay attention to the above warnings when using the filters.

The EMG filters is an adaptive, non-linear and time- variant low pass filter that is designed to apply on ECG signals. Thus using the EMG filter may affect P, QRS and T waves.

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

- **Periodic Recording:** Press 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 Interval Repetition:** Press to set repetition of recording. Available options are **1-20** and **Infinite**.

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

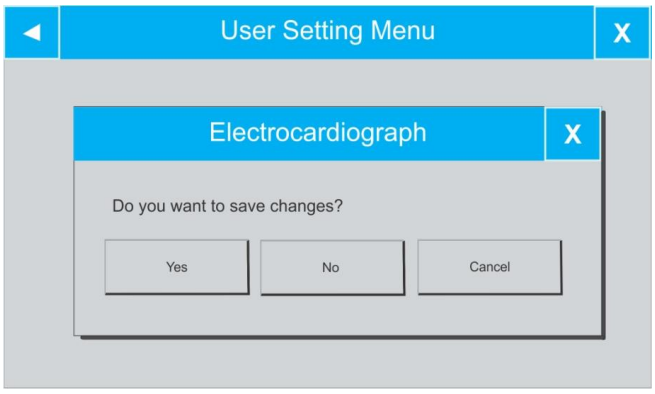


Figure 3-9 Conformation Menu

Section 4-Patient Information

This section will explain how to manage the patient information.

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

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

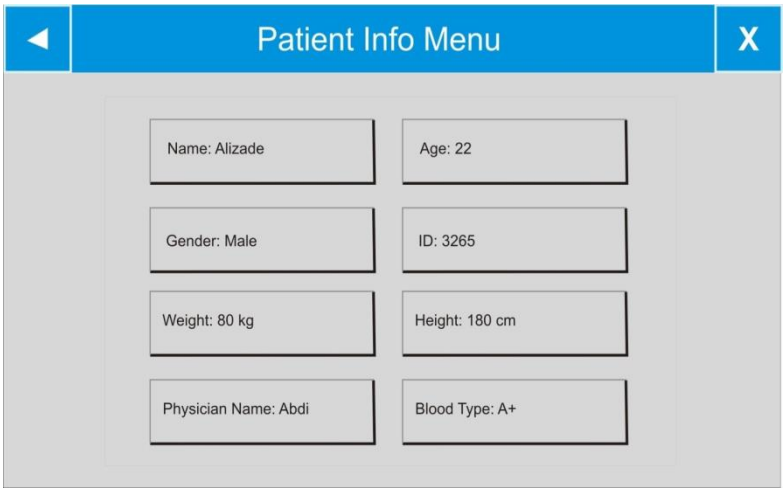


Figure 4-1 Patient Info Menu

Patient Data Entry

Select each item to access the related window.

- **Name**

Enter the patient name and press **Save** to exit from this window (**Figure 4-2)**. Up to 15 characters can be input in this field.

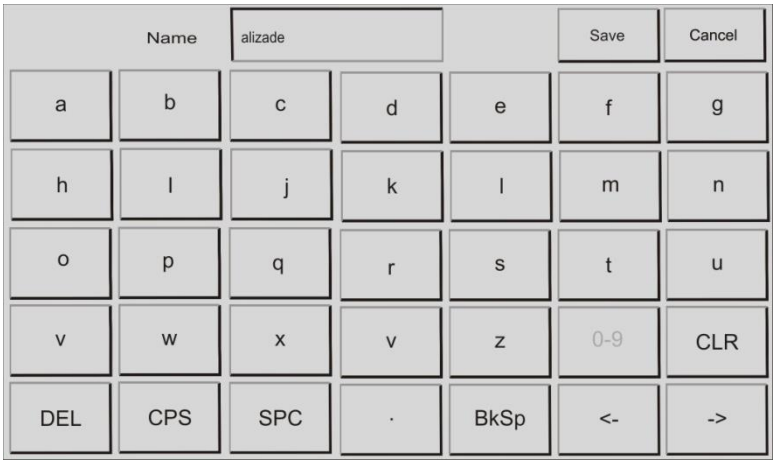


Figure 4-2 Name

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

■ **Age**

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

According to the selected option, year or month of patient age should be entered in this field.

Patient age can be registered in year or month according to the selected option.

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

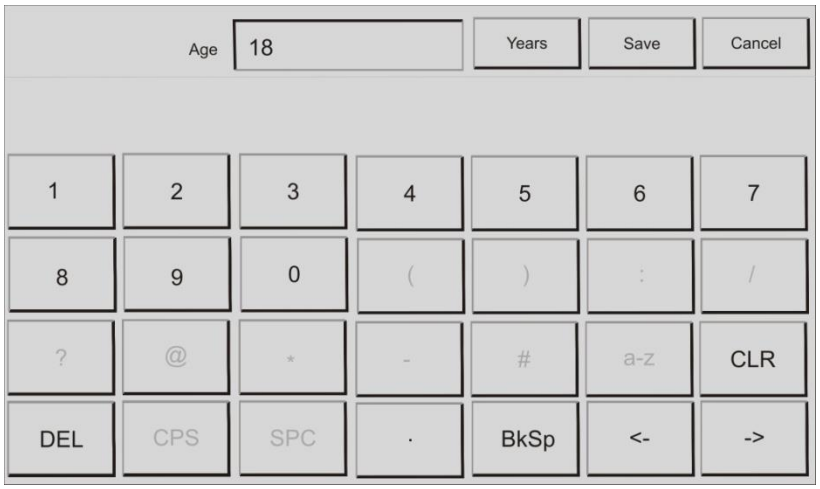


Figure 4-3 Age

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

■ **Gender**

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

■ **ID**

Enter the patient ID number and press **Save** to exit this window. Up to 10 characters can be input in this field.

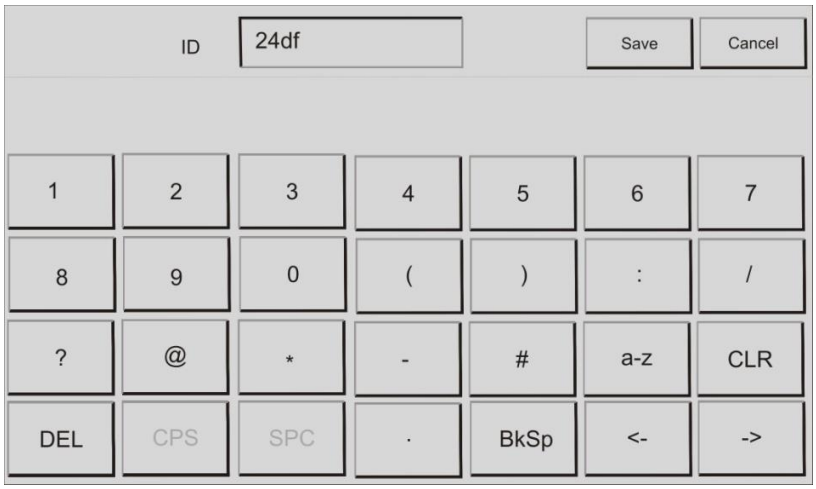


Figure 4-4 ID

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

- **Height**

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

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

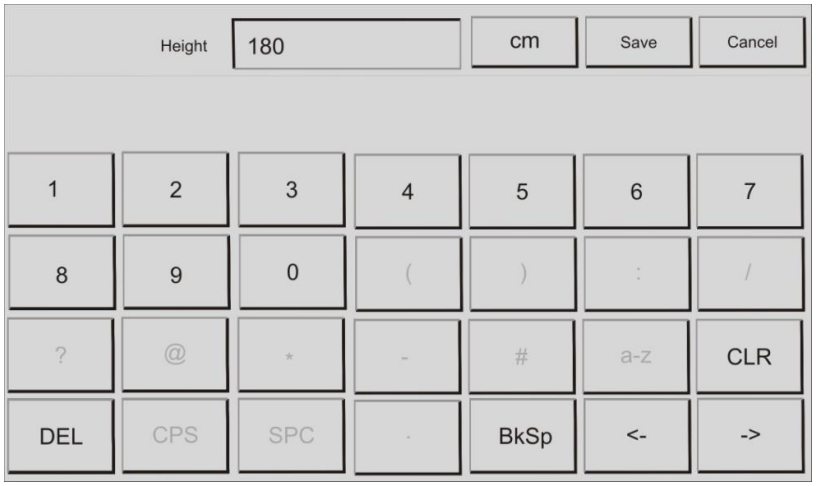


Figure 4-5 Height

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

- **Weight**

Available options are **Kg** and **1b**. Factory default setting is **Kg.**

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

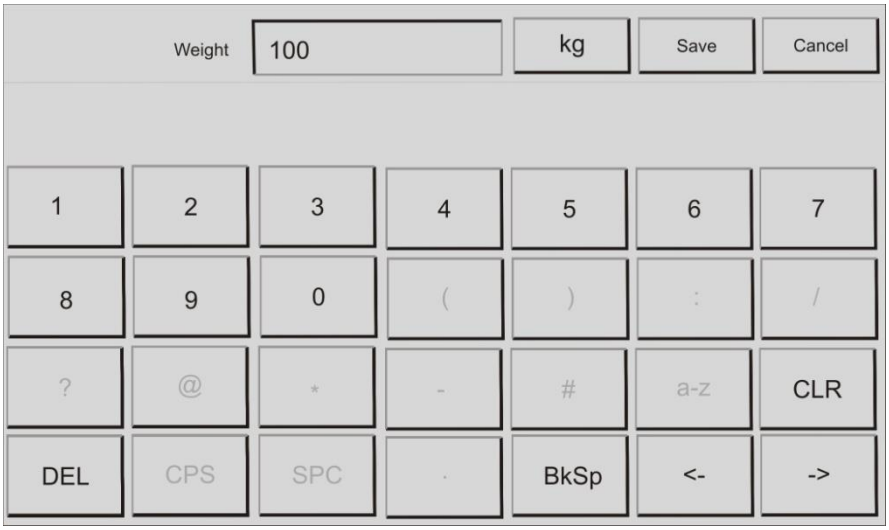


Figure 4-6 Weight

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

■ **Physician Name**

Enter the physician name and press **Save** to exit this window. Up to 15 characters can be input in this field.

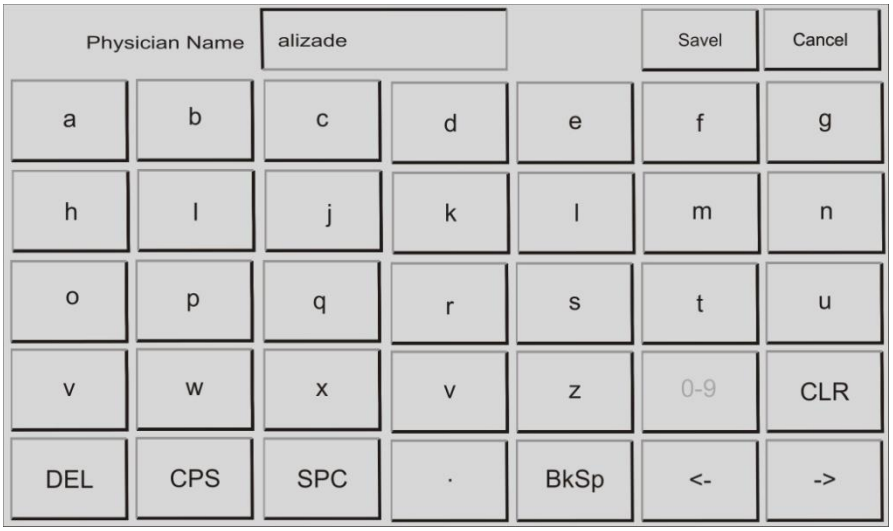


Figure 4-7 Physician Name

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

▪ **Blood Type**

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

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

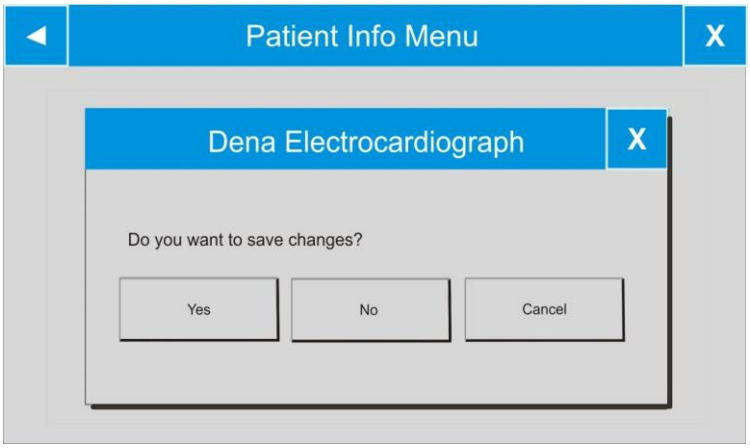


Figure 4-8 Confirmation Menu

Section 5- Data Management

General

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

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

Memory Menu

Select **Memory** in the **Main Menu** to access **Memory Menu** (Figure 5-1).

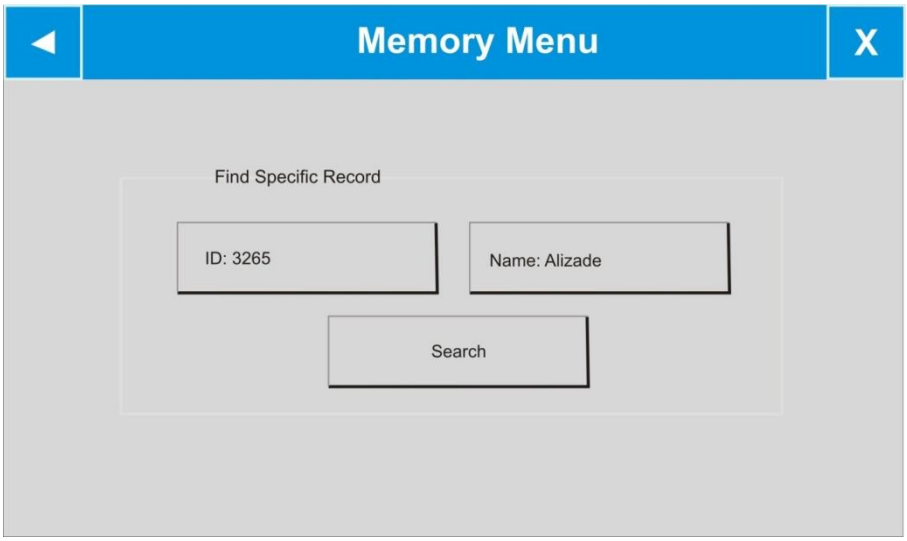


Figure 5-1 Memory Menu

- **Name:** Select to enter the patient name (Figure 5-2).

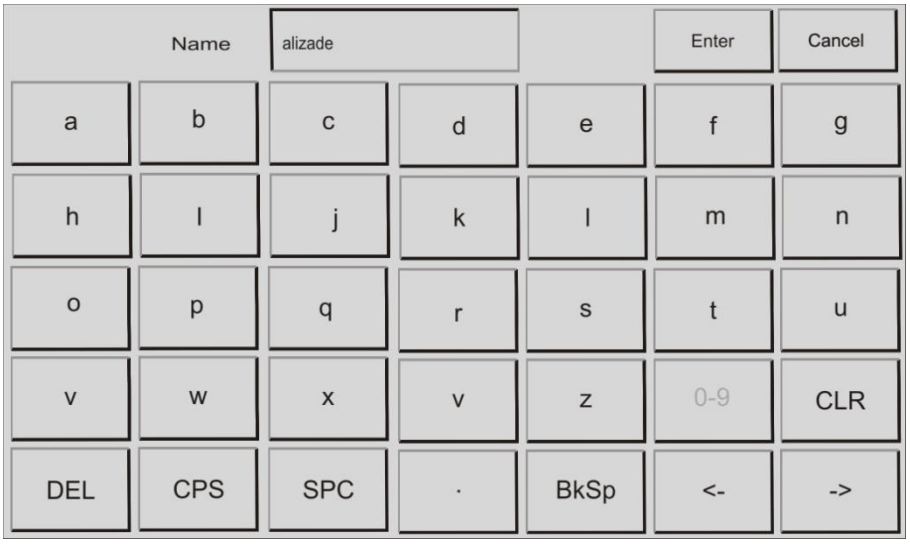


Figure 5-2 Name/ Memory Menu

■ **ID:** Select to enter the patient ID as shown in the figures below.

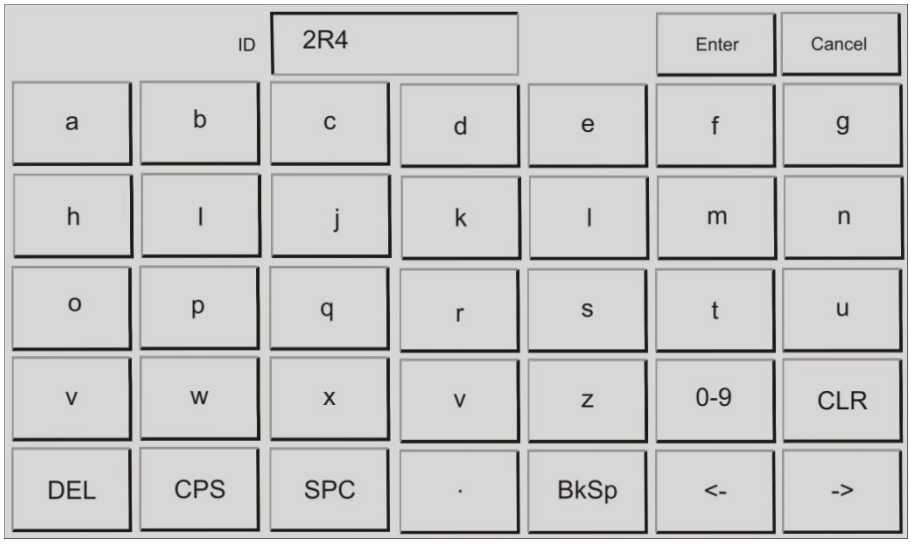


Figure 5-3 ID/ Memory Menu

■ **Search:** Enter patient name/ID and press Search to view all stored data of the patient.

If you leave Patient name/ID blank and select Search, all stored records in the memory will be displayed in a list as shown in the figure 5-4.

If no data is available, the message **"There is no record"** will appear.

If patient name/ID is entered incorrectly, the message "**There is no record, change selection**" will appear.

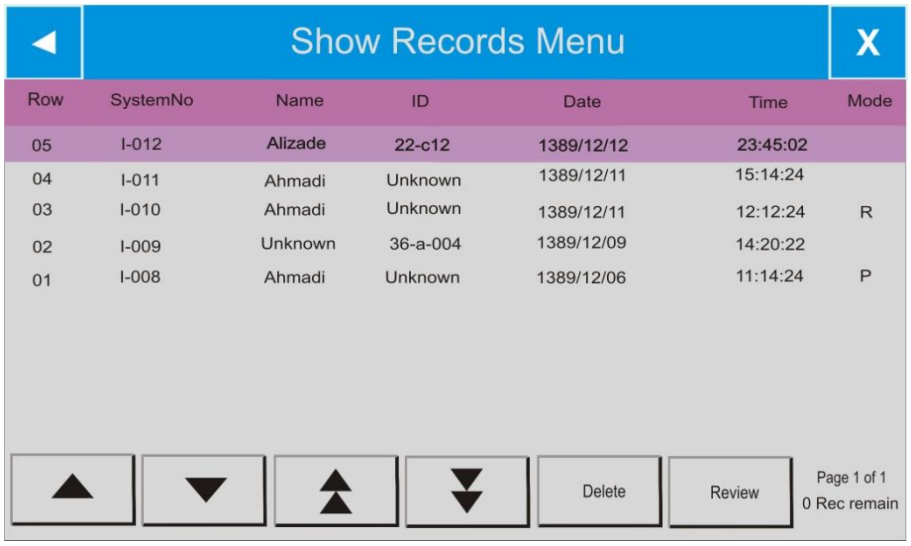


Figure 5-4 Show Records Menu

Each record in **Show Records Menu** contains the following information:

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

You can also see current page number, total pages and remaining records for storage in this window.

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

- Press ⏬ or ⏫ to move to the previous or next pages.
- Press ▼ orthe previous or next records.move to to ▲
- Press **Delete**, the following dialog box appears. If you select **Yes**, the highlighted record will be deleted.

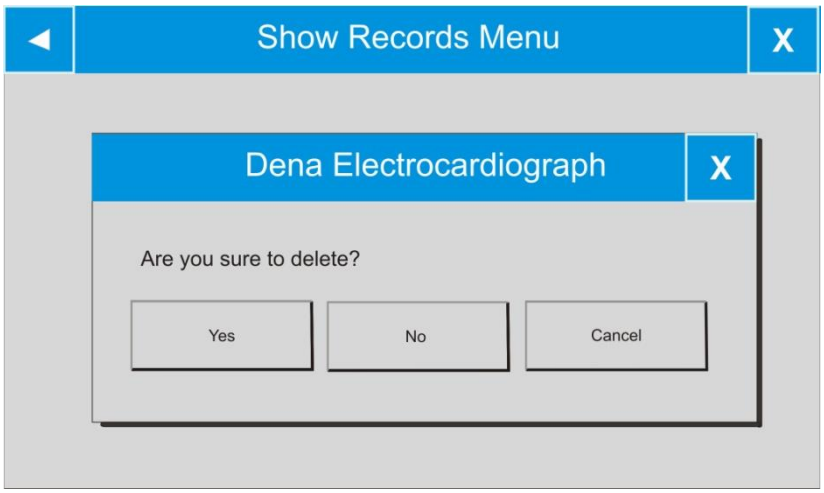


Figure 5-5 Delete

Deleted data cannot be recovered.

- Press **Review** to observe the information of highlighted record.

"Reviewing…" is displayed below the screen (Figure 5-6).

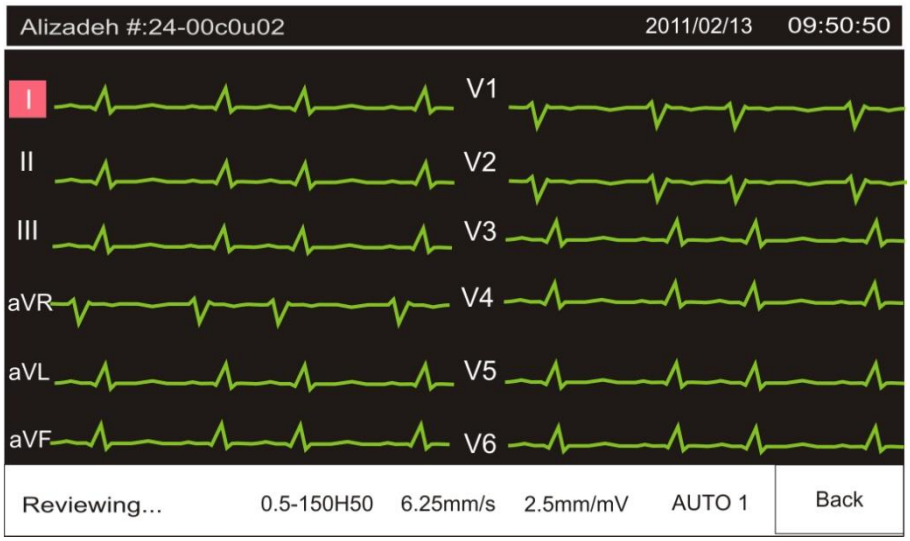


Figure 5-6 Review

This page contains:

- ECG waveforms
- HR value
- Speed, Gain and recording mode
- Filter name
- Patient name and ID
- Date and time of recording

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

Section 6- Recording Operation

This section will explain recorder operation.

Please refer to section 2, "User Setting Menu", for details on recording settings.

Signal recovery accuracy:
With regard to maximum frequency bandwidth of 150 Hz and sampling rate of 1000 samples/s, the signal recovery accuracy of Dena Electrocardiograph complies with AAMI EC11 standard requirements.

General

Dena electrocardiograph is equipped with Saadat thermal recorder.

Features

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

Recording Type

Manual Recording

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

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

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

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

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

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

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

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

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

Automatic Recording

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

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

It is not possible to toggle between different leads using **Lead►** and **◄Lead** keys.

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

Auto 1+1: lead I

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

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

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

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

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

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

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

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

Rhythm Recording

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

There are always six channels of recording in this mode.

Periodic Recording

To perform periodic recording:

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

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

3. Select recording mode using Mode key.

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

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

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

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

Copy Mode

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

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

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

Recorder Paper

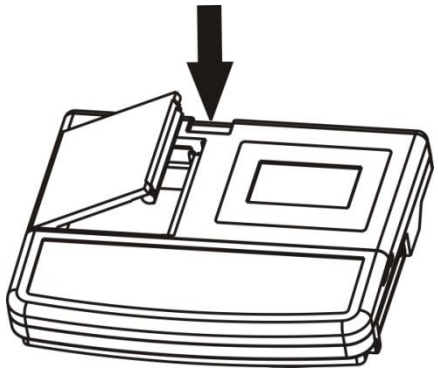
Use only heat sensitive recording paper with 110 mm width.

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

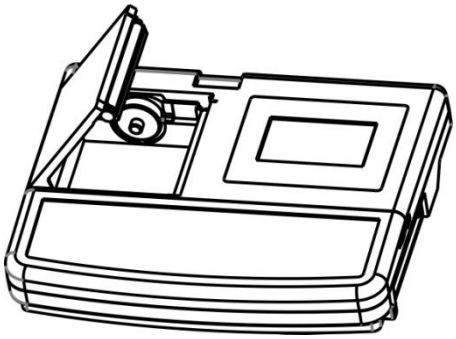
Do not touch the recorder head while recording and immediately after recording because it is so hot and may lead to personal injury including burns.

Paper loading

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

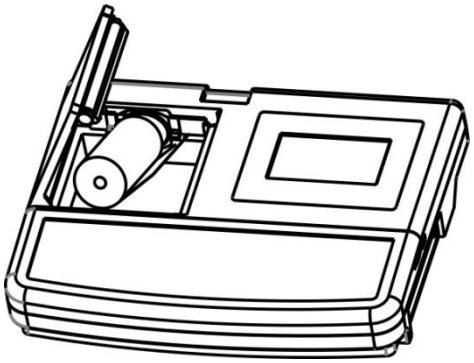


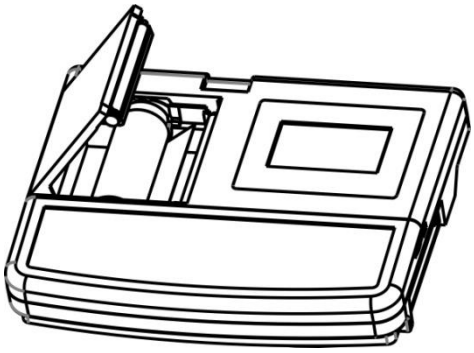
■ Open the recorder door.



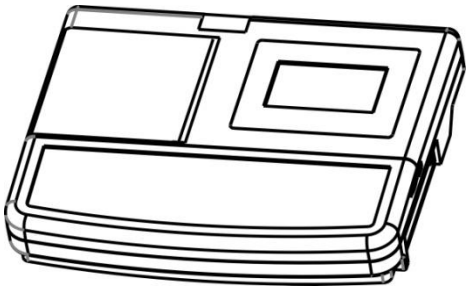
■ Place the paper roll in the recorder and push it.

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





■ Close the recorder door firmly.



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

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

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.

Be careful when loading the paper in the recorder. Avoid damaging the thermosensitive printhead. Do not touch thermosensitive print head.

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

The following information are printed on the recorder paper:

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

Recorder Cleaning

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

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

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

Section 7- Patient Safety

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

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

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

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

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

Grounding the electrocardiograph

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

Equipotential Grounding

Protection class I instruments are already included in the protective grounding (protective earth) system of the room by way of grounding contacts in the power plug. For internal examinations on the heart or the brain, the electrocardiograph must have a separate connection to the equipotential grounding system. One end of the equipotential grounding cable (potential equalization conductor) is connected to the equipotential grounding terminal on the rear panel of the device and the other end to one point of the equipotential grounding system. The equipotential grounding system is for the safety function of the protective grounding conductor if ever there is a break in the protective grounding system. Examinations in or on the heart (or brain) should only be carried out in medically used rooms incorporating an equipotential grounding system. Check each time before use that the instrument is in perfect working order.

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

Section 8- Getting Started

8-1 Open the package.

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

■ Check the device for any mechanical damage.

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

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

If there is any problem, contact the distributor immediately.

8-2 Connect the power cable to the device.

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

100-240 VAC, 50 /60Hz.

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

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

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

8-3 Power on the electrocardiograph system.

Press Power key to turn on the electrocardiograph.

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

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

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

8-4 Connect the patient sensor.

Connect all necessary accessories to patient and the electrocardiograph.

Section 9- Technical Specifications

CLASSIFICATION	
Protection against electroshock	Class I, Type CF Defibrillation proof (based on IEC 60601-1)
Mode of operation	Continues operation equipment
Harmful Liquid Proof Degree	Ordinary equipment, (without Liquid Proof)
Method of disinfection	Refer to chapter 10 for detail
Safety of anesthetic mixture	Not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
DISPLAY	
Display	TFT COLOR 480×272, 5”
Waveforms	12 Lead ECG/ Rhythm Lead
Numeric Parameters	HR
Operation Method	Membrane Keys and Touch
Displayed data	Waveforms, Patient information (Name and ID), Recording Speed, Operation Mode, Filter, HR Value Message
ECG	
Input Channel	Simultaneous acquisition of all 12 leads/ Rhythm Lead
Standard leads acquired	I, II, III, aVR, aVF, aVL, V1, V2, V3, V4, V5, V6
Gain Selection	2.5, 5, 10, 20 mm/mV
Filters	Drift: on or off
	HUM: 50 or 60 HZ, off
	Low pass: 25, 35, 150 HZ , Off
	EMG: on or off
Calibration	1 mV
Dynamic Range	±5 mV
Leakage Current	10 µA<
CMRR	98 dB>
Time Constant	3.2 sec.
Frequency Response	0.05~150Hz
Pace	Detection & Rejection: 0.1~2 ms, ±2~±250 mV Indication : 0.5~2 ms, ±2~±250 mV
Standards	IEC 60601-2-25:2011
ECG Storage	
Internal Memory	Up to 100 Records
Recorder	
Model	Thermal Printer
Print Method	Thermal dot line printing
Dots per line	832 dots
Resolution	16 dots/mm (Horizontal)

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

Section 10- Care and Cleaning (PM)

10-1 System Check

Before using the device,

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

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

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

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

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

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

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

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

10-2 Cleaning

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

The electrocardiograph system must be kept dust-free.

Regular cleaning of the device and the LCD screen is strongly recommended.

Please pay special attention to the following items:

1- Don't use strong solvents such as acetone or ammonia.

2- Most cleaning agents must be diluted before use.

3- Don't use rough material, such as steel wool, etc.

4- Don't let the cleaning agent enters into the chassis of the system.

5- Don't leave the cleaning agents on any part of the equipment.

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

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

ECG Cable:

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

Recorder:

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

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

10-3 Disinfection

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

- Hydrogen Peroxide 3%
- Alcohol 70%
- Isopropanol
- Enpropanol

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

Do not use ETO gas to disinfect the electrocardiograph.

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

Daily check of the following items is recommended:

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

Weekly check of the following items is recommended:

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

Monthly check of the following items is recommended:

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

It is recommended that the system is calibrated by manufacturer every year, but it has to be calibrated once every 2 years. In addition the system lifetime is 10 years.
The medical center can request the system calibration whenever the system accuracy is in doubt.

10-4 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.

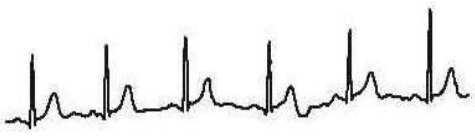
SAADAT Co.					
Form No. : PL-F-33		**PM Form (Electrocardiograph)**			
State:		**City:**	**Medical center:**		**Ward:**
Device model:		**Serial number:**	**Installation date:**		**Inspection date:**
No.	**Test and Inspection Item**		**OK**	**NOK**	**N/A**
1	**Visual inspection**	**No damage or breakage in the case**			
		Correct function of the touch			
		Correct function of the keyboard			
		Cleaning and disinfection according to the user manual			
2	**Display screen**	**Correct display of Waveform area and information**			
3	**Battery**	**Unplugging the system (check the battery function)**			
		Periodic usage of the battery			
4	**Saving date& time settings**				
5	**Saving system settings**				
6	**Accessories**	**Check ECG cable (clamps, leadwire, trunk)**			
		Check ECG clip clamp and suction bulb (visual and sulfation test)			
		Cleaning and disinfection according to the user manual			
7	**Recorder**	**Correct function**			
		Appropriate size of the recorder paper			
		Check the eject key function on the recorder door			
		Check the paper holder			
		Check the recorder error messages			
8	**Review**	**Review performance test periodically**			

Section 11- Troubleshooting

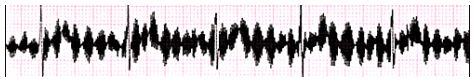
Repairing the internal parts of the electrocardiograph must be only done by trained and authorized personnel of After Sale Service; otherwise the manufacturer will not take any responsibility for any possible hazard to the patient and the device.

Troubleshooting guide is intended to help users to solve minor problems caused by incorrect use of the electrocardiograph or failure of accessories.

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

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

Problem	Possible Cause	Solution

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

APPENDIX I- Accessories

General

This section lists the recommended accessories used for the electrocardiograph.

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

Accessories	Part #
• 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

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

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

Item	Selection	Default
Task bar Menu		
Recording Mode	Manual 1+1, Manual 3, Manual 3+1, Manual6, Auto 1+1, Auto 3, Auto 3+1, Auto 6, Rhythm	Auto 3
Sensitivity	2.5, 5, 10, 20 mm/mv	10
Paper Speed	6.25, 12.5, 25, 50 mm/s	25
User Setting Menu		
Beat Volume	1, 2, 3, Off	Off
Rec Time	3-12 Seconds interval=1(s)	3
Rec Mode	Sync in Auto/Real time	Real time
Rhythm lead	I, II, III, aVL, aVF, aVR, V1, V2, V3, V4, V5, V6	II
Length of Rhythm Recording	30, 60, 90, 120, 150, 180 Seconds	30
Low Pass Filter	25, 35, 75, 150 HZ	150
HUM Filter	50, 60 HZ, Off	50
Drift Filter	On/Off	On
EMG Filter	On/Off	Off
Periodic Recording	5-60 min,Off interval=5	Off
Periodic Interval Repetition	1-20, Infinite interval=1	Infinite
Pace	On/Off	On

Item	Selection	Default
System Setting Menu		
Date/Time		
Power Off	5-60 min-Off interval:5min	Off
Rec Test		
Factory default		
About		
Factory Setting		
Key Sound	On/Off	On
Hospital/Ward		Blank
Date/Time Menu		
Calendar	Solar/Christian	Christian
Date		
Time		
About Menu		
Manufacture	-	
Version	-	
Fax	-	
Website	-	
E-mail	-	
Tel	-	

Item	Selection	Default
Memory Menu		
Name		
ID		
Search	-	
Show Records Menu		
Page up	-	
Page down	-	
Cursor up	-	
Cursor down	-	
Delete	-	
Review	-	
Review		
Back	-	
Patient Info Menu		
Name		Blank
ID		Blank
Age	Years/Months	Years
Gender	Male/Female/None	None
Weight	Kg/lb.	Kg
Height	Cm/Foot	Cm
Physician Name		Blank
Blood Type	A+/A-/B+/B-/AB+/AB-/O+/O-/ Unknown	Unknown

APPENDIX III -Error Messages

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

Message	Cause	Solution	Remarks
Head Hight Vol	The Print head voltage is high.	Turn the system off and on. If problem still exists, contact the manufacturer's After Sales Service.	The message blinks in red 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 problem still exists, contact the manufacturer's After Sales Service.	The message blinks in red color on the screen.
Time out Error	The recorder could not record.	Turn the system off and on. If problem still exists, contact the manufacturer's After Sales Service.	The message blinks in red color on the screen.
Battery Error Messages			
Battery Low	Low battery voltage	Connect the power cable to the system.	The message blinks in red color on the screen.

APPENDIX IV-EMC

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 the Electrocardiograp is used in the electromagnetic environment specified

To prevent EMC effect on the Electrocardiograp, 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 interference with the Electrocardiograph performance.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Dena Electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the Dena should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Dena 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 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 Electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the Dena should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (>60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T for 0.5 cycle 40% U_T for 5 cycles 70% U_T for 25 cycles <5% U_T for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Dena requires continued operation, it is recommended that the ***Dena Electrocardiograph*** be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The Dena Electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the Dena should assure that it is used in such an environment.

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

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

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

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

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

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

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

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

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

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