

**SAADAT Co.**

# **User Manual**

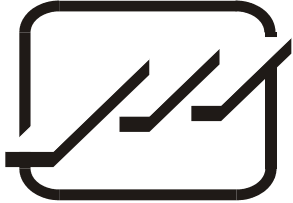
## **Dena Electrocardiograph**

**Dena 350**



**CE** 2195

D00718-5



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## Table of Contents

About this manual.....	1
Explanations of the symbols in the Manual and device .....	1
Chapter 1. General Warnings .....	1
1-1 General Warnings .....	2
Chapter 2. System Configuration .....	4
2- 1 General Information.....	5
2- 2 System Description.....	6
2- 3 ECG Electrodes Connection .....	15
Chapter 3. Device Setting.....	20
3- 1 General.....	20
3- 2 Main Menu.....	21
3- 3 System Setting Menu .....	21
3-4 User Setting Menu .....	24
Chapter 4. Patient Information .....	28
Chapter 5. Data Management .....	33
5- 1 General.....	33
5- 2 Memory Menu .....	33
Chapter 6. Recording Operation.....	35
6- 1 General.....	35
6- 2 Recording Type.....	36
6- 3 Copy Mode .....	38
6- 4 Recorder Paper.....	39
Chapter 7.Patient Safety .....	44
Chapter 8. Getting Started .....	46
Chapter 9. Technical Specifications .....	48
Section 10- Care and Cleaning .....	51
10-1 System Check .....	51
10-2 Cleaning and Disinfection .....	52
10-3 Preventive Maintenance (PM) .....	56
Chapter11. Troubleshooting .....	58
APPENDIX I - Accessory .....	60
APPENDIX II-List of System Parameters (Selections and Defaults) .....	61
APPENDIX III-Error Messages .....	64
APPENDIX IV-EMC .....	66

## About this manual

### 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
Jul 2022	D00718-5

## 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.
	For protection against defibrillator, use only manufacturer recommended accessories.
	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.
	The equipment shall be disposed of in an environmentally-friendly manner.
	Equipotential grounding system.
 <b>AC Source</b>	AC power supply
<b>SD</b>	SD port
<b>SN</b>	Serial number
	Manufacture date
	Manufacturer information
	European community representative
	USB port

## **Chapter 1. General Warnings**

Please refer to this section for overall safety information.

## 1-1 General Warnings

---

### Warning

- **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.**
  - **Equipment is not suitable for use in the presence of a flammable anesthetic mixture.**
  - **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.**
  - **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.**
  - **To prevent electric shock, connect the protection earth wire of electrocardiograph device.**
  - **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 simultaneously.**
  - **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 .**
  - **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 and turn on the system after at least 30 minutes.**
  - **Clean the gel from limb electrodes and chest electrodes after using them.**
  - **Entering any conductive sharp objects into device ports may cause danger.**
-

- **Unplug the system after being completely charged.**
  - **If you want to use device with patient defibrillator simultaneously, use patient cables approved by manufacturer (with internal resistor of 10k $\Omega$ , 3W at least) and do not use other cables.**
  - **If device is in saturation or inoperable state, Lead-off message will be appeared on screen and record is flat line and not valid.**
-



## **Chapter 2. System Configuration**

Dena350 electrocardiograph system is capable of:

- \_ Displaying 12-lead ECG waveform
- \_ Displaying Rhythm-lead waveform separately on the screen
- \_ 3-channel waveform recording
- \_ Data storage in Internal and External memory
- \_ Displaying and printing stored data

## 2- 1 General Information

System is equipped with 5-inch color TFT, touch screen, recorder and built-in battery.

Dena350 is a small, light-weight and portable Electrocardiograph device and can be used anywhere.

### Environment:

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

### Product Lifetime:

Since electric parts have lifetime of 10 years and recommended calibration interval of the device is 1 year and its mandatory calibration interval is 2 years, the expected lifetime of the device is 10 years.

### Intended use:

Dena350 is an Electrocardiograph that integrates ECG module, Recorder module, display screen and power supply in one device. Compactness, lightweight, portability of this system facilitates transportation.

DENA350 is applicable to variety of ages ranging from neonates to adults in all medical awards by skilled medical staff for diagnostic purpose.

## 2- 2 System Description

### 2-2-1-Top Panel

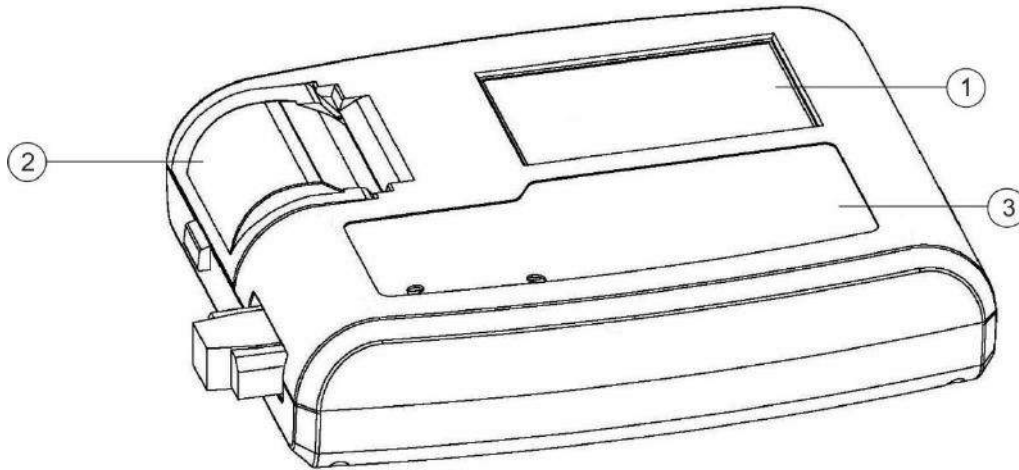


Figure 2-1 Top Panel

- ① Display Screen: ECG waveforms, patient information, messages, etc. are displayed on this screen (See Display Screen for details).
- ② Recorder: to load recording paper and print ECG waveforms.
- ③ Control panel: to control the system operation (See Control Panel for details).

- **Display Screen**

Dena350 is equipped with a TFT color screen. All 12-lead ECG waveform, HR value, Patient ID, Date and Time, system and battery operating status, error and informative messages are displayed on the screen. The screen is divided into three areas: Header area (Figure 2-2) Waveform / Menu area (Figure 2-2), Messages area (Figure 2-2).

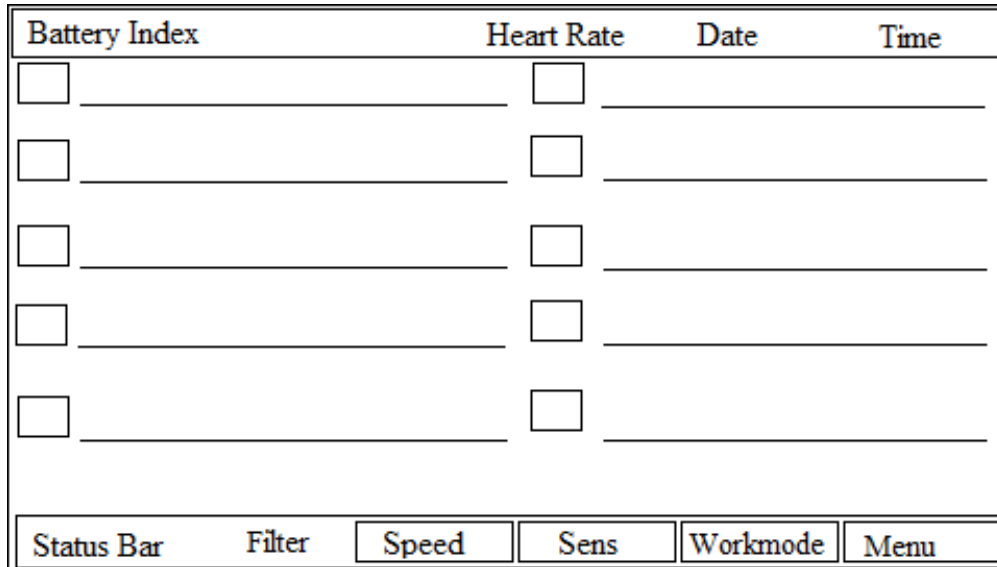


Figure 2-2 Display Screen

**Header Area:**

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

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 could 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.

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

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

(Refer to Appendix III for the system messages).

### **Touch screen keys**

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

Refer to Control Panel for details.

---

### **Warning**

- **Do not touch the screen with sharp objects.**
-

- **Control Panel**

Dena350 is designed in such a way that user can easily perform operations by using keys and touch screen.

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

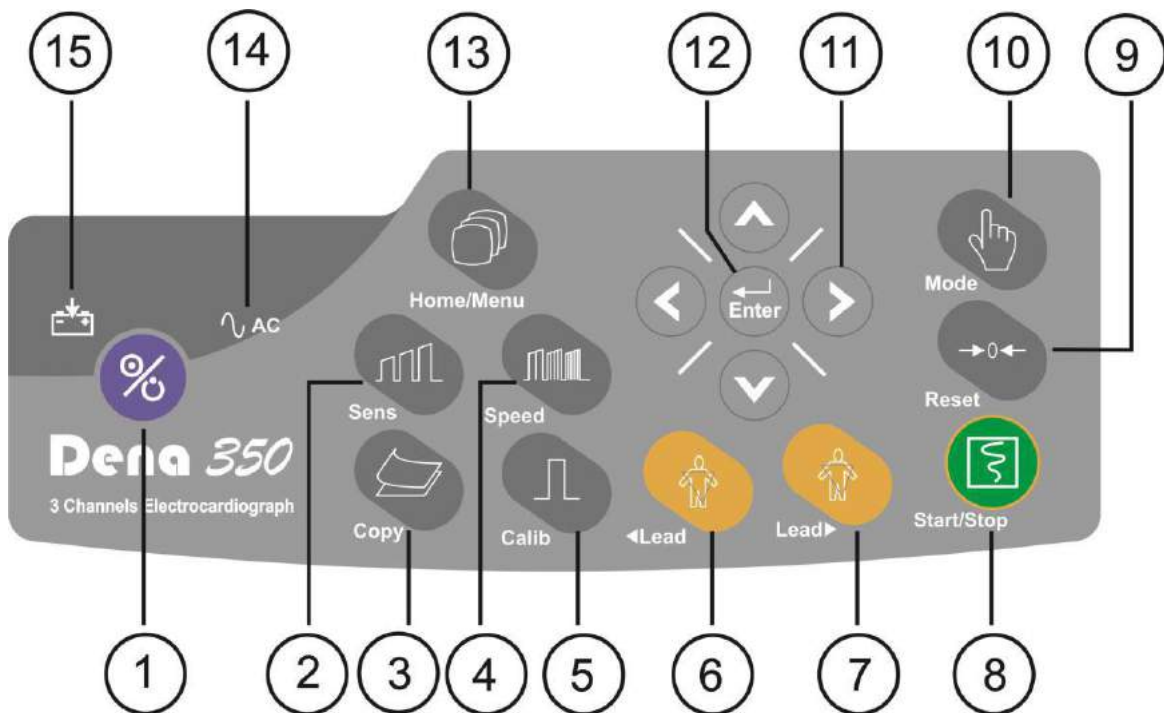


Figure 2-3 Control Panel

## Warning

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

- **Indicators**

The POWER switch (On/Off) is located on the control panel (in Figure 2-3- ①). There are two indicators for power and battery on the control panel. The green power indicator lights up when the device is powered on (in Figure 2-3- ⑭).

The battery indicator Turns into green when the battery is fully charged, yellow when it is half charged, otherwise it is red. (in Figure 2-3- ⑮).

14-AC indicator: This LED lights on when AC power is plugged in

15- Battery indicator: Battery indicator can change color according to battery status

### 2-2-2-Bottom Panel

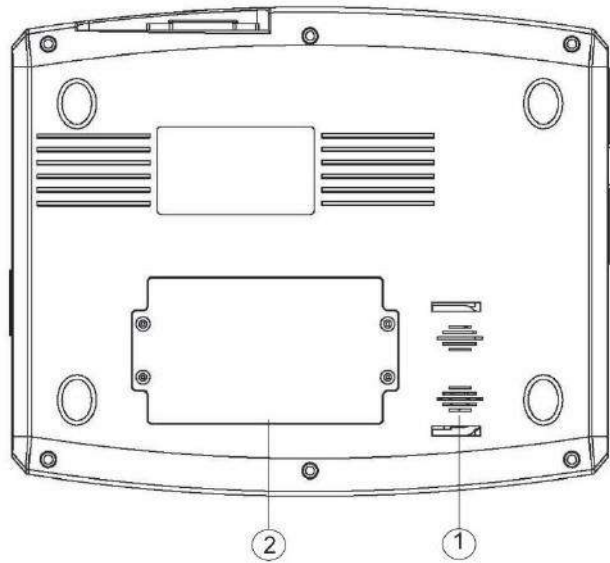


Figure 2-4 Bottom Panel

- ① Speaker outlet
- ② Battery Compartment: For loading the battery.

### 2-2-3-Peripheral Connectors

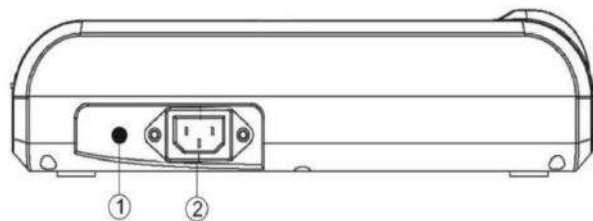


Figure 2-5 Rear Panel

- ① Equipotential grounding terminal.
- ② Power Supply jack: 100-240 VAC, 0.8 A 50/60 Hz.



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

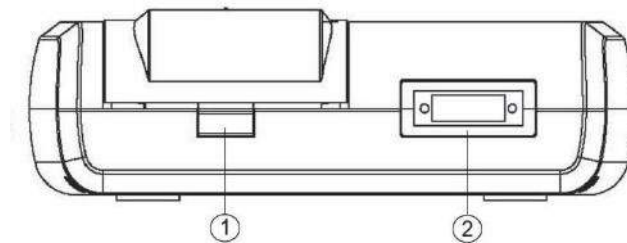


Figure 2-6 Side Panel\Left

- ① Recorder Release Button: to open the recorder door.
- ② Connector of ECG cable

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

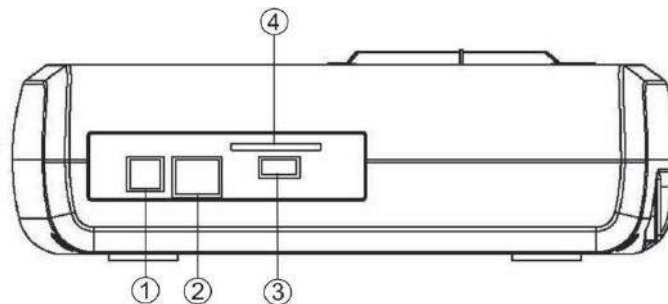


Figure 2-7 Side Panel\right

- ① USB Device connector: for transferring data to pc software.
- ② RJ-45 connector: Future capability (optional).
- ③ USB Host: For upgrading firmware by qualified operator.
- ④ Slot for SD Card : for saving recorded ecg signal data on SD card.

### **2-2-4-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).

For Battery specification, please refer to battery specification in Technical specification chapter.

---

#### **Warning**

- **When the battery is depleted in less than 2 hour, it needs to be replaced. Please call customer service for the battery replacement.**
  - **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. Using unapproved battery will void the device warranty.**
- 

Symbol  in the Header Area indicates the battery charge capacity, in which the color 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. When the battery is charging, the AC indicator is on and battery indicator is off.

### **2-2-4-1-Battery placement**

**Put battery in compartment which placed on the bottom plane first, then connect battery 2-wire female connector to the male connector on the charger board. Then fasten 4 fixing screws size3 located on the door to bottom plane. It is recommended to use the same battery which mentioned in “Technical specification” chapter.**

## 2- 3 ECG Electrodes Connection

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

---

### Warning

- **Use only one type of electrode on the same patient to avoid variations in electrical impedance. It is recommended to use silver/silver chloride electrode. When dissimilar metals are used for different electrodes, the electrodes may cause large offset potentials due to polarization, which may be severe enough to prevent obtaining an ECG trace. Using dissimilar metals may also increase recovery time after defibrillation.**
  - **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 10K resistance. Other ECG cables and leads may cause improper performance and/or provide inadequate protection during defibrillation.**
  - **Use disposable electrodes when the device is used in the vicinity of electrosurgical unit or defibrillator.**
  - **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 (L)
- Right arm( R)
- Left leg ( F)
- Right leg (N)

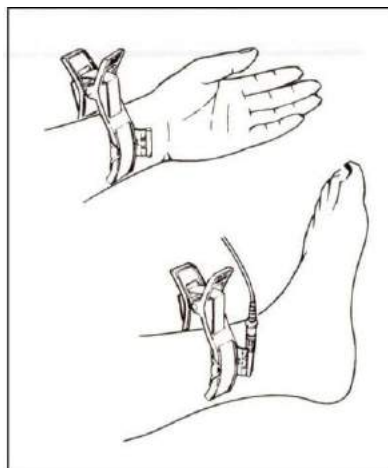


Figure 2-8 Connection of the Limb Electrodes

## 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

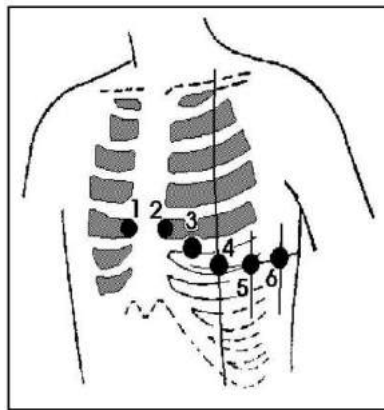


Figure 2-9 Connection of the Chest Electrodes

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 (European standard) color coding 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

**AAMI/AHA (American standard) color-coding standards:  
(Association for the Advancement of Medical Instrumentation)**

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

**NOTE**

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

### Lead Placement Diagram

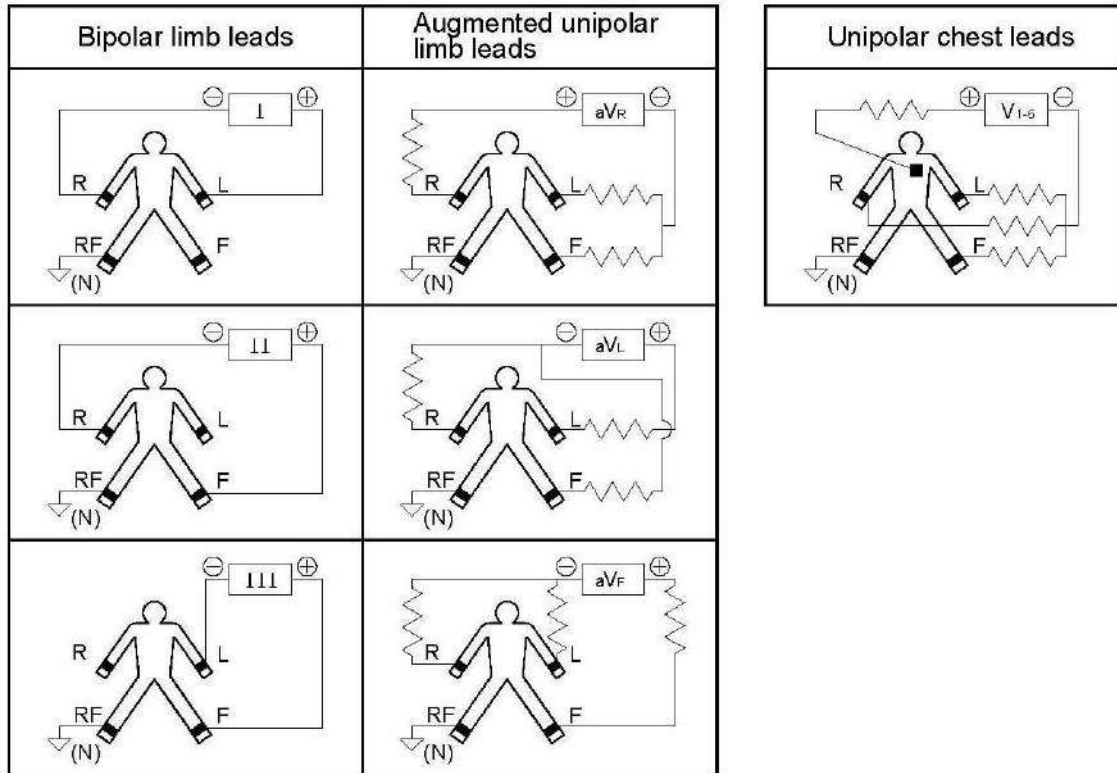


Figure 2-10 Lead placement diagram



## Chapter 3. Device Setting

### 3- 1 General

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

- For date and time settings, please refer to **Menu/System setting/Time and Date.**
- For manufacturer information, please refer to **Menu/System setting/About.**
- For recording setting, please refer to **Menu/User Setting.**

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

### 3- 2 Main Menu

Dena350 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).

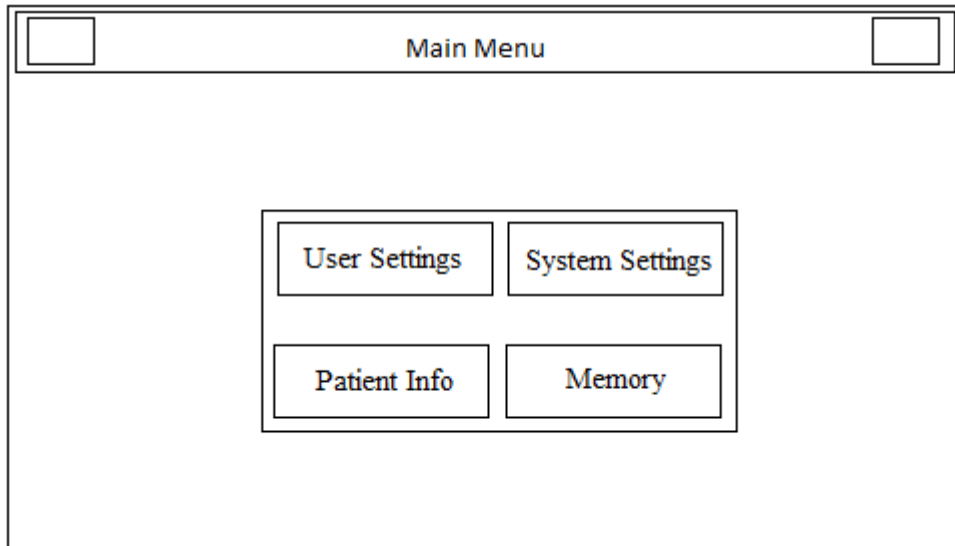


Figure 3-1 Main Menu

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

### 3- 3 System Setting Menu

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

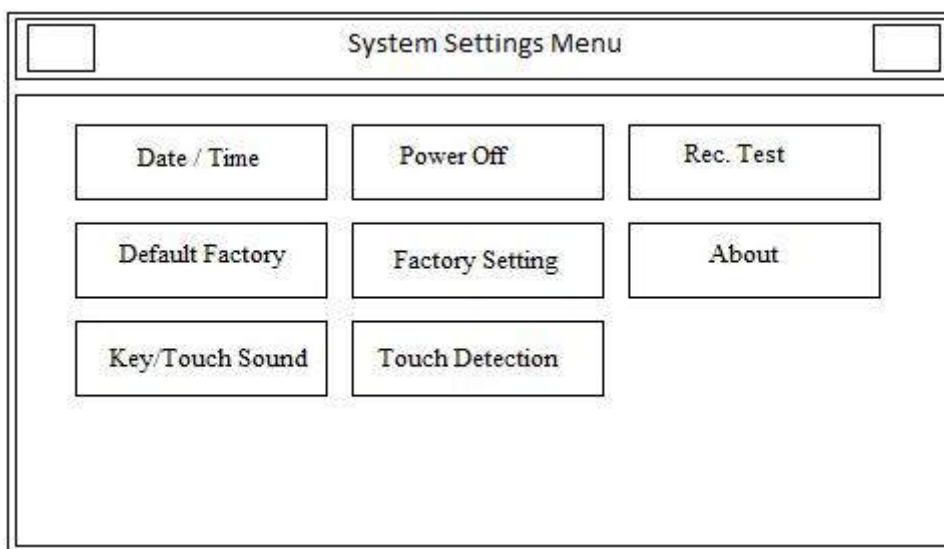


Figure 3-2 System Setting Menu

The following parameters can be set in this menu:

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

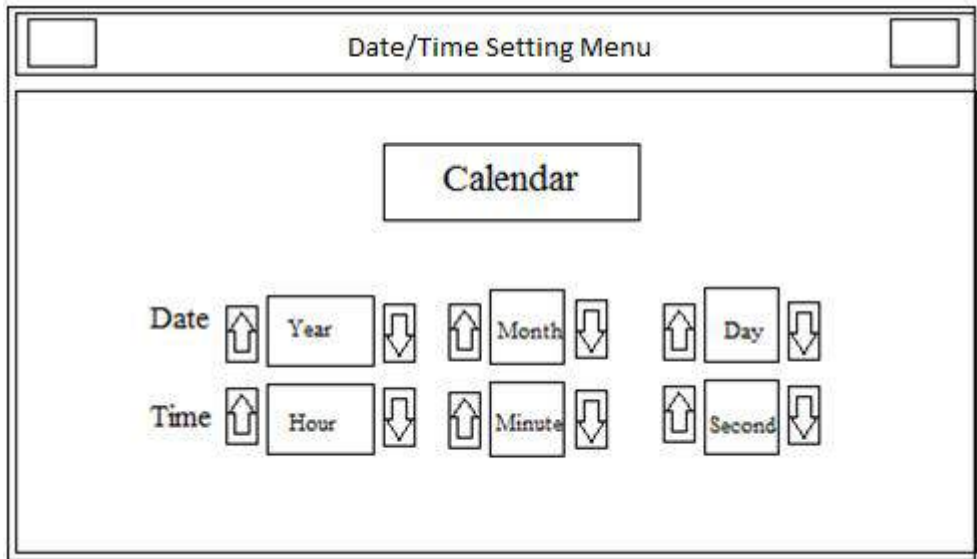


Figure 3-3 Date/Time Setting Menu

**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).

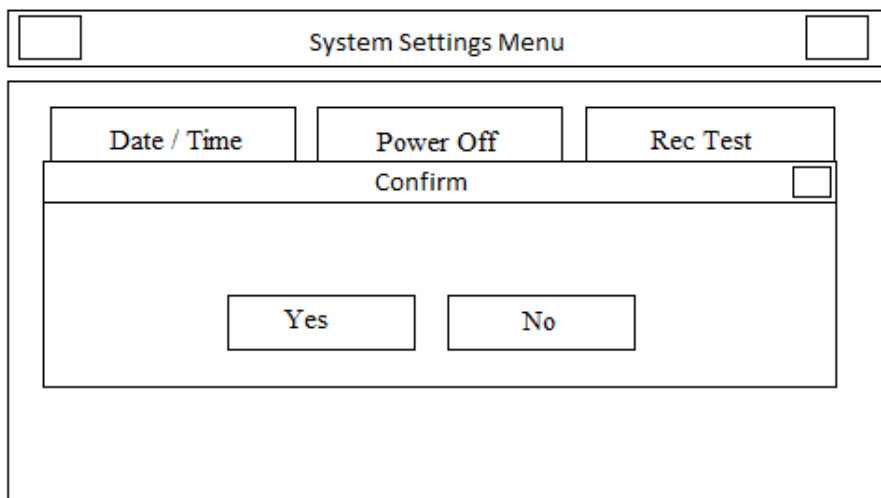


Figure 3-4 Confirm

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

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

Factory code	*****	Save	Cancel			
1	2	3	4	5	6	7
8	9	0	(	)	:	/
?	@	*	-	#	a~z	CLR
DEL	CPS	SPC		BkSp	<-	->

Figure 3-5 Factory Code

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

System Settings Menu		
Date / Time	Power Off	Rec Test
About Menu		
Manufacture	Website	
Version	E_mail	
Fax	Tel	

Figure 3-6 About Menu

- **Key/Touch Sound:** To switch ON/OFF the sound of touch or hard keys.
- **Touch Detection:** To enable or disable touch screen capability.

### 3-4 User Setting Menu

By pressing **User Setting** in the Main menu, you can access **User Setting Menu** (Figure 3-7).

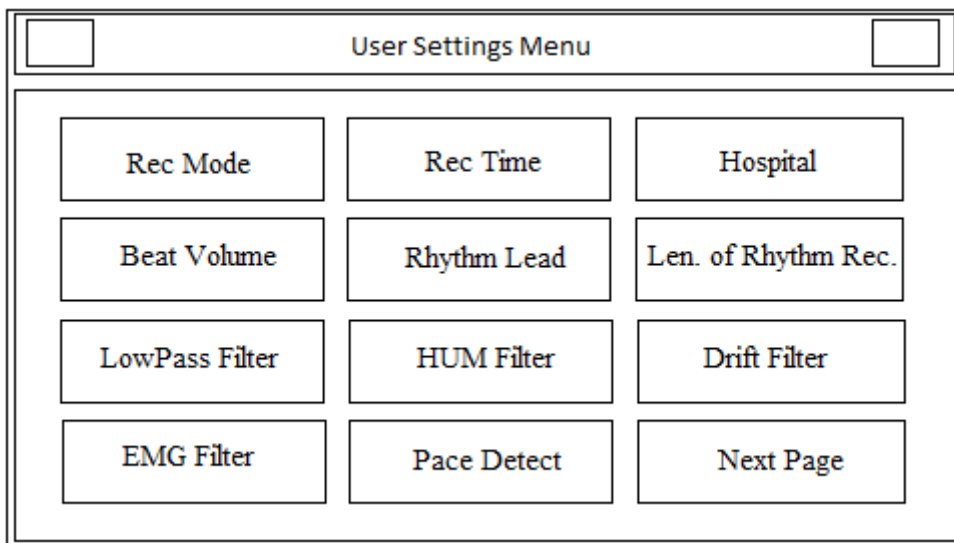


Figure 3-7 User Setting Menu

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.

---

#### **NOTE**

- **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 3to12 seconds.

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

Hospital					Save	Cancel
a	b	c	d	e	f	g
h	i	j	k	l	m	n
o	p	q	r	s	t	u
v	w	x	y	z	0~9	CLR
DEL	CPS	SPC		BkSp	<-	->

Figure 3-8 Hospital/Ward

- **Beat Volume:** Available options are 1, 2, 3 and Off. Select "Off" to mute the heart beat sound.
- **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 F1=25, F2=35, F3=75 and F4=150 Hz.

---

### Warning

- Do not use 25 Hz and 35 Hz filters for diagnostic cases. These filters may cause low quality ECG signal especially in P, QRS waves.
- 

**HUM Filter:** Press to toggle between 50 Hz, 60 Hz and Off. Select this filter with regard to your local AC frequency.

- **Drift Filter:** Press to switch On or Off. This filter is used to reduce signal oscillations.

---

### NOTE

- Drift filter is used to remove signal baseline oscillations and does not have any effect on ST Segment analysis.
-

- **EMG Filter:** Press to toggle between On and Off. This filter is used to reject muscular noise between 15 to 25Hz.
- **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.

---

### Warning

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

- Next page: By pressing this button from **User Setting** menu, the window depicted below will be displayed.

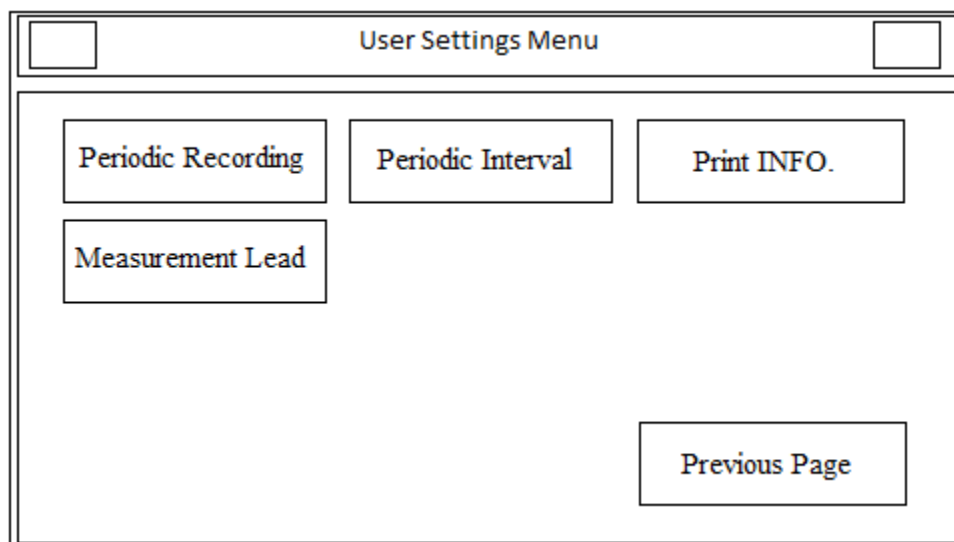


Figure 3-9 second page of user setting

- **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.

- **Print info:** Select on to record header of the printed paper and select off to remove it.
- **Measurement Lead:** Future capability.
- **Previous page:** Press to come back to User Setting Menu page.



## Chapter 4. Patient Information

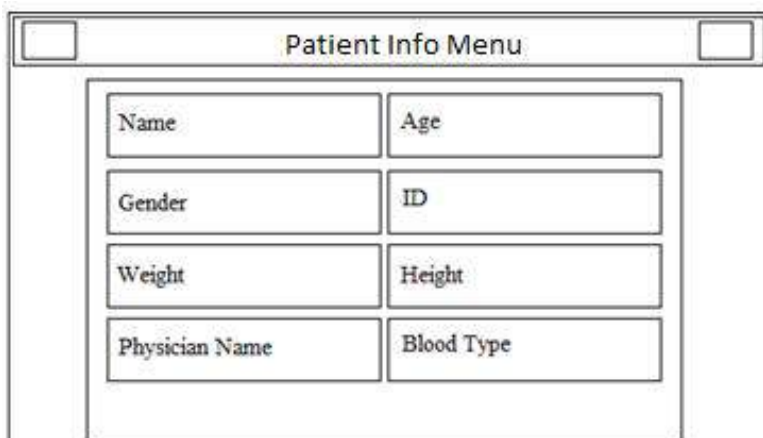
This section will explain how to manage the patient information.

---

### Warning

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

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



The image shows a screenshot of a software interface titled "Patient Info Menu". The window has a title bar with the text "Patient Info Menu" and two small square buttons on either side. The main content area contains a grid of eight input fields arranged in four rows and two columns. The fields are labeled as follows:

Name	Age
Gender	ID
Weight	Height
Physician Name	Blood Type

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 12 characters can be input in this field.

Name					Save	Cancel
a	b	c	d	e	f	g
h	i	j	k	l	m	n
o	p	q	r	s	t	u
v	w	x	y	z	0~9	CLR
DEL	CPS	SPC		BkSp	<-	->

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.

Age					Years	Save	Cancel
1	2	3	4	5	6	7	
8	9	0	(	)	:	/	
?	@	*	-	#	a~z	CLR	
DEL	CPS	SPC		BkSp	<-	->	

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 12 characters can be input in this field.

ID	<input type="text"/>	Save	Cancel			
1	2	3	4	5	6	7
8	9	0	(	)	:	/
?	@	*	-	#	a~z	CLR
DEL	CPS	SPC		BkSp	<-	->

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.

Height	<input type="text"/>	cm	Save	Cancel		
1	2	3	4	5	6	7
8	9	0	(	)	:	/
?	@	*	-	#	a~z	CLR
DEL	CPS	SPC		BkSp	<-	->

Figure 4-5 Height

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

▪ **Weight**

Available options are Kg and Lb. Factory default setting is Kg.

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

Weight	<input type="text"/>	Kg	Save	Cancel		
1	2	3	4	5	6	7
8	9	0	(	)	:	/
?	@	*	-	#	a~z	CLR
DEL	CPS	SPC		BkSp	<-	->

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 12 characters can be input in this field.

Physician	<input type="text"/>	Save	Cancel			
a	b	c	d	e	f	g
h	i	j	k	l	m	n
o	p	q	r	s	t	u
v	w	x	y	z	0~9	CLR
DEL	CPS	SPC		BkSp	<-	->

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.
-

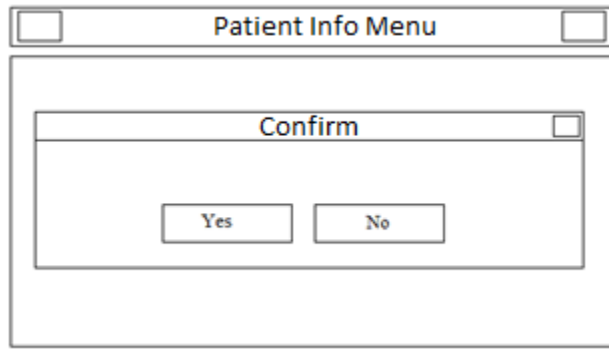


Figure 4-8 Confirmation Menu

## Chapter 5. Data Management

### 5- 1 General

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

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

### 5- 2 Memory Menu

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

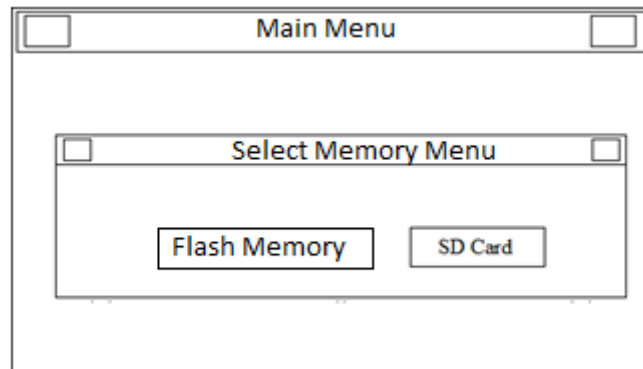


Figure 5-1 Select Memory Menu

- **Flash Memory:** Select to access Flash Memory (Figure 5-2).

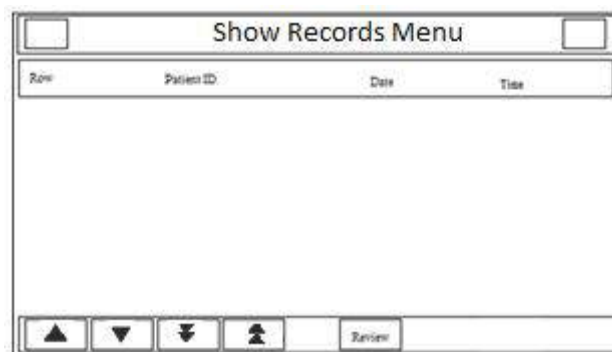


Figure 5-2 Flash Memory

- **SD Card:** Select to enter the patient ID on SD Card as shown in the figures below.

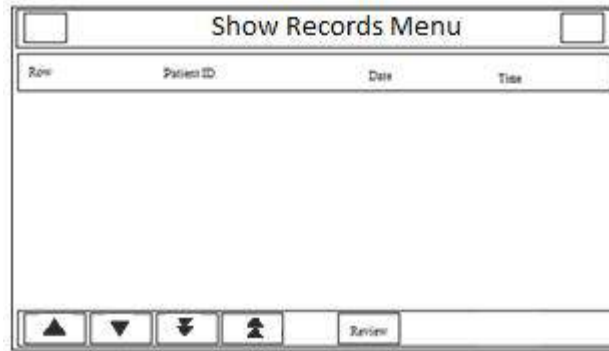


Figure 5-3 SD Card Menu

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
- Press **▼** or **▲** to move to the previous or next pages.
  - Press **▼** or **▲** to move to the previous or next records.
  - Press **REVIEW** to see the record information which is Highlighted.

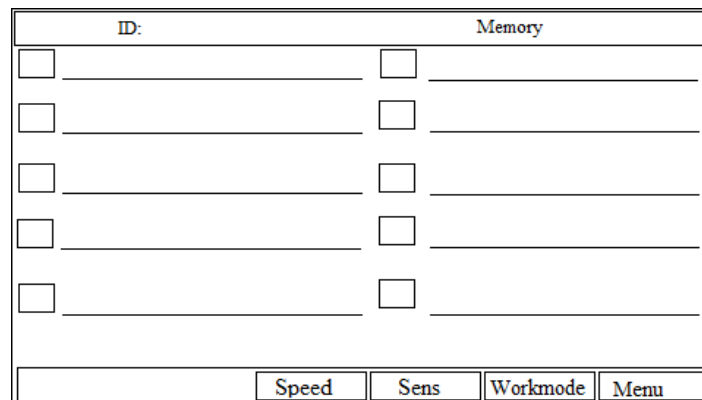


Figure 5-4

This page contains this information:

- \_ ECG waveforms
  - \_ Speed, Gain and recording mode
  - \_ Filter name
  - \_ Patient ID
  - \_ Memory(indicates that user is in Memory page not Main page)
- Press Start/Stop key to print the stored ECG signals in the same condition as the recording time.

## Chapter 6. Recording Operation

This section will explain recorder operation.

---

### **NOTE**

- 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 Dena350 Electrocardiograph complies with AAMI EC11 standard requirements.
- 

### **6- 1 General**

Dena350 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)
- 3- channel waveform recording
- Real time and Synchronous recording
- Periodic recording with adjustable time intervals
- Rhythm lead recording in three channels



## 6- 2 Recording Type

### 6-2-1- Manual Recording

Press **Mode** key on the screen or the control panel to toggle between Manual 1, Manual 1+1, Manual 2, Manual 2+1 and Manual 3.

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

- Note that you can only record the selected leads.
  - Augmented (+1) in these modes refer to Rhythm Lead. Select this lead in menu setting.
- 

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

■ Manual 1+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 above waveform indicates the waveform of selected lead and the below one is the waveform of selected Rhythm lead.

■ Manual 2 :Select this mode and press **◀Lead** and **Lead▶** keys to choose between lead groups. Then press the Start/Stop key to start recording.

■ Manual 2+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 above waveform indicates the waveform of selected lead and the below 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.

In manual modes, press **◀Lead** and **Lead▶** keys to choose between lead groups and press Start/Stop key to stop recording.

### 6-2-2- Automatic Recording

Press **Mode** key on the screen or the control panel to toggle between **Auto1**, **Auto 1+1**, **Auto2**, **Auto2+1** and **Auto3**.

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

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

In the recording paper the above waveform indicates the waveform of selected lead and the below one is the waveform of Rhythm lead.

- Auto 2: Select this mode and press the Start/Stop key to start recording.
- Auto 2+1: Select this mode and press the Start/Stop key to start recording.

In the recording paper the above waveform indicates the waveform of selected lead and the below one is the waveform of Rhythm lead.

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

### 6-2-3- 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 three channels of recording in this mode.

### 6-2-4- Periodic Recording

To perform periodic recording:

1. Set On “Periodic Recording” (Menu>>User Setting>> Next page>>Periodic Recording) and select your desired time interval (5-60 min).
2. Select number of recording repetition(Menu>>User Setting>> Next page>>Periodic Interval Repetition). 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.

## 6- 3 Copy Mode

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

---

### **NOTE**

- Only in Automatic and Periodic modes, stored data can be copied.
  - When the system is turned off and on, data cannot be copied.
-

## 6- 4 Recorder Paper

Use only heat sensitive recording paper with 63 mm width.

---

### Warning

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

#### 6-4-1- Paper loading

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

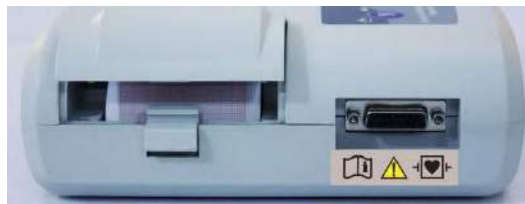


Figure 6-1

- Place the paper roll in the recorder.

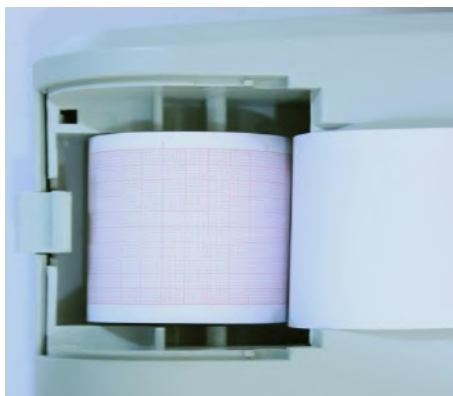


Figure 6-2

- Place the recorder door.



Figure 6-3

- Close the recorder door firmly.

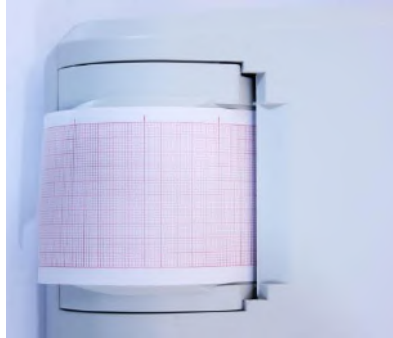


Figure 6-4

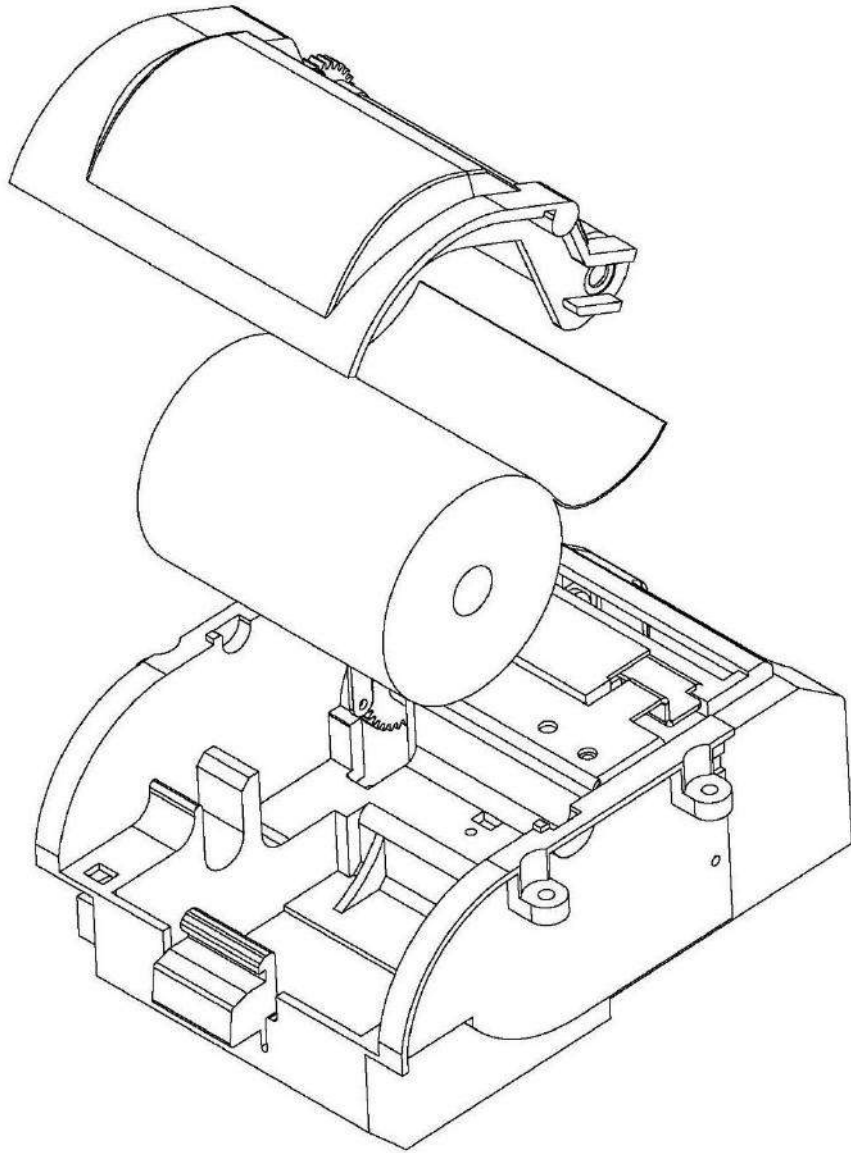


Figure 6-5

---

## **Warning**

- **Do not open the recorder door during recording. This can damage it.**
  - **During the recorder operation the record paper fed out with constant speed. 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 object. Therefore, if you find foreign matter on the detector, remove it and clean the detector.**
  - **Be careful when loading the paper in the recorder. Avoid damaging the thermal head. Do not touch thermal 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.**
-

**6-4-2- The following information are printed on the recorder paper**

- Recording mode
- Date and time
- Patient information
- Recording speed
- ECG lead, gain and filter
- System model, Software and Hardware version
- Patient blood type
- Heart Rate value



## Chapter 7. Patient Safety

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



This symbol indicates that the device has CF type and Defibrillation Proof applied part according to IEC60601-1. The modules with this symbol contain a CF-Type (Cardiac Float) and Defibrillation Proof applied part providing a high degree of protection against shock, and is usable during defibrillation.

---

### Warning

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

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

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

The electrocardiograph system is designed to operate under ambient temperatures between 5°C and 40°C. 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.

---

### **Warning**

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

## Chapter 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 power cable.

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, 2- 0.8 A 50/60 Hz.

- 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.

## **NOTE**

- **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 some hours while it is off.**
  - **The battery must be recharged after a while to ensure adequate electricity reserve. To do so, you only connect the system to AC INPUT.**
- 

8-3 Power on the electrocardiograph system.

Press Power key to turn on the electrocardiograph.

---

## **Warning**

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

## Chapter 9. Technical Specifications

<b><u>CLASSIFICATION</u></b>	
<b>Protection against electroshock</b>	Class I, Type CF Defibrillation proof (based on IEC 60601-1)
<b>Mode of operation</b>	Continues operation equipment
<b>Harmful Liquid Proof Degree</b>	Ordinary equipment, (without Liquid Proof)
<b>Method of disinfection</b>	Refer to chapter 10 for detail
<b>Safety of anesthetic mixture</b>	Not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
<b><u>DISPLAY</u></b>	
<b>Display</b>	TFT COLOR 800×480, 5”
<b>Waveforms</b>	12 Lead ECG/ Rhythm Lead
<b>Numeric Parameters</b>	HR
<b>Operation Method</b>	Membrane Keys and Touch
<b>Displayed data</b>	Waveforms, Patient Information (Name and ID), Recording Speed, Operation Mode, Filter, HR Value, Message
<b><u>ECG</u></b>	
<b>Input Channel</b>	Simultaneous acquisition of all 12 leads/ Rhythm Lead
<b>Standard leads acquired</b>	I, II, III, aVR, aVF, aVL, V1, V2, V3, V4, V5, V6
<b>Sensitivity Selection</b>	2.5, 5, 10, 20 mm/mV
<b>Filters</b>	Drift: on or off
	HUM: 50 or 60 HZ, off
	Low pass: 25, 35, 75, 150 HZ
	EMG: on or off
<b>Calibration</b>	1 mV
<b>Dynamic Range</b>	±5 mV
<b>Leakage Current</b>	< 10 μA
<b>CMRR</b>	> 98 dB
<b>Time Constant</b>	3.2 sec.
<b>Frequency Response</b>	0.05~150 Hz
<b>Pace</b>	Detection & Rejection: 0.1~2 ms, ±2~±250 mV Indication : 0.5~2 ms, ±2~±250 mV
<b>Standards</b>	IEC 60601-2-25:2011
<b><u>ECG Storage</u></b>	
<b>Internal Memory</b>	Up to 100 Records
<b><u>Recorder</u></b>	
<b>Model</b>	Thermal Printer
<b>Print Method</b>	Thermal dot line printing
<b>Dots per line</b>	448 dots

<b>Resolution</b>	32 dots/mm @ 25 mm/s (Horizontal)
	8 dots/mm (Vertical)
<b>Printing Speed</b>	6.25, 12.5, 25, 50 mm/s
<b>Paper Width</b>	63 mm
<b>Print Width</b>	56 mm
<b>Printed data</b>	12 Lead ECG Waveforms, HR Value, Patient Information, system model, software version, date and time, paper speed, sensitivity, filter
<b>Recording Mode</b>	Auto, Manual, Periodic
<b>Recording Format</b>	Auto 1, Auto1+1, Auto 2, Auto 2+1, Auto 3, Manual 1, Manual 1+1, Manual 2, Manual 2+1, Manual 3 and Rhythm
<b><u>GENERAL</u></b>	
<b>Safety</b>	Class I ( Based on IEC60601-1)
<b>Protection</b>	Against Defibrillator
<b>AC Power</b>	100-240 VAC, 60 VA, 50/60 Hz
<b>Internal Rechargeable Battery</b>	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
<b>Dimension</b>	210 mm (W) x 65 mm (H) x 260 mm (L)
<b>Weight</b>	1.5 Kg (approximately)
<b><u>Environment</u></b>	
<b>Temperature</b>	Operating: 5~40° C
	Storage : -25~60° C
<b>Humidity</b>	20~90 % (Non condensing)
<b>Altitude</b>	-200~3500 m
<b><u>Optional Interface</u></b>	
<b>USB Host</b>	FS/HS Speed – 5Vdc-MAX. 500 mA
<b>USB Device</b>	FS/HS Speed – 5Vdc-MAX. 500 mA
<b>SD Card</b>	



---

## Section 10- Care and Cleaning

### 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.

---

#### 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 electrocardiograph runs on the battery, at least once a month, until it turns itself off and then recharge the battery.**
-



---

## 10-2 Cleaning and Disinfection

- **General Points**

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 company.**
- **Allow the Electrocardiograph system to dry completely before making connections. And please make sure all connectors tightly connected to the system before using the system.**
- **Do not use ETO gas to disinfect the electrocardiograph.**

---

### **NOTE**

- **The electrocardiograph system and its belongings must be kept dust-free.**
  - **Do not use strong solvents such as acetone or ammonia.**
  - **Most cleaning agents must be diluted before use.**
  - **Don't use rough or sharp material or your fingernail to remove stubborn stains.**
  - **Do not let the cleaning agent enters into the chassis of the system.**
  - **Do not leave the cleaning agents on any part of the equipment.**
-

---

- **External surfaces**

In-between patients and as required:

For cleaning: wipe gently using a moist cloth and warm soapy water or mild detergent and for disinfection use the following recommended agents:

- Alcohol 70%
- Isopropyl alcohol
- N-propanol

- **Display screen**

In-between patients and as required use clean and soft cloth with neutral detergent and with Isopropyl alcohol may be used for cleaning and disinfection.

---

**NOTE**

- **Take extra care when cleaning the screen because it is more sensitive to rough cleaning methods than the housing.**
  - **Don't spray a liquid directly on the screen.**
- 

- **Accessories**

To clean, disinfect and sterilize reusable ECG cable, lead wires & electrodes (Clamp electrode, Chest electrode, Suction chest electrode), and so forth, refer to the instructions delivered with the accessories.

Also, trolley (if applicable) should be cleaned and disinfected after each patient or when necessary, using a soft, clean cloth soaked in mild soapy water and, if necessary, Isopropyl alcohol, and then wiped with a dry cloth.

---

**Warning**

- **To avoid damaging of the ECG cable, lead wires and electrodes do not immerse it in any liquid.**
  - **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.**
-

---

- **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 because thermal head and its surrounding area are hot during and after recording.**
-

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

Device parts	Single-use	Cleaning	Disinfection	Sterilization
<b>External surface of device</b>	-	In-between patients and as required wipe gently using a moist cloth and warm soapy water or mild detergent.	In-between patients and as required use <ul style="list-style-type: none"> <li>■ Alcohol 70%</li> <li>■ Isopropyl alcohol</li> <li>■ N-propanol</li> </ul>	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.
<b>Trolley</b>	-		In-between patients and as required use <ul style="list-style-type: none"> <li>■ Isopropyl alcohol</li> </ul>	
<b>Display screen</b>	-	In-between patients and as required: <ul style="list-style-type: none"> <li>Clean and soft cloth with screen cleaner or mild soapy water</li> </ul>		
<b>Recorder (printhead)</b>	-	as required: <ol style="list-style-type: none"> <li>1. Gently wipe around the printhead using cotton swabs dampened with alcohol.</li> <li>2. After the alcohol has completely been dried, reload the paper and close the recorder door.</li> </ol>	use as required <ul style="list-style-type: none"> <li>■ Isopropyl alcohol</li> </ul>	
<b>ECG Accessory</b> (Cables, lead wires, Electrodes)	disposable electrodes	<b>According to the instructions delivered with the reusable accessories</b> To clean, disinfect and sterilize reusable accessories, refer to the instructions delivered with them.		

### 10-3 Preventive Maintenance (PM)

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

---

#### **NOTE**

- **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.**
- 

Daily check of the following items is recommended:

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

Weekly check of the following items is recommended:

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

Monthly check of the following items is recommended:

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

**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.

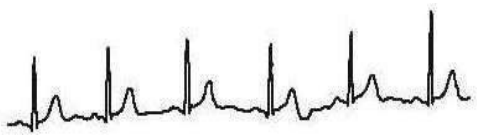
<b>SAADAT Co.</b>					
<b>Form No. : PL-F-33-V1</b>		<b>PM Form ( Electrocardiograph )</b>			
<b>State:</b>		<b>City:</b>	<b>Healthcare center:</b>	<b>Ward:</b>	
<b>Device model:</b>		<b>Serial number:</b>	<b>Installation date:</b>	<b>Inspection date:</b>	
<b>No.</b>	<b>Test and Inspection Item</b>		<b>OK</b>	<b>NOK</b>	<b>N/A</b>
<b>1</b>	<b>Visual inspection</b>	No damage or breakage in the case			
		Correct function of the touch screen			
		Correct function of the keyboard			
		Cleaning and disinfection according to the user manual			
<b>2</b>	<b>Display screen</b>	Correct display of Waveform area and information			
<b>3</b>	<b>Battery</b>	Unplugging the system (check the battery function)			
		Periodic usage of the battery			
<b>4</b>	<b>Saving date&amp; time settings</b>				
<b>5</b>	<b>Saving system settings</b>				
<b>6</b>	<b>Accessories</b>	Check ECG cable (clamps, leadwires, trunk)			
		Check ECG clip clamp and suction bulb (visual and sulfation test)			
		Cleaning and disinfection according to the user manual			
<b>7</b>	<b>Recorder</b>	Correct function of the recorder			
		Appropriate size of the recorder paper			
		Check the eject key function on the recorder door			
		Check the paper holder			
		Check the recorder error messages			
<b>8</b>	<b>Review</b>	Check Review window periodically			
<b>Final result: Pass <input type="checkbox"/> Fail <input type="checkbox"/></b>					
<b>Expert recommendation:</b>					
<b>Name and signature of person in charge:</b>			<b>Name and signature of expert:</b>		


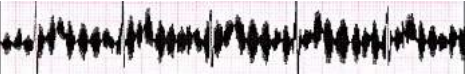
## Chapter 11. Troubleshooting

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		<ul style="list-style-type: none"> <li>● Check AC power path</li> <li>● Call After- Sales Services.</li> </ul>
The device is unable to run on the battery	<ul style="list-style-type: none"> <li>● Battery is discharged.</li> </ul>	<ul style="list-style-type: none"> <li>● Charge the battery for 5 hours</li> <li>● Call After- Sales Services.</li> </ul>
NO ECG waveform	<ul style="list-style-type: none"> <li>● ECG cable connection failure</li> <li>● Faulty ECG cable</li> <li>● Improper placement of electrodes</li> </ul>	<ul style="list-style-type: none"> <li>● Check ECG cable connection.</li> <li>● Short circuit all leads with each other. If ECG cable is ok, lead error message will not appear.</li> <li>● Do not use old and faulty electrodes.</li> <li>● Call After- Sales Services.</li> </ul>
Inappropriate HR value	<ul style="list-style-type: none"> <li>● Noisy and improper ECG signal</li> </ul>	<ul style="list-style-type: none"> <li>● Check leads and electrodes</li> <li>● Put the patient in a stable condition.</li> <li>● Call After- Sales Services.</li> </ul>
<p>There is irregular up and down shifts in ECG waveform from baseline</p> 	<ul style="list-style-type: none"> <li>● Various electrodes are used together</li> <li>● Loose connection of electrodes to lead wires</li> <li>● Electrodes are placed on bony site of body.</li> <li>● Unclean or sulfated electrodes</li> <li>● Insufficient gel is applied to electrodes.</li> <li>● Patient skin is not clean</li> <li>● Abnormal patient breathing</li> </ul>	<ul style="list-style-type: none"> <li>● Check connection of electrodes to lead wires.</li> <li>● Check proper placement of electrodes.</li> <li>● Clean electrodes after each use.</li> <li>● Apply sufficient gel.</li> <li>● Clean patient skin by alcohol.</li> <li>● Relax patient in a comfortable position.</li> <li>● Press Reset key.</li> <li>● If the problem still persists, use Drift filter.</li> </ul>

Problem	Possible Cause	Solution
<p>High frequencies and muscle artifacts make ECG signal noisy. (This may occur concurrently with AC noises)</p> 	<ul style="list-style-type: none"> <li>● Patient has stress or placed in an uncomfortable condition.</li> <li>● Patient feels cold and starts shaking.</li> <li>● Improper placement of patient hands and feet.</li> <li>● Bed dimensions are not suitable for comfortable placement of patient hands and feet.</li> <li>● Limb electrodes are attached tightly.</li> </ul>	<ul style="list-style-type: none"> <li>● Relax the patient.</li> <li>● Check electrodes connection.</li> <li>● If the problem persists, use Low pass filter.</li> <li>● Call After- Sales Services.</li> </ul>
<p>Noisy ECG signal due to AC power interferences</p> 	<ul style="list-style-type: none"> <li>● Electrodes are placed on bony site of the patient body.</li> <li>● Unclean or sulfated electrodes</li> <li>● Insufficient gel is applied.</li> <li>● Contact with metal parts of bed, trolley, etc.</li> <li>● Lead wires, patient cable or power cable fails to make connection.</li> <li>● There are other electronic devices in the vicinity of the electrocardiograph.</li> <li>● Improper ambient light for example using fluorescent lamp in the room which ECG record is taken.</li> <li>● Incorrect HUM Filter is used.</li> <li>● Improper Earth system</li> </ul>	<ul style="list-style-type: none"> <li>● Check electrodes and lead wires connection.</li> <li>● Check that lead wires are not tangled.</li> <li>● Check that the patient does not contact the metal parts.</li> <li>● Check that patient cable and power cable have no contact.</li> <li>● Check the selected HUM Filter.</li> <li>● 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.</li> <li>● 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.</li> </ul>



## APPENDIX I - Accessory

### General

This section lists the recommended accessories used for the electrocardiograph.

### Warning

- 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.
- The electrocardiograph system should be used with outlet by earth wire.
- Use only the manufacturer recommended ECG cable. Other ECG cables and leads may cause improper device performance, patient injury and inadequate protection during defibrillation.
- Use only the manufacturer recommended paper.
- It is recommended to use manufacturer recommended suction, chest electrodes and gel.

Accessories	Part #
• EKG Clamp electrodes, Adult, FIAB, Ref F9024SSC	P28042
• EKG Suction chest electrode, Adult , FIAB, Ref F9009SSC	P28043
• EKG Clamp electrodes, Pediatric, FIAB , Ref F9023SSC	P28047
• ECG Suction chest electrode, Pediatric-FIAB , Ref F9015SSC	P28048
• Electrocardiograph Cable,10wires, Banana Ends (SAADAT)	P28078
• ECG GEL	P28045
• Recorder Paper, 63 mm , Roll	P31017

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

Item	Selection	Default
<b>Task bar Menu</b>		
Recording Mode	Manual 1, Manual 1+1, Manual 2, Manual2+1, Manual3, Auto 1 , Auto1+ 1 , Auto 2 ,Auto 3, Auto 2+1, Auto 3 and Rhythm	manual1
Sensitivity	2.5, 5, 10, 20 mm/mv	10
Paper Speed	6.25, 12.5, 25, 50 mm/s	25
<b>User Setting Menu</b>		
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
Hospital/Ward		blank
Periodic Recording	5-60 min, Off interval=5	Off
Periodic Interval Repetition	1-20, Infinite interval=1	Infinite
Pace	On/Off	On

Appendix II – List of System Parameters

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

Item	Selection	Default
<b>Memory Menu</b>		
Name		
ID		
Search	-	
<b>Show Records Menu</b>		
Page up	-	
Page down	-	
Cursor up	-	
Cursor down	-	
Delete	-	
Review	-	
<b>Review</b>		
Back	-	
<b>Patient Info Menu</b>		
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
<b>Leads Error Messages</b>			
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.

Message	Cause	Solution	Remarks
<b>System Memory Messages</b>			
load File Error	SD Card or inner memory loading problem.	Select record again from the memory page.	The message blinks in red color on the screen.
Check SD Card	There is no SD Card in the SD Card socket.	Put a SD Card in the SD Card socket properly.	The message blinks in red color on the screen.
SD Init. Error	Problem in preparing SD Card.	Open the saved records on SD Card. Turn the system off and on.	The message blinks in red color on the screen.
Error101	Error in connecting with analog board.	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.
Error102	Error in connecting with inner memory.	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.
Error103	Error in connecting with Touch Screen module.	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.
Error104	Error in connecting to the RTC module	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.
<b>Battery Error Messages</b>			
Battery Low	Low battery voltage	Connect the power cable to the system.	The message blinks in red color on the screen.
<b>Touch Screen Error Messages</b>			
Touch is Off	Touch is deactivated	Enable touch screen in System Settings menu	The message blinks in red color on the screen.
<b>Recorder Error Messages</b>			
Check Paper	Paper roll is used up.	Insert a new paper roll into the recorder.	The message blinks in red color on the screen.
Door Open	Recorder door is open.	Close the recorder door.	

## APPENDIX IV-EMC

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

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



<b>Guidance and manufacturer's declaration – electromagnetic immunity</b>			
<b>The electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the electrocardiograph should assure that it is used in such an environment.</b>			
<b>Immunity test</b>	<b>Port</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
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 % $U_T$ ; 1 cycle and 70 % $U_T$ ; 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.			

<b>Guidance and manufacturer's declaration – electromagnetic immunity</b>			
<b>The Electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the electrocardiograph should assure that it is used in such an environment.</b>			
<b>Immunity test</b>	<b>Port</b>	<b>Compliance level</b>	<b>Electromagnetic environment – guidance</b>
Conducted RF IEC 61000-4-6	Input a.c. power	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz	
	Electrocardiograph coupling	80 % AM at 1 kHz	
	Signal input/output parts		
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 <sup>a)</sup> (MHz)	Service <sup>a)</sup>	Modulation <sup>b)</sup>	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation <sup>b)</sup> 18 Hz	1.8	0.3	27
450	430-470	GMR S 460, FRS 460	FM <sup>c)</sup> ±5 KHz deviation 1 KHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation <sup>b)</sup> 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GS M 800/900, TETRA A 800, iDEN 820, CDMA A 850,	Pulse modulation <sup>b)</sup> 18 Hz	2	0.3	28
870						
930						

1720	1700-1990	GS M 1800; CDM A 190 0; GS M 1900; DECT; LTE Band 1, 3, 4 25; UMTS	Pulse modulation <sup>b)</sup> 217 Hz	2	0.3	28
1845						
1970						

2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation <sup>b)</sup> 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation <sup>b)</sup> 217 Hz	0.2	0.3	9
5500						
5785						

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