POOYANDEGAN RAH SAADAT Co.

Electrocardiograph

DENA 1210

User Manual

CE 2195

D00948-9

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Contents

About the user manual I
Symbols II
Patient's safety III
1) Introduction 1
DENA 1210 introduction 2
General description 2
Intended use 2
Indications 2
Contraindications 2
Target population 2
Intended user 2
Principle of operation 2
Performance characteristics 2
Undesired side effects 3
Intended environment 3
Get started 4
Top panel 5
Display screen 5
Buttons and indicators 8
Recorder 10
Bottom panel 14
Rear panel 15
Side panel 15
2) System settings 17
General information 18
Recording Mode menu 19
Rec. Setting menu 21
Filter menu 22
User Setting menu 24
Patient Information 25
Setting menu 27
3) Patient preparation 38
Actions before recording 39
ECG electrodes connection 39

Connection of the Limb electrodes 40
Connection of the Chest Electrodes 40
Detection of electrode disconnection 41
Color codes and Labels of electrodes 42
Lead placement diagram 43
4) Recording Operation 44
Recording Types 45
Manual Recording 45
Automatic Recording 45
Rhythm Recording 46
Periodic Recording 47
PACS 48
PACS Archive 50
5) ECG analysis and measurement 51
General information 52
Reported parameters in Global mode 52
Heart Axis 53
QTc parameter 53
Reported parameters in Details mode 54
6) Data management 57
General information 58
Archive menu 58
Transfer menu 60
Online data transfer to PC 61
7) Care and Cleaning 63
System check 64
Maintenance 65
Cleaning & Disinfection 66
External surfaces of the device 66
Display screen 66
Recorder 67
Accessories 67
Preventive Maintenance 69
8) Troubleshooting and Error messages 71
Troubleshooting 72
Error messages 74
9) Technical specifications 77

Appendix 1: Accessories....81
Appendix 2: System parameters....83
Appendix 3: Electro-magnetic compliance....87
Appendix 4: The GLASGOW program....93
Appendix 5: Dena Viewer software....101
Software installation....102
Connecting the device....105
Using the software....109
Online mode....110
Offline mode....114

About the user manual

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 knowledge of medical actions, terminology and procedures as required for correct device operation.

Explanations of the used expressions in this manual

Warning

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

Note

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

Version information

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

Release date	Version
Dec. 2024	D00948-V9

Symbols

Symbol	Description
	Consult user manual of the device and pay attention to the warnings and cautions.
	The device is IEC60601-1 type CF (Defibrillation proof applied part) equipment. The units displaying this symbol provide an F-type isolated (floating) patient applied part with a high degree of protection against shock and is suitable to use with defibrillator simultaneously.
	For protection against defibrillator, use only manufacturer recommended accessories.
	The equipment shall be disposed of in an environmentally-friendly manner.
100-240 VAC 120 VA 50/60 Hz	AC power supply
	10 A fast fuse
SN	Serial number
MD	Medical device
CE 2195	CE mark and NB identification number
UDI	Unique device ID
IR **20XX**	Manufacture date and country code
	Manufacturer information
EC REP	European community representative
	Equipotential grounding system.

Patient’s safety

Introduction

The DENA 1210 electrocardiograph device is designed to comply with the international safety standards requirements for medical electrical equipment. This device has floating input (isolated electricity) and is protected against the effects of defibrillation. If correct electrodes are used in accordance with the manufacturer instructions, the display screen will recover within 10 seconds after defibrillation.

Grounding

To protect the patient and hospital personnel, the electrocardiograph system must be grounded. The DENA 1210 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

- Dena 1210 electrocardiograph is intended to be used only by qualified medical staff.
- Before using the Dena 1210 electrocardiograph, read the user manual and its accessories thoroughly.
- Dena 1210 electrocardiograph is intended for use only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.
- DENA 1210 is not a therapeutic device. The results provided by the device should be evaluated based on the patient's clinical condition and these results cannot replace routine examinations.

- 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 electrocardiograph and devices connected to it should form an equipotential body to ensure effective grounding.
- Before using the Dena 1210 electrocardiograph, the operator must ensure the safety and correct operation of the device and its accessories. (Device calibration date must be valid).
- Do not touch the patient, bed or devices nearby during defibrillation.
- Disposable electrodes are recommended when using defibrillator and electrosurgery with an electrocardiograph.
- When defibrillator is used, the signals may be disturbed for a few seconds, after which the device will continue to operate normally.
- For people who have a pacemaker, be sure to enable the pacemaker detection feature on the device.
- The physician shall consider all known side effects when using the Dena 1210 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 connect devices that are not part of the Dena 1210 electrocardiograph.
- Do not expose DENA 1210 near any local heating item such as the direct Sunlight.
- It is possible to increase leakage current when touching the patient and connected devices, or when several systems as well as DENA 1210 are connected to the patient simultaneously.
- Due to the possibility of explosion, the equipment is not suitable for use in the presence of a flammable anaesthetic mixture or in oxygen-rich places.
- To protect patient against the electrical shock hazards, DENA 1210 needs to be connected to grounded power receptacle.
- The location of the device shall be such that when necessary, the plug of the device can be easily disconnected from the electrical outlet.
- If any liquid is spilled on the system or accessories, immediately turn off the system and wipe up it by a soft cloth. If water seeps into the device, it should be inspected by trained personnel before reuse.
- Electric and magnetic fields cause the device to malfunction. The Dena 1210 electrocardiograph must be installed and serviced in accordance with the information in Appendix 3 Electromagnetic Compatibility (EMC).
- To prevent EMC effect on DENA 1210, 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.
- DENA 1210 is not intended for MRI use.
- Do not use DENA 1210 during X-ray and Magnetic Resonance imaging. Induced current could potentially cause burns and may affect the accuracy of DENA 1210 measurements. DENA 1210 may also adversely affect MRI and X-ray images.

Note

- Before connecting the device to the power supply, make sure that the voltage and frequency match the specifications of the device.
- The environment in which the device is used must be free from vibration, dust, corrosive and flammable gases, high temperature and humidity.
- The device is designed to work well at temperatures between 5 and 40 degrees Celsius. When the ambient temperature exceeds this range, it adversely affects the measurement accuracy of the device and may damage electrical circuits.
- The Dena 1210 electrocardiograph software is designed in such a way that minimize the risk of software errors.
- According to the frequency band up to 150 Hz and the sampling rate of 1000 samples per second, the accuracy of signal reconstruction in Dena 1210 electrocardiograph is in accordance with the requirements of IEC 60601-2-25.

1) Introduction

DENA 1210 introduction

General description

DENA 1210 (ECG Recorder) is one of the most important, safest, and simplest medical devices for measuring, displaying, storing, and recording cardiac signals to diagnose many heart diseases of adults, children and infants. This device is intended to be used by trained medical staff in all medical centers that have complied with the requirements of the medical locations.

Intended use

DENA 1210 is a device to acquire, analyze, display, store, and record ECG signal.

Indications

DENA 1210 is a device to acquire, analyze, display, store, and record Electrocardiographic data using surface electrodes for clinical diagnosis.

Contraindications

The device is not intended to be used in the following conditions:

- In case the patient is moving.
- To be used with high frequency surgery equipment
- To be used for Open Heart Applications (Intra-cardiac Application)
- To be used as a physiological vital signs monitor

Target population

Adults, children and infants

Intended user

Trained medical staff

Principle of operation

Acquisition of electrical cardiac signal via electrodes

Performance characteristics

- Color display and touch screen
- Lightweight and portable
- Works with rechargeable batteries or AC power
- Modern software based on Linux operating system
- Simultaneous displaying and recording of 12 leads ECG waveform
- Different modes of recording (Manual/ Auto/ Rhythm)
- Displaying Long-lead (3 leads maximum) waveform separately on the screen
- Smart Recording capability (assigning of proper space to each channel for minimizing interference of traces)
- Data storage in internal and external memories

- Displaying and recording stored data
- Data transfer via USB
- Upgrading the software via USB
- Signal analysis and diagnosing cardiovascular abnormalities – Measurement and Interpretation
- Measurement of cardiac angles
- Network Connection Capability
- Connectable to External Printer
- Ability to transmit patient signals to the PACS system

Optional:

- Transfer stored records or online signals to a computer via the USB port and display them in the Viewer software
- USB Type-B port to transfer online signals to a computer and display them in Dena Viewer
- Internal Wi-Fi
- Support Barcode Reader

Undesired side effects

Skin allergy when electrodes are attached.

Intended environment

Medical centers that have complied with the requirements of the medical locations

Get started

1- Open the package and take out the DENA 1210 and accessories carefully. Keep the package for possible future transportation or storage. If trolley is available, assemble it according to its instruction and place the electrocardiograph on it properly.

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

2- Connect the power cable to the device.

- Make sure the AC power supply complies with 100-240 VAC, 50 /60Hz.
- Plug the power cable to the power supply socket of the device. Connect the other end of the power cable to a grounded power receptacle.

3- Power on the DENA 1210.

- Press the Power key to turn on the electrocardiograph.

4- Connect the patient cable. Connect all necessary accessories to patient and the DENA 1210.

Warning

- If any sign or error message is observed in DENA 1210 that may be due to its failure, please do not use the device on the patient until the sign or error is eliminated.

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

Top panel

Figure 1-1 DENA 1210 top panel

① Display screen: ECG waveforms, patient information, messages, etc. are displayed on the screen. (More information follows).
② Recorder Release Button: to open the recorder door.
③ Recorder: to load recording paper and record ECG waveforms.
④ Control panel: to control the system operation. (More information follows).

Display screen

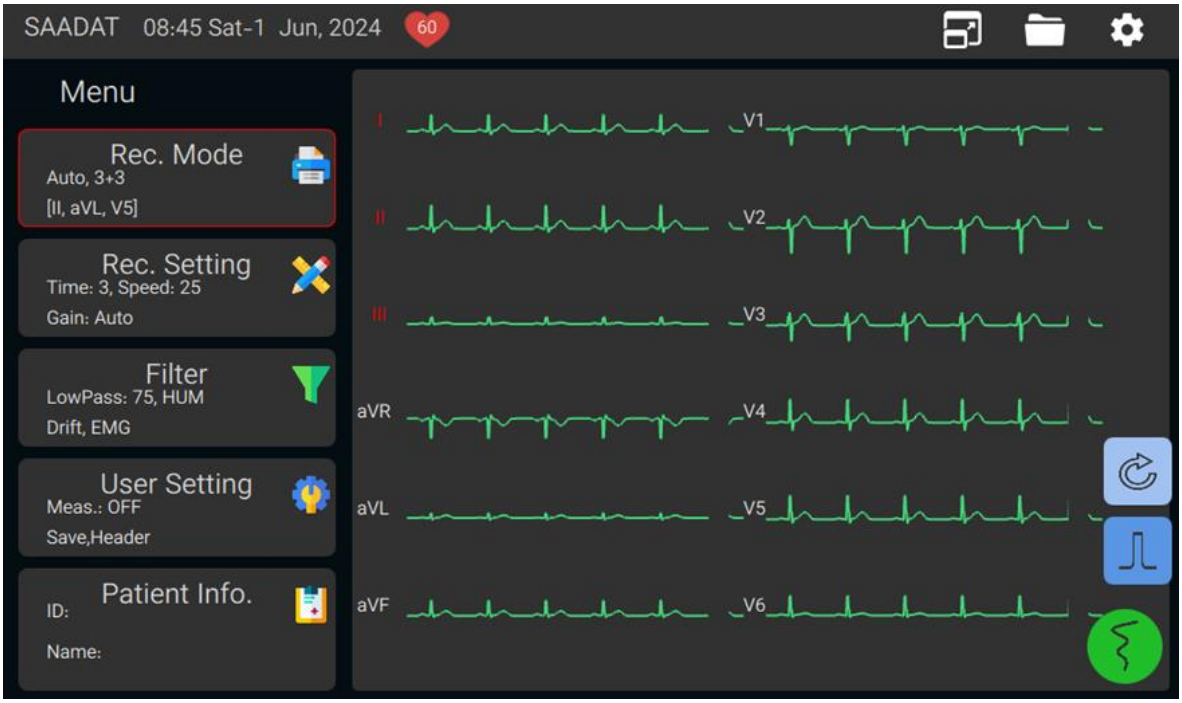


Figure 1-2 DENA 1210 display screen (default)

DENA 1210 has a TFT color screen. The 12-wave ECG waveform, HR numerical value, patient name and ID, date and time, device status and system messages are displayed on this screen. The screen can be divided into four parts:

1- Header area (figure 1-3)
2- Menus (figure 1-3)
3- Waveform and message area (figure 1-3)
4- Touch keys (figure 1-4)

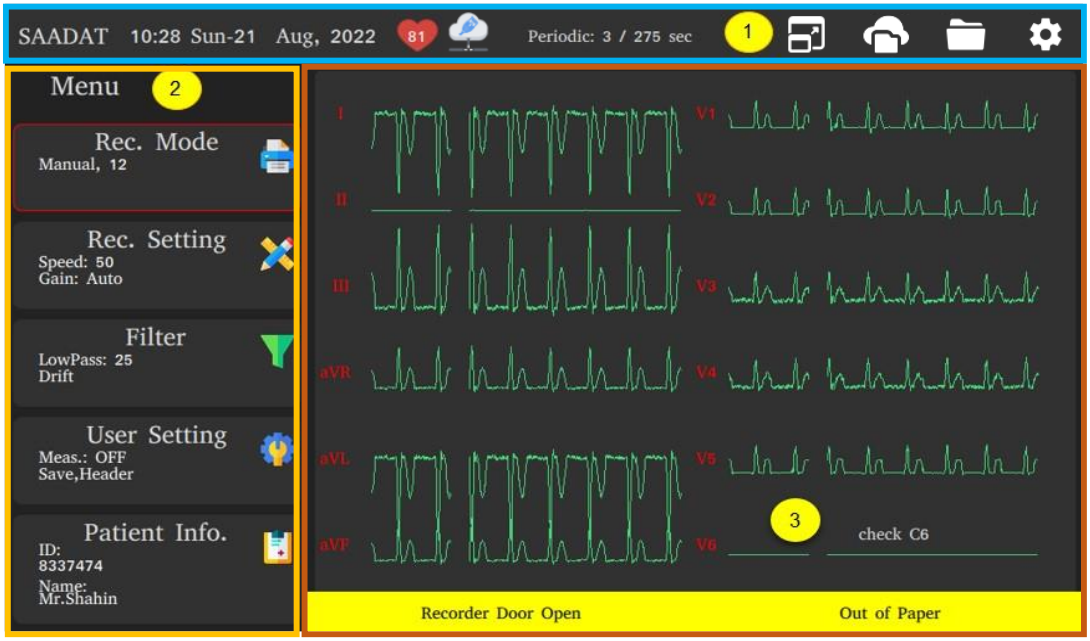


Figure 1-3 DENA 1210 display screen (with messages)

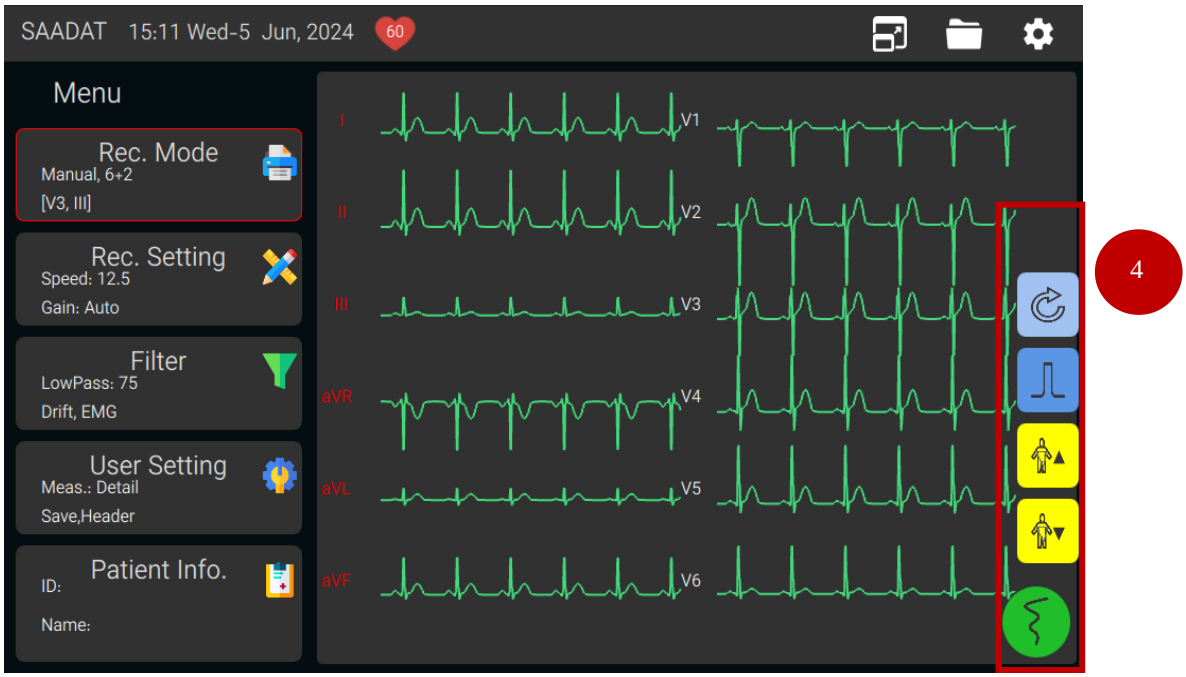


Figure 1-4 Touch keys

1. Header Area

The upper section of the screen is called Header Area. The parameters displayed in this area include PACS connection status (if PACS is activated), the numerical value of the HR, time, date and operating conditions of the device. This information is always displayed on the screen when the device is on. Touch keys to change the display mode, access the settings and archive menus are also in this area. If the device is not plugged in to the mains, the remaining battery charge is displayed in this area. It should be noted that the numerical value of HR is measured and updated in real-time.

Table 1-1: Touch keys of header area

	Used to switch waveform and message area to full screen or regular.
	Used to access PACS archive. (Displayed if PACS is activated.)
	Used to access archived data.
	Used to access device settings.

2.Menus

Using this section, you can easily change the recording settings, filters and patient information settings. More details can be found in the System Settings chapter.

3.Waveform and message area

12-lead ECG waveforms or Long lead waveform(s) are displayed on the screen. The name of the lead is displayed on the area corresponding to the ECG waveform.

Dena 1210 electrocardiograph constantly checks the connection of the electrodes and, if it detects that the electrodes are not connected properly, displays a message in the signal drawing area (such as lead V6 in Figure 1-3).

Device notification and error messages are displayed in yellow box at the bottom of this area.

4.Touch keys

Touch keys are located on the right corner of the screen. These keys become inaccessible while entering menus, recording or when error messages appear.

The function of Record key is exactly like Start/Stop button on the keyboard. The green color of this key means that touching it starts recording. While recording, the key turns red. When the word “Stop” is displayed on the key, touching it will stop recording. When recording the signal in the Rhythm mode, its color will be displayed in blue and a counter will appear inside the key. If External printer is selected in settings, Record key turns purple while recording.

Table 1-2: Touch keys

	Used to reset the Drift filter and return signals quickly to the screen.

	Used to record 1mv calibration signal.
	Used to retrieve the last saved record.
	Used to select the next lead / group of leads in Manual 3+, 6, 6+ modes.
	Used to select previous lead / group of leads in Manual 3+, 6, 6+ modes.
	Pressing the green key can record ECG signals. When recording is started, the key turns to red and pressing this key will stop recording. If PACS is activated, the record will be sent to PACS server.

Buttons and indicators

The Dena 1210 electrocardiograph is designed so that the operator can easily work with it using Start/Stop button along with a touch screen. Figure 1-5 shows the buttons and indicators of the Dena 1210 electrocardiograph.

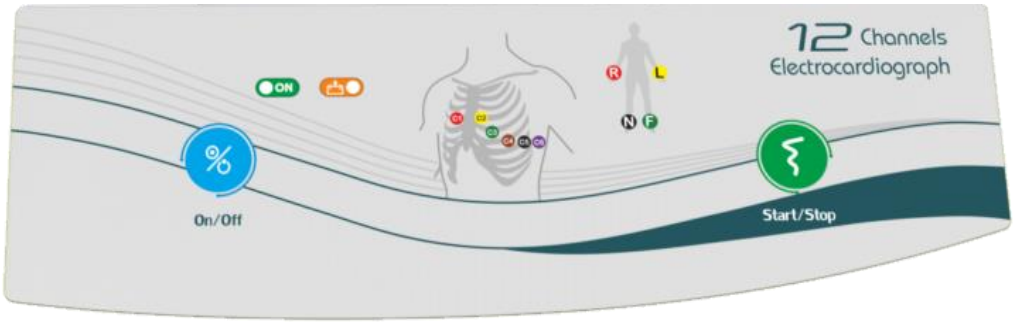


Figure 1-5 Buttons and indicators

Table 1-3 Functional keys and Indicators

	This key is used to turn the device ON and OFF.
	Indicates that the device is powered on
	Battery indicator (when the battery is fully charged it is green, otherwise it is red).
	Pressing this key can record ECG signals, and pressing this key again will stop recording.

Warning

- Before starting work with the Dena 1210 electrocardiograph, first check all the keys and make sure that they work correctly.
- Do not use sharp objects to touch the screen.

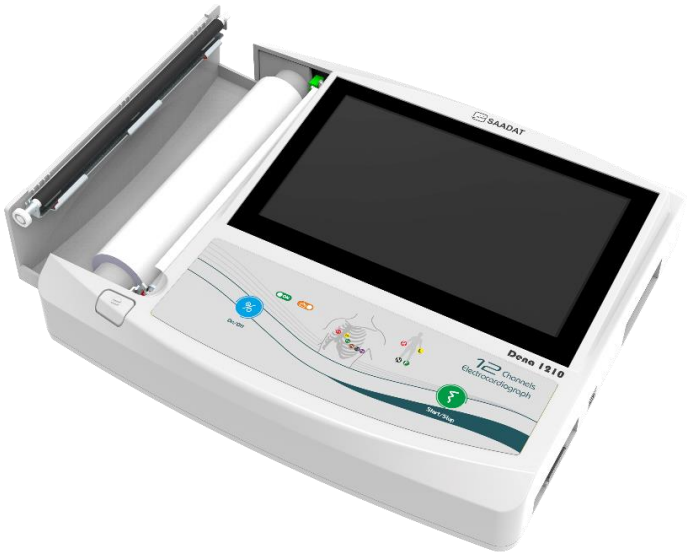
Recorder

Paper placement

1. Press the recorder release button as shown below and open the recorder door.

2. Place the roll of paper obliquely on the intended place and push it.

3. Place the other side of the paper roll in its proper place. Open the paper roll to leave some of it out of the recorder.



4. Close the recorder door.

Warning

- Use only the record paper recommended by the manufacturer, otherwise the quality of the record may be poor and the thermal head may be damaged.
- Only 210 mm heat-sensitive record paper should be used.
- The thermal head and its surroundings are very hot during and immediately after recording, and touching it can cause injuries such as burns.
- Do not open the recorder while the recorder is operating. This can damage it.
- The paper comes out at a constant speed while the recorder is working. Pulling the paper will damage the recorder.
- If the paper is jammed, do not pull it out by force. Open the recorder door and take out the paper.

Note

- • If there is paper or foreign object on the sensor, it cannot work properly. Therefore, if you see a foreign object on the sensor, remove it and clean the sensor.
- Be careful when loading the paper in the recorder. Avoid damaging the thermosensitive print head. Do not touch thermosensitive print head.
- It is recommended to use papers with colored markings to warn of approaching completion. The user must always make sure that the amount of paper is sufficient before recording.

Information printed on the recorder paper

1- Recording time and date,
2- System settings:
   - Recording type (Auto, Manual, Rhythm) and Status (Normal, Copy, Review, Periodic), and Format.
   - Recording time for each group of leads,
   - Rhythm lead(s),
   - Recording speed,
   - Recording gain,
   - Filters,
   - Pace status,
   - signal interpretation status,
   - Power supply type (AC, Battery),
   - Smart Record status
   - Save status
3- Patient Info:
   - Heart Rate numerical value,
   - Patient’s name, ID, gender, height, weight, age and blood type,
   - Physician name,
   - Hospital/Ward Name,
4- Device Info:
   - Manufacturer and device model,
   - Software version.

Note

- The paper space is divided according to the size of the signals. It should be noted that after connecting the cable, the patient should be given at least 4 seconds to calculate these values and the space should be divided proportionally between the leads. This feature is known as Smart Record and its activation / deactivation is determined by the user and the selected status is displayed as Smart Record in the record header. (Refer to chapter **2: System Settings** for more information)
- If there is a DC offset and the Drift filter is off or there is a Pacemaker in the patient's body and the device Pace option is off, the space may not be allocated properly.

Bottom panel

The following parts are located in the bottom panel of the device (Figure 1-5):

① **Handle**: Used to move and carry the device.
② **Battery compartment**: The device battery is placed in this box.
③ **Fast 10A fuse:** To prevent battery discharge in storage.

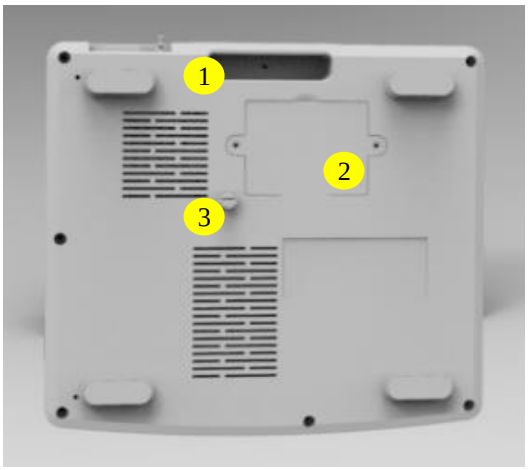


Figure 1-6 Bottom panel

Built-in battery

The Dena 1210 electrocardiograph has a rechargeable battery. The battery starts charging automatically when the device is connected to AC outlet. Turning the device on and off has no effect on charging the battery.

The charging and discharging time of the device can vary according to the type of battery used (its types are described in chapter **9: Technical Specifications**) and also the duration of use.

When the device is plugged in and charging, the battery indicator is not displayed on the header area. When the device is not connected to the power supply, the battery indicator shows the remaining charge in green. When the battery is running low, the charge level is shown in red.

Warning

- If the device is not to be used for a long time (more than 10 days), remove the fuse from the device to prevent full discharge of the battery.
- If the battery discharge time is less than 1 hour, the battery is defective and contact after-sales service to replace it.
- DENA 1210 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 cause a fire.

Note

- Make sure the battery indicator light is turned on. If the battery indicator does not light up, check the local power supply and power cord connection. If this problem persists, contact after-sales service.
- The battery needs to be charged after transport or storage. If in this case you try to turn on the device without connecting the power cable, the device cannot be turned on due to insufficient charge. In this case, connect the device to the mains for a period of time according to the type of battery (by referring to chapter **9: Technical specifications**).
- After working with the battery for a while, the battery needs to be recharged. To do this, it is enough to connect the device to AC mains.

Rear panel

The following parts are located in the rear panel of the device (Figure 1-7):

Figure 1-7 Rear panel

① **Power socket:** To connect the device to mains electricity supply
② **Equipotential jack**: To equalize the potentials of devices connected to the patient or each other simultaneously. (More information described in **Patient's safety** section)

Side panel

The following connectors are located in the side panel of the device (Figure 1-8):

Figure 1-8 Side panel

① **ECG cable connector:** To connect patient cable for ECG acquisition
② **PC Connector:** To connect the device to PC (optional)
③ **Network:** To connect the device to LAN
④ **USB connector for data extraction and software update:** To connect devices with USB such as flash memory, external printer or barcode reader.

2) System settings

General information

This chapter describes the different menus of the device.

Note

- Before recording, it is better to adjust the device according to your desired conditions.

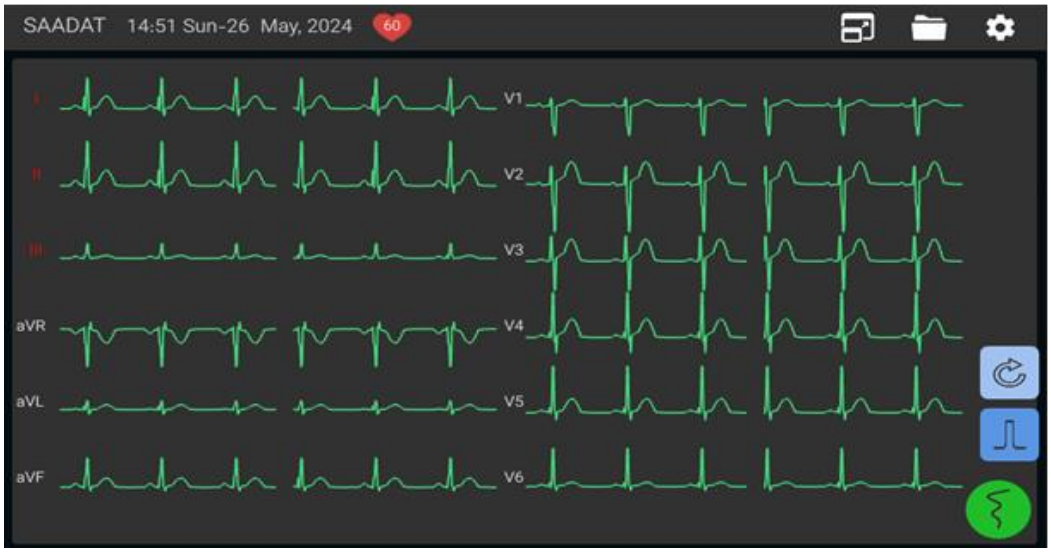


Figure 2-1 Main menu (full screen)

Dena 1210 electrocardiograph has a flexible configuration. By default, the Menu is on the left side of the screen. By changing the display mode to "Full screen" (by touching the icon), the Menu section is hidden and the waveforms are drawn in full screen.

In the Menu, there are Rec Mode, Rec Setting, Filter, User Setting and Patient Info sections, which can be selected according to the need. Other settings are in the Setting section (Touch icon). The following is a description of each of these sections.

Recording Mode menu

By selecting Rec. Mode from the main menu, different recording modes can be set as shown.

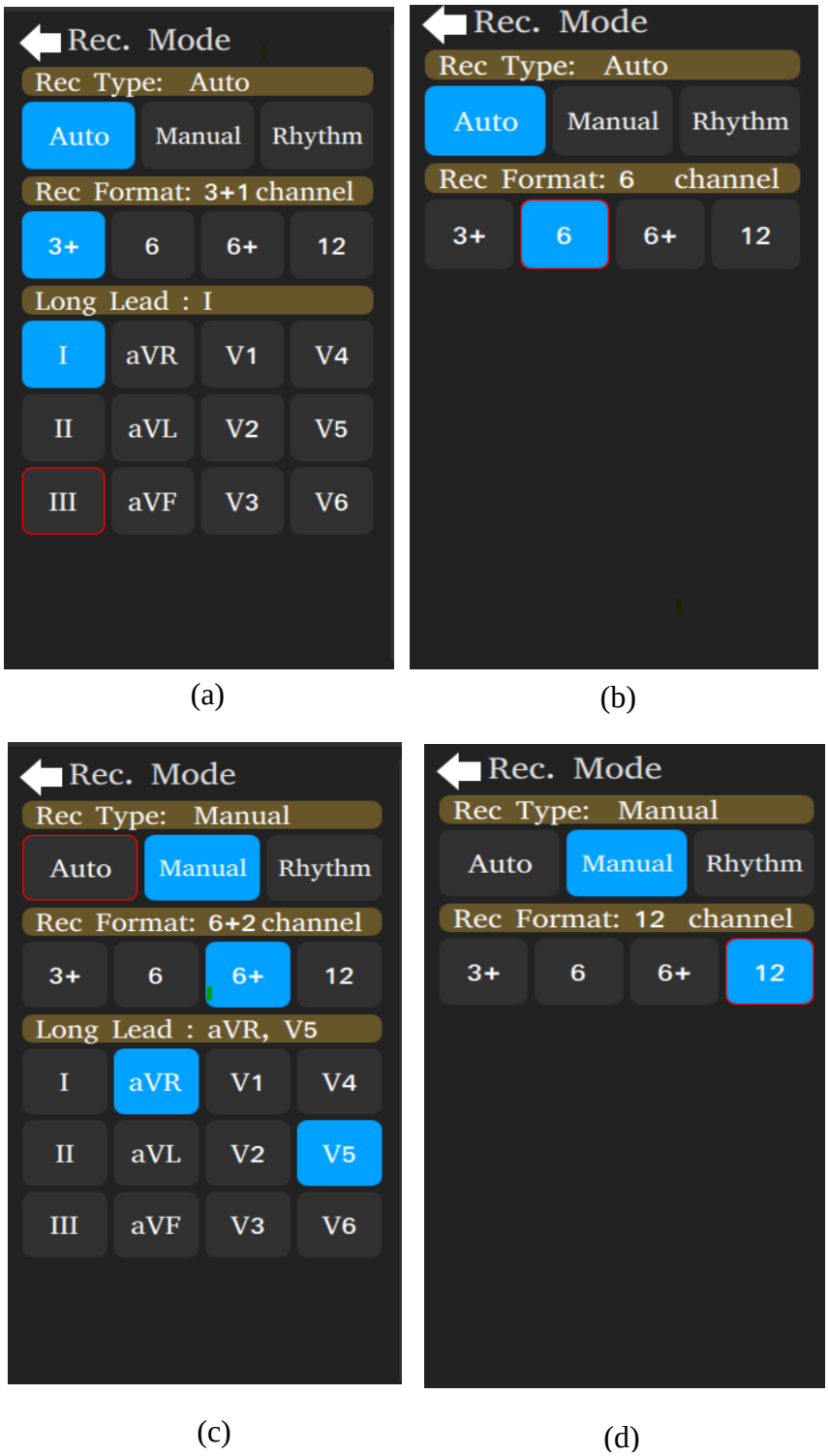


Figure 2-2 Rec. Mode menu:

(a) Auto3+1, (b) Auto 6,
(c) Manual 6+2, (d) Manual 12.

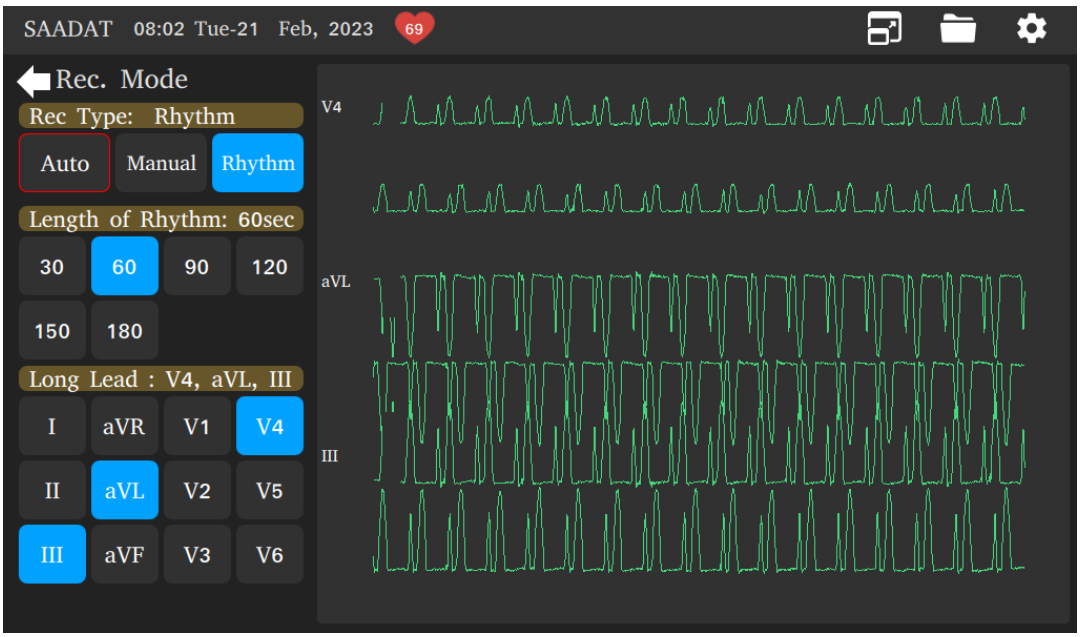


Figure 2-3 Rec. Mode menu: Rhythm

Based on the option selected in the Rec Type section, the following modes can be selected:

- Auto:
  - Rec. Format: 3+, 6, 6+ and 12 modes can be selected for recording. Selected option is displayed in the Rec. Mode brown box.
  - Long Lead (only in 3+ and 6+ modes): In this section, you can select at least 1 and at most 3 Long Lead leads. Selected items are highlighted in blue and written in the Long Lead brown box. You must re-select each item to delete or replace it.

- Manual:
  - Rec. Format: 3+, 6, 6+ and 12 modes can be selected for recording. Selected option is displayed in the Rec. Mode brown box.
  - Long Lead (only in 3+ and 6+ modes): In this section, you can select at least 1 and at most 3 Long Lead leads. Selected items are highlighted in blue and written in the Long Lead brown box. You must re-select each item to delete or replace it.

- Rhythm: In this case, the waveform area is assigned only to the rhythm lead(s).
  - Length of Rhythm: In this section, the recording time of the rhythm lead(s) can be selected from 30, 60, 90, 120, 150 and 180 seconds.
  - Long Lead: You can select at least 1 and at most 3 rhythm leads. Selected items are highlighted in blue and written in the Long Lead brown box. You must re-select each item to delete or replace it.
    Available rhythm lead are I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5 and V6.

Note

- For more details on recording types, see chapter **4: Recording Operation**.
- Recording in Auto and Rhythm modes is done as Sync, and in Manual mode as Real-time.

Rec. Setting menu

By selecting Rec Setting from the main menu, the following window will appear:

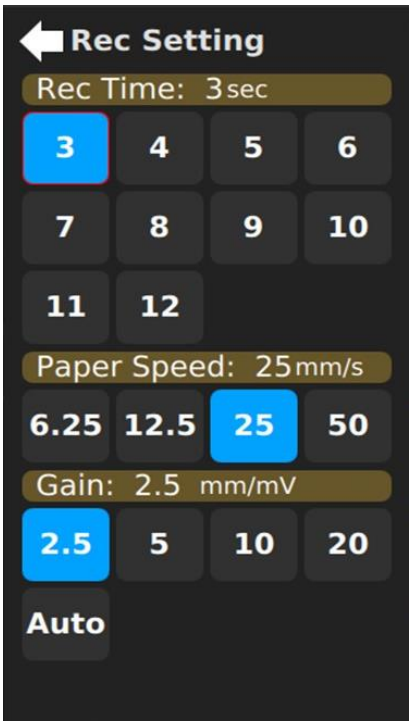


Figure 2-4 Rec. Setting menu

The following settings are applicable in this menu:

- Rec Time (Only when Rec Type: Auto): This option is used to set the recording time of leads in Auto mode, the available options are 3-12 seconds.
- Paper Speed: Used to set the recording speed. Available options are 6.25, 12.5, 25 and 50 (mm / sec).
- Gain: Used to adjust the ECG amplitude in the main screen and record. Available options are 2.5, 5, 10, 20 and Auto (mm / mV).

Note

- If Smart Record is activated (Refer to **System settings**), the Auto option for Gain is also activated and displayed and can be selected by the user. If this option is disabled, the Auto mode in Gain is also removed and its default option (10 mm/mV) is selected.
- If you select the Auto option, the device will automatically select the best gain for recording and display screen, and its value will be entered in the record header.
- Also, if the patient has a pacemaker and the Pace option is OFF, the Auto Gain function will be impaired.

Filter menu

By selecting Filter from the main menu, the following window will appear:

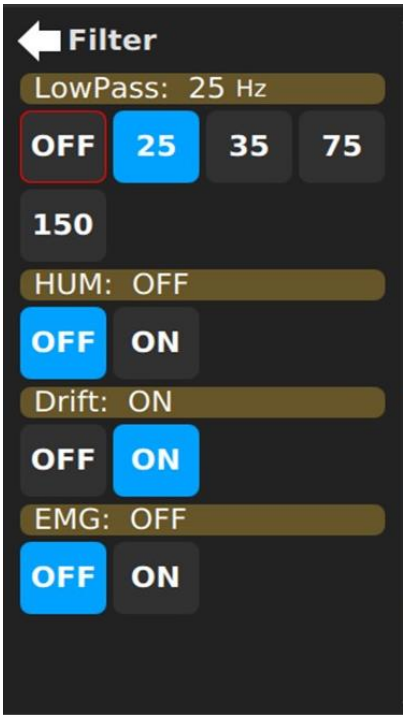


Figure 2-5 Filter menu

The following settings are applicable in this menu:

- Low Pass: Available options are Off and 25, 35, 75, 150 Hz. This filter is used to remove muscle noise and high frequency noise. Using these filters make the heart signal smoother and cleaner. The selected filter type or frequency is displayed on the screen and in the record header. If you select the Off option, this filter will be disabled.
- HUM: Available options are Off and On. The function of this filter is to eliminate the effects of mains noise on signals. By selecting the On option, the phrase "HUM" will be displayed on the screen and the record header, and if the Off option is selected, the phrase on the screen and the record header will not be displayed.
  This filter is automatically adjusted to the power line frequency (50 or 60 Hz) if it is On.
- Drift: Available options are On and Off. This filter reduces signal fluctuations (up and down signal reference line) that are mainly due to the patient's breathing and movement. By setting Drift filter: On, the phrase "Drift" is displayed on the record header and the screen.
- EMG: Available options are On and Off. This filter is used to remove muscle noise. By setting On, the phrase EMG is displayed on the screen and in the record header.

Warning

- The use of 25, 35, and 75 Hz Low Pass filters may reduce the amplitude of the heart signal and omit some useful signal details.
- If you turn on the local power noise cancellation filter, in proportion to the selected frequency, its third harmonic will also be removed. In other words, if the local power frequency is 50 Hz, in addition to the 50 Hz frequency, the 150 Hz frequency is also removed. If the power frequency of the local city is 60 Hz, in addition to the frequency of 60 Hz, the frequency of 180 Hz is also removed. The reason for this is to make the heart signal clearer and smoother.
- If the EMG filter is turned on, only 75 or 150 Hz options for the low-pass filter are available. Because if the EMG and the 25 or 35 Hz low-pass filters are on at the same time, significant changes will be observed in the signal amplitude.
- The EMG filter is a time-varying nonlinear adaptive filter designed solely for application to ECG signals. Due to the non-linear nature of this filter, the user should turn on and use it after receiving sufficient training from qualified people. In some cases, the above filter may reduce the amplitude of P and T waves and the QRS complex.

Note

- After setting EMG: On, first wait a few seconds, then start recording.
- Refer to chapter **8: Troubleshooting and Error messages** to eliminate ECG signal noise.
- If the drift filter is inactive and the signals have offset, the signals may not be at the same level with the corresponding labels and the paper space may not be partitioned correctly.
- For Low Pass Filters, the -3dB cut-off frequencies are at 150 ± 20 Hz, 75 ± 5 Hz, 35 ± 2 Hz and 25 ± 2 Hz, respectively.
- For Drift filter, -3dB cut-off frequency is at 0.6 ±0.1 Hz. If the drift filter is switched off, the cut-off frequency will be about 0.05Hz.
- It should be noted that the Drift filter can affect the analysis of the ST segment.
- Failure to display the signal and reaching the final line above or below the display range can mean that the signal is saturated.
- For EMG filter, -3dB cut-off frequency increases to about 55Hz in areas where the signal slope is high and decreases to about 10Hz when the signal slope is low.

User Setting menu

By selecting User Setting from the main menu, the following window will appear:

Figure 2-6 User Setting menu

The following settings are applicable in this menu:

- Pace: Available options are Off and On. DENA 1210 detects and rejects pacemaker-generated signals from ECG signal, so that they will be ignored in determining heart rate.
  For patients with Pacemaker, a red indicator is displayed on the screen where the Pace signal is detected in the ECG signal. In the record sheet, vertical bars are drawn at the location of the pace.
- Save: If this option is turned on, all Auto and Rhythm mode signals are saved along with patient information and are available in the Archive menu.
- Meas. & Interp.: If you select the Global or Details options, the corresponding measurement table will be printed at the end of the record. See chapter **5: Measurement and Interpretation** for more information. This option may not be enabled on your device at all. In order to activate it, contact the after-sales service unit.
- Header: By selecting On, the desired signal is printed along with the recording information at the beginning of the recorder paper, and if selected Off, this information is not printed and only the desired heart signal is printed without any information.

Warning

- For patients with Pacemaker, Pace should be On. Otherwise, Pacemaker signals may be considered as QRS.
- In patients with Pacemaker, if Pace is Off, it is best to turn off the 25Hz, 35Hz and EMG filters to diagnose Pacemaker malfunctions.

Patient Information

By selecting Patient Info from the main menu, the following window will appear:

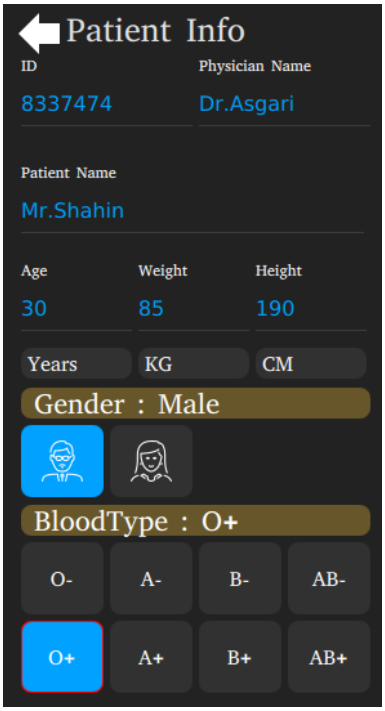


Figure 2-7 Patient Information menu

Note

- To enter textual or numeric information, the appropriate virtual keyboard (Figure 2-8) opens.
- Touch  key to access other languages of the keyboard.

- ID: Patient identification number, which can be up to 12 letters or numbers.
- Physician Name: The name of the physician, which can contain up to 20 letters or numbers.
- Patient Name: The patient’s name, which can contain up to 20 letters or numbers.
- Age: Indicates the patient's age. Patient age can be entered in Years or Months. To change the unit, just touch the unit button. The maximum value that can be selected for the patient's age is 150 months or 150 years. By default, the age unit is in years.
- Weight: Select the Weight field to enter the patient's weight up to 552 lbs (pounds) or 250Kgs. In this menu there is a unit option that is set to Kg by default and the other option for it is lbs.
- Height: Select the Height field to enter the patient's height up to 9 Feet or 250 cm. In this menu there is a unit option that is set to cm by default and the other option for it is Foot.
- Gender: The patient's gender is selected in this section. By default, this option is set to NONE, and the available options are Female and Male. Touching the selected option again, the gender becomes None.
- Blood Type: By default, the blood type is set to Unknown. Other available options for it are A +, A-, B +, B-, AB +, AB-, O +, O-. Touching the selected option again makes the blood type Unknown.

Warning

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

(a)

(b)

(c)

Figure 2-8 Keyboard:

a) Letters, b) Numbers and signs, c) Numbers

Setting menu

Selecting Setting from the Header area will open this menu. On the left side of the screen, access to the settings of different sections is provided. By selecting each, the settings for that option are displayed.

Date & Time:

- Date & Time: Available options are Christian and Solar.
- NTP server: If you select this option, the date and time will be automatically downloaded and set from the inserted IP based on the Time Zone (If connected to the network). If you do not select this option, the date and time can be set manually. By touching each section, a drop-down list with different options is provided to the user; By dragging it up and down, the desired value can be found and by touching it again, that option is selected and saved.

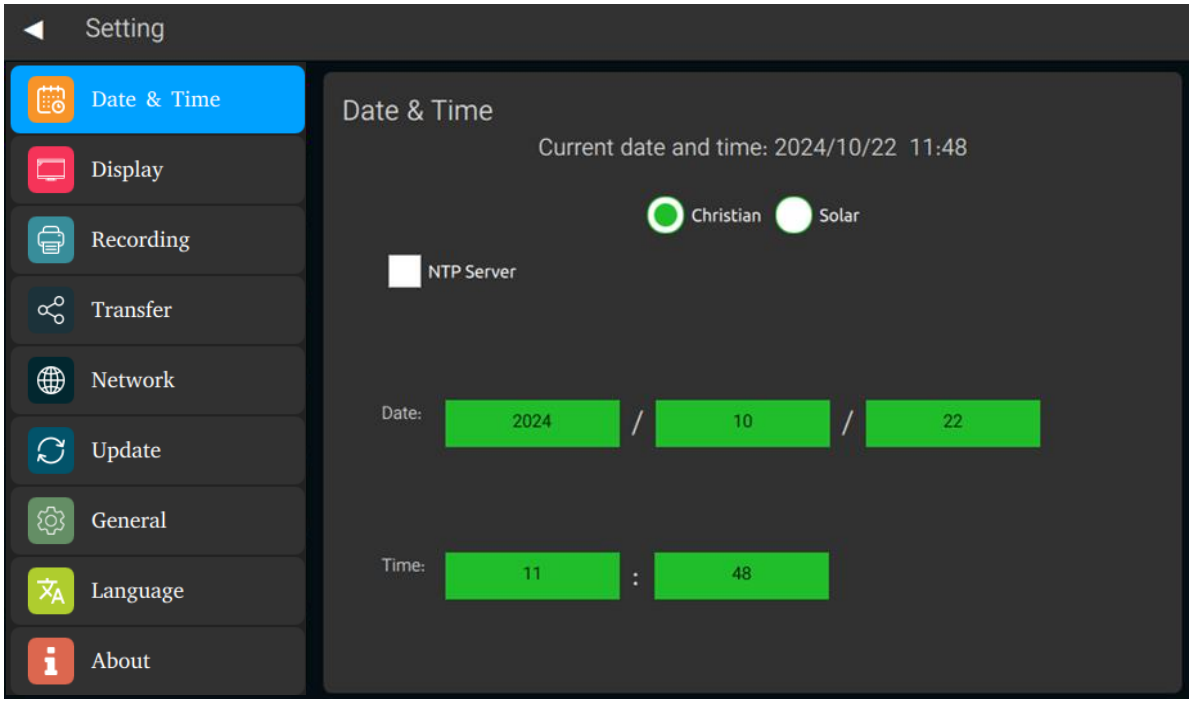


Figure 2-9 Date & Time setting menu

Note

- If NTP Server is selected, entering or editing the corresponding server Ip address is possible.
- If PACS is activated, NTP Server is automatically activated and the user can not disable it.

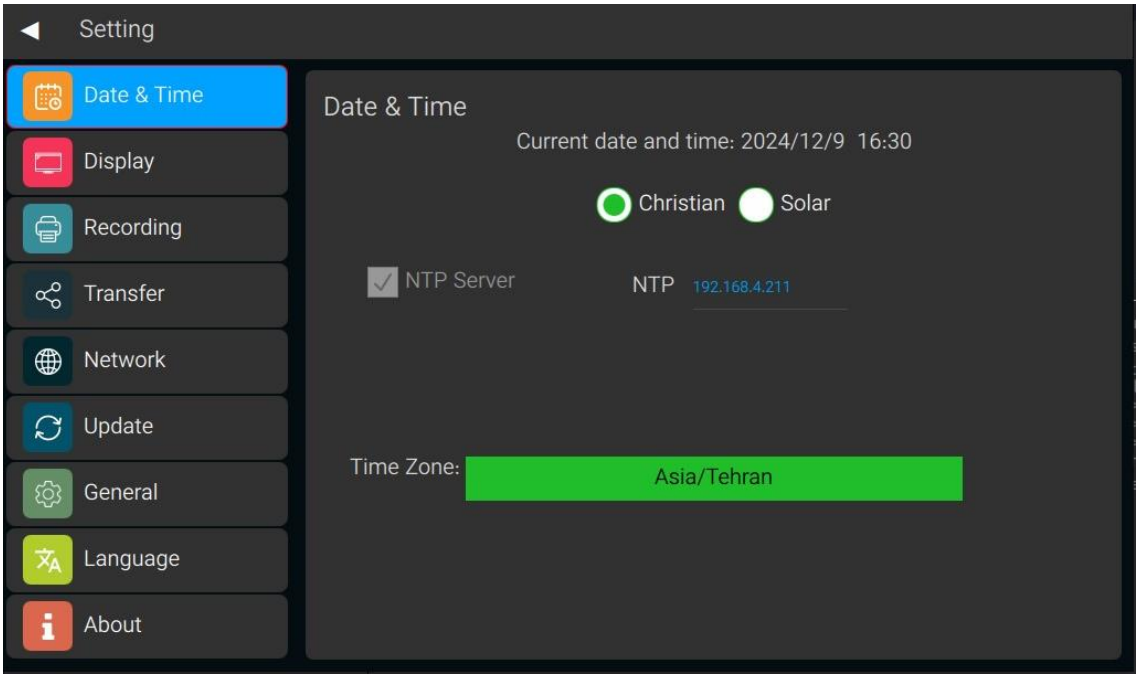


Figure 2-10 Date & Time Setting Menu

Display:

- Brightness: Not activated in the current version.
- Theme: It has two options, Dark and Light. By selecting the Dark option, the color of all menus and the background of the signal display will be dark. By selecting the Light option, the menus and the background of the signal display are displayed in bright color.
- Screen saver: When the selected time is passed, the screen of the device turns off. By touching the screen or pressing any button, the screen turns on in seconds.
- Trace type: Not activated in the current version.

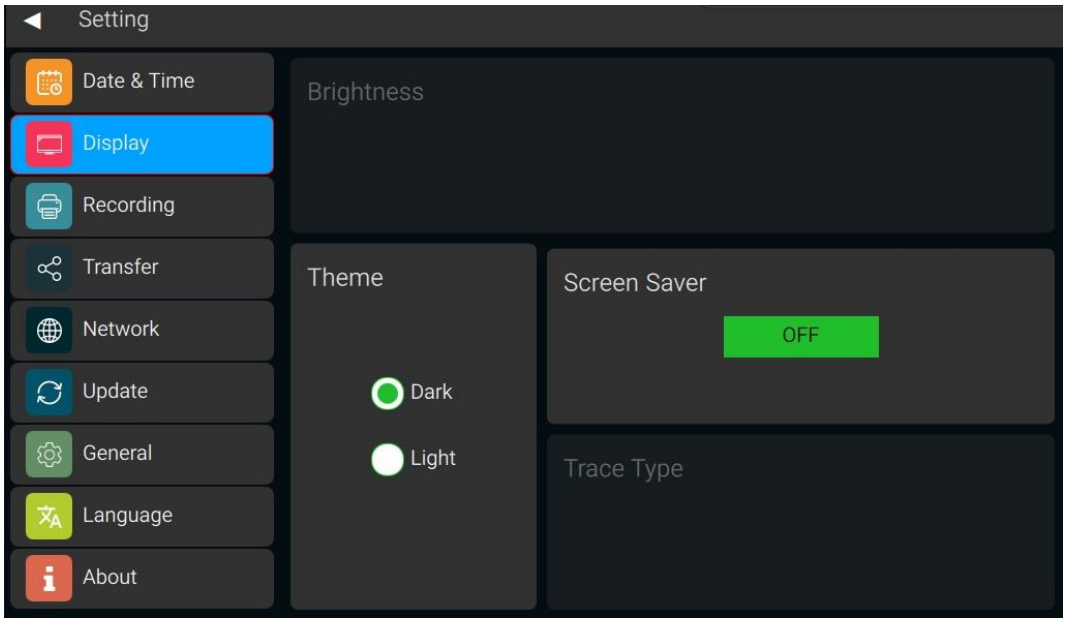


Figure 2-9 Display setting menu

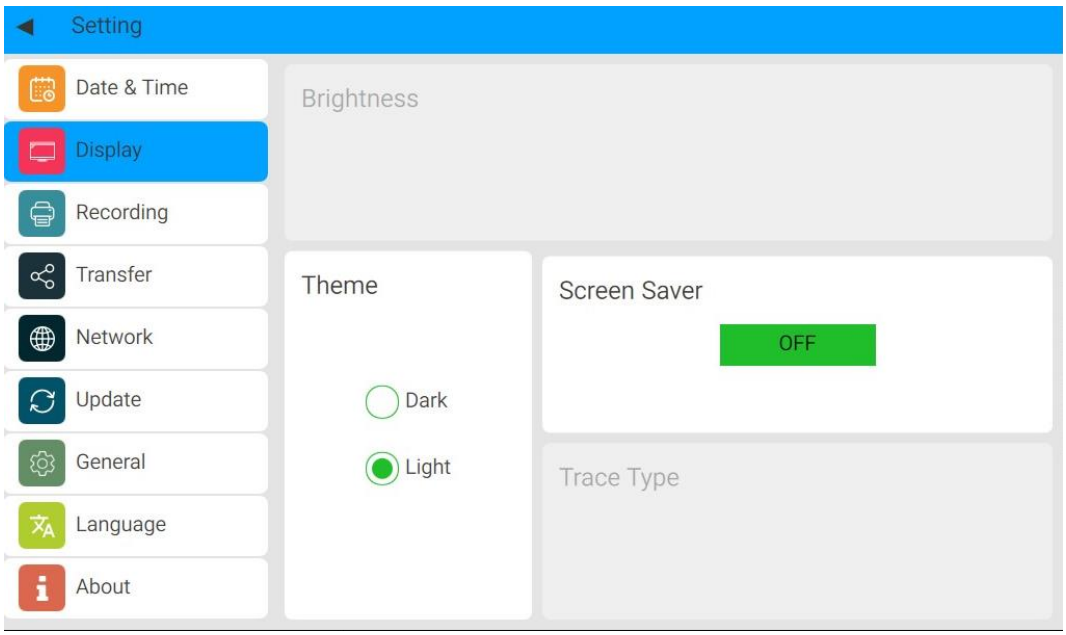


Figure 2-8 Display setting menu: Light theme selected

Recording: At the top of this page, you can select the internal thermal recorder or external printer.

- Thermal

By selecting this option, the thermal recorder of the device will print the record. Press icon to print a test signal.

The Periodic Recording Interval section is used to enable / disable periodic mode. By setting the Periodic Interval other than off, the intervals of the periodic recordings are determined and the Periodic Repetition option is available to adjust the number of repetitions of the periodic recordings. By activating the periodic mode, the counters of the number of remaining records and the time remaining until the start of the next record are displayed at the top of the main screen.

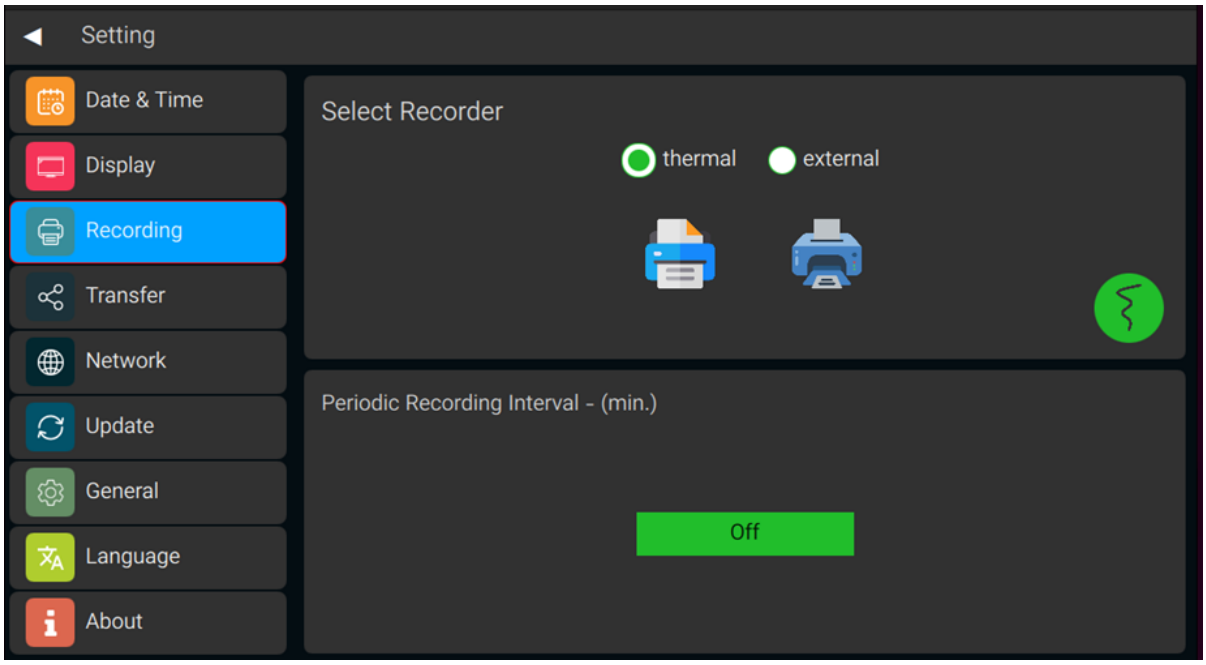


Figure 2-13 Recording setting menu

- External

By selecting this option, you can use an external printer connected to the device with a USB cable for recording. Select the name and model of your external printer on **Select Printer** section.

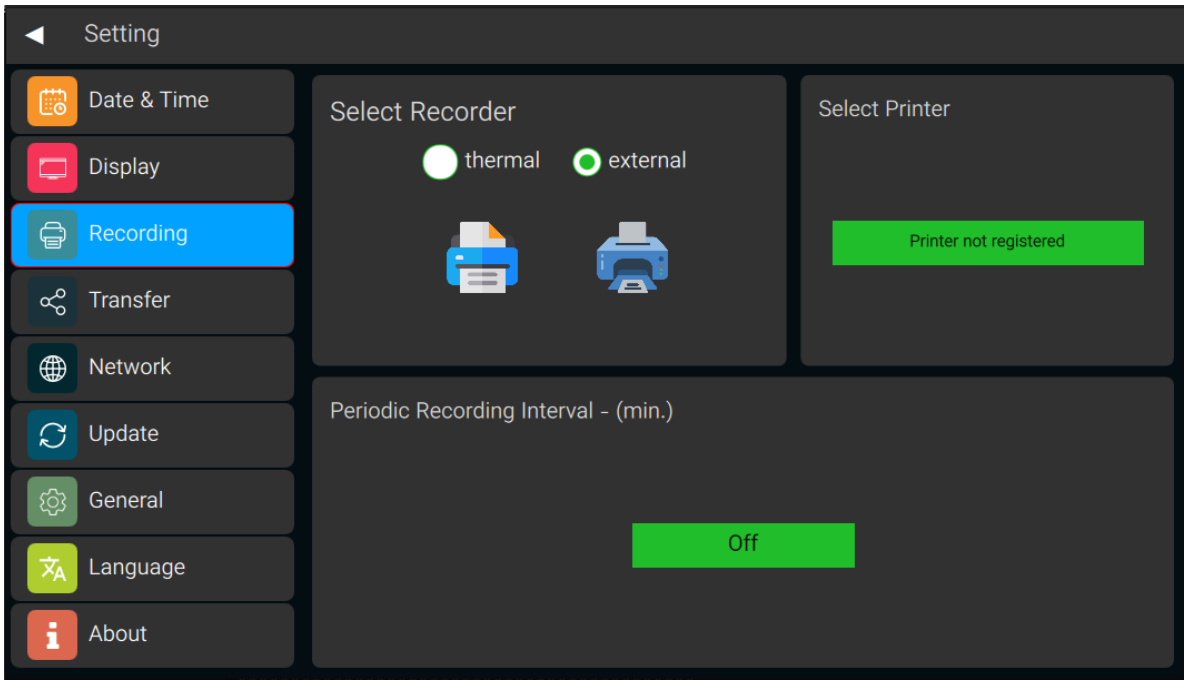


Figure 2-14 Recording setting menu

Note

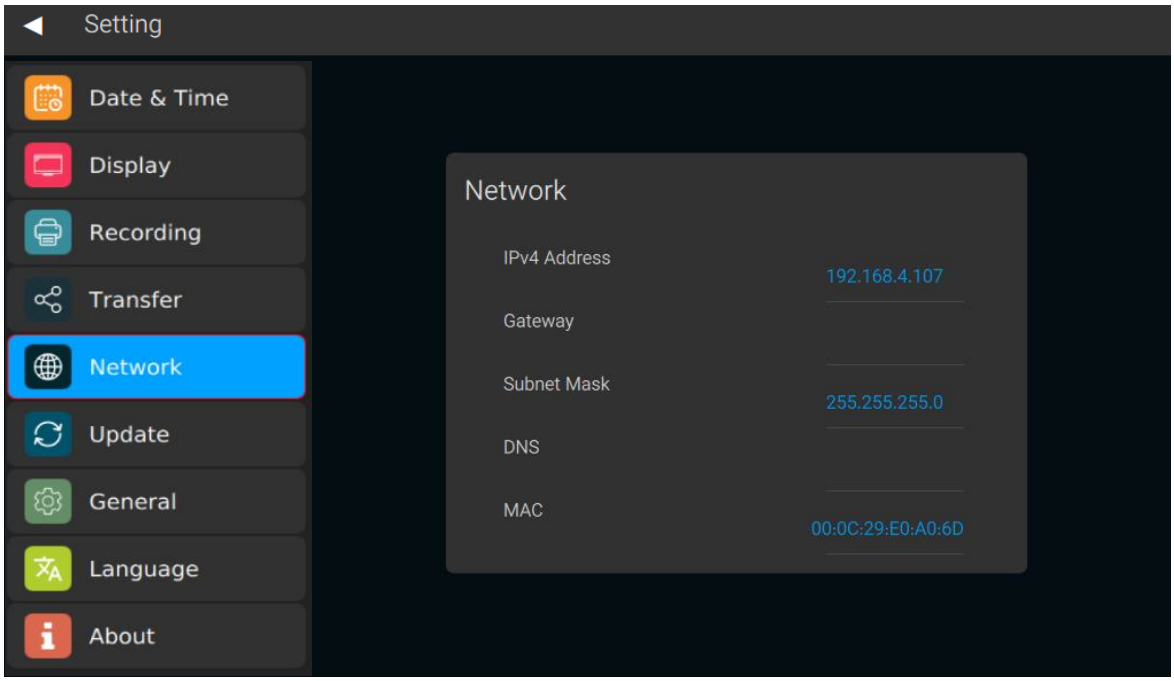
- If external printer is selected, **Rec. Mode** is set to **Auto** automatically.
- Refer to chapter **4: Recording Operation** for more details.

Transfer: This page is used to transfer or erase information from the device's internal storage.

Note

- Refer to chapter **6: Data Management** for more details.

Network: Used to view and apply network and PACS settings.



Note

- Changing Network and PACS settings must be done by authorized people and needs a password.

Update: Update the software, or restore the device settings to the default state, and clear the memory on this page. By default, only the Update section is enabled.

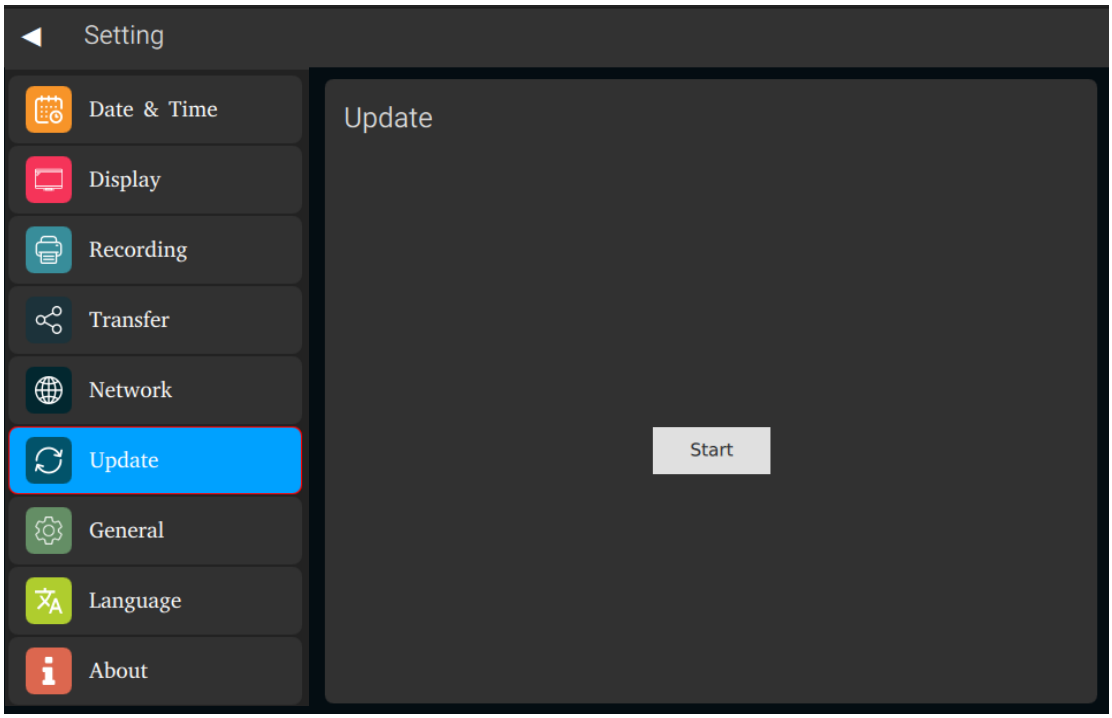


Figure 2-16 Update setting menu

By pressing the password keys, the Reset option will also be available. This menu can be used to clear saved data and restore system settings to factory settings.

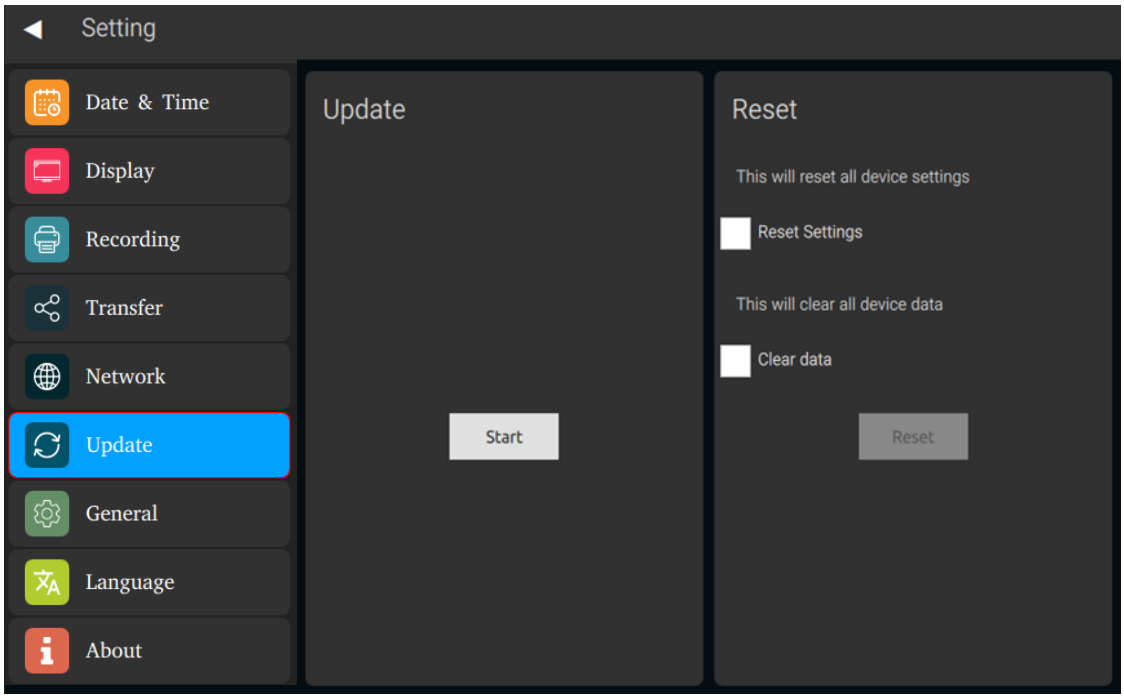


Figure 2-17 Update setting menu

General: The name of the hospital can be entered on this page. Sound setting and Smart Record are also done on this page.

Smart Record: By activating this option, according to the range of signals in each group of leads, the device will automatically allocate the appropriate space to each lead in the group. If this option is enabled, the relevant phrase will be inserted in the record header.

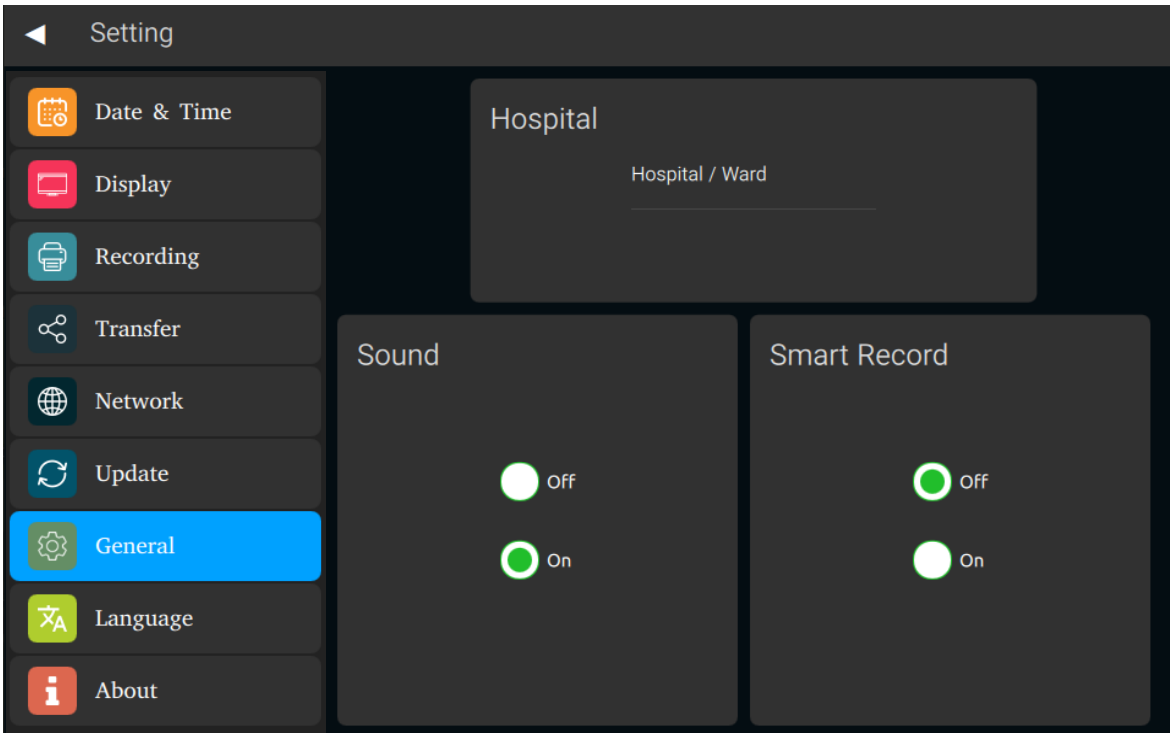


Figure 2-10 General setting menu

Note

- When selecting Smart Record, the drift filter must be On.

By pressing the password keys, Demo and remote access options will also be available.

- Demo: By activating this option, the simulated signals are displayed on the main screen.
- Remote Access: By activating this option, system information will be accessible via network.

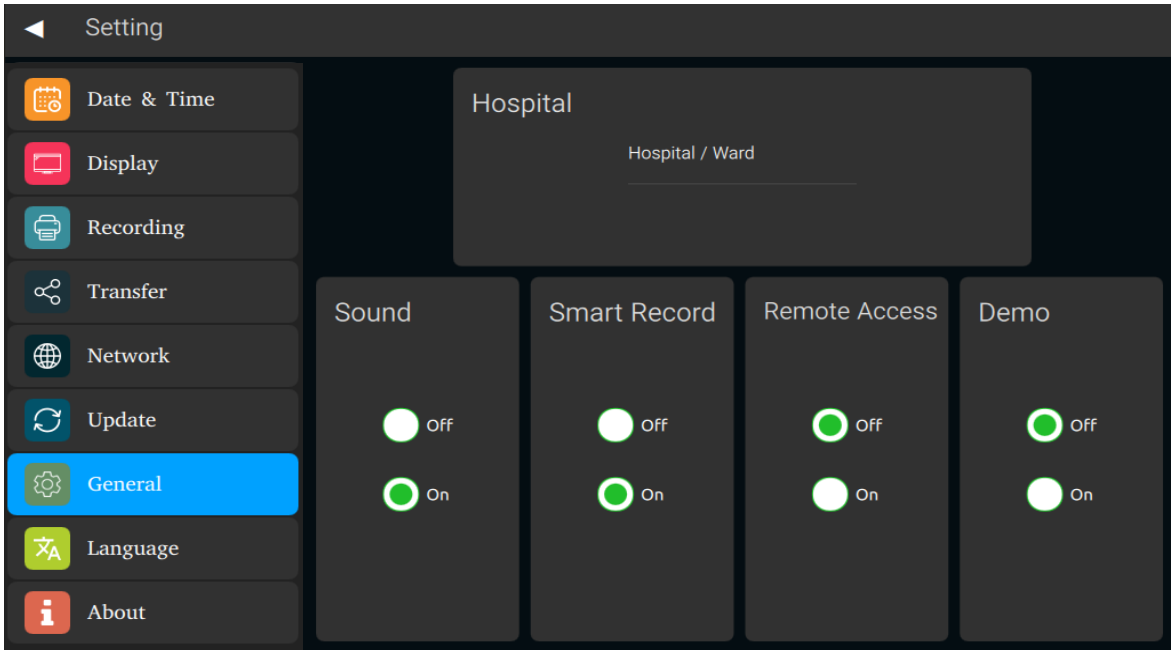


Figure 2-19 General Setting Menu

Language: On this page, you can select the language of the device from the فارسی and English options. By selecting فارسی, all texts in the device menus and record header are displayed in Persian language. By selecting English, these texts are displayed in English.

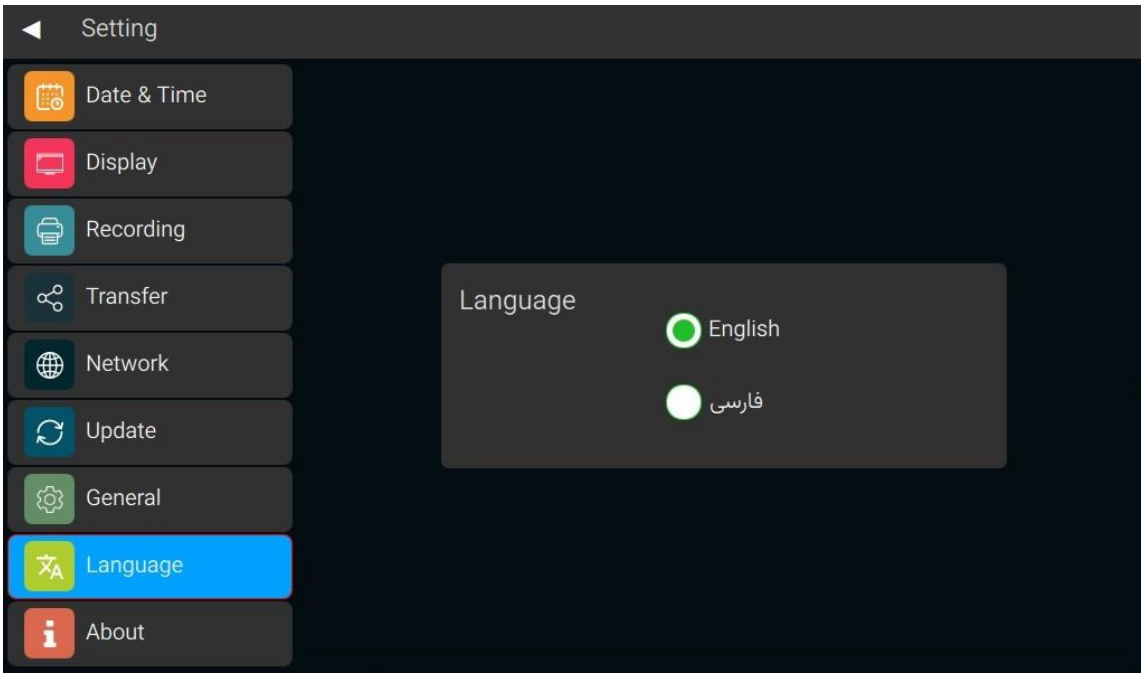


Figure 2-20 Language setting menu

Note

- If فارسی is selected, by touching  key and changing keyboard language to فارسی, you can enter patient information in Farsi language.

About: Selecting this option will open the following window with the details of the device and the name and contact information of the manufacturer.

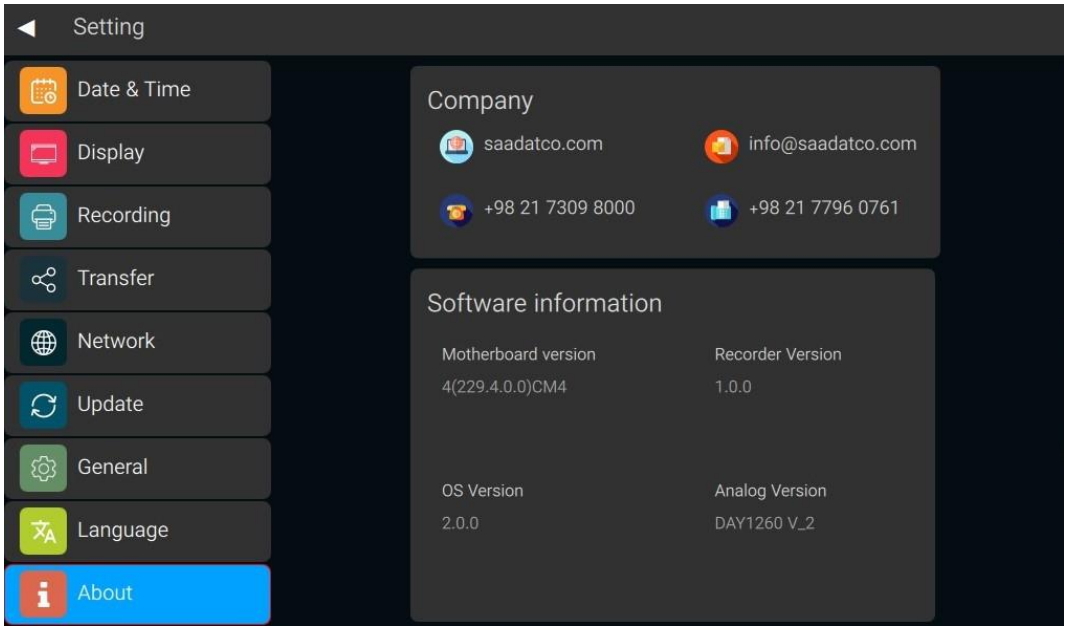


Figure 2-21 About

3) Patient preparation

Actions before recording

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

ECG electrodes connection

The ECG cable consists of two parts: the connector that connects to the device and the lead wires that connect to the patient (Figure 4-1).

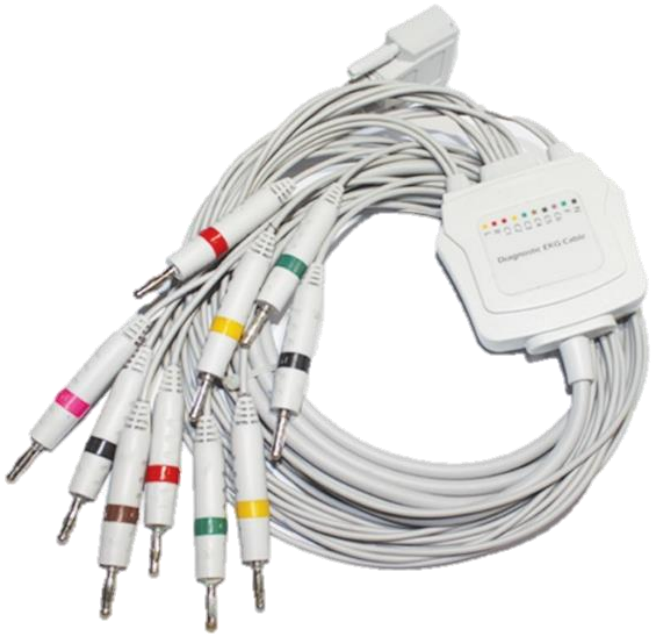


Figure 3-1 ECG cable

Warning

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

- When you connect the cables and electrodes, make sure that no metal part is in contact with the safety ground.
- Check that all ECG electrodes are properly attached to the patient's body.
- Interference from non-grounded devices near the patient or ESU (Electrosurgical Unit) can cause inaccurate ECG waveforms.
- Use only the manufacturer recommended ECG cable with internal resistance. Other ECG cables and leads may cause burns, improper performance and/or provide inadequate protection during defibrillation.
- When the device is used with electrocautery unit, please note the position of leads. In order to reduce the hazard of burns, the leads should be located away from the electrocautery pen and return electrode.

Connection of the Limb electrodes

4 electrodes of 10 ECG electrodes are attached to the limbs. The location of the limb electrodes for the 12-lead ECG is as follows (Figure 3-2):

- Left hand (L)(LA)
- Right hand (R)(RA)
- Left foot (F)(LL)
- Right foot (N)(RL)

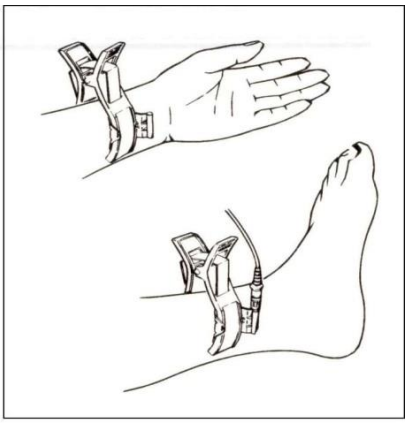


Figure 3-2 Connection of the Limb electrodes

Connection of the Chest Electrodes

Press the suction bulb and place the chest electrode on proper site (Figure 3-3) and then release. The location of the chest electrodes is as follows:

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

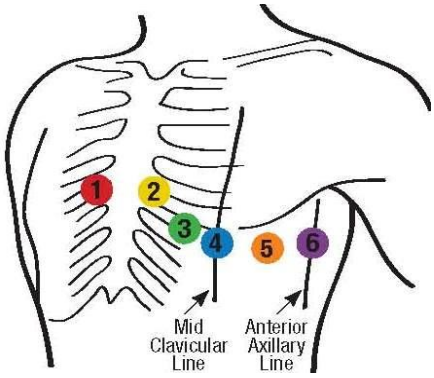


Figure 3-3 Connection of the Chest electrodes

Detection of electrode disconnection

DENA 1210 continuously monitors the connection status of the electrodes, and in the event of a disconnection, displays the relevant messages at the location of the signals on the screen (Figure 1-3).

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

Note

- Refer to chapter **8: Troubleshooting and Error messages** for more details.

Color codes and Labels of electrodes

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

- IEC standard:

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

- AHA standard:

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

Lead placement diagram

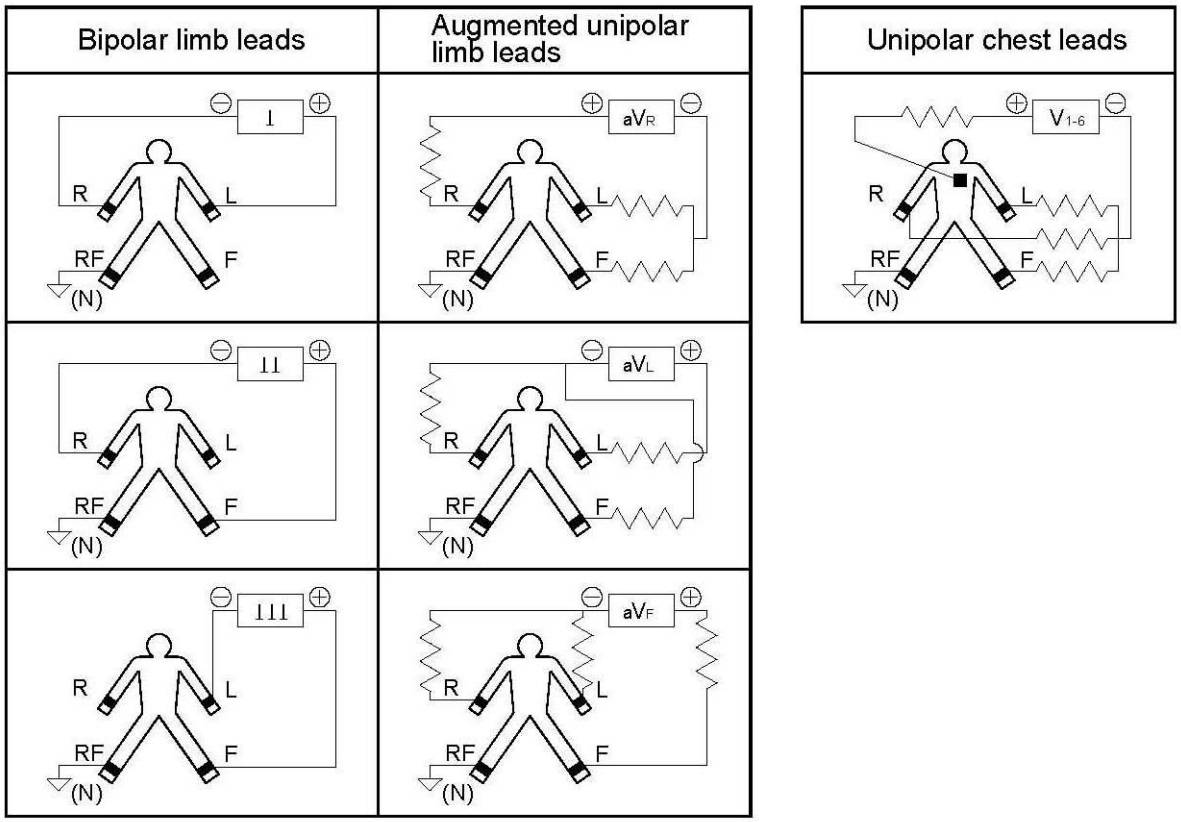


Figure 3-4 Lead placement diagram

4) Recording Operation

Note

- Refer to chapter **2: System settings** chapter to view the recording settings.
- Recording starts by pressing the Start/Stop key and during this operation, the color of the key changes on the screen and the lock symbol appears in the background. As long as the screen is in this mode, all keys and menus except the Start/Stop key, touch key, and keys in manual mode, will be inactive.

Recording Types

Manual Recording

It has 3+, 6, 6+ and 12 types which can be adjusted using Rec Mode menu. on the screen.

In this mode, by pressing the "Start / Stop" key on the front panel or touch screen of the device, recording begins and the recording continues until the "Start / Stop" key is pressed again.

Also, during recording, you can change the group of leads being recorded with the help of and keys. Selected labels are displayed in red color.

It should be noted that only the selected leads will be recorded.

- **Manual 3+:** In this case, the three selected leads will be recorded, along with one to three selected Long Lead(s). In the record, the top three waveforms represent the selected leads and the bottom waveform(s) represent the Long Lead(s).
- **Manual 6:** In this case, the six selected leads will be recorded.
- **Manual 6+:** In this case, the six selected leads will be recorded, along with one to three selected Long leads. In the record, the top six waveforms represent the selected leads and the bottom waveform(s) represent the Long Lead(s).
- **Manual 12:** In this case, the leads will be recorded in a set of 12.

Automatic Recording

It has 3+, 6, 6+ and 12 types which can be adjusted using Rec Mode menu. on the screen.

Pressing the "Start / Stop" button on the front panel of the device starts recording and after the time specified in the Rec. Setting → Rec Time from the 3 to 12 second options, the recording ends automatically.

In this mode, the leads are switched automatically at the specified schedule.

- **Auto 3+:** In this case, groups of 3 leads will be recorded along with one to a maximum of three selected Long leads. In the record, the top three waveforms represent the leads that are automatically recorded, and the bottom waveform(s) represent the Long Lead(s).
- **Auto 6:** In this case, the leads will be recorded in sets of 6.
- **Auto 6+:** In this case, groups of 6 leads will be recorded along with one to a maximum of three selected Long Leads. In the record, the top six waveforms represent the leads that are automatically recorded, and the bottom waveform(s) represent the Long Lead(s).
- **Auto 12**: In this case, the leads will be recorded in a set of 12.

Rhythm Recording

By selecting Rhythm from the Rec Mode menu, the waveform corresponding to the selected rhythm lead(s) (one to three leads) is drawn on the screen. In this mode, according to the number of selected leads, the screen is divided into one to three parts and displays one of the leads in each part. Pressing the “Start / Stop” key on the front panel of the device or display starts the signal storage phase according to the time specified in the Length of Rhythm (the data acquisition message is displayed. The record key on the display turns blue and a counter on it counts down to zero from the set time), and then, a record is taken of the stored signal.

Note

- During Manual recording in +3, 6 or +6 modes, you can record from the previous or next set of leads by pressing the  and  keys.
- In manual mode, after the recording starts, the recording stops just by pressing the “Start / Stop” key again.
- When recording in all modes, you can stop recording by pressing the “Start / Stop” key in front panel or touching the “Stop” key in the screen.
- Copy key is used to retrieve the last record (except manual modes). By turning the device on and off due to the lack of a previous record, the information cannot be copied.

Periodic Recording

This mode is used to generate consecutive records with a time interval and specified repetition. Recording in this mode is always done according to the latest settings of the device and changing the settings does not interfere with this operation. Also, the number and time remaining until the next record is always displayed in the header area.

To perform recording operations in periodic mode:

1- First, by entering the Setting menu and selecting the Recording section, go to the Periodic Recording Interval option and select the desired time intervals for recording from the 5-60 minutes options. By touching each section, a drop-down list with different options is provided to the user; By dragging it up and down, the desired value can be found and by touching it again, that option is selected and saved.
2- Choose the number of times (Periodic Recording Repetition) from options 1 to 20 and.∞.
3- Recording mode in this type, is similar to other types of recording and is determined using the Rec. Mode menu.

Returning to the main screen, the number and time remaining until the next record is displayed in the header area of the screen, and when the counter number reaches zero, periodic recording according to the current settings of the device begins.

Note

- In this case, the recording is always done according to the latest settings of the device.
- If needed, during periodic recording, recording can be done in Auto, Manual and Rhythm modes. For this purpose:
  1- Set the desired settings and Rec Mode.
  2- Press the "Start / Stop" key.
  At the end of this operation, periodic recording will resume automatically according to the latest settings.
- It should be noted that if the device is set to Manual but periodic recording is active, Rec Type will change to the equivalent Auto mode and remains as long as the recording settings are not changed by the user, periodic recording will be performed in this mode. For example, it records Manual 3+ like Auto 3+ mode.
- When it is time to record periodically, no recording will be performed while each menu is open, and the message “Rec’s waiting” will be displayed in the header area. After returning to the main page, periodic recording begins.
- It is possible to copy the stored information only in Auto and Rhythm modes (since recording in periodic mode is also done in automatic mode, it is also possible to copy in this mode).

PACS

If PACS is activated and its related settings are done properly, by pressing the record button, data will be sent to PACS server.

PACS status is displayed at the top of the main window.

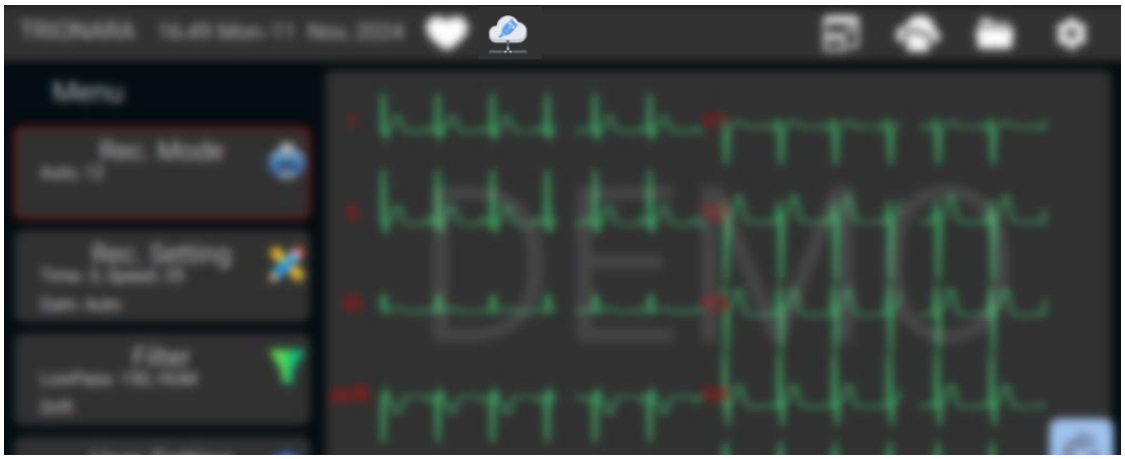


Figure 4-1 PACS status icon

 This icon is displayed when PACS is activated but network is not connected.

 This icon indicates that the device is attempting to connect to PACS server.

 This icon is displayed while communicating with PACS server.

If PACS is not activated, no icon will be displayed.

While recording, messages related to PACS are displayed at the bottom of the window:

Figure 4-2 PACS messages

Message	Meaning
PACS data sent successfully.	Record is successfully sent to PACS server.
Not connected to PACS.	The device is not connected to PACS server.
Not sent to PACS (Manual).	Record is not sent to PACS because **REC. Mode** is set to **Manual**. Set **Rec. Mode** to **Auto**.
Not sent to PACS (Rhythm).	Record is not sent to PACS because **REC. Mode** is set to **Rhythm**. Set **Rec. Mode** to **Auto**.
Check patient information.	Patient ID is not set. Try again after entering the patient ID.
Timeout	Record is sent to server, but no confirmation was received from the server.

Note

- Activating and configuring PACS settings are done by the IT or medical engineering department of the hospital or the after-sales service of Pooyndangan Rah Saadat Company.
- In order to send data to PACS server, patient ID must be entered. In case patient Id is not entered, “Check Patient information” error message will be displayed while recording.
- Data sending to PACS is only possible when **Rec. Mode** is set to **Auto**.
- If PACS is activated, **NTP** on **Date & Time** menu will be set to **ON** and cannot be changed.
- In case the NTP server is not connected, PACS data will not be sent.

PACS Archive

If the device is not connected to PACS server, the recorded data will not be sent and will be inserted on **PACS Archive** list. Press  at the top of the main window to open **PACS Archive**. You can select the records and try to send them to PACS server again.

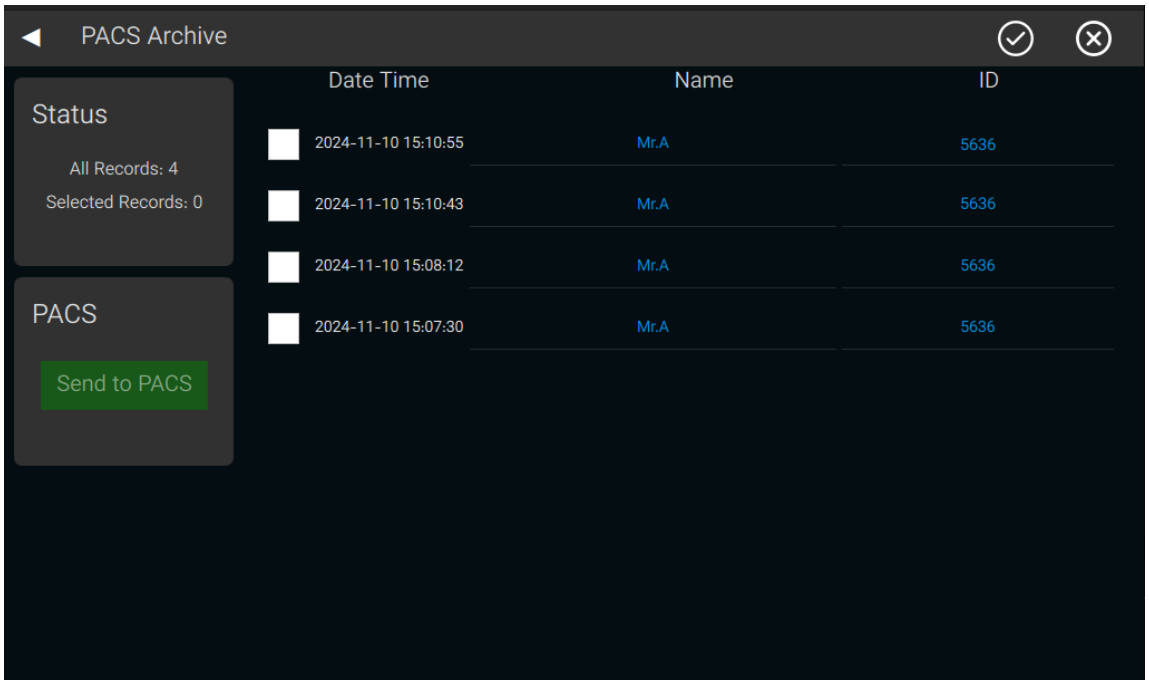


Figure 4-3 PACS Archive

Note

-  icon will be displayed at the top of the main window after PACS is activated.
- Only records with IDs are displayed on the list.
- One or multiple records can be selected and sent.
- In case one or multiple records are selected and the device is connected to PACS server, “Send to PACS” button is activated.

5) ECG analysis and measurement

General information

In order to automatically analyze the ECG signal, the analysis and interpretation software of the University of Glasgow (The Glasgow Program) has been added to DENA 1210. This software helps in more accurate diagnosis of the disease in two parts: Measurement and Interpretation. The Measurement section measures and reports the important parameters of the ECG signal and the Interpretation section uses the results of the Measurement section to diagnose the disease.

For best results, the physician must enter the patient's gender and age. It should be noted that the Glasgow software analyzes and interprets 10 seconds of the ECG signal.

Reported parameters in Global mode

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

Table 5-1 Reported parameters in Global

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

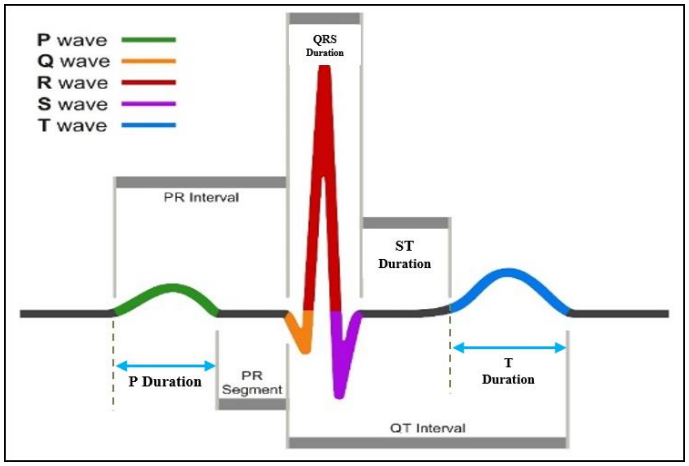


Figure 5-1 Signal parameters in Global

Heart Axis

The cardiac vector (Heart axis) is the average sum of the electrical forces inside the heart, or in other words, the angle of the result of the vector of the heart's electrical activity.

The electric vector can be calculated for P, QRS and T waves.

Among cardiac angles, the QRS axis has the most clinical use and is easily calculated. Leads I, II and III or aVF, aVL and aVR leads can be used to calculate the QRS axis. Each of these leads shows the electrical activity of the heart in a specific direction. The normal cardiac vector is in the range of -30 to +90 degrees. The following figure shows the angles corresponding to each lead.

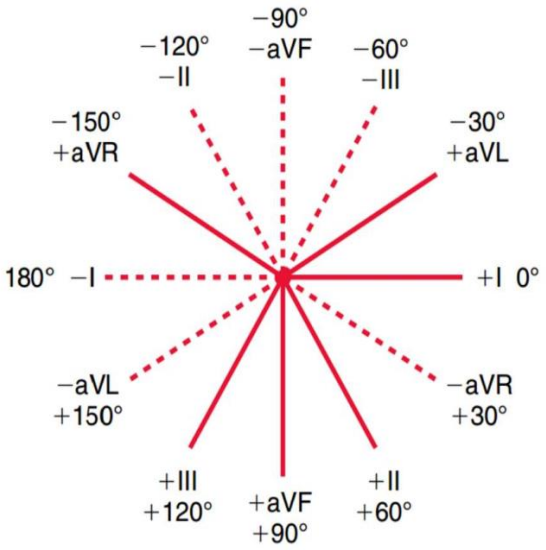


Figure 5-2 Heart angles related to different leads

QTc parameter

The QT Interval is from the beginning of the QRS to the end of the T wave, which indicates the duration of ventricular depolarization and repolarization.

Since QT is affected by heart rate, it needs to be corrected and normalized to the heart rate (normalizing QT means eliminating its dependence on HR). For example, increasing HR reduces QT, and this dependence needs to be removed to make a diagnostic comparison with the normal range.

In order to normalize the QT parameter, the following equations are used:

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

Each Interpretation phrase begins with a special letter that indicates the following:

{H}: Indicates the title of report and is written in first line.
{R}: Corresponds the rhythm interpretation.
{D}: Indicates the details of the signal analysis and identifies the diagnostic terms.
{S}: Shows a summary of the signal analysis status.

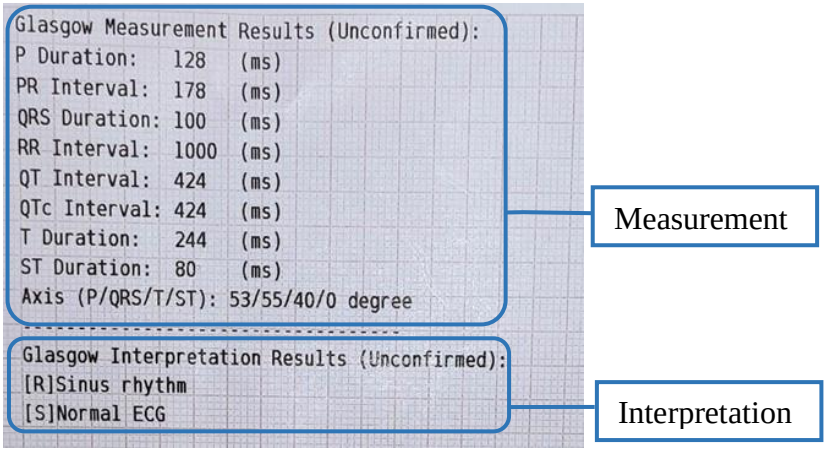


Figure 5-4 Reported parameters in Global

Reported parameters in Details mode

In this mode, the details of 12 leads are reported in addition to the Global mode. These details are given in table 5-2.

Table 5-2 Reported parameters in Details

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

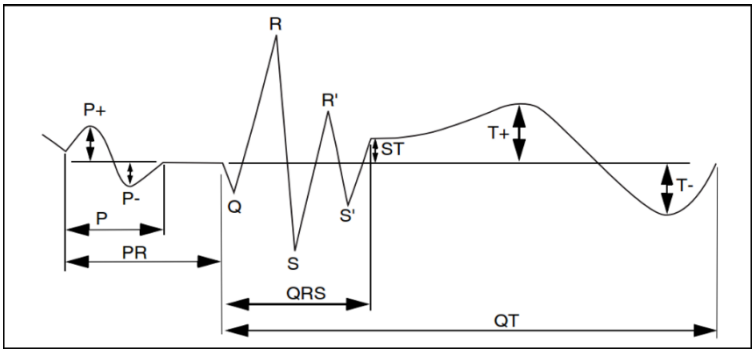
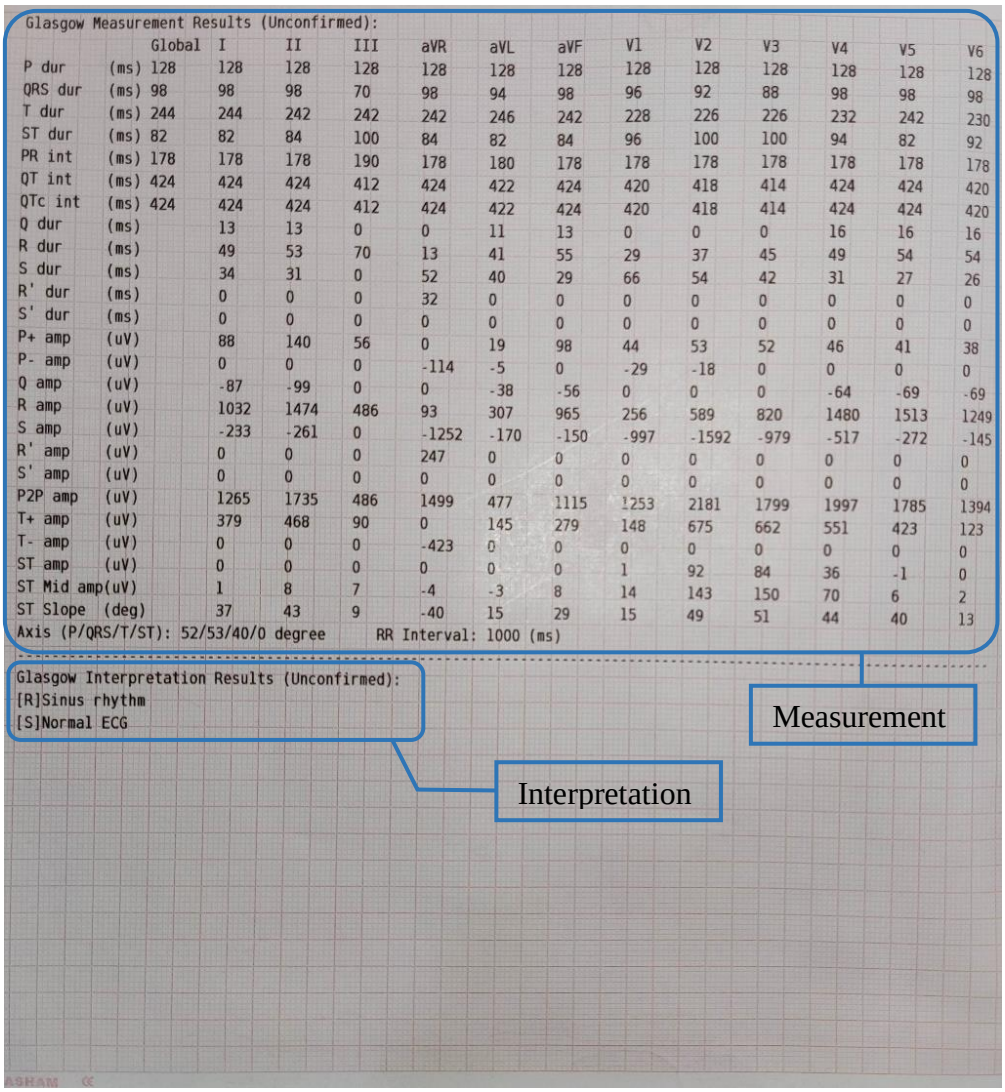


Figure 5-3 Signal parameters in Details

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

Each Interpretation phrase begins with a special letter that indicates the following:

{H}: Indicates the title of report and is written in first line.
{R}: Corresponds the rhythm interpretation.
{D}: Indicates the details of the signal analysis and identifies the diagnostic terms.
{S}: Shows a summary of the signal analysis status.



Glasgow Measurement Results (Unconfirmed):

		Global	I	II	III	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6
P dur	(ms)	128	128	128	128	128	128	128	128	128	128	128	128	128
QRS dur	(ms)	98	98	98	70	98	94	98	96	92	88	98	98	98
T dur	(ms)	244	244	242	242	242	246	242	228	226	226	232	242	230
ST dur	(ms)	82	82	84	100	84	82	84	96	100	100	94	82	92
PR int	(ms)	178	178	178	190	178	180	178	178	178	178	178	178	178
QT int	(ms)	424	424	424	412	424	422	424	420	418	414	424	424	420
QTc int	(ms)	424	424	424	412	424	422	424	420	418	414	424	424	420
Q dur	(ms)		13	13	0	0	11	13	0	0	0	16	16	16
R dur	(ms)		49	53	70	13	41	55	29	37	45	49	54	54
S dur	(ms)		34	31	0	52	40	29	66	54	42	31	27	26
R' dur	(ms)		0	0	0	32	0	0	0	0	0	0	0	0
S' dur	(ms)		0	0	0	0	0	0	0	0	0	0	0	0
P+ amp	(uV)		88	140	56	0	19	98	44	53	52	46	41	38
P- amp	(uV)		0	0	0	-114	-5	0	-29	-18	0	0	0	0
Q amp	(uV)		-87	-99	0	0	-38	-56	0	0	0	-64	-69	-69
R amp	(uV)		1032	1474	486	93	307	965	256	589	820	1480	1513	1249
S amp	(uV)		-233	-261	0	-1252	-170	-150	-997	-1592	-979	-517	-272	-145
R' amp	(uV)		0	0	0	247	0	0	0	0	0	0	0	0
S' amp	(uV)		0	0	0	0	0	0	0	0	0	0	0	0
P2P amp	(uV)		1265	1735	486	1499	477	1115	1253	2181	1799	1997	1785	1394
T+ amp	(uV)		379	468	90	0	145	279	148	675	662	551	423	123
T- amp	(uV)		0	0	0	-423	0	0	0	0	0	0	0	0
ST amp	(uV)		0	0	0	0	0	0	1	92	84	36	-1	0
ST Mid amp	(uV)		1	8	7	-4	-3	8	14	143	150	70	6	2
ST Slope	(deg)		37	43	9	-40	15	29	15	49	51	44	40	13

Axis (P/QRS/T/ST): 52/53/40/0 degree RR Interval: 1000 (ms)

Glasgow Interpretation Results (Unconfirmed):
[R]Sinus rhythm
[S]Normal ECG

Figure 5-5 Reported parameters in Details

Note

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

6) Data management

General information

All ECG recorded data in Auto and Rhythm modes, as well as Periodic recordings, will be stored in the internal memory of DENA 1210 for future reference. For this purpose, the Save option in User settings menu should be Enable. In case of disabling the Save option no data is saved in the Archive.

Up to 500 records can be stored in the internal memory. When the memory is full the new data will overwrite the oldest data.

In order to transfer or delete stored data, data can be accessed via the "Transfer" section in the Setting menu and transferred to flash memory, or erased from the device memory.

Note

- Signal storage is always done as Sync.

Archive menu

Selecting Archive from the header area will open this window:

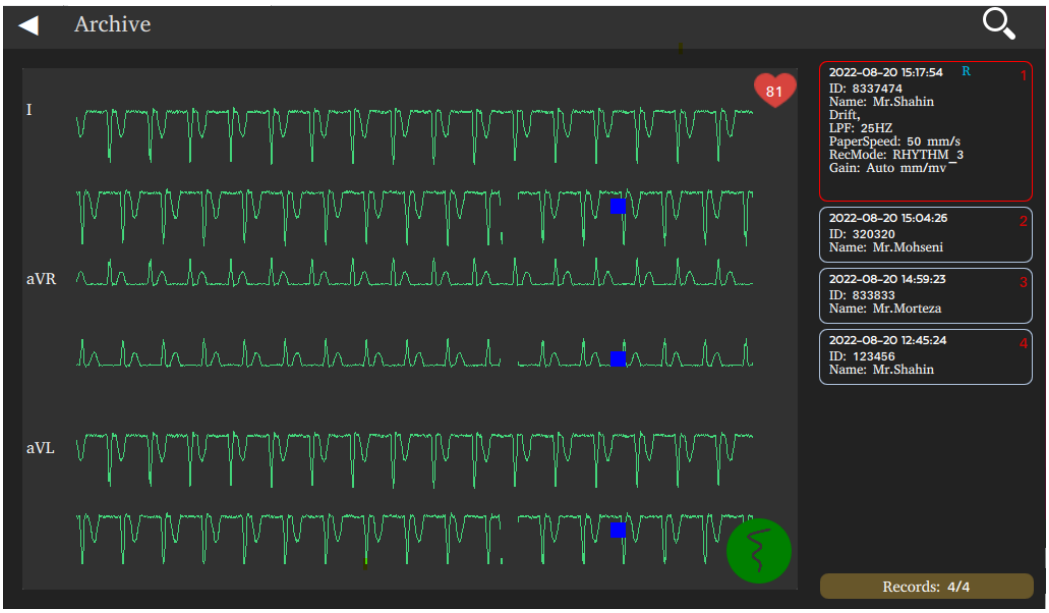


Figure 6-1 Archive menu

By entering the Archive menu, the saved signals along with the recording date and time, ID and Name are visible in the list on the right side of the page. By selecting any of the records from this list, that record will be marked with a distinct color in the list and more information such as filters, recording mode, etc. will be displayed. The stored signals are also displayed in the space to the left of this window (where the signals are drawn). The number of records saved is displayed at the bottom of the page.

The following information about each saved record can be seen in the Archive window:

- Date and time of recording
- Patient ID (if any)
- Patient name (if any)
- Filter settings at the time of recording
- Speed, mode and gain of recording
- Recording mode: If the save is done in Rhythm mode, the letter "R" is displayed and in Periodic mode, the letter "P" is displayed. Thus, if the storage is in both Rhythm mode and Periodic, the phrase "PR" is displayed.
- Heart rate: displayed on the top right of the signals, inside the heart shape.

To access the previous and next records, just drag the list to the top and bottom of the page.

Search: There is a search option on the right side of the Header area. By selecting this option, the virtual keyboard (Figure 2-8) is displayed, which by entering all or part of the name or ID of the desired patient, all the stored information that contains the entered phrase is displayed. At the bottom of the page, the number of records found and the total number of records are displayed.

Note

- The information in this window is related to the recording time.
- Using the key  in the upper left corner of the screen, returns to the home screen.
- In this page, by touching the Start / Stop key on the screen or pressing the Start/Stop button, stored ECG signals can be printed in conditions quite similar to the recording time.
- The blue symbols in the waveforms indicate the beginning of the signal.
- If the record is done in 3+ or 6+ modes, the rhythm leads will not be saved. Therefore, they will not be recorded when recording the saved files.

Transfer menu

By selecting the "Transfer" section in the Setting menu, this window will appear:

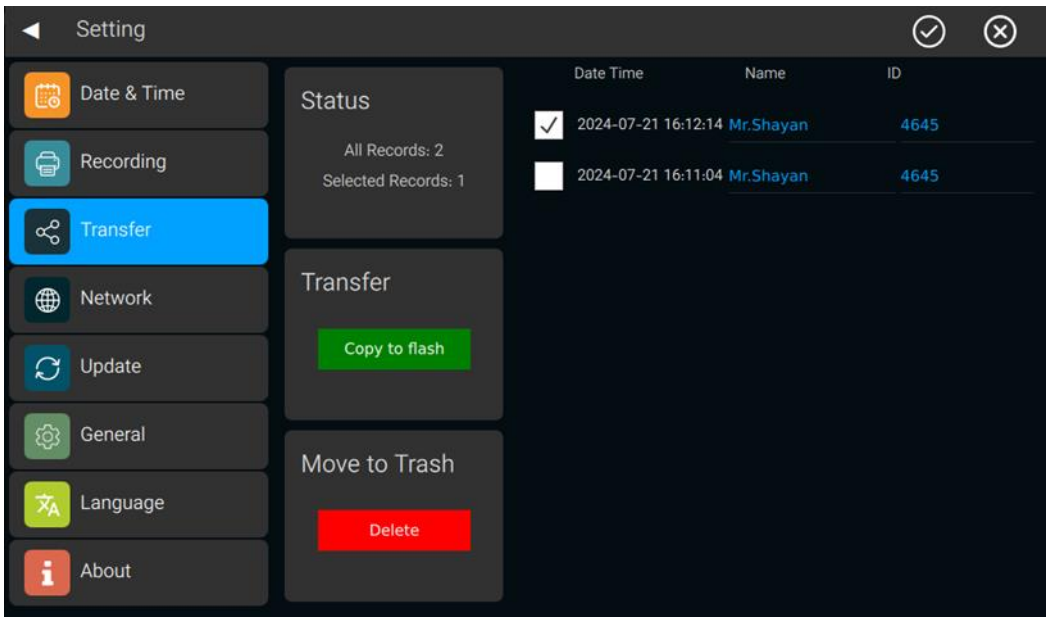


Figure 6-2 Transfer setting menu

On the right side of the screen, records stored in memory are displayed and the user can select the desired items. There are also two touch keys at the top of the screen to select all and deselect all.

In the Status section, the number of records and the number of items selected are displayed.

In the Transfer section, you can transfer the selected items to the flash memory by touching the Copy to flash option.

Selecting the Delete option in the Move to Trash section will clear the selected items from the device memory.

Make sure the flash memory is connected to the device before transferring data. If the flash memory is not connected to the device, by selecting the Copy to Flash option, the message "Make sure you have a USB connection, then try again" will be displayed.

By connecting the flash memory to the device and selecting the Copy to Flash option, all selected records can be extracted from the device. Filling the green bar up to 100% in this menu indicates the complete process of extracting information and the message “Copied successfully” will be displayed.

Note

- Do not remove the flash memory before completing the data transfer process.
- To access the previous and next records, just drag the list to the top and bottom of the page.

Online data transfer to PC

The Dena 1210 electrocardiograph has the ability to transfer the information of the signals being drawn on the screen to a personal computer via the USB port of the Device type. After installing the relevant software on the personal computer, by connecting the port to the computer via a USB cable, it is possible to transfer data online.

The software also has the ability to display files that have been transferred to flash memory via the "Data Transfer" option. After displaying the files, it is also possible to print and save the transferred information on a personal computer.

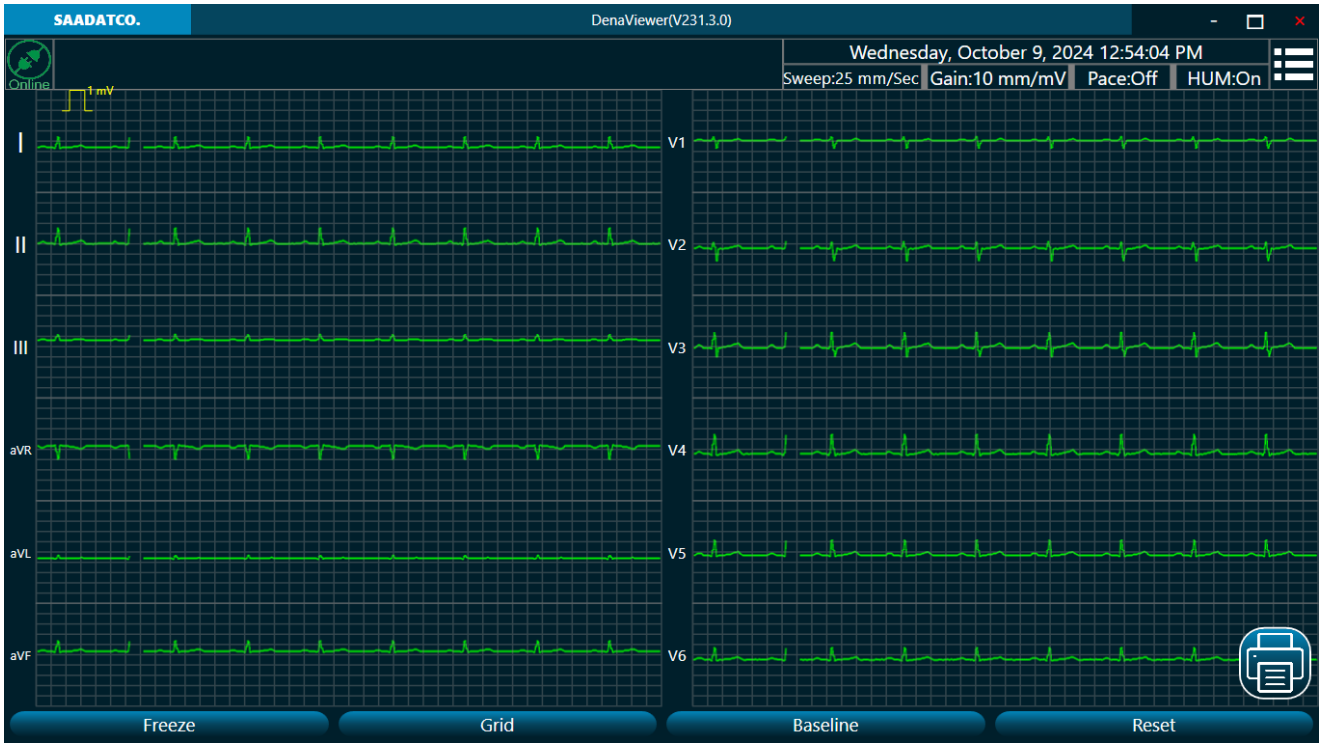


Figure 6-3 ECG Viewer

Note

- Refer to **Appendix 5: Dena Viewer software** for more details.
- Contact the manufacturer to install a USB Type-B Port and use this feature.

7) Care and Cleaning

System check

Before using the device,

- Check if there is any mechanical damage in the system and accessories.
- Check if the power cable and accessories are firmly connected.
- Check if all the keys function correctly and are in proper condition.

Warning

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

Note

- To ensure maximum battery life, let the DENA 1210 runs on the battery, at least once a month, until it turns itself off and then recharge the battery.
- If you find any damage in DENA 1210, stop using it on patient, and contact the biomedical engineer of the hospital or the manufacturer After Sales Service.
- The overall check of the device, including the safety check, should be performed only by qualified personnel.
- All checks which need the electrocardiograph to be opened or may affect the device safety should be performed by After Sales Service

Maintenance

Note

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

It is recommended that the following be checked daily:

- Accessory physical health
- Accessory function

It is recommended that the following be checked weekly:

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

It is recommended that the following be checked monthly:

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

Cleaning & Disinfection

Use only the substances approved by the manufacturer and methods listed in this chapter to clean or disinfect your equipment.

Manufacturer makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection.

For the method to control infection, consult your hospital's Infection Control Officer or Epidemiologist. See also any local policies that apply within your hospital.

Warning

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

Note

- DENA 1210 and accessories should be kept away from dust.
- Do not use detergents that contain ammonia or acetone.
- 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.

Warning

- Do not use ETO gas to disinfect DENA 1210.

External surfaces of the device

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

Display screen

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

Note

- Take extra care when cleaning the screen of the monitor because it is more sensitive to rough cleaning methods than the housing.

- Avoid direct spray of a liquid on the screen.

Recorder

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

Warning

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

Accessories

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

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

Warning

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

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

<table>
<tr><th>Device arts</th><th>Single-use</th><th>Cleaning</th><th>Disinfection</th><th>Sterilization</th></tr>
<tr><td>External surface</td><td>-</td><td rowspan="2">In-between patients and as required wipe gently using a moist cloth and warm soapy water or mild detergent.</td><td>In-between patients and as required use
■ Alcohol 70%
■ Isopropyl alcohol
■ N-propanol</td><td rowspan="4">To avoid extended damage to the equipment, sterilization is not recommended for this device, related products, accessories or supplies unless otherwise indicated in the Instructions for Use that accompany the accessories and supplies or when stipulated as necessary in the Hospital Maintenance Schedule.</td></tr>
<tr><td>Trolley</td><td>-</td><td rowspan="2">In-between patients and as required use
■ Isopropyl alcohol</td></tr>
<tr><td>Display screen</td><td>-</td><td>In-between patients and as required:
Clean and soft cloth with screen cleaner or mild soapy water.</td></tr>
<tr><td>Recorder (print head)</td><td>-</td><td>as required:
1.Gently wipe around the print head using cotton swabs dampened with alcohol.
2.After the alcohol has completely been dried, reload the paper and close the recorder door.</td><td>Use as required
■ Isopropyl alcohol</td></tr>
<tr><td>ECG accessory (Cables, Lead wires Electrodes)</td><td>Disposable electrodes</td><td colspan="3">According to the instructions delivered with the reusable accessories
To clean, disinfect and sterilize reusable accessories, refer to the instructions delivered with them.</td></tr>
</table>

Preventive Maintenance

The preventive maintenance (PM) checklist #PL-F-33 should be completed by responsible individuals of healthcare center. It should be noted that PM checklist only is used to perform systematic inspection of the equipment and will not guarantee their correct function.

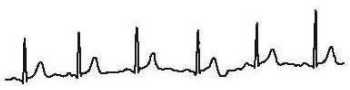
Pooyandegan Rah Saadat Co.					
Form No. : PL-F-33-V1 **PM Form (DENA 1210 Electrocardiograph)**					
State: **City:** **Healthcare center:** **Ward:**					
Device model: **Serial number:** **Installation date:** **Inspection date:**					
No.	**Test and Inspection Item**		**OK**	**Not OK**	**N/A**
1	**Visual inspection**	**No damage or breakage in the case**			
2		**Correct function of the touch screen**			
3		**Correct function of the keyboard**			
4		**Cleaning and disinfection according to the user manual**			
5	**Display screen**	**Correct display of Waveform area and information**			
6	**Battery**	**Unplugging the system (check the battery function)**			
7		**Periodic usage of the battery**			
8	**Saving date& time settings**				
9	**Saving system settings**				
10	**Accessories**	**Check ECG cable (clamps, lead wires, trunk)**			
11		**Check ECG clip clamp and suction bulb (visual and sulfation test)**			
12		**Cleaning and disinfection according to the user manual**			
13	**Recorder**	**Correct function of the recorder**			
14		**Appropriate size of the recorder paper**			
15		**Check the eject key function on the recorder door**			
16		**Check the paper holder**			
17		**Check the recorder thermal head**			
18		**Check the recorder error messages**			
19	**Review**	**Check Review window periodically**			
Final result: **Pass □** **Fail □**					
Expert recommendation:					
Name and signature of person in charge: **Name and signature of expert:**					

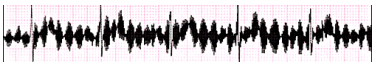
8) Troubleshooting and Error messages

Troubleshooting

Repairing the internal parts of DENA 1210 must be only done by trained and authorized personnel of After Sale Service; otherwise, the manufacturer will not take any responsibility for any possible hazard to the patient and the device.

Troubleshooting guide is intended to help users to solve minor problems caused by incorrect use of the DENA 1210 or failure of accessories. When you face any problem, please ensure that you have followed all actions mentioned in Solution column before you contact After-Sales Services.

Problem	Possible cause	Solution
The device is not turned on		● Check AC power path. ● Call After- Sales Services.
The device is unable to run on the battery	● Battery is discharged. ● Faulty fuse	● Charge the battery for 5 hours. ● Check the battery fuse. ● Call After- Sales Services.
NO ECG waveform	● ECG cable connection failure ●Faulty ECG cable ●Improper placement of electrodes	● Check ECG cable connection to the device. ● Check ECG cable connection to the electrodes. ● Check ECG cable connection to the patient. ● Short circuit all leads with each other. If ECG cable is ok, lead error message will not appear. ● Do not use old and faulty electrodes. ● Call After- Sales Services.
Inappropriate HR value	● Noisy and improper ECG signal ● After connecting the electrodes and before recording, wait for a few moments.	● Check the leads and electrodes. ● Make sure the patient is relaxed and immobile. ● Pay attention to the following points (related to signal quality) ● Call After- Sales Services.
There is irregular up and down shifts in ECG waveform from baseline 	● Various electrodes are used together ● Loose connection of electrodes to lead wires ● Electrodes are placed on bony site of body. ● Unclean or sulfated electrodes ● Insufficient gel is applied to electrodes. ● Patient skin is not prepared. ● Abnormal patient breathing	●Use the same electrodes. ●Check connection of electrodes to lead wires. ● Check proper placement of electrodes. ● Clean electrodes after each use. ● Apply sufficient gel. ● perform actions before recording (Patient preparation chapter). ● Relax patient in a comfortable position. ● If the problem still persists, use Drift filter.

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

Error messages

Message	Cause	Solution	Remarks
Leads Error Messages			
CHECK R	Lead R is not properly connected to patient.	Make sure that mentioned electrode is properly connected.	The message is displayed in white in the corresponding signal drawing area.
CHECK L	Lead L is not properly connected to patient.	Make sure that mentioned electrode is properly connected.	The message is displayed in white in the corresponding signal drawing area.
CHECK F	Lead F is not properly connected to patient.	Make sure that mentioned electrode is properly connected.	The message is displayed in white in the corresponding signal drawing area.
CHECK C1	Improper connection of C1 electrode	Make sure that C1 electrode is properly connected to patient.	The message is displayed in white in the corresponding signal drawing area.
CHECK C2	Improper connection of C2 electrode	Make sure that C2 electrode is properly connected to patient.	The message is displayed in white in the corresponding signal drawing area.
CHECK C3	Improper connection of C3 electrode	Make sure that C3 electrode is properly connected to patient.	The message is displayed in white in the corresponding signal drawing area.
CHECK C4	Improper connection of C4 electrode	Make sure that C4 electrode is properly connected to patient.	The message is displayed in white in the corresponding signal drawing area.
CHECK C5	Improper connection of C5 electrode	Make sure that C5 electrode is properly connected to patient.	The message is displayed in white in the corresponding signal drawing area.
CHECK C6	Improper connection of C6 electrode	Make sure that C6 electrode is properly connected to patient.	The message is displayed in white in the corresponding signal drawing area.
System Messages			
Recorder Error Messages			
Rec. Hardware Error	Recorder hardware error	Turn the system off and on. If the problem still exists, contact the	The message is displayed in black in the yellow box at the bottom of the screen.

Message	Cause	Solution	Remarks
		manufacturer's After Sales Service.	
Recorder Door Open	The recorder door is open.	Close the recorder door.	The message is displayed in black in the yellow box at the bottom of the screen.
Out of Paper	Paper roll is used up or the paper is not exited from the recorder.	Check the paper placement or insert a new paper roll into the recorder.	The message is displayed in black in the yellow box at the bottom of the screen.
Head High Temp	The Print head is too hot.	Stop operation for a few minutes.	The message is displayed in black in the yellow box at the bottom of the screen.
Head High Vol	The Print head voltage is high.	Turn the system off and on. If the problem still exists, contact the manufacturer's After Sales Service.	The message is displayed in black in the yellow box at the bottom of the screen.
Head Low Vol	1- The print head voltage is low. 2- The battery voltage is low.	1- Turn the system off and on. 2- Make sure that the battery is sufficiently charged. If the problem still exists, contact the manufacturer's After Sales Service.	The message is displayed in black in the yellow box at the bottom of the screen.
Time out Error	The recorder could not record.	Turn the system off and on. If the problem still exists, contact the manufacturer's After Sales Service.	The message is displayed in black in the yellow box at the bottom of the screen.
Battery Error Messages			
Battery Low	Low battery voltage	Connect the power cable to the system.	The message is displayed in black in the yellow box at the bottom of the screen.
Save & Copy Messages			
Rec's Saving	The system is saving data	Wait a few minutes to finish data saving	The message is displayed in black in the yellow box at the bottom of the screen.

Message	Cause	Solution	Remarks
Data Acquisition	The system is loading saved file	Wait a few minutes to load the file	The message is displayed in black in the yellow box at the bottom of the screen.
There's No Copy Rec	The last stored data could not be recorded after turning the system off and on	Avoid turning the system off and on when the Copy key is pressed.	The message is displayed in black in the yellow box at the bottom of the screen.
PACS Messages			
PACS data sent successfully.	Record is successfully sent to PACS server.	-	The message is displayed in black in the yellow box at the bottom of the screen.
Not connected to PACS.	The device is not connected to PACS server.	Check network connections, network and PACS settings.	The message is displayed in black in the yellow box at the bottom of the screen.
Not sent to PACS (Manual).	Record is not sent to PACS because **REC. Mode** is set to **Manual**.	Set **Rec. Mode** to **Auto** and record again.	The message is displayed in black in the yellow box at the bottom of the screen.
Not sent to PACS (Rhythm).	Record is not sent to PACS because **REC. Mode** is set to **Rhythm**. Set **Rec. Mode** to **Auto**.	Set **Rec. Mode** to **Auto** and record again.	The message is displayed in black in the yellow box at the bottom of the screen.
Check patient information.	Patient ID is not set.	Try again after entering the patient ID.	The message is displayed in black in the yellow box at the bottom of the screen.
Timeout	Record is sent to server, but no confirmation was received from the server.	Record again using  .	The message is displayed in black in the yellow box at the bottom of the screen.

9) Technical specifications

CLASSIFICATION	
Protection against electroshock	Class I, Type CF, defibrillation-proof applied part
Mode of operation	Continuous operation equipment
Harmful Liquid Proof Degree	Ordinary equipment, (without Liquid Proof)
Method of sterilization and disinfection	Refer to Care and cleaning chapter for detail.
Safety in presence of anesthetic mixture	Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
DISPLAY	
Display	TFT COLOR, 10.1", Capacitive touch screen
Resolution	1024*600
Waveforms	12 Lead ECG/Long Lead(s)
Numeric Parameters	HR
Operation Method	Membrane Keys and Touch
Displayed data	Waveforms, Patient Information (Name and ID), Date & Time, Recording Speed, Gain, Operation Mode, Filter, HR Value, Message
ECG	
Input Channel	Simultaneous acquisition of all 12 leads/Long Lead(s)
Standard leads acquired	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Gain Selection	2.5, 5, 10, 20 mm/mV , Auto
Filters	Drift: on or off
	HUM: on or off
	Low pass: 25, 35, 75, 150 HZ & off
	EMG: on or off
Calibration	1 mV
Dynamic Range	±5 mV
Leakage Current	< 10 μA
CMRR	> 98 dB
Time Constant	3.2 sec.
Frequency Response	0.05~150 Hz
Pace	Detection & Rejection: 0.1~2 ms, ±2~±250 mV Indication: 0.5~2 ms, ±2~±250 mV
Protection	Defibrillator & Electro surgery
Standards	IEC 60601-2-25

ECG Storage		
Internal Memory	Up to 500 Records	
Recorder		
Model	PT2161P	
Recording Method	Thermal dot line printing	
Dots per line	1728 dots	
Resolution	40 dots/mm (Horizontal) @ 25 mm/sec	
	8 dots/mm (Vertical)	
Recording Speed	6.25, 12.5, 25, 50 mm/s	
Paper Width	210mm	
Recording Width	216mm	
Recorded data	12 Lead ECG Waveforms, HR Value, Patient Information, Hospital/ward, system model, software version, date and time, paper speed, Gain, filter	
Recording Mode	Type	Auto, Manual, Rhythm
	Format	3+, 6, 6+, 12
	Status	Normal, Periodic, Copy, Review
Equipment Connector		
Patient cable connector	DB-15, Connects patient cable for ECG acquisition	
USB connector	Type-A: For Flash memory, External printer, Barcode reader, Wireless network dongle	
	Type-B: For data transmission to PC (Optional)	
Network Connector	RJ45: Network connection (PACS, HIS, …)	
GENERAL		
Safety	Class I (Based on IEC60601-1)	
Protection	Against Electro surgery and Defibrillator	
AC Power	100-240 VAC, 120 VA 50/60 Hz	
Internal Rechargeable Battery	**Lithium-Ion, 11.1V, 5 Ah** **Charge time: ~ 7 h** **Usage (New & Full Charged): ~ 8 h or 120 records** **or** **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**	
Dimension	310mm (W) x 95mm (H) x 360mm (L)	
Weight	6 Kg (with battery)	
Environment		
Temperature	Operating: 5~40 °C	
	Storage: -25~60 °C	
Humidity	20~90 % (Non condensing)	
Altitude	-200~3500 m	

Appendix 1: Accessories

Warning

- The accessories listed below are specified to be used for DENA 1210. Manufacturer does not take responsibility for any possible hazard to the patient or device if other accessories are used.
- Use only the manufacturer recommended ECG cable. Other ECG cables and leads may cause improper device performance, patient injury and inadequate protection during defibrillation.

Accessories

Accessories	Part #
Diagnostic EKG Cable,10 wires, Launch, Ref 60101010	P28041
EKG Clamp electrodes, Adult, FIAB, Ref F9024SSC	P28042
EKG Suction chest electrode, Adult, FIAB, Ref F9009SSC	P28043
EKG Clamp electrodes, Pediatric, FIAB, Ref F9023SSC	P28047
ECG Suction chest electrode, Pediatric-FIAB, Ref F9015SSC	P28048
Electrocardiograph Cable,10wires, Banana Ends (SAADAT)	P28078
ECG GEL	P28045
Recorder Paper, 210mm, Roll	P28114
Trolley	P09248

Appendix 2: System parameters

ITEM	SELECTION	DEFAULT
Rec. Mode Menu		
Rec. Modes	Auto, Manual, Rhythm	Auto
Auto / Manual		
Modes	3+, 6, 6+, 12	6
Long Lead	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6	I, II, III
Rhythm		
Length of Rhythm Recording	30, 60, 90, 120, 150, 180 Seconds	30
Long Lead	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6	I, II, III
Rec. Setting Menu		
Rec Time (Rec. Type: Auto)	3-12 Seconds, Interval=1(s)	3
Paper Speed	6.25, 12.5, 25, 50	25
Gain	2.5, 5, 10, 20, Auto	10
Filter Menu		
LowPass Filter	Off, 25, 35,75, 150 Hz	150
HUM Filter	ON/ OFF	ON
Drift Filter	ON/ OFF	ON
EMG Filter	ON/ OFF	OFF
User Setting Menu		
Pace	ON/ OFF	OFF
Save	ON/ OFF	ON
Meas. & Interp.	Global/Details/OFF	OFF
Header	ON/ OFF	ON
Patient Info. Menu		
ID		Blank
Physician Name		Blank
Patient Name		Blank
Age	Years/Months	Years
Weight	Kg/lb.	Kg

ITEM	SELECTION	DEFAULT
Height	cm/Foot	cm
Gender	Male/Female/None	None
Blood Type	A+/A-/B+/B-/AB+/AB-/O+/O-/ Unknown	Unknown
Setting Menu		
Date & Time		
Date & Time	Christian/Solar	Christian
NTP Server	☐ / ☑	☑
Time Zone		Asia/Tehran
Display		
Theme	Dark, Light	Dark
Screen Saver	OFF, 10, 20, 30, 60(min)	OFF
Recording		
Select Recorder	thermal printer/ external printer	thermal printer
Periodic Recording Interval	Off, 5-60 Min, Interval=5	Off
Select printer	1-20, Infinite, Interval=1	
Network		
Network	Enable, Disable	Disable
PACS	Enable, Disable	Disable
General		
Hospital	Hospital/Ward	Blank
Sound	On/Off	On
Smart Record	On/Off	On
Language		
Language	English /فارسی	English

Appendix 3: Electro-magnetic compliance

Warning

- Use only the recommended manufacturer accessory. Using the accessory other than in relevant chapter may cause to increase the EMISSION or decrease the IMMUNITY of system.
- Measurements can be affected by mobile and RF communications equipment. It should be assured that DENA 1210 is used in the electromagnetic environment specified.
- To prevent EMC effect on DENA 1210, 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. Strong level of electromagnetic radiation emitted from such devices may interfere with DENA 1210 performance.

Guidance and manufacturer's declaration – electromagnetic emissions		
The **DENA 1210** Electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the **DENA 1210** Electrocardiograph should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The **DENA 1210** 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 **DENA 1210** 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	

Guidance and manufacturer's declaration – electromagnetic immunity			
The **DENA 1210** electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the **DENA 1210** electrocardiograph should assure that it is used in such an environment.			
Immunity test	**Port**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	Enclosure	±8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	electrocardiograph coupling		
	Signal input/output parts		
Electrical fast transient/burst IEC 61000-4-4	Input a.c. power	± 2 kV, 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
	Signal input/output parts	± 1 kV 100 kHz repetition frequency	
Surge IEC 61000-4-5	Input a.c. power	± 0,5 kV, ± 1 kV Line-to-line ± 0,5 kV, ± 1 kV, ± 2 kV Line-to-ground	Mains power quality should be that of a typical commercial or hospital environment.
	Signal input/output parts	± 2 kV Line-to ground	
Voltage dips, IEC 61000-4-11	Input a.c. power	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	
		0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	
Voltage interruptions IEC 61000-4-11	Input a.c. power	0 % U_T; 250/300 cycle	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	Enclosure	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of test level.			

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The DENA 1210 electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the DENA 1210 electrocardiograph should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>Port</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td rowspan="3">Conducted RF IEC 61000-4-6</td><td>Input a.c. power</td><td rowspan="3">3 V
0,15 MHz – 80 MHz
6 V
in ISM bands between 0,15 and 80 MHz</td><td rowspan="4"></td></tr>
<tr><td>Electrocardiograph coupling</td></tr>
<tr><td>Signal input/output parts</td></tr>
<tr><td>Radiated RF IEC 61000-4-3</td><td>ENCLOSURE</td><td>3 V/m
80 MHz – 2,7 GHz
80 % AM at 1 kHz</td></tr>
<tr><td>Proximity fields from RF wireless communications equipment IEC 61000-4-3</td><td>ENCLOSURE</td><td>Refer to the following table (table 9 of EN 60601-1-2: 2015)</td></tr>
</table>

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment						
Test frequency (MHz)	**Band [a] (MHz)**	**[a] Service**	**[b] Modulation**	**Max power (W)**	**Distance (m)**	**IMMUNITY TEST LEVEL (V/m)**
385	380-390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [C] ±5 KHz deviation 1 KHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM800/900, TETRA 800, iDEN 820, CDMA850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11, b/g/n, RFID, 2450, LTE band 7	Pulse modulation [b] 217 HZ	2	0.3	28
5240	5100-5800	WLAN, 802.11, a/n	Pulse modulation [b] 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

Appendix 4: The GLASGOW program

In this section, diseases and abnormalities which are diagnosable by Glasgow program are listed.

ATRIAL ABNORMALITIES

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

QRS AXIS DEVIATION

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

CONDUCTION DEFECTS

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

WOLFF-PARKINSON-WHITE PATTERN

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

- WPW pattern – probable left anterolateral accessory pathway
- WPW pattern – probable left posteroseptal accessory pathway
- WPW pattern – probable left posterolateral accessory pathway

HYPERTROPHY

LEFT VENTRICULAR HYPERTROPHY

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

RIGHT VENTRICULAR HYPERTROPHY

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

BIVENTRICULAR HYPERTROPHY

- Biventricular hypertrophy
- Possible biventricular hypertrophy

MYOCARDIAL INFARCTION

INFERIOR INFARCTION STATEMENTS

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

LATERAL INFARCTION STATEMENTS

- *** LATERAL INFARCT – POSSIBLY ACUTE ***
- Lateral infarction – age undetermined

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

ANTEROSEPTAL MYOCARDIAL INFARCTION STATEMENTS

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

ANTERIOR MYOCARDIAL INFARCTION STATEMENT

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

SEPTAL INFARCTION STATEMENTS

- *** SEPTAL INFARCT – POSSIBLY ACUTE ***
- Cannot rule out septal infarct – age undetermined
- Q in V1/V2 may be normal variant but septal infarct cannot be excluded
- Q in V1/V2 may be due to lead placement error though septal infarct cannot be excluded
- Q in V1/V2 may be due to LVH though septal infarct cannot be excluded
- Abnormal Q waves of undetermined cause

- Septal QRS changes may be due to ventricular hypertrophy
- Septal QRS changes may be due to corrected transposition
- QRS changes in V2 probably due to LVH but cannot rule out septal infarct
- Poor R wave progression – cannot rule out septal infarct
- Poor R wave progression may be due to pulmonary disease
- Q waves may be due to cardiomyopathy

POSTERIOR MYOCARDIAL INFARCTION

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

ANTEROLATERAL MYOCARDIAL INFARCTION

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

EXTENSIVE MYOCARDIAL INFARCTION

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

ST ABNORMALITIES

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

MISCELLANEOUS

LOW QRS VOLTAGES

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

TALL T WAVES

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

CRITICAL VALUES

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

INTERVALS

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

DOMINANT RHYTHM STATEMENTS

- Sinus rhythm
- Sinus tachycardia
- Sinus bradycardia
- Sinus arrhythmia
- Sinus tachycardia with sinus arrhythmia
- Sinus bradycardia with sinus arrhythmia
- Atrial tachycardia
- Atrial flutter
- Atrial fibrillation
- Junctional rhythm
- Accelerated junctional rhythm
- Junctional bradycardia
- Atrial pacing
- Ventricular pacing
- A-V sequential pacemaker
- Pacemaker rhythm
- Possible ectopic atrial rhythm
- Possible ectopic atrial tachycardia
- Possible ectopic atrial bradycardia
- Irregular ectopic atrial rhythm
- Irregular ectopic atrial tachycardia
- Irregular ectopic atrial bradycardia
- Probable atrial tachycardia
- Probable sinus tachycardia
- Probable supraventricular tachycardia
- Marked sinus bradycardia
- Probable atrial flutter
- Probable atrial fibrillation

- Probable junctional rhythm
- Probable accelerated junctional rhythm
- Probable ventricular tachycardia
- Wide QRS tachycardia
- Accelerated idioventricular rhythm
- Possible idioventricular rhythm
- Possible atrial flutter
- Possible junctional rhythm
- Possible accelerated junctional rhythm
- Possible junctional bradycardia
- A-V dissociation
- Undetermined rhythm
- Regular supraventricular rhythm
- Irregular supraventricular rhythm

SUPPLEMENTARY RHYTHM STATEMENTS

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

Appendix 5: Dena Viewer software

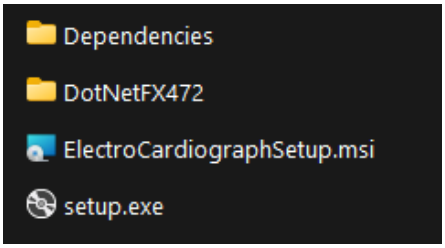
Dena Viewer software is able to display online signals, generate pdf file and print the acquired signal by Dena electrocardiograph. It Is also able to display exported signals using flash memory on offline mode.

- The software is provided with a dongle which must be connected to the USB port of the computer while the app is being used. If the dongle is disconnected, the software will stop working.

Dongle

Software installation

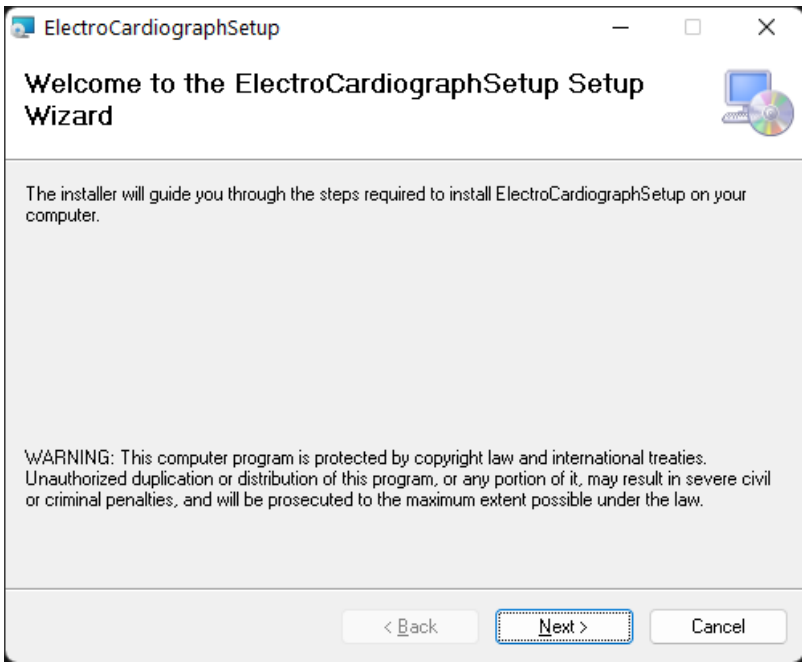
1. In order to install **Dena viewer windows software**, run “setup.exe” file in the installation folder.



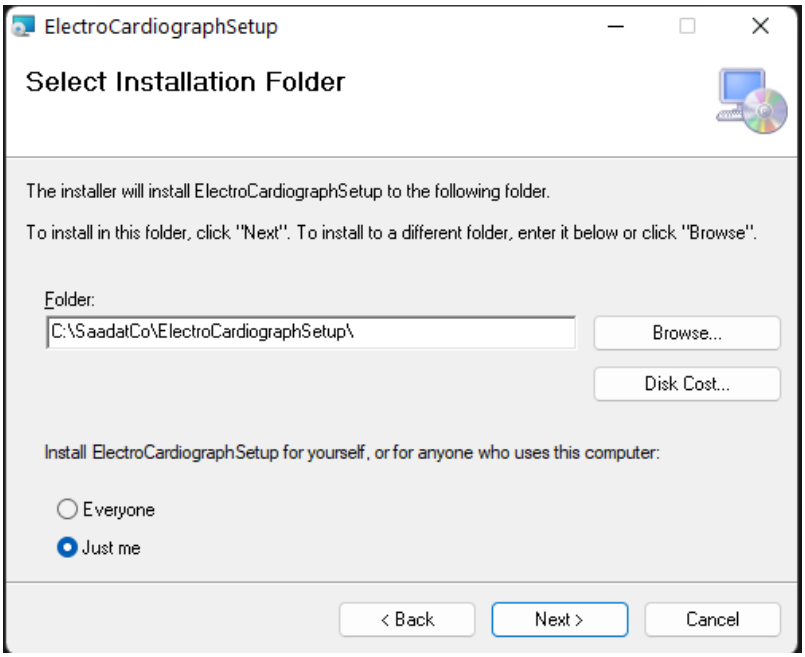
NOTE

- .Net Framework4.7.2 library must be already installed in order to install Dena viewer. The library will be automatically downloaded and installed if your operating system does not have it. Make sure you have an internet connection.
- If your operating system does not have .Net Framework4.7.2 installed and it is not connected to internet, install the library from “Dependencies\DotNetFrameworkOfflineInstaller” path, then install the software.

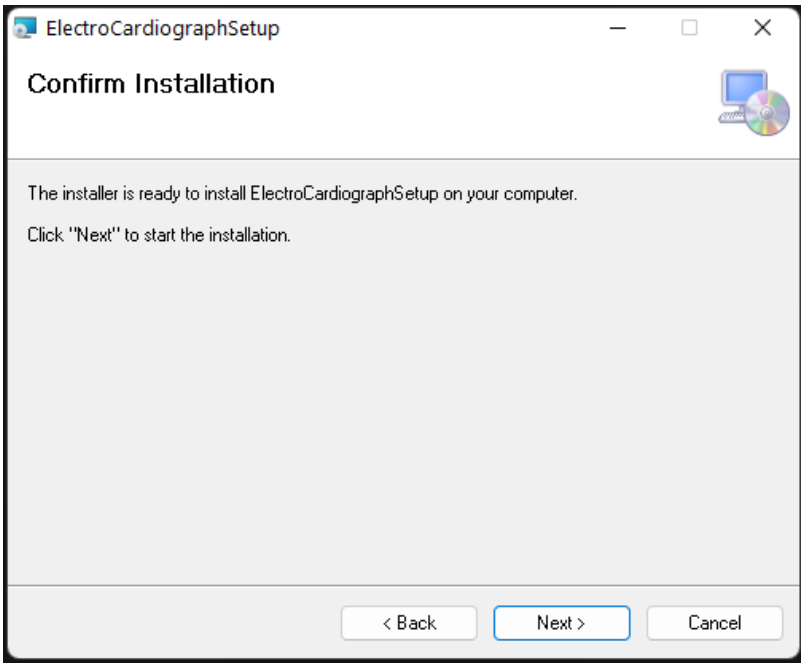
2. Click on “Next”.



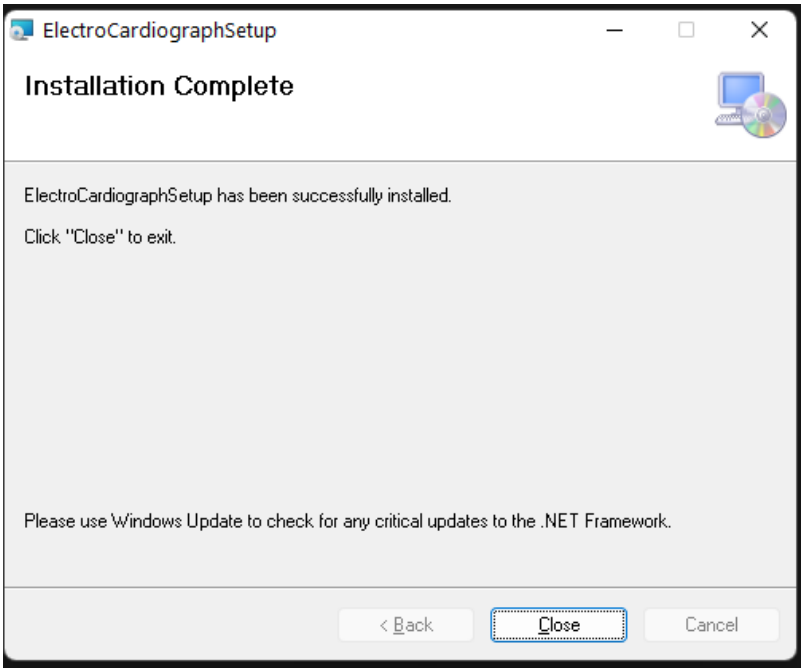
3. Select the installation path. For proper software function, it is recommended not to change the default insatllation path and click on “Next”.



4. Click on “Next”. If the operating system needs installation permission, Click on “Yes” and allow the software to be installed.



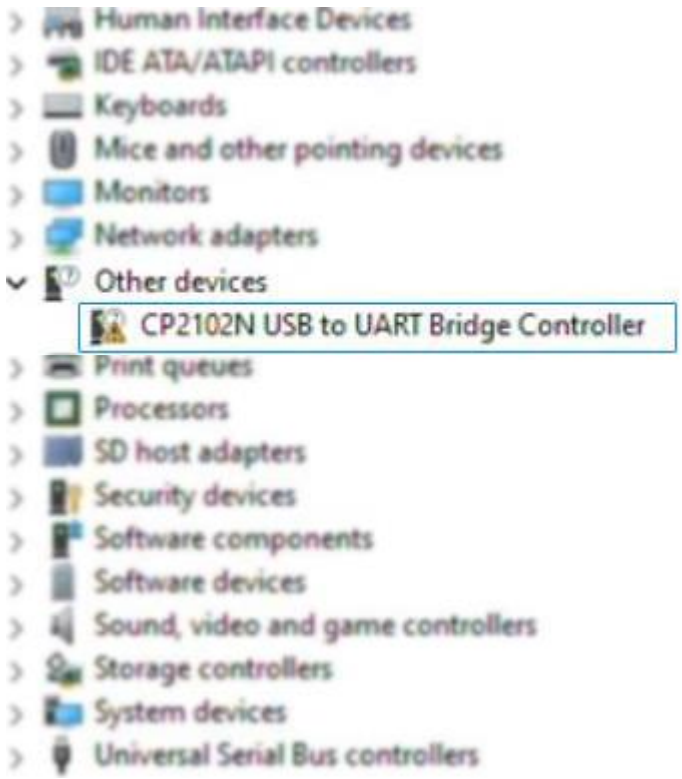
5. The software was successfully installed. Click on “Close”.



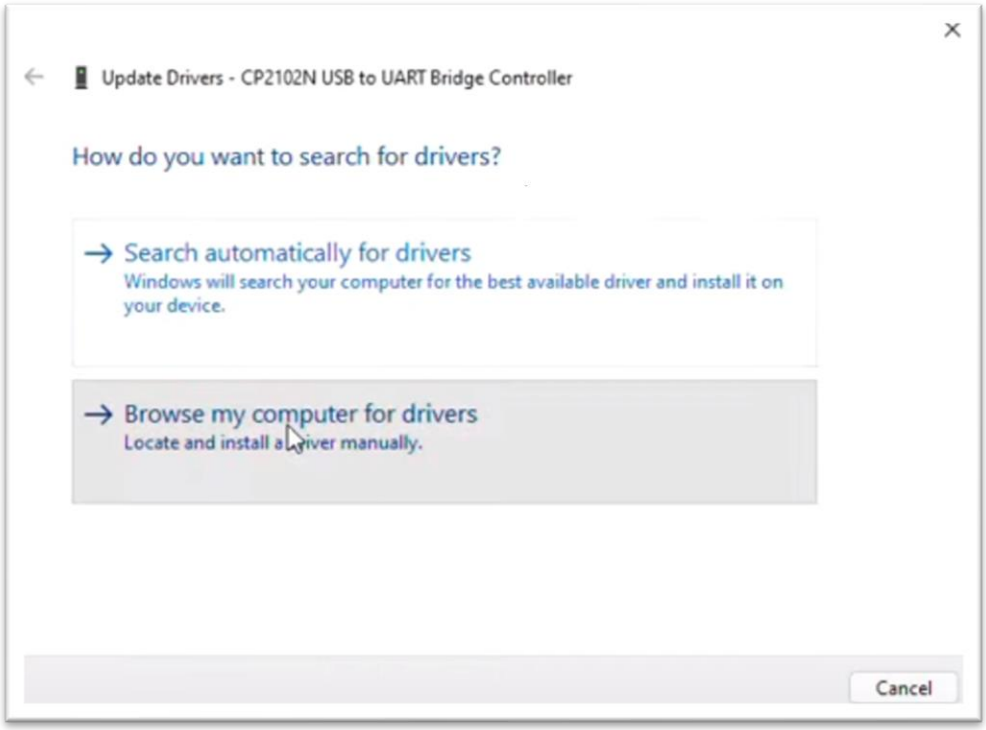
Connecting the device

Turn the device on and connect it to the PC using a proper cable (USB Type A to Type B). Connect the dongle to the PC. If the device has not been detected by your computer, the PC screen will become like the following image:

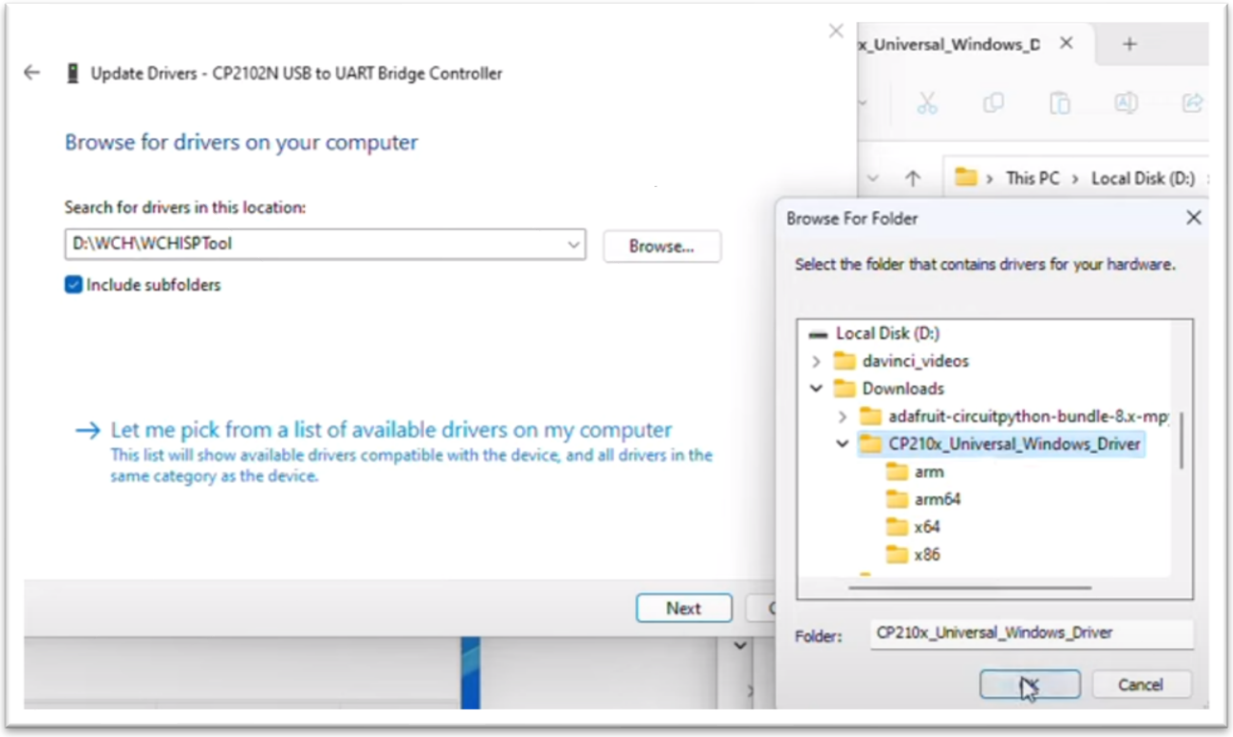
If this happens, it is necessary to install the driver. While the device is connected to the PC, Enter “Control Panel” and open “Device Manager”. A new item is added as following:



1. Right click on the unknown item and click on “Update driver”.
2. Click on “Browse my computer for drivers” as the following image. (The driver file is located in **Dependencies\UsbPortDriver** on installation folder.)



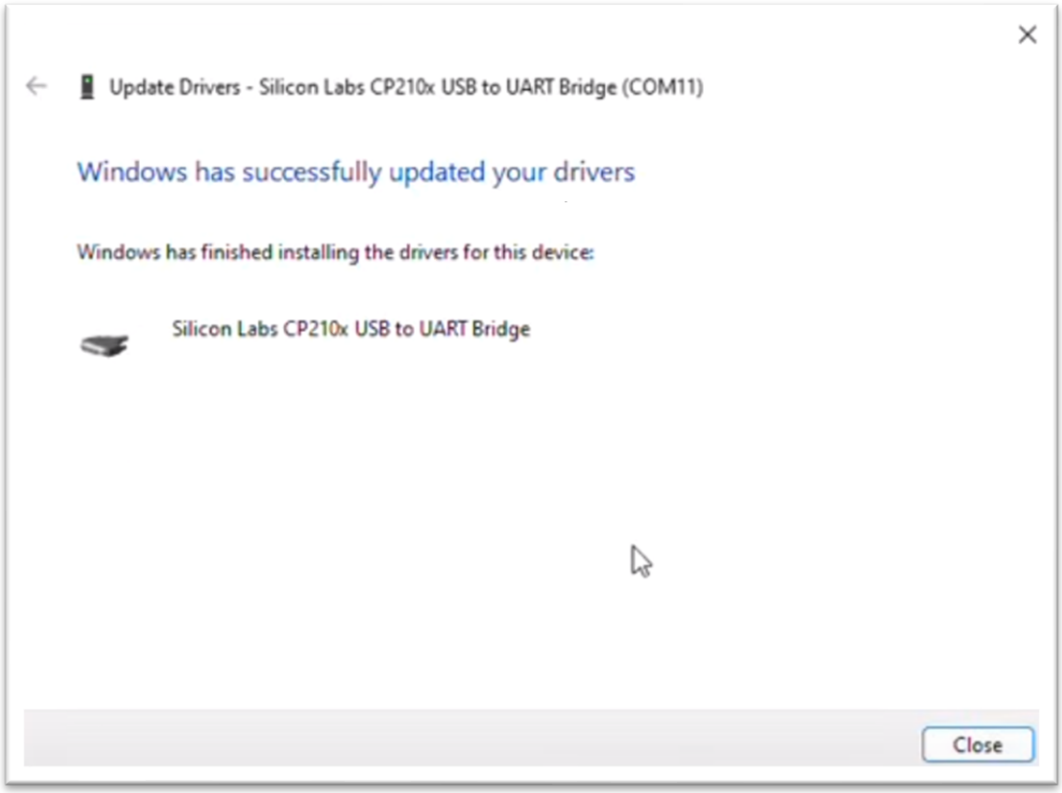
3. Click on “Browse” and select “CP210x_Universal_Windows_Driver” from **Dependencies\UsbPortDriver** on installation folder, select “Include subfolders” and then click on “OK”.



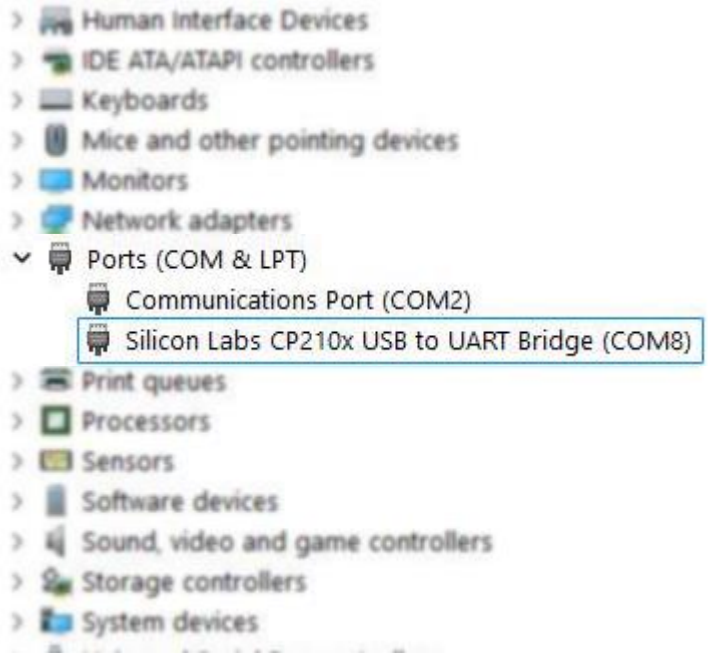
NOTE

- You can also download the driver. To do so, you can enter the following link and from “Downloads” section, download the “CP210x Universal Windows Driver” driver and then unzip the downloaded file.
  - https://www.silabs.com/developers/usb-to-uart-bridge-vcp-drivers

4. Click on “Next” to install the driver. Click on “Close” after the driver was successfully installed.



5. Disconnect the cable and then plug it in again. In “Device Manager”, “Ports” section, a new item will be added to which a COM port is assigned.



The operating system has detected the device and the software is ready to use.

Using the software

The dongle must remain connected to the computer while using the software. If the dongle is disconnected, the software can't be used and will indicate as following:

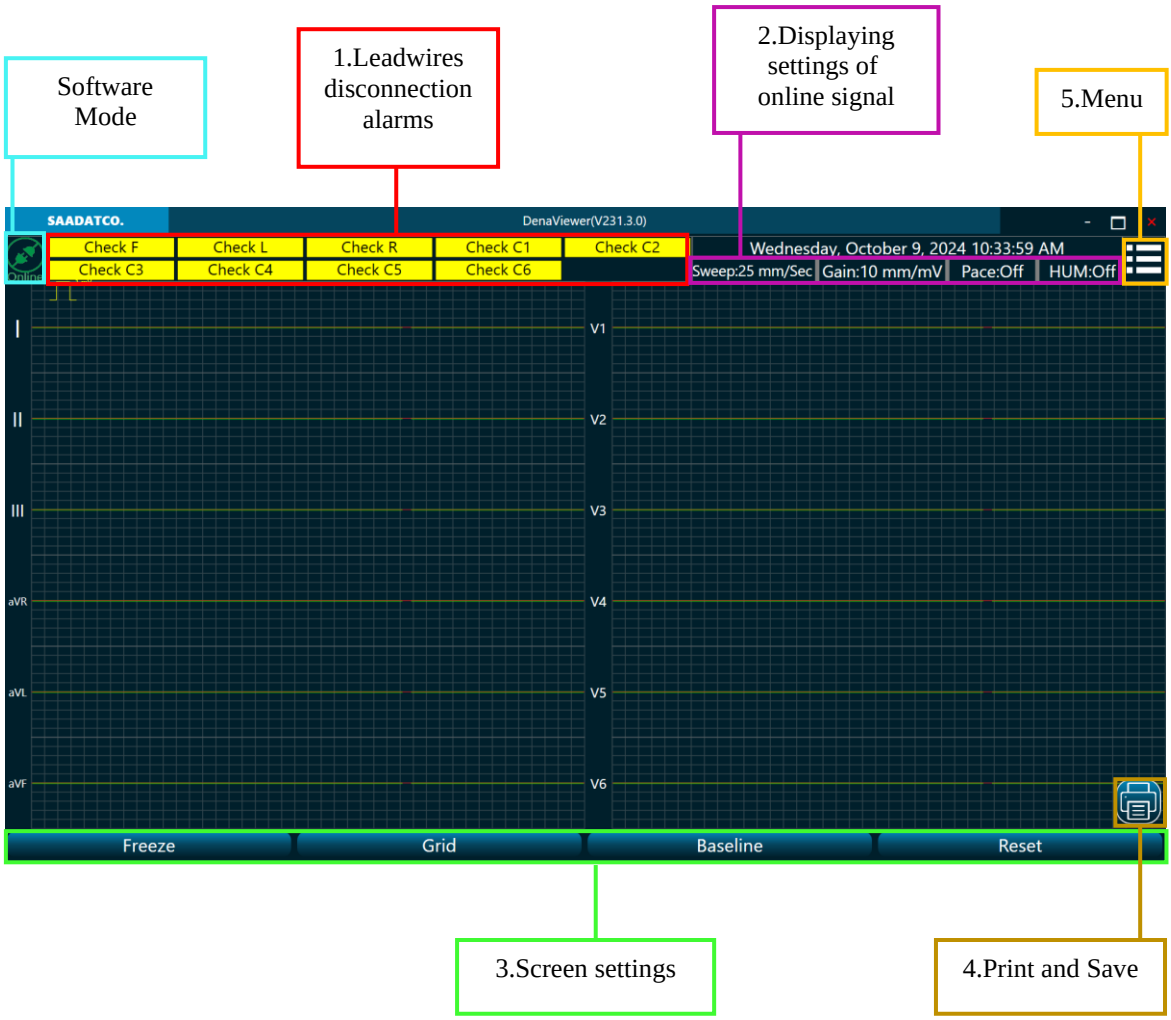
The software has 2 modes, which are selectable by clicking on the **mode** icon.

- Online mode 

- Offline mode 

Online mode

On **Online** mode, the acquired signal by Dena is simultaneously displayed on the software; however, signal settings and filters are set only on the software and the selected settings on the device do not affect the displayed signal on the software.



1. Lead wires disconnection alarms

In case a lead wire is disconnected from patient's body, the corresponding alarm will be displayed on this region.

2. Displaying settings of online signal

Settings and filters applied on the online signal are displayed here.

3. Screen settings

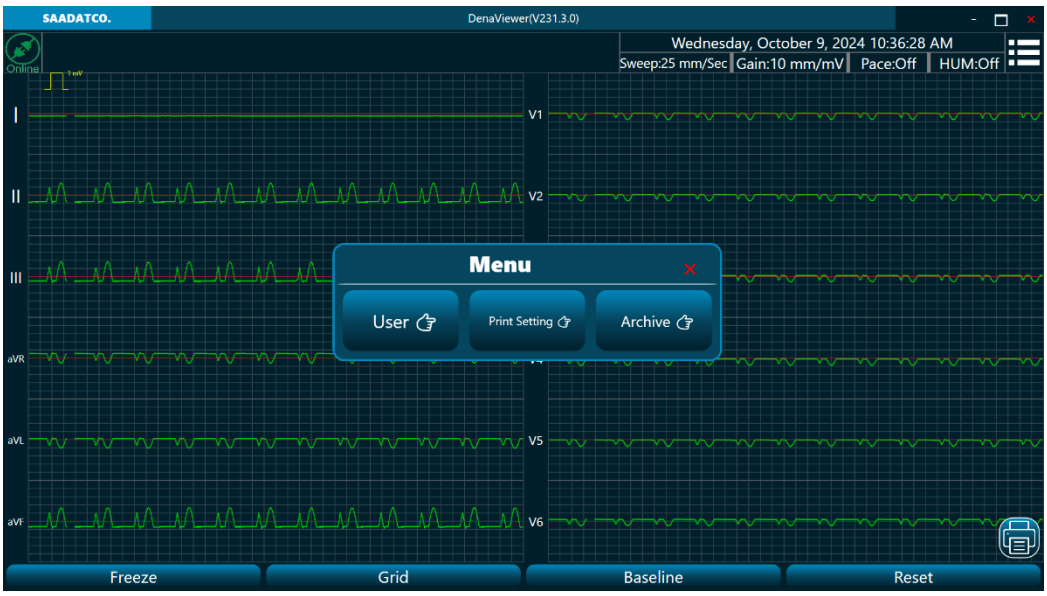
The signal can be frozen, baseline and grid can be enabled or disabled. Reset button is used to reset the Drift filter and return signals quickly to the screen.

4. Print and Save

Print or save the signal.

5. Menu

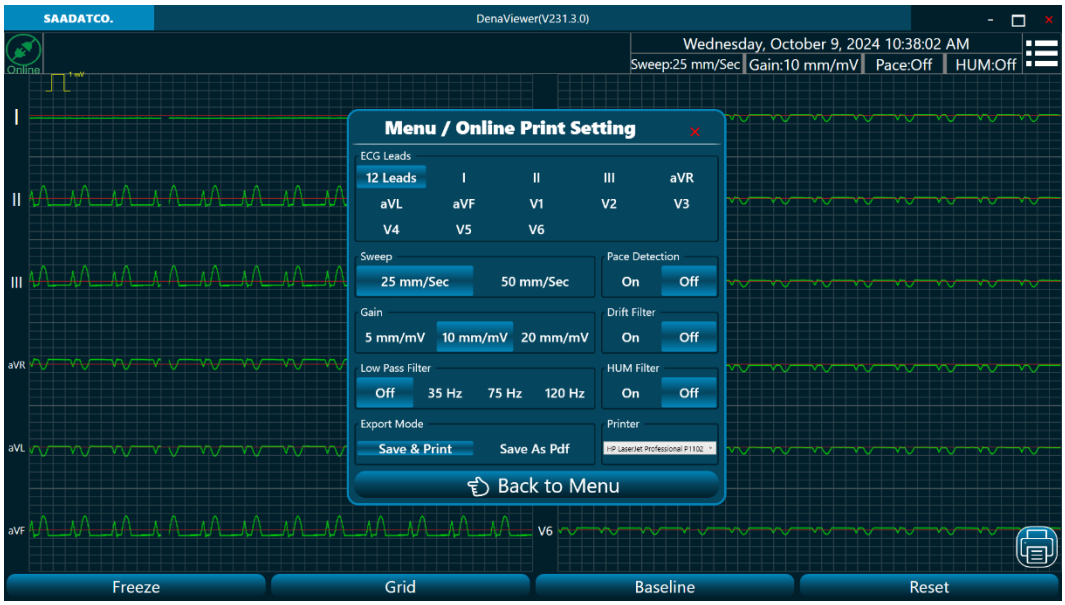
Click on this item and the following window will appear:



- Click on “User” and the following window will appear:

Enter patient information in this section.

- Click on “Print Setting” and the following window will appear:



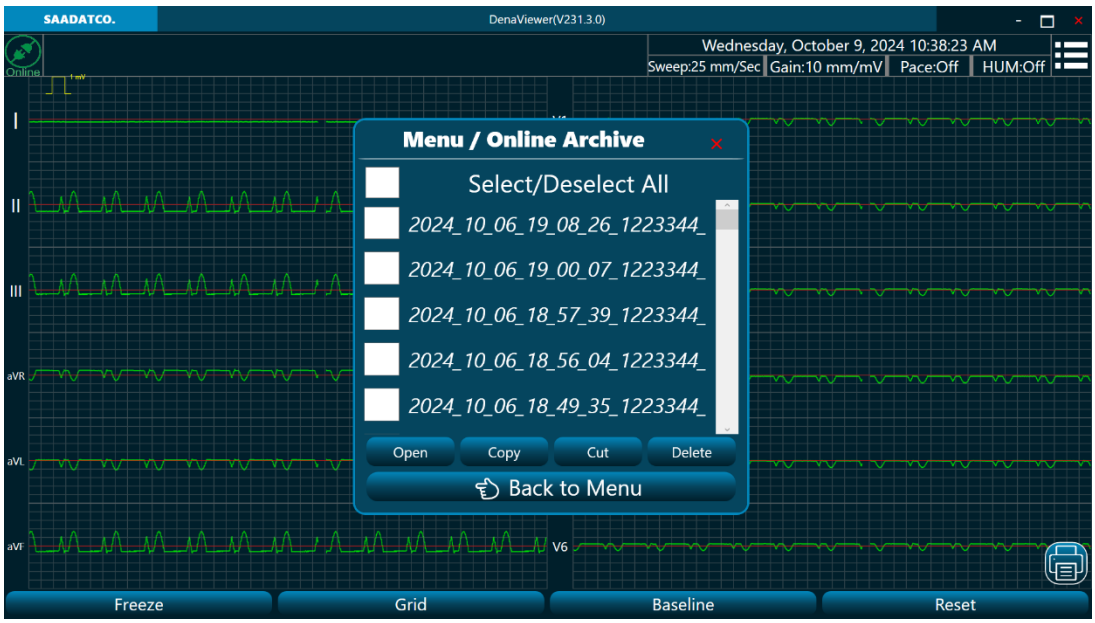
Signal settings and filters can be set in this section.

- **ECG Leads**: Desired leads
  On **ECG Leads**, “12 Leads” is selected, 10 seconds of all leads will be printed or saved. If other options are selected, 30 seconds of the selected lead will be printed or saved.
- **Sweep**: Signal sweep speed
- **Gain**: Signal gain
- **Low Pass Filter**
- **Pace Detection**
- **Drift Filter**
- **HUM Filter**: Mains power noise removal filter
- **Export Mode**: if “Save & Print” is selected, the software saves the signal and prints it. In this case, select the desired printer from **Printer** section.
  If “Save As PDF” is selected, the software only saves the PDF file.

NOTE

- **Sweep**, **Gain**, **Pace Detection** and **HUM Filter** are settings for displayed and sved signal; other settings are for saved signal.

- Click on “Archive” and the following window will appear:

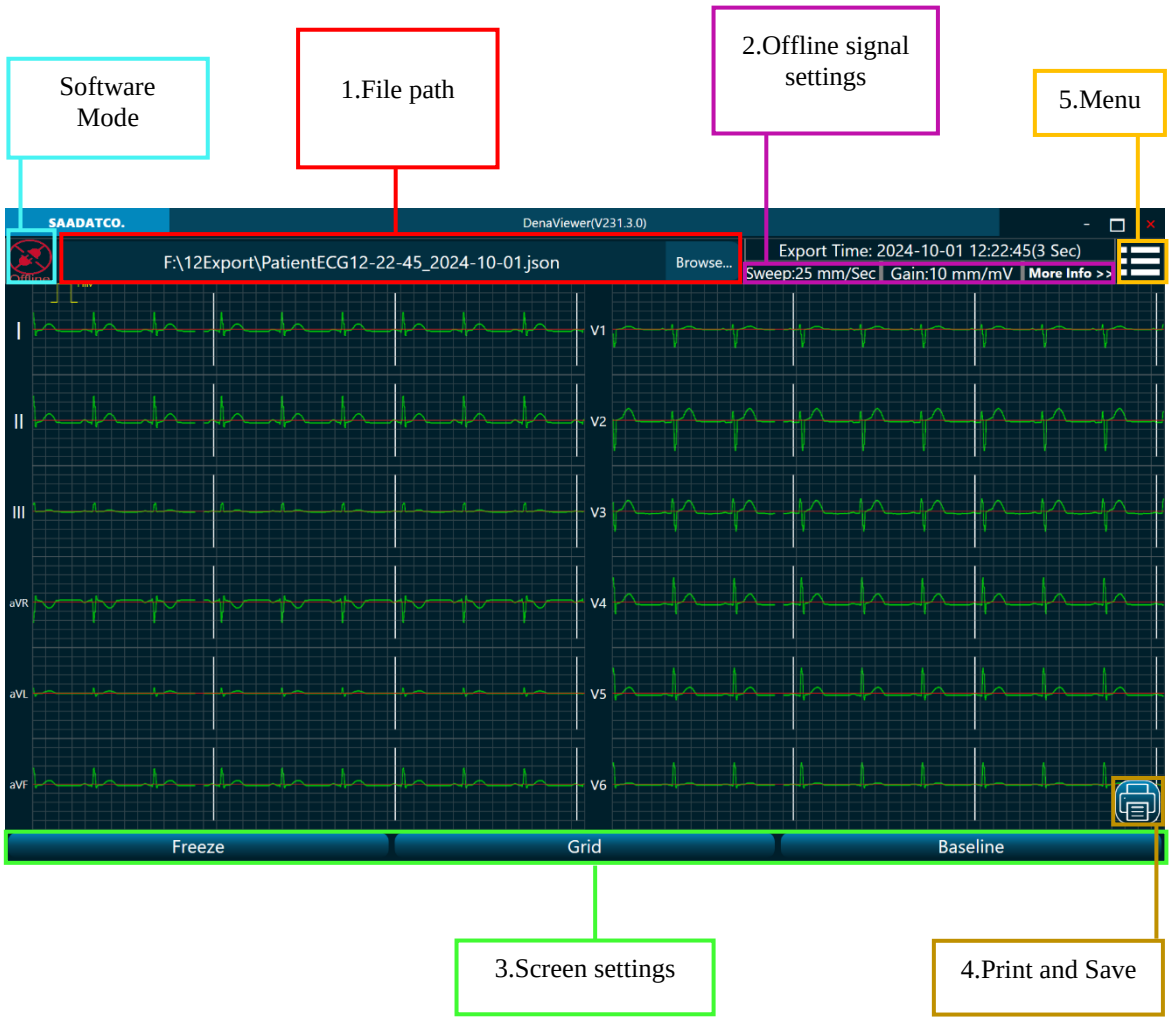


The signals saved on Online mode are displayed here.

- Open: Opens the selected PDF file.
- Copy: Copies the selected PDF file.
- Cut: Cuts the selected PDF file.
- Delete: Deletes the selected PDF file.

Offline mode

In this mode, the signals exported using a flash memory can be displayed or printed.



1. File path

Click on “Browse” to select the exported file; the signal will be displayed on the screen.

2. Offline signal settings

Signal settings and patient information, which were set when the signal was acquired by the device, are displayed.

NOTE

- On offline mode, signal settings and patient information are not changeable.

3. Screen settings

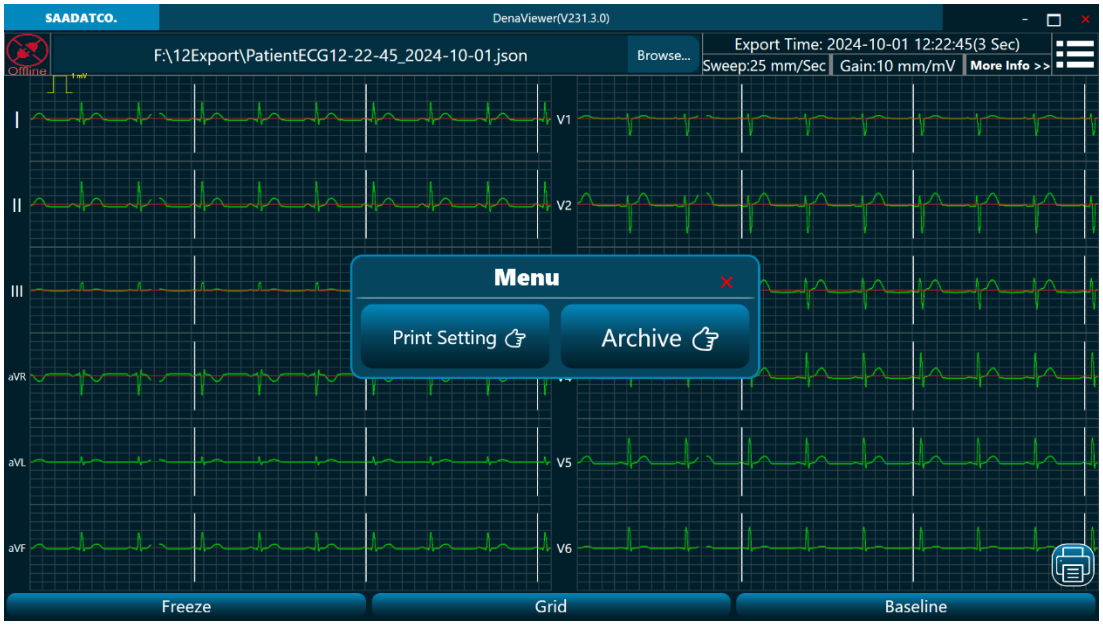
The signal can be frozen, baseline and grid can be enabled or disabled.

4. Print and Save

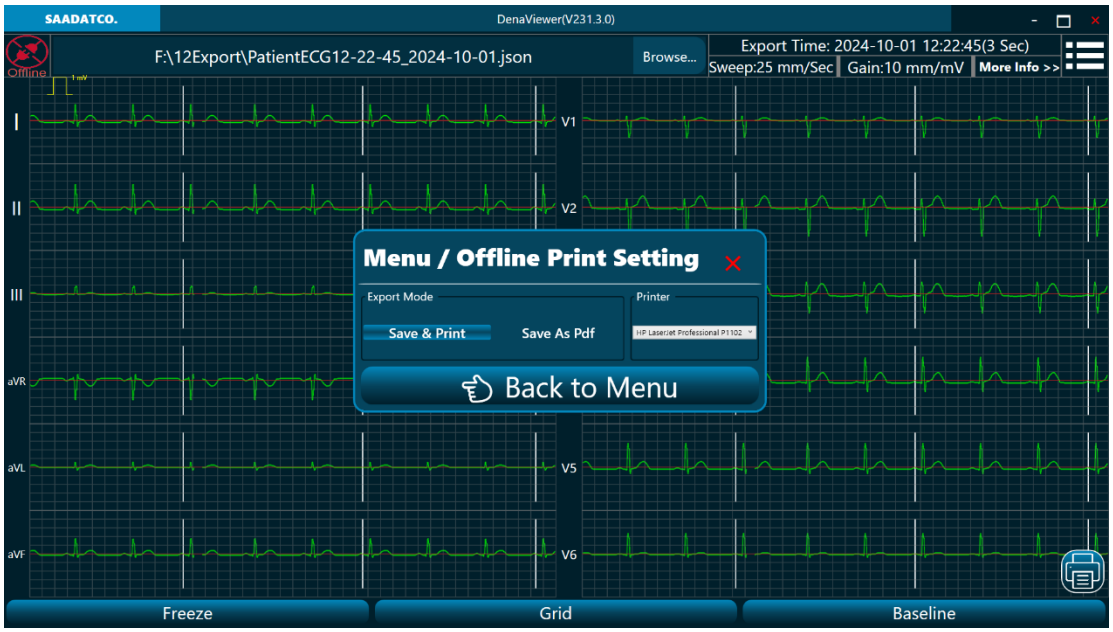
Print or save the signal as PDF file.

5. Menu

Click on this item and the following window will appear:

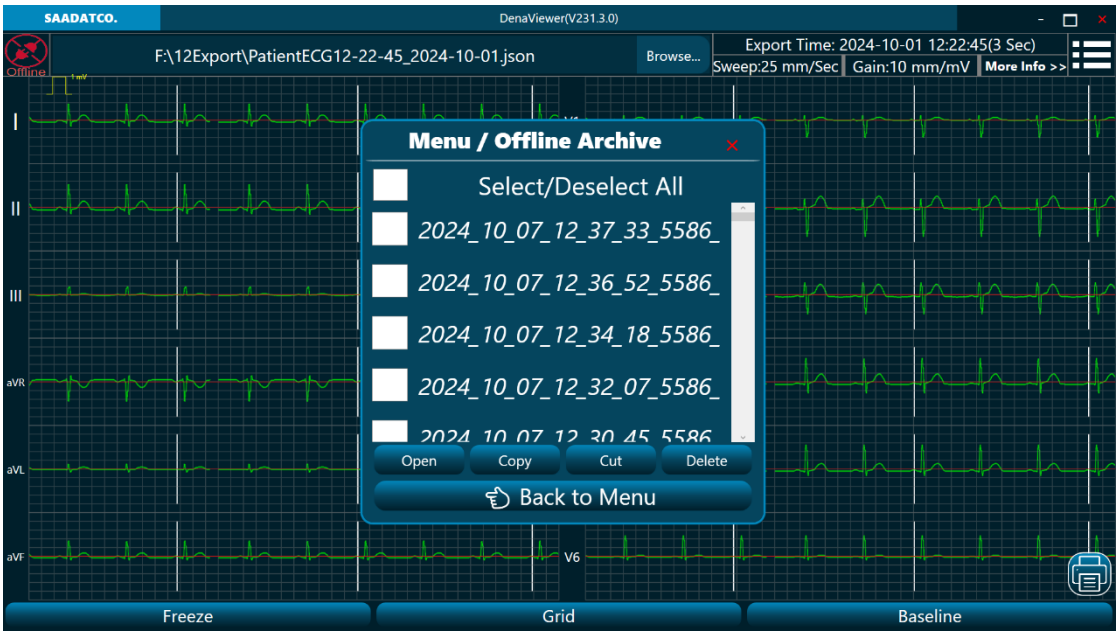


- Click on “Print Setting” and the following window will appear:



- On **Export Mode**, if “Save & Print” is selected, the software saves the signal and prints it. In this case, select the desired printer from **Printer** section.
  If “Save As PDF” is selected, the software only saves the PDF file.

- Click on “Archive” and the following window will appear:



The signals saved on Offline mode are displayed here.

- Open: Opens the selected PDF file.
- Copy: Copies the selected PDF file.
- Cut: Cuts the selected PDF file.
- Delete: Deletes the selected PDF file.