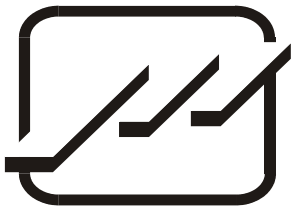
POOYANDEGAN RAH SAADAT

OPERATOR'S MANUAL

JAM S3 Wearable Patient Monitor

CE 2195

D00873-V5



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Contents

About manual

Manual purpose

This manual is an integral part of the product and describes its proper and safe intended use to the patient and user. Observance of the manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

In order to use the equipment safely, it is necessary to follow the instructions in this manual. However, the instructions in this manual are in no way a substitute for medical patient care practices.

Intended Audience

This manual is provided for the clinical medical professionals. Clinical medical professionals are expected to have practical knowledge of medical terminology and procedures as required for patient monitoring.

Indications used in this manual

Warning

The items listed in this indication, remark a warning to avoid any danger or injury to the patient, user or device.

Note

The items listed in this indication, contain additional recommendations and explanations for better use of the device.

Version of manual

This manual has a version number. The version number changes whenever the manual is updated. The version information of this manual is as follows.

Code and Version	Issue date
D00873 – V5	June 2022

- Read this manual carefully before patient use of the monitor.
- All illustrations in this manual are provided as examples only. They may not necessarily reflect your monitoring setup or data displayed on your monitor.
- Pooyandegan Rah Saadat Co. reserves the right to make changes to this manual and improvements to the product it describes at any time without notice obligation.
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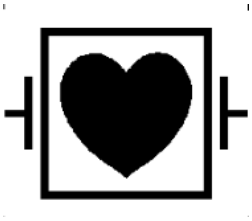
Symbols

1	Protected from tools and wires greater than 2.5 millimeters. Protected from water spray less than 15 degrees from vertical.	**IP32**
2	Manufacturer address	
3	**Consult operator's manual:** Refer to the operator's manual for complete information. This label on the device points the user to the operator's manual for complete information. In the operator's manual, this symbol cross-references the label.	
4	This symbol indicates that the equipment shall be disposed of in an environmentally-friendly manner.	
5	Manufacture Date	
6	Serial Number	SN
7	CE sign & NB identification number	CE
8	DEFIBRILLATION-PROOF TYPE BF APPLIED PART: This symbol indicates that the monitor has CF type and Defibrillation Proof applied part according to IEC60601-1. The modules with this symbol contain a CF-Type isolated (Cardiac Float) patient applied part providing a high degree of protection against shock, and is usable during defibrillation.	
9	**Caution sign:** This symbol beside the patient connector indicates that a part of protection against effects of defibrillator is provided by the accessory connected to patient. Therefore, use only accessories approved by the manufacturer.	
10	Wireless connection	

Chapter 1) Safety & General Warnings

The following Warnings and Notes have to be obeyed to guaranty a safe operation of the monitor. Additional Warnings and Notes, which apply to specific parameters, are listed in the related sections for each parameter.

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

⚠ Warning

- The device shall be used in accordance with the instructions for use.
- The warranty does not cover damages resulting from the use of accessories and consumables from other manufacturers.
- The manufacturer is responsible for the effects on safety, reliability, and performance of the product, only if assembly, operations, extensions, readjustments, modifications, or repairs are carried out by the personnel authorized by the manufacturer.
- The monitor is not intended for diagnostic use. The health care professional should seek a full capability ECG system for diagnostic purposes.
- The JAM S3 Monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.
- Do not connect more than one patient to a monitor. Do not connect more than one monitor to a patient.
- Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low-level during patient monitoring may result in a hazard to the patient. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.

- Electromagnetic Compatibility (EMC) - The equipment needs special precautions if it is placed close to a strong transmitter such as X-ray equipment, MRI devices, TV, AM/FM radios, police/fire stations, a HAM radio operator, an airport, or cellular phone. Their Signals could interfere with the monitor, which may result in disruption of performance of this device or prevents the clear reception of signals by the monitor.
- There will be some risks of polluting the environment associated with the disposal of the device and cables at the end of their useful lives. The device and accessories 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.
- Qualified biomedical engineering personnel only must interface monitoring equipment with other types of medical equipment. Be certain to consult manufacturers' specifications to maintain safe operation.
- Measurements may be affected in the presence of strong electromagnetic sources such as electro surgery equipment.
- When using a defibrillator, parameters and signals will be temporarily interrupted; this interruption resolves almost immediately after the end of the shock.
- To avoid device malfunction, liquids must not be allowed to enter the device. If liquids have entered a device, take it out of service and have it checked by a service technician before it is used again.
- Route all cables away from patient's throat to avoid possible strangulation.
- There could be hazard of electrical shock by the monitor casing. To avoid risk of electric shock, this equipment must only be connected to a mains supply with protective earth.
- Pressing the touch or membrane keys with a sharp or pointed instrument may permanently damage the switch membrane. Press the keys using only your finger.
- Do not use in the presence of flammable liquids, vapors or anesthetic mixtures with air or oxygen or nitrous oxide.

Note

- The monitor has been designed to promote patient safety. All equipment parts are protected against the effects of the discharge of a defibrillator. No separate actions are required when using this equipment with a defibrillator.

Chapter 2) Introduction

Intended Use

The JAM S3 Monitor is intended to continuously monitor a patient's ECG, heartrate (HR), functional arterial oxygen saturation (SPO2) and respiration rate (RR). The monitor is designed as a bedside/portable monitor and is intended for use on adult (over twelve), pediatric (from three to twelve) and neonatal (from birth to age three) patients in the care of health care professionals.

Contraindications

- ECG electrodes are contraindicated for use on patients with limited skin access or allergic reaction to electrode adhesive or application gel.
- Reusable ECG electrodes are contraindicated for use for prolonged periods of use. It is not intended for long term monitoring. Electrodes must be removed and repositioned if indicated by skin integrity, and reapplied to a different monitoring site.
- Respiration monitoring is contraindicated for patients who are receiving high frequency ventilation assistance.
- Reusable SPO2 sensors are contraindicated for use for prolonged periods of use. It is not intended for long term monitoring. It must be removed and repositioned every four (4) hours and if indicated by circulatory condition or skin integrity, reapplied to a different monitoring site.
- Disposable SPO2 sensors are contraindicated for patients that exhibit allergic reactions to adhesive tape. The sensors must be removed and repositioned every eight (8) hours and if indicated by circulatory condition or skin integrity, reapplied to a different monitoring site.
- Do not use the JAM S3 monitor for Open Heart Applications (Intra-cardiac Application).
- The JAM S3 monitor is not intended to be used in Oxygen Enriched Atmospheres.
- Do not use the monitor in the presence of Magnetic Resonance Imaging (MRI) equipment.
- Do not use the JAM S3 monitor for any purpose other than specified in this manual. Doing so will invalidate the monitor's warranty.

Installation and Setup

The JAM S3 monitor is used as a portable monitor that provides the possibility of monitoring the patient vital signs in the different places and situations. This monitor is hanged to the patient's neck with a neck strap along with the device and after connecting the corresponding electrodes, monitors his vital signs. Data transmission on the central system at the nurse station or on mobile/tablet is possible through the Wi-Fi network.

Since the JAM S3 monitor continuously monitors the patient vital signs, it is hanged to the patient neck and transferred with him during the awaking time and placed next to him during the sleep and rest time.

Environmental conditions

Magnetic and electric fields may interfere with the monitor, so make sure the electric devices around the monitor meet relevant EMC requirements. Listed below are some warnings but not limited to:

Warning

- The JAM S3 is intended for use in the electromagnetic environment specified in Appendix, in the EMC Declaration section. The customer or the user of the JAM S3, should assure that it is used in the mentioned environment.

Note

- To access information about operating and storage and transport temperature and humidity, refer to technical specification chapter.

Getting Start

Turn On

Press and hold the POWER key on the side panel for 5 seconds to turn the monitor on (figure 2-5).

Turn Off

When the monitor is not being used, by pressing the POWER key for 5 seconds, the message "Device will be ShutDown, Are You Sure?" will be shown (figure 2-6). If selected YES, the display will turn blank and the unit is no longer monitoring the patient.

Figure 2-1: JAM S3 monitor front view

Figure 2-2: JAM S3 monitor rear view

Figure 2-3: JAM S3 monitor top view

Figure 2-4: JAM S3 monitor side view

Figure 2-5: Side panel keys

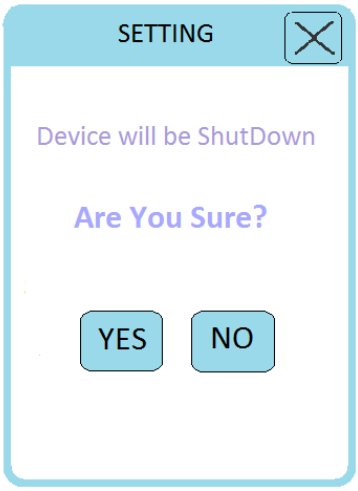


Figure 2-6: Power off message

Lock Mode

The touch screen of JAM S3 monitor will be locked and inactive by selecting the “Display Lock” option in the display section of the setting. When “Display Lock” option is selected, the Lock

indicator is shown in the upper-right corner of display page. For canceling the lock mode, power key should be pressed once, and the Lock indicator will be disappeared from the screen. For further information about the “Display Lock” option, refer to Setting chapter.

Figure 2-7 Lock Mode

Front Panel Touch Keys

The monitor can be operated via the front panel touch buttons (Figure 2-8) and touch screen.

Figure 2-8: Touch keys and indicators

- **Page Key:** The Page Key is used for switching between the pages.

Note

- At the moment the JAM S3 monitor has three pages that the first page is portrait and the second and third pages are landscape. The third page is SPO2 page.

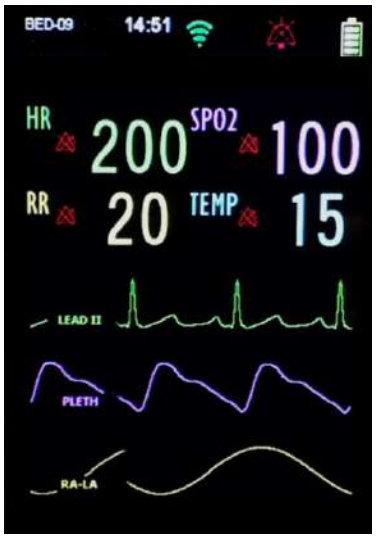


Figure 2-9: Portrait page

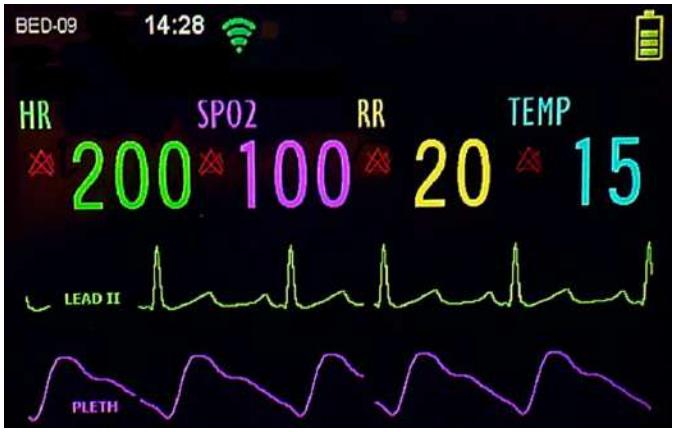


Figure 2-10: Landscape page

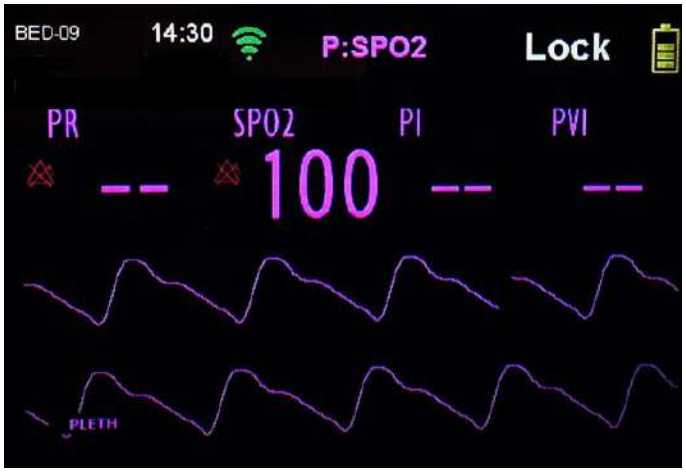


Figure 2-11: SPO2 page

- **Setting Key:** The Setting key is used for entering to the device Setting Menu.
- **Back Key:** The Back key is used for returning to the last menu.

Main Page

The main display contains the following sections:

1. **Status Bar**

Time, bed number, Battery indicator, Alarm Silence indicator, Wi-Fi indicator and Lock indicator can be observed in the status bar.

Note

- When the Alarm Silence key is pressed, (figure 2-8) the alarm silence indicator appears in this section B.

2. **Technical Alarm Bar**
3. **Physiological Alarm Bar**
4. **Parameters area:**

- The upper-left parameter is HR. (Heart Rate)
- The upper-right parameter is SPO2.
- The lower-left parameter is RR. (Respiration Rate)
- The lower-right parameter is Temp. (This parameter will be active in the future.)

5. **Waveforms:**
   - ECG wave form
   - SPO2 wave form
   - Respiration wave form

Connecting the Accessories

The various accessories are connected to the appropriate input connectors in the upper part of the monitor.

In the upper part of the monitor, the ECG/Respiration, SPO2 and USB connectors are placed from left to right respectively.

- ECG/Respiration connector  : Is used for ECG cable connection
- SPO2 connector  : Is used for the connection of Masimo pulse oximetry probe and extension
- USB connector  : At the moment this connector is placed only to the authorized trained personnel of manufacturer. and is used for upgrading the device software or saving the device information on the computer.

Battery Operation

The JAM S3 monitor is working with 2 AA Disposable or Rechargeable Batteries. The Manufacturer suggests using of 2 NI-MH batteries which have high capacity, and are environmentally friendly.

The device is working about 24 continues hours in telemetry mode, which sends ECG signals to the central device and with turned off monitor, by means of 2 AA, 2400 mAh batteries. Working time is different according to device setting and selected battery types.

To insert the batteries into the monitor, follow these steps.

1. Open the Battery Container by pulling its handle back (Figure 2-12).
2. Bring the container out of the monitor's case.
3. Insert the batteries into the container by being concerned about the "+" and "-" signs, which show the right direction of each battery.
4. Put the batteries' container back into its location in monitor and make sure that it has been locked correctly.

Warning

- The device will not work, if the batteries are not inserted correctly; however, this fault will not harm the monitor.

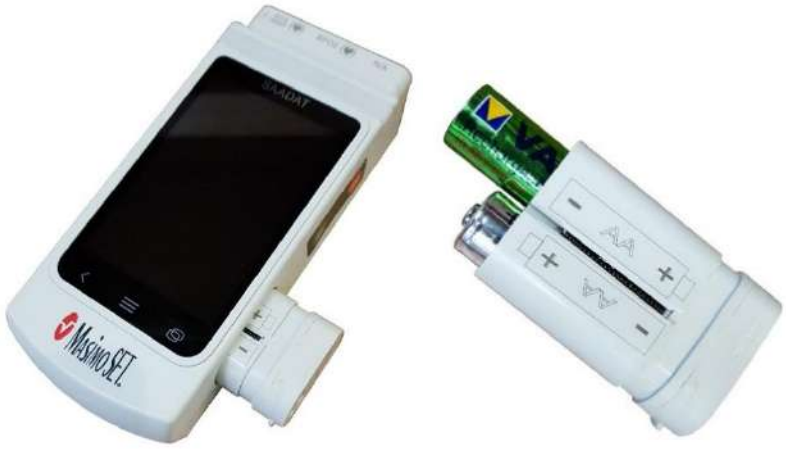


Figure 2-12: Battery Operation

Battery Status

The battery level is displayed using the battery indicator .

This indicator informs the user about the amount of battery charge in 5 levels include full charge, %75, %50, %25 and under %5. In two levels %25 and under %5, the Low Battery alarm is issued.

Charger

A USB charger (charging head and USB cable) is included with the device for charging the battery. For charging the battery using the charger, follow the instructions below.

1. Connect the USB cable to the charging head, and then plug the charging head into a standard outlet.
2. Insert the USB cable into the charger port of the device.
3. The red LED near the charging port indicates that the device is being charged.
4. Unplug the charging head from the outlet and remove the USB cable from the device when charging is complete.

Figure 2-13: Charger

Warning

- Use only charging devices and batteries approved by manufacturer.

Connecting to Wi-Fi Status

If the device is set on Central or Smart Phone mode, the Wi-Fi indicator is shown in white and after connecting the Wearable Monitor to the network, the indicator color changes from white to green.

Chapter 3) Alarms

Introduction

Alarms can be classified into three categories: physiological alarms, technical alarms and messages.

The JAM S3 Monitor distinguishes between physiological and technical alarms and messages.

Warning

- Always verify the audible and visible alarms when monitor is powered on.
- Alarm settings including priority, limits and volume should be done with regard to the patient and environment conditions in a way that the patient life is not threatened and reoccurrence of alarms is prevented.

Physiological alarms

Physiological alarms also called patient alarms are triggered by a parameter value that violates adjusted alarm limits or an abnormal patient condition.

Warning

- Before each use, verify that the alarm limits are appropriate for the patient being monitored.

Note

- All patient alarms, based on continuously monitored parameters (e.g. Heart Rate, SpO2, etc.) will clear automatically when the alarm cause is no longer persistent.
- To access physiological alarm list, refer to Messages and Alarms chapter.

Manifestation of Physiological Alarms

- Numeric display of the alarming parameter flashes.
- Alarm LED's are activated.
- Audible tone is generated. (The tone is appropriate to the alarm level.)
- Flashing text in physiological alarm's bar explains the cause.

Note

- When an ongoing patient alarm is acknowledged by pressing the ALARM SILENCE key, all alarm indicators, except the alarm label on display, will be suspended for 2 minutes or until the time of happening a new alarm.
- The delay time from an alarm occurrence to alarm manifestation (parameter blinking, alarm message, alarm sound) is less than 1 second. (Delay time of APNEA alarm is corresponding to APNEA LIMIT setting in RESP menu.)

Technical alarms

Technical alarms also called equipment alarms are triggered by a device malfunction or a patient data distortion due to improper operation or mechanical problems.

Note

- All equipment alarms will clear automatically when the alarm cause is no longer persistent.
- To access technical alarm list, refer to Messages and Alarms chapter.

Manifestation of Technical Alarms

- Alarming parameter display flashes.
- Alarm LED's are activated.

- Audible tone is generated. (The tone is appropriate to the alarm level.)
- Flashing text in technical alarm's bar explains the cause.

Note

- When an ongoing patient alarm is acknowledged by pressing the ALARM SILENCE key, all alarms, except the alarm label on display, will be suspended for 2 minutes or until the time of happening a new alarm.

Messages

In fact, prompt messages are not alarm messages. In addition to physiological and technical alarm messages, the patient monitor displays some messages indicating the system status. All messages are displayed in the Message Area.

Note

- To access messages list, refer to Messages and Alarms chapter.

Manifestation of Messages

- Flashing text in the message area explains the cause.

Alarm Level and Setup

JAM S3 Monitor has three levels of alarm.

- **Level I:** alarm indicates the patient's life is in danger or the monitor under use has serious problems. It is the most serious alarm.
- **Level II:** alarm means serious warning.
- **Level III:** alarm is a general warning.

JAM S3 monitor has preset the alarm level for the parameters. You can also modify alarm level of each module in its own window. Refer to the settings section for each parameter to learn how to configure settings.

Alarm Modes

Alarm messages, LEDs and sounds are designed in such a manner that can be recognizable by the operator from a distance of 1 m.

Display Screen

When an alarm is triggered by a parameter, the parameter value will blink on the screen and alarm message with regard to its level will be displayed in different backgrounds.

- **Level I alarm message:** Red background – White text
- **Level II alarm message:** Yellow background – Black text
- **Level III alarm message:** Cyan background – Black text

Note

- If the monitor displays an informative message or after pressing Alarm Silence key, the background will change to gray.

Alarm Indicator

Alarm indicator flashes red for Level I alarm and yellow for Level II alarm and lights yellow for Level III alarm.

Audio Alarm

Corresponding alarm sound will be activated, if the alarm is not silent (i.e., the ALARM SILENCE button has not been pressed).

The audio alarms are activated with three levels.

- Level I alarm sounds "DO-DO-DO--DO-DO" every 10 seconds;
- Level II alarm sounds "DO- DO-DO" every 20 seconds;
- Level III alarm sounds "DO-" every 30 seconds.

The alarm sound pressure in front of the monitor and at the distance of 1m is 54 dB(A).

Note

- When alarms of different levels occur at the same time, the alarm LED prompts the alarm of the highest level (red color) and the other alarms are displayed alternately in a background color corresponding to their levels.
- If two or more alarms of the same level occur simultaneously, the alarm messages will be displayed alternately.

Alarm verification

Every time the monitor turns on, a buzz sound is heard and blue, orange and red indicators light respectively. The indicators turn off after the monitor powers on completely. If no buzzer sound is heard or no alarm indicator lights, do not use the monitoring system on any patient and notify After Sales Service.

Alarm Silence Button Function

ALARM SILENCE feature provides suspending all alarms, except the alarm label on display, for 2 minutes or until the time of happening a new alarm. If within the 2 minutes of alarm suspension the operator presses "Alarm Silence" button, the alarm suspension status will be ended and the normal alarm status resumed immediately.

Chapter 4) ECG module

Introduction

Both, the ECG signal and the respiratory signal (based on the thorax impedance change) are measured through the same set of ECG electrodes. The user can select ECG lead related to a 3-wire or a 6-wire (optional) patient cable.

The JAM S3 monitor determines respiration by impedance pneumography. The monitor detects changes in thoracic impedance that occur as a result in chest movements. Impedance normally increases with inspiration and decreases with expiration. Respiration detection is based on an inspiration and an expiration.

Through ECG monitoring you can see a continuous waveform of the patient's cardiac electric activity which enables physician to perform a precise assessment of patient current physiological condition. The process of depolarization and repolarization of the myocardium generates an electric potential that are sensed by ECG electrodes on the skin.

These electrodes are typically attached to the patient's right arm, left arm and left leg. The monitor processes and amplifies this signal and displays it as ECG waveform on the screen. Proper connection of the ECG cables and electrodes can ensure accurate assessment.

- In order to calculate HR Average, heart rate is sent to averaging section every second and based on the user setting the calculated average value is displayed.
- The time of changing or updating the heart rate in the JAM S3 monitor with regard to HR Average in every eight seconds is as below.
- To change HR from 80 to 120 bpm: 4 sec
- To change HR from 80 to 40 bpm: 10 sec

The above results are for lead II.

- When Tachycardia (HR>120 bpm) happens, it takes 6 seconds to activate alarm sound by the system. (If low alarm limit is adjusted 60 bpm and high alarm limit 100 bpm) .

- It takes 10 seconds to activate alarm sound by the system when a cardiac arrest happens. (from 80 bpm to 0 bpm)
- The ECG module is able to reject 1.2 mV TALL-T.
- The current that is applied to the patient for lead-sensing is 90nA.
- Noise suppression circuit: common noise signal of 10 µA is given reversely to the reference lead.
- According to IEC60601-2-27:2011 standard, the measured heart rates for irregular signals are as follows.

Irregular rhythm	HR (bpm)- adult	HR (bpm)- pediatric	HR (bpm)- neonate
ventricular bigeminy	70-80	70-80	70-80
slow alternating ventricular bigeminy	30	30	67
rapid alternating ventricular bigeminy	126	126	126
bidirectional systoles	60-97	60-97	93-117
Normal, Gain: 1, Sweep speed: 25, Lead II			

- The ECG patient cable consists of 2 parts: The cable that is connected to the monitor and the lead set that is connected to the patient.

Warning

- When you connect the cables and electrodes, make sure that no metal part of electrodes is in contact with the safety ground. Check that all ECG electrodes are correctly attached to the patient.
- Before monitoring check ECG cable to ensure that there are no signs of damage. Do not use scratched or ripped cables or the cables with flexed lead wires.
- Make sure that ECG cable is not under tension during monitoring.
- Select the patient mode carefully, because QRS detection thresholds and HR measurement algorithm are different in Neonatal and Adult modes.

- Do not touch patient, monitor and bed during defibrillation.
- Use only manufacturer recommended ECG cable for monitoring. Other ECG cables and leads may cause improper system performance and decrease safety during defibrillation.
- ECG cable may be damaged if it is connected to the patient during defibrillation. Cables which have been connected to the patient during defibrillation should be checked functionally before being used again.

Note

- Interference from devices near the patient like electrosurgical units can cause inaccurate ECG waveform.
- If ECG waveform is not accurate despite the proper connection of the electrodes, try changing the lead.

Safety

Warning

- If uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means and then make sure the monitor is functioning correctly.
- The monitor does not detect arrhythmias and does not alarm on irregular ECG rhythms.
- ECG electrodes are contraindicated for use on patients with limited skin access or allergic reaction to electrode adhesive or application gel.
- Reusable ECG electrodes are contraindicated for use for prolonged periods of use. It is not intended for long term monitoring. Electrodes must be removed and repositioned if indicated by skin integrity, and reapplied to a different monitoring site.

- Verify the cable fault detection prior to monitoring. Unplug the ECG cable from the socket, the monitor will display the error message "ECG NO CABLE" on the screen.
- When using Electrosurgery equipment, leads should be placed in a long distance from the grounding plate and electrosurgical pencil to prevent unwanted burns.
- Patient burning is possible due to improper connection of the grounding plate of the electrosurgical unit.
- For any diagnostic purposes, please do not rely solely on ECG waveforms.

Preparations

Warning

- Prior to patient monitoring, ensure the monitor is configured to the appropriate patient mode (Neonate, Pediatric or Adult). Refer to paragraph “Age Cat” in Setting chapter.

Note

- The quality of ECG information is a direct result of the quality of the electrical signal received at the electrode.
- Proper skin preparation is necessary for good signal quality at the electrode.
- Always check the expiration date of the electrodes prior to applying them to the patient.
- Do not use the 6-Lead Patient Cable for 3-Lead monitoring. A “Leads OFF” message would be displayed.

Skin Preparation

The following is a suggested guideline for skin preparation and should be followed for all electrode types.

- Choose flat, non-muscular areas to place electrodes.
- Make sure the skin area where the electrodes are to be placed is clean, dry, intact and free of powder, oil or lotion.
- If necessary, shave hair from skin at chosen sites.
- Place chest leads on the proper place on the patient's body. If the chest lead has no conductive gel, apply some conductive gel on intended site of the skin.
- Attach the clips or snaps to the chest leads.

⚠ Warning

- Use only one type of electrode on the same patient to avoid variations in electrical resistance. For ECG monitoring, 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 it can cause problems with ECG waveform. Using dissimilar metals may also increase recovery time after defibrillation.
- Do not touch the patient, bed, table nearby or the monitor during defibrillation.
- Use only the manufacturer recommended ECG cable for monitoring. Other ECG cables and leads may cause improper performance and/or reduce protection during defibrillation.

ECG 3-lead electrode placement

- Right arm (RA): red electrode, near the right shoulder, directly below the clavicle.
- Left Arm (LA): yellow electrode, near the left shoulder, directly below the clavicle.
- Left Leg (LL): green electrode, on the left hypogastrium.

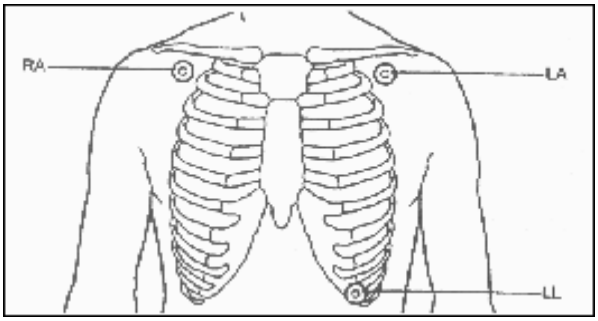


Figure 4-1:ECG 3-lead electrode placement

ECG 6-lead electrode placement

Right arm (RA): red electrode, near the right shoulder, directly below the clavicle.

Left Arm (LA): yellow electrode, near the left shoulder, directly below the clavicle.

Left Leg (LL): green electrode, on the left hypogastrium.

Right Leg (RL): black electrode, on the right hypogastrium.

Chest (Vx): The placements are shown in the figure 4-2.

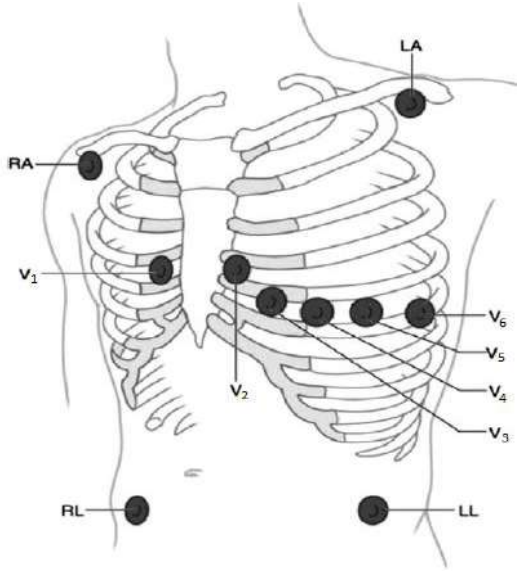


Figure 4-2: ECG 6-lead electrode placement

For ECG 6-lead set, the Vx electrode can be placed on one of the following positions on the chest:

- V1 on the fourth intercostal space at the right sternal border.
- V2 on the fourth intercostal space at the left sternal border.
- V3 midway between V2 and V4 electrode positions.
- V4 on the fifth intercostal space at the left midclavicular line.
- V5 on the left anterior axillary line, horizontal with V4 electrode.
- V6 on the left middle axillary line, horizontal with V4 electrode.
- V3R-V6R on the right side of the chest in positions corresponding to those on the left.
- VE over the xiphoid position.

For posterior lead placement, place the Vx electrode at one of the following positions:

- V7 on posterior chest at the left posterior axillary line in the fifth intercostal space.
- V7R on posterior chest at the right posterior axillary line in the fifth intercostal space.

Note

- To ensure the patient safety, all leads must be attached to the patient.
- The lead used for Pace and HR is the main lead which is displayed.
- The voltage of signal amplitude in leads II and V is higher than other leads.

Depending on lead type (3-lead wire or 6-lead wire), you can choose different leads including I, II, III, aVR, aVL, aVF and Vx.

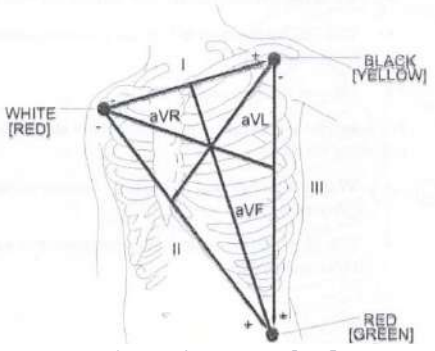


Figure 4-3: ECG leads

Normal QRS waveform

- Tall R-wave completely above or below the baseline.
- T -wave less than one-third of the R-wave height.
- P-wave much smaller than the T -wave.

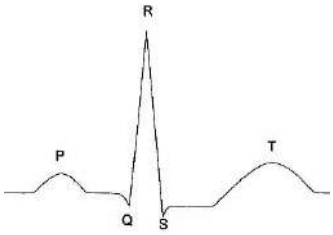


Figure 4-4: Standard ECG waveform

ECG Appearance

- ECG waveform is displayed in green.
- The main lead name is displayed in green on the left side of the signal.
- The selected ECG filter is displayed in green at the top of the signal.
- The pacemaker detection is displayed at the top right of the signal. If pacemaker is enabled, “PaceOn” will be shown in white, and if disabled, “PaceOff” will be shown in green.
- The gain index is displayed in the right corner of the ECG signal in white (or red). Touching the bar will change the gain among x/8, x/4, x/2, x, 2x values. When the bar color turns to red, it means that gain selector is in automatic status and it will choose the best signal to display. Gain is in automatic mode when the device turns on.

ECG MENU

By pressing on the HR parameter area (Figure 4-5), ECG MENU will pop up (Figure 4-6) and you can reach following items:

- ECG Lead
- Lead Type
- HR Source
- HR Alarm
- ECG Filter
- Pace Detect
- Sweep

Figure 4-5: HR parameter area

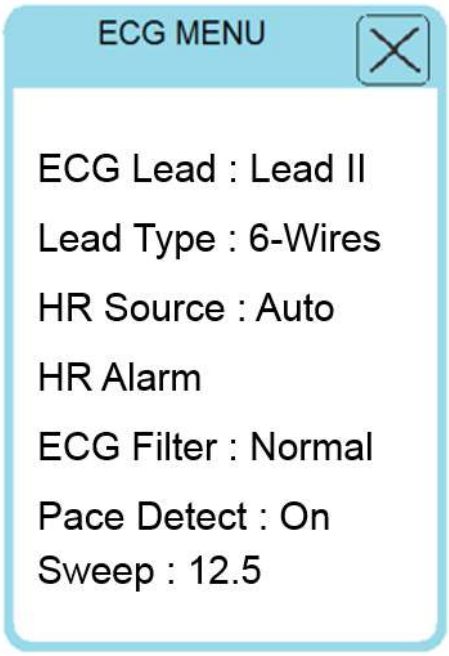


Figure 4-6: ECG MENU

ECG Lead

To adjust ECG Lead, follow the instruction below:

Note

- This menu is inactivated, if the ECG cable is not connected to the device.

- Press the HR parameter area and select ECG Lead.
- Available options are Lead I, Lead II, Lead III, Lead V2, Lead V5, Lead AVR, Lead AVL, Lead AVF. Default setting for this item is Lead II.
- Choose the item you wish.
- By pressing OK, the changes will be saved and the main page is shown.

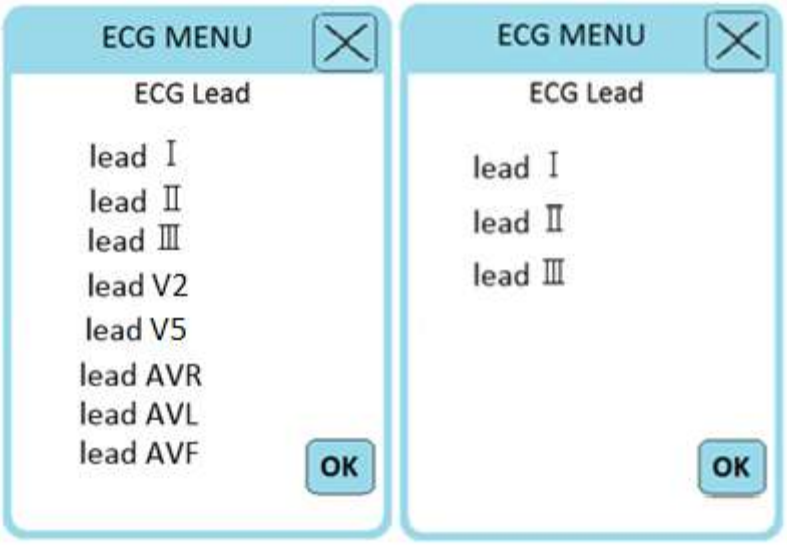


Figure 4-7: ECG Lead

Available options for adjusting the ECG Leads are:

"I" to count the heart rate and show RA-LA waveform

"II" to count the heart rate and show RA-LL waveform

"III" to count the heart rate and show LA-LL waveform

"**aVR**" to count the heart rate and show RA-$\frac{LA+LL}{2}$ waveform

"**aVL**"to count the heart rate and show LA-$\frac{RA+LL}{2}$ waveform

"**aVF**"to count the heart rate and show LL-$\frac{RA+LA}{2}$ waveform

"**Vx**" to count the heart rate and show Vx-$\frac{RA+LA+LL}{3}$ waveform

Note

- Depending on the lead type (3-Wires or 6-Wires), you can choose different leads I, II, III, aVR, aVL, aVF, V2 and V5.
  - Lead I, lead II, lead III are selectable for 3-Wires lead type.
  - Lead I, lead II, lead III, lead V2, lead V5, lead AVR, lead AVL, lead AVF are selectable for 6-Wires lead type.

Lead Type

To adjust Lead Type, follow the instruction below:

Note

- This menu is inactivated, if the ECG cable is not connected to the device.

- Press the HR parameter area and select Lead Type.
- Available options are 3-Wires and 6-Wires. Default setting for this item is 3-Wires.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

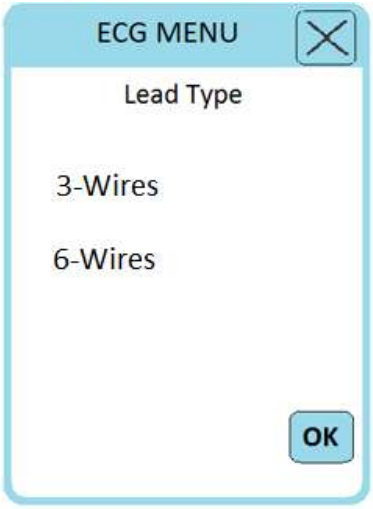


Figure 4-8: Lead Type

HR Source

To adjust HR source, follow the instruction below:

- Press the HR parameter area (Figure 4-7) and select HR source.
- Available options are Auto, ECG and SPO2. Default setting for this item is Auto.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

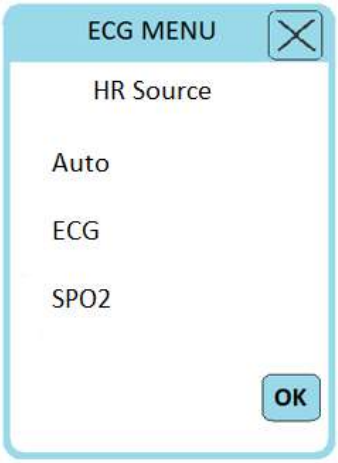


Figure 4-9: HR Source

Available options for adjusting the heart rate source (HR Source) are:

- **ECG:** By selecting this item, the heart rate is derived from ECG signal and it will be shown in green.

- **SPO2:** By selecting this item, the heart rate is derived from SPO2 signal and it will be shown in purple.
- **Auto:** By selecting this item, the heart rate may be derived from “ECG” or “SpO2” signals.

Note

- If two or more signals are being monitored simultaneously, the heart rate derivation will be done based on the signals priority, i.e. the heart rate will be derived respectively from ECG and then SpO2.

HR Alarm

To adjust HR Alarm, follow the instruction below:

- Press the HR parameter area and select HR Alarm.
  Available options are On and Off. Pick "ON" to enable alarm functions such as parameters blinking, audio alarm and light indicator. Pick "OFF" to disable the HR alarm functions and there will be a "  " symbol in the HR Parameter Area. Default setting for this item is Off.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

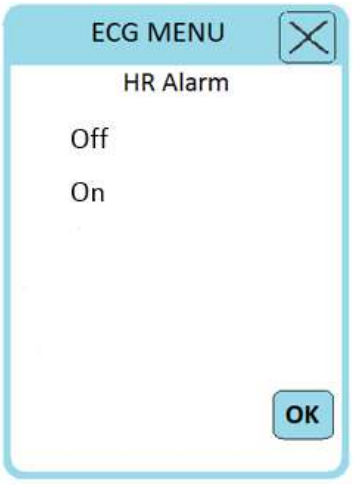


Figure 4-10: HR Alarm

HR Alarm Level

To adjust HR Alarm Level, follow the instruction below:

- Press the HR parameter area and select HR Alarm Level.
- Available options are 1 (default) and 2.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

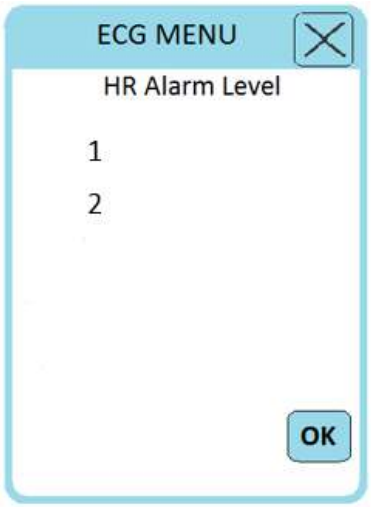


Figure 4-11: HR Alarm Level

HR Alarm Limit

ECG alarm is activated when the heart rate exceeds adjusted MAX value or falls below adjusted MIN value. To adjust HR Alarm Limit, follow the instruction below:

- Press the HR parameter area and select HR Alarm Limit.
- Min and Max values are selectable from 30 to 300. Default setting for this item is 50-120.
- Choose the item you wish.
- By pressing OK, the changes will be saved

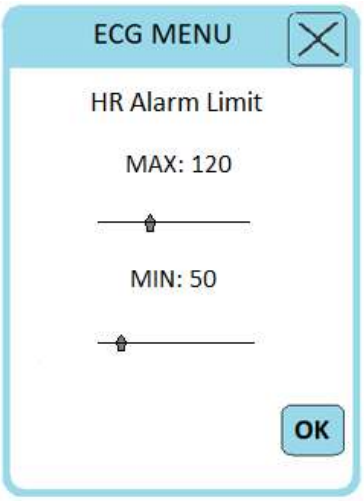


Figure 4-12: HR Alarm Limit

ECG Filter

To adjust ECG Filter, follow the instruction below:

Note

- This menu is inactivated, if the ECG cable is not connected to the device.

- Press the HR parameter area and select ECG Filter.
- Available options are Monitor, Normal, Extended. Default setting for this item is Extended.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

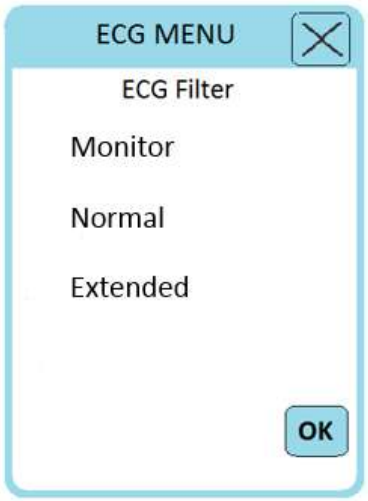


Figure 4-13: ECG Filter

Use the following table for clearer and more detailed waveform.

FILTER TYPE	FREQUENCY RANGES	APPLICATION
NORMAL	0.5-40HZ	In normal use.
EXTENDED	0.05-100HZ	In diagnostic application. but the ECG waveform might have some noises
MONITOR	0.5-24HZ	This mode may reduce interference from Electrosurgery equipment or can be used when the system has high noises or doesn't have equipotential earth.

Also, The Notch filter by default has been set on 50 Hz and it's not possible to change it. Notch filter is automatically deactivated when the Pace Detection is ON.

Pace Detect

Note

- This menu is inactivated, if the ECG cable is not connected to the device.

To adjust Pace Detect, follow the instruction below:

- Press the HR parameter area and select Pace Detect.
- Available options are On and Off. Default setting for this item is Off.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

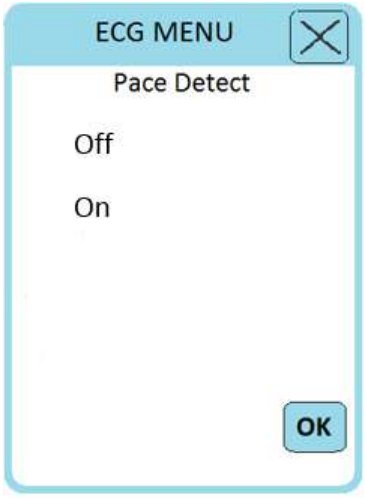


Figure 4-14: Pace Detect

Warning

- For patients with pacemaker, PACE DETECT must be switched "ON", otherwise, the pace pulses may affect HR counting and result in low precision of HR value.
- For the patients with pacemaker, the monitor may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon monitor alarms. Keep the patients with pacemaker under close surveillance.

Note

- The Pace Detect item should be "ON" for patient with pacemaker and" OFF" for patient without pacemaker. When PACE DETECT is "ON", the ECG monitoring system detects and rejects pacemaker-generated signals from ECG signal so that they will be ignored in determining heart rate. Detected pacemaker signals will be marked on the ECG waveform as 1 centimeter spike. Monitoring of patients with pacemaker is not generally affected when PACE DETECT is enabled. However, in some instances if the patient does not have a

pacemaker, it may be desirable to turn the detection function OFF so that artifacts in the waveform will not be mistaken for a pacemaker signal.

- ECG signals with the slope of up to 1 V/s will not be counted as Pace signal.
- Ineffectively paced QRS beside atrial pace pulses which precede ventricular paces by 150 ms to 250 ms will be rejected in addition to normal pace pulses.

Sweep

In this section, making change in the sweep (the recording speed) of the SPO2 and ECG signals between "12.5 mm/s" and "25 mm/s" is possible. To adjust Sweep follow the instruction below:

- Press the Setting option  enter the password, press Ok and select Sweep.
- Available options are 12.5 and 25(mm/sec). Default setting for this item is 12.5.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

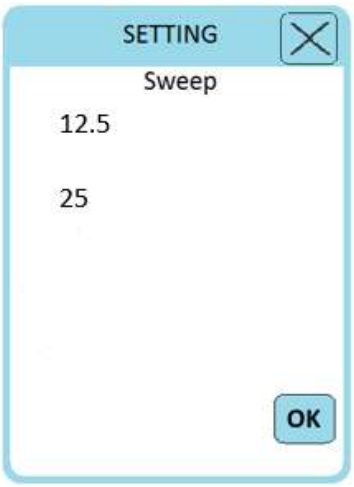


Figure 4-15: Sweep

Chapter 5) Respiration module

Respiration Monitoring

Several considerations have to be made when the patient's respiration is monitored.

Electrode Placement for Respiration

Electrode placement is crucial to monitoring respiration by the impedance method. The sensitivity of the monitor and its ability to accurately detect respiration is greatly enhanced or impeded by the quality of the electrodes and optimal electrode placement.

Note

- The respiration signal is received from the LA/L and RA/R electrodes. These leads are available on 3-lead and 6-lead cables.

Observe the patient and place the electrodes where the greatest breathing movement occurs on the chest.

Checklist for RESP Monitoring

1. Prepare the patient's skin prior to placing the electrodes.

2. Attach the electrodes to the patient and attach snap or clip to the electrodes.

3. Switch on the monitor.

Note

- Place the red and green electrodes diagonally to optimize the respiration waveform. Avoid the liver area and the ventricles of the heart in the line between the RESP electrodes to prevent cardiac overlay or artifacts from pulsating blood flow. This is particularly important for neonates.

Respiration Appearance

- Respiration waveform is displayed in yellow.
- The main lead name is displayed in yellow on the left side of the signal.
- The Respiration rate parameter (RR) is also displayed in yellow.

RESP MENU

By pressing on the RR parameter area (Figure 5-1), RESP MENU will pop up (Figure 5-2) and you can reach following items:

Figure 5-1 RR parameter area

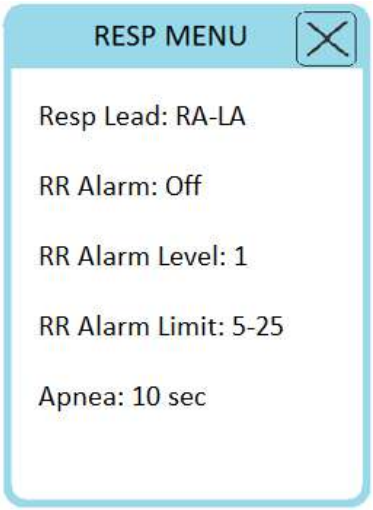


Figure 5-2 RESP MENU

RESP Lead

To adjust Resp Lead, follow the instruction below:

Note

- In 3-wire mode, the Resp lead will be chosen automatically.

- Press the RR parameter area and select Resp Lead.
- Available options are RA-LA and RA-LL. Default setting for this item is RA-LA.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

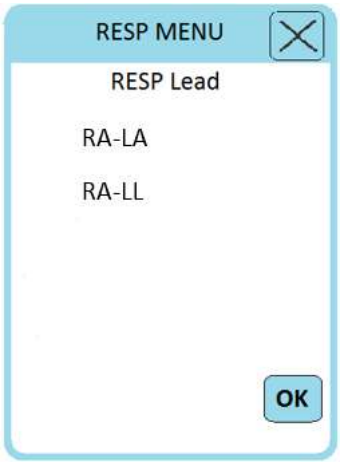


Figure 5-3 Resp Lead

RR Alarm

To adjust RR Alarm, follow the instruction below:

- Press the RR parameter area and select RR Alarm.
- Available options are On and Off. Default setting for this item is Off. Pick "ON" to enable RR alarm functions such as parameters blinking, audio alarm, and light indicator. Pick "OFF" to disable the alarm functions and there will be a " " symbol in the RR Parameter Area.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

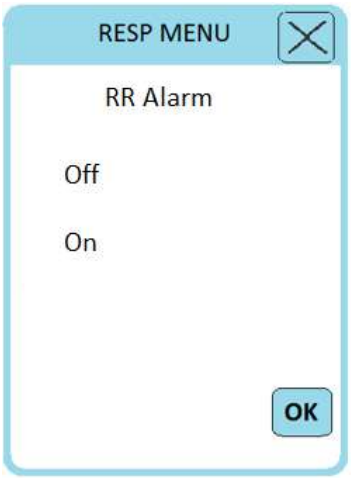


Figure 5-4 RR Alarm

RR Alarm Level

To adjust RR Alarm Level, follow the instruction below:

- Press the RR parameter area and select RR Alarm Level.
- Available options are 1,2 and 3. Default setting for this item is 1.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

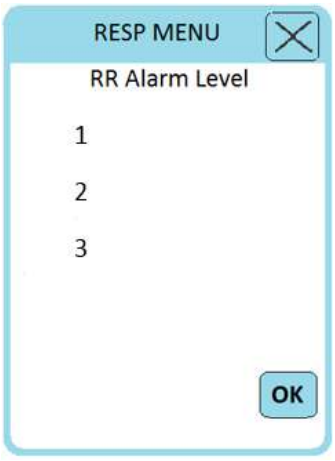


Figure 5-5 RR Alarm Level

RR Alarm Limit

Respiration alarm is activated when the respiration rate exceeds adjusted MAX value or falls below adjusted MIN value. To adjust RR Alarm Limit, follow the instruction below:

- Press the RR parameter area and select RR Alarm Limit.
- Min and Max values are selectable from 5 to 99. Default setting for this item is 5-25.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

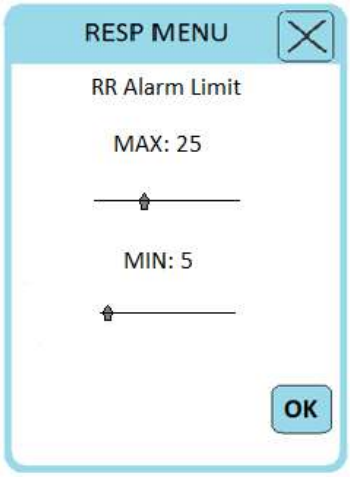


Figure 5-6 RR Alarm Limit

Apnea

Apnea alarm is activated to set the standard of judging an apnea case. To adjust Apnea, follow the instruction below:

- Press the RR parameter area (Figure 5-1) and select Apnea.
- Available options are Off, 10sec (Default), 15sec, 20sec, 25sec, 30sec, 35sec and 40sec.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

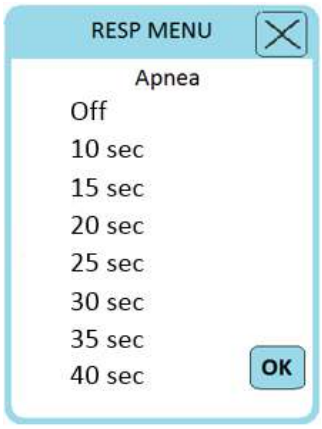


Figure 5-7 Apnea

Note

- Apnea alarm is always enabled with level 1 and ON/OFF status of RR alarm has not any effect on it.

Chapter 6) SPO2 module

Introduction

Pulse oximetry is a continuous and non-invasive method of measuring the level of arterial oxygen saturation in blood. The pulse oximetry system of this monitor has been design as an external module and includes the following:

1. uSPO2 cable
2. Sensor
3. JAM S3 monitoring system

The external SPO2 cable is a patient cable with an integrated pulse oximetry board. The sensor is connected to the uSPO2 cable due to collecting signal data from the patient and sending it to the board for calculating parameters. Finally, the JAM S3 monitor just displays signal waveform and parameters. This module is designed and provide by Masimo Company and submitted to its approved companies.

Warning

- The pulse oximeter is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use.
- The pulse oximeter should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.
- Use only the manufacturer recommended SPO2 sensor for monitoring. Other SPO2 sensors may cause monitor malfunction, thus operator is responsible to select an appropriate sensor before use.
- Do not use the pulse oximeter if it appears or is suspected to be damaged.
- Do not use the pulse oximeter during magnetic resonance imaging (MRI) or in an MRI environment.

- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Do not place the pulse oximeter or accessories in any position that might cause it to fall on the patient.
- Do not start or operate the pulse oximeter unless the setup was verified to be correct.
- To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.
- To protect against injury, follow the directions below:
  - Avoid placing the device on surfaces with visible liquid spills.
  - Do not soak or immerse the device in liquids.
  - Do not attempt to sterilize the device.
  - Use cleaning solutions only as instructed in this operator's manual.
  - Do not attempt to clean the device while monitoring a patient.
- To protect from electric shock, always remove the sensor and completely disconnect the pulse oximeter before bathing the patient.
- The pulse oximeter is not an apnea monitor.
- The pulse oximeter should not be used for arrhythmia analysis.
- The pulse oximeter may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.
- The pulse oximeter may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.
- **Explosion hazard:** Do not use the pulse oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- Do not adjust, repair, open, disassemble, or modify the pulse oximeter or accessories. Injury to personnel or equipment damage could occur. Return the pulse oximeter for servicing if necessary. Changes or modifications shall void the guaranty for the pulse co-oximeter accessories.
- If any measurement seems questionable, first check the patient’s vital signs by alternate means and then check the pulse oximeter for proper functioning.

- Prolonged and continuous monitoring may increase jeopardy of unexpected change of dermal condition such as abnormal sensitivity, vesicle, repressive putrescence, and so on. It is especially important to check the sensor placement of neonate and patient of poor perfusion. Check per 2-3 hours the sensor placement and move it when the skin deteriorates. More frequent examinations may be required for different patients.
- Tissue damage or inaccurate measurement can be caused by incorrect application or use of an SPO2 sensor, for example by wrapping the sensor too tightly or by applying supplemental tape.
- Loss of pulse signal can occur when
  - The patient is in cardiac arrest or in shock.
  - The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
  - There is arterial occlusion proximal to the sensor.
- Inaccurate SPO2 readings may be caused by:
  - Improper sensor application and placement
  - Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SPO2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
  - Elevated levels of bilirubin
  - Elevated levels of dyshemoglobin
  - Vasospastic disease, such as Raynaud's, and peripheral vascular disease
  - Hemoglobinopathies and synthesis disorders such as thalassemia, Hb s, Hb c, sickle cell, etc.
  - Hypocapnic or hypercapnic conditions
  - Severe anemia
  - Very low arterial perfusion
  - Extreme motion artifact
  - Abnormal venous pulsation or venous constriction
  - Severe vasoconstriction or hypothermia
  - Arterial catheters and intra-aortic balloon
  - Intravascular dyes, such as indocyanine green or methylene blue
  - Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.

  - Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.
  - Skin color disorders
- Interfering Substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.
- SPO2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).
- If SPO2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.
- Do not place the pulse oximeter where the controls can be changed by the patient.
- **Electrical shock and flammability hazard:** Before cleaning, always turn off the device and disconnect from any power source.
- Do not place the pulse oximeter on electrical equipment that may affect the device or preventing it from working properly.
- When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.
- If "SPO2 LOW PERFUSION" message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.
- Change the application site or replace the sensor when a "Replace Sensor", or a persistent poor signal quality message (such as "Low SIQ") is displayed on the monitor. These messages may indicate that patient monitoring time is exhausted on the patient sensor.
- If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the instrument might read zero for the duration of the active irradiation period.
- To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the pulse oximeter.

- Variation in measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.
- **Electrical Shock Hazard:** Carry out periodic tests to verify that leakage currents of patient applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1 and UL60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.
- Disposal of product - Comply with local laws in the disposal of the device and/or its accessories.
- Replace the cable or sensor when a "replace sensor" or when a "low SIQ" message is consistently displayed while monitoring consecutive patients after completing troubleshooting steps listed in this manual.

Note

- For Masimo patent information, please refer to the following address: "https://www.masimo.com/patents/"
- No Implied License Statement: "Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone or in combination with this device, fall within the scope of one or more of the patents relating to this device."
- A functional tester cannot be used to assess the accuracy of the pulse oximeter.
- Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.
- Materials used in our SPO2 sensors are innoxious.

Signal Extraction Technology (SET)

Masimo (SET) signal processing differs from conventional pulse oximeters. Conventional pulse oximeters assume that arterial blood is the only blood moving (pulsating) in the measurement site. During patient motion, however, the venous blood also moves, causing conventional pulse oximeters to read low values, because they cannot distinguish between the arterial and venous blood movement (sometimes referred to as noise).

Masimo SET pulse oximetry utilizes parallel engines and adaptive digital filtering. Adaptive filters are powerful because they are able to adapt to the varying physiologic signals and/or separate them by looking at the whole signal and breaking it down to its fundamental components. The Masimo SET signal processing algorithm, Discrete Saturation Transform (DST), readily identifies the noise, isolates it and, using adaptive filters, cancels it. It then reports the true arterial oxygen saturation for display on the monitor.

SPO2 Measurement

Applying the sensor is as follows.

1. Turn on the monitor.
2. Attach the sensor to the appropriate site of the finger (Figure 6-1 shows the proper method).
3. Plug the connector of the sensor extension cable into the SPO2 socket on the top side of the device.

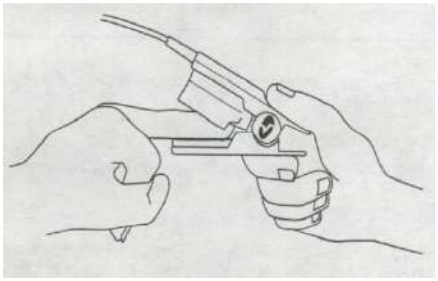


Figure 6-1: SpO2 sensor placement

Note

- Make sure the nail covers the light window.

- The wire should be on the backside of the hand.
- Do not use the sensor on extremities with arterial catheter or venous syringe.
- Do not perform SpO2 and NIBP measuring in same arm simultaneously; because obstruction of blood flow during NIBP measuring may adversely affect the SpO2 value.
- High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow the pulse oximeter to obtain vital sign readings.
- Additional information specific to the Masimo sensors compatible with the pulse oximeter, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).
- Sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Sensor DFU for the specified duration of the patient monitoring time.

SPO2 Signal and Parameter Area

The following items are displayed in SPO2 parameter area:

- The SPO2% value can be displayed on the main screen (main page) and SPO2%, PR, PI and PVI values are displayed on the SPO2 page. The pleth waveform is displayed as normalized waveform and its amplitude does not comply with real blood volume variations.
- If "HR Source" is set to "SPO2", PR value will be displayed in purple color, otherwise it will be displayed in green.
- User can be informed of inadequacy of signal and physiological parameters values by various messages and alarms in necessary situations.

General Description for pulse oximetry measurement

Pulse oximetry is governed by the following principles:

1. Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood) species differ in their absorption of visible and infrared light.

2. The amount of arterial blood in tissue changes with your pulse (photoplethysography). Therefore, the amount of light absorbed by the varying quantities of arterial blood, changes as well.

% SPO2

Extent of oxygen saturation in hemoglobin of arterial blood can be detected from the SPO2 waveform. For example, if 97% hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has an oxygen saturation of 97%. The SPO2 value on the monitor will be 97%. The SPO2 value shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin.

$$SPO_2 = \frac{O_2Hb}{O_2Hb + HHb} \times 100$$

Pulse rate

PR indicates the Heart Rate per minute which SPO2 module extracts from the pulse oximetry signal.

Perfusion Index

Perfusion index (PI) indicates arterial pulse signal strength as a ratio of pulsatile blood flow to the non-pulsatile blood.

Perfusion Index enables you to choose the best position for sensor placement and value greater than 1% is preferable.

$$PI = \frac{AC}{DC} \times 100$$

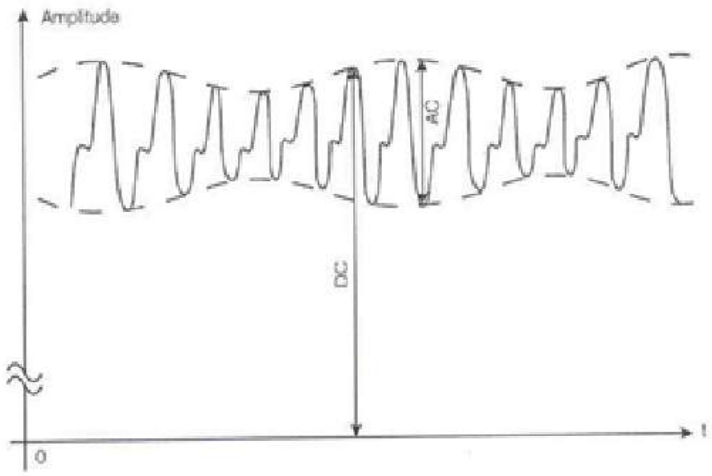


Figure 6-2: PI definition

Pleth Variability Index

This parameter is to measure dynamic changes in PI during the respiratory cycle which can be extremely associated with intrathoracic pressure changes.

PVI can be a useful noninvasive monitoring method or an advanced indicator to detect physiological changes of intrathoracic pressure. During one or two complete respiratory cycle, PVI is calculated as follows:

$$PVI = \frac{PI_{Max} - PI_{Min}}{PI_{Max}} \times 100\%$$

PVI can help clinicians predict fluid responsiveness in patients.

SPO2 Appearance

- Pleth waveform is displayed in purple.
- The word “PLETH” is displayed in the bottom left of the signal in purple.
- The SPO2% value can be displayed on the main screen (main page) and SPO2%, PR, PI and PVI values are displayed on the SpO2 page.

SPO2 MENU

By pressing on the SpO2% parameter area, (Figure 6-3) SPO2 MENU will pop up (Figure 6-4) and you can reach following items:

Figure 6-3: SPO2 parameter area

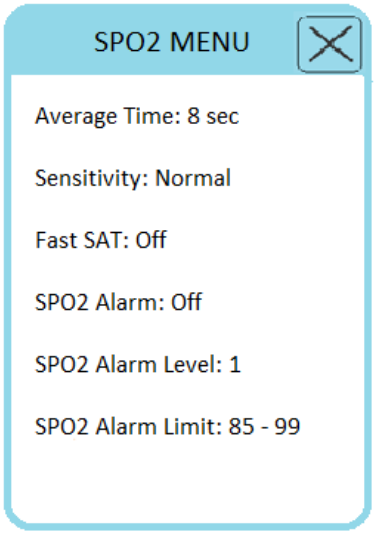


Figure 6-4: SPO2 menu

Average Time

To adjust Average Time, follow the instruction below:

- Press the SPO2% parameter area and select Average Time.
- Available options are 2-4 sec, 4-6 sec, 8 sec (Default), 10 sec, 12 sec, 14 sec and 16 sec.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

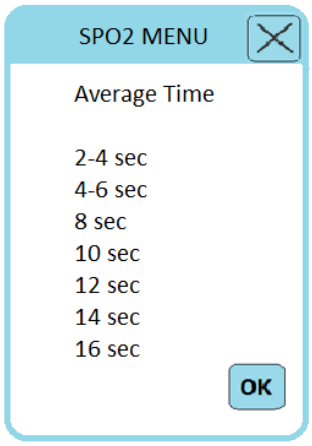


Figure 6-5: Average Time

Sensitivity

The sensitivity mode setting allows the clinician to adapt the SPO2 measurement sensitivity to the patient's level of SPO2 signal strength and quality at the measurement site. To adjust Sensitivity, follow the instruction below:

- Press the SPO2% parameter area and select Sensitivity.
- Available options are Normal, APOD and MAX. Default setting for this item is Normal.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

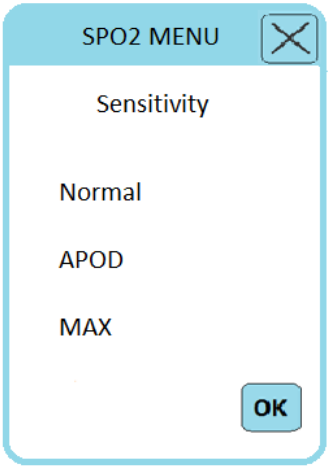


Figure 6-6: Sensitivity

Available options for Sensitivity are as follows:

- **Normal Sensitivity:** The perfusion threshold has different limits as the perfusion calculation is data dependent. Specially; there is an intelligent algorithm which adjusts the low perfusion limit in accordance with the quality of the incoming plethysmography waveform between 0.5% and 0.02%. This mode provides the best combination of sensitivity and probe-off detection performance. This mode is recommended for the majority of patients.
- **Maximum Sensitivity (MAX):** Recognizing that some clinicians may want the absolute low perfusion performance (0.02%) all of the time and may be willing to sacrifice sensor off detection, Masimo provides a maximized sensitivity mode. This mode should be used for the sickest patients, where obtaining a reading is most difficult. Maximum Sensitivity is designed to interpret and display data for even the weakest of signals. This mode is recommended during operation and when clinician and patient contact is continuous. In MAX mode, the message "SPO2 MAX SENS." displays on the screen with yellow color.

Note

- When using the Maximum Sensitivity setting, performance of the “Sensor Off” detection may be compromised. If the instrument is in the setting and the sensor become dislodged from the patient, the potential for false reading may occur due to environmental “noise” such as light, vibration, and excessive air movement.

- **Adaptive Probe Off Detection (APOD):** This mode is not advisable for patients with low perfusion because the system has the least sensitivity to signal changes in this mode. It is used in situations having risk of probe detachment (e.g. children or uneasy patients). By selecting this mode, “SPO2 APOD MODE” appears on the screen with yellow color.

Fast SAT

Fast SAT enables rapid response to, and display of, fast changes in SPO2 by giving priority to the most recent data. This aids the clinician in clinical settings requiring fast response time such as those seen with induction, intubation, sleep studies and resuscitation. To adjust Fast SAT, follow the instruction below:

- Press the SPO2% parameter area and select Fast SAT.
- Available options are Off and On. Default setting for this item is Off.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

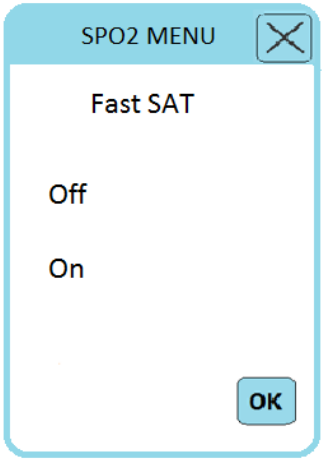


Figure 6-7: Fast SAT

Note

- As a result of the increased fidelity of this mode, Fast Sat is not recommended for routine use as there may be an increase of the frequency of alarms caused by rapid, transitory SpO2 changes. When the device is set to Fast Sat On, the averaging algorithm evaluates all the saturation values providing an averaged saturation value that is a better representation of the patient's current oxygenation status. With Fast Sat, the averaging time is dependent on the input signal. Fast Sat is always on for 2-4 and 4-6 averaging modes, but there is no message displayed that Fast Sat is on.

SPO2 Alarm

To adjust SPO2 Alarm, follow the instruction below:

- Press the SPO2% parameter area and select SPO2 Alarm.

- Available options are Off and On. Pick "ON" to enable SPO2 alarm functions such as parameters blinking, audio alarm, and light indicator. Pick "OFF" to disable the alarm functions and there will be a "  " symbol in the SPO2% Parameter Area. Default setting for this item is Off.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

Figure 6-8: SPO2 Alarm

SPO2 Alarm Level

To adjust SPO2 Alarm Level, follow the instruction below:

- Press the SPO2% parameter area and select SPO2 Alarm.
- Available options are 1 (Default) and 2.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

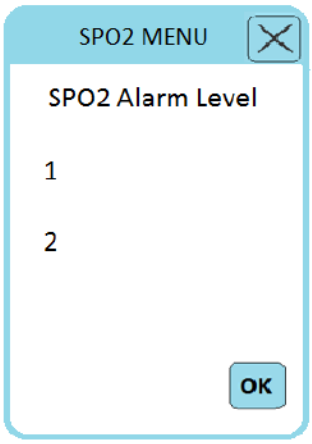


Figure 6-9: SPO2 Alarm Level

SPO2 Alarm Limit

SPO2 alarm is activated when the SPO2% exceeds adjusted MAX limit or falls below adjusted MIN limit. To adjust SPO2 Alarm Limit, follow the instruction below:

- Press the SPO2% parameter area and select SPO2 Alarm Limit.
- Min and Max values are selectable from 1 to 99. Default setting for this item is 85.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

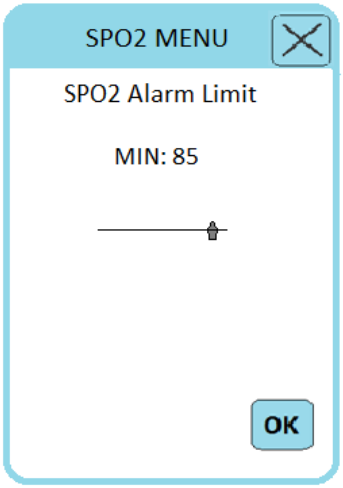


Figure 6-10: SPO2 Alarm Limit

SPO2 page

SPO2 page is available in Page 3 as Figure 6-11. In this page, PR is always extracted from SPO2 signal without considering selected HR source.

Figure 6-11: SPO2 Page

Warning

- To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the pulse oximeter is used.

Note

- SPO2 module updates SPO2 and pulse rate values every 1 sec.

PULSE RATE MENU

By pressing on the PR parameter area (Figure 6-12) on SPO2 page, PULSE RATE MENU will pop up (Figure 6-13) and you can reach following items:

Figure 6-12: SPO2 Page

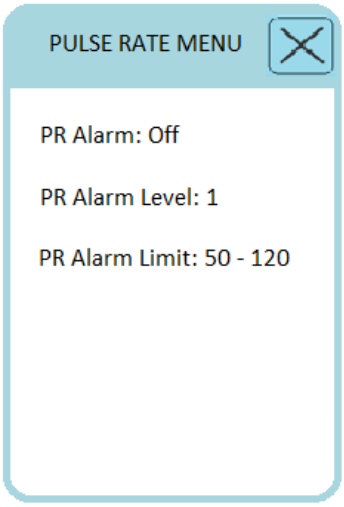


Figure 6-13: PULSE RATE MENU

PR Alarm

To adjust PR Alarm, follow the instruction below:

- Press the PR parameter area on SPO2 page and select PR Alarm.
- Available options are Off and On. Pick "ON" to enable PR alarm functions such as parameters blinking, audio alarm, and light indicator. Pick "OFF" to disable the alarm functions and there will be a " " symbol in the PR Parameter Area. Default setting for this item is Off.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

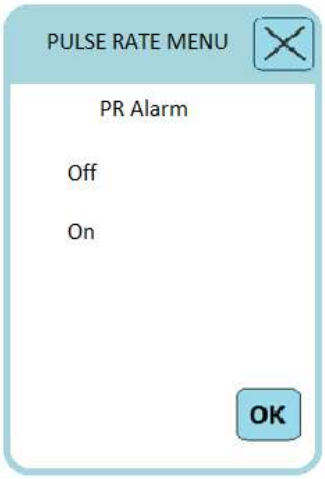


Figure 6-14: PR Alarm

PR Alarm Level

To adjust PR Alarm Level, follow the instruction below:

- Press the PR parameter area on SPO2 page and select PR Alarm.
- Available options are 1 (Default) and 2.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

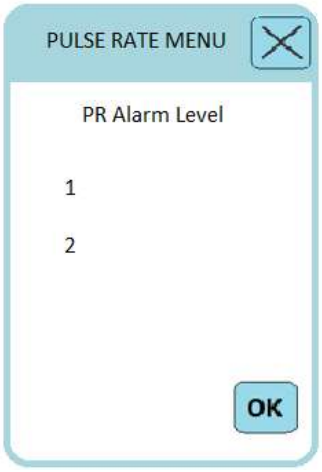


Figure 6-15: PR Alarm Level

PR Alarm Limit

PR alarm is activated when the PR exceeds adjusted MAX limit or falls below adjusted MIN limit. To adjust PR Alarm Limit, follow the instruction below:

- Press the PR parameter area on SPO2 page and select PR Alarm Limit.
- Min and Max values are selectable from 30 to 300. Default setting for this item is 50-120.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

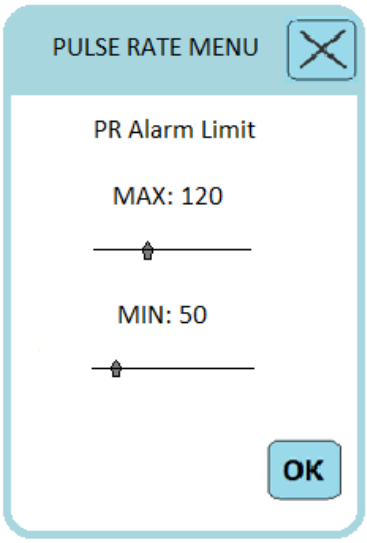


Figure 6-16: PR Alarm Limit

Chapter 7) Setting Menu

Access to Setting Menu

For accessing to Setting Menu, follow the instruction bellow.

- While the device is on, press this indicator .
- Enter the password and press Ok. If you enter a wrong password the message “Invalid Password: Try Again “will show up.

Note

- The required password for this section is “0000”.

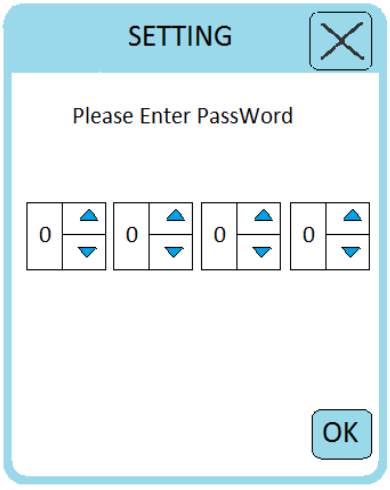


Figure 7-1 Setting password

- After entering the password, the Setting Menu shows up (Figure 7-2).
- Select and adjust the item you wish.
- By pressing OK, the changes will be saved.

Note

- Battery run out or system turning off will not change device settings.

Figure 7-2 Setting Menu

Mode

This option is used to set the monitoring mode on Monitor, Central or Smart Phone. To adjust Mode, follow the instruction below:

- Press the Setting option  ,enter the password, press Ok and select Mode.
- Available options are Monitor (Default), Central and Smart Phone.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

Figure 7-3 Mode

Factory Settings

Note

- At the moment, only manufacturer's authorized personnel have access to this window and it is used for the adjustments related to AP Name, AP Password, Bed Number and Demo.

Alarm

This section is to enable or disable the alarm notifications and having access to alarm review. To adjust Alarm, follow the instruction below:

- Press the Setting option enter the password, press Ok and select Alarm.
- Available options are Alarm Buzzer, Alarm LED, Alarm Review.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

Figure 7-4 Alarm

Alarm Buzzer

This section is to enable or disable the audio alarm. To adjust Alarm Buzzer, follow the instruction below:

- Press the Setting option enter the password, press Ok and select Alarm.
- Press the Alarm Buzzer option.
- Available options are On and Off. Pick "ON" to enable the audio alarm. Pick "OFF" to disable the audio alarm. Default setting for this item is On.
- By pressing OK, the changes will be saved.

Figure 7-5 Alarm Buzzer

Alarm LED

This section is to enable or disable the LED light indicator. To adjust Alarm LED, follow the instruction below:

- Press the Setting option enter the password, press Ok and select Alarm.
- Press the Alarm LED.
- Available options are On and Off. Pick "ON" to enable the LED light indicator. Pick "OFF" to disable the LED light indicator. Default setting for this item is On.
- By pressing OK, the changes will be saved

Figure 7-6 Alarm LED

Alarm Review

By selecting Alarm Review, all the alarms related to HR, SPO2 and RR parameters and the date and the time of alarm occurrence will be shown. Further information is accessible in Archive chapter.

Display

This option is for adjusting the display brightness, enabling lock, turning off the display, adjusting the time duration before display goes off and adjusting the time duration before lock goes off when the device is idle. To adjust Display, follow the instruction below:

- Press the Setting option enter the password, press Ok and select Display.
- Available options are Display TimeOut, Lock TimeOut, Brightness, Display Off and Display Lock.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

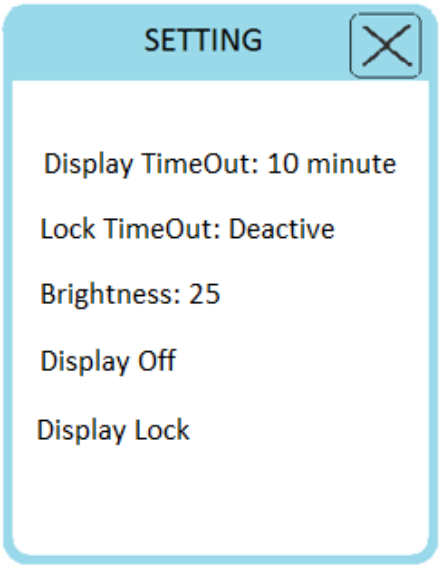


Figure 7-7: Display Menu

Display Time Out

The JAM S3 Monitor incorporates a display time out feature that, when enabled by user, turns the display's backlight automatically off after some minutes (based on the user-defined time). To exit this mode, press the power button once.

To adjust Display TimeOut, follow the instruction below:

- Press the Setting option enter the password, press Ok and select Display.
- Press the Display TimeOut option.
- Available options are Always On, 1 minute, 2 minute, 5 minute, 10 minute and 30 minute. Default setting for this item is 10 minute.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

When the display goes off, if "Alarm LED" is activated, the LED lights at the top of the front panel, will notify ongoing alarms. Furthermore, if the "Alarm Silence" is activated, a blue flashing LED at the top of the front panel, will be enabled for 120 seconds showing that the monitor is On.

Figure 7-8 Display TimeOut

Lock Time Out

The JAM S3 Monitor incorporates a lock time out feature that, when enabled by user, the touch screen of the monitor will be automatically locked and inactive after some minutes (based on the user-defined time). The lock indicator is shown in the upper-right corner of display page. To adjust Lock TimeOut, follow the instruction below:

- Press the Setting option enter the password, press Ok and select Display.
- Press the Lock TimeOut option.
- Available options are Deactive, 15 Second, 1 minute, 3 minute, 10 minute and 30 minute. Default setting for this item is Deactive.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

For canceling the lock mode, the power key should be pressed once, and the lock indicator will be disappeared from the screen.

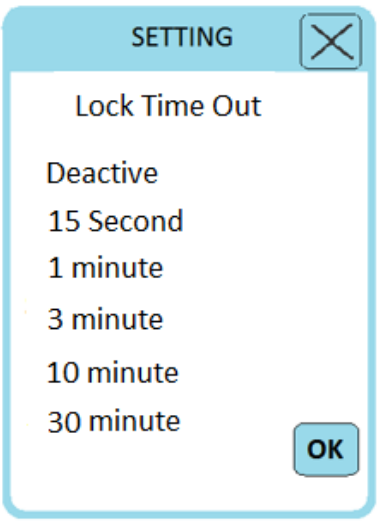


Figure 7-9 Lock TimeOut

Brightness

To adjust Brightness, follow the instruction below:

- Press the Setting option enter the password, press Ok and select Display.
- Press the Brightness option.
- The Brightness value is selectable from 5 to 99. Default setting for this item is 25.
- By scrolling, choose the proper brightness for the device.
- By pressing OK, the changes will be saved.

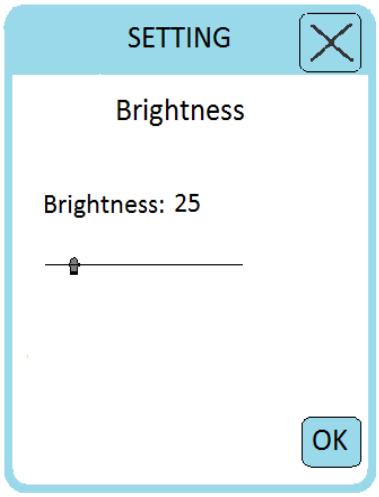


Figure 7-10 Brightness

Display Off

To turn off the display manually, follow the instruction below:

- Press the Setting option  enter the password, press Ok and select Display.
- Press the Display Off option so that the display turns off.
- To exit this mode, press the power button once.

When the display goes off, if "Alarm LED" is activated, the LED lights at the top of the front panel, will notify ongoing alarms. Furthermore, if the "Alarm Silence" is activated, a blue flashing LED at the top of the front panel, will be enabled for 120 seconds showing that the monitor is On.

Display Lock

When this option is selected, the touch screen of JAM S3 monitor will be locked and inactive and the lock indicator will be shown in the upper-right corner of display page. To enable lock option manually, follow the instruction below:

- Press the Setting option  enter the password, press Ok and select Display.
- Press the Display Lock option.
- The device will be on the lock mode.

➢ For canceling the lock mode, power key should be pressed once, and the lock indicator will be disappeared from the screen.

Patient

In this section, patient information, including gender, age category and blood type can be set. Furthermore, patient's information can be erased. To adjust Patient, follow the instruction below:

- Press the Setting option  enter the password, press Ok and select Patient.

- Available options are Gender, Age Cat, Blood and Patient Discharge.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

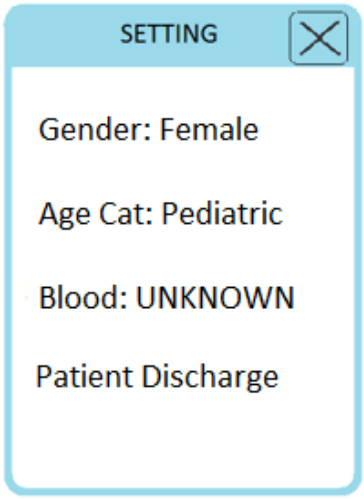


Figure 7-11 Patient

Gender

To adjust Gender, follow the instruction below:

- Press the Setting option enter the password, press Ok and select Patient.
- Press the Gender option.
- Available options are Male and Female (Default: Female).
- Choose the item you wish.
- By pressing OK, the changes will be saved.

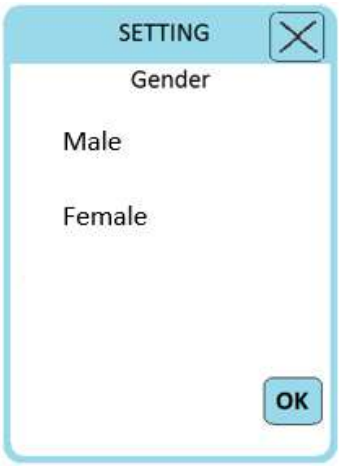


Figure 7-12 Gender

Age Cat

To adjust Age Cat, follow the instruction below:

- Press the Setting option  enter the password, press Ok and select Patient.
- Press the Age Cat option.
- Available options are Adult, Pediatric (Default) and Neonate.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

Figure 7-13 Age Category

Blood

To adjust Blood, follow the instruction below:

- Press the Setting option enter the password, press Ok and select Patient.
- Press the Blood option.
- Available options are A+, A-, B+, B-, AB+, AB-, O+, O- and Unknown. Default setting for this item is UNKNOWN.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

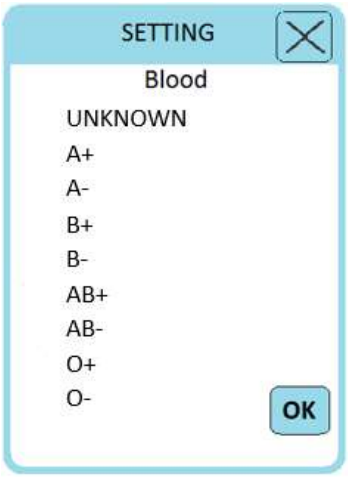


Figure 7-14 Blood

Patient Discharge

This option is to erase the patient's information and return to default settings. To reach to the Patient Discharge option, follow the instruction below:

- Press the Setting option enter the password, press Ok and select Patient.
- Press the Patient Discharge option.
- By opening Patient Discharge window, the message "system will be completely erased, Are You Sure?" will be shown. If selected YES, the settings will return to their default values.

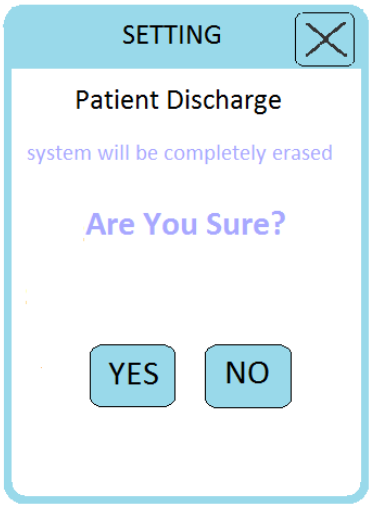


Figure 7-15 Patient Discharge

Setup

In this menu, time and date could be set, and the Factory Reset and About, are accessible here. By enabling Factory Reset, all of the settings will change to their default value. To adjust Setup, follow the instruction below:

- Press the Setting option enter the password, press Ok and select Setup.
- Available options are Time, Date and Factory Setting.
- Choose the item you wish.
- By pressing OK, the changes will be saved.

Figure 7-16 Setup

Time

To set the time, follow the instruction below:

- Press the Setting option  enter the password, press Ok and select Setup.
- Press the Time option.
- Select the proper hour and minute.
- By pressing OK, the changes will be saved.

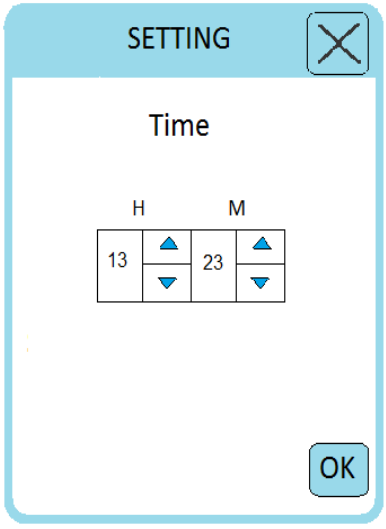


Figure 7-17 Time

Date

To set the date, follow the instruction below:

- Press the Setting option enter the password, press Ok and select Setup.
- Press the Date option.
- Select the proper day, month and year.
- By pressing OK, the changes will be saved.

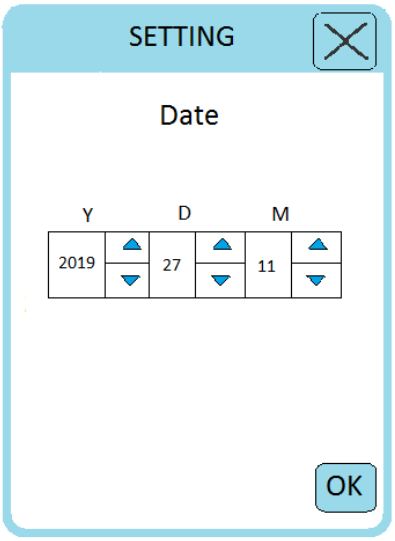


Figure 7-18 Date

Factory Reset

To reach to the Factory Reset option, follow the instruction below:

- Press the Setting option enter the password, press Ok and select Setup.
- Press the Factory Reset option.
- By opening Factory Reset window, the message “system will be completely erased, Are You Sure?” will be shown. If selected YES, the settings will return to their default values.

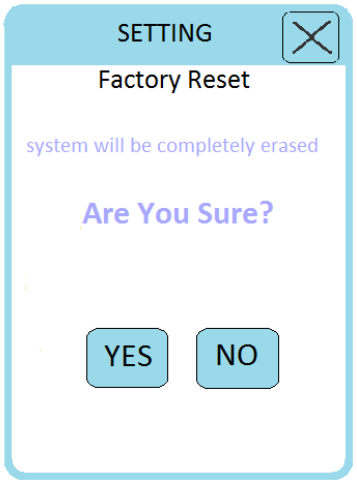


Figure 7-19 Factory Reset

About

In this section, some information regarding the device and the manufacturer. To observe the About option, follow the instruction below:

- Press the Setting option  enter the password, press Ok and select About.
- The following information will be displayed.
    - Product name
    - Manufacturer name
    - Company Fax Number
    - Support line
    - Release Date
    - Version of software
    - Company email address

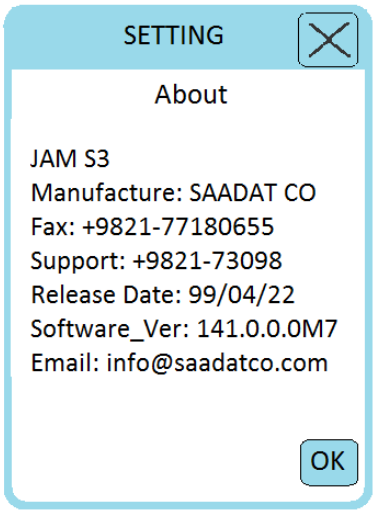


Figure 7-20 About

Param Trend

In Param Trend page, all the HR, SPO2, RR and TEMP values are saved every one minute and can be observed. Further information is accessible in Archive chapter.

Chapter 8) Archive

In this chapter, further information related to the Alarm Review section and Param Trend page are accessible. By selecting Alarm Review, all the alarms related to HR, SPO2 and RR parameters, and the date and the time of alarm occurrence will be shown. Furthermore, in Param Trend page all the HR, SPO2, RR and TEMP values of the patient are saved every one minute and can be observed.

Alarm Review

By selecting Alarm Review, all the alarms related to HR, SPO2 and RR parameters and the date and the time of alarm occurrence will be shown. To observe Alarm Review, follow the instruction below:

- Press the Setting option  enter the password, press Ok and select Alarm.
- Press the Alarm Review.
- By pressing <PRV and NEXT> alarms can be observed.

Figure 8-1: Alarm Review

Param Trend

The history of the recorded parameters for the admitted patient (HR, Spo2, RR) can be seen through this menu. To observe the Trend page, follow the instruction below:

- Press the Setting option  enter the password, press Ok and select Param Trend.
- All the HR, SPO2, RR and TEMP values are saved every one minute and can be observed in Param Trend. Press <<1hour, <5min, 5min> and 1hour>> options for observing parameters. All the data for the last two months are accessible.
- To leave this page, press back.

Figure 8-2: Param Trend

Chapter 9) Mobile Application

Introduction

The ECG Analyzer application is designed to communicate with the Jam S3 monitor and can connect to the monitor simultaneously via Wi-Fi connection and display all of the parameters and signals. One of the advantages of the application is the possibility of making 12 leads of ECG out of 4 leads sent from the monitor and the ability to display Multi-lead ECG signals. The application is also capable of communicating with the internet-based server to archive the records, 10 seconds of signals, and to receive the sophisticated interpretation of ECG analyzed by Glasgow software on the server side; also, the resulted report will be sent to any predefined email automatically for further evaluation.

Application download

To install the Android application, just search for the phrase "ECG Analyzer" in the Bazaar site or application, and download and install the application with the logo  . You can also download and install directly through the link (https://cafebazaar.ir/app/com.wearable.wearable). After installation, this application called Wearable, will run on the device (mobile or tablet).

Setup and Initial settings

1- Enter the mobile hotspot settings, and set the Network Name and Password values to “Saadatap01” and “12345678”, respectively.

2- Turn on the mobile’s hotspot.

3- Set the monitor to Smart Phone mode. If the hotspot is set correctly, you can see the name of the Wearable monitor, “XXXXX-mysimplelink", in the Hotspot settings section as Connected Devices.

Figure 9-1 Indicator of connection between Mobile and Monitor

Connecting the Monitor to Application

1- Put the monitor in “Smart Phone” mode

2- Turn on your mobile hotspot.

Note

- Make sure that no VPN is active on the mobile phone.
- Before using the hotspot, if you use the Wi-Fi module to access the Internet, be sure to turn off the Wi-Fi module and turn Mobile Data on to use the SIM card Internet.
- Some of the phones have 2 Wi-Fi modules and it is possible to use 2 modules simultaneously, one in the form of a hotspot and the other to connect to the Internet; But in order to use the Saadat application, in any case, it is necessary to turn off the Wi-Fi before using the hotspot.
- If you run the app before the hotspot is turned on, the mobile IP will not be registered in the app and the connection will not be established. Therefore, be sure the hotspot is turned on before running the App.
- When turning on the hotspot, the mobile phone uses the Wi-Fi module to communicate with other devices. In this case, if others know the Network Name and Password of the phone, they can connect to the Internet through your phone and use it. Therefore, be careful in maintaining the confidentiality of this information.

3- Launch the Wearable app and wait for the signals and parameters to be displayed. After connecting, the monitor connection indicator will turn green and you will see the bed number (BED No) set on the monitor at the top of the main page of the application (refer to the user guide section for more information.).

4- By pressing the “Record and Send” button, you can record and send the data to the server and receive the email containing the report at the defined email address. Also, immediately after sending the signal and receiving the interpretation from the server, the report summary will be displayed in the signal panel for 1-minute blinking, and you can also view the signals and reports by referring to the Records menu.

Note

- Report email will be sent by the server as soon as possible and it may take a few minutes to receive it.
- Receiving the results of interpretation and reviewing the submitted records is subject to communication with the Internet and the server.

Application User Manual

Main page introduction

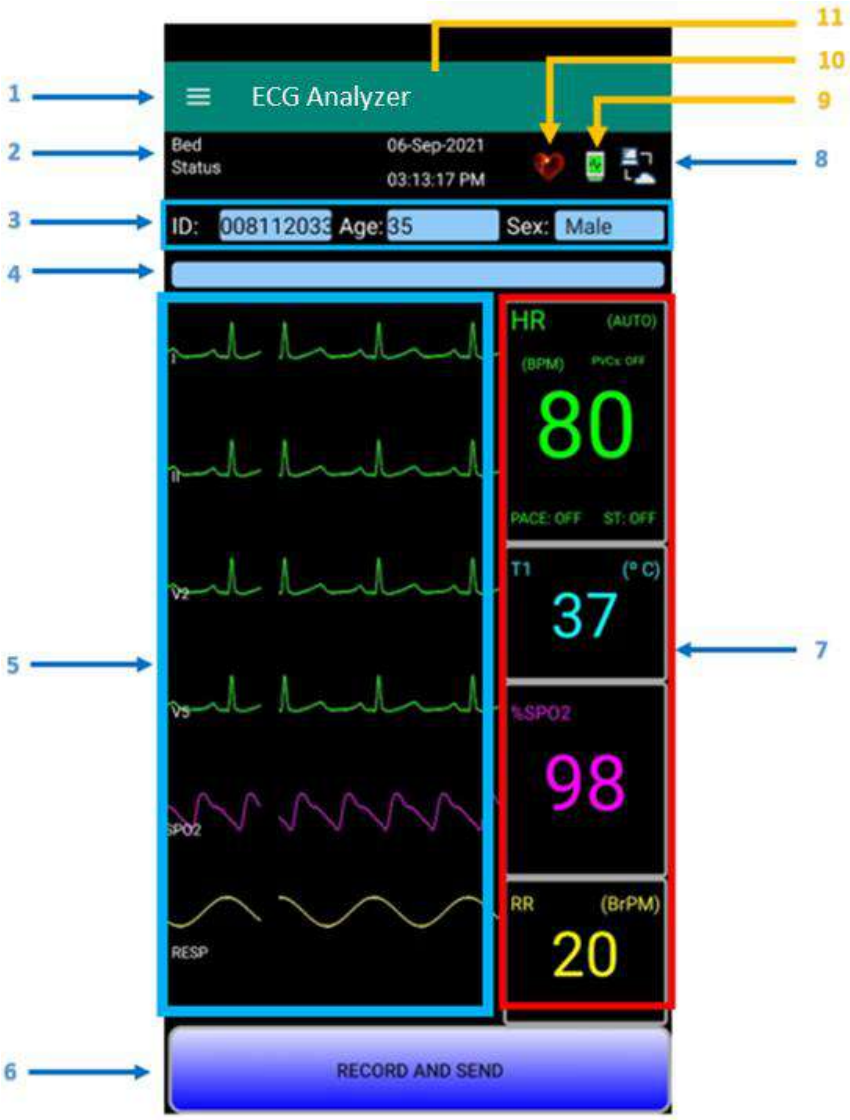


Figure 9-2 Application's main page

1- Menu: Use this key to enter the main Menu

2- Bed no & Status Message indicator: The bed number is received and displayed when connected to the monitor. Messages indicating the successful start, completion and sending of the record and etc., are also displayed here.

Status Messages	
Message	**Definition**
Start Record	Start data recording for 10 seconds
Stop Record	End of Data Recording
Recording x%	The percentage of recording progress proportional to the registration progress bar
Send File OK	Data has been sent to the server successfully
File Remain: --	The number of files, waiting to be sent to the server
Waiting for result	Waiting for the report to be received
IP: xx.xx.xx.xx	Phone's IP that is used with monitor to make connection
Downloading Pdf	Downloading the PDF Report
Download Pdf End	PDF report is downloaded and ready to be checked

3- Patient Information Panel: Patient information including national identity number (shown at the top of the report), age and gender that must be entered correctly at the time of registration (information in this section could be modified from the USER tab in the main menu).

Note

- The Glasgow software uses information about the patient's age and gender, in order to interpret the ECG signals accurately.

4- Record Progress Bar: Displays the progress of the recording process; the application will record and send 10 seconds of ECG signals per each record.

5- Signal Panel: In this section, ECG, Plethysmograph (SPO2), and Respiration signals are displayed in different arrangements.

- Swipe from bottom to top or vice versa in the Signal panel to view the available layouts. This way you can see other ECG leads.
- Moreover, to view the ECG multi-lead view, swipe from right to left or vice versa in the Signal panel. On this page, the 12 leads of ECG are displayed simultaneously in the signal panel (Leads V1, V3, V4, V6 are computationally generated using the data of other leads and displayed in light blue.).

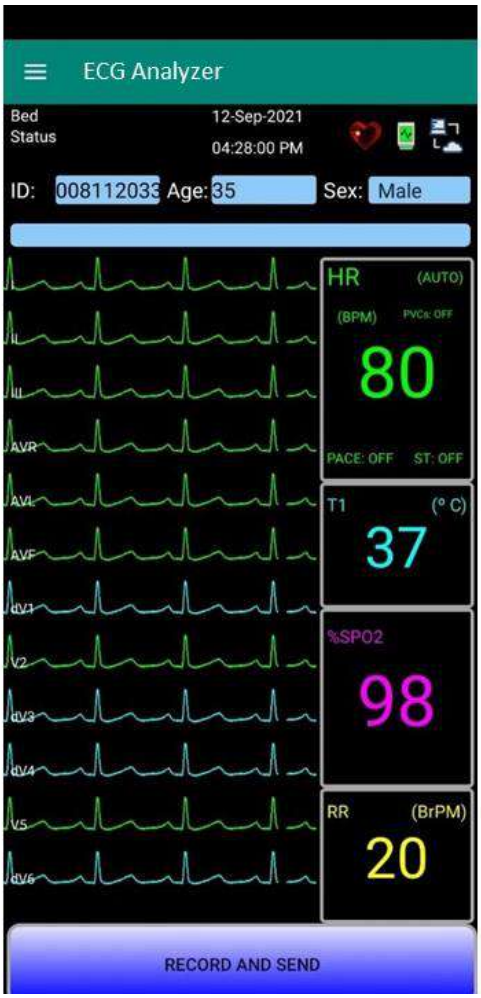


Figure 9-3 ECG Multi-Lead view

6- Record & Send key: Pressing this key will start the 10-second process of recording of 12 ECG leads, and after that, the signals and HR and SPO2 values will be sent to the server automatically.

Note

- Before pressing the record key, make sure about the quality of the signals as well as the connection to the Internet, via mobile data. If you do not have an internet access, the data will be recorded, and the transmission will be postponed until the internet connection is established.

- Before pressing the key, make sure that the signals are of good quality, and for this purpose it is necessary for the patient to be in a relaxed and motionless state for 15 seconds before the start of the recording and during the recording (for 10 seconds).
- The application is capable of adjusting the gain of display signals automatically based on the amplitude of the input signals.

7- Parameter Panel: The parameters sent by the monitor are displayed here with a fixed layout.

8- Server Connection Indicator: After recording the signals and in case of internet connection, this symbol will turn green that means establishing a connection with the server and sending the data. In this case, the message “Send File OK” is also displayed in the status messages area.

Note

- In case of no internet connection, the number of records that are in the sending queue will be displayed status messages area as “File Remain: --“.
- After sending the data to the server and seeing the “Send File OK” message, displaying the message “Waiting for result”, means that the report is being prepared and you can soon see the results under the Records menu. The summary of the interpretation is also displayed in the signal panel for 1-minute blinking.

		
Communicating with the server and sending data	Absence of data submission requests	Lack of Internet access and requests to send data

Figure 9-4 Server Connection Indicator states

9- Monitor Connection Indicator: This symbol turns green in case of establishing a stable connection with monitor

Figure 9-5 The interpretation summary displayed in the signal panel for 1 minute after sending data to the server

	
Disconnected from Monitor	Connected to Monitor

Figure 9-6 Monitor Connection Indicator states

10- Heart Rate Detection Symbol: Appears on the screen when receiving the HR parameter, which is calculated via ECG signals or the SPO2 sensor.

11- Data & Time: The date and time that is automatically received from the mobile phone and is also specified in each recorded data.

Main Menu introduction

By pressing the menu key, you will enter the main menu of the application and you will have access to the following options:

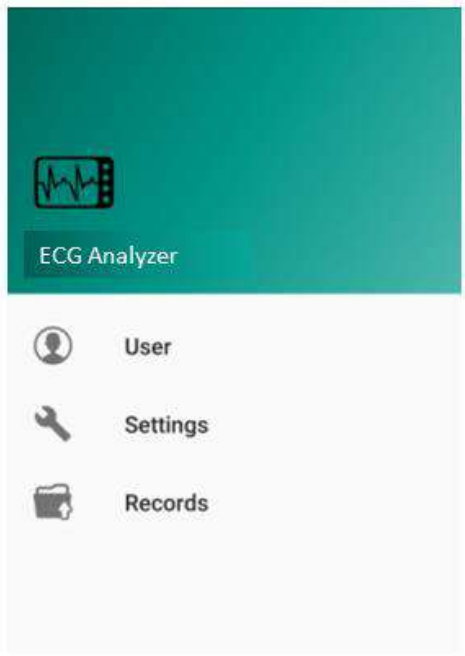


Figure 9-7 Application main menu

User Tab

Device Code	Device ID which can be the name / nickname of the mobile phone owner or preferably his / her national identity number.
Personal ID	Unique Patient Identifier (Patient National identity Number)
Age	Patient Age
Sex	Patient Sex
Physician Email	The email address in which the report will be received

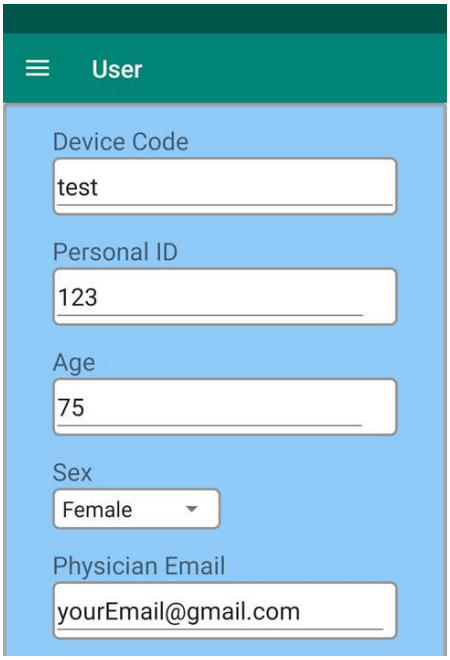


Figure 9-8 User Tab

Setting Tab

The necessary settings for this section are included in the software by default and there is no need to make changes. If it is necessary to change, the new settings are applied by the authorized experts of the manufacturer.

Records Tab

At the top of this page, all recorded data can be seen. A green checkmark next to each record means that the record has been sent to the server and the report has been prepared.

keys function

1- SIGNAL VIEW: By clicking on each record and pressing this key, the signals related to that record are displayed on a separate page.

2- INTERPRETATION: By selecting each record and pressing this key, the interpretations and measured parameters related to that record can be seen (signals without a green checkmark are un-interpreted due to not being sent to the server).

3-PDF VIEW: Touch to see the PDF report contains signals, measurements and interpretations.

4- RESEND: By selecting each record and pressing this key, the selected record will be sent to the server once again. If there is no green checkmark next to the record or you do not receive an email containing the report within 5 minutes after sending the signal (if connected to the Internet), it is recommended to use the RESEND key to resend the record.

5- DELETE: Use this key to delete the selected record.

6-DELETE ALL: Use this key to delete the whole archive.

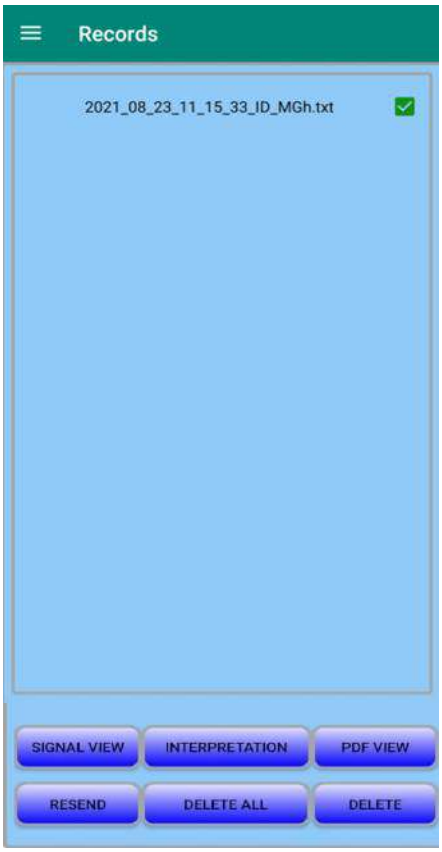


Figure 9-9 Archive of recorded signals

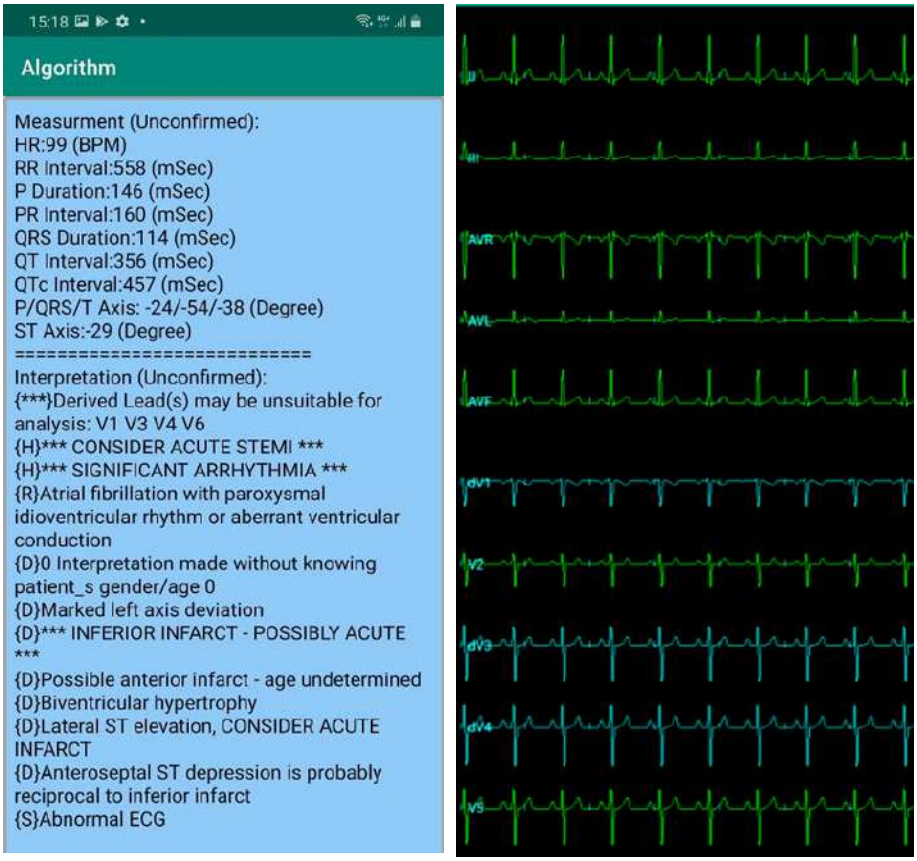


Figure 9-10 Interpretation (Left figure) & signal view pages (Right figure)

Chapter 10) Accessories

ECG Accessories

- ECG patient cable, 3 leads

  Part Number: P33048

- ECG patient cable, 6 leads

Part Number: P33049

ECG Electrodes

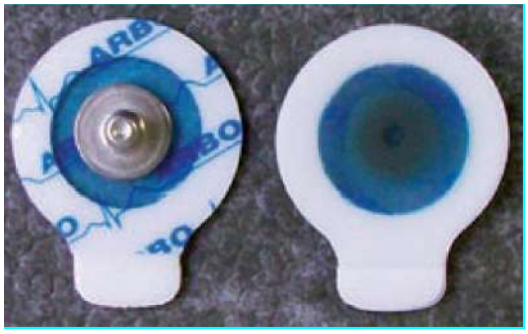
- Adults ECG Disposable Electrodes, FIAB Manufacturer

  REF: F9060
- Pediatric ECG Disposable Electrodes, FIAB Manufacturer

  REF: F9060P

- Arbo H124SG, COVIDIEN Manufacturer

  REF: 31.1245.21



SPO2 (MASIMO) Accessories

The following accessories are recommended:

● Masimo Adult Reusable Sensor, Weight > 30 Kg, (LNCS DCI)

Part Number: 1863

● Masimo Neonatal SPO2 Disposable Sensor, Weight <1 Kg, (LNCS NeoPt)

Part Number: 2330

● Masimo Neonatal SPO2 Disposable Sensor, Weight <3 Kg or >40 Kg, (LNCS Neo)

Part Number: 2329

- Masimo SOP2 Extension, Red LNC-10 –
  Part Number: 2056

● Masimo SPO2 Reusable Y- Sensor, (Adult, Neonate), Weight > 1 Kg (LNCS)

Part Number: 2258

● Masimo USpO2 Cable, (LNCS)

Part Number: 3315

Battery

- Battery, Ansmann Manufacturer - 1.2V 2500 mA

  Part Number: 5035431

- Charger

Warning

- Before using accessories, pay attention to its expiry date.

Note

- Other SpO2 accessories may not compatible with your device.

Chapter 11) Care and Cleaning

System Check

Before using the monitor

- Check if there is any mechanical damage in the system and accessories.
- Check if all the charger and accessories are firmly connected.
- Check all the functions of keys, touch and modules to make sure that the monitor is in proper condition.

Warning

- If you find any damage on the monitor, stop using the monitor on patient, and contact the biomedical engineer of the hospital or local After Sale Service.
- The overall check of the monitor, including the safety check, should be performed only by qualified personnel. All checks which need the monitor to be opened and safety and maintenance checks should be performed by After Sales Service.
- If user does not follow a satisfactory maintenance schedule, the monitor may become invalid, and human health may be endangered.

Note

- It is recommended that the system is calibrated by manufacturer every year, but it has to be calibrated once every 2 years. The medical center can request the system calibration whenever the system accuracy is in doubt.
- The system lifetime is 5 years.
- Use only the substances approved by us and methods listed in this chapter to clean or disinfect your equipment. Manufacturer makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control

infection, consult your hospital's Infection Control Officer or Epidemiologist. Also observe any local policies that apply within your hospital.

Cleaning and Disinfection

Warning

- Before cleaning the monitor or the sensors, make sure that the equipment is switched off and disconnected from the power line.
- Sterilization may cause damage to the device and is therefore not recommended for this patient monitor otherwise indicated in the instructions delivered with accessories or your hospital's servicing schedule.
- If you see any signs of damage or deterioration in the device and its accessories, do not use it, and if necessary, contact the after-sales service company.
- Allow the monitoring system to dry completely before making connections. And please make sure all connectors tightly connected to the system before using the system.
- Do not use EtO gas to disinfect the monitor.
- Do not sterilize the device with gas or autoclave.

Note

1- The monitor system and its accessories should be kept away from dust.

2- Do not use detergents that contain ammonia or acetone.

3. Most detergents should be diluted during use.

4- Avoid sharp nails or tools to clean hard stains.

5- Be careful not to put detergent inside the system case.

6- Dry the remaining detergent.

External surfaces

In-between patients and as required, in order to cleaning the device, wipe gently using a moist cloth and warm soapy water or mild detergent, and for disinfection use the following recommended agents:

■ Alcohol 70%
■ Isopropyl alcohol
■ N-propanol

Display screen

In-between patients and as required use clean and soft cloth with 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.
- Don't spray a liquid directly on the screen.

Accessories

Please observe the following cautions for cleaning and disinfecting the accessories.

Warning

- To avoid damaging of the cable, probe, sensor or connector, do not immerse it in any liquid.
- Disposable accessories shall not be sterilized or reused.
- To prevent environmental pollution, the disposal of single-use accessories shall be done in accordance with the policies of the hospital.
- Manufacturer has no responsibility for the effectiveness of controlling infectious disease using these chemical agents. Please contact infectious disease experts in your hospital for details.

Note

- Daily check of the accessories intactness (no mechanical damage) and accessories function is recommended.

ECG Cable

Use soft cloth moistened with mild soap liquid or cleaning agent containing 70% ethanol to clean the ECG cable. To avoid extended damage to the equipment, disinfection is only recommended when stipulated as necessary in the Hospital Maintenance Schedule. Disinfection facilities should be cleaned first.

Warning

- Do not immerse ECG cable completely in water, solvents, or cleaning solutions since it is not waterproof.
- Do not submerge the ECG cable in any cleaning solution or do not attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method.
- If there is any sign indicating that the ECG cable may be damaged or deteriorated, replace it with a new one instead of continuing its application on the patient.

SPO2 Probe

To clean, disinfect and sterilize reusable SPO2 accessories, refer to the instructions delivered with the accessories.

Warning

- Do not immerse sensor and patient cable completely in water, solvents, or cleaning solutions because the sensor and patient cable are not waterproof.

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

Device parts	Single-use	Cleaning	Disinfection	Sterilization
External surface of device	-	In-between patients and as required wipe gently using a moist cloth and warm soapy water or mild detergent.	In-between patients and as required use ■ Alcohol 70% ■ Isopropyl alcohol ■ N-propanol	To avoid extended damage to the equipment, sterilization is not recommended for this monitor, 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.
Display screen	-	In-between patients and as required: Clean and soft cloth with screen cleaner or mild soapy water	In-between patients and as required use ■ Isopropyl alcohol	
ECG Accessory	disposable electrodes	-	-	-
	ECG cable	Use soft cloth moistened with mild soap liquid or cleaning agent containing 70% ethanol to clean the ECG cable.	Disinfection is only recommended when stipulated as necessary in the Hospital Maintenance Schedule. Disinfection facilities should be cleaned first.	To avoid extended damage to the equipment, sterilization is not recommended for this monitor, 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
SpO2 Accessory	disposable sensor	--	--	--
	SPO2 Probe	**According to the instructions delivered with the reusable SPO2 accessories** To clean, disinfect and sterilize reusable SPO2 accessories, refer to the instructions delivered with the accessory.		

Preventive Maintenance (PM)

To ensure that the device is kept in the best condition, it shall be kept clean and all points related to the maintenance of the system shall be observed. There are no repairable parts in the system and all repairs shall be done by the manufacturer.

Storage

The storage environment shall be clean and dry. If possible, use the original packaging of the device.

Note

- If the monitor or equipment falls from a height and is damaged or in the vicinity of a very high temperature and high humidity, contact the company's after-sales service at the earliest opportunity to ensure the correct operation.
- Thoroughly clean the system before and after the system is not used for a while.

Weekly check of the following items is recommended:	Monthly check of the following items is recommended:
1. Device cleanness 2. Visual inspection of device (case, screen, keys and indicators) in terms of mechanical damage 3. Visual inspection of accessories in terms of mechanical damage 4. Function of accessories 5. Disposable accessories and accessories with limited time of use.	1. Calibration label (Sending the device to the manufacturer for calibration at the specified date). 2. Visual inspection of device in terms of mechanical damage 3. Device cleanness 4. Function of keys and indicators 5. Visual inspection of accessories in terms of mechanical damage

The preventive maintenance (PM) checklist #PL-F-24 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.

Preventive Maintenance (PM) Checklist

SAADAT Co.					
Form No. : PL-F-24/0		**PM Form (JAM S3)**			
State:	**City:**	**Medical center:**	**Ward:**		
Device model:	**Serial number:**	**Installation date:**	**Inspection date:**		
No.	**Test and Inspection Item**		**OK**	**NOK**	**N/A**
1	**Visual inspection**	**No damage or breakage in the back case and panel**			
		Cleaning and disinfection according to the user manual			
2	**Touch**	**Correct function**			
3	**Display screen**	**Correct display of Waveform area, Parameter area and Message area**			
4	**Battery**	**Unplugging the system (check the battery function)**			
		Check the fuse			
		Periodic usage of the battery			
5	**Alarm**	**Alarm activation**			
		Clarity of alarm sound			
		Correct function of alarm LEDs			
6	**Setup**	**Saving date& time settings**			
7	**ECG**	**Check ECG cable**			
		Check ECG window (Pacemaker, etc)			
		Cleaning and disinfection according to the user manual			
8	**RESP**	**Check parameters of RESP window**			
9	**SpO2**	**Check SpO2 probe (extension, if any)**			
		SpO2 window settings (Measurement mode and sensitivity)			
		Cleaning and disinfection according to the user manual			
10	**Connection to the Central System**	**Check secure connection of the device and central system**			
		Check Network indicator on the central and waveforms and parameters on the central system			
		Check connection between the device and the central system			

Final decision: **Pass** □ **Fail** □

Expert Recommendation:

Name and signature of responsible individual: **Name and signature of expert:**

Chapter 12) Troubleshooting

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

Troubleshooting guide is intended to help users to solve minor problems caused by incorrect use of the monitor or failure of accessories. When you face any problem, please be sure that you have followed all procedure mentioned in Correct Action column before you contact with After Sale Service.

Fault Symptoms	Possible Cause	Correct Action
The monitor does not turn on		• Press the power button for 5 seconds and a little more to turn the monitor on. • Make sure that the batteries are inserted correctly into battery container according to the signs. • Make sure that current batteries are charged and check the change the batteries with two un-used ones. • Check if the device is turned on while the charger is connected. If so, call the after sales service to make them aware that device is not working on batteries. • Check POWER AC path • Call for service
The monitor is unable to run on battery	• Battery is discharged • Fuse of the battery is faulty • etc.	• Make sure that the batteries are inserted correctly into battery container according to the signs. • Change the batteries with two unused ones which are approved by manufacturer. • Call for service

Fault Symptoms	Possible Cause	Correct Action
NO ECG waveform	• ECG cable is notconnected correctly • ECG cable failure • Bad placement of leads and electrodes • etc.	• Connect ECG cable correctly • Check leads and electrodes. • Short-circuit all the leads, if the cable is perfect, no error message will be displayed. • Don't use old and faulty electrodes • Call for service
Noisy ECG waveform	• Loose connection of electrodes • Wrong ECG filter • etc.	• Check electrodes and leads • Check applied gel on the chest lead or change the chest lead, if necessary. • Make the other sources of noises such as cell phones and etc. far from the device. • Set filter mode correctly • Call for service
Spike on ECG waveform	• If "PACE ON" is activated for patient without Pace marker, ECG noise will be received as PACE. • etc.	• Turn "Paced detection" OFF in ECG menu
Unstable HR	• ECG signal is noisy or isn't suitable • etc.	• Check leads and electrodes. • Select the patient age category (Adult, Paediatric and Neonate) according to patient age. • Change lead to display the best ECG signal • Call for service
No "RESP" signal **No good waveform** **Unstable RR**	• Electrodes are not connected correctly • Patient moves during measurement • etc.	• Check leads and electrodes. • Change RESP lead • Calm patient • Call for service

Fault Symptoms	Possible Cause	Correct Action
No SPO2 waveform noisy SPO2waveform	• SPO2 probe in an unsuitable place. • Faulty sensor • etc.	• Change the place of probe on patient • Unplug and plug the SPO2 socket • Change the probe and check the waveform. Contact the manufacturer to replace the probe with a new one, if necessary. • Call for service
Invalid SPO2 value	• Patient movement during measurement • Probe is placed in an unsuitable position. • etc.	• Calm patient • Change the place of probe • Pay attention to technical alarms which are related to SPO2; Such as, Low perfusion and etc. to do the correct modification. • Call for service
Alarm Indicators are not working		• Check if the alarm indicators are working once during the device initialization, it demonstrates the accuracy of indicators. Alarms settings should be changed to On mode. • Call for service
No connection between device and central system.		• Check the Access Point setting (SSID, Password) • Check the bed number and make sure it is not conflicting with another device. • Call for service

Fault Symptoms	Possible Cause	Correct Action
Device resets repeatedly	• The inserted batteries are not suitable for the device and they are not approved by manufacturer. • The batteries are going to be depleted	• Batteries should be charged or replaced with full charged ones. • Reduce the display brightness and turn the WIFI off, if it is not required. • Call for service

Note

Some advices to reduce measurement errors:

- If patient is walking or moving, connect the device to the patient's body by means of designed belt in order to prevent from device's excessive movements.
- In lying position, put the device in a proper distance beside the patient's bed, in order to prevent the patient from falling on device.
- When the device is connected to AC supply to charge the batteries, it is more probable to get noisy signals.

Chapter 13) Technical Specifications

CLASSIFICATION	
Protection against electroshock	INTERNALLY POWERED MEE, Type CF for all modules (based on IEC 60601-1).
Mode of operation	Continues operation equipment
Harmful Liquid Proof Degree	IP32
DISPLAY	
JAM S3	TFT COLOR 480 × 320, 3.5”
Waveforms	ECG, SPO2, RESP
Numeric Parameters	HR, SPO2, PR, RR, Alarm Limits
Operation Method	Membrane/Keys, Touch Screen
ECG	
Lead and wire options	Selectable 3 or 6 Wires For 3 wire: I, II, III For 6 wire :I, II, III, V2, V5, aVR, aVF, aVL
Dynamic Range	+-5mv
Lead Off Current	70 nA
Gain	2, 1, 1/2, 1/4, 1/8, Auto
Calibration	1mV, 0.5 sec
Filters	“MONITOR” (0.5 - 24 Hz) “NORMAL” (0.5 - 40 Hz) “EXTENDED” (0.05-100 Hz)
CMRR	110 dB
Internal Noise	< 22 uV
Input Impedance	0.94 GΩ @ 10 Hz
QRS Detection	Duration: 40 to 120 msec
	Amplitude: 0.25 to 5 mV for Adult/Pediatric 0.2 to 5 mV for Neonate
Heart Rate Range	15 - 300 BPM for adult/pediatric
	15 - 350 BPM for neonate
Accuracy	±1% or 2 BPM
Tall T-Wave	Reject up to 1.2 mV Amp

Pacer Detection/Rejection	Duration : 0.1 - 2 msec
	Amp: ±2 to ± 700 mV (Without over/undershoot)
	Reject from heart rate counter
	Re-insert into ECG to display on screen
	Ineffective pace rejection: HR:0, Pace: 60 HR:60, Pace:60 HR:30, Pace:80
	Beside rejection of atrial paces precede ventricular paces by 150 or 250 ms
Protection	Defibrillator and Electro surgery
Standards	ANSI/AAMI EC-13, EN 60601-2-27
SPO2 (Masimo Set)	
Method	2 Wave length pulse wave type
Range	SpO2 0 – 100 %
	PR 25 – 240 bpm
	PI 0 – 20.0 %
Accuracy	Oxygen Saturation
	No motion conditions: Adult/Pediatric: ±2% (SPO2 70 ~ 100%), Neonate: ±3% (SPO2 70 ~ 100%)
	During motion conditions: Adult/Pediatric/Neonate: ±3% (SPO2 70 ~ 100%)
	During low perfusion conditions: Adult/Pediatric/Neonate: ±2% (SPO2 70 ~ 100%)
	Pulse Rate
	During no motion conditions: Adult/Pediatric/Neonate: ±3bpm (PR 25 ~ 240)
	During motion conditions: Adult/Pediatric/Neonate: ±5bpm (PR 25 ~ 240)
	During low perfusion conditions: Adult/Pediatric/Neonate: ±5bpm (PR 25 ~ 240)
Resolution	SpO2 1 %

	PI 0.1 % PR 1 BPM
RESPIRATION	
Method	Impedance
Base Resistance	250 -1250 Ohm
Dynamic Range	0.2 - 2 Ohm
Breath Rate Range	0 - 253 BrPM
Accuracy	±2% or 2 BrPM
ALARM	
Sources	Error messages, All other parameter limits
Alarm On/Off	Selectable for all parameters
Alert	Blinking on Display, Volume Selectable Audio Alarms, Light indicator
TREND	
Sources	HR, SPO2, RR ()
Trend Time Save	96 Hours
Trend Time Interval	1 sec
INPUT/OUTPUT PROTOCOL	
Network	Reliable TCP/IP Protocol over WIFI standard 802.11 b/g/n @ 2.4 GHz
GENERAL	
Safety	Based on IEC 60601-1, Class I
Protection	Against Electro surgery and Defibrillator
Internal Battery	Rechargeable: 1.2 V, 2400 mAh
	Charge Time: Around 3 Hours
	Usage: More than 18 Hours
Physical Specification	
Weight (approximately)	With Battery: 218 gr
	Without Battery: 152 g
Dimension (Cm)	135(W) × 65(H) × 30(D)
ENVIROMENTAL	
Temperature	Operating: 5 to 40 ◦C (41 ~ 104 ◦F)

	Storage & Transport: -25 to 60 ◦C (-13 ~ 140 ◦F)
Humidity	Operating: 20-90 % (Noncondensing) Storage & Transport: 10-100 % (Noncondensing)
Altitude	-200 to 3000 m

Chapter 14) Messages and Alarms

Physiological Alarms

Alarm	Situation	Visual Alarm	Audio Alarm
ECG Alarms			
ECG Asystole	Heart beat is not detected in last 10 seconds.	• HR is "0" and blinks. • Alarm indicator flashes. • Message "ECG ASYSTOLE" is displayed in red background.	Activated
HR High	Heart rate violates adjusted high limit.	• HR value blinks. • Alarm indicator flashes. • Alarm message is displayed in a background corresponding to its level.	Activated
HR Low	Heart rate violates adjusted low limit.	• HR value blinks. • Alarm indicator flashes. • Alarm message is displayed in a background corresponding to its level.	Activated
Respiration Alarms			
Apnea	Non-respiration condition overruns adjusted time.	• Alarm indicator flashes • "RESP APNEA" is displayed in red background.	Activated

RR High	Respiration rate violates adjusted high limit.	• RESP value blinks • Alarm indicator flashes. • Alarm message is displayed in a background corresponding to its level.	Activated
RR Low	Respiration rate violates adjusted low limit.	• RESP value blinks • Alarm indicator flashes. • Alarm message is displayed in a background corresponding to its level.	Activated
SPO2 Alarms			
%SPO2 HIGH	SPO2 violates adjusted high limit	• SPO2 value blinks. • Alarm indicator flashes. • Alarm message is displayed in a background corresponding to its level.	Activated
%SPO2 LOW	SPO2 violates adjusted low limit	• SPO2 value blinks. • Alarm indicator flashes. • Alarm message is displayed in a background corresponding to its level.	Activated
PR High	PR value violates adjusted high limit.	• PR value blinks. • Alarm indicator flashes. • Alarm message is displayed in a background corresponding to its level.	Activated

PR Low	PR value violates adjusted low limit.	• PR value blinks. • Alarm indicator flashes. • Alarm message is displayed in a background corresponding to its level.	Activated

Technical Alarms

Alarm	Cause	Solution	Explanation
System Alarms			
LOW BATTERY	Battery charge is less than %25.	Change the batteries with full charge batteries.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, alarm is disabled and ignores this fault.
ECG Alarms			
ECG NO CABLE	ECG cable is not connected to the system.	Connect ECG cable.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, alarm is disabled and ignores this fault until reconnecting the cable.
ECG_NOISE	ECG signal is noisy or saturated.	Check for any possible sources of signal noise in the area around the cable and	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, alarm

		electrode, and check the patient for great motion and also check the lead wires.	is disabled and ignores this fault.
ECG DEFECT	ECG module failure	Power off and then on the system .If this message is displayed again the user should contact local After Sale Service.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, alarm is disabled and ignores this fault.
ECG CHECK LL	Mentioned lead is not properly connected to the patient.	Make sure that mentioned electrode is properly connected to the patient.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, alarm is disabled and ignores this fault.
ECG CHECK LA	Mentioned lead is not properly connected to the patient.	Make sure that mentioned electrode is properly connected to the patient.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, alarm is disabled and ignores this fault.
ECG CHECK RA	Mentioned lead is not properly connected to the patient.	Make sure that mentioned electrode is properly connected to the patient.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, alarm is disabled and ignores this fault.

ECG CHECK V2	Mentioned lead is not properly connected to the patient.	Make sure that all electrodes esp. V2 and ECG cable are properly connected to the patient.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, alarm is disabled and ignores this fault.
ECG CHECK V5	Mentioned lead is not properly connected to the patient.	Make sure that all electrodes esp. V5 and ECG cable are properly connected to the patient.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, alarm is disabled and ignores this fault.
ECG CHECK RL OR ALL	RL or other leads are not properly connected to the patient when ECG lead is V, aVR, aVF or aVL.	Make sure that all electrodes esp. RL and ECG cable are properly connected.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, alarm is disabled and ignores this fault.
ECG CHECK LEAD	The ECG leads are not properly connected to the patient.	Make sure that all electrodes, lead are properly connected to the patient.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, alarm is disabled and ignores this fault.
Respiration Alarms			
RESP CHECK LEADS	The RESP leads are not properly connected to the patient.	Make sure that all electrodes, lead are properly connected to the patient.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, alarm is disabled and ignores this

			fault .Alarm is activated when RR ALARM is "ON".
SPO2 Alarms			
SPO2 NO MODULE	SPO2 external module is not connected to the device.	Make sure that the external module is firmly connected to the device.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, alarm is disabled and ignores this fault.
SPO2 NO SENSOR	SPO2 sensor is disconnected from the cable.	Make sure that the sensor is firmly connected to the cable.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, alarm is disabled and ignores this fault.
SPO2 SENSOR OFF	SPO2 sensor may be detached from the patient.	Make sure that SPO2 sensor is properly attached to the patient	Alarm level 2- The message is displayed in yellow background. By pressing ALARM SILENCE, alarm is disabled and ignores this fault.
SPO2 NO CABLE	SPO2 cable is not fully inserted to the module.	Make sure that the SpO2 cable is correctly connected into the module.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, alarm is disabled and ignores this fault.
SPO2 REPLACE SENSOR	The SPO2 sensor is damaged or the	Change the SPO2 sensor.	Alarm level 2- The message is displayed in yellow background. By pressing

	proper sensor is not used		ALARM SILENCE, alarm is disabled and ignores this fault.
SPO2 INCOMP SENSOR	Incompatible SpO2 sensor is used	Change the SPO2 sensor.	Alarm level 2- The message is displayed in yellow background. By pressing ALARM SILENCE, alarm is disabled and ignores this fault.
SPO2 SENSOR EXPIRED	The patient sensor life has expired.	Replace the SPO2 sensor.	Alarm level 2- The message is displayed in yellow background. By pressing ALARM SILENCE, alarm is disabled and ignores this fault.
SPO2 CHECK SENSOR	SPO2 sensor is damaged or disconnected from the cable.	Make sure that the sensor is firmly connected to the cable/ Replace the sensor	Alarm level 2- The message is displayed in yellow background. By pressing ALARM SILENCE, alarm is disabled and ignores this fault.
SPO2 NO TAPE	When a single-patient use sensor is used, the adhesive portion of the sensor is not connected.	Make sure that the adhesive portion is firmly connected to the sensor.	Alarm level 3- the message is displayed in cyan background. By pressing ALARM SILENCE, background becomes gray and alarm is disabled and ignores this fault.
SPO2 TAPE EXPIRED	The adhesive patient sensor life has expired.	Replace the adhesive SPO2 sensor.	Alarm level 2- The message is displayed in yellow background. By pressing

			ALARM SILENCE, alarm is disabled and ignores this fault.
SPO2 INCOMP TAPE	Incompatible SpO2 adhesive sensor is used	Change the SPO2 adhesive sensor.	Alarm level 2- The message is displayed in yellow background. By pressing ALARM SILENCE, alarm is disabled and ignores this fault.
SPO2 REPLACE TAPE	The adhesive SPO2 sensor is damaged or the proper sensor is not used	Change the adhesive SPO2 sensor.	Alarm level 2- The message is displayed in yellow background. By pressing ALARM SILENCE, alarm is disabled and ignores this fault.
SPO2 LOW PERFUSION	The SPO2 signal amplitude is too weak or undetectable.	Change the sensor position.	Alarm level 2- The message is displayed in yellow background. By Pressing ALARM SILENCE, alarm is disabled and ignores this fault.
SPO2 AMBIENT LIGHT	This may be caused by entering environmental light into the sensor.	Make sure that SPO2 sensor is properly connected to the patient.	Alarm level 2- The message is displayed by yellow background. By pressing ALARM SILENCE, alarm is suspended for at least 120s. Alarm is activated when SPO2 ALARM is "ON".
SPO2 INTERFERENCE	High intensity light such as	Place a Masimo Optical Light	Alarm level 2- The message is displayed by yellow

	pulsating strobe lights, excessive ambient light sources such as surgical lights or direct sunlight, or other monitor displays.	Shield over the sensor.	background. By pressing ALARM SILENCE, alarm is suspended for at least 120s. Alarm is activated when SPO2 ALARM is "ON".
SPO2 CABLE EXPIRED	The patient cable life has expired.	Replace the SPO2 cable.	Alarm level 2- The message is displayed in yellow background. By pressing ALARM SILENCE, alarm is disabled and ignores this fault.
SPO2 REPLACE CABLE	The SPO2 cable is damaged or the proper cable is not used	Change the SPO2 cable.	Alarm level 2- The message is displayed in yellow background. By pressing ALARM SILENCE, alarm is disabled and ignores this fault.
SPO2 INCOMP CABLE	Incompatible SpO2 cable is used	Change the SPO2 cable.	Alarm level 2- The message is displayed in yellow background. By pressing ALARM SILENCE, alarm is disabled and ignores this fault.
SPO2 CHECK PROBE	cable or/and sensor is not working properly.	Check cable and sensor	Alarm level 2- The message is displayed in yellow background. By pressing ALARM SILENCE, alarm

			is disabled and ignores this fault.
SPO2 BOARD FAILURE	SPO2 board failure	Power off and then on the system. If this message is displayed again, Change the uSPO2 cable.	Alarm level 2- the message is displayed in yellow background. By pressing ALARM SILENCE, alarm is disabled and ignores this fault.

Messages

Message	Cause	Solution	Explanation
SPO2 Messages			
SPO2 PULSE SEARCH	Instrument is searching for pulse.	If instrument fails to display within 30 seconds, disconnect and reconnect. If pulse search continues, move sensor to better perfused site.	In this condition SPO2 value is displayed blank.
SPO2 SENSOR NEAR EXP	The patient sensor life is near expired.	Provide a new sensor to replace it if necessary.	In this condition SPO2 value is displayed.
SPO2 TAPE NEAR EXP	The patient adhesive sensor life is near expired.	Provide a new sensor to replace it if necessary.	In this condition SPO2 value is displayed.
SPO2 CABLE NEAR EXP	The patient cable life is near expired.	Provide a new cable to replace it if necessary.	In this condition SPO2 value is displayed.

SPO2 LOW SIGNAL IQ	Low signal quality.	Ensure proper sensor application. Move sensor to a better perfused site.	In this condition SPO2 value is displayed.
SPO2 DEMO MODE	A Demonstration tool is currently connected to the sensor	Replace with a patient cable and sensor (if necessary)	-
SPO2 ONLY MODE	Occurs during an unsuccessful sensor initialization/pulse search routine or during monitoring.	See the accessory directions for use. Use a Masimo light shield to cover the sensor and adjust the sensor.	In this condition SPO2 value is displayed.
SPO2 SENSOR INIT	Device is checking the sensor for proper functioning	If values are not displayed within 30 seconds, disconnect and reconnect sensor. If values are still not displayed, replace with a new sensor.	In this condition SPO2 value is not displayed.

Appendix I) System Default Parameters

ITEMS	SELECTION	DEFAULT
MODE		
Mode	Monitor, Central, Smartphone	Monitor
ALARM		
Buzzer	On, Off	On
LED	On, Off	On
FACTORY SETTING		
AP Name	00~09	01
AP Password	1234xxxx	5678
Bed number	1~16	08
Demo	On, Off	Off
DISPLAY		
Display timeout	Always on, 1min, 2min, 5min, 10min, 30min	10 min
Lock timeout	Dactive, 15sec, 1min, 3min, 10min, 30min	Deactive
Brightness	5~99	25
PATIENT		
Gender	Female, Male	Female
Age cat.	Neonate, Pediatric, Adult	Pediatric
Blood	Unknown, A+, A-, B+, B-, AB+ AB-, O+, O-	UNKNOWN
ECG MENU		
ECG Lead	I, II, III, V2, V5, AVR, AVL, AVF	II
Lead type	3 wires, 6 wires	6 wires
HR source	ECG, SPO2, Auto	Auto
HR Alarm		

ITEMS	SELECTION	DEFAULT
Alarm state	On, Off	Off
Alarm level	1, 2	1
Alarm limit	30~300	50~120
ECG filter	Monitor, Normal, Extended	Extended
Pace detect	On, Off	Off
Sweep	12.5, 25	25
RESP MENU		
RESP lead	RA-LA, RA-LL	RA-LA
RR alarm	On, Off	Off
RR alarm level	1, 2, 3	1
RR alarm limit	5~99	5~25
Apnea	Off, 10, 15, 20, 25, 30, 35, 40 sec	10 sec
SPO2 MENU		
Average time	2~4, 4~6, 8, 10, 12, 14, 16 sec	8 sec
Sensitivity	Normal, APOD, MAX	Normal
Fast SAT	On, Off	Off
SPO2 alarm	On, Off	Off
SPO2 alarm level	1, 2	1
SPO2 alarm limit	1~99 (min)	85~100
TEMP. MENU		
Unit	C, F	C
Alarm	On, Off	Off
Alarm level	1, 2, 3	1
Alarm limit	0~50	35~39

Appendix II) EMC

Warning

- Use only the recommended manufacturer accessory. Using the accessory other than in relevant chapter may cause to increase the EMISSION or decrease the IMMUNITY of system.
- Measurements can be affected by mobile and RF communications equipment. It should be assured that the wearable monitor is used in the electromagnetic environment specified.
- To prevent EMC effect on the monitor, 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 correct performance in the configuration in which it will be used.
- Do not use cellular phone in the vicinity of this equipment. High level of electromagnetic radiation emitted from such devices may result in strong interference with the monitor performance.

EMC Declaration for Jam S3

Guidance and manufacturer's declaration – JAM S3 emissions		
The JAM S3 is intended for use in the electromagnetic environment specified below. The customer or the user of the JAM S3, should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 2	The JAM S3 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The JAM S3 is suitable for use in all establishments.
Harmonic emissions IEC 61000-3-2	N.A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N.A	

Guidance and manufacturer's declaration – electromagnetic immunity

The JAM S3 is intended for use in the electromagnetic environment specified below. The customer or the user of the JAM S3 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, ± 4kV, ± 8kV, ± 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%.
	Patient coupling	N.A	
	Signal input/output parts	N.A	
Electrical fast transient/burst IEC 61000-4-4	Input a.c. power	N.A	
	Signal input/output parts	N.A	
Surge IEC 61000-4-5	Input a.c. power	N.A	
	Signal input/output parts	N.A	
Voltage dips, IEC 61000-4-11	Input a.c. power	N.A	
		N.A	
Voltage interruptions IEC 61000-4-11	Input a.c. power	N.A	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	Enclosure	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of test level.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Jam S3 is intended for use in the electromagnetic environment specified below. The customer or the user of the JAM S3 should assures that it is used in such an environment.			
Immunity test	**Port**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	Input a.c. power	N.A	
	PATIENT coupling		
	Signal input/output parts		
Radiated RF IEC 61000-4-3	ENCLOSURE	3 V/m, 80 MHz - 2,7 GHz, 80% AM at 1 kHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	ENCLOSURE	Refer to the following table (table 9 of EN 60601-1-2: 2015)	

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment						
Test frequency (MHz)	**Band [a] (MHz)**	**Service [a]**	**Modulation [b]**	**Maximum 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	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, 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 while it does not represent actual modulation, it would be worst case.