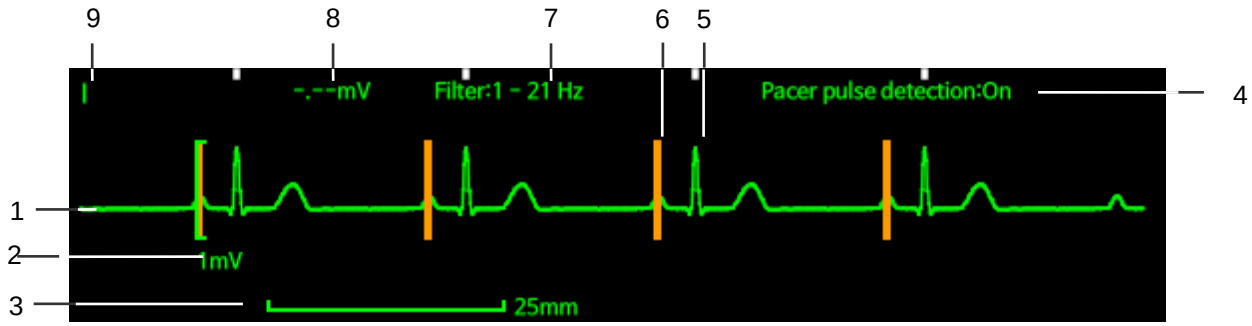
Description of ECG Waveform Menu Functions



1	ECG waveform	6	Pacer pulse marker
2	ECG size reference bar	7	Filter mode setting value
3	ECG 25mm/s size bar	8	ST level value
4	ECG pacer pulse detection	9	ECG waveform title
5	ECG filter		

Figure 26. ECG waveform display

Table 27. ECG waveform menu

Level 1 Menu	Level 2 Menu or Response
ECG WAVEFORM MENU	
Grid	On, Off
Sweep speed	12.5 mm/s, 25.0 mm/s, 50.0 mm/s
Size	Auto, 5.0 mm/mV, 10.0 mm/mV, 15.0 mm/mV, 20.0 mm/mV
Pacer pulse detection	On, Off
ST level measurement position	60 ms, 62 ms, 64 ms, 66 ms, 68 ms, 70 ms, 72 ms, 74 ms, 76 ms, 78 ms, 80 ms
Filter mode	0.05 - 150 Hz, 0.05 - 40 Hz, 0.5 - 40 Hz, 0.5 - 30 Hz, 1 - 21 Hz

Grid
User can turn the grid on or off that is behind the ECG waveform area.

Sweep Speed
The user-selectable sweep speed determines the speed at which the ECG waveform trace moves across the screen. **Sweep Speed** can be selected from 12.5 mm/s, 25.0 mm/s and 50.0 mm/s.

Size
The user-selectable ECG waveform size allows user to adjust the amplitude of an ECG waveform. The size can be selected from Auto, 5.0 mm/mV, 10.0 mm/mV, 15.0 mm/mV, 20.0 mm/mV. When the size is set to Auto, The monitor automatically determines the optimal size of the ECG waveform to fit the space.

Pacer Pulse Detection
Pacer Pulse Detection should always be ***On*** for patients with pacemakers (refer to the warning in this section). User can toggle Pacer pulse detection mode via ***Patient Information menu*** and **ECG menu** in ***Waveform menu*** of ***Configure menu***. When Pacer Pulse Detection is ***On***, the monitor detects and filters pacemaker-generated signals so that they will not be calculated in determining a patient's heart rate. When monitoring patients without pacemakers, Pacer pulse detection should be set to ***Off*** to avoid misdiagnosis.

Note: When pacer pulse detection is on, Pacer pulse is not included in QRS calculation

ST Level Measurement Position
ST level is measured by calculating average the range of 60 ~ 80msec after J point. ST measurement point can be changed by QTc value according to heart rate.

Filter Mode
The defibrillator/monitor can filter ECG waveform noise with different ranges of frequency response.

- 0.05 Hz to 150 Hz: Choose this mode in the just low noise environment, assumes a motionless for diagnostic information.
- 0.05 Hz to 40 Hz: Expands the range to display very low frequencies down to 0.05 Hz.
- 0.5 Hz to 40 Hz: Choose this mode to see just the ECG waveform monitoring.
- 0.5 Hz to 30 Hz: Generally called a filter mode, it reduces ECG waveform noise.
- 1 Hz to 21 Hz: Generally called a filter mode, it reduces ECG waveform noise.

Note: The clause 201.12.4.107.1 Frequency response of IEC60601-2-25 are tested only for 0.05 Hz to 150 Hz of ECG filter mode menu.

SpO_2 MONITORING

⚠ WARNING	For best product performance and measurement accuracy, use only accessories manufactured by Medtronic® or supplied by Mediana. Use accessories according to the manufacturer's directions for use and your facility's standards.
⚠ WARNING	Tissue damage can be caused by incorrect application or use of an SpO_2 sensor. Harm can be caused, for example, by wrapping the sensor too tightly, by applying supplemental tape, or by leaving a sensor on too long in one place. Inspect the sensor site as directed in the sensor directions for use to ensure skin integrity, correct positioning, and adhesion of the sensor.
⚠ WARNING	Do not use damaged SpO_2 sensors. Do not use an SpO_2 sensor with exposed optical components. Do not immerse sensor completely in water, solvents, or cleaning solutions because the sensor and connectors are not waterproof. Do not sterilize SpO_2 sensors by irradiation, steam or ethylene oxide. Refer to the cleaning instructions in the directions for use for reusable SpO_2 sensors.
⚠ WARNING	Inaccurate measurements may be caused by: ● incorrect sensor application or use ● significant levels of dysfunctional hemoglobin (such as carboxyhemoglobin or methemoglobin) ● intravascular dyes such as indocyanine green or methylene blue ● exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight ● excessive patient movement ● high-frequency electrosurgical interference and defibrillators ● venous pulsations ● placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line ● patient conditions such as hypotension, severe vasoconstriction, severe anemia, hypothermia, cardiac arrest, or shock ● arterial occlusion proximal to the sensor ● environmental conditions ● unspecified length of the extension cable
⚠ WARNING	Do not attach any cable to the sensor port connector that is intended for computer use.
⚠ WARNING	Do not pull the cable because pulling the cable could cause the disconnection of the cable from the defibrillator/monitor and can cause the error for the measurement.
⚠ WARNING	Do not use a damaged sensor or cable. Do not alter the sensor or cable in any way. Alternations or modification may affect performance and/or accuracy. Never use more than one cable between the pulse oximeter and the sensor to extend the length.
⚠ WARNING	Sensors exposed to ambient light when incorrectly applied to a patient may exhibit inaccurate saturation readings. Securely place the sensor on the patient and check the sensor's application frequently to help ensure accurate readings.
⚠ WARNING	Do not rely solely on SpO_2 reading: assess the patient at all times. SpO_2 readings may be inaccurate in the presence of significant levels of carboxyhemoglobin or methemoglobin, in patients with restricted blood flow to the extremities (such as those in severe shock or hypothermia),

	or in the presence of excessive motion.
⚠ WARNING	**Failure to apply the sensor properly may reduce the accuracy of the SpO_2 measurement.**
⚠ WARNING	**Inspection the sensor application site at least every two hours for changes in skin quality, correct optical alignment, and proper sensor application. If skin quality is compromised, change the sensor site. Change the application site at least every four hours. More frequent checking may be required due to individual patient's condition.**
⚠ WARNING	**Severe anemia, methemoglobin, intravascular dyes that change usual blood pigmentation, excessive patient movement, venous pulsations, electrosurgical interference, exposure to irradiation and placement of the sensor on an extremity that has a blood pressure cuff, intravascular line, or externally applied coloring(such as nail polish) may interfere with oximeter performance. The operator should be thoroughly familiar with the operation of the oximeter of the oximeter prior to use.**
⚠ WARNING	**The pulsations from intra-arotic ballon support can be additive to the pulse rate on the oximeter pulse rate display. Verify patient's pulse rate against the ECG heart rate.**
⚠ WARNING	**Prolonged, continuous use of a sensor may cause irritation, blistering, or pressure necrosis of the skin. Check the sensor site regularly based on patient condition and type of sensor. Change the sensor site if skin changes occur. Do not use tape to hold the sensor in place as this may cause inaccurate readings or damage to the sensor or skin.**
⚠ WARNING	**Carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.**
⚠ WARNING	**Carboxyhemoglobin and methemoglobin may erroneously increase SpO_2 readings. The amount that SpO_2 increases is approximately equal to the amount of carboxyhemoglobin or methemoglobin that is present.**
⚠ CAUTION	**The sensor disconnect error message and associated alarm indicate the sensor is either disconnected or the wiring is faulty. Check the sensor connection and, if necessary, replace the sensor, extension cable or both.**
⚠ CAUTION	**Reusable sensors may be used on the same site for a maximum of 4 hours, provided the site is inspected routinely to ensure skin integrity and correct positioning.**

Refer to the notice below if the Medtronic SpO_2 module is installed.

Note: Purchase of this instrument confers no express or implied license under any Medtronic patent to use the instrument with any sensor that is not manufactured or licensed by Medtronic.

Note: The user should check that the monitor is functioning while measurements are being made and check display periodically.

Note: Check the display motion before accepting any displayed data as a current measurement.

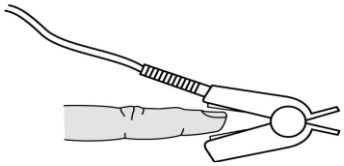
General

The defibrillator/monitor uses pulse oximetry to measure functional oxygen saturation in the blood. Because a measurement of SpO_2 is dependent upon light from the SpO_2 sensor, excessive ambient light can interfere with this measurement. SpO_2 and Pulse rate are updated every second. This defibrillator/monitor measures functional saturation - oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen. It does not detect significant amounts of dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin.

Setup Connections

When selecting a sensor, consider the patient's weight and activity, adequacy of perfusion, availability of sensor sites, need for sterility, and anticipated duration of monitoring. Refer to Table 32, or contact Medtronic® or Mediana sales department for ordering information.

1. Select the proper sensor for the patient.
2. Connect the extension cable to the SpO_2 connector on the defibrillator/monitor's front panel and lock it.
3. Connect the sensor to the extension cable and lock it.
4. Carefully apply the sensor to the patient, as described in the sensor directions for use. Observe all warnings and cautions in the directions for use.



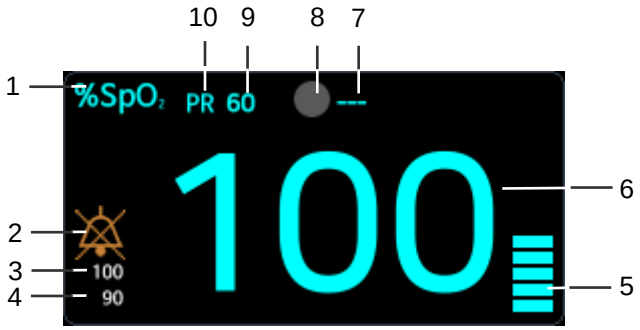
Note: Refer to directions for use to ensure the proper placement for various types of SpO2 sensors.

Note: Periodically check to see that the sensor remains properly positioned on the patient and that skin integrity is acceptable. Refer to the sensor directions for use.

Table 28. SpO_2 sensors

Module	Sensor	Model	Patient Size
For Mediana Module	*SpO_2 reusable sensor*	YM-1	
For Medtronic Module	*OXIMAX Durasensor ® Oxygen transducer (*Reusable, non-sterile*)*	DS-100A	>40 kg
	*OXIMAX oxygen transducer (*Single-use only, sterile*)*	MAX-N	<3 or >40 kg
		MAX-I	3 ~ 20 kg
		MAX-P	10 ~ 50 kg
		MAX-A	>30 kg

Description of SpO_2 Menu Functions



1	SpO_2 title	6	SpO_2 value
2	Alarm audio status	7	SatSeconds setting
3	Alarm limit upper	8	SatSeconds icon
4	Alarm limit lower	9	Pulse rate value
5	SpO_2 pulse amplitude	10	Pulse rate title

Figure 27. SpO_2 display

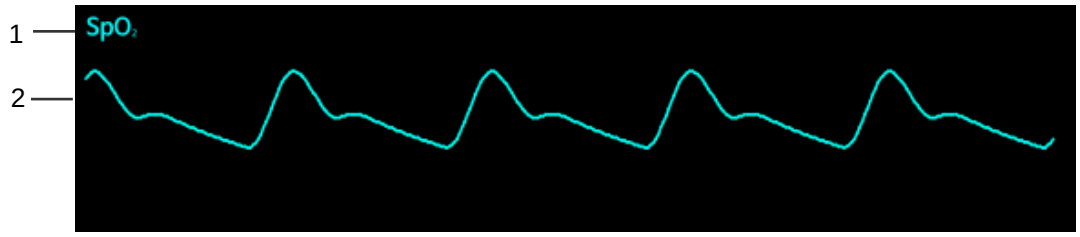
Table 29. SpO_2 menu

Level 1 Menu	Level 2 Menu or Response
SpO_2 MENU	
SatSeconds	Off, 10, 25, 50, 100
SpO_2 alarm limits	Upper/lower alarm limits
SpO_2 limits audio alarm	On, Off

SetSeconds
The alarm management is provided for minor or temporary SpO_2 limit violations. When the SatSeconds is enabled, the SatSeconds icon fills in the clockwise direction when the SatSeconds alarm management system detects a SpO_2 reading that is outside of the limit settings. The SatSeconds icon will be blanked counterclockwise when the SpO_2 reading is within limits. When all the SatSeconds icons are filled, a medium priority alarm will sound. User can set to Off, 10, 25, 50 and 100 SatSeconds through SpO_2 menu.

Limit alarm audio off
When the limit alarm audio off is set to **On**, the limit alarm for SpO_2 is went off.

Description of SpO_2 Waveform Menu Functions



1 SpO_2 title 2 SpO_2 Waveform

Figure 28. SpO_2 waveform display

Table 30. SpO_2 waveform menu

Level 1 Menu	Level 2 Menu or Response
SpO_2 WAVEFORM MENU	
Sweep speed	12.5 mm/s, 25.0 mm/s, 50 mm/s

Sweep Speed

The user-selectable Sweep Speed determines the speed at which the SpO_2 waveform trace moves across the screen. ***Sweep Speed*** can be selected from 12.5 mm/s, 25.0 mm/s and 50.0 mm/s, and the SpO_2 waveform is synchronized with the ECG waveform.

Theory of Operation

The defibrillator/monitor uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying a Medtronic™ pulse oximetry sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photodetector. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO_2). Ambient conditions, sensor application, and patient conditions can influence the ability of the pulse oximeter to accurately measure SpO_2. Pulse oximetry is based on two principles: oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (measured using spectrophotometry), and the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (registered using plethysmography). A defibrillator/monitor determines SpO_2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the sensor serve as light sources; a photo diode serves as the photo detector. Since oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. The defibrillator/monitor uses the pulsatile nature of arterial flow to identify the oxygen saturation of arterial hemoglobin. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The defibrillator/monitor bases its SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

Functional versus Fractional Saturation

This defibrillator/monitor measures functional saturation where oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen. It does not detect significant amounts of dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin. In contrast, hemoximeters such as the IL482 report fractional saturation where oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobin. To compare functional saturation measurements to those from an instrument that measures fractional saturation, fractional measurements must be converted using the listed equation.

$$\textbf{functional saturation} = \frac{\textbf{fractional saturation}}{\textbf{100 – (\%carboxyhemoglobin + \%methemoglobin)}} \times \textbf{100}$$

Measured versus Calculated Saturation

When calculating saturation from a blood gas partial pressure of oxygen (PO_2), the calculated value may differ from the SpO_2 measurement of a defibrillator/monitor. This usually occurs when saturation calculations exclude corrections for the effects of variables such as pH, temperature, the partial pressure of carbon dioxide (PCO_2), and 2,3-DPG, that shift the relationship between PO_2 and SpO_2.

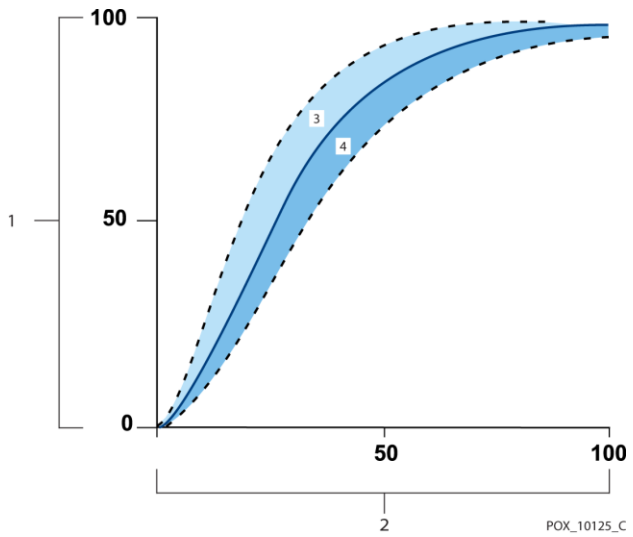


Figure 29. Oxyhemoglobin dissociation curve

1 % Saturation Axis
2 PO_2 (mmHg) Axis
3 Increased pH; Decreased temperature, PCO_2, and 2,3-DPG
4 Decreased pH; Increased temperature, PCO_2, and 2,3-DPG

Data Upload Period, Data Averaging and Signal Processing

The advanced signal processing of the Oximax™ algorithm automatically extends the amount of data required for measuring SpO_2 and pulse rate depending on the measurement conditions. The Oximax™ algorithm automatically ex tends the dynamic averaging time required beyond 7 seconds during degraded or difficult measurement conditions caused by low perfusion, signal artifact, ambient light, electrocautery other interference, or a combination of these factors, which results in a n increase in the dynamic averaging. If the resulting dynamic averaging time exceeds 20 seconds for SpO_2, the algorithm sets the pulse search bit while continuing to update SpO_2 and pulse rate values every seconds.

As such measurement conditions extend, the amount of data required may continue to inc rease. If the dynamic averaging time reaches 40 seconds and/or 50 seconds for pulse rat e, a low priority alarm state results: the algorithm sets the Pulse Timeout bit and the monit or reports a zero saturation indicating a loss of pulse condition, which should result in an a larm audio.

Clinical Studies

Clinical studied conducted for the Mediana Sensors

Overview

Pulse oximeters are routinely used clinically for functional arterial oxygen saturation (SpO_2), a physiologically important measure. The accuracy of the pulse oximeter is usually performed by a CO-oximeter comparison. Comparisons will be made of SpO_2 measurements using calculated values of deoxygenated hemoglobin concentrations from arterial blood using mediana modules and oxy- and CO-oximeters. Monitor safety will be closely monitored through clinical investigations.

Methods

Data from 10 healthy volunteers were included in the analysis for 2 days. The study participants are based in Severinghaus and have been approved by the IRB of the Medical University of Wisconsin and the Milwaukee VA Medical Center. Subjects signed a consent form and completed a case report form prior to the clinical investigation. Subjects with health problems, such as diabetes or asthma, smokers, or subjects who do not provide informed consent, cannot participate in the clinical investigation. The study subjects received oral or written consent, and the radial arterial catheter was inserted by the anesthesiologist. The sensors are located on the second, third, fourth, and fifth fingers. The monitor is connected to a computer data acquisition system through a device for serial multiplexing.

Study Population

Table 31. Demographic data

Type	Class	Total
Gender	Male	6 people
	Female	4 people
Race	Caucassian	6 people
	Hispanic	3 people
	African American	1 people
Age	-	19 ~ 48 years
Weight	-	105 ~ 225 lb

Study Results

Accuracy was calculated using the root mean square difference (RMSD).

Conclusion

When the pooled results indicate that for a saturation range of 70-100% for SpO_2, the acceptance criterion was met.

Clinical studied conducted for the Medtronic™ Sensors

Overview

This appendix contains data from clinical studies conducted for the Medtronic™ sensors used with the defibrillator/monitor.

One (1) prospective, controlled hypoxia clinical study was conducted to demonstrate the accuracy of Medtronic™ sensors when used in conjunction with the defibrillator/monitor. The study was performed with healthy volunteers at a single clinical laboratory. Accuracy was established by comparison to CO-oximetry.

Methods

Data from 11 healthy volunteers were included in the analysis. Sensors were rotated on digits and brow to provide a balanced study design. SpO_2 values were continuously recorded from each instrument while inspired oxygen was controlled to produce five steady state plateaus at target saturations of approximately 98, 90, 80, 70 and 60%. Six arterial samples were taken 20 seconds apart at each plateau resulting in a total of approximately 30 samples per subject. Each arterial sample was drawn over two (2) respiratory cycles (approximately 10 seconds) while SpO_2 data were simultaneously collected and marked for direct comparison to CO_2. Each arterial sample was analyzed by at least two of the three IL CO-oximeters and a mean SaO_2 was calculated for each sample. End tidal CO_2, respiratory rate, and respiratory pattern were continuously monitored throughout the study.

Study Population

Table 32. Demographic data

Type	Class	Total
Gender	Male	5 people
	Female	6 people
Race	Caucasian	8 people
	Hispanic	2 people
	African American	1 people
	Asian	0 people
Age	-	19 ~ 48 years
Weight	-	108 ~ 250 lb
Skin pigment	Very light	2 people
	Olive	5 people
	Dark olive/Medium black	3 people
	Extremely dark/Blue black	1 people

Study Results
Accuracy was calculated using the root mean square difference (RMSD).

Table 33. SpO_2 accuracy for Medtronic™ sensors

SpO_2 Decade	MAX-A		MAX-N		MAX-FAST	
	Data Points	Arms	Data Points	Arms	Data Points	Arms
60-70	71	3.05	71	2.89	71	2.22
70-80	55	55	55	2.32	55	1.28
80-90	48	1.84	48	1.73	48	1.48
90-100	117	1.23	117	1.68	117	0.98

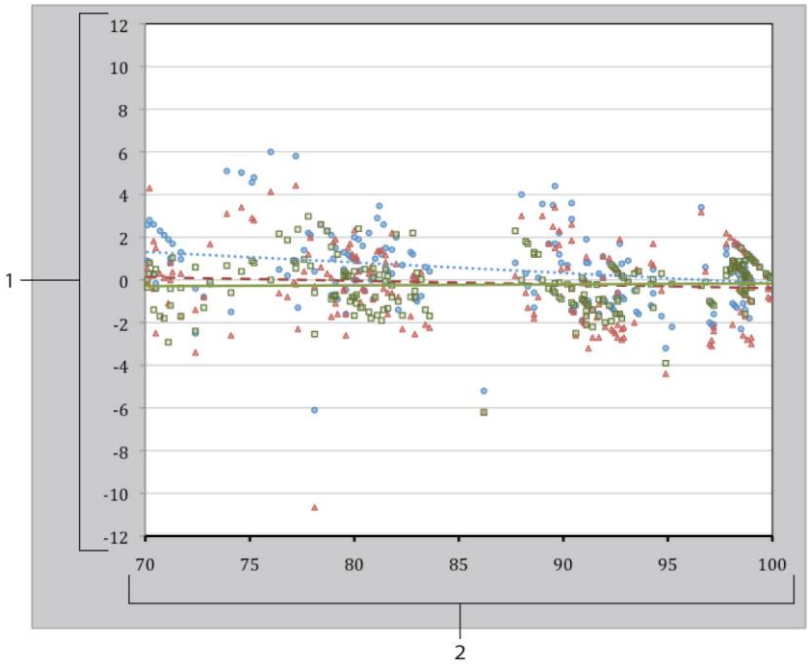


Figure 30. Modified bland-altman plot

1	Test Sensor: Avg CO-oximeter value 70-100% SpO_2	2	Avg CO-oximeter value 70-100% SpO_2
	Oximetry board with MAX-A sensor		Trendline of MAX-A sensor
	Oximetry board with MAX-N sensor		Trendline of MAX-N sensor
	Oximetry board with MAX-FAST sensor		Trendline of MAX-FAST sensor

Adverse Events or Deviations
The study was conducted as expected with no adverse events and no deviations from the protocol.

Conclusion
The pooled results indicate that for a saturation range of 60-80% for SpO_2, the acceptance criterion was met for the defibrillator/monitor when tested with MAX-A, MAX-N and MAX-FAST sensors. The pooled results indicate that for a saturation range of 70-100% for SpO_2, the acceptance criterion was met.

RESPIRATION MONITORING

⚠ WARNING	**For best product performance and measurement accuracy, use only accessories supplied or recommended by Mediana. Use accessories according to the manufacturer's directions for use and your facility's standards.**
⚠ WARNING	**The defibrillator/monitor does not detect apnea when the respiration signal is measured by trans-thoracic impedance.**
⚠ WARNING	**Keep patients under close surveillance when monitoring respiration. Respiration signals are relatively more sensitive to interference from radiated electromagnetic signals. Thus, it is possible, although unlikely, that radiated electromagnetic signals from sources external to the patient and defibrillator/monitor can cause inaccurate respiration readings. Do not rely entirely on the defibrillator/monitor respiration readings for patient assessment. If measured waveforms are not appropriate readings, check external conditions to ensure there is no equipment causing electromagnetic interference.**
⚠ CAUTION	**Impedance respiration technology is very sensitive to any of artifacts. If impedance respiration is doubtful due to artifacts, it is not recommended to assess the clinical state of patient only with impedance respiration parameter.**

General

The patient's respiration is detected by using two of the three leads of the ECG electrodes and cable. Real-time respiratory information is presented as a waveform and numeric data; Impedance respiration source (IM).

The airway respiration measurement uses gases coming into the airway adapter in case of the CO_2 equipped. The defibrillator/monitor detects respiration rate by computing each breath cycle form the continuous $EtCO_2$ waveform; Airway respiration source (AW).

The respiration monitoring is designed to use the variation of this thoracic impedance. The chest contains various materials, ranging from bone to air. Each of these materials has different electrical properties and is located in a different portion of the chest. The materials of the chest vary in electrical resistivity (the amount of electrical resistance between opposite faces of a cube of that material), which is an important determinant of electrical impedance in the body.

Setup Connections

Refer to the ***ECG Monitoring*** section for how to acquire the respiration signal by patient impedance using the ECG electrodes, leads and cable.

The performance of impedance respiration can be improved by the particular placement of the Left arm (LA) and Right arm (RA) electrodes. (See Standard ECG electrode placement in Figure 23.)

Description of Respiration Menu Functions

1	Respiration title	4	Alarm limit lower
2	Alarm audio status	5	Respiration rate value
3	Alarm limit upper	6	Respiration unit

Figure 31. Respiration display

Note: If the RESP measurement setting is OFF, the indication related to RESP is not displayed.

Note: If the alarm limit display setting is set to ON, the alarm limit is displayed next to the measured value.

Note: Even if the alarm limit display setting is set to on, the alarm limit may not be displayed depending on some specifications.

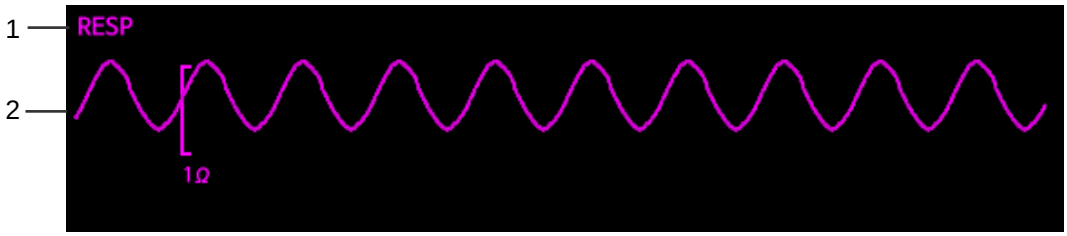
Table 34. Respiration menu

Level 1 Menu	Level 2 Menu or Response
RESPIRATION MENU	
Apnea time	10 sec, 15 sec, 20 sec, 25 sec, 30 sec, 35 sec, 40 sec
Respiration alarm limits	Upper/lower alarm limits
Respiration limits audio alarm	On, Off

Apnea time
When the defibrillator/monitor does not detect a respiration signal from the impedance measurement for Apnea time, the defibrillator/monitor will activate a loss of respiration alarm.

Limit alarm audio off
When the limit alarm audio off is set to **On**, the limit alarm for Respiration is went off.

Description of Respiration Waveform Menu Functions



1 Respiration waveform title 2 Respiration waveform

Figure 32. Respiration waveform display

Table 35. Respiration waveform menu

Level 1 Menu	Level 2 Menu or Response
RESPIRATION WAVEFROM MENU	
Sweep speed	6.25 mm/s, 12.5 mm/s, 25.0 mm/s
Size	Auto, 5.0 mm/Ω, 10.0 mm/Ω, 15.0 mm/Ω, 20.0 mm/Ω

Sweep Speed

The user-selectable sweep speed determines the speed at which the respiration waveform trace moves across the screen. ***Sweep Speed*** can be selected from 6.25 mm/s, 12.5 mm/s, and 25.0 mm/s.

Size

Size allows user to adjust the waveform size. When the size is set to Auto, 5.0 mm/Ω, 10.0 mm/Ω, 15.0 mm/Ω or 20.0 mm/Ω. The monitor automatically determines the optimal size of the respiration waveform to fit the space.

Theory of Operation

The respiration monitoring is designed to use the variation of this thoracic impedance. The chest contains various materials, ranging from bone to air. Each of these materials has different electrical properties and is located in a different portion of the chest. The materials of the chest vary in electrical resistivity (the amount of electrical resistance between opposite faces of a cube of that material), which is an important determinant of electrical impedance in the body.

Two of the major components of the chest, blood and air, are at opposite ends of the scale. Furthermore, the volume of each of these materials varies with time over the cardiac and breathing cycles. The variation of the thoracic impedance is caused by the difference between air and blood in the thoracic impedance. Blood has relatively low resistivity, which varies over the cardiac cycle owing to changing blood volumes in the heart and in the vascular compartment. Air, on the other hand, has high electrical resistivity and hence impedance, and it undergoes wide volume changes in the lungs during normal breathing. i.e. the impedance of blood is 150 ohm/cm and the one of air is 5=000 ohm/cm.

The patient's respiration is detected by using two of the three leads of the ECG electrodes (RA and LA, or RA and LL) and cable. The electrical impedance between a pair of electrodes is determined by dividing the voltage difference between the two electrodes by the current that passes between them. When the electrodes are placed on the actual structure, respective structures change.

A low-level excitation signal is applied to these leads, and the variation of the thoracic impedance caused by the breathing is sensed and processed for display and measurement. This variation is processed to the voltage value for the measurement.
In order to transfer the thoracic impedance by a transformer, it is used a minimum constant current of the sine wave carrier signal. The transferred thoracic impedance is changed to the voltage signal by using bridge circuit and differential amplifier. Then, ECG signal is removed by filter, and carrier frequency is removed by full wave rectifier and filter in order to extract only thoracic impedance in amplifying at the definite level of signal. This extracted thoracic impedance signal is used to measure the respiration by digital signal processing.

SELF-TEST FUNCTION

General

This defibrillator/monitor incorporates a Self-test function. The defibrillator/monitor should be checked at regular intervals so that it will always be ready-to-use for emergency situations. There are three modes: Manual Self-test, Auto Self-test and Button test. Additionally, the external shock test should be performed prior to use.

10

Manual Self-test

Manual self-test covers the following items:

- Therapy module alive test
- Impedance test
- ECG circuit test
- Internal shock test
- Internal pacing output test
- Installed module alive test
- Real-time clock test
- Battery test

If any of above items fails, the service indicator will be illuminated. If mainboard, Defib/Pacer function, or monitor function fails, a low level technical alarm **'Last user test failed**' will be displayed in the Physiologocal/Technical Alarm Message Area. We recommend you to perform a successful User Test to clear this alarm.

Auto Self-test

When the defibrillator/monitor has been turned off, Auto Self-test (or scheduled Self-test) is operated automatically according to the user's setting. The Self-test interval can be selected as Off, 24, 48, and 72 hours. If the residual of battery power is less than 60% without using the AC or DC, the Self-test will not be performed.
If the defibrillator/monitor is in use at the time of a scheduled Auto Self-test, the Auto Self-test will be canceled. If the defibrillator/monitor is turned on when the Auto Self-test is in process, the Auto Self-test will be canceled and the defibrillator/monitor will be operated normally.

Note: The setting of the Auto self-test (time and interval) can only be changed by authorized personnel via the Service Setting Menu.

Button test

Button Test covers the following items. Refer to the Service manual for detail.

- Operating mode selection knob
- All hardware buttons on the front panel of Defibrillator/monitor

LCD test

LCD test can be used to verify that the LCD is working properly. Refer to the Service manual for detail.

Sound test

Sound test can be used to verify that the sound is working properly. Refer to the Service manual for detail.

External Shock Test 10

The user must verify the ability to deliver defibrillation energy once a week.

1. Make sure the paddles and the paddle tray are thoroughly clean and there is no residue including the conductive material on electrode surfaces of the paddle and paddle tray.
2. Place the paddles on the paddle tray. (see Figure 2)
3. Turn on the defibrillator/monitor.
4. Select the defibrillation energy by pressing the ***Energy level button*** on paddle.
5. Charge the selected energy to pressing the ***Charge button*** on paddle.
6. When completing the charge, the charge indicator of the paddle turns on in red. Before 7 steps, check the charge indicator.
7. Press the ***Shock button*** on paddle.
8. Confirm the energy level on the display.

Trouble Shooting

After finish the auto self-test, the defibrillator/monitor will be turned off itself again. If there was no fail, the service LED will be blinking. But if any fail was detected, service LED and buzzer sound will be generated. (when the defibrillator/monitor is using the AC or DC power, the result of auto self-test will be displayed). But when the residual of battery power has dropped less than 60 %, those LED and buzzer will be turned off for saving the power.

EVENT REPORT

General

The event data is stored in memory. The defibrillator/monitor saves data of elapsed time before and after 10 seconds from the point of event generation. The events are saved including Defibrillation, Pacer mode, Heart rate alarm, VF alarm or Mark event. The data remains even if the defibrillator/monitor is powered off. When the saved data is more than 250 data, the defibrillator/monitor will delete the oldest data and save the new data.

Note: When storage space is exceeded, the defibrillator/monitor will delete the oldest data sequentially.

Figure 33. Event report

1. Press the ***Configure Soft key.***
2. Rotate the ***Multi function knob*** to ***Review menu*** and press the ***Multi function knob*** to display.
3. Rotate the ***Multi function knob*** to ***Event report menu*** and press the ***Multi function knob*** to display.

Scroll
User can scroll the event data by using the scroll button.

Review
User can review the event data by using the review button.

Figure 34. Event review

Print
User can print the event data by using the print button.

Report
User can be back into the event report screen by using the report button.

Scroll
User can scroll the event data by using the scroll button.

TRENDS

General

The Trend data is stored in memory. When the defibrillator/monitor turns on and starts to measure the vital signs, the defibrillator/monitor saves the data at 1 minute intervals. The data remains even if the defibrillator/monitor is powered off. When the trend data are saved more than 5,000 data, the defibrillator/monitor will delete the oldest data and save the new data.

⚠ CAUTION	**Please erase the trend data for the patient information before applying for the equipment to other patient for prevention of the mixing of personal data.**

Note: When storage space is exceeded, the defibrillator/monitor will delete the oldest data sequentially.

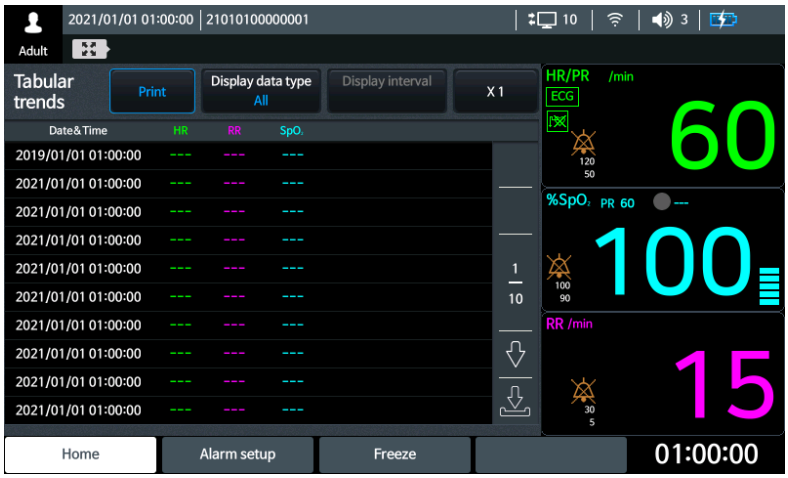


Figure 35. Trend – Tabular trend

1. Press the ***Configure Soft key.***
2. Rotate the ***Multi function knob*** and select the ***Review menu***.
3. Rotate the ***Multi function knob*** and select the ***Trend menu***.

Print
User can print the tabular trend data by using the print button.

Display data type
User can select the display data type.
- All: All trend data.
- by interval: Data saved automatically according to the set storage interval.
- by alarm occurrence: Data saving when the alarm occurs.

Display Interval
User can select the display interval of the trend displayed on the monitor of 1, 2, 5, 10, 30 or 60 min. The display interval button can be used only when the display data type is selected in 'by interval'.

Scroll speed
User can select the scroll speed of x1, x10 or x100.

Scroll
User can scroll the trend data by using the scroll button.

DATA MANAGEMENT

General

The data is stored in memory. The defibrillator / monitor will automatically generate and save an Event summary for the patient event. Event summary can be stored up to 40 hours of cumulative storage, and when the maximum storage time has elapsed, the defibrillator / monitor will clear the oldest data and save the new data.

⚠ CAUTION	**Please erase the patient information before disposal of equipment for prevention of the personal data leakage.**

Note: When storage space is exceeded, the defibrillator/monitor will delete the oldest data sequentially.

Event summary

Event summary can save up to 8 hours for each event. After 8 hours, it stops recording, creates and saves a new event summary.

Note: The number of event summaries that can be stored depends on the duration of each individual event summary. For example, the defibrillator/monitor may store about 50 event summaries with a duration of 30 minutes and about 5 event summaries with a duration of 8 hours.

Collected Event summary data

Collected Event summary data are as follows.

- 1 ECG waveform
- Add the Patient event information:
  - Patient ID, Type, Name, Gender, Birth Date
  - Parameter information/Trend Data
  - Physiological alarm and alarm limits
  - Shock and Pacing event
  - Shock decision
  - Mark event
- Add the technical/Device event information:
  - Power On/Off
  - Technical alarm
  - Initial mode and mode change
  - Initial battery status and change

Data Management Mode

Data Management Mode is non-clinical mode used to manage the event data record. The event summary can be reviewed or downloaded by printing and SD card.

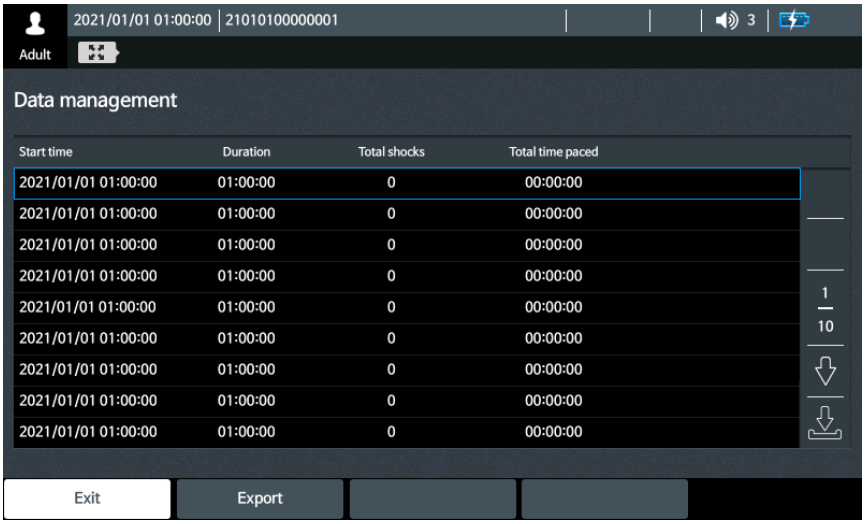


Figure 36. Data management

1. Press the ***Configure Soft key.***
2. Rotate the ***Multi function knob*** and select the ***Review menu***.
3. Rotate the ***Multi function knob*** and select the ***Data management menu***.
4. Select ***YES*** on the message screen stopping the monitor mode.

Exit
User can exit to the Data management screen by using the Exit button.

Export
User can move to the Export menu screen by using the Export button.

Scroll
User can scroll the event summary by using the scroll button.

Export Event summary window

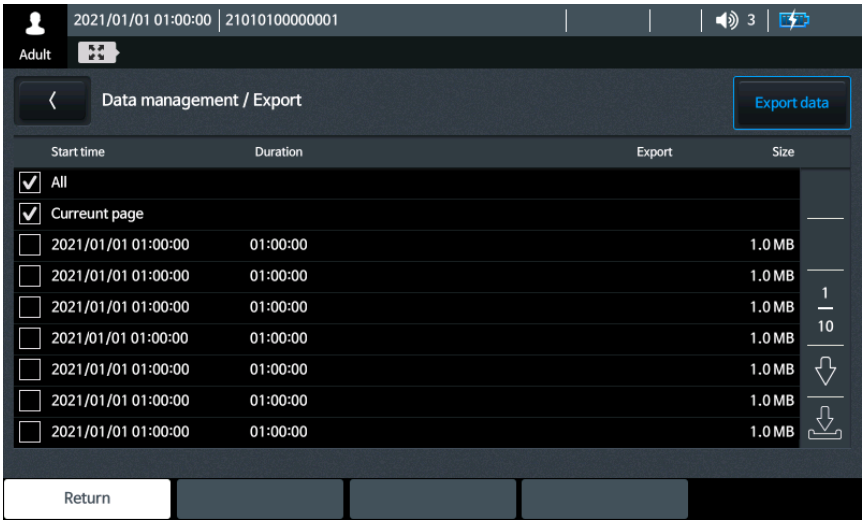


Figure 37. Data management – Export

Export data
User can download Event summary report to SD card by using the Export button. When there are the records using the voice recording, download the event summary report including voice recording file.

Return
User can return the Data management display by using the return button.

Scroll
User can scroll or select the event summary by using the scroll button.

Event summary review window

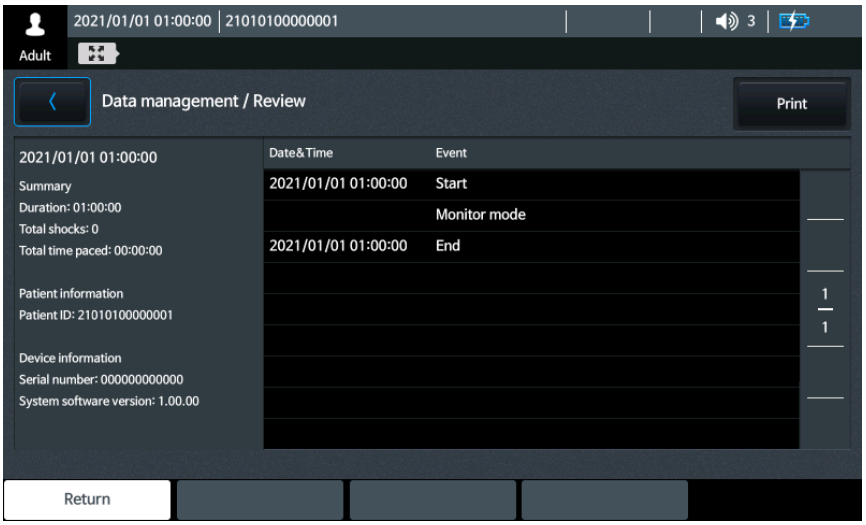


Figure 38. Data management – Review

Return
User can return the Data management display by using the return button.

Print
User can print the event summary review data by using the print button.

Scroll
User can scroll or select the list table by using the scroll button.

PRINTING

General

The defibrillator/monitor can print the real-time measurement data, trend data, event data, event summary and system setting.

- Set up Print on shock delivery, Print on shock decision, Print on pacing output, Print on alarm, Print on mark event, Print on self-test or Printing waveform by using printing menu on setting menu.
- Start printing by pressing PRINT button.

Note: The defibrillator/monitor only supports English version regardless setting languages.

Note: In critically low battery or low battery status, the defibrillator/monitor has invalid tone and the message is displayed.

Note: User can set Printing Date and Time in "YYYY/MM/DD", "MM/DD/YYYY" or "DD/MM/YYYY" on Service Menu.

Table 36. Printer Menu

Level 1 Menu	Level 2 Menu or Response
Print Menu	
Print on shock delivery	On, Off
Print on shock decision	On, Off
Print on pacing output	On, Off
Print on alarm	On, Off
Print on mark event	On, Off
Print on self-test	On, Off
Printing waveform	Printing speed, Printing time

Print on shock delivery
When Print on shock delivery is On, automatically print whenever shock delivery event occurs.

Print on shock decision
When Print on shock decision is On, automatically print whenever shock decision event occurs.

Print on pacing output
When Print on pacing output is On, automatically print whenever pacing output starts.

Print on alarm
When Print on alarm is On, automatically print whenever alarm status occurs.

Print on mark event
When Print on mark event is On, automatically print whenever the event by pressing mark event button is marked.

Print on self-test
When Print on self-test is On, automatically print whenever self-test is completed.

Printing waveform

The Printing waveform can be changed on Printing waveform menu. Printing speed, Printing time and Waveform can be set.

Table 37. Printing waveform menu

Level 1 Menu	Level 2 Menu or Response
Printing waveform menu	
Printing speed	25 mm/s, 50 mm/s
Printing time	10 sec, 20 sec, Continuous

Note: Printing detail parameter is active only when Printing diagnosis/detection result is On.

Type of Print-Out

Measurement data printing

User can print the data by pressing PRINT button on Home screen.

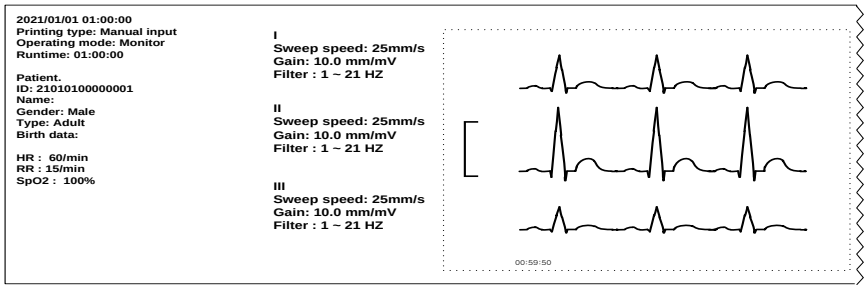


Figure 39. Measurement data printing

Trend data printing

User can print Trend data by pressing PRINT button on Tabular trend screen.

Date & Time	HR	RR	SpO2
2021/01/01 01:00:00	60	15	100
2021/01/01 01:00:00	60	15	100
2021/01/01 01:00:00	60	15	100
2021/01/01 01:00:00	60	15	100
2021/01/01 01:00:00	60	15	100
2021/01/01 01:00:00	60	15	100
2021/01/01 01:00:00	60	15	100
2021/01/01 01:00:00	60	15	100
2021/01/01 01:00:00	60	15	100
2021/01/01 01:00:00	60	15	100

Figure 40. Trend data printing

Event data printing

User can print Event data by pressing PRINT button on review screen of event report.

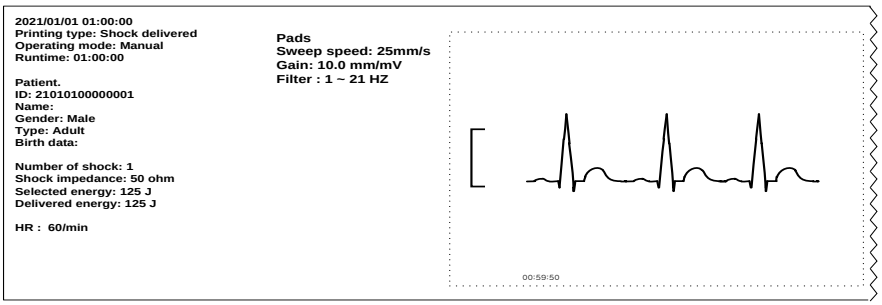
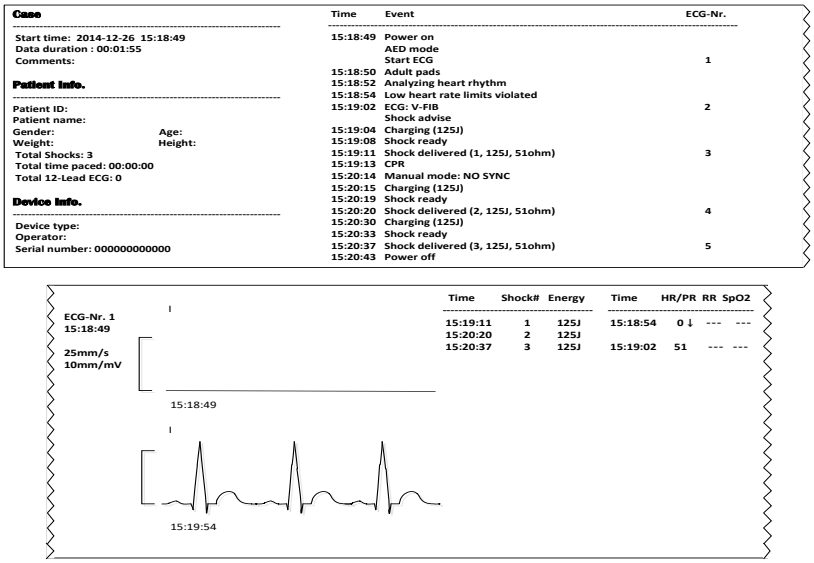


Figure 41. Event data printing

Event summary review data printing

User can print the Event summary review data by pressing PRINT button on event summary review screen of Data management.



Case

Start time: 2014-12-26 15:18:49
Data duration : 00:01:55
Comments:

Patient Info.

Patient ID:
Patient name:
Gender: Age:
Weight: Height:
Total Shocks: 3
Total time paced: 00:00:00
Total 12-Lead ECG: 0

Device Info.

Device type:
Operator:
Serial number: 000000000000

Time	Event	ECG-Nr.
15:18:49	Power on	
	AED mode	
	Start ECG	1
15:18:50	Adult pads	
15:18:52	Analyzing heart rhythm	
15:18:54	Low heart rate limits violated	
15:19:02	ECG: V-FIB	2
	Shock advise	
15:19:04	Charging (125J)	
15:19:08	Shock ready	
15:19:11	Shock delivered (1, 125J, 51ohm)	3
15:19:13	CPR	
15:20:14	Manual mode: NO SYNC	
15:20:15	Charging (125J)	
15:20:19	Shock ready	
15:20:20	Shock delivered (2, 125J, 51ohm)	4
15:20:30	Charging (125J)	
15:20:33	Shock ready	
15:20:37	Shock delivered (3, 125J, 51ohm)	5
15:20:43	Power off	

ECG-Nr. 1
15:18:49

25mm/s
10mm/mV

15:18:49

15:19:54

Time	Shock#	Energy
15:19:11	1	125J
15:20:20	2	125J
15:20:37	3	125J

Time	HR/PR	RR	SpO2
15:18:54	0 ↓	---	---
15:19:02	51	---	---

Figure 42. Event summary review data printing

Setting value printing

User can print System setting of the defibrillator/monitor by pressing PRINT button on System setting screen of **Service Menu**. For details, refer to the service manual

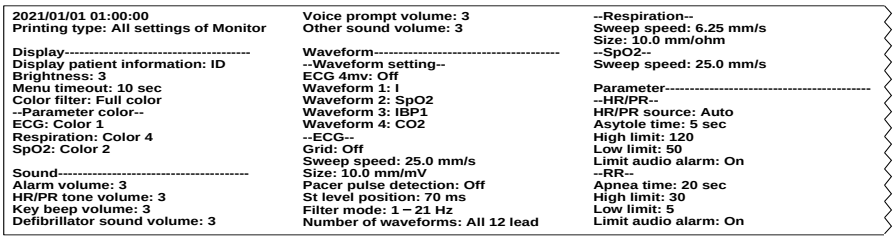


Figure 43. Setting value printing

Self-test result printing

User can print Self-test result on Self-test screen in Setting menu after Self-test.

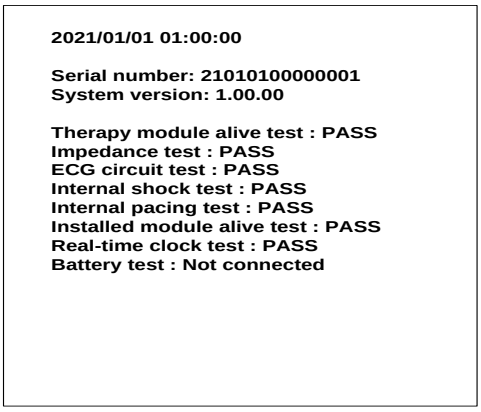


Figure 44. Self-test result printing

Replace printer paper

⚠ CAUTION	**Use only printer paper supplied by Mediana. Using other printer paper may cause the printer to perform improperly and be damaged.**

Replace printer paper as follows.

1. Open the printer door.
2. Remove the printer paper.
3. Insert the new printer paper with the striped side up.
4. Close the printer door by pushing it.

Note: Check the printer paper is properly positioned and is not jammed in the door.

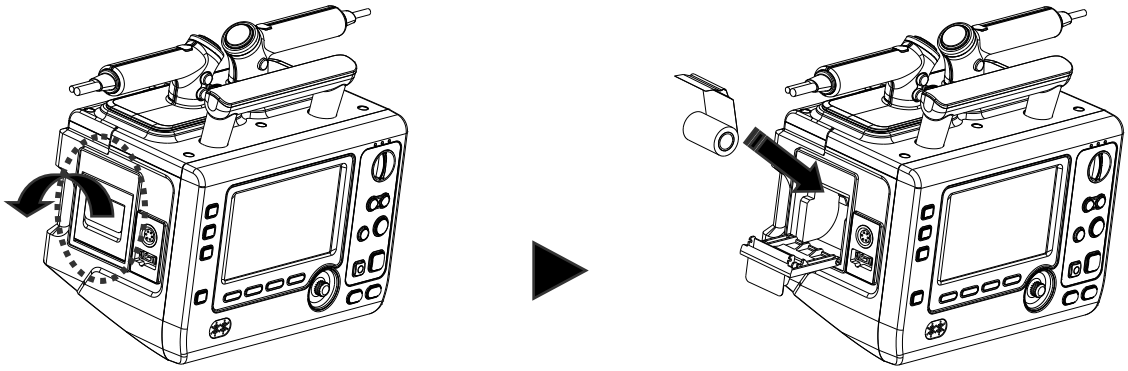


Figure 45. Replace print paper

EXTERNAL COMMUNICATIONS

General

The defibrillator/monitor provides external connectors on the right panel to support communication with external equipment and functions such as software upgrade or data download. The defibrillator/monitor with its optional wireless module, functionality performs the same as a defibrillator/monitor connected to the central system. The defibrillator/monitor with a wireless network can send and receive patient data through the central system.

⚠ **WARNING**	**Any connections between this defibrillator/monitor and other devices must comply with applicable medical systems safety standards such as IEC 60601-1. Failure to do so could result in unsafe leakage current and grounding conditions.**
⚠ **WARNING**	**Inserting or removing the data card while the defibrillator/monitor is on or reading and writing on the data card can corrupt the Data Card and prevent the defibrillator/monitor from powering on again. If this occurs, see Troubleshooting Tips.**
⚠ **WARNING**	**Use only a Mediana defibrillator/monitor-compatible SD Card. These cards, or other types of cards (such as memory cards) will not work, and may cause the defibrillator/monitor to malfunction.**
⚠ **WARNING**	**Do not turn off the Mediana defibrillator/monitor by using Mode selection knob or disconnecting the power cord or battery. The data stored will be damaged.**

Note: The defibrillator/monitor is to be used on a wireless network are limited to inside of the building.

SD Memory Card

The SD Memory Card is used to the new system software and to load voice prompt data and to download the trend data. Trend data downloaded on SD card can be viewed on PC.

Wireless Connection

The defibrillator/monitor can connect to a network using a wireless network. The wireless connection can only be set by authorized personnel via the ***Service Setting Menu***.

Central System Communication

The transmitted data by using the wireless module is divided as follows;

- All vital signs are transmitted to the medical person in the hospital.
- The self-test result and the log file are transmitted to the biomedical engineer in the hospital.

The defibrillator condition, service action according to the self-test and the history of the key pressing are transmitted by the wireless network. All vital sign can be transmitted in real-time.

Note: The details are provided in the central system manual. Please contact the representative of Mediana for more information.

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MENU STRUCTURE

- Configure
  - Display
    - Display patient information
      - ID
      - Name
      - None
    - Brightness
      - 1
      - 5
    - Menu timeout
      - Off
      - 10 sec
      - 20 sec
      - 30 sec
    - Color filter
      - Full color
      - Grayscale
    - Parameter color
      - ECG
        - Color 1
        - Color 17
      - Respiration
        - Color 1
        - Color 17
      - SpO_2
        - Color 1
        - Color 17
  - Sound
    - Alarm volume
      - 1
      - 5
    - HR/PR tone volume (Step: 1)
      - Off
      - 1
      - 5
    - Key beep volume (Step: 1)
      - Off
      - 1
      - 5
    - Defibrillator sound volume (Step: 1)
      - 1
      - 5
    - Voice prompt volume (Step: 1)
      - 1
      - 5
    - Other sound volume (Step: 1)
      - Off
      - 1
      - 5
  - Waveform
    - Waveform setting

- - - ECG 4mV
- - - - On
- - - - Off
- - - Waveform 1
- - - - Pads
- - - - I (ECG, 3, 5 lead wire)
- - - - II (ECG, 3, 5 lead wire)
- - - - III (ECG, 3, 5 lead wire)
- - - - aVR (ECG, 5 lead wire)
- - - - aVL (ECG, 5 lead wire)
- - - - aVF (ECG, 5 lead wire)
- - - - V (ECG, 5 lead wire)
- - - Waveform 2 ~ 3
- - - - Pads
- - - - I (ECG, 3, 5 lead wire)
- - - - II (ECG, 3, 5 lead wire)
- - - - III (ECG, 3, 5 lead wire)
- - - - aVR (ECG, 5 lead wire)
- - - - aVL (ECG, 5 lead wire)
- - - - aVF (ECG, 5 lead wire)
- - - - V (ECG, 5 lead wire)
- - - - RESP
- - - - SpO_2
- - ECG
- - - Grid
- - - - On
- - - - Off
- - - Sweep speed
- - - - 12.5 mm/mV
- - - - 25.0 mm/mV
- - - - 50.0 mm/mV
- - - Size
- - - - Audo
- - - - 5.0 mm/mV
- - - - 10.0 mm/mV
- - - - 15.0 mm/mV
- - - - 20.0 mm/mV
- - - - 30.0 mm/mV
- - - - 40.0 mm/mV
- - - Pacer pulse detection
- - - - On
- - - - Off
- - - ST level measurement position

60 ms
80 ms
- - - Filter mode
- - - - 0.05 - 150 Hz
- - - - 0.05 - 40 Hz
- - - - 0.5 - 40 Hz
- - - - 0.5 - 30 Hz
- - - - 1 - 21 Hz
- - Respiration
- - - Sweep speed
- - - - 6.25 mm/mV
- - - - 12.5 mm/mV
- - - - 25.0 mm/mV

- - - Size
- - - - Auto
- - - - 5.0 mm/Ω
- - - - 10.0 mm/Ω
- - - - 15.0 mm/Ω
- - - - 20.0 mm/Ω
- - SpO_2
- - - Sweep speed
- - - - 12.5 mm/mV
- - - - 25.0 mm/mV
- - - - 50.0 mm/mV
- Parameter
- - HR/PR
- - - HR/PR Source
- - - - Auto
- - - - HR
- - - - PR
- - - Asytole time (Step: 1 sec)

3 sec
10 sec
- - - HR/PR high
- - - - 25 ~ 300 BPM
- - - HR/PR low
- - - - 20 ~ 295 BPM
- - - HR/PR limit audio alarm
- - - - On
- - - - Off
- - Respiration
- - - Apnea time

10 sec
40 sec
- - - RR high
- - - - 4 ~ 150 /min
- - - RR low
- - - - 3 ~ 149 /min
- - - RR limit audio alarm
- - - - On
- - - - Off
- - SpO_2
- - - SatSeconds
- - - - Off
- - - - 10
- - - - 25
- - - - 50
- - - - 100
- - - SpO_2 high (Step: 1 /min)
- - - - 21 ~ 100 %
- - - SpO_2 low
- - - - 20 ~ 99 %
- - - SpO_2 limit audio alarm
- - - - On
- - - - Off
- Alarm Setup
- - Alarm limits
- - - HR/PR high
- - - - 25 ~ 300 BPM

- - - HR/PR low
- - - - 20 ~ 295 BPM
- - - HR/PR limit audio alarm
- - - - On
- - - - Off
- - - RR high (Step: 1 /min)
- - - - 4 ~ 150 /min
- - - RR low
- - - - 3 ~ 149 /min
- - - RR limit audio alarm
- - - - On
- - - - Off
- - - SpO_2 high (Step: 1 /min)
- - - - 21 ~ 100 %
- - - SpO_2 low
- - - - 20 ~ 99 %
- - - SpO_2 limit audio alarm
- - - - On
- - - - Off
- - Alarm limit display
- - - On
- - - Off
- - Audio alarm pause/off
- - - On
- - - Off
- Patient
- - Patient information
- - Discharge patient
- - Modify
- - New patient
- - - Patient ID
- - - Patient type
- - - - Adult
- - - - Pediatric
- - - - Neonatal
- - - Pacer pulse detection
- - - - On
- - - - Off
- - - Name
- - - - First name
- - - - Last name
- - - - Middle name
- - - Gender
- - - - None
- - - - Male
- - - - Female
- - - - Other
- - - Birth date
- - - - Year
- - - - Month
- - - - Date
- - - Cancel button
- - - Save button
- Printer
- - Print on shock delivery
- - - On

- - - Off
- - Print on shock decision
- - - On
- - - Off
- - Print on pacing output
- - - On
- - - Off
- - Print on alarm
- - - On
- - - Off
- - Print on mark event
- - - On
- - - Off
- - Print on self-test
- - - On
- - - Off
- - Printing waveform
- - - Printing speed
- - - - 25 mm/s
- - - - 50 mm/s
- - - Printing time
- - - - 10 sec
- - - - 20 sec
- - - - Continuous
- Review
- - Event report
- - Tabular trend
- - Data management
- - Clear event report
- - Clear trends
- - Clear data management
- Service setting
- - Password
- - Numeric keyboard
- - - OK button
- - - Cancel button
- Others
- - Date & Time
- - - Year
- - - - 2000 ~ 2037
- - - Month
- - - - 1 ~ 12
- - - Date
- - - - 1 ~ 28 / 1 ~ 29 / 1 ~ 30 / 1 ~ 31
- - - Hour
- - - - 0 ~ 23
- - - Minute
- - - - 0 ~ 59
- - - Set button
- - User test

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