OPERATOR'S MANUAL

Defibrillator/Monitor D100

EU representative
EC REP **OBELIS S.A**
Bd. Général Wahis, 53, 1030 Brussels, Belgium

Manufacturer
Mediana Co., Ltd.
132, Donghwagongdan-ro, Munmak-eup,
Wonju-si, Gangwon-do, Korea
Tel: (82) 2 542 3375 (82) 33 742 5400
Fax: (82) 2 542 7447 (82) 33 742 5483

D100 Operator's Manual
Part Number: A7741-2
Revised Date: 2022-10

CE 2797

Directive

- Copyright law allows no part of this instruction manual to be reproduced without permission.
- The content of this manual are subject to change without notice.
- The contents of this manual should be correct. If for some reason, there are any questionable points, please do not hesitate to contact our service center.
- The manual will be replaced if any pages are missing or collation is incorrect.

Warranty

- Please contact your local distributor about the warranty period.
- Device failure or damage related to the following situations during the guarantee period is not covered by this warranty:
    - Installation, transfer installation, maintenance and repairs by any person other than an authorized employee or technician by Mediana.
    - Damage sustained to the Mediana product(s) caused by product(s) from another company excluding products delivered by Mediana.
    - Damage – caused by mishandling and/or misuse – is the responsibility of the user.
    - Maintenance and repairs utilizing maintenance components that are not specified by Mediana.
    - Device modifications or use of accessories not recommended by Mediana.
    - Damage caused by accidents or natural disasters (earthquakes, flooding, etc.).
    - Damage resulting from usage where caution statements and operating instructions shown in this manual have not been followed.
    - Damage due to neglect of specified maintenance checks.
- This warranty only covers the hardware of the D100. The warranty does not cover the following selections:
    - Whatever damage or loss results from the attachment of accessories or their operation.
    - In the event of a defect in the product, contact our sales outlet or EU representative as noted on the back cover.
- The D100 conforms to the EMC standard IEC60601-1-2.

Note that mobile phones should not be used in the vicinity of the D100.
Note, however, any device not complying to the EMC standard that is used with the D100 renders the D100 as non-compliable to the EMC standard.

Trademark

Product brand names shown in this manual are likely to be the trademark or registered trademark of the company concerned.

CONTENTS

Figures

Tables

SAFETY INFORMATION

General Safety Information

This section contains important safety information related to general use of the D100 defibrillator/monitor. Other important safety information appears throughout the manual. The D100 defibrillator/monitor will be referred to as the defibrillator/monitor throughout this manual.

Important! Before use, read carefully the manual, accessory directions for use, all precautionary information and specifications.

Warning

Warnings alert you to potential serious outcomes (death, injury, or adverse events) to the patient or user.

⚠ **WARNING**	**When using the defibrillator/monitor with anesthetics, nitrous oxide or high concentrations of oxygen, connect the gas outlet to a scavenger system.**
⚠ **WARNING**	**When using the defibrillator/monitor with a commercial electric power source, use the defibrillator/monitor with an electric power wall socket with a grounding wire for medical use. Not doing so could cause electric shock.**
⚠ **WARNING**	**Do not connect grounding wire to gas pipes. This could cause fire.**
⚠ **WARNING**	**Only doctors and officially certified personnel should use this defibrillator/monitor. Do not allow patients to touch the defibrillator/monitor. Allowing patients to touch the defibrillator/monitor could cause accidents.**
⚠ **WARNING**	**The defibrillator/monitor cannot be used when MRI is in progress. If MRI is in use, keep patient attachments away from patients to prevent accidents.**
⚠ **WARNING**	**The defibrillator/monitor conforms to the requirements of the EMC standard (IEC60601-1-2), and may therefore be used simultaneously with pacemakers and other electrical simulators. It should, however, be noted that the defibrillator/monitor may be affected by electrical scalpels and microwave therapeutic apparatus. Please check operation of the defibrillator/monitor during and after use of such equipment.**
⚠ **WARNING**	**Do not take mobile phones or transceivers into a room where this defibrillator/monitor is installed, as such devices may cause accidents.**
⚠ **WARNING**	**In order to avoid accidents, do not use any unauthorized accessories or options.**
⚠ **WARNING**	**Thoroughly read the instruction manuals supplied with accessories and options to ensure correct use. This instruction manual does not carry the caution selections for such equipment.**
⚠ **WARNING**	**Do not open cover or disassemble this defibrillator/monitor. Doing so could cause electric shock or fire. It is prohibited by law to modify the defibrillator/monitor without authorization.**
⚠ **WARNING**	**Do not use power source other than the specified voltage, (100-240V~50/60Hz) as this may cause fire or electric shock.**

⚠ WARNING	Pre-use inspection and preventive maintenance must be performed for safe use.
⚠ WARNING	The defibrillator/monitor may be used with electrical surgical equipment. Follow the instruction manuals for medical instruments – notably electrosurgical and diathermy instruments – when used, as their high–frequency energy units may cause burns to patients via attachments.
⚠ WARNING	This defibrillator/monitor is protected against the discharge of a defibrillator. However, do not touch the defibrillator/monitor when a defibrillator is being discharged (electrified), as doing so may cause electric shock.
⚠ WARNING	The following cautions apply when connecting the defibrillator/monitor with other equipment. 1. Ensure that the connected equipment is in accordance with the IEC60601-1 or IEC safety standards, so that the system complies with IEC60601-1. 2. Employ additional protective measures (e.g. additional protective earthing) as necessary.
⚠ WARNING	Do not connect devices that do not meet medical safety standards (such as commercial PCs), as they may cause electric shock. This defibrillator/monitor meets the restricted level of leakage current required for medical devices. Therefore, this defibrillator/monitor cannot be connected to a device that would give a combined total of leakage current beyond the restricted level.
⚠ WARNING	Avoid connecting the patient to several devices at once. Leakage current limits may be exceeded. Do not use a second defibrillator on the patient while pacing with the defibrillator/monitor.
⚠ WARNING	Do not place anything on top of this defibrillator/monitor. If something is spilled over the defibrillator/monitor or gets into it, such spillage may cause fire or electric shock. If fluid spills on the defibrillator/monitor accidentally, disconnect power cord, wipe dry immediately, and have the defibrillator/monitor serviced to make sure that no hazard exists.
⚠ WARNING	Do not place heavy objects on the power cord, as doing so may cause fire or electric shock.
⚠ WARNING	Before conducting maintenance work, turn the power off and unplug the power cord from the wall socket to prevent electric shock.
⚠ WARNING	When the following occur, turn the power off immediately and unplug the power cord from the wall socket. Continued use in such situations may cause fire or electric shock. ● There is smoke or a strange odor leaking out of the defibrillator/monitor. ● The defibrillator/monitor has been dropped or impacted by an object. ● Liquid or foreign matter gets inside the defibrillator/monitor. ● Defibrillator/monitor failure has occurred. Also, when any of the above occurs, promptly do the following: 1. Check to see that the power cord has been unplugged from the wall socket. 2. Place an ‘Out of Order’ sign on the defibrillator/monitor and do not use it. 3. Have the defibrillator/monitor serviced to make sure that no hazard exists.

⚠ WARNING	Do not connect more than one patient to the defibrillator/monitor. Do not connect more than one defibrillator/monitor to a patient.
⚠ WARNING	The defibrillator/monitor is a prescription device and is to be operated by qualified personnel only.
⚠ WARNING	As with any medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
⚠ WARNING	Never lift the defibrillator/monitor by the sensor cable, power cord, or any other accessory. Such accessories could detach, causing the defibrillator/monitor to fall on the patient.
⚠ WARNING	Do not make any clinical judgments based on this defibrillator/monitor's measurement only.
⚠ WARNING	Emergency defibrillation should be performed only by appropriately trained, skilled and qualified personnel who are aware of the protocol for handling a patient in medical emergency such as cardiac arrest and have been certified in Advanced Cardiac Life Support (ACLS) or Basic Life Support (BLS).
⚠ WARNING	Synchronized electrical cardioversion should be performed only by skilled personnel trained in Advanced Cardiac Life Support (ACLS) and practiced in equipment operation. The precise cardiac arrhythmia must be determined prior to performing defibrillation.
⚠ WARNING	The defibrillator delivers up to 200 joules of electrical energy. Unless properly used as described in this manual, this electrical energy may cause serious injury or death. Do not attempt to operate this defibrillator/monitor unless thoroughly familiar with this manual and the function of all controls, indicators, connectors and accessories.
⚠ WARNING	Do not discharge standard paddles on top of pads or ECG electrodes. Do not allow standard paddles (or pads) to touch each other, ECG electrodes, lead wires, dressings, transdermal patches, etc. Such contact can cause electrical arcing and patient skin burns during defibrillation and may divert defibrillating energy away from the heart muscle.
⚠ WARNING	Discharging the defibrillator/monitor with the standard paddle surfaces shorted together can pit or damage the paddle electrode surface. Pitted or damaged paddle surfaces may cause patient skin burns during defibrillation. Discharge the defibrillator only as described in theses operating instructions.
⚠ WARNING	If a person is touching the patient, bed, or any conductive material in contact with the patient during defibrillation, the delivered energy may be partially discharged through that person. Clear everything away from contact with the patient, bed, and other conductive material before discharging the defibrillator/monitor.
⚠ WARNING	Do not discharge the defibrillator into the open air. To remove an unwanted charge, change the energy selection, or change the mode, or turn off the defibrillator/monitor.
⚠ WARNING	Conductive gel on the paddle handles can allow the electrical energy to be discharged through the operator during defibrillation. Completely clean the paddle electrode surfaces, handles, and storage area after defibrillation.
⚠ WARNING	A gel pathway on the skin between the standard paddles will cause defibrillating energy to arc between paddles and delivery energy away from the heart muscle. Do not allow conductive gel (wet or dry) to

	become continuous between paddle sites.
⚠ WARNING	During defibrillation checks, the discharged energy passes through the cable connectors. Securely attach cable connectors to the simulator.
⚠ WARNING	Do not touch the patient or any equipment connected to the patient during defibrillation. Warn all persons around patient to DO NOT TOUCH THE PATIENT prior to defibrillation.
⚠ WARNING	The defibrillator/monitor should be out of contact with water (puddles or water spray). It may cause electrical shocks and defibrillator/monitor failure. Electrical safety of the defibrillator/monitor may not work properly when wet.
⚠ WARNING	Defibrillation may cause implanted devices to malfunction. Place standard paddles or pads away from implanted devices if possible. Check implanted device function after defibrillation.
⚠ WARNING	Implanted pacemakers may cause the heart rate meter to count the pacemaker rate during incidents of cardiac arrest or other arrhythmias. Pacemaker patients should be carefully observed. Check the patient's pulse; do not rely solely on heart rate meters. Dedicated pacemaker detection circuitry may not detect all implanted pacemaker spikes. Patient history and physical exam are important in determining the presence of an implanted pacemaker.
⚠ WARNING	To ensure patient electrical isolation, connect only to other equipment with circuits that are electrically isolated.
⚠ WARNING	To avoid risk of electric shock, the defibrillator/monitor must only be connected to a supply mains with protective earth.
⚠ WARNING	The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include: Use of the accessory in the PATIENT VICINITY. Evidence that the safety certification of the ACCESSORY has been performed in accordance with the appropriate IEC (EN) 60601-1 and/or IEC (EN) 60601-2-XX particular standards.
⚠ WARNING	Check leakage levels prior to use. Leakage current may be excessive if more than one defibrillator/monitor or other piece of equipment is connected to the patient.
⚠ WARNING	Do not place or use the defibrillator/monitor when flammable gas presents in atmospheres or other flammable material exist near/around. Eg. Oxygenrich area, flammable anesthetic gases, gasoline and any flammable material or gas. Do not use the defibrillator/monitor near the place of a gasoline or other volatile substances spill may cause an explosion.
⚠ WARNING	Do not disassemble the defibrillator. It contains no operator serviceable components and dangerous high voltages may be present. Contact authorized service personnel for repair.
⚠ WARNING	Do not immerse any portion of this defibrillator in water or other fluids. Avoid spilling any fluids on defibrillator or accessories. Spilled liquids may cause the defibrillator and accessories to perform inaccurately or fail. Do not clean with ketones or other flammable agents. Do not autoclave or sterilize this defibrillator or accessories unless otherwise specified.
⚠ WARNING	Use care when operating this device close to oxygen sources (such as bag-valve-mask devices or ventilator tubing). Turn off gas source or

	move source away from patient during defibrillation.
⚠ WARNING	**If you are monitoring a patient and using the system connector, all equipment connected to the system connector must be battery powered or electrically isolated from AC power according to EN 60601-1. If in doubt, disconnect the patient from the defibrillator before using the system connector. Only use Mediana recommended data transmission cables. For more information, contact Mediana Technical Support.**
⚠ WARNING	**The defibrillator/monitor delivers up to 200 joules of electrical energy. When discharging the defibrillator, do not touch the paddle electrode surfaces or disposable paddle/pads electrodes. Do not attempt to perform this test unless you are qualified by training and experience and are thoroughly familiar with these operating instructions.**
⚠ WARNING	**Electric shock hazards exist internally. Do not remove assembly screws. Refer servicing to qualified personnel.**
⚠ WARNING	**Monitors, defibrillators, and their accessories (including electrodes and cables) contain ferromagnetic materials. As with all ferromagnetic equipment, these products must not be used in the presence of the high magnetic field created by a Magnetic Resonance Imaging (MRI) device. The high magnetic field created by an MRI device will attract the equipment with a force sufficient to cause death or serious personal injury to persons between the equipment and the MRI device. This magnetic attraction may also damage the equipment. Skin burns will also occur due to heating of electrically conductive materials, such as patient leads and pulse oximeter sensors. Consult the MRI manufacturer for more information.**
⚠ WARNING	**Medical electrical equipment which does not incorporate defibrillator protection should be disconnected during defibrillation.**
⚠ WARNING	**Operating the defibrillator/monitor or its accessories in conditions outside the environmental specifications can result in device or accessory malfunction. The defibrillator/monitor should be allowed to stabilize within the operating temperature range prior to operation.**
⚠ WARNING	**Do not position the defibrillator/monitor so it is difficult to operate the disconnection device when a separable plug is used as isolation.**

Cautions

Caution statements identify conditions or practices that could result in damage to the equipment or other property.

⚠ **CAUTION**	**Always check that the defibrillator/monitor functions properly and is in proper condition before use.**
⚠ **CAUTION**	**Federal law restricts this device to sale by or on the order of a physician.**
⚠ **CAUTION**	**The defibrillator/monitor may not operate properly if it is operated or stored at conditions outside the ranges stated in this manual, or subjected to excessive shock or dropping.**
⚠ **CAUTION**	**When connecting the defibrillator/monitor to any instrument, verify proper operation before clinical use. Both the defibrillator/monitor and the instrument connected to it must be connected to a grounded outlet.**
⚠ **CAUTION**	**Accessory equipment connected to the defibrillator/monitor's data interface must be certified according to IEC60950 for data-processing equipment or IEC60601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC60601-1-1 system requirements. Anyone who connects additional equipment to the signal input or signal output port configures a medical system and is therefore responsible that the system complies with the requirements of IEC 60601-1-1 and the electromagnetic compatibility system standard IEC60601-1-2. If in doubt, consult Mediana Technical Support Representative.**
⚠ **CAUTION**	**Where the integrity of the external protective conductor in the installation or its arrangement is in doubt, equipment shall be operated from its internal electrical power source.**
⚠ **CAUTION**	**Risk of explosion if battery is replaced by an incorrect type.**
⚠ **CAUTION**	**Software alone does not encrypt data and should be used only in closed hospital networks, and use a PC equipped with a security system such as a firewall or vaccine that conforms to the hospital's policy.**
⚠ **CAUTION**	**In the event of an accident involving cybersecurity, contact qualified service personnel or your local supplier for assistance and wait until the administrator takes action.**

INTRODUCTION

⚠ WARNING	**Patient conditions may result in erroneous readings. If the measurements are suspect, verify the reading using another clinically accepted measurement method.**

Intended Use for the D100

1 The defibrillator/monitor is intended for use by trained medical technician, doctor, nurse or medical specialist in outdoor and indoor emergency care settings including ground ambulances within the environmental conditions specified. Manual and Automated external defibrillation, External pacing, Diagnostic electrocardiography are intended for use on adult and pediatric patients.

The other monitoring functions (Electrocardiography (ECG, Heart Rate), Functional arterial oxygen saturation (SpO_2), Respiration (RESP)) are intended for use on adult, pediatric and neonatal patients.

Indications for Use

	Indications	Contraindications
Manual Defibrillation 2.3.1	Manual defibrillation is indicated for the termination of certain potentially fatal arrhythmias, such as ventricular fibrillation and ventricular tachycardia.	Defibrillation is contraindicated in the treatment of Pulseless Electrical Activity (PEA), such as idioventricular or ventricular escape rhythms, and in the treatment if asystole.
2.3.2	Delivery of this energy in the synchronized mode is a method for treating atrial fibrillation, atrial flutter.	Defibrillation is not intended for patient who is conscious and has a palpable pulse and is contraindicated for use on neonates.
Automated External Defibrillation 2.3.3	AED mode is to be used only on patients in cardiopulmonary arrest. The patient who must be unconscious, pulseless and not breathing normally before using the defibrillator to analyze the patient's ECG rhythm.	AED is not intended for patient who is conscious and has a palpable pulse and is contraindicated for use on neonates.
External Pacing	External pacing is indicated for symptomatic bradycardia in patients with a pulse. Increased heart rates in response to external pacing often suppress ventricular ectopic activity and may prevent tachycardia.	External pacing is contraindicated for the treatment of ventricular fibrillation and asystole. External pacing in the presence of severe hypothermia may be contraindicated and is contraindicated for use on neonates.

	Indications	Contraindications
Electrocardiography	The electrocardiogram is used to identify, diagnose and treat patients with cardiac disorders and is useful in the early detection.	No known contraindications
Pulse Oximetry	Pulse oximetry monitoring is intended to be used to monitor functional arterial oxygen saturation and pulse rate.	Pulse Oximetry is not intended for use with severe peripheral vascular disease and severe anemia (decreased Hemoglobin).

About This Manual

This manual explains how to set up and use the defibrillator/monitor.

Read the entire manual including the ***Safety Information*** section, before you operate the defibrillator/monitor.

Identifying the D100 Configurations

The following table identifies D100 defibrillator/monitor configurations and how they are indicated. The reference number and serial number are located on the back of the product.

All information in this manual, including the illustrations, is based on a device configured with the Battery, Pacing module, Mediana or Medtronic SpO_2 module, Infoware X module and Cradle/External adaptor.

Product Code	Description
Basic	0: Manual Defibrillation, Automated External Defibrillation, ECG (3/5 lead), Respiration, Printer
Top case	H: with paddles
	X: without paddles
Pacing module	P: Mediana Pacing module
	X: Not installed
SpO_2 module	S: Medtronic SpO_2 module
	D: Mediana SpO_2 module
	X: Not installed
Infoware X module	W: Mediana InfoX-W(Wi-Fi) module
	E: Mediana InfoX-E(mobile) module
	X: Not installed
Cradle / External adaptor	A: Cradle / External AC Adaptor
	C: Cradle / External DC Adaptor
	X: Not installed

Note: 'X' in the product code is not indicated from the real product code.

This page is intentionally left blank.

DESCRIPTION OF THE DEFIBRILLATOR/MONITOR

Front Panel Components

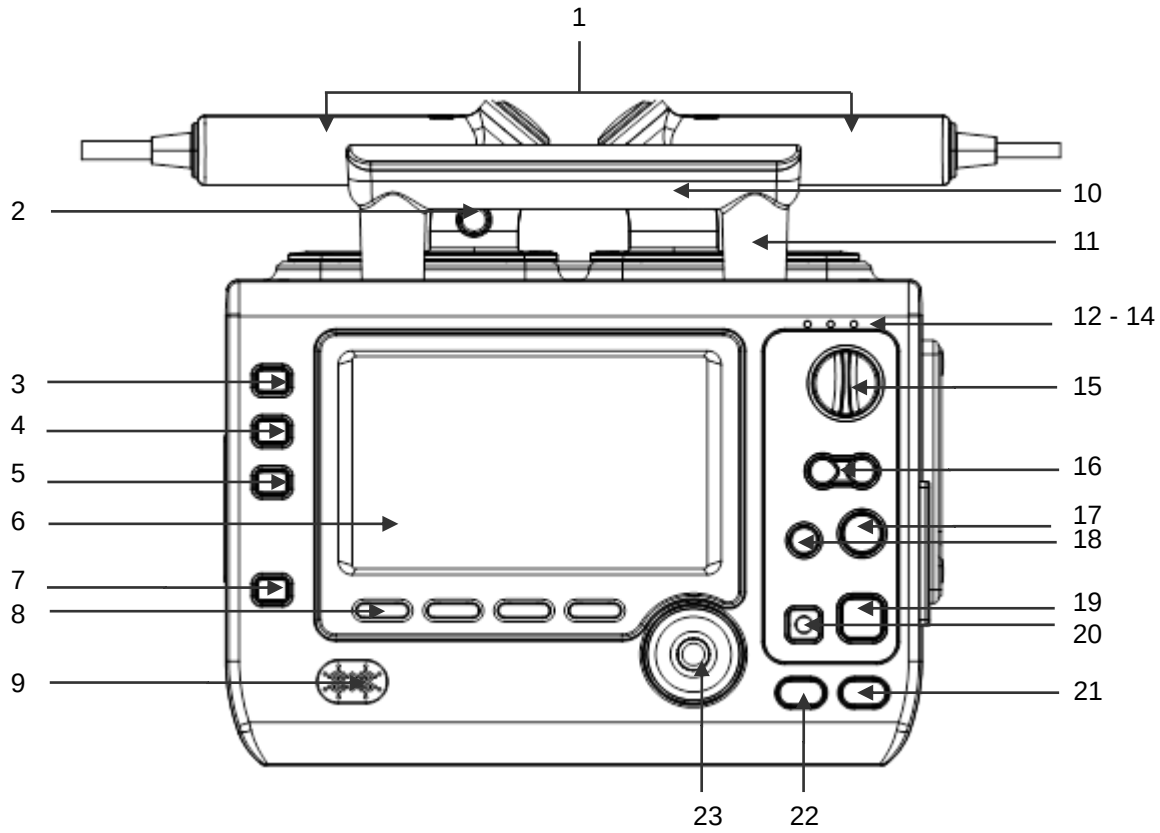
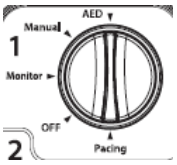
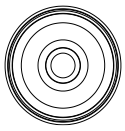


Figure 1. Front panel components

1	Paddle	13	Service LED
2	Paddle energy level button (+,-)	14	Battery charging status LED
3	Patient type button	15	Mode selection knob
4	ECG Lead button	16	Energy level button(+,-)
5	ECG Size button	17	Charge button
6	LCD	18	Analyze button
7	Print button	19	Shock button
8	Soft key (1st from left)	20	Sync button
9	Speaker	21	Event button
10	Paddle charge button	22	Alarm button
11	Handle	23	Multi function knob
12	AC/DC in LED		

Table 1. D100 controls

Symbol	Function
	**Mode selection knob** selects five modes of operation. (AED, Manual, Monitor, OFF, Pacing)
	**Energy level button(+,-)** selects the defibrillation energy level.
	**Analyze button** operates the advisory mode from the manual mode. analyzes the patient's ECG in the AED mode.
	**Sync button** selects sync or async mode.
	**Charge button** charges defibrillation energy.
	**Shock button** delivers a shock.
	**Patient type button** selects patient type. (Adult, Pediatric, Neonatal)
	**ECG Lead button** selects lead to display the first ECG waveform on the screen.
	**ECG Size button** selects to display the amplitude of an ECG waveform.
	**Print button** starts and stops the printing on operating.
	**Alarm button** pauses the audible alarm temporarily. turns off the audible alarm.
	**Event button** selects and records event data.
	**Soft key x 4EA** operates the assigned function according to the operation mode.
	**Multi function knob** selects the function for change, search, select, enter, add, cancel, etc..

Top Panel Components

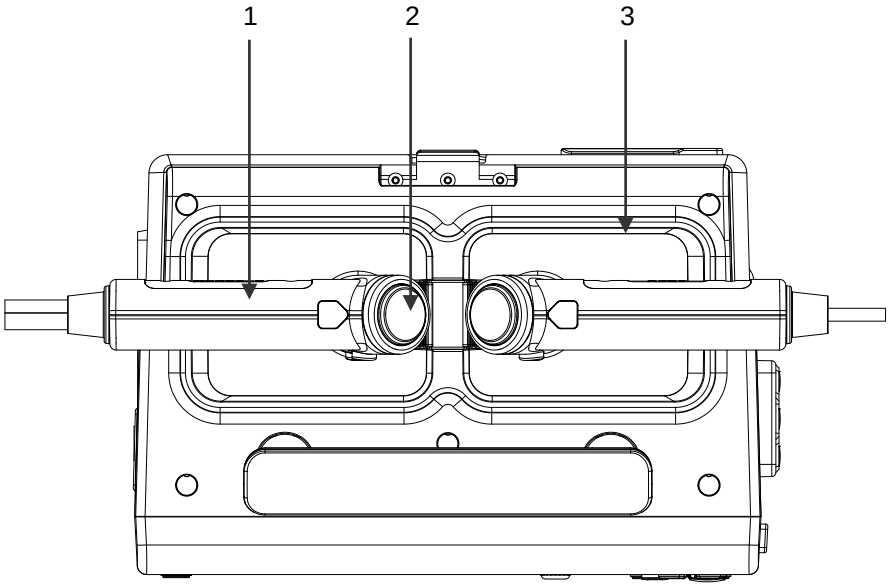


Figure 2. Top panel components

1 Paddle
2 Shock Button
3 Paddle Cradle

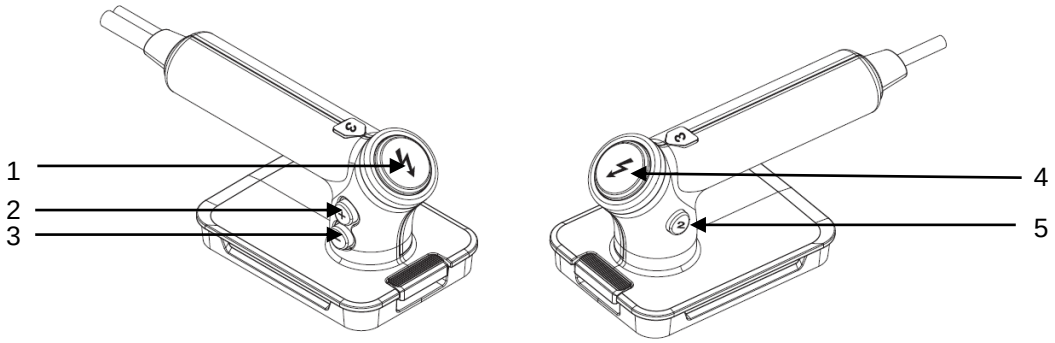


Figure 3. Defibrillator/Patient monitor paddle controller

1 Shock Button
2 Energy Level Button(+)
3 Energy Level Button(-)
4 Shock Button
5 Charge Button

Rear Panel Components

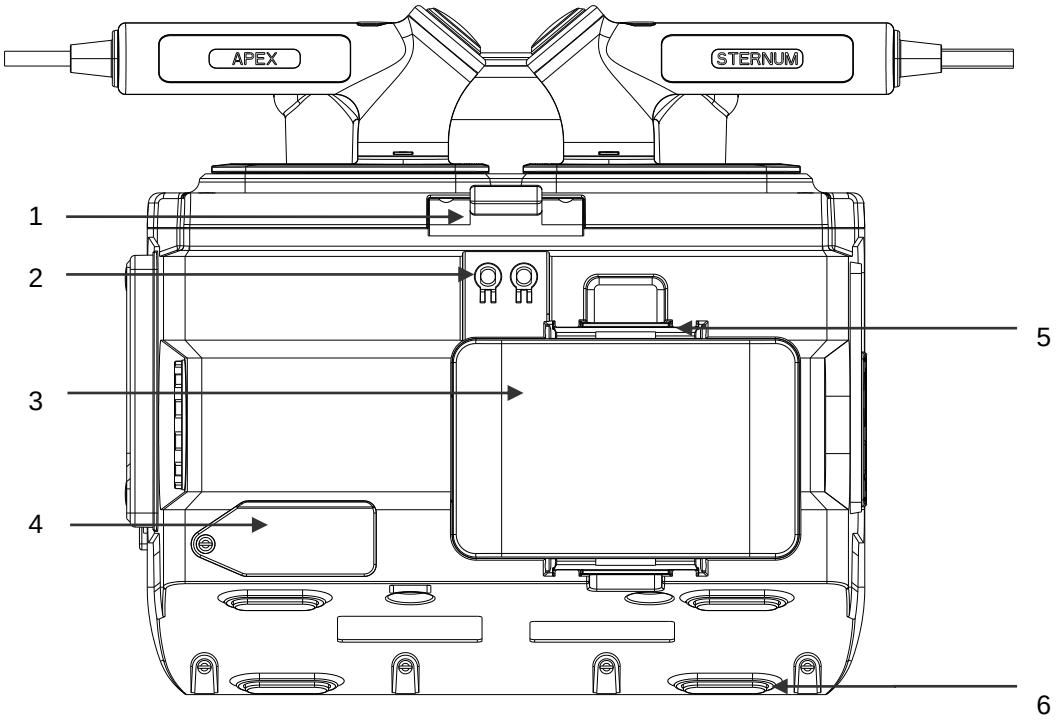


Figure 4. Rear panel components

1	Cradle Hook	4	AC inlet cover
2	DC Power Connector	5	Battery Hook
3	Battery	6	Rubber Foot

Left Panel Components

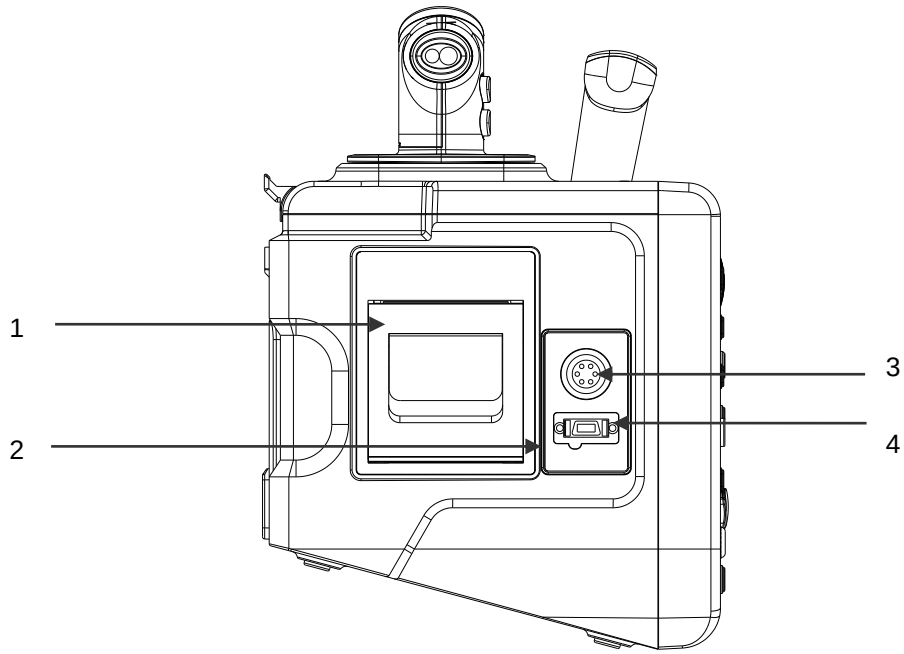


Figure 5. Left panel components

1 Printer
2 Option Case
3 ECG Connector
4 SpO_2 Connector

Right Panel Components

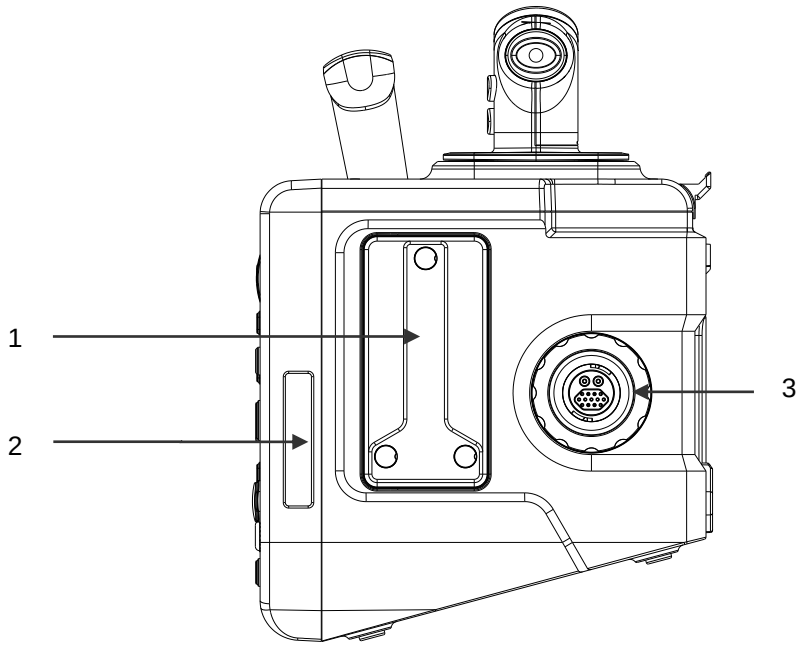


Figure 6. Right panel components

1 Side Cover
2 USB & SD Card Cover
3 Paddle/Pads Connector

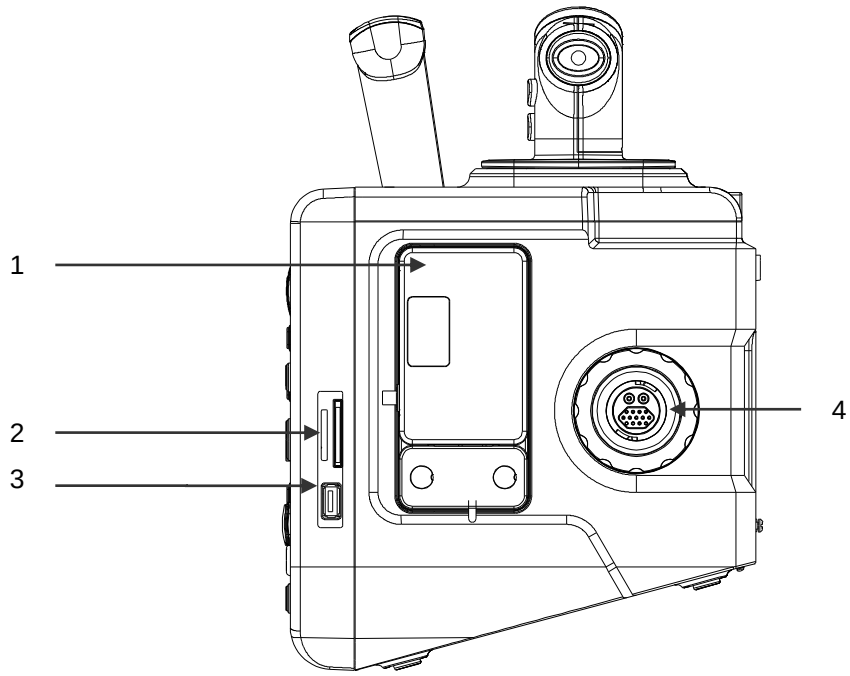
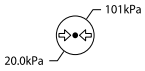
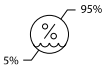


Figure 7. Right panel components (Option)

1 Wireless Module
2 SD Card Insertion Hole
3 USB port
4 Paddle/Pads Connector

Table 2. Panel and label symbols

Symbols	Description	Symbols	Description
	AC indicator		Follow instructions for use
	Direct current		Separate Collection
	Battery charging status indicator	EC REP	EU representative
	Service indicator		Manufacturer
	Type BF- Defibrillator Proof		Date of manufacture
	Type CF- Defibrillator Proof	REF	Reference number
ECG	ECG connector	SN	Serial number
SpO_2	SpO_2 connector		Environmental shipping/storage altitude limitations
	AC power input rating		Environmental shipping/storage humidity limitations
	Equipotential terminal		Environmental shipping/storage temperature limitations
Rx ONLY	Prescription only device		Fragile
IP44	Dust and water resistance (D100)		Keep dry
IP22	Dust and water resistance (Cradle/External adapter)		This way up
CE 2797	CE mark		Single patient use only

SETTING UP THE DEFIBRILLATOR/MONITOR

⚠ **WARNING**	**To ensure accurate performance and prevent defibrillator/monitor failure, do not expose the defibrillator/monitor to extreme moisture, including direct exposure to rain. Such exposure may cause inaccurate performance or device failure. Refer to Specification section.**
⚠ **WARNING**	**The defibrillator/monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the defibrillator/monitor should be observed to verify normal operation in the configuration it is to be used.**
⚠ **WARNING**	**Make sure that the defibrillator/monitor speaker is not obstructed. Failure to do so could result in an inaudible alarm tone.**
⚠ **CAUTION**	**Recharging the battery is strongly recommended when the battery has not been recharged for 6 or more months.**
⚠ **CAUTION**	**Follow local government ordinances and recycling instructions regarding disposal or recycling of defibrillator/monitor components, including batteries.**
⚠ **CAUTION**	**The use of accessories, cables, transducers and sensors sourced from manufacturers, which Mediana has not recommended may cause incorrect analysis.**
⚠ **CAUTION**	**Electrical installation of the room or the building in which the defibrillator/monitor is to be used must comply with regulations specified by the country in which the equipment is to be used.**

Unpacking and Inspection

The defibrillator/monitor is shipped in one carton. Examine the carton carefully for evidence of damage. Contact Mediana Technical Support Representative immediately if any damage is discovered. Refer to the ***Maintenance*** section for instructions on returning damaged items.

Note: Refer to the Performance Verification section in the service manual for detailed information.

Set the defibrillator/monitor to the user's intended position where the user can easily recognize the visual and audible monitoring conditions. Normally it is recommended to set at a distance of 1m from the user. Also the viewpoint is at any point within the base of a cone by an angle of 30° to the center of the monitoring display.

List of Components

The following items are standard in the package.

Table 3. Standard accessories

Items	Qty
D100 defibrillator/monitor	1
Operator's manual	1
AC Power cord	1
Print paper	2
Shock/Pacing Pads	1
Pads extension cable	1
ECG 3 leads Cable (SNAP)	1
For Mediana SpO_2 Module SpO_2 reusable sensor YM-1 SpO_2 extension cable MEX03 * Only when Mediana SpO_2 option is installed	1
For Medtronic SpO_2 Module SpO_2 reusable sensor DS-100A SpO_2 extension cable DOC-10 * Only when Medtronic SpO_2 option is installed	1
Rechargeable Li-ion Battery Pack	1

Table 4. Optional accessories

Items	Qty
External Paddle	-
Shock only pads	-
ECG 3 leads cable (SNAP)	
ECG 3 leads cable (GRAB)	-
ECG 5 leads cable (SNAP)	-
ECG 5 leads cable (GRAB)	-
ECG 3 leads trunk cable	-
ECG 5 leads trunk cable	-
ECG 3 lead set (SNAP)	-
ECG 3 lead set (GRAB)	-
ECG 5 lead set (SNAP)	-
ECG 5 lead set (GRAB)	-
Service manual (English)	-
Cradle / External AC Adaptor	-
Cradle / External DC Adaptor	-
Mediana InfoX-W(Wi-Fi) module	-
Mediana InfoX-E(mobile) module	-
Carry bag	-

Optional items may be ordered if needed. Contact your local supplier for pricing and ordering information.

Power Cable Connections

⚠ **WARNING**	**Do not connect to an electrical outlet controlled by a wall switch or dimmer because the defibrillator/monitor may be accidentally turned off.**
⚠ **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.**
⚠ **CAUTION**	**If the integrity of the AC power source is in doubt, the defibrillator/monitor must be operated from its internal battery.**

AC Power

Make sure that the AC outlet is properly grounded and supplies the specified voltage and frequency (100-240V~ 50/60 Hz).

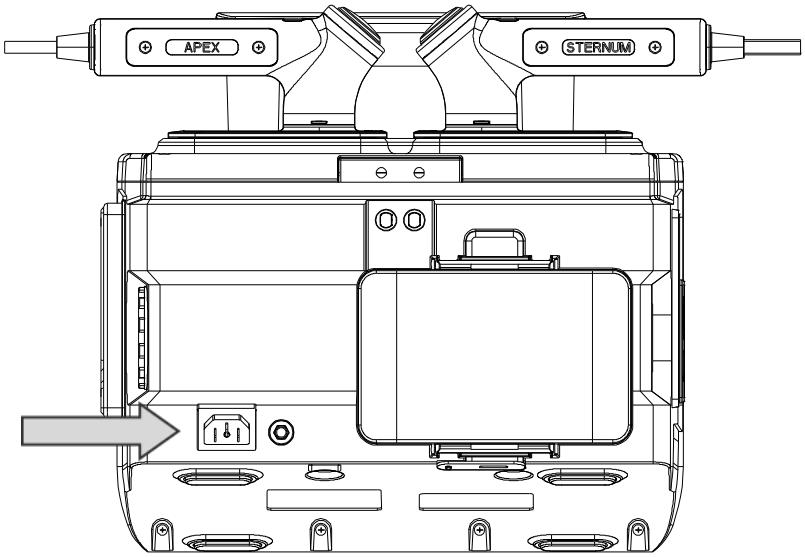


Figure 8. AC power connection

1. Connect the AC power cord to AC power connector on the rear of the Defibrillator/Monitor.
2. Connector the power cord to a grounded AC socket.
3. Connect a grounding wire if needed. After connection a ground wire socket to the equipotential grounding terminal on the rear, and then attach the clip end of the grounding wire to the medical device grounding terminal on the outer wall.
4. After connection, check if the **Battery charging status LED** and **AC/DC in LED** on the front of the Defibrillator/Monitor.

*Note: **Battery charging status LED** indicates battery is installed and being charged by the AC power.*

*Note: Even if the defibrillator/monitor is not turned on, the **Battery charging status LED** is lit when the AC power cord is connected into a mains outlet.*

Note: Do not place the defibrillator/monitor so that it is difficult to disconnect the AC power cord.

Cradle / External adapter

The DC power source can be used, when the defibrillator/monitor is used for the emergency condition in the moving car. Cradle uses AC or DC power.

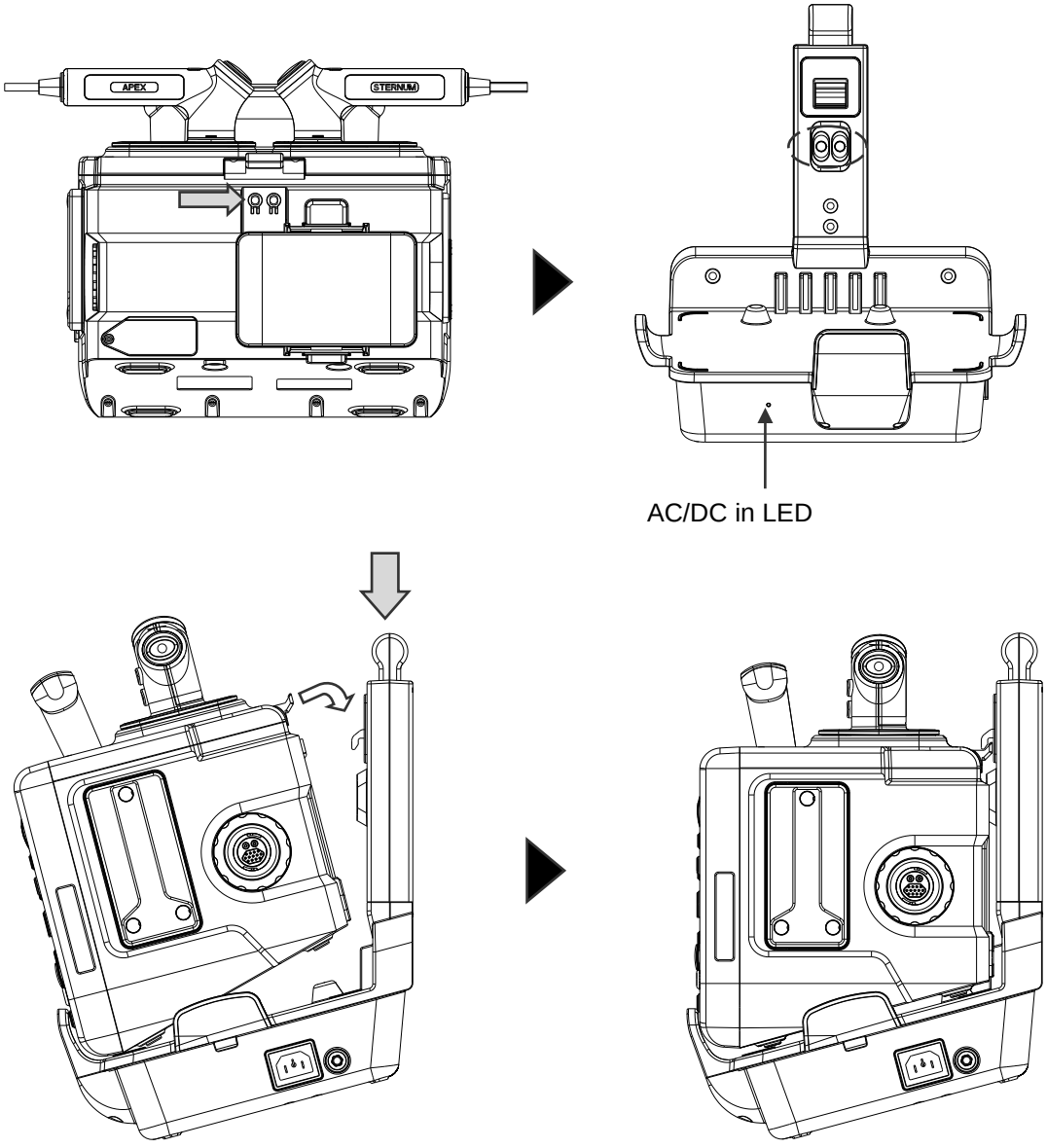


Figure 9. Cradle installation

1. Connect an AC or DC power to cradle and verify that the ***AC/DC Power Input LED*** is lit.
2. Set the defibrillator/monitor as Figure 9.
3. Verify that the DC power input icon appears on the screen, ***Battery charging status LED*** and ***AC/DC in LED*** on the defibrillator/monitor's front panel is lit.

*Note: **Battery charging status LED** turns on in orange and **AC/DC in LED** turns on in green when battery is installed and being charged by the AC or DC power.*

*Note: Even if the defibrillator/monitor is not turned on, the **Battery charging status LED** is lit when a Cradle/External DC adaptor is connected into AC or DC input connector.*

Note: If the Battery charging status LED is not lit, check:

- *the power cord*
- *the AC or DC input connector*
- *the Cradle/External DC adaptor*
- *the power/ mains outlet*
- *No Battery*

Note: If the Battery charging status LED still is not lit although no problem is found, contact qualified service personnel or your local supplier for assistance.

Battery Operation

⚠ WARNING	**Do not disassemble, puncture, crush, heat above 100°C (212°F), or incinerate the battery. Be careful not to short the battery terminals because this could result in a fire hazard.**
⚠ WARNING	**Mediana has no information regarding the performance or effectiveness of its Mediana defibrillator/monitors if other manufacturers' batteries or battery chargers are used. Using other manufacturers' batteries or battery chargers may cause the defibrillator/monitor to perform improperly and invalidate the safety agency certifications. Use only Mediana's battery or battery charger.**
⚠ WARNING	**Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked 'HOSPITAL ONLY' or 'HOSPITAL GRADE'. If the grounding integrity of the line cord or AC receptacle is in doubt, operate on battery only.**
⚠ 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.**
⚠ CAUTION	**Recharging the battery is strongly recommended when it has not been fully recharged for 6 or more months.**
⚠ CAUTION	**Do not install the battery into the defibrillator/monitor when storage may exceed 90 days. Battery damage may occur.**
⚠ CAUTION	**When the voltage of the battery is very low, it is a possibility of not operating.**
⚠ CAUTION	**Check for the battery-in-use indication when the defibrillator/monitor is operating on mains and apply corrective action.**
⚠ CAUTION	**Do not operate the defibrillator/monitor without a battery. Keep a fully charged spare battery pack with the defibrillator/monitor at all times.**
⚠ CAUTION	**Partial charge of battery results in a shortened service life.**
⚠ CAUTION	**Storing at temperatures above 40°C (104°F) for extended periods of time will significantly reduce a battery's life-expectancy.**
⚠ CAUTION	**Using an improperly maintained battery to power the defibrillator/monitor may cause power failure without warning. Use the appropriate battery charger to charge batteries.**
⚠ CAUTION	**Battery pins in the defibrillator/monitor may be damaged if batteries are dropped or forced into battery wells. Inspect pins routinely for signs of damage. Keep batteries installed at all times except when defibrillator/monitor is removed from service for storage.**
⚠ CAUTION	**When storing the defibrillator/monitor for an extended period of time, the battery should be removed from the defibrillator/monitor.**
⚠ CAUTION	**Stored batteries lose charge. Failure to charge a stored battery before use may cause device power failure without warning. Always charge a stored battery before placing it in active use.**

Note: It is recommended that keep AC power source connected to the defibrillator/monitor when not in use. This will ensure a fully charged battery whenever it is needed.

Note: As the battery is used and recharged over a period of time, the amount of time between the onset of the low battery alarm and the defibrillator/monitor shut-off may become shorter. It is recommended for service personnel to check periodically or replace the battery if necessary.

Operating the defibrillator/monitor on Battery Power

The defibrillator/monitor has the rechargeable battery that can be used to power the defibrillator/monitor when AC power source is not available. The battery status icon appears on the screen when the defibrillator/monitor is on battery power.

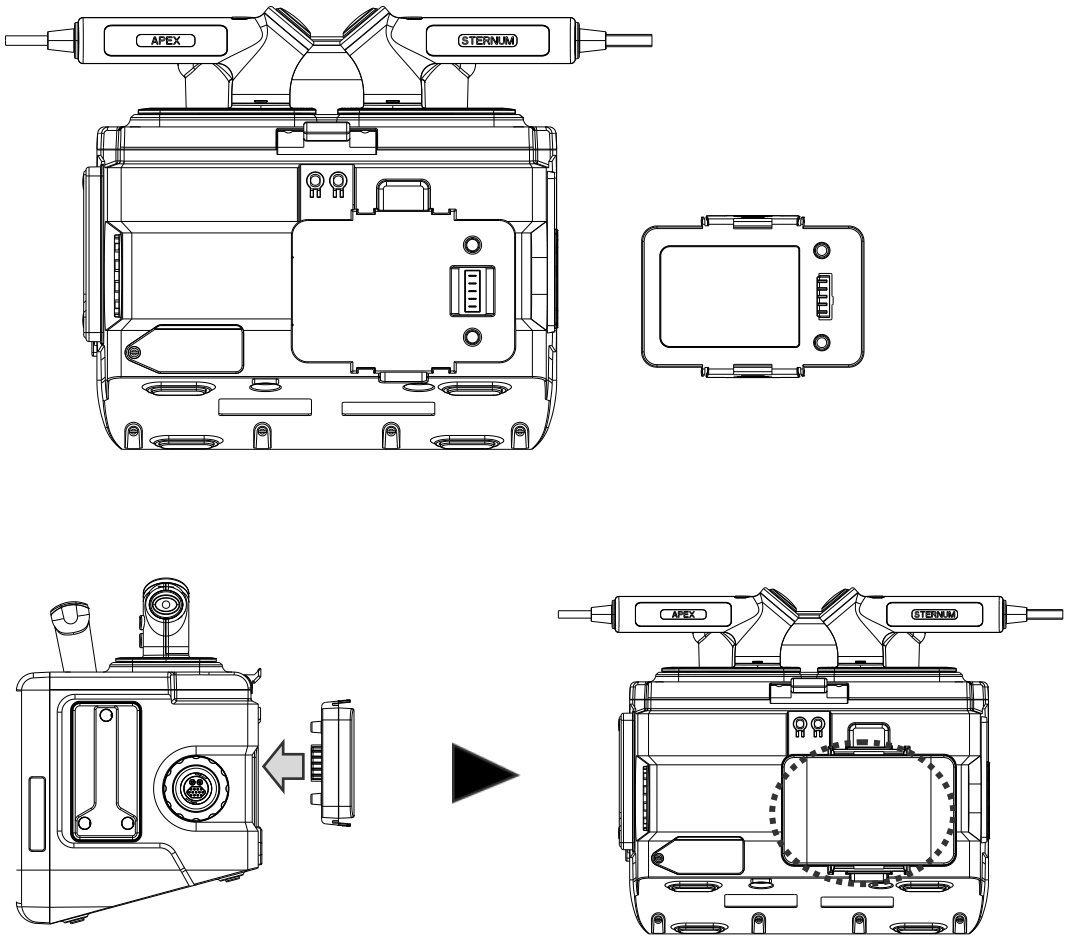


Figure 10. Battery placement

1. Turn off the defibrillator/monitor.
2. Push the **Battery hook**.
3. Insert the battery into the defibrillator/monitor carefully.

Table 5. Front panel indications for power source

Power Connections	Front Panel Indications
AC source	AC power input icon appears on the screen. AC/DC in LED is lit.
DC source	DC power input icon appears on the screen. AC/DC in LED is lit.
Battery	Battery status icon appears on the screen.

The defibrillator/monitor cannot operate with a completely discharged battery. Before turning on the defibrillator/monitor with a battery that has been completely discharged, plug the defibrillator/monitor into an AC outlet to charge the battery for a minimum of 3 minutes. The defibrillator/monitor may then be powered on.

A new, fully charged battery will provide 5 hours monitoring operation in *Monitor mode* or at least 200 times of shock delivery in 200J selected energy in *Manual mode or AED mode* or 2 hours monitoring operation in *Pacing mode* (pacing rate: 80 ppm, pacing output: 60mA, load resistance: 50Ω) under the following conditions:

- No audible alarm sound
- No data Output, No communication (Communication system is installed)
- No printing out (Printer module is installed)
- All monitoring parameters are active
- LCD Backlight: default
- Ambient temperature at 25°C

Battery Status Indication

When operating on batteries, the battery status icon in the lower part of the display indicates the battery charge condition. See Table 6.

Table 6. The defibrillator/monitor battery status icon

Battery Status Icons	Battery Status
	Normal, Fully charged
	More than 4/5 from fully charged
	More than 3/5 from fully charged
8 	More than 2/5 from fully charged
	More than 1/5 from fully charged
	Battery charging
	Battery charging error
	Low
	Critical low

Note: The battery status icon is displayed in 5 levels depending on the amount of battery. User can check the approximate amount of battery by the number of bars inside the battery status icon.

A low priority alarm occurs when the remaining battery power is only enough for 15 minutes of operation. The '**System: Low battery condition**' message is displayed on the screen and visual alarm window is lit with yellow. Connect the AC power or replace the battery with a fully charged battery immediately when alarm occurs.

This alarm audio cannot be paused while running on battery power. Connecting the defibrillator/monitor to AC power will stop the alarm.

A high priority alarm occurs for about 5 minutes before the defibrillator/monitor shuts off. The '**System: Critically low battery condition**' message is displayed on the screen and the visual alarm window is lit with red. After that, the monitor will automatically shut down. Connect the defibrillator/monitor to an AC power source immediately to avoid any loss of trend data or settings.

User cannot use printer while the device is in low battery and critically low battery condition.

Note: The battery will not be charged for safety if the operating temperature exceeds 40°C.

Note: In critically low battery condition, the monitor is not turned on once the monitor is turned off.

Measurement Cable Connections

⚠ **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. Use only accessories that have passed the recommended biocompatibility testing in compliance with ISO10993-1.**
⚠ **WARNING**	**Connect the sensor, probe, cuff/hose or transducer firmly into socket and do not use a damaged sensor, probe or cuff/hose.**
⚠ **WARNING**	**To avoid damage to the cable, always hold by the connector rather than the cable, when connecting or disconnecting either end.**
⚠ **WARNING**	**The sensor connector should not be connected to anything other than a sensor.**

Note: Both frequent checks by the operator on a daily basis and more comprehensive technical checks less frequently are covered by this requirement in order to detect mechanical damage and damage to cables, etc.

ECG Cables and Leads

1. Connect an ECG cable to the ECG connector making sure that the connector arrow is pointing panel (see Figure 5)
2. Connect an ECG leadwire cable to the ECG cable.

Defibrillator Paddle and Pads

1. Connect a paddle or pads to paddle / pads connector on the defibrillator/monitor's right panel. (see Figure 6)
2. Use ***ECG lead button*** to select pads. (If paddle is connected, the mode is automatically changed to paddle.)

SpO_2 Cables and Sensors (if configured with SpO_2 option)

1. Select an appropriate sensor for the patient and desired application. (Refer to the ***SpO_2 Monitoring*** section.)
2. Connect the extension cable to the SpO_2 connector on the defibrillator/monitor's front panel. (see Figure 5)
3. Attach the sensor to the end of the cable.

Note: If lead wire cable, sensor and transducer are not connected firmly, the defibrillator/monitor could lose signal from patient.

USING THE DEFIBRILLATOR/MONITOR

⚠ WARNING	Each time the defibrillator/monitor is used, check alarm limits to make sure that they are appropriate for the patient being monitored.
⚠ WARNING	If different alarm presets are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating room, a potential hazard can exist.
⚠ WARNING	Keep patients under close surveillance when monitoring. It is possible, although unlikely, that radiated electromagnetic signals from sources external to the patient and the defibrillator/monitor can cause inaccurate measurement readings. Do not rely entirely on the defibrillator/monitor readings for patient assessment.
⚠ WARNING	Be aware of patient cables, including ECG monitoring equipment when used with high frequency surgical equipment.
⚠ WARNING	When inaccurate analysis is suspected because of motion artifact do not analyze in a moving vehicle. Motion artifact may affect the ECG signal resulting in an inappropriate SHOCK ADVISED or NO SHOCK ADVISED message. Motion detection may delay analysis. Stop vehicle and stand clear of patient during analysis.
⚠ WARNING	To avoid risk of electrical shock, do not touch gelled area of the pads while pacing or shock. When defibrillating with paddles use your thumbs to operate the Shock button in order to avoid inadvertent operator shock. No portion of the hand should be near the paddle plates.
⚠ WARNING	Pediatric defibrillation energy levels should be set based on site-specific clinical protocols.
⚠ WARNING	The metronome sounds do not indicate information regarding the patient's condition. Because patient status can change in a short time, the patient should be assessed at all times. Do not perform CPR on a patient who is responsive or is breathing normally.
⚠ WARNING	Place the patient on a firm surface before performing CPR.
⚠ WARNING	Ventricular fibrillation may be induced with improper synchronization. Do not use the ECG from another monitor (slaving) to synchronize the defibrillator/monitor's discharge. Always monitor the patient's ECG directly through the defibrillator/monitor's ECG cable or pad cable.
⚠ WARNING	Pitted or damaged paddles may cause patient skin burns during defibrillation.
⚠ WARNING	The ECG rhythm analysis function does not warn the operator of patient asystole, as it is not a shockable rhythm.
⚠ WARNING	Determination of electrical capture should only be performed by viewing the ECG on the screen with its ECG cable directly attached to the patient.
⚠ WARNING	Connect the device only to a three-wire, grounded, hospital grade receptacle. The three-conductor plug must be inserted into a properly wired three-wire receptacle; if a three-wire receptacle is not available, a qualified electrician must install one in accordance with the governing electrical code. Do not under any circumstances remove the grounding connector from the power plug. Do not use extension cords or adapters of any type. The power cord and plug must be intact and undamaged.
⚠ CAUTION	Only use thumbs to depress the paddle Shock button. Failure to do so could result in the inadvertent depression of the energy select buttons, causing the defibrillator/monitor to disarm itself.

⚠ **CAUTION**	**Do not discharge the defibrillator/monitor except as indicated in the instructions.**
⚠ **CAUTION**	**Do not permit gel to accumulate between the paddle electrodes on the chest wall (gel bridge). This could cause burns and reduce the amount of energy delivered to the heart.**
⚠ **CAUTION**	**Changing the selected energy while the defibrillator/monitor is charging or charged will cause the defibrillator/monitor to disarm itself. Press the Charge button again to charge the defibrillator/monitor.**
⚠ **CAUTION**	**If using defibrillation pads, make sure that the size of the pad is large enough to cover the entire paddle electrode area.**
⚠ **CAUTION**	**Pads should be replaced after 8 hours of continuous pacing to ensure maximum patient benefit.**
⚠ **CAUTION**	**Be sure to safely discharge external paddles.**
⚠ **CAUTION**	**Do not use high conductivity gel manufactured by other than manufacturer recommended for defibrillation using paddle. It may cause burns to the patients or device failure.**

Note: Check if the defibrillator/monitor correctly operates according to the displays or signal sounds during the measurement.

Note: If the power has some changes, the buzzer sound of the monitor will occur.

Note: To reduce the risks due to the software error, use the new software.

Note: If there is a software error, please contact qualified service personnel or your local supplier.

Note: If the software or hardware is not restored after rebooting the device, the defibrillator / monitor will beep. Forcibly shut down the equipment by disconnecting the power and contact your local dealer or headquarter service.

Note: After the power turns on, check if the battery status indicator, display and other indicators operate normally.

Turning On and Off the Defibrillator/Monitor

Before using the defibrillator/monitor, confirm that the defibrillator/monitor is working properly and is safe to use as described below.

⚠ **CAUTION**	**Look for display motion before accepting any displayed data as a current measurement.**

Note: If unusable sound like buzzer can be heard, do not use the defibrillator/monitor. Instead, please contact qualified service personnel or your local supplier.

Turning On

The defibrillator/monitor can start to be used by rotating the Mode select knob of the device that turned off.

1. Rotate ***Mode select knob*** to select one mode from AED, manual, monitor or pacing mode.
2. While the defibrillator/monitor turns on, the LEDs of Alarm button and Shock button are turned on.
3. The defibrillator/monitor automatically starts the Power On Self Test (POST) that does the test for the function of the device.
4. When the Power On Self Test (POST) is completed successfully, the defibrillator/monitor will display the selected mode screen.

Note: If internal problem is detected or the final self test result is failed during the Power

On Self Test (POST), the alarm of the defibrillator/monitor will occur and the error code is displayed. When the error code is displayed, please contact qualified service personnel or your local supplier.

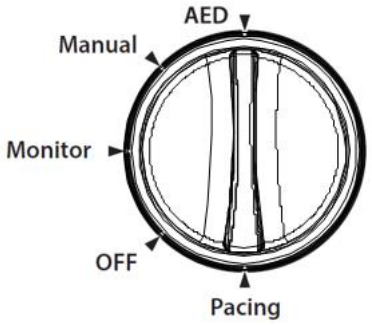


Figure 11. Mode select knob

- Pacing mode - to enable pacing mode for Demand or Fixed mode pacing.
- Manual mode - to enable manual mode for asynchronous or synchronous defibrillation.
- Monitor mode - to enable monitor mode for 3- or 5-lead ECG monitoring and vital signs trending, or monitoring of optional parameters.
- AED mode - to enable AED mode for semi-automated external defibrillation.

Turning Off

The defibrillator/monitor can start to be used by rotating the Mode select knob of the device that turned off.

1. To turn off the defibrillator/monitor, rotate **Mode select knob** to select Off mode. After selecting Off mode, the settings will be stored and the defibrillator/monitor will be turned off.

Displays

The screen below is a default screen in manual mode. The screen may be different according to other modes. For screens in other modes, refer to the ***AED mode***, ***manual mode***, ***monitor mode*** and ***pacing mode*** section.

A typical screen in Manual Mode is shown below.

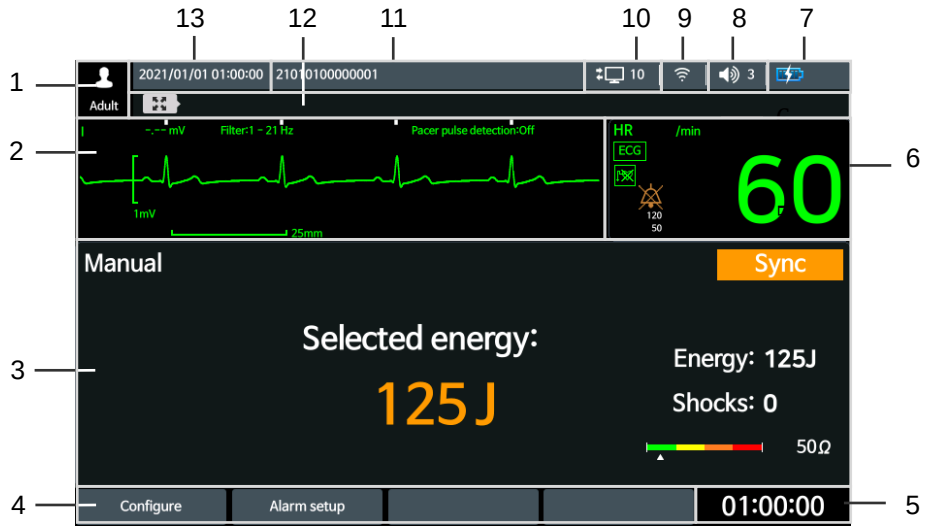


Figure 12. Displays (Manual mode)

1	Patient type	8	Alarm volume
2	Waveform area	9	Connection type
3	Operating information	10	CMS status
4	Soft key	11	Patient information
5	Runtime	12	Physiological/Technical alarm message
6	Numeric area	13	Date/Time display
7	Power status		

Note: CMS (Central Monitoring System) bed number is not displayed on the screen if there is no set bet number.