MAINTENANCE

⚠ WARNING	**The cover should be removed only by qualified service personnel. There are no internal user-serviceable parts except for the battery.**
⚠ WARNING	**Do not use the defibrillator/monitor when the case appears damaged.**
⚠ WARNING	**Do not spray, pour, or spill any liquid on the defibrillator/monitor, its accessories, connectors, switches or openings in the chassis.**
⚠ WARNING	**Unplug the power cord from the defibrillator/monitor before cleaning the defibrillator/monitor.**
⚠ CAUTION	**Disposal of the defibrillator/monitor with the battery inserted presents a potential shock hazard.**
⚠ CAUTION	**Do not autoclave, ultrasonically clean, or immerse the Mediana defibrillator/monitor. Do not use abrasive cleaners or strong solvents such as acetone or acetone-based cleaners.**
⚠ CAUTION	**Do not ultrasonically clean or immerse the paddles and paddles cables.**
⚠ CAUTION	**Do not ultrasonically clean, immerse, autoclave or steam sterilize the pads cable.**
⚠ CAUTION	**Do not ultrasonically clean, immerse, autoclave or steam sterilize the ECG cable. Do not clean the ECG cable with alcohol. Alcohol can cause the plastic to become brittle and may cause the cable to fail prematurely.**
⚠ CAUTION	**Do not clean any part of this defibrillator/monitor or accessories with bleach dilution or phenolic compounds. Do not use abrasive or flammable cleaning agents. Do not attempt to sterilize this defibrillator/monitor or any accessories unless otherwise specified in accessory operation instructions.**
⚠ CAUTION	**Do not soak or immerse the sensors or cables in any liquid solution. Do not attempt to sterilize.**

Recycling and Disposal

When the defibrillator/monitor, battery, or accessories reach the end of useful life, recycle or dispose of the equipment according to appropriate local and regional regulations.

Note: The defibrillator/monitor should be disposed of separately from the municipal waste stream via designated collection facilities appointed by the government or the local authorities.

Note: The correct disposal of your old appliance will help prevent potential negative consequences for the environment and human health.

Note: For more detailed information about disposal of your old appliance, please contact your city office, waste disposal service or the shop where you purchased the defibrillator/monitor.

Returning the Defibrillator/Monitor and System Components

Pack the defibrillator/monitor with sensors, cable or other accessory items in its original shipping carton. If the original carton is not available, use a suitable carton with appropriate packing material to protect the defibrillator/monitor during shipping.

Service

The defibrillator/monitor requires no routine service other than cleaning, battery maintenance, and service activity which is mandated by the user's institution. For more information, refer to the defibrillator/monitor service manual. Qualified service personnel in the user's institution should perform periodic inspections of the defibrillator/monitor. If service is necessary, contact qualified service personnel or your local supplier.

Periodic Safety Checks

It is recommended that the following checks be performed every year.

- Inspect the equipment for mechanical and functional damage.
- Inspect the external safety labels for legibility.

Cleaning

The defibrillator/monitor may be surface-cleaned by using a soft cloth dampened with either a commercial, nonabrasive cleaner or one of the solutions listed below. Lightly wipe the top, bottom and front surfaces of the defibrillator/monitor.

- 70% Isopropyl alcohol

The cleaning method for paddles and paddle plates are same as defibrillator/monitor.

For cables and sensors follow the cleaning instructions in the directions for use shipped with those components.

Avoid spilling liquid on the defibrillator/monitor, especially in connector areas. If liquid is accidentally spilled on the defibrillator/monitor, clean and dry thoroughly before reuse. If in doubt about defibrillator/monitor safety, refer the unit to qualified service personnel for checking.

Battery Maintenance

⚠ **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**	**Do not short-circuit the battery, as it may generate heat. To avoid short-circuiting, do not let the battery come in contact with metal objects at any time, especially when transporting.**
⚠ **CAUTION**	**Do not solder the battery directly. Heat applied during soldering may damage the safety vent in the battery's positive cover.**
⚠ **CAUTION**	**Do not deform the battery by applying pressure. Do not throw, hit, drop, fold or impact the battery.**
⚠ **CAUTION**	**Do not connect the battery reversed in positive (+) and negative (-) terminals. Do not charge the battery with polarities reversed, as it may swell or explode.**
⚠ **CAUTION**	**Do not use any chargers not specified by Mediana.**
⚠ **CAUTION**	**Do not use the battery with other maker's batteries, different types or models of batteries such as dry batteries, nickel-metal hydride batteries, or Li-ion batteries together, as they might leak electrolyte heat or explode.**
⚠ **CAUTION**	**Do not mistreat the battery, or use the battery in applications not recommended by Mediana.**
⚠ **CAUTION**	**Keep the battery out of reach of babies and children to avoid any accidents.**
⚠ **CAUTION**	**If there are any problems with the battery, immediately put the battery in a safe place and contact qualified service personnel.**

If the defibrillator/monitor has not been used for 6 months, the battery will need charging. To charge the battery, connect the defibrillator/monitor to an AC or DC power source as described in the ***Battery Operation*** section.

Note: Storing the defibrillator/monitor for a long period without charging the battery may degrade the battery capacity. It would take about 8 hours to fully charge the battery from the moment that low battery alarm is activated.

Note: The battery should be removed from the defibrillator/monitor if placed in storage or if it will not be used for a long period.

It is recommended that the defibrillator/monitor's Li-ion battery be replaced every 24 months. Refer to the service manual for battery replacement and general service instructions.

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TROUBLESHOOTING

⚠ **WARNING**	**If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means; then make sure the defibrillator/monitor is functioning correctly.**
⚠ **WARNING**	**The cover should be removed only by qualified service personnel. There are no user-serviceable parts inside except for the battery.**
⚠ **WARNING**	**The large current draw required for defibrillator charging may cause the defibrillator to reach a shutdown voltage level with no low battery indication.**

General

If the defibrillator/monitor detects an error or potential problem during use, it displays a system or momentary message. If service is necessary, contact qualified service personnel. Before calling to qualified service personnel or your local supplier, make sure it meets environmental conditions provided in the manual as temperature, humidity, altitude and so on.

Note: For repair instructions or for additional technical information, refer to the defibrillator/monitor Service Manual.

Obtaining Technical Assistance

For technical information and assistance, or to order a service manual, call your local supplier. The service manual provides information required by qualified service personnel when servicing the defibrillator/monitor.
When calling your local supplier, you may be asked to provide the software version number of your defibrillator/monitor. The software version can confirm in ***Service Setting Menu***.

EMI (Electromagnetic Interference)

⚠ **WARNING**	**Keep patients under close surveillance when monitoring. It is possible, although unlikely, that radiated electromagnetic signals from sources external to the patient and defibrillator/monitor can cause inaccurate measurement readings. Do not rely entirely on the defibrillator/monitor readings for patient assessment.**
⚠ **WARNING**	**It is possible that any radio frequency transmitting equipment and other nearby sources of electrical noise may result in disruption in the defibrillator/monitor operation. Operator's manual is attached for the minimum recommended separation distance between the RF emitting equipment and the device.**
⚠ **WARNING**	**It is possible, although unlikely, that large equipment using a switching relay for its power on/off may affect defibrillator/monitor operation. Do not operate the defibrillator/monitor in such environments.**
⚠ **WARNING**	**Using cables, electrodes or accessories not specified for use with this device may result in increased emissions or decreased resistance to electromagnetic interference which could affect the performance of this defibrillator/monitor or of equipment in close proximity. Use only parts and accessories specified in this manual.**
⚠ **WARNING**	**Defibrillator/monitor may cause electromagnetic interference (EMI) especially during charge and energy transfers. EMI may affect the performance of equipment operating in close proximity. If possible, verify the effects of defibrillator discharge on other equipment prior to using the defibrillator in an emergency situation.**
⚠ **WARNING**	**Operating high frequency electrosurgical equipment in the vicinity of the defibrillator/monitor can produce interference in the defibrillator/monitor and cause incorrect measurements.**
⚠ **WARNING**	**Do not use the defibrillator/monitor with nuclear spin tomography (MRT, NMR, NMT) as the function of the defibrillator/monitor may be disturbed.**

This device has been tested and found to comply with the limits for medical devices to the IEC60601-1-2, and the Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in health care environments (such as electrosurgical equipment, defibrillator, cellular phones, mobile two-way radios, electrical appliances, and high-definition television), it is possible that high levels of such interference due to close proximity or strength of a source may affect defibrillator/monitor operation.

⚠ WARNING	**The defibrillator/monitor is designed for use in environments in which the signal can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the defibrillator/monitor may not seem to operate correctly.**

The defibrillator/monitor disruption may be indicated by erratic readings, cessation of operation, or other incorrect functioning. If this occurs, survey the site to determine the source of this disruption. Try the following actions to see if they eliminate the disruption:

- Turn equipment in the vicinity off and on to isolate the offending equipment.
- Reorient or relocate the interfering equipment.
- Increase the separation between the interfering equipment and this equipment.

The defibrillator/monitor generates, uses, and can radiate radio frequency energy. If the defibrillator/monitor is not installed and used in accordance with these instructions, the defibrillator/monitor may cause harmful interference with other devices in the vicinity.
If assistance is required, contact your local supplier.

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FACTORY DEFAULTS

General

The defibrillator/monitor is shipped with factory default settings. Authorized personnel can use the procedures described in the service manual to change default settings.

Parameter Ranges and Default Settings

Table 38. Parameter ranges and factory defaults

Parameter	Ranges/Selections	Factory Defaults
ECG		
ECG Waveform Grid	On, Off	Off
ECG Sweep Speed	12.5, 25.0, 50.0 mm/s	25.0 mm/s
ECG Size	Auto, 5.0, 10.0, 15.0, 20.0, 30.0, 40.0 mm/mV	10.0 mm/mV
ECG Pacer Pulse Detection	On, Off	Off
ST Level Measurement Position	60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80 ms	70 ms
ECG Filter Mode	0.05 - 150, 0.05 - 40, 0.5 - 40, 0.5 - 30 , 1 - 21 Hz	1 - 21 Hz
HR/PR Source	Auto, HR, PR	Auto
Asystole Time	3, 4, 5, 6, 7, 8, 9, 10 sec	5 sec
HR/PR Upper Alarm Limits	25 to 300 BPM (5 BPM step)	Adult: 120 BPM Pediatric: 160 BPM Neonatal: 200 BPM
HR/PR Lower Alarm Limits	20 to 295 BPM (5 BPM step)	Adult: 50 BPM Pediatric: 70 BPM Neonatal: 100 BPM
HR/PR Limit Alarm Audio Off	On, Off	On
Respiration		
Respiration Sweep Speed	6.25, 12.5, 25.0 mm/s	6.25 mm/s
Respiration Size	Auto, 5.0, 10.0, 15.0, 20.0 mm/Ω	10.0 mm/Ω
Respiration Apnea time	10, 15, 20, 25, 30, 35, 40 sec	20 sec
RR Upper Alarm Limits	4 to 150 /min (1 /min step)	Adult: 30 /min Pediatric: 40 /min Neonatal: 65 /min
RR Lower Alarm Limits	3 to 149 /min (1 /min step)	Adult: 5 /min Pediatric: 10 /min Neonatal: 65 /min
RR Limit Alarm Audio Off	On, Off	On
SpO_2		
SpO_2 Sweep Speed	12.5, 25.0, 50.0 mm/s	25.0 mm/s
SatSeconds	Off, 10, 25, 50, 100	Off
%SpO_2 Upper Alarm Limits	21 to 100 % (1 % step)	100 %
%SpO_2 Lower Alarm Limits	20 to 99 % (1 % step)	Adult/Pediatric: 90 % Neonatal: 85 %
%SpO_2 Limit Alarm Audio Off	On, Off	On
Others		
Patient Type	Adult, Pediatric	Adult
Display Patient Information	ID, Name, None	ID
Pacer pulse detection	On, Off	Off

Parameter	Ranges/Selections	Factory Defaults
Brightness	1, 2, 3, 4, 5	3
Menu Timeout	Off, 10, 20, 30 sec	10 sec
Color Filter	Full color, Grayscale	Full color
ECG Color	Color 1, Color 2, Color 3, Color 4, Color 5, Color 6, Color 7, Color 8, Color 9, Color 10, Color 11, Color 12, Color 13, Color 14, Color 15, Color 16, Color 17	Color 1
Respiration Color	Color 1, Color 2, Color 3, Color 4, Color 5, Color 6, Color 7, Color 8, Color 9, Color 10, Color 11, Color 12, Color 13, Color 14, Color 15, Color 16, Color 17	Color 4
SpO_2 Color	Color 1, Color 2, Color 3, Color 4, Color 5, Color 6, Color 7, Color 8, Color 9, Color 10, Color 11, Color 12, Color 13, Color 14, Color 15, Color 16, Color 17	Color 2
Alarm Volume	1, 2, 3, 4, 5	3
HR/PR Tone Volume	Off, 1, 2, 3, 4, 5	3
Key Beep Volume	Off, 1, 2, 3, 4, 5	3
Defibrillator Sound Volume	1, 2, 3, 4, 5	3
Voice Prompt Volume	1, 2, 3, 4, 5	3
Other Sound Volume	Off, 1, 2, 3, 4, 5	4
ECG 4mV	On, Off	Off
Waveform 1	Pads, I, II, III, aVR, aVL, aVF, V	I
Waveform 2	Pads, I, II, III, aVR, aVL, aVF, V, Respiration, SpO_2	SpO_2
Waveform 3	Pads, I, II, III, aVR, aVL, aVF, V, Respiration, SpO_2	Respiration
Alarm Limit Display	On, Off	Off
Print On Shock Delivery	On, Off	Off
Print On Shock Decision	On, Off	Off
Print On Pacing Output	On, Off	Off
Print On Alarm	On, Off	Off
Print On Mark Event	On, Off	Off
Print On Self-test	On, Off	On
Printing Speed	25 mm/s, 50 mm/s	25 mm/s
Printing Time	10, 20 sec, Continuous	20 sec
Power On Default*	Back up, Custom, Factory Default	Back up
Date Format*	YYYY/MM/DD, MM/DD/YYYY, DD/MM/YYYY	YYYY/MM/DD
Language*	English, Korean, Turkish, Russian, French, Polish, Spanish, Italian, Romanian, Czech, Hungarian, Portuguese, Greek, German	English
Demo mode*	On, Off	Off
AC Line Filter*	Off, 50, 60, 50 + 60 Hz	50 Hz + 60 Hz
Respiration Measurement*	On, Off	On
Manual Mode Access*	Direct, Confirm, Passcode	Direct
Pacing mode Access*	Direct, Confirm, Passcode	Direct
Audio Alarm Pause/Off Period*	Off, 1, 3, 5, 10, 20, 30, 60 min, Indefinite	Indefinite
Audio Alarm Acknowledged Period*	30, 60, 90, 120 sec	60 sec
Audio Alarm Reminder*	Off, 3, 10 min	3 min
High Priority Audio Alarm Interval*	2.5, 3, 9, 15 sec	9 sec

Parameter	Ranges/Selections	Factory Defaults
Medium Priority Audio Alarm Interval*	3, 15, 30 sec	15 sec
Low Priority Audio Alarm Interval*	15, 30, 60 sec	30 sec
Manual Mode - Display parameters*	On, Off	Off
Manual Mode - Time To Auto Disarm*	20, 60 sec	60 sec
Sync After Shock Delivery*	On, Off	Off
Manual Mode – Contact Indicator*	On, Off	On
Paddles Open Circuit Display*	On, Off	Off
Default Energy (Adult) *	100, 125, 150, 175, 200 J	125 J
Default Energy (Pediatric) *	10, 15, 20, 30, 40, 50, 75, 100 J	30 J
Advisory Mode - Time To Auto Disarm*	20, 60 sec	20 sec
Auto Charging*	On, Off	On
Continuous Mode*	On, Off	On
Voice Prompt*	On, Off	On
Advisory Mode - Energy Escalation*	On, Off	On
Advisory Mode - Energy 1 (Adult) *	100, 125, 150, 175, 200 J	125 J
Advisory Mode - Energy 2 (Adult) *	100, 125, 150, 175, 200 J	150 J
Advisory Mode - Energy 3 (Adult) *	100, 125, 150, 175, 200 J	200 J
Advisory Mode - Energy 1 (Pediatric) *	10, 15, 20, 30, 40, 50, 75, 100 J	30 J
Advisory Mode - Energy 2 (Pediatric) *	10, 15, 20, 30, 40, 50, 75, 100 J	40 J
Advisory Mode - Energy 3 (Pediatric) *	10, 15, 20, 30, 40, 50, 75, 100 J	50 J
AED Mode - Time To Auto Disarm*	20, 60 sec	60 sec
AED Mode - Display parameters*	On, Off	Off
CPR First*	On, Off	Off
AED Mode – Contact Indicator*	On, Off	On
AED Mode - Energy Escalation*	On, Off	On
AED Mode - Energy 1 (Adult) *	100, 125, 150, 175, 200 J	125 J
AED Mode - Energy 2 (Adult) *	100, 125, 150, 175, 200 J	150 J
AED Mode - Energy 3 (Adult) *	100, 125, 150, 175, 200 J	200 J
AED Mode - Energy 1 (Pediatric) *	10, 15, 20, 30, 40, 50, 75, 100 J	30 J
AED Mode - Energy 2 (Pediatric) *	10, 15, 20, 30, 40, 50, 75, 100 J	40 J
AED Mode - Energy 3 (Pediatric) *	10, 15, 20, 30, 40, 50, 75, 100 J	50 J
CPR Metronome Sound*	On, Off	On
Compression Rate*	100, 105, 110, 115, 120 CPM	100 CPM
Adult Compression-To-	Compression only, 30:2, 15:2	30:2

Parameter	Ranges/Selections	Factory Defaults
Ventilation Ratio*		
Adult CPR Time*	60, 90, 120, 150, 180 sec	120 sec
Adult CPR Set*	3, 4, 5, 6, 7 cycles	5 cycles
Pediatric Compression-To-Ventilation Ratio*	Compression only, 30:2, 15:2	30:2
Pediatric CPR Time*	60, 90, 120, 150, 180 sec	120 sec
Pediatric CPR Set*	3, 4, 5, 6, 7, 8, 9, 10 cycles	5 cycles
Default Pacing Mode*	Demand mode, Fixed mode	Demand mode
Default Pacing Rate*	30 ~ 180 ppm	70 ppm
Pacing Current Step*	2, 5 mA	5 mA
Auto Self-test Time*	0 ~ 23 o'clock	0 o'clock
Auto Self-test Interval*	Off ,24, 48, 72 hours	24 hours
Internal Shock Energy*	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 40, 50 J	10 J
Note: An asterisk (*) by a parameter in the above table indicates that the parameter can only be changed by authorized personnel as described in the service manual		

SPECIFICATION

Display

Screen Size	7’ TFT-LCD screen
Screen Type	Liquid Crystal Display (LCD) Color
Resolution	800 x 480 pixel
Number of Traces	3 waveforms
Language	English, Korean, Turkish, Russian, French, Polish, Spanish, Italian, Romanian, Czech, Hungarian, Portuguese, Greek, German

Controls

Standard	Multi function knob; Mode selection knob (Power Off, AED, Manual, Monitor and Pacing); 12 buttons (Paddle Energy Level(+, -), Patient type, ECG Lead, ECG Size, Print, Energy Level, Charge, Analyze, Shock, Sync, Event and Alarm button), 4 Soft key (Refer to the soft key section)

Alarms

Categories	Patient Status and System Status
Priorities	Low, Medium and High Priorities
Notification	Audible and Visual
Setting	Default and Individual
Alarm Volume Level	45 to 85 dB
Distributed Alarm System Delay	Less than 3 sec.

Physical Characteristics and Printer

Instrument		
Dimensions	310 x 220 x 215 mm (W x H x D)	
Weight	5.5kg	
Degree of Protection against Electric Shock	ECG:	Type CF with defibrillator protection
	SpO_2:	Type CF with defibrillator protection
	External Paddle:	Type BF with defibrillator protection
	Pads:	Type BF with defibrillator protection
Mode of Operation	Continuous	
Printer		
Type	Thermal	
Weight	150g (without the printer paper)	
Resolution	8 dot/mm	
Number of Channels	1 to 3 channels	
Paper Type	Thermal	
Paper Width	50 mm	
Printer Speed	25 mm/sec, 50 mm/sec	

Electrical

Instrument	
Power Requirements	AC Mains 100 - 240Vac, 50/60Hz, 140 - 130VA DC Mains 19Vdc, 8A Used with Cradle/External AC adaptor (Cradle/External AC adaptor: Input:100 - 240Vac, 50/60Hz, 140 - 130VA, Output: 19Vdc, 8A) 18V, 7A Used with Cradle/External DC adaptor) (Cradle/External DC adaptor: Input:12 - 16Vdc, 12A, Output: 18V, 7A)
Note: For 120 Volt applications, use only UL Listed detachable power cord with NEMA configuration 5-15P type (parallel blades) plug cap. For 240 Volt applications use only UL Listed Detachable power supply cord with NEMA configuration 6-15P type (tandem blades) plug cap.	
Battery (option)	
Type	Li-ion battery
Dimension	144.70 x 91.60 x 27.40 mm (W x H x D)
Voltage/Capacity	4S2P 14.4V/6800mAh
Discharge	A minimum of 200 shocks at 200 Joules (per battery)
Operating time	5 hours (per battery) in Monitor mode or 2 hours monitoring operation in Pacing mode (pacing rate: 80 ppm, pacing output: 60mA, load resistance: 50Ω) *At the following condition:* *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: 25°C*
Recharge	Over 8 hours with defibrillator/monitor turned on Over 5 hours with turned off (It would take about hours to fully charge the battery from the moment that low battery alarm is activated.)
Life Cycle	6 months, new battery fully-charged (- The battery life cycle may vary with the number of recharging, operating temperature, and storage condition. Typically, about 80% capacity of battery may remain after 300 cycles of recharge. If one cycle of recharging would be about 2 or 3 days, the life cycle of the battery is about 24 months. - After 2 months storage the defibrillator/monitor would run for 50% of stated battery life.
Note: The battery will not be charged for safety if the operating temperature exceeds 40°C.	

Environmental Conditions

Operation	
Temperature	0 to 45°C (32 to 113°F)
Humidity	5 to 95% RH, non-condensing
Atmospheric pressure	583.28 ~ 1013.25 hpa (0 ~ 4,575m at 25℃)
Note: The system may not meet its performance specifications if stored or used outside the specified temperature and humidity range.	
Note: The battery will not be charged for safety if the operating temperature exceeds 40°C.	
Shipping and Storage (in shipping container)	
Temperature	-20℃~60℃ (-4℉~140℉)
Humidity	5 ~ 95% RH, non-condensing
Atmospheric pressure	200.36 ~ 1013.25 hpa (0 ~ 12,192m at 25℃)
Note: The system may not meet its performance specifications if stored or used outside the specified temperature and humidity range.	

Tone Definition

High Priority Alarm Tone	
Volume level	Adjustable (level 1~5)
Pitch (± 48.8Hz)	540 Hz
Pulse width (± 10msec)	250 msec
Number of pulses	10 pulses per sec, 10 sec inter burst
Repetitions	Continually
Medium Priority Alarm Tone	
Volume level	Adjustable (level 1~5)
Pitch (± 34.85Hz)	480 Hz
Pulse width (± 10msec)	270 msec
Number of pulses	3 pulses per sec, 15 sec inter burst
Repetitions	Continually
Low Priority Alarm Tone	
Volume level	Adjustable (level 1~5)
Pitch (± 9.4Hz)	400 Hz
Pulse width (± 10msec)	270 msec
Number of pulses	1 pulse per 0.25 sec, 30 sec inter burst
Alarm Reminder Tone	
Volume level	Adjustable (level 1~5)
Pitch (± 40Hz)	800 Hz
Pulse width (± 10msec)	200 msec
Number of pulses	1 pulse per sec, 3 min, 10 min inter burst
Repetitions	Continually
HR/PR Tone	
Volume level	Adjustable (Off, level 1~5)
Pitch (± 32.5Hz)	650 Hz (ECG) 158 to 662 Hz (SpO_2)
Pulse width (± 5msec)	100 msec
Number of pulses	N/A

Repetitions	No repeat
Key Beep	
Volume level	Adjustable (Off, level 1~5)
Pitch	440 (± 22) Hz (valid) 168 (± 8.4)Hz (invalid)
Pulse width (± 5msec)	110 msec
Number of pulses	N/A
Repetitions	No repeat

Measurement Parameters

Pacing Mode

Pacing Mode	
Pacing rate	Variable from 30 bpm(ppm) to 180 bpm(ppm) ± 1.5% (increments or decrements by a value of 2 bpm(ppm))
Accuracy	± 1.5 %
Output current	0 mA to 140 mA
Resolution	2 mA
Accuracy	± 5% or 5 mA, whichever is greater.
Pulse Type	40 ms constant current pulse
Pulse Amplitude	40 ms ±2 ms
*Output current can be low because of impedance difference according to pad attach or patient status.	

Defibrillator

AED mode	
Patient Impedance	25 ~ 175 Ohm
Heart Rate	20 to 300 BPM
Accuracy	±1 BPM or ±1%, whichever is greater
Detection	Ventricular Fibrillation at a amplitude greater than or equal to 0.2mV, Ventricular Tachycardia at a heart rate greater than or equal to 150 bpm (Adult) Ventricular Tachycardia at a heart rate greater than or equal to 180 bpm (Pediatric)
Shock Analysis Time	< 10 seconds typical *Note: Shock analysis time will take up to 20 seconds if the signal is disturbed by movement and etc.*
Charging Time to 200J*	Within 6 seconds with rated AC/DC voltage Within 7 seconds with fully charged battery
*Charging time for other cases, refer to defibrillator (technical specification)	
Manual Mode	
Shock Energy Level	Adult: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 40, 50, 75, 100, 125, 150, 175, 200 J Pediatric: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 40, 50, 75, 100 J
Automatic Discharge Time	20, 60 seconds
Charging Time to 200J*	Within 6 seconds with rated AC/DC voltage Within 7 seconds with fully charged battery
*Charging time for other cases, refer to defibrillator (technical specification)	

ECG

Heart Rate	
Measurement Range	0, 20 to 300 BPM 3.2
Resolution	1 BPM
Accuracy	±1 BPM or ±1%, whichever is greater
Maximum Response Time	10 seconds (For all measurement ranges)
ECG (Electrocardiograph)	
Leads 3.1	3 Lead: Lead I, II, III 5 Lead: Lead I, II, III, aVR, aVL, aVF, V
Lead Off Detection	Detected and displayed
Input	
Input Impedance	2.5 M ohm or more (for 0.05 to 40 Hz, with lead cable and relay cable)
Input Dynamic Range	±5 mV AC, ±300 mV DC
Voltage Range	±0.3 mV ~ ±5 mV
Signal Width	±5 mV
Signal Saturation Range	±800 mV DC or more
Lead fail detection	Yes
Output	
Filter mode	
Interpretation	0.05 to 150 Hz
Low	0.05 to 40 Hz
Med	0.5 to 40 Hz
High	0.5 to 30 Hz
Hum filter	50 Hz and 60 Hz (None or 60 dB or more)
ECG Size 3.3	Auto, 5.0, 10.0, 15.0, 20.0, 30.0, 40.0 mm/mV
ECG (Arrhythmia Supplemental Information as required by AAMI EC13)	
Respiration, leads-off sensing, and active noise suppression	Lead off sensing current : Maximum DC 24nA
Tall T-wave rejection capability	Maximum T-Wave amplitude 1.8 mV
Accuracy of input signal reproduction	Displacement: 0.1 mV, Slope: 0.1 mV/s
Heart rate meter accuracy and response to irregular rhythm	Provides correct heart rates, as follows: Ventricular bigeminy: 79 ~ 82 BPM Slow alternating ventricular bigeminy: 60 ~ 62 BPM Rapid alternating ventricular bigeminy: 120 BPM Bidirectional systoles: 90 BPM
Response time of heart rate meter to change in heart rate	HR change from 80 to 120 BPM: 8.78 sec HR change from 80 to 40 BPM: 9.77 sec
Time to alarm for tachycardia 2.5.2	Vent Tachycardia 1 mVpp, 206 BPM: Amplitude 0.5 mV: 3.88 sec Amplitude 1 mV: 11.95 sec Amplitude 2 mV: 6.05 sec Vent Tachycardia 2 mVpp, 195 BPM: Amplitude 1 mV: 8.23 sec Amplitude 2 mV: 6.13 sec Amplitude 4 mV: 4.17 sec
Time to alarm for heart rate alarm conditions	Fast ECG

Pacemaker pulse rejection capability	Rejection of pacemaker pulses with amplitudes from ±2mV to ±700mV with pulse widths of 0.1 to 2msec, Overshoot time constant 4 ms, Test method B (with overshoot)
ECG (Miscellany)	
CMRR	90 dB or more
Defibrillator Discharge Recovery	<5 sec per IEC60601-2-27
Pacer Pulse Detection	On, Off (Detect pacer pulses of ±2mV ~ ±700mV with pulse width of 0.1 to 2.0 msec)
Rhythm Analysis	Bradycardia, Normal, Tachycardia
ST Level	
Range	-2 ~ 2 mV
Accuracy	±15% or ±0.05 mV (whichever is greater)
Resolution	0.01 mV

Respiration

IM Respiration	
Technique	Thoracic Impedance Measurement
Carrier Frequency	64 kHz
Current	≤100μA
Range	0 ~ 150 /min
Resolution	1 BPM
Accuracy	±3 BPM
Input	
Base Impedance	500 ~ 2000 ohm
Delta Impedance	≥3 ohm
Respiration Detection	≥0.3 ohm
Lead Off Detection	Yes
Output	
Waveform Size	Auto, 5.0, 10.0, 15.0, 20.0 mm/ohm

SpO_2

Pulse Rate	
Range	*Mediana module:* 30 to 300 BPM *Medtronic module:* 20 to 300 BPM
Accuracy	*Mediana module:* ±2 % or ±2 BPM (whichever is greater) *Medtronic module:* ±3 digits (at 20 ~ 250 BPM, Adult/Pediatric/Neonatal) ±3 digits (at 20 ~ 250 BPM, Low Perfusion) ±5 digits (at 20 ~ 250 BPM, Adult/Pediatric/Neonatal with Motion)
SpO_2	
Range	*Mediana module:* 0 to 100 % *Medtronic module:* 1 to 100 %
Accuracy	*Mediana module:* Adult/Pediatric/Neonatal ±2 digits (at 70 to 100 %) (less than 70% is unspecified) *Medtronic module:*

	Adult/Pediatric/Neonatal	±2 digits (at 70 to 100 %)
	Adult/Pediatric/Neonate Low Saturation	±3 digits (at 60 to 80 %)
	Low Perfusion	±2 digits (at 70 to 100 %)
	Adult/Pediatric/Neonate with Motion	±3 digits (at 70 to 100 %)

Note: The wavelength range of the light emitted are near 660 nm and 890 nm with the energy not exceeding 15mW.

Note: SpO_2 saturation accuracy - Monitoring system measurements are statistically distributed; about two-thirds of monitoring system measurements can be expected to fall in this accuracy (ARMS) range. Reference the Clinical Studies section for test results. For a complete listing of SpO_2 accuracy across the full line of available Medtronic™ sensors, contact Medtronic, a local Medtronic representative, or locate it online at www.medtronic.com.

Note: Specification applies to monitoring system performance. Reading accuracy in the presence of low perfusion (detected IR pulse modulation amplitude 0.03% - 1.5%) was validated using signals supplied by a patient simulator. SpO_2 and pulse rate values were varied across the monitoring range over a range of weak signal conditions and compared to the known true saturation and pulse rate of the input signals.

Event/Trend

Type	Event, Trends
Data storage	Internal memory, SD card
Memory	Event saves total 250 data saves defibrillation shock information (number of shock, energy level, actual passed energy, impedance) saves pacing information (pace rate, pace current, async mode) saves clinical action list saves 1 channel ECG waveform saves Event date and time saves HR/PR, SpO_2, RESP numeric data saves alarm condition Trend saves total 5,000 data saves date and time saves HR/PR, SpO_2, RESP numeric data saves alarm condition

Defibrillator (Technical Specification)

AED Mode

<table>
<tr><th colspan="3">AED Mode</th></tr>
<tr><td rowspan="4">Charging Time - 200J</td><td>Charging condition</td><td>Time (sec)</td></tr>
<tr><td>With Rated Mains Voltage</td><td>5.8</td></tr>
<tr><td>With DC Mains Voltage</td><td>5.8</td></tr>
<tr><td>With fully charged battery</td><td>6.4</td></tr>
<tr><td rowspan="10">Charging Time - 200J (including time from the initiation of rhythm analysis with a clear ECG signal to readiness for discharge.)</td><td>Charging condition</td><td>Time (sec)</td></tr>
<tr><td>With Rated Mains Voltage</td><td>17.9</td></tr>
<tr><td>With DC Mains Voltage</td><td>17.9</td></tr>
<tr><td>With fully charged battery</td><td>18.6</td></tr>
<tr><td>With Mains Voltage of 90% of the Rated value</td><td>17.4</td></tr>
<tr><td>With DC Mains Voltage of 90% of the Rated value</td><td>17.4</td></tr>
<tr><td>After 15 maximum energy discharges taken from a new fully charged battery</td><td>18.5</td></tr>
<tr><td>With Mains Voltage of 90% of the Rated value, but measured from initially switching power on to ready for discharge at maximum energy</td><td>23.6</td></tr>
<tr><td>With DC Mains Voltage of 90% of the Rated value, but measured from initially switching power on to ready for discharge at maximum energy</td><td>23.6</td></tr>
<tr><td>After 15 maximum energy discharges taken from a new fully charged battery, but measured from initially switching power on to ready for discharge at maximum energy</td><td>24.5</td></tr>
<tr><td colspan="3">Note: A used battery normally takes more time than the charging time specified in above.</td></tr>
</table>

Manual Mode

Manual Mode		
Charging Time – 200J	Charging condition	Time (sec)
	With Rated Mains Voltage	5.8
	With DC Mains Voltage	5.8
	With fully charged battery	6.4
	With Mains Voltage of 90% of the Rated value	5.8
	With DC Mains Voltage of 90% of the Rated value	5.8
	After 15 maximum energy discharges taken from a new fully charged battery	6.8
	With Mains Voltage of 90% of the Rated value, but measured from initially switching power on to ready for discharge at maximum energy	11.7
	With DC Mains Voltage of 90% of the Rated value, but measured from initially switching power on to ready for discharge at maximum energy	11.7
	After 15 maximum energy discharges taken from a new fully charged battery, but measured from initially switching power on to ready for discharge at maximum energy	12.7
	Note: A used battery normally takes more time than the charging time specified in above.	

ECG Analysis Accuracy

Table 39. ECG analysis algorithm accuracy: Adult

Rhythm	Sample no.	Objective	Observed specification	90% one-sided confidence error limit
Defibrillation enable				
Rough VF	291	> 90% Sensitivity	Meet IEC 60601-2-4 requirements and AHA recommendations	> 92.99%
Fast VT	90	> 75% Sensitivity	Meet IEC 60601-2-4 requirements and AHA recommendations	> 90.12%
Defibrillation disable				
NSR	2043	> 99% Specificity	Meet IEC 60601-2-4 requirements and AHA recommendations	> 99.11%
Asystole	121	> 95% Specificity	Meet IEC 60601-2-4 requirements and AHA recommendations	> 92.60%
Other rhythm	837	> 95% Specificity	Meet IEC 60601-2-4 requirements and AHA recommendations	> 98.13%

Table 40. ECG analysis algorithm accuracy: Pediatric

Rhythm	Sample no.	Objective	Observed specification	90% one-sided confidence error limit
Defibrillation enable				
Rough VF	18	> 90% Sensitivity	Meet IEC 60601-2-4 requirements and AHA recommendations	> 86.67%
Fast VT	33	> 75% Sensitivity	Meet IEC 60601-2-4 requirements and AHA recommendations	> 91.32%
Defibrillation disable				
NSR	265	> 99% Specificity	Meet IEC 60601-2-4 requirements and AHA recommendations	> 98.88%
Asystole	0	N/A	N/A	N/A
Other rhythm	391	> 95% Specificity	Meet IEC 60601-2-4 requirements and AHA recommendations	> 96.34%

Database for ECG Analysis

- AHA DB, MIT-BIH DB, CU DB, VF DB, EUROPEAN ST-T DB

ECG rhythm to determine if a shock is appropriate

- Ventricular Fibrillation at a amplitude greater than or equal to 0.2mV
- For adult, Ventricular Tachycardia at a heart rate greater than or equal to 150 bpm
- For pediatric, Ventricular Tachycardia at a heart rate greater than or equal to 180 bpm

Reference

- Young KD, Lewis RJ: 'What is confidence? Part 2: Detailed definition and determination of confidence intervals.' Annals of Emergency Medicine, September 1997; 30; 311-218

- Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety. American Heart Association (AHA) Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy. Circulation. 1997: Vol. 95: 1677-1682.

Biphasic Waveform Characteristics

The efficiency of Mediana's Biphasic waveform has been clinically verified during a ventricular fibrillation (VF) and ventricular tachycardia (VT) defibrillation study. This study (which was conducted using D100 defibrillator/monitors) and the findings are described below.

Table 41. Delivered energy at every defibrillator settings into a range of loads

Selected Energy	Load							Accuracy
	25	50	75	100	125	150	175	
1	1.0	1.0	1.0	1.0	1.0	0.9	1.0	2J
2	2.1	2.2	2.1	2.2	2.1	2.1	2.1	2J
3	3.3	3.3	3.2	3.2	3.2	3.2	3.1	2J
4	4.4	4.4	4.3	4.3	4.2	4.2	4.2	2J
5	5.4	5.4	5.3	5.3	5.2	5.2	5.2	2J
6	6.5	6.5	6.4	6.4	6.2	6.3	6.3	2J
7	7.5	7.5	7.5	7.4	7.3	7.3	7.3	2J
8	8.6	8.6	8.5	8.4	8.3	8.4	8.4	2J
9	9.7	9.7	9.6	9.5	9.5	9.3	9.4	2J
10	10.7	10.7	10.7	10.6	10.5	10.5	10.5	2J
15	16.1	16.0	15.9	15.8	15.7	15.6	15.6	15%
20	21.3	21.3	21.0	20.9	20.8	20.8	20.9	15%
30	32.0	31.9	31.6	31.3	31.2	31.1	31.1	15%
40	42.7	42.5	41.9	41.8	41.6	41.4	41.6	15%
50	53.3	53.1	52.5	52.2	52.0	51.7	51.9	15%
75	79.8	79.6	78.5	77.8	77.6	77.6	77.7	15%
100	105.4	106.0	105.6	104.8	104.4	103.9	103.9	15%
125	131.7	132.2	131.9	130.8	130.4	129.9	129.8	15%
150	144.8	158.9	158.2	157.0	156.4	155.9	155.6	15%
175	167.6	185.1	183.0	182.8	182.3	181.5	181.3	15%
200	194.3	211.2	208.8	208.1	207.7	207.2	206.6	15%

2.1

Figure through show the biphasic waveforms that are produced when the defibrillator/monitor is discharged into loads of 25, 50, 75, 100, 125, 150 and 175 ohms at each energy setting (200, 175, 150, 125, 100, 75, 50, 40, 30, 20, 15, 10, 9, 8, 7, 6, 5, 4, 3, 2 and 1 joule[s]).
The vertical axis shows the voltage in volts (V); the horizontal axis shows the duration in milliseconds (ms).

PADS / External Paddle

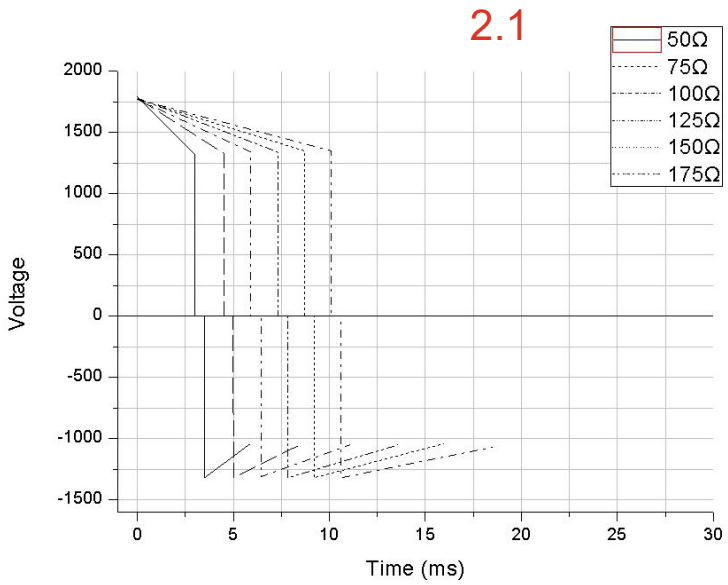

Figure 46. Biphasic waveforms at 200 joules

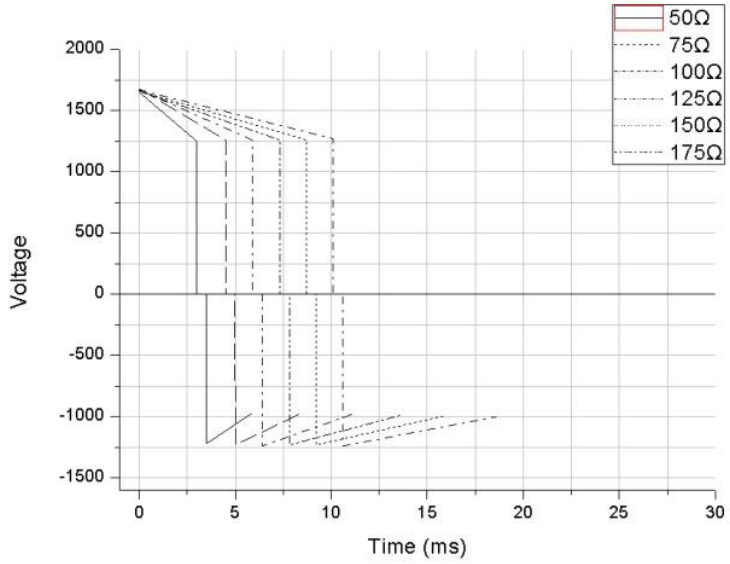

Figure 47. Biphasic waveforms at 175 joules

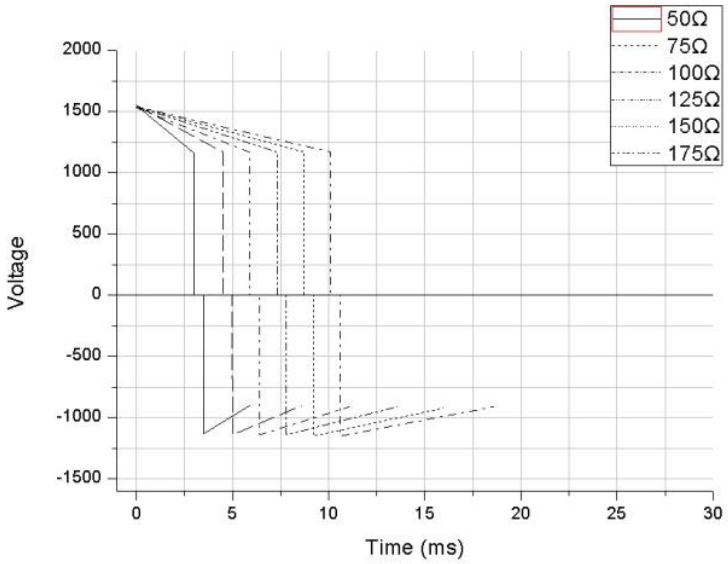

Figure 48. Biphasic waveforms at 150 joules

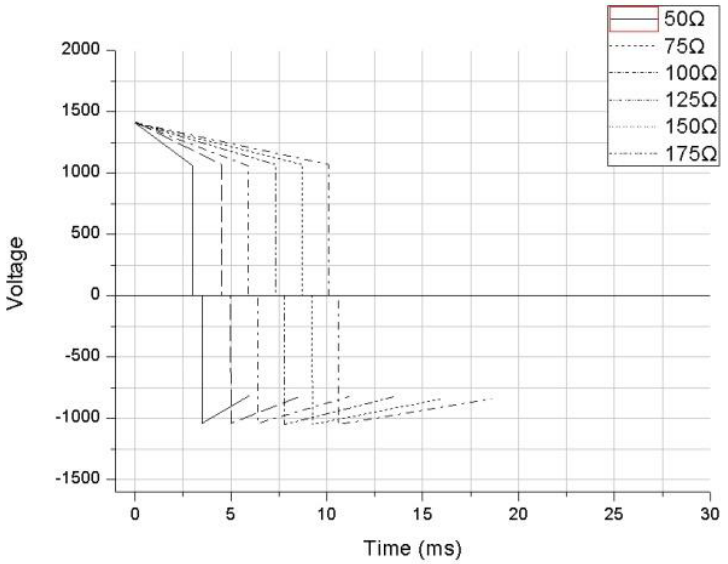

Figure 49. Biphasic waveforms at 125 joules

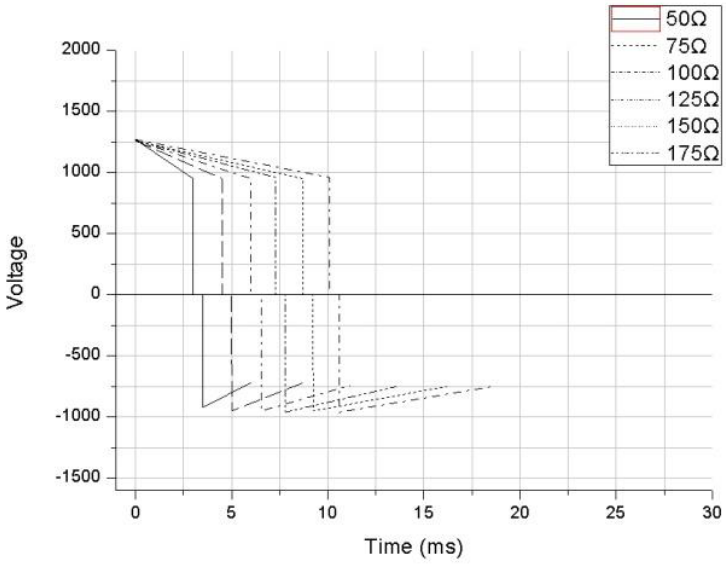

Figure 50. Biphasic waveforms at 100 joules

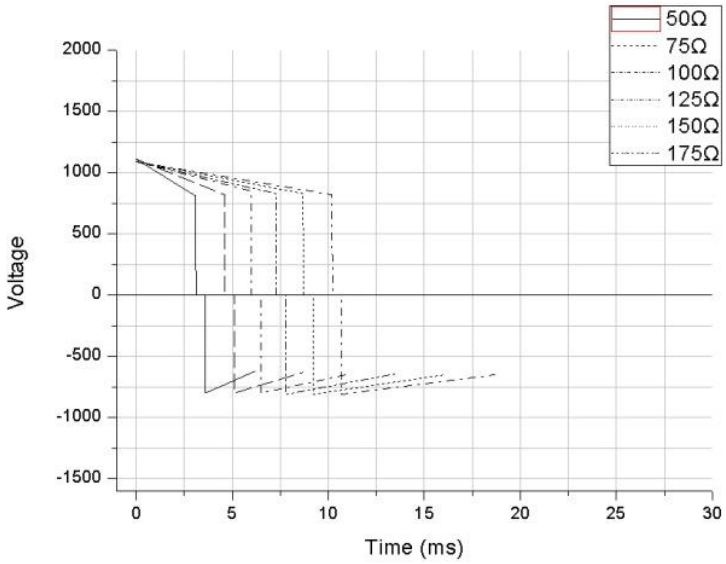

Figure 51. Biphasic waveforms at 75 joules

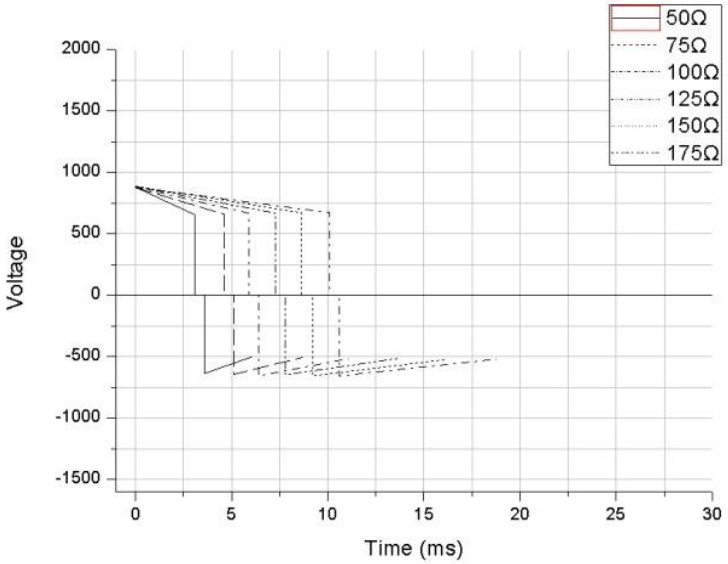

Figure 52. Biphasic waveforms at 50 joules

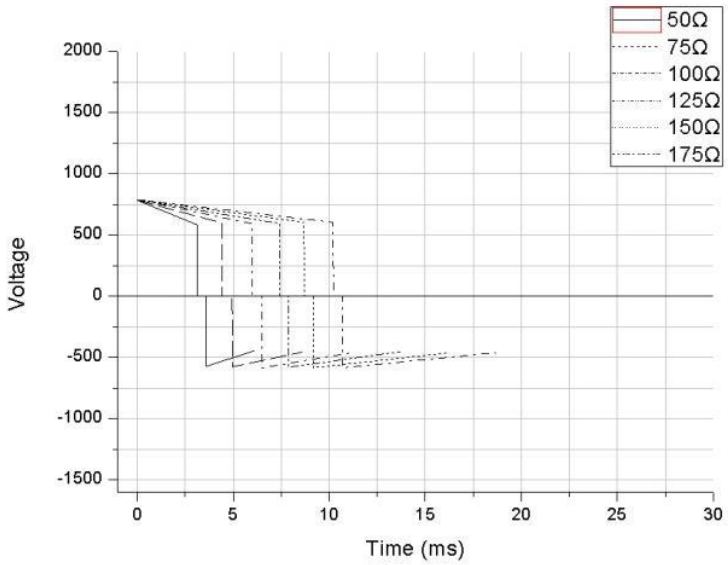

Figure 53. Biphasic waveforms at 40 joules

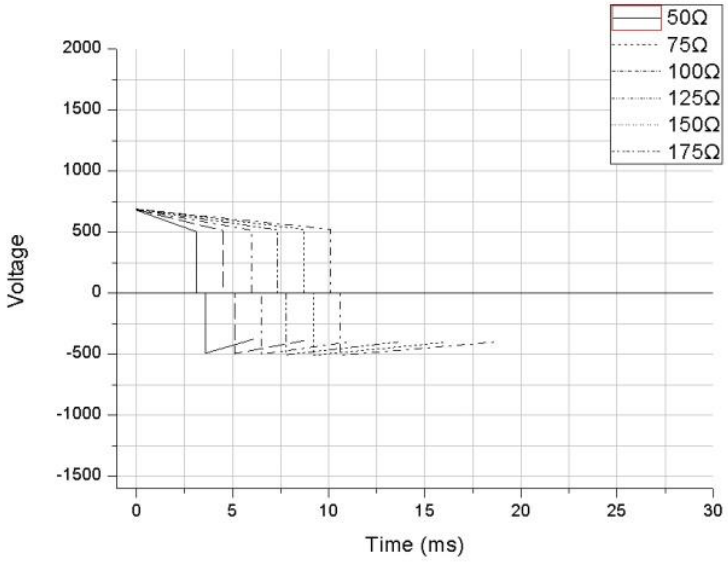

Figure 54. Biphasic waveforms at 30 joules

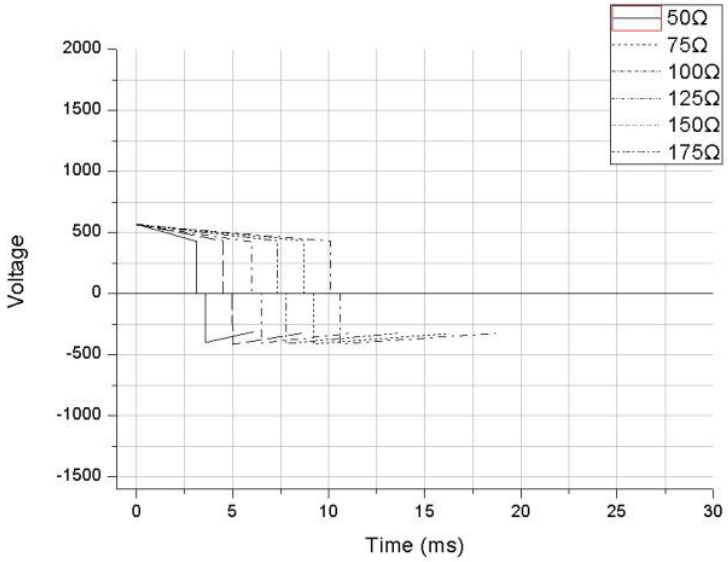

Figure 55. Biphasic waveforms at 20 joules

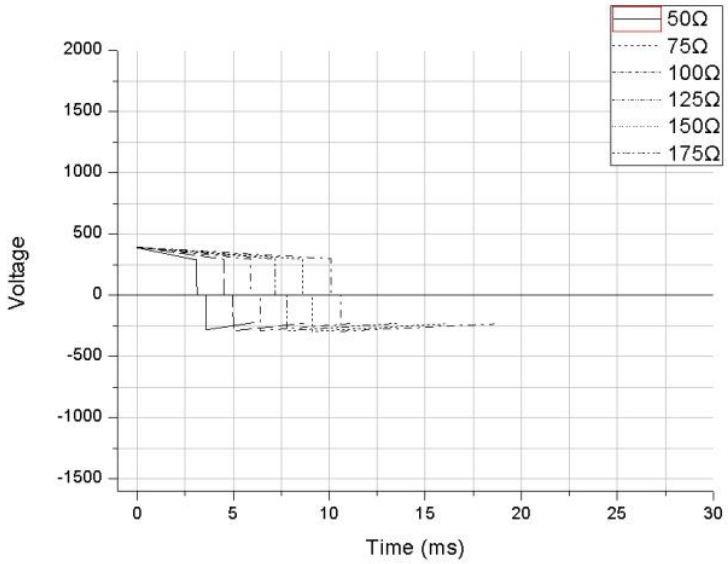

Figure 56. Biphasic waveforms at 10 joules

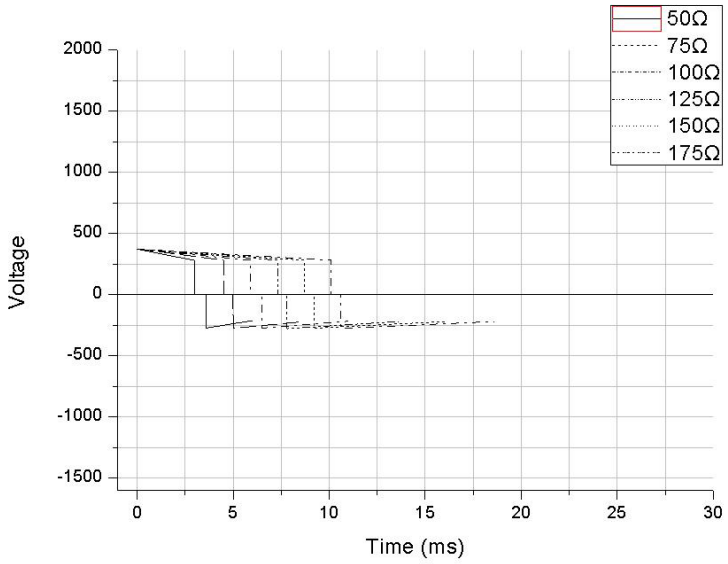

Figure 57. Biphasic waveforms at 9 joules

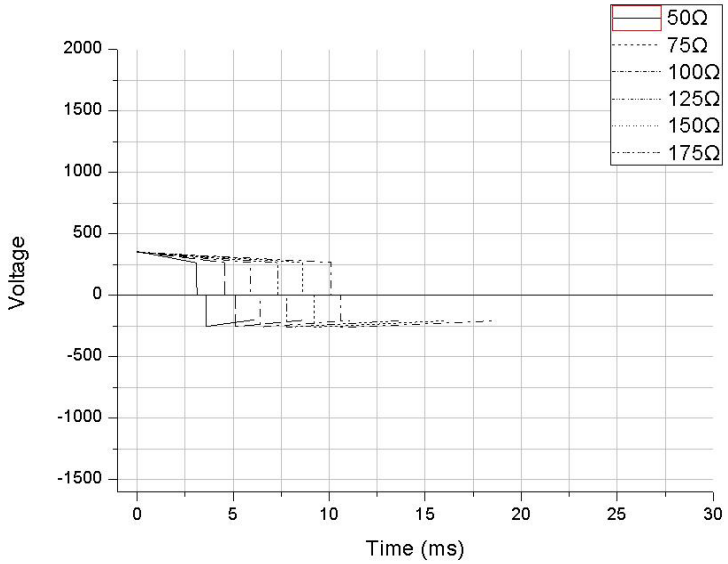

Figure 58. Biphasic waveforms at 8 joules

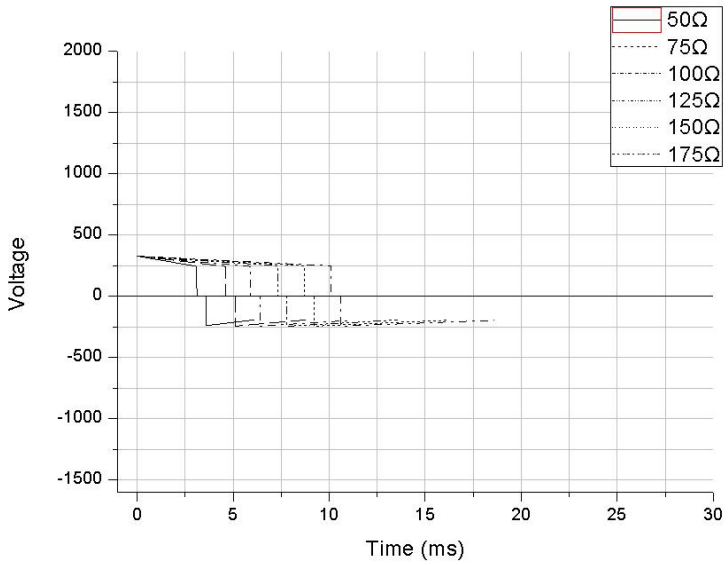

Figure 59. Biphasic waveforms at 7 joules

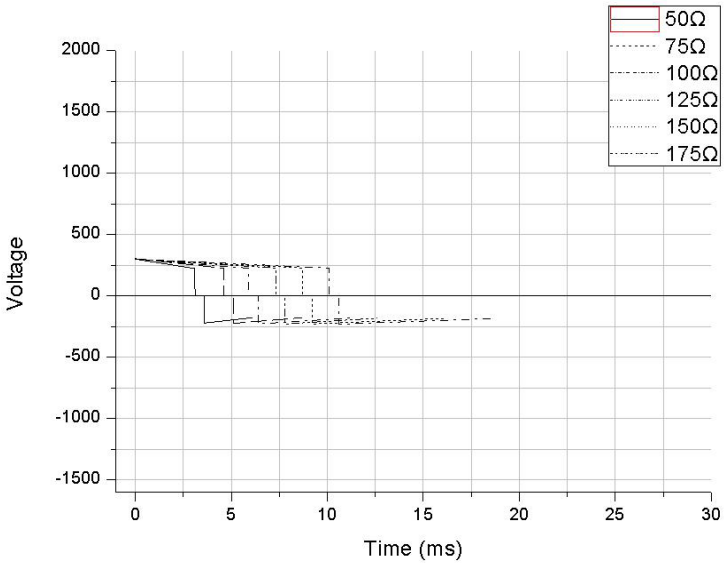

Figure 60. Biphasic waveforms at 6 joules

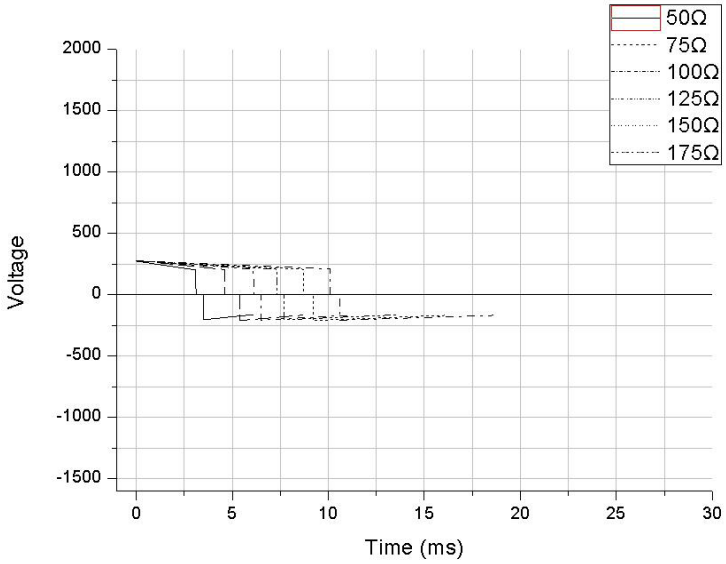

Figure 61. Biphasic waveforms at 5 joules

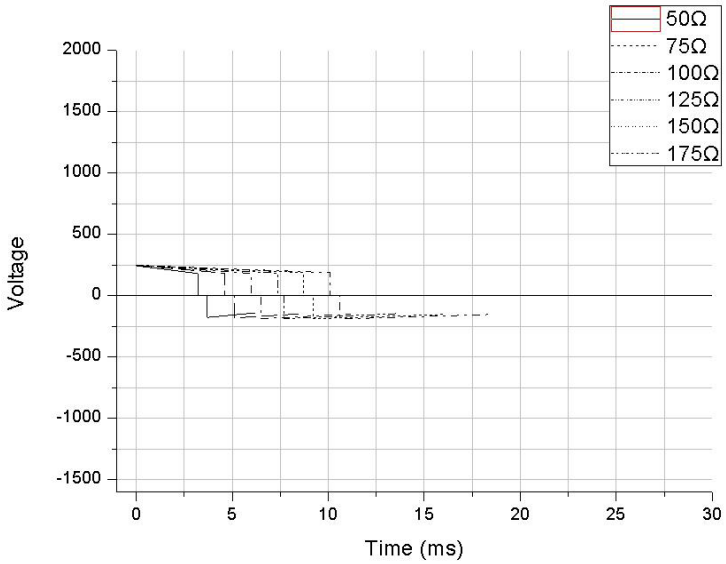

Figure 62. Biphasic waveforms at 4 joules

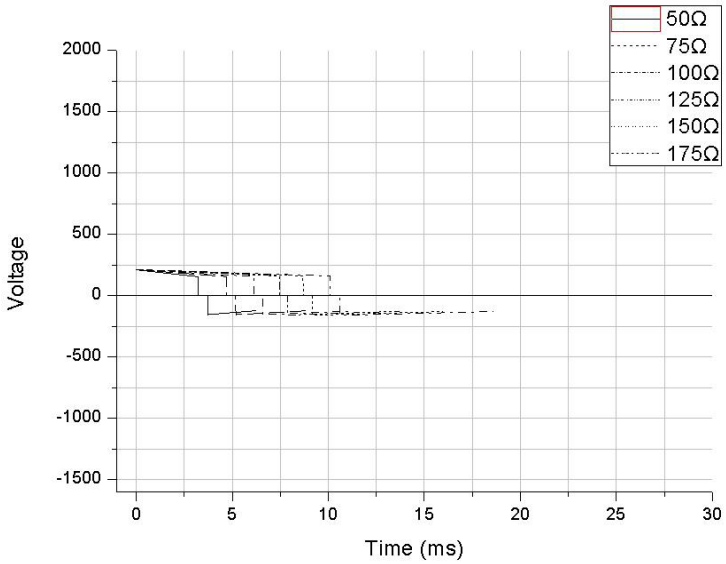

Figure 63. Biphasic waveforms at 3 joules

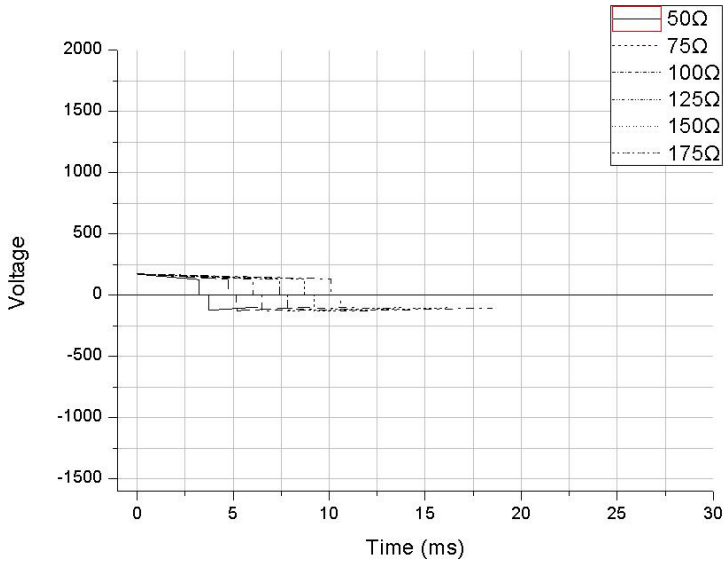

Figure 64. Biphasic waveforms at 2 joules

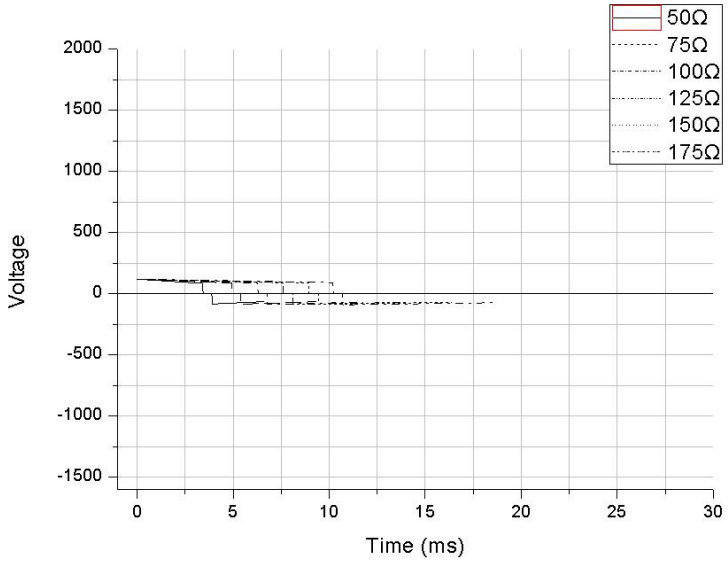

Figure 65. Biphasic waveforms at 1 joule

Compliance

Item	Standard	Description
Classification	IEC 60601-1:2005+AMD1:2012+AMD2:2020 EN 60601-1:2006+A1:2013	Class I (on AC power) Internally powered (on battery power)
Type of protection	IEC 60601-1:2005+AMD1:2012+AMD2:2020 EN 60601-1:2006+A1:2013	Type BF and Type CF – Applied part
Mode of operation	IEC 60601-1:2005+AMD1:2012+AMD2:2020 EN 60601-1:2006+A1:2013	Continuous
Degree of protection	IEC 60529:1989+A1:1999+A2:2013, EN 60529:1991+A1:2000 +A2:2013	IP44 (provided by enclosures) IP22 (provided by Cradle / External adaptor)
General	ISO 13485:2016	Quality systems - Medical Devices - Requirements for regulating purposes
	ISO 14971:2019, EN ISO14971:2019	Risk analysis managements – medical devices
	IEC 60601-1-6:2010+A1:2013 EN 60601-1-6:2010	Collateral standard for usability
	IEC 62366-1:2015, EN 62366-1:2010	Medical devices - Application of usability engineering to Medical devices
	IEC 80601-2-49:2018 EN 80601-2-49:2019	Particular requirements for multifunction patient monitoring equipment
	IEC 62304:2006+A1:2015 EN 62304:2006/AC:2008	Medical device software – Software life-cycle processes
Ambulatory	EN 1789:2007+A2:2014	Medical vehicles and their equipment – road ambulance
	IEC 60601-1-12:2014+A1:2020 EN 60601-1-12:2015	Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
Alarms	IEC 60601-1-8:2006+A1:2012+A2:2020 EN 60601-1-8:2007+A1:2013/AC:2014	Alarm systems requirements, tests and guidance in medical electrical equipments systems
Electrocardiograph	IEC 60601-2-27:2011, EN 60601-2-27:2014	Particular requirements for the safety of Electrocardiographic monitoring equipment
Oxygen saturation	ISO 80601-2-61:2017 EN ISO 80601-2-61: 2019	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

Item	Standard	Description
Defibrillator	IEC 60601-2-4:2010+A1:2018 EN 60601-2-4:2011+A1:2019	Safety of cardiac defibrillators
Electromagnetic compatibility	IEC 60601-1-2:2014+A1:2020 EN 60601-1-2:2015+A1:2021	Electromagnetic compatibility-requirements & test
Package	ISTA (Procedure 2A, 2011)	Pre-Shipment test procedures (Package)
Battery	IEC 62133-2:2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications

Manufacturer’s EMC Declaration

⚠ 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. The use of accessories, transducers, and cables other than those specified may result in increased emission and/or decreased immunity of the defibrillator/monitor.**
⚠ WARNING	**Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the D100, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**

The defibrillator/monitor is suitable for use in the specified electromagnetic environment. The customer and/or user of the defibrillator/monitor should assure that it is used in an electromagnetic environment as described below;

Table 42. Electromagnetic emissions (IEC60601-1-2)

Emission Test	Compliance	Electromagnetic Environment
RF emission CISPR 11	Group 1, Class B	The defibrillator/monitor is suitable for use in all establishments
Harmonic emissions IEC 61000-3-2	Class A	The defibrillator/monitor is suitable for use in all establishments.
Voltage fluctuations/flicker emission IEC 61000-3-3	Complies	The defibrillator/monitor is suitable for use in all establishments.

Table 43. Electromagnetic immunity (IEC60601-1-2)

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8, 15 kV air	±8 kV contact ±2, 4, 8, 15 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electric fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial and/or hospital environment
Surge IEC 61000-4-5	(Input Power Ports) ± 0.5, 1 kV differential mode ±0.5, 1, 2 kV common mode (Signal input/output) 2 kV common mode	(Input Power Ports) ± 0.5, 1 kV differential mode ±0.5, 1, 2 kV common mode (Signal input/output) 2 kV common mode	Mains power quality should be that of a typical commercial and/or hospital environment
Voltage dips, short interruptions and voltage variations on power supply	Voltage dips >95 % U T for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Voltage dips >95 % U T for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the defibrillator/monitor requires continued operation during

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
IEC 61000-4-11	Voltage dips >95 % U T for 1 cycle At 0°	Voltage dips >95 % U T for 1 cycle At 0°	power mains interruption, it is recommended that the defibrillator/monitor be powered from an uninterruptible power supply or battery.
	Voltage dips 30 % U T for 25/30 cycle At 0°	Voltage dips 30 % U T for 25/30 cycle At 0°	
	Voltage interruption >95 % U T for 250/300 cycle At 0°	Voltage interruption >95 % U T for 250/300 cycle At 0°	
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	It may be necessary to position the defibrillator/monitor further from the sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
Note: UT is the AC mains voltage prior to application of the test level.			

Table 44. Electromagnetic immunity (IEC60601-2-4)

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
The defibrillator/monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the defibrillator/monitor should assure that it is used in such an environment.			
Conducted RF IEC 61000-4-6	3 V RMS outside the ISM band 6 V RMS in the ISM and amateur radio bands 150 kHz to 80 MHz	3 Vrms 6 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the defibrillator/monitor including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. **Recommend separation distance** $d = 1.2\sqrt{p}$ $d = 0.6\sqrt{p}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz (80 % AM at 2 Hz) According to IEC60601-1-2:2007 10 V/m 80 MHz to 2.7 GHz (80 % AM at 1 kHz) According to IEC60601-1-2:2014 20 V/m 80 MHz to 2.5 GHz (80 % AM at 1 kHz) According to particular standards	3 V/m 10 V/m 20 V/m	$d = 1.2\sqrt{p}$ 80 MHz to 800 MHz $d = 2.3\sqrt{p}$ 800 MHz to 2.5 GHz $d = 0.4\sqrt{p}$ 80 MHz to 800 MHz $d = 2.3\sqrt{p}$ 800 MHz to 2.7 GHz $d = 0.2\sqrt{p}$ 80 MHz to 800 MHz $d = 0.4\sqrt{p}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters as deter-mined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Note: At 80 MHz and 800 MHz, the higher frequency range applies. *Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.* *Note: According to the standard IEC60601-1-2: 2014, there is no difference in the safety and performance of Life-Supporting and not Life-Supporting equipment.*			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the defibrillator/monitor is used exceeds the applicable RF compliance level above, the defibrillator/monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the defibrillator/monitor. [b] Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m			

Table 45. Electro-surgical unit interference (IEC60601-2-27, IEC-60601-2-30)

Interference Test	IEC 60601 test level	Complies with
Test in cut mode	Output power 300W, 5 times	IEC 60601-2-2
Test in coagulation mode	Output power of 100W, Working frequency of 400 kHz ± 10 % 5 times	

Table 46. Recommended separation distances

Recommended separation distance between portable and mobile RF communications equipment and the defibrillator/monitor				
The defibrillator/monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the defibrillator/monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the defibrillator/monitor as recommended below, according to the maximum output power of the communications equipment.				
Rated Maximum Output Power of Transmitter in watt	**Separation distance according to frequency of transmitter in meter**			
	150 kHz to 80MHz $d = 1.2\sqrt{p}$	***150 kHz to 80MHz (ISM and amateur radio bands)*** $d = 0.6\sqrt{p}$	***80 MHz to 800MHz (Test level 20 V/m)*** $d = 0.2\sqrt{p}$	***800 MHz to 2.5GHz (Test level 20 V/m)*** $d = 0.4\sqrt{p}$
0.01	0.12	0.06	0.02	0.04
0.1	0.38	0.19	0.06	0.13
1	1.2	0.6	0.2	0.4
10	3.8	1.9	0.63	1.3
100	12	6	2	4
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. *Note: At 80MHz and 800MHz, the separation distance for the higher frequency range applies* *Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.*				

Table 47. Immunity to proximity fields from RF wireless communications equipment (IEC60601-1-2)

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	360 – 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
1720 1845 1970	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240 5500 5785	5100 – 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9

Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

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

Table 48. Cables (IEC60601-1-2)

Cables and Sensors	Maximum Length	Complies with
AC Power Cable	2.6m	-RF emissions, CISPR 11, Class B/ Group 1 -Harmonic emissions, IEC 61000-3-2 -Voltage fluctuations/flicker emission, IEC 61000-3-3 -Electrostatic discharge (ESD), IEC 61000-4-2 -Electric fast transient/burst, IEC 61000-4-4 -Surge, IEC 61000-4-5 -Conducted RF IEC 61000-4-6 -Radiated RF, IEC 61000-4-3
ECG Lead Cable	4.0 m	
Pad Extension Cable	3.5 m	
SpO_2 Cable (MEX03)	3.7 m	
SpO_2 Cable (DOC-10)	4.2 m	