

# User's Manual MD-100





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## Introduction

Welcome to your MD-100 Tablet PC.

 $\label{thm:constraints} To \ ensure \ the \ optimal \ performance \ of \ this \ product, \ please \ take \ the \ time \ to \ read \ this \ manual \ carefully.$ 

MD-100 is a rugged tablet intended for medical/commercial uses.

#### **Explanation of Advisements**

In this manual we use three (3) levels of Advisements as follows:



The Note symbol is used for notifying the user of something important or of something that needs special attention.



 $The \textit{Caution} symbol is \textit{used} to inform of something that \textit{could} \textit{cause} \, harm to, \textit{ormal} function of, the \textit{equipment}.$ 



The Warning symbol is used to inform of something in which there is a conceivable risk of harm to the user if the Warning is ignored.

### Symbols and Markings

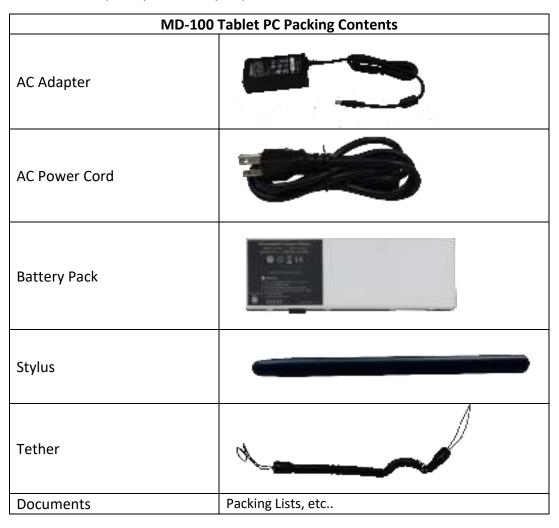
This section provides information about the symbols that are used on the MD-100, its accessories, or packaging.

Symbol or Markings	Description
ڻ ن	Power On/Off Indicator
_	Dispose of in accordance with your country's requirements.
CE	CE is the abbreviation of the European Communities and this mark tells customs officials in the European Union that the product complies with one or more of the EC Directives.
C E F©	This is a certification mark employed on electronic products manufactured or sold in the United States which certifies that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission.
<b>(</b>	Consult User´s Manual
, Wis	UL Marking
c Us us	The product meet UL's requirements for Canada and the United States.
C	Conforms to relevant Australian EMC requirements
MD1001001001	The "1901" in this label means the production date is January 2019. The "0001" at the last 4 numbers mean the serial number of this tablet.
IP65	The water prevent is 5 and the dust prevent is 6.

# 2. Exploring Your Device

#### **Package Contents**

In addition to the primary tablet unit, your product carton should contain all of the below items.



Please inspect all items. If any items are missing or appear damaged, please inform your dealer immediately.



This packing list applies to standard models. Select models may have different items.

# **Device Layout**

## Front View



Item	Component	Description
1	Finger Print	Provides Fingerprint Authentication and Security for your device (if
	Reader	equipped).
2	MIC	Audio Recording Device
3	Ambient Light	Provides Automatic Adjustment of Screen Brightness for Various
	Sensor	Lighting Conditions
4	Front Camera	Record Still and Video Images – 8 MP
5	Power LED	Green – Power On
	Indicator	Green Blink – Sleep Mode
6	Charge LED	White light Blink – Battery Charging
	Indicator	Solid Green – Charge Complete
		Red Blink– Low Battery (Battery Below 10%)
7	Function Key 1	Programmable – Can be used for common special functions
8	Function Key 2	Programmable – Can be used for common special functions
9	Windows Key	Opens or closes the Start menu.
10	Volume + Button	Increases the audio volume.
11	Volume - Button	Decreases the audio volume.
12	Power Button	Turn power On/Off – Hold 10s to Reset

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## Left-side View



Item	Components	Description
14	Barcode Reader (Optional)	Optically Scans 1D or 2D Barcodes, if Equipped
15	Audio	Connect headphones, speakers, or another external audio device.
16	USB 3.0	Connect any external USB device or storage volume.
17	HDMI	Connect a secondary display via HDMI.

## Top View



Item	Component	Description
18	Barcode Reader	Press to activate Barcode Reader Scanning Device (button will
	Button	be deactivated if tablet not equipped with barcode reader).
19	Stylus Tether Hole	The stylus can be tethered through this hole.

## **Bottom View**



Item	Component	Description
20	<b>Docking Connector</b>	Connects the tablet with the Tablet Docking Station

## Right-side View



Position	Components	Description
21	CAC Card Reader	For reading Common Access Card for ID authentication.
22	IO Cover Lock	Cover the IO port for waterproof.
23	DC in	Direct current (DC) power for charging/using the tablet.
24	RJ45 Port	10/100/1000 MB network port
25	Speaker	Sends out sound and voice.

## Rear View



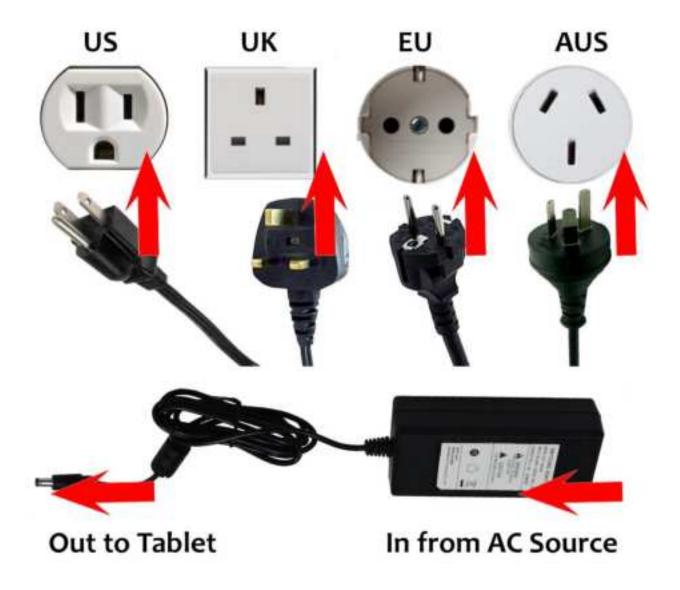
Position	Components	Description
26	Stylus Tether Hole	Stylus can be tethered to this hole.
27	LED	Flash light, controlled by P1&P2 button, Press P1 to turn on the Flash light and P2 to turn off.
28	Stylus pen	Serves as the input device by tapping on the touchscreen to make selections and enter information.
29	Rear Camera	Allows you to use the camera function.
30	Hot Swappable Battery Lock	To lock/unlock the hot swappable battery
31	Hot Swappable Battery	Supplies power to your Tablet PC when external power is not connected.
32	SIM Slot	Insert SIM card to enable 4G LTE service (optional)
33	MicroSD Slot	Accepts MicroSD Memory Cards

## 4. Managing Device Power

#### AC adapter

The AC adapter accepts 100-240VAC Input.

A standard US polarized, grounded three-pin plug adapter is included. International plug AC adapters are available for certain regions.



Use only the AC adapter included with your Tablet PC. Using other AC adapters may damage the device.

#### **Battery Pack**

The MD-100 device has one small, permanent, internal battery and one hot-swappable battery. When hot swappable battery has low voltage and needs to be replaced, the built-in battery will power the tablet for up to 10 minutes.

#### To charge the Battery Pack:

- 1. Connect the power cable to the charging port on the device.
- 2. Connect the power adapter to an electrical outlet and charge the tablet until the battery is fully charged.
- 3. After your device is fully charged, disconnect the charger from both the device and the electrical outlet.
- 4. Additional hot-swappable batteries can be charged independently of the Tablet PC by placing the battery into a docking station with a battery charging bay (available separately).
- NOTE: To prevent damage to batteries, please see Section 8: Safety
- Battery life naturally degrades over time. Failure to follow instructions for recommended operating temperatures, charge and discharge rates, and other instructions may accelerate battery decay rates. If your tablet battery will not accept or hold a satisfactory charge, it may need to be replaced.
- For battery storage and charging temperatures, see Section 8: Safety

#### Checking the Battery Level

To check the battery charge level of the MD-100, you may use the battery monitor within Windows operating system or the voltage gauge of hot swappable battery pack.

When the hot swappable battery pack is not installed in the Tablet PC and you want to know the battery level, press the Battery Test (1) button. The gauge will display the current battery charge level.



Any battery level indication is an estimated result. The actual operating time can be different from the estimated time, depending on how you are using the Tablet PC.

#### Hot Swapping the Battery Pack

The MD-100 Tablet PC battery can be replaced without shutting down the tablet or interrupting your work, by use of the built-in battery. The built-in battery can sustain power for up to 30 minutes, during which period the swappable battery must be changed to prevent loss of function.



To swap the battery, lay the tablet on a flat surface, and pull the two tabs indicated towards the edges of the tablet. The battery will pop loose and a replacement can be slid into place.

- The appropriate temperature range for hot swapping the battery pack is between -10 °C (14 °F) and 50 °C (122 °F).
- Check the Bridge Battery Indicator after unlocking the battery latch. Replace the battery pack only when the indicator lights in green. A red light means the internal bridge battery level is too low for you to safely

hot swap the battery pack.

- When the battery latch is unlocked, the display brightness level will be fixed at a low level and cannot be adjusted
- If the hot swappable battery pack is not inserted within 30 minutes, the Tablet PC enters Hibernation mode or may switch off entirely.

#### **Internal Battery**

The internal battery is not user-replaceable and is not visible to the operating system. It never functions as the power source as long as the hot swappable battery pack is installed. It enables the hot-swapping function, since it provides power only when the battery pack is removed. The internal battery should not be used to power the tablet during regular operation.



By default, the internal battery is charged by external AC power (if connected) or the main battery pack if it is not fully charged. To preserve battery life, it is possible to set the internal battery to charge only when connected to an AC Power Source.

## 5. Using optional features

#### Using the CAC (Common Access Card) Card Reader

This device may include an internal CAC card module for ID authentication. Its location is shown in chapter 2 (Position 21). For more details, see Technical Specifications in Appendix A.

• Users can insert the smart card into the Reader, please follow the instructions in the specific software for your application to use CAC card function properly.



- If you cannot get the CAC Card reader function work properly, try different CAC card and check again. Also ensure the cards are the correct type and inserted fully in the slot. If still not working, please contact your supplier for instruction.
  - If you want to check the CAC card hardware is working properly, you may use eController app to test. See Chapter 6: eController App and its Applications.

#### Using the Finger Print Reader

This device may include an internal Finger Print Reader module to identify a person's fingerprint for security purposes. Its location is shown in product layout in Chapter 2(Position 1). For more details, see Technical Specifications in Appendix A.

• Place your finger on the scanner. Please follow the instructions in the specific software for your application touse finger print reader function properly.



- For optimal performance, both the scanning surface and the finger should be clean and dry. Clean the scanning surface when needed.
- Users must place the finger in the finger print reader area, otherwise the internal Reader module may not receive the signal from the finger.
- If you cannot get the Finger Print reader function work properly, clean the reader area and try again. if still not working, please contact your supplier for instruction.
  - If you want to check whether the Finger print reader hardware is working properly, you may use eController app to test. See Chapter 6: eController App and its Applications.

#### Using the Barcode Reader

This device may have an optional internal Barcode Reader module. It is an optical input device used to capture and read information contained in a bar code. Most common 1D and 2D barcode formats can be read. The location of the reader is shown in the product layout in Chapter 2 (Position 14).

Press the physical scan button on the tablet to activate the scanner. A barcode placed win the scanner field of view will be read. To enable the barcode function, please follow the instructions in the specific software for your application to use barcode reader function properly.



- The maximum operating temperature for the barcode scanner is 50 °C (122 °F).
- The barcode reader only works at close range under appropriate ambient light conditions. A small beep indicates that the barcode has been successfully read.
  - If you want to check the Barcode Reader hardware is working properly, you may use eController app to test. See Chapter 6: eController App and its Applications.

#### **USING GPS**

This device may include an internal GPS module for navigation. Pplease follow the instructions in the specific software for your application for GPS applications. For more details, see Technical Specifications in Appendix A.

• If you want to check whether the GPS hardware is working properly, you may use eController app to test. See Chapter 6: eController App and its Applications.

#### Using the Digitizer Pen

MD-100 Tablet offers either a standard, passive stylus (Digitizer Pen) or an active stylus.



The standard stylus can be used for writing and selecting elements on the screen. The active stylus works together with a specialized touch sensor panel to support functions like Double Click, Palm Reject, Hover, Accurate Drawing, Legal Signatures, and other special functions. For more details, see Technical Specifications in Appendix A.

To use double click function, Tap the desired point on the screen twice in quick succession with the pen.

When using the Hover Function, if the stylus is hovered slightly above the screen, a hover indicator will appear.

i

In Hover Mode, please keep the pen within 3mm of the touch screen, otherwise the mark might not be displayed in the screen.

Palm Rejection Function: when you are writing using an active digitizer, a finger or the palm on the screen won't produce input, as the screen recognizes a difference between the input from your hand and input from your stylus.

## 6. eController App and its Applications

The eController App is designed to quickly check if device modules are working properly. It tests the following modules:

- 1. Fingerprint Reader
- 2. CAC (Common Access Card) Card
- 3. Barcode Scanner
- 4. GPS
- 5. Assign function to programmable buttons F1 and F2.
- Most of the above the modules are optional items. If the eController top menu bars are greyed out or unselectable on certain items, the related modules are not installed (or have been disabled).
- The eController is not application software. You need install the proper application software (App) to use the module for your desired functions.

#### System information

The System Information component of the eController App will automatically check the tablet's information.



#### Fingerprint scanner

When activated, the user may place a fingertip on the scanner, and the scanner will read the print and display it in the indicated area of the screen, until removed.



The fingerprint scanner will operate continuously once this test is selected until exited. To preserve battery and enable all tablet functions, please exit the test when complete.



#### **CAC Card Reader**

When activated, the user may place an enabled card into the chip card reader. Users should then select "Read" on the screen, and the screen will display whether the card was read properly or not.



If the reader indicates that the card cannot be read, please remove and reinsert the card, checking that it is inserted fully and in appropriate orientation. If the card still cannot be read, try a different card.



#### **Barcode Scanner**

To test the barcode scanner, select the barcode test, point the scanner at a barcode (or QR code), and press the SCAN button on the screen or press the physical scan button on the handle of the tablet. System will quickly scan and display the barcode information on screen.

Press the button again to read the barcode again. The displayed info will refresh and display the new barcode information.



Please aim the laser at the center of barcode. Do not place the scanner too far from barcode.



Barcode scanner uses laser technology, do not point it toward anyone's eyes.



#### **Button configuration**

Button configuration can program the F1 and F2 buttons on your tablet. Select the button you want to program, choose the desired function and press the SAVE button to save settings, or you can select cancel to discard the changes.

If you want to program the buttons to a function not on the list, please contact your supplier for further instructions.



#### **GPS**

The eController GPS test is based on Chart cross Limited APP.

Turn on Location Services. The App will automatically run and check the GPS signal, satellite positions, your current location, speed, heading and altitude.

#### In the graphic below:

- 1. GPS signal bar chart, showing the signal strength for each satellite detected, as well as the accuracy and status of the GNSS network.
- 2. Satellite positions in the sky, shown on a rotating compass.
- 3. Your current location on the earth shown as text and on a world map. The current position of the sun and the day/night transition curve is also shown.
- 4. Compass
- 5. The current time read from the GPS and the local time in your current time zone, as well as the sunrise and sunset times at your location.
- 6. Your current speed, heading and altitude shown as text.
- Please test GPS in an open outdoor area. Otherwise, the GPS may not work properly.



If you have any further questions about this help file, please contact the supplier.

#### 7. Product Care

#### **Temperature & Humidity**

#### General Use - Operating temperature

The MD-100 is best kept in dry conditions at room temperature. The recommended range for temperature and the humidity value for the device is as follows:

- Ambient temperature:  $0^{\circ}C$  to  $35^{\circ}C$  ( $32^{\circ}F$  to  $95^{\circ}F$ )
- Relative humidity: 10% to 90% (no condensation on the device)
- Atmospheric Pressure: 80 kPa to 106 kPa (600 mmHg to 795 mmHg)

#### **Transportation and Storage**

For transportation and storage, the recommended range for temperature and the humidity value for the device is as follows:

- Temperature:  $-20^{\circ}C$  to  $60^{\circ}C$  (  $-4^{\circ}F$  to  $140^{\circ}F$ )
- Relative humidity: 10% to 90% (no condensation on the device)

#### Transporting the MD-100 Device

Disconnect all the cables from the MD-100 while carrying the device.

When you transport the device for any reason, use the original casing and packaging materials. It is recommended to keep the original packaging materials for the MD-100.

If the device needs to be returned to Device Manufacturer for Warranty related issues or repair, it is beneficial that the original packaging or equivalent is used for shipping. Most shipping carriers require at least 2 inches of packing material around the device.



Due to Joint Commission regulations, any shipping materials including boxes sent to Device Manufacturer must be discarded.

## 8. Safety



The MD-100 device has been tested and approved as compliant to all the Specifications and Standards listed in Appendix B Compliance Information, and in the Appendix A Technical Specifications. Nevertheless, in order to ensure safe operation of your MD-100 device, there are a few safety warnings to bear in mind:



Do not disassemble this product. You may receive an electric shock, or foreign matter may enter and result in a fire. If a malfunction or trouble occurs, immediately turn the power off and unplug the AC power source. Then contact your supplier's technical support office for repair.



Do not service or perform maintenance on the device while the device is in use. Make sure to shut the device down and unplug all cables before starting and service or maintenance work on the device.

#### 2.1 Power Supply and Batteries

The MD-100 device contains two rechargeable batteries. All rechargeable batteries degrade over time. Thus, the possible usage times for the MD-100 after a full charge can become shorter over time than when the device was new.



The MD-100 device uses a Li-ion Polymer battery.

If you are in a hot environment, be aware that it can affect the ability to charge the battery. The internal temperature must be between 0  $^{\circ}$ C/32  $^{\circ}$ F and 45  $^{\circ}$ C/113  $^{\circ}$ F for the battery to charge. If the internal battery temperature rises above 45  $^{\circ}$ C/113  $^{\circ}$ F the battery will not charge at all.



Avoid exposing the MD-100 device to fire or to temperatures above 60  $^{\circ}$ C/140  $^{\circ}$ F. These conditions may cause the battery to malfunction, generate heat, ignite or explode. Be aware that it is possible, in a worst-case scenario, for temperatures to reach greater than those stated above in, for example, the trunk of a car on a hot day.

Only charge the MD-100 battery in an ambient temperature of 0  $^{\circ}$ C/32  $^{\circ}$ F to 45  $^{\circ}$ C/113  $^{\circ}$ F.



Only qualified personnel with appropriate service documentation should replace the backup battery. Otherwise, personal injury or equipment damage could occur.



Use only the supplied power adapter to charge the MD-100 device. Using unauthorized power adapters may severely damage the MD-100 device.



For safe operation of the MD-100 device, use only charger and accessories approved by Device Manufacturer.

If the Power Supply Cord is damaged it needs to be replaced by Service Personnel only. Do not use the Power Sup- ply Cord until replaced.



Disconnect the AC power plug of the Power adapter from the wall socket when not charging the device and disconnect the power cable from the device.



Special regulations apply to shipping devices containing Li-ion Polymer batteries. If dropped, crushed, or short- circuited, these batteries can release dangerous amounts of heat, may ignite, and may be dangerous near fires.



The plug/adapter plug pins insulate the device from the main supply. Do not position the device in a position where it is difficult to disconnect the device from the supply mains to safely terminate operation of the device.

#### 2.2 Temperature



Due to use in direct sunshine or in any other hot environment the MD-100 device may have hot surfaces. There is a built-in temperature sensor that monitors the temperature. If the sensor detects high internal temperature, the device will automatically trigger a Windows Shut Down or Hibernate (depending on Windows Power Button configuration). It may take a while before MD-100 device can be restarted as the unit may first need time to cool down.

#### 2.3 Electricity



The device contains no user serviceable parts. Do not open the case of the MD-100 Tablet Device. Doing so will void the product warranty and may expose you to electrical hazards.

#### 2.4 Software



Using an antivirus program is strongly recommended.



Software other than that which is pre-installed on the MD-100 is installed at the user's own risk. External software could cause the MD-100 to malfunction and might not be covered by the warranty.

#### 2.5 Magnetic Field



The MD-100 device contains magnets. Magnetic fields may interfere with pacemakers, defibrillators, or other medical devices. As a rule, maintain a minimum distance of 6 inches (15 centimeters) between any item with magnets and your heart device.

#### 2.6 Third Party



Any use of the MD-100 outside the intended use and together with any third-party software or hardware that changes the intended use voids the responsibility of the device manufacturer

Being a medical device, parts connected for a SIGNAL INPUT/OUTPUT must be compliant to the Medical IEC standard 60601-1.

## 9. Trouble shooting

In most cases, restarting your device will cure any problem. To restart your device, Select Start and then select Power - Shut down. If your device has crashed, hold down the power button or remote power button for 5+ seconds to hard shutdown. Press it again to turn it back on.

If this does not fix the problem, contact your supplier.

Please have your serial number ready. This can be found on the back of your device.

Appendix A	Technical	Specifications
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Ruggedness	IP-65 Waterproof
	Drop: 4FT drop resistant on 4 corners to plywood (MIL-STD-810G)
	Shock resistant: MIL-STD-810G, method 516.6, procedure I
	ESD Protection: 4KV touch, 8KV air
	Ultra-LCD protection (Option)
Processor	Intel® Apollo Lake N4200
	Quad-core, base 1.1GHz, Burst 2.5GHz
GPU	Intel® HD Graphics 505
	Base 200MHz, Burst 750MHz
	Max Video Memory 8GB
OS	Windows 10 Pro/IOT, Linux
Security	Intel® AES New Instructions Support
	Support TPM 2.0
System Memory	4GB LPDDR3-1866
	Option: 8GB LPDDR3
Storage	128GB SSD M.2 interface (2280)
	Options: 256GB, 512GB, 1TB
Button	Power on/off (Hold 7s will reset system)
	Vol- / Vol+
	Windows button
	2x program buttons
	Barcode scan button (Option)
LCD	10.1" IPS, 1920 x 1200 Resolution
	400 NIT Brightness
	Option: 1000 NIT LCD, sunlight readable
Touch Screen	Capacitive 10-point Multi-touch
	Chemical harden cover glass
	Anti-AG, AR, AF coating (Option)
	Support multi touch mode (include water splash)
	Ultra-screen protection (Option)
Digitizer (Option)	Active Capacitive Coupled, Pressure Level: 256~1024,
	Support double click, hoover, palm rejection,
	High accuracy for legal signature
	Compliant to Microsoft Pen Protocol v.2.0
Audio	Built-in microphone
	One internal 8ohm 0.5W speaker
Camera	Front camera: 2MP
	Rear Camera: 5MP with Auto Focus
	Option: 8MP rear camera
Wireless	2.4G WiFi 802.11 a/b/g/n
	Bluetooth 4.2

GPS (Option)	UBox 7
	Support GPS/QZSS L1 C/A, GLONASS L1 FDMA, SBAS: WAAS, EGNOS, MSAS
	Cold start: 40s
CAC card reader	EMV 2000 Level 1, ISO 7816, CCID
(Option)	

Finger Print Reader	Capacitive
(Option)	Compliant to FIPS 201
Barcode scanner	Built-in 1D/2D (QR) Barcode Reader, support multi 1D and 2D code
(Option)	Lighting: Red LED 625±10 nm
Sensors	Gyroscope, Light sensor, compass.
Battery	40 WH Hot Swappable battery with voltage meter
	(3S1P, 11.1V, 3700mAh)
	Internal Battery, 30 minutes run time for battery hot swap
	(2S1P, 7.4V, 440mAh)
I/O	1x USB 3.0 @1.5A Type A
	1x HDMI output: Type A
	1x Audio jack (3.5mm, 4 pole, support MIC input)
	1x DC jack: 5.5mm OD jack
	1x RJ45 port: 10/100/1000M
	1x Micro SD slot (under hot swappable battery)
	1x Micro SIM slot (under hot swappable battery)
	1x Docking connector (12V DC and 2x USB)
Mechanical	Front chassis: Plastic+ TPU
	Rear chassis: Plastic+ TPU
	Option: Anti-Microbial medical chassis
	Dimension: 280*256*22mm
	Weight: 1.1KG
AC adaptor	Option1:Output 19V, 3000mA
	Input: 100 -240V AC in, standard US plug, or multi-nation plugs
	Option2: medical AC adapter Output: 18V/3.4A , input: 100-240V, 50/60Hz, 1.5A
Environmental	Operation temperature: 0-35° C
	Storage Temperature: -20 $-$ 60 $^{\circ}$ C
	Humidity: 10% to 90%
	ROHS: Compliant
	Waterproofing: IP25
Regulatory	FCC
	IATA/IEC62133
	IEC60601-1

## Appendix B Compliance Information

#### **B1** FCC Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- -Reorient or relocate the receiving antenna.
- -Increase the separation between the equipment and receiver.
- -Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- -Consult the dealer or an experienced radio/TV technician for help.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

#### Part 15B Equipment

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.

- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.



Any changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment. Modifications not expressly approved by Device Manufacturer could void the user's authority to operate the equipment under FCC rules.

#### FCC RF Radiation Exposure Statement:

- This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
- This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This device was tested for typical hand-held operations with the device contacted directly to the human body to the sides of the de-vice. To maintain compliance with FCC RF exposure compliance requirements, avoid direct contact to the transmitting antenna during transmitting.

This equipment complies with FCC/IC/EU RF radiation exposure limits set forth for an uncontrolled environment. The highest SAR value for the MD-100 device is <0.88W/kg.

In order to maintain compliance as a Class 1 Medical device, the switches that are used in combination with the MD-100 device must fulfill the isolation requirements of IEC/EN 60601-1 based on 15 VDC. They must be electrically floating switches (switches that are not grounded).

#### **B2 CE Statement**

This equipment complies with the requirements relating to electromagnetic compatibility, the essential protection requirement of Electromagnetic Compatibility (EMC) Directive 2014/30/EU on the approximation of the laws of the Member States relating to electromagnetic compatibility and Radio Equipment Directive (RED) 2014/53/EU to meet the regulation of the radio equipment and telecommunications terminal equipment.

#### **B3** Directives and Standards

The MD-100 complies with the following directives:

- Medical Device Regulation (MDR)
- Low voltage Directive 2014/35/EU
- Electromagnetic Compatibility (EMC) Directive 2014/30/EU
- Radio Equipment Directive (RED) 2014/53/EU
- RoHS2 Directive 2011/65/EU
- WEEE Directive 2012/19/EU
- Reach Directive 2006/121/EC, 1907/2006/EC Annex 17
- Batteries Directive 2013/56/EU

The device has been tested to comply with FCC, IEC 60601-1, IATA/IEC62133, and other relevant standards for the intended markets.