mBOX600

Medical Embedded System

User's Manual

USER'S MANUAL

AXIOMTEK

www.axiomtek.com

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Safety Precautions

Before getting started, please read the following important safety precautions.

1. The mBOX600 does not come with an operating system which must be loaded first before installation of any software into the computer.
2. Use a wrist grounding strap and place all electronic components in any static-shielded devices. Most electronic components are sensitive to a static electrical charge.
3. A sudden surge of power could ruin sensitive components. Make sure the mBOX600 is properly grounded.
4. Make sure the voltage of the power source is correct before connecting it to any power outlet.
5. Turn Off system power before cleaning. Clean the system with an antistatic cloth only.
6. Do not leave equipment in an uncontrolled environment where the storage temperature is below 0°C or above 40°C as it may damage the equipment.
7. Do not open the system's back cover. For safety reasons, the equipment shall be opened only by qualified service person.
8. WARNING: Do not modify this equipment without the authorization of Axiomtek Co., Ltd. Please go to "Support (axiomtek.com) ". Use this site to resolve a hardware problem and get more information about your product. You can also find information on how to contact AXIOMTEK and open a support case.
9. WARNING! Danger of an unacceptable high leakage current for the patient may be caused by insufficient system configuration: Accessories being connected to analog or digital interfaces must comply with the respective European or international standards (e.g. EN 60601–1 for medical devices). Furthermore, all configurations building an ME system must comply with the European or international standard 60601–1. Every person connecting additional devices to a signal input or output is configuring a medical system and is therefore responsible for the ME system complying with the applicable version of the European or international standard 60601–1. If you have questions, please contact customer support or your local representative.
10. WARNING! To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth.
11. Disconnect device: Appliance inlet of Power Adapter, please do not to position the Power Adapter too far to difficultly operate the disconnection device.
12. External surfaces of ME EQUIPMENT that are likely to be touched for a time "t"

Time	ME EQUIPMENT and its parts
1s ≤ t < 10s	Outer metal enclosure surface Outer surface of Power Adapter Plastic panel near standby switch

13. Environmental Conditions

Operation	Temperature (°C)	0 ºC to +40 ºC
	Relative Humidity (%)	10 to 90%RH
	Atmospheric Pressure (kPa)	106 to 80 kPa
Storage / Transportation	Temperature (°C)	0°C to +40°C
	Relative Humidity (%)	10 to 90%RH
	Atmospheric Pressure (kPa)	106 to 80 kPa

14. If one of the following situations arises, get the equipment checked by service personnel:
    a. The power cord or plug is damaged.
    b. Liquid has penetrated into the equipment.
    c. The equipment has been exposed to moisture.
    d. The equipment does not work well, or you cannot get it to work according to the user's manual.
    e. The equipment has been dropped and damaged.
    f. The equipment has obvious signs of breakage.

15. If your computer is losing dramatic time or the BIOS configuration reset to default, the RTC battery has no power.

Caution	*1. Do not replace battery yourself. Please contact a qualified technician or your retail.* *2 .The Computer is provided with a battery-powered real-time clock circuit. There is a danger of explosion if battery is incorrectly replaced. Replace only with same or equivalent type recommended by the manufacture. Discard used batteries according to the manufacturer's instructions.*
Caution	*1. Ne pas remplacer vous-même. Veuillez contacter un technicien qualifié ou votre commerce de détail.* *2 . L'ordinateur est fourni avec une pile de l'horloge en temps réel du circuit. Il y a un risque d'explosion si la batterie est remplacée de manière incorrecte. Remplacez-la uniquement par une batterie de type identique ou équivalent recommandé par le fabricant. Jetez les piles usées conformément aux instructions du fabricant.*

Explanation of Graphical Symbols

Symbol	Description
	Follow the national requirement to dispose unit.
	European Conformance
	US Conformance
	On ME EQUIPMENT "Follow instructions for use”
	ISO 15223-1 Indicates the medical device manufacturer
	IEC 60417-5031: Direct current.
	*IEC 60417-5032: AC*
	Stand-by
	Equipotentiality

Intended User Profile

1. Education: Medical Experts
2. User group: Medical Professionals
3. Knowledge base: User should possess medical professional knowledge

CAUTION: Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information in the XXX sections of this document. Portable and mobile RF communications equipment can affect medical electrical equipment.

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following. Portable and mobile RF communication equipment (e.g. cell phones) can affect Medical Electrical Equipment.
The use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the unit.

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The A&D unit is intended for use in the electromagnetic environment specified below. The customer or the user of the A&D unit should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF
emissions
CISPR 11</td><td>Group 1</td><td>The A&D unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause anyinterference in nearby electronic equipment.</td></tr>
<tr><td>RF
emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The A&D unit is suitable for use in all establishments, including domestic establishments and those directly connectedto the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations
/flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Recommended separation distances between portable and mobile RF communications equipment and the A&D unit

The A&D unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the A&D unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the A&D unit as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitterm**		
	150 kHz to 80 MHz $d = 1.2\ P$	**80 MHz to 800 MHz** $d = 1.2\ P$	**800 MHz to 2.5 GHz** $d = 2.3\ P$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (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 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

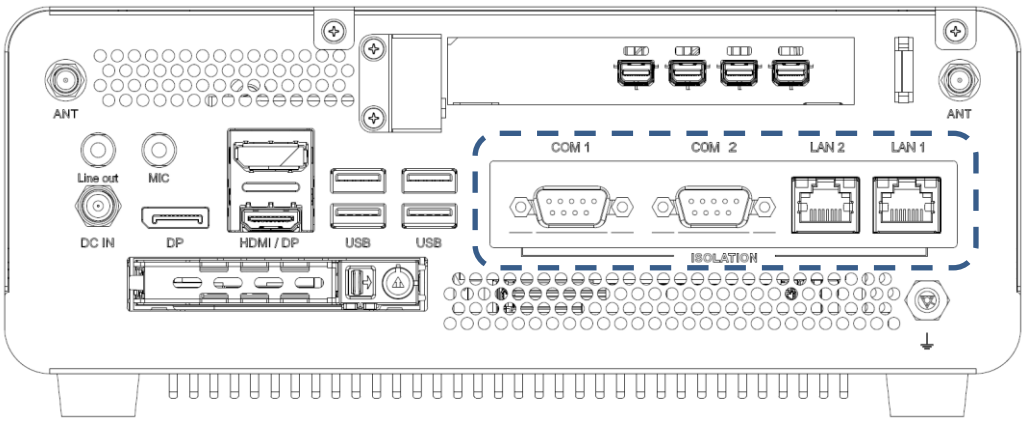
Guidance and manufacturer's declaration – electromagnetic immunity			
The A&D unit is intended for use in the electromagnetic environment specified below. The customer or the user of the A&D unit should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –guidance**
Conducted RFIEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V rms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V rms 3 V/m	Portable and mobile RF communications equipment shouldbe used no closer to any part of theA&D unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.2\ P$ $d = 1.2\ P$ 80 MHz to 800 MHz $d = 2.3\ P$ 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* isthe recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliancelevel in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the followingsymbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. Toassess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in thelocation in which the A&D unit is used exceeds the applicable RF compliance level above, the A&D unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the A&D unit. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The A&D unit is intended for use in the electromagnetic environment specified below. The customer or the user of the A&D unit should assure that it is used in such an environment.			
Immunit ytest	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD)IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile.If floors are covered withsynthetic material, the Relative humidity should beat least 30%.
Electrical fast transient/burstIEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/outputlines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line ±2 kV line to earth	± 1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variationson power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T)for 0.5 cycle 40% U_T (60% dip in U_T)for 5 cycles 70% U_T (30% dip in U_T)for 25 cycles < 5% U_T (> 95% dip in U_T)for 5 s	< 5% U_T (> 95% dip in U_T)for 0.5 cycle 40% U_T (60% dip in U_T)for 5 cycles 70% U_T (30% dip in U_T)for 25 cycles < 5% U_T (> 95% dip in U_T)for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the A&D unit requires continued operation during power mains interruptions, itis recommended that theA&D unit be powered from an uninterruptible powersupply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magneticfields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Classifications

1. Equipment not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.
2. Mode of operation: Continuous.

3. Supply CLASS I Power Adapter see “1.5 Packing List” for power adapter detail information.
4. No Applied Part
5. IPX0
6. Pollution degree of equipment: Pollution Degree 2
7. Operation altitude of equipment: 0-5000m
8. Material group IIIb
9. Two MOPP insulations were provided between primary and secondary. One MOPP insulation was provided between primary and earth.
10. Two MOPP insulations were provided between primary and secondary. One MOPP insulation was provided between primary and earth.
11. ISOLATION ports provide one MOOP 1.5 kVac against other secondary circuits.



General Cleaning Tips

Please keep the following precautions in mind while understanding the details fully before and during any cleaning of the computer and any components within.

A piece of dry cloth is ideal to clean the device.

1. Be cautious of any tiny removable components when using a vacuum cleaner by the system.
2. Turn the system off before cleaning up the computer or any components within.
3. Avoid dropping any components into the computer or getting the circuit board damp or wet.
4. For cleaning, be cautious of all kinds of cleaning solvents or chemicals which may cause allergy to certain individuals.
5. Keep foods, drinks or cigarettes away from the computer.

Cleaning Tools:

Although many companies have created products to help improve the process of cleaning systems and peripherals, users can also use household items accordingly for cleaning. Listed below are items available for cleaning computer or computer peripherals.

Pay special attention to components requiring designated products for cleaning as mentioned below.

- Antistatic cloth: A piece of antistatic cloth is the best tool to use when cleaning up a component. Although paper towels or tissues can be used on most hardware as well, it is recommended to use a piece of antistatic cloth.
- Water or rubbing alcohol: A piece of antistatic cloth may be somewhat moistened with water or rubbing alcohol before cleaning the computer. Unknown solvents may be harmful to plastic parts.
- Clean the dust, dirt, hair, cigarette and other particles outside of a computer can be one of the best methods of cleaning a computer. Over time these items may restrict the airflow in a computer and cause the circuitry to corrode.
- Foam swabs: If possible, it is better to use lint free swabs such as foam swabs.

Note

It is strongly recommended that customer should shut down the system before starting to clean any component.

Shutdown procedure
Please follow the steps below:

1. Close all application programs.
2. Close operating software.
3. Turn off the power switch.
4. Remove all devices.
5. Pull out the power cable.

Scrap Computer Recycling

Please inform the nearest Axiomtek distributor as soon as possible for suitable solutions in case computers require maintenance or repair; or for recycling in case computers are out of order.

Trademarks Acknowledgments

Table of Contents

Section 1
Introduction

This section contains general information and detailed specifications of the mBOX600. Section 1 includes the following sub-sections:

- General Descriptions
- System Specifications
- Dimensions
- I/O Outlets
- Packing List

Please take a few moments to review the contents of this document to ensure that the setup and startup proceed smoothly. The Medical-Grade System is ready for use, out of the box, in its default configuration when powered by the power source provided. The following documentation offers guidance on the hardware elements and features of the computer. Please refer to your device provider for information pertaining to the software operating system or software applications.

1.1 General Descriptions

The mBOX600 is powered by the high-performance 9th/8th Intel® Core™ i7/i5/i3 & Celeron® processor, COM Express® structure.

The system offers two RS-232/422/485, four USB 3.1 Gen 2 ports, two Gigabit Ethernet ports, two DisplayPort output, one HDMI output and one LED power status light. Moreover, it's equipped with one M.2 2280 Key M slot for NVMe SSD, one swappable 2.5" SATAIII SSD with security lock, one PCIe x16 slot for expansion use, and one screw-type 12V-24VDC power input connector.

mBOX600 solely intended to be high-performance server system to collect, transfer, store, convert formats of data or results for general purpose in hospital environment without specific software to interpret or analyze clinical laboratory test results or other devices' data or control other medical devices.

After installed with specific software, the potential functions involved with medical use shall be evaluated according to proper medical equipment standards including but not limited to IEC 60601 series and local regulatory authority requirements.
Please refer to your device provider for information pertaining to the software operating system or software applications.

Features

- Intel® 9th/8th Gen Core™ i7/i5/i3 & Celeron® processor, COM Express® structure
- Two DisplayPort supports 4K resolution
- One HDMI supports 4K resolution
- Two COM ports and two GbE LAN ports support 1.5kV isolation
- One M.2 2280 Key M for NVMe SSD
- One swappable 2.5" SATAIII SSD tray with security lock
- One PCIe x16 slot for expansion use
- One Mic-in and one Line-out
- IEC60601-1 compliance

Reliable and Stable Design

The medical embedded system is equipped with Intel® 9th/8th Gen Core™ i7/i5/i3 & Celeron® processor, and comes with ultra-slim design and provides high performance. It is a solution for hospitals, clinics and medical inspection stations.

Flexible Connectivity

- It comes with basic interfaces including two RS-232/422/485 ports, four USB 3.1 Gen 2 ports, two DisplayPort, one HDMI port, two GbE LAN ports, one Mic-in and one Line-out, and one PCIe x16 slot for expansion use.

Embedded O.S. Supported

The mBOX600 supports Windows® and Linux.

Easy maintain storage Supported

The mBOX600 supports one SATA SSD and one M.2 NVMe SSD slot.

1.2 System Specifications

1.2.1 CPU

- **CPU**
  - Intel® 9th/8th Gen Core™ i7/i5/i3 & Celeron® processor

- **Chipset**
  - QM370.

- **BIOS**
  - American Megatrends Inc. UEFI (Unified Extensible Firmware Interface) BIOS.

- **System Memory**
  - Two 260-pin SO-DIMM sockets. Supports DDR4-2666/2400 MHz, maximum up to 64 GB

1.2.2 I/O System

- **Display**
  - Two DisplayPort supports DP 1.2.
    The DP resolution is up to 3840x2160 @60Hz.
  - One HDMI support HDMI 1.4a.
    The HDMI resolution is up to 3840x2160 @30Hz.

- **Ethernet**
  - Two 1000/100/10 Ethernet ports (i210-AT, i219-LM)
    LAN1: Intel® i219-LM supports 1000/100/10Mbps Gigabit/Fast Ethernet with Wake-on-LAN, PXE Boot ROM, and Intel® AMT supported.
    LAN2: Intel® i210-AT supports 1000/100/10Mbps Gigabit/Fast Ethernet with Wake-on-LAN and PXE Boot ROM.

- **USB Ports**
  - Four USB 3.1 Gen 2.

- **Serial Ports**
  - Two RS-232/422/485 (in 9-pin D-Sub male connector).

- **Expansion Interface**
  - One full-size PCIe mini card slot (USB+PCIe signal).

- **Storage**
  - One 2.5" SATAIII SSD.
  - One M.2 2280 key M slot for NVMe SSD.

- **Indicator**
  - One blue LED power button as indicator for power status.
    Status Color: blue. **Description: Power on status,**
    Status Color: No Light. **Description: Power off status,**
- **Switch**
  - One power on/off button.

1.2.3 System Specification

- **Watchdog Timer**
  - 1~65535 seconds; up to 65535 levels.

- **Power Supply**
  - 24V DC in see "1.5 Packing List" for power adapter detail information.

- **Operation Temperature**
  - 0°C to +40°C (+32°F to 104°F).

- **Humidity**
  - 10%RH ~ 90%RH (non-condensing).

- **Vibration Endurance**
  - 3 grms STD, random 5~500Hz, 1hr/axis.

- **Weight**
  - 4 kg (8.82 lb) without package

- **Dimensions**
  - 250 mm (9.84") x 240 mm (9.44") x 90 mm (3.54")

1.2.4 Driver CD Content

Please download system drivers and user's manual from Axiomtek website.

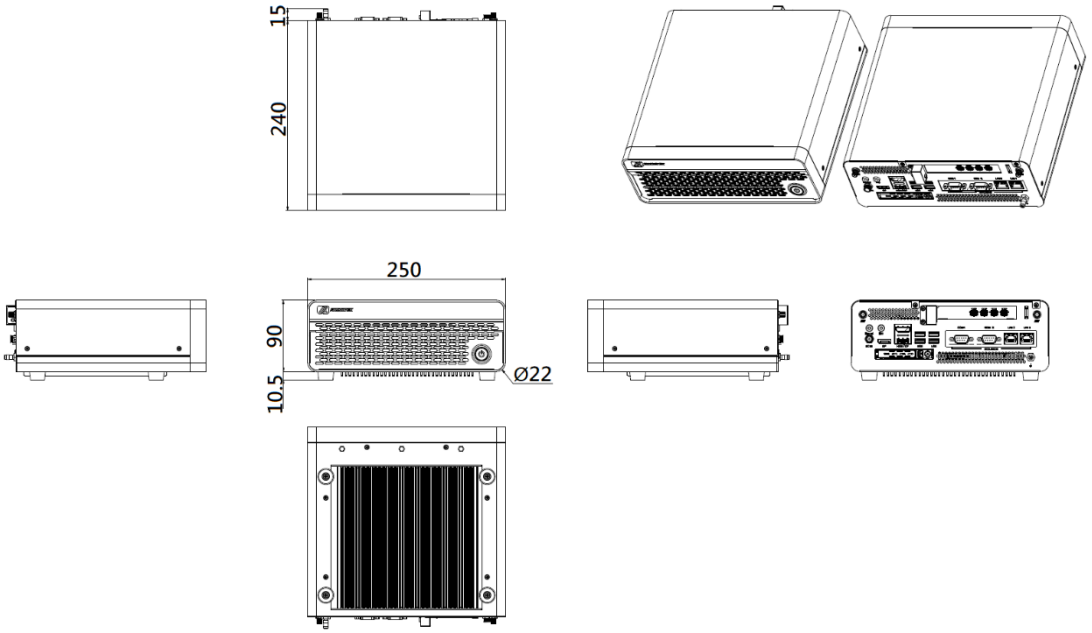
- **Chipset**
- **Ethernet**
- **Graphic**
- **Intel® ME**
- **Serial Patch**

Note

All specifications and images are subject to change without notice.

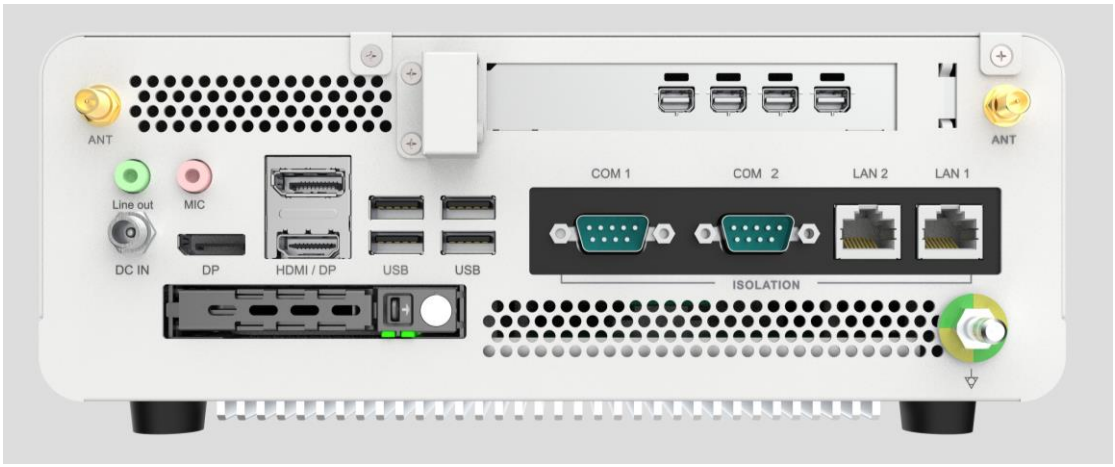
1.3 Dimensions

The following diagrams show dimensions and outlines of the mBOX600.



1.4 I/O Outlets

The following figures show I/O outlets on the mBOX600.



1.5 Packing List

The mBOX600 comes with the following bundle package:

- **mBOX600 system unit x1**
- **Medical grade 150W adapter x1 (FSP Technology Inc. Model FSP150M-KAA)**
- **Power cord x1**
  Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "Hospital Only" or "Hospital Grade".

  Use a power cord that matches the voltage of the power outlet, which has been approved and complies with the safety standard of your particular country. If use of incorrect power cord may present a risk of fire.

  Use U.S.A and Canada power supply cord information as below

U.S.A. and Canada	
Plug type	HOSPITAL GRADE
Cord type	Min. Type SJT
	Min. 18 AWG
Minimum rating for plug and appliance couplers	10A / 125V
Safety approval	UL Listed and CSA

  The power cord length not longer than 3m.

- **SDD tray screw pack x1**

Note

Please download user's manual from Axiomtek website.

Section 2
System Setup

2.1 Quick Start

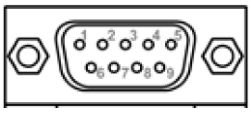
Connect the adapter to the "DC Input Jack". Please note that using a non-genuine adapter may pose a potential risk to the system.
Press "Power On/Off". The button will turn white.

Installed only by qualified service person. Go to "Support (axiomtek.com) " for contact information.

2.2 COM Ports Setup

2.2.1 COM Ports Pin Definition

Pin	RS-232	RS-422	RS-485
1	DCD	TX-	Data-
2	RXD	TX+	Data+
3	TXD	RX+	No use
4	DTR	RX-	No use
5	GND	No use	No use
6	DSR	No use	No use
7	RTS	No use	No use
8	CTS	No use	No use
9	RI	No use	No use



2.2.2 COM Ports Mode Selection

The users can choose to use RS232, RS422 or RS485 function through BIOS settings.

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Section 3
mBOX600 Medical Computer Cleaning and Disinfecting

3.1 mBOX600 Medical Computer Cleaning and Disinfecting

During normal use of the mBOX600, the device may become dirty and should be regularly cleaned.

Steps:

1. Prepare cleaning fluid as below list.
2. Wipe the mBOX600 with a clean antistatic cloth that has been moistened in the cleaning solution.
3. Wipe thoroughly with a clean antistatic cloth.

Cleaning: Use a soft/non-abrasive cloth moistened with water to clean the enclosure.

Caution!

- *Do not immerse or rinse the AMIS or its peripherals. If you accidentally spill liquid on the device, disconnect the unit from the power source. Contact your Biomed Department regarding the continued safety of the unit before placing it back in operation-Do not spray cleaning agent on the chassis.*
- *Do not use disinfectants that contain phenol.*
- *Do not autoclave or clean the AMIS or its peripherals with strong aromatic, chlorinated, ketone, ether, or ether solvents, sharp tools or abrasives. Never immerse electrical connectors in water or other liquids.*