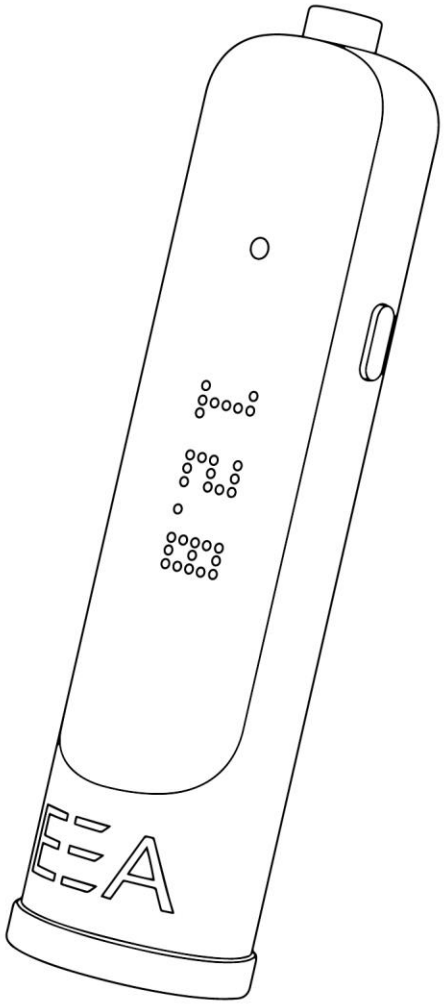
E3A Healthcare

Instruction Manual

Bilimonitor Jaundice Meter
Model: BJM-20



E3A Healthcare Pte Ltd

Thank you for choosing BJM-20 transcutaneous jaundice meter. This manual provides detailed instructions on the usage, functionality, and features of the BJM-20 transcutaneous jaundice meter. Please read this manual carefully before use.

Product Name: Bilimonitor Jaundice Meter

Model: BJM-20

Product Registration Certificate Number (China): 20212071690

Production License Number (China): 20214579

Registered/Manufacturing Company Name: E3A Healthcare Pte Ltd

Registered Company Address: 83 Science Park Drive #02-03 The Curie Singapore (118258)

Production Address: 2nd Floor, No.83 Pinghuan Industrial City, Pinghuan Community, Maluan Street, Pingshan District, Shenzhen City, China

Production Date: As indicated on the product label or certificate of conformity

Product Lifecycle: 3 years

Contact Us:

Customer Service Centre Hotline: +65-6236-6400 (Monday to Friday, 9:00 am to 6:00 pm)

Email: info@e3ahealth.com or contact your local dealer For

more information, please visit E3A Healthcare's website at: www.e3ahealth.com

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Table of Contents

1 Overview

1.1 Expected Usage and Operating Environment

1.1.1 Expected Usage

Used to measure serum bilirubin levels in neonates before, during, and after phototherapy.

1.1.2 Contraindications

No known contraindications.

1.1.3 Intended Use

The transcutaneous jaundice meter (BJM-20) is a non-invasive transcutaneous bilirubinometer. It measures yellowness of subcutaneous tissue in newborn infants. The unit pro-vides a visual digital measurement that has been shown to correlate with serum bilirubin in newborn infants.

The device is intended for use in hospitals, clinics or doctor's offices under a physicians supervision / direction to assist clinicians in monitoring of newborn infants. The device is not intended as a standalone for diagnosis of hyperbiliru-binemia. It is to be used in conjunction with other clinical signs and laboratory measurements.

Newborn infants whose the transcutaneous jaundice meter (BJM-20) test results are indicative of hy-perbilirubinemia should be evaluated by their physician(s) for appropriate patient management. Specific neonatal patient Bilirubin levels should be confirmed by other methods, such as serum bilirubin, prior to treatment determinations.

The transcutaneous jaundice meter (BJM-20) is a prescription medical device

The transcutaneous jaundice meter (BJM-20)is not intended for home use.

The transcutaneous jaundice meter (BJM-20) may only be used at the sternum measurement site for Physician's office applications.

1.2 Standard Configuration List

Instrument	1unit
Instruction Manual	1copy
Certificate of Quality	1sheet

1.3 Product Dimensions

Dimensions:141mm×Φ36mm.

1.4 Storage Environment

Conditions Environmental temperature range:-20°C ～ 60°C（-4°F ～ 140°F）;
Relative humidity range:5%～95%。

1.5 Operating Environment

Conditions Environmental temperature range:10°C ～ 40°C（50°F ～ 104°F）；
Relative humidity range:5% ～ 95%（without condensation）；
Atmospheric pressure range:700hPa～1060hPa（-400m ～ 3000m）。

1.6 Transportation

The BJM-20 transcutaneous bilirubin meter should be packed using the specified materials to avoid exposure to rain, sunlight, impact, and collision, and should not be transported with harmful gases.

1.7 Warning Symbols

The warning symbols used in this manual are explained as follows:

⃠：Prohibition symbol, indicating that the operation is prohibited.

⚠：Attention and warning symbol, indicating that special attention is required, and the instructions should be carefully read and followed.

2 Product Introduction

2.1 Working Principle

This product combines photonic technology with information processing technology to determine the concentration of bilirubin in newborn skin tissue by measuring the absorption of blue and green light waves by the skin.

2.2 Product Composition

The instrument consists of a measurement probe, LED display panel, function keys, indicator lights, control circuits, and a battery pack.

2.3 Structure and Functions

2.3.1 Front Panel

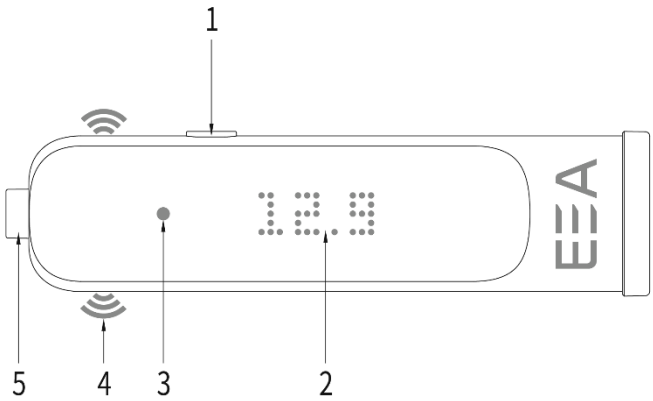

Figure 2-1 Instrument Front View and Indicator Descriptions

NO.	Name	Function Description
1	Function Keys	In power-off state: Short press the function key to power on; In operating state: Short press the function key to switch measurement modes; long press the function key for 3 seconds to power off; Quickly press the function key 5 times to view the instrument's connection number.
2	LED Display Panel	Displays information.
3	Indicator Light	The color of the indicator light is green, and when the indicator light is on, it means that the instrument is in operation.
4	Vibration Function	Vibration Function.
5	Measurement Probe	Used to measure newborn skin to detect bilirubin concentration.

2.3.2 Rear Panel

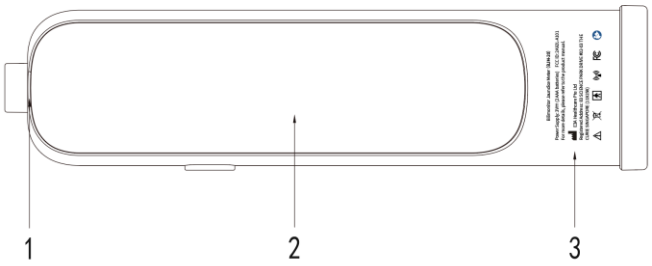

Figure 2-2 Instrument Rear View and Indicator Descriptions

NO.	Name	Function Description
1	Battery Cover Opening	Opening for battery cover.
2	Battery Cover	Protective cover of the battery compartment. Open the battery cover to install or remove batteries.
3	Product Label	Label with various product information.

2.3.3 Legend Display

Figure 2-3

Figure 2-4

Figure 2-5

Figure 2-6

Figure 2-7

Figure 2-8

Figure 2-9

Figure 2-10

Figure 2-11

Figure 2-12

Part Number	Name	Function Description
2-3	Measurement value	Displays the numerical value of the measurement result.
2-4	Measurement unit	Displays the unit of measurement in mg/dL
2-5	Ready mode	Indicates the instrument is in single measurement mode when "READY" is displayed.
2-6	Average mode	Indicates the instrument is in 3-time average mode when "0/3" is displayed.
2-7	Error code “E01”	Indicates measurement result exceeded the maximum measurement range.
2-8	Error code “E02”	Indicates a hardware error which requires maintenance.
2-9	Power off message	Displays "BYE" when the instrument is turned off.
2-10	Low battery warning	Indicates low battery power.
2-11	Instrument activation reminder	Reminds user to activate the instrument through the App before first use.
2-12	Instrument connection number	The instrument's connection number to the App, represented by a 5-digit code.

2.4 Main Performance Parameters

- Power Supply:：DC3.0V　(AAA 1.5V×2 batteries)

- Measurement Time: <2 seconds
- Measurement Range: 0.0mg/dL～20.0mg/dL
- Measurement Accuracy:±1.5 mg/dL
- Repeatability (Coefficient of Variation): <5%
- Transmission Frequency Band: 2402~2480MHz
- Modulation Method:GFSK
- Receiving Frequency Band:2402~2480MHz

2.5 The following parameters of the instrument are considered basic performance parameters:

- Measurement Accuracy
- Repeatability (Coefficient of Variation)

3 User Manual

3.1 Activating the Instrument

When using the instrument for the first time, it will be in an unactivated state and will display the" " icon.You need to register and activate the instrument by downloading the "E3A Healthcare Baby Care" App.

3.2 App Introduction

Scan the below QR code to download the "E3A Healthcare Baby Care" App and register your account as prompted.

Figure 3-1 QR Code for App Download

Figure 3-2 E3A Healthcare Baby Care App Icon

The mobile App includes features such as syncing detection data, automatically generating charts, detecting and alerting abnormal values, and consulting with online doctors.

- ✧ Syncing detection data: Record detection data through synchronization.
- ✧ Automatic chart generation: Automatically generate charts and statistics.
- ✧ Detecting and alerting of abnormal values: Promptly alert abnormal values.

- ✧ Consulting with online doctors: Consult with online doctors at any time.

✧ Note: Supports Android 8.1 and above, and iOS 13 and above.

3.3 App Connection

(1) Make sure the instrument is turned on and in close proximity to the mobile phone.
(2) Open the "E3A Healthcare Baby Care" App.
(3) Turn on the mobile phone's Bluetooth and location services, and click the "Search Device" button on the App homepage to search for the instrument. When the instrument icon appears on the App interface, click the icon to connect. (If multiple instruments are nearby, you can press the function button five times in quick succession to view the Bluetooth number and connect accurately by number.)

Note: For Android systems, both Bluetooth and location services need to be turned on; for iOS systems, Bluetooth only needs to be turned on.

3.4 Starting Measurement

(1) Turn on the instrument by pressing the function button.

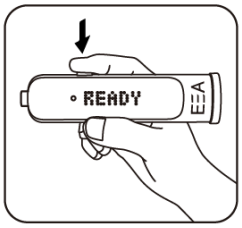

Figure 3-3 Instrument Power On

(2) Measurement Method:
(3) Measurement Method: We recommend measuring on the forehead (slightly above the eyebrow area).
(4) Place the sensor of the instrument vertically against the forehead and gently press it until the instrument makes a "click" sound, which indicates that the instrument is positioned correctly and measurement has started. Keep the pressure steady until the instrument triggers a vibration, which indicates the measurement is completed.

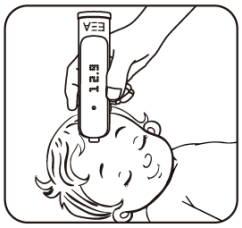

Figure 3-4 Measurement Method

Note: The components of this product in direct contact with the human body have achieved the bio-compatibility requirements of medical device application standards.

(5) Measurement Mode Switching:

①Single measurement mode: The instrument defaults to single measurement mode when turned on; in average mode, press the function button to switch to single measurement mode. In single measurement mode, the instrument displays the word "READY." After each measurement, the instrument displays the corresponding measurement value.

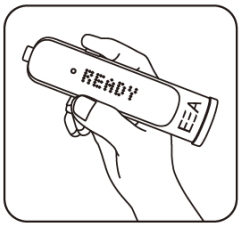

Figure 3-5 Single measurement mode

②Average mode: In single measurement mode, press the function button to switch to average mode. In average mode, the instrument displays the word "0/3." Conduct three consecutive measurements, and after the third measurement is completed, the instrument displays the average value of the three measurements. (After completing three consecutive measurements, the instrument will automatically return to single measurement mode.)

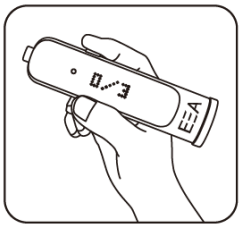

Figure 3-6 Average mode

3.5 Powering Off

Manual Power Off: Press and hold the function button for 3 seconds to shut down.

Automatic Power Off: The instrument will automatically shut down after 60 seconds of inactivity.

When powering off, the instrument displays the word "BYE" (as shown in Figure 2-9).

3.6 Battery Inspection and Replacement

Before use, please check if the positive and negative terminals of the battery are installed correctly and ensure that the battery has sufficient power. If the instrument displays a low battery warning (as shown in Figure 2-10), please replace the battery.

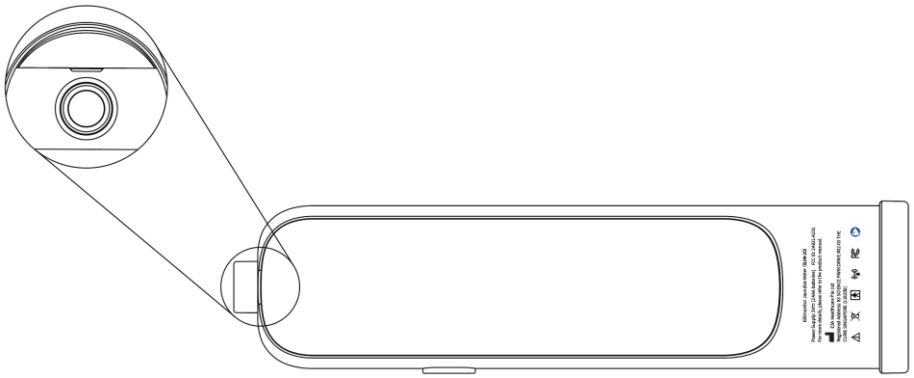

Figure 3-7 Battery cover opening

3.7 Precautions for Use

⚠Warning:

- The light source emitted by the instrument probe may cause eye damage. Do not stare at it directly.
- Use with caution for photosensitive patients and for patients with damaged skin in the measuring area.

⚠Note:

- For premature or underweight neonates, measurement errors may be higher. It is recommended to consult a doctor for care.
- When measuring neonates, place the sensor perpendicularly against the measuring area and keep the probe flat against the skin surface. If there is a gap, it may cause significant measurement errors.a
- Install batteries in the correct positive and negative directions.
- Do not dispose of used batteries casually; follow local regulations for recycling.
- No modification of this equipment is allowed.
- The MANUFACTURER will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist SERVICE PERSONNEL to repair those parts of ME EQUIPMENT that are designated by the MANUFACTURER as repairable by SERVICE PERSONNEL.

4 Maintenance and Care

4.1 Daily Inspection

(1) Check whether the device has any obvious physical damage and if its functions are normal. If any damage is found, please contact E3A Healthcare's after-sales service for assistance;

(2) When the device is not used for a long time, remove the battery.

4.2 Storage Method

(1) Please place the device in a cool and dry place, avoiding strong light or heat sources. (Refer to sections 1.4 and 1.5 for temperature and humidity ranges in the storage location.)

(2) Avoid dropping or subjecting the device to external forces such as vibration or impact.

4.3 Maintenance and Care

(1) The probe can be regularly wiped with medical alcohol;

(2) The device should not be soaked or washed with water, but the surface of the device can be wiped with medical alcohol.

⃠Prohibition: It is prohibited to use diluent and solvents such as benzene to wipe the device.

⚠Caution: Before cleaning the device, please turn off the device and remove the battery first.

4.4 Service Life

This product can be used for up to 3 years.

1. When the device reaches the end of its service life, it needs to be disposed of in accordance with the "Waste Electrical and Electronic Equipment (WEEE) Regulations" or local regulations.
2. Regarding specific information on the recycling of electrical and electronic equipment, please consult the manufacturer or local dealer.

5 Symbol Explanation

Symbol	Explanation	Symbol	Explanation
	Physiological effect		BF type applied part
	Disposal in compliance with local regulations		Non-ionizing radiation
	Read the instructions before use		FCC Certification

6 After-sales Service

Fault and Fault Explanation：

Fault	Possible Causes	Solutions
Unable to power on	No battery installed	Check if the battery is installed, if not, install two AAA batteries
	Battery insulation film not	Check if the battery insulation

	removed	film is removed, if not, remove the film
	Battery polarity reversed	Check if the battery polarity is correctly installed
Power indicator not lit	Device malfunction	Check if the power is working properly Repair or replace the product immediately
Probe does not emit light during measurement	Device malfunction	Repair or replace the product immediately
Screen displays code "E01"	Measuring non-neonatal skin	Measure neonatal skin
	Incorrect measuring position	Refer to the user manual and follow the instructions
	Measuring time too short	Refer to the user manual and follow the instructions
	Strong ambient light	Avoid measuring under strong light, measure in a weak light environment
Significant deviation in measurement results	Inappropriate measuring site	Check the user manual, measure at the recommended measuring site
	Probe surface not clean	Use alcohol wipes to clean the probe
Unable to connect to phone	Device beyond the range of phone connection	Check the user manual, keep the device within a valid distance from the phone
	Phone not granting Bluetooth, location services, etc. permissions	Grant Bluetooth, location services, and other relevant permissions to the phone as prompted
	Device malfunction	Repair or replace the product immediately

Warranty Statement:

(1) Please keep the warranty card properly as proof for repair.

(2) The warranty period is 12 months from the date of purchase.

(3) During the warranty period, if the product malfunctions due to its own quality problems and is verified as such, our company provides free repair service.

(4) E3A Healthcare Pte Ltd reserves the right of final interpretation.

The following conditions are not within the scope of repair:

(1) The model number on the invoice does not match the model number of the product for repair or has been altered.

(2) Malfunctions or damages caused by improper or incorrect use, storage, maintenance, or operation of the device as required by the instructions.

(3) Malfunctions or damages caused by accidental factors or human factors (including operational errors, liquid ingress, scratches, handling, impacts, etc.).

(4) Repairs carried out by non-designated repair departments or repairs carried out by users themselves.

If the free warranty terms are not met, E3A Healthcare Pte Ltd will provide paid repair services, and our customer service center will be dedicated to serving you. Customer Service Center Hotline: 0755-2660 4862 Email: info@e3ahealth.com

7 Warranty Card

Warranty Card

Product Name		**Product Mode**	
Product Number			
Date of Purchase		**Limited Warranty Period**	12 months
Invoice Number			
Customer Name		**Contact Phone Number**	
Customer Address			

8 Attachment C FCC Caution

Part 15.21

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

Part 15.19

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.

FCC RF Radiation Exposure Statement:

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

2. This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.

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

Part 15.105

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.

9 Attachment C ELECTROMAGNETIC COMPATIBILITY

The basic performance parameters of BJM-20 include measurement accuracy and repeatability (coefficient of variation).This ESSENTIAL PERFORMANCE will not be lost or degraded by electromagnetic interference.

The purchaser or user of the BJM-20 should use the device in the electromagnetic environment specifiedin this section to ensure the operating functions of the device.

WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING

Use of accessories, transducers and cables other than those specified or provided by

the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the scanner ,including cables specified by the manufacturer . Otherwise, degradation of the performance of this equipment could result.

Note

Portable and mobile radio frequency communication equipment may affect the normal use of scanner .Hospitals except for near active HF SURGICAL and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high. Please use the recommended electromagnetic environment during use of the scanner.

The use of non-specified accessories and cables may result in an increase in the emission or immunity of the scanner . E3A Healthcare Pte Ltd cannot guarantee that accessories, lines and transformers acquired outside of and not delivered from E3A Healthcare Pte Ltd, will correspond with EMC requirements of IEC 60601-1-2.

Note

The scanner is exclusively intended for use by medical professionals. In residential areas, the scanner may cause radio interference in certain circumstances so that it may be necessary to undertake suitable measures such as realigning, rearranging or screening the scanner, or filtering the connection with the public power supply.

Note

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required)this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures,such as relocating or re-orienting the equipment.

Note

The scanner do not contain magnetically sensitive components or circuitry within the enclosure or as part of an attached accessory.

C.1 Components information

Accessory part/name	Length/dimensions
N/A	N/A

C.2 RF Transmitting

Manufacturer's declaration - Electromagnetic emission	
The scanner is intended for use in the electromagnetic environment specified below, and the purchaser or user shall ensure that it is used in such an electromagnetic environment.	
Emission Tests	Compliance
CISPR 11 Conducted emission	Group 1,Class B
CISPR 11 Radiated emission	Group 1,Class B
IEC 61000-3-2 Harmonic emissions	N/A
IEC 61000-3-3 Voltage Fluctuations and Flicker	N/A

C.3 IMMUNITY TEST LEVELS

IMMUNITY TEST LEVELS for BASIC SAFETY and ESSENTIAL PERFORMANCE of scanner shall be according to the professional healthcare facility environment,baser on the IEC 60601-1-2.

ENCLOSURE PORT

Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS
		professional healthcare facility environment
ELECTROSTAIC DISCHARGE(ESD)	IEC 61000-4-2	±8 kV contact ±2 kV,±4kV,±8 kV 15kV air
Radiated RF EMfields a)	IEC 61000-4-3	3 V/m f) 80 MHz - 2.7 GHz b) 80 % AM at 1 kHz c)
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Table X
RATED power frequency magnetic fields d)	IEC 61000-4-8	30A/m 50Hz or 60Hz
a) The interface between the PATIENT physiological signal simulation, if used, and the ME EQUIPMENT or ME SYSTEM shall be located within 0,1 m of the vertical plane of the uniform field area in one orientation of the ME EQUIPMENT OF ME SYSTEM. b) ME EQUIPMENT and ME SYSTEMS that intentionally receive Rf electromagnetic energy for the purpose of their operation shall be tested at the frequency of reception, Testing may		

be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS. This test assesses the BASIC SAFETY and ESSENTIAPERFORMANCE of an intentional recelver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.
Testing may be performed at other modulation frequencies identified by the RISK MANACEMENT PROCESS.
d) Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.
e) Void.
f) Before modulation is applied.

Input a.c. power port

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS
		professional healthcare facility environment
Electrical fast transients/ bursts	IEC 61000-4-4	±2 kV 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	±0.5 kV,±1 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V 0.15MHz-80MHz 6V in ISM bands between 0.15MHz and 80MHz 80% AM at 1kHz
Voltage dips	IEC 61000-4-11	0% UT；0.5 cycle At 0°,45°,90°,135°,180°,225°，270°and315°
		0% UT; 1 cycle and 70% UT;25/30 cycle Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% UT；250/300 cycle

Table X
The specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	IMMUNITY TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM	28

			± 5 kHz deviation 1 kHz sine	
710	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
870				
930				
1720	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28
1845				
1970				
2450	2 400 to 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
5240	5 100 to 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
5500				
5785				

WARNING

Keep away from strong radiation sources and electromagnetic interference environment. External RFI and electromagnetic interference will affect the normal operation! Such as cardiac pacemakers and other device sensitive to electromagnetic environment, please try to avoid using together.