DAVID

BM-100 series

TRANSCUTANEOUS JAUNDICE DETECTOR

Operator's Manual

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SECTION PAGE

NOTE: THE PRODUCT'S APPEARANCES MAYBE DIFFER FROM THE ONE IN THIS MANUAL, BUT IT DOSE NOT AFFECT THE CAPABILITY OF PRODUCT. PLEASE UNDERSTAND IF IT BRINGS YOU TROUBLES.

SECTION 1
GENERAL INFORMATION

1.1 PREFACE

The manual introduces installation, debugging, operation, cleaning and maintenance methods of BM-100 series Transcutaneous Jaundice Detector (hereinafter referred to as jaundice detector) produced by the Company. The Company shall not be liable for any misoperation caused by the user's neglect of instructions on operation and maintenance in this manual, or for any accident caused by maintenance carried out by technicians not certified by the Company.

The user should carefully read and understand the contents of this manual.

Keep this manual together with the device for reference at any time. Please contact your local agent or our After-sales Service Department in case of any technical problems.

Hemolytic Jaundice/ Praecox Jaundice

In Hemolytic Jaundice and Praecox Jaundice (Blood group incompatibility), the total serum bilirubin concentration (TSB) increases rapidly, and it may deviate from the transcutaneous bilirubin concentration (TcB). Use this device to perform high-frequency measurements to observe the changes in transcutaneous bilirubin concentration (TaB), but in order to make a diagnosis of pathological jaundice, please take blood to measure the total serum bilirubin concentration (TSB).

When Newborns Receive Blue Light Therapy

During the blue light treatment, the bilirubin concentration (TSB) in the skin area decreases. Use this device to observe the changes in

transcutaneous bilirubin concentration (TcB), and to make a diagnosis such as prolonged blue light therapy, please take blood sample to measure the total serum bilirubin concentration (TSB).

1) For the part covered with the light-blocking plate, the concentration of transcutaneous bilirubin (TSB) may decrease more slowly than the total concentration of serum bilirubin (TSB). Due to the difference in decreasing speed, it may happen that TcB may have a deviation in the total concentration of serum bilirubin (TSB).

2) In the illuminated area, it may happen that the concentration of bilirubin in the subcutaneous tissue (TcB) decreases before the total concentration of serum bilirubin (TSB) improves.

3) If the total serum bilirubin concentration (TSB) increases again after the treatment, then the bilirubin concentration (TcB) in the subcutaneous tissue may gradually increase later.

1.2 SAFETY MATTERS

NOTE: For procedures or situations that may be overlooked or misunderstood, "Note" information should be added to draw enough attention. "Note" information may also be used to clarify facts that seem contradictory or confusing.

WARNING: "Warning" information is used to warn dangers or risks associated with operation, cleaning and maintenance of the device, and it may result in life-threatening or serious personal injury to the operator or patient if the user fails to follow the operating instructions highlighted in this way.

1.3 ASSURANCE ASSERTION

The products described in this manual are guaranteed for one year from the date of shipment if they are defective in materials and workmanship, but except for the following circumstances:

1) For all consumables, free warranty is provided for defects delivered only.

2) What confirmed as normal maintenance is not covered under the one-year warranty.

3) Damage caused by improper handling, such as damage caused during transportation or movement.

4) Damage caused by fires, earthquakes, floods and other natural disasters.

In addition to those listed above, any defective part can be replaced for the user free of charge within the warranty period.

WARNING
The Company shall not be liable for any personal injury or property loss due to the following reasons: 1. Any malfunction or damage caused by incorrect operation. 2. Any malfunction or damage caused by the user maintaining the device without following the methods specified in this manual. 3. Any malfunction or damage caused by use of the parts not designated by the Company during modification or maintenance. 4. Any malfunction or damage caused by neglect of operation precautions or instructions specified in this manual. 5. Any malfunction or damage caused by the operating environment, including electrical condition does not meet the requirements specified in this manual.

6. Any malfunction or damage caused by maintenance by any unauthorized distributor/ maintenance service provider.
7. Any malfunction or damage caused by ancillary devices that do not meet the safety requirements are used to this device, resulting in a reduction of the system's safety performance.
8. Any malfunction or damage caused by thoughtless or improper modification.

WARNING: Any modifications to the device are not allowed.

The Company requires users to test the complete performance of the device before official use and to test it at least once every 12 months afterwards. It is suggested to attend the relevant training courses organized by the Company or the distributor authorized by the Company during the warranty period, so as to comply with this guideline.

To obtain relevant maintenance service information, contact your local dealer or our After-Sales Department .

1.4 PRECAUTIONS

OPERATION PRECAUTIONS

1. Operators should read and be familiar with operating instructions of the device before use, and understand the intended usage of and related risks.
2. It is strictly prohibited to use the device in places where there are flammable or explosive gases (such as anesthetic gases, volatile gasoline, etc.), otherwise it may lead to a fire.
3. The device is used to estimate the total serum bilirubin concentration, which is necessary for screening jaundice in newborns. The device is designed for newborns only.

4. DO NOT press the optical probe when it is pointed at the eyes, otherwise it may hurt eyes.

5. DO NOT scan the barcode when the device barcode scanner is facing toward the eyes, otherwise it may hurt eyes.

6. DO NOT place photosensitive drugs around the device, otherwise it will reduce the function of photosensitive drug therapy.

7. DO NOT place the device on an unstable or sloped surface, otherwise the device or the base may fall or turn over, resulting in personal injuries. Please be careful not to drop the device during handling.

8. Be sure the device is placed close to a power outlet, so as to facilitate inserting or unplugging the power adapter plug.

9. Please unplug the power adapter from the outlet during maintenance; otherwise it may lead to an electric shock.

10. DO NOT use the jaundice detector in a place with strong electromagnetic fields. Portable and mobile RF communication devices may have an effect on the device.

11. DO NOT use devices susceptible to magnetic-field interference near the jaundice detector, because the detector may interfere with them.

12. The service life of the jaundice detector is 6 years. The jaundice detector and its accessories or packaging, if discarded casually, will cause damage to the local environment, so the detector must be disposed of in accordance with local laws or returned to the Company for disposal.

ELECTRIC PRECAUTIONS

1. Always use the base and the power adapter equipped with the device, and the adapter shall be connected to a power outlet (AC100-240V, 50/60Hz). If the used base and power adapter are different from those described above or connected to an unspecified voltage, then it may cause damage to the device, base or power adapter and cause accidents, e.g. fire or electric shock.

2. Unplug the power adapter from the power outlet if the device is not used for a long time. It may cause a fire if the part of the power adapter plugged into the power outlet is stained with dust or water drops. Please make sure that no foreign body is attached to the part of the power adapter plugged into the power outlet before use, and use it after cleaning if the part is stained with dust or drops of water.

3. When unplugging the power adapter, please holding the power plug. If pulling the power cord, it will be damaged, and may cause accidents, e.g. fire or electric shock.

4. Please insert the power plug exactly to the end. It may cause accidents, e.g. fire or electric shock if the plug is not inserted completely.

5. DO NOT insert or unplug the power plug with wet hands, otherwise it may lead to an electric shock.

6. The operator shall not contact the patient and the charging interface simultaneously.

7. The base shall not be connected to the power adapter and the data transmission line simultaneously.

8. DO NOT overbend, twist or stretch the power cord. Moreover, DO NOT put heavy objects on the power cord, damage the power cord or process it. It may cause accidents, e.g. fire or electric shock if the power cord is broken.

9. The device has a built-in battery. Non-professional maintenance personnel shall NEVER replace the battery by disassembling the device.

10. DO NOT disassemble or modify the device, base and power adapter, otherwise it may cause accidents, e.g. fire or electric shock.

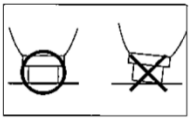
11. DO NOT spill the liquid on the device and the base or drop metal objects into it, otherwise it may cause accidents, e.g. fire or electric shock. If the liquid is spilled on the device and the base or metal objects are dropped into it, please disconnect the power supply immediately, unplug the power adapter plug from the power outlet and contact local agent or Company After-sales Service Department.

12. Please stop using it immediately if the device, base and power adapter are damaged (including housing damage), or there is smoke, foreign odor and other unusual conditions, otherwise it may lead to a fire. In such cases, please disconnect the power supply, unplug the power adapter plug from the power outlet and contact local agent or Company After-sales Service Department.

MEASUREMENT PRECAUTIONS

1. The device shall be used in the specified environment, see Section 2.6 Device Performance for details.

2. When measuring, place the optical probe vertically onto the measuring point as shown in the figure below and press it gently. If the optical probe is not placed vertically, the measurements may fluctuate.



3. The device may not be able to obtain accurate measurements in the following situations:

a. The ambient light (panel light, fluorescent lamp, infrared heating lamp, direct sunlight, etc.) is too strong;

b. Interfered by electromagnetism from other electronic devices when subjected to electromagnetic interference from other electronic equipment (e.g. close to TV, medical device and other electrical appliances);

c. Using a mobile phone during measuring.

4. Measured values from multiple jaundice detectors may vary. The relationship between the values measured by the jaundice detector and those from serum actual analysis should be tested before using each device, so as to obtain precise measurements.

5. The device emits an intense light when it carries out measurements. Measurements on the forehead or sternum are recommended. Because of the rich blood flow in these two places. The area where the blood flow is small and the subcutaneous tissue is keratinized may have a decrease in the bilirubin concentration in the subcutaneous tissue. DO NOT aim the intense light emitted by the device at human eyes.

6. The device should be wiped with a dry cloth or cloth dipped with mild, neutral detergent. DO NOT clean the device with diluent or benzene and other solvents, because these solvents may dissolve the housing.

7. Clean the measuring probe with medical alcohol before use.

8. The device can only be used clinically in battery mode, not in charging mode.

PERIODIC SAFETY CHECK

The following safety checks should be carried out by a trained professional with sufficient knowledge and practical experience at least once every 12 months, and the check data should be kept.

① Check the mechanical structure and functional integrity of the device.

② Check if the symbols and marks listed in this manual are clear and distinguishable.

③ Check if the performance index of the device is consistent with the values alleged in Section 2.6.

④ Test the leakage current of the device's housing as per the test method specified in IEC 60601-1:2005, and the current shall not exceed 100μA in normal state; it shall not exceed 500μA in single failure state.

⑤ Test the patient leakage current of the device as per the test method specified in IEC 60601-1:2005, and the alternating current shall not exceed 100μA in normal state; the direct current shall not exceed 10μA.

⑥ Test the patient leakage current of the device as per the test method specified in IEC 60601-1:2005, and the alternating current shall not exceed 500μA in single failure state; the direct current shall not exceed 50μA.

⑦ Test the patient leakage current of the device (add grid voltage to the applied part) as per the test method specified in IEC 60601-1:2005, and the current shall not exceed 5000μA in single failure state.

SECTION 2
PRODUCT INTRODUCTION

2.1 INTENDED USE

This device is used to measure the serum bilirubin levels of neonates before, during and after phototherapy.

2.2 INTENDED USE ENVIRONMENT

The device is intended to be used in: Medical institutions with Practice License (e.g. hospitals). Specific operating environments include: Neonatology Dept., Pediatric Dept., Maternity and Child Care Centers, delivery rooms, baby wards and neonatal intensive care units.

2.3 CONTRAINDICATION

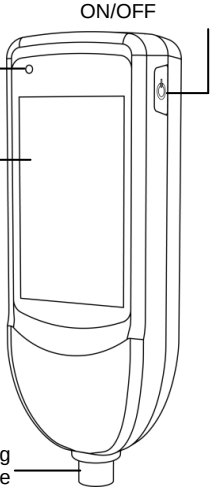
It is not clear yet.

2.4 STRUCTURAL COMPOSITION

The jaundice detector consists of a host, a base and a power adapter. The host is composed of optical probe, display screen, battery, barcode reader and host circuit. The base can be used to charge the host and contains a check screen. The optical probe is the application part, the head is composed of polymer fiber arrangement, and the contact part of the end is made of PMMA. The spectrum application range of the optical probe is 350nm and 700nm, The spectral response peak is 550nm. The pulse duration of this product is 3ms and the pulse interval is greater than 2s. The differences between models and specifications are described below:

Model/Specification	USB Data Transmission Function	Barcode Scanner
BM-100A	No	No
BM-100B	Yes	No
BM-100C	Yes	Yes

2.4.1 HOST



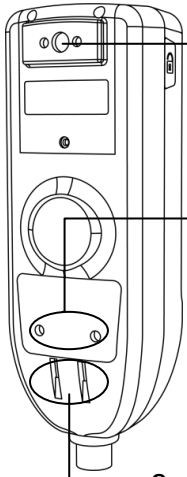
Switch
Long press the switch to set the host to ON/OFF

Barcode Scanner
Scan nurse ID and baby ID

Ready indicator light
The device is ready for the next measurement when the green light is on

Display screen
Display measurements and error messages, etc.
Select and confirm by touching screen

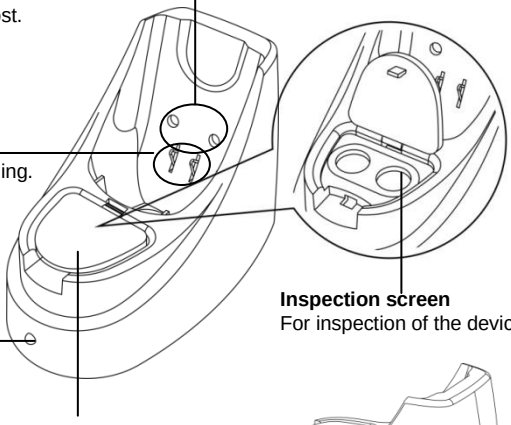
Optical probe
Start measuring by attaching the optical probe to the measuring point



Data transmission interface
Communicate with the host.

Contact for charging
Connecting the base during charging

2.4.2 BASE



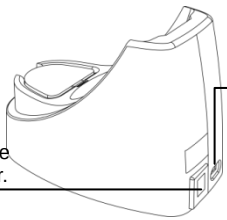
Data transmission interface
Communicate with the host.

Charging terminal
Connecting the host when charging.

Base indicator light
Indicate the base state.

Inspection screen
For inspection of the device.

Inspection screen cover
Please open the cover upon inspection.

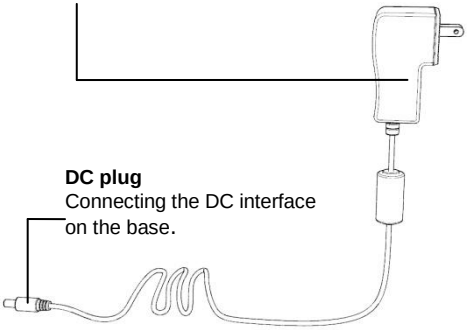


USB interface
For data output.

DC interface
Connecting the power adapter.

2.4.3 POWER ADAPTER

Power plug
Connecting to a power outlet.



DC plug
Connecting the DC interface on the base.

2.5 SYMBOLS

2.5.1 SYMBOLS ON THE HOST

	Switch symbol		Unlock/lock screen symbol
	Type BF applied part	Ready	Ready indicator light symbol
SN	Serial number		Date of manufacture
	Follow instructions for use		Direct current
CE 0123	CE MARKING	EC REP	European union representative

2.5.2 SYMBOLS ON THE BASE

	General warning sign	0	Inspection screen with predetermined value "0"
20	Inspection screen with predetermined value "20"	SN	Serial number
	Date of manufacture		

2.5.3 SYMBOLS ON THE POWER ADAPTER

	General warning sign		Class II device

2.6 DEVICE PERFORMANCE

Classification according to the type of protection against electric shock: Class II, internal power supply device.

Classification according to the degree of protection against electric shock: Type BF applied part.

Not AP , APG device.

Classification according to operational mode: Continuous operation.

General parameters

Intended users .....Neonates

Requirements of operating environment ..... Temperature: 5℃-40℃;

Humidity: ≤90%RH;

Atmospheric pressure: 700hPa-1060hPa

Requirements of transportation and storage environment……Temperature: -20-55℃;

Humidity: ≤90%RH;

Atmospheric pressure: 500hPa-1060hPa;

It should be stored in a ventilated and dry storehouse; it should prevented from rain, water immersion, sun exposure, fall and mechanical losses during transportation; it shall not be stored or transported together with poisonous, harmful or corrosive substances

Liquid ingress protection grade IPX0

1.1.15 Prietaiso svoris su akumuliatoriumi

Host weight .....≤ 250g

Host size .....60mm×46mm×175mm

Base weight.....≤ 250g

Base size.....85mm×155mm×106mm

Expected service life .....6 years

Applied environmental altitude .....≤3000m

Pollution level 2

Performance parameters

1.1.2 Display range……No less than 25.0 mg/dL (425μmol/L)

Accuracy……± 1.5 mg/dL （± 25.5 μmol/L）

1.1.3 Repeatability……..No more than 3%

Information prompt……Low voltage prompt

Inspection screen .....The transmittance ratio of the spectra with wavelength of 550nm and 461nm is:
The inspection screen with predetermined value of "0" is 1±0.1
The inspection screen with a predetermined value of "20" is 5±0.5;

Average measurement function .....1~5 times average measurement can be set

Scan code function (BM-100C only).....The nurse ID and the baby ID can be obtained by scanning the code

Set the time.....Time and date modifications can be implemented

Sound Settings.....Touch screen key tone can be set to on/off

Brightness Settings .....The brightness of the screen can be adjusted by 5 levels

Unit of measure.....The unit of measurement can be switched between mg/dL and μ mol/L

The screen saver .....Screen saver time can be set to 1 minute or 5 minutes

Historical data saving .....Nurse ID number, baby ID number, measurement result, measurement time, measurement is priority, blue light completion mark can be saved

Data transmission (BM-100B and BM-100C only)……You can export a TXT file containing all the historical data

Other parameters

Rated voltage and frequency of the device when it is supplied by the supply main: AC 100-240V , 50/60Hz

Input power of the device when it is supplied by the supply main: 30 VA

Power supply type of the host when it is supplied by the internal power: Rated voltage7.4V ⎓(lithium battery)

Base output .....8.4V⎓ 1A

Light source.....Xenon flash lamp

Light source life .....Not less than150000 times

Other .....The base has a built-in inspection screen

The optical radiation parameters are shown in the table below:

Maximum output of optical radiation

Radiance Output	Risk group classified by IEC60601-2-57:2011	Maxi.value
Euva: Eye UV-A	Exempt Group	6.28×10^{-6} W·m^{-2}
ES: Actinic UV skin & eye	Exempt Group	8.02×10^{-6} W·m^{-2}
EIR: Infrared radiation hazard exposure limits for the eye	Exempt Group	5.89×10^{-1} W·m^{-2}
LB: Blue light	Exempt Group	4.03×10^{-3} W·m^{-2}·sr^{-1}
LR: Retinal thermal	Exempt Group	8.49×10^{-1} W·m^{-2}·sr^{-1}

SECTION 3
FUNCTION DESCRIPTION

3.1 OVERALL FUNCTION DESCRIPTION

The jaundice detector is a device used to dynamically detect the transcutaneous value of neonatal serum bilirubin, which applies optical fiber technology, photoelectric technology, electronic and information processing technologies to quickly and non-invasively determine the transcutaneous bilirubin value related to serum bilirubin concentration on the neonatal skin outer epidermis.

3.2 DETECTION PRINCIPLE

Serum bilirubin builds up in the skin tissue, making the skin yellow. The jaundice detector uses the absorption difference between blue light waves (461nm) and green light waves (550nm) in the skin tissue to detect the concentration of bilirubin deposited in the neonatal skin tissue.

After the probe is placed on the baby's forehead and powered up, the ray emitted from the xenon flash lamp is guided to skin surface via the light-guide fiber of the probe's outer ring and directly to the subcutaneous area. The light waves are repeatedly scattered and absorbed on the skin, and finally returned to the light-guide fiber of the probe's inner ring, and transmitted to the corresponding photodiode. The measured value (also known as the transcutaneous value) of the jaundice detector is obtained by calculating the optical density difference between light waves of 461nm and 550nm.

The transcutaneous value, demonstrated by clinical trials, has a good linear correlation with neonatal serum bilirubin concentration, which means that a certain transcutaneous value corresponds to a certain concentration of serum bilirubin. The level and change of serum bilirubin concentration, therefore, can be determined according to the transcutaneous value and its change, especially the change of serum bilirubin concentration can be accurately reflected, so as to effectively detect neonatal jaundice.

NOTE: DO NOT press the measuring probe when it is pointed toward the eyes.

3.3 DATA COMMUNICATION INTERFACE

The base is equipped with a Micro USB data communication interface, which is used for data terminal output.

NOTE
1. If auxiliary equipment connects to the interface, then it needs to be evaluated as per the requirements of IEC 60950-1:2005 within its service life.
2. The data communication interface shall be maintained by the device maintenance department of the medical institution, and the data communication shall be inspected regularly and annually.
3. The data communication shall be connected and used by the specially trained medical personnel who are aware of the risks associated with it.
4. DO NOT touch the data communication interface and the patient simultaneously.
5. Please consult our agent or our After-sales Service Department if there is any question.

WARNING: Percutaneous jaundice USES USB data interface and standard USB transmission protocol.

3.4 ALARM INFORMATION AND SYSTEM FAILURE INFORMATION

The screen may display the following warnings.

Please process according to the failure information.

3.4.1 BATTERY POWER DISPLAY

Battery symbol and action	Cause	Solution
 Battery symbol lights up	It may be charged insufficiently.	The measurement can be continued after the warning is shown the first time, but we suggest charging the battery as soon as possible.

3.4.2 OTHERS

Display (errors)	Cause	Solution
Er1 (measurement error)	The measured value is out of display range.	Please place the probe vertically at the recommended point (forehead or sternum) and measure again

SECTION 4
INSTALLATION AND CALIBRATION PROCEDURE

4.1 UNPACKING

The jaundice detector is generally packed in a carton. It shall be handled with care when unpacking to avoid damaging parts or accessories. Please check for the following items.

1) Host ×1

2) Base ×1

3) Power adapter ×1

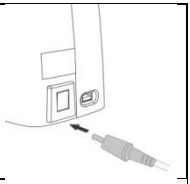
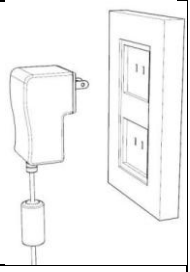
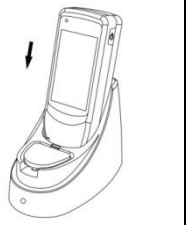
4) Operator's manual ×1

4.2 INSTALLATION

Please follow the procedure given below, so as to ensure that the following measurements can be carried out stably.

4.2.1 CHARGING

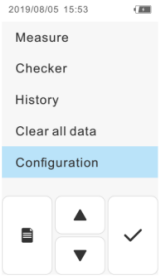
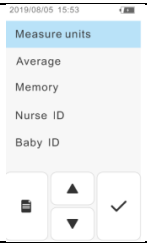
NOTE: Please make sure that the battery has been fully charged at the first time to use.

① Connect the DC plug of the power adapter to the DC interface on the base.	
② Connect the power plug of the power adapter to the power outlet and the base green indicator light lights up.	
③ Place the device on the base. Please place the display screen towards you as shown in the figure. The base yellow indicator lights up when the device is properly placed on the base. If the initial setting is not conducted when the device power is set to ON for the first time, it will take about 4 hours to complete charging. The base green indicator lights up when the battery is fully charged.	

4.2.2 SETTINGS

The measuring conditions and the device settings are preset.

Follow the following steps when changes are required.

① Press the power switch for more than 5 seconds to set the power to ON.	
② Select "Configuration" on the menu screen after pressing button on the screen. Press ▲ or ▼ button to move the highlighted cursor over "Configuration", then press ✓ button. You can also select by directly pressing the highlighted "Configuration" instead of ✓ button. Display the setting screen.	
③ Select the items you want to change in sequence on the setting screen, and then set them separately.	

Items that can be set up and related descriptions are as follows:

Setting Screen Item	**Description**	**Setting Content**	**Description**
Measure units	Set the unit displayed during measurement	mg/dL● μmol/L	
Average	Set the number of times when the average measurement is carried out.	1 ● 2 3 4 5	

Memory	Set whether the measured data is saved in the host or not.	Off●	Not save measurement results in the host
		Memory only	Save the measurement results in the host
Nurse ID	Select the standard input method for the nurse ID	None●	Not enter nurse ID
		Barcode input	Scan ID with a barcode scanner
		Touch input	Enter ID via touch input
Baby ID	Select the standard input method for the baby ID	Barcode input	Scan ID with a barcode scanner
		Touch input●	Enter ID via touch input
Buzzer	Set the sound	Off	Silent
		On●	Make a sound when touching, etc.
Time setting	Set date and time		
Data transmission	Upload PC data		Enter password and connect with PC for data transmission, The initial password is: 787223

Brightness	Change the screen contrast	1 2● 3 4 5	The smaller the value is, the darker the screen turns.
Screen saver time	Set the screen saver time	1 min● 5 min	
Software version	Display the software version		
Initialization	Initialize the host settings.		
NOTE: "**●**" indicates the preset initial setting value when the power is turned ON for the first time and initialization is performed.			

4.3 CALIBRATION PROGRAM

The user should execute the following operation calibration program before each use. If the device is used immediately without any inspection, the existing failures may not be found, leading to potentially unfavourable consequences.

The specific distance between the user and the device shall be subject to the comfort level during operation.

4.3.1 CHECK THE INTEGRITY OF THE DEVICE

- Confirm that the device is cleaned;
- Confirm that the device is free of cracks;

- Confirm that all required parts and auxiliary equipments are available any time and in good order;
- Confirm that the electric wire is properly connected and the installation is secure.

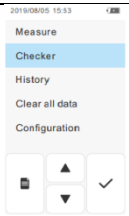
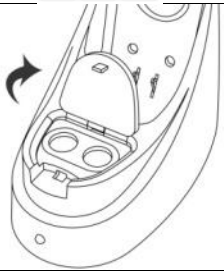
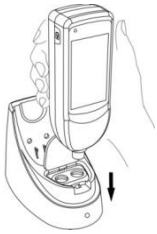
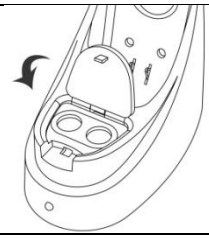
WARNING: Once a certain function of the device is found missing or the housing is damaged, stop using it immediately, and it should be repaired by the qualified personnel.

4.3.2 USAGE OF THE INSPECTION SCREEN

NOTE
1. DO NOT touch the surface of the inspection screen with fingers. If the inspection screen becomes dirty, wipe it with a soft cloth dampened with water and then with a dry cloth.
2. If the result is not within the reference range, please measure again after cleaning the inspection screen and the measuring probe.
3. If the result is still not within the range, please contact our company and designated agent for more detailed guidance.

Follow the following steps to use the inspection screen:

① Set the power to ON by pressing and holding the power switch for over 5 seconds. About 1 year after purchase or calibration through the manufacturer's service, a "Please calibrate regularly" interface pops up. This is to suggest and inform you to perform a periodic calibration once a year for the device. If you need to entrust the calibration, please contact our company or authorized maintenance agency. Press the button below the interface to exit the interface.	

② Select "Checker" on the menu screen.	
③ Open the inspection screen cover.	
④ Place the optical probe vertically on the inspection screen and gently push until it glows. If the measuring probe is not vertical to the inspection screen at contact, please place it vertically and measure again.	
⑤ Confirm the measured value. Reference range is 0.0-1.5 for white screen Reference range is 20.0±1.5 for yellow screen	
⑥ Close the inspection screen cover.	

SECTION 5
SETTING AND USING

5.1 OPERATION

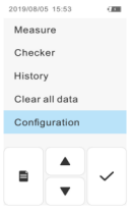
WARNING
1. Please carefully read the operation precautions in Section 1.4 of this manual before operation.
2. The jaundice detector shall not be used if it fails the calibration, and it shall be repaired by the authorized and qualified maintenance personnel.

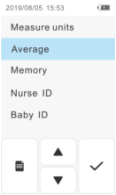
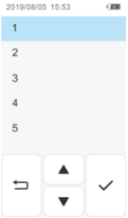
The device can perform "1 time", that is to process the result of each measurement as the measured value. The device can also perform "average value measurement", that is to process the average result of 2-5 measurements as measured value.

In addition, measurement result can be saved or not.

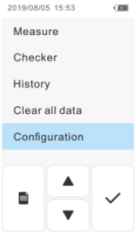
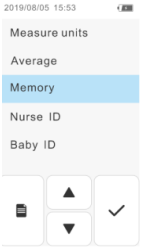
Please set the measurement times and set whether to save or not according to the measurement point and measurement state.

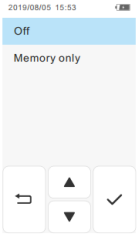
5.1.1 SETTING OF AVERAGE MEASUREMENT TIMES

① Select "Configuration" on the menu screen after pressing button on the screen.	

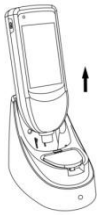
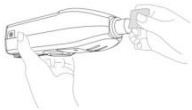
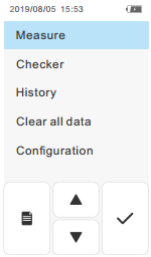
② Select "Average" on the setting screen. The setting of "1" to "5" for the last measurement is highlighted.	
③ Select the expected average times. 1 time: (take the result of 1 time as the measured value) 2 to 5 times: Average measurement (take the average result of 2 to 5 measurements as the measured value). "AVE" appears on the screen when a number between "2 " to "5 " is selected	

5.1.2 SETTING OF SAVING/NOT SAVING THE MEASUREMENT RESULT

① Select "Configuration" on the menu screen after pressing button on the screen.	
② Select "Memory" on the setting screen. The setting of "Off", "Memory only" for the last measurement is highlighted.	

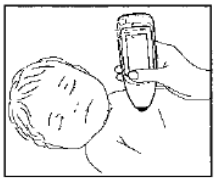
③ Select the expected memory function. Off: Not save measurement results in the host. Memory only: Save the measurement results in the host.	

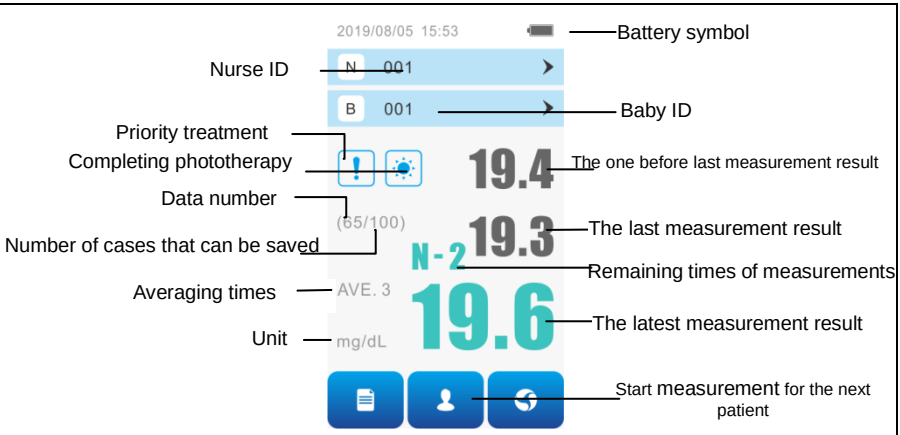
5.1.3 MEASUREMENT STEPS

① Remove the device from the charger.	
② Clean the optical probe with medical alcohol.	
③ If the power is OFF, press and hold the power switch for more than 5 seconds to set the power to ON. If the idle time of the device is more than 1 min, there will be no display on the screen. Please touch the display screen to wake up.	
④ If the display screen is not the measurement screen, press button and select "Measure" in the menu screen. The display screen will turn to the measurement interface. In a few seconds, the "Ready" indicator green light lights up, indicating that the device is ready for measurement.	

5.1.3.1 WHEN PERFORMING MEASUREMENTS WITHOUT SAVING MEASUREMENT RESULTS

The "Memory" setting must be set to "Off".

① Make sure that the Ready indicator light is on.	
② Place the optical probe vertically on the measuring point (sternum or forehead) and gently push until it glows. The measurement is performed at this moment. If "Average" is already set to a number between "1" to "5 ", the remaining times of measurements will be displayed. Repeat the remaining times of measurements while ensuring that the Ready indicator light is on.	
③ The measured values will be displayed on the display screen. If "Average" is already set to a number between "1" to "5 ", the average value of the measured values will be displayed after the selected measurement times are completed.	



④ Read the measured value.

A maximum of 3 measurements can be performed/ displayed. If the measured value flickers, it indicates that the value is out of guaranteed measurement accuracy range. If "Er1" is displayed, it indicates that the measured valued is out of the measurement range.

To exit the measurement, perform the operation in "Device Placement".

To perform another measurement, press button to delete the displayed measurement results and continue from Step 5.

The latest measurement result will be deleted if pressing button once.

All displayed measurement results will be deleted if pressing and holding the button.

NOTE
If the measured value is out of the display range (26.6mg/dL, 451 μmol/L),it will display "Er1".

5.1.3.2 WHEN PERFORMING MEASUREMENTS THAT NEED TO SAVE RESULTS

The "Memory" setting must be set to "Memory only".

a. If the "nurse ID" has been set as "Barcode input" or "Touch input", enter the nurse ID. It is OK not to enter the nurse ID and leave it blank.

b. Enter the baby ID.

c. Make sure that the Ready indicator light is on.

About ID input

You can enter up to 16 characters for nurse ID and baby ID.

Enter ID with a barcode reader

① Press and hold button when the barcode reader is pointed towards the barcode to be scanned.

The following barcodes can be scanned:

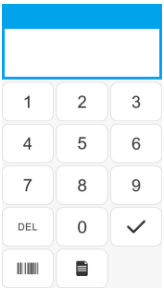
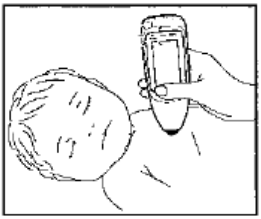
Code EAN/JAN, CODE128, ANSI/HIBC, CODE39 barcode

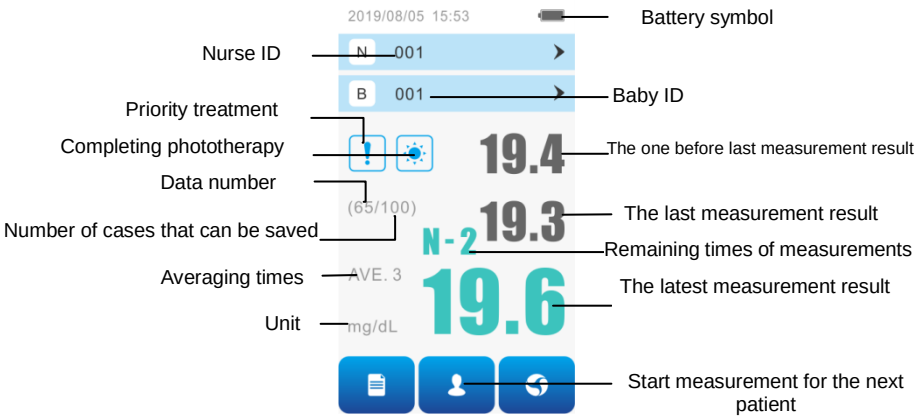
② The scanned ID will be displayed when the barcode reader glows and scans the barcode. Please confirm if the displayed ID is correct.

③ Press ✓ button, then enter the next screen after ID input.

④ To switch to the input mode to the touch input, press button.

<table>
<tr><td>Enter ID via the touch screen

① Press DEL button to delete a character and re-enter.
Enter the character, press ✓ button, complete ID input, then enter the next screen.</td><td> 
</td></tr>
<tr><td>② Place the optical probe vertically on the measuring point (sternum or forehead) and gently push until it glows.
The measurement is performed at this moment. If "Average" is already set to a number between "1" to "5" times, the current times of measurements will be displayed. Repeat the remaining times of measurements while ensuring that the Ready indicator light is on.</td><td>  </td></tr>
<tr><td colspan="2">③ The measured values will be displayed on the display screen.
If "Average" is already set to a number between "1" to "5" times, the measure value (average value) will be displayed after the selected measurement times are completed.</td></tr>
</table>



④ Read the measured value.

A maximum of 3 measurements can be performed/ displayed for each patient.

Press ··· ··· to add the priority sign ! that indicates the bilirubin value is at high risk and sign ☀ of phototherapy completing indicating the completion of the phototherapy to record the patient's status.

To exit the measurement, go to Step ⑨ or "5.2 Device Placement".

To continue measuring other patients, press 👤 button and continue from Step ⑤-b.

If 100 measurement results are saved, further measurements cannot be carried out.

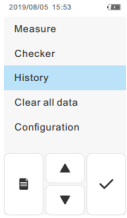
Please continue further measurements after deleting the history record one by one on the "History" screen or deleting all history records on the "Clear all data" screen.

⑤ To view the history, press button on the display screen and select "History" on the menu screen. The history data are displayed in the form of baby ID list.

Select the expected baby ID, then the details of the measurement results will be displayed.

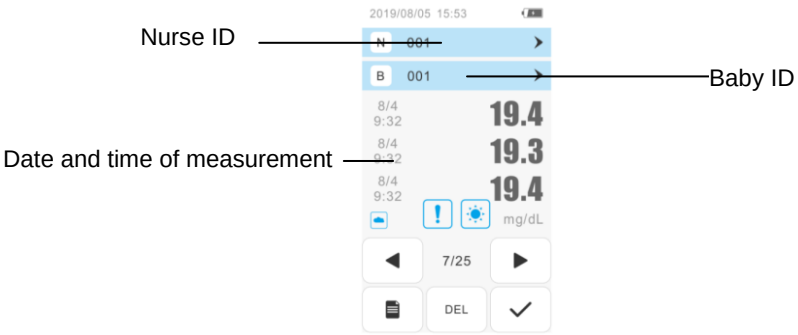
View the history data

a. Select "History" on the menu screen.



b. The history data are displayed in the form of baby ID list.

c. Select the expected baby ID and press ✓ button, then the details of the measurement results will be displayed.



d. To view the data before and after, press ◀or ▶ button.

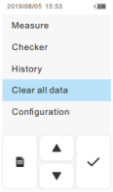
To delete the history data, press DEL , and press ✓ button on the confirmation screen.

Delete all history data

Select "Clear All Data" on the menu screen.

All data will be deleted after pressing "Clear all Data" on the confirmation screen and pressing ✓ button on the confirmation screen displayed again.

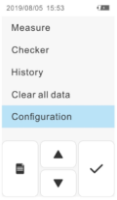
The data can be deleted one by one from the "History" screen.

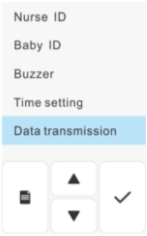


Transmission of historical data (for BM-100B and BM-100C only)

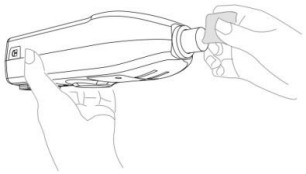
① Connect the computer with USB data cable;

② Select Configuration on the menu screen.



③ Select Data transmission on the setting interface.	
④ After the correct password is entered on the password input page, the host is placed on the base correctly, and the USB cable is connected to the base and the computer. Displaying the transfer progress from 0% to 100%, you can export a TXT file containing all the historical data on your computer.	

5.2 DEVICE PLACEMENT

① Clean the optical probe with medical alcohol	
② Place the device on the base	
③ Please place the device on the base when no measurement is carried out. The power will be ON when placed on the base. After placing the device on the base for 1 min, the screen will be OFF, but the power will turn to OFF. If the device is not placed on the base when the power is ON, the screen will turn OFF in 1 minute. If the device is placed in the same state for 9 min (10 min in total), the power will turn OFF. If the device is not placed on the device, press and hold the power switch for over 5 seconds, the power will turn OFF.	

SECTION 6
CLEANING AND MAINTENANCE

6.1 CLEANING

Optical probe: After each newborn is measured, the equipment is first cleaned by dipping a small amount of cold or warm water with a damp flexible cloth, or with a neutral cleaning solvent or solution approved by the state. After cleaning, wipe the residual moisture on the dry surface with a clean soft cloth or absorbent paper towel, and then wipe and disinfect the optical probe with a flexible cloth dampened with 75% alcohol (more than three times is recommended).

Host，Base: Use a damp flexible cloth dipped in a small amount of cold or warm water, or a neutral cleaning solvent or solution approved by the state to clean the equipment. After cleaning, wipe the residual moisture on the surface of the dry equipment with a clean soft cloth or absorbent paper towel to avoid residue attachment on charging terminals (if residue attachment on charging terminals, etc., will lead to poor charging).Then dip in with 75% alcohol flexible cloth to host, base for wiping disinfection. Under normal circumstances, the host and base should be cleaned and disinfected once or twice a week. Do not use other methods or solvents

DO NOT clean the device with diluent or benzene and other solvents, because these solvents may dissolve the housing.

6.2 MAINTENANCE

6.2.1 ROUTINE MAINTENANCE

The routine maintenance and inspection shall be carried out by a trained professional with sufficient knowledge and practical experience at least every 12 months, the testing data shall be kept, and the inspection contents are as follows:

A Inspection of related files:

Operator's manual is available

B Perform functional tests on the following features as per the manual:

Optical measurement

Internal battery

C Inspect that the device combination is in good condition:

All labels are complete and legible

No visible damage on the device or power cords

D. Inspect that all parts and accessories used to run the device are available according to the operator's manual.

E. Carry out electrical safety inspection as per IEC 60601-1:2005.

6.2.2 PREVENTIVE MAINTENANCE

The device shall be charged every 15 days if it is not used for a long time. The battery charger shall meet the requirements of IEC 60601-1:2005.

The battery shall be replaced by the professional maintenance personnel at least every 24 months. B1 and J6 marks can be seen on the circuit board of the host when the device housing is opened with a tool. Where B1 is button battery interface and J6 is power battery interface.

NOTE: Device failures can be caused by part wear and material fatigue.

WARNING
1. Disconnect all power supplies before performing any maintenance work.
2. Replacement of batteries by poorly trained personnel can cause hazards (such as overtemperature, fire, or explosion).

6.2.3 CALIBRATION

Calibrating the device every 12 months is recommended. It shall be returned to the authorized maintenance center. The validity of initial calibration is within one year from the date of manufacture. The validity of subsequent calibration shall be within one year from the previous calibration date.

6.3 COMMON TROUBLESHOOTING GUIDE

The following table lists the failures the jaundice detector may occur during use. If the failures cannot be solved by following the recommended solutions in the table, please ask the authorized and qualified maintenance personnel to repair the jaundice detector or seek help from the Company's authorized maintenance service provider or After-sales Service Department.

Problem	Inspection Item	Solution	Reference Section
The display screen remains blank when the power switch is set to ON.	Is the battery run out?	Please place the device on the base for charging	4.2.1
The display screen suddenly goes blank during measurement.	Is it in idle for more than 1 minute after the power is set to ON?	The screen has been turned OFF. Please touch the display screen to wake up.	5.1.3
The device has been placed on the base, but the charging indicator does not light up.	Is the base and power adapter properly connected to the power outlet?	Please connect the base to the power adapter properly.	4.2.1
	Is the device properly placed on the base?	Please place the device properly.	

The battery power consumption seems too fast.	Do you operate the display screen frequently?	Lots of battery power will be consumed if changing settings too much and operating too often. Please adopt some methods in use, e.g. making the setting of the measurement condition constant, etc.	/
Reduced number of consecutive measurements	Dose the device stop running after dozens of lighting (the image disappears during operation)?	It may due to battery ageing. Please ask the authorized and qualified maintenance personnel to repair the jaundice detector or seek help from the Company's authorized maintenance service provider or After-sales Service Department.	/
Unable to measure	Is the Ready indicator on?	Before the measurement, please check that the Ready indicator is on.	5.1.3.1 5.1.3.2
		If the battery's residual voltage is low or the battery is running out, please place the device on the base for charging	4.2.1
	Whether the display is invalid or not	Please press the screen lock button to unlock	2.4.1

APPENDIX A: EMC INFORMATION

This section is precaution for electromagnetic compatibility. The device shall be installed, operated and used according to the electromagnetic compatibility information specified in this section.

A.1 ENVIRONMENTAL CONDITIONS OF ELECTROMAGNETIC COMPATIBILITY

1. The equipment intend to use in the professional healthcare facility environment.

2. Equipment cannot be operated or exposed in RFID, X-RAY, MRI environments.

3. 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 equipment,including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

4. Equipment should not be used adjacent to or stacked with other equipment and that if adjacent orstacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.

5. If the essential performance is lost or degraded due to EMC disturbances, the user might need to take mitigation measures, such as relocating or re-orienting the equipment.

A.2 Classification of Electromagnetic Interference:

Group 1, Class A

A.3 Cable List Provided by the Manufacturer

Name	Cable length	Shielded or not	Manufacturer
Power cord	1.4 m	No	Taiwan Xingbo Electronics Co, Ltd.
USB data cable	1.0 m	Yes	Shenzhen Shanchuang Electronics Co. Ltd.

A.4 EMC Immunity Performance Test (essential performance)

The deviation of bilirubin measurement is less than ±1.5mg/dL

A.5 Warning

1.Pay attention to the electromagnetic environment at the scene, because the equipment may be affected by the electromagnetic environment at the scene.

2.Use of 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.

Guidelines and Manufacturer's Declaration - Electromagnetic Emission

Guidelines and Manufacturer's declaration - Electromagnetic Emission	
The *Jaundice* is intended for use in the electromagnetic environment specified below. The customer of the user of the *Jaundice* should assure that it is used in such and environment.	
Emission Test	**Conformance**
RF emission CISPR 11	Group 1
RF emission CISPR 11	Class A
Harmonic emission IEC61000-3-2	Class A
Voltage fluctuation/scintillation emission IEC61000-3-3	Conform
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.	

Guidelines and Manufacturer's Declaration - Electromagnetic Immunity

Guidelines and Manufacturer's declaration - Electromagnetic Immunity		
The *Jaundice* is expected to be used in the following specified electromagnetic environment, and the purchaser or user shall ensure that it is used in this electromagnetic environment:		
Immunity Test	**IEC60601 Test Electrical Level**	**Compliance Level**
Electrostatic discharge IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air
Electrical fast transient burst IEC 61000-4-4	±2 kV for power supply lines ±1kV for signal input/output	±2kV for power supply lines ±1kV for signal input/output
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode
Voltage dips, short interruptions and voltage variations on the power input line IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25 cycles Single phase: at 0° 0 % UT; 250cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25 cycles Single phase: at 0° 0 % UT; 250 cycle
Power frequency magnetic field(50 Hz) IEC 61000-4-8	30A/m	30A/m
NOTE: U_T is the a.c. mains voltage prior to application of the test level.		

Guidance and Manufacture'S Declaration – Electromagnetic Immunity –for Equipment and Systems that are Life-Supporting

Guidance and manufacture's declaration – electromagnetic immunity		
The *Jaundice* is intended for use in the electromagnetic environment specified below. The customer or the user of jaundice should assure that it is used in such an environment.		
Immunity test	**IEC 60601 test level**	**Compliance level**
Conducted RF IEC 61000-4-6	$3V_{rms}$ 150 kHz to 80 MHz $6\ V_{rms}$ 150 kHz to 80 MHz in ISM bands	$3\ V_{rms}$ $6\ V_{rms}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3V/m
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]The ISM(industrial, scientific and medical) bands between 150kHz and 80MHz are 6.765MHz to 6.795MHz; 13.553 MHz to 14.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

[b]The compliance levels in the ISM frequency bands between 150kHz and 80MHz and in the frequency range 80 MHz to 2.5GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] 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. 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 *Jaundice* is used exceeds the applicable RF compliance level above, the *Jaundice* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *Jaundice*.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Guidance and manufacturer's declaration – electromagnetic immunity –for all EQUIPMENT and SYSTEMS

IMMUNITY to proximity fields from RF wireless communications equipment

The ENCLOSURE PORT of ME EQUIPMENT and ME SYSTEMS shall be tested as specified in Table 9 using the test methods specified in IEC 61000-4-3..

Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHZ)	Band a) (MHZ)	Service a)	Modulation b)	Maximum Power (W)	Distance (m)	Immunity test level (v/m)
385	380-390	TETRA400	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	704-787	LTE Band13,17	Pulse modulation b) 217Hz	0,2	0,3	9
745						
780						
810	800-960	GSM800/900, TETRA 800,iDEN 820,CDMA 850,LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28
870						
930						

Test frequency (MHZ)	Band [a] (MHZ)	Service [a]	Modulation [b]	Maximum Power (W)	Distance (m)	Immunity test level (v/m)
1720	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
1845						
1970						
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	5100-5800	WLAN 802.11a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5500						
5785						

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.

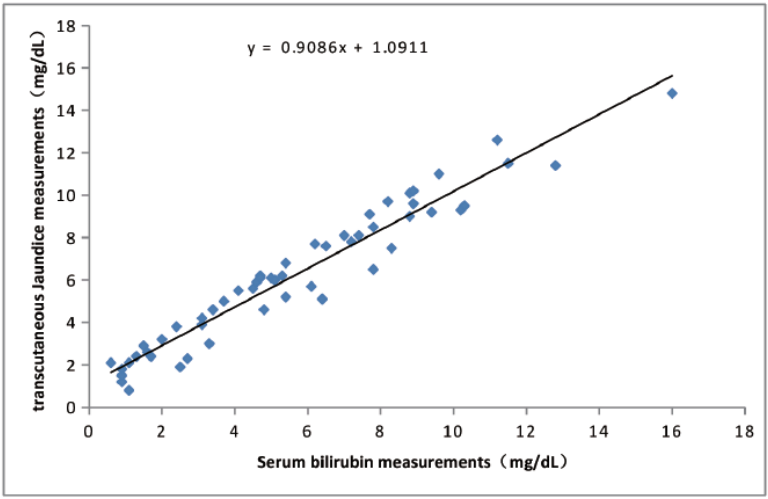
[b]The carrier shall be modulated using a 50 % duty cycle square wave signal.

[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.

Appendix B REPORT OF CLINICAL TRIAL RESULTS

To verify the availability of the BM-100 series percutaneous jaundice instruments, the correlation between instrument measurements (TcB: Transcutaneous Bilirubin) and TSB: Total Serum Bilirubin obtained from blood sampling was tested in the hospital.

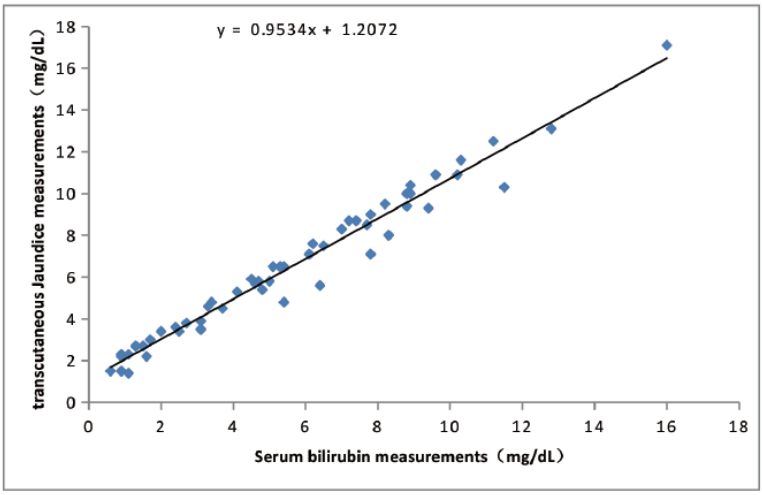
Relationship between serum bilirubin measurements (TSB) and percutaneous jaundice measurements (TcB $_{\text{anterior chest}}$)



The data showed that the measured serum bilirubin (TSB) was linearly correlated with the measured TcB anterior chest, and the standard error of the linear regression line (δ^*) was ±0.83.

* : The standard error (δ) is ±0.83, indicating that about 65% of the data obtained from the in vivo measurements are within this range.

Relationship between serum bilirubin measurements (TSB) and percutaneous jaundice measurements (TcB $_{forehead}$)



The data showed that the measured serum bilirubin (TSB) and the measured TcB forehead were linearly correlated within the measurement range, and the standard error of the linear regression line (δ*) was ±0.62.

* : The standard error (δ) of ±0.62 indicates that 81% of the data obtained from the in vivo measurements are within this range.

SPECIAL STATEMENT: All of the content in the manual is checked carefully, if there is any error or content of printing misunderstanding, our company retains finally explanation of this card-usage.

NOTE: The product's appearances maybe differ from the one in this manual, but it does not affect the capability of product. Please understand if it brings you troubles.

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