Transcutaneous Jaundice Detector

MBJ20 Service Manual

V1.1

®Beijing M&B Electronic Instruments Co., Ltd.

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CONTENT

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- Battery voltage is beyond the scope of product specification.
- Natural disasters.
- Replaced accessories, consumables without M&B brand.
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Contact

Please call the following number if you want to call the service phone or get products' support:

+86 10 61253803 (Working Time: Monday ~ Friday，8:30 ~ 17:30);

Or contact with your local distributor or agent.

Any other products' information, please contact with the following department.

Purchasing consumables and maintenance parts

Order –

Please order consumables and maintenance parts in M&B demanded address or after-sale service department.

Maintenance Parts-

Before calling, please prepare the following information in advance

- Part Number of Faulty parts
- Device model and serial number

Headquarter:

Company: BEIJING M&B ELECTRONIC INSTRUMENTS CO., LTD

Address: ROOM 6319, BUILDING1, NO.27, YONGWANG ROAD, DAXING BIOENGINEERING AND MEDICINE INDUSTRY BASE, ZHONGGUANCUN SCIENCE PARK, DAXING DISTRICT, BEIJING

CHAPTER 1 DEVICE INTRODUCTION

1.1 Overview

MBJ20 is used in the dynamic clinical examination of neonate jaundice and determines instantly and non-invasively the transcutaneous bilirubin value correlative with serum bilirubin concentration. It is used for the initial screening and monitoring of bilirubin values change trend during jaundice treatment.

This service manual is aimed at transcutaneous jaundice detector MBJ20 for operators and serviceman reference. The manual collects device and each unit circuit working principle，maintenance, common fault and some examples of maintenance etc. Readers can consult other materials about clinical medicine, computer software, machine and so on. Meanwhile, please combine MBJ20 user manual with this service manual when using, which can help serviceman clearing trouble quickly. The manual was edited by technical department. Any improvement about device, we won't have a further notice and please contact with our after-sale service department.

1.2 Safety Instruction

Terms

This manual is using the term of "ATTENTION", "WARNING" and "DANGER", etc. from beginning to end, which aims to indicate the danger and specified severity degree or level. Please be familiar with its definition and importance.

⚠ **ATTENTION: Denotes potential danger or unsafe treatment which may result in slight injury or damage to the device or other property. The note provides application hints or other useful information. Read the note carefully to ensure safe and correct use.**

⚠ **WARNING: Denotes potential danger or unsafe treatment which may lead to death or serious physical injury.**

⚠ **DANGER : Definition of danger is based on potential injury source to people. Danger denotes urgent risk which may lead to death or serious**

physical injury.

Warning mark explanation

Mark	Explanation
⚠	Denotes a note or warning content; Please read seriously for using the device accurately.
⃠	Denotes a prohibited operation. The operation must never be performed;
❗	Perform the operation accurately. The instruction must be strictly adhered to.

Safety

The safety instruction of this chapter aims at devices in general situation. But in most cases, these phases apply to all aspects of jaundice detector. MBJ20 design meets demand of GB9706.1-2007.

This section presents the safety instructions according to the general specifications of the equipment, and in most cases, the statement applies to all aspects of the jaundice detector. The design of MBJ20 meets with the international safety requirements EN60601-1.

⚠ **WARNING: ❗Denotes that failure to adhere to the following points may result in death or serious injury, and may also cause equipment damage or fire danger.**

⚠ **ATTENTION: ❗Please follow the instruction manual to ensure correct and safe operation. If you have any questions or find any errors, please contact M&B authorized service facility.**

Attention and Warnings

We will try our big best to guarantee safety and reliability of device performance as an electronic instruments manufacturer. To ensure safety operation, user should read this chapter seriously before using MBJ20. Please put service manual nearby MBJ20 after reading for an easy check when needed. The following measures are related to safety, please follow strictly:

Environment

⚠ **WARNING: ⃠Jaundice Detector should not be used in situations, including**

environmental vibration, dust, corrosive or flammable, explosive gas (anesthetic gas, gasoline), extreme temperatures and humidity, and ensure that there is enough space for easy operation.

⚠ **ATTENTION: ⃠ Ambient temperature exceeding the range of technical specification will affect the jaundice detector's accuracy, which will cause the machine damaged or machine life reduced.**

Preparation

⚠ **ATTENTION: ❗Before using the device, operator must verify whether work procedures and conditions are appropriate for the use of this instrument.**

Power

ATTENTION: ❗If the device is not in use, the battery will discharge automatically. Remove the batteries to store. Before use, check the battery adequacy in case of sudden power off during operation.

Protection

⚠ **WARNING: ⃠Prohibit operating MBJ20 during magnetic resonance imaging (MRI) scan. (MBJ20 running may affect the MRI images and MRI may affect accuracy of MBJ20.)**

⚠ **ATTENTION: ⃠Magnetic and electrical fields can interfere with the normal operation of the instrument. Therefore, make sure that all external devices working in the vicinity of the jaundice detector comply with the relevant EMC requirements. X-ray equipment or MRI devices can emit a high level of electromagnetic ray and they may be a source of interference. In addition, please ensure cell phones or other telecommunications equipment are kept away from the instrument.**

Preventive check and maintenance

⚠ **WARNING：❗In order to avoid possible problems and to ensure normal operation, preventative maintenance is essential. Generally, preventative maintenance should be conducted at least annually. The maintenance should include an overall check of the device. If the**

following occurs, the device must be stopped using until rectified by a qualified service person:

- ⊙ **if the detector suffers excessive impact force, such as dropping.**
- ⊙ **if any solid or liquid touches the external case or permeates into the device.**
- ⊙ **if the instrument does not operate normally.**
- ⊙ **if the external case is ruptured or damaged.**

⚠ **WARNING: ❗Inspection:**

- ⊙ **perform a routine inspection daily or before use each time, including instrument case, probe and batteries.**
- ⊙ **perform a regular inspection at least every three months, including battery shell and plate beside the content mentioned above**
- ⊙ **perform a preventative maintenance inspection by an authorized professional person every 12 months to ensure MBJ20's safety.**

Other notices

⚠ **ATTENTION: ⃠In order to avoid electric shock or detector failure, do not allow any liquid to permeate into the device. If liquid has permeated into it, please contact your local service partner or distributor of M&B to inspect the detector.**

⚠ **ATTENTION: ⃠Do not use the detector near flammable anesthetic gases, steam or liquid.**

⚠ **ATTENTION: ❗If expired, the device must be disposed of as described in the manual. If you have any questions about proper disposal of the device, please contact Beijing M&B Electronic Instruments Co. Ltd or their local representative.**

⚠ **ATTENTION: ❗For safe operation of the device, the user must follow this instruction manual. However, these instructions do not supersede established medical procedures concerning neonatal care.**

⚠ **ATTENTION: ❗Only people who have been trained properly should use this device.**

Transportation and storage

⚠ **ATTENTION: ❗Put the MBJ20 into the specified storage case during transportation.**

Interference Instruction

⚠ **ATTENTION: ❗The MBJ20 has functions that it does not affect normal operation of other devices, or is not affected by other devices (except MRI equipment).**

Classification

Type of protection against electric shock	**Internal power device**
Degree of protection against electric shock	**Type B applied part**
Degree of protection against liquid penetration	**IPO, ordinary equipment**

⚠ **ATTENTION: ❗The classification of the electrical shock, fire disaster, machinery and other special risks is done according to EN60601-1.**

Safety operation and treatment condition

The sterilization or disinfection method recommend by manufacturer	**Not applicable**
Electromagnetic interference	**Avoid the using of wireless telephones or other strong interference equipment near the detector**
Electric surgical interference damage	**No damage**
Work Mode	**Interval**

Device Symbols

⚠ **ATTENTION: ❗ Some symbols may not appear on all devices.**

Power: ON=TURN ON; OFF=TURN OFF

Figure 1-1 Nameplate of MBJ20 Jaundice Detector

The concrete content and interpretation of the outside label and nameplate as following:

Explanation of the product external logos and marks are as follows:

SN Serial number

Date of manufacture

Manufacture information

Trademark

EC REP European delegate information: company and address

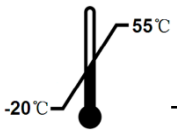
Warning

B type applied part

Waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately.

CE 0123 CE mark

External package symbols:



The maximum range of temperature in transport should be between -20 deg

C and 55 deg C.

Rain prevention

The maximum number of layers stacked is 4.

The correct direction for stacking in transport is straight up.

Fragile, be careful when carrying.

Standards and Regulations Compliance

MDD-Medical Device Directive (MDD) 93/42/EEC;

EN 60601-1-2006: Medical Electrical Equipment-General Requirements for Safety;

EN 60601-1-2-2001: Medical Electrical Equipment-Safety Requirements-EMC;

EN 980-2008: Symbols for use in the labeling of medical devices;

EN 1041-2008: Information supplied by the manufacturer of medical device.

1.3 Specification

1) Display: LCD, 3 figures

2) Power: AA 1.5V×2 alkaline battery

3) Indicator for ready: Green

4) Measurement range: 0.0mg/d L ~ 32.0 mg/d L

5) Measurement accuracy: Range is ±1.5 mg/d L (±25.5 μmol/L)

6) Charging preparation time: < 12 seconds

7) Record function: record 21 previous measurement values and review recorded data

8) Repeatability: < 10%

1.4 Transportation and Storage Conditions

1) Environment temperature of -20 degree centigrade ~ ＋55 degree centigrade;
2) Relative humidity of ≤93%;
3) Atmospheric pressure of 500hPa～1060hPa.

1.5 Operating Conditions

1) Environment temperature of ＋10 degree centigrade～＋40 degree centigrade;
2) Relative humidity of ≤80%;
3) Atmospheric pressure of 860hPa～1060hPa.

1.6 Appearance

1) Front panel

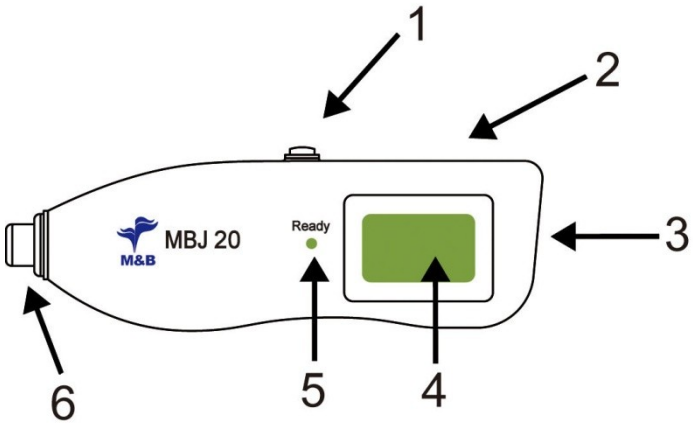


Figure 1-2 Explanation of front view and indicators

Table 1- 1

No.	Name	Function Description
1	Reset Button	Deletes the measured value displayed currently and prepares for the next measurement. Use this switch in combination with the POWER switch and SET button to delete or playback previous measurements.
2	Set Button	Use this switch in combination with the Power switch and Reset button to delete or playback previous measurements.
3	POWER Switch	Slide this switch to turn the power on/off. Use this switch in combination with the Set button and Reset button to delete or playback previous measurements.
4	Display	Display the measured value.
5	READY lamp	Lights up to indicate that the instrument is ready for measurement.
6	Measuring Probe	Takes measurement when pressed against the measuring point on the patient's body.

2) Ground plan

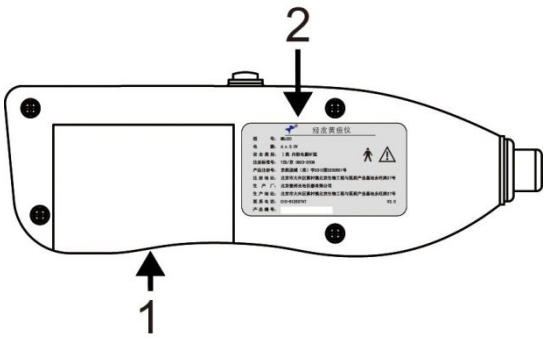


Figure 1-3 Instruments Ground plan and instructions

Table 1-2

No.	Name	Function Description
1	Battery cover	Open the battery cover, can the battery into the battery box, or take out the battery from the battery compartment
2	Product nameplate	Indicate the information of the product

CHAPTER 2 WORKING PRINCIPLE OF THE MACHINE

2.1 Introduction of the Machine Working Principle

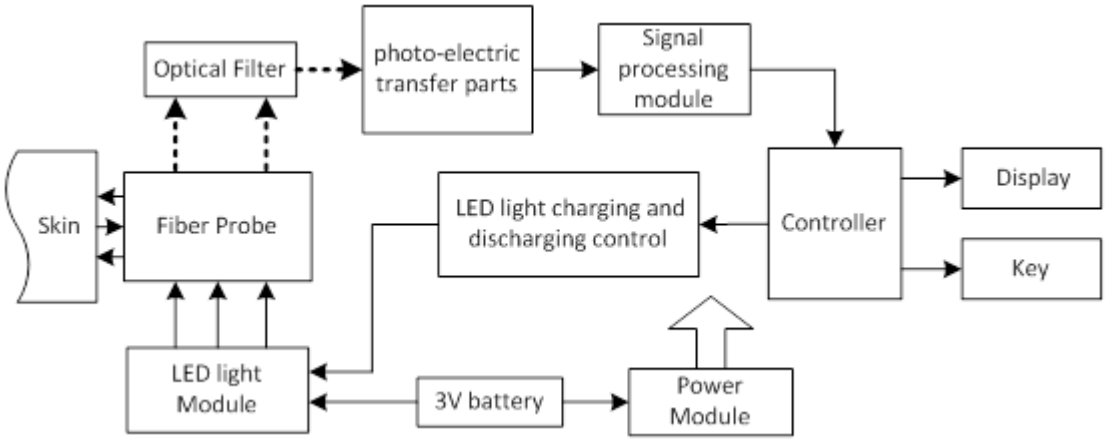


Figure 2-1 Block Diagram of the Machine Principle

Because of different wavelengths of light, the bilirubin absorption is different. Meanwhile, bilirubin concentration is higher, the absorption of light is more serious. The device calculates the bilirubin concentration by testing the reflected light of skin.

There is light source inside of the device. When testing, the inside light source of the device will emit light which will enter to the skin of the subjects through fiber probe. The light penetrates epidermis and dermis, be absorbed and reflected from subcutaneous tissue, some of light reflected back to the inside of probe by different path. Reflected light through the processing of optical element, the useful optical signal will be extracted. The device covert the optical signal to electrical signal through the photoelectric parts, it is convenient for signal processing and analysis. The bilirubin concentration will be get after processed and analyzed the obtained signal. Controller will show the result through the LCD.

2.2 Power

Using two ordinary AA alkaline batteries, power supply voltage is 3V.

2.3 The Principle of Power Module

Output voltage of battery is about 3V, R32 and R19 formed battery capacity detection circuit. Battery powered though booster chip U1 and its peripheral circuit to convert the voltage to 3.3V, and 3.3V stabilized the voltage to 3.0V through LDO regulator chip U16. 3.0V is most of the power supply on the circuit board.

2.4 LED Charging and Discharging Control Module

This machine adopts LED as light source, which mainly consist of charging circuit, charging control circuit, energy-storage part, flash lamp trigger circuit etc.

Charging circuit mainly consists of boost chip U6 and external circuit, which can boot the battery voltage up to d.c.17.4 V.

Charging control circuit is mainly consist of device charging voltage detection circuit and central processing chip U4 and related capacitances and resistors, this part control charging energy for LED flashing, and make sure the electricity energy is same every time.

Energy storage component provide energy when LED flashing, mainly consist of component C27, after through charging circuit, energy stored into capacitor C27.

When trigger LED light flashing, discharging is carried out by component Q1 and resistance R11, R14.

2.5 The principle of signal processing unit

All functions of the device is completed under the control of Central Processing Chip U4. Central Processing Chip is supplied power by 3.0V, which basic components also include crystal oscillation part which is consist of X1 and other components.

Central Processing Chip controls logic of other circuit by IO. Battery power status, all keys status, signals after processing etc., which will be sent to Central Processing Chip U4 to process. Central Processing Chip will do actions according to the received information, or display the result by LCD Module.

2.6 Principle of Key And Display Module

Transcutaneous Jaundice Detector MBJ20 has two buttons “Set” and “RESET”. Usually “RESET” can control the charging to capacitor, “SET” can switch the unit of measurement value. In other mode, “RESET” and “SET” can do special setting when

power on

LCD can display the measurement value, measurement numbers, measurement status, battery level etc.

CHAPTER 3 FAILURE ANALYSIS AND EXCLUSION OF MAIN MACHINE

In order to normal use, read the MBJ20 USER MANUAL carefully before use. For the maintenance and daily inspection of MBJ20 are detailed in Chapter 5 of MBJ20 User Manual, here do not make further introduction. Because the integration level of this device is very high, component density is high, software/hardware function is complex, it will not easy to determine the scope of the fault when some problem happened. When you encounter the complex fault, need to debug by professional detecting instrument, or please contact local maintenance station or manufacturer in time, please not open and repair by yourself to avoid extending failure.

No.	Fault Phenomenon	Fault Reason
1	Can't Open the machine	① Check whether there is battery or not inside of the machine, the battery voltage is sufficient or not. ② Check the power switch is breakover or not. ③ Check 3.3V(U1-8 pin) and 3.0V (U16-5 pin) on the board is normal or not ④ If the above are normal, may have problem of the Control Chip.
2	Too long time to Ready	① Check the battery voltage is sufficient or not ② Check U6 output voltage (diode D2 negative pole) whether between the range [16.4V～17.4V] or far below 16.4V
3	Unable to Charge	① After press RESET button, check the LCD whether enter to measurement status. If not, means the button is broken, needs to change the button. ② If it can enter to measurement status after press RESET button, in this state, needs to test the U6-4 pin whether is high level or not. ③ If the electric level of U6-4 pin is normal, can check L3, D2, R2, R4, R10 whether welding normal or not.
4	Unable to Discharge, show E03 on screen	When the READY is bright, press the probe, the LED light inside of machine is not bright, and display in normal test status, may appear the following problems: ① check the welded LED light wire on the main board is disconnect or not, or the welded point has fracture phenomenon or not ② LED light is broken and can't flash light ③ when press probe, Central processing chip U4-19 pin do not have high level to output, Central

		processing chip U4 is broken ④ Chip Q1, Resistor R11, R14 broken, can't discharge.

5	The LED can be bright and shows "E02"	① Observe whether four signal wire has been broken, if the wire is in broken phenomenon, weld it; ② Check if the 3.0V which is power supply to chip U9 on the circuit board is normal; ③ Measure if the signal of test point TP1 and TP2 is normal, if not normal, may have the following situation: There is problem in the circuit referred to signal processing and the device U9; R7; R31; R32; R16; R17; R34; R35 and so on, or the optical filter has problem and need to be replaced. ④ If the signal of test point TP1 and TP2 is normal，the control chip may have problem, please change control chip or rewrite the program .
6	Measurements are not accurate	① The device is limited to the newborn, not others. ② Whether meets the requirements of the device measurement, please refer to the contents of section 4.1 in the "MBJ20 user manual". ③ Recalibrate. The user can do the calibration based on the contents of section 7.4 in the "MBJ20 user manual", specialized serviceman can do the calibration based on the company internal calibration method. ④ If it is not normal after the calibration, replace optical filters, etc.
7	The probe structure failure	Probe can't be pressed or probe has no response after press, it declares that the probe structure is not suitable and need to adjust.

CHAPTER 4 DISASSEMBLE INSTRUCTION

4.1 Battery Replacement Way

Prepare 2 batteries (AA1.5V), open the battery casing cover at the back of detector, fix batteries and close battery casing cover (See figure 4-1).

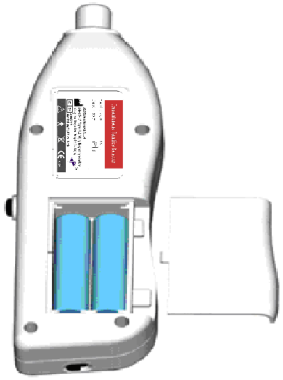


Figure 4-1 Battery Install Way

⚠ **ATTENTION: ❗ Insert batteries as indicated.**

⚠ **ATTENTION: ❗ When Low Battery indicator appears, replace batteries.**

⚠ **ATTENTION: ❗ Remove the batteries when the device is not in use for extended times.**

⚠ **ATTENTION: ❗ The battery should be disposed in accordance with local regulations.**

⚠ **ATTENTION: ❗ Energizer batteries are recommended.**

4.2 The Back Side of MBJ20

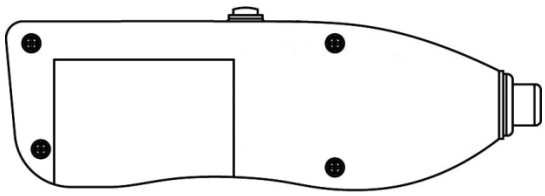


Figure 4-2

4.3 Disassemble

Figure4-3