BILINFANT
MEDICAL APPARATUS

User Manual

Transcutaneous Jaundice Meter

July 2014

Contents

Fashion Technology Diamond Quality

BILINFANT MEDICAL APPARATUS

- Hi-tech
- EC REP Zurich Swiss
- CE No.: 1254

Warning!

This manual is prepared according to registered standard YZB/SU0372/2007 of our company. It will prompt you how to install, operate and maintain BILINFANT transcutaneous jaundice meter properly. Users should read this manual carefully before using and follow the procedures strictly.
The performance features, operating methods, precautions in operating process, maintenance methods and comprehensive information on after sales service which you should pay attention to, are introduced in this manual. This manual is suitable for BILINFANT transcutaneous jaundice meter.
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↘ Description of Internal and External Marks and Symbols

- **External mark**
  - Enterprise name: High-Tech Co., Ltd.;
  - Product name and model: BILINFANT Transcutaneous Jaundice Detector;
  - Power voltage: rechargeable batteries, voltage: 4.8V;
  - Input power: 6VA;
  - Safety classification of equipment: Class II Type BF, with internal power unit;
  - Physiological effect: The probe of this instrument will send strong flash. Do not aim the probe at or keep it close to eyes;
  - Production license number: SUSYJXSCX NO. 0603-2001;
  - Registered product standard number: YZB/SU2007/0372;
  - Product registration certificate number:
  - Product number:
  - Zürich Swiss CE no. 1254
- **Symbol description**
  - Anti-electric shock classification is class II
  - BF type equipment
  - Please refer to accessory documents

↘ Functions and Application Scope

BILINFANT transcutaneous jaundice meter, this instrument hereinafter, is mainly used to measure transcutaneous bilirubin value relating to serum bilirubin value of newborns and infants. It is a kind of screening medical testing instrument that blood sampling is not necessary and there is no pain or bacteria infection.
This instrument utilizes fiber, photoelectric, electronic and SCM technologies. It has no injury and is small, light and easy for operation. You can just press the probe lightly on the forehead skin of newborns and infants, and it will measure the transcutaneous bilirubin value relating to serum bilirubin value at once directly and accurately and display the concentration value of serum bilirubin directly after conversion. This instrument will provide reliable data for clinical treatment of doctors and is widely used in Neonatology Department and Children Health Care Department of hospitals.
This instrument utilizes LCD display and rechargeable batteries are installed inside. It is light, easy for operation and safe.

↘ Operating environment

- Temperature: 5-40 C°
- Relative humidity: ≤%80
- Atmospheric pressure: 1060-860hPa

- **Composition**
  This instrument is composed of main body of jaundice meter, color calibration screen and charger.
- **Main Technical Indexes**
- Requirements of normal working conditions:
  - Environment temperature: 5-40 C°
  - Relative humidity: ≤%80R.H.
  - Atmospheric pressure: 106-86KPa
  - Power voltage: DC4.8V6-V
- **Type: Class II Type BF, with internal power unit**
- **Technical indexes**
  - Power supply: rechargeable batteries, voltage: 4.8V
  - Charger: input AC50 ,220Hz
  - Input power: 6VA
  - Display function: Digital display should be clear and right;
  - The indicator (READY) should be lit when the voltage satisfies the requirement of detection by jaundice meter.
  - The unit can be set as μmol/L, mg/dL or none (transcutaneous bilirubin).
  - Accuracy: 97%
  - Continuously variable: 3%
  - Prompt function: The symbol  will be displayed to prompt you that the batteries need to be charged when the battery voltage is lower than 4.4V.
  - Average measurement function: set 2-5 times average measurement.

MEDICAL APPARATUS BILINFANT

↘ Appearance Photo and Panel Structure

Appearance photo

Light Probe, LC Display, Ready indicator

Reset key, Charging outlet, Set key

Power Switch

Cover of battery

↘ Working Principle

- **Working principle of test**

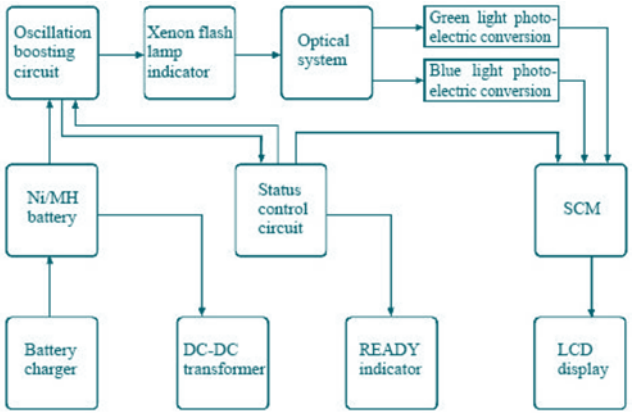
Bilirubin will accumulate in blood, tissue and interstitial fluid, xanthochromia appears on skin, mucosa, sclera and some body fluids, and this phenomenon is called jaundice clinically. Serious jaundice of newborns will cause bilirubin brain-dysfunction, so the jaundice changes of newborns must be monitored. Usually, the monitor of jaundice changes of newborns is to observe the skin visually and make blood sampling test to diagnose accurately under the condition of high jaundice degree. But, besides the complicated process, sampling test will bring pain to newborns and has the danger of infection. People had begun to find method to test serum bilirubin value without sampling since long time ago.

It has been experimented that bilirubin has obvious absorption peak to light wave of 460nm in subcutaneous tissue and hemoglobin has same absorption value to light waves of 460nm and 550nm in subcutaneous tissue. Basing on the characteristic that the above two light wave lengths have absorption peak and same absorption value, this meter utilizes fiber, photoelectric, electronic technology and data processing to measure transcutaneous bilirubin. Put the probe of the meter on forehead of newborn, start xenon flash tube which will send strong light and shoot into subcutaneous tissue through the external core of optical fiber inside the probe, then the reflected light will be sent to inner splitter of the meter through internal core optical fiber inside the probe. The splitter has the characteristic of reflecting blue light and transmitting green light. Then the splitter will be divided into two light paths: one is blue light (wave length is 460nm) and the other is green light (wave length is 550nm). The blue light path will irradiate on the light intercepting side of silicon photocell to carry out photoelectrical conversion after filtered by filter with 460nm maximum transmittance. According to the same principle, green light path will irradiate on the light intercepting side of silicon photocell to carry out photoelectrical conversion after filtered by filter with 550nm maximum transmittance. After amplifying, comparing and calculating the differences of the two signals, it will display the result, which is the transcutaneous bilirubin value. It has linear relationship with serum bilirubin concentration. Evaluate corresponding value according to regression equation Y=A+Bx, then you can find the total serum bilirubin value in regression numerical table.

- **Working principle of light path and electric circuit**

The light path and electric circuit diagram is in the following figure. The working principle of light path and electric circuit is as follow:

The oscillation boosting circuit could convert the 4.8V voltage of rechargeable Ni/MH batteries to DC isolation high voltage for xenon flash tube. The effect of light path system is to shoot the light sent from xenon flash tube into subcutaneous tissue through external core of optical fiber inside the probe, and then the reflected light will be divided into blue light and green light by internal core optical fiber in probe and inner splitter. The two photoelectric transformers carry out photoelectric conversion of lights with different lengths and amplify the electric signals separately. Gate circuit, SCM and LCD display calculate the difference of the two lengths and display values. Ni/MH battery provides stable power voltage through DC-DC transformer. Status control circuit controls oscillation boosting, READY indicator, etc.



Working principle diagram

↘ Using method

- **Preparation before using**
  Please check the electricity quantity of battery before using. The screen will display symbol if the electricity quantity is few and please charge in time. Please turn the power switch of the instrument to "OFF" before charging, then insert the plug of charger into charging outlet, connect the power of charger and the orange power indicator will be lit. In the charging process, the green indicator will be lit; when the charging is finished, the green indicator will go out; please stop charging in time.

- **Test procedures**

A. Use disinfectant alcohol to clean the test probe.
B. Move the power switch to "ON".
Usually, it displays "n1-"; when doing average measurement, it will display "n2-" "n5-".
C. Check whether the READY indicator is lit.
The "READY" indicator will be lit in several seconds; if the screen displays symbol or nothing else, please refer to "Preparation before using" and charge in time.
D. Make the probe to contact the test position vertically, then, press the instrument lightly until the sound of click and flash appear and the test results will be displayed on screen.
E. It will enter procedure F when the measurement is finished; press "Reset" and return to procedure C if you continue to measure.
In average measurement, you need to repeat necessary times, i.e. procedure C and D if you do not press "Reset".
F. Move the power switch to "OFF" when the measurement is finished. Use disinfectant alcohol to clean the test probe and put the instrument back to packing box.

- **Switch measuring unit**
  Move the power switch to "ON", or press "Reset" to make the instrument in measuring state. After getting a measuring result, press "Set" to set the measuring unit as umol/L, mg/dL or none (skin bilirubin). The instrument can keep the measuring unit when it is power off.

Unit conversion	no unit= mg/dL + 1.5	μmol/L= mg/dL × 17.1	
Normal range	no unit: 3.5~7.5	2~6 mg/dL	34~101 μmol/L
Phototherapy necessity range	no unit: 7.50-15.50	6-14 mg/dl	102-240 μmol/L

- **Average measurement mode**
  Move the power switch to "ON", or press "Reset" to make the instrument in measuring state. Long press the "Reset" key for about three seconds and the display will switch in the sequence of "n-1"→"n-2"→"n-3"→"n-4"→"n-5"→ "CHE" → "n-1". Release the "Reset" key when the average measuring times or "CHE" status you need to set is displayed.
  The using method of average measurement will be explained with the example of three times' average measurement:
  Display "n3-" and confirm that "READY" indicator is lit; make the probe to contact the test position vertically, press the instrument lightly until the sound of click and flash appear, then, actual measurement will start and the left measuring times "2--" and "AVERAGE(3)" will be displayed; carry out the left measurements while confirming the "READY" indicator is lit; when the set measuring times are finished, the averaged result after calculation will be displayed.
  If the left measurements are not finished, the test result won't be displayed. Press "Reset" to begin to measure if you need to carry out average measurement again. Please refer to contents above if you want to change average measuring times.
  The set average measuring times and unit will be kept when the instrument is power off.

- **Records stored checking**
  When displaying "CHE", release "Reset" key, on the upper right of the screen displays "(c)", then short pressing "Reset" key to check the stored records, totally 50pcs of records can be checked.

- **Data calibration**
  This instrument has the function of calibrating test result. Users can compare with standard calibration board and imported instrument and calibrate.
  Before calibrating, you must measure the standard calibration board first. Average measurement is recommended. The result should be in the test scope, i.e. 30-0mg/dl or the displayed value won't flicker.

Then, long press "Set" key for about three seconds and it will enter calibration state. "A" (adjustment) will be displayed at the upper right corner of the screen. The second digit of the measured value will flicker. Change the displayed three digits according to the value of known standard calibration board or measuring data of imported instrument. The method is as follow :
Short press "Set" to change the position of flickering digit and press "Reset" to change the value until the three digits are modified. Long press "Set" key for about three seconds to save modified values and quit calibration state when finished. The calibration data deviates from standard value must be within (%50±, take 20.0 as an example, calibrated value should be between 10.0 and 30.0), the calibration is invalid and display "-n" when out of calibration limitation and you need to calibrate again.

- **Clear history and restore factory calibration data**
  - Clear history data: When the apparatus is in power on state, long press "Reset" key to n1-,n-2,n3-.....CHE, then long press "set" key till displays "Clr", release "Set" key and the apparatus will enter working state.
  - Restore factory data: When the apparatus is in power off state, long press "Set" key, meanwhile, move power switch to "ON" and connect the power until the screen displays "rET" , then, release "Set" key and apparatus will eneter working state.

↘ Maintenance

A. Put the instrument in dry and cool places and keep it away from direct sun light irradiation when it is not used.
B. Avoiding dropping, otherwise, the probe may be damaged.
C. The power of the instrument is supplied by rechargeable Ni/MH battery. Use special charger to charge for three hours before using the instrument for the first time. After using for about 200 times (flashing about 200 times), use special charger to charge for about three hours and you'd better to charge everyday if you use it continuously. Move the power switch to "OFF" position when charging.

↘ Disinfection and Sterilization

The probe needs to be cleaned with alcohol cotton regularly to disinfect and sterilize.
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↘ Replacing Method of Batteries and Maintenance of Charger

If the batteries are invalid because of long time using, you can just disassemble the battery cover, pull out the plug from battery outlet and changer corresponding Ni/MH batteries.
The charger utilizes self-recovery fuse and has the effect of automatic protection. Please send back to our company or ask professionals to repair if there is any fault.

↘ Precautions

- Read this instruction before using the instrument.
- The probe should be put on the forehead of infant and should be vertical and contact the skin completely. Measure for two to three times in same position and take the average value.
- Do not aim the probe at or put it close to eyes because it will send strong flash.
- Put the instrument in cool and dry place and keep it away from strong light and heat source. Keep it away from direct sun light irradiation; otherwise the instrument will be damaged.

↘ Conditions of Transportation and Storage

Sales package: the jaundice meter is packaged in aluminum case with shockproof liner. In the case, there are:
- a. Jaundice meter;
- b. Necessary accessories and tools;
- c. Operation instruction;
- d. Product certificate;
- e. Quality report
- f. Packing list.

Transportation package: The external package is corrugated box. The package is solid and reliable and can bear normal environmental stress in transportation and storage.

Transportation: Can be transported by general transportation means. Avoid rain, water immersion, exposure, fall and mechanical damage in transportation process. Do not transport together with poisonous, harmful or permanent materials.
Storage condition: The jaundice meter should be stored in ventilated and dry warehouse and do not store together with poisonous, harmful or permanent materials.
Storage term: If the jaundice meter has been stored for more than one year, please take it out from storage case, connect power and deliver only when it is qualified after recheck.

↘ After Service

1. We will provide one year warranty from the day of installation of this meter and are responsible for life-long maintenance when warranty is expired (charge maintenance fee according to regulations).
2. The faults caused by the following reasons are not in the warranty scope. For example:

– Disassemble or refit this product without permission.
– Drop or fall by accident in the using and transportation processes.
– Lack reasonable maintenance or do not meet the environmental requirements.
– Don't operate according to the correct indication of this instruction.
– Repair without our authorization.

3. If you need warranty service, you can contact our technical service center :

– Parsian Az Teb Eng. Co. Ltd
– www.parsianteb.com
– Tel: 9-982188715707+
– Fax: 982188715710+

↘ Others

This operation instruction (technical instruction) is not attached with circuit diagram. We will only provide it to customers who have been trained by our company and have the maintenance ability.

– Manufacturer: High Technology Co., Ltd.
– Production license number: SSYJXSC NO. 0603-2001
– Registered product standard number: YZB/SU2007/0372
– Product registration number: SSYJX (Z) 2007NO. 2210365
– AG Zürich AG, P.O. Box 6335, CH8050- Zürich, Switzerland