

BILITEST 2000

Photometrical dual-wavelength two-channel
hyperbilirubinemia transcutaneous automatic
analyzer for screening of newborn

PHAn-04-"NPP-TM"

Instruction for Use

Ver.2. English – 03/2012

Always keep this IFU near the instrument.

Read carefully prior to starting work with
the instrument!



TECHNOMEDICA

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BILITEST 2000

INTRODUCTION

The present Instruction for Use (IFU) is intended for personnel familiarization with the device, rules of operation and maintenance of Photometrical dual-wavelength two-channel hyperbilirubinemia transcutaneous automatic analyzer for screening of newborn PHAn-04-"NPP-TM" (further in this text "device" or BILITEST 2000).

Identification of the product

The device BILITEST 2000 is jaundice meter for newborn by means of measurement spectral coefficients of luminous reflectance of hypodermic tissues at two wave lengths.

It is intended for determination of transcutaneous bilirubin index (TBI) when evaluating the degree of neonatal hyperbilirubinemia. The device can be applied for screening of hyperbilirubinemia level, it is convenient for a wide scope of practical applications and allows to limit the number of newborns requiring blood sampling for bilirubin examination. The device provides the opportunity of detailed monitoring of the course of jaundice and efficiency of the therapy applied.

The device measures spectral coefficients of luminous reflectance of hypodermic tissues at the wave lengths of 492 nm and 523 nm in each of two channels and provides for their re-calculation into TBI. TBI values, indicated on device display, have a high degree of correlation with the corresponding values of serum bilirubin concentration obtained in course of neonatal laboratory blood analysis.



The readings in TBI units multiplied by 10 approximately correspond to serum bilirubin concentration in $\mu\text{mol/l}$ units.

Field of application – in maternity hospitals, midwifery clinics, children hospitals as well as in midwifery, gynecology and perinatology centers in case of application of noninvasive method for determination of degree of neonatal hyperbilirubinemia.

Procedures of switching the device on for making a measurement and indication of measurement result on the monitor is performed automatically within less than 2 seconds. Measurement is performed by pushing the end of movable optical light guide head against the forehead or other location of the patient's skin. The measurement result is stored on the monitor for about 30 s, afterwards it is automatically erased and the device switches to the standby mode with minimal energy consumption. If measurements are not in progress the device should be placed in the casing, where the light guide head is in contact with the «white standard», and the device performs calibration several times per hour. This allows to avoid calibration each time the device is taken out of the casing.

1. GENERAL DIRECTIONS

1.1. Please study this IFU carefully before you start using the device in medical practice you should also thoroughly study recommendations for its clinical usage, specified in the section 6.

1.2. To ensure operability of the device and prevent its outage during operation it is necessary to observe safety measures set forth in the IFU.

1.3. The packaging material, the type plate on the instrument and the Instruction may contain the following symbols or abbreviations:



Logo J-S CO. "TECHNOMEDICA"



Manufacturer



Authorized Representative in the European Community



This product fulfils the requirements of Directive 93/42/EEC with Revision 2007/47/EC on medical devices, Annex VI



Please consult instructions for use



Caution (refer to accompanying documents)!

Please refer to safety-related notes in the Instruction accompanying this device



Keep away from sunlight



Keep Dry



Fragile, Handle With Care



Temperature limitation



Catalogue number



Serial number



Date of manufacture



Symbol for the marking medical devices according to Directive 2002/96/EC on waste electrical and electronic equipment (WEEE)



The degree of protection against electric shock corresponds to the Type B applied part



BILITEST 2000

2. SPECIFICATION

2.1. Method of measurement – reflectance bichromatic photometry.

2.2. Light source – two white light-emitting diodes (LED).

2.3. Detector – two photocell systems.



2.4. Measuring range 0-50 TBI approximately corresponds to 0-500 $\mu\text{mol/l}$

2.5. Correlation between TBI and laboratory values for serum bilirubin concentration (SeBC) – no less than 0.92.

2.6. Optical density measurement error - < 10 percent.

2.7. Readout – three digits liquid crystal display (LCD).

2.8. Measuring cycle time - ~ 2 seconds.

2.9. The number of decimal code bits on the digital indicating monitor of the device amounts to three. The unit of the smallest code bit on the digital monitor of the device, TBI – 1.

2.10. Power source – 3 batteries of AAA (LR03) type.

Note. The discharge of internal power supply causes the following indication of the device: «UUU».

2.11. Current consumption with the supply voltage amounting to 4.5 V – not more than 20 mA during measurement cycle. As a result, the number of cycles of measurements of not less than 100,000 with one battery set.

2.12. Usable life 5 years.

2.13. Weight (with batteries) ≤ 150 grams.

Weight with casing ≤ 310 grams.

2.14. Dimension Width x Height x Depth – 135x65x35 mm.

Dimension with casing – 180x90x40 mm.



2.15. The device should be used in rooms at the temperature from 15°C to 35°C.

3. DELIVERY SET

The delivery set of the device corresponds to the list provided in Table 1.

Table 1

Designation	Reference number	Quantity, pcs.
Photometrical dual-wavelength two-channel hyperbilirubinemia transcutaneous automatic analyzer for screening of newborn.PHAn-04-"NPP-TM"	TU 9443-006-11254896-2004	1
Casing with control reading checkers RC1, RC2	DGVI.943129.003	1
Direct current power supply element 1.5 V, AAA or LR03 type		3
Instruction for Use including the checking procedure	DGVI.941416.004 RE	1

4. SAFETY MEASURES

4.1. BILITEST 2000 meets EN 60601-1, EN 60601-1-2 and EN ISO 14971 requirements set for medical devices with built-in power supply.

4.2. Never attempt to disassemble the device. Non-expert service of the device may damage it.

4.3. PROHIBITED:
to hit the device;
to open industrial or user packaging of the device, which was exposed to frost, in a warm room earlier than after expiration of 4 hours.

4.4. During the measurement the LEDs emit light flux. The device has no photobiological risk with normal use according to safety standard IEC 62471:2006. Nevertheless please avoid excessive illumination of baby's eyes. Never press the movable light guide head nearby the baby without contact with his skin.



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5. PRINCIPLE OF OPERATION AND STRUCTURE OF THE DEVICE

Transcutaneous bilirubinometry is based on the phenomenon of bilirubin diffusion from blood into surrounding tissue (derma). Increase in bilirubin blood concentration results in bilirubin derma concentration increase and vice versa, decrease in bilirubin blood concentration (for example, during blood transfusion) causes reverse motion of bilirubin from derma into blood, until balance between these two systems occurs.

BILITEST 2000 is an optoelectronic device and consists of the movable light guide head, control board and battery compartment for three direct current power supply elements 1.5 V (AAA or LR03 type).

Appearance of the device is provided in Appendix A.

The movable light guide head consists of analog board and optical part. The following elements are located on analog board: photocurrent amplifier, LED current stabilizer and analog-to-digital converter. The optical part contains two LEDs, two interference optical filters, as well as three light guides: two of them convey light beam from LEDs to skin, while the third one conveys light flux scattered by the skin in the backward direction to photodiodes. The light guides which convey light flux are located at different distances from the receiving light guide, therefore two optical measuring channels are formed: the near one (located closer to the receiving light guide) and the distant one (located farther from the receiving light guide). Two channels allow to take into consideration light reflected only from the depth of the skin when calculating transcutaneous bilirubin index (TBI).

Structural flowchart which explains principle of operation of the device is provided in Appendix B.

The device measures spectral coefficients of luminous reflectance by hypodermic tissues: I_{BN} , I_{BF} , I_{GN} , I_{GF} :

I_{BN} – signal amplitude at the wave length 492 (blue) by the near measuring channel;

I_{BF} – signal amplitude at the wave length 492 (blue) by the distant measuring channel;

I_{GN} – signal amplitude at the wave length 523 (green) by the near measuring channel;

I_{GF} – signal amplitude at the wave length 523 (green) by the distant measuring channel.

The microcontroller performs calculation of TBI according to the specified algorithm, which links up signals I_{BN} , I_{BF} , I_{GN} , I_{GF} , and numerical coefficients K_1 , K_2 , K_3 , K_4 . The numerical coefficients are set at the manufacturing plant and can be changed (or checked up) by means of buttons L and R according to clause 10 of the IFU. Selection of wave lengths 492 nm and 523 nm is caused by the fact that light absorption by hemoglobin at these wave lengths is roughly the same, while light absorption by bilirubin differs substantially. This practically allows to eliminate blood hemoglobin influence in case of TBI changing. Microcontroller and digital display device (monitor) are installed on the control board.

When pushing on the head of the device the following occurs:

1. The lightguide head moves a little inwards the device. A measurement cycle is launched. The device produces an audio signal. The light flux alternately emitted by LEDs and directed to transmitting light guides illuminates the so called contact area – a fragment of the skin surface, which is being analyzed.

2. The light flux is partially reflected (scattered) in reverse direction, while light absorption by bilirubin and hemoglobin contained in hypodermic tissues occurs in spectral bands typical for them. The spectral distribution of reflected (scattered in reverse direction) light flux differs from that of the incident beam. Scattered light passes through the receiving light guide. The receiving light guide is Y-shaped, and «blue» and «green» interference filters are installed on its ends.

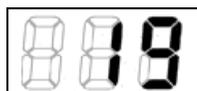
3. After passing through interference filters the light flux reaches photodiodes. Photodiodes form four signals, which are used for calculation of TBI value.

4. In the end of the measurement cycle (which is accompanied by discontinuation of audio signal) «-O-» symbol is displayed on the monitor and then – numerical TBI value. The TBI value is left on the monitor for 20-30 s.



BILITEST 2000 is calibrated so that the value of TBI multiplied by 10 approximates the value of serum bilirubin concentration (SeBC) in $\mu\text{mol/l}$ if TBI measuring is made against infant's forehead.

For example



$\approx 190 \mu\text{mol/l}$



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6. RECOMMENDATIONS FOR CLINICAL USE

The intended use of the Photometrical Hyperbilirubinemia Analyzer BILITEST 2000 is to screen newborn infants for hyperbilirubinemia, including:

- to determine the degree of jaundice and to screen its dynamics;
- to identify newborn infants whose degree of hyperbilirubinemia indicates that a serum bilirubin test is (or is not) necessary;
- to estimate the therapy efficiency.

MEASUREMENT PRINCIPLE

High correlation between non-invasive measurement results of bilirubin concentration in derma and bilirubin concentration in blood has provided the basis for promoting the Method of Transcutaneous Bilirubinometry into medical practice. This concept has been embodied in BILITEST 2000.

The correlation is caused by existing dynamical balance between bilirubin concentration in blood and subcutaneous tissues due to reversible diffusion of bilirubin between blood and tissues.

High level of bilirubin concentration in blood leads to a high bilirubin concentration in derma and vice versa - low level of bilirubin concentration in blood (for example, during exchange transfusion) results in bilirubin counterflow from tissues to blood until the balance between these two bilirubin reserving systems is reached.

It is important that after such therapeutic measures as phototherapy and exchange transfusion a balance between these two bilirubin reserving systems is reached typically within 5 - 6 hours.

BILITEST 2000 FEATURES

BILITEST 2000 is a portable fully automated photometer. The operation is based on the principle of bichromatic skin reflectance measurements. It analyses spectrum of optical signal reflected from infant's subcutaneous tissues.

In essence the device determines bilirubin concentration in derma through the use of subcutaneous tissues photometry.

OPERATING PROCEDURE

Transcutaneous Bilirubinometry Operating Procedure is rather simple with the use of the Photometrical Hyperbilirubinemia Analyzer. BILITEST 2000 movable optic head is gently pressed against infant's skin (usually forehead or upper part of sternum). The measuring procedure of BILITEST 2000 lasts for 2 - 3 seconds and is accompanied by a soft sound. When the sound has finished, the procedure is over. BILITEST 2000 indicates the result, and is now ready for a next measurement. Display keeps the result of a single measurement for about 30 seconds then BILITEST 2000 removes it and goes to standby mode. BILITEST 2000 is in standby mode until next measurement is initiated.

The verification of BILITEST performance should be made before and after a set of measurements, using two Control Reading Checkers.



WARNINGS

1. It is recommended to perform three additional measurements at a time. If three obtained readings differ, the median value should be chosen, discarding the largest and the smallest values. To avoid hyperaemia another part of infant's skin should be chosen for repeat measurement. Hyperaemia may influence the result.

2. Avoid measurements against bruise, birthmarks and subcutaneous haematoma.

3. Remember that in a number of clinical cases, described in subsection 6, the balance between bilirubin concentration in blood and in subcutaneous tissues is disrupted. In these cases, serum bilirubin testing is needed and the use of BILITEST 2000 for estimation of the serum bilirubin concentration is not recommended.



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ESTIMATION OF SERUM BILIRUBIN CONCENTRATION USING BILITEST READINGS

BILITEST 2000 is calibrated so that the value of TBI multiplied by 10 approximates the value of serum bilirubin concentration (SeBC) in $\mu\text{mol/l}$ if TBI measuring is made against infant's forehead. Normally the actual serum bilirubin concentration doesn't differ from corresponding estimation more than $34 \mu\text{mol/l}$.

NOTES



BILITEST 2000 has been calibrated for the newborn infants without intensive skin pigmentation (for Caucasian race).

To obtain calibration coefficients for BILITEST 2000 the bilirubin concentration in blood was measured with an aid of bichromatic photometrical method. The newborn capillary blood plasma was put through a direct photometrical process. Near 300 newborn infants (Caucasian race), with gestational ages of 30 - 40 weeks and weights of 1400 - 3500 g, were examined. In parallel with determining bilirubin concentration in blood, all the infants were examined for TBI on forehead, on upper part of sternum and inner surface of leg. Correlation coefficients between bilirubin concentration in blood and corresponding TBI values were equal to: $r = 0.92$ for forehead; $r = 0.86$ for sternum; $r = 0.54$ for leg inner surface.

Because the best correlation between TBI and bilirubin concentration in blood was shown on forehead, the corresponding data had been chosen for BILITEST 2000 calibration. Measuring TBI on forehead also allows infant's examinations to be performed without additional manipulations with the newborns (e.g. taking clothes off).

To estimate the reproducibility of BILITEST 2000 readings 76 infants were examined. During examination, every infant was subjected to measurement 5 times and the coefficient of variation (CV %) for each of it was calculated.

The results of examination were the following:

- the average inaccuracy (CV %) of TBI readings is 4 percent (varies from 2 to 5 percent, sometimes to 7 percent);
- inaccuracy of BILITEST 2000 itself (on Reading Checkers) does not exceed 2 percent.

The examinations have shown that medical staff (even with a little experience) can use BILITEST 2000.

TRANSCUTANEOUS BILIRUBINOMETRY FEATURES

Please keep in mind that the result may be incorrect if measurements are carried out against bruising or subcutaneous haematomas (for example, after infusion therapy). In this case, it is preferable to make the TBI measurement on the upper part of sternum.

While measuring TBI of the low weight newborns who suffer from hemodynamics disorder and are in severe somatic state, the hyperaemia spot appears in the area where BILITEST's optic head is pressed against the skin. Repeated measurements over this area show overestimated results due to emerged local stasis of the blood. Although such spot vanishes quickly, repeat measurements are recommended to be made on near-by locations.

When phototherapy is used, photooxidation of bilirubin takes place and it is converted into water-soluble non-toxic lumirubin form. In this case, direct correlation between bilirubin concentration in subcutaneous tissues and in blood is not observed. Thus, TBI determination during phototherapy does not permit to estimate bilirubin concentration level in blood. However, the estimation of newborn phototherapy efficiency can be made based on the dynamics of BILITEST's readings during the whole treatment period.

In case of haemolytic disease of newborn infants BILITEST 2000 should not be used to assess bilirubin concentration in blood because the rate of bilirubin penetration growth due to intensive intervascular haemolysis. In this case, even relatively small TBI values need a bilirubin level control in the blood to be carried out.



JAUNDICE TREATMENT USING THE TBI MEASUREMENT RESULTS

In case of Jaundice, it is recommended to carry out TBI measurements not less than 4 times a day to control the disease dynamics and therapy efficiency.

Premature infants (having weight less than 1500 g) are recommended to undergo phototherapy treatment if TBI value equals to 12 - 15 units. They are extremely sensitive to high bilirubin concentration which may cause Encephalopathy. As a rule, if on the second-fourth day of an infant's life TBI value exceeds 15 units, this point out to serious diseases and demands combined conservative treatment.

If TBI value is more than 20 units, one should control bilirubin concentration growth in blood and make measurements every hour. The same recommendations can be used if TBI value exceeds 20 and 25 on the 4th-7th day correspondingly. In case TBI value is more than 27-30 units, an urgent serum bilirubin testing is needed (including determination of concentration of bilirubin fractions).



WARNINGS

1. If there are no indications of jaundice, it is impossible to estimate bilirubin concentration in blood using TBI values. It is necessary to determine bilirubin concentration in venous and umbilical blood of the newborn, who runs the danger of haemolytic disease, in order to make decision on exchange transfusion during the first day.

2. REMEMBER that estimation of bilirubin levels in blood using the TBI readings is approximate. If exchange transfusion is considered to be made, the serum bilirubin concentration measurement must be done.

7. PREPARATION AND OPERATION

7.1. The device should be in the instrument-case if measurements are not carried out. While in the case the light guide head of BILITEST 2000 is pressed against a white rectangular plate and the device periodically performs calibration.

On removal the device from a case it is ready for making measurements in 10 seconds.



NOTE: it is not recommended to carry out the measurements near bright sources of illumination.

7.2. The device performance control is carried out by means of control light filters (RC), mounted in a case.

The check up with RC1 and RC2 is carried out at initial installation of the device and then repeated periodically (once a month) or in case of doubt in results of TBI measurements. To check the device performance with RC1 and RC2 do the following:

1) Take the device out of the case and put the case on a flat horizontal surface e.g. a table. The surface of RC should be clean. Wipe the surface of RC with a soft dry fabric (gauze, lawn) if necessary.

2) Not pressing the device put it so that the surface of light guide head end face is tightly adjoined to a surface of control light filter RC1 and is perpendicular to it.



ATTENTION: if during a measuring cycle the device is inclined at some angle to RC surface, then the results of measurements can be incorrect.

3) Slightly press the device, not inclining it, until the occurrence of a sound beep. After that the display will first indicate « - - », then «-0-» and then a "number". When sound signal ends stop pressing the device. The "number" will be kept on a display for about 20-30 seconds. If after the ending of pressing a display is showing « - - - », it means, that the device failed to make a correct measurement and it is necessary to repeat the calibration with RC once again.

If during a measuring cycle other symbol then «-0-» was displayed, it is necessary to check up setting of factors according to paragraph 10.3 of IFU.

Values measured with RC in course of device performance test should not exceed the values specified in section 11 "Acceptance certificate" of IFU.

The same values are specified on a sticker in device case close to RC filters.

In the same way carry out the check up with control optical filter RC2.



If instrument readings obtained with RC measurements do not meet required values:

Repeat measurements, taking special care of the device being perpendicular to RC surface.

If it did not help - fulfill the calibration of the device. Get the device from a case, wait for 10 seconds and insert it again into a case completely and without skews, so that the light guide head adjoins to the white rectangular plate and the device produces a sound beep. If after installation of the device into the case the sound signal is absent, it is necessary to get the device from the case, pull forward slightly the mobile head from the device cabinet, and then insert the device into the case once again. If a result of measurement is one of the following values: 0,-0, 1,-1 then calibration is correct. Wait for the second sound signal (approximately in 20-30 sec.), then the display will go off. Calibration is complete.

If you are convinced that the device was calibrated correctly and during measurements with RC it was perpendicular to RC surface, but the device shows values not meeting section 11 of IFU, please clear the surface of RC filters and of the optical head and check up that the factors K_1 , K_2 , K_3 , K_4 are set correctly refer to paragraph 10.3 «Setting (checking) of numerical factors». Then repeat measurements. If after that the values measured on RC still do not correspond to paragraph 11 of the IFU it is necessary to address to the manufacturer.

Measurement of TBI

The factors K_1 , K_2 , K_3 , K_4 set in the device are chosen so that TBI value measured at a forehead area of a newborn and then multiplied by 10 is approximately equal to total bilirubin concentration ($\mu\text{mol/l}$) in blood serum.



Please keep in mind that factory calibration is optimized for the newborn infants without intensive skin pigmentation (for Caucasian race).

In other cases the correspondence between TBI and serum bilirubin concentration values (SeBC) should be refined. The User should refine it himself, comparing the readings of BILITEST 2000 with the corresponding laboratory data of serum bilirubin testing.

7.3. It is necessary to make three repeated measurements successively to improve the accuracy of TBI measurement, each time shifting the device for a few millimeters along the forehead of the child. In case of difference in results choose the median value, discarding the largest and the smallest ones.

While carrying out the measurements it is necessary to keep in mind that the results will be doubtful if there are hypodermic haematomas or vascular stain in the area of measurement (for example, after carrying out infusional therapies). In this case it is more preferable to carry out TBI measurements on the top part of sternum.

7.4. It is mandatory to disinfect the device before measuring TBI for each patient. Do it in a following way: holding the device with the moving head downwards and not pressing the light guide head wipe its end face with a soft fabric (gauze, lawn or a cotton tampon) moistened with alcohol-rectificate. It is necessary to dry the end face after processing and to wipe it with a soft dry fabric (gauze, lawn). Take special care to prevent alcohol from penetrating inside the device.

7.5. For measurement of newborn TBI it is necessary to apply closely the end face of the mobile head of the device keeping it perpendicularly to the chosen site of a dermal surface and to press the device, smoothly enlarging the effort, till a sound signal occurs. Hold the device until the end of a sound signal (about 1-3 seconds), and then take off the effort of pressing. If symbol « - - - » is displayed instead of digital value, then it means that the mobile head was taken off too early before the ending of a sound signal and the measurement should be repeated. The end of a sound signal indicates the end of measurement and the result is indicated on a digital display.

At first the symbol «-O-» is displayed and then digital value of TBI which remains on a display for 20-30 sec. It is recommended to repeat measurement 3 times, each time shifting the device for a few millimeters. In case of difference of results choose median value, rejecting the largest and the smallest values.

7.6. Upon the end of measurement it is necessary to make disinfection of the device, and then to put it back into the case completely and avoiding skews. The device with installed batteries does not require to turn it on or off.



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NOTE: If after putting a device in a case it shows the numbers distinct from: 0, -0, 1, -1 on white color standard, then take it out from a case not waiting for re-calibration and insert into a case again. If the result of measurement still differs from: 0, -0, 1, -1, leave the device in a case for 3 minutes for its calibration. In this situation previously made measurements are probably ambiguous and we recommend to repeat them if possible.

7.7. The brief order of operations for measurement of transcutaneous bilirubin index (TBI) is summarized in Table 2.

Table 2

Operation	
1. Remove the device out of the casing. The device with installed power supply elements does not require switching on and is ready in 10 seconds after its removal from the casing.	
2. Process the end of the light guide head with the soft cloth (gauze, lawn) or with a cotton tampon moistened with rectified alcohol. It is mandatory to dry up the head after this processing and wipe it with soft dry cloth (gauze, lawn). This procedure should be performed before measuring TBI of each patient.	
3. Perform measurement of TBI of a newborn. In order to do it closely apply the end of movable head of the device keeping it perpendicularly to the chosen location of the skin surface and push on the device, smoothly increasing the effort until the sound signal is produced. Retain the device and do not move it until the sound signal stops (1-3 s), afterwards move the device away from the skin. The result of TBI measurement will be displayed on the digital monitor.	

Table 2 (completed)



If the symbol «- - -» is displayed on the monitor instead of numerical value, it means that the movable head was pulled out before termination of the sound signal, and the measurement should be repeated once again.

The measurement result is retained on the monitor for about 30 s, afterwards the device goes to «standby mode». Measurement can be repeated over the nearest adjoining location of the skin. Perform 3 measurements and chose the median result.

Determination of TBI on forehead over bridge of nose of a newborn is performed most frequently (a).

If needed, in order to obtain additional information dynamics of «paintings» of the infant's skin, TBI is determined at a sternum of a newborn (b) and at his heel (c).



(a)



(b)



(c)

4. Perform measurement of TBI of the next patient by carrying out procedures according to the clauses 2 and 3.

5. Process the head of the device after completing the work according to clause 2. Insert the device into the casing. The device with installed power supply elements does not require switching off.



8. MAINTENANCE

8.1. Maintenance of the device is carried out by medical staff which studied the present IFU.

8.2. Disinfection of the device is performed once a week by wiping outer surfaces with tampon moistened with 3% hydrogen peroxide solution with addition of 0,5% detergent solution at the temperature of not less than 18°C.

8.3. Replacement of power supply elements is carried out if the symbol «UUU» is indicated on the display while measurements are performed (see paragraph 10.2 of IFU). In case of long-term storage of the device it is necessary to remove power supply elements out of the battery compartment beforehand.

9. MAINTENANCE CHECK

9.1. Maintenance check-up of the device is carried out to verify its fitness for further intended use.

9.2. Maintenance verification of the device is carried out by medical staff before putting the device into operation and later on in case of need by means of RC1 and RC2, which are included in the device delivery set. Before starting maintenance check-up of the device it is necessary to check the device calibration (see paragraph 7.2) and perform measurements against RC1 and RC2. If the device is technically operable, measurement results should fall within the ranges specified in section 11. The acceptable values are specified for an each individual device on the label on device casing.

10. TROUBLESHOOTINGS

10.1. Possible device faults and ways of troubleshooting are summarized in Table 3.

Table 3

Indication of malfunction	Probable reason	Troubleshooting
Absence of indication, sound signal and no flashes of light in the optical head during measurement or while pressing the optical head.	There is no power because of low or defective batteries.	Replace batteries with fresh ones according to the clause 10.2 of the IFU, and then calibrate the device according to clause 7.2 of the IFU.
	Bad contact in the battery compartment	Clean contacts of the batteries and battery compartment.
A symbol «UUU»* is indicated on a display; at the same time while pressing the optical head the device does not perform measurement (no light flashes and no sound signal)	Calibration of the device is lost. The optical head of the device was pressed for more than 1 minute when the device was not in a case.	Make calibration of the device according to clause 7.2 of the IFU.
	Batteries are down.	Insert fresh batteries according to clause 10.2 of the IFU, and then calibrate the device according to item 7.2 of the IFU.
	Bad contact in the battery compartment.	Clean contacts of the batteries and battery compartment.

* Symbol «UUU» appears in the device during calibration if a level of light signal is insufficient. In this case the measuring cycle of the device is blocked. Symbol «UUU» disappears after calibration with a white color standard in the case, if a light signal goes normal or after battery replacement.



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Table 3 (completed)

Indication of malfunction	Probable reason	Troubleshooting
The results do not meet acceptable values for measurements with RC specified in clause 11 of the IFU.	During the measurement the device has been inclined at some angle to RC surface.	Put a case with the device on a flat horizontal surface, and then carry out measurements with RC according to clause 7.2 of the IFU.
	Wrong calibration.	Make calibration of the device according to clause 7.2 of the IFU.
	The end face of the light guide head or the surface of RC is contaminated.	Wipe the end face of light guide head or the surface of RC according to clause 7.2 of the IFU.
	The numerical factors set in the device do not correspond to the values specified in item 11 of the IFU.	Check up and set correct factors if necessary. Refer to clause 10.3 of the IFU.
While measuring TcB a symbol «-H-» is displayed instead of «-0-».	Factor K_1 is entered incorrectly.	Check up and set correct value of factors if necessary. Refer to clause 10.3 of the IFU.
While measuring TcB a symbol «-_-», «-U-» or «-E-» is displayed instead of «-0-».	The sequence of setting numerical factors was incorrect. The last value entered was not K_4 .	Check up and set numerical factors in strictly following the correct sequence. Refer to clause 10.3 of the IFU.
The display indicates the symbol «EEE».	An error of data reading from non-volatile memory occurred.	Enter (check up) again numerical factors (refer to clause 10.3) and calibrate the device (refer to clause 7.2 of the IFU).

In other cases service and maintenance is performed by qualified personnel of the Manufacturer.

10.2. Replacement of batteries

Replacement of batteries should be made when the symbol "UUU" is displayed while performing measurements.

The battery compartment is on the back side of the device under a cover. Remove a cover and take out power batteries. Insert fresh batteries of AAA or LR03 type, keeping polarity specified at the bottom of a battery compartment.

After inserting new batteries into the device first the alphanumeric code will be displayed, indicating the version of the device firmware, and then «- -» symbol. In one second the display fades.

Calibrate the device according to clause 7.2 of this IFU.



ATTENTION! You should ensure that your batteries are of high quality. Three batteries connected in series should provide the voltage not less than 4 V at a current of 20 mA. Therefore the use of re-charging accumulators is not supposed. It is not recommended to use together batteries from different vendors or different models or old batteries together with new.

10.3. Setting (checking) of numerical factors

The buttons L and R under a cover of battery compartment serve for setting (checking) of numerical factors.

Numerical coefficients are set by the manufacturer and are specified in Section 11 for each individual unit.



ATTENTION! The procedure of setting (checking) of factors should **always** be finished with setting of factor K_4 (even if it is not necessary to change it). It is caused by the fact that the device stores the display mode corresponding to the last entered factor. Thus at the subsequent measurements the corresponding symbol «- _ -» either «-U-» or «-E-» and the corresponding service data will be displayed.

To set or check the factors it is necessary to get the device out of the case and take off a cover from battery compartment, slightly pressing corrugated marks of an arrow in direction specified by an arrow, and shifting a cover from the case. Then carry out operations following the sequence described in Tab. 4.



BILITEST 2000

Table 4

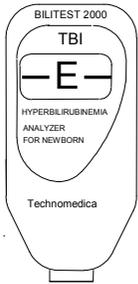
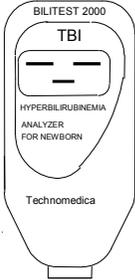
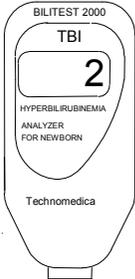
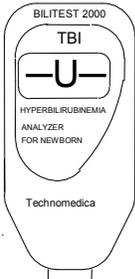
Operation	Indication of the display
<p>1. To check (set) K_1 value press and hold L button. The symbol «-E-» will be displayed. If the symbol «-_-», «-U-» or «-H-» is displayed then press and release repeatedly L button until the symbol «-E-» is displayed.</p>	 <p>The diagram shows the device's display with the following text: 'BILITEST 2000' at the top, 'TBI' below it, a large '-E-' in the center, 'HYPERBILIRUBINEMIA ANALYZER FOR NEWBORN' below that, and 'Technomedica' at the bottom.</p>
<p>2. Press R button holding down L button and release both buttons. Numerical value of numerical coefficient K_1 will appear on the display (it will be shown for about 5 s).</p> <p>Note: values of numerical coefficients specified in this table are conventional, they can differ for an exact device (see the section 11 «Acceptance certificate» of the IFU).</p>	 <p>The diagram shows the device's display with the following text: 'BILITEST 2000' at the top, 'TBI' below it, a large '141' in the center, 'HYPERBILIRUBINEMIA ANALYZER FOR NEWBORN' below that, and 'Technomedica' at the bottom.</p>
<p>3. If K_1 differs from the value specified in section 11 of the IFU, then set the correct value of K_1. When numerical value of the K_1 is indicated, press and release R button to increment the value by 1 or press and release L button to decrement the value by 1. Holding down R or L buttons for more than 5 s will cause the value to be successively incremented or decremented until the button is released. After setting up of K_1 wait until the device «stores» the coefficient.</p>	<p>The device will produce a sound signal and the monitor will go off.</p>

Table 4 (continued)

<p>4. To check (set) K_2 value press and hold L button. The symbol «-_-» will be displayed. If the symbol «-E-», «-U-» or «-H-» is displayed then press and release repeatedly L button until the symbol «-_-» is displayed.</p>	 <p>The diagram shows the BILITEST 2000 TBI device. The display screen shows the symbol «-_-». The text on the device includes 'BILITEST 2000', 'TBI', 'HYPERBILIRUBINEMIA ANALYZER FOR NEWBORN', and 'Technomedica'.</p>
<p>5. Press R button holding down L button and release both buttons. Numerical value of numerical coefficient K_2 will appear on the display (it will be shown for about 5 s).</p> <p>Note: values of numerical coefficients specified in this table are conventional, they can differ for an exact device (see the section 11 «Acceptance certificate» of the IFU).</p>	 <p>The diagram shows the BILITEST 2000 TBI device. The display screen shows the numerical value '2'. The text on the device includes 'BILITEST 2000', 'TBI', 'HYPERBILIRUBINEMIA ANALYZER FOR NEWBORN', and 'Technomedica'.</p>
<p>6. Perform actions for the numerical coefficient K_2 similarly to those described in the clause 3 of the Table 4.</p>	<p>The device will produce a sound signal and the monitor will become dim.</p>
<p>7. To check (set) K_3 value press and hold L button. The symbol «-U-» will be displayed. If the symbol «-_-», «-E-» or «-H-» is displayed then press and release repeatedly L button until the symbol «-U-» is displayed.</p>	 <p>The diagram shows the BILITEST 2000 TBI device. The display screen shows the symbol «-U-». The text on the device includes 'BILITEST 2000', 'TBI', 'HYPERBILIRUBINEMIA ANALYZER FOR NEWBORN', and 'Technomedica'.</p>



BILITEST 2000

Table 4 (completed)

<p>8. Press R button holding down L button and release both buttons. Numerical value of numerical coefficient K_3 will appear on the display (it will be shown for about 5 s).</p> <p>Note: values of numerical coefficients specified in this table are conventional, they can differ for an exact device (see the section 11 «Acceptance certificate» of the IFU).</p>	
<p>9. Perform actions for the numerical coefficient K_3 similarly to those described in the clause 3 of the Table 4.</p>	<p>The device will produce a sound signal and the monitor will become dim.</p>
<p>10. To check (set) K_4 value press and hold L button. The symbol «-H-» will be displayed. If the symbol «-_-», «-U-» or «-E-» is displayed then press and release repeatedly L button until the symbol «-H-» is displayed.</p>	
<p>11. Press R button holding down L button and release both buttons. Numerical value of numerical coefficient K_4 will appear on the display (it will be shown for about 5 s).</p> <p>Note: values of numerical coefficients specified in this table are conventional, they can differ for an exact device (see the section 11 «Acceptance certificate» of the IFU).</p>	
<p>12. Perform actions for the numerical coefficient K_4 similarly to those described in the clause 3 of the Table 4.</p>	<p>The device will produce a sound signal and the monitor will become dim.</p>

Sequence of output of symbols and then – numerical coefficients on the monitor of the device is the following:

Symbol displayed on the monitor when L button is pressed once	Numerical coefficient
«-E-»	«K ₁ »
«-_-»	«K ₂ »
«-U-»	«K ₃ »
«-H-»	«K ₄ »



Important Notice about Readout of values

Perform output of intermediate measured values on the monitor of the device with the help of L button after TBI measurements or measurements of control reading checkers RC1, RC2, if necessary. In order to do that press and release L button when numerical TBI value is displayed on the monitor of the device (during 20-30 s). The symbol «-E-», and then symbol «---» will appear on the monitor of the device.

When pressing and releasing L button once again, the following will be displayed on the monitor of the device: symbol «-_-» and then the value of logarithmic relation of spectral reflectance coefficients by the near optical measuring channel.

When pressing and releasing L button once again, the following will be displayed on the monitor of the device: symbol «-U-» and then the value of logarithmic relation of spectral reflectance coefficients by the distant optical measuring channel.

When pressing and releasing L button once again, the following will be displayed on the monitor of the device: symbol «-H-» and then TBI values. And further in that way in cycle.

To exit this mode it is necessary to wait for about 20 sec without pressing the button. The monitor becomes dim and the device is ready to TBI measurements.



BILITEST 2000

11. ACCEPTANCE CERTIFICATE

Photometrical dual-wavelength two-channel hyperbilirubinemia transcutaneous automatic analyzer for screening of newborn

PHAn-04-"NPP-TM" **SN** _____

meets technical requirements TU 9443-006-11254896-2004, technical documentation set DGVI.941416.004 and acknowledged to be ready for operation.

Symbol displayed on the monitor	Numerical coefficients set in the device
«-E-»	«K ₁ » =
«-_-»	«K ₂ » =
«U»	«K ₃ » =
«-H-»	«K ₄ » =

Aspect ratio C = _____

Program version _____

RC1 _____ ± _____

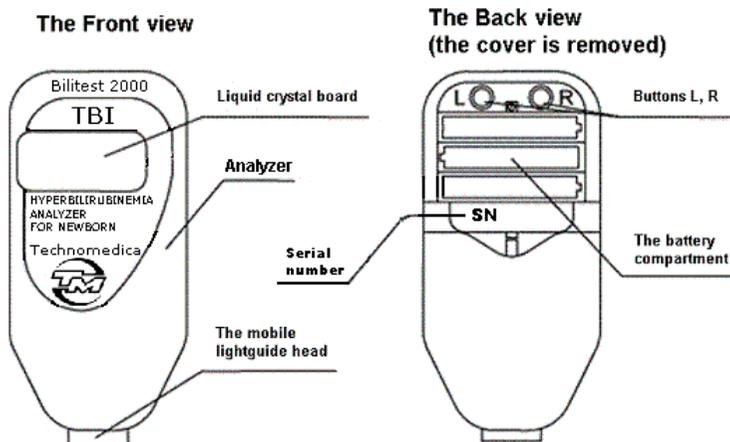
RC2 _____ ± _____

Manufacturing date  " " 201

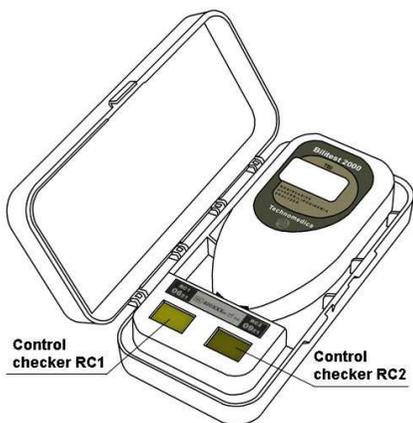
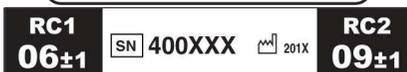
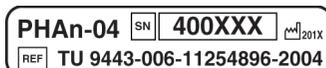
Seal place Quality control department representative

Appendix A

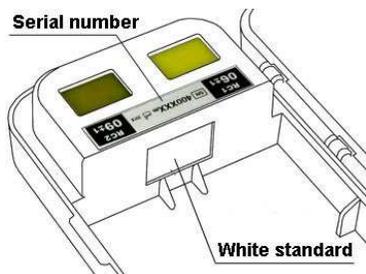
Appearance of the device



Serial number SN is located on the rear side of the analyzer under the cover of the battery pack and the same SN is located on casing above the control checkers



Analyzer in the casing

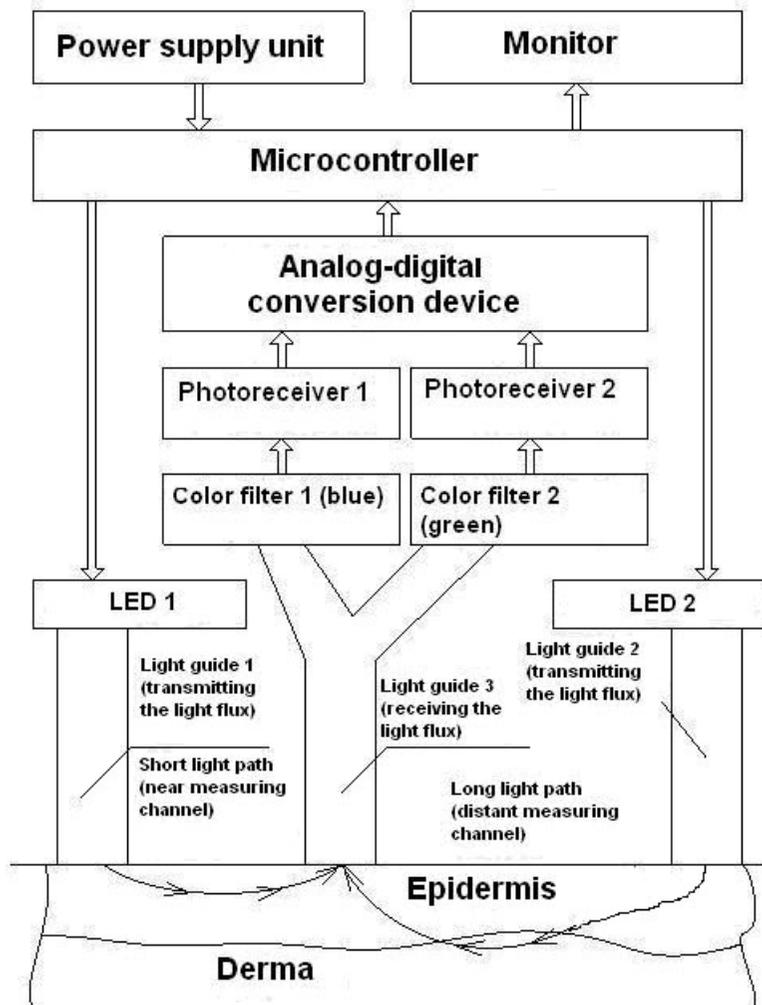


The device should be placed in the casing, where the light guide head is in contact with the "white standard"



Appendix B

Structural flowchart explaining operation principle of the device



Appendix C

EMC Guidance (electromagnetic emission)

Guidance and manufacture's declaration – electromagnetic emission		
The BILITEST 2000 is intended for use in the electromagnetic environment specified below. The customer or the user of BILITEST 2000 should assure that it is used in such an environment.		
Immunity test	Compliance	Electromagnetic environment - guidance
RF emission CISPR11	Group 1	The BILITEST 2000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR11	Class B	The BILITEST 2000 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	



BILITEST 2000

EMC Guidance (electromagnetic immunity)

Guidance and manufacture's declaration – electromagnetic immunity			
The BILITEST 2000 is intended for use in the electromagnetic environment specified below. The customer or the user of BILITEST 2000 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50Hz, 60Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacture's declaration – electromagnetic immunity			
The BILITEST 2000 is intended for use in the electromagnetic environment specified below. The customer or the user of BILITEST 2000 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the BILITEST 2000 than the recommended separation distance

<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 V rms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 V rms</p> <p>3 V/m</p>	<p>calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$d = 1.2\sqrt{P}$, 150 kHz to 80 MHz</p> <p>$d = 1.2\sqrt{P}$, 80 MHz to 800 MHz</p> <p>$d = 2.3\sqrt{P}$, 800 MHz to 2.5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a, should be less than the compliance level in each frequency range ^b. Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>
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Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

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

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitter, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BILITEST 2000 is used exceeds the applicable RF compliance level above, the BILITEST 2000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BILITEST 2000.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

EC Declaration of Conformity

Product Identification

Product name: Photometrical dual-wavelength two-channel hyperbilirubinemia transcutaneous automatic analyzer for screening of newborn
Model/Type: PHAn-04- "NPP-TM" **BILITEST 2000**
Serial number:

Manufacturer

Name: J-S CO. "TECHNOMEDICA"
Address: Starovatutinsky proezd, dom 5, stroenie 3, Moscow, 129281
Country: Russia

Authorized Representative in Europe

Name: Wellkang Ltd
Address: Suite B, 29 Harley Street, London, W1G 9QR
Country: England, United Kingdom

Notified Body

Name: EUROCAT Institute for Certification and Testing GmbH
Address: Wittichstrasse 2, 64295 Darmstadt
Country: Germany
Identification No. 0535

Conformity assessment procedure: Annex VI EC verification of the Directive 93/42/EEC

EC-CERTIFICATE No. CE 580365

J-S CO. "TECHNOMEDICA" hereby declares on our own responsibility that the product listed meets all the provisions of the Council Directive **93/42/EEC with Revision 2007/47/EC** which apply to him.

This Declaration is only valid when the product is used in accordance to the "Instruction for Use" and becomes void if the device is modified without our consent.

Place and Date: J-S CO. "TECHNOMEDICA"

Signature:

Name: Alexander Bezrukov
Director



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"TECHNOMEDICA"

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