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TECHNOMEDICA

BILIRUBIN EVALUATION IN NEWBORNS

NONINVASIVE TRANSCUTANEOUS HYPERBILIRUBINEMIA ANALYSER

BILITEST

BILITEST is a portable fully automatic measurement device, intended for objective evaluation of hyperbilirubinemia level in newborns using noninvasive transcutaneous method

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1. Special features of transcutaneous bilirubinometry

BILITEST is a portable bichromatic reflecting type photometer. Practically the extent of yellowness of hypodermic tissues of a baby is measured. This measurement is performed on the high background signal caused by haemoglobin.

Transcutaneous bilirubinometry is a screening method for revealing a group with risks of heavy hyperbilirubinemia progress. Among this group of risks further direct measurement of bilirubin must be performed using other laboratory techniques.

The use of BILTEST allows reducing the number of newborns subjected to blood collection for laboratory investigations.

BILITEST permits thorough control and monitoring in newborns for the jaundice progress and for the efficiency of the course of treatment.

2. Bilirubin evaluation

Commonly in newborns bilirubin evaluation is performed on a forehead near nose or on the upper part of a breast. Only a slight touch of a mobile measuring head to a baby's derma is needed for measure. Measuring process takes 1-2 seconds. The result is given in international units - transcutaneous bilirubin index (TBI).

TBI has a high correlation degree with plasma bilirubin concentration.

The evaluation of blood bilirubin concentration in µmol/litre can be easily obtained by multiplying the device's readings by factor 10.

3. Advantages of the device

Three AA batteries supply power, the lifetime of a single battery set exceeds 100,000 measuring cycles. No turning on/of is needed as BILITEST continuously is at a waiting power-saving mode. Measuring cycle takes no more than 1-2 sec. The cycle starts automatically on touching baby's derma with a sensitive mobile head. Following measures can be repeated in each of 5 seconds. Readings of a previous measure are erased automatically.

4. Control

For routine check-up of device's readings special optical filters (standards) are included into the basic set. There's no need in other calibration or checking procedures for device's efficiency verification.

5. Technical specifications

Measuring range – 2-50 units TBI (20-500 µmol/litre)
Correlation coefficient with plasma bilirubin concentration – > 0.90
Accuracy – ± 10 %
Imprecision (CV%) – ± 3.5 units TBI
Dimensions – 135x65x35 mm
Weight – = 150 grams
Power supply – 3 batteries, size AAA
Measuring cycles with one battery set – > 100,000

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The intended use of the Photometrical Hyperbilirubinemia Analyzer is to screen newborn infants for hyperbilirubinemia, including:
• to evaluate 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 assess 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 Method of Transcutaneous Bilirubinometry into medical practice. This concept has been embodied in BILITEST. The correlation is caused by existing dynamical balance between bilirubin concentration in blood and subcutaneous tissues due to reversible diffusion of a 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 counterblow from tissues to blood until the balance between these to 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 commonly within 5 - 6 hours.

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

In other cases correspondence between TBI and serum bilirubin concentration values (SeBC) should be refined. The User refine it himself, comparing the readings of BILITEST with the corresponding laboratory data of serum bilirubin testing. To obtain calibration coefficients for BILITEST 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, with gestational ages of 30 - 40 weeks and weights of 1400 - 3500 g, were examined. In parallel with determining a 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 calibration. Measuring TBI on forehead also allows infant's examinations to be performed without additional manipulations with the newborns (e.g. taking clothes off).

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, the TBI measurement is preferable to be made on the upper part of sternum.

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 quoted. Thus, TBI determination during phototherapy does not permit to assess the 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 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 receive phototherapy if TBI value equals approximately 14 TBI, as they are highly sensitive to bilirubin and lower bilirubin concentration may cause Encephalopathy. As a rule, if on the second-fourth day of an infant's life TBI value exceeds 14, this point out to serious diseases and demands combined conservative treatment.

If TBI value is more than 17, one should control bilirubin concentration growth in blood and make measurements every hour.

The same recommendations can be used if TBI value exceeds 17 and 25 on the 4th-7th day correspondingly. In case TBI value is more than 25-30, an urgent serum bilirubin testing is needed (with fractions of bilirubin).

If there is no Jaundice, it is impossible to assess bilirubin concentration in blood using TBI values. It is necessary to determine bilirubin concentration in venous and umbilical blood of the newborn, which run the danger of haemolytic disease, in order to make decision on exchange transfusion during the first day.

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

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