BM-BS 1.0 - Bilistick System

Technical Data Sheet

General Description of the System

The Bilistick System is a Point-of-Care diagnostic device able to measure Total Serum Bilirubin (TSB) concentration on whole blood of newborn infants. It is composed by the ***Bilistick Reader***, a hand held rechargeable battery reflectance reader; ***Bilistick Test Strips***, test strips with a cell-plasma separator coupled with a nitrocellulose membrane, both encased in a plastic cassette; and ***Bilistick Sample Transfer Pipettes***, used for loading the appropriate volume of blood on the strip. The test requires the collection of a small blood sample directly from a heel stick or a tube by using the Bilistick Sample Transfer Pipette, and its application on a Bilistick Test Strip. The later separates the plasma from cells and allows the determination of TSB by reflectance spectroscopy using the Bilistick Reader. The TSB determination by the Bilistick System does not require the use of reagents simplifying the process of measurement.

Intended Use

The Bilistick System is intended for use in hospitals, clinics, doctor's offices or family counseling under a physician supervision/direction to assist clinicians in monitoring the bilirubin levels in the blood of newborn infants. The System is not intended as a standalone for diagnosis of hyperbilirubinemia. It is to be used in conjunction with other clinical signs and laboratory measurements.

Bilistick System Technical Specifications

Sample Features	
Sample Type	Newborn infant whole blood
Sample Size	35 µL
Hematocrit	25 – 70%

Bilistick Reader	
Units	mg/dL and µmol/L
Range	1 mg/dL to 40 mg/dL / 17µmol/L to 684 µmol/L
Measure System	Photometric based in two wavelength at 465 nm and 570 nm
Resolution	± 0.1 mg/dL / 1.0 µmol/L
Repeatability	Up to 25 mg/dL: Within ± 0.2 mg/dL / 3 µmol/L Over 25 mg/dL: Within ± 0.6 mg/dL / 10 µmol/L
Test Time	< 2 minutes depending on hematocrit
Sensors	Optical sensor
Optical filters	Glass protection inside the optical chamber

Calibration	Standard for periodic calibration Blank self-calibration after Test Strip insertion
Hemolysis	Automatic system for hemolysis detection
Results Report	Color display, dimension 36.0 x 29.0 mm
Interface	Mini B - USB port
Operating Conditions	Temperature: 15°C to 40°C Relative Humidity (non-condensing): 5 to 75%
Storage Conditions	10 °C to 40 °C low humidity, non-corrosive gas atmosphere.
Long-term Storage	1) In case of long-term storage, store the reader at 15-25 °C, low humidity, non-corrosive gas atmosphere. 2) When storing the reader for a period longer than six months, charge the battery at least once six months
Power Supply	Mini B - USB – DC 5V – 0.5A – 2.5 W
Recommended Charging Conditions	Average charging time: 4 hours (while no bilirubin test are been performed) Charging temperature: 15 – 40 °C (Recommended 15-25°C) Voltage: 5V
Dimensions	31.3 mm H x 72.9 mm W x 140 mm D
Net Weight	220 g
Shipping Weight	760 g

Battery Charger

Power Supply	USB – DC 5V – 1.5A - 7.5 W UL Certificated Accessory
USB Cable	Type A - Mini B (5pin) M/M USB 2.0 UL Certificated Accessory

Bilistick Test Strips

Cell-Plasma Separator	Nitrocellulose
Reading membrane	Nitrocellulose
Plastic Cassette	High Impact Polystyrene (HIPS)
Storage Conditions	15 -30 °C temperature, in its original packing in a dry atmosphere and protected from light and heat sources
Dimensions	3.70 mm H x 15.00 mm W x 48.65 mm D
Net Weight	1.86 g

Bilistick Sample Transfer Pipettes

Composition	Plastic and Glass
Total Length	70.00 ± 0.20 mm

Glass Tube Diameter	1.60 ± 0.05 mm
Drawing Capacity	35.00 ± 3.50 µL

Directives and conformity

The Bilistick System has been projected and built in accordance with:

- Directive IVD 98/79/EC of the European Parliament and of the council of 27 October 1998 on in vitro diagnostic medical devices
- UNI CEI EN ISO 13485 Medical devices -- quality management systems -- requirements for regulatory purposes
- UNI CEI EN ISO 15223-1 Medical devices -- symbols to be used with medical device labels, labelling and information to be supplied -- part 1: general requirements
- UNI CEI EN ISO 14971 medical devices -- application of risk management to medical devices
- CEI EN 61010-1 - Safety requirements for electrical equipment for measurement, control, and laboratory use - part 1: general requirements
- CEI EN 61010-2-101 - Safety requirements for electrical equipment for measurement, control and laboratory use – part 2-101: particular requirements for in vitro diagnostic (IVD) medical equipment
- CEI EN 61326-1 - Electrical equipment for measurement, control and laboratory use - EMC requirements - part 1: general requirements
- Electrical equipment for measurement, control and laboratory use - EMC requirements - part 2-6: particular requirements - in vitro diagnostic (IVD) medical equipment
- CEI EN 62304 Medical device software – software life cycle processes
- CEI EN 62366 Medical devices - application of usability engineering to medical devices