

General Description of the System

The Bilistick® System is a Point-of-Care assay able to measure Total Serum Bilirubin (TSB) concentration on whole blood of newborn infants. It is composed by: **Bilistick® Reader**, a portable 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 test strip. The test with the Bilistick® System requires the collection of a small blood sample directly from a heel stick or a test tube, by using the Bilistick® Sample Transfer Pipette, and its loading on a Bilistick® Test Strip once already inserted in the reader. The Strip separates the plasma from corpuscular components of the blood 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. Once loaded on the strip, the bilirubin concentration result is obtained within few minutes. The Bilistick® System allows the determination of bilirubin concentrations between 1 mg/dL and 40 mg/dL (17 and 684 µmol/L) with an accuracy comparable to traditional clinical laboratory methods.

The new Bilistick® System 2.0 has been implemented with Wi-Fi connection, allowing quick and simple access to the Bilistick® Reader User Interface for creating Operator profiles and associate Patients IDs to bilirubin results. Measures information can be easily printed on a label using the optional small and portable Bilistick® System Printer. Moreover, this new version allows the Bilistick® Reader to be connected to the hospital network through Wi-Fi or LAN port using HL7 protocol.

Intended use

The Bilistick® System is intended to be use in hospitals, clinics, physician’s offices, or family counseling under a physician’s supervision/direction to assist clinicians in monitoring the bilirubin levels in the blood of newborn infants. Even if it was demonstrated that the Bilistick® System provide accurate results, its use is advised for quick screening of hyperbilirubinemia. The use of other laboratory methods for results confirmation are recommended and left to the user criteria in each case.

The expected users of the Bilistick® System are:

- Neonatologists
- Physicians/Pediatricians
- Midwives
- Nurses
- Laboratory technicians

Before start using the Bilistick® System, the user must be trained following the instructions described in the User Manual.

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 / 17 µmol/L to 684 µmol/L
Data storing	Internal memory – Storing capacity up to 999,999 bilirubin results
Measure System	Photometric based in two wavelength at 465 nm and 570 nm
Resolution	± 0.1 mg/dL / 1.0 µmol/L
Repeatability	Till 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
Connectivity	Mini B-USB port USB / LAN port (via USB / RJ45 adapter) Wi-Fi (via USB port / Wi-Fi dongle)
Operating Conditions	Temp. 15°C - 40°C / Hum. 15% - 90%
Storage Conditions	Temp. 1°C - 35°C / Hum. 25% - 60%, non-corrosive gas atmosphere.
Long-term Storage	1 - In case of long-term storage, store the reader at temp. 15°C - 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 a month
Power Supply	Mini B - USB – DC 5V – 0.5A – 2.5W
Charging Conditions	Average charging time: 4 hours (while no bilirubin test is been performed) Charging temperature: 15°C – 40°C (Recommended 15°C - 25°C) Voltage: 5V
Dimensions	31.3 mm H x 72.9 mm W x 140 mm D
Net Weight	220 g
Shipping Weight	650 g
Transport Conditions	Temp. -5°C - 40°C / Hum. 25% - 60%, in its original packing, in a dry atmosphere and protected from light and heat sources

Power Supply

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

Wi-Fi Dongle

Interface	USB 2.0
LED	Status
Weight	2.1 g
Dimensions	18.6 x 15 x 7.1 mm
Antenna	Internal antenna
Standard wireless	IEEE 802.11b, IEEE 802.11g, IEEE 802.11n
Frequency	2.400 - 2.4835 GHz
Signal rate	11b: Up to 11Mbps (dynamic) 11g: Up to 54Mbps (dynamic) 11n: Up to 150Mbps (dynamic)
Reception signal	130M: -68dBm@10% PER 108M: -68dBm@10% PER 54M: -68dBm@10% PER 11M: -85dBm@8% PER 6M: -88dBm@10% PER 1M: -90dBm@8% PER
Transmission power	<20dBm
Environment	Operative conditions: Temp. 0°C ~ 40°C / Hum. 10% ~ 90% without condensation Storage conditions: Temp. -40°C ~ 70°C / Hum. 5% ~ 90% without condensation

USB/Rj45 Adapter

Chipset	Realtek RTL8152B
Compatibility	USB 2.0/1.1 standard
Power	Through USB port
Network connection speed	10/100Mbps
Standard	IEEE802.3 and IEEE802.3u

Bilistick® Test Strips

Cell-Plasma Separator	Nitrocellulose
Reading membrane	Nitrocellulose
Plastic Cassette	High Impact Polystyrene (HIPS)
Dimensions	3.70 mm H x 15.00 mm W x 48.65 mm D
Operative Conditions	Temp. 15°C - 40°C / Hum. 15% - 90%
Storage Conditions	Temp. 1°C - 35°C / Hum. 25% - 60%, in its original packing in a dry atmosphere and protected from light and heat sources
Transport Conditions	Temp. -5°C - 40°C / Hum. 25% - 60%, in its original packing in a dry atmosphere and protected from light and heat sources

Net Weight 1.86 g

Bilistick® Sample Transfer Pipettes

Composition	Plastic and Glass
Total Length	70.00 ± 2.00 mm
Glass Tube Diameter	1.60 ± 0.05 mm
Drawing Capacity	35.00 ± 3.5 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