

# Bilistick System 2.0

In Vitro Point of Care Test  
Total Serum Bilirubin



## EVERYWHERE

Home Care,  
NICU, Nursery,  
Clinic

## EVERYONE

Can use it  
following  
in-service training

## EVERY BABY

all ethnicities, only  
one drop of whole  
blood, no limitations

## EVERY TIME

for testing before,  
during and after  
phototherapy

# Early Diagnosis of Hyperbilirubinaemia

Neonatal Jaundice is a physiologic condition occurring in approximately 60% of term and 80% of preterm newborns. Jaundice is a sign of elevated levels of bilirubin in the blood. The baby presents with a yellowish appearance resulting from the accumulation of bilirubin in the skin, mucous membranes and conjunctiva.

When jaundice has a high peak level regardless of the cause, treatment is required to prevent brain damage. In addition, some underlying causes of hyperbilirubinaemia are serious or even life-threatening illnesses that require urgent treatment. The early detection and prompt treatment of severe hyperbilirubinemia are crucial for the newborn's health.

The Bilistick® System 2.0 is a Point of Care bilirubin assay able to provide early diagnosis of hyperbilirubinemia by measuring Total Serum Bilirubin (TSB) concentration in whole blood samples.

The system is composed of the 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 requires collection of a small whole blood sample (35µL) directly from a heel stick or a test tube, by using the Sample Transfer Pipette, loading on a Test Strip inserted in the Reader.

## Bilistick® System 2.0 features



**Portable and usable everywhere, following in-service training**



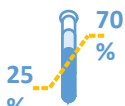
**Minimally invasive, requiring only one blood drop of blood**



**Results are immediate without the need for any reagents**



**Validated against Laboratory Analysers**



**Able to measure in blood samples with wide range of HCT**



**Applicable to newborn babies of all ethnicities**



**Operator identification**



**Patient ID association**



**Hematocrit screening**



**Results printing on adhesive labels (Optional)**



**WiFi Connection**



**Clinical network connection**

# Simple Steps for Reliable Results

1



Insert the Test Strip

2



Collect the blood sample

3



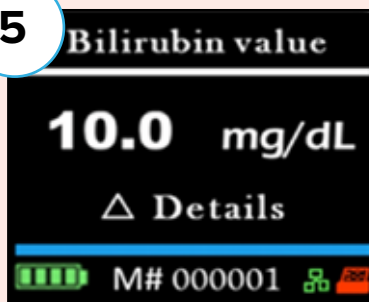
Load the sample

4



Press M key and wait for result

5



Check bilirubin concentration in the display

6



Check the Test Strip

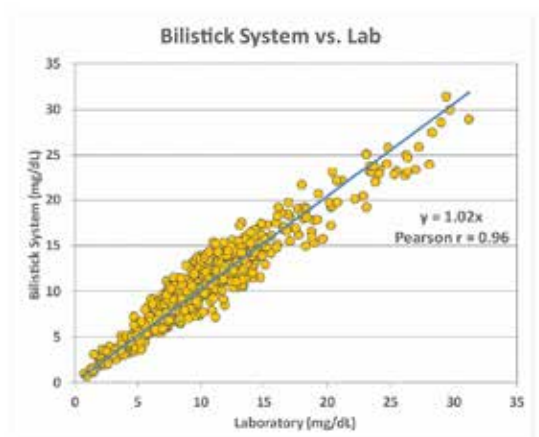
## Validated against Laboratory Measurements

The Bilistick® System has been validated against Laboratory Blood Gas Analysers in Hospital Clinical Trials.

A comparison of Bilistick® Total Serum Bilirubin results with common methodologies routinely used in Hospital Laboratories has demonstrated results with excellent correlation of bilirubin.

Several studies support the use of the Bilistick® System for routine Total Serum Bilirubin screening.

It may facilitate the early identification of newborns requiring phototherapy treatment and therefore contribute to a substantial reduction in the prevalence of Acute Bilirubin Encephalopathy and Kernicterus.



### References

- Neonatology 2013;103:176–180 – "Bilistick: A Low-Cost Point-of-Care System to Measure Total Plasma Bilirubin"
- Journal of Perinatology (2017) 00, 1 – 4 – "Comparison between Bilistick System and transcutaneous bilirubin in assessing total bilirubin serum concentration in jaundiced newborns"
- EClinicalMedicine 1 (2018) 14–20 – "Diagnostic Performance Analysis of the Point-of-Care Bilistick System in Identifying Severe Neonatal Hyperbilirubinemia by a Multi-Country Approach"

# TECHNICAL INFORMATION

<b>USE</b>	<b>Measurement of Total Serum Bilirubin Concentration in Newborns</b>
<b>SAMPLE</b>	<b>Whole blood</b>
<b>VOLUME</b>	<b>35 µL</b>
<b>HEMATOCRIT RANGE</b>	<b>25 – 70%</b>
<b>UNIT OF MEASUREMENT</b>	<b>1 mg/dL to 40 mg/dL - 17µmol/L to 684 µmol/L</b>
<b>DATA STORAGE</b>	<b>Internal memory – Storage capacity up to 999,999 bilirubin results</b>
<b>TYPE OF MEASUREMENT</b>	<b>Photometric based in two wavelengths at 465 nm and 570 nm</b>
<b>INTERFERENCE</b>	<b>Automatic System for Haemolysis Detection</b>
<b>AVERAGE READING TIME</b>	<b>&lt; 60 seconds</b>
<b>MAX. RESOLUTION</b>	<b>± 0.1 mg/dL / 1.0 µmol/L</b>
<b>REPEATABILITY</b>	<b>&lt;25 mg/dL: ± 0.2 mg/dL / 3 µmol/L   &gt;25 mg/dL: ± 0.6 mg/dL / 10 µmol/L</b>
<b>SENSOR</b>	<b>Optical sensor</b>
<b>CALIBRATION</b>	<b>Standard periodic calibration / Blank self-calibration after Test Strip insertion</b>
<b>RESULTS OUTPUT</b>	<b>OLED display, PC, Printer (optional)</b>
<b>ADDITIONAL FUNCTIONS</b>	<b>Mini USB/LAN/WiFi connectivity – Hematocrit screening</b>
<b>DIMENSIONS</b>	<b>31.3 mm H x 72.9 mm W x 140 mm D</b>
<b>WEIGHT</b>	<b>220 grams</b>
<b>POWER SUPPLY</b>	<b>Mini B - USB – DC 5V – 0.5A – 2.5 W</b>

Product Code	Product Description
BURBM-BS 2.0C	Bilistick® System 2.0
BURBC1-50	Bilistick® Test Strip and Pipette (50)
BURBC2-200	Bilistick® Sample Transfer Pipette (200)
BURBC1-50-GHKIT	Bilistick Test Strip + Pipette + Heal Incision Kit (50)

Product Code	Product Description
BURBC3	Bilistick® Calibration Kit
BURBC4	Bilistick® Cleaning Kit
BURBSP	Bilistick® System Printer
BURBSP-L1	Bilistick® System Printer Label roll 50x25mm

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