



Reichert UNISTAT® Bilirubinometer

Chemistry-free, no dilution solution for point-of-care Total Serum Bilirubin measurement



Clinical Implications: Bilirubin is a byproduct of the breakdown of hemoglobin by the liver. Newborns may have difficulty with filtering blood and excreting this excess bilirubin. Because of this risk of bilirubin toxicity, newborns must be monitored to identify those who might develop hyperbilirubinemia and kernicterus. The Total Serum Bilirubin test measures the concentration of bilirubin in the newborn. This detection is needed before a diagnosis and treatment program can be initiated.

- Simple to operate. Requires no complicated chemistry or waiting time.
- UNISTAT®'s photometric analyzer measures Total Serum Bilirubin (TSB) concentration easily and accurately **within 5 seconds**.
- UNISTAT® provides 99% correlation to widely recognized method (diaz Jendrassik-Grof) for accurate TSB measurement.¹
- **Low operating cost** with no expensive slides, carousels, or reagents. UNISTAT® uses an inexpensive disposable specimen cuvette and re-usable glass calibration cuvette.
- A study published in the *Journal of Perinatology* showed that UNISTAT® meets the 2004 AAP guidelines "Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation" for physicians taking TSB measurements as a point-of-care test (*J Perinatol.* 2006; 26:100-105).^{2*}

Point-of-care testing for all skin types and ethnicities.

Reichert's UNISTAT® Bilirubinometer uses a proven photometric analyzer to provide accurate and rapid measurements of total serum bilirubin (TSB) concentration in undiluted serum. The photometric analyzer is the ideal STAT-level analyzer for determining TSB in newborn infants. Other methods use visual detection of skin color. This has proven to be unreliable where skin color pigments can mask the jaundice symptom.

continued



Analytical Instruments • Clinical & Diagnostic



^{1,2} H A Barko, G L Jackson, W D Engle; **Evaluation of a point-of-care direct spectrophotometric method for measurement of total serum bilirubin in term and near-term neonates;** *Journal of Perinatology*; 01 Feb 2006; **26**, 100 - 105

*Mention of the AAP guidelines does not imply endorsement of any product by the AAP.

Principles of Operation:

The Reichert UNISTAT® is a direct spectrophotometer that measures total bilirubin in neonatal serum samples. Dilution is not necessary. A beam of light is passed through the sample cuvette. The beam is split by a dichroic mirror and directed toward the 460nm and 550nm filters. The transmittance of the light exiting the filters is measured by photodetectors. The control electronics calculate total bilirubin based on output from the photodetectors. Since peak absorbance is shared by bilirubin and oxyhemoglobin at 460nm, it is necessary to measure oxyhemoglobin at 550nm. The difference in the readings at 460nm and 550nm is the total bilirubin value, corrected for the presence of oxyhemoglobin. Since the UNISTAT® measures and subtracts oxyhemoglobin, bilirubin results are not affected by hemolyzed samples.

UNISTAT® Bilirubinometer Technical Specifications	
Catalog Number	1310310C
Model	UNISTAT® Bilirubinometer comes with: box of 51 disposable cuvettes, calibration and high-level check cuvettes, reference manual, replacement lamp, 3-wire cord with grounded plug, 115V, 50/60 Hz
Sample Size	20µL undiluted serum
Results Displayed	5 seconds
Turnaround Time	15 seconds
Readout	Digital direct reading, mg/dL or µmol/L
Range	0-40 mg/dL 0-684 µmol/L
Accuracy	±5% [0-30 mg/dL (0-513 µmol/L)] ±10% [30.1-40 mg/dL (515-684 µmol/L)]
Operating Range	115 V, 50/60 Hz
Approvals	ETL, CE

UNISTAT® Bilirubinometer Options & Accessories	
1310311C	UNISTAT® Bilirubinometer, same as above but 230 V, 50/60 Hz
13102140	Disposable cuvettes for UNISTAT® Bilirubinometer, package of 51
13103410	Calibration cuvette (approximate assay value 20 mg/dL, 342 µmol/L)
13103420	High-level check cuvette (approximate assay value 41 mg/dL, 701 µmol/L)
13103430	Low-level cuvette (approximate assay value 12 mg/dL, 205 µmol/L)

UNISTAT® Bilirubinometer



Part #	Description
1310310C	UNISTAT® BILIRUBINOMETER 115V
1310311C	UNISTAT® BILIRUBINOMETER 230V
13102140	SPECIMEN CUVETTES (51 PER PKG)

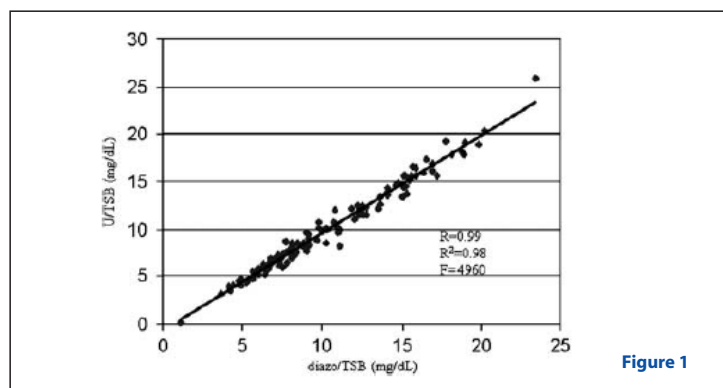


Figure 1

Figure 1 chart shows the extremely high correlation of measurements taken by the UNISTAT® Bilirubinometer compared against the same patient samples measured by a clinical hospital analyzer using the diazo Jendrassik-Grof method. This method is a widely recognized diazo method for Total Serum Bilirubin measurement. The UNISTAT® demonstrated a correlation of 99% with the diazo Jendrassik-Grof method. This is important for the physician's office and satellite location to obtain accurate measurements that correlate to the hospital. ³

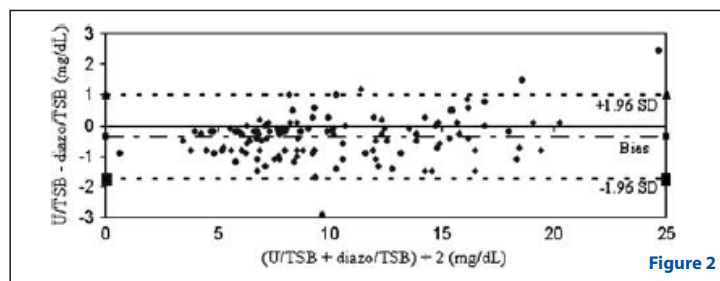


Figure 2

Figure 2 chart shows agreement between the two methods (UNISTAT® and diazo Jendrassik-Grof) using a Bland-Altman plot analysis. Bland-Altman plots in analytical chemistry and biostatistics is a method of data plotting used in analyzing the agreement between two different assays. ⁴

For more technical detail regarding these studies, please visit our website at www.reichertai.com. Go to the UNISTAT® Bilirubinometer product page under our Clinical and Diagnostic Instruments link and click on "Downloads and Resources" tab.

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MERCOFRAMES OPTICAL CORP

5555 Nw 74 Ave. Miami, FL 33166
www.mercoframes.net
ale@mercoframes.net