



## Name: Bilirubinometer


**Purpose:** Quantification of serum bilirubin in neonates for the diagnosis and management of jaundice at the patient's bedside

### General Description/ System Components

Transcutaneous bilirubinometers do not require a blood sample. A light-emitting sensor is placed on the infant's skin (optimally on the forehead or sternum). The reflected light is split into two beams by a dichroic mirror, and wavelengths of 455 nm and 575 nm are measured by optical detectors.

### Technical Specifications

Category	Specification	Compliance		If non-compliant, state your specs
		Y	N	
Mobility	Handheld			
Technical Characteristics	Linear Range: 0-40 mg/dL (0-684 $\mu\text{mol/L}$ )			
	Accuracy: $\pm 10\%$ from 5-30mg/dL (85.5 - 513 $\mu\text{mol/L}$ )			
	Results Format: quantitative across whole linear range			
	Result Units: must display mg/dL or $\mu\text{mol/L}$ (shall have ability to select or switch between either)			
	Sample: Whole blood heel-stick sample $<50 \mu\text{L}$ ; does not require user to separate serum/plasma using a centrifuge			
	Precision: 4% CV			
	Light source: two white light-emitting diodes (LED)			
	Detector: two photocell system			

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		Y	N	
	Kit Stability & Storage: Stable for 12 months with harsh ambient conditions (temperature 5-45 °C, humidity 15%-95% elevation up to 2000 meters) and transport stress (48h with fluctuations up to 50°C and down to 0°C)			
Power Source & Battery	Mains with rechargeable battery			
	Rechargeable battery, >100 tests on a single charge			
Similar to:	Dräger - JM-105			
Typical Photo		This Area is for Technical Evaluation by Consultant		