

Transcutaneous bilirubin measurement system for infants

Country of origin | United States of America

Health problem addressed

Hyperbilirubinaemia is a common condition in many newborns, affecting nearly 1 in 10 newborns and nearly 90% of premature infants in the first week of life. If undetected and untreated the levels of bilirubin may rise high enough to pass through the blood brain barrier and is deposited in the brain causing kernicterus and brain damage.



Product description

The device provides a numerical measurement of predicted bilirubin count in mg/dL or $\mu\text{mol/L}$ within a clinically beneficial range that has been correlated with total serum bilirubin concentration measured by High Pressure Liquid Chromatography (HPLC).

Product functionality

The device works by directing white light into the skin of the newborn and measuring the intensity of the specific wavelengths that are returned. By knowing the spectral properties of the components within the skin, one can subtract out the interfering components and determine the concentration of bilirubin.

Developer's claims of product benefits

The technology of the device evaluates melanin, collagen, hemoglobin and bilirubin in a patient's subcutaneous tissues through a proprietary algorithm and optics system. Existing technologies measure the yellowness of the skin as it relates to jaundice.

Operating steps

Simple button push for calibration, place on infants head or sternum and press the measurement button 5 times in succession and the results appears on the screen. Test taken in minutes.

Development stage

This product has been sold globally since 2002. To date over 5000 units have been delivered to hospitals, clinics, physicians and community health workers.

Technical evaluation and health technology assessment review: FDA 510K # k010052.

Regulatory approval complete. Conformity assessment has been carried out (USA).

Future work and challenges

The product is not registered as a medical device in all countries. Depending on the country of use, the product may need to be registered before it is used.

User and environment

User: Nurse, midwife, physician

Training: Technique education on how to properly take a measurement.

Maintenance: Manufacturer

Environment of use

Setting: Rural and urban health care facilities.

Requirements: Power supply to charge the battery, disposal of calibration tip and cleansing products for pre-patient use.

Product specifications

Dimensions (mm): 2045 x 50.23 x 59.4

Weight (kg): 0.346

Consumables: Disposable calibration tip (per test)

Life time: 5 years

Shelf life: 20 months

Retail Price (USD): 3500

List price (USD): 4295

List price of consumables (USD): approx. 360 (bag of 50)

Other features: Portable and reusable. Runs on batteries and uses software.

Year of commercialization: 2009 (first version in 1996)

Currently sold in: Most of Europe, as well as in Australia and several African, Asian, North- and South-American countries (65 countries)

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http://www.who.int/medical_devices