international BIOMEDICAL

BiliChek

Noninvasive Bilirubin Assessment Tool

Results with a simple touch

BiliChek noninvasive bilirubin assessment tool

Assess risk
and elevate care

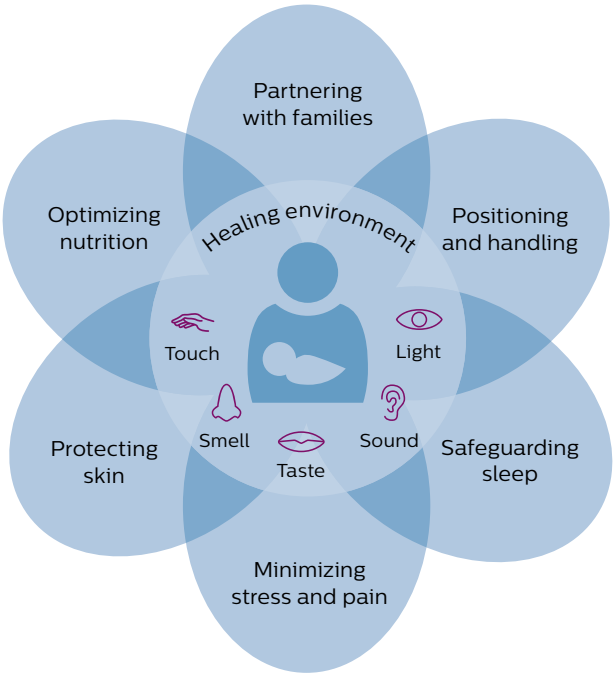
Measuring bilirubin levels invasively with a heel stick is seldom predictable. There's no way to foresee how the baby will react. And often, lab results take longer than you – or the anxious parents – would like. BiliChek, a noninvasive, transcutaneous bilirubin measurement system, can help address these issues.

BiliChek allows you to assess the risk of hyperbilirubinemia in newborns. Using light instead of a needle, BiliChek measures a newborn's bilirubin levels in your newborn nursery, the mother's room, the NICU or right in your office. There is no heel stick, no lab test, and no waiting for lab results – just a simple, gentle touch and results are at your fingertips in minutes.

The BiliChek was developed in line with the Neonatal Integrative Developmental Care model,[1] which advocates creating a healing environment. Because BiliChek is a transcutaneous device, you simply place the disposable BiliCal tip lightly on the baby's forehead or sternum. There is low risk of infection, minimal trauma and no pain – all while helping facilitate decisions on the appropriateness of treatment for elevated bilirubin levels.

Neonatal Integrative Developmental Care model

BiliChek promotes several of the core measures of neonatal Integrative Developmental Care, our framework for delivering patient-focused care to mother and child.

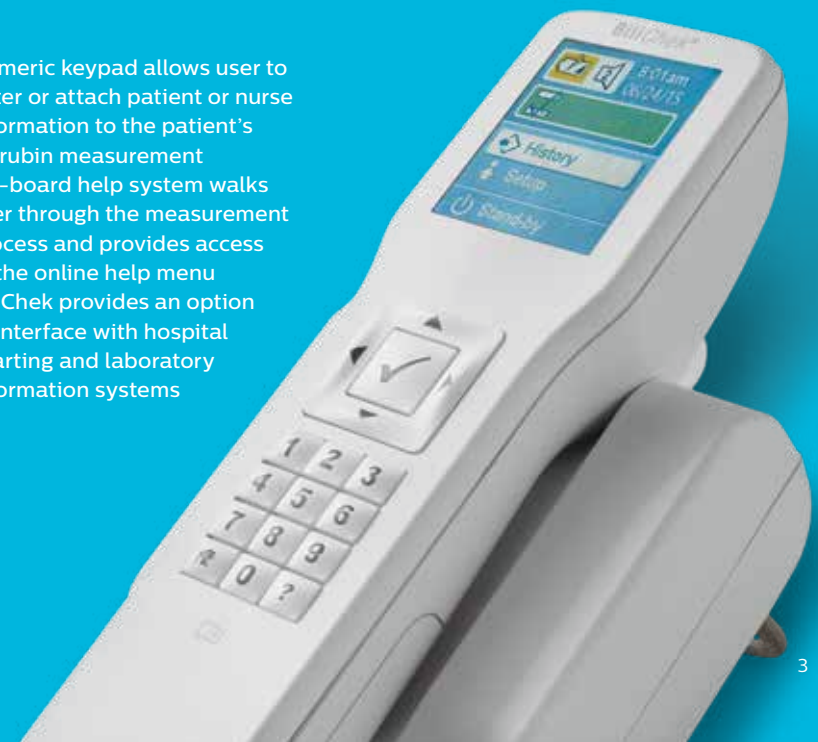


BiliChek offers

- Noninvasive administration to minimize stress and pain
- No needles, to protect skin
- Minimal light and sound and only a gentle touch, to safeguard newborns' sleep by minimizing disturbances
- Measurements taken at easy access sites (forehead and sternum) to limit unnecessary handling of the newborn

BiliChek at a glance

- Slim, light, ergonomic design facilitates easy measurements
- LCD color screen facilitates operating in the low light levels of a nursery
- Easy-to-read, step-by-step instructions, graphics and a fast measurement system contribute to enhanced proficiency and productivity
- Barcode scanning allows for accurate identification of patient or nurse information and decreases risk of charting errors
- Numeric keypad allows user to enter or attach patient or nurse information to the patient's bilirubin measurement
- On-board help system walks user through the measurement process and provides access to the online help menu
- BiliChek provides an option to interface with hospital charting and laboratory information systems



Results at your fingertips

You'll love how easy it is to assess bilirubin levels with BiliChek. Just five light touches and BiliChek's proprietary algorithm will capture subtle differences in the baby's skin to provide accurate results.

An LCD color menu screen offers you step-by-step instructions, so that even new users can feel confident that they are using the device correctly. The BiliChek screen has a tip pressure indicator that changes from yellow to green to indicate when the correct pressure is being applied during a measurement.

Lightweight and ergonomic, the device also features a long-lasting, rechargeable lithium-ion battery.

Proven, reliable measurements

Clinical trials have proven that BiliChek correlates with a high degree of confidence to high-end, research-based blood analyzers (high pressure liquid chromatography or HPLC). And BiliChek correlates to HPLC at a .90 correlation coefficient value with accuracy (RMSE) of +/- 1.5 mg/dL. More than ten years of field use support those clinical findings.[2]

BiliChek features technology advances that enhance its speed, reliability and applicability.

- BiliChek directs white light into the skin and measures the intensity of the returning wavelengths. It measures hemoglobin, dermal maturity, melanin and bilirubin, and then, by using known spectral characteristics of each of these components, subtracts all but the bilirubin to arrive at a measurement.
- BiliChek can be used before, during and after phototherapy.
- BiliCal disposable tips are discarded after each use, so no time is spent re-sterilizing each tip.* When you apply a new tip, the system automatically recalibrates without the use of reagents. BiliChek provides feedback on whether the calibration was successful. There is no need for periodic recalibration by the manufacturer.
- BiliChek can be used at just 27 weeks gestational age and up to a post-natal age of 20 days.
- BiliChek can be used with all variations in skin tone.

The BilEclipse Phototherapy Protective Patch isolates a section of skin before, during and after phototherapy so that transcutaneous bilirubin measurements can be taken with BiliChek.

BiliCal individual calibration tips are disposable plastic to decrease risk of infection from cross-contamination associated with multiple patient devices.

* As part of your comprehensive HAI policy, incorporating single use and single patient use supplies can help support your goals in reducing HAIs.

Verify, store and track patient information

If you choose, you can use BiliChek to share data with other hospital information systems.

An integrated barcode scanner automates data entry, storing patient and nurse ID, medical record number, patient name and date of birth. Automated data entry saves time and reduces the likelihood of manual input errors. Alternatively, you can still input key patient information at the bedside with the keypad. BiliChek can then record, store and download bilirubin test results to your hospital's electronic medical records system via a LAN connection to your laboratory information system.

BiliChek and your laboratory information system

How it works

Step 1

Nurse scans barcode and visually verifies patient scan

Step 2

Nurse measures total bilirubin levels using BiliChek

Step 3

Nurse docks BiliChek to cradle

Step 4

BiliChek sends patient ID and measurement result to Laboratory Information System (LIS) point-of-care connectivity software

Step 5

LIS creates order, applies measurement results, verifies and (optionally) charges for test

Step 6

LIS forwards BiliChek results to hospital's electronic medical record system and updates the system to include patient's bilirubin level test results

BiliChek

Specifications

Intended use	Pre, during and post phototherapy
Gestational age	27–42 weeks
Post-natal age	0–20 days
Patient weight range	950–4,995 g
Total serum bilirubin range	0–20 mg/dL 0–340 µmol/L
Accuracy (RMSE)	+/- 1.5 mg/dL at 66% of the time or one sigma +/- 26 µmol/L at 66% of the time or one sigma
Repeatability (SD)*	+/- 0.66 mg/dL +/- 11.2 µmol/L
Correlation	r = 0.90

BiliChek hand-held unit

Dimensions	5.23 x 20.45 x 5.94 cm 2.06 x 8.05 x 2.34 in (W x L x H)
Weight (with battery pack)	250 g (9 oz)

Battery pack

Type	Lithium-ion
Voltage	3.7 V
Expected battery life (minimum)	One year
Recharge time (maximum)	Eight hours
Measurements with a fully charged battery	200 single measurements

Charger base

Dimensions	9.14 x 9.01 x 4.30 cm 3.60 x 3.55 x 1.69 in (W x L x H)
Weight (with battery pack)	140 g (5 oz)

Power supply

Input	100–240 VAC, 50/60 Hz, 0.4 A
Output	5 V DC, 2.0 A

Connectivity

Ethernet specification	10 baseT half duplex

Ordering information

Product number	Description	Quantity per case	Part number
1067554	BiliChek system with wall-mount power supply (North America only)	1	989805644871
1067561	BiliChek system with desktop power supply (North America only)	1	989805644881
1062275	BiliChek manual (languages Eng, FR, DE, IT, ES, PT)	1	989805622461
B800-50	BiliCal – BiliChek disposable calibration tip	1 (50 pack)	989805607841
B800-11	BilEclipse Phototherapy Protective Patch	1 (50 pack)	989805607751

* Instrument-to-instrument repeatability

References

1. Altimer L. Mother and child integrative developmental care model: A simple approach to a complex problem. Newborn & Infant Nursing Reviews. Sept 2011;11(3):105-108.
2. Jangaard K, Curtis H, Goldbloom R. Estimation of bilirubin using BiliChekTM, a transcutaneous bilirubin measurement device: effects of gestational age and use of phototherapy. Paediatr Child Health (Oxford). 2006;11(2):79–83.

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