



BiliChek® Noninvasive Bilirubin Analyzer

Suggested Usage Protocol

Purpose

To outline and define the use of the **BiliChek** Noninvasive Bilirubin Analyzer in the clinical setting, which may include the Newborn Nursery, Neonatal Intensive Care Unit, Outpatient Clinic, Laboratory, Home Nursing Agency, Emergency Department and Physician Office.

Scope

The **BiliChek** Noninvasive Bilirubin Analyzer is approved for use as an accurate predictor of total serum bilirubin (TSB) in infants and neonates. Intended use:

- Pre, during and post phototherapy
- Gestational age: 27 to 42 weeks
- Postnatal age: 0 to 20 days
- Weight range: 950 to 4995 grams

Classifications and Definitions

The **BiliChek** Noninvasive Bilirubin Analyzer device is an alternative to subcutaneous (traditional heel stick TSB) bilirubin testing as correlated to High Performance Liquid Chromatography (the gold standard in serum bilirubin analysis). Because **BiliChek** is noninvasive, there is no pain, trauma or risk of infection to the patient.

BiliChek performance has been clinically proven in patients within the following parameters:

- Gestational age: 27 to 42 weeks
- Postnatal age: 0 to 20 days
- Weight: 950 to 4995 grams

BiliChek should not be used in the following situations:

- Following exchange transfusion.
- The measurement site on the forehead contains excessive bruising, birthmarks, hematomas or excessive hairiness as this can produce erroneous results.

Note: If unable to use the forehead, we recommend using the sternum as an alternative measurement site.

Only properly trained personnel should perform **BiliChek** testing. Such personnel may include:

- Nursing staff
- Laboratory personnel
- Physician
- Home health provider

Staff Competency Validation

All clinical personnel responsible for performing **BiliChek** testing must be properly trained prior to use of the device in a clinical setting to ensure accurate test results. Training will be documented as follows:

- ① Clinical personnel will receive a demonstration of the equipment by an experienced **BiliChek** operator and will be responsible for reading the information provided in the "User Instruction Manual" and any other training materials provided by the manufacturer.
- ② Clinical personnel will perform a return demonstration on three infants in the presence of an experienced **BiliChek** operator.
- ③ Successful completion of training will be documented in the employee's education record.

Testing Procedure

Initialize the Unit

- ① Install a fully charged battery pack into the battery compartment of the unit.
- ② Press and release either the F1 (blue) or F2 (gray) button on the front of the **BiliChek** unit to turn the device on.
- ③ The device will perform a self-test, momentarily displaying all LCD indicators. When the self-test is complete, the home screen will be visible displaying the last measurement, time and date or an error code message (if applicable).

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- ④ If this is the first time the **BiliChek** device is used, it will be necessary to enter the set-up mode and program the display settings before proceeding. Please refer to the "User Instruction Manual" for complete set-up instructions.
- ⑤ **BiliChek** does not have an off switch and will automatically turn off if it is idle for a user-specified period of time (60 or 120 seconds).

Perform Calibration

- ① Remove a new BiliCal™ disposable tip from its foil pouch and apply it to the optical sensor on the **BiliChek** handheld device before each use.
- ② Firmly press the BiliCal on the **BiliChek** handheld device to ensure proper seating of the tip.
- ③ With the home screen displayed, press and release the trigger button (blue button located on the hand grip) to start calibration.
- ④ Three dashes (---) will flash in the display window and the Measurement Status Indicator (MSI) will be amber if the BiliCal is properly seated, indicating the device is ready to calibrate. (If the BiliCal is not properly seated, the MSI will be red and an E01 error message will be displayed.)
- ⑤ Press and release the trigger button again. The dashed lines will stop flashing indicating that **BiliChek** is calibrating.
- ⑥ The MSI will be amber colored and a beep will be heard (if audible alarm is enabled). The display window will read (005) to indicate that the calibration was completed successfully. If there is a failure in calibration an error message will be displayed and you will be unable to proceed with testing. Refer to the troubleshooting section of the "User Instruction Manual."
- ③ Gently press the BiliCal against the infant's forehead or sternum. The MSI on the display will change from amber to green and "005" will stop blinking when proper pressure is applied.
- ④ Hold the **BiliChek** handheld device steady until the measurement is complete (1 to 3 seconds). The device will beep if the audible alarm is enabled.
- ⑤ Perform a series of five measurements by lifting and replacing the BiliCal on the center of the infant's forehead or sternum. Press and release the trigger button before each measurement. The current measurement will be indicated on the display (005...003...001).
- ⑥ Upon completion of the five measurements, a final beep will sound and the test result will be displayed along with the current time and date. Remove and discard the disposable tip.
- ⑦ Place the blue protective tip cover onto the **BiliChek** handheld device (an un-used BiliCal can be used if the protective cover becomes lost or damaged).
- ⑧ The **BiliChek** unit will turn off automatically.

Document Result

- ① Document the patient test result, date and time in the appropriate area on the patient's chart.
- ② Notify the attending physician as appropriate.
- ③ Obtain follow-up measurements in accordance with physician orders.

QA Documentation Procedure

The **BiliChek** device performs internal calibration controls prior to each patient test. The device will not permit testing to occur if the calibration does not meet the control specifications. In order to document completion of the calibration prior to each test to meet JCAHO requirements you should complete a "Quality Documentation Record" similar to the sample on the next page. An individual record should be maintained for each **BiliChek** device and tracked by serial number.

Perform Patient Test

- ① After performing the calibration, pull on the BiliCal tab and peel away the protective covering (calibration material) from the disposable tip and discard.
- ② Press and release the trigger button. The device is now activated and ready to take a measurement. ("005" will be displayed and blinking.)



BiliChek® Noninvasive Bilirubin Analyzer
QUALITY DOCUMENTATION RECORD

Device Serial #: _____

Patient ID	Date	New Tip Applied	Calibration Passed	Display	Tcb Measurement Mg/dL/mmol/L
Xxxxxx	4/10/06	Y	Y	005	5.6
Yyyyyy	4/11/06	Y	Y	005	7.8
Zzzzzz	4/11/06	Y	Y	005	12.6

Cleaning and Maintenance

The following is a list of recommended cleaning agents for the **BiliChek**:

- KleenAseptic®
- Cavicide®
- 70% - 90% Isopropyl alcohol
- 1% Bleach

To clean, spray the cleaning agent of choice onto a damp cloth and wipe the **BiliChek** system and display window clean.

Warning: Do not immerse the BiliChek in water or other liquid. If liquids spill onto the unit, wipe with a cloth and let unit dry before use.

Warning: Do not attempt to clean and/or reuse the BiliCal disposable tip.

Patient Test Implementation Guidelines

Infants with one or more of the following risk factors for hyperbilirubinemia will be screened for elevated bilirubin levels with the **BiliChek** Noninvasive Bilirubin Analyzer.

- 10% loss of birth weight
- Poor feeder
- Excessive bruising
- Blood group incompatibility
- < 37 weeks gestation and/or 2500 grams
- Visible jaundice

A total serum bilirubin (TSB) (blood draw) will be obtained prior to the initiation of phototherapy treatment ordered by the attending physician, based on the following criteria:

- Infants < 24 hours of age with **BiliChek** TcB of ≥ 10 mg/dL
- Infants ≥ 24 hours of age with **BiliChek** TcB of ≥ 12 mg/dL
- Infants ≥ 48 hours of age with **BiliChek** TcB of ≥ 15 mg/dL
- Infants ≥ 72 hours of age with **BiliChek** TcB of ≥ 17 mg/dL

Note: These guidelines are intended to serve only as a reference. They shall be used only in conjunction with the instructions and/or protocol set forth by the physician and institution in which the device is being used. The guidelines are not intended to supersede established medical protocols.

Use During Phototherapy

Prior to the initiation of phototherapy, the measurement site on the infant's forehead or sternum must be covered with a photo-opaque material such as the BilEclipse™ Phototherapy Protective Patch. The patch must remain in place throughout phototherapy. To take a measurement:

- ① Turn off the phototherapy light(s) (fiberoptic or overhead).
- ② Open the BilEclipse flap or remove other photo-opaque patch.
- ③ Perform the **BiliChek** measurement according to manufacturer's instructions.
- ④ Replace the BilEclipse flap or other photo-opaque patch.
- ⑤ Resume phototherapy as ordered.

Note: Clinical studies indicate that up to 48 hours may be required before the skin treated by phototherapy returns to the bilirubin level of an unexposed site. Therefore measurements from an unprotected site are not reliable.

Note: Newborns that are placed near a window with high exposure to sunlight may experience "natural phototherapy" which may alter the **BiliChek** results.

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Device Serial #: _____

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