Suggested BiliChek® Usage Protocol

I. Subject:

BiliChek® Non-Invasive Bilirubin Analyzer

II. Purpose:

To outline and define the use of the BiliChek Non-Invasive Bilirubin Analyzer in the hospital setting which may include the Newborn Nursery, Neonatal Intensive Care Unit, Outpatient Clinic, Laboratory, Home Nursing Agency and/or Emergency Department.

III. Scope:

The BiliChek Non-Invasive 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: 27-42 weeks
- Post-natal age: 0-20 days
- Weight range: 950-4995 grams

IV. Clarification & Definitions:

- The BiliChek Non-Invasive Bilirubin Analyzer device is an alternative to subcutaneous (traditional heel stick TSB) bilirubin testing as correlated to High Performance Liquid Chromatography. Because BiliChek is non-invasive there is no pain, trauma or risk of infection to the patient.
- The 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
- The 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 at this can produce erroneous results.
- Only properly trained hospital personnel should perform BiliChek testing. Such personnel may include:
  - Nursing Staff
  - Laboratory Personnel
  - Physician

V. Staff Competency Validation:

All hospital 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. Hospital 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. Hospital Personnel will perform a return demonstration on 3 infants in the presences of an experienced BiliChek operator.
3. Successful completion of training will be documented in the employee's education record.

VI. Testing Procedure

A. 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).
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 setting before proceeding. Please refer to the "User Instruction Manual" located _____ for complete set-up instructions.
5. The 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).

B. Perform Calibration

1. Remove a new disposable tip from its foil pouch and apply it to the optical sensor on the BiliChek hand held device before each use.
2. Firmly press the disposable tip on the BiliChek hand held 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 disposable tip properly seated, indicating the device is ready to calibrate. (If the disposable tip is not properly

seated, the MSI will be red and E01 error message will be displayed.)

5. Press and release the trigger button again. The dashed lines will stop flashing indicating the 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 "Usual Instruction Manual."

C. Perform Patient Test

1. After performing the calibration, pull on the disposable tip 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 not activated and ready to take a measurement. ("005" will be displayed and blinking.)
3. Gently press the disposable tip against the infant's forehead. 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 hand held device steady until the measurement is complete (1 to 3 seconds). The device will beep if audible alarm is enabled.
5. Perform a series of 5 measurements by lifting and replacing the disposable tip on the center of infant's forehead. 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 protective tip cover onto the BiliChek hand held device (An un-used disposable tip can be used if the protective cove becomes lost or damaged).
8. The BiliChek unit will turn off automatically

D. 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.

VI. 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 provided. An individual record should be maintained for each BiliChek device and tracked by serial number.

VII. Cleaning and Maintenance

The BiliChek System surface may be cleaned with the following agents:

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 disposable tip.

Warning: The optical measurement tip should only be cleaned with 90% or higher Isopropyl Alcohol using a soft optical surface cleaning wipe.

VIII. 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 Transcutaneous Bilirubinometer.

1. 10% loss of birth weight
2. Poor feeder
3. Excessive bruising
4. Blood group incompatibility
5. <37 weeks gestation and/or 2500 grams
6. Visible jaundice

A total serum bilirubin (TSB) (blood draw) will be obtained prior to the initiation of the 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 > 15mg/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 supercede established medical protocols.

Rubaltelli, FF, Gourley GR, Loskamp N, Modi N, Roth-Kleiner M, Sender A, Vert P: Transcutaneous bilirubin measurement: a multicenter evaluation of a new device. *Pediatrics* 2001; 107: 1264-1271.