

BILICHEK NON-INVASIVE BILIRUBIN ANALYZER

A. PRINCIPLE

The *BiliChek* Non-Invasive Bilirubin Analyzer is a computer assisted non-invasive transcutaneous bilirubinometer which is intended as an index to predict serum bilirubin levels in neonates less than eight days old, without regard to gender, gestational age, race, or body weight. The *BiliChek* works by directing white light into the skin of the newborn and measuring the intensity of the specific wavelengths which 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.

B. SPECIMEN

This is a non-invasive test; no specimen is necessary.

C. MATERIALS

1. *BiliChek* Hand-Held Unit with Protective Cover
2. Disposable Tips

D. CALIBRATION

Calibration must be performed prior to each patient test

1. Remove the blue Protective Cover from the *BiliChek*.
2. Turn the unit on by pressing the F1 or F2 button.
3. Remove the Disposable Tip from the pouch and apply it to the *BiliChek*.
4. Press and release the **TRIGGER** button to start calibration.
 - a. Three dashes (- - -) will flash in the display window and the Measurement Status Indicator (MSI) will be amber if a Disposable Tip is in place, indicating the system is ready to calibrate.
 - b. If a Disposable Tip is not in place, 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 the system is calibrating.

- a. The MSI will be amber and a beep will be heard (if the audio is on).
- b. The display window reads "005" and the calibration measurement is complete.

Note: If a problem occurs during calibration an error message will be displayed. Refer to the Troubleshooting Section of the manual for instruction.

E. PROCEDURE

1. After performing calibration, pull on the Disposable Tip tab. Peel away the protective covering and calibration material from the Disposable Tip and dispose.
2. Press and release the **Trigger** button. The unit is now activated and ready to take a measurement.
3. Gently press the Disposable Tip against the infant's forehead. The MSI on the display will change from amber to green when proper pressure is applied.

Note 1: Do not continue to increase pressure; this will result in an E04 error message.

Note 2: The display will read "005" and will stop blinking when proper pressure has been applied. The measurement should take approximately one to three seconds.

4. Take measurements at various locations by lifting and replacing the Disposable Tip on the center of the infants forehead.
 - a. A total of five measurements will be taken.
 - b. Press and release the **Trigger** button before each measurement.
 - c. The current measurement being taken will be indicated on the display (005,004,003,002,001).
5. Upon completion of the five measurements, a beep sounds (if the audio is on) and the test results are displayed with the current time and date.
6. Complete the Transcutaneous Bilirubin Results report form.

Note: Laboratory Services personnel will enter results in the Laboratory Computer/Hospital Computer.
7. Remove and dispose of the Disposable Tip.

8. Place the blue Protective Cover onto the *BiliChek*.

Note: The Hand-Held Unit will turn off automatically.

F. WARNINGS AND PRECAUTIONS

There are no known risks associated with proper use of the transcutaneous bilirubin measurement device.

Note 1: Do not point at eyes while taking a measurement.

Note 2: Do not use on areas of the skin with visible bruising, birthmarks, hematomas or excessive hairiness.

1. This product is for use only with a physician's order.
2. If the *BiliChek* is dropped and frequent error messages occur, it must be inspected for proper operation by an authorized service representative.
3. Do not immerse in water or other liquid.
4. Do not place in direct sunlight.
5. The charger base unit (battery charger) should be plugged into a properly grounded outlet. Do not operate with a damaged plug or cord. Do not allow the cord to hang over the counter/table.

G. NORMAL VALUES

0.0 - 7.0 mg/dL

H. ALERT VALUE

>14 mg/dL

Note: Results >14 mg/dL must be verified. Physician must order a serum bilirubin.

I. CLEANING MAINTENANCE

The *BiliChek* System is made of an easy to clean smooth surface. The following cleaning agents are recommended for use:

- Cavicide
- 70% - 90% Isopropyl Alcohol

Spray cleaning agent of choice onto a damp cloth to wipe clean the *BiliChek* System and the display window.

J. LIMITATIONS

1. If a measurement obtained by the *BiliChek* is greater than 20 mg/dL, the *BiliChek* display window will present E05-HIGH. Should this occur, the patient's physician should be contacted.
2. The *BiliChek* should not be used under the following conditions:
 - a. During phototherapy.
 - b. After phototherapy has been discontinued.
 - c. Following an exchange transfusion.
 - d. Measurements taken on sites other than the forehead.

K. REFERENCE

BiliT Chek_{TM} Non-Invasive Bilirubin Analyzer User Instruction Manual,
Respironics, Inc., Marietta, GA., PN 577-0148-00 Rev. D, 1998