

# St. Alexius Medical Center

## POLICY AND PROCEDURE

### Policy:

Infants with one or more of the following risk factors are screened for elevated bilirubin levels with a bilirubin meter.

1. 10% loss of birth weight
2. Poor feeder
3. Excessive bruising
4. Blood group incapability
5. Less than 37 weeks gestation and/or 2500 grams.
6. Visible jaundice at any time during hospital stay.

A total *serum* bilirubin, performed by the laboratory, is ordered and the physician called with results before discharge based on the following criteria:

1. Infants discharged <24 hours with a bilirubin meter screen of  $\square$  10 mg/dL.
2. Infants discharged  $\square$  24 hours with a bilirubin meter screen of  $\square$  12 mg/dL.
3. Infants discharged  $\square$  48 hours with a bilirubin meter screen of  $\square$  15 mg/dL.
4. Infants discharged  $\square$  72 hours with a bilirubin meter screen of  $\square$  17 mg/dL.

### Purpose/Intended Use:

The BiliChek meter is a computer assisted non-invasive transcutaneous bilirubinometer which is intended as an index to predict (screen) serum bilirubin levels in neonates:

- Intended use: pre, during and post phototherapy
- Gestational age: 27-42 weeks
- Post-natal age: 0-20 days
- Patient weight range: 950-4995 grams

### Material Required:

- BiliChek Hand Held Unit with battery pack
- Disposable tip: Do not expose to extended periods of light. Keep in package prior to use

Storage: -40 C –60 C (-40 F –140 F)

Operational Temperatures: 5 C –40 C (41 F –104 F)

### Calibration and Quality Control: (For meter Set-Up, refer to the “User Instruction Manual”)

An internal quality control calibration is performed by the meter each time the meter is turned on.

#### *Calibration Procedure:*

1. Apply a new disposable tip to the unit.
2. Firmly press the disposable tip on the BiliChek hand-held unit to ensure proper seating of the tip while making sure there is easy movement of the tip back and forth.  
DO NOT REMOVE THE PROTECTIVE COVERING, it is the calibration material.
3. Press and release either **F1** or **F2**.
4. The unit will perform a self-test, momentarily displaying all LCD indicators, measurement status indicator, software revision, configuration screen and end at the home screen.

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5. Press and release the TRIGGER button to start calibration.
6. Three dashes (---) will flash in the display window and the MSI (Measurement Status Indicator-the small light below the window) will be amber if a tip is in place, indicating the system is ready to calibrate. If a tip is not the MSI will be red and E01 error message will be displayed.
7. Press and release the TRIGGER button. The dashed lines will stop flashing indicating the system is calibrating.
8. The MSI will be amber and you will hear a beep (if the audio is on) the display window reads "005" and the calibration measurement is complete. Continue with patient test procedure.

Should the meter not pass the internal calibration, an error code will be indicated on the LCD screen. Turn the meter off and on again so that a repeat calibration will be performed. Should the error appear again, call technical support at 800-421-8754.

### *Safety precautions:*

*Safety equipment; Ordinary protection against the ingress of liquids. Waste produced is not considered biohazardous and may be disposed of in a non-regulated waste receptacle.*

*Caution: Do not point at eyes while taking a measurement.*

### **Procedure:** (Patient measurement)

1. After performing the calibration, pull on the tip tab and peel away the protective covering.
2. Press and release the TRIGGER button. The unit is now ready for five spot checks on the infant's forehead. Gently press the tip against the infant's forehead until the MSI on the display changes from amber to green. (Do not continue to apply pressure, this will result in an E04 error message.)
3. The display will read "005" and will stop blinking when proper pressure has been applied. The measurement should take one to three seconds.
4. Take "005" measurements at various locations by lifting and replacing the tip on the center of the infant's forehead. Press and release the trigger before each measurement. The current measurement being taken is indicated on the display (005...003...001).
5. After 5 measurements, a beep sound and the total bilirubin result is displayed with the date and time.
6. Remove and dispose of the tip in a non-regulated waste container. *Note: For infection control purpose, always change tip before testing another patient.*
7. Clean meter with 70% isopropyl alcohol after use (rubbing alcohol).
8. After final place the Protective Cover onto the BiliChek. The unit will turn off automatically.

### **Reference Range:**

Age	Premature	Full Term
24hrs	1.0-6.0 mg/dl	2.0-6.0 mg/dl
48hrs	6.0-8.0 mg/dl	6.0-7.0 mg/dl
3-5days	10.0-15.0 mg/dl	4.0-12.0 mg/dl

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Action Range: Order a total *serum* bilirubin to be performed by the laboratory based on the following criteria:

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### Critical Range:

20 mg/dL Notify physician of any critical result.

Linear Range: 0 – 20 mg/dL

If a measurement obtained by the BiliChek is greater than 20 mg/dL, error code E05 will appear (see below). Should this occur, call the laboratory for a heel stick serum bilirubin immediately.

*NOTE: Confirm a BiliChek reading that does not match the patient's status with a serum bilirubin from the laboratory.*

### Limitations:

1. The BiliChek meter should not be used under the following patient conditions:
  - Following an exchange blood transfusion.
  - Measurements taken on sites other than the forehead.
2. When using the BiliChek meter, avoid taking measurements from sites on the forehead with the following conditions since they can produce erroneous results:
  - Bruising
  - Birthmarks
  - Hematomas
  - Excessive Hairiness

**Troubleshooting Quick Reference:** (For complete troubleshooting guide, refer to the “User Instruction Manual”)

Following are some of the more commonly encountered error codes that may appear on the analyzer's LCD display screen:

1. E01: Calibration failure. Remove tip and replace it again. Repeat calibration procedure. Replace tip if necessary.
2. E02: Erroneous measurement. Clear error and try again. Replace tip if necessary.
3. E03: Tip removed during measurement. Start over with a new tip.
4. E04: Too much pressure applied to infant forehead. Clear error and try again.
5. E05: Meter is reading too high. Perform a heel stick.
6. E10: Light bulb burned out. Replace bulb.
7. E99: System error. Call for service. (800) 421-8754

BiliChek™ User Instruction Manual; 1198 Respironics, Inc.; PN 577-0148-00 Rev. B

BiliChek™ Product Sheet, 2001 Respironics, Inc.; PN 1007490 KB 06/28/01

