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**TITLE: BiliChek® Noninvasive Bilirubin Analyzer**

**PRINCIPLE**

The BiliChek® was designed to test bilirubin levels without regard to gender, gestational age, or bodyweight without needing a blood sample for hospital and homecare use.

Jaundice is the single most common medical condition affecting newborns and is the #1 cause of hospital readmissions of newborn babies. Complications from hyperbilirubinemia have been on the rise. Jaundice refers to the yellow discoloration of the tissues, mucous membranes of the mouth, sclera that is caused by the deposit of bilirubin. Clinically, jaundice is defined by serum bilirubin concentrations greater than 5 mg/dL or 85.5 µmol/L. Currently about 60% of full term infants become clinically jaundiced in the first week of life and > 80% of preterm babies become clinically jaundiced.

The BiliChek® generates a white light source that contains over 100 wavelengths in the light spectrum. As the light passes through the skin, some of the light loses its energy and is absorbed by the components of the skin: melanin, collagen, hemoglobin and bilirubin. Other light is scattered about and is uncollected. The remaining light that is reflected back to the BiliChek® unit is analyzed by the microprocessor and based on the composition of the reflected light, a bilirubin level is calculated. Individual photodiodes converts the reflected light to an electrical signal. The electrical signal is converted into numbers and the result is displayed in mg/dL.

**SUPPLIES**

- handheld unit, BiliChek®
- disposable tips
- charger base
- 2 battery packs – rechargeable, power supply
  - BilEclipse™ phototherapy patch.

**INTENDED USE**

These products are for use with the following infants in mind:

- 27-42 weeks gestational age
- 0-20 days post-natal age
- 950 – 4,995 grams
- Pre, during and post phototherapy

**WARNINGS AND PRECAUTIONS*****BilEclipse™* Phototherapy Protective Patch**

When a baby requires phototherapy it is imperative a *BilEclipse™* be placed on the baby's forehead or sternum prior to the initiation of phototherapy.

- Always clean the skin site before you place the *BilEclipse™* on the infant. Any liquids, lotions, or creams will reduce the adhesiveness of the patch and increase the likelihood that it will fall off during phototherapy.
- When you lift the lip of the patch to take a measurement, it may be helpful to place your finger on the edge of the base in order to make sure that the entire patch is not pulled off of the infant's skin.
- When you close the lip, make sure that it is in good contact with the base around the entire patch. Although it is unlikely that light will penetrate the sides, any light that does reach the skin could affect the BiliChek measurement.
- After phototherapy has been completed, it is recommended that the *BilEclipse™* be left on the skin until no future BiliChek measurements are likely to be made. Although no further changes in the skin will occur after the phototherapy lights are turned off, leaving the patch in place will ensure that future measurements are made from the same, protected location.

**WARNING: IT IS CRITICAL TO CALIBRATE THE UNIT AND APPLY A NEW BILICAL IMMEDIATELY PRIOR TO PERFORMING A TEST. INACCURATE TEST RESULTS WILL OCCUR IF THIS IS NOT DONE.**

**OVERVIEW OF THE BiliChek®**Functional overview of the hand held unit:

- 2 function buttons: power on and entering user setup date and clearing errors.
- Trigger: initiates calibration and ALL measurements
- Display window: bilirubin measurement, time and date, audio and battery icons, Measurement Status Indicator (MSI) as well as other system and error messages

Charger base:

- Well "A" and "B"  
The BiliChek® is placed in the left hand well "A" with the display window facing the operator. The spare battery pack is placed in the right hand well "B" with the latch up and facing the operator.
- Battery Status Indicator (BSI) – red, green and amber
- Charger/deep discharge switch

BiliCal Individual calibration material

- Devise calibration before each patient measurement
- Protection of the fiber-optic probe
- Protection of the surface of the calibration material
- Positioning aid to ensure proper placement of the probe
- A clean surface for each patient measurement

**The LCD display** is used to setup the customized options, perform a self test. display all LCD indicators, MSI, software revisions, current configuration screen and end at the home screen displaying the last measurement, time and date or error code message.

**In User-Set-up Mode**

- **The F1 button** (blue) advances to the next item.
- **The F2 button** (grey) changes the value of the current item.
- **The Battery** to install the battery pack inset the bottom of the battery pack into the bottom of the BiliChek® then rotate batter and snap into place.
- **The Charger Base** contains two wells, A and B, which recharge the battery pack in the BiliChek® and a spare battery pack, respectively. The two small lights on the front of the charger base BSI indicate the operation of the battery charger and battery charge status.
- The charger base has the ability to manually drain the battery by using the "Charge/Deep Discharge" switch located on the bottom of the charger base.
- **The BiliCal** disposable calibration tip snaps into the BiliChek®. After successfully calibrating remove the tab and begin performing the patient test.
- **The Trigger button** (single blue button on the back of the hand held unit) initiates calibration and patient measurement of the BiliCal™.

**Initial Set-Up of the BiliChek®**

Before starting to measure and monitor bilirubin levels, the BiliChek® needs to be setup. This setup can be done after the batteries are fully charged.

- After receiving the BiliChek® visually inspect that all components are without physical damage.
- Plug the power cord into the power supply and then into a grounded outlet.
- Connect the power supply to the charger base by inserting the plug into the socket on the rear of the charger base. The BSI lights will flash red. Green, amber, and then off (approximately 1 second each) to indicate proper operations.
- To install the battery pack, inset the bottom of the battery pack into the bottom of the BiliChek® then rotate batter and snap into place.
- To remove the battery pack press the release latch at the top of the battery pack and rotate out of the BiliChek®
- After installing one of the battery packs into the BiliChek®, insert the BiliChek® into the charger base well "A". The indicator light will glow amber to indicate that the batter pack is being charged.
- Insert the auxiliary battery pack into well "B". The BSI will glow amber to indicate that it is charging.
- Charge battery packs fully until a solid than green light is displayed on the BSI.

### Set-Up Mode

Before you use the BiliChek® for the first time, you may want to review or change certain factory setting. You can also use these procedures to change any of the settings at a later time. The following is a list of features that can be customized to your specific institution:

- Audio on/Off
- Measurement Units (mg/dL or  $\mu\text{mol/L}$ )
- Automatic Power off Time Interval (60 or 120 seconds)
- Time Format (12 H or 24 H)
- Time
- Date format (MO/DA or DA/MO)
- Date

### **To Turn the BiliChek® On**

- Install a charged battery pack into the battery compartment. Ensure the battery pack is all the way in and securely latched.
- Press and release either **F1** or **F2**.
- The unit will perform a self test, momentarily displaying all LCD indicators. MSI, software revisions, current configuration screen and end at the home screen displaying the last measurement, time and date or error code message.

### **To Access the User Set-Up Function**

- Press **F1** and **F2** at the same time, hold until you see the word “ON” in the LCD display window. This places the unit in the Set-Up Mode.
- While in this mode, the **F1** button (blue) advances to the next item. The **F2** button (grey) changes the value of the current item.

### Audio On/Off

The audio Set-up, indicated by the speaker icon on the display, allows you to determine whether you want the system to provide sound (beeps) during operations.

### **Note: ON is the default setting**

- Press and release **F2** to toggle the speaker on and off.
- Press and release **F1** to accept your choice and advance to the next Set-up function.

### Setting the Measurement Units

The system allows you to select the units in which the measurement will be displayed. The display will say SET and either mg/dL or  $\mu\text{mol/L}$  (European) will be displayed

- Press and release **F2** to toggle between mg/dL and  $\mu\text{mol/L}$ .
- Press and release **F1** to accept your choice and advance to next Set-up function

**NOTE: The default value is mg/dL and will only give a value up to 20; if the bilirubin is higher than 20mg/dL an error code E05 will appear instructing reading too high, do a heel stick.**

### **Automatic Power-Off Time Interval**

To conserve battery power, the unit has an automatic time-out feature. This means that the system will automatically turn off if it is idle for a specified period of time. Pressing **F1** or **F2** will restart the unit after it has powered off.

**Note: The default is 120 seconds.**

- Press and release **F2** to toggle between the options 60 and 120 seconds
- Press and release **F1** to accept your choice and advance to next Set-up function

### **Selecting the Time Format**

You can specify the time display format—in the 12 hour clock format or the 24 hour clock format.

**NOTE: The 12 hour format is the default setting.**

- Press and release **F2** to toggle between 12H and 24H format
- Press and release **F1** to accept your choice and advance to setting the time.

### **Setting the Time**

After choosing the time format, SET appears on the display and the current clock time will be shown.

1. The hour digit will flash
2. Press and release **F2** to scroll through the hours.
3. Press and release **F1** when the hour you want is displayed. The minute digit will now flash.
4. Press and release **F1** to select what is displayed, or
5. Press and release **F2** to scroll through the minutes.
6. Press and release **F1** to accept your choice and advance to setting the date format.

### **Selecting the Date Format**

You can choose to display the date in the month/day format or in day/month format.

1. Press and release **F2** to toggle between MO/DA and DA/MO format.
2. Press and release **F1** to accept your choice and advance to setting the date

### **Selecting the Date**

Depending on the date format you selected, the current month or day will flash first.

1. The month (day) will flash.
2. Press and release **F2** to scroll through the months (days)..
3. Press and release **F1** when the correct month (day) is displayed. The day (month) digit will now flash.
4. Press and release **F1** to select the displayed value, or
5. Press and release **F2** to scroll through the days (months).
6. Press and release **F1** to accept your choice.

7. Press and release **F1** to scroll through the year.
8. Press and release **F2** scroll through the year.
9. Press and release **F1** to accept your choice. The next digit will flash.
10. Press and release **F1** to accept your choice.
11. Continue this sequence until all digits have been entered

When you have accepted the desired date, your changes will automatically be saved and the unit will return to the home screen.

### **Turning the unit ON**

1. If there is no battery pack, insert a charged battery pack onto the battery compartment.
2. Apply a new BiliCal to the unit.
3. Firmly press the BiliCal on to the BiliChek® Hand held unit to ensure proper seating the BiliCal.
4. Press and release either **F1** or **F2**.
5. The unit will perform a self-test, momentarily displaying all LCD indicators, MSI. Software revisions, configuration screen and end at the home screen.

**NOTE: Press and hold F1 to illuminate the back light of the display window. This option is not available in the Set-up Mode.**

**NOTE: The home screen will remain until the TRIGGER button is pressed or the user Set-up Mode is entered.**

### **CALIBRATION**

1. Press and release the **Trigger** button to start calibration.
2. Three dashes (---) with flash in the display window and the MSI will be amber if the BiliCal™ is in place, indicating the system is ready to calibrate.
3. Press and release the **Trigger** button. The dashed lines will stop flashing indicating the system is calibrating.
4. 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.

If the BiliCal™ is not in place the MSI will be red and an EO1 error message will be displayed.

**NOTE: If a problem occurs during calibration an error message will be displayed. Refer to the Quick Reference Card for instructions.**

**NOTE: This unit is equipped with a Critical Power-Off feature. After completing the calibration, the unit will sound an alarm if no measurement is performed within a present period of time. The unit will power-off 20 seconds later if F1 or F2 is not pressed. If the unit automatically shuts off, it is necessary to perform another calibration after restarting**

**PROCEDURE**

1. After performing the calibration, peel away the protective covering and calibration material from the BiliCal tip and dispose.
2. Press and release the **TRIGGER** button. The unit is now activated and ready to take a measurement. **GENTLY AND SLOWLY** pressing the BiliCal against the infant's forehead. The MSI on the display will change from amber to green when proper pressure is applied. Do NOT continue to increase pressure; this will result in an E04 error message.

**NOTE: Always look at the amber light, gently and slowly press the BiliCal against the infant's forehead until the amber light turns to green, wait for the beep (if on audio) then lift from infants head.**

- The display will read "005" and will stop blinking when proper pressure has been applied. The measurement should take approximately one to three seconds.
- Take "005" measurements by **lifting and replacing** BiliCal on the center of the infant's forehead. Press and release the trigger button before each measurement. The current measurement being taken will be indicated on the LCD display and will count down from "005 – 004 – 003 – 002 – 001" and the unit will beep one time (if the audio is on) for each measurement successfully completed.
- 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.
- Remove and dispose of the BiliCal.
- Place Protective Cover onto the BiliChek® per manufacturer's recommendations.
- The BiliChek® hand held unit will turn off automatically.

**NOTE: If during a measurement the user moves out of the "pressure zone" the MSI turns red and an E04 error is displayed. Press and release F1 and F2 at the same time to retake the measurement. All previous successful measurements are saved.**

**REFERENCES**

BiliChek® self study guide