

BiliCare™

Neonatal Noninvasive Bilirubin Meter

User Manual



Important

This User Guide is subject to periodic review, update and revision.

The user of this product has sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, unauthorized service, damage, or alteration by anyone other than Gerium Medical.

The safety, reliability and performance of this product can only be assured under the following conditions:

1. The product has been used according to the accompanying operating instructions.
2. All updates, extensions, readjustments, changes or repairs have been carried out by Gerium Medical's authorized representatives.

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CE Notice



The symbol CE 0483 indicates compliance of this device with the MDR/2017/745.

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**PLEASE READ THIS USER GUIDE BEFORE
OPERATING THE SYSTEM**

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1. INTRODUCTION

1.1. ABOUT THIS USER GUIDE

This User Guide provides the information necessary to operate the BiliCare System. **PLEASE READ THIS USER GUIDE BEFORE OPERATING THE SYSTEM.** If any part of this User Guide is not clear, contact the product distributor for assistance.

1.2. THE BILICARE SYSTEM

The BiliCare System is a medical instrument for noninvasive measurement of the bilirubin levels of neonates, using the neonate's ear as the measuring site. The BiliCare System is a prescription Medical Device.

1.3. FEATURES OF THE BILICARE SYSTEM

- Accurate noninvasive measurement of the bilirubin of neonates
- Measures on the neonate's ear (Scaphoid Fossa)
- Semiconductor LEDs as light source
- Semiconductor photodiodes as sensors
- Color touch screen
- Record of results history
- Option to choose number of measurements (1, 2 or 3) per each test
- Option to choose the frequency of calibration checks
- Barcode scanner
- Option to choose the IDs entered by the user (2 patient IDs and 1 Nurse ID)
- Option to connect to PC via USB cable and to upload results to PC and to hospital information system together with dedicated PC software service
- Option to connect to PC via USB cable, to upload results to PC and to view and analyze patient measurements with BiliCare Viewer, dedicated PC software
- Option to charge the device via USB cable instead of AC/DC adapter power source.

2. CONDITIONS FOR USE

2.1. INTENDED USE AND INDICATIONS

The BiliCare is a non-invasive transcutaneous bilirubin meter for neonates. It measures yellowness of subcutaneous tissue in newborn infants and displays a measured value which correlates with serum bilirubin. The device is for use by medical / trained personnel to assist clinicians in monitoring the status of newborn infants for the development of hyperbilirubinemia. The device is not intended as a standalone for diagnosis of hyperbilirubinemia. It is to be used in conjunction with other clinical signs and laboratory measurements. Newborn infants whose BiliCare test results are indicative of hyperbilirubinemia are evaluated by their doctor(s) for appropriate patient management. Bilirubin levels should be confirmed by other methods, such as serum bilirubin, prior to treatment determinations.

2.2. CONTRAINDICATIONS

The device is not indicated for use during or after exchange transfusion.

Utilize the BiliCare after phototherapy only if the ear was covered by a special earmuff that prevented the passage of light.

2.3. TRAINING

The BiliCare device is user-friendly and can be easily operated with the aid of the Instructions for Use (IFU) provided with the device. Nevertheless, Gerium Medical or its authorized distributor will provide training for the system user as per the intended use of the device if required.

The training may be personal or by training the trainers.

2.4. DISPOSAL OF BILICARE DEVICE, DETACHABLE COMPONENT AND ACCESSORIES

Dispose of the equipment and its accessories, according to the rules and regulations of your country.

3. SAFETY

3.1. TYPES OF WARNINGS, CAUTIONS AND NOTES

Three types of special message appear in this User Guide:



Warning: A **warning** indicates precautions to avoid the possibility of personal injury or death.



Caution: A **caution** indicates a condition that may lead to damage to equipment, or a lower quality of treatment.



Note: A **note** provides other important information.

3.2. GENERAL SAFETY INSTRUCTIONS



Warnings:



DO NOT USE BEFORE READING THIS USER GUIDE.



Charge the handheld unit only with the provided base unit charging stand.



Ensure that the base unit charging stand is connected to a Gerium authorized Power supply.



Do not use on bruised skin, birthmarks or other skin lesions.



Do not use in an extremely bright environment or in direct sunlight.



Clean BiliCare before any use according to the Manufacturer instructions as appear in Chapter 13. Verify that the sensor windows are clean, transparent and without debris.



The tip cover is not reusable. Do NOT use it in more than one measurement. If the tip is re-used it may cause a transition of an infection from one patient to another.



Do not use the tip cover if it came into contact with any foreign surface



Do not use the tip cover if the blister cell is open.



Make sure the measurement area of the ear is clean before using the device.



Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally



Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation



Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of BiliCare System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result



Do not touch the charging pins in the cradle.



The charging via USB should be only by standard USB 1.X, 2 and 3.



Cautions:



If the system is not working correctly, discontinue use and refer servicing to qualified service personnel.



The device is not immersible – do not autoclave or place in water.



Do not disassemble any part of the system. This system is not user-serviceable.



Do not use the device if the LCD screen is dirty or cracked.



Do not use the device if the LCD screen has missing pixels or is not working correctly. Contact the product distributor for service.



Do not use the device if it is dropped or is otherwise roughly handled. Contact the product distributor for service.



BiliCare may be used on any ear. Avoid locating BiliCare on an ear that the baby lied on.



Note:

If a comparison is made between TcB and TSB, BiliCare measurements shall be taken within 30 minutes of every TSB measurement taken in each participating neonate

3.3. ELECTRICAL SAFETY

The device complies with IEC/EN 60601-1 for general requirements of medical electrical equipment safety.

3.4. EMC COMPLIANCE

The unit has IEC 60601-1-2 compliance.

4. OVERVIEW OF SYSTEM COMPONENTS

4.1. DESCRIPTION OF DEVICE

The BiliCare System is a medical instrument for non-invasive measurement of the bilirubin levels of neonates. It uses the upper part of the patient's ear (Scaphoid Fossa) as the measuring site. It emits light in several wavelengths on the ear and measures the light transmitted through the ear and the ear thickness. These measurement results allow the calculation of the bilirubin levels.

4.2. SYSTEM COMPONENTS AND ACCESSORIES

The BiliCare System -Catalog No. 81000200. consists of the following:

	Catalog No.	Definition	Quantity	Comments	
BiliCare parts	81000300.	BiliCare Handheld Unit	1		
	71000300.	BiliCare Charging Cradle	1		
	81000850.	International Power Supply Set	1	4 adapters for: US, EU, UK and China	
	38000110.	Pack of Calibration Check Tips	1	Includes 3 Calibration Check Tips	
	G13420100	Standard USB to Mini-USB cable	1	1.8m	
Labeling materials	DDBG81019	User manual - English	1	Printed	-
	DDBG81017	Quick guide - English	1	A5	-

Illustrated below is a detailed view of the Handheld Device, showing its individual components.



Detailed view of handheld device - front

Handheld Device	
No.	Description
1	Color Touch Screen
2	Sensor Clip
3	On/Off Button
4	Measurement Button
5	Charging Connector
6	Bar code reader
7	BiliCare label



Detailed view of handheld device - back



Caution: Ensure that the sensor windows are kept clean, transparent and without debris.



Caution: Do not use the device if the Sensor Clip spring is stuck or does not move easily.

5. FREQUENT OPERATIONS

5.1. PROPER USE OF THE TOUCH SCREEN

The touch screen of the BiliCare device is a "resistive" type touch screen.

This means that the screen is responsive to pressure.

Thus, **the user is required to press the screen firmly and distinctively.**

The following pictures show the proper way to press the BiliCare touch screen:

1. Use your index finger:



2. Use the edge of your finger or your fingernail to press the screen:



3. You may also use other options, such as a stylus or a closed pen.

5.2. PERFORMING A BASIC MEASUREMENT

➡ **Very important - Before measuring** ⬅

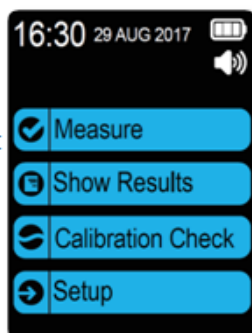
**The measuring site in the infant's ear is the Scaphoid Fossa, as seen in the picture.*



***Touch the clips lever only when you want to open or close the clip.*

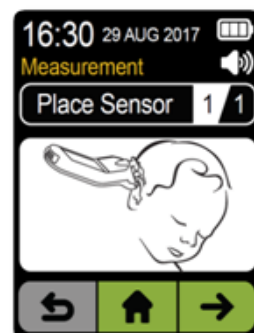
Step 1

- Lift the device and press the On/Off button.
- If the Home Screen is displayed, make sure that the device is not in contact with the patient.
- Press **Measure** or ✓ for beginning the measurement process.



Step 2

- A beep will be heard and the "Place Sensor" screen will appear.



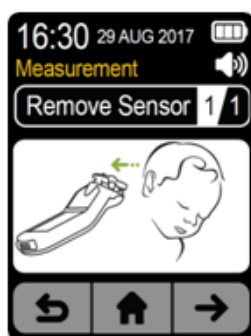
Step 3

- Hold BiliCare as shown in the following figure.
- Get BiliCare close to the infant, near the head, and press the clip lever with your index finger.
- Locate the sensor on a flat and clean surface in the Scaphoid Fossa of the free ear, and close the clip at the back of the ear.
- **Do not touch the clip's lever during the measuring process.**



Step 4

- When the buzzer sounds and "Remove sensor" screen appears, press the clip's lever and remove BiliCare from the infant's ear.
- Close the clip.



Step 5

- If the measurement was successful and **no more measurements are needed**, the result will be displayed.
- Read the result and operate according to the medical protocol procedures.
- Return the device to the charging stand. The orange light will turn on.



6. SETTING UP THE DEVICE FOR THE FIRST TIME

6.1. CONNECT CHARGING STAND TO AC POWER

Connect the power cord to the charging stand. Then plug the power cord into an AC outlet. **Allow the unit to charge for at least five hours** before first use.



Note: There is an option to charge the device via the USB cable but it should be taken into account that it's very slow. For charging the device with USB cable, Connect the USB cable from the cradle into USB port (e.g. PC USB Port..).



Note: The BiliCare handheld unit is equipped with a factory-installed battery. When and if the battery requires replacement, please contact your local distributor.

6.2. CHARGING

Once the handheld device has been set into the cradle charger stand, the charging process begins. While being charged a red LED is activated, once the device is completely charged, the LED changes to green, as shown in the pictures below.

The LED light indicates that the battery is charging and that the charging stand is properly connected to the power supply.

In order to view the battery level, remove the device from the charging stand and turn it on. The battery level will display in the upper right corner of the screen.

The battery should be fully charged within 3-4 hours of being placed in the charging stand.

Important:

In order to keep a fully charged battery, the BiliCare should be turned off when pulled out of the cradle:

1. Remove the BiliCare from the Cradle
2. Turn the BiliCare on
3. Turn the BiliCare off



Red LED, indicating that the battery is charging



Green LED, indicating that the battery is fully charged

7. USING THE DEVICE

7.1. ACTIVATE THE DEVICE

Lift the handheld unit from the charging stand and press the On/Off button to activate the device.



Note: The unit must be charged for a full five hours before the first use.



Note: If the Charging LED on the Charging Stand does not light when the handheld unit is inserted, contact the product distributor for service.

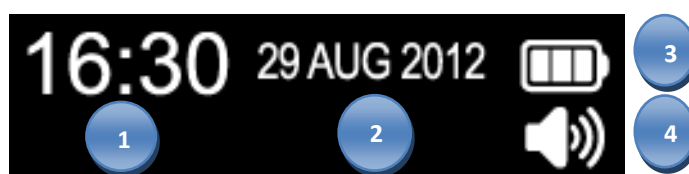


Note: If a test tone (beep) is not heard when you activate the device, contact the product distributor for service.

7.2. BILICARE SCREENS

BiliCare screens are consistent. In most screens the Header and the Footer are same.

The top of the Screens shows the **Header**, as follows:

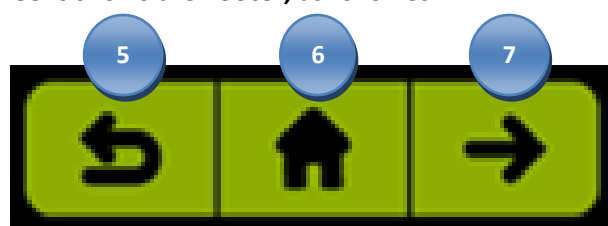


Key to Screen Header		
No.	Description	Notes
1	Time	
2	Date	
3	Battery status	Indicates remaining battery charge
4	Sound status	Sound on or off



Note: If the Battery Status indicates a low battery, charge the battery by inserting the Handheld unit into the Charging Stand.

The bottom of the Screens shows the **Footer**, as follows:



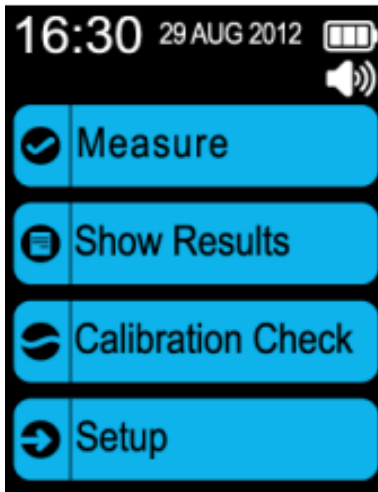
Key to Screen Footer		
No.	Description	Notes
5	Back Key	Erases or returns 1 step
6	Home Key	Returns to Home Screen
7	Next Key	Confirmation

7.3. HOME SCREEN

The Home Screen is the starting point for BiliCare functions.

Reach the Home Screen by pressing the “Home” key  at the bottom of most screens.

Pressing **Measure** on the Home Screen initiates the measurement process.



Four options are available on the Home Screen:

- **Measure** (page 19) – Perform a measurement.
- **Show Results** (page 30) – See the results of previous measurements.
- **Calibration Check** (page 19) – Check the device to ensure that it accurately works and is correctly calibrated.
- **Setup** (page 33) – Set values for system parameters such as sound volume, screen brightness, frequency of calibration checks, etc.

7.4. MEASURE – BEGIN THE MEASUREMENT PROCESS

When the device is activated by pressing the On/off button, the measurement process is initiated.

In addition, pressing **Measure** on the Home Screen also initiates the measurement process.

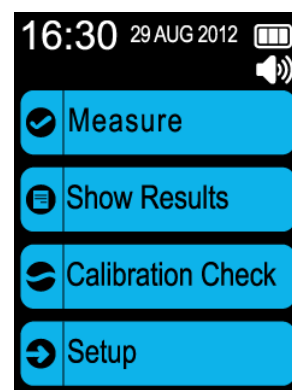
There may be other screens preceding the measurement screen once a measurement process is initiated, depending on the selected user settings for:

- Calibration check period
- Measuring password
- IDs
- Use of tip covers

For more details, refer to the following sections, according to the chosen options:

- Section **7.5. Device Calibration Check**
- Section **7.6. Measurement password (If Required)**
- Section **7.7. Nurse and Patient IDs**
- Section **7.8. Using tip covers**

The basic measurement procedure is presented in section **5.2. Performing a basic measurement**



7.5. DEVICE CALIBRATION CHECK

The Calibration Check is the device's self test, to ensure the measurement is accurate. If the results show the check is unsuccessful, the device should be sent to service.



Caution: The Calibration Check is NOT a calibration process. It is a self test to ensure accurate measurements. A failure in the Calibration Check necessitates the device to be examined by Gerium Medical service.



Note: Depending on the Setup options chosen, you may be asked to check the calibration of the device once a day, once a week or not at all. The default calibration check setup is to check calibration whenever the user decides to, with no set period.



Note: Bilicare does not need continuous calibration. But, Gerium Medical recommends to do a Calibration Check once a week.

See **section 10.12. Setup Calibration Period** for instructions on how to adjust the Calibration Check frequency.

If a calibration check is scheduled or when the system detects that a calibration check is required (if defined so in setup), the Calibration Check screen displays automatically. This screen is also displayed when you choose **Calibration Check** from the **Home Screen**.

The initial screen displays:



Check that the Clip is closed and press  or  to continue.

Do not put on the calibration check tip until directed to by the next screen.

The next screen displays:



Install the calibration tip, as shown in three steps here.

Install Calibration Tip,
Step 1 of 3



Install Calibration Tip,
Step 2 of 3



Install Calibration Tip,
Step 3 of 3



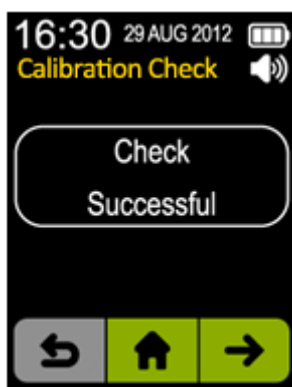
Then press  or 



During the calibration check, the **Processing Screen** displays for a few seconds:

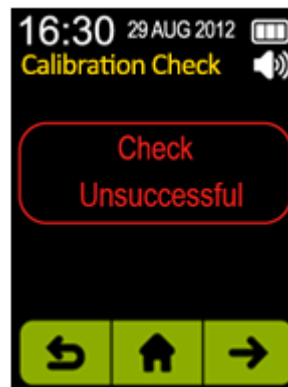
Depending on the success or failure of the calibration check, you will see one of the following screens:

If calibration check **was successful**:



Press  and the next screen displayed will be according to the device's Setup.

If calibration check **was unsuccessful**:



Press  to attempt calibration check again.



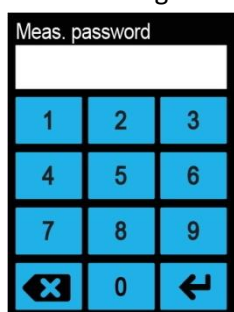
Note: If repeated attempts at calibration check fail, contact the product distributor for service.

7.6. MEASUREMENT PASSWORD (IF REQUIRED)

Depending on the Setup options in section **10.20. Set up: Measurement password**, the BiliCare System may ask for the Measurement password. This optional password assures that only authorized personnel may measure with BiliCare.

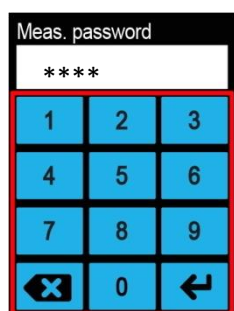
Once The Measuring Password was enabled, it allows the measurement function until returning the handheld device to a BiliCare charging stand.

The following Screen will be shown:

The image shows a handheld device screen titled "Meas. password". Below the title is a white rectangular input field. Below the input field is a numeric keypad with buttons for digits 1 through 9, 0, a backspace button (represented by a blue square with a white 'X'), and an enter button (represented by a blue square with a white right-pointing arrow).

Enter 4862 and press  or the  button.

If the password was correctly entered, the next screen will be displayed according to the device's Setup.

The image shows the same handheld device screen titled "Meas. password". The input field now displays four asterisks "****". The entire keypad area, including the backspace and enter buttons, is enclosed in a red rectangular border.

If an erroneous password was entered, a red rectangle will blink twice and 3 short beeps will be heard.

BiliCare is ready for receiving another password.

7.7. NURSE/PATIENT IDS (IF REQUIRED)

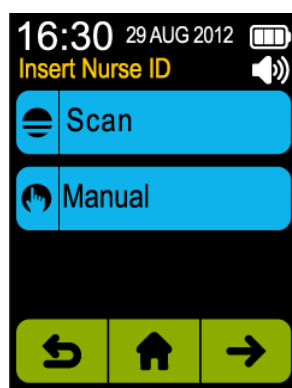
Depending on the Setup options (section 10.7. Setup: ID Set), the BiliCare System may ask for Nurse and/or Patient IDs. IDs can be scanned with the built-in barcode reader or can be entered manually using the onscreen keyboard. The maximum number of characters that may be entered per ID is 20 characters.



Note: Check the ID scanned by the barcode reader with the actual ID number on the scanned label.

One or more of the following IDs may be required:

If you see this screen:



⇒ Enter the **Nurse ID**



Note: If the nurse ID was entered previously then the previously entered Nurse ID would be displayed for confirmation just in case the device is in sleep mode and didn't turn off. If the device has been turn off or put in the charging stand since the last measurement this screen would be presented.

Nurse ID

Instructions for Entering the ID

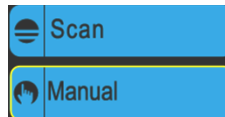
There are two methods for entering the ID

1. Scan the barcode using the barcode reader by pressing **Scan** or :



Barcode Reader on Handheld Unit

2. You may also press **Manual**:

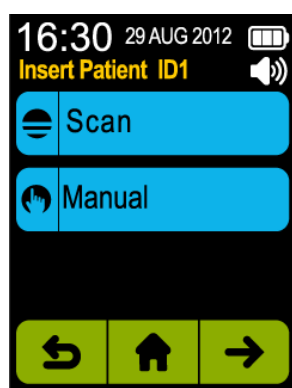


Note: You may skip an ID by pressing  and that will result in a blank



Note: If the ID is blank when the onscreen keyboard is displayed, pressing  will move to the previous screen.

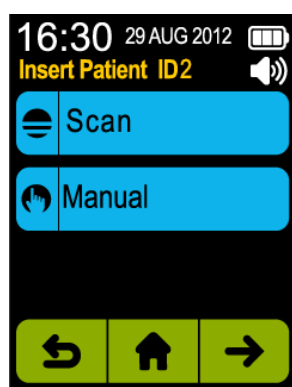
If you see this screen:



⇒ Enter the **first Patient ID**

First Patient ID

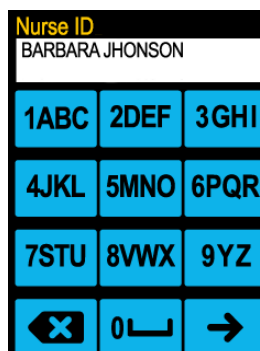
If you see this screen:



⇒ Enter the **second Patient ID**

Second Patient ID

Enter the ID using the on screen keyboard.



Caution: If the keyboard does not work properly, do not operate the device.

Check and confirm the ID pressing  or :



The next screen will be displayed according to the device's Setup.

7.8. USE OF TIP COVERS - OPTIONAL

The BiliCare tip covers arrive in a dispenser pack of 10 covers. Each cover is packed individually.

The tip covers are for optional use and are designated for one time use only.

The tip covers are manufactured and packed in a clean room environment that guarantees high standards for cleanliness.



Depending on the Setup options in **section 10.15. Setup: Tip Cover**, the BiliCare System may ask to locate a disposable tip cover.



Note: Make sure the device is **not** in contact with the baby.



The following two screens are displayed in order to instruct the user on how and when to put the tip cover:

Close the Clip and press  or  to continue.

Do not put on the tip cover until directed to by the next screen.



Put on the tip cover as described below.

The device **should not** be in contact with the baby at this stage.

1. Remove the tip cover from the cell and place the upper part of the cover in front of the clip tip.



2. Push the clip tip into the cover until the clip is all the way inside the cover.



3. Push the bottom part of the cover inward as demonstrated in the picture until the cover covers the bottom part of the sensor.



4. Close the clip.

The cover has been put on successfully.



Click  or  to continue.

BiliCare will show you the **Place Sensor** screen.

7.9. POSITION THE HANDHELD UNIT ON THE BABY'S EAR



Warning: Do not leave the device on the baby's ear unattended or for more than a few seconds.



Warning: Make sure the measurement area on the ear is clean before using the device.



Caution: A maximum of 100 measurements are saved in the memory of the device. Be sure to record the measurement before it is overwritten by subsequent measurements.

To start the measurement process itself:

The Place sensor Screen will be shown as follows:



Open the Clip and place the unit on the baby's ear.

The Clip should be positioned on the *Scaphoid Fossa*, as shown to the right.

See paragraph 5.2 Performing a basic measurement



Yellow area marks position of Scaphoid Fossa on ear



Side view of device sensor on ear

7.10. TAKE THE INITIAL MEASUREMENT

After locating the BiliCare clip on the baby's ear, you may either:

- Wait a few seconds for automatic measurement to begin (this is the recommended method)
- Press the **green check mark**  on the handheld unit
- Press the **Next** key  on the screen

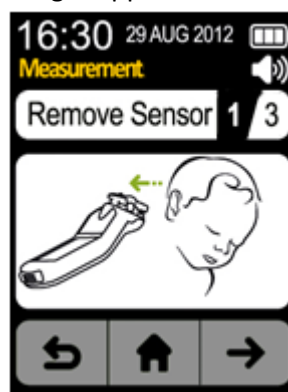
During the brief measurement process, the following two messages appear in succession:



Measurement in Progress...



Note: The screen will indicate 1/1, 1/2, 1/3, etc., depending on how many measurements are required, and how many have been made.



Measurement Complete – Remove device



Note: When the measurement is complete, you will hear a "beep" tone if sound has been enabled in Settings. Remove the sensor and close the clip.



If measurement **was successful** and **more measurements are required**, the next Place Sensor screen is displayed:

Open the Clip and place the unit on the baby's ear, as shown in **Section 7.9** above.



If measurement **was successful** and **no more** measurements are required, the measurement result is displayed:

Press  or  or  to return to the Home Screen.



Note: All three IDs are displayed, even if one or more was not entered (as described in section 7.7. Nurse/Patient IDs - If required). In this example, patient ID2 is blank.

If measurement **was unsuccessful** then a “Measurement Failed” message would be displayed followed by three short beeps:



Remove the clip from the baby's ear and close it.

Open the Clip and reposition the sensor on the ear.

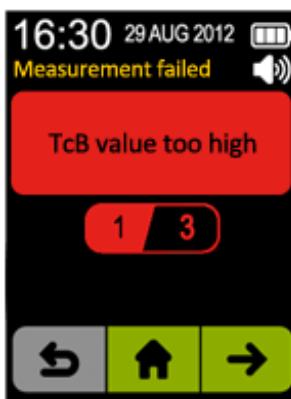
Continue from section **7.9 Position the Handheld unit on the baby's ear**



Note: A detailed error message will display with a yellow title describing the particular error that has occurred. See **Section 14.2. Possible Causes for Measurement Failure** for more details.



Note: If repeated attempts at measurement fail, contact the product distributor for service.



Remove the clip from the baby's ear and close it.

If the legend is “TcB value too high” or “Abnormal TcB reading” the device will not measure again. Return to the main screen and try to measure again.



Note: The baby may have bilirubin above the maximum reading level.

Measure the bilirubin level by other methods, such as serum bilirubin.

7.11. TAKING ADDITIONAL MEASUREMENTS

Depending on the setup options that you have chosen for the device, you may be required to take more than one measurement for each bilirubin check. This can be changed via the setup screens.

For each additional measurement required, repeat the measurement as described starting in **Section**

7.9 Position the Handheld unit on the baby's ear.

7.12. VIEWING THE BILIRUBIN LEVEL

After completing the required number of measurements the bilirubin level will be displayed on the screen, as described above.

7.13. TURN OFF THE UNIT

When you finished taking the measurement, turn off the handheld unit and return it to the charging stand, then the screen will turn On for a second and then Off. If you don't return the handheld unit to the charging stand, you may press the On/Off button to turn off the device and to conserve the battery. If you do not turn off the device, after a short period it will automatically lower the brightness level, and after an additional period of time it will go into sleep mode



Note: Even though the device is in sleep mode, it isn't turned off and it still consumes the battery (although not as much as in normal operation mode). If will not return the device in the charging stand, after a period of time the battery will run out.

8. VIEWING PREVIOUS MEASUREMENTS

The BiliCare System stores previous measurement results automatically and can be used to review the measurement data. A maximum of 100 measurements may be stored in the memory. Once the memory is full, every new measurement with ID, replaces the oldest measurement.



Caution: When the memory is full, an error message “**ERROR 37**” appears upon activating the BiliCare (turning ON the device).

8.1. HISTORY SCREEN

The History Screen is activated by pressing **Show Results** on the **Home Screen**. It appears as follows:



Press  to see the next result

Press  to see the previous result

Press  to return to the Home Screen

8.1.1. MEASUREMENT UPLOAD STATUS

Next to the yellow title “History” there is an icon of an envelope. There are three different types of envelope icons which represent the computer upload status of a specific measurement.



Note: These envelope icons are only relevant in case your BiliCare stand is connected to a PC in order to upload the measurements from the BiliCare handheld device. If you do not use the BiliCare system this way then you may ignore the envelope icons.



This icon indicates that for the specific measurement, “Patient ID 1” is not blank and that the measurement could be uploaded to the PC but was not uploaded yet.



This icon indicates that the specific measurement was uploaded successfully to the PC.



This icon indicates that for the specific measurement, “Patient ID 1” is blank and that the measurement will not be uploaded to the PC.

9. UPLOADING MEASUREMENTS TO THE PC AND TO THE HOSPITAL INFORMATION SYSTEM

The BiliCare system comes with a feature that allows the user to upload the measurements from the device to a PC (Personal Computer) and from the PC to the HIS (Hospital Information System).

The software that can be installed on the PC has following functions:

BiliCare Viewer – This software allows the user to view all measurements of the BiliCare device in an organized manner. Measurements are organized per patient and displayed in chronological view. The BiliCare Viewer is a tool that lets the user keep track of the patient's BiliCare measurements in a convenient and effective way. Combined with trend views, bilirubin nomograms and more, the tool provides a comprehensive solution for neonatal jaundice management.

1. BiliCare HL7 Interface Program – The software is also responsible for two tasks:
 - a. Upload measurements from the BiliCare device to the PC.
 - b. Send the results to the hospital information system (this option may be disabled by the user).

9.1. REQUIREMENTS

1. The BiliCare handheld device must have software version 3.11.04 or higher. The version number is displayed on the last screen of the setup menu in the device.
2. The BiliCare stand must be of revision B or higher. Note the writing “Rev. B” either on a sticker under the stand or written on the label of the stand.
3. PC Pre-requirements:
 - a. CPU speed – Intel Pentium IV or better
 - b. Memory – Minimum free 35MB
 - c. Disk space – Minimum 100MB free space
 - d. Network card – Minimum one 100Mb/sec network card
 - e. USB port – Minimum 1 free USB port.
 - f. Operating System - Windows XP or higher.

9.2. SETUP AND INSTALLATION

In order to begin uploading measurements from the BiliCare device to the hospital information or the PC, make sure that all requirements are met as indicated in section **9.1. Requirements**.

Afterwards, follow the installation guide in the document “BiliCare HL7 Interface Installation Guide” in order to install the BiliCare HL7 Interface Program on the PC.

If you would like to use the BiliCare Viewer program on the PC too then follow the installation instructions in the document “BiliCare Viewer User Guide”.

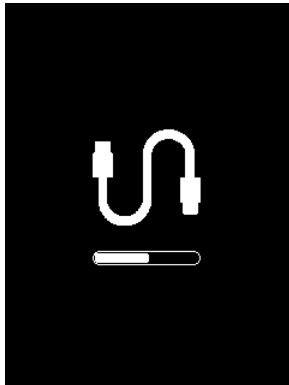
No modification or special setup is required on the BiliCare device.

Connect the BiliCare charging stand (Rev B) to the PC using the USB cable supplied with the system.

After performing measurements with the device place the device in the charging stand and continue to section **9.3. BiliCare PC Communication Screens**.

9.3. BILICARE PC COMMUNICATION SCREENS

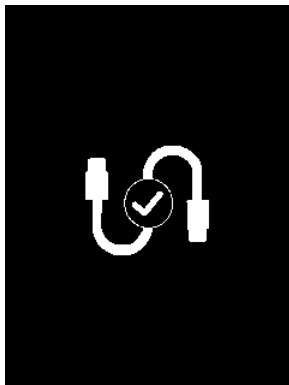
Assuming the correct steps depicted in section **9.2. Setup and Installation** were followed then once the BiliCare device is placed in the charging stand the following screen should appear:



This screen indicates that initial communication with the PC has been established and that the measurements are being sent to the PC.

Each measurement is unique and defined by Patient ID1, and the time and date of the measurement. Measurements cannot be duplicated on the PC. This is because once a measurement was sent to the PC, it is “marked” as sent on the BiliCare device (as can be seen in section **8.1.1. Measurement Upload Status**). So even if the device is placed in the stand again with the same measurements, the results would be reviewed by the PC and only those that weren’t marked as sent would be uploaded to the PC.

If all measurements were uploaded successfully to the PC (or if there were no new measurements in the BiliCare device to upload to the PC) then the following screen would appear on the BiliCare screen:



The screen would remain on for a few seconds and then turn off.

If not all measurements were uploaded successfully (for example the BiliCare device was taken off the stand before all measurements could be uploaded) then the following screen would appear on the BiliCare screen followed by three beeps:



The screen would remain on for a few seconds and then turn off.

10. SETUP

The BiliCare System allows you to customize the device actions using the Setup screens.

10.1. SETUP PASSWORD

The Setup options are password protected. This password assures that only authorized personnel may change the Setup options in BiliCare.

Every new entrance to the Setup function demands a password confirmation.

The following Screen is shown:

Setup password		
1	2	3
4	5	6
7	8	9
X	0	↵

Enter 7931 and press  or the  key.

If the password was correctly entered, the first Setup screen is displayed.

Setup password		

1	2	3
4	5	6
7	8	9
X	0	↵

If an erroneous password was entered, a red rectangle will blink twice and 3 short beeps will be heard.

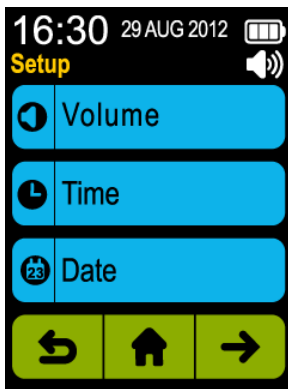
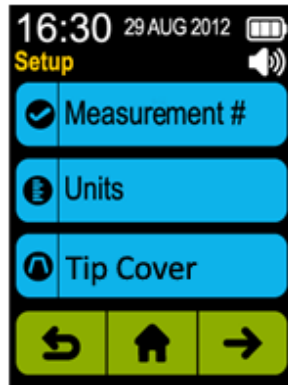
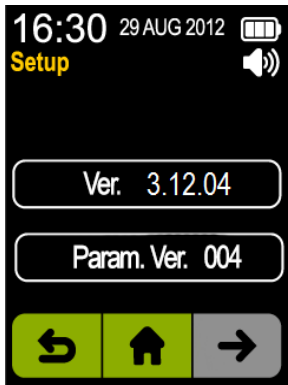
BiliCare is now ready for receiving another password.

10.2. SETUP SYSTEM OPTIONS

The Setup screens are activated by pressing **Setup** on the **Home Screen** and inserting the right password.

Press  and  to cycle through 17 setup options in seven screens.

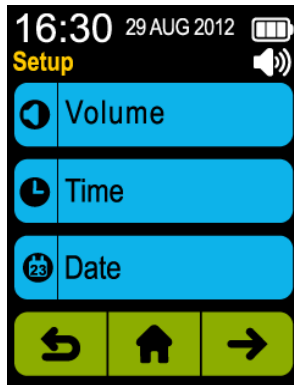
Each setup option is described in detail on the indicated page.

	See page		See page		See page
Volume 33		Brightness 36		Standby Elapse 40	
Time 34		ID Set 37		Sleep Elapse 41	
Date 35		Erase History 38		Calibration Period 42	
					
Measurement # 43		Defaults 46		Meas. password 50	
Units 44		Language 48			
Tip Cover 45		Technician Mode N/A*			
					
Ver. 3.12.04					
Param. Ver. 004					

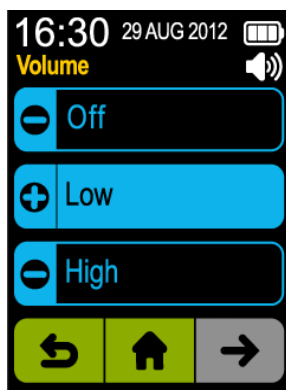


* Note: Technician Mode is reserved for use by the Gerium Medical service technician. Technician Mode is disabled in normal day-to-day operation.

10.3. SETUP: VOLUME



Press on **Volume** to show the Volume Setup screen.



Then press:

Off to turn off the audible tone. It is NOT recommended to work with the volume Off

Low to choose a low volume level

High to choose a high volume level.

When you have made your selection, press:

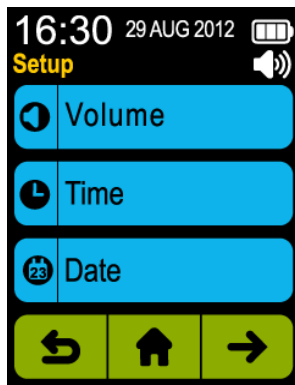


to return to the previous screen

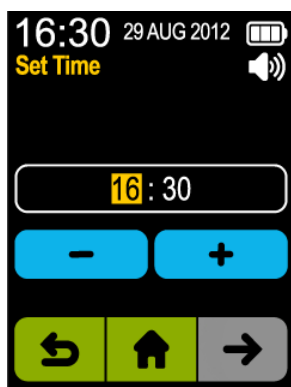


to go to the Home Screen.

10.4. SETUP: TIME



Press on **Time** to show the Time Setup screen.



Then press:

The **Hour** value (**16** in the example) to change the hour, or the **Minute** value (**30** in the example) to change the minute:



to choose a lower value



to choose a higher value.

When you have made your selection, press:

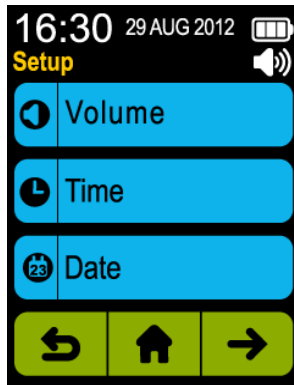


to return to the previous screen



to go to the Home Screen.

10.5. SETUP: DATE



Press on **Date** to show the Date Setup screen.



Then press:

The **Day** value (**28** in the example) to change the day, the **Month** value (**AUG** in the example) to change the month, or the **Year** value (**2011** in the example) to change the year

to choose a lower value



to choose a higher value



When you have made your selection, press:



to return to the previous screen



to go to the Home Screen.

10.6. SETUP: BRIGHTNESS



Press on **Brightness** to show the Brightness Setup screen.



Then press:



to choose a lower value



to choose a higher value

When you have made your selection, press:



to return to the previous screen

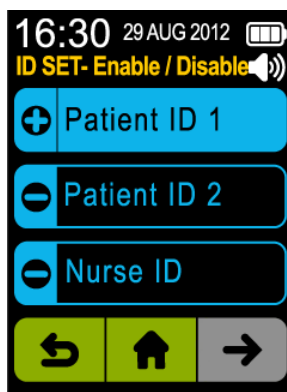


to go to the Home Screen.

10.7. SETUP: ID SET



Press on **ID Set** to show the ID Set Setup screen.



Then press on any ID field to enable it ( will appear) or to disable it ( will appear) Each ID can be separately enabled or disabled, as follows:

Patient ID 1 to require the first Patient ID to be entered before a measurement

Patient ID 2 to require the second Patient ID to be entered before a measurement

Nurse ID to require the Nurse ID to be entered before a measurement.

When you have made your selection, press:



to return to the previous screen



to go to the Home Screen.



Note: Each of the three ID options can be separately enabled or disabled.

For example, you may wish to require **one Patient ID** and a **Nurse ID** to be entered before a measurement. In this case, simply **enable** Patient ID 1 and Nurse ID, and **disable** Patient ID 2.

10.8. SETUP: ERASE HISTORY (1 OF 2)



Press on **Erase History** to clear all previous measurements from the device memory. A confirmation screen will then display.

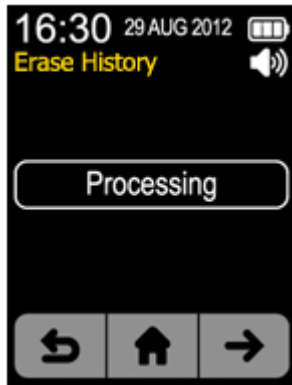


Then press:

Yes to confirm the Erase History request

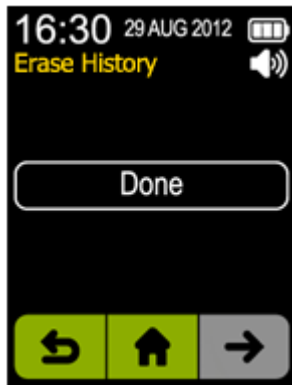
No to cancel the Erase History request.

10.9. SETUP: ERASE HISTORY (2 OF 2)



During Erase History the **Processing** screen will display for a few seconds. This indicates that the device is busy.

Wait until this screen automatically changes.



The **Erase History Done** screen now displays. This indicates that the Erase History operation has completed.

You may now press:



to return to the previous screen



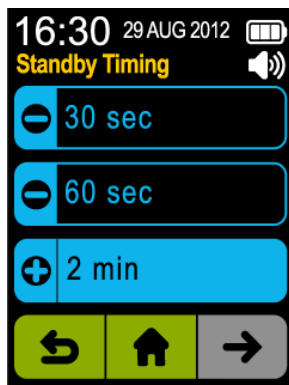
to go to the Home Screen.

10.10. SETUP: STANDBY ELAPSE



Press on **Standby Elapse** to show the Standby Elapse Setup screen.

After the **Standby Elapse** time, BiliCare shows the Main Screen at reduced brightness.



Then press:

30 sec to automatically enter Standby Mode after 30 seconds of idle use

60 sec to automatically enter Standby Mode after 60 seconds of idle use

2 min to automatically enter Standby Mode after two minutes of idle use.

When you have made your selection, press:



to return to the previous screen



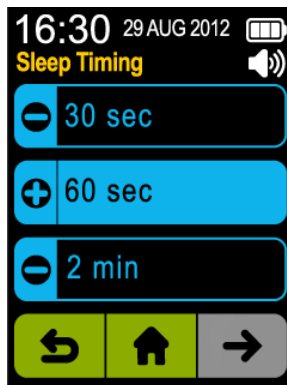
to go to the Home Screen.

10.11. SETUP: SLEEP ELAPSE



Press on **Sleep Elapse** to show the Sleep Elapse Setup screen.

After the **Sleep Elapse** time, BiliCare screen is off and goes to sleep mode.



Then press:

30 sec to automatically enter Sleep Mode after 30 seconds of idle use while within standby mode

60 sec to automatically enter Sleep Mode after 60 seconds of idle use while within standby mode

2 min to automatically enter Sleep Mode after two minutes of idle use while within standby mode.

When you have made your selection, press:



to return to the previous screen



to go to the Home Screen.

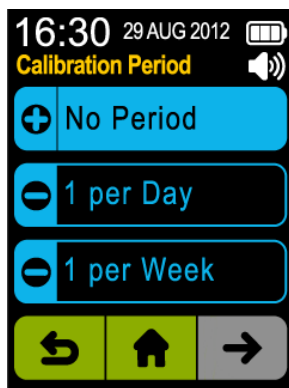


Note: It is important to distinguish between sleep mode and power off mode, when the device is in sleep mode the screen is off but there is still a consumption of battery. When power off the device by pressing the On/Off button, then the device goes into power off mode and then it conserves the battery and does not consume it.

10.12. SETUP: CALIBRATION PERIOD



Press on **Calibration Period** to show the Calibration Period Setup screen.



Then press:

No Period to never require an automatically scheduled Calibration Test

1 per Day to require a Calibration Test once each day

1 per Week to require a Calibration Test once each week.

When you have made your selection, press:



to return to the previous screen

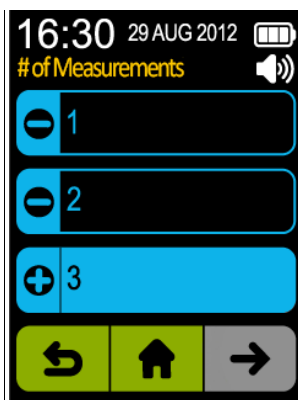


to go to the Home Screen.

10.13. SETUP: MEASUREMENT NUMBER



Press on **Measurement #** to show the Measurement Number Setup screen.



Then press:

1 to require one measurement for each bilirubin test

2 to require two measurements for each bilirubin test

3 to require three measurements for each bilirubin test.

When you have made your selection, press:



to return to the previous screen

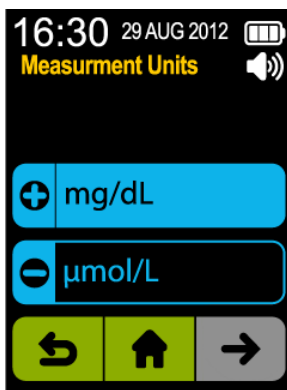


to go to the Home Screen.

10.14. SETUP: UNITS



Press on **Units** to show the Units Setup screen.



Then press:

mg/dL to set the measurement units to milligrams/deciliter

μmol/L to set the measurement units to micromoles/liter

When you have made your selection, press:



to return to the previous screen

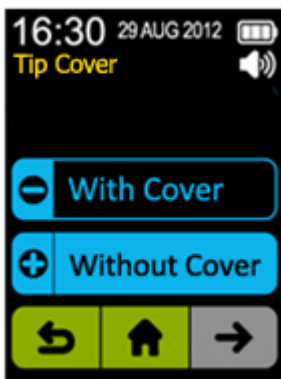


to go to the Home Screen.

10.15. SETUP: TIP COVER



Press on **Tip Cover** to show the Tip Cover Setup screen.



Then press:

With Cover to choose working with Tip Covers

Without Cover to choose working without Tip Covers.

When you have made your selection, press:



to return to the previous screen



to go to the Home Screen.

10.16. SETUP: DEFAULTS (1 OF 2)



Press on **Defaults** to reset Setup options to their system defaults.



Then press:

Yes to confirm the request

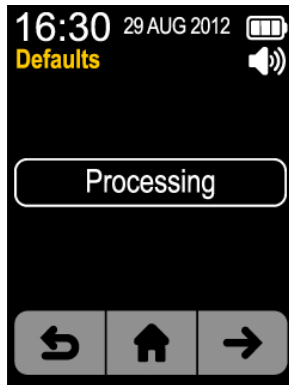
No to cancel the request.



Note: Not all setup options are reset to their sysetm defaults. The options that are not reset are the following:

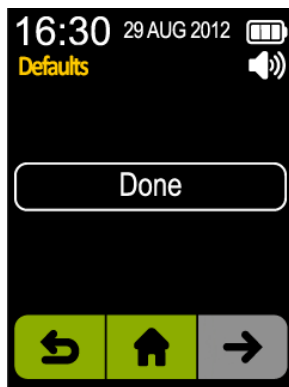
Language, Tip Cover, Time and Date.

10.17. SETUP: DEFAULTS (2 OF 2)



A **Processing** screen will display for a few seconds. This indicates that the device is busy.

Wait until this screen automatically changes.



The **Defaults Done** screen now displays. This indicates that all Setup values have been reset to their system defaults.

You may now press:



to return to the previous screen



to go to the Home Screen.

10.18. SETUP: LANGUAGE



Press on **Language** to show the Language Setup screen.



Then press:

English to choose English as the screen language.

Russian to choose Russian as the screen language.

French to choose French as the screen language.

Press  to see the next screen of optional languages



Then press:

Spanish to choose Spanish as the screen language.

German to choose German as the screen language.

Italian to choose Italian as the screen language.

Press  to see the next screen of optional languages



Then press:

Chinese or Japanese to choose Chinese or Japanese as the screen language.

Portuguese to choose Portuguese as the screen language.

Turkish to choose Turkish as the screen language.

Press  to see the next screen of optional languages



Then press:

Swedish to choose Swedish as the screen language.

When you have made your selection, press:



to return to the previous screen

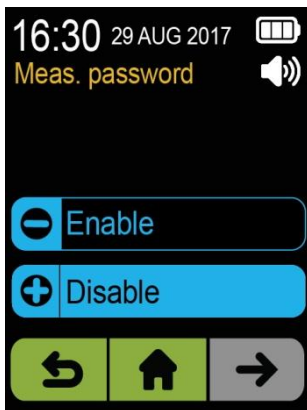


to go to the Home Screen.

10.19. SETUP: MEASUREMENT PASSWORD



Press on **Meas. password** to show the Measurement password Setup screen.



Then press:

Enable to choose working with Measurement password.

Disable to choose working without Measurement password.

When you have made your selection, press:



to return to the previous screen



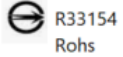
to go to the Home Screen.

11. SYMBOLS

EXPLANATION OF SYMBOLS

The following symbols may appear on the device or shipping materials.

Description	Symbol
Item Part number	
Item Serial number	
Item Lot number	
Date of manufacture	
CE mark of conformity	
Medical device	
Recycle for WEEE	
Refer to Instruction manual	
Consult instructions for use	
Type BF equipment, Class II m	
Caution	
DC Voltage	
Manufacturer name	
Storage temperature range	
Storage humidity range	
European representative	
Do not reuse	
Do not reuse if package is damaged	
Expiration date	
Package is recyclable	
Class II	

Comply with Federal Communications Commission Standard	
RoHS Compliance. Rohs stands for Restriction of Hazardous Substances	
Regulatory Compliance Mark (RCM)	
UR / RU is UL's mark	

12. SPECIFICATIONS



BiliCare™

Non-Invasive Transcutaneous Bilirubin Meter

Gestational Age	>24 weeks gestational age
Skin Tones	All Skin Tones
Post-Natal Age	0-20 days
Total Serum Bilirubin Range	0-20mg/dL 0-340 µmol/L
Correlation	r=0.90
Repeatability ¹³ (SD) ¹⁴	±0.7mg/dL ±12 µmol/L
Accuracy (RMSE) ¹²	+/- 1.5 mg/dL at 66% of the time or 1 standard deviation +/- 26 µmol/L at 66% of the time or 1 standard deviation

HAND HELD UNIT

Dimensions	57mm W x 150mm L x 23mm H (Total height: 54mm)
Weight (including battery pack)	160g (5.64oz)
Barcode Reader	Yes

BATTERY PACK

Type	Lithium ion
Voltage	3.7V
Capacity	1050 mAh
Measurements per Full Charge	250 (minimum)
Expected Battery Life	1 year (minimum)
Recharge time (maximum)	4 hours

CHARGING CRADLE

Dimensions	80mm W x 80mm L x 67mm H
Weight	100g

LIGHT SOURCE

Type	Green and Blue LEDs
Life	>200,000 measurements

POWER SUPPLY

Input	100-240VAC, 50/60 Hz, 150mA
Output	5V, 1100mA

CONNECTIVITY

Connectivity to PC ¹⁵	USB connection
Connectivity to HIS ¹⁶	HL7 protocol via PC ¹⁷

ENVIRONMENTAL INFORMATION

Operating temperature	0°C to 40°C (32°F to 104°F)
Relative humidity	30% to 85% non-condensing
Atmospheric pressure	0.78 to 1.05 atm
Storage temperature	-10°C to +65°C (14°F to +149°F)

¹² RMSE – Root Mean Square Error

¹³ Device to device repeatability

¹⁴ SD – Standard Deviation

¹⁵ A PC software program is required (supplied by your distributor)

¹⁶ HIS – Hospital Information System

¹⁷ A PC software program is required (supplied by your distributor)

Based on BiliCare Specification Sheet DGB-G81-001 Rev. C March 2023

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13. CLEANING AND MAINTENANCE

13.1. NOTES ON CLEANING AND MAINTENANCE

The BiliCare System requires maintenance and cleaning, as suggested in this User Guide. Any other service should only be provided by Gerium Medical Ltd. authorized representative or by your local distributor. Failure to do so voids the warranty.

Maintenance

The BiliCare device utilizes transmittance technology with an LED light source. The LED light source provides stable and consistent performance over the lifetime of the device. When the device is used in accordance with the manufacturer's instructions, periodic calibration is not required.

Recommended routine maintenance of the BiliCare device shall be performed once a year by the end user and includes the following activities:

- Cleaning and disinfection in accordance with the instructions provided in this User Manual
- Visual inspection of the device for signs of damage or wear
- Calibration verification (calibration check), as specified in this User Manual

If damage is identified during visual inspection, or in the event of abnormal occurrences (e.g. device drop, exposure to fluids, or other conditions that may affect device performance or safety), the device shall be removed from use and tested by a certified technician prior to being returned to service.

13.2. GENERAL CLEANING PROCEDURES

Please observe the following cautions when cleaning the device:



Caution: Use cleaning solution sparingly. Excessive solution can cause damage to internal components.



Caution: Contact with solvents can cause severe deterioration of plastic parts and malfunctioning of the instrument and accessories.

13.2.1. CLEANING THE DEVICE

The device should be cleaned between patients.

The recommendation for the routine cleaning procedure should be as follows:

Four thick Q-tips soaked in 70% Ethanol solution should be used to remove any residual of debris from the eyepiece area, while making maximum use of all the Q-tips wigs, with special focus on the edges of the device.

In addition, four Isopropyl Alcohol 70% pharma wipes should be used for wiping the eyepiece area. The contact time of the alcohol should be at least 10 minutes.

The plastic outer surface of the device may be cleaned with a soft, lint-free cloth dampened in a mild soap and water solution, ethyl alcohol (70-85%) or isopropyl alcohol (IPA).

13.3. EQUIPMENT END OF LIFE

CAUTION! Disposal of old equipment (BiliCare device and its detachable components and accessories) that is out of service, must take into account.

The environmental requirement according to the regulations of the user country.

Take special care when disposing of batteries.

The BiliCare device has a service lifetime of 7 years when used and maintained in accordance with the manufacturer's instructions.

The device does not have an expiration date when stored under the recommended storage conditions. Under proper storage, the device is expected to maintain its integrity and functionality until placed into service.

14. TROUBLESHOOTING

14.1. POSSIBLE CAUSES FOR MALFUNCTIONS

The following table lists some typical conditions that may occur with the BiliCare System.

If any problem arises, please contact the product distributor for service.

Condition	Possible Cause	Recommended Action
Barcode reader gives incorrect ID scan	Dust or dirt on barcode reader	Clean the device (see page 57)
Device not working	Incorrectly connected power supply to Charging Stand Insufficient charge to Handheld Unit Battery for Handheld Unit needs replacement	Check that the Charging Stand is connected correctly to the AC power. Charge the Handheld Unit by placing it into the Charging Stand. Return the unit to your local distributor for battery replacement
Onscreen keyboard not responding properly to finger pressure	LCD is dirty User isn't pressing the screen properly	Clean LCD surface. Be sure to press the screen firmly and distinctively with limited finger surface in contact with the screen (e.g. using just the tip of the finger) If problem persists, contact the product distributor for service.

14.2. POSSIBLE CAUSES FOR MEASUREMENT FAILURE

If the following screen appears (could be also be 2/3, 3/3, 1/1, 1/2, 2/2), a measurement failure has occurred. The type of error would be indicated in yellow letters where the word "Measurements" is written in the following picture.

Type of error:

1. **"Tissue too Thin"** - The thickness of the tissue at the measurement point is too thin.
2. **"Tissue too Thick"** - The thickness of the tissue at the measurement point is too thick.
3. **"TcB value too high"** - The level of bilirubin measured is too high, above the BiliCare range specified in section 12. **Specifications**.
4. **"Abnormal TcB reading"** - The level of bilirubin measured is extremely out of range indicating an abnormal TcB measurement.
5. **"Big Difference"** – Only relevant when two or more measurement were defined to be done per patient. The difference between the results of the different measurements is too big.
6. **"Measurements"** –
 - a. The intensity of the light measured is too high as if a measurement was performed without the device being put on the baby's ear.



- b. The intensity of the light measured is too low as if something is blocking the light from being emitted from the sensor.

Possible Solutions:

- Be sure that the clip has been placed correctly on the ear of the baby.
- Make sure the baby isn't moving too much during the measurement.
- Make sure the sensor is clean in both the lower and upper part of the clip.
- In case of the level of bilirubin being too high ("TcB value too high"), it could indeed be that the level of bilirubin is very high. In such case, proceed to utilize other methods to measure the bilirubin level.
- Repeat measurement several more times. If the same error screen appears, perform the Check Calibration self test and contact the product distributor for service.

14.3. MEMORY FULL ERROR

The BiliCare System stores previous measurement results. A maximum of 100 measurements may be stored in the memory. Once the memory is full, every new measurement with ID, replaces the oldest measurement.

When the memory is full, an error message “**Memory Full**” appears upon activating the BiliCare (turning ON the device).

15. REPAIR POLICY

When under warranty, repair and service must be performed through your local distributor. When the BiliCare System warranty is not applicable, repairs may be made also through your local distributor.



Warning: Do not remove the covers of the device components. Only perform maintenance procedures specifically described in this User Guide.

15.1. OBTAINING SERVICE

15.1.1. SERVICE QUESTIONS

For technical support or service, please, contact your local Distributor.

Gerium Medical Customer Service:

Email: info@mmi.co.il

Telephone: +972-8932-3333

Fax: +972-8932-8510

Website: www.mennenmedical.com or <http://mennenmedical.com/bilicare/>

15.1.2. SHIPPING ENCLOSURES

Please enclose the following items when shipping the device for service:

- Warranty information: device serial number, a copy of the invoice, or other applicable documentation
- *Ship to* and *bill to* information
- Purchase order number
- Name and phone number of the person to contact for questions
- A brief description of the problem encountered, or the repairs felt necessary.

16. WARRANTY

Service Support

Repairs of the BiliCare System under warranty must be made by authorized repair centers. If the device needs repair, contact the product distributor.

If you need to ship the device, pack the device and its accessories carefully to prevent shipping damage.

17. EMC GUIDANCE AND MANUFACTURER DECLARATION

Electromagnetic emissions

- The BiliCare System is intended for use in the electromagnetic environment specified below.
- The Customer or the user of the BiliCare System should assure that it is used in such an environment

Emissions test	Compliance	Guidance
RF emissions CISPR 11	Group 1 Class B	The BiliCare System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	The BiliCare System is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's declaration – Electromagnetic immunity

- The BiliCare System is intended for use in the electromagnetic environment specified below.
- The Customer or the user of the BiliCare System should assure that it is used in such an environment

Immunity test	IEC 60601 test level	Compliance level	Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8, 15 kV air	±8 kV contact ±2, 4, 8, 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power-supply input lines IEC 61000-4-11	0% UT; 0.5cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	0% UT; 0.5cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BiliCare System requires continued operation during a power mains interruption, it is recommended that the BiliCare System be powered from an interruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer's declaration – Electromagnetic immunity

- The BiliCare System is intended for use in the electromagnetic environment specified below.
- The Customer or the user of the BiliCare System should assure that it is used in such an environment

Immunity test	IEC 60601 test level	Compliance level	Guidance
Conducted RF IEC 61000-4-6	3V, 6V	3V, 6V	Portable and mobile RF communications equipment should be used no closer to any part of the BiliCare System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3 ⁻	10V/m 10V/m from 0.15 to 80MHz; 10V/m from 0.15 to 80MHz and 80% AM at 1kHz 10V/m from 80MHz to 2.7GHz	10V/m 10V/m from 0.15 to 80MHz; 10V/m from 0.15 to 80MHz and 80% AM at 1kHz 10V/m from 80MHz to 2.7GHz	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed EF transmitters, an electromagnetic site survey should be considered. If the measured field strength in location in which the BiliCare System is used exceeds the applicable RF compliance level above. The BiliCare System should be observed to verify normal operation. If abnormal performance is observed' additional measures may be necessary, such as reorienting or relocating the BiliCare System.
- Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m

Recommended separation distances between portable and mobile RF communication equipment and the BiliCare System

The BiliCare System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of BiliCare can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and BiliCare System as recommended below, according to the maximum output power of the communication equipment.

Recommended separation distances between portable and mobile RF communication equipment and BiliCare System are given in table B-1

Table B-1: Separation Distances in meters

Recommended separation distances between portable and mobile RF communications equipment and the BiliCare System				
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM bands $d = [\frac{3,5}{V_1}] \sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = [\frac{12}{V_2}] \sqrt{P}$	80 MHz to 800 MHz $d = [\frac{12}{E_1}] \sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{23}{E_1}] \sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

For transmitters rated at maximum output power not listed in the table, the recommended separation distance **d** in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where **P** is the maximum output power rating in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance level (V/m)
385	380 – 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1.8	0.3	27	27
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9	9
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28	28
1720 1845 1970	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0.3	28	28
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28	28
5240 5500 5785	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9	9

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

^{a)} For some services, only the uplink frequencies are included.

^{b)} The carrier shall be modulated using a 50 % duty cycle square wave signal.

^{c)} As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

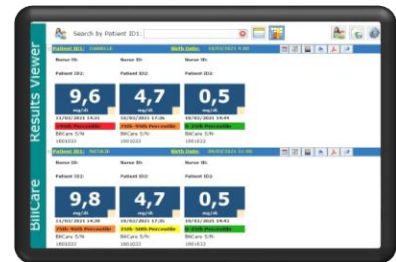
Any **BiliCare™** comes with a FREE Viewer software

Download it here:



Upon connecting via USB you can see all readings for all babies

You can switch to “Large Numbers” display instead of a table...



All data can be transmitted via HL7 to the Hospital Information System

You can view each baby's trend on top of the Nomogram, Export to Excel or a PDF report can be generated for each baby

BiliCare™
Neonatal Noninvasive Bilirubin Meter

