

The Wallaby[®] 3 Phototherapy System Parents' Manual

Order Number PGM302



Warning

This guide is not meant as a substitute for the services of a physician or other healthcare professional. The Wallaby® 3 Phototherapy System was developed to provide effective, state of the art phototherapy as a safe, comfortable treatment method of jaundice in newborn babies.

Warranty

Respironics Georgia warrants your Wallaby® Phototherapy System against defects in material and workmanship of the Illuminator unit only for a period of one (1) year from the date of purchase, one hundred eighty (180) days on the fiberoptic panels, EG-2000 and EG-2000N. This warranty does not cover the lamp, or any damage to the illuminating unit or the fiberoptic panel caused by accident, misuse, tampering, or negligence such as failure to follow the instructions provided in this guide. In the event your phototherapy illumination unit fails to give satisfactory performance within the warranty period and conditions, Respironics Georgia will repair or replace your illuminating unit at no charge for parts or labor. The foregoing warranties are in lieu of all other warranties expressed or implied, including without limitation any implied warranty of merchantability or fitness for a particular purpose.

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Product Responsibility

This Product will perform in conformity with the description thereof contained in this manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This Product must be checked periodically. A defective Product should not be used. Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately. Failure to use Respiroics replacement parts, including lamps, renders any written or implied warranty on the unit null and void. Should repair or replacement become necessary, Respiroics recommends that a telephone or written request for service advice be made to the nearest Respiroics Service Center. This Product or any of its parts should not be repaired other than in accordance with written instructions provided by Respiroics and by Respiroics trained personnel. The Product must not be altered without the prior written approval of Respiroics, Inc. Quality Assurance Department. The user of this Product shall have the sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than Respiroics.

Wallaby[®] is a registered trademark of Respiroics, Inc.

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Overview

Congratulations on the birth of your new child. A new child is always special, but your child has an extra need. Your doctor has prescribed phototherapy for the treatment of your child's jaundice. The purpose of this manual is to instruct you on the proper method of equipment use and child care during phototherapy.

What is Jaundice

Jaundice is a temporary condition. It is an excess of bilirubin that has accumulated in the fatty tissues of the skin, giving it a yellow color.

What is Bilirubin

Bilirubin is nothing more than a naturally occurring molecule of the red blood cells in our bodies. It is released into the bloodstream when red blood cells break down. This breaking down of red blood cells occurs all the time as a normal part of the constant renewing of our bodies. The level of bilirubin in our bodies is of no concern since our livers break down the bilirubin so it is excreted.

In newborns, it is a little different. Infants are born with extra red blood cells that provide the oxygen that is needed while the infant grows in the mother's uterus. Once the baby is born, the excess red blood cells are broken down and bilirubin begins to build up. Newborns have premature livers, which can not effectively process the extra bilirubin so it builds

Overview

up in the fatty tissues giving the skin its yellowish color. In all newborns, it is normal for bilirubin to rise during the first 3 or 4 days of life, peak, and slowly decline.

In a few babies, your is one of them, the bilirubin rises beyond what is considered an acceptable level, so your physician is practicing some “preventative medicine” by ordering phototherapy treatment. Left untreated, high bilirubin levels can be toxic and possibly cause brain damage. After treatment has begun, the baby’s bilirubin level should be measured to make sure that the therapy is effective.

With the phototherapy treatment your physician has ordered, your baby’s bilirubin level should drop to an acceptable level in a few days.

What is Phototherapy?

Phototherapy simply means “treatment with light.” In phototherapy the special light used causes the bilirubin to break down into a form that can be excreted by the baby. This takes some of the burden off the liver and allows the baby to excrete larger amounts. It is a proven treatment that has been in use for over 25 years.

Until recently phototherapy was only done in the hospital. Today, however, with the development of portable lights and now especially with the WALLABY Phototherapy System, babies can be kept at home where they belong while treatment takes place.

What is the Wallaby 3 Phototherapy System?

The Wallaby 3 Home Phototherapy System is a state of the art system developed to provide safe and effective home phototherapy through the use of high-tech fiberoptics.

The Wallaby System consists of

- ❑ an illuminator box which is the source of the therapeutic light,
- ❑ a fiberoptic panel which delivers the therapeutic light to your baby,
- ❑ and panel covers, which provide a comfortable surface for the baby, protect the panel, and allow the panel to be wrapped securely to your baby.

Overview

The illuminator unit sends light out the fiberoptic cable to the entire area of the panel. The panel is inserted into a protective cover. This wrap is soft and comfortable and allows the therapeutic light to be sent to the baby. The baby can be held and fed while treatment is administered.

Intended Use:

The Wallaby 3 is intended to treat hyperbilirubinemia through phototherapy in the home or hospital.

Warnings and Cautions

Warnings

A *warning* indicates a potentially harmful situation.

Federal law (USA) restricts this device to sale by, or on the order of, a licensed physician. This instrument should be used only under the supervision of a physician.

1. Use the Wallaby only for its intended use as described in this manual.
2. Eye patches are only necessary if the panel will be illuminated while not attached to the patient. Normal use of the Wallaby Illuminator with the panel in a disposable or reusable cover does not require the use of eye patches.
3. Do not leave the Wallaby unit on when the fiberoptic panel is not around the baby.
4. Always turn off and unplug the Wallaby unit when cleaning, changing the lamp, or servicing the unit.
5. Do not use the Wallaby unit in the presence of flammable substances such as anesthetics or cleaning agents.

Warnings and Cautions

6. Do not use the Wallaby unit where oxygen is administered.
7. Do not use while bathing the baby.
8. Do not place or store the Wallaby unit where it can fall or be pulled into a tub or sink.
9. If the Wallaby unit falls into water or if fluid is spilled on the device do not reach for it without first unplugging the cord. Discontinue use of the device and contact your home care provider,
10. Always connect the Wallaby unit to a properly grounded outlet.
11. Never operate the Wallaby if it has a damaged cord or plug. Do not insert anything into the end of the plug.
12. Do not use an extension cord.
13. Do not walk around with the baby wrapped in the fiberoptic panel.
14. Carefully place the panel cord to avoid entanglement.
15. Always place the illuminator on a hard flat surface.
16. Do not place the Illuminator unit in an isolette or infant warmer. Do not place a temperature sensor for these devices under the panel.






17. Do not operate the Wallaby unit on its side.
18. Never block the air vents of the unit or place it on a soft surface such as a bed, crib, carpeted floor, or couch where the air vents may be blocked.
19. Never put fingers or objects into the openings of the Wallaby unit.
20. The inside of the Wallaby unit becomes very hot during use. Wait 10 minutes before changing light bulbs.
21. The Wallaby device utilizes high voltage, refer servicing to qualified service personnel.
22. The reusable panel covers are for use in home care phototherapy only.

Cautions

A *caution* indicates a condition that may lead to equipment damage, malfunction, or inaccurate operation.

1. Keep the unit away from any heated surface.
2. Do not scratch, damage, or soil the light input end of the panel. Also, do not place sharp or heavy items on the panel. This can damage the panel and affect its light output.
3. Do not dry the fiberoptic panel with artificial heat.
4. Allow the unit to cool for 10 minutes before moving.

Symbols

	Attention: Read accompanying documents
	High Temperature
	High Voltage
	Type BF applied part
	Alternating Current
REF	Part Number
SN	Serial Number
I	On (power:connection to the mains)
O	Off (power: connection to the mains)

Electromagnetic Compatibility

The Wallaby 3 Phototherapy System complies with Electromagnetic Compatibility Standards for Medical Devices. If you suspect that the Wallaby 3 is interfering with the operation of other appliances or if they are interfering with the Wallaby 3:

- ❑ Move the Wallaby 3 away from the appliance
- ❑ Connect the Wallaby 3 and the appliance to different AC outlets so that they are operating off of different circuit breakers

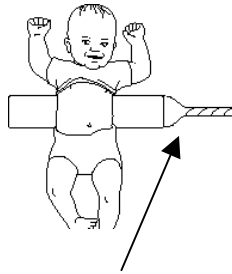
Classification

The Wallaby 3 Phototherapy System is classified as:

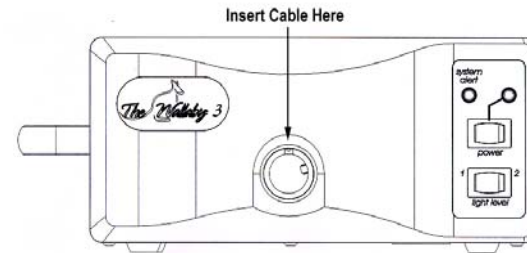
- ❑ IEC Class I Equipment
 - ❑ Type BF Applied Part
 - ❑ Ordinary protection against the ingress of liquids
 - ❑ Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
- Continuous operation

Getting Familiar with the Wallaby System

Here are the components of the Wallaby system.



Fiberoptic Panel with Cable.
The light from the illuminator is transmitted to the panel via the cable and therapy provided to your baby. It comes in a wrap-around or neonatal style.

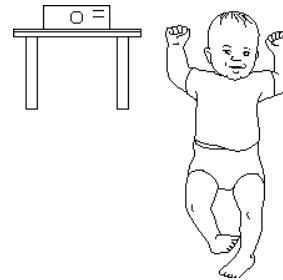


Illuminator Box (Light Source)
This provides the therapeutic light for your baby.

Setting Up Your Baby

Setting Up the Wallaby System

1. Place the illuminator unit on a hard, flat surface, away from any heat source. It should be no more than four feet from your baby.



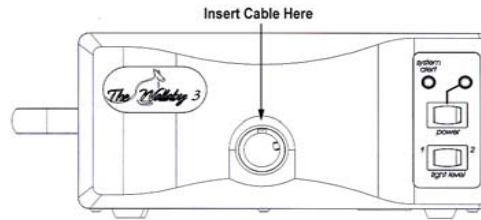
Do not block any of the air vents on the sides of the illuminator unit.



Do not place the illuminator unit on its side.

Setting up Your Baby

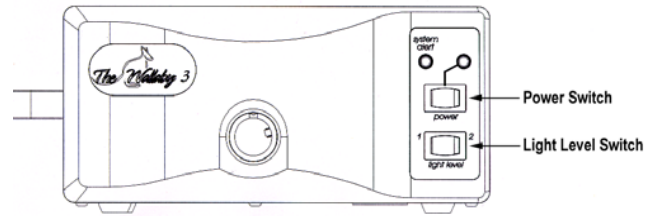
2. Insert the metal end of the cable, with the metal post facing up, into the opening. Twist the panel $\frac{1}{4}$ turn to lock into place. The light will not come on if the panel is not inserted into the Illuminator.



3. Plug the illuminator unit into an electrical outlet.

4. Place the panel on the baby. (See the section on Setting Up Your Baby Using the Wrap-Around Panel or Neonatal Panel.)

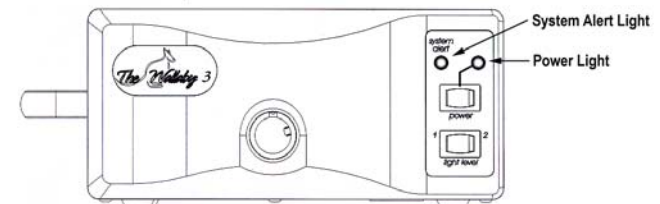
5. Be sure the Light Level on the illuminator unit is at the setting recommended by the physician. Then, turn the illuminator unit **ON**.



6. After the power is turned on, the green power light will illuminate. The System Alert light will indicate the

System Alert light will indicate the bulb status.

- ❑ If one bulb is burned out, the yellow light will flash. There is nothing you need to do. This is just an alert for your home care company.
- ❑ If both bulbs have burned out or if the unit overheats, the yellow light is solid. The panel around the baby will not light.
 1. The system may have over heated. Simply turn OFF the system for 5 minutes and then turn back on.
 2. Both light bulbs may be burned out. Call your home care company.

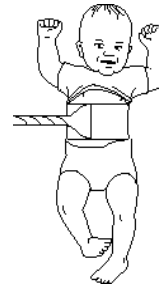
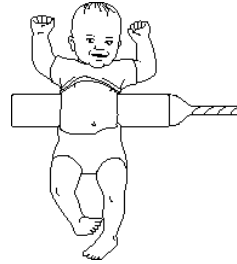


Setting Up Your Baby Using the Wrap-Around Panel

This section explains how to prepare a baby for a phototherapy treatment using the wrap-around fiberoptic light panel.

This panel provides full coverage. It is most commonly used on patients at home.

- 1.** Insert the panel into a disposable or single-patient use cover with the light facing the sheer side of the cover.
- 2.** Put a T-shirt on the baby and roll it up from the bottom until it fits comfortably under the baby's arms.
- 3.** Place the covered panel under the baby's torso, positioning it so it is under the baby's armpits.
- 4.** Wrap the panel around the baby as shown in the illustration. Use the tape or Velcro tabs to secure the panel around the baby.



- 5.** If the cover becomes soiled, discard it (disposable) or replace it with a clean one and wash the soiled cover (cloth).



IMPORTANT! Keep panel away from sharp objects that could scratch or puncture the cover.



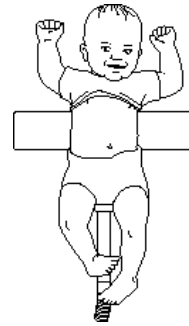
- For a larger or more active baby, you may want to tape the panel to the baby's diaper.
- To be sure the panel is not wrapped too tightly, insert your finger between the panel and the baby's body. Your finger should fit easily.
- You may wrap your baby in a blanket or put the baby in a sleeper.

Setting Up Your Baby Using the Neonatal Panel

This section explains how to prepare a baby for a phototherapy treatment using the flat neonatal fiberoptic light panel.

This panel is ideal for preemie or underweight infants; it may also be used on full term infants.

- 1.** The protective cover for the neonatal panel is a T-vest. Insert the panel in the vertical section of the T with the light facing the sheer side of the cover.
- 2.** Lay the covered panel on a flat surface. Be sure the light emitting side is facing up.
- 3.** Position the baby's chest or back directly on the panel. The cable connected to the panel should be between the baby's legs.
- 4.** Secure the T-vest to the baby by first wrapping the side without the tape around the baby's midsection. Then, wrap the side with the tape tab over the infant, peel off the protective cover on the tab, and secure it. Be sure the vest is snug.



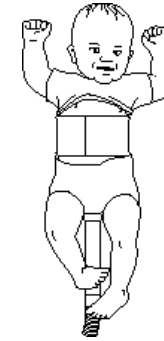
5. If the T-vest becomes soiled, discard it and replace it with a new one.



IMPORTANT! Keep panel away from sharp objects that could scratch or puncture the cover.



- If your baby is large or very active, you may want to tape the panel to the baby's diaper.
- Make sure the panel is not wrapped too tightly, insert your finger between the panel and the baby's body. Your finger should fit easily.
- You may wrap your baby in a blanket or put the baby in a sleeper.



Treating Your Baby

After you set up your baby, follow these steps to administer Phototherapy.

1. Be sure your baby is comfortable and the light panel is properly attached.
2. Be sure the Light Level selector is as your home care provider has instructed you.
3. Turn **ON** the illuminator unit.
4. Administer phototherapy at the frequency (for example, daily) and duration set by your physician.



Be sure to turn OFF the Wallaby system after each use or any time that the panel is not around your baby. At all times, your physician should carefully regulate phototherapy treatment.

Keep records of your baby's treatment as instructed by your physician. You may be asked to

track some or all of the following information:

Duration of treatment You will record the actual time that the light is used on the baby. All you need to do is record the number from the Hours Meter on the back of the Wallaby illuminator unit when you turn the light **ON** and again when you turn the light **OFF**. The meter records in hours and hundredths of hours.

Baby's Temperature Your physician will advise you of the best method of taking your baby's temperature and inform you of an acceptable range. It is important that you use the same method each time so your records will be consistent.

Wet Diapers Record the number of wet diapers. This will help determine if your baby is getting enough fluids during treatment.



Determining when your baby has urinated can be a problem if you use super absorbent disposable diapers. These diapers contain a chemical that changes urine into a gel that is difficult to see or feel. If you use this type of diaper, put a handkerchief or paper towel between the baby and the diaper.

Bowel Movements Normally, during phototherapy your baby will have more bowel movements than usual and the stools will be watery and dark

movements than usual and the stools will be watery and dark brown or dark green in color.

Feedings

A newborn baby usually requires feeding every three to four hours. Your physician will explain proper feeding requirements and schedules during treatment. Follow the feeding schedule prescribed and note the number of feedings, times and amounts.

Blood Tests


While your baby receives phototherapy daily blood tests will be required to monitor the progress of the treatment. Your healthcare professional will obtain the blood sample in your home or your physician will have you bring the baby to the office.

Common Questions and Answers

How long will my baby need to use the Wallaby System?	Each baby's phototherapy treatment time varies. Normal phototherapy treatment time is 2 to 4 days. Your physician will prescribe the amount of time your baby will be on the Wallaby each day. Daily blood tests will determine when your physician will discontinue treatment.
Can I hold and feed my baby while using the Wallaby System?	Yes, you can hold and breast-feed or bottle feed your baby without interrupting the phototherapy treatment. You can continue all normal routines except bathing while your baby receives treatment.
Can the Wallaby System be used while my baby sleeps?	Phototherapy can continue during all the baby's normal routines, including sleeping. The protective panel covers helps the light panel to stay in place while the baby is sleeping.
Will the lights emitting from the fiberoptic panel heat my baby?	No, fiberoptic light is a cool light; therefore no heat will come in contact with your baby.

Common Questions and Answers

Can any electricity come in contact with my baby?	No, only light can be transmitted through the cable to the fiberoptic panel. No electricity or heat comes in contact with your baby.
How do I clean the Illuminator?	Use a wet soft sponge or cloth. Wipe down the fiberoptic panel and illuminator. Allow the equipment to air dry. DO NOT DRY WITH ANY MEANS OF ARTIFICIAL HEAT.
Why is my baby's skin a different color in the area that the panel has been covering?	The babies skin is in direct contact with the therapeutic light. The bilirubin in the skin tissue (which causes the yellow color) is broken down in that area first. Since the majority of bilirubin is in the blood, as the blood circulates to the lighted area, the rest of the bilirubin will be removed. As the bilirubin level starts to approach a normal level, all the baby's skin will return to a normal color.

<p>Should I protect my baby's eyes from the light?</p>	<p>Unless you are using conventional overhead light in conjunction with the Wallaby System, eye protection should not be necessary when the fiberoptic panel is in a panel cove and is placed around your baby.</p>  <p>Since any bright light can affect the baby's eyes, always turn the unit OFF prior to removing the fiberoptic panel.</p>
<p>At what position should the light intensity switch on the unit be set?</p>	<p>Your physician will determine the light intensity to use for your baby's treatment. The intensity setting will be set when you first get the unit and should not be changed without orders from your physician.</p>
<p>How often should I change the light panel covers?</p>	<p>The cover should be changed any time it becomes soiled or wet.</p>
<p>How do I clean the fiberoptic panel if it becomes soiled?</p>	<p>Disconnect the power cord from the illuminator unit and wipe down the panel with mild detergent such as a dishwashing liquid. Do not immerse the panel in liquid. Do not use abrasive cleaners.</p>

Basic Troubleshooting

Following is a list of problems that may occur while using the Wallaby 3 System. For additional information, please contact your home-care company.

Problem	Reason/Action
Power Light is not green	<ul style="list-style-type: none"><li data-bbox="892 565 1409 651">❑ Check to make sure power cord is properly attached and plugged into an active electrical outlet.<li data-bbox="892 675 1409 703">❑ Ensure the unit is turned on.
System Alert LED is blinking yellow	<ul style="list-style-type: none"><li data-bbox="892 730 1409 846">❑ This is just an alert to your home-care company that one light has burned out. Your baby is still receiving the proper therapy from the remaining light bulb.
System Alert LED is solid yellow	<ul style="list-style-type: none"><li data-bbox="892 868 1409 1013">❑ Unit may have overheated or both light bulbs have burned out. Allow unit to cool, if condition persists contact your home care company for light bulb replacement.

Problem	Reason/Action
Light is not being emitted from fiberoptic panel	<input type="checkbox"/> Check to make sure panel is securely locked into illuminator box. <input type="checkbox"/> Check System Alert LED. If solid yellow, call your home-care company.
Light is emitted from the Illuminator unit when the fiberoptic panel is not inserted	<input type="checkbox"/> Contact your home care company.

Appendix

Informed Consent Form

I understand that my baby _____ has been diagnosed to have newborn jaundice and that my physician has prescribed home phototherapy treatment using the Wallaby Phototherapy System.

- ◆ I have been fully instructed on the use of the Wallaby Phototherapy System to my satisfaction and will use the system for my baby's phototherapy treatment.
- ◆ I have received and will read and follow the instructions provided in the Wallaby Parent's Guide to Home Phototherapy.

I understand the responsibility of:

1. Having daily visits by healthcare professionals.
2. Having daily blood tests for bilirubin levels.
3. Carefully monitoring my baby.

4. Recording on the sheets provided if required by my physician, my baby's:
- Treatment time
 - Temperature
 - Number of wet diapers
 - Bowel movements
 - Feeding schedule and amounts

I understand that the WALLABY Phototherapy System is rented and I agree to:

1. Contact my home care provider immediately if the unit does not function properly
2. Maintain the unit and return it in the condition it was received
3. Return the unit promptly after treatment is discontinued

PARENT OR GUARDIAN'S SIGNATURE

PARENT OR GUARDIAN'S SIGNATURE

DATE

Parents' Record Sheets

Please fill out the Parents' Record Sheets as requested and according to the plan of treatment set up by your physician. These sheets will ultimately go into your baby's records in the physician's office. Each sheet represents a 24-hour period starting at 8:00 a.m.

Column 1 Lists the hours of the day. Circle the hour if phototherapy is stopped for any reason.

Column 2 In this column list the baby's temperature next to the hour in which it was taken according to your physician's instructions.

Column 3 In this column, if the baby is being bottle fed, list the amount of formula the baby has taken next to the hour he/she was fed. If the baby is being breast fed, note the amount of time the baby nursed, and the effectiveness of the suck.

Column 4 In this column mark each diaper change with an X next to the time it took place.

Column 5 In this column note the number, color (black, brown, greenish-brown, green, yellow), and the amount of the bowel movements (small, medium, large).

Column 6 In this column list any pertinent comments you feel will be helpful to your physician in assessing your baby's treatment.

PARENT'S RECORD SHEET
Day 1

PATIENT'S NAME

TODAY'S DATE _____ DAY OF PHOTOTHERAPY _____

BILIRUBIN LEVEL _____ DATE AND TIME DRAWN _____

HOURLY METER READING _____ FORM OF TEMP TAKING _____

IRRADIANCE LEVEL SELECTOR SWITCH SETTING _____ HIGH _____ LOW _____

TIME-Circle Hour if lights are turned off	TEMPERATURE	BREAST OR BOTTLE AMOUNT	NUMBER OF WET DIAPERS	NUMBER OF STOOLS AND COLOR	COMMENTS
MIDNIGHT					
1 AM					
2 AM					

Appendix

TIME-Circle Hour if lights are turned off	TEMPERATURE	BREAT OR BOTTLE AMOUNT	NUMBER OF WET DIAPERS	NUMBER OF STOOLS AND COLOR	COMMENTS
3 AM					
4 AM					
5 AM					
6 AM					
7 AM					
8 AM					
9 AM					
10 AM					
11 AM					
NOON					
1PM					

TIME-Circle Hour if lights are turned off	TEMPERATURE	BREAST OR BOTTLE AMOUNT	NUMBER OF WET DIAPERS	NUMBER OF STOOLS AND COLOR	COMMENTS
2 PM					
3 PM					
4 PM					
5 PM					
6 PM					
7 PM					
8 PM					
9 PM					
10 PM					
11 PM					

Day 2

PATIENT'S NAME

TODAY'S DATE

DAY OF PHOTOTHERAPY

BILIRUBIN LEVEL

DATE AND TIME DRAWN

HOURLY METER READING

FORM OF TEMP TAKING

IRRADIANCE LEVEL SELECTOR SWITCH SETTING

HIGH

LOW

TIME-Circle Hour if lights are turned off	TEMPERATURE	BREAST OR BOTTLE AMOUNT	NUMBER OF WET DIAPERS	NUMBER OF STOOLS AND COLOR	COMMENTS
MIDNIGHT					
1 AM					
2 AM					
3 AM					
4 AM					

TIME-Circle Hour if lights are turned off	TEMPERATURE	BREAST OR BOTTLE AMOUNT	NUMBER OF WET DIAPERS	NUMBER OF STOOLS AND COLOR	COMMENTS
5 AM					
6 AM					
7 AM					
8 AM					
9 AM					
10 AM					
11 AM					
NOON					
1 PM					
2 PM					
3 PM					

Appendix

TIME-Circle Hour if lights are turned off	TEMPERATURE	BREAST OR BOTTLE AMOUNT	NUMBER OF WET DIAPERS	NUMBER OF STOOLS AND COLOR	COMMENTS
4 PM					
5 PM					
6 PM					
7 PM					
8 PM					
9 PM					
10 PM					
11 PM					

Day 3

PATIENT'S NAME _____

TODAY'S DATE _____ DAY OF PHOTOTHERAPY _____

BILIRUBIN LEVEL _____ DATE AND TIME DRAWN _____

HOURMETER READING _____ FORM OF TEMP TAKING _____

IRRADIANCE LEVEL SELECTOR SWITCH SETTING _____ HIGH _____ LOW _____

TIME-Circle Hour if lights are turned off	TEMPERATURE	BREAST OR BOTTLE AMOUNT	NUMBER OF WET DIAPERS	NUMBER OF STOOLS AND COLOR	COMMENTS
MIDNIGHT					
1 AM					
2 AM					
3 AM					

Appendix

TIME-Circle Hour if lights are turned off	TEMPERATURE	BREAST OR BOTTLE AMOUNT	NUMBER OF WET DIAPERS	NUMBER OF STOOLS AND COLOR	COMMENTS
4 AM					
5 AM					
6 AM					
7 AM					
8 AM					
9 AM					
10 AM					
11 AM					
NOON					
1 PM					
2 PM					

TIME-Circle Hour if lights are turned off	TEMPERATURE	BREAST OR BOTTLE AMOUNT	NUMBER OF WET DIAPERS	NUMBER OF STOOLS AND COLOR	COMMENTS
3 PM					
4 PM					
5 PM					
6 PM					
7 PM					
8 PM					
9 PM					
10 PM					
11 PM					

When phototherapy is over, return these record sheets to your physician for his/her records. If you have any questions about filling out these sheets, contact your homecare company or physician.

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