PEP Bed – Ultra Bili Light
Professionals' Guide

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Introduction

Congratulations on choosing your PEP Bed phototherapy equipment! As a **health professional** dealing with neonatal jaundice, you strive to deliver the best possible service. Likewise, Physician Engineered Products, Inc. (PEP) strives to provide you the best possible phototherapy products to help you achieve your goals.

The PEP Bed (Ultra BiliLight) is a hospital-grade, portable device that utilizes custom, high intensity blue/white light technology. Advantages of the PEP Bed include:

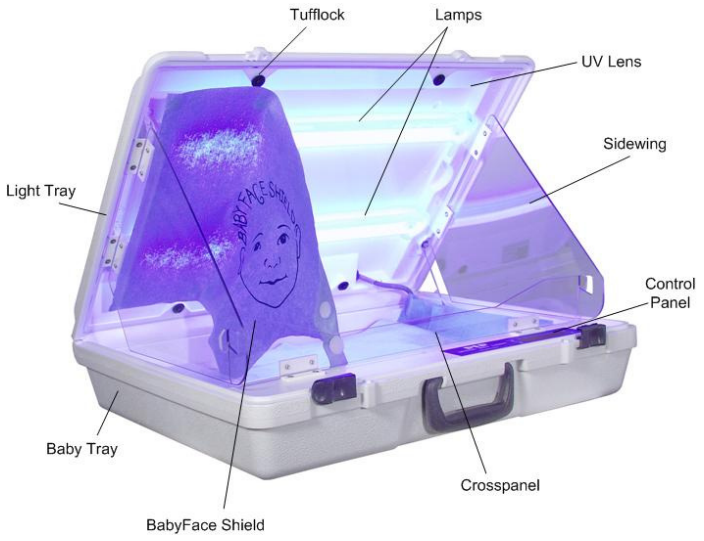
- Lightweight – only 14 pounds!
- Sets up in less than a minute
- No loose parts
- No UV
- Improved eye protection – BabyFace Shield eliminates the need for uncomfortable eye patches
- High irradiance as recommended by the American Academy of Pediatrics
- Unique thermostatic temperature control system
- Simplified irradiance monitoring – no dosimeter required**
- Sturdy triangular design
- Bedside cart for hospital use
- Diagnostic Certification program to help ensure JCAHO or other accreditation compliance
- Complete line of disposable products
- **Free** unlimited in-services
- **Free** tech support
- **Free** marketing support

This guide is intended to help you create and maintain a successful phototherapy program by detailing how the PEP Bed system works, giving protocols for use and outlining maintenance procedures for your personnel.

PLEASE READ THESE INSTRUCTIONS CAREFULLY!

Caution: Federal Law requires this device to be used under the direction of a physician.

Regulatory clearance of the PEP Bed is contingent on lamp changes EVERY 2,000 HOURS! No dosimeter is required, but bulbs MUST be replaced to ensure compliance.



Advantages of Home Phototherapy

A. What is phototherapy?

B. Convenience and Comfort.

High intensity home phototherapy allows most jaundiced babies to be treated without readmission to the hospital. With proper training, new parents can enjoy the comforts of home while helping their newborns receive first-rate treatment without the stress and cost of re-hospitalization and the inconvenient daily visits that hospital treatment requires.

C. Medical Advantages of Home Phototherapy.

1. **Bonding**: Studies show the importance of parent/child bonding within the first few days of life. Home phototherapy allows this bonding to take place with minimal disruption.
2. **Feeding**: Feeding schedules are much easier to maintain with home phototherapy – especially breast feeding. Babies receive timely feedings and mothers are less fatigued when both are at home.

D. Home Phototherapy is Effective.

Home care doesn't have to be "slow care". The American Academy of Pediatrics (AAP) recommends that treatment of hyperbilirubinemia (jaundice) should provide "high intensity" light - at least 30 mw/cm. sq. /nm of irradiance – over as much skin surface area as possible. To measure the effectiveness of a device, consider the Phototherapy Treatment Units (PTUs), which is the irradiance x surface area treated. While some home devices provide 200-800 PTUs (e.g., 30 mw x 10% surface area = 300 PTUs), the PEP Bed provides up to 2400 PTUs (60 mw x 40% surface area). More light covering more skin surface area translates into faster healing times. Outcome studies using the PEP Bed show an average treatment time of 30 hours, with few babies requiring over 48 hours.

D. Home Phototherapy is Safe.

1. **Parents are Important:** Parents are usually highly motivated and very capable of overseeing their newborn's phototherapy treatment. The occasional parent who is unwilling or unable to carry out this treatment must be identified, so effective therapy can be undertaken in hospital. The clinician usually identifies such a parent at the time of initial phototherapy decision-making.
2. **Temperature Control:** The PEP Bed provides a temperature-controlled environment at home. Home phototherapy devices are admittedly less temperature controlled than a hospital incubator. The results of many studies, however, indicate that temperature control is seldom a problem for a healthy, full-term jaundiced infant. The PEP Bed is the only home device with a built-in thermal "safety net."
3. **Eye Protection:** Although it is not proven that eye protection is necessary during phototherapy treatment, animal studies suggest that shielding babies' eyes is prudent and health industry standards require the use of eye protection. The PEP Bed provides 100% UV protection and unique eye shielding to protect baby eyes from bright light. PEP's BabyFace Shield allows eye contact between baby and parents. Or, eye patches may be used.
4. **Daily Clinical Visits:** Home phototherapy incorporates a protocol whereby the baby is checked daily by a health professional. The attending clinician has regular opportunities to evaluate the infant, much the same as hospital treatment.

E. Home Phototherapy is Cost-Effective.

One of the best reasons for home phototherapy is the potential savings of health dollars. Hundreds of millions of dollars are spent annually for hospital phototherapy. Home treatment costs a small fraction of in-hospital treatment while offering you, the Provider, an added revenue source for your home-care business.

Advantages of Hospital Phototherapy

A. Medical Advantages

1. **Very high bilirubin levels:** Clinicians determine the need for phototherapy based on the age (in hours) and the bilirubin level of the infant. Jaundiced babies are then categorized as: "consider phototherapy" (common), "intensive phototherapy" (less common), "exchange transfusion if intensive phototherapy fails" (rare), or "exchange transfusion plus intensive phototherapy" (very rare). Many clinicians assume that intensive phototherapy can only be achieved with hospital equipment, so the last 3 categories listed above are often treated in hospital. **As the PEP Bed provides intensive phototherapy, it is an excellent choice for hospital as well as home use.**
2. **Co-morbidities:** A jaundiced baby may have other medical problems that deserve hospitalization. Use of the PEP Bed in the hospital setting assures intense treatment of the hyperbilirubinemia. Note, however, that the PEP Bed is not approved for use with oxygen or other medical equipment that a baby may need.
3. **Prematurity:** Many premature infants have jaundice that deserves phototherapy. These babies tend to stay in hospital until they have gained weight, or because their bilirubin levels initially tend to fluctuate rapidly. If a preemie does not require invasive medical support, the PEP Bed may be a good choice for treating the hyperbilirubinemia.
4. **Clinician comfort:** Some clinicians are unfamiliar with home phototherapy or have had an unsatisfactory experience with low-dose home phototherapy equipment. They are simply more comfortable treating jaundiced babies in hospital. The PEP Bed will allow them to treat their jaundiced babies effectively, so the babies can go home as soon as possible.

B. Social Advantages

1. **Rooming in with mom:** The PEP Bed can be mounted to a bed-side cart. It may be ideal for the treatment of the baby's jaundice if mom is also hospitalized during baby's phototherapy.
2. **Limits to home phototherapy:** Perhaps 20% of healthy, term infants who deserve phototherapy cannot safely receive it at home. For a variety of reasons, parents may not be able to participate, or the home environment may not be physically or socially appropriate for home phototherapy. In such cases, hospital phototherapy with the PEP Bed may be the best choice. The clinician usually makes this determination prior to starting phototherapy.
3. **Transition from hospital to home:** If a baby begins phototherapy in hospital and finishes at home, the PEP Bed may be ideal. Baby enjoys the intense treatment in hospital or at home with the PEP Bed. Parents can become familiar with the hospital-grade PEP Bed while baby is in hospital and confidently carry the same equipment home with their baby.

Ultra BiliLight Features

A. The Product Line

PEP provides a state-of-the-art line of home phototherapy products that allows you, the professional, to offer this treatment modality with confidence:

- **Ultra BiliLight (the "PEP Bed") – Model 2000 or Model 2220**
- **Case Covers** (to protect your PEP Bed)
- **Eye Protection Options:**
  - BabyFace Shield (recommended)
  - Posey Eye Patches
- **Ultra BiliLight Treatment Kits** (normally cover a 2 day treatment)
  - Kits include:1 "Parents' Guide to PEP BiliLights", 2 BabyFace Shields, Disposable Mattress, Disposable Mattress Pads, Light Permeable Mini-Diapers (optional)
- **Bulk Supplies:**
  - "Parents' Guide to PEP BiliLights"
  - BabyFace Shields
  - Disposable Mattresses
  - Disposable Mattress Pads
  - Light Permeable Mini-Diapers
  - Replacement Lamps
  - Cavi-Wipes (disinfectant cleaning wipes)
- **Hospital Bed-side Cart**

B. Ultra BiliLight Specifications

1. Design and Construction:

- 14 lbs.; portable case; lights in the top half, baby in bottom half.
- Case and supports are of high density plastics; nonconductive and easy to clean.
- Easy to handle and set up.
- Interlocking panels make unit rigid and safe.
- Special UV Lens gives protection against ultraviolet light and maintains integrity of light array.
- Clear visibility of infant from 3 sides.
- BabyFace Shield is applied to the unit, not the baby – eliminates the need for eye patches.

2. Lighting:

- Special blue and white fluorescent lamps provide irradiance of higher than 60 mw/sq.cm./nm.
- Distance of lights to baby is 8" to 15".
- Baby bed surface is white for increased light reflection.

3. Electrical:

- LED control panel for easy tracking of system/lamp hours.
- 110 VAC for Model 2000 (or 220 VAC for Model 2220); unit fused for 5 amps.
- Internal heating element maintains bed at 75° F – ideal for most babies.
- Temperature warning and control system shuts unit off if excess temperature is reached.

C. Ultra BiliLight Sets New Standard for Home Phototherapy Units.

1. Compact and Lightweight

At 14 pounds, the Ultra BiliLight is easy for most adults to handle. Designed like a suitcase, the PEP Bed is easily carried to and from the home. The device fits inside a crib for added stability and protection. Best of all, the PEP Bed is easy to set up and take down. Simply lift the lid and interlock the side panels with the front cross-panel. Plug it in, make sure there is a mattress, mattress pad and a BabyFace Shield in place, and it is ready to use.

2. Excellent Light Dosage

PEP Bed lamps – at 60 μW/cm²/nm - give intense irradiance (>30 μW/cm²/nm) and an extra margin of effectiveness as lamps gradually decay with use. This feature allows the use of a lamp replacement schedule based simply on hours of use, with no need to rely on expensive dosimeters after every use. Maintenance is simple, as the PEP Bed provides an average irradiance well above standard. Even with heavily used lamps (2,000 hours), the irradiance drops no more than 20% - still well above the recommended >30 μW/cm²/nm. Replacing lamps per the FDA cleared maintenance schedule (at least **every 2,000 hours**) assures you of maximal dosing, every time you use the equipment.

3. Intermittent Therapy

Historically, phototherapy has been delivered with as few interruptions as possible, theoretically to maximize treatment. However, many clinicians feel intermittent therapy with intense equipment is as effective as continuous therapy. This is because bilirubin in the skin breaks down quickly when exposed to the blue light from bright phototherapy devices, but the migration of bilirubin to the skin is slow. Intermittent therapy takes advantage of this slow migration and fast break-down of bilirubin. Intermittent breaks from the phototherapy allows for the normal feeding, cuddling, playing and skin-to-skin bonding between baby and parents that ideally takes place during the first few days of life. It also reassures you and the clinician that parents will be compliant with the prescribed treatment, since they are allowed reasonable contact with their newborn.

4. Improved Eye Protection

The BabyFace Shield is the result of PEP's desire to provide the best possible phototherapy equipment available. Until the development of the BabyFace Shield, eye protection was provided by eye patches held in place with straps or adhesive. Parental complaints about losing eye contact with their infant and the rare events of patches slipping over babies' noses and obstructing airways have made eye protection the most complained about feature of phototherapy.

The BabyFace Shield solves these problems of shielding baby's eyes from the light by attaching to the unit, not the baby. A baby may occasionally scoot out from under the BabyFace Shield (and parents must be instructed to watch for this), but studies show this to be a rare event. Usually, babies will push further under the Shield, until the bed edge stops them. The infant can be "blocked" into position by placing a rolled-up towel at the foot of the bed. The skin surface area that is lost to treatment is about 5% with the eye patches and 9% with the BabyFace Shield - a small amount when considering the high PTU output of the PEP Bed. PEP offers eye patches to those who still prefer them, but we recommend the BabyFace Shield as a safe and effective option for eye protection.

5. High/Low Thermal Protection Adds Safety

Although thermal problems are rare in home phototherapy, they can occur. To help avoid these problems, the PEP Bed has been designed to be small and lightweight – easy to set up in a warm area of the house, preferably in a crib. The recessed baby bed and surrounding clear plastic panels (Sidewings and Crosspanel) protect against drafts. With lights on, the baby bed temperature is 6 to 7° Fahrenheit warmer than room air.

In addition, the PEP Bed has a unique temperature warning and protection system built into the unit. If the temperature sensor in the baby bed drops below 75° Fahrenheit (23.9° Celcius), the amber-colored "Heater ON" indicator light located on the control panel turns on and the heating element beneath the baby tray gradually warms the bed until the temperature is 75° F (23.9° C), at which point the heating element and indicator light automatically turn off. If the bed temperature rises to 95° F (35° C), the red-colored "High Room Temp" control panel lamp will light and the phototherapy lamps will flash and automatically turn off until the baby tray temperature drops below 95° F (35° C).

Parents should be educated to this system and taught to recognize that if the "Heater ON" light is lit and the therapy lights are on, the infant may be getting too cool. Parents must monitor baby's temperature while the room temperature is increased. Likewise, an infant may occasionally get too warm. If the power and "High Room Temp" indicator lights are on, and the therapy lights are off, the unit temperature is probably over 95° F (35° C), and the room should be cooled. PEP's experience indicates that hyperthermia (excessively high body temperature) occurs in less than 0.5% of babies undergoing phototherapy. Excessively warm rooms, babies over 9 lbs. and very active babies may be associated with a higher risk for hyperthermia. The baby's temperature should be monitored more frequently, every one to two hours, under these conditions. It should be emphasized that regular checking of baby's temperature is required under all circumstances (see Parents' Guide to PEP BiliLights).

6. Control Panel Features

- A simple On/Off switch
- An LED display for system hours - simple and easy to read
  - Re-settable lamp hours display for 3 seconds on each start-up to aid in lamp maintenance
  - Non-re-settable, total system hours display while treatment lights are on – used to track baby treatment time
- Audible alarms sound for High Room Temperature and lamp test on start-up.
- An amber "Heater On" indicator lights when the unit temperature is under 75° F (23.9° C) and the warming unit is on.
- A red "High Room Temp" indicator lights and the treatment lights flash, then shut down when 95° F (35° C) has been exceeded in the unit.
- An amber "Service Soon" indicator lights when lamps have reached **1800 hours**.
- A red "Replace Lamps" indicator lights when lamps have reached **2000 hours** and lamps need to be replaced.

Protocol for Using the PEP Bed

Models UBL 2000, UBL 2220

A. How to Use the PEP Bed:

1. Set Up

- Unlock the case latches and open the lid, holding the two Sidewings against the UV Lens. Remove the Power Cord from the Baby Tray and place at the side of the unit.
- Swing Sidewings out and raise the Crosspanel.
- Interlock Sidewings to Crosspanel as shown below.

- Place (1) one disposable PEP Bed Mattress in the Baby Tray.
- Place (1) one disposable mattress pad on top of the PEP Bed Mattress.
- Attach (1) one BabyFace Shield to the UV Lens, pressing firmly on the 4 Dual Lock dots.
- Insert the Power Cord into the Power Module. Plug the Power Cord into a wall outlet.
- Turn the PEP Bed ON. Notice that the Control Panel will show Lamp Hours for 3 seconds before displaying System Hours (UBL 2000, UBL 2220). All lamps should light. If they do not, carefully remove the (4) four black tuflocks from the UV Lens (with pliers if necessary), remove the UV Lens Assembly (UV Lens+Sidewings) and check that the lamps are seated properly in the sockets. Occasionally, a lamp connection will become loose in shipping or carrying. BE CAREFUL NOT TO SQUEEZE LAMPS TOO TIGHTLY OR THEY MAY BREAK! Be sure to replace the UV Lens Assembly and Tuflocks before using unit.

2. Using the PEP Bed

- Set up PEP Bed as outlined above, making sure to turn the unit ON.
- Place baby in the Baby Tray – on its back - with the head toward the left of the unit.
- Secure the BabyFace Shield to the Crosspanel using the appropriate Dual Lock dot. The BabyFace Shield will protect baby's eyes without the need for eye patches.
- Occasionally, a baby will push out from under the BabyFace Shield. To avoid this, PEP recommends placing a rolled-up towel at the feet of the baby.
- The unit should be turned OFF when baby is out of the unit and not receiving treatment.

B. Use the "Parents' Guide"

After the baby has been identified as a candidate for home phototherapy, the parents are brought into the treatment team. While discussing home phototherapy with the parents, you, the instructor, should assess their ability and willingness to succeed with the treatment protocol. A few parents will be unable or unwilling to do so, and hospital therapy may be the best alternative for their babies. Consult with the clinician if you are concerned. Parents' comfort and success should be re-evaluated at each daily visit. Most will do very well.

Proceed step-by-step through the Parents' Guide with the parents. Use the "Instructor's Checklist" to ensure you do not miss important points. Instruct them to read the Guide thoroughly.

C. Demonstrate to Parents

- Site Selection - Assist the parents in selecting the best location for the unit, preferably in an easy-to-monitor, warm location. Many parents prefer to use the PEP Bed in the baby's crib.

- Setting up the Unit - Review deployment and closing. Make sure the parent's understand that the PEP Bed must be treated with care. No excessive force should be applied to the case and the lid should NEVER be closed with anything inside the unit. The Sidewings must be folded into the unit before closing and no heavy objects should be placed on the unit or the lamps may break.
- Use of the Mattress, Baby Pad, Mini-Diapers and/or rolled towels
- Eye Protection for baby:
    - Use of the BabyFace Shield – application to the unit and the correct placement of baby under the shield and the importance of monitoring baby's position, **or**
    - Use of eye patches – application on baby and the importance of correct position and monitoring.
- Temperature Checks
    - Show Axillary Technique (thermometer is placed in baby's armpit for 2-3 minutes)
    - Review the importance of regular checks
- The temperature warning and control system
- Intermittent or continuous treatment regimen ordered by the clinician
- Keeping the Record Sheet - Review All Information.
- System Check of Lamps and Indicators

D. Safety Features - Ultra BiliLight Model 2000 or Model 2220 Control Panel Indicators

- Amber "Heater ON" indicator lamp – lower right of display; unit is warming up to 75° F (23.9° C).
  Baby Tray is below desired temperature. Let unit warm up, or move to warmer location before placing baby in the unit.
- Red "High Room Temp" indicator lamp – upper right corner of display; unit is over 95° F (35° C); audible alarm will sound and Treatment Lights will flash and turn off. **Baby Tray is above desired temperature. Reduce room temperature and monitor baby's temperature closely before resuming phototherapy.**
- Amber "Service Soon" – lower left of display; 1800 hours have accumulated on the lamps; **Treatment lamps need to be replaced soon.**
- Red "Replace Lamps" indicator lamp – upper left corner of display; 2000 hours have accumulated on the lamps. **Treatment lamps must be replaced prior to the next baby.**

Note: This device is not approved for use with oxygen, infant monitors, or other electronic devices, or high risk patients.

Trouble Shooting

A. Failure of Treatment Light(s)

- First ensure that the room air temperature is not too warm - Baby Tray temperature is under 95° F (35° C).
- Check that lamps have not become loose in their sockets. Remove the UV Lens Assembly (clear panel covering the lamps & side supports) and reseat the lamps. Replace the UV Lens Assembly and black Tuflocks prior to use.
- Less likely, lamps may burn out and require replacement. A reserve supply of lamps should be maintained.
- Least likely, a circuit or ballast may fail and require factory repair.

B. Failure to Maintain Normal Temperature

If the "Heat ON" (Model 2000 or 2220) or "Low Temp" (Model 100) warning light comes on indicating a cool room temperature or treatment lights go off repeatedly indicating an overly warm room temperature, increase or reduce the room temperature as needed which will automatically return the unit to normal operating conditions.

It is recommended that the unit be returned to PEP yearly to certify that the temperature warning and control system is operating correctly (see Diagnostic Certification). **This system cannot be effectively tested in the field.**

Maintenance Instructions

PEP Beds are designed to require a minimum of care, but regular maintenance is recommended in the following areas.

A. Cleaning

Clean all exposed surfaces between each use. Use a non-abrasive cleaning agent, such as Cavi-Wipes (PEP recommended), which is bactericidal, fungicidal, and tuberculocidal. Avoid all abrasive cleaners - they will scratch the clear plastic panels of the unit. You may also periodically clean the UV Lens, Sidewings and Crosspanel with warm, soapy water. Prevent water from leaking under the internal panels. **Do not immerse the unit in any liquid.**

B. Lamp Replacement

To ensure adequate irradiance, the PEP Bed depends on periodic lamp changes and avoids the use of expensive dosimeters. To satisfy regulatory requirements and provide maximum light output, **lamps must be changed after every 2,000 hours of use.** (Each set of lamps will probably treat over 80 babies.) To determine when lamps need to be changed for the:

a) **Ultra BiliLight Model 2000 or 2220** - lamp hours are automatically recorded when the unit is on. The digital clock will display these lamp hours for the first 3 seconds each time the unit is turned on. In addition, the "Service Soon" indicator lamp will come on at 1800 hours – giving you 200 hours of lead-time to change the lamps. If the "Replace Lamps" indicator light comes on, the device has exceeded the 2000 hour limit, and the lamps must be changed before the next baby is treated;

To change the phototherapy lamps:

a) You can send the device to PEP for a **2000-hour Check-Up**. At such time, your device will also receive the recommended 13-point **Diagnostic Certification**;
b) You can change the lamps yourself by obtaining them from PEP. It is good policy to have replacement lamps in your inventory for this purpose. Complete field replacement instructions are included with the lamps.

C. Diagnostic Certification & Repair Programs

To help provide better service to our customers, PEP offers **Diagnostic Certification** and **2,000 Hour Check-Up** programs for the **Ultra BiliLight Model 2000** & **Model 220**. These programs will assist you in creating a factory testing and maintenance certification program that can be used as documentation support for your accreditation requirements. They can also be used as a verification procedure to ensure that your device is operating properly to reduce liability risks and improve the usable life of the unit. All testing and maintenance are done by factory-trained technicians, providing the highest quality control, to ensure that your equipment is functioning within industry standards. PEP recommends diagnostic testing of all equipment every year or every 2,000 hours, whichever comes first.

PEP's Diagnostic Certification services include the following:

- Complete electrical diagnostic testing – leakage, resistance, grounding, temperatures
- Testing of all major components – switch, meters, controller, heater, plastic parts
- Fluorescent lamp replacement ***2,000 Hour Check-Up***
- Estimate for any major component problems
- Complete certified maintenance and diagnostic documentation for your files
- Equipment normally tested, repaired (if necessary) and re-shipped within 48 hours upon receipt of Purchase Order.

To contact PEP for more information or to request a Return Authorization for a Diagnostic Certification, please call: 800.622.6240 or email: shop@peponline.com

Warranty, Repair, Return Information

A. Limited One Year Warranty

PEP warranties your new PEP Bed phototherapy unit against any defect in materials or workmanship for a period of one (1) year from date of purchase. This warranty **does not** cover consumable supplies or any damage caused by accident, misuse, abuse, tampering or negligence such as failure to follow operating instructions. In the event your phototherapy unit fails to give satisfactory performance within the warranty, PEP will repair or replace your unit at no charge for parts or labor. Please contact PEP at **800-622-6240** to receive a Return Authorization Number for any warranty repairs or returns.

Should your unit require service, please return it prepaid to:

Physician Engineered Products, Inc.
103 Smith Street
Fryeburg, ME 04037

B. Repair Policy

PEP maintains a rigorous quality assurance program during manufacturing. You deserve equipment that works. PEP recognizes, however, that any electro-mechanical device can, from time to time, fail to function properly. Please contact PEP at **800-622-6240** to receive a Return Authorization Number for any repairs or diagnostic certifications. Please include a memo with the unit including your company information, contact number and details of the problem. All units must be sent in the original packaging, if possible. If not, please package your PEP Bed with sufficient packing material to safely ship your unit (at least 3" of material on all sides of the unit). The PEP Bed is a delicate piece of medical equipment and broken lamps or other parts can be costly and easily avoided if packed properly. New boxes and inserts can be purchased from PEP to ensure that your unit arrives undamaged.

Any unit needing repair should be sent to:

Physician Engineered Products, Inc.
103 Smith Street
Fryeburg, ME 04037

PEP strives to repair all units rapidly. With our inventory of components, most repair work can be turned around within two working days. If you require a loan unit while yours is in the process of being repaired, phone PEP at 800-622-6240 or email: shop@peponline.com and a loan agreement will be forwarded to you.

C. Return Policy

For PEP products purchased and returned to PEP at the buyer's discretion:

- Up to 30 days after shipping – no re-stocking fee
- **After 30 days – 25% re-stocking fee?? Until when???**

For PEP products returned due to product failure (**under normal use**):

- Up to 1-year Warranty Period – replacement or repair at no charge to client (see above)
- After 1-year Warranty Period – replacement or repair at normal charge to client