Neonatal jaundice is a condition affecting newborn infants in which bilirubin levels rise abnormally, causing skin and other tissue to have a yellowish appearance. Hyperbilirubinemia, also known as jaundice, is the most common medical condition requiring treatment in newborns, affecting up to 60% of term newborns and 80% of preterm newborns. Although most recover from the condition quickly, in approximately 5-11% it can pose a serious risk to the health, and even life, of the infant. \[1\][2]

This paper serves as a brief introduction to the BiliBee, an LED phototherapy system that is completely portable and provides effective treatment for neonatal jaundice. It will examine the BiliBee’s role in the context of current treatment options and its effectiveness relative to competing products.

**Why use portable phototherapy technology?**

As with any medical intervention, compliance is the key to successful outcomes. Because the BiliBee is the only portable device on the market that doesn’t require an electrical outlet, it can provide approximately four hours of continuous treatment, even during visits to the doctor and breastfeeding, before needing to be recharged or plugged into an outlet. This can greatly improve the effectiveness of phototherapy in reducing bilirubin levels. Its simple design also makes it easier to operate than some other systems, meaning it will be more likely to be used regularly, thus increasing compliance further.

Increased compliance has been shown to increase phototherapy treatment effectiveness in terms of speed of recovery through both independent studies and Illumination Technologies’ own trials. \[3\] [4]
What is neonatal jaundice?

Neonatal jaundice is a yellowing of the skin and other tissues in newborn infants caused by hyperbilirubinemia, bilirubin levels of 5 mg/dL or more. Although not always dangerous, in some severe cases the condition can be extremely serious, with victims experiencing tiredness, poor feeding, fever, seizures, and even death.

Complications

In severe hyperbilirubinemia, bilirubin toxicity can occur. When serum bilirubin levels overtake the binding capacity of albumin, unbound bilirubin can cross the blood brain barrier, causing kernicterus, a brain dysfunction that can result in permanent brain damage, hearing loss and in some cases death. At this point, the baby can fully recover without permanent damage to the brain if bilirubin levels are lowered rapidly enough. However, if bilirubin levels are not lowered rapidly, the condition can quickly deteriorate into chronic bilirubin encephalopathy, with infants suffering severe and permanent neurological lesions. Newborns are particularly vulnerable to this condition so it is critical that jaundice be treated promptly and bilirubin levels be reduced as quickly as possible.

What causes neonatal jaundice?

Jaundice is caused by abnormally high levels of bilirubin. When a baby is growing inside its mother’s womb, the placenta is responsible for removing bilirubin from the body, but when the infant is born, it must use its own liver to perform the function. Physiologic jaundice is very common, found in 45-60% of infants within their first few days postpartum. This condition is usually harmless and will often go away within two weeks, but it still requires treatment as the liver is unable to cope with the excess bilirubin.

However, pathologic jaundice which results from a blood incompatibility issues is also known as positive coombs or ABO incompatibility. It is usually discovered after birth when the baby’s blood is tested and found to be either A, B or AB with the mother having type O blood. Type O mothers carry the anti-A and anti-B antibodies, thus they are the most prone to have infants with this issue. While not all positive coombs babies are jaundiced, the risk of needing phototherapy is increased. This type of jaundice requires longer treatment times, and in some cases, more aggressive treatment such as multiple phototherapy devices.

Jaundice can be caused by a number of factors, including:

- High red blood cell count
- Low Oxygen Levels
- Infection
- Inherited Disorders
- Baby born preterm
- Bruising
- Blood incompatability (ABO)
What current treatment options are available?

In some rare, extremely severe cases, the patient may need to undergo a blood transfusion in order to overcome jaundice. However, the most common course of treatment for jaundice is exposing the baby’s skin to high levels of light in the blue visible spectrum. Although not entirely understood, the process, called phototherapy, breaks down bilirubin and helps to normalize bilirubin concentration in the baby’s body. The treatment can be applied either by overhead lamp or closer to the baby’s body with personal devices, such as the BiliBee. A variety of light sources, including LEDs, fluorescent tubes, and quartz halogen bulbs can also be used.

Phototherapy is an extremely effective treatment for neonatal jaundice, with success rates averaging 99.8% and repeated treatments necessary in only .75% of cases. Highly concentrated treatment can lower a 500 µmol/l bilirubin level by as much as 150 µmol/l in 2-4 hours. Phototherapy is also very safe. By limiting the spectral range of the light, nearly all negative effects of UV exposure are negligible. Because the LEDs used in the BiliBee are limited to a very specific range of light, UV exposure is not a concern.
The BiliBee: Truly Portable LED Phototherapy

For infants whose condition is determined to require treatment, the BiliBee LED is a fully portable phototherapy system designed to provide effective and fast reduction of bilirubin levels. It offers a narrow spectral range between 455 to 485 nm, improved temperature regulation thanks to its relatively small size, and a competitive price point.

The system uses an LED pad, eliminating the need for fiber optic cable. The pad is placed directly against the patient’s skin, providing extremely effective 24 hour treatment until the infant’s bilirubin has been lowered to acceptable levels.

**BiliBee features:**

- **IEC Certified** - Adheres to IEC60601-2-50 “Particular Requirement for the Safety of Infant Phototherapy Equipment”
- **Easy to Use** - No moving parts and simple design makes it easier for mothers to use.
- **Light Weight** - Total Panel weight is 8 oz., compared to 8 lbs. for some competitive units
- **Compact** - Panel Dimensions 5.1” by 8.3”
- **Truly Portable** - The rechargeable battery pack provides to 4 to 5 hours of continuous treatment without an AC outlet, thus enabling treatment while traveling.
- **Cost Effective** - The BiliBee LED Phototherapy System is a competitively priced alternative to other expensive devices while offering the same or even better treatment of jaundice given its portability.
- **Low Maintenance** - The Bilibee doesn’t use expensive halogen bulbs or fiber optic panels that need to be replaced. The BiliBee also has no moving parts, making it one of the simplest systems to use and maintain.
- **Disposable Sheaths** – Keep the BiliBee clean
- **Optional Disposable Air Mattress** – provides an optional layer of comfort
- **One Year Warranty, and an optional 5 year extended warranty is available.**
BiliBee specifications:

Performance:

- Light Bandwidth Peak: 455-485 nm
- Irradiance Level: 60 ± 10 μW/cm² /nm
- Mode of Operation: Continuous

Physical Characteristics:

- Illuminator Pad Size: 5.1” W x 8.3” L x ¼” H
- Treatment Area: 4” x 6”
- Combined Unit Weight: 13.3 oz.

Environmental/Storage Conditions

- Environmental Operating Temperature: 15 to 35°C (59 to 95°F)

Electrical Characteristics

- AC/DC Operating Capability
- Rechargeable Internal Battery
What are the advantages of using the BiliBee?

Increased compliance improves phototherapy effectiveness

There is evidence to suggest that more continuous application of phototherapy improves its effectiveness. Stopping treatment for even a short time can cause bilirubin levels to rebound, potentially resulting in an increased duration of the illness.

According to the study, “Controlled trial comparing agar, intermittent phototherapy, and continuous phototherapy for reducing neonatal hyperbilirubinemia” conducted by Maurer et al. applying phototherapy continuously allows the treatment to reduce bilirubin levels more significantly than intermittent applications, particularly if the intermittent application has significant gaps between doses. This study also shows that “Infants who received intermittent light or agar had daily mean values which were not significantly different from those of the control subjects except on Day 4.” This indicates that for the first four days sporadic treatment is as ineffective as no treatment. [3]

These findings are confirmed by the investigations conducted by Rubaltelli et al. who found that continuous application of phototherapy treatment “Caused a greater and more rapid rate of decline (in bilirubin levels) than did intermittent phototherapy.” The study found that bilirubin concentration reached low levels (8.0 mg/100 ml) up to four days faster for those infants receiving continuous treatment than those that received treatment intermittently. The results of the study are reprinted to the right. [4]

This data indicates that compliance plays a very significant role in the effectiveness of phototherapy in neonatal jaundice. This perhaps suggests that compliance should be considered with similar weight to other metrics of phototherapy device evaluation, such as treatment area and light intensity.

Increased compliance improves phototherapy effectiveness

Using a portable phototherapy device such as the BiliBee should increase compliance (and thus treatment effectiveness) since it greatly increases the ability of the mother to apply treatment continuously. Visits to the doctor alone can take several hours when wait and travel times are considered. Because non portable units cannot be used during this time, the infant has the potential to miss a significant amount of critical treatment, reducing effectiveness and increasing risks of rebound and lengthened treatment duration. The BiliBee can be used in the car, at the doctor’s office, and nearly anywhere else, meaning that treatment can be truly continuous.
The BiliBee is easier to use

Many home phototherapy systems were not designed for ease of use or simplicity. This could create significant treatment compliance problems for two reasons: avoidance of treatment application and system malfunctions. Many phototherapy systems are complicated and have moving parts. Unfortunately, moving parts can lead to system malfunctions that cause lapses in treatment, additional expense for the equipment provider, and frustration for the family. The complexity of other home phototherapy systems also makes them more difficult to use. This can reduce the likelihood that the infant will receive regular, continuous treatment, as the family is more likely to delay treatment or avoid using the device altogether.

The BiliBee features a simpler design with only two components; the LED illuminator pad and battery pack which are attached to each other. Additionally, the BiliBee has no moving parts that can be damaged or malfunction. This makes fixing any problem with the device simple and reduces the risk that there will be technical malfunctions in the first place.

The BiliBee is more cost effective

Because the BiliBee uses a simpler design with an LED pad rather than fiber optics, it is far more cost effective than many of its competitors. Fiber optic panels found on competitor’s products must be replaced annually or bi-annually depending on the amount of use. The fiber optic cables become damaged with repeated flexing, resulting in substantial reductions in light transmissions. This can cause them fall below manufacturer’s specifications and require replacement, which can present a significant expense with refurbished cables costing up to $700 and new panels costing over $1000. These costs drastically reduce profitability for the equipment provider.

Although fluorescent light sources provide another relatively low cost alternative, they have been shown to have reduced light intensity with use ranging from 1,000 to 2,000 hours. This can significantly decrease the effectiveness of the treatment and present additional difficulties in the application of treatment. Blue LEDs last at least 10,000 hours and do not decrease in intensity with age. The potential of equipment falling below standards is not present with the BiliBee, as it does not use fiber optic panels or fluorescent lighting. The BiliBee also reduces costs for equipment providers, thus increasing the potential for more infants to get the treatment they need by being more readily available.

Portability promotes mother/baby bonding

There is significance evidence to suggest that close contact while feeding, bottle or breast, strengthens the maternal bond, resulting in improved caretaking by the mother. Aside from the potential of using a portable device to lower bilirubin levels faster, it can also help strengthen this bond because of its lightweight, portable design.

Some other competing devices are not able to be used during the breastfeeding process, forcing the mother to choose between providing her baby with the health and bonding advantages of breastfeeding, or providing phototherapy. On average, nursing mothers breastfeed their infants eight to twelve times a day, with the average session lasting 15 to 20 minutes. Based on these averages, and taking into account learning curve and the baby falling asleep, it is likely that a mother spends at least six hours each day breastfeeding, or 25 to 30% of the day. That’s a significant amount of treatment time that could be lost if the phototherapy device does not allow for the mother to hold the infant during application. This loss of treatment time can translate into longer illness durations. The BiliBee can easily be used during feeding, allowing the mother to continue caring for the baby as she normally would and further strengthening the maternal bond.
Is the BiliBee as intensive as non-portable systems?

Although the BiliBee’s portability and relatively small pad size might raise questions about its efficacy, in practice it is as effective as or even more so than some of its competitors.

The BiliBee adheres to the standards of maximum effectiveness

The AAP recommends that phototherapy treatment systems use blue fluorescent tubes or a specifically designed LED emitting light in the 430-490 nm bands. They also recommend that the light source be placed as close to the infant as possible, stating that distance has a “dramatic effect” on spectral irradiance and thus effectiveness of treatment. [18]

In almost all areas, the BiliBee meets or exceeds AAP guidelines. It uses a specifically designed LED pad that emits light between 455 to 485 nm, well within the recommended parameters. The light pad is also designed to be placed directly against the infant’s body, providing the maximum proximity benefit.

The BiliBee’s LED panel is designed to provide maximum exposure to the large surface area of skin on the neonates back. One popular competitor’s product appears to have a larger treatment area, but once certain factors are taken into consideration, the real treatment areas turn out to be nearly identical.

The competitor’s device uses a jacket-like device that keeps the infant on its back while the screen allows light to penetrate upwards to the infant’s back. The patient’s arms are placed in sleeves with the neonate wearing a diaper during treatment. While the infant’s legs are potentially exposed to the light, in practice neonates often keep their legs pulled up in the fetal position rendering any exposure to the lights to be of little to no effect. When the infant’s legs are in this position, the actual treatment area is from the patient’s shoulders down to the diaper’s waistline, identical to the BiliBee’s treatment area.

The BiliBee is the only therapy system that was designed specifically to meet the AAP’s guidelines for continuous treatment, which state that in the most severe cases, “Phototherapy should be administered continuously until a satisfactory decline in the serum bilirubin levels occurs...” [18] Because the BiliBee is lightweight and able to be used without constant access to an AC power source, it is the only option that can provide continuous treatment.

The BiliBee excels over competitors in real world trials

Real world tests of the BiliBee in treating neonatal jaundice confirm that its specifications make it as effective as or more so than its competitors. In one recent trial, 75 patients with average bilirubin levels between 15 and 16 mg/dL were treated with either the BiliBee or one of two leading competitors. The BiliBee was able to reduce bilirubin content to safe levels within an average of 4.0 days, whereas the two competitors took 6.5 and 6.4 days respectively. These treatment times include an additional day of non-treatment to ensure the patient was past the threat of rebound.
Because greater lengths of hyperbilirubinemia are correlated with the development of kernicterus and eventual chronic bilirubin encephalopathy, this trial indicates that the device may even have the potential to reduce the risk of complication from neonatal jaundice, although this has not been shown definitively. [9]

This trial reassert the findings of Maurer et al. and Rubaltelli et al. suggesting that compliance plays a very important role in the effectiveness of jaundice treatment. The BiliBee's portability, ease of use, and innovative LED technology make it one of the most capable phototherapy systems available. Further use of the BiliBee in the real world continues to prove that it is one of the most intensive phototherapy treatment devices available.

<table>
<thead>
<tr>
<th>BiliBee Trial Results</th>
<th>BiliBee</th>
<th>Bed-like Unit</th>
<th>Fiber Optic Unit</th>
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<tr>
<td>Avg. Age of Patient</td>
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<td>Avg. Starting Bilirubin Level</td>
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<td>6.4 Days</td>
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</table>
Want to learn more about the BiliBee?

Illumination Technologies is dedicated to creating effective phototherapy devices and companion products for neonatal jaundice. Our technology provides impressive results in an easy to use, portable system.

If you're interested in learning more about how a portable LED phototherapy system like the BiliBee can reduce costs, improve results, and reduce treatment time, contact an Illumination Technologies representative by calling 877-772-4445 or emailing info@illuminationtechnologies.net.

References: