Neonatal Phototherapy

A review
including evaluations of

Ohmeda
BiliBlanket®Plus

Medela
BiliBed™
INTRODUCTION

This issue of Evaluation is our first examination of phototherapy equipment for the treatment of neonatal jaundice (hyperbilirubinaemia). A survey in the Appendix 1 & 2 covers both equipment currently available in the UK and equipment no longer available but in use in the NHS.

Phototherapy Equipment Available

Phototherapy equipment can be divided into two main categories. The first type consists of a light unit which may be positioned above or below the baby. These units may include blue or white lamps. This type of phototherapy has been on the market for some 40 years and is usually referred to as conventional phototherapy.

A newer development is the fibreoptic form of phototherapy equipment. This type delivers light from a halogen bulb via a fibreoptic cable to a pad containing woven optical fibres. The pad is placed next to the baby's skin. This newer type has been on the market for around 10 years.

Devices covered

This issue includes evaluations of two devices currently available in the U.K. Comparative technical data is given in Appendix 2 for three other devices currently used in the NHS. Further evaluations will be published in later issues.

You are encouraged to contact our evaluation centre, CEDAR (see Appendix 3) in Cardiff for further information on our evaluations. For details of configurations, prices and other factors you should contact the manufacturers or suppliers.

Issues to Consider in Purchase

A phototherapy unit should be selected after consideration of the following important but by no means exhaustive criteria: the ability to meet clinical need, technical performance, ease of use, compliance with European Directives, compliance with Standards, likely reliability, ease of servicing, and price.

Meeting Clinical Need

This is discussed in the Appendix 1 - Current Thinking on Phototherapy.

Likely Reliability and Running Costs

Phototherapy units tend to be of a fairly simple construction with little to go wrong. The main costs will lie in the purchase of consumables. All units will need replacement lamps and some may need replacement filters. In devices using fluorescent lamps, light output decreases with time; the lamps, therefore, need to be replaced after some 1000 to 1500 hours in use, as per the manufacturers instructions. Devices using halogen lamps have a more steady output and they need to be replaced only when they fail.

Those devices which may come into contact with the patient may require disposable or washable covers. As with all medical devices regular servicing and safety checks are essential to ensure efficient operation of the device and safety for the patients and staff.

SPECIAL NOTE: Warranties and Servicing

In common with many medical devices, phototherapy equipment requires routine servicing. The service period is typically 3 or 6 months. Although new equipment normally has a one-year warranty against breakdown, servicing is still required within the warranty period (e.g. to check output from the lights).

Any purchasing decision should include service provision from the date of purchase, not from the date of expiry of the warranty.
OHMEDA BILI BLANKET PLUS

SUMMARY

Advantages: Negligible heat production at therapy pad, no eye pads necessary when used on its own, infant may be nursed during therapy, can be used in special care baby units and in the community.

Disadvantages: Pad only available in a small size*, considered a little inflexible and hard by some users, bulbs do not last as long as expected.

Overall: Modern fibreoptic phototherapy system suitable for high intensity therapy for pre-term babies and less intensive therapy for larger full-term babies. Well received by parents and nursing staff.

BRIEF DESCRIPTION

The Ohmeda BiliBlanket Plus is a fibreoptic neonatal phototherapy device. Light from a halogen bulb is filtered and channelled into a flat pad of woven optic fibres via a fibreoptic cable. The filter in the main unit removes most of the ultraviolet and infrared components of the light and the light appears blue-green to the user. It has an effective bandwidth of 400 to 550nm, peaking around 530nm wavelength.

The fibreoptic pad is placed against the infant's skin and they may be fed, changed and cuddled without interfering with therapy. The intensity of the light can be varied. The unit is designed to make infant eye protection unnecessary when used as a single therapy. An LCD meter on the front of the main box shows the number of hours the device has been in use.

MAIN FEATURES

- Fibre optic pad
- Variable intensity
- One halogen bulb
- Wide waveband 400nm to 550nm
- Meter to show total hours in use

Options

The BiliBlanket Plus is available as
- Phototherapy only
- Phototherapy and Transilluminator ready
- Phototherapy and Transilluminator

Replacement Items

- Bulb (box of 6) £144
- Pad £565
- Disposable pad covers (50) £26
- Disposable vests (50) £50

Life span of lamp - Manufacturer states lamp life of 700 hours when used continuously at 25 °C on the high intensity setting. Lamp to be changed when it fails.

SERVICING

No training courses are available for technical staff.

There is a combined operating and service manual available.

<table>
<thead>
<tr>
<th>Price ex VAT</th>
<th>£2,000 includes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 transilluminator</td>
</tr>
<tr>
<td></td>
<td>5 disposable vests</td>
</tr>
<tr>
<td></td>
<td>10 disposable covers</td>
</tr>
<tr>
<td></td>
<td>1 spare bulb</td>
</tr>
</tbody>
</table>

Manufacturer

Ohmeda Medical 9065
Guilford Road, Columbia MD 21046 USA

Supplier:

Datex-Ohmeda Ltd
71 Great North Road
Hatfield
Hertfordshire
AL9 5EN
Tel:01707 263570
Fax:01707 260065
web page:
www.datex-ohmeda.com

CE Marking

MD Directive, Annex II Notified Body BSI (ID 0086)

How is safety demonstrated?

EN 60601-1-2:1993

* See Manufacturer's Comments
MEDELA BILIBED

SUMMARY

Advantages: Low heat production at therapy site, no infant eye protection necessary when used on its own. Therapy can be carried out beside mother to avoid separation. Can be used in hospital units or the community.

Disadvantages: Not for use in incubators.

Overall: Modern easy to use phototherapy unit. Small patient-to-light distance enables high intensity therapy. Well received by parents and nursing staff.

Supplier:
Tel: 01538 399541
Fax: 01538 399572
web page: www.centralmedical.co.uk

BRIEF DESCRIPTION

The Medela BiliBed is a fluorescent lamp type neonatal phototherapy device for neonates not needing an incubator. The unit fits into a crib or bassinet and a stretched plastic cover provides a soft surface over the light for the infant. A specially designed "baby suit", called a Bilicombi, attaches to the plastic cover with Velcro, this keeps the child in position and is designed to reduce unwanted light and glare to carers and parents. The unit is designed to make infant eye protection unnecessary when used as a single therapy. Two LCD meters indicate the number of hours the device has been in use and the number of hours of patient treatment; the second meter can be reset between patients.

MAIN FEATURES

- Lightweight bed unit
- One blue-light fluorescent tube
- Wide waveband 400nm to 550nm
- Meter to show length of therapy (hours)
- Meter to show total hours in use
- Hand switch

Options include:
- Washable "baby suit"
- Disposable "baby suit"

Replacement Items

- Blue-light fluorescent tube £18
- Washable "baby suit" £38
- Disposable "baby suit" £15
- Plastic cover £38
- Frame for plastic cover £125

Life span of lamp - Manufacturer recommends lamp change after 1,500 hours of use

SERVICING

Servicing Training Courses
Training courses are available for technical staff if required. The Service Manual is provided free of charge.

Typical Servicing Costs
Units may be returned to Central Medical Supplies Ltd for annual servicing and repairs.

<table>
<thead>
<tr>
<th>Service</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor repair</td>
<td>£95</td>
</tr>
<tr>
<td>Major repair</td>
<td>£120</td>
</tr>
<tr>
<td>Annual service and safety check</td>
<td>£70</td>
</tr>
<tr>
<td>Carriage</td>
<td>£10</td>
</tr>
</tbody>
</table>

Price ex VAT £1,695 Includes
- two washable "baby suits"

Manufacturer
Medela AG Medical technology, Lattichstrasse 4, 6341 Baar/Switzerland

Central Medical Supplies Ltd
CMS House, Basford Lane, Leekbrook, Leek, Staffs.
ST13 7DT

CE Marking
MD Directive, Annex II Notified Body TUV (ID 0123)

How is safety demonstrated?
Independent certification to IEC 601-1:1988/EN 60601-1:1990 (Nemko)
USER ASSESSMENT

We assessed two user groups independently, one for each device. The groups comprised nurses and midwives, both new and existing users. The respondents completed a questionnaire which asked them to score the facilities and attributes on a scale from 0 to 10, where 0 was unacceptable and 10 was excellent.

We subsequently conducted a structured interview with most respondents in which they explained the reasons for their scores. We have included their comments and conclusions in the report. No attempt has been made to prioritise facilities.

Ohmeda BiliBlanket Plus

Eleven new users and ten existing users commented on the Ohmeda BiliBlanket Plus, and a further ten existing users commented on the previous version of the device called the Ohmeda BiliBlanket. This group was drawn from six hospitals. From the users' perspective the Ohmeda BiliBlanket is essentially the same as the Ohmeda BiliBlanket Plus. The newer version has an hours meter, a transilluminator and a few technical changes. The reactions of the users to the Ohmeda BiliBlanket Plus are shown in Figure 1.

Users considered the Ohmeda BiliBlanket Plus an effective phototherapy device. They found it easy to set up and use, but some users considered the unit noisy. Bulbs were changed by the Medical Physics/Clinical Engineering departments. The device was used for continuous treatment and medical procedures were performed during phototherapy. The nursing staff thought this was advantageous. In post delivery units the BiliBlanket Plus was used to treat babies beside their mothers. This was liked by both the staff and parents. Keeping the mother and baby together reduces parental anxiety and promotes the bonding process.

Clinical users found this device relatively easy to use with other neonatal devices. It was used in incubators in the neonatal departments. The cable was passed through a tubing port at the foot end of the incubator. Our users preferred to use it with newer incubators which had larger and more numerous tubing ports. In some post-natal and neonatal departments it was used in conjunction with overhead phototherapy devices to provide higher dose double phototherapy.

Main light box: Users considered the main light box easy to set up and use. Our users commented that the controls and the attachment of the fibre-optic cable was easy.

Photo 1: Ohmeda BiliBlanket Plus Light Box

Several users would have preferred a less heavy device, particularly those in units where patient devices were placed on shelves around the patient. Some users would have preferred a smaller box as the space around the patient, especially in a neonatal unit, is at a premium. They found it easy to position either on the canopy of the incubator or on a small trolley. Users commented that it took up less room than a conventional overhead unit.

BiliBlanket pad: The light cable was easy to attach to the main light box. However, some users would have preferred a longer cable; they would also have liked it to have been more flexible. This was especially the case where the Ohmeda BiliBlanket Plus was used to treat a baby in an incubator.

Photo 2: BiliBlanket Plus Fibreoptic Pad
User Assessment

The size of the light pad was considered to be acceptable for small babies. A larger pad would have been preferred for larger babies. Some users would have liked adjustable or interchangeable pads to suit the size of the baby.

Our users did not think that the pad was particularly comfortable for the baby to lie on nor was it considered flexible enough. Some users would have preferred to have been able to wrap it around the baby.

The light glare from the pad was not considered to be a problem and no member of staff reported any headache or nausea problems while working with the Ohmeda BiliBlanket Plus. Eye protection was not needed for the neonate as the light is positioned behind the baby's head. This was considered an advantage by both staff and parents. **CEDAR Note:** When used with overhead phototherapy units for double phototherapy, eye protection was necessary.

The pad covers and "vests" are specifically designed to be used with the BiliBlanket pad and to allow as much of the therapeutic light through as possible. **CEDAR note:** Using cotton sheets or absorbent paper towels instead of a pad cover or "vest" reduces the light output from the pad, decreasing the effectiveness of the treatment.

**Photo 3: Ohmeda BiliBlanket Plus fibreoptic pad with cover.**

The Ohmeda BiliBlanket Plus pad was considered easy to clean. The pad may be used directly against the neonate's skin or may be covered using either a disposable pad cover or a disposable "vest". The pad covers slide over the pad and attach to the light cable with sticky tabs, as shown in **Photo 3**, and they were well liked by our users.

The "vests" also slide over the pad and attach to the light cable but they have an additional strap section for securing around the baby's mid-section. The "vests" available to existing users were liked; but users found that if they were not correctly positioned they could chafe the baby's axillae. These users would have liked the "vests" to have softer edges. The "vests" were not seen during the evaluation.

**Photo 4: Ohmeda Biliblanket Plus with trans-illuminator accessory attached**

**Transilluminator:** Users found this easy to use and the light cable was sufficiently long. One user commented that the light output was not as bright as from a dedicated transilluminator unit in the neonatal department. However, its light output was considered sufficient.

**Overview:** The reaction of the users to the Ohmeda BiliBlanket Plus was generally satisfactory. There were no large discrepancies between the reactions of the new and existing users.

**Medela Bilibed**

Five new users and nine existing users, drawn from five hospitals, commented on the Medela BiliBed. Their reactions are shown in **Figure 2**.

Existing users considered the BiliBed an effective phototherapy device. It was in use in special care baby units and in post-natal wards. All users used the device in continuous therapy. They found it easy to set up and use.

Medical Physics/Clinical Engineering departments attached the plastic film to the frame for most users' departments. Those users who had set up the frame themselves found it fiddly. Bulbs were changed by Medical Physics/Clinical Engineering departments.

Nursing and midwifery staff particularly noted that the baby settled well on the BiliBed and that there...
**User Assessment**

**Figure 1: Ohmeda BiliBlanket Plus User Responses**

- både Weight, Size, Ease of setup, Controls, Pad size, Length of light cable, Ease of attachment, Flexibility of pad, Flexibility of cable, Perceived comfort of baby, Light output/glare, Ease of use of covers, Ease of cleaning, Perceived effectiveness, Length of trans cable.

- New Users (11) vs. Existing Users (10).

**Figure 2: Medela BiliBed User Responses**

- både Weight, Size, Ease of set up, Controls, Perceived comfort for baby, Light output/glare, Ease of use of suits, Ease of cleaning, Ease of use, Perceived effectiveness.

- New users (5) vs. Existing users (9).
was less parental anxiety for the baby when a Medela BiliBed, as opposed to an overhead device, was used for phototherapy. The mothers were also more content when their babies were being treated beside them. In some units the usual method of treatment with phototherapy required the baby to be placed in an incubator and an overhead phototherapy unit used; the incubator being required to keep the baby warm. The users commented that this had a negative psychological effect on the mothers who then saw their babies as being seriously ill even though their condition was considered mild by the clinical staff.

Clinical staff found the bed and the "baby suits" easy to clean. One user noted that the "baby suits" took a long time to dry.

The Medela BiliBed was used in some units in conjunction with an overhead unit to provide higher dose double phototherapy and the users found this satisfactory. During double phototherapy eye protection was provided for the neonate.

All of our users liked using the Medela BiliBed. Two existing users in different hospitals commented that although they had overhead phototherapy devices available in their unit they preferred to use the Medela BiliBed. Several users commented that they would like to see more published clinical research using the BiliBed to confirm their convictions.

Overview: The general reaction of the users to the Medela BiliBed was good. The largest discrepancy of opinion between new and existing users was over the issue of effectiveness in reducing bilirubin levels.
TECHNICAL EVALUATION

There is currently no specific standard for phototherapy devices so we tested those performance characteristics of the devices we considered important to clinical effectiveness and safety. Measurements were made of the light output for therapy using a Bentham double monochromator spectroradiometer. This was used to measure the light intensity at each wavelength within a pre-set waveband. The temperature rise at the treatment site while the device warmed up and over a period of several hours was also measured. Phototherapy units are not designed to warm babies. These performance tests were carried out on "unloaded" devices, that is, not during a patient's treatment.

Ohmeda BiliBlanket Plus

The Ohmeda BiliBlanket Plus phototherapy device consists of a main unit containing a halogen bulb and a fibreoptic pad for delivering the light to the baby. The light from the bulb is filtered in the main unit and the therapeutic light passed down fibre optic cables. These cables are then woven into a pad, which is encased in a protective plastic cover. The filter in the main unit removes most of the infrared (IR) and ultraviolet (UV) components of the light. A fan cools the components in the main unit.

The temperature of the BiliBlanket pad was measured during the warm up of the bulb and in operation. The temperature was found to be no more than 2°C above room temperature after being run for three hours. This is an acceptable result since the pad is not intended to warm up. Filters in the main box are designed to remove the warming infra-red component of the light from the bulb and prevent it from reaching the pad.

The light output was measured between 320nm to 600nm, a waveband chosen to include all possible therapeutic wavelengths (see Appendix). The output spectrum shown in Figure 3 is as expected from a halogen light source. An Ohmeda protective cover was then placed over the pad and the irradiance remeasured. This irradiance plot is also shown in Figure 3 and shows negligible reduction.

The light intensity output from the BiliBlanket pad is sufficient to reduce the bilirubin level in infants, but it is not considered to be the most effective device because of its size (see Appendix). The irradiance is only slightly reduced by the covers. However, it is important that only the covers (or "vests") are used to protect the pad; other materials such as paper towels or cotton sheets if placed between the infant and the light will attenuate the light to an unknown degree and will probably reduce the effectiveness of the therapy. Ohmeda state that only Ohmeda disposable vests and covers should be used to protect the BiliBlanket Plus pad as "use of other materials may reduce therapeutic light output".

Manuals

The user manuals were supplied free of charge with the device. They contained clear photographs and explanations. The service manual is chargeable.

Servicing

The Ohmeda BiliBlanket Plus was thought by technical staff in a sample of NHS Trusts, to be easy to service. The manufacturer states that the bulbs should be changed when they fail. The bulbs were changed when they failed and this occurred more often than expected.

Medela BiliBed

The Medela BiliBed phototherapy device consists of a rectangular unit which fits neatly into hospital bassinets or cots. The unit contains one compact fluorescent lamp. The lamp is recessed within the bed and covered by a transparent perspex sheet with a diagram of a baby on it. A frame with a plastic stretch film on it is then placed over the perspex and a special "baby suit" attached to the frame using Velcro. Both the diagram of the baby and the "baby suit" are designed to aid the clinical staff position the baby correctly for treatment.

The temperature rise on the perspex cover and the flexible bed cover were measured while the device warmed up. The temperature increased by no more than 6°C above ambient temperature after three hours of operation. The Medela BiliBed is not designed to keep the infant warm and neither should it increase the infant's temperature.

The light output was measured and is shown in Figure 4. The output spectrum is as expected for a compact fluorescent bulb. The "baby suit" designed to hold the infant in place over the light source was then attached and the irradiance remeasured. This is the second spectrum shown. With the "baby suit" in place there is no appreciable attenuation of the irradiance by the gauze. The two spectra are so similar they are difficult to distinguish on the figure.
Technical Evaluation

Figure 3: Ohmeda BiliBlanket Plus Spectra with and without Protective Cover

![Figure 3](image1)

- Irradiance from 400nm to 550nm
  - without cover: 4.63 mW.cm\(^{-2}\) nm\(^{-1}\)
  - with cover: 4.52 mW.cm\(^{-2}\) nm\(^{-1}\)

Figure 4: Medela BiliBed Spectra with and without "Baby Suit" Gauze

![Figure 4](image2)

- Irradiance from 400nm to 550nm
  - without cover: 5.56 mW.cm\(^{-2}\) nm\(^{-1}\)
  - with cover: 5.54 mW.cm\(^{-2}\) nm\(^{-1}\)

Curves are very nearly coincident

Figure 5: Spectral Irradiance Comparison

![Figure 5](image3)
Manuals  User manuals and service manuals were supplied free of charge. They are clear and concise.

Servicing  The Medela BiliBed was thought easy to service by technical staff in the two NHS Trusts which we sampled. The manufacturer states that the lamp should be changed after 1,500 hours of use. Occasional replacement of perspex covers, plastic film and frames will be required and these are available from the supplier.

SPECTRAL COMPARISON
The two devices were compared technically on the basis of their irradiance, spectral plots, see Figure 5, and effective light areas.

Table 1

<table>
<thead>
<tr>
<th>Irradiance, mW/cm²</th>
<th>BiliBlanket</th>
<th>BiliBed</th>
</tr>
</thead>
<tbody>
<tr>
<td>320nm to 400nm (UV)</td>
<td>0.0248</td>
<td>0.0004</td>
</tr>
<tr>
<td>400nm to 550nm</td>
<td>4.83</td>
<td>5.56</td>
</tr>
<tr>
<td>Approximate effective Surface area (cm²)</td>
<td>176</td>
<td>704</td>
</tr>
</tbody>
</table>

The UV component of the radiation emitted by each device shown in Table 1 can be considered insignificant. They are below published safety limits.

The irradiance from each device in the waveband of interest, 400nm to 550nm, is similar. The effective surface area is the treatment area available from the light source. For the Ohmeda BiliBlanket Plus the effective surface area is the area of the pad, for the Medela BiliBed it is the area of the gauze panel.

The Medela BiliBed has the larger effective surface area although it must be appreciated that not all of the light in this area will reach the baby. The geometry becomes more complicated than a flat plane because the "baby suit" is attached to a plastic surface, which gives under the baby's weight to provide a comfortable surface to lie on. The whole of the Ohmeda BiliBlanket surface area should be in contact with the baby.

The shape of the spectra from the two devices are very different, the Medela BiliBed lamp produces a peak at around 430 to 450nm, which is in the usually accepted range for treating hyperbilirubinemia. The Ohmeda BiliBlanket Plus spectrum peaks in the green area of the visible spectrum. There is currently debate over whether this is more effective therapeutically (see Appendix). The gently rising slope is as expected from the halogen bulb light source.

Both devices may be used for double phototherapy when used in conjunction with an overhead phototherapy device.

MANUFACTURERS’ COMMENTS
Datex-Ohmeda: Thank you for your kind invitation to comment on the draft of the report. We would like to make the following points.
1. New pad sizes are currently being evaluated, and are restricted because of loss of efficiency due to output versus area.
2. The BiliBlanket Plus is designed so that changing the bulb should be easy and possible without special tools or technical help, making it especially useful in busy units and in the community.
3. Wrapping a fibre optic bundle pad around a baby would probably restrict the efficiency of the treatment as the pad may not exactly fit the baby. Fixing it around the baby would be impractical and treatment may need to be interrupted to carry out routine checks. The action of wrapping and unwrapping may also increase the potential for damage to the light bundles. CEDAR Note: At least one phototherapy device using a wraparound pad exists but it is not available in this country.

Medela/Central Medical Supplies: Thank you for the opportunity to review the draft of the report. Medela AG were very satisfied with your conclusions.
This section is a summary of a full literature review currently being submitted for publication in a peer reviewed journal, and the full text and reference sources are available on request, from CEDAR. The recommendations given here are based on papers published in clinical or scientific journals, however, this summary should not be viewed as exhaustive or definitive.

A SUMMARY OF CURRENT THINKING ON NEONATAL PHOTOTHERAPY.

Neonatal hyperbilirubinaemia is an excess of bilirubin in the blood and it causes the baby to look jaundiced. Phototherapy takes advantage of the effect that certain wavelengths of light have on the bilirubin molecule.

The production of bilirubin is a normal process; it is a breakdown product of haemoglobin. Normally bilirubin is conjugated by the liver and excreted in bile. Before birth, foetal bilirubin is removed by the placenta and is excreted by the mother. Immediately after birth the biochemical process for removal of bilirubin by the neonate’s liver must be "switched on". The baby is then able to excrete bilirubin itself. In some babies the liver is unable to conjugate sufficient bilirubin because of immaturity and the blood serum bilirubin level rises. By circulating in the blood the bilirubin reaches almost all organs in the body, including the skin, causing the characteristic yellow jaundice colour. It is important to monitor levels of bilirubin in jaundiced neonates because, if the blood plasma concentration exceeds a certain level, there is a danger of bilirubin causing brain damage.

Before the 1940s bilirubin encephalopathy was a leading cause of neonatal death and cerebral palsy. Since then exchange transfusions, reduction in rhesus haemolytic disease and better cross-matching of blood transfusions have greatly reduced the incidence of mortality and brain damage from hyperbilirubinaemia. In 1958 a nursing sister noticed that the yellow colouring of a baby's skin faded following exposure to sunlight. This led to the development of phototherapy. By studying the effect of light on bilirubin in the laboratory an "action spectrum" of light on bilirubin in vitro was derived. The "action spectrum" peaks around 450nm. Light containing this wavelength should be the most effective.

The efficiency of phototherapy to reduce bilirubin levels is directly related to three factors: the intensity and waveband of the light used and the surface area of skin illuminated.

Intensity
Research has shown that given that the light is in the effective waveband, the decline in the bilirubin level is proportional to the irradiance of the light.

Guidelines published by DoH in 1992 stated that the irradiance should be no lower than 0.45mW.cm⁻² for mild hyperbilirubinaemia and it should be higher than 1mW.cm⁻² for more serious cases. The irradiance can be increased by either using a more intense light source, or by bringing the light source closer to the patient. Care must be taken when reducing the distance between the light source and the patient as certain light sources produce appreciable levels of infrared radiation that can burn patients. Hazard Notice HN9606 covering this problem was issued by the MDA and is summarised in Box A1.

Box A1-
HAZARD MDA HN 9606-A SUMMARY
Phototherapy - Potential burns to patients.
Problem: The MDA has received reports of phototherapy devices not being used according to the manufacturers' instructions, resulting in burns to patients.
Action: Managers and staff are advised to ensure that the manufacturers' instructions for the use of phototherapy devices are available and followed. In particular ensure that;
• The lamp is at the correct height above the patient.
• Filters required for safe operation are in place.
• The correct type of replacement lamps are used as recommended by the manufacturer
• Device is regularly inspected/ maintained.
• Users are fully trained in the safe use of the device.

It is also important that the intensity and the waveband in which the intensity is measured are clearly stated so that direct comparisons between devices can be made. If irradiance is stated in either µW.cm⁻², (as used by the American Academy of Pediatrics) or mW.cm⁻² for an agreed waveband, devices can be compared.

Colour: Waveband of Light
Bilirubin only absorbs light within a given waveband. The "action spectrum" was derived from in vitro tests on bilirubin and peaks around 450 nm, which is in the blue region of the visible spectrum.
However, blue light may not be the most effective against bilirubin in vivo. Longer wavelength light, in the green region, penetrates the skin further. There has been extensive debate about whether blue or green light is more effective. Further work claimed that using a blue-green phototherapy light was highly therapeutic. This work using the waveband 480-520 nm, claimed a reduction in bilirubin levels exceeding those achieved with blue lamps. However, this technique does not appear to have been fully accepted yet by the clinical community. Care must be taken when considering green light for neonatal phototherapy because photo-toxic effects have been reported.

**Area of Skin Illuminated**

The area of skin illuminated needs to be as large as possible to maximise the efficiency of the phototherapy. Many overhead devices can illuminate up to one third of the infant's skin. Methods using a light source above and below the infant, termed double phototherapy, further increase the area of skin irradiated.

**Phototherapy Devices**

Two types of phototherapy device are currently available: the conventional phototherapy illuminators, in use for over 40 years, and the fibreoptic phototherapy devices, which have been available for nearly 10 years.

Conventional phototherapy equipment is either in the form of a Tungsten halogen spotlight, a metal halide gas discharge lamp or fluorescent lamps. Spotlights typically have ultraviolet (UV) emissions filtered out in the bulb housing to prevent unnecessary irradiation of the infant. Metal halide discharge lamps were developed from mercury gas discharge lamps and are housed in a canopy with separate UV filters. Fluorescent tube devices use a single tube or a set of 4 or 8 tubes and again the light emission is filtered to reduce the UV component to safe levels.

The lights are positioned above or below the baby and the effective irradiance depends on the distance between the baby and the lights. The relationship is related to the inverse square law but is made more complex because the light is rarely a point source. Obviously, the closer the lights can be positioned to the infant the more effective the phototherapy. Care must be taken to prevent overheating the infant whilst ensuring that as much of the skin is illuminated as possible. Obeying the operating instructions is essential (MDA Hazard HN9606 June 1996. See Box A1).

Fibreoptic neonatal phototherapy devices consist of a Tungsten-halogen light source, whose emission is filtered to remove UV and infrared (IR). The remaining wavelengths are guided down a fibre optic bundle and into a flat pad of woven optical fibres. The pad is, therefore, cool to the touch and may be used directly in contact with the baby's skin or through a transparent cover. These pads often have a high level of irradiance but the effectiveness can be limited by the size of the pad.

**Efficiency of available systems**

Several research studies have compared the efficiency of fibreoptic pads with conventional phototherapy. One clinical trial used four systems

- a standard fibreoptic pad
- a larger fibreoptic pad
- two fibreoptic pads, one front, one back
- a conventional overhead system

The double fibreoptic and the conventional phototherapy systems were the most effective. The effectiveness of fibreoptic pads was lower than conventional phototherapy in full-term infants, even though the fibreoptic irradiance was greater. The researchers attributed this effect to the relatively small area of the pad, and thus the surface area of the baby irradiated. The authors recommended fibreoptic phototherapy can be used in mild to moderate cases. High intensity phototherapy, illuminating as much of the infant as possible, is optimum for rapid reduction of bilirubin in severe cases.

The speed at which phototherapy reduces the bilirubin level is important for improving the health of the patient, reducing separation time from the parents and efficiently using hospital resources. Several published reports include tables, graphs and flow diagrams to help clinicians decide when phototherapy is appropriate.

**Side Effects and Safety**

Phototherapy is generally considered a safe therapy for hyperbilirubinaemia. There are, however, a few safety issues and potential side effects.

The intensity of the light directed into the baby's eyes can lead to retinal damage. Therefore, when a baby is placed under a set of phototherapy lamps it is important that its eyes are covered. Two methods are available: opaque eye pads fixed over the eyes, or an amber coloured Perspex shield placed over the baby's head. There is a danger with the eye pads that they may move and suffocate the baby.
baby; they have also been shown to increase the incidence of eye infection. Some research suggests that there is very little difference in the transmittance characteristics of commercial and "home made" eye protection. The amber Perspex shield is more acceptable to parents, but again the baby must be carefully monitored so that it does not "shuffle" out from the protective area.

During phototherapy treatment the baby's temperature is likely to rise because there is a marked increase in skin blood flow and, to some extent, muscle blood flow. Therefore, the temperature of a baby undergoing phototherapy must be carefully monitored. If the infant is in an incubator or a radiant warmer the potential for overheating must be considered and the device adjusted accordingly. Guidelines for this are often covered in the incubator/radiant warmer manufacturer's instructions. In an open cot, however, an unclothed child may lose too much heat as the phototherapy lamps are not designed to provide a comfortable thermal environment for the child.

Elevated skin temperature can increase insensible water loss from the skin. The clearance of bilirubin may also produce diarrhoea as the bilirubin irritates the bowel and adds to total water loss. Fluid balance must, therefore, be monitored and maintained.

Babies with hepatitis or cholestatis, where the biliary ducts may be obstructed should not be treated with phototherapy as they may develop "bronze baby syndrome". However, this skin colouration fades a few months after phototherapy.

Rashes have been reported after phototherapy but these have been found to be infrequent and minor and they rapidly resolve.

Parents may be concerned that their baby is "uncared for" when they see him/her being treated with conventional phototherapy, as the baby may be naked, or nearly so, and have their eyes bandaged. Treatment may also be in a more isolated part of the unit to reduce exposure to other babies and staff. The separation of the parents and child both physically and through loss of eye contact adversely affects the "bonding" process.

The use of fibreoptic phototherapy devices is often more acceptable to parents and nursing staff as they are able to nurse, feed, and cuddle the baby during treatment. When the fibreoptic pad is used alone the baby's eyes do not need to be covered since the light source is placed against their back. This is also true of devices where the light source is positioned beneath the baby.

Nursing staff tend to find the fibreoptic devices more acceptable and easier to use than the conventional overhead phototherapy devices. The intense blue light produced by overhead devices impedes detection of increasing "blueness" in the skin from hypoxia. Conventional overhead phototherapy devices often combat this by including extra lamps that allow assessment of the baby's condition whilst being treated. One example is the use of "gold" lamps, which try to rebalance the observed colour of the blue lamps. In some devices the treatment lamp is called a "daylight" lamp as its spectrum tries to mimic daylight whilst giving an enhanced blue component. Devices with "daylight" or colour adjusted lamps are more pleasant for the nursing staff to use. Some nursing staff have reported experiencing headaches and nausea when working with intense blue light.

Retinal hazard to staff from phototherapy devices positioned over incubators is insignificant. The effect on nearby neonates, who are not receiving phototherapy, has not been studied but it has been indicated that it has less effect than placing the child by a window.

Conclusions
Neonatal phototherapy has been studied in many centres over the last 40 years. The efficiency of phototherapy is directly related to the intensity of the light in the most effective waveband and the area of infant's skin irradiated.

Conventional phototherapy devices have been shown to produce the highest intensity and to rapidly reduce bilirubin levels. Such equipment includes all overhead devices and the Medela BiliBed because the technology is essentially the same. Fibreoptic pad devices, such as the BiliBlanket, are more acceptable in use for nursing staff and parents, but because they are currently small, they are not as effective as overhead devices which can illuminate more of the infant.

Phototherapy effectiveness can be further enhanced using either two conventional phototherapy units, above and below the infant, or a combination of overhead and fibreoptic phototherapy.
SURVEY OF NEONATAL PHOTOTHERAPY DEVICES IN USE IN THE NHS

The spectral irradiance of devices currently in use in NHS Trusts were measured at a distance of 30 cm, if appropriate, in the range 400 nm to 550 nm. Some devices are still available and some have been superseded but are still in use. Phototherapy devices tend to be of simple construction with little maintenance required and as such are used for many years after manufacturers have ceased production. Table A1 shows a summary of devices found in use in the NHS and Figures A4, A5 and A6 show an example of their spectral irradiance curves.

<table>
<thead>
<tr>
<th>Phototherapy Device</th>
<th>Available to buy</th>
<th>Irradiance in the 400nm to 550nm waveband</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draeger Phototherapy 800 - Heraeus</td>
<td>No</td>
<td>7.54 mW.cm(^{-2}) (405 hours lamp life)</td>
</tr>
<tr>
<td>Draeger Phototherapy 4000</td>
<td>Yes</td>
<td>2.81 mW.cm(^{-2}) (775 hours lamp life)</td>
</tr>
<tr>
<td>Vickers Medical 80/0155</td>
<td>No</td>
<td>1.18 mW.cm(^{-2}) (7 months lamp life)</td>
</tr>
</tbody>
</table>

**Table A1**

**Figure A4:** Irradiance Spectrum for a Draeger Heraeus Phototherapy Unit measured at 30cm and approximately 405 hours lamp life.

**Figure A5:** Irradiance Spectrum for a Draeger Phototherapy 4000 measured at 30cm at approximately 775 hours lamp life

**Figure A6:** Irradiance spectrum for a Vickers Medical 80/0155 measured at 30cm. - lamps approximately 7 months old. No hour meter.
ACKNOWLEDGEMENTS

This report was prepared by Dr S D P Wentworth, Dr N J Cook and Dr D C Crawford of CEDAR (Clinical Engineering Device Assessment and Reporting), Medical Physics and Clinical Engineering Directorate, University Hospital of Wales and Llandough Hospital NHS Trust, under contract to the Medical Devices Agency.

- Enquires to Dr Stephanie Wentworth, CEDAR, Cardiff Medicentre, University Hospital of Wales, Heath Park, Cardiff CF14 4UJ. e-mail stephanie.wentworth@uhw-tr.wales.nhs.uk, Tel: 029 2068 2120 or Fax: 029 2075 0239 (or Tel: 01222 682120 or Fax: 01222 750239)
- Or Mr Arthur Goodman, Evaluation Manager, Medical Devices Agency, Hannibal House, Elephant & Castle, London SE1 6TQ. e-mail Arthur.Goodman@doh.gsi.gov.uk Tel 0207 972 8156 (or Tel 0171 972 8156)

We would like to thank Dr Mark Drayton, the Neonatal Intensive Care Unit and the Maternity Unit (University Hospital of Wales), Special Care Baby Units and Post Delivery units in Gloucestershire Royal Hospital, Cheltenham General Hospital, East Glamorgan General Hospital, Singleton Hospital, Eastbourne District General Hospital, Princess Royal Hospital, Haywards Heath and Salisbury District Hospital for their co-operation in carrying out the user assessment. With special thanks to Mr D K Taylor, Mr T Fenech, Sr M Dibden and Sr J Phillips. We also thank those, with experience in the field of neonatal phototherapy, who peer reviewed the literature review included in this issue.

We also wish to thank Dr C J Hacking for his work on this report prior to taking up a new position in the NHS.

Finally, we would like to thank Central Medical Supplies and Datex-Ohmeda for supplying samples of their phototherapy units free of charge for evaluation.

HOW TO OBTAIN MDA EVALUATION REPORTS

MDA Evaluation Reports are free of charge to NHS Trusts and Clinics

<table>
<thead>
<tr>
<th>In England</th>
<th>In Scotland</th>
<th>In Wales</th>
<th>In Northern Ireland</th>
</tr>
</thead>
</table>
| Medical Devices Agency
Room 1207
Hannibal House
Elephant & Castle
London SE1 6TQ
Tel: 020 7972 8181 or Tel: 0171 972 8181 | E TB Support Services
Room D073A, Scottish Health Care Supplies
Trinity Park House
South Trinity Road
Edinburgh
Tel: 0131 5518908 | Welsh Office
Health Services & Management 1 Division
Cathays Park
Cardiff CF1 3NQ
Tel 029 2082 3641 or Tel: 01222 823 641 | Defect Centre
Estate Services Directorate
Health Estates
Stoney Road
Dundonald
Belfast BT16 0US
Tel: 028 9052 3714 or Tel: 01232 523 714 |

DISTRIBUTION OF THIS REPORT

This report should be distributed to the following departments:
Clinical Engineering, EBME, Medical Physics, Maternity, Neonatal Units, Special Care Baby Units, Nursing, Obstetrics & Gynaecology, Paediatrics, Scientific Officers, Health Authority Libraries, Supplies.

© CROWN COPYRIGHT 1999

Apart from any fair dealing for the purpose of research or private study, or criticism or review, as permitted under the Copyright, Designs & Patents Act, 1988, this publication may only be reproduced, stored or transmitted in any form or by any means with the prior permission, in writing, of the Controller of Her Majesty's Stationery Office (HMSO). Enquiries about reproduction should be made to the MDA at the above address.