SUMMARY

Advantages: Compact, easy to use, lightweight, flexible unit with a low wheel-base. Considered to be effective by users, and has a tube replacement indicator.

Disadvantages: No treatment or lamp life timer, noticeable patient heating effect.

BRIEF DESCRIPTION

The Medela overhead phototherapy lamp is a lightweight, compact unit with four 18W folded blue fluorescent tubes. It is attached to a mobile stand and the head can be adjusted vertically, extended horizontally and tilted in the horizontal plane. There is no treatment timer or tube life timer but an indicator is illuminated when the tubes need to be changed.

MAIN FEATURES

- 4 x 18W folded blue fluorescent tubes
- Lightweight unit
- Two switches for two or four lamps lit
- Tube replacement indicator
- Mobile stand with wheel locks

Replacement items
18W folded blue fluorescent tube £18.50 each

Life span of tubes - Manufacturer recommends changing the tubes when red indicator light is permanently illuminated. Expected tube life is approximately 1,500 hours

Price ex VAT £1,395

Manufacturer
Medela AG Medical Technology, Lattichstrasse 4, 6341 Baar, Switzerland

Supplier
Central Medical Supplies Ltd, CMS House, Basford Lane, Leekbrook, Leek, Staffs ST13 7DT
Tel: 01538 399541
Fax: 01538 399572
Web page: www.centralmedical.co.uk

CE marking? Yes MD directive

Notified Body
TÜV Product Service GMBH: (0123)

Manufactured to Standard?
Manufactured under EN ISO 9001, EN 46001, EN/IEC 60601-1
DESCRIPTION

The Medela Phototherapy Lamp is a conventional overhead phototherapy device. The head contains four folded 18W blue fluorescent tubes. The two inner tubes may be replaced with two white tubes to allow easier assessment of the baby’s skin during treatment, but using four blue tubes provides more effective therapy. Two switches activate the tubes, switching on the outer or inner two tubes as indicated by diagrams beside them.

A reflective grid positioned over the tube housing is designed to focus the light on the baby and reduce light spread and glare.

The Medela Phototherapy Lamp has no timer to monitor the length of time a patient is treated or how long the tubes have been in use. The blue light level is monitored opto-electronically by a sensor located close to the tubes. When irradiance in the waveband 425-475nm drops to approximately 75% of the irradiance of a new fluorescent tube an indicator light is illuminated beside the switches. When blinking it indicates a significant decrease in irradiance, when on continuously it means that the tubes need changing. The tube manufacturer states that the expected tube life is approximately 1,500 hours.

The lamp is mounted on a mobile stand with two lockable wheels. The wheel-base is 95mm high, low enough to pass underneath all currently available incubators. The lamp height can be adjusted vertically from 107 to 159cm above the ground and the arm length can be extended from 30 to 51cm from the stand upright allowing it to stretch over the canopy of an incubator. Hand sized blue "clamps" twist to release or fix the vertical and horizontal positioning bars. In addition the head can be turned up to 90°, allowing positioning for illumination from the side of an incubator.

There is no symbol on the lamp head warning the user to cover the baby's eyes during therapy - but this is stated in the manual.

USER ASSESSMENT

48 neonatal nurses in four hospitals participated in our user assessment. Three hospitals had purchased Medela Phototherapy Lamps, and 39 nurses with at least five months experience completed our questionnaire. A further nine users had used a Medela on trial for six weeks.

Our questionnaire asked users to rate features of the phototherapy unit as unacceptable, poor, satisfactory, good or excellent. To clarify issues raised by the questionnaire an evaluator visited each neonatal unit. The averaged response of the nurses is shown in Figure 1.

![Figure 1 Averaged user response, new and existing users.](image)

- New users
- Existing users

MDA evaluation 01161, December 2001
The mobility of the lamp was the most highly rated feature, all users considered this and the stability of the unit to be satisfactory, good or excellent. The lamp was also considered easy to store and clean.

New users rated the vertical height adjustment (VHA) better than existing users. All but two existing users considered it satisfactory or better. The two nurses who rated it as poor found the VHA’s clamp twist design awkward to use.

The horizontal extension mechanism of the lamp made it possible for nurses to site the lamp at the end of an incubator and stretch the head over the top. The flexibility to tilt the lamp head to 90° was well liked and allowed users to position the lamp head to the side of the incubator.

Lamp: Our users rated the on/off switches highly. The two-tube configuration was used in two hospitals for babies with borderline serum bilirubin levels, but most babies were treated using all four tubes.

Both groups considered the Medela Phototherapy Lamp effective in clearing bilirubin. In the three units where it had been purchased, it replaced older phototherapy devices.

The glare from the lamp was the worst rated feature of the device. Although most users considered the glare to be satisfactory and it was not a problem for them, five (15%) existing users rated it as poor.

Additional heating of the baby was noticed by some nurses when this lamp was positioned over an incubator. Although users reduced the incubator control temperature in some cases this was not enough to reduce the baby’s temperature. In one hospital nurses noted that it was more of a problem with larger babies and hotter ambient conditions. See Technical Assessment.

The distance at which treatment was given varied from unit to unit. The user guide does not state a minimum treatment distance, but states that The distance should be kept as small as possible (ie approx 25cm) for maximum therapeutic effect. Often the lamp was positioned directly over an incubator; some users set it a few centimetres clear of the canopy and others as close to the canopy as possible. Users were able to provide double and triple phototherapy using a combination of lamps, as they were small and flexible enough to fit easily around an incubator. The Medela lamp was positioned closer when the baby was in a cot. None of the nurses had used the lamp with a radiant warmer.

TECHNICAL ASSESSMENT

Our technical tests are designed to assess the clinical performance and safety of the device. A primary concern for a phototherapy lamp is the light output, or irradiance. Baby heating effects have been associated with phototherapy lamps prompting us to also measure the heating effect of this lamp in a simulated clinical situation.

Figure 2 Irradiance Spectra at 25cm and 40cm
The Medela Phototherapy Lamp irradiance was measured using a Bentham double monochromator spectroradiometer at distances of 25cm and 40cm, shown in Figure 2. The spectrum is typical for a blue fluorescent tube. 25cm is a distance suggested by the user manual and 40cm approximates to the distance of an incubator canopy above the mattress. Total irradiance from 400-550nm, blue-green, and 320-400nm, ultraviolet (UV)A, are shown in Table 1. Moving the lamp from 40cm to 25cm from the baby doubles the blue-green irradiance incident on the skin. The irradiance measured at both distances is considered effective with respect to current guidelines recommending a minimum irradiance of 1mW.cm\(^{-2}\). Measured UVA levels are insignificant and are below published safety levels for adults, separate levels for infants have not yet been agreed by international bodies.

### Table 2 Irradiance

<table>
<thead>
<tr>
<th>Bandwidth (nm)</th>
<th>Irradiance through air At 25cm</th>
<th>Irradiance through air At 40cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>320-400 (UVA)</td>
<td>0.016 mW.cm(^{-2})</td>
<td>0.007 mW.cm(^{-2})</td>
</tr>
<tr>
<td>400-550</td>
<td>4.66 mW.cm(^{-2})</td>
<td>2.08 mW.cm(^{-2})</td>
</tr>
<tr>
<td>Effective surface area</td>
<td>~2000cm(^{2})</td>
<td>&gt;2800cm(^{2})</td>
</tr>
</tbody>
</table>

The heating effect was measured by monitoring the core temperature rise of a matt black aluminium disc positioned at the centre of the mattress in a thermally stable incubator. The Medela lamp was sited directly over the canopy, above the disc, 40cm from the mattress. After 3.5 hours of illumination the temperature rise due to the lamp had stabilised at 2.6°C above the initial disc temperature.

Without the incubator canopy in place and with no additional heat source, simulating phototherapy with an unheated cot, a temperature rise of 5.2°C was recorded. However, this small heating effect alone may not be enough to keep a baby warm during therapy. At 25cm a 9.6°C temperature rise was recorded.

**CEDAR Note** : Users were aware of a rise in temperature when using this phototherapy device.

**MANUFACTURER’S COMMENTS**

Thank you for giving us the opportunity to preview the draft of the report. Medela is very satisfied with your work.

**ACKNOWLEDGEMENTS**

This report was prepared by Dr SDP Wentworth & Dr DC Crawford of CEDAR, Medical Physics and Clinical Engineering Directorate, Cardiff & Vale NHS Trust, under contract to the Medical Devices Agency (MDA).

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We thank all the nursing staff in the Neonatal Units of, University Hospital of Wales, Cardiff, Sandwell General Hospital, West Bromwich, Sunderland General Hospital and North Tyneside General Hospital, who helped in this evaluation.

Thanks also to Central Medical Supplies for loaning this device for evaluation free of charge.

**OTHER MDA REPORTS ON NEONATAL PHOTOTHERAPY DEVICES**

This phototherapy device may be compared with others by obtaining the following Evaluation Reports from the MDA Tel : 020 7972 8181. Available free to NHS staff. Also available on http://cymruweb.wales.nhs.uk/cedar/index.htm

391 A review including the Ohmeda BiliBlanket Plus and Medela BiliBed
00091 Hill-Rom Micro-Lite
00092 Ohmeda spot phototherapy lamp
coming soon Mediprema Cradle 360
Draeger 4000 phototherapy lamp

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