Neonatal Phototherapy

Datex-Ohmeda Spot Phototherapy Lamp

**SUMMARY**

**Advantages:** Adjustable lamp head, can be used with incubators or infant radiant warmers. Variable white light field treatment area. Can be wall, rail or stand mounted. Considered effective by users.

**Disadvantages:** Bulky stand, short bulb lifetime in clinical use, noticeable patient heating effect.

**BRIEF DESCRIPTION**

The Datex-Ohmeda Spot Phototherapy lamp uses a 150W, 20V tungsten halogen lamp. It may be mounted on a mobile floor stand, a wall or rail. The lamp head houses a halogen bulb, a cooling fan, a filtering lens and an aperture control wheel to allow a choice of four sizes of the spotlight beam. The head can be rotated and is mounted on an articulated arm.

**MAIN FEATURES**

- Mains power supply
- 150W tungsten halogen bulb
- Choice of 4 apertures
- Wide waveband
- Adjustable head

**Options**

The Ohmeda Spot Phototherapy Lamp is also available mounted on a rail or a wall.

£1,547.88 (ex VAT)

**Replacement Items**

- Bulb (box of 6) £192.84

**Life span of bulb** - manufacturer states bulb life of 100 to 500 hours, depending on conditions of use. Vibration of lamp may decrease bulb life.

**Price ex VAT** £1,622.87 (on mobile stand)

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Ohmeda Medical 9065 Guilford road, Colombia MD 21046 USA</th>
</tr>
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<tbody>
<tr>
<td>Supplier</td>
<td>Datex-Ohmeda Ltd, 71 Great North Road Hatfield, Herts. AL9 5EN Tel: 01707 263570 Fax: 01707 260065 <a href="http://www.datex-ohmeda.com">www.datex-ohmeda.com</a></td>
</tr>
<tr>
<td>CE marking:</td>
<td>MD Directive, Annex II Notified body BSI (0086)</td>
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**DESCRIPTION**

The Datex-Ohmeda Spot Phototherapy lamp is a conventional neonatal phototherapy device. The sample evaluated was mounted on its own mobile stand as seen on the cover. The lamp head is attached to an articulated arm mounted on the pole. Other configurations are available in which the articulated arm and lamp is mounted on the wall or mounted on an incubator or radiant warmer rail. The unit has a simple toggle on/off switch which, in the model seen, was located in the base and could be foot operated. Other configurations have the on/off switch on the pole or on the wall.

The lamp head contains a 150W tungsten halogen bulb and filters to reduce ultraviolet (UV) and infrared (IR). An aperture wheel located on the lamp head allows the user to select one of 4 apertures. These apertures produce light fields of diameter 4, 6, 10 and 23cm when the lamp is 40cm from the mattress, approximately the height of an incubator canopy above the mattress. The head of the unit carried a warning to shield the baby's eyes to prevent damage from UV.

CEDAR note 1: UV emission from the lamp should be negligible. Baby's eyes should be shielded to prevent retinal damage from exposure to bright light, as the eye is prone to damage from blue light.

A cooling fan operates while the lamp is switched on. The unit does not have either a bulb or treatment timer.

**USER ASSESSMENT**

21 clinical users in two hospitals participated. Seven users had used the device on a mobile stand and 14 were familiar with the wall mounted configuration. All had used the device for at least 3 months, and many for several years. The arm and lamp in each case was the same model. Each group had purchased the device. 19 of the users were neonatal nurses and two were paediatricians. Both hospitals had purchased the device.

The users completed a questionnaire rating the facilities and attributes as unacceptable, poor, satisfactory, good or excellent. To clarify issues both neonatal units were visited by an evaluator after the questionnaires were completed. The averaged response to each question is shown in Figure 1.

**Lamp** The users considered the device an effective phototherapy unit and tended to use it for neonates with high bilirubin levels. Glare was not considered to be a problem by most users and two users commented that glare was less than with some other phototherapy units.

Users of both the mobile stand version and the wall mounted version commented that failing
bulbs was a significant problem. They were aware that halogen bulbs are sensitive to movement and vibration. Where possible they allowed the bulbs to cool before moving the phototherapy unit, following the advice of the manufacturer and their Trust's Clinical Engineering departments. One user of the mobile stand version commented that as a consequence of the problem with failing bulbs, the lamps were not used as often as other phototherapy devices. Equipment maintenance departments changed the bulbs in both neonatal units. In one unit many nurses were trained to do this to prevent interruption of therapy, but some commented that they found changing the bulb fiddly.

Users also noted that the area illuminated heated up and the baby's temperature had to be carefully monitored. Clinical and nursing staff in both neonatal units were well aware of this heating effect and it was sometimes used to deliberately augment warming in a carefully controlled way. CEDAR note 2: Halogen bulbs tend to produce more heat than other phototherapy light sources and the baby's temperature must therefore be carefully monitored.

**Mounting** Wall mounted versions were used frequently as they were conveniently positioned next to each intensive care cot. Users appreciated being able to fold the device away against the wall, so taking up less space than a mobile unit. However, care was required to ensure the lamp stayed in place and did not swing out. Ward staff occasionally found it necessary to tighten a screw in the wall to ensure the lamp was held in position.

Nurses using the lamps with a mobile stand found the base stable but some consider the "base of stand quite bulky".

**TECHNICAL ASSESSMENT**

Our technical testing is designed to test criteria we consider important to clinical effectiveness and safety, and takes into account the forthcoming neonatal phototherapy standard EN 60601-2-50.

The light intensity (irradiance) at 40cm was measured for each wavelength from 300nm to 700nm using a Bentham double monochromator spectroradiometer (see **Figure 2**). The shape is typical for a halogen light source with ultraviolet (UV) and infrared (IR) filters.

Total irradiance from 400nm to 550nm (blue-green) and from 320nm to 400nm (UV) are shown in **Table 1** (page 4) for treatment distance of 40cm and 50cm from the lamp lens. The irradiance in the therapeutic blue-green waveband is high compared to some other phototherapy devices. UV levels are also high; but limits on UV exposure for infants undergoing phototherapy have not yet been agreed by international bodies. The UV emission here is, however, below published safety levels for adults.

**CEDAR note 3:** The user manual does not recommend a treatment distance, therefore, a distance of 40cm was used in our measurements because it is approximately the treatment distance when used with an incubator hood. Datex-Ohmeda provide irradiance levels for treatment distances of 50.8cm (20") to 89cm (35").

![Figure 2 Irradiance Spectra through air, using the largest aperture](image-url)
Table 1 Irradiance using largest aperture

<table>
<thead>
<tr>
<th>Bandwidth (nm)</th>
<th>Irradiance through air</th>
<th>Effective surface area</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>At 50cm</td>
<td>At 40cm</td>
</tr>
<tr>
<td>320 - 400</td>
<td>0.12 mW.cm⁻²</td>
<td>0.18 mW.cm⁻²</td>
</tr>
<tr>
<td>400 - 550</td>
<td>7.75 mW.cm⁻²</td>
<td>11.71 mW.cm⁻²</td>
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Irradiance available for treating patients will be less than the values shown in Table 1 when an incubator and/or smaller aperture are used.

This lamp produces more red and yellow light (above 550nm in Figure 2) compared with some other phototherapy devices. This prompted our assessment of the lamp's heating effect. To simulate phototherapy of a neonate in an incubator we monitored the temperature of five matt black aluminium blocks (as described in BS EN 60601-2-21 1997) placed in an incubator at a stable temperature. The Ohmeda Spot Phototherapy Lamp was placed 40cm above the central disc and the largest aperture selected. A temperature rise of 10 °C, in the central disc was recorded, only the central disc of the arrangement was illuminated, the other four discs were not and their temperatures did not rise. Without the incubator canopy and with no additional heat source, simulating phototherapy with an unheated cot, the temperature rise was 9°C above the room temperature.

CEDAR note 4: These are significant temperature rises and close monitoring of the baby's temperature is particularly important when using this lamp. The users were well aware of the inadvertent heating effect (see User Assessment).

MANUFACTURER'S COMMENTS

Thank you for your kind invitation to comment on the draft of the report. We would like to make the following points:

1. During in-servicing of the Spot Phototherapy Lamp, Ohmeda Medical recommends* the minimum treatment distance between the patient and the Lamp be 50.8cm (20 inches), and not the 40cm distance used throughout the testing in this report.

*see CEDAR note 3: p3

2. The 10°C temperature rise quoted in this report was obtained while testing the Lamp at only 40cm distance, and not the recommended* 50.8cm. The reader should note that the simulation model used in the test is not representative of the human newborn. The test model is a black aluminium disc, that lacks the skin surface area and the vasoactive mechanism capable of heat dissipation as in the human newborn. Additionally, babies do not absorb as much heat as the black discs.

ACKNOWLEDGEMENTS

This report was prepared by Dr S D P Wentworth, Dr D C Crawford and Dr N J Cook of CEDAR, Medical Physics and Clinical Engineering Directorate, Cardiff & Vale NHS Trust, under contract to the Medical Devices Agency (MDA).

- Enquiries to : S Wentworth at CEDAR, Cardiff Medcentre, Heath Park, Cardiff, CF14 4UJ. Email : cedar@cardiffandvale.wales.nhs.uk Tel: 029 2068 2120 Fax : 029 2075 0239
- Or : Arthur Goodman at the MDA, Hannibal House, Elephant & Castle, London SE1 6TQ Email: arthur.goodman@doh.gsi.gov.uk Tel : 0207 972 8156 Fax : 0207 972 8105

We thank all the medical and nursing staff at Royal Victoria Hospital, Newcastle and Royal United Hospital, Bath, who helped in the evaluation.

Thanks also to Datex-Ohmeda 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

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