Neonatal Phototherapy

*Draeger Photo-Therapy 4000 Unit*

**SUMMARY**

**Advantages:** Easy to use, compact, mobile unit. White lamps alongside blue ones reduce glare and make it "easier on the eyes" to work with. Considered effective by users.

**Disadvantages:** Stand wheel-base too high to fit under some incubators (including some Draeger 8000 incubators). Can be awkward to adjust tilt.

**BRIEF DESCRIPTION**

The Draeger Photo-Therapy 4000 is a compact overhead phototherapy unit, which can be mounted on a mobile stand (as shown) or placed directly onto an incubator canopy. The standard unit houses four blue and two white folded fluorescent tubes. When on the mobile stand it can be tilted and adjusted vertically.

**MAIN FEATURES**

- 4 blue and 2 white folded fluorescent tubes, or optionally 6 blue tubes
- separate switches for blue & white lights
- hours counter
- mobile stand with wheel locks

**Options**

Unit may be mounted on a mobile stand. Mobile stand costs **£450**

**Replacement items**

18W fluorescent tubes - Blue **£ 32.50 each**
White **£ 26.50 each**

**Life span of tubes** - Manufacturer recommends changing the tubes after 1000 hours operation.
Description & User Assessment

DESCRIPTION

The Draeger Photo-Therapy 4000 lamp is a conventional overhead phototherapy device. The head contains four 18W folded blue fluorescent tubes in the central section and two 18W folded white fluorescent tubes, one at each end of the central section. The two white tubes may optionally be replaced by two blue tubes for enhanced treatment. Blue tubes provide the therapeutic light and the white tubes provide light to make it easier for the nurses to work with the lamp by balancing the intense blue colour. The white lights do not produce therapeutic light.

Once connected to the power supply the four central blue tubes are switched on by pressing the blue switch, the white tubes are lit by pressing the white switch. On pressing in the switches their central circular area lights up green, see Photo 1. If blue tubes have replaced the white ones then these will illuminate when the white switch is pressed. When the central blue tubes are switched on an LCD timer beside the two switches illuminates and displays the number of hours the device has been in use. The timer cannot be reset but can be used to calculate when the lamps should be changed. The manufacturer recommends a change of all blue tubes after 1000 hours. The duration of illumination of the two end tubes, whether white or blue, is not monitored by the timer.

When on the stand the lamp can be adjusted vertically between 116 to 164cm above the ground by releasing a black screw lock. On release the head rises automatically, but it can be pushed down and secured at the desired height. Another screw on the back of the cradle holding the lamp head facilitates adjustment of the tilt angle of the lamp up to a maximum of 30° from the horizontal. This adjustment is easiest to do if the lamp is supported or removed from the cradle prior to turning the screw.

The user manual advises that if the lamp is switched off it is allowed to cool for a minute before being switched on again.

USER ASSESSMENT

One consultant and 52 neonatal nurses in five hospitals participated in our user assessment. 42 users including the consultant had used the device for at least two months and 11 new users had used it on a trial basis 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 users is shown in Figure 1. In asking users to score a device we had to be aware of other phototherapy devices they had used.

The unit was well liked by all users and every feature's averaged ratings was better than satisfactory for both new and existing users. The new users mainly had access to old devices no longer available for purchase and this may account for their general higher scoring of the Draeger 4000 over the existing users. The new users' averaged scores for all features were higher than the existing users with the exception of the timer.

Many users were unaware of the timer or its purpose. Of those who had seen it a few were aware of its use in determining when the tubes should be changed and that it was generally used by Clinical/Medical Engineering Departments. However, two nurses stated that they found it useful "to gauge when needs servicing" and "very useful to gauge how long lamps have been in use".

Mobility of the stand was scored quite highly and many considered it light and easy to manoeuvre, however some stated that it was quite heavy and difficult to turn.

Photo 1 Lamp switches and timer

The phototherapy lamp can be mounted on a mobile stand or it can be placed directly onto the canopy of an incubator. The mobile stand has four wheels, all four have wheel-locks, see cover photo. The stand's wheel-base is 12.7cm high.

Handles on the side of the lamp slot into a cradle attached at the top of the stand (see Photo 1).
Users were also asked about the use of this phototherapy unit with other equipment in their neonatal unit. One particular problem highlighted was that it was difficult, and in some cases impossible, to get the base of the stand under some incubators. This was not a problem with all types of incubators but of those with which this was a problem one type, surprisingly, included the Draeger 8000 series incubators. CEDAR Note: The wheel base height for the standard model was measured and is noted in the description. The clearance under three modern incubators may be found in Evaluation 375. Draeger technical documentation states that there are two stands available, the second stand may have a lower wheel-base but has not been seen by a CEDAR evaluator. (see Manufacturer’s comments).

The tilt mechanism was used in several hospitals, but was found to be heavy. One nurse commented that it was easier to use than older models of Draeger phototherapy equipment. Another nurse commented that she would find it helpful if the tilt would extend to 90° from the horizontal. The vertical height adjustment (VHA) was used by most nurses and was found easy to use but the adjustment knob was thought to stick out too much in one unit and nurses found it “gets caught on things”.

Lamp: The glare from the lamp was considered satisfactory and several users commented that it was easier on the eyes when the white lights were used as well as the blue. One nurse commented that it was no worse than other lamps in that it still gave nurses headaches at times.

Both new and existing users considered that the device was effective in clearing bilirubin and it was scored as good or better.

The distance at which treatment was given varied from unit to unit but the Draeger 4000 was not used at a distance closer than the minimum recommended by the manufacturer, 30cm. Most neonatal units used the Draeger 4000 with incubators and radiant warmers, and one unit sampled also used it over open cots.

The Draeger 4000 was used for double phototherapy in all three neonatal units sampled. Usually this was achieved using the Draeger 4000 and another overhead phototherapy unit, often a second Draeger 4000, if available. One user commented that in this arrangement the second unit blocked the front access of the incubator.

Overall the lamp was well liked and one nurse stated that it was the first choice of phototherapy device in her unit.
Figure 2 Spectral irradiance of the Draeger Photo-Therapy 4000 at 30cm, using 4 blue and 2 white tubes together, 4 blue tubes only and then 2 white tubes only.

Figure 3 Spectral irradiance comparison of the 4 blue and 2 white standard mode and the 6 blue tube enhanced mode at 30cm.
TECHNICAL ASSESSMENT

Our technical tests are designed to assess the clinical performance and safety of the device. Of primary concern for a phototherapy lamp are the light output or irradiance, the wavelengths of light emitted and the effective treatment area. 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.

The irradiance from the Draeger 4000 lamp was measured using a Bentham double monochromator spectroradiometer with Teflon cosine diffuser at 30cm and 40cm. 30cm is the manufacturer's recommended minimum treatment distance, and 40cm is the approximate distance of an incubator canopy from the mattress. Measurements at 40cm were made both with and without an incubator canopy, as in previous reports.

The Draeger Photo-Therapy 4000 unit in its standard configuration has two types of fluorescent tubes. Our initial measurements were made using this standard configuration of four blue tubes and two white tubes. We also made measurements with only the four blue and then just the two white tubes illuminated as shown in Figure 2. The contribution from the white tubes is clearly visible as small peaks between 400nm and 550nm, and their additional contribution to the total spectra at either end of this range. They can be seen to have little therapeutic effect. The white light is designed to allow the nurses to view the baby easily and assess its skin colour by providing a better colour balance for the human eye. It can be left on during treatment and makes working with the unit more pleasant (see User Assessment).

The enhanced treatment configuration using six folded blue fluorescent tubes, the two white tubes being replaced by two blue tubes, was also studied. The time these two extra tubes are in use is not monitored by the timer as this is only linked to the four central tubes.

A comparison of the irradiance of six blue tubes to four blue tubes plus two white tubes is shown in Figure 3. The additional contribution of therapeutic light, an extra 20%, can be clearly seen and the irradiance in our standard waveband is shown on Figure 3 and in Table 2 below. Figure 3 also clearly shows the contribution of the two white tubes above 600nm.

It must be noted from Table 2 that the ultraviolet (UV) irradiance from the 6 blue tubes is less than from the blue and white tube combination. On examination it was found that the white tubes have a greater UV component than the blue tubes. However, the UV component from either combination of tubes is insignificant and is below currently published safety levels for adults. Levels for infants have not yet been agreed by international bodies.

The heating effects were measured by monitoring the core temperature of a matt black aluminium disc located at the centre of the mattress in a thermally stable incubator. The Draeger lamp was sited directly over the canopy, above the disc, 40cm from the mattress. After four hours of illumination the temperature rise due to the lamp had stabilised at 1.7°C above the initial temperature of the disc.

Without the incubator canopy in place and with no additional heat source, simulating phototherapy in an unheated cot at 40cm, a temperature rise of 5.5°C was recorded. Repeating this at the minimum recommended distance of 30cm, a temperature rise of 6.5°C was recorded.

User Manual: This was easy to use and was clearly illustrated with line diagrams.

<table>
<thead>
<tr>
<th>Bandwidth (nm)</th>
<th>At 30cm</th>
<th>At 40cm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4 Blue &amp; 2 White (Wt)</td>
<td>6 Blue</td>
</tr>
<tr>
<td>320-400 (UVA)</td>
<td>0.009 mW.cm⁻²</td>
<td>0.008 mW.cm⁻²</td>
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<tr>
<td>400-550</td>
<td>3.39 mW.cm⁻²</td>
<td>4.07 mW.cm⁻²</td>
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<tr>
<td>Effective surface area (irr &gt;1mW.cm⁻²)</td>
<td>~2800 cm²</td>
<td>~4100 cm²</td>
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Certification & Manufacturer's Comments

Certification and Standards

Medical devices placed on the market in the European Union are required to comply with the relevant European Union Medical Devices Directive. Manufacturers must display the CE mark on the device as a declaration that it meets all the appropriate provisions of the relevant legislation including those relating to safety and where required has been assessed in accordance with these.


The Notified Body is an organisation authorised by a Competent Authority of a European Union country to certify CE marking by medical device manufacturers. The Competent Authority in the UK is the Medical Devices Agency.

The International Electrotechnical Commision (IEC) safety standard which covers all general medical equipment is IEC 601-1, equivalent to the European harmonised standard EN 60601-1. The particular standard for neonatal phototherapy devices, IEC 60601-2-50:2000, is due to be published very soon. If a device complies with the relevant harmonised standard then this will be accepted as evidence that the device meets the relevant applicable Essential Requirements of the Medical Devices Directive. It is not, however, necessary for a device to comply with a standard in order to meet the Essential Requirements and carry the CE mark.

Safety Notice

In 1999 an MDA Safety Notice was issued on the Draeger Photo-Therapy 4000 unit: SN1999(19). It said that there was a risk of electric shock from touching the pins of the mains plug or the pins of the mains inlet. Draeger instigated the necessary work and all modifications were scheduled to have been completed by August 1999.

Procurement Issues

All prices in this report exclude VAT, and are correct at time of going to print, however, you are encouraged to contact Draeger Medical Ltd at the address given for current prices and configurations.

In common with many medical devices, phototherapy devices require routine servicing. Although new devices normally have a one-year warranty against breakdown, servicing is still required (eg to check the irradiance output of the lamps) within the warranty period. Any purchasing decision should include consideration of service provision from the date of purchase, not from the date of expiry of the warranty.

Training: User knowledge and skills have major implications for safety. Procurement of a new medical device should include a resource allocation for user training and also for any technical training for the Clinical Engineering/EBME technical staff should they be required to maintain it.

MANUFACTURER'S COMMENTS

Thank you for your report on the Draeger Photo-Therapy 4000 unit we are pleased that it demonstrates the power and efficiency of the Draeger Phototheraphy 4000. We recognise the issue raised about the height of the stand wheel-base. The incompatibility with Draeger 8000 incubators only applies to models over ten years old. In view of this report and our own vigilance, we offer two solutions. The customer may purchase a trolley with smaller wheels, or where only one or two Draeger incubators have small wheels they may wish to replace the incubator wheels with larger diameter wheels. The alternative stand, with smaller wheels, is an older design and was used on the Draeger Heraeus Phototherapy unit. The serial no for this stand is in the technical manual. The lamp tilt is easy to adjust if the light is supported whilst turning the screw.

We welcome the data provided by Cedar showing the heat absorption by a black aluminium disc. This clearly illustrates that an adjustment needs to be made to incubator settings (open and closed) when using Phototherapy. Should phototherapy be used over an open cot, monitoring of the baby’s temperature is imperative.
### Manufacturer’s Data

**Manufacturer**
Draegerwerk AG, Moislunger Allee 53-55 D-Lubeck, Germany

**Country of Origin**
Germany

**Supplier**
Draeger Medical Ltd. The Willows, Hemel Hempstead, HP2 7BW
Tel : 01442 213452, Fax : 01442 240327
www:drager.com

**Prices (ex VAT)**

<table>
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<tr>
<th>Item</th>
<th>Price (£)</th>
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<tr>
<td>Photo-Therapy 4000</td>
<td>£1,950</td>
</tr>
<tr>
<td>Stand, adjustable for height and tilt (Standard version supplied)</td>
<td>£450</td>
</tr>
<tr>
<td>Stand (Alternative version with lower wheel-base)</td>
<td>£450</td>
</tr>
<tr>
<td>Blue tubes (each)</td>
<td>£32.50</td>
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<tr>
<td>White tubes (each)</td>
<td>£26.50</td>
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**Physical data**

**Dimensions in cm (W x D x H)**

- **Lamp**: 47 cm x 28.5 cm x 13 cm
- **Stand (standard)**: Base dimensions = 69 cm x 60 cm x 12.7 cm; VHA = 116 cm to 164 cm (base of lamp to ground); Wheel-base height = 12.7 cm
- **Stand (alternative)**: Base dimensions = 66cm x 55cm x 10cm; Wheel-base height = 10cm

**Weight**

- **Lamp**: 5.5 kg
- **Stand**: 13.6 kg

**Power rating**

- 120 W

**Lamps**

- (Standard set-up): 4 x 18W (blue) and 2 x 18W (white)
- (Enhanced set-up): 6 x 18W (blue)

**Product Support**

**Guarantee**

- 1 Year

**Servicing (ex VAT)**

- **Comprehensive**: £321 per unit
  - Inclusive of two routine service checks per annum, calibration, unscheduled engineer visits and non-consumable parts.

- **Standard**: £238 per unit
  - Inclusive of two routine service checks per annum and calibration. Spare parts are charged at list price, unscheduled engineer visits are charged at:
    - Labour on site/travel time: £62
    - Mileage: 62 pence per mile

**Additional information**

**Labour per hour**

- Field contract - £62
- Field non-contract £90
- Workshop contract £54
- Workshop non-contract £72

**Travel (per hour)**

- £62

**Mileage**

- 62 pence per mile
ACKNOWLEDGEMENTS

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

- Enquiries to Dr Stephanie Wentworth at CEDAR, Cardiff Medicentre, Heath Park, Cardiff, CF14 4UJ stephanie.wentworth@cardiffandvale.wales.nhs.uk Tel: 029 2068 2120 Fax 029 2075 0239 INTERNET www.imaging.uwcm.ac.uk/mpce/sctns/cedar/index.htm
- Or Mr Robert Allen at MDA, Hannibal House, Elephant and Castle, London,SE1 6TQ. robert.allen@medical-devices.gov.uk Tel :0207 972 8226 Fax : 0207 972 8105 INTERNET www.medical-devices.gov.uk

We thank all the nursing staff in the Neonatal Units of, Royal Glamorgan Hospital, Gloucestershire Royal Hospital, University Hospital of Wales, Cardiff, Princess Anne Hospital, Southampton and Taunton and Somerset District Hospital for their help in carrying out the user assessment. We would also like to thank Mrs SM Hancock for her administrative help.

Finally we would like to thank Draeger Medical for loaning this device for evaluation free of charge.

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<tr>
<td>Medical Devices Agency</td>
<td>Mr R Stock</td>
<td>Mr J Lewis</td>
<td>Mr D Calfolla</td>
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<tr>
<td>Room 1207, Hannibal House</td>
<td>Health Planning &amp; Quality Division, Scottish Executive, Health Department, St Andrew's House, Edinburgh, EH1 3DG</td>
<td>National Assembly for Wales, HIMTE 3, Cathays Park, Cardiff, CF10 3NQ</td>
<td>Health Estates, Stoney Road, Dundonald, Belfast, BT16 OUS</td>
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<tr>
<td>Tel: 020 7972 8181</td>
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<tr>
<td>01161</td>
<td>Medela Phototherapy Lamp</td>
<td>Dec 2001</td>
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<td>00092</td>
<td>Ohmeda spot phototherapy lamp</td>
<td>May 2001</td>
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<td>00091</td>
<td>Hill-Rom Micro-Lite</td>
<td>Jan 2001</td>
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<tr>
<td>391</td>
<td>A review including the Ohmeda BiliBlanket Plus and Medela BiliBed</td>
<td>Apr 2000</td>
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</table>

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