Quantitative Radiometric Assessment of Neonatal Phototherapy Units used in the Treatment of Hyperbilirubinaemia

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Hyperbilirubinaemia

- Build-up of bilirubin produced by the normal breakdown of haemoglobin in the body
- Bilirubin removed by placenta before birth
- After birth neonatal liver must take over
- Premature neonates – liver is often too immature to excrete bilirubin – serum bilirubin levels increase – neonatal jaundice – potential irreversible brain damage / death
- Phototherapy – treatment of choice for condition
Factors effecting Phototherapy

- Irradiance / Spectral Irradiance
  - $> 2 \text{ mW/cm}^2$ (Tan, 1982)
  - $> 35 \mu\text{W/cm}^2/\text{nm}$ (430 – 490 nm) (AAP, 2004)
- Treatment Distance
- Mode of Delivery

- Effective Surface Area (ESA)
  - As much of the infant’s skin as possible
  - Single / Double Phototherapy
  - Uniformity across ESA

- Wavelength
  - Area of controversy
  - *In vivo* Action Spectrum (Cremer, 1958)
**In vivo Action Spectrum (Cremer 1958)**

- a plot of relative therapeutic efficiency of visible light in the decomposition of bilirubin as a function of wavelength
In vitro Action Spectrum (Agati 1993)
Optimum Phototherapy (adapted from Dicken et al, 2000)

- Irradiance > 2 mW/cm² (Tan et al, 1982)
- Spectral Output of lamps must match BR Action spectrum!
- Uniform irradiance of the Infant

![Dose Response Relationship](image_url)
Current Phototherapy Equipment

- Fluorescent lamps e.g. Medela Bilibed, Vickers 80, Drager Phototherapy 4000
- Metal Halide Gas Discharge lamps e.g. Drager 8000
- Quartz Halogen incandescent filament lamps e.g. Ohmeda Biliblanket, Ohmeda Giraffe Spot PT Lite
- LED’s e.g. Natus neoBLUE, neoBLUE mini, neoBLUE cozy
Fluorescent Lamps
Quartz Halogen Lamps
LED’s
• No Output measurements performed on Phototherapy Systems
• Absence of output measurements in Service Contract reports
• Treatment based on serum bilirubin measurements
• Required to establish a Quality Assurance Program

**Objective of Study:**

• Survey the radiometric output of the Phototherapy systems in clinical use using available Radiometer

• Estimate the ability of the systems to provide uniform irradiation to the Infant

• Determine the suitability of hand-held Radiometers for Phototherapy system measurements
Methodology:

Irradiance: International Light Radiometer 1400A
- 410nm - 485 nm (10% cut-off points)

Radiometer response (weighted for action spectrum of Bilirubin!)
Uniformity of irradiance distribution:
- Preterm and Term Grids (Dicken, 2000)
- 9 equal area segments in a 160 x 280 mm planar surface
- 9 equal area segments in a 200 x 350 mm planar surface
- Ratio of min to max irradiance value (IEC 60601-2-50)
Uniformity of irradiance distribution:
- Ohmeda Biliblanket
- separate calibration factor
- 150 x 200 mm light pad
- 6 point Irradiance Average (manufacturer recommended)
- 4 point Irradiance Average (used in this study)
Experimental Arrangement:

- all radiometer measurements made at typical clinical treatment distances (45 cm)
### Summary

<table>
<thead>
<tr>
<th>System</th>
<th>Peak Irradiance (mW/cm²)</th>
<th>Uniformity - Preterm (Min/Max)</th>
<th>Uniformity - Term (Min/Max)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air Shields S400 1</td>
<td>1.37</td>
<td>93%</td>
<td>89%</td>
</tr>
<tr>
<td>Air Shields S400 2</td>
<td>1.43</td>
<td>90%</td>
<td>87%</td>
</tr>
<tr>
<td>Drager 4000</td>
<td>0.89</td>
<td>88%</td>
<td>84%</td>
</tr>
<tr>
<td>Hill Rom Microlite</td>
<td>0.74</td>
<td>56%</td>
<td>41%</td>
</tr>
<tr>
<td>Medela 1</td>
<td>0.86</td>
<td>74%</td>
<td>70%</td>
</tr>
<tr>
<td>Medela 2</td>
<td>0.65</td>
<td>79%</td>
<td>69%</td>
</tr>
<tr>
<td>Medela 3</td>
<td>0.59</td>
<td>79%</td>
<td>76%</td>
</tr>
<tr>
<td>Vickers 80</td>
<td>1.27</td>
<td>89%</td>
<td>81%</td>
</tr>
<tr>
<td>Ohmeda Biliblanket*</td>
<td>1.69</td>
<td>65%</td>
<td>65%</td>
</tr>
<tr>
<td>Natus neoBLUE mini</td>
<td>2.27</td>
<td>25%</td>
<td>18%</td>
</tr>
<tr>
<td>Natus neoBLUE</td>
<td>2.07</td>
<td>84%</td>
<td>84%</td>
</tr>
<tr>
<td>Giraffe Spot PT Lite 1</td>
<td>2.05</td>
<td>6%</td>
<td>5%</td>
</tr>
<tr>
<td>Giraffe Spot PT Lite 2</td>
<td>0.85</td>
<td>11%</td>
<td>14%</td>
</tr>
<tr>
<td>Giraffe Spot PT Lite 3</td>
<td>1.56</td>
<td>8%</td>
<td>1%</td>
</tr>
</tbody>
</table>
Uniformity - Preterm
Uniformity - Term

The image shows a bar chart titled "Uniformity - Term". The x-axis represents various medical devices, including Air Shields 5400, Drager 400, Hill Rom, Microlite, Medela 1, Medela 2, Medela 3, Vickers 80, Ohmeda Bioblanket, Medisana neoBLUE, Medisana neoBLUE mini, Giraffe Spot PT Lite 1, Giraffe Spot PT Lite 2, and Giraffe Spot PT Lite 3. The y-axis represents the percentage of uniformity, ranging from 0% to 100%.

The chart compares the uniformity of these devices, with some devices showing higher uniformity percentages than others.
Giraffe Spot PT Lite - Preterm
Natus neoBLUE mini - Term
Drager 4000 - Preterm
Medela

Medela 1 - Air - 2 Blue & 2 White - Preterm
Conclusions

• Treatment of Hyperbilirubinaemia with Phototherapy is far from being optimised
  - < 50% of recommended output in some cases
  - Systems with higher output should be made available
  - in some new models little consideration is given in the design to producing uniform irradiation of the infant
  - BR action spectrum (not internationally agreed)

• In developing QA protocols spectral output must match radiometer response (advise Nursing/Clinical staff)
  - important consideration when purchasing a radiometer to measure output from a number of systems

• In general, radiometers only suitable for constancy checking

• Accurate measurements demand a portable calibrated spectroradiometer
Further Work

- Comparison between Spectroradiometer and Radiometer measurements – development of calibration factors for IL1400A/SED033/BR/W radiometer.
- Affect of Incubator Hoods and Covers on Irradiance and Uniformity
## Initial Measurements

**Natus neoBLUE (High Setting)**

<table>
<thead>
<tr>
<th>Detector</th>
<th>Irradiance (mW/cm²)</th>
<th>Spectral Irradiance (μW/cm²/nm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bentham DMc150 (Total) (410 – 485 nm)</td>
<td>1.90</td>
<td></td>
</tr>
<tr>
<td>Bentham DMc150 (Weighted) (410 – 485 nm)</td>
<td>1.32</td>
<td></td>
</tr>
<tr>
<td>IL1400A/SED033/BR/W (410 - 485 nm)</td>
<td>1.2</td>
<td>16 ?</td>
</tr>
<tr>
<td>Ohmeda Bilimeter (420 - 480 nm)*</td>
<td>1.5 ?</td>
<td>25</td>
</tr>
<tr>
<td>IL74-BI (425 - 475 nm)*</td>
<td>2.8 ?</td>
<td>56</td>
</tr>
</tbody>
</table>

Bandwidth (10% cut-off)
Bandwidth (50% cut-off) *
### Initial Measurements

**Drager 4000 (4 Blue + 2 White)**

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<tr>
<td>Bentham DMc150 (Weighted) (410 – 485 nm)</td>
<td>1.66</td>
<td></td>
</tr>
<tr>
<td>IL1400A/SED033/BR/W (410 - 485 nm)</td>
<td>1.24</td>
<td>17?</td>
</tr>
</tbody>
</table>

**Bandwidth (10% cut-off)**
Spectral Irradiance: International Light Radiometer IL-74BI

- 425nm - 475 nm (50% cut-off points - bandwidth)
- 450 nm (Peak)
Spectral Irradiance: Ohmeda Biliblanket Meter

- 420 nm - 480 nm (50% cut-off points - bandwidth)
- 450 nm (Peak)