The Ohmeda IWS 3400 is a microprocessor based, servo-controlled infant radiant warmer. It incorporates a tilting bassinet with folding sidewalls. The overhead heater unit includes an observation lamp and alarm light. There are two modes of operation: skin temperature servo control and manual control.

The warmer is mounted on castors, two of which have foot operated brakes. Storage space is provided by drawers and optional shelving.

**SUMMARY**

**Advantages:** easy to use; compact; useful tubing ports in rear sidewall; good storage space in deep drawer; easy to use switches for vertical height adjustment.

**Disadvantages:** our users would have preferred integrated phototherapy and more shelving. The unit evaluated did not have brackets for mounting oxygen cylinders.

**MAIN FEATURES**

- **Maximum power output**
  - 540 Watts ± 5%

- **Skin temperature sensor**
  - Displayed range: 22°C to 42°C

- **Manual mode**
  - Heater output set in increments of 5%

- **Servo mode**
  - Set temperature range: 35°C to 37.5°C
  - Resolution: 0.1°C

- **Vertical height adjustment**
  - Finger-switch on control panel and foot-switches on base

- **Apgar timer**
  - Tones after one minute and every five minutes thereafter for one hour

- **Alarms (auditory and visual)**
  - Control temperature: ± 1°C
  - High skin temperature: over 42°C
  - Low skin temperature: below 30°C
  - System failure: yes
  - Sensor failure: yes
  - Sensor calibration drift: ± 0.3°C
  - Power failure: yes

**Price ex VAT** £7,761

**Supplier** Datex-Ohmeda Ltd
71 Great North Road
Hatfield, Herts AL9 5EN
Tel: 01707 263570
Fax: 01707 260065

**CE Marking?** Yes, MD Directive

**Notified Body** BSI

**Manufactured to Standard?**
Manufacturer states compliance with: IEC 601-1, EN 60601-2-21 & IEC 601-1-2
**Description**

**DESCRIPTION**

The Ohmeda Ohio 3400 Infant Warmer System delivers heat via an overhead, microprocessor-controlled radiant heater. The system incorporates a tiltable bassinet and equipment drawers, and is mounted on lockable castors.

The overhead heater with integral control unit is mounted at a fixed distance (69cm) above the bassinet, and includes observation and alarm lights. The heater may be operated in either skin temperature servo-controlled or manual controlled mode, and has various alarms and safety features.

**FACILITIES**

**Heating control**

All heater controls are positioned on the front of the control unit, which is below and to the rear of the overhead heater, see Photo 1. This unit may be rotated by 180° to face away from the bassinet for use by an anaesthetist.

**Photo 1: Heater Control Unit**

The control panel consists of: tactile membrane switches; numeric LED displays of temperatures and time; and LED indicator lights for alarms, control mode, and Apgar tones operation.

There are two modes of operation: skin temperature servo-control and manual control. After an initial system check, the warmer begins operation in the manual mode; an intermittent auditory tone and flashing ‘% Power’ display prompt the user to set the manual power level.

**Manual Control Mode**

The heater output can be set in 5% increments up to 100% of the 540 Watts available using the [△] and [▽] switches next to the multi-segment ‘% Power’ indicator. To enable an unattended system to be kept in a warm condition, the heater will operate continuously in ‘Preheat’ mode when set at or below 25%. At higher power settings an auditory and visual ‘Check Patient’ alarm will activate after twelve minutes; if this is not silenced within a further three minutes a two tone alarm will sound and the heater will switch off. The skin temperature sensor is not used to control the heater output in manual mode, but may be used to monitor the skin temperature of the infant; skin temperatures are measured and displayed in the range 22°C to 42°C.

**Skin Temperature Servo-Control Mode**

This mode must be positively selected using the ‘Mode’ switch on the control unit. Heater output is controlled by the microprocessor, which uses the measured patient temperature and the pre-selected control temperature to calculate the appropriate level of heater power. The control temperature can be set in the range 35°C to 37.5°C with a resolution of 0.1°C. The servo-controlled mode cannot be used when the patient temperature reading is below 30°C. The warmer has a memory function, which can retain settings for up to 10 minutes in the event of a power failure.

**Skin Temperature Sensor**

The skin temperature sensor plug (Photo 2) is inserted into the socket on the left-hand side of the control unit in Photo 1.

**Photo 2: Skin temperature sensor**

Photo 2 also shows a reusable skin temperature sensor, a reflective patch for fixing the sensor and a penny to convey scale. The reflective patch has a circle of perforations to make a reduced reflective area possible for use on smaller infants.
Description and User Evaluation

Alarms
An alarm is signalled by an intermittent auditory tone with a simultaneous flashing of the red alarm-light. The specific alarm condition is indicated by a light in the ‘Alarms’ section of the control panel.

Alarm indications are provided for both servo-controlled and manual modes in the event of: processor system failure, heater deactivation due to rotation of the heater module, and power failure.

In servo-control mode there are alarms for skin temperature sensor failure and deviation of skin temperature from control temperature. The temperature deviation alarm may be changed from the default 1°C to between 0.5°C and 2°C.

In manual mode there is a timer alarm which allows 12 minutes of operation before a user reset must be operated.

All the auditory alarms except those for processor system failure and power failure can be silenced for varying periods of time.

Bassinet
Mattress area The removable mattress lies in a bassinet with clear perspex sides, which can be folded down for easy access and removed for cleaning; one of the shorter sidewalls has several cut-outs for organising tubing. The bassinet can be tilted to a head-up or feet-up position, using a hydraulically damped mechanism, to a maximum of 10°, (front cover photo). A chest drainage hanger is located beneath the bassinet.

X-ray facilities There is an X-ray cassette shelf below the mattress which enables radiographs to be taken without disturbing the patient. This shelf can be accessed from either side and may also be used as storage space for light articles (Photo 3).

Vertical Height Adjustment (VHA) The height of the bassinet may be altered for ease of access. The height is continuously adjustable using switches on the control panel or foot-switches on either side of the chassis (Photo 4).

Photo 4: VHA Footswitches

Storage and Accessories
The unit evaluated had non-rotating storage drawers, one deep and one standard; the deep drawer may be replaced by two standard drawers. A rotating drawer package is available with other IWS models; these may also have a larger mattress area. There are additional shelving options for all IWS models, including a rotating 30×30cm shelf and a fixed 30×77cm shelf. See Manufacturer’s Comments.

A range of accessories is available including a resuscitation system, incorporating a suction regulator, an oxygen flowmeter and an airway pressure manometer. Phototherapy may be provided using Ohmeda’s BiliBlanket system. Both these systems may be mounted on the upright supports of the heater.

USER EVALUATION
The Ohmeda IWS 3400 was used for one period of three weeks in a single neonatal intensive care unit. The device was not available for further user trials in other hospitals. Training was received either directly from the manufacturer or from other clinical staff.

After this trial the users were asked to score the facilities and attributes of the warmer on a five-point scale, ranging from unacceptable to excellent. Six senior nursing staff, (grade E or F), with experience of other Ohmeda warming systems, completed evaluation questionnaires.

The questionnaire results were averaged and the features eliciting the best and worst responses are given in a bar chart in Figure 1.
**Vertical Height Adjustment:** This facility received a high rating from our users. The height is adjustable by foot-switches on either side of the base, and finger-switches on the control panel. The movement was smooth and provided a comfortable bassinet working level for all our users, ranging between 98 and 118 cm off the floor.

**Stability:** Our users liked the stability and general mobility of the IWS 3400. These qualities become more important when the weight is added to by ancillary equipment and the device is used to transport infants inside the hospital.

**Warmer Controls:** The control panel is accessible, clear and easy to use. Each alarm condition is indicated by an LED light next to the appropriate legend.

**Side Panels:** The side panels were thought to provide good security for the infant. The rear panel has cut-outs for organising tubing.

**Mattress Area:** The warmer provided for evaluation had mattress dimensions of 64×47cm. Our users thought this area would only be appropriate for smaller infants, larger infants would leave insufficient working room, see **Manufacturer’s Comments**.

**Fixing of Ancillary Equipment:** The warmer provided for evaluation did not have the brackets required to mount an oxygen cylinder for transfer to theatre.

**Shelving:** The warmer provided for evaluation did not have sufficient shelving space for our users. There was not enough room to place all the monitoring equipment necessary for a theatre transfer.

**Phototherapy:** Phototherapy was not required during our evaluation; this score, therefore, was based on the users’ previous experience of similar devices. One user suggested the warmer would benefit from an integral phototherapy system, in line with recent changes to market expectations. Ohmeda can supply a ‘Biliblanket’ phototherapy unit that may be fixed to the warmer’s upright supports.

**Other Facilities:** The user questionnaire contained over 40 questions covering all performance aspects of the Ohmeda IWS 3400. All features not included in Figure 1 received an averaged score above satisfactory.

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**Figure 1: Features Receiving the Four Best and Four Worst User Responses (Over Forty Features Considered).**
TEMPERATURE measurements were made using aluminium test discs located on the level mattress, in accordance with BS EN 60601-2-21. The warmer was operated in the servo-controlled mode, with a reusable Ohmeda sensor affixed to the top surface of the central test disc.

Figure 2 shows how the core temperature of the central test disc varied as the Ohmeda IWS 3400 was taken through a sequence of settings. The readings were taken over two separate periods and are shown together for simplicity. The slight temperature mismatch at the data break was probably due to differences in ambient temperature.

The readings start with the heater manually set to 25% output, (‘Preheat’ mode). The initial core temperature of the central test disc was approximately 28°C with an ambient temperature of 21°C. The ‘Warm up to 36-5°C’ section shows that the test disc temperature rose from 28°C to 36-5°C in 23 minutes.

The servo temperature was then adjusted from 36-5°C to 37-5°C, a steady state was allowed to develop before the servo temperature was changed back to 36-5°C. The test disc took approximately 6 minutes to reach the set temperature in both cases. There was negligible temperature undershoot or overshoot as the system reached each pre-selected temperature.

The overhead heater was then turned fully to the side for ten minutes; the heat is automatically cut off when the heater unit is rotated. This resulted in a 2-4°C fall in the temperature of the test disc. When the heater was replaced the previous temperature was regained in 12 minutes.

The final section of the graph shows the fall in disc temperature when the heater is turned off but allowed to remain over the mattress. The disc temperature falls to 28°C in 59 minutes.

In all tests the radiant heater operated to maintain the temperature of the top surface of the central test disc (as measured by the Ohmeda sensor) within 0-5°C of the servo temperature.

The contour plot on page 6 of this report shows how the surface temperature varied across the mattress. These measurements were taken with the unoccupied warmer set at 50% output in manual mode and the mattress covered with a black polyester-cotton sheet. Four sets of surface temperatures were taken in a 5cm grid and the results were averaged. All points on the sheet had temperatures within 2°C of the average mattress temperature, and almost all points in the ‘Infant Zone’ (defined by Ohmeda) have temperatures within 1°C of the mattress average.
Technical Evaluation

An interesting point to note is the increase in mattress temperature near the side panels. This is due to an intentional focusing of heat to raise the side panel temperatures and reduce radiant heat loss from the infant to these panels.

During the course of our tests it was noted that the calibration of the temperature sensing circuitry had drifted outside set limits. This calibration can be tested using the warmer control unit. An Ohmeda engineer was able to recalibrate the circuitry, after which the Ohmeda temperature sensor had an accuracy of ±0.3°C.

**ACCOMPANYING DOCUMENTS**

The Operation and Maintenance Manual was comprehensive and well written.

**COMPLIANCE WITH STANDARDS**

The device carries CE Marking in respect of the Medical Devices Directive (MDD). By affixing CE Marking to the device, the manufacturer has indicated that it complies with the UK regulations implementing the Medical Devices Directive (93/42/EEC); the Notified Body was BSI.

The supplier has submitted an NHS Pre Purchase Questionnaire Form, which states that the device has been tested to the following standards:
- IEC601-1, tested by BSI
- EN60601-2-21, tested by BSI
- IEC601-1-2, tested by Inchcape Testing.

**MANUFACTURER’S COMMENTS**

The clear perspex side panels are marked with alignment lines to allow easy x-ray plate placement. These lines correspond to similar lines on the x-ray tray beneath. All four sides drop and are removable and interchangeable.

The design of the IWS range is one of Open Architecture: that is, the user defines the ergonomics involved to facilitate a more efficient working environment. The dovetail mounting system allows a wide range of variable ancillary equipment fixation sites. There is no need for tools, and unrequired ancillary devices can be easily removed for safe storage. There is a large range of IWS products which can influence the variability of the storage available – including rotating drawers.

The IWS 3400 has a standard bed size. Another model, the IWS 4400, has a bigger mattress and a correspondingly larger heater element. This mattress size is 61.2 × 76.5 cm, which would allow nursing of bigger babies with the same thermal characteristics as the 3400.
**PRODUCT DATA**

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<th><strong>Manufacturer</strong></th>
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<td>Cylinder Basket – C size cylinders £134</td>
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<td>Patient Temperature Probe (re-usable) £41</td>
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<td>Heat Reflecting Patches (Pack of 50) £12</td>
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**Physical Data**

- Size (H × W × D) 183 to 203 × 77 × 114 cm depending on Vertical Height Adjustment
- Weight 91 kg (add 25 kg for stationary drawers, 32 kg for rotating drawers)
- Mattress Size 47 × 64 cm
- Standard Drawer Size 38 × 39 × 10 cm
- Deep Drawer Size 38 × 39 × 23 cm
- Bed Tilt Positions ± 10° continuously adjustable

**Options**

- Thermalink Available to units with version 5.0 software or higher.
  The Serial Data interface can be used with a computer or commercial RS232 monitor.
  The Nurse Call System interface lets you use the warmer with your current remote alarm system.
  Contact the supplier for more details on these options.
- Rotating Drawers Allows access to the storage drawers from the front or from either side of the warmer. This option is not available on some Ohmeda IWS models.

**PRODUCT SUPPORT**

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<th><strong>Supplier</strong></th>
<th>Datex-Ohmeda Ltd</th>
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<td>Fax: 01707 260065</td>
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<tr>
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<td>Web: <a href="http://www.ohmedamedical.com">www.ohmedamedical.com</a></td>
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**Guarantee** 12 months

**Maintenance Provisions**

The supplier is able to provide training to the purchaser’s technical personnel on:
- calibration, planned preventative maintenance, and repair.
- The supplier is able to provide ‘as required’ and contract repair/maintenance services.

**Spare Parts**

The Operation and Maintenance Manual contains a comprehensive list of spare parts.
Appendix

ACKNOWLEDGEMENTS

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

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- Or: Mr Arthur Goodman, Evaluation Manager, Medical Devices Agency, Hannibal House, Elephant & Castle, London SE1 6TQ. Tel 0207 972 8156, e-mail: Arthur.Goodman@doh.gsi.gov.uk

We thank Dr Mark Drayton and the Neonatal Intensive Care Unit (University Hospital of Wales) for their cooperation in carrying out the user assessment.

We thank Datex-Ohmeda for their cooperation in providing a sample of the IWS 3400 for the evaluation.

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

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