EVALUATION

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Centre for Evidence-based Purchasing

Report 06046

Market survey: infant warming and phototherapy (update)

September 2006

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Market survey: infant warming and phototherapy

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Contents

Summary

A new NHS purchasing framework agreement for infant warming and phototherapy equipment* (IWpF) was established by NHS Purchasing and Supplies Agency (NHS PASA) in March 2005. This makes it easier, quicker and cheaper for NHS organisations to purchase a range of neonatal care products. Constraints imposed by European legislation and standing financial instructions are removed as these were taken into consideration when drawing up the framework, which covers all NHS Trusts in England, Northern Ireland, Scotland and Wales.

This comparative report has been updated following the contract renewal in March 2006. One of the original suppliers has been replaced and a mobile warming device removed. Several typographic and editorial errors have also been corrected. This report provides an extensive independent information resource to help purchasers identify the full range of products and issues that can influence suitability. An assessment of each department's technical and clinical needs can be compared to the products on the NHS PASA IWpF website [1] to select the best value product.

Approximately 50 IWpF products have been grouped as: nursing incubators (8 product listings), transport incubators (2), warming therapy (23, including 2 resuscitation cabinets, 12 complex care units, 6 mobile devices and 3 warming mattresses) and phototherapy lamps (16). An overview of relevant clinical and procurement issues is provided for each section.

The information presented here comprises comparative tables of key dimensions and features, and a product summary page for each model. This market survey contains data provided by the nine UK suppliers and the NHS PASA IWpF website. In some cases, further evaluation information is available in previously published reports. These are noted on the relevant product pages.

Prices quoted are the suppliers' list prices from the PASA website. NHS organisations can obtain discounted prices via the NHS PASA IWpF website [1].

Suppliers may have other, similar products not included in the IWpF contract. Any NHS organisation interested in purchasing items not listed on the IWpF must conduct the relevant competitive tender exercise, depending on the value of the order. The contract is subject to ongoing review to encompass new suppliers and new technologies. For further information about the contract please contact NHS PASA (infantwarmings@pasa.nhs.uk).

* Following acquisition of Air-Shields by Dräger Medical, the UK Competition Commission recommended that price stabilisation and increased market competition should be encouraged [2]. The IWpF project fulfilled these recommendations.

Introduction

Infant Warming and phototherapy Framework (IWpF)

The NHS Purchasing and Supply Agency (NHS PASA) has developed a national contract for infant warming and neonatal phototherapy equipment (IWpF). This framework agreement was designed to stabilise prices and encourage more manufacturers to supply quality products to the UK and circumvents the need for purchasing departments to tender for larger purchases of neonatal care equipment [3]. This reduces the time involved and may also provide lower prices than are available to individual organisations. The equipment covered by this contract includes:

- nursing incubators
- transport incubators
- warming devices (radiant warmers and heated mattresses)
- phototherapy lamps (for hyperbilirubinaemia)

Not every device in the IWpF contract is listed in this report. Items which might be considered as accessories do not have separate product pages but may be listed on the main item product pages.

Purpose of this report

The information in the comparative tables and product pages has been compiled from documents supplied by the manufacturing/supplying companies, from their websites and from the NHS PASA IWpF website [1]. It is designed as a ‘first stop’ brochure to allow quick and simple comparisons between similar devices so that purchasers can identify which products are most likely to suit their individual requirements. The report provides information of interest to neonatal clinicians, nurses and managers, technologists and equipment managers and procurement staff. Inclusion in this report does not constitute an endorsement of any of the devices or companies, nor does it replace the need for departments to carry out their own evaluations prior to purchase.

Creating the optimal thermal environment for infants

The use of warming therapy has been shown to reduce mortality in low birth-weight babies. Premature babies have greater difficulty maintaining their body temperature than full-term babies and adults because they have a larger surface area relative to their volume. Heat is lost through the skin by radiation (infra-red), convection (warming the air), conduction (contact with surfaces) and evaporation of moisture from the skin. The latter is highly effective for cooling the body, and is particularly a problem if the skin is uncovered and the air has low humidity.

Three different types of devices have been developed to actively warm neonates and infants:

- Incubators use warm air circulating in a closed environment to transfer heat through the skin. Humidification is frequently added to minimise cooling and dehydration
- Radiant warmers provide infra-red radiation which penetrates and transfers heat to the upper skin layers
- Heated mattresses warm the baby's skin surface by conduction.

Monitoring of the infant's temperature and adjustment of the device's thermal output levels is required to maintain an optimal environment as the infant's physical condition changes.

Neonatal phototherapy

Phototherapy lamps transfer radiant energy into the skin specifically to achieve a therapeutic reduction in the bilirubin concentration in the blood. Blue or blue-green light interacts with the bilirubin molecules in the superficial blood vessels. These devices may be used in combination with incubators or other warming therapies.

Standards

All equipment in the IWpF contract is CE marked. This means that the manufacturer claims that the device meets the Essential Requirements of the European Medical Devices Directive [4]. CEDAR have requested evidence from each supplier which demonstrates this conformity. A list of relevant standards and an explanation of how compliance is demonstrated is contained in the Appendix. Each product page includes information about the standards with which the manufacturer claims compliance and the Notified Body (NB) that has certified the process.

Contract details

Prices included in the product pages are the list prices from the NHS PASA IWpF website which was published in March 2005. In order to obtain up-to-date details of prices and products, users should consult the website [1] from a computer linked to NHSnet. Some user training is included in the purchase price

Evaluation reports

Several products in this report have been the subject of previous evaluation reports which may contain detailed descriptions, technical and user evaluations. These are listed in the product pages. Where these reports refer to previous models, this has

been made clear. These reports are available from the NHS PASA Centre for Evidence-based Purchasing (CEP) [5].

Procurement issues

It is good practice to compare the total cost of devices over their expected lifetime, for example ten years. Where initial capital cost is low, the costs of consumables and maintenance may be relatively high, and vice versa.

Additional features can add to the total cost and complexity of a device and may be unnecessary in some cases. Storage facilities for accessories and baby clothes, shelves for placing equipment during interventions and poles for affixing accessories can be important considerations.

The installation of equipment, including electrical and gas supplies, and related labour costs for fitting wall, ceiling and cabinet mounted warmers should be included in the total cost. Some user training is included in the purchase price by all suppliers, further details of which can be found on the IWpF website [1]. The cost of technical manuals and service training for technical support staff is given in the product pages, where available. Also on the product pages are costs for common consumables (i.e. component items or accessories which are replaced at set intervals or which have an estimated lifetime of a year or less).

Organisation of this report

Products are grouped into sections according to the four categories listed on page 2. Each section has an introduction that provides general information to consider when choosing a device, and guidance on interpreting the product pages and comparative tables. Product pages provide an overview of the key features of each product. A Glossary explaining the terms used in the comparative tables and product pages is included in the Appendix. The Appendix also contains a table with the contact details of the suppliers.

Disclaimer

Every effort has been made to ensure that the information in this report is correct. However, the large number and variety of products and the continuous improvements that suppliers and manufacturers make to their ranges and specifications means that prospective purchasers should seek up-to-date details from the suppliers before making a final decision. Blank rows on the product pages indicate that specific information was not provided by the supplier.

Nursing incubators

How incubators work

Nursing incubators provide a warm, stable microenvironment for small and sick babies so that the energy they would use to keep warm can instead be used for growth, recovery and development. The environment can be controlled either by maintaining the air temperature or the baby's core skin temperature (measured at the abdomen) at a pre-set value. All the incubators in this document include

- air temperature control mode
- skin temperature control mode
- tilting mattress
- a minimum of 4 hand ports (2 in each long side), to allow nursing care without compromising the regulated environment in the enclosure

Other facilities may be included as standard or charged as optional extras (Table 1). Warm internal canopy surfaces reduce radiant heat loss (double walls can improve this function) and low air velocity over the baby's skin reduces convective heat loss. Humidified air also reduces heat lost due to evaporation of moisture from the skin and is beneficial for the respiratory tract. Controlled humidification is particularly used for the most premature babies, but should be designed to discourage infection.

Babies may require oxygen-enriched air, which can be delivered using nasal prongs, headboxes, or by increasing oxygen levels within the whole canopy. This can be accomplished using externally-fixed flowmeters to maintain a set gas flow rate (manufacturers will provide tables of approximate concentrations that will be achieved at different flows), or by monitoring the concentration in the enclosure (servo-controlled oxygen).

Increasing use is being made of simultaneous monitoring of the skin temperature at the abdomen (close to core temperature) and at a peripheral site (usually the foot). Products with peripheral temperature measurement as a standard or optional feature are capable of dual temperature monitoring.

Kangaroo nursing, using skin-to-skin contact with a parent for warming sick and premature neonates, is becoming increasingly popular as it also encourages parent-child bonding. Some incubators provide a special kangaroo mode, whereby the infant's temperature is monitored whilst the incubator temperature is maintained separately. Other incubators may allow kangaroo nursing care, but do not specifically label this as a feature.

The frequency and level of access to the baby that nurses and medical staff require varies depending on the typical size and medical condition of babies on each unit. This will influence the ideal physical dimensions of canopy and mattress, range of vertical height adjustment and mattress tilt and optimum access features (ports, doors, tubing ports, removable canopy). Comparing the trolley wheelbase height of

other mobile equipment and the incubator's ground clearance will indicate whether they can be used together. Key incubator dimensions and characteristics are compared in Table 2.

Table 1: Comparison of nursing incubators features

Supplier	Beaver			Dräger		GE Healthcare		Inspiration			MIS	
Model	**MP5 ISIS-A**	**MP5 ISIS SI/REA**	**SATIS**	**Caleo**	**Isolette**	**Giraffe**	**Omnibed**	**V-2100G A**	**V-2100G B**	**V-2100G C**	**C186**	**Vision 2186**
Peripheral temperature				✓	✓	✓	✓		✓	✓		
Controlled humidificaton	✓	✓	✓	O	O	✓	✓	✓	✓	✓	#	✓
X-ray tray		✓	✓	✓	✓	✓	✓	✓	✓	✓	†	✓
Weighing scales		O	O	O	O	O	O			✓	O	O
Kangaroo mode			✓	✓				✓	✓	✓	✓	✓
Oxygen monitoring			✓	O	O	O	O	✓	✓	✓		O
Servo-controlled O2				O	O	O	O		✓	✓		O
Double walls		O	O	O	✓	✓	✓	✓	✓	✓	O	O
Mattress elevation					✓			✓	✓	✓	✓	✓
Powered VHA	O	O	O	O	O	✓	✓	O	O	O	O	O
Access doors both sides		✓	✓	✓	O	✓	✓	O	O	O		
Hand ports	4	6	6	6	4-6	4-6	4-6	6	6	6	6	6
Trending / history	O	O	✓	✓	✓	✓	✓					✓
Computer/ network	O	O	✓	O	✓	O	O					✓
Control panel lock / cover			✓	✓	✓	✓	✓	✓	✓	✓		✓

✓ - included as standard
O - available as an optional extra

- no X-ray tray, but includes a gap beneath the mattress for plates
† - air is humidified, but not monitored or controlled

Table 2: Comparison of nursing incubators specifications

Supplier	Beaver			Dräger		GE Healthcare		Inspiration	MIS	
Model	**MP5 ISIS-A**	**MP5 ISIS SI/REA**	**SATIS**	**Caleo**	**Isolette**	**Giraffe**	**Omnibed**	**V-2100G A / B / C**	**C186**	**Vision**
Dimensions L W (cm)	104 x 53	104 x 60	102 x 58	117 x 69	99 x 67	114 x 66	114 x 66	100 x 63	107 x 56	105 x 56
Height (cm)	130 - 153	130 - 153	159 - 182	122 - 152	133 - 152	147 - 177	147 - 238	135 - 152	134 - 154	130 - 150
Mattress L W (cm)	61 x 39	61 x 39	61 x 38	65 x 50	81 x 41	66 x 48	66 x 48	74 x 36	63 x 34	63 x 34
VHA (mattress height) (cm)	93 - 116	93 - 116	94 - 117	80 - 110	90 - 111	81 - 111	81 - 111	92 - 113	94 - 114	93 - 113
Mattress tilt	±10º	+20º -10º	+20º -10º	±13º	±12º	±12º	±12º	±12º	±12º	±12º
Weight incl VHA (kg)	90	90	90	130	90	131	131	88	68	93
Canopy L W H (cm)	89 x 45 x 34	89 x 45 x 50	89 x 45 x 50					100 x 59 x 42	86 x 41 x 47	86 x 41 x 47
Ground clearance (cm)	16	16	16	13	11.5	9.5	9.5	12	13.5	13.5
Tubing ports	3	10	10	10	10	8	8	10	4	4
Warm-up time (mins)	20 (25 - 37ºC	20 (25 - 37ºC)	20 (25 - 37ºC)	20 (20 - 31ºC)	<35 (11ºC above ambient)	<50 (25 - 39ºC)	<50 (25 - 39ºC)	<60	30 (11ºC above ambient)	40 (11ºC above ambient)
Water tank capacity (L)	2.5	2.5	1	2.8	1	1	1	1.3	1	1

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Supplier: Beaver

MP5 ISIS A & SI/REA (Mediprema)

ID Number	3552 (A)	3555 (SI/REA)
Available since	1997	
General		
Dimensions L W H	104 x 53 x 130-153 cm 104 x 60 x 130-153 cm	
Lockable wheels	2 out of 4	
VHA (mattress height)	93-116 cm	
Mattress tilt	±10° non-continuous (A) +20º -10º continous (SI/REA)	
Ground clearance	13 cm	
Weight (incl VHA)	90 kg	

3555 SI/REA shown

Description	Mediprema promote continuous self-checking of the controls and sensors, feet-to-head air circulation to reduce heat loss with open ports/doors, and silent operation of ports and doors.	
Options		
Storage options	Left and right cupboards or shelves, swing aside tray, IV pole, extra rails	
Standard package includes	1 skin probe, X-ray tray (3555 SI/REA)	
Optional features	Powered VHA, extended mattress pull-out (120%), trending & key-press history. For 3555 SI/REA: weighing scales and 2 double walls.	
Baby compartment		
Canopy size L W H	3552 (A) - 89 x 45 x 34 cm	3555 (SI/REA) - 89 x 45 x 50 cm
Mattress size	61 x 39 cm	
Double walls	3552 (A) – no	3555 (SI/REA) – optional for head and foot walls
Tubing ports	3552 (A) – 3	3555 (SI/REA) – 10
Canopy flat area	89 x 35 cm	
Air circulation	Feet to head	
Access to the infant		
Mattress slides out	75% (optional 120%)	
Access doors	3553 (A) – 2 side-opening doors in front 3555 (SI/REA) – 2 side-opening doors each in front and rear walls	
Hand ports	3552 (A) – 4 3555 (SI/REA) – 6 (2 additionally at head and foot ends)	

MP5 ISIS A & SI/REA (Mediprema)

Nursing & medical	
Control panel location	Front panel
Control panel lock	No
Air temperature	Min: 28°C Max: 37°C Override: 39°C
Skin temperature	Min: 35°C Max: 37°C Override: 38°C
Warm-up time	18mins (25ºC to 37º)
Humidification	Levels 1, 2 & 3 produce a range of 45-70% (at 36°C)
Water reservoir	Directly into drawer in front panel, level visible from front, 2.5L capacity
Oxygen control	Inlet for external flow-controlled supply, analyser optional for 3555 (SI/REA)
Trending / history	Optional
Computer / network	Optional. DOS / Win 95 / Win 98 operating systems, for technical & clinical monitoring
Alarms	Lights on control panel indicate alarm condition
Maintenance	
Access	Canopy tilts open. Air filter access on rear panel.
Water system	Drain and clean every 24hrs
Consumables	Air filters (every 6mths). Skin temperature probes/covers.
Service training	Service manual – FOC (available on disk), training is chargeable (cost not supplied), additional connectors required
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb – Full Quality Assurance ISO13485 (G-MED, 0459)
Supplier's Quality System	ISO9001 (BSI 0086)
Device complies with	EN60601-1, EN60601-2, IEC60601-1-19
Financial	
Consumables	Air filters (x3) - £188.15, skin sensor - £123.86
Evaluation report	NA
MRRP	3552 (A) - £5,888.89 3555 (SI/REA) - £7,571.90 (VHA adds £768.42)

Supplier: Beaver

SATIS (Mediprema)

ID Number	3600
Available since	2003
General	
Dimensions L W H	102 x 58 x 159-182 cm
Lockable wheels	2 out of 4
VHA (mattress height)	94-117 cm
Mattress tilt	+20º -10º
Ground clearance	13 cm
Weight (incl VHA)	90 kg

Photo courtesy of Mediprema

Description	Same continual self-checking as ISIS models. Humidification is by ultrasonic nebulisation and includes a UV germicidal lamp in the internal water tank.
Options	
Storage options	Left and right cupboards or shelves, swing aside tray, IV pole, extra rails
Standard package includes	1 skin probe, 2 water bottles, 2 bottle supports
Optional features	Powered VHA, extended mattress pull-out, trending & key-press memory, weighing scales, double walls, oxygen analyser, peripheral skin temperature
Baby compartment	
Canopy size L W H	89 x 46 x 50 cm
Mattress size	61 x 38 cm
Double walls	At head/foot ends, long sides optional
Tubing ports	10
Canopy flat area	89 x 35 cm
Air circulation	Feet to head
Access to the infant	
Mattress slides out	75% (optional 120%)
Access doors	2 side opening doors in front and rear
Hand ports	6 (2 each long side, 1 each head and foot ends)

SATIS (Mediprema)

Nursing & medical	
Control panel location	Above canopy on rotating arm, touch screen control
Control panel lock	Yes
Air temperature	Min: 20ºC Max: 37ºC Override: 39ºC
Skin temperature	Min: 35ºC Max: 37ºC Override: 39ºC
Warm-up time	20 mins (25ºC to 37ºC)
Humidification	35-80% (at 39ºC) Override: 90%
Water reservoir	External bottle (1L) feeds secondary internal tank
Oxygen control	Inlet for external flow-controlled supply; optional analyser
Trending / history	2hr trends for air and skin temperatures and weights; longer histories available
Computer / network	Yes. Win 95/ 98 / 2000 / XP operating systems, for technical and clinical monitoring
Alarms	Light on top of control panel; condition message on display; adjustable volume; programmable thresholds for temperature and oxygen alarms
Maintenance	
Access	Canopy tilts open. Air filter access in rear panel.
Water system	Water bottle autoclavable, should be replaced every 24hrs; water tank should be drained every 12hrs; tank includes germicidal UV lamp; incubator should be cleaned every 8 days
Consumables	Air filter (every 6mths), UV lamp (annual), skin temperature probes.
Service training	Service manual – FOC (available on disk), training is chargeable (cost not supplied), additional connectors required
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb – Full Quality Assurance ISO13485 (G-MED, 0459)
Supplier's Quality System	ISO9001 (BSI 0086)
Device complies with	EN60601-1, EN60601-2, IEC60601-1-19
Financial	
Consumables	Air filters (x3) - £188.15, skin sensor - £123.86
Evaluation report	NA
MRRP	£10,072.35 (VHA add £1,436.96)

Supplier: Dräger

Caleo (Dräger)

ID Number	3209940
Available since	2000
General	
Dimensions L W H	117 x 69 x 122-152 cm
Lockable wheels	3 out of 4 (+1 directional lock)
VHA (mattress height)	80 – 110 cm
Mattress tilt	±13º
Ground clearance	13 cm
Weight (incl VHA)	137 kg (not incl VHA)
Description	Incubator with large baby compartment which tilts as a whole (i.e. not just the mattress). Can accommodate twins up to 5kg combined weight. Canopy is removable for increased access. Vertical corners are opaque and fixed, but all side walls fold down.
Options	
Storage options	Large single drawer, IV pole, shelves
Standard package includes	X-ray tray
Optional features	VHA, humidity, servo-controlled oxygen, weighing scales, double walls
Baby compartment	
Canopy size L W H	80 x 56 x 17 cm
Mattress size	65 x 50 cm
Double walls	Optional, in canopy roof
Tubing ports	10
Canopy flat area	Information not supplied
Air circulation	Up front & back walls, down head & foot walls.
Access to the infant	
Mattress slides out	Yes
Access doors	2 front and back, plus two smaller doors at the head and foot ends
Hand ports	4

Caleo (Dräger)

Nursing & medical	
Control panel location	Variable – attaches to extension pole on either side
Control panel lock	Yes
Air temperature	Min: 28ºC Max: 37ºC Override: 20-27.5ºC and 37.5-39ºC
Skin temperature	Min: 34ºC Max: 37ºC Override: 38ºC
Warm-up time	20 mins (20ºC to 31ºC at 20ºC ambient temperature)
Humidification	Optional, 30% - 99% (in 1% increments) or auto-set according to air temperature
Water reservoir	External bottle (2.8L), or can use a water bag
Oxygen control	Optional, 21% - 75% (in 1% increments)
Trending / history	3hrs – 7days
Computer / network	Optional (2 x RS232 and 1 x nurse call)
Alarms	Lamp on top of sensor unit (at head end) and message on control panel
Maintenance	
Access	Canopy roof tilts and is removable
Water system	External bottle and pipe are removable for cleaning. There is a 'cleaning mode' whereby the water heater is boiled dry.
Consumables	Air filters (every two months), water connection tube (weekly or every patient), temperature probes, O2 sensor (annually)
Service training	Service manual - £52 (available on disk), training is chargeable (cost not suppied)
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb – Full Quality Assurance ISO9001 (TÜV Product Services, 0123) – certificate not seen
Supplier's Quality System	ISO9001 (TÜV Product Services, 0123) – certificate not seen
Device complies with	EN60601-1, EN60601-2, EN60601-2-19
Financial	
Consumables	
Evaluation report	Evaluation 04020 (Mar 2004)
MRRP	£9,947.00 (powered VHA extra)

Supplier: Dräger

Isolette C2000 (Air-Shields)

ID Number	83 D2A2-10
Available since	2000
General	
Dimensions L W H	99 x 67 x 133 - 152 cm
Lockable wheels	3 out of 4 (+1 directional lock)
VHA (mattress height)	90 - 111 cm
Mattress tilt	12º
Ground clearance	11.5 cm
Weight (incl VHA)	90 kg
Description	Incubator with swing-out drawers and relatively long baby compartment.
Options	
Storage options	Swivel-opening drawers (single deep or double shallow), shelves, IV pole
Standard package includes	X-ray tray, 2 humidity reservoirs
Optional features	VHA, servo-controlled oxygen, controlled humidity, weighing scales, gas bottle holder
Baby compartment	
Canopy size L W H	41 cm (mattress to hood)
Mattress size	81 x 41 cm (tray size)
Double walls	Yes, front and rear (long) sides
Tubing ports	10
Canopy flat area	
Air circulation	Up front and rear (long) sides, down foot (short) side
Access to the infant	
Mattress slides out	
Access doors	1, additional door optional
Hand ports	6 (2 additional ports in head and foot walls)

Isolette C2000 (Air-Shields)

Nursing & medical	
Control panel location	Front panel below enclosure
Control panel lock	Yes
Air temperature	Min: 20ºC Max: 37ºC Override: 39ºC
Skin temperature	Min: 34ºC Max: 37ºC Override: 38ºC
Warm-up time	< 35mins (at 22ºC ambient temperature)
Humidification	Optional. Min: 30% Max: 95%
Water reservoir	Drawer in front panel, 1L capacity
Oxygen control	Optional. Min: 21% Max: 65%
Trending / history	2-24 hrs, 7 days for weight
Computer / network	Yes, RS232 ('VueLink' software)
Alarms	Increasing volume with alarm duration, light on sensor module near top of enclosure
Maintenance	
Access	Canopy tilts open or can be removed
Water system	Reservoir is removable from the drawer
Consumables	Skin temperature probes/covers, air filters (every three months),
Service training	Service manual - 1st copy FOC, £34.70 thereafter. Training is chargeable (cost not supplied)
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb - compliance method not supplied ISO9001 (Kerma Medical Quality, 0344 - certificate not seen)
Supplier's Quality System	ISO9001, ISO46001, ISO13485 (TÜV Gmbh, 0123 - certificate not seen)
Device complies with	IEC601-1, IEC601-2-19
Financial	
Consumables	Disposable skin sensors (x10) - £150.00
Evaluation report	Evaluation 375 (Air-Shields Isolette, Feb 1999 - previous model)
MRRP	£10,050.00

Supplier: GE Healthcare

Giraffe & Omnibed (Ohmeda)

ID Number	6651 - #### - 902 (Giraffe) 6650 - #### - 902 (Omnibed)
Available since	2001, 2000
General	
Dimensions L W H	114 x 66 x 147-177 cm Omnibed raised canopy: 208-238 cm
Lockable wheels	4 out of 4
VHA (mattress height)	81-111 cm
Mattress tilt	±12º
Ground clearance	9.5 cm
Weight (incl VHA)	131 kg

Giraffe incubator shown

Description	The Omnibed acts as a combined incubator and radiant warmer unit (see warming therapy section). The top of the canopy can be raised electrically to operate as a warmer. The Giraffe is a standard incubator with one-piece canopy.
Options	
Storage options	Single large drawer, with organiser tray, pulls through from either side (included in price). Rails are non-standard 'dovetail' design. Additional IV poles and shelves available.
Standard package includes	X-ray tray, VHA, controlled humidity
Optional features	Oxygen control, weighing scales, access / iris / tubing port in foot end, gas cylinder holder, RS232 connection ('Thermalink'), examination light
Baby compartment	
Canopy size L W H	
Mattress size	66 x 48 cm
Double walls	Yes, on long sides.
Tubing ports	8
Canopy flat area	
Air circulation	Bi-directional (up both long sides). Additional air curtain 'boost' button increases the fan speed for extended access procedures.
Access to the infant	
Mattress slides out	Slides out either sides, mattress rotates 360º
Access doors	2, one on each long side
Hand ports	4, two in each long side; optional access or iris port in foot end; iris sleeves can be installed on each port

Giraffe & Omnibed (Ohmeda)

Nursing & medical	
Control panel location	Above canopy at head end.
Control panel lock	
Air temperature	Min: 20ºC Max: 37ºC Override: 39ºC
Skin temperature	Min: 35ºC Max: 37ºC Override: 37.5ºC
Warm-up time	<50mins (28ºC to 38.5ºC, with 50% ambient RH)
Humidification	Min: 30% Max: 95%
Water reservoir	Directly into drawer at foot end,1L capacity, level visible on outside, uses distilled water.
Oxygen control	<65% (optional)
Trending / history	Yes, up to 96hrs
Computer / network	Optional, RS232 (‘Thermalink’)
Alarms	Four volume levels, two tones. Temperature difference alarm can be set at 0.5 or 1.0ºC. Condition message on control panel and large alarm light on top of panel.
Maintenance	
Access	Giraffe canopy tilts open for cleaning, Omnibed canopy can be raised. Air filter access behind water reservoir.
Water system	Reservoir drawer is removable. Clean weekly/between patients.
Consumables	Air filters (every three months), temperature probes
Service training	Service manual available following training, training is chargeable (cost not supplied)
Medical Devices Directive	
Manufacturer’s MDD compliance (NB)	Class IIb – Full Quality Assurance ISO9001, EN46001, ISO13485 (BSI, 0086)
Supplier’s Quality System	ISO9001, ISO13485 (BSI 0086)
Device complies with	IEC601-1, IEC601-2, IEC601-2-19, IEC601-2-21(Omnibed)
Financial	
Consumables	Air filters (x10) - £53.30, disposable temperature sensors (x50) - £672.75, reusable temperature sensors - £155.25
Evaluation report	MDA 02090 (July 2002, Giraffe Omnibed)
MRRP	Giraffe - £14,500 - £15,007.50 (depending on port options) Omnibed - £27,900 - £27,945 “ “

Supplier: Inspiration

V 2100G A / B / C (ATOM)

ID Number	A - ATCM6484R B - ATCM6485R C - ATCM6486R
Available since	2000
General	
Dimensions L W H	100 x 58 x 126-146 cm
Lockable wheels	2 out of 4
VHA (mattress height)	89-109 cm
Mattress tilt	± 12º
Ground clearance	12 cm
Weight (incl VHA)	88 kg
Description	Three versions of a single model incubator with increasing functionality. The mattress tilt mechanism can also be used to raise the mattress within the canopy.
Options	
Storage options	Large or small drawers (pull or swing open), IV pole
Standard package includes	VHA, 1 central & 1 peripheral skin temperature probe, 2 access port covers, air filter, dust cover, 2 oxygen sensors.
Optional features	Type B includes peripheral temperature and oxygen controller. Type C additionally includes weighing scales. Ports at head and foot ends can be configured as iris ports or patient circuit holders.
Baby compartment	
Canopy size L W H	100 x 59 x 42 cm
Mattress size	74 x 36 cm
Double walls	Front and rear sides
Tubing ports	Variable depending on options (5-10)
Canopy flat area	83 x 23 cm
Air circulation	Between the front and rear double walls
Access to the infant	
Mattress slides out	18 cm
Access doors	Front and rear sides pull down
Hand ports	6 (additional 2 in short walls configured as required)

V 2100G A / B / C (ATOM)

Nursing & medical	
Control panel location	Front panel
Control panel lock	Flip-cover conceals buttons (photo shows cover in up position)
Air temperature	Min: 23ºC Max: 37ºC Override: 39ºC
Skin temperature	Min: 35ºC Max: 37.5ºC Override: 39ºC
Warm-up time	< 60 mins (from 25ºC ambient temperature)
Humidification	Min: 40% Max: 95% (90% for type A)
Water reservoir	Removable tank in front panel. 1.3L capacity
Oxygen control	Oxygen sensor on all models. Internal oxygen controller for B and C types (external flowmeter control also possible).
Trending / history	No
Computer / network	Printer connection on Type C to print weight
Alarms	Lights on control panel indicate condition, red light on top of sensor unit (near top of canopy)
Maintenance	
Access	Canopy tilts open for cleaning. Air filter access on rear panel.
Water system	Empty and refill every 24hrs
Consumables	Air filters (every three months), skin temperature probes
Service training	Service manual - £85. Training is FOC for 1st day, £750/day thereafter.
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb – Full Quality Assurance ISO9001, ISO13485, EN46001 (TÜV Product Services, 0123)
Supplier's Quality System	ISO9001, ISO13485, EN46001 (CQS Ltd)
Device complies with	IEC601-1, IEC601-2, IEC601-4, IEC601-2-19, EN55011, ISO7767
Financial	
Consumables	Air filters (x5) - £95, disposable temperature probes (x10) – £250
Evaluation report	Report 05061 (Sept 2005)
MRRP	A - £7,400.00, B - £9,000.00, C - £12,500.00

Supplier: Medical Imaging Systems

C186-TS (Fanem)

ID Number	92000800 (DW) 92001800 (SW)
Available since	
General	
Dimensions L W H	107 x 56 x 134-154 cm
Lockable wheels	4 out of 4
VHA (mattress height)	94 - 114 cm
Mattress tilt	±12º (non-continuous)
Ground clearance	13.5 cm
Weight (incl VHA)	68 kg
Description	Basic incubator, available as single (SW) or double-walled (DW) version. Air is humidified passively, without control or monitoring, although an active humidification module is available. Available in four trim colours.
Options	
Storage options	2 small & 1 large drawer on each side, IV pole, shelves for use above unit
Standard package includes	1 skin temperature sensor, 1 air fiter, elastic cuffs for the hand ports
Optional features	Double walls, VHA, weighing scales, humidification of oxygen, heater disinfection tray
Baby compartment	
Canopy size L W H	86 x 41 x 47 cm
Mattress size	63 x 34 cm
Double walls	Optional (DW model has double walls in roof and one long side)
Tubing ports	4
Canopy flat area	
Air circulation	Head to feet
Access to the infant	
Mattress slides out	1/3 of the mattress length
Access doors	1
Hand ports	6 (additional 2 in head (iris) and foot ends – can be configured differently)

C186-TS (Fanem)

Nursing & medical	
Control panel location	Front panel, below canopy.
Control panel lock	No
Air temperature	Min: 20ºC Max: 37ºC Override: 39ºC
Skin temperature	Min: 34ºC Max: 37ºC Override: 38ºC
Warm-up time	30 mins (rise time to 11ºC above ambient)
Humidification	Approx: 60 to 90% (not user set, not controlled/monitored), 1L capacity
Water reservoir	Directly into inlet at head end of base.
Oxygen control	Inlet for externally regulated flow. In normal operation, concentrations of 27-40% are achieved, but air intake can be occluded to increase the oxygen concentration up to 75%.
Trending / history	No
Computer / network	No
Alarms	Condition indicated by LEDs on control panel. Audible alarms silenced for 10mins.
Maintenance	
Access	Canopy tilts open. A tray is available for disinfecting the heater.
Water system	Underneath mattress tray.
Consumables	Air filter (every 90 days, located in rear panel), silver nitrate for water tank
Service training	
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb - Full Quality Assurance ISO9001 (DNV, 0434)
Supplier's Quality System	
Device complies with	IEC60601-1, IEC60601-2, IEC60601-2-19
Financial	
Consumables	
Evaluation report	NA
MRRP	SW - £3,192.00 DW - £3,297.60 (VHA extra - £1,673.00)

Supplier: Medical Imaging Systems

Vision 2186 (Fanem)

ID Number	090.009.800 (LCD) 090.010.800 (ELV)
Available since	
General	
Dimensions L W H	96 x 51 x 127-147 cm
Lockable wheels	4 out of 4
VHA (mattress height)	93 – 113 cm
Mattress tilt	±12º
Ground clearance	13.5 cm
Weight (incl VHA)	93 kg
Description	Two types of display available: LCD (with back light) or electroluminescent (ELV)
Options	
Storage options	2 small & 1 large drawer or cabinets each side, IV pole & shelves for use above unit
Standard package includes	Servo-controlled humidity, X-ray tray, double walls, 1 skin temperature sensor, 1 air filter, elastic cuffs for hand ports
Optional features	Display type, VHA, weighing scales, servo-controlled oxygen, pulse oximeter
Baby compartment	
Canopy size L W H	86 x 41 x 47cm
Mattress size	63 x 34 cm
Double walls	Yes. Single panel covers top of canopy and rear wall, separate panel inside front access door
Tubing ports	4
Canopy flat area	
Air circulation	Head to feet
Access to the infant	
Mattress slides out	1/3 of the mattress length
Access doors	1
Hand ports	6 (additional 2 in head (iris) and foot ends – can be configured differently)

Photo courtesy of MIS

Vision 2186 (Fanem)

Nursing & medical			
Control panel location	Front panel, below canopy. LCD or ELV options.		
Control panel lock	Yes		
Air temperature	Min: 20ºC Max: 37ºC Override: 39ºC		
Skin temperature	Min: 34ºC Max: 37ºC Override: 38ºC		
Warm-up time	40 mins (rise time to 11ºC above ambient)		
Humidification	Min: 30% Max: 95%		
Water reservoir	Tank in drawer, 1L capacity		
Oxygen control	Inlet for externally controlled flow. Optional servo-controlled supply up to 65%.		
Trending / history	Yes, up to 24hrs (weight – 8 days)		
Computer / network	Yes, RS232 serial port, can print at set intervals.		
Alarms	Condition is indicated on the display together with a light on the control panel.		
Maintenance			
Access	Canopy tilts open. A tray is available for the disinfection of the heater unit.		
Water system	Removable tank in drawer accessed from rear panel (autoclavable, every patient).		
Consumables	Air filter (every 3mths, located in rear panel), O_2 cell (every 6mths)		
Service training			
Medical Devices Directive			
Manufacturer's MDD compliance (NB)	Class IIb - Full Quality Assurance ISO9001 (DNV, 0434)		
Supplier's Quality System			
Device complies with	IEC60601-1, IEC60601-2, IEC60601-2-19		
Financial			
Consumables			
Evaluation report	NA		
MRRP	LCD - £7,762.80	ELV - £10,021.00	(VHA extra - £1,689.00)

Transport incubators

How transport incubators work

Transportation of babies can require different levels of intensive care support depending on whether they are very premature and require high levels of warming therapy and ventilation, or larger, sick babies being transferred for specialist surgery, who require intensive monitoring but minimal thermal support. The best choice of transport incubator will depend on the characteristics of the patient group regularly requiring transportation, and the distance to be covered (between hospitals, or between separate buildings on the same site).

Compatibility of trolley fixation equipment and the power supply in the vehicle is vital, whether it be ambulance, plane or helicopter. A transport incubator must include an internal power source (i.e. a rechargable battery) and should have some means for reducing the movement of the infant within the enclosure. All the features appropriate for intensive care nursing incubators may be desirable during transportation and should be securely mounted. These include:

- an effective warming system to keep the baby at a stable temperature
- a warmed internal surface of the canopy to reduce radiant heat loss to cold surfaces
- humidification to reduce evaporative heat loss
- mechanical and/or manual devices for supporting respiration (preferably using warmed and humidified air)
- oxygen enrichment (possibly using a blender)
- rails or poles for accessories (infusion pumps, additional monitors, etc.)
- temperature monitoring
- examination light
- oxygen and medical air supplies

Not all this equipment may be provided by the supplier of the transport incubator, but means to attach such devices should be available. Contact the supplier for information regarding specific accessory features.

The MHRA publications ‘Transfer of Neonates in Ambulances’ (Sept 2001) and ‘Safe use of Ambulance Stretcher Trolleys’ (DB2003(04), Mar 2003) provide useful advice and may be downloaded from www.mhra.gov.uk.

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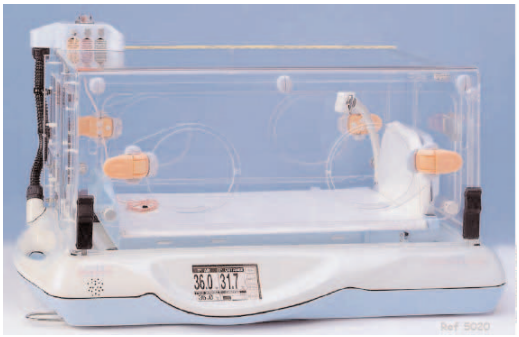
Supplier: Beaver

NITE (Mediprema)

ID Number	5020 (not incl trolley)
Available since	
General	
Dimensions L W H	96 x 58 x 54 cm
Mattress tilt	+10º (non-continuous)
Mattress size	53 x 39 cm
Double walls	No
Tubing ports	1 at head end
Weight	36.5 kg



Description	The baby compartment is heated primarily using a grid of fine wires set into the top surface of the canopy (bit like a radiant warmer). A secondary source of heating (scavenging heat from the power supply) is located under the mattress tray. Several trolley options are available.
Options	
Superstructure & trolley options	5032 – protection & carrying structure (£601.07) 5076 – short superstructure (£1782.38) 5049 – light superstructure w/o trolley (£3091.91) 5071 – TC3000 trolley (£2775.83) 5070 – trolley (£2147.83) 5035 – resuscitation trolley (£2251.21)
Standard package includes	Oxygen analyser, skin temperature probes
Optional features/accessories	Clinical/technical history modules, cover, light, ventilator, shelves & rails, 1hr or 2hr battery packs
Access to the infant	
Mattress slides out	Long side or head end (for resuscitation)
Access doors	4 - one on each side, long sides tilt up, head end opens horizontally from the middle, foot end slides up
Hand ports	4 – two in each long side

NITE (Mediprema)

Nursing & medical	
Control panel location	Below compartment on long side
Control panel lock	No
Air temperature	Min 28ºC Max 37ºC Override 39ºC
Skin temperature	Min 35ºC Max 37ºC Override 38ºC
Warm-up time	20mins (20ºC to 36ºC)
Humidification	No
Oxygen control	Analyser included
Trending / history	Yes, 2hrs to 1 week
Computer / network	IMM software for maintenance
Alarms	Up to 3 alarm messages displayed, red light on top of sensor housing (top of canopy).
Transport	
Battery life	15mins at 39ºC then degrades over 45mins
Battery indicator	Display indicates when there is insufficient voltage to produce the set temperature conditions. The power supply can also be indicated (incl the percentage charge remainging in the battery). Warning messages indicating low battery are also displayed.
Charging time	10hrs
Gas cylinders	Fittings for 2 x gas cylinders; takes Air Liquide B5 size (dia 150mm, length 620mm)
Security	Holes along mattress tray sides for optional straps
Maintenance	
Access	Canopy tilts open
Consumables	Air filters, skin temperature sensors/covers
Service training	
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb - Full Quality Assurance ISO13485 (G-MED, 0459)
Supplier's Quality System	ISO9001 (BSI 0086)
Device complies with	EN60601-1, EN60601-2, EN60601-2-20, EN60601-2-21
Financial	
Consumables	
Evaluation report	NA
MRRP	£13,765.34 (no trolley)

Supplier: Medical Information Systems

IT158-TS (Fanem)

ID Number	158001800
Available since	
General	
Dimensions L W H	102 x 57 x 88 – 119 cm (incl trolley)
Mattress tilt	No
Mattress size	63 x 32 cm
Double walls	Yes
Tubing ports	3 – 1 at head end and 1 either side of access door
Weight	87 kg (incl accessories)
Description	Triangular-tube shaped baby compartment with folding transport trolley. Includes basic humidification.
Options	
Superstructure & trolley options	Variable or fixed height trolley (2 locking wheels), stretcher-type for ambulance fixation
Standard package includes	Two batteries, 1 skin temperature sensor, 1 air filter, elastic cuffs for hand ports
Optional features/accessories	Air temperature control only or skin and air temperature control, IV pole, shelves
Access to the infant	
Mattress slides out	Head end
Access doors	2 (front and head end)
Hand ports	3 (with iris covers)

IT158-TS (Fanem)

Nursing & medical	
Control panel location	Below baby compartment on long side
Control panel lock	No
Air temperature	Min: 30ºC Max: 39ºC
Skin temperature	Optional. Min: 34ºC Max: 37.5ºC Override: 38ºC
Warm-up time	1hr
Humidification	Yes, sponge soaked in 450ml distilled water & placed under mattress tray lasts 12+hrs
Oxygen control	Inlet at head end of compartment
Trending / history	No
Computer / network	No
Alarms	LED and message on display panel.
Transport	
Battery life	4 hrs
Battery indicator	Four LEDs indicate power output to heater
Charging time	30 hrs (LED indicates when charge is completed)
Gas cylinders	2 x E size cylinders fit horizontally between incubator and trolley
Security	Two straps attached to mattress tray
Maintenance	
Access	Hood is detachable
Consumables	Air filters (replace every three months), sponges
Service training	
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	ISO9000 (DNV, 0434 - certificate not seen)
Supplier's Quality System	
Device complies with	IEC60601-1, IEC60601-2, IEC60601-2-20
Financial	
Consumables	
Evaluation report	NA
MRRP	£ 4,823.56 (incl trolley)

Warming therapy

How warming therapy devices work

Today there are many types of baby warmers available on the UK market. Infant radiant warmers can be bought as mobile lamps, mounted permanently on a wall, ceiling or in a cupboard, or as a mobile cot unit. Heated mattresses are commonly foam, gel or water-filled pads heated electrically, which conduct heat to the baby's skin through direct contact.

Radiant warmers and heated mattresses may be used together or separately, and require regular monitoring of the baby's core and skin temperature and adjustment of warmer controls to avoid overheating or cooling. Some cot units offer combined radiant and mattress warming. When a heated mattress is used alone the baby should be covered up. However, if radiant warmers are used (either alone, or in combination with a heated mattress) then manufacturers generally recommend that the baby is not covered, to provide maximum heat transfer to the baby's skin.

The combined use of a radiant warmer and heated mattress will alter the relative effects of heat transfer to and from the baby's skin, compared with when these devices are used separately. The best temperature settings when warming units are used together are likely to be different from those required when they are used alone, in order to achieve the same core and skin temperatures. Regular patient observations are especially important where more than one heat source is used.

Babies should not be placed onto cold warmer units as heat will be conducted away from their skin surface and lost to the environment, causing rapid cooling. This is especially true of warming mattresses as these are designed to be particularly conductive, although the use of surface temperature settings below normal skin temperature can be used to deliberately cool a hyperthermic infant.

Grouping of devices in this report

The devices in this report have been grouped according to the physical design and therapeutic use to facilitate comparison of like with like. However, the range of device types is very diverse and purchasers should consider which types of warmer will best suit their own needs. Most warming devices in this section can be used to provide warmth during infant resuscitation, in combination with the appropriate accessories and facilities. However, some devices are specifically designed for this use, others are for long-term complex care and some best suited to short procedures (examination, treatment and changing).

The device types are summarised in Table 3.

- **Resuscitation cabinets (pages 38-39)**: designed primarily for resuscitation and assessment in the delivery room, and include as a

minimum a resuscitator, suction and APGAR timer. Can be useful for installation in rooms with limited space.

- **Complex care units (pages 40-63)**: radiant warmer and/or heated mattress in a self-contained mobile unit. These include side walls so that the baby can be left unattended. Optional features/accessories can include a resuscitator/ventilator, gas delivery and blender, drip stand, battery, examination light and phototherapy lamp. These allow for flexible use of space and equipment and may also be used for transportation between departments or surgery in the open cot.
- **Free-standing lamps with baby support (pages 64-65)**: a mobile unit for use during treatment, examination or changing, but not suitable for leaving the infant unattended.
- **Free-standing lamps (pages 66-69)**: mobile, overhead radiant devices intended primarily for long-term use with open cribs.
- **Table-top/wall/ceiling mount**: radiant warmers for use on fixed or mobile surfaces, or for long-term care with a portable bassinet. Fixed position or mounted on a flexible arm.
- **Heated mattresses (pages 70-72):** warmed portable surfaces for table-top use or for placement inside a cot

Several radiant warmers are available as different device types, so there are no separate product pages for table top/wall/ceiling mount warmers as the heaters are described on other pages. Note that complex care units solely using heated mattresses have fewer features than those including radiant warmers.

Thermal control

Heater power and irradiance give an indication of the radiant heat capability of the warmer but these should not be compared directly between devices as there are many variables that can affect the ability of the heater to warm the infant. A lower power may not be less effective than a higher value (for difficulties with comparing irradiance values see the Phototherapy introduction).

A heated mattress can maintain a warmed environment for a short duration after the power is removed, especially if the baby is covered. Alternatively a battery can power a mobile warming unit during transferral from one department to another.

Table 3: Warming therapy device types

Resuscitation cabinets	Mobile complex care unit – radiant (with/out warming mattress)		Mobile complex care unit – mattress heating only	Free-standing lamp with baby support	Free-standing lamp	Table-top, wall & ceiling mounts	Heated mattresses
CosyCabinet * (Fisher & Paykel)	ISIS Radiant * (Mediprema)	ISIS Ambiance (Mediprema)	Infant Warming System (Kanmed)	Variotherm Easy Care (Weyer)	ISIS Ambiance (Mediprema)	ISIS Ambiance (Mediprema)	Thermocare Convenience (Weyer)
Infant Resuscitation Cabinet * (Viamed)	CosyCot * (Fisher & Paykel)	Thermocare 2000 KCE (Weyer)	Thermocare 2000 K (Weyer)	Ceratherm with DINO Mobil (Nufer)	Ceramotherm (Weyer)	Ceramotherm (Weyer)	Baby Warmer Complete (Kanmed)
	Multisystem 2051 * (Fanem)	Variotherm 2000 REA-KCE (Weyer)	BabyTherm 8000 (Dräger)		Mobile Infant Warmer (Fisher & Paykel)	Ceratherm (Nufer)	Amecosy (ARDO)
	Resuscitaire * (Air-Shields)	Ohio 3400 / 4400 (Ohmeda)			Ceratherm (Nufer)		
	BabyTherm 8004 / 8010 * (Dräger)	Variotherm 2000 REA-C (Weyer)					
		Giraffe Omnibed (Ohmeda)					

* Indicates devices intended for use as a resuscitation unit

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Table 4: Mobile complex care warming units - features and specifications

Supplier	Beaver		Central Medical Supplies				Dräger
Model	ISIS Radiant	ISIS Ambiance	Infant Warming System	Thermocare 2000 K	Thermocare 2000 KCE / Variotherm 2000 REA-KCE	Variotherm 2000 REA-C	Babytherm 8000
Powered VHA	O	O	O	✓	✓	O	O
Manual control					✓	✓	
Skin temperature control	✓	✓					
Other temperature control	✓	✓	✓	✓	✓		✓
Pre-warm mode							
APGAR timer	✓			O	O	O	O
Examination light	✓	✓			✓	✓	
X-ray tray	✓						
Weighing scales							
Oxygen monitoring	O	O					O
Trending / history	✓	✓					
Computer / network	✓	✓					
Battery							
Resuscitation:							
suction		O			O	O	O
resuscitator	O	O			O	O	
oxygen delivery		O			O	O	O
blender		O			O	O	
Dimensions L W (cm)	110 x 67	62 x 103	75 x 51	114 x 59	114 x 59	114 x 59	95 x 62
Height (cm)	169 - 192	170 - 190	125 - 159	109 - 139	183 - 213	186	123 - 152
Mattress L W (cm)	70 x 27 70 x 40	65 x 51	66 x 45	75 x 50	75 x 50	75 x 50	75 x 49
VHA (mattress height) (cm)	73 - 79	86 - 106	70 - 104	85 - 115	85 - 115	96	89 - 118
Mattress tilt	±15º	±15º	±12º	+20º -10º	+20º -10º	+20º -10º	+20º -15º
Weight incl VHA (kg)	59 62	110	41	70	90	80 ‡	83

✓ - included as standard
O - available as an optional extra
‡ - weight without VHA

Table 4 contd.

Dräger			F&P	GE Healthcare			MIS
Babytherm 8004	Babytherm 8010	Resuscitaire	CosyCot	Omnibed	Ohio 3400	Ohio 4400	Multisystem 2051
O	O	✓	O	✓	✓	✓	O
✓	✓	✓	✓	✓	✓	✓	✓
✓	✓	✓	O	✓	✓	✓	✓
	✓						
		✓	✓	✓	✓	✓	
O	O	✓	✓	✓	✓	✓	✓
✓	✓	✓	✓	O	✓	✓	✓
✓		O	O	✓	✓	✓	#
				O			O
O	O			O			
				✓			
O	O	✓		O	O	O	
			O				
O	O	O	O				O
		O	O				O
O	O	O	O	O			O
		O	O				O
95 x 62	95 x 62	115 x 75	77 x 111	114 x 66	104 x 76	114 x 76	63 x 107
123 - 152	123 - 152	185 - 206	174 - 189	147 - 238	183 - 203	183 - 203	183 - 203
75 x 49	75 x 49	66 x 53	62 x 62 , 62 x 72	66 x 48	66 x 48	77 x 61	64 x 44, 63 x 33
89 – 118	89 – 118	90 - 109	93 - 108	81 – 111	98 - 118	98 - 130	90 - 110
+20º -15º	+20º -15º	±10º	±10º	± 12º	±10º	±10º	+12º -8º ±10º
83	83	127	60	131	91	91	

- no X-ray tray, but includes a gap beneath the mattress for plates

Supplier: Fisher & Paykel

CosyCabinet (Fisher & Paykel)

ID Number	IW980CAB	IW990CAB
Available since	1999	
General		
Dimensions H W D	90 x 73 x 27 cm (closed)	
Mattress size	62 x 62 cm	
Nursing & medical		
Control panel location	Below heater	
Heater control	IW980 – baby/servo control IW990 – manual control	
Examination light	Yes	

Photo supplied courtesy of Fisher & Paykel

Description	Wall-mounted, fold-out cabinet based around manual (990) or baby/servo (980) controlled radiant heater. Uses same heater as for Mobile Infant Warmer and CosyCot (see relevant product pages for warmer details).
Options	
Storage options	Yes
Standard package includes	IW980CAB – Baby-controlled Infant Warmer, skin temp sensor IW990CAB – Manual controlled Infant Warmer Both - Neopuff Infant Resuscitator, test lung, 10 x patient circuits, mattress, 2 x O_2 flowmeters, suction (jar & filter), halogen light, APGAR timer
Optional features / accessories	Left or right opening
Maintenance	
Consumables	Skin sensor & covers, resuscitator circuits
Service training	Service manual - £22.00, training is chargeable - £160
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb (warmer) - Full Quality Assurance ISO9001, EN46001, ISO13485 (TÜV Product Services, 0123)
Supplier's Quality System	ISO9001 (TÜV Product Services, 0123)
Device complies with	IEC60601-1, IEC60601-1-2, IEC60601-2-21 (all devices) ISO8382 (resuscitators)
Financial	
Consumables	Skin sensor - £120.00, sensor covers (x10) - £10.00, resuscitator circuits (x3) - £9.00
Evaluation report	NA
MRRP	Servo controlled - £6,500.00 Manual control - £5,500.00

Supplier: Viamed

Infant Resuscitation Cabinet (Various)

Photos courtesy of Viamed

ID Number	0310002
Available since	1986 (cabinet) 1984 (resuscitator) 1992 (suction controller)
General	
Dimensions H W D	66 x 65 x 28 cm (closed)
Mattress size	66 x 35 cm
Nursing & medical	
Control panel location	Front of heater
Heater control	Manual (4 settable levels)
Examination light	Yes
Description	Fold-out cabinet plus externally wall-mounted Ceratherm 600-2 radiant warmer (see separate product page for details). Sold as a complete unit. Products manufactured by Viamed except where stated otherwise.
Options	
Storage options	Shelf & 3 small bins, rail clamp, dovetail rail
Standard package includes	Ceratherm 600-2 (Nufer), low suction controller & jar, mattress, APGAR timer, Tom Thumb resuscitator, patient circuit (Intersurgical), cabinet (Hospital Metalcraft Ltd)
Optional features / accessories	Suction controller (Therapy Equipment or Oxylitre), jar (Therapy Equipment or Vaxsax)
Maintenance	
Consumables	Suction tubes, patient circuit, tapered connectors, jar liners
Service training	Training charge TBA. Tom Thumb Resuscitator service manual - £30 (available on disk or website). Suction controller service manual - £30 (PPM only). Ceratherm - see warmer product pages.
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Viamed: (Tom Thumb Resuscitator) Class IIa - Full Quality Assurance ISO9001, ISO13485 (BSI 0086). Therapy Equipment: (suction controller) Class IIa – Production Quality Assurance, ISO9002, EN46002 (BSI 0086). Oxylitre: (suction controller) Class IIa - Full Quality Assurance, ISO9001, BS EN46001 (Amtac 0473). Nufer: (Ceratherm) see warmer product pages.
Supplier's Quality System	BS EN ISO9001, ISO13485 (CMDCAS - certificate not seen)
Device complies with	Suction controller: ISO10079-3, BS7259 Pt2 Ceratherm: see warmer product pages.
Financial	
Consumables	Patient circuit - £9.00, Vacsax liners (x25) - £35.10, suction tubing - £1.50/metre
Evaluation report	NA
MRRP	£3,300.00

Supplier: Beaver

ISIS Ambiance (Mediprema)

ID Number	2931/2951 (Maternity Crib) 2932/2952 (Care Crib)
Available since	
General	
Dimensions H W D	62 x 103 x 170 -190 cm
Lockable wheels	2 out of 4
VHA (mattress height)	73 – 79 cm
Mattress tilt	±15º (MC, non-continuous) ±15º (CC)
Ground clearance	NA
Weight (incl VHA)	59 kg (MC), 62 kg (CC)

2952 (Care Crib with VHA) shown

Description	Radiant heater unit with two baby compartment options: 29#1 with a bassinet (maternity crib, MC) or 29#2 with a fixed cot with fold-down sides (care crib, CC). Uses air or baby temperature control. Also available as mobile warmer without crib and wall-mounted warmer.
Options	
Storage options	One large or two smaller drawers
Standard package includes	
Optional features / accessories	VHA, crib type, oxygen analyser, maintenance & trending software, resuscitator, ventilator
Baby compartment	
Crib size L W H	28 x 71 cm (MC), 41 x 71 cm (CC)
Mattress size	27 x 70 cm (MC), 40 x 70 cm (CC)
Walls	Care crib (CC) has four fold-down walls
Tubing ports	None
Treatment distance	75 cm

ISIS Ambiance (Mediprema)

Nursing & medical	
Control panel location	Touch screen on front of heater
Manual control	No
Skin temperature	Min: 35ºC Max: 37ºC Override: 38ºC
Other temperature	Air temperature. Min: 28ºC Max: 37ºC Override: 39ºC
Irradiance / heater power	650 W
Heater 'swing away'	Yes
Examination light	Yes
APGAR timer	No
Oxygen control	No
Trending / history	Up to 2hrs as standard, optional module provides up to a week
Computer / network	Yes. RS232, for clinical and technical monitoring / interrogation
Alarms	Variable volume, settable thresholds, red light under heater
Maintenance	
Consumables	Skin temperature sensors/covers
Service training	Service manual – FOC (available on disk), training is chargeable (cost not supplied)
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb – Full Quality Assurance ISO13485 (G-MED, 0459)
Supplier's Quality System	ISO9001 (BSI 0086)
Device complies with	EN60601-1, EN60601-2, EN60601-2-21
Financial	
Consumables	
Evaluation report	NA
MRRP	2951 - £5,404.03 (MC), 2952 – £6,082.84 (CC) (incl powered VHA)

Supplier: Beaver

ISIS Radiant (Mediprema)

ID Number	4200
Available since	2004
General	
Dimensions H W D	62 x 103 x 170 -190 cm
Lockable wheels	2 out of 4
VHA (mattress height)	86 - 106 cm
Mattress tilt	± 15º
Ground clearance	16 cm
Weight (incl VHA)	110 kg

Description	Radiant warmer bed unit suitable for resuscutation, with additional air-temperature controlled mode – whereby ambient temperature is measured and temperature at the mattress surface is estimated.
Options	
Storage options	Drawers, trays, IV pole,
Standard package includes	APGAR timer, X-ray tray, 1 skin probe
Optional features / accessories	VHA, O_2/air/vacuum panel, blender, oxygen analyser, fold-down front wall, cylinder holder, resuscitator, ventilator
Baby compartment	
Crib size L W H	
Mattress size	65 x 51 cm
Walls	Front and rear are removable, sides fold down (front can also fold down as an option)
Tubing ports	Slots in rear wall
Treatment distance	

ISIS Radiant (Mediprema)

Nursing & medical	
Control panel location	Above head end, touch screen
Manual control	No
Skin temperature	Min: 35ºC Max: 37ºC Override: 38ºC
Other temperature	Air temperature. Min: 28ºC Max: 37ºC Override: 39ºC
Irradiance / heater power	1200 W
Heater 'swing away'	90º
Examination light	Yes
APGAR timer	Yes
Oxygen control	Optional gas distribution panel
Trending / history	Yes, when attached to a PC
Computer / network	Yes. RS232
Alarms	LED alarm message display
Maintenance	
Consumables	Skin temperature probe, suction containers
Service training	Service manual – FOC (available on disk), training is chargeable (cost not supplied)
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb – Full Quality Assurance ISO13485 (G-MED 0459)
Supplier's Quality System	ISO9001 (BSI 0086)
Device complies with	EN60601-1, EN60601-2, EN60601-2-21
Financial	
Consumables	Skin temperature sensor - £123.86, reuseable suction containers - £108.99
Evaluation report	NA
MRRP	£6,372.96 (VHA extra - £1,166.88)

Supplier: Central Medical Supplies

Infant Warming System - Kanmed AB

ID Number	BB-100
Available since	1999 - Baby Bed 1996 - Baby Warmer Complete
General	
Dimensions H W D	75 x 51 x 125 - 159 cm
Lockable wheels	2 out of 4
VHA (mattress height)	70 – 104 cm
Mattress tilt	± 12º
Ground clearance	16 cm
Weight (incl VHA)	approx 33 kg (bed) + 7.5 kg (Baby Warmer Complete)

Photo courtesy of Central Medical Systems

Description	Baby Warmer Complete plus mobile crib suitable for long-term care (see separate product page for mattress details).
Options	
Storage options	Shelf below crib, 2 drawers, IV pole
Standard package includes	Baby Warmer Complete (water mattress, heating pad, 2 nests, control unit), Baby Bed (BB-01 - mobile crib with VHA, tent pole, tent), drawer
Optional features / accessories	VHA, larger bed size for twins, canopy lid
Baby compartment	
Crib size L W H	67 x 45 x 24 cm
Mattress size	66 x 45 cm
Walls	Front and side walls fold down
Tubing ports	Slots in rear wall and gaps between walls.

Infant Warming System (Kanmed AB)

Nursing & medical	
Control panel location	Separate box, hangs from rail below crib
Surface temperature	Min: 34ºC Max: 38ºC (water temperature)
APGAR timer	No
Oxygen control	No
Maintenance	
Consumables	Nests (change at least annually), anti-algae solution (mattress uses tap water – change every three months)
Service training	Service manual - FOC, training - £70/person + expenses
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb (warmer) - Full Quality Assurance ISO9001, ISO13485 (Intertek Semko, 0413)
Supplier's Quality System	ISO9001 (ISOQAR)
Device complies with	EN60601-1, EN60601-2, EN60601-2-35 (Baby Warmer Complete)
Financial	
Consumables	Re-useable nests (each) - £65, anti-algae solution (x20) - £95
Evaluation report	NA
MRRP	£3,995.00

Supplier: Central Medical Supplies

Thermocare 2000 K (Weyer)

ID Number	WY2030
Available since	2003
General	
Dimensions H W D	114 x 59 x 109-139 cm
Lockable wheels	4 out of 4
VHA (mattress height)	85 – 115 cm
Mattress tilt	+20º -10º
Ground clearance	12 cm
Weight (incl VHA)	70 kg

Photo courtesy of Central Medical Supplies

Description	Conductive gel mattress with underbed heating in mobile, enclosed baby compartment.
Options	
Storage options	Shelves and drawers, IV pole
Standard package includes	
Optional features / accessories	APGAR timer, thermometer, oxygen therapy
Baby compartment	
Crib size L W H	76 x 51 cm
Mattress size	75 x 50 cm
Walls	Four fold-down walls, sides also retract into base.
Tubing ports	2

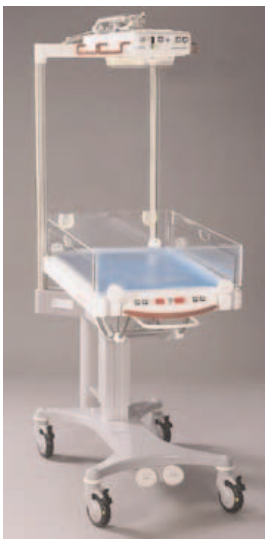
Thermocare 2000 K (Weyer)

Nursing & medical	
Control panel location	Front of unit
Surface temperature	Min: 35ºC Max: 37ºC Override: 30-35ºC and 37-38ºC
APGAR timer	Optional
Oxygen control	No
Maintenance	
Consumables	None
Service training	Service manual - FOC, training is chargeable - £75/person + expenses
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb - Full Quality Assurance ISO9001, ISO13485 (TÜV Rheinland, 0197)
Supplier's Quality System	ISO9001 (ISOQAR)
Device complies with	BS EN60601-1, BS EN60601-2-35
Financial	
Consumables	None
Evaluation report	NA
MRRP	£5,830.00

Supplier: Central Medical Supplies

Thermocare / Variotherm 2000 (Weyer)

ID Number	2032-Thermocare 2000 KCE 2041-Variotherm 2000 REA-C 2043-Variotherm 2000 REA-KCE
Available since	2003
General	
Dimensions H W D	2041 - 114 x 59 x 186 cm 2032/2043 - 114 x 59 x 183 - 213 cm
Lockable wheels	4 out of 4
VHA (mattress height)	2041 - 96 cm 2043/2032 - 85–115 cm
Mattress tilt	+20º -10º
Ground clearance	12 cm
Weight (incl VHA)	2041 – 80 kg (not incl VHA) 2032/2043 – 90 kg
Description	All models use Ceramotherm overhead radiant heaters. The Variotherm REA-C uses a Ceramotherm 1200 heater and does not have powered VHA. Both KCE models use Ceramotherm 2200 heaters and underbed conductive heating. The Thermocare additionally has a fold-up canopy with higher side walls.
Options	
Storage options	Shelves and drawers, IV pole
Standard package includes	
Optional features / accessories	Variotherm 2000 REA-C can be upgraded (to Ceramotherm 2200, VHA (£748), ‘swing away’ heater and underbed conductive warming), vacuum suction unit, gas flowmeters and distributors, resuscitation bag and PEEP valve, APGAR timer, gas bottle holder, higher side walls for Variotherm models, blender
Baby compartment	
Crib size L W H	76 x 51 cm
Mattress size	75 x 50 cm
Walls	Four walls fold-down, side walls also retract into base. Variotherm models have 17cm walls as standard, Thermocare 25cm.
Tubing ports	2
Treatment distance	80 cm



Variotherm 2000 REA-KCE shown. Photo courtesy of Central Medical Supplies.

Thermocare / Variotherm 2000 (Weyer)

Nursing & medical	
Control panel location	On front of heater unit for radiant heater. On front of baby compartment for conductive mattress heater.
Manual control	Continuously variable (output not displayed on Ceramotherm 1200)
Skin temperature	No
Other temperature	Min: 35ºC Max: 37ºC Override: 30-35ºC and 37-38ºC (not Variotherm 2000 REA-C)
Irradiance / heater power	0-30 mW/cm^2
Heater 'swing away'	2041 – No 2032/2043 – Yes, swivel action means the heater remains aimed at the mattress surface
Examination light	Yes
APGAR timer	Optional
Oxygen control	Optional
Trending / history	No
Computer / network	No
Alarms	Yes
Maintenance	
Consumables	None
Service training	Service manual - FOC, training is chargeable - £75/person + expenses
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Variotherm REA-C - Class IIa Variotherm REA-KCE, Thermocare KCE - Class IIb Full Quality Assurance, ISO9001, ISO13485 (TÜV Rheinland, 0197)
Supplier's Quality System	ISO9001 (ISOQAR)
Device complies with	EN60601-1, EN60601-2-21, EN60601-2-35
Financial	
Consumables	None
Evaluation report	NA
MRRP	2041 - £4,995.00 2043 - £7,995.00 2032 - £8,250.00

Supplier: Dräger

Resuscitaire (Air-Shields)

ID Number	82A0#60CEU
Available since	1994
General	
Dimensions H W D	115 x 75 x 185 - 206 cm
Lockable wheels	4 out of 4
VHA (mattress height)	90 - 109 cm
Mattress tilt	± 10º
Ground clearance	
Weight (incl VHA)	127 kg
Description	Warmer unit intended for resuscitation use, also suitable for complex care. Uses quartz heating element.
Options	
Storage options	Large drawers, shelves/trays, IV pole
Standard package includes	VHA, APGAR timer, 2 gas cylinder fittings
Optional features / accessories	Blender, resuscitator, suction, X-ray tray
Baby compartment	
Crib size L W H	
Mattress size	66 x 53 cm
Walls	All walls fold down and also removeable
Tubing ports	Slots in rear wall and gaps between walls
Treatment distance	74 cm

Resuscitaire (Air-Shields)

Nursing & medical	
Control panel location	On stand below heater
Manual control	0-100% (in 10% increments). Automatically adjusted down if ambient temp exceeds 26ºC.
Skin temperature	Min: 34ºC Max: 37ºC Override: 38ºC
Other temperature	No
Irradiance / heater power	750 W
Heater 'swing away'	Yes
Examination light	Yes
APGAR timer	Yes
Oxygen control	Optional
Trending / history	No
Computer / network	Yes, RS232
Alarms	Increasing volume with duration
Maintenance	
Consumables	Auto-breath breathing circuit & valves, breathing circuit diphragms, suction bottle (various sizes) & tubing, suction filters, skin temperature probes/covers
Service training	Service manual – 1st copy FOC, then £45, training is chargeable (cost not supplied)
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb – compliance method not supplied ISO9001, EN46001, EN13485 (Kema Medical Quality, 0344 - certificate not seen)
Supplier's Quality System	ISO9001 (TÜV Gmbh, 0123 - certificate not seen)
Device complies with	
Financial	
Consumables	
Evaluation report	MDA 01043 (Sept 2001)
MRRP	£9,250.00 - £11,680.00 (depending on blender & ventilator options)

Supplier: Dräger

BabyTherm 8000 ('CosiTherm') (Dräger)

ID Number	3208055
Available since	
General	
Dimensions H W D	95 x 62 x 123 – 152 cm
Lockable wheels	2 out of 4
VHA (mattress height)	89 – 118 cm
Mattress tilt	+20º -15º
Ground clearance	13 cm
Weight (incl VHA)	83 kg
Description	Conductive gel mattress with underbed heating in mobile, enclosed baby compartment.
Options	
Storage options	1 or 2 swivel drawers, open to front or side, standard rail
Standard package includes	
Optional features / accessories	VHA, oxygen delivery & monitoring, suction, APGAR timer, canopy lid, nebuliser
Baby compartment	
Crib size L W H	75 x 49 cm
Mattress size	
Walls	Four sides fold-down and have 7cm inner walls
Tubing ports	4 + ventilation tube

BabyTherm 8000 ('CosiTherm') (Dräger)

Nursing & medical	
Control panel location	Front of unit, below enclosure
Surface temperature	Min: 35ºC Max: 37ºC Override: 30-35ºC and 37-38.5ºC
APGAR timer	Optional
Oxygen control	Optional
Maintenance	
Consumables	None
Service training	
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb - compliance method not supplied ISO9001 (TÜV Product Services, 0123 - certificate not seen)
Supplier's Quality System	ISO9001 (TÜV Product Services, 0123 - certificate not seen)
Device complies with	EN60601-1, EN60601-2-35, EN55001, EN55014
Financial	
Consumables	None
Evaluation report	Evaluation 324 (BabyTherm 8000 OC, Apr 1997)
MRRP	£5,150.00

Supplier: Dräger

BabyTherm 8004 / 8010 (Dräger)

ID Number	3208817 - 8004 320848# - 8010
Available since	1997
General	
Dimensions H W D	32 x 75 x 200 – 221 cm
Lockable wheels	2 out of 4
VHA (mattress height)	89 – 118 cm
Mattress tilt	+20º -15º
Ground clearance	13 cm
Weight (incl VHA)	110 kg - 8004 120 kg - 8010
Description	8010 uses underbed conductive warming, 8010 and 8004 use radiant heaters and 8004 includes an X-ray tray. The overhead unit can include halogen phototherapy lamps (for hyperbilirubinaemia) as an option. Peripheral skin temperature is measured in addition to core skin temperature.
Options	
Storage options	1 or 2 swivel drawers, open to front or side,
Standard package includes	Peripheral temperature measurement, X-ray tray (8004), RS232 connector
Optional features / accessories	Phototherapy lamps integrated into overhead heater, VHA, higher side walls (8010 only), oxygen therapy, aspirator, APGAR timer, canopy lid
Baby compartment	
Crib size L W H	75 x 49 cm
Mattress size	
Walls	Four sides fold-down and have 7cm inner walls. Both models have 15cm walls, the 8010 can optionally have 23cm.
Tubing ports	4 + ventilation tube
Treatment distance	80 cm

BabyTherm 8004 / 8010 (Dräger)

Nursing & medical	
Control panel location	8004 - radiant warmer controls on stand below heater 8010 - radiant and mattress controls on stand below heater
Manual control	Levels 1-10 (overhead radiant)
Skin temperature	Min: 35ºC Max: 37.5º C
Other temperature	Min: 30ºC Max: 38.5ºC (surface temperature of mattress)
Irradiance / heater power	< 30 mW/cm^2
Heater 'swing away'	Yes, remains directed at baby
Examination light	Yes, two brightness levels
APGAR timer	Optional
Oxygen control	Optional flowmeters, distributor, hood & monitor
Trending / history	No
Computer / network	Optional, RS232
Alarms	Red (for alarm) and yellow (for caution) LEDs and message on control panel, red light at end of overhead heater
Maintenance	
Consumables	Core and peripheral skin probes, lamps
Service training	Service manual – £50, training is chargeable (cost not supplied)
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb - compliance method not supplied ISO9001 (TÜV Product Services, 0123 - certificate not seen)
Supplier's Quality System	ISO9001 (TÜV Product Services, 0123 - certificate not seen)
Device complies with	EN60601-1, EN60601-1-2, EN60601-2-35 (8010), EN60601-1-21
Financial	
Consumables	
Evaluation report	Evaluation 324 (BabyTherm 8000 OC, Apr 1997), Evaluation 235 (BabyTherm 4200, Dec 1994)
MRRP	8004 - £8,147.00 8010 - £9,390.00 £10,490.00 (incl phototherapy lamp)

Supplier: Fisher & Paykel

CosyCot (Fisher & Paykel)

ID Number	IW930 series IW950 series
Available since	1996
General	
Dimensions H W D	77 x 111 x 174-189 cm
Lockable wheels	4 out of 4
VHA (mattress height)	93 – 108 cm
Mattress tilt	±10º
Ground clearance	12 cm
Weight (incl VHA)	60 kg
Description	Manual (950 series) or baby (930 series) controlled models with the option of two crib sizes.
Options	
Storage options	Large drawer under bassinet with integral shelf, mounting poles, pole-mounted shelves
Standard package includes	IW930 includes 1 skin sensor and 10 sensor covers, also 2 procedure timers
Optional features / accessories	VHA, crib size, storage, phototherapy lamp (see neoBLUEmini in phototherapy section), flowmeter oxygen delivery, Neopuff infant resuscitator, X-ray tray, gas cylinder rack, pressure relief valve, oxygen supply hose
Baby compartment	
Crib size L W H	65 x 65 cm, 75 x 65 cm
Mattress size	62 x 62 cm, 62 x 72 cm
Walls	Front and sides drop down or can be removed.
Tubing ports	6
Treatment distance	68 cm

CosyCot (Fisher & Paykel)

Nursing & medical	
Control panel location	Front of stand, below heater
Manual control	0-100% (both models)
Skin temperature	Min: 34.5ºC Max: 37.5ºC
Other temperature	NA
Irradiance / heater power	< 32 mW/cm^2 (at 68 cm)
Heater 'swing away'	Yes
Examination light	Yes
APGAR timer	Yes
Oxygen control	Optional flowmeter delivery and blender
Trending / history	No
Computer / network	No
Alarms	Yes
Maintenance	
Consumables	Skin sensors & covers, resuscitator circuits
Service training	Service manual - £22, training is chargeable - £160
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb - Full Quality Assurance ISO9001, EN46001, ISO13485 (TÜV Product Services, 0123)
Supplier's Quality System	ISO9001 (TÜV Product Services, 0123)
Device complies with	IEC60601-1, IEC60601-1-2, IEC60601-2-21
Financial	
Consumables	Skin temperature sensor - £120.00, sensor covers (x10) - £10.00, resuscitator circuits (x10) - £41.00
Evaluation report	NA
MRRP	IW950 (manual) - £3,525.00 IW930 (servo) - £3,945.00 (VHA adds £475)

Supplier: GE Healthcare

Giraffe Omnibed (Ohmeda)

ID Number	6650-0###-902
Available since	2000
General	
Dimensions H W D	114 x 66 x 147 – 238 cm
Lockable wheels	4 out of 4
VHA (mattress height)	81 – 111 cm
Mattress tilt	± 12º
Ground clearance	9.5 cm
Weight (incl VHA)	131 kg
Description	Dual-purpose unit converts from incubator to radiant warmer by raising canopy (details given in incubator section).
Options	
Storage options	Single large drawer, with organiser tray, pulls through from either side (included in price). Rails are non-standard ‘dovetail’ design. Additional IV poles and shelves available.
Standard package includes	X-ray tray, VHA, APGAR timer, controlled humidity (as an incubator)
Optional features / accessories	Oxygen control, weighing scales, access / iris / tubing port in foot end, gas cylinder holder, RS232 connection (‘Thermalink’), examination light
Baby compartment	
Crib size L W H	
Mattress size	66 x 48 cm
Walls	Front and sides fold down
Tubing ports	8
Treatment distance	

Giraffe Omnibed (Ohmeda)

Nursing & medical	
Control panel location	At rear, above compartment
Manual control	0-100% in 5% increments
Skin temperature	Min: 35ºC Max: 37.5ºC
Other temperature	NA
Irradiance / heater power	400 W
Heater 'swing away'	No
Examination light	Optional
APGAR timer	Yes
Oxygen control	Optional
Trending / history	Yes, up to 96hrs
Computer / network	Optional, RS232
Alarms	Adjustable sound levels
Maintenance	
Consumables	Air filters (every three months), skin temperature probes/covers
Service training	Service manual – available following training, training is chargeable (cost not supplied)
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb – Full Quality Assurance ISO9001, EN46001, ISO13485 (BSI, 0086)
Supplier's Quality System	ISO9001, ISO13485 (BSI, 0086)
Device complies with	IEC601-1, IEC601-2, IEC601-2-19, IEC601-2-21
Financial	
Consumables	Air filters (x10) - £53.30, disposable skin temperature sensors (x 50) - £672.75, reusable skin temperature sensors - £ 155.25, reflective probe covers (x50) - £14.50
Evaluation report	MDA 02090 (July 2002)
MRRP	£27,945.00 - £30,118.31 (depending on options)

Supplier: GE Healthcare

Ohio 3400 3400 (Ohmeda)

ID Number	3400 - 6612-6001-902 4400 - 6613-6051-902	
Available since	1996	
General		
Dimensions H W D	3400 - 104 x 76 x 183-203 cm 4400 - 114 x 76 x 183-203 cm	
Lockable wheels	2 out of 4	
VHA (mattress height)	3400 - 98 – 118 cm 4400 - 98 – 130 cm	
Mattress tilt	± 10º	
Ground clearance	14.5 cm	
Weight (incl VHA)	91 kg	
Description	Radiant heater units with manual / baby control and optional weighing scales. Incorporates ‘dovetail’ rails, unique to Ohmeda products.	
Options		
Storage options	Shallow or deep drawers, open at front of unit or rotate 360º. Rails are non-standard ‘dovetail’ design. Additional IV poles and shelves available.	
Standard package includes	VHA, X-ray tray, APGAR timer, examination light	
Optional features / accessories	RS232 connection	
Baby compartment		
Crib size L W H		
Mattress size	3400 - 48 x 66 cm	4400 - 61 x 77 cm
Walls	Four fold-down walls	
Tubing ports	Slots in rear wall	
Treatment distance		

Ohio 3400 3400 (Ohmeda)

Nursing & medical	
Control panel location	At rear, below heater – can be rotated to face towards the back of the product (e.g. to face the anaethetist during surgery).
Manual control	0-100% in 5% increments
Skin temperature	Min: 35ºC Max: 37.5ºC
Other temperature	NA
Irradiance / heater power	540 W
Heater 'swing away'	Yes
Examination light	Yes
APGAR timer	Yes
Oxygen control	No
Trending / history	No
Computer / network	Optional, RS232
Alarms	Adjustable sound levels
Maintenance	
Consumables	Skin temperature probes/covers
Service training	Service manual – available following training, training is chargeable (not required for 1st line maintenance, cost not supplied)
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb – Full Quality Assurance ISO9001, EN46001, ISO13485 (BSI, 0086)
Supplier's Quality System	ISO9001, ISO13485 (BSI, 0086)
Device complies with	IEC60601-1, IEC60601-2, IEC60601-2-19
Financial	
Consumables	
Evaluation report	MDA 00390 (Ohio 3400)
MRRP	3400 - £8,129.72 4400 - £9,794.72

Supplier: Medical Imaging Systems

Multisystem 2051 (Fanem)

ID Number	004 0## 800
Available since	
General	
Dimensions H W D	63 x 107 x 183-203 cm
Lockable wheels	4 out of 4
VHA (mattress height)	90 – 110 cm
Mattress tilt	+12º -8º (ICU model) ±10º (bassinet)
Ground clearance	13.5 cm
Weight (incl VHA)	90 kg (incl accessories)
Description	Radiant warmer unit with two style of crib: 'ICU' with fold down walls, or a fixed bassinet-style shape. Bassinet unit can have integral phototherapy tubes and a silicon mattress.
Options	
Storage options	Large shelf under crib, with or without 2 or 4 drawers. Small shelves and IV poles from central column.
Standard package includes	X-ray plate slot, APGAR timer, 1 skin temperature sensor,
Optional features / accessories	VHA (foot pedals extra), crib type (fold down walls or fixed bassinet shape), weighing scales (ICU unit only), resuscitation kit (flowmeters, venturi aspirator & bottle, gas & suction inlets), blender, 2 x E size gas bottle holders & pressure reduction valves with flowmeters, resuscitator, halogen or fluorescent examination lamp
Baby compartment	
Crib size L W H	81 x 57 cm (ICU model)
Mattress size	64 x 44 cm (ICU model) 63 x 33 cm (bassinet)
Walls	ICU model has fold-down walls on front and sides, rear wall is removable
Tubing ports	Gaps between walls and cut-outs in rear wall
Treatment distance	

Multisystem 2051 (Fanem)

Nursing & medical		
Control panel location	Front of stand below heater	
Manual control	0-100% (indicated by 4-LED bar)	
Skin temperature	Min: 25ºC Max: ºC Override: 38ºC	
Other temperature	No	
Irradiance / heater power	560 W	
Heater 'swing away'	Yes	
Examination light	Yes, fluorescent tube or spot halogen	
APGAR timer	Yes	
Oxygen control	Optional flowmeter provision	
Trending / history	No	
Computer / network	No	
Alarms	LEDs indicate alarm condition	
Maintenance		
Consumables	Skin temperature probes/covers/adhesive pads, suction/resuscitation circuits	
Service training	Training is chargeable (trainer's expenses only)	
Medical Devices Directive		
Manufacturer's MDD compliance (NB)	Class unknown - compliance method not supplied ISO9000 (DNV, 0434 - certificate not seen)	
Supplier's Quality System		
Device complies with		
Financial		
Consumables		
Evaluation report	NA	
MRRP	ICU crib - £3,745.56 - £5,131.46	Bassinet crib - £3,178.00

Supplier: Central Medical Supplies

Variotherm Easy Care (Weyer)

ID Number	2020
Available since	2003
General	
Dimensions H W D	91 x 56 x 190 cm
Lockable wheels	4 out of 4
VHA (mattress height)	95 cm
Mattress tilt	Yes
Ground clearance	13.5 cm
Weight (incl VHA)	62 kg

Photo courtesy of Central Medical Supplies

Description	Ceramic heater with additional baby-support surface suitable for examination and changing. Uses Ceramotherm 1100. Includes examination light.
Heater	
Heat source	Ceramic element(s)
Treatment distance	80 cm
Irradiance / heater power	2-18 mW/cm^2 600 W
Positioning aid	NA
Nursing & medical	
Manual control	Continuously variable (output intensity not displayed on 1100 models)
Skin temperature	No
Alarms	Yes (regulates radiated intensity rather than temperature)
Maintenance	
Consumables	None
Service training	Service manual - FOC, training is chargeable – £75/person + expenses
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIa – Full Quality Assurance ISO9001, EN46001 (TÜV Rheinland, 0197)
Supplier's Quality System	ISO9000 (ISOQAR)
Device complies with	EN60601-1, EN60601-2-21
Financial	
Consumables	None
Evaluation report	NA
MRRP	£3,850.00

Supplier: Viamed

Ceratherm 600-2 with DINO Mobil (Nufer)

ID Number	0310041 (DINO Mobil)
Available since	1998
General	
Dimensions H W D	70 cm (length)
Lockable wheels	2 out of 4
VHA (mattress height)	75 cm
Mattress tilt	No
Ground clearance	5.5 cm
Weight (incl VHA)	4.9 kg (heater)

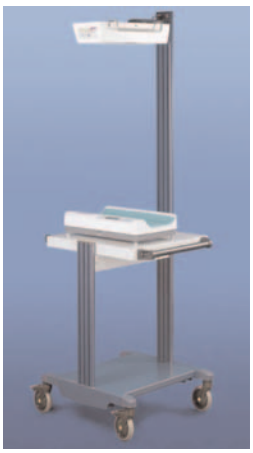


Photo courtesy of Viamed.

Description	Ceramic heater available with mobile stand or with additional baby surface suitable for examination, treatment and changing (DINO Mobil). Includes examination lamp. Also available as a wall/ceiling mounted heater.
Heater	
Heat source	Ceramic element
Treatment distance	80 cm
Irradiance / heater power	< 10 mW/cm^2 600 W
Positioning aid	NA
Nursing & medical	
Manual control	4 levels can be set to any value between 20-99%
Skin temperature	No
Alarms	Yes
Maintenance	
Consumables	None
Service training	Service manual - 1st copy FOC, £25 thereafter, training – TBA
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb – Full Quality Assurance ISO9001, EN46001 (TÜV Product Service, 0123)
Supplier's Quality System	ISO9001, ISO13485 (CMDCAS - certificate not seen)
Device complies with	BS EN60601-2, BS EN60601-2, BS EN60601-2-21
Financial	
Consumables	None
Evaluation report	NA
MRRP	£3,300.00

Supplier: Beaver

ISIS Ambiance (Mediprema)

ID Number	2930, 2950 (with VHA)
Available since	
General	
Dimensions H W D	84 x 67 x 177 cm 95 x 67 x 169 -192 cm
Lockable wheels	2 out of 4
VHA (mattress height)	79 - 102 cm
Mattress tilt	No
Ground clearance	11.5 cm
Weight (incl VHA)	2930 - 36 kg 2950 - 49 kg
Description	Radiant warmer using air temperature control rather than manual output power. Optional oxygen analysis and technical history software module (not incl O_2 probe). Also available as a wall/ceiling mount.
Heater	
Heat source	Ceramic
Treatment distance	75 cm
Irradiance / heater power	650 W
Positioning aid	No
Nursing & medical	
Manual control	NA. Air temperature - Min: 28ºC Max: 37ºC Override: 39ºC
Skin temperature	Min: 35ºC Max: 37ºC Override: 38ºC
Alarms	Variable volume, settable thresholds, red light under heater
Maintenance	
Consumables	Skin temperature probes/covers,
Service training	Service manual – FOC (available on disk), training is chargeable (cost not supplied)
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb – Full Quality Assurance ISO13485 (G-MED, 0459)
Supplier's Quality System	ISO9001 (BSI 0086)
Device complies with	EN60601-1, EN60601-2, EN60601-2-21
Financial	
Consumables	
Evaluation report	NA
MRRP	2930 - £3,228.96 2950 (incl VHA) - £5,042.59

Supplier: Central Medical Supplies

Ceramotherm (Weyer)

ID Number	2112, 2212
Available since	2001
General	
Dimensions H W D	56 x 56 x 154 - 194 cm
Lockable wheels	2 out of 4
VHA (mattress height)	89 – 129 cm
Mattress tilt	Yes
Ground clearance	10 cm
Weight (incl VHA)	8.7 kg (heater) + 16 kg (stand)

Photo courtesy of Central Medical Supplies

Description	Ceramic heater with mobile stand (2112 - Ceramotherm 2100, 2212 - Ceramotherm 2200). Includes examination light. Heaters can be calibrated for other treatment distances (65-90cm).
Heater	
Heat source	Ceramic element(s)
Treatment distance	65cm (default)
Irradiance / heater power	2-28/30 mW/cm^2 2100 – 600W 2200 – 2 x 400W
Positioning aid	Yes, on stand
Nursing & medical	
Manual control	Continuously variable (set and output intensity displayed)
Skin temperature	No
Alarms	Yes (regulates radiated intensity rather than temperature)
Maintenance	
Consumables	None
Service training	Service manual – FOC (available on disk), training is chargeable - £75/person + expenses
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIa – Full Quality Assurance ISO9001, EN46001 (TÜV Rheinland, 0197)
Supplier's Quality System	ISO9001 (ISOQAR)
Device complies with	EN60601-1, EN60601-2-21
Financial	
Consumables	None
Evaluation report	NA
MRRP	2100 - £3,113.00 2200 - £3,311.00

Supplier: Fisher & Paykel

Mobile Infant Warmer (Fisher & Paykel)

ID Number	IW910 IW920
Available since	1996
General	
Dimensions H W D	65 x 19 x 151-191 cm
Lockable wheels	5 out of 5
VHA (mattress height)	86 - 126 cm
Mattress tilt	No
Ground clearance	12 cm
Weight (incl VHA)	22 kg

Photo courtesy of Fisher & Paykel

Description	Manual (IW920) or baby/servo (IW910) controlled mobile heater. Includes examination light, prewarm setting, APGAR and 2 countdown timers.
Heater	
Heat source	Metal element
Treatment distance	65 cm
Irradiance / heater power	< 32 mW/cm^2 450W
Positioning aid	No
Nursing & medical	
Manual control	0-100% (in 5% increments)
Skin temperature	Min: 34.5ºC Max: 37.5ºC
Alarms	Yes
Maintenance	
Consumables	Skin sensors & covers
Service training	Service manual - £22, training is charged - £160
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb - Full Quality Assurance ISO9001, EN46001, ISO13485 (TÜV Product Services, 0123)
Supplier's Quality System	ISO9001 (TÜV Product Services, 0123)
Device complies with	IEC60601-1, IEC60601-1-2, IEC60601-2-21
Financial	
Consumables	Skin sensor - £120.00, sensor covers (x10) - £10.00
Evaluation report	NA
MRRP	Manual (IW920) - £2,525.00 Servo (IW910) - £2,945.00

Supplier: Viamed

Ceratherm 600-2 (Nufer)

ID Number	0310040
Available since	1998
General	
Dimensions H W D	61 x 82 x 170 - 195 cm
Lockable wheels	2 out of 3
VHA (mattress height)	90 – 115 cm
Mattress tilt	Yes
Ground clearance	6 cm
Weight (incl VHA)	4.9 kg (heater)

Photo courtesy of Viamed

Description	Ceramic heater available with mobile stand. Includes examination lamp. Several variants of wall or ceiling mounting are also available.
Heater	
Heat source	Ceramic element
Treatment distance	80 cm
Irradiance / heater power	< 10 mW/cm^2 600 W
Positioning aid	No
Nursing & medical	
Manual control	4 levels can be set to any value between 20-99%
Skin temperature	No
Alarms	Yes
Maintenance	
Consumables	None
Service training	Service manual - 1st manual FOC, £25 thereafter, training – TBA
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb – Full Quality Assurance ISO9001, EN46001 (TÜV Product Service, 0123)
Supplier's Quality System	BS EN ISO9001, ISO13485 (CMDCAS - certtificate not seen)
Device complies with	EN60601-1, EN60601-2, EN60601-2-21
Financial	
Consumables	None
Evaluation report	NA
MRRP	£1,900.00

Supplier: Central Medical Supplies

Baby Warmer Complete (Kanmed AB)

ID Number	BW-50-001
Available since	1996
General	
Control box L W H	21 x 17 x 12 cm
Cable length	3m (mains to control box) 1m (control box to mattress)
Mattress size	65 x 45 x 8 cm (incl nest)
Weight	approx 6 kg (mattress, etc.) 3 kg (control unit)

Photo courtesy of Central Medical Supplies

Description	Water mattress and heating pad, with cover and padded 'nest' for conductive heating. Nest is machine-washable and can be drawn together around the baby using pull-cords (2 are supplied in the purchase price). Device can be battery powered (12-24V) or used inside an enclosed incubator. Mattresses and nests are available in other sizes.
Nursing & medical	
Control panel location	Separate box – can be hung from a horizontal rail.
Surface temperature	Min: 34ºC Max: 38ºC (water temperature)
Warm-up time	4ºC / hr (at 22ºC ambient temperature)
Alarms	Yes
Maintenance	
Consumables	Nests (change at least annually), anti-algae solution (mattress uses tap water – change every three months)
Service training	Service manual - FOC (available on disk), training is chargeable - £75/person + expenses
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb - Full Quality Assurance ISO9001, ISO13485 (Intertek Semko, 0413)
Supplier's Quality System	ISO9001 (ISOQAR)
Device complies with	EN60601-1, EN60601-2, EN60601-2-35
Financial	
Consumables	Re-useable nests (each) - £65, anti-algae solution (x20) - £95
Evaluation report	NA
MRRP	£1,995

Supplier: Central Medical Supplies

Thermocare Convenience (Weyer)

ID Number	WY2011
Available since	2003
General	
Control box L W H	NA
Cable length	2 m
Mattress size	72 x 60 cm
Weight	12 kg

Photo courtesy of Central Medical Supplies

Description	Table-top gel mattress on heating pad, suitable for examination, treatment and changing.
Nursing & medical	
Control panel location	Top surface of support at rear.
Surface temperature	Min: 35ºC Max: 37ºC Override: 30 - 34.5ºC and 37.5 - 38.5ºC
Warm-up time	Approx 30mins
Alarms	Yes
Maintenance	
Consumables	None
Service training	Service manual - FOC, training is chargeable - £75/person + expenses
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIa - Full Quality Assurance ISO9001, ISO13485 (TÜV Product Service , 0197)
Supplier's Quality System	ISO9001 (ISOQAR)
Device complies with	EN60601-1, EN60601-2-35
Financial	
Consumables	NA
Evaluation report	NA
MRRP	£2,695.00

Supplier: Viamed

Amecosy NC1, NC2, NC3 (ARDO)

ID Number	1910010 (NC1) 1910011 (NC2) 1910012 (NC3)
Available since	1997
General	
Control box L W H	25 x 24 x 7 cm
Cable length	3m (mains to control box) 1.8m (control box to mattress)
Mattress size	60 x 77 cm – NC1 84 x 46 cm – NC2 65 x 33 cm – NC3
Weight	4.2 kg (control box) 5.5 kg (NC1) 4.6 kg (NC2) 2.8 kg (NC3)

Image courtesy of Viamed

Description	Table-top or in-bed device with a separate control unit and a choice of three mattress sizes (interchangeable). Rigid base with covered foam mattress. Suitable for examination, changing and treatment. Control box can be hung from a horizontal rail.
Nursing & medical	
Control panel location	Separate control unit
Surface temperature	Min: 28ºC Max: 38ºC (at 24ºC ambient temperature)
Warm-up time	90 mins (for largest mattress, NC1)
Alarms	Variable volume
Maintenance	
Consumables	None
Service training	Service manual - FOC, training is chargeable - TBA
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIa - Full Quality Assurance ISO9001, ISO13485 (TÜV Product Service, 0123)
Supplier's Quality System	BS EN ISO9001, ISO13485 (CMDCAS - certificate not seen)
Device complies with	EN60601-1, EN60601-2, EN60601-2-35
Financial	
Consumables	None
Evaluation report	NA
MRRP	NC1 - £2,100.00, NC2 - £2,100.00, NC3 – £2,050.00 (incl control box)

Phototherapy

How neonatal phototherapy works

Bilirubin is a by-product of the break-down of red-blood cells which is normally excreted by the liver. Neonates, and especially premature babies, may have livers that are not mature enough to perform this task adequately, so that the levels in the blood increase resulting in hyperbilirubinaemia (neonatal jaundice). This is treated by phototherapy because the light at blue or blue-green wavelengths converts the bilirubin molecule into a form that is either easier to excrete or is less toxic to the neonate. The effective spectrum for this process has been identified *in vitro* to peak at around 450nm (blue light). However, light with longer wavelengths (blue-green light) can penetrate further into the skin, so that these may be more therapeutic *in vivo*.

Some devices use strong, white light sources that include significant output at the blue end of the spectrum. The use of these and mixed light sources does not interfere with visual assesment of the neonate's colour and can prevent or alleviate the side effects of intense blue light on carers (e.g. headaches and nausea). However, they may have a reduced therapeutic effect compared to pure blue or blue-green sources.

Irradiance/light sources

The level of light output at different wavelengths is the spectrum of the source. Different light sources produce different shapes of light spectrum, for example the fluorescent tubes used in various devices in this report are not the same type between manufacturers and therefore have different spectra.

Irradiance values provide an indication of the 'strength' of the light and, in this context, represents a total light level over the 400-550nm range. However, direct comparisons between the values given by manufacturers are not generally possible. There are several reasons why an irradiance value provided by a manufacturer is not a good indicator of the relative clinical effectiveness of a lamp:

- The best wavelengths for therapy are not known, therefore one shape of spectrum may be more effective than another with the same total irradiance. A source may have all its energy concentrated in a narrow peak (e.g. LEDs) or distributed across a wide band of wavelengths (e.g. white light sources).
- Irradiance values are usually given at the recommended treatment distance which varies between manufacturers.
- The device used to measure the irradiance (a radiometer) will have a variable sensitivity to different wavelengths and should be calibrated individually for each type of source measured. Even then, the amount of

light collected by the radiometer (the input optics) can have a large effect on the measured value.

- The output can vary from one lamp to another, even when they are of the same type and age (i.e. there is some natural variation in the production of the lamps). The European Standard (EN60601-2-50) allows for a 25% variation in irradiance from that stated by the manufacturer.
- The output of fluorescent tubes declines with age, so they must be replaced at intervals specified by the manufacturer. Halogen and LED sources remain steady until they fail.

Particularly, comparisons cannot be made between manufacturers who quote irradiance (in mW/cm^2) and those who quote spectral irradiance (in $\mu W/m^2/nm$). The first is the sum of the output energy over a particular bandwidth (i.e. over a range of wavelengths) and the second is a measure at the peak of the output spectrum.

To summarise – a higher irradiance value does not necessarily indicate a more effective therapy.

Heating

Phototherapy lamps may also act as a source of radiant heat to an infant. Halogen bulbs can produce a significant amount of heat, although the bulb itself may be remote from the point of delivery of the light (e.g. Giraffe Spot and Ohmeda BiliBlanket). Blue fluorescent tubes produce less heat than white ones and LED sources do not produce a significant heating effect. Although a phototherapy lamp can be useful as supplementary heating, careful temperature monitoring and adjustment of any additional warming devices will be required to avoid overheating.

Treatment

Manufacturers state a minimum treatment distance for each device. For lamps that are designed to be used resting on the canopy of an incubator, the distance from the lamp to the mattress/neonate should be established so that this is not violated. It is important to treat as large a surface area as possible of the infant's body. As the source to mattress distance increases, the illuminated area gets larger but the irradiance (strength) decreases.

Blue light is a hazard to the retina, so that an infant's eyes must be protected from direct phototherapy light. Most manufacturers of neonatal phototherapy devices also produce proprietary eye protection accessories. However, these are not specific to a light source and may be used interchangeably

Table 5: Phototherpay lamps - features and specifications

Supplier	Beaver		CMS	Dräger		GE Healthcare		Medical Imaging Systems				GMS	GMS/ F&P	Viamed		
Model	Ampliflux	Cradle 360°	Bili-Compact	PT 4000	Micro-Lite	Biliblankt Plus	Giraffe Spot	Biliberco	Bilispot	Bilitron	Octofoto	neoBLUE	neoBLUE mini	Amelux	Bilicrystal Mono/Duo	Bulle 2
Installation:																
mobile stand	✓		✓	✓	✓				✓	✓	✓	✓		✓	✓	
pole mounted							✓		✓	✓			✓			
incubator top			✓	✓	✓					✓		✓				
enclosed/surface		✓						✓								✓
Power control						✓				✓		✓		✓		
Treatment timer	✓	✓			✓					✓	O			✓	✓	✓
Lamp hours meter	✓	✓	✓	✓	✓	✓	✓			✓				✓		
Light colour (Blue, White, Mixed)	BWM	B	B	BM	W	B	W	BWM	W	B	BM	M	M	BM	B	B
Lamp replacement interval (hrs)	2000		1000	1000		#	2500	2000		20000				2000	3000	3000
Light source	Fl	Fl	Fl	Fl	H	H	Halide	Fl	H	LED	Fl	LED	LED	Fl	Fl	Fl
Treatment distance (cm)	36	NA	20	30	43	NA	38	NA		30		31	31	35	25	NA

Fl - fluorescent tubes
LED - light emitting diodes
H - halogen bub
- 800-10000 hrs, depending on intensity used

Supplier: Beaver

Ampliflux 1 or 2 Hoods (Mediprema)

ID Number	1922 (1 hood) 1925 (2 hoods)
Available since	1986
General	
Dimensions L W H	71 x 100 x 133-167 cm
Lockable wheels	1922 - 3 out of 3 1925 - 4 out of 4
VHA (mattress height)	97-131 cm
Head tilt	± 90º
Wheelbase height	
Weight	1922 – 29kg 1925 – 45kg
Description	One or two lamp hoods on one stand. For 1925 model, the two lamps are controlled as a single unit (control box on top of stand). For 1922 model, the control in on the front of the hood. White tubes are available as an option. Includes one set of protective eyewear.
Light	
Light source	6 fluorescent tubes per lamp (TL 20W/52)
Peak spectrum	450-460 nm
Treatment distance	36 cm
Irradiance	3.7 mW/cm^2 per hood (using blue tubes only)
Illumination area	
Nursing & medical	
Power control	No
Treatment timer	0-12 hrs, 1925 allows temporary treatment interruption
Alarms	No
Maintenance	
Lamp hours meter	Yes. Check every 500hrs, replace every 2000hrs
Consumables	Tubes
Service training	Service manual – FOC (available on disk), training is chargeable (cost not supplied)
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIa – Full Quality Assurance ISO13485 (G-MED, 0459)
Supplier's Quality System	ISO9001 (BSI 0086)
Device complies with	IEC 60601-1, IEC60601-1-2, EN60601-1-50
Financial	
Consumables	
Evaluation report	NA
MRRP	1922 - £1,549.96 1925 - £4,617.83

Photo courtesy of Mediprema

Supplier: Beaver

Cradle 360 (Mediprema)

Photo courtesy of Mediprema

ID Number	1926
Available since	1990
General	
Dimensions L W H	64 x 90 x 150-182 cm
Lockable wheels	2 out of 4
VHA (mattress height)	97-129 cm
Head tilt	NA
Wheelbase height	17 cm
Weight	65 kg
Description	Tubular light box providing whole body irradiation. Neonate lies on a mesh hammock which slides out to the front. Screens at ends reduce stray light. Enclosure temperature is monitored but not regulated and will reach approximately 33ºC. The top half can be raised manually, altering the irradiance and the air temperature inside the Cradle.
Light	
Light source	16 fluorescent tubes (TL 20W/52)
Peak spectrum	450-460 nm
Treatment distance	Fixed
Irradiance	5 mW/cm^2 per half-hood (at the centre)
Illumination area	Whole body
Nursing & medical	
Power control	Top half can be raised, decreasing the total irradiance.
Treatment timer	1 min – 40 hrs
Alarms	No
Maintenance	
Lamp hours meter	Yes
Consumables	Tubes, hammocks (machine washable - 2 included in purchase price)
Service training	Service manual – FOC (available on disk), training is chargeable (cost not supplied)
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIa – Full Quality Assurance ISO13485 (G-MED, 0459)
Supplier's Quality System	ISO9001 (BSI 0086)
Device complies with	IEC60601-1, IEC60601-1-2, EN60601-2-50
Financial	
Consumables	
Evaluation report	MDA 01160 (December 2001)
MRRP	£6,999.68

Supplier: Central Medical Supplies

Bili-Compact (Weyer)

ID Number	WY1816
Available since	2003
General	
Dimensions L W H	52.5 x 22 x 9 cm (lamp) 70 x 60 x 139 -206 cm (stand)
Lockable wheels	2 out of 4
VHA (mattress height)	103-149 cm (stand)
Head tilt	Tilt and swivel
Wheelbase height	17 cm (stand)
Weight	4.8 (lamp) + 18 kg (stand)

Photo courtesy of Central Medical Supplies

Description	Lamp sold separately for use on top of incubator, or with mobile stand.
Light	
Light source	10 fluorescent tubes (blue - BAM/PL/9/52)
Peak spectrum	450-460nm
Treatment distance	20 cm
Irradiance	3 mW/cm^2
Illumination area	30 x 60 cm
Nursing & medical	
Power control	No
Treatment timer	No
Alarms	No
Maintenance	
Lamp hours meter	Yes
Consumables	Tubes, replace after 1000-1200 hrs
Service training	Service manual – FOC, training is chargeable - £75/person + expenses
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIa – Full Quality Assurance ISO9001, ISO13485 (TÜV Rheinland, 0197)
Supplier's Quality System	ISO9000 (ISOQAR)
Device complies with	EN60601-1, EN60601-2, EN60601-2-50
Financial	
Consumables	Tubes - £22
Evaluation report	NA
MRRP	Lamp - £1,895.00 Stand (WY2003) - £695.00

Supplier: Dräger

Micro-Lite (Air-Shields)

ID Number	2M22310
Available since	
General	
Dimensions L W H	68x73 x 104-160cm (stand) 13 x 59 x 26 cm (lamp)
Lockable wheels	
VHA (mattress height)	
Head tilt	Yes
Wheelbase height	12.7 cm
Weight	9 kg (stand) + 6 kg (lamp)
Description	White-light bulbs with UV and IR filters. Can be used with or without stand (on top of incubator roof).
Light	
Light source	3 quartz halogen bulbs (50W each)
Peak spectrum	
Treatment distance	43 cm
Irradiance	< 10 μW/m^2/nm (400-520nm, blue light)
Illumination area	
Nursing & medical	
Power control	No
Treatment timer	Yes
Alarms	No
Maintenance	
Lamp hours meter	Yes, bulb life > 1000 hrs
Consumables	Bulbs
Service training	
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class unknown - compliance method not supplied ISO9001 (TÜV Product Services, 0123 - certificate not seen)
Supplier's Quality System	ISO9001 (TÜV Product Services, 0123 - certificate not seen)
Device complies with	
Financial	
Consumables	
Evaluation report	MDA 00091(January 2001)
MRRP	£2,750.00

Supplier: Dräger

Photo-Therapy 4000 (Dräger)

ID Number	2M22310
Available since	1994
General	
Dimensions L W H	69 x 60 x 107-162cm(stand) 47 x 29 x 13 cm (lamp)
Lockable wheels	4 out of 4
VHA (mattress height)	77 – 132 cm
Head tilt	Yes
Wheelbase height	13 cm
Weight	5.5 kg (lamp) + 13.6 kg (stand)
Description	Single hood for use with or without mobile stand (slots into holder). Separate on/off switches for blue and white tubes.
Light	
Light source	4 blue + 2 white fluorescent tubes. 6 blue tubes optional – additional blue tubes are not monitored for lamp hours.
Peak spectrum	460 nm
Treatment distance	30 cm
Irradiance	2.4 mW/cm^2 (4 blue tubes) 3.4 mW/cm^2 (6 blue tubes)
Illumination area	
Nursing & medical	
Power control	No
Treatment timer	No
Alarms	No
Maintenance	
Lamp hours meter	Yes, replace after 1000 hrs
Consumables	Blue & white tubes
Service training	Service manual – £5 (available on disk), training is chargeable (cost not supplied)
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIa - compliance method not supplied ISO9001 (TÜV Product Services, 0123 - certificate not seen)
Supplier's Quality System	ISO9001 (TÜV Product Services, 0123 - certificate not seen)
Device complies with	EN60601-1, EN60601-1-2
Financial	
Consumables	
Evaluation report	MDA 01162 (December 2001)
MRRP	£3,000.00

Supplier: GE Healthcare

BiliBlanket Plus (Ohmeda)

ID Number	6600-0415-912
Available since	1996
General	
Dimensions L W H	27 x 11 x 28 cm (light box)
Lockable wheels	NA
VHA (mattress height)	NA
Head tilt	NA
Wheelbase height	NA
Weight	3.2 kg (light box)
Description	A filtered white light source delivering blue therapeutic light via fibre-optics to a plastic pad on which the neonate lies. Optional transillumination cable. Disposable vests can secure the pad to the baby for kangaroo care.
Light	
Light source	Filtered tungsten halogen lamp
Peak spectrum	450 nm
Treatment distance	Skin surface
Irradiance	45 $\mu W/m^2/nm$
Illumination area	10 x 15 cm (pad area)
Nursing & medical	
Power control	Continuously variable (19-45 $\mu W/m^2/nm$)
Treatment timer	No
Alarms	Overheating of light box
Maintenance	
Lamp hours meter	Yes, lifetime of 800-10000 hrs depending on intensity used.
Consumables	Bulbs, disposable pad covers and vests.
Service training	Service manual – in user manual, training is chargeable (not required for first line maintenance, cost not supplied)
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIa - Full Quality Assurance ISO9001, EN46001, ISO13485 (BSI, 0086)
Supplier's Quality System	ISO9001, ISO13485 (BSI, 0086)
Device complies with	IEC 60601-1, IEC60601-1-2
Financial	
Consumables	Bulbs (each) - £43.25, Covers (x50) - £32.00, Vests (each) - £1.18
Evaluation report	Evaluation 391 (April 2000)
MRRP	£2,567.10

Supplier: GE Healthcare

Giraffe Spot PT Lite (Ohmeda)

ID Number	6600-0845-811
Available since	2002
General	
Dimensions L W H	20 x 30 x 13 cm
Lockable wheels	NA
VHA (mattress height)	NA
Head tilt	Flexible arm
Wheelbase height	NA
Weight	4.2 Kg
Description	Light box with flexible arm, delivering spot-light therapy. Fixes to Ohmeda dovetail rails.
Light	
Light source	Metal halide lamp
Peak spectrum	430-440 nm
Treatment distance	38 cm
Irradiance	35 μW/m²/nm
Illumination area	20 cm diameter
Nursing & medical	
Power control	No
Treatment timer	No
Alarms	Overheating of unit.
Maintenance	
Lamp hours meter	Yes, replace after 2500 hrs
Consumables	Bulb, air filter (check quarterly)
Service training	Service manual – in user manual, training is chargeable (cost not supplied)
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIb - Full Quality Assurance ISO9001, EN46001, ISO13485 (BSI, 0086)
Supplier's Quality System	ISO9001, ISO13485 (BSI, 0086)
Device complies with	IEC 60601-1, IEC60601-1-2, IEC60601-2-50
Financial	
Consumables	
Evaluation report	NA
MRRP	£2,700.00

Supplier: Medical Imaging Systems

Biliberco 006FB (Fanem)

ID Number	006005800 (mixed tubes) 006009800 (white tubes)	
Available since		
General		
Dimensions L W H	87 x 43 x 102 cm	
Lockable wheels	2 out of 4	
VHA (mattress height)	NA	
Head tilt	NA	
Wheelbase height	12.5 cm	
Weight	53 kg	
Description	Mobile cabinet with light box on which a clear bassinet is placed. The neonate lies on a clear gel mattress and a curved reflector covers the bassinet. Optional extras include a heated mattress, IV pole and 1 or 2 drawers. 30º mattress tilt optional.	
Light		
Light source	7 fluorescent tubes (4 white + 3 blue as standard, or 7 white)	
Peak spectrum	400-500 nm	
Treatment distance	NA	
Irradiance	14.5 μW/m²/nm (mixed tubes with reflector) 12.1 μW/m²/nm (mixed tubes without reflector)	
Illumination area	NA	
Nursing & medical		
Power control	No	
Treatment timer	Optional	
Alarms	No	
Maintenance		
Lamp hours meter	No (replacement interval 2000hrs)	
Consumables	Tubes, air filter	
Service training		
Medical Devices Directive		
Manufacturer's MDD compliance (NB)	Class unknown - complicance method not supplied ISO9000 (DNV, 0434 - certificate not seen)	
Supplier's Quality System		
Device complies with		
Financial		
Consumables		
Evaluation report	NA	
MRRP	Mixed tubes – £1,769.44	White tubes - £1,710.49

Supplier: Medical Imaging Systems

Bilispot 006BP or 006BB (Fanem)

ID Number	006 002 800 (006BP) 006 003 800 (006BB)
Available since	
General	
Dimensions L W H	145-176 cm (006BP - height)
Lockable wheels	5 out of 5
VHA (mattress height)	
Head tilt	Yes
Wheelbase height	
Weight	13 kg (006BP)
Description	Large spot-light available with mobile stand (006BP) or for mounting on Fanem incubators/warmers (006BB). Light is applied at an oblique angle.
Light	
Light source	Dichroic halogen bulb (white)
Peak spectrum	400-500nm
Treatment distance	40-50 cm
Irradiance	
Illumination area	
Nursing & medical	
Power control	No
Treatment timer	Optional
Alarms	No
Maintenance	
Lamp hours meter	
Consumables	Bulb
Service training	
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class unknown - compliance method not supplied ISO9000 (DNV, 0434 - certificate not seen)
Supplier's Quality System	
Device complies with	
Financial	
Consumables	
Evaluation report	NA
MRRP	BP - £816.13 BB - £596.62

Supplier: Medical Imaging Systems

Bilitron 3006 (Fanem)

ID Number	00600#900
Available since	
General	
Dimensions L W H	12 x 23 x 5 cm (BTI) 4 x 10 x 30 cm (BTB) 50 x 50 x 100-140 cm (BTP)
Lockable wheels	2 out of 3 (BTP)
VHA (mattress height)	70 - 110 cm (BTP)
Head tilt	Yes (BTP and BTB)
Wheelbase height	
Weight	1 kg (lamp) + 2 kg (rail) 9 kg (lamp + stand)

Image not available

Description	Small 'super LED' lamp available with rail attachment for bassinets and incubators (BTB), lamp-only for use on incubator canopies (BTI), or with mobile stand (BTP). LCD display and RS232 output for a PC or printer. Optional attachment allows device to be used as a radiometer.
Light	
Light source	5 super LEDs (blue)
Peak spectrum	450-460 nm
Treatment distance	30 cm (minimum, for babies less than 2.5kg)
Irradiance	35-40 $\mu W/m^2/nm$
Illumination area	25 cm
Nursing & medical	
Power control	Yes, 20-100% (in 10% increments)
Treatment timer	Yes
Alarms	No
Maintenance	
Lamp hours meter	Yes, replace after 20,000 hrs or when irradiance is reduced by 25%
Consumables	LEDs (replaced as a single source unit)
Service training	
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class unknown - compliance method not supplied ISO9000 (DNV, 0434 - certificate not seen)
Supplier's Quality System	
Device complies with	
Financial	
Consumables	
Evaluation report	NA
MRRP	BTB - £1,695.88, BTI - £1,672.53, BTP - £1,868.11

Supplier: Medical Imaging Systems

Octofoto (Fanem)

ID Number	006018700 (4blue + 4white) 006019700 (8blue)
Available since	
General	
Dimensions L W H	94 x 60 x 126 - 164 cm
Lockable wheels	3 out of 3
VHA (mattress height)	76 - 124 cm (approx)
Head tilt	± 180º
Wheelbase height	
Weight	23 kg
Description	Standard overhead fluorescent unit with optional number of blue & white tubes (4 or 8 blue).
Light	
Light source	8 fluorescent tubes (8 blue, or 4 blue + 4 white)
Peak spectrum	400-500 nm
Treatment distance	40-50 cm
Irradiance	
Illumination area	
Nursing & medical	
Power control	No
Treatment timer	Optional
Alarms	No
Maintenance	
Lamp hours meter	No (replacement interval 2000 hrs)
Consumables	Tubes
Service training	
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class unknown - compliance method not supplied ISO9000 (DNV, 0434 - certificate not seen)
Supplier's Quality System	
Device complies with	
Financial	
Consumables	Blue tubes - £29, white tubes - £12
Evaluation report	NA
MRRP	Mixed (4+4) - £949.23 8 Blue - £1,028.62

Supplier: Genesys Medical Solutions

neoBLUE (Natus)

ID Number	10069 (with stand) 40761 (without stand)
Available since	2002
General	
Dimensions L W H	52 x 27 x 183 cm
Lockable wheels	2 out of 5
VHA (mattress height)	77-120 cm
Head tilt	40º
Wheelbase height	10 cm
Weight	3.6 kg (lamp only), 18 kg (with stand)

Photo courtesy of Natus Medical Incorporated

Description	Available with mobile stand or as lamp-only having rubber feet for placement on incubator canopies. A red light allows the user to centre the area of illumination on the infant.
Light	
Light source	Blue and yellow LEDs with diffuser
Peak spectrum	450-475 nm
Treatment distance	30.5 cm
Irradiance	12-15 μW/m²/nm (low) 30-35 μW/m²/nm (high)
Illumination area	50 x 25 cm
Nursing & medical	
Power control	2 intensity settings
Treatment timer	No
Alarms	No
Maintenance	
Lamp hours meter	No. Check output every 6mths – can be adjusted by technician.
Consumables	Blue diodes replaced in groups of 6. Device can continue in use with a few non-working diodes.
Service training	Service manual (fault-finding and PPM) - FOC (available on disk). Training is not required for 1st line maintenance, PPM, calibration or repair.
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIa - Full Quality Assurance EN46001, ISO9001, ISO13485 (TÜV Rheinland, 0197)
Supplier's Quality System	(Working towards ISO9001)
Device complies with	EN60601-1, EN60601-1-2, EN60601-1-2-50
Financial	
Consumables	Blue diodes - £1200
Evaluation report	MHRA 04143 (Dec 2004)
MRRP	£2,850.00 (with stand), £2,710.00 (no stand)

Supplier: Fisher & Paykel, Genesys Medical Solutions

neoBLUEmini (Natus)

Photo courtesy of Natus Medical Incorporated

ID Number	10102
Available since	2004
General	
Dimensions L W H	19 x 14 x 5 cm (lamp only) Arm extends < 81 cm
Lockable wheels	NA
VHA (mattress height)	NA
Head tilt	Yes
Wheelbase height	NA
Weight	2.7 kg (lamp & arm)
Description	Small LED lamp on flexible arm for pole mounting.
Light	
Light source	Blue and yellow LEDs with diffuser
Peak spectrum	450-475 nm
Treatment distance	30.5 cm (minimum)
Irradiance	30-35 μW/m²/nm
Illumination area	20 x 13 cm
Nursing & medical	
Power control	No
Treatment timer	No
Alarms	No
Maintenance	
Lamp hours meter	No. Check output every 3000hrs – can be adjusted by technician.
Consumables	Blue diodes replaced in groups of 6. Device can continue in use with a few non-working diodes.
Service training	Service manual (fault-finding and PPM) - FOC (available on disk). Training is not required for 1st line maintenance, PPM, calibration or repair.
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIa – Full Quality Assurance EN46001, ISO9001, ISO13485 (TÜV Rheinland, 0197)
Supplier's Quality System	Fisher & Paykel - ISO9001 (TÜV Product Services, 0123) Genesys Medical - (Working towards ISO9001)
Device complies with	EN60601-1, EN60601-1-2, EN60601-1-2-50
Financial	
Consumables	
Evaluation report	neoBLUE - MHRA 04143 (Dec 2004)
MRRP	£1,500.00

Supplier: Viamed

Amelux (ARDO)

ID Number	1910000
Available since	2004
General	
Dimensions L W H	72 x 69 x 115 - 160 cm
Lockable wheels	2 out of 3
VHA (mattress height)	80 - 125 cm
Head tilt	Yes
Wheelbase height	7.5 cm
Weight	18 kg
Description	Standard option uses 4 blue and 2 white tubes (6 blue tubes available as a separate model). The four blue and two white/blue tubes are operated independently.
Light	
Light source	4 blue (18W71) and 2 white (18W950) fluorescent tubes
Peak spectrum	430-440 nm
Treatment distance	35 cm
Irradiance	3.5 mW/cm^2 (4 blue tubes)
Illumination area	46 x 23 cm
Nursing & medical	
Power control	Can select 2 or 4 blue tubes
Treatment timer	Yes (does not switch off or alarm)
Alarms	No
Maintenance	
Lamp hours meter	Counts operating time of four blue lights. Replace after 2000 hrs
Consumables	Tubes
Service training	Service manual – FOC, training is chargeable – £TBA
Medical Devices Directive	
Manufacturer's MDD compliance (NB)	Class IIa - Full Quality Assurance ISO9001, ISO13485 (TÜV Product Service, 0123)
Supplier's Quality System	BS EN ISO9001, ISO13485 (CMDCAS - certificate not seen)
Device complies with	EN60601-1, EN60601-2, EN60601-2-50
Financial	
Consumables	Blue tubes - £35 White tubes - £31.50
Evaluation report	NA
MRRP	£1,295.00

Photo courtesy of Viamed

Supplier: Viamed

BiliCrystal System (Medestime)

Light			
Light source	Blue-green fluorescent tubes (DZC 11/75W)		
Peak spectrum	Broadband peak at 446 nm, plus lines at 435 nm and 545 nm		
Nursing			
Power control	No		
Treatment Timer	Yes, up to 12 hrs with buzzer (not Bulle 2)		
Alarms	No		
Maintenance			
Lamp hours meter	Mono/Duo – no	Bulle – yes	(replace after 3000 hrs)
Consumables	Tubes, hammocks		
Service training	Training - TBA		
Medical Device Directive			
Manufacturer's MDD compliance (NB)	Class unknown – Full Quality Assurance ISO9001, ISO13485, EN46001 (SNCF, 0499)		
Supplier's Quality System	BS EN ISO9001, ISO13485 (CMDCAS - certificate not seen)		
Device complies with	IEC60601-1		
Financial			
Consumables	Tubes (each, bought in 6's or 8's) - £20	Hammocks (each) - £20	
Evaluation report	NA		

BiliCrystal Mono/Duo 2 (Medestime)

ID Number	Mono - 2110101 / 2110105 Duo - 2110102 (68 x 62 cm) 2110103 (68 x 77 cm)
Available since	
Description	Overhead lamp on mobile stand with one (Mono) or two (Duo) hoods. Duo - two hoods are controlled simultaneously, are horizontally adjustable and is available in two sizes.
Dimensions L W H	65 x 20 x 11 cm (Mono hood) Duo - 68 x 62 x 105 – 140 cm 68 x 77 x 105 – 140 cm
Lockable wheels	2 out of 4
Head tilt	Yes, 360º
Wheelbase height	9.5 cm
Weight	Mono - 13 kg Duo - 18 kg
Source	4 tubes each hood
Treatment distance	18-25 cm
Irradiance	Mono - 4 mW/cm^2 Duo - 4.3 mW/cm^2
Illumination area	
MRRP	Mono - £3400.00 Duo - £3230.00 or £3350.00

BiliCrystal Bulle 2 (Medestime)

ID Number	2110104
Available since	
Description	Light box with cradles, for use on tabletops, in incubators/warmers and with Medestime trolleys. Neonate lies on a mesh hammock or clear gel mattress. Requires a standard (IV) cradle (15cm high) or shorter incubator cradle. If used in an incubator, the Bulle must be equipped with silicone pipes that extend outside the enclosure to facilitate cooling of the device.
Dimensions L W H	67 x 39 x 12 cm
Lockable wheels	NA
Head tilt	NA
Wheelbase height	NA
Weight	3 kg
Source	6 tubes
Treatment distance	NA
Irradiance	8.9 mW/cm^2
Illumination area	NA
MRRP	Bulle 2 - £2,735.00 IV cradle - £350 Incubator cradle - £280 Silicone pipes - £75

BiliCrystal IV 2 (Medestime)

ID Number	2110100
Available since	
Description	System comprising Bulle 2 and Mono sources, with high-walled IV cradle mounted on trolley. Includes digital thermometer (skin temperature as standard, but air temperature as an option), single control box and two hammocks.
Dimensions L W H	68 x 54 x 116 - 132 cm
Lockable wheels	2 out of 4
Head tilt	Yes
Wheelbase height	NA
Weight	25 kg
Source	2 x 6 tubes
Treatment distance	25 cm (for Mono)
Irradiance	4 (Mono) + 8 (Bulle) mW/cm^2
Illumination area	NA
MRRP	£6,375.00

BiliCrystal Trans (Medestime)

ID Number	2110106
Available since	
Description	System comprising Bulle, high-walled cradle, treatment timer and reflector canopy, mounted on a folding trolley. Designed to fold together for easy storage and transferal between wards, etc.
Dimensions L W H	68 x 45 x 114 cm
Lockable wheels	2 out of 4
Head tilt	NA
Wheelbase height	NA
Weight	10 kg
Source	6 tubes & reflector
Treatment distance	NA
Irradiance	8.9 mW/cm^2
Illumination area	NA
MRRP	£3,725.00

Appendix

Suppliers' contact details

Supplier	Beaver Medical Plc	Central Medical Supplies Ltd	Dräger Medical UK Ltd
	BMP House 21 Mansion Close Moulton Park Northampton NN36 6RU	CMS House Basford Lane Leek Staffordshire ST13 7DT	The Willows Mark Road Hemel Hempstead Hertfordshire HP2 7BW
Warranty	1 year	Weyer 2 years Kanmed 1 year	1 year
Tel	01604 499427	01538 399541	01442 213542
Fax	01604 492212	01538 399572	01442 240327
Website	www.beavermedical.com/ukhomepage.htm	www.centralmedical.co.uk	www.draeger.com/MT/internet/UK/uk/index.jsp
Manufacturer	Mediprema (France)	Kanmed AB (Sweden) Weyer GMBH (Germany)	Dräger (Germany & USA)

Supplier	Fisher & Paykel Healthcare UK	GE Healthcare	Genesys Medical Solutions (UK) Ltd
	Unit 16, Cordwallis Park Clivemont Road Maidenhead Berkshire SL6 7BU	71 Great North Road Hatfield Hertfordshire AL9 7EN	Gibbs House Kennel Ride ASCOT Berks SL5 7NT
Warranty	1 year	1 year	1 year
Tel	01628 626136	01707 263570	0870 6009940
Fax	01628 626146	01707 271013	0870 6009941
Website	www.fphcare.com	www.gehealthcare.com/uken/index.html	www.nibsp-web.com/genesysmedicalsolutions
Manufacturer	Fisher and Paykel Healthcare (New Zealand)	Ohmeda Medical (USA)	Natus Medical Ltd (USA)

Supplier	Inspiration Healthcare Ltd	Medical Imaging Systems	Viamed
	Unit 14, Barshaw Park Leycroft Road Beaumont Leys Leicestershire LE4 1ET	12 Kingsbury Trading Estate Church Lane Kingsbury London NW9 8AU	15 Station Road Cross Hills Keighley West Yorkshire BD20 7DT
Warranty	2 years	1 Year	1 Year
Tel	0116 2351010	0208 205 9500	01535 634542
Fax	0116 2350150	0208 205 0585	01535 635582
Website	www.inspiration-healthcare.co.uk	www.medical-imaging-systems.co.uk	www.viamed.co.uk
Manufacturer	Atom Medical International Inc (Japan)	Fanem (Brazil)	Viamed (UK) Ardo Medical AG (Switzerland) Medestime (France) Nufer Medical AG (Switzerland)

Manufacturing standards for medical devices

Table 6: Standards relevant for the design and manufacture of infant warming and phototherapy equipment

Manufacturing standard	Description
BS EN ISO**13485**:2003 BS EN ISO13485:2001 BS EN ISO13485:1996 ISO13485:1996	Quality systems applied to medical devices. Particular requirements for the application of ISO9001
EN**55011**:1991	Specification for limits and methods of measurement of radio disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment
BS EN**60529**	Specification for degrees of protection provided by enclosures (IPX4: equipment can withstand 'splashing' liquid)
BS EN**60601-1**:1990 IEC60601-1:1988	Medical electrical equipment. General requirements for safety.
BS EN**60601-1-2**:2002 IEC60601-1:1988	Medical electrical equipment. General requirements for safety. Collateral standard. Electromagnetic compatibility. Requirements and tests.
BS EN**60601-2-19**:1997 IEC60601-2-19:1990	Medical electrical equipment. Particular requirements for safety. Specification for baby incubators.
BS EN**60601-2-20**:1997 IEC60601-2-20:1990	Medical electrical equipment. Particular requirements for safety. Specification for transport incubators.
BS EN**60601-2-21**:1997 IEC60601-2-21:1994	Medical electrical equipment. Particular requirements for safety. Specification for infant radiant warmers.
BS EN**60601-2-35**:1997 IEC60601-2-35:1996	Medical electrical equipment. Particular requirements for safety. Specification for blankets, pads and mattresses intended for heating in medical use.
BS EN**60601-2-50**:2001 IEC60601-2-50:2000	Medical electrical equipment. Particular requirements for the safety of infant phototherapy equipment.
ISO**7767**:1997	Oxygen monitors for monitoring patient breathing mixtures. Withdrawn, replaced by ISO21647:2004.
ISO**8382**:1988	Resuscitators intended for use with humans
BS EN ISO**9001**:2000 ISO9001:2000	Quality management systems. Requirements.
ISO**10079**:1999	Medical suction equipment. (BS7259:1993 withdrawn)

BS – British Standard
EN – European harmonised standard
ISO – International Organisation for Standardisation
IEC – International Electrotechnical Commission

A brief guide to the Medical Devices Directive

The European Union Council published the Medical Devices Directive (MDD) in June1993 [4] (93/42/EEC) and it became mandatory in June 1998. It sets out the

'Essential requirements' which a medical device must comply with in order to be eligible for CE-marking. These are necessarily written in very general terms as they cover all products which could fall within the definition of a medical device. The CE mark means that a product can be marketed in any country within the EU as there are no further country-specific requirements.

The European harmonised standards have been developed to provide more specific guidance for manufacturers. It is not necessary to meet the applicable standards in order to be compliant with the 'Essential requirements', but it is the simplest method for a manufacturer to obtain the CE mark. In the UK the British Standards Institute (BSI) publishes European Standards with the prefix "BS EN". The ISO and IEC standards also cover countries beyond the EU borders and may have slightly different requirements to the European standards.

Under the MDD a medical device is classed (I, IIa, IIb or III) according to the risk associated with its use. All the devices in this report are 'medium risk', either IIa or IIb. In order to prove conformity with the MDD for these devices a manufacturer must follow one of the routes in Table 7. The route used by manufacturers in this report has been documented in the product pages (where known).

Table 7: Routes for proving conformity with the Medical Devices Directive

Device Class	Routes to satisfying the Medical Devices Directive & obtaining CE marking	
IIa or IIb	Full Quality Assurance System covering design, production and quality monitoring of the process	
IIa	Declaration of conformity by the manufacturer **AND**	Product Verification (e.g. batch testing) **OR** Product Quality Assurance (i.e. how a unit is tested at the end of the production) **OR** Production Quality Assurance (i.e. how a device is produced)
IIb	Type testing of the device **AND**	

The assessment of the Quality Assurance, type-testing and verification must be carried out by a Notified Body. This is an organisation that has been accredited to carry out these tasks in accordance with various EU directives. Each device is then labelled with a CE mark incorporating the Notified Body's four-digit code number, which is also documented on the product pages in this report (NB).

CEDAR has requested that suppliers provide evidence of the method by which each device has achieved its CE mark.

Glossary

Access door(s)	Large rectangular door in one or more incubator walls allowing greater access to the baby, e.g. for more complex procedures or for the baby or equipment (X-ray tray, headbox, etc.) to be moved in or out of the enclosure
Access doors both sides	Allows easier access for procedures requiring more than one carer
Air circulation	The direction of air flow within an incubator enclosure. Some devices attempt to maintain a 'warm air curtain' across the access ports/doors.
Air temperature	Range of pre-set air temperature values. All incubators and some warmers have a 'normal' and 'extended' range. An 'Override' function must also be used to select a temperature in the extended range.
Alarms	Audible and visual alarms are required to provide feedback to the carer of abnormal sensor and equipment conditions, as specified in the relevant standards. The product pages only document unusual features, such as adjustable volume levels.
APGAR timer	A newborn infant is assessed at 1 and 5 mins after birth (and again at 10 min if there are difficulties) according to set criteria: Activity, Pulse, Grimace, Appearance and Respiration. An APGAR timer provides tones at these set intervals to prompt the assessment.
Available since	The date that the device was first placed on the market (as given on the PPQ – NHS Pre-Purchase Questionnaire)
Battery (complex care units)	The warmer may have the option of a battery to maintain operation, for example, between delivery room and intensive care or the operating theatre.
Battery indicator	Display indicating battery power remaining or the output power level.
Battery life	Duration that the transport incubator can be run off the battery pack provided. Transport incubators can be powered from the mains, from the battery or from a 12V or 24V dc supply (i.e. in an ambulance or helicopter).
Blender	Current standard practice is often to use 100% oxygen for respiratory resuscitation. However, there is growing evidence that room-air can be as effective and that 100% oxygen may result in adverse effects. New ERC guidelines indicate that anything between air (21%) and 100% oxygen is considered "reasonable" [7].
Canopy / crib size	External dimensions of the baby compartment.
Canopy flat area	Area of upper canopy surface, for compatibility with phototherapy lamps which stand on the canopy (see Format).
Charging time	Time to full battery charge from complete discharge.
Complex care	An infant requiring sustained warming therapy, possibly with the inclusion of oxygen enrichment and humidification. This indicates a device in which the infant can be safely left unattended.
Computer / network	The device can be connected to a printer, PC or network to communicate trending data or for central monitoring or analysis.
Consumables	Accessories or parts that (may) require replacement at specific intervals more frequently than once per year. Ordering multiples and list prices are given, where known.
Control box	Warming mattresses may have a separate control box connected to the warming device by a cable.

Control panel lock / cover	The control panel can be locked or covered to prevent accidental changes to set parameters.
Controlled humidification	Relative humidity of the air in the enclosure is monitored and regulated by the device.
Device complies with	A list of the European standards with which the device is claimed to be compliant.
Dimensions	In this report all dimensions are given to the nearest cm, except for the ground clearance/wheelbase height.
Double walls	An internal, non-structural layer of the canopy or crib, designed to reduce the baby's radiant heat loss by providing an internal surface with a higher temperature. May be fitted to only side walls or the canopy roof.
Evaluation report	Number and publication date of any relevant evaluation report featuring the device or an earlier model, obtainable from www.pasa.nhs.uk/cep
Examination light	A white lamp to facilitate visual infant assessment and therapeutic procedures. Useful if ambient light levels are reduced, such as during transportation or ward 'quiet periods', or at night.
Format	Phototherapy devices are now available in a number of physical configurations: overhead lamps which may be attached via a rail or pole, mounted on a wheeled stand or placed on the incubator canopy (see Canopy flat area). Other devices deliver light underneath the infant or surround the baby from many angles.
Gas cylinders	The provision of gas cylinder holders enables continued oxygen therapy and suction during transport.
Ground clearance	Distance between the floor and lowest central region of an incubator or warming device. This should exceed the wheelbase height of accessories.
Hand ports	Small door sufficient to allow a single arm to perform nursing and medical care, usually supplied with catches that can be opened with the elbow for aseptic access. Some may be configured as iris ports, which have a rotating flexible sleeve that can be partially closed, e.g. to secure tubing. Specialised clamps may be available for some devices as optional extras.
Head tilt	Overhead therapy devices (such as radiant warmers and phototherapy lamps) may be positioned at an angle other than directly over the mattress and still direct the heat/light at the infant. Can facilitate simultaneous therapy from several lamps.
Heater 'swing away'	The hood of an overhead radiant heater unit should be able to be moved out of the way, for example, so that a portable X-ray device can be positioned over the infant.
Heater control (resuscitation cabinets)	The overhead heater may have manual control or baby (servo) control of output.
Humidification	Humidifiers may be an optional extra for some incubator models and the product page will list range of pre-set humidity values. Note that humidity is more difficult to monitor and regulate than temperature, and that achievable values depend on the ambient humidity.
ID number	Product code on the IWpF contract on the NHS PASA website for ordering information.
Illumination area	The mattress area that is covered by a therapeutic level of light at the recommended treatment distance – this is 60 x 30 cm unless otherwise stated [8]. The irradiance will decrease from the centre of the field and the infant should have as much of the body surface as possible exposed to the therapeutic light.

Irradiance	This is how the amount of radiation on a surface is measured – whether it is visible light (phototherapy) or infra-red (radiant warmers). The units are mW/cm^2, which is the radiant power per unit area, summed over a range of wavelengths. Some manufacturers quote μW/m^2/nm instead, where it is measured at a single wavelength. Values stated by different manufacturers cannot be compared as they may use different wavelength ranges and be measured by different devices. See also Phototherapy Introduction for information about comparing values.
Kangaroo mode	The infant's temperature can be monitored whilst it is outside the incubator allowing a parent to provide skin-to-skin care. Research has indicated that premature babies are able to maintain their core and peripheral temperatures well during this contact.
Lamp hours meter	The light output of phototherapy lamps using fluorescent tubes gradually decreases with usage, so timers displaying the total number of treatment hours should be used to prompt tube replacement after the manufacturer's stated lamp replacement interval. Other light sources have an expected lifetime, although the output should not decrease for halogen or LED sources.
Light colour	The therapeutic wavelengths for the degradation of bilirubin in vitro are in the visible blue light range. Sources are usually either blue (or blue-green), white or a mixture of the two. Blue light can have adverse effects on carers (symptoms such as nausea and headaches) and make assessment of the infant's colour impossible. White lights may be included to 'balance' the light colour to offset these problems or an intense white light source (which includes the blue wavelengths) may be used for therapy.
Light source	Phototherapy lamps can use fluorescent tubes (blue or white), halogen bulbs (white or filtered) or blue LEDs (light-emitting diodes).
Lockable wheels	The number of locking wheels out of the total number of wheels.
Manual control	Warming devices may be operated at a set level of output indicated in % of maximum or as a certain number of output levels.
Manufacturer's MDD compliance	The classification of the device according to the European Medical Devices Directive (REF) and the means by which the device has achieved a CE mark. Unless otherwise stated CEDAR has been supplied with copies of certificates. See Appendix for a brief explanation.
Mattress elevation	Indicates whether the mattress level can be altered relative to the incubator canopy roof, for example to allow easier access from the ports and doors or reduce the treatment distance for neonatal phototherapy.
Mattress size	Larger bassinets may require staff to reach further to provide nursing care but are appropriate for surgery and may accommodate twins.
Mattress sliding access	The extent to which a mattress can be extended outside the enclosure to allow increased access to the neonate.
Mattress tilt	+ head-up tilt (Trendelenburg) - head-down tilt (reverse Trendelenburg)
MRRP	Manufacturer's Recommended Retail Price – the list price of the standard package as given on the PASA IWpF website. NHS purchasers can access the current IWpF contract prices from the NHS PASA website. (See the Contract details sections of the Introduction). Where powered VHA is an option and not included in this price, the additional cost is provided (where known).
Optional features	Features or additional items that are available if required. They may be charged per item as an additional cost or be available as standard in a different device specification at a higher price.

Other temperature control	Radiant warmers may operate in a mode that regulates the air temperature at the mattress surface. The heated mattress devices in this report operate by regulating the temperature of the heating element or the estimated temperature at the mattress surface.
Oxygen control	The facility to administer oxygen, either by flow meter or servo control, is required for providing oxygen enrichment of an enclosed space or resuscitation of ventilation. Supply can be via a hospital piped gas supply or from cylinders attached to the unit– both oxygen and air are advisable (see Blender).
Oxygen monitoring	Measurement and display of the oxygen concentration in the air. Hoods may be available to concentrate the gas around the infant's head.
Peak spectrum	Approximate wavelength of the light at which the source is strongest. The range of therapeutic light covers 400-550nm (nanometres, $x10^{-9}$m) (BS EN60601-2-50).
Peripheral temperature	Additionally measures skin temperature at a peripheral site (usually the foot). Core-peripheral difference can be used as an indicator of cold stress.
Positionaing aid	Indicates the manufacturer's recommended treatment distance from the radiant heater.
Power control (phototherapy)	Indicates whether the light output can be varied.
Powered VHA	Vertical height adjustment (VHA) allows the height of the mattress surface to be altered to a suitable working height for carers and for seated relatives (e.g. for Kangaroo care or wheelchairs users). The ability to alter the working height of the device is considered necessary for the health and safety of staff in the UK .
Pre-warm mode	A stand-by mode maintaining a warm mattress surface temperature to prevent the rapid cooling of a naked baby, when placed on a cold surface.
Resuscitator	A manually operated device to blow oxygen/air into an infant's lungs during resuscitation. This may use a small bag that is squeezed by hand or operate semi-automatically whereby respiratory pressures are regulated by the device and only the duration of inspiration and expiration are operated manually. This is not the same as a ventilator, which operates entirely automatically, although a device may operate in both modes.
Service training	The availability and cost of service manuals and training for medical equipment technicians/ technologists. FOC = free of charge. Some user training is included in the purchase price by all suppliers.
Servo-controlled oxygen	Oxygen is delivered to the infant to maintain a pre-set concentration in the enclosure. Hoods are available so that the oxygen can be concentrated within a small volume around the infant's head.
Skin temperature	Range of pre-set core skin temperature values (usually measured at the abdomen). All incubators and some warmers have a 'normal' and 'extended' range. An 'Override' function must also be used to select a temperature in the extended range.
Skin temperature (servo) control	Some warmers and all incubators can be operated so that the heat output is regulated to maintain a set core skin temperature, usually measured at the abdomen. For radiant warmers a reflective, adhesive patch should be used to attach the probe to the skin surface to shield the sensor from the heater.
Standard package includes	Equipment features and consumables included in the Manufacturer's Recommended Retail Price (MRRP).
Storage options	Devices are often configurable with a variety of drawer types and sizes and may be accessorised with additional shelves, trays and poles/rails.

Suction	A device suitable for resuscitation should provide suction (may be known as an aspirator) to remove mucous from the infant's airways. This may be connected to the piped vacuum supply in the wall or operate using the Venturi effect from a pressurised air supply (cylinder or piped supply).
Superstructure & trolley options	Transport incubators are designed to operate in several environments: in hospital, in an ambulance or helicopter and in transit between these. The frame/trolley to which the incubator is fastened may be more suitable for one mode than another.
Supplier's quality system	The supplier should maintain an accredited Quality System for the supply and servicing of the devices. Unless otherwise stated CEDAR has been supplied with copies of certificates obtained from a Quality System audit.
Surface temperature	Pre-set values of the mattress surface temperature may be slightly different from the actual temperature achieved if the ambient temperature is particularly high or low.
Treatment distance	The recommended distance from an overhead unit (radiant warmer or phototherapy lamp) to the mattress. The value given is often a minimum distance. The source-mattress distance should be measured as overheating or under treatment can occur if not correctly positioned.
Treatment timer	Phototherapy may be prescribed for a particular time, alternatively intense sources may have an upper limit to the duration of a single therapeutic episode. The timer may count up or down but may not necessarily alarm or turn off the lamp at the end of the pre-set period.
Trending / history	The device can display variations in physiological parameters or device settings over several hours. Alternatively, the device may store a history of instructions. This feature may only be available when the device is connected to a PC.
Tubing ports	Gaps in the enclosure walls containing grommets which help to hold tubing or wires. Slots without tubing support, or gaps between walls are not included in the numerical value.
VHA (mattress height)	Height range of the mattress surface for devices with an integrated mattress and powered VHA. For devices on mobile stands this is the height range of the mattress surface which should be used for treatment. This will depend on the recommended treatment distance and the height range of the stand.
Walls	The walls of a complex care unit may fold down or be removable to facilitate better access to the infant.
Warm-up time	The time to reach a therapeutic temperature from ambient. The manufacturer may state a particular temperature increase at a set ambient temperature.
Water reservoir	Location and capacity of the reservoir for humidification.
Water system	Special instructions for cleaning the humidification water system and the interval, if different from the rest of the device.
Weighing scales	Scales under the mattress support so that the infant does not have to be removed from the device for weighing.
Wheelbase height	The distance from the ground to the top of the base of a mobile lamp (heater or phototherapy). This should be less than the ground clearance of incubators or complex care units that it may be used with.
X-ray tray	Drawer or gap under the mattress into which an X-ray plate can be inserted so that the infant does not have to be moved for imaging. However, this can impair image quality and increase the radiation dose [9], therefore some radiographers may prefer to place the X-ray plate immediately beneath the infant.

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