

Specificație Completată

Model: Giraffe Warmer; Producător: Datex-Omeda, GE Medical Systems GE Healthcare;

Țara: SUA.

| Specificarea tehnică deplină solicitată de către autoritatea contractantă | Specificarea tehnică deplină propusă de către autoritatea contractantă |
|---|--|
| <p>1. Masă de încălzire pentru nou-născuți Masă mobilă pe patru roți antistatice Min 2 roți cu frână Carcasă construită din metal pulverizat rezistent Mîner de transportare Modulul de încălzire cu posibilitatea de rotire orizontală: stînga și dreapta $\geq \pm 50^\circ$ Pătuc pacient cu margini transparente pliabile, detasabile Ajustarea electrică a înălțimii patului Inclinare patuc pacient: tredelemburg, reversetredelemburg $\geq +15^\circ/-15^\circ$ Lampa pentru fototerapie incorporate in modulul de incalzire tip LED Lampă pentru examinare pacient min. 2 regimuri de iluminare Suport pentru monitorul de pacient Suport pentru perfuzie Suport bara laterala pentru dispozitive medicale cu fixator Sertar pentru accesorii medicale (scutece) Saltea siliconica (gel) pentru pacient Modul de monitorizare si control Ecran LCD Buton anulare Alarmer Buton blocare butoane Min. 2 senzori de temperatura pentru pacient (central si periferic) Mod de functionare: preincalzire, mod manual, mod copil Vizualizare pe ecran regim de functionare setat Patuc pacient cu functia de incalzire Control încălzire patuc pacient, 25 – 38 C° Monitorizare: temperature setata/masurata incalzitor, temperature setata/masurata patuc, indicator nivel puterea incalzitor, timp fototerapie Posibilitatea de vizualizare a graficelor pe ecran: temperatura/timp Timer APGAR Controlul temperaturii in modul "Copil" 34,5 C° – 37,5 C° Acuratete control temperature, $\leq 0,5$ C° Acuratetia sensor de temperature, $\leq 0,2$ C° Alarmer incalzitor Alarmer sursa de tensiune Alarma sensor defect Alarma sistem defect Buton anulare alarmer Buton blocare ecran Consumabile si accesorii:</p> | <p>1. Masă de încălzire pentru nou-născuți DA Masă mobilă pe patru roți antistatice DA Min 2 roți cu frână DA Carcasă construită din metal pulverizat rezistent DA Mîner de transportare DA Modulul de încălzire cu posibilitatea de rotire DA orizontală: stînga și dreapta $\geq \pm 50^\circ$ Pătuc pacient cu margini transparente pliabile, detasabile DA Ajustarea electrică a înălțimii patului DA Inclinare patuc pacient: tredelemburg, reversetredelemburg $\geq +12^\circ/-12^\circ$ Lampa pentru fototerapie incorporate in modulul de incalzire tip LED – lampa se livrează ca modul separat, ceea ce dă posibilitatea de a efectua terapii fără unitatea de bază – modelul Lullaby LED PT. Lampă pentru examinare pacient min. 2 regimuri de iluminare – Luminile de observare reglabile încorporate și lumina de procedură orientabilă sunt standard la Girafe Suport pentru monitorul de pacient DA Suport pentru perfuzie DA Suport bara laterala pentru dispozitive medicale cu fixator DA Sertar pentru accesorii medicale (scutece) DA Saltea siliconica (gel) pentru pacient – saltea dintr-un material ignifug și care fi spălat la mașină Modul de monitorizare si control DA Ecran LCD DA Buton anulare Alarmer DA Buton blocare butoane DA Min. 2 senzori de temperatura pentru pacient (central si periferic) – <i>1 sezor de temperatură</i> Mod de functionare: preincalzire, mod manual, mod copil - DA Vizualizare pe ecran regim de functionare setat DA Patuc pacient cu functia de incalzire - Nu Control încălzire patuc pacient, 25 – 38 C°, DA Monitorizare: temperature setata/masurata incalzitor, temperature setata/masurata patuc, indicator nivel puterea incalzitor, timp fototerapie - <i>Indicator nivel puterea încălzitor, temperatura setată/măsurată.</i> Posibilitatea de vizualizare a graficelor pe ecran: temperatura/timp DA Timer APGAR DA Controlul temperaturii in modul "Copil" 34,5 C° – 37,5 C° DA Acuratete control temperature, $\leq 0,3$ C° Acuratetia sensor de temperature, $\leq 0,1$ C°</p> |

| | |
|--|--|
| <p>Senzor temperatura, 4 buc. Saltea siliconica (gel) , 2 buc. 2. NCPAP pentru nou-nascuti Modul nCPAP integrat pe masa de incalzire Decantor extern pentru condensat cu posibilitatea de purjare Ecran color min. 4,5 inch Generator CPAP integrat Regim de ventilare CPAP Regim de ventilare HFNC Control digital al parametrilor ventilatorii Concentratia de oxigen ajustabila 21%- 100% Flux ajustabil, $\geq 1 - 20$ lpm Presiune CPAP ajustabilă $\geq 0 - 10$ cmH2O Măsurarea presiunii în căile respiratorii Vizualizarea pe ecran: flux, concentratie oxigen, presiune CPAP, alarme, nivel baterie La modificarea fluxului concentratia de oxigen rămîne stabilă Alarme audibile și sonore Buton anulare alarme Baterie interna cu autonomia min. 4 ore în regim de ventilare Umidificator inclus integrat pe masa de incalzire: Măsurarea temperaturii în circuitul respirator Posibilitatea de încălzire a circuitului respirator Afișarea digitală a temperaturii Regim de funcționare neinvaziv Tensiune: 220V, 50Hz Presiune aer si oxigen 3-4 bar Accesorii si consumabile incluse: Compresor de aer 1 buc. Umidificator cu functie automata de incalzire 1 buc. Camera de umidificare pentru n/n reutilizabila 2 buc. Cablul cu senzori de temperatura umidificator 3 buc. Cablul adaptor pentru circuitul de încălzire 3 buc. Tub aer și oxigen cu conector de tip DIN Circuite nCPAP pentru n/n cu incalzire, canule nazale de diferite mărimi, min. 50 buc. Kit de mentenanță 2 buc. Garanție 2 ani</p> | <p>Alarme incalzitor DA Alarme sursa de tensiune DA Alarma sensor defect DA Alarma sistem defect DA Buton anulare alarme DA Buton blocare ecran DA Consumabile si accesorii: Senzor temperatura, 4 buc. DA Saltea siliconica (gel) , 2 buc. – DA, saltea dintr-un material ignifug și care fi spălat la mașină</p> <p>2. NCPAP pentru nou-nascuti DA Modul nCPAP integrat pe masa de incalzire DA Generator CPAP integrat DA Regim de ventilare CPAP DA Concentratia de oxigen ajustabila 21%- 100% DA Flux ajustabil, $\geq 1 - 15$ lpm Presiune CPAP ajustabilă $\geq 0 - 30$ cmH2O DA Presiune aer si oxigen 3-4 bar DA Accesorii si consumabile incluse: Tub aer și oxigen cu conector de tip DIN DA Circuite nCPAP pentru n/n canule nazale de diferite mărimi, min. 50 buc. DA Kit de mentenanță 2 buc. DA Garanție 2 ani DA</p> |
|--|--|



Giraffe Warmers

For Neonatal Intensive Care

Helping make sick babies well...

The Giraffe® Warmer, along with the Giraffe Incubator and Giraffe OmniBed®, is designed to meet the needs of the NICU patient and clinician. The innovative heater design eliminates a large overhead heater making it easier to observe the patient and perform procedures such as X-ray examinations. A brilliant full color control panel displays patient parameters and trending. The Giraffe Warmer eliminates alarms during Warmup Mode so you can warm the bed before the baby arrives without disturbing other patients, family or clinicians. Integrated resuscitation and SpO₂ options support the latest resuscitation guidelines. Weighing your baby can be a difficult procedure, but with our integrated in-bed scale option you can weigh the baby at the bedside and easily chart daily weight trends.



Technical Specifications

Giraffe Warmer

| | |
|---------------------------|--|
| Height | (adjustable) 193-218 cm (76-86 in) |
| Depth | 119.4 cm (47 in) |
| Width | 63.5 cm (25 in) |
| Weight | Approx. 100 kg (220 lbs) |
| Standard 2 Drawer | 6.8 kg (15 lbs) |
| Standard Deep Drawer | 6.8 kg (15 lbs) |
| Foot Print | 119.4 x 63.5 cm (47 x 25 in) |
| Floor Space | 7,582 sq cm (1,175 sq in) |
| Mattress Size | 65 x 48 x 4 cm (25.5 x 19 x 1.5 in) |
| Bed to Floor (fixed base) | 83.8-107.9 cm (33-42.5 in) with 4 cm (1.6 in) fixed increments |
| Bed to Floor (elevating) | 83.8-107.9 cm (33-42.5 in) |
| Bed Capacity | Patient weight up to 13.6 kg (30 lbs) |
| Bed Tilting | ± 12° continuous tilt; Bubble level indicates level bed |

Operational Environment

| | |
|--------------------------|---------------|
| Operating Temp. Range | 18°C to 30°C |
| Operating Humidity Range | 5% to 75% |
| Storage Temp. Range | -25°C to 60°C |
| Storage Humidity Range | 0% to 85% |

Resuscitation Unit

| | |
|--------------------------|-------------------|
| Operating Temp. Range | 18°C to 41°C |
| Operating Humidity Range | 0% to 90% |
| Storage Temp. Range | -25°C to +60°C |
| Storage Humidity Range | 0% to 95% |
| Storage Pressure Range | 50 kPa to 106 kPa |

Electrical Power Requirements

115 VAC, 50/60 Hz Models: 115 V ±10%; 6.6 Amps
220-240 VAC, 50/60 Hz Models: 230 V ±10%; 3.3 Amps*
Nominal Power Consumption: 520 W at max. heater power, max. lighting
Complies with IEC 60601-1 for electrical safety

Integrated Resuscitation Characteristics

| | |
|--------------------|-------------------------|
| Input pressure | 40-75 psi (275-517 kPa) |
| Minimum Input Flow | 70 lpm |

Venturi Vacuum Subsystem

| | |
|----------|-------------------|
| Range | 0-150 mm Hg |
| Accuracy | ±5% of full scale |

Adjustable PIP (T-Piece system only)

| | |
|---------------|---|
| Range | 0-30 cm H ₂ O, w/override up to 45 cm H ₂ O |
| Flow Capacity | 15 lpm |

Flowmeters

| | |
|----------|--|
| Range | 0-15 lpm |
| Accuracy | 0-5 lpm ± ½ lpm 5-10 lpm ± 1.5 lpm 10-15 lpm ± 2 lpm |

Air/O₂ Blender

| | |
|----------|------------------------|
| Range | 21-100% O ₂ |
| Accuracy | ±5% O ₂ |

Airway Pressure Manometer

| | |
|---------------|-------------------------------|
| Display Range | -10 to 80 cm H ₂ O |
| Accuracy | ±5% of full scale |

Integrated SpO₂ Characteristics

| Parameter | Masimo SET® | Nellcor Oximax™ |
|---------------------|-------------------------|-------------------------|
| Measurement Range | | |
| SpO2 | 30-100% | 1-100% |
| Pulse Rate | 25-240 bpm | 20-300 bpm |
| SpO2 Accuracy | | |
| From 70-100% | ± 3 digits for neonates | ± 3 digits for neonates |
| Below 69% | Unspecified | Unspecified |
| Pulse Rate Accuracy | | |
| No Motion | ± 3 bpm | ± 3 bpm |
| Motion | ± 5 bpm | N/A |

Integrated Scale Characteristics

| | |
|----------|--------------------------------------|
| Accuracy | ±10 g (0.35 oz) |
| Range | 300 g to 8 kg (0.66 lbs to 17.6 lbs) |

System Control Characteristics

| | |
|--------------------|--|
| Full Color Display | 16.5 cm (6.5 in) |
| Observation Lights | 2 dimmable halogen lights (35 W each), 0-1500 lux average |
| Procedure Light | 50 W, 2000 lux average; estimated life 3000 hrs based on manufacturer's rating |

Warmup Mode

- Automatically started at power up
- Heater operates at 100% power for 7 minutes, then reverts to 50% power
- Check patient alarms eliminated during Warmup mode

Microprocessor Based Control System

| | |
|--|--|
| Self-test function performed at power on and continuously during operation | |
| Heater Warmup Time at 100% Power | less than 3 minutes |
| Heater Element | 360 watts |
| Heater Output | adjustable from 0-100% in 5% increments |
| Patient Control (Baby) Mode | 34°C to 37.5°C in increments of 0.1°C (95°F to 99.5°F) |
| Manual Mode | Indicates manual mode heat selection range from 0 to 100% in 5% increments |
| Temperature Measurement Accuracy | ±0.3°C |
| Resolution | ±0.1°C |
| Probe Accuracy | ±0.1°C |
| Range | 30-42°C (71.6-107.6°F) |

* International specification, not available in the USA



Imagination at work

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JB58605XX

GE Healthcare

Lullaby LED Phototherapy System

Excellent clinical performance,
effortlessly achieved, for a
lifetime of savings



DISCLAIMER: This brochure shares general information on product capabilities. Brochure images are provided for illustration purposes only. Please refer to specification sheets set out with the product in e-catalogue for actual product configuration.



It always starts with excellent clinical performance

An astounding 80% of pre-term and 60% of full-term infants are at risk of hyperbilirubinemia. The Lullaby* LED equips you to deliver high-intensity phototherapy to treat this potentially hazardous condition.

Optimal 458-nm wavelength

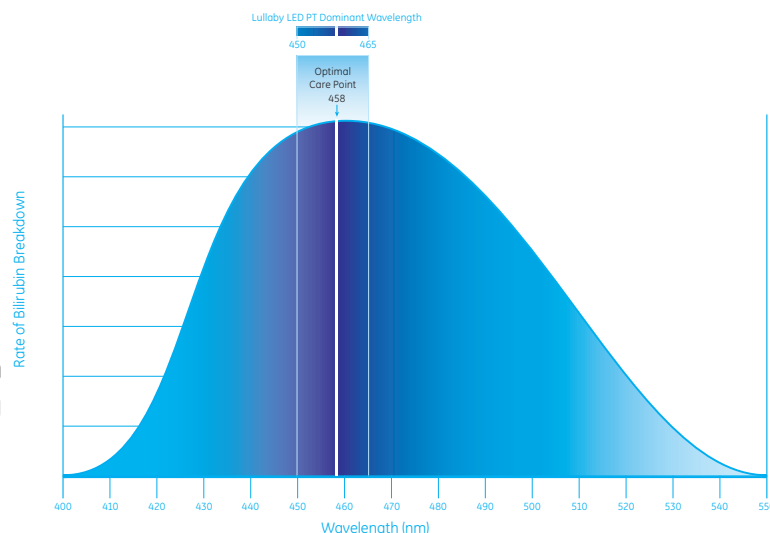
Our LEDs focus tightly on the optimal wavelength (450-465nm) for maximizing bilirubin metabolism.

Ideal irradiance levels

With a high irradiance of 45 $\mu\text{W}/\text{cm}^2/\text{nm}$ and a low irradiance at 22 $\mu\text{W}/\text{cm}^2/\text{nm}$, Lullaby LED allows treatment tailored to each patient's needs.

Uniform light distribution

Our optical design ensures uniform light distribution to the patient's exposed surface area, maximizing bilirubin breakdown.



Lullaby LED focuses tightly on the optimal 458-nm wavelength for maximum bilirubin metabolism.



Designed to promote developmental care for infants

Whisper-quiet operation

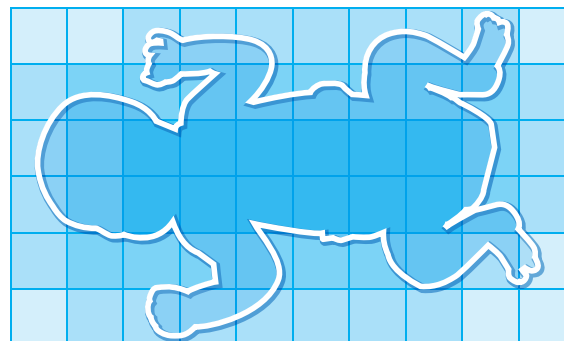
Designed with no fan and no other mechanical moving parts, it operates at 22.4 dB(A) – significantly quieter than prescribed IEC guidelines of 60 dB(A).

No spill, no glare

Our innovative optical design minimizes spill light outside the bed so neither caregivers nor other patients receive undesired exposure to light from the Lullaby LED.

Key ($\mu\text{W}/\text{cm}^2/\text{nm}$)

| |
|-------|
| 10-20 |
| 20-30 |
| 30-40 |
| 40-50 |



Lullaby LED provides high intensity coverage of total body surface area. Above represents the light delivery to a full-term (38-week) infant.

28%
FASTER

The combination of optimal wavelength, high intensity and uniform light distribution yields a 28% faster total serum bilirubin breakdown¹

¹ Based on calculations from Osaku NO, Lopes HS. A dose response model for the conventional phototherapy of the newborn. *Journal of Clinical Monitoring and Computing*. 2006;20(3):159-164



Treat the patient, not the equipment

The Lullaby LED PT is designed to be user friendly and provide worry-free operation day after day.

Removable head - For seamless use with incubators

Light weight - Only 10 kgs for exceptional maneuverability

Ultra compact - Small footprint takes minimal space

Adjustable height - By up to 47 cm

Lamp unit tilt - Up to 90° tilt, allowing use in conjunction with a radiant warmer

Omnidirectional, small wheels - Slide under most bassinets or warmers



An investment for today and tomorrow

Almost 6 years of night and day performance

Our LEDs are rated to last up to an incredible 50,000 hours² before requiring replacement: 50X longer than CFL tubes that require replacement every 1000 hours.

Result? A dramatic reduction in replacement costs, including cost of downtime.

Only 20-watt power consumption

Operating at just 20 watts – up to 80% less than other phototherapy systems – the Lullaby LED can offer almost US\$400 in energy savings over the life of the LEDs.³

² Before a 30% drop in irradiance. Rating is by LED manufacturer under specified operating conditions

³ Over lifetime of 50,000 hours compared to a 100 Watt phototherapy system, assuming a rate of \$0.1 per kWh of electricity

High performance. High productivity.

And a total cost of ownership that's almost too good to be true.



Clinical Performance



Ease of Use



Total Cost of Ownership

Introducing the Lullaby LED phototherapy system with cutting-edge LED technology. It's just what you would expect from a system that builds on the Lullaby legacy. Because every baby deserves the highest standard of care.

Specifications

Performance specifications

| | |
|---|---|
| Spectral irradiance <small>* Using an Ohmeda Medical BiliBlanket* Meter II</small> | High irradiance mode: > 45 $\mu\text{W}/\text{cm}^2/\text{nm}$ Low irradiance mode: > 22 $\mu\text{W}/\text{cm}^2/\text{nm}$ |
| Wavelength range | Dominant wave length range of 450-465 nm |
| LED lamps | LED lamps are rated to last up to 50,000 hours at high power (with 30% lumen depreciation) |
| Maximum noise level | 22.4 dB (A) |

Physical specifications

| | |
|-----------------------------------|--|
| Overall dimensions (L x W x H) | 530 mm x 550 mm x 1700 mm (at maximum height) |
| Total unit weight | 10 kg |
| Footprint | 530 mm x 550 mm |
| Height adjustment | 1130 mm to 1600 mm from light source to floor (Adjustment of 470 mm) |
| Lamp unit weight | 2 Kg |
| Lamp unit dimensions | 360 mm x 230 mm x 80 mm |
| Lamp unit tilt | Continuous up to 90° |
| Effective surface area | 50 cm x 30 cm at 35 cm from the light source |
| Uniformity ratio | > 0.4 (IEC Compliant) |

Packaging details

| | |
|----------------------|---------------------------|
| Box dimensions | 1070 mm x 500 mm x 210 mm |
| Total package weight | 13.5 Kg |

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Electrical specifications

| | |
|--------------------------------------|---|
| 20 W maximum at 100-240 V ~ 50/60 Hz | |
| Overheat protection | Power cutoff for temperature $\geq 85^\circ\text{C}$ |
| Touch current | Less than 500 μA at 264 VAC RMS (power on) with ground intact for normal and reverse polarity and with ground open for normal and reverse polarity |

Environmental operations

| | |
|----------------------|------------------------------|
| Ambient temperature | +10° C to +40° C |
| Humidity | 20% to 95% RH non-condensing |
| Atmospheric pressure | 70 kPa to 106 kPa |

Storage and transportation requirements

| | |
|----------------------|------------------------------|
| Temperature | 0° C to +70° C |
| Humidity | 10% to 95% RH non-condensing |
| Atmospheric pressure | 50 kPa to 106 kPa |

Regulatory standards

| | |
|---------------------------------------|---|
| IEC class 1 (continuous operation) | TUV Rheinland CB certified to the following standards: IEC 60601-2-50; IEC 60601-1; IEC 60601-1-2 |
| EMC class-A, CISPR 11, group 1 | Certified under IECEE CB scheme |

The Lullaby LED is backed by GE Healthcare, a stable partner with global resources to provide you with prompt, expert service support when you need it. Contact your GE Healthcare representative.

About GE Healthcare

Healthymagination is GE's \$6 billion commitment to improve health care access, affordability and quality through advanced technologies, research and development.

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The Giraffe Family

Helping to send babies home healthy



Every Step of the Way

From delivery to discharge, the Giraffe Family provides continuity across the product platform which makes it easier for the user to learn and use multiple products, and reduces staff training time.

Streamlined workflow

Because every patient is different, the Giraffe Family enables a **personalized approach to care** helping to closely monitor patient progress. The enhanced user interface offers a more intuitive and efficient interaction with the equipment while the alarm management minimizes alarm fatigue so clinicians remain focused on patient care.



Away screen: large numerics to get quick update on care

The care station enabler One Baby. One Bed.

When combined with the Giraffe Shuttle, Giraffe beds' convert into a mobile NICU care station providing continuity of care, uninterrupted warmth for the smallest patients and an efficient workflow for caregivers during intra-hospital transport.



The Giraffe Family has **connectivity capabilities** which enable communication to electronic healthcare records and hospital information systems; it is also equipped for future updates and upgrades.

Infection control

With advanced features and a hands-free alarm silence, the Giraffe Family is designed not to promote bacterial or fungal growth.



Hands-free alarm

Promoting healthy growth, development and Family Centered Care

The innovative Giraffe Family delivers exceptional thermoregulation and creates a protected environment for the optimal deployment of neurodevelopmental care by reducing unnecessary distractions and disruptions from touch, light and sound, while supporting family centered care to accelerate parental-baby bonding.



Full 360° rotation pressure-diffusing mattress.



Family Centered Care

Peace of mind and reduced total cost of ownership (TCO)

Leveraging the Giraffe common platform, GE supports your clinical and technical teams over the long run with backward compatibility and few upgradeable features so your fleet remains up-to date. Moreover, with the Giraffe Family you benefit from a tailored service offering maximum operational safety.

A Clinical Commitment

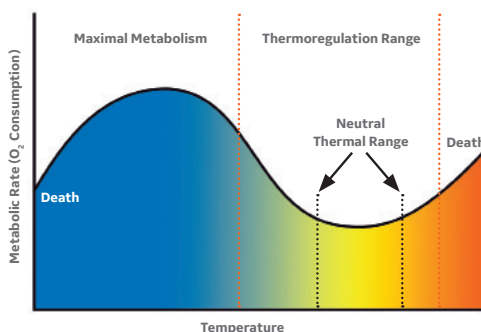
The management of premature infants has evolved over the past three decades to the point where infants now born as early as 22 weeks' gestation have a chance of survival.

Neuro-developmental Care approach

These tiny patients are at high risk of a variety of developmental problems including motor impairments, cognitive deficits, poor achievement, and behavioral disorders. For GE, promoting neuro-developmental care involves supporting the behavioral organization for each individual infant, enhancing physiological stability, protecting sleep rhythms, and promoting growth and maturation. These interventions include handling and positioning measures, reducing noxious environmental stimuli, and cue-based care. Educating and involving parents, acknowledging that they are the most important people in the infant's life and are critical to the infant's emotional, social and physical wellbeing, is a crucial part of Family Centered Care.

Thermoregulation

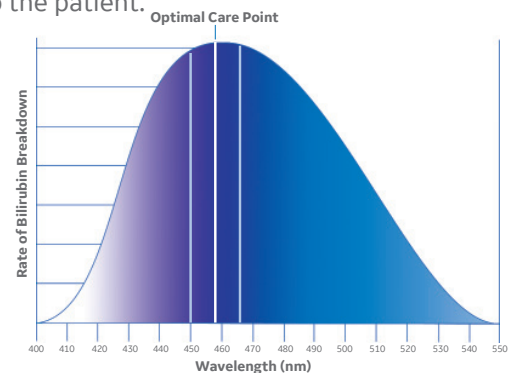
In premature infants, temperature regulation by the central nervous system control is not fully developed. The brain is unable to regulate the metabolism in order to adjust heat production in response to environmental temperature changes¹. Therefore, when environmental temperature changes occur, the premature infant is unable to maintain thermal stability.



Cold stress and hyperthermia may have serious consequences for all newborns. In small-gestational-age and preterm infants (<2500 g) these consequences may be devastating and may increase both morbidity and mortality rates.² Therefore it is extremely important that the micro-environment³ is able to maintain a Neutral Environmental Temperature (NTE) at which: oxygen consumption and metabolic rate are at a minimum, no additional calories are used for heat production and there is no heat loss.

Jaundice treatment

Elevated bilirubin levels can be toxic to the infant's central nervous system. 60% of all newborns become clinically jaundiced (up to 80% of preterms). It is the number one reason for hospital readmissions during the first week of life. The primary purpose for treating hyperbilirubinemia with phototherapy is to avoid the development of kernicterus, a condition with devastating long-term neurologic sequelae. Advances in technology offer the clinician choices about light intensity and delivery methods. There are couple of factors which influence the performance of phototherapy: the wavelength of light (nm), the irradiance level or intensity, the body surface area (cm²), the duration of phototherapy exposure and distance of the light to the patient.



Resuscitation

When it comes to infant resuscitation, time is as precious as your patient. Accurate assessment and rapid responses are necessary to help achieve positive outcomes in compliance with the latest neonatal resuscitation guidelines. Immediate access to everything you need right where you need it is essential to quickly and safely delivering neonatal resuscitation therapy.



Giraffe OmniBed Carestation

Healthy Growth and Development is a Journey

The Giraffe OmniBed Carestation is a full-featured incubator and radiant warmer in one, making its patient micro-environment very special. It was designed to bring babies one step closer to caregivers' expertise and their parents' embrace, and to going home healthy.



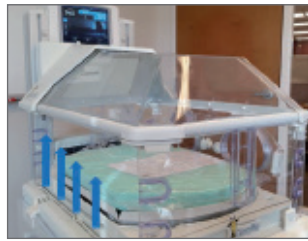
The Best of Both Worlds

- Giraffe OmniBed Carestation allows thermal and physiological stability by delivering a 0.49°C temperature higher than conventional incubators⁴ thanks to:
 - double-wall design**
 - cascade heating algorithm** minimizing temperature swings
 - Comfort Zone⁵** coach to set the NTE
 - active air boost**

Using Giraffe OmniBed appears to deliver “improvements of at least 15% in clinical outcomes such as body temperature, growth velocity, ventilator use, chronic lung disease, weight stabilization, and electrolyte balance.”⁶



Comfort Zone



Active Air Boost

- A versatile bed:** Its ability to smartly convert from a close incubator to an open warmer system offers the major advantage of an **unrestricted patient access** while helping to reduce the risk of infant stress as a result of bed transitions.”³ The Giraffe OmniBed Carestation delivers appropriate thermoregulation needed during most clinical procedures from resuscitation to the surgery or any other NICU procedures such as intubation.
- Safe intra-hospital transports:** From the delivery room to the NICU and beyond, the combination of the Giraffe OmniBed Carestation and the Giraffe™ Shuttle™ founds **One Baby. One Bed. solution.** The solution enhances the continuity of care by eliminating bed transfers and provides the power necessary for thermal and physiologic stability⁶ during intra-hospital transport.
- Hands-free silence alarm** and **hand-free canopy lift** allows continuous sterile environment.

Giraffe OmniBed Carestation minimizes stressful touches as it helps reduce bed transfers in the first critical 10 days and ensures the best position of the patient during procedures thanks to the full **360° rotating, pressure diffusing Baby Susan mattress.** Furthermore, the bed design encourages clinicians to provide positive touches and secure patient (bed tilting, XRay, canopy lift).

- The humidifier** is designed with universal precautions of sterility in mind to protect against infection by boiling small amounts of water and **directly inject the steam** into the environment (**ability to drain the system, no dedicated cleaning mode for humidifier**). Easy to change and refill water reservoir on the go. **2 weeks cleaning cycle*.**
- A quiet micro environment:** Giraffe OmniBed Carestation operates at **40 dBA sound level** which is below the AAP recommendation (45 dBA). In addition, its designs attenuates the outside noise level by about 12 dBA⁷ (double wall design, hood cover, loudspeaker position).
- Easy Kangaroo care:** designed specifically to support parental bonding and contact as adjustable height, passthrough drawer, removable side wall panels. The patented mattress makes easy the first contact of the mother and the establishment of bonding to the child through barrier-free access - no disturbing components in the mother seating area. Furthermore, the Giraffe OmniBed Carestation helps create the needed cosy environment with **adapted alarm management** during skin to skin procedure, **simplified screen** for parents.



Bonding to the child through barrier-free access

- Secure additional equipments from both sides' rails and customize your own care station.

Giraffe Incubator Carestation

Newborns in the NICU need extra special care from clinicians and their families. As one of the most advanced, neurodevelopmentally supportive closed microenvironments, the Giraffe Incubator Carestation is specially designed to give babies the comfort and stability they need to grow, heal and go home healthy. Features include:

- **Air boost protects the baby from heat loss** when either panel is opened to support thermal stability.
- **Large color display (10.4") and touchscreen user interface** helps clinicians streamline their workflow while monitoring and controlling the baby's environment.
- **Customized screens** contribute to the personalized, patient and family-friendly care environment while providing continued visual monitoring.
- **Hands free alarm silence** allows clinicians to quickly silence the alarms while providing care and maintaining a quiet environment
- **Patented Baby Susan 360 ° rotating mattress** enhances productivity by allowing the clinician to easily position the baby for clinical procedures, optimizing their efforts to get it right the first time and minimizing unnecessary baby stimulation.
- **Pressure diffusing mattress** reacts to the impact of the baby's body, reducing pressure points while minimizing motion, and disruption and maximizing comfort.
- In **Whisper Quiet Mode**, the Giraffe Carestation delivers a quiet acoustic environment. As the Giraffe Carestation provides a low noise level (40 dBA), the ambient noise in the NICU room becomes the major factor affecting neonate noise exposure in incubators.
- **Smart Graphics trends** help closely monitor changes in weight, thermo-regulation, humidity & servo oxygen.
- **Connectivity capabilities** enables communication with electronic healthcare records and hospital information systems; it is equipped for future updates and upgrades.

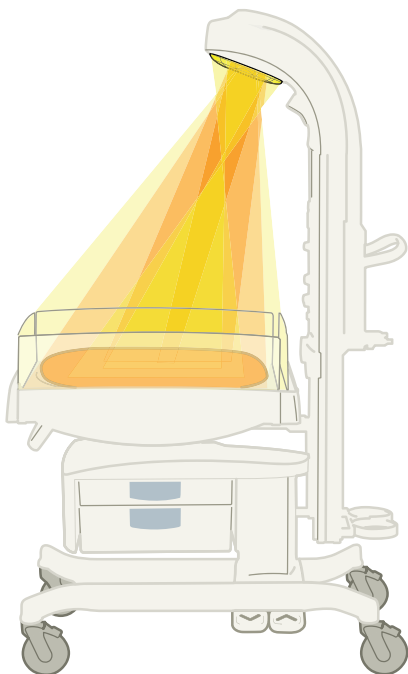


Giraffe Warmer

The Giraffe Warmer delivers powerful, uninterrupted thermal performance with fully-integrated features and options.

The result? A warm, comfortable, and developmentally-supportive environment for the baby. Complete access, visibility and control for the caregiver.

- **Recessed Heater** provides exceptional access and consistent, focused heat therapy during interventions.
- **Warm up with no nuisance alarms** prepares the surface for the baby without interrupting your caregiver activities – heater warmup time at 100% power is less than 3 minutes.
- **Hands-Free Alarm Silence** allows you to control alarms without touching any surfaces during procedures.
- **Full-color Display** was designed to be easy to read nearby or from far. Full color trends track temperature, pulse rate, SpO₂, and weight.
- **Integrated Resuscitation option** helps to standardize the resuscitation practice.
- **Built-in, dimmable observation lights** and adjustable procedure light provide the lighting you need, when and where you need it.
- **Tall wall configuration** available to accommodate term babies.
- **Giraffe Shuttle compatibility for One Baby. One Bed. workflow**



Heat where you need it

The patented Hourglass Heat Profile provides uniform heat coverage across the mattress and the baby without warming the caregivers.



Giraffe Shuttle

The Giraffe Shuttle converts any Giraffe bed into a mobile NICU care station. It offers up to 45 minutes of electrical power⁸ to Giraffe beds, allowing you to provide continuity of care for sick babies while helping to provide a simplified and efficient intra-hospital transport for the infant. Fewer bed transfers and a simpler & quicker patient move – staff and patient stress reduction.

- **Reduce the need for bed-to-bed transfers thanks to the One Baby. One Bed. solution**

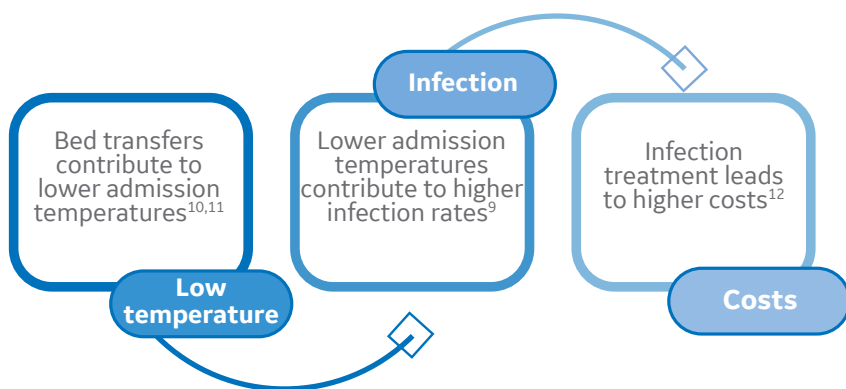
The Giraffe Shuttle, in combination with the Giraffe bed, helps reduce the potential clinical problems that can result from interrupted patient thermal regulation, patient touch, handling and movement, potentially challenging physiological stability when moving babies to and from a transport incubator.

- **Customize your intra-hospital transport system.**

The Giraffe Shuttle provides the capability of mounting various accessories and auxiliary equipment.

- **Enjoy maneuverability.** The Giraffe Shuttle connects smoothly with any Giraffe; designed to make it easier for you to steer the bed in tight spaces, through doorways, down hallways, and around corners.
- **Achieve workflow efficiency.** In addition to all of its clinical advantages, the Giraffe Shuttle can help save time spent on transferring a baby from one bed to another and reduce the number of pieces of equipment to clean.

For every 1°C decrease in NICU admission temperature, the odds of late-onset sepsis were increased by 11% and the odds of dying were increased by 28%⁹



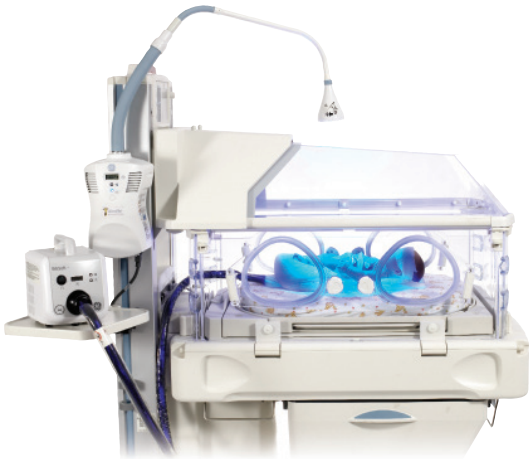
Giraffe beds combined with the Giraffe Shuttle eliminate the stress of moving sick babies from one bed to another.

Phototherapy solutions



Giraffe Blue Spot PT Lite – Offers high-intensity spot phototherapy for effective treatment of hyperbilirubinemia.

- **Developmental care focus:** Phototherapeutic Blue LED Light in one bulb only with a high irradiance and a narrow wavelength. Since the light source is tucked safely away in a box well removed from your patients, it protects the baby from ambient noise and heat.
- **Lightweight package, innovative gooseneck design:** focused light therapy directed at the patient minimizing undesired exposure, full integration with the Giraffe devices to save valuable NICU space.
- **Lower Total Cost of Ownership:** significant bulb cost savings, lasts up to 10,000hrs, significantly lower in-service costs (device downtime) than halogen and fluorescent bulbs.



BiliSoft 2.0 Phototherapy System - Intensive therapy, as easy as wrapping a baby in a blanket

- **A flexible LED pad** brings light to the patient for a soft treatment maintaining skin integrity and allowing swaddling wherever baby is.
- **High Output Intensity** depending on the size of pad chosen, short and focus wavelength, long lasting light source (50,000+ hours)*.
- **Designed for developmental care and family-centered care** – allows parents to bond with the child, does not block access to the bed, non-interruptive therapy.
- **Available for Home Care:** BiliSoft 2.0 is fully complied with class II double insulated requirement that's validated for home setting.



Combined together, the Giraffe Blue Spot PT Lite and BiliSoft LED Phototherapy System deliver healing phototherapy that meets and exceeds the recommendations of the American Academy of Pediatrics¹⁴ to provide intensive phototherapy treatment: high irradiance while maximizing surface treatment coverage.

*Under continuous use, tested at room temperature, a typical LED module will run > 50,000hours before the light intensity drops

Resuscitation solutions

The **Giraffe Stand-alone Infant Resuscitation System** puts the life-saving capabilities your patients need right at your fingertips.

Clinical Efficacy

- Improved transition time for adjustment of the T-Piece system results in an approximately 3x faster transition to the desired pressure and correspondingly fewer breaths within the transition time.^{15,16}
- Easy to use with single knob to adjust PIP combined with a PIP override release knob to safely control the delivery of pressure > 30 cm H₂O.

All-in-one system

- Combines all critical features (as per ERC guidelines) to deliver a complete solution.
- Supports both T-piece and bag and mask configurations, suction, blended air/O₂ gas delivery, precise pressure and flow controls.

Streamlined design

- Quick, convenient, and unobstructed access to suction, blended gases, and monitored positive pressure capability.
- Innovative T-piece circuit promotes comfortable hand positioning and single-handed control of breathing.

Compact and portable

- Accepts both wall and tank gas inputs.
- Priority valve conserves tanks so they are available for transport.
- Quick and easy set-up at the bedside or on the go.
- Flexible mounting options on the Giraffe Shuttle, from roll-stands to GCX arms.



T-piece Resuscitation System

Bag-and-Mask Resuscitation System

The resuscitation systems are also available as an integrated option on the Giraffe Warmer.

Accessories



Giraffe OmniBed hood cover 6600-0825-800
Giraffe Incubator hood cover 6600-0846-800



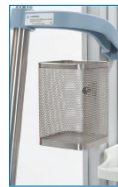
Corner trays
SE & NW
6600-1793-500
SW & NE
6600-1794-500



Giraffe tubing management arm
6600-0837-800



Giraffe silo support
6600-0853-800



Dovetail basket assembly
M1187887



Swivel instrument shelf (12 in x 12 in)
90° / 6600-0865-700
360° / 6600-0513-801



Giraffe Shuttle center shelf with shelf restraints attached
M1171297



IV pole dual hook
12" 0217-5378-800
24" 6600-0491-801



IV pump mounting post
(20 in x 1 in)
0217-5376-800



GCX articulating arm with channel monitor/display mount
16" M1235864
8" M1236833



North end dovetail handle
M1159084



Utility post (3.5 x 1 in) dovetail
0217-5374-800



Cord wrap holders (2)
M1151830



Ventilator mounting pole
0217-5357-800



Retaining clips (6)
6600-0055-851



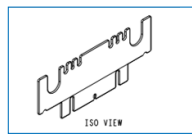
Giraffe easy-load E-cylinder holder
6600-0836-800



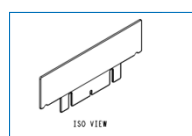
Dovetail rail mount and slide bracket (female)
6600-0031-900



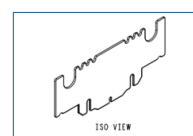
South end DIN rail
M1181783



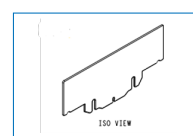
Door Tubing MGT North LDR
6600-2145-500



Standard North Wall - Panda
6600-2063-500



Door Tubing MGT North NICU
6600-2146-500



Door, North Giraffe NICU
6600-1655-500



Bag and mask holder clip
2107357-001

Giraffe Family options

| Giraffe Family options | Part Numbers |
|--------------------------------------|---------------|
| Giraffe Pressure Diffusing mattress | M1046467 |
| Foam mattress | 6600-1116-500 |
| Humidification reservoir | 6600-0216-850 |
| Air filter (10 pcs.) | 2107356-001 |
| Disposable patient probe (box of 10) | 2074816-001 |
| Disposable patient probe (box of 50) | 2074817-001 |
| Reusable patient probe | 2075796-001 |
| Heat reflecting patch (box of 50) | 2044385-001 |

Giraffe Family options

| Giraffe Family options | Part Numbers |
|---|--------------|
| T-piece, disposable (20 pack) | 2109059-001 |
| T-piece, disposable with mask size 0 (10 pack) | 2109060-001 |
| T-piece, disposable with mask size 1 (10 pack) | 2109061-001 |
| Suction canister – 800 cc (box of 100) | M1154789 |
| LED exam light system with IEC plug | 2111193-001 |
| LED exam light system with CE wall plug | 2105364-001 |
| Giraffe OmniBed Retrofit Kit for Enhanced Canopy Seal | M1208286 |

**BLUE connector for Giraffe Warmer
(GE Masimo/Masimo SET1)****Part Numbers****LNCS**

Masimo LNCS, LNC-10 GE SP02 Interconnect Cable, 3 m 2027263-002

Masimo LNCS Neonatal Adhesive Sensor, 20/box 2051069-001

Masimo LNCS Neonatal PT Adhesive Sensor, 20/box 2051070-001

RD

RD Set GE-05, Patient cable, 1.5 m MASIMO-RD-4084

RD Set GE-12, Patient cable, 3.6 m MASIMO-RD-4085

RD Set NEO, Adhesive Sensor, Box 20 MASIMO-RD-4003

RD Set NEO PT, Adhesive Sensor, Box 20 MASIMO-RD-4004

**RED connector for Giraffe Warmer
(Masimo Rainbow/Masimo SET2)****Part Numbers****LNCS**

Masimo MX-3 LNCS-10 GE Cable, 3,0 m 2059006-001

MASIMO CABLE RED LNC-04 2059005-001

Masimo LNCS Neonatal Adhesive Sensor, 20/box 2051069-001

Masimo LNCS Neonatal PT Adhesive Sensor, 20/box 2051070-001

RD

RD Set MD20-05, Patient cable, 1.5 m MASIMO-RD-4103

RD Set MD20-12, Patient cable, 3.6 m MASIMO-RD-4104

RD Set NEO, Adhesive Sensor, Box 20 MASIMO-RD-4003

RD Set NEO PT, Adhesive Sensor, Box 20 MASIMO-RD-4004

Nellcor**Part Numbers**SpO₂ Adapter Cable, DOC10, 2.9 m for
DINAMAP Pro 1000 v2, Pro and ProCare 2008773-001

Cable DOC-4 Pulse Oximetry Interface Cable, 1.2 m 2059001-001

SpO₂-Sensor MAX-N, Neo, Adhesive (24/box) 70124032**Covers & Nests****Part Numbers**

Bilisoft 2.0 Disposable Pad Covers, Small, 50/box 2105418-001

Bilisoft/Bilisoft 2.0 Disposable Pad Covers, Flat, Large,
50/box 2105419-001

Bilisoft 2.0 Disposable Pad Covers, Small, 20/box 2105422-001

Bilisoft/Bilisoft 2.0 Disposable Pad Covers, Flat, Large,
20/box 2105423-001

Bilisoft Disposable Pad Covers, Small, 50/box 2107200-001

Bilisoft Disposable Pad Covers, Small, 20/box 2107201-001

Bilisoft 2.0 Disposable Nest Pad Covers, Small, 15/box 2105420-001

Bilisoft Disposable Nest Pad Covers, Small 2107202-001

BiliSoft/BiliSoft 2.0 Disposable Nest Pad Covers, Large,
15/box 2105421-001**References**

- 1 Maternal and Newborn Health/Safe Motherhood Unit, Division of Reproductive Health, World Health Organization 1997 Thermal Protection of the Newborn: a practical guide. Retrieved from WHO_RHT_MSM_97.2.pdf.
- 2 Knobel, R. (2007). Thermoregulation and heat loss prevention after birth and during neonatal intensive-care unit stabilization of extremely low-birth weight infants. JOGNN, May-Jun, 36, (3), 280-7.
- 3 M. Gaylord, L. Mefford, J. Stafano, K. Leef, L. Lynam. "An Evaluation of a New Device in Maintaining Thermal and Physiological Homeostasis in Human Newborns". NANN, 2001
- 4 F. Loersch, M Schindler, K. Starr of GE Healthcare, J. Moore, L Lynam Bayne. "Risk Factors for intrahospital transport of newborn patients: A new solution to an old problem". Journal of Neonatal Nursing (2011) 17, 203-214
- 5 Influence of variations in the ambient humidity on insensible water loss and thermoneutral environment of low birth weight infants. 1984 Sauer PJ, Dane HJ, Visser HK
- 6 Kim SM et al. Improved care and growth outcomes by using hybrid humidified incubators in very preterm infants. Pediatrics 125(1), 137-145, 2010
- 7 Wubben, et al: 2011 The sound of operation and the acoustic attenuation of the Ohmeda Medical Giraffe OmniBed Noise Health J. 13:50 37-44
- 8 Batteries are a fixed life storage device. As such, the use and care of the batteries will greatly affect battery life. Heavy loads and long run times will drastically reduce the life of the batteries. Refer to the product labeling for additional information. Giraffe Carestation or Panda Warmer combination and Giraffe Shuttle comply to IEC 60601-2-19, Medical electrical equipment (Giraffe OmniBed Carestation or Panda Warmer obtains power during transport, all functions are fully supported, temp & O₂ values are shown and visual and audio alerts are working in the event of any deviations).
- 9 Laptok AR, et al. Admission temperature of low birth weight infants: Predictors and associated morbidities. Pediatrics 2007; 119:e643-e649.
- 10 Nedrelo J, Bloom BT, and Clark RH. Admission temperature is an independent predictor of survival for infants born between 24-29 weeks gestation. Pediatric Academic Society Meeting, 5/7/2007, E-PAS2007:617934.25.
- 11 Bhatt DH, Carlos CG, Parikh AN, White R, Seri I, and Ramanathan R. Prevalence of transitional hypothermia in newborn infants on admission to newborn intensive care units. Pediatric Academic Society Meeting, 5/7/2007, E-PAS2007:617933.23. From 24 to 29 weeks... temperature had an independent effect on survival. "For each degree change there was an increase in survival by approximately 10%."
- 12 Payne NR, et al. Marginal increase in cost and excess length of stay associated with nosocomial bloodstream infections in surviving very low birth weight infants. Pediatrics 2004; 114:348-355.
- 13 Clinical Study proved the equivalency to the overhead light. Galylord et al. 2008
- 14 American Academy of Pediatrics, clinical practice guideline, subcommittee on hyperbilirubinemia: Management of hyperbilirubinemia in the newborn infant of 35 or more weeks of gestation, 2004; 297-316.
- 15 Bennett, S; Finer, N.N.; Rich, W., and Vaucher, Y. A comparison of three neonatal resuscitation devices. Resuscitation. 67 (2005): 113-8.
- 16 Lynam, L.; Boyd, L.C., and Tsitlik, A. Bench evaluation of a novel T-Piece Resuscitation System design Abstract, GE Healthcare, 2007.

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JB04154XE 06/21

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60145555 0001

Report No.: 31794047 004

Manufacturer: Datex-Ohmeda, Inc.
9900 Innovation Drive
Wauwatosa WI 53226
USA

Products: Medical Devices
(see attachment for products included)
Replace Approval, Registration No.: HD 60125804 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-02-27

Date: 2020-02-27



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Certificate**

Registration No.: HD 60145555 0001
Report No.: 31794047 004

Manufacturer: Datex-Ohmeda, Inc.
9900 Innovation Drive
Wauwatosa WI 53226
USA

Products:

- Infant Radiant Warmers
- Infant Incubators
- Infant Resuscitation Devices
- Phototherapy Devices
- Medical Electrical Power Supply Devices;

Aspects of manufacture concerned with conformity of
products with the metrological requirements of Infant Scales

Date: 2020-02-27



EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60125804 0001

Report No.: 31792937 002

Manufacturer: Datex-Ohmeda, Inc.
9900 Innovation Drive
Wauwatosa WI 53226
USA

Products: Infant Radiant Warmers, Infant Incubators, Infant Resuscitation Devices, Phototherapy Devices, Medical Electrical Power Supply Devices;

Aspects of manufacture concerned with conformity of products with the metrological requirements of Infant Scales

Expiry Date: 2023-03-14

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2018-05-11

Date: 2018-05-11



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Certificate



**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2004795-1

Organization: Datex-Ohmeda, Inc.
9900 Innovation Drive
Wauwatosa WI 53226
USA

Scope: Design and Development, Manufacture, Distribution, Installation and Service of Infant Radiant Warmers, Infant Incubator, Infant Resuscitation Devices, Phototherapy Devices, Infant Scales, Medical Electrical Power Supply Devices, Mattresses, IV Poles, Lights (Diagnostic Luminaries), and Skin Temperature Probes

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

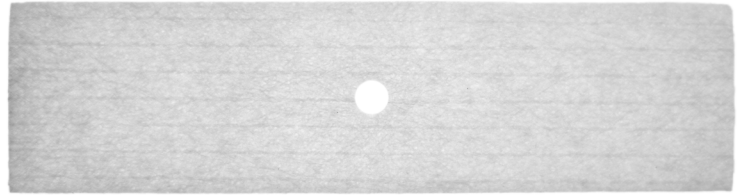
Report No.: 234168343-30
Effective date: 2021-03-15
Expiry date: 2022-01-21
Issue date: 2021-03-14



S. Liu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



Air Filter

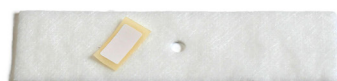


For use with the Giraffe™ Incubator Carestation and the Giraffe™ Omnibed Carestation.

Maintain incubator airflow while providing high-efficiency filtration

Features

- Simple installation
- Bi-directional, fits in the cover in any direction
- Blank label to mark installation date and track for replacement



Air Filter, bi-directional

**Our equipment.
Our accessories.
Simply compatible.**

You can trust GE Healthcare accessories and consumables to keep your clinical devices working efficiently.

- Simplified ordering process
- Fast delivery
- One contact point for expert advice
- Quality support at every step

PRODUCT SPECIFICATIONS

| Part Information | |
|--------------------|--|
| Micro Filter | 0.3μ -99.8% efficiency @ flow rate of 1 cm/sec |
| System Performance | CO ₂ level ≤ 0.3% |
| Weight | 3.54 to 5.31 oz. (120 to 180 GSM) |
| Dimensions | 5.58" x 1.43" x 0.08" (L x W x T) approximate |

Materials

Electrostatic synthetic, non-woven

100% synthetic fibers

PP spunbond, non-woven

Product use

Air filter should be changed every 3 months. In addition, it should be changed after the bed was used by an infected patient or when visibly dirty.

Label the filter site with the date of last change and inspect filter at every cleaning.

Operating environment

| | |
|--------------|---------------------------|
| Temperature: | 20° to 30°C (68° to 86°F) |
| Humidity: | ≤ 85% RH (non-condensing) |
| Pressure: | 50-106kPa |

Storage

| | |
|--------------|------------------------------|
| Temperature: | -25° to 60°C (-13° to 140°F) |
| Humidity: | ≤ 85% RH (non-condensing) |
| Pressure: | 50-106kPa |

Product may not be available in all countries and regions. Contact a GE Healthcare Representative for more information. Please visit www.gehealthcare.com.

Imagination at work

Disposal considerations

Dispose as clinical waste, in accordance with hospital policy, local guidelines and regulations.

Packaging materials

Primary: Polybag – Polyethylene (PE)

Compliance

Not a medical device.

Regulatory standards

Air filter compliant with REACH regulation (EC)/1907/2006.

Air filter compliant with (RoHS) directive, 2011/65/EU, (Ref: GEHC ROHS compliant per 5240305GSP).

PART LIST

| Part Number | Description | Quantity |
|-------------|----------------------------|----------|
| 2107356-001 | Air filter, bi-directional | 10 |

