Dräger

D-27764-2009

The Caleo® Effect

Caleo provides superior care for very low birth weight infants

Dräger. Technology for Life®

A stable thermo-neutral zone supports better outcomes.

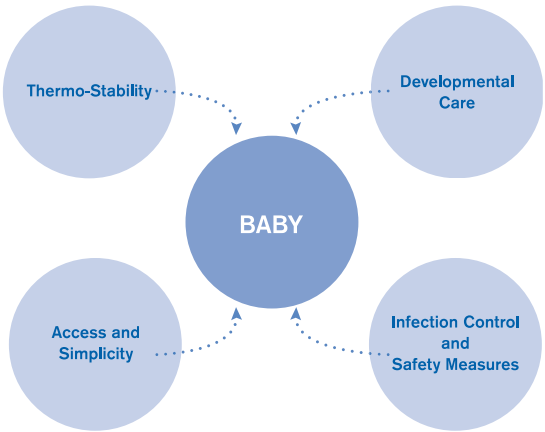
At birth, premature infants are thrust into a world of enormous challenges. The younger the baby and the lower the birth weight, the more critical it is to provide a microenvironment as close as possible to the womb.

A growing body of clinical research demonstrates just how critical temperature, humidity, oxygen, sound and light levels are to the successful development of very low birth weight babies. Factors such as direct skin-to-skin contact with family members also contribute to a positive outcome. At Dräger, we took a no-compromise approach to each of these aspects of care in order to create a microenvironment that's closer to the ideal.

The natural environment of a preterm baby is closed. That's why Dräger designed the Caleo as a unique closed-care microenvironment that addresses all the diverse needs of your babies. This booklet explains the difference the Caleo can make for preterm babies in terms of thermoregulation, developmental care, patient access, and infection control measures. The net result is a stable thermo-neutral zone that supports better outcomes—both long- and short-term.

Connecting to the Baby's Needs

Enhancing the Quality of Care



Thermoregulation

CONSISTENTLY MAINTAIN PRECISE TEMPERATURE AND HUMIDITY

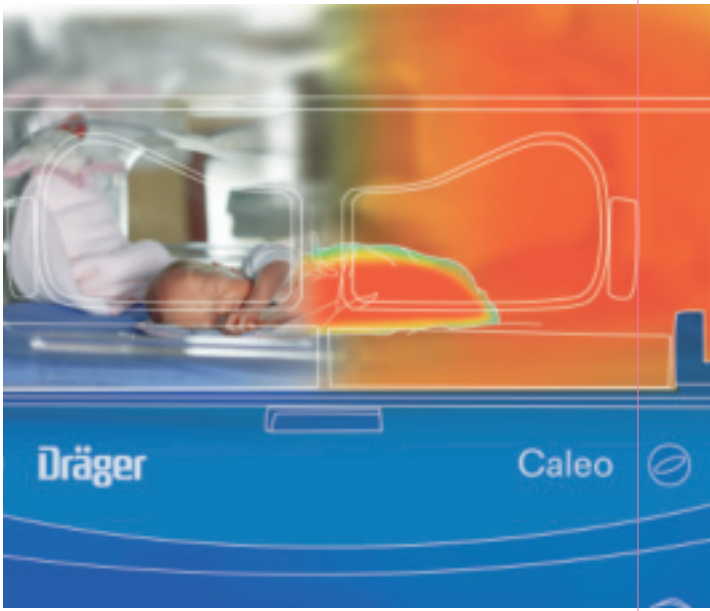
Infants with extremely low birth weight are at particular risk for cold stress. When such an infant experiences heat loss, the physiological responses create demands that exceed the infant's normal physiological balance. This is because the infant will need to expend energy and metabolize oxygen to produce heat.[1]

This temperature imbalance can lead to a loss of heat and cause cascading conditions with long-term effects such as hypothermia. Hypothermia may lead to a fall in systemic arterial pressure, decreased plasma volume, decreased cardiac output, and increased peripheral resistance.[2] If left unchecked, these conditions can lead to permanent tissue damage, brain damage, or death.[3]

For the fragile neonate, an environment that is less than one degree off can mean the difference between a success and a setback. The thermoregulation capabilities of the Caleo have been clinically documented to meet the specific needs of the preterm baby.

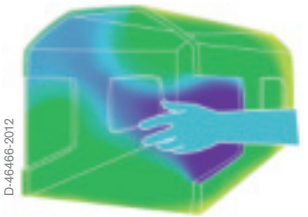
While the ideal is to keep the pre-term baby in a totally undisturbed environment, the reality is that clinicians must have access to the baby to perform necessary procedures. This access can have a significant effect on the baby. For example, in preterm infants weighing less than 1500 g, decreases in both peripheral and central temperature occurred with caregiving episodes lasting 15 to 45 minutes, and it took up to two hours for the baby to recover its temperature.[4]

The ultimate goal of closed care is to create an environment so stable that extremely low birth weight babies are able to maintain a constant body temperature. This state is called the thermo-neutral zone. Because of the inability of these infants to sustain temperature fluctuations, the Caleo was designed with advanced technologies to stabilize the internal environment during necessary interventions. The following graphics explain these capabilities.



D-46465-2012

1. (A J Lyon, Y Freer Goals and options in keeping preterm babies warm Arch Dis Child Fetal Neonatal Ed 2011;96:F71–F74.)
2. (Sinclair, 1992)
3. (Deshpande & Platt, 1997)
4. (Mok Q, Bass CA, Ducker DA, McIntosh N. Temperature instability during nursing procedures in preterm neonates. Arch Dis Child 1991;66:783–786.)



Incubator without an air curtain

Caleo air curtain

GAIN EASY ACCESS TO THE BABY, WITHOUT COMPROMISING THE ENVIRONMENT

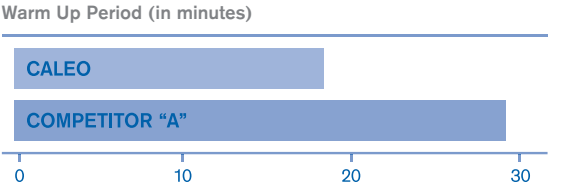
In a typical nursing shift, multiple caregiver procedures can occur – such as umbilical line insertions, intubations, obtaining chest x-rays, taking vital signs, manipulating intravenous lines, repositioning, and suctioning – which necessitates repeated opening of the incubator to access the baby. Exclusive JumboPorts™, which are 40% larger than conventional access ports, provide unencumbered access to the baby during interventions.

The Caleo directly compensates for drop of temperature due to opening by creating an innovative dual air curtain that enables the temperature and humidity to remain stable – even while routine procedures are being performed. The dual air curtain allows Caleo to maintain thermal stability better than other leading systems tested.

STAY PREPARED FOR THE NEXT BABY

Because there often isn't advanced warning with admissions of extremely low birth weight infants, a warm incubator should be available at all times for unexpected deliveries.[5]

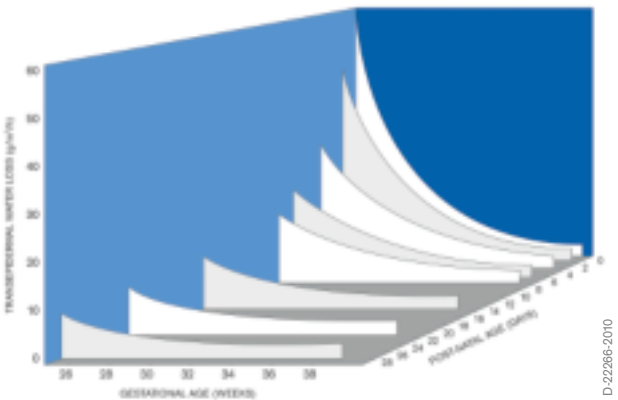
Therefore, it is critical to have an incubator that can warm up quickly. In an in vitro comparison of warming devices, the Caleo was documented to warm faster and maintain heat and humidity better, even when access ports were opened.



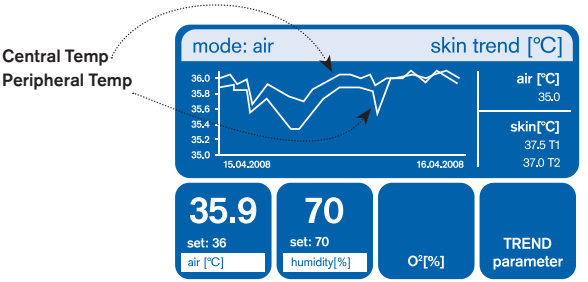
PROVIDE THE IDEAL HUMIDITY

Humidity inside the incubator is critical in avoiding transepidermal water loss (TEWL) in pre-term infants. The chart below illustrates the exponential relationship between gestational age and transepidermal water loss at the first day after birth. In the most preterm infants, TEWL gradually decreases and the difference in TEWL between the most preterm and the term appropriate for gestational age infant diminishes with age. Even four weeks after birth, TEWL is still twice as high in the former as in the latter.

Transepidermal Water Loss in Newborns
Heat loss through epidermal water loss: (560 cal/ml)



D-22266-2010



INSTANTLY RECOGNIZE TEMPERATURE FLUCTUATIONS

In a thermograph of a preterm baby, you can see a wide variation in temperature throughout the body. The infant's core temperature is not constant in all tissues and organs, with the brain probably having the highest temperature. The measurement of a single temperature indicates how well a baby is able to maintain that temperature, but does not give any information on the energy being used for thermoregulation.

As the only solution that measures, documents and displays both central body and peripheral temperatures, the Caleo offers true ThermoMonitoring. As a result, you can see the instant a baby is exposed to cold stress and address the issue before it becomes more serious.

---

5. (Knobel, Holditch-Davis Thermoregulation and Heat Loss Prevention After Birth and During Neonatal Intensive-Care Unit Stabilization of Extremely Low-Birthweight Infants JOGNN , 36, 280-287; 2007. DOI: 10.1111/J.1552-6909.2007.00149.x).

HEAT BALANCE, MADE EASY TO LEARN

Dräger created Heat Balance, a simple, interactive way for caregivers to learn about the different types of heat loss and gain, how they affect the baby, and how to use the Caleo settings to create the most thermo-neutral environment possible.

This training tool simulates the heat balance of infants in an incubator and shows the influences of the different types of heat loss and gain. Based on the physical algorithms known for heat loss and on documented clinical experience, it demonstrates how the Caleo can maintain thermal stability. This program will also show the importance of all relevant parameters to achieve heat balance for preterm infants.

Because Heat Balance is a smart phone application, it can be used for training purposes anytime, anywhere.

D-22263-2010

Developmental Care

The in-utero environment of a developing baby is quiet, comforting and connected to the mother. In sharp contrast, the environment of a preterm infant is often painful and noisy, with interruptions in sleep and separation from the mother – which research shows can permanently alter normal brain development.[6]

Designed to align with developmental care guidelines, the Caleo provides functions and features that take into account the critical importance of family involvement, sound levels in the incubator, light management, and positioning of the baby to create an individualized cocoon that wraps the baby in a safe and stable nurturing zone.

D26679-2000

SUPPORT FAMILY-CENTERED CARE

Research shows that family-centered care provides significant benefits for the pre-term baby[7] – including improved well-being, better mental health outcomes, decreased length of stay, and enhanced parent-infant bonding.

The Caleo offers a kangaroo mode that allows you to continue to monitor the baby's temperature during skin-to-skin care and automatically adjusts the temperature in the incubator based on the baby's temperature for a smooth transition back to an ideal environment.

- Low height setting (80cm / 31.5in) – accommodates wheelchair-bound mothers who are still recovering from birthing or c-sections.
- Large hand ports – give parents comfortable access to the infant in a closed care setting, allowing them to participate in the care of their child.
- Large, unobstructed hood area – provides clear visibility of the baby. The hood material is scratch-resistant, durable, and is designed with rounded corners to eliminate distorted views.
- Inviting cocoon shape – looks less intimidating and more inviting to parents who are experiencing the intensive care unit for the first time. The monitor can be moved to make it less obtrusive, taking the technology away from the mother's face for more human bonding.

---

6. & 7. Als H., Duffy FH, McAnulty BG, et. al. Early Experience Alters Brain Function and Structure. Pediatrics. 2004;113;846.

PROVIDE A QUIET ENVIRONMENT

Safe sound levels within the NICU are essential for the healthy development of preterm infants.[8] One of the ways the Caleo represents a major advance in performance is by keeping sound levels as low as possible. It is designed to reduce disturbances that can disrupt normal sleep patterns, impact the development of the nervous system, and cause cochlear damage.

- Quiet capsule – the Caleo and all of its components were designed for quiet operation and low internal noise levels (less than 47 dbA). It allows for low air velocity around the infant (less than 8 cm/s), which means a calm environment with minimal ambient noise. A study conducted at Duke University found the Dräger Caleo to be significantly quieter than all others tested.[9]

- Smart alarm – sound is emitted out of a speaker that is placed away from the infant compartment and is designed to ramp up over time in a chime-like sound. Because it is smart, the alarm can be adjusted to 8 different volume levels and can be identified by different colored lights.

- Whisper-quiet hand ports – unlike most incubator ports that are so loud they disturb the baby, the Caleo's ports are ultra quiet both opening and closing.

- Quiet tilt – the Caleo can be tilted to move the complete capsule away from sources of air turbulence and noise in the NICU.

- Quiet height adjustment – the Caleo's height adjustment mechanism is very quiet, unobtrusively accommodating necessary adjustments between shifts.

---

8. (Krueger, C., Wall, S., Parker, L. & Nealis, R. (2005). Elevated Sound Levels within a Busy ICU. Neonatal Network. 24(6), 33–37.)

SUPPORT PROPER POSITIONING

Correct positioning of the infant is essential for the development of postural control and subsequent locomotion functions. Caleo's positioning accessories help the baby maintain a stable posture against the influence of gravity.

- SoftBed mattress – designed specifically to reduce pressure on the infant's skin, the mattress is made of a visco-elastic foam and has a breathable cover that is comfortable for the nesting baby.

- Hug it, the Nest, and Pillows – these accessories are specially designed to provide physiological stability, containment, and support for the baby. They can also double as an extra 'set of hands' for clinicians during procedures.

MANAGE LIGHT LEVELS

Obviously, bright lights are not part of a preterm infant's in utero environment. While light is necessary for providing care, light levels must be controlled for the wellbeing of the baby.

- Custom light cover – provides effective protection from unwanted and damaging lights, replicating the natural environment of preterm infants and providing the safe haven they need to thrive.

- 3 dimming levels – offers a range of dimming at the control panel to reduce illumination during night shifts.

- Explore other Dräger offerings such as the Circadian Illumination System that simulates the passing day and helps maintain circadian rhythms that are so important for both you and your patients.

---

9. (Brandon, D. H., Ryan, D. & Barnes, A. (2007). Effect of Environmental Changes on Noise in the Neonatal Intensive Care Unit. Neonatal Network. 26(4), 213-216.)

Access and Simplicity

Without question, caregivers need access to the baby to perform necessary procedures. Because of the Caleo's size, ergonomics and access features, environmental conditions in the baby compartment remain undisturbed at all times – with stable temperature, high levels of humidity, and low levels of noise – even during interventions. As a result, caregivers can perform virtually all clinical procedures without compromising the baby's physiological parameters.

D-27764-2009

Caleo also provides features that minimize unnecessary touching of the baby that would induce added stimuli. We configured these options for maximum usability so you can focus on what's important: the baby.

- Access doors – lightweight, easy-to-manage doors are located on both sides of the Caleo.
- Side doors – large doors on the short sides of the Caleo open up, providing new access for procedures such as ultrasound.
- Hood – in case of an emergency, the hood can be lifted from either side.
- Pull-out mattress – provides easy access to the baby when necessary, even when the Caleo is in the tilted position.
- Integrated x-ray tray – enables easy access to the baby without disturbing the baby.
- Exclusive JumboPorts™ – are 40% larger than conventional hand ports, open quietly and are ergonomically designed to facilitate interventional care. Centrally positioned hand port opening mechanism facilitates opening of both ports simultaneously with a single hand/elbow.
- Tilt function – provides smooth tilt function at a touch of a button.
- Variable height – allows smooth adjustment from either side.
- Repositionable control panel – place the control panel where it best supports individual workflow.
- Touch-Turn-Confirm – intuitive operation is fast and easy.

Infection Control and Safety Measures

Considering that the smallest, least-mature infants often require the most frequent and invasive procedures, have sensitive and immature skin that does not provide a strong barrier against environmental organisms, and immune systems that are marginally responsive to infection from any portal of entry, high-infection rates seem inevitable[10].

As a result, hygiene in an incubator is imperative. This is why one of the key design goals of the Caleo was to protect the baby against nosocomial infections.

- Closed loop humidity system – prevents airborne organisms from penetrating the system in the baby compartment.
- High temperature cleaning mode – the 110° C cleaning mode disinfects the unit and remove any residual water in the internal mechanism.
- Tight positive closures and a hood capsule with rounded corners prevents bacteria from forming in precarious places.
- Minimal-parts design – having only 11 parts in total simplifies the cleaning process and ensures thorough disinfection.

SAFETY FEATURES

Protecting the baby through safety measures was a priority in the design of the Caleo. Special features and mechanisms were implemented to avoid added stress to the baby and allow the caregiver to focus on day-to-day care.

- Automatic self-tests – the Caleo tests the entire electronics, sensors and functionality system. It is monitored every eight minutes, ensuring the efficiency of the whole system.
- Quality sensors – the quality of Dräger sensors ensures that the measured displayed values are reliable: “what you see is what you get.”
- No higher temperatures – thanks to the innovative dual air curtain concept, there is no need for higher temperatures to achieve excellent performance with minimal warm-up times.
- Heat shield technology – limits the outlet temperature to maximal 45°C, ensuring a maximum surface temperature of 43°C for all touchable parts.
- Unobstructed ports – the bed tilt does not obstruct port holes as it moves the whole capsule, providing access at any position.
- Wall locks – walls require locking before the caregiver walks away from the incubator because of a spring mechanism that does not allow them to stay up if not locked.

---

10. (Newby J. Nosocomial Infection in Neonates: Inevitable or Preventable? Journal of Perinatal and Neonatal Nursing. 2008;22:221-227)

In summary, the philosophy behind the Caleo is that the care approach to preterm infants should be weighed against the possible negative outcome of morbidity and mortality rates. It is imperative to maximize the baby's chances for the best possible outcome through clinical and practical evidence, by creating an environment that is closest to the ideal.

D-52696-2012

CORPORATE HEADQUARTERS
Drägerwerk AG & Co. KGaA
Moislinger Allee 53–55
23558 Lübeck, Germany

www.draeger.com

REGION EUROPE CENTRAL AND EUROPE NORTH
Dräger Medical GmbH
Moislinger Allee 53–55
23558 Lübeck, Germany
Tel +49 451 882 0
Fax +49 451 882 2080
info@draeger.com

REGION EUROPE SOUTH
Dräger Médical S.A.S.
Parc de Haute
Technologie d'Antony 2
25, rue Georges Besse
92182 Antony Cedex, France
Tel +33 1 46 11 56 00
Fax +33 1 40 96 97 20
dlmfr-contact@draeger.com

REGION MIDDLE EAST, AFRICA, CENTRAL AND SOUTH AMERICA
Dräger Medical GmbH
Branch Office Dubai
Dubai Healthcare City
P.O. Box 505108
Dubai, United Arab Emirates
Tel + 971 436 24 762
Fax + 971 436 24 761
contactuae@draeger.com

REGION ASIA / PACIFIC
Draeger Medical
South East Asia Pte Ltd
25 International Business Park
#04-27/29 German Centre
Singapore 609916, Singapore
Tel +65 6572 4388
Fax +65 6572 4399
asia.pacific@draeger.com

REGION NORTH AMERICA
Draeger Medical, Inc.
3135 Quarry Road
Telford, PA 18969-1042, USA
Tel +1 215 721 5400
Toll-free +1 800 437 2437
Fax +1 215 723 5935
info.usa@draeger.com

Manufacturer:
Dräger Medical GmbH
23542 Lübeck, Germany
The quality management system at Dräger Medical GmbH is certified according to ISO 13485, ISO 9001 and Annex II.3 of Directive 93/42/EEC (Medical devices).

90 66 525 | 0712-2 | Marketing Communications | DMS | PR | LE | Printed in Germany | Chlorine-free – environmentally compatible | Subject to modifications |