

Calesca

**Gentle, safe and waterless warming
of human milk**

*No. 1 choice
of hospitals
& mothers*

Gentle warming and thawing of human milk, whenever needed. Safe, hygienic, simple to use and easy to clean. A new approach for neonatal intensive care units, maternity wards and paediatric departments.



Calesca

Ensures that newborns receive gently and safely warmed human milk.

Benefits of human milk for a newborn



Few interventions rival breastfeeding in promoting the health of a mother and her infant. A wealth of scientific evidence demonstrates why, and systematic reviews of the literature have consistently established that the provision of human milk can permanently modify an individual's biological, neural and social growth and development¹. Mother's own milk has the ability to adapt to the ever changing needs of the growing infant and provides more than just nutrition. It has developmental and immunological benefits that are suited to the individual infant. Breastfeeding is the gold standard for feeding and nourishing the human newborn².

Human milk is acknowledged as being especially important for the premature infant. Schanler et al. (1999)³ studied human milk-fed premature infants and concluded that "the unique properties of human milk promote an improved host defence and gastrointestinal function compared with the feeding of formula". A reduction in infection-related morbidity in human milk-fed premature infants has been reported in nearly a dozen descriptive and a few quasi-randomised studies in the past 25 years; including one from Berseth (1996)⁴ that clearly demonstrated an increase in gut motility. This in turn ensures a reduction in bacterial growth, thereby decreasing the risk of infection, in particular necrotising enterocolitis. Human milk-fed infants also have decreased rates of re-hospitalisation after discharge⁵.

Human milk provides vulnerable nutrients with ideal bioavailability as well as bioactive components that support optimal growth and development. There are certain constituents that are at risk when preparing human milk. Proteins, which play a key role in the developmental, nutritional and immunological stability of the infant, are also the most heat sensitive. Other key components that have been shown to be sensitive to heat include vitamins, growth factors and living cells.

The provision of human milk for the premature infant, who cannot be breastfed, involves a warm chain of support for the mother and careful handling of her milk to ensure its life giving benefits are compromised as little as possible.

Effect of high temperature on human milk

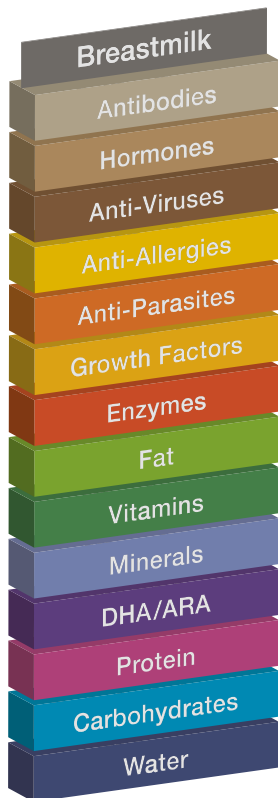


Figure 1 – Some of the components in human milk

Breastfeeding, which provides fresh milk at body temperature, certainly delivers the best quality of human milk to the infant. However, certain circumstances (such as a sick, handicapped or premature infant or a sick mother, etc.) may not allow direct breastfeeding. The next best option is then the expression, storage and later feeding of the own mother's milk, or donor milk. However, the handling of human milk may compromise its bioactivity and practices must therefore be carefully optimised.

Various human milk components show very different sensitivity. Proteins and vitamins are among the most sensitive constituents, whereas carbohydrates and most fats are much more stable. In fact, monoglycerides, free fatty acids and even the polyunsaturated long chain fatty acids linoleic and α -linolenic acid are not even affected by Holder pasteurisation (62.5 °C for 30 min) typically used for milk preservation⁶, while proteins may easily lose their original protective, developmental or nutritive functionality by proteolysis, oxidative damage or temperature-induced change of their three-dimensional structure (denaturation)⁷⁻¹⁰.

Whilst there are many studies on milk feeding in the hospital environment, very little research has been conducted concerning the warming or thawing of feeds. According to the Human Milk Banking Association of North America, there are no studies on the optimal method of the basic process of thawing human milk for feedings¹¹. However, with the increased use of donor milk and the need for pasteurisation as a means to destroy pathogens whilst still attempting to preserve the milk's bioactivity, there is now research to determine the effect of temperature on unpasteurised human milk^{7, 9, 12-15}.

Proteins

Human milk contains a wide variety of proteins that contribute to its unique qualities. In combination, its proteins assist in providing adequate nutrition to breastfed infants while simultaneously aiding in the defence against infection and facilitating optimal development of important physiologic functions in newborns.

I Lactoferrin

Lactoferrin is one of the major whey proteins in human milk (1–3 g/L)¹⁶. It is primarily an iron binding glycoprotein that mediates iron absorption by binding to the lactoferrin receptor on the surface of the infantile small intestine's epithelial cells. Lactoferrin from human milk has therefore been implicated in intestinal iron absorption in infants¹⁷, in addition to playing an important role in host defence against microbial and viral attack¹⁸.

A number of factors combine to predispose the premature infant to a negative iron balance since iron is mostly accumulated during the third trimester of gestation¹⁹. Therefore lactoferrin is important to support in building up the iron content for the infant. Breastfed infants have demonstrated better iron accessibility than infants on formula²⁰.

Although lactoferrin is heat-sensitive and milk treated at 62.5 °C for 30 min retains only 28 % of lactoferrin, Czank et al. (2009)⁹ demonstrated that milk kept at 40 °C for 30 min could preserve lactoferrin retention at around 94 %. Molinari (2011)¹⁰ found no effect after storage at 25 °C for 24 h, but proteolysis reduced lactoferrin concentration to 89% after storage at 25 °C for 48 h.

I Enzymes

Pancreatic digestive function, especially for fat and carbohydrates, is not well developed at birth²¹. One of the key issues in the treatment of preterm infants with low birth weight is the need for improvement in uptake of energy and fatty acids, essential for normal growth and development. Proper fat absorption is especially important for the preterm infant because of the high calorie content of fat and its role in brain development²². There is evidence that bile salt-stimulated lipase present in human milk might compensate for low endogenous pancreatic lipase, since it improves fat absorption in newborns^{12, 23}.

However, human milk lipases are deactivated by heat. Wardell et al. (1984)¹³ observed that bile salt-stimulated lipase becomes inactive at temperatures greater than 40 °C; this corresponded with previous research from Williamson et al. (1978)¹². Andersson et al. (2007)²⁴ confirmed these findings and also noted a lower weight gain or reduced growth in preterm infants fed heat-treated (pasteurised) compared to raw human milk.

I Immunoglobulins

Infants are born with a limited supply of antibodies that were acquired from the maternal immune system. The continuous supply ends at birth.

Human milk contains maternal immunoglobulins against antigens that the mother has been exposed to, which are also relevant for the infant. The most abundant of these antibodies by far is secretory immunoglobulin A (sIgA), with a concentration of up to 12 g/L in colostrum and 0.5–1.0 g/L in mature breastmilk¹⁶. Secretory IgA is resistant to proteolysis in the infant's gut and protects the infant very effectively from infections.

Nevertheless, high temperatures such as those used for pasteurisation (62.5 °C), reduce the concentration of sIgA by 20–30%⁹ and significantly reduce specific antibody titer against *Escherichia coli*²⁵. While immunoglobulin G (IgG) was found to be reduced by as much as 30%, no immunoglobulin M (IgM) was found at all after Holder pasteurisation²⁶. Lowering the temperature and shortening the pasteurisation time to 56 °C for 15 min preserves sIgA, IgG and IgM at > 90%⁷. Czank et al. (2009)⁹ found retention of sIgA to be 94% after heating milk at 40 °C for 30 min and no significant loss of sIgA was observed by Molinari et al. (2011)¹⁰ even after storage of milk at 25 °C for 72 h.

Vitamins

Low birth weight infants have an increased requirement of vitamins. There is some evidence that the concentration of vitamins in human milk is influenced by the mother's intake²⁷ and it is therefore important to discuss diet with the mother. All vitamins are "critical" by definition for the growing infant. However, some of them (vitamins D, E, K and folic acid) are particularly relevant to the preterm or low birth weight infant in whom a deficiency can occur more frequently than in a full-term newborn, due to low body stores at birth, low intake, limited absorption and increased need or utilisation²⁸.

Storage and handling of human milk may affect the concentrations of vitamins. While Holder pasteurisation does not affect the concentration of the vitamins A, B2, B12, D, and E, there are significant losses of vitamins B6 (15%), C (36%), and folic acid (vitamin B9, 31%)¹⁴. Van Zoeren-Grobbe et al. (1987)¹⁴ also observed a significant loss of vitamins C (44%) and B6 (19%) during enteral feeding. It is therefore important to use gentle heat treatment to preserve the vitamin content whilst processing the milk.

Warming of human milk in the hospital environment



In studies investigating the feeding of premature infants, the temperature of feeds is rarely monitored^{29, 30}. In fact, the feeding bottle is typically tempered in a cup of “warm” tap water without measuring the temperatures of neither the tap water nor the milk. An investigation involving three different NICUs and a total of 426 measurements of milk temperature showed a variation of resulting feed temperatures of between 22 °C and 37 °C with some exceptions showing temperatures of up to 46.4 °C and an average feed temperature of around 31 °C³⁰.

In order to understand the practices commonly used to warm human milk in hospitals, Medela AG conducted a market assessment in 5 markets (the Netherlands, Germany, France, Italy and the United Kingdom), visiting a total of 48 hospitals (NL 10, DE 14, FR 9, IT 8, UK 7)³¹. Procedures used to warm human milk are shown in Figure 2.

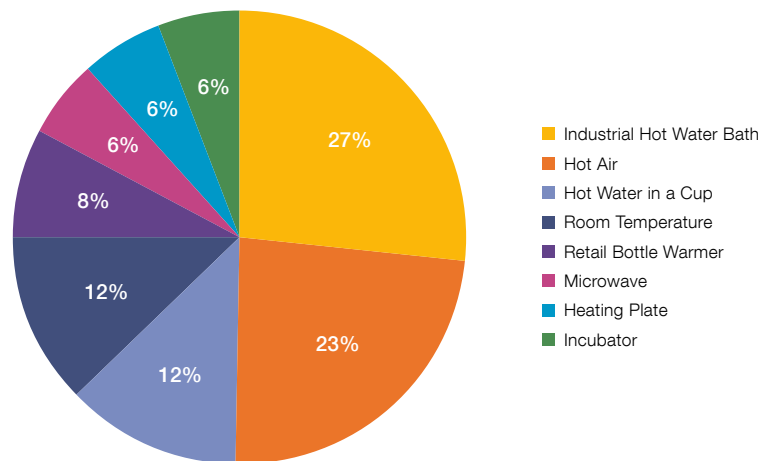


Figure 2 – Procedures for warming of human milk from 48 European hospitals³¹

It can be seen that almost half of the hospitals (47%) use a warming method involving water (27% Hot Water Bath, 12% Hot Water Cup, 8% Retail Bottle Warmer). Only 12% of the visited hospitals fed the milk to the infant at room temperature.

Milk temperature and premature infants

Premature infants are born with very little body fat, thin skin and underdeveloped thermoreceptors and sweat glands resulting in inefficient thermoregulation³². These infants are neither able to carefully sense if milk is too high or too low in temperature, nor to respond appropriately. It has been theorised that milk temperature can influence infant body temperature³³, and research has shown that infant stomach temperature decreases when room temperature gavage feeding is given³⁴. Just as it has been recommended that intravenous fluids are warmed prior to infusion^{32, 35}, warming of human milk feeds would appear beneficial for keeping infants in the thermo neutral zone. Feeding preterm infants milk at body temperature has also been associated with improved feed tolerance (decreased gastric residuals)²⁹. While this study did not control for the type of milk that was fed to the infant, these findings may still indicate that warming milk to body temperature, whilst maintaining the bioactivity of its delicate compounds, is beneficial to preterm infants.

Different thawing and warming practices for human milk

Water bath or cup

Microorganisms such as bacteria, yeasts and moulds need water to grow. Most bacteria grow faster at higher temperatures. Besides the tap water itself, open, warm (standing) water baths are considered to offer microorganisms a good growth substrate and are consequently a source of nosocomial infections.

Hospital tap water has long been identified as a potential source of nosocomial infections from bacterial and other contaminants including *Cryptosporidium*, *Giardia*, *E. coli* and *Pseudomonas*^{36, 37}.

For example, in 2009, 23 strains of *Pseudomonas aeruginosa* were found in the tap water supply of a children's hospital in the US³⁸. Moreover, *Staphylococcus* and *Klebsiella*, identified in hospital tap water that was used to heat milk, were determined to be directly responsible for an outbreak of septicaemia in a hospital's NICU³⁹.

More recently, following a tap water related *Pseudomonas* outbreak and the death of three infants in a NICU in Northern Ireland, the RQIA (Regulation and Quality Improvement Authority) issued recommendations not to warm or defrost milk by placing the container in warm tap water⁴⁰. There is a potential for contamination of not only the container and the human milk, but also the nurses' hands. Thus, to prevent waterborne infections and other water-related risks, like burns⁴¹ or scalding, some hospitals' guidelines include the use of dry warming devices to heat fluids and/or waterless hand washing products for hospital staff in areas where high risk patients are hospitalised⁴².

Microwave

In some NICUs, it has become common practice to use microwave thawing and warming of frozen milk for more rapid accessibility³¹. Quan et al. (1992)⁴³ carried out a preliminary study to evaluate the effects of microwave treatment on the anti-infective factors in human milk. Even at a very low microwave setting (20 °C–25 °C) there was a significant loss of immunologic properties. Moreover, Chan et al. (2011)⁴⁴ found that thawing to 4 °C, 20 °C, 50 °C and with a microwave had differing effects; with increasing loss as one advances from 4 °C to 20 °C to 50 °C to microwave. Microwave had the most effects on human milk fat concentration, free fatty acid concentration and total antioxidant capacity. This supports the notion that microwaves do not heat liquids evenly. This is an important issue since uneven heating of the milk can lead to inactivation of certain milk components in the overheated areas. The danger of scalding due to overheating should not be underestimated either.

Heating Plate

Some hospitals use heating plates to warm the milk. However, there is no research showing that this method is suitable for heating infant feeds. The high temperatures at the edge of the bottle or syringe can destroy milk components. Moreover, sometimes the temperature cannot be chosen and if the pre-set temperature is too high, this can have detrimental effects on the milk.

When heating numerous milk bottles, these do not always have the same starting temperature and, thus, do not need to be warmed the same amount of time. Additionally, the quantity in the bottles may not be the same, thus requiring different warming times. Lastly, from a practical point of view, these devices carry a risk of burning one's skin as the heating plates can get very hot.

Multiple bottle warmers

In many hospitals multiple bottle warmers are used. In Italy, according to a survey conducted by Medela AG, multiple bottle warmer water bath devices were used in 6 out of 8 hospitals³¹. The amount of bottles warmed together can vary from two up to 24 bottles³¹. If bottles with milk from different mothers are placed in such devices, there is a risk of milk mix-up.

Results from the Vermont Oxford Network, a voluntary error-reporting system conducted for one year, show that 25% of reported misidentification errors involved human milk^{45, 46}.

In addition, an even temperature distribution is difficult to achieve. The milk temperature inside the bottle not only depends on the time the bottle has been in the water bath, but also on the amount of liquid inside the bottle and its starting temperature. Therefore, temperature outcome is difficult to control.

Conclusion

Gentle warming is key to keeping all the important, living, bioactive and essential components of stored human milk intact, so that it remains as similar to fresh human milk as possible. The importance of controlled warming is clearly made evident by the fact that a temperature increase of just 1.7% (from 57 °C to 58 °C) decreases the retention of sIgA, lactoferrin, and lysozyme by 8.5, 34, and 31%, respectively⁹.

When looking at the different warming methods, it is apparent that thawing and warming milk with water involves a complex interaction of several aspects and that there are many variables that can have a negative effect on human milk itself. There is no indication as to when the milk is at the correct temperature for feeding and, as has been previously demonstrated, the perceived temperature can vary greatly³⁰. Determining when milk is at a desired temperature is inexact, often subjective and can be time consuming. Therefore, a standard, safe and easy-to-use warming/thawing device is an essential item for all NICU or maternity wards.

Calesca



This warming/thawing device is designed for safe and efficient warming and thawing of milk in a hospital environment:

- I Human milk can be thawed from a completely frozen state to a refrigerated temperature.
- I Thawed human milk can be portioned and refrigerated for use during the day.
- I Individual portions of milk can be warmed to an ideal feeding temperature (range 30 °–38 °C) without the use of water.

Calesca involves the use of plastic inserts, placed inside a small cavity with warm circulating air. This unique system provides both a hygienic and convenient method for the management of milk in the hospital environment.

Convenient warming and thawing of human milk

Time is of the essence when it comes to feeding a preterm infant and if the milk has been frozen, it may be necessary to defrost it fairly quickly. Calesca will provide a safe environment to do this in an easy way. Moreover, milk for the day can be thawed, portioned and subsequently stored in the refrigerator until it is needed. These portions can then be heated to the correct temperature for feeding.

Additionally, Calesca will maintain the warm temperature for up to 30 minutes after its completion time to allow the users to retrieve the milk at their convenience.

Safe warming of human milk

The use of warm circulating air in an enclosed chamber eliminates the possibility of contamination from the use of water. The heating profile of the device is controlled by a software program and maintained within safe operating limits through a series of thermal sensors and safety shut-offs. Whether the milk is frozen, cooled or at room temperature, a slow and gentle warming profile is utilised to ensure that the milk does not exceed the temperatures or times that could affect milk composition, thus, helping to preserve milk's delicate components.

Flexibility

Calesca can be used with a variety of bottles and syringes. It can accommodate very small amounts of milk in plastic syringes ranging from 1–60 mL. This flexibility is especially important for preterm infants as feeding volumes for very low birth weight infants can be extremely small. As feeding volumes increase, Calesca can take bottles up to 250 mL and either plastic or glass is safe.

Calesca shows the total cycle time and counts down to zero so that it is clear at all times how much longer the warming or thawing process will last. Visual and acoustic signals on the device (the acoustic signals can be turned off) clearly show when the warming or thawing cycle is completed.

Furthermore, once the warming or thawing cycle is complete, Calesca will continue to 'count up' providing the health professional with an indication of how long the milk has been in the warming/thawing device.



Infection Prevention and Control

Calesca uses disposable inserts that hold the milk bottle or syringe. These inserts fit neatly into the cavity of the device.

Each insert is assigned to a particular infant and can be labelled with the patient's information, date and time – thus avoiding mix-up and cross-contamination.

The device is designed as a single bedside unit, whereby parents can warm their own child's feed, but Calesca can also be used on the ward. However, when used in this manner, it is especially important to label the inserts for individual mother's milk.

The recommendation is to change such an insert every 12 hours to fulfil hygienic requirements.

Human milk feedings in the hospital setting involve a complex matrix of issues related to the intricate nature of human milk and the potential hazards of milk storage and preparation. Through the use of innovative technology, and with effective clinical implementation, Calesca may help maintain the optimal integrity of human milk ensuring a safe, hygienic and standardised method for preparation of feedings for hospitalised infants.

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