

## Human milk safety and infection control in the NICU

Maintaining human milk's protective properties and minimising the chances of contamination are fundamental for preterm infant health. Medela provides evidence-based solutions that support safety and infection control in the NICU.





## Human milk safety and infection control in the NICU

Human milk has potent anti-infective properties that resist the growth of microbes. However, due to the unique composition of human milk, a complex set of issues arises that places milk at risk of contamination when collecting, storing and handling it for feeding in the NICU (Neonatal Intensive Care Unit). Although the benefits of human milk far outweigh the consideration of it as an infection source, it is essential that the human milk pathway is optimised to ensure safety and infection control.

Medela strives to provide knowledge and products that help to improve the human milk pathway in the NICU. This brochure aims to support NICU professionals with evidence-based solutions when it comes to the safe and hygienic handling of human milk. It is an overview of Medela's NICU solutions and an entry point to more detailed materials and initiatives dedicated to human milk and breastfeeding.

## Medela: Comprehensive solutions for human milk and breastfeeding

For more than 50 years Medela has strived to enhance mother and baby health through the life-giving benefits of breastmilk. During this time, the company has focussed on understanding mothers' needs and infants' behaviour. The health of both mothers and their infants during the precious breastfeeding period is at the centre of all activities. Medela continues to support exploratory research into human milk and breastfeeding, and incorporates the outcomes into innovative breastfeeding solutions.

Through new discoveries surrounding the components of human milk, the anatomy of the lactating breast and how the infant removes milk from the breast, Medela has developed a set of solutions to support NICUs in providing human milk and improving breastfeeding.

Medela understands the difficulties of providing human milk in the NICU. There are challenges from the mother's side to reach an adequate milk supply and from the infant's side to ingest the milk; plus there are issues of hygiene and logistics when meeting these challenges. The portfolio Medela offers is directed towards obtaining human milk, promoting human milk feeding, and supporting all infants in achieving breastfeeding as early as possible.

Medela aims to provide the most recent, evidence-based knowledge to support breastfeeding and human milk use in the NICU. The goal of the innovative, research-based products, together with the educational materials, is to overcome the difficulties associated with human milk provision in the NICU.



#### Scientific research

Medela strives for excellence in scientific research – an attitude that has enabled the company to develop advanced breastpump

and breastmilk feeding technologies. Medela works with experienced medical professionals and seeks collaboration with universities, hospitals and research institutions worldwide.



#### **Products**

Helping mothers to express milk is Medela's core competency. This includes careful and hygienic collecting of breastmilk in

BPA-free containers. Easy solutions for labelling, storing, transporting, warming and thawing – all help to safely manage precious human milk. And for human milk to reach the infant, Medela has developed a range of innovative products for different feeding situations.



#### Education

Within Medela, research and education are closely linked. Medela connects clinicians and educators in ways that lead to professional

growth, exchange of knowledge and interaction with the broader scientific community.







#### Passionate about human milk

Breastfeeding is indisputably the most natural and optimal way to provide the complete nutritional, immunological and developmental benefits of human milk <sup>1</sup> to the growing infant. Moreover, breastfeeding provides physical and psychological benefits to both, mother and child <sup>2, 3</sup>. As a global public health recommendation, infants should be exclusively breastfed for the first six months of life to achieve optimal growth, development and health <sup>2, 4, 5</sup>.

#### Breastfeeding protects mother and child

Breastfeeding reduces the risk of short-term and long-term morbidities in the infant, including necrotising enterocolitis (NEC), gastrointestinal tract infections, respiratory tract infections, otitis media, atopic dermatitis, childhood asthma, childhood leukaemia, diabetes type I, obesity, and sudden infant death syndrome (SIDS) 6-8. Breastfeeding also facilitates maternal-infant bonding through complex behavioural and neuro-endocrine responses between the mother and her infant 9. Additionally, women who breastfeed or provide milk for their infants have a reduced risk of breast and ovarian cancers, osteoporosis, diabetes type II, cardiovascular disease, and rheumatoid arthritis 10.

#### The potent properties of human milk

Evidence supporting the use of human milk for preterm infants is just as extensive and compelling as that related to breastfeeding term infants. Human milk reduces the risk and severity of debilitating morbidities in premature infants in a dose-response manner, with higher quantities of human milk leading to the greatest protection <sup>6, 11</sup>. Preterm infants who receive human milk during their stay in the NICU have a reduced risk of NEC, chronic lung disease, retinopathy of prematurity, SIDS, and rehospitalisation after NICU discharge <sup>7, 8, 12–19</sup>. The positive impact of human milk appears to be linked to precise exposure in the early post-birth period, during which the exclusive use of human milk and the avoidance of commercial formula, are most vital <sup>5</sup>. This is especially important for hospitalised and preterm infants <sup>1</sup>.

Compared to term milk, preterm milk has higher levels of energy, lipids, protein, nitrogen, some vitamins, some minerals, and in particular immune factors, including live cells, immunoglobulins and anti-inflammatory elements <sup>20, 21</sup>. These work synergistically to provide protection against infection, provide nutrition and promote optimal development of critical bodily systems <sup>6, 22</sup>. The composition of preterm milk is therefore especially important for the development of the gastrointestinal tract, for neurological development and for conferring immunological protection to preterm infants <sup>5</sup>.

The components of human milk, especially the live cells from the infant's mother, cannot be replaced by artificial sources, which is why the feeding of human milk should be a NICU priority <sup>6, 22</sup>. Fresh human milk, defined as milk that is either directly breastfed to the infant or newly expressed <sup>23</sup>, has the highest level of functional nutrients, growth factors, and many other protective components such as lactoferrin, secretory IgA and lysozyme <sup>5, 24</sup>. Moreover, fresh human milk is not sterile but rather contains a wide variety of living organisms, including non-pathogenic bacteria that colonise the infant intestine <sup>23</sup>.

It is essential to ensure that human milk is provided to NICU infants in an optimal form. This means not only catered to the preterm infant's requirements for appropriate growth and development, but that the composition of the milk itself maintains its protective properties and that the likelihood of any contamination is minimised. To achieve this, the entire NICU human milk pathway should be optimised from a safety and infection control standpoint, starting from hygienic milk collection practices during pumping, to storing, and finally feeding the infant.

Breastfeeding is the most effective way to provide nutrition, protection against infection, and promotion of normal growth and development. When direct breastfeeding is not possible, a NICU must optimise the hygiene and safety of the human milk pathway to ensure that infants are safely provided with the protective properties of human milk.









## Human milk safety and infection control challenges in the NICU

Human milk fed directly from the breast contains optimal nutritional, protective and bioactive components. When infants are unable to breastfeed, the aim is to provide human milk as close to direct breastfeeding as possible. However, retaining the integrity and safety of expressed milk is a challenging goal for the NICU. Due to the intricate nature of human milk and the complex pathway required to prepare it for feeding, safety and infection control considerations in the NICU include

- I the bacterial load in human milk
- I milk being potentially exposed to pathogens during expression and handling
- I risks of mix-ups, and the subsequent delivery of milk to the incorrect infant

Sub-optimal milk collection, storage and labelling practices are among the sources of these risks. Despite the challenges, it is widely recognised that the benefits of receiving human milk, particularly own mother's milk, outweigh the challenges associated with human milk handling.

#### Risk factors in human milk

Fresh human milk contains bacteria, including intestinal bacteria that are thought to contribute to vital programming of the infant's immune system to respond to commensal and pathogenic bacteria <sup>23</sup>. The majority of identified organisms in milk are non-pathogenic normal skin flora from the mother's nipple or breast. Nonetheless, potentially pathogenic bacteria are also common in human milk. Staphylococcus aureus, including MRSA, B-haemolytic streptococci, Pseudomonas species, Klebsiella species, Proteus species, and enterobacteria are frequently identified <sup>25-28</sup> and may place the infant at risk of infection.

There are also some occasions when own mother's milk (OMM) is contraindicated; for example in the case of some maternal medications or maternal infections. One infection

that is commonly discussed in the NICU is Cytomegalovirus (CMV). While the actual chances of severe, symptomatic CMV infection are low, preterm infants infected with CMV can present with a variety of signs and symptoms, some quite serious. CMV is therefore a concern for the NICU <sup>29–31</sup>.

Medications and other substances, such as alcohol and nicotine, may circulate in a mother's body. Their concentrations in human milk vary depending on a host of factors. While the list of medications that are contraindicated during lactation is fairly short, each maternal-infant situation must be evaluated individually <sup>32</sup>.







#### Concerns when handling human milk

Human milk can become contaminated at various points along the milk pathway, including pumping, storage and handling processes <sup>24</sup>.

Mothers and families are frequently tasked with collecting, logging and labelling the milk. They require appropriate containers and consistent instructions for the management of the milk they pump, as well as for the transport of any milk expressed at home, in order to reduce the likelihood of contamination and bacterial growth <sup>24</sup>.

In the NICU setting, even the most benign flora may have a negative effect on the vulnerable, immunocompromised infant. Consequently, it is critical that during the processing of human milk, the anti-infective properties are maintained as much as possible, while avoiding the entry of pathogenic organisms. Milk storage should therefore be optimised in terms of duration, temperature and labelling.

After storage, milk preparation most likely requires thawing, warming and fortification. Each process may affect the composition of the milk and jeopardise its hygiene. Microwaving milk or using hot or boiling water are not recommended since they destroy the anti-infective properties of milk  $^{24}$ . In addition, microwaves have been shown to unevenly warm milk, creating 'hot spots' that can question the temperature safety of the milk and lead to scalds  $^{33,\,34}$ .

Human milk, in particular donor milk, is pasteurised to prevent the potential transmission of pathogens. Holder pasteurisation is a widely used low-temperature long-time (62.5 °C for 30 min) heat treatment. However, heat treatment is well known to also result in significant loss of immunological and anti-inflammatory components, probiotic bacteria and white blood cells in milk <sup>33, 34</sup>. In addition, pasteurisation has been shown to negatively impact the ability of the milk to resist bacterial growth <sup>35</sup>.

Consequently, there are different management processes and recommendations in place for pasteurised milk and unpasteurised milk. NICU professionals should be aware that they may need to take even more care with pasteurised milk than with own mother's milk, particularly with storage conditions, in order to control bacterial growth <sup>24</sup>.









# Bridging the gap: Safe and hygienic handling of human milk

When breastfeeding is not possible, the NICU must ensure that human milk is of minimal hazard to the infant, and of maximum quality. All processes involving human milk therefore need to

- I minimise the possibility of contamination
- I promote safe collection and cleaning practices
- I maintain the integrity of bioactive components
- I reduce disease transmission risks
- I make the most efficient use of the available volume
- I minimise the chances of mix-ups

Medela shares these goals. Utilising research-based and process-optimised innovations, as well as research reviews and the latest study summaries, Medela supports you and your patients in making informed choices.

Preventing contamination, ensuring infection control and maximising the nutritional and protective components of human milk is critical in the NICU. Incorrect handling can result in loss of milk quality, improper hygiene or mix-ups;

and if hygienic issues are detected, mother's precious milk will most likely need to be discarded. In the worst case, hygienic issues may go undetected and increase the infant's risk of acquiring an infection <sup>36–38</sup>.







### Medela's NICU solutions for human milk safety and infection control

Human milk in the NICU has commonly lacked standardised processes. Protocols for collecting, handling and feeding human milk vary between institutions, are dependent on regulatory policies and on the resources available at each hospital.

Goals of a human milk safety and infection control portfolio for the NICU By combining innovative products and knowledge, Medela strives to support hospitals in their attempt to optimise human milk processes. In this particular case, the focus is on infection control and safety in order to maintain the milk's quality as much as possible up to the time it is fed to the infant.

#### Hygienic collection of human milk

Milk can be contaminated at any point along the milk pathway when it comes in contact with foreign surfaces. This can be during pumping, collection, transport, storage and processing of milk <sup>24</sup>. Common skin bacterial flora and microbial species may be introduced *via* the collection equipment <sup>26, 39</sup>. In particular, contaminated pumps have been identified as reservoirs for bacteria <sup>40–42</sup>, especially after being used by multiple mothers and inadequately cleaned between each use. Hygienic collection of milk should therefore begin prior to pumping. In order to minimise bacterial growth and the chances of infection, some simple steps should be followed:

- I Mothers should maintain normal maternal breast hygiene; no additional cleaning of the breast prior to milk expression is required <sup>43, 44</sup>.
- I Pumping mothers are recommended to wash and dry their hands thoroughly prior to pumping <sup>24</sup>.
- I Hand drying with single-use towels is regarded as best practice, in conjunction with turning taps off in a way that does not recontaminate hands <sup>45</sup>. Clean disposable paper towels, commonly used in hospitals and homes, are the most hygienic drying method <sup>46, 47</sup>.
- I Fingernails should be kept short and jewellery removed <sup>45</sup>. While this has been noted specifically for healthcare personnel, this can also be applied for mothers' hand hygiene prior to breast pumping.











#### Membrane cap



Protective membrane

#### Symphony breastpump system

Breastpumps and pump sets, like all hospital equipment, are potential carriers of pathogenic microorganisms <sup>37, 48</sup>. Each mother needs her own pump set, consisting of breastshield, breastshield connector, valve head, valve membrane, bottle, tubing, membrane cap and protective membrane.

#### Medela's milk overflow protection system

Medela's Symphony breastpump system was developed to minimise the risk of contamination. Thanks to the innovative milk overflow protection system, called media separation, a division is created between the pump and the milk, making the Symphony a hygienic multi-user breastpump. Firstly, Medela's breastshields have a splash guard that guides milk flow directly into the collection bottle. Secondly, the protective membrane of the media separation is placed on the pump with the membrane cap. This protective membrane moves up and down with vacuum and makes sure that no milk can flow into the breastpump. The mother can simply take her complete pump set, including tubing, protective membrane and membrane cap, directly from the Symphony, leaving it ready for use by the next mother. This supports hygienic pumping sessions and prevents potential cross-contamination between mothers.





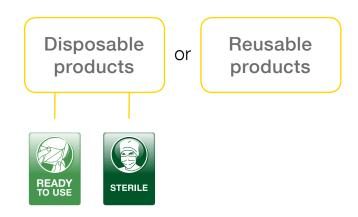


#### Collection containers and pump sets

Medela's collection containers and pump sets are an integral part of the Symphony pump system. The choice of what collection containers and pump sets to use in the NICU depends on many factors, including national regulations, internal guidelines, sterilisation facilities, and environmental considerations.



To accommodate for the diverse and individual needs of each hospital, Medela provides three types of collection containers and pump sets:









#### Disposable products

Medela disposable products are available as Ready-to-Use and EO sterile lines. They are intended for single- or one-day-use in hospitals, without a need for cleaning prior to first use. Disposable products are an attractive choice for hospitals that do not have time, resources or infrastructure to process reusable products in large quantities or for which this is economically not justifiable.



**Ready-to-Use:** Medela Ready-to-Use products are hygienically safe <sup>49</sup> to use without prior cleaning. To maintain the high hygienic standards of Ready-to-Use products, production and packaging take place in especially designed units with highly purified air circulating under laminar flow conditions or in clean rooms. The

products are formed at over 150 °C (302 °F) and packaging takes place in a validated, fully automated production line, resulting in these products being 10 times cleaner than bottled water <sup>50</sup>. Additionally, samples from every production LOT are microbiologically tested <sup>51</sup> before release for sale.



**Sterile:** Medela sterile products are validated according to the applicable EN/ISO  $^{52,\,53}$  standards for sterile medical devices. "Sterilised" or "pre-sterilised" products are not to be confused with "sterile" products. Only the term and symbol "STERILE" guarantee that the product is actually sterile. Medela sterile

products are individually packed in sterile barrier packaging, which guarantees sterility for each individual product until the moment that the packaging is opened or the expiry date is reached. Medela sterile products are single-use products, for a minimum risk of contamination.

#### Reusable products

For hospitals with sterilisation processes in place, Medela offers autoclavable pump sets and bottles. These reusable products can therefore be used by multiple mothers after sterilisation between users <sup>54</sup>. For hospitals with validated cleaning processes, equipment and personnel in place, Medela's reusable products may be economically and ecologically a good option.

Medela offers a suitable solution for the individual situation of any hospital. To assess your priorities and what option works best for you, please contact your local Medela sales representative.

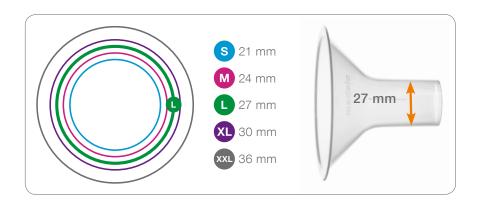






#### Adaptable for all needs and processes

Breastshields are available for the hospital in sizes S (21 mm), M (24 mm), L (27 mm), XL (30 mm) and XXL (36 mm) to cater to the needs of all mothers.





Medela collection containers have grading in small and precise volume increments to accurately and easily check the quantity of breastmilk that has been expressed. They are available in a range of different sizes, from 35 mL to 250 mL. The smaller range covers the majority of the pumping, storing and feeding requirements in the NICU. The larger bottles help to cover the more specific needs on the paediatric ward, the centralised milk kitchen or the milk bank.



The Medela disposable Colostrum Container has been developed with health-care professionals and mothers in mind. The container is designed to carefully deal with small volumes of breastmilk. The curved bottom allows the user to easily draw milk from the container into a syringe. With this ease of extraction, the chances of contaminating the milk during handling can be minimised. The small size of the 35 mL container is intended to make sure that mothers remain motivated while pumping breastmilk, as it puts their expectations regarding the initial milk production into a realistic perspective.



The containers used for both storage and feeding should have minimal effects on the nutritional and immunologic composition of the milk. Medela breastmilk bottles, storage containers, feeding products and breastpump kits are made from food-grade material and without BPA.







### Hygienic handling and storing practices

Hygienic practices after pumping are just as important as those that occur prior to and during pumping. After pumping, in order to minimise the chances of bacterial growth and infection, the following actions should be undertaken:

- I External surfaces of hospital breastpumps and kits, particularly those touched by mothers or staff in the process of pumping, should be disinfected with solutions or wipes between users. Both mothers or the NICU staff can be involved in cleaning hospital pumps <sup>55</sup>.
- I In the hospital and at home, the surface upon which cleaned pump set parts are placed should also be disinfected with solutions or wipes.
- I Pump set parts that come in contact with milk should be completely separated and thoroughly cleaned after each use. After the pump set parts are disassembled, they should be rinsed in cool water to remove milk residue, especially milk proteins <sup>24</sup>. Parts should be washed with washing-up liquid and water, either under running water or in a clean bowl or basin designated solely for this purpose. Patient specific bottle brushes can be used to clean parts, especially tight crevices <sup>54</sup>.
- I After washing, parts should be rinsed thoroughly and then placed on a disinfected surface for drying. Clean cloth towel drying may be acceptable, or air-drying is another option. Once clean and dry, pump set parts should be removed from the sink area to prevent contamination from splash back from the sink.

In the NICU there is a requirement to transfer and store pumped milk. This comes with the potential hazard of nutrient loss and contamination <sup>5</sup>. The NICU must optimise storage conditions to minimise loss of nutrients, growth factors and many other protective components in milk, whilst also minimising the possibilities of contamination at the NICU or mother's home <sup>24</sup>. With both time and varying temperatures, components in human milk decrease in potency while the growth of pathogens increases.

Facilities should aim to standardise milk handling practices with the objective of minimising introduction of pathogens, chances of mix-ups, the loss of milk through unnecessary transfers between containers as well as any quality loss of the milk components offered to the infant.

#### Provide the right milk to the correct infant

Appropriate labelling is one of the prerequisites for safe storage. Labelling with the patient's name, date of expression and volume expressed may assist in minimising milk mix-ups. Methods like storage boxes for each individual mother in a freezer or fridge, as well as bar codes more commonly seen in milk banks, may also be advantageous <sup>24, 56, 57</sup>.







#### Pre-printed labels

Medela's pre-printed labels help to ensure traceability. This is particularly important for precious colostrum. While many hospitals have differing protocols, a general rule is to use fresh milk where possible, and expose the infant to colostrum first <sup>24</sup>. The early oral exposure to colostrum is particularly important in the first days of life. This follows the first-in-first-out (FIFO) principle, whereby the milk expressed first should be fed first if fresh milk is not available <sup>24</sup>. With this in mind, Medela labels request the following data:

- I Name of the infant
- I Date of expression
- I Time of expression
- I Quantity of expressed milk

This information helps to bring the milk from the mother to her own infant in the correct order. Additionally, if milk is frozen in a container that was not held upright, it can be difficult to assess how much milk the container holds. Using the label to record the volume of milk will help with the logistics of preparing and providing the prescribed milk volumes.



A dedicated storage area in the refrigerator and freezer can help to manage milk in the NICU, and where possible, each mother and infant can be provided with their own individual and coloured tray in order to minimise the chance of mix-ups.









Similar to the handling of other critical fluids in the hospital, the 4-eyes principle has been recommended for the distribution of human milk to infants. The 4-eyes principle calls for two people to check the label before feeding to ensure that all infants actually get the appropriate milk of their own mother.

### Make the most efficient use of the available human milk: Appropriate storing

Once milk has been expressed and labelled as per hospital guidelines, how the milk is subsequently stored and fed to the infant must be considered.

Human milk should be refrigerated or frozen as soon as possible if it is not to be used within a short period of time after expression ( $<4\,\mathrm{hours}$ ). Each hospital should have policy recommendations for mothers about storage containers, conditions and times  $^{58}$  as well as specific recommendations that differentiate between donor milk and own mother's milk, especially when fortifier has been added. Mothers transporting milk from home to hospital should be instructed on how to keep milk cold during transport with freezer packs and carry bag insulation around the milk containers  $^{58-60}$ .

Guidelines for storing and thawing milk will differ according to the environment (NICU, maternity ward or home) and the state of the infant (NICU, high risk, healthy term newborn or older). In all instances, and particularly in the NICU, storage times should be kept as short as possible. Current recommendations for NICU infants vary between hospitals. Storage recommendations also differ significantly depending on whether the milk is fresh, at room temperature, refrigerated, frozen, thawed or fortified <sup>24</sup>. The following recommendations are research-based and cover the human milk pathway in the NICU <sup>24</sup>:

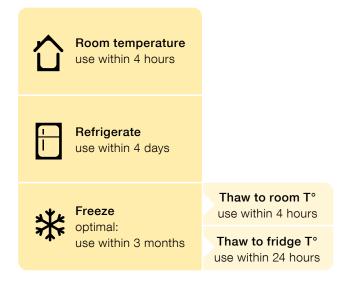






Storage guidelines for human milk in the NICU

#### Freshly expressed milk



### Fortified or thawed pasteurised milk



#### Pasteurisation and the use of donor milk

Pasteurisation is a process commonly utilised to reduce bacterial load <sup>5</sup> and to eliminate viruses that may be passed from a mother to the milk <sup>61</sup>. When milk from an infant's own mother is either not available or not acceptable in a NICU setting (as in the case of mothers with HIV-1, HTLV I and II, illicit substances, contraindicated medications or insufficient milk supply), donor human milk is the next best option <sup>62</sup>. International standards include specific processes for donor screening and culturing of processed milk to ensure sterility and minimal risk to preterm infants <sup>24, 62</sup>. The use of unpasteurised donor milk is practiced in some facilities, but is limited as a result of national and hospital policies <sup>24, 56, 57</sup>. The downside of current pasteurisation processes is the loss of some immunological and nutritional components. The loss of the anti-infective activity of human milk means that the bacterial growth rate of pasteurised human milk is higher than in untreated human milk <sup>35</sup>.

Medela offers bottles that can withstand pasteurisation temperatures and are suitable for the milk volumes handled in centralised milk kitchens or milk banks. In addition, the multi-user Symphony breastpump system, with the range of hygienic pump sets, serves as a partner for the collection of milk from donors.







#### Fortification

Due to the high nutritional demands of preterm infants in order to appropriately grow, fortification is recommended for those born < 1500 g, and in some cases other infants <sup>63</sup>. Despite the benefits of fortification, bacterial growth in milk stored at refrigerator temperature is significantly greater in fortified milk compared to unfortified milk <sup>64</sup>. This occurs because fortification is associated with changes in the anti-microbial activity of milk <sup>65-67</sup>. Milk storage recommendations are hence impacted; fortified milk should be refrigerated immediately, not be frozen, and be used within 24 hours (see storage guidelines for human milk in the NICU) <sup>24</sup>.

The necessary step of fortification adds concerns of possible colonisation by various bacteria; in particular powdered fortifiers may be of concern <sup>68, 69</sup>. Since bacterial growth and osmolality increase faster in fortified milk <sup>64, 70</sup>, it is crucial to observe guidelines and manufacturer's instructions. The addition of fortifiers using aseptic techniques <sup>68, 69</sup> at room temperature or cooler has been suggested to help minimise changes in osmolality levels <sup>71</sup>.









#### Safe, hygienic and gentle warming of human milk

Thawing and warming of human milk are the final stages of preparing milk for feeding. They are usually considered as two separate processes, but they can be combined into one step. Controlling the temperature of milk is not only important for maintaining its integrity, but may also be beneficial for the high risk infant. Fluids such as saline and blood are usually warmed prior to infusion in order to avoid decreases in infant body temperature <sup>72, 73</sup>. In line with this, it has been theorised that milk temperature can also impact infant body temperature <sup>74</sup>. Therefore, warming neonatal feeds has become a common practice in many NICUs, with the idea that feeds warmed to body temperature may improve infant outcomes, such as the infant's ability to tolerate gavage feeds <sup>75, 76</sup>.

Water-based methods have been used for both thawing and warming human milk. These usually involve placing bottles or containers of milk in water baths or water-filled containers that should not exceed 37 °C <sup>24, 37</sup>. Regulating and achieving optimal temperature with these various water-based methods is challenging <sup>77</sup>. Additionally, water, particularly when warm, can harbour pathogens.

In light of this, there is a possibility that water can get under or inside the bottle lid and into the milk <sup>24</sup>. Historically, contaminated hospital tap water used in bottle warmers has been identified as a source of nosocomial infection and outbreak in the NICU <sup>77-79</sup>. Some NICUs now subsequently use dry, waterless warmers, rather than water-based methods, to provide constant temperature and to prevent potential contamination of milk <sup>80,81</sup>.



Medela offers Calesca, a waterless warming and thawing device that helps with optimising and standardising human milk processes, and minimising the challenges associated with human milk handling. Designed for individual care in the NICU, Calesca aims to maintain the integrity of human milk by warming it towards body temperature without exposing it to high heat.

- I Hygienic: The use of circulating warm air in an enclosed chamber eliminates the possibility of contamination from the use of water.
- I Individual: The disposable inserts reduce cross-contamination and make the device easy to clean.
- I When used as a single bedside unit, Calesca helps to keep track of each infant's milk, thus minimising mix-ups.
- I Fast thawing: Human milk can be efficiently thawed, portioned and subsequently stored in the refrigerator until it is needed.
- I Process standardisation: Taking into account the milk volume and its initial state (frozen, refrigerated or room temperature) helps to standardise the thawing and warming process.
- I Gentle warming: Individual portions of human milk can be warmed to an ideal feeding temperature without overheating. This aims to preserve valuable nutrients and vitamins.











With Calesca, Medela has moved away from water-based warming and thawing methods. By relying on dry heat, Medela aims to reduce the risk of exposing the infant to contaminated water, while maintaining milk quality.







#### Education

NICU professionals know that products are only one part of the equation to successful breastfeeding in the NICU. It is as important for all stakeholders to receive consistent, accurate information in order to

- I support human milk use and breastfeeding by all staff and parents
- I make evidence-based decisions
- I develop efficient and effective practices for human milk handling and feeding

Medela works together with experts around the world to tackle and remove the barriers to the use of human milk and breastfeeding in the NICU.

Beyond direct support of various basic and clinical research projects, Medela summarises existing knowledge on the various challenges and disseminates this knowledge through different materials, channels and events.











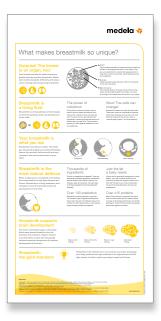
#### Research review: Human milk safety and infection control

Comprehensive examination of the published literature on human milk safety and infection control in the NICU has been carried out. The resulting review highlights up-to-date and evidence-based procedures to support safe and hygienic human milk practices in the NICU.



#### Study abstract papers

The study abstract papers provide the scientific and clinical context to specific process- and product innovations. By summarising, analysing and explaining the clinical research, they help to set the right expectations when implementing a new procedure or technology.



#### Infographics

Infographics take a large amount of information and then condense it into a combination of images, text and numbers. This allows viewers to quickly grasp the essential insights the data contains. The visual representations of data sets and instructive materials are a quick way for audiences of all levels to learn about a topic.









#### Posters and DVDs

Medela supports numerous research projects. The most significant outcomes of these projects are described and visualised through posters and DVDs. These include topics such as the science of infant sucking and breast anatomy.



#### Online

For further and up-to-date information please visit http://www.medela.com/nicu.



#### Knowledge transfer events

Medela organises diverse symposia on different topics connected to human milk as regional stand-alone events or as part of national conferences. However, Medela's most important event is the annual International Breast-feeding and Lactation Symposium. Through this Symposium, Medela makes knowledge directly accessible to the practitioners. The Symposium is a platform for internationally renowned researchers to give insights into their latest research findings in three key areas: latest recommendations for research-based practice, the unique components of human milk and the value of human milk in the NICU.

Please contact your sales representative for more information on all the items above, or visit www.medela.com

#### References

- 1 Callen,J. & Pinelli,J. A review of the literature examining the benefits and challenges, incidence and duration, and barriers to breastfeeding in preterm infants. Adv Neonatal Care 5, 72-88 (2005).
- WHO & UNICEF. Global strategy for infant and young child feeding (World Health Organization, Geneva, 2003).
- Winberg, J. Mother and newborn baby: Mutual regulation of physiology and behavior - a selective review. Dev Psychobiol 47, 217-229 (2005).
- 4 UNICEF Facts for life (United Nations Children's Fund, New York, 2010).
- 5 American Academy of Pediatrics Section on Breastfeeding. Breastfeeding and the use of human milk. Pediatrics 129, e827-e841 (2012).
- Meier,P.P., Engstrom,J.L., Patel,J.L., Jegier,B.J., & Bruns,N.E. Improving the use of human milk during and after the NICU stay. Clin Perinatol 37, 217-245 (2010).
- 7 Quigley,M.A., Henderson,G., Anthony,M.Y., & McGuire,W. Formula milk versus donor breast milk for feeding preterm or low birth weight infants. Cochrane Database Syst Rev1-41 (2007).
- 8 Schanler R.J., Lau,C., Hurst,N.M., & Smith,E.O. Randomized trial of donor human milk versus preterm formula as substitutes for mothers' own milk in the feeding of extremely premature infants. Pediatrics 116, 400-406 (2005).
- 9 Uvnas-Moberg,K. Neuroendocrinology of the mother-child interaction. Trends Endocrinol Metab 7, 126-131 (1996).
- 10 Chung, M., Raman, G., Trikalinos, T., Lau, J., & Ip, S. Interventions in primary care to promote breastfeeding: An evidence review for the U.S. Preventive Services Task Force. Ann Intern Med 149, 565-582 (2008).
- 11 Patel,A.L. et al. Impact of early human milk on sepsis and health-care costs in very low birth weight infants. J Perinatol 33, 514-519 (2013).
- 12 Arslanoglu,S., Ziegler,E.E., Moro,G.E., & WAPM working group on nutrition. Donor human milk in preterm infant feeding: Evidence and recommendations. J Perinat Med 38, 347-351 (2010).

- 13 Bisquera, J.A., Cooper, T.R., & Berseth, C.L. Impact of necrotizing enterocolitis on length of stay and hospital charges in very low birth weight infants. Pediatrics 109, 423-428 (2002).
- 14 Furman, L., Taylor, G., Minich, N., & Hack, M. The effect of maternal milk on neonatal morbidity of very low-birth-weight infants. Arch Pediatr Adolesc Med 157, 66-71 (2003).
- Hylander, M.A., Strobino, D.M., & Dhanireddy, R. Human milk feedings and infection among very low birth weight infants. Pediatrics 102, E38 (1998).
- Hylander, M.A., Strobino, D.M., Pezzullo. J.C., & Dhanireddy, R. Association of human milk feedings with a reduction in retinopathy of prematurity among very low birthweight infants. J Perinatol 21, 356-362 (2001).
- 17 Schanler,R., Shulman,R.J., & Lau,C. Feeding strategies for premature infants: Beneficial outcomes of feeding fortified human milk versus preterm formula. Pediatrics 103, 1150-1157 (1999).
- 18 Vohr,B.R. et al. Beneficial effects of breast milk in the neonatal intensive care unit on the developmental outcome of extremely low birth weight infants at 18 months of age. Pediatrics 118, e115-e123 (2006).
- 19 Vohr,B.R. et al. Persistent beneficial effects of breast milk ingested in the neonatal intensive care unit on outcomes of extremely low birth weight infants at 30 months of age. Pediatrics 120, e953-e959 (2007).
- 20 Schanler R.J. Evaluation of the evidence to support current recommendations to meet the needs of premature infants: The role of human milk. Am J Clin Nutr 85, 625S-628S (2007).
- 21 Schanler,R.J. The use of human milk for premature infants. Pediatr Clin North Am 48, 207-219 (2001).
- 22 Hale, T.W. & Hartmann, P.E. Textbook of human lactation (Hale Publishing LLP, Amarillo TX, 2007).
- Jeurink, P.V. et al. Human milk: A source of more life than we imagine. Benef Microbes 4, 17-30 (2013).

- 24 Human Milk Banking Association of North America 2011 Best practice for expressing, storing and handling human milk in hospitals, homes, and child care settings (HMBANA, Fort Worth, 2011).
- Novak,F.R., Da Silva,A.V., Hagler,A.N., & Figueiredo,A.M. Contamination of expressed human breast milk with an epidemic multiresistant Staphylococcus aureus clone. J Med Microbiol 49, 1109-1117 (2000).
- 26 Eidelman, A.I. & Szilagyi, G. Patterns of bacterial colonization of human milk. Obstet Gynecol 53, 550-552 (1979).
- 27 Carroll, L., Osman, M., Davies, D.P., & McNeish, A.S. Bacteriological criteria for feeding raw breast-milk to babies on neonatal units. Lancet 2, 732-733 (1979).
- 28 Perez,P.F. et al. Bacterial imprinting of the neonatal immune system: Lessons from maternal cells? Pediatrics 119, e724-e732 (2007).
- 29 Sharland, M., Khare, M., & Bedford-Russell, A. Prevention of postnatal cytomegalovirus infection in preterm infants. Arch Dis Child Fetal Neonatal Ed 86, F140 (2002).
- Meier, J. et al. Human cytomegalovirus reactivation during lactation and mother-to-child transmission in preterm infants. J Clin Microbiol 43, 1318-1324 (2005).
- 31 Capretti,M.G. et al. Very low birth weight infants born to cytomegalovirus-seropositive mothers fed with their mother's milk: A prospective study. J Pediatr 154, 842-848 (2009)
- 32 Hale, T.W. & Rowe, H.E. Medications and mothers' milk (Hale Publishing, Plano TX, 2014)
- 33 Quan,R. et al. Effects of microwave radiation on anti-infective factors in human milk. Pediatrics 89, 667-669 (1992).
- 34 Sigman,M., Burke,K.I., Swarner,O.W., & Shavlik,G.W. Effects of microwaving human milk: Changes in IgA content and bacterial count. J Am Diet Assoc 89, 690-692 (1989).
- 35 Christen,L., Lai,C.T., Hartmann,B., Hartmann,P.E., & Geddes,D.T. The effect of UV-C pasteurization on bacteriostatic properties and immunological proteins of donor human milk. PLoS One 8, e85867 (2013).

- 36 Gransden, W.R., Webster, M., French, G.L., & Phillips, I. An outbreak of Serratia marcescens transmitted by contaminated breast pumps in a special care baby unit. J Hosp Infect 7, 149-154 (1986).
- 37 Brown,S.L., Bright,R.A., Dwyer,D.E., & Foxman,B. Breast pump adverse events: Reports to the food and drug administration. J Hum Lact 21, 169-174 (2005).
- 38 Donowitz,L.G., Marsik,F.J., Fisher,K.A., & Wenzel,R.P. Contaminated breast milk: A source of Klebsiella bacteremia in a newborn intensive care unit. Rev Infect Dis 3, 716-720 (1981).
- el-Mohandes, A.E., Keiser, J.F., Johnson, L.A., Refat, M., & Jackson, B.J. Aerobes isolated in fecal microflora of infants in the intensive care nursery: Relationship to human milk use and systemic sepsis. Am J Infect Control 21, 231-234 (1993).
- 40 Schanler,R.J. et al. Breastmilk cultures and infection in extremely premature infants. J Perinatol 31, 335-338 (2011).
- 41 Boo,N.Y., Nordiah,A.J., Alfizah,H., Nor-Rohaini,A.H., & Lim,V.K. Contamination of breast milk obtained by manual expression and breast pumps in mothers of very low birthweight infants. J Hosp Infect 49, 274-281 (2001).
- 42 el-Mohandes, A.E., Schatz, V., Keiser, J.F., & Jackson, B.J. Bacterial contaminants of collected and frozen human milk used in an intensive care nursery. Am J Infect Control 21, 226-230 (1993).
- 43 Tan, L., Nielsen, N.H., Young, D.C., & Trizna, Z. Use of antimicrobial agents in consumer products. Arch Dermatol 138, 1082-1086 (2002).
- 44 Aiello,A.E., Larson,E.L., & Levy,S.B. Consumer antibacterial soaps: Effective or just risky? Clin Infect Dis 45 Suppl 2, S137-S147 (2007).
- 45 Pittet, D., Allegranzi, B., & Boyce, J. The World Health Organization guidelines on hand hygiene in health care and their consensus recommendations. Infect Control Hosp Epidemiol 30, 611-622 (2009).
- 46 Harrison, W.A., Griffith, C.J., Ayers, T., & Michaels, B. Bacterial transfer and cross-contamination potential associated with paper-towel dispensing. Am J Infect Control 31, 387-391 (2003).

- 47 Harrison, W.A., Griffith, C.J., Michaels, B., & Ayers, T. Technique to determine contamination exposure routes and the economic efficiency of folded paper-towel dispensing. Am J Infect Control 31, 104-108 (2003).
- 48 Jones,B. et al. An outbreak of Serratia marcescens in two neonatal intensive care units. J Hosp Infect 46, 314-319 (2000).
- Deutsches Beratungszentrum für Hygiene. Conclusion of the Risk Assessment of the Production Method for "Ready-to-Use" Products (2014).
- 50 Bundesministerium der Justiz. Verordnung über die Qualität von Wasser für den menschlichen Gebrauch (Trinkwasserverordnung -TrinkwV 2001) (2001).
- 51 DIN EN ISO 11737-1. Sterilization of medical devices – Microbiological methods – Part 1:Determination of a population of microorganisms on products.
- 52 DIN EN ISO 11135-1. Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
- 53 DIN EN ISO 11607-1. Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems, DIN EN ISO 11607-2. Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes.
- 54 Gilks, J., Price, E., Hateley, P., Gould, D., & Weaver, G. Pros, cons and potential risks of on-site decontamination methods used on neonatal units for articles indirectly associated with infant feeding, including breast pump collection kits and neonatal dummies. J Infect Prev 13, 16-23 (2012).
- Meier,P.P., Engstrom,J.L., Mingolelli,S.S., Miracle,D.J., & Kiesling,S. The Rush Mothers' Milk Club: Breastfeeding interventions for mothers with very-lowbirth-weight infants. J Obstet Gynecol Neonatal Nurs 33, 164-174 (2004).
- 56 Dougherty,D. & Nash,A. Bar coding from breast to baby: A comprehensive breast milk management system for the NICU. Neonatal Netw 28, 321-328 (2009).

- 57 Drenckpohl,D., Bowers,L., & Cooper,H. Use of the six sigma methodology to reduce incidence of breast milk administration errors in the NICU. Neonatal Netw 26, 161-166 (2007).
- 58 Eglash,A. ABM clinical protocol #8: Human milk storage information for home use for full-term infants (original protocol March 2004; revision #1 March 2010). Breastfeed Med 5, 127-130 (2010).
- 59 Centers for Disease Control and Prevention. Assisted Reproductive Technology. http://www.cdc.gov/art/ (2012).
- 60 Food and Drug Administration. Breast milk. http://www.fda.gov/medicaldevices/ productsandmedicalprocedures/ homehealthandconsumer/consumerproducts/breastpumps/ucm061952.htm (2012).
- 61 Kurath,S., Halwachs-Baumann,G., Muller,W., & Resch,B. Transmission of cytomegalovirus via breast milk to the premat. Clin Microbiol Infect 16, 1172-1178 (2010).
- 62 National Institute for Health and Care Excellence. Donor milk banks: The operation of donor milk bank services. 2010. http://www.nice.org.uk/guidance/CG93/chapter/1-Guidance (2014).
- 63 American Academy of Pediatrics - Committee on Nutrition. Nutritional needs of low-birth-weight infants. Pediatrics 75, 976-986 (1985).
- 54 Jocson, M.A., Mason, E.O., & Schanler, R.J. The effects of nutrient fortification and varying storage conditions on host defense properties of human milk. Pediatrics 100, 240-243 (1997).
- 65 Chan, G.M. Effects of powdered human milk fortifiers on the antibacterial actions of human milk. J Perinatol 23, 620-623 (2003).
- 66 Santiago, M.S., Codipilly, C.N., Potak, D.C., & Schanler, R.J. Effect of human milk fortifiers on bacterial growth in human milk. J Perinatol 25, 647-649 (2005).
- 67 Chan,G.M., Lee,M.L., & Rechtman,D.J. Effects of a human milk-derived human milk fortifier on the antibacterial actions of human milk. Breastfeed Med 2, 205-208 (2007).

- 68 Barash, J.R., Hsia, J.K., & Arnon, S.S. Presence of soil-dwelling clostridia in commercial powdered infant formulas. J Pediatr 156, 402-408 (2010).
- 69 WHO. Safe preparation, storage and handling of powdered infant formula guidelines (2007).
- 70 Janjindamai, W. & Chotsampancharoen, T. Effect of fortification on the osmolality of human milk. J Med Assoc Thai 89, 1400-1403 (2006).
- 71 Fenton, T.R. & Belik, J. Routine handling of milk fed to preterm infants can significantly increase osmolality. J Pediatr Gastroenterol Nutr 35, 298-302 (2002).
- 72 Nilsson,K. Maintenance and monitoring of body temperature in infants and children. Paediatr Anaesth 1, 13-20 (1991).
- 73 Knobel,R. & Holditch-Davis,D. Thermoregulation and heat loss prevention after birth and during neonatal intensive-care unit stabilisation of extremely low-birthweight infants. J Obstet Gynecol Neonatal Nurs 36, 280-287 (2007).
- 74 Meier,P. Bottle- and breast-feeding: Effects on transcutaneous oxygen pressure and temperature in preterm infants. Nurs Res 37, 36-41 (1998).
- 75 Eckburg, J. J., Bell, E. F., Rios, G. R., & Wilmoth, P.K. Effects of formula temperature on postprandial thermogenesis and body temperature of premature infants. J Pediatr 111, 588-592 (1987).
- 76 Gonzales,I., Durvea,E.J., Vasquez,E., & Geraghty,N. Effect of enteral feeding temperature on feeding tolerance in preterm infants. Neonatal Netw 14, 39-43 (1995).
- 77 Büyükyavuz,B.I., Adiloglu,A.K., Onal,S., Cubukcu,S.E., & Cetin,H. Finding the sources of septicemia at a neonatal intensive care unit: Newborns and infants can be contaminated while being fed. Jap J Infect Dis 59, 213-215 (2006).
- 78 The Regulation and Quality Improvement Authority. Independent review of incidents of Pseudomonas aeruginosa infection in neonatal units in Northern Ireland - Final report (2012).
- 79 Molina-Cabrillana, J. et al. Outbreak of Pseudomonas aeruginosa infections in a neonatal care unit associated with feeding bottles heaters. Am J Infect Control 41, e7-e9 (2013).

- 80 Handa,D. et al. Do thawing and warming affect the integrity of human milk? J Perinatol 34, 863-866 (2014).
- 81 Lawlor-Klean, P., Lefaiver, C.A., & Wiesbrock, J. Nurses' perception of milk temperature at delivery compared to actual practice in the neonatal intensive care unit. Adv Neonatal Care 13, E1-E10 (2013).



www.medela.com



Medela AG Lättichstrasse 4b 6341 Baar, Switzerland www.medela.com

#### International Sales

Medela AG Lättichstrasse 4b 6341 Baar Switzerland Phone +41 41 562 51 51 Fax +41 41 562 51 00 ism@medela.ch www.medela.com

#### Australia

Medela Pty Ltd, Medical Technology 3 Arco Lane, Heatherton Vic 3202 Australia Phone +61 3 9552 8600 +61 3 9552 8699 contact@medela.com.au

www.medela.com.au

#### Canada

Medela Canada Inc. 4160 Sladeview Crescent Unit # 8 Mississauga, Ontario Canada, L5L 0A1 Phone +1 905 608 7272 Fax +1 905 608 8720 info@medela.ca www.medela.ca

United Kingdom Medela UK Ltd. Huntsman Drive Northbank Industrial Park Irlam, Manchester M44 5EG UK

Phone +44 161 776 0400 Fax +44 161 776 0444 info@medela.co.uk www.medela.co.uk