

TECHNICAL BULLETIN

Date: March 2018

Topic: Freezer Storage of Prolacta® Human Milk-based Neonatal Nutritional Products

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Making the commitment to an exclusive human milk diet (EHMD) means a hospital is taking a vital step to protect the health and well-being of the most fragile patients in the neonatal intensive care unit (NICU). This commitment involves training staff and preparing the facility for proper handling, storage, and usage of Prolacta human milk-based neonatal nutritional products. In addition to having a prepared facility and trained staff, an essential component for success is the use of a commercial freezer designed for biomedical applications.

While no specific brand of commercial-grade freezer is required, a biomedical-grade freezer is recommended. Here are features that hospitals should consider when selecting a freezer unit:

Capacity: Choose a freezer that has enough capacity to store your Prolacta products but is not greatly oversized. A freezer that is mostly empty is susceptible to greater temperature fluctuations. Conversely, a freezer that is packed full with product may experience less air circulation, which may lead to cold and hot spots that could affect stored items.

Temperature Requirement: The product must be stored continuously at $\leq -20^{\circ}\text{C}$. It is advised that the freezer be able to maintain a temperature at $\leq -25^{\circ}\text{C}$ to address the temperature fluctuation due to the opening and closing of the door. To ensure that the freezer remains at -25°C and does not rise above -20°C , a set point of -28°C is advisable.¹

Temperature Monitoring: A calibrated temperature readout on the outside of the freezer that provides an accurate display of the temperature inside the unit will help with monitoring to make sure the unit is performing as expected. A freezer unit that is equipped with a data logger that assesses temperature at set intervals and allows staff to view temperature performance is beneficial and required in some states.

Temperature Alerts: A freezer should have an alarm that alerts staff if the temperature goes out of its required range or there is a loss of power. Optimally, the alarm should link to a centralized alarm system or security system for timely notification.¹ Furthermore, an open-door alarm provides an extra measure of safety that alerts staff if a door is accidentally left open, usually for 1 or 2 minutes, before the interior temperature changes enough to sound the alarm.

Shelving: The best systems are ones that have wire shelving or are perforated with ventilation holes. Solid shelving surfaces can obstruct cool-air circulation and should be avoided. Some freezers are built with interior drawers, which are useful because they help shield freezer contents from ambient temperatures when the door is open.

Placement: Positioning a freezer so that it is tilted slightly backward may help the doors close automatically.¹

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Properly stored, Prolacta's human milk-based neonatal nutritional products will remain stable for use throughout their shelf life. In addition to keeping products in an appropriate commercial freezer, steps can be taken to ensure that products remain optimum for usage and free of ice crystal formation² that can occasionally happen if there is repeated fluctuation in the freezer's temperature:

Reduce repeated opening and closing of the freezer door, especially during power outages. Every time the door is opened, items inside are exposed to ambient temperature. Over time, this can impact the items stored in the freezer.

Keep bottles tightly packed, far away from the door, and as close to the cooling source as possible.

Keep bottles upright (cap end up) and avoid storing bottles on their side or upside down.

Keep shelves evenly spaced for consistent cold-air flow and less head space for ambient temperature contact.

Keep freezer in good working order by routinely inspecting door gaskets, cleaning out the interior frost build-up, and removing dust build-up around the freezer coils in the back. Door seals are often overlooked but should not be forgotten, as they are important for keeping ambient air out and cooled air in.

Besides taking measures to ensure the highest quality and safety in human milk product development and manufacturing, Prolacta seeks to facilitate best practices in using human milk by providing clinicians with informational resources such as this technical bulletin.

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References

¹ Lessen, R., Sapsford A. Expressed Human Milk. In: *Infant Feedings: Guidelines for Preparation of Human Milk and Formula in Health Care Facilities*. 2nd ed. American Dietetic Association, Chicago; 2011.

² Data on file. (Presence of ice particles once the product was thawed and properly mixed demonstrated that the contents of the bottles did not change in terms of bioburden, protein, or fat content when compared to product-release testing results.)

