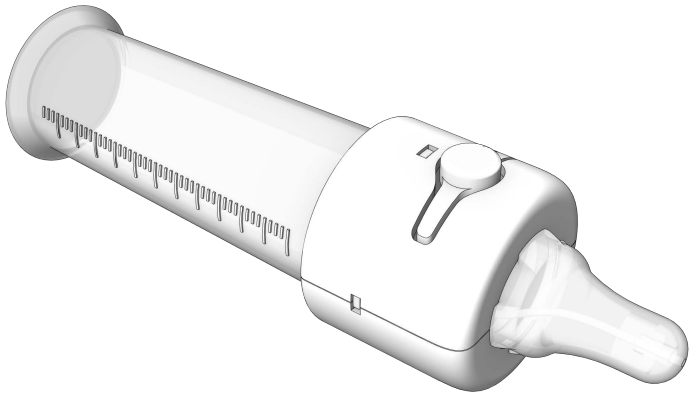




User Guide v2.0



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Preemie-Pacer™

User Guide

v2.0

An improved method for preterm
infant feeding.

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1.0 INTRODUCTION

What is the Preemie-Pacer?

The Preemie-Pacer bottle is a unique feeding device that enables the caregiver to start and stop the flow of milk during the feeding. The Preemie-Pacer bottle can improve the delicate process of early oral feeding in infants born preterm and with other complex medical conditions. Improved early feeding can enable maximal nutritional intake without physiological consequences, which could result in shorter periods to full oral feeds, shorter hospitalization, fewer feeding related problems, and increased parenting confidence.

The Problem

Healthy full-term infants usually have mature feeding skills and are able to regulate or “pace” their oral feeding without support. During oral feeding, there is sucking, swallowing, and breathing which happens in a quick and coordinated pattern without any external support of the process needed. However, pacing of the flow of milk is essential for many high-risk infants. For preterm infants, pacing is important due to their immature central nervous system, which does not signal them to pause for breathing while feeding. This results in inadequate air exchange with physiological compromise, specifically oxygen desaturation and dangerous drops in heart rate. Such events deplete energy stores needed to adequately grow and can be life threatening.

Methods of Pacing

To address issues of suck-swallow-breathe discoordination, caregivers often pace the flow of milk by either tilting the bottle to remove milk from the nipple or removing the nipple from the infant’s mouth completely. However, these methods disrupt the feeding process for the infant, requiring increased energy to re-gain a sucking pattern and with some infants unable to re-organize during the feeding at all.

An Innovative Approach with the Preemie-Pacer

The Preemie-Pacer allows the feeder to stop the flow of milk without tilting or removing the bottle nipple from the infant’s mouth, allowing non-nutritive sucking to continue while the infant regains their physiological and energy balance to continue the feeding. Milk flow is enabled by releasing the finger on the flow button and is stopped by pushing the flow button (note that only a small amount of pressure on the flow button stops the flow

of milk; no significant force should be applied). This allows the infant to reduce energy expenditure and physiological stress, which could provide them the opportunity to optimize consumption of the full feeding amount.

Other Populations

The Premie-Pacer bottle can also be used with infants with swallowing challenges, such as those who have had cerebral injury. The caregiver is able to carefully control the flow of milk (dictating when it flows and when the flow of milk is stopped) and give the infant ample opportunity to clear previous volume before allowing more milk to be introduced. The Premie-Pacer allows the infant to achieve organization with very small volume without having to manage full volume that comes from a regular bottle nipple. It also can be used to administer milk drops, but with appropriate oral motor/sucking patterns which can increase therapeutic response.

The Premie-Pacer can be used with infants who have gastroesophageal reflux, with the ability to consume volume at a significantly slower pace and with more time for full clearance following each bolus. Finally, parents can simulate breastfeeding by enabling quick succession of sucks for a few minutes at the beginning of the feeding before allowing milk to flow, which can aid in easier transition between breast and bottle.

Premie-Pacer Bottle Specifications

The Premie-Pacer bottle has a standard slow flow rate of 0.1ml/second/ 6ml per minute (range of 5-7 ml) when continuously flowing from sucking pressure of 28mmHg to 38mmHg, based on laboratory testing. The Premie-Pacer nipple and bottle cap attachment weighs approximately 1 ounce and has a straight nipple. This weight does not include the bottle and milk.

The caregiver who is feeding the infant can control whether the milk is stopped (which would result in an experience similar to the infant sucking on a pacifier with no ability for milk to be extracted) or is flowing (functioning like a regular bottle) by pushing and releasing the button on the side of the Premie-Pacer bottle (conveniently located where hand placement typically occurs using a bottle). The Premie-Pacer bottle allows the feeder to externally pace the infant, but instead of removing the nipple from the infant's mouth, the feeder can release and push the button to stop and start the flow of milk. The Premie-Pacer bottle enables the infant to orally feed from a standard shape nipple. Each nipple cap attachment arrives sanitized and ready for use. This is combined with a bottle (gradufeeder/ volufeeder) which are typically available in large quantities within a NICU.

All parts are disposable and should be discarded after each use. The bottle can be put together and ready to feed the infant in less than 30 seconds.

How to Provide Paced Feedings for a Preterm or Immature Infant

First, the infant is encouraged to root and latch onto the bottle nipple and initiate sucking. Pacing the flow of milk can happen in different sequences, based on a number of sucks, or can be used based only on when the infant demonstrates stress signs.

For predetermined patterned pacing— It can be assumed that each suck lasts 1 second, with an associated breath also being one second. There is literature to support allowing 3 sucks (3 seconds) and then 3 seconds of a pause with no milk exchange to enable breathing. Therefore, the feeder can count three sucks while the bottle has milk flow (approximately 3 seconds) followed by lightly pressing the button to shut off the flow of milk for 3 seconds. Some infants will be able to tolerate longer sequences (up to 10 sucks without a break), while some babies may need to be paced after each suck with the need for longer pauses.

For pacing based on infant signs— To allow the infant to drive the feeding process, the start and stop of milk can be controlled based on the infant's stress signs. The flow of milk can be stopped (by placing the finger on the flow button) **when** relevant stress signs are observed such as wide-eyed stare, eye tearing, and/or increased neuromuscular tone. Other indicators to pace or stop the flow of milk include: repeated suck-swallow sequences without pausing to breathe and showing signs of risk for physiological compromise. In these instances, the feeder pushes the button on the side of the Premie-Pacer bottle to stop the flow of milk. The flow should not be restarted, by releasing the flow button, until the indicator for stopping the flow has resolved.

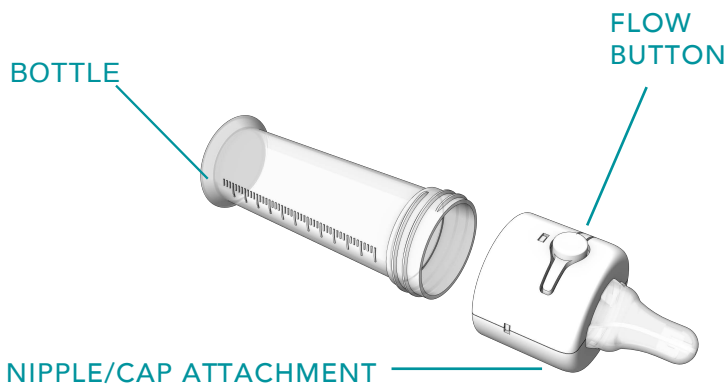
Future Development

There is another, more complex Premie Pacer device that stops and starts the flow of milk based on caregiver timing or preprogrammed algorithms, which are currently under development using clinical data from high risk infant feeding. This will allow the bottle to be programmed to self pause milk flow in a specific pattern, based on specific infant factors. This device is also a data collection device, capturing the timing that caregivers use for external pacing.

2.0 OVERVIEW

IMPORTANT: Read, understand and follow all instructions, warnings, and precautions in this manual.

FIG 1.1



2.1 Components

The Premie-Pacer system consists of the **Nipple/Cap Attachment** and **Bottle**.

The **Nipple/Cap Attachment** contains a nipple, medical grade tubing and cap. The Nipple/Cap Attachment accepts a standard 40mm neck screw-on **Bottle** that can hold different volumes of breast milk or formula. The Cartridge is for one-time use. For best performance, 60cc **Bottles** work best.

The **FLOW BUTTON on the Nipple/Cap Attachment** is capable of stopping and resuming the flow of milk at intervals dictated by the User.

3.0 PRECAUTIONS AND WARNINGS

3.1 Trained Use

This Device is ONLY to be used by trained and authorized users familiar with neonatal feeding of premature and high-risk infants. Do not attempt to use this Device if you have not been authorized to do so.

4.0 INTENDED USE

The Premie-Pacer is intended for oral feeding of premature and other high-risk infants during research studies and trials authorized by Premie-Pacer, LLC. Users of the Premie-Pacer shall be limited to trained practitioners familiar with feeding of premature and other high-risk infants.

5.0 USER OPERATION

5.1 Preparation

5.1.1 Pour the desired volume of milk into the **Bottle**.

5.1.2 Open the package and inspect the **Nipple/Cap Attachment** closely. Ensure that there is no residue and that everything appears as pictured.

5.1.3 Screw the **Nipple/Cap Attachment** onto the **Bottle**. Do not overtighten, but screw until snug.

5. 1.4 The Preemie Pacer is then ready to use.

Hold the infant and feed as you would with a normal bottle.

5.1.5. Milk will be available to the infant when the flow is "ON", when the flow button is not being pressed.

5.1.6. Milk will not be available to the infant when the flow is "OFF", when the flow button is being pressed. Only light pressure on the flow button is needed to close off the flow of milk.

5.1.7. Discard the Preemie-Pacer **Nipple Cap Attachment** and **Bottle** after single use.

6.0 CARE AND MAINTENANCE

6.1 Cleaning

6.1.1 The Preemie Pacer is designed to be disposable and for single use.

6.1.2 Dispose of the Preemie Pacer components after each use.

NOTES

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