



User Guide v1.0



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Preemie-Pacer™

User Guide

v1.0

A patented and 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 and patented 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 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 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

placing the finger on a flow button and is stopped by releasing the finger from the flow button. This allows the infant to reduce energy expenditure and physiological stress, which could provide them the opportunity to successfully consume 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 weighs approximately 3 ounces and has an angled nipple. The angled design optimizes infant position during oral feeding to ensure the neck is in neutral alignment, as well as aids the caregiver in the feeding process.

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. In addition to pacing the stop and flow of milk, the Premie-Pacer bottle is a data collection device. It collects information on the timing of stops and flow of milk throughout a feeding. This data can be downloaded for analysis.

The Premie-Pacer bottle enables the infant to orally feed from a standard shape nipple. There are disposable parts that contact the baby's mouth and milk. There are also permanent pieces that can be wiped down and used across infants or feedings. The bottle can be put together and ready to feed the infant in less than 30 seconds. The bottle has an internal rechargeable battery that has a life of approximately 2 hours of feeding time. It is recharged using a USB cord plugged into a standard outlet.

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 lifting the finger from the flow 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 enabled (by placing the finger on the flow button) until relevant stress signs are observed such as wide-eyed stare, eye tearing, and/or increased neuromuscular tone (at which time the finger is released from the flow button). 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 releases the button on the side of the Premie-Pacer bottle to stop the flow of milk. The flow should not be re-started, by putting the finger back on the button, until the indicator for stopping the flow has resolved.

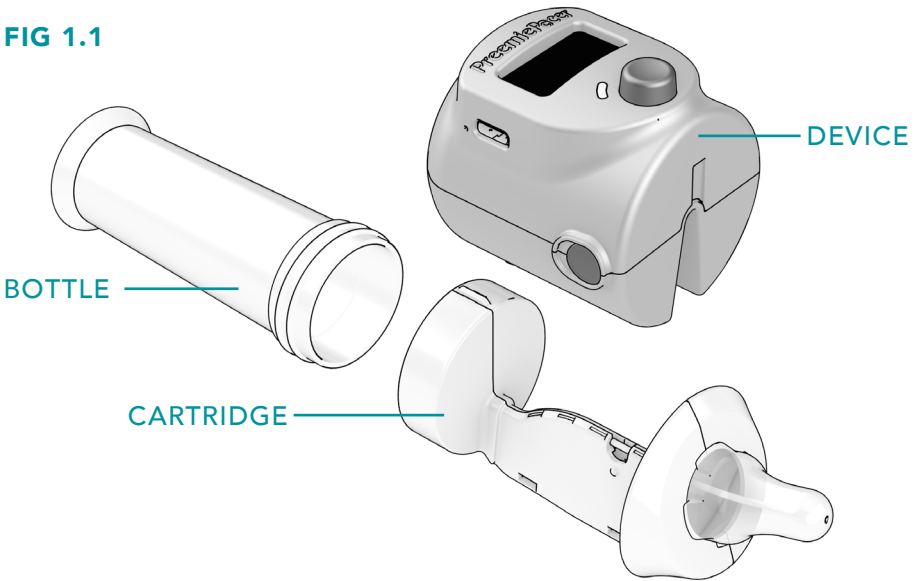
Future Development

Algorithms are currently being developed using clinical data from high risk infant feeding. This will allow for automated pacing, in which the bottle can be programmed to self pause milk flow in a specific pattern, based on specific infant factors.

2.0 OVERVIEW

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

FIG 1.1



2.1 Components

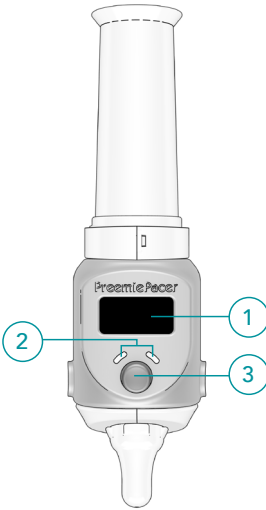
The Premie-Pacer system consists of the **Device**, **Cartridge** and **Bottle**.

The **Device** includes the electronics, battery, user interface and data storage to enable the control of milk flow during infant feedings and to capture information about those feeding sessions. The Device does not contact milk or the infant's mouth and may be wiped down and reused.

The **Cartridge** contains a nipple, medical grade tubing and tubing compartment. The Cartridge 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.

The Device is capable of stopping and resuming the flow of milk at intervals dictated by the User.

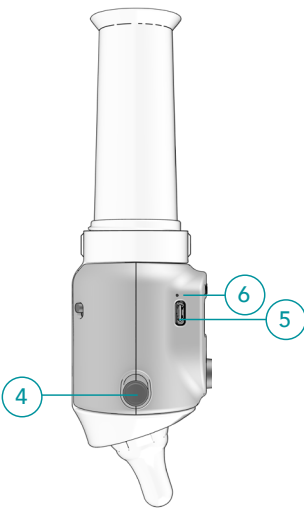
FIG 2.2



2.2 Front View

- 1 - Screen
- 2 - Flow Indicator Lights
- 3 - Input Knob

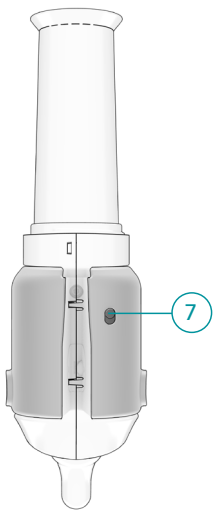
FIG 2.3



2.3 Side View

- 4 - Flow Buttons
- 5 - USB-C Port
- 6 - Charge Indicator Light

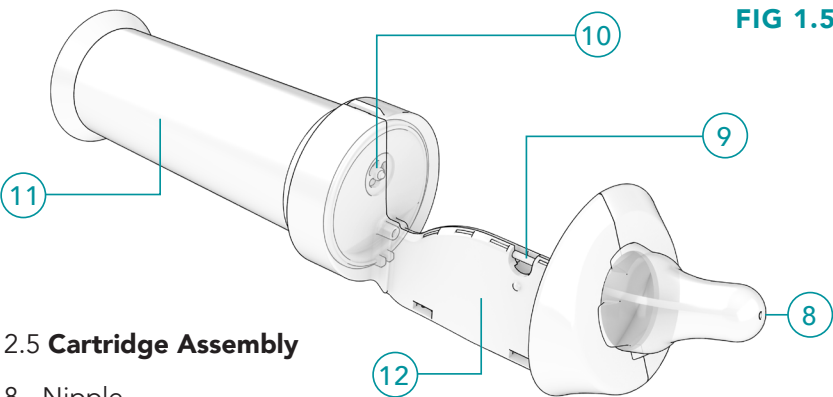
FIG 2.4



2.4 Back View

- 7 - Power Switch

FIG 1.5



2.5 Cartridge Assembly

- 8 - Nipple
- 9 - Tubing Pinch Area
- 10 - Bottle Cap/Vent
- 11 - Bottle
- 12 - Tubing Compartment

3.0 PRECAUTIONS AND WARNINGS

3.1 Battery

The battery contained in the Device is a Lithium Ion type. It should not be replaced. It is rechargeable via a USB-C cable using a PC USB port or wall charger. Remaining battery life is indicated on the screen (see 4.0 User Operation).

3.2 Charging

The Device is charged via the USB-C port on the side of the housing. Charging is active when the blue LED is illuminated.

NOTE: In order to charge, the Power Switch must be in the ON position.

3.3 Power Switch

The Power Switch should be in the ON position for use and for charging. For storage or transport, slide the switch to the OFF position. Keep the Power Switch in the OFF position when the Device is not in use.

3.4 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 Device 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 Device 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 Have milk or formula ready in the bottle before beginning this process.

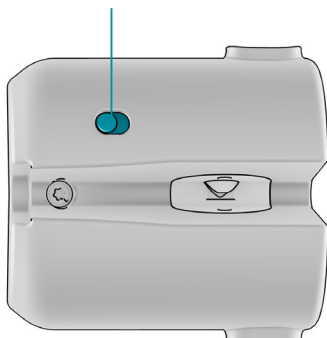
5.1.2 Slide the Power Switch to the ON position.

CAUTION: Follow the on-screen menu to set up a feeding. Do not proceed through the setup before loading the Cartridge. Doing so could cause damage to the Cartridge leading to leakage and/or inadequate feeding and data collection.

5.1.3 Open the package and inspect the Cartridge closely. Ensure that the tubing is secure in the end of the nipple, and that a small section of tubing is visible and centered in the tubing pinch area.

FIG 5.1.2

OFF Position



OFF



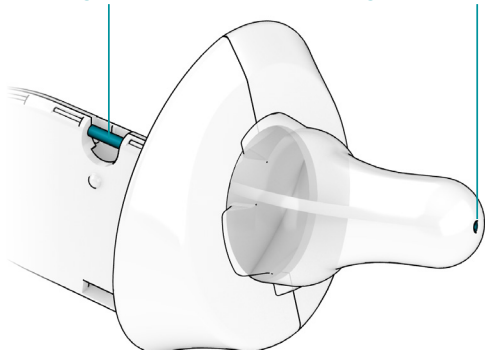
ON



FIG 5.1.3

Tubing Pinch Area

Tubing Secured



5.2 Assembly

5.2.1 Carefully align the Cartridge and Device as shown and push the Cartridge in until it snaps into place.

FIG 5.2.1

Tubing Pinch Area Faces Down

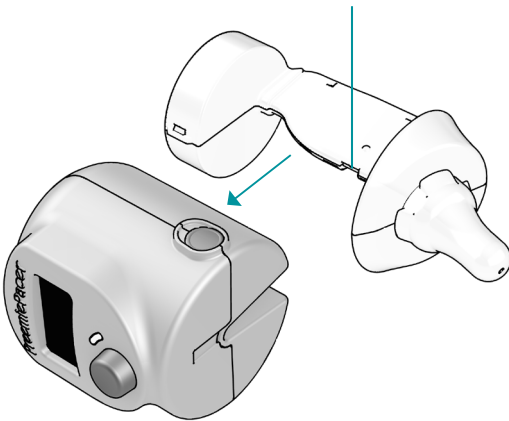
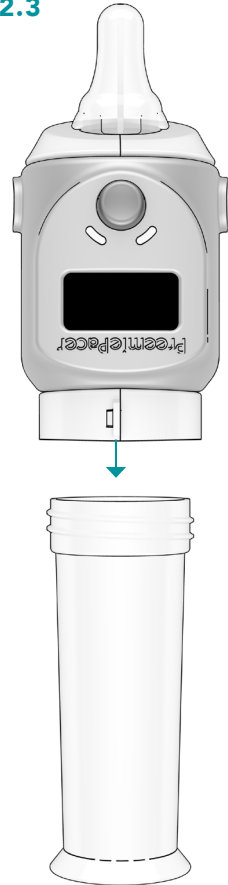


FIG 5.2.3



5.2.2 If the Cartridge does not snap in smoothly, or appears to be jammed, remove it and ensure that it is aligned correctly (it will not snap in if reversed in position). If the problem persists, inspect the tubing in the pinch area. If damage to the tubing can be seen, dispose of the Cartridge and start the process again.

5.2.3 Proceed through the feeding setup as described in section 5.3. When prompted, load the milk bottle onto the cartridge.

NOTE: Do not load the bottle onto the device before being prompted to do so.

5.3 Menu Navigation and Use

5.3.1 General instructions for navigation and input:

- A. Slide the Power Switch to the ON position. Power will be indicated by the screen illuminating.
- B. Use the Input Knob to highlight menu items. Highlighted items have a box around them with letters reversed out.
- C. Push in on the Input Knob to make a selection or activate an input area.
- D. Active input values will blink slowly.
- E. Turn the Input Knob to change blinking values; push in on the Input Knob to enter the new setting.
- F. Follow on-screen prompts for when to load cartridge and milk.

5.3.2 Main Menu

A. Manual Feeding

1. Select Manual Feeding and follow the screen prompts to enter the following information: (highlight and select BACK at any point to return to previous screen)

- Infant ID
- Infant PMA
- Starting Volume

2. START. Press the Input Knob to begin a feeding session (see 5.4 Operation and Feeding)

B. Automated Feeding (see 5.4 Operation and Feeding)

1. This mode is not available at this time.
2. In the future, it will enable the User to select a setting that will play an algorithm for starting and stopping the flow of milk based on the infant's characteristics.

5.3 Menu Navigation and Use *(continued)*

C. Settings

1. Time and Date

- Use this menu to set the time and date so feeding data is recorded accurately.

2. Flow Button Operation

- Set the Flow Button operation to your preference:
 - 1- Right Handed: Only the Flow Button on the left (when viewing the Device from the front) is active.
 - 2- Left handed: Only the Flow Button on the right (when viewing the Device from the front) is active.
 - 3- Both buttons: both Flow Buttons will be active.

3. About

- Displays version information

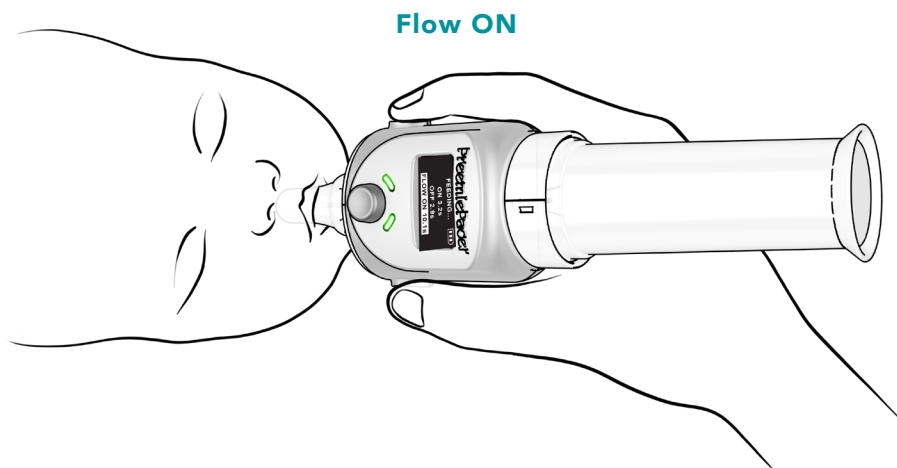
5.3.3 Data Retrieval

- A. Ensure the Power Switch is in the OFF position.
- B. Plug the Device into a PC using a USB-C cable.
- C. The Device should appear on the PC's file browser.
- D. Copy the feeding data files to the PC.
- E. You may delete the files from the Device via the PC or leave them as a backup copy.

5.4 Operation and Feeding

5.4.1 When ready to begin feeding, hold the Device with the screen facing up and your hand placed below allowing your index or middle finger to reach the Flow Button that is most comfortable.

FIG 5.4.1



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

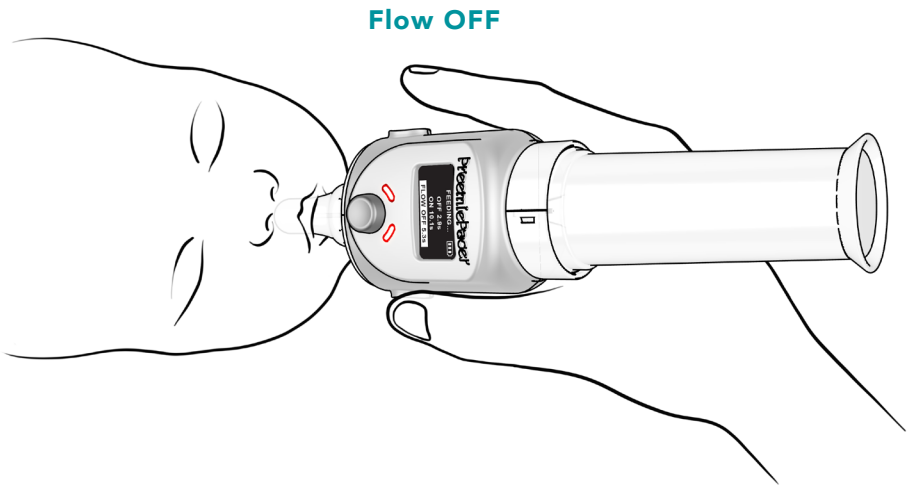
5.4.3 Milk will be available to the infant when the flow is “ON” as indicated by the green lights and the on screen text. Note that the Premie-Pacer Device does not pump or force milk when flow is ON, but the infant can drink freely.

To enable flow, place a finger over an active Flow Button (see 5.3.2 Flow Button Operation) and keep it there. The Flow Buttons are touch sensitive and do not require pressure to operate.

5.4 Operation and Feeding (continued)

5.4.4 Flow will be stopped by the internal valve in the tubing compartment when the finger is removed from the Flow Button. Flow is "OFF" as indicated by the red lights and the on-screen text. To stop flow, remove the finger from the Flow Button.

FIG 4.4.4



NOTE: The Flow Buttons are very sensitive and it may be necessary to move the finger 0.25 inches or more away from the Flow Button.

5.4.5 Pause a feeding session by pressing the Input Knob.

From the Pause screen, the session may be ended or resumed.

When ending a session, input the remaining milk volume.

6.0 CARE AND MAINTENANCE

6.1 Cleaning

6.1.1 Remove and dispose of Cartridges after feeding.

6.1.2 Dispose or clean the Bottle.

6.1.3 Wipe down the Device with disinfectant.

6.2 Charging

NOTE: To charge the battery, the Power Switch must be in the ON position.

6.2.1 Charge by plugging a USB-C cable into the Device, with the other end plugged into a suitable AC/DC adapter (phone charger) or a PC USB port.

6.2.2 When the battery is charging, the Charge Indicator Light will illuminate blue.

6.3 Storing

6.3.1 Remove the Cartridge and clean/disinfect the Device before storage.

6.3.2 Always store the Device with the Power Switch in the OFF position.

6.3.3 Devices should be returned to Premie-Pacer, LLC.

NOTES

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