



Enteral Feeding Pump Instructions For Use



Table of Contents

1 • General Information	4
1.1 Indications	4
1.2 Contraindications	4
1.3 Complications	4
1.4 Safety and warning	4
1.5 Device recycling	6
2 • Pump Overview	7
2.1 General description	7
2.2 Front panel	7
2.3 Initial pump set up	8
3 • Starting Up	12
3.1 Installation of the pump	12
3.2 Loading tubing	12
3.3 Installation of tubing on the pump	13
3.4 Switching on the pump	14
3.5 Tubing priming	15
4 • Using the Pump	16
4.1 Simplified mode programming	16
4.2 Pause mode in simplified mode	18
4.3 Locking the keypad	18
5 • Navigating in the Menu	19
5.1 Accessing the menu	19
5.2 Pump settings	20
5.3 Nutrition mode	20
5.3.1 Code access for nutrition mode	20
5.3.2 Lock rate and volume mode	22
5.3.3 Intermittent mode	23
5.3.4 Nutrition mode deactivation	26
5.4 Pump data	27

Table of Contents

6 • Resuming an Unfinished Nutrition	28
7 • Stopping the Pump	29
8 • Alarms and Troubleshooting Guide	30
9 • Batteries	35
9.1 Charge	35
9.2 Battery replacement	35
10 • Maintenance	36
10.1 Cleaning	36
10.2 Disinfection	37
10.3 Storage	37
10.4 Technical maintenance	37
11 • Warranty	38
12 • Technical Specifications and Symbols	39
2.1 Specifications	39
12.2 Performance accuracy	39
12.3 Other performances	40
12.4 Accessories.....	41
12.5 Medical equipment	42
12.6 Symbols	42
13 • Contact	43
14 • Electromagnetic Conformity Declaration	44
Appendix A • Accuracy Graphs	49

1 • General Information

1.1 Indications

The PUGGLE™ Enteral Feeding Pump and Feeding Set are intended to deliver nutritional formula through all routes of administration to the gastrointestinal system (nasogastric, nasojejunal, percutaneous endoscopic gastrostomy, jejunostomy) of a patient age infant and older who is physically unable to eat and swallow. Not for use with neonates.

The PUGGLE™ Enteral Feeding Pump and Feeding Sets are intended to be used in clinical or home care settings by users ranging from laypersons to physicians. They are intended to be used in both stationary and ambulatory conditions (ground transport only).

The PUGGLE™ Enteral Feeding Pump and Feeding Set shall be used together only. The PUGGLE™ Enteral Feeding Sets are able to be connected with all feeding tube sizes (pediatric and adult population) through coned or ENFit® Distal Connectors.

The PUGGLE™ Enteral Feeding Pump and Feeding Set are intended to be used with the whole range of commercially available prepacked or commercially prepared feeding solutions (Polymeric, Hydrolyzed, Elemental, Blenderized in standard and concentrated form intended to be used with infant, pediatric, and adult population).

1.2 Contraindications

- Do not use the PUGGLE™ Enteral Feeding Pump and Feeding Set for parenteral feeding. This device is not intended for intravenous use.
- Do not use the PUGGLE™ Enteral Feeding Pump and Feeding Set if enteral feeding is contraindicated. We recommend you contact your healthcare provider for further instructions.
- The PUGGLE™ Enteral Feeding Pump and Feeding Set should only be used for patients who can tolerate the flow rates and the accuracy levels delivered by the pump.
- The PUGGLE™ Enteral Feeding Pump and Feeding Set are not intended for neonatal patients.

1.3 Complications

Pump feeding may lead to digestive complications such as diarrhea, bloating, etc. Feed rate must be adapted to suit the patient and the patient's condition should be assessed regularly.

1.4 Safety and warning

Note to healthcare personnel who provide training to clinicians, care providers, and end users:

Be sure to include all of the below warnings when providing training to clinicians, care providers, and end users, especially in a home care environment. Clinicians, care providers, and end users should be instructed to contact Customer Service if there is a change in the performance of the pump. Additionally, clinicians, care providers, and end users should be instructed on proper cleaning procedures to avoid hazards such as electric shock. Clinicians, care providers, and end users should also be trained on inappropriate environments for use (e.g. bathtub) of the pump. For guidance on training, please contact Customer Service.

1. Read these instructions thoroughly before using the pump.
2. Use only dedicated PUGGLE™ Enteral Feeding Sets with PUGGLE™ Enteral Feeding Pump. The PUGGLE™ Enteral Feeding Pump is not compatible with other pump sets.
3. Use only the supplied AC adapter to charge your PUGGLE™ Enteral Feeding Pump (see section 12.4).
4. Do not use pump near flammable gases.
5. Do not install the pump in dusty places or places likely to be exposed to vibrations, shocks, heat ignition sources, etc.
6. Do not store pump in damp places.
7. Do not store pump in the refrigerator.
8. Do not disassemble the pump. Opening may affect function of device and voids the warranty.
9. Never use a damaged pump without first having it inspected by the manufacturer.
10. Always disconnect the AC adapter and turn off the pump before cleaning or servicing.
11. After cleaning, make sure the AC adapter is completely dry before plugging into an electrical outlet.
12. Proper operation of pump requires that the door is closed and latched. Make sure door is closed and latched when pump is running.
13. Patients with diabetic disorders are subject to enhanced surveillance.
14. Use ONLY commercially available prepacked or commercially prepared feeding solutions formulated for use with a feeding pump that is prescribed by a licensed healthcare provider, dietician, or nutritionist.
DO NOT USE HOMEMADE BLENDERIZED OR LIQUIDIZED FOODS, OR OTHER NON-PRESCRIBED, NON-COMMERCIALY AVAILABLE FEEDING SOLUTIONS.
15. The PUGGLE™ Enteral Feeding Pump is not intended to be used in MRI environments or in the presence of strong magnetic fields.
16. Use only tubing having a state of cleanliness compatible with medical use. The tubing and the feeding tube should be flushed after each feeding. Tubing should not be used for more than 24 hours.
17. Do not use the power adapter if it is damaged or if it comes in contact with any liquid.
18. Strangulation Hazard: Avoid leaving the power adapter cord, feeding set tubing, or other choking hazards where infants or young children can come in contact with them. If these objects become wrapped around a child's neck, strangulation and death can occur.
19. Choking Hazard: The pump and disposable feeding sets contain small parts which could become detached and pose a choking hazard. Some of these components could be inhaled or swallowed by a small child, toddler, or infant, which could result in suffocation and death.

Keep all small components out of reach of small children.

20. The power adapter cord, feeding set tubing, and pump accessories may cause a tripping hazard. Avoid leaving wires, cords, or tubing in a pathway where a person could trip and sustain an injury.

21. Avoid using accessories, detachable parts, and materials with the pump that are not recommended in this manual. Use only approved PUGGLE™ Accessories with the pump. Failure to use approved PUGGLE™ Accessories could result in damage to the pump or physical injury.
22. Always place the formula bag above the pump. Not doing so will have an adverse effect on the pump's accuracy.
23. The pump is intended to be programmed while stationary. Do not program pump during ambulation.
24. Patients with implanted devices, such as an implantable cardioverter defibrillator, pacemaker, or neurostimulator, need to refer to the implanted device's Instructions For Use to know if there is any restriction to use electrical equipment with a DC motor and other items that cause electromagnetic interference, such as the PUGGLE™ Enteral Feeding Pump.
25. For pediatric use, precisely follow the instructions for use in sections 3.2 and 12.2B to ensure accurate and correct flow. The feeding bag shall be placed at 6.0 inches above the pump. When administering formulas or milk containing thickeners, it is recommended to program the volume to administer whether than using the "Use entire bag" (see page 17).
26. Small foam bubbles may accumulate and may create a maximum volume of 1.5 mL without being detected by the pump, which corresponds to a maximum length of 35 cm. Patients who are extremely sensitive to receiving air in the stomach during enteral feeding should be provided with enhanced surveillance. "Use entire bag" mode must not be used with seriously ill patients, children, or patients extremely sensitive to air introduction in the stomach when enterally fed. It is recommended to use continuous mode with a specific volume set up for these users.
27. The pump is intended for ambulatory use during ground transport, such as when walking, or using carts, road vehicles, or trains. Do not use in water and air transport (ships and aircraft).

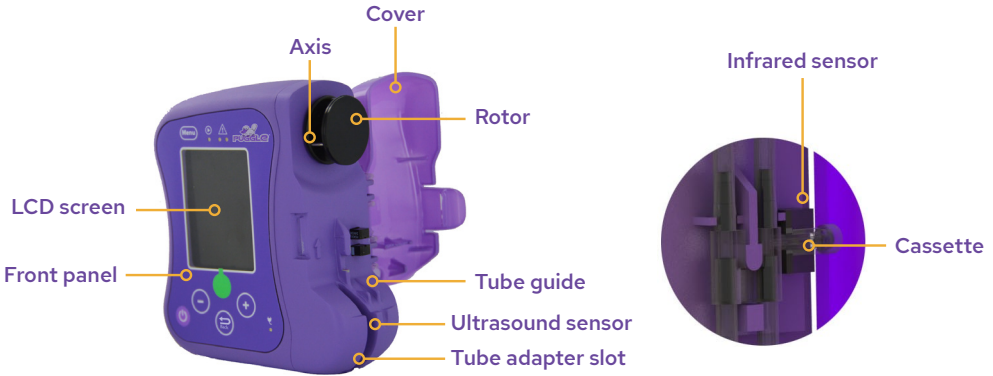
1.5 Device recycling

At the end of the product's life cycle, the pump should be discarded at an electrical/electronic waste recycling center.

Important: The PUGGLE™ Enteral Feeding Pump contains a battery that should be recycled according to appropriate regulations.

2 • Pump Overview

2.1 General description



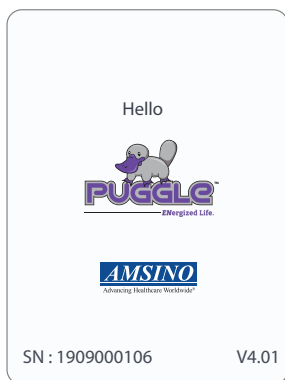
2.2 Front panel

- 4 LED indicator lights
- Large, color LCD display
- Buttons used to program or launch the feeding



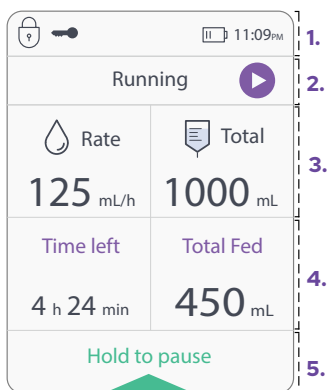
2.3 Initial pump set up

Press the On/Off Button to turn on the pump and initiate the device software.



The initial screen will display the pump serial number and software version.

Description of LCD screen icons and sections:



1. Notification header

🔒 «Lock rate and volume» mode is activated

🔌 The «Intermittent» mode is activated (not shown)

🔑 The keypad is locked (see section 4.3)

🔋 Indicates battery charge level

11:09 PM Clock

2. Activity information

The text «Running» and the flashing «Play» symbol on the screen, plus the solid green LED light on the case (not shown in this illustration) indicate that feeding is in progress.

3. Upper part of the screen

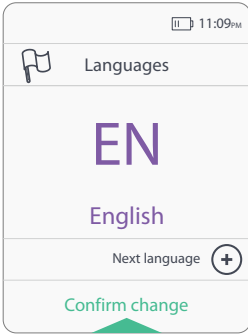
Displays the parameters programmed for the feeding (flow rate and volume to be administered).

4. Lower part of the screen

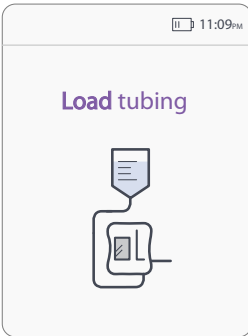
Displays time left and volume administered.

5. Action option

To pause the feeding, press and hold the multifunction button [●] until the green progress bar fills entirely (see section 4.2).

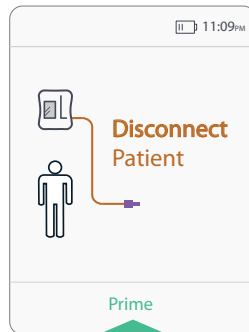
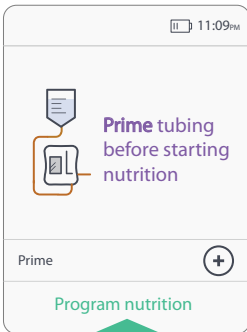


If used for the first time, the pump will prompt the language to select.



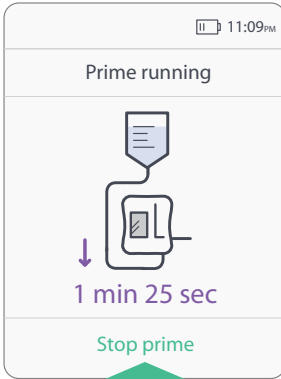
The pump will indicate if no tubing is installed.

Note: If the tubing is correctly installed and this message persists, replace tubing.



To prime the tubing, press ⊕ then press the multifunction button [●].

Note: Before priming the tubing, the screen will display an instruction to disconnect tubing from patient.



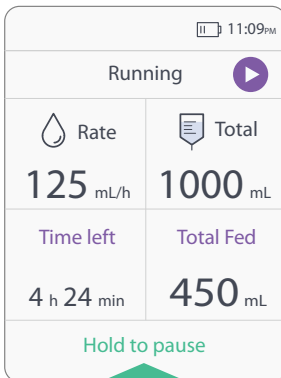
The screen will display that the tubing is being primed. The remaining priming time is displayed at the bottom of the screen. The prime may be stopped at any time by pressing the multifunction button [●].

Priming duration is approximately 1 minute 25 seconds. If tubing is not completely primed, repeat priming.

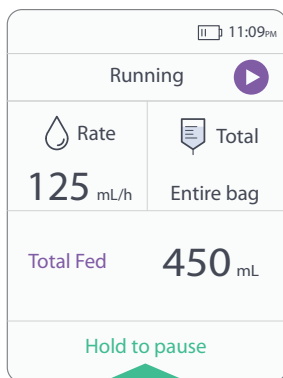
When pump is running, the following icons will be displayed:

Icons	Explanation
Rate	The flow rate: In mL/h, from 1 to 400 mL/h
Total	The volume programmed: Programmed in mL, from 1 to 9,999 mL
Total Fed	The volume administered: In mL, since the launch of the feeding
Time left	Time left: Time remaining before the end of feeding
	Flashing symbol: Indicates the pump is operating
	Battery symbol: Indicates the battery's charge level and/or charging status








If a volume was set, the screen will display:



If no volume was programmed and «Use entire bag» was selected, this display will appear:



Note: The screen backlighting can be changed at anytime during the feeding by pressing any button.

Button	Function	Notes
	PUMP SWITCH ON by pressing the button OFF by pressing and holding for 3 seconds	Home screen will be displayed. Shutdown screen will be displayed.
	MULTIFUNCTION BUTTON Enables selecting or launching a sequence: <ul style="list-style-type: none"> • Stop the prime • Validate flow rate and volume to be delivered • Start the feeding • Activate «Pause» mode • Mute the alarm for 2 minutes • Resume feeding from paused state • Select settings in the menu 	Button requires either a single press of the button or a press and hold to select a function.
	PROGRAMMING <ul style="list-style-type: none"> • Flow rate from 1 to 400 mL/h • Volume range from 1 to 9,999 mL • Navigate in the menu by scrolling through settings DURING NUTRITION: To use the lock keypad option, press and hold  and  for 3 seconds to lock or unlock the keypad.	Buttons are locked from the launch of the feeding. For more information about lock keypad option, see section 4.3.
	Go back to the previous screen, used on p 17	This button is locked during feeding and pause.
	ACCESS MENU <ul style="list-style-type: none"> • Adjust pump settings • Adjust «Nutrition» mode (access protected by a code) • Visualize pump data 	Access Menu is available outside of the «Nutrition» mode. Available in limited access (without «Nutrition» mode) when pump is paused.

3 • Starting Up

3.1 Installation of the pump

The PUGGLE™ Enteral Feeding Pump is delivered with an uncharged battery. Before use, charge by using the AC adapter provided with the pump (see section 9.1).

The PUGGLE™ Enteral Feeding Pump may be fixed onto a vertical pole using the pole clamp provided with the pump. It is also available as an accessory (see section 12.4).

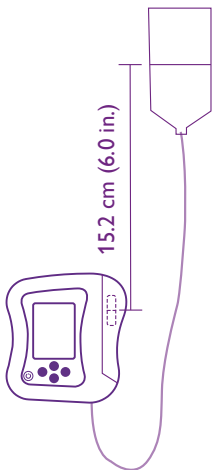
Important: In order for the PUGGLE™ Enteral Feeding Pump and its alarms to operate properly, use only PUGGLE™ Enteral Feeding Sets with this device.

Pump is not compatible with other pump sets.

3.2 Loading tubing

Connecting tubing to the feeding bag:

- Check the integrity of the packaging
- Open the bag and remove the tubing
- Connect the tubing to the feeding bag
- Hang the feeding bag on the vertical pole
- Install the tubing on the pump and prime the tubing (see section 3.3)



Place feeding bag above the pump.

For better accuracy, the initial fluid level shall be at 15.2 cm (6.0 inches) higher than the pump and the pump shall be placed higher than the injection site.

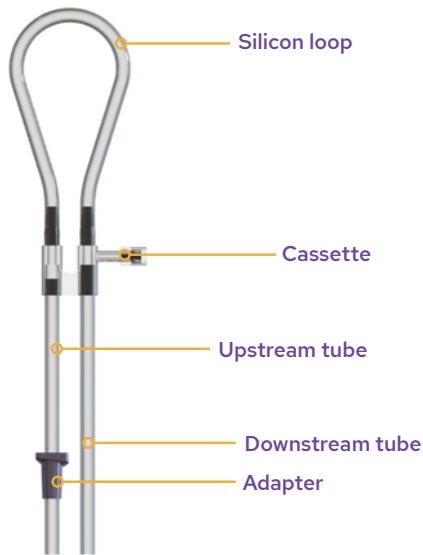
Do NOT use homemade or non-prescribed formula.

The setting range of operating head height is 0~50 cm (0~19.68 inches) which has been verified as worst case condition.

Note: Refer to section 12.4 for backpack loading instructions.



3.3 Installation of tubing on the pump

Tubing diagram:



<p>1. Open pump cover.</p>	
<p>2. Place the silicone loop around the rotor and make sure the cassette is in the right direction.</p>	
<p>3. Push the cassette in the middle of the pins with your thumb and make sure the cassette is positioned correctly between the two black pins. Guide both tubes down, in line with their respective slots.</p>	
<p>4. Close the pump cover, then place the adapter into the designated slot.</p>	
<p>Remove the protective cap from the distal connector (end of downstream tube that goes on the patient's feeding tube).</p>	
<p>Launch automatic priming (see section 3.5).</p>	
<p>Connect the tubing to the patient enteral feeding tube and program the pump.</p>	

3.4 Switching on the pump

Action	Effects	Screen Display
Press on/off button [] until a beep is heard.	Switching on the pump initiates a self-test of the: <ul style="list-style-type: none"> • 4 LED lights • Beeping sound • Screen 	

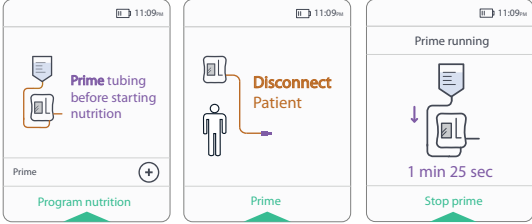
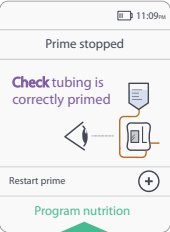
Note: The menu is accessible without installing tubing by pressing menu button []. If the tubing is not installed, the message «Load tubing» appears (see section 3.3).

You will only be able to program the feeding when the tubing has been installed and primed.

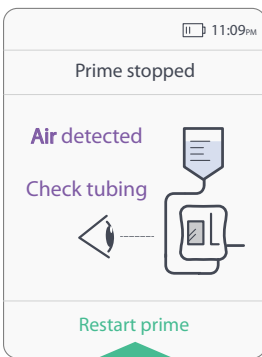
The pump comes with the following default setting:

Settings	Default Settings
«Nutrition» mode	Normal mode
Screen brightness	High
Language	English
Flow rate	- - - mL/h
Programmed volume	Volume option choice

3.5 Tubing priming

Action	Effects	Screen Displays
<p>2 steps to launch priming:</p> <ul style="list-style-type: none"> • Press [+] : Prime message appears. • Press multifunction button [●]: Launch prime. 	<p>Automatically primes pump tubing</p> <p>Duration: Approximately 1 minute 25 seconds.</p> <p>Automatic priming may be stopped before completion by pressing multifunction button [●].</p>	
<p>After the 1 min. 25 sec. priming is completed or after pressing multifunction button [●].</p>	<p>Priming is completed. Verify the tubing is fully primed.</p>	
<p>Press multifunction button [●].</p>	<p>Program the feeding.</p>	<p>See sections 4 and 6.</p>

During priming, the pump checks whether the tubing is filling properly. If priming does not run smoothly, the following message is displayed:



Air in tubing was detected. Check tubing to find the source of the problem:

- Verify that the tubing connection is secured with the bag
- Verify that the bag is not empty

After solving the problem, press multifunction button **[●]** to prime tubing again. If the priming message error persists and no air is in the line, please contact customer service.

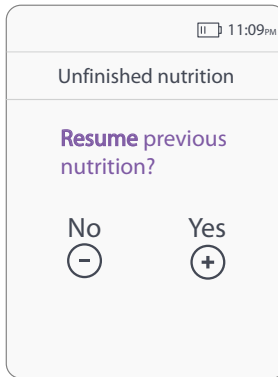
Important: Prime tubing before starting feeding. Patient should not be connected to enteral pump tubing while priming the tubing.

4 • Using the Pump

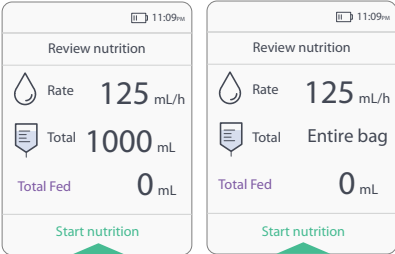
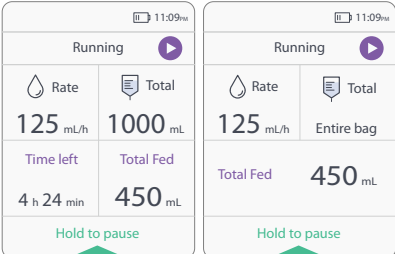
4.1 «Simplified» mode programming

When the priming phase is completed, follow the «Simplified» mode programming instructions below to program the pump.

Note: The following screen may be displayed after the priming phase. For more information, refer to section 6.

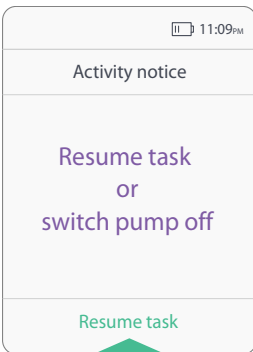


Action	Effects	Screen Displays
Press \oplus or \ominus then the multifunction button \bullet	Set the flow rate from 1 to 400 mL/h.	
Press \oplus or \ominus then the multifunction button \bullet	Choose your volume option: Press \ominus to use entire bag* Press \oplus to set the volume to be delivered. This value must be from 1 to 9,999 mL.	

Action	Effects	Screen Displays
Press multifunction button [●]	Overview of the feeding parameters (with or without a programmed volume).	
Press multifunction button [●]	Start the feeding (with or without a programmed volume).	

Important: Before launching the feeding, it is important to make sure the feeding parameters registered are verified.

*Use entire bag: If the user selects the multifunction button [●], the pump will be programmed to operate without setting a specific volume. The pump will operate until the feeding bag is empty.



Activity notice: No action during the last 2 minutes.

During the pump configuration phase, any programming interruption of more than 2 minutes will trigger an alarm. The pump will beep and display a message indicating the operation to be carried out. A beep confirms that the action has been taken after pressing the multifunction button [●] and returns to the previous screen.

4.2 «Pause» mode in «Simplified» mode

It is possible to pause the feeding at any time for a maximum period of 15 minutes:

Action	Effects	Screen Displays
Press and hold the multifunction button [●] for 3 seconds while the progress bar fills up (green bar at the bottom of the screen)	Pump paused Feeding stopped: Remains PAUSED as long as no other buttons are pressed on the keypad (duration of the pause: 15 min.)	

Important: When the pump is PAUSED, both the Infrared and Ultrasound sensors remain active. If the tubing is pulled out, the pump will detect this anomaly by signaling a «Downstream set error» or an «Upstream set error» alarm (see section 8).

Note: To pause the pump, make sure the keypad is not locked (key icon [🔒] is displayed in the header). In this case, refer to section 4.3 to unlock the keyboard and then pause the pump.

When the «Pause» mode is activated in «Simplified» mode, both the flow rate [💧] and the volume [📄] programs can be modified.

Press the ⊕ button to access the flow rate screen.

The action will always reflect the data displayed at the time of the operation.

Important: BEFORE launching the feeding, make sure the feeding parameters programmed are verified.

4.3 Locking the keypad

During the feeding, it is possible to lock the keypad. This feature allows deactivation of the keypad buttons. When the keypad is locked, the pump cannot be paused or switched off. To lock the keypad press ⊕ and ⊖ buttons together for 3 seconds. Do the same action to unlock it.

The key icon [🔒] appears in notification header when the keypad is locked.

Special case: When the alarm is triggered, the keypad automatically unlocks.

5 • Navigating in the Menu

5.1 Accessing the menu

The menu is not accessible during feeding. Navigation is accessible through the menu button [Menu].

The menu has three options:

- Pump settings
- «Nutrition» mode
- Pump data

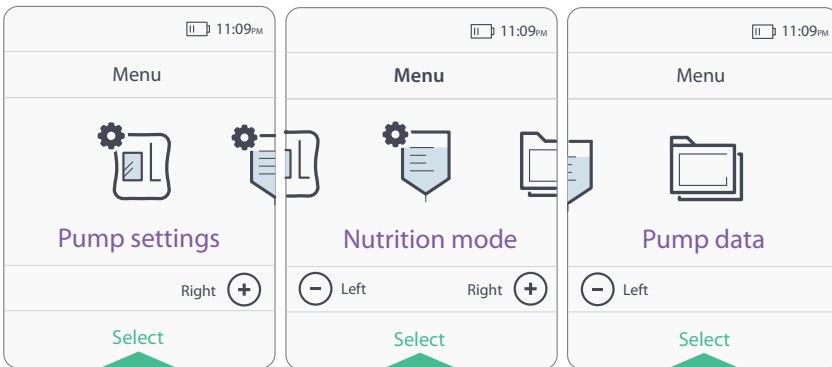
Special case: «Nutrition» mode

This mode is protected by a passcode. The access is limited and not available during feeding or «Pause» mode.

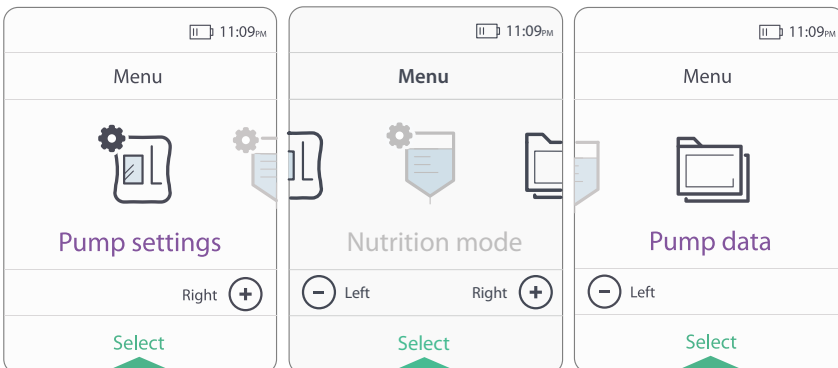
Scroll through the menu by pressing ⊕ or ⊖.

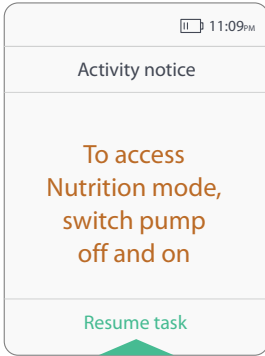
Pressing the back button [Back] or the menu button [Menu] to exit the menu will bring the user to the prior screen.

Menu options during programming:



Menu options during feeding or «Pause» mode:

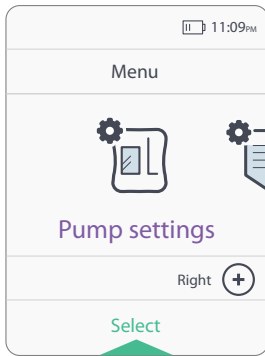




Access to «Nutrition» mode is not possible when the pump is running or in «Pause» mode. If the user tries to access this mode while the pump is running or in «Pause» mode, this screen will be displayed.

To access the «Nutrition» mode, switch pump off and back on. Refer to section 5.3 to program a «Nutrition» mode.

5.2 Pump settings



Press the menu button [Menu] to access the pump menu, then press the multifunction button [●] to access pump settings.

It is possible to set:

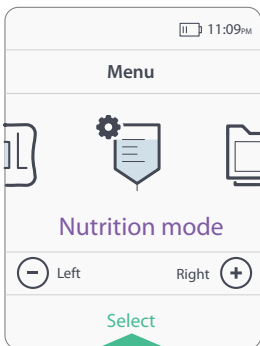
- Screen brightness
- Date and time
- Languages

To navigate between the categories, press ⊕ or ⊖.

Once the category has been selected, press the multifunction button [●] to select the parameter you want to set. Then press the menu button [Menu] to exit.

5.3 «Nutrition» mode

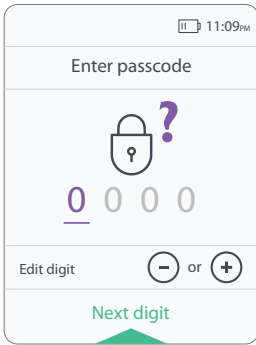
5.3.1 Code access for «Nutrition» mode



Press the menu button [Menu] to access the pump menu.

Press ⊕ or ⊖ to scroll through the configuration options then press the multifunction button [●] to select the «Nutrition» mode.

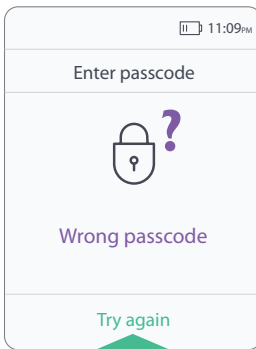
It is possible to program two specific modes: «Lock rate and volume» mode and «Intermittent» mode. Only one mode can be activated at a time.



Navigation through the «Nutrition» mode is authorized by entering a 4-digit passcode.

The default code is «1234». This code may be changed by using the software.

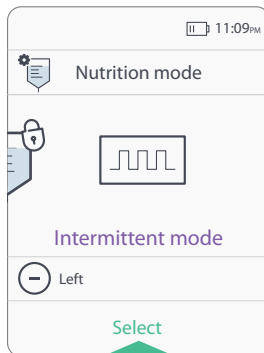
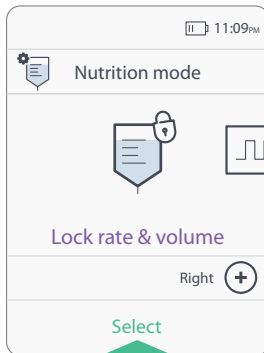
Press \oplus or \ominus to scroll through the numbers, then press the multifunction button \bullet to move on to the next digit. Repeat this operation until code is selected.



This screen is displayed when the wrong passcode is entered.

Use the following buttons to navigate:

- Multifunction button \bullet , enter passcode again.
- Use the back button \leftarrow to go back to the previous screen.



Press \oplus or \ominus to select the «Nutrition» mode you want to use.

Press the multifunction button \bullet to enter the passcode again.

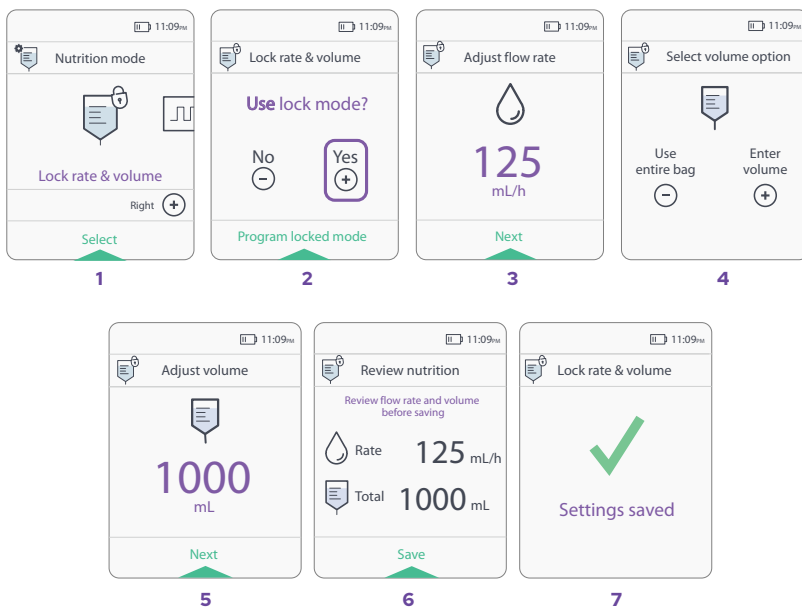
5.3.2 «Lock rate and volume» mode

This mode locks in the selected flow rate and volume settings. When switching on the pump, the feeding is started with the flow rate and volume that was programmed in this mode.

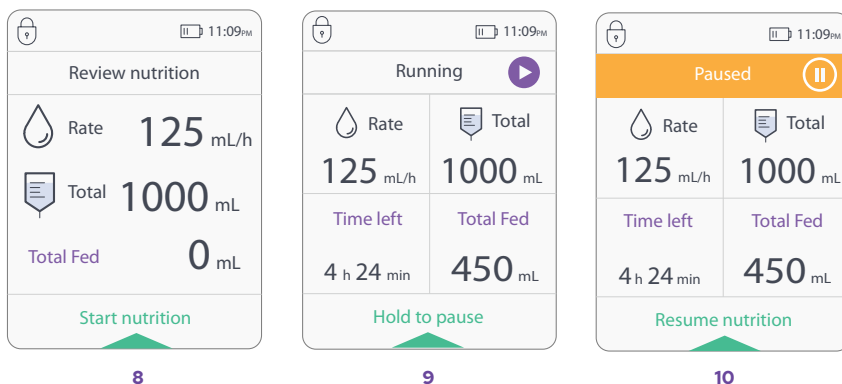
Important: The «Lock rate and volume» mode cannot be modified when the «Pause» mode is activated during a feeding (see section 5.3.4). The «Lock rate and volume» mode is deactivated if the pump is not used within 24 hours.

To set the «Lock rate and volume» mode, follow the instructions below:

- Press the multifunction button [●] to select the mode. (Fig. 1)
- Press ⊕ or ⊖ to use the «Lock rate and volume» mode by selecting «Yes» or «No». (Fig. 2)
- Adjust the flow rate [💧] by pressing ⊕ or ⊖. (Fig. 3)
- Then select the volume option by pressing ⊖ to «Use entire bag» or press ⊕ to enter volume. (Fig. 4)
- To adjust the volume [📄], press ⊕ or ⊖. Press the multifunction button [●] to move to the next step. (Fig. 5)
- Review the flow rate and volume to be administered. (Fig. 6)
- Press the multifunction button [●] to save the settings. The «Lock rate and volume» and «Settings saved» notifications will appear after 2 seconds. The pump automatically goes back to priming or the review step, depending on where the user was before choosing the «Lock rate and volume» mode. (Fig. 7)



- The lock icon [🔒] will appear at the top of the screen. (Fig. 8)
When the parameters are locked and tubing has been primed (see section 3.5), a «Review nutrition» screen will be displayed before launching the feeding.
- Screen display when feeding is «Running» (Fig. 9)
- Screen display when feeding is «Paused» (Fig. 10)

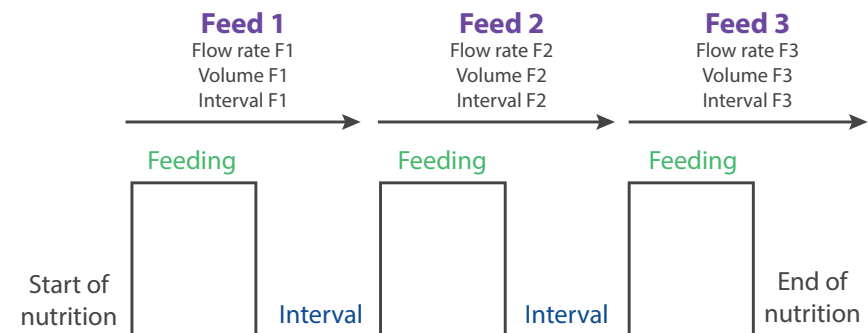


Note: To lock the keypad, refer to section 4.3.

5.3.3 «Intermittent» mode

This mode allows the user to program up to 8 feeds*. This will allow the user to switch on the pump and start the feeds without programming. The pump will automatically start the programmed feed.

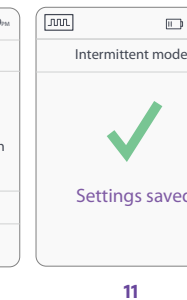
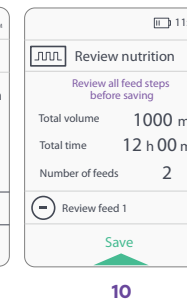
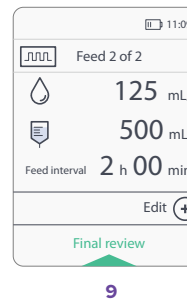
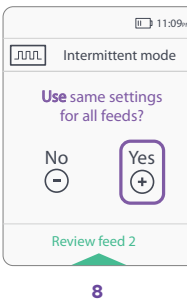
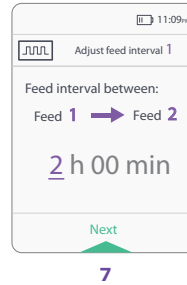
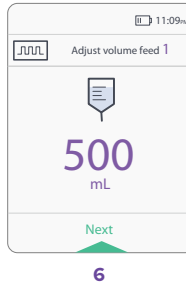
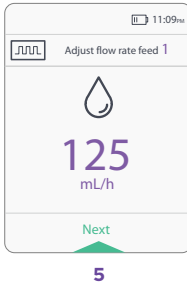
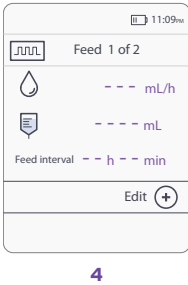
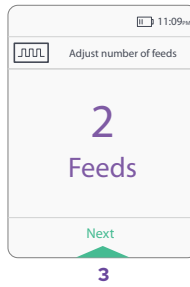
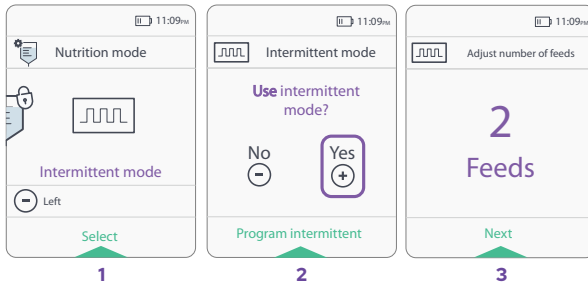
*«Nutrition» mode is where flow rate and volume are programmed.

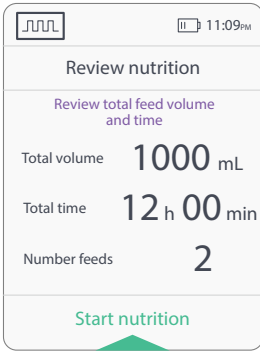



Important: The «Intermittent» mode parameters cannot be modified when «Pause» mode is activated during a feeding (see section 5.3.4). The «Intermittent» mode is deactivated if the pump is not used within 24 hours.

To set the «Intermittent» mode, follow the instructions below:

- Press the multifunction button [●] to select the «Intermittent» mode. (Fig. 1)
 - Press ⊕ or ⊖ to use the «Intermittent» mode by selecting «Yes» (program intermittent) or «No» (disable intermittent). (Fig. 2)
 - Choose the number of feeds (number of feeds + feed interval) from 1 to 8. (Fig. 3)
 - In the programming screen, adjust the flow rate [🔹], the volume [📄], and the interval between each feeding by pressing ⊕ or ⊖. (Fig. 4-7)
- Note: When setting the volume, it is not possible to select the «Use entire bag» option in «Intermittent» mode.**
- Choose to keep the same settings for all feeds or define new ones by pressing ⊕. When programming is complete, continue to the next step by pressing the multifunction button [●]. (Fig. 8-9)
 - Final review screen appears. Check that total volume, total time and number of feeds are correct, then press the multifunction button [●] to save the settings. (Fig. 10)
 - The display «Settings saved» appears for 2 seconds. (Fig. 11)





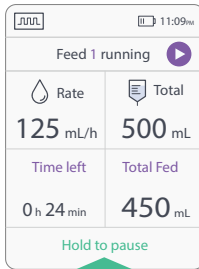
Once all the parameters have been confirmed, the «Intermittent» mode will be active and the «Intermittent» mode icon [] will appear at the top of the screen.

After tubing has been primed (see section 3.5), a “Review nutrition” screen will be displayed before launching the feeding.

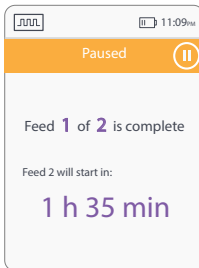
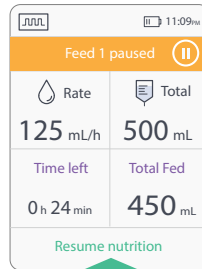
Note: It is possible to program a delayed feeding with the «Intermittent» mode.

Different screens in «Intermittent» mode:

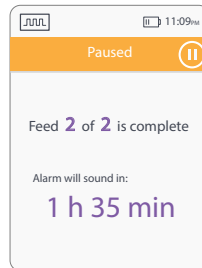
Nutrition running



«Pause» mode



This screen shows the programmed feed interval between the two feeds.



This screen shows the time left before the end of the feeding. The alarm will sound in 1 hour and 35 minutes.

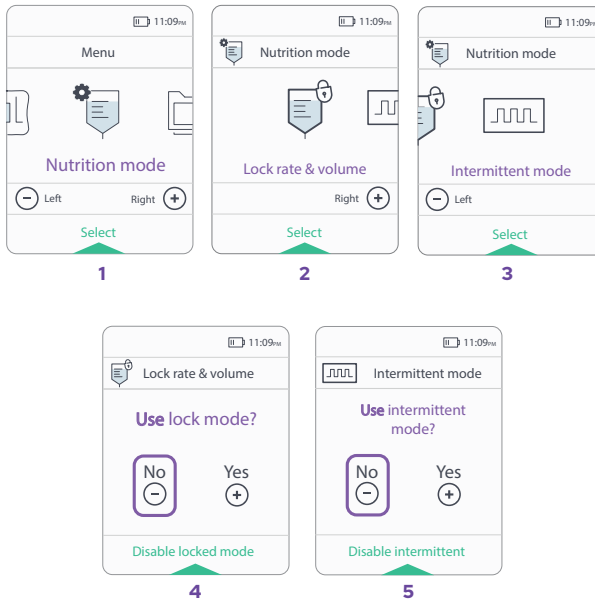
To lock the keypad refer to section 4.3.

5.3.4 «Nutrition» mode deactivation

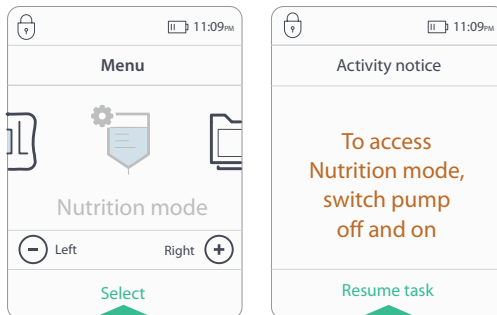
Programmed «Lock rate and volume» and «Intermittent» mode are stored in the pump for 24 hours after the pump has been switched off.

To deactivate the «Lock rate and volume» or «Intermittent» mode, follow the steps below:

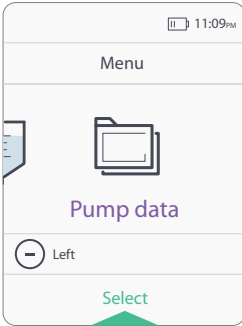
- After switching on the pump, press the menu button [Menu] to access the menu.
- Press ⊕ and ⊖ to select the «Nutrition» mode and press multifunction button [●] to confirm. (Fig. 1)
- Use the ⊕ or ⊖ buttons to select the mode to deactivate. Confirm by pressing the multifunction button [●]. (Fig. 2-3)
- Select «No» with ⊕ or ⊖ and confirm by pressing the multifunction button [●]. (Fig. 4-5)



Note: During a feeding, it is not possible to enter the «Nutrition» mode. To enter this mode, switch the pump off and on as the screens display below:



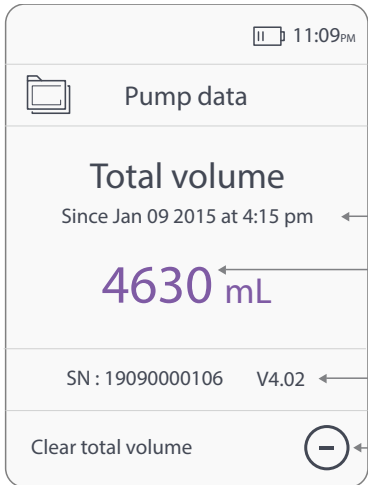
5.4 Pump data



Press the menu button [**Menu**] to access the pump menu. Press **+** or **-** to scroll through the configuration options then press the multifunction button [**●**] to select the pump data.

The pump data enables you to view the total volume administered, the pump serial number and the pump data.

Use the back button [**Back**] to return to the menu.



Date the pump was last reset to zero.

Since Jan 09 2015 at 4:15 pm

Total volume: Cumulative amount of volume administered since the last pump data reset.

4630 mL

Note: If the value is not reset before 9,999 mL, the total volume returns automatically to zero.

SN: 19090000106

V4.02


Serial number and software version.

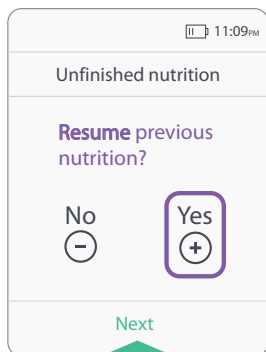
Clear total volume






"Reset pump data" function button: Resets total volume to 0 mL and sets the reset date.

6 • Resuming an Unfinished Nutrition

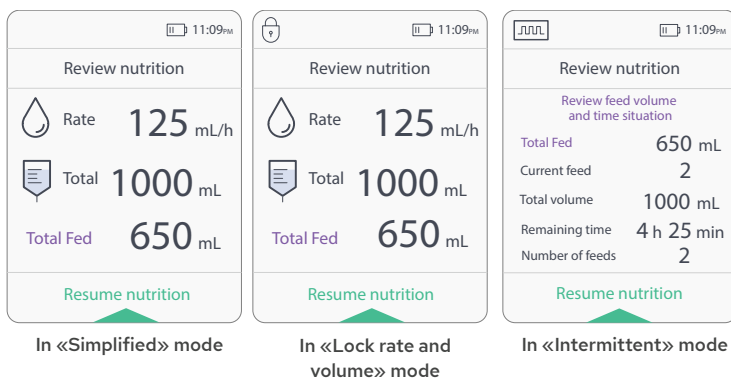
It is possible to resume an unfinished feeding after the pump has been switched off. The pump stores the information linked to the previous feeding for 4 hours, as long as the volume programmed has not been reached ($\text{Total Fed} < \text{Volume}$ []). To resume feeding, prime the tubing and the pump will prompt to resume the previous unfinished feeding.




Press  or  to choose whether to resume feeding by selecting «Yes» or «No».

If you press  and confirm «Yes», a «Review nutrition» screen will display the status of the feeding to be resumed.

This function works in all modes.



If you press the multifunction button [] to confirm, the feeding will resume from the time it was stopped.

By restarting an unfinished feeding with the same settings, **Total Fed** stored will continue to be administered to complete the total volume programmed.

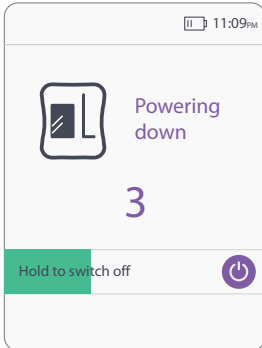
In the example above, the patient received 650 mL and stopped the feeding.

When the feeding is resumed, 350 mL will be administered to complete a targeted total volume of 1000 mL.

7 • Stopping the Pump

The PUGGLE™ Enteral Feeding Pump may be stopped under the following conditions:

- Programming phase or menu
- Pause during feeding
- Alarm



Press and hold the on/off button [🔌] for 3 seconds to stop the pump.

The progress bar will fill up.



The exit screen indicates the pump shutdown.

Important: Rinse and clean the feeding tube and the pump set according to the rules of the facility. Do not use the pump set for more than 24 consecutive hours.

8 • Alarms and Troubleshooting Guide

When an anomaly is detected, the pump will signal alerts and/or alarms visually and audibly:

- Beeping sounds
- Alarm light switched on
- Message on the screen

Alerts will not stop the feeding; alarms will stop the feeding.

In case of an alarm, press the multifunction button [●] to silence alarm. Then, correct the cause of the anomaly and press the multifunction button [●] to resume the feeding.

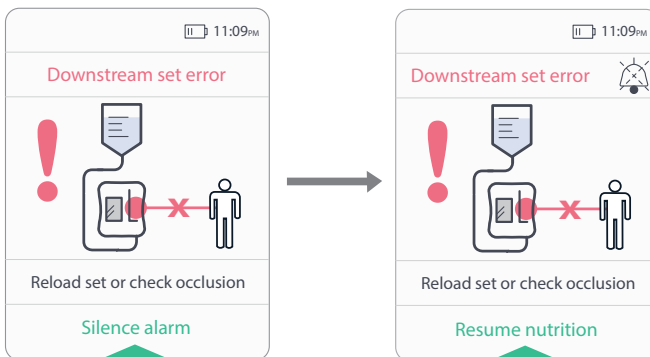
Note: The alarm will start sounding again after 2 minutes of silencing. To silence it again for 2 minutes, press the multifunction button [●]. The alarm will sound every 2 minutes until the problem is resolved. Press the multifunction button [●] again to resume feeding.

Should any of these alarms or indications continue after troubleshooting, please contact your customer service or your healthcare provider for pump service.

4 levels of alerts/alarms:

- Information: No sound and no LED lights
- Low priority alerts and alarms: Specific sound and solid yellow LED (66.1 dBA at 1 meter from device, at maximum volume)
- Medium priority alarms: Specific sound and flashing yellow LED light (66.1 dBA at 1 meter from device, at maximum volume)
- High priority alarms: Specific sound and flashing red LED light (66.2 dBA at 1 meter from device, at maximum volume)

When the alarm is muted, the user will have to resolve the problem and restart the feeding again by pressing the multifunction button [●].



This example screen is displayed when the alarm is sounding

This example screen is displayed when the alarm is muted

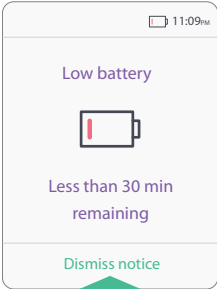
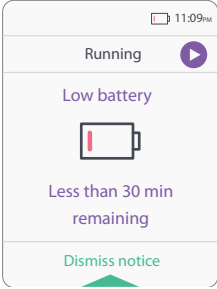
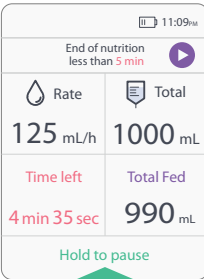
When the Alarm Silenced  is displayed on the screen, this means that the audible alarm is silenced for a period of 2 minutes.

Note: Depending on very low programmed flows (1 to 10 mL/h), some high priority alarms (upstream and downstream occlusion) may have a long detection time to trigger the alarm. This detection time may lead to a delay in therapy, depending on the case.

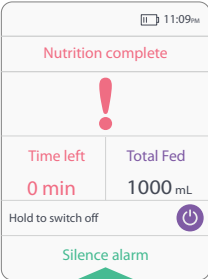
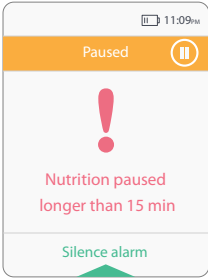

Important: Always ensure appropriate, timely, and regular patient monitoring, especially if an interruption of the tube feeding delivery may lead to a patient hazard.

Alerts/Alarms messages and corrective actions

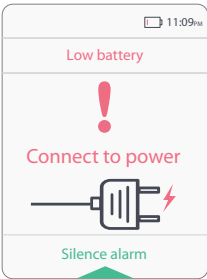
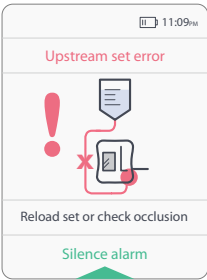
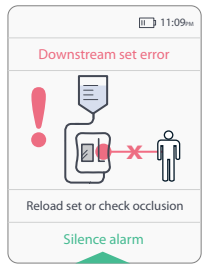
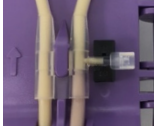
Solid yellow LED - Low priority alert

Display	Alarms	Priority	Solutions
	<p>Battery change alert</p> <ul style="list-style-type: none"> • Does not stop the feeding • 30 minutes remaining • Indicates pump status (running, pause, «Intermittent» mode) 	Low	Charge the battery by connecting the AC adapter to the pump and power source.
			
	<p>End of feeding alert</p> <ul style="list-style-type: none"> • Does not stop the feeding • 5 minutes remaining in programmed feeding 	Low	<ul style="list-style-type: none"> • Wait until the end of the feeding, or; • Pause the pump to modify the feeding settings, or; • Switch the pump off

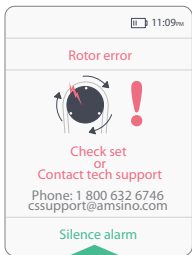
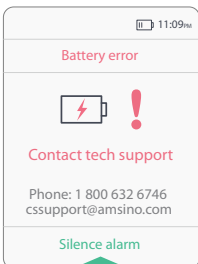
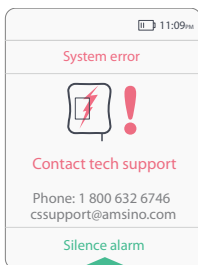
Flashing yellow LED - Medium priority alarm

Display	Alarms	Priority	Solutions
	<p>Feeding is complete alarm</p>	<p>Medium</p>	<p>Switch the pump off or press the multifunction button [●] to program a new feeding.</p>
	<p>Long pause alarm</p>	<p>Medium</p>	<p>Relaunch pause or resume feeding.</p>
	<p>Air in the tubing, or empty bag alarm</p> <ul style="list-style-type: none"> • Stops the feeding <p>Time to trigger an alarm at 1 mL/hr: 15 min Time to trigger an alarm at 120 mL/hr: 45 sec</p>	<p>Medium</p>	<p>In case of an unexpected «Air» alarm, check that the tubing is properly positioned in its slot, disconnect from patient, then launch another automatic prime.</p>

Flashing red LED - High priority alarm

Display	Alarms	Priority	Solutions
	<p>Low battery alarm</p> <ul style="list-style-type: none"> • Stops the feeding • 5 minutes remaining 	<p>High</p>	<p>Charge the battery by connecting the AC adapter to the pump and power source.</p> <p>Note: After plugging into the power supply, the user has to restart the feeding by pressing the multifunction button [●].</p>
	<p>Upstream set error alarm</p> <ul style="list-style-type: none"> • Stops the feeding • Upstream tubing occlusion • No tubing, or the tubing is not fitted properly into the slot of the ultrasound sensor <p>Time to trigger an alarm at 1 mL/hr: 30 min Time to trigger an alarm at 120 mL/hr: 1 min</p>	<p>High</p>	<p>Release upstream occlusion. Make sure the tubing is positioned correctly.</p>
	<p>Downstream set error alarm</p> <ul style="list-style-type: none"> • Stops the feeding • Occlusion between the pump and patient, or; • The cassette is not positioned correctly between the two black pins, or; • Presence of feeding is in the cassette branch between the two black pins (see picture) <p> Time to trigger an alarm at 1 mL/hr: 95 min Time to trigger an alarm at 120 mL/hr: 2 min</p>	<p>High</p>	<p>If there is an occlusion between the pump and the patient, release the occlusion and ensure that the branch of the cassette is empty.</p> <p>If alarm is not resolved, check that the cassette is positioned correctly between the two black pins and that there is no presence of feeding solution between the two black pins (see picture).</p> <p>If the alarm is still not resolved, replace the tubing.</p>

Flashing red LED - High priority alarm (continued)

Display	Alarms	Priority	Solutions
	Rotor error alarm <ul style="list-style-type: none"> • Stops the feeding 	High	Contact customer service or your healthcare provider.
	Battery error alarm <ul style="list-style-type: none"> • Stops the feeding 	High	Contact customer service or your healthcare provider.
	System error alarm <ul style="list-style-type: none"> • Stops the feeding • Self test or internal failure 	High	Contact customer service or your healthcare provider.
Power indicator light remains off	Faulty power adapter	N/A	Request a new AC adapter (see section 12.4).

Other alarms

Display	Alarms	Priority	Solutions
Continuous beeping sound	Total power failure alarm <ul style="list-style-type: none"> • Stops the feeding • Battery and AC adapter failure • Battery failure in battery mode 	Same frequency as high priority, 67.2 dB	Contact customer service or your healthcare provider.

9 • Batteries


9.1 Charge

The PUGGLE™ Enteral Feeding Pump runs on an internal NiMH battery that is not accessible to users. The pump is supplied with a uncharged battery.

Charging time: 2 hours 30 minutes.

To charge the battery, connect the pump using the power adapter supplied with the PUGGLE™ Enteral Feeding Pump or by Amsino.

Important: The battery must be fully charged before using for the first time.

This icon  indicates the pump is connected to a power source when the LED light is green.

If the pump is stored for long periods of time, the battery must be recharged at least once every three months.

Room temperature during charging must be between 10°C to 40°C (50°F to 104°F).

9.2 Battery replacement

The battery must be replaced by authorized Amsino personnel, who will dispose of the faulty battery according to appropriate regulations.

10 • Maintenance

10.1 Cleaning

General cleaning directions

Caution:

- Only personnel trained in the cleaning of medical devices should perform cleaning.
- Failure to follow the cleaning procedures described herein could result in hazards to users.

WARNING: To avoid electrical shock, never clean PUGGLE™ Enteral Feeding Pump or AC adapter with the power cord plugged into an outlet or with the pump switched on.

WARNING: Prevent liquid from entering into the pump to avoid electrical shock hazard, fire hazard or damage to electrical components. Do not submerge the PUGGLE™ Enteral Feeding Pump or its accessories in water or cleaning solutions.

WARNING: Make sure the AC adapter is completely dry before plugging into an electrical outlet.

Cleaning chemicals

- For general cleaning, use a solution of warm water and a mild dishwashing detergent.
- To remove all visible soil, wipe down the pump with non-abrasive paper towel, sponge, or soft cloth moistened with the cleaning solution.
- To remove soil from hard to reach crevices, use a soft brush.

Caution: The use of cleaners and disinfectants other than the cleaning solution described in the instructions for use may cause significant damage to the pump and may void warranty.

Cleaning frequency

- It is recommended that the pump be cleaned to eliminate stains and soils after each tubing use or at least every day.
- A cleaning is also necessary when the pump is allocated to a new patient.

Pump housing cleaning

- Refer to General Cleaning Directions before starting.
- Clean the outside surface with a solution of warm water and a mild dishwashing detergent and a non-abrasive sponge, paper towel, or soft cloth.

AC adapter cleaning

- Refer to General Cleaning Directions before starting.
- The AC adapter normally does not require cleaning. If soiling of the AC adapter is observed, unplug from outlet and wipe the exterior surfaces of the AC adapter with a non-abrasive dry or slightly damp cloth.
- Allow excess moisture to evaporate from the AC adapter prior to use.

Caution: Avoid exposing AC adapter to excess moisture, as this can lead to an electrical shock or fire hazard. The power adapter is rated IP40 which is not water resistant.

Rotor cleaning

- Refer to General Cleaning Directions before starting.
- Open the door.
- Use a cotton swab to clean the rollers thoroughly with a solution of warm water and a mild dishwashing detergent.

Sensors cleaning

- Open the door.
- Use a damp cotton swab to clean the sensors and the pathway where the cassette is seated.

10.2 Disinfection

Disinfection chemicals

The pump can be disinfected with the following solution:

- An alcoholic disinfection spray suitable for medical device with less than 40% of alcohol.
- A 0.5% chlorine bleach mixture for a minimum duration contact of 10 minutes.

Note: Repeated disinfections with these solutions can damage the plastic housing.

Important: The device can not be sterilized.

Disinfection frequency

- For better patient and personnel protection against the risks of contamination, cleaning according to the General Cleaning Directions and disinfecting per facility guidelines is recommended daily for the housing surfaces of the device.
- It is necessary to clean and disinfect the pump after each use when these devices are used for multiple patients. This is to prevent spreading bacteria, viruses, and other germs between patients that interact with the same pump.

Important: The device can not be sterilized.

10.3 Storage

Clean the PUGGLE™ Enteral Feeding Pump before storing it. When using the PUGGLE™ Enteral Feeding Pump after extended storage, the battery must be fully recharged (see section 9.1).

The PUGGLE™ Enteral Feeding Pump must be stored in a cool, dry place:

- Storage temperature: 0°C to 40°C (32°F to 104°F).
- Maximum ambient humidity is 93% without condensation.

10.4 Technical maintenance

For safety reasons, and in order to retain the warranty, only persons authorized by Amsino can carry out maintenance on the PUGGLE™ Enteral Feeding Pump.

There is no routine calibration or adjustment procedure required for the PUGGLE™ Enteral Feeding Pump. Regular technical maintenance is recommended. In the event of faulty operation, technical maintenance must be carried out systematically.

For technical maintenance, contact:

Amsino International, Inc., Customer Service
708 Corporate Center Drive, Pomona, CA 91768

800.632.6746 • cssupport@amsino.com

Pumps sent to customer service must be returned in their original packaging, along with a description of the product defect and only after a Return Goods Authorization has been issued.

11 • Warranty

The PUGGLE™ Enteral Feeding Pump warranty covers technical faults occurring during normal use within 24 months of its delivery date, not including the battery for which the warranty is 6 months.

The warranty covers repair and replacement of faulty parts due to material and workmanship defects. Warranty is valid for the original purchaser only.

The warranty shall not apply if:

- The pump is damaged following inappropriate use, after being dropped or incorrectly stored.
- The serial number has been changed.
- The pump has been opened, repaired, altered or adjusted by personnel other than those authorized by Amsino.
- The pump has not been used with Amsino tubing, battery or power adapter.

Pumps under warranty should be returned in accordance with the instructions.

For repairs, including during the warranty period, shipping, postage, insurance and call out costs to or from Amsino are at the customer's expense.

Amsino shall not be liable for loss of or damage to the device during transport to our customer service center. With the exception of the obligations set out in this limited warranty, Amsino shall not be liable for direct or indirect damage or damage by natural forces, regardless of the damage, whether based on an agreement or the law or any other legal theory, even if Amsino has been informed of the potential damage.

If, upon receipt, the pump packaging is damaged, you must ensure it is noted on the courier's paperwork.

12 • Technical Specifications and Symbols

12.1 Specifications

Dimensions	5.4 x 5.0 x 2.5 inches (H x W x D)
Weight	1.4 lbs (with battery)
Casing	PC ABS V0
Protection	IP 44
Battery	7.2 V 2 Ah NiMH (Nickel Metal Hybride)
Display	LCD
Front panel	6 sealed keys
Indicators	4 lights
Main power adapter	External AC/DC - IP 40
Input	100 V ~240 V ~ 50 Hz - 60 Hz
Output	12 V direct current / 1.5A
Charging temperature	10°C (50°F) to 40°C (104°F)
Operating temperature	5°C (41°F) to 40°C (104°F)
Storage temperature	0°C (32°F) to 40°C (104°F)
Operating humidity	15% - 93% RH non-condensing
Storage humidity	< 93% RH non-condensing
Operating pressure	700 hPa - 1060 hPa
Operating and storage illuminance 50 lux - 3000 lux	
Keep away from sunlight in operating and storage	

12.2 Performance accuracy

Pump with continuous volumetric rotary peristalsis for enteral feeding.

Flow rate range: From 1 to 400 mL/h - Setting increments: 1 mL/h.

A. General conditions:

The PUGGLE™ Enteral Feeding Pump delivers the feed at the specified rate within $\pm 5\%$ over one hour.

Conditions:

- Using new feeding set for no longer than the recommended time use (24h).
- All different types of the PUGGLE™ Enteral Feeding Set.
- Accuracy testing is run at a room temperature of 22°C ± 2°C (72°F ± 3°F).
- For commercially prepacked or prepared feeding solutions formulated for use with a feeding pump.
- Fluid level (head height) 15.2 cm with respect to the center of the pump rotor.
- The setting range of operating head height is 0~50 cm (0~19.68 inches) which has been verified as the worst case condition.

Note: To perform the accuracy testing within ± 5%, the nominal back pressure is established at the distal connector on the end of the feeding set. This is compared with the back pressure that would be experienced when the distal connector is plugged into a 6 fr nasogastric tube.

The accuracy of the pump within ± 5% is maintained at this maximum back pressure exerted by this feeding tube.

B. Accuracy under infusion standard test conditions:

Under the infusion standard (IEC 60601-2-24) test protocol, the PUGGLE™ Enteral Feeding Pump delivers the volume at the specified rate within ± 5%. For more information on pump accuracy, in particular for intermediate rate (120 mL/h) during 2 hours, see appendix A.

12.3 Other performances

Single fault conditions:

The PUGGLE™ Enteral Feeding Pump triggers an alarm when the following single fault conditions occur:

- Downstream occlusion
- Upstream occlusion
- Wrong set position
- Torque of rotor out of specifications
- System failure

Defaults in normal conditions:

The PUGGLE™ Enteral Feeding Pump triggers an alarm when the following faults occur in normal conditions:

- Air presence
- Low battery charge

Priming: Automatic filling of the tubing at 600 mL/h for 1 minute 25 seconds

Occlusion pressure: 0.9 bar ± 0.2 bar (13 ± 3 psi)

Volume range: From 1 to 9,999 mL - Setting increments: 1 mL

Memorization of feeding parameters: 24 hrs

Pause: 2 minutes, renewable - unlimited if deliberate

Autonomy: 20 hours at the intermediate flow rate of 120 mL/h (fully charged battery)

(If the pump is out of battery charge and automatically switches off, the running feeding and/or the modes programmed will still appear when switching on the pump after the complete charge.)

Charging time: 2 hours 30 minutes (depending on the state of the battery and the ambient temperature).

The expected service life of the PUGGLE™ Enteral Feeding Pump battery is 2 to 3 years, depending on usage.

The pump and accessories are designed to provide a minimum of 5 years of shelf life.

Amsino may modify these specifications without notice or obligation.

12.4 Accessories

Reference	Designation	Comments
PIACA	AC adapter	Supplied with pump
PIPPC	Pole clamp	Supplied with pump
PICBK	Compact backpack	Optional

Use of PUGGLE™ Enteral Feeding Pump backpack:

- Install the set on the pump according to section 3.2.
- The feeding bag shall be hooked to the specific clip.
- The pump shall be placed in the bottom pouch.
- Program the feeding according to section 3.

Use of pole clamp:













- Install the pole clamp on the IV pole and make sure it is correctly attached.
- Attach the PUGGLE™ Enteral Feeding Pump to the pole clamp.
- Verify that everything is correctly attached.
- Program the feeding according to section 3.

12.5 Medical equipment

The PUGGLE™ Enteral Feeding Pump complies with FDA recognized standards:

- Electrical shock, fire, and mechanical hazards were mitigated according to ES 60601-1 (3rd edition).

12.6 Symbols

	Follow instructions for use in the Operator's Manual before operating the PUGGLE™ Enteral Feeding Pump
Rx ONLY	Federal (USA) law restricts this device to sale by or on the order of a physician
	EN 60601-1 Type BF degree of protection against electrical shock: No electrical connection to patient drop from any angle from height of 3 feet (1 meter) shall not damage pump operation
	Class II equipment (degree of protection against electrical shock), double insulated
IP44	EN 60529 degree of protection: <ul style="list-style-type: none"> • Protected against tools, wires or solid foreign bodies with $\varnothing > 1$ mm • Splashed water from any direction shall have no effect
IPOX	EN 60529 degree of protection (Adapter): Not water resistant
	MR unsafe (Magnetic resonance)
	Manufacturer
	Date of manufacture
SN	Serial number
REF	Order reference
	Keep away from sunlight (Label located on box)
	Keep dry (Label located on box)
	Humidity limitations (Label located on box)
	Limit temperature (Label located on box)
	The pump is an electrical and electronic device and must be disposed according to WEEE Directives
	<p>UL classification marks for Canada and the United States</p> <p>Control number: E489659</p> <p>Based on the certification coverage of the product, the standard number is as selected below and applicable Amendments and/or Particular and/or related Collateral Standards for which the product has been found to comply by UL.</p> <p>Base Standard(s): ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14</p> <p>Additional Standards: IEC 60601-1-6:2010 (Third Edition) + A1:2013, IEC 60601-1- 8: 2006 (Second Edition) + A1: 2012, IEC 60601-1-11:2010 (First Edition), IEC 60601-2-24: 2012 (Second Edition).</p>

13 • Contact

Contact Amsino's customer service if you have additional questions:

Amsino International, Inc., Customer Service
708 Corporate Center Drive, Pomona, CA 91768
800.632.6746 • cssupport@amsino.com

14 • Electromagnetic conformity declaration

The PUGGLE™ Enteral Feeding Pump has been built and tested according to ES 60601-1 (3rd edition), IEC 60601-1-2:2007 and 60601-1-2:2014.

The pump is intended for use in the electromagnetic environment specified in the table. The user of the pump should ensure that it is used in such an environment.

Electromagnetic disturbances could cause disruption or malfunction of the pump with essential performance alteration. See section 12.2 and 12.3 for essential performance details.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The PUGGLE™ Enteral Feeding Pump is intended for use in the electromagnetic environment specified below. The user of the PUGGLE™ Enteral Feeding Pump should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions (CISPR 11)	Group 1	The PUGGLE™ Enteral Feeding Pump uses RF energy for its internal function. PUGGLE™ Enteral Feeding Pump must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions (CISPR 11)	Class B	The PUGGLE™ Enteral Feeding Pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions (IEC 61000-3-2)	Class A	
Voltage Fluctuations/Flicker Emissions (IEC 61000-3-3)	Complies	
Radiated Disturbance Immunity (IEC60601-1-2/IEC 61000-4-3:2006)	Complies	
Conducted Disturbance Immunity (IEC 60601-1-2/IEC 61000-4-6:2013)	Complies	
Power Frequency Magnetic Field Immunity (IEC 60601-1-2/IEC 61000-4-8:2009)	Complies	
Voltage Dips and Sags Immunity (IEC 60601-1-2/IEC 61000-4-11:2004)	Complies	
Electrical Fast Transient/ Bursts Immunity (IEC 60601-1-2/IEC 61000-4-4:2012)	Complies	
Electrostatic Discharge Immunity (IEC 60601-1-2/IEC61000-4-2:2008)	Complies	
Surge Immunity (IEC 60601-1-2/IEC 61000-4-5:2005)	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity


The PUGGLE™ Enteral Feeding Pump is intended for use in the electromagnetic environment specified below. The user of the PUGGLE™ Enteral Feeding Pump should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge(ESD) (IEC 61000-4-2 per IEC 60601-1-2:2014)	± 6 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (>95% dip in UT) for 5 sec	>95% dip in 0.5 cycle 60% dip in 5 cycles 30% dip for 25 cycles >95% dip in 5 seconds	Main power quality should be that of a typical commercial or hospital environment. The PUGGLE™ Enteral Feeding Pump allows continued operation during main power interruptions via the internal battery.
Power frequency (50/60 Hz) magnetic field (EN IEC 61000-4-8 per EN IEC 60601-1-2: 2014)	30 A/m	Class 2 (30 A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: UT is the AC main voltage prior to application of the test level.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The PUGGLE™ Enteral Feeding Pump is intended for use in the electromagnetic environment specified below. The user of the PUGGLE™ Enteral Feeding Pump should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 V from 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the PUGGLE™ Enteral Feeding Pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz
	6 V in amateur radio bands	6 V	
Radiated RF IEC 61000-4-3	10 V/m from 80 MHz to 2.7 GHz	10 V/m	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PUGGLE™ Enteral Feeding Pump is used exceeds the applicable RF compliance level above, the PUGGLE™ Enteral Feeding Pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PUGGLE™ Enteral Feeding Pump.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the PUGGLE™ Enteral Feeding Pump

The PUGGLE™ Enteral Feeding Pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PUGGLE™ Enteral Feeding Pump can help prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communications equipment (transmitters) and the PUGGLE™ Enteral Feeding Pump recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3 \sqrt{P}$
W			
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

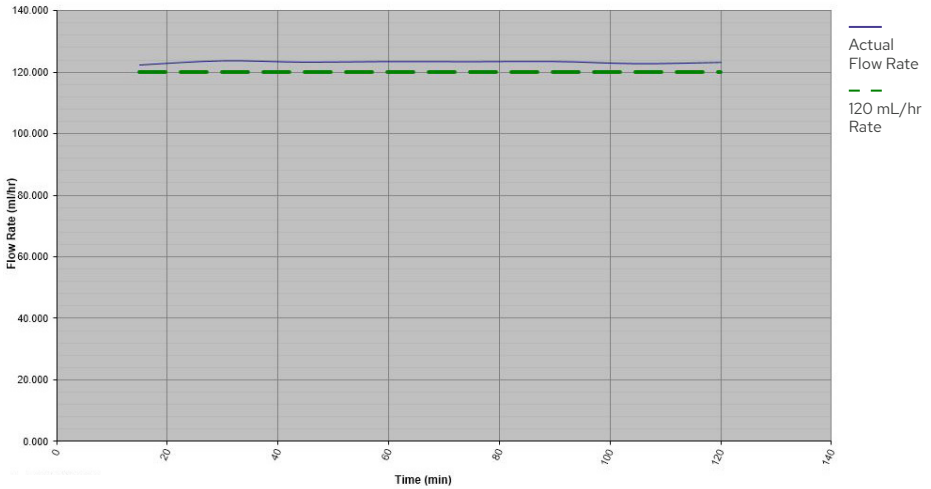
WARNING: Use of an AC adapter other than one specified or provided by Amsino could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the PUGGLE™ Enteral Feeding Pump including AC adapter specified by Amsino. Otherwise, degradation of the performance of this equipment could result.

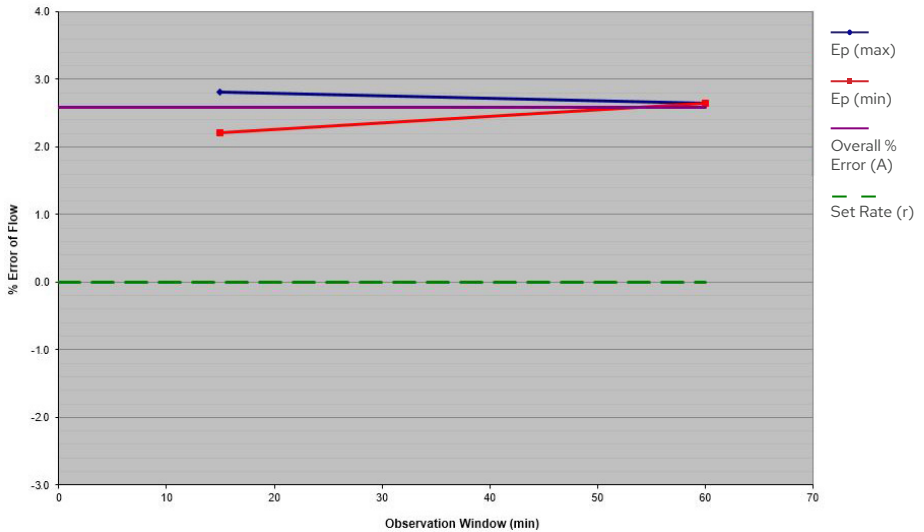
Appendix A • Accuracy Graphs

The following graphs illustrate the accuracy of the pump per the IEC 60601-2-24 standard. The graphs are shown for the intermediate rate 120 mL/hr for 2 hours and 8 hours; and a minimum flow rate of 1 mL/h for 24 hours.

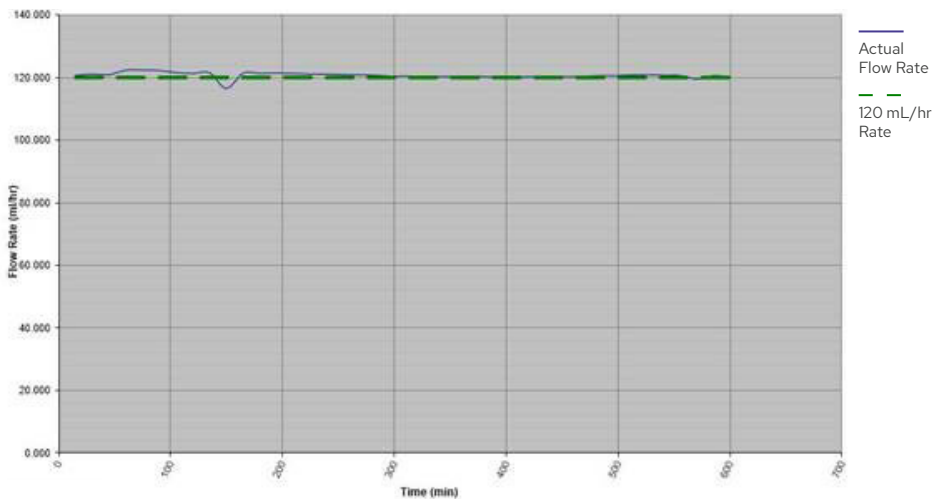
Hours 0-2: Accuracy Curve at 120 mL/hr Rate



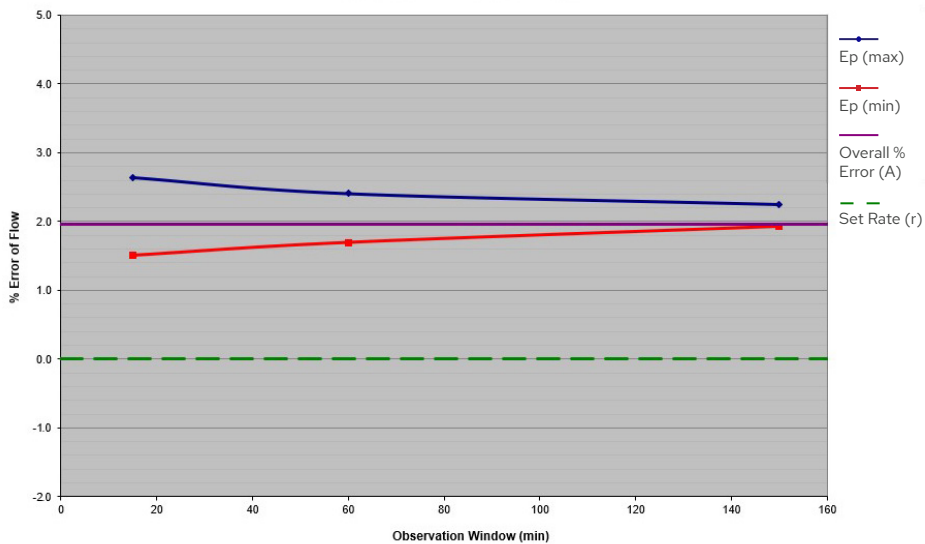
Hour 2: Accuracy Trumpet Curve at 120 mL/hr Rate



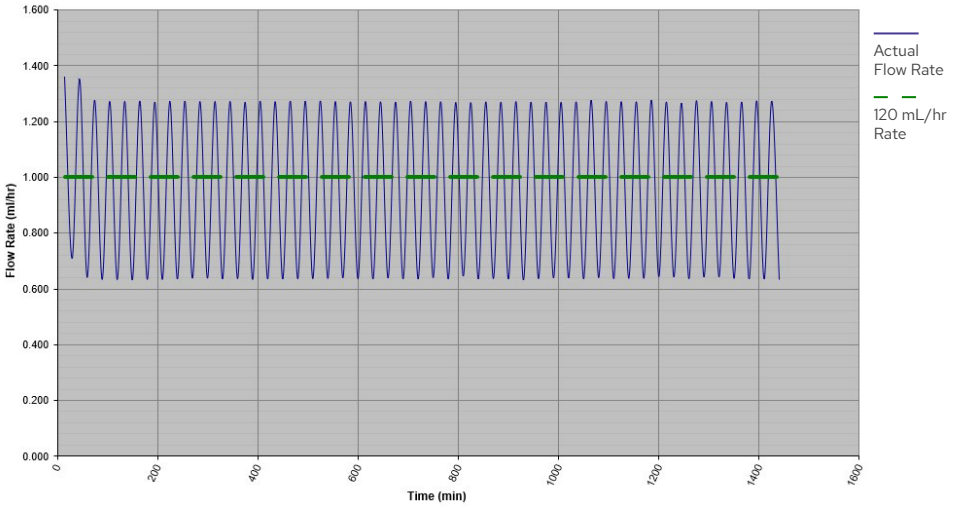
Hour 8: Accuracy Curve at 120 mL/hr Rate



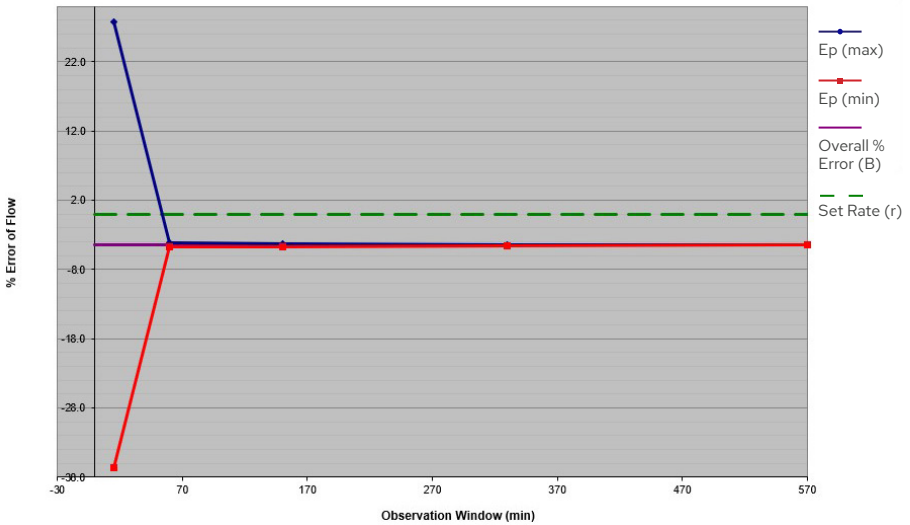
Hour 8: Accuracy Trumpet Curve at 120 mL/hr Rate



Hour 23: Accuracy Curve at 1 mL/h



Hour 23: Accuracy Trumpet Curve at 1 mL/h



Who to Call Your Healthcare Provider

Amsino International, Inc., Customer Service
708 Corporate Center Drive, Pomona, CA 91768
800.632.6746 • cssupport@amsino.com

NOTES

NOTES

NOTES

The logo for AMSINO, featuring the word "AMSINO" in a bold, white, serif font, set against a dark blue rectangular background with a thin white border.

Advancing Healthcare Worldwide®

Amsino International, Inc.

708 Corporate Center Drive, Pomona, CA 91768 • Amsino.com

Phone: 800.632.6746 • **Fax:** 909.626.3888 • **Email:** info@amsino.com

Product(s) described may not be licensed or available for sale in all countries. ENFit is a registered trademark of GEDSA. The symbol ® indicates the trademark is registered in the U.S. Patent and Trademark Office and certain other countries. © Copyright 2021, Amsino International, Inc. All rights reserved.

Manufactured by:

MEDWIN France

9 Allée de la Vigne Grande

34600 Les Aires - France

PM6/NT02/7
L10137 Rev.B