

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 1 of 81

**AMSure® Enteral Feeding Pump IFU**

	Name Printed	Job Title/Function	Signature	Date
Written By	Jason Jiao	Product Manager		2022/7/15
Reviewed By	Othon Pan	Senior RA Specialist		2022/7/15
Reviewed By	Leo Qiu	Director of Product Management		2022/7/15
Approved By	Jane Gao	VP of R&D and RA		2022/7/15

**Document Revision History**

Rev	Date	Description	Originator
B	2022/7/15	Based on FDA AI Requirement	Jason Jiao
A	2021/9/20	First issue	Jason Jiao

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 2 of 81

## Index

1. Symbols, Marking Instructions and Warnings.....	5
1.1 Description of Graphics and Symbols.....	5
1.2 Contraindication .....	6
1.3 Warning .....	6
1.4 Caution .....	7
1.5 Complications .....	<del>98</del>
2. Glossary of Terms.....	<del>98</del>
3. Introduction and Application Scope.....	9
3.1 Device Description .....	9
3.2 Indication for Use.....	<del>109</del>
3.3 Model Naming.....	<del>109</del>
4. Critical Features.....	10
5. Technical Specifications .....	<del>114</del>
5.1 Basic Parameters .....	<del>114</del>
5.2 Main Performance .....	11
5.3 Others .....	<del>124</del>
6. Pump Overview.....	<del>124</del>
6.1 General Description.....	<del>124</del>
6.2 System Description.....	13
6.2.1 Front Panel Icon Description .....	13
6.2.2 Operation Interface Layout.....	14
6.2.3 Continuous Mode Icon Description .....	<del>154</del>
6.2.4 Intermittent Mode Icon Description .....	16
7. Operation Guidance .....	18
7.1 Preparation before Use .....	19
7.1.1 Pump Installation.....	19
7.1.2 Connect to AC Power Supply.....	20
7.1.3 Switch on and Self-Testing .....	22
7.1.4 Feeding Set Identification System.....	23
7.1.5 Load Feeding Set.....	26
7.2 Feeding Operation Guidance .....	27

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 3 of 81

7.2.1 Feeding Mode Selection .....	27
7.2.2 Prime and Connect Feeding Set to Patient .....	29
7.2.3 Set Feeding Parameters .....	30
7.2.4 Start Feeding .....	31
7.2.5 Stop Feeding and Start a New Feeding.....	32
7.2.6 Interval Waiting .....	34
7.2.7 Feeding Complete and Switch Off .....	35
7.2.8 KTO .....	36
7.2.9 Screen Lock .....	39
7.2.10 Parameter Out of Range .....	40
7.2.11 Feeding Entire Bag .....	41
7.3 Other Functions.....	42
7.3.1 Feed History .....	42
7.3.2 Log Record .....	43
7.3.3 Quick Guidance .....	44
7.3.4 System Setting .....	45
7.3.5 System Maintenance .....	49
8. Alarm .....	54
9. Dedicated Enteral Feeding Sets (Disposable) .....	63
10. Accuracy Graphs .....	64
10.1 Accuracy Curve at 1 mL/hr. Rate .....	64
10.2 Accuracy Curve at 25 mL/hr. Rate.....	65
10.3 Accuracy Curve at 25 mL/hr. Rate under +13.3kpa .....	67
10.4 Accuracy Curve at 25 mL/hr. Rate under -13.3kpa.....	68
10.5 Accuracy Curve at 25 mL/hr. Rate under -0.5m.....	70
11. Internal Battery Maintenance .....	71
12. Product Maintenance and Warranty .....	71
12.1 Technical Maintenance.....	71
12.2 Cleaning.....	71
12.3 Disinfection .....	72
12.2 Warranty .....	73























File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 4 of 81

13. Characteristics of ALARM SIGNALS .....	74
14. Waste Disposal.....	77
14.1 Battery .....	77
14.2 Enteral feeding set .....	77
14.3 Pump.....	77
15. Electromagnetic Compatibility .....	77
16. Anti-Static Precautions .....	80
17. Packing List.....	81
18. Manufacturer Information .....	81

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 5 of 81

## 1. Symbols, Marking Instructions and Warnings

### 1.1 Description of Graphics and Symbols

	Caution		Refer to instruction manual/booklet
	BF type equipment		Class II equipment
	Date of manufacture		WEEE Signifies waste from electrical and electronic equipment
	Serial No.		Alternating current
	IPX4 protection level		Number of Units
	Direct current		Manufacturer
	Stand-by		Temperature limit
	Medical Device		Atmospheric pressure limitation
	Humidity limitation		Keep dry (Label located on box)
	Keep away from sunlight (Label located on box)		
	MR unsafe (Magnetic resonance)		
	Federal (USA) law restricts the use of this device to sale by or on the order of a physician.		
	Catalog #: Indicates the manufacturer's catalog # so that the medical device can be identified.		

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 6 of 81

## 1.2 Contraindication

1. Do not use the **AMSure**® enteral feeding pump and feeding set for parenteral feeding. This device is not intended for intravenous use.
2. Do not use the **AMSure**® enteral feeding pump and feeding set if enteral feeding is contraindicated. We recommend you contact your healthcare provider for further instructions.
3. The **AMSure**® 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.
4. The **AMSure**® enteral feeding pump and feeding set are only intended for adult patients, not for pediatric use.

## 1.3 Warning

Please read the following warning information carefully. If not avoided, could result in death or serious injury.

Read these instructions thoroughly before using the pump.

1. Do not use the pump and set for parenteral feeding of patients and the infusion of blood, analgesia, anesthesia, insulin, and chemotherapy drugs.
2. Do not operate the pump by untrained personnel. Users should read this manual carefully to prevent medical accidents caused by improper operation. Operator shall stand in front of the pump while setting it up and operating.
3. Do not install the pump in dusty places or in an environment where flammable or explosive materials are placed to prevent fire or explosion. Such as flammable anesthetic gas or a mixture of oxygen and nitrous oxide gas.
4. Do not use the pump in an environment of strong shocking vibrations and strong external electromagnetic interference and radiation, such as MRI environments.
5. Do not immerse the pump in the liquid. The pump is an IPX4 water-proof device. Avoid liquid infiltration into the pump, including nutrient solution, and always keep the pump clean and dry.
6. Do not use the enteral feeding set which is not listed in this instruction for use for enteral feeding, otherwise feeding may not accurate. Use of the RFID technology, when enabled on the pump, is one of the solutions for user to avoid using incorrect sets.
7. Do not use an enteral feeding set for over 24 hours.
8. Do not place the pump adjacent to or stacking together with other equipment unless it is necessary to do so. Ensure the pump is working correctly if it is proximity to other equipment. If the same or similar equipment is used in a separate area, there will be dangers if different alarm presets are used, such as an intensive care unit or a heart operating room.
9. Do not connect other tubes to the patient's gastric tube when pump is in a feeding at the same time. This may affect patient feeding.
10. Do not use the pump as a portable device.

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 7 of 81

11. Do not repair and calibrate the pump by untrained technicians or persons who is not authorized by Amsino. It may cause the failure of the pump or serious injury. Before repairing, be sure to unplug the power cable that supplies power to the device.
12. Do not using accessories, detachable parts and materials with the pump that are not recommended by Amsino. It could result in damage to the pump or serious injury.
13. Do not modify the software and hardware of this product without any authorization. It could result in damage to the pump or serious injury.
14. Do not use the pump which is subject to strong impact or dropped from a height. It could result in damage to the pump or serious injury.
15. Do not maintain the pump by unauthorized person by Amsino, except for cleaning the outer surface of the pump, otherwise it could result in damage to the pump or serious injury.
16. Do not replace the battery by unauthorized person by Amsino. It could result in damage to the pump or serious injury.
17. Do not use a power adapter of a brand or model not specified by Amsino to charge the pump. It could result in damage to the pump or serious injury.
18. Do not adjust the alarm volume below the ambient noise. Auditory alarm signal sound pressure levels, which are less than ambient levels, can impede OPERATOR recognition of ALARM CONDITIONS and the ALARM SYSTEM provides
19. 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 step motor and other items that cause electromagnetic interference. It could result in damage to the device or serious injury.
20. Do not use homemade foods, or other non-prescribed, non-commercially available feeding solutions. 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.
21. When the ambient temperature and humidity (refer to Section 5.2 main performance), or the head height (refer to Fig 7.1.1-2 Initial Fluid Level (Head Height), or altitude (refer to Section 10.0 accuracy graphs) are out of these ranges, the feeding accuracy will not be guaranteed.

#### 1.4 Caution

Please read the following information carefully. If not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.

- 1 The pump is only used in medical facilities.
- 2 During use, the external power supply should be connected properly, and the pump should be firmly fixed to an I.V. pole, or place the pump on a horizontal table.

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 8 of 81

- 3 The pump should be in a place where it is easy to connect or disconnect the power plug.
- 4 Always disconnect the power adapter and turn off the pump before cleaning or repairing. After cleaning, make sure the power adapter is completely dry before plugging into an electrical outlet.
- 5 Patients with diabetic disorders are subject to enhanced surveillance. Hypoglycemia, diabetic patients with under or delay feeding may cause coma.
- 6 After the feeding set is loaded, the operator needs to confirm that the feeding set is correctly installed. The liquid in the feeding set should not flow by itself, otherwise stop using it and contact customer service.
- 7 Do not use nails or sharp objects to operate the buttons and screen. It may damage the pump.
- 8 Store the pump in accordance with the storage conditions in this instruction for use.
- 9 The user should set the feeding parameters in accordance with the requirements of the physician. The wrong feeding parameters may cause injury to the patient.
- 10 When the pump generates high priority alarm, it will automatically stop running. After removing the alarm source, press the "Start/Stop" button to continue running. Refer to Section 8. Alarm.
- 11 The pump should be wiped regularly to ensure that it is clean. Blocking the sensors will cause detection failure or false alarms. Refer to Section 12.1 Maintenance.
- 12 The pump and accessories are designed to provide a minimum of 5 years shelf life.
- 13 Use Amsino specified power adapter. Do not use unknown power adapter.
- 14 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.
- 15 Small foam bubbles may accumulate and may create a maximum volume of 1.6mL without being detected by the pump, which corresponds to a maximum length of 23cm air in the tubing. Patients who are extremely sensitive to receiving air in the stomach during enteral feeding should be provided with enhanced surveillance.
- 16 This device complies with Part 15 of the FCC. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses



File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 9 of 81

and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

## 1.5 Complications

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

## 2. Glossary of Terms

1. **Enteral Feeding Set:** A device that transfers nutrient solution or water to the patient from the liquid supply through the equipment, feeding set or tubing for short.
2. **Interval:** When pump in intermittent feeding mode, the system will display interval waiting status between two single feedings.
3. **Free Flow:** The liquid in delivery set is not controlled by the equipment and flows freely under gravity.
4. **KTO:** Keep Tube Open. A feature that effectively pauses the pump but keeps the rotor turning very slowly to prevent fluid from clogging in the feeding set tube.
5. **RFID:** Radio Frequency Identification.
6. **Head Height:** The distance from the top of the fluid in the feeding set bag (or container) to the top of the pump.
7. **Dose:** A feature that allows a fixed amount of fluid to be delivered during a feeding. The pump will stop operation when the programmed amount of fluid is delivered.
8. **Rotor:** The wheel on the pump that rotates to push fluid through the feeding set.

## 3. Introduction and Application Scope

### 3.1 Device Description

The **AMSure**® enteral feeding pump and feeding set consists of an enteral feeding pump and disposable enteral feeding sets that deliver formula via

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 10 of 81

rotary peristaltic pumping system to provide nutrition for those who do not have the ability to orally ingest food.

### 3.2 Indication for Use

The **AMSure**® Enteral Feeding Pump and Feeding Set are intended to deliver nutritional formula to the gastrointestinal system of a patient age as adults who are physically unable to eat and swallow or who are unable to get sufficient nutrition through eating and swallowing.

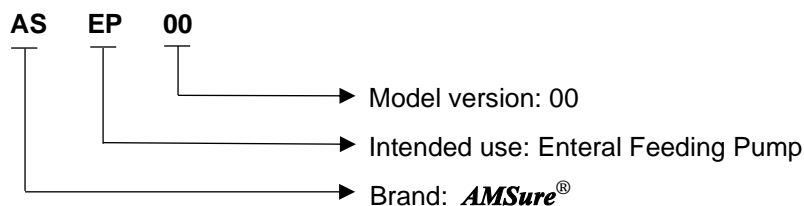
Only intended for adult patients, not for pediatric use.

The feeding pump and feeding sets are intended to be used in medical facilities by licensed healthcare professional users only.

The **AMSure**® Enteral feeding pump is for use with only the Amsino **AMSure**® feeding sets.

### 3.3 Model Naming

**AMSure**® Enteral Feeding Pump Model: ASEP00



## 4. Critical Features

1. Two options for feeding history review: 1) View previous 72 hours of feeding history; 2) View cumulative feeding history record since it was cleared last time.
2. Audible and visual alarm to indicate errors.
3. 4.3-inch touch screen is used for direct parameter setting to reduce the operation steps.
4. Contains a rechargeable lithium battery, which can support pump working without grid power for short term use.
5. RFID Identification to ensure a match between the pump and dedicated feeding set.
6. Sensor technology detects both upstream and downstream flow conditions.
7. Continuous feed and Intermittent feed capability.
8. Auto-prime feature reduces the need for time-consuming manual priming.
9. "Keep Tube Open" (KTO) feature.

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 11 of 81

## 5. Technical Specifications

### 5.1 Basic Parameters

Dimensions		133mm×110mm×170mm	
Weight		1.08 Kg	
Power adapter			
No.	Parameter	Specification	
1	Power adapter specification	US market	LXCP26-150160A
		EU market	LXCP26-150160B
2	Frequency	50/60Hz	
3	Input voltage	AC 100 ~ 240V	
4	Input current	0.8A	
5	Output voltage	15V	
6	Output current	2.0A	
Built-in battery			
No.	Parameter	Specification	
1	Quantity	1pcs	
2	Nominal battery voltage	DC 11.1V	
3	Battery capacity	2200mAh	
4	Working time	Continuously working for 7 hours with a feeding rate of 120ml/h after fully charged.	
5	Battery power	24.42Wh	
Requirement of enteral feeding set		Refer to “9. Dedicated Enteral Feeding Sets (Disposable)”	

### 5.2 Main Performance

Range of feeding rate	1~400mL/h, step value = 1mL/h
Range of feeding volume	1~9999mL, step value = 1mL
Feeding accuracy	±10%
Interval waiting (Intermittent Mode)	00h01min ~ 23h59min
Feed count (Intermittent Mode)	2~8
Feeding mode	Continuous mode or Intermittent mode
Recoverable alarm sound and automatic recovery time	1min50s – 2mins
No-operation timeout alarm time	1min50s – 2mins
Occlusion pressure	50±25kPa
Classification	Type II BF equipment IPX4 level; not AP or APG type.

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 12 of 81

Working and storage condition	<ul style="list-style-type: none"> <li>- Working ambient temperature: +16°C~+40°C</li> <li>- Transportation and storage environment temperature: -20°C~+60°C</li> <li>- Transportation, storage and use of environmental humidity: 20% ~ 90%</li> <li>- Transportation, storage and use of atmospheric pressure: 700Hpa ~ 1060Hpa</li> </ul>
Period of use	5 years

### 5.3 Others

- The method of controlling the bolus before the occlusion is relieved: The method of controlling the reversal of the stepping motor is used to release the pressure in the tubing after the occlusion to control the bolus.
- The storage time of the electronic memory function after shutdown: the equipment life cycle.
- The unit of measurement used for equipment calibration: milliliters, namely mL.

## 6. Pump Overview

### 6.1 General Description

This pump is composed of pump shell, motor drive system, input system, storage system, control system, display system, sensing and monitoring system, alarm system, power adapter and built-in battery. Below Figures from 6.1-1 to 6.1-3 for the diagram of the pump.

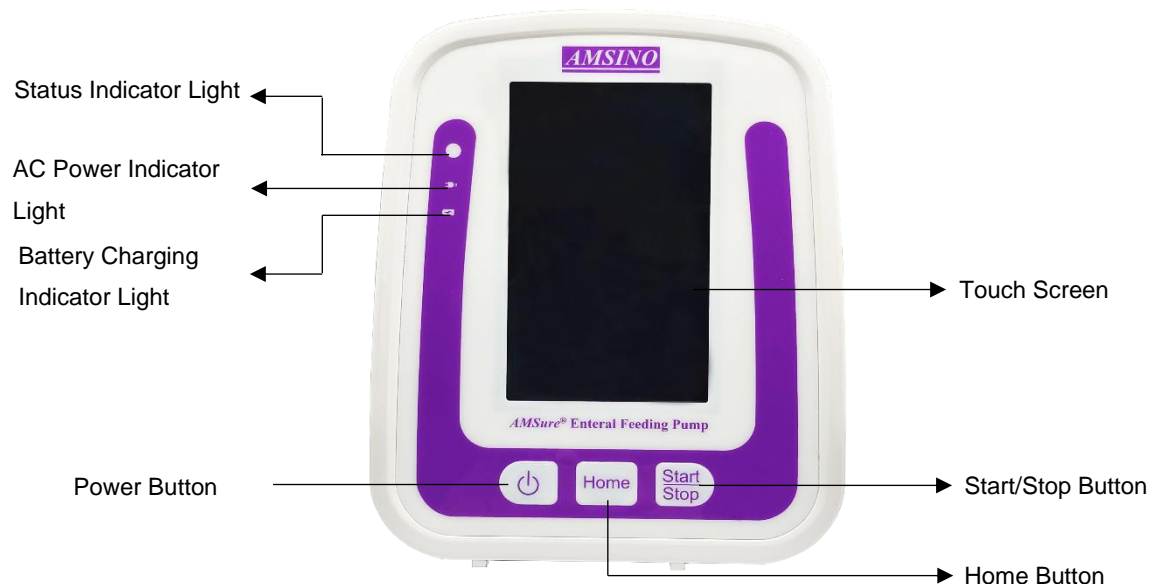


Fig 6.1-1 Front View

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 13 of 81

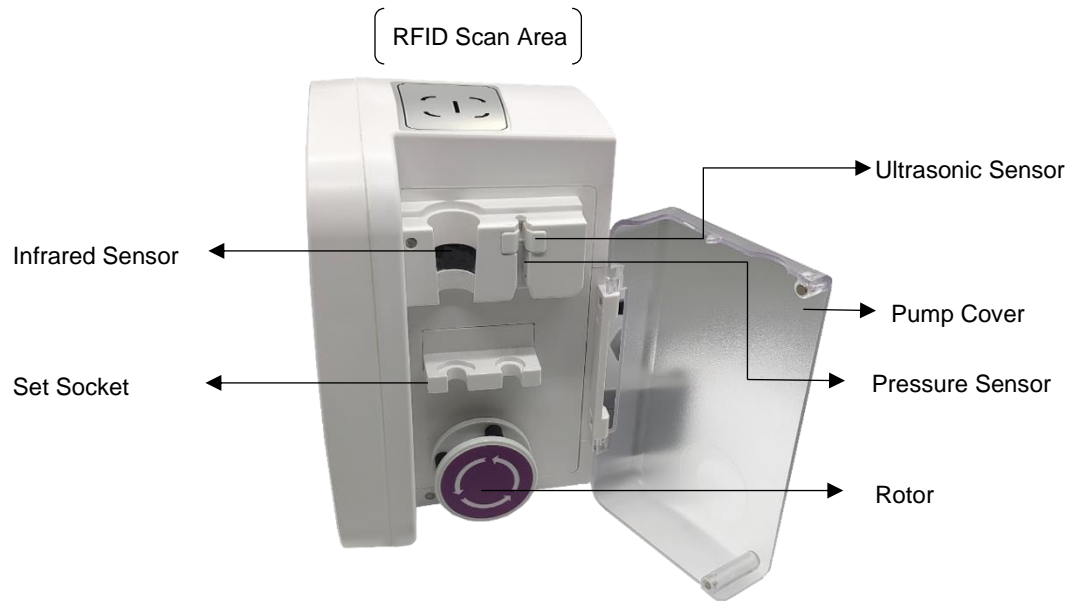


Fig 6.1-2 Side View

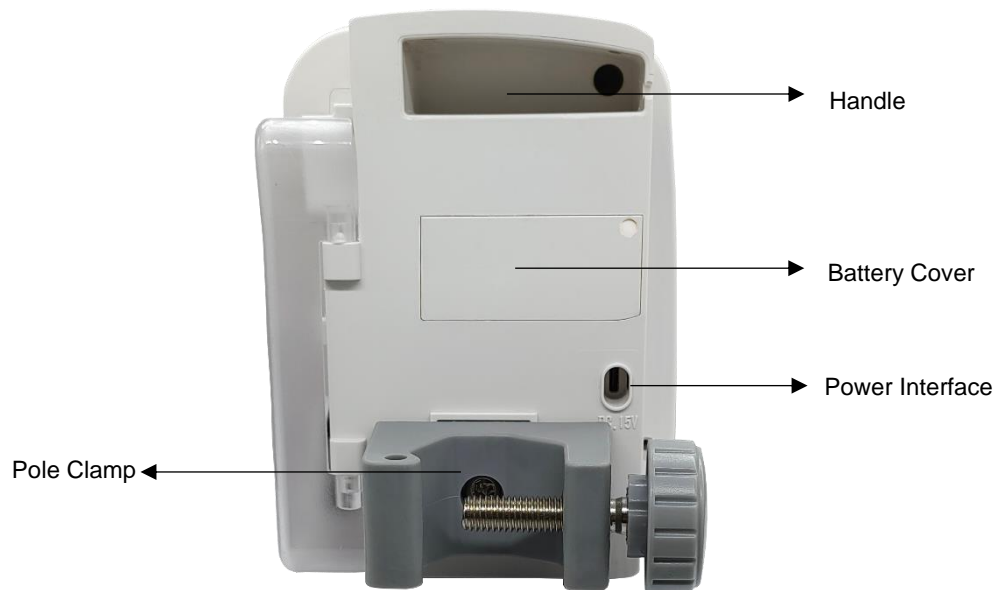













Fig 6.1-3 Back View

## 6.2 System Description

### 6.2.1 Front Panel Icon Description

No.	Indicator and Button	Status		Description
1	Status Indicator Light		Green	Normal status
			Yellow	Medium or Low priority alarm

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 14 of 81

			Red	High priority alarm
			Not lit	Pump is not powered on
2	AC Power Indicator Light		Green	AC power supply is connected
			Not lit	AC power supply is disconnected
3	Battery Charging Indicator Light		Green	Battery is in charging
			Not lit	Battery is not in charging
4	Power Button		Switch the pump on or off	
5	Start/Stop Button		Pump run or stop	
6	Home Button		Fast back to home page	

## 6.2.2 Operation Interface Layout

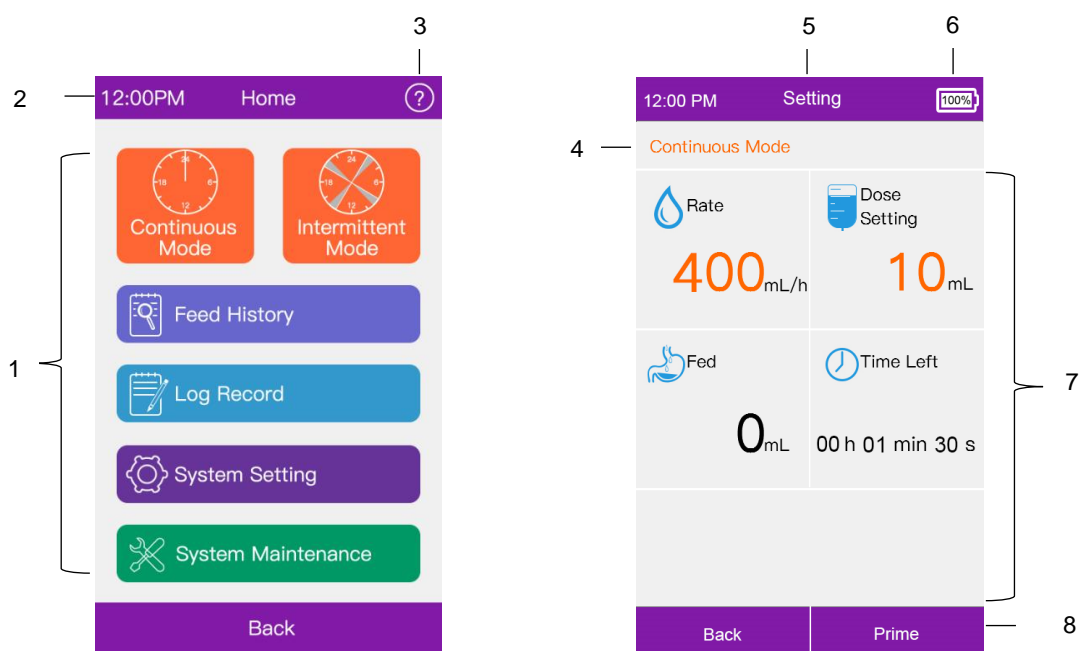


Fig 6.2.2-1 Operation Interface

No.	Name	Description
1	Function selection area	User can select the function by touch the screen directly.
2	System time display area	Display system time with 12-hour time format.
3	Quick guidance button	User can touch this icon to enter quick guidance page.

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>15</b> of <b>81</b>

4	Feeding mode display and switch	User can touch the mode, switching to another feeding mode.
5	Status bar	Display system status such as: Setting, Running, Stop, alarms, tubing status
6	Remaining Battery Capacity	User can check the remaining battery capacity when pump is not connected to AC supply.
7	Feeding parameters setting and display area	User can set feeding parameters by touching the numbers in <b>orange</b> .
8	Function button	Display the related function button.

Note: All the **orange** color words in the parameter setting page are editable.

### 6.2.3 Continuous Mode Icon Description

This feeding mode allows the device to feed the patient by setting flow rate and dose. When the actual feeding amount reaches the dose, the feeding ends. Below is the continuous feeding interface.

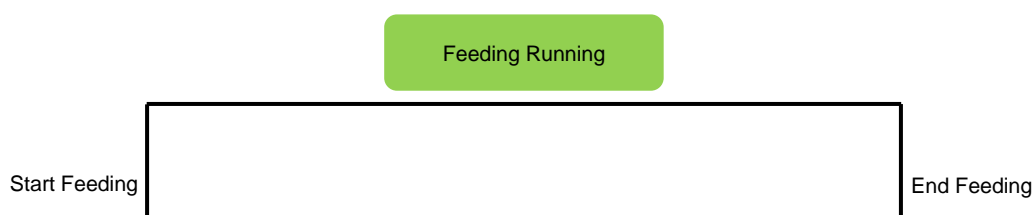


Fig 6.2.4-1 Continuous Mode Sequence

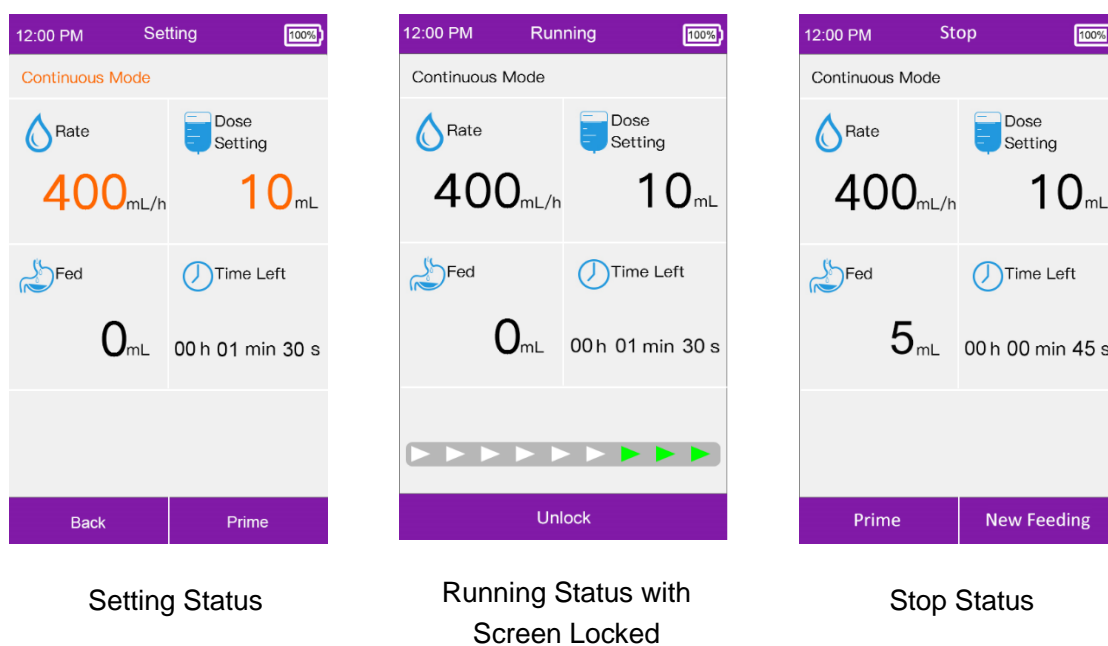





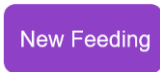






Fig 6.2.4-2 Continuous Mode

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>16</b> of <b>81</b>

No.	Icon	Name	Description
1	<b>Continuous Mode</b>	Continuous Mode	User can touch it to switch to intermittent feeding mode.
2		Rate	Indicate number of feeding rate
3		Dose Setting	Indicate number of feeding dose
4		Fed	Indicate volume delivered to patient
5		Time left	Indicate time left to feeding end
6		Prime	Enter prime page. Refer to 7.2.2 for Prime section.
7		New Feeding	End current feeding task and goes to setting page.
8		Lock	Execute screen lock function. Refer to 7.2.9 Screen lock
9		Unlock	Execute screen unlock function. Refer to 7.2.9 Screen lock
10		KTO	Execute KTO function. Refer to 7.2.8 KTO
11		Back	Back to previous page.

Note: All the **orange** color words in the parameter setting page are editable.

#### 6.2.4 Intermittent Mode Icon Description

This feeding mode allows the pump to be programed and automatically run up to 8 feeds with same set time intervals, single feeding dose and flow rate. Below is the intermittent feeding sequence.

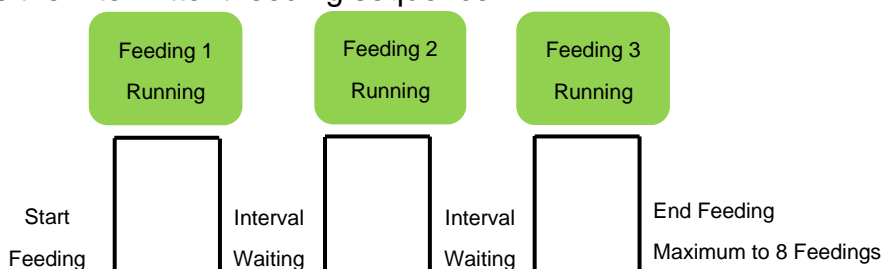
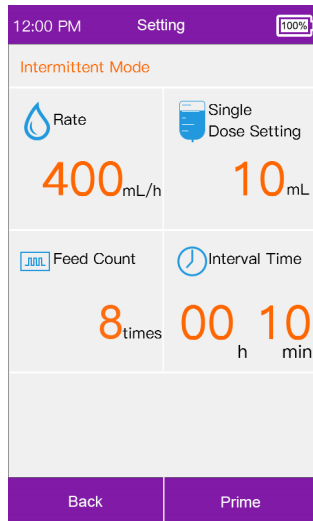


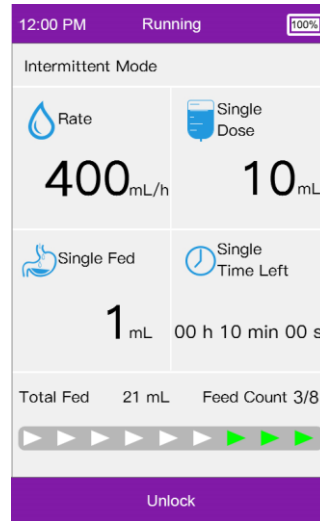
Fig 6.2.5-1 Intermittent Mode Sequence



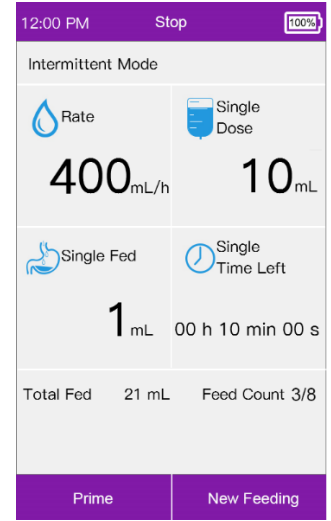
File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 17 of 81



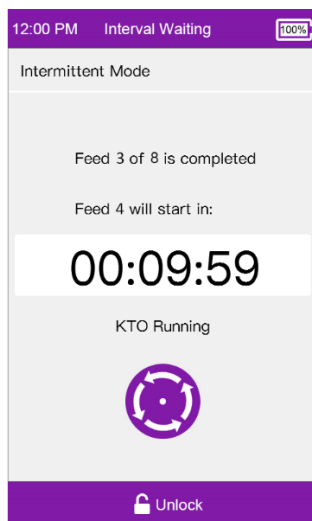
Setting Status



Running Status



Stop Status














Interval Waiting

Fig 6.2.5-2 Intermittent Mode

No.	Icon	Name	Description
1	<b>Intermittent Mode</b>	Intermittent Mode	User can touch it to switch to continuous mode.
2		Rate	Indicate number of feeding rate

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>18</b> of <b>81</b>

3		Single Dose	Indicate number of single feeding dose
4		Feed Count – In Setting Status	Indicate number of feedings
5		Single Fed	Indicate volume delivered in current single feeding task
6		Interval time – In Setting Status	Interval time to be set between feedings Note: the maximum interval time is 23 h 59 mins.
		Single Time Left – In Running/Stop Status	Indicate time left to feeding end of current single feeding task
7	-	<b>Total Fed</b>	Indicate total fed volume delivered to the patient
8	-	<b>Feed Count</b> – In Running/Stop Status	Indicate number of feeds that have been run from total programed feeds.
9		KTO Running	The icon is rotating to show KTO running status. Refer to 7.2.8 KTO
10		Prime	Enter prime page. Refer to 7.2.2 for Prime section.
11		New Feeding	End current feeding task and goes to setting status.
12		Lock	Execute screen lock function. Refer to 7.2.9 Screen lock
13		Unlock	Execute screen unlock function. Refer to 7.2.9 Screen lock
14		KTO	Execute KTO function. Refer to 7.2.8 KTO
15		Back	Back to previous page.

Note: In all programmed feeds in one intermittent setting, all feeding parameters including feeding rate, single feeding dose, interval waiting time are same.

## 7. Operation Guidance



### Caution

All the enteral feeding sets are disposable. The operation steps are as following: install the pump → switch on with self-testing → install the feeding set → RFID tag swipe → set parameters → priming → connect to patient's

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 19 of 81

gastric tube → start feeding → complete feeding → remove the feeding set → switch off.

## 7.1 Preparation before Use

### 7.1.1 Pump Installation

Before fix the pump to the I.V. pole, hang the formula bag and feeding set to I.V. pole and adjust the pump head height to the fluid level in the formula bag. For better accuracy, the initial fluid level shall be at **45±5cm (17.7±1.96 inches)** higher than the pump and the pump shall be placed higher than the feeding site to the patient.

Note: To reach the required head height, fold the upstream tube in half, the pump position can be adjusted on the I.V. pole with the door's upper edge flushing to the tube middle point.

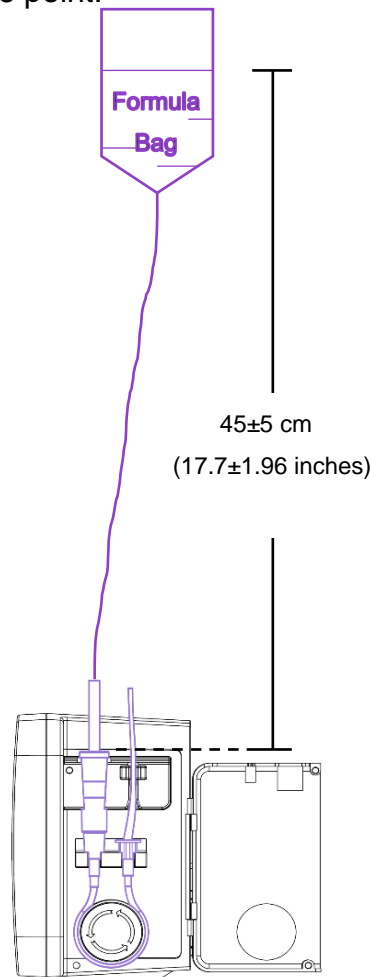


Fig 7.1.1-1 Initial Fluid Level (Head Height)

As shown in Figure 7.1.1-2, loosen the locking bolts of the pole clamp, mount the pole clamp to the I.V. pole, then tight the clamp to fix the pump.

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>20</b> of <b>81</b>



Fig 7.1.1-2 Pump Installation

## 7.1.2 Connect to AC Power Supply

Connect the pump to AC power supply as below shown.

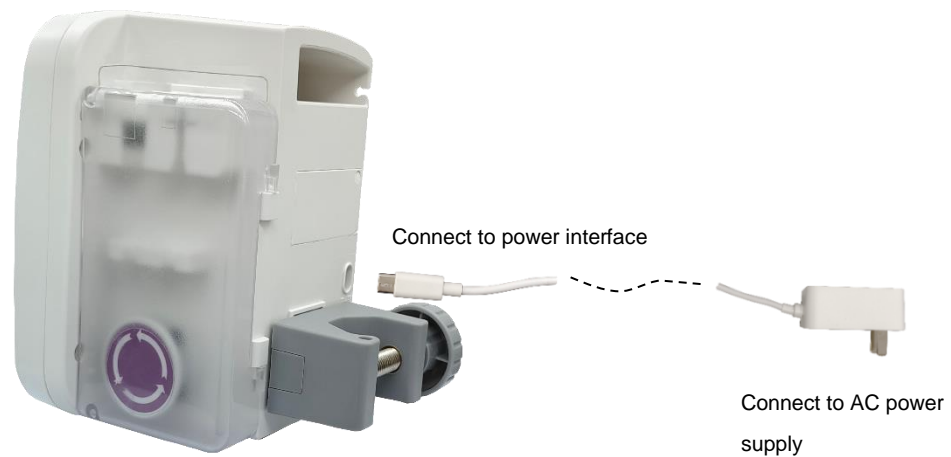


Fig 7.1.2-1 Connect to AC Power Supply

AC Power Indicator turns green, and a message “AC Power Connected” prompt on the status bar for 2 seconds once AC power supply is connected when pump is switched on.

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>21</b> of <b>81</b>



Fig 7.1.2-2 AC Power Connected

AC Power Indicator turns off and a message “AC Power Disconnected” prompt on the status bar for 2 seconds once AC power supply is disconnected when pump is switched on.



Fig 7.1.2-2 AC Power Disconnected

To protect battery life, the battery will be charged only when the battery capacity is below 92% and the charging indicator light turns green. When the battery is charged to 100%, it stops charging and battery indicator light turns off. Refer to 6.2.1 Front Panel Icon and 6.2.3 System Icon Description.

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 22 of 81

## 7.1.3 Switch on and Self-Testing

### 7.1.3.1 Switch On


Press the power button  on the front panel to switch on the pump and the pump will perform self-testing automatically.



Fig 7.1.3.1-1 Switch on and Self-Testing

A prompt will pop up to ask if last parameter settings are kept. Detail information refer to 7.2.5 Stop Feeding and Start a New Feeding and 7.2.11 Feeding Entire Bag

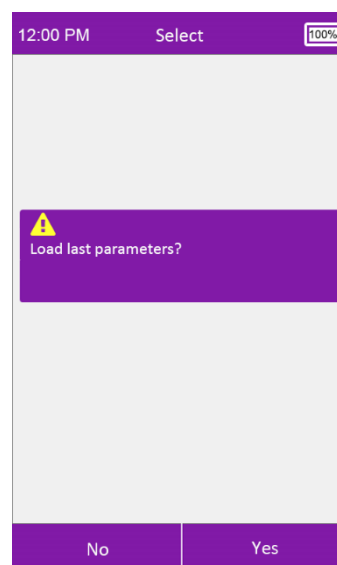


Fig 7.1.3.1-2 Prompt for load parameters confirmation

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>23</b> of <b>81</b>

### 7.1.3.2 Self-Testing

After the pump is switched on, the pump will automatically perform a safety self-check. After the self-check is passed, user will hear two short beeps of “DiDi”. The system automatically enters to the next step. If the self-test fails, the system will display the following prompt message “System error detected. Please contact your customer service.”

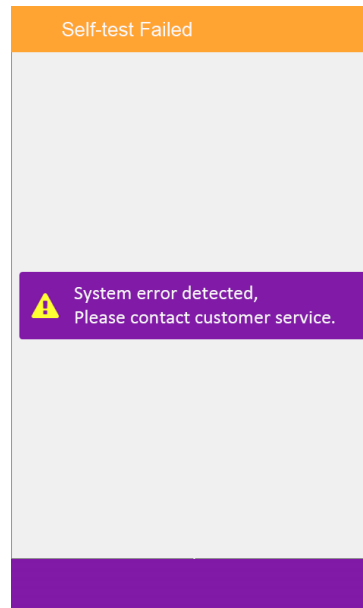


Fig 7.1.3.2-1 Self-Testing Failed



#### **Caution**

When self-testing failed, pump is not allowed to run for feeding, but user still can check other interfaces through Home button.

### 7.1.4 Feeding Set Identification System

To guarantee the feeding accuracy of the pump, only the feeding sets listed in chapter 9 “Dedicated Enteral Feeding Sets (Disposable)” are recommended. RFID identification technology when is enabled on the pump is one of the solutions for user to avoid using incorrect sets. The pump confirms whether it is a dedicated enteral delivery set by swiping the RFID tag on the feeding set.

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>24</b> of <b>81</b>

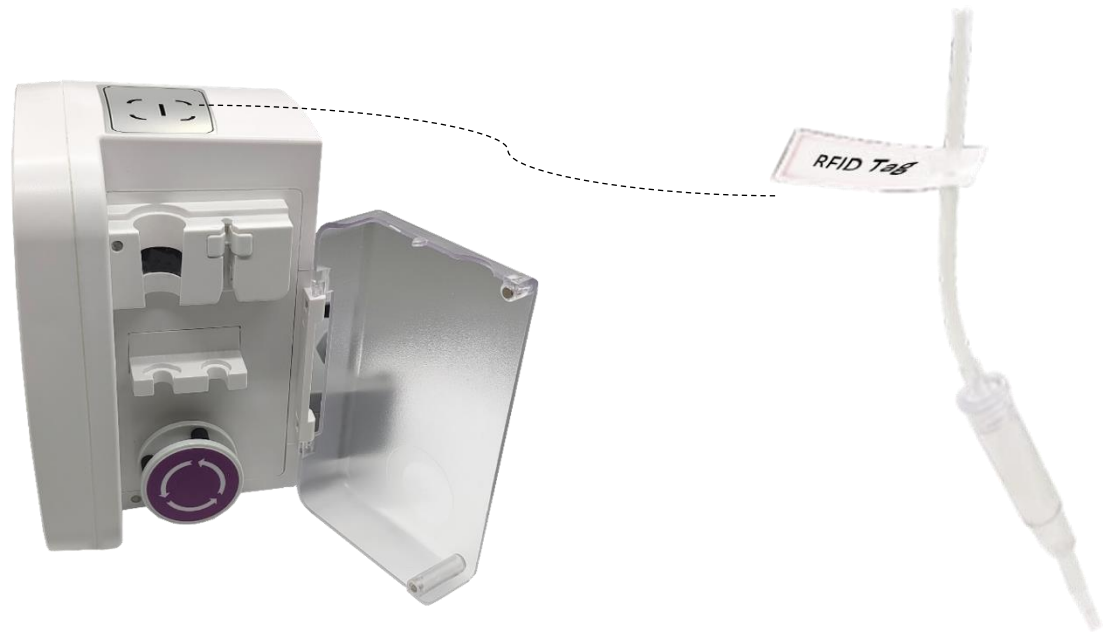


Fig 7.1.4-1 Swipe RFID Tag

There is a RFID tag on the feeding set located above the drip chamber. Swipe the RFID tag on the pump reader area for identification (Tag needs to touch the reader area until the beeps heard) The status bar displays the remaining use time, which lasts for seconds, then the pump can be used for feeding. After the RFID tag identified, keep the RFID tag away from the scanning area to avoid the pump to keep reading and beeps.

Correct Tubing, Remaining Time 23h59min

Continuous Mode

Rate <b>400</b> mL/h	Dose Setting <b>10</b> mL
Fed <b>0</b> mL	Time Left 00 h 01 min 30 s

Back Prime

Correct Tubing,  
Remaining time  
23h59min

Swipe the label of the feeding set after 3 hours again if user want to inspect the set used time.

⇒

Correct Tubing,  
Remaining time  
21h00min

Correct Tubing, Remaining Time 21h00min

Continuous Mode

Rate <b>400</b> mL/h	Dose Setting <b>10</b> mL
Fed <b>0</b> mL	Time Left 00 h 01 min 30 s

Back Prime

Correct Tubing,  
Remaining time  
21h00min

Fig 7.1.4-2 Correct Tubing Inserted



File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>25</b> of <b>81</b>

Note:

- 1) RFID tag should contact the scanning area directly.
- 2) User can swipe the RFID tag on the feeding set to check the remaining time of usage.

If a feeding set is not identified by the pump, the pump cannot be started for feeding. A prompt will pop up showing “Please swipe the RFID tag”

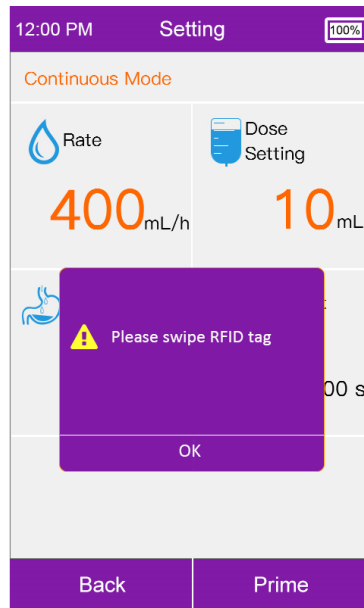


Fig 7.1.4-3 Swipe RFID Tag

After 24 hours from the first time of RFID tag swipe, the system will show prompt info on status bar that tubing used >24hrs.

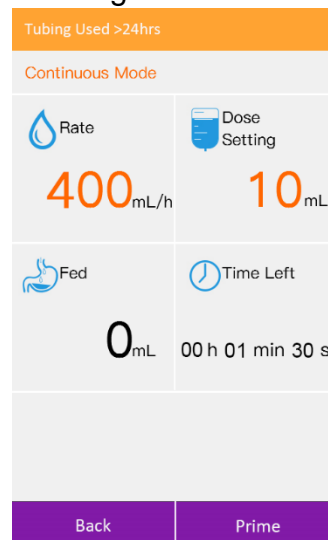


Fig 7.1.4-4 Tubing Used > 24hrs

Note:

The prompt, “Tubing Used > 24 hrs”. can only be cleared by installing a new feeding set.

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>26</b> of <b>81</b>

If the wrong feeding set (with RFID tag) or damaged RFID tag is used, the system will alert “Incorrect Tubing” on status bar.

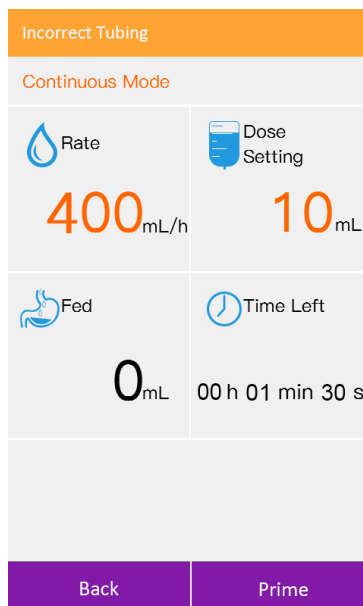


Fig 7.1.4-5 Incorrect Tubing



### Caution

Feeding set identification system is an optional function on the pump. User can switch on/off it in system maintenance page, referring to 7.3.5.2 RFID Switch. The default setting is switch on.

RFID tag can record the feeding set usage time. When set usage > 24 hours:

- 1) The prompt that the tubing used > 24 hrs. will always be rolling display on the status bar to remind user to replace a new feeding set.
- 2) It will not interrupt the feeding task until feeding complete alarm occurred.
- 3) If new feeding button is touched, it will end current feeding task. The pump cannot be used for feeding until a new feeding set is replaced to clear this prompt. If user press start/stop button, a prompt will pop up to remind “Please swipe RFID tag”
- 4) When alarm occurs, the alarm will come out first instead of the RFID prompt info. The RFID prompt will pop out once alarm is eliminated.

### 7.1.5 Load Feeding Set

1. Close the roller clamp and insert the drip chamber of the feeding set on the drip chamber socket.
2. Roll and stretch the silicone tube around the rotor, seat the adaptor in socket.
3. Insert downstream tube into slot.

The final assembly is as below:

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>27</b> of <b>81</b>

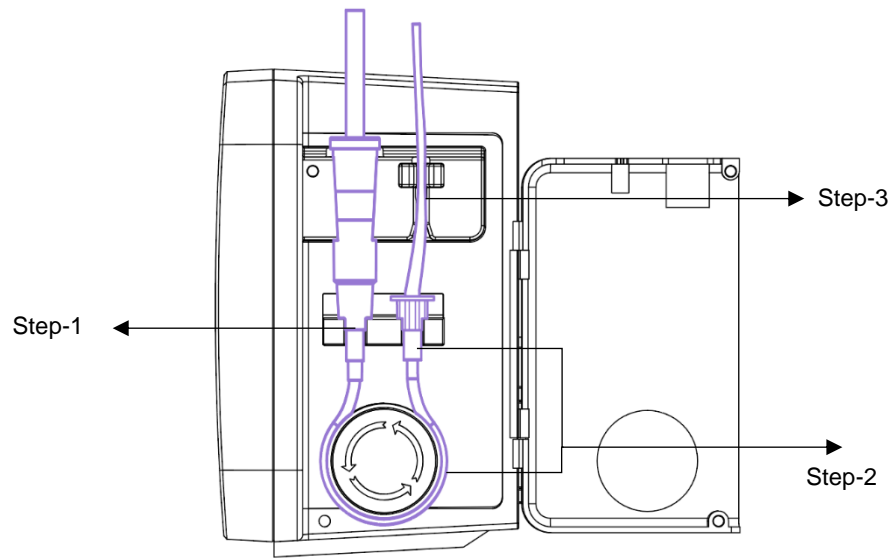


Fig 7.1.5-1 Tubing Installation Diagram



### Caution

Make sure that the drip chamber is inserted vertically and in position and the drip chamber is clean.

## 7.2 Feeding Operation Guidance

### 7.2.1 Feeding Mode Selection

On setting page, the user can switch the feeding mode in the following 2 methods:

Method-1:

Touch the “**Continuous Mode**” or “**Intermittent Mode**” on the screen to switch feeding mode.

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>28</b> of <b>81</b>

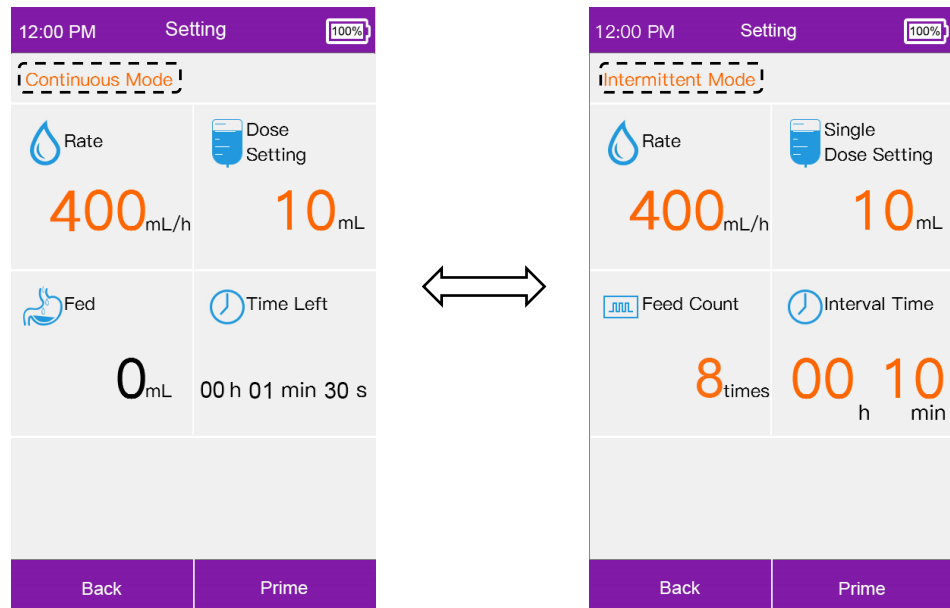



Fig 7.2.1-1 Switch Feeding Mode on Setting Page

Method-2:

Press Home button  to enter home page. Touch the “Continuous Mode” or “Intermittent Mode” button to select feeding mode.

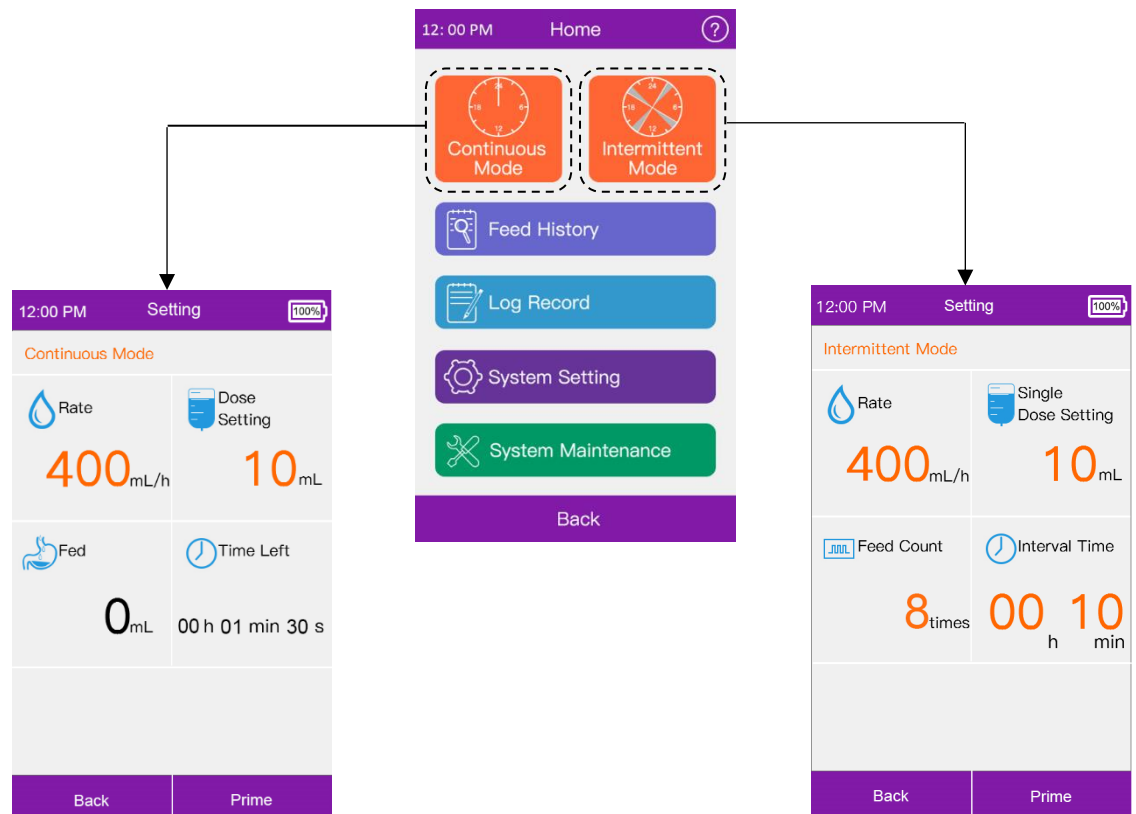


Fig 7.2.1-2 Select Feeding Mode on Home Page

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>29</b> of <b>81</b>

Note:

If a feeding task is stop and not finished, a prompt will pop up to remind user Switch feeding mode? Need user to double confirm.

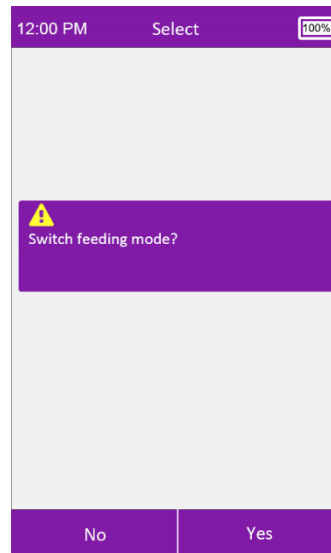


Fig 7.2.1-3 Switch Feeding Mode

### 7.2.2 Prime and Connect Feeding Set to Patient

Open the roller clamp of the enteral feeding set. Touch the “Prime” button on the setting page (Figure 7.2.1-1) and the following prompt will appear on the screen:

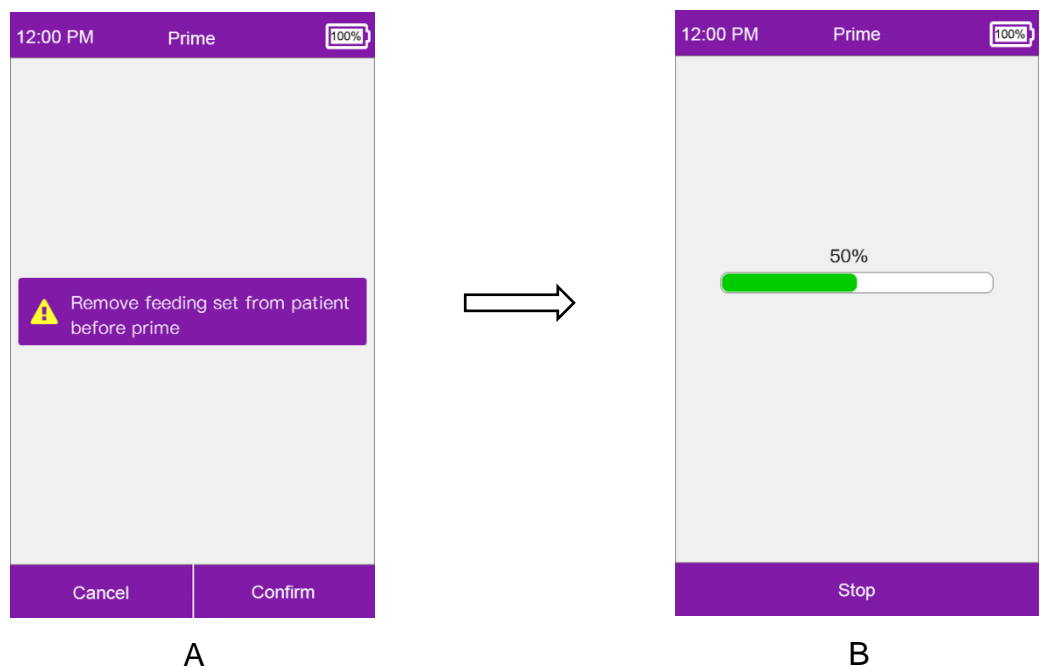


Fig 7.2.2-1 Prime

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>30</b> of <b>81</b>

Touch the “Confirm” button to start prime. After prime, the page returns to the setting page (Figure 7.2.1-1). Repeat the prime process until the distal connector leaking the liquid and then user can terminate prime by touching “Stop” button.

Connect distal connector of the feeding set to the patient’s gastric tube as shown below:

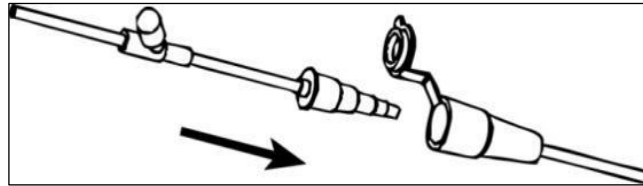


Fig 7.2.2-2 Connect to Patient



### Caution

Before the connection to the patient, it must be ensured that there is no air in the feeding set.

When the set has been primed and connected to the patient’s gastric tube, user can start feeding.

Note:

- 1) Prime rate is 1200mL/h and cannot be adjusted.
- 2) When prime is in processing, the function of infrared sensor, ultrasonic sensor will be bypassed, however the pressure sensor will keep monitor the tube pressure.
- 3) The prime warning page will prompt (Fig 7.2.2-1 A) in any conditions once Prime button is pressed, which is to prevent the injury to patient caused by mis-operation.

### 7.2.3 Set Feeding Parameters

Touch the numbers in **orange** to enter keyboard and type the feeding parameters as below (Fig 7.2.3-1). Touch the “Enter” button to confirm setting.

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 31 of 81

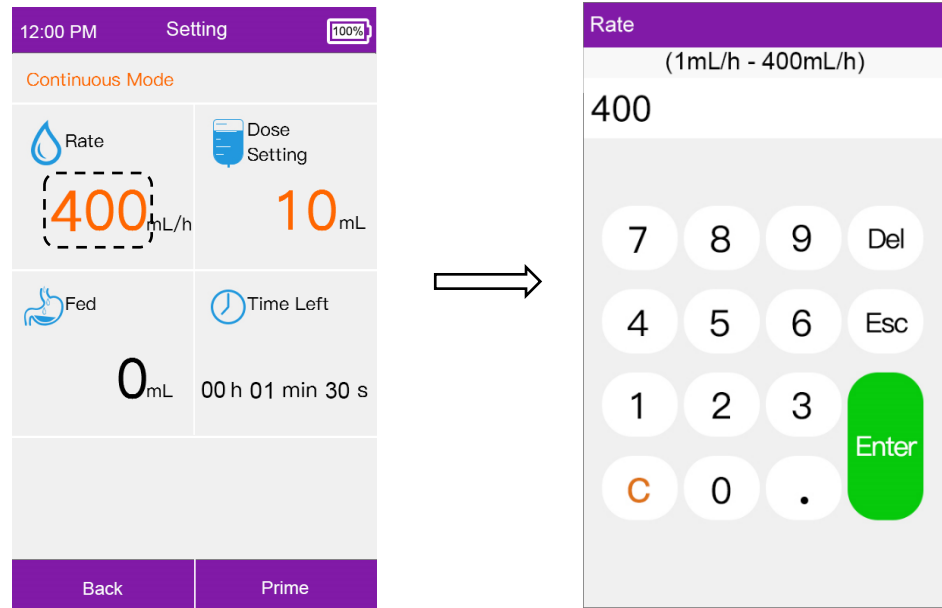



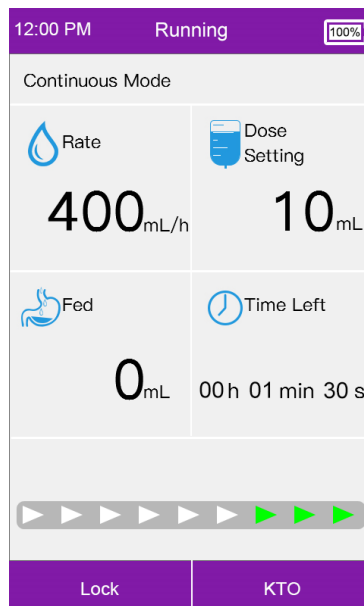
Fig 7.2.3-1 Set Feeding Parameter

In the same way, other parameters can be set.

Note: In the operation interface, all the contents in **orange** can be edited by touching. The contents in blank, such as “Fed”, “Time Left” are information automatically displayed.

## 7.2.4 Start Feeding

Press the “Start/Stop” button . The pump will run and display the set parameter and progress as shown in the figure below. The green arrow will be rolling to the right direction to indicate that feeding is running.



File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 32 of 81




Fig 7.2.4-1 Running Status

Regarding KTO function please refer to 7.2.8 KTO.

Regarding Lock function please refer to 7.2.9 Screen Lock.



### Caution

- 1) When pump is running, to avoid the user's mis-operation and affect the patient, "Power" button  and "Home" button  cannot be used during running status. User needs to press "Start/Stop"  button to stop feeding firstly before using them.
- 2) Long press the power button for 4 seconds still can switch off the pump for emergency.

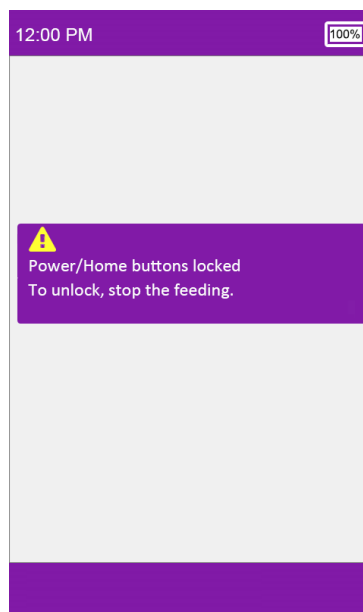


Fig 7.2.4-2 Home and Start/Stop Button Lock Prompt

## 7.2.5 Stop Feeding and Start a New Feeding

Press "Start/Stop"  button to stop feeding.

User can perform prime (Refer to the prime portion of 7.2.2 Prime section).

If user wants to terminate current feeding task, please touch "New Feeding" button to enter setting page for reset.



File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>33</b> of <b>81</b>

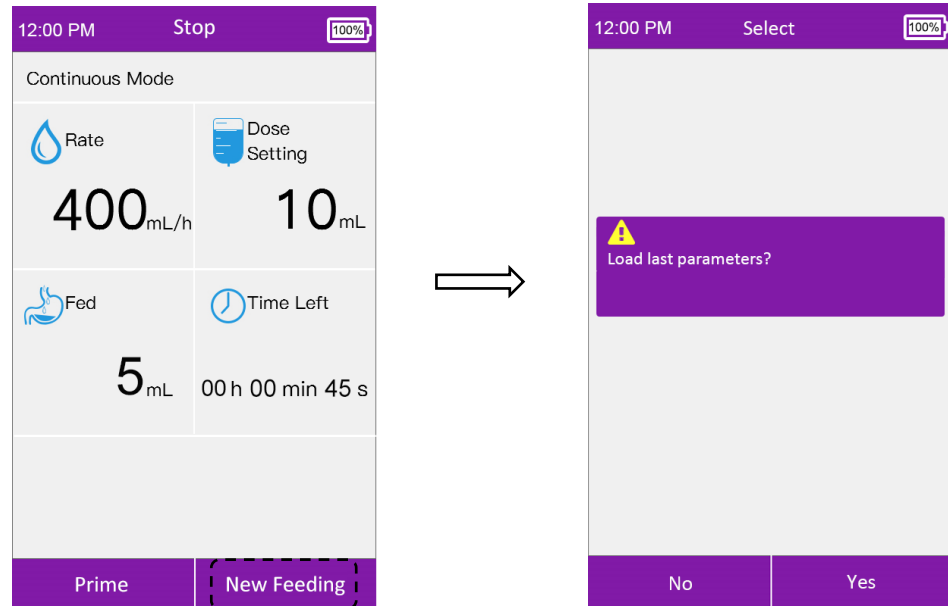


Fig 7.2.5-1 Stop Feeding and Start a New Feeding

Note: a prompt will pop up to ask whether to keep the last feeding parameters.

- 1) If selecting yes, the last feeding parameters will be loaded in setting page.

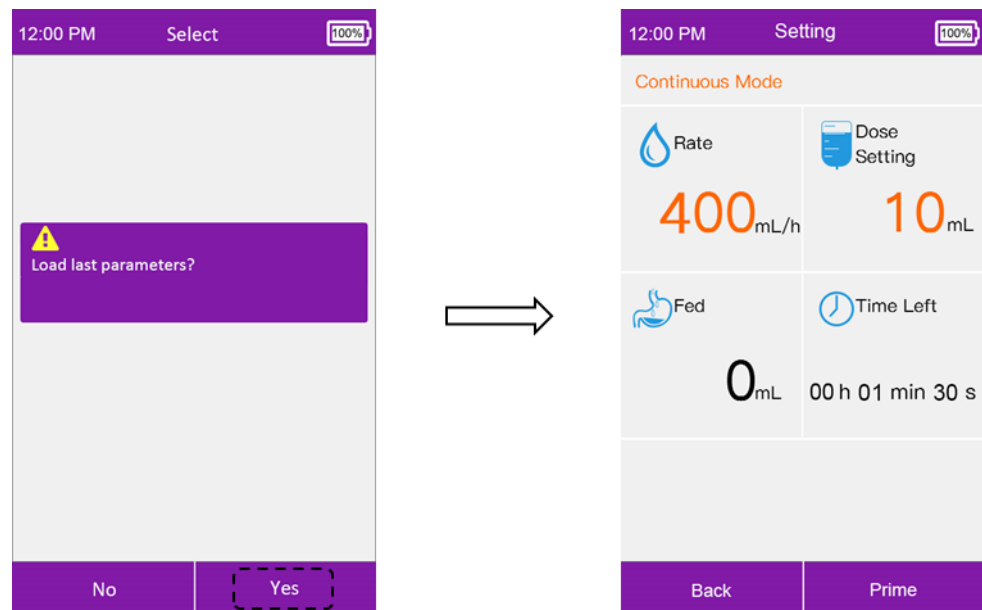


Fig 7.2.5-2 Load Last Feeding Parameters

- 2) If selecting no, the setting page will come out with feeding parameters in blank as "---". In this page, the blank can be touched and input with new parameters. It also supports feeding entire bag. Refer to 7.2.11 Feeding Entire Bag.

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>34</b> of <b>81</b>

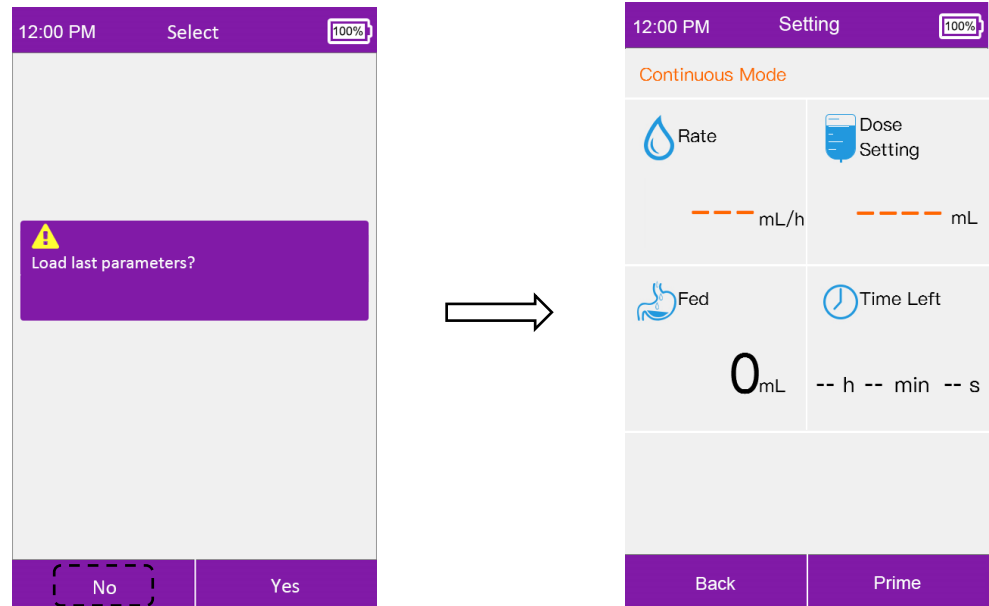


Fig 7.2.5-3 Not Select Last Feeding Parameters



### Caution

If user decides to start a new feeding, the “Fed” volume will be cleared. User can check the fed volume in feed history (Refer to 7.3.1 Feed History).

## 7.2.6 Interval Waiting

Under intermittent feeding mode, when each single feeding task finished, the system will start interval waiting. (Refer to 6.2.5 Intermittent Feeding Mode Icon Description)

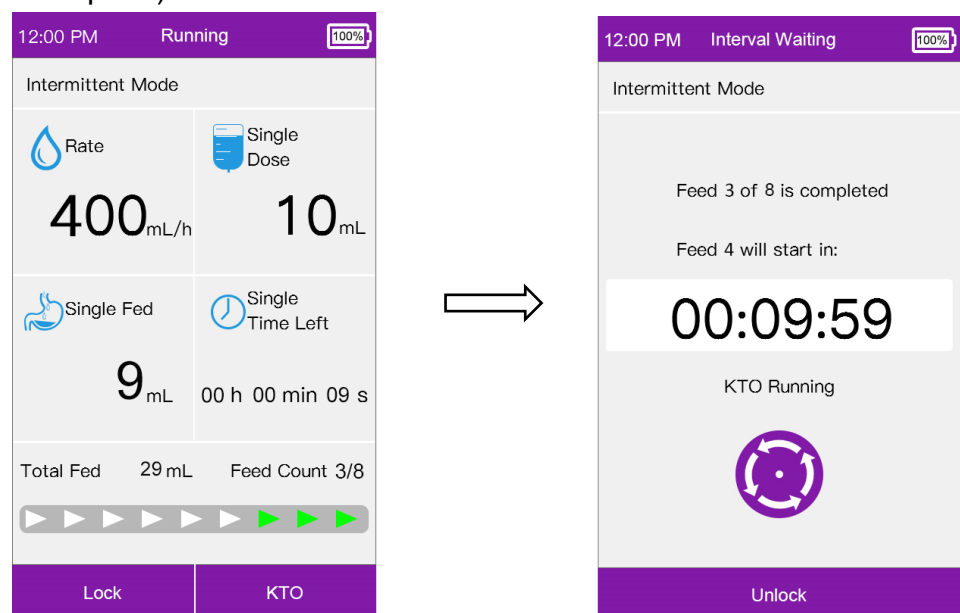


Fig 7.2.6-1 Interval Waiting

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>35</b> of <b>81</b>

For example, as the page above, when the last 1mL is fed, the 3<sup>rd</sup> feeding is finished, the pump start interval waiting. The page indicate the Feed 3 is completed from the programed 8 feeds; the next task Feed 4 will start when time count down to zero.

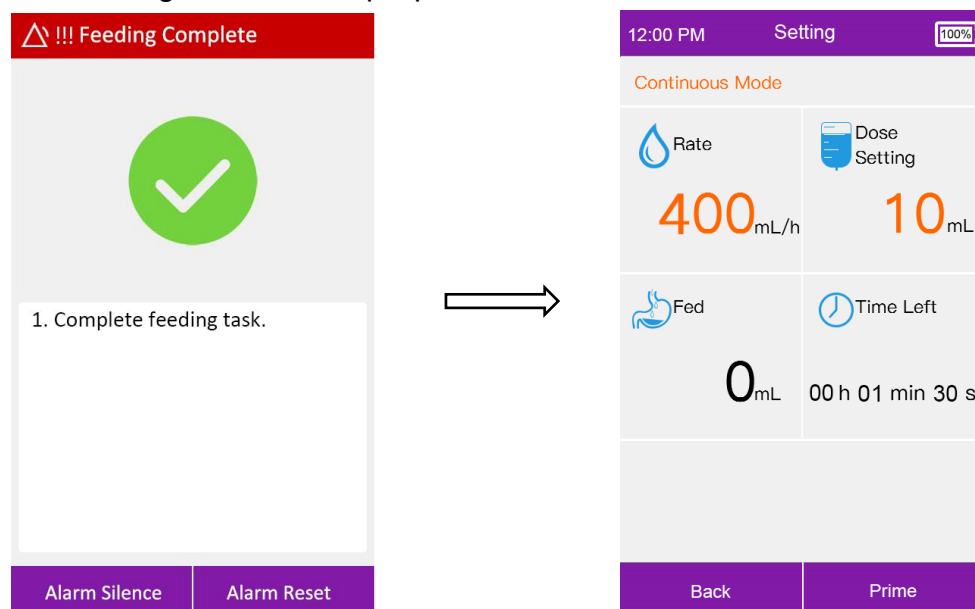


### Caution

KTO function will be performed during interval waiting if KT O between meals is switched on in system setting (Refer to 7.2.8 KTO)

## 7.2.7 Feeding Complete and Switch Off

When the fed volume reaches the dose setting volume, the system triggers the feeding complete alarm. Press the “Alarm Reset” button to eliminate the feeding complete alarm. The pump returns to the last setting page and then the next feeding task can be prepared.





7.2.7-1 Feeding Complete

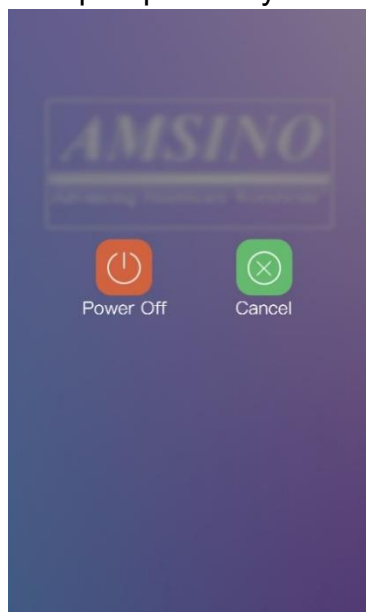
### Notes:

- 1) Continuous mode, the fed volume reaches dose setting volume, the feeding complete alarm will occur (Refer to 8.5 Feeding Complete).
- 2) Intermittent mode, when all the feeds are finished, the feeding complete alarm will occur (Refer to 8.5 Feeding Complete).
- 3) Intermittent mode, when each single feeding is finished, the feeding complete will not occur. However, an alarm “Single Dose Complete” will occur and remind user to flush the tubing per protocol, which will not interrupt the programmed intermittent feeding task.  
When user touches “Alarm Reset”, system will return to the interval waiting page. Refer to 8.14 Single Dose Complete Alarm

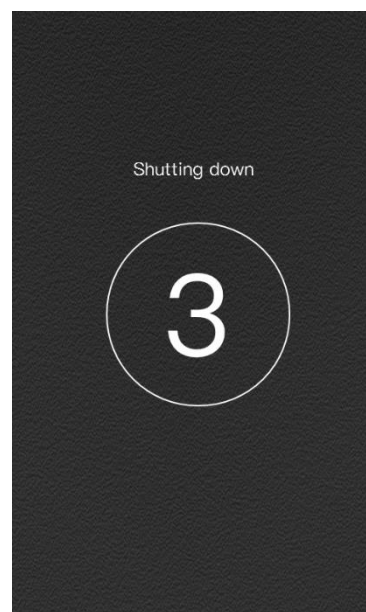
When the feeding task is completed. Unload the feeding set. Press the

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>36</b> of <b>81</b>

“Power” button  and touch the “Switch Off” button on the screen to turn off the pump. User also can hold the “Power” button  for 4 seconds to turn off the pump directly.



Press the power button to turn off the pump



Hold the power button to turn off the pump

Fig 7.2.7-2 Switch Off



### Caution

Close the roller clamp, disconnect the tubing from the patient’s enteral access before unloading tube from the pump. Otherwise, the free flow may occur by gravity causing over feeding and harm to patient if there is still nutrition in the container.

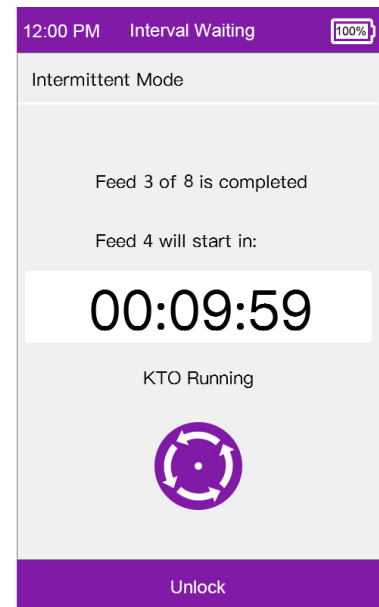
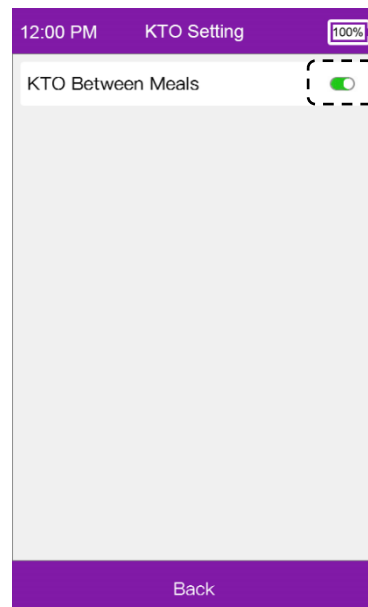
## 7.2.8 KTO

The Keep Tube Open (KTO) function within the pump will help prevent a blockage of the feeding set by moving the feeding solution periodically within the tube. On regular intervals, calculated from the pump’s presently programmed feed rate, a small and clinically insignificant portion of feeding solution (0.2mL/bolus) is moved through the tube.

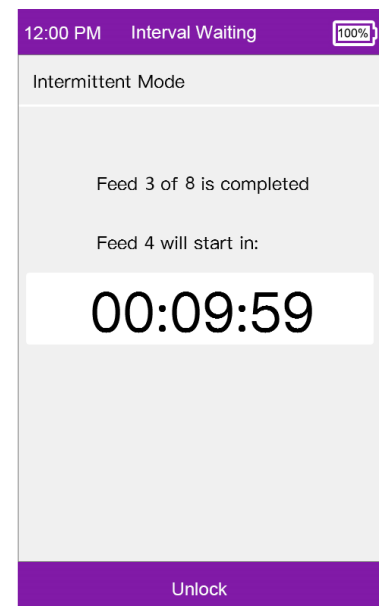
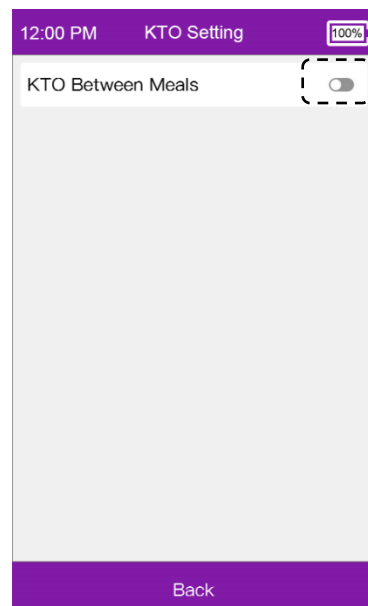
KTO includes Automatic KTO for intermittent feeding mode only and Manual KTO when pump is running for both continuous mode and intermittent mode.

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 37 of 81

Automatic KTO: When “KTO Between Meals” switched on in system setting, the pump will automatically run KTO during waiting intervals under intermittent mode.



7.2.8-1 KTO Between Meals Switched on for Interval Waiting



7.2.8-2 KTO Between Meals Switched off for Interval Waiting

#### Manual KTO:

Feeding task can be paused and auto resumed after set period.

It can be used for both continuous mode and intermittent mode that user want to pause some time. When pump is running, the user touches the “KTO” button (Fig 7.2.8-3 Running Page, Fig 7.2.8-4 Running page) and enters KTO setting

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>38</b> of <b>81</b>

page. Touch the **orange** number to edit KTO time and then touch "Start KTO". The feeding task stops and KTO runs.

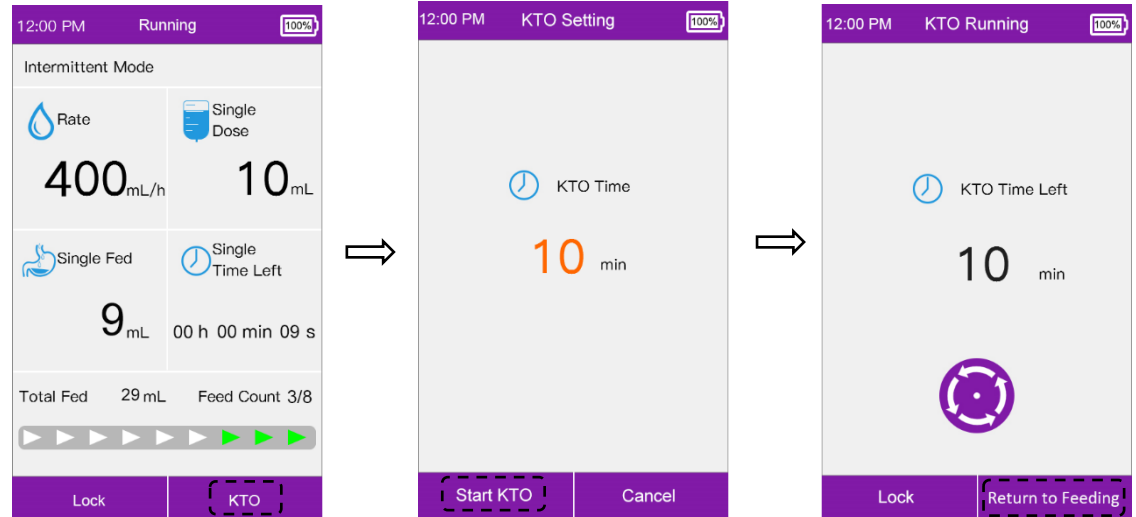


Fig 7-2-8-3 Manual KTO for Continuous Mode

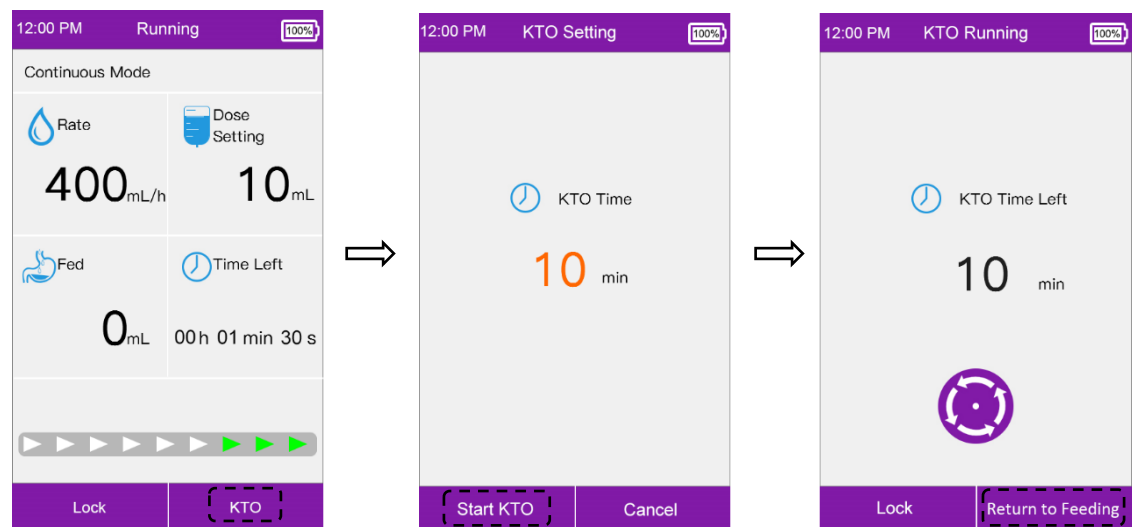


Fig 7-2-8-4 Manual KTO for Intermittent Mode

When KTO time reached, the pump will continue the unfinished feeding task.

Note:

- For manual KTO, KTO time can be set from 5 ~ 240 mins.
- For automatic KTO under intermittent mode, KTO time equals to the interval waiting time.
- If KTO time/Interval Waiting time > 30mins, 0.2ml bolus is run every 30 mins.
- If KTO time/Interval Waiting time ≤ 30mins, 0.2mL bolus is run one time in the middle of time window. For example, when KTO time is set as 20 mins, 0.2mL bolus is run when KTO time goes 10 mins.

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 39 of 81



### Caution

The amount of delivered fluid during KTO is monitored, tracked, and calculated into the final feed volume totalizer amounts displayed to the user. Displayed volume is actual and programmed volume.

## 7.2.9 Screen Lock

To avoid the user accidentally touching the wrong key, accidental input, or erroneously changing pump settings, the pump enters the screen lock status when running. The start time is according to the “Auto-Lock Time” set in the system setting. When the screen locked, both the touch screen and physical buttons cannot be used.

- To set “Auto-Lock Time” in system setting refers to 7.3.4.3 Auto-Lock Time Settings
- Another way is to touch the "Lock" button on the running page, and the pump will enter the lock screen status.

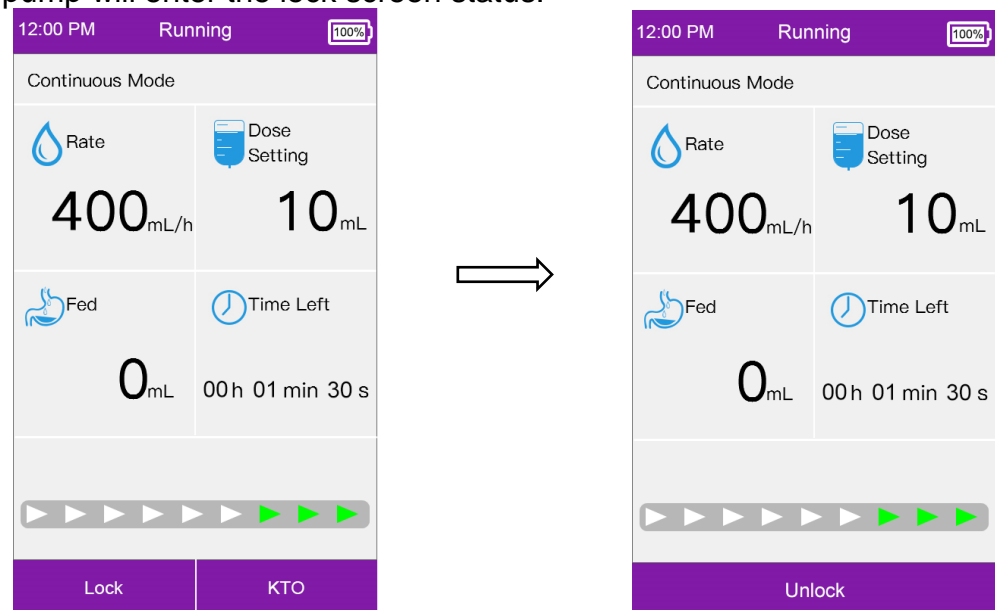


Fig 7.2.9-1 Screen Lock

Unlock:

- 1) When the lock screen encounters an alarm, it will be automatically unlocked.
- 2) Touch the "Unlock" button on the running page. A prompt page appears as in the figure below. Touch "Yes" button to unlock the screen.

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>40</b> of <b>81</b>

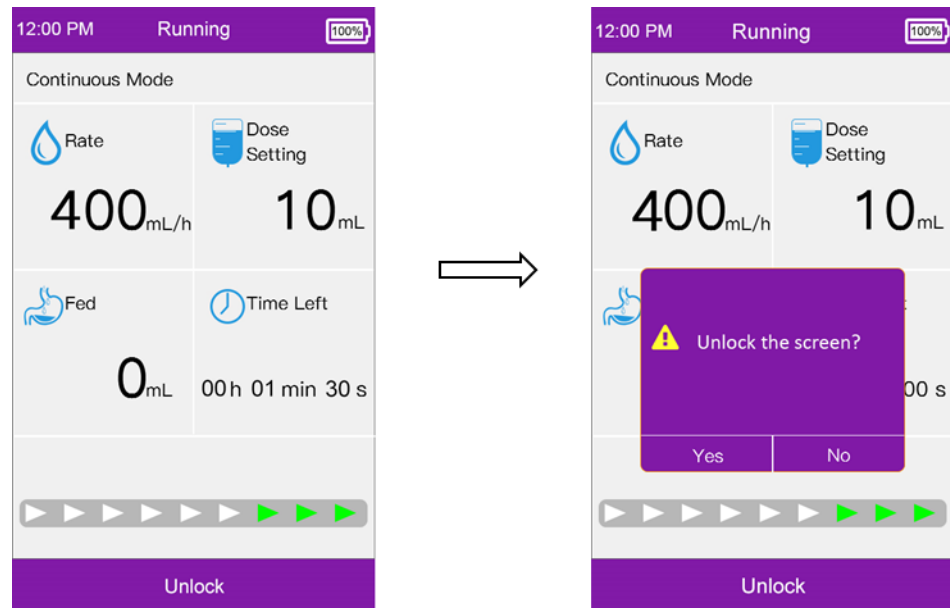


Fig 7.2.9-2 Screen Unlock

Note: If users press the Start/Stop button, Home or Power button when screen is locked, a prompt will pop up the remind for 2-3 seconds. Unlock the screen to operate the pump if needed.

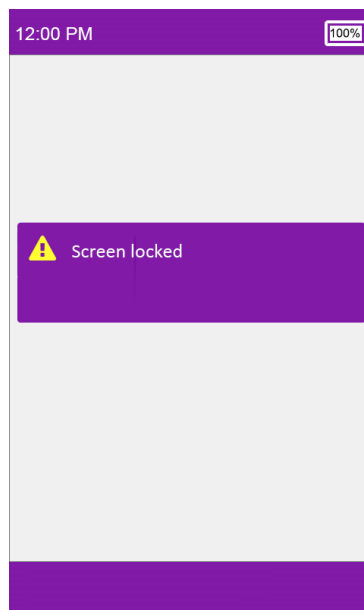


Fig 7.2.9-3 Screen Locked Prompt

### 7.2.10 Parameter Out of Range

When the parameters input is out of the range specified in display, a prompt will pop up in 2~3 seconds to remind user that “Invalid Entry – numbers entered are outside of allowable range”.



File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 41 of 81

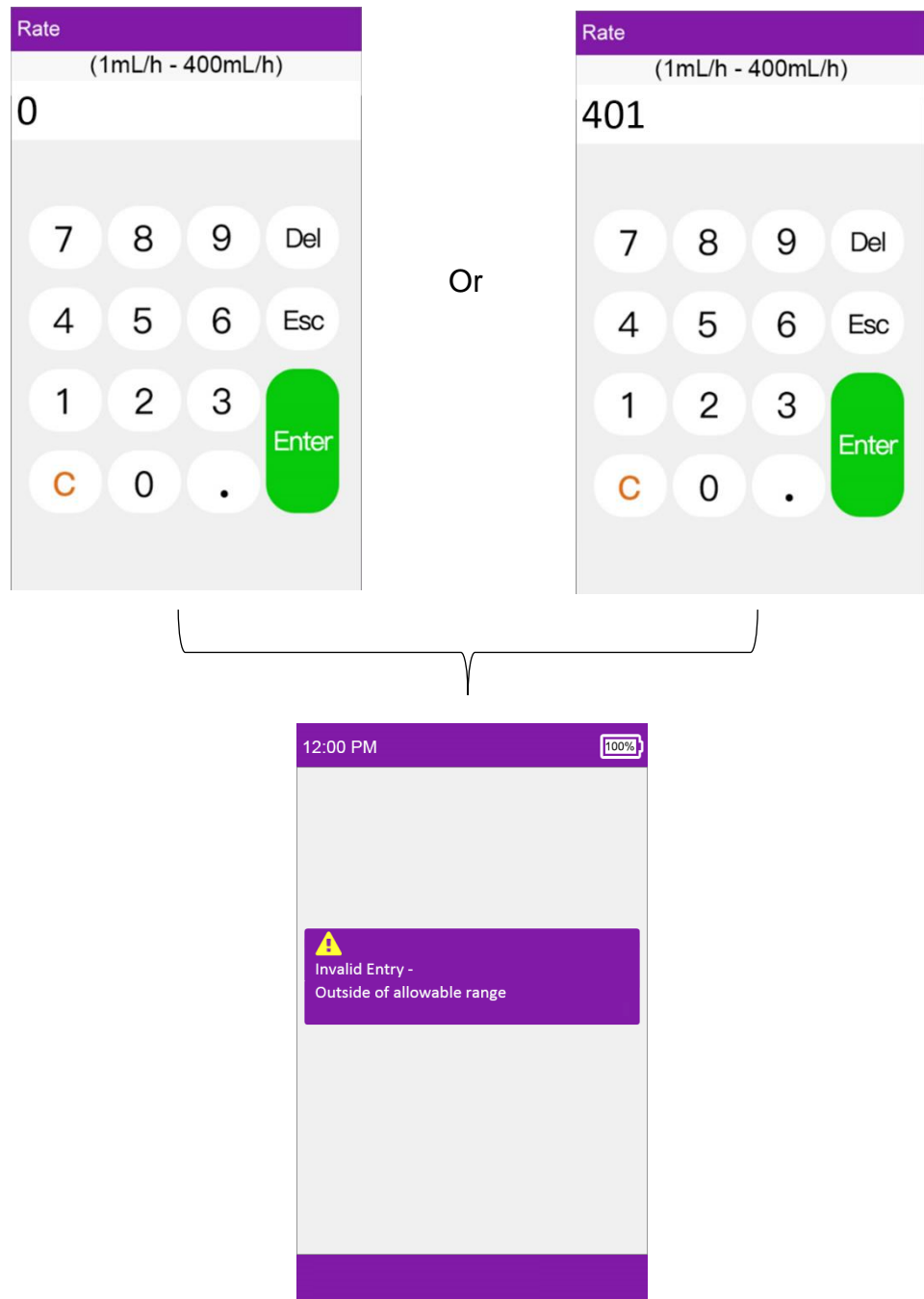


Fig 7.2.10 Invalid Entry Prompt

Note: Invalid entry prompt includes the rate, dose, feed count, interval time, KTO time setting etc.

### 7.2.11 Feeding Entire Bag

When solution bag is empty, Upstream Tube Alarm (display contents include Bag Empty) will occur.

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>42</b> of <b>81</b>

For entire bag feeding, it can be run under continuous mode. There are two ways to set entire bag feeding.

- Route 1: Switch on the pump, a prompt will pop up to ask user if to keep the last feeding parameters.
- Route 2: Touch “New Feeding” button to start a new feeding task, a prompt will pop up to ask user whether to keep the last feeding parameters.

In both conditions, selecting “No”, set Rate setting only, keep Dose Setting as “---”, the pump run for Entire Bag Feeding under this program.

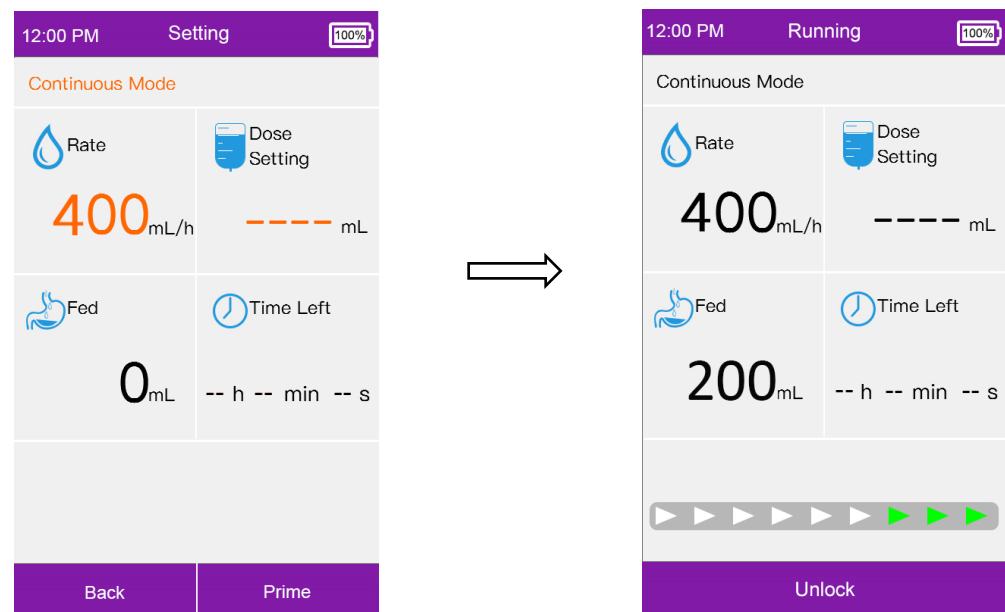


Fig 7.2.11 Feeding Entire Bag



### Caution

Upstream alarm may be caused by other reasons. For details of Upstream Tube Alarm, refers to 8.1 upstream tube alarm.

## 7.3 Other Functions

### 7.3.1 Feed History

Touch "Feed History" button on the home page to check feeding record.

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>43</b> of <b>81</b>

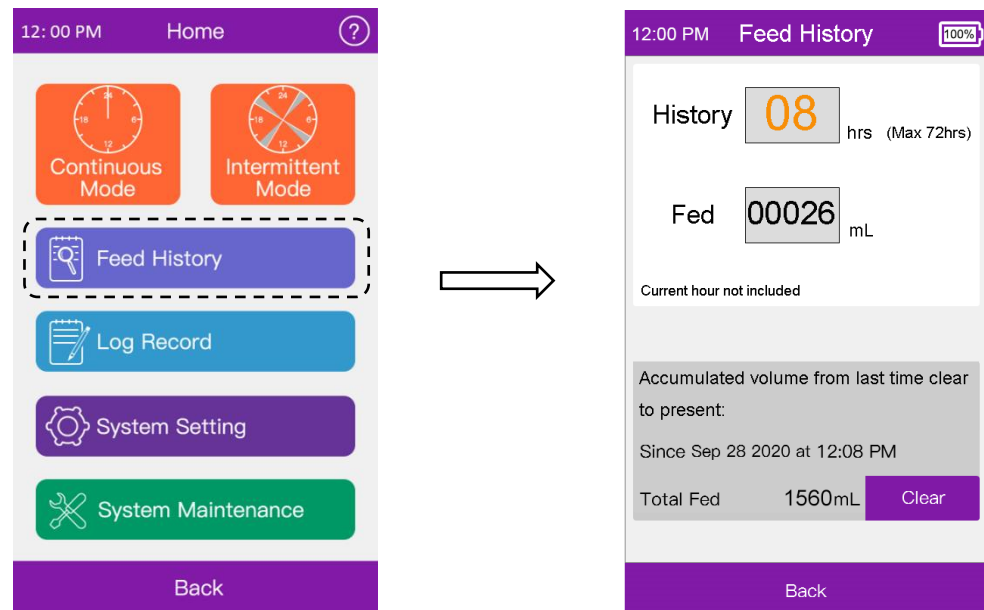
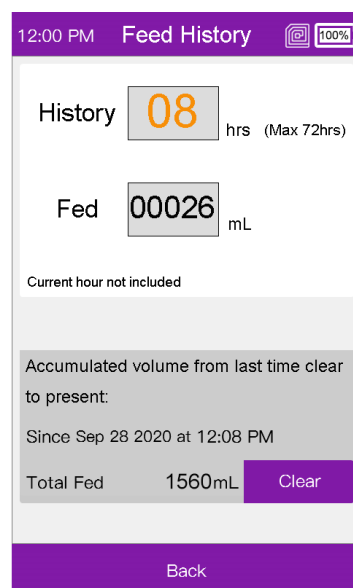


Fig 7.3.1 Feed History



⇒ A maximum of 72 hours of feeding history can be retrieved, excluding data from the current hour. Input hour number (1-72) in the upper "History" window by touching the **orange** number to check the fed volume during the time range.

⇒ The Total Fed volume from the time when the data was cleared. The data is real-time record. It's normally cleared for a new patient or before a new feeding.

Note: The 72-hour history includes time when the pump is powered off.

### 7.3.2 Log Record

Touch "Log Record" button from the home page to query operation and alarm records. The pump can save approximately 10,240 logs. When the memory is full, the latest 2048 logs still will be saved. but earlier log records will be deleted so that the pump can keeps saving the latest log records.

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 44 of 81

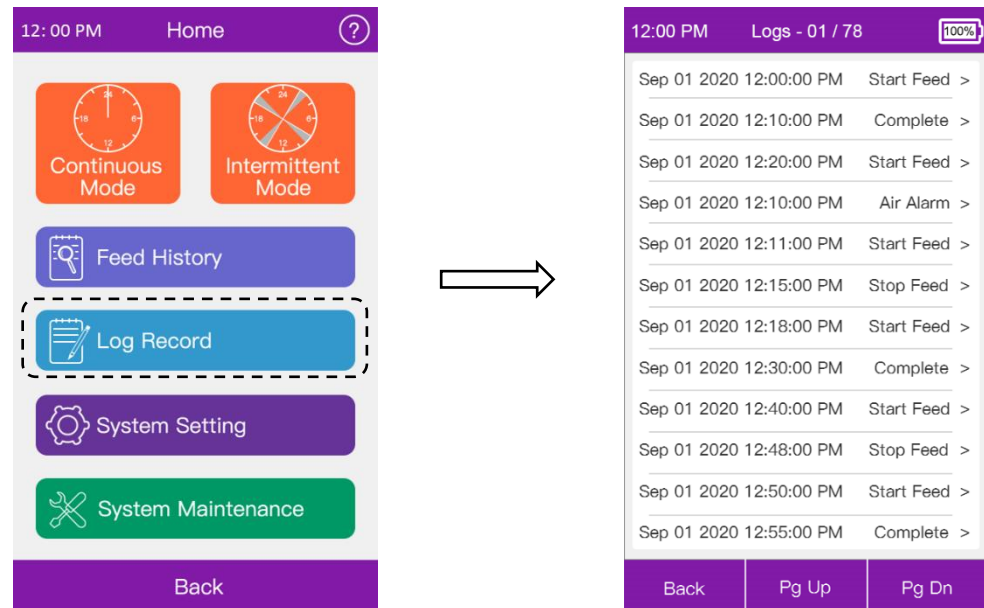



Fig 7.3.2 Log Record

### 7.3.3 Quick Guidance

Touch the icon  on the status bar on the home page (Refer to 6.2.2 System Icon Description) to enter the quick guidance page. It can help user learn to quickly set up the pump.

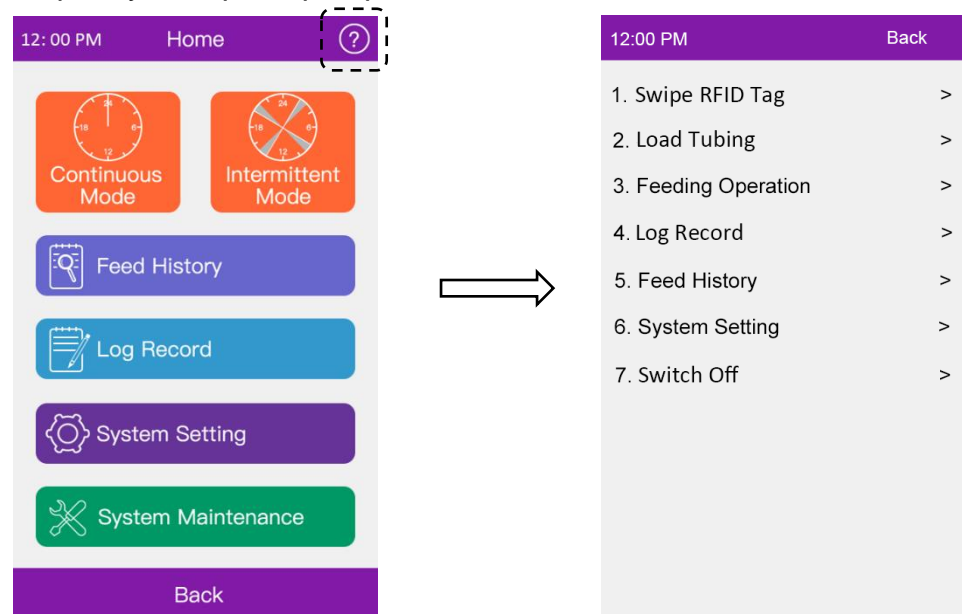


Fig 7.3.3 Quick Guidance

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 45 of 81

### 7.3.4 System Setting

Touching the "System Settings" button on the "Home" page leads into the interface for settings of screen brightness, alarm volume, lock screen time, date, and time etc.

Note: English is the default language in the pump. There is no entry in the pump language setting.

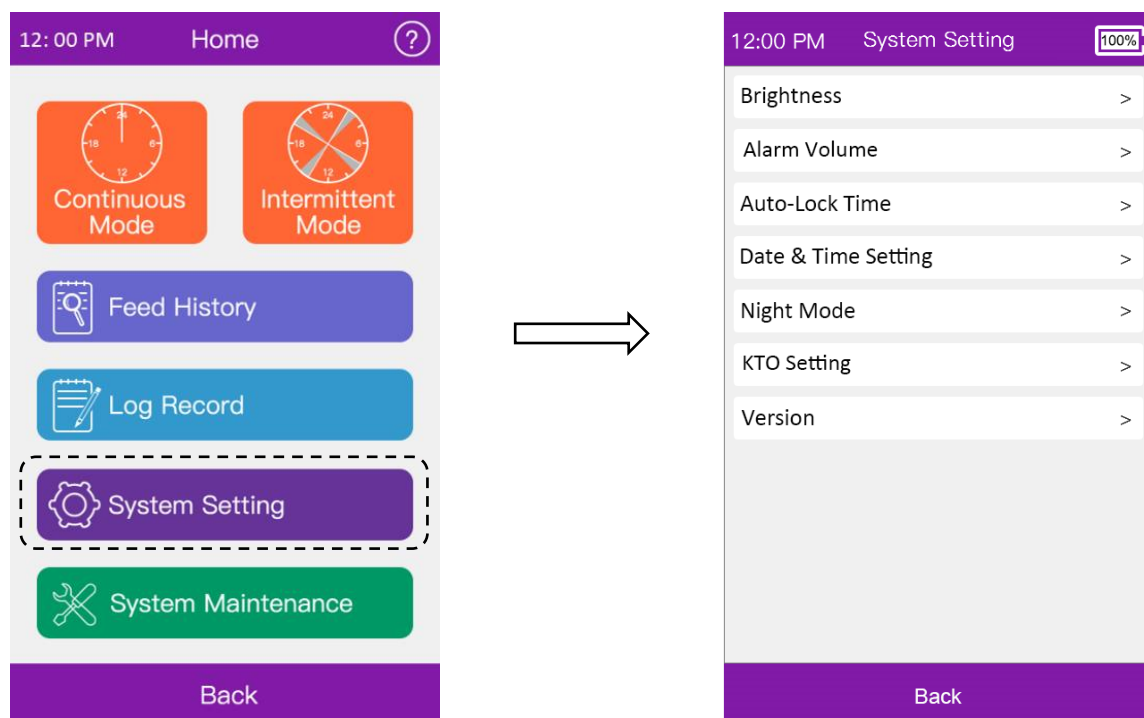


Fig 7.3.4 System Setting

#### 7.3.4.1 Brightness

The pump provides 8-level brightness settings. Touch the blocks of each level to set brightness, then touch "Confirm " button to save the setting, otherwise system will restore the original brightness. From level 1 to level 8, the brightness increases in sequence and level 8 is the maximum brightness.

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 46 of 81

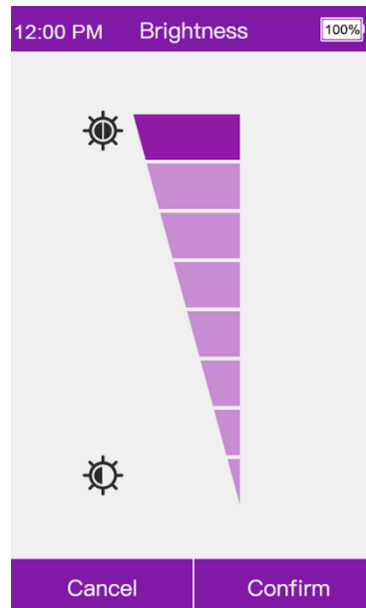


Fig 7.3.4.1 Brightness

#### 7.3.4.2 Alarm Volume

The pump provides 5-level alarm volume settings. The setting method can be referred to the brightness setting. From level 1 to level 5, the volume increases in sequence and level 5 is the maximum volume.

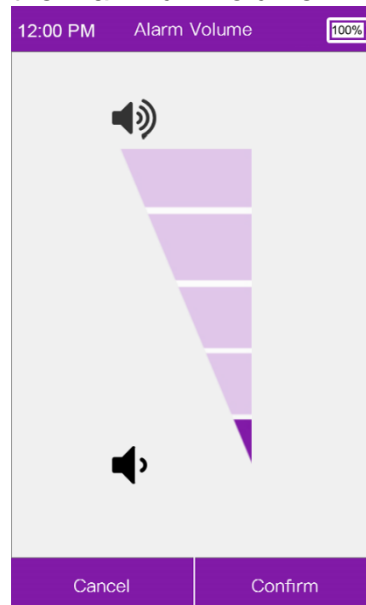


Fig 7.3.4.2 Alarm Volume

#### 7.3.4.3 Auto-Lock Time

The pump provides 5-level settings for screen automatic lock time. From level 1 to level 4, the waiting time to auto-lock screen increases in turn and level 5 is to turn off the screen lock function.

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 47 of 81

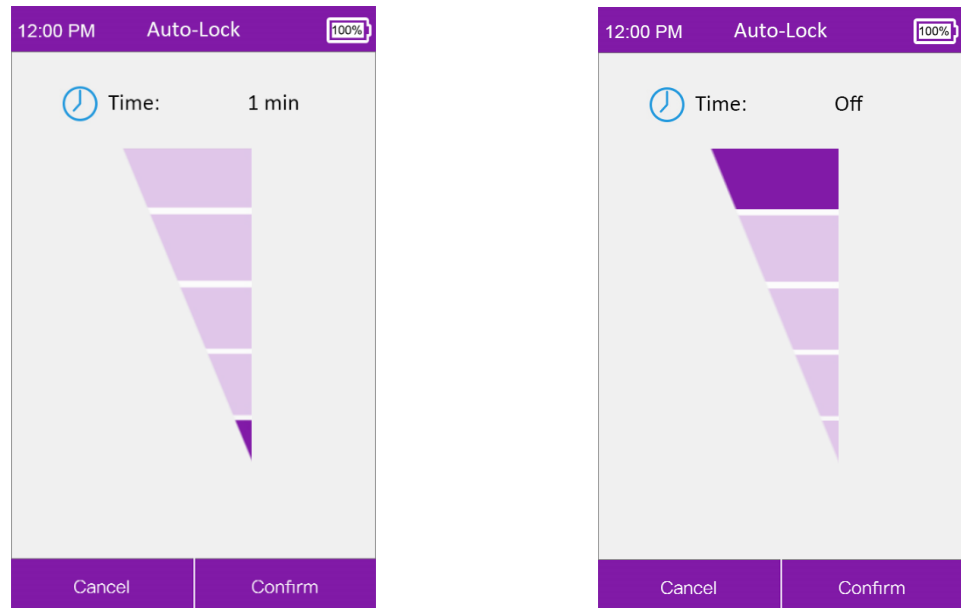
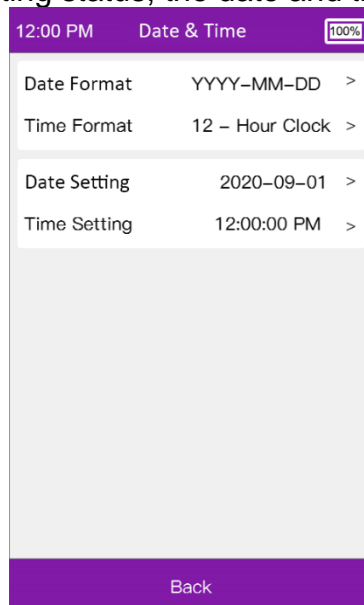


Fig 7.3.4.3 Auto-Lock Time

#### 7.3.4.4 Date & Time Setting

Enter "Date & Time settings" page from the "System Settings", touch "Date Settings" or "Time Setting" to set the date or time and touch the "Confirm" button to save it.

Note: when pump is in setting status, the date and time can be modified.



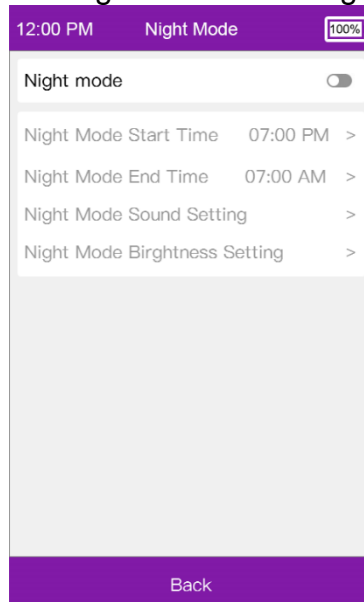
7.3.4.4 Date / Time Setting

#### 7.3.4.5 Night Mode

Enter the "Night Mode" page from the "System Settings". Touch the on/off button to switch on/off night mode.

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 48 of 81

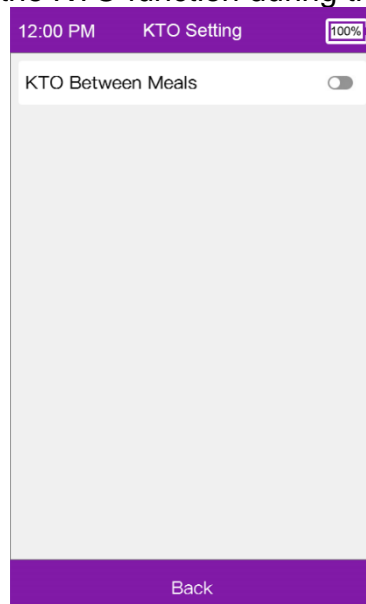
Users can set the start time and end time of the night mode, as well as the alarm sound level and screen brightness for the night mode.



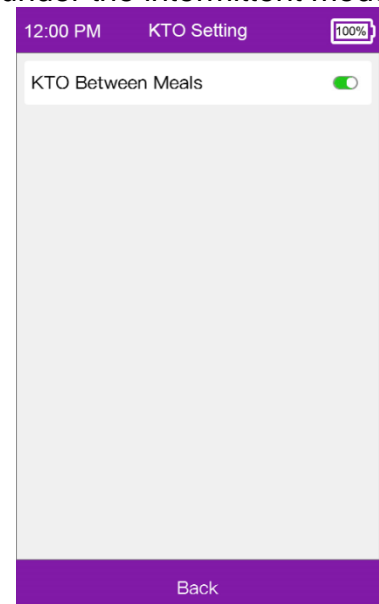
7.3.4.4 Night Mode

#### 7.3.4.6 KTO Setting

Enter the "KTO Settings" page from the "System Settings". User can switch on /off the KTO function during the interval waiting under the intermittent mode.



Switch Off



Switch On

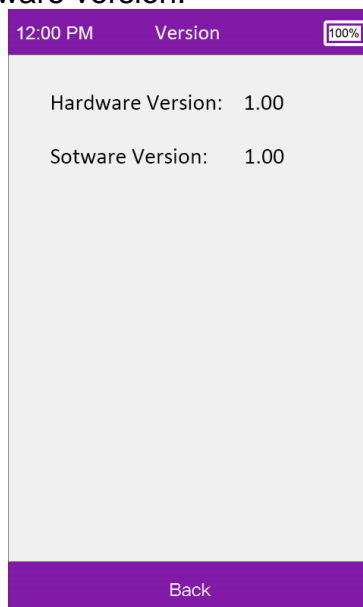
7.3.4.6 KTO Setting



File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 49 of 81

### 7.3.4.7 Version

Enter the “Version” page from the "System Settings". User can check the current software and hardware version.



7.3.4.7 Version

### 7.3.5 System Maintenance

System Maintenance section is only for product maintenance engineers. The authorization is managed via password from Amsino.

#### User Definition

Commands	Normal User	Maintenance Engineer
Serial Number Check	Yes	Yes
Product Name Check	Yes	Yes
Log (Event)	Yes	Yes
Feed History	Yes	Yes
System Setting	Yes	Yes
Brightness	Yes	Yes
Alarm volume	Yes	Yes
Auto-Lock time	Yes	Yes
Date & Time setting	Yes	Yes
Night Mode	Yes	Yes
KTO setting	Yes	Yes
Version	Yes	Yes
System Maintenance	No	Yes
Calibration	No	Yes
RFID switch	No	Yes
Sensor parameter	No	Yes
Self-test	No	Yes
Restore to factory setting	No	Yes
Update software	No	Yes
Sensor threshold	No	No

Note:

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>50</b> of <b>81</b>

1) "Yes" means the people who has the permission.

2) "No" means the people who doesn't have the permission.

Enter "System Maintenance" page from the home page, which can provide the functions such as calibration, RFID switch on/off, sensor parameter viewing, system self-test, and factory setting restoration. Maintenance engineers should provide the password before entering "System Maintenance".

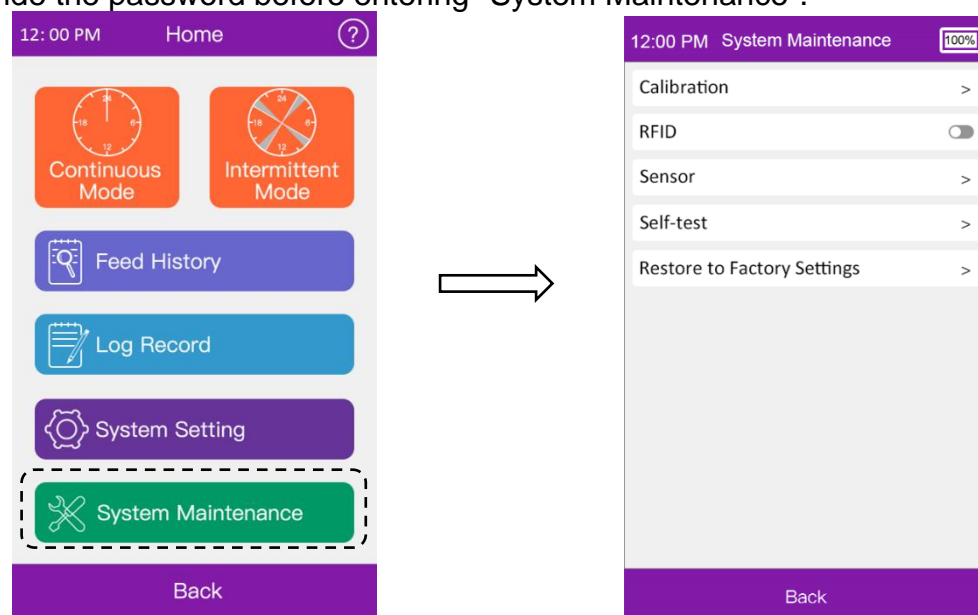


Fig 7.3.5 System Maintenance

### 7.3.5.1 Calibration

This pump can only be used with dedicated enteral feeding set. The pump has been calibrated before leaving the factory and can be used directly. To keep normal use, re-calibrate the pump every 12 months.

Carry out accuracy calibration according to the following steps:

#### 1. Items Required for Calibration

The calibration shall be carried out at room temperature.

No.	Items	Model	Quantity(pcs)	Remark
1	Enteral feeding pump	ASEP00	1	
2	Enteral feeding set	ENF-1004K2	1	
3	Feeding container	/		
4	Water	Distilled water	1	Density (g/mL) 0.998
5	I.V. pole	/	1	
6	Electronic balance	/	1	Accuracy:0.01g
7	Collecting container	About 10mL	1	

Note:

- 1) No model specified for feeding container, IV pole and electronic balance.
- 2) ENF-1004K2 is selected as representative. User also can choose other enteral feeding set in the list (refer to 9. Dedicated Enteral Feeding Sets (Disposable))

#### 2. Preparation for Calibration

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>51</b> of <b>81</b>

- 1) Close the roller clamp, connect the feeding set to feeding container and hang the container on IV pole.
- 2) Load the tubing and swipe RFID tag to identify the tubing.
- 3) Fill approximately 200ml distilled water into the feeding container, open the roller clamp and prime the feeding set. Make sure there is no air in the tubing and distal connector.
- 4) Adjust the feeding container height as fig 7.3.5.1-1.
- 5) Put the collecting container on the electronic balance. Hang the distal connector above the container, clear the balance to zero.

Refer to the fig 7.3.5.1-1 as below:

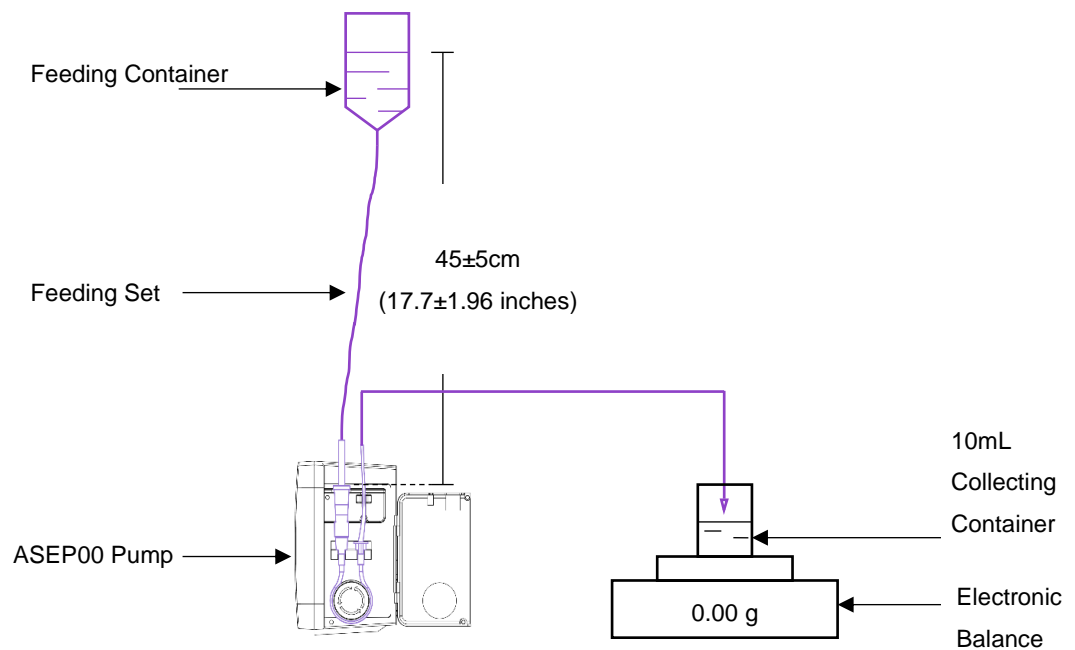


Fig 7.3.5.1-1 Calibration Preparation

### 3. Procedures for Calibration

- 1) Enter the calibration page. Select the rate range that needs to be calibrated by touching the "✓". For the selected ones, "✓" turns green.
- 2) Each rate range has a corresponding accuracy factor. The testing of accuracy calibration for each rate ranges shall be performed separately.

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>52</b> of <b>81</b>

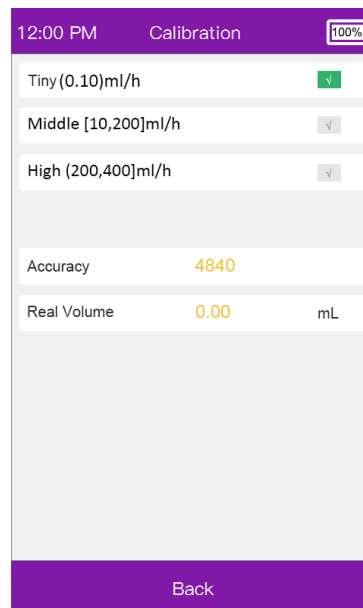



Fig 7.3.5.1-2 Calibration Page

- 3) Press the "Start/Stop" button . The pump will run automatically until progress bar to 100%. Then it returns to the calibration page.

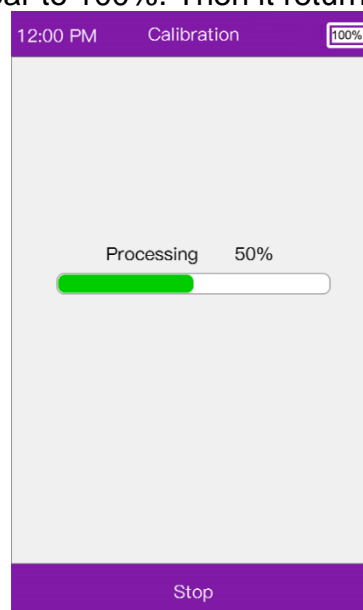


Fig 7.3.5.1-3 Calibration Running

- 4) Read the electronic balance weight and calculate the real volume via the following formula.

$$V = \frac{M}{\rho}$$

M: electronic balance reading (g)

ρ: distill water density (0.998 g/cm<sup>3</sup>)

V: real volume (ml)

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>53</b> of <b>81</b>

- 5) For example, V=2.55ml after calculation. Input 2.55 into the space of Real Volume. The pump may calculate and update the accuracy factor from 4840 to 4745 automatically as figure below.

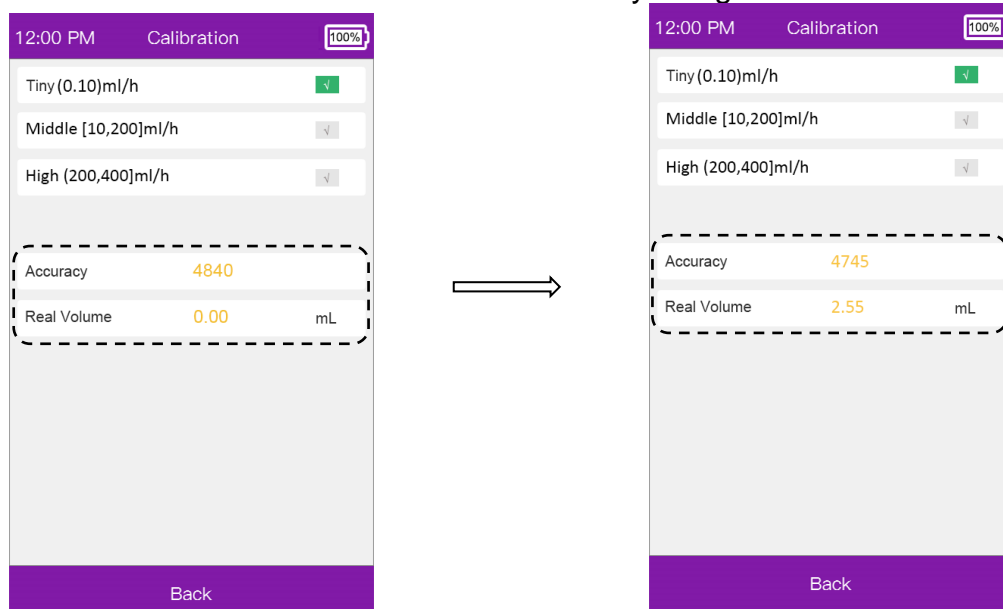


Fig 7.3.5.1-4 Accuracy Factor Updated



### Caution

Only trained personnel can perform pump calibration.

### 7.3.5.2 RFID Switch

Touch the RFID switch and enter the password to switch on/off the RFID identification of the dedicated feeding set.



### Caution

To avoid using incorrect tubing for the pump, there is a separate password for RFID switch function. Only authorized person can switch on/off the RFID identification.

### 7.3.5.3 Sensor

Enter the "Sensor" page to check the sensor real time return values, which may help technicians diagnose the issues of pump.

Note: The threshold of each sensor cannot be adjusted.

### 7.3.5.4 Self-test

The self-test has been performed during pump start up process. If the pump self-test fails, the feeding tasks cannot be performed.

The results of the starting self-test can be reviewed on the "System Self-Test" page under "System Maintenance". After reviewing, the pump maintenance engineer can touch the "Retest" button on the page to double check whether the pump is normal. If it still fails, please contact the customer service.

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>54</b> of <b>81</b>

### 7.3.5.5 Restore to Factory Setting

Touch "Restore Factory Settings" and enter the password to restore the screen brightness, alarm volume, system date and time, accuracy factor and other parameters to the system factory default values. System log records will not be deleted after factory setting restore. The follows items will be restored:

NO	Item	Restore to
1	Feeding Parameters	0
2	RFID	Switch On
3	Brightness	4
4	Alarm volume	1
5	Auto-Lock Time	Off
6	1) Night Mode	Switch On
	2) Start time	7:00PM
	3) End time	7:00AM
	4) Brightness	1
	5) Alarm volume	1
7	KTO (KTO between meals)	Switch on



### Caution

Please be cautious to restore factory settings.

## 8. Alarm

### Overview

The **AMSure**® Enteral Feeding Pump has alarms that are broken into three different priorities: High Priority, Medium Priority, and Low Priority. Light signals are listed as below. Alarm signal can be perceived correctly at distance of 4m from the alarm system. The delay time of triggering the alarm signal is not more than 2s.

- High Priority (Red Blinking Indicator Light),
- Medium Priority (Yellow Blinking Indicator Light),
- Low Priority (Solid Yellow Indicator Light)

These alarms occur based upon feedback from different sensor inputs from the pump. Key inputs for the alarms include the following:

- Motor Optocoupler Voltage
- Battery Voltage
- Upstream Infrared Sensor Voltage

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>55</b> of <b>81</b>

- Downstream Ultrasonic Sensor Voltage
- Pressure Sensor Voltage
- Microprocessor Timer
- Microprocessor handshake Voltage

**The breakdown for each alarm is as follows:**

- No Operation Alarm

Sensor Input: Microprocessor Timer

The pump uses the microprocessor timer to know when certain time of inactivity has elapsed.

- Upstream Tube Alarm

Sensor Input: Infrared Sensor Voltage.

The pump determines there is an upstream tube alarm if the upstream sensor voltage drops below the set minimum voltage level for certain time.

- Motor Error Alarm

Sensor Input: Motor optocoupler voltage

Based on the change of motor optocoupler voltage to judge whether the motor is faulty.

- Downstream Tube Occlusion Alarm

Sensor Input: Downstream Pressure Sensor Voltage

The pump determines downstream tube alarm based upon voltage value levels it receives from the Downstream Pressure Sensor.

- Air in Line Alarm

Sensor Input: Downstream Ultrasonic Sensor Voltage.

The pump determines Air in line alarm based upon the voltage values it receives. The downstream Ultrasonic Sensor Voltage will drop to a set minimum voltage level for certain time.

- Free Flow Alarm

Sensor Input: Infrared Sensor Voltage

The pump determines Free Flow alarm when the sensor voltage will drop to a set minimum voltage level.

- Low Battery Alarm

Sensor Input: Battery Voltage

The pump determines if the battery reaches a set low voltage level, which cannot support running for 30 minutes. When this voltage level is reached, the alarm will activate.

- Out of Battery Alarm

Sensor Input: Battery Voltage

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>56</b> of <b>81</b>

The pump will alarm when the battery voltage reaches a set minimum level, which is not able to support 3 minutes running.

- Battery Degradation Alarm

Sensor Input: Battery Voltage

The pump will determine Battery Degradation Alarm when the battery voltage reaches a set minimum level after charging to the full capacity.

- Battery Error Alarm

Sensor Input: Battery Voltage

The pump will determine Battery Error Alarm when the battery voltage reaches a set minimum level or no battery voltage signal received, which means the battery loses function or is not connected.

- Total Power Failure Alarm

Sensor Input: Battery Voltage and Grid Voltage

The pump will determine Total Power Failure Alarm when no battery voltage and Grid voltage signals received.

- Communication Fault Alarm

Sensor Input: Microprocessor handshake Voltage

The pump will determine Communication Fault Alarm when no handshake Voltage received between Control CPU and Monitor CPU.

### **Fluid Occlusion/Air in Line Detection Overview**

The **AMSure**® Enteral Feeding Pump uses infrared sensor, pressure sensors for fluid detection. One sensor is positioned on the upstream side of the rotor and the other sensor is positioned on the downstream side of the rotor. The dual sensor system also provides the capability to distinguish between upstream occlusions, downstream occlusions. When an occlusion occurs in the tubing on the fluid supply side of the pump rotor, fluid will be evacuated from the upstream silicone tubing but not from the downstream tubing. In this scenario, the pump will continually detect fluid at the downstream sensor but detect no fluid at the upstream sensor. As a result, an Upstream Tube Alarm will be generated. When an occlusion occurs in the tubing on the patient side, the tubing at the sensor will expand improving the pressure signal at the pressure sensor. In this scenario, the pump will issue a Downstream Occlusion Alarm.

When there's air in the tubing moving forward, the air will go through the downstream tubing where the ultrasonic sensor located. In this scenario, the pump will initially detect fluid at the sensor, then observe a period where there is air at the downstream sensor or detect fluid at the sensor again, and then the air volume is calculated and recorded based on the flow rate and time. When this occurs, an Air in Line alarm will be generated.



File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 57 of 81

### Priority Handling of Alarms

In all cases, higher priority alarms are more important and override any lower priority alarm conditions. A lower priority alarm will never disable a higher priority alarm.

The High Priority alarms have same ranking. The latest alarm will not override the current alarm. When the earlier alarm is eliminated, the later alarm can be triggered if the alarm condition is still met.

There're three Medium Priority alarms. When there is a situation several medium priority alarms are occurring at the same time, the medium alarm will be triggered based on the ranking number listed in the table. The alarms are triggered as the sequence below:

Single Dose Complete>Low Battery = Battery Degradation

For alarms of Low Battery and Battery Degradation, when both happen, the latest alarm will not override the current alarm. When the earlier alarm is eliminated, the later alarm can be triggered if the alarm condition is still met.

The pump never changes the priority of alarms based on situational or environmental conditions. Alarm priority of the pump remains fixed. Additionally, the pump does not change Alarm Signal Generation Delay or Alarm Condition delay as a result of situational or environmental conditions. Finally, the pump does not change the characteristic of the generated alarm signals. Below is the listing of alarm priorities for the pump:

Ranking No.	Alarm	Priority	Latching or not
1	Upstream Tube Alarm	High	Latching
1	Downstream Occlusion	High	Latching
1	Free Flow	High	Latching
1	Air in Line	High	Latching
1	Feeding Complete	High	Latching
1	Out of Battery	High	Latching
1	Battery Error	High	Latching
1	Motor Error	High	Latching
1	Communication Fault	High	Latching
1	Total power failure alarm	Same sequence as High priority	Non-latching
2	Single Dose Complete	Medium	Non-latching
3	Low Battery	Medium	Non-latching
3	Battery Degradation	Medium	Non-latching

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>58</b> of <b>81</b>

4	No Operation	Low	Non-latching
---	--------------	-----	--------------



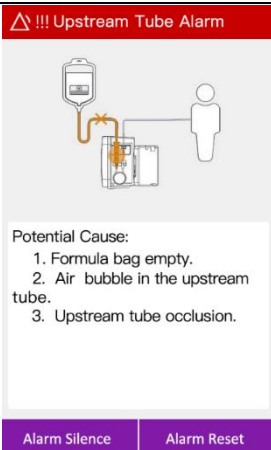
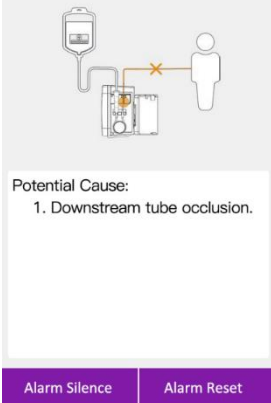
### Caution

**Latching alarm signal:** Alarm signal that continues to be generated after its triggering event no longer exists until stopped by deliberate operation action (press "Alarm Reset").

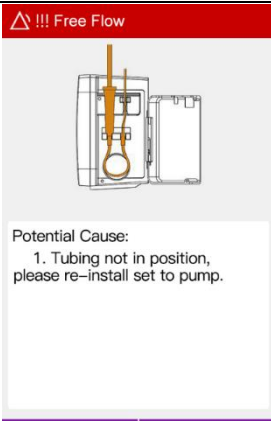
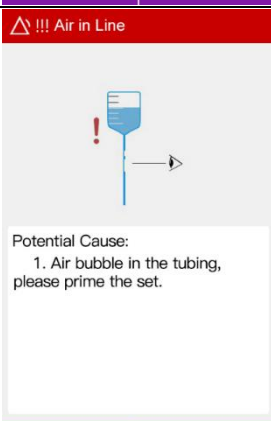
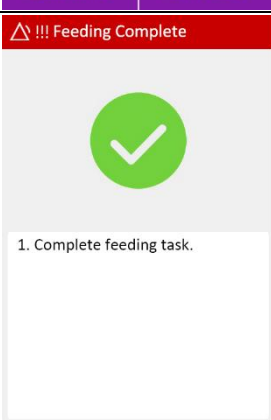

**Non-latching alarm signal:** Alarm signal that automatically stops being generated when its associated triggering event no longer exists.

Recoverable alarm sound: automatic recovery time is 2 mins since alarm muted.

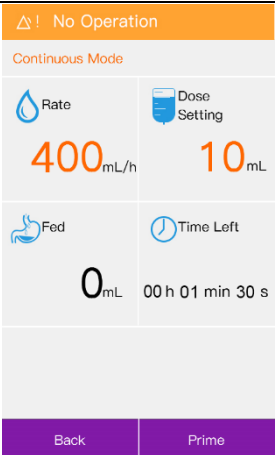
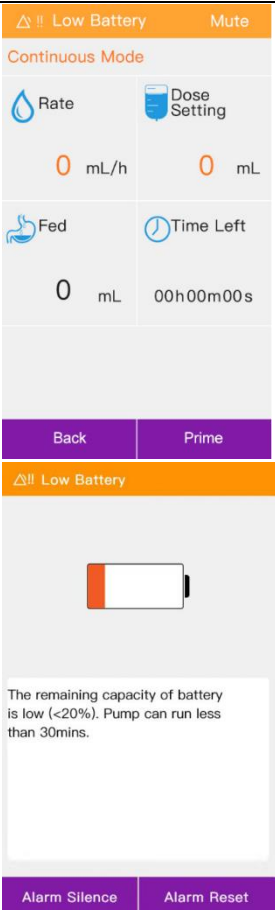
### Alarm Messages and Corrective Actions

No.	Display	Alarm	Solutions
8.1		<b>Upstream Tube Alarm</b>  Stops the feeding  Potential Cause: <ul style="list-style-type: none"> <li>• Formula bag empty</li> <li>• Air bubble in the upstream tube</li> <li>• Upstream tube occlusion</li> </ul>	<ul style="list-style-type: none"> <li>• Check whether the roller clamp of the enteral delivery set is open.</li> <li>• Release upstream occlusion.</li> <li>• Check whether the nutrition bag is empty.</li> </ul>
8.2		<b>Downstream Occlusion</b>  Stops the feeding  Potential Cause: <ul style="list-style-type: none"> <li>• Downstream tube occlusion</li> </ul>	<ul style="list-style-type: none"> <li>• Check if the downstream tubing is kinked.</li> <li>• Check if the feeding set or gastric tube is occluded.</li> <li>• Flush the tubing per protocol.</li> </ul>

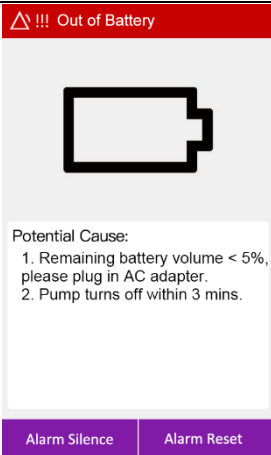
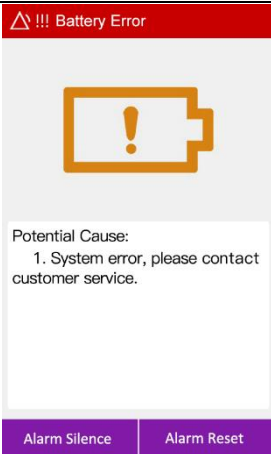
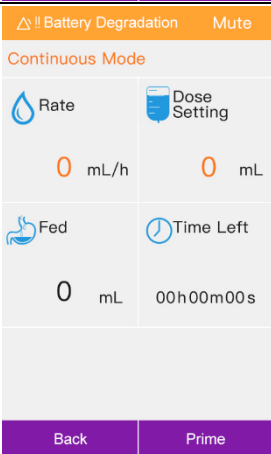
File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>59</b> of <b>81</b>

8.3	 <p>Potential Cause: 1. Tubing not in position, please re-install set to pump.</p> <p>Alarm Silence    Alarm Reset</p>	<p><b>Free Flow</b></p> <p>Stops the feeding</p> <p>Potential Cause:</p> <ul style="list-style-type: none"> <li>• Tubing is not in position</li> </ul>	<ul style="list-style-type: none"> <li>• Close the roller clamp on the feeding set.</li> <li>• Check if the silicone tube of the feeding set is in position. If not, please re-install the set to pump.</li> </ul>
8.4	 <p>Potential Cause: 1. Air bubble in the tubing, please prime the set.</p> <p>Alarm Silence    Alarm Reset</p>	<p><b>Air in Line</b></p> <p>Stops the feeding</p> <p>Potential Cause:</p> <ul style="list-style-type: none"> <li>• Air bubble in the tubing.</li> </ul>	<ul style="list-style-type: none"> <li>• To remove air bubbles in the feeding set, disconnect the set from the patient's gastric tube and prime the feeding set.</li> </ul>
8.5	 <p>1. Complete feeding task.</p> <p>Alarm Silence    Alarm Reset</p>	<p><b>Feeding Complete</b></p> <p>Stops the feeding</p> <p>Potential Cause:</p> <ul style="list-style-type: none"> <li>• A feeding task has completed</li> </ul> <p> <b>Caution</b></p> <ul style="list-style-type: none"> <li>• To unload the tubing, close the roller clamp, disconnect the tubing from the patient's enteral access and then unload the tube from the pump. Otherwise, the free flow may occur by gravity causing over feeding to harm patient.</li> </ul>	<ul style="list-style-type: none"> <li>• Reset the alarm for other operations.</li> </ul>

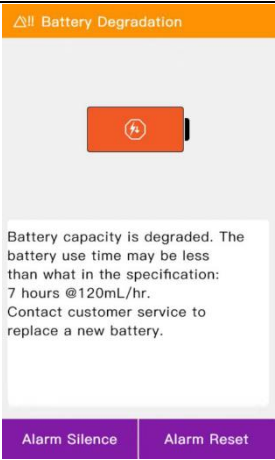

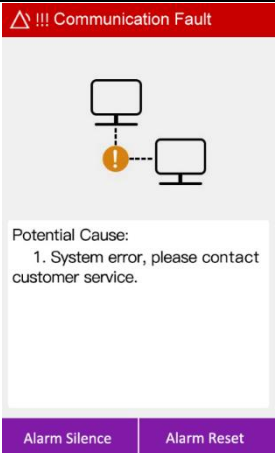
File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>60</b> of <b>81</b>

8.6		<b>No Operation</b>  All functions remain effective  Potential Cause: • When the pump is turned on and not running, there is not any other operations within 1min50s-2min, the alarm will be generated	• Any operations can eliminate this alarm.
8.7		<b>Low Battery</b>  Doesn't stop the feeding Pump keeps running < 30 mins  Potential Cause: • When the remaining capacity of battery is low (<20%), the alarm is triggered.	• Touch "Mute", a prompt page will pop up with detail information.  • Connect the pump to AC power supply.

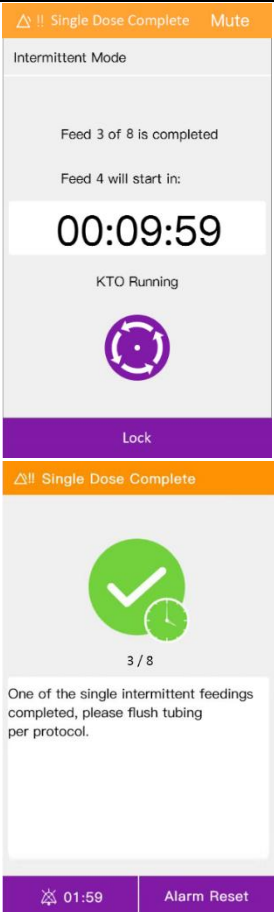
File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>61</b> of <b>81</b>

8.8		<b>Out of Battery</b>  Stops the feeding Pump turns off within 3 mins  Potential Cause: • When the remaining capacity of battery is almost exhausted (<5%), the alarm is triggered.	<ul style="list-style-type: none"> <li>• Connect the pump to AC power supply immediately.</li> </ul>
8.9		<b>Battery Error</b>  Stops the feeding  Potential Cause: • System error for battery.	<ul style="list-style-type: none"> <li>• Please contact customer service.</li> </ul>
8.10		<b>Battery Degradation</b>  Doesn't stop the feeding Use time < 7 hours @120mL/hr  Potential Cause: • Battery degrades.	<ul style="list-style-type: none"> <li>• Touch "Mute", a prompt page will pop up with detail information.</li> <li>• Contact customer service to replace a new battery</li> </ul>

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>62</b> of <b>81</b>

			
8.11	<p>Continuous beeping sound lasting approximately 3 mins.</p>	<p><b>Total Power Failure</b></p> <p>Stops the feeding Pump turns off.</p> <p>Potential Cause:</p> <ul style="list-style-type: none"> <li>• Battery and power adapter failure.</li> </ul>	<ul style="list-style-type: none"> <li>• Connect the pump to AC power supply immediately and restart the pump.</li> </ul>
8.12		<p><b>Motor Error</b></p> <p>Stops the feeding</p> <p>Potential Cause:</p> <ul style="list-style-type: none"> <li>• The motor is malfunction.</li> </ul>	<ul style="list-style-type: none"> <li>• Please contact customer service.</li> </ul>
8.13		<p><b>Communication Fault</b></p> <p>Stops the feeding</p> <p>Potential Cause:</p> <ul style="list-style-type: none"> <li>• System error for processor.</li> </ul>	<ul style="list-style-type: none"> <li>• Please contact customer service.</li> </ul>

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>63</b> of <b>81</b>

8.14	 <p>The screenshot shows the pump's intermittent mode interface. At the top, it says 'Intermittent Mode' and 'Feed 3 of 8 is completed'. Below that, it indicates 'Feed 4 will start in:' followed by a large digital timer showing '00:09:59'. A 'KTO Running' status is shown with a circular arrow icon. A 'Lock' button is visible. An orange banner at the bottom of the screen reads 'Single Dose Complete'. Below the banner, a green checkmark icon is shown with '3 / 8' underneath it. A message states: 'One of the single intermittent feedings completed, please flush tubing per protocol.' At the very bottom, there is an alarm icon with '01:59' and an 'Alarm Reset' button.</p>	<p><b>Single Dose Complete</b></p> <p>Doesn't stop the intermittent feeding task</p> <p>Potential Cause:</p> <ul style="list-style-type: none"> <li>• One of the single intermittent feeds completed.</li> </ul>	<ul style="list-style-type: none"> <li>• Touch "Mute", a prompt page will pop up with detail information.</li> <li>• Remind user to flush the tubing per protocol.</li> </ul>
------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

## 9. Dedicated Enteral Feeding Sets (Disposable)

The pump needs to be used with Amsino enteral delivery pump set (510(k) No. K992719) together to achieve the designed feeding flow rate accuracy. Below are detail lists.

Recommended list of **AMSure®** enteral delivery sets

No.	REF	Description
1	ENF500K	Enteral feeding set with 500mL bag
2	ENF1004K	Enteral feeding set with spike
3	ENF1200K	Enteral feeding set with 1200mL bag
4	ENF500K2	Enteral feeding set with 500mL bag and RFID tag
5	ENF1004K2	Enteral feeding set with spike with RFID tag
6	ENF1200K2	Enteral feeding set with 1200mL bag with RFID tag

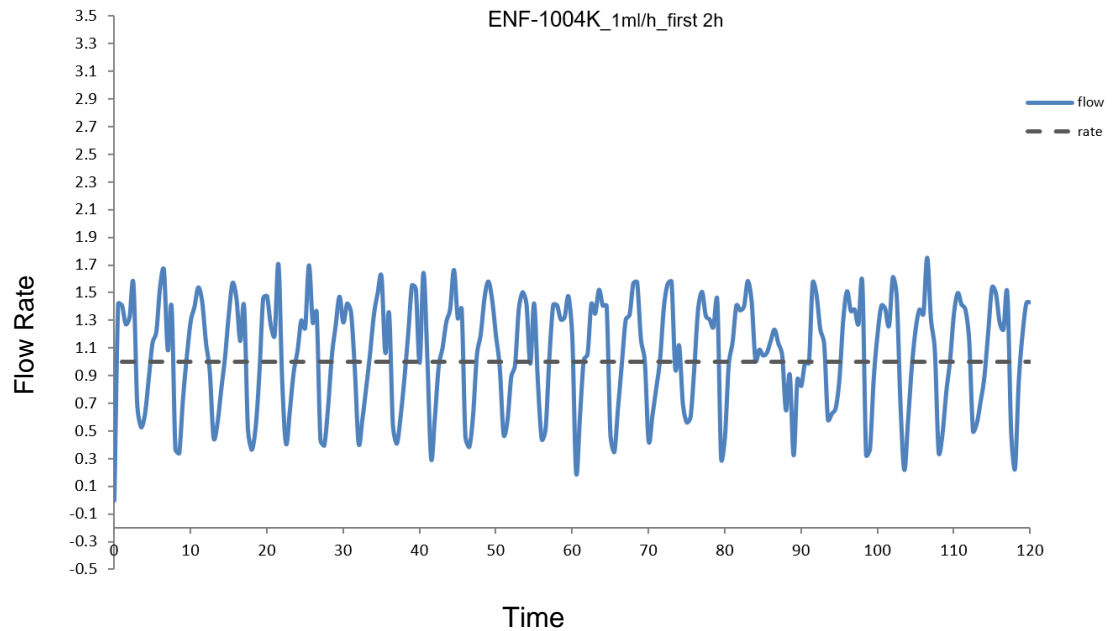
Note:

The accuracy could not be guaranteed with unlisted enteral feeding set.

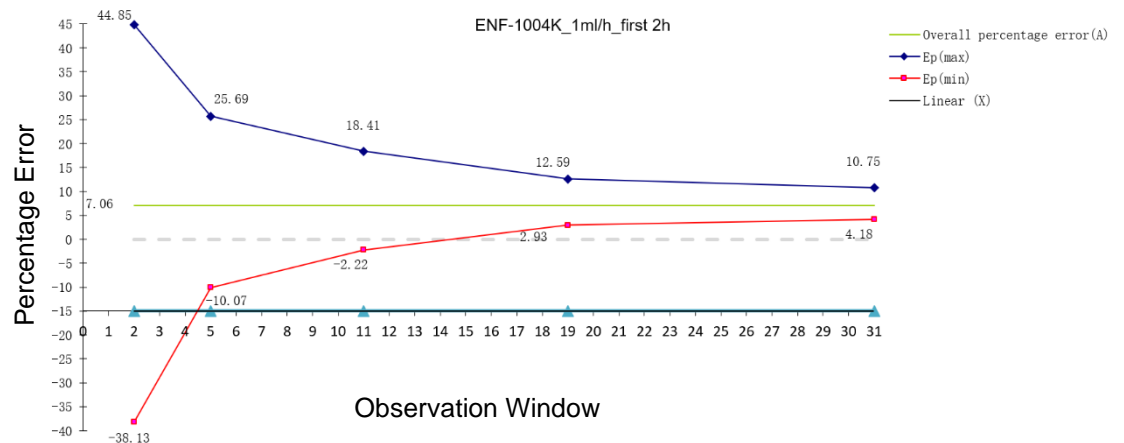
File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>64</b> of <b>81</b>

## 10. Accuracy Graphs

### 10.1 Accuracy Curve at 1 mL/hr. Rate



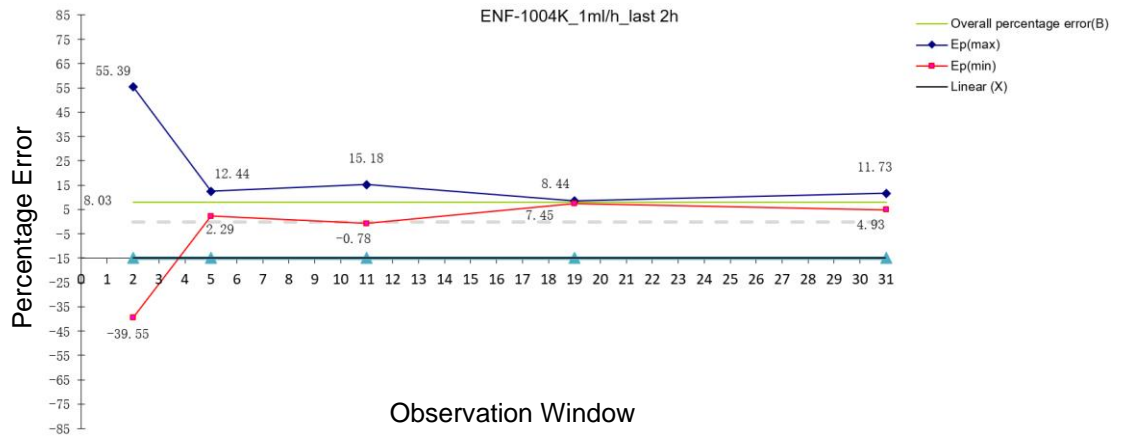
### Hours 0-2: Accuracy Curve at 1 mL/hr. Rate



### Hour 0-2: Accuracy Trumpet Curve at 1 mL/hr. Rate

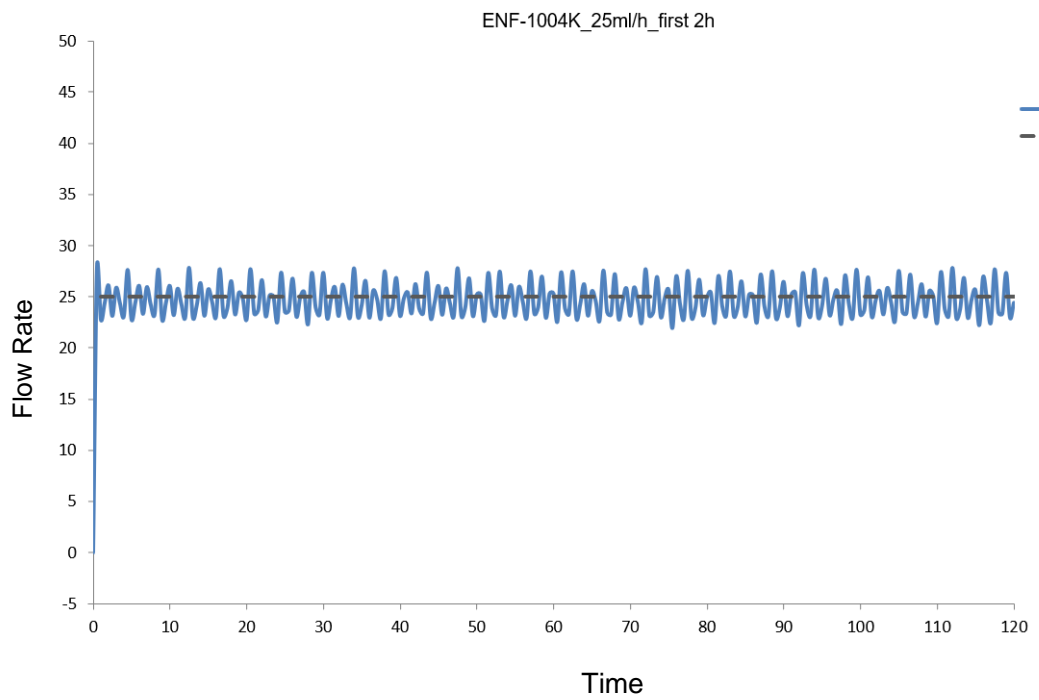


File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>65</b> of <b>81</b>



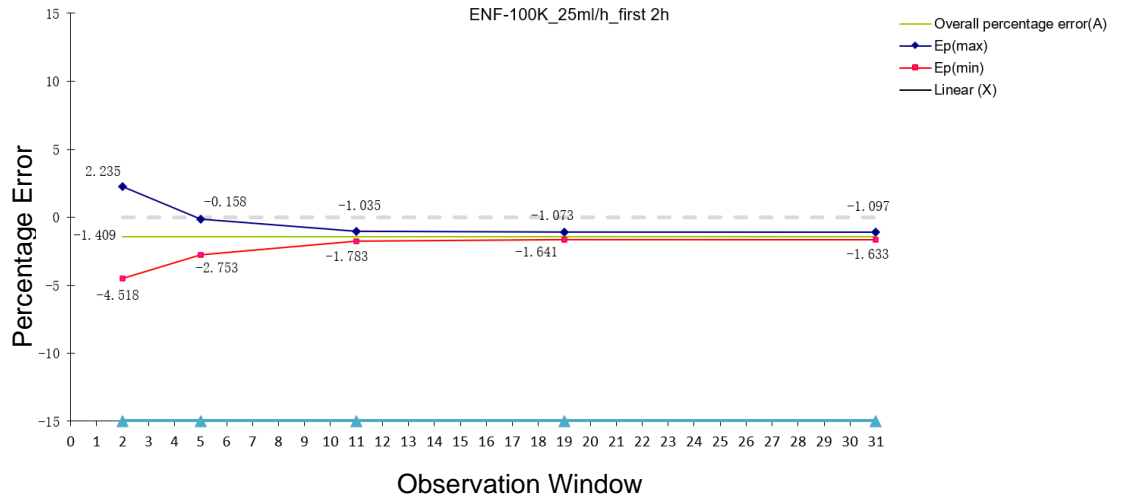
Hours 23-24: Accuracy Trumpet Curve at 1 mL/hr. Rate

## 10.2 Accuracy Curve at 25 mL/hr. Rate

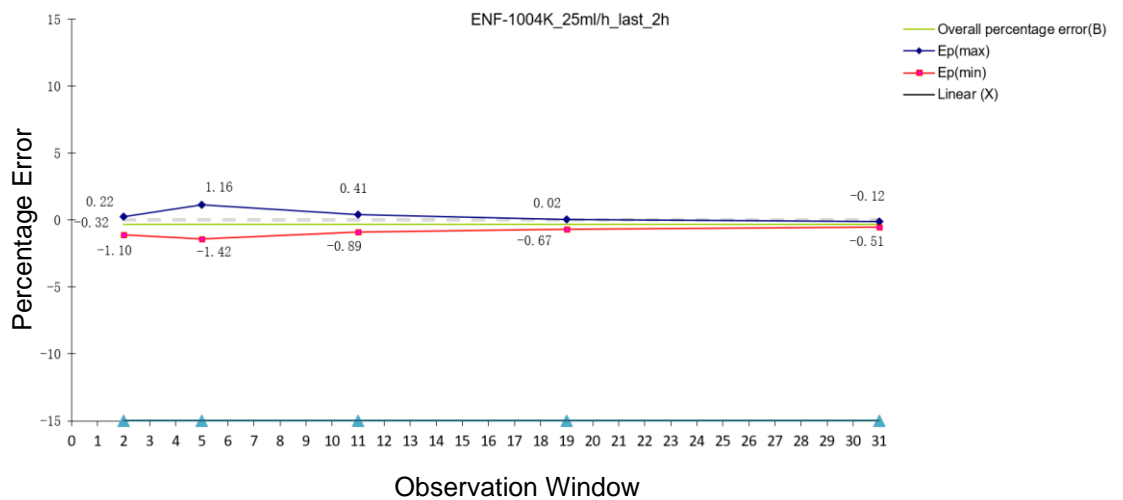


Hours 0-2: Accuracy Curve at 25 mL/hr. Rate

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>66</b> of <b>81</b>



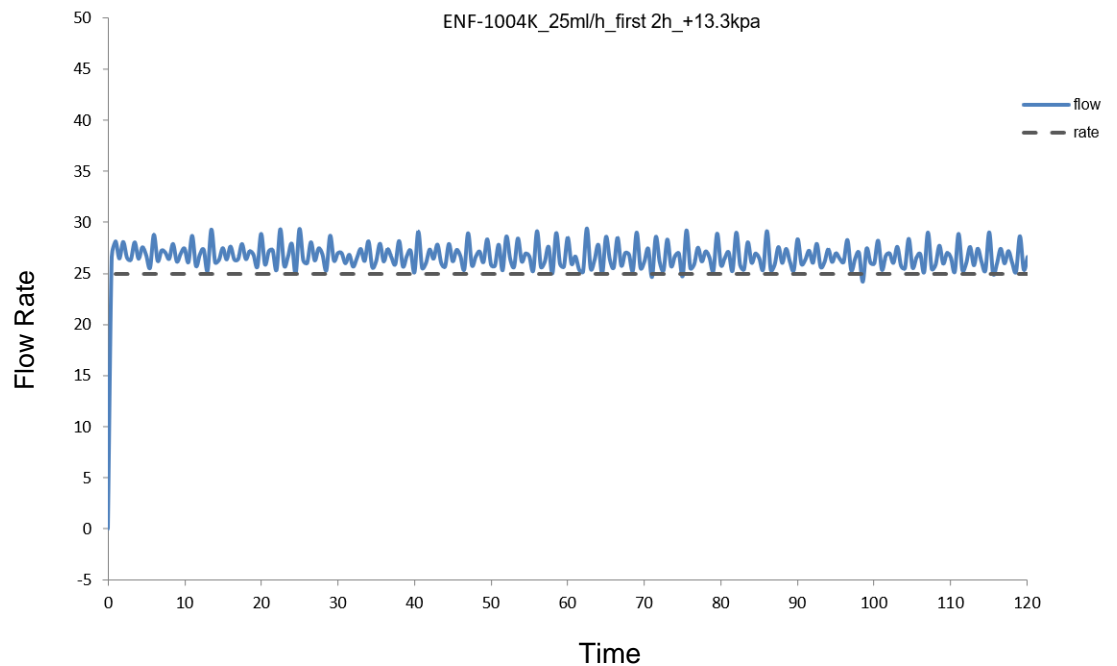
Hours 0-2: Accuracy Trumpet Curve at 25 mL/hr. Rate



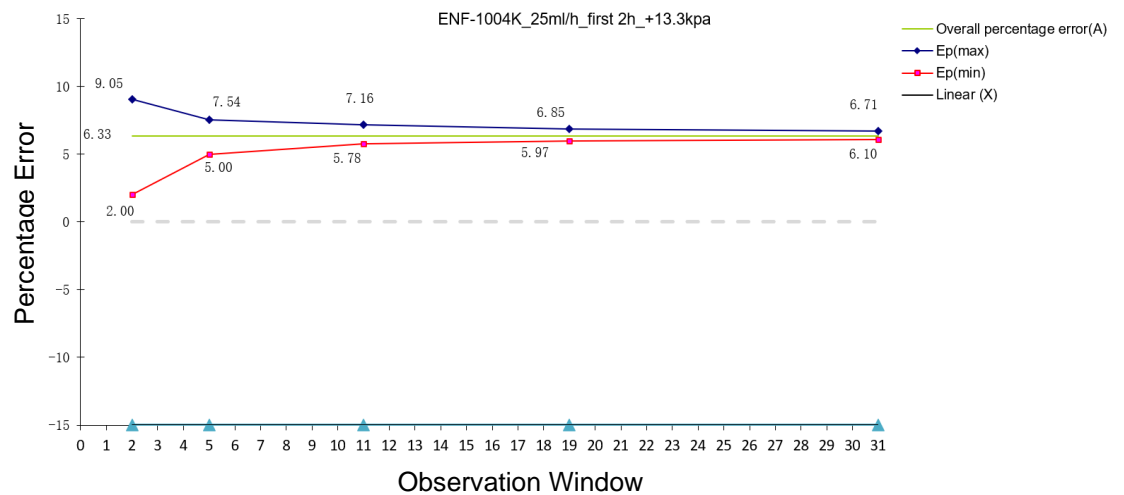
Hours 23-24: Accuracy Trumpet Curve at 25 mL/hr. Rate

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 67 of 81

### 10.3 Accuracy Curve at 25 mL/hr. Rate under +13.3kpa

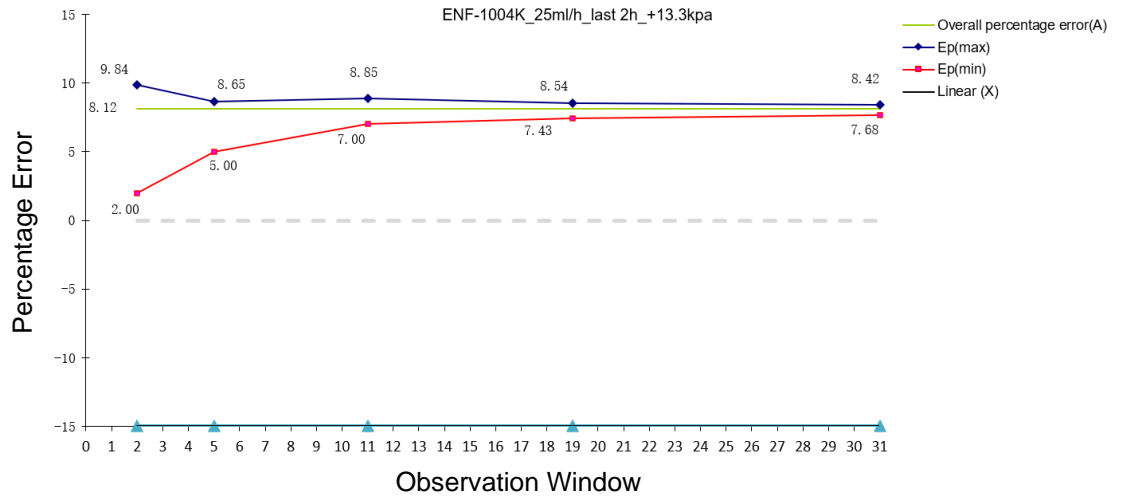


### Hours 0-2: Accuracy Curve at 25 mL/hr. Rate under +13.3kpa



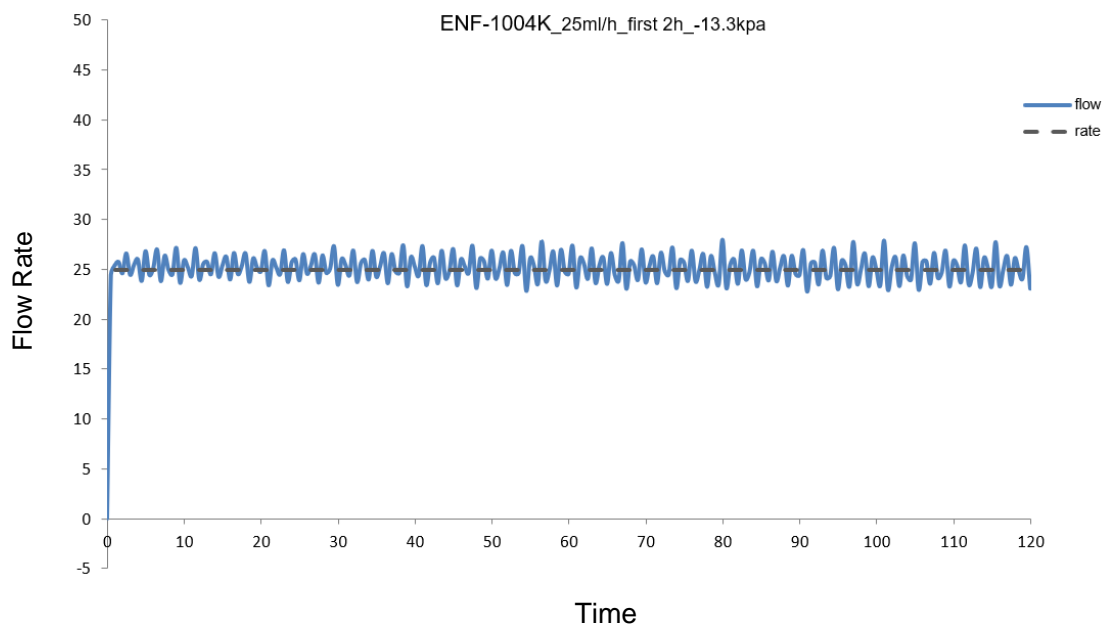
### Hours 0-2: Accuracy Trumpet Curve at 25 mL/hr. Rate under +13.3kpa

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>68</b> of <b>81</b>



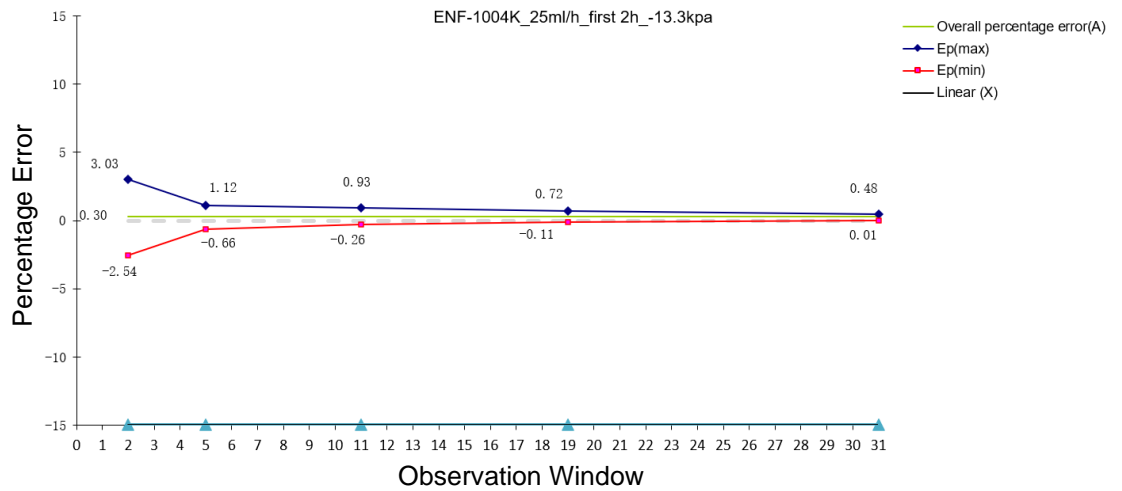
Hours 23-24: Accuracy Trumpet Curve at 25 mL/hr. Rate under +13.3kpa

#### 10.4 Accuracy Curve at 25 mL/hr. Rate under -13.3kpa

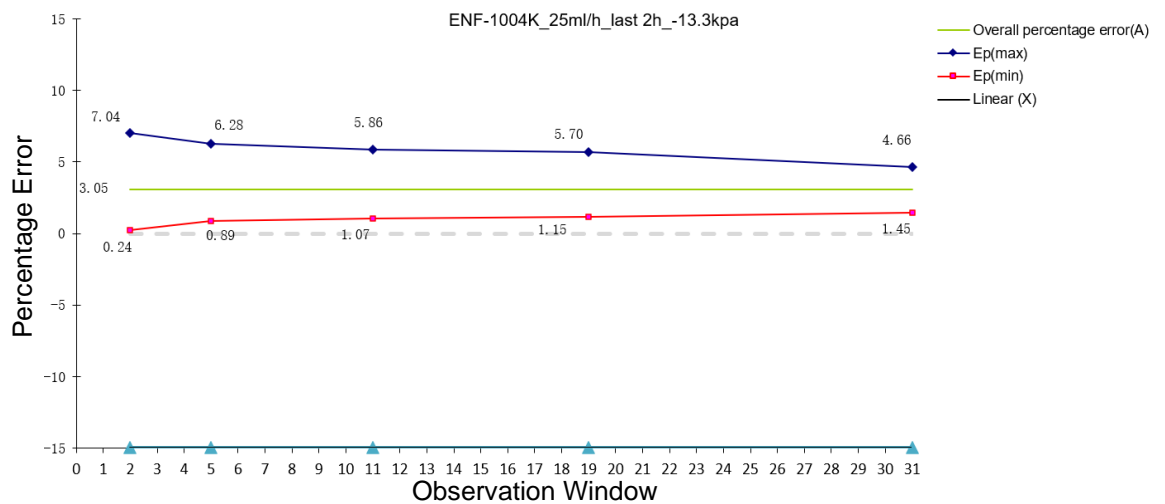


Hours 0-2: Accuracy Curve at 25 mL/hr. Rate under -13.3kpa

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>69</b> of <b>81</b>



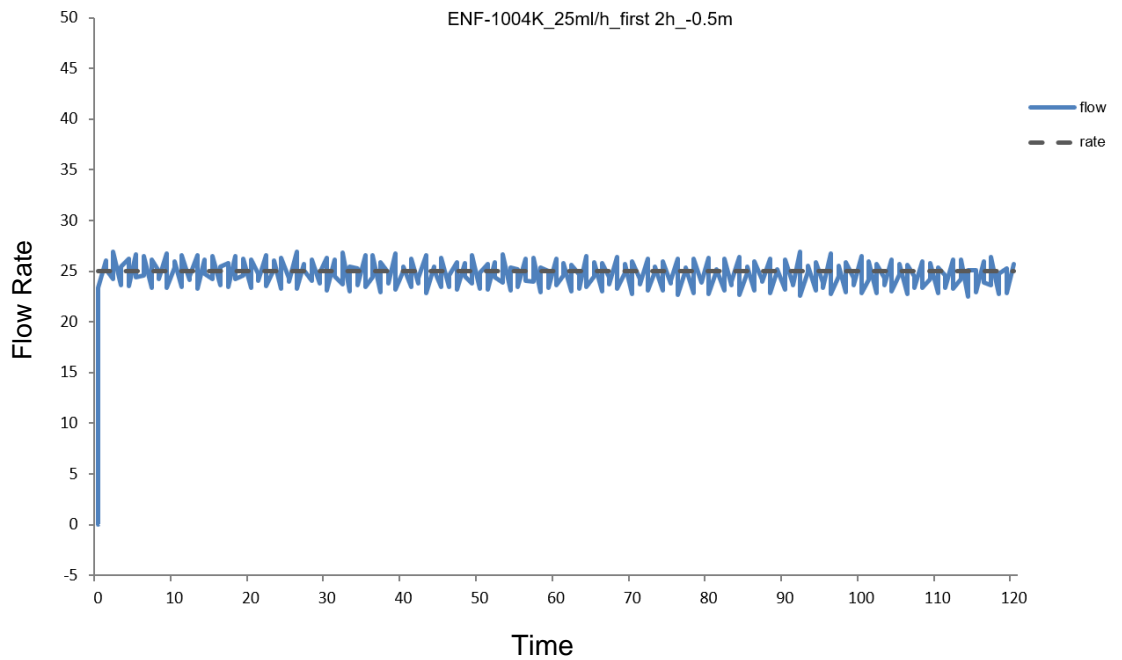
Hours 0-2: Accuracy Trumpet Curve at 25 mL/hr. Rate under -13.3kpa



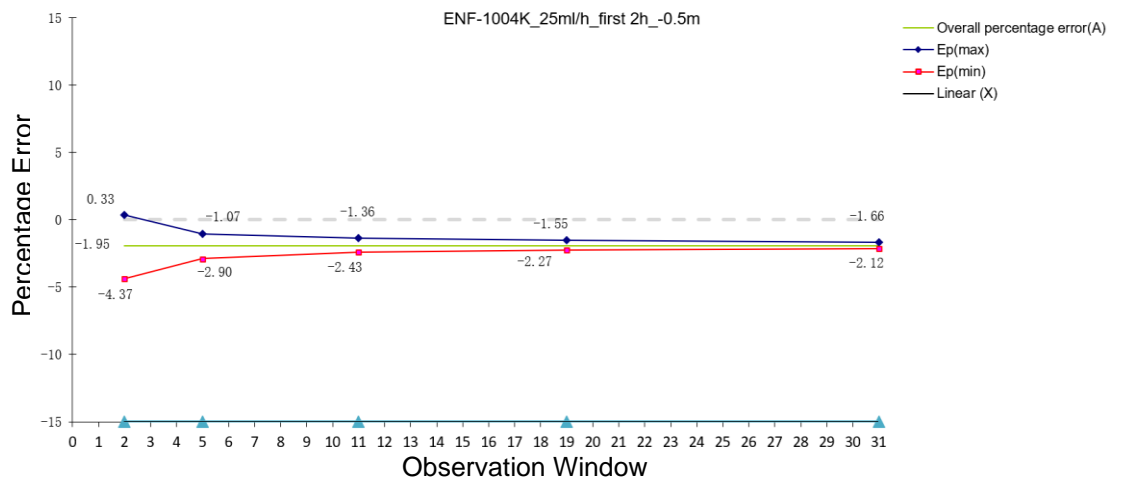
Hours 23-24: Accuracy Trumpet Curve at 25 mL/hr. Rate under -13.3kpa

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>70</b> of <b>81</b>

### 10.5 Accuracy Curve at 25 mL/hr. Rate under -0.5m

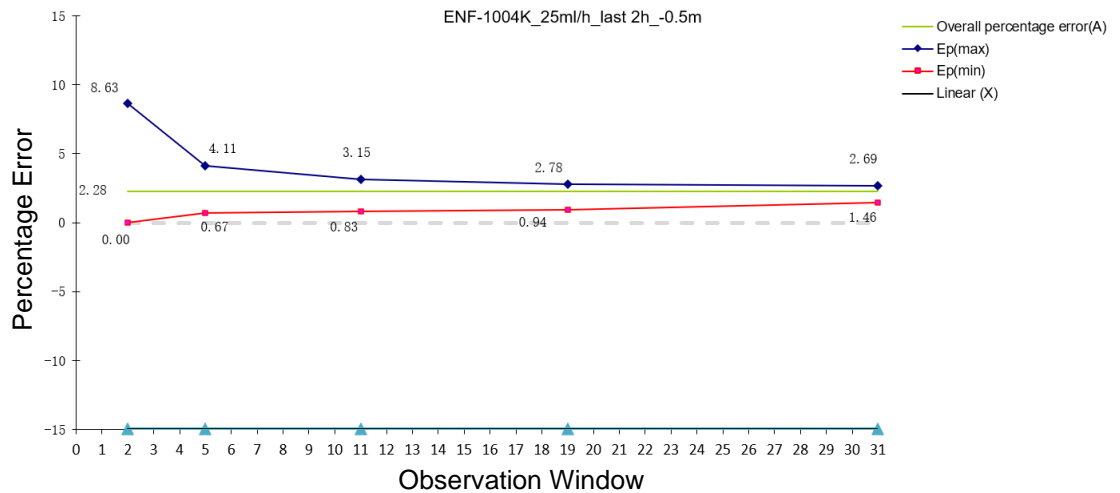


### Hours 0-2: Accuracy Curve at 25 mL/hr. Rate under -0.5m



### Hours 0-2: Accuracy Trumpet Curve at 25 mL/hr. Rate under -0.5m

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 71 of 81



Hours 23-24: Accuracy Trumpet Curve at 25 mL/hr. Rate under -0.5m

## 11. Internal Battery Maintenance

The pump has a built-in rechargeable lithium battery with specifications: 18650/11.1V-2200mAh. After the grid power supply is interrupted, the system will automatically switch to the built-in battery working state.

Daily maintenance of the battery:

1. When the equipment is not used for a long time, the battery should be connected to the grid power supply to charge the battery every 3 months to avoid batter degradation.
2. Do not disassemble or install the battery, contact customer service for battery replacement.
3. For detailed battery replacement method, refer to “L10201 Maintenance Manual - 7.2.6 Disassembly and Reassembly of Battery”.

## 12. Product Maintenance and Warranty

### 12.1 Technical Maintenance

Regular calibration and other technical maintenance are recommended. Only persons authorized by Amsino can carry out maintenance on the **AMSure**® Enteral Feeding Pump.

### 12.2 Cleaning

1. Cleaning Chemicals
  - For general cleaning, use a solution of warm water and a mild dishwashing detergent (pH 5~7).
  - In case of blood contamination, it is necessary to use a detergent containing enzymes.
2. General Cleaning Directions

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>72</b> of <b>81</b>

- To remove all visible soil, wipe down the pump with non-abrasive paper towel, sponge, or lint free soft cloth moistened with cleaning solution.
  - To remove soil from crevices, use a soft brush.
  - After the first cleaning, replace it with a new wet wipe and clean it again.
3. Cleaning Frequency
    - It is recommended that the pump is cleaned to eliminate stains and soils after each use or at least every day.
    - A cleaning is also necessary when the pump is allocated to a new patient.
  4. 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.
  5. Power Adapter Cleaning
    - Refer to General Cleaning Directions before starting.
    - The power adapter normally does not require cleaning. If soiling of the power adapter is observed, unplug from outlet and wipe the exterior surfaces of the power adapter with a non-abrasive dry or slightly damp cloth.
    - Allow excess moisture to evaporate from the power adapter prior to use.
  6. 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.
  7. Sensors Cleaning
    - Open the door.
    - Use a damp cotton swab to clean the sensors and the pathway of the feeding set.

### 12.3 Disinfection

#### 1. Disinfection Chemicals

The pump can be disinfected with the following solution:

- Alcohols, ammonium salt disinfectants can be used for disinfection of the product.
- To wet the devices, use wetted lint free wipes and wipe as necessary to maintain visual wetness for 5 minutes.

#### 2. Disinfection Frequency



File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>73</b> of <b>81</b>

- For better patient and personnel protection against the risks of contamination, disinfect per facility guidelines 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.



### **Caution**

1. Failure to follow the cleaning procedures described herein could result in hazards to users.
2. 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.
3. Avoid exposing power adapter to excess moisture, as this can lead to an electrical shock or fire hazard. The power adapter is rated IPX4 which is not water resistant.
4. To avoid electrical shock, never clean **AMSure**® Enteral Feeding Pump or power adapter with the power cord plugged into an outlet or with the pump switched on.
5. Prevent liquid from entering the pump to avoid electrical shock hazard, fire hazard or damage to electrical components. Do not submerge the **AMSure**® Enteral Feeding Pump or its accessories in water or cleaning solutions
6. The device cannot be sterilized.
7. Make sure the power adapter is completely dry before plugging into an electrical outlet.

## **12.2 Warranty**

The **AMSure**® Enteral Feeding Pump warranty covers technical faults occurring during normal use within 12 months from its delivery date, not including the battery.

Battery lifetime is about 2 years; however, the actual battery replacement depends on when the “battery degradation alarm” occurs.

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:

1. The pump is damaged following inappropriate use, after being dropped or incorrectly stored.
2. The serial number has been changed.
3. The pump has been opened, repaired, altered, or adjusted by personnel other than those authorized by Amsino.
4. 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.

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>74</b> of <b>81</b>

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, user must ensure it is noted on the courier's paperwork.

### 13. Characteristics of ALARM SIGNALS

#### Alarm light indicator characteristics

Alarm type	Indicator Color	Flashing Frequency	Duty Cycle
High priority alarm signal	Red blinked	2Hz	50%
Medium priority alarm signal	Yellow blinked	2Hz	50%
Low priority alarm signal	Solid Yellow	Normally open	100%

#### Volume of auditory alarm signals

Unit: dB(A)

Alarm Condition	Volume level setting	Positions as specified in Table F.1 of ISO 3744	Measured sound pressure level (dB)	A-weighted sound pressure level averaged over the measurement surface (dB)	Remarks
HIGH PRIORITY	Maximum	2	77.9	78.6	
		4	78.0		
		6	76.6		
		8	78.0		
		10	80.2		
		12	80.6		
	Minimum	2	76.4	75.1	
		4	73.4		
		6	73.3		
		8	73.9		
		10	77.1		
		12	76.6		
HIGH PRIORITY	Maximum	2	80.5	75.2	
		4	71.9		
		6	75.0		
		8	72.1		
		10	75.7		
		12	75.9		
	Minimum	2	70.9	68.1	
		4	65.7		
		6	65.8		

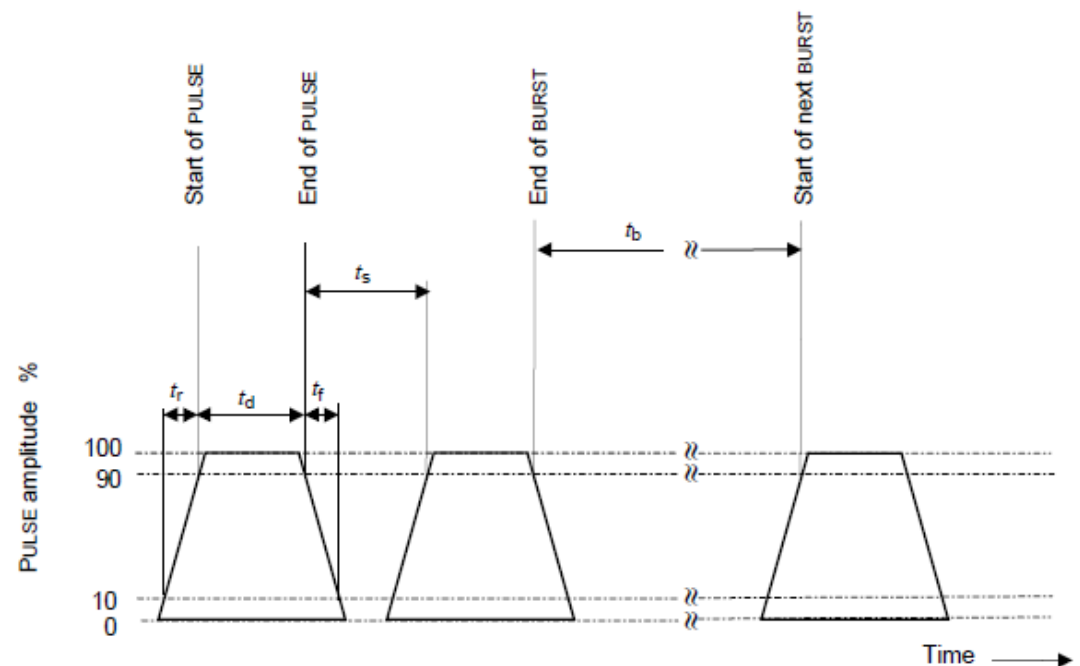
File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>75</b> of <b>81</b>

		8	64.9		
		10	70.2		
		12	70.8		

Supplementary information

1. Including HIGH, MEDIUM, and LOW PRIORITY ALARM CONDITIONS
2. Including maximum and minimum settings
3. Position selected based on STATIONARY ME EQUIPMENT

### Illustration of temporal characteristics of auditory ALARM SIGNALS



Characteristic	High Priority Alarm Signal	Medium Priority Alarm Signal	Low Priority Alarm Signal
Number of PULSES in BURST a, e	10	-	3
$t_r$ (ms)	17~24	-	21~25
$t_d$ (ms)	112~123	-	167~182
$t_f$ (ms)	10~20	-	68~81
$t_s$ (ms)	119	-	143
	122	-	146
	329	-	-
	119	-	-
	1071	-	-
	118	-	-

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>76</b> of <b>81</b>

	123	-	-
	337	-	-
	126	-	-
$t_b$ (s)	18.12	-	-
Any two pulses amplitude difference	3.6dB	-	0.7dB
$f_0$	<p>Pulse frequency <math>f_0=512\text{Hz}</math> 6 harmonic components in the range 300Hz-4000Hz</p> <p>Pulse frequency <math>f_0=288\text{ Hz}</math> 8 harmonic components in the range 300Hz-4000Hz</p> <p>Pulse frequency <math>f_0=384\text{ Hz}</math> 7 harmonic components in the range 300Hz-4000Hz</p> <p>Pulse frequency <math>f_0=288\text{Hz}</math> 6 harmonic components in the range 300Hz-4000Hz</p> <p>Pulse frequency <math>f_0=528\text{Hz}</math> 4 harmonic components in the range 300Hz-4000Hz</p>	-	<p>Low priority Alarm: Pulse frequency <math>f_0=528\text{Hz}</math> 6 harmonic components in the range 300Hz-4000Hz</p> <p>Pulse frequency <math>f_0=288\text{ Hz}</math> 6 harmonic components in the range 300Hz-4000Hz</p> <p>Pulse frequency <math>f_0=384\text{ Hz}</math> 7 harmonic components in the range 300Hz-4000Hz</p>
Number of harmonic components that meet the requirements	5	-	3

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page 77 of 81

## 14. Waste Disposal

### 14.1 Battery

Please follow local regulations to dispose of used batteries.

### 14.2 Enteral feeding set

After use, it shall be disposed of in accordance with relevant medical waste disposal regulations.

### 14.3 Pump

The designed service life of the pump is 5 years. After the service life is exceeded, it should be disposed of in accordance with relevant medical waste disposal regulations.

## 15. Electromagnetic Compatibility

The **AMSure**® Enteral Feeding Pump has been built and tested according to 60601-1-2:2020. FCC to be updated.

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.

### Basic performance

Item	Description
Internal power operation	Start normal operation at 25mL/h, the feeding accuracy error is within $\pm 10\%$ , and the operation is normal during the process, there should be no abnormal phenomena and malfunctions
Grid power connection operation	Start normal operation at 25mL/h, the feeding accuracy error is within $\pm 10\%$ , and the operation is normal during the process, there should be no abnormal phenomena and malfunctions

## Guidelines and manufacturer's declaration-electromagnetic emissions

Guidelines and manufacturer's declaration-electromagnetic emissions The equipment is expected to be used in the following electromagnetic environment, and the purchaser or user should ensure that it is used in this electromagnetic environment:		
Test	Compliance	Electromagnetic environment-guide
Radio frequency emission CISPR 11	1	The device uses RF energy only for its internal functions, so its RF emission is very low, and the possibility of causing interference to nearby electronic devices is very small
Radio frequency emission CISPR 11	Class A	The equipment is suitable for use in non-domestic and all facilities that are not

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>78</b> of <b>81</b>

Harmonic distortion IEC61000-3-2 <sup>b)</sup>	NA	directly connected to the public low-voltage power supply network of households.
Voltage fluctuation/flicker IEC61000-3-3 <sup>b)</sup>	NA	

### Guidelines and manufacturer's declaration-electromagnetic immunity

Guidelines and manufacturer's declaration-electromagnetic immunity The equipment is expected to be used in the following electromagnetic environment, and the purchaser or user should ensure that it is used in this electromagnetic environment:			
Immunity test	Experimental level	Coincidence level	Electromagnetic environment-guide
Electrostatic discharge (ESD) IEC61000-4-2	±8KV Contact discharge ±15 KV Air discharge	±8KV Contact discharge ±15KV Air discharge	The floor should be wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient burst IEC61000-4-4	±2KV To the power cord±1 KV For input/output lines	±2 KV To the power cord NA	The grid power supply should have the quality used in a typical commercial or hospital environment
Surge IEC61000-4-5	±1 KV Wire to wire ±2 KV Wire to ground	±1 KV Wire to wire NA	The grid power supply should have the quality used in a typical commercial or hospital environment
Voltage dip IEC61000-4-11	<5%U <sub>T</sub> , continued 0.5 period (>U <sub>T</sub> , >95% Suspended) 40%U <sub>T</sub> , continued 5 period (> U <sub>T</sub> , 60% Suspended) 70%U <sub>T</sub> , continued 25 period (>U <sub>T</sub> , 30% Suspended) <5%U <sub>T</sub> , continued 5s (>U <sub>T</sub> , >95% Suspended)	<5%U <sub>T</sub> , continued 0.5 period (>U <sub>T</sub> , >95% Suspended) 40%U <sub>T</sub> , continued 5 period (> U <sub>T</sub> , 60% Suspended) 70%U <sub>T</sub> , continued 25 period (>U <sub>T</sub> , 30% Suspended) <5%U <sub>T</sub> , continued 5s (>U <sub>T</sub> , >95% Suspended)	The grid power supply should have a quality suitable for a typical commercial or hospital environment. If the user of the equipment needs continuous operation during the power interruption, it is recommended that the equipment use uninterruptible power supply or battery power supply.
Rated power frequency magnetic field (50/60 Hz) IEC61000-4-8	30A/m	30A/m	The power frequency magnetic field should have the level characteristics of the power frequency magnetic field in a typical place in a typical commercial or hospital environment
Note: U <sub>T</sub> refers to the AC grid power before the experimental power is applied.			

File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>79</b> of <b>81</b>

## Guidelines and manufacturer's declaration-electromagnetic immunity-for non-life support equipment and systems

Guidelines and manufacturer's declaration-electromagnetic immunity			
The equipment is expected to be used in the following electromagnetic environment, and the purchaser or user should ensure that it is used in this electromagnetic environment:			
Immunity test	IEC60601 Experimental level	Coincidence level	Electromagnetic environment-guide
<p>Conducted disturbances induced by RF fields IEC61000-4-6</p> <p>Radiated RF EM fields IEC61000-4-3</p>	<p>3 V (Effective value) 150 kHz ~ 80MHz</p> <p>3V /m 80MHz ~ 2.7GHz</p>	<p>3V (Effective value)</p> <p>3V/m</p>	<p>Portable and mobile radio frequency communication equipment should not be used closer to any part of the equipment, including cables, than the recommended isolation distance. The distance should be calculated by the formula corresponding to the transmitter frequency.</p> <p>Recommended isolation distanced  <math display="block">= [3.5/V_1] \sqrt{(P)}</math> <math display="block">d = [3.5/E_1] \sqrt{(P)} \quad 80\text{MHz}-800\text{MHz}</math> <math display="block">d = [7/E_1] \sqrt{(P)} \quad 800\text{MHz}-2.7\text{GHz}</math>                     P—According to the maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W);                      d—Is the recommended isolation distance in meters (m).<sup>b</sup></p> <p>The field strength of the fixed radio frequency transmitter is determined by surveying the electromagnetic field c, and in each frequency range d should be lower than the compliance level.</p> <p>Interference may occur near equipment marked with the following symbols:</p> 
<p>Note 1: At 80 MHz and 800 MHz frequency points, the higher frequency band formula is used.</p> <p>Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects, and humans.</p>			
<p>a) Fixed transmitter. Such as: wireless (cellular/wireless) telephone and ground mobile radio base stations, amateur radio, AM and FM radio broadcasting, and television broadcasting, etc., the field strength cannot be accurately predicted in theory. In order to assess the electromagnetic environment of fixed radio frequency transmitters, the survey of electromagnetic fields should be considered. If the measured field strength of the equipment is higher than the above applicable RF compliance level, the equipment should be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary, such as reorienting or relocating the device.</p> <p>b) In the whole frequency range of 160kHz ~ 80MHz, the field strength should be lower than 3V/m</p>			

## Recommended isolation distance between portable and mobile radio frequency communication equipment and equipment or systems-for non-life support equipment and systems

Recommended isolation distance between portable and mobile RF communication equipment and equipment
-----------------------------------------------------------------------------------------------------

File Name	IFU of <b>AMSure®</b> Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>80</b> of <b>81</b>

The equipment is expected to be used in an electromagnetic environment where radio frequency radiation disturbances are controlled. According to the maximum rated output power of communication equipment, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between portable and mobile radio frequency communication equipment (transmitter) and the equipment as recommended below.

The maximum rated output power of the transmitter/W	Corresponding to the isolation distance of the transmitter at different frequencies/m		
	150kHz ~ 80MHz $d = [3.5/V_1] \sqrt{P}$	80MHz ~ 800MHz $d = [3.5/E_1] \sqrt{P}$	800MHz ~ 2.7GHz $d = 2.3 \sqrt{P}$
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 the maximum rated output power of the transmitter not listed in the above table, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where P is the emission provided by the transmitter manufacturer. The maximum rated output frequency of the machine, in watts (W).  
Note 1: At 80 MHz and 800 MHz frequency points, the higher frequency band formula is used.  
Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and human bodies.

## 16. Anti-Static Precautions

When using this equipment, users should not touch the pins of connectors marked with electrostatic discharge warning symbols and should not connect to these connectors unless electrostatic discharge precautions are used.

Users should note:

- Unless the following appropriate precautions have been taken, do not touch the accessible connector contacts marked with electrostatic discharge warning symbols with your hands or hand tools. Preventive measures include,
  - Methods to prevent static charge accumulation (such as air conditioning, humidification, conductive floor coatings, non-synthetic clothing);
  - Make the human body discharge to the frame of the equipment or system or to the ground or to large metal objects.
  - Use the wrist strap method connects the body to the device or system or ground.
- All staff who may touch the connector marked with the electrostatic discharge warning symbol should receive this explanation and training. This also includes clinical/biomedical engineering and healthcare personnel.
- Electrostatic discharge training should include an introduction to the physics of electrostatic charge and the voltage levels that may be generated in normal practice, as well as the damage of electronic components if an operator with static electricity touches electronic components. Furthermore, it should explain the methods to prevent the accumulation of static charge, and how and why the human body is discharged to the ground or the frame of the equipment or system, or to connect the body to the equipment or system or to the ground through a wrist strap before working.



File Name	IFU of <b>AMSure</b> ® Enteral Feeding Pump and Feeding Set	REF#	L10196_US	
		Version	B	Page <b>81</b> of <b>81</b>

## 17. Packing List

The list of packaging with this product (single unit) is as follows:

Accessory	Quantity	Unit
IFU	1	Set
Power Adapter	1	Set
Pump	1	Set

## 18. Manufacturer Information

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.  
**AMSure**® 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.