

Alaris™ Enteral Plus Syringe Pump MK4

Model: 8007ENT01

Directions For Use
en



Contents

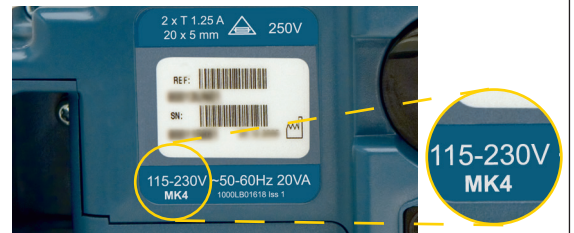
	Page
Introduction	2
About This Manual	3
Features of the Alaris™ Enteral Plus Syringe Pump	4
Controls and Indicators	5
Symbol Definitions	6
Main Display Features	7
Operating Precautions	8
Getting Started	11
Syringe Loading	13
Starting the Alaris™ Enteral Plus Syringe Pump	16
Basic Features	17
Alarms and Warnings	20
Configured Options	22
Specifications	25
Recognised Syringe Types	28
Associated Products	29
Maintenance	30
IrDA, RS232 and Nurse call Specification	33
Occlusion Pressure Limits	35
Trumpet Curves and Start-up Curves	36
Spare Parts	37
Document History	38
Contact Us	39

Introduction

This Directions For Use applies to Alaris™ Enteral Plus Syringe Pump MK4.



The Pumps can be identified as MK4 version by the MK4 on the label on the rear case, see image right, or by verifying the software version as 4.4.X or above on power up.



The Alaris™ Enteral Plus Syringe Pump functions with a wide range of standard, single-use, disposable enteral syringes together with the appropriate enteral Administration sets. The Alaris™ Enteral Plus Syringe Pump accepts syringe sizes from 5ml to 50/60ml. A list of recognised syringes can be found in the Recognised Syringes section of this manual.

Intended Purpose

The Alaris™ Enteral Plus Syringe Pump is intended exclusively for enteral administration.

Conditions of Use

The Alaris™ Enteral Plus Syringe Pump should only be operated by a clinician competent in use of automated enteral pumps and post-placement management of enteral catheters. Only enteral syringes and catheters should be used.



Wrong route errors can be life threatening. Connectors used on enteral feeding systems should be incompatible with other medical device connectors (especially those used for intravenous or other parenteral routes). BD recommends use of enteral catheters and enteral giving sets meeting European Standard EN 1615:2000. Three-way taps and syringe tip adaptors should not be used in enteral feeding systems.



BD cannot guarantee the continued system accuracy with other manufacturer's enteral syringes as identified in the 'Recognised Syringe Types' table. Manufacturers may change syringe specification significant to system accuracy without prior notification.

Indications

The Alaris™ Enteral Plus Syringe Pump is specifically indicated for the delivery of enteral therapies via Nasogastric, Orogastric or Gastrostomy (e.g. PEG - Percutaneous Endoscopic Gastrostomy) routes.

Contraindications

The Alaris™ Enteral Plus Syringe Pump is contraindicated for:

- intravascular infusion therapies
- subcutaneous infusion therapies
- intrathecal and epidural infusion therapies

About This Manual

Users are advised to read, to understand this manual and to be thoroughly familiar with the Alaris™ Enteral Plus Syringe Pumps prior to operating.



All illustrations used in this manual show typical settings and values which may be used in setting up the functions of the Alaris™ Enteral Plus Syringe Pump. These settings and values are for illustrative use only. Where stated, a minimum delivery rate refers to a nominal rate of 1.0ml/h, and an intermediate delivery rate refers to a nominal rate of 5.0ml/h. The complete range of delivery rates, settings and values are shown in the 'Specifications' section.



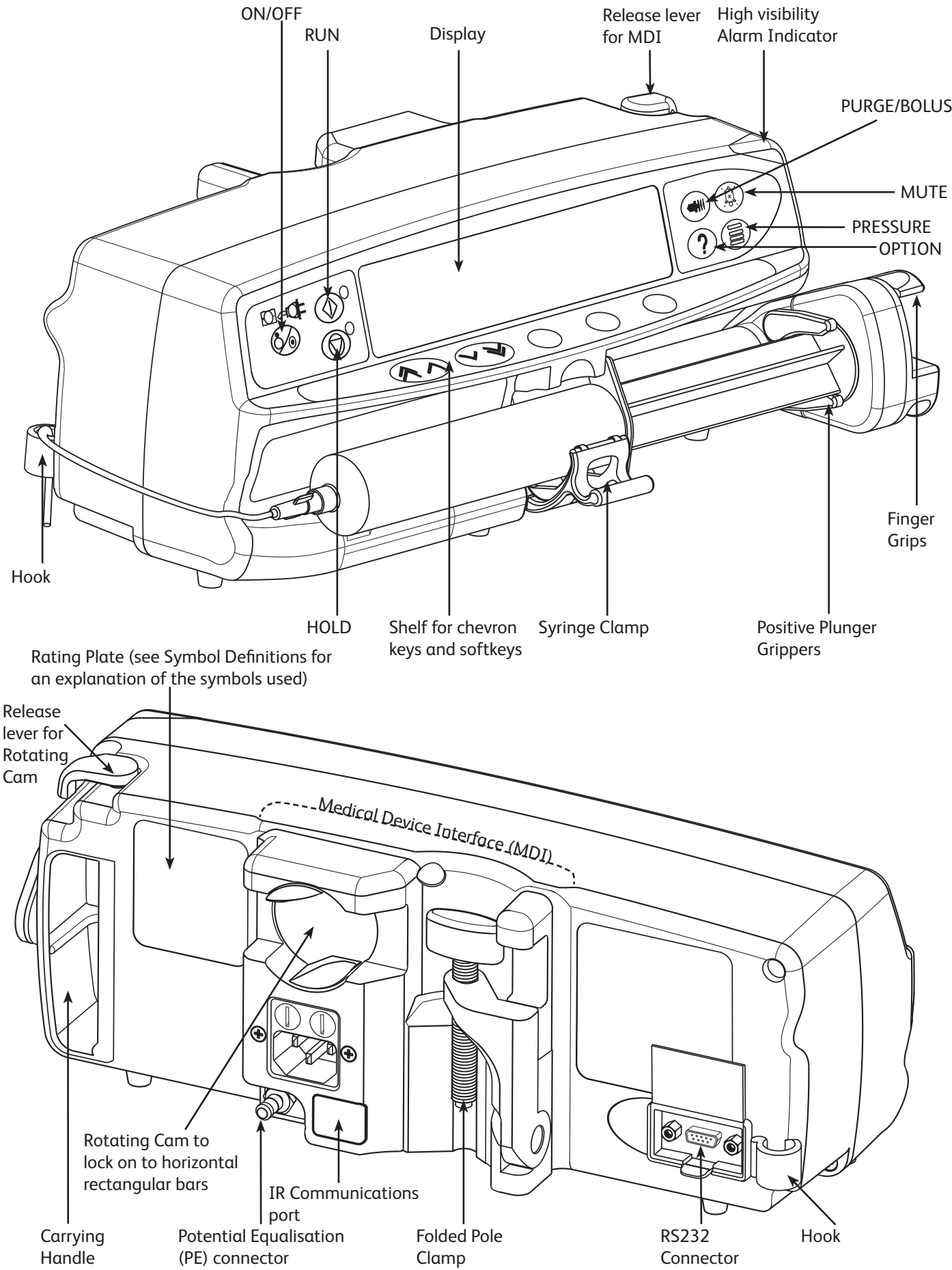
Keep this Manual for future reference during the Pump's operational life.

It is important to ensure that you only refer to the most recent version of the Directions for Use and Technical Service Manual for your BD products. These documents are referenced on bd.com. Paper copies of the Directions For Use can be obtained free of charge by contacting your local BD representative. An estimated delivery time will be provided when the order is placed.

Conventions used in this manual










BOLD	Used for Display names, software commands, controls and indicators referenced in this manual, for example, Battery Indicator , PURGE , ON/OFF button.
'Single quotes'	Used to indicate cross-references made to another section of this manual.
<i>Italics</i>	Used to refer to other documents or manuals and also used for emphasis.
	Warning symbol. A warning is a statement that alerts the User to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the Pump.
	Caution symbol. A caution is a statement that alerts the User to the possibility of a problem with the Pump associated with its use or misuse. Such problems may include Pump malfunction, Pump failure, damage to the Pump or damage to other property. The caution statement includes the precaution(s) that should be taken to avoid the hazard.

Features of the Alaris™ Enteral Plus Syringe Pump





Controls and Indicators

Controls:












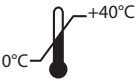
Symbol	Description
	ON/OFF button - Press once to switch the Alaris™ Enteral Plus Syringe Pump on. Press and hold down for 3 seconds to switch the Alaris™ Enteral Plus Syringe Pump off.
	RUN button - Press to start feeding. The green LED will flash during delivery.
	HOLD button - Press to put the delivery on hold. The amber LED will be lit while on hold.
	MUTE button - Press to silence alarm for two minutes. To re-enable the alarm audio press the Mute button a second time. Note: Callback alarm - When not in alarm press and hold until four audible beeps are sounded for 15 minutes silence
	PURGE/BOLUS button - Press to access PURGE or BOLUS soft keys. Press and hold down soft key to operate. PURGE - primes the feeding tube during initial set up. <ul style="list-style-type: none"> • Alaris™ Enteral Plus Syringe Pump is on hold • Administration set must not be connected to the patient • Volume Delivered is not added to total volume delivered BOLUS - fluid or drug delivered at an accelerated rate. <ul style="list-style-type: none"> • Alaris™ Enteral Plus Syringe Pump is delivering • Administration set should be connected to the patient • Volume Delivered is added to total volume delivered
	OPTION button - Press to access optional features, see 'Basic Features' section.
	PRESSURE button - Use this button to display the Alaris™ Enteral Plus Syringe Pumping pressure and alarm level.
	CHEVRON keys - Double or single for faster/slower increase or decrease of values shown on display.
	BLANK SOFTKEYS - Use in conjunction with the prompts shown on the display.

Indicators:

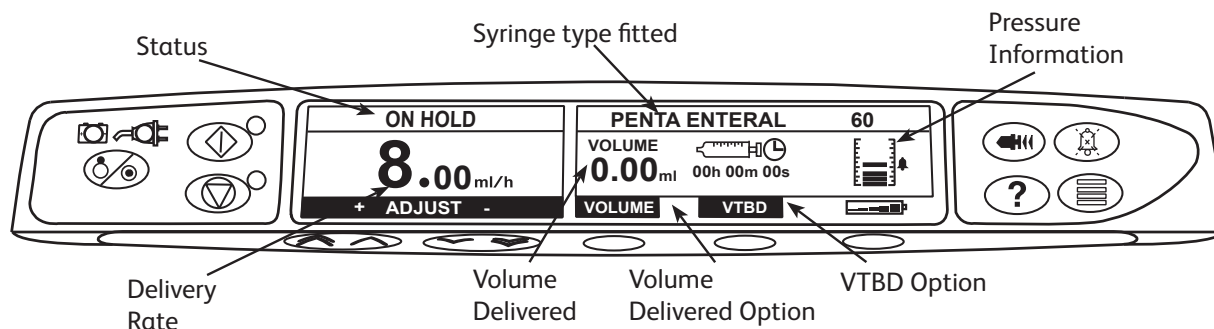
Symbol	Description
	BATTERY indicator - When illuminated the Alaris™ Enteral Plus Syringe Pump is running on the internal battery. When flashing the battery power is low with less than 30 minutes of use remaining.
	AC POWER indicator - When illuminated the Alaris™ Enteral Plus Syringe Pump is connected to an AC power supply and the battery is being charged.

Symbol Definitions

Labelling Symbols:

Symbol	Description
	Consult accompanying documents
	Potential Equalisation (PE) Connector
	RS232/Nurse call Connector
	Defibrillation-proof type CF applied part (Degree of protection against electrical shock)
IP32	Protected against direct sprays of water up to 15° from vertical and protected against solid objects greater than 2.5mm. Note: IP33 applies if AC power cable retainer kit, part number 1000SP01294, is fitted.
	Alternating Current
	Device complies with the requirements of Council Directive 93/42/EEC as amended by 2007/47/EC.
	Date of Manufacture
	Manufacturer
	Not for Municipal Waste
	Fuse Rating
	Protective Earth; Protective Ground
	Operating Temperature Range - Alaris™ Enteral Plus Syringe Pump can be used between 0 and 40 degrees centigrade.

Main Display Features

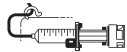
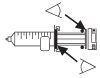


Screen Icons

Symbol	Description
	Time remaining display icon - Indicates time before syringe will require replacement.
	BATTERY icon - Indicates battery charge level to highlight when the battery will require recharging or re-connection to AC power supply.

Operating Precautions

Disposable Syringes and Administration Sets



- The Alaris™ Enteral Plus Syringe Pump has been calibrated for use with single-use enteral syringes. To ensure correct and accurate operation, only use the brand, model and size of enteral syringes described in this manual. Use of non recognised enteral syringe types may impair the operation of the Alaris™ Enteral Plus Syringe Pump and the accuracy of the delivery.
- Users are advised to re-evaluate syringe performance periodically as the syringe manufacturer may change specifications significant to accuracy without notice. Users concerned about any observed change in performance are advised to contact their local BD representative.
- Uncontrolled flow or syphoning may result if the syringe is located incorrectly in the Alaris™ Enteral Plus Syringe Pump, or if it is removed from the Alaris™ Enteral Plus Syringe Pump before the administration set is properly isolated from the patient. Isolation may include closing a tap in the patient line or activating a flow stop clamp.
- The user must be thoroughly familiar with instructions in this Directions For Use and understand how to load and confirm the syringe on the Alaris™ Enteral Plus Syringe Pump. Incorrect syringe loading may result in misidentification of the syringe brand/model and size which may lead to significant inaccuracy of the delivery rate and may also affect Alaris™ Enteral Plus Syringe Pump performance.
- Secure the feeding tube to the Alaris™ Enteral Plus Syringe Pump using the hook at the rear of the Alaris™ Enteral Plus Syringe Pump. This provides protection against accidental dislodging of the syringe from the Alaris™ Enteral Plus Syringe Pump.

Operating Environment

- Intended environments include general wards, neonatal wards, paediatric wards, critical and intensive care, operating rooms, accident and emergency rooms. Ensure that the Alaris™ Enteral Plus Syringe Pump is appropriately attached using the provided pole clamp. If the Alaris™ Enteral Plus Syringe Pump is dropped or experiences any severe physical disturbances, remove it from service and arrange a thorough inspection by appropriately trained technical personnel as soon as is practically possible.
- The Alaris™ Enteral Plus Syringe Pump is suitable for use in hospital and clinical environments other than domestic establishments and those directly connected to the public single phase AC power supply network that supplies buildings used for domestic purposes. However, it may be used in domestic establishments under the supervision of medical professionals with additional necessary appropriate measures. (Consult *Technical Service Manual*, Qualified Service Personnel or BD for further information).
- The Alaris™ Enteral Plus Syringe Pump is not intended to be used in the presence of a flammable anaesthetic mixture with air or oxygen or nitrous oxide.

Operating Pressure

- This is a positive pressure pump designed to achieve accurate fluid administration.

Mounting the Alaris™ Enteral Plus Syringe Pump

- When more than one pump is being used on a patient, those containing high risk, critical medications must be positioned as close to the patient's heart level as possible to avoid the risk of variations in flow or syphoning.
- Raising an Alaris™ Enteral Plus Syringe Pump whilst delivering may result in a bolus of the delivery, whereas lowering an Alaris™ Enteral Plus Syringe Pump whilst delivering may result in a delay in the delivery (an under-delivery).

Alarm Conditions



- Several alarm conditions detected by the Alaris™ Enteral Plus Syringe Pump will stop the delivery and generate visual and audible alarms. Users are to remain vigilant during delivery to ensure that the therapy is progressing correctly and no alarms are operating.

Hazards



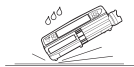
- An explosion hazard exists if the Alaris™ Enteral Plus Syringe Pump is used in the presence of flammable anaesthetics. Exercise care to locate the Alaris™ Enteral Plus Syringe Pump away from any such hazardous sources.



- Dangerous Voltage: An electrical shock hazard exists if the Alaris™ Enteral Plus Syringe Pump's casing is opened or removed. Refer all servicing to Qualified Service Personnel.



- When connected to an external power source, a three-wire (Live, Neutral, Earth) supply must be used. If the integrity of the external protective conductor in the installation or its arrangement is in doubt, the Alaris™ Enteral Plus Syringe Pump should be operated from the battery.
- Do not open the RS232/Nurse Call protective covering when not in use. Electrostatic discharge (ESD) precautions are required when connecting RS232/Nurse Call. Touching the pins of the connectors may result in ESD protection failure. It is recommended that all actions must be taken by appropriately trained personnel.



- If the Alaris™ Enteral Plus Syringe Pump is dropped, subjected to excessive moisture, fluid spillage, humidity or high temperature, or otherwise suspected to have been damaged, remove it from service for inspection by Qualified Service Personnel. When transporting or storing the Alaris™ Enteral Plus Syringe Pump, use original packaging where possible, and observe to temperature, humidity and pressure ranges stated in the 'Specifications' section and on the outer packaging.



- Alaris™ Enteral Plus Syringe Pumps should not be modified or altered in any way, except where explicitly directed or authorised by BD. Any use of Alaris™ Enteral Plus Syringe Pumps which have been altered or modified otherwise than in strict application of directions provided by BD, is at your sole risk, and BD does not provide any warranty for or endorsement on any Alaris™ Enteral Plus Syringe Pump that has been so modified or altered. BD product warranty shall not apply in the event the Alaris™ Enteral Plus Syringe Pump has suffered damage or premature wear, or malfunctions or otherwise operates incorrectly, as a result of unauthorised modification or alteration of the Alaris™ Enteral Plus Syringe Pump.

Electromagnetic Compatibility and Interference




- The Alaris™ Enteral Plus Syringe Pump is protected against the effects of external interference, including high energy radio frequency emissions, magnetic fields and electrostatic discharge (for example, as generated by electrosurgical and cauterising equipment, large motors, portable radios, cellular telephones etc.) and is designed to remain safe when abnormally high levels of interference are encountered.
- Therapeutic Radiation Equipment: Do not use the Alaris™ Enteral Plus Syringe Pump in the vicinity of any Therapeutic Radiation Equipment. Levels of radiation generated by the radiation therapy equipment such as Linear Accelerator, may severely affect functioning of the Alaris™ Enteral Plus Syringe Pump. Please consult manufacturer's recommendations for safe distance and other precautionary requirements. For further information, please contact your local BD representative.
- Magnetic Resonance Imaging (MRI): The Alaris™ Enteral Plus Syringe Pump contains ferromagnetic materials which are susceptible to interference with magnetic field generated by the MRI devices. Therefore, the Alaris™ Enteral Plus Syringe Pump is not considered an MRI compatible pump. If use of the Alaris™ Enteral Plus Syringe Pump within an MRI environment is unavoidable, then BD highly recommends securing the Alaris™ Enteral Plus Syringe Pump at a safe distance from the magnetic field outside the identified 'Controlled Access Area' in order to evade any magnetic interference to the Alaris™ Enteral Plus Syringe Pump; or MRI image distortion. This safe distance should be established in accordance with the manufacturers' recommendations regarding electromagnetic interference (EMI). For further information, please refer to the product *Technical Service Manual* (TSM). Alternatively, contact your local BD representative for further guidance.
- Accessories: Do not use any non-recommended accessory with the Alaris™ Enteral Plus Syringe Pump. The Alaris™ Enteral Plus Syringe Pump is tested and compliant with the relevant EMC claims only with the recommended accessories. Use of any accessory, transducer or cable other than those specified by BD may result in increased emissions or decreased Alaris™ Enteral Plus Syringe Pump immunity.
- This Alaris™ Enteral Plus Syringe Pump is a CISPR 11 Group 1 Class A device and uses RF energy only for its internal function in the normal product offering. Therefore, its RF emissions are very low and are not likely to cause any interference with the nearby electronic equipment. However, the Alaris™ Enteral Plus Syringe Pump emits a certain level of electromagnetic radiation which is within the levels specified by IEC/EN60601-1-2. If the Alaris™ Enteral Plus Syringe Pump interacts with other equipment, measures should be taken to minimise the effects, for instance by repositioning or relocation.
- In some circumstances the Alaris™ Enteral Plus Syringe Pump may be affected by an electrostatic discharge through air at levels close to or above 15kv; or by radio frequency radiation close to or above 10v/m. If the Alaris™ Enteral Plus Syringe Pump is affected by this external interference the Alaris™ Enteral Plus Syringe Pump will remain in a safe mode; the Alaris™ Enteral Plus Syringe Pump will stop the delivery and alert the user by generating a combination of visual and audible alarms. Should any alarm condition persist after user intervention, it is recommended to remove the Alaris™ Enteral Plus Syringe Pump from service. (Consult *Technical Service Manual* for further information).

Getting Started



Initial Set-up



Before operating the Alaris™ Enteral Plus Syringe Pump read this Directions For Use manual carefully.

1. Check that the Alaris™ Enteral Plus Syringe Pump is complete, undamaged and that the voltage rating specified on the label is compatible with your AC power supply.
2. Items supplied are:
 - Alaris™ Enteral Plus Syringe Pump
 - User Support CD (Directions For Use)
 - AC Power Cable (as requested)
 - Protective Packaging
3. Connect the Alaris™ Enteral Plus Syringe Pump to the AC power supply for at least 2½ hours to ensure that the internal battery is charged (verify that the  is lit).

Language Selection

1. On initial start-up the Alaris™ Enteral Plus Syringe Pump will display the Select Language screen.
2. Select the required language from the list displayed using the   keys.
3. Press the **OK** softkey to confirm your selection.



The Alaris™ Enteral Plus Syringe Pump will automatically operate from its internal battery if the Alaris™ Enteral Plus Syringe Pump is switched on without being connected to the AC power supply.



Should an Alaris™ Enteral Plus Syringe Pump fail commissioning, replace in its original protective packaging, where possible and contact Qualified Service Personnel for investigation.



Do not mount the Alaris™ Enteral Plus Syringe Pump with the AC power inlet pointing upwards. This could affect the electrical safety in the event of a fluid spill.

Pole Clamp Installation

The pole clamp is fitted to the rear of the Alaris™ Enteral Plus Syringe Pump and will provide secure fixing to vertical drip poles of a diameter between 15 and 40 mm.

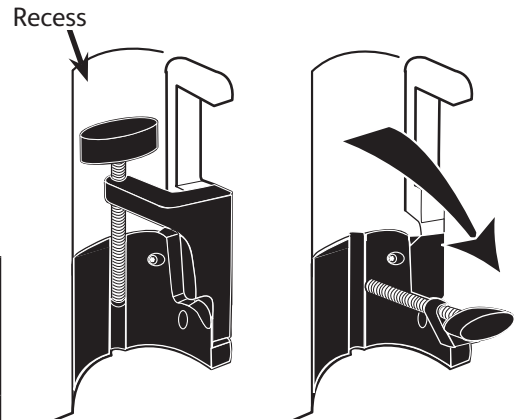
1. Pull the folded pole clamp towards you and unscrew the clamp to leave enough room for the size of the pole.
2. Place Alaris™ Enteral Plus Syringe Pump around pole and tighten screw until the clamp is secured to the pole.



Ensure the pole clamp is folded away and stored within the recess at the rear of the Alaris™ Enteral Plus Syringe Pump before connecting to a Docking Station/Workstation* or when not in use.



Never mount the Alaris™ Enteral Plus Syringe Pump such that the stand becomes top heavy or unstable.



Prior to each use, check the pole clamp:

- does not show any signs of excessive wear,
- does not show any signs of excessively loose movement in the extended, mountable position.

If these signs are observed, the Pumps should be taken out of service for examination by Qualified Service Personnel.

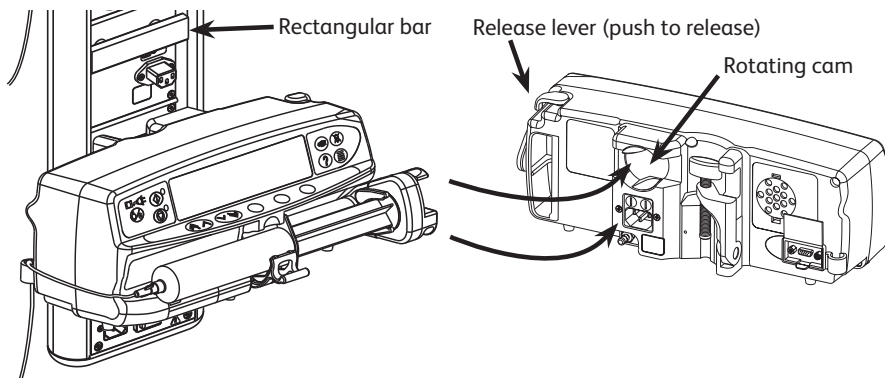
Docking Station/Workstation* or Equipment Rail Installation

The rotating cam can be fitted to the rectangular bar on the Docking Station/Workstation* or the equipment rail measuring 10 by 25mm.

1. Align the rotating cam on the rear of the Alaris™ Enteral Plus Syringe Pump with the rectangular bar on the Docking Station/Workstation* or the equipment rail.
2. Hold the Alaris™ Enteral Plus Syringe Pump horizontally, push the Alaris™ Enteral Plus Syringe Pump firmly onto the rectangular bar or equipment rail.
3. The Alaris™ Enteral Plus Syringe Pump should *click* into position when fitted to the bar.
4. Ensure that the Pump is positioned securely. Verify Pump is secure by gently pulling the Pump away from the Docking Station/Workstation* without using the release lever. When the Pump is securely attached, it should not come off the Docking Station/Workstation*.
5. To release, push the release lever and pull the Alaris™ Enteral Plus Syringe Pump forwards.



Pump may fall off the Docking Station/Workstation* if not properly mounted which could result in user and/or patient harm.



* Alaris™ Gateway Workstation and Alaris™ DS Docking Station

Syringe Loading

Prepare Syringe and Administration Set

To decrease potential start-up delays, delivery inaccuracies and delayed generation of occlusion alarms each time a new syringe is loaded:

- Use smallest syringe size possible, for example, if delivering 9 ml of fluid, use a 10 ml syringe.
- Use the **PURGE SYRINGE** or **PURGE** option on the Alaris™ Enteral Plus Syringe Pump to decrease the delay in the start of the delivery, see *Starting the Alaris™ Enteral Plus Syringe Pump* section.



Use the smallest compatible syringe size necessary to deliver the fluid or medication.



Purge the Alaris™ Enteral Plus Syringe Pump system before starting a delivery or after replacing a near-empty syringe with a replacement syringe. When Purging ensure that the administration set is not connected to the patient.

Positioning of Pump

Ensure that the Alaris™ Enteral Plus Syringe Pump is as close to level of patient's stomach as possible. Patient's stomach level should be in line with the middle of the Alaris™ Enteral Plus Syringe Pump.



Adjusting the Alaris™ Enteral Plus Syringe Pump's height relative to the patient's stomach level can lead to temporary increases or decreases in delivery



If using multiple syringe pumps place the high risk or life-sustaining medications as close to the patient's heart level as possible.

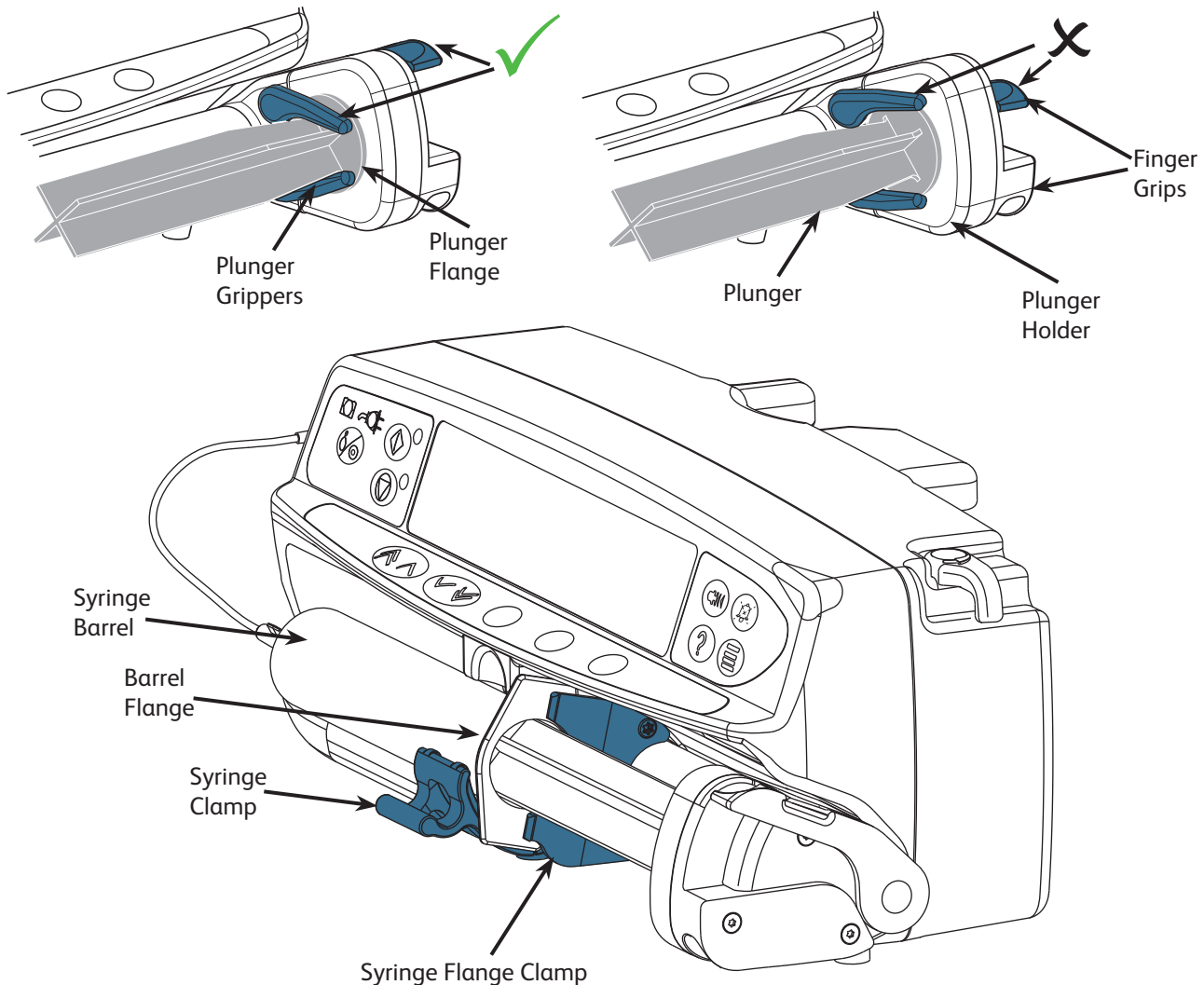
Loading and Confirming a Syringe



To securely load and confirm a syringe carefully follow the steps below. Loading a syringe incorrectly may result in misidentification of the syringe. If incorrectly confirmed, this may lead to significant inaccuracy of the delivery rate and may also affect Alaris™ Enteral Plus Syringe Pump performance.

Only use a syringe of the brand/model stated on the Alaris™ Enteral Plus Syringe Pump display or in this manual. Using a non recognised enteral syringe type could adversely affect the accuracy of the delivery rate and may also affect Alaris™ Enteral Plus Syringe Pump performance.

When drawing fluid into the syringe, draw enough to compensate for any 'dead space' volume in the feeding tube and syringe at the end of delivery as this cannot be fully administered.



Place the Alaris™ Enteral Plus Syringe Pump on a stable horizontal surface or secure as described previously.

Prepare, load and prime the single-use enteral syringe and administration set using standard techniques.

1. Squeeze the finger grips together on the plunger holder and slide the mechanism to the right.
2. Pull the syringe clamp forward and down.



3. Insert the syringe ensuring that the barrel flange is located in the slots on the syringe flange clamp.



To ensure the syringe is loaded correctly, place the barrel flange in the space between the syringe clamp and the syringe flange clamp. This is correct if the syringe remains in position before the syringe clamp is closed.



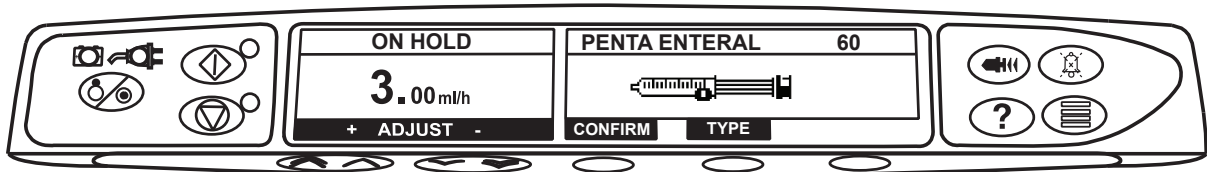
4. Lift the syringe clamp until it locks against the syringe barrel.



5. Squeeze the finger grips on the plunger holder and slide the mechanism to the left until it reaches the plunger end.
6. Release the finger grips. Ensure that the plunger grippers are securing the plunger in place and the finger grip returns to its original position.



7. Ensure that the syringe type and size match those displayed on the Alaris™ Enteral Plus Syringe Pump display then press **CONFIRM**. If required, the make of syringe can be changed by pressing the **TYPE** softkey.




Secure the feeding tube using the hook at the rear of the Alaris™ Enteral Plus Syringe Pump. This provides protection against accidental dislodging of the syringe from the Alaris™ Enteral Plus Syringe Pump. Ensure that both plunger grippers are fully locked onto the plunger flange and the upper finger grip has returned to its original position.

Starting the Alaris™ Enteral Plus Syringe Pump



When operating the Pump, the User should position themselves at a distance of 0.5 metres from the display.






1. Connect the Alaris™ Enteral Plus Syringe Pump to an AC power supply using the AC power cable.
2. Press the  button.
 - The Alaris™ Enteral Plus Syringe Pump will run a short self-test.



Two beeps are activated during this self-test and the red alarm beacon illuminates and then clears. No action is required during this self-test.

- Check the display test pattern and ensure that no rows are missing.
- Check that the displayed time and date are correct.
- Finally check display shows the data set name and version number.

Note: A warning - **REPAIRING LOGS**, may be displayed if event log information was not completely stored at the previous power down. This is for information only, the Alaris™ Enteral Plus Syringe Pump will continue to power up as normal.

3. **CLEAR SETUP**
 - Selecting **NO** will keep previous setup and go to step 8.
 - Selecting **YES** will clear previous setup and will go to step 4.
4. Load the syringe according to the procedure in this manual.
5. Ensure that the syringe type and size match those displayed on the Alaris™ Enteral Plus Syringe Pump then press **CONFIRM**. If required, the make of syringe can be changed by pressing the **TYPE** softkey.
6. Purge (if required) - Press the  button and then press and hold the **PURGE** softkey until fluid flows and the purging of the administration set is complete. Release the softkey. The volume used during purging will be displayed.
7. Check the rate shown if set and change the rate if necessary using the   keys.
8. Connect the administration set to the patient access device.
9. Press  to commence operation.
 - The *amber stop* light will be replaced by the flashing *green start* light to indicate that the Alaris™ Enteral Plus Syringe Pump is in operation. **RUNNING** will be displayed.
10. Press  to halt the operation. **ON HOLD** will be displayed. The *amber stop* light will replace the *green start* light.

Basic Features

Bolus Delivery






Bolus Administering a controlled volume of fluid or drug at an increased rate.
Bolus can be used at the start of a delivery or during feeding.




During **BOLUS** the pressure limit alarm is temporarily increased to the maximum level.

Hands-Free

The Hands-Free Bolus is delivered with a single press of the (flashing) **BOLUS** softkey.




1. During delivery press the  button to display the Hands-Free bolus selection screen.
2. Press the **YES** softkey to go to Hands-Free selection bolus screen.
3. Use the   keys to set the bolus volume/dose required; If necessary use the **RATE** softkey and the   keys to adjust the bolus delivery rate.

Note: Rate may be restricted by the syringe size and the **CAP BOLUS RATE**.

4. Press the flashing **BOLUS** softkey once to begin the delivery of the preset bolus. The display will show the bolus being delivered, the bolus counting down and revert to main delivery display upon completion of the bolus.
5. To terminate a bolus being delivered press **STOP** softkey. This will stop the bolus and continue delivery at the set rate. Press the  button to stop the bolus delivery and place the pump on hold.
6. If the bolus volume reaches the set bolus volume the bolus will stop and the pump will revert to deliver at the set delivery rate and continue delivery.


Hands-On

In Hands-On Bolus, press and hold the (flashing) **BOLUS** softkey to deliver the required bolus. The bolus rate can be adjusted. The bolus volume is limited in the configuration.


1. During delivery press the  button once to display the bolus screen.
2. Press the **HANDS ON** softkey for Hands-On bolus.
3. Use the   keys to adjust the bolus rate if required.
4. To deliver the bolus press and hold the **BOLUS** softkey. During the bolus, the volume being delivered is displayed. When the desired bolus volume has been delivered or the bolus volume limit is reached, release the softkey. The bolus volume is added to the total volume delivered.




If the Hands-Free bolus option is active, then this feature will be cancelled following any interruption in delivery, e.g. occlusion, even if the bolus delivery is incomplete.

If the volume to be delivered (VTBD) is reached during a bolus, the VTBD complete alarm will sound. Press  to silence the alarm or **CANCEL** to acknowledge the alarm. See VTBD section for more details on VTBD operation.

Purge

The  button allows the delivery of a limited volume of fluid in order to purge the administration set prior to being connected to a patient or after changing a syringe.

1. Press the  button when the Alaris™ Enteral Plus Syringe Pump is not delivering. Ensure that the administration set is not connected to the patient.
2. Press and hold the **PURGE** softkey until fluid flows and the purging of the administration set is complete. The volume used during purging will be displayed, but it is not added to the volume delivered.
3. When purging is complete release the **PURGE** softkey. Press the **QUIT** softkey to exit back to the main display.





Note: When maximum purge volume is reached, the pump will return to the main display screen.



During **PURGE** the pressure limit alarms are temporarily increased to their maximum level.

Volume to be Delivered (VTBD)

This option allows a specific volume to be delivered to be set. Rate at the end of this VTBD can also be set, selecting from stop, KTO (Keep Tube Open), or continuous delivery at the set rate.

1. Press the **VTBD** softkey to select the volume to be infused option.
2. Enter the volume to be delivered using the   keys and press the **OK** softkey.
3. Select the rate at the end of the VTBD using the   keys to scroll through the on-screen choices. The default is stop.
4. Press the **OK** softkey to confirm and exit the VTBD menu.

Note: When current VTBD has finished, no other delivery will be allowed unless a new VTBD is set or current VTBD is cleared.

Clear Volume








This option enables the volume delivered to be cleared.

1. Press the **VOLUME** softkey to display the **CLEAR VOLUME** option.
2. Press the **YES** softkey to clear the volume. Press the **NO** softkey to retain the volume.

Note: Selecting **YES** resets the volume delivered in the **24H LOG** option.




Set VTBD over Time

This option allows a VTBD and delivery time to be specified. The rate necessary to deliver the required volume within the specified time is calculated and displayed.

1. Ensure the pump is on hold. Press the  button to access the options menu.
2. Select the **SET VTBD OVER TIME** option using the   keys and press the **OK** softkey.
3. Adjust the volume to be delivered using the   keys. When the desired volume has been reached press the **OK** softkey.
4. Enter the time over which the volume is to be delivered. The delivery rate will automatically be calculated. Press the **OK** softkey to enter the value.
5. Select the rate at VTBD end from the list using the   keys and press the **OK** softkey. The default is **STOP**.

24 Hour Log

This option allows the 24 hour log of volume delivered to be reviewed.

1. Press the  button to access the options menu.
2. Select the **24H LOG** option using the   keys and press the **OK** softkey.






The display shows the hourly volume delivered. The volume delivered shown in brackets is the total volume delivered since the volume was last cleared. See example below:

```
07:48 - 08:00 4.34ml (4.34ml)-
08:00 - 09:00 2.10ml (6.44ml)
09:00 - 10:00 2.10ml (8.54ml)
VOLUME CLEARED
```

3. Press the **QUIT** softkey to exit the log.

Event Log




This option allows the event log to be reviewed.

1. Press the  button to access the options menu.
2. Select the **EVENT LOG** option using the   keys and press the **OK** softkey.
3. Scroll through the log using the   keys. Press the **QUIT** softkey to exit the log.

Note: When the event log reaches full capacity, the oldest events will be overwritten by the most recent events.

Data Set Details

To review currently selected data set information:




1. Press the  button to access the options menu.
2. Select **DATA SET DETAILS** option using the   keys and press the **OK** softkey.
3. Review the information and then press the **QUIT** softkey.



The data set for the Alaris™ Enteral Plus Syringe Pump is factory set and can not be configured.

Pump Details

To review Alaris™ Enteral Plus Syringe Pump information.




1. Press the  button to access the options menu.
2. Select **PUMP DETAILS** option using the   keys and press the **OK** softkey.
3. Review the information and then press the **QUIT** softkey.

Note: The following information will be displayed:

- SN The serial number of the Alaris™ Enteral Plus Syringe Pump
- S/W Software version of the Alaris™ Enteral Plus Syringe Pump

Adjust Alarm Volume




To change the alarm volume.

1. Press the  button to access the options menu.
2. Select **ADJUST ALARM VOLUME** option using the   keys and press the **OK** softkey.

Note: The Alaris™ Enteral Plus Syringe Pump will beep at the selected alarm volume setting. The user must assess whether the alarm volume setting is loud enough for the intended operating environment, and adjust appropriately.

3. Select alarm volume required and press the **OK** softkey.

Pressure Level



1. To check and adjust the pressure level press the  button. A bar graph will be displayed showing the pressure alarm level and the current pressure level.
2. Press the   keys to increase or decrease the alarm level. The new level will be indicated on the display.
3. Press **OK** to exit the screen.



The interpretation of the pressure readings and occlusion alarms are the responsibility of the clinician and should include the clinical context in which the Alaris™ Enteral Plus Syringe Pump is being used.

Alarms and Warnings

Alarms are indicated by a combination of an audible alarm, alarm indicator and a descriptive message in the display.

1. First press the  button to silence the alarm for 2 minutes, then check the display for an alarm message. Press **CANCEL** to cancel the alarm message.
2. If the delivery has stopped, rectify the cause of the alarm then press the  button to resume feeding.






If the Alaris™ Enteral Plus Syringe Pump initiates a safety processor alarm condition (an audible high pitched continuous trill accompanied with a red alarm indicator) and there is no error message displayed on the Alaris™ Enteral Plus Syringe Pump, remove the Alaris™ Enteral Plus Syringe Pump from service for examination by Qualified Service Personnel.



Delivery will stop for all high priority alarms.

Display	Alarm Priority	Description and Troubleshooting Guide
DRIVE DISENGAGED	High	The drive system has been disengaged during operation. Check the finger grips and the position of the syringe.
OCCCLUSION	High	Excessive pressure measured at the syringe plunger exceeding the alarm limit. Identify and remove the cause of the blockage in the drive, syringe, or administration system before restarting delivery.
CHECK SYRINGE	High	<p>Incorrect size of syringe has been fitted, the syringe has not been positioned correctly or has been disturbed during operation. Check the syringe location and the position.</p> <p>A CHECK SYRINGE alarm may indicate the incorrect size of syringe has been fitted; the syringe has not been positioned correctly, or has been disturbed during operation, for example, the user opens the syringe clamp, or If the syringe plunger loses contact with the plunger button.</p> <p>If there is no identifiable cause for the CHECK SYRINGE alarm(s) then the pump should be removed from clinical use and examined by Qualified Service Personnel in accordance with the Alaris™ Syringe Pump Technical Service Manual.</p>
BATTERY LOW	Medium	<p>Battery charge low with 30 minutes operation remaining. Reconnect to the AC power supply to charge the internal battery and continue operation. If action is not taken the battery indicator will flash for 30 minutes followed by a continuous audible alarm, red alarm indicator and message BATTERY EMPTY displayed, indicating that the battery is too low to operate the Alaris™ Enteral Plus Syringe Pump.</p> <p>*Optional reminder signals may sound. These auditory signals have four beeps that occur every ten minutes once the Low Battery alarm has been cancelled</p>
BATTERY EMPTY	High	The internal battery is too low to operate the Alaris™ Enteral Plus Syringe Pump. Immediately connect the Alaris™ Enteral Plus Syringe Pump to the AC power supply and cycle the power to resume operation.
NEAR END OF DELIVERY	Low	<p>The Alaris™ Enteral Plus Syringe Pump is nearing the end of the delivery.</p> <p>*Optional reminder signals may sound. These auditory signals have four beeps that occur every ten minutes once the Near End Of Delivery alarm has been cancelled.</p>
END OF DELIVERY	High	The Alaris™ Enteral Plus Syringe Pump has reached the end of the delivery and the Alaris™ Enteral Plus Syringe Pump has stopped delivering. A pre-set volume will remain in the syringe.
VTBD DONE (STOP)	High	The pre-set Volume To Be Delivered is complete and the Alaris™ Enteral Plus Syringe Pump has stopped delivering.
VTBD DONE (KVO/CONTINUE)	Medium	The pre-set Volume To Be Delivered is complete and the Alaris™ Enteral Plus Syringe Pump continues to deliver at set rate or at KTO rate.

Display	Alarm Priority	Description and Troubleshooting Guide
AC POWER FAIL	Low	AC Power has been disconnected and the Alaris™ Enteral Plus Syringe Pump is operating on battery power. If this occurs when the Alaris™ Enteral Plus Syringe Pump is operating the message DELIVERY CONTINUES will be displayed. Reconnect AC power supply or press the  button to silence the alarm and continue with battery operation. The alarm will automatically cancel if the AC power supply is reconnected.
Error Code and Message	High	The alarm system has detected an internal malfunction. Note the malfunction code. Remove the Alaris™ Enteral Plus Syringe Pump from service for examination by Qualified Service Personnel.
ATTENTION	Low	If the Pump has been left on for more than 2 minutes* (referred to as ATTENTION in the log) without starting the operation, a low priority alarm will be generated. Press the  button to silence the alarm for a further 2 minutes. For extended Attention Timeout press and hold down the  button and wait for four beeps in succession, this will put the Pump on standby for 15 minutes.

*Configurable option.

Note: The audio sound pressure level is at least 45 dB depending on configuration of the alarm sound level.



Setting the alarm sound pressure level lower than the ambient sound pressure level can impede User recognition of alarm conditions.

Alarm Priority Level Indicators

Priority	Audio Indicator	Visual Indicator (Beacon)
High	Ten beep sequence followed by a three second pause	Flashing Red
Medium	Three consecutive beeps followed by a four second pause	Flashing Amber
Low	Three consecutive beeps followed by a sixteen second pause	Solid Amber

Configured Options

This section comprises a list of configurable options, which can be entered via the Pump configuration menu (available in Technician Mode).

Enter the access code on the Alaris™ Enteral Plus Syringe Pump for Configured Options, see the *Technical Service Manual* for details.



Access codes should only be entered by qualified technical personnel.

Alarm Presets

Pumps with version 4.4.x software have a choice of two configurable alarm tones:

- Single tone: Low, medium and high priority alarm tones in accordance with IEC 60601-1-8:2012 and IEC 60601-1-2-24:2012
- Classic tone: Low, medium and high priority alarm tones that sound like the auditory alarms from software versions prior to 4.4.x

Enter the access code on the Pump for Alarm Presets, see the Technical Service Manual or Information Notice for details. The default alarm preset is a single tone alarm in accordance with IEC 60601-1-8:2012 and IEC 60601-2-24:2012.

1. Use the keys to select alternative alarm tones
2. When the desired alarm tone has been selected press the **OK** softkey.
3. When all the required modifications have been carried out press the **QUIT** softkey.



All pumps in a single care area should be configured with the same alarm tones to avoid User confusion. The Hospital/Facility is responsible for selecting and configuring the desired alarm scheme.



The Alaris™ Gateway Workstation (Workstation) with software versions 1.1.3, 1.1.3MR, 1.1.5, 1.2 or 1.5 do not support the new Pump low priority visual alarms scheme defined in IEC 60601-1-8:2012. For Pumps with version 4.4.x software or higher docked into the Workstation there will be a mismatch of alarm priority displayed. As a result, Near End of Delivery, AC Power Fail and Attention alarms will display as a medium visual priority alarms on the Workstation beacon and a low priority alarm on the Pump. In the event of an alarm priority mismatch, the User should refer to the alarm on the Pump for the correct priority.

Clock Set

1. Select **CLOCK SET** from the Configured Options menu using the keys and press the **OK** softkey.
2. Use the keys to adjust the date displayed, pressing the **NEXT** softkey to access the next field.
3. When the correct time and date are displayed press the **OK** softkey to return to the Configured Options menu.

Language

This option is used to set the language of messages shown on the Alaris™ Enteral Plus Syringe Pump display.

1. Select **LANGUAGE** from the Configured Options menu using the keys and press the **OK** softkey.
2. Use the keys to select the language.
3. When the desired language has been selected press **SELECT** softkey to return to the Configured Options menu.







Contrast

This option is used to set the contrast on the Alaris™ Enteral Plus Syringe Pump display.



1. Select **CONTRAST** from the Configured Options menu using the keys and press the **OK** softkey.
2. Use the keys to select a contrast ratio value. The contrast of the display will change when scrolling through the numbers.
3. When the desired value has been reached press the **OK** softkey to return to the Configured Options menu.

Enable Syringes

This option is used to pre-configure the syringe brand and size permitted for use on the pump. Select all permitted syringes and disable any that should not be used.

1. Select **ENABLE SYRINGES** from the Configured Options menu using the   keys and press the **OK** softkey.
2. Use the   keys to scroll through the list of syringe brands and press **SELECT** to access syringe sizes.
3. Use the   keys to scroll through the list of syringe sizes and press **MODIFY** to enable/disable a syringe size(s) within the brand.
4. When the desired modifications have been selected press the **QUIT** softkey to return to the Configured Options menu.

General Options

1. Select **GENERAL OPTIONS** from the Configured Options menu using the   keys and press the **OK** softkey.
2. Select the option required to enable/disable or adjust and press the **MODIFY** softkey.
3. When all the required modifications have been carried out press the **QUIT** softkey.
4. Either select the next configuration option from the menu or turn the Alaris™ Enteral Plus Syringe Pump off, returning it to operation as required.

NURSE CALL FITTED	Enables Nurse Call (hardware option).
NURSE CALL INVERT	When enabled, the nurse call output is inverted.
RS232 SELECTED	Sets the Alaris™ Enteral Plus Syringe Pump's communications to use RS232 (hardware option). The NURSE CALL FITTED option must be enabled to allow RS232 to function.
QUIET MODE	Mode to silence key press tones and power down sequence.
REMINDER SIGNAL	When enabled there is an audible notification, consisting of four beeps every 10 minutes for the Low Battery and Near End of Delivery alarms.
NEOD	When disabled, delivery will continue until end of delivery is reached.
CAP RATE	Sets the maximum value for delivery rate.

Configured Options Table

Option	Description	Default
NEOD Warning	Sets the Near End Of Delivery warning time, as time left to End Of Delivery.	10 minutes
EOD Point	Sets the End Of Delivery point.	0.1%
KTO Rate	The Alaris™ Enteral Plus Syringe Pump will switch to running at the KTO rate when EOD is reached.	0.1ml/h
VTBD Max	Maximum permissible Volume To Be Delivered value.	1000ml
Display Syringe Brand	Displays the Syringe Brand on the main display.	
Auto Save	Feature to retain previous settings when Alaris™ Enteral Plus Syringe Pump is switched on.	
AC Fail	The AC Power Failure Alarm will sound if the AC power is disconnected.	
Bolus Mode	Bolus feature is set to be Hands-On or Hands-Free.	
Pressure Display	Displays the Pressure Icon on the main display.	
Bolus Rate Default	The default value for bolus rate.	10ml/h
Bolus Rate Max	The maximum value for bolus rate.	200ml/h
Bolus Volume Max	The maximum permissible bolus volume.	1ml
Cap Pressure	Sets the maximum pressure value.	L10
Pressure Default	Sets the default occlusion alarm level.	L4
Purge Rate Max	Sets the purge rate.	500ml/h
Purge Volume Max	Sets the maximum permissible purge volume.	2.0ml
Call Back Time	The time for the Alaris™ Enteral Plus Syringe Pump to sound the call back alarm.	2 minutes
Event Log Display	The event log can be displayed.	
Battery Icon	Displays the Battery Icon on the main display.	
Audio Volume	Sets the alarm volume of the Alaris™ Enteral Plus Syringe Pump at high, medium or low.	Low
Auto Night Mode	Backlight dims between hours 21:00 and 06:00.	
VTBD Clear Rate	Rate will be set to zero when VTBD is complete.	

Specifications

Delivery Specifications

Maximum delivery rate is set at the following:

0.1ml/h - 150ml/h	5ml syringes
0.1ml/h - 200ml/h	10ml syringes
0.1ml/h - 200ml/h	20ml syringes
0.1ml/h - 200ml/h	50ml syringes

The Volume Delivered range is 0.0ml - 9990ml.



The Alaris™ Enteral Plus Syringe Pump displays Volume Delivered to 4 characters; however a volume delivered greater than 999ml will increment on the display in multiples of ten.

Bolus Specifications

Maximum Bolus rates is set at the following

10 ml/h - 150ml/h	5ml syringes
10 ml/h - 200ml/h	10ml syringes
10 ml/h - 200ml/h	20ml syringes
10 ml/h - 200ml/h	50ml syringes

Bolus rates are user adjustable, in increments of 10ml/h.

The bolus volume limit maximum is 1.0ml

During BOLUS the pressure limit alarms are temporarily increased to their maximum level.

Bolus Volume Accuracy*

Bolus Volume	Typical	Typical Maximum	Typical Minimum	Pump Specification
0.1ml	1.9%	6.2%	-7.3%	± 10%
25ml	0.2%	0.5%	-0.1%	± 5%

* - Using Pentafer® 60ml syringe at 5ml/h under normal conditions (95% confidence / 95% of pumps).

Critical Volume

The bolus which can occur in the event of a single internal fault condition with a 50 ml syringe is : Maximum Overdelivery - 0.87ml

Purge Specifications

The purge rate is limited to 500ml/h.

The purge volume is 2.0ml.

During PURGE the pressure limit alarms are temporarily increased to their maximum level.

End Of Syringe Rate

Stop

Volume To Be Delivered (VTBD)

0.10ml - 1000ml, 1min - 24h

VTBD Complete Rate

Stop, KTO (0.1ml/h), set rate if lower than KTO or continue at set rate.

Near End Of Delivery Alarm

10min to end of delivery or 10% of syringe volume, whichever is smaller.

End Of Delivery (EOD) Alarm

0.1% of syringe volume

Maximum Pumping Pressure Limit

Highest alarm level 1000mmHg (nominal at L-10)

Occlusion Accuracy (% of full scale)*

	Pressure mmHg			
	L-0 approx. 200mmHg	L-3 approx. 300mmHg	L-5 approx. 500mmHg	L-10 approx. 1000mmHg
Temp. 23°C	±18%	±21%	±23%	±28%

* - Using most common 60ml syringes under normal conditions (95% confidence / 95% of Alaris™ Enteral Plus Syringe Pumps).

System Accuracy

Rate	Typical	Pump Specification
≥ 1ml/h	± 2%	± 5%
< 1ml/h	± 2%	± 10%

- Derating - Temperature +/- 0.5% (5 - 40°C), High Rates +/-2.0% (rates > syringe volume/h eg. >50ml/h in a 50ml syringe.)



System accuracy is +/-2% typical by volume as measured using deionised water at rates of 1.0ml/h (23°C) and above when the Alaris™ Enteral Plus Syringe Pump is used with the Pentaferte Enteral and BD Enteral syringes. Differences in factors such as size and plunger force in recognised syringes can cause variations in accuracy.

Electrical Classification

Class I product. Continuous Mode Operation, Transportable

Battery Specifications

Rechargeable sealed NiMH. Automatically charges when the Alaris™ Enteral Plus Syringe Pump is connected to AC power. Mean Time To Battery Empty from fully charged at 5ml/h and 23°C under normal conditions is 6 hours*

*95% lower confidence interval of 5 hours 50 minutes

Charging takes 2½ hours from discharge to 90% charge.

Memory Retention

The electronic memory of the Alaris™ Enteral Plus Syringe Pump will be retained for at least 6 months when not powered up.

Fuse Type

2 x T 1.25H, 250V

AC Power Supply

115 - 230VAC, 50 - 60Hz, 30VA (under maximum charging conditions) 10VA (nominal)

Dimensions

310 mm (w) x 121 mm (h) x 200 mm (d).

Weight

2.4 kg (excluding power cable).

Protection against fluid ingress

IP32 - Protected against direct sprays of water up to 15° from vertical and protected against solid objects greater than 2.5mm.

Note: IP33 applies if AC power cable retainer kit, part number 1000SP01294, is fitted.

Alarm Conditions

Drive Disengaged	Occlusion	Attention (Nurse Callback)
Check Syringe	Battery Low	AC Power Fail
Internal Malfunction	Battery Empty	VTBD Done
Near End Of Delivery	End of Delivery	

Environmental Specifications

Operating Temperature	0°C - +40°C
Operating Relative Humidity	20% - 90%
Operating Atmospheric Pressure	700hPa - 1060hPa
Transport & Storage Temperature	-30°C - +50°C
Transport & Storage Relative Humidity	10% - 95%
Transport & Storage Atmospheric Pressure	500hPa - 1060hPa

Electrical/Mechanical Safety

Complies with EN/IEC60601-1 and EN/IEC60601-2-24.

EMC

Complies with EN/IEC60601-1-2 and EN/IEC60601-2-24.

Potential Equalisation Conductor

The function of the Potential Equalisation Connector (Conductor) is to provide a direct connection between the pump and the potential equalisation busbar of the electrical installation. To use the Potential Equalisation Connector, connect the Potential Equalisation Connector on the pump to the potential equalisation busbar of the electrical installation.

Recognised Syringe Types

The Alaris™ Enteral Plus Syringe Pump is designed to recognise single-use disposable enteral syringes. The table below lists the enteral syringes recognised by the Alaris™ Enteral Plus Syringe Pump.

Model	5ml	10ml	20ml	30ml	50ml	60ml
Pentaferte Enteral	2022590	2022690	2022790			2022990
Vygon Enteral*		1015.102	1015.212			1015.602
Vygon A-VY Enteral*			1015.213			1015.603
Medicina Enteral*	PE05	PE10	PE20			PE60
Nutricair*		SE10	SE20		SE50	

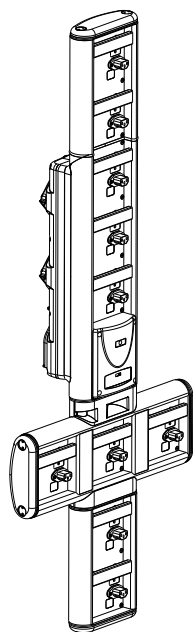
¹ Please contact your local BD representative for availability.



BD has characterized a range of enteral syringes as identified in the 'Recognised Syringe Types' table. BD cannot guarantee the continued system accuracy of these recognised enteral syringes* as the manufacturer may change syringe specification significant to system accuracy without prior notification. In no event shall BD be liable for any damages of any kind or nature, including without limitation, direct or indirect, special, consequential, or incidental damages arising from, or in connection with the use of enteral syringes not listed in the 'Recognised Syringe Types' table.

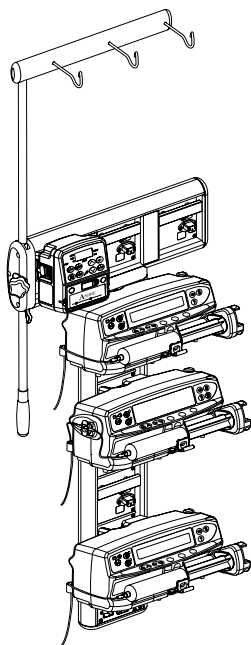
Associated Products

The Alaris™ Gateway Workstation



Product SKU	80203UNS0y-xx
Supply Voltage	115-230VAC, ~50-60Hz
Electrical Rating	460VA (Maximum)
Protection Against Electrical Shock	Class 1
Classification	Continuous Operation
Supply to pump	115-230V, ~50-60Hz, 60VA

The Alaris™ DS Docking Station



Product SKU	80283UNS00-xx
Supply Voltage	230VAC, 50 or 60Hz
Electrical Rating	500VA (nominal)
Protection Against Electrical Shock	Class 1
Classification	Continuous Operation
Supply to pump	20VA max 230V 50-60Hz

y = Connectivity option - 1, 2 or 3
xx = Configuration

Maintenance

Routine Maintenance Procedures

To ensure that this Alaris™ Enteral Plus Syringe Pump remains in good operating condition, it is important to keep it clean and carry out the routine maintenance procedures described below.

Interval	Routine Maintenance Procedure
As per Hospital Policy	Thoroughly clean external surfaces of the Alaris™ Enteral Plus Syringe Pump before and after prolonged period of storage.
Each usage	1. Inspect AC power supply plug and cable for damage.
	2. Inspect case, keypad and plunger for damage.
	3. Check Start up self test operation is correct.
Before the transfer of the Alaris™ Enteral Plus Syringe Pump to a new patient and as required	Clean the Alaris™ Enteral Plus Syringe Pump by wiping over with a lint-free cloth lightly dampened with warm water and a standard disinfectant / detergent solution.



If the Alaris™ Enteral Plus Syringe Pump is dropped, damaged, subjected to excessive moisture or high temperature, immediately take it out of service for examination by Qualified Service Personnel.

All preventative and corrective maintenance shall be performed at a compliant work place in accordance with the information supplied. BD will not be responsible should any of these actions be performed outside the instructions or information supplied by BD. For Preventative and Corrective Maintenance instructions please refer to the Technical Service Manual (TSM).

All preventative and corrective maintenance and all such activities should be performed by Qualified Service Personnel only, with reference to the TSM.



Please refer to Technical Service Manual for calibration procedures. The units of measurement used in the calibration procedure are standard SI units (The International System of Units).

Battery Operation

The internal rechargeable battery allows continued operation when the AC power is unavailable, for example during patient transfer or AC power failure. Mean Time To Battery Empty from fully charged @ 5ml/h & 23°C under normal conditions is 6 hours*. From the battery low alarm it will take 2½ hours to 90% charge when reconnected to the AC power supply, whether the Alaris™ Enteral Plus Syringe Pump is in use or not.

The battery is maintenance free, sealed Nickel Metal Hydride and requires no routine servicing. However, to achieve optimum operation, ensure that the battery is fully recharged after full discharge, before storage, and at regular 3 month intervals during storage.

It is recommended that only Qualified Service Personnel replace the battery, only use a BD recommended battery. For further information regarding the replacement of batteries refer to the Technical Service Manual.

The battery pack used in this Alaris™ Enteral Plus Syringe Pump is manufactured by BD and includes a proprietary PCB (printed circuit board) designed specifically for the Alaris™ Enteral Plus Syringe Pump, and in conjunction with Alaris™ Enteral Plus Syringe Pump software, controls battery use, charge and temperature. Any use of battery packs that are not manufactured by BD in the Alaris™ Enteral Plus Syringe Pump is at your sole risk, and BD does not provide any warranty for or endorsement on any battery packs that are not manufactured by BD. BD product warranty shall not apply in the event the Alaris™ Enteral Plus Syringe Pump has suffered damage or premature wear, or malfunctions or otherwise operates incorrectly, as a result of use with a battery pack that is not manufactured by BD.

*95% lower confidence interval of 5 hours 50 minutes

Cleaning and Storage

Before the transfer of the Alaris™ Enteral Plus Syringe Pump to a new patient and periodically during the use, clean the Alaris™ Enteral Plus Syringe Pump by wiping over with a lint-free cloth lightly dampened with warm water and a standard disinfectant / detergent solution.

Do not use the following disinfectant types:

- Disinfectants which are known to be corrosive to metals must not be used, these include:
 - NaDcc (such as Presept),
 - Hypochlorites (such as Chlorasol),
 - Aldehydes (such as Cidex),
 - Cationic Surfactants >1% (such as Benzalkonium Chloride).
 - Mixture of Alcohol & Chemicals with Cationic surfactants >1% Chlorohydrocarbons (such as Amberclens)
- Use of Iodine (such as Betadine) will cause surface discoloration.
- Concentrated Isopropyl alcohol based cleaners will degrade plastic parts.

Recommended cleaners are:

Brand	Concentration
Hibiscrub	20% (v/v)
Virkon	1% (w/v)

The following products were tested and are acceptable for use on the Alaris™ Enteral Plus Syringe Pump if used in accordance with the specified manufacturer's guidelines.

- Warm soapy water
- Mild detergent in water (e.g. Young's Hospec)
- 40% Isopropyl Alcohol in water
- Chlor-Clean
- Clinell Universal Wipes
- Hibiscrub
- Tristel Fuse sachets
- Tristel Trio wipes system
- Tuffie 5 wipe
- Virkon Disinfectant



Before cleaning always switch off and disconnect from the AC power supply. Never allow liquid to enter the casing and avoid excess fluid build up on the Alaris™ Enteral Plus Syringe Pump. Do not use aggressive cleaning agents as these may damage the exterior surface of the Alaris™ Enteral Plus Syringe Pump. Do not steam autoclave, ethylene oxide sterilise or immerse this Alaris™ Enteral Plus Syringe Pump in any fluid.

If the Alaris™ Enteral Plus Syringe Pump has visible cracks or damage to the case do not clean and immediately take out of service for examination by Qualified Service Personnel.


The syringe and administration sets are disposable single use items and should be discarded after use according to their manufacturers' instructions.

If the Alaris™ Enteral Plus Syringe Pump is to be stored for an extended period it should be first cleaned and the internal battery fully charged. Store in a clean, dry atmosphere at room temperature and, if available, employ the original packaging for protection.

Once every 3 months during storage, carry out functional tests as described in the *Technical Service Manual* and ensure that the internal battery is fully charged.

Disposal


Information on Disposal for Users of Waste Electrical & Electronic Equipment

This  symbol on the product and/or accompanying documents means that used electrical and electronic products should not be mixed with household waste.

If you wish to discard electrical and electronic equipment, please contact your BD affiliate office or distributor for further information.

Disposing of this product correctly will help to save valuable resources and prevent any potential negative effects on human health and the environment which could otherwise arise from inappropriate waste handling.

Information on Disposal in Countries outside the European Union

This  symbol is only valid in the European Union. The product should be disposed of taking environmental factors into consideration. To ensure no risk or hazard, remove the internal rechargeable battery and the Nickel Metal Hydride battery from the control board and dispose of as outlined by the local country regulations. All other components can be safely disposed of as per local regulations.

IrDA, RS232 and Nurse call Specification

IrDA / RS232 / Nurse call Feature

The IrDA or RS232 / Nurse call is a feature on the Alaris™ Enteral Plus Syringe Pump that allows connection to a PC or another Alaris™ Enteral Plus Syringe Pump. This allows data to be transferred between the Alaris™ Enteral Plus Syringe Pump and a PC or another Alaris™ Enteral Plus Syringe Pump, (e.g. Event Reports to be downloaded from the Alaris™ Enteral Plus Syringe Pump and the Alaris™ Enteral Plus Syringe Pump to be monitored remotely via a suitable central monitoring or computer system).



The nurse call interface provides a remote backup to the internal audible alarm. It should not be relied upon to replace monitoring of the internal alarm.

Refer to the Technical Service Manual for further information regarding the RS232 interface. Since it is possible to control the Alaris™ Enteral Plus Syringe Pump using the RS232 interface at some distance from the Alaris™ Enteral Plus Syringe Pump and hence remote from the patient, responsibility for the control of the Alaris™ Enteral Plus Syringe Pump is vested in the software run on the computer control system.

The assessment for the suitability of any software used in the clinical environment to control or receive data from the Alaris™ Enteral Plus Syringe Pump lies with the user of the equipment. This software should include detection of the disconnection or other failure of the RS232 cable. The protocol is detailed in the Alaris™ Enteral Plus Syringe Pump Communications Protocol and is for general information only.

Any connected analogue and digital components are required to meet IEC/EN60950 for data processing and IEC/EN60601 for medical devices. Anyone connecting additional devices to the signal input or output is a system configurator and responsible for meeting the requirements of the system standard IEC/EN60601-1-1.

IrDA

Baud Rate	115.2 kBaud
Start Bits	1 Start Bit
Data Bits	8 Data Bits
Parity	No Parity
Stop Bits	1 stop bit

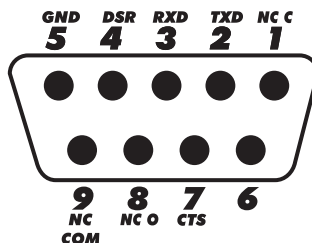
RS232 / Nurse call Connection Data

Nurse call Specification -

Connector	D Type - 9 Pin	
TXD/RXD	EIA RS232-C Standard	
TXD Output Voltage Range	Minimum: -5V (mark), +5V (space)	
	Typical: -7V (mark), +7V (space) with 3kΩ load to ground	
RXD Input Voltage Range	-30V - +30V max.	
RXD Input Thresholds	Low: 0.6V minimum	
	High: 3.0V maximum	
RXD Input Resistance	3kΩ minimum	
Enable	Active, Low:-7V to -12V	- powers up the isolated RS232 circuitry
	Active, High:+7V to +12V,	
	Inactive: Floating/open circuit, allows isolated RS232 circuitry to power down.	
Isolation Socket/Alaris™ Enteral Plus Syringe Pump	1.5kV (dc, or ac peak)	
Baud Rate	115.2 kBaud	
Start Bits	1 Start Bit	
Data Bits	8 Data Bits	
Parity	No Parity	
Stop Bits	1 stop bit	
Nurse Call Relay Contacts	Pins 1, 8 + 9, 30V dc, 1A rating	

Typical Connection Data -

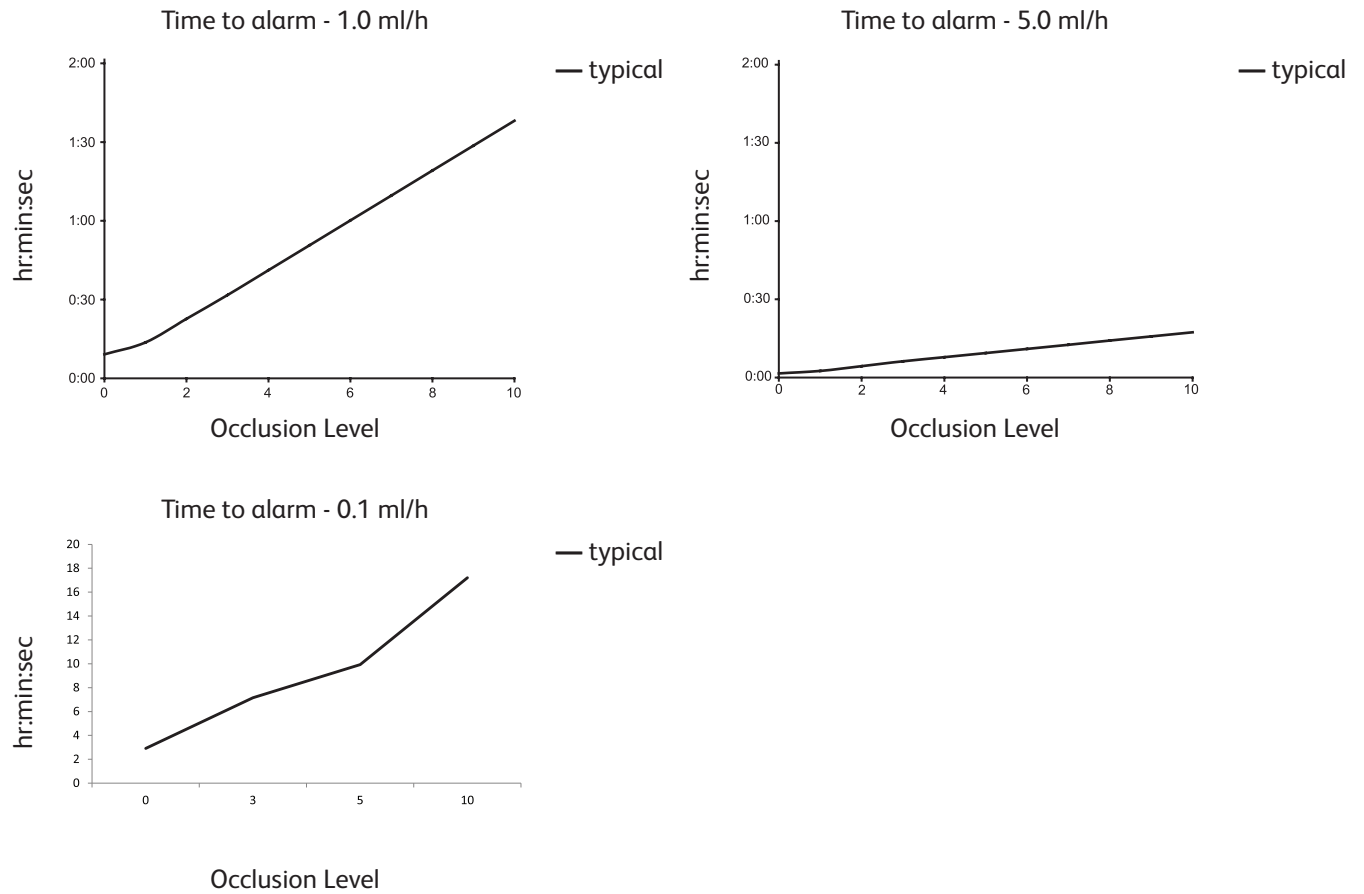
1. Nurse call (Relay) Normally Closed (NC C)
2. Transmit Data (TXD) Output
3. Received Data (RXD) Input
4. Power Input (DSR)
5. Ground (GND)
6. Not used
7. Power Input (CTS)
8. Nurse call (Relay) Normally open (NC O)
9. Nurse call (Relay) Common (NC COM)



Occlusion Pressure Limits

Time to alarm following occlusion is achieved in less than 30 minutes at rates of 1 ml/h and higher by the appropriate selection of occlusion levels.

The following graphs show the typical values for time to alarm and bolus volume that can be expected in the event of an occlusion when the Penta Enteral 60 ml feeding syringe is selected with a Pentaferte standard administration set.



Tests at low alarm levels may alarm immediately - the force at these levels is commonly less than the friction in the syringe (with no additional fluid pressure). The result is that the pressure relating to the low forces will be less than the nominal quoted occlusion pressure.


Trumpet Curves and Start-up Curves

In this pump, as with all infusion systems, the action of the pumping mechanism and variations in individual syringes cause short-term fluctuations in rate accuracy.

The following curves show typical performance of the system in two ways: 1) the delay in onset of fluid flow when infusion commences (start-up curves), and 2) the accuracy of fluid delivery over various time periods is measured (trumpet curves). The start-up curves represent continuous flow versus operating time from the start of the infusion. They exhibit the delay in onset of delivery due to mechanical compliance and provide a visual representation of uniformity. Trumpet curves are derived from the second hour of this data. Tests performed per *EN/IEC60601-2-24:1998 standard*.

Trumpet curves are named for their characteristic shape. They display discrete data averaged over particular time periods or *observation windows*, not continuous data versus operating time. Over long observation windows, short term fluctuations have little effect on accuracy as represented by the flat part of the curve. As the observation window is reduced, short term fluctuations have greater effects as represented by the *mouth* of the trumpet.

Knowledge of system accuracy over various observation windows may be of interest when certain drugs are being administered. Short term fluctuations in rate accuracy may have clinical impact depending on the half-life of the drug being infused, therefore the clinical effect cannot be determined from the trumpet curves alone.

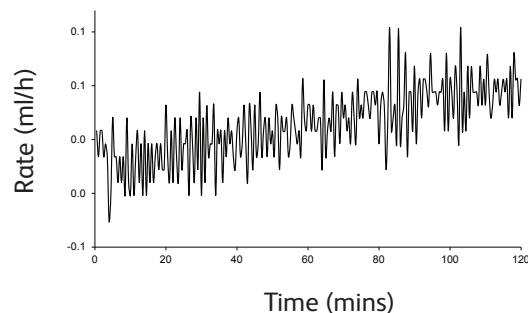


Start-up and trumpet curves may not be indicative of operation under negative pressure.

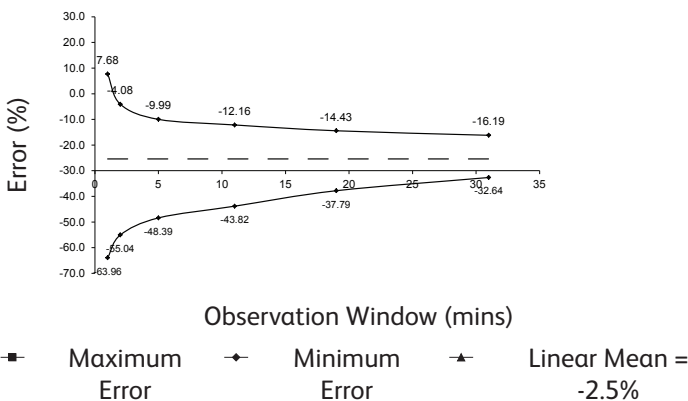
Differences in factors such as size and plunger force in recognised syringes produced by other manufacturers can cause variations in accuracy and trumpet curves as compared to those represented. Additional curves for recognised syringes are available upon written request.

For applications where flow uniformity is a concern, rates of 1.0ml/h or above are recommended.

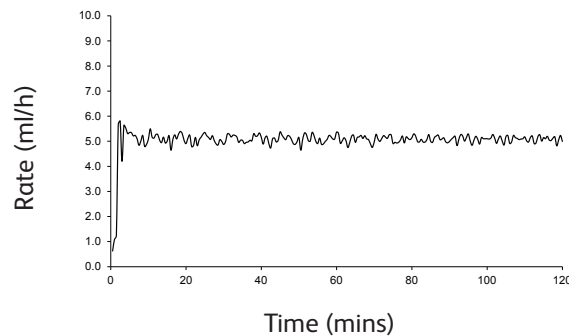
Start-up Trend. Pentaferte 60ml @ 0.1ml/h



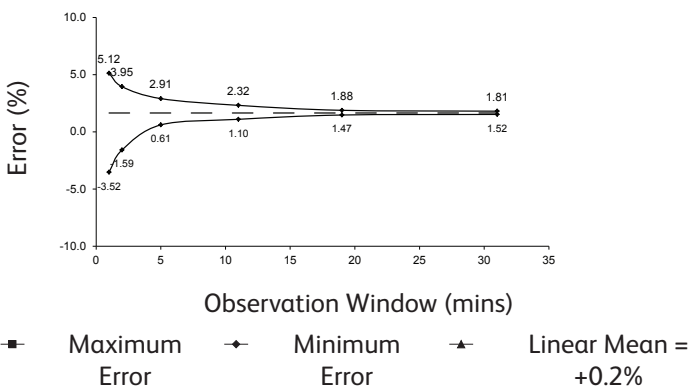
Trumpet Curve. Pentaferte 60ml @ 0.1ml/h



Start-up Trend. Pentaferte 60ml @ 5.0 ml/h



Trumpet Curve. Pentaferte 60ml @ 5.0 ml/h



Spare Parts

A comprehensive list of spare parts for this Alaris™ Enteral Plus Syringe Pump is included within the *Technical Service Manual*.

The *Technical Service Manual* (1000SM00024) is now available in electronic format on the World Wide Web at :-
bd.com/int-alaris-technical

A username and password are required to access our manuals. Please contact a local customer services representative to obtain login details.

Part Number	Description
1000SP01122	Internal Battery Pack
1001FAOPT91	AC Power Lead - UK
1001FAOPT92	AC Power Lead - European

Document History

Issue	Date	Software Version	Description
1	July 2019	4.4.11	Initial release
2	Nov 2020	4.4.11	Updates for regulations
3	April 2021	4.4.11	Update of Fuse Specification

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