Alaris™ GP (Guardrails™) Volumetric Pump

(with Plus Software)

Models: 9002TIG03, 9002TIG03-G

Directions For Use

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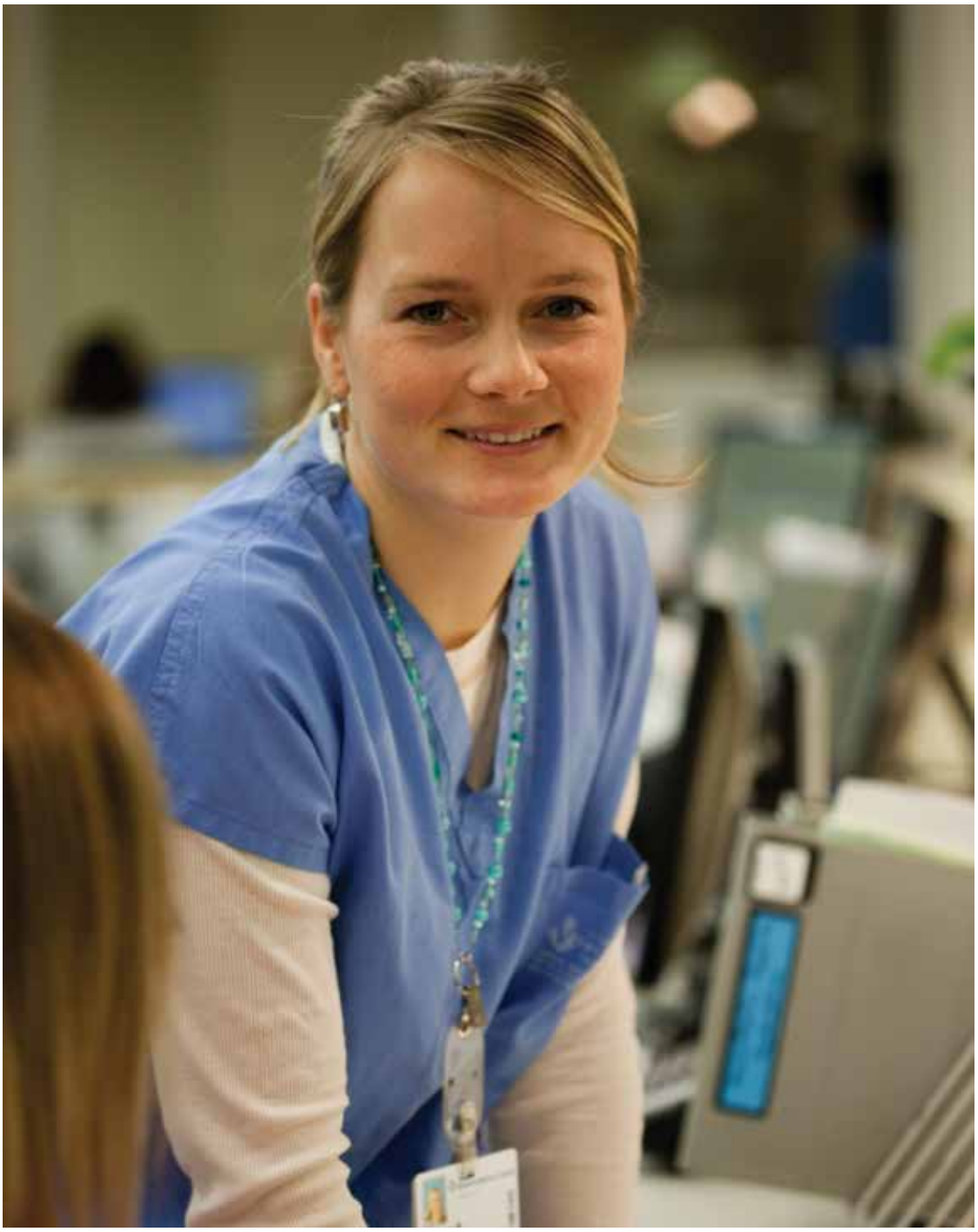

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Contents

Introduction

The Alaris™ GP Volumetric Pump and Alaris™ GP Guardrails™™ Volumetric Pump (hereinafter referred to as 'Pump') are small lightweight volumetric infusion pumps that provide accurate and reliable infusions over a range of rates.

The Alaris™ Editor software is a medical device accessory, which allows the hospital to develop a best-practice data set of IV medication dosing guidelines for patient-specific care areas referred to as profiles. Each profile contains a specific library of drugs, as well as an appropriate Pump configuration.

A profile also contains hard limits that cannot be overridden during infusion programming.

For the Alaris™ GP Guardrails™ Volumetric Pump only, Guardrails™ soft limits are available and can be overridden, based on clinical requirements.

The Alaris™ GP Guardrails™ Volumetric Pump with a data set loaded, provides automatic alerts when a dosing limit, bolus limit, concentration limit, or weight limit has been exceeded. These safety alerts are provided without the need for the Pump to be connected to a PC or network.

The hospital defined data set is developed and approved through pharmacy and clinical input, and then transferred into the Pump by Qualified Service Personnel.

Intended Purpose

The Alaris™ GP Volumetric Pump and Alaris™ GP Guardrails™ Volumetric Pump are intended for use by medical staff for the purpose of controlling infusion rate and volume.

Conditions for Use

The Alaris™ GP Volumetric Pump and Alaris™ GP Guardrails™ Volumetric Pump should only be operated by medical staff competent in the use of automated volumetric pumps and in the management of infusion therapy. Medical staff should determine the suitability of the device in their care area for its intended purpose.

Indications

The Alaris™ GP Volumetric Pump and Alaris™ GP Guardrails™ Volumetric Pump are indicated for the infusion of fluids, medications, parenteral nutrition, blood and blood products through clinically acceptable routes of administration; such as intravenous (IV), subcutaneous or irrigation of fluid spaces. The Alaris™ GP Volumetric Pump and Alaris™ GP Guardrails™ Volumetric Pump are indicated for use on adults and paediatrics.

Contraindications

The Alaris™ GP Volumetric Pump and Alaris™ GP Guardrails™ Volumetric Pump are contraindicated for enteral or epidural therapies.

About This Manual

The user must be thoroughly familiar with the Pump described in this manual prior to use.

The Pump has minor functionality differences to the Alaris™ GH/CC Guardrails™ Syringe Pumps.

All illustrations used in this manual show typical settings and values which may be used in setting up the functions of the Pump.

These settings and values are for illustrative use only. The complete range of settings and values are detailed 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.
Italics	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 a Pump.
	Caution symbol. A *caution* is a statement that alerts the user to the possibility of a problem with a Pump associated with its use or misuse. Such problems may include Pump malfunction, Pump failure, damage to a Pump or damage to other property. The caution statement includes the precaution(s) that should be taken to avoid the hazard.

Creating a Data Set

To create a data set for the Pump, first the hospital will need to develop, review, approve, upload according to the following process. Refer to the Alaris™ Editor help file for further details and operating precautions.

1. Create care area data set (Using the Alaris™ Editor)

Data Set	There are two types of data set which can be created; • Non-Guardrails™ Data Set - Creates a new Non-Guardrails™ data set for the Alaris™ Infusion Pumps to be edited in the application. • Guardrails™ Data Set - Creates a new Guardrails™ data set for the Alaris™ GP Guardrails™ Infusion Pumps to be edited in the application. A Guardrails™ Data Set provides additional safety features.
Profile	A unique set of configurations and best-practice guidelines for a specific population, patient type or care area. Each profile consists of: Pump Configuration / Drug Library Up to 30 profiles can be defined for each Data Set for the Pump.
Pump Configuration	Pump configuration settings and units for dosing only.
Drug Library	Drug names and concentrations for a data set with default value and maximum limits. Up to 100 unique drug protocol set-ups.

2. Master List (Using the Alaris™ Editor)

Master Drug List	A BD defined drug is a usability aid to pre populate drug names for the Master Drug Lists. Alternate drug names and concentrations can be created.

3. Review, approve and export data set

Review and Approve	Entire data set report to be printed, reviewed and signed as proof of approval by an authorised person, according to hospital protocol. Signed printout to be kept safe by hospital. Data set status to be set to Approved (Password is required).
Export	Export data set for use by the Alaris™ Transfer Tool or to back up a data set, or to move the data set to another PC.

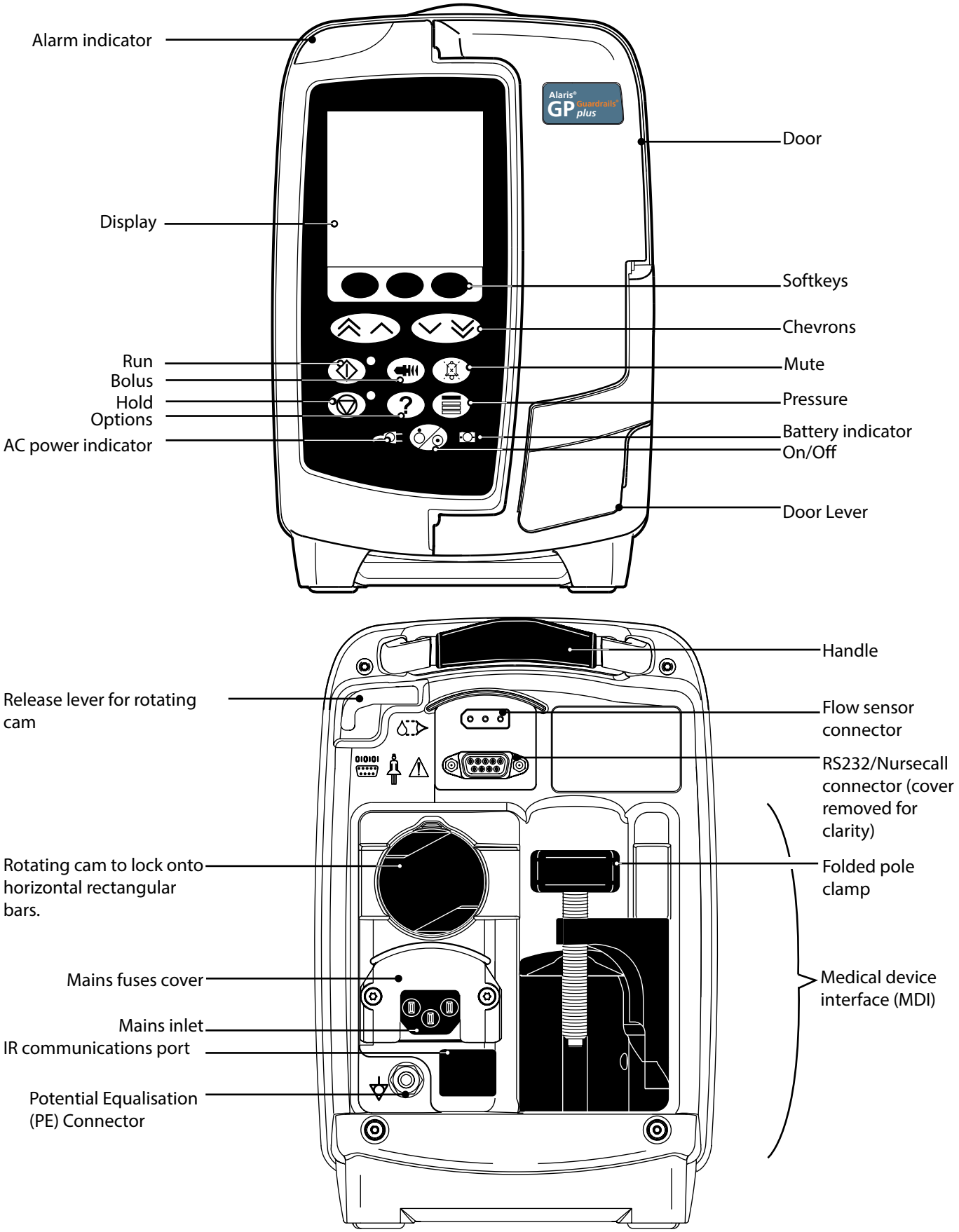
4. Upload data set to the Pump (Using Alaris™ Transfer Tool)

Note: One profile selection will be required when uploading the data set to the Alaris™ GP Volumetric Pump.

5. Verify that the correct data set is loaded into the Pump and accept it.
6. Switch the Pump off.
7. Switch the Pump on and verify that the software version screen displays the correct data set version. The Pump is now ready to use.

Data set transfers should only be performed by Qualified Service Personnel.
The Pump serial number and the hospital name are stored in the event log, they can also be obtained via the PUMP DETAILS option, refer to 'Pump Details' section.
Drug parameters have to be in accordance with local regulation and prescribed information.
It is recommended that prior to deploying a data set to all Alaris Compatible Guardrails Volumetric Pumps via Alaris Communication Engine (ACE), the Guardrails data set should be deployed, to a sample of pumps on a fully loaded AGW, in a non-clinical environment, and the pumps checked to ensure the settings and the drug library available on the pump are the same as included in the approved data set report.
After data set deployment using ACE, if a pump is found to have a corrupted data set, the specific pump, and Alaris Gateway Workstation (AGW) should be removed from service, and the data set transferred using a RS232 cable. The AGW should be checked by qualified service personnel.

Features of the Volumetric Pump



Controls and Indicators

Controls:

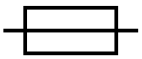
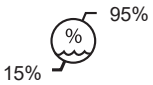
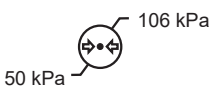
Symbol	Description
	**ON/OFF** button - Press once to switch the Pump on. Press and hold down for approximately three seconds to switch the Pump off. **Note:** Logs are maintained for power down events including when the Pump is powered down or unexpected power loss.
	**RUN** button - Press to start the infusion. The green LED will flash during infusion.
	**HOLD** button - Press to put the infusion on hold. The amber LED will be lit while on hold.
	**MUTE** button - Press to silence alarm for two minutes. The alarm will resound after this time. To re-enable the alarm audio press the **MUTE** button a second time. **Note:** Attention alarm only: when not in alarm press and hold until four audible beeps are heard to extend the silence period to 15 minutes.
	**PRIME/BOLUS** button - Press to access **PRIME** or **BOLUS** softkey. Press and hold down softkey to operate. PRIME - primes the infusion set with fluid when setting up an infusion for the first time. • Pump is on hold. • Infusion set is not connected to a patient. • Volume infused (VI) is not added to the total volume infused displayed. BOLUS - fluid or drug delivered at an accelerated rate. • Pump is infusing • Infusion set is connected to patient. • Volume infused (VI) is added to the total volume infused displayed.
	**OPTION** button - Press to access optional features.
	**PRESSURE** button - Use this button to display the pumping pressure and adjust the alarm limit.
	**CHEVRON** keys - Double or single for faster / slower increase / decrease of values shown on display.
	**BLANK SOFTKEYS** - Use in conjunction with the prompts shown on the display.

Indicators:

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

Symbol Definitions

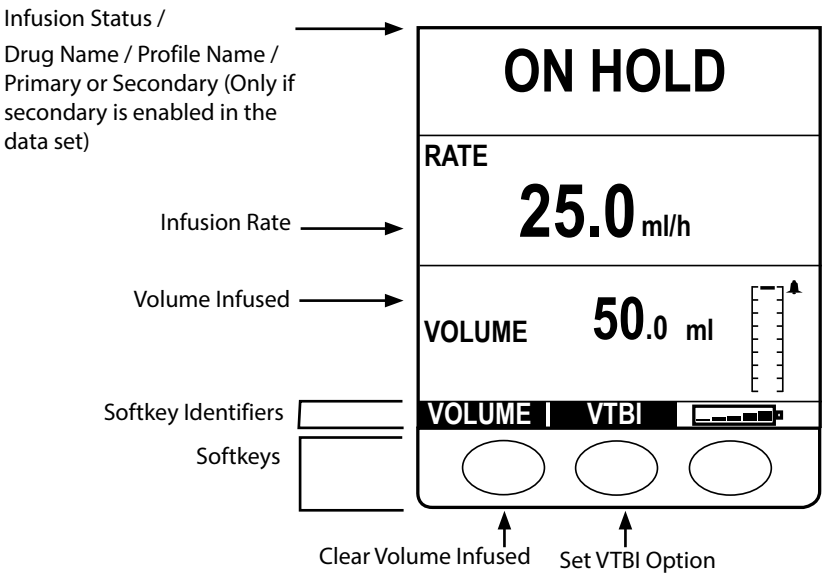
Labelling Symbols:

Symbol	Description
	Attention (Consult accompanying document)
	Potential Equalisation (PE) Connector
	RS232/Nursecall Connector.
	Defibrillation-proof type CF applied part (Degree of protection against electrical shock).
IP33	Protected from solid objects greater than 2.5mm. Protected against direct sprays up to 60° from the vertical.
	Alternating Current
CE 2797	Device complies with the requirements of Council Directive 93/42/EEC as amended by 2007/47/EC.
	Date of Manufacture
	Manufacturer
	Connector for Flow Sensor
	Not for Municipal Waste
	Fuse rating
	Operating Temperature Limit
	Transport and Storage Temperature limit
	Transport and Storage Humidity limitation
	Transport and Storage Atmospheric Pressure limitation
	This Way Up

	Fragile
	Keep Dry
REF	Catalogue number
SN	Serial Number
MD	Medical device

Main Display Features

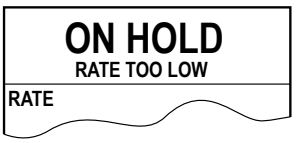
Main Display - If VTBI has not been set (flow sensor must be used)



a)

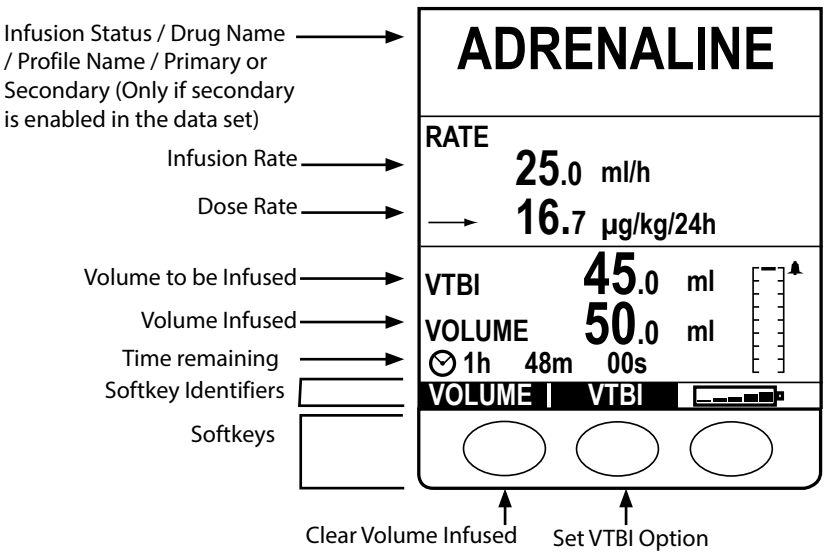
If the rate has not been set and is showing at 0.0ml/h, then message **a)** will be displayed.

b)



If programmed rate is between 0.0ml/h and 0.1ml/h exclusive in drug protocol, message **b**) will be shown.

Main Display - If VTBI is set



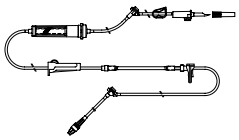
c)

If programmed rate is greater than the **Infusion Rate Max** in drug protocol, message **c)** will be shown.

Screen Icons

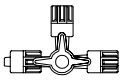
Symbol	Description
	Time remaining display icon - Indicates time remaining before VTBI will be completed. If the time is greater than 24 hours then 24+ will be displayed.
	Battery icon - Indicates battery charge level to highlight when the battery will require recharging.
	Pressure Information icon - Shows the pressure from level 0 being the first bar to level 8. Alarm limits: level 0 - 8.
?	Indicates that the value entered is outside of the Guardrails™ soft limits. The warning can be overridden (Indicates Guardrails™ safety protocol is in use).
!	Indicates that the value entered is outside of the hard limits. The warning can NOT be overridden. This symbol is also used to prompt the user to set the rate.
	Indicates that the Pump is running at a rate below (pointing down) a Guardrails™ Soft Limit.
	Indicates that the Pump is running at a rate above (pointing up) a Guardrails™ Soft Limit.

Operating Precautions



Infusion Sets

- To ensure correct and accurate operation, only use BD single use infusion sets described in this Directions For Use.
- It is recommended that infusion sets are changed according to the instructions in the 'Changing the Infusion Set' section. Carefully read the Directions For Use supplied with the infusion set prior to use.
- Use of non-specified infusion sets may impair the operation of the Pump and the accuracy of the infusion.



- When combining several apparatus and/or instruments with infusion sets and other tubing, for example via a 3-way tap or multiple infusion, the performance of the Pump may be affected and should be monitored closely.

- Uncontrolled flow may result if the infusion set is not properly isolated from the patient i.e. closing a tap in the set or activating an in-line clamp / roller clamp.
- BD infusion sets are fitted with an in-line clamp, which can be used to occlude tubing in case it is required to stop fluid flow.
- The Pump is a positive pressure pump, which should use infusion sets fitted with Luer lock fittings or equivalent locking connectors.
- To infuse from a burette, close the roller clamp above the burette and open the clamp on the vent on top of the burette.
- Discard infusion set if the packaging is not intact or the protector cap is detached. Ensure sets are not kinked as this may occlude the tubing.

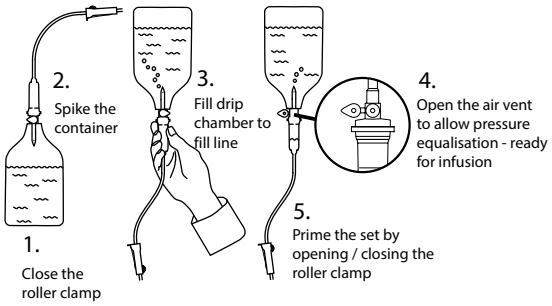
Using Collapsible bags, Glass Bottles & Semi Rigid containers

- It is recommended that the air vent be opened on the Pump sets if using glass bottles or semi-rigid containers, to reduce the partial vacuum formed as the fluid is infused from the container. This action will ensure the Pump can maintain volumetric accuracy whilst the container empties. The action of opening the air vent for semi-rigid containers should take place after the spiking of the container and priming of the drip chamber.

Steps for the Collapsible bags

Follow steps 1 to 3 as shown for the semi-rigid containers, however do not open vent as in step 4, but prime the set as per step 5. Ensure the bag outlet is fully pierced before filling the drip chamber.

Steps for Semi-rigid containers



Operating Environment

- Intended environments include general wards, critical and intensive care, operating rooms, accident and emergency rooms. The Pump may be used in an ambulance environment. Ensure that the Pump is appropriately attached using the provided pole clamp. The Pump is designed to withstand possible bumps and vibrations whilst being used in an ambulance, complying with the standard EN 1789. If the Pump is dropped or experiences any severe physical disturbances, arrange a thorough inspection by Qualified Service Personnel as soon as is practically possible. The Pump may also be used outside the ambulance as long as the temperature is within the specified range as stated in the 'Specifications' section and on the Pump label.
- When using any infusion pump in conjunction with other pumps or devices requiring vascular access, extra care is advised. Adverse delivery of medication or fluids can be caused by the substantial variation in pressures created within the fluid channels of such pumps. Typical examples of those pumps are used during dialysis, bypass or cardiac assist applications.
- The Pump is suitable for use in hospital and clinical environments other than domestic establishments that have access to single phase AC power supply.
- This Pump is not intended to be used in the presence of a flammable anaesthetic mixture with air or oxygen or nitrous oxide.

Operating Pressure

- The pumping pressure alarm system is not designed to provide protection against, or detection of extravasation or tissuing, complications which can occur.

Alarm Conditions

- Several alarm conditions detected by this Pump will stop the infusion and generate visual and audible alarms. Users must perform regular checks to ensure that the infusion is progressing correctly and no alarms are operating.
- Alarm tone settings are preserved in the case of a power loss, however some system faults will result in loss of alarm settings. The new alarm tone settings will be stored when powering down from tech mode after a change. The settings will be lost if a cold-start is performed, but should be saved for faults that don't require a cold start.

Electromagnetic Compatibility and Interference

- This 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 unreasonable levels of interference are encountered.
- Therapeutic Radiation Equipment: Do not use the 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 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 Pump contains ferromagnetic materials which are susceptible to interference with magnetic field generated by the MRI devices. Therefore, the Pump is not considered an MRI compatible Pump as such. If use of the Pump within an MRI environment is unavoidable, then BD highly recommends securing the Pump at a safe distance from the magnetic field outside the identified 'Controlled Access Area' in order to evade any magnetic interference to the 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 Pump. The 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 Pump immunity.
- In some circumstances the 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 Pump is affected by this external interference the Pump will remain in a safe mode; the Pump will duly stop the infusion and alert the user by generating a combination of visual and audible alarms. Should any encountered alarm condition persist even after user intervention, it is recommended to replace that particular Pump and quarantine the Pump for the attention of appropriately trained technical personnel.

- This Pump is a CISPR 11 Group 1 Class B 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, this Pump emits a certain level of electromagnetic radiation which is within the levels specified by IEC/EN60601-2-24 and IEC/EN60601-1-2. If the Pump interacts with other equipment, measures should be taken to minimise the effects, for instance by repositioning or relocation.

Earth Conductor

- The Pump is a Class I device, therefore must be earthed when connected to an AC power supply.
- This Pump also has an internal power source.
- 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 on the AC power cable has been compromised, the Pump should be disconnected from the AC power source and operated utilising the internal battery.

Hazards

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

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

- 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 this 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 Pump, use original packaging where possible, and adhere to temperature, humidity and pressure ranges stated in the Specifications section and on the outer packaging.
- If this Pump behaves abnormally, remove from service and contact Qualified Service Personnel.
- Care should be taken to ensure power leads and RS232 cables do not present a trip hazard.
- Care should be taken in the placement of power leads and RS232 cables to prevent accidental tugging.

- Alaris™ GP (Guardrails™) Volumetric Pump should not be modified or altered in any way, except where explicitly directed or authorised by BD. Any use of Alaris™ GP (Guardrails™) Volumetric 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™ GP (Guardrails™) Volumetric Pump that has been so modified or altered. BD product warranty shall not apply in the event the Alaris™ GP (Guardrails™) Volumetric Pump has suffered damage or premature wear, or malfunctions or otherwise operates incorrectly, as a result of unauthorised modification or alteration of the Alaris™ GP (Guardrails™) Volumetric Pump.
- All Pumps in a single care area should be configured with the same alarm tones to avoid User confusion

Getting Started

Before operating the Pump read this Directions For Use (DFU) manual carefully.

Initial Set Up

1. Check that the 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™ GP or Alaris™ GP Guardrails™ Volumetric Pump
   - AC Power Cable (as requested)
   - Alaris™ Editor Software and/or Alaris™ Transfer Tool - per hospital
   - Directions For Use (CD)
   - Protective Packaging
   - Electronic Instructions For Use Insert
3. Connect the Pump to the AC power supply for at least 2½ hours to ensure that the internal battery is charged (verify that the  is lit).

- **The Alaris™ Editor software can be used to create an approved data set that can be uploaded into the Pump. However, a default data set is already installed in the Pump (See details below).**
- **The Pump will automatically operate from its internal battery if the Pump is switched on without being connected to the power supply.**
- **Should the Pump fail to perform correctly, replace in its original protective packaging, where possible and contact Qualified Service Personnel for investigation.**

Power Input

The Pump is powered from the AC supply through a standard IEC AC connector. When connected to the AC supply the AC Power indicator is illuminated.

- **To isolate the Pump from AC supply remove the AC connector from the source socket.**
- **The Pump should be positioned to allow access for disconnecting the AC connector.**

Factory Default Data Set

The Pump is supplied with the following factory default data set:

Parameter	Factory Default Setting
AC Fail Warning	Enabled
Audio Volume	Medium
Alarm Volume Adjustable	Disabled
Occlusion Alarm Pressure	L5
Pressure Max	L8
Rate Titration	Disabled
Infusion Rate Max	1200ml/h
Rate Lock	Disabled
Bolus Mode	Hands-On Only
Bolus Rate Default	500ml/h
Bolus Rate Max	1200ml/h
Bolus Volume Max	5ml
Weight Default	1kg
Weight Soft Min*	1kg
Weight Soft Max*	150kg
AIL Limit	100µl
Primary VTBI Max	9999ml
Secondary Infusion	Disabled

Default Units Enabled for Dosing Only:
µg/min
µg/24h
mg/24h
unit/24h
mmol/24h
ml/kg/min
ng/kg/h
µg/kg/min
µg/kg/h
mg/kg/min
mg/kg/h
g/kg/min
unit/kg/min
mmol/kg/min
mmol/kg/h

- **Refer to 'Display of Units' section of this DFU for configurable units.**
- **The default data set does not have drug related Guardrails™ limits. To set the limits use the Alaris™ Editor software. Care should be taken when specifying the Guardrails™ limits.**

* Only available on the Alaris™ GP Guardrails™ Volumetric Pump.

Pole Clamp Installation

Mount the Pump on the pole or Docking Station/Workstation as close to patient heart level as possible.

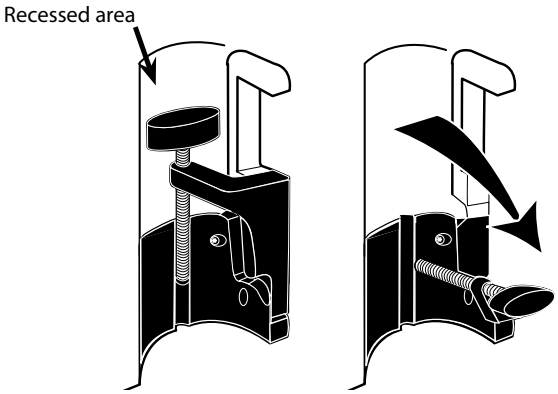
Prior to each use, check the pole clamp:

- **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.

The pole clamp is fitted to the rear of the Pump and will provide secure fixing to vertical I.V. 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 Pump around pole and tighten screw until the clamp is secured to the pole.



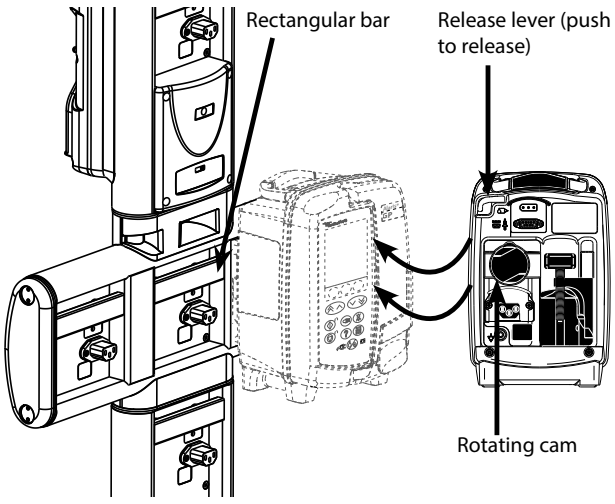
Never mount the Pump such that the I.V. infusion stand becomes top heavy or unstable.

Ensure the pole clamp is folded away and stored within the recessed area at the rear of the Pump before connecting to a Docking Station/Workstation* or when not in use.

Docking Station / Workstation or Equipment Rail Installation*

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

1. Align the rotating cam on the rear of the Pump with the rectangular bar on the Docking Station/Workstation* or the equipment rail.
2. Push the Pump firmly onto the rectangular bar or equipment rail.
3. 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*.
4. To release, push the release lever and pull the Pump forwards.



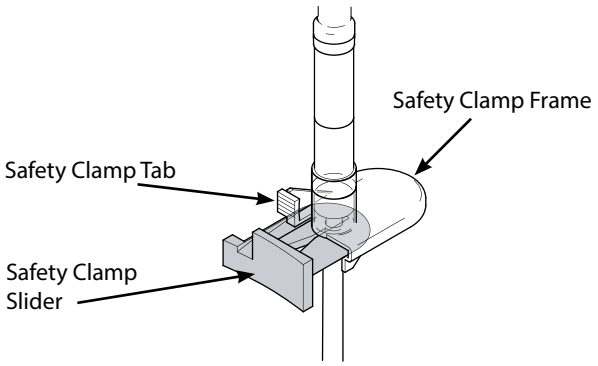
Pump may fall off the Docking Station/Workstation* if not properly mounted which could result in user and/or patient harm.

* Alaris™ DS Docking Station and Alaris™ Gateway Workstation.

It is recommended that infusion bags be located on a hanger directly above the Pump with which they are being used. This minimises the potential for confusion of infusion sets when multiple volumetric pumps are used. Pump can only be mounted on the horizontal section of the docking stations listed above.

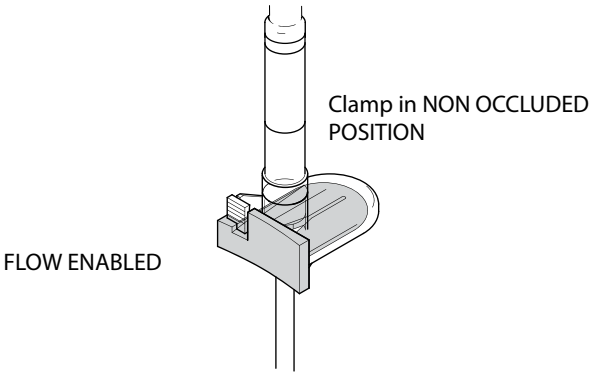
The Alaris™ Safety Clamp

Alaris™ Safety Clamp*:



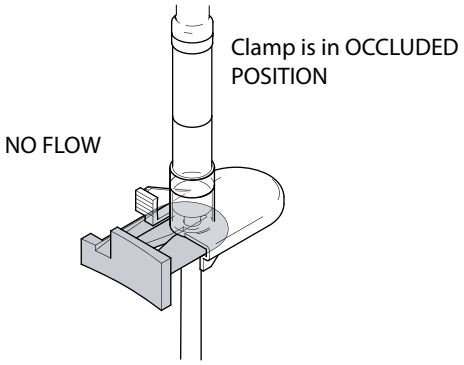
Safety Clamp In Non Occluded Position:

When a new infusion set is removed from packaging the Safety Clamp will be in this position**:



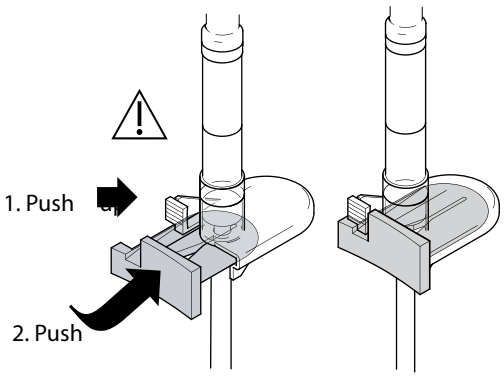
Safety Clamp In Occluded Position:

After infusion set is loaded into the Pump, opening the door activates door hooks which will pull the Safety Clamp slider out, as shown:



Manually Operating The Safety Clamp

To move the slider into the non occluded position manually, push up Safety Clamp Tab and push Safety Clamp Slider completely into Frame:



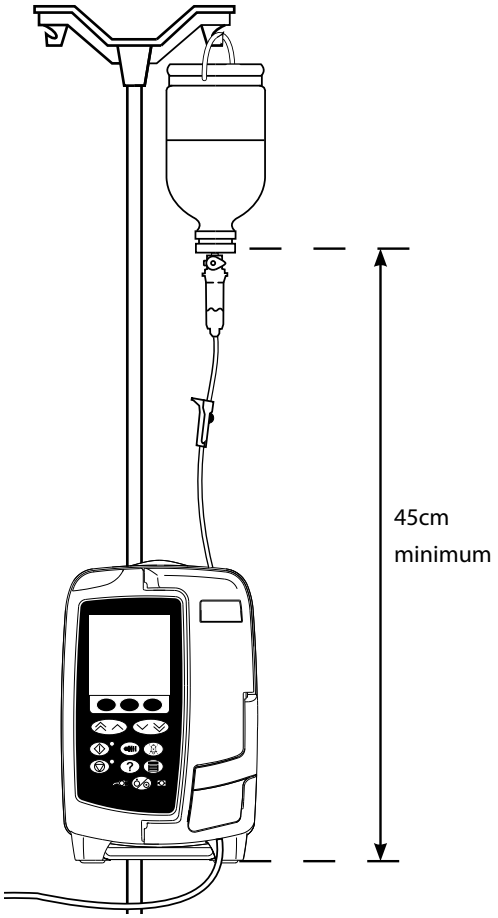
- **Pushing on the Safety Clamp Slider enables full set flow to the patient. Therefore it is recommended to always close the roller clamp as well.**
- **However, if gravity infusion is required, push up Safety Clamp Tab and push orange Safety Clamp Slider completely into Frame to enable flow. The gravity infusion can be regulated using the roller clamp on the set.**

***** Hereinafter referred to as to as 'Safety Clamp'.

****** This is necessary to avoid tube damage during storage and to ensure correct sterilisation and allows immediate priming.

Loading an Infusion Set

- **Ensure the appropriate infusion set for the fluid / drug to be infused has been selected.**
- **Follow the instructions supplied with the individual infusion set.**
- **Only use Alaris™ GP and Alaris™ GP Guardrails™ Volumetric Pump infusion sets, (refer to 'Infusion Sets' section of the DFU)**
- **Position the fluid container to avoid spillage onto the Pump.**
- **Ensure that the tubing is inserted completely into the top set retainer through to the tubing guide avoiding any slack.**
- **Do not pull or stretch the infusion set, when priming/loading/re-loading the infusion set.**
- **Mount the Pump on the pole or Docking Station/Workstation as close to patient heart level as possible.**

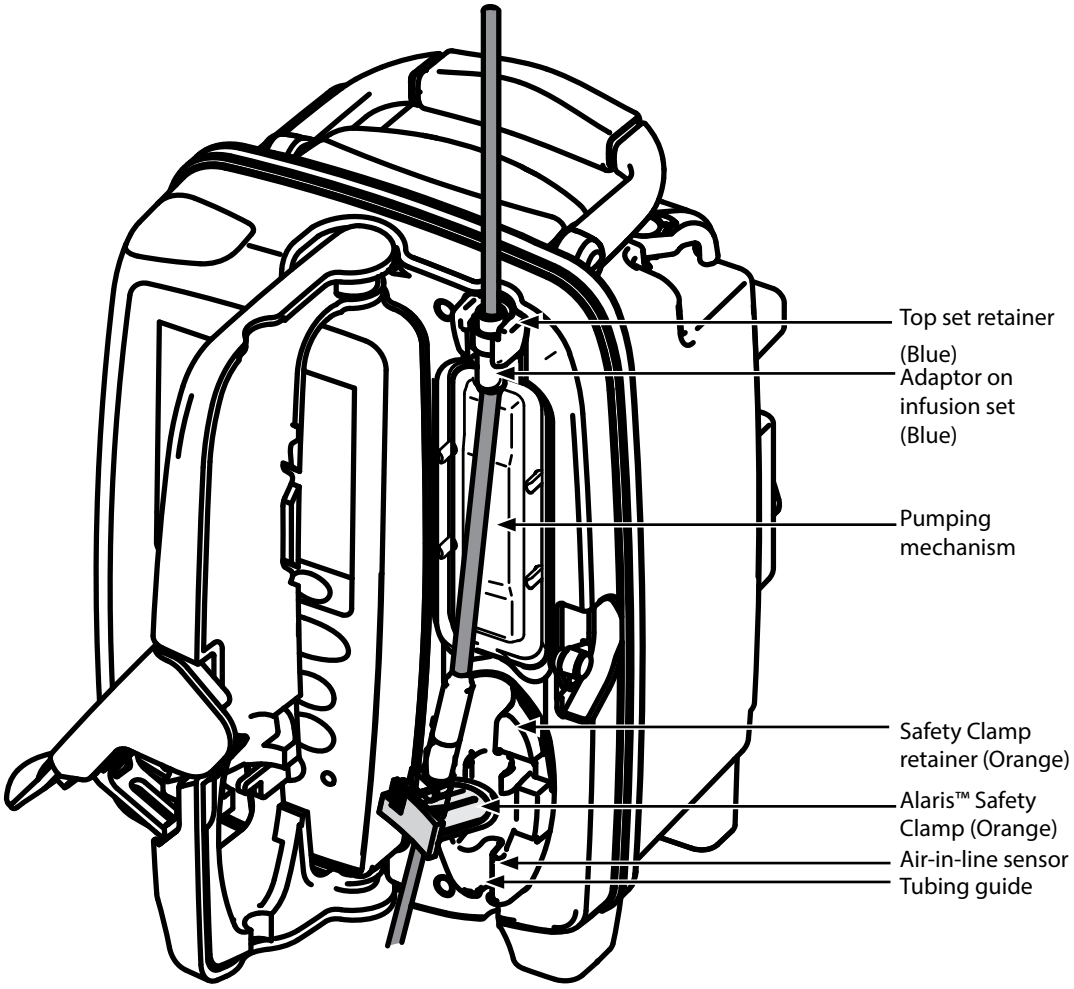
Step	**Notes**
1. Remove infusion set/burette from packaging, apply roller clamp, ensure air vent(s) are closed/clamped.	• Opening the air vent too soon can wet the filter and prevent flow
2. Spike fluid container ensuring spike is fully inserted into the container.	• Where possible the fluid in container should be at room temperature • Spike being fully inserted ensures the fluid path from the container is fully open
3. Fill the drip chamber to at least ½ full.	• Do not overfill the drip chamber when using a flow sensor • When using blood sets, fill the chamber to the top of the filter
4. Prime infusion set slowly, inverting pumping segment.	• Priming quickly causes turbulence resulting in air bubbles, which may lead to air in line alarms • For burette, glass bottles and semi-rigid containers, open air vent(s) after the infusion set has been primed half full. Leave closed for collapsible containers.
5. Hang the fluid container at a minimum height of 45 cm from the bottom of the Pump to the bottom of the fluid container. Raise the fluid container higher than the minimum height when possible, to minimise loops and kinks in the infusion set tubing.	

Step

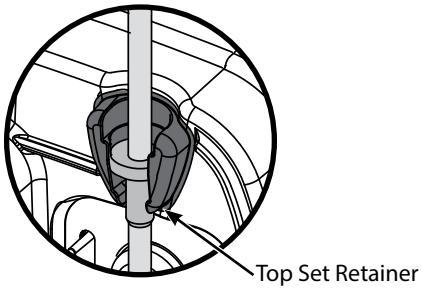
6. Close roller clamp.
7. Open door and load infusion set as follows:

Notes

- Ensure infusion set tubing above the Pump is as straight as possible with no kinks

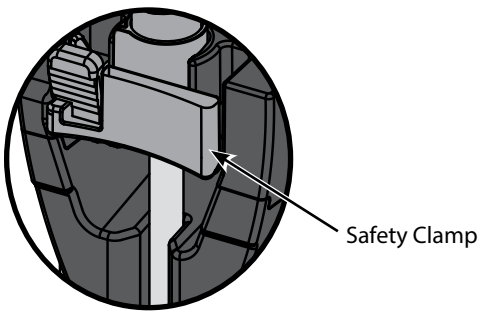


i) Fit top adaptor of infusion set into top set retainer.



ii) Insert Safety Clamp into retainer.

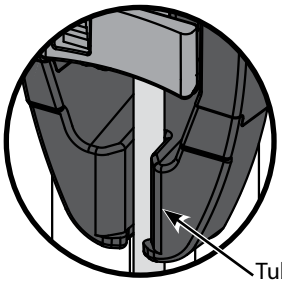
- Avoid any stretching of the silicone segment when loading, priming and re-loading the infusion set



Pushing on the Safety Clamp Slider may lead to uncontrolled flow to the patient. Therefore, always close the roller clamp before pushing on the safety clamp slider.

Step

iii) Ensure infusion set is fully inserted into tubing guide and all air is removed from the infusion set.



8. Close door and open roller clamp. Ensure no drops are falling in the drip chamber.
9. Ensure all air is removed from the set.
10. Connect the infusion set to the patient access device.

Notes

Starting the Infusion

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

Prime and load the set (Refer to 'Priming the Infusion Set' and 'Loading an Infusion Set')

1. Ensure the Pump is connected to an AC power supply (also operates from battery).
2. Connect flow sensor, if required (See 'Flow Sensor Operation' section).
3. Press the key.

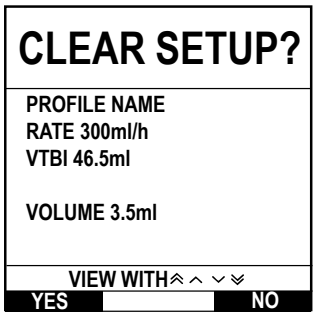
The Pump will run a short self-test. Check two beeps are activated during this test.

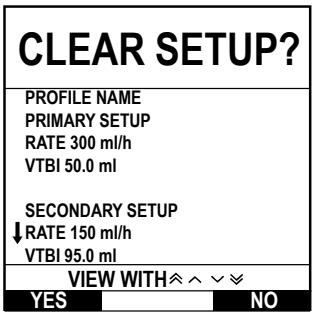
Check the displayed date and time are correct. Check display shows the data set name and version number.

Note: The Pump starts up and displays previous settings.

4. **CLEAR SETUP?** - Selecting **NO** will retain all previous rate and volume settings, go to step 7. Selecting **YES** will automatically reset the rate and volume settings to zero and the **CONFIRM PROFILE?** screen will be displayed.

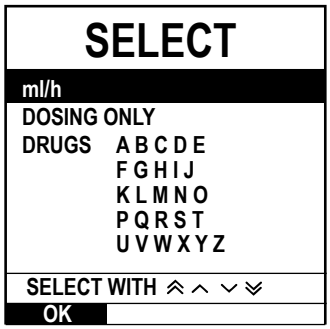
- ml/h
- Drug Protocol
- Dosing Only
- Primary/Secondary
- Drug Protocol





5. **CONFIRM PROFILE?** screen will show the data set name, version number and profile name:
   a) Press **YES** softkey to confirm current profile and go to step 6.
   b) Selecting **NO** will display the profile selection screen, select correct profile using keys and press **OK** softkey to confirm. Confirm profile screen will display again, press **YES** softkey and **SELECT** screen will be displayed, go to step 6.

Note: The **CONFIRM PROFILE** screen is only shown if more than one profile (For Alaris™ GP Guardrails™ Volumetric Pump only) is available in the data set. If a profile has been filtered, then the option to select **ALL** will be displayed in the profile selection screen. Selecting **ALL** will show the filtered profiles (If enabled).



6. Select either **ml/h**, **DOSING ONLY** or **DRUGS (A-Z)** and press **OK** to confirm. Then follow the prompts as required (Refer to 'Basic Features -Drugs and Dosing' *section).*
7. Clear **VOLUME** infused , if required (Refer to 'Clear Volume Infused' section, this is recommended for a new patient or when a new infusion is set-up).
8. Enter **VTBI** (if required) by selecting **VTBI** softkey on main display. Set VTBI by using the **BAGS** option and/or keys and press **OK** to confirm (Refer to 'Setting a VTBI' or 'Setting VTBI over Time' section).
9. Enter or adjust the RATE (if necessary) using the keys.
10. Press key to start the infusion. **INFUSING** will be displayed.

Note: The green run LED will flash to show that the Pump is infusing.

If the infusion requires to be stopped immediately, the following actions may be applied:

- **by pressing the key (recommended action)**
- **by closing the roller clamp**
- **by opening the door**

Basic Features

Drugs and Dosing

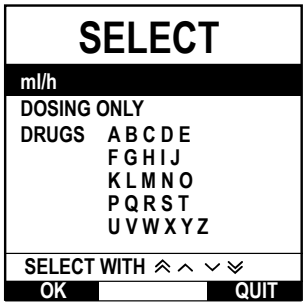
The following options enable the Pump to be set-up for use with a specific drug protocol. Drugs are pre-configured in the Alaris™ Editor to enable rapid selection of the drug protocol, dosing units and default rate. For increased security when using a configured drug, maximum and minimum safety limits can be set for concentrations and dose rates via the Alaris™ Editor.

⚠ **When adjusting an infusion using the dose rate, the display may not show any corresponding changes to the infusion rate in ml/h. This does not affect the accuracy of the infusion.**

Selecting the INFUSION SETUP

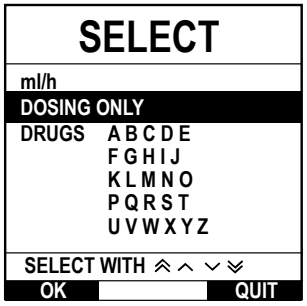
1. Press the ⑦ button to first access the options menu.
2. Drugs and dosing set-up options are available by selecting **INFUSION SETUP** from the list using the ⏫🔼🔽⏬ keys.
3. Select from the list of the options (**ml/h**, **DOSING ONLY** or **DRUGS**) as detailed below and press the **OK** softkey to confirm the selection.

ml/h



1. Select **ml/h** from the list using the ⏫🔼🔽⏬ keys (if necessary).
2. Press **OK** to confirm.
3. Enter the ml/h rate as prompted on the display in the next screen.

Dosing Only

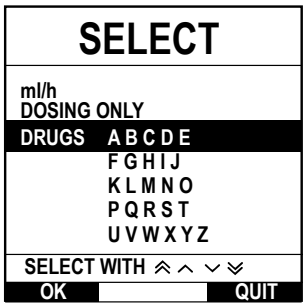


1. Select **DOSING ONLY** from the list using the ⏫🔼🔽⏬ keys.
2. Press **OK** to confirm.
3. Select the dosing units from the list using the ⏫🔼🔽⏬ keys, press **OK** to confirm.
4. Enter **DRUG AMOUNT** using the ⏫🔼🔽⏬ keys and if units need to be changed, select **UNITS** which will scroll through the units available. Press **OK** to confirm selection.
5. Use the ⏫🔼🔽⏬ keys to select the **TOTAL VOLUME**[2], press **OK** to confirm.
6. Enter **WEIGHT**[1] using the ⏫🔼🔽⏬ keys, press **OK** to confirm.
7. A summary of the **DOSING ONLY** information is displayed, to **CONFIRM?** all details shown press **OK**. The **BACK** softkey may be used at any time to return to the previous screen.

[1] Only displayed if weight based units are used.

[2] Total Volume = Drug Volume + Diluent Volume i.e. Total Volume of fluid in the fluid container after a drug is added.

Drugs



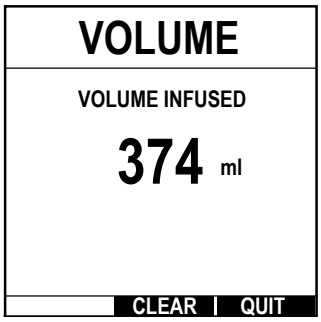
1. Select the required **DRUGS** alphabetical row from the list using the ⏫🔼🔽⏬ keys.
2. Press **OK** to confirm.
3. Select the drug from the displayed list using the ⏫🔼🔽⏬ keys, press **OK** to confirm.
4. Enter **DRUG AMOUNT** using the ⏫🔼🔽⏬ keys, press **OK** to confirm selection.
5. Use the ⏫🔼🔽⏬ keys to enter the **TOTAL VOLUME**[2], press **OK** to confirm.
6. Enter **WEIGHT**[1] using the ⏫🔼🔽⏬ keys, press **OK** to confirm.
7. A summary of the **DRUG** information is displayed, to **CONFIRM?** all details shown press **OK**. The **BACK** softkey may be used at any time to return to the previous screen.

[1] Only displayed if weight based units are used.

[2] Total Volume = Drug Volume + Diluent Volume i.e. Total Volume of fluid in the fluid container after a drug is added.

Clear Volume Infused

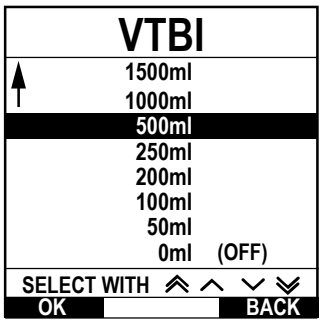
When a new drug or a new concentration has been setup and the previous volume infused has not been cleared, then the message DOSE INFUSED HAS BEEN CLEARED will be displayed.



This option enables the volume infused to be cleared.

1. Press the **VOLUME** softkey on main display to show the clear **VOLUME INFUSED** option.
2. Press the **CLEAR** softkey to clear the volume infused. Press the **QUIT** softkey to retain the volume.

Setting a VTBI



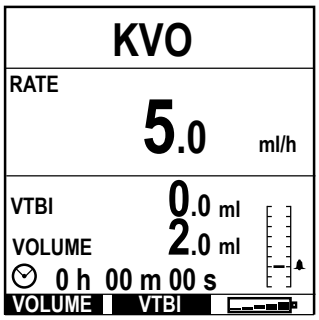
This feature allows a specific volume to be infused to be set. The rate at the end (**END RATE**) of this VTBI can also be set, selecting from **STOP**, **KVO** or **CONTINUE** for continuous infusion at the set rate.

1. Using the keys:
   a) Press the **VTBI** softkey on main display to enter the volume to be infused screen.
   b) Enter the volume to be infused using the keys and press **OK** to confirm.
   c) Select the **END RATE** using the keys to scroll through the on-screen choices.
   d) Press the **OK** softkey to confirm and exit the **END RATE** menu.

or

2. Using the **BAGS** softkey:
   a) Press the **VTBI** softkey on main display to enter the volume to be infused screen.
   b) Select the **BAGS** softkey, select the required bag volume using the keys and press **OK** to confirm the selection.
   c) Press **OK** to confirm again, or adjust the **VTBI** using the keys and press **OK**.
   d) Select the **END RATE** using the keys to scroll through the on-screen choices.
   e) Press the **OK** softkey to confirm and exit the **END RATE** menu.

KVO (Keep Vein Open) Rate



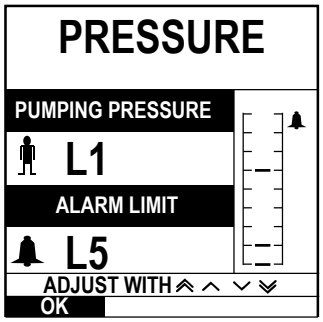
At the end of VTBI, the Pump will first display **VTBI DONE/INFUSING KVO**. Press **CANCEL** to display **KVO** screen.

The Pump continues to infuse at a very low (Default) rate. KVO is used to keep the patients vein open, in order to prevent blood clots and catheter occlusions.

Note: If the KVO rate (Default 5ml/h) is greater than the set infusion parameters then the Pump will continue to infuse at the set infusion rate. The KVO rate will flash on screen to indicate this is not the usual infusion rate.

The Pump will beep every 5 seconds while in KVO mode.

Pressure



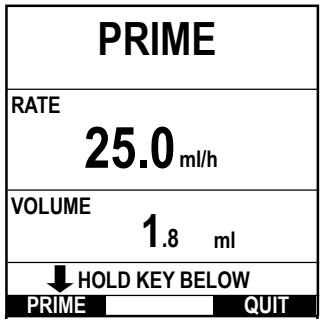
To check and adjust the pressure level, press the button. The display will change to show the current pumping pressure level and the pressure alarm limit. The default pressure alarm limit can be set via the Alaris™ Editor.

1. Press the keys to increase or decrease the alarm limit (L0 to L8). The new limit will be indicated on the display.
2. Press **OK** to exit the screen.

- **Higher rates generate higher pumping pressures. To avoid nuisance alarms, L0 and L1 levels should not be used for rates above 200ml/h.**
- **The interpretation of pressure readings and occlusion alarms are the responsibility of the clinician depending on the specific application.**
- **Occlusion levels for the Pump are configured in the Alaris™ Editor by profile and by drug.**

Priming the Infusion Set

- **Ensure the infusion set is not connected to a patient before priming the set.**
- **The prime rate and prime volume limit are configured in the data set via the Alaris™ Editor.**
- **The default prime rate is 500ml/h.**
- **The Pump will not prime if rate lock has been activated. During PRIME the pressure alarm limit is temporarily increased to the maximum level (L8).**



The button allows the delivery of a limited volume of fluid in order to prime the infusion set prior to being connected to a patient.

1. Press key to switch the Pump on.
2. Load the infusion set. Refer to 'Loading an infusion set' section.
3. Follow the 'Starting the Infusion' section, but do not connect the infusion set to the patient until the set has been primed.
4. Open the roller clamp.
5. Press button to display the **PRIME** screen.
6. Press and hold the (flashing) **PRIME** softkey until the fluid flows and the priming of the infusion set is complete. The volume used during priming will be displayed, but it is not added to the volume infused.
7. When priming is complete release the **PRIME** softkey.

Bolus Infusions

Bolus - Administering a controlled volume of fluid or drug at an increased rate for diagnostic or therapeutic purposes. The Pump should always be infusing and always attached to the patient (Drugs given by an IV bolus could achieve immediate and high drug concentration levels).

Bolus can be used at the start of an infusion or during an infusion.

The bolus feature can be configured via the Alaris™ Editor to:

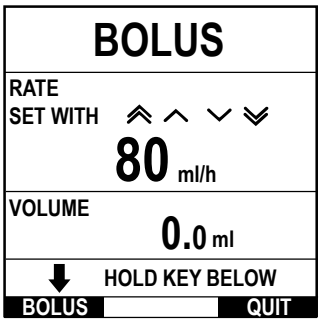
a) Bolus Mode - Disabled
b) Bolus Mode - Enabled
   i) HANDSON only
   ii) HANDSON and HANDSFREE

Bolus Mode - Disabled

If configured to *Disabled*, pressing the button will have no effect and the Pump will continue to infuse at the set rate.

A Bolus cannot be administered if the feature is disabled for the selected data set or specific drug. During BOLUS the pressure limit alarm is temporarily increased to the maximum level (L8).

Bolus Mode Enabled - HANDSON and HANDS ON and HANDSFREE



BOLUS Enabled - HANDSON Only

In **HANDSON** 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 via Alaris™ Editor.

1. During infusion press the button once to display the **BOLUS MODE** screen.
2. Use the keys to adjust the bolus rate if required.
3. To deliver the bolus press and hold the **BOLUS** softkey. During the bolus, the volume being infused 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 infused displayed.

> ⚠ **If the volume to be infused (VTBI) is reached during a bolus, the VTBI complete alarm will sound. Press to silence the alarm or CANCEL to acknowledge the alarm. See VTBI section for more details on VTBI operation.**
> **When using infusion set 63280NY the maximum infusion rate is 150ml/h.**

BOLUS Enabled - HANDSON and HANDSFREE

The **HANDSFREE** bolus is delivered with a single press of the (flashing) **BOLUS** softkey. Bolus rate and bolus volume are at default values and can be changed. The default bolus volume is 0.1ml.

1. During infusion press the button once to display the **BOLUS MODE** screen.
2. Press the **YES** softkey to go to the **HANDSFREE** bolus screen or press **HANDSON** softkey to go to the HANDSON bolus (see section above)
3. Use the keys to adjust the bolus **DOSE** if required. If necessary press the **RATE** softkey to adjust the bolus delivery rate.
4. Press the flashing **BOLUS** softkey once to begin the delivery of the preset bolus. The display will show the bolus being delivered by the bolus counting down and will revert to the main display upon completion of the bolus.
5. To terminate a bolus being delivered press **STOP** softkey. This will stop the bolus and continue infusing at the set rate. Press the button to stop the bolus delivery and place the Pump on hold.

Note: If the bolus volume reaches the set bolus volume limit the bolus will stop and the Pump will revert to infuse at the set infusion rate and continue infusing.

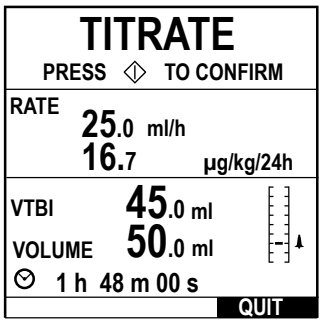
Note: Rate may be restricted by the **Bolus Rate Max** which is configured in the Alaris™ Editor.

Note: If the **BOLUS** exceeds the soft (Alaris™ GP Guardrails™ Volumetric Pump only) or hard limits, a prompt will display.

Note: The bolus rate will be automatically set to the current infusion rate, when the default bolus rate is lower than the current infusion rate. A bolus rate cannot be configured lower than the current infusion rate.

Note: When more than one bolus is programmed without clearing the infusion setup, the bolus rate will be set to the previous bolus rate for all subsequent bolus infusions.

Rate Titration



If Rate Titration is enabled (via the Alaris™ Editor) the infusion rate or dose rate (if available) can be adjusted while infusing.

1. Select the new rate using the keys. The message <**TITRATE PRESS TO CONFIRM**> will flash on screen and the Pump continues to infuse at the original rate.
2. Press the button to confirm the new infusion rate and start infusing at the new rate.

If Rate Titration is disabled the rate can only be adjusted whilst **ON HOLD**:

1. Press the button to put the Pump **ON HOLD**.
2. Select the new rate using the keys.
3. Press the button to start infusing at the new rate.

Rate Lock (If enabled)

If Rate Lock is enabled, when the infusion rate has been set and the infusion started (or following a bolus infusion) the rate lock prompt will appear on the main display.

To select the rate lock function press the **YES** softkey to confirm. Press the **NO** softkey if the rate lock is not required.

When rate lock is enabled, the following are unavailable:

- Changing the infusion rate / titration
- Bolus / Prime
- Switching the Pump off
- VTBI over time infusions.
- Secondary infusions (if enabled)

To turn rate lock off:

1. Press the ⓘ button to access the options menu.
2. Select **UNLOCK RATE** and press the **OK** softkey.

To turn rate lock on:

1. Press the ⓘ button to access the options menu.
2. Select **RATE LOCK** and press the **OK** softkey.

Adjusting Existing Dosing or Protocol Infusions - Set By ml/h / Set by Doserate

To set doserate or flowrate in precise increments it may be necessary to switch between the rate adjust options **SET BY DOSERATE** and **SET BY ml/h**. An arrow to the left of the rate display shows the rate changed when the ⏫🔼🔽⏬ keys are used to increase/decrease the infusion rate.

To set a doserate precisely the arrow must be pointing to the doserate (for example: mg/kg/h); the flowrate will be calculated from the doserate.

To precisely set a flowrate the arrow must be pointing to flowrate (ml/h); the doserate will be calculated from the flowrate.

Selecting the SET BY ml/h Option

1. Press the ⓘ button to access the options menu.
2. Select the **SET BY ml/h** option using the ⏫🔼🔽⏬ keys and press the **OK** softkey indicated on the screen. This will select the set by flowrate option, the arrow on the display will automatically select the flowrate, the flowrate can be adjusted if necessary.

Selecting the SET BY DOSERATE Option

1. Press the ⓘ button to access the options menu.
2. Select the **SET BY DOSERATE** option using the ⏫🔼🔽⏬ keys and press the **OK** softkey indicated on the screen. This will select the set by doserate option, the arrow on the display will automatically select the doserate, the doserate can be adjusted if necessary.

Dosing Summary

To review currently selected dosing information:

1. Press the ⓘ button to first access the options menu.
2. Select **DOSING SUMMARY** option using the ⏫🔼🔽⏬ keys and press the **OK** softkey.
3. Review the information and then press the **QUIT** softkey.

Add Drug (Only available when infusing)

1. Press the ⓘ button to access the options menu.
2. Select **ADD DRUG** option using the ⏫🔼🔽⏬ keys and press the **OK** softkey.
3. Select from **DRUGS (A-Z)** from the displayed list using the ⏫🔼🔽⏬ keys, press **OK** to confirm.
4. Select drug name using the ⏫🔼🔽⏬ keys, press **OK** to confirm and then follow the on screen prompts as required.

Infusion Setup

To change the Infusion Setup, refer to 'Basic Features - Drugs and Dosing, Selecting the INFUSION SETUP' section.

Primary Setup

If a secondary infusion has already been setup (See 'Secondary (Piggyback) Infusions' section), then access to the primary infusion setup is as follows:

1. Press to put the Pump **ON HOLD**.
2. Press the ? button to access the options menu.
3. Select **PRIMARY Setup** and press the **OK** softkey to confirm. Make changes to the primary setup as necessary.

Secondary Setup

To setup a secondary infusion refer to 'Secondary (Piggyback) Infusions' section

Setting VTBI over Time

This option allows a specific VTBI and delivery time (Maximum of 24 hours) to be set. The rate necessary to deliver the required volume within the specified time is calculated and displayed.

1. Stop the infusion. Press ? button to access the options menu.
2. Select the **SET VTBI OVER TIME** option using the keys and press the **OK** softkey.
3. Adjust the volume to be infused using the keys (Or select **BAGS** softkey to set the VTBI). When the desired volume has been reached press the **OK** softkey.
4. Enter the time over which the volume is to be infused using the keys . The infusion rate will automatically be calculated.
5. Press **OK** softkey to enter the value or **BACK** to return to the VTBI.

Adjust Alarm Volume

This option allows adjustment of the volume if enabled.

1. Press the ? button to access the options menu.
2. Select **ADJUST ALARM VOLUME** using the keys and press **OK** softkey to confirm.
3. Select **HIGH**, **MEDIUM** or **LOW** using the keys.
4. Press **OK** softkey to confirm or **QUIT** to exit screen.

Event Log

This option allows the event log to be reviewed. The event log holds up to 99,960 events. When the log is full, the oldest events will be overwritten by the newest occurring events.

1. Press the ? button to access the options menu.
2. Select **EVENT LOG** using the keys and press **OK** softkey to confirm.
3. View the events using the keys.
4. Select **BACK** to return to the previous screen, if required.

Pump Details

To review Pump information:

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

Profile Filter (Only available on the Alaris™ GP Guardrails™ Volumetric Pump)

This option allows selected profiles to be filtered from view. It can be enabled/disabled via the Alaris™ Editor.

1. Press the ? button to access the options menu.
2. Select **PROFILE FILTER** using the keys, press the **OK** softkey to confirm.
3. Select profile that requires filtering using the keys.
4. Press **MODIFY** to disable profile and press **OK** to confirm or **QUIT** to return to main display.

Note: If only one profile is available and all others are disabled in this option, the **CONFIRM PROFILE** screen will not display upon start up.

Standby

This option allows the Pump to be placed on standby mode. It can be enabled/disabled via the Alaris™ Editor.

1. Press the ? button to access the options menu.
2. Select **STANDBY** using the keys, press the **OK** softkey to confirm.
3. Select **CANCEL** to return to main display.

Changing the Infusion Set

1. Press to put the Pump **ON HOLD**.
2. Close in-line clamp and ensure the access to the patient is isolated.
3. Disconnect the infusion set from the patient.
4. Open Pump door and remove infusion set from the Pump and discard the set and fluid container according to hospital protocol.
5. Prepare the new infusion set, load infusion set into Pump and close the door, see 'Loading the Infusion Set'.
6. Restart infusion, see 'Getting Started'.

When changing the infusion set or the fluid container use aseptic technique according to hospital protocol.
It is recommended that infusion sets are changed in accordance with the Directions For Use.
Carefully read the Directions For Use supplied with the infusion set prior to use. The set change interval is generally 72 hours with the following exceptions;

- **Transfusion (Blood) Sets**
- **60953 Alaris™ GP Low Sorbing Infusion Set**
- **60033E Alaris™ GP Low Sorbing Infusion Set**
- **60950E Alaris™ GP Oncology Infusion Set**

Changing the Fluid Container

1. Press to put the Pump **ON HOLD**.
2. Remove bag spike on infusion set from empty / used container. Discard empty / used container according to hospital protocol.
3. Insert the bag spike into the fluid container and hang following the instructions in the 'Loading an Infusion Set' section.
4. Squeeze the drip chamber approximately half full or up to fill line (if the drip chamber is marked) with fluid.
5. Restart infusion, see "Getting Started".

When changing the infusion set or the fluid container use aseptic technique according to hospital protocol.
It is recommended that infusion sets are changed in accordance with the Directions For Use.
Carefully read the Directions For Use supplied with the infusion set prior to use.

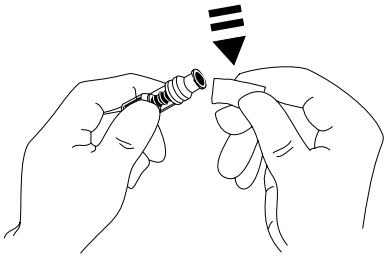
SmartSite™ Needle-Free System Instructions

SmartSite™ Needle-Free Valve is designed to permit safe gravity flow and automated flow, injection and aspiration of fluids without the use of needles by utilising Luer lock and luer slip connectors.

Precautions:
Discard if packaging is not intact or protector caps are unattached.
If Needle-Free Valve is accessed by a needle in an emergency the valve will be damaged causing leakage. Replace Needle-Free Valve immediately.
Needle-Free Valve contraindicated for blunt cannula system.
Do not leave slip luer syringes unattended.

DIRECTIONS - Use Aseptic Technique

1. Prior to every access, swab top of Needle-Free Valve port with 70% Isopropyl alcohol (1-2 seconds) and allow to dry (approximately 30 seconds).



Note: Dry time is dependent on temperature, humidity, ventilation of the area.

2. Prime valve port. If applicable, attach syringe to Needle-Free Valve port and aspirate minuscule air bubbles.
3. When used with administration sets always refer to individual set directions for use as change interval may vary according to clinical application (e.g. infusions of blood, blood products, and lipid emulsions).

Note: During use of Needle-Free Valve port, fluid may be observed between the housing and blue piston. This fluid does not enter the fluid path and requires no action.

Note: For product questions or needle-free valve educational materials, contact your BD representative. Consult facility protocols. Consult other organizations that publish guidelines useful in developing facility protocols.

Secondary (Piggyback) Infusions

Secondary (or piggyback) Infusion mode is only available if it has been configured.

The application of secondary infusions should be limited to the intermittent therapy of medications which are not sensitive to the total time required to complete an infusion.

- **Typically antibiotics may be infused using a secondary infusion, where the primary infusion is limited to maintenance fluid. If intending to use the secondary infusion facility, the primary infusion should be a maintenance fluid only and is not indicated for drug therapy.**
- **The application of secondary infusions for delivery of critical drugs, particularly those with a short half life, is NOT indicated for use. These drugs should be administered through a dedicated pump channel.**
- **Dependent upon factors such as fluid viscosity, the secondary infusion rate, head height between the secondary and primary fluid containers and the use of clamps, flow may occur from the primary fluid container during a secondary infusion. This could result in drug remaining in the container at the end of the secondary infusion, delaying its delivery for a period of time which is dependent upon the primary infusion rate. For example, a secondary infusion of 250ml at 300ml/h could result in approximately 33ml remaining, requiring up to 25 minutes additional time to complete the delivery, assuming a primary infusion rate of 80ml/h (and the use of a 72213N-0006 secondary infusion set and its supplied extension hook). Therefore it is recommended that flow sensors (if used) are disconnected from the Pump during secondary infusions.**
- **Regular monitoring for unexpected primary flow is recommended. If flow from the primary fluid container is not desired during secondary infusion and/or the patient is sensitive to fluid balance, the clamp on the primary infusion set should be closed. Check that no drops fall in the primary drip chamber.**
- **On completion of the primary infusion the Pump will continue at Keep Vein Open rate (KVO) rate.**

Setting up a secondary infusion

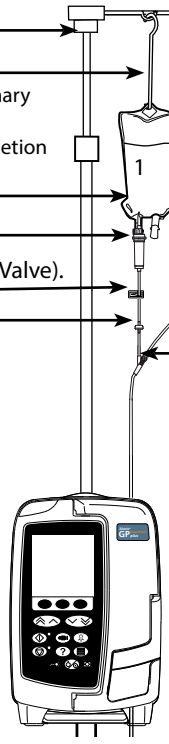
1. Ensure Primary infusion has been setup in ml/h (rate > 0ml/h).
2. Press ⏻ to put the Pump **ON HOLD**.
3. Press ? to access the **OPTIONS** screen.
4. Select **SECONDARY SETUP**, press **OK** to confirm.
5. Select either **ml/h** or **DRUGS A-Z**. Press **OK** to confirm either selection.
6. Enter the secondary **RATE** using the ▲▲▼▼ keys.
7. Press **OK** to confirm.
8. Set **VTBI** using the ▲▲▼▼ keys (Refer to 'Setting a VTBI' section).
9. Press **OK** to confirm.
10. Review **PRIMARY/SECONDARY** setup summary.
11. If correct, press **OK** to continue, or **BACK** to adjust **VTBI** or **RATE** of the **SECONDARY** mode.
12. Press ⏻ to start the infusion in secondary mode. An advisory screen will be displayed - **ENSURE SECONDARY INFUSION SET OPEN**.
13. Press **OK** to start infusing at the displayed rate.

Setting up a subsequent secondary infusion:

On completion of the secondary VTBI, the Pump will automatically transition to the primary infusion, an audible beep will be heard.

1. Press ⏻ to place the primary infusion **ON HOLD**.
2. Follow instructions 3 to 13 of 'Setting up a secondary infusion'.

Typical Secondary infusions



IV Pole

Extension Hook (approx.26cm)

Normally included with the secondary Infusion set. Primary fluid container must hang lower to allow the secondary infusion to run and primary infusion to restart on completion of the secondary infusion.

Primary Fluid Container

Primary Infusion set

e.g. 63420E with an upper Y-Site (SmartSite Needle-Free Valve).

In-line Clamp

Check Valve

Prevents secondary infusions from flowing back up the primary Infusion set instead of to the patient.

Secondary Fluid Container
Usually a smaller container e.g. 50ml, 100ml, 200ml or 250ml.

Secondary Infusion Set

e.g. 72213N-0006. Usually shorter tubing to reach the Y-site on the primary Infusion set.

In-line Clamp e.g. roller clamp.

Upper Y-Site (SmartSite Needle-Free Valve) on Primary Infusion Set.

Ensure primary set has a backcheck valve upstream from the Y-site.

The secondary set connects to the upper Y-connection on the primary Infusion set.

Service Configuration Mode

This section comprises of a list of options which can be configured. Some can be entered via the Pump **SERVICE** menu (available in Technician Mode) and others through the Alaris™ Editor Software.

Access codes should only be entered by Qualified Service Personnel.

Alarm Presets

Pumps with version 2.3.4 software have 2 alarm tones to choose from during configuration:

- **ORIGINAL ALARMS**: Low, medium and high priority alarm tones that sound like the auditory alarms and warnings from software versions prior to 2.3.4
- **3RD EDITION ALARMS**: Low, medium and high priority alarm tones in accordance with IEC 60601-1-8: 2012 and IEC 60601-2-24:2012

Enter the access code on the Pump for Alarm Presets, see the *Technical Service Manual* or *Information Notice* for details.

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

Alaris™ Gateway Workstation (Workstation) with software versions 1.1.3, 1.1.3 MR, 1.1.5, 1.2, 1.3.0, 1.6.0 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 2.3.4 software or higher docked into these Workstations there will be a mismatch of alarm priority displayed. As a result, Near End Of Infusion, AC Power Fail, Add Drug Not Complete, and Attention alarms will display as a medium visual priority alarms on the Workstation beacon and a low priority alarm on the Pump. Additionally, for certain information signals, e.g. those associated with Add Drug Not Complete and Titration Not Confirmed, the Workstation beacon will illuminate while the beacon on the pump will not. In the event of an alarm priority mismatch, the User should refer to the alarm on the Pump for the correct priority.

Configured Options

Enter the access code on the Pump for **SERVICE** mode, then select **CONFIGURATION**, see the Technical Service Manual for details.

Use Alaris™ Editor to configure the Pump configuration, drug library and units enabled for each data set.

Date & Time

1. Select **DATE & TIME** from the **CONFIGURATION** menu using the keys and press the **OK** softkey.
2. Press the **OK** softkey to confirm.
3. Use the keys to adjust the date displayed, pressing the **NEXT** softkey to access the next field.
4. When the correct date and time are displayed press the **OK** softkey to return to the **CONFIGURATION** menu.
5. Press the **QUIT** softkey to return to the **SERVICE** menu and press to exit and power down.

Pump Reference

This option is used to add reference text to be shown on the Pump start up display.

1. Select **PUMP REFERENCE** from the **CONFIGURATION** menu using the keys and press the **OK** softkey.
2. Use the keys to enter the text and **NEXT** to move to the next character.
3. When the desired text has been selected press **OK** softkey to return to the **CONFIGURATION** menu.
4. Press **QUIT** to exit back to the main **SERVICE** menu and press to exit and power down.

Language

This option is used to set the language of messages shown on the Pump display.

1. Select **LANGUAGE** from the **CONFIGURATION** 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 **OK** softkey to return to the **CONFIGURATION** menu.
4. Press **QUIT** to exit back to the main **SERVICE** menu and press to exit and power down.

Backlight & Contrast

This option is used to set the backlight and contrast on the Pump display.

1. Select **BACKLIGHT & CONTRAST** from the **CONFIGURATION** menu using the keys and press the **OK** softkey.
2. Use the keys to adjust **BACKLIGHT, CONTRAST** and **DIMMING**. The contrast of the display will change when scrolling through the numbers. (Use **PARAM** to scroll between each option)
3. When the desired value has been reached press the **OK** softkey, then **QUIT** to get back to the **SERVICE** menu and press to exit and power down.

Pump Configuration available via the Alaris™ Editor Software

The following options are only configurable via the Alaris™ Editor Software (PC based), see Alaris™ Editor help files for further details.

Data Set Configuration Settings

Profile Filtering	Controls whether the user is able to filter which profiles will be available on the Pump.
Unit Display	The text used to display units.

General Pump Configuration Settings

AC Fail Warning	Controls whether, when main power has been disconnected, a warning is generated to inform the user that the Pump is operating solely on battery power.
Audio Volume	Controls the audio volume used for alarms and warnings.
Audio Volume Adjustable	Controls whether the user is able to adjust the audio volume setting.
Auto Night Mode	Controls whether, between defined times, the Pump makes changes consistent with usage at night (e.g. dimmed backlight).
Auto save	Controls whether, when the Pump is powered down, the active infusion settings are preserved for restoration at the next power-up.
Battery Icon	Controls whether or not the battery icon (which indicates state of charge) is displayed.
Callback Time	The time that is allowed to elapse between the user's last recorded interaction with the Pump and generation of a callback alarm.
Drug Override Mode	Always **-** Any changes made to the dose rate that are outside of the Guardrails™ Soft Alerts will require confirmation before starting infusion. Smart – Confirmation of setting will be required on first dose rate set outside of the Guardrails™ Soft Alert. Any subsequent changes will not require confirmation until after the dose rate has been confirmed inside the Guardrails™ Soft Alert limits.
Event Log	Controls whether or not it is possible for the user to inspect the contents of the event log using the Pump's display and keypad.
Pressure Display	Controls whether or not the bar graph indication of downstream pressure is displayed.
Quiet Mode	Controls whether or not the Pump operates in a mode whereby generation of sound is minimised.
Rate Lock	Controls whether the Rate Lock feature is available for use.
Rate Titration	Allows the adjustment of the infusion rate while the Pump is infusing, without putting the Pump on hold.
Standby Mode	Controls whether or not standby mode is available on the Pump.
VTBI Clear Rate	Controls whether or not the Pump forces the user to define a new rate following completion of delivery of a previous VTBI.
Weight Default	The default patient weight.
Weight Soft Min	(For Alaris™ GP Guardrails™ Volumetric Pump only) The minimum patient weight for weight-based drug dosing calculations before alerting the user.
Weight Soft Max	(For Alaris™ GP Guardrails™ Volumetric Pump only) The maximum patient weight for weight-based drug dosing calculations before alerting the user.

Large Volume Pump Configuration Settings

AIL Limit	The single bubble Air-in-line alarm setting.
Bolus Mode	Controls whether or not the Pump allows bolus delivery method.
Bolus Rate Default	The default value for bolus rates.
Bolus Rate Max	The maximum permissible bolus rate.
Bolus Volume Max	The maximum permissible bolus volume.
Occlusion Alarm Pressure	The default occlusion limit.
Pressure Max	The maximum permitted occlusion limit.
Infusion Rate Max	The maximum permissible infusion rate.
KVO Rate	The maximum infusion rate when performing KVO delivery.
Near End of Infusion Point	The point defined in terms of remaining time at which the infusion is deemed to be *Near end* i.e. nearly complete.
Primary VTBI Max	The maximum VTBI for primary infusions.
Prime Rate	The rate at which priming is performed.
Prime Volume Max	Determines the maximum volume that can be purged as part of a given prime operation.
Secondary Infusion	Allows the use of a secondary infusion (Piggyback) in the same channel.
Sec. Infusion Rate Max	The maximum permissible infusion rate for secondary infusions.
Sec. VTBI Max	The maximum permissible setting for the Volume To Be Infused for secondary infusions.

Drug Library available via the Alaris™ Editor Software

The following drug parameters are only configurable via the Alaris™ Editor Software (PC based), see Alaris™ Editor help files for further details.

Concentration Settings

Concentration Units	The unit for concentration parameters.
Concentration Min	The weakest permissible concentration for this drug.
Concentration Max	The strongest permissible concentration for this drug.

Dose Rate Settings

Dose Rate Units	The unit for dose rate parameters.
Weight based units	Controls whether weight based units are enabled or disabled for use.
Dose Rate Default	The default dose rate for infusing this drug.
Dose Rate Soft Min	(For Alaris™ GP Guardrails™ Volumetric Pump only) The minimum permissible dose rate which does not generate an alert on the Pump.
Dose Rate Soft Max	(For Alaris™ GP Guardrails™ Volumetric Pump only) The maximum permissible dose rate which does not generate an alert on the Pump.
Dose Rate Hard Max	The maximum permissible dose rate for infusing this drug.

Bolus Settings

Bolus Mode	Controls bolus delivery method. These settings override the Pump configuration settings in the profile.
Bolus Dose Units	The unit for bolus dose parameters. Applies to Hands-on and Hands-free bolus.
Weight based units	Controls whether weight based units are enabled or disabled for use.
Bolus Dose Default	The default bolus dose for this drug. Applies to Hands-free bolus.
Bolus Dose Soft Min	(For Alaris™ GP Guardrails™ Volumetric Pump only) The minimum bolus dose that the Pump allows before the user is required to confirm the selected bolus dose in response to a warning of the possibility of under-infusion. Applies to Hands-free bolus.
Bolus Dose Soft Max	(For Alaris™ GP Guardrails™ Volumetric Pump only) The maximum bolus dose that the Pump allows before the user is required to confirm the selected bolus dose in response to a warning of the possibility of over-infusion. Applies to Hands-free bolus.
Bolus Dose Hard Max	The maximum permissible bolus dose for this drug. Applies to Hands-on and Hands-free bolus.
Bolus Rate Default	The default bolus rate for this drug.

Pressure Settings

Occlusion Alarm level	The occlusion alarm level can be set from L0-L8.

Display of Units

Units are selected via the Alaris™ Editor.

Micrograms can be displayed as mcg or µg depending upon the configuration in the Alaris™ Editor.

Units can be displayed as U or units depending upon the configuration in the Alaris™ Editor.

Alarms

Alarms vary by priority and are indicated on the Pump in the following manner:

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

> ⚠ **The default alarm system is ORIGINAL ALARMS (ISO60601-1-8 2nd Edition alarms). 3RD EDITION ALARMS (ISO60601-1-8 3rd Edition alarms) are also installed. To change the Pump alarm system from ORIGINAL ALARMS to 3RD EDITION ALARMS please refer to the Technical Service Manual. Please note that this change should only be performed by Qualified Service Personnel.**

ORIGINAL ALARMS

High Priority Alarms

High priority alarms stop the infusion and are indicated by a combination of an audible sound, flashing red alarm indicator and a message on the display. See the 'Alarm Priority Level Indicators' table for more details on how high priority alarms are indicated.

Alarms can be addressed in the following manner:

1. Check the display for an alarm message and review table below for cause and action. Press to silence the sound for 2 minutes, or press a second time to re-enable alarm audio, **CANCEL** to clear the message. The **CANCEL** feature clears the alarm signal, but the signal will return if the alarm condition still exists.
2. When the cause of the alarm has been rectified, press the key to resume the infusion. (Exceptions are **DO NOT USE** and **BATTERY EMPTY**)

Display	*Infusion Status*	*Cause(s)*	*Action*
AIR IN LINE	Infusion stopped	*Single air bubble* exceeds alarm limit. Set not fitted correctly into air in line detector.	• Assess the amount of air detected by air in line detector. • Opening the door may cause an air bubble to rise in the set. Check set for air. • Remove air according to hospital policy. • Ensure set is fitted correctly in the air in line detector. • Check level of fluid in container. • Check enough fluid left in drip chamber. • Restart infusion.
AIR IN LINE	Infusion stopped	Accumulated air bubbles have exceeded alarm limit. Multiple bubbles smaller than the single bubble alarm limit, have been detected at >1ml over a rolling 15 minute window period.	• Review infusion set for air bubbles and take appropriate action. • Check level of fluid in container. • Check enough fluid left in drip chamber. • Restart infusion.
DOOR OPEN	Infusion stopped	Door was opened during an infusion.	• Close door or clamp infusion set using roller clamp. • Restart infusion.
DOWNSTREAM OCCLUSION	Infusion stopped	A blockage has occurred downstream.	• Check fluid path between Pump and patient for clamps, connectors, kinks or blockages. • Examine access site for signs of complications (redness, swelling, pain, heat).
UPSTREAM OCCLUSION	Infusion stopped	A blockage has occurred upstream. Possible container empty.	• Check set above the Pump. • Check all clamps above Pump. • Check fluid level in container. • Ensure drip chamber is half filled. • Ensure that the bag spike is inserted correctly. • Ensure air vent on drip chamber is open on all glass and semi rigid containers.

Display	*Infusion Status*	*Cause(s)*	*Action*
NO FLOW	Infusion stopped	Flow sensor detects no flow.	• Check flow sensor. • Check fluid level in container. • Ensure all clamps above Pump are open. • Ensure drip chamber is half filled. • Ensure that the bag spike is inserted correctly. • Check flow sensor is clean.
FLOW ERROR	Infusion stopped	Gross difference between detected drops and expected amount of drops.	• Clamp infusion set using roller clamp. • Check flow sensor. • Check fluid level in drip chamber.
FLOW ERROR (In secondary infusion mode only)	Infusion stopped	Unexpected drops detected.	• Hang secondary container above primary. • Check drops are from secondary container when infusing. • Flow sensor disconnection is recommended.
FREE FLOW	Infusion stopped	Uncontrolled flow possible.	• Clamp infusion set using roller clamp. • Remove Pump from use.
BATTERY EMPTY	Infusion stopped	The internal battery is exhausted. The Pump will automatically switch off in the immediate future.	• Connect to power supply immediately or switch Pump off.
SAFETY CLAMP	Pump on hold	Safety clamp broken or missing.	• Clamp infusion set using roller clamp. • Replace infusion set. • Investigate and correct set loading.
SET MISLOAD	Pump on hold	Set loaded incorrectly.	• Clamp infusion set using roller clamp. • Investigate and correct set loading.
FLOW SENSOR DISCONNECT	Infusion stopped	Flow sensor unplugged during infusion.	• Check / replace flow sensor or set VTBI.
WRONG SET	Pump on hold	Safety clamp not detected.	• Clamp infusion set using roller clamp. • Check set and close door. • Replace infusion set (If necessary).
DOOR CLOSE INCOMPLETE	Pump on hold	Safety clamp in non-occluded position with door open or obstructed.	• Clamp infusion set using roller clamp. • Investigate and correct set loading. • Close door.
DO NOT USE	Pump on hold / infusion stopped	Internal error has occurred.	• Remove Pump from use.
LEVER OPEN	Infusion stopped	Door lever is open	• Check door lever. • Check lever hooks. • Check lever is not obstructed, if so, free obstruction.
VTBI DONE	Infusion stopped	Intended VTBI completed.	• Set new VTBI or clear VTBI.
SET CLOCK	Pump on hold	Date / time not set.	• Qualified Service Personnel must set date / time. • Press **CANCEL** softkey to continue.
SET SERIAL NUMBER	Pump on hold	Serial number not set.	• Contact Qualified Service Personnel to set the serial number.

Medium Priority Alarms

Medium priority alarms alert the user but may not stop the infusion and are indicated by an audible sound, a flashing amber warning indicator and a message on the display. See the 'Alarm Priority Level Indicators' table for more details on how medium priority alarms are indicated.

1. Check the display for a warning message. Press to silence the sound for 2 minutes, or press a second time to re-enable alarm audio, **CANCEL** to clear the message.
2. Rectify the cause of the alarm or proceed with caution.

Display	*Infusion Status*	*Cause(s)*	*Action*
BATTERY LOW	Infusion continues	Less than 30 minutes of battery life remaining.	• Connect to power supply. • Check power cable.
VTBI DONE (KVO/Continue)	Infusing KVO or set rate	Intended VTBI completed.	• Set new VTBI or clear VTBI.
AIR-IN-LINE	Pump on hold	Air detected in infusion set at the start of infusion. Set not fitted correctly into air in line detector.	• Ensure set is fitted correctly in the air in line detector. • Assess air in infusion set. • Check fluid level in drip chamber. • Check level of fluid in container.
LOG FAILURE	Pump on hold	Unable to update event log.	• Qualified Service Personnel may need to service the Pump.
SET NOT FITTED	Pump on hold	No infusion set fitted.	• Fit infusion set.
AC POWER FAIL	Infusion continues*	AC power disconnected or failed.	• Reconnect to power supply.
NEAR END OF INFUSION	Infusion continues	Less than XX (Configurable) minutes of infusion remaining.	• Set new VTBI. • Prepare new fluid container (Refer to 'Changing the Fluid Container' section)

* If pump was on hold the alarm will still be activated but this message will not be displayed.

Attention Tones

Attention tones alert the user but may not stop the infusion and are indicated by an audible sound, a flashing amber warning indicator and a message on the display. See the 'Alarm Priority Level Indicators' table for more details on how Attention tones are indicated.

1. Check the display for message. Press to silence the sound for 2 minutes, or press a second time to re-enable tone audio, **CANCEL** to clear the message.
2. Rectify the cause of the tone or proceed with caution.

Display	*Infusion Status*	*Cause(s)*	*Action*
ATTENTION	Pump on hold	Pump left on hold for 2 minutes without starting the infusion.	• Review Pump setup. • Start infusion or turn off Pump.
ADD DRUG	Infusion continues	Drug selection required.	• Press to access options menu. • Select **DRUGS A-Z** using the keys. • Press **OK** to confirm.
TITRATION	Infusion continues	Rate titration not confirmed.	• Confirm or cancel new rate.
RATE LOCK	Infusion continues	Rate lock not confirmed. **Note:** After five seconds the User will be notified by an auditory cue. After two minutes have expired a medium priority alarm is generated.	• Select **YES** or **NO** as required.
KVO	Infusing KVO or set rate	Intended VTBI completed.	• Set new VTBI or clear VTBI.

Alarm Priority Level Indicators

Priority	**Audio Indicator**	**Visual Indicator (Beacon)**
HIGH	One urgent tone pulse followed by one second pause	Flashing Red
MEDIUM	One warning tone pulse followed by one second pause	Flashing Amber
ATTENTION	Three attention tone pulse followed by a three second pause	Flashing Amber

Note: Original Alarms legacy attention tone is intended as the reminder or notification having less significance. The low volume audio sound pressure level may be below 45 dB to avoid distraction.

3RD EDITION ALARMS

High Priority Alarms

High priority alarms stop the infusion and are indicated by a combination of an audible sound, flashing red alarm indicator and a message on the display. See the 'Alarm Priority Level Indicators' table for more details on how high priority alarms are indicated.

Alarms can be addressed in the following manner:

1. Check the display for an alarm message and review table below for cause and action. Press to silence the sound for 2 minutes, or press a second time to re-enable alarm audio, **CANCEL** to clear the message. The **CANCEL** feature clears the alarm signal, but the signal will return if the alarm condition still exists.
2. When the cause of the alarm has been rectified, press the key to resume the infusion. (Exceptions are **DO NOT USE** and **BATTERY EMPTY**)

Display	*Infusion Status*	*Cause(s)*	*Action*
AIR IN LINE	Infusion stopped	*Single air bubble* exceeds alarm limit. Set not fitted correctly into air in line detector.	• Assess the amount of air detected by air in line detector. • Opening the door may cause an air bubble to rise in the set. Check set for air. • Remove air according to hospital policy. • Ensure set is fitted correctly in the air in line detector. • Check level of fluid in container. • Check enough fluid left in drip chamber. • Restart infusion.
AIR IN LINE	Infusion stopped	Accumulated air bubbles have exceeded alarm limit. Multiple bubbles smaller than the single bubble alarm limit, have been detected at >1ml over a rolling 15 minute window period.	• Review infusion set for air bubbles and take appropriate action. • Check level of fluid in container. • Check enough fluid left in drip chamber. • Restart infusion.
DOOR OPEN	Infusion stopped	Door was opened during an infusion.	• Close door or clamp infusion set using roller clamp. • Restart infusion.
DOWNSTREAM OCCLUSION	Infusion stopped	A blockage has occurred downstream.	• Check fluid path between Pump and patient for clamps, connectors, kinks or blockages. • Examine access site for signs of complications (redness, swelling, pain, heat).
UPSTREAM OCCLUSION	Infusion stopped	A blockage has occurred upstream. Possible container empty.	• Check set above the Pump. • Check all clamps above Pump. • Check fluid level in container. • Ensure drip chamber is half filled. • Ensure that the bag spike is inserted correctly. • Ensure air vent on drip chamber is open on all glass and semi rigid containers.
NO FLOW	Infusion stopped	Flow sensor detects no flow.	• Check flow sensor. • Check fluid level in container. • Ensure all clamps above Pump are open. • Ensure drip chamber is half filled. • Ensure that the bag spike is inserted correctly. • Check flow sensor is clean.

Display	*Infusion Status*	*Cause(s)*	*Action*
FLOW ERROR	Infusion stopped	Gross difference between detected drops and expected amount of drops.	• Clamp infusion set using roller clamp. • Check flow sensor. • Check fluid level in drip chamber.
FLOW ERROR (In secondary infusion mode only)	Infusion stopped	Unexpected drops detected.	• Hang secondary container above primary. • Check drops are from secondary container when infusing. • Flow sensor disconnection is recommended.
FREE FLOW	Infusion stopped	Uncontrolled flow possible.	• Clamp infusion set using roller clamp. • Remove Pump from use.
BATTERY EMPTY	Infusion stopped	The internal battery is exhausted. The Pump will automatically switch off in the immediate future.	• Connect to power supply immediately or switch Pump off.
SAFETY CLAMP	Pump on hold	Safety clamp broken or missing.	• Clamp infusion set using roller clamp. • Replace infusion set. • Investigate and correct set loading.
SET MISLOAD	Pump on hold	Set loaded incorrectly.	• Clamp infusion set using roller clamp. • Investigate and correct set loading.
FLOW SENSOR DISCONNECT	Infusion stopped	Flow sensor unplugged during infusion.	• Check / replace flow sensor or set VTBI.
WRONG SET	Pump on hold	Safety clamp not detected.	• Clamp infusion set using roller clamp. • Check set and close door. • Replace infusion set (If necessary).
DOOR CLOSE INCOMPLETE	Pump on hold	Safety clamp in non-occluded position with door open or obstructed.	• Clamp infusion set using roller clamp. • Investigate and correct set loading. • Close door.
DO NOT USE	Pump on hold / infusion stopped	Internal error has occurred.	• Remove Pump from use.
LEVER OPEN	Infusion stopped	Door lever is open	• Check door lever. • Check lever hooks. • Check lever is not obstructed, if so, free obstruction.
VTBI DONE	Infusion stopped	Intended VTBI completed.	• Set new VTBI or clear VTBI.
SET CLOCK	Pump on hold	Date / time not set.	• Qualified Service Personnel must set date / time. • Press **CANCEL** softkey to continue.
SET SERIAL NUMBER	Pump on hold	Serial number not set.	• Contact Qualified Service Personnel to set the serial number.

Medium Priority Alarms

Medium priority alarms alert the user but may not stop the infusion and are indicated by an audible sound, a flashing amber warning indicator and a message on the display. See the 'Alarm Priority Level Indicators' table for more details on how medium priority alarms are indicated.

1. Check the display for a warning message. Press to silence the sound for 2 minutes, or press a second time to re-enable alarm audio, **CANCEL** to clear the message.
2. Rectify the cause of the alarm or proceed with caution.

Display	*Infusion Status*	*Cause(s)*	*Action*
BATTERY LOW	Infusion continues	Less than 30 minutes of battery life remaining.	• Connect to power supply. • Check power cable.
VTBI DONE (KVO/Continue)	Infusing KVO or set rate	Intended VTBI completed.	• Set new VTBI or clear VTBI.
AIR-IN-LINE	Pump on hold	Air detected in infusion set at the start of infusion. Set not fitted correctly into air in line detector.	• Ensure set is fitted correctly in the air in line detector. • Assess air in infusion set. • Check fluid level in drip chamber. • Check level of fluid in container.
LOG FAILURE	Pump on hold	Unable to update event log.	• Qualified Service Personnel may need to service the Pump.
SET NOT FITTED	Pump on hold	No infusion set fitted.	• Fit infusion set.

Low Priority Alarms

Low priority alarms alert the user but may not stop the infusion and are indicated by an audible sound, a solid amber warning indicator and a message on the display. See the 'Alarm Priority Level Indicators' table for more details on how low priority alarms are indicated.

1. Check the display for message. Press to silence the sound for 2 minutes, or press a second time to re-enable alarm audio, **CANCEL** to clear the message.
2. Rectify the cause of the alarm or proceed with caution.

Display	*Infusion Status*	*Cause(s)*	*Action*
ATTENTION	Pump on hold	Pump left on hold for 2 minutes without starting the infusion.	• Review Pump setup. • Start infusion or turn off Pump.
ADD DRUG*	Infusion continues	Drug selection required.	• Press to access options menu. • Select **DRUGS A-Z** using the keys. • Press **OK** to confirm.
RATE LOCK*	Infusion continues	Rate lock not confirmed.	• Select **YES** or **NO** as required.
AC POWER FAIL	Infusion continues**	AC power disconnected or failed.	• Reconnect to power supply.
NEAR END OF INFUSION	Infusion continues	Less than XX (Configurable) minutes of infusion remaining.	• Set new VTBI. • Prepare new fluid container (Refer to 'Changing the Fluid Container' section)
TITRATION*	Infusion continues	Rate titration not confirmed.	• Confirm or cancel new rate.

***Note:** After five seconds the User will be notified by an auditory cue. After two minutes have expired a low priority alarm is generated.

** If pump was on hold the alarm will still be activated but this message will not be displayed.

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

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

Prompts

Prompts are indicated by an audible alarm and message, they cannot be silenced and do not have a visual indicator.

Display	*Infusion Status*	*Cause(s)*	*Action*
SET VTBI	Pump on hold	No VTBI / flow sensor.	• Set VTBI or fit flow sensor.
LOCKED	Infusion continues	Rate change attempted whilst locked.	• Unlock rate to adjust infusion settings.

Advisories

Display	*Infusion Status*	*Cause(s)*	*Action*
DOSE WOULD EXCEED	Pump on hold (If titration is disabled) Infusion continues (If titrating)	Infusion rate set exceeds a Guardrails™ soft limit.	• Check infusion setting. • To confirm **CONFIRM DRUG?** press **YES**. • To deny **CONFIRM DRUG?** press **NO**.
DOSE UNDER	Pump on hold (If titration is disabled) Infusion continues (If titrating)	Infusion rate/dose rate set is under a Guardrails™ soft limit.	• Check infusion setting. • To confirm **CONFIRM DRUG?** press **YES**. • To deny **CONFIRM DRUG?** press **NO**.
DOSE NOT PERMITTED	Pump on hold (If titration is disabled) Infusion continues (If titrating)	Dose rate entered is greater than the dose rate hard maximum set.	• Check infusion setting and adjust to appropriate required rate.
RATE NOT PERMITTED	Pump on hold (If titration is disabled) Infusion continues (If titrating)	Infusion rate set exceeds a hard limit.	• Check infusion setting and adjust to appropriate required rate.
CONCENTRATION NOT PERMITTED	Pump on hold	Concentration set exceeds hard max limit, or is under hard minimum limit.	• Check concentration and adjust to a more appropriate amount.
WEIGHT ABOVE LIMIT	Pump on hold	Patient weight set exceeds a Guardrails™ soft limit.	• Check weight setting. • To confirm **CONFIRM?** press **YES**. • To deny **CONFIRM?** press **NO**.
WEIGHT BELOW LIMIT	Pump on hold	Patient weight set is under a Guardrails™ soft limit.	• Check weight setting. • To confirm **CONFIRM?** press **YES**. • To deny **CONFIRM?** press **NO**.
BOLUS DOSE NOT PERMITTED	Infusion continues	Bolus dose rate entered is greater than the bolus dose rate hard maximum limit.	• Check the bolus setting and adjust to a more appropriate dose.
BOLUS DOSE WOULD EXCEED	Infusion continues	Bolus dose rate set exceeds a Guardrails™ soft limit.	• Check the bolus setting. • To confirm **OVERRIDE LIMIT?** press **YES**. • To deny **OVERRIDE LIMIT?** press **NO**.
BOLUS DOSE UNDER	Infusion continues	Bolus dose rate set is under a Guardrails™ soft limit.	• Check the bolus setting. • To confirm **OVERRIDE LIMIT?** press **YES**. • To deny **OVERRIDE LIMIT?** press **NO**.

Restarting an Infusion following an Air-in-Line Alarm

> ⚠ **The Pump may be restarted by opening the door, assessing and removing any air from the tubing guide area and in the infusion set on the patient side of the Pump (if required) according to hospital policy. Close the door and cancel the air-in-line alarm. Restarting the infusion will reactivate the air-in-line system and will alarm if the preset air-in-line limit is exceeded.**

Air ingress and bubble formation within the administration set is a known risk of infusion therapy.

This risk is multiplied when (a) multiple infusions are being administered simultaneously, and (b) where drugs or fluids which are known to have a tendency to degas, are being infused, with a potential consequence of an increase of air accumulation within a patient's circulation.

At an elevated risk of suffering potential consequences of air ingress are patient groups with Atrial Septal Defects. It is therefore recommended for this group that in addition to the existing air in line detection mechanism of the Pump, an air venting filter is used on the infusion set.

We advise you to also consider using an air venting filter:

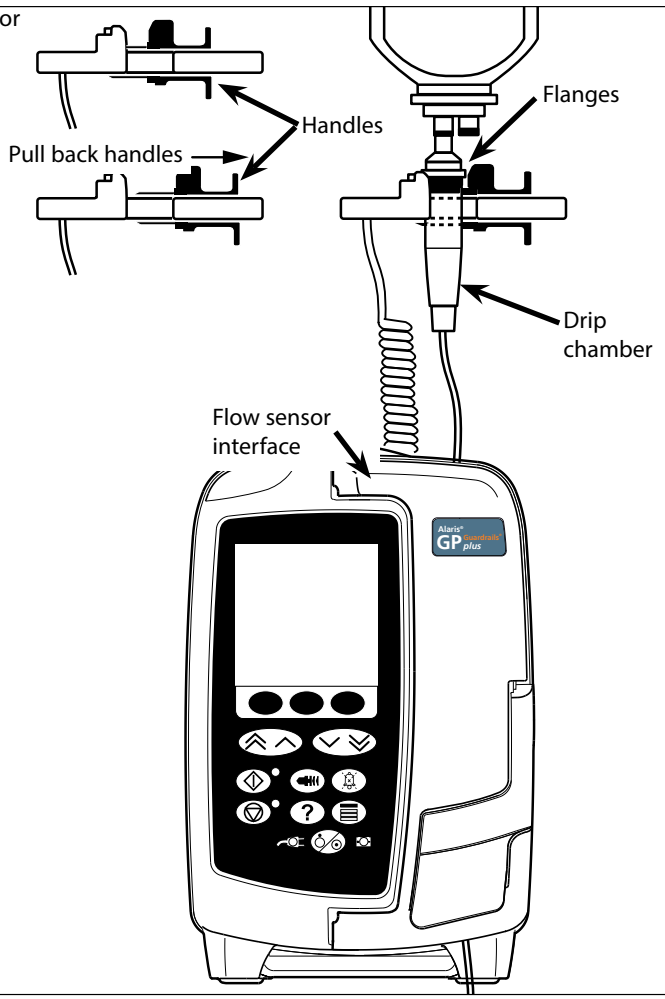
a) for other patient groups known to be at an elevated risk of suffering potential consequences of air ingress, such as neonates and
b) for situations presenting a multiplied risk of air ingress, such as can be found in critical care areas (multiple parallel infusions) or where drugs or fluids which are known to have a tendency to de-gas are being infused.

Where air venting filters cannot be used consider using anti siphon valves.

Flow Sensor Operation (Optional)

- **The flow sensor automatically monitors the infusion flow rate through the drip chamber. The flow sensor will cause the Pump to alarm if a significant deviation from the infusion rate occurs. The flow sensor will also be able to detect empty containers. For this reason we recommend use of a flow sensor wherever possible excluding secondary infusions.**
- **When infusing critical drugs, it is recommended to use a flow sensor, in addition to entering a VTBI.**

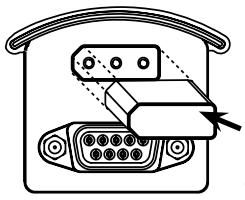
IVAC™ Model 180 Flow Sensor



1. Plug the flow sensor into the flow sensor interface located on the top rear part of the Pump.
2. Attach the IVAC™ Model 180 Flow Sensor to the drip chamber of the infusion set, by pulling back the handles. Refer to the illustration above.
3. Proceed with load, priming, and set-up instructions as described in section 'Getting Started'.

Note: Ensure drip chamber is half full and upright.

Always attach the flow sensor before you start an infusion .
Avoid using the flow sensor in direct sunlight.
Always ensure lens is clean.

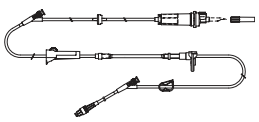
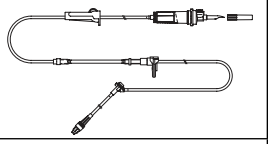
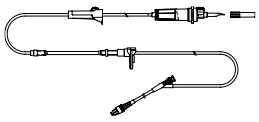
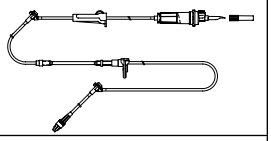
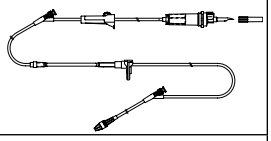
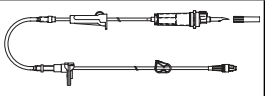
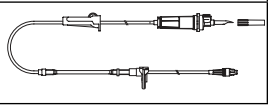


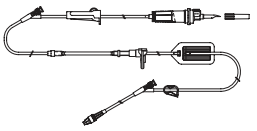
Always replace the flow sensor interface cover when the flow sensor is disconnected.

Infusion Sets

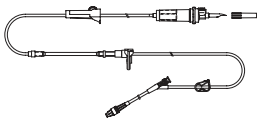
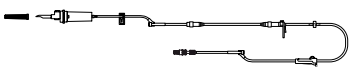
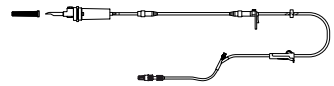
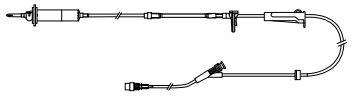
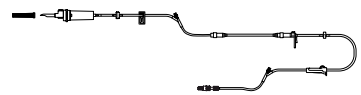
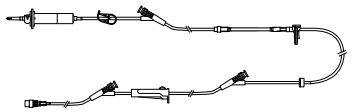
The Pump uses standard, single-use, disposable infusion sets. The user is responsible for verifying the suitability of a product used, if it is not recommended by BD.

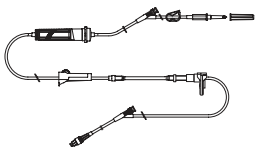
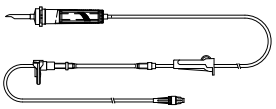
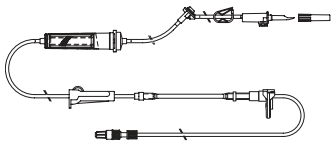
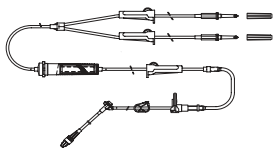
- **New sets are continuously being developed for our customers. Please contact your local BD representative for availability.**
- **Check infusion set materials and drug compatibility before selecting an infusion set.**
- **It is recommended that infusion sets are changed according to the instructions in the 'Changing the Infusion Set' section. Carefully read the Directions For Use supplied with the infusion set prior to use.**

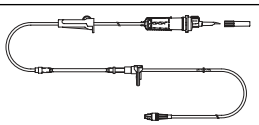
Alaris™ GP standard infusion sets (with filter)		
60093E	• 2 SmartSite Needle-Free Valve Ports • 15 Micron Filter • 1 Backcheck Valve • Length: 270cm	
60693	• 1 Injection Port • 15 Micron Filter • Length: 255cm	
60693E	• 1 SmartSite Needle-Free Valve Port • 15 Micron Filter • Length: 255cm	
60793	• 2 Injection Ports • 15 Micron Filter • Length: 255cm	
60793E	• 2 SmartSite Needle-Free Valve Ports • 15 Micron Filter • Length: 255cm	
60903	• 15 Micron Filter • Length: 265cm	
60593	• 15 Micron Filter • Length: 265cm	

Alaris™ GP TPN infusion sets		
60123E	• 2 SmartSite Needle-Free Valve Ports • 1.2 & 15 Micron Filter • Length: 275cm	

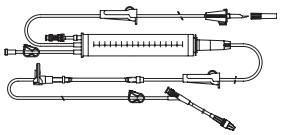
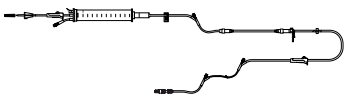
Please note these drawings are not to scale

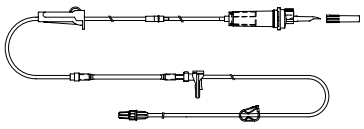
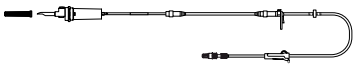
Alaris™ GP standard infusion sets (no filter)		
63200NYB	• No Filter • Length: 260cm	
60173E	• 1 SmartSite Needle-Free Valve Port • No Filter • Length: 265cm	
63110V	• 2 Split Septum Injection Ports • No Filter • Length: 290cm	
63401EB	• 1 SmartSite Needle-Free Valve Port • No Filter • Length: 275cm	
63402BE	• 1 SmartSite Needle-Free Valve Port • 1 Backcheck Valve • No Filter • Length: 265cm	
63420EB	• 2 SmartSite Needle-Free Valve Ports • 1 Backcheck Valve • No Filter • Length: 295cm	
63423BE	• 3 SmartSite Needle-Free Valve Ports • 1 Backcheck Valve • No Filter • Length: 285cm	

Alaris™ GP blood infusion sets		
60393E	• 2 SmartSite Needle-Free Valve Ports • 200 Micron Filter • Length: 275cm	
60895	• 200 Micron Filter • Length: 270cm	
60894	• 1 Injection Port • 200 Micron Filter • Length: 295cm	
60980	• Twin Spike • 1 Injection Port • 200 Micron Filter • Length: 295cm	
63477EB	• 2 Non- Vented Spikes • 180 Micron Filter • Length: 305cm • 1 SmartSite Needle-Free Valve Port	

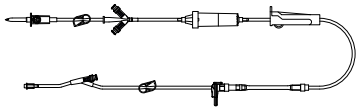
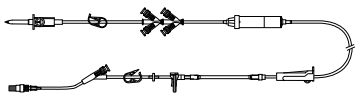
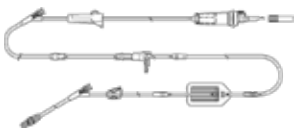
Alaris™ GP light resistant infusion sets		
60643	• 15 Micron Filter • Length: 250cm	

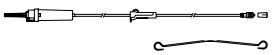
Please note these drawings are not to scale

Alaris™ GP burette infusion sets		
60103E	• 2 SmartSite Needle-Free Valve Port • 1 Burette (150ml) • Length: 275cm	
63441E	• 4 SmartSite Needle-Free Valve Port • 1 Burette (150ml) • Length: 330cm	

Alaris™ GP low sorbing infusion sets		
60953V	• 15 Micron Filter • Polyethylene lined PVC tubing • Length: 270cm	
63260NY	• Polyethylene lined PVC tubing • No Filter • Length: 295cm	

Alaris™ GP syringe adapter infusion sets		
63280NY	• Length: 270cm Restricted to maximum infusion rate of 150ml/h	

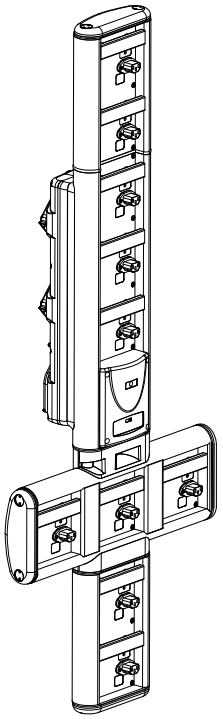
Alaris™ GP oncology infusion sets		
60950E	• 5 SmartSite Needle-Free Valve Ports • 15 Micron Filter • Length: 260cm	
60951E	• 3 SmartSite Needle-Free Valve Ports • 15 Micron Filter • Length: 260cm	
60952E	• 5 SmartSite Needle-Free Valve Ports • 15 Micron Filter • Light Resistant • Length: 260cm	
60033E	• 2 SmartSite Needle-Free Valve Ports • 0.2 Micron Filter • Length: 265cm	

Alaris™ GP secondary infusion set		
72213N-0006	• Male luer and hanger • Length: 76cm	
72951NE (For use with 60950E)	• 1 SmartSite Needle-Free Valve Port • Male luer with Backcheck Valve • Length: 35cm Do not use with Pump in secondary infusion mode when infusing critical drugs.	

Please note these drawings are not to scale

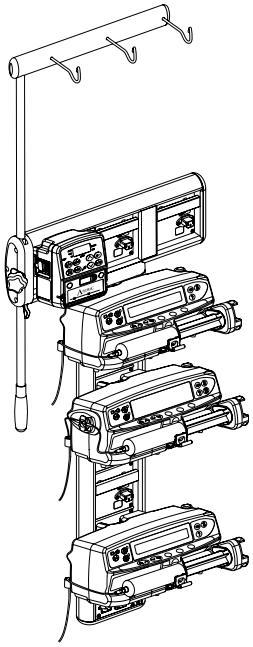
Associated Products

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 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 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 mechanism for damage.
	3. Check Start up self test operation is correct.
Before the transfer of the Pump to a new patient and as required	Clean the Pump by wiping over with a lint-free cloth lightly dampened with warm water and a standard disinfectant / detergent solution.

⚠ **If the 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 and all such activities 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 servicing should only be performed by Qualified Service Personnel with reference to the TSM.

⚠ **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.**

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

⚠ **It is recommended that prior to deploying a data set to all Alaris Compatible Guardrails Volumetric Pumps via Alaris Communication Engine (ACE), the Guardrails data set should be deployed, to a sample of pumps on a fully loaded AGW, in a non-clinical environment, and the pumps checked to ensure the settings and the drug library available on the pump are the same as included in the approved data set report.**
After data set deployment using ACE, if a pump is found to have a corrupted data set, the specific pump, and Alaris Gateway Workstation (AGW) should be removed from service, and the data set transferred using a RS232 cable. The AGW should be checked by qualified service personnel.

Battery Operation

The internal rechargeable battery allows continued operation when the AC power is unavailable, for example during patient transfer or AC power failure. When connected to the AC power supply for 4 hours, (whether the Pump is in use or not) a new battery pack will be fully charged.

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.

Charge retention will eventually degrade. Where retention is critical the internal battery should be replaced every 3 years.

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

The battery pack used in this Alaris™ Volumetric Pump is manufactured by BD and includes a proprietary PCB (printed circuit board) designed specifically for the Alaris™ Volumetric Pump, and in conjunction with Alaris™ Volumetric Pump software, controls battery use, charge and temperature. Any use of battery packs that are not manufactured by BD in the Alaris™ Volumetric 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™ Volumetric 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.

Cleaning and Storage

Cleaning the Pump

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

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 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
- Hibiscrub
- Tristel Fuse sachets
- Tristel Trio wipes system
- Virkon Disinfectant

Do not use the following disinfectant types:

- Disinfectants which are known to be corrosive to metals must not be used, which include:
  - NaDcc (such as Presept),
  - Hypochlorites (such as Chlorasol),
  - Aldehydes (such as Cidex),
  - Cationic Surfactants (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.

Cleaning the door

Refer to the Technical Service Manual for information for removing the door to facilitate cleaning of the fluid path, the use of a screwdriver (torx) is required and should only be carried out by Qualified Service Personnel.

Cleaning and storing the infusion set

The infusion set is a disposable single use item and should be discarded after use according to hospital protocol.

Cleaning the Flow Sensor

Before the transfer of the flow sensor to a new infusion set and periodically during use, clean the flow sensor by wiping over with a lint-free cloth lightly dampened with warm water and a standard disinfectant / detergent solution. Ensure the connector does not get wet. Dry flow sensor before use.

To aid cleaning of flow sensors which have been heavily soiled, contaminated or if the handle operation is not free moving, then the flow sensor may be immersed and soaked in clean soapy water. The inside of the spring mechanism can be cleaned by activating it whilst submerged in the water.

After cleaning, the sensor should be allowed to dry fully prior to use.

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 Pump. Do not use aggressive cleaning agents as these may damage the exterior surface of the Pump. Do not steam autoclave, ethylene oxide sterilise or immerse this Pump in any fluid. Please ensure the membrane covering the pumping mechanism is intact prior to cleaning. If faulty, remove from use and contact Qualified Service Personnel.
The plug of the flow sensor must not be immersed in water as damage will occur.

Storing the Pump

If the 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.

Specifications

Electrical Protection

Class I, Type CF (Defibrillation-proof)

Electrical/Mechanical Safety

Complies with IEC/EN60601-1 and IEC/EN60601-2-24.

Electro Magnetic Compatibility (EMC)

Complies with IEC/EN60601-1-2 and IEC/EN60601-2-24.

Electrical Safety

Typical earth leakage current 78µA.
Typical Enclosure Leakage Current (Normal Condition) = 0µA
Typical Protective Earth Resistance = 32mOhms
The above measurements are for guidance only, IEC/EN60601-1 limits are defined below:
Earth Leakage Current (Normal Condition) <= 500µA
Enclosure Leakage Current (Normal Condition) <= 100µA
Protective Earth Resistance <= 200mOhms

Classification

Continuous mode of operation, Portable Equipment

AC Power Supply

100 - 230 VAC, 50 - 60Hz, 60VA (Maximum).

Fuse Type

2 X T 1.25H, 250V

Dimensions

148mm (w) x 225mm (h) x 148mm (d). Weight: approx. 2.5kg (excluding power cable).

Protection against fluid ingress

IP33 - Protected against direct sprays up to 60° from the vertical.

Environmental Specifications

Condition	**Operating**	**Transport & Storage**
Temperature	+0°C - +40°C	-20°C - +50°C
Humidity	20% - 90%*	15% - 95%*
Atmospheric Pressure	700hPa - 1060 hPa	500hPa - 1060hPa

*Non condensing.

Battery Specifications

Rechargeable NiMH (Nickel Metal Hydride). Automatically charges when the Pump is connected to AC power.

- Battery Charging - 2.5 hours to 95%.

Battery Life

Infusion Rate	**Mean Time To Battery Empty from fully charged**
25ml/h	5.8 hours
125ml/h	5.65 hours
1200ml/h	3.4 hours

Memory Retention

The electronic memory of the Pump will be retained for more than 2 years with normal use.

Alarm Conditions

Alarms	**Warnings**	**Prompts**	**Advisories**
AIR IN LINE (SINGLE BUBBLE)	AC POWER FAIL	ATTENTION	DOSE WOULD EXCEED
AIR IN LINE (ACCUMULATED)	VTBI DONE	SET VTBI	DOSE UNDER
DOOR OPEN	BATTERY LOW	SET NOT FITTED	DOSE NOT PERMITTED
DOWNSTREAM OCCLUSION	AIR-IN-LINE	LOCKED	RATE NOT PERMITTED
UPSTREAM OCCLUSION	TITRATION	ADD DRUG	WEIGHT ABOVE LIMIT
NO FLOW	SET CLOCK		WEIGHT BELOW LIMIT
FLOW ERROR	RATE LOCK		CONCENTRATION NOT PERMITTED
FREE FLOW	LOG FAILURE		BOLUS DOSE NOT PERMITTED
BATTERY EMPTY	SET SERIAL NUMBER		BOLUS DOSE WOULD EXCEED
SAFETY CLAMP	NEAR END OF INFUSION		BOLUS DOSE UNDER
SET MISLOAD			
FLOW SENSOR DISCONNECTED			
WRONG SET			
DOOR CLOSE INCOMPLETE			
DO NOT USE			
LEVER OPEN			

IrDA, RS232 and Nursecall Specification

IrDA / RS232 / Nursecall Feature

The IrDA (or RS232 / Nursecall optional feature) is a feature that allows the Pump to be connected to an external device for the purpose of data communication.

⚠ **The nursecall interface provides a remote backup to the internal audible alarm. It should not be relied upon to replace monitoring of the internal alarm. The signal leaves the IrDA port and the RS232 for Nurse call within one second after the alarm condition is detected.**
Refer to the Technical Service Manual for further information regarding the RS232 interface.
The assessment for the suitability of any software used in the clinical environment to control receive data from the Pump lies with the user of the equipment. This software should include detection of the disconnection or other failure of the RS232 cable.
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.
To connect to the RS232 port use spare part 1000SP01183 - RS232 cable.

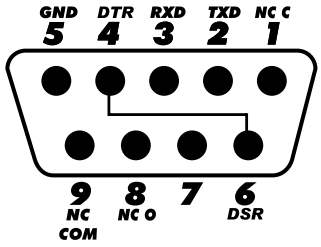
RS232 / Nursecall Connection Data

Nursecall Specification:

Connector	D Type - 9 Pin
TXD/RXD	EIA RS232-C Standard
Baud Rate	115k Baud
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. Nursecall (Relay) Normally Closed
2. Transmit Data (TXD) Output
3. Received Data (RXD) Input
4. DTR ➞ DSR (6)
5. Ground (GND)
6. DSR ➞ DTR (4)
7. Not used
8. Nursecall (Relay) Normally Open
9. Nursecall (Relay) Common



IrDA

Baud Rate	115k Baud
Start Bits	1 Start Bit
Data Bits	8 Data Bits
Parity	No Parity
Stop Bits	1 Stop Bit

Infusion Specifications

System Accuracy:

The System includes the Pump and any of the compatible Infusion Sets available from BD.

Rate Accuracy is ±5%, achieved under nominal conditions[1a,2]

Rate Accuracy is ±10%, achieved under low flow conditions[1b,2]

Occlusion Alarm Limits

Achieved under nominal conditions[1a,4]

Level	L0	L2	L5	L8
Pressure (mmHg) approx.	**90**	**250**	**519**	**811**

Maximum Pumping Pressure:

1000 mmHg

Maximum Occlusion Alarm Pressure:

1038 mmHg

Post Downstream Occlusion Bolus:

The management of post downstream occlusion bolus is the responsibilty of the clinician and must be determined for each situation.

Bolus volume generated at 25 ml/h when the minimum occlusion alarm threshold is reached <0.16 ml

Bolus volume generated at 25 ml/h when the maximum occlusion alarm threshold is reached <0.95 ml

Bolus Volume Accuracy:

Typical: -4.1%, Max: -3.2%, Min: -5.5% 1ml @ 10ml/h

Typical: -1.3%, Max: -0.9%, Min: -1.6% 100ml @ 1200ml/h

Maximum time for activation of occlusion alarm:

At Maximum Pressure, time to alarm at 0.1ml/h is nominally 735 [±50] minutes (Maximum <883 min)

At Minimum Pressure, time to alarm at 0.1ml/h is nominally 82 [±35] minutes (Maximum <112 min)

At Maximum Pressure, time to alarm at 1.0ml/h is nominally 65 [±4] minutes (Maximum <95 min)

At Minimum Pressure, time to alarm at 1.0ml/h is nominally 5 [+6-2] minutes (Maximum <10 min)

At Maximum Pressure, time to alarm at 25ml/h is nominally 119 [±7] seconds (Maximum <3 min)

At Minimum Pressure, time to alarm at 25ml/h is nominally 10 [+8.5-6.5] seconds (Maximum <18.5 sec)

Administering a Bolus

Parameter	Range
Bolus Rate	10 - 1200ml/h in steps of 10ml/h
Bolus Volume Displayed	0.0ml - 100.0ml in steps of 0.1ml

Starting the Infusion / Set-up

Infusion Parameter	Range
Infusion Rate	0.1 - 99.9ml/h in steps of 0.1ml/h 100 - 999ml/h in steps of 1ml/h 1000 - 1200ml/h in steps of 10ml/h
VTBI Primary	(0 - OFF), 1 - 9999ml
VI (Total)	0.1 - 9999ml

Air Sensor:

Integral Ultrasonic Sensor.

Air in line detection:

Single Bubble (configurable): 50µl, 100µl, 250µl & 500µl.

Bubble accumulation: 1ml over a 15 minute window.

Air in line detector accuracy is ±3%.

Critical Volume

The maximum volume infused following a single fault condition is for rates < 10ml/h: +/- 0.25 ml, rates < 100ml/h: +/- 0.5ml, rates ≥100ml/h: +/- 2 ml

The Alaris™ Safety Clamp

Set based, Pump activated Safety Clamp Device to prevent free flow

Notes

1a. Nominal conditions are defined as:
Set Rate: 1 to 1200 ml/h;
Recommended disposable: 60593;
Needle: 18 gauge x 40 mm;
Solution Type: De-ionized & Degassed Water;
Temperature: 23°C ± 2°C
Fluid Head Height: +300 ± 30 mm;
Back Pressure: 0 ± 10 mmHg.

1b. Low flow conditions are defined as:
Set Rate: less than 1.0ml/h
Recommended disposable: 60593;
Needle: 18 gauge x 40 mm;
Solution Type: De-ionized & Degassed Water;
Temperature: 23°C ± 2°C
Fluid Head Height: +300 ± 30 mm;
Back Pressure: 0 ± 10 mmHg.

2. The system accuracy will change by the following percentages:[3]
Temperature: nominally -5.7 (±1.5)% at 5 °C and nominally +0.3 (±1.7)% at 40 °C
Fluid Head Height: nominally -3.4 (±1.3)% at -0.5 m and 0.0 (±1.1)% at +0.5 m
Duration: nominally -1.1 [±0.2] % over 24 hours of continuous use
Back Pressure: nominally +2.0 (±1.3)% at -100 mmHg, -13.4 (±1.8)% at +800 mmHg respectively
Atmospheric pressure: ± 5% at 25ml/h at 700hPa

3. Tested using Distilled water, 20% lipid, 50% glucose, 0.9% Normal Saline and 5% Alcohol solutions.

4. The occlusion pressure accuracy will change by the following:
Temperature: Low setting nominally 7 (±12) mmHg at 5 °C and -24 (±17) mmHg at 40 °C respectively
Normal setting nominally 4 (±16) mmHg at 5 °C and -41 (±18) mmHg at 40 °C respectively
High Pressure nominally 4 (±14) mmHg at 5 °C and -38 (±21) mmHg at 40 °C respectively

The specified accuracy may not be maintained if the above conditions are not met, see notes 1 to 4.

Trumpet and Flow Rate Curves

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

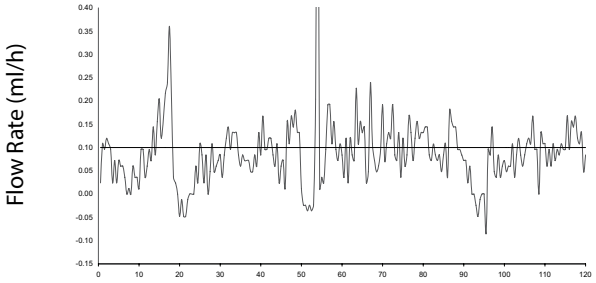
The following curves show typical performance of the system in two ways: 1) the accuracy of fluid delivery over various time periods is measured (trumpet curves), and 2) the delay in onset of fluid flow when infusion commences (start-up curves).

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.

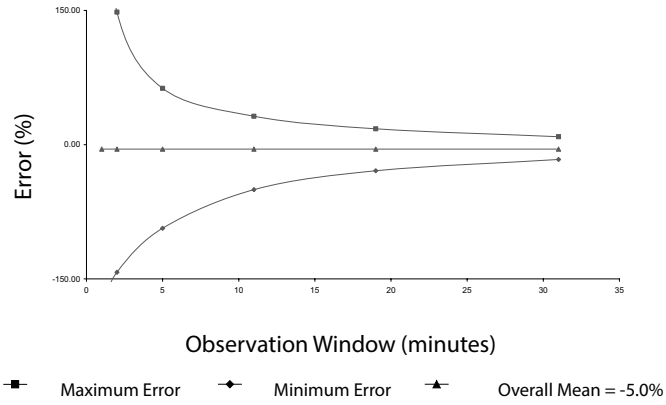
Knowledge of system accuracy over various observation windows may be of interest when certain drugs are being administered. Short term fluctuations in rate accuracy may have clinical impact depending on the half-life of the drug being infused and the degree of inter vascular integration, the clinical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

The start-up curves represent continuous flow versus operating time for two hours 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 IEC/EN60601-2-24 standard.

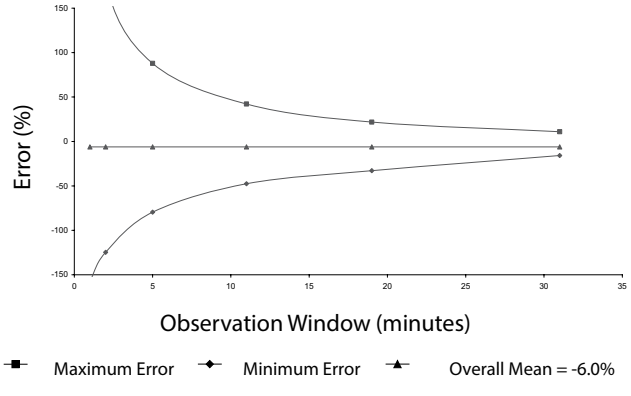
Start-up Graph at 0.1ml/h (Initial Period)



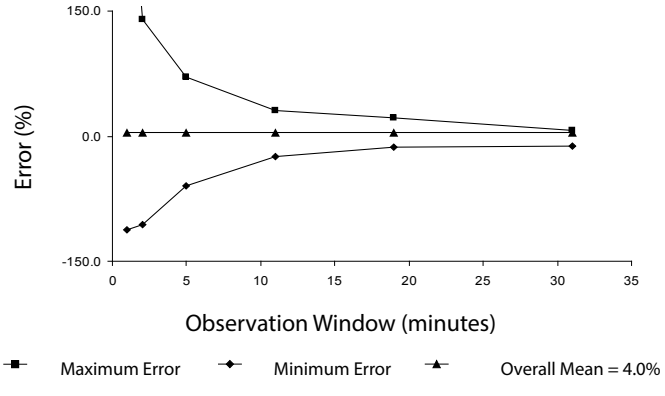
Trumpet Graph at 0.1ml/h (After 24 Hours)



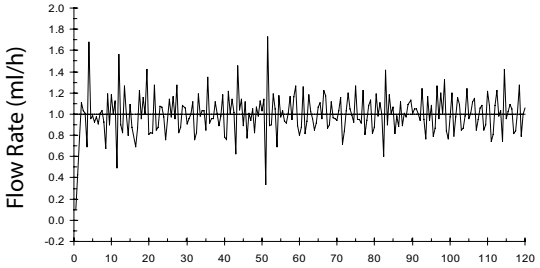
Trumpet Graph at 0.1ml/h (Initial Period)



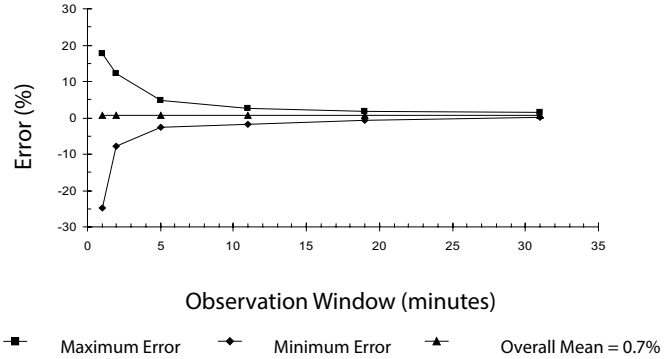
Trumpet Graph at 0.1ml/h (After 72 Hours)



Start-up Graph at 1.0ml/h (Initial Period)



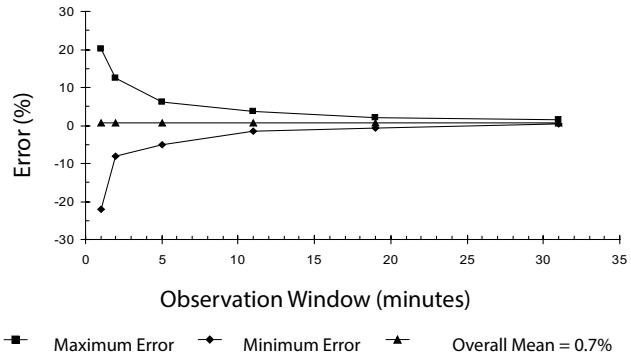
Trumpet Graph at 1.0ml/h (After 24 Hours)



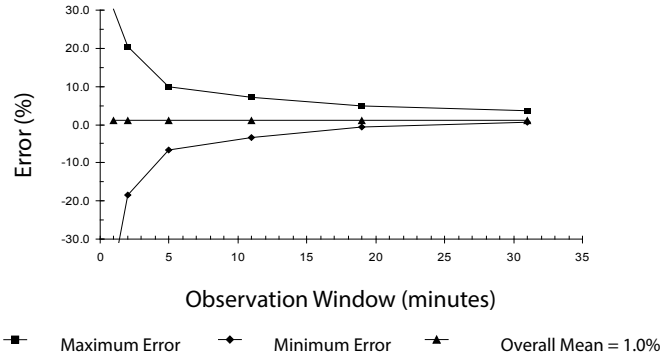
Note: The typical flow rate and trumpet curves are achieved using a recommended infusion set.

The plot range has been increased to ± 150%, to allow visualization of the graph.

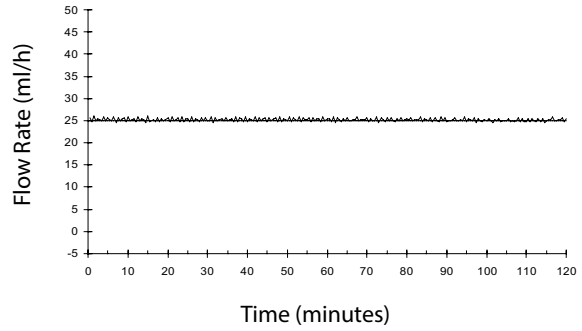
Trumpet Graph at 1.0ml/h (Initial Period)



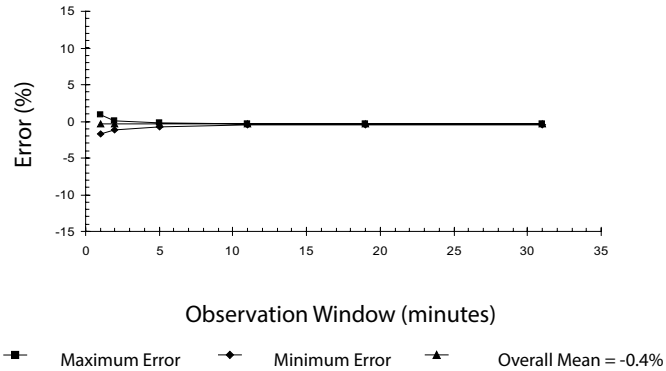
Trumpet Graph at 1.0ml/h (After 72 Hours)



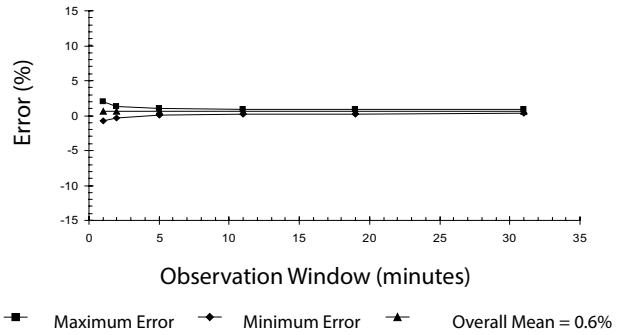
Start-up Graph at 25.0ml/h (Initial Period)



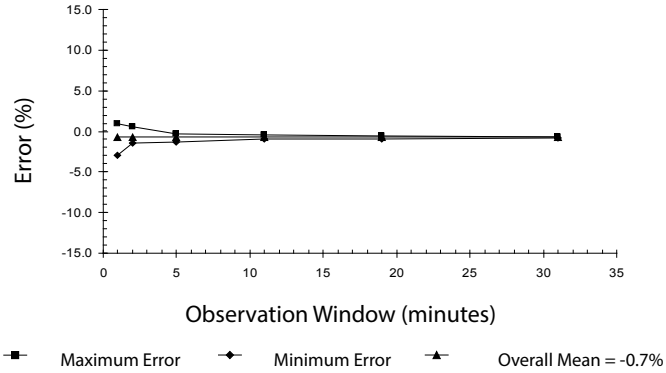
Trumpet Graph at 25.0ml/h (After 24 Hours)



Trumpet Graph at 25.0ml/h (Initial Period)



Trumpet Graph at 25.0ml/h (After 72 Hours)



Note: The typical flow rate and trumpet curves are achieved using a recommended infusion set.

Products and Spare Parts

Spare Parts

A comprehensive list of spare parts for this Pump is included within the Technical Service Manual.

The Technical Service Manual (1000SM00013) 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**
1000SP00487	Internal Battery Pack
1000SP01183	RS232 Cable
1001FAOPT91	AC Power Lead - UK
1001FAOPT92	AC Power Lead - European

Alaris™ Editor Software

Part Number	**Description**
1000SP01462	Alaris™ Editor and Alaris™ Transfer Tool Software Kit
1000SP01463	Alaris™ Transfer Tool Software Kit

Document History

Issue	Date	Software Version	Description
1	July 2019	2.3.4	Initial release
2	October 2020	2.3.4	Updates for regulations
3	October 2020	2.3.4	Updates for regulations
4	December 2021	2.3.x	Updates for regulations

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