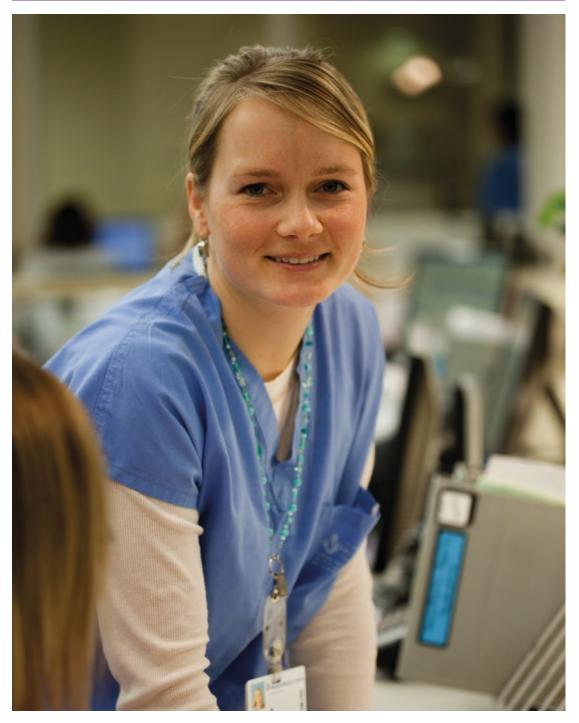
Alaris™ GP (Guardrails™) Volumetric Pump

(with Plus Software)

Directions For Use **en**











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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 technical 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.

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 CareFusion products. These documents are referenced on www.carefusion.com. Copies can be obtained by contacting your local CareFusion representative.

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.	
•	Important Information: Wherever this symbol is shown an Important note is found. These notes highlight an aspect of use that is important for the user to be aware of when operating the pump.	

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;

- 1. 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 CareFusion 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.

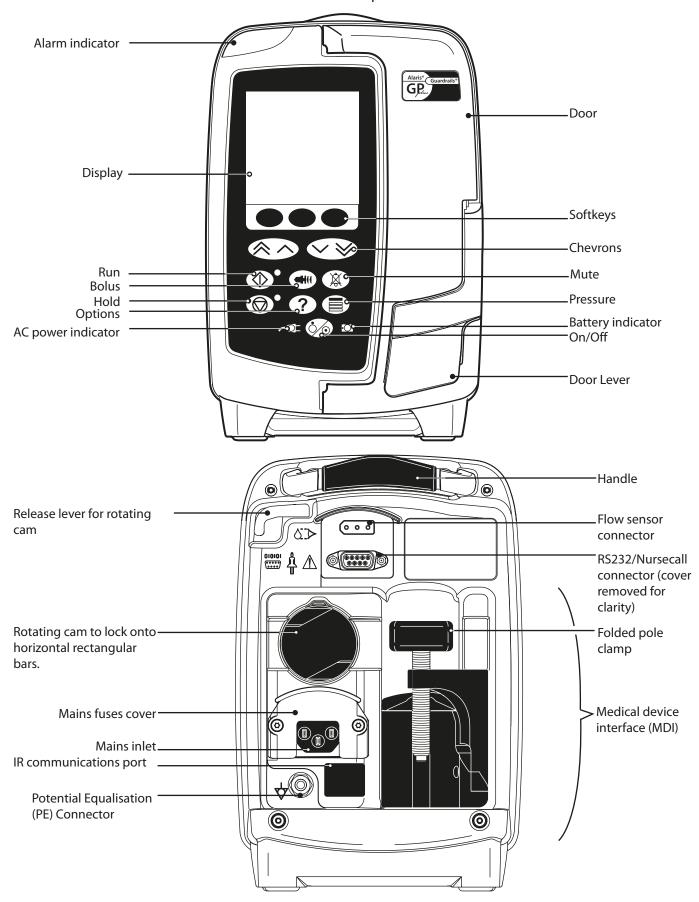


Data set transfers should only be performed by qualified technical personnel.

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.

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.
⊕3	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 (approximately) two minutes (configurable). The alarm will resound after this time. Press and hold until three beeps are heard for 15 minutes silence (If enabled via the Alaris Editor).
4(1)	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
€QĪ	AC POWER indicator - When illuminated the pump is connected to an AC power supply and the battery is being charged.
÷Ō-	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.

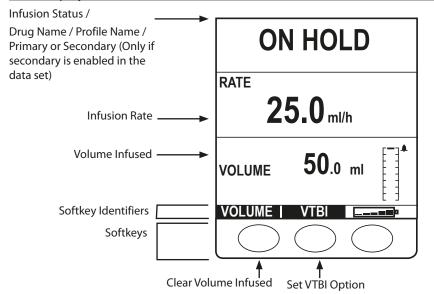
Symbol Definitions

Labelling Symbols:

Symbol	Description				
\triangle	Attention (Consult accompanying document)				
₩	Potential Equalisation (PE) Connector				
010101	RS232/Nursecall Connector.				
4 P	Defibrillation-proof type CF applied part (Degree of protection against electrical shock).				
IPX3	Protected against direct sprays up to 60° from the vertical.				
	Alternating Current				
€ 0086	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				
EC REP	Authorised representative in the European Community				

Main Display Features

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





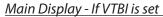
If the rate has not been set and is showing at 0.0ml/h, then message **a)** will be displayed.

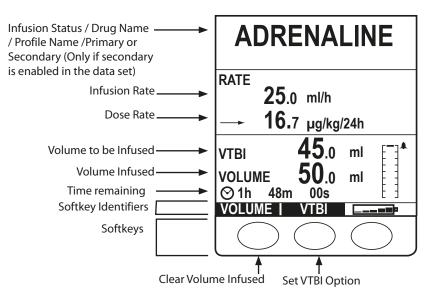


b)

c)

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







If programmed rate is greater than the **INFUSION RATE MAX** in drug protocol, message **c**) will be shown.

Screen Icons

Symbol	Description
\odot	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).
Į.	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.
1111	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 CareFusion 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.
- CareFusion 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.

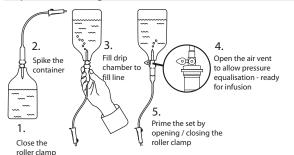
Using Collapsible bags, Glass Bottles & Semi Rigid containers

• 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

- 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 all establishments, including domestic establishments and those directly
 connected to the public low voltage power supply network that supplies buildings used for domestic
 purposes.
- 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.

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
 CareFusion 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
 CareFusion 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 CareFusion 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 CareFusion 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

Earth Conductor



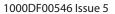
• The pump is a Class I device, therefore must be earthed when connected to an AC power supply.



• This pump also has an internal power source.

instance by repositioning or relocation.

• 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 a qualified service engineer. 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 a qualified service engineer.
- · 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.

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
 - Directions For Use (CD)
 - AC Power Cable (as requested)
 - · Protective Packaging
 - Alaris Editor Software and/or Alaris Transfer Tool per hospital
- 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 $\subset \mathbb{Q}^{\mathbb{Z}}$ 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 a qualified service engineer for investigation.

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	100μΙ
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



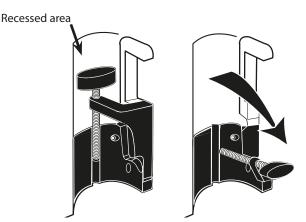
- Refer to 'Display of Units' section of this DFU for configurable units.
- The default data set does not have drug related Guardrails limits. To set the limits use the Alaris Editor software. Care should be taken when specifying the Guardrails limits.

^{*} Only available on the Alaris GP Guardrails Volumetric Pump.

Pole Clamp Installation

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.



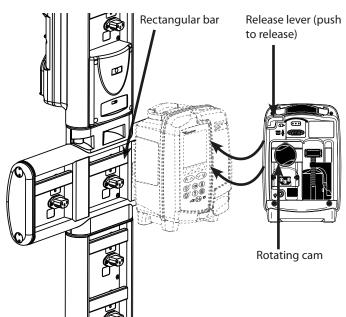


Never mount the pump such that the I.V. infusion stand becomes top heavy or unstable. Ensure the pole clamp is folded away and stored within the recessed area at the rear of the pump before connecting to a Docking Station/Workstation* or when not in use.

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.



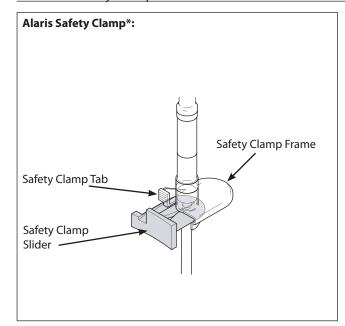
Warning: Pump may fall off the Docking Station/Workstation* if not properly mounted which could result in user and/or patient harm.

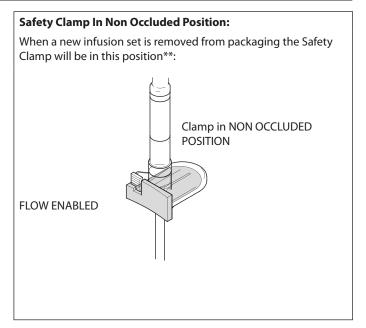
* Alaris DS Docking Station and Alaris Gateway Workstation.



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.

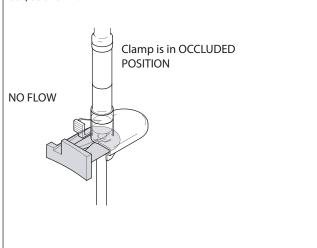
The Alaris Safety Clamp





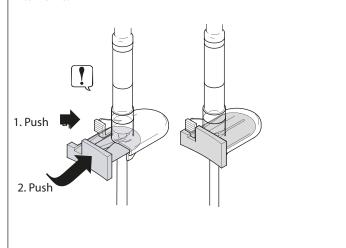
Safety Clamp In Occluded Position:

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'.

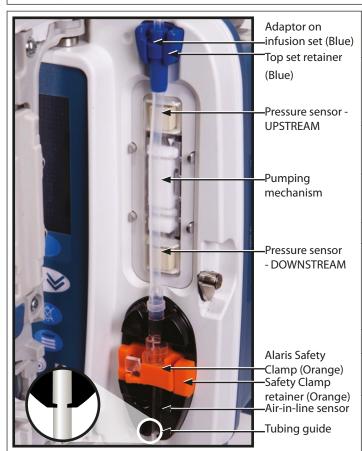
^{**} This is necessary to avoid tube damage during storage and to ensure correct sterilisation and allows immediate priming.

Loading an Infusion Set

Loading an Infusion Set: Alaris Safety Clamp in the NON OCCLUDED position - FLOW ENABLED:



- 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.



- 1. Remove infusion set from package and close roller clamp.
- Insert the bag spike into the fluid container and hang appropriately at a minimum height of 300 mm above the pump.
- 3. Fill the drip chamber to the fill line if shown (Approximately half full). Refer to operating precaution section 'Using Collapsable bags, Glass Bottles & Semi-Rigid containers'.
- 4. Open roller clamp and prime set slowly (to prevent air bubbles) ensuring all air is removed. To use the pump to prime refer to 'Priming the Infusion Set' section.
- Close roller clamp.
- Switch the pump on. Open door and load infusion set as follows:
 - Fit blue adaptor of infusion set into blue top set retainer.
 - Insert orange safety clamp into orange retainer.
- 7. Ensure infusion set is fully inserted into tubing guide.
- 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. Connect the infusion set to the patient access device.

Loading an Infusion Set: Alaris Safety Clamp in the OCCLUDED position - NO FLOW:



Alaris Safety
Clamp (Orange)
in occluded
position (See
previous page)

-Tubing guide

- 1. Follow steps 1 to 4 as above where necessary.
- 2. Ensure roller clamp is closed.
- Switch the pump on. Open door and load infusion set as follows:
 - Fit blue adaptor of infusion set into blue top set retainer.
 - Insert orange safety clamp (leaving slider extended) in the occluded position into orange retainer.



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.

- 4. Ensure infusion set is fully inserted into tubing guide.
- 5. Close door and open roller clamp. Ensure no drops are falling in the drip chamber.
- 6. Ensure all air is removed from the set. Connect the infusion set to the patient access device.

Starting the Infusion



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 6 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.

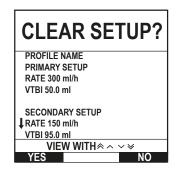
- 4. **CLEAR SETUP?** Selecting **NO** will retain all previous rate and volume settings, go to step 7. Selecting **YES** will automatically reset the rate and volume settings to zero and the **CONFIRM PROFILE?** screen will be displayed.
 - ml/h

- 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).



- 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).
- 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:

- ullet by pressing the igotimes 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 ② 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 **SOLUTION** 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.
- 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.

¹Only 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 **EXESS** 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 **EXAMPLE** 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.

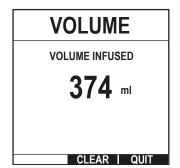
¹Only displayed if weight based units are used.

 $^{^2}$ Total Volume = Drug Volume + Diluent Volume i.e. Total Volume of fluid in the fluid container after a drug is added.

Clear Volume Infused



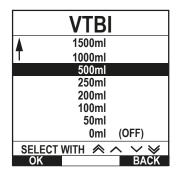
When a new drug or a new concentration has been setup and the previous volume infused has not been cleared, then the message DOSE INFUSED HAS BEEN CLEARED will be displayed.



This option enables the volume infused to be cleared.

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

Setting a VTBI



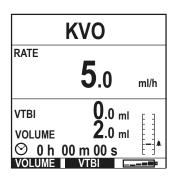
This feature allows a specific volume to be infused to be set. The rate at the end (**END RATE**) of this VTBI can also be set, selecting from **STOP**, **KVO** or **CONTINUE** for continuous infusion at the set rate

- 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 **EXES** 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.

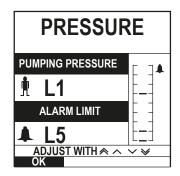
The pump continues to infuse at a very low (Default) rate. KVO is used to keep the patients vein open, in order to prevent blood clots and catheter occlusions.

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.

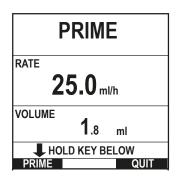


- Higher rates generate higher pumping pressures. To avoid nuisance alarms, L0 and L1 levels should not be used for rates above 200ml/h.
- The interpretation of pressure readings and occlusion alarms are the responsibility of the clinician depending on the specific application.
- Occlusion levels for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

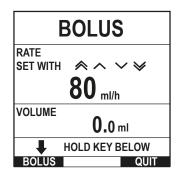
Bolus Mode - Disabled

If configured to Disabled, pressing the embutton 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 MODE

HANDSFREE?

YES QUIT THANDSON

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 (3) 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 0.1 ml.

- 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.

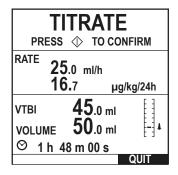
NOTE: Rate may be restricted by the **BOLUS RATE MAX** which is configured in the Alaris

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.

- . 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 ③ 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. 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 ② 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 ② button to access the options menu.
- 2. Select the **SET BY ml/h** option using 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.
- 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 ② 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 ② 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 ② 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 **MACON** keys.
- 4. Press **OK** softkey to confirm or **QUIT** to exit screen.

Event Log

This option allows the event log to be reviewed.

- 1. Press the ② 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.
- $4. \quad \text{Select } \textbf{BACK} \text{ to return to the previous screen, if required.} \\$

Pump Details

To review pump information:

- 1. Press the ② button to access the options menu.
- 2. Select **PUMP DETAILS** using the R 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 ② 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 ② 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 spike into new container.
- 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 CareFusion 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

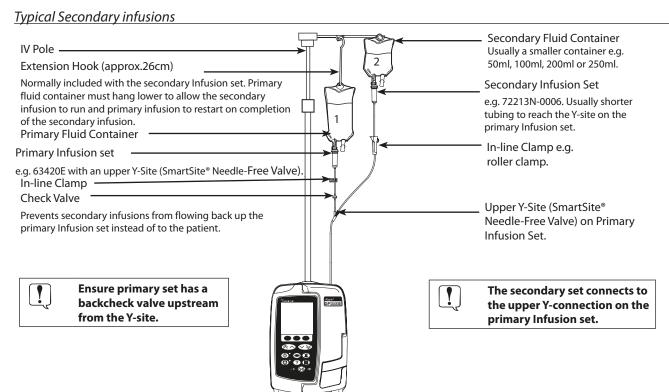
- 1. Ensure Primary infusion has been setup in ml/h (rate > 0ml/h). 11. If correct, press **OK** to continue, or **BACK** to adjust **VTBI** or
- 2. Press to put the pump **ON HOLD**.
- 3. Press ? to access the **OPTIONS** screen.
- 4. Select **SECONDARY SETUP**, press **OK** to confirm.
- Select either ml/h or DRUGS A-Z. Press OK to confirm either selection.
- 6. Enter the secondary **RATE** using the **RATE** keys.
- 7. Press **OK** to confirm.
- Set VTBI using the keys (Refer to 'Setting a VTBI' section).
- 9. Press **OK** to confirm.
- 10. Review PRIMARY/SECONDARY setup summary.

- If correct, press OK to continue, or BACK to adjust VTBI o RATE of the SECONDARY mode.
- 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 of to place the primary infusion **ON HOLD**.
- 2. Follow instructions 3 to 13 of 'Setting up a secondary infusion'.



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.

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.



Access codes should only be entered by qualified technical personnel.

Date & Time

- 1. Select **DATE & TIME** from the **CONFIGURATION** menu using the **EXECUTE** keys and press the **OK** softkey.
- 2. Press the **OK** softkey to confirm.
- 3. Use 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 **SOME** 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 6 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 **6** 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 WARNINGControls 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 VOLUMEControls 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 MODEControls whether, between defined times, the pump makes changes consistent with usage at

night (e.g. dimmed backlight).

AUTO SAVEControls 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 TIMEThe time that is allowed to elapse between the user's last recorded interaction with the pump and

generation of a callback alarm.

DRUG OVERRIDE MODEAlways - 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 MODEControls 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.

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 MAXThe 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.

		c
(ancon	tration	Settinas
COLICELL	папоп	Jellinas

CONCENTRATION UNITS The unit for concentration parameters.

CONCENTRATION MINThe 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 UNITSControls 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 MAXThe 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 MAXThe 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 stop the infusion and are indicated by a combination of an audible sound, flashing red alarm indicator and a message on the display.

- 1. Check the display for an alarm message and review table below for cause and action. Press (3) to silence the sound for 2 minutes, **CANCEL** to clear the message.
- 2. When the cause of the alarm has been rectified, press the we key to resume the infusion. (Exceptions are **DO NOT USE** and **BATTERY EMPTY**)

Display	Infusion Status	Cause	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 exceeds alarm limit. (Multiple bubbles smaller than the single bubble alarm limit, which has been detected over a 15 min. window and >1ml.)	 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	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.

Warnings

Warnings 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.

- 1. Check the display for a warning message. Press (3) to silence the sound for 2 minutes, **CANCEL** to clear the message.
- 2. Rectify the cause of the warning or proceed with caution.

Display	Infusion Status	Cause	Action
BATTERY LOW	Infusion continues	Less than 30 minutes of battery life remaining.	Connect to power supply.Check power cable.
AC POWER FAIL	Infusion continues*	AC power disconnected or failed.	Reconnect to power supply.
VTBI DONE	Infusing KVO	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.
SET CLOCK	Pump on hold	Date / time not set.	 A qualified service engineer must set date / time. Press cancel softkey to continue.
TITRATION	Infusion continues	Rate titration not confirmed.	Confirm or cancel new rate.
RATE LOCK	Infusion continues	Rate lock not confirmed.	Select YES or NO as required.
LOG FAILURE	Pump on hold	Unable to update event log.	A qualified service engineer may need to service the pump.
SET SERIAL NUMBER	Pump on hold	Serial number not set.	Contact a qualified service engineer to set the serial number.
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.

Prompts

Prompts 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.

- 1. Check the display for a prompt message. Press to silence the sound for 2 minutes, **CANCEL** to clear the message.
- 2. Rectify the cause of the prompt or proceed with caution.

Display	Infusion Status	Cause	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.
SET VTBI	Pump on hold	No VTBI / flow sensor.	• Set VTBI or fit flow sensor.
SET NOT FITTED	Pump on hold	No infusion set fitted.	• Fit infusion set.
LOCKED	Infusion continues	Rate change attempted whilst locked.	Unlock rate to adjust infusion settings.
ADD DRUG	Infusion continues	Drug selection required.	 Press

Advisories

Display	Infusion Status	Cause	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:

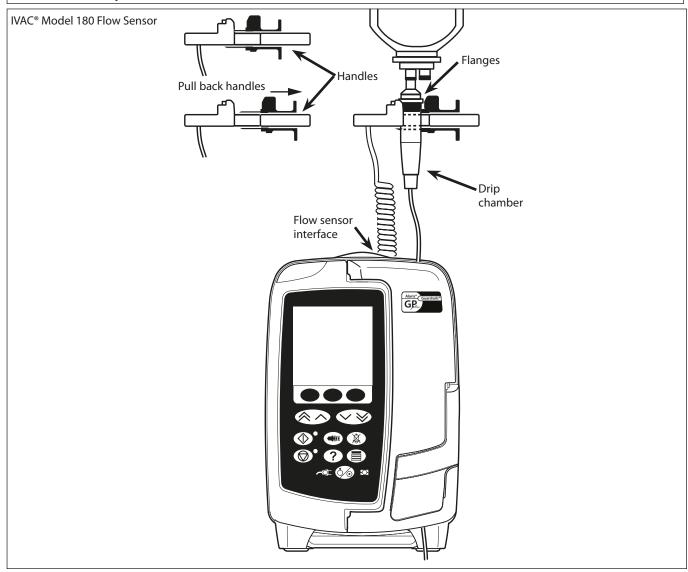
- a) for other patient groups known to be at an elevated risk of suffering potential consequences of air ingress, such as neonates and
- b) for situations presenting a multiplied risk of air ingress, such as can be found in critical care areas (multiple parallel infusions) or where drugs or fluids which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

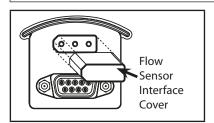


- 1. Plug the flow sensor into the flow sensor interface located on the top rear part of the pump.
- 2. Attach the IVAC® Model 180 Flow Sensor to the drip chamber of the infusion set, by pulling back the handles. Refer to the illustration above.
- 3. Proceed with load, priming, and set-up instructions 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 CareFusion.



- New sets are continuously being developed for our customers. Please contact your local CareFusion 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				
60093E	 2 SmartSite® Needle-Free Valve Ports 15 Micron Filter 1 Backcheck Valve Length: 270cm 			
60123E	 2 SmartSite® Needle-Free Valve Ports 1.2 & 15 Micron Filter Length: 275cm 			
60293E	 2 SmartSite® Needle-Free Valve Ports 1 Backcheck Valve No Filter 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			
60173E	 1 SmartSite® Needle-Free Valve Port No Filter Length: 265cm 			
63120V	 2 Split Septum Injection Ports 1 Backcheck Valve No Filter Length: 305cm			

Please note these drawings are not to scale

Alaris GP standard infusion sets		
63200NY	No Filter Length: 260cm	
63110V	 2 Split Septum Injection Ports No Filter Length: 290cm	
63401E	 1 SmartSite* Needle-Free Valve Port No Filter Length: 275cm 	
63402BE	 1 SmartSite* Needle-Free Valve Port 1 Backcheck Valve No Filter Length: 265cm 	
63420E	 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	
63477E	 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	

	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		
60953	15 Micron FilterPolyethylene lined PVC tubingLength: 270cm	
63260NY	Polyethylene lined PVC tubingNo FilterLength: 295cm	
60033E	• 2 SmartSite® Needle-Free Valve Ports • 0.2 Micron Filter • Length: 265cm	

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

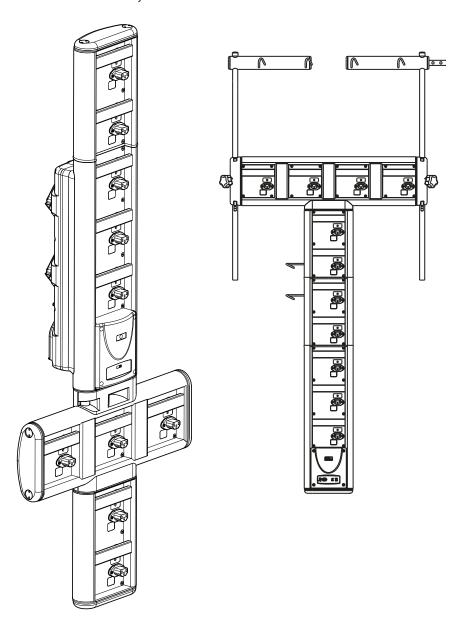
Alaris GP oncology infusion sets		
60950E	 5 SmartSite® Needle-Free Valve Ports 15 Micron Filter Length: 260cm 	
60951E	3 SmartSite® Needle-Free Valve Ports 15 Micron Filter Length: 260cm	
60952E	 5 SmartSite® Needle-Free Valve Ports 15 Micron Filter Light Resistant Length: 260cm 	

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 DS Docking Station
- The Alaris Gateway Workstation



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

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

Clean the pump by wiping over with a lint-free cloth lightly dampened with warm water and



new patient and as required

If the pump is dropped, damaged, subjected to excessive moisture or high temperature, immediately take it out of service for examination by a qualified service engineer.

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

All servicing should only be performed by a qualified service engineer with reference to the TSM.

a standard disinfectant / detergent solution.



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 CareFusion products. These documents are referenced on www.carefusion.com. Copies can be obtained by contacting your local CareFusion representative.



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.

Battery Operation

The internal rechargeable battery allows continued operation when the AC power is unavailable, for example during patient transfer or AC power failure. Mean Time To Battery Empty from fully charged is a minimum of 6 hours. 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 a qualified service engineer replaces 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 CareFusion 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 CareFusion in the Alaris Volumetric Pump is at your sole risk, and CareFusion does not provide any warranty for or endorsement on any battery packs that are not manufactured by CareFusion. CareFusion's 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 CareFusion.

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)	

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).
- 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 a qualified service engineer.

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 a qualified service engineer.

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 CareFusion 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) = 0μ A

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) \leq 100 μ A

Protective Earth Resistance <= 200mOhms

Classification

Continuous mode of operation, Portable Equipment

AC Power Supply

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

Fuse Type

2 XT 1.25 A, slow blowing.

Dimensions

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

Protection against fluid ingress

IPX3 - Protected against direct sprays up to 60° from the vertical.

Environmental Specifications

Condition	Operating	Transport & Storage
Temperature	+5°C - +40°C	-20°C - +50°C
Humidity	20% - 90%*	15% - 95%*
Atmospheric Pressure 700hPa - 1060 hPa 500hPa - 1060hf		500hPa - 1060hPa

^{*}Non condensing.

Battery Specifications

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

- Battery Life For a 24 hour battery charge time, the pump at 25ml/h will have a Mean Time To Battery Empty of 6 hours.
- Battery Charging 2.5 hours to 95%.

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.

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.

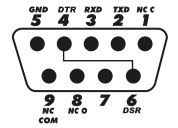
RS232 / Nursecall Connection Data

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:

Rate Accuracy is ±5%, achieved under nominal conditions^{1a,2}

Rate Accuracy is $\pm 10\%$, achieved under low flow conditions^{1b,2}

Occlusion Alarm Limits

Achieved under nominal conditions^{1a,4}

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

Maximum Occlusion Alarm Pressure:

1038 mmHg

Post Occlusion Bolus:

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 $[\pm 4]$ 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
	0.1 - 99.9ml/h in steps of 0.1ml/h &
Infusion Rate	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.

Critical Volume

The maximum volume infused following a single fault condition is for rates < 10ml/h: +/- 0.25 ml, rates < 10ml/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 (\pm 1.3)% at -0.5 m and 0.0 (\pm 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

- Tested using Distilled water, 20% lipid, 50% glucose, 0.9% Normal 3. Saline and 5% Alcohol solutions.
- The occlusion pressure accuracy will change by the following: 4.

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

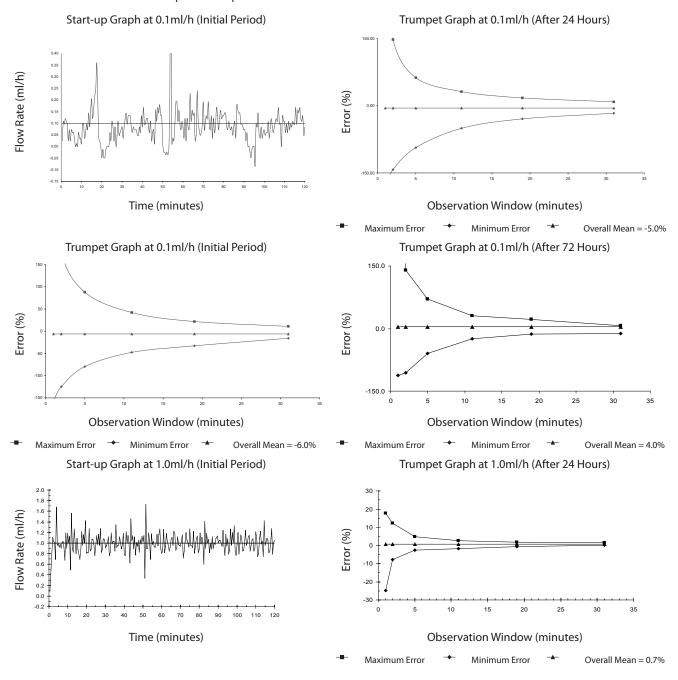
In this pump, as with all infusion systems, the action of the pumping mechanism and variations cause short-term fluctuations in rate accuracy.

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).

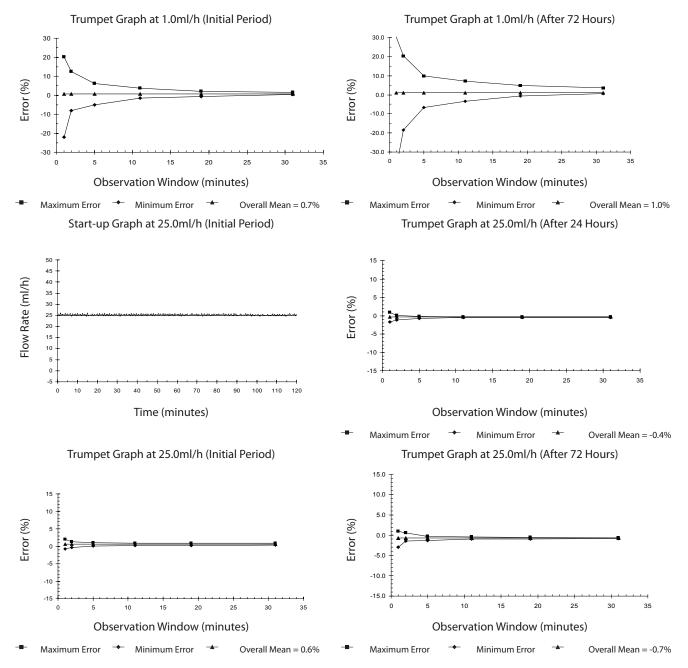
Trumpet curves are named for their characteristic shape. They display discrete data averaged over particular time periods or 'observation windows', not continuous data versus operating time. Over long observation windows, short term fluctuations have little effect on accuracy as represented by the flat 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.



Note: The typical flow rate and trumpet curves are achieved using a recommended infusion set. The plot range has been increased to \pm 150%, to allow visualization of the graph.



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 :-

www.carefusion.co.uk/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

Service Contacts

For service contact your local Affiliate Office or Distributor:

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235 Shield Markham, Ontario L3 Canada. Tel: (1) 90	ds Court, , 3R 8V2, 05-752-3333	2, rue René Caudron 78960 Voisins le Bretonneux France Tél: (33) 01 30 02 81 41	1363 HØVIK Norge.	Oude Molen Road, Ndabeni, Cape Town 7405, South Africa. Tel: (27) (0) 860 597 572 Tel: (27) 21 510 7562
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235 Shield Markham, Ontario L3 Canada. Tel: (1) 90 CH CareFusio A-One Bu: Zone d'ac n° 10 1180 Rolle	ds Court, 1, 3R 8V2, 05-752-3333 05-752-3343 on, ssiness Centre ctivitiés Vers-la-Pièce e / Switzerland 244 433	2, rue René Caudron 78960 Voisins le Bretonneux France Tél: (33) 01 30 02 81 41 Fax: (33) 01 30 02 81 31 FI CareFusion, Kuortaneenkatu 2, 00510 Helsinki	1363 HØVIK Norge. Tel: (47) 64 00 99 00 NZ CareFusion, 14B George Bourke Drive, Mt Wellington 1060, PO Box 14-518, Panmure 1741, Auckland, New Zealand Tel: 09 270 2420	Oude Molen Road, Ndabeni, Cape Town 7405, South Africa. Tel: (27) (0) 860 597 572 Tel: (27) 21 510 7562
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1000DF00546 Issue 5

