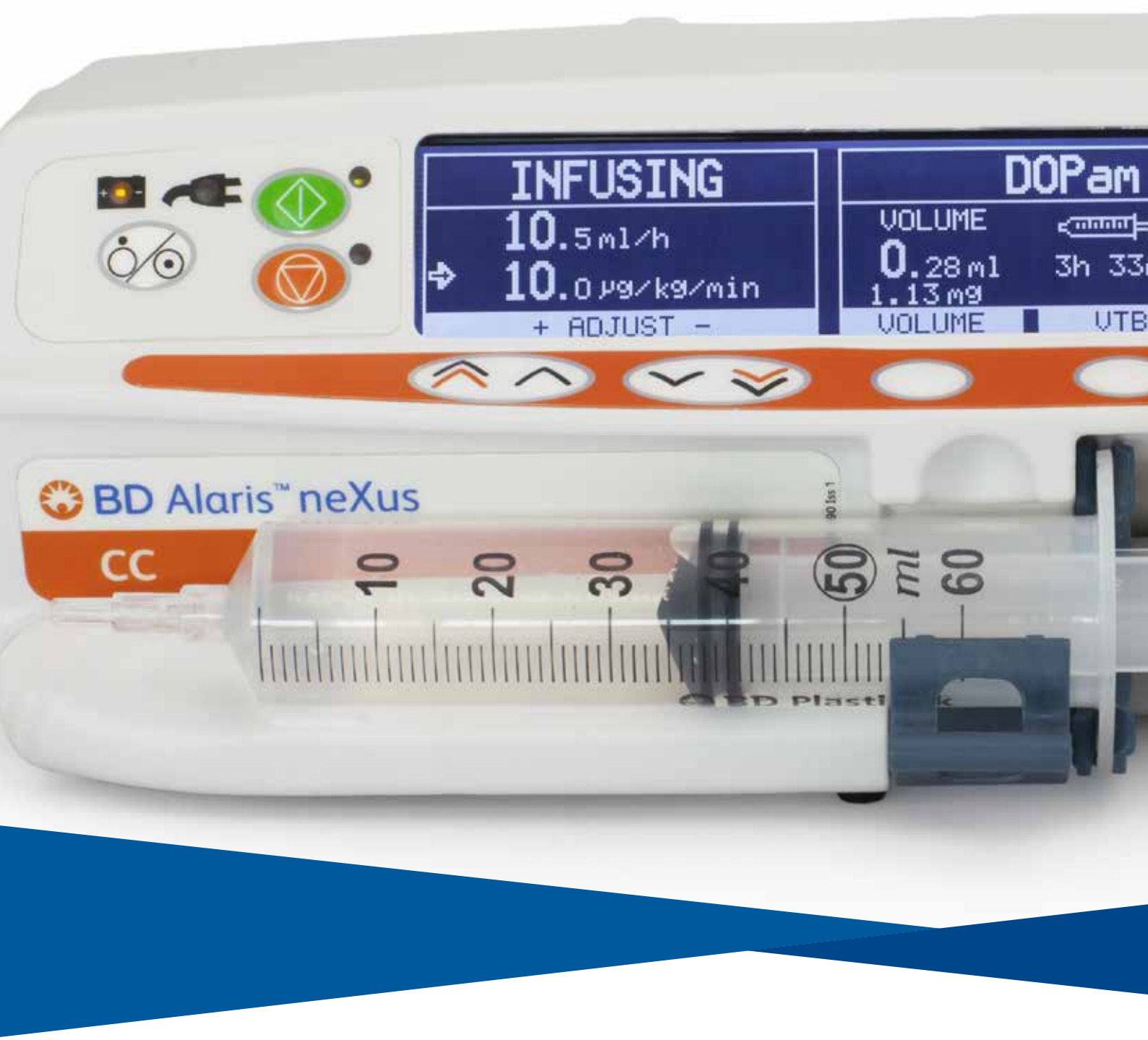


BD Alaris™ neXus CC Syringe Pump Model: CCneXus1-S

en Directions For Use

CE 2797

BD

Contents

About This Manual

The user must be thoroughly familiar with the BD Alaris™ neXus CC Syringe Pump (hereinafter referred to as *Pump*) described in this manual prior to use.

All illustrations used in this manual show typical settings and values which may be used in setting up the functions of the Pump. These settings and values are for illustrative use only. The complete range of settings and values are detailed in the specifications section.

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

Conventions Used in this Manual

Bold	Used for Display names, software commands, controls and indicators referenced in this manual, for example, **Battery Indicator**, **PURGE**, **ON/OFF** button.
'Single quotes'	Used to indicate cross-references made to another section of this manual. For example, see 'Recognised Syringes' section.
Italics	Used to refer to other documents or manuals. For example, Refer to the relevant *Directions For Use* (DFU) for further information. Also used to define custom terminology specific to a manual e.g. The BD Alaris™ neXus CC Syringe Pump (hereinafter referred to as *Pump*).
	Warning symbol. A *warning* is a statement that alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of a Pump.
	Caution symbol. A *caution* is a statement that alerts the user to the possibility of a problem with a Pump associated with its use or misuse. Such problems may include Pump malfunction, Pump failure, damage to a Pump or damage to other property. The caution statement includes the precaution(s) that should be taken to avoid the hazard.
Note:	*Notes* contain supplementary information or emphasize a point or procedure.

Overview

Introduction

These *Directions For Use* can be used with the BD Alaris™ neXus CC Syringe Pump (Model: CCneXus1-S).

The BD Alaris™ neXus CC Syringe Pump is a small lightweight Pump that provides accurate and reliable infusions over a range of rates.

If the model number is CCneXus1, then refer to the relevant *Directions For Use* for those Pumps.

Note: Any serious incident that occurs in relation to this Pump should be reported to the manufacturer, and to the relevant local regulatory authority.

The BD Alaris™ neXus CC Syringe Pump functions with a wide range of standard, single-use, disposable Luer lock syringes together with extension sets. The Pump accepts syringe sizes from 5ml to 50ml. A full list of recognised syringes can be found in the 'Recognised Syringes' section. A list of recommended extension sets can be found in the 'Compatible Extension Sets' section.

The BD Alaris™ neXus CC Syringe Pump can be programmed to deliver fluids utilising rate, volume over time, dose rate calculation, and pre-programmed drug dosing protocols containing concentration values, and Guardrails™ dosing safety limits.

The BD Alaris™ neXus 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 Guardrails™ Soft and Hard Limits, based on clinical requirements. Soft limits may be overridden during infusion programming and Hard Limits may not be overridden.

The BD Alaris™ neXus CC Syringe Pump with a data set loaded, provides automatic alerts when a dosing limit, bolus limit, loading dose limit, age or weight limit has been exceeded. These safety alerts are provided without the need for the Pump to be connected to a PC or network.

The hospital-defined data set is developed and approved through pharmacy and clinical input, and then transferred into the Pump by Qualified Service Personnel, either manually using BD Alaris™ neXus Transfer Tool or automatically via BD Alaris™ Communication Engine.

The BD Alaris™ neXus CC Syringe Pump can connect to the BD Alaris™ Communication Engine, if one is deployed at the medical facility. Then connected, either by docking to a connected Alaris™ Gateway Workstation or via hospital Wi-Fi. Pumps infusion data, logs and configuration information will be automatically detected.

The BD Alaris™ neXus CC Syringe Pump allows use of both extension sets with pressure disc for more precise pressure monitoring or standard extension sets for occlusion detection. The BD Alaris™ neXus CC Syringe Pump features an in-line pressure sensor technology, capable of highly accurate, real time pressure monitoring. This capability requires the use of an extension set with a pressure disc to improve the early detection of occlusions, by reducing time to alarm, and reducing the potential risk of post occlusion bolus.

Intended Purpose

The BD Alaris™ neXus CC Syringe Pumps are used within hospitals, healthcare facilities and during medical ambulance ground transport to deliver either continuous or intermittent therapy through clinically acceptable routes of administration. The BD Alaris™ neXus CC Syringe Pump is intended to be used for the purpose of controlling rate and volume. The BD Alaris™ neXus CC Syringe Pump is indicated for use on adults, paediatrics and neonates.

Intended Users

The primary users of the BD Alaris™ neXus CC Syringe Pump are:

- Nurse
- Physician
- Biomedical Engineer/Technician
- Nurse Educator

Secondary users of the BD Alaris™ neXus CC Syringe Pump include:

- Pharmacist
- Materials Manager

Clinical Benefits

The BD Alaris™ neXus CC Syringe Pump provides continuous or intermittent infusion of parenteral fluids and or drugs to treat a variety of medical conditions. Electronic infusion devices are used when the patient's critical medical condition dictates a more immediate, accurate and sustained impact from the fluids and medications than can be achieved with oral therapies or other forms of intravenous administration (e.g. gravity administration or IV pushes). The fluids and drugs being administered either sustain normal physiologic bodily functions or provide therapeutic effects to combat disease or an unhealthy patient condition due to injury or other compromised status. The BD Alaris™ neXus CC Syringe Pump incorporates an in-line pressure monitoring system which allows clinicians to monitor the pressure in the infusion set in real time. In-line pressure monitoring significantly shortens the time to alarm in the event of an occlusion.

Conditions for Use

The BD Alaris™ neXus CC are restricted medical devices intended for use by qualified, trained personnel to deliver either continuous or intermittent infusion therapy of:

- Fluids
- Medications
- Nutritional supplements
- Blood and blood products

BD cannot guarantee the continued system accuracy with other manufacturers' syringes as identified in the 'Recognised Syringes' table. Manufacturers may change syringe specification significant to system accuracy without prior notification.

Indications

The BD Alaris™ neXus CC Syringe Pumps are indicated for delivery of therapies through the following clinically acceptable routes:

- Intravenous (IV)
- Subcutaneous
- Irrigation of fluid spaces

Contraindications

The BD Alaris™ neXus CC Syringe Pump is contraindicated for:

- Enteral therapies

Undesirable Side-Effects

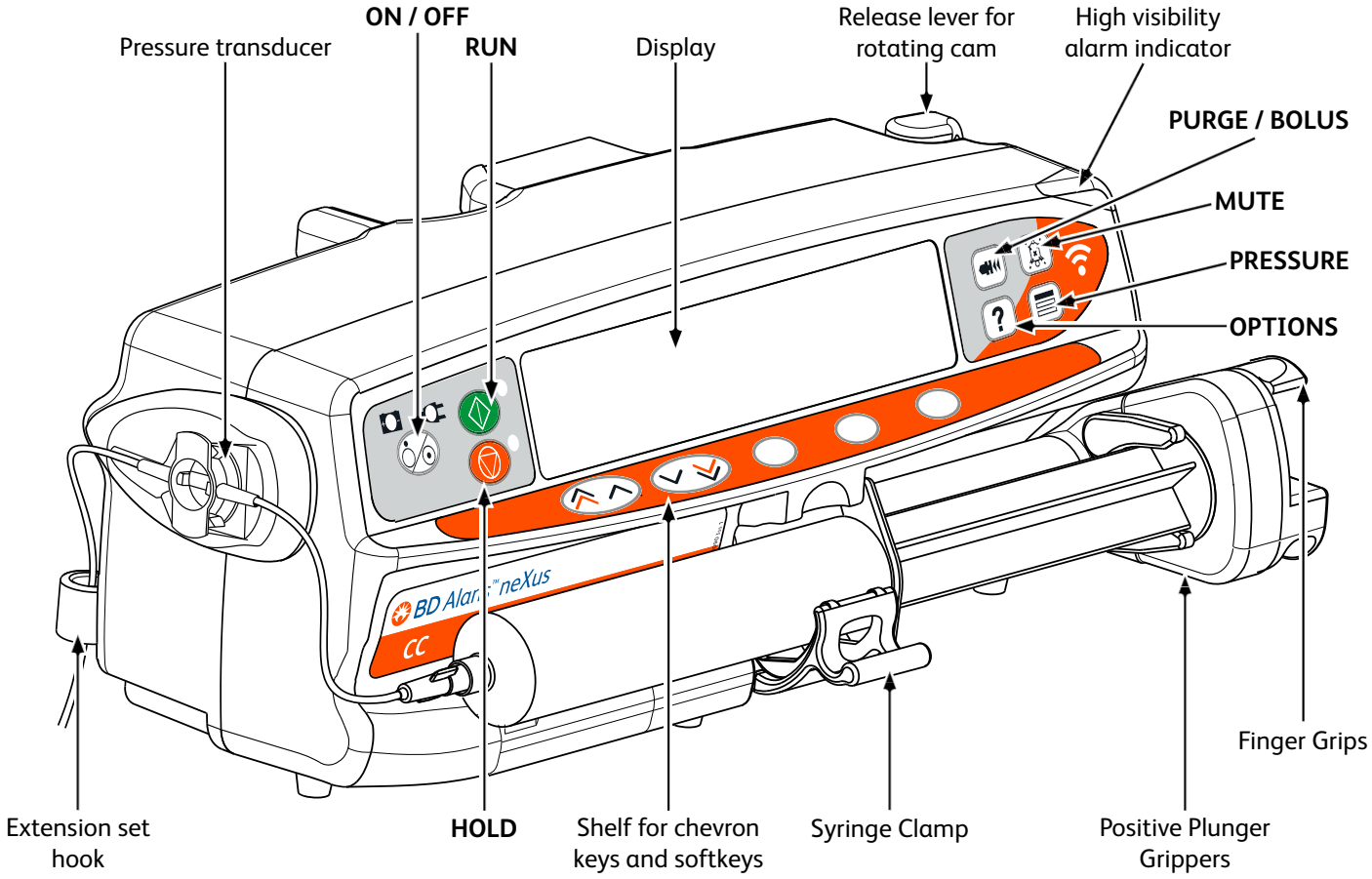
The BD Alaris™ neXus CC Syringe Pump has no undesirable side-effects associated with its use when used in accordance with the *Directions For Use*.

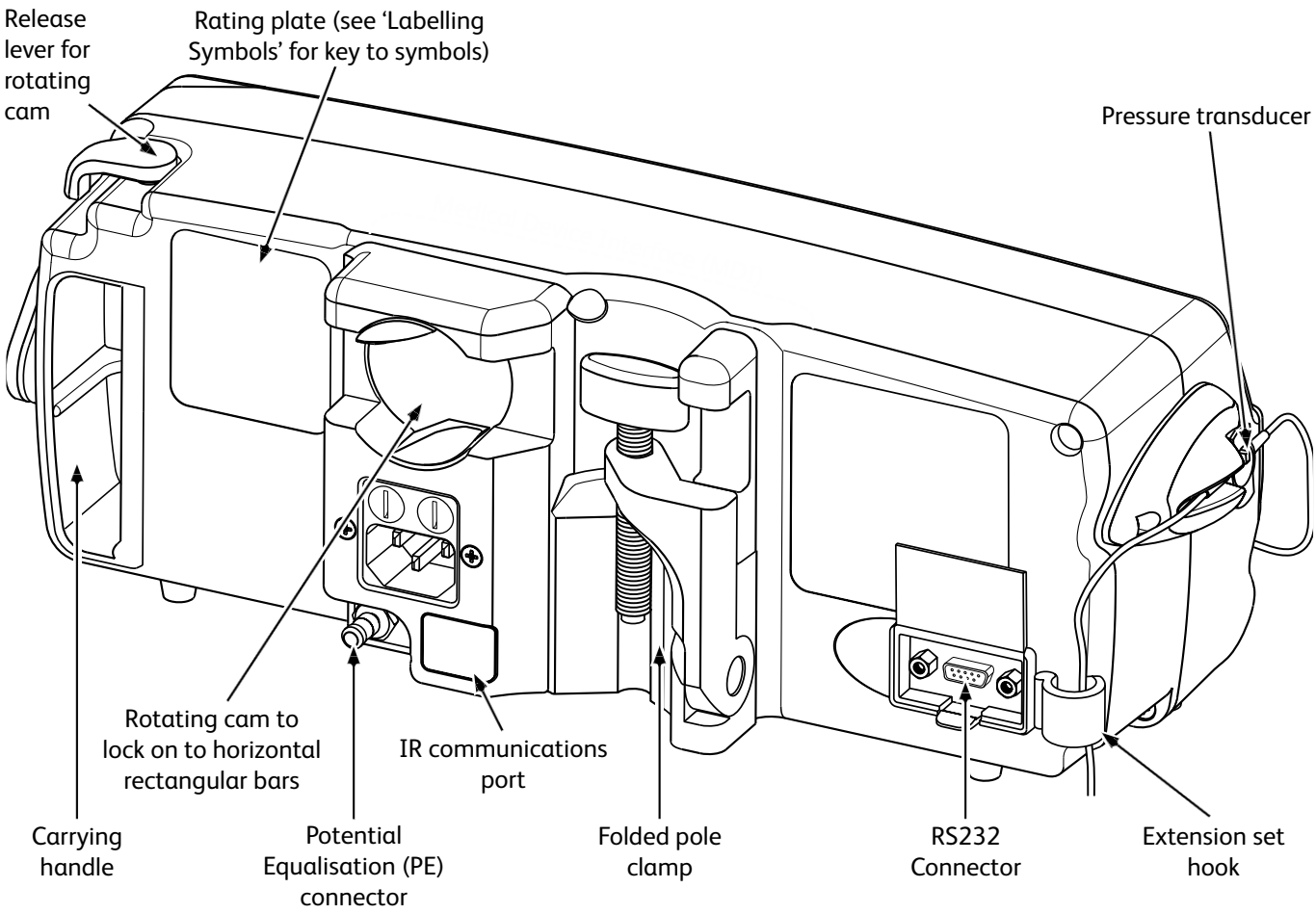
Compatibility

The BD Alaris™ neXus CC Syringe Pump is compatible with the following:

- The Alaris™ Gateway Workstation v1.3.x and v1.6.x and the BD Alaris™ MRI Capsule v1.3.x – see 'Associated Products'
- Standard, single-use, disposable extension sets and syringes with Luer lock connectors – see 'Compatible Extension Sets' and 'Recognised Syringes'
- The Active RFID asset tag supplied by BD with this Pump
- The following software products are also compatible – see 'Products and Spare Parts'
  - BD Alaris™ neXus Editor v5.0
  - BD Alaris™ neXus Transfer Tool v5.0
  - BD Alaris™ Technical Utility v2.0
  - BD Alaris™ Communication Engine v2.0
  - BD Alaris™ CQI Event Reporter v4.4

Features of the Pump





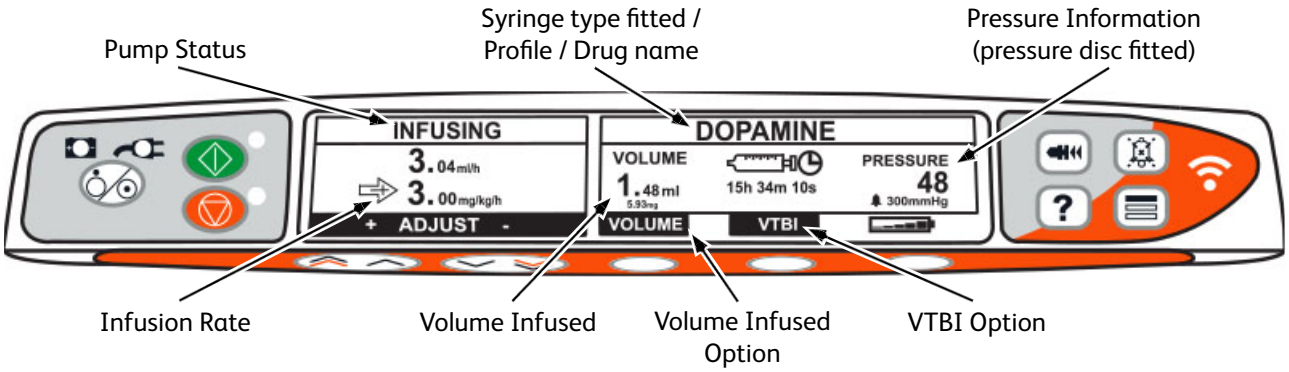
Controls

Symbol	Description
	**ON / OFF** button – Press once to switch the Pump on. Press and hold down for three seconds to switch the Pump off. **Note:** Logs are maintained for power down events including when the Pump is powered down or unexpected power loss.
	**RUN** button – Press to start the infusion. The green LED will flash during infusion.
	**HOLD** button – Press to put the infusion on hold. The amber LED will be lit while on hold.
	**MUTE** button – Press to silence alarm for two minutes. To re-enable the alarm audio press the **MUTE** button a second time. **Note:** Attention alarm only: when not in alarm press and hold until four audible beeps are heard for 15 minutes silence.
	**PURGE / BOLUS** button – Press to access **PURGE** or **BOLUS** soft keys. Press and hold down soft key to operate. **PURGE** – primes the extension set with fluid or drug during initial set up. • Pump is on hold • Extension set must not be connected to the patient • Volume Infused (VI) is not added **BOLUS** – fluid or drug delivered at an accelerated rate. • Pump is infusing • Extension set should be connected to the patient • VI is added
	**OPTIONS** button – Press to access additional feature options.
	**PRESSURE** button – Use this button to display the pumping pressure and alarm level. This button will also display the pressure trend display.
	**CHEVRON** keys – Double or single for faster/slower increase or decrease of values shown on display.
	**BLANK SOFTKEYS** – Use in conjunction with the prompts shown on the display.

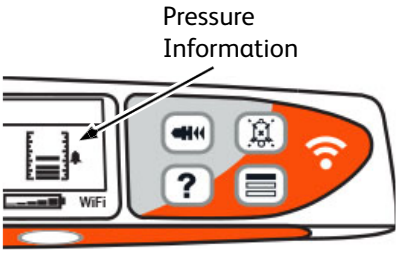
Indicators

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

Main Display Features



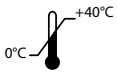
Note: If using a standard extension set without a pressure disc then the pressure information will be as below.



Screen Icons

Symbol	Description
00:00	**Time remaining display** icon – Indicates time before syringe will require replacement.
	BATTERY icon – Indicates battery charge level to highlight when the battery will require recharging or re-connection to AC power supply. **Note:** This can be enabled/disabled with the BD Alaris™ neXus Editor software
⬆INFUSING⬆ ⬇INFUSING⬇	**Guardrails Soft Alert** icons – Indicates the Pump is running at a rate or dose above (pointing up) or below (pointing down) a Guardrails™ Soft Alert.
	Hard Limit Warning icon – Indicates the setting entered is not permitted as it is over or under a Guardrails™ Hard Limit, as defined in the data set. The warning cannot be overridden.
WiFi	Indicates when the Pump is connected, via Wi-Fi, to the BD Alaris™ Communication Engine (ACE).
~~WiFi~~	Indicates when the Pump is not connected via Wi-Fi to ACE.

Labelling Symbols

Symbol	Description
	Consult accompanying documents
	Potential Equalisation (PE) Connector
	RS232/Nurse call Connector
	Defibrillation-proof type CF applied part (Degree of protection against electrical shock)
IP32	Protected against direct sprays of water up to 15° from vertical and protected against solid objects greater than 2.5mm. **Note:** IP33 applies if AC power cable retainer kit, part number 1000SP01294, is fitted.
	Alternating Current
CE 2797	Device complies with the requirements of Council Directive 93/42/EEC as amended by 2007/47/EC
	Date of Manufacture
	Manufacturer
	Do not dispose of battery in municipal waste. Separate collection for battery is required.
	Not for Municipal Waste
	Fuse Rating
	Operating Temperature Range – Pump can be used between 0 and 40 degrees centigrade
	Pump is able to communicate with BD Alaris™ Communication Engine via Wi-Fi
MD	Medical Device

Getting Started

Initial Set-up

Before operating the Pump read this *Directions For Use* **manual carefully.**

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:
   - BD Alaris™ neXus CC Syringe Pump
   - User Support CD (*Directions For Use*)
   - AC Power Cable (as requested)
   - Protective Packaging
3. Connect the Pump to the AC power supply for at least 2½ hours to ensure that the internal battery is charged (verify that the  is lit).

Language Selection

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

- **The Pump will require a data set to be uploaded and activated prior to using the Pump. Any data set created for installation must be approved by an appropriately qualified person with clinical authority in accordance with hospital protocol prior to upload and activation.**
- **The Pump will automatically operate from its internal battery if the Pump is switched on without being connected to the AC power supply.**
- **Should the Pump fail to perform correctly, replace in its original protective packaging, where possible and contact Qualified Service Personnel for investigation.**

Power Input

The Pump is powered from the AC Power supply through a standard IEC AC Power connector or the Alaris™ Gateway Workstation (Workstation) when docked. When connected to the AC Power supply the AC Power indicator is illuminated.

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

Wi-Fi Configuration

The Pump is able to utilize a hospital Wi-Fi network to connect to the BD Alaris™ Communication Engine if one is deployed at the facility. A Wi-Fi Configuration Package must be first created and transferred to the Pump using the BD Alaris™ Technical Utility (ATU) by Qualified Service Personnel.

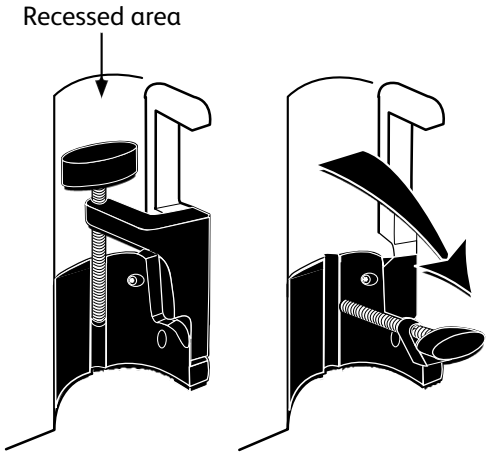
Do not mount the Pump with the AC power inlet or the syringe pointing upwards. This could affect the electrical safety in the event of a fluid spill or lead to the infusion of air which may be in the syringe.

Pole Clamp Installation

The pole clamp is fitted to the rear of the Pump and will provide secure fixing to vertical IV poles of a diameter between 15 and 40mm.

Pull the folded pole clamp towards you and unscrew the clamp to leave enough room for the size of the pole.

Place Pump around pole and tighten screw until the clamp is secured to the pole.



Ensure the pole clamp is folded away and stored within the recessed area at the rear of the Pump before connecting to an Alaris™ Gateway Workstation (*Workstation*) or when not in use.

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

Prior to each use, check that the pole clamp:

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

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

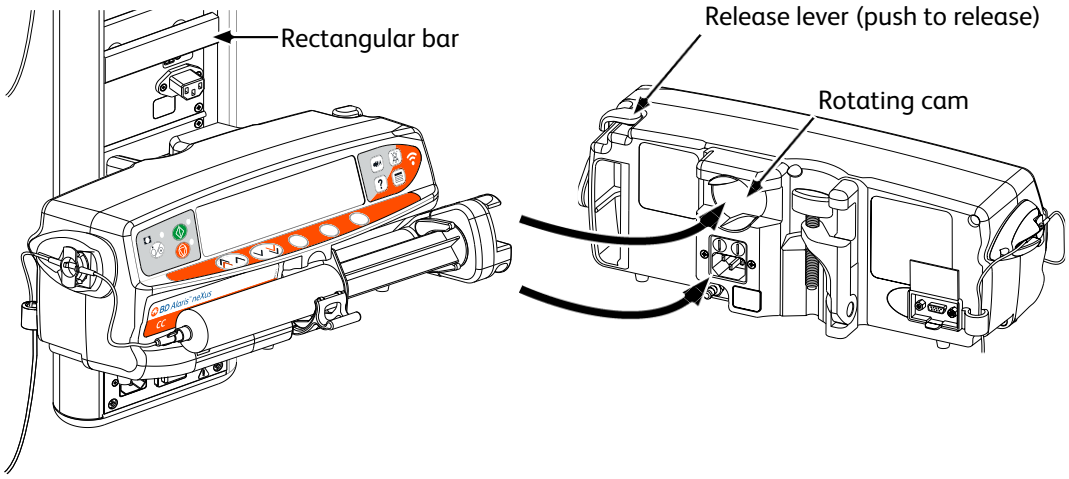
Workstation or Equipment Rail Installation

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

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

Note: The Pump will stop communicating over Wi-Fi once docked to a Workstation and will disable its internal wireless module. The Pump will instead use the Workstation as a conduit for connecting to BD Alaris™ Communication Engine, as long as the Workstation is powered on and is functional.

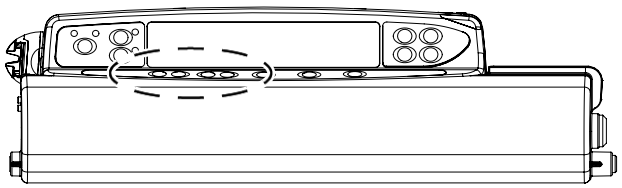
Pump may fall off the Workstation if not properly mounted which could result in user and/or patient harm.



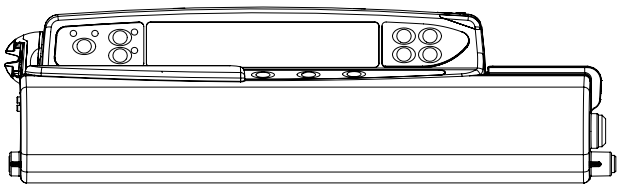
Securing the Syringe with Optional Lock box

Lock box operation

The optional lock box is a available in two configurations:



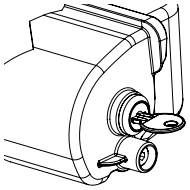
- Rate Unlocked lock box – is designed to allow the user to adjust rate whilst infusing.



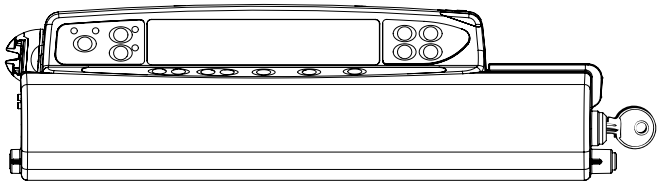
- Rate Locked lock box – is designed to prevent rate change whilst infusing. If using this lock box users would need to put the Pump on hold and open the lock box to change the rate.

When mounting a Pump with lock box ensure that there is sufficient clearance for the cover to be fully opened. A gap of 130mm minimum below the Pump is recommended.

Open Lock box



1. Insert the key into the lock and turn key either way to unlock.

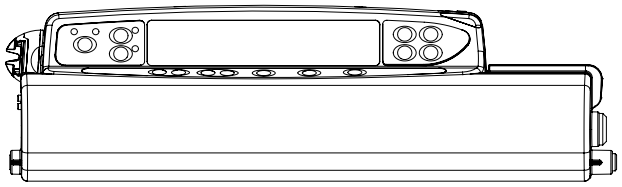


2. Lock box will move to the right and can then be opened.

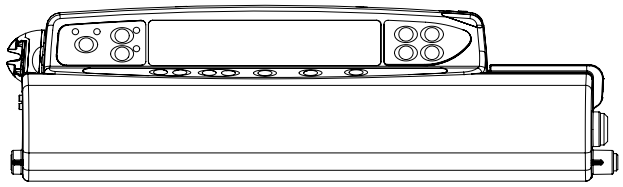
Close Lock box

1. Load the syringe according to the instructions in the 'Loading and Confirming a Syringe' section.
2. Ensure the extension set is connected to the syringe and threaded through the lock box.

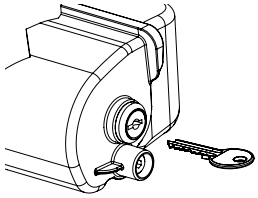
   Note: The pressure disc must be fitted prior to closing the lock box.
3. Set up the Pump according to the instructions in the 'Starting the Pump' section prior to closing the lock box for the Rate Locked version only.



4. Close the cover until it makes contact with the Pump case.



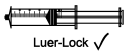
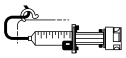
5. Push the lock box from right to left until a click is heard.

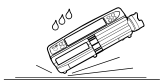


6. Remove the key.

- **Pumps with a lock box fitted should only be used when fitted to an Alaris™ Gateway Workstation or an IV Pole.**
- **When transporting the Pump with lock box fitted it is recommended that two hands are used when holding or carrying the Pump.**
- **If lock or lock box appears to be damaged, remove the Pump from service for examination by Qualified Service Personnel.**
- **When the Pump is not in use ensure the lock box is locked.**
- **Lock box keys should be stored separately. Take care not to lock keys inside lock box.**
- **Refer to the 'Routine Maintenance Procedures' section for instructions on lockbox cleaning and maintenance.**

Operating Precautions

Disposable Syringes and Extension Sets	
	The Pump has been calibrated for use with single-use disposable syringes. To best ensure correct and accurate operation, only use three piece Luer lock versions of the syringe brand specified on the Pump or described in this manual. Use of non-specified syringes or extension sets may impair the operation of the Pump and the accuracy of the infusion.
	Uncontrolled flow or syphoning may result if the syringe is located incorrectly in the Pump, or if it is removed from the Pump before the extension set is properly isolated from the patient. Isolation may include closing a tap in the patient line or activating a flow stop clamp.
	The user must be thoroughly familiar with instructions in these *Directions For Use* and understand how to load and confirm the syringe on the Pump. Incorrect syringe loading may result in misidentification of the syringe type and size leading to significant under or over infusion.
	Secure the extension set to the Pump using the extension set hook at the rear of the Pump. This provides protection against accidental dislodging of the syringe from the Pump.
	When combining several apparatus and/or instruments with extension sets and other tubing, for example via a 3-way tap, the performance of the Pump may be impacted and should be monitored closely.
	Always clamp or otherwise isolate the patient line before unclamping or removing a syringe from the Pump. Failure to do so may result in unintended administration.
Mounting the Pump	
	When more than one Pump is being used on a patient, those containing high risk, critical medications must be positioned as close to the patient's heart level as possible to avoid the risk of variations in flow or siphoning.
	Raising a Pump whilst infusing may result in a bolus of the infusate, whereas lowering a Pump whilst infusing may result in a delay in the infusion (an underinfusion).
	Do not mount the Pump in a vertical position with the syringe pointing upwards as this could lead to an infusion of air which may be in the syringe. To protect against the introduction of air the user should regularly monitor the progress of the infusion, syringe, extension line and patient connections and follow the priming procedure specified herein.
Operating Environment	
	Intended environments include general wards, critical and intensive care, operating rooms, accident and emergency rooms. The Pump may be used in an ambulance environment. Ensure that the Pump is appropriately attached using the provided pole clamp. The Pump is designed to withstand possible bumps and vibrations whilst being used in an ambulance, complying with the standard EN 1789. If the Pump is dropped or experiences any severe physical disturbances, arrange a thorough inspection by appropriately trained technical personnel as soon as is practically possible.
	When using any infusion pump in conjunction with other pumps or devices requiring vascular access, extra care is necessary. Adverse delivery of medication or fluids can be caused by the substantial variation in pressures created within the infusion system by such pumps. Typical examples of those pumps are used during dialysis, bypass or cardiac assist applications.
	The Pump is suitable for use in hospital and clinical environments other than domestic establishments that have access to single phase AC power supply.
	The Pump is not intended to be used in the presence of a flammable anaesthetic mixture with air or oxygen or nitrous oxide.

Operating Pressure	
	This is a positive pressure Pump designed to achieve very accurate fluid administration by automatically compensating for resistance encountered in the infusion system.
	The pumping pressure alarm system is not designed to provide protection against, or detection of, IV complications which can occur.
Alarm Conditions	
	Several alarm conditions detected by this Pump will stop the infusion and generate visual and audible alarms. Users must perform regular checks to ensure that the infusion is progressing correctly and no alarms are operating.
	Alarm tone settings are preserved in the case of power loss, however some system faults will result in loss of alarm settings. The new alarm tone settings will be stored when powering down from tech mode after a change. The settings will be lost if a cold-start is performed, but should be saved for faults that do not require a cold start.
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.
	When connected to an external power source, a three-wire (Live, Neutral, Earth) supply must be used. If the integrity of the external protective conductor in the installation or its arrangement is in doubt, the Pump should be operated from the battery.
	Do not open the RS232/Nurse Call protective covering when not in use. Electrostatic discharge (ESD) precautions are required when connecting RS232/Nurse Call. Touching the pins of the connectors may result in ESD protection failure. It is recommended that all actions must be taken by appropriately trained personnel.
	If the Pump is dropped, subjected to excessive moisture, fluid spillage, humidity or high temperature, or otherwise suspected to have been damaged, remove it from service for inspection by Qualified Service Personnel. When transporting or storing the Pump, use original packaging where possible, and adhere to temperature, humidity and pressure ranges stated in the 'Specifications' section and on the outer packaging.
	BD Alaris™ neXus CC Syringe Pump should not be modified or altered in any way, except where explicitly directed or authorised by BD. Any use of BD Alaris™ neXus CC Syringe Pumps which have been altered or modified otherwise than in strict application of directions provided by BD, is at your sole risk, and BD does not provide any warranty for or endorsement on any BD Alaris™ neXus CC Syringe Pump that has been so modified or altered. BD product warranty shall not apply in the event the BD Alaris™ neXus CC Syringe Pump has suffered damage or premature wear, or malfunctions or otherwise operates incorrectly, as a result of unauthorised modification or alteration of the BD Alaris™ neXus CC Syringe Pump.
	Care must be taken when removing covers or handling moving mechanisms.
	All Pumps in a single care area should be configured with the same alarm tones to avoid user confusion.

Electromagnetic Compatibility and Interference	
	Medical Electrical Equipment requires additional precautions regarding EMC. Commissioning, installation and use should be in accordance with the EMC information provided within this *Directions For Use* and the *Technical Service Manual*.
	Therapeutic Radiation equipment: Do not use the Pump in the vicinity of any Therapeutic Radiation Equipment. Levels of radiation generated by the radiation therapy equipment such as Linear Accelerator, may severely affect functioning of the Pump. Please consult manufacturer's recommendations for safe distance and other precautionary requirements. For further information, please contact your local BD representative.
	Magnetic Resonance Imaging (MRI): The Pump contains ferromagnetic materials which are susceptible to interference with magnetic field generated by the MRI devices. Therefore, the Pump is not considered an MRI compatible Pump as such. If use of the Pump within an MRI environment is unavoidable, then BD highly recommends securing the Pump at a safe distance from the magnetic field outside the identified 'Controlled Access Area' in order to evade any magnetic interference (EMI). For further information, please refer to the product *Technical Service Manual* (TSM). Alternatively, contact your local BD representative for further guidance.
	The Pump is compatible with HF surgical equipment provided the Pump is located at distance greater than 15cm (6 inches) from the active component of the HF surgical device. Direct contact between HF surgical equipment and the Pump and or associated accessories and cabling must be avoided.
	Accessories: Do not use any non-recommended accessory with the Pump. The Pump is tested and compliant with the relevant EMC claims only with the recommended accessories. Use of any accessory, transducer or cable other than those specified by BD may result in increased emissions or decreased Pump immunity.
	The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or repositioning the Pump. This Pump emits a certain level of electromagnetic radiation, which is within the levels specified by EN/IEC 60601-2-24 and EN/IEC 60601-1-2.
	The Class B digital Device limits are designed to provide reasonable protection against harmful interference when the device is operated as intended. The device generates, uses and can radiate radio frequency energy. If it is not installed and used in accordance with the applicable Directions For Use, it might cause harmful interference to radio communications. Operation of this device in a residential area is likely to cause harmful interference, in which case the user is required to correct the interference at their own expense. There is, however, no guarantee that the interference will not occur in a particular installation.
	Approval of the wireless module excludes co-location with any other transmitter.
	The Pump should not be used adjacent to or stacked with other equipment outside of the Alaris™ Gateway Workstation or the BD Alaris™ MRI Capsule; however, if adjacent or stacked use is necessary, the Pump should be observed to verify normal operation in the configuration in which it will be used.
	Portable RF Communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the Pump including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
	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 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 personnel (Consult *Technical Service Manual* for further information).

Operation

Syringe Loading

Prepare Syringe and Administration Set

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

- Use smallest syringe size possible, for example, if infusing 9ml of fluid, use a 10ml syringe.
- Use the **PURGE** function on the Pump to decrease the delay in the start of the infusion. See 'Operating the Pump' section.

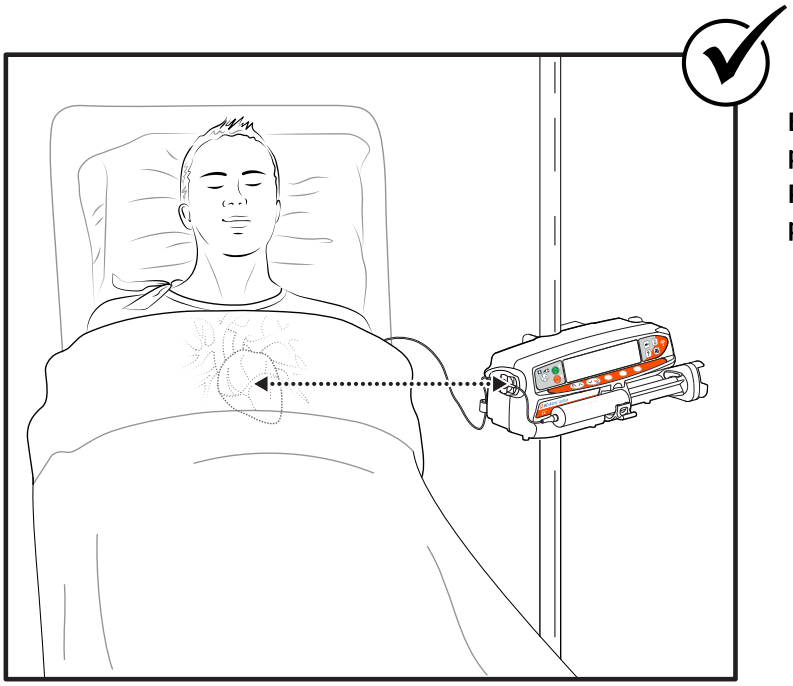
Use the smallest compatible syringe size necessary to deliver the fluid or medication; this is especially important when infusing high risk or life-sustaining medications at low infusion rates, especially flow rates <0.5ml/h.

Purge the Pump system before starting an infusion or after replacing a near-empty syringe with a replacement syringe. When Purging ensure that the extension set is not connected to the patient.

Practice Recommendations:

- Tubing internal diameter: Smallbore or microbore tubing is recommended when infusing at low rates
- Filters: Internal volume, dead space, of in-line filters should be minimized
- Connection sites: Critical drugs should be connected as close to the vascular access site as possible

Positioning of Pump



Ensure that the Pump is as close to level of patient's heart as possible.

Patient's heart level should be in line with the pressure disc holder.

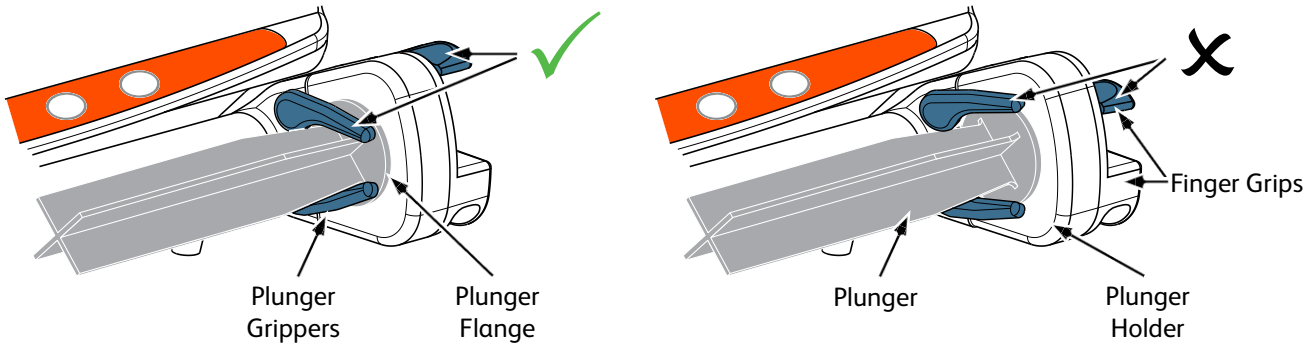
Adjusting the Pump's height relative to the patient's heart level can lead to temporary increases or decreases in fluid delivery.

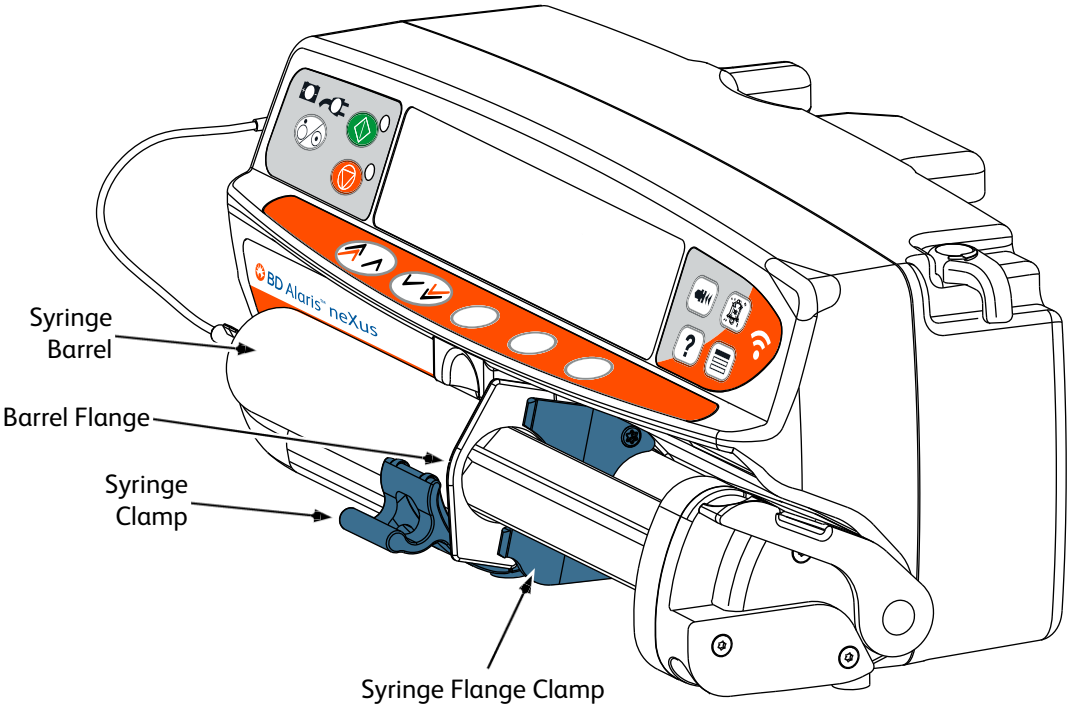
If using multiple syringe Pumps and it is not clinically feasible to have all Pumps level with the patient's heart, place the high risk or life-sustaining medications as close to the patient's heart level as possible.

When infusing multiple high risk or life-sustaining medications, consider placing the Pumps infusing at the lowest rates as close to the level of the patient's heart as possible.

Loading and Confirming a Syringe

- **To securely load and confirm a syringe carefully follow the steps below. An incorrect loading of a syringe may result in misidentification of the syringe type and size. If then confirmed, this may lead to significant inaccuracy of the infusion rate and may also affect Pump performance.**
- **Only use a syringe of the type stated on the Pump or in this manual. Using an incorrect syringe could adversely affect the accuracy of the infusion rate and may also affect Pump performance.**
- **When drawing fluid into the syringe, draw enough to compensate for any dead space volume in the extension set and syringe at the end of infusion as this cannot be fully infused.**





Place the Pump on a stable horizontal surface or secure as described previously.

Prepare, load and prime the single-use disposable syringe and extension set using standard aseptic techniques.

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

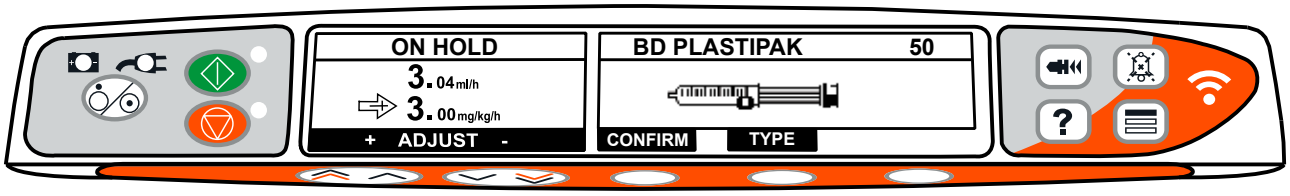
3. Insert the syringe ensuring that the barrel flange is located in the slots on the syringe flange clamp.

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

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

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

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



Note: If the **PURGE SYRINGE** option has been enabled in the data set via BD Alaris™ neXus Editor then the prompt to purge screen is displayed and the extension set can be purged as required, however ensure that the extension set is not connected to the patient during this process.

- **BD recommends limiting the number of configured syringe types and sizes available for selection on the Pump in the data set via the BD Alaris™ neXus Editor.**
- **Secure the extension set using the extension set hook at the rear of the Pump. This provides protection against accidental dislodging of the syringe from the Pump.**
- **Ensure that both plunger grippers are fully locked onto the plunger flange and the upper finger grip has returned to its original position.**

Operating the Pump

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

1. Connect the Pump to an AC power supply using the AC power cable.
2. Press the ⏻ button.
   - The Pump will run a short self-test.

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

- Check the display test pattern and ensure that no lines are missing.
- Check that the displayed time and date are correct.
- As the Pump starts up, check that display shows the data set name, version number and data set ID.

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

3. **CLEAR SETUP?**
   - Selecting **NO** will retain all previous rate and volume settings. Go to step 9.
   - Selecting **YES** will automatically reset the rate and volume settings to zero. If a new (pending) data set was uploaded to the Pump, it will be automatically activated and **DATA SET** screen will be displayed. Go to step 4. Otherwise, the **CONFIRM PROFILE?** screen will be displayed. Go to step 5.

The CLEAR SETUP? screen will only be displayed if a previous setup was used.

4. **DATA SET** – A new (pending) data set has been activated.
   a) Confirm the details shown on the screen for data set name, release date and time, version, and ID code by selecting **OK** softkey.
   b) **PROFILE** screen will be displayed (if more than one is available in the data set). Select the desired profile using ⏫⏬ keys and press **OK** softkey. If only one profile is available, go to step 6.
5. **CONFIRM PROFILE?**

   Note: The **CONFIRM PROFILE** screen will not be displayed if there is only one profile available in the data set.

   a) **NO** will display select profile screen
      - Select profile from list, if required press **ALL** to update the list displayed to include all the profiles within the data set.
      - Press **OK** to confirm.

The ALL softkey will only be displayed if there are some profiles in the data set not being displayed, since their selectable status is disabled.

   b) **YES** will display drug select screen or clear setup screen.
6. **DRUG SELECT?** – Select one of the following:

   Note: The **DRUG SELECT** screen will not be displayed if there are no drugs setup in the profile.

   - **ml/h** – allows infusions to be given inml/h only, after selecting **OK** to confirm. Go to step 8.
   - **DOSING ONLY** – enables the Pump to be set-up with a dosing protocol, after selecting **OK** to confirm. Go to step 6.

No concentration or dose rate limits are used when ml/h or DOSING ONLY modes are selected.

   - **DRUGS** – select a drug name from profile's drug library, after selecting **OK** to confirm. Go to step 7.

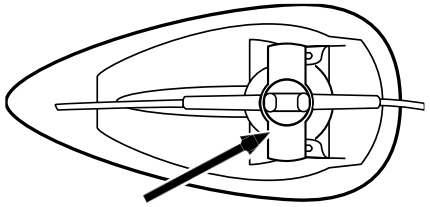
   Note: Drugs are listed in alphabetical groups as follows: A–E, F–J, K–O, P–T and U–Z. Select group containing the drug name required and then the required drug and all other drugs can be seen.

7. **DOSING ONLY –**
   a) Select Dosing unit and **OK** to confirm.
   b) Select Concentration Amount and **OK** to confirm. Use **UNITS** softkey to change concentration unit, if required.
   c) Select Total Volume to be used and **OK** to confirm.
   d) Adjust Weight and **OK** to confirm, if required.
   e) Press **OK** to confirm dosing information. Go to step 8.
8. **DRUGS –**
   a) Select Concentration required, press **OK** to confirm Concentration or **MODIFY** to change Drug amount and total volume to be used. If the dose amount and total volume are not defined in the data set then they will need to be set as follows:
      - Adjust dose amount and **OK** to confirm. Use **UNITS** softkey to change concentration unit, if required.
      - Adjust Total Volume and **OK** to confirm
   b) Adjust Weight and **OK** to confirm, if required.
   c) Press **OK** to confirm setup. Go to step 8.

⚠ **Steps for Drugs setup may vary, depending on how the profile is configured in the data set via the BD Alaris™ neXus Editor.**

9. Load the syringe according to the procedure in this manual. See 'Syringe Loading' section.
10. Insert the pressure disc into the pressure transducer, if required.

⚠
- **Pressure Transducer – Detects if an extension set with a pressure disc is fitted. The pressure transducer will measure positive pressures within the extension set.**
- **To remove or insert pressure disc from or into pressure transducer assembly, insert finger into the recess in the pressure disc and pull forward or push back with care. Do not pull the extension set to remove or to insert the pressure disc.**



11. Ensure that the syringe type and size match those displayed on the Pump then press **CONFIRM**. If required, the brand of syringe can be changed by pressing the **TYPE** softkey.

    Note: If the **PURGE SYRINGE** option has been enabled then the prompt to purge screen is displayed and the extension set can be purged as required, however ensure that the extension set is not connected to the patient during this process.

    Note: If the Drug Confirmation after Syringe Change option has been enabled in the profile, then review the information on the screen and press **CONFIRM**.
12. Purge (if required) – Press the ⏮ button and then press and hold the **PURGE** softkey until fluid flows and the purging of the extension set is complete. Release the softkey. The volume used during purging will be displayed.

⚠ **Purge extension set, if using an extension set with pressure disc massage pressure disc to prevent ballooning and ensuring all air removal.**

13. Check the rate shown if set and change the rate if necessary using the ⏫⏬ keys.
14. Connect the extension set to the patient access device.
15. Press ⏻ to commence operation.
    - The *amber stop* light will be replaced by the flashing *green start* light to indicate that the Pump is in operation. **INFUSING** will be displayed.

    Note: If infusion rate exceeds the Guardrails™ Hard Limit then the Pump will not start and the display will show **DOSE NOT PERMITTED**.
    - If the infusion settings are within the Guardrails™ Soft Limits then the *amber stop* light will be replaced by the flashing *green start* light to indicate that the Pump is in operation. **INFUSING** will be displayed.

Note: If infusion rate exceeds or is under the Guardrails™ Soft Limits then check infusion setting, to continue with infusion at set rate press ⓞ and then confirm **OVERRIDE LIMIT** by pressing **YES**. If **OVERRIDE LIMIT** is not required press **NO** and adjust rate to be within the Guardrails™ Soft Limits.

Note: Fast Start is a Pump feature to automatically reduce the mechanical slack between the plunger mechanism and syringe at the start of an infusion.

If infusion rate running exceeds or is under the Guardrails™ Soft Limits then the display will show INFUSING with either Up or Down arrows on both sides.

16. Press ⓞ to halt the operation. **ON HOLD** will be displayed. The *amber stop* light will replace the *green start* light.

Advanced Features

Bolus Infusion

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 to:

a) **BOLUS Disabled**

b) **BOLUS Enabled**

- **Hands-On**
- **Hands-Free and Hands-On**

BOLUS Disabled

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

A Hands-On bolus and Hands-Free bolus cannot be administered if the rate lock is active or if the feature is disabled for the selected Profile or specific drug. During BOLUS the pressure limit alarm is temporarily increased to the maximum level.

BOLUS Enabled – Hands-On

In Hands-On Bolus, press and hold the (flashing) **BOLUS** softkey to deliver the required bolus. The bolus rate can be adjusted. The bolus volume is limited in the data set via BD Alaris™ neXus Editor.

1. During infusion press the button once to display the bolus 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.

BOLUS Enabled – Hands-Free and Hands-On

The Hands-Free Bolus is delivered with a single press of the (flashing) **BOLUS** softkey. The default rate, default and maximum bolus volume are set by drug profile in the data set and can be changed within limits set by the data set.

1. During infusion press the button to display the Hands-Free bolus selection screen.
2. Press the **YES** softkey to go to Hands-Free selection bolus screen, press the **HANDS ON** softkey for Hands-On bolus (see section above).
3. Use the keys to set the bolus volume/dose required; If necessary use the **RATE** softkey and the keys to adjust the bolus delivery rate.

   Note: Rate may be restricted by the syringe size and the **CAP BOLUS RATE**.
4. Press the flashing **BOLUS** softkey once to begin the delivery of the preset bolus. The display will show the bolus being delivered, the bolus counting down and revert to main infusion 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.
6. If the bolus volume reaches the set bolus volume the bolus will stop and the Pump will revert to infuse at the set infusion rate and continue infusing.

- **If the Hands-Free bolus option is active, then this feature will be cancelled following any interruption in delivery, e.g. occlusion, even if the bolus delivery is incomplete.**
- **If the volume to be infused (VTBI) is reached during a bolus, the VTBI complete alarm will sound. Press to silence the alarm or CANCEL to acknowledge the alarm. See 'Volume To Be Infused (VTBI)' section for more details on VTBI operation.**
- **Any Hands-Free Bolus dose setting which exceeds or is under a Guardrails™ Soft Limit must be confirmed before operation can be continued.**

Manual Bolus

The Manual Bolus is delivered by moving the plunger drive mechanism forward while the Pump is infusing. This method of delivering a bolus is not recommended as best clinical practice.

The syringe must be confirmed and the plunger mechanism has to move from an engaged position to disengage and then re-engage position. A minimum travel of 1mm (leadscrew pitch) must be detected to register.

Delivering a bolus via Manual Bolus may lead to inconsistencies in the volume infused display and Volume To Be Infused (VTBI) calculation, compared to the actual volume contained in the syringe.

Purge

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

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

The Pump will not purge if the RATE LOCK has been enabled. During PURGE the pressure limit alarms are temporarily increased to their maximum level.

Volume to be Infused (VTBI)

This feature allows a specific volume to be infused to be set. Rate at the end of this VTBI can also be set, selecting from stop, KVO, or continuous infusion at the set rate.

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

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

Clear Volume

This feature enables the volume infused to be cleared. The Dose Infused for a drug is displayed if the Volume Infused is attributable to a single drug setup. Clearing the volume will display the Dose Infused.

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

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

Rate Lock

If Rate Lock is enabled, when the infusion rate has been set and the infusion started, the rate lock prompt will appear on the display following any rate titrations, bolus infusions and loading dose infusions.

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

When rate lock is enabled, the following are unavailable:

- Changing the infusion rate / titration
- Bolus / purge
- Switching the Pump off
- VTBI over time infusions.

To disable the rate lock if selected:

1. Press the ⑦ button to access the options menu.
2. Select the **UNLOCK RATE** option using the ⏫🔼🔽⏬ keys and press the **OK** softkey.

To enable the rate lock if not selected:

1. Press the ⑦ button to access the **OPTIONS** menu.
2. Select **RATE LOCK** option using the ⏫🔼🔽⏬ keys and press the **OK** softkey.

Rate Titration

If Rate Titration is enabled the rate can be adjusted while infusing:

1. Select the new rate using the ⏫🔼🔽⏬ keys.
2. The message **< START TO CONFIRM >** will flash on screen and Pump continues to infuse at the original rate.
3. Press the ▶ button to confirm the new infusion rate and start infusing at the new rate.

   Note: Press the **QUIT** softkey to exit titration and return to original rate.

   Note: If the new infusion rate setting exceeds or is under a Guardrails™ Soft Alert confirmation is required before infusion can start infusing at the new rate.

If Rate Titration is disabled the rate can only be adjusted whilst on hold:

1. Press the ⏸ button to put the Pump on hold.
2. Select the new rate using the ⏫🔼🔽⏬ keys.
3. Press the ▶ button to start infusing at the new rate.

Dosing Summary

To review currently selected dosing information:

1. Press the ⑦ button to first access the **OPTIONS** menu.
2. Select **DOSING SUMMARY**.
3. Review the information and then press the **QUIT** softkey.

Set VTBI over Time

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

1. Stop the infusion. Press the ⑦ 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. When the desired volume has been reached press the **OK** softkey.
4. Enter the time over which the volume is to be infused. The infusion rate will automatically be calculated. Press the **OK** softkey to enter the value.
5. Select the rate at VTBI end from the list using the ⏫🔼🔽⏬ keys and press the **OK** softkey. The default is **STOP**.

24 Hour Log

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

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

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

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

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

Event Log

This option allows the event log to be reviewed, if enabled.

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

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

Data Set Details

To review currently selected data set information:

1. Press the ⓘ button to access the **OPTIONS** menu.
2. Select **DATA SET DETAILS**.
3. Review the information and then press the **QUIT** softkey.

Infusion Setup

To change Infusion Setup

1. Stop the infusion. Press the ⓘ button to access the **OPTIONS** menu.
2. Select **INFUSION SETUP**.
3. Select Infusion Setup required and press the **OK** softkey.

Pump Details

To review Pump information.

1. Press the ⓘ button to access the **OPTIONS** menu.
2. Select **PUMP DETAILS**.
3. Review the information and then press the **QUIT** softkey.

Note: The following information will be displayed:

- **UNIT REFERENCE** An identifier configured in Technician Mode by Qualified Service Personnel.
- **SN** The Serial Number of the Pump
- **S/W** Software version of the Pump

Add Drug

This option allows the user to add a drug whilst the Pump is running a ml/h infusion.

1. Press the ⓘ button to access the **OPTIONS** menu.
2. Select **ADD DRUG** option using the ⏶⏷ keys and press the **OK** softkey.
3. Select the Drug from the displayed list using the ⏶⏷ keys, press **OK** to confirm.

⚠ **Drugs are configured via BD Alaris™ neXus Editor software based on the units available (time / weight based):**

- **Gram base: ng, mcg/µg, mg and g**
- **Unit base: mU/mUnits, U/Units and kU/kUnits**
- **mmol base: mmol, mEq**
- **Energy base: kcal**
- **Volume base: ml**

4. Select concentration using the ⏶⏷ keys, press **OK** to confirm, if applicable.
5. Select patient weight using the ⏶⏷ keys, press **OK** to confirm, if applicable.
6. Confirm drug, overriding Guardrails™ soft limits, as appropriate.

Adjust Alarm Volume

To change the alarm volume, if enabled.

1. Press the ⓘ button to access the **OPTIONS** menu.
2. Select **ADJUST ALARM VOLUME**.

   Note: The Pump will beep at the selected alarm volume setting. The user must assess whether the alarm volume setting is loud enough for the intended operating environment, and adjust appropriately.
3. Select alarm volume required and press the **OK** softkey.

Profile Filter

Configure the profiles to be enabled or disabled in the list of selectable profiles, if enabled.

1. Stop the infusion. Press the ⓘ button to access the **OPTIONS** menu.
2. Select **PROFILE FILTER**.
3. Select Profile(s) required to change and press the **MODIFY** softkey.
4. Press the **OK** softkey to confirm.

Standby

This option allows the Pump to be placed on standby mode, if enabled.

1. Stop the infusion. Press the ⓘ button to access the **OPTIONS** menu.
2. Select **STANDBY** using the ⏶⏷ keys, press the **OK** softkey to confirm.
3. Select **CANCEL** to return to main display.

Date and Time

This option shows the Pump's current date and time. This can be updated via Pump's Service mode by Qualified Service Personnel or will automatically update when the Pump connects to the BD Alaris™ Communication Engine, if one is deployed at the facility.

Network Status

This option allows information about the wireless network connection status to be viewed by Qualified Service Personnel. Refer to the *Technical Service Manual* for the description of network data displayed on these screens.

1. Press the ⓘ button to access the **OPTIONS** menu.
2. Select Network Status using the ⏶⏷ keys. Press **OK** to confirm.
3. Enter password to see the **Network Status** information.
4. Navigate through the pages using the softkeys.
5. Select **Quit** to return to the main display.

Access code to display NETWORK STATUS menus should only be entered by Qualified Service Personnel.

Note: For information on Network Status codes, please refer to the *Technical Service Manual*.

Wireless Connection

The Pump disables wireless communication when docked to a Workstation, and will automatically attempt to re-connect if enabled, and removed from the Workstation. This option allows for wireless communication to be enabled/disabled manually.

Note: It may take up to five minutes for the Pump to reconnect to a Wi-Fi network if connection was disabled manually.

Note: If Wi-Fi is disabled manually, that setting will remain through power cycles.

1. Press the ⓘ button to access the **OPTIONS** menu.
2. Select **Wireless Connection** using the ⏶⏷ keys. Press **OK** to confirm.
3. To toggle the **Wireless Connection** status between enabled and disabled press **MODIFY**.
4. Press **OK** to confirm. Press **QUIT** to disregard changes and return to the main display.

Pressure Monitoring Features

The precision of pressure monitoring will be determined by the extension set being used. The pressure transducer will detect if an extension set with pressure disc is fitted.

Auto Set Pressure (If enabled)

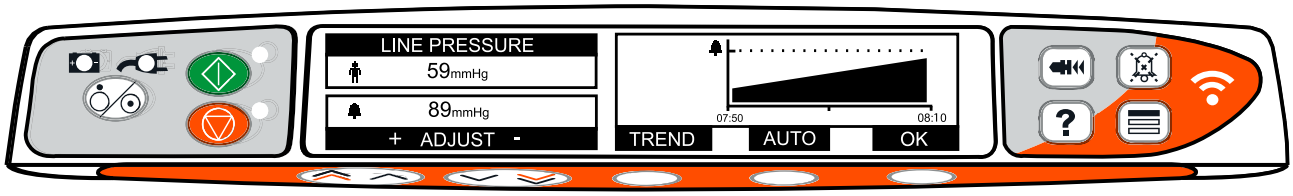
If the Auto Set Pressure Option is enabled then the Pump *automatically* adjusts the pressure occlusion limit.

After 15 minutes of infusion the Pump *automatically* adjusts the occlusion pressure limit to *xx* mmHg above the average infusion pressure, taken from the average of the last five minutes of infusion.

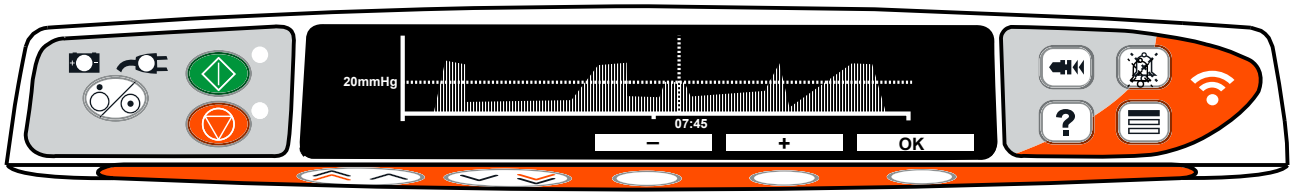
Note: *xx* is the **AUTO OFFSET** pressure and is determined by the user. This adjustment, **AUTO OFFSET** value 15–100mmHg, is configurable by profile within the data set via BD Alaris™ neXus Editor. At pressures up to 100mmHg the **AUTO OFFSET** value is added. For pressures above 100mmHg the alarm level is set to whatever the **AUTO OFFSET** value is as a percentage above the average infusion pressure up to the maximum pressure defined within the data set.

Pressure Level with Pressure Disc fitted

1. To check and adjust the pressure level press the ☰ button. The display will change to show a 20 minute pressure trend graph displaying the pressure alarm level and the current pressure level.



2. Press the ⏶⏷ keys to increase or decrease the pressure alarm level. The new level will be indicated on the display.
3. The **AUTO** Pressure feature may be used when a stable pressure has been achieved over a short period of infusion. If **AUTO** Pressure has been enabled the automatic pressure alarm level is calculated and set by pressing the **AUTO** softkey.
4. Press the **TREND** softkey to view the pressure trend of the previous 12 hours. The pressure trend can be viewed at 15 minute intervals by using the **–** and **+** softkeys. The pressure trend graph displays the pressure at a given time.
5. Press the **OK** softkey to exit the pressure screen.



Pressure Level without Pressure Disc fitted

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

⚠	**The interpretation of the pressure readings and occlusion alarms are the responsibility of the clinician and should include the clinical context in which the Pump is being used.**

Alarms and Warnings

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

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

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

Infusion will stop for all high priority alarms.

The default alarm system is ORIGINAL ALARMS (IEC 60601-1-8 Second Edition alarms). THIRD EDITION ALARMS (IEC 60601-1-8 Third Edition alarms) are also installed. To change the Pump alarm system from ORIGINAL ALARMS to THIRD EDITION ALARMS please refer to the *Technical Service Manual*. **Please note that this change should only be performed by Qualified Service Personnel.**

Original Alarms

Display	Alarm Priority	Description and Troubleshooting Guide
<Error Code and Message>	High	The alarm system has detected an internal malfunction. Note the malfunction code. Remove Pump from service for examination by Qualified Service Personnel.
DRIVE DISENGAGED	High	The drive system has been disengaged during operation. Check the finger grips and the position of the syringe.
OCCLUSION	High	Excessive pressure measured at the syringe plunger exceeding the alarm limit. Identify and remove the cause of the blockage in the drive, syringe, or administration system before restarting the infusion.
LINE OCCLUSION	High	Excessive pressure measured in the extension set at the pressure sensing disc exceeding the alarm limit. Identify and remove the cause of the blockage in the drive, syringe, patient access site, or administration system before restarting the infusion.
CHECK SYRINGE	High	Incorrect size of syringe has been fitted, the syringe has not been positioned correctly or has been disturbed during operation. Check the syringe location and the position. A **Check Syringe** alarm may indicate the incorrect size of syringe has been fitted; the syringe has not been positioned correctly, or has been disturbed during operation, for example, the user opens the syringe clamp, or If the syringe plunger loses contact with the plunger button. If there is no identifiable cause for the **Check Syringe** alarm(s) then the Pump should be removed from clinical use and examined by Qualified Service Personnel in accordance with the *Technical Service Manual*.
PRESSURE DISC OUT	High	The pressure disc has been removed from the pressure transducer during the infusion. Replace the pressure disc then restart the infusion.
BATTERY EMPTY	High	The internal battery is too low to operate the Pump. Immediately connect the Pump to the AC power supply and cycle the power to resume operation.

Display	Alarm Priority	Description and Troubleshooting Guide
VTBI DONE (STOP)	High	The pre-set Volume To Be Infused is complete and the Pump has stopped infusing.
END OF INFUSION	High	The Pump has reached the end of the infusion and the Pump has stopped infusing. A pre-set volume will remain in the syringe to minimise the risk of the infusion of air bubbles into the set. This value can be configured.
END OF INFUSION	Medium	The Pump has reached the end of the infusion and the Pump continues to infuse at KVO or set rate if lower.
BATTERY LOW	Medium	Battery charge low with 30 minutes operation remaining. Reconnect to the AC power supply to charge the internal battery and continue operation. If action is not taken the battery indicator will flash for 30 minutes followed by a continuous audible alarm, red alarm indicator and message **BATTERY EMPTY** displayed, indicating that the battery is too low to operate the Pump. Optional* reminder signals may sound, they are auditory signals that have four beeps that occur every ten minutes once the Low Battery alarm is cancelled.
TITRATION NOT CONFIRMED	Medium	The infusion rate has been changed, but has not been confirmed after five seconds of no activity the user will be notified by an auditory cue. The infusion has not been confirmed and two minutes has expired without any operation, a medium priority alarm will be generated. Press the button to silence the alarm, then press the **CANCEL** softkey to clear this message and silence the alarm. Check infusion rate and confirm by pressing the button or press the button to revert to the previous rate. (This alarm only occurs if rate titration is enabled). Pressing **QUIT** will cancel the titration and keep the original rate.
VTBI DONE (KVO/CONTINUE)	Medium	The pre-set Volume To Be Infused is complete and the Pump continues to infuse at set rate or at KVO rate.
AC POWER FAIL	Medium	AC Power has been disconnected and the Pump is operating on battery power, if this occurs when the Pump is infusing the message **INFUSION CONTINUES** will be displayed. Reconnect AC power supply or press the button to silence the alarm and continue with battery operation. The alarm will automatically cancel if the AC power supply is reconnected.
NEAR END OF INFUSION	Medium	The Pump is nearing the end of the infusion. This value can be configured. Optional* reminder signals may sound, they are auditory signals that have four beeps that occur every ten minutes once the NEOI alarm is cancelled. This reminder signal will not occur for a continuous infusion in which the NEOI alarm is set for less than ten minutes.
ADD DRUG NOT COMPLETE	Medium	The **ADD DRUG** operation has not been completed after five seconds the user will be notified by an auditory cue. After two minutes have expired and the **ADD DRUG** operation has not been completed, a low priority alarm is generated. Press **CANCEL** softkey and complete **ADD DRUG** operation.
ATTENTION LOADING DOSE COMPLETE	Medium	If Pause After Loading Dose has been configured in the data set, then a low priority alarm will be generated when the loading dose has completed.
ATTENTION	Low	If the Pump has been left on for more than two minutes* (referred to as **ATTENTION** in the log) without starting the operation, a low priority alarm will be generated. Press the button to silence the alarm for a further two minutes. For extended Attention Timeout press and hold down the button and wait for four beeps in succession, this will put the Pump on standby for 15 minutes.

*Configurable option.

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

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

Alarm Priority Level Indicators

Priority	Audio Indicator	Visual Indicator (Beacon)
High	One urgent tone pulse followed by one second pause	Flashing Red
Medium	One warning tone pulse followed by one second pause	Flashing Amber
Low	Three attention tone pulse followed by a three second pause	Flashing Amber

Third Edition Alarms

Display	Alarm Priority	Description and Troubleshooting Guide
<Error Code and Message>	High	The alarm system has detected an internal malfunction. Note the malfunction code. Remove Pump from service for examination by Qualified Service Personnel.
DRIVE DISENGAGED	High	The drive system has been disengaged during operation. Check the finger grips and the position of the syringe.
OCCLUSION	High	Excessive pressure measured at the syringe plunger exceeding the alarm limit. Identify and remove the cause of the blockage in the drive, syringe, or administration system before restarting the infusion.
LINE OCCLUSION	High	Excessive pressure measured in the extension set at the pressure sensing disc exceeding the alarm limit. Identify and remove the cause of the blockage in the drive, syringe, patient access site, or administration system before restarting the infusion.
CHECK SYRINGE	High	Incorrect size of syringe has been fitted, the syringe has not been positioned correctly or has been disturbed during operation. Check the syringe location and the position. A **Check Syringe** alarm may indicate the incorrect size of syringe has been fitted; the syringe has not been positioned correctly, or has been disturbed during operation, for example, the user opens the syringe clamp, or If the syringe plunger loses contact with the plunger button. If there is no identifiable cause for the **Check Syringe** alarm(s) then the Pump should be removed from clinical use and examined by Qualified Service Personnel in accordance with the *Technical Service Manual*.
PRESSURE DISC OUT	High	The pressure disc has been removed from the pressure transducer during the infusion. Replace the pressure disc then restart the infusion.
BATTERY EMPTY	High	The internal battery is too low to operate the Pump. Immediately connect the Pump to the AC power supply and cycle the power to resume operation.
VTBI DONE (STOP)	High	The pre-set Volume To Be Infused is complete and the Pump has stopped infusing.
END OF INFUSION	High	The Pump has reached the end of the infusion and the Pump has stopped infusing. A pre-set volume will remain in the syringe to minimise the risk of the infusion of air bubbles into the set. This value can be configured.
END OF INFUSION	Medium	The Pump has reached the end of the infusion and the Pump continues to infuse at KVO or set rate if lower.
BATTERY LOW	Medium	Battery charge low with 30 minutes operation remaining. Reconnect to the AC power supply to charge the internal battery and continue operation. If action is not taken the battery indicator will flash for 30 minutes followed by a continuous audible alarm, red alarm indicator and message **BATTERY EMPTY** displayed, indicating that the battery is too low to operate the Pump. Optional* reminder signals may sound, they are auditory signals that have four beeps that occur every ten minutes once the Low Battery alarm is cancelled.

Display	Alarm Priority	Description and Troubleshooting Guide
TITRATION NOT CONFIRMED	Medium	The infusion rate has been changed, but has not been confirmed after five seconds of no activity the user will be notified by an auditory cue. The infusion has not been confirmed and two minutes has expired without any operation, a medium priority alarm will be generated. Press the button to silence the alarm, then press the **CANCEL** softkey to clear this message and silence the alarm. Check infusion rate and confirm by pressing the button or press the button to revert to the previous rate. (This alarm only occurs if rate titration is enabled). Pressing **QUIT** will cancel the titration and keep the original rate.
VTBI DONE (KVO/CONTINUE)	Medium	The pre-set Volume To Be Infused is complete and the Pump continues to infuse at set rate or at KVO rate.
ATTENTION LOADING DOSE COMPLETE	Low	If Pause After Loading Dose has been configured in the data set, then a low priority alarm will be generated when the loading dose has completed.
AC POWER FAIL	Low	AC Power has been disconnected and the Pump is operating on battery power, if this occurs when the Pump is infusing the message **INFUSION CONTINUES** will be displayed. Reconnect AC power supply or press the button to silence the alarm and continue with battery operation. The alarm will automatically cancel if the AC power supply is reconnected.
NEAR END OF INFUSION	Low	The Pump is nearing the end of the infusion. This value can be configured. Optional* reminder signals may sound, they are auditory signals that have four beeps that occur every ten minutes once the NEOI alarm is cancelled. This reminder signal will not occur for a continuous infusion in which the NEOI alarm is set for less than ten minutes.
ADD DRUG NOT COMPLETE	Low	The **ADD DRUG** operation has not been completed after five seconds the user will be notified by an auditory cue. After two minutes have expired and the **ADD DRUG** operation has not been completed, a low priority alarm is generated. Press **CANCEL** softkey and complete **ADD DRUG** operation.
ATTENTION	Low	If the Pump has been left on for more than two minutes* (referred to as **ATTENTION** in the log) without starting the operation, a low priority alarm will be generated. Press the button to silence the alarm for a further two minutes. For extended Attention Timeout press and hold down the button and wait for four beeps in succession, this will put the Pump on standby for 15 minutes.

*Configurable option.

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

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

Alarm Priority Level Indicators

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

Prompts

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

Display	Icon	Description and Troubleshooting Guide
DOSE WOULD EXCEED		The dose rate has been set to a value which exceeds a Guardrails™ Soft Limit. Check infusion setting, to continue with infusion at set rate confirm **OVERRIDE LIMIT** by pressing the **YES** softkey. If **OVERRIDE LIMIT** is not required press the **NO** softkey and adjust rate below Guardrails™ Soft Limit.
DOSE UNDER		The dose rate has been set to a value which is under a Guardrails™ Soft Limit. Check infusion setting, to continue with infusion at set rate confirm **OVERRIDE LIMIT** by pressing the **YES** softkey. If **OVERRIDE LIMIT** is not required press the **NO** softkey and adjust rate above Guardrails™ Soft Limit.
DOSE NOT PERMITTED		The dose rate has been set above a Hard Limit. Check infusion setting and adjust rate to appropriate required rate.
BOLUS DOSE OVER		The bolus dose has been set to a value which exceeds a Guardrails™ Soft Limit. Check the bolus setting, to continue with the bolus confirm **OVERRIDE LIMIT** by pressing the **YES** softkey. If **OVERRIDE LIMIT** is not required press the **NO** softkey and adjust dose below Guardrails™ Soft Limit.
BOLUS DOSE UNDER		The bolus dose has been set to a value which is under a Guardrails™ Soft Limit. Check the bolus setting, to continue with the bolus confirm **OVERRIDE LIMIT** by pressing the **YES** softkey. If **OVERRIDE LIMIT** is not required press the **NO** softkey and adjust dose above Guardrails™ Soft Limit.
BOLUS DOSE NOT PERMITTED		The bolus dose has been set above a Guardrails™ Hard Limit. Check bolus setting and adjust to appropriate required dose.
CONCENTRATION NOT PERMITTED		The drug concentration has been set above or below a Guardrails™ Hard Limit. Check the amount and total volume and adjust to give the appropriate required concentration.
WEIGHT OUTSIDE LIMIT		The patient weight has been set to a value which exceeds or is under a Guardrails™ Soft Limit. Check the weight setting, to continue confirm **OVERRIDE LIMIT** by pressing the **YES** softkey. If **OVERRIDE LIMIT** is not required press the **NO** softkey and adjust the value within the limits.
RATE NOT PERMITTED		The infusion rate has been set above a Hard Limit. Check infusion setting and adjust to appropriate required rate.
LOADING DOSE ABOVE MAXIMUM		The loading dose has been set to a value which exceeds a Guardrails™ Hard Limit. Check infusion settings and adjust to appropriate loading dose.
LOADING DOSE WOULD EXCEED		The loading dose has been set to a value which exceeds a Guardrails™ Soft Limit. Check the loading dose setting. To continue with the loading dose confirm **OVERRIDE LIMIT** by pressing the **YES** softkey. If **OVERRIDE LIMIT** is not required press the **NO** softkey and adjust loading dose below Guardrails™ Soft Limit.
LOADING DOSE UNDER		The loading dose has been set to a value which is under a Guardrails™ Soft Limit. Check the loading dose setting. To continue with the loading dose confirm **OVERRIDE LIMIT** by pressing the **YES** softkey. If **OVERRIDE LIMIT** is not required, press the **NO** softkey and adjust loading dose above Guardrails™ Soft Limit.

Configuration

Configured Options

This section comprises of a list of options which are configurable. Some can be entered via the Pump configurations (available in Technician Mode) and others through the data set via BD Alaris™ neXus Editor Software.

Access codes should only be entered by Qualified Service Personnel.

Use BD Alaris™ neXus Editor to configure general options, drug library and units enabled for each profile and to configure Syringe Brands and Models to be enabled.

Enter the access code on the Pump for Configured Options. (Refer to *Technical Service Manual* for details.)

Alarm Presets

Pumps have two alarm tones to choose from during configuration:

- **ORIGINAL ALARMS**: Low, medium and high priority alarm tones that sound similar to legacy Alaris™ Infusion Pumps.
- **3RD EDITION ALARMS**: Low, medium and high priority alarm tones in accordance with IEC 60601-1-8:2012 and IEC 60601-2-24:2012

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

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

- **All Pumps in a single care area should be configured with the same alarm tones to avoid user confusion.**
- **The Hospital/Facility is responsible for selecting and configuring the desired alarm scheme.**
- **Alaris™ Gateway Workstation (Workstation) with software versions 1.1.3, 1.1.3 MR, 1.1.5, 1.1.6, 1.2, 1.5 or 1.6.0 do not support the new Pump low priority visual alarms scheme defined in IEC 60601-1-8:2012.**
- **Low priority alarms (Near End of Infusion, AC Power Fail, Add Drug Not Complete, and Attention) will display as medium visual priority alarms on the Workstation beacon and a low priority alarm on the Pump. For certain Information signals, e.g. those associated with Add Drug Not Complete and Titration Not Confirmed, the Workstation beacon will illuminate while the beacon on the Pump will not. The user should refer to the alarm on the Pump for the correct priority.**

Additional Configured Options Available

- Clock Set
- Language
- Contrast
- General Options
  - **NURSE CALL FITTED**
  - **NURSE CALL INVERT**
  - **RS232 SELECTED**
  - **DOUBLE DECIMAL ML/H**
  - **REMINDER SIGNAL**

BD Alaris™ neXus Editor Software Profile Configuration

The following options are only configurable via the BD Alaris™ neXus Editor Software (PC based). See *BD Alaris™ neXus Editor Directions For Use* for details on how to configure Profile Configurations.

Data Set Configuration Settings

Setting	Description
Hospital Name	Configure the name of the facility to be displayed on the Pump.
Profile Filter	Controls whether the user is able to filter which profiles will be available on the Pump.
Unit Display – Microgram	The text used to display micrograms: either **mcg** or **µg**.
Unit Display – Unit	The text used to display Units, either **mU**, **U** and **kU** or **mUnit**, **Unit** and **kUnit**

General Pump Configurations

Setting	Description
AC Fail	The AC Power Failure Alarm can be set to sound or be silent if the AC power is removed.
Audio Volume	The audio alarm volume of the Pump (**High**, **Medium** or **Low**).
Audio Volume Adjustable	Sets whether the user is able to adjust the audio volume setting.
Auto Night Mode	Main Display (Backlight) dims between hours 21:00 and 06:00.
Auto Save	Feature to retain previous settings when Pump is switched on.
Battery Icon	Indicator displaying the remaining estimated battery capacity.
Callback Time	Adjusts the length of time before the Pump sounds the Attention alarm.
Drug Override Mode	• **Always** – Confirmation of setting will be required for any changes made to the dose rate that are outside of the Guardrails™ Soft Limits. • **Smart** – Confirmation of setting will be required on first dose rate set outside of the Guardrails™ Soft Limit. Any subsequent changes will not require confirmation until after the dose rate has been confirmed inside the Guardrails™ Soft Limits. Additionally any changes in dose rate from above a Soft Limit Max to below a Soft Limit Min or from below a Soft Limit Min to above a Soft Limit Max will also need to be confirmed.
Event Log	The event log can be set to be displayed or not on the main display. Regardless of the display setting, events are always recorded in the log.
Pressure Display	Sets whether Pressure Information is available on the display.
Quiet Mode	Mode to silence key press tones and power down sequence.
Rate Titration	Feature to adjust the infusion rate while the Pump is infusing, without putting the Pump on hold.
Rate Lock	Anti-tamper feature which prevents rate changes, bolus operations and powering Pump down.
Standby Mode	Sets whether the Standby Mode is available on the Pump.
VTBI Clear Rate	Infusion rate will be set to zero when VTBI has been completed.
Weight Default	The default patient weight in kg.
Weight Soft Minimum	The minimum patient weight in kg. This is a Guardrails™ Soft Limit and can be overridden.
Weight Soft Maximum	The maximum patient weight in kg. This is a Guardrails™ Soft Limit and can be overridden.

General Syringe Pump Configurations

Setting	Description
Back Off	An automatic feature which is activated following an occlusion. The Pump action reverses and pumps backwards to release the pressure which has built up in the infusion system, this minimises the post occlusion bolus.
Display Syringe Brand	Sets whether the syringe brand and size is shown while Pump is infusing.
Manual Bolus	Bolus delivered by manually moving the plunger mechanism during an infusion or while on hold. Volume infused displayed will be increased accordingly.
Bolus Mode	Bolus feature can be set to one of the following options: • **Disabled** • **Hands-On Only** • **Hands-Free and Hands-On**
Bolus Rate Default	The default value for bolus rates.
Bolus Rate Max	The maximum value for bolus rate.
Bolus Volume Max	The maximum permissible bolus volume.
Infusion Rate Max	The maximum value for infusion rate.
Near End of Infusion Point	Sets the Near End Of Infusion (NEOI) warning time, as time left to End Of Infusion (EOI).
End of Infusion	Sets the End Of Infusion point, as a percentage of syringe volume.
KVO at EOI	Sets whether the Keep Vein Open (KVO) at End Of Infusion is available.
KVO Rate	Sets the Keep Vein Open rate at which the Pump will operate when End of Infusion is reached.
Purge Syringe	Feature which prompts the user to purge the extension set prior to the start of the infusion.
Purge Rate	The rate used during purge operation.
Purge Volume Max	The maximum permissible purge volume.
VTBI Max	The maximum value for Volume To Be Infused (VTBI).
Pressure Maximum	The maximum occlusion pressure alarm value that can be selected during an infusion.
Occlusion Alarm Pressure	The default occlusion pressure alarm value that can be selected during an infusion.
Auto Pressure	Feature to set the occlusion pressure alarm level to an amount (mmHg) above the current in-line pressure, using a single key press.
Auto Set Pressure	Automatic feature to set the occlusion pressure alarm level to an amount (mmHg) above the current in-line pressure, 15 minutes after starting the infusion.
Auto Offset	The automatic offset value in mmHg used by auto pressure and auto set pressure.
Drug Confirmation After Syringe Change	This feature, when enabled, specifies if an additional confirmation screen displays current drug setup on syringe change.

The approved data set contains configurable option values per profile.

Dose Rate Units

All of the following dose rate units can be used when defining the Guardrails™ dose rate settings. The following dose rate units can be configured for use in Dosing Only mode. Checking the ALL checkbox will select all of the listed units.

Amount	**Non Patient Weight Based**			**Patient Weight Based**		
	minute	**hour**	**24 hours**	**minute**	**hour**	**24 hours**
ng	ng/min	ng/h	ng/24h	ng/kg/min	ng/kg/h	ng/kg/24h
µg	µg/min	µg/h	µg /24h	µg/kg/min	µg/kg/h	µg/kg/24h
mg	mg/min	mg/h	mg/24h	mg/kg/min	mg/kg/h	mg/kg/24h
g	g/min	g/h	g/24h	g/kg/min	g/kg/h	g/kg/24h
mU	mU/min	mU/h	mU/24h	mU/kg/min	mU/kg/h	mU/kg/24h
U	U/min	U/h	U/24h	U/kg/min	U/kg/h	U/kg/24h
kU	kU/min	kU/h	kU/24h	kU/kg/min	kU/kg/h	kU/kg/24h
mmol	mmol/min	mmol/h	mmol/24h	mmol/kg/min	mmol/kg/h	mmol/kg/24h
ml	ml/min	ml/h	ml/24h	ml/kg/min	ml/kg/h	ml/kg/24h
mEq	mEq/min	mEq/h	mEq/24h	mEq/kg/min	mEq/kg/h	mEq/kg/24h
kcal	kcal/min	kcal/h	kcal/24h	kcal/kg/min	kcal/kg/h	kcal/kg/24h

BD Alaris™ neXus Editor Software Profile Drug library

The following drug parameters are only configurable via the BD Alaris™ neXus Editor Software. See *BD Alaris™ neXus Editor Directions For Use* for details on how to configure Profile Drug Library. These parameters are used when the Pump is operated with a drug name selected.

Item		**Description**
Concentration Units		The unit for concentration parameters.
Concentration Limits (Min and Max)		These define the range over which the drug concentration can be modified during programming of the Pump.
Loading Dose	Units	The loading dose units. Can be based on patient weight.
	Soft Min	The loading dose value, below which override confirmation is required.
	Default	The default loading dose offered when the drug is selected.
	Soft Max	The loading dose value above which override confirmation is required.
	Hard Max	The maximum allowed loading dose.
	Default Duration	The default duration over which the loading dose will be delivered.
	Pause After Loading Dose	If Pause After Loading Dose is enabled, then a low priority alarm will be generated when the loading dose has completed.
Dose Rate Settings	Units	The dose rate units. Can be based on patient weight.
	Soft Min	The dose rate value below which override confirmation is required.
	Default	The default dose rate offered when the drug is selected.
	Soft Max	The dose rate value above which override confirmation is required.
	Hard Max	The maximum allowed dose rate.
Bolus Mode		Bolus feature can be set to one of the following options: • **Disabled** • **Hands-On Only** • **Hands-Free and Hands-On**
Bolus Dose	Units	The bolus dose units. Can be based on patient weight.
	Soft Min (Hands-Free only)	The bolus dose value below which override confirmation is required.
	Default (Hands-Free only)	The default bolus dose offered.
	Soft Max (Hands-Free only)	The bolus dose value above which override confirmation is required.
	Hard Max	The maximum allowed bolus dose.
Bolus Rate	Default	The default value for bolus rate in ml/h.
Occlusion Alarm Pressure		The default occlusion alarm pressure.

Profile Syringe Library

The Profile Syringe Library is created from the predefined Master Syringe Library.

Check the boxes of the syringes to be included in the profile. Checking the **All Syringes** checkbox under **Operations** selects all the syringes.

For syringe brands and sizes available see 'Recognised Syringes' section.

Note: It is recommended that only syringe types and sizes used in the care area are selected.

Associated Products

Recognised Syringes

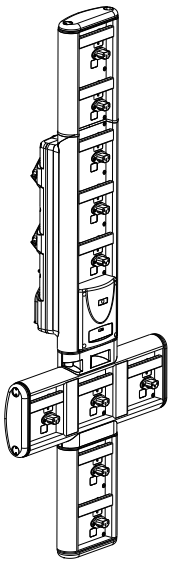
The Pump is calibrated and labelled for use with single-use disposable Luer lock syringes. Only use the size and type of syringe specified on the Pump display.

Manufacturer	Model	Part Number	Alternative Part Numbers		
BD Plastipak	5ml	309649	302553	302135	309646
	10ml	300912	—	—	—
	20ml	301189	300629	302562	—
	30ml	301229	302832	—	—
	50ml	300865	309653	—	—
BD Precise	20ml	300141	—	—	—
	50ml	300144	—	—	—
Braun Omnifix*	5ml	4617053V	—	—	—
	10ml	4617100V	—	—	—
	20ml	4617207V	—	—	—
	30ml	4617304F	—	—	—
	50ml	4617509F	—	—	—
Braun Perfusor*	20ml	8728615	—	—	—
	50ml	8728844F-06	8728844F-04	8728844F-20	—
Codan Perfusion*	50ml	62.8455	—	—	—
Fresenius Injectomat*	50ml	9000711	—	—	—
Monoject*	5ml	1180600777	—	—	—
	10ml	1181200777	—	—	—
	20ml	1182000777	—	—	—
	30ml	1183500777	—	—	—
	50ml	1186000777	—	—	—
Pentaferte*	5ml	002022520F	—	—	—
	10ml	002022620F	—	—	—
	20ml	002022720F	—	—	—
	50ml	002022970F	002022920AF (amber)	—	—
Terumo*	5ml	SS-05L	SS*05LE1	—	—
	10ml	SS-10L	SS*10LE1	—	—
	20ml	SS-20L2	—	—	—
	30ml	SS*30LE1	—	—	—
	50ml	SS*50LE	—	—	—

To minimise the risk of incorrect confirmation of the syringe type it is recommended that only syringe types available in the hospital are configured on the Pump.

- **BD has characterized a range of syringes as identified in the 'Recognised Syringes' table. BD cannot guarantee the continued system accuracy of these recognised syringes* as the manufacturer may change syringe specification significant to system accuracy without prior notification.**
- **Subject to the above, BD branded Luer lock syringes can be confirmed as BD Plastipak syringes due to there being no significant variance in dimensions.**
- **In no event shall BD be liable for any damages of any kind or nature, including without limitation, direct or indirect, special, consequential, or incidental damages arising from, or in connection with the use of syringes not listed in the 'Recognised Syringes' table.**

Alaris™ Gateway Workstation v1.3.x or v1.6.x



Product SKU	80300UNS*y-xx* or 80223UNS*y-xx*
Supply Voltage	115–230V AC, ~50–60Hz
Electrical Rating	460VA (Maximum)
Protection Against Electrical Shock	Class 1
Classification	Continuous Operation
Supply to Pump	115–230V, ~50–60Hz, 60VA

y = Connectivity option – 1, 2 or 3

xx = Configuration

BD Alaris™ MRI Capsule v1.3.x

Product SKU	80300MRI01-33

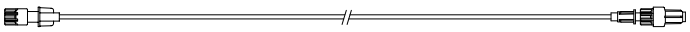
Compatible Extension Sets

The Pump uses standard, single-use, disposable extension sets and syringes with Luer lock connectors. The user is responsible for verifying the suitability of a product used, if it is not recommended by BD.

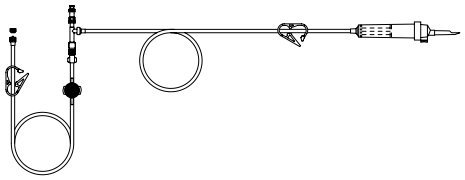
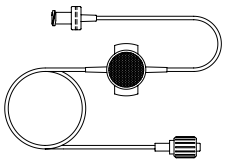
- **New sets are continuously being developed for our customers. Contact your local BD representative for availability.**
- **It is recommended that extension sets are changed in accordance with the** *Directions For Use*. **Carefully read the** *Directions For Use* **supplied with the extension set prior to use.**

Please note these drawings are not to scale.

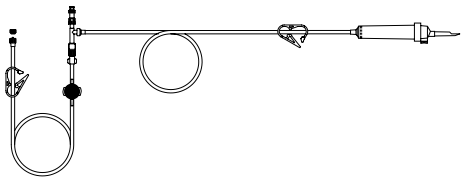
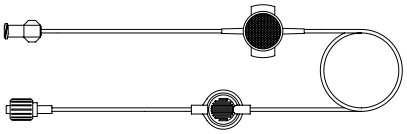
Standard Sets

G30402M	Standard PVC Syringe Extension Set with occlusion sensing disc. (200cm). Priming Volume: 1.5ml
	
04103215162	Standard PVC Syringe Extension Set (155 cm). Priming Volume: 1.4ml
	
G40020B	Standard PVC Syringe Extension Set (200 cm). Priming Volume: 1.5ml

Blood Sets

MFX2207E	Neonatal closed blood set with occlusion sensing disc. (320cm). Priming Volume: 15ml
	
MFX2213	Blood extension set with occlusion sensing disc. (200cm). Priming Volume: 0.8ml
	

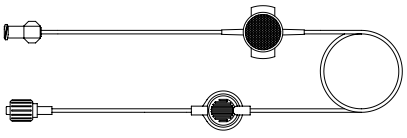
TPN Sets

MFX2206E	Dedicated Neonatal TPN system light resistant extension set with occlusion sensing disc. (115cm). Priming Volume: 15ml
	
MFX2211	Dedicated TPN system light resistant extension set with occlusion sensing disc. (200cm). Priming Volume: 1.3ml
	

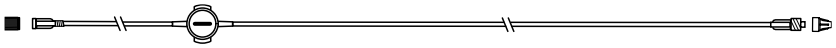
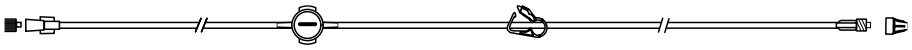
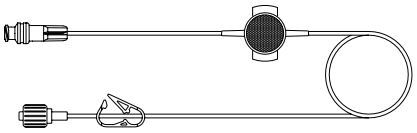
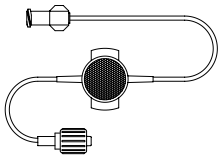
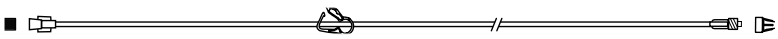
Light Protected Sets

G30653V	Opaque White PVC Syringe Extension Set with occlusion sensing disc. (200cm). Priming Volume: 1.5ml
	
MFX2294	Opaque White PVC Syringe Extension Set with occlusion sensing disc. (200cm). Priming Volume: 1.5ml
	
G40215K	Amber PE Syringe Extension Set (150 cm). Priming Volume: 1.2ml
G40320V	White PVC Syringe Extension Set (200 cm). Priming Volume: 3.6ml

NICU Sets

MFX2210	Syringe Extension Set with occlusion sensing disc. (200cm). Priming Volume: 1.6ml
	

Low Sorbing Sets

G30453V	Opaque White PVC low sorbing Syringe Extension Set with occlusion sensing disc. (200cm). Priming Volume: 1.5ml
	
G30302M	Polyethylene Lined Syringe Extension Set with occlusion sensing disc and clamp. (200cm). Priming Volume: 1.6ml
	
MFX2299E	Polyethylene Lined Syringe Extension Set with occlusion sensing disc and clamp. (205cm). Priming Volume: 1ml
	
MFX2214	Amber Polyethylene Lined Syringe Extension Set with occlusion sensing disc and clamp. (30cm). Priming Volume: 0.3ml
	
G40615K	Polyethylene Syringe Extension Set (150 cm). Priming Volume: 1.5ml
	
G40620K	Polyethylene Syringe Extension Set (200 cm). Priming Volume: 2ml
PB-G40720	Polyethylene Lined Syringe Extension Set with clamp. (200 cm). Priming Volume: 1.5ml
	
04105010509K	Polyethylene Syringe Extension Set (100 cm). Priming Volume: 1ml

Maintenance

Routine Maintenance Procedures

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

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

- **If the Pump is dropped, damaged, subjected to excessive moisture or high temperature, immediately take it out of service for examination by Qualified Service Personnel.**
- **All preventative and corrective maintenance and all such activities shall be performed at a compliant work place in accordance with the information supplied. BD will not be responsible should any of these actions be performed outside the instructions or information supplied by BD. For Preventative and Corrective Maintenance instructions refer to the *Technical Service Manual* (TSM).**
- **All preventative and corrective maintenance and all such activities should be performed by Qualified Service Personnel only, with reference to the TSM.**

Refer to *Technical Service Manual* for calibration procedures. The units of measurement used in the calibration procedure are standard SI 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.

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 three month intervals during storage.

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

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

Cleaning and Storage

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:

- Hibiscrub 20% (v/v)
- Virkon Disinfectant 1% (w/v)

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

- Warm soapy water
- Mild detergent in water (e.g. Young's Hospec)
- 40% isopropyl alcohol in water
- Chlor-Clean
- Clinell Universal Wipes
- Reynard
- TriGene Advance
- Tristel Fuse sachets
- Tristel Trio wipes system
- Tuffie 5 wipe
- Tuffie Disinfectant

Do not use the following disinfectant types:

- Disinfectants which are known to be corrosive to metals must not be used. These include:
  - NaDcc (such as Presept)
  - Hypochlorites (such as Chlorasol)
  - Aldehydes (such as Cidex)
- Cationic surfactants >1% (such as benzalkonium chloride)
- Mixture of alcohol and chemicals with cationic surfactants >1% chlorohydrocarbons (such as Amberclens)
- Use of iodine (such as Betadine) will cause surface discoloration.
- Concentrated isopropyl alcohol based cleaners will degrade plastic parts.

- **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.**
- **If the Pump has visible cracks or damage to the case do not clean and immediately take it out of service for examination by Qualified Service Personnel.**
- **Ensure the pressure transducer is free from residues, which may prevent correct operation of the disc detector.**

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

The lock box can be removed for cleaning. This should be performed by Qualified Service Personnel only, with reference to the TSM.

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 three 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 and Electronic Equipment

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

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

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

Information on Disposal in Countries outside the European Union

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

Technical Data

Specifications

Infusion Specifications

Maximum infusion rate can be set as part of the configuration in the data set via BD Alaris™ neXus Editor.

Infusion Rate	Syringe Size
0.1ml/h to 150ml/h	5ml syringes
0.1ml/h to 300ml/h	10ml syringes
0.1ml/h to 600ml/h	20ml syringes
0.1ml/h to 900ml/h	30ml syringes
0.1ml/h to 1200ml/h	50ml syringes

Infusion Rate Increments:

Rate Range (ml/h)	Single Chevron Key Increments (ml/h)	Double Chevron Key Increments (ml/h)
0.10 to 9.99	0.01	0.10
10.0 to 99.9	0.1	1.0**
100 to 999	1	10
1000 to 1200	10	100
0.1 to 9.9**	0.1	1

** – Infusion rate increment changes when the double decimal option is disabled in the General Options.

The Volume Infused range is 0.0ml to 9990ml.

Bolus Specifications

Maximum Bolus rates can be set as part of the configuration. Bolus rates are user adjustable, in increments of 10ml/h.

Bolus Rate	Syringe Size
10ml/h to 150ml/h	5ml syringes
10ml/h to 300ml/h	10ml syringes
10ml/h to 600ml/h	20ml syringes
10ml/h to 900ml/h	30ml syringes
10ml/h to 1200ml/h	50ml syringes

The bolus volume limit can be set as part of the configuration.

- Minimum: 0.1ml; maximum 25.0ml
- Increments of 0.1ml; default 5.0ml

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

Bolus Volume Accuracy*

With pressure disc

Bolus Volume	Typical	Typical Maximum	Typical Minimum	Pump Specification
0.1ml	1.7%	5.1%	–2.5%	±10%
25ml	0.1%	0.5%	–0.6%	±5%

Without pressure disc

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

* – Using BD Plastipak 50ml syringe at 5ml/h under normal conditions (95% confidence / 95% of Pumps).

Critical Volume

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

Purge Specifications

The purge rate is limited to the maximum rate for the syringe and can be set as part of the configuration.
100 to 500ml/h.
The purge volume range is 0.5 to 5ml.
During **PURGE** the pressure limit alarms are temporarily increased to their maximum level.

Keep Vein Open (KVO) Rate

0.1 to 2.5ml/h.

End Of Syringe Rate

Stop, KVO (0.1 to 2.5ml/h), or set rate if lower than KVO.

Volume To Be Infused (VTBI)

0.10 to 1000ml, 1 minute to 24 hours.

VTBI Complete Rate

Stop, KVO (0.1 to 2.5ml/h), set rate if lower than KVO or continue at set rate.

Near End Of Infusion Alarm

1 to 15 minutes to end of infusion, or 10% of syringe volume, whichever is smaller.

End Of Infusion (EOI) Alarm

0.1 to 5% of syringe volume.

Maximum Pumping Pressure Limit

Highest alarm level 1000mmHg (nominal at L10).

Occlusion Accuracy

Without pressure disc (% of full scale)*

	Pressure			
	L0 approx. 50mmHg	**L3 approx. 300mmHg**	**L5 approx. 500mmHg**	**L10 approx. 1000mmHg**
Temp. 23°C	±18%	±21%	±23%	±28%

With pressure disc (% of full scale)*

	Pressure			
	0mmHg	**25mmHg**	**500mmHg**	**1000mmHg**
Temp. 23°C	±2%	±4%	±5%	±6%
Temp. 5°C to 40°C	±4%	±7%	±7%	±10%

* Using most common 50ml syringes under normal conditions (95% confidence / 95% of Pumps).

System Accuracy

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

- Derating – Temperature ±0.5% (5 to 40°C), High Rates ±2.0% (rates > syringe volume/h e.g. >50ml/h in a 50ml syringe.)

- **System accuracy is ±2% typical by volume as measured using the trumpet curve test method defined in EN/IEC 60601-2-24 at rates of 1.0ml/h (23°C) and above when the Pump is used with the recommended syringes.**
- **Infusion volume accuracy may be compromised at rates below 1.0ml/h. Differences in factors such as size and plunger force in recognised syringes can cause variations in accuracy and trumpet curves. See also 'Trumpet Curves and Start-Up Curves' section in this manual.**

Data Set Specification

A maximum of 30 profiles can be set, with a total number of 3000 drugs per data set. See *BD Alaris™ neXus Editor Software Directions For Use* for more details.

Electrical Classification

Class I product. Continuous Mode Operation, Transportable

Battery Specifications

Rechargeable sealed NiMH. Automatically charges when the Pump is connected to AC power.

Mean Time To Power Down from fully charged at 5ml/h and 23 ± 2°C under normal conditions is 6 hours.*

Mean Time To Power Down from fully charged at 5ml/h and 23 ± 2°C, Wi-Fi ON, is 4 hours.

*95% lower confidence interval of 5 hours 50 minutes.

Charging takes 2½ hours from discharge to 90% charge.

Wi-Fi Specifications

The Pump's wireless module contains a radio frequency, wireless, local-area network interface (RF) card. The wireless module supports Wi-Fi communication between Pump and BD Alaris™ Communication Engine (if deployed at the facility). The wireless module is compliant with the rules and regulations in the locations where the Pump is sold. Network settings are programmed by Qualified Service Personnel using BD Alaris™ Technical Utility.

Wi-Fi network standards: 802.11a (Wi-Fi 2), 802.11b (Wi-Fi 1), 802.11g (Wi-Fi 3) and 802.11n (Wi-Fi 4).

Frequency band of operation: 2400–2483.5MHz for 2.4GHz, effective radiated power 18dBm;
5150–5350MHz and 5470–5725MHz for 5GHz, effective radiated power 18dBm.

Interconnected data communications systems must be certified to IEC 60950 (data processing equipment) or IEC 60601-1 (electromedical equipment).

Radio Equipment Directive Declaration of Conformity Statement

Hereby, BD Switzerland Sàrl, declares that the radio equipment type 'BD Alaris™ neXus CC' is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address:

https://www.bd.com/en-uk/Infusion/Conformity-Declaration-CC-neXus

Memory Retention

The electronic memory of the Pump will be retained for at least six months when not powered up.

Fuse Type

2 × T 1.25H, 250V

AC Power Supply

115–230V AC, 50–60Hz, 30VA (under maximum charging conditions) 10VA (nominal).

Dimensions

335mm (w) × 121mm (h) × 200mm (d)

Weight

2.4kg (excluding power cable)

Protection against fluid ingress

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

Note: IP33 applies if mains retainer kit, part number 1000SP01294, is fitted.

Alarm Conditions

Drive Disengaged	Occlusion	Attention (Nurse Callback)
Check Syringe	Battery Low	Titration Not Confirmed
Line Occlusion	Battery Empty	VTBI Done
Near End Of Infusion	End of Infusion	AC Power Fail
Internal Malfunction	Pressure Disc Out	Dose Under
Dose Would Exceed	Dose Not Permitted	Bolus Dose Not Permitted
Bolus Dose Under	Bolus Dose Over	Rate Not Permitted
Concentration Not Permitted	Weight Outside Limit	Add Drug Not Complete
Loading Dose Above Maximum	Loading Dose Under	Loading Dose Would Exceed
Loading Dose Complete		

Environmental Specifications

Condition	Acceptable Range
Operating Temperature	0°C to +40°C
Operating Relative Humidity	20% to 90% non-condensing
Operating Atmospheric Pressure	70kPa to 106kPa
Transport and Storage Temperature	–30°C to +50°C
Transport and Storage Relative Humidity	10% to 90% non-condensing
Transport and Storage Atmospheric Pressure	50kPa to 106kPa

Electrical/Mechanical Safety

Complies with EN/IEC 60601-1 and EN/IEC 60601-2-24.

Potential Equalisation Conductor

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

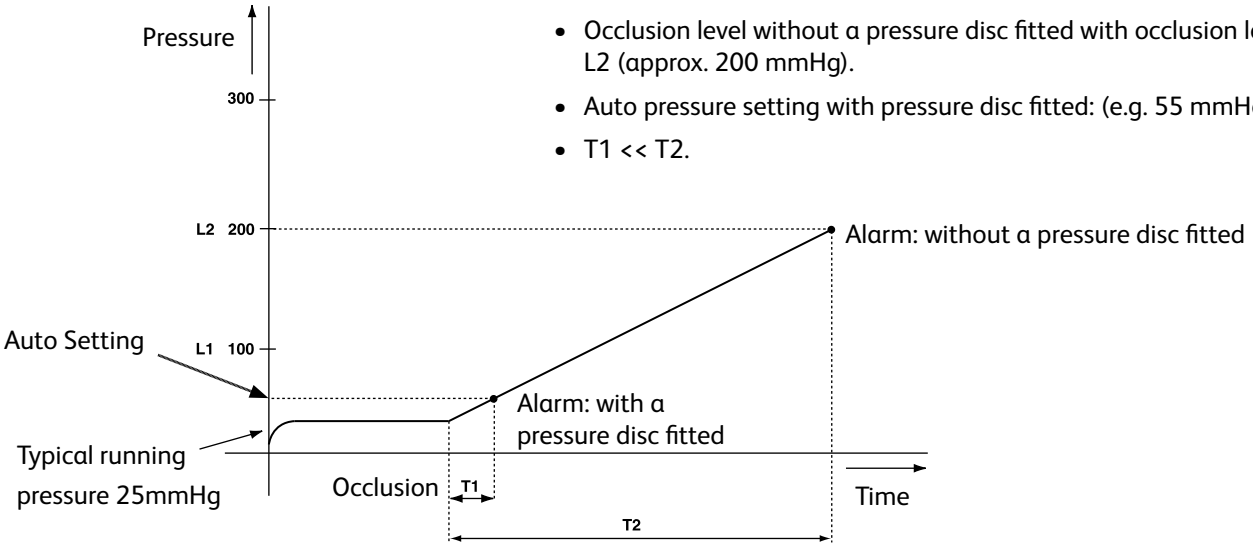
EMC

Complies with EN/IEC 60601-1-2 and EN/IEC 60601-2-24.

Occlusion Pressure Limits

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

Use of the dedicated pressure disc permits the occlusion alarm pressure (mmHg) to be set accurately, with a small operating margin between the alarm and normal infusion pressures. When using the Pump without a pressure set, pressures are estimated from pumping force. For this reason the occlusion alarm needs to be set with an operating margin of at least one level between the alarm and normal infusion levels. The ability to set a small operating margin permits short time to alarm and small potential bolus volumes to be achieved. Bolus volumes can be minimised as described in the Alarms and Warnings – Occlusion or by enabling the back off general option.

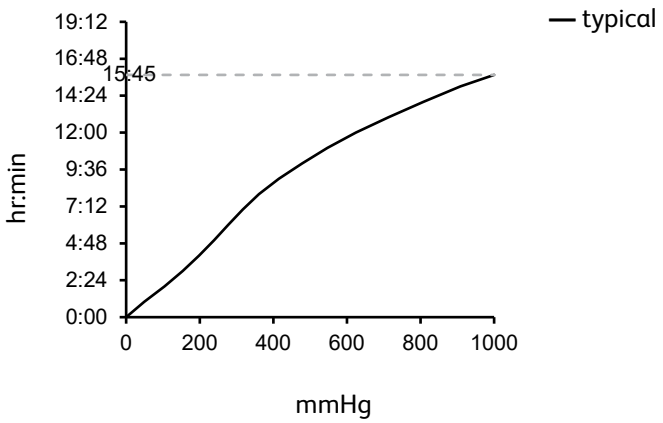


- Occlusion level without a pressure disc fitted with occlusion levels: L2 (approx. 200 mmHg).
- Auto pressure setting with pressure disc fitted: (e.g. 55 mmHg).
- T1 << T2.

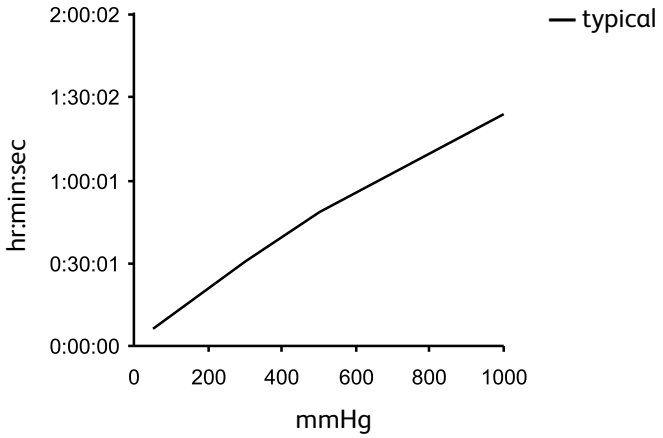
With a Pressure Extension Set fitted, G30402M – Standard disposable extension set

The following graphs show the typical values for time to alarm and bolus volume that can be expected in the event of an occlusion when the BD Plastipak 50ml syringe is selected with a G30402M extension set with occlusion sensing disc.

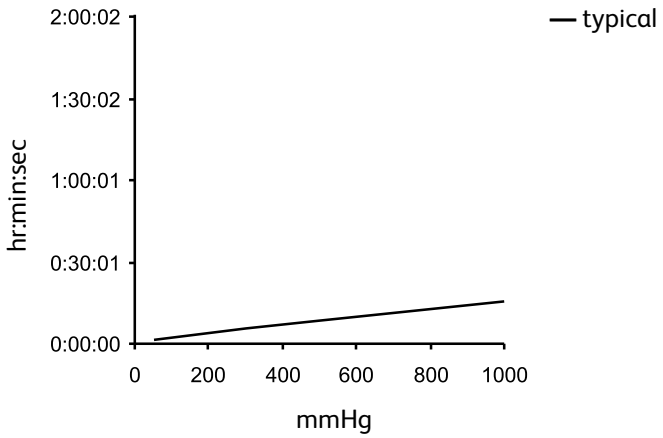
Time to alarm at 0.1ml/h



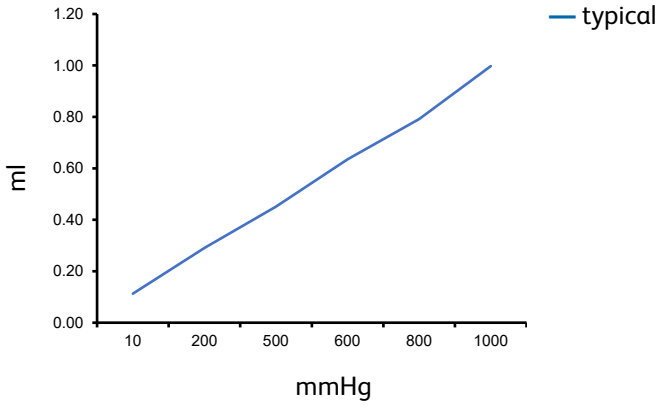
Time to alarm at 1.0ml/h



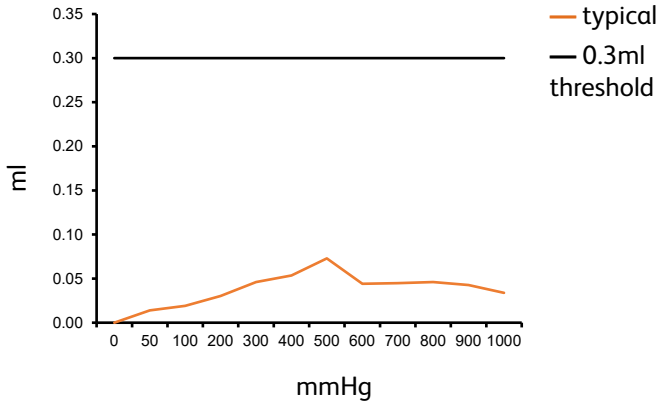
Time to alarm at 5.0ml/h



Unintended bolus volume at 5.0ml/h back off disabled



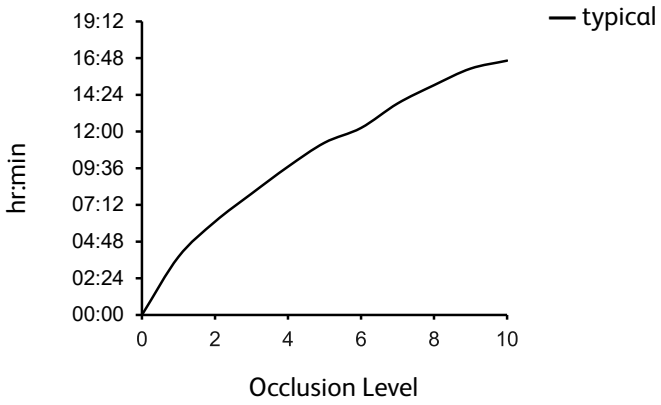
Unintended bolus volume at 5.0ml/h back off enabled



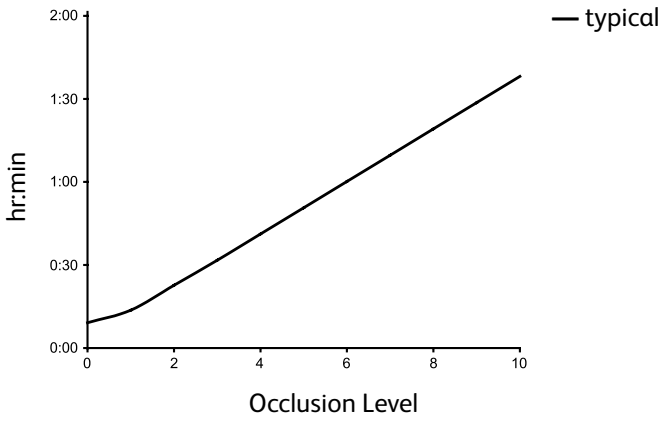
Without a Pressure Extension Set fitted, G40020B – Standard disposable extension set

The following graphs show the typical values for time to alarm and bolus volume that can be expected in the event of an occlusion when the BD Plastipak 50 ml syringe is selected with a G40020B standard extension set.

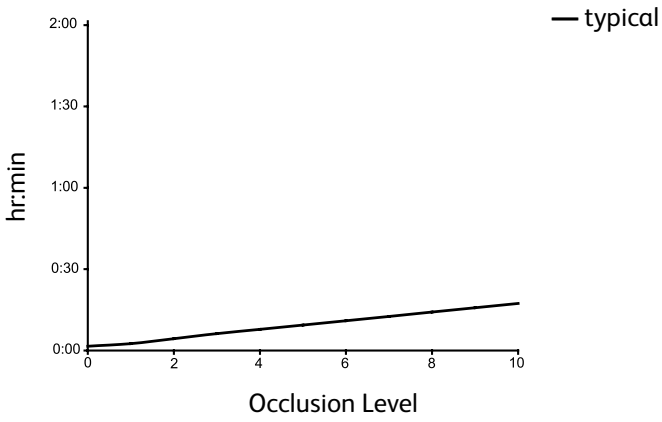
Time to alarm at 0.1ml/h



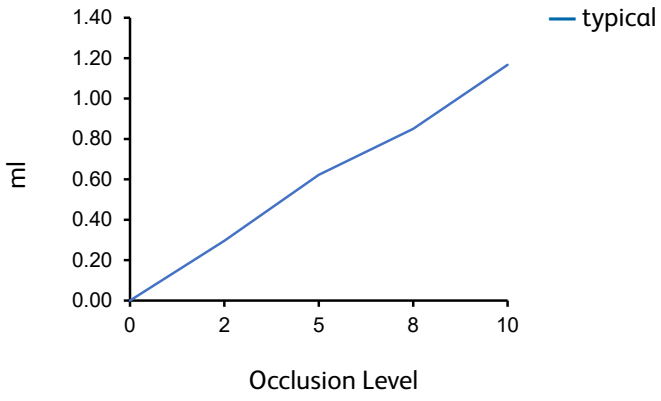
Time to alarm at 1.0 ml/h



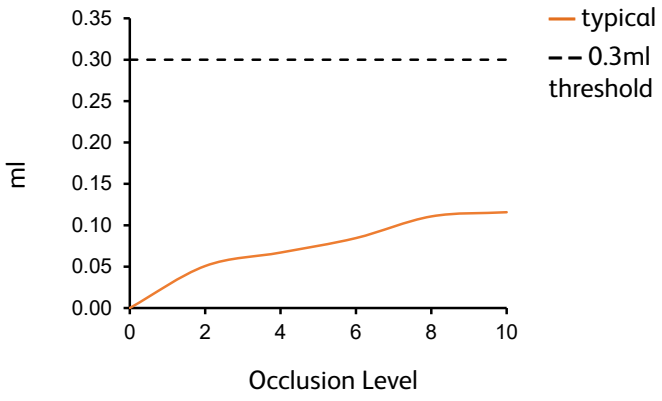
Time to alarm at 5.0 ml/h



Unintended bolus volume at 5.0ml/h back off disabled



Unintended bolus volume at 5.0ml/h back off enabled



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

Bolus volume following occlusion will be minimised by the back off feature if enabled. The back off will reduce the line pressure by removing the volume stored in the occluded line and deduct this volume from the volume infused. Back off will terminate if the pressure reaches the level recorded by the Pump when the infusion was last started, or a maximum back off volume has been withdrawn from the extension set. It will also terminate if the volume infused reaches 0.0ml, or a VTBI reaches the value at which it was set.

IrDA, RS232 and Nurse call Specification

IrDA / RS232 / Nurse call Feature

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

- **The nurse call interface provides a remote backup to the internal audible alarm. It should not be relied upon to replace monitoring of the internal alarm.**
- **The signal leaves the IrDA port and the RS232 for Nurse call within one second after the alarm condition is detected.**
- **Refer to the** *Technical Service Manual* **for further information regarding the RS232 interface.**
- **The assessment for the suitability of any software used in the clinical environment to control or 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. The protocol is detailed in the BD Alaris™ neXus CC Syringe Pump Communications Protocol and is for general information only.**
- **Any connected analogue and digital components are required to meet EN/IEC 60950 for data processing and EN/IEC 60601 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 EN/IEC 60601-1-1.**

IrDA

Item	Value
Baud Rate	115.2kBaud
Start Bits	1 start bit
Data Bits	8 data bits
Parity	No parity
Stop Bits	1 stop bit

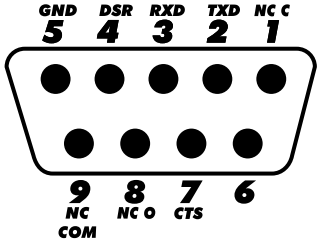
RS232 / Nurse call Connection Data

RS232 / Nurse call Specification

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

Typical Connection Data

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



Trumpet Curves and Start-up Curves

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

The following curves show typical performance of the system in two ways:

1. The delay in onset of fluid flow when infusion commences (start-up curves), and
2. The accuracy of fluid delivery over various time periods is measured (trumpet curves).

The start-up curves represent continuous flow versus operating time from the start of the infusion. They exhibit the delay in onset of delivery due to mechanical compliance and provide a visual representation of uniformity. Trumpet curves are derived from the second hour of this data. Tests performed per EN/IEC 60601-2-24 standard.

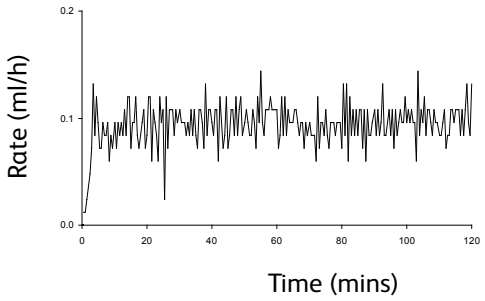
Trumpet curves are named for their characteristic shape. They display discrete data averaged over particular time periods or *observation windows*, not continuous data versus operating time. Over long observation windows, short term fluctuations have little effect on accuracy as represented by the flat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

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

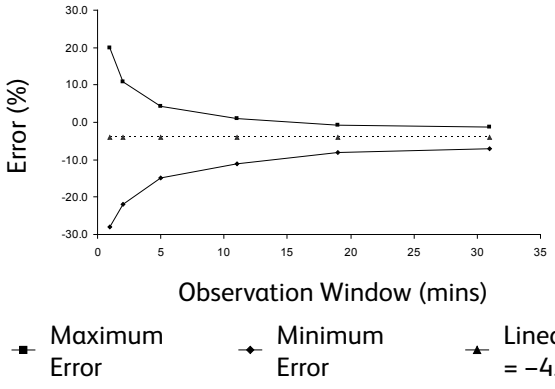
- **Start-up and trumpet curves may not be indicative of operation under negative pressure.**
- **Differences in factors such as size and plunger force in recognised syringes produced by other manufacturers can cause variations in accuracy and trumpet curves as compared to those represented. Additional curves for recognised syringes are available upon written request.**
- **For applications where flow uniformity is a concern, rates of 1.0ml/h or above are recommended.**

With a Pressure Extension Set fitted, G30402M – Standard disposable extension set

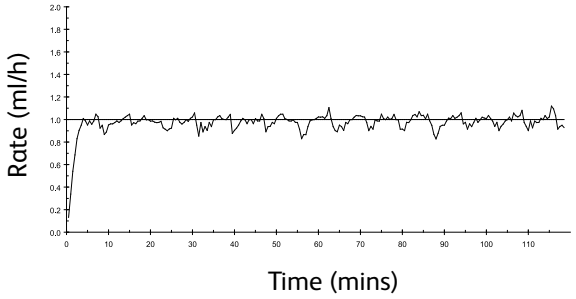
Start-up trend. BD Plastipak 5ml at 0.1ml/h



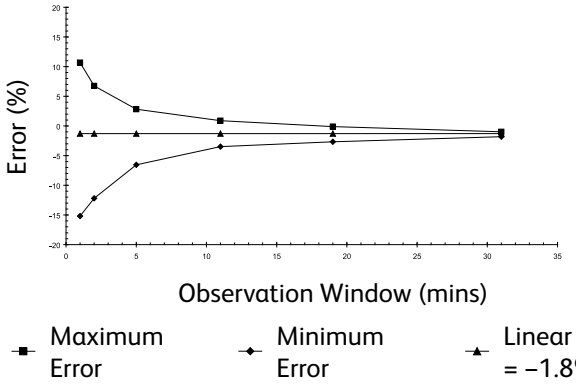
Trumpet curve. BD Plastipak 5ml at 0.1ml/h



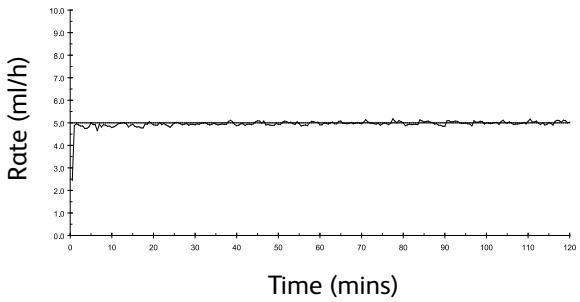
Start-up trend. BD Plastipak 50ml at 1.0ml/h



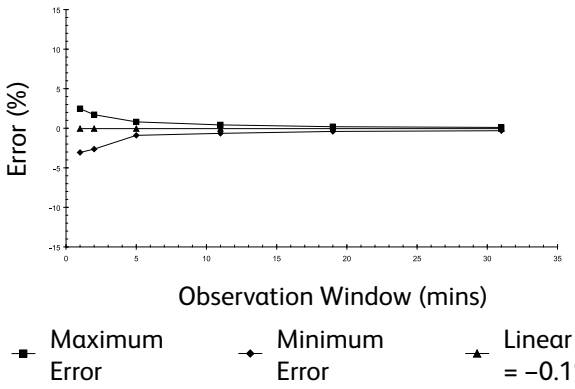
Trumpet curve. BD Plastipak 50ml at 1.0ml/h



Start-up trend. BD Plastipak 50ml at 5.0ml/h

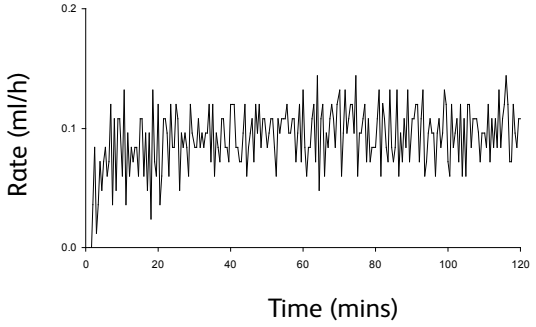


Trumpet curve. BD Plastipak 50ml at 5.0ml/h

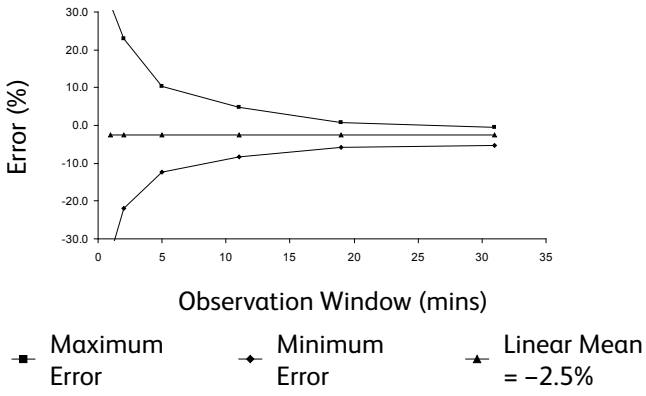


Without a Pressure Extension Set fitted, G40020B – Standard disposable extension set

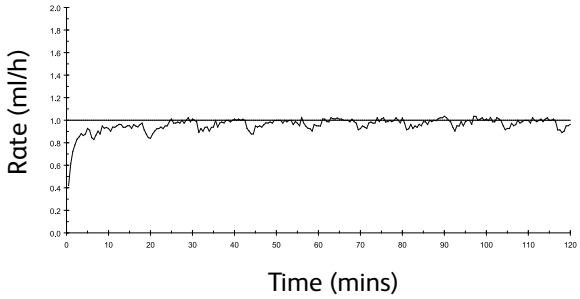
Start-up Trend. BD Plastipak 5ml at 0.1ml/h



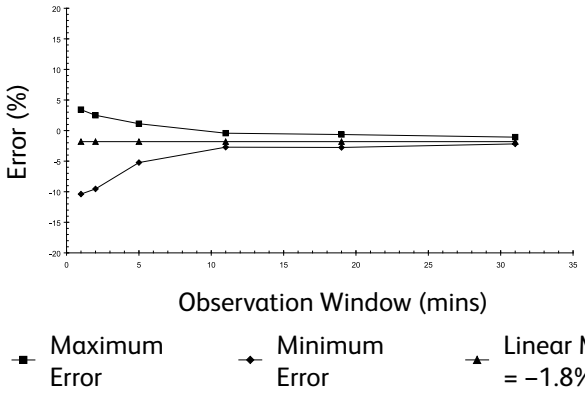
Trumpet Curve. BD Plastipak 5ml at 0.1ml/h



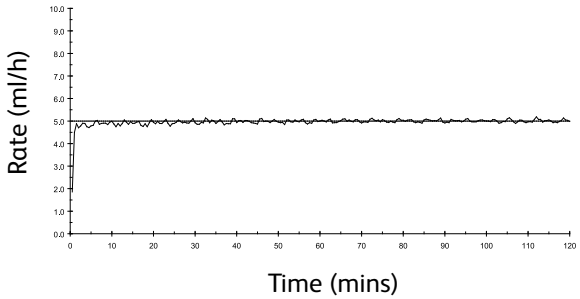
Start-up Trend. BD Plastipak 50 ml at 1.0 ml/h



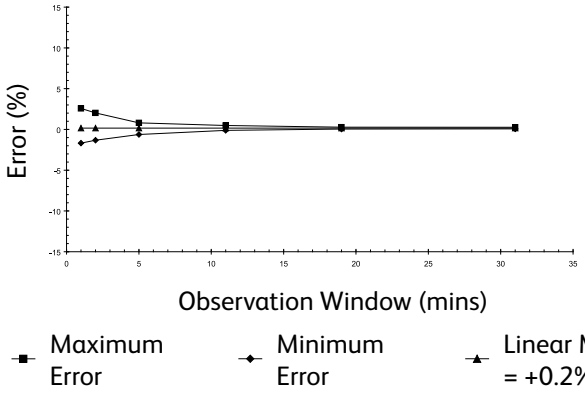
Trumpet Curve. BD Plastipak 50 ml at 1.0 ml/h



Start-up Trend. BD Plastipak 50 ml at 5.0 ml/h



Trumpet Curve. BD Plastipak 50 ml at 5.0 ml/h



Products and Spare Parts

Spare Parts and Accessories

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

The *Technical Service Manual* (BDTM00010) is now available in electronic format on the World Wide Web at bd.com/int-alaris-technical

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

Part Number	Description
1001FAOPT91	AC Power Lead – UK
1001FAOPT92	AC Power Lead – European
1000SP01798	Internal Battery Pack
1000SP01884	Lock box Accessory (Rate Un-Locked)
1000SP01885	Lock box Accessory (Rate Locked)

Software

Part Number	Description
1000SP02156	BD Alaris Communication Engine v2.0
1000SP02157	BD Alaris CQI Event Reporter v4.4
1000SP02158	BD Alaris Technical Utility v2.0
1000SP02159	BD Alaris neXus Editor v5.0

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For full contact information please refer to bd.com.

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Document History

Issue	Date	Software Version	Description
1	April 2020	5.0.x	Initial release
2	September 2020	5.0.x	Specifications
3	October 2020	5.0.x	Recognised Syringes
4	February 2021	5.0.x	Recognised Syringes

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