Alaris™ PK Plus Syringe Pump MK4

Model: 8005TIG03

Directions For Use

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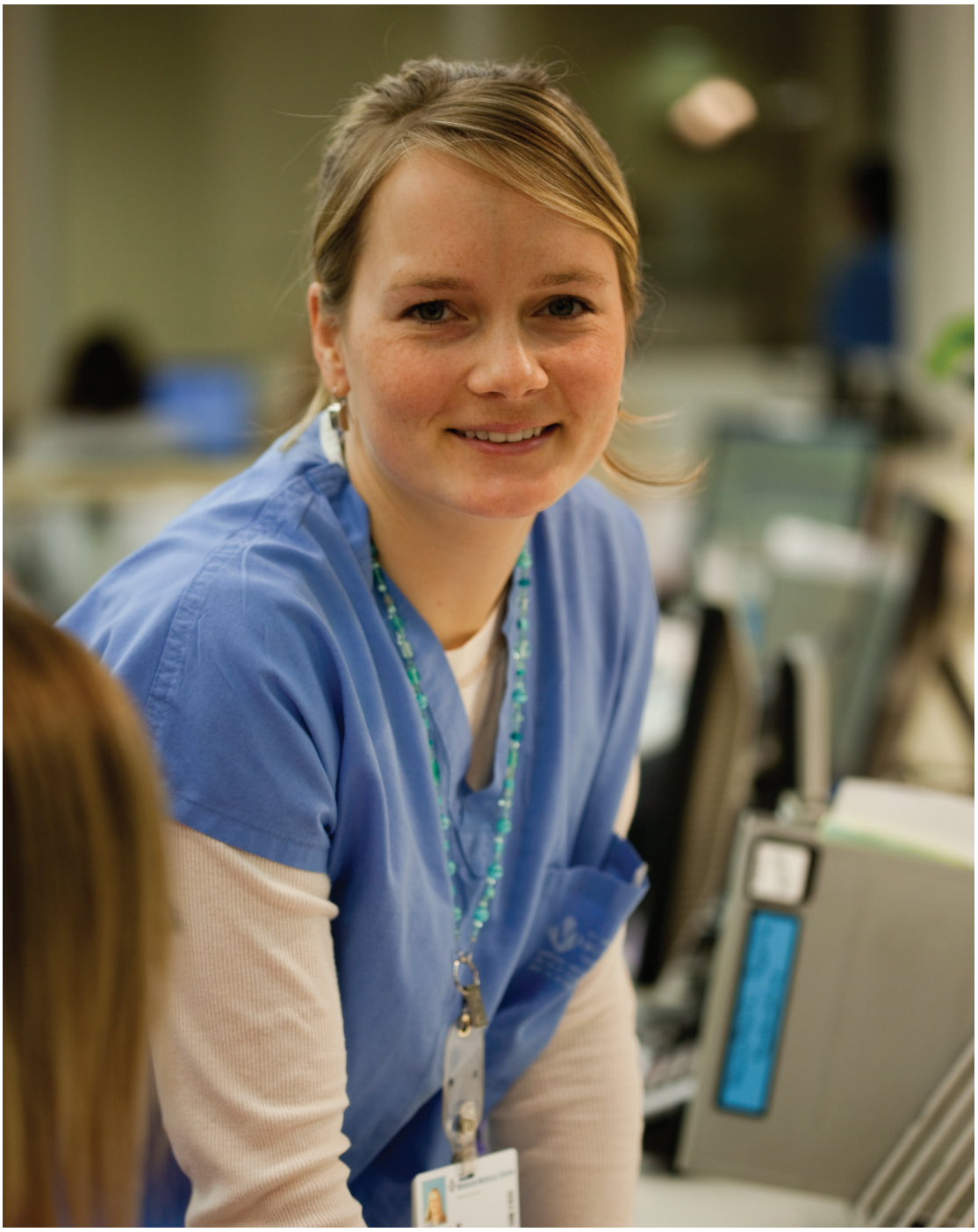

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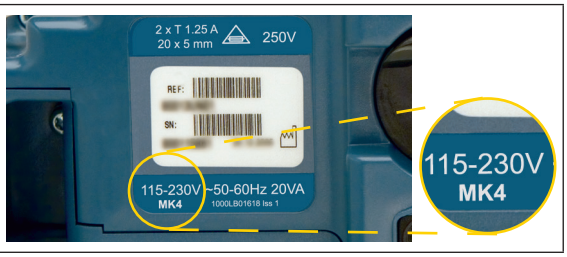
Introduction

This Directions for use can be used with the Alaris™ PK Plus Syringe Pump MK4.

The Pumps can be identified as MK4 version by the MK4 on the label on the rear case, see image right, or by verifying the software version as 3.4.x or above on power up.



The Alaris PK Plus Syringe Pump (hereinafter referred to as Pump) provides the user with an infusion tool for the administration of drugs for anaesthesia. The embedded software within the Pump is loaded with three compartment pharmacokinetic predictive models and has 4 modes of operation:

1. Continuous infusion (ml/h)
2. Total Intravenous Anaesthesia (TIVA) mode.
   - In this mode the user is able to select the infusion rate and administer bolus doses as required.
3. Total Intravenous Anaesthesia (TIVA) with TCI predictions mode.
   - In this mode the user is able to select the infusion rate and administer bolus doses as required. The pharmacokinetic model is used to estimate the plasma and effect site concentration.
4. TCI Mode
   - Plasma target-controlled infusion (TCI).
     - In this mode the user selects the desired (target) plasma drug concentration, and the pharmacokinetic model is used to calculate the infusion rates required to achieve that concentration. A graphic display shows the trajectory of the estimated plasma and effect site drug concentration over time.
   - Effect Site target-controlled infusion (TCI).
     - In this mode the user sets the desired effect site target concentration and the pharmacodynamic model is used to calculate the infusion rates required to achieve that concentration. A graphic display shows the trajectory of the estimated effect site and plasma concentration over time.

The Alaris PK Plus Syringe Pump has a user friendly interface that displays the infusion rate, the total drug dose delivered, and the estimated plasma and effect-site concentrations to enable the user to follow the drug prescription information from the relevant country.

Intended Purpose

The Alaris PK Plus Syringe Pump is intended for use by medical staff for purposes of controlling infusion rate and volume.

Conditions of Use

The Alaris PK Plus Syringe Pump should only be operated by a clinician competent in use of automated syringe pumps and post-placement management of intravenous catheters.

Use of the Alaris PK Plus Syringe Pump does not limit the responsibility of the anaesthetist for drugs administration. It is important that users operating the Alaris PK Plus Syringe Pump are fully aware of the available literature for any model used in association with a drug and that they refer to the prescribed information for rate and dosing limits. Pharmacokinetic and Pharmacodynamic Interactions among anaesthetic drugs are known, but are not taken into account in the calculation of the plasma and effect site concentrations.

The user should be appropriately trained in the use of the Pump and should follow the recommendations of this Direction For Use (DFU).

In particular, the user must be aware that starting the Pump in a TCI mode will result in the automatic infusion of a pre-calculated bolus dose followed by an infusion to achieve the selected target concentration. The initial parameter calculations are displayed on screen prior to starting the infusion. It is thus essential that the user verifies that the patient characteristics and the selected infusion rate or target concentration conform with the drug prescribing information of the relevant country.

BD has verified the accuracy of the mathematical model implementation as well as pump delivery accuracy - (specification and accuracy of pump - delivery are available in 'Profiles from TCI Mode' section).

Different drugs are associated with dedicated models – each model consists of a set of standard pharmacokinetic parameters which can be selected and used by the embedded 3 compartment model used in the Alaris PK Plus Syringe Pump (where use of that drug in TCI mode is authorised);

Diprivan from ASTRA-ZENECA is the only recommended Propofol formulation to be used in TCI mode as per prescribing information. This Pump includes the Marsh model for the calculation of the Diprivan infusion rates, and plasma and effect-site concentrations.

When Remifentanil and Sufentanil are used in TCI mode, – the Minto and Gepts models respectively – are used to calculate the required infusion rates.

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

Indications

The Alaris PK Plus Syringe Pump is indicated for the administration of drugs for anaesthesia

Contraindications

The Alaris PK Plus Syringe Pumps are contraindicated for:

- enteral therapies
- epidural infusion therapies

About This Manual

The user must be thoroughly familiar with the Alaris PK Plus Syringe 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. Where stated, a minimum infusion rate refers to a nominal rate of 1.0ml/h, and an intermediate infusion rate refers to a nominal rate of 5.0ml/h. The complete range of infusion rates, settings and values are shown in the 'Specifications' section.

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

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

Conventions used in this manual

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

TCI Overview

The dose-response relationship can be divided into three parts: the relationship between administered dose and plasma concentration (the pharmacokinetic phase), the relationship between effect organ concentration and clinical effect (the pharmacodynamic phase) and the coupling between pharmacokinetics and dynamics. The ultimate goal when administering a particular dose of a drug is to obtain the desired clinical effect, for which a specific therapeutic concentration of the drug at the site of action (the receptor) is necessary.

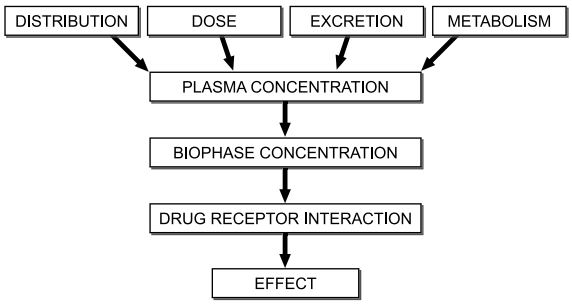


Fig. 1: Schematic representation of the pharmacokinetic and dynamic processes determining the relationship between administered dose and resulting effect intensity of a drug. Pharmacokinetic factors such as distribution, metabolism, and/or excretion determine the relationship between drug dose and drug-concentration in the plasma and bio-phase (effect-site). In the bio-phase the drug interacts with the receptor resulting in the pharmacological effect.[1]

Until recently, when intravenous anaesthetic agents were used for induction or maintenance of anaesthesia, they were administered either manually (by hand) or by simple infusion pumps (the anaesthetist calculated the infusion according to the body weight of the patient). Inline measurement of concentrations is not possible, and the polyexponential equations required to predict the concentrations requires vast computer processing power. Based on the pioneering work of Kruger-Thiemer[2] and Schwilden et al.[3], the TCI concept was developed during the 1980's and early 1990's, as advances in computer technology made inline predictions of drug concentrations feasible.

The pharmacokinetic behaviour of most anaesthetic drugs can be described mathematically with a 3-compartment model: usually a central compartment (V1), a vessel-rich compartment (V2) and a vessel-poor compartment (V3) are described. Transfer of drug between different compartments (distribution) is described by rate constants (k_{12}, k_{21}, k_{31} and k_{13}) or clearances. Drug metabolism is described by the rate constant k_{10} (Fig. 2). The aim of TCI techniques is to use pharmacokinetic modelling to calculate the infusion rates required to achieve a desired plasma concentration. Thus, instead of specifying an infusion rate, the user specifies a "target" concentration, based on clinical judgement. When a concentration in the plasma compartment is targeted, this is called "open-loop plasma targeted TCI". When a certain concentration at the effect compartment is targeted, then this is called "open-loop effect-site targeted TCI".

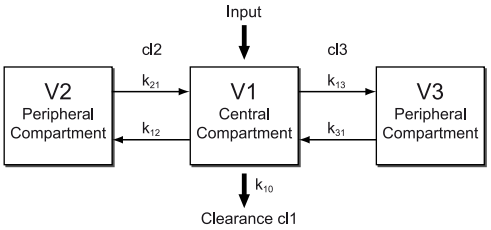


Fig. 2: Schematic representation of the three compartment model used for target-controlled infusions.

For anaesthetic agents the effect-site (or bio-phase) is not the plasma[4] but the brain, where concentrations cannot be directly measured. Until the early 1990's it was considered that blood-brain equilibration was virtually instantaneous. Early TCI systems were thus all plasma-targeted. For many drugs the relationship between plasma concentration and clinical effect was described, usually in terms of the Cp50 or Cp95 (the concentrations required to elicit a specified clinical effect in 50 or 95% of patients respectively). For an example see Ausems et al.[5]

During the 1990's it was increasingly appreciated that after a change in plasma concentration there is a temporal delay in equilibration between the plasma and effect-site concentrations. The clinical effect changes in parallel with the effect-site concentration, and so for most drugs the rate of drug transfer into and from the site of action can be characterized by the time-course of drug effect[6,7]. This means that the effect can be transferred to concentrations, thereby resulting in a quantitative approach. The concentration at the site of action is called "the effect-site concentration" and the corresponding compartment[8] (see Fig. 3) is called "the effect-site compartment". Because the actual amount of drug entering the brain is very small, the effect-site compartment can be regarded as having no volume, the rate constant k_{1e} can be ignored and the rate constant k_{eo} can be used to describe the rate of equilibration between the plasma and effect-site compartments.

Knowledge of the k_{eo} for various agents has made targeting of the effect-site possible. With effect-site targeting the TCI system first calculates the necessary plasma concentration profile required to achieve the effect-site target as rapidly as possible, and then calculates the infusion rates required to achieve that plasma concentration profile (Fig 3). Effect Site vs Plasma Concentration will generate a larger induction dose followed by a pause in the infusion to allow plasma to equilibrate with effect site concentration.

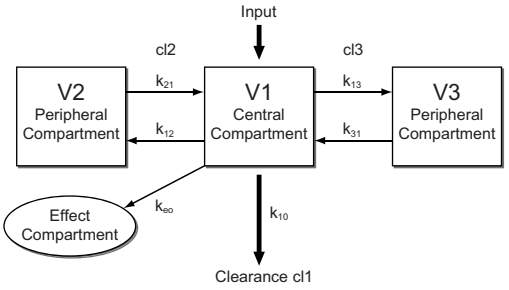


Fig. 3: Schematic representation of the concentration-effect relationship.

TCI infusion pumps can provide optimal control of anaesthesia when the three elements mentioned above have been accurately modelled and described. Firstly, the model that controls the Pump has to work accurately (The models used in the Alaris PK Plus Syringe Pump are well-validated and accepted). Secondly, the pharmacokinetic parameter set of a particular drug used by the computer model should match the pharmacokinetics of the patient (it should be remembered that the models described in the literature are based on "population" data, and apply to an "average" patient. They do not take account of the inter-patient pharmacokinetic variability). Thirdly, the pharmacodynamics of the administered drug should be well understood to enable the user to select the plasma or effect-site concentration needed for the required effect (with most anaesthetic agents there is broad inter-patient pharmacodynamic variability, and so the user needs to match knowledge of the general population pharmacodynamic data with careful observation of the individual patient to ascertain that individual's sensitivity to the drug, to enable titration to effect if necessary).

Note: Specific model parameters are available in the "TCI Overview" section or directly on the Pump via the information key when selecting drugs. Users should refer to the drug- prescribing information to verify that TCI mode is authorised in their respective countries.

References :

1. Danhof M: Does variability explain (all) variability in drug effects ?, Topics in pharmaceutical science. Edited by Breimer DD, Crommelin DJA, Midha KK. Noordwijk, Amsterdam Med. Press BV, 1989, pp 573-586
2. Kruger-Theimer E: Continuous intravenous infusion and multicompartment accumulation. Eur J Pharmacol 1968; 4: 317-324
3. Schwilden H: A general method for calculating the dosage scheme in linear pharmacokinetics. Eur J Clin Pharmacol 1981; 20: 379-86
4. Shafer SL: Towards optimal intravenous dosing strategies. Seminars in Anesthesia 1993; 12: 222-234
5. Ausems ME, Hug CC, Jr., Stanski DR, Burm AG: Plasma concentrations of alfentanil required to supplement nitrous oxide anesthesia for general surgery. Anesthesiology 1986; 65: 362-73
6. Schnider TW, Minto CF, Stanski DR: The effect compartment concept in pharmacodynamic modelling. Anaesthetic Pharmacology Review 1994; 2: 204-213
7. Shafer SL: Principles of pharmacokinetics and pharmacodynamics., Principles and practice of anesthesiology. 2nd Edition. Edited by Longnecker DE, Tinker JH, Morgan GE. New York, Mosby-Year Book, 1998, pp 1159- 1210
8. Shafer SL, Gregg KM: Algorithms to rapidly achieve and maintain stable drug concentrations at the site of drug effect with a computer-controlled infusion pump. J Pharmacokinet Biopharm 1992; 20: 147-69

TCI Precautions

When first starting the infusion the pharmacokinetic / pharmacodynamic models within the Alaris PK Plus Syringe Pump are reset to zero. Therefore, for any reason, if the Pump is switched off during the surgical procedure all current pharmacokinetic / pharmacodynamic model information will be lost. Under such circumstances switching the Pump off and on and restarting the infusion whilst the patient contains a significant residual drug dose could result in an over-infusion and, therefore, the Pump should not be restarted in TCI mode.

Pharmacokinetic models in Alaris PK Plus Syringe Pump and their parameters

Drug: Diprivan Model: Marsh (weight adjusted)
Age Limit: 16 years upwards
Unit of Plasma Concentration: µg/ml
Max. Plasma Concentration: 15 µg/ml
Vc = 0.228 x mass (litres x kg^{-1})
k_{10} = 0.119 $minutes^{-1}$
k_{12} = 0.112 $minutes^{-1}$
k_{13} = 0.0419 $minutes^{-1}$
k_{21} = 0.055 $minutes^{-1}$
k_{31} = 0.0033 $minutes^{-1}$
k_{eo} = 0.26 $minutes^{-1}$
Reference from the literature: Marsh et al.: Brit J Anaesth 1991, 67, 41-48

Drug : Remifentanil Model: Minto
Age Limit: 12 years upwards
Unit of Plasma Concentration: ng/ml
Max. Plasma concentration: 20 ng/ml
Vc = 5.1 - 0.0201 x (age-40) + 0.072 x (lbm-55)
V2 = 9.82 - 0.0811 x (age-40) + 0.108 x (lbm-55)
V3 = 5.42
cl1 = 2.6 - 0.0162 x (age - 40) + 0.0191 x (lbm - 55)
cl2 = 2.05 - 0.0301 x (age - 40)
cl3 = 0.076 - 0.00113 x (age - 40)
k_{10} = cl1 / Vc
k_{12} = cl2 / Vc
k_{13} = cl3 / Vc
k_{21} = cl2 / V2
k_{31} = cl3 / V3
k_{eo} = 0.595 - 0.007 x (age - 40)
Reference from the literature : Minto et al.: Anesthesiology 1997, 86, 10 - 33

Drug : Sufentanil Model: Gepts (not weight adjusted)
Age Limit: 12 years upwards
Unit of Plasma Concentration: ng/ml
Max. Plasma concentration: 2 ng/ml
Vc = 14.3 l
k_{10} = 0.0645 $minutes^{-1}$
k_{12} = 0.1086 $minutes^{-1}$
k_{13} = 0.0229 $minutes^{-1}$
k_{21} = 0.0245 $minutes^{-1}$
k_{31} = 0.0013 $minutes^{-1}$
Reference from the literature : Gepts et al.: Anesthesiology 1995, 83, 1194-1204

Additional :
k_{eo} calculated with time to peak effect 5.6 minutes (k_{eo} = 0.17559 $minutes^{-1}$) (reference: Shafer et al Anesthesiology. 1991 Jan;74(1):53-63)

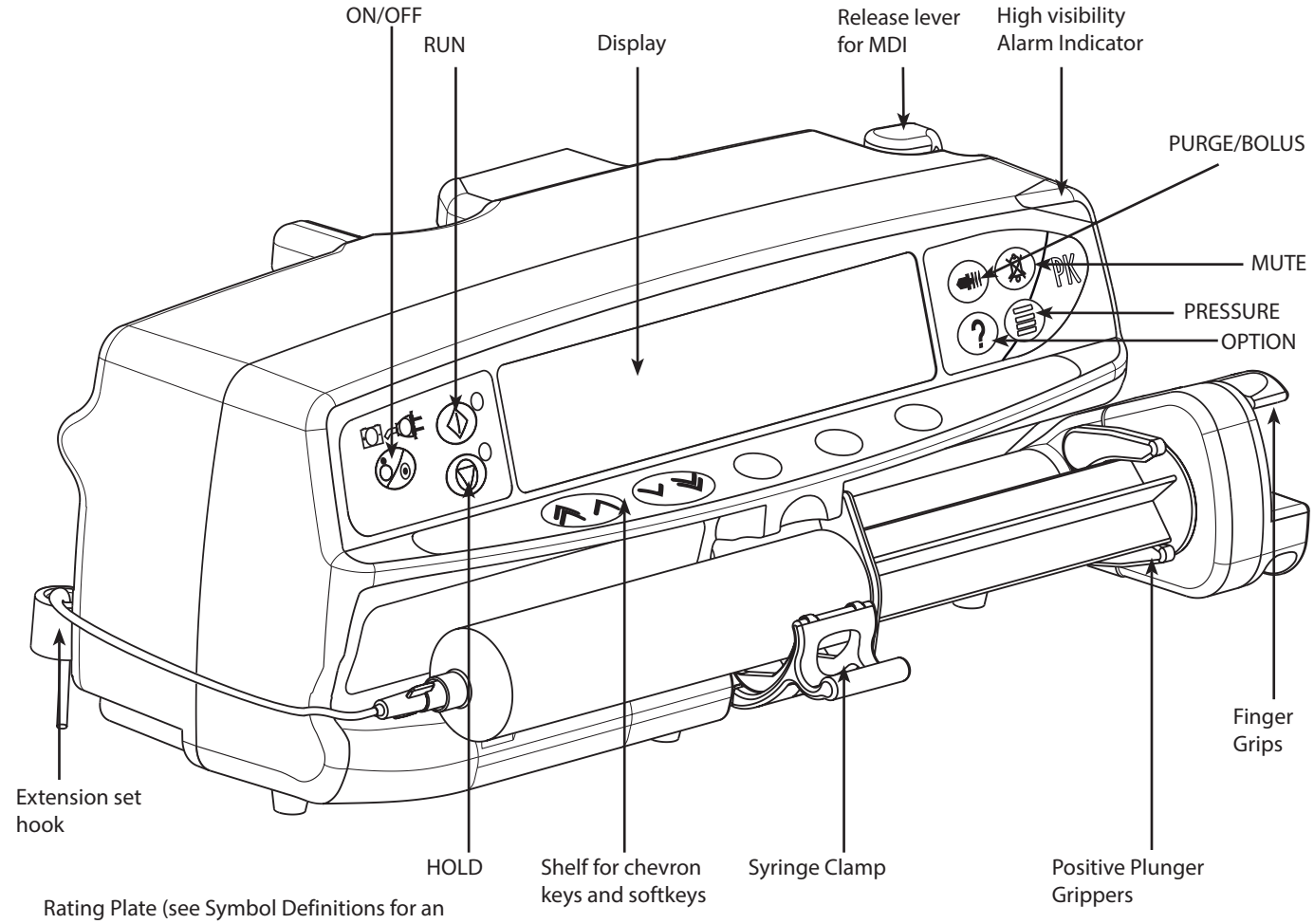
Creating a Data Set

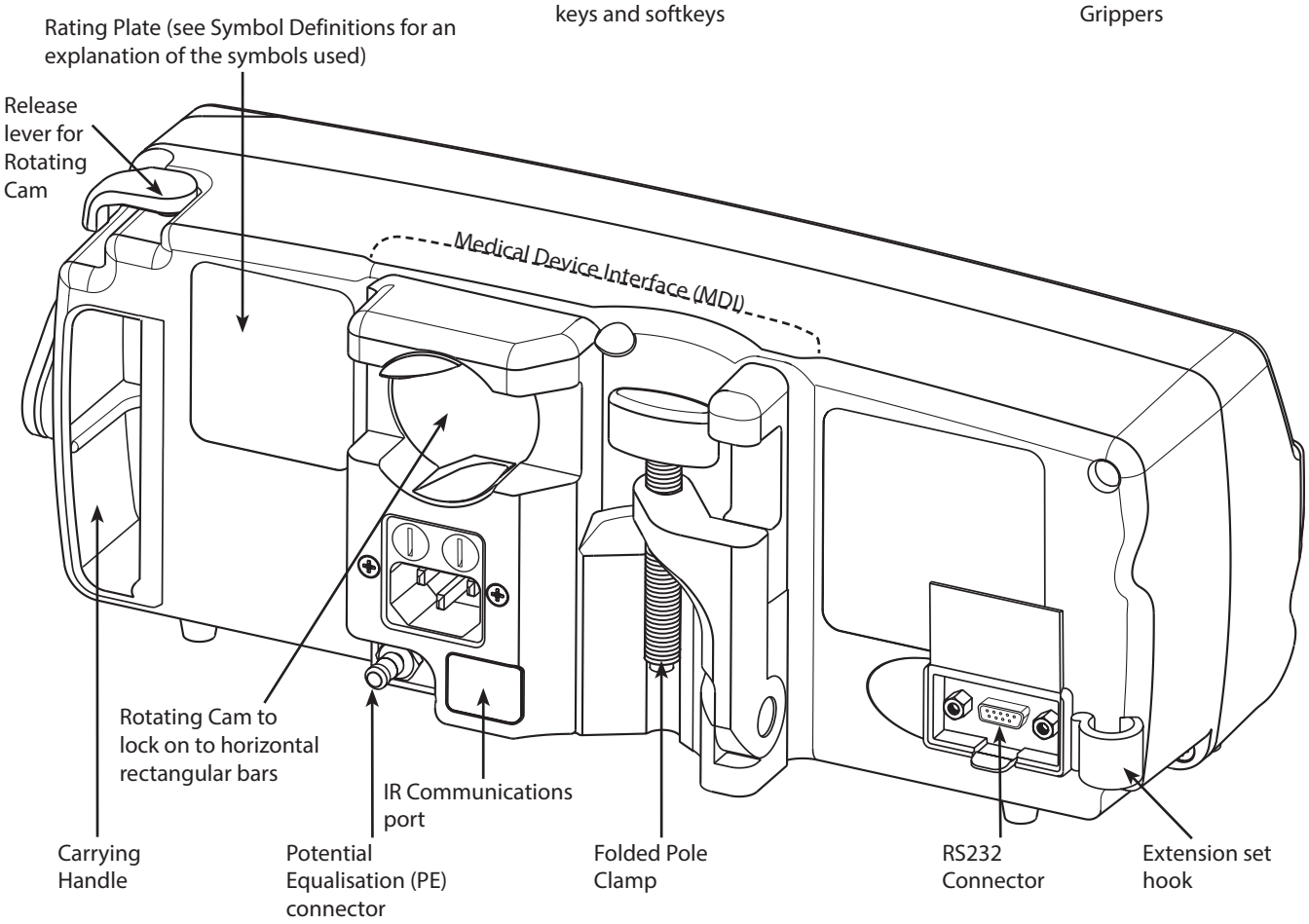
To fully utilise the Alaris PK Plus Syringe Pump a Data Set will need to be developed, reviewed, approved, released, uploaded and verified according to the following process. Refer to the Alaris PK Editor Software Directions for Use (1000CH00016) for further details and operating precautions.

1. Create Master Lists (Using Alaris PK Editor Software)
   - Master Drugs* — A list of drug names and standard concentrations. These may be for TIVA use or may have an associated PK/PD model for TCI use.
   - Alaris PK Syringe Library — Configure syringes enabled for use
2. Create Profile (Using Alaris PK Editor Software)
   - Profile Drugs* — Drugs and concentrations for this profile with defaults, minimum and maximum limits and targets and occlusion level.
   - Pump Configuration** — Pump configuration settings and general options.
3. Review, Approve and Release (Using Alaris PK Editor Software)
   - Review and Approve — Entire Data Set Report to be printed, reviewed and signed as proof of approval by an authorised person according to Hospital protocol. Signed printout to be kept safe for use during verification procedure.
   - Release — Data Set status to be promoted to Released (password is required).
4. Upload Data Set to Alaris PK Plus Syringe Pump (Using Alaris PK Editor Transfer Tool)
5. Verify Data Set Upload
   - First or Individual Pump Verification — On completion of upload record CRC (Cyclic Redundancy Check) number shown on the Alaris PK Plus Syringe Pump.
     Download the Data Set from the Pump using the Alaris PK Verification Tool.
     Compare Data Set downloaded with the approved signed Data Set printout. Reviewer should sign the printout and also record the CRC number on the printout as record.
   - Subsequent Pump Verification — On subsequent uploads of the Data Set compare CRC number on the Pump with CRC number recorded on First Pump Verification.
6. Switch the Pump on and verify that the start-up splash screen displays the correct data set name and version. The Pump is now ready to use.

***Drug parameters have to be in accordance to local protocols and prescribed information.**
Data set transfers should only be performed by qualified technical personnel.
**** See important note in Configured Options section.**

Features of the Pump





Controls and Indicators

Controls:

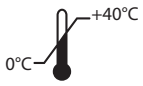
Symbol	Description
	**ON/OFF** button - Press once to switch the Pump on. Press and hold down for 3 seconds to switch the Pump off. **Note:** Pump can only be switched off at specific stages of operation, see 'Power Down Sequence' section in Configured Options for further details. **Note:** Logs are 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: – The two minutes silence can be configured using the Alaris PK Editor Software. – when not in alarm press and hold until four audible beeps are sounded for 60 minutes silence
	**PURGE/BOLUS** button - Press to access **PURGE** or **BOLUS** softkeys. Press and hold down softkey to operate. **PURGE** the extension set during 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 is connected to the patient • VI is added
	**OPTION** button - Press to access optional features, see 'Basic Features' section.
	**PRESSURE** button - Use this button to display the pumping pressure and alarm level.
	**CHEVRON** keys - Double or single for faster/slower increase or decrease of values shown on display.
	**BLANK SOFTKEYS** - Use in conjunction with the prompts shown on the display.

Indicators:

Symbol	Description
	**BATTERY** indicator - When illuminated the 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.

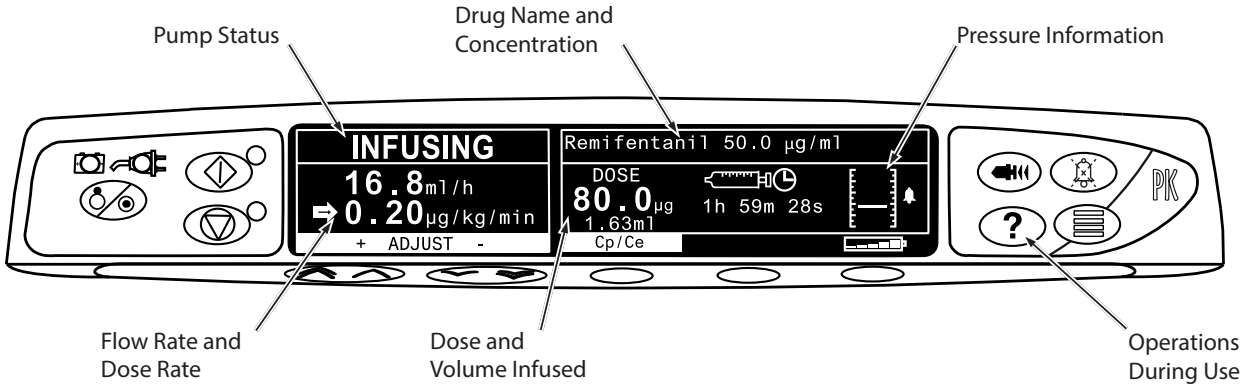
Symbol Definitions

Labelling Symbols:

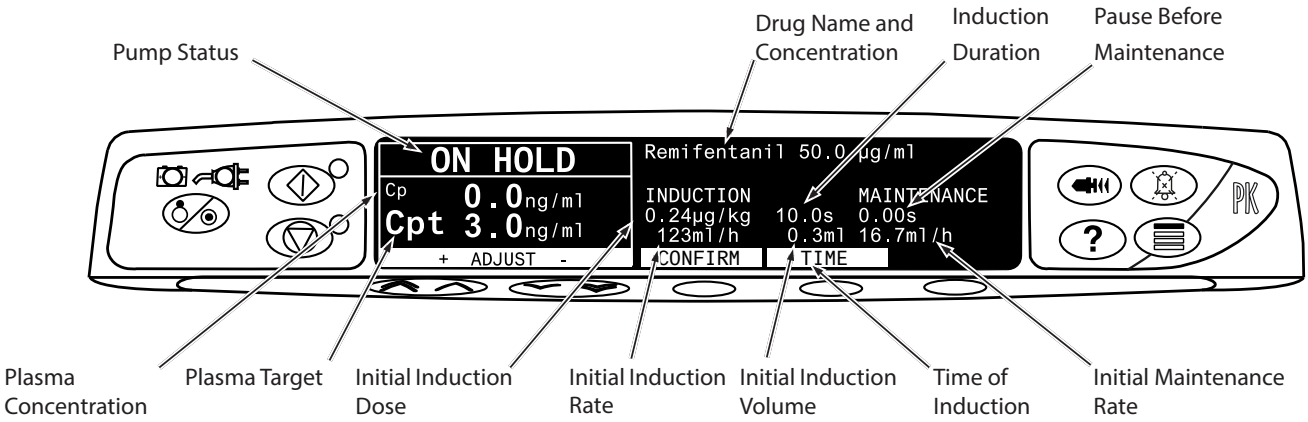
Symbol	Description
	Consult accompanying documents.
	Potential Equalisation (PE) Connector
	RS232/Nurse call Connector
	Defibrillation-proof type CF applied part (Degree of protection against electrical shock)
IP32	Protected against direct sprays of water up to 15° from vertical and protected against solid objects greater than 2.5mm. **Note:** IP33 applies if AC power cable retainer kit, part number 1000SP01294, is fitted.
	Alternating Current
CE 2797	Device complies with the requirements of Council Directive 93/42/EEC as amended by 2007/47/EC.
	Date of Manufacture
	Manufacturer
	Not for Municipal Waste
	Fuse Rating
	Protective Earth; Protective Ground
	Operating Temperature Range - Pump can be used between 0 and 40 degrees centigrade.

Main Display Features

TIVA Mode

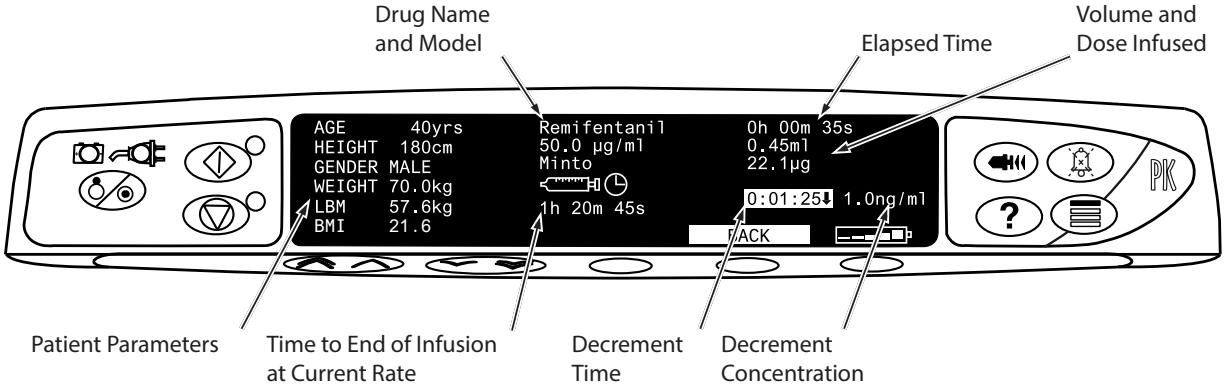


TCI Mode



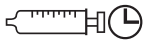
TCI Mode - **MORE** *Information Screen*

Selecting the **MORE** softkey will display the following additional information:



Press the **BACK** softkey to return to the TCI screen. The display will automatically revert to the TCI screen after approximately 20 seconds.

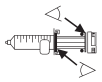
Screen Icons

Symbol	Description
	**TIME REMAINING DISPLAY** icon - Indicates time before syringe will require replacing.
	**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 Alaris Editor software
	**Induction Phase Dose** (Displayed on protocol confirmation screen)
	**Duration of Induction Phase** (Displayed on protocol confirmation screen)
	**Duration of Hands Free Bolus** (Displayed in bolus set-up screen)
	**Maintenance Phase Dose Rate** (Displayed on protocol confirmation screen)
	**SOFT ALERT** - Indicates the Pump is running at a rate above (pointing up) or below (pointing down) a Soft Alert. (Number of arrows vary depending on drug name length)
	**LIMIT WARNING** - Indicates the setting entered is under or exceeds a Soft Alert or setting entered is not permitted as it exceeds a Hard Limit.
	**DOWN MODE** - Infusion status indicating that the target concentration is below current concentration.

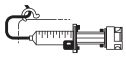
Operating Precautions

Disposable Syringes and Extension Sets

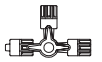
- The Pump has been calibrated for use with single-use disposable syringes. To best ensure correct and accurate operation, only use 3 piece Luer lock versions of the syringe make specified on the Pump or described in this manual. Use of non-specified syringes or extension sets may impair the operation 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.



- 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 intensive care and operating rooms. The pump may be used in an ambulance environment. Ensure that the Pump is appropriately attached using the provided pole clamp. The pump is designed to withstand possible bumps and vibrations whilst being used in an ambulance, complying with the standard EN 1789. If the Pump is dropped or experiences any severe physical disturbances, arrange a thorough inspection by Qualified Service Personnel as soon as is practically possible. The Pump may be used as long as the temperature is within the specified range as stated in the 'Specifications' section and on the Pump label.
- When using any infusion pump in conjunction with other pumps or devices requiring vascular access, extra care is 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 don't 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.
- The embedded Pump software incorporates limits and Pump configuration parameters. Qualified personnel must ensure the appropriateness of the limits, the compatibility of the drugs, and the performance of each Pump, as part of the overall infusion. Potential hazards include drug interactions, and inappropriate delivery rates and pressure alarms.
- Alaris Syringe Pumps should not be modified or altered in any way, except where explicitly directed or authorised by BD. Any use of Alaris Syringe Pumps which have been altered or modified otherwise than in strict application of directions provided by BD, is at your sole risk, and BD does not provide any warranty for or endorsement on any Alaris Syringe Pump that has been so modified or altered. BD product warranty shall not apply in the event the Alaris Syringe Pump has suffered damage or premature wear, or malfunctions or otherwise operates incorrectly, as a result of unauthorised modification or alteration of the Alaris Syringe Pump.

- All pumps in a single care area should be configured with the same alarm tones to avoid User confusion.

Electromagnetic Compatibility and Interference

- The Pump is protected against the effects of external interference, including high energy radio frequency emissions, magnetic fields and electrostatic discharge (for example, as generated by electrosurgical and cauterising equipment, large motors, portable radios, cellular telephones etc.) and is designed to remain safe when unreasonable levels of interference are encountered.
- Therapeutic Radiation Equipment: Do not use the Pump in the vicinity of any Therapeutic Radiation Equipment. Levels of radiation generated by the radiation therapy equipment such as Linear Accelerator, may severely affect functioning of the Pump. Please consult manufacturer's recommendations for safe distance and other precautionary requirements. For further information, please contact your local BD representative.

- Magnetic Resonance Imaging (MRI): The Pump contains ferromagnetic materials which are susceptible to interference with magnetic field generated by the MRI devices. Therefore, the Pump is not considered an MRI compatible pump as such. If use of the Pump within an MRI environment is unavoidable, then BD highly recommends securing the Pump at a safe distance from the magnetic field outside the identified 'Controlled Access Area' in order to evade any magnetic interference to the Pump; or MRI image distortion. This safe distance should be established in accordance with the manufacturer's recommendations regarding electromagnetic interference (EMI). For further information, please refer to the product *Technical Service Manual* (TSM). Alternatively, contact your local BD representative for further guidance.
- Accessories: Do not use any non-recommended accessory with the Pump. The Pump is tested and compliant with the relevant EMC claims only with the recommended accessories. Use of any accessory, transducer or cable other than those specified by BD may result in increased emissions or decreased pump immunity.
- This Pump is a CISPR 11 Group 1 Class A device and uses RF energy only for its internal function in the normal product offering. Therefore, its RF emissions are very low and are not likely to cause any interference with the nearby electronic equipment. However, this Pump emits a certain level of electromagnetic radiation which is within the levels specified by IEC/EN60601-1-2 and IEC/EN60601-2-24. If the Pump interacts with other equipment, measures should be taken to minimise the effects, for instance by repositioning or relocation.

- In some circumstances the Pump may be affected by an electrostatic discharge through air at levels close to or above 15kv; or by radio frequency radiation close to or above 10v/m. If the Pump is affected by this external interference the Pump will remain in a safe mode; the Pump will duly stop the infusion and alert the user by generating a combination of visual and audible alarms. Should any encountered alarm condition persist even after user intervention, it is recommended to replace that particular Pump and quarantine the Pump for the attention of Qualified Service Personnel. (Consult Technical Service Manual for further information).

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:
   - Alaris PK Plus Syringe Pump
   - User Support CD (Directions For Use)
   - Electronic Instructions For Use Insert
   - 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 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.**

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.

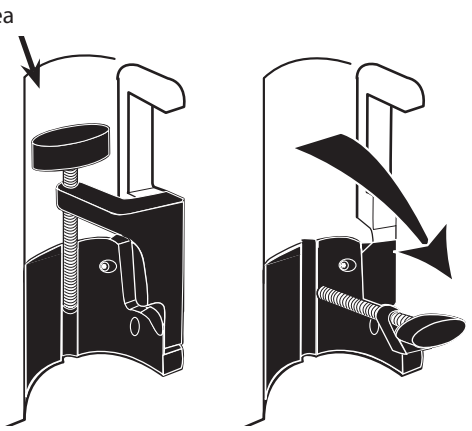
Pole Clamp Installation

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

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

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

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



Prior to each use, check the pole clamp:

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

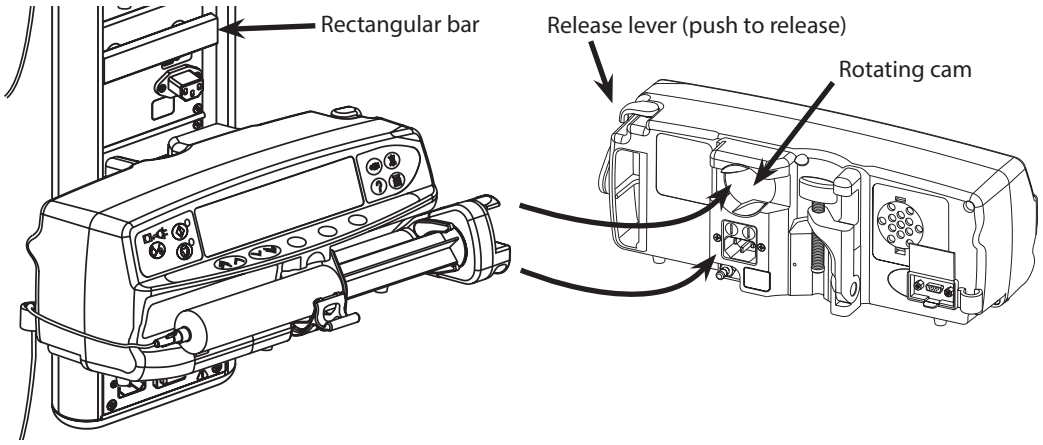
If these signs are observed, the Pumps should be taken out of service for examination by Qualified Service Personnel.

Docking Station/Workstation or Equipment Rail Installation*

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

1. Align the rotating cam on the rear of the Pump with the rectangular bar on the Docking Station/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 Docking Station/Workstation* without using the release lever. When the Pump is securely attached, it should not come off the Docking Station/Workstation*.
5. To release, push the release lever and pull the Pump forwards.

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



* Alaris Gateway Workstation and Alaris DS Docking Station

Syringe Loading

Prepare Syringe and Administration Set

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

- Use smallest syringe size possible, for example, if infusing 9 ml of fluid, use a 10 ml syringe.
- Use the **PURGE SYRINGE** or **PURGE** option on the Pump to decrease the delay in the start of the infusion, see *Starting the Pump* section.

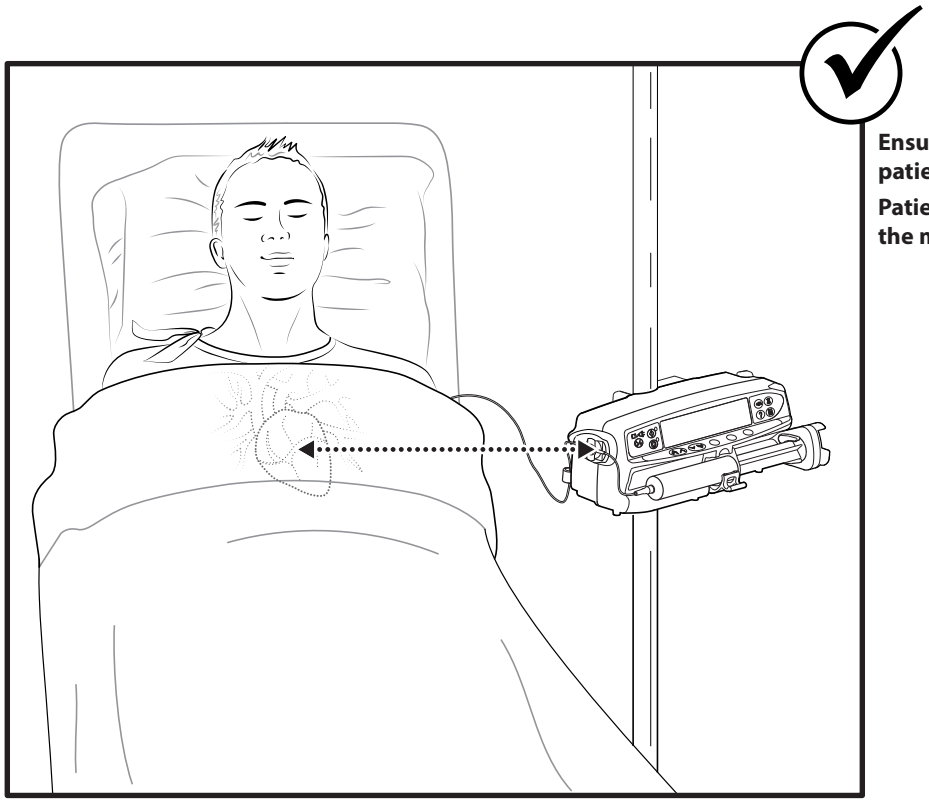
Use the smallest compatible syringe size necessary to deliver the fluid or medication; this is especially important when infusing high risk or life-sustaining medications at low infusion rates, especially flow rates < 0.5 ml/h.

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 middle of the Pump.

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.

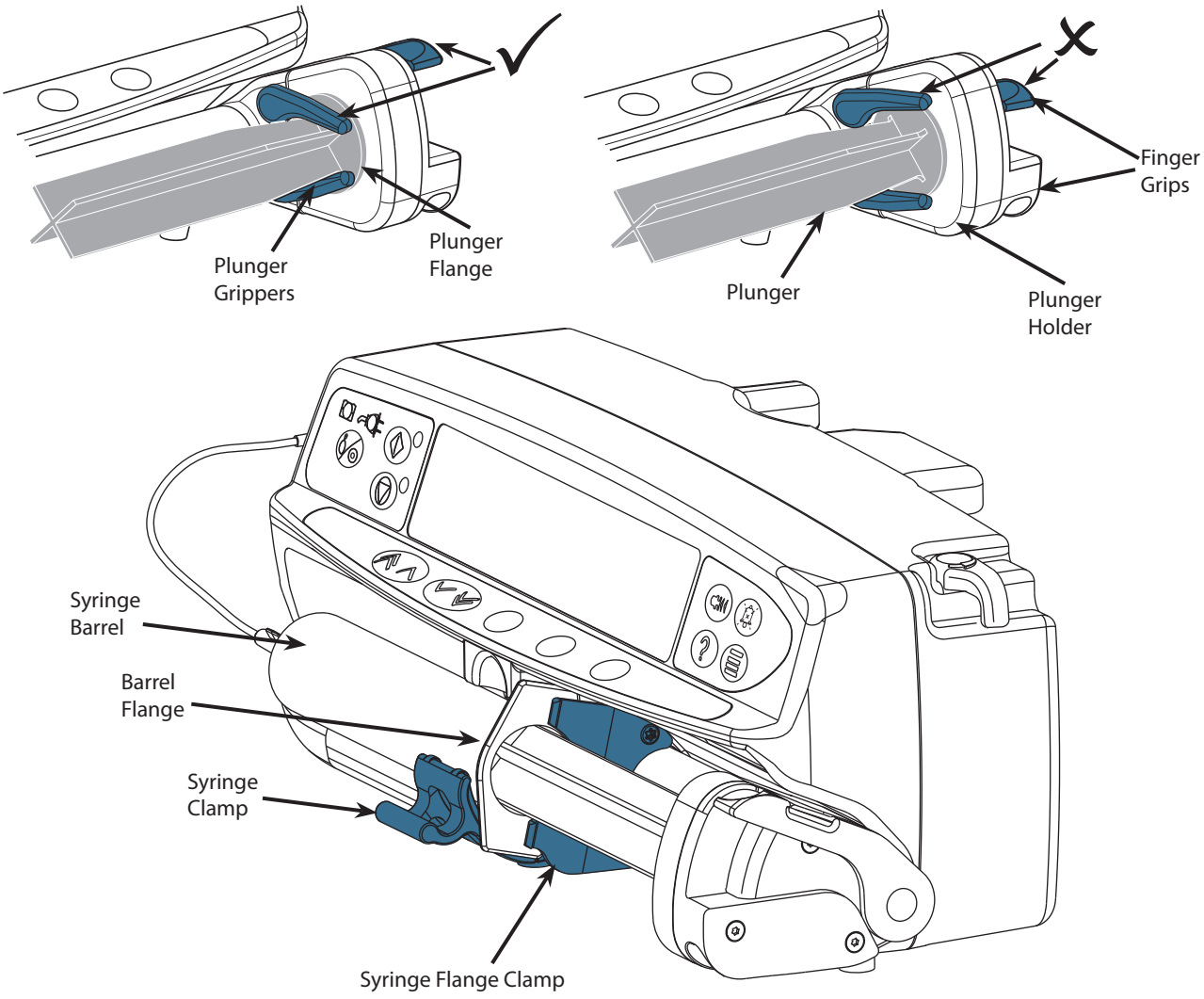
When infusing multiple high risk or life-sustaining medications, consider placing the Pumps infusing at the lowest rates as close to the level of the patient's heart as possible.

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.

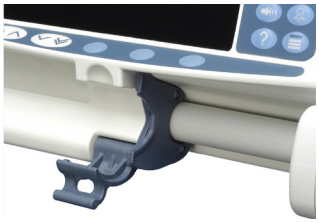
When drawing fluid into the syringe, draw enough to compensate for any 'dead space' volume in the extension set and syringe at the end of infusion as this cannot be fully infused.



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.

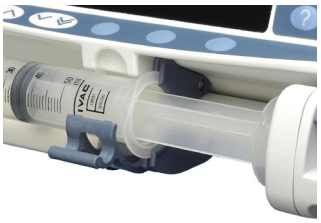
1. Squeeze the finger grips together on the plunger holder and slide the mechanism to the right.
2. Pull the syringe clamp forward and down.



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

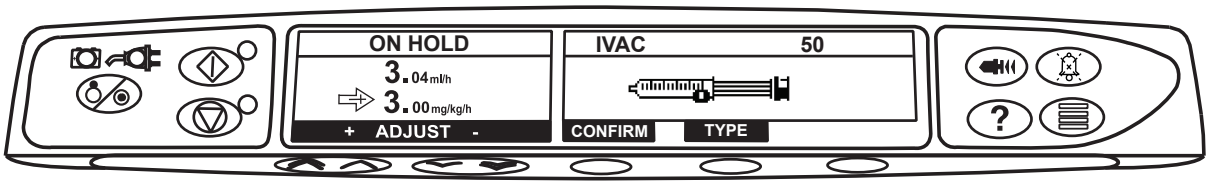
To ensure the syringe is loaded correctly, place the barrel flange in the space between the syringe clamp and the syringe flange clamp. This is correct if the syringe remains in position before the syringe clamp is closed.

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 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.**

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.

Starting 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 coloured rows are missing.
   - Finally check that the displayed time and date are correct.

   Note: A warning - **REPAIRING LOGS**, may be displayed if event log information was not completely stored at the previous power down. This is for information only, the Pump will continue to power up as normal.
3. **CONFIRM PROFILE**
   a) **NO** will display select profile screen
      – Select profile.
      – Press **OK** to confirm.
   b) **YES** will display the **TCI MODE** screen.
4. The **TCI MODE** selection is displayed - Answering **YES** selects the TCI Mode, **NO** will enter **TIVA MODE**.

The Alaris PK Plus Syringe Pump allows the user to select a TCI or TIVA mode of operation. The user may, at any time, switch mode by stopping the infusion and selecting the appropriate mode from the options menu. When in TIVA mode, if a drug with an associated model has been selected, the current plasma and effect site concentration will be displayed. This will demonstrate to the user unfamiliar with TCI, the Pharmacokinetics and Pharmacodynamics of the drug while still using TIVA mode.

TIVA Mode (with or without prediction)

1. A list of available drugs and models will be displayed. Use the ⏶⏷ keys to select the required drug and press the **OK** softkey. If the drug has an associated model, an **INFO** softkey will be displayed. Pressing the **INFO** softkey will show more information on the selection. The ml/h option allows infusions without doserate calculation.
2. **CONCENTRATION** -
   a) Select Concentration required and **OK** to confirm (Only required if more than one concentration is available).
   b) Press the **OK** softkey to confirm Concentration or press the **MODIFY** softkey to change Drug amount and diluent volume.
3. **WEIGHT** - adjust the patient weight using the ⏶⏷ keys, press the **OK** softkey to confirm.
4. The remaining patient parameters for the selected drug must be entered using the ⏶⏷ keys and press the **OK** softkey to confirm. The required parameters may include the following depending on the model:
   - **AGE**
   - **HEIGHT**
   - **GENDER**
   - **LBM and BMI** (Lean Body Mass and Body Mass Index. This is for information only and is not an adjustable parameter).
5. The **CONFIRM** drug setup screen shows the initial infusion parameters for the drug. Press the **OK** softkey to accept or **MODIFY** to change the drug setup.
6. **INDUCTION** - Using the ⏶⏷ keys, enter the induction dose amount per kg of patient weight (if required for dosing). Press the **OK** softkey to enter. The Induction feature may be disabled reducing the dose to zero until **OFF** is displayed and press **OK** softkey to confirm.
7. **TIME** - Enter the induction time in seconds over which the induction dose will be delivered. Press the **OK** softkey to enter.
8. **MAINTENANCE** - Set the maintenance dose rate in the drug protocol units. Press the **OK** softkey to enter.

Prime the extension set.

9. Load the syringe according to the procedure in this manual.
10. Check that the syringe type and size being used matches the display. If required, the make of syringe can be changed by pressing the **TYPE** button. Press **CONFIRM** when the correct type and size are shown.
11. Purge (if required) - Press the ⏩ button and then press and hold the **PURGE** softkey until the fluid flows and the purging of the extension set is complete. Release the softkey. The volume used during purging will be displayed.
12. Connect the extension set to the patient access device.
13. Press the ▶ button to commence operation. **INFUSING** will be displayed. The amber stop light will be replaced by the flashing green start light to indicate that the Pump is in operation. If the infusion rate exceeds the Soft Alerts then check infusion setting, to continue with infusion at set target press the ▶ button and then confirm **OVERRIDE LIMIT** by pressing the **YES** softkey. If **OVERRIDE LIMIT** is not required press the **NO** softkey and adjust target concentration to be within the Soft Alerts.

If a model has been selected, the VOLUME softkey will be replaced by a Ce/Cp softkey. This will allow the user access to screens showing predicted target concentrations. In this mode of operation the volume may never be cleared.

14. Press the ⏸ button to halt the operation. **ON HOLD** will be displayed. The amber stop light will replace the green start light.

TCI Mode

1. A list of available drugs and models will be displayed. Use the keys to select the required drug and associated model and press the **OK** softkey. Pressing the **INFO** key will show more information on the selection.
2. **CONCENTRATION** -
   a) Select Concentration required and **OK** to confirm (Only required if more than one concentration is available).
   b) Press the **OK** softkey to confirm Concentration or press the **MODIFY** softkey to change drug amount and diluent volume.
3. **AGE** - adjust the patient age using the keys, press the **OK** softkey to confirm.
4. The remaining patient parameters for the selected drug must be entered using the keys and press the **OK** softkey to confirm. The required parameters may include the following depending on the model:
   - **HEIGHT**
   - **GENDER**
5. **WEIGHT** - adjust the patient weight using the keys, press the **OK** softkey to confirm. A permissible weight range, calculated using the models LBM limitations, is displayed.
   - **LBM and BMI** (Lean Body Mass and Body Mass Index. This is for information only and is not an adjustable parameter).
6. If configuration allows, select Plasma targeting or Effect Site targeting.

> ⚠ **Prime the extension set.**

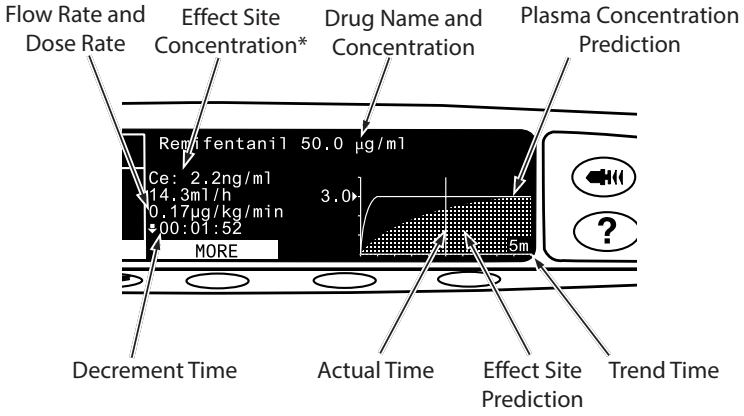
7. Load the syringe according to the procedure in this manual.
8. Check that the syringe type and size being used matches the display. If required, the syringe brand or type can be changed by pressing the **TYPE** softkey. Press the **CONFIRM** softkey when the correct type and size are shown.
9. The **CONFIRM** induction screen shows the initial infusion parameters for the drug and model selected. The screen will show blank data until the syringe has been loaded and confirmed.
10. When a slower titration is required the induction time may be increased in Plasma Targeting (Cpt) only. Press the **TIME** softkey and cap the maximum induction rate or doserate to increase the desired induction time. The cap rate will be cleared when first titration occurs.
11. Target Concentration (**Cpt** or **Cet**) - Adjust the Target Concentration if necessary using the keys. Confirm the Target Concentration and Initial Infusion predicted parameters. On confirmation, if the Target Concentration exceeds any limits, a warning will be displayed.

> ⚠ **Infusion cannot be started until confirmation has been made.**
>
> **Initial infusion parameters may fluctuate from the displayed predicted values as a result of real time recalculation.**
>
> **If the induction time is greater than 10s the flow rate may decrease on the last 10s period to adjust the dose to be administered.**
>
> **Maintenance flow rate will decrease over time for a fixed target.**

12. Purge (if required) - Press the button and then press and hold the **PURGE** softkey until the fluid flows and the purging of the IV infusion set is complete. Release the softkey. The volume used during purging will be displayed.
13. Connect the extension set to the patient access device.
14. Press the button to commence operation. **INFUSING** will be displayed. The amber stop light will be replaced by the flashing green start light to indicate that the Pump is in operation. If the infusion rate exceeds the Soft Alerts then check infusion setting, to continue with infusion at set target press the button and then confirm **OVERRIDE LIMIT** by pressing the **YES** softkey. If **OVERRIDE LIMIT** is not required press the **NO** softkey and adjust target concentration to be within the Soft Alerts.

> ⚠ **If Target Concentration running exceeds the Soft Alerts then the display will cycle between Drug Name and Up arrows.**

15. Pressing the button during infusion will maintain the current Plasma or Effect site.
16. Press the button to halt the operation. **ON HOLD** will be displayed. The amber stop light will replace the green start light.



* The Ce value will not be displayed if there is no k_{41} (k_{eo}) defined for the selected model.

Basic Features

Bolus Infusion

BOLUS is disabled in TCI mode.

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

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 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 configuration.

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

The Hands-Free Bolus is delivered with a single press of the (flashing) **BOLUS** softkey. The bolus rate and 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. 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**.
3. 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.
4. 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.
5. 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.

Any Hands Free Bolus dose setting which exceeds or is under a Soft Alert must be confirmed before operation can be continued. This is not applicable in TCI mode.

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.

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

Pressure Level

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

> ⚠ **During PURGE, BOLUS and INDUCTION the pressure limit alarms are temporarily increased to their maximum level. For TCI operation a threshold rate may be set above which the pressure limit alarms are temporarily increased to their maximum level.**

Rate Titration

Note: This is not applicable in TCI mode.

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 display on screen, titration callback tone will sound 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.

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.

Clear Volume

Note: Clear Volume is not permitted in TCI mode or predictive TIVA mode.

This option enables the volume infused to be cleared.

1. Press the **VOLUME** softkey to display the **CLEAR VOLUME** option.
2. Press the **YES** softkey to clear the volume. Press the **NO** softkey to retain the volume.
   Note: Selecting **YES** resets the volume infused in the **24H LOG** option.

Concentration Target Titration

Note: This only applies to TCI mode.

Concentration Target Titration allows the rate to be adjusted while infusing:

1. Select the new target using the keys.
   - The Pump status is shown as **TITRATE** and the Pump continues to infuse at the original concentration target.
2. Press the button to confirm the new concentration target and start infusing at the new rate. If the new concentration target setting exceeds or is under a Soft Alert, confirmation is required before infusion can resume.

Operations During Use

End of Operation

This option will only appear in the options menu when the infusion has been stopped.

1. Press the ⓘ button to access the options menu.
2. Select the **END OF OPERATION** option using the ⏫🔼🔽⏬ keys.
3. Press the **OK** softkey indicated on the screen.
   Note: Selecting this option will reset parameters for a new patient.

TCI Mode

When the Pump is on hold in predictive TIVA mode, the user is able to switch from TIVA to TCI mode.

1. Press the ⓘ button to access the options menu.
2. Using the ⏫🔼🔽⏬ keys, select the **TCI MODE**.
3. Press the **OK** softkey indicated on the screen. A confirmation screen will be displayed.
   Note: When the mode is changed to TCI mode, the initial target will be set to zero.

TIVA Mode

When the Pump is on hold in TCI mode, the user is able to switch from TCI to predictive TIVA mode.

1. Press the ⓘ button to access the options menu.
2. Using the ⏫🔼🔽⏬ keys, select the **TIVA MODE**.
3. Press the **OK** softkey indicated on the screen. A confirmation screen will be displayed.
   Note: When the mode is changed to predictive TIVA mode, the initial doserate will be set to zero.

DECREMENT CONC.

In TCI mode only:

1. Press the ⓘ button to access the options menu.
2. Select **DECREMENT CONC**.
3. Select the required **DECREMENT CONC** and press the **OK** softkey to exit.

Trend Size

The user is able to select the Trend Size of the Concentration Prediction graph.

1. Press the ⓘ button to access the options menu.
2. Using the ⏫🔼🔽⏬ keys, select **TREND SIZE**.
3. Using the ⏫🔼🔽⏬ keys, select the required **TREND SIZE** option (**5 Mins**, **15 Mins**, **30 Mins** or **60 Mins**).
4. Press the **SELECT** softkey indicated on the screen.
5. Press the **RESIZE** softkey to rescale the vertical axis of the graph. The initial displays calculates the scale so the peak value fills graph. If the trend is downward the graph only fills lower part and the **RESIZE** option forces it to rescale.

Text/Graph Display

When in TCI mode, the user is able to select a numerical or graphical display.

1. Press the ⓘ button to access the options menu.
2. Using the ⏫🔼🔽⏬ keys, select the display mode (**TEXT** or **GRAPH DISPLAY**). The options menu shows the available display mode option.
3. Press the **OK** softkey indicated on the screen.

Dosing Summary

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

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. It can be enabled/disabled.

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 press the **QUIT** softkey to exit.

SET BY DOSERATE/SET BY ml/h (TIVA mode only)

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

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

Selecting the **SET BY ml/h** option:

1. Whilst the Pump is infusing, press the ⓘ button to access the options menu.
2. Select the **SET BY ml/h** option using the ⏶⏷ keys and press the **OK** softkey indicated on the screen. This will select the **SET BY FLOWRATE** option, the arrow on the display will automatically select the flowrate, the flowrate can be adjusted if required.

Selecting the **SET BY DOSERATE** option:

1. Whilst the Pump is infusing, press the ⓘ button to access the options menu.
2. Select the **SET BY DOSERATE** option using the ⏶⏷ keys and press the **OK** softkey indicated on the screen. This will select the **SET BY DOSERATE** option, the arrow on the display will automatically select the doserate, the doserate can be adjusted if required.

EFFECT SITE TCI

When in **PLASMA TCI** mode the user is able to switch to **EFFECT SITE TCI** mode if the configuration permits:

1. Press the ⓘ button to access the options menu.
2. Select **EFFECT SITE TCI** using the ⏶⏷ keys.
3. Press the **OK** softkey indicated on the screen. A confirmation screen will be displayed.

PLASMA TCI

When in **EFFECT SITE TCI** mode the user is able to switch to **PLASMA TCI** mode if the configuration permits:

1. Press the ⓘ button to access the options menu.
2. Select **PLASMA TCI** using the ⏶⏷ keys.
3. Press the **OK** softkey indicated on the screen. A confirmation screen will be displayed.

Alarms and Warnings

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

1. First press the button to silence the alarm for a maximum of 2 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 (ISO60601-1-8 2nd Edition alarms). 3RD EDITION ALARMS (ISO60601-1-8 3rd Edition alarms) are also installed. To change the Pump alarm system from ORIGINAL ALARMS to 3RD EDITION ALARMS please refer to the Technical Service Manual. Please note that this change should only be performed by Qualified Service Personnel.

Original Alarms

Display	Alarm Priority	Description and Troubleshooting Guide
DRIVE DISENGAGED	High	The drive system has been disengaged during operation. Check the finger grips and the position of the syringe.
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.
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 Alaris Syringe Pump Technical Service Manual.
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.
BATTERY EMPTY	High	The internal battery is exhausted. Connect the Pump to the AC Power Supply.
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.
COMMS. TIMEOUT	High	While being controlled remotely, the Pump does not receive a message during the defined timeout period. Attempt to re-establish connection to resolve this alarm condition and restart the infusion.
UNACHIEVABLE RATE STOP	High	The infusion rate specified is not achievable with the current setup. Cancel the alarm message and reprogram the infusion with an achievable rate.
BATTERY LOW	Medium	Battery charge low with 30 minutes operation remaining. Battery indicator will flash and after 30 minutes a continuous audible alarm will indicate that the battery is exhausted. Reconnect to the AC Power Supply to continue operation and charge the internal battery. 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.
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.

Display	Alarm Priority	Description and Troubleshooting Guide
TITRATION NOT CONFIRMED	Medium	The infusion rate has been changed, but has not been confirmed and 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. Check infusion rate and confirm by pressing the button or press the button to revert to the previous rate. Press the button to start infusion. (This alarm only occurs if rate titration is enabled).
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.
ATTENTION	Low	Three beeps will sound if the Pump has been left on for more than 2 minutes* (referred to as **CALLBACK** in the log) without starting the operation. Press the button to silence the alarm for a further two minutes. Alternatively press and hold down the button and wait for four beeps in succession, this will put the alarm on standby for 60 minutes.

*Configurable option.

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

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

Alarm Priority Level Indicators

Priority	Audio Indicator	Visual Indicator (Beacon)
HIGH	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

3rd Edition Alarms

Display	Alarm Priority	Description and Troubleshooting Guide
DRIVE DISENGAGED	High	The drive system has been disengaged during operation. Check the finger grips and the position of the syringe.
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.
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 Alaris Syringe Pump Technical Service Manual.
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.
BATTERY EMPTY	High	The internal battery is exhausted. Connect the Pump to the AC Power Supply.
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.
COMMS. TIMEOUT	High	While being controlled remotely, the Pump does not receive a message during the defined timeout period. Attempt to re-establish connection to resolve this alarm condition and restart the infusion.
UNACHIEVABLE RATE STOP	High	The infusion rate specified is not achievable with the current setup. Cancel the alarm message and reprogram the infusion with an achievable rate.
BATTERY LOW	Medium	Battery charge low with 30 minutes operation remaining. Battery indicator will flash and after 30 minutes a continuous audible alarm will indicate that the battery is exhausted. Reconnect to the AC Power Supply to continue operation and charge the internal battery. 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.
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.
TITRATION NOT CONFIRMED	Medium	The infusion rate has been changed, but has not been confirmed and 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. Check infusion rate and confirm by pressing the button or press the button to revert to the previous rate. Press the button to start infusion. (This alarm only occurs if rate titration is enabled).
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.
ATTENTION	Low	Three beeps will sound if the Pump has been left on for more than 2 minutes* (referred to as **CALLBACK** in the log) without starting the operation. Press the button to silence the alarm for a further two minutes. Alternatively press and hold down the button and wait for four beeps in succession, this will put the alarm on standby for 60 minutes.
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.

*Configurable option.

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

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

Alarm Priority Level Indicators

Priority	**Audio Indicator**	**Visual Indicator (Beacon)**
HIGH	Ten beep sequence followed by a three second pause	Flashing Red
MEDIUM	Three consecutive beeps followed by a four second pause	Flashing Amber
LOW	Three consecutive beeps followed by a sixteen second pause	Solid Amber

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 infusion rate has been set to a value which exceeds a Soft Alert. Check infusion setting, to continue with infusion at set rate press the button and then confirm **OVERRIDE LIMIT** by pressing the **YES** softkey. If **OVERRIDE LIMIT** is not required press the **NO** softkey and adjust rate below Soft Alert.
DOSE UNDER		The infusion rate has been set to a value which is under a Soft Alert. Check infusion setting, to continue with infusion at set rate press the button and then confirm **OVERRIDE LIMIT** by pressing the **YES** softkey. If **OVERRIDE LIMIT** is not required press the **NO** softkey and adjust rate above Soft Alert.
DOSE NOT PERMITTED		The infusion rate has been set above a Hard Limit. Check infusion setting and adjust rate to appropriate required rate.
TARGET WOULD EXCEED		The target has been set to a value which exceeds a Soft Alert. Check infusion setting, to continue with infusion at set target press the button and then confirm **OVERRIDE LIMIT** by pressing the **YES** softkey. If **OVERRIDE LIMIT** is not required press the **NO** softkey and adjust rate below Soft Alert.
BOLUS DOSE OVER		The bolus dose has been set to a value which exceeds a Soft Alert. Check the bolus setting, to continue with the bolus press the button and then confirm **OVERRIDE LIMIT** by pressing the **YES** softkey. If **OVERRIDE LIMIT** is not required press the **NO** softkey and adjust dose below Soft Alert.
BOLUS DOSE UNDER		The bolus dose has been set to a value which is under a Soft Alert. Check the bolus setting, to continue with the bolus press the button and then confirm **OVERRIDE LIMIT** by pressing the **YES** softkey. If **OVERRIDE LIMIT** is not required press the **NO** softkey and adjust dose above Soft Alert.
BOLUS DOSE NOT PERMITTED		The bolus dose has been set above a Hard Limit. Check bolus setting and adjust to appropriate required dose.
WEIGHT OUTSIDE LIMIT		The patient weight has been set to a value which exceeds or is under a Soft Alert. Check the weight setting, to continue press the button and then 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.

Configured Options

This section comprises of a list of options which are configurable. Some can be entered via the Pump configuration menu (available in Technician Mode) and others through the Alaris PK Editor Software.

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

Access codes should only be entered by qualified technical personnel.

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

Alarm Presets

Pumps with version 3.5.2 software have 2 alarm tones to choose from during configuration:

- **ORIGINAL ALARMS**: Low, medium and high priority alarm tones that sound like the auditory alarms and warnings from software versions prior to 3.5.2
- **3RD EDITION ALARMS**: Low, medium and high priority alarm tones in accordance with IEC 60601-1-8: 2012 and IEC 60601-2-24:2012

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

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

All pumps in a single care area should be configured with the same alarm tones to avoid User confusion.

The Hospital/Facility is responsible for selecting and configuring the desired alarm scheme.

Alaris Gateway Workstation (Workstation) with software versions 1.1.3, 1.1.3 MR, 1.1.5, 1.2, 1.3.0, 1.6.0 or 1.5 do not support the new Pump low priority visual alarms scheme defined in IEC 60601-1-8: 2012. For Pumps with version 3.5.2 software or higher docked into these Workstations there will be a mismatch of alarm priority displayed. As a result, Near End Of Infusion, AC Power Fail, and Attention alarms will display as a medium visual priority alarms on the Workstation beacon and a low priority alarm on the Pump. Additionally, for certain information signals, e.g. those associated with Titration Not Confirmed, the Workstation beacon will illuminate while the beacon on the pump will not. In the event of an alarm priority mismatch, the User should refer to the alarm on the Pump for the correct priority.

Configured Options

Enter the access code on the Pump for Configured Options, see the *Technical Service Manual* for details.

Clock Set

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

Language

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

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

Contrast

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

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

Alaris PK Plus Syringe Pump General Options

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

NURSE CALL FITTED	Enables Nurse Call (hardware option).
NURSE CALL INVERT	When enabled, the nurse call output is inverted.
RS232 SELECTED	Sets the Pump's communications to use RS232 (hardware option). The **NURSE CALL FITTED** option must be enabled to allow RS232 to function.
REMINDER SIGNAL	When enabled there is an audible notification, consisting of four beeps, every 10 minutes for the **Low Battery** and **Near End Of Infusion** alarms.

Power Down Sequence

Enter the access code on Alaris PK Plus Syringe Pump for alternative Power Down Sequence, see the Technical Service Manual for details.

⚠ **Access codes should only be entered by qualified technical personnel.**

ENABLED When running TCI or TIVA with predictive TCI the Pump may only be powered down by stopping the infusion, selecting END OF OPERATION from the options menu, confirming the selection and then power down the Pump.

DISABLED In TCI or TIVA with predictive TCI the Pump may be powered down after putting the Pump on hold.

Alaris PK Editor Software - Pump Configuration

The following options are configurable via the Alaris PK Editor Software (PC based), see the Alaris PK Editor Software Directions for Use (1000CH00016) for details on how to alter the profile configurations.

General Pump Configurations

AC Fail Warning	The AC Power Failure Alarm can be set to sound or be silent if the AC power is disconnected.
Audio Volume	The audio alarm volume of the Pump (high, medium or low).
Auto Night Mode	Main Display (Backlight) dims between hours 21:00 and 06:00.
Battery Icon	Indicator displaying the remaining estimated battery capacity.
Callback Time	Adjusts the length of time before the Pump sounds the Attention alarm.
Event Log	The Event Log can be set to be displayed on the main display. Events are still recorded in the Event Log if disabled.
Drug Override Mode	Always - Any changes made to the dose rate or target concentration that are outside the editor Soft Alerts will require confirmation before starting infusion. Smart - Confirmation of setting will be required on the first dose rate or target concentration set outside the editor Soft Alerts. Any subsequent changes will not require confirmation until after the dose rate or target concentration has been confirmed inside the editor Soft Alerts. Additionally, any changes in dose rate or target concentration from above a Soft Alert Max to below a Soft Alert Min or from below a Soft Alert Min to above a Soft Alert Max will also need to be confirmed.
Pressure Default	The default occlusion pressure alarm level.
Pressure Display	Sets whether the Pressure Information is available on the main display.
Purge Rate	The rate used during purge operation.
Purge Volume Max	The maximum permissible purge volume.
Purge Syringe Prompt	Feature which prompts the user to purge the extension set prior to the start of the infusion.
Bolus [1]	Bolus feature can be set to HANDS ON or HANDS FREE.
Bolus Rate Default [1]	The default bolus rate.
Bolus Volume Default [1]	The default bolus volume.
KVO	Allows the enabling or disabling of Keep Vein Open (KVO) at End of Infusion (EOI).
KVO Rate	Sets the KVO rate at which the Pump will operate when EOI is reached.
Near End of Infusion Time	Sets the Near End of Infusion warning time as time left to End of Infusion.
End of Infusion %	Sets the End of Infusion point as a percentage of syringe volume.
Weight Default [2]	The patient default weight in kg.
Weight Minimum [2]	The minimum patient weight in kg. This is a Soft Alert and can be overridden.
Weight Maximum [2]	The maximum patient weight in kg. This is a Soft Alert and can be overridden.
Age Default [2]	The default patient age in years.
Age Minimum [2]	The minimum age in years. This is a Soft Alert and can be overridden.
Age Maximum [2]	The maximum age in years. This is a Soft Alert and can be overridden.

The approved data set contains configurable option values per profile.

[1] The bolus configurations are used only when the Alaris PK Plus Syringe Pump is being used in ml/h mode. If a drug is selected then the drug's own configuration settings are used.

[2] Although a default and Soft Limits can be set for age and weight, the actual selectable range may be limited by the drug and model chosen.

Alaris PK Editor Software - Profile Drugs

The following drug parameters are only configurable via the Alaris PK Editor Software (PC based), and are referenced when the Alaris PK Plus Syringe Pump is being used with a drug name selected. Refer to the Alaris PK Editor Software Directions for Use (1000CH00016) for details on how to configure the Profile Drug Library.

TCI - these options are only displayed if the selected drug has an associated TCI model.	
Clinical Trial Indicator	Should be set to cause the Alaris PK Plus Syringe Pump to identify that a selected drug/model is used under the responsibility of the investigator of a clinical trial protocol. Specifically for publication studies and when drug does not make reference to the selected TCI mode of administration in the prescribing information or, when parameter selection deviates from it.
TIVA Predictive Mode Only	Only allows drugs with associated TCI model to be used in TIVA predictive mode.
Default Target Concentration	The default target concentration offered when the drug is selected.
Enable Effect Site Targeting	Enable effect site targeting if the model associated with the drug supports it.
Enable Target Swapping	Enable switching between plasma and effect site targeting if the model associated with the drug supports both modes.
Enable TIVA/TCI Switching	Enable switching between TIVA and TCI modes.
Target Soft Alert Max	Sets the target concentration soft alert maximum.
Default Decrement Concentration	Sets the default decrement target concentration.
TIVA Induction Parameters	
Induction ON/OFF	Enables/Disables induction stage of TIVA protocol.
Dosing Units	The induction dose units. This can be based on patient weight.
Default Dose	The default induction dose offered.
Default Induction Time	Sets the default induction time.
Soft Alert Min	The induction value below which an override confirmation is required.
Soft Alert Max	The induction value above which an override confirmation is required.
Hard Limit Max	The maximum allowed induction dose.
Pause After Induction	Enables/Disables pause after induction.
TIVA Maintenance Parameters	
Dose Rate Units	The maintenance rate units.
Default Dose Rate	The default maintenance dose.
Soft Alert Min	The maintenance dose rate below which an override confirmation is required.
Soft Alert Max	The maintenance dose rate above which an override confirmation is required.
Hard Alert Max	The maximum allowed maintenance dose rate.
TIVA Bolus Parameters	
Bolus Type	Determines bolus operation when required.
Default Rate	The default bolus rate.
Dosing Units	The bolus dose units. This can be based on patient weight.
Default Dose (HANDS FREE only)	The default bolus offered.
Soft Alert Min (HANDS FREE only)	The bolus dose value below which an override confirmation is required.
Soft Alert Max (HANDS FREE only)	The bolus dose value above which an override confirmation is required.
Hard Limit Max (HANDS FREE only)	The maximum allowed bolus dose.
Occlusion Alarms	
Occlusion Alarm Pressure	The default occlusion alarm level.
Desensitise Threshold Rate	The infusion rate that, when exceeded in TCI mode, causes the occlusion detection to be desensitised.
Concentration Limits	
Minimum Concentration	The minimum drug concentration.
Maximum Concentration	The maximum drug concentration.

Default Drug Profile Library

The following drug parameters are programmed in the Pump.

	Diprivan 1%	Diprivan 2%	Remifentanil	Remifentanil TIVA*	Sufentanil
Model	Marsh	Marsh	Minto	n/a	Gepts
Min Concentration	10mg/ml	20mg/ml	20µg/ml	20µg/ml	0.2µg/ml
Max Concentration	10mg/ml	20mg/ml	50µg/ml	250µg/ml	5.0µg/ml
Induction Default	1.0mg/kg	1.0mg/kg	1.0µg/kg	1.0µg/kg	0.15µg/kg
Induction Soft Max	2.5mg/kg	2.5mg/kg	1.5µg/kg	1.5µg/kg	0.5µg/kg
Induction Hard Max	4.0mg/kg	4.0mg/kg	2.0µg/kg	2.0µg/kg	2.0µg/kg
Induction Time	30s	30s	45s	45s	45s
Maintenance Default	8mg/kg/h	8mg/kg/h	0.2µg/kg/minutes	0.2µg/kg/minutes	0.1µg/kg/h
Maintenance Soft Max	14mg/kg/h	14mg/kg/h	1µg/kg/minutes	1µg/kg/minutes	1µg/kg/h
Maintenance Hard Max	20mg/kg/h	20mg/kg/h	2µg/kg/minutes	2µg/kg/minutes	2µg/kg/h
Default Bolus Rate	1200ml/h	600ml/h	600ml/h	600ml/h	1200ml/h
Default Bolus	1.0mg/kg	1.0mg/kg	1.0µg/kg	1.0µg/kg	0.15µg/kg
Bolus Soft Max	2.5mg/kg	2.5mg/kg	1.5µg/kg	1.5µg/kg	1.0µg/kg
Bolus Hard Max	5.0mg/kg	5.0mg/kg	2.0µg/kg	2.0µg/kg	2.0µg/kg
Default Target Conc.	4.0µg/ml	4.0µg/ml	3.0ng/ml		0.15ng/ml
Target Conc. Soft Max	10µg/ml	10µg/ml	8.0ng/ml		1.0ng/ml
Target Conc. Hard Max	15µg/ml	15µg/ml	20ng/ml		2.0ng/ml
Decrement Conc.	1µg/ml	1µg/ml	1ng/ml		0.05ng/ml
Infusion Rate Limits	1200ml/h	600ml/h	1200ml/h	1200ml/h	1200ml/h

*This drug does not have an associated model and, therefore, cannot be run in TCI mode.

Default values are derived from publications and expert assessment and are given as reference only. It is recommended that, before starting the infusion or confirming a titrated value, the values are checked to ensure that they conform to hospital protocol.

Specifications

Infusion Specifications

Maximum infusion rate can be set as part of the configuration.

0.1ml/h - 150ml/h	5ml syringes
0.1ml/h - 300ml/h	10ml syringes
0.1ml/h - 600ml/h	20ml syringes
0.1ml/h - 900ml/h	30ml syringes
0.1ml/h - 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

The Volume Infused range is 0.0ml - 9990ml.

Bolus Specifications

Selected maximum rates are shown below

150ml/h	5ml syringes
300ml/h	10ml syringes
600ml/h	20ml syringes
900ml/h	30ml syringes
1200ml/h	50ml syringes

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

- Minimum: 0.1ml
- Maximum: 100.0ml
- Increments of 0.1ml; default 5.0ml

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

*Bolus Volume Accuracy**

Selected maximum rates are shown below

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 50 ml syringe is : Maximum Overinfusion - 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.

100ml/h - 500ml/h.

The purge volume range is 0.5ml - 5ml.

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

End Of Syringe Rate

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

Near End Of Infusion Alarm

1 minute -15minutes to end of infusion, or 10% of syringe volume, whichever occurs later.

End Of Infusion (EOI) Alarm

0.1% - 5% of syringe volume.

Maximum Pumping Pressure Limit

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

*Occlusion Accuracy without pressure set (% of full scale)**

	Pressure mmHg			
	L-0 approx. 50mmHg	L-3 approx. 300mmHg	L-5 approx. 500mmHg	L-10 approx. 1000mmHg
Temp. 23°C	±18%	±21%	±23%	±28%

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

System Accuracy (continuous ml/h and TIVA)

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

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

System accuracy is +/-2% typical by volume as measured using the trumpet curve test method defined in EN/IEC60601-2-24 at rates of 1.0ml/h (23ºC) and above when the Pump is used with the recommended syringes. Caution: 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' section in this manual.

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 @ 5ml/h and 23°C ± 2°C under normal conditions is 6 hours*.

*95% lower confidence interval of 5 hours 50 minutes

Charging takes 2½ hours from discharge to 90% charge.

In TCI mode, a fully charged battery allows at least one full syringe to be infused.

Memory Retention

The electronic memory of the Pump will be retained for at least 6 months when not powered up.

Fuse Type

2 x T 1.25H, 250V

AC Power Supply

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

Dimensions

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

Weight

2.4 kg (excluding power cable).

Protection against fluid ingress

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

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

Alarm Conditions

Drive Disengaged	Occlusion	Attention (Nurse Callback)
Check Syringe	Near End Of Infusion	End of Infusion
Battery Low	Battery Empty	AC Power Fail
Titration not confirmed	Internal Malfunction	Concentration not Permitted
Dose Would Exceed	Target Would Exceed	Dose Under
Dose not Permitted	Bolus Dose not Permitted	Rate not Permitted
Bolus Dose Under	Bolus Dose Over	Weight Outside Limit
Comms. Timeout	Unachievable Rate Stop	

Environmental Specifications

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

Electrical/Mechanical Safety

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

Potential Equalisation Conductor

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

EMC

Complies with EN/IEC60601-1-2, EN/IEC60601-2-24

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. The full list of permitted syringe models is dependent on the software version of the Pump.

	5ml	10ml	20ml	30ml	50ml
IVAC™					✓
AstraZeneca*					✓
B Braun Omnifix*	✓	✓	✓	✓	✓
B Braun Perfusor*			✓		✓
BD Perfusion*					✓
BD Plastipak*	✓	✓	✓	✓	✓
BD Precise*			✓		✓
Codan*		✓	✓	✓	✓
Codan Perfusion*					✓
Fresenius Injectomat*		✓			✓
Monoject[2*]	✓	✓	✓	✓	✓
Pentaferte*	✓	✓	✓		✓
Rapiject[1*]					✓
Terumo*	✓	✓	✓	✓	✓

[1] - The Rapiject 50ml syringe is a specialised syringe with a large diameter barrel. To provide protection against accidental dislodging always ensure the extension set is secured using the extension set hook - see 'Loading and Confirming a Syringe' section.

[2] - Ξ TYCO / Healthcare KENDALL - MONOJECT.

⚠ **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.**

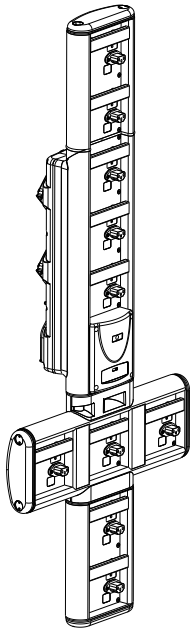
⚠ **BD has characterized a range of syringes as identified in the 'Recognised Syringes' table. BD cannot guarantee the continued system accuracy of these recognised syringes* as the manufacturer may change syringe specification significant to system accuracy without prior notification.**

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.

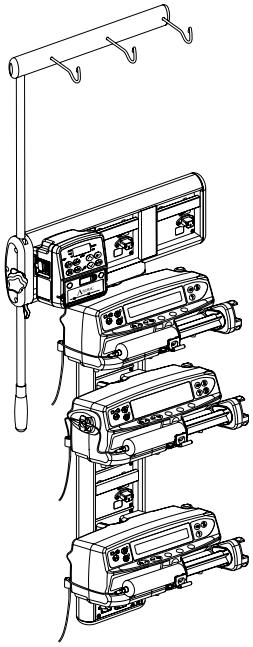
Associated Products

The Alaris Gateway Workstation



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

The Alaris DS Docking Station



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

y = Connectivity option - 1, 2 or 3

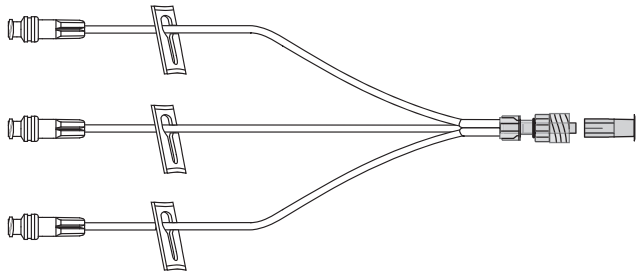
xx = Configuration

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.

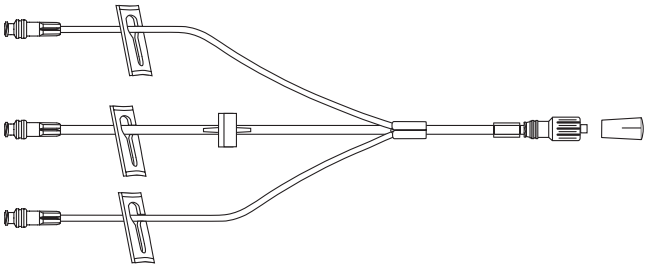
20038E7D

3 way extension set with 3 SmartSite™ Needle-Free Valves, low priming volume, 13cm



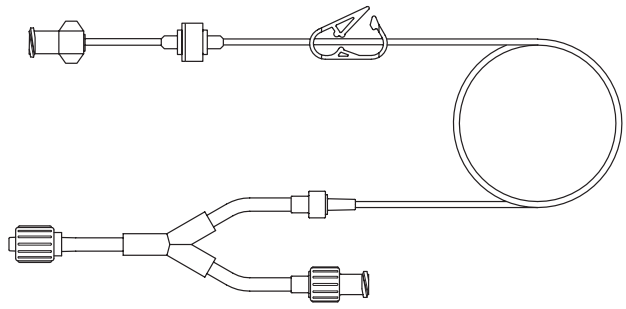
20062E7D

3 way extension set with 3 SmartSite Needle-Free Valves and one backcheck valve, 16cm



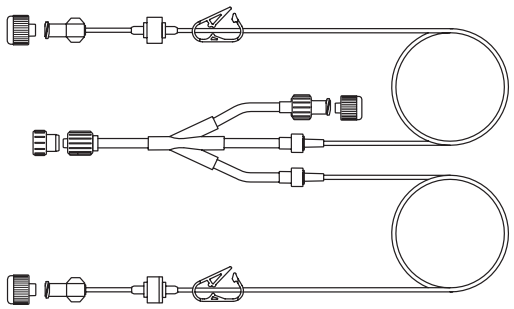
MFX2271

2 way set with anti-syphon valve and backcheck valve, 210cm



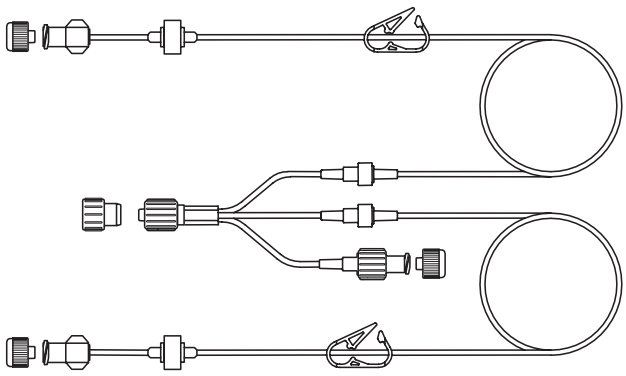
MFX2270

3 way set with 2 anti-syphon valves and backcheck valve, 210cm



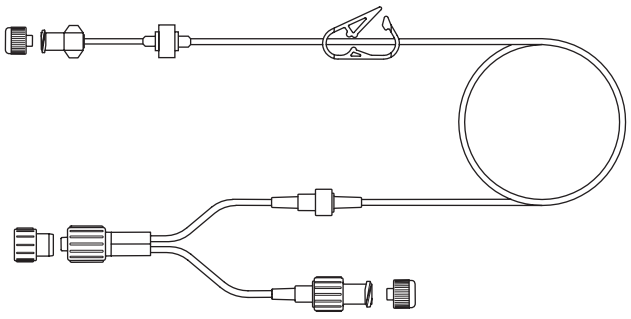
MFX2290

3 way set with 2 anti-syphon valves and backcheck valve, low priming volume, 209cm



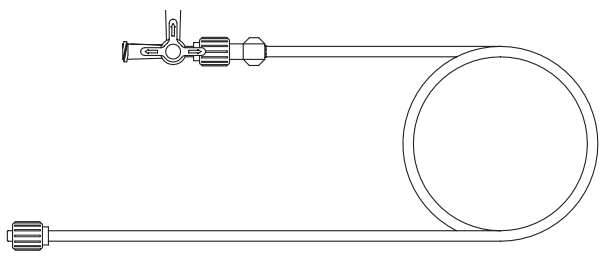
MFX2291

2 way set with anti-syphon valve and backcheck valve, low priming volume, 209cm



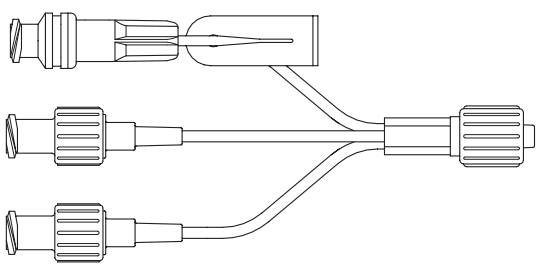
MFX2284

3 way tap (blue) with extension, 100cm

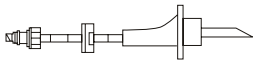


MFX2233E

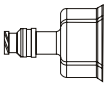
3 way extension set with 2 backcheck valves, SmartSite Needle-Free Valve and clamp, low priming volume 10cm



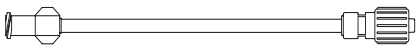
2309E-0006
Bag spike with SmartSite Needle-Free Valve and backcheck valve



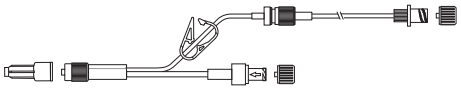
2205E-0006
Vial adaptor with SmartSite Needle-Free Valve, for 20mm vials



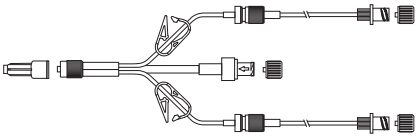
MFX2293
Extension set with backcheck valve, 14cm. Priority Volume: 0.9ml



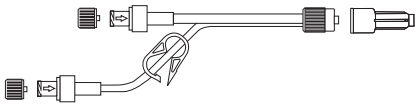
500-012V
Y Connector set 2-way with anti-syphon valve and backcheck valve, 210cm



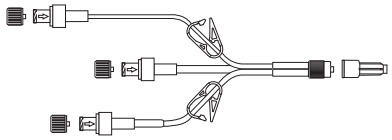
500-013V
Y Connector set 3-way with 2 anti-syphon valves and backcheck valve, 190cm



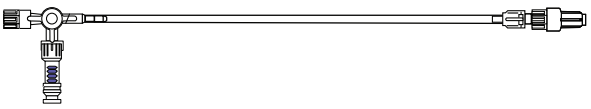
500-002V
Y Connector set 2-way with anti-syphon valve and backcheck valve, 15cm



500-003V
Y Connector set 3-way with 2 anti-syphon valves and backcheck valve, 15cm



MFX2280EV
3 way tap with extension and SmartSite Needle-Free Valve, 10cm



MFX2282EV
3 way tap with extension and SmartSite Needle-Free Valve, 30cm

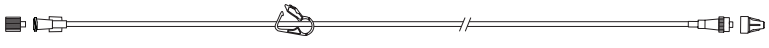
MFX2283EV
3 way tap with extension and SmartSite Needle-Free Valve, 50cm

MFX2284EV
3 way tap with extension and SmartSite Needle-Free Valve, 100cm

MFX2285EV
3 way tap with extension and SmartSite Needle-Free Valve, 120cm

PB-G40710
Low Sorbing PE lined extension set with clamp, 100cm

PB-G40715
Low Sorbing PE lined extension set with clamp, 150cm

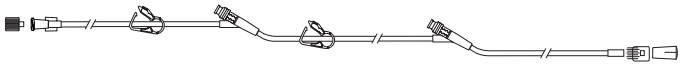


PB-G40720
Low sorbing PE lined extension set with clamp 200cm

G40615K
Low sorbing PE extension set 150cm

G40215K
Extension set, opaque PVC, 150cm

30262E-0006
Extension set with 2 SmartSite Needle-Free Valve ports, 102cm



G40015
Standard PVC Syringe Extension Set, 150cm.
Priming Volume: 2.6ml

G40020B
Standard PVC Syringe Extension Set, 200cm.
Priming Volume:1.4ml

G40320V
Opaque White PVC Syringe Extension Set, 200cm.
Priming Volume: 1.4 ml

G40620K
Polyethylene Syringe Extension Set, 200cm.
Priming Volume: 1.8ml

- **New sets are continuously being developed for our customers. Please 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

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 please refer to the Technical Service Manual (TSM).

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

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

Battery Operation

The internal rechargeable battery allows continued operation when the AC power is unavailable, for example during patient transfer or AC power failure. Mean Time To Battery Empty from fully charged @ 5ml/h and 20°C under normal conditions is 6 hours*. From the battery low alarm it will take about 2½ hours to 90% charge when reconnected to the AC Power Supply, whether the Pump is in use or not.

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

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

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

*95% lower confidence interval of 5 hours 50 minutes

Cleaning and Storage

Before the transfer of the 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.

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).
- Use of Iodine (such as Betadine) will cause surface discoloration.
- Concentrated Isopropyl alcohol based cleaners will degrade plastic parts.

Recommended cleaners are:

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

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

- Warm soapy water
- Mild detergent in water (e.g. Young's Hospec)
- 70% Isopropyl Alcohol in water
- Chlor-Clean
- Clinell Universal Wipes
- Hibiscrub
- TriGene Advance
- Tristel Fuse sachets
- Tristel Trio wipes system
- Tuffie 5 wipe
- Virkon Disinfectant

Before cleaning always switch off and disconnect from the AC Power Supply. Never allow liquid to enter the casing and avoid excess fluid build up on the 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.

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

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

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

Disposal

Information on Disposal for Users of Waste Electrical 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

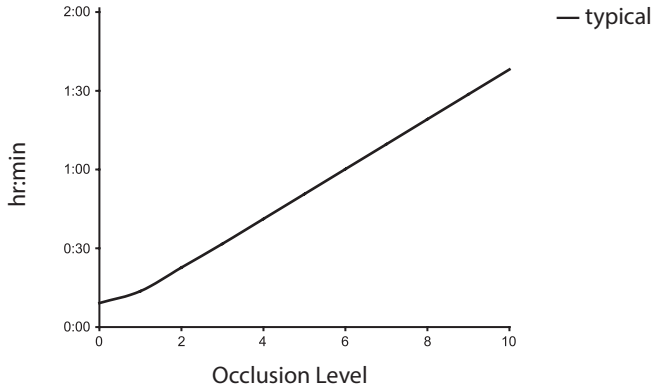
This symbol is only valid in the European Union. The product should be disposed of taking environmental factors into consideration. To ensure no risk or hazard, remove the internal rechargeable battery and the Nickel Metal Hydride battery from the control board and dispose of as outlined by the local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

Occlusion Pressure Limits

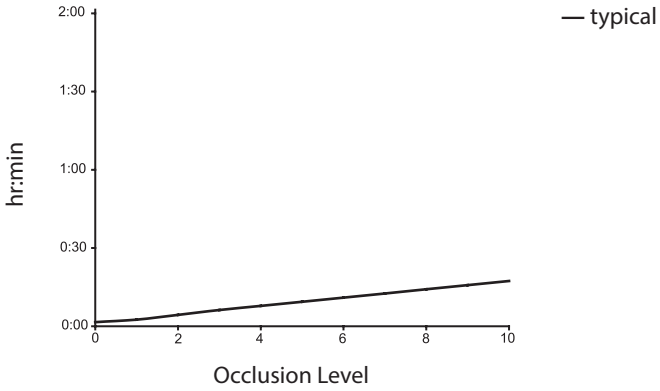
Time to alarm following occlusion is achieved in less than 30 minutes at rates of 1 ml/h and higher by the appropriate selection of occlusion levels.

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

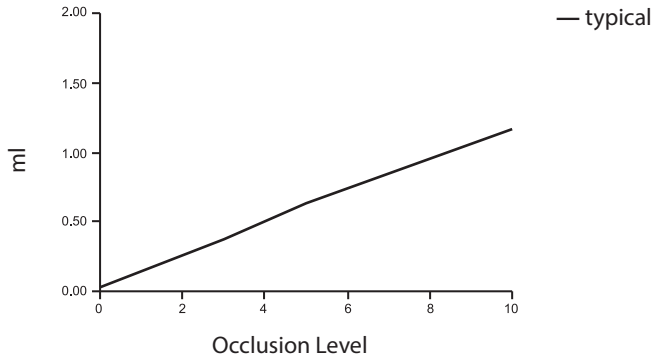
Time to alarm - 1.0 ml/h



Time to alarm - 5.0 ml/h



Bolus Volume



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.

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 Alaris Syringe Pump. This allows data to be transferred between the Pump and a PC or another Alaris 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. Since it is possible to control the syringe Pump using the RS232 interface at some distance from the Pump and hence remote from the patient, responsibility for the control of the Pump is vested in the software run on the computer control system.

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

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

IrDA

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

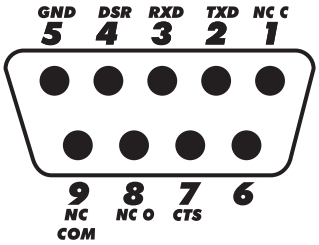
RS232 / Nurse call Connection Data

Nurse call Specification -

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

Typical Connection Data -

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



Trumpet Curves and Start-up Curves

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

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

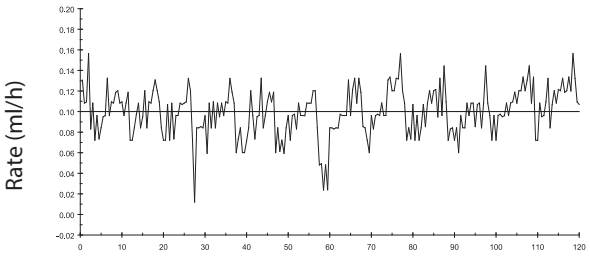
The start-up curves represent continuous flow versus operating time from the start of the infusion. They exhibit the delay in onset of delivery due to mechanical compliance and provide a visual representation of uniformity. Trumpet curves are derived from the second hour of this data. Tests performed per *EN/IEC60601-2-24:1998 standard*.

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

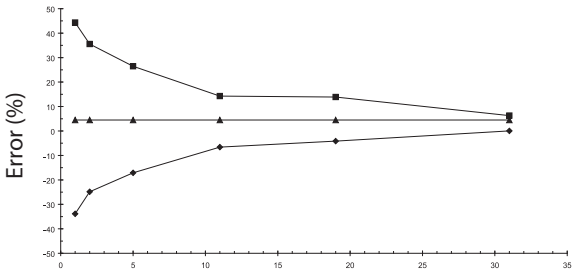
Knowledge of system accuracy over various observation windows may be of interest when certain drugs are being administered. Short term fluctuations in rate accuracy may have clinical impact depending on the half-life of the drug being infused, therefore the clinical effect cannot be determined from the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

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

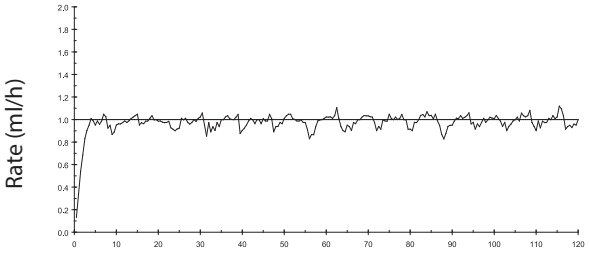
Start-up Trend. BD Plastipak 5ml @ 0.1ml/h



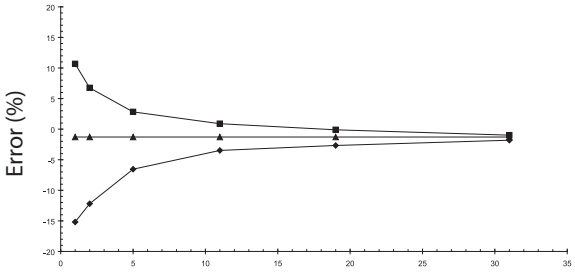
Trumpet Curve. BD Plastipak 5ml @ 0.1ml/h



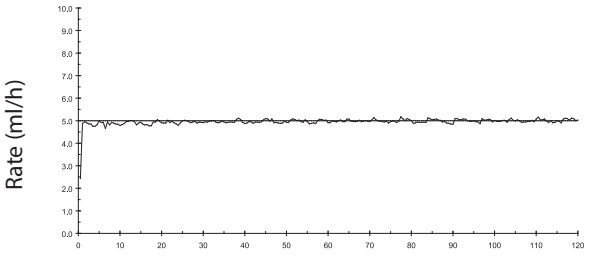
Start-up Trend. BD Plastipak 50 ml @ 1.0 ml/h



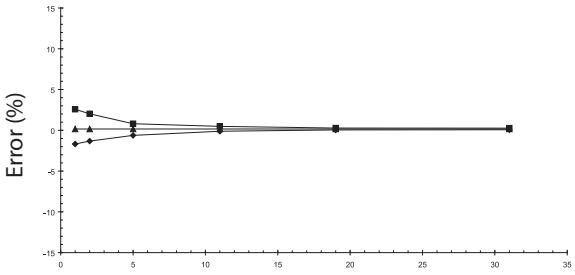
Trumpet Curve. BD Plastipak 50 ml @ 1.0 ml/h



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



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



Profiles from TCI Mode

When targeting in TCI Mode the Alaris PK Plus Syringe Pump will automatically calculate the flow rate profile from the specific pharmacokinetic/pharmacodynamic model for the selected drug. This section of the Directions For Use is intended to help users understand the profiled infusion and the performance accuracy attained from the TCI Pump.

Induction Bolus and maintenance rates are displayed before starting the titration. When initially starting the infusion or after increasing the target (plasma or effect) concentration by titration, the Pump will first deliver a bolus dose through a typically short, high rate infusion. On completion of this bolus, the Pump will immediately switch to a lower maintenance rate (when plasma target mode is used) or will pause for a period of time before switching to a lower maintenance rate (when effect site targeting mode is used). Once the maintenance phase is reached, any reduction made to the target (plasma or effect) concentration will typically result in the infusion rate reducing to zero until the predicted plasma (or effect) concentration reduces the new target value.

The Alaris PK Plus Syringe Pump updates the pharmacokinetic model driving the plasma (or effect) concentration prediction and the infusion rate every 10 seconds. The infusion rate graph, shown in the Infusion Rate vs Target concentration graphs was measured in accordance with the protocol described in the IEC60601-2-24[1] Standard, with the data sample period reduced from 30 to 10 seconds.

The Pump solves the pharmacokinetic/pharmacodynamic algorithms so that the target (plasma or effect) concentration is attained as rapidly and as accurately as possible. However, the User may need to take into consideration the limitations of the physical system in attaining the target (plasma or effect) concentration; this includes:

- The limit on the flow rate permitted by the infusion pump mechanism;
- The limit on the flow rate permitted by the syringe size;
- The patient / drug dose limitation from the prescribing information to insure the safety of the administration;
- The variation in individual patient response to reach the plasma (or effect) concentration;
- The model specific cap rate.

A true assessment of the performance of the Alaris PK Plus Syringe Pump can be made if the volumetric error, that is the difference between the actual volume infused and the predicted volume infused, is calculated.-For the-Infusion Rate vs Target concentration graphs, over a one hour period, the Alaris PK Plus Syringe Pump has a mean volumetric accuracy in TCI Mode better than ±5%[2].

By measuring the volume from the flow rate profile delivered from the Alaris PK Plus Syringe Pump and then introducing this into a reverse pharmacokinetic model the predicted plasma (or effect) concentration can be calculated from the flow rate. These are illustrated in the Predicted vs Ideal Concentration graphs, showing the typical performance of the system against changes in the target plasma (or effect) concentration for a typical, idealised profile. For the same targeted profile, the deviation of the predicted plasmatic (or effect) concentration (back calculated from the volume collected) from the expected Ideal plasma (or effect) concentration, results from the volumetric inaccuracy of the system (Pump and syringe). The Alaris PK Plus Syringe Pump will track the predicted plasma (or effect) concentration to within ±5%[2] of that calculated by pharmacokinetic model over a one hour period. Flow rate inaccuracies and start-up delays may decrease the accuracy of the predicted plasma (or effect) concentration particularly where high syringe drug concentrations are used in conjunction with large sizes of syringes and low target plasma (or effect) concentrations as the syringe plunger motion over time (proportional to the flow rate accuracy) will be significantly reduced.

⚠ **For a given drug concentration, the volumetric error is proportional to the dose rate error. Knowledge of the system accuracy over different time intervals may be of interest when assessing the impact of administering short-half life drugs. In these circumstances, short-term fluctuation in the infusion rate could have a clinical impact that cannot be determined from the performance profiles shown in Figures below. In general, the volumetric error will increase with small induction and maintenance rates, which may occur when with large volume syringes, high syringe concentrations, low patient weights and low target (plasma or effect) concentrations. For applications where system accuracy is important, maintenance rates less than 1.0 ml/h are not recommended; syringe sizes, drug concentrations / dilutions and target (plasma or effect) concentrations should be selected accordingly to ensure the maintenance rate exceeds this lower limit.**

The graphs illustrated in this section are for a Diprivan (1% Concentration); Diprivan (2% concentration), Remifentenil (50µg/ml concentration), and Sufentanil (5µg/ml concentration) are given for comparison. As an illustration of the effect the syringe size has on system performance, Remifentenil (50µg/ml concentration) is shown with a 50ml and 5ml syringe respectively.

The target (plasma or effect) concentrations shown are for illustrative purposes only.

Note:

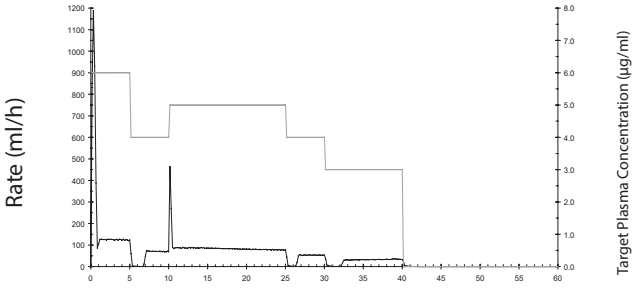
[1] IEC60601-2-24: Particular Requirements for the Safety of Infusion Devices;

[2] 95% Confidence / 95% Population.

Infusion Rate vs Target Concentration

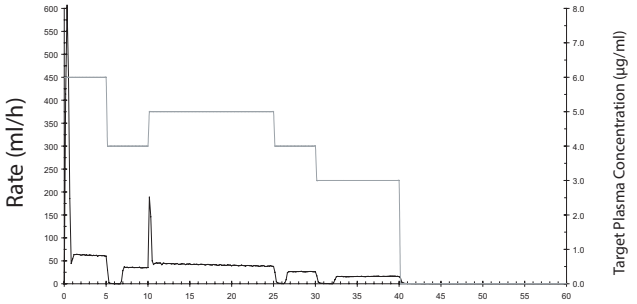
Diprivan 1% Marsh Model BD 50ml Syringe

- Patient Age: 40 Years
- Patient Weight: 60kg
- Drug Concentration: 10mg/ml
- Volumetric Accuracy: +0.1%



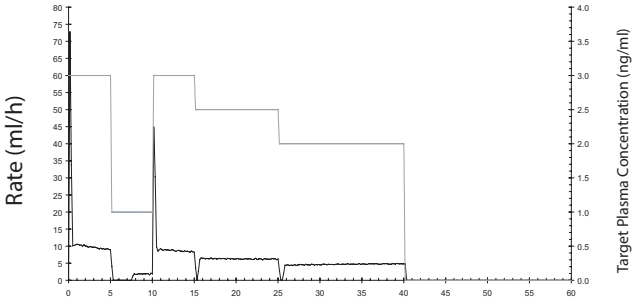
Diprivan 2% Marsh Model BD 50ml Syringe

- Patient Age: 40 Years
- Patient Weight: 60kg
- Drug Concentration: 20mg/ml
- Volumetric Accuracy: -0.4%



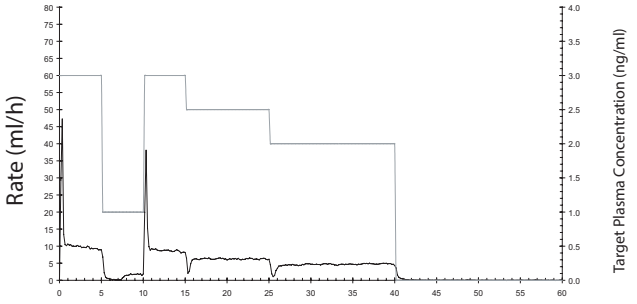
Remifentanil Minto Model BD 5ml Syringe

- Patient Age: 75 Years
- Patient Weight: 65kg
- Patient Height: 175cm
- Patient Gender: Male
- Drug Concentration: 50µg/ml
- Volumetric Accuracy: -0.2%



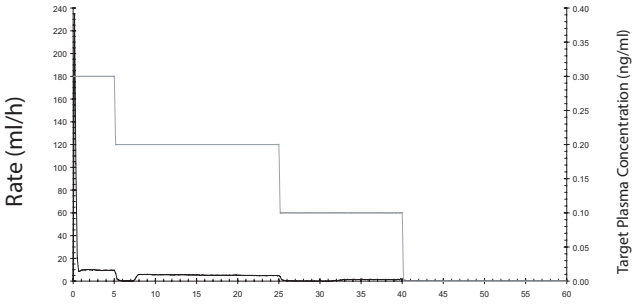
Remifentanil Minto Model BD 50ml Syringe

- Patient Age: 75 Years
- Patient Weight: 65kg
- Patient Height: 175cm
- Patient Gender: Male
- Drug Concentration: 50µg/ml
- Volumetric Accuracy: -1.6%



Sufentanil Gepts Model BD 50ml Syringe
(Plasma Target)

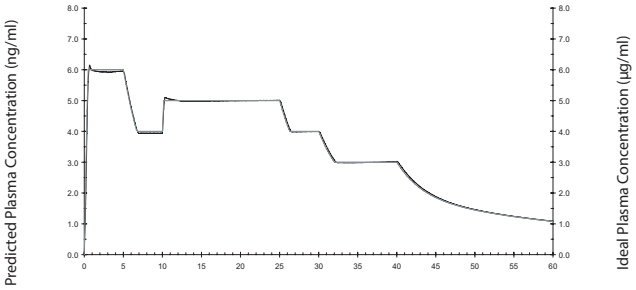
- Drug Concentration: 5.0µg/ml
- VTarget Plasma Concentration (ng/ml)



Predicted vs Ideal Concentration

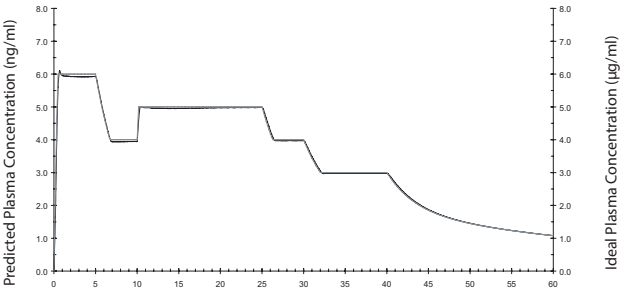
Diprivan 1% Marsh Model BD 50ml Syringe

- Patient Age: 40 Years
- Patient Weight: 60kg
- Drug Concentration: 10mg/ml
- Plasma Concentration Accuracy: +0.2%



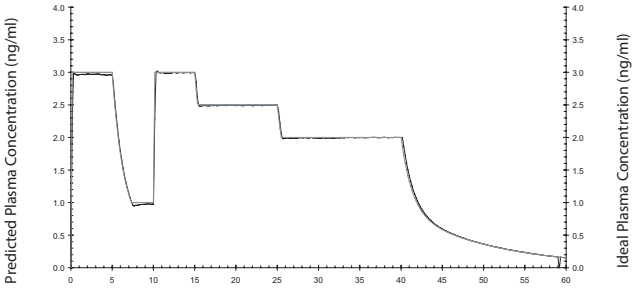
Diprivan 2% Marsh Model BD 50ml Syringe

- Patient Age: 40 Years
- Patient Weight: 60kg
- Drug Concentration: 20mg/ml
- Plasma Concentration Accuracy: -0.3%



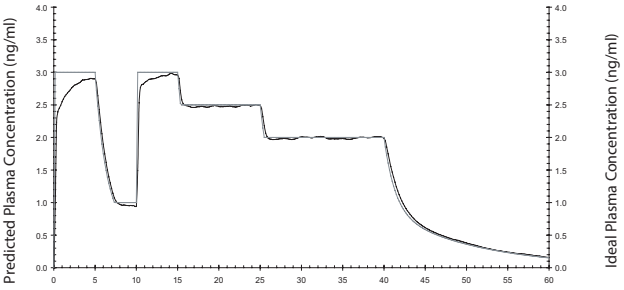
Remifentanil Minto Model BD 5ml Syringe

- Patient Age: 75 Years
- Patient Weight: 65kg
- Patient Height: 175cm
- Patient Gender: Male
- Drug Concentration: 50µg/ml
- Plasma Concentration Accuracy: +0.2%



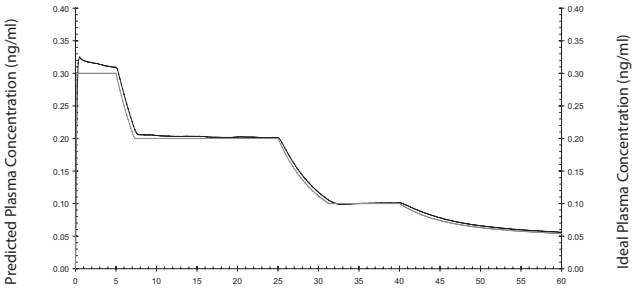
Remifentanil Minto Model BD 50ml Syringe

- Patient Age: 75 Years
- Patient Weight: 65kg
- Patient Height: 175cm
- Patient Gender: Male
- Drug Concentration: 50µg/ml
- Plasma Concentration Accuracy: +0.5%



Sufentanil Gepts Model BD 50ml Syringe

- Drug Concentration: 5.0µg/ml
- Plasma Concentration Accuracy: +3.1%



Products and Spare Parts

Spare Parts

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

The *Technical Service Manual (1000SM00024)* is now available in electronic format on the World Wide Web at :-

bd.com/int-alaris-technical

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

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

Alaris PK Editor Software

Part Number	Description
1000SP00624	Alaris PK Editor
1000CD00123	Alaris PK Editor Drug Models - Adult
1000CD00124	Alaris PK Editor Drug Models - Paediatric

Document History

Issue	Date	Software Version	Description
1	July 2019	3.5.2	Initial release
2	November 2020	3.5.2	Updates for regulations
3	April 2021	3.5.2	Update of Fuse Specification

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