ALARIS®
MEDICAL SYSTEMS

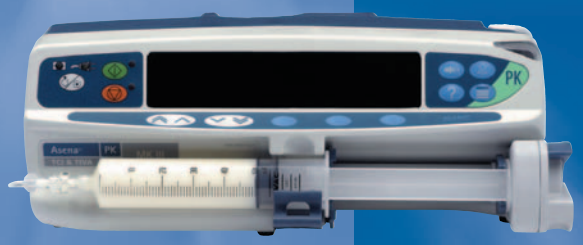
Asena®

PK Syringe Pump

Asena® PK Syringe Pump

Directions for Use

ENGLISH



1000PB01489 Issue 4

Contents

Introduction

The Asena® PK Syringe 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. The pharmacokinetic model is used to estimate the plasma and effect site concentration
3) 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.
4) 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 Asena® PK 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.

The Asena® PK Syringe Pump is compatible with a wide range of standard single use, 3 piece Luer-lock syringes. It accepts syringe sizes from 5ml to 50ml. Specifications are available in the relevant section.

Use of the Asena® PK Syringe Pump **DOES NOT** limit the responsibility of the anaesthetist for drugs administration. It is important that users operating the Asena® PK 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.

ALARIS Medical Systems 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, pages 27-29).

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 Asena® PK 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.

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.

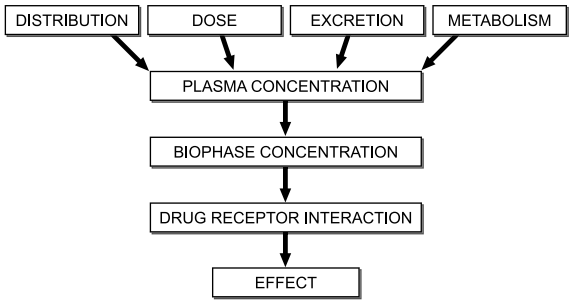


Fig. 1: Schematic representation of the pharmacokinetic and dynamic processes determining the relationship between administered dose and resulting effect intensity of a drug. Pharmacokinetic factors such as distribution, metabolism, and/or excretion determine the relationship between drug dose and drug-concentration 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".

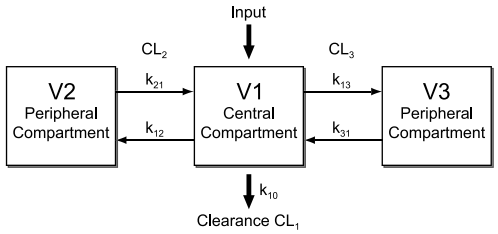


Fig. 2: Schematic representation of the three compartment model used for target-controlled infusions.

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.

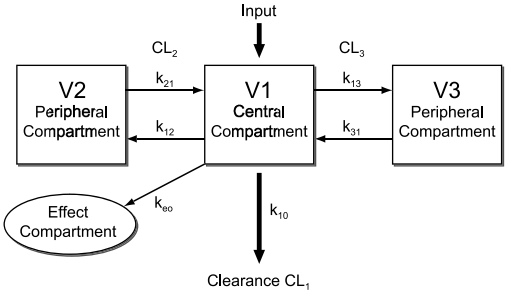


Fig. 3: Schematic representation of the concentration-effect relationship.

TCI Overview (continued)

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 Asena® PK 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 Asena® PK 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 Asena® PK 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})
$k_{10} = 0.119\ min^{-1}$
$k_{12} = 0.112\ min^{-1}$
$k_{13} = 0.0419\ min^{-1}$
$k_{21} = 0.055\ min^{-1}$
$k_{31} = 0.0033\ min^{-1}$
$K_{eo} = 0.26\ min^{-1}$
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
CL_1 = 2.6 - 0.0162 x (age - 40) + 0.0191 x (lbm - 55)
CL_2 = 2.05 - 0.0301 x (age - 40)
CL_3 = 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
$k_{10} = 0.0645\ min^{-1}$
$k_{12} = 0.1086\ min^{-1}$
$k_{13} = 0.0229\ min^{-1}$
$k_{21} = 0.0245\ min^{-1}$
$k_{31} = 0.0013\ min^{-1}$
Reference from the literature : Gepts et al.: Anesthesiology 1995, 83, 1194-1204

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

Creating a Data Set

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

1. Create Master Lists (Using Asena® 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.
Asena® PK Syringe Library	Configure syringes enabled for use.

2. Create Profile (Using Asena® PK Editor Software)

*Drug Library**	Drugs and concentrations for this profile with defaults, minimum & maximum limits and targets and occlusion level.
*Configuration***	Instrument configuration settings and general options.

3. Review, Approve and Release (Using Asena® 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 Asena® PK Syringe Pump (Using Asena® PK Editor Transfer Tool)

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

5. Verify Data Set Upload

   First or Individual Instrument Verification

   On completion of upload record CRC number shown on the Asena® PK Syringe Pump.

   Download the Data Set from the pump using the Asena® 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.

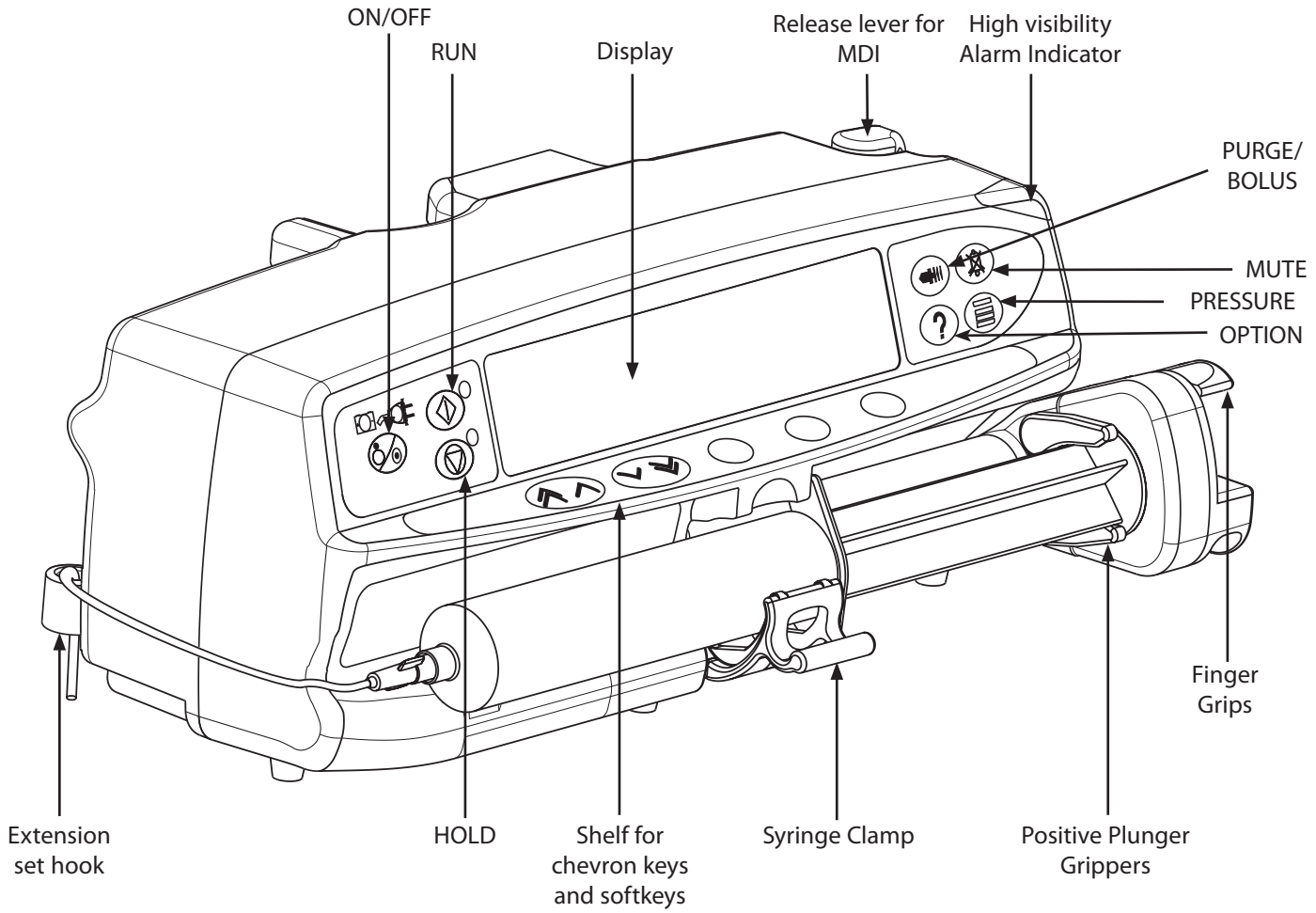
   Subsequent Instruments Verification

   On subsequent uploads of the Data Set compare CRC number on the instrument with CRC number recorded on First Instrument Verification.

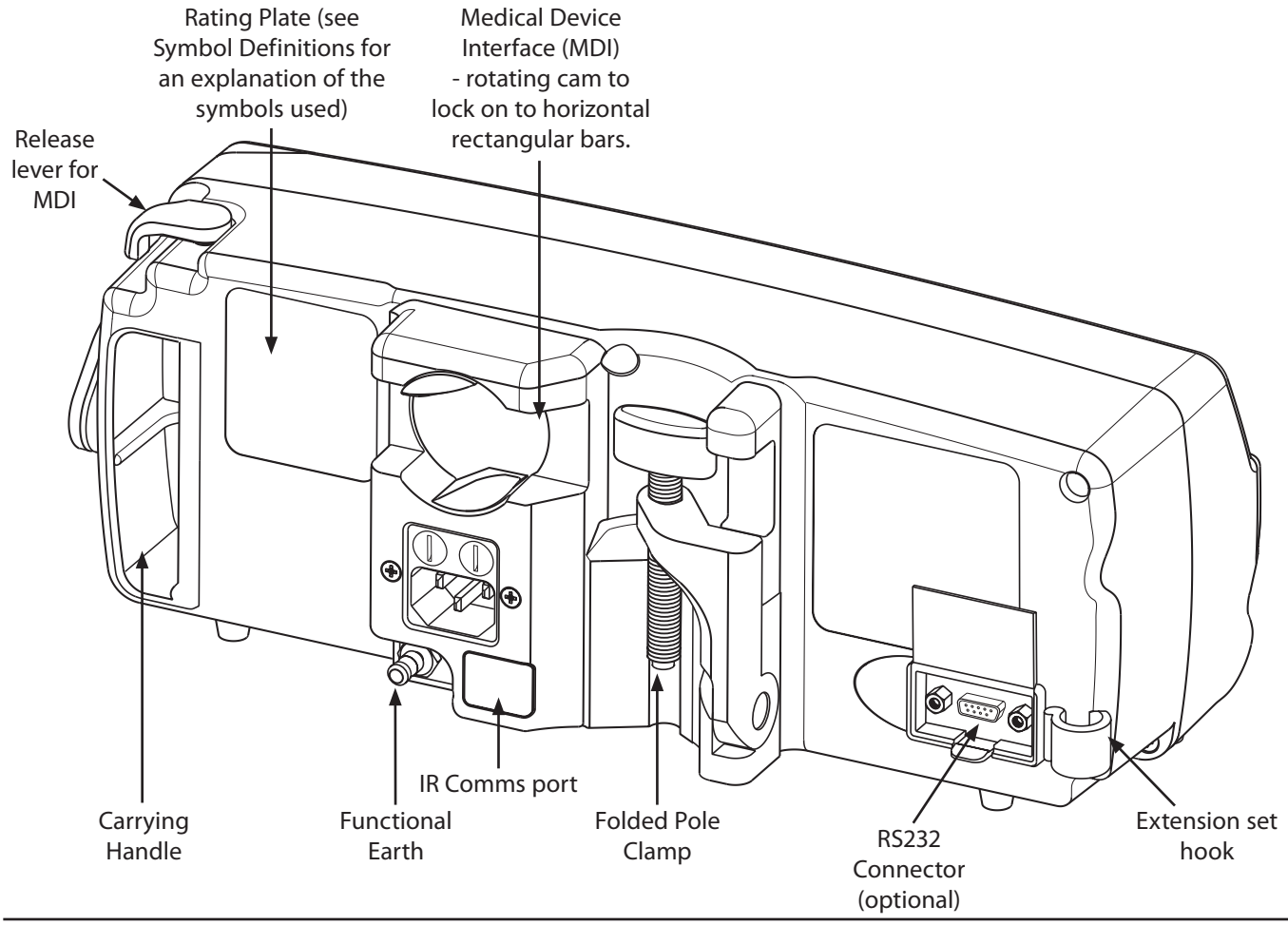
* Note: Drug parameters have to be in accordance to local regulation and prescribed information.

** See important note in Configured Options section.

Features of the Asena® PK Syringe Pump - Front View



Features of the Asena® PK Syringe Pump - Rear View



Controls and Indicators

ON/OFF - Press once to switch the pump ON. Press and hold down for 3 seconds to switch the pump OFF.

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 - Press to silence alarm for 2 minutes. Press and hold until 3 beeps are heard for 15 minutes silence.

PURGE/BOLUS - Press to access **PURGE** or **BOLUS** soft keys. Press and hold down soft key to operate. **PURGE** the extension set during set up. Pump on hold, extension set not connected to patient, Volume Infused (VI) not added. **BOLUS** delivered at an accelerated rate. Pump infusing, extension set connected to patient, VI added.

OPTION button - Press to access optional features (see page 12).

PRESSURE - Use this button to display the pumping pressure trend display and alarm level.

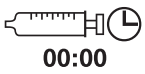
CHEVRONS - Double or single for faster/slower increase or decrease of values shown on display.

BLANK SOFTKEYS - Use in conjunction with the prompts shown on the display.

Indicators

BATTERY - 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 - When illuminated the pump is connected to an AC power supply and the battery is being charged.



TIME REMAINING DISPLAY - Indicates time before syringe will require replacing.

BATTERY ICON - Indicates battery charge level to highlight when the battery will require recharging.

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)

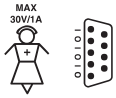
LIMIT WARNING - Indicates the setting entered is under or exceeds a Soft Alert or setting entered is not permitted as it exceeds a Hard Limit.

DOWN MODE - Infusion status indicating that the target concentration is below current concentration.

Symbol Definitions

Attention (Consult accompanying documents)

Functional Earth



RS232/Nurse Call Connector (Optional)

Type CF Equipment (Degree of protection against electrical shock)

Protected against vertically falling drops of water

Alternating Current

Pump complies with the requirements of the EC Directive 93/42/EEC. Registered with the CE Mark.

Date of Manufacture

Important Information

Induction Phase Dose (Displayed on protocol confirmation screen)

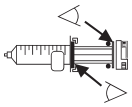
Duration of Induction Phase (Displayed on protocol confirmation screen)

Maintenance Phase Dose (Displayed on protocol confirmation screen)

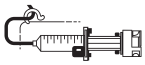
Duration of Hands Free Bolus (Displayed on bolus set-up screen)

Operating Precautions

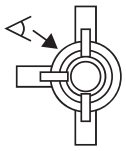
This ALARIS® syringe pump has been calibrated for use with single-use disposable syringes. To ensure correct and accurate operation, only use 3 piece luer-lock versions of the syringe make specified on the pump or described in this manual. Use of non-specified syringes or administration sets may impair the operation of the pump and the accuracy of the infusion.



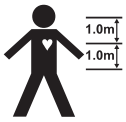
Uncontrolled flow or syphoning may result if the syringe is located incorrectly in the pump, or if it is removed from the pump before the extension set is properly isolated from the patient. Isolation may include closing a tap in the patient line or activating a flow stop clamp.



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 administration sets and other tubing, for example via a 3 way tap, the performance of the pump may be impacted and should be monitored closely.



The pump must be mounted within 1.0m above or below the patient's heart. The most accurate pressure monitoring in the extension set is achieved when the pump is positioned close to the patients heart level. 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 set and patient connections and follow the priming procedure specified herein.

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, infiltration conditions which can occur at low pressures.

Several alarm conditions detected by this pump will stop the infusion and generate audible alarms and lights. Users must perform regular checks to ensure that the infusion is progressing correctly and no alarms are operating.

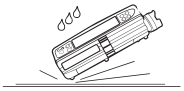
This pump is protected against the effects of external interference, including high energy radio frequency emissions, magnetic fields and electrostatic discharge (for example, as generated by electrosurgical and cauterising equipment, large motors, portable radios, cellular telephones etc.).

When using any infusion pump in conjunction with other instruments requiring vascular access, extra care is advised. Adverse delivery of medication or fluids can be caused by the substantial variation in pressures created within the local vascular system by such instruments.

Typical examples of those instruments are used during dialysis, bypass or cardiac assist applications.

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 fail safe or reset (after which a call back alarm will occur). Should false alarm conditions be encountered, either remove the source of the interference, or regulate the infusion by another appropriate means.

This pump emits a certain level of electromagnetic radiation which is within the levels specified by IEC60601-2-24 and IEC60601-1-2:2002. If however the pump interacts with other equipment, measures should be taken to minimise the effects, for instance by repositioning or relocation.



If this pump is dropped, subjected to excessive moisture, fluid spillage, humidity or high temperature, or otherwise suspected to have been damaged, remove it from service for inspection by a qualified service engineer. When transporting or storing the pump, use original packaging where possible, and adhere to temperature, humidity and pressure ranges stated on page 16 and on the outer packaging.

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. An electrical shock hazard exists if the units 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 equipment should be operated from the battery.

A comprehensive Technical Service Manual is available for this pump. The part number is 1000SM00001.

All illustrations used in this manual show typical settings and values which may be used in setting up the functions of the pump. These settings and values are for illustrative use only. The complete range of settings and values are specified on page 16. 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 are shown on page 16.

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.

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. In order to prevent any potential failure generated by ESD close to or above 15kV, it is recommended that all actions must be taken by appropriately trained personnel and the pump should not be attached to the patient when connecting RS232/Nurse Call.

Getting Started

Installation

Check that the pump is complete, undamaged and that the voltage rating specified on the base plate is compatible with your AC power supply. Items supplied are:

- **ALARIS® Asena® PK Syringe Pump**
- **User Support CD**
- **AC Power Cable (as requested)**
- **Protective Packaging**

Connect the pump to the AC power supply for 2½ hours to ensure that the internal battery is fully charged prior to use.

Should the pump fail to perform correctly, replace in its original protective packaging and contact a qualified service engineer for investigation.

On initial start-up the pump will display the Select Language screen.

Select the required language from the list displayed using the ⏫🔼🔽⏬ keys.

Press the **OK** softkey to confirm your selection.

A pole clamp is fitted to the rear of the pump and will provide secure fixing to standard vertical IV poles of a diameter of between 15 and 40 mm. It should be folded away when not in use.

There is a Medical Device Interface (MDI) at the rear of the pump used for mounting the pump onto horizontal rectangular bars, for instance the ALARIS® Asena® Docking Station. Holding the pump horizontally push the pump firmly on to the bar. Ensure that the pump clicks securely into position on the bar. To release, push the release lever and pull the pump forward.

Important: 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.

The pump will automatically operate from its internal battery if the pump is switched on without being connected to the AC power supply.

Loading a Syringe

Place the pump on a stable horizontal surface or secure as described above.

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

Important: 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 and the performance of the pump.

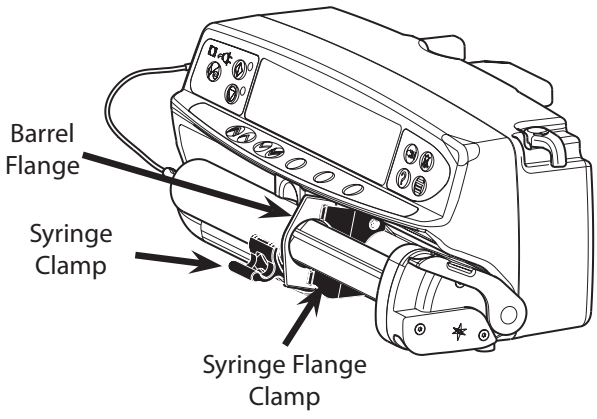
When initially loading the syringe, allow for the volume of fluid contained in the extension set and retained in the syringe at the end of infusion as this "dead-space" will not be infused.

1. Squeeze the finger grips together on the plunger holder and slide the mechanism to the right. Pull the syringe clamp forward and down.
2. Insert the syringe ensuring that the finger flanges are located in the slots on the syringe holder.
3. Lift the syringe clamp until it locks against the syringe barrel.
4. Squeeze the finger grips on the plunger holder and slide the mechanism to the left until it reaches the plunger end.
5. Release the finger grips. Ensure that the plunger grippers are securing the plunger in place and the finger grip returns to its original position.

Important: 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.

Important: Ensure that both plunger grippers are fully locked onto the plunger flange and the upper finger grip has returned to its original position.

Important : 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.



Starting the Pump

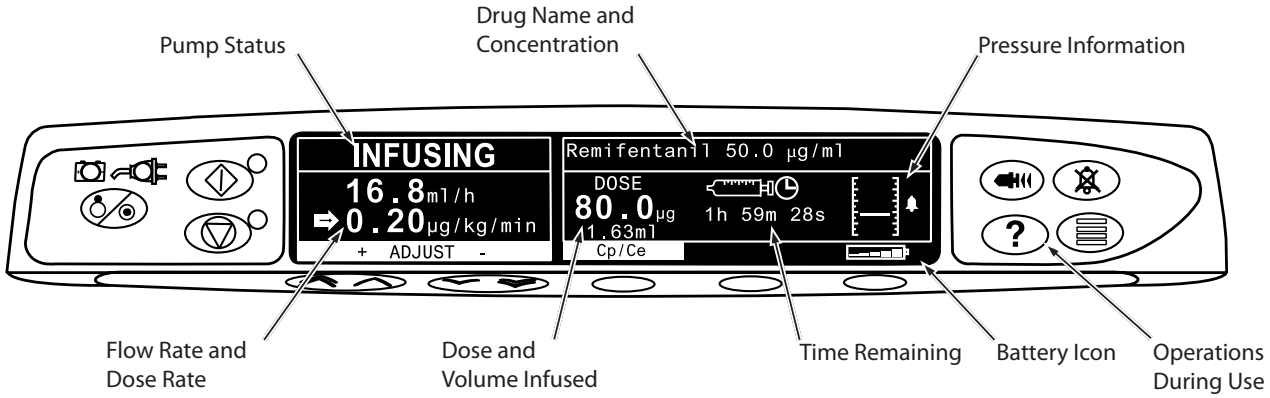
1. Connect the pump to an AC power supply using the AC power cable. Press the ⏻ button.
   - The pump will run a short self-test. Ensure that two beeps are activated during this test.
   - Check the display test pattern and ensure that no coloured rows are missing.
   - Finally check that the displayed 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.

2. **CONFIRM PROFILE?** - Answering **NO** will display **SELECT PROFILE** screen, select profile and press the **OK** softkey. **YES** will display the **TCI MODE** screen.
3. The **TCI MODE** selection is displayed - Answering **YES** selects the TCI Mode, **NO** will enter **TIVA MODE**.

The Asena® PK 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.

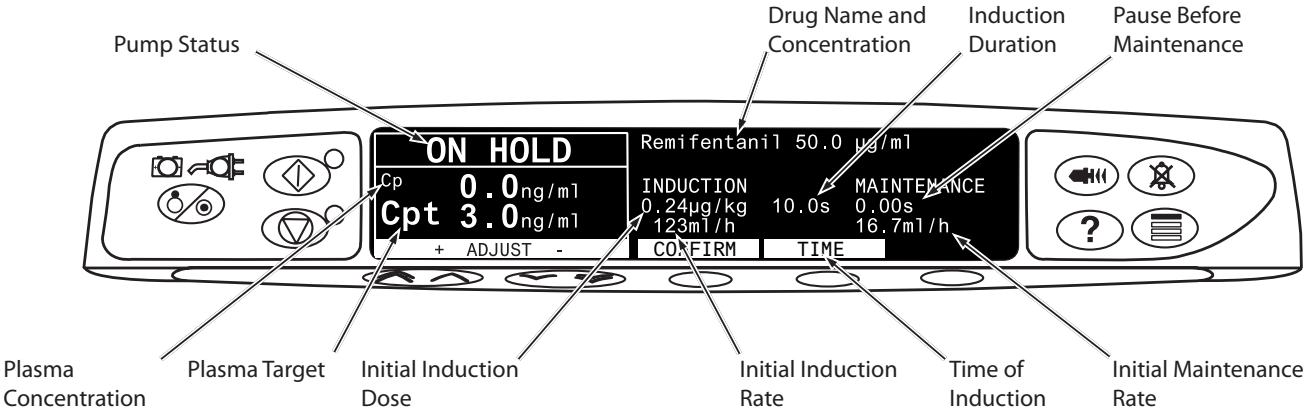
Important: Prime IV infusion set.

9. Load Syringe - Load the syringe according to the procedure in this manual.
10. Confirm Syringe - 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 IV infusion set is complete. Release the softkey. The volume used during purging will be displayed.
12. Connect To Patient - Connect the extension set to the patient access device.
13. Start - 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.

Note: 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. Stop - 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 permissable 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.

Important: Prime IV infusion set.

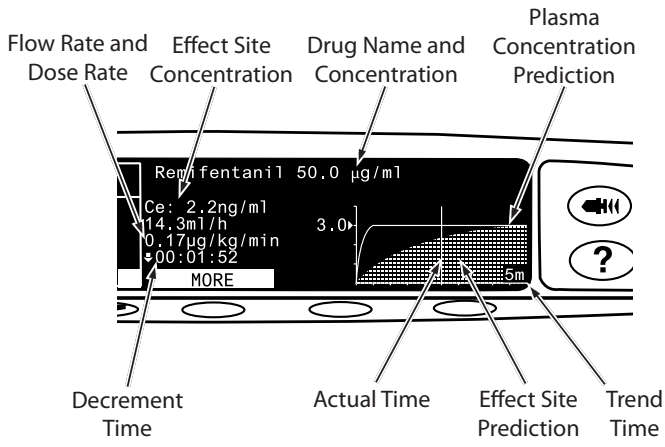
7. Load Syringe - Load the syringe according to the procedure in this manual.
8. Confirm Syringe - Check that the syringe type and size being used matches the display. If required, the syringe brand or type can be changed by pressing the **TYPE** softkey. Press the **CONFIRM** softkey when the correct 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.

Note: Infusion can not 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 To Patient - Connect the extension set to the patient access device.
14. Start - 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.

Note: 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.

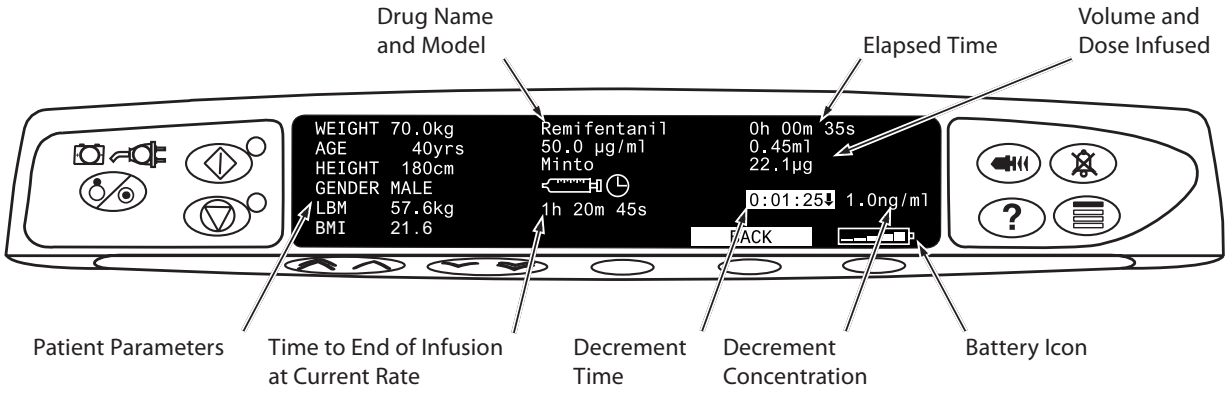


16. Stop - Press the ⏹ button to halt the operation. **ON HOLD** will be displayed. The amber stop light will replace the green start light.

Getting Started (continued)

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.

Basic Features

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. Stop the pump and press the button. 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 syringe 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.

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

Rate Titration

Note: This is not applicable in TCI mode.
Rate Titration allows the rate to be adjusted while infusing:

1. Select the new rate using the keys.

   The message < START TO CONFIRM > will flash on the screen and the pump continues to infuse at the original rate.
2. Press the button to confirm the new infusion rate and resume infusion. If the new infusion rate setting exceeds or is under a Soft Alert, confirmation is required before infusion can resume.

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 resume infusion. If the new concentration target setting exceeds or is under a Soft Alert, confirmation is required before infusion can resume.

Bolus Infusion

If the bolus volume reaches the set limit the bolus will stop and the pump will revert to infuse at the set infusion rate.

1. During infusion press the button once to display the Hands Free bolus selection screen.
2. Use the keys to set the bolus dose/volume required; If necessary press the **RATE** softkey to adjust the bolus delivery rate (150/300/600/900/1200ml/h).
3. Press the **BOLUS** softkey once to begin the delivery of the preset bolus. The display will show the bolus being delivered, the bolus counts down on the screen and will count down to zero upon completion of the bolus. On completion of the bolus the pump will automatically revert to the set infusion rate and continue infusing.
4. To terminate a bolus being delivered press **STOP** softkey. This will stop the bolus and continue infusing at the set rate.

Important: 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.

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 the **OK** softkey to exit the screen.

Important: 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.

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.

Operations During Use

? END OF OPERATION

The **END OF OPERATION** option is only available 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. A confirmation screen will be displayed.

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 and predictive TIVA mode:

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.

? 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

To review currently selected dosing information:

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

? 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.

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.

ⓘ DATA SET DETAILS

To review the 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, flashing 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.

Display	Description and Troubleshooting Guide
DRIVE DISENGAGED	The drive system has been disengaged during operation. Check the finger grips and the position of the syringe.
OCCLUSION	Pumping pressure has reached the alarm limit. Squeeze the finger grips on the plunger holder to release the drive mechanism and relieve any excessive pressure in the syringe and extension set. Identify and remove the cause of the blockage in the drive, syringe, or administration system before restarting the infusion.
CHECK SYRINGE	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.
BATTERY LOW	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.
BATTERY EMPTY	The internal battery is exhausted. Connect the pump to the AC power supply.
NEAR END OF INFUSION	The pump is nearing the end of the infusion.
END OF INFUSION	The pump has reached the end of the infusion. A preset volume will remain in the syringe to minimise the risk of the infusion of air bubbles into the extension set.
TITRATION NOT CONFIRMED	The infusion rate has been changed, but has not been confirmed and 2 minutes has expired without any operation. Press the button to silence the alarm, then press **CANCEL** to clear this message and silence the alarm. Check infusion rate and confirm by pressing the button or press the button to revert to the previous rate. Press the button to start infusion. (This alarm only occurs if rate titration is enabled.)
AC POWER FAIL (Infusion continues)	AC Power has been disconnected and the pump is operating on battery power. Reconnect AC power supply or press the button to silence the alarm and continue with battery operation. The alarm will automatically cancel if the AC power supply is reconnected.
Error Code and Message	The alarm system has detected an internal malfunction. Note the malfunction code. Remove pump from service for examination by a qualified service engineer.
ATTENTION (with "3 Beeps")	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 2 minutes. Alternatively press and hold down the button and wait for 3 beeps in succession, this will put the warning alarm on standby for 60 minutes.
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 the rate below Soft Alert.
DOSE UNDER	The infusion rate has been set to a value that 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 then press the **NO** softkey and adjust the rate above Soft Alert.
DOSE NOT PERMITTED	The infusion rate has been set or has attempted to be 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 the target below Soft Alert.

Alarm Indicator Colour	Alarms indicated
AMBER	AC POWER FAIL; NEAR END OF INFUSION; ATTENTION; TITRATION NOT CONFIRMED; BATTERY LOW; DOSE WOULD EXCEED; DOSE UNDER; TARGET WOULD EXCEED.
RED	All others.

Configured Options

This section comprises of a list of configurable options which are entered via the pump configuration menu (available in Technician Mode).

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

Important: Access codes should only be entered by qualified technical personnel.

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 **OK** 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.

Asena® PK 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 you wish to enable/disable or adjust and press the **MODIFY** softkey.
3. When all the desired modifications have been carried out press the **OK** 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 pumps communications to use RS232 (hardware option).

Configured Options (continued)

Asena® PK Editor Software - Pump Configuration

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

Important Information:

The approved Data Set contains configurable option values per profile.

The originator and approvers of the Data Set should be aware that, unless a rationale for safety is provided, it is not recommended to set the callback time to a value greater than the default setting of 2 minutes since doing so would not be in compliance with EN60601-2-24:1998 standard.

[1] The bolus configurations are used only when the Asena® PK Syringe Pump is being used in ml/h mode. If a drug is selected then the drugs 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.

Configured Options (continued)

Asena® PK Editor Software - Profile Drugs

The following drug parameters are only configurable via the Asena® PK Editor Software (PC based), and are referenced when the Asena® PK Syringe Pump is being used with a drug name selected. Refer to the Asena® 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 Asena® PK 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.

Configured Options (continued)

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
Maintenance Default	8mg/kg/h	8mg/kg/h	0.2µg/kg/min	0.2µg/kg/min	0.1µg/kg/h
Maintenance Soft Max	14mg/kg/h	14mg/kg/h	1µg/kg/min	1µg/kg/min	1µg/kg/h
Maintenance Hard Max	20mg/kg/h	20mg/kg/h	2µg/kg/min	2µg/kg/min	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.

Important:
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 rates are syringe dependant.

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

The Volume Infused range is 0.0ml - 9990ml.

Bolus Specifications -

Bolus rates are syringe dependant.

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

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

Critical Volume -

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

Maximum Overinfusion: 0.25ml

Purge Specifications -

Purge rate: 100-500ml/h.

Purge volume: 0.5-5ml.

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

Near End Of Infusion Alarm -

5min to end of infusion, or 10% of syringe volume, whichever is smaller.

End Of Infusion (EOI) Alarm -

0.5% of syringe volume

Electrical Classification -

Class I product. Continuous Mode Operation, Transportable

Maximum Pumping Pressure Limit -

Highest alarm level 1000mmHg (nominal at L-10)
(Factory Default: L-5 - adjustable via Asena® PK Editor Software)

Occlusion Accuracy (% of full scale)* -

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

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

System Accuracy (continuous mode ml/h and TIVA) -

Volumetric Mean +/- 2% (nominal).

Temperature +/- 0.5% (5 - 40ºC)

High Rates +/- 2.0% (rates > syringe volume/h eg. > 50ml/h in a 50ml syringe.)

Important: System accuracy is +/-2% typical by volume as measured using the trumpet curve test method defined in IEC60601-2-24 at rates of 1.0ml/h (23ºC) and above when the pump is used with the recommended syringes. Differences in factors such as size and plunger force in compatible syringes can cause variations in accuracy and trumpet curves. See also trumpet curves section in this manual.

Battery Specifications -

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

Battery life is typically 4h from fully charged @ 5.0ml/h & 20ºC under normal conditions. 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 more than 6 months when not powered up.

Fuse Type -

2 x T 1.25A, slow blowing.

AC Power Supply -

115/230VAC, 50/60Hz, 20VA (nominal).

Case Material -

GE Cycolac S157 (fire retardant to UL94V-2)

Dimensions -

335 mm (w) x 121 mm (h) x 200 mm (d). Weight: 2.5 kg (excluding power cable).

Alarm Conditions -

Drive Disengaged	Occlusion
Check Syringe	Battery Low / Battery Empty
Near End Of Infusion	End of Infusion
AC Power Failure	Internal Malfunction
Attention (Nurse Callback)	Titration not confirmed
Dose Would Exceed	Dose not Permitted
Dose Under	Target Would Exceed

Environmental Specifications -

Operating Temperature	**+5°C - +40°C**
Operating Relative Humidity	**20% - 90%**
Operating Atmospheric Pressure	**700mbar - 1060mbar**
Transport Temperature	**-30°C - +50°C**
Transport Relative Humidity	**10% - 95%**
Transport Atmospheric Pressure	**500mbar - 1060mbar**

Electrical/Mechanical Safety -

Complies with IEC60601-1 (EN60601-1) and IEC60601-2-24 (EN60601-2-24).

EMC -

Complies with IEC60601-1-2:2002 and IEC60601-2-24.

Compatible Accessories

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.

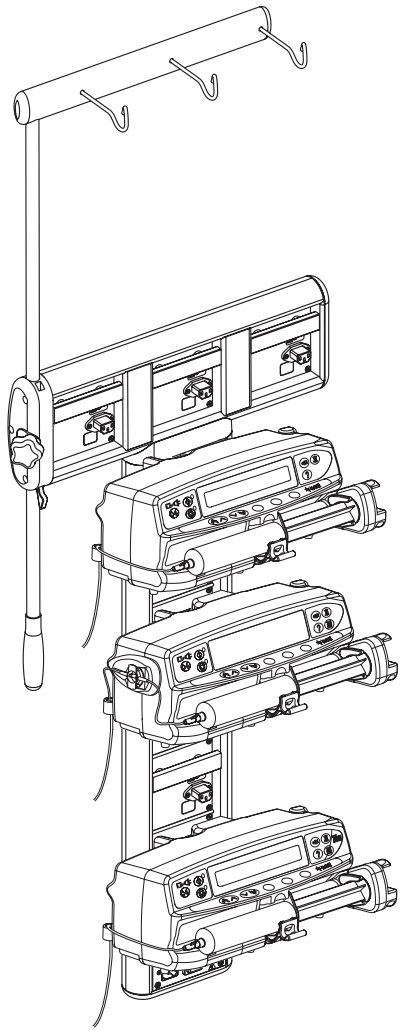
	5ml	10ml	20ml	30ml	50ml
IVAC®					✓
AstraZeneca					✓
B Braun Omnifix	✓	✓	✓	✓	✓
B Braun Perfusor			✓		✓
BD Perfusor					✓
BD Plastipak	✓	✓	✓	✓	✓
BD Precise			✓		✓
Codan		✓	✓	✓	✓
Codan Perfusion					✓
Fresenius Injectomat		✓			✓
Monoject**	✓	✓	✓	✓	✓
Nipro	✓		✓	✓	✓
Pentaferte	✓	✓	✓		✓
Rapiject*					✓
Terumo	✓	✓	✓	✓	✓

***** - The Rapiject 50ml syringe is a specialised syringe with a large diameter barrel. To provide protection against accidental dislodging always ensure the infusion line is secured using the infusion set hook - see Loading a Syringe section.
** - ≡ TYCO / Healthcare KENDALL - MONOJECT.

Recommended Accessory - Asena® Docking Station

Recommended accessory to use in conjunction with the Asena® PK Syringe Pump is:

- The Asena® DS Docking Station



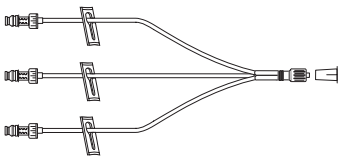
Compatible Accessories (continued)

Extension Sets

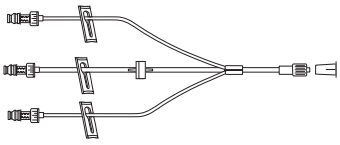
The pump uses standard, single-use, disposable extension sets and syringes with Luer-lock connectors. The user is responsible for verifying the suitability of a product used if it is not ALARIS recommended.

Please check the availability of the sets listed below with your local ALARIS Medical Systems® Affiliate or Distributor.

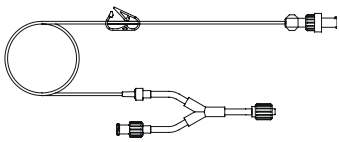
20038E
3 way extension set with 3 SmartSite® Needle-Free Valves, low priming volume, 13cm



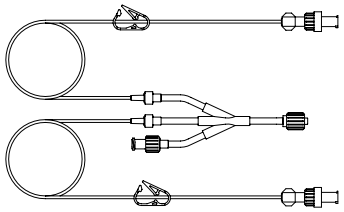
20062E
3 way extension set with 3 SmartSite® Needle-Free Valves and one backcheck valve, 16cm



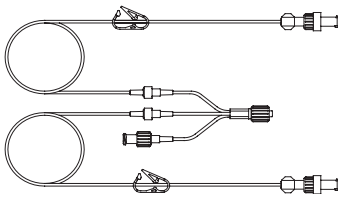
MFX 2271
2 way set with anti-syphon valve and backcheck valve, 210cm



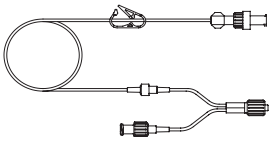
MFX 2270
3 way set with 2 anti-syphon valves and backcheck valve, 210cm



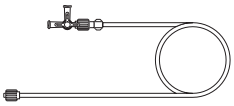
MFX 2290
3 way set with 2 anti-syphon valves and backcheck valve, low priming volume, 209cm



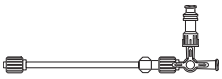
MFX 2291
2 way set with anti-syphon valve and backcheck valve, low priming volume, 209cm



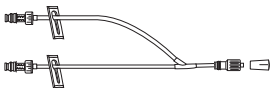
MFX 2284
3 way tap (blue) with extension, 100cm



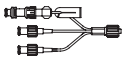
MFX 2280E
3 way tap with extension and SmartSite® Needle-Free Valve, 10cm



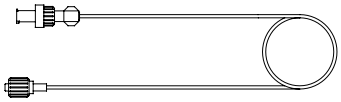
20061E
Y extension set with 2 SmartSite® Needle-Free Valves, 18cm



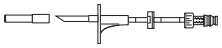
MFX 2233E
3 way extension set with 2 backcheck valves, SmartSite® Needle-Free Valve and clamp, low priming volume 10cm



MFX 2260
Extension set with anti-syphon valve, 200cm



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

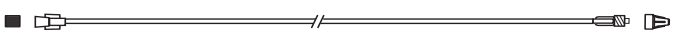


2205E
Vial adaptor with SmartSite® Needle-Free Valve, for 20mm vials

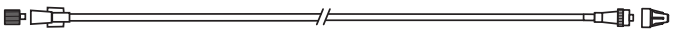
MFX 2293
Extension set with backcheck valve, 14cm. Priming Volume: 0.9ml

G40720
Low sorbing PE lined extension set with clamp 200cm

G40615
Low sorbing PE extension set 150cm

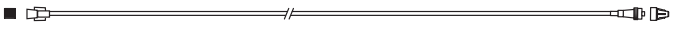


G40215
Extension set, opaque PVC, 150cm



30262E
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: 1.5ml

G40320
Opaque White PVC Syringe Extension Set, 200cm.
Priming Volume: 3.6ml

G40620
Polyethylene Syringe Extension Set, 200cm.
Priming Volume: 1.6ml

It is recommended that the extension sets are changed according to hospital protocol or as per the extension set 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. All servicing should only be performed by a qualified service engineer with reference to the Technical Service Manual (TSM) for this product (TSM reference: 1000SM00001).

Refer to the Technical Service Manual for the access code for technical service features.

Interval	*Routine Maintenance Procedure*
As required	Thoroughly clean external surfaces of the pump before and after prolonged period of storage.
At least once per year	1. Inspect AC power supply plug and cable for damage. 2. Perform functional tests as outlined in the Technical Service Manual. 3. Operate the pump on battery power until the battery low alarm then charge the battery to confirm battery operation and charging.

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.

Disinfectants which are known to be corrosive to metals must not be used. These include the following disinfectant types:

NaDcc (such as Presept),

Hypochlorites (such as Chlorasol),

Aldehydes (such as Cidex),

Cationic Surfactants (such as Benzalkonium Chloride).

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

Recommended cleaners are:

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

The syringe and extension lines 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.

Important: 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.

Replacing the AC Fuses

If the pump continually illuminates the battery symbol and the AC power indicator light does not illuminate when the pump is connected to the AC power supply and switched ON, suspect that either the power supply fuse in the AC plug (if fitted) or the internal fuses have blown.

First check the power supply fuse in the AC mains plug (if fitted). If the AC power indicator light does not illuminate remove the pump from service.

It is recommended that only a qualified service engineer replaces the AC fuses. For further information regarding the replacement of internal AC fuses refer to the Technical Service Manual.

Battery Operation

The internal rechargeable battery allows continued operation when the AC power is unavailable, for example during patient transfer or AC power failure. A fully charged battery will provide over 4 hours of operation at typical infusion rates. From the battery low alarm it will take about 2 hours to fully recharge 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.

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

It is recommended that only a qualified service engineer replaces the battery. For further information regarding the replacement of batteries refer to the Technical Service Manual.

Disposal

The pump 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 as per local regulations.

Test Routines

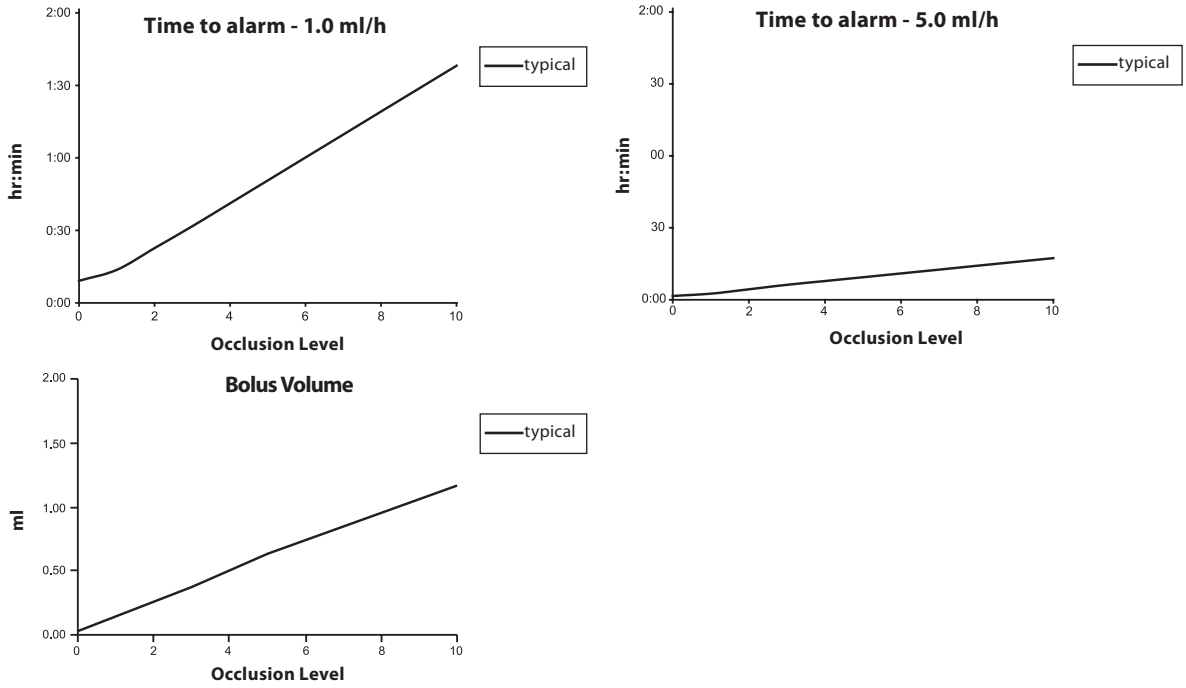
The test routines are designed to allow confirmation of many of the pump functions, defaults and calibrations without requiring internal inspection. They do not represent a full calibration check.

Important: See the Technical Service Manual for a complete list of the test procedures, access codes and calibration procedures.

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.



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 optional feature) is a feature on Asena® Syringe Pumps that allows the pump to be connected to a PC or other Asena® Syringe Pumps. This allows data to be transferred between the Asena® Syringe Pump and a PC or another Asena® Syringe Pump.

Important: The Nurse Call interface provides a remote backup to the internal audible alarm. It should not be relied upon to replace monitoring of the internal alarm.

Refer to the Technical Service Manual for further information regarding the RS232 interface.

The assessment for the suitability of any software used in the clinical environment to 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 Technical Service Manual and is for general information only.

Any connected analogue and digital components are required to meet EN60950 for data processing and 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 EN60601-1-1.

IrDA

Baud Rate	38.4 kBaud

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 3K load to ground
RXD Input Voltage Range	-30V - +30V max.
RXD Input Thresholds	Low: 0.6V minimum / High: 3.0V maximum
RXD Input Resistance	3K minimum
Enable	Active, Low:-7V to -12V Active, High:+7V to +12V, powers up the isolated RS232 circuitry Inactive: Floating/open circuit, allows isolated RS232 circuitry to power down.
Isolation Socket/Pump	1.5kV (dc, or ac peak)
Baud Rate	38.4 kBaud
Start Bits	1 Start Bit
Data Bits	8 Data Bits
Parity	Odd 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

2 Transmit Data (TXD) Output

3 Received Data (RXD) Input

4 Power Input (DSR)

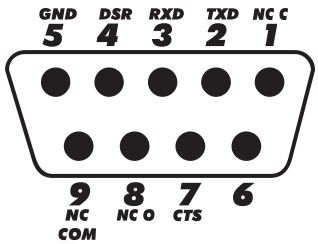
5 Ground (GND)

6 Not used

7 Power Input (CTS)

8 Nurse Call (Relay) Normally open

9 Nurse Call (Relay) Common



Trumpet Curves & 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 IEC60601-2-24 standard.

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

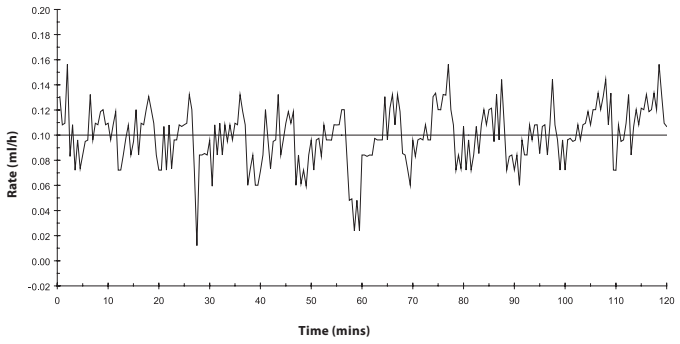
Knowledge of system accuracy over various observation windows may be of interest when certain drugs are being administered. Short term fluctuations in rate accuracy may have clinical impact depending on the half-life of the drug being infused, therefore the clinical effect cannot be determined from the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

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

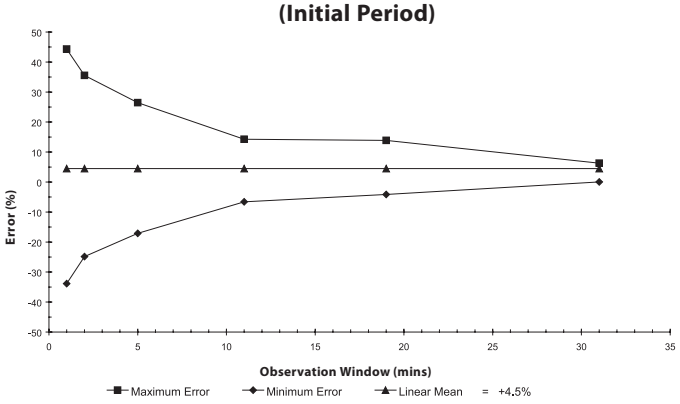
Differences in factors such as size and plunger force in compatible syringes produced by other manufacturers can cause variations in accuracy and trumpet curves as compared to those represented. Additional curves for compatible syringes are available upon written request.

For applications where flow uniformity is a concern, rates of 1.0ml/hr or above, or concentrations resulting in a rate above 1ml/h, are recommended.

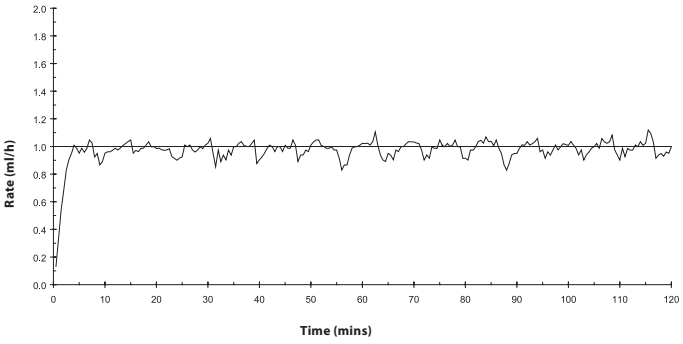
Start-up Trend. BD Plastipak 50ml @ 0.1ml/h



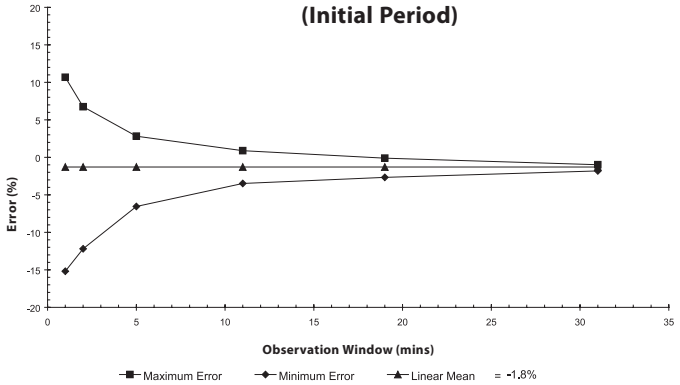
Trumpet Curve. BD Plastipak 50ml @ 0.1ml/h (Initial Period)



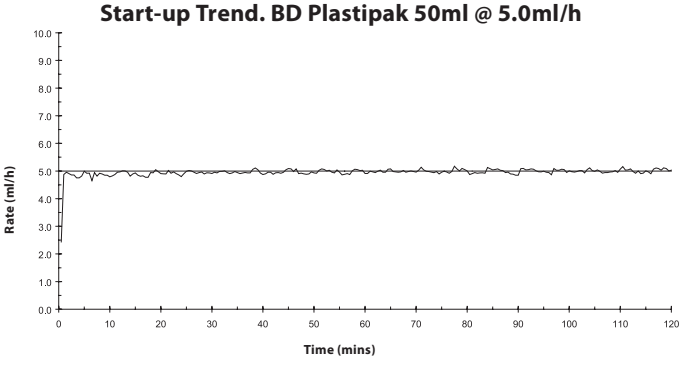
Start-up Trend. BD Plastipak 50ml @ 1.0ml/h



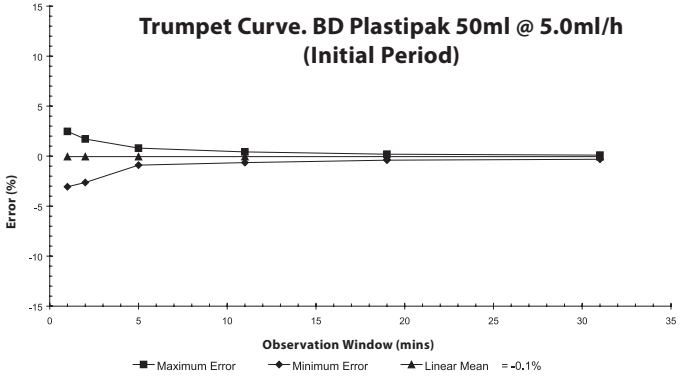
Trumpet Curve. BD Plastipak 50ml @ 1.0ml/h (Initial Period)



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



Trumpet Curve. BD Plastipak 50ml @ 5.0ml/h (Initial Period)



Profiles from TCI mode

When targeting in TCI Mode the Asena® PK 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 Asena® PK 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 on page 28, were 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 Asena® PK 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 performance graphs shown on page 28, over a one hour period, the Asena® PK 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 Asena® PK 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 on page 29, 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 Asena® PK 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.

Note: 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 performance 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.

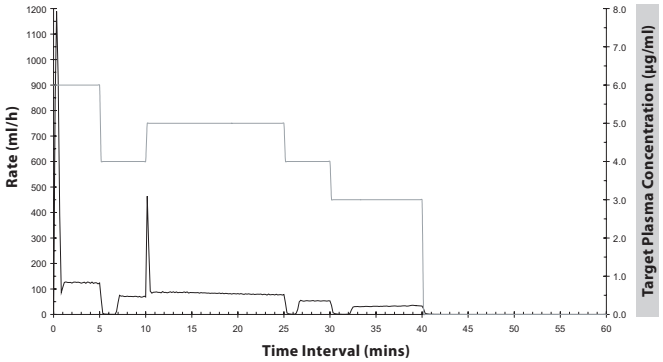
The target (plasma or effect) concentrations shown are for illustrative purposes only

Note:
[1] IEC60601-2-24: Particular Requirements for the Safety of Infusion Devices;
[2] 95% Confidence / 95% Population.

Profiles from TCI mode - Infusion Rate vs Target Concentration

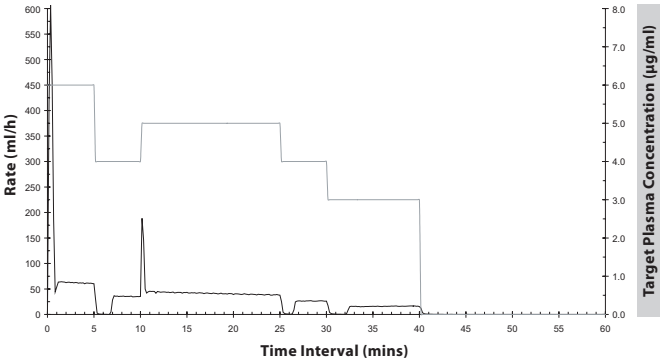
Diprivan 1% Marsh Model BD 50ml Syringe

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



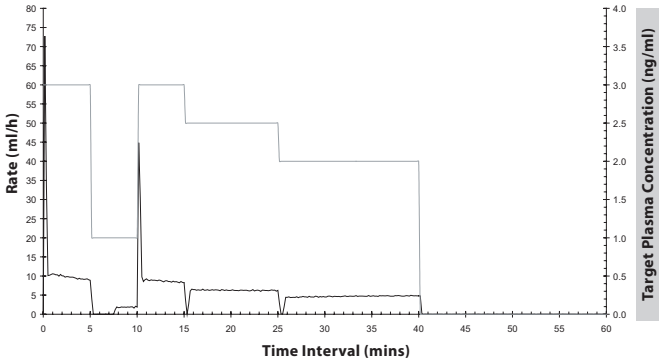
Diprivan 2% Marsh Model BD 50ml Syringe

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



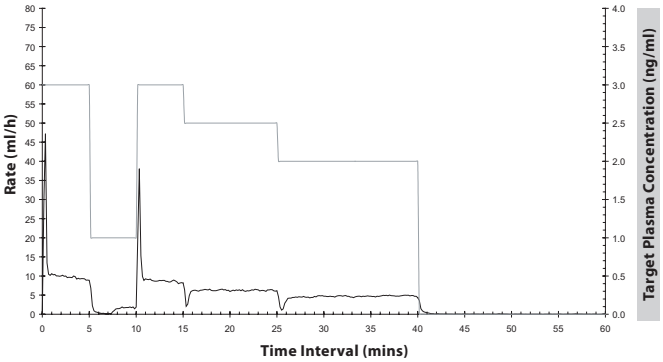
Remifentanil Minto Model BD 5ml Syringe

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



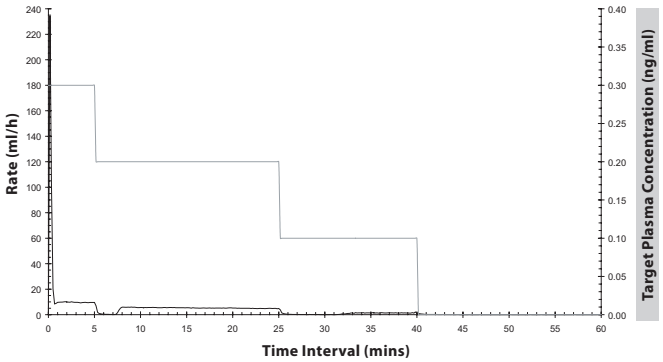
Remifentanil Minto Model BD 50ml Syringe

Patient Age: 75 Yrs
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)

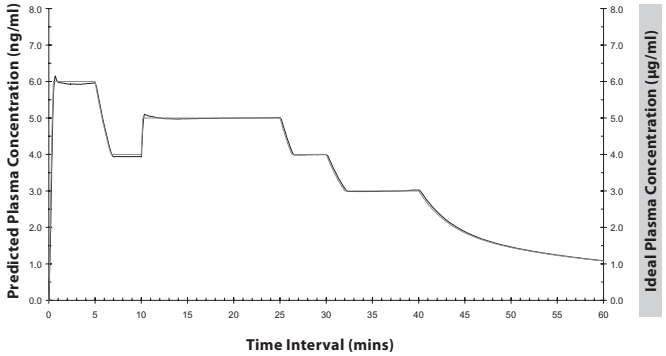
Drug Concentration: 5.0µg/ml
Volumetric Accuracy: +3.0%



Profiles from TCI mode - Predicted vs Ideal Concentration

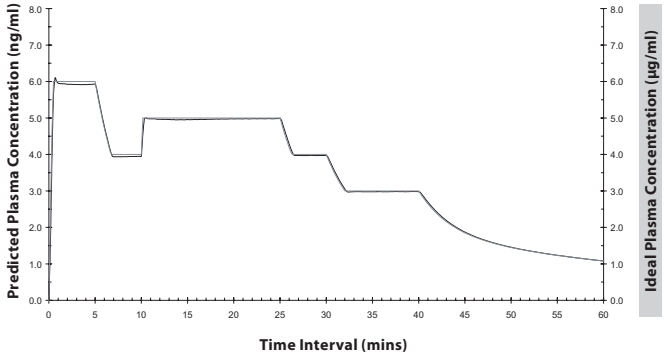
Diprivan 1% Marsh Model BD 50ml Syringe

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



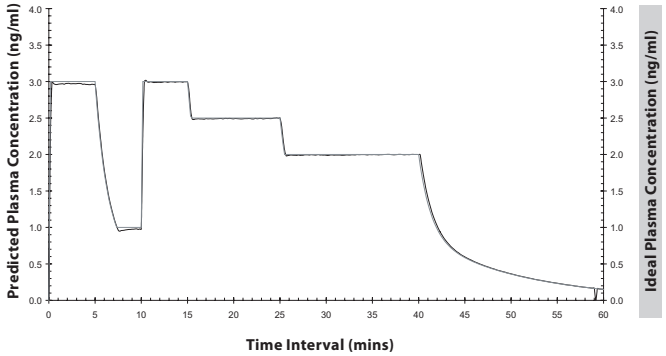
Diprivan 2% Marsh Model BD 50ml Syringe

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



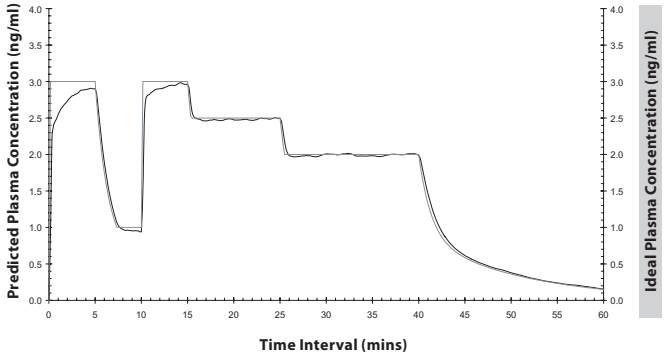
Remifentanil Minto Model BD 5ml Syringe

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



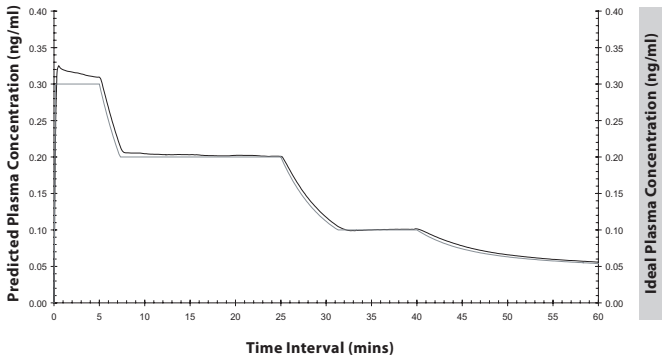
Remifentanil Minto Model BD 50ml Syringe

Patient Age: 75 Yrs
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%



Service Contacts

For service contact your local ALARIS Medical Systems® Affiliate Office or Distributor. ALARIS Medical Systems® Service Centre Addresses:

AE
ALARIS Medical Systems Middle East Office,
PO Box 5527,
Dubai, United Arab Emirates.
Tel: (971) 4 28 22 842
Fax: (971) 4 28 22 914

AU
ALARIS Medical Australia Pty Ltd,
8/167 Prospect Highway,
Seven Hills, NSW 2147,
Australia.
Tel: (61) 2 9838 0255
Fax: (61) 2 9674 4444
Fax: (61) 2 9624 9030

BE
ALARIS Medical Belgium B.V.,
Otto De Mentockplein 19,
1853 Strombeek - Bever,
Belgium.
Tel: (32) 2 267 38 99
Fax: (32) 2 267 99 21

CA
ALARIS Medical Canada, Ltd, 235 Shields Court,
Markham,
Ontario L3R 8V2,
Canada.
Tel: (1) 905-752-3333
Fax: (1) 905-752-3343

CN
ALARIS Medical Systems,
Shanghai Representative Office,
Suite 9B,
Century Ba-Shi Building,
398 Huai Hai Rd(M.),
Shanghai 200020,
China.
Tel: (56) 8621-6384-4603
Tel: (56) 8621-6384-4493
Fax: (56) 8621-6384-4025

DE
ALARIS Medical Deutschland, GmbH,
Pascalstr. 2,
52499 Baesweiler,
Deutschland.
Tel: (49) 2401 604 0
Fax: (49) 2401 604 121

ES
ALARIS Medical Espãna, S.L.,
Avenida Valdeparra 27,
Edificio Alcor,
28108 - Alcobendas, Madrid,
España.
Tel: (34) 91 657 20 31
Fax: (34) 91 657 20 42

FR
ALARIS Medical France, S.A.,
95, rue Péreire,
78105 St Germain en Laye Cedex.
France.
Tél: (33) 0 820 821 123
Fax: (33) 1 30 61 22 23

GB - Manufacturer's Address:
ALARIS Medical UK Ltd,
The Crescent, Jays Close,
Basingstoke,
Hampshire, RG22 4BS,
United Kingdom.
Tel: (44) 0800 389 6972
Fax: (44) 1256 388 411

HU
ALARIS Medical Hungary
Döbrentei tér 1,
H-1013 Budapest,
Magyar.
Tel: (36) 14 88 0232
Tel: (36) 14 88 0233
Fax: (36) 12 01 5987

IT
ALARIS Medical Italia S.P.A.
Via Ticino 4,
50019 Sesto Fiorentino,
Firenze, Italia.
Tél: (39) 055 34 00 23
Fax: (39) 055 34 00 24

NL
ALARIS Medical Holland, B.V.,
Kantorenpand "Hoefse Wing",
Printerweg, 11,
3821 AP Amersfoort,
Nederland.
Tel: (31) 33 455 51 00
Fax: (31) 33 455 51 01

NO
ALARIS Medical Norway A/S
Solbråveien 10 A,
1383 ASKER,
Norge.
Tel: (47) 66 98 76 00
Fax: (47) 66 98 76 01

NZ
ALARIS Medical NZ Ltd,
Unit 14, 13 Highbrook Drive,
East Tamaki, Auckland,
New Zealand.
Tel: (64) 9 273 3901
Fax: (64) 9 273 3098

SE
ALARIS Medical Nordic, AB
Hammarbacken 4B,
191 46 Sollentuna,
Sverige.
Tel: (46) 8 544 43 200
Fax: (46) 8 544 43 225

US
ALARIS Medical Systems, Inc.
10221 Wateridge Circle,
San Diego, CA 92121,
USA.
Tel: (1) 800 854 7128
Fax: (1) 858 458 6179

ZA
ALARIS Medical S.A. (Pty) Ltd,
Unit 2 Oude Molen Business Park,
Oude Molen Road, Ndabeni,
Cape Town 7405, South Africa.
Tel: (27) (0) 860 597 572
Tel: (27) 21 510 7562
Fax: (27) 21 5107567

Document History

Revision	CO Number	Date	Description of Change/Changed by
1	5080	01/06/04	Initial release - Martin Burnett
2	5248	16/06/04	Amendment to graph data values - MPB
3	5296	07/07/04	Minor amendments to text - SED
4	5446	21/09/04	Update to include Asena® PK Editor Software - MPB

Warranty

ALARIS Medical Systems, Inc. (herein after referred to as "ALARIS Medical Systems") warrants that:

(A) Each new infusion instrument (pump, controller or peripheral instrument) is free from defects in material and workmanship under normal use and service for a period of two (2) years from the date of delivery by ALARIS Medical Systems to the original purchaser.

(B) Each new accessory is free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by ALARIS Medical Systems to the original purchaser.

(C) Each Mains Cable, Battery, Flow Sensor (ECD) and non-disposable probe is free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by ALARIS Medical Systems to the original purchaser.

(D) Each new Thermometer is free from defects in material and workmanship under normal use and service for a period of one (1) year from the date of delivery by ALARIS Medical Systems to the original purchaser.

If any product requires repair during the applicable warranty period, the purchaser should communicate directly with its local ALARIS Medical Systems® service centre to determine the appropriate service facility. Except as provided otherwise in this warranty, repair or replacement will be carried out at ALARIS Medical Systems' expense. The product requiring service should be returned promptly, properly packaged, and postage prepaid by purchaser. Loss or damage in return shipment to ALARIS Medical Systems shall be at purchaser's risk.

In no event shall ALARIS Medical Systems be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any ALARIS Medical Systems® product. This warranty shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product.

Furthermore, this warranty shall not apply to, and ALARIS Medical Systems shall not be responsible for, any loss or damage arising in connection with the purchase or use of any ALARIS Medical Systems® product which has been:

(A) repaired by anyone other than an authorised ALARIS Medical Systems® service representative;

(B) altered in any way so as to affect, in ALARIS Medical Systems' judgement the stability or reliability of the product or has had the product's serial or lot number altered, effaced or removed;

(C) subjected to misuse or negligence or accident; or

(D) improperly maintained or used in any manner other than in accordance with the written instructions furnished by ALARIS Medical Systems.

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(1000PB01391 Iss 2)

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This pump is designed and manufactured in the U.K. by ALARIS Medical UK Ltd. ALARIS Medical UK Ltd reserves the right to alter product specifications without notice.

AU Patent No. 723,884; 144,125; 144,122; 144,123; CA Patented/Breveté 90,906; 91,584; FR Brevete No. 997,137; DE D.B.P. No. 49910883.3; 29920378.6; GB Patent No. 2,083,563; 2,083,560; 2,083,561; IE Patent No. D13001; D13003; D13007; JP Patent No.登録第1,117,996号; 登録第1,117,997号; 登録第1,117,999号; U.S. Patent No. 6,407,335; 6,428,509.

Other patents pending.

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