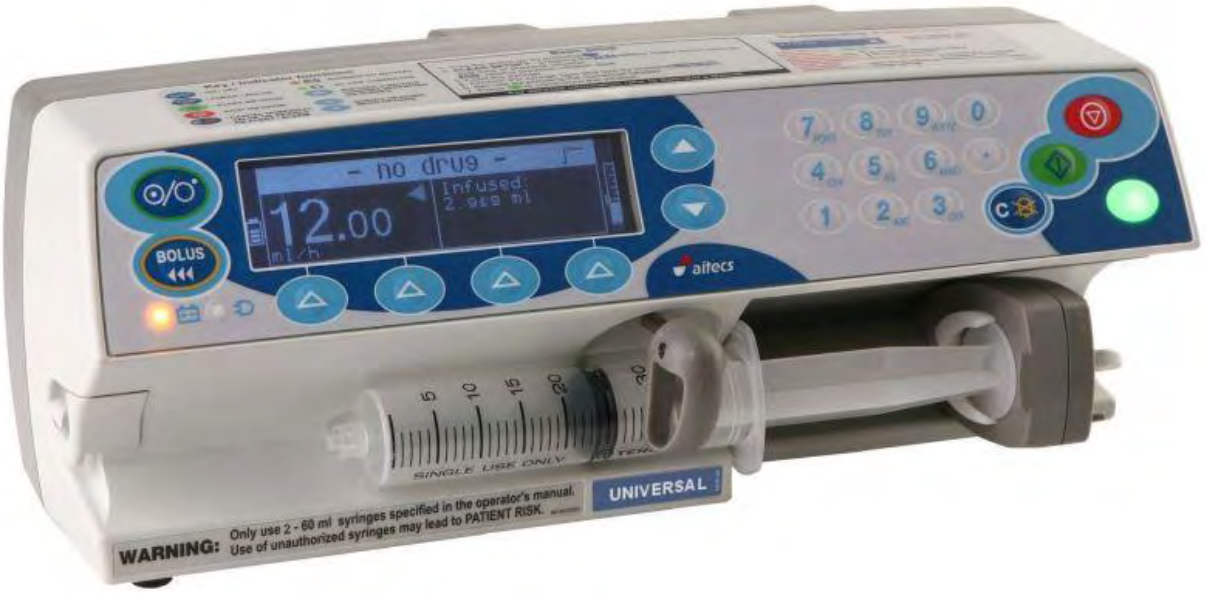
Operator's Manual

Aitecs 2016

SYRINGE INFUSION PUMP

UNIVERSAL



aitecs®

Prior to using this pump, read this manual carefully to fully understand the pump's functionality and to ensure safe and proper operation.

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CE 0123

This symbol represents compliance with the essential requirements according to Council Directive 93/42/EEC (14 June 1993) amended by 2007/47/EEC of the European Communities concerning medical devices.

The pump is classified of Class IIb as per European Council Medical Devices Directive 93/42/EEC Annex IX Rule 11.

Compliance

The pumps comply with IEC/EN 60601-1, IEC/EN 60601-1-2, IEC/EN 60601-1-6, IEC/EN 60601-1-8, IEC/EN 60601-2-24.

The pumps have been manufactured by the company, which has implemented and maintains a Quality Assurance System meeting the requirements of the standard ISO 13485.

The pump complies with the valid revisions of stated standards at the time of the device release.

Devices:	Aitecs 2016 (hereinafter – the pump)
Manufacturer:	UAB Viltechmeda, Mokslininku 6, LT-08412 Vilnius, Lithuania

Material Specifications

Steel	
Stainless Steel	
Copper	
Aluminium	
Bronze	
Brass	
Acetal	(POM)
Glass-filled acetal	(POM+GF)
Composition of Polycarbonate and ABS	(PC+ABS)
Silicone rubber	
Battery NiMH	

Hazardous components to be separated at the end of life

Battery NiMH

Printed circuit boards containing brominated flame retardant (TBBA 79-94-7) and lead

Electrolyte capacitors

AC power lead

INTRODUCTION

Intended use / Indications for use

- The pump is designed to meet the fluid and drug delivery requirements of today's changing clinical environment including general wards, critical and intensive care, neonatal, operating rooms and emergency rooms.
- The pump is indicated for infusion via intravenous (IV), intra-arterial (IA), epidural, or subcutaneous routes of administration.
- The pump is suitable for use only by appropriately trained clinicians and nurses.

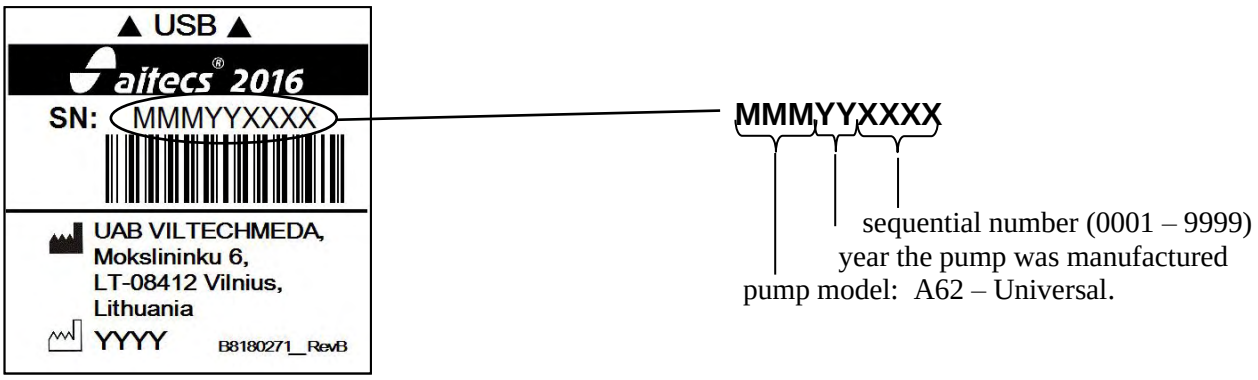
Contraindications

- At present no contraindications are known that would not allow to use the device.

Brief description of the device

- The pump accepts wide range, single-use, disposable Luer-lock syringes with volumes from 2 to 60 ml.
- The pump can be custom-configured to select key features that meet specific requirements. The selected options can be easily reviewed and the chosen configuration can be changed to meet new or different requirements.
- The pump can operate in Continuous rate mode with variety of dosing units, Intermittent and TIVA mode.

Serial Number Description



Items supplied with pump

1. The pump
2. Mounting clamp
3. Operator‘s manual
4. AC power cord
5. Packaging

Operational Warnings and Cautions

General

- If a software change occurs and the operation/specification for the device changes, new or additional operating instructions will be issued, if needed.

- Although the pumps have been designed and manufactured to exact specifications, it is not intended to replace trained personnel in the supervision of IV infusions.

- In accordance with the international standard, IEC/EN 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety, the pump is classified as:
• Class II
• Defibrillation-proof type CF applied part
• IP43 (ingress protection)
• Not suitable for use with flammable anesthetic mixtures with air, oxygen or nitrous oxide
• Continuous operation

- Prior to operating the pump, the user should carefully read this manual to fully understand the functionality and to ensure safe and proper operation.
- This manual has been developed with consideration to the requirements in the International Standard, IEC/EN 60601-2-24

Medical Electrical Equipment – Part 2-24: Particular Requirements for Safety of Infusion Pumps and Controllers. Data presented in the Technical Specifications reflect specific test conditions defined in this standard. Other external factors such as, varying back pressure, temperature, head height, set usage, fluid restrictions, solution viscosity, or combinations of these factors, may result in deviations from the performance data enclosed.

Definitions:

! WARNING ! messages indicate a possible hazard which, if not avoided, could result in severe personal injury or death.

! CAUTION ! messages indicate a problem or unsafe practice which, if not avoided, could result in minor or moderate personal injury, product or property damage.

NOTE messages provide supplemental information to the accompanying text.

Symbol definition

Attention consult accompanying documents

Protection Class II

Defibrillation-proof type CF applied part

IP43

Protection from entry by tools, wires, etc., with a diameter of thickness greater than 1.0 mm and spraying water up to 60° from the vertical

CE 0123

Council Directive 93/42/EEC concerning medical devices

Nurse call connector (optional)

USB USB interface (peripheral)

Manufacturer

Date of manufacture

Do not dispose of this product as unsorted municipal waste.
Follow local municipal waste ordinances for proper disposal provisions to reduce the environmental impact of waste electrical and electronic equipment (WEEE).

Warnings

! WARNING ! **Possible explosion hazard if used in the presence of flammable anesthetics.**

! WARNING ! **Always read and follow the instructions which accompany the syringe and extension sets you are using. Carefully follow the instructions for priming the set, as well as the recommended set change interval. Set use should not exceed the label set change interval.**

! WARNING ! **Viltechmeda will assume no responsibility for incidents which may occur if the product is not used in accordance with product labeling.**

! WARNING ! **The pump has no means to detect air presence in the extension set. The pump operator shall ensure there is no air in the extension set**

! WARNING ! **The pump must be mounted within 1.0m above or below the patient's heart. 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.**

! WARNING ! **Do not connect the IV extension set to the patient when purging.**

! WARNING ! **This device should be used only with Viltechmeda accessories specified for this device. There are risks associated with using anything other than the recommended accessories with this device.**

! WARNING ! **The specified accuracy of the syringe pump can only be maintained when recommended syringe and accessories are used.**

! WARNING ! **Inter-connection of several devices into a single infusion system can have substantial influence on the accuracy of the infusion rate, at least for one of these devices. In such situations, the operation of devices using gravitational forces can be unstable or impossible at all.**

! WARNING ! **The syringe should be disposed of in an appropriate manner, considering the nature of the residual fluid that may be contained within, in accordance with the hospital disposal practices.**

! WARNING ! **Though the factory-supplied configuration settings are suitable for most therapies, the operator and hospital professionals should verify that the pump settings are appropriate for the clinical application.**

! WARNING ! **Do not use hard or sharp objects on the keypad.**

! WARNING ! **Be sure to PURGE THE SYSTEM OF ALL AIR BEFORE ADMINISTERING ANY MEDICATION. Failure to follow this normal infusion procedure could precipitate serious**

consequences.

! WARNING ! **Remember that the volume of fluid contained in the connecting tubing is a residual amount and cannot be infused. Allow for this extra volume of fluid when initially filling the syringe.**

! WARNING ! **CAUTION must be employed to assure that the pump is in good working order before putting it into use. If the pump is being operated on battery power alone, ensure that the battery has been charged as described in this manual.**

! WARNING ! **If the mains supply is not possible and the internal power supply is depleted the operator as a alternative life-supporting method have to manually take the syringe out of the device to infuse the drugs to the patient.**

! WARNING ! **Verify all program data before pressing START.**

! WARNING ! **Wipe off spills immediately. Do not allow fluid or residues to remain on the pump.**

! WARNING ! **Caution must be exercised in the selection of drugs intended to be delivered via any infusion pump. If the drug contained in the syringe will be exposed to extreme environmental conditions for prolonged time periods, IT IS IMPORTANT TO SELECT DRUGS THAT WILL NOT CHANGE PHARMACOLOGICALLY UPON SUCH EXPOSURE.**

! WARNING ! **Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.**

• Epidural administration of anesthetics is limited to short term infusion (not to exceed 96 hours) with indwelling catheters specifically indicated for short term anesthetic epidural drug delivery.
• Epidural administration of analgesics is limited to use with indwelling catheters specifically indicated for either short term or long term analgesic epidural drug delivery.
• To prevent infusion of drugs not indicated for epidural use, do not use IV administration sets incorporating injection sites during epidural delivery.
• Clearly distinguish pumps used for epidural drug delivery from pumps used for other routes of administration.

! WARNING ! **A possible hazard can exist if the same model pumps with different alert configuration are used in the same care area.**

! WARNING ! **Additional infusion monitoring is required if life-saving or short half-life medication is being delivered.**

! WARNING ! **The pump executes self-test when powered up. Ensure that during test three status LED (green, orange, red) flashing, audible sounds heard (one at the beginning and another one afterwards). If any of self-test items fail to operate contact your local Service Centre.**

Cautions

! CAUTION ! **As with all medical electronic equipment, care must be exercised to avoid exposing this device to powerful sources of electromagnetic interference. This device design has been tested to current European standards and guidelines for medical devices. The device was not found to be affected adversely by these susceptibility tests and will perform safely. The device's emissions also were found to be acceptable.**
Using the pump near operating equipment which radiate high energy radio frequencies (such as electrosurgical/cauterising equipment, two-way radios, or cellular telephones)
may cause false alarm conditions. If this happens, reposition the pump away from the source of interference; or
turn off the pump.

! CAUTION ! **This unit emits a certain level of electromagnetic radiation, which is within the levels specified by IEC/EN 60601-2-24 and IEC/EN 60601-1-2.**

! CAUTION ! **Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 Safety of information technology equipment for data processing equipment or IEC/EN 60601-1 for medical equipment).**

! CAUTION ! **The USB is a standard feature on the syringe pump. Connection to the computer while pump is connected to the patient is prohibited.**

! CAUTION ! **Refer to the Service Manual for information regarding the USB interface.**

! CAUTION ! **The assessment for suitability of any software used in the clinical environment to receive data from syringe pump lies with the user of the equipment.**

! CAUTION ! **When infusing through a central line catheter, Viltechmeda recommends using sets with a Luer lock adaptor.**

! CAUTION ! **Follow the cleaning schedule and methods defined under Chapter 7 Maintenance and Storage, to ensure proper maintenance of the device.**

! CAUTION ! **Do not clean, disinfect, or sterilise any part of the device by autoclaving or with ethylene oxide gas. Doing so may damage the device and void the warranty. Only external parts of the device should be disinfected.**

! CAUTION ! **Do not use the following chemicals on the device, as they will damage the front panel: acetone, acetoaldehyde, ammonia, benzene, hydroxytoluene, methylene chloride, and ozone. Do not use cleaners containing n-alkyl dimethyl ethylbenzyl ammonium chloride unless they appear in the list of recommended cleaners in chapter 7.**

! CAUTION ! **When attaching the pump to an IV pole or other mounting locations, ensure it has been securely clamped.**

! CAUTION ! **Ensure device is mounted where main body is easily accessible and syringe can be installed in the loading mechanism without stretching or kinking the tubing.**

! CAUTION ! **To avoid personal injury, ensure that the IV pole is stable and secure. Ensure that the pole is able to support the pump, along with any other devices, without tipping or falling. The pole diameter should be between 1.5 and 4.0 cm.**

! CAUTION ! **Only use approved and pressure proved syringes with Luer lock connections and lines in accordance with chapter 2.**

! CAUTION ! **Safe and proper pump operation can be guaranteed only if the combination of pump and syringes was validated by the manufacturer.**

! CAUTION ! **It is recommended that the extension lines are changed according to hospital protocols.**

! CAUTION ! **It is recommended to minimize number of parameters, types of syringes, drug names and other functions leaving only that necessary for work. It will help to avoid errors in parameters programming and thereby decrease patient's risk.**

! CAUTION ! **Before initially powering on the device, charge the battery.**

! CAUTION ! **Never operate the pump if it was dropped. Remove it from service and have it checked by trained biomedical service technician.**

! CAUTION ! **The time of 25 minutes is required for device to warm up from the minimum storage temperature between uses until the device is ready for its intended use when the ambient temperature is 20 C.**

! CAUTION ! **The time of 5 minutes is required for device to cool down from the maximum storage temperature between uses until the device is ready for its intended use when the ambient temperature is 20 C.**

Notes

NOTE: **Pressure limit alarm is temporarily increased to the maximum level during Bolus, Loading dose/Initial bolus and Induction.**

1. PUMP DESCRIPTION

Front view

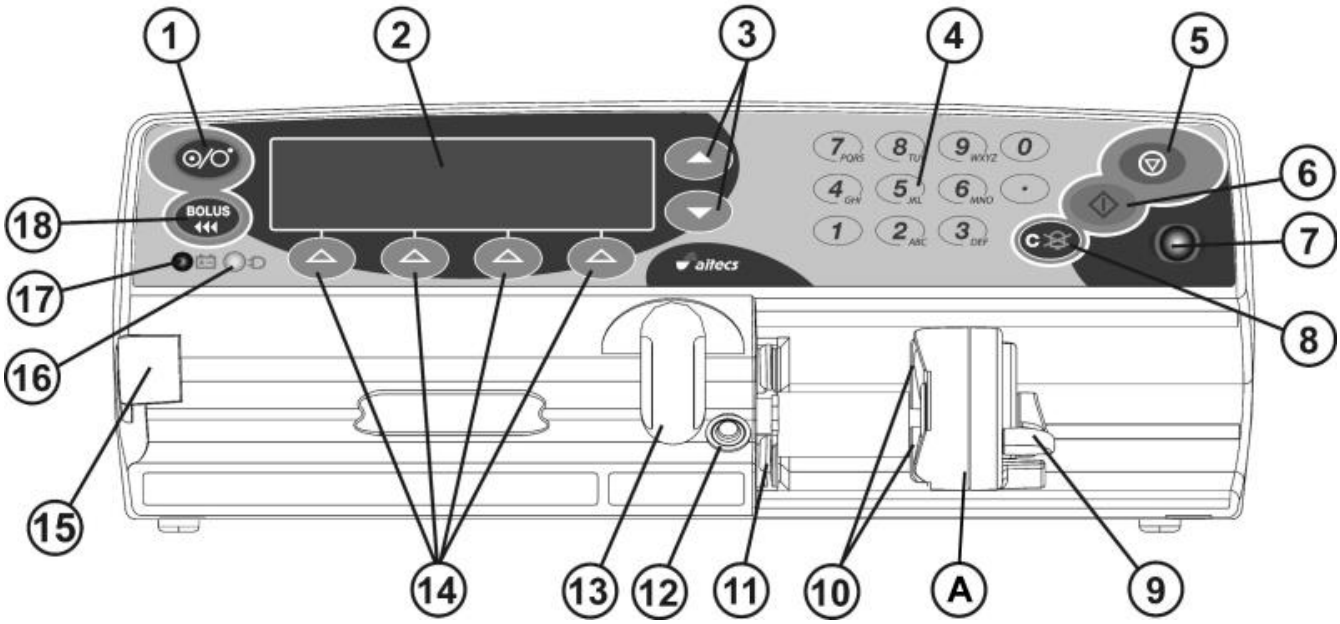


Figure 1.1 Pump's front view

1. ON/OFF key
2. Display
3. Scroll UP / DOWN keys
4. Numerical keypad
5. STOP key
6. START key
7. Status indicator
8. CANCEL / MUTE key
9. Pusher lever
10. Plunger grippers
11. Syringe flange retainer
12. Syringe barrel sensor
13. Syringe clamp
14. Softkeys
15. Extension set retainer
16. Mains led
17. Battery led
18. BOLUS / PURGE key

A. Syringe pusher

Keys description

Table 1.1 Key description

Key	Description
	The key is used to switch the pump on and off. Keep the key pressed for at least 2 seconds to switch the pump off.
	The key is used to commence the infusion.
	The key is used to halt the infusion. If the pump is in hold state for more than 2 minutes, an alert signal is activated. **NOTE:** *Pressing the*  *key while on hold calls up the standby time programming screen (if enabled in User Configuration menu).*
	The key is used to pause the audible alarm or alert signals for 2 minutes. **NOTE:** *By pressing the*  *key during infusion, the message prompting to lock the keypad will be indicated. Pressing the YES softkey will lock keypad.*
	The key is used to initiate priming the extension line or to bolus at an accelerated rate while an infusion is running. The  key must be pressed once to display the Bolus screen.
 	The keys are used to scroll up / down the parameter options. **NOTE:** *The keys can also be used to scroll the information in the right segment of the main window (available only with set VTBI parameter).*
	Softkeys - function changes depending on screen.
	Numerical keys to enter numerical values of the parameter being programmed or characters.

Rear Panel Assembly

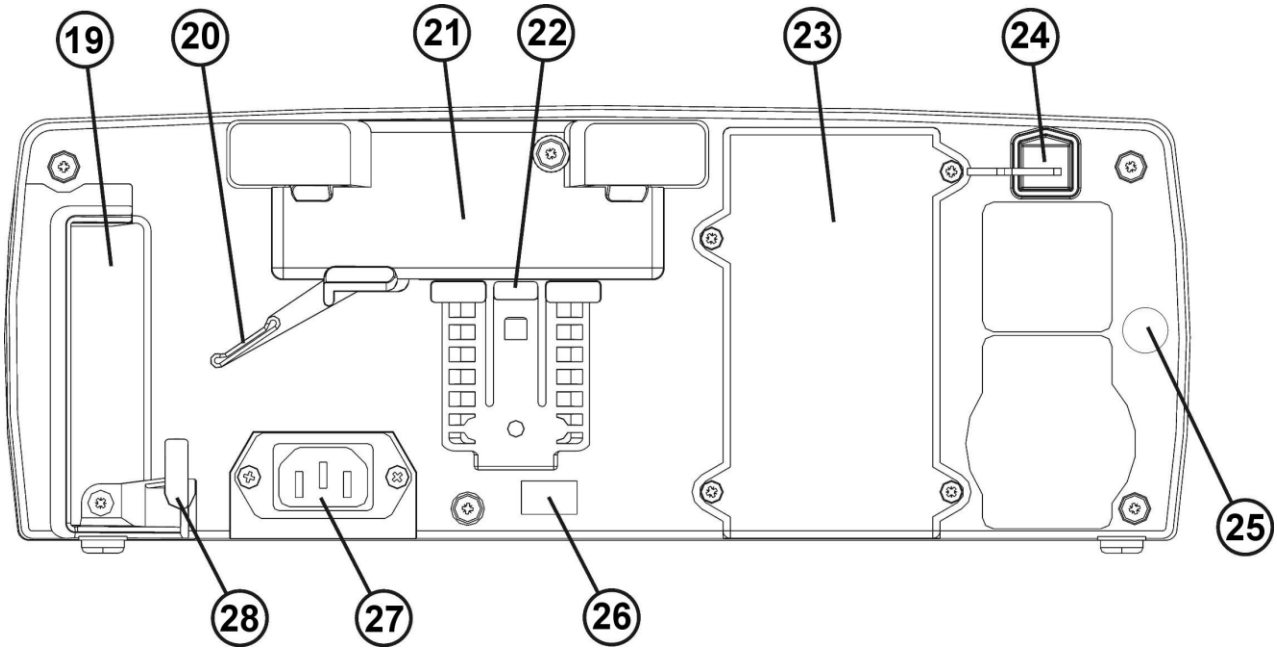


Figure 1.2 Pump's rear view

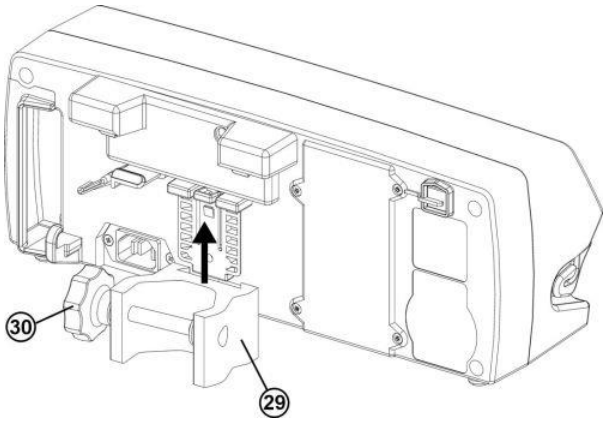


Figure 1.3 Attaching the mounting clamp

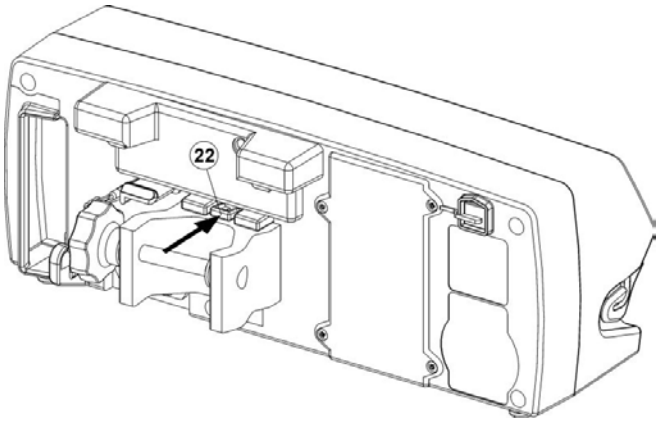


Figure 1.4 Detaching the mounting clamp

19. Carrying handle
20. Release lever
21. Slot for mounting on horizontal rectangular bars or docking station
22. Mounting clamp release button
23. Lid of battery compartment
24. USB connector
25. External 12VDC or Nurse call (optional)
26. IR Comms port
27. Mains inlet
28. Mains lead retaining hook
29. Mounting clamp (detachable) or mounting clamp for use in ambulances (optional) with dedicated holder
30. Mounting clamp handle

Main display reference guide

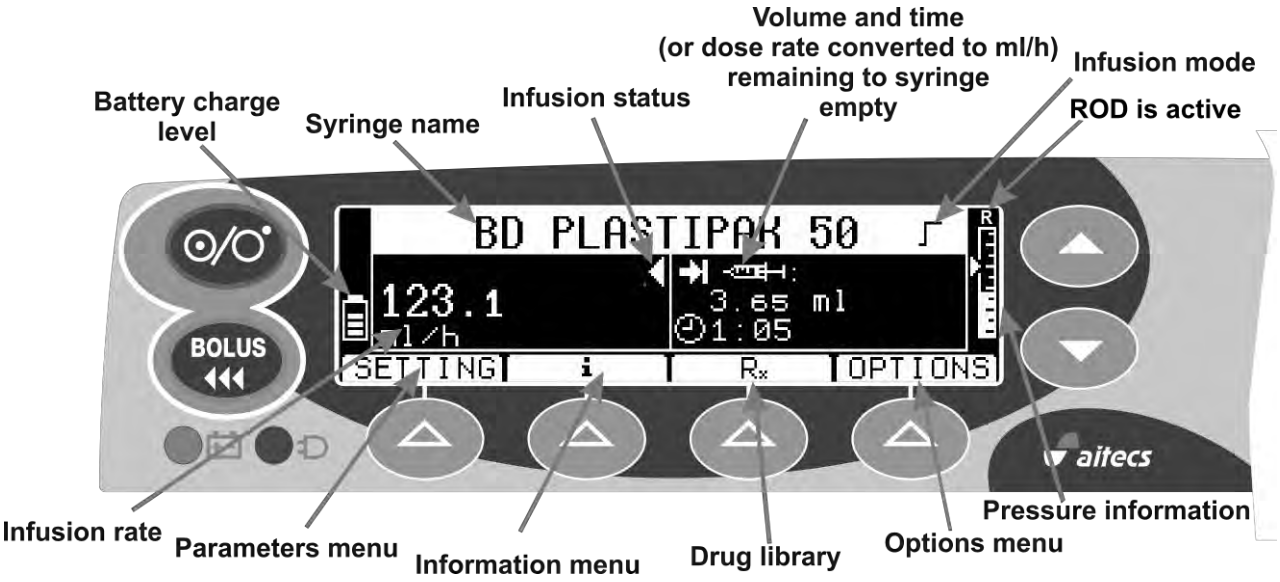


Figure 1.5 Main window

Table 1.2 Keypad indicators and display symbols reference guide

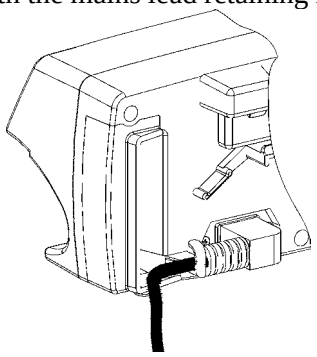
Keypad indicators reference guide	
	The orange BATTERY LED lights when the pump is operating on battery power. Flashing if LOW BATTERY alarm condition occurs.
	The green MAINS LED lights when the pump is connected to the AC and battery is charging.
STATUS INDICATOR (green, red, orange)	Green – infusion is in progress, red – alarm condition, orange – alert condition, orange and green alternately – KVO mode or alert condition during infusion.
Display symbols reference guide	
	Infusion status indicator: Loading Bolus or Purging
	Infusion status indicator: Infusion in progress
	Infusion status indicator: Infusion halted
	Infusion status indicator: Infusion halted during Intermittent pause time
KVO	Infusion status indicator: KVO mode in progress
	Keypad lockout symbol
	Battery charge level indicator (indicated when pump is operating on battery)
	Remaining value
	Infused/elapsed value

	Current pressure level
	Set occlusion pressure alarm level
	Active alarm/alert signal
	Paused alarm/alert audio signal
	Infugard® symbol
<< X – Y >>	Hard limits
< x – y >	Soft limits
	Entered rate value is under or exceeds the Soft limit.
	Continuous mode
	Intermittent mode
	Tiva mode
R	Rapid occlusion detection (ROD)

2. BASIC OPERATION

Initial Installation

1. Fasten the pump to the stand by turning the pole clamp handle or place the pump in docking station.
2. Connect the power cord to the corresponding socket on the pump securing it with the mains lead retaining hook.



3. Connect the power cord into the mains receptacle. The green indicator will light on.

NOTES:
1. When plugged into the mains, the MAINS LED will light.
2. If the pump is not plugged into the mains and the device is powered on, the BATTERY LED will light indicating that the pump is operating on battery power.

Mounting the pump

The Aitecs 2016 is equipped with a detachable mounting clamp. A mounting clamp is fitted to the rear of the pump and will provide secure fixing to a vertical IV poles. Fasten the pump to the IV pole by turning the mounting clamp handle (see Figure 1.3, *30*).
The pump has also slot (see Figure 1.2, *21*) for mounting on horizontal rectangular bars or docking stations. For that the mounting clamp (see Figure 1.3, *29*) must be detached. Press the clamp release button (see Figure 1.4, *22*) to detach the clamp from the pump.
As an option pump can be provided with rotatable mounting clamp.
As an option pump can be provided with clamp and rod for connecting Aitecs 2016 syringe pumps together (see Figures 2.1, 2.2).

Preparing mounting clamp for connecting pumps (optional)

1. Insert the rod in to the mounting clamp.

2. To secure the rod in the mounting clamp in designated deepenings (A) tighten the screw (C) using a wrench (you will find it in the package)**.**

Figure 2.1 Preparing mounting clamp for connecting pumps

! CAUTION ! **Make sure that screw (C) holds both parts tightly. Unintentional disconnection of these parts may cause corporeal damage.**

Connecting two or three pumps (optional)

1. Place the second pump on the top so that the rod of the bottom mounting clamp went in to the mounting clamp of top pump.

3. If needed make the same steps with the third pump.

2. Use clamp (D) to fasten pumps together. Turn the clamp clockwise in the mounting clamp designated deepenings (B)**.**

4. Place the handle (E) on the rod from the top and use clamp (D) to attach the handle for carrying connected syringe pumps.

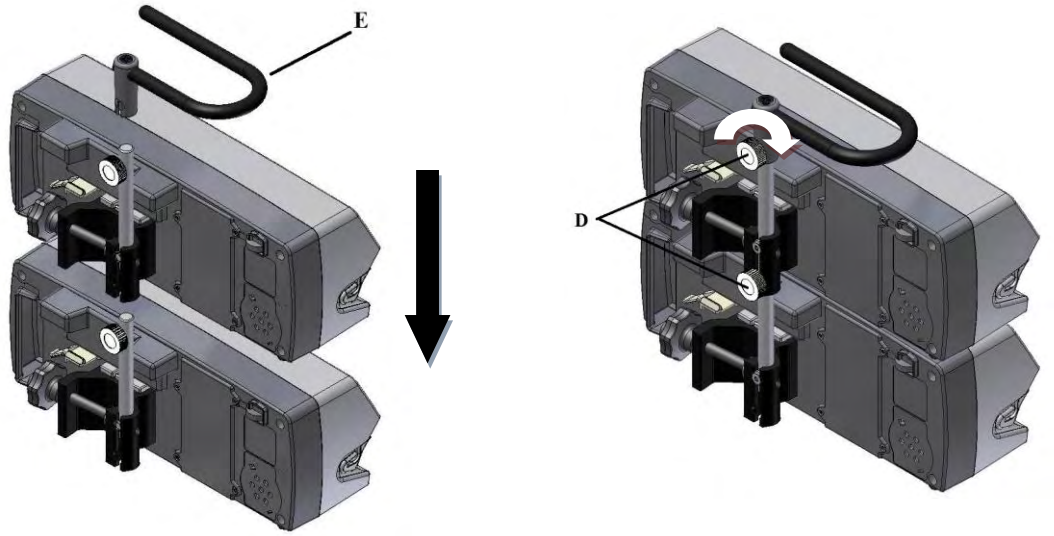


Figure 2.2 Connecting pumps

NOTE:
Mounting construction can be changed upon request of a customer.

! CAUTION ! **Ensure device is mounted where main body is easily accessible and syringe set can be installed in the loading mechanism without stretching or kinking the tubing.**

! CAUTION ! **To avoid personal injury, ensure that the IV pole is stable and secure. Ensure that the pole is able to support the pump, along with any other devices, without tipping or falling. The pole diameter should be between 1.5 and 4.0 cm.**

Recommended Syringes

Table 2.1 Recommended syringes

	Syringe size (ml)					
BD PLASTIPAK (IE)	**3 ml**	**5 ml** ROD **(REF 300911)**	**10 ml** ROD **(REF 300912)**	**20 ml** ROD **(REF 300629)**	**30 ml** ROD	**50 ml** ROD **(REF 300865)**
PERFUSOR (BBraun) (DE)				**20 ml** ROD **(REF 872615)**		**50 ml** ROD **(REF 8728844F)**
OMNIFIX (BBraun) (DE)	**2 ml**	**5 ml**	**10 ml** ROD **(REF 4617100V)**	**20 ml** ROD **(REF 4617207V)**	**30 ml** ROD **(REF 4617304F)**	**50 ml** ROD **(REF 4617509F)**
MONOJECT USA (US)			**12 ml** ROD **(REF 1181200777)**	**20 ml** ROD **(REF 1182000777)**	**35 ml** ROD **(REF 1183500777)**	**60 ml** ROD **(REF 1186000777)**
PENTAFERTE (IT)		**5 ml** ROD	**10 ml** ROD	**20 ml** ROD	**30 ml** ROD	**60 ml** ROD
SHANCHUAN (CN)			**10 ml** ROD	**20 ml**		**50 ml** ROD
SHANCH-SOFTJECT (CN)				**20 ml**		**50 ml** ROD
TERUMO EUROPE (BE)	**2.5 ml**	**5 ml**	**10 ml**	**20 ml** ROD	**35 ml** ROD	**50 ml** ROD
MARGOMED (PL)						**50 ml** ROD
JANPOL (PL)						**50 ml** ROD
BOGMARK (PL)		**5 ml** ROD	**10ml** ROD	**20 ml** ROD		
POLFA (PL)				**20 ml** ROD		**50 ml** ROD
ERG (PL)						**50 ml** ROD
UNIXFARM (RU)				**22 ml** ROD		
ELEC (RU)				**20 ml**		
CHIRANA (SK)						**50 ml** ROD **(REF CH0305LL)**
ESKULAP-KURSK (RU)						**50 ml** ROD
HAYAT PERFUSA (TR)						**50 ml** ROD
ECOJECT (DE)						**50 ml** ROD **(REF 21052)**
PERFUJECT (DE)						**50 ml** ROD **(REF 22052)**
HSW SOFT-JECT (DE)	**2.5 ml** ROD	**5 ml** ROD	**10 ml** ROD	**20 ml** ROD		
SHUANGGE (CH)			**10 ml** ROD	**20 ml** ROD		**50 ml** ROD
PERFVIZYON PLUS (TR)						**50 ml** ROD
VIZYOJECT LUER LOCK (TR)	**2 ml**	**5 ml** ROD	**10 ml** ROD	**20 ml** ROD		**50 ml** ROD
INJECTOMAT SPRITZE (DE)						**50 ml** ROD
SAFEWAY (IN)						**50 ml** ROD
KD-JECT (DE)				**20 ml** ROD		
KD-JECT (DE)						**50 ml** ROD

NOTES:
1. The Manufacturer of the pump can change the syringe list, including syringes of new brands or removing the included ones. The list of syringe brands is dependant on the software version of the pump.
2. Rapid Occlusion Detection and Line disconnection functions are supported with syringes marked with the ROD *symbol.*

! CAUTION ! **It is recommended to use approved and pressure proved syringes with Luer lock connections and lines.**

! CAUTION ! **Using the syringes with Luer slip connections double check the fixation of extension set with syringe.**

! CAUTION ! **Safe and proper pump operation can be guaranteed only if the combination of pump and syringes was validated by the manufacturer.**

Preparing the Syringe and Extension Set

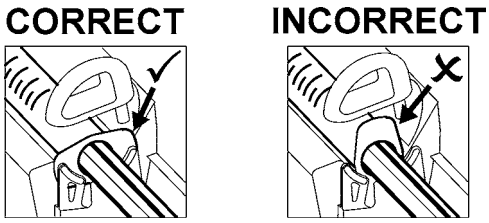
1. Prepare the syringe following the manufacturers' directions of use.
2. Attach an appropriate extension set to the syringe and purge.
3. Ensure all air is expelled from the extension set.

Loading the syringe

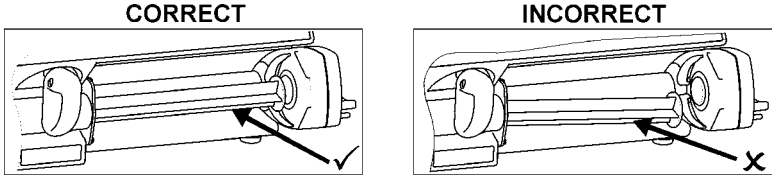
1. Press down the pusher lever (See Figure 1.1, *9*) and wait until pusher reaches the rightmost position. Pull the syringe clamp (See Figure 1.1, *13*) forwards and turn it clockwise by 90°.
2. Insert the syringe ensuring that the syringe flanges are located in the corresponding slots (See Figure 1.1, *11*) on the pump.
3. Turn the syringe clamp (See Figure 1.1, *13*) counter-clockwise by 90° and lower it onto syringe barrel.

NOTES:

1) Ensure syringe barrel and syringe finger grips are correctly positioned:



2) Ensure syringe plunger is correctly positioned:



4. Select the required syringe type and size. Press the **CONFIRM** softkey when the loaded syringe type and size matches the shown on display. Wait until pusher reaches and grabs the syringe plunger. Ensure that syringe plunger is securely captured.

NOTES:

1. It is possible to stop moving drive by pressing ⏚ at any time.

2. Pressing the ⏚ key while pump pusher is moving towards the syringe plunger stops the pusher movement and the question „Continue loading?" appears on screen. Pressing the YES softkey resumes pusher movement towards the syringe plunger while the NO softkey causes pusher to move backwards.

! CAUTION ! **Never leave pump unattended during syringe loading.**

! CAUTION ! **Keep hands away from advancing pump pusher.**

Starting infusion

1. Connect the pump to the power supply by means of the power cord and press the  key. The pump starts its internal tests.
2. Ensure that the displayed date and time are correct.
3. Clear Set-up? – pressing the **YES** softkey clears stored Rate, VTBI, Total/Infused volume, Drug Infused and Drug name of the previous infusion, pressing the **NO** softkey retains previous infusion data.
4. Load the syringe as described in above section.
5. Check if the loaded syringe conforms to type and size on the displayed. Select the required syringe type and press the **CONFIRM** softkey when the loaded syringe type and size matches the shown on display. Wait until pusher reaches and grabs the syringe plunger.

NOTE:
Due to inaccurate syringe graduation, the drug volume displayed on the screen may differ from that which is indicated on the syringe.

6. If it is necessary to purge the extension set, press the 

key. Then press and hold the **PURGE** softkey until air is removed from the extension set.
7. Connect the extension set to the patient. The syringe extension set should not be connected to the patient during Purge.

NOTE:
It is recommended to Purge the system on installation of a syringe to minimize mechanical backlash and hence improve start up time.

8. Using the numerical keys set the desired infusion rate. Confirm the rate by pressing the **OK** softkey.
9. Press the  key to start the infusion. The green indicator starts flashing, indicating that infusion is in progress.

3. USING MAIN MENUS

"SETTING" menu - Continuous mode

Menu SETTING allows to program main infusion parameters, i.e.:

- DOSE MODE
- WEIGHT
- SURFACE
- CONCENTRATION
- DOSE RATE
- RATE
- VTBI
- TIME

NOTES:
1. Programming of parameter value is initiated by pressing the CHANGE softkey or by pressing the numerical keypad directly after selection of parameter to be programmed.
2. Menu settings are accepted after pressing the CONFIRM softkey only. Pressing the BACK softkey restores previous settings.

Dose mode programming (available for modification only if no drug protocol is selected from Rx menu)

1. Press the **SETTING** softkey.
2. Select the **DOSE MODE** option using the scroll keys.
3. Press the **CHANGE** softkey and select the desired dosing units using the scroll keys.

NOTES:
1. List of dose units available by default: ml/h, mg/h, mcg/h mg/kg/h, mg/kg/min, mcg/kg/h, mcg/kg/min.
2. In order to create new dose units and to add those to existing list press the ADD softkey. Use the scroll keys together with  *keys to create the required dosing units and press OK. Created dosing units will be added to the list. Press the DELETE softkey to delete the units from the list.*
3.List of dose units available for creation:

ml/min, ml/24h, ml/kg/h, ml/kg/min, ml/kg/24h, g/h, g/min, g/24h, g/kg/h, g/kg/min, g/kg/24h, mg/min, mg/24h, mg/kg/24h, mg/m^2/h, mg/m^2/min, mg/m^2/24h,	mcg/min, mcg/24h, mcg/kg/24h, mcg/m^2/h, mcg/m^2/min, mcg/m^2/24h, ng/h, ng/min, ng/24h, ng/kg/h, ng/kg/min, ng/kg/24h, U/h, U/min, U/24h, U/kg/h, U/kg/min, U/kg/24h,	kU/h, kU/min, kU/24h, kU/kg/h, kU/kg/min, kU/kg/24h, mU/h, mU/min, mU/24h, mU/kg/h, mU/kg/min, mU/kg/24h, mcU/h, mcU/min, mcU/24h, mcU/kg/h, mcU/kg/min, mcU/kg/24h,	mol/h, mol/min, mol/24h, mol/kg/h, mol/kg/min, mol/kg/24h, mmol/h, mmol/min, mmol/24h, mmol/kg/h, mmol/kg/min, mmol/kg/24h, mcmol/h, mcmol/min, mcmol/24h, mcmol/kg/h, mcmol/kg/min, mcmol/kg/24h,	nmol/h, nmol/min, nmol/24h, nmol/kg/h, nmol/kg/min, nmol/kg/24h, mEq/min, mEq/h, mEq/24h, mEq/kg/min, mEq/kg/h, mEq/kg/24h

4. Press the **OK** softkey to confirm or press the **BACK** softkey to revert to the settings screen with previous setting.

Patient weight programming (available for modification only if no drug protocol is selected from Rx menu)

1. Press the **SETTING** softkey.
2. Select the **WEIGHT** option using the scroll keys.
3. Press the **CHANGE** softkey and enter weight using the numerical keypad.
4. Press the **OK** softkey to confirm or press the **BACK** softkey to revert to the settings screen with previous setting.

NOTE:
The programmed patient's weight shall not exceed the value of 300 kg.

Patient surface programming (available for modification only if no drug protocol is selected from Rx menu)

1. Press the **SETTING** softkey.
2. Select the **SURFACE** option using the scroll keys.
3. Press the **CHANGE** softkey and enter patient surface using the numerical keypad.
4. Press the **OK** softkey to confirm or press the **BACK** softkey to revert to the settings screen with previous setting.

NOTE:
The programmed patient's surface shall not exceed the value of 10 m^2.

Concentration programming

1. Press the **SETTING** softkey.
2. Select the **CONCENTRATION** option using the scroll keys.
3. Press the **CHANGE** softkey and enter concentration using the numerical keypad. If necessary press the **UNITS** softkey to set the required concentration units.

NOTE:
If concentration calculation is enabled in User Configuration menu the UNITS softkey is not available. To set concentration, press the CHANGE softkey and enter drug amount and diluent volume. Press OK.

4. Press the **OK** softkey to confirm or press the **BACK** softkey to revert to the settings screen with previous setting.

NOTE:
In order to calculate the concentration from entered drug amount and diluent volume press the [▓▓▦▓▓] *softkey at concentration programming screen. Enter drug amount and diluent volume each time pressing the OK softkey. Having entered above parameters concentration is calculated automatically.*

Dose rate programming
1. Press the **SETTING** softkey.
2. Select the **DOSE RATE** option using the scroll keys.
3. Press the **CHANGE** softkey and enter dose rate value using the numerical keypad.
4. Press the **OK** softkey to confirm or press the **BACK** softkey to revert to the settings screen with previous setting.

Rate programming
1. Press the **SETTING** softkey.
2. Select the **RATE** option using the scroll keys.
3. Press the **CHANGE** softkey and enter rate value using the numerical keypad.
4. Press the **OK** softkey to confirm the entered infusion rate value or press the  key to clear the entered value. To restore previous value and return to the settings screen press the **BACK** softkey.

NOTES:
1. Rate value can be set directly from the main screen by pressing numerical keypad.
2. The pump allows for VTBI and time programming in addition to infusion rate programming. When two of these parameters are entered, the third is calculated by the pump, e.g. when rate and time is entered, VTBI is calculated automatically.

Volume to be Infused (VTBI) programming
1. Press the **SETTING** softkey.
2. Select the **VTBI** option using the scroll keys.
3. Press the **CHANGE** softkey and enter the volume to be infused using the numerical keypad. Press the **UNITS** softkey to change the VTBI units and press the **OK** softkey to confirm or press the **BACK** softkey to revert to the settings screen with previous setting.
4. Select the rate after completion of VTBI (Stop, KVO or continue with the set rate – only if configured in User

Configuration menu) using the scroll keys and press the **OK** softkey to confirm the selection or press the **BACK** softkey to return to the previous screen.

NOTES:
1. The purpose of the function KVO (Keep Vein Open) is to continue infusion of very small amount of drug after the end of infusion.
2. To reset previously entered value and execute the infusion without the preset VTBI, press the CLEAR softkey. CLEAR does not appear unless there is a numerical value in the VTBI. Resetting of the VTBI clears the time value as well.

Time programming

1. Press the **SETTING** softkey.
2. Select the **TIME** option using the scroll keys.
3. Press the **CHANGE** softkey and enter the time using the numerical keypad and press the **OK** softkey to confirm or press the **BACK** softkey to revert to the setting screen with previous settings.

NOTES:
1. TIME value can be entered faster by pressing the numerical keypad directly i.e. without necessity of pressing the SET softkey.
2. Use the  key to skip between hours, minutes and seconds.

"SETTING" menu - Intermittent mode

Intermittent mode allows to program an infusion where specific dose is delivered over a period of time, after which infusion stops for a period of time and then repeats the cycle.
Intermittent parameters are indicated in setting menu only having selected Intermittent drug protocol through **Rx** menu (see below **Rx** menu description).
Menu SETTING contents in Intermittent mode:

- Loading dose / Initial dose (if configured in protocol)
- Loading rate / Initial rate (if configured in protocol)
- Loading time/ Initial time (if configured in protocol)
- Weight (availability depends on configured dose units)
- Surface (availability depends on configured dose units)
- Concentration (availability depends on configured dose units)
- Intermittent dose
- Intermittent dose rate
- Intermittent dose time
- Pause time
- Pause rate

Having entered SETTING menu only currently active Intermittent mode parameters are indicated. In order to review entire Intermittent mode parameters scroll down to select the **MORE…**

option and press the **OK** softkey. Scroll down through the list of parameters.
To modify the required parameter press the **CHANGE** softkey, enter new value and press the **OK** softkey to confirm. Once all changes are completed press the **CONFIRM.**

"SETTING" menu - TIVA mode

TIVA mode allows anaesthetist to work in the way the drugs are delivered in the operating room, including dose based calculations of induction and maintenance rate. The typical sequence of operation in TIVA mode is Inducion, Pause and Maintenance rate.

TIVA parameters are indicated in setting menu only having selected TIVA drug protocol through **Rx** menu (see below **Rx** menu description).
Menu SETTING contents in TIVA mode:

- Weight (availability depends on configured dose units)
- Surface (availability depends on configured dose units)
- Concentration (availability depends on configured dose units)
- Induction dose/rate/time (if configured in protocol)
- Pause time (if configured in protocol)
- Maintenance rate

Having entered SETTING menu only currently active TIVA mode parameters are indicated. In order to review all TIVA mode parameters scroll down to select the **MORE…** option and press the **OK** softkey. Scroll down through the list of parameters.

To modify the required parameter press the **CHANGE** softkey, enter new value and press the **OK** softkey to confirm.

"i" (information) menu

Menu "i" contents:

- Volume infused
- Syringe
- Battery
- Rate graph
- Pressure graph
- Drug infused graph
- Patient history
- Date and time

Volume infused

Provides volume infused counters, i.e.:
Volume – volume infused from currently used syringe;
Drug– infused drug volume;
Total – total volume infused (e.g. from several syringes).

1. Press the **i** softkey and select the **Volume infused** option using the scroll keys.
2. Press the **OK** softkey to enter volume infused screen.
3. Select the volume to be cleared using the scroll keys.
4. Press the **CLEAR** softkey to clear the selected volume. Press the **BACK** softkey to retain the volume and revert to the main screen.

NOTE:
Clearing Total Volume the Drug Infused and Volume Infused will be cleared as well.

Syringe

This option provides information on confirmed syringe brand and size as well as infused and remaining volume from the syringe in use.

1. Press the **i** softkey and select the **Syringe** option using the scroll keys.
2. Press the **OK** softkey to enter syringe screen.
3. Press the **BACK** softkey to return to main screen.

Battery

This option provides information on battery status, particularly remaining percentage of battery charge level and approximate time of pump operation on battery.

1. Press the **i** softkey and select **Battery** option using the scroll keys.
2. Press the **OK** softkey to review battery information.
3. Press the **BACK** softkey to return to main screen.

Rate graph

This option allows to review rate changes during the infusion.

1. Press the **i** softkey and select **Rate graph** option using the scroll keys.
2. Press the **OK** softkey to enter.
3. Use the  softkeys to zoom in/out. After pressing  use the scroll keys to move the graph to the left/right.
4. Press the **BACK** softkey to return to main screen.

NOTE:
To change the scale of rate axis use numerical keypad (1- 1 ml/h, 2 – 3 ml/h, 3 – 5ml/h, 4 – 10 ml/h, 5 – 30 ml/h, 6 – 100 ml/h, 7 – 300 ml/h, 8 – 1000 ml/h, 9 – 2200 ml/h).

Pressure graph

This option allows to review pressure changes during the infusion.

1. Press the **i** softkey and select **Pressure graph** option using the scroll keys.

2. Press the **OK** softkey to enter.
3. Use the [redacted] softkeys to zoom in/out. After pressing [redacted] use the scroll keys to move the graph to the left/right.
4. Press the **BACK** softkey to return to main screen.

NOTE:
To change the scale of pressure level axis use numerical keypad (1- L 2, 2 –L 4, 3 – L 5, 4 –L7, 5 –L 9, 6 –L10).

Drug infused graph

This option allows to review drug infused hourly records.
1. Press the **i** softkey and select **Drug infused graph** option using the scroll keys.
2. Press the **OK** softkey to enter.
3. Use the scroll keys to select the required hourly drug infused record.

Patient history

This option allows the patient history to be reviewed.

1. Press the **i** softkey and select **Patient history** option using the scroll keys.
2. Press the **OK** softkey to enter.
3. Scroll through the history using the scroll keys.
4. Press the **BACK** softkey to return to main screen.

NOTES:
1. Patient history log is stored even if the pump is powered down. Refer to Service manual in order to review preceding history records.
2. Total power loss (including mains and internal battery) does not affect contents of history log.

Date and time

This option allows date and time to be reviewed.

1. Press the **i** softkey and select **Date and time** option using the scroll keys.
2. Press the **OK** softkey to review date and time.
3. Press the **BACK** softkey to return to main screen.

“Rx” (drug library) menu

This configurable feature allows you to display drug name on the main screen. Drug names are chosen from the pre-configured list of drug names. When the feature is enabled, the user can select from the list of available drug names.

NOTES:
*1. Press the **i** softkey to view settings of the selected drug name.*
*2. Select –**none**– from the drug list to clear previously selected drug and continue infusion with unidentified drug name.*
3. Feature unavailable during infusion.

Select a drug name with hard rate limits

1. Press the **Rx** softkey to enter drug library.
2. Select the desired drug name from the list and press the **OK** softkey to confirm the selection or press the **BACK** softkey to return to the main screen.

Select a drug name with Infugard protocol

1. Press the **Rx** softkey to enter drug library.
2. Select the drug name with Infugard symbol and press the **OK** softkey.
3. Enter patient weight/surface using the numerical keypad and press the **OK** softkey (available only if protocol dose units are based on patient weight/surface).
4. Default parameters are shown one by one. Verify the correctness of each parameter value. In order to modify the particular value use the scroll keys to select the parameter to be modified and press the **CHANGE** softkey. Enter required value and press **OK**.
5. Press the **CONFIRM** softkey to accept the protocol parameters.

NOTES:
1. If the entered rate or dose rate exceeds the soft limit, the pump will generate a message "Override soft limit?"(if enabled in UC menu). Press the YES softkey to override soft limit and confirm the entered value or press the NO key to reject the entered value and return to the previous screen.
2. When the pump is running outside soft limits will be indicated in the upper left corner of the display.

Select a drug name with Intermittent protocol

1. Press the **Rx** softkey to enter drug library.
2. Select the drug name with Intermittent symbol and press the **OK** softkey.
3. Enter patient weight/surface using the numerical keypad and press the **OK** softkey (available only if protocol dose units are based on patient weight/surface).
4. Default parameters are shown one by one. Verify the correctness of each parameter value. In order to modify the particular value use the scroll keys to select the parameter to be modified and press the **CHANGE** softkey. Enter required value and press **OK**.
5. Press the **CONFIRM** softkey to accept the protocol parameters.

Select a drug name with TIVA protocol

1. Press the **Rx** softkey to enter drug library.
2. Select the drug name with TIVA symbol and press the **OK** softkey.

3. Enter patient weight/surface using the numerical keypad and press the **OK** softkey (available only if protocol dose units are based on patient weight/surface).
4. Default parameters are shown one by one. Verify the correctness of each parameter value. In order to modify the particular value use the scroll keys to select the parameter to be modified and press the **CHANGE** softkey. Enter required value and press **OK**.
5. Press the **CONFIRM** softkey to accept the protocol parameters.

"OPTIONS" menu

Menu "Options" contents:

- Occlusion level
- ROD sensitivity
- Display backlight
- Display contrast
- Audio volume

Occlusion level

With this function the pressure alarm level is adjustable from app. 50 to 950 mmHg. Ten occlusion pressure alarm levels can be selected. The pressure alarm level may be changed without stopping the infusion.

In order to change the pressure level:
1. Press the **OPTIONS** softkey and select **Occlusion level** option using the scroll keys.
2. Press the **OK** softkey to enter.
3. Use the scroll keys to adjust the pressure alarm level.
4. Press the **OK** softkey to confirm the changes or press the **BACK** softkey to exit the pressure screen with previous level setting.

NOTES:
1. The pump has an anti-bolus function which reduces the pressure in the syringe and the extension set in case of occlusion and at the same time diminishes the volume of unwanted Bolus injected to the patient after removal of the occlusion cause.
2. There is some delay between the occlusion condition occurrence and occlusion alarm activation depending on set occlusion alarm level and infusion rate. The higher the occlusion level is set, the higher pressure must form in the extension line to trigger the occlusion alarm.

ROD sensitivity

Note that this option is available only if it's turned on in the User Configuration menu.
Rapid Occlusion Detection (ROD) can be set to function at one of three sensitivity levels (High, Medium and Low) which define response time to the blockage in the line:

Level	**Time (approx.)**
High	5 min
Medium	10 min
Low	15 min

To change the sensitivity level:
1. Press the **OPTIONS** softkey and select **ROD sensitivity** option using the scroll keys.
2. Press the **OK** softkey to enter.
3. Select the level using the scroll keys and press **OK**.

NOTE:
Refer to the chapter "User Configuration menu" -> "Parameter set" for more information on ROD.

Display backlight

This option allows to adjust display backlight level.

1. Press the **OPTIONS** softkey and select **Display backlight** option using the scroll keys.
2. Press the **OK** softkey to enter.
3. Adjust the desired backlight level using the scroll keys and press the **OK** softkey when changes are complete.

Display contrast

This option allows to adjust display contrast level.

1. Press the **OPTIONS** softkey and select **Display contrast** option using the scroll keys.
2. Press the **OK** softkey to enter.
3. Adjust the desired contrast level using the scroll keys and press the **OK** softkey when changes are complete.

Audio volume control

This option allows to adjust sound volume level of alert/alarm signals.

1. Press the **OPTIONS** softkey and select **Audio volume** option using the scroll keys.
2. Press the **OK** softkey to enter.
3. Adjust the desired audio volume level using the scroll keys and press the **OK** softkey when changes are complete.

NOTE:
Audio volume cannot be completely switched off.

4. USING ADVANCED FUNCTIONS

Purge

This function is available only after power-up until an infusion has been started. The user can fill an empty extension set and remove air bubbles in the system or line.

! WARNING ! **The syringe extension set should not be connected to the patient during Purge.**

NOTE:
It is recommended to Purge the system on installation of a syringe to minimize mechanical backlash and hence improve start up time.

In order to purge the extension set execute the following steps:

1. Press the BOLUS key.
2. Press and hold the **PURGE** softkey until air is removed from the extension set. The purged volume will be displayed.

NOTE:
Purge volume is limited and can be set through User Configuration menu. Pressure limit alarm at the Purge mode is temporarily increased to the maximum level.

3. Release the **PURGE** softkey when purging is complete and press the **BACK** softkey to exit.

Bolus Application

The bolus dose can be injected during infusion only. When the preset bolus volume limit is reached the bolus is stopped and the pump reverts to infuse at the set rate. When VTBI is reached during bolus session the alarm on the VTBI completion will be generated. Press the C key to pause the alarm audio signal or press the **CANCEL** softkey to cancel the alarm message as well as silence alarm.

NOTE:
1. During bolus, the pump produces short audible beeps every 0.5 ml of infused drug.
2. During bolus "X min/ml NEAR END OF INFUSION", "LOW BATTERY", "NO MAINS" and "CHECK PATIENT LINE" alarms are delayed until the BOLUS key is released or automatic bolus stops.

Manual Bolus

1. Press the BOLUS key to display the bolus screen.
2. Press the **MANUAL** softkey to view manual bolus screen (available only if both Manual and Automatic boluses enabled in User Configuration menu).
3. Press the **SETTING** softkey and using numerical keypad set the desired bolus rate or dose rate (if infusion rate programmed in dose units). Press the **OK** softkey to confirm the entered value. Press **CONFIRM** once programming completed.

NOTE:
Bolus rate value can be entered using numerical keypad directly i.e. without pressing the SETTING softkey.

4. Press the **CONFIRM** softkey to confirm the Bolus rate (required only if Bolus Confirmation feature enabled in User Configuration menu).
5. To infuse Bolus manually press and hold depressed the **BOLUS** softkey or the BOLUS key. Release the **BOLUS** softkey or the BOLUS key to stop bolus.

NOTES:
1. Pressure limit alarm during Bolus is temporarily increased to the maximum level.
2. The Bolus volume is added to the Volume infused history.
3. Bolus can also be started by pressing the BOLUS key twice (available only if Bolus Confirmation feature and Automatic bolus disabled in UC menu).

Automatic Bolus

1. Press the BOLUS key once to display the bolus screen.
2. Press the **AUTO** softkey to view automatic bolus screen (available only if both Automatic and Manual boluses enabled in User Configuration menu).
3. Press the **SETTING** to view automatic bolus settings. Select the automatic bolus parameter to be set/modified and press the **CHANGE** softkey. Using numerical keypad enter required bolus value and press the **OK** softkey. When all required automatic bolus parameters are set press the **CONFIRM** softkey.

NOTE:
Bolus rate can be entered using numerical keypad directly i.e. without pressing the SETTING softkey.

4. Press the **CONFIRM** softkey to confirm the Bolus values (required only if Bolus Confirmation feature enabled in User Configuration menu).
5. Press the **BOLUS** softkey to infuse the preprogrammed Bolus dose.

NOTE:
Already preprogrammed bolus can also be started by pressing the  *key twice (available only if Bolus Confirmation feature and Manual bolus disabled in UC menu).*

6. When the preset bolus limit is reached the pump reverts to infuse at the set rate. Bolus infusion can be halted by pressing the **BACK** softkey.

NOTES:
1. Pressure alarm limit during Bolus is temporarily increased to the maximum level.
2. The Bolus volume is added to the Volume infused history.

Standby mode

With this function it is possible to set an individual standby time. This function is available in the stop mode only if enabled in User Configuration menu.

1. While in stop mode press the  key to view the standby time programming screen.
2. Enter the standby time using the numerical keypad.
3. Press the **OK** softkey to start the standby function.

NOTE:
*Use the **EXIT** softkey to halt the standby function before the set time.*

Keypad lock

The keypad lock feature minimizes the potential for keypad tampering. It disables the programming, halting the infusion and switching off the pump.
Keypad lock function can only be enabled from the main screen when pump is running by pressing the  key and afterwards the **YES** softkey. There is also an Auto Lock option available as a configurable option. This option automatically locks the keypad within 2 minutes after start of infusion, bolus infusion or change of any parameter (during infusion). The keypad lock icon is displayed at the upper left corner of the screen. To unlock the keypad repeat the above procedure.

NOTE:
The keypad lock feature can be enabled/disabled through User Configuration menu.

5. USER CONFIGURATION MENU

User Configuration menu includes a list of optional configurable functions.
In order to access configurable menu:

1. While pressing the  key turn the pump on  .
2. Enter 237 code using the numerical keypad. Refer to Service Manual for a full list of access codes.
3. Press **OK** to confirm the code. The User Configuration menu will be displayed.

In order to exit configurable menu power off the pump.

Parameter set

1. Select **PARAMETER SET** from the configuration menu.
2. Press the **OK** softkey.
3. Select required group of parameters/functions and press the **OK** softkey.
4. Select the required parameter/function and press the  softkey to enable (✓) /disable (×) it. Adjustable functions and parameters can be modified by pressing the **CHANGE** softkey.

NOTE:
*Adjustable parameters can be entered directly from the numerical keypad, i.e. without pressing the **CHANGE** softkey.*

5. Press once the **BACK** softkey to return to parameter set groups menu or twice to return to User Configuration menu.

Table 5.1 List of Parameters

PARAMETER GROUP	**PARAMETER**	**DESCRIPTION**	**FACTORY DEFAULT** ***(X – disabled,*** **√ – enabled)**
Infusion modes	Continuous label	Enables/disables drug labels in drug library.	√
	Continuous infugard	Enables/disables drug labels with Infugard® protocol in drug library.	√
	Intermittent	Enables/disables drug labels with Intermittent protocol in drug library.	**X**
	TIVA	Enables/disables drug labels with TIVA protocol in drug library.	**X**

PARAMETER GROUP	PARAMETER	DESCRIPTION	FACTORY DEFAULT *(X – disabled, √ – enabled)*
	Protocol confirmation	Enables/disables demand to confirm the protocol values after drug selection.	√
Caps	Infusion rate limit	Sets the upper infusion rate limit.	**X**
	Modify drug protocol	Enables/disables capability to modify drug protocol parameters.	√
	Override soft limits	Enables/disables capability to override parameter soft limits set in drug protocols.	**X**
VTBI	VTBI	Enables/disables VTBI (Volume to be Infused) feature.	√
	KVO after VTBI	Enables/disables infusing at the KVO rate after completion of VTBI.	√
	Continue after VTBI	Enables/disables infusing at the preset infusion rate after completion of VTBI	**X**
	VTBI limit	Sets the VTBI limit for programming.	**X**
Clinician bolus	Automatic bolus	Enables/disables delivery of preprogrammed bolus volume automatically.	**X**
	Manual bolus	Enables/disables manual bolus infusion.	√
	Bolus confirmation	Enables/disables prompt to confirm the bolus values before each bolus administration.	**X**
	Bolus volume limit	Sets the maximum permissible bolus volume.	**X**
	Default bolus vol.	Sets the default bolus volume.	0.5 ml
	Bolus rate limit	Sets maximum permissible bolus rate.	**X**
	Default bolus rate	Sets the default bolus rate.	500 ml/h
Purge	Purge volume limit	Sets maximum permissible purge volume.	4 ml

PARAMETER GROUP	PARAMETER	DESCRIPTION	FACTORY DEFAULT *(X – disabled, √ – enabled)*
	Purge for syringe 2/3, 5/6, 10/12, 20, 30/35, 50/60	Sets the maximum permissible purge rates for particular syringe sizes.	2/3ml – 50 ml/h 5/6ml – 150 ml/h 10/12ml – 300 ml/h 20ml–600 ml/h 30/35ml–900 ml/h 50/60ml–1200 ml/h
KVO (KOR)	KVO at syringe empty	Enables/disables infusing at the KVO rate when syringe is emptied.	√
	KVO rate	Sets the KVO rate.	0.5 ml/h
	Residual volume	Sets the KVO volume.	1.0 % of the syringe volume
Alerts	X min near EOI	Sets Near End of Infusion (EOI) warning time (time left to the end of infusion or empty syringe).	3 min
	X ml near EOI	Sets Near End of Infusion (EOI) warning volume (volume left to the end of infusion or empty syringe).	**X**
	NEOI audio limit	Sets the number of audible beeps for Near End of Infusion alert and Near Syringe empty alert.	**X**
	Line disconnection	Enables/disables alert of rapid pressure drop in line.	√
	No mains @ power up	Enables/disables alert on condition the pump is powered up while not connected to the mains.	√
	Quiet mode	Enables/disables short beep accompanying any keystroke.	**X**
Graphs	Pressure graph	Enables/disables displaying of pressure graph.	√
	Rate graph	Enables/disables displaying of rate graph.	√
	Drug infused graph	Enables/disables displaying of drug infused graph.	√
Other parameters	Titration	Enables/disables programming of infusion rate and VTBI without stopping the infusion.	√
	Standby	Enables/disables programming of standby time.	**X**
	Auto save	Enables/disables retaining of infusion information when pump is powered off.	√

PARAMETER GROUP	PARAMETER	DESCRIPTION	FACTORY DEFAULT *(X – disabled, √ – enabled)*
	Auto lock	Enables/disables automatic keypad lockout function.	**X**
	Backlight on battery	Adjusts backlight level of the pump display when running on battery.	Level 4
	Night mode	Sets night mode duration.	21:00–06:00
	Restart after occlus.	Sets the number of automatic restart after an occlusion.	**X**
	Default pressure	Sets the default occlusion pressure level.	5
	Patient history	Enables/disables patient history reviewing feature.	√
	Hide softkey	Enables/disables macro mode, i.e. indication of softkeys in the main screen. **NOTE:** *When enabled press any key to call up softkey indication during infusion.*	**X**
	Back to main screen	Sets the duration of automatic returning to the main screen from the submenus.	30 sec.
	Rapid occl. detection (ROD)*	Allows an early detection of possible occlusion.	√
	Concentr. calculation	Enables/disables automatic concentration calculation as: drug amount per diluent volume.	**X**

* ROD is a functionality that provides an early detection of occlusion. It generates a warning message when rising trend in pressure is identified, but occlusion level has not been reached yet.

ROD functionality is supported only for certain range of flow rates depending on syringe size and type, e.g. approximately 0.3-6 ml/h for 10 ml syringes, and 0.6-20 ml/h for 50 ml syringes.

NOTE:
Refer to page 23 for full list of syringes which have the ROD function.

If ROD is enabled and is supported for used syringe and programmed flow rate, the ‘R’ symbol appears on the screen. At the beginning of infusion, as well as after changing flow rate during the infusion the ‘R’ symbol is blinking. This indicates that

ROD is temporarily disabled until pressure in the line is settled. This transient period may continue 5-30 min depending on syringe size and flow rate. Steady state of symbol 'R' indicates that ROD is monitoring pressure in the line.
The "Pressure increasing" preliminary message (pre-alert of lower reliability) is displayed without audible and visual alerts immediately after pressure rise is detected. If pressure continues to rise, ROD triggers an alert. But if consequent measuring does not confirm the rise of pressure, the preliminary message is cancelled.

NOTE:
1. ROD can be set to function at one of three sensitivity levels (high, medium, low) in the OPTIONS menu.
2. Higher sensitivity level provides a faster alert, but also increases probability of false alerts in response to line pressure changes not linked to occlusions (e.g. syringe sticking or lowering of the pump).

Syringe set

This option is used to configure the type and size of syringe permitted for use on the pump. Select all possible syringes, which may be used, and disable any that should not be used.

1. Select the **SYRINGE SET** from the User Configurations menu and press the **OK** softkey.
2. Scroll through the list of syringes using the scroll keys and press the √/X softkey to enable/disable syringe brand or press the **OK** softkey to enter syringe sizes of the selected brand for further configuration.
3. Press the **BACK** softkey to return to User Configuration menu when all changes are complete.

Drug library

This option allows to compose drug label library to be used on the pump and configure for each drug protocol. Drug library can comprise up to 350 drug labels.

NOTE:
Drug name length is limited to 15 characters.

1. Select **DRUG LIBRARY** from the User Configuration menu and press the **OK** softkey.
2. Scroll through the library using the scroll keys and press the √/X softkey to enable/disable drug label.
3. Press the **BACK** softkey to return to User Configuration menu.

Creating new drug label with upper and lower hard rate limits

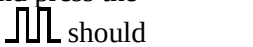
1. Having entered drug library select <**New drug**> and press the **CREATE** softkey.
2. Enter new drug label using the numerical keypad.
3. Press the **OK** softkey to acknowledge.
4. Using scroll down key select UPPER or/and LOWER HARD RATE LIMIT press the **CHANGE** softkey to enter required value for the selected parameter using the numerical keypad each time pressing the **OK** softkey to confirm the set values.
5. Press the **CONFIRM** softkey to acknowledge the set protocol.

Creating new drug with Infugard protocol

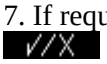
1. Having entered drug library select <**New drug**> and press the **CREATE** softkey.
2. Enter drug name using the numerical keypad and press the **TYPE** softkey. The Infugard symbol should appear at the right side to the entered drug.
3. Press the **OK** softkey.
4. Press the **CHANGE** softkey and select the required dosing units. To add new dosing units to the list press the **ADD** softkey Use the scroll keys together with < > keys to create the required dosing units and press the **OK**. Created dosing units will be added to the list. Press the **OK** softkey to confirm the selected dose units.
5. Press the **CHANGE** softkey and/or using numerical keypad enter max. patient weight/surface (available only if set dosing units are based on patient weight/surface). Press the **OK** softkey to confirm.
6. Press the **CHANGE** softkey and/or using numerical keypad enter required concentration (availability depends on configured dose units). If required press the **UNITS** softkey to change the concentration units. Once programming completed, press the **OK** softkey.
7. One by one enter Upper hard, Lower hard, Upper soft and Lower soft limits each time pressing the **OK** softkey.
8. Enter Default rate using the numerical keypad and press the **OK** softkey.
9. Press the **CONFIRM** softkey to confirm the protocol or if required continue programming to set the bolus parameters for the drug protocol. For this sake press the √/X softkey to enable bolus feature.
10. Enter Max. bolus dose and if required change units by pressing the **UNITS** softkey. Press the **OK** softkey.
11. Enter default bolus dose and press the **OK** softkey.
12. Enter default bolus rate and press the **OK** softkey.
13. Press the **CONFIRM** softkey once all required parameters are entered. The Infugard® configuration procedure for drug is completed.

Creating new drug with Intermittent protocol

1. Having entered drug library select <**New drug**> and press the **CREATE** softkey.

2. Enter drug name using the numerical keypad and press the **TYPE** softkey. The Intermittent protocol symbol  should appear at the right side to the entered drug.
3. Press the **OK** softkey.
4. Press the **CHANGE** softkey and select the required dosing units. To add new dosing units to the list press the **ADD** softkey Use the scroll keys together with < > keys to create the required dosing units and press **OK**. Created dosing units will be added to the list. Press the **OK** softkey to confirm the selected dose units.
5. Press the **CHANGE** softkey and/or using numerical keypad enter max. patient weight/max surface (available only if set dosing units are based on patient weight/surface). Press the **OK** softkey to confirm.
6. Press the **CHANGE** softkey and enter concentration using the numerical keypad. If necessary press the **UNITS** softkey to set the required concentration units. Press the **OK** softkey to confirm.

NOTE:
In order to calculate the concentration from entered drug amount and diluent volume press the  *softkey at concentration programming screen. Enter drug amount and diluent volume each time pressing the OK softkey. Having entered above parameters concentration is calculated automatically.*

7. If required, enable Loading dose or Initial bolus by pressing the  softkey.

NOTE:
1. Functionality of Loading dose and Initial bolus is the same, i.e. it is a dose to be delivered at the beginning of infusion with an increased rate.
2. They both can not be enabled at the same time.

8. Depending on what you enabled select and enter two required parameters (third is calculated automatically) from the proposed three: Loading dose/Initial dose, Loading rate/Initial rate, Loading time/Initial time each time pressing the **CHANGE** softkey and/or using numerical keypad to initate the programming. If required press the **UNITS** softkey to change the units. Press the **OK** softkey to confirm the entered value.
9. Select and enter two required parameters (third is calculated automatically) from the proposed three: Intermittent dose / Intermittent rate / Intermittent time each time pressing the **CHANGE** softkey and/or using numerical keypad to initate the programming and the **OK** softkey to confirm the entered value.
10. Press the **CHANGE** softkey and/or using numerical keypad enter pause time. Press the **OK** softkey to confirm.

NOTE:
Use the  *key to skip between hours, minutes and seconds.*

11. If required set the rate which will be active during pause time. For this sake press the **CHANGE** softkey and/or using numerical keypad set the Pause rate. Press the **OK** softkey to confirm.

12. Press the **CONFIRM** softkey to confirm the protocol or if required continue programming to set the bolus parameters for the drug protocol. For this sake press the ✓/X softkey to enable bolus feature.
13. Enter default bolus dose and press the **OK** softkey.
14. Enter default bolus rate and press the **OK** softkey.
15. Enter default bolus time and press the **OK** softkey.
16. Press the **CONFIRM** softkey once all required parameters are entered. The Intermittent configuration procedure for drug is completed.

Creating new drug with TIVA protocol

1. Having entered drug library select <**New drug**> and press the **CREATE** softkey.
2. Enter drug name using the numerical keypad and press the **TYPE** softkey several times. The TIVA protocol symbol ⎍ should appear at the right side to the entered drug.
3. Press the **OK** softkey.
4. Press the **CHANGE** softkey and select the required dosing units. To add new dosing units to the list press the **ADD** softkey Use the scroll keys together with < > keys to create the required dosing units and press **OK**. Created dosing units will be added to the list. Press the **OK** softkey to confirm the selected dose units.
5. Press the **CHANGE** softkey and/or using numerical keypad enter max. patient weight/max surface (available only if set dosing units are based on patient weight/surface). Press the **OK** softkey to confirm.
6. Press the **CHANGE** softkey and enter concentration using the numerical keypad (availability depends on configured dose units). If necessary press the **UNITS** softkey to set the required concentration units. Press the **OK** softkey to confirm.

NOTE:
In order to calculate the concentration from entered drug amount and diluent volume press the [▦] *softkey at concentration programming screen. Enter drug amount and diluent volume each time pressing the OK softkey. Having entered above parameters concentration is calculated automatically.*

7. If required, enable Induction by pressing the ✓/X softkey.
8. Select and enter two required parameters (third is calculated automatically) from the proposed three: Induction dose / Induction rate / Induction time each time pressing the **CHANGE** softkey and/or using numerical keypad to initate the programming and the **OK** softkey to confirm the entered value.
9. If required, enable Pause after induction by pressing the ✓/X softkey.
10. Press the **CHANGE** softkey and/or using numerical keypad enter pause time. Press the **OK** softkey to confirm.

NOTE:
Use the (•) *key to skip between hours, minutes and seconds.*

11. Press the **CHANGE** softkey and/or using the numerical keypad enter Maintenance rate. If necessary press the **UNITS** softkey to change units. Press the **OK** softkey to confirm.
12. If required, enable Bolus by pressing the √/X softkey.
13. Select and enter two required parameters (third is calculated automatically) from the proposed three: Bolus dose / Bolus rate / Bolus time each time pressing the **CHANGE** softkey and/or using numerical keypad to initate the programming and the **OK** softkey to confirm the entered value.
14. Press the **CONFIRM** softkey once all required parameters are entered. Drug configuration procedure is completed.

Editing drug name and modifying drug label settings

1. Select the drug label using the scroll keys and press the **i** softkey.

2. Press the **CHANGE** softkey and using  cancel current drug label. Enter new drug label name using the numerical keypad.
3. Using scroll down key select the parameter to be changed. Press the **CHANGE** softkey to enter required value for the selected parameter using the numerical keypad each time pressing the **OK** softkey to confirm the set values.
4. Press the **CONFIRM** softkey once all changes are completed.

Deleting drug from the list

1. Select the drug name to be removed using the scroll keys and press the **DELETE** softkey.
2. Press the **YES** softkey in response to message “Delete drug?“.

Language set

This option allows the language of the pump to be set.

1. Select **LANGUAGE SET** from the User Configuration menu and press the **OK** softkey.
2. Select necessary dialog language using the scroll keys.
3. Press the **OK** softkey to set the selected dialog language.

Hospital name

This option allows to program hospital name or other information, which will be indicated on the display when switching the pump on.

1. Select **HOSPITAL NAME** from the User Configuration menu and press the **OK** softkey.
2. Enter hospital name using the numerical keypad. Press the **OK** softkey to confirm or press the **BACK** softkey to revert to previous screen.

NOTE:
Hospital name length is limited to 15 characters.

Date and Time

1. Select **DATE AND TIME** from the User Configuration menu and press the **OK** softkey.
2. Enter date and afterwards time using the numerical keypad and press the **OK** softkey.

NOTE:
Use the  *key to skip between numbers when entering date and/or time.*

Link to PC

This option is used to allow pump to communicate with computer when using software utilities.

1. Select **LINK TO PC** from the User Configuration menu and press the **OK** softkey. Connect the pump to PC using USB cable.
2. Press the **START** softkey. The pump is ready for communication.
3. When communication is completed press the **BACK** softkey.

NOTE:
If the link is interrupted before completion of configuration file upload to pump, the pump will restore factory configuration once powered up.

6. VISUAL AND AUDIBLE ALARM SIGNALS

Troubleshooting Alerts

Alerts (MEDIUM priority) call attention to conditions that may require user intervention without stopping the infusion. During an alert condition, the pump indicates a message on the display. In addition, the orange indicator flashes (alternately with green indicator during infusion) and an alert tone sounds.

To pause the alert audio tone press the  key. To cancel the alert message as well as to silence the alert tone press the **CANCEL** softkey.

NOTES:
1. It is recommended to position the operating pump with a front side always visible for the operator.

2. It is possible to regenerate already cancelled alert by pressing the  *key and the UNDO softkey afterwards (available if alarm conditions remain active).*

Table 6.1 Troubleshooting Pump Alert Messages

MESSAGE	CAUSE	CORRECTION	CHECKING
NO MAINS	The pump has been disconnected from the AC power supply and is operating on internal battery.	Reconnect the pump to AC power supply or press the CANCEL softkey to silence the alert and continue operation on internal battery.	Connect the mains cable to the pump. Switch on the pump and launch infusion. After few seconds disconnect the mains cable.
LOW BATTERY	Battery charge low with 30 minutes operation remaining.	Connect the pump to AC power supply and charge the internal battery.	Run the pump on battery until alert is generated.
CHANGE not CONFIRMED	Programmed parameter has not been confirmed.	Confirm the required parameter.	Launch infusion, then enter new rate value, but do not confirm it. Wait for few seconds.
XX ml (min) to SYRINGE EMPTY	The pump is nearing the end of syringe.	The volume (time) the pump will alarm can be modified in User Configuration menu.	In the User Configuration menu (UC) set 5 min NEAR EOI option. Launch infusion and wait until indicated time to syringe empty goes below 5 min.
XX ml (min) to End of INFUSION	The pump is nearing the end of infusion.	The volume (time) the pump will alarm can be modified in User Configuration menu.	In the User Configuration menu set 5 ml NEAR EOI option. Launch infusion and wait until plunger goes below 5 ml.
2 min. INACTIVE	The pump is left for 2 min without starting the operation.	Press the CANCEL softkey.	Switch on the pump and wait for 2 min.
STANDBY TIME ELAPSED	The preprogrammed standby time interval elapsed.	Press the CANCEL softkey.	In the UC menu switch on the STANDBY function. Launch infusion, and after few seconds stop it. Set standby time to 3 min and wait until it is elapsed.
END OF INFUSION (KVO, CONTINUE)	The pump has reached the end of infusion.	Replace the syringe or turn the pump off.	Set the VTBI and select KVO (CONTINUE) option. Launch infusion and wait until indicated VTBI value goes to 0.
SYRINGE EMPTY KVO	The syringe is empty.	Replace the syringe or turn the pump off.	In UC menu switch on the KVO AT SYRINGE EMPTY function. Launch the infusion and wait until syringe is emptied.
CHECK PATIENT LINE	Pressure in the extension line has rapidly decreased.	Check whether the extension line is properly connected.	In the UC menu switch on the LINE DISCONNECTION function. Launch infusion, block the extension line and wait until pressure in the line forms. Release the pressure quickly.
PRESSURE INCREASING	The pump has detected possible blockage in the syringe or extension set.	Remove the cause of the blockage.	While infusion is in progress (ensure that ROD is active) block the extension line and wait until alarm is generated.

Troubleshooting and checking Alarms

Alarms (HIGH priority) automatically stop the infusion and require immediate attention before the infusion can be restarted. During an alert condition, the pump indicates a message on the display. In addition, the red indicator flashes and the alarm tone sounds.

NOTES:
1. It is recommended to position the operating pump with a front side always visible for the operator.

2. It is possible to regenerate already cancelled alarm by pressing the  *key and the UNDO softkey afterwards (available if alarm conditions remain active).*

Table 6.2 Troubleshooting Pump Alarm Messages

MESSAGE	CAUSE	CORRECTION	CHECKING
RECHARGE BATTERY	The internal battery is depleted.	Connect the pump to AC power supply.	Run the pump on battery until it is depleted completely.
PLUNGER DISENGAGED	The syringe plunger has been disengaged during infusion.	Check the correctness of syringe position.	Load syringe properly, launch infusion and after few seconds push the pusher lever.
SYRINGE BARREL NOT FITTED	The syringe barrel has been displaced during infusion.	Check the correctness of syringe position.	Load syringe properly, launch infusion and after few seconds move syringe barrel slightly down.
SYRINGE PLUNGER NOT FITTED	The syringe plunger has been displaced during infusion.	Check the correctness of syringe position.	Load syringe barrel without plunger. Insert fixture between the grippers to keep them in plunger inserted position. Launch infusion and after few seconds pull the fixture out of grippers.
CLAMP OPEN	The syringe barrel clamp has been opened during infusion.	Close the clamp and resume the infusion.	While infusion is in progress lift up the syringe barrel clamp.
OCCLUSION	Pressure in the extension set and the syringe has reached the alarm limit.	Identify and remove the cause of the blockage in the extension set, syringe or drive.	While infusion is in progress block the extension line and wait until alarm is generated.
SYRINGE EMPTY STOP	The syringe is empty.	Replace the syringe or turn the pump off.	In UC menu switch off the KVO AT SYRINGE EMPTY function. Launch the infusion and wait until syringe is emptied.
END OF INFUSION STOP	The pump has reached the end of infusion.	Replace the syringe or turn the pump off.	In the UC menu switch on the STOP AFTER VTBI function. Set the VTBI and select STOP option. Launch the infusion and wait until syringe is emptied.
INTERNAL MALFUNCTION (code)	The pump has detected an internal malfunction.	Remove the pump from service and have the pump checked by qualified personnel.	———

Informational messages

Informational messages provide description of improper activities or actions that can not be done. Occurrence of informational messages does not halt an infusion. However it calls an attention on appeared circumstances and help to fix the problem.

Table 6.3 Troubleshooting Pump Informational Messages

MESSAGE	CAUSE	CORRECTION
<Value too high!>	Entered parameter's value exceeds the set limit.	Enter parameter's value within set limits or modify limits (if available).
<Value too low!>	Entered parameter's value below the set limit.	Enter parameter's value within set limits or modify limits (if available).
Keypad locked	The keypad is locked.	To unlock keypad press the C key and then YES.
<VTBI completed>	Infusion of set VTBI value has been completed.	Modify settings or replace syringe.
<Syringe empty>	The syringe is empty.	Replace the syringe or turn the pump off.
Incorrect parameters	One or more parameters are invalid or cannot be adopted to the chosen syringe size.	Review parameters or change syringe size.
Incorrect syringe	Inserted syringe doesn't match any of the syringes available in the pump.	Use a syringe from the list of Recommended syringes.
Configured Infusion rate limit too low!	Infusion rate limit setting in User Configuration menu below the drug name lower rate limit.	Modify infusion rate limit in User Configuration menu or drug name lower rate limit.
Configured Bolus rate limit too low!	Bolus rate limit setting in User Configuration menu is below the current infusion rate.	Modify bolus rate limit in User Configuration menu.
<Pressure increasing>	Pressure in the extension set and syringe is continually increasing.	Make sure that there is no blockage in the line.
Bolus disabled	Both Manual and Automatic boluses are disabled.	Enable required bolus mode in User Configuration menu.
Maintenance overdue	The time period of preventative maintenance set by the Biomedical engineer has expired.	Schedule operational checkout by qualified biomedical personnel or authorised service representative.

7. MAINTENANCE AND STORAGE

! CAUTION ! **The pump has to be switched off and must be unplugged from the line for cleaning.**

! CAUTION ! **Do not clean, disinfect, or sterilise any part of the device by autoclaving or with ethylene oxide gas. Doing so may damage the device and void the warranty. Only external parts of the device should be disinfected.**

! CAUTION ! **Do not use the following chemicals on the device, as they will damage the front panel: acetone, acetoaldehyde, ammonia, benzene, hydroxytoluene, methylene, chloride, and ozone. Do not use cleaners containing n-alkyl, dimethyl, ethylbenzyl, ammonium chloride unless they appear in the list of recommended cleaners overleaf.**

! CAUTION ! **Keep the syringe pump clean and dry.**

! CAUTION ! **After cleaning, check for the absence of liquid in the mains inlet. The presence of liquid can cause shortening of the contacts. Clean the mains inlet using a dry pad of gauze and only then reconnect the pump to the mains.**

Cleaning Overview

The exterior of the device may be cleaned with a soft cloth, sparingly dampened with any of the cleaners listed below. **Do not spray cleaners directly into the syringe mechanism, the area where the power cord enters the device or the interface connectors. Do not use hard instruments for cleaning.** Follow the manufacturer's dilution instructions for concentrated cleaners. Always clean/disinfect the device after each use. For a device that has been in an Isolation Area, select those agents from the list below that both clean and disinfect.

While the product design safeguards against fluid spillage, if fluid enters the pump, contact your dealer or manufacturer's servicing department for assistance. This should be done immediately to minimise any potential difficulties with the solutions pooling and drying on the mechanism.

Recommended cleaners

Before using a cleaner on the pump, it should be tested on a small area beforehand.

- A solution of 3% hydrogen peroxide
- Soapy water
- Ethyl alcohol

Preventive Maintenance

The table below contains a schedule of basic maintenance tasks that should be performed on the device. If the device cannot be cleaned using the basic methods described earlier or components are missing or damaged, discontinue use and notify the appropriate authorised service personnel.

Table 7.1 Preventive Maintenance Actions

Check	Action
Perform as required but recommended after every use	
Housings	Clean housing and front panel as recommended in the cleaning instructions in this section. Check for cracks and large dents.
Labels	Clean as recommended in the cleaning instructions. Check for scratches, cuts or obliterated words.
Power cord	Verify that the power cord is undamaged over the entire length of the cord and the moulded plug.
Rear housing accessory	Verify that there are no loose or missing parts and that connectors and accessories are undamaged.
Battery	Recharge by plugging into 100-240 VAC 50/60 Hz power outlet for at least 5 hours. Check that the MAINS LED is illuminated during this time.
Perform as required but recommended monthly	
Battery	Recharge by plugging into 100-240 VAC 50/60 Hz power outlet for at least 5 hours. Check that the MAINS LED is illuminated during this time.
Perform as required but recommended every 12 months or when the prompt "Maintenance overdue" appears.	
Entire device	Schedule operational checkout by qualified biomedical personnel or authorised service representative.

Battery Operation Overview

The device can be battery operated in emergency situations and for temporary portable applications. When operating on battery the Battery LED lights.

Battery Charging

The battery is charging whenever the device is plugged into mains outlet, regardless of whether the device is on or off. If the pump is not used for a long time, the battery should be charged at least once in a 2 months.

In general, if the battery being discharged and recharged up to 500 cycles it will need to be replaced. Notify an authorized service person for battery inspection according to service manual. **Batteries should only be replaced by authorized service personnel.**

Battery Disposal

Battery should be disposed of as outlined by the local country regulation.

Storage

It is recommended that the device remain plugged in during storage to maintain the battery at full charge. Do not store the device with the key ON and the device unplugged.
When unpackaged, ensure the product is stored in a clean and dry (15-90%, RH, non-condensing) environment to safeguard against prolonged exposure to dust and moisture. In conditions falling outside the Environmental Operating Limits (see the Technical Specifications Table), Viltechmeda recommends that the device be repackaged in the original shipping materials.

Test routines

The test routines are designed to allow confirmation of many of pump parameters, functions and calibration without requiring internal inspection. Refer to Service Manual for a complete list of test and calibration procedures.

Repair

The right to repair the pump or carry out periodical part replacements is reserved only to the Manufacturer or its authorised service representative.

8. TECHNICAL SPECIFICATIONS

Table 8.1 Technical specifications

Component	Description
Infusion rates	2/3 ml syringes – 0.01–60 ml/h 5/6 ml syringes – 0.10–150 ml/h 10/12 ml syringes – 0.10–300 ml/h 20/22 ml syringe – 0.10–600 ml/h 30/35 ml syringes – 0.10–900 ml/h 50/60 ml syringes – 0.10–2200 ml/h (0.01-99.99 ml/h in steps of 0.01 ml/h 100.0-999.9 ml/h in steps of 0.1 ml/h 1000-2200 ml/h in steps of 1 ml/h)
Bolus rates	2/3 ml syringes – 0.10–60 ml/h 5/6 ml syringes – 0.10–150 ml/h 10/12 ml syringes – 0.10–300 ml/h 20/22 ml syringe – 0.10–600 ml/h 30/35 ml syringes – 0.10–900 ml/h 50/60 ml syringes – 0.10–2200 ml/h (0.1 - 999.9 ml/h in 0.1 ml/h steps, 1000 - 2200 ml/h in 1 ml/h steps)
Purge rates	2/3 ml syringes – 1–60 ml/h 5/6 ml syringes – 1–150 ml/h 10/12 ml syringes – 1–300 ml/h 20/22 ml syringe – 1–600 ml/h 30/35 ml syringes – 1–900 ml/h 50/60 ml syringes – 1–2200 ml/h (1-2200 ml/h in steps of 1 ml/h)
Syringe sizes	2/3, 5/6, 10/12, 20/22, 30/35, 50/60 ml of all major brands including additional brands upon agreement
Dose rate units	ml, g, mg, mcg, ng, Units, kUnits, mUnits, mcUnits, mol, mmol, mcmol, nmol, mEq (/kg or m^2) /min or h or 24h
Bolus volume limit	0.10 – 60.0 ml in steps of 0.1 ml
Purge volume	0.1 – 4.0 ml in steps of 0.1 ml
Maximum volume under single fault condition	<0.5 ml
Volumetric accuracy	±2 % (according to EN 60601-2-24 standard)
Volume To Be Infused (VTBI)	0.10 - 99.99 ml in steps of 0.01 ml 100.0 – 999.9 ml in steps of 0.1 ml 1000-9999 in steps of 1 ml 0 – no limit
Programmable infusion time	1 s – 200 h

Keep Vein Open (KVO) rate	0.10 - 5.00 ml/h for syringes 10 ml and above 0.01 - 5.00 ml/h for syringes 5 ml and below
KVO volume	0.1% - 10% of the syringe volume
Post VTBI rate	Stop, KVO or continue with set rate
Standby time	1 min – 23 h 59 min
Patient body surface area	0.1 – 10 m^2
Patient weight	0.3 – 300 kg
Near End Of Infusion Alerts	3 min – 60 min (time warning) 1.0 ml – 50.0 ml (volume warning)
Restart after Occlusion	0 - 2
Rapid occlusion detection	Less than 5 min at 1 ml/h with 60 ml syringe
Occlusion alarm pressure	10 levels for syringes 10 ml and above: L1 (app. 50 mmHg), L2 (app. 150 mmHg), L3 (app. 250 mmHg), L4 (app. 350 mmHg), L5 (app. 450 mmHg), L6 (app. 550 mmHg), L7 (app. 650 mmHg), L8 (app. 750 mmHg), L9 (app. 850 mmHg), L10 (app. 950 mmHg)
	6 levels for syringes 5/6 ml and smaller: L5 (app. 450 mmHg) – L10 (app. 950 mmHg)
	4 levels for 2/3 ml syringes: L7 (app. 650 mmHg) – L10 (app. 950 mmHg)
Event log	>2000 events
Patient history log	>500 events
Service log	50 events
Mounting	- table top operation - universal pole clamp - Draeger bar - infusion device rack
Protection against current leakage	Defibrillation-proof type CF applied part
Protection against electrical shocks	Class II
Protection against splashing liquid	IP43 (protection from entry by tools, wires, etc., with a diameter of thickness greater than 1.0 mm and spraying water up to 60° from the vertical)

CE 0123 marked	Council Directive 93/42/EEC concerning medical devices
Class	IIb acc. to the Directive of the Council of Medical Products 93/42/EC
Use in ambulances	With dedicated mounting clamp and holder (optional) complying with EN 1789
Standards conformity	IEC/EN 60601-(1, 1-2, 1-6, 1-8, 2-24)
EMS	IEC / EN 60601-1-2/ 60601-2-24
AC power supply	100 - 240VAC, 50/60 Hz, 50VA
Battery: Battery type Battery operation Battery charging time Battery lifetime	 NiMH, 7.2 V/2.5 Ah (NiMH, 7.2 V/2.7 Ah) at least 10 h @ 5 ml/h Up to 5 hours to 100% charge Up to 500 cycles according to usage and environmental conditions
External DC power supply	12-16 VDC (2 A) - optional
Operating temperature range	0°C – +40°C
Transport and storage temperature	-40°C – +70°C
Transient operating conditions	-20°C – +50°C
Operating atmospheric pressure	60 kPa – 106 kPa
Permissible relative humidity	15 - 90%, no condensation
Memory retention	For more than 9 months when not powered up
Interfaces	USB IrDA Nursecall - optional
Screen: Screen type Screen dimensions Screen diagonal Screen pixel density	 Graphic LCD 108.6 x 29.6 mm 4.43 ” / 112.56 mm 256 x 64
Alarm loudness	3 levels

Dimensions	(WxHxD) 320 × 120.5 × 137 mm
Weight	2.3 kg

Volumetric Accuracy of the System

The pump, using the appropriate syringe (identified in Chapter 2), maintains a volumetric accuracy with delivery errors not exceeding ±2% for the second hour of infusion at 5 ml/h.

Note that flow fluctuations can be caused by unusual conditions or combinations of conditions that may involve, but are not limited to, the following: fluid density, positive and negative pressure and the environment. Flow fluctuations are most likely to occur when the conditions mentioned above are exacerbated or when the device is operated in conditions outside of its normal limits.

The accuracy figures as stated are based upon operation at a room temperature of 22°C.

NOTE:
The all data shown is for the BD Plastipak 50 ml syringe with BALTON, PPI/LL – 120 cm extension set

Startup Graph Description

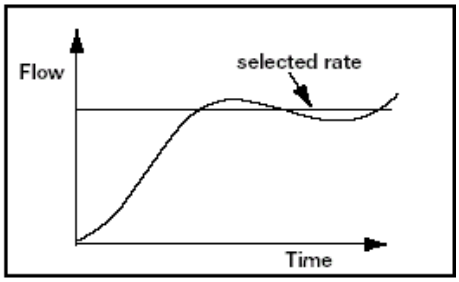


Figure 8.1 Startup Graph Example

The Startup Graph was developed in accordance with IEC/EN 60601-2-24.
The Startup data shown in the graph illustrates the startup performance of the pump during the first 120 minutes of operation with a sampling period of 30 seconds.

A Startup graph of flow versus time illustrates initial stability with time.
Even with the proper components and set up, the flow of any manufacturer's pump may be erratic during the 120-minute startup period. Therefore, we have included the startup, or stabilisation data. It should be noted that as the time interval over which accuracy is measured is lengthened, all pumps show considerable improvement in flow accuracy.

How Trumpet Curve Graphs are Interpreted

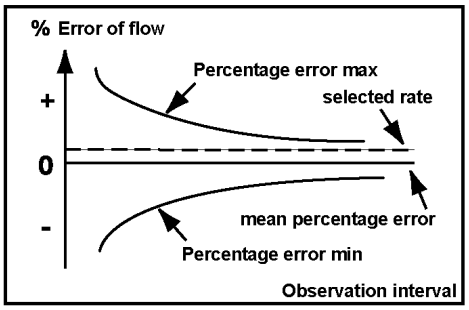


Figure 8.2 Trumpet Graph Example

The trumpet curve provides a graphical view of the maximum deviation in flow rate from the programmed delivery rate for specific segments of delivery time. The horizontal axis does not represent elapsed delivery time, but rather acts as a graphical reference for selecting specific observation time intervals. The widest area of the trumpet curve (greatest deviation) reflects the smallest sampling intervals or observation windows. As the sizes of the sampling intervals increase (in minutes), the deviations in flow from the programmed delivery rate are reduced as the deviations are spread out over the longer periods of time. This results in the narrowing of the trumpet curve giving a more realistic representation of the device's average flow rate accuracy over longer intervals of time.

For example, if you were to look at the maximum and minimum percentage error points corresponding to the 5-minute interval point on the Observation Interval axis, you would be looking at the average flow variance for any 5-minute period throughout the infusion.

Similarly, if you were to look at the 60-minute interval point on the Observation Interval axis, you would be looking at the average flow variance for any 60-minute period throughout the infusion.

How Trumpet Curves Can Be Used

Trumpet curves can be important sources of information for the medical professional who must decide whether a certain infusion pump can be used with a particular drug. For example, when delivering a drug with a short half-life, very small deviations in flow over the course of an infusion would be desirable to ensure that the deviations in plasma level also remained small. The device's ability to deliver very closely to the programmed rate would ensure that the drug's efficacy was being maintained. In this example, the medical professional would be wise to select a device whose trumpet curve indicated a small or narrow range of deviations in flow rate.

Startup and Trumpet Curves

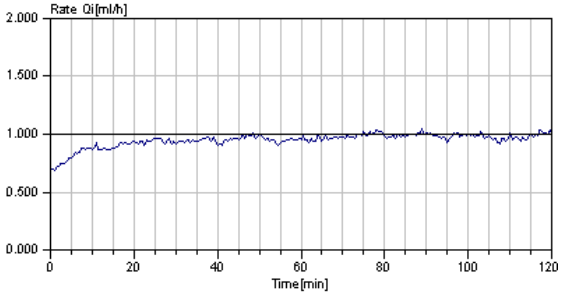


Figure 8.3 Startup graph. BD Plastipak 50 ml @ 1 ml/h

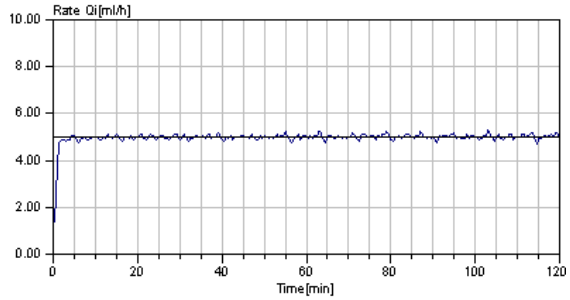


Figure 8.4 Startup graph. BD Plastipak 50 ml @ 5 ml/h

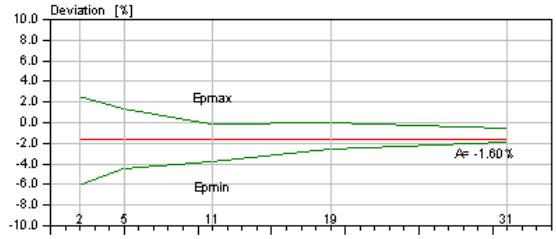


Figure 8.5 Trumpet graph. BD Plastipak 50 ml @ 1 ml/h

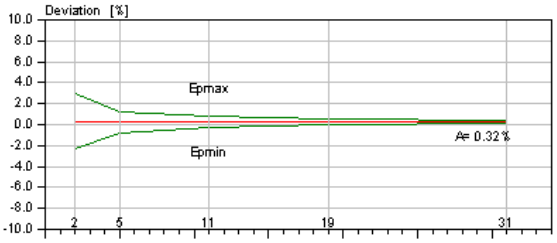


Figure 8.6 Trumpet graph. BD Plastipak 50 ml @ 5 ml/h

Influences of Back Pressure at 5 ml/h

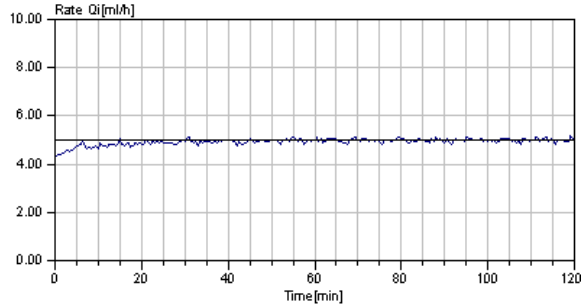


Figure 8.7 Startup graph. BD Plastipak 50 ml (+100 mmHg)

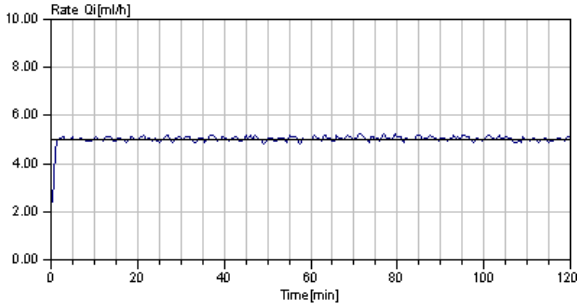


Figure 8.8 Startup graph. BD Plastipak 50 ml (-100 mmHg)

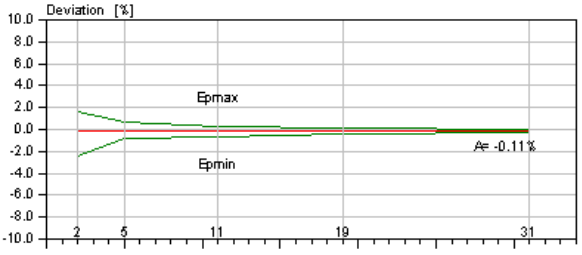


Figure 8.9 Trumpet graph. BD Plastipak 50 ml (+100 mmHg)

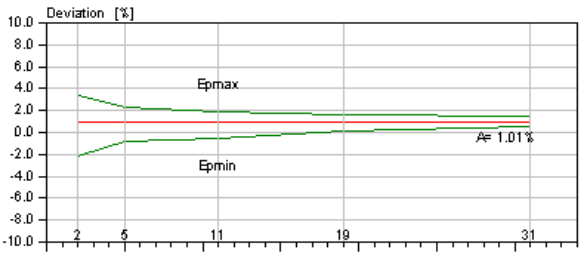


Figure 8.10 Trumpet graph. BD Plastipak 50 ml (-100 mmHg)

Maximum Infusion Pressure Generated

The maximum infusion pressure prior to alarm activation is 1170 mmHg**.**

Alarm Delay at Occlusion

Table 8.2 Alarm delay at occlusion

Rate	Occlusion alarm pressure level	Time to Alarm activation (max)
1 ml/h	Minimum: L1* Maximum: L10	14 min 1 h 55 min
5 ml/h	Minimum: L1* Maximum: L10	3 min 23 min

Bolus Volume at Occlusion

Table 8.3 Bolus volume at occlusion

Rate	Occlusion alarm pressure level	Bolus volume (max)
5 ml/h	Minimum: L1* Maximum: L10	0.1 ml 0.3 ml

** - using some syringes at low alarm levels, occlusion alarm can be generated immediately after start of infusion – the force at these levels is commonly less than the friction in the syringe (with no additional fluid pressure).*

Alarm signal sound pressure

Table 8.4 Alarm signal sound pressure

Alarm signal sound level	Measured value
High	67,3 dB
Low	46,9 dB

9. TECHNICAL DESCRIPTION

General

The pump is intended for precise dosing of drug at the rate programmed by the operator. The speed of syringe pusher is set by the microprocessor, based on the syringe model. Information on pump status and programming data are outputted to the graphics format display. Operation of the microprocessor is monitored by the watch-dog circuit which unconditionally switches off the motor in case of failure.

Battery charging system

Pump comprises internal battery charging system based on the fast-charge controller. Charging is initiated each time the pump is reconnected to the mains (either AC or 12 VDC in ambulance car). In fast charge mode controller is forcing into battery a constant current of approx 0.6 A. Once full charge is detected, the charging is stopped. The device monitors three variables to determine when the battery reaches full charge: voltage slope, battery temperature, and charge time.

Means to protect the patient

Self-TESTING

Automatic testing of pump program is executed after switching the pump on. In case of program fault, pump generates audible alarm and “Internal malfunction” message is displayed, which indicates the error code for service personnel. Operation of the pump in this case is impossible;

Watch-dog

In case of failure, Watch-dog circuit stops infusion, blocks stepper motor and activates alarm;

Syringe size detector

Presence of the syringe size detector helps to avoid entering of erroneous syringe size when programming, thus preventing over- or under-infusion. Infusion cannot be started before syringe type is confirmed. In case when size of installed syringe does not correspond with any pre-programmed size, the “Incorrect syringe size” message is generated.
In order to minimize risk of improper selection of syringe with similar, but different parameters, or due to improper syringe loading, when different syringe make can be indicated, which is slightly bigger than the loaded syringe – the pump provides the possibility of configuring only frequently used syringes.

Syringe barrel and plunger detectors
Presence of these detectors allows to prevent unauthorized infusion when syringe is loaded improperly and generate an alarm to inform the user the infusion has been halted.

Plunger position detector
Presence of this detector allows to generate XX min NEAR SYRINGE EMPTY pre-alarm and XX ml NEAR SYRINGE EMPTY pre-alarm, and in that way medical personnel is warned on the necessity of preparing next syringe for infusion.

Occlusion detector
As a syringe force sensor a strain gauge is used, which is mounted on a steel plate within the drive mechanism. When this plate is deflected by applied force on the plunger mechanism, a signal is generated at gauge output. If generated signal exceeds the set value an occlusion alarm is generated. Appropriate occlusion value is set when operator selects occlusion level. There are 10 occlusion pressure levels available.

Anti-Bolus Function
In case of occlusion (e.g. due to kink of administration set), excessive pressure is created in the administration set and syringe, which can lead to unwanted Bolus of drug when origin of occlusion is eliminated. To avoid this the pump is provided with Anti-Bolus function, i.e. motor makes certain number of steps backwards after occlusion is detected. Anti-Bolus function decreases risk of unwanted Bolus.

Anti-Siphoning System
Syringe clamping fixtures are designed so as to eliminate backlashes between syringe and drive. This prevents unwanted Bolus during rapid change of the pump elevation relative to patient's heart level, e.g. during transportation of the patient.

Minimization of number of parameters and limitation of parameter values
Additionally, to avoid drug over-dosage due to erroneous programming of infusion rate by operator, there is possibility to set safety limits of parameters in the set-up menu, as well as possibility to select only necessary parameters.

User configuration access

Access controlled by combination of keys and code during pump power up.

Maintenance

Refer to the Service Manual for replacement, calibration, testing, or other information.
In case of any fault of the pump immediately consult the Manufacturer or the dealer.
The right to repair the pump or to carry out periodical part replacement is reserved only to the Manufacturer or to persons authorized by the Manufacturer.

10. GUIDANCE AND MANUFACTURER'S DECLARATION ON ELECTROMAGNETIC EMISSIONS

Electromagnetic Compatibility Statement

This statement and the information provided in the following tables are required by IEC/EN 60601-1-2. The tables can be used to identify what EMC (electromagnetic compatibility) standards Aitecs 2016 syringe pump (hereinafter – Syringe pump) was subjected to, the minimum test level identified in the standard, the level that the pump meets and general guidance on the EMC environment. The pump is intended for use in the electromagnetic environment specified in the following tables. As with most microprocessor-based electronic products, syringe pump creates RF (radio frequency) energy as a side effect of its internal functions.

Precautions should be taken to avoid exposing syringe pump to powerful sources of electromagnetic radiation such as MRI (magnetic resonance imaging) and ESU (electro-surgical equipment).

Note that portable and mobile communications equipment such as cell phones can affect MEDICAL ELECTRICAL EQUIPMENT such as syringe pump.

! WARNING ! **The use of ACCESSORIES and cables other than those specified in the Operator's Manual may result in increased EMISSIONS or decreased IMMUNITY of syringe pump.**

! WARNING ! **Syringe pump should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, syringe pump should be observed to verify normal operation in the configuration in which it will be used.**

Table 10.1 Guidance and manufacturer's declaration - electromagnetic emissions

Syringe pump is intended for use in the electromagnetic environment specified below. The customer or the user of syringe pump should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	Syringe pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Syringe pump is suitable for use in professional healthcare facility environment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 10.2 Guidance and manufacturer's declaration – electromagnetic immunity

Syringe pump is intended for use in the electromagnetic environment specified below. The customer or the user of syringe pump should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 8 kV air	+/- 8 kV contact (1) +/- 15 kV air (1)	Floors should be wood, concrete, or ceramic tile. If the floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient burst IEC 61000-4-4	+/- 2 kV @ PRR 100kHz for power supply lines	+/- 2 kV @ PRR 100kHz for power supply lines	Mains power quality should be that of a professional healthcare facility environment.
Surge IEC 61000-4-5	+/- 1kV differential mode	+/- 1kV differential mode	Mains power quality should be that of a professional healthcare facility environment.

Table 10.2 Guidance and manufacturer's declaration – electromagnetic immunity – continued

Syringe pump is intended for use in the electromagnetic environment specified below. The customer or the user of syringe pump should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	70 % U_T; 25/30 cycles single phase: at 0° 0 % U_T; 1 cycle 0 % *U*T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % *U*T; 250/300 cycle (5s)	70 % U_T; 25/30 cycles single phase: at 0° 0 % U_T; 1 cycle 0 % *U*T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % *U*T; 250/300 cycle (5s)	Mains power quality should be that of a professional healthcare facility environment. If the user of the syringe pump requires continued operation during power mains interruptions, it is recommended that the syringe pump be powered from an uninterruptible power supply or a battery. User should always have battery installed per Operator's Manual.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic characteristic of a professional healthcare facility environment.

NOTE 1: Syringe pump was designed to meet the requirements of IEC/EN 60601-1-2 and IEC/EN 60601-2-24.

NOTE 2: Pump automatically transfers to battery operation if there is a loss of main power.

Table 10.3 Guidance and manufacturer's declaration - electromagnetic immunity - for LIFE-SUPPORTING EQUIPMENT and SYSTEMS

Syringe pump is intended for use in the electromagnetic environment specified below. The customer or the user of syringe pump should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of syringe pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz TO 80 MHz outside ISM bands[a] 80% AM at 1 kHz	3 Vrms	***d=1.17√P***
	6 Vrms 150 kHz to 80 MHz in ISM bands[b] 80% AM at 1 kHz	6 Vrms	***d=1.2√P***
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m	***d=1.2√P 80 MHz to 800 MHz*** ***d=2.3√P 800 MHz to 6 GHz*** where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).[b]
Proximity fields from RF wireless communication equipment IEC/EN 61000-4-3	9 V/m to 28 V/m 15 specific frequencies up to 5.785 Ghz	9 V/m to 28 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 6 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

Table 10.3 Guidance and manufacturer's declaration - electromagnetic immunity - for LIFE-SUPPORTING EQUIPMENT and SYSTEMS – continued

Syringe pump is intended for use in the electromagnetic environment specified below. The customer or the user of syringe pump should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which syringe pump is used exceeds the applicable RF compliance level above, syringe pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating syringe pump.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 10.4 Recommended separation distances between portable and mobile RF communications equipment and syringe pump - for LIFE - SUPPORTING EQUIPMENT and SYSTEMS

Syringe pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of syringe pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and syringe pump as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**			
	150 kHz to 80 MHz outside ISM bands $d=1.17\sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d=1.2\sqrt{P}$	**80 MHz to 800 MHz** $d=1.2\sqrt{P}$	**800 MHz to 6 GHz** $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.37	0.38	0.38	0.73
1	1.17	1.20	1.20	2.30
10	3.70	3.80	3.80	7.28
100	11.70	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Table 10.4 Recommended separation distances between portable and mobile RF communications equipment and syringe pump - for LIFE - SUPPORTING EQUIPMENT and SYSTEMS – continued

Syringe pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of syringe pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and syringe pump as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**			
	150 kHz to 80 MHz outside ISM bands $d=1.17\sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d=1.2\sqrt{P}$	**80 MHz to 800 MHz** $d=1.2\sqrt{P}$	**800 MHz to 6 GHz** $d=2.3\sqrt{P}$

NOTE 1 At 80 MHz and 800 MHz, the separation distance of the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 6 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

11. WARRANTY AND SERVICE INFORMATION

Warranty

- The Manufacturer warrants that pump is free from defects in material and workmanship under normal use and service for a period of 12 months (excluding batteries) after the purchase date.
- The Manufacturer or its authorised representative takes obligation to carry out the warranty repair of the pump or to replace the pump with an operational one in case the Manufacturer or its authorised representative determines that the cause of the pump's failure was related to the manufacturing process.
- If the customer finds a defect in the pump during the Warranty period, he must report it and inform the Manufacturer or its authorised representative within 30 days.
- A pump sent for testing, repair or replacement shall be submitted to the Manufacturer or its authorised representative in its original or equivalent packaging. The pump is sent for repair at customer expense.
- If no defect is found during testing, the Manufacturer or its authorised representative will charge the customer for the work carried out.
- This Warranty is not applicable to pumps when failure was caused by violations of requirements of this Operation Manual and labelling, by mains voltage non-conformity to the requirements of IEC/EN, by spills of liquids, by mechanical damages caused by shocks or a pump being dropped, by pump damages caused during transportation, or when packaging is damaged. Modification, alternation, recalibration, or abuse, and service by other than Manufacturer or its authorised representative may void the warranty.

Service Information

For service and repair contact manufacturer:
UAB Viltechmeda
Mokslininku 6, LT-08412 Vilnius, Lithuania
Tel.: (+370 5) 2776 745
Fax: (+370 5) 2763 867
www.aitecs.com
Shipping costs for all units returned to Viltechmeda shall be paid for by the customer. The unit must be packed in its original container or in another Viltechmeda approved container that will provide adequate protection during shipment. To ensure prompt return, a Viltechmeda's authorised dealer must be notified before shipping any unit for repair.
When calling for service, please be prepared to provide model and serial number of the unit. A brief written description of the problem should be attached to the instrument when it is returned for service.

Viltechmeda will not be responsible for unauthorised returns or for units damaged in shipment due to improper packing.

12. ACCESSORIES

Table 12.1 Accessories

Description		Part Number
12VDC cable		B6650035
Nurse Call cable		B6650034
USB		Q0000155
Power cable		V5570016 (EUR)
		V5570018 (UK)
		V5570019 (USA)
		V5570054 (USA) (clear plug and connector)
Clamp		B6400008
Clamp for connecting syringe pumps		B6400009
Clamp		B6400009-01
Clamp		Q0000509
Rod for connecting Aitecs 2016 syringe pumps together	without integrated handle	B6302059
	with integrated handle	B6302057
Handle (for rod B6302059)		B6302055
Mounting holder for secure fixation of Aitecs 2016 in ambulance cars, complying with EN 1789		B6090006

13. RELATED PRODUCTS

Infusion station IDS

Table 13.1 Infusion station IDS

IDS-04	
	Also available: - IDS 03 (accommodates 3 Aitecs 2016 syringe pumps) - IDS 04 (accommodates 4 Aitecs 2016 syringe pumps) - IDS 06 (accommodates 6 Aitecs 2016 syringe pumps) - IDS 08 (accommodates 8 Aitecs 2016 syringe pumps)

Software utilities

Aitecs 2016 Event History

FAAA2716 - Aitecs 2016 Event History utility allows downloading and saving to database three types of event logs which are recorded in the memory of the pump while it is working. Moreover, Event History utility allows reviewing events and printing the report.