Operator's Manual

SEP-10S Plus
SEP-12S Plus
SP-12S Pro

SYRINGE INFUSION PUMPS

aitecs

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Document history

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CE 0408

This symbol represents compliance with the essential requirements according to MDD 93/42/EEC (14 June 1993) of the European Communities concerning medical devices.

Compliance

The pumps comply with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-24 standards.

SEP-10S Plus and SP-12S Pro intended for use in road ambulances comply with EN 1789:1999.

SEP-10S Plus and SP-12S Pro - FDA approved.

The pumps have been manufactured by the company, which has implemented and maintains a Quality Assurance System meeting the requirements of the standards EN ISO 9001:2000 and EN ISO 13485:2003.

Devices:	SEP-10S Plus, SEP-12S Plus, SP-12S Pro (hereinafter – the pump)
Manufacturer:	Viltechmeda, 125 Kalvariju Str., 08221 Vilnius, Lithuania.

Material Specifications

Steel	
Stainless Steel	
Copper	
Aluminium	
Bronze	
Brass	
Polyamide	PA6 (PA)
Polycarbonate	(PC)
Composition of Polycarbonate and ABS	(PC+ABS)
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

Overview

- The pump is designed to meet the fluid and drug delivery requirements of today's changing clinical environment.

- The pump is indicated for infusion via intravenous (IV), intra-arterial (IA), epidural, or subcutaneous routes of administration. Infusion rates are programmable from 0.1 to 1500 ml/h.

- The pump accepts wide range, single-use syringes with volumes from 10 to 100 ml, optional – 5 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.

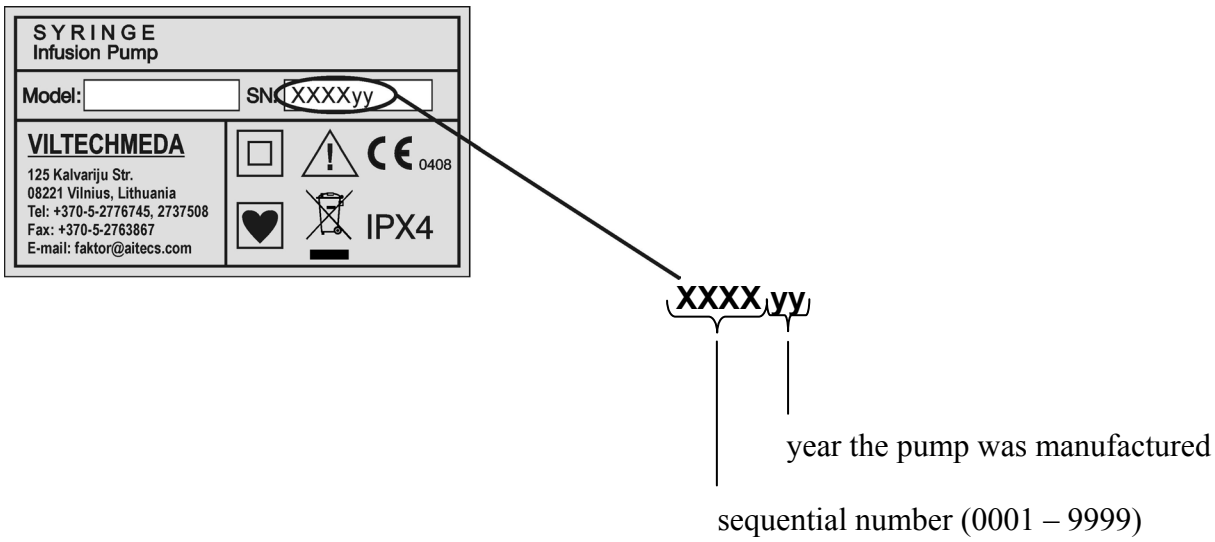
Pump description

SEP-10S Plus – General ward syringe pump

SEP-12S Plus – Anaesthesia syringe pump

SP-12S Pro – Universal syringe pump

Serial Number Description



Items supplied with pump

1. The pump
2. Operator‘s manual
3. AC power cord
4. Packaging
5. Spare parts: cap B8123009 – 2 pcs.

Additional items supplied with pump to be used in ambulance:

1. The pump with clamp for Draeger bar mounting
2. 12VDC cable

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 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety, the pump is classified as:
• Class II
• Type CF
• IPX4 (splashproof)
• 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 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

CF type device (leak currents protection)

IPX4 Splashing water protected

CE 0408 Complies with MDD 93/42/EEC directive

Nurse call connector (optional)

RS 232 RS232 interface

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).

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xxxxxx

Complies with the directive 95/54/EEC concerning the suppression of radio interference in road ambulances (optional in SEP-10S Plus and SP-12S Pro).

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 ! **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 ! **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.

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 60601-2-24 and IEC 60601-1-2.**

! CAUTION ! **The RS232 is a standard (optional – SEP-10S Plus) feature on the syringe pump. Connection to the computer while pump is connected to the patient is prohibited.**

! CAUTION ! **Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC 60601-1-1. Everybody who connects additional equipment to the signal output configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC 60601-1-1. If in doubt, consult manufacturer's service department.**

! CAUTION ! **Refer to the Service Manual for further information regarding the RS232 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 8 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 8.**

! 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.**

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

! 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**

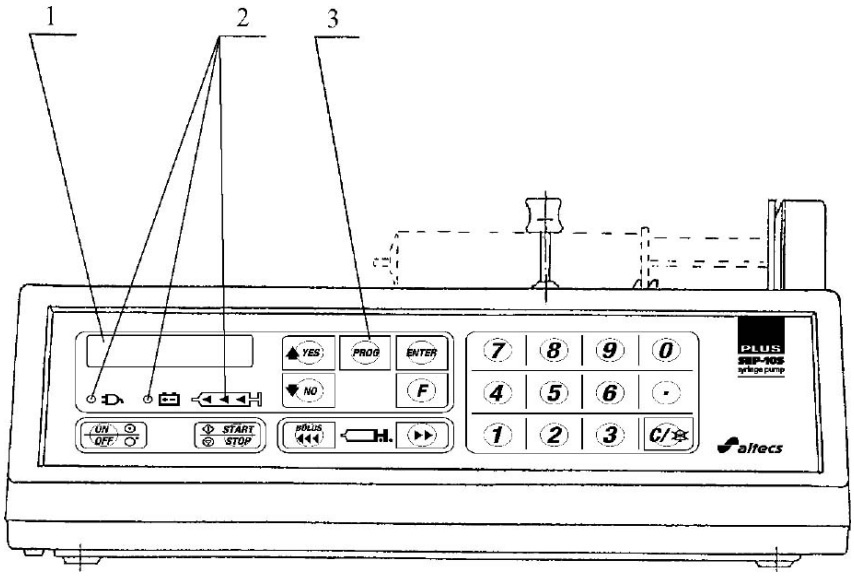
necessary for work. It will help to avoid errors in parameters programming and thereby decrease patient's risk.

Notes

NOTE **Before initially powering on the device, charge the battery.**

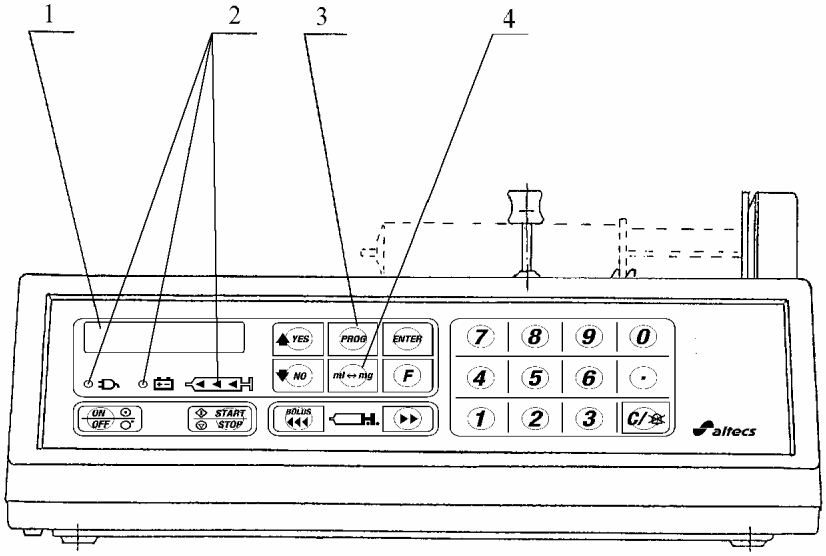
1. PUMP DESCRIPTION

Front view of SEP-10S Plus



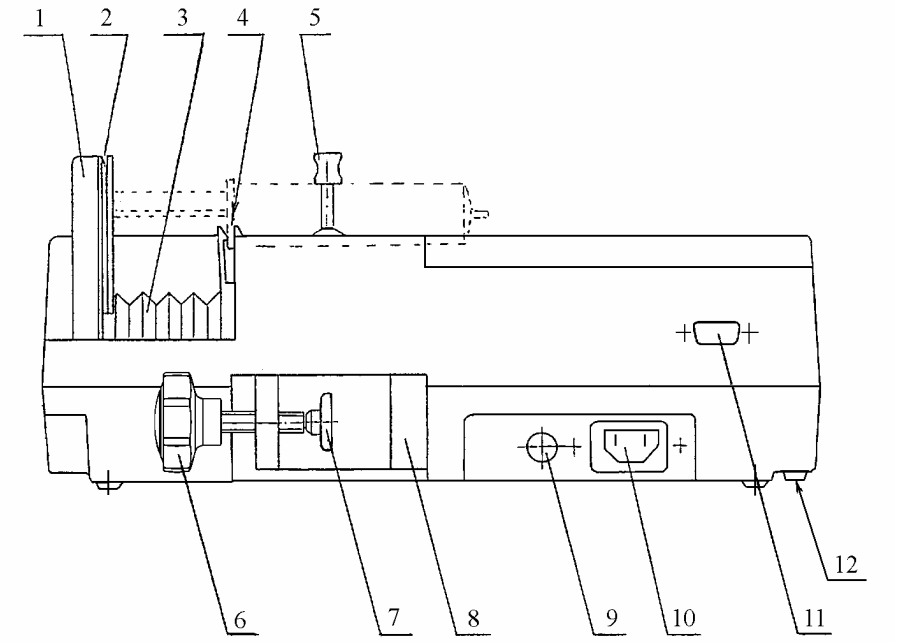
1. Display 2. Indicators 3. Keypad

Front view of SEP-12S Plus, SP-12S Pro



1. Display 2. Indicators 3. Keypad 4. Key to select dimensions of parameters

Rear Panel Assembly



1. Syringe driver arm
2. Slot for inserting the push-button of the syringe plunger
3. Rubber bellows
4. Slot for inserting the finger grips of the syringe barrel
5. Syringe clamp
6. Mounting clamp handle
7. Cap
8. Mounting pole clamp
9. Fuse holder
10. Mains inlet
11. MFC*
12. Audio volume control

* - optional in SEP-10S Plus

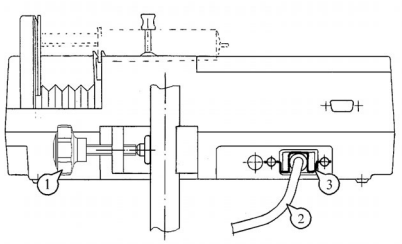
Keypad indicators reference guide	
	The green BATTERY LED lights when the pump is operating on battery power. Flashing if LOW BATTERY alarm condition occurs.
	The green MAINS LED lights when the pump is connected to the AC and battery is charging.
	During infusion, three yellow LEDs are sequentially flashing. If the rightmost LED is on permanently – the infusion is stopped.
Keypad keys reference guide	
	Key to switch the pump on/off; keep it pressed for several seconds in order to switch off.
	Key to start/stop the infusion.
	Key to move the syringe driver arm rapidly to the left-hand side during syringe insertion or to initiate the Bolus mode; it is also intended for air removal from the extension set after syringe insertion.
	Key to move the syringe driver arm to the right-hand side.
	Keys to scroll up/down the list of parameters and syringe brands or answer positively or negatively the dialog questions.
	Key to select dimensions of parameters when programming (only in SEP-12S Plus and SP-12S Pro).
	Key to program (modify) parameters. Pressing it once more restores previous values.
	Key to confirm the selected parameter.
	Numerical keys to enter digits of the parameter being programmed.
	Key to select additional functions or to review programmed parameters.
	Key to cancel the numerical value or the meaning of the parameter or silence the alarm signal. It deletes TOTAL INFUSED and INFUSED DOSE values and clears the numerical value on display when programming.

2. BASIC OPERATION

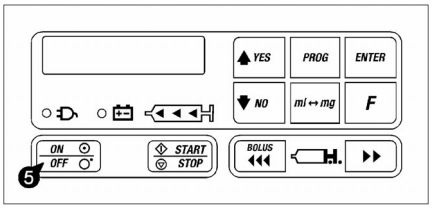
Switching pump on

1. Fasten the pump to the stand by turning the pole clamp handle.
2. Connect the power cord to the corresponding socket on the pump.
3. Secure the power cord to the pump by means of the metal clamp.

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



5. Switch the pump on by pressing the ON/OFF key.



There are three possible situations:
a) the following message is displayed:

Insert SYRINGE into SLOTS!

Insert the syringe filled and with the extension set connected (see Section - Loading the syringe);

or b) the following message is displayed:

Close CLAMP!

Remove air from the extension set and fasten the syringe by means of the clamp (see Section - Loading the syringe);
or c) the following message is displayed (if syringe inserted prior to switching the pump on):

Syringe:
XX ml **(syringe brand name)**

Confirm syringe size and name (see Section - Loading the syringe)

NOTES:
1. If the following message is displayed:

NO MAINS!!!
Check power cord

after pressing the ON/OFF key, it means the pump is not connected to the mains. Either connect the pump to the mains or confirm by pressing the C key that the pump will be powered with the internal battery.
2. If the message:

VERY LOW BATTERY

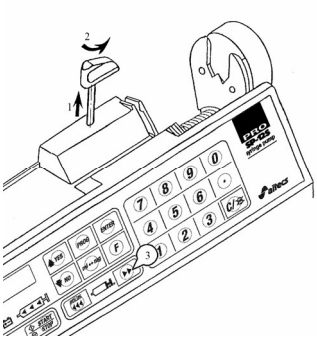
is displayed after pressing the ON/OFF key when the pump is connected to the mains, then switch it off by pressing the ON/OFF key once more and wait for approximately 15 min to allow the internal battery to charge. Then the pump will be prepared for syringe insertion and infusion parameter programming.

The internal battery may be charged permanently because it is protected against overcharging. In order to have the battery fully charged, keep the pump constantly connected to the mains.

Switching pump off

The pump is switched off by keeping the ON/OFF key pressed for 3 sec.

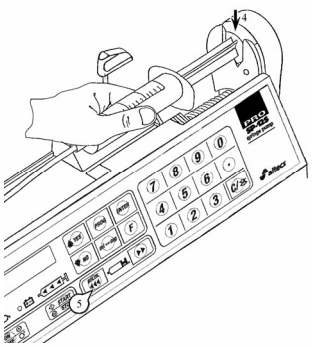
Loading the syringe



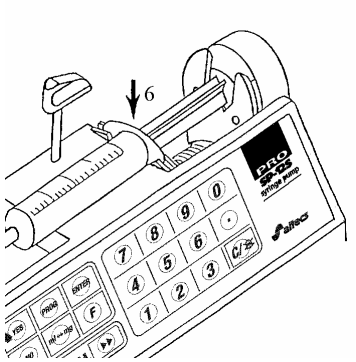
1. Lift the syringe clamp to its upper position.
2. Turn the syringe clamp counter-clockwise by 90°.
3. Pressing the ⏩ key move the syringe driver arm to the right to the distance needed for syringe insertion.

Insert the filled syringe into the pump when the following message is displayed:

Insert SYRINGE
into SLOTS!



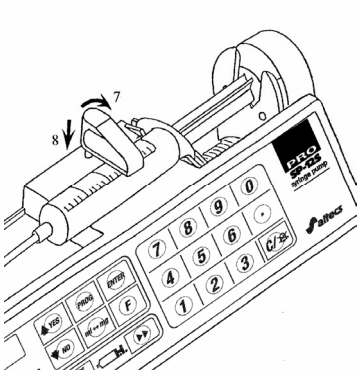
4. Insert the syringe push-button into the syringe driver arm slot to the depth to ensure minimal distance between the syringe barrel and the pump body.
5. Holding the syringe by hand, keep pressing the BOLUS key until the syringe finger grips will fit into the corresponding pump slot.



6. By pressing the syringe barrel and push-button down, insert fully the syringe finger grips and push-button into corresponding pump slots.
The cylindrical syringe barrel shall lay on the pump body with no gap. Axes of the syringe barrel and its plunger shall be on the same line.

The following message is displayed:

Close CLAMP!

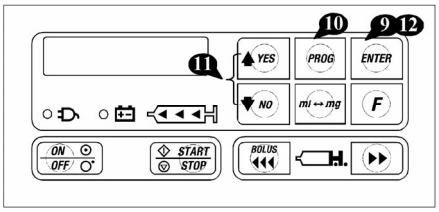


7. Turn the syringe clamp clockwise by 90°.
8. Lower the syringe clamp onto the syringe barrel.

The syringe size sensor determines the syringe size automatically.
The following message is displayed:

Syringe:
XX ml(syringe brand name)

where: XX – syringe size.



9. If the syringe size and brand are correct, press the ENTER key.
10. Otherwise press the PROG key.
11. Select the required syringe name with the scrolling keys.
12. Confirm the selected syringe name and size selected by pressing the ENTER key.

! CAUTION ! Use of syringes not pre-programmed or incorrect insertion of the syringe increase patient's risk.

NOTES:

1. When you insert a syringe having a diameter not complying with any syringe installed, the following message is displayed:

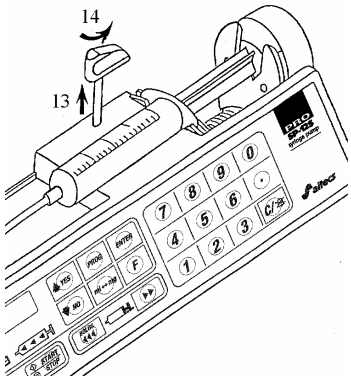
ILLEGAL SYRINGE!
Change SYRINGE!

2. When you insert a syringe of different type (brand or size) than used previously, the following message is displayed:

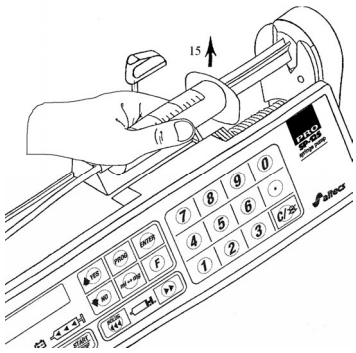
CHECK SYRINGE!
(syringe size and brand)?

If inserted syringe size and brand are the same as displayed, press the YES key or the ENTER key. Otherwise press the PROG key and select different syringe type or check the correctness of syringe insertion.
3. User can minimize syringe list through setup menu in accordance with the chapter 6.

Syringe removal



13. Lift the syringe clamp to its upper position.
14. Turn the syringe clamp counter-clockwise by 90°.



15. Remove the syringe.

Purging

Air can be removed from the extension set after syringe is inserted and brand confirmed, before entering the STOP mode (before pressing the YES key when the message

Total: XXX ml
Ready to run?

is displayed.)

In order to remove air from the extension set press the BOLUS key. The following message is displayed:

PURGE?
press BOLUS

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

Recommended Syringes

	5 ml (optional)	10 ml	20 ml	30 ml	50/60 ml	100 ml
BD PLASTIPAK	√	√	√	√	√	
BD PRECISE			√		√	
BD PrecisG		√				
BD PERFUSOR					√	
BD USA					√	
MONOJECT (Kendall)	√	√	√	√	√	
OMNIFIX (BBraun)			√		√	
PERFUSOR (BBraun)					√	
IVAC					√	
INJECTOMAT (Fresenius)					√	
TERUMO (Europe)			√	√	√	
TERUMO (USA)		√	√	√	√	
NIPRO		√	√	√	√	
JMS						√
KD-JECT III	√	√	√		√	
ELVIONY		√				
EXELMED					√	
DIMES		√	√			
DISPOMED					√	
PolfaBol					√	
PolfaLub			√		√	
JANPOL					√	
HAYAT PERF					√	
HAYAT 10, 20, 50		√	√		√	
MAYBOD YAS		√				
WEIHAI			√		√	√
XINHUA		√	√		√	
HONGDA					√	
HUI CHUN			√	√	√	
YAZD			√			
POMAT		√				
MEDIZ		√				
SHIFA		√	√		√	
INFUJECT				√	√	
PENTAFERTE					√	
ONCE		√	√		√	
MK BG					√	
USC					√	
DISPO VAN		√	√		√	
VITTA		√	√		√	
ROMSONS		√	√		√	
V.MED					√	

NOTE:

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.

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

3. PROGRAMMING OF INFUSION PARAMETERS

◆ All parameters can be programmed after syringe is loaded and syringe make confirmed. When all the parameters are programmed and infusion started pump keypad can be locked.

◆ Previously programmed parameters are reviewed using the scrolling up/down keys. It is necessary to confirm all the parameters. To confirm the parameter press the ENTER key or the scrolling up key. Only then the pump will switch to STOP mode.

◆ In order to modify the selected parameter, press the PROG key. Enter the parameter value using the numerical keys and press the ENTER key to confirm it. Using the ml↔mg, during programming of parameter value, it is possible to select the required measurement unit (only in SEP-12S Plus and SP-12S Pro).
When the parameter has no numerical value, then select the required message by means of the scroll keys and confirm it by pressing the ENTER key. To cancel newly entered (selected) value and restore previous value press the PROG.

Selecting drug name

1. After syringe is inserted and brand confirmed, press the PROG key.
2. Select the required drug name by the scrolling keys.
3. Press the ENTER key to confirm selected drug name.

NOTES:
1. If you don't want the drug name to be displayed select "NONE" from the drug list and press ENTER.
2. You can enter new drug name to the list in accordance with instruction given in the chapter 6 of this manual.

Selecting dose mode (only in SEP-12S Plus and SP-12S Pro)

Select the message

Dose mode:

1. Press the PROG key.
2. Select the required infusion rate unit by pressing the ml↔mg key.
3. Press the Enter key to confirm the selected dose mode.

NOTE:
Available only if mass units enabled in setup menu.

Programming drug concentration (only in SEP-12S Plus and SP-12S Pro)

Select the message

Concentration:

on the display.
1. Press the PROG key.
2. Select the required drug concentration measurement unit using the ml↔mg key.
3. Enter the required value of drug concentration using the numerical keypad.
4. Confirm drug concentration by pressing the ENTER key.

NOTES:
1. In order to have drug concentration calculated from entered drug mass and diluent volume, select the message

Calculate concentration?

using the ml↔mg key.
Press the YES key. Enter drug mass and diluent volume analogously to concentration programming above.
2. Drug concentration can be programmed only if infusion rate is set in mass units.
3. Drug concentration value can not be set to 0.

Programming patient's weight (only in SEP-12S Plus and SP-12S Pro)

Select the message

Patient weight:

on the display.
1. Press the PROG key.
2. Enter the patient weight using the numerical keypad.
3. Press the ENTER key to confirm the selected patient weight.

NOTE:

The programmed patient's weight shall not exceed the value of 200 kg.

Programming infusion rate or volume over time

Select the message

Infusion rate:

on the display.
1. Press the PROG key.

2. Enter the required value of infusion rate using the numerical keypad.
3. Press the Enter key to confirm the selected infusion rate.

NOTE:
In order to have infusion rate calculated from entered volume to be infused (VTBI) value and time, press the F key during infusion rate programming (i.e. after pressing the PROG key). The following message is displayed:

Volume over time?

Press the YES key. Enter VTBI value and Time analogously to infusion rate programming above.

Programming volume to be infused (VTBI)

Select the message

VTBI:

on the display.
1. Press the PROG key.
2. Enter VTBI value using the numerical keypad.
3. Press the ENTER key to confirm VTBI value.

NOTE:
To reset previously entered value and execute the infusion without the preset VTBI, set the VTBI value to 0.

Programming bolus rate

Select the message

BOLUS rate:

on the display.
1. Press the PROG key.
2. Enter the required value of Bolus rate with the numeric keypad. When Bolus function is not required, the Bolus rate value will be set to zero.
3. Press the ENTER key to confirm the selected Bolus rate.

NOTE:
Bolus rate can be programmed only if BOLUS RATE PROGRAMMING feature enabled in Setup menu (see chapter 6).

Programming bolus dose

Select the message

BOLUS dose:

on the display.

1. Press the PROG key.
2. Select the required Bolus dose measurement unit using the ml↔mg key (only in SEP-12S Plus and SP-12S Pro).
3. Enter the required value of Bolus dose using the numeric keypad.
4. Press the ENTER key to confirm the selected Bolus dose.

NOTE:
When the Bolus rate value is set to zero, the Bolus dose can not be programmed as well.

Programming occlusion pressure level

Occlusion pressure level can only be programmed for 50/60 and 100 ml syringes. For syringes from 5 to 30 ml only HIGH occlusion pressure level is available.

Select the message

Occlusion level:

on the display.

1. Press the PROG key.
2. Select the required occlusion pressure level using the scroll keys.
3. Confirm selected occlusion pressure level by pressing the ENTER key.

NOTE:
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.

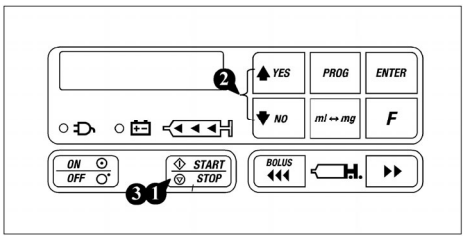
4. INFUSION

Starting and stopping infusion

The infusion is started from the STOP mode when the following message is displayed:

Stop ... X.X ml
XX ml/h

(X.X – amount of drug in ml, mg or µg, infused during observation time, i.e. period from the last clearing of this parameter by means of the C key or by switching the pump off; XX – programmed infusion rate.)



1. Press the START/STOP key.
Segments of the indicator begin to flash sequentially.
2. You may review the following parameters using the scroll keys:

(drug name)
XXX ml/h

(XXX– infusion rate);

VTBI: XX ml
TIME: XX:XX.XX

(X – Volume to be infused;
XX:XX.XX – time remaining to the end of VTBI);

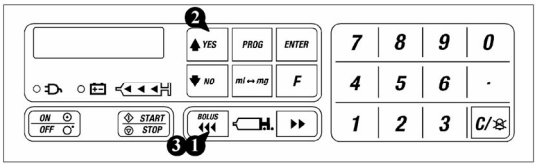
Infused: X.X ml
Total: XX ml

(X.X – amount of drug infused during current session;
XX – total infused amount of drug);

3. Press the START/STOP key when you wish to stop the infusion.
Segments of the indicator stop flashing and the rightmost segment only is left on.

Bolus dose injection

Bolus may be injected during infusion only.



1. Press the BOLUS key.
The following message is displayed:

BOLUS?
Press YES/BOLUS

NOTE:
While the keypad lock is active bolus injection is prevented. To inject bolus, first unlock the keypad.

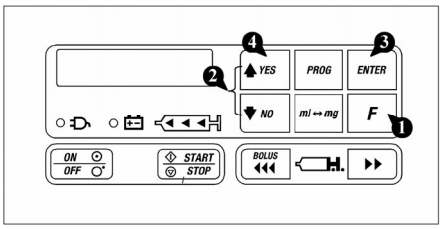
2. If you want to inject the programmed Bolus dose, press the YES key.
During Bolus performance the following message is displayed:

BOLUS ...X.X ml XXX ml/h

(X.X – amount of drug injected in Bolus mode,
XXX – Bolus rate).

3. If you want to inject Bolus manually, press and keep the BOLUS key depressed. Infusion is performed at the Bolus rate until BOLUS key is released and is accompanied by short beeps.

Review of programmed parameters



Programmed parameters may be reviewed during the infusion or after stopping it.
1. Press the F key.
2. Select the following message by the scrolling keys:

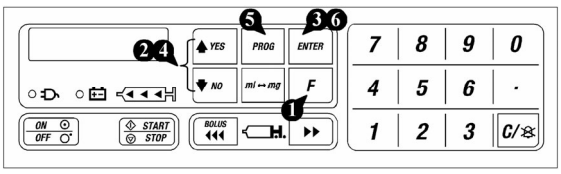
SETTINGS REVIEW

or

SETTINGS

3. Press the ENTER key.
4. It is possible to review all the programmed parameters by pressing the scroll up key.
5. It is possible to exit REVIEW mode by pressing the C key.

Change of programmed parameters



Programmed parameters may be modified only when the infusion is stopped (Infusion rate can be changed (Titration) during infusion as well as in the stop mode).

1. Press the F key.
2. Select the following message using the scroll keys:

SETTINGS

3. Press the ENTER key.
4. Select the parameter to be modified by the scroll keys.
5. Press the PROG key.
Enter or select the new value of the parameter (see chapter 3).
6. Confirm the new value of the parameter by pressing the ENTER key.

NOTES:

1. It is possible to change following parameters:

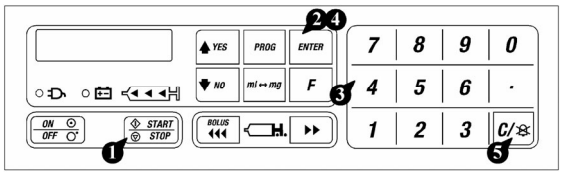
- *Infusion rate*
- *Bolus rate*
- *Bolus dose*
- *VTBI*
- *Occlusion pressure level*

2. Another way to change parameters in the stop mode is as follows:
Open and close the syringe clamp. When the message

Continue infusion?

is displayed, press the NO key.
3. If keypad locked, first unlock the keypad to change the parameters.

Standby mode



Standby mode can be activated if such feature is enabled in setup menu.
1. Stop the infusion by pressing the START/STOP key.
2. Press the ENTER key.

The following message is displayed:

STANDBY!
Duration: min

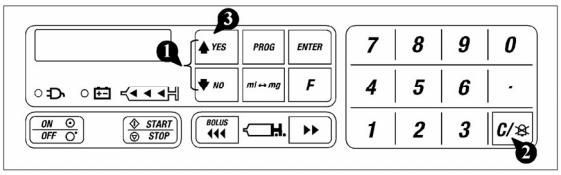
3. Enter the pause duration using the numeric keys.
4. Confirm the pause duration by pressing the ENTER key.
The following message is displayed:

STANDBY!
Rest: XX:XX.XX

(X:XX.XX – time remaining to the end of pause).
5. Press the C key to cancel the pause.

Clearing infused drug volume, total infused volume

(available only when infusion is stopped)



1. Select the parameter to be cleared with the scroll keys:

Stop ... X.X ml
XX ml/h

or

Total infused:
X X ml

2. Press the C key.

The appropriate question is displayed:

CLEAR infused volume?

or

CLEAR total infused volume?

3. Press the YES key, and the corresponding parameter value is cleared.

Locking and unlocking keypad

Keypad lock feature is enabled/disabled through the setup menu. When keypad lock feature enabled in setup menu:
1. After infusion parameters have been set and the infusion started or following the bolus infusion (or after parameter change) the following message is displayed:

Lock keypad?
Press YES/NO

To enable the keypad lock function press the YES key. Press the NO key if the keypad lock is not required.

NOTE:
The keypad is locked automatically if none of keys is pressed in response to above message within 10 sec.

2. In order to disable keypad lock (if enabled) first press the F key, when message

Keypad LOCKED!
ENTER to unlock

is displayed, press the ENTER key.
3. In order to enable keypad lock (if disabled) first press the F key, when message

Keypad UNLOCKED!
ENTER to lock

is displayed, press the ENTER key.

Viewing date and time

Date and time can be selected for temporary viewing by means of the F key and scroll keys in STOP mode and during infusion.

Turning off/on the display backlight (night mode)

Display backlight can be turned off/on using the 

key. When running from the internal battery, display backlight is turned off automatically.

5. ADVANCED FEATURES

Drug protocols **(optional in SEP-12S Plus and SP-12S Pro, unavailable in SEP-10S Plus)**

There is a possibility to configure 5 profiles with up to 10 steps each. Profile scheme can be custom configured for various applications, i.e. it is possible to set (or disable if unnecessary) induction dose and pause time after it, program each step rate in different units and duration, set post profile rate. The profile mode can be used for Propofol, Dobutamine, Remifentanil and other drugs infusion requiring special drug administration schemes, using the best hospital practice.

Parameters used to configure drug protocol

- Drug name T
- Dose mode (ml/h, mg/h, mg/min, mg/kg/h, mg/kg/min, µg/h, µg/min, µg/kg/h, µg/kg/min)
- Concentration (mg/ml, µg/ml)
- Maximum patient weight
- Induction/Loading dose/Initial bolus (mg(µg)/kg, mg, µg, ml)
- Duration
- Step count (0-10)
- Rate N (ml/h, mg/h, mg/min, mg/kg/h, mg/kg/min, µg/h, µg/min, µg/kg/h, µg/kg/min)
- Time N
- Post-profile mode

Creating drug protocol

To create drug name with protocol enter Drug Set (code 147).

Drug name T

Press the PROG key, the following message is displayed:

Replace drug name?

Press the YES key to edit selected drug name or the NO key and afterwards the YES key in response to message (to add drug name):

Add drug name?

- Enter the new drug name using keys in accordance with the table shown in chapter 6.
- Having entered required drug name press the F key to place T symbol at the end of drug name (T symbol initiates programming of protocol).
- Confirm the new drug name by pressing the ENTER key.

Dose mode
Press the PROG key. Select the required rate units using the ml↔mg key and press the ENTER key.

Concentration (available if dose mode in mass units)
Press the PROG key. Select the required units using the ml↔mg key and enter concentration value using the numerical keypad. Press the ENTER key to confirm.

MAXIMUM PATIENT WEIGHT (available if dose mode based on patient weight)
Press the PROG key. Enter maximum patient weight using the numerical keypad and press the ENTER key.

Induction/Loading dose/Initial bolus
Press the PROG key. Select the required units using the ml↔mg key and enter required value using the numerical keypad.

NOTE:

Using the F key during programming it is possible to select the naming of parameter: Induction, Loading dose or Initial Bolus.

Duration
Press the PROG key. Enter the Induction/Loading dose/Initial bolus duration (h:min.sec) using the numerical keypad. Use the

key to skip between hours, minutes and seconds.

NOTES:

1) When duration is disabled (set to 0), Induction/Loading dose/Initial bolus will be infused at the bolus rate.

2) In order to set the pause after Induction/Loading dose/Initial bolus it is necessary to leave profile first step rate 0 and set the step duration conforming to the required pause time (see below 8. Rate N, Time N).

Step count
Press the PROG key and enter the number of steps using the numerical keypad. Confirm the entered value by pressing the ENTER key.

Rate N, Time N
Select one by one and program parameters of each step, pressing the PROG key and having entered required value confirm it pressing the ENTER key.

Post profile mode
Press the PROG key, set the post profile rate and press the ENTER key to confirm (set 0 to stop the infusion after profile completion).

NOTES:
1) It is possible to exit drug protocol programming by pressing the START key and afterwards the YES key. In such case all previous settings are discarded.
2) To review the programmed protocol, select the drug name with ▌ symbol and press the F key. When the message

PROTOCOL review

is indicated, press the ENTER key and review the drug protocol using the scroll keys. Press the C key to exit review mode.

Modyfing drug protocol

Enter Drug set and select the drug name with ▌ symbol. Press the PROG key. Following message will be displayed:

Modify protocol?

Press the YES key to start modifying protocol as described above. Pressing the NO key allows to add new drug name to library.

Infusion of drug with protocol

Infusion of drug protocol can be started after confirmation of loaded syringe, selection drug name with ▌ symbol, setting patient weight (if rate units based on patient weight), programming of bolus rate and/or dose (if enabled in set up menu) and setting the occlusion level.
User is able to change rate and duration of the current step of the drug profile during infusion.
Use the scroll keys to review current parameters during infusion.
NOTES:
1. Having achieved the required therapeutic level it is possible to terminate the profile by pressing the STOP key. The following message will appear:

End Profile?
YES/NO

1.1. Press the YES key. If you press the START key afterwards infusion will be continued with the rate profile was terminated at until syringe is emptied.
1.2. Press the NO key. If you press the START key afterwards infusion will be continued from the point profile was terminated.
2. To stop the Induction/Loading dose/Initial bolus during their delivery and switch to the first step execution, press the STOP key and afterwards the START.

Drug protocol review

To review drug protocol parameters, press the F key (available only having selected and confirmed drug name). The following message will be displayed:

Protocol review

Press the ENTER key. Review the protocol profile parameters using the scroll keys.

6. SETUP MENU

In order to access optional functions or certain parameters, keep the START key in pressed position and switch the pump on by pressing the ON/OFF key. When short beep is heard, release the START key, enter appropriate code (see codes below) using the numerical keys. Confirm it by pressing the ENTER key.
List of optional functions may be reviewed using the scroll keys. If displayed name is marked with the asterisk, it means that function is active. To activate an inactive function press the ENTER key, and the asterisk will appear in front of the item name.
To deactivate a function, press the C key. The asterisk shall disappear.
To exit setup menu press the START/STOP key.

Pump mode
(code: 100)

This option is used to set the infusion mode the pump will operate in. Following infusion modes are available: Continuous rate mode, Easy pump mode.

Event history review (optional)
(code:111)

This option is used to review the event history. Use the scroll keys to review the events. In order to get more detailed information on events use the Event History utility to upload the event history to PC.

Syringe set
(code: 137)

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.

Drug set
(code: 147)

This option allows to compose drug library to be used on the pump. Drug library can comprise up to 30 drug names.

To replace drug name open the drug list and select the drug name to be replaced by the new one. Press the PROG key, the following message is displayed:

Replace drug name?

Press the YES key to edit selected drug name or the NO key and afterwards the YES key in response to message (to add drug name):

Add drug name?

Enter the new drug name using keys in accordance with the table below (e.g. to enter letter Z press the 9 key four times):

Key	1	2	3	4	5	6	7	8	9	0	.	YES	NO, C
Character	1	A,B, C,2	D,E, F, 3	G,H, I, 4	J, K, L, 5	M, N, O, 6	P,Q, R, S, 7	T, U, V, 8	W, X, Y, Z, 9	0, /, -, #, %	.	Space	Backspace

Confirm the new drug name by pressing the ENTER key.

NOTES:
1. Entered character can be reset by means of the C or NO keys.
2. Old drug name can be restored by means of the PROG key until new name is confirmed.

Default drug set
(code: 157)

This option restores default (manufacturer‘s) drug set.

Language set
(code: 337)

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

Date and Time setting
(code: 637)

This option allows to set of date and time.

Parameter set
(code: 237)

Function name	Enables/disables	Factory default	SEP-10S Plus	SEP-12S Plus	SP-12S Pro	Notes
VTBI	programming of volume to be infused	*	√	√	√	
VOLUME OVER TIME	programming of VTBI over time	-	√	√	√	
INFUSION RATE LIMIT: XXXX ml/h	programming of infusion rate upper limit	1500 ml/h	√	√	√	**1,5**
MANUAL BOLUS	manual bolus infusion	*	√	√	√	**2**
AUTOMATIC BOLUS	delivery of preprogrammed bolus volume	*	√	√	√	**2**
BOLUS RATE PROGRAMMING	programming of bolus rate	-	√	√	√	

BOLUS RATE LIMIT:XXXX ml/h	programming of bolus rate upper limit	1500 ml/h	√	√	√	**1**
40, 80, 120 kPa 30, 60, 90 kPa	programming occlusion pressure level for 50/60 and 100 ml syringes – " –	40, 80, 120 kPa	**X**	**X**	√	
RATE: mg (µg)/h	programming of infusion rate in mass units	*	**X**	√	√	
RATE: mg (µg)/kg/h (min)	programming of infusion rate in mg/kg/h;µg/kg/h; mg/kg/min; µg/kg/min	*	**X**	√	√	
CALCULATION OF CONCENTRATION	calculation of concentration from entered drug mass and diluent volume	-	**X**	√	√	
TOTAL VOLUME DISPLAY	displaying of total infused volume	*	√	√	√	
AUTOSAVE	saving of settings and total infused volume after switching the pump off	*	√	√	√	
DRUG NAME DISPLAY	display of drug name	*	√	√	√	
TITRATION	programming of infusion rate without stopping the infusion	*	√	√	√	
STANDBY	programming of standby time	-	√	√	√	
KEYPAD LOCK	protection of the keypad against accidental or unauthorized usage	-	√	√	√	
QUIET MODE	short beep accompanying any keystroke	-	√	√	√	
NO MAINS ALARM AT POWER UP	alarm on condition the pump is powered up while not connected to the mains	*	√	√	√	
KOR FUNCTION	executing of KOR function	*	√	√	√	
KOR RATE: XX ml/h	programming of KOR rate	-	√	√	√	**1, 3, 4**
DATE and TIME DISPLAY	displaying of date and time	*	√	√	√	

* – enabled

- – disabled

√ – available
X – unavailable

NOTES:

1. To modify the value of parameter, press the PROG key, enter the new value using the numerical keypad and confirm it by pressing the ENTER key.
2. These parameters are not displayed when both Manual and Automatic boluses disabled.
3. Parameter is not indicated when KOR FUNCTION disabled.
4. If parameter disabled, default KOR rate is 5.0 ml/h.
5. Does not affect infusion rates set in drug protocols.

7. VISUAL AND AUDIBLE ALARM SIGNALS

Alarm signals are issued by means of sound, flashing display backlight and corresponding message displayed. Alarm signals are cancelled by pressing the C key. Sound volume can be adjusted with rotary switch (optional) on the bottom of the pump.

Table 1 Troubleshooting Pump Alarm Messages

MESSAGE	CAUSE	CORRECTION	CHECKING
NO MAINS Check power cord	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 key to silence the alarm 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* (and BATTERY LED flashing)	Battery charge low.	Connect the pump to AC power supply and charge the internal battery.	Run the pump on battery until alarm signal is generated.
VERY LOW BATTERY	The internal battery is depleted	Connect the pump to AC power supply.	Run the pump on battery until it is depleted completely.
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.
OCCLUSION or END	The pump ceased its operation due to blockage in the extension set, syringe or drive or if the syringe plunger has reached the end of its travel. It may happen when syringe was not fully filled.	If the cause of stopping is an occlusion, remove the cause of blockage and resume infusion by pressing the START / STOP key. When the cause of stopping is the syringe plunger reaching the end of its travel, the syringe shall be replaced.	Use BD Plastipak 50 ml syringe. Pull out syringe plunger to the value of 1 ml. Launch the infusion and wait until alarm is generated.
SYRINGE EMPTY!*	The syringe is empty.	Replace the syringe or turn the pump off.	Use BD Plastipak 50 ml syringe. Pull out syringe plunger to the value of 20 ml. Launch the infusion and wait until syringe is emptied.
Stop X.X ml KOR XX ml/h**	Infusion has been stopped and not resumed within 2 min.	Resume the infusion or press the CANCEL key to silence the alarm.	In the setup menu switch on the KOR FUNCTION. Launch the infusion and after few seconds stop it. Wait until alarm is generated.
END OF INFUSION! KOR XX ml/h**	The pump has reached the end of infusion.	Replace the syringe or turn the pump off.	In the setup menu switch on the KOR FUNCTION. Set the Volume limit. Launch the infusion and wait until preset volume limit is infused.

Table 1 Troubleshooting Pump Alarm Messages-continued

MESSAGE	CAUSE	CORRECTION	CHECKING
SYRINGE EMPTY! KOR XX ml/h**	The syringe is empty.	Replace the syringe or turn the pump off.	In the setup menu switch on the KOR FUNCTION. Launch the infusion and wait until syringe is emptied.
ATTENTION! 2 min INACTIVE!	The pump is left for 2 min without starting the operation.	Press the CANCEL key.	Switch on the pump and wait for 2 min.
STANDBY TIME ELAPSED	The preprogrammed standby time interval elapsed.	Press the CANCEL key.	In the setup 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.
X min. PREALARM!	The pump is nearing the end of infusion.	Press the CANCEL key.	Use BD Plastipak 50 ml syringe. Pull out syringe plunger to the value of 20 ml. Launch the infusion and wait until alarm is generated.
ILLEGAL SYRINGE! Change SYRINGE!	Loaded syringe having a diameter not complying with any syringe from the pump syringe library.	Load the proper syringe.	Load BD Plastipak 50 ml syringe. Slowly lift up the syringe barrel clamp until message is indicated on the display.
CLAMP OPENED!	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.
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.
ERROR: XX (XX-error code)	The pump has detected an internal malfunction.	Remove the pump from service and have the pump checked by qualified personnel.	----------

** - Audible signal accompanying these messages is an intermittent one.*
*** - The purpose of the function KOR (Keep Open Rate) is to continue infusion of very small amount of drug after the end of infusion.*

8. 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.

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 mains power outlet. Check that the MAINS LED is illuminated during this time.
Perform as required but recommended every 24 months.	
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, the more often a battery is discharged and recharged, the sooner it will need to be replaced. Notify a authorised service person for replacement. **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

(20-95%, 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 in chapter 9), 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 authorised service representative.

The pump as well as its replaceable spare parts shall be disposed of taking local legislation into consideration. Do not send back to the manufacturer. None of the pump's components does not pose hazard to environment and can be safely disposed of in accordance with hospital protocols.

Table 1 Pump part to be periodically replaced

Part Number	*Part Name*	*Periodicity of Replacement**	*Criterion for Replacement*
B6640001	Battery	3–4 years	Cordless work time has diminished more than twice (check at 25 ^{o}C)
B8123009	Cap	3–4 years	Damages (cracks, etc.)

** - periodicity of replacement depends mainly on the frequency of use for each part*

9. TECHNICAL SPECIFICATIONS

Component	Description	
	SEP-10S Plus	**SEP-12S Plus, SP-12S Pro**
Syringe sizes	10-100 ml of main brands; 5 ml – optional.	
Infusion rates	0.1 to 99.9 ml/h in 0.1 ml/h steps; 100 to 1500 ml/h in 1 ml/h steps. **Note:** **Maximal infusion and Bolus rates:** **– 200 ml/h for syringe 5 ml;** **– 450 ml/h for syringe 10 ml;** **– 750 ml/h for syringe 20 ml;** **– 950 ml/h for syringe 30 ml;** **– 1500 ml/h for syringes 50/60 ml and 100 ml.**	
Volumetric accuracy	+/- 2% or +/- 0.1 ml/h (the greater of these values) – with approved syringes	
Mechanical accuracy	+/- 1%	
Volume To Be Infused (VTBI)	0.1 to 99.9 ml 0.1 ml steps; 100 to 999 ml in 1 ml steps; unlimited volume.	
Bolus rates	0; 10 to 1500 ml/h in 1 ml/h steps;	
KOR (Keep Open Rate) rate	0.1 - 10.0 ml/h in 0.1 ml/h steps (or set rate if lower than KOR).	
KOR volume	1.0 % of syringe volume.	
Standby time	1 to 999 min in 1min steps.	
Volume infused	0.1 to 99999 ml	
Occlusion alarm pressure	high – 120 kPa ± 25 kPa; medium – 80 kPa ± 20 kPa ; low – 40 kPa ± 15 kPa; or (only for SP-12S Pro) high – 90 kPa ± 20 kPa medium – 60 kPa ± 15 kPa low – 30 kPa ± 15 kPa Medium and low levels for 50/60 ml and 100 ml syringes only.	
Concentration	———————	0.01 to 9.99 (µg)mg/ml in 0.01 (µg)mg/ml steps; 10.0 to 99.9 (µg)mg/ml in 0.1 (µg)mg/ml steps; 100 to 999 (µg)mg/ml in 1 (µg)mg/ml steps.

Infusion rate in mass units	_____	0.01 to 9.99 (µg)mg/h, (µg)mg/kg/h(min) in 0.01 (µg)mg/h, (µg)mg/kg/h(min) steps; 10.0 to 99.9 (µg)mg/h, (µg)mg/kg/h(min) in 0.1 (µg)mg/h, (µg)mg/kg/h(min) steps; 100 to 999 (µg)mg/h, (µg)mg/kg/h(min) in 1 (µg)mg/h, (µg)mg/kg/h(min) steps;
Bolus doses	0.1 to 99.9 ml in 0.1 ml steps;	0.1 to 99.9 ml in 0.1 ml steps; 0.01 to 9.99 µg,mg,(µg)mg/kg in 0.01 µg,mg,(µg)mg/kg steps; 10.0 to 99.9 µg,mg,(µg)mg/kg in 0.1 µg,mg,(µg)mg/kg steps; 100 to 999 µg,mg,(µg)mg/kg in 1 µg,mg,(µg)mg/kg steps; no automatic bolus.
Patient weight	_____	0.4 to 99.9 kg in 0.1 kg steps; 100 to 200 kg in 1 kg steps.
Mounting	- table top operation - universal pole clamp - Draeger bar (optional) - Mains splitter (optional)	
AC power supply	220-230 VAC ±10%, 50/60 Hz, or 115 VAC (optional) ±10%, 50/60 Hz	
External DC power supply	12 VDC	
Battery: Battery type Battery operation Battery charging time	 NiMH, 9.6 V / 1300 mAh 8 h @ 5 ml/h Up to 24 hours to 100% charge	
Power consumption	10 VA (max).	
Fuses	T80 mA/L250 V (for 220-230 VAC); T160 mA/L250 V (for 115 VAC).	
Protection against current leakage	Type CF equipment	
Protection against electrical shocks	Class II	
Protection against splashing liquid	IPX4 (splashing water protected)	
CE 0408	Council Directive 93/42/EEC (14 June 1993) concerning medical devices	
Electrical safety and EMC	IEC 60601-(1, 1-2, 2-24)	
Maximum volume under single fault condition	<0.5 ml	

Operating temperature range	+5°C – +40°C
Transport and storage temperature	-20°C – +40°C
Operating atmospheric pressure	60 kPa – 106 kPa
Permissible relative humidity	20 - 90%, no condensation
Memory retention	For more than 10 years when not powered up.
Event log	up to 2000 events
Infusion modes	Continuous, Profile (optional in SEP-12S Plus, SP-12S Pro)
Use in ambulances	Optional in SEP-10S Plus and SP-12S Pro
Interfaces	RS 232 (optional in SEP-10S Plus) Nursecall (optional)
Dimensions (WxHxD)	305 x 135 x 195 mm
Weight	2.6 kg
Transport	In the original packaging

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 any one hour period over 72 hours at 5 ml/h.

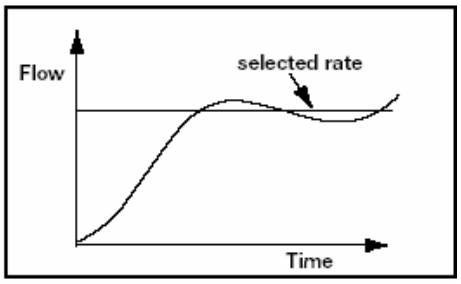
Note that flow fluctuations can be caused by unusual conditions or combinations of conditions that may involve, but are not limited to, the following: fluid density, positive and negative pressure and the environment. Flow fluctuations are most likely to occur when the conditions mentioned above are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

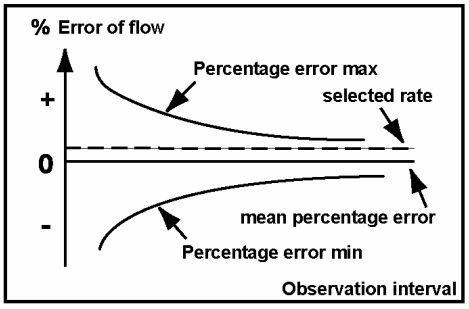
The Startup Graph was developed in accordance with IEC 60601-2-24.
The Startup data shown in the graph illustrates the startup performance of the pump during the first 120 minutes of operation with a sampling period of 30 seconds.



Startup Graph Example

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



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.

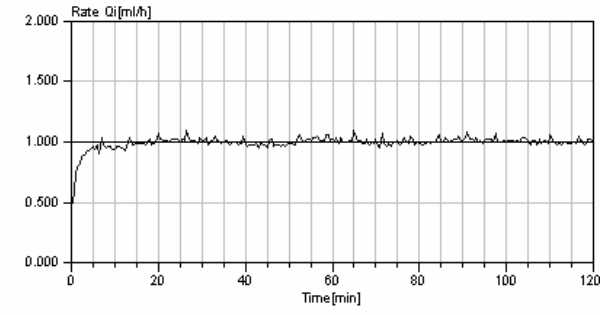
Similarly, if you were to look at the 60-minute interval point on the Observation Interval axis, you would be looking at the average flow variance for any 60-minute period throughout the infusion.

How Trumpet Curves Can Be Used

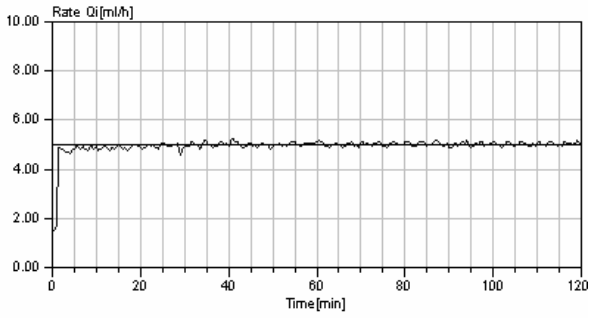
Trumpet curves can be important sources of information for the medical professional who must decide whether a certain infusion pump can be used with a particular drug. For example, when delivering a drug with a short half-life, very small deviations in flow over the course of an infusion would be desirable 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

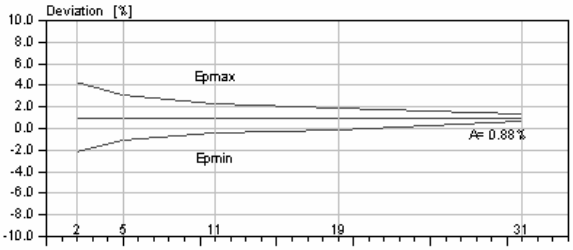
Startup graph. BD Plastipak 50 ml @ 1 ml/h



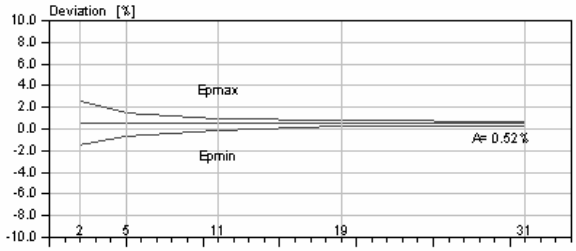
Startup graph. BD Plastipak 50 ml @ 5 ml/h



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

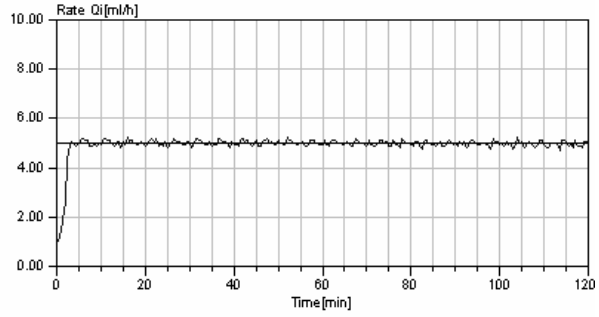


Trumpet graph. BD Plastipak 50 ml @ 5 ml/h

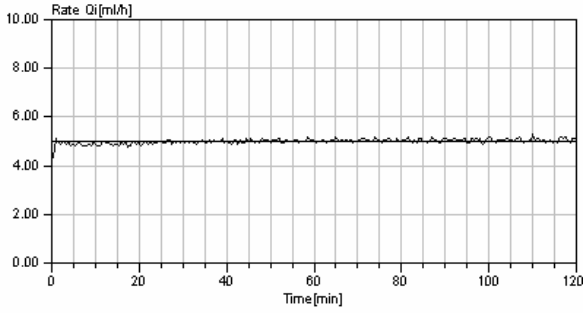


Influences of Back Pressure at 5 ml/h

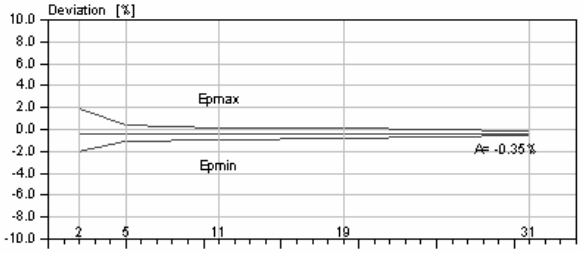
Startup graph. BD Plastipak 50 ml (+100 mmHg)



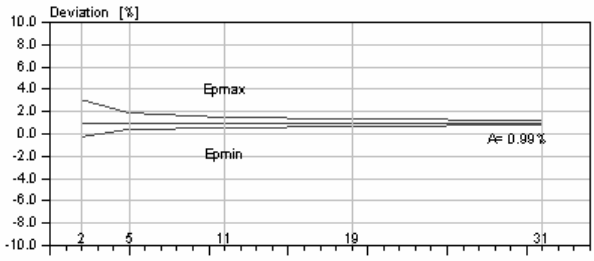
Startup graph. BD Plastipak 50 ml (-100 mmHg)



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



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



Maximum Infusion Pressure Generated

The maximum infusion pressure prior to alarm activation is 145 kPa.

Alarm Delay at Occlusion

Rate	Occlusion alarm pressure level	Time to Alarm activation (max)	
		low – 40 kPa ± 15 kPa; high – 120 kPa ± 25 kPa.	low – 30 kPa ± 15 kPa; high – 90 kPa ± 20 kPa.
1 ml/h	Low High	1 h 20 min 2 h	1 h 1 h 40 min
5 ml/h	Low High	15 min 25 min	10 min 20 min

Bolus Volume at Occlusion

Rate	Occlusion alarm pressure level	Bolus volume (max)
5 ml/h	Low High	0.3 ml 0.5 ml

Automatic Bolus volume accuracy

The information in the following table represents laboratory testing conducted per Sub-Clause 50.106 of IEC 60601-2-24 Part 2.

Set value	Deviation		
	Mean	Maximum positive	Maximum negative
0.1 ml	- 0.6 %	+ 2.0 %	- 4.0 %
1 ml	+ 0.5 %	+ 1.2 %	- 0.2 %
20 ml	+ 0.3 %	+ 1.4 %	- 0.3 %

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 60601-1-2:2001. The tables can be used to identify what EMC (electromagnetic compatibility) standards SEP-10S Plus, SEP-12S Plus, SP-12S Pro syringe pumps (hereinafter – Syringe pump) were 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 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 all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 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	+/- 6 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 for power supply lines +/- 1kV for input/output lines	+/- 2 kV for power supply lines +/- 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1kV differential mode +/- 2 kV common mode	+/- 1kV differential mode +/- 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Table 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	<5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30%dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30%dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 sec (2)	Mains power quality should be that of a typical commercial or hospital 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	3 A/m	3 A/m 400 A/m (1)	Power frequency magnetic characteristic of a typical location in a typical commercial or hospital environment. The pump functions normally when exposed to power frequency magnetic fields of 400 A/m.

Note 1: Syringe pump was designed to meet the requirements of EN 60601-1-2: 2001 and IEC 60601-2-24: 1998

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

Table 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]	3 Vrms	***d=1.17√P***
	10 Vrms 150 kHz to 80 MHz in ISM bands[b]	10 Vrms	***d=1.2√P***
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	***d=1.2√P 80 MHz to 800 MHz*** ***d=2.3√P 800 MHz to 2.5 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] 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 2.5 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 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 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 2.5 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 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 2.5 GHz** $d=2.3\sqrt{P}$

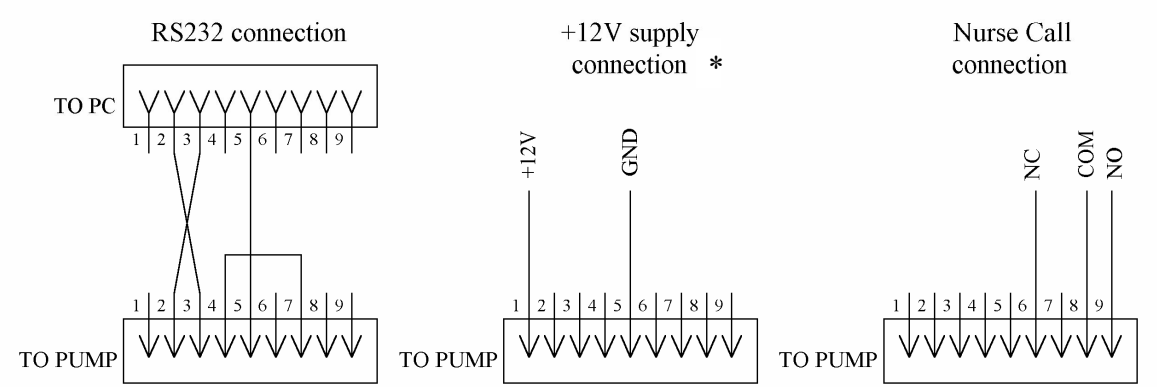
NOTE 1 At 80 MHz and 800 MHz, the separation distance of the higher frequency range applies.

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 2.5 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. DRAWING OF CABLES FOR MULTIFUNCTIONAL CONNECTOR (MFC)



Connection Data:
Ground (GND)
Normally Closed (NC)
Common (COM)
Normally Open (NO)

NOTE:
Use standard D Type - 9 Pin connectors.

* – the internal batteries are not fully charged when operating from 12VDC. When operating pump from 12 VDC permanently recharge the internal batteries (connect pump to the MAINS) after 1 week of operation.

12. WARRANTY AND SERVICE INFORMATION

Warranty

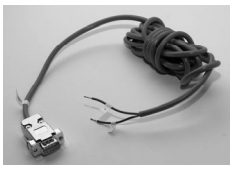
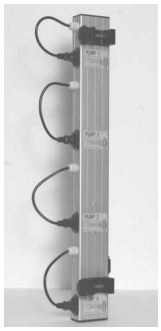
◆ The Manufacturer warrants that pump is free from defects in material and workmanship under normal use and service for a period of 12 months after the purchase date.
◆ The Manufacturer or its authorised representative takes obligation to carry out the warranty repair of the pump or to replace the pump 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 and back at customer expense.
◆ If no defect is found during testing, the Manufacturer or its authorised representative reserves the right to submit the invoice to the customer for the work carried out.
◆ This Warranty is not applicable to pumps with damaged seal or when failure was caused by violations of requirements of this Operation Manual, by mains voltage non-conformity to the requirements of IEC, 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.

Service Information

For service and repair contact manufacturer:
Viltechmeda, 125 Kalvariju Str., 08221 Vilnius, Lithuania.
Tel.: (+370 5) 2776 745, 2737 508, 2737 506
Fax: (+370 5) 2763 867
E-mail: service@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.

13. ACCESSORIES

	Description	Part Number
	Headboard/footboard mounting clamp	B6302003
	Clamp for mounting in ambulance cars, required by EN 1789:1999+A1:2003	B6090003
	RS 232 cable	B6650007
	12VDC cable	B6650008
	Mains splitter MS-04	B2087019
	IV stand	I-235
	Clamp for Draeger bar mounting	B6302019-01
	Nurse Call cable	B6650009

Model:
Serial No:
Delivery date:
Quality inspector: