• Certified Management System
• EN ISO 9001
• EN ISO 13485

SYRINGE INFUSION PUMPS
SEP 11S and SEP 21S

OPERATING MANUAL

Model:
Serial no:

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1. Use and operating principle

1.1 Use of the pump

The SEP-11S and SEP-21S syringe infusion pumps, are designed for precise dosing of infusion liquids and drugs. They are designed for use in

. intensive care units
. operation rooms
. pediatric wards
. ambulances

The pumps are easy to operate, fully reliable and have a wide range of uses. They are adapted to work with tens of different types of disposable syringes. If our client wishes, they can be adapted to work with practically every type of syringe of 10 to 60 ml volume.

The BOLUS function enables multiple, quick injections of initial shock doses, of precise volume, at any time of infusion.

The pumps can operate without being connected to the power mains. The built in batteries, switch on automatically in case of power failure, they also allow transportation of the patient whilst infusing.

The simply designed casing, without any protruding knobs or buttons on the front panel, ease maintenance and disinfecting.

This manual concerns two types of pumps - the single-syringe type SEP-11S and the double-syringe type SEP-21S. The specifications and the methods of programming of both types are identical.

1.2 Pump operating principle

The operating principle rests on the syringe piston pressing forward at a given speed, equivalent to an infusion rate. The piston is operated by means of a linear motor, whose revolution speed is steered by a microprocessor. The motor drives the lead-screw, which in its turn puts the pressure arm into motion.

The microprocessor calculates the motor speed with great precision, in accordance with the set infusion parameters. This is one of the main functions of the microprocessor but not the only one. The microprocessor also steers the infusion time and volume count, the display of messages and warnings, checks if their is no occlusion and the backup battery level.

2. SAFETY INFORMATION

2.1 Infusions using syringe pumps must only be carried out under the supervision of clinical or nursing staff.

2.2 The SEP pumps should only be used with syringes and accessories listed in section 16 of this handbook.

CAUTION: Use of unauthorized syringes or accessories may endanger the patient.

2.3 All components connected to the infusion equipment i.e. additional infusion apparatus, extension sets, catheter, filters, 3-way valves, line connectors, etc., must comply with the technical requirements for pressure infusion equipment.

2.4 The use of appropriate cannulae and kink-free layout of lines is of particular importance.

2.5 Syringes should be changed when empty and the lines should be changed at least every 24 hours.

2.6 The infusion must be carried out using an identical syringe to the one set during programming. The use of another type even identically looking and of the same volume does not guarantee obtaining the required infusion parameters with the accuracy stated in the specifications.

2.7 It is recommended to use syringes topped with a Luer-Lock connection. This connection guarantees that the drain will net slip off, e.g. due to a rise in pressure during occlusion

2.8 Before each use, the audible and visual alarms, as well as the remote nurse call facility (if fitted), should be checked for correct operation

2.9 Use of inappropriate disposables and accessories may affect the functional safety of this pump.

2.10 Further relevant safety details are given in the section 14 and 15.

2.11 The SEP pumps were designed and manufactured to be used only for IV infusions.

2.12 **CAUTION**: The connection of several infusion types (gravity, syringe pumps, peristaltic pumps) together into the same tube can be very dangerous. This type of connection should only be used if expressively specified in the operation manual of each device and approved by a notified body.

2.13 **CAUTION**: The pump does not have an integrated drain air-bubble detection system. The user must make sure that there are no air-bubbles in the drain and the syringe. To fill the drain it is recommended to use the pressure arm activating button **[<]**

2.14 During operation the pump should be placed either below or at the level of the patient.

2.15 It should be remembered that the pump detects occlusion only when the too big pressure in the drain and the syringe stops the movement of the pressure arm. Of course the pressure rises gradually, so the occlusion will be signaled with a small delay, dependent on the infusion rate, as well as the elasticity and length of the drain tube (which in such a case behaves like a blown up balloon). In order to shorten the occlusion detection time and lower the volume of liquid that is gathered in the drain, it is advised to use drains made for such situations, which have a small inner diameter (about 1mm) and thick walls (especially for low infusion rates).

In situations where the occlusion pressure is a crucial parameter, it is recommended to use large syringes, of 50/60ml volume. Syringes of 10-20ml volume should only be used for very small infusion rates (1-2ml/h).

2.16 The connection of the pump to the mains outlet is signaled by the lighting of the MAINS green indicator. This also activates the loading of the battery. The pump can be left connected to the mains for an indefinite lime.

2.17 The pump should be operated on batteries only in special situations (e.g. no mains power or while transporting the patient)

2.18 The infusion pump starts the administration with a small delay. This is mainly due to the loose fitting of the syringe in relation to the pump mountings (slacks). The smaller the infusion rate, the longer the delay. The SEP pumps enable total elimination of this delay . Proceed as follows, when "READY to run ? ? " message appears :

Set the pressure arm into motion (in the forward direction) using the **[<]** button, until the syringe piston begins to move. This move should be carried out prior to connecting the patient to the pump

2.19 The pump has to be operated in environments satisfying temperature and humidity limits specified in chapter 15

2.20 According to legal regulations and safety requirements, technical safety checks have to be performed once a year (see chap. 13)

2.21 The pump has to be connected to mains supplies in accordance to DIN VDE 0107 (see also chap. 15)

2.22 **CAUTION** :Do not operate pump in an explosive gas environment.

3. MECHANICAL LAYOUT

3.1 View of SEP 11S pump

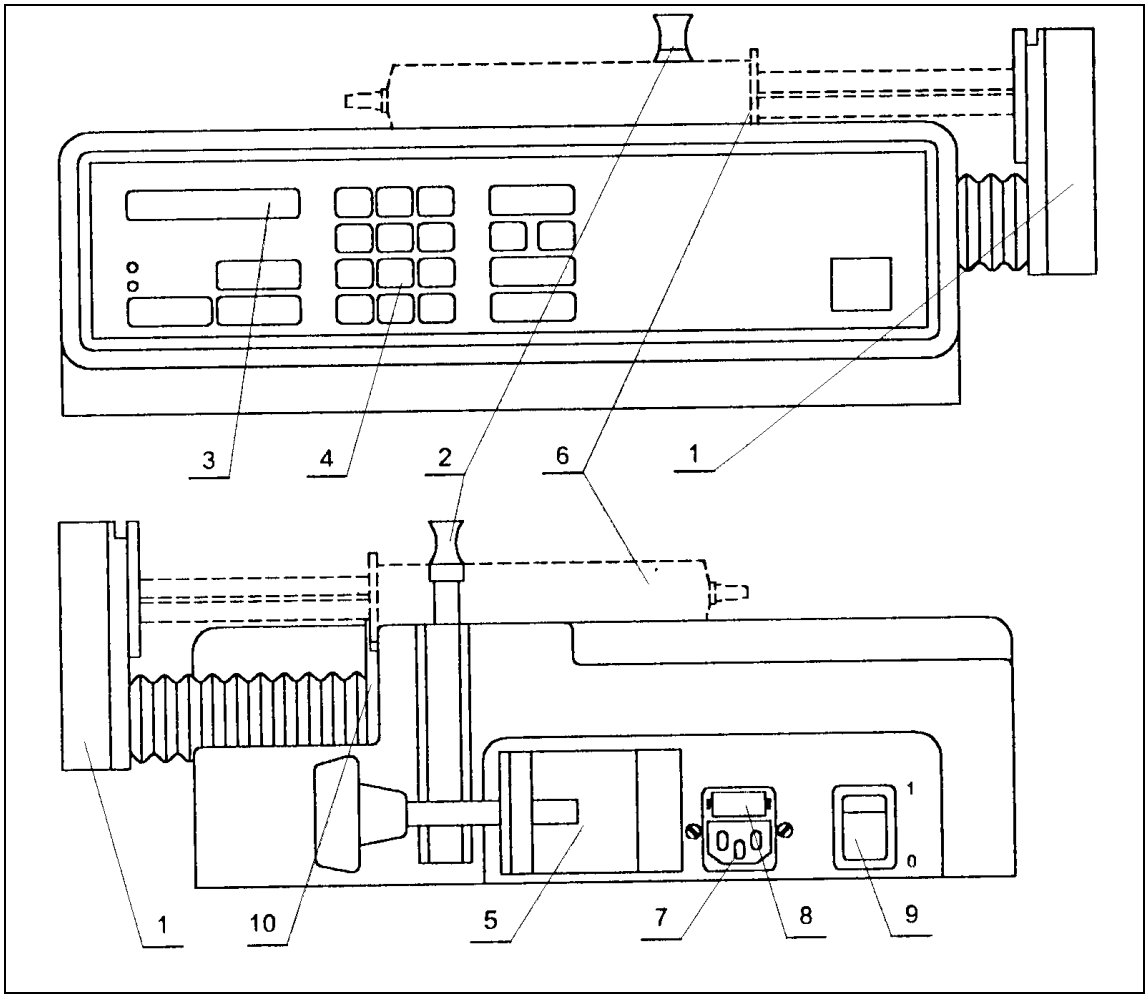


Fig.1 View of SEP 11S pump: a) front side, b) back side

1. heel
2. syringe holder
3. display
4. keyboard
5. clamp assembly
6. syringe
7. mains input
8. fuses
9. power switch
10. blocking plate

3.2 View of SEP 21S pump

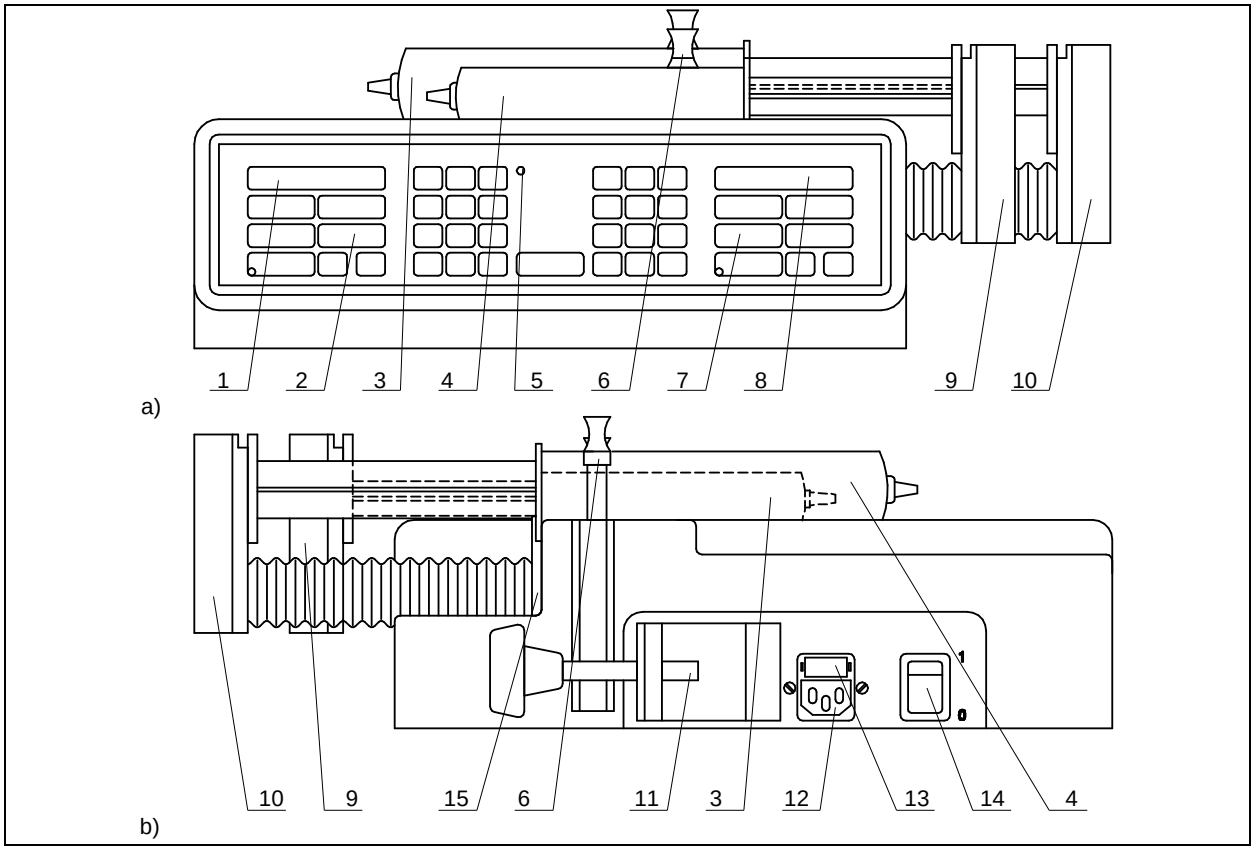
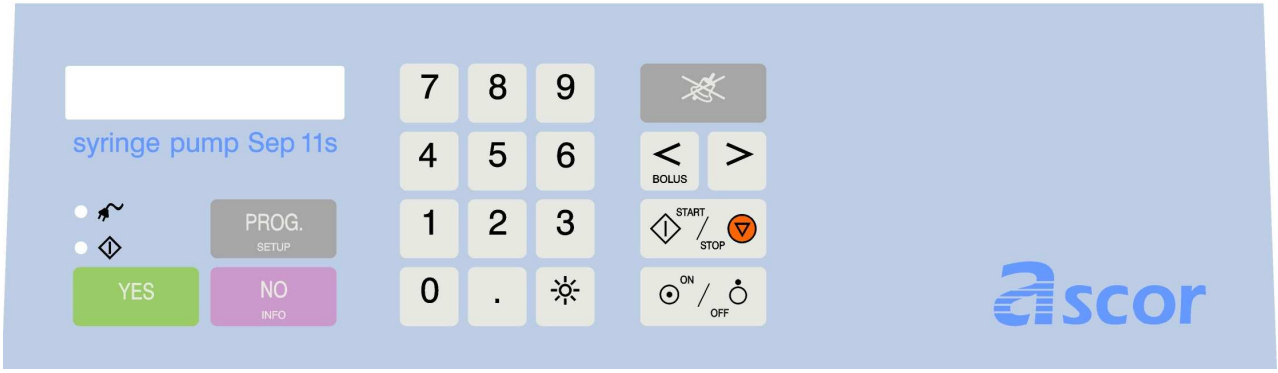


Fig.2 View of SEP 21S pump: a) front side, b) back side

1. display A
2. keyboard A
3. syringe B
4. syringe A
5. RUN diode
6. syringe holder
7. keyboard B
8. display B
9. heel A
10. heel B
11. clamp assembly
12. mains input
13. fuses
14. power switch
15. blocking plate

3.3 Keyboard of SEP 11S



SEP 11S

Green indicator, showing that the pump has been connected to the 230V mains and the built in batteries are being loaded

[RUN] yellow indicator, flashing during infusion

[YES] button for accepting displayed values or messages
This button should be pressed after each introduction or modification of infusion parameters.

[NO] button for deleting or confirming rejection of the displayed message. It also enables scrolling through infusion data: volume infused, time left, infusion pressure

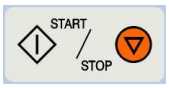
[PROGRAMME] button commencing programming (setting) the pump parameters, it also enables to scroll through pre-set infusion parameters

Button which changes the brilliance of the display.

[SILENCE] - alarm muting button

Number buttons for setting infusion parameters

[<] and [>] buttons that enable quick movement to the right or left of the syringe piston; the left movement button can also be used to start the BOLUS function.



[START/STOP] button used to start or stop the infusion.

[ON/OFF] button for switching the pump on or off.

3.4 Keyboard of SEP 21S

SEP 21S

Green indicator, showing that the pump has been connected to the 230V mains and the built in batteries are being loaded

[RUN] yellow indicator, flashing during infusion

[YES] button for accepting displayed values or messages
This button should be pressed after each introduction or modification of infusion parameters.

[NO] button for deleting or confirming unacceptance of the displayed message. It also enables scrolling through infusion data: volume infused, time left, infusion pressure

[PROGRAMME] button commencing programming (setting) the pump parameters, it also enables to scroll through pre-set infusion parameters

Button which changes the brilliance of the display.

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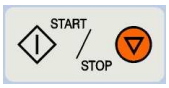

[START/STOP] button used to start or stop the infusion. A yellow or orange indicator lights up during infusion.

[ON/OFF] button for switching the pump on or off.

4. UNPACKING / INSTALLATION

4.1 OPERATING CONDITIONS

The SEP is not designed for use in an explosive atmosphere and can be used only in medical rooms in accordance to VDE 0107.8.81. Protection degree I, type BF.

4.2 UNPACKING

The SEP should be checked for damage on unpacking. If damage is evident, the SEP should not be used and should be returned to ASCOR S.A. or authorized distributor.

4.3 FIXING

The SEP can be desktop operated or IV stand mounted using the clamp assembly (5).

4.4 NURSE CALL CONNECTION - ONLY IN OPTION !!!

The SEP can be connected to the local ward alarm system using an optional lead from the nurse call output socket(optional) on the rear of the pump.

CAUTION: Always check the correct operation of the remote alarm system (if installed) before each use of the pump.

4.5 MAINS CABLE

CAUTION: Make sure that the line voltage shown on serial number label (underneath the pump) is the same as your mains supply voltage. If indicated voltage does not correspond, do not connect or use the pump, it may be damaged, contact Medico-Technique or your local dealer.

Connect the pump to the mains supply using the supplied power cord. Plug one end of the power cord into socket (7) on the rear of the pump and the other end into a mains electrical supply socket.

5. ELEMENT DESCRIPTION

The Sep syringe pumps have been carefully developed without sacrificing the high quality of the materials and electronic components used. The clear alphanumeric display simplifies the programming and the operation of the pump.

5.1 Chassis and housing

The syringe pump has a steel chassis which carries the IV pole clamping assembly, the transport handle, the mains connector socket, the power supply unit and the battery bloc. The plastic top housing surrounds the entire pump, offering a full protection against liquid penetrations.

5.2 Infusion stand clamping device

The infusion stand clamp (5), found on the back of the steel chassis can be adjusted from 0mm to 39mm.

5.3 The linear motion unit

This unit consists of a lead screw driven by a robust stepper motor. The syringe piston can this way be pushed at a constant speed controlled by the microprocessor. The stepper motors, as such, have electronic switching and therefore are without carbon brushes hence are maintenance free.

The lead screw is made from steel, this guarantees long, maintenance free performance.

5.4 ELECTRONICS

5.41 Power supply

The power supply is found at the rear of the pump. This circuit carries the transformer, the rectifiers and capacitors. The mains filter is integrated in the mains input connector.

The fuses are placed in a drawer right above the mains input connector. In order to change the fuses, the power cord should be disconnected, the drawer pulled out using a screwdriver and the fuses changed. If the fuses burn again then the service station should be contacted.

5.42 Front panel, display

The front panel consist of:

- Keyboard panel, with the advantage of conventional stroke (moving) keys on one plate.
- Several control keys are found on the right and left side of the operating panel
- The orange light emitting diode ( in SEP 11S and  in SEP 21S) indicates pump running.
- The LCD 16 characters alphanumeric display, displays all information clearly, in whatever language is chosen. The display has several advantages:

  - 5 x 7 dot matrix characters
  - Back lighted black characters on a yellow background
  - Can be read easily from a good 2 meters away
  - Negligible power consumption

5.43 Microprocessor

The CPU controls all functions of the pump i.e. display, keyboard, motor, alarm functions, etc. It also has a program especially built in which will run self tests every time the pump is switched on. This program will check every element and function for a sign of failure. Should any failure occur then a message will immediately come up on the display. There is also a plausibility test which prevents any false data entry.
The microprocessor is continuously controlled by a watch-dog circuit.

5.5 NiCad Battery

The NiCad battery pack is fixed on the steel chassis.

The battery has a capacity of 9.6 V 600mAH which allows operation of up to 10 hours. The battery module will be recharged by the pump electronic as soon the pump is connected to the mains. The pump can be, without worry, left permanently connected to the mains for an optimal battery charge.

The time needed to fully charge the batteries from total discharge (signaled by the "BATTERY !I!" message is approximately 36 hrs.

During operation, the battery capacity is measured through a special unit. When battery is low, an audible alarm will be generated, and a message displayed. During loading, the pump can operate normally.

CAUTION: The battery must be safety checked every 6 months. To accomplish this see section 13

6. SETTING-UP INFUSION

6.1 MAINS CONNECTION

Connect the pump to the line voltage by means of the mains cable (see section 4.5). Switch the pump on with the **power switch** which is provided at the rear of the device.

Mains connection is indicated with a green LED ().

6.2 SWITCHING THE PUMP ON

To switch on the pump depress 

. Pump checks all important functions in an automatic self-test sequence. During that test, the message

AUTO-TEST Vx.y

appears in the readout and the alarm tone is audible. When all hardware functions and software procedures have been performed, correct operational state is indicated when pump displays the type of syringe to be installed.

When the line voltage is not present and the pump runs on batteries, correct operational state is indicated by the message:

NO MAINS ! ! !

Press **YES** to confirm battery operation.

Hardware failures:

When a hardware failure is detected, an alarm tone will be generated.

And the pump cannot be put into operation.

If a hardware failure occurs, immediately turn off the pump and contact your service department or return the pump to ASCOR S.A.

6.3 INSTALLING THE SYRINGE

This following message signals the moment for mounting the filled syringe onto the pump.

INSERT SYRINGE !

It should be remembered that **the syringe should be filled with abt. 2.5 – 3 ml more drug** for priming the extension line.
Install the syringe as follows : (make sure that the entire system is air free and the lines are kink free.

The **[<]** and **[>]** buttons are used to position the pressure arm. Pressing one of them for longer than 2 seconds, increases the speed at which the arm moves. Automatic movement of the arm without the need to press the **[>]** button, is activated only in the backwards direction (for security reasons). This movement can be stopped using the **[START/STOP]** or **[<]** button.

The syringe should be mounted in such a way so that its back-end rests in the heel of the pump (fig.1), whilst its wings are inserted into the graves between the casing and the blocking plate. Then the syringe should be locked in place using the holder, setting it perpendicularly to the syringe axis. One should make sure that the syringe piston moves directly along the axis of the syringe.

If the syringe has been correctly installed, the following message appears:

READY to run .. ? ?

Using the **[<]** button, activate the slow movement of the piston in order to e.g. fill the extension line, cancel slacks in the mounting and remove air bubbles from the system. The slacks in the syringe mounting could become the source of delays in the administration of the drug to the patient, especially at low infusion rates. That is why it is much advised to fill the extension line using the movement of the pressure arm by pressing **[<]** button. The infusion begins at the moment the **START/STOP** or the **YES** button is pressed

IMPORTANT REMARK !

To achieve proper accuracy for activation of „empty syringe" alarm, the pump, from time to time, carries out a self-test in order to make corrections to the arm setting. The display shows the following message:

press '>' !!!

The pump arm should then be moved completely back using „**>"** button**.**

7. PROGRAMMING

The infusion parameters are programmed in both pump types in the same fashion. In the SEP-21S pump the programming is done separately for syringe A and for syringe B.

Operator guidance and fault diagnostics are given by means of the clear text display.

Enter data: Push-button "**YES**"

To confirm a data entry, press **YES** key, then the next message appears.

Clear data: Push-button "**NO**"

Press the corresponding button and the data in the display is cleared and a new value can be introduced.

7.1. Infusion parameters

The infusion parameters can be divided into three groups:

1. Basic parameters
. the syringe type
. the flow rate (in ml/h)
. the infusion volume or time

2. Auxiliary parameters
. the BOLUS dose infusion rate
. the volume of the BOLUS dose
. the occlusion pressure level

3. Additional parameters
. the infusion rate in KVO mode
. type of audible alarm
. switching on and off of the STAND-BY function

The basic parameters require to be set or confirmed before each and every infusion The programming of the auxiliary parameters, can but does not have to be carried out before each infusion. This step can be performed either or during the infusion. Finally the additional parameters are programmed very rarely.

7.2 Setting Basic parameters

After having pressed the **ON/OFF** button the following message is displayed:

AUTO TEST Vx.y

This informs the operator that the pump has performed a series of self-checking tests if any irregularity is found, the pump blocks further operations and switches on an audible alarm if this were to persist, please contact our nearest servicing station, which will carry out a maintenance check or repair the pump.

After the self-checking has ended, the pump readies itself for operation.

Three situations might follow:

a) the following warning is displayed

NO MAINS ! ! !

No AC power, green indicator MAINS does not light
If the pump is then to be powered from the mounted backup battery, the **YES** button should be pressed. Otherwise one should reconnect the pump to the mains

b) the following question is displayed

CONTINUE ?

Continue the previous infusion ?
If the previous infusion had not been fully carried out (e.g. the pump had been turned down during operation using the ON/OFF switch). Pressing the **YES** button will mean continuation of the previous program picked up from the point the counters stopped.

Pressing **NO** will zero the counters and begin the programming.

c) the following information on the last used syringe type is displayed

50 ml Monoject

The type is described by the volume in (ml) and the brand name of the producer. If this type is accepted press the **YES** button, than the pump moves onto programming the infusion rate. Pressing **NO** for lack of acceptance, makes the following question appear :

CHANGE SYR ? ? ?

Change syringe?
Pressing **YES** whilst the message is displayed, begins the reprogramming of the new syringe type. The scrolling through the list of syringe types is done by pressing the **NO** button, until the right one appears. Final acceptance is done by pressing again the **YES** button.

The next message to appear is:

rate XX.X ml/h

According to the programmed syringe type, the maximum outflow rate is 200ml/h for a 50/60ml syringe, 100ml/h for 20-30ml and 50ml/h for 10ml. If the rate is set to high, the pump will inform about this by displaying the maximum admissible rate for that type of syringe:

max. XX.X ml/h

By pressing any button we clear the display (it will dear itself after 5 seconds), then we set the correct rate and press the **YES** button. This makes the next message appear:

volume XX.X ml

The XXX stands for the last previously set volume. This value can be zeroed using the **NO** button, which enables a new one to be set and confirmed using the **YES** button. The maximum admissible dose is 1000ml.

Setting the value at 0ml or leaving this parameter unprogrammed (pressing YES without any value set) is admissible, but will mean that not alarm will sound at the end of infusion (for description of alarms see further).

Instead of setting the infusion volume, it is possible to set the infusion time. Of course only one of those parameters can be programmed. Changing to setting time (or the other way round) is done either way by means of double-pressing the **NO** button. The display will the show the message:

time XX :XX.XX

The maximum infusion time that can be set is 99 hours:59 minutes.59 seconds.

The time XX :XX.XX can also show the last programmed value. If this value is not the currently needed one, we zero it by pressing the **NO** button. The display will show all zeroes. We set the time digits from left to right. The flashing digit shows the position which can be set with the number keys. Of course at any moment during setting we can delete the set digits by pressing the **NO** button. After setting the right time we press the **YES** button.

Just as with the volume, it is allowed to leave this parameter unprogrammed with the same effect.

If the pump is to operate in the STANDBY mode, then another two parameters will have to be dealt with that are described in 7.4

The correct programming of the pump is confirmed by the message:

INSERT SYRINGE

and the automatic retraction of the pressure arm of the pump. If a syringe has already been mounted onto the pump the following message will be displayed :

READY to run.. ? ?

This signals that the pump is fully ready to operate.
Press [<] button to fill the extension line.

By pressing again the **PROG.** button, we can check (read off) all the infusion parameters. If any one of them is set incorrectly, then we can zero it using the **NO** button and setting the correct value. After each such change, the **YES** button should be pressed in order to accept the new value.

All the basic parameters, apart from the syringe type, can be modified at any moment, including during infusion.

7.3 Setting auxiliary parameters

The changing or scrolling of auxiliary parameters can be performed right after having programmed the basic parameters or at any other moment e.g. during infusion. In order to begin programming those parameters, one should press and hold the **PROG.** button for one second (**Attention !!** - pressing this button just for a moment will instead enable the basic parameters). The following message should show up:

BOLUS XXX ml/h

in which XXX ml/h stands for the infusion rate of the BOLUS dose. Depending on the type of syringe used, the maximum value of this parameter can be l'000ml/h (for a 50/60ml syringe), 500ml/h (for 20-30ml) and 300ml/h (for 10ml). In the case of leaving this parameter unset, the pump will infuse the BOLUS does at the maximum admissible rate for the chosen (from the list) syringe volume.

ATTENTION :

- If the value set for the BOLUS infusion rate is smaller than the basic infusion (outflow) rate, then the BOLUS will be administered at twice the infusion rate (e.g., if the outflow rate is 100mllh and the BOLUS rate 50mllh, then the BOLUS dose will be administered at 200mllh)
- If the value set for the BOLUS rate is higher than is admissible for that type of syringe, then the BOLUS dose will be administered at this maximum rate

The next parameter is the volume of the BOLUS dose:

BOLUS XX ml

Range : 0 up to used syringe volume. If this value is not set, then the volume will correspond to the time of pressing the **< (BOLUS)** button (the display will show the current volume in ml). The activation of the BOLUS function is described in chapter 8.2

The next parameter is the pressure level at which the OCCLUSION alarm is sounded.

Three occlusion pressure levels can be chosen from:

- low 0.6 Kg/cm^2 (450mm Hg)
- medium 0.9 Kg/cm^2 (675 mm Hg)
- high 1.2 Kg/cm^2 (900 mm Hg)

The precision of estimating the pressure is dependent on the quality and volume of the syringes used. The lower the syringe volume (diameter), the harder it is to precisely estimate the infusion pressure. Situations in which the occlusion pressure is the critical parameter, it is advised to use 50-60ml volume syringes. Syringes of 10-20ml volume should only be used for very low infusion rates (less than 1-2ml/h). The display will show the currently set pressure level:

PRESSURE low

or

PRESSURE medium

or

PRESSURE high

The level can be changed by pressing the **NO** button until we come to the desired level. Pressing the **YES** button, will set and memorize the chosen level.

7.4 Setting additional parameters

Start the setting of these parameters by switching the pump off by using the **ON/OFF** button. Then press the **PROG.** button and whilst holding it, switch the pump on again with the **ON/OFF** button. The following message appears:

K.V.O X.X ml/h

then the **PROG.** button can be released.

In the KVO mode (which stands for Keep Vein Open), instead of stopping the infusion, the patient is administered a minimal constant dose of liquid, so as to keep the veins patent (prevent clotting). The rate of such an infusion is typically 1ml/h, but under certain circumstances should have another value. That value can be programmed between the following limits 0-5ml/h. Leaving the parameter unset, is equivalent to programming the value at 1.0ml/h, whilst setting the value 0ml/h switches off this mode.

The volume of drug administered during activation of the KVO mode, is counted as part of the whole volume administered to that patient.

Infusion in the KVO mode, activates immediately after stopping the pump using the **START/STOP** button or if the, "EMPTY SYRINGE" or, "END of infusion " messages appear.

ATTENTION:
If the rate set for the KVO mode is bigger than the basic infusion rate, then the KVO infusion will be operated at the rate of the basic infusion (e.g. if the outflow rate is 0.5ml/h and the KVO rate is 1.5ml/h, then the KVO infusion will be performed at 0.5ml/h, which means that the basic infusion will be carried on till the end of the dose)

The next parameter is the type of audible alarm. Using the **NO** button we choose the right option:

ALARM _____

(_____means continuous)

or

ALARM - - - - - - - -

(- - - - - - - means intermittent)

After having accepted the type of alarm using the **YES** button, the following message will appear :

STAND-BY on

or

STAND-BY off

which enable the STAND-BY function to be used, it enables a periodical pause in the infusion. Choosing "STAND-BY on", will mean the appearance of two additional parameters at the end of the basic group.

On-time XX :XX.XX

and

Off-time XX :XX.XX

where XX:XX.XX determine the time in "hours:minutes.seconds" respectively of the infusions and the breaks in between. The operation begins with the first infusion of the set time. After this time has elapsed an alarm sounds and a message requests the introduction of a break using the **START/STOP** button. After the button has been depressed, the countdown of the set break length begins. After the break has elapsed, the alarm sounds once again requesting to restart the infusion. This cycle is repeated until the whole dose has been administered to the patient or until the pump has been switched off.

ATTENTION: during the break the KVO mode is not active

8. INFUSION RUNNING AND DATA DISPLAY

8.1. Starting and stopping infusion

After having programmed the pump and installed the syringe we can start the infusion. This is done by pressing the **START/STOP** button, which starts and stops the pump operation. The flow of the liquid is signaled by the flashing of the yellow RUN LED and the message:

inf... XX.X ml/h

XX.X is the programmed infusion rate (outflow).

If we want to interrupt the infusion for a moment without switching-off the power, we should press the **START/STOP** button. The RUN yellow LED stops flashing and the following message appears.

STOP XX.X ml/h

The pump switches itself to KVO mode, displaying alternately the above and below messages:

K.V.O. X.X ml/h

X.X stands here for the infusion rate in KVO mode.

By pressing the **START/STOP** button a second time, the infusion can be restarted again. However if the process is stopped for more than 2 minutes then the « pump stopped alarm » will sound.

The infusion can also be stopped by means of the **ON/OFF** button. After switching back ON the pump, the infusion can be restarted (by pressing the **YES** button in answer to the "CONTINUE ?" message), since the pump has memorized all the settings including the current value of the volume counter that measures the drug already administered to the patient. This method of interruption is recommended when there is a need for pauses exceeding 2 minutes.

8.2. BOLUS mode

The SEP pumps enable the patient to receive the shock dose during the infusion. The administration will begin 3 seconds after pressing **[<]** and will be signaled by the message:

BOLUS X.X ml/h

The rate and the volume of the BOLUS will be administered according to the programmed parameters. (see 7.3). If the value of the volume has not been set, then the administration of the BOLUS continues as long as the **[<]** button is depressed, otherwise this operation will stop after the programmed volume has been fully administered, (in this case, no need to keep **[<]** pressed)

The volume of the drug administered in the shock dose, is counted as part of the volume prescribed for the infusion. If during the BOLUS mode the programmed volume of the infusion is reached, then the pump will stop the delivery of the drug, signaling this situation with the ,,END of INFUSION" message. The same is valid for a situation in which the syringe becomes empty.

8.3. Checking and displaying infusion details

During the infusion it is possible to check the volume of the drug that has already been administered, the time left for the syringe to empty and the set occlusion pressure-level

After each short press of the **NO** button, the display will change the information shown

inf.. XX.XX ml

where XX.XX stands for the already administered volume (in ml)

inf...XX :XX.XX

where XX :XX.XX stands for the time left to empty the syringe or till the end of infusion (in hours, minutes. seconds)

inf. low

signals the programmed occlusion pressure level.

Another pressing of the **NO** button, returns the display to showing the infusion rate. This data display sequence can be performed an indefinite number of times and does net disturb the administration. The same is valid if the pump's operation has been stopped, the syringe empty, end of infusion or end of occlusion alarms have sounded.

8.4. Scrolling and changing parameters

During the infusion, it is possible to change nearly all programmed parameters, without the need to stop the infusion.

8.4.1 Changing infusion rate

The simplest to do is changing the infusion rate. The new rate should be introduced by means of the number keys and accepted by pressing the **YES** button. Lack of acceptance will lead to the old value to be kept, for the security of the patient.

8.4.2 Changing BOLUS volume, BOLUS rate and OCCLUSION pressure

These parameters can be changed by pressing the **PROG** for about 2 seconds and then following the same sequence as described in chapter 7.3 This procedure does not include the change of additional parameters (KVO, STAND-BY), which require stopping the pump operation. It is also impossible to change the syringe type during operation, This can only be done if the infusion is interrupted and the syringe pulled out.

8.4.3. Zeroing the volume counter

Zeroing the volume counter during infusion will lead to irretrievable loss of information about the amount of drug administered to the patient. This can be done as follows: Press NO button as for scrolling infusion data until the volume appears on the display, then press **NO** again for 3 seconds. After the 3 seconds have elapsed, a short beep will sound and the pump will restart counting the volume from zero. The counter will also be zeroed if in answer to the ,,CONTINUE ?" message, we press the **NO** button.

9. ALARMS AND WARNINGS

All alarms are indicated by a message in the display (flashing display back-light) and an audible alarm tone. The alarm ca be muted by means of the **SILENCE** button. The following alarms can appear :

ALARM	CLEARANCE/EXPLANATION
5 min PREALARM	Five minutes before the syringe goes empty, an alarm sounds informing the personnel that the infusion process will shortly end. This signal is muted using the **SILENCE** button. It will disappear automatically after 5 seconds or by pressing any button. Of course the infusion carries on till the end
EMPTY SYRINGE	The near empty syringe (about 0.5ml still left) is signaled by this alarm with the pump changing over to KVO mode. After mounting another full syringe, the infusion can be restarted. A positive answer to the "CONTINUE ?" message (by pressing **YES**) enables the volumes of following syringes to be summed.
END of infusion	The infusion volume or time have been reached. The basic infusion will end and the pump will change over to KVO mode, signaling it with an audible alarm, flashing of the display back-light and the alternate display of the KVO messages:
OCCLUSION ! ! !	Pressure in tube or syringe is too high. The correct flow to the patient has been blocked by a kinked line, blocked cannula or some other cause. PUMP OPERATION HAS BEEN SUSPENDED. It should be remembered that the pump detects occlusion only when the too big a pressure in the drain and in the syringe stop the movement of the pressure arm. Of course the pressure rises gradually, so the occlusion will be signaled with a small delay, dependent on the infusion rate, as well as the elasticity and length of the drain tube (which in such a case behaves like a blown up balloon).. In order to shorten the occlusion detection time and lower the occlusion bolus volume that is gathered in the drain, it is advised to use drains made for such situations, which have a small inner diameter (about 1mm) and thick walls, especially for low infusion rates. The occlusion alarm can also appear if the infusion flow meets resistance due to the poor quality of the syringes used and/or the big density of the drug liquid infused at high rates. In such a case the programmed occlusion pressure-level should be raised or the syringe changed. The precision with which the pressure is established, depends in a great part on the quality and capacity of the syringes used. The smaller the capacity (diameter) of the syringe, the harder it is to precisely set the pressure during infusion. In situations where the occlusion pressure is a crucial parameter and the pump should be operated at its low values, it is recommended to use big syringes, of 50/60ml volume. Syringes of 10-20ml volume should only be used for very small infusion rates (1-2ml/h). Remove the problem and clear the "OCCLUSION" message, by pressing **NO** it is now possible, just as during the basic infusion, to scroll through all the infusion details (volume administered, time left infusion rate, occlusion pressure). Pressing **START/STOP** enables further infusion

NO SYRINGE During the administration of the drug, the syringe has been pulled out by the personnel or accidentally ripped-off by the patient After clearing it and remounting the syringe, the pump will display "CONTINUE ? ? ". Pressing the **YES** key, will mean continuation of the interrupted infusion, whilst pressing **NO** will ready the pump for a new infusion

NO MAINS The pump has switched over to the built-in battery, because AC power has been cut, a fuse has blown, the power cord has been disconnected or is damaged, the mains switch has been turned down or the pump has a malfunction that requires servicing. Pressing **YES** means acceptance of this situation

LOW BATTERY There is reserve power for some teens (for high infusion rates) to tens of minutes. The pump should then be connected as quickly as possible to an AC outlet

BATTERY ! ! ! The built-in battery powering is impossible, to continue the infusion the pump must be connected to an AC outlet. PUMP OPERATION HAS BEEN STOPPED

10. USER CHECKS

To ensure safety and correct operation of the pump, check for the following before each use:

Cleanliness

Signs of damage

Suitable disposables and accessories

Nurse call (if fitted)

Connect to mains and switch on - green MAINS LED is turned on

Satisfactory self-test with audible alarm signals

Set up as described in section 6

11. CLEANING AND DISINFECTING

Always switch the SEP off and disconnect from the mains before cleaning.

The SEP may be cleaned using water, household cleaning agents, alcohol or neutral surface cleaners.

Before use, allow at least 1 minute drying time.

CAUTION: Do not sterilize

12. MAINTENANCE / CUSTOMER SERVICE

According to legal regulations and safety requirements, maintenance and repair may only be carried out by persons authorized in writing by the supplier.

Technical safety checks according to section 13 have to be performed once a year by a trained and authorized person.

The necessary technical documentation is made available on demand by ASCOR S.A.

13. TECHNICAL SAFETY CHECKS

13.1 Visual Check Yes No

- Dirty ?
- Damaged ?
- Script legible ?
- Membrane panel OK ?
- Heel and blocking plate clean ?

13.2 Mechanical Function Yes No

- Syringe holder moves freely ? -

Clamping unit knob OK ?

13.3 Pump Function in ON state Yes No

(Set-up as handbook section 6)

- Switch pump on.
- Display shows: "AUTO-TEST Vx.Y" ?
- Move pressure arm left and right using [<] and [>]
- Set-up an infusion and press RUN/STOP.
- Operating state display "inf... XXX ml/h" ?
- Audible and visual alarms ?
- RUN/STOP button (STOP and KVO function) ?
- Display of alarms ? (see section 9)

13.4 Function Check, pump Running -

Remove mains cable. Pump runs on battery supply ?

- Connect mains again and measure flow rates with 50/60 ml syringe:
  10ml/h
  100 ml/h
  Volume has to be within 3%

- Check occlusion pressure (according to set occlusion level)
- Electrical safety
- Earth leakage resistance < 0,1 Ohm
  (as per IEC 601.1, 18)
- Earth leakage current < 0,5 mA
  (as per IEC 601.1, 19)
- Isolation 1.5 KV, 1 min
  (as per IEC 601.1, 20)

13.5 Battery test

Connect pump to mains power supply and switch ON (Power switch at the back). Load batteries for 36 Hours . Set up infusion (see section 6) at 100 ml/h with a 50/60 ml syringe, START the infusion and remove mains cable to operate on battery. The pump should run for a minimum of 2 hours (do not forget to restart the infusion immediately after syringe is empty). If during that time, no battery alarm occurs, then the built-in battery is considered to be OK. Don't forget to recharge If not, change battery module.

14. RISK AND DANGER

14.1 Emboli: To avoid this risk, make sure to purge infusion lines and syringes before use.

14.2 Pulmonary oedema: Caution: An excessive or too rapid infusion may endanger the patient or cause death.

14.3 Use: The SEP pumps were designed and manufactured to be used only as a IV infusion pump.

15. ABOUT PRODUCT AND MANUFACTURER

Syringe pumps SEP 11S and SEP 21S have been manufactured by the Company ASCOR S.A. which introduced and maintains the Quality Management systems, complying with the word and European standards, what has been approved by ISO 9001 and ISO 13485 certificates.

Above certificates have been issued by TÜV Rheinland Product Safety GmbH – Am Grauen Stein – D-51105 Köln (code 0197).

Manufacturer:

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16. TECHNICAL DATA

Basic infusion rates: (programmable by 0.1 ml/h)	0.1 – 500 mi/h for 50/60 ml syringe 0.1 – 300 ml/h for 30 ml syringe 0.1 – 250 ml/h for 20 ml syringe 0.2 – 150 ml/h for 10 ml syringe
Displayed volume	0.1 - 999 ml
BOLUS infusion rate: (programmable)	max. 1000 ml/h for 50/60 ml syringe max. 600 ml/h for 30 ml syringe max. 500 ml/h for 20 ml syringe max. 300 ml/h for 10 ml syringe
BOLUS Volume (programmable)	0 - up to syringe size
KVO Rate (programmable)	0 - 5 ml/h
Infusion rate precision:	<= 3% for volumes >= 6ml
Infusion time	1min. - 99hours 59minutes 59seconds, in 1 min.step
Occlusion pressure: low medium high	0.6 kG/cm^2 ± 0.2 (450mm Hg ±150) 0.9 kG/cm^2 ± 0.2 (675mm Hg ±150) 1.2 kG/cm^2 ± 0.2 (900mm Hg ±200)
Syringe brands (basic):	B. BRAUN 10/20/30/50/60 ml, MONOJECT 10/20/50/60 ml, BD 20/30/50/60 ml, CODAN/ONCE 10/20/30/50/60 ml, TERUMO 50 ml, IVAC 50 ml Accessories & extension lines have to be pressure resistant
Power supply: Mains fuses	AC 230V ± 10%, 50/60Hz, or from built-in NiCad battery 2 x T 0,16 A /250V
Maximum power consumption:	8 VA for SEP-11S, 10 VA for SEP-21S
Battery life:	minimum 24h for rate 5ml/h
Recharging time :	36h
Alarms	Audible and visual
Display:	LCD display with 16 characters, matrix 5 x 7 points with back light.
IV stand clamping unit	0 - 35 mm
Operating temperature	10 - 40°C
Relative humidity:	maximum 80%
Weight. SEP 11S SEP 21S	2.8 kg (including batteries) 4.6 kg (including batteries)
Protection class: Interference level: Protection type:	1 N BF (according to IEC 601.1)
Dimensions (WxHxD): SEP 11S SEP 21S	310x140x170 mm 310x140x220 mm
Earth leakage current	< 0.5 mA
Earth leakage resistance	< 0.1 Ohm
Isolation	1,5 KV, 1 min.
Technical safety check	Once a year, every 6 months for the battery
Conformity	IEC 601.1
ASCOR S.A. certificates	ISO 9001, ISO 13485

17. SHORTENED OPERATING MANUAL FOR ANESTE AND PROPOFOL MODES OF OPERATION

Single Syringe Infusion Pump SEP 11S and Double Syringe Infusion Pump SEP 21S can be operated in three modes:

- **STANDARD** (according to section 7)
- **ANESTE**
- **PROPOFOL**

17.1 Changing the mode of operation.

Press the button **PROG** and while keeping it pressed switch the pump on with **ON/OFF** button. Do not release **PROG** button until one of the following information is displayed: "MODE standard" or "MODE aneste" or "MODE propofol".

By pressing **NO** button choose the required mode of operation and accept it by pressing **YES**.
The following parameters will be displayed:
K.V.O xx ml/h – can be programmed up to 5 ml/h
ALARM ----- or **- - - -** (tone continuous or intermittent
STAND-BY on or **off** (this function is active only in Standard mode of operation)

Delete by pressing **NO** and accept by pressing **YES** the required parameters until ANESTE … or PROPOFOL … or STANDARD … is displayed (depending on the chosen mode of operation).
At this moment the setting of infusion parameters can be started.

17.2 Programming parameters in ANESTE mode

Switch on the pump with ON/OFF button.
The first information appearing on the display is the name and volume of the previously used syringe.

- If you intend to use the syringe of the same brand and size just accept by pressing **YES.**
- If you are going to use a different syringe (brand and/or size) press **NO.**

The question "**Change syr ???**" (change syringe ?) appears on the display. Press **YES** and then by pressing **NO** you can go through the menu of syringes adapted to the pump. Accept the required syringe by pressing **YES.**

The next parameter displayed will be "**rate.....** " of the last infusion.
If you are going to infuse with exactly the same rate, press **YES.**

If you are going to change the flow rate, press **NO.** By pressing again **NO** and **keeping it pressed for abt. 3 seconds** you can change also the rate's unit and choose one of the following:

ml/h, µg/h, mg/h, µg/kg/h, mg/kg/h, µg/kg/min, mg/kg/min.

Choose the unit by pressing NO repeatedly unless the required one is displayed. Accept it by pressing **YES**, introduce a new value and confirm by **YES.**
Maximum infusion rate for 50/60 ml syringe is 500 ml/h.

"conc. " Drug concentration - appears in: µg/ml or mg/ml. By pressing **NO** you can change the unit. Determine the value and confirm by **YES** both value and unit.

"weight … kg" - Determine the patient weight (up to 9,99 kg in 0,01 kg increments, up to 99,9 kg in 0,1 kg increments, above 100 kg in 1 kg increments) and confirm by **YES**.
REMARK! If the rate's unit is not a mass unit – not connected with the patient weight (ml/h, µg/h, mg/h), this parameter will not be displayed.

"init. " Induction (initial) dose - the quantity of drug to be infused at the very beginning of infusion. It is displayed in correspondent unit to that chosen for the delivery rate: ml, µg, mg, µg/kg or mg/kg. Introduce the required value of induction dose and confirm by pressing **YES.**
Please note that the max. dose of induction dose cannot exceed the syringe capacity.

"bolus " (bolus volume) - It is displayed in correspondent unit to that chosen for the delivery rate: ml, µg, mg, µg/kg or mg/kg. The way of programming is the same as for induction dose, described above. The max. bolus volume programmed cannot exceed the syringe capacity
You can programe the Bolus volume or not. If it is not programmed, the Bolus will be infused as long as the **Bolus** button is pressed.

.

INSERT SYRINGE !
The arm of a pump will be automatically adjusted (will move right) to enable inserting the syringe filled with a drug (the syringe volume **+ abt. 2,5 - 3 ml for priming the extension line**). Install the syringe correctly and press **YES**.

READY to run ?
Prime the extension line by pressing [<]. This operation will enable you removing any air bubbles from the extension line. Insert the needle into the patient's vein (or canula**)** and press **YES.**

Infusing of both induction dose and bolus is signaled with sound. You can stop delivering induction dose by pressing START**/STOP** button , without stopping the infusion.

Full information about the infusion status.
Any time during infusion you can get the following information simply by pressing NO repeatedly:

- volume (in mg/kg) already infused to the patient
- the infusion rate in ml/h (calculated by a microprocessor)
- volume (in ml) already infused to the patient
- occlusion pressure level

Scrolling through all programmed parameters:
By quick pressing **PROG**. button and then repeatedly **YES** after each data displayed, you can easily look through all the parameters programmed, i.e.:
syringe size and type, rate, conc.., weight, init., bolus

Bolus rate and dose as well as occlusion pressure can be changed in running course without the necessity to stop the infusion. Just **press PROG for abt. 3 seconds**., insert new value and confirm by pressing **YES.**
Max. Bolus dose is the syringe capacity in ml
Max. Bolus rate is 1.000 ml/h for 50 ml syringe.

Occlusion pressure limit, just like in a standard version can be preset on one of 3 levels:

Low	abt. 450 mmHg
Medium	abt. 625 mmHg
High	abt. 900 mmHg

17.3 Programming parameters in PROPOFOL mode.

The name and volume of syringe. Choose the proper syringe in the same way as in standard and ANESTE mode.

Basic parameters of **PROPOFOL** mode pre-set in a pump by manufacturers are as follows:

Conc. (Drug concentration)	-	10 mg/ml	
Rate 1	-	10 mg/kg/h	
Rate 2	-	8 mg/kg/h	
Rate 3	-	6 mg/kg/h	
Time 1	-	10 min.	- time of infusion at RATE1
Time 2	-	10 min.	- time of infusion at RATE2
Init. (Induction dose)	-	1mg/kg	

Time of infusion at RATE3 is unlimited (strictly connected with the time of surgery).
The above parameters are kept in the memory of the pump unless changed by the operator (by pressing **NO**, introducing new values and confirming by pressing **YES**).

bolus …. mg/kg
The next parameter displayed is **BOLUS** in mg/kg. You can program it or not. If not, Bolus will be administered as long as Bolus button is pressed.

weight ….kg
Determine the **patient weight** (up to 9,99 kg in 0,01 kg increments, up to 99,9 kg in 0,1 kg increments, above 100 kg in 1 kg increments) and confirm it by pressing **YES.**

INSERT SYRINGE !
Install the syringe correctly. The syringe should be filled with abt. 2,5 ml more drug (for priming the extension line).

READY to run…
Prime the extension line by pressing **[<]** button and confirm by **YES**.

➢ **I M P O R T A N T R E M A R K !**
After switching the pump off with **ON/OFF** button and restarting it again (provided the mode of operation in the meantime has not been changed), only the following parameters will be displayed:
- type and size of syringe
- concentration
- patient weight.

In order to have all the parameters of PROPOFOL mode displayed in turn (RATE1, RATE2, RATE 3, TIME1, TIME2) and if need arise, modified, you have to **introduce concentration again** (even the same value as it was displayed). This will be a signal for a pump to display all parameters one by one. When being displayed, all the parameters can be easily changed by pressing **NO**, introducing new values and confirming them by pressing **YES**.

The infusion rate in PROPOFOL mode cannot be changed in running course without stopping the infusion.

Propofol can also be successfully administered in ANESTE mode of operation.

Infusing Induction dose and Bolus is signalled with a sound. You can stop delivering induction dose by pressing RUN**/STOP** button, then infusion will be continued at the programmed flow rate.

When RATE1 changes into RATE2, and consequently RATE2 changes into RATE3, there is an alarm NEW RATE.

Any moment during infusion you can get the following information about the course of infusion by pressing repeatedly **NO** button:
- volume administered to the patient in mg/kg
- the infusion rate in ml/h (calculated by a microprocessor)
- volume administered to the patient in ml
- programmed occlusion pressure level (low, medium or high)

Bolus rate and dose as well as occlusion pressure can be changed in the same way like in standard or aneste mode **by pressing PROG (for abt. 3 seconds) , introducing new value and confirming.**

17.4 Programming parameters in STANDARD mode.

According to section 7.

IMPORTANT !!!
The pump must not be connected with the patient's vein before programming is fully completed and air bubbles removed.

Notes:

Notes:

Notes:

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