- Certified Management System
- EN ISO 9001
- EN ISO 13485

OPERATING MANUAL

SYRINGE INFUSION PUMPS

AP 12 and AP 22

CE
0197

Dear Customer,

thank you very much for purchasing medical equipment from Ascor S.A. We can assure you that you have made a good choice. Our Company devotes much effort and time to improve its products. It will be a pleasure and satisfaction for us if our product fulfils your requirements and expectations. If during operation of our equipment you have any doubts or remarks regarding its operation or functionality, please do not hesitate to inform us about them. We will do our best to remedy all your problems and your remarks will be taken into consideration in designing our new products.

President of the Board

Table of Contents

1. Be sure to read this section!

Considerations on safety of operation

Before starting the pump operation, read carefully this instruction manual.

- **The pump may only be operated by qualified medical personnel, familiar with this instruction manual and/or trained by authorized personnel of Ascor S.A.**

- **Attention! For infusion with pumps AP 12 and AP 22, syringes specified by the pump manufacturer may only be used. Failure to observing this may be a danger to the patient's health or life. All syringes accepted for usage with the pumps are listed in a table on page 6. They are all three-part syringes, i.e. they all have a rubber plunger. Their manufacturer's name, capacity and type matches the syringe that can be chosen in the pump program. Using a syringe that is not listed in the table may lead to significant infusion errors, which, in consequence, may be a danger to the patient.**
- **In case of any doubts concerning the syringes used or infusion errors experienced, you should immediately contact Ascor local distributor or the manufacturer.**
- **In case of any suspecting of incorrect pump operation, the syringe should immediately be removed from the pump assembly.**
- **Attention! Lifting the syringe, which is connected with patient's body through extension tube, more than 30 cm higher than the position of syringe needle, may result in spontaneous flow-in caused by the negative pressure generated in the syringe.**
- **Syringes, as disposable components, should not be used longer than 24 hours.**
- **The pump does not have its own system of air detection in the drain. The pump user must check if there are any bubbles of air in the drain or in the syringe. To fill the drain with fluid, „<" button should be used to shift the pump arm.**
- **Pumps AP 12 and AP 22 were tested using a standard 150 cm long PVC extension tube, external diameter 2.3 mm and internal diameter 1.1 mm (if not otherwise stated).**
- **Attention! BOLUS flow rate is set automatically (minimum double infusion flow rate) if its previous value was lower than double infusion flow rate.**
- **Delivering BOLUS doses with flow rates exceeding 1000 ml/h requires the usage of standard drains with internal diameter equal to 1.1 mm. In case of using extension tubes with internal diameter 0.9 mm, the pump will indicate occlusion even at infusion pressure set to maximum.**
- **We recommend that the pump be connected to the hospital call system.**
- **The pumps can only be hanged on the specially designed poles.**
- **No other devices or things (e.g. aprons) can be hanged on the pump assembly.**
- **No vessels with fluids (e.g. coffee, tea) can be placed on or by the pump.**
- **The pump should only be operated within a safe distance from the patient, so that its moving parts (i.e. pump arm) are out of the reach of patient's body.**
- **The patient must be informed by the medical personnel that touching the pump keyboard by any unauthorized persons may cause a risk to his health or life.**

- **If a pump undergoes an impact, e.g. as a result of falling on a hard surface, it should be sent to hospital service department in order to be tested, in accordance with tests described in this instruction manual, for correct operation. In case of any irregularities the pump should be sent to authorized servicing company.**
- **Any irregularities in functioning of the pump should immediately be notified to manufacturer, together with a detailed description of the problem, working conditions, environment, external factors, etc., which might influence functioning of the equipment.**
- **Operation of the pumps in environmental conditions not foreseen by the manufacturer (e.g. in temperatures exceeding the ranges described in this instruction manual) may be a menace to patient's life or health.**
- **The equipment must not work in environment where inflammable or explosive mixtures of anesthetic gases or explosive vapors are present.**
- **Pumps AP 12 and AP 22 have batteries ensuring their operation without connection to the mains. If the pumps are stored without connection to the mains, their batteries must be recharged every two months. During normal operation, the pump indicates the status of the batteries.**
- **Before dispatching the pump to the maintenance workshop, it should be disinfected in accordance with the included disinfection instruction manual.**
- **Pump life is estimated at 10 years, on condition of compliance with guidelines included in this Operation Manual and systematic maintenance inspections conducted every 12 months (post-guarantee period)**
- **It is advisable that a pump is returned to the manufacturer, after completing its operation period, in order to be utilized in accordance with a proper ecological process.**
- **Pumps AP 12 and AP 22 meet requirements of conformity with the European standard EN 60601-2-24 and general standard PN-EN 60601-1 in the basic range of safety requirements.**
- **Pumps AP 12 and AP 22 meet requirements of conformity with the standard concerning electromagnetic compatibility (EMC) EN 60601-1-2. In spite of this we recommend that the pumps should not work in a short distance from other equipment that does not meet requirements of EMC and do not have CE marking, which may emit strong electromagnetic radiation. This refers also other devices that emit strong electromagnetic field, such as e.g. x-ray instruments, defibrillators, mobile telephones, electro-surgery instruments, etc.**

- **Standard kit includes:**

  - **one pump AP 12 or AP 22,**
  - **power lead 230 V AC.**

Additional equipment, supplied on customer's request:

- **External alarm cable,**
- **12 V power cord**

Please check the completeness of the delivery according to the order specification.
Even if adequate packing is used, Ascor S.A. cannot exclude all transport damages.
In case any irregularities are noticed, please inform our service department before you start the equipment.

List of syringes acceptable for usage with pumps AP 12 and AP 22

Message displayed for pumps AP 12/22	Full name of the syringe	Manufacturer
10 BBRAUN OMNIFX	BRAUN OMNIFIX 10 ml	B.Braun Melsungen AG
10 CODAN/ONCE	CODAN 10 ml, ONCE 10 ml	CODAN Medical System
10 MONOJECT	MONOJECT 10 ml	TYCO/Healthcare UK KENDALL
10 TERUMO	TERUMO Syringe 10 ml	TERUMO Europe N.V.
20 BBRAUN OMNIFX	BRAUN OMNIFIX 20 ml	B.Braun Melsungen AG
20 BBRAUN PERFUS	BRAUN PERFUSOR 20 ml	B.Braun Melsungen AG
20 B-D PLASTIPAK	BD PLASTIPAK 20 ml	Becton Dickinson &Co
20 CODAN/ONCE	CODAN 20 ml, ONCE 20 ml	CODAN Medical System
20 MONOJECT	MONOJECT 20 ml	TYCO/Healthcare UK KENDALL
30 BBRAUN OMNIFX	BRAUN OMNIFIX 30 ml	B.Braun Melsungen AG
30 B-D PLASTIPAK	BD PLASTIPAK 30 ml	Becton Dickinson &Co
30 CODAN/ONCE	CODAN 30 ml, ONCE 30 ml	CODAN Medical System
30 MONOJECT	MONOJECT 30 ml	TYCO/Healthcare UK KENDALL
30 TERUMO	TERUMO Syringe 30 ml	TERUMO Europe N.V.
50 B-D PERFUSION	BD PERFUSION 50 ml	Becton Dickinson &Co
50 B-D PLASTIPAK	BD PLASTIPAK 50 ml	Becton Dickinson &Co
50 B-D PRECISE	BD PRECISE 50 ml	Becton Dickinson Singapore
50 BBRAUN ADALAT	Adalat – BARAUN 50 ml	B.Braun Melsungen AG
50 BBRAUN OMNIFX	BRAUN OMNIFIX 50 ml	B.Braun Melsungen AG
50 BBRAUN PERFUS	BRAUN PERFUSOR 50 ml	B.Braun Melsungen AG
50 BBRAUN PROINJ	BRAUN PROINJEKT 50 ml	B.Braun Melsungen AG
50 CODAN/ONCE	CODAN 50 ml, ONCE 50 ml	CODAN Medical System
50 DISPOMED PL	DISPOMED 50 ml	Dispomed Lublin
50 INJECTOMAT	INJECTOMAT Spritze 50 ml	FRESENIUS Kabi Gmbh
50 IVAC	IVAC 50 ml	IVAC U.K. Ltd.
50 JANPOL	JANPOL 50 ml	JANPOL Ursus
50 MONOJECT	MONOJECT 50 ml	TYCO/Healthcare UK KENDALL
50/60 ONCE PERF.	ONCE Perfusion 50/60 ml	CODAN Medical System
50 TERUMO	TERUMO 50 ml	TERUMO Europe N.V.
60 PENTA	PENTA (PF) 60 ml	PENTAFERTE Campli Teramo

2. Application of the pumps

Infusion syringe pumps AP 12 and AP 22 are designed for accurate dosage of drugs to the patient and infusion fluids. They are indispensable for:

- intensive care units,
- open-heart surgery units,
- pediatric units,
- surgery units,
- ambulances.

The pumps are characterized by simplicity of operation, reliability and diversity of applications. They are suitable for various types of single-use syringes. BOLUS function enables a quick and repeated delivery of bolus doses to the patient, with accurately established volume and within a chosen time of infusion.

The pumps can be operated without connection to the mains. The pump is supplied by the internal battery automatically if there is, for example, a mains failure. It also enables to continue the infusion when the patient is being transported.

Simple casing, without any parts protruding from the front panel, facilitates maintenance and disinfection.

This instruction manual is designed for two types of syringe pumps: single-syringe pump AP 12 and double-syringe pump AP 22. Technical parameters, software as well as the way of operating are identical for both types.

3. Pump construction

3.1 Pump AP 12

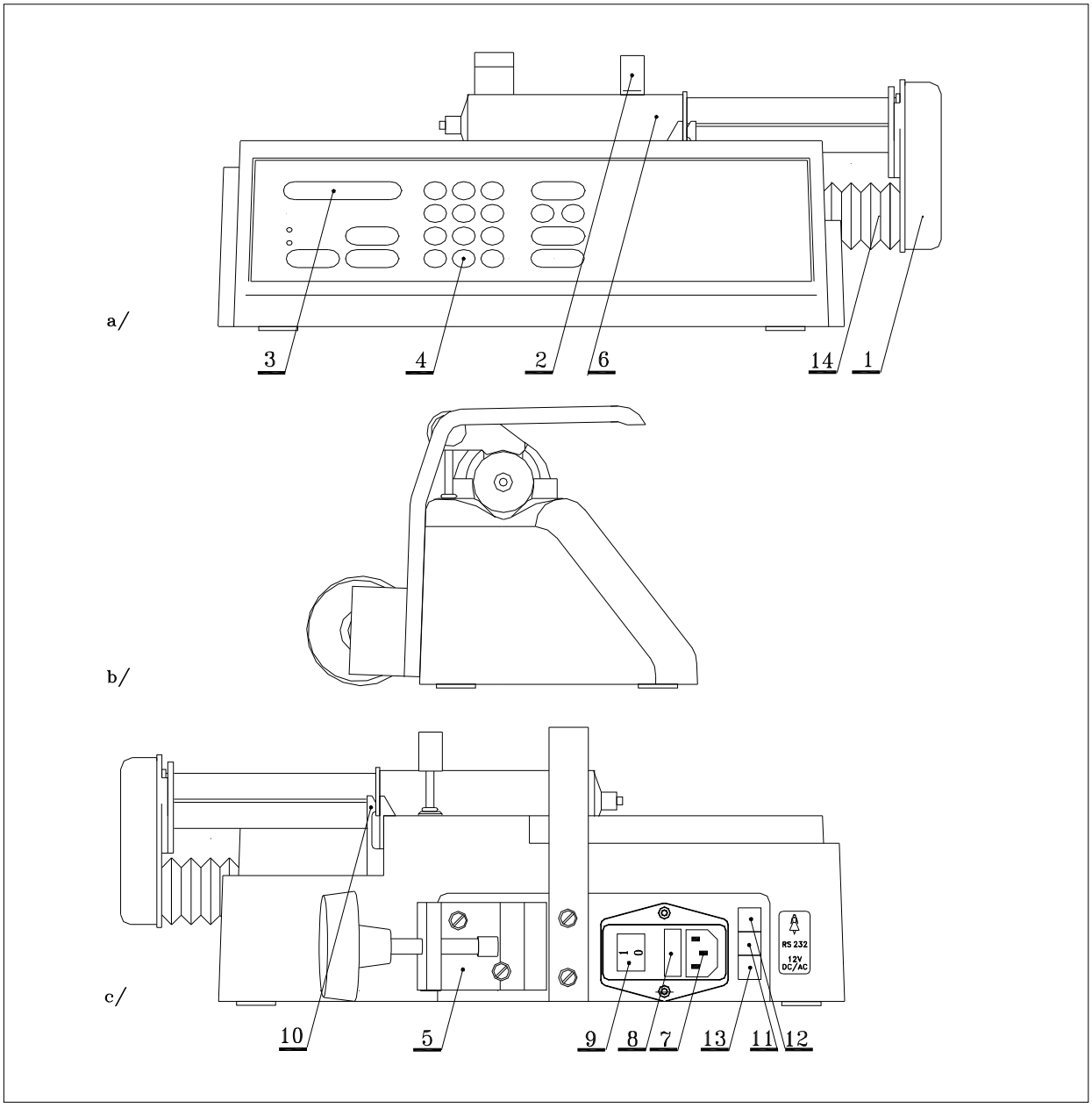


Fig. 1. **Pump AP 12, view from:** a) front , b) side , c) back
1 – pump stem end, 2 – syringe holder, 3 - display, 4 - keyboard, 5 - clamp,
6 - syringe, 7 - socket, 8 - fuses, 9 – main switch, 10 – locking plate, 11 – RS 232,
12 – external alarm socket, 13 – external power supply 12V, 14 – pump arm.

3.2 Pump AP 22

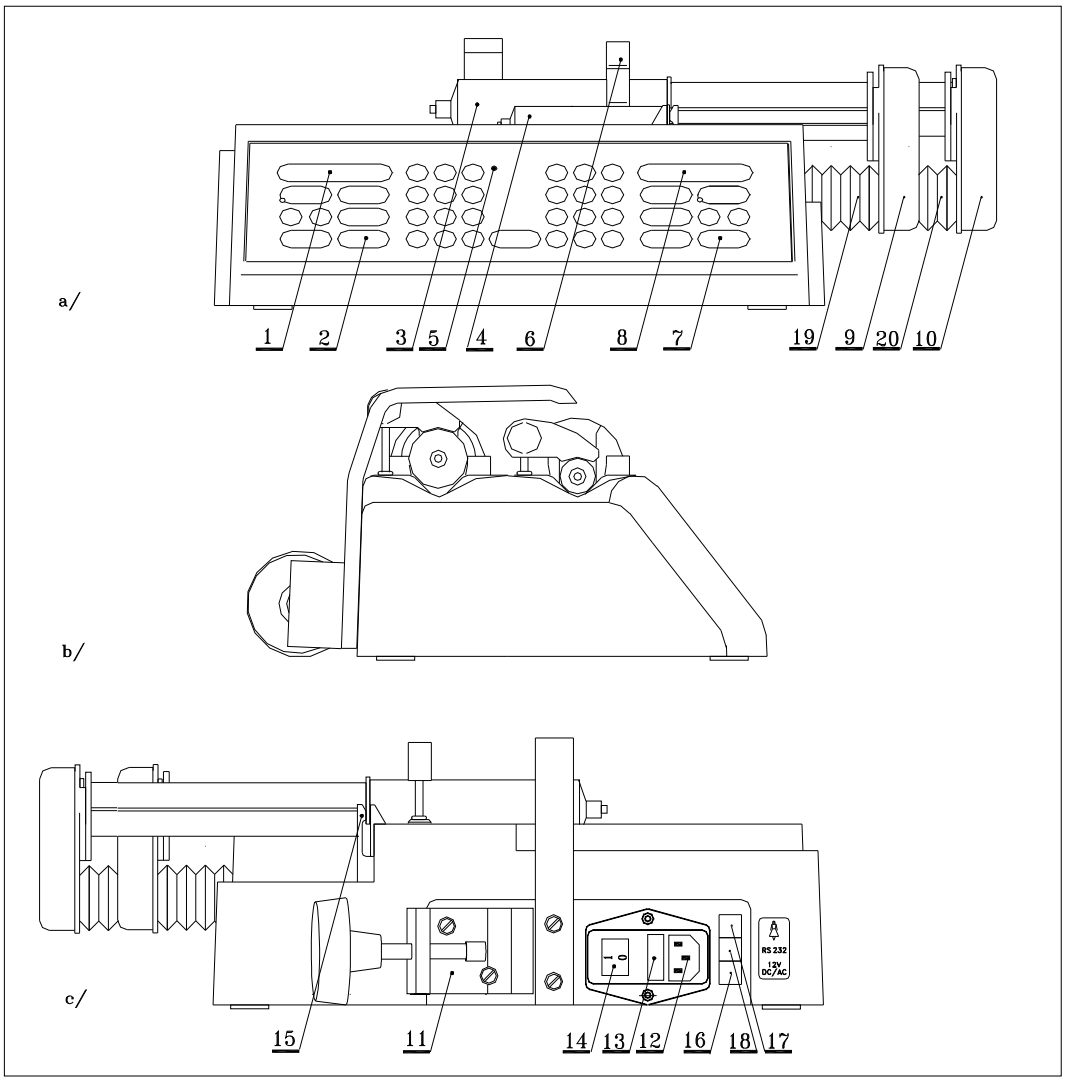


Fig. 2. **Pump AP 22, view from:** a) front, b) side, c) back

1 - system A display, 2 – system A keyboard, 3 - system B syringe, 4 - system A syringe, 5 - "MAINS" indicating lamp, 6 – syringe clamp, 7 - system B keyboard, 8 - system B display, 9 – system A pump stem end, 10 – system B pump stem end, 11 - clamp, 12 - socket, 13 - fuses, 14 – main switch, 15 - locking plate, 16 – external power supply 12V, 17 – external alarm socket, 18 – RS 232, 19 – system A pump arm, 20 - system B pump arm

4. Pump functioning

In order to limit the risk of mistake, pumps AP are equipped with a sensor detecting the syringe size (10, 20-30, 50ml) and comparing them with preset parameters.

Pumps AP are also equipped with a sensor for detecting the correct fixing of syringe plunger in pump arm, which makes it impossible to start the pump in case of incorrect fixing of the syringe.

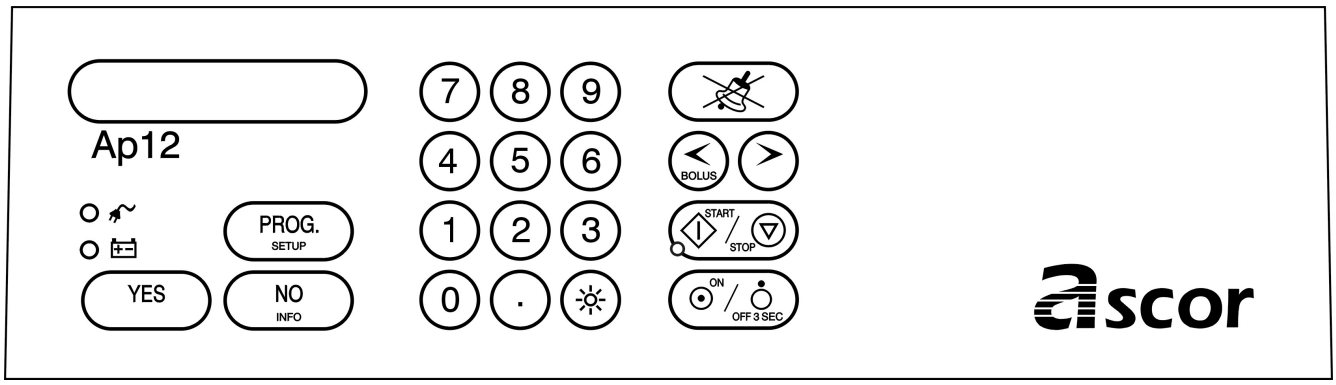
Operation of the pump consists in moving the syringe plunger with user-preset speed, which corresponds to a defined infusion flow rate. The pump arm is driven by a step motor, whose speed of rotation is controlled by a microprocessor. The step motor drives the guide screw, which causes the arm movement.

The internal microprocessor calculates with high accuracy the speed of rotation of the motor in accordance with properly preset infusion parameters. Moreover, the microprocessor controls infusion timing and volume, displays information and messages, checks for occlusion and monitors the battery status.

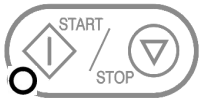
The operation of the microprocessor is supervised by additional safety circuit, so called “watchdog”, which stops the pump operation and activates an alarm in case of detecting any irregularities.

5. Operation of the pumps

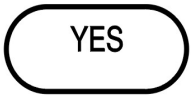
Pump AP 12 – Keyboard description



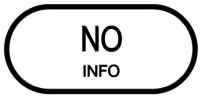
green lamp indicates connection of the pump to mains 230 V AC and charging of the battery;
when it is flashing in red, it means that the pump is powered by the battery



Flashing orange lamp indicates infusion in progress

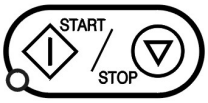


button **"yes"** used to confirm / memorize information displayed

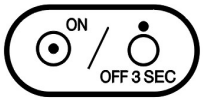


button **"no"** used to reset or reject information displayed;
it also serves as **INFO** button and enables scrolling the infusion data: volume infused, time left, pressure, battery status

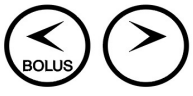
button **"program"** used to start setting up infusion parameters; it also enables scrolling the pre-set infusion parameters



Button **"start/stop"** used to start or stop the infusion



Button used to switch on or off the pump
(to switch off the pump, the button should be pressed for abt. 3 seconds)



buttons enabling quick movement of a syringe plunger to the left or to the right; left button is also used for starting BOLUS function

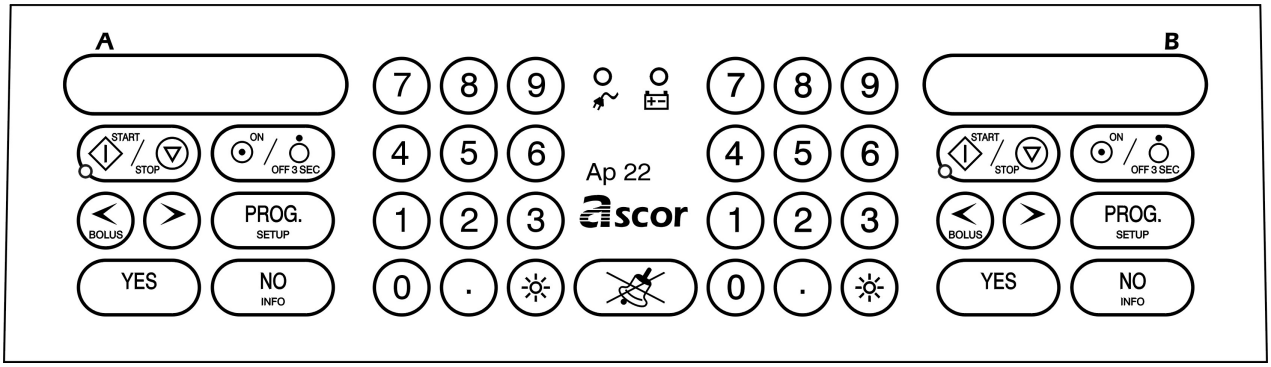
0 – 9

numeric keys for entering parameters

acoustic alarm muting button

button for changing the background light of the display

Pump AP 22 – Keyboard description



green lamp indicates connection of the pump to mains 230 V AC and charging of the battery;
when it is flashing in red, it means that the pump is powered by the battery

flashing orange lamp indicates infusion in progress

button **"yes"** used to confirm / memorize information displayed

button **"no"** used to reset or reject information displayed;
it also serves as **INFO** button and enables scrolling the infusion data: volume infused, time left, pressure, battery status

button **"program"** used to start setting up pump parameters; it also enables scrolling the pre-set infusion parameters

button **"start/stop"** used to start or stop the infusion

button used to switch on or off the pump
(to switch off the pump, the button should be pressed for abt. 3 seconds)

buttons enabling quick movement of a syringe plunger to the left or to the right; left button is also used for starting BOLUS function

0 - 9 Numeric keys for entering parameters

Acoustic alarm muting button

button for changing the background light of the display

5.1 Installation and preparing the pump for operation

Preparing the pump for operation needs performing a few simple steps. The pump can be fixed to a pole (diameter between 20 and 40 mm) or placed on a horizontal surface near the patient's bed. The pump can be positioned above, below or at patient level.

It is possible for the pump to be mounted on a horizontal tube (e.g. by patient's bed). This can be done by removing two screws that hold the clamp (Fig. 1, pos. 5) turn the clamp by 90^{o} and replace the two fixing screws. Make sure that the clamp is correctly fixed to the pump body and begin the installation on a horizontal tube.

Attention! With this positioning there is a risk that the pump turns downwards, e.g. during setting up, if the clamp is not tightened correctly.

Preparing the pump for operation:

1. Position the pump on a horizontal surface or fix it on the pole using the clamp (AP 12 - Fig.1, pos. 5; AP 22 - Fig.2, pos. 11).
2. Insert the plug of pump supplying cable* into the 230 V mains socket equipped with grounding pin.
3. Set the pump main switch in position "1" (green lamp MAINS should light up).

The pump is ready for inserting the syringe and setting up infusion parameters.

General notes

- Syringe, as a disposable component, should not be used longer than 24 hours.
- **Attention!** Removing the full syringe, which is connected with patient's body through the extension line, is a danger for the patient. Lifting such a syringe more than 30 cm over the level of needle position (in patient's body) may result in intrinsic infusion caused by the under-pressure in the syringe.
- **Attention!** The above described situation of free flow of the drug from the syringe to patient's vein may also appear when the pump is positioned more than 30 cm above the level of needle in patient's vein, and when the syringe plunger is incorrectly fixed on the pump arm.
- The syringe should be fixed in such way that its stem end is inside of pump arm end (Fig.1, pos. 1), and the syringe wings are in the gap between the casing and the locking plate (Fig. 1, pos. 10). Then the syringe must be locked with clamp (Fig.1, pos. 2) positioning it perpendicularly to syringe axis. Make sure the syringe plunger is positioned along syringe axis
- After inserting the syringe with drug, pressing „**<"** button will cause slow movement of the plunger, which fills the drain with the fluid. Care should be taken to remove all air from the drain – infusion fluid must flow out of the needle – before the needle is inserted into patient's vein. **Manufacturer recommends filling the extension line with fluid using the pump, as described above.**

- 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**.**

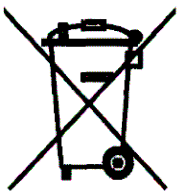
- In case occlusion pressure is a critical parameter, we recommend usage of large syringes, of volume up to 50/60 ml.

It should be kept in mind that the pump detects occlusion only as soon as the pump arm is stopped by excessive pressure in the extension line and syringe. As the pressure increases gradually, due to expansion of the extension line, occlusion indication is delayed, and the delay depends on the infusion flow rate and length and flexibility of the extension line. In order to shorten the time of occlusion detection as well as reduce volume of the drug collected in the expanding extension line, usage of special high-pressure, short, low internal diameter and thick-wall extension lines is recommended, especially with low infusion flow rates.

Description of the most important symbols:

- Attention! Read the Operating manual

- Class BF device



- Separate collection

5.2 Setting up infusion parameters

Infusion parameters are set up the same way for both types of pumps. For pump AP 22 setup is carried out separately for syringe A and syringe B.

Infusion parameters can be divided into three groups:

1. **Basic parameters:**
   - syringe type,
   - flow rate,
   - volume or time of infusion,
   - drug name

or:

   - syringe type,
   - volume,
   - time,
   - drug name

Additionally, the following parameters may be used:

   - infusion time,
   - time of pause,

These parameters are activated during setup of parameters included in group of additional parameters (see below).

2. **Auxiliary parameters:**
   - BOLUS rate,
   - BOLUS volume,
   - occlusion pressure.
3. **Additional parameters:**
   - password,
   - infusion rate in K.V.O. mode,
   - volume and type of sound alarm,
   - drug library modification,
   - STAND-BY function on/off,
   - ANTI–BOLUS function on/off,
   - name of hospital ward.

Parameters of the first group must be set or confirmed before each infusion.

The second group includes auxiliary parameters, which can (but need not to) be set for each infusion. They can be changed during infusion, if necessary.

The third group includes parameters that are not set very often. They can be changed only before starting the infusion.

5.2.1 Primary parameters

After starting the pump with **ON/OFF** button, the following message is displayed:

AUTO-TEST – X.X	where X.X defines the software version installed

informing the user of the self-checking tests being carried out by the pump.

If any irregularities are detected, the pump is automatically locked and a sound alarm is activated. If such situation appears repeatedly, please contact our maintenance personnel, in order they carry out inspection or repair.

As soon as the self-testing is completed, the pump starts its work preparation cycle.

The following situations are possible:

a) two following messages alternate on the display:

NO MAINS !!!	**BATTERY** □□□

230V or 12V power supply is not present;

lamp is flashing red. If the pump should be powered from an internal battery, press **YES**. Otherwise he pump should be connected to the mains.

b) in case of an interrupted infusion, a message is displayed:

Continue...??	"should the preceding infusion be continued ?",

This happens when the previous infusion was not completed because the pump was switched off using **ON/OFF** button during the course of infusion. Pressing **YES** means that the infusion should be continued according to the previously set up parameters and existing status of the volume counter. Pressing **NO** will cause resetting the volume counter and beginning setup of new infusion.

c) type of previously used syringe is displayed, e.g.:

50ml B-D PLASTIPAK

Syringe type describes its volume in ml and manufacturer's name. The syringe can be accepted by pressing **YES** button.

Then the next step is setting up infusion flow rate. If syringe type is not confirmed, by pressing **NO** button, the following question is displayed:

change syr ???	Change syringe ???

Confirming with **YES** button starts procedure of changing syringe type. Selection can be made by pressing **NO** repeatedly until the right type of syringe appears on the display. The choice should be confirmed by pressing **YES** button.

The next parameter to be set is:

rate XX.X ml/h	"infusion rate in ml/hour".

Flow rates below 100 ml/h can be set with accuracy of 0,1 ml. Higher ones – with accuracy of 1 ml.

The pump enables <u>volume over time</u> operation. This can be done by pressing **NO** button (at the moment when rate is displayed) thus deleting the infusion flow rate, and pressing **NO** button once again for abt. 1 second. The display will show:

volume XXml	"infusion volume in ml".

As soon as volume is set, time of infusion has to be entered:

time : XX:XX.XX	"infusion time: hours : minutes" (seconds are not set).

When setting up the infusion flow rate, it should be kept in mind that, depending on previously set type of syringe, maximum infusion flow rates are: 500 ml/h (for syringes 50 ml), 300 ml/h (for syringes 30 ml), 250 ml/h (for syringes 20 ml) and 150 ml/h (for syringes 10 ml). If the flow rate setting is too high, the system informs of this fact by displaying the maximum acceptable value for the chosen syringe type:

max. XX.X ml/h	"maximum infusion flow rate is XX.X ml/h".

This message can be deleted by pressing any key (it disappears automatically after approx. 5 seconds), and then correct value can be entered and confirmed by pressing **YES** button.

If the previous parameter was flow rate, and not volume and time, the next parameter would be:

volume XX.X ml

The field XX.X shows the volume of the previously performed infusion. Pressing **NO** will delete this value and allow for entering a new one, which should be confirmed by pressing **YES** button. The maximum value of infusion volume is 1000 ml. **Leaving this parameter out (by pressing YES button without entering any number) or setting it to zero is acceptable, but in such case "END OF INFUSION" alarm will not be activated (see chapter 5.5), and the pump will not stop working until the syringe is emptied.**

Instead of infusion volume, it is possible to set up the time of infusion. Obviously, only one of these two parameters can be set. **Change from volume to time setting (or vice versa) is achieved by pressing NO button, in order to delete the existing value, and then pressing it again and holding for more than approx. 1 second.** As a result, the following will be displayed:

time: XX:XX.XX	"infusion time: hours : minutes".

Minimum infusion time is 00 hours 01 minutes and maximum: 99 hours and 59 minutes. Seconds cannot be set up.

The field XX:XX.XX can show the previously set time value. If it is not correct, delete it by pressing **NO** button. The following will be displayed: 00:00:00. Enter new numbers from left to right. Blinking zero indicates position, where a digit can be entered from the numeric pad. The entered digit can be deleted at any time by pressing **NO** button. On completion of entering the correct time value, press **YES** button for confirmation. **Similar to volume, this parameter can be left out (with no value entered) or set to zero, which will result in the above described pump performance**.

If the pump is going to be used in STAND-BY mode, two additional parameters, described under item 5.2.3, will have to be set up.

The final parameter to be set is drug name. The following question is displayed:

choose a drug ?

Pressing **NO** will automatically finish setting up the primary parameters, which means that a correct syringe is to be inserted and a programmed infusion started.

If, however, **YES** button is pressed, the display will show the name of the drug infused previously. Drug library can be scrolled by pressing **NO** repeatedly. When a desired drug name is found, press **YES** to confirm it.

In case a desired drug name is not found, pressing **PROG** button will take the operator back to the previous question: "**choose a drug?".** Pressing **NO** will finish setting up the primary parameters.

The drug library is described in more details in Chapter 5.2.3. (page 21,22).

If up to that moment the syringe has not been fixed on the pump assembly, correct settings of the pump are indicated alternately with the following message:

INSERT SYRINGE!	**pre-set syringe type**

and automatic adjustment (movement right) of the pump arm. **It should be remembered that the syringe should be filled with abt. 2-3 ml of drug more to fill the extension line at the moment when FILL THE LINE message is displayed**. In some cases, instead of the above message, the following can be displayed:

wait !!!

This means, that the pump is carrying out a self-test in order to correct the stetting of the pump arm. Wait a moment and then continue, following the messages displayed.

Pumps AP have a sensor for detecting syringe sizes (10, 20-30, 50ml) and comparing them with the preset types. If a syringe of volume different than the preset one is inserted, a message will be displayed:

WRONG SYRINGE !

When the syringe is inserted and clamped on the pump, the following message is displayed:

FILL the LINE!

The extension line should be filled with infusion fluid in such a way that there are no air bubbles in it, by pressing **<** button.

The next message:

READY to run .. ??

means that the pump is ready for operation.

To start the infusion, button YES or START should be pressed**.**

Pressing the **PROG** button**,** it is possible to check (read) the preset infusion parameters. If any of them is incorrect, it can be deleted with **NO** button and correct value can be entered. After any change it should be confirmed with **YES** button.

All primary parameters, except for syringe type, can be changed at any time, also during the infusion process.

5.2.2 Auxiliary parameters

BOLUS and OCCLUSION PRESSURE

Modification or scrolling the auxiliary parameters can be done as soon as primary parameters are set up or at any time, e.g. during infusion. **It is not necessary to set parameters for each infusion, since they are memorized by the system. Subsequent infusion will be carried out according to the existing settings.**

Setting up BOLUS

In order to begin setting parameters of this group **PROG** button should be pressed and held for more than **1 second.**

Attention! A short pressing of this button will enable scrolling the above-described primary parameters.

The first auxiliary parameter is:

BOLUS XXX ml/h	BOLUS flow rate in ml/h

XXX ml/h defines BOLUS flow rate. Depending on the syringe size used, the maximum value is: 2000 ml/h for 50 ml syringe, 1200 ml/h for 30 ml syringe, 1000 ml/h for 20 ml syringe and 600 ml/h for 10 ml syringe. In case of leaving this parameter without any value is equal, the pump will deliver a bolus dose at a flow rate of 1000 ml/h for 50 ml syringe, 600 ml/h for 30 ml syringe, 500 ml/h for 20 ml syringe and 300 ml/h for 10 ml syringe.

Attention!

- **If the preset BOLUS flow rate exceeds the maximum permissible value for the syringe chosen, then the maximum permissible flow rate for this syringe will be used.**
- **The pump will not accept a BOLUS flow rate lower than the preset doubled infusion flow rate. For example, when the infusion flow rate is equal to 5 ml/h then the minimum bolus flow rate will be 10 ml/h.**

When the set value of BOLUS flow rate is confirmed with **YES** button, the next parameter – BOLUS volume – will appear on the display:

BOLUS XX ml	BOLUS volume in ml

Its value must not exceed the volume of the syringe chosen.

If the BOLUS volume value is not preset, infusion in BOLUS mode is continued as long as BOLUS button is held. The volume of the delivered dose in ml is displayed. The volume of fluid administered during activated BOLUS mode adds up to total volume of drug administered to the patient.

Starting the BOLUS function is described with more details in Chapter 5.4.2. BOLUS function can be stopped by pressing **START/STOP** button.

Setting the limit level of infusion pressure.

The next parameter that will be shown after pressing the **YES** button is pressure level, at which ”OCCLUSION” alarm should be activated. The reason for activating this alarm may be, e.g. crushed extension tube (drain) or obstructed syringe needle. Four pressure levels can be preset:

- minimum 0.04 MPa (300 mm Hg),
- low 0.06 MPa (450 mm Hg),
- medium 0.09 MPa (675 mm Hg),

- high 0.12 MPa (900 mm Hg).

One of the following messages, informing of the currently set value, will appear on the display:

PRESS minimum

PRESS low

PRESS medium

PRESS high

The selection is made by pressing **NO** button repeatedly until the right pressure level is displayed. Pressing **YES** button will result in setting up and memorizing the selected value.

The accuracy of measuring the occlusion pressure is proportional to the quality and volume of the syringes used. The lower the volume (diameter) of the syringe, the more difficult an accurate measurement is. In case occlusion pressure is a critical parameter, usage of large syringes, at volume of 50÷60 ml, is recommended.

Attention!

- **Syringes at volume of 10÷20 ml should only be used for very low infusion flow rates, i.e. below 1 ÷ 2 ml/hour.**
- **Low quality syringes (not designed for usage with infusion pumps – with a cone instead of thread) may cause accidental, false occlusion alarms for the lowest infusion pressure levels.**

5.2.3 Additional parameters

This group of parameters enables the user to customize the pump features. Setting up parameters in this group should begin with switching the pump off using **ON/OFF** switch**.** Then press **PROG** button and, holding it, switch the pump on with **ON/OFF**. The following message will be displayed:

password 0

now **PROG** button can be released**.**

Entering a number in the range between 1 and 999999 enables protecting the infusion parameters against any modification by unauthorized persons. If a password has been entered, then, before any modification of any infusion parameter, a message is displayed:

PASSWORD

Correct password must be entered from the keyboard and confirmed by pressing **YES** button**. If password protection is not to be used, [0] should be entered as the parameter and confirmed with YES button.**

ATTENTION!

If you forgot the password code 555.555 will unblock the system.

The next parameter is:

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

KVO (Keep Vein Open) function consists in the fact that instead of stopping infusion, a minimum flow rate is maintained in order to keep needle patiency (avoiding clot creation). Typical flow rate of such infusion is 0.5 ml/h, but in certain cases it should be different. Its value can therefore be set at 0 - 5.0 ml/h. Leaving this parameter without any value is equal to setting it to 0,5 ml/h, while entering 0 ml/h will switch this function off. Volume of fluid received by the patient during activated K.V.O. function adds up to total quantity of drug received by the patient.

K.V.O mode infusion is activated after stopping the pump with **START/STOP** button or after displaying the alarm message **"empty syringe"** or **"end of infusion"**.

ATTENTION! If the value of flow rate set for K.V.O. function is higher than the basic infusion flow rate (delivery), then infusion in K.V.O. mode will be effected with flow rate equal to basic infusion (e.g. if basic infusion flow rate = 0.5 ml/h, and K.V.O. flow rate = 1.5 ml/h, then infusion in K.V.O. mode = 0.5 ml/h, i.e. infusion is not stopped).

The next parameter defines type of signal used as acoustic alarm. The required option can be chosen with **NO** button.

ALARM ----------	Continuous alarm sound

or

ALARM - - - - - - - -	Intermittent alarm sound

As soon as the selected option is confirmed with **YES** button, parameter defining the volume level of the acoustic signal.

ALARM (1-3,*)

"1" means the lowest level. * – alarm volume increasing over time (press button '**.**')

The next two parameters refer to the drug library.
The drug library consists of two lists: "manufacturer's basic list" and "operator's extended list".
"Manufacturer's basic list" consists of the drug names entered by the manufacturer and cannot be modified by the operator. The drug names are listed in alphabetical order and displayed in small letters.

"Operator's extended list" can be created by the user by adding new drug names (up to fourteen). The following question is displayed:

add a drug ???

Pressing **YES** button enables entering a new drug name, which will be displayed in capital letters. Each letter to be entered can be chosen with **<** or **>** buttons and must be confirmed by pressing **YES**. The letter order is alphabetical. When a new drug name is entered, pressing **YES** will include it in the drug library and then once again message **"add a drug ???"** is displayed. It is possible to enter several drug names in a row, as long as the above question is answered by pressing **YES.**

Pressing **NO** will take the operator to the next question:

erase a drug ???

This function enables to remove an unnecessary drug name from the “operator’s extended list”. After pressing **YES** choose a drug name to be erased by pressing **NO** repeatedly and when it is displayed, press **YES** to erase it.

The next parameter in this group is:

STAND_BY yes

or

STAND_BY no

enabling to switch on/off the **STAND_BY** function. With this function infusion is periodically held up. Choosing ”yes” results in adding two parameters to primary group:

On_time XX.XX:XX	Time of infusion

and

Off_time XX.XX:XX	Time of pause in infusion

XX.XX:XX defines infusion time and infusion breaks in hours. min. sec. The cycle begins with infusion whose duration is equal to the preset ”infusion” parameter. After this time an alarm is activated and the infusion is stopped. Break in infusion begins, its duration being defined by „pause” parameter. Completion of this period is signaled with another alarm and demand of continuing the infusion. The cycle is repeated until the patient receives the set volume of drug or the pump is switched off.

Another additional parameter is **ANTI- BOLUS**. This function ensures reduction of negative consequences of occlusion occurring in the infusion fluid transportation system. Activating this function (see Chapter ALARMS) will cause return of the pump arm, reduction of pressure in extension line and withdrawal of drug excess from the flexible extension line to the syringe. Thanks to this, when the line is patent again, there is no uncontrolled flow of drug under pressure.

ANTI-BOLUS. Yes

ANTI-BOLUS function can be activated by pressing **>** button after resetting OCCLUSION alarm. The following message will be displayed:

Reduce BOLUS ?

If the answer is **YES**, then the over pressure caused by occlusion will be automatically reduced. This function reduces the risk of injecting a dose of drug under too high pressure when the fluid transportation system is again patent, i.e. so called „occlusion bolus” volume is reduced.

Attention! During infusion break, caused by occlusion, the K.V.O. function is inactive.

The next parameter, which can be entered, is name of the hospital unit, where the pump is used.

NAME OF WARD ?	Name of the hospital ward

If **NO** button is pressed, the name can be modified choosing the required letters with **<** or **>** keys and confirming them with **YES** button**.** The characters are arranged in alphabetical mode. As soon as the name is entered and confirmed with **YES button,** the following message will be displayed:

Password

This function enables creating a separate password for the entered hospital unit name.

Entering a number in the range between 1 and 999999 enables protecting the hospital unit name parameter against changing by unauthorized persons. If a password has been entered, then, before any modification of the hospital unit name, a message is displayed:

PASSWORD

Correct password must be entered from the keyboard and confirmed by pressing **YES** button**.** If password protection is not to be used, 0 should be entered as the parameter and confirmed with **YES** button**.**

ATTENTION!

If you forgot the password, code 555.555 will unblock the system.

5.3 Inserting the syringe into the pump

As soon as the presetting procedure is completed, the following messages are displayed alternately:

INSERT SYRINGE!	**Pre-set syringe type**

They inform of the necessity of fixing a syringe, previously filled with drug, on the pump assembly.

The pump arm will be adjusted automatically (will move right) to enable inserting the syringe filled with a drug (the syringe volume + about 2,5 – 3 ml for priming the extension line). So the syringe should be filled with an according volume of a drug.

Buttons **<** or **>** are used for setting pump arm in a correct position. Pressing **<** or **>** for more than 2 seconds will cause increasing the speed of arm travel. Automatic arm movement, without the necessity of pressing **>** button, is enabled, due to safety reasons, only in case of arm return movement. The arm can then be stopped using **START/STOP** or **<** buttons.

The syringe should be fixed in such a way that its stem end is positioned inside the pump arm end (Fig.1, pos. 1), while the syringe wings should be inserted in the gap between the casing and locking plate (Fig. 1, pos. 10). Then the syringe must be fixed

with the clamp (Fig. 1, pos. 2) positioning it perpendicularly to syringe axis. Make sure the syringe plunger is positioned along syringe axis.

Pumps AP have a sensor for detecting syringe sizes (10, 20-30, 50 ml) and comparing them with preset types. If a syringe of volume different than the preset one is inserted, a message will be displayed:

WRONG SYRINGE !	**Preset syringe type**

When a correct syringe is fixed, a message is displayed:

FILL the LINE !

The extension line should be filled with infusion fluid by pressing **<** button in such a way that all air bubbles are removed from it.

Attention! Before starting the infusion process make sure there are no air bubbles in the syringe and in the extension tube (drain). Otherwise, they should be removed using the above procedure.

Then the following message appears:

READY to run....??

The infusion is initiated when the **START/STOP** or **YES** button is pressed.

5.4 Infusion

5.4.1 Starting and stopping infusion

Having set pump parameters and fixed the syringe, infusion can be started. It can be done by pressing **START/STOP** button, which starts or stops the pump operation. Infusion is indicated by blinking of a yellow lamp described with a word **START** as well as by the following alternate messages:

Inf... XX.X ml/h	**Preset drug name**

Where XX.X ml/h is the set flow rate (pump delivery).

In order to stop infusion for a while (without switching the pump off), **START/STOP** button should be pressed. The yellow lamp **START** stops flashing and a message is displayed:

STOP XX.X ml/h

The pump switches over to **"KVO"** mode, and the following message is displayed alternately with word **STOP**:

K.V.O X.X ml/h

where X.X ml/h is the flow rate in this mode**.**

If the **START/STOP** button is pressed again, the infusion is continued. Stopping the infusion for more than 2 minutes will switch off the acoustic alarm (so called "reminder").

Infusion can also be stopped using **ON/OFF** button, which switches the pump off. When the pump is switched on again, it is possible to continue the infusion by pressing **YES** in reply to **CONTINUE ?** message, (the set parameters are memorized by the system). Also the status of the counter of drug volume administered to the patient is memorized. This method of stopping infusion is recommended in case infusion has to be stopped for more than 2 minutes.

As soon as the pump delivers the preset volume of the fluid, the following message will be displayed:

END of infusion

Setting up the next infusion is possible as soon as the empty syringe is removed from the pump.

5.4.2 BOLUS function

Pumps AP 12/22 enable administering a bolus dose to the patient during infusion or when the infusion has been stopped with **START/STOP** button. Bolus function will be activated after 3 seconds from pressing and holding the **<** button**.** This will be announced with the message:

BOLUS X.X ml	"volume of currently delivered bolus dose "

Both flow rate and volume of BOLUS are programmable parameters (see item 5.2.2). If volume is not entered, then infusion in "bolus" mode is continued as long as button **<** is pressed**.** If the volume is set, the infusion will be stopped as soon as the set volume of drug is administered. In this case it is not necessary to hold **<** button.

Administering of the drug using BOLUS preset function can be stopped by pressing START/STOP button (or ON/OFF switch).

Bolus volume adds up to the quantity of drug administered during normal infusion. If during BOLUS infusion the preset volume of infusion is reached, then the infusion will be stopped, and „end of infusion" message will be displayed.

5.4.3 Scrolling infusion information

During infusion it is possible to scroll:

- volume of drug already administered to the patient,
- time left till emptying the syringe or time left till end of infusion,
- pressure in the fluid transportation system,
- battery status.

After each short pressing of **NO** button, information will be changing in the following sequence on the display:

infused XX.X ml	XX.X - volume in ml, received by the patient**;**

empty.. XX.XX:XX	XX.XX:XX – time till emptying syringe - hrs.mins.secs
to end XX.XX:XX	XX.XX:XX – time till end of infusion - hrs.mins.secs
press... low	Infusion pressure
battery □□□	battery status, if pump is powered by the internal battery
or	
battery →→□□	Information on battery recharge

Pressing **NO** button again will result in return to displaying infusion flow rate. Cyclical scrolling of information on the infusion status can be executed as often as required, without affecting the process of infusion. The same method can be used for viewing information when the pump is stopped as well as when „empty syringe" or „end of infusion" or „occlusion" alarms are activated.

5.4.4 Modification of parameters

It is possible to change almost all infusion parameters in running course without the necessity of the infusion interruption. It is especially easy to change the flow rate. Just enter a new value from the numeric keypad and confirm it with **YES** button**.** Lack of confirmation/entering with **YES** button, for safety reasons, will result in keeping the previous infusion flow rate, which will appear on the display.

Other basic parameters (like: volume or time of infusion) can be changed by pressing **PROG** button shortly, thus entering the possibility of scrolling pre-set parameters of infusion. When the parameter to be modified is displayed, the previous value should be deleted by pressing **NO**, and the new value introduced with number keys and confirmed with **YES**.

The auxiliary parameters can be changed by pressing **PROG** button (for at least **1 second**) and following the steps used for setting them up.

This does not refer to group of additional parameters (e.g. **K.V.O**, **STAND-BY** etc.), whose change requires switching off the pump. It is also impossible to change syringe type during the infusion process. This parameter can be modified after stopping infusion and removing the syringe from the pump.

5.4.5 Resetting Volume Counter during Infusion

This procedure is carried out as follows: first, information on the preset volume should be displayed, and then **NO** button should be pressed and held for 3 seconds. After this time a short acoustic signal will sound and the system will start counting volume from zero. Volume counter will also be reset when **NO** button is pressed to answer the message **"CONTINUE ?"**, appearing during pump operation, or on completion of the infusion.

Attention! Resetting the volume counter during infusion will cause loss of information on the quantity of drug administered to the patient till that moment.

5.5 Alarms, messages and warnings

Situations requiring intervention of the personnel are signaled with acoustic and visual alarms (display flashing). Acoustic alarm can be switched of using

button. Type of the alarm is described on the display with adequate message.

Five minutes before complete emptying of the syringe the system switches on an acoustic alarm informing the personnel of the approaching end of infusion. When

the button is pressed, the following message is displayed:

5 min. PREALARM

If the preset or resulting infusion time is shorter than 5 minutes – the alarm will not be activated.

When the drug in the syringe runs low – approx. 0.5 ml before its complete emptying – an acoustic alarm sounds and the following message is displayed:

EMPTY SYRINGE !!

The pump is automatically switched over to **K.V.O.** mode. Infusion can be restarted as soon as a new syringe, filled with the drug, is inserted into the pump. Answering **YES** to the message „**CONTINUE ?"** will enable adding up the fluid volumes of the subsequent syringes.

It is also possible to empty the syringe completely (including 0.5 ml remnant). To do this, having reset EMPTY SYRINGE alarm, button **START** should be pressed. As soon as the syringe is emptied completely, „empty syringe" alarm will reappear.

If infusion volume or time was set, then as soon as the set value is exceeded, infusion will be stopped and the pump will be switched over to **K.V.O** mode. End of infusion will be signaled with acoustic alarm and messages displayed alternately:

END of infusion	**KVO XX ml/h**

Stoppage of the pump arm movement caused by occlusion is indicated by a sound and the following message:

OCCLUSION !!!

At this moment pump operation is stopped.

It should be kept in mind that the system detects occlusion only when too high pressure in the extension line and in the syringe stops the movement of the pump arm. Since the pressure increases gradually, because of expansion of the tubing, occlusion is signaled with a certain delay, which depends on infusion flow rate and length and flexibility of the extension line. In order to shorten the occlusion detection time and reduce the drug volume collected in the extension line, it is recommended that special high-pressure, short, low internal diameter and thick-wall tubing is used, especially with low infusion flow rates.

Pumps AP12/22 have a special **ANTI-BOLUS system** enabling an automatic reduction of the residual bolus volume on occlusion release. It ensures reduction of negative effects of occlusion in the extension line. When this function is activated, the pump arm is retracted, pressure of the system reduced and excess of drug withdrawn from the flexible tubing to the syringe. As a result, as soon as the system is patent again, there is no uncontrolled flow of

drug under pressure. The risk of infusing Bolus after occlusion release is thus significantly reduced.

ANTI-BOLUS is started by pressing **[>]** button after muting OCCLUSION alarm. Then the following question appears on the display:

Reduce BOLUS ?

If the answer is **YES**, the pump will automatically reduce the overpressure caused by occlusion.

Attention! During the infusion break, caused by occlusion, K.V.O. function is inactive.

Occlusion alarm may also appear as a result of increased infusion resistance caused by high density of the fluid delivered at high flow rates. In this case, the preset occlusion pressure should be increased or the syringe used should be changed. Also flexible tube (drain) of greater internal diameter is recommended.

The accuracy of measuring the occlusion pressure is proportional to the quality and volume of the syringes used. The lower the volume (diameter) of the syringe, the more difficult an accurate measurement is. In case occlusion pressure is a critical parameter, usage of large syringes, at volume of 50÷60 ml, is recommended.

<u>Attention!</u> Syringes at volume of 10÷20 ml should only be used for very low infusion flow rates, i.e. below 1 ÷ 2 ml/hour.

Having reset **"OCCLUSION"** alarm and pressing **NO** button it is possible, just as during infusion, view all information on the current infusion, i.e. entered volume, time till emptying the syringe, flow rate, occlusion pressure, battery status. As soon as the cause of occlusion is removed, pressing the **START/STOP** button allows for continuing the process.

If during infusion the syringe is removed by the personnel or (accidentally) by the patient, the following message will be displayed:

NO SYRINGE !!

and alarm will be activated. After resetting the alarm and inserting the syringe, the question will appear:

Continue..... ?

Pressing **YES** button means completing the stopped infusion. Pressing **NO** button means preparing the pump for a new infusion.

Alarm:

NO MAINS !!!

and flashing of red lamp

informs the operator of the fact that the pump has automatically switched over to power supply from internal battery. This could happen as a result of mains failure, fuse blow-out, disconnecting the supply cable or switching off the main switch (Fig.1 pos. 9). Pressing **YES** button means confirming this situation.

Alarm:

LOW BATTERY !!

means that the battery will be completely discharged within 30 minutes (at medium infusion flow rates, i.e. approx. 5 ml/h). The pump should be connected to the mains as soon as possible. If the infusion is continued without connection to the mains, the infusion message “inf. XX.X ml/h” will be displayed alternately with the following message:

LOW BATT	Low battery

together with a short acoustic signal.

When the message:

VERY LOW BATT !	Battery discharged

is displayed permanently and accompanied with a continuous acoustic signal, pump operation with battery is impossible and infusion has been stopped - START/STOP lamp is lit permanently.

In order to restart the infusion it is necessary to connect the pump to 230 V or 12 V mains.

5.6 Remarks for the Users

- Infusion must be carried out only with the syringe whose name has been set. Using another syringe, even if its appearance and volume are identical, does not guarantee achieving the set infusion parameters with accuracy indicated in the pump technical data. **This may have an impact on patient’s health.**
- Usage of syringes with thread for fixing the extension line – Luer Lock – is recommended. The thread secures the extension line against slipping off, e.g. when the pressure increases because of occlusion.
- **Attention !** The pump does not have its own system for detecting air in the line. The pump user must check if there are any bubbles of air in the extension or in the syringe. To fill the extension line with fluid, „<” button should be used to shift the pump arm.
- During operation the pump should be positioned below or at patient level. This secures the patients against free flow of drug from the syringe to his vein in case the syringe is removed from the pump → see **General Notes** on Page 13.
- Connection of the pump to the mains is indicated by a green lamp

  It is recommended that the pump be connected to the mains also when it is not operated, in order to continue recharging of the pump battery (the pump can stay connected to the mains for any time). This guarantees a complete recharging of the battery.
- It is also recommended that the pump be supplied from the battery only in situations where mains supply is impossible e.g. power failure, transporting the patient. Time necessary for full recharging the completely discharged battery (message: **VERY LOW BATT !!!**) is approx. 24 hours. The pump can be normally operated during recharging of the battery.
- If electric voltage is present in the socket, and the message **NO MAINS !!!** is displayed, it may mean that:

  1. the main switch is in position “0” – pump is switched off;
  2. the fuse is blown;

3. electric cable is damaged;
4. the pump is out of order and it requires intervention of a servicing personnel.

- The fuses are in the “drawer” just above electric cable. **In order to replace the fuses, disconnect the cable from the socket,** open the “drawer” using a screwdriver, remove the blown fuses and insert identical new ones. If they are blown again, contact the servicing personnel as soon as possible.
- Every application of the pump should be carefully considered, because the operator (e.g. doctor or nurse) is responsible for its application and he/she should take into considerations all technical parameters of the equipment, declared by the manufacturer, as well as infusion parameters.
- Attention: Pumps AP 12/22 are devices of Class A. It may cause radio-electric disturbances in residential environment. In such cases the user may be demanded to use proper preventive measures.

  VERY IMPORTANT !!!!!!!!!
- **In case all used passwords are lost, entering code 555.555 will unblock the system**.

6. Cleaning and Disinfection

Before starting the cleaning procedure, the pump should be switched off with **ON/OFF** button and the supply line should be disconnected (plug removed from the socket).

Cleaning can be carried out using a cloth and water solution of detergent (e.g. for cleaning dishes) or others, based on isopropyl alcohol.

After cleaning the pump should be dried before connecting it back to the mains and starting.

7. Manufacturer’s Responsibilities

Manufacturer is responsible for safe, both for patient and user, and correct operation of the equipment, according to the technical data detailed in this instruction manual, on condition that:

- the equipment is operated in accordance with its use and in environment conditions proper for this type of equipment.
- installation of the equipment is performed in accordance with requirements included in this instruction manual,
- the equipment is operated in accordance with this instruction manual by trained medical personnel,
- inspections, repairs and modifications were only made by authorized servicing company.

Manufacturer recommends carrying out a technical inspection before the end of guarantee period, and later on every two years.

8. User Tests

Pumps AP 12/22 are equipped with a set of tests with which it is possible to check correct operation of its main subassemblies. These tests can be helpful for evaluating the condition of the pump, but they do not guarantee detection of all existing faults. In case of any doubts regarding the condition of the equipment or accuracy of its operation, the pump should be immediately delivered to the hospital maintenance department in order to check it and/or

take decisions as regards further steps to be taken, e.g. repair by the authorized servicing company.

To start User Tests the pump should be switched on with **ON/OFF** button and then **START/STOP** button should be pressed immediately. The display will show a broken line:

Enter **0** and confirm with **YES** button. This will activate the user test module. The first test will be displayed. To carry out the test, select it pressing **YES** button**.** Otherwise press **NO** button repeatedly until the right test is displayed**.**

1. Test for acoustic alarm, visual alarm external alarm relay.

ALARM test ?

This test will switch pump alarm system on/off (alternately):

Alarm on

Alarm off

Test can be stopped with **YES** button. During this test it is possible to check if the pump is correctly connected to the hospital personnel calling system.

2. Display test.

DISPLAY test.?

It is carried out automatically until the following is displayed:

END OF TEST

Check if the lamps on the control panel are flashing and if the characters are properly displayed.

3. Keyboard Test.

KEYBOARD test ?

Press buttons indicated on the display. If the keyboard operation is correct, the following message appears on the display:

END OF TEST

4. Test of syringe detection system

SYR. Detection ?	Syringe detection?

Syringes of 10, 20, 30, 50 ml volume should be inserted. If the volume of inserted syringe does not correspond to the information displayed, the system of syringe detection is broken and the pump should be sent to an authorized servicing company. Test can be stopped with **YES** button.

5. Pump arm test

PUMP ARM test ?

The pump arm is moved alternately to the left and to the right. Test completion is indicated with the following message:

END OF TEST

The following message:

DAMAGE !!!

means that the pump should be sent to an authorized servicing company. Test can be stopped with **YES** button.

In order to stop the testing procedures the pump should be switched off using the **ON/OFF** button and started again with this button in order to continue the operation.

In order to finish the user tests procedure, the pump should be switched off with **ON/OFF** button.

9. Maintenance and Repairs

All servicing issues should be directly notified to the manufacturer or distributor of the equipment.

Any repairs of the pumps can be performed only by a trained servicing company indicated by the manufacturer or distributor of the equipment. Manufacturer will secure after-guarantee servicing of syringe pumps AP 12 and AP 22.

If it is necessary to send the equipment to the servicing company, it should be properly disinfected as described in this instruction manual. Otherwise, the customer will be charged for cleaning and disinfection of the equipment.

10. Technical Data - Pumps AP 12 and AP 22

Flow rate:		**0.1 – 500 ml/h**
		0.1 ÷ 99.9 ml/h in 0.1 ml/h steps
		100-500 ml/h in 1 ml/h steps
	0.1 ÷ 500 ml/h	for syringe 50 ml
	0.1 ÷ 300 ml/h	for syringe 30 ml
	0.1 ÷ 250 ml/h	for syringe 20 ml
	0.1 ÷ 150 ml/h	for syringe 10 ml
Maximum BOLUS rate:		**2000 ml/h**
		set in 1 ml/h steps
	2000 ml/h	for syringe 50 ml
	1200 ml/h	for syringe 30 ml
	1000 ml/h	for syringe 20 ml
	600 ml/h	for syringe 10 ml
BOLUS volume:		0.1ml up to syringe volume, set in 0.1ml steps
KVO volume:		**0 ÷ 5ml/h**
		set in 0,1ml/h steps
Flow rate accuracy:		≤ ± 2% (as per EN 60601-2-24)
Infusion volume:		**0.1 – 1000 ml**
		0.1 ÷ 99.9ml in 0.1 ml steps
		100 to 1000 ml in 1 ml steps
Infusion time:		**max 99 hrs. 59 min.**
Occlusion pressure:		Programmable 4 levels:
	minimum:	0.04 MPa ±0.01 (300 mm Hg ± 75)
	low:	0.06 MPa ±0.02 (450 mm Hg ±150)
	medium:	0.09 MPa ±0.02 (675 mm Hg ±150)
	high:	0.12 MPa ±0.03 (900 mm Hg ±225)
Syringe types:		10, 20, 30, 50/60 ml
		(producers listed in operating manual)
Power supply:		230VAC ± 10%, 50 Hz, max. 10 W or 11-15 V DC
Fuse:		2x160 mA / 250 V (delayed, type T)
Power consumption:		max 10 VA
Battery:		Ni/Cd
	4 hours	at flow rate of 100 ml/h
	24 hours	at flow rate of 5 ml/h
Battery recharge time:		24 hours
Alarm volume adjustment:		3 volume levels,
		increasing volume option,
		continuous or intermittent
		tone
Interface:		Optional - RS 232 C 1200 BD
External alarm socket:		24V, 1A
Other features:		Reduction of occlusion bolus (ABS)(Anti-Bolus-System)
		Automatic syringe size detection
		Information on battery recharge level
		drug library
		infusion pressure monitoring and indication
		hospital ward setting
		password protected change of parameters
		Priming
		STAND-BY function
		user tests
Pump weight:		AP 12 - 3.1 kg, AP 22 - 4.7 kg
Protection class:		I, type BF, IP31
Dimensions (w × d × h):		AP 12 320 × 180 × 140 mm
		AP 22 320 × 250 × 140 mm
Working conditions:		Ambient temperature +5°C - 40°C
		Relative humidity 20% - 90%
Safety:		The device complies with:
		EN 60601-1,
		EN 60601-1-2 (EMC),
		EN 60601-2-24,
		MDD 93/42/EEC

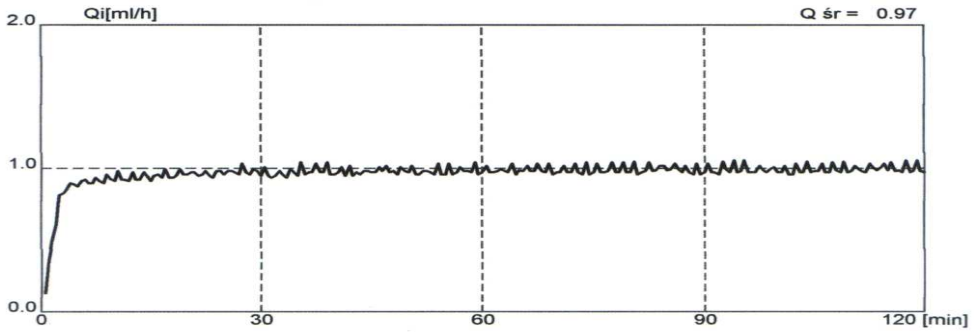
11. Examples of Trumpet Curve for selected syringes

Test of dosing accuracy for the syringe

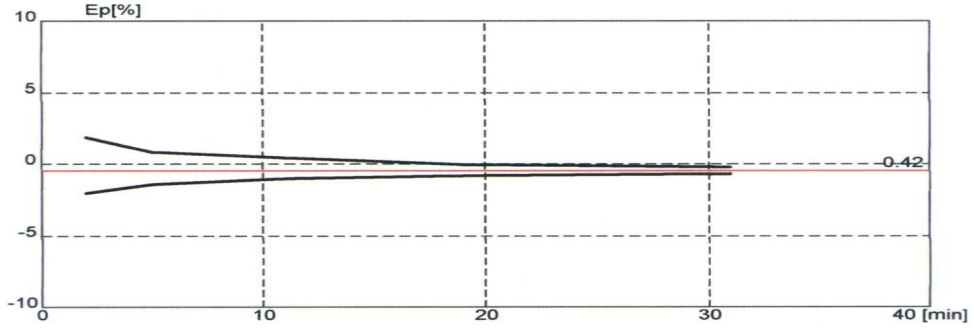
20 ml Monoject

Performed in accordance with EN 60601-2-24 test 50.102

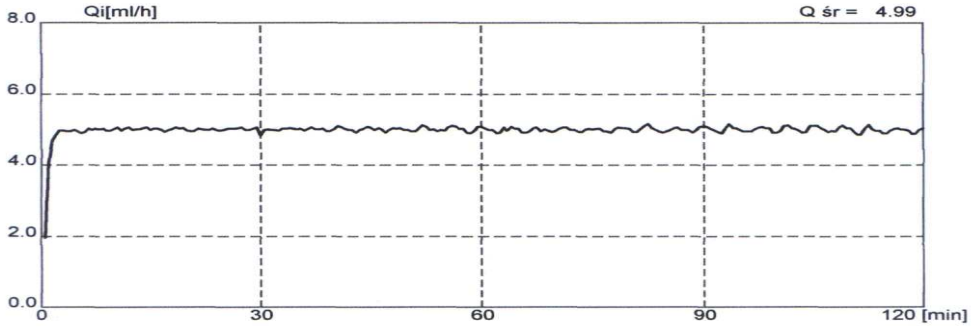
Flow rate 1ml/h and 5 ml/h. Liquid density 0,99823 [g/ml]



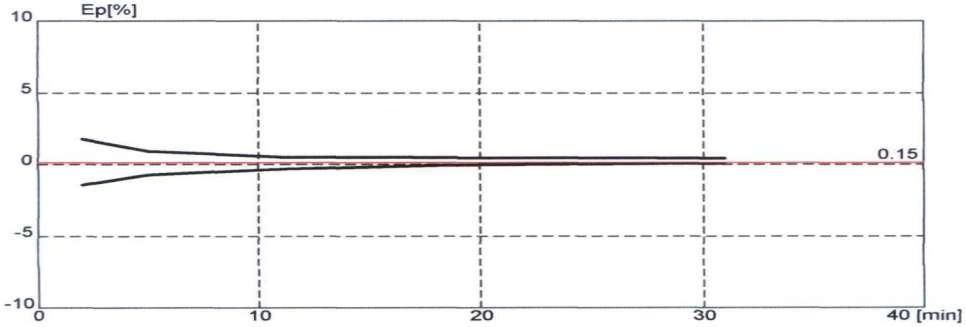
start-up-graph



trumpet curve



start-up-graph



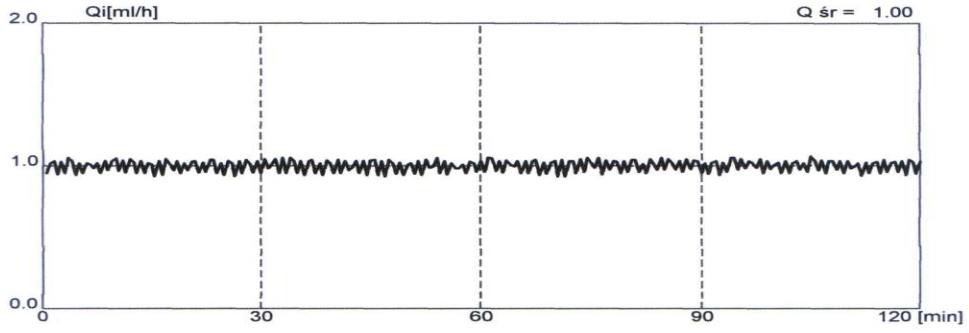
trumpet curve

Test of dosing accuracy for the syringe

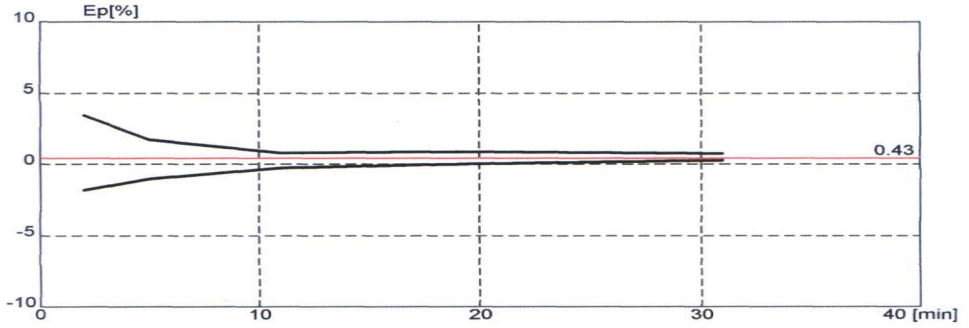
30 ml B-D PLASTIPAK

Performed in accordance with EN 60601-2-24 test 50.102

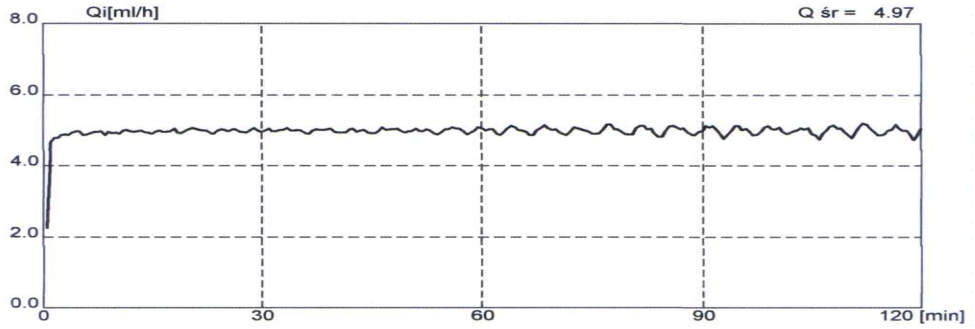
Flow rate 1ml/h and 5 ml/h. Liquid density 0,99973 [g/ml]



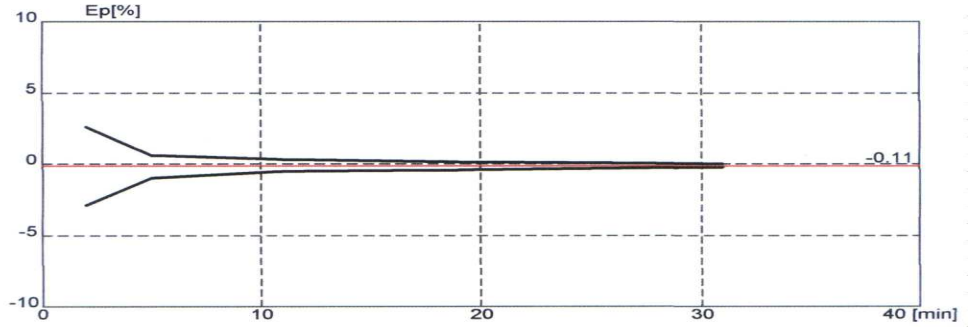
start-up-graph



trumpet curve



start-up-graph



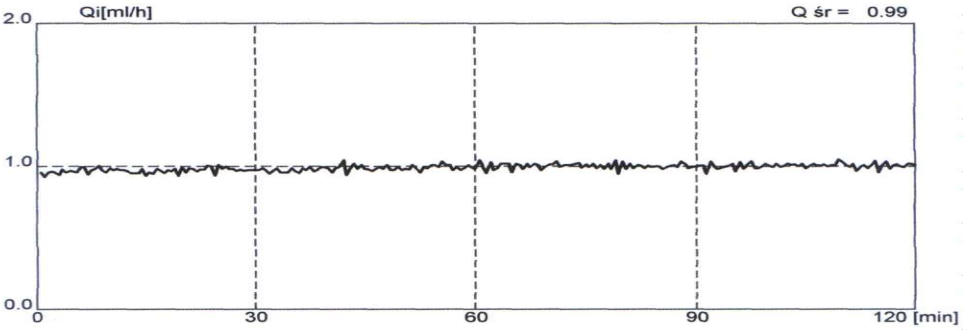
trumpet curve

Test of dosing accuracy for the syringe

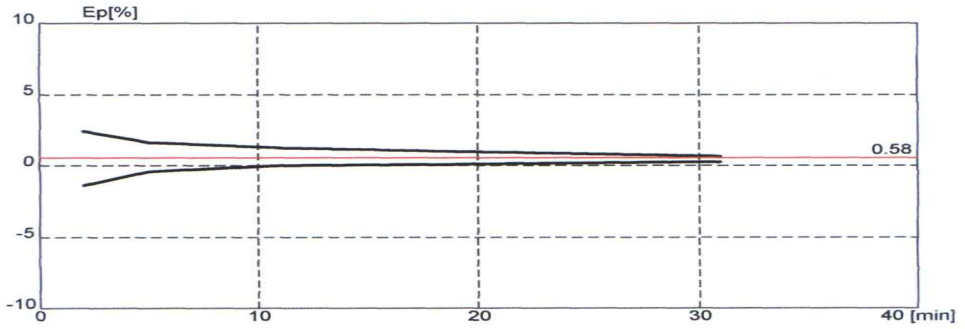
50 ml B-D PLASTIPAK

Performed in accordance with EN 60601-2-24 test 50.102

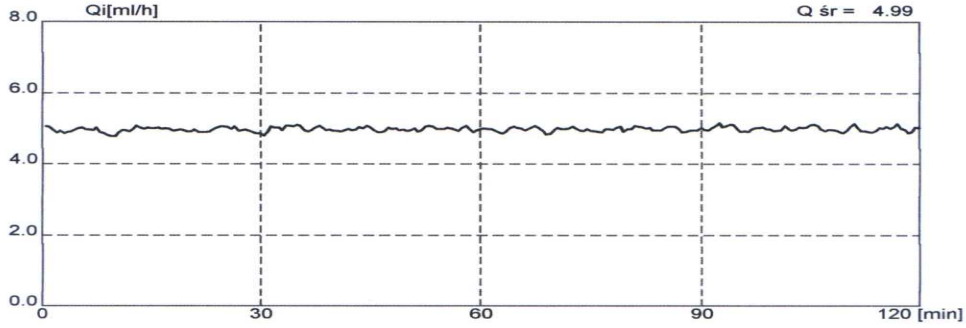
Flow rate 1ml/h and 5 ml/h. Liquid density 0,99756 [g/ml]



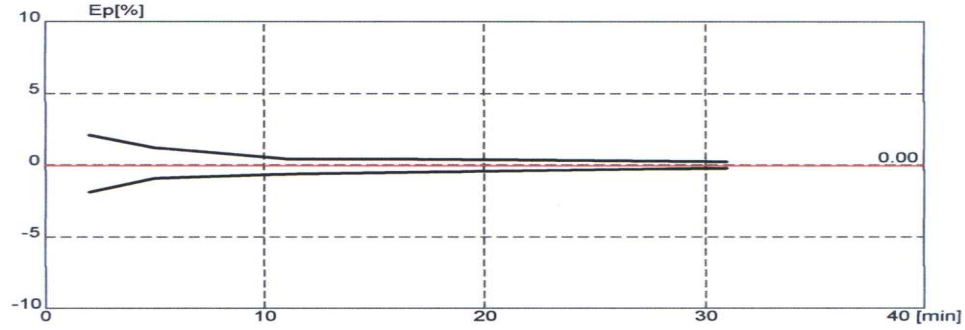
start-up-graph



trumpet curve



start-up-graph



trumpet curve

12. About product and manufacturer

Syringe pumps AP family (AP 12 and AP 22) have been produced by the Company ASCOR S.A. which introduced and maintains the Quality Management system, complying with the word and European standards, what has been approved by ISO 13485 and ISO 9001 certificates.

The devices meet the requirements of the Council Directive 93/42/ EEC - Medical Devices and are CE-marked.

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

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Guidance and manufacturer's declaration – electromagnetic emissions		
The AP 12 AND 22 is intended for use in the electromagnetic environment specified below. The customer or the user of the AP 12 AND 22 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The AP 12 AND 22 uses 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	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The AP 12 AND 22 is intended for use in the electromagnetic environment specified below. The customer or the user of the AP 12 AND 22 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	Complies	Floors should be wood, concentrate or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%r
Electrical fast transient burst IEC 61000-4-4	+/- 2kV for power supply lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1kV differential mode +/- 2kV common mode	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% Ut (dip in Ut>95%) for 0,5 cycle, <40% Ut (dip in Ut>60%) for 5 cycles, <70% Ut (dip in Ut>30%) for 25 cycles, <5% Ut (dip in Ut>95%)for 5 seconds	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AP 12 AND 22 requires continued operation during power mains interruptions, the AP 12 AND 22 is powered from the battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Spełnia normę	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: Ut is the AC mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The AP 12 AND 22 is intended for use in the electromagnetic environment specified below. The customer or the user of the AP 12 AND 22 should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated IEC 61000-4-3	3 Vrms 150 kHz-80MHz 3 V/m 80MHz-2,5GHz	2,9 V 2,9 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the AP 12 AND 22, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80MHz - 800MHz $d = 2{,}3\sqrt{P}$ 800MHz – 2,5GHz 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). Field strengths for fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. 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.

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 asses 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 the AP 12 AND 22 is used exceeds the applicable RF compliance is observed, additional measures may be necessary, such as reorienting or relocating the AP 12 AND 22

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 2,9 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the AP 12 AND 22

The AP 12 AND 22 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AP 12 AND 22 can help prevent electromagnetic interference my maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AP 12 AND 22 as recommended below, according to the maximum output of the communications equipment.

Rated maximum output power or transmitter [W]	**Separation distance according to frequency of transmitter [m]**		
	150 kHz – 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz – 800MHz $d = 1{,}2\sqrt{P}$	800MHz – 2,5 GHz $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at maximum output power not listed above, the recommended separation distance 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 range applies.

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.

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Model:
Serial no: