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

OPERATING MANUAL

SYRINGE PUMP

CE
0197

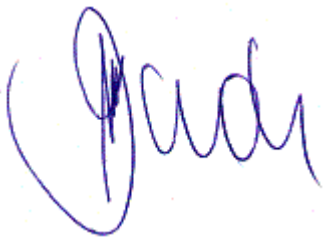
Model:	**AP 14**
Serial no.:	

Dear Customer,

Purchasing ASCOR S.A. medical equipment, You have chosen quality and reliability.

Taking into consideration the basic principles for patient's safety, ASCOR S.A. as a manufacturer of medical equipment, constantly improves its products and adjusts them to Your requirements and expectations. So, our company is willingly waiting for Your suggestions and notes concerning usage and working of our devices.

We may guarantee that all reported remarks will be taken into consideration whilst designing of our new products.



President of the Board

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1. Read this section carefully!

Remarks on operation safety

Read this instruction manual carefully before the pump startup.

- **The pump may be operated only by qualified medical personnel, thoroughly acquainted with this manual instruction and/or trained by an authorized personnel of Ascor S.A.**
- **Before the first put into operation, the device should be connected to the mains supply for full battery charge before first operation (power cable plugged in and power switch on the back side of the pump in position I, green LED on the front panel should light up).**
- **Attention! Use syringes specified by the pump manufacturer for infusion with AP pumps. All syringes accepted for usage with the AP 14 pumps are listed in Table on page 6. These are three-part syringes, i. e. with a rubber plunger. The manufacturer's name, capacity and corresponding messages are included in the table on page 6.**

Usage of inappropriate syringe or a syringe different from programmed one, may lead to significant infusion errors, which in consequence may cause a danger to patient's life!

- **Should contact the Ascor S. A. local distributor or Ascor S. A. directly, in case of any doubts concerning used syringes or infusion errors.**
- **Should contact the Ascor S. A. local distributor or Ascor S. A. directly, in case of any doubts concerning the accuracy of infusion and attach the pump with appropriate syringe to send to authorized Ascor S. A. service.**
- **Should the syringe be immediately removed from the pump assembly, in case of any suspicion incorrect pump operation.**
- **Attention! Lifting a non-installed syringe connected with patient's body by extension line higher than 30 cm from the position of syringe needle may result in uncontrolled inflow caused by the negative pressure generated in the syringe.**
- **Syringes, as disposable components, should not be used longer than 24 hours.**
- **The pump is not equipped with extension line of air detection system. Before starting the infusion, the pump operator is obliged to check for any air bubbles in the extension tubing or in the syringe. Use button "<" (at the moment when "PRIME <<" message is displayed) to prime the extension line with fluid.**
- **It is recommended to connect the pump to the external alarm (nurse call) system.**
- **The pumps can only be hanged on the specially designed infusion stands.**
- **No other devices or objects (e. g. aprons) can be hanged on the pump assembly.**
- **No vessels with fluids (e. g. cup of coffee or tea etc.) can be placed on or by the pump.**
- **AP 14 pumps were tested on a standard, 150 cm long, PVC extension tube, external diameter 2.3 mm and internal diameter 1.1 mm (if not stated otherwise).**
- **Attention! BOLUS flow rate and volume is set automatically (default flow rate for each syringe type and 0 ml volume).**
- **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 patient's reach.**
- **The medical personnel should inform the patient that tampering with the pump keyboard by any unauthorized person may cause serious risk to the patient's health or life.**
- **If a pump underwent an impact, e.g. as a result of falling on a hard surface, it should be sent to the hospital service department in order to undergo correct operation tests described in this instruction manual. Should the pump be sent to an authorized Service Company, in case of any irregularities.**

- **Any irregularities interfering with the proper functioning of the pump should be immediately notified to the manufacturer, together with a detailed description of the problem, working conditions, environment, external factors, equipment operating in the pump vicinity, etc., which have influenced on performance of the equipment.**
- **Operation of the pumps in operational conditions not foreseen by the manufacturer (e.g. in temperatures exceeding the ranges described in this instruction manual) may pose risk to patient's life or health.**
- **The device should not operate in an environment where inflammable or explosive mixtures of anesthetic gases or explosive vapors are stored.**
- **AP 14 pumps are equipped with batteries that allow their operation without connection to the mains. If pumps are stored without connection to the mains, their batteries must be recharged every two months. The pump indicates the battery status while operation.**
- **Before sending the pump to the Service Company, it should be disinfected according to the disinfection instruction included in the manual.**
- **Pump life is estimated for 10 years, fulfilling guidelines included in this Operation Manual and systematic maintenance inspections conducted every 12 months (post-guarantee period).**
- **It is advisable for the pump to be returned to the manufacturer, after its operation period has expired, in order to be legally utilized.**
- **AP 14 pumps meet the conformity requirements of the European standard EN 60601-2-24:2004 and the general standard PN-EN 60601-1:1999 within the scope of safety requirements.**
- **Pumps AP 14 meet the conformity requirements of the standard on electromagnetic compatibility (EMC) EN 60601-1-2:2002. However, we suggest that the pumps should not work in immediate proximity to other equipment that does not meet the requirements of EMC and has no CE marking, and which may emit strong electromagnetic radiation. This also refers to 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 AP 14 pump,**
  - **230 V AC power cable,**
  - **operating manual.**

  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 an adequate packing is used, Ascor S.A. cannot guarantee avoidance of transport damages.
  In case any irregularities are noticed, please inform our service department before the device startup.

List of syringes acceptable for usage with AP14 pump

Message displayed	Full name of the syringe	Manufacturer
10 BBRAUN OMNIFX	B/BRAUN Omnifix 10 ml	B.BRAUN Melsungen AG
10 B-D PLASTIPAK	B-D Plastipak 10 ml	BECTON DICKINSON Drogheda, IRELAND
10 CODAN/ONCE	CODAN 10 ml or ONCE 10 ml	CODAN Medical System
10 MONOJECT	MONOJECT Kendall 12 ml(cc)	TYCO / Healthcare UK KENDALL
10 PENTA	PENTA (PF) 10 ml	PENTAFERTE S.p.A. Campli -Teramo - ITALY
10 SHAN CHUAN	SHAN CHUAN Syringe Set 10 ml/cc	SHANCHUAN Medical Instrument Co. Ltd.
10 TERUMO	TERUMO SYRINGE 10 ml	TERUMO Europe N.V., BELGIUM
20 BBRAUN OMNIFX	B/BRAUN Omnifix 20 ml	B.BRAUN Melsungen AG
20 BBRAUN PERFUS	B/BRAUN Original- Perfusor 20 ml	B.BRAUN Melsungen AG
20 B-D PLASTIPAK	B-D Plastipak 20 ml	BECTON DICKINSON Drogheda, IRELAND
20 CODAN/ONCE	CODAN 20 ml or ONCE 20 ml	CODAN Medical System
20 MONOJECT	MONOJECT Kendall 20 ml	TYCO / Healthcare UK KENDALL
20 PENTA	PENTA (PF) 20 ml	PENTAFERTE S.p.A. Campli -Teramo - ITALY
20 SHAN CHUAN	SHAN CHUAN Syringe Set 20 ml/cc	SHANCHUAN Medical Instrument Co. Ltd.
30 BBRAUN OMNIFX	B/BRAUN Omnifix 30 ml	B.BRAUN Melsungen AG
30 B-D PLASTIPAK	B-D Plastipak 30 ml	BECTON DICKINSON Drogheda, IRELAND
30 CODAN/ONCE	CODAN or ONCE 30-35 ml	CODAN Medical System
30 ICOGAMMA	ICOGAMMA Plus 30 ml	NOVICO S.p.A Ascoli Piceno, ITALY
30 INFUJECT	INFUJECT 30 ml	DISPOMED WITT oHG Gelnhausen, GERMANY
30 MONOJECT	MONOJECT Kendall 30 ml	TYCO / Healthcare UK KENDALL
30 PENTA	PENTA (PF) 30 ml	PENTAFERTE S.p.A. Campli -Teramo - ITALY
30 TERUMO	TERUMO SYRINGE 30 ml	TERUMO Europe N.V., BELGIUM
50 BBRAUN OMNIFX	B/BRAUN Omnifix 50 ml	B.BRAUN Melsungen AG

50 BBRAUN PERFUS	B/BRAUN Original Perfusor 50 ml STANDARD or SCHWARZ	B.BRAUN Melsungen AG
50 B-D PERFUSION	B-D Perfusion 50 ml STANDARD or AMBER	BECTON DICKINSON Drogheda, IRELAND
50 B-D PLASTIPAK	B-D Plastipak 50 ml STANDARD or AMBER	BECTON DICKINSON Drogheda, IRELAND
50 B-D PRECISE	B-D Precise 50 ml	BECTON DICKINSON SINGAPORE * 639461
50 CODAN/ONCE	CODAN or ONCE 50-60 ml STANDARD or AMBER	CODAN Medical System
50 CODAN PERF.	CODAN Perfusion 50-60 ml STANDARD or AMBER	CODAN Medical System
50 ERG	ERG Kołobuck	ERG Kołobuck S.A., POLAND
50 ICOGAMMA	ICOGAMMA Plus 50 ml	NOVICO S.p.A Ascoli Piceno, ITALY
50 INFUJECT	INFUJECT 50 ml STANDARD or AMBER	DISPOMED WITT oHG Gelnhausen, GERMANY
50 INJECTOMAT	INJECTOMAT-Spritze 50 ml	FRESENIUS Kabi Gmbh, DEUTSCHLAND
50 IVAC	IVAC 50 ml	IVAC Medical System
50 MARGOMED	MARGOMED 50(60) ml STANDARD or AMBER	MARGOMED Lublin, POLAND
50 MONOJECT	MONOJECT Kendall 50 ml	TYCO/Healthcare UK KENDALL
50 PENTA/AMBER	PENTA (PF) 50 ml AMBER	PENTAFERTE S.p.A. Campli -Teramo - ITALY
50 PERFUJECT	PERFUJECT 50 ml STANDARD or SCHWARZ or AMBER	DISPOMED WITT oHG Gelnhausen, GERMANY
50 SET INJECT	SET Inject 50 ml	TIBSET Istambul, TURKEY
50 SHAN CHUAN	SHAN CHUAN Syringe Set 50 ml/cc	SHANCHUAN Medical Instrument Co. Ltd.
50 TERUMO	TERUMO Syinge 50 ml STANDARD or AMBER	TERUMO Europe N.V., BELGIUM
60 PENTA	PENTA (PF) 60 ml	PENTAFERTE S.p.A. Campli -Teramo - ITALY

ASCOR S.A. guarantees that the basic requirements of 93/42/EEC Directive are fulfilled for syringe pumps operating with syringes with CE mark and listed in the Table above.

2. Pump application

AP 14 syringe pump is designed for precise dosage of drugs and infusion fluids to the patient. It is intended for:

- intensive care units,
- cardiosurgery units,
- pediatric units,
- operating theatres,
- ambulances.

The pump is simple to operate, reliable and is of general application. It is suitable for various types of single-use syringes. BOLUS function enables quick and repeated delivery of bolus doses to the patient, with accurately established volume and within a specified infusion time.

Pump can operate without connection to the mains. The pump is automatically supplied by the internal battery in cases, e. g. of 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.

3. Pump view

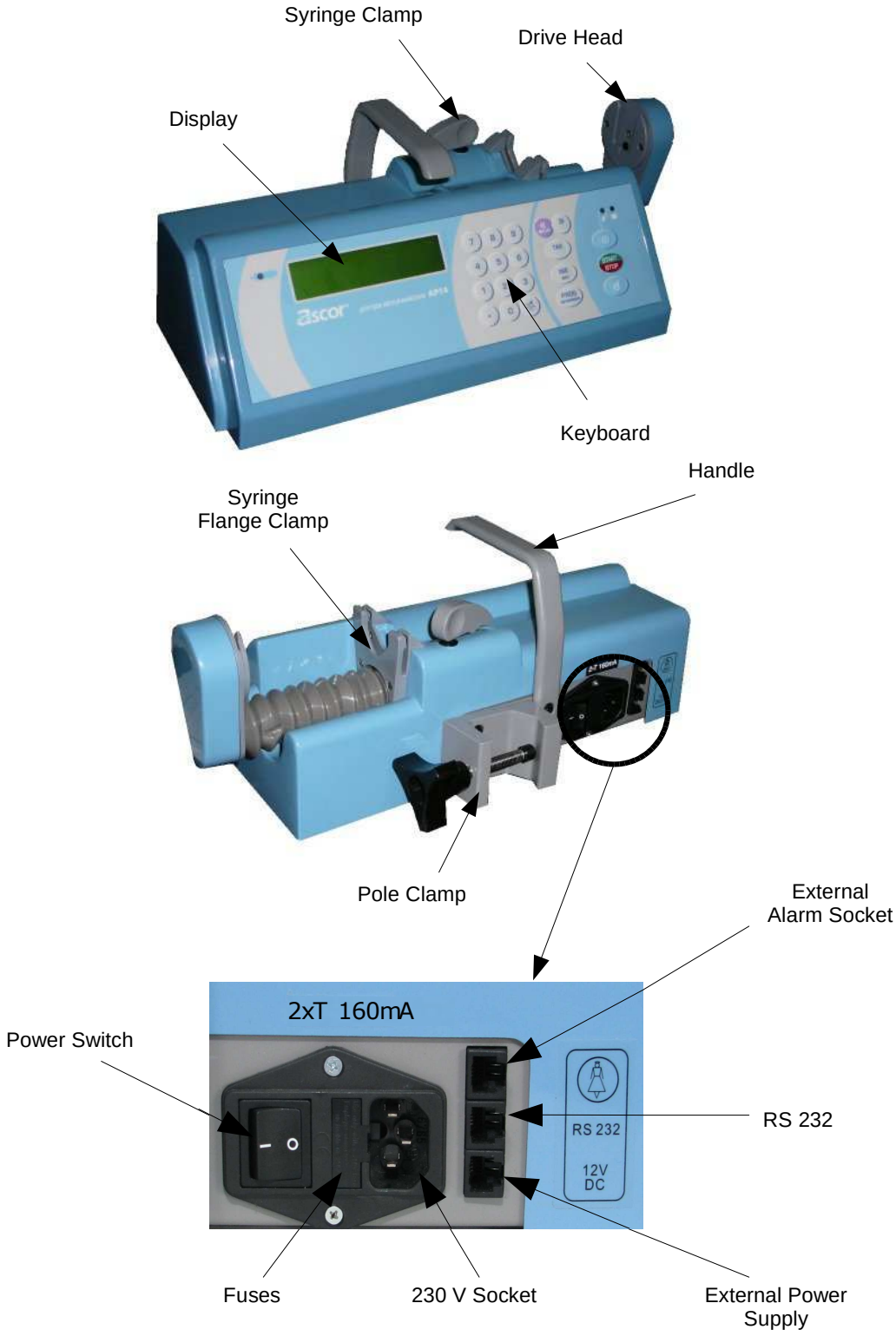


Fig. 1. AP 14 pump.

4. Pump performance

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

AP pumps are also equipped with a correct fixing sensor of a syringe plunger in the pump arm, which makes the pump startup impossible in case of incorrect syringe installation.

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

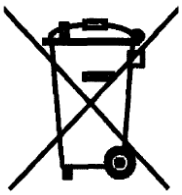
The internal microprocessor calculates with high accuracy the speed of motor rotation in accordance with the properly preset infusion parameters. Moreover, the microprocessor controls infusion timing and volume, displays information and messages, checks for occlusion and monitors the battery status.

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

Description of the most important symbols:

– Attention! Read the Operating Manual

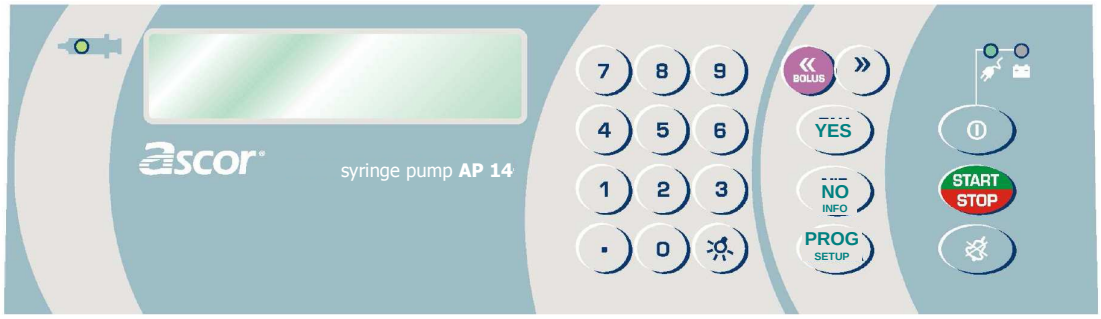
– Class BF device

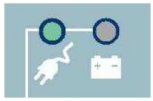


- Separate collection

5. Pump operation

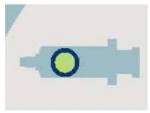
AP 14 pump – Keyboard description





Green lamp indicates the pump connection to 230 V AC mains and battery charging;

When the right LED flashes in orange, the pump is powered by the battery



Shining green lamp indicates infusion in progress

Shining in red, signals the end of infusion or alarm

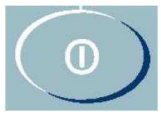
Used for confirming displayed information and saving any new entries or modifications of infusion parameters

Resets or rejects displayed information;

It also serves as **INFO** and enables scrolling the information on infusion status

PROGRAM - starts setting infusion parameters;
It also enables setting or modification of bolus volume, bolus rate and pressure limit in running course

Used to start or stop the infusion

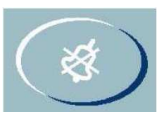


ON/OFF - used to switch on or switch off the pump;
Press for 3 seconds to switch off the pump

Enable quick movement of an arm to the left or to the right;
left button is also used for activating BOLUS function;
both can be used for NAME entering procedure

0-9

Numeric buttons for entering parameters



Acoustic alarm mute button

Used for changing the backlight of the display

Button for entering decimal values and for sending history information to the computer. It gives a possibilities to an interview of changes of characteristic infusion parameters during their persitence

5.1. Installation and preparation for operation

Preparing the pump for operation includes 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's level.

It is possible to mount the pump on a horizontal tube (e.g. by patient's bed) by removing two screws that hold the pole clamp (Fig. 1), turn the clamp by 90° and replace the two fixing screws. Make sure the clamp is correctly fixed to the pump body and begin the installation on a horizontal tube.

Attention! In horizontal positioning the pump may turn downwards, e.g. while setting the parameters (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 pole clamp.
2. Insert the pump plug power cable into the 230 V mains socket equipped with grounding pin.
3. Set the pump main switch to "1" (green lamp MAINS should light up).

The pump is ready for setting 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 to the patient's body through the extension tubing, is dangerous for the patient. Lifting of the syringe higher than 30 cm over the level of the needle position (in patient's body) may result in intrinsic infusion caused by under-pressure inside the syringe.
- The syringe should be installed only at the moment when the pump arm has been automatically adjusted to fit the syringe and "**Install syringe"** message is displayed. Do not push or pull the pump arm by force to install the syringe. Arm position can be adjusted either automatically or only by pressing "**<**" or "**>**" buttons.
- The syringe should be fixed in such a way that its stem end is inside the drive head, and the syringe flange is in the syringe flange clamp (Fig. 1). Next, the syringe must be locked with the syringe clamp (Fig.1), positioned perpendicularly to a syringe axis. Make sure the syringe plunger is positioned along the syringe axis.
- After inserting a syringe filled with drug, when the message **"Prime <<"** is displayed press "**<**" button to prime the extension line and remove air bubbles from it. Be careful to remove all air from the tubing – infusion fluid must flow out of the needle – before the needle is inserted into the patient's vein. **Manufacturer recommends priming the extension line with fluid using the pump, as described above.**
- If the occlusion pressure is a critical parameter, we recommend to use large syringes, of volume up to 50/60 ml.

One should bear in mind that the pump detects occlusion only when the pump arm is stopped by excessive pressure in the catheter and in the syringe. Since the pressure increases gradually due to catheter expansion, occlusion indication is delayed. The delay depends on the infusion flow rate, the length and flexibility of the catheter. In order to shorten the time of occlusion detection as well as to reduce the volume of drug collected in the expanding extension tubing, we recommend using special

high-pressure, short, low internal diameter and thick-wall catheter, especially with low infusion flow rates.

5.2. Setting infusion parameters

Syringe pumps AP 14 can be operated in standard (STANDARD) or anesthesia (ANESTE) mode. Infusion parameters are set in the same way in both operation modes.

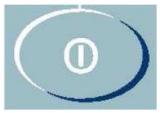
STANDARD MODE enables programming of infusion parameters in basic units, such as: rate in ml/h, volume in ml and time in hours/minutes.

ANESTE MODE has a drug/dose calculation capability and enables programming of infusion parameters in mass units (e. g. flow rate in mg/kg/h) with additional presetting of drug concentration (e.g. mg/ml) and patient weight (in kg).

Operation mode can be selected in the following way.

Press:

and while keeping it pressed, switch the pump on with ON/OFF button:



The following information will appear on the display:

Menu

And after a while:

→ **Settings**
Service

Press **YES** to enter Settings.

→ **Change password**
Operation mode

Press **NO** to switch over to **Operation mode.**

→ **Operation mode**
KVO

Enter Operation mode by pressing **YES.**

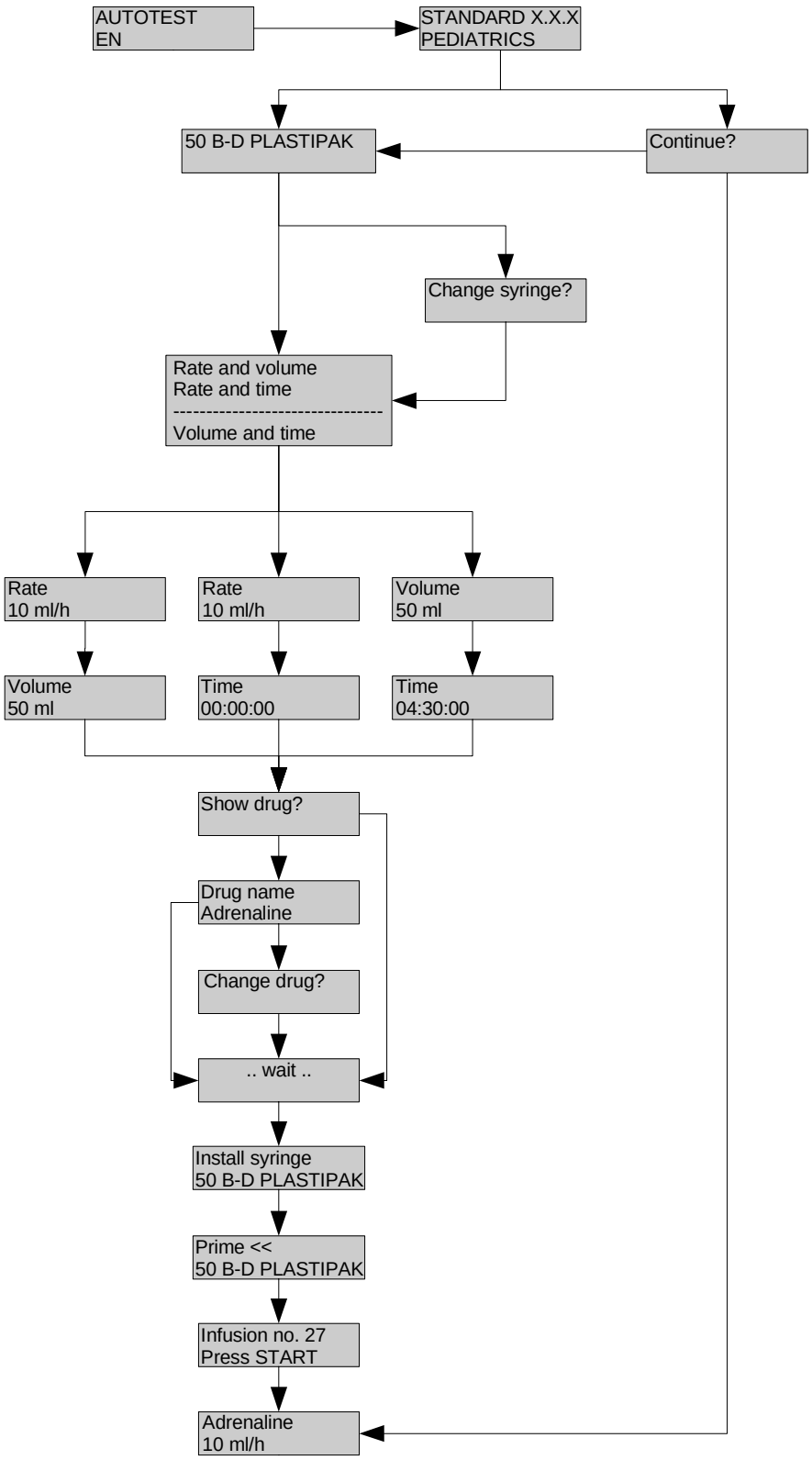
Operation mode
→ **STANDARD**

Press **NO** to select the STANDARD or ANESTE operation mode and confirm it by pressing **YES**.

Press **PROG** to exit **Operation mode** and then by pressing **NO** select **Setup exit**. Press **YES**.

5.2.1. Setting infusion parameters in STANDARD mode

The program diagram for the STANDARD mode:



All infusion parameters are divided into three groups, depending on the usage frequency. Simplified scheme of particular parameters, which allows quick orientation in their localization, is shown below.

1. Basic parameters:

These parameters allow setting the basic infusion.

Their overview and setting is possible directly after switching on the pump.

The basic parameters are as follows:

- syringe type,
- flow rate (ml/h) & volume to be infused (ml)

or:

- flow rate (ml/h) and time of infusion,

or:

- volume (ml) and the time of infusion

Additionally, the following parameters may be used:

- drug name,

and

- time of infusion,
- time of pause,

The last two parameters are activated during the setup of parameters (STANDBY – on) included in the group of additional parameters (see below).

For detailed description of programming basic parameters read Chapter 5.2.1.1 (page 16).

2. Auxiliary parameters:

This group of parameters is available during the infusion and can be preset or, should need arise, modified in running course without the need for infusion interruption. Auxiliary parameters are available when press button:

They can (but don't need) be set for each infusion.

Attention!

After turning on the pump, values of BOLUS flow rate and volume return to basic settings (default flow rate for each syringe type and 0 ml volume).

Pressure limit is memorized from the last infusion.

The auxiliary parameters are as follows:

- Bolus rate in ml/h,
- Bolus volume in ml,
- Pressure limit

For detailed description of setting auxiliary parameters read Chapter 5.2.1.2 (page 19).

3. Additional parameters:

Parameters of this group are rarely set. Once programmed they will be memorized by the pump. They can be programmed or modified only before starting the infusion setup. Any modification in running course (without switching the pump off) in not possible.

The following additional parameters can be programmed in AP syringe pump:

- Password protecting all infusion parameters against unauthorized modification
- Operation mode (STANDARD or ANESTE),
- KVO - infusion rate in keep-vein-open mode in ml/h,
- Alarm – volume and type of sound alarm,
- Standby - STAND-BY function on/off
- Anti-bolus – enabling residual bolus reduction after occlusion release,
- Ward name
- Drug library - edition or introduction of a new drug name,

For detailed description of programming additional parameters read p. 5.2.1.3 (page 20).

5.2.1.1. Basic parameters

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

Standard – X.X.X PEDIATRICS	where X.X .X defines the software version installed

If any irregularities are detected, the pump is automatically locked and a sound alarm is activated. Please contact with our maintenance personnel in order to carry out inspection or repair if such situation repeats.

A ward name will appear in case when it was introduced earlier in additional parameters.

After a test conducting the pomp starts preparing cycle to work.

In case of AC mains power failure or if the pump is not connected to the mains, the following message will be displayed:

NO MAINS	230V AC or 12V DC power supply is absent

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

Next two different messages may appear:

a) for continuing the interrupted infusion, the following message is displayed:

Continue ?	should the previous infusion be continued?

This occurs when the pump was switched off before the infusion has been completed. Pressing **YES** will enable the recent infusion to be continued according to the previously set parameters and the

existing status of the volume counter. Pressing **NO** will mean resetting the volume counter and beginning the setup of a new infusion.

b) type of the syringe (e. g. 50 ml syringe, type B-D PLASTIPAK) used for the last infusion is displayed:

50 B-D PLASTIPAK	check, whether this type of syringe is to be used in the current infusion

The syringe type describes its volume in ml and the manufacturer's name. Should be confirmed by pressing **YES** if recent syringe type is going to be used for current infusion. Then pump pass to the programming infusion speed. **NO** button should be pressed, if another syringe volume or type is to be used.

The following question is displayed:

Change syringe ?

Confirming by pressing **YES** begins the procedure of changing the syringe type. Selection can be made by pressing **NO**, "**<**" **or** "**>**" repeatedly, until the right type of syringe appears on the display. To make the selection faster press number **5** if 50 ml syringe is to be used thus 50 ml syringes will be displayed one by one (accordingly pressing **2** will make 20 ml syringes available). The choice should be confirmed by pressing **YES**.

Next, the type of parameters setting should be selected, which is:

- Rate and volume, or
- Rate and time, or
- Volume and time.

→ **Rate and volume**
Rate and time

Select by pressing **NO** and confirm by pressing **YES**.

Having selected e. g. **Rate and volume**, the following message appears on the display:

Rate **xxx ml/h**	enter the required infusion rate in ml/hour

Flow rate can be set in 0.1 ml/h increments. The maximum infusion rates are as follows: 2000 ml/h (for syringes 50 ml), 1200 ml/h (for syringes 30 ml), 1000 ml/h (for syringes 20 ml) and 600 ml/h (for syringes 10 ml), depending on the previously set syringe type. If the set flow rate is too high, the system displays the maximum acceptable value for the chosen syringe type:

Maximum **XXX.X ml/h**	maximum infusion flow rate is XX.X ml/h

The display will show Rate with the maximum level. The correct data should be entered and confirmed by pressing **YES**.

The next parameter will be:

Volume **XX.X ml**	enter the required infusion volume in ml

The field xx.x shows the volume of the last infusion. Pressing **NO** will delete this value and allow entering a new one, which should be confirmed by pressing **YES**. The maximum value of the infusion volume is 999 ml and equals the volume of a few (more than a dozen) syringes. Exceeding the total infusion time of 100 hours can cause limitation of the entered volume.

Leaving this parameter out (by pressing NO – to delete the previous value and then YES to exit without entering any value) or setting it for zero (0) is acceptable, but in such case "END OF INFUSION" alarm will not be activated (see chapter 5.5 page 36), and the pump will not stop working until the syringe is emptied (the alarm EMPTY SYRINGE will be activated).

When **Rate and time** has been selected, after setting rate of infusion the time of infusion may be entered:

Time **XX.XX.XX**	enter infusion time: hours : minutes : seconds

The maximum infusion time is 100 hours (exactly 99 hours, 59 minutes and 59 seconds). Frequent limitation of the time entered is the exceed condition of the total infusion volume of 999 ml.

The field XX:XX.XX can show the previously set time value. If it is to be changed, enter new numbers from left to right. Blinking digit indicates a position, where a number can be entered from the numeric pad. The entered single digit can be deleted at any time by pressing **NO**. When the correct time value is completed, press **YES** for confirmation. **Similarly as in case of volume, this parameter can be left out (with no value entered) or set to zero, which will result in the above described pump performance**.

The same way of programming should be applied when **Volume and time** has been selected. In such case, the microprocessor will automatically calculate the infusion rate in ml/h.

Next, the following question appears on the display:

Show drug?

If both drug name and flow rate are to be displayed during infusion, answer **YES** and the name of the drug recently used shall appear as follows:

Drug name **Adrenaline**	name of drug recently preset

If the same drug is to be infused, press **YES**. To change the drug name press **NO**. The following question will appear on the display:

Change drug?

Answer **YES** and information about one of four subsequent drug groups will be displayed:

Group of drugs
Group 1

You can change groups by pressing **NO** and confirm with **YES** to enter the group and select a specific drug name. **Selection of drug names can be easily done with** "**<**" **and** "**>**" **buttons.** First two drug groups include drugs entered by the manufacturer in alphabetical order, whereas the next two include drugs of the user (information on how to enter the drug names, see: 5.4.6, page 34).

If the pump is to be used in a STAND-BY mode, two additional parameters, described under item 5.4.4, page 33, should be set.

After pressing **YES** the message **... wait...** is displayed and the pump arm automatically withdraws into proper position for syringe installation and the following message appears on the display:

Install syringe
50 B-D Plastipak

The syringe filled up with drug should be installed (**according to the notes of chapter 5.3, page 30**). Both buttons of the arm movement "**<**" and "**>**" are active and allow its proper adjustment to the position of the syringe plunger.

AP pumps are equipped with a sensor which detects the syringe size (10, 20-30, 50ml) and compares it with the preset types. If the inserted syringe volume is different from the preset one, the following message will be displayed:

WRONG SYRINGE

When the correct syringe is installed and clamped, the following message is displayed:

Prime <<
50 B-D Perfusion

Prime the tubing by pressing**"<"** to remove air bubbles.

Afterwards the following massage could show:

LOW LIQUID

This message indicates amount of oversized liquid, which was destined to drain priming. Remained amount of liquid in the syringe is lower than programmed dose. It means that before "Syringe empty" message appears, infusion will not be ended and programmed dose will not be fully dosed. In that case, it is necessary to take the syringe out and prime it. Otherwise, press **START** or **YES** button to start infusion , which require inserting next syringe to finish the infusion.

The next message means that the pump is ready for operation.

Infusion no. 158
Press START

Press **START** or **YES** to start the infusion.

5.2.1.2. Auxiliary parameters

Presetting, modification or viewing the auxiliary parameters can be done as soon as basic parameters are set, or any time in the running course or during a temporary pause in infusion. It is recommended to set parameters for each infusion, because they are not memorized by the system. After turning on the pump, values of BOLUS flow rate and volume return to basic settings (default flow rate for each syringe type and 0 ml volume).

BOLUS setting

Access to the described parameters is possible by pressing **PROG**:

The first auxiliary parameter is:

Bolus rate
XXX ml/h

Bolus rate in ml/h

where XXX defines the default bolus rate for the syringe which is currently in use. Depending on the syringe size used, the default Bolus rate can be as follows: 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 blank, the pump will deliver a bolus dose at a doubled infusion flow rate.

Attention!

- **The pump will not accept a BOLUS flow rate lower than the preset doubled infusion flow rate. For example, when the infusion flow rate amounts to 5 ml/h, 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 will appear on the display:

Bolus volume XX.X ml	Bolus volume in ml

Enter the required value and confirm it by pressing **YES**.

If the Bolus volume is not preset, the infusion in BOLUS mode will be continued as long as BOLUS button is pressed. When infusing Bolus, its already delivered volume will be displayed in ml. The volume of the drug administered in BOLUS mode will be summed up with the total volume of the drug administered to the patient during the basic infusion.

Startup of the BOLUS function is described in more details in chapter 5.4.2., page 32. BOLUS function can be stopped by pressing **START/STOP**.

Setting the limit level of infusion pressure.

The next parameter that will be shown is the pressure level, at which ”OCCLUSION” alarm should be activated. The alarm may be activated due to an excessive pressure caused by , e.g. a crushed tubing (catheter) or an obstructed syringe needle.

The occlusion pressure limit can be preset on one of the following 9 levels:

- from 40 to 120 kPa, every single 10 kPa.

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

Pressure Limit 80 kPa

Selection and changing of the new pressure is made by pressing **NO** button repeatedly, until the required occlusion pressure level is displayed. Confirm it by pressing **YES**.

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

Attention!

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

5.2.1.3. Additional parameters

This group of parameters enables the user to customize the pump features. The setting procedure should start when the pump is switched off.

To enter the additional parameters, proceed as follows: press the button:

and switch the pump on, while keeping it pressed. The following message will be displayed:

Menu

Automatic access to the following options is available:

"Settings" **– setting of additional parameters**

"Service" - reserved for authorized service only

"Tests" - user tests, see chapter 7, page 40,

"Event log" - saved infusion history, see chapter 5.6, page 37,

"Setup exit" - allows **EXIT** from Menu

"Production" - reserved for manufacturer's production staff only

Selection of Menu options can be easily done with "<" or ">" or NO buttons.

Select **Settings** to program additional parameters of infusion:

→Settings
Service

and enter by pressing **YES**. Further selection in Settings of the additional parameters can be done with "**<" or ">" or NO** buttons.

The first parameter which appears on the display is:

→Change password
Operation mode

"Change password" option enables entering a new one or modifying the previous password to protect all infusion parameters against any unauthorized modification.

Press **YES** to enter:

→PASSWORD

In this case, the parameters were not locked with a password. Entering a number (**other than zero**) in the range between 1 and 999999 and confirming it by pressing **YES** will mean that the infusion parameters will be protected with a password. In such case, before any modification of infusion parameters, the following message will be displayed: "**PASSWORD**". To get access to modification of infusion parameters, the correct password must be entered from the keyboard and confirmed by pressing **YES**.

Attention!

If you forgot the password – read chapter 5.7, page 39.

If the password protection is not to be used, enter "**0"** and confirm by pressing **YES**.

The next parameter is the **"Operation mode"** of the pump:

→Operation mode
KVO

Press **YES** to enter and than select by pressing **NO** the operation mode: STANDARD or ANESTE. Confirm it by pressing **YES**.

STANDARD mode allows programming infusion rate in ml/hour only. ANESTE mode has a drug/dose calculation capability and allows programming infusion rate in mass units, e. g. mg/kg/h with regard to the patient weight. From this data and the drug concentration, the pump will automatically calculate the rate in ml/h.

Setting a particular operation mode of the pump means that the pump shall be ready for operation in this particular mode, right after the pump start-up.

The next parameter is the infusion flow rate in the KVO mode:

KVO
X.X ml/h

KVO (Keep Vein Open) function means that instead of complete infusion stopping, e.g after pressing **STOP** button, a minimum flow rate is maintained in order to keep the needle patency (avoiding clotting). A typical flow rate of such infusion is 0.5 ml/h, but in certain cases its increase is required. Its value can therefore be set within the range 0 - 5.0 ml/h. Leaving this parameter out means setting it for 0,5 ml/h, **while entering "0" ml/h and confirming by pressing YES will switch this function off.** Volume of the fluid received by the patient during the activated KVO function adds up to the total quantity of drug received by the patient. KVO 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! KVO rate cannot be higher than the basic infusion flow rate. Therefore, if the infusion rate is 0,5 ml/h and KVO rate preset at 0,6 ml/h, it will actually be activated at the rate of 0,5 ml/h, that means equal to the rate of the basic infusion.

The third parameter is:

→ Alarm
Standby

There are two settings of this parameter: type and volume.

→ Alarm type
Alarm volume

Press **YES** to chose the type of alarm. The acoustic alarm sound can be continuous

(_____) or intermittent (- - - -).

→ Alarm type
_ _ _ _ _ _ _ _

Choose the required one by pressing **NO** and confirm it by pressing **YES**.

The next parameter is **Alarm volume:**

→ Alarm volume
Alarm vol. 0

Enter this option by pressing **YES**, and select the required alarm volume by pressing **NO**. You can select:

- Alarm vol. 0 - low volume
- Alarm vol. 1 - medium volume

- Alarm vol. 2 - high volume

Confirm the required alarm volume by pressing **YES** and exit by pressing **PROG**. Subsequently, you go to the next parameter" "Standby".

→ Standby
Anti-bolus

This function allows to cyclically stop the infusion. Selecting "Standby on" will result in adding two additional parameters to the basic group: the time of infusion (infusion) and the time of pause (pause). For description of "STANDBY" function, see chapter 5.4.4, page 33.

Another parameter is "Anti-bolus":

→ Anti-bolus
Ward name

Its activation means that in case of excessive pressure in the tubing, the pump shall automatically reduce the pressure to the normal level once the alarm is triggered. Thus the residual bolus after occlusion release will be significantly reduced.

The next parameter is "WARD NAME":

→ Ward name
Drug library

Here, the name of the hospital ward may be entered. It can be entered in accordance with "Procedure of NAME introduction", chapter 5.4.6, page 34.

The next parameter allow entering the name of the administered drug, which is displayed during infusion, together with the infusion flow rate.

→ Drug library
Change password

By pressing **NO** button we can move on between individual drug groups and enter to the one selected with **YES** button. All drugs previously entered into the library can be viewed, cancelled and modified here.

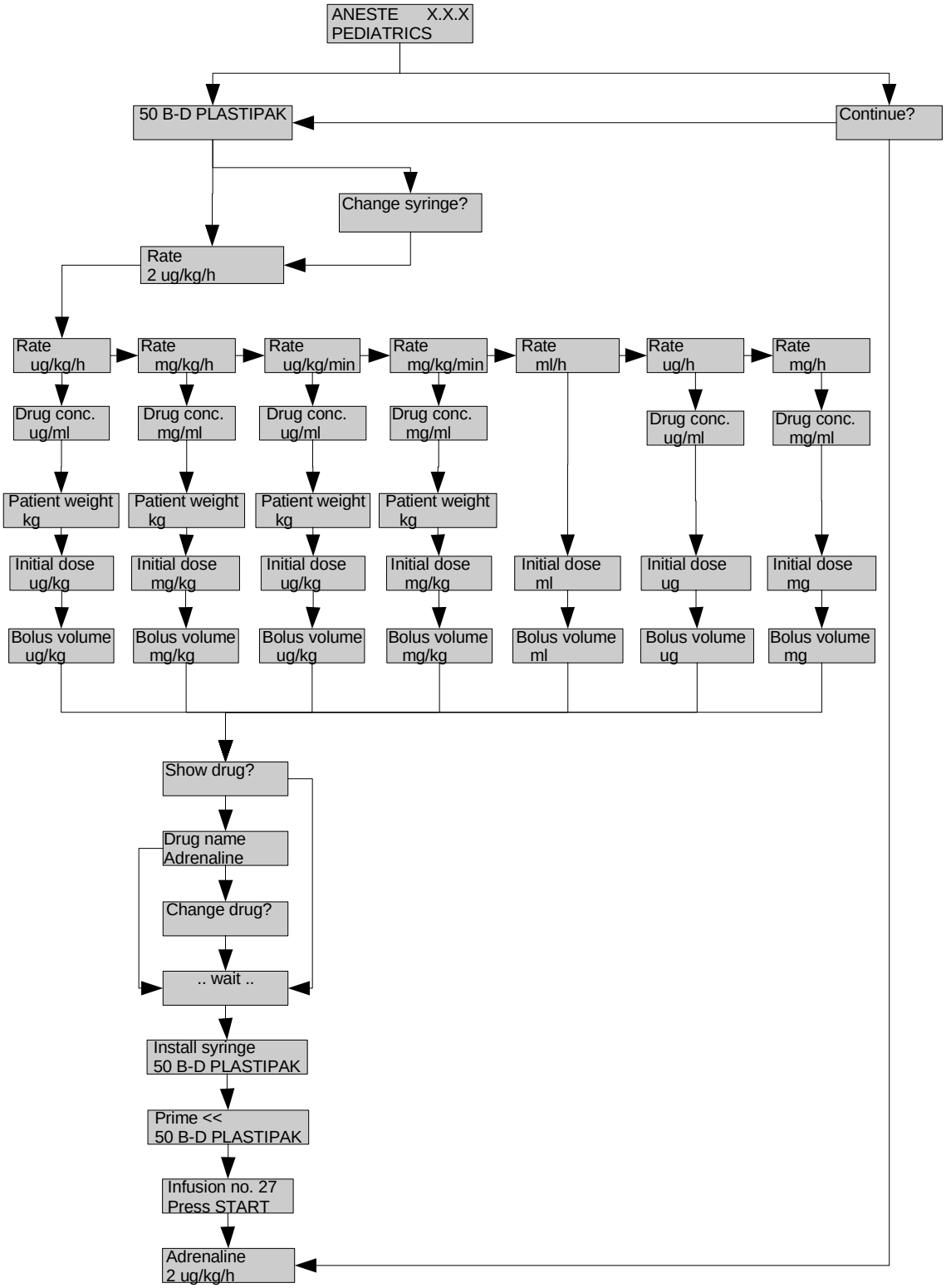
→ Group of drugs
Drugs 1 - 4

The first two groups include drugs in alphabetical order entered by the manufacturer, the next two enable to create the user's drug list. Information on how to enter drug names, see "Procedure of NAME introduction", chapter 5.4.6, page 34.

For exit press:

5.2.2. Setting infusion parameters in ANESTE mode

The program diagram for the ANESTE mode:



The way of setting infusion parameters in ANESTE mode is analogous to the way of settings in STANDARD mode. ANESTE operation mode should be set first in “Settings” parameters (see 5.2.1.3, page 20). Infusion parameters in this mode are additionally divided in three groups:

1. Basic parameters:

- syringe type and volume,
- Rate - infusion flow rate (ml/h; µg/h, mg/h, µg/kg/h, mg/kg/h, mg/kg/h, µg/kg/min, mg/kg/min),
- Drug conc. - drug concentration (µg/ml, mg/ml),
- Patient weight (kg),
- Initial dose (ml, µg, mg, µg/kg or mg/kg),
- Bolus volume (ml, µg, mg, µg/kg or mg/kg)

In addition, other parameters may appear (after setting Standby on in additional parameters):

- drug name,
- infusion time,
- time of pause,

2. Auxiliary parameters:

- Bolus rate,
- Bolus volume,
- Pressure Limit - occlusion pressure limit.

3. Additional parameters:

- Password
- Operation mode (STANDARD or ANESTE),
- KVO rate (ml/h),
- Alarm type,
- Alarm volume,
- STAND-BY function on/off,
- Anti-bolus option on/off
- Ward name - name of the hospital ward
- Drug library edition or introduction of a new name,

5.2.2.1. Basic parameters

After switching the pump on with **ON/OFF** button, if no irregularities were found the display will show:

Aneste X.X.X EN PEDIATRICS	where X.X .X defines the software version installed

If any irregularities are detected, the pump is automatically locked and a sound alarm is activated. This alarm could be switched off by mute button. If such situation appears repeatedly, please contact our maintenance personnel in order to carry out inspection or repair, if such a situation appears repeatedly.

A ward name will appear in case introducing it earlier in additional parameters.

In case of AC mains power failure or if the pump is not connected to the mains, the following message will be displayed:

NO MAINS	230V AC or 12V DC power supply is absent battery lamp blinks on orange

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

Next, two different information can appear:

a) for continuing the interrupted infusion, the following message is displayed:

Continue ?	should the previous infusion be continued?

This occurs when the pump was switched off before the infusion has been completed. Pressing **YES** will enable the recent infusion to be continued according to the previously set parameters and the existing status of the volume counter. Pressing **NO** will mean resetting the volume counter and beginning the setup of a new infusion.

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

50 B-D PLASTIPAK

The syringe type describes its volume in ml and the manufacturer's name. Should be confirmed by pressing **YES**, if recently used syringe type is going to be used for current infusion. **NO** button should be pressed, if another syringe volume or type is to be used.

The following question is displayed:

Change syringe ?

Confirming with **YES** begins the procedure of changing the syringe type. Selection can be made by pressing **NO** repeatedly, until the right type of syringe appears on the display. To make the selection faster press "5" if 50 ml syringe is to be used thus 50 ml syringes will be displayed one by one (accordingly pressing "2" will make 20 ml syringes available). The choice should be confirmed by pressing **YES** button. To change type of syringe, arrow buttons could be use too.

The next parameter to be set is as follows:

Rate
xx.x µg/kg/h

infusion flow rate in µg/kg/h

The infusion units can be changed. The existing value can be cancelled by pressing **NO** and then a new one selected by pressing **NO** until the required one is displayed**.** The following units are available in ANESTE operation mode:

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

Confirm the chosen unit by pressing **YES** enter the required value from the keyboard and confirm it by pressing **YES** (confirmation of the value and the selected unit of the infusion).

The next parameter is as follows:

Drug conc.
xxx.x µg/ml

Enter a drug concentration with numerical keyboard and confirm it by pressing **YES**.

The next parameter is as follows:

Patient weight
xx.x kg

Enter the patient weight in kg (max. 300 kg in 0,01 kg steps) and confirm by pressing **YES**. Once the weight is entered and accepted, the next parameter appears on the display:

Next parameter:

Initial dose
xx.x µg/kg

initial dose to be infused at the very beginning of infusion

The initial dose appears in the unit: **ml, µg, mg, µg/kg** or **mg/kg** respectively to the infusion unit selected earlier.

Enter the required initial dose value and confirm it with **YES** button or leave the parameter blank or preset as "**0**".

The next parameter is as follows:

Bolus volume
xx.x µg/kg

bolus volume in µg/kg

Bolus volume can be programmed in ml, µg, mg, µg/kg, or mg/kg. The value of the unit could be defined or not. If the value of the bolus volume will not be defined, bolus amount will be dependent on time pressing 'bolus' button. After volume confirmed (**YES** button) the following question will appear on the display:

Then the following question will appear on the display:

Show drug ?

show the drug name during infusion

When answered with **NO**, the infusion can be started. If answered with **YES**, the drug name can be selected and confirm by pressing **YES**.

Additionally, other parameters may also be displayed, once the group of the required additional parameters (STANDBY) has been set

- infusion time
- time of pause

When programming of infusion parameters has been completed, the following messages will be displayed:

Remove syringe	This will appear if the syringe is installed in the pump

or

.. wait ..

Remove the syringe (if earlier installed) and wait until the pump's arm withdraws into proper position to fit the syringe. The automatic arm withdrawal is necessary for it's correct calibration.

When arm stops, the following message appears:

Install syringe **50 B-D Plastipak**

By pressing "**<**" or "**>**" buttons, adjust the arm position for the syringe installation. Do never push or pull the pump's arm by force. The syringe filled with drug should be installed in the pump and clamped (according to **"Syringe installation" chapter 5.3, page 30**).

AP pumps are equipped with a sensor which detects the syringe size (10, 20-30, 50-60 ml) and compares it with the preset types. If a syringe is inserted with volume different from the preset one, the following message will be displayed:

WRONG SYRINGE

Install the correct (preset) syringe type or change the preset syringe type, if mistake was made (according to p. 5.2.2.1, page 26). When the correct syringe is installed and clamped on the pump, the following message is displayed:

Prime << **50 B-D PLASTIPAK**

Press "**<**" button to prime the extension tubing and thus remove air bubbles from it.

At the moment when the extension line is filled with the infusion liquid, press **STOP**.

The next message:

Infusion no. 268 **Press START**

means that the pump is ready for operation.

To start the infusion, press **YES** or **START**.

5.2.2.2. Auxiliary parameters

Auxiliary parameters include Bolus rate, Bolus volume and Pressure limit, i.e. occlusion pressure.

Modification or scrolling for viewing the auxiliary parameters can be done as soon as the primary parameters are set 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 existing settings.

This group of parameters is the same way in STANDARD and ANESTE operation modes. Their set-up is analogous.

For the detailed description of set-up see chapter 5.2.1.2, page 19.

5.2.2.3. Additional parameters

This group of parameters is analogous to the standard operation mode.

For the detailed description of set-up see chapter 5.2.1.3, page 20.

5.3. Syringe installation

As soon as the presetting procedure is completed, the following message is displayed:

.. wait ..

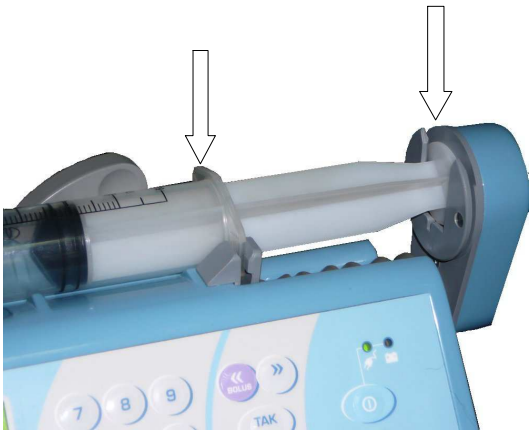
and the pump's arm will be adjusted automatically to install the syringe according to the earlier preset parameters. Additionally button "**<**" and "**>**" can be use to accurately alignment.

Install syringe **50 B-D Plastipak**

preset syringe type is displayed in bottom line

Hook the syringe plunger in the clamp

Press **[<<]** or **[>>]** for precise positioning of the pump arm to fit in the syringe flange into the clamp



If a volume of syringe is different than the preset one is inserted, the following message will be displayed:

WRONG SYRINGE

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

Prime << **Press START**

Press "**<**" button to prime the extension tubing and thus remove air bubbles from it. At the moment when the extension line is filled with the infusion liquid, press **STOP**.

Attention! Before starting the infusion process make sure there are no air bubbles in the syringe and in the tubing.

Next, the following message appears:

Infusion no. 368 **Press START**

To start the infusion press **START** or **YES**.

5.4. Infusion

5.4.1. Starting and stopping infusion

Once the pump parameters are set and the syringe is fixed, the infusion can be initiated. It can be done by pressing **START**. Infusion is indicated by yellow LED blinking as well as by the following alternate messages:

Nitroglycerine **X.X ml/h**	Drug name - Nitroglycerine X.X – preset flow rate in ml/h

In order to stop infusion for a while (without switching the pump off), **START/STOP** button should be pressed.

The pump switches over to delivering in "**KVO**" (keep-vein-open) mode, and the following message is displayed:

STOP X.X ml/h **KVO X.X ml/h**

where XX ml/h is the preset infusion rate and KVO rate (bottom line)**.**

Press **START** to continue infusion. Stopping the infusion for more than 2 minutes will activate an acoustic alarm.

If the infusion is going to be stopped for more than 1 minute, it is advisable to do this by switching the pump off with **ON/OFF** button. The pump will memorize all data of the recent infusion (also volume infused). When the pump is switched on again, the question **Continue?** will be displayed. Answering it with **YES** will mean continuation of the interrupted infusion.

As soon as the infusion has been completed (volume preset has been delivered or preset time of infusion has elapsed), the following message will be displayed:

END OF INFUSION
KVO X.X ml/h

The pump automatically switches over to KVO mode.

5.4.2. BOLUS function

AP 14 pumps have a bolus (quick shock dose) administration capability. To activate Bolus, press and hold for 3 seconds

This will be announced with the message:

BOLUS XXX ml/h
X.XXX ml

Bolus rate in ml/h
Bolus volume delivered in ml

Both the **Bolus rate** and the **Bolus volume** are programmable parameters.

For the detailed description of the way of programming Bolus rate and Bolus volume, read chapter 5.2.1.2, page 19.

If the volume is not preset, the infusion in "bolus" mode is continued as long as button "**<**" is kept pressed**.** If the volume is set, the infusion will be stopped as soon as the set volume of drug is administered. In such case holding "**<**" button is not necessary.

Infusing Bolus of preset volume can be stopped by pressing STOP or switching the pump off with ON/OFF.

Infused Bolus volume is summed up with the volume of drug administered during a basic infusion. If the preset volume of basic infusion is reached during the Bolus infusion, the infusion will be stopped, and „END OF INFUSION" alarm will be activated.

ANTI-BOLUS – is the next additional parameter. This function assures decrease of negative results of occlusion. Anti-bolus causes receding pump arm, decrease of pressure in drain and recapture of drug excess from elastic drain to syringe. Due to it, after opening drain, uncontrolled emerging of drug does not follow.

OCCLUSION
ANTI-BOLUS?

Function ANTY-BOLUS starts up by pressing **YES** button. Then, pump automatically reduces hypertension caused by occlusion. This function allows to decrease risk of injection under accrued pressure of drug portion after opening drain. If button **NO** will be pressed, the following message will appear:

OCCLUSION
Press Start

Attention!

During the infusion pause caused by occlusion, K.V.O function is unavailable.

5.4.3. Information on the infusion status

At any moment during infusion, there is a possibility of checking its status. This can be easily done by pressing **INFO** button repeatedly.

The following information will be displayed one by one:

→ Volume XX.X ml	XX.X – total volume to be infused in ml
→ Volume infused XX.X ml	XX.X – volume in ml, already infused
→ Remaining volume X.X ml	XX.X – remaining volume in ml, to be infused
→ Time/empty XX:XX:XX	XX:XX:XX – time left until the syringe gets empty – hour:min:sec
→ Time/end XX:XX:XX	XX:XX:XX – time left to complete the infusion – hour:min:sec
Pressure ■■■■■■□□□□□□□□	current pressure level
Battery ■■■■■■■■■■■■□□	current battery status

Press **NO** in order to return to infusion rate display. The information on the infusion status can be checked as often as it is required and will not affect the infusion process

5.4.4. STANDBY function

In order to get STANDBY function active, enter additional parameters and select Standby on option. Standby function allows to program the time of infusion and the time of pause. When Standby on option is selected, the following two parameters are added to the basic group:

Infusion
XX.XX:XX

and

Pause
XX.XX:XX

XX.XX:XX describes the time of infusion and the time of pause in hours/minutes/seconds. When the infusion time expires the alarm "MUTE ALARM, PRESS STOP" is activated, the infusion should be stopped. Pause will last as long as the Pause time has been preset. After that period, alarm "MUTE ALARM, PRESS START" will be activated and the infusion should be continued. This cycle will be continued until the end of infusion.

5.4.5. Modification of parameters

It is possible to change the parameters in running course without the need for infusion interruption.

- To change the **flow rate**, enter a new value with number keys and confirm it by pressing **YES**.
- To change the **volume,** press **INFO** key, and when Volume is displayed enter a new value and confirm it by pressing **YES**.
- To change **Bolus rate**, press **PROG** in running course of infusion, and when Bolus rate is displayed enter a new value and confirm it by pressing **YES**.
- To change **Bolus volume**, press **PROG** in running course of infusion, and when Bolus volume is displayed, enter a new value and confirm it by pressing **YES**.
- To change **Pressure limit**, press **PROG** in running course of infusion, select Pressure limit (by pressing **NO**)**,** enter a new value and confirm it by pressing **YES**.

Please remember that if not confirmed (entered) by pressing **YES**, the modification will not be active.

Modification of additional parameters (KVO rate, Standby, Alarm type, Alarm volume, Drug name) requires switching off the pump.

It is also impossible to change the syringe type during the infusion process. This parameter can only be modified after stopping the infusion and removing the syringe from the pump.

5.4.6. Cancellation of capacity numerator while infusion

Pressing **NO** button, answering on question "**Continue?**", will cause cancellation of capacity numerator. Similar infusion end will cause its cancellation.

Attention!

Cancellation of numarator capacity while infusion will cause losing information about d amount of drug served to patient.

5.4.7. Procedure of NAME entering

Hospital ward name can be entered before setting the pump, the drug library can also be modified by entering new items. It is necessary to become acquainted with the method of entering character. The names are entered during the navigation through the pump menu. Two parameters Ward name and Drug library can be reached in the SETTINGS set.

- **Ward name**

After entering WARD NAME (by pressing **YES**), the following information will appear on the display:

Ward name _	or “empty” name without entry

or previously entered:

Ward name **ONCOLOGY_**	or “empty” name without entry

In the first case, it is possible to enter directly a new name, in the second case, the previous name should be deleted by pressing **NO** to delete each character separately and only then a new drug name can be entered.

Horizontal cursor indicates the edition spot of a new character. The characters should be entered with the following buttons.

Figures could be entered directly from the keyboard, or by pressing “**<**” generates subsequent figures from 1 to 9 and alphabet characters from A to Z and after each successive pressing the next character appears in the position indicated by cursor. By pressing “**>**” alphabet characters appear in a reverse sequence. Each separate character entered must be confirmed by pressing **YES**. The cursor moves on the position of the successive character, which you can enter in the same way.

To save the entered name press YES for 3 seconds.

- **Drug name**

To change the drug name or to enter its new name the procedure described above should be followed.

You can view drugs which have been saved by selecting with **YES** button the **Drug library**. Drugs are grouped in four catalogues. Two of them contain drugs entered by the manufacturer group - 1 (drugs A - L) and group – 2 (drugs L - Z) and the two other consist in drug names entered by the user (group – 3 and group - 4). Each catalogue contains 16 names, which means that there are 64 drugs at the disposal of a user. To change or enter the drug into the user catalogue, select:

Group of drugs **→ Group - 4**

Next, accept the selected group and the information on the individual drugs appears on the display:

Drug name **→ 32**

Press the dot button “**.**” and then **YES** or **twice YES** to start the edition of the text. The cursor will indicate the character to be edited (it can be moved left by pressing NO), for example:

Drug name **→ 32**

or “empty” name e. g. also with the cursor

Changing the name and entering a new one according to the description above.

5.5. Alarms, messages and warnings

If an intervention of the personnel is required, it is signaled by acoustic and visual alarms (display flashing). Acoustic alarm can be switched off by button (mute)  .Type of the alarm is described on the display by respective message.

- Five minutes before the end of infusion or before the syringe gets empty one of the following alarms is activated.

5 min/end

or

5 min/empty

If the preset or the 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 it’s complete emptying – the acoustic alarm sounds and the following message is displayed:

SYRINGE EMPTY

The pump is automatically switched over to **K.V.O.** mode. The infusion can be restarted as soon as a new syringe filled with drug is installed in the pump.

- At the moment when the infusion has been completed (preset volume infused or preset time elapsed), the infusion will be stopped and the pump will be switched over to **K.V.O** mode. Infusion end will be signaled with the acoustic alarm and the following messages displayed alternately:

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

- In case of an excessive pressure in the system and consequently stoppage of the pump arm movement caused by the occlusion the following alarm is activated:

OCCLUSION!!!

The same moment operation is stopped.

The system detects occlusion only when the pressure in the tubing and the syringe is too high and thus stops the movement of the pump arm. Since the pressure increases gradually due to the expansion of the tubing, the occlusion is signaled with a delay, which depends on the infusion flow rate and the length and flexibility of the tubing. In order to shorten the occlusion detection time and to reduce the drug volume collected in the tubing, it is recommended to use special high-pressure, short, low internal diameter and thick-wall tubing, especially with low infusion flow rates.

To continue infusion, the reason of occlusion should be removed.

AP14 pumps have a special **ANTI-BOLUS** function enabling an automatic reduction of the residual bolus volume on occlusion release. It ensures reduction of negative effects of occlusion in the tubing.

When this function is activated (Menu > Settings > Anti-bolus), the pump arm is retracted, the pressure of the system reduced and the 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 the drug under pressure. This function allows to significantly reduce the risk of Bolus infusing on the occlusion release.

Attention! During the infusion pause caused by the occlusion, the KVO function is inactive.

The occlusion alarm may also appear as a result of an 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. Moreover, a flexible tube (catheter) of greater internal diameter is recommended.

The measure accuracy of 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 accurate measurement is. When the occlusion pressure is a critical parameter, the usage of large syringes, of 50÷60 ml volume, is recommended.

Attention!

Syringes of 10÷20 ml volume should be used only for very low infusion flow rates, e. g. below 1 ÷ 2 ml/hour.

During the occlusion alarm isn't possible to browse infusion parameters. These parameters are enable only after switching occlusion alarm off. As soon as the occlusion cause is removed, pressing **START** allows continuing the infusion.

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

STOP X.XX ml
NO SYRINGE

and the alarm will be activated. After the alarm is muted, and the syringe properly installed and clamped the following message will be displayed:

STOP X.XX ml
Press START

Pressing **YES** will allow the infusion to be continued.

- Alarm:

NO MAINS

and flashing red lamp  informs the operator that there is a failure of mains supply. After muting the alarm, the pump automatically switches over to the battery powering. This may be a result of the mains failure, fuse blow-out, disconnection of the power cable or switching off the main switch (Fig.1).

- Alarm:

LOW BATTERY The battery is near discharge

means that the battery will be completely discharged within about 30 minutes (at medium infusion flow rates, e. g. approx. 5 ml/h). Display will show information about infusion and battery mains.

The pump should be connected to the mains as soon as possible.

BATTERY !!!	The battery is fully discharged

5.6. Event log

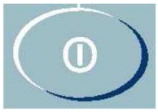
Attention! Some messages can be shown in a "cut off" version, depending on a space available on the display.

Event log allows to retrace ca 2000 events of the previous infusions. These are dates, hours, parameters and other information on the performed infusions.

Event log can be selected in **Menu** in the following way.

Press:

and while keeping it pressed, switch the pump on with ON/OFF button:



The following information will appear on the display:

Menu

And after a while:

→ **Settings**
Service

Select **Event log** by pressing **NO** or "**<**" or "**>**" and enter it by pressing **YES**.

The number and date of the last infusion will appear on the display, for example:

Infusion No. 14
2006.03.25

After pressing **NO**, information on the earlier infusions is accessible, e.g.:

Infusion No. 13
2004.03.24

After having selected the infusion number and date by pressing **YES**, the following information will be displayed:

30 B-D PLASTIPAK	Syringe type used during the infusion

Rate 6 ml/h **Volume 20 ml**	Rate of infusion Preset volume of infusion

The next information on the display is the following question:

Parameters?	Other infusion parameters?

By pressing **YES** button again, you will see in turn other preset infusion parameters:

KVO **0.5 ml/h**
Bolus rate **300 ml/h**
Bolus volume **4 ml**
Pressure limit **120 kPa**

The next information is:

Events?	Infusion events review?

Press **YES** to see the events connected with the infusion e. g.:

START 6 ml/h **13:17:09**	Infusion start hour
inf start 6 ml/h **13:17:09**	Infusion rate after the start
RATE CHANGE 10 m **14:17:09**	Change of infusion rate during the infusion
bolus start 300 **14:18:02**	Bolus administration during the infusion (bolus rate in ml/h)
inf. start 10 ml/ **14:18:50**	Return to the basic infusion
5 min/end **15:12:57**	Alarm “5 min left till the infusion end”
END **15:17:57**	Temporary stop of the infusion (pause)

KVO start 5 ml/h 14:18:02	Start time and rate of KVO
CONTINUATION 14:18:02	Continuation time of infusion

5.7. Remarks for the users

- It is important to carry out the infusion with the preset syringe type. Using other syringe, even if its appearance and volume are identical, does not guarantee a safe and accurate infusion according to the pump technical data. **This may have an impact on the patient's health and life.**
- It is recommended to use syringes with Luer Lock connectors. The Luer Lock connector secures the tubing against slipping off, e.g. when the pressure increases because of occlusion.
- **Attention!** The pump is not equipped with a system for detecting air in the tubing. The pump user must check if there are any bubbles of air in the tubing or in the syringe. To prime the extension line use "**<**" button at the moment when **Prime <<** message is displayed.
- While operation, the pump should be positioned below or at the patient's level. This secures the patient against free flow of drug from the syringe to their vein in case the syringe is removed from the pump → see **General Notes** on Page 12.
- Connection of the pump to the mains is indicated by a green lamp  . It is recommended to connect the pump with the mains even if it does not operate, in order to continue the pump battery charging (the pump can be connected to the mains for indefinite period of time). It guarantees the complete recharging of the battery.
- It is also recommended for the pump to be battery powered only in situations where the mains supply is impossible to use e.g. power failure or during the patient transportation between the hospital wards. The time necessary for the complete recharging of the discharged battery (message: **BATTERY!!!**) is approx. 24 hours. The pump can operate during the battery recharging.
- If electric voltage is present in the socket and the message **NO MAINS!!!** is displayed, it may mean that:
  1. the main power switch is in position "0" – the 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 the service personnel.
- The fuses are in the "**drawer**" just above the 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 service personnel as soon as possible.
- Every application of the pump should be carefully considered, since the operator (e.g. doctor or nurse) is responsible for its application and they should take into consideration all technical parameters of the equipment, declared by the manufacturer, as well as infusion pharmacokinetics.
- Attention: AP 14 pumps are Class A devices. It may cause radio-electric disturbances in residential environment. In such cases the user may have to use proper preventive measures.
- **In case all passwords are lost, entering code 550555 will unblock the system**.

6. Cleaning and Disinfection

Before starting the cleaning procedure, the pump should be switched off with 
button and the supply cable should be disconnected (plug removed from the socket).

Cleaning can be carried out with a cloth and a 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 its operation.

7. Manufacturer's Responsibilities

Manufacturer is responsible for safety, both of patient and user, and correct operation of the device, 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 in the working environment is performed in accordance with the requirements included in this instruction manual,
- the device is operated in accordance with this instruction manual by trained medical personnel,
- inspections, repairs and modifications were only made by an authorized service company.

The manufacturer recommends carrying out technical inspection before and after the expiry of guarantee period. These are so called TESTS, which may be conducted by the user.

After the expiry of guarantee period, systematic review of the equipments should be conducted every twelve months by an authorized manufacturer service point.

8. User Tests

AP 14 pumps are equipped with a set of tests to check the correct operation of its main subassemblies. These tests can be helpful in evaluating the condition of the pump, but they do not guarantee detection of all existing faults, if any. 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 further steps, e.g. repair by an authorized servicing company.

To start User Tests the pump should be connected to the 230 V powers supply. Press

button and without releasing it, switch the pump on

The following information will appear on the display:

Menu

and within a moment:

→Settings Service

Select **Tests** by pressing **NO** or "**<**" or "**>**" and enter it by pressing **YES**.

→Tests Event log

This will activate the user test module. The first test will be displayed. To carry out the test, enter it by pressing **YES**. Otherwise press **NO** or "**<**" or "**>**" to select the right test and enter it by pressing **YES**.

1 Display test

→Display

The test allows to state whether the display is fully active. To exit press **PROG**.

2 Keyboard Test

→Keyboard

Pressing subsequent buttons allows to check whether all buttons are active.

To exit press **PROG <u>for three seconds</u>.**

3 Test of syringe detection system

→Syringe sensor

It enables to check the syringe size identification system. Installing syringes in different sizes gives opportunity to notice whether the pump identifies the syringes in the correct way. Press **PROG** to exit.

4 Battery Test

→Battery

The battery condition is displayed here. In order to receive exact information, the power supply should be disconnected (power switch off). If the battery voltage is below 9 V or it will diminish continuously – the battery should be replaced with a new one. Press **PROG** to exit.

5 Operation Time Test

→Operating time

The parameter informs on the number of hours the pump has been operating.

Press PROG to exit a separate test and once again PROG to exit Tests option.

9. Maintenance and Repairs

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

Any repairs of the pumps can be performed only by a trained servicing company indicated by the manufacturer or the equipment distributor. Manufacturer will secure after-guarantee servicing of AP 14 syringe pump.

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 - AP 14 Pump

Flow rate:		set in 0.1 ml/h steps
	0.1 ÷ 2000 ml/h	for 50 ml syringe
	0.1 ÷ 1200 ml/h	for 30 ml syringe
	0.1 ÷ 1000 ml/h	for 20 ml syringe
	0.1 ÷ 600 ml/h	for 10 ml syringe
Mass units available:	ml/h; µg/h, mg/h, µg/kg/h, mg/kg/h, mg/kg/h, µg/kg/min, mg/kg/min	
Drug concentration:	µg/ml, mg/ml	
Patient mass:	0.1 – 300 kg	
Maximum BOLUS rate:		set in 0,1 ml/h steps
	2000 ml/h	for 50 ml syringe
	1200 ml/h	for 30 ml syringe
	1000 ml/h	for 20 ml syringe
	600 ml/h	for 10 ml syringe
BOLUS volume:	programmable in 0,1 ml 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 ÷ 999ml in 0.1 ml steps	
Infusion time:	Max. 99 hrs. 59 min. 59 sec.	
Occlusion pressure:		
Programmable 9 levels:	40-120 kPa every 10 kPa	
Syringe types:	10, 20, 30, 50 ml (producers listed in operating manual)	
Power supply:	230VAC±10%, 50Hz, 12-15 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 20 hours at flow rate of 5 ml/h
Battery recharge time:	24 hours	
Safety class:	I, BF type, IP31	
Alarm volume adjustment:	3 volume levels	
Alarm type adjustment:	continuous or intermittent tone	
Interface:	RS 232 C 9600 BD	
External alarm socket:	24V, 1A	
Other features:	reduction of residual occlusion bolus (Anti-Bolus-System)	
	automatic syringe size detection	
	large, liquid crystal display monitor 2 / 16 characters	
	information on battery status	
	drug library	
	event log	
	infusion pressure monitoring	
	hospital ward setting	
	password protected modification of parameters	
	priming	
	STAND-BY function	
	user tests	
Pump mass:	AP 14 - 3.1 kg,	
Dimensions (w × h × d):	320 × 140 × 180 mm	
Working conditions:	ambient temperature +5°C - 40°C	
	relative humidity 20% - 90%	
Time of data storage in electronic memory	10 years	
Safety:	The device complies with:	EN 60601-1, EN 60601-1-2 (EMC), EN 60601-2-24, MDD 93/42/EEC

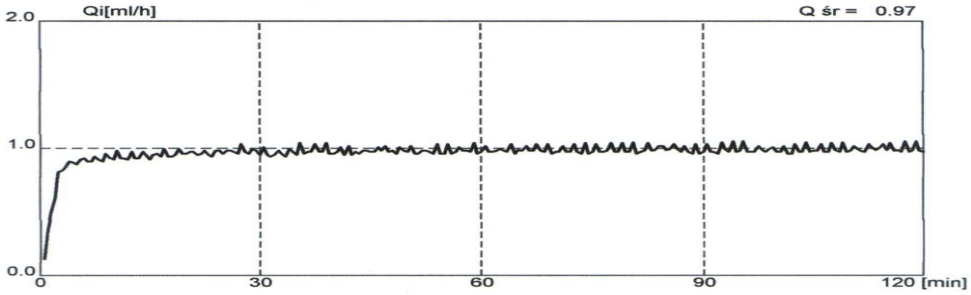
11. Examples of Trumpet Curve for selected syringes

Test of dosing accuracy for the syringe

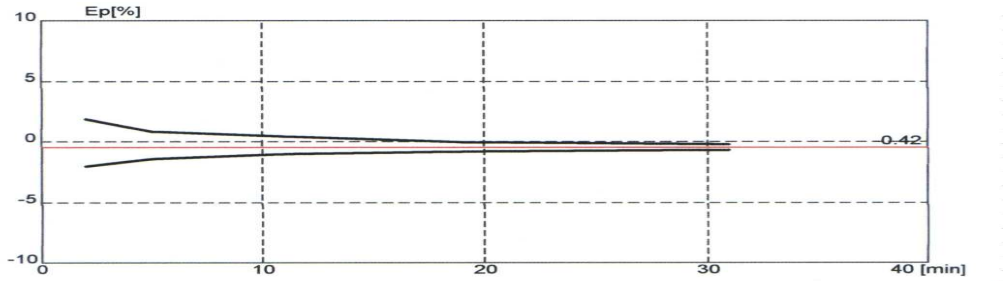
20 ml MONOJECT

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

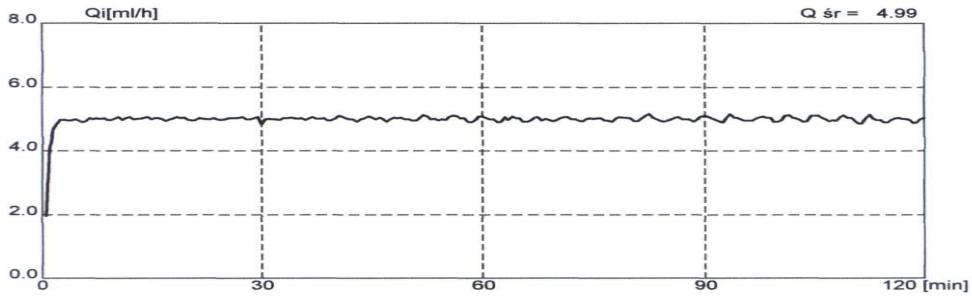
Flow rate 1ml/h and 5 ml/h. Liquid density 0,99823 [g/ml]



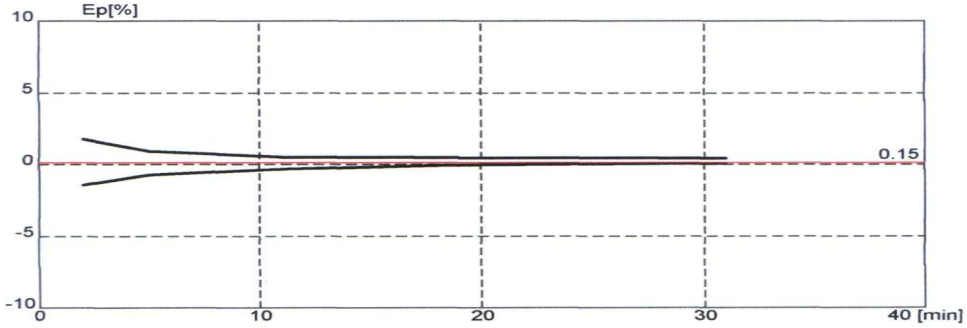
start-up-graph



trumpet curve



start-up-graph



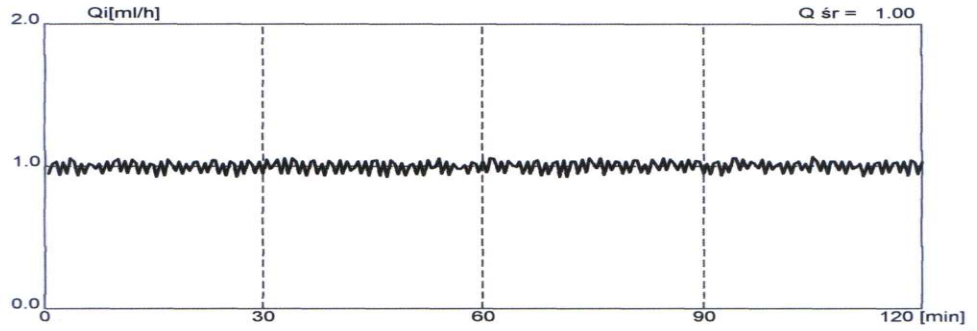
trumpet curve

Test of dosing accuracy for the syringe

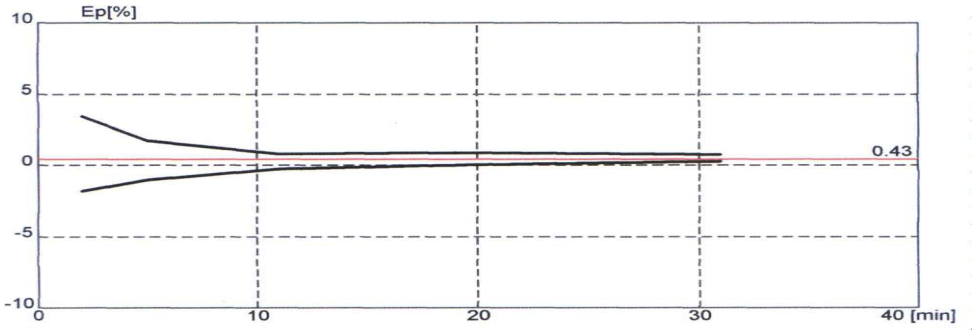
30 ml B-D PLASTIPAK

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

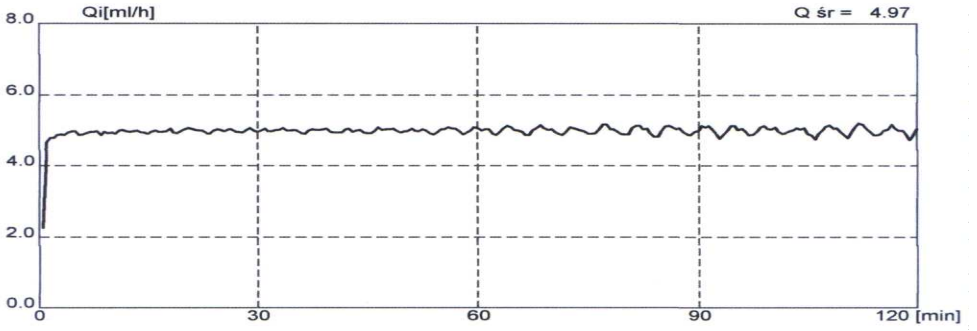
Flow rate 1ml/h and 5 ml/h. Liquid density 0,99973 [g/ml]



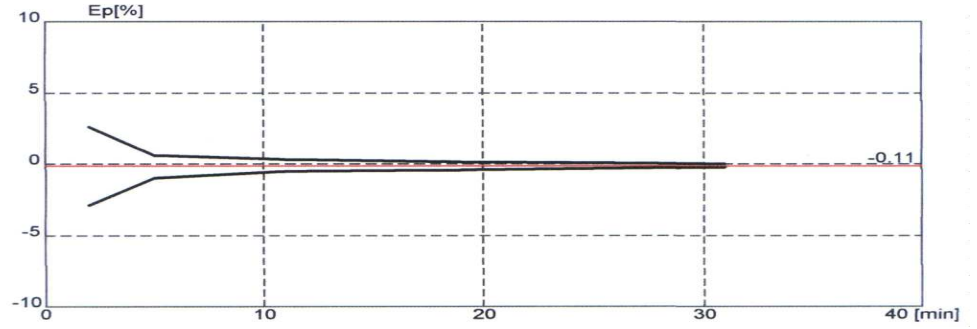
start-up-graph



trumpet curve



start-up-graph



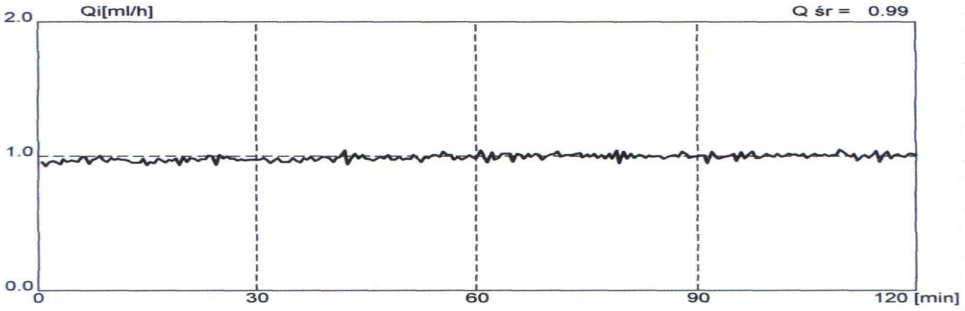
trumpet curve

Test of dosing accuracy for the syringe

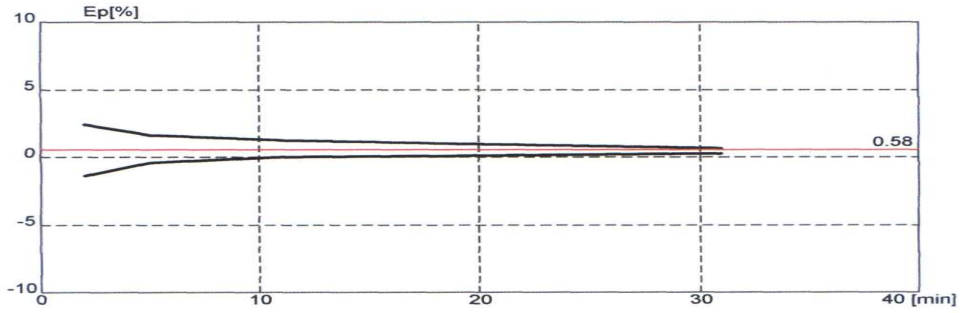
50 ml B-D PLASTIPAK

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

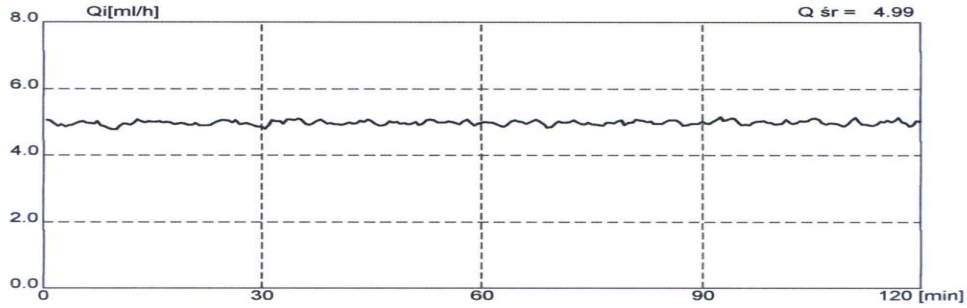
Flow rate 1ml/h and 5 ml/h. Liquid density 0,99756 [g/ml]



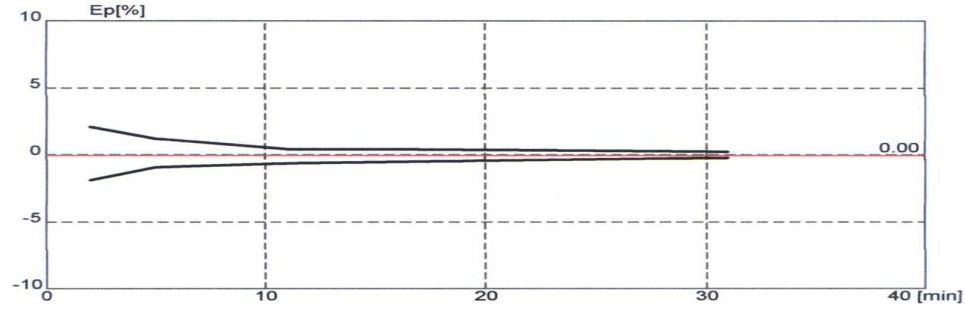
start-up-graph



trumpet curve



start-up-graph



trumpet curve

12. About product and manufacturer

AP Syringe pumps family **(AP 14)** have been produced by ASCOR S.A. Company which introduced and maintains the Quality Management System, complying with the international and the European standards, approved by ISO 13485 and ISO 9001 certificates.

The above certificates have been issued by a German notifying entity TÜV Rheinland Product Safety GmbH – Am Grauen Stein – D-51105 (not. No. 0197).

Guidance and manufacturer's declaration – electromagnetic emissions		
The AP 14 is intended for use in the electromagnetic environment specified below. The customer or the user of the AP 14 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The AP 14 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 14 is intended for use in the electromagnetic environment specified below. The customer or the user of the AP 14 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 14 requires continued operation during power mains interruptions, the AP 14 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 14 is intended for use in the electromagnetic environment specified below. The customer or the user of the AP 14 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 14, 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 14 is used exceeds the applicable RF compliance is observed, additional measures may be necessary, such as reorienting or relocating the AP 14

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 14

The AP 14 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AP 14 can help prevent electromagnetic interference my maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AP 14 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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