SYRINGE INFUSION PUMP
USER'S MANUAL

MODEL S

CE
1011

Please read these instructions carefully prior to using the device to ensure correct operation and to avoid patient injury. In case of any doubts please contact an authorized MEDIMA representative or manufacturer directly.

WI-06-01V0.0

CONTENS

1. PATIENT'S SAFETY – WARNINGS AND PRECAUTIONS

- Syringe infusion pumps are designed for the precise intravenous infusion, feeding nutrition etc. Decision concerning usage of the device can be made by the qualified healthcare professionals only.
- Only syringes of volume, name and type chosen in infusion parameters can be used. Use of another syringe than specified in the pump even of the same volume may cause significant infusion errors and patient injury. A list of recommended syringes is entered into the pump and is available during infusion programming. These are three-piece syringes with a rubber plunger and a Luer-Lock end.
- In case of any doubts concerning the used syringes, infusion errors or pump operation, immediately contact an authorized MEDIMA representative or the manufacturer directly. The pumps should be properly marked and secured to prevent accidental use until the problem is resolved.
- Connecting the extension set to the patient should be done after the syringe is loaded into the pump and the extension line is filled with fluid. Otherwise uncontrolled infusion or back flow could occur and endanger the patient. The extension set and the pump should be carefully checked for the presence of air as the pump does not have its own system of air detection in the extension line.
- The replacement of syringe should be done after the extension set is isolated from the patient. Every new connection to the patient should be done after checking for the presence of air in the line and the fixation of the syringe.
- Uncontrolled flow of medicine may result if the syringe is removed from the pump before the extension set is properly isolated from the patient.
- The pump should be mounted not higher than 70 cm above the patient heart, as it may worsen the uniformity of infusion. The most accurate pressure monitoring in the extension set is achieved when the pump is positioned close to the patient's heart level.
- The pump should be operated within a safe distance from the patient, so his accidental movements cannot stop the infusion.
- The patient must be informed by the medical personnel that touching the pump keyboard by any unauthorised persons may cause a risk to his health or life.
- If several pieces of infusion equipment are connected together, it is possible there may be mutual influence.
- Please note that simultaneous administration of various medications in the same line may cause unwanted medical effects and affect patient safety or the efficiency of the treatment. Information about possible interference between different medications should be obtained directly from their manufactures.
- The pumps should be protected against infusion fluids spills. Do not place containers with fluid directly above the pump. Any spills should be cleaned immediately.
- An explosion hazard exists if the instrument is used in the presence of flammable anaesthetics. Locate the unit away from any hazardous sources.

- (EMC) EN 60601-1-2. However, measures should be taken to place the pumps a sufficient distance from equipment emitting a strong electromagnetic field (i.e. x-ray instruments, electro surgical equipment, defibrillators and cellular telephones). If the pump is affected by this external interference it may stop the infusion and the alarm will sound.
- If the pump is struck or dropped it should be removed from service for inspection by a qualified service engineer. In case of any doubts please contact an authorized MEDIMA representative or the manufacturer directly. The damaged device should be properly marked or secured as to prevent accidental use.
- For power supply use grounded outlets only.

2. DIFFERENCES BETWEEN MODELS

- Medima - Model **S**
  A base, very simple model operates in: ml/h, ml/min, ml/24h, ml+h and in continuous infusion mode only. Gives the possibility to enter and display up to 120 drug names.
- Medima - Model **S1**
  This model allows infusion in ml/h and in many other mass units like: ng, µg, mg, µU, mU, U, kU, µmol, mmol, mol, / kg / min, h, 24h and operates in many advanced modes: continuous infusion, infusion with profile and intermittent infusion. Additionally allows recording drug library (up 120 drugs) but without limits on parameters.
- Medima - Model **S2**
  Offers capabilities of model S1 and additionally enables to enter upper and lower, soft and hard limits for all infusion parameters (see p. 19.3 , page 26)
- Medima - Model **S-PCA**
  The pump is designed to improve management of acute post operative pain. Syringe cover with lock and patient's bolus button is provided. Additionally the pump offers capabilities of model S2.

3. MAINTENANCE

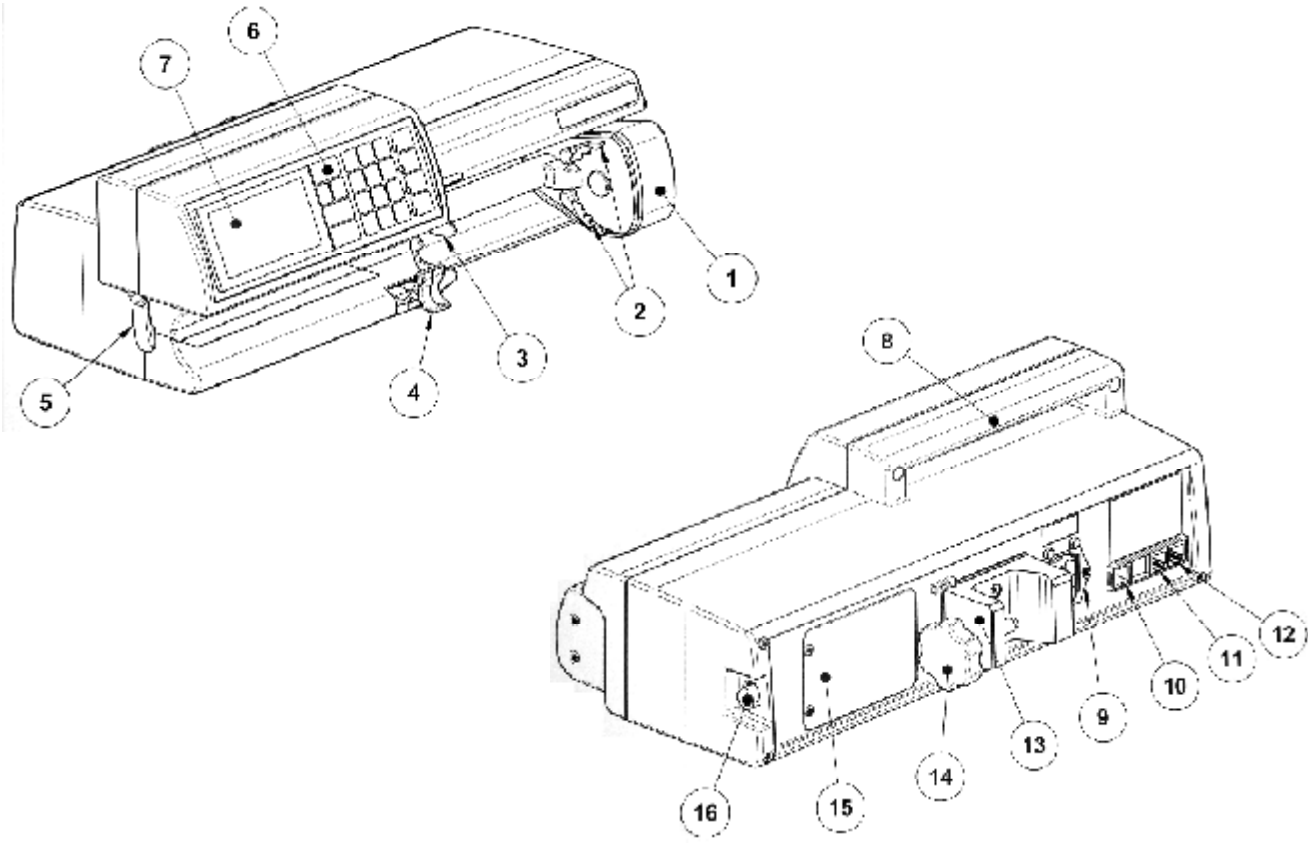
- For correct and safe operation the manufacturer recommends to carry out a technical inspection every two years.
- All maintenance work and repair should be done only by the personnel trained by the manufacturer. In case of any doubts concerning correct pump operation, the device should be removed from service and properly marked or secured as to prevent accidental use until the problem is resolved by an authorized MEDIMA representative or the manufacturer.
- Before dispatching the pump to the maintenance workshop, it should be cleaned and disinfected.
- Original packaging is recommended to prevent possible damages during transport.

4. MANUFACTURER'S RESPONSIBILITY

The manufacturer is responsible for the safety, reliability and correct operation of the pump on the condition that:

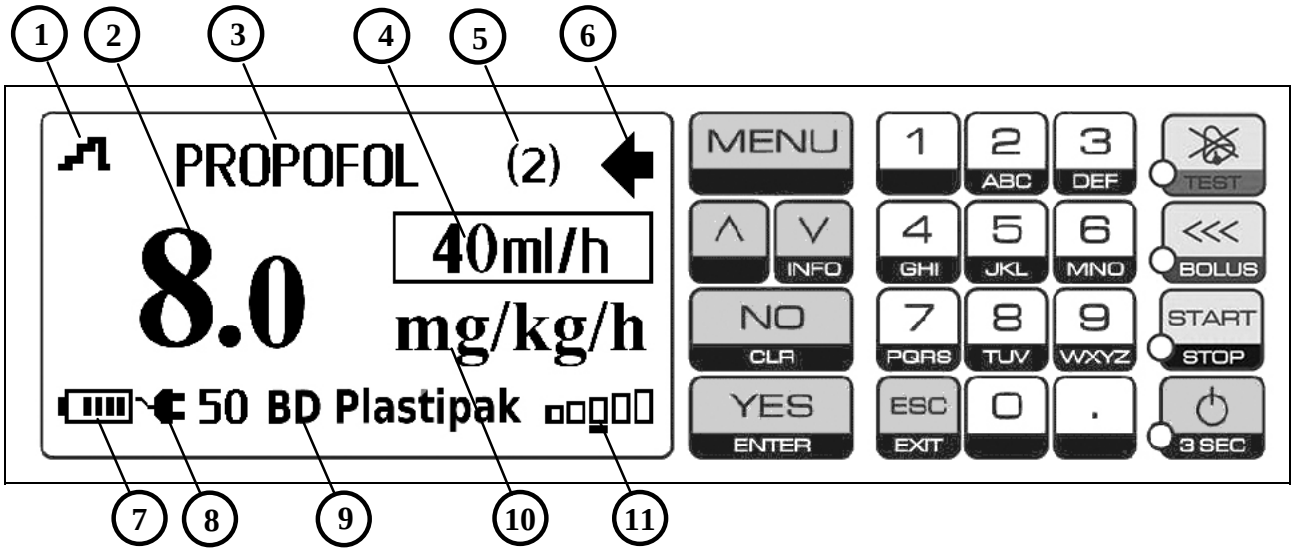
- Installation, operation and modification are performed in accordance with the user's manual and manufacturer's instructions.
- Inspections and repairs are made be authorized personnel trained by MEDIMA.
- Technical inspections of devices are carried out every two years.

5. PUMP CONSTRUCTION



1. Pump stem end
2. Plunger grippers
3. Syringe flange clamp
4. Syringe clamp
5. Extension set hook
6. Keyboard
7. Display
8. Caring handle
9. Mains socket
10. 12V connector socket
11. RS232C socket
12. Alarm connector
13. Pole clamp
14. Clamp knob
15. Battery cover
16. Release button for the docking station

5.1. Keyboard



MENU — Additional functions button. Exit from MENU by ESC. Internal functions can have additional options – check by pressing MENU again.

^ V INFO — Buttons used to select parameters or functions.
Review of the infusion parameters V INFO

YES ENTER — Button used to confirm value or information displayed.

NO CLR — Button used to reset or reject information displayed.

0 9 WXYZ — Numeric keys for entering parameters and names

ESC EXIT — Button used to stop or exit selected window or entered data.

START STOP — Starts / stops infusion
Infusion indicator – yellow, flashing

TEST — Acoustic alarm reset button. Longer pressing starts alarm tests.
Alarm – red, flashing.

<<< BOLUS — Purge / bolus button
Bolus indicator – blue, flashing during bolus infusion

3 SEC — Turn on / turn off button. To turn off press for 3 sec.
Power status indicator. - Green – mains or 12V, Yellow, flashing – battery

5.2. Display

1. Mode of infusion
2. Infusion rate
3. Drug name
4. Infusion rate in ml/h
5. Infusion cycle number
6. Infusion status – flashing during infusion
7. Battery charge status
8. Power status
9. Chosen syringe type and size
10. Infusion rate units
11. Infusion pressure and chosen occlusion level indicator

6. UNPACKING

Despite careful packaging, the risk of transport damage cannot be entirely eliminated. Upon delivery please check that nothing is missing and the device is not damaged. In case of any problems please contact an authorized Medima representative or the manufacturer. Complete set includes:

- Syringe pump – model according to the order specification
- AC power supplying cable
- User's manual

Prior the first use of the device, plug the pump power cord into the electrical outlet to fully charge the battery. Ensure that after connecting the mains the green led on the keyboard lights and the Medima logo appears on the display.

If the pumps were kept or transported in low temperature (below 0 °C), it is recommended to leave them for a few hours at room temperature prior to connecting to the power supply. In case of condensation on exterior of the device, it should be left out for 4 to 8 hours until the casing surface is dry.

7. PUMP INSTALLATION

7.1. Attaching the Pump to the IV Pole or Vertical Column

1. Unscrew the clamp knob 14 (see the picture, page 8) to fit it to the diameter of the IV pole.
2. Put the IV pole inside the pole clamp.
3. Screw on the clamp knob and ensure that the pump is securely fastened to the IV pole.
4. Plug in the power cord.

- Never attach the pump on the unstable IV stand.
- Is it not recommended to use more than two pumps with one IV stand.
- Do not mount the pump in a vertical position with the syringe pointing upwards as this could lead to an infusion of air which may be in the syringe.

7.2. Mounting the pump into the docking station (recommended)

1. Hold the pump horizontally and push it into a free space in the docking station. Ensure that the pump clicks and is fastened securely. If the pump is not fixed properly, display shows:" Improper fixing". In such case push the pump firmly into the docking station.
2. To release the pump from the docking station press release button (16) at the right side of casing and pull the pump forward (see drawing page 8).

3. Check if the green mains indicator on the pump's keyboard is on, if not check the docking station's power supply or the pump's fixation.

Both the pumps and docking station should be plugged into a grounded electrical outlet only.

8. EDITING PARAMETERS

Use ^ v to select the parameter. Start modification of the parameter by clearing the previous value pressing NO or entering it with numeric keys. Each new value should be confirmed pressing YES.
If the entered value exceeds the allowed limits, a window with the upper and lower limits will appear. The window with the warning will close after pressing ESC or after 5 seconds. Not all parameters have to be entered.

8.1. Entering theValue of Numeric Parameters (i. e. rate, volume)

- Press NO or enter value with numeric keys, confirm YES.
- Pressing NO clears last number
- Pressing and holding NO allows you to change the unit of the parameter. Use ^ v or press NO to select the proper units and confirm YES.

8.2. Entering Time

- Press NO or enter value for hours.
- Enter minutes after pressing . or YES
- To start entering minutes omitting hours press .
- Press YES to finish.
- Pressing NO clears last number, and long holding the button clears all entered value.

8.3. Permanent Resetting of Parameters

If you want to clear the value of a parameter, leave it without entering a value, and press NO and then press YES.

8.4. Change the Type of Syringe

- Using ^ v select the type of syringe, press NO; a list of syringes will appear.
- Using ^ v select desired syringe type and confirm YES.
- During the syringe type selection, MENU with additional functions is available; user's own list of syringes can be simply created. (see p. 21, page 29)

9. SWITCHING THE PUMP ON

- Ensure that the pump is not damaged. In case of problems contact technical staff immediately.
- Press ⏻. The pump will start AUTOTEST.
- Two audible signals will sound.
- Check screen for completeness of all pixels on the display.
- Check if all control indicators on the keyboard are working.
- After finishing the tests **CONTINUE??** may appear on the display.
  NO will clear all information about the course of the previous infusion (dose or volume and time of infusion) and allow continuing setting the parameters of new infusion, YES allows to continue previous infusion (dose, volume and time of the previous infusion will not be cleared).

10. INFUSION PROGRAMMING – ml/h

After every change or entry of parameters check, whether they are correct and the units are proper.

After switching the pump on, the device goes to AUTOTEST and displays the parameters of the last infusion. You can:

- Confirm each parameter pressing YES
- Modify parameter entering new value and confirm pressing YES
- Clear all displayed parameters and return basic infusion parameters in ml/h:
  - Press MENU
  - Using ∧ ∨ select „Clear parameters" and confirm YES
  - Basic infusion parameters in ml/h will appear

10.1. Infusion Rate Only (way I)

- Ensure the type and size of syringe on display is accurate. If not:
  - Use ∧ ∨ to find the name and the size of syringe.
  - Press NO - list of syringes will appear.
  - Use ∧ ∨ to select the appropriate syringe and confirm YES
- Enter infusion rate and confirm YES - you can choose the following units: ml/h, ml/min, ml/24h:
  - Press and hold NO, until the units field starts flashing.
  - Pressing ∧ ∨ or NO , select the proper units and confirm them YES
- Clear infusion volume: press NO and confirm YES

- Enter, clear, or omit BOLUS parameters when displayed (can be switched on/off, see p.19.3 “Options - Additional Infusion Parameters”, page 26)
  - Press NO; a window with bolus parameters will open
  - Enter or clear bolus dose pressing NO and confirm pressing YES
  - Enter time of bolus dose in seconds and confirm YES – rate will be counted. You can omit the time and enter the rate only.
- Using ▽ select „---Confirm---” and press YES -a window with parameters will be closed .
- You can revert to the infusion parameters window:
  - Press and hold MENU until parameters appear,

  or:
  - Press MENU
  - Using △ ▽ select „Parameters” and confirm YES
  - Using △ ▽ review or change parameters
  - Press ESC to finish

In addition in can programme an induction dose previously enabled (see p. 19.3“Options-Additional Infusion Parameters”, page 26) programmed as the BOLUS function.

For this infusion the alarm „INFUSION END” would not occur, because volume and time of infusion were not programmed. Infusion would last until the syringe is empty or infusion is stopped.

10.2. Rate and Volume of Infusion (way II)

- Ensure the type and size of syringe on display is accurate. If not, choose the correct one.
- Enter infusion rate and confirm YES (you can choose following units: ml/h, ml/min, ml/24h)
- Enter volume of infusion and confirm YES; the pump will calculate and show time of infusion.
- Enter, clear or omit BOLUS parameters.
- Using ▽ select „---Confirm---” and press YES -a window with parameters will be closed.
- You can revert to the infusion parameters window (see way I).

In addition you can programme an induction dose previously enabled (see p. 19.3 “Options-Additional Infusion Parameters”, page 26) programmed as the BOLUS function.

After infusing the programmed volume of medicine the pump will stop the infusion and the alarm „ INFUSION END” will appear.

10.3. Rate and Time of Infusion (way III)

- Ensure the type and size of syringe on display is correct. If not, choose the appreciate one.
- Enter infusion rate and confirm YES (you can choose following units: ml/h, ml/min, ml/24h)
- Enter time (hours &minutes) and confirm YES; the pump will calculate and show volume of infusion.
  - Enter the hour number.
  - Enter minutes after pressing . or YES.
  - To enter minutes without hours press .
  - Press YES to finish
- Enter, clear or omit BOLUS parameters.
- Using V select „---Confirm---" and press YES - the window with parameters will be closed
- You can revert to the infusion parameters window (see way I).

In addition you can programme the induction dose previously enabled (see p. 19.3 "Options-Additional Infusion Parameters", page 26) programmed as the BOLUS function.

After infusing the **calculated** volume of medicine the pump will stop the infusion, and the alarm „INFUSION END" will appear.

10.4. Volume and Time of Infusion (way IV)

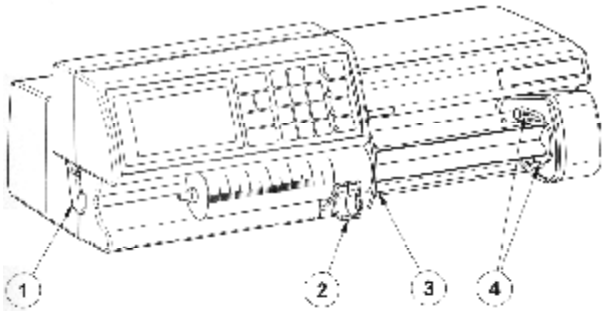
- Ensure the type and size of syringe on display is accurate. If not, choose the correct one.
- Clear rate of infusion (enter 0 or press NO and confirm YES).
- Enter volume of infusion and confirm YES.
- Enter time (hours & minutes) and confirm YES; the pump will calculate and show rate of infusion in ml/h.
- Enter, clear or omit BOLUS parameters.
- Using V select „---Confirm---" and press YES - the window with parameters will be closed
- You can revert to the infusion parameters window (see way I).

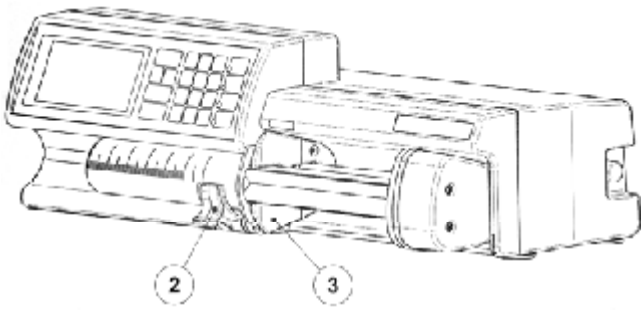
In addition you can programme an induction dose previously enabled (see p. 19.3 "Options-Additional Infusion Parameters", page 26) programmed as the BOLUS function.

After infusing the programmed volume of medicine, the pump will stop the infusion, and the alarm „INFUSION END" will occur.

11. LOADING A SYRINGE

After proper entering infusion parameters the pump waits for a syringe to be loaded, displaying "**INSERT SYRINGE"**

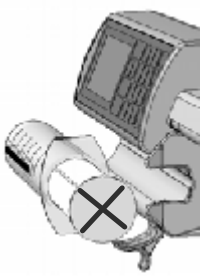




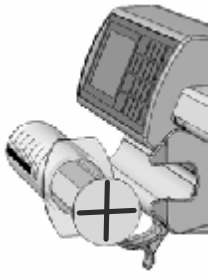
Never load a syringe to the pump if the extension set is connected to a patient. Uncontrolled infusion or back flow may occur and cause danger to the patient's life. For safety reason isolate the patient by closing the tap in the extension line. Check if there is air in the syringe and if yes, remove it.

- Ensure that the used syringe type and size are the same as on the display.
- Pull the syringe clamp (2); on display: **SYRINGE UNLOCKED**
- Set the plunger in the position „x" not „+"

Correct **x** position



Incorrect **+** position



- Insert the syringe ensuring that the finger flanges are located between the casing and syringe flange clamp (3) and the syringe is properly located.
- Let go off the syringe clamp (2); **CHECK SYRINGE** on display means the syringe is improperly inserted or the type or size of syringe is incorrect. Change the syringe or make a change in programming parameters. To make a change in programming parameters press and hold MENU until a parameters window appears.
- Ensure that the syringe plunger is correctly located. If yes on display: **PRESS** <<<.
- Check, if the syringe plunger lies horizontally (in the syringe axle).
- Press <<<; the pump will move the arm and grippers will lock the syringe plunger.
- Ensure that the grippers (4) are fully locked and the syringe plunger is secured; otherwise danger of auto infusion will occur. (see p.14, page 17).

Unloading a syringe is possible only when the pump is switched on or switched off but connected to the mains.

12. PRIMING THE LINE, START OF INFUSION

The pump enables to fulfil an extension line with medicine. In order to do this:

- Press and hold <<<; a progressive bar will be displayed and after its disappearance the pump will start to prime the line until the button is released (maximal volume is limited to 5 ml). Ensure that there is no air in the extension line or in the syringe.
- Secure the extension set using the extension set hook (1) on the left side of casing, to protect against accidental dislodging of syringe from the clamp.
- Connect the extension line to a patient. Please note that the pump does not signal accidental removal of the needle from the vain. Check the connection as much as possible or practical.
- Check the alarm operation – press and hold ;
  - audible signal will sound
  - all controlled lamps on the keyboard will flash
  - display will show: **ALARM**
- Press START/STOP - to start the infusion:
  - yellow lamp by START/STOP button will flash,
  - flashing arrow in the upper right corner of display will indicate that the pump is in operation.

Never prime the line when a patient is connected to the line.
Filling the line is possible only before the start of infusion or when empty syringe is replaced.
Volume infused during priming the line is not added to the volume of infusion.

13. UNLOADING A SYRINGE

- Press START/STOP to stop the infusion by safety valve!
- **Isolate the extension line from the patient!**
- Pull the syringe clamp down and wait until the plunger grippers will release the syringe (about 2 sec.).
  In case of any problems with the plunger grippers lock the syringe clamp, move the syringe plunger and pull the syringe clamp again.
- Unload the syringe when the arm is moving.
- Unloading a syringe is possible only when pump is switched on or switched off but connected to the mains.

Never load and unload the syringe with the extension line connected to the patient. Uncontrolled, dangerous infusion or back flow may occur. Use a safety valve, in the patient's line, for protection. Every new connection of the extension set to the patient should be done after ensuring that there is no air in the line and in the syringe.

14. AUTO-INFUSION – Life and Health of Patient under Threat

Auto-infusion during drug delivery is one of the largest threats for patients' life and health. It appears when a syringe is above the patient's body and it is caused by gravitation. Liquid in the infusion line, beneath a syringe, makes negative pressure, which can cause an automatic plunger motion and uncontrolled infusion. Its' rate depends on:

- Height above patient's heart on which a syringe is held when the pump is mounted.
- Syringe diameter; for small volume syringes the force of plunger movement caused by negative pressure is smaller – probability of auto-infusion is smaller. The biggest danger is for 50/60ml syringes mostly used in the infusion. For the typical syringe of the mentioned volume, rise of syringe for the height of 70 cm above patient's heart causes plunger suction force about 0,5 kg and sudden auto-infusion with the rate much higher than 1000ml/h.

In order to minimize threat of auto-infusion, exchanging a syringe must be made extremely carefully, after isolation of an extension line from a patient. Isolation may include closing a tap in the patient line.

15. FUNCTIONS AVAILABLE BEFORE THE START OF INFUSION

After the confirmation of infusion parameters, before the start of infusion and during the infusion the following functions are available after pressing MENU (for details see p.17 "INFUSION MENU ", page 20):

16. INFUSION

Button START/STOP starts / stops the infusion

16.1. Quick Change of Infusion Rate (without stopping the infusion)

- Enter new infusion rate with numerical keys: you can start entering by pressing NO
- Confirm YES; leaving entered new value without confirmation will not change the rate

16.2. Bolus

Bolus shock dose is a volume dose delivered with high flow rate to increase quickly the concentration of medicine in blood serum. It can be delivered several times during infusion.

Depending on programmed bolus parameters, it can be infused as follows:

1. When volume /dose of bolus is not programmed, bolus will be infused until <<< is pressed. After infusing 1ml of medicine the infusion will be stopped for 2 seconds and short sound will occur.

2. When volume /dose of bolus are programmed, pump will infuse the programmed volume of medicine and revert to standard infusion. Press START/STOP to stop the infusion of bolus and revert to standard infusion.

To start delivery of Bolus dose:
Press <<< . The window with the information about programmed bolus dose will appear.
If the value is proper, press <<< again. Delivery of bolus dose will start.
If there is necessity of change the value, enter new value and confirm YES. Press <<< to start delivery of bolus in changed value.
When bolus dose was not programmed or was cancelled, press and hold <<< and bolus will be delivered until the button is pressed.

All parameters of bolus (dose, time & rate) can be modified during the infusion :

- Press and hold MENU until a window with parameters appears

or :

- Press MENU
- ^ v Select „Parameters" and confirm YES: a window with parameters will appear
- ^ v Select „Bolus" and press NO : a window with Bolus parameters will open
- Enter new parameters and confirm YES
- Coming back to the infusion window after pressing ESC.

If none of Bolus function parameters is programmed the function will not be available.

Delivery of bolus dose gives a signal through blinking of the blue lamp near the button <<< and information about the delivered volume and dose will appear on the display. If during delivery of bolus dose the programmed volume/dose of the total infusion is exceeded the pump will stop the infusion and "END OF INFUSION" will appear on the display.

BOLUS dose is included in the programmed dose of infusion. It means that a patient will receive only such a dose of medicine that has been programmed regardless from the quantity of delivered bolus doses. The total dose delivered to the patient can be read in information about infusion after pressing V INFO (see p.16.3 "Review of Information about Infusion ", page 18).

16.3. Review of Information about Infusion

- Press V INFO
- Review information using ^ v
- Coming back to the infusion window after pressing ESC or automatically after 10 seconds.

During the infusion process the following information about infusion is available:

- Infused volume / dose (it can be cleared: press and hold NO until a progressive bar disappears
- Time to the end of syringe
- Time to the end of infusion (if programmed volume or time of infusion)
- Time of infusion
- Battery charge status
- KVO rate

16.4. Suspension and Restart of Infusion

To stop the infusion for longer period of time:

- Press START/STOP to stop the infusion
- Leave the syringe in the pump
- Switch the pump off.

To restart the infusion:

- Switch the pump on again :

On display „Continue ?" – press YES

- Press START/STOP to start the infusion; all previous data and volume / dose counter will be retained.

To remind about suspended infusion use the Timer function (see p. 22.7 "Timer", page 37) that starts alarm after expiry of the programmed time.

16.5. Empty Syringe

Just before a syringe is empty the pump will stop infusion and alarm will occur (the volume remaining in the syringe can be, although it's not recommended, infused by restarting the infusion process – press START/STOP). The syringe can be unloaded after turning the alarm off (see p.13, page 16), exchanged for a full one and the infusion can be

restarted without necessity of programming parameters. Please observe all safety precautions when changing the syringe. Volume/dose counter will add volumes of all consecutive syringes. A counter can be reset when needed (see p.17 "Infusion Menu", page 20).

Depending on the size of the syringe used for infusion the amount of medicine left in the syringe is as follows:

- 0,5 ml for syringes 50 and 30 ml
- 0,25 ml for syringes 20 and 10 ml
- 0,1ml for syringes 5ml

Due to different types and volumes of syringes the volume remaining in the syringe can be different.

16.6. End of Infusion

After infusing programmed volume of medicine, pump will stop the infusion and alarm will sound displaying **INFUSION END**. If you want to repeat the infusion with the same parameters:

- Change empty syringe for full one (see p.13 " Unloading a Syringe", page 16)
- Prime the extension line (see p.12 " Priming the Line, Start of Infusion", page 16)
- Start the infusion pressing START/STOP.

Alarm "INFUSION END" will not occur if volume/dose or time is not programmed.

17. INFUSION MENU

During the infusion or during the brake in infusion the following functions are available after pressing MENU:

- **Parameters** Allows reviewing and modifying some of infusion parameters.
- **New infusion** Resetting the volume of medicine counter and allows to change all the infusion parameters. Induction dose (if it is programmed) will start the infusion
- **Clear dose** Enables to reset the counter of the delivered medicine during infusion or before the next one.
- **Pressure, KVO** Enables change of the level of occlusion pressure and KVO
- **Event log** Enables reviewing full history about previous infusions
- **Time, date** Enables changing time and date
- **Ward name** Allows reviewing entered ward name
- **Information** Information about the pump and the drug library downloaded from the MEDIMA DRUG EDITOR software (name, version, creation date and modification date) and about the total time of the pump's work.

17.1. Parameters

During infusion all programmed parameters can be reviewed and the following can be modified during the infusion course:

- Flow rate
- Volume of infusion (total dose)
- Bolus parameters

To modify parameters during infusion or during pause in infusion:

- Press and hold MENU until a window with parameters appears

Or

- Press MENU
- ^ v select „ Parameters” and confirm YES

Review and modification like in programming parameters.
Pressing ESC will revert to infusion window. It will happen automatically after 10 sec.

Entered changes do not reset volume / dose counter and the infusion will be continued with the new parameters.

17.2. New infusion

„New infusion” function is available when the infusion is finished or stopped by pressing START/STOP. After selecting that function:

- The infused volume counter will be reset and new infusion parameters programming option will be available.
- Induction dose starts the infusion if it was previously programmed.

Start of new infusion according to new parameters or previous parameters :

- Press START/STOP to stop the infusion.
- Press MENU.
- Using ^ v select „New infusion” and confirm YES.
- Select, enter and confirm new parameters.
- Load a syringe, prime the extension line, connect the extension line to a patient and press START/STOP.

or:

- Press START/STOP to stop the infusion.
- Turn off the pump.
- Turn on the pump.
- „CONTINUE” - NO
- Select, enter and confirm new parameters.
- Load a syringe, prime the extension line, connect the line to a patient and press START/STOP.

17.3. Clear Dose

In any time during infusion the reset of volume /dose of medicine is possible. Infusion will be continued and induction dose will not be infused again.

- Press MENU during infusion or during pause in infusion.
- ^ v Select „Clear dose”
- Press and hold YES : a progressive bar will appear and the dose will be cleared after its disappearance
- The pump will return to the infusion window

or

- Press V INFO : information about the amount of delivered medicine will appear
- Press and hold NO : a progressive bar will appear. The dose will be cleared after its disappearance.

17.4. Pressure, KVO

In any time during the infusion process modifications of pressure level and KVO rate are possible.

- Press MENU during infusion or during pause in infusion
- Select „Pressure, KVO" and confirm YES

After selecting this function the following parameters are available:

Occlusion pressure	levels 1- 6	press NO to change the level
KVO	0 - 5,0 ml/h	(**K**eep **V**ein **O**pen)- the rate of the delivery of medicine to keep vein open when the infusion is stopped

The resistance depends on the following factors:

- rate of infusion
- density of fluid
- inside diameter and the length of the extension line
- diameter of the needle
- usage of additional elements like antibacterial filters that increase resistance with increase of time of infusion
- quality of used syringes

The resistance is difficult to estimate and different at each case. At the lowest pressure levels the alarm may occur despite the lack of occlusion. In this case:

- change an antibacterial filter
- change a pressure level for higher (see above)
- change a syringe for a new one

A syringe itself could cause a problem. It is forbidden to prime the syringe again even with the same drug.

Because of the higher resistance of high flow rates, the pump automatically changes preset pressure level as follows:

- Above 500 ml/h lowest level 2
- Above 1000 ml/h lowest level 3
- Above 1500 ml/h lowest level 4

This regards induction dose, bolus, normal infusion mode and priming the line.

The pump is equipped with ANTY-BOLUS SYSTEM which enables the automatic reduction of residual bolus after occlusion release. The excess of medicine accumulated in the extension line is removed by withdrawal of the syringe plunger. The system also corrects the counter of delivered volume/dose of medicine. This function is activated automatically **after muting** "OCCLUSION" alarm.

KVO
This parameter determines the rate of the delivery of medicine to keep vein open in the following cases:

- Stop of infusion by pressing START/STOP
- End of infusion
- Empting a syringe (there is always a residual amount of medicine in a syringe)
- Pause in intermittent infusion

The KVO function is shown on the display by a blinking lettering and is active until a syringe is unloaded.
The KVO function can be programmed in the limits 0 – 5.0 ml / h .When the value 0 is entered or KVO values are cleared the function will be disabled. When infusion rate is lower than KVO the infusion will not be stopped in the above mentioned cases.

17.5. Event Log

The pump records in the memory full history of infusion, each alarm and all parameters with date and time. Stored information is available during the infusion and when the pump is switched off .The information about the current and previous infusions could be reviewed. The following information is stored:

- Infusion parameters
- Loading / unloading a syringe
- Start / stop of infusion
- Start, pause and end of induction and bolus doses
- Each change of parameters during infusion
- All alarms including the moment of their muting by an operator
- Exceeding the value limits of infusion parameters- model S2

Detailed information on review about infusion history is in p.22.1, page 30.

17.6. Time, date

This function allows changing time and date of the internal clock
Enter new data and confirm YES. Press ESC, to close the window.

17.7. Ward Name

Entered Ward Name will display after choosing this function (see p.22.4.9 “Enter Ward Name”, page 35).

- Press MENU during infusion or during a pause in infusion
- Using ^ v select „Ward Name” and confirm YES.

17.8. Information

This function allows reading information about the pump.

- Press MENU during infusion or during a pause in infusion
- Using ^ v select „Information" and confirm YES.

The following will appear:

- Drug names — Information about drug names (name, version, creation date and modification date) entered using DRUG EDITOR. (see p. 20.5, page 28)
- Pump — Information about the pump (see p.22.6, on page 36)
- Statistics — Statistical information about pump and battery working time. (see p. 22.6, page 36)

17.8.1 Information about Drug Names Version

This information appears only if a drug names have been downloaded to the pump using MEDIMA DRUG EDITOR (see p. 20.5, page 28). The information is very important as it enables to check weather the drug names in the pump are the proper ones – the latest version and weather they were modified in the pump.

18. ALARMS

Alarms are indicated by:

- Audible sound with a descriptive message on the display
- Blinking of the display flashing and a red lamp next to

To silence the alarm press or

NO MAINS	• **Doesn't stop the infusion!** • Regards both DC-12V and AC power
BATTERY LOW	• **Doesn't stop the infusion!** • Minimum 30 minutes of operation left. • After muting the sound the red lamp still flashes and the sound activates periodically
BATTERY EMPTY	• **INFUSION STOPPED (KVO also)** • After muting the sound or after 3 minutes pump will switch off • Restart of operation possible on AC power.
OCCLUSION	• **INFUSION STOPPED (KVO also)** • **When the alarm is cancelled !!** the pump moves the arm back to reduce a residual bolus after occlusion release. (ANTI-BOLUS-SYSTEM). The pump reduces infused volume counter. • Change the occlusion pressure level if needed. (see p. 17.4 "Pressure, KVO" page 22).

HIGH PRESSURE	• **Doesn't stop the infusion!** • Pre-alarm at 75% of programmed pressure level, enables personnel intervention, before the infusion is stopped. • Alarm needs activation. (see p. 22.4.6 "Alarm Options" page 34)
LINE DISCONNECTED	• **INFUSION STOPED (KVO also)** • Rapid pressure drop; it can occur when line is disconnected during delivery fluids at high rates (for e.g. bolus, induction dose) • Alarm needs activation. (see p. 22.4.6 "Alarm Options" page 34) • **Alarm will be activated only when the occlusion pressure is set above the 2-nd level**
CHECK SYRINGE	• **INFUSION STOPED – KVO active until the syringe unloaded** • Improper syringe fixation during the infusion. It can be caused for example by too tight pulling of the extension line.
5 MIN TO INFUSION END	• **Doesn't stop the infusion!** • Occurs when volume / dose or infusion time is programmed. Time can be programmed from 1 to 30 minutes (see p.22.4.6 "Alarm Options", page 34)
INFUSION END	• **INFUSION STOPPED – KVO active up to syringe unloading.** • Occurs when volume / dose or infusion time is programmed.
5 MIN TO SYRINGE EMPTY	• **Doesn't stop the infusion!** • Warning that the syringe will be empty soon. Time can be programmed from 1 to 30 minutes (see p. 22.4.6 "Alarm Options", page 34)
SYRINGE EMPTY	• **INFUSION STOPPED – KVO active until the syringe unloaded.** • Occurs just before a syringe is totally empty (0,5 ml for syringes 50 and 30 ml , 0,25 ml for syringes 20 and 10 ml, 0,1 ml for syringes 5 ml). • Possibility to delivery left drug quantity after switching the infusion on. Due to different types and volumes of syringes the volume remaining in the syringe can be different than mentioned above..
? ? ? (2 min)	• Occurs every two minutes when the switched on device is left without the infusion.
MALFUNCTION XXX	• **INFUSION STOPPED (KVO also)**

19. ADDITIONAL POSSIBILITIES OF INFUSION (programming)

19.1. MENU - parameters (available during programming)

During programming infusion parameters but before the infusion is started the following functions are available after pressing MENU, that enable modification of the current infusion.

- Clear parameters — Allows clearing all entered parameters and reverting to basic infusion in ml/h
- Drug names — Drug names saved in the pump's memory (see p.20. page 27)
- Options — Additional infusion parameters (see p.19.3, page 26)

19.2. Clear parameters – come back to infusion in ml/h

After choosing this function all programmed infusion parameters will be cancelled and return to the basic (continuous) infusion in ml/h will be available.

19.3. Options – Additional Infusion Parameters

The additional parameters will appear after selection of below options. There is no need to select and programme these parameters for each infusion – they remain in the memory and they are used in following infusions. They will be also saved in the pump's memory in each dosing protocol in the drug library (each dosing procedure can have different options, if enabled/disabled before entering.) MEDIMA DRUG EDITOR software offers the same possibilities.

Option selection (window with the infusion parameters):

- Press MENU,
- Using ^ v select „Options" and confirm YES. A window with list of parameters will open:
  - Total dose YES/NO total dose enabled /disabled
  - Bolus YES/NO bolus enabled/disabled
  - Start time YES/NO start time enabled/disabled
- Using ^ v select a parameter and press YES to activate it or NO to deactivate it.
- Press ESC to revert to the parameters modified according to the chosen parameters options.

19.3.1 Total Dose

If this option is enabled / disabled “Total dose” parameter will appear / disappear on the display. It is recommended to disable it if not required. For the infusion in ml/h “Volume” and “Time” will disappear and “Total Dose” for infusion in other units. It should be remembered that if the above mentioned parameters are disabled or their volume not entered “INFUSION END” alarm will not occur. Only “SYRINGE EMPTY” alarm will occur.

19.3.2 Bolus

If this option is enabled /disabled “Bolus” parameter will appear /disappear on the display. It is recommended to disable it if not required. It is very important because the delivery of bolus dose could be dangerous for a patient. It is worth adding that the delivery of bolus dose can be also secured by a password (see p. 22.4.8“Security”, page 34).

19.3.3 Start Time

This function enables automatic start of infusion at programmed time. After selecting this option an additional parameter -time of infusion start- will appear in the programming window. This parameter can be omitted; the infusion will start without the delay.

20. DRUG NAMES

Up to 100 drug names could be entered into memory and then displayed during the infusion.

20.1. Enter Drug Name

- Press MENU
- Using ^ v select „Drug names” and confirm YES; the list of drug names will appear,
- Press MENU
- Using ^ v select „Add name” and confirm YES
- Enter drug name using numeric keys (like SMS in mobiles):
  - next pressing changes entered letter for e.g. to enter C you have to press 2 three times.
  - enter of next sign available after 1 sec. or after pressing next button
  - short pressing NO cancels last sign and long pressing cancels whole name
  - to enter space press 1
  - press YES to finish entering the name
  - pressing ESC will cancel entering the name and will revert to infusion parameters window.

If the entered name already exists the warning will appear.

20.2. Recall Drug Name

- Press MENU
- Using ^ v select „Drug names” and confirm YES
- Using ^ v select desired drug name and confirm YES; instead of ^ v the numerical keys can be used to chose the first letter from drug name.

20.3. Delete Drug Name

- Press MENU
- Using ^ v select „Drug names” and confirm YES
- Using ^ v select desired drug name and confirm YES; instead of ^ v the numerical keys can be used to chose the first letter from drug name.
- Press MENU
- Using ^ v select „Delete name” and confirm YES
- Press ESC to exit.

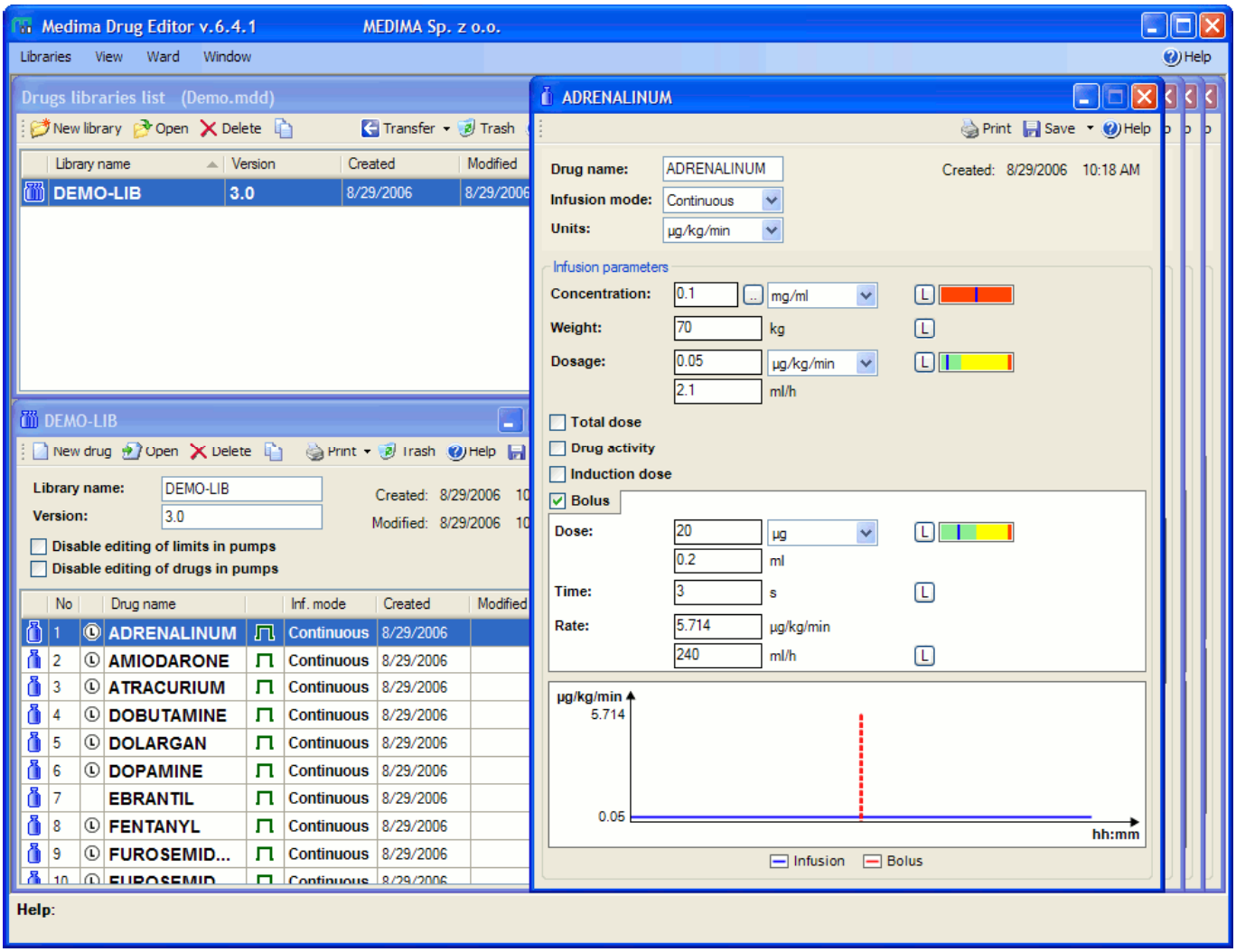
20.4. Pump to Pump Drug Library Transfer

In case of big quantity of pumps at one hospital ward is very important all of them have the same drug names. Manual entering of many drug names takes time and can cause errors. In such a case entering all names to one pump and transferring to all others is recommended.
A function “Send drugs” (see p. 22.9, page 38) enables to transfer of data by interface RS232. A special connection cord is needed (see p. 29, page 41).
Transfer of data between different models (S, S1 S2, S-PCA) is not allowed.

20.5. DRUG EDITOR Software

Drug names can be entered from the pump keyboard, but it is easier to use MEDIMA DRUG EDITOR software and create a drug library in PC.
MEDIMA DRUG EDITOR software enables to create from simple to very sophisticated drugs protocols. It is a very easy and useful tool which allows keeping records of the all versions of drug libraries and safe transfer to all pumps at the hospital ward. For safety reason modification of all entered data can be disabled.
Although MEDIMA DRUG EDITOR software is designed for use with models S1, S2 and S-PCA it can be used for creation of drug names for model S.

MEDIMA DRUG EDITOR software is not a standard delivery enclosure. Contact an authorized MEDIMA representative or the manufacturer directly to obtain an information. More details at our website www.medima.com.pl



21. CREATION OF USER'S OWN LIST OF SYRINGES

Parameters of many syringe types are calibrated in the pump. Not all of them are used in each hospital. To shorten the list:

- Start programming of infusion parameters
- Using ∧ ∨ select displayed syringe type
- Press NO; list of syringes will appear
- Press MENU
- Using ∧ ∨ select „Create own list" and confirm YES.
- Using YES and NO select desired syringes to create own list,
- Press ESC to finish.

To revert to the full list of syringes after pressing MENU select „All syringes".

22. FUNCTIONS AVAILABLE WHEN THE PUMP IS SWITCHED OFF

There are options available when the pump is switched off but connected to the power supply.

- Switch off the pump and connect a power supply cord - MEDIMA logo will be displayed
- Press and hold MENU - a list of available options will be displayed:

• Event log	Review of information about the previous infusions
• Battery	Information about battery charge status and time left to full battery recharge
• Time, Date	Settings of time and date,
• Configuration	Set of configuration parameters
• Ward name	Display of programmed ward name (pump's identity)
• Information	Information about the pump and drug library (name, version, creation date and modification date) entered using DRUG EDITOR software.
• Timer	Switch on of alarm after programmed time
• Tests	Check of proper pump's operation
• Service	Features for hospital service department

22.1. Event Log

The pump records in the memory full history of infusion, each alarm and all parameters with date and time. Stored information is available during the infusion and when the pump is switched off. The information about the current and previous infusions could be reviewed. The following information is stored:

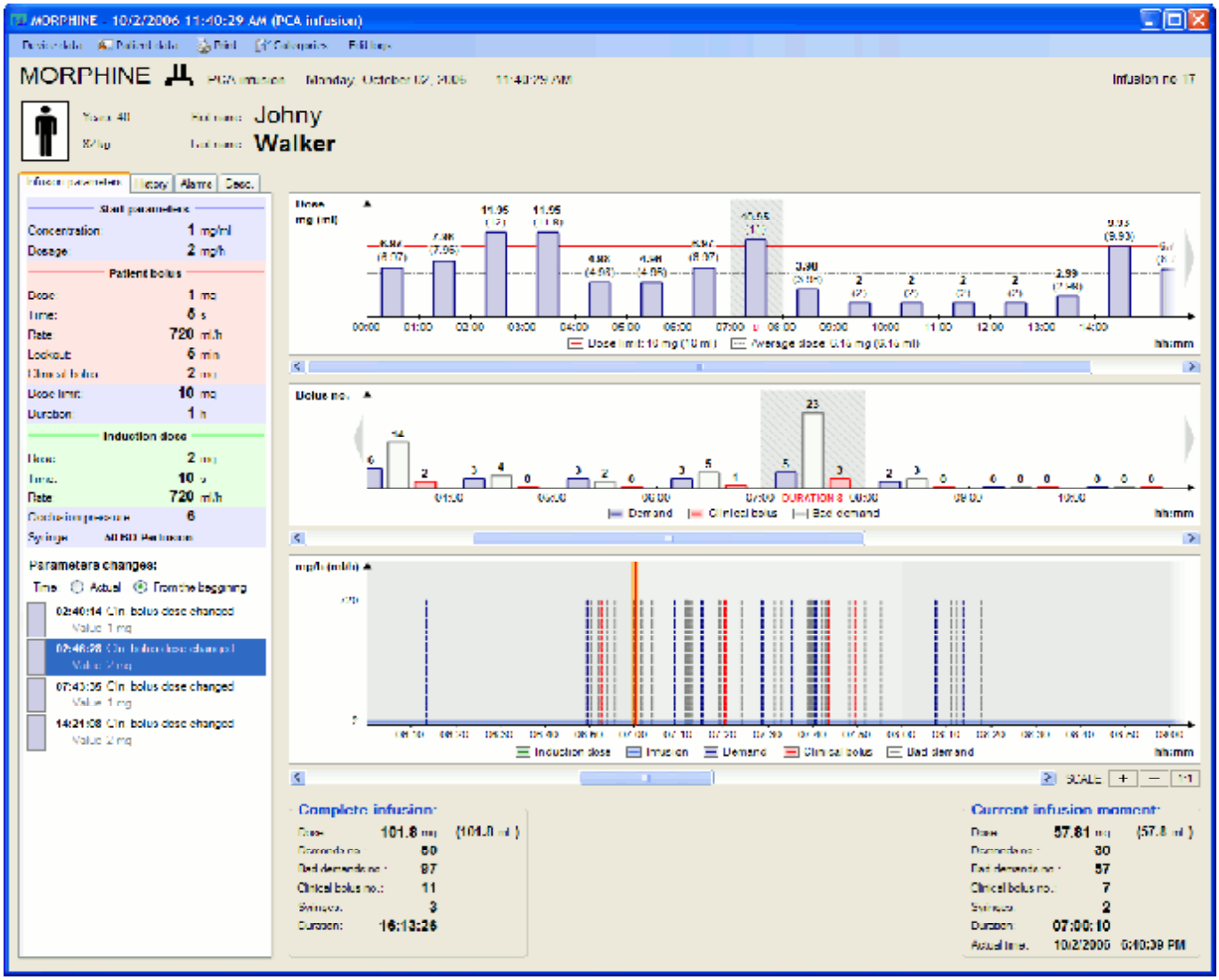
- Infusion parameters
- Loading / unloading a syringe
- Start / stop of infusion
- Start, pause, end of the delivery of induction and bolus doses
- Each change of parameters during infusion
- All alarms including also these with moment of their muting by operators
- Overridden limits values for infusion parameters- Model S2

- Press and hold MENU
- Select „Event log" and confirm YES
- Using ^ v select required infusion and confirm YES ;a list of events for selected infusion will be displayed
- Parameters of selected infusion could be reviewed :
  - Press once again MENU.
  - Select „Drug parameters" and press YES ; parameters of selected infusion will be displayed

- The required infusion can be found easily:
  - Press once again **MENU**.
  - Choose „Search” and press **YES**; enter the date, the pump will find and display the list of all infusions executed during that day.

For easy review and to keep records about the previous infusions event log could be transferred to the PC. MEDIMA HISTORY FILE software enables presentation of all data (infused volume and dose, time of infusion, number of boluses etc.) in a graphic or chart form.
MEDIMA HISTORY FILE software is not a standard delivery enclosure. Contact an authorized MEDIMA representative or the manufacturer directly to obtain an information. More details at our website www.medima.com.pl

- Data stored in event log cannot be reset.
- If the event log fills up, the oldest information will be removed.
- Event log capacity is about 2000 records. It is difficult to estimate how many full infusions can be stored in the memory, as it depends on quantity of events during infusion (alarms, parameters etc.).



22.2. Battery

To obtain the information about the battery charge status and time of full recharge:

- Press and hold MENU
- Using ^ v select „Battery" and confirm YES; an information window will be displayed
- Press ESC to finish.

22.3. Time, Date

The proper time and date setting is necessary for proper information in the Event log.

- Press and hold MENU
- Using ^ v select „Time, date" and confirm YES.
- Using ^ v select „Time" and enter hours, minutes and seconds.
  - Short pressing NO will cancel last number and long pressing will cancel whole number.
  - Press YES when entered time is the same as real time.
  - Press ESC to close the window or set date.
- Using ^ v select „Date", enter date and confirm YES (see p. 22.4.2 "Date format", page 33)
- Short pressing NO will cancel last number and long pressing will cancel whole date.
- Press ESC to close the window.

22.4. Pump Configuration

Configuration Menu contains parameters which allow adapting the device to special user's needs. To modify configuration:

- Press and hold MENU
- Select ^ v „Configuration" and confirm YES

If the configuration of device was locked by password and pump would ask for password; enter password and confirm YES. If the password was forgotten read information in p. 30. page 42 very carefully.

The following parameters will appear:

• Password	Locks access to pump configuration and other options
• Date Format	dd.mm.yyyy / mm.dd.yyyy / yyyy.mm.dd
• Contrast	Display contrast setting
• Default Values	Typical parameters, set after change of infusion mode
• Limits	Maximal limits for parameters
• Alarm Options	Alarm parameters
• Night mode options	Night Mode parameters
• Security	Security parameters
• Enter Ward Name	Possibility of entering hospital ward name for identification

22.4.1. Password

The user can enter the password to lock pump configuration and other options (see p. 22.4.8 “Security”, page 34).

- Using [^] [v] select „ Password” and confirm [YES]
- Enter password and confirm [YES]
- Enter password again and confirm [YES]
- In case of lose of password read carefully information in p. 30. page 42.

To cancel the password:

- Using [^] [v] select „ Password” and confirm [YES]
- Press [NO] and confirm [YES]
- On display ”Password Cancelled”

The password and the serial number should be written on the last page of User’s manual.

22.4.2. Date Format

- Using [^] [v] select „Date Format ”
- Press [NO]; after every pressing the new format will appear.
- Selected format confirm [YES]

22.4.3. Contrast

Change of display contrast:

- [^] [v] Select „Contrast”
- Press [NO] to select proper contrast
- Press [YES] to confirm
- Press [ESC] to close the window.

22.4.4. Default Values

Default values- typical, standard values that appear after the change of infusion mode:

• Bolus	500	ml/h	Bolus rate
• Bolus time	15	sec.	Time of bolus dose delivery
• Induction time	60	sec.	Time of induction dose delivery

Entering parameters:

- Using [^] [v] select the parameter
- Enter value and confirm [YES]
- Press [ESC] to finish.

22.4.5. Limits

There are:

• Max Rate	2000 ml/h	Limits max infusion rate
• Max Bolus	2000 ml/h	Limits max bolus rate
• Prime the line	1000 ml/h	Rate for priming

- Using ^ v select the parameter
- Enter value and confirm YES
- Press ESC to finish.

22.4.6. Alarm Options

Alarm parameters description:

• Volume	level	Level of alarm loudness
• Melody	[1 – 9]	Type of sound
• Pre-alarm time	5 min	Time to the SYRINGE EMPTY and INFUSION END; 1-30 min
• Occlusion pre-alarm	YES/NO	Warning of pressure increase switch on/off (see p. 18, page 24)
• Line disconnected	YES/NO	Warning of pressure drop switch on/off (see p. 18, page 24)

Entering the value:

- Using ^ v select the parameter
- Enter value and confirm YES
- Press ESC to finish.

22.4.7. Night Mode Options

Night Mode allows tuning of alarm loudness and backlight brightness.

• Switch on	YES/NO	Switch on / Switch off of night mode
• Volume	level	Level of alarm loudness
• Melody	[1 – 9]	Type of sound
• Start	22:00	Time of start of night mode
• Finish	07:00	Time of finish of night mode

22.4.8. Security

This function allows configuration of security options; the list with the following parameters will appear:

• Switch on	YES/NO	Activation or locking of all the security options
• Drug library	YES/NO	Locking of recording, modification, reset and change of name of programs stored in pump memory. Does not lock recalling and start of infusion based on program
• Parameters change	YES/NO	Locking of parameters modification
• Date / time change	YES/NO	Locking of date and time modification
• Infusion start	YES/NO	Locking of start of infusion (stop is not locked)
• Bolus start	YES/NO	Locking of bolus dose delivery
• Off	YES/NO	Locking switching the pump off

Enter password before using the functions secured by password. If the password was forgotten read information in p. 30. page 42 very carefully.

Setting security options:

- Pressing YES activate " Security" function
- Using ^ v select desired security option and pressing YES / NO activate it or lock it
- Press ESC to exit security options.

In case of switching off all security options entered password will secure configuration parameters only. Removal of the password results in unlocking pump configuration and switching off the "Security" function.

22.4.9. Enter Ward Name

For the easy identification of the owner of the pump there is a possibility to enter the ID number (16 signs) or name including maximal four lines 20 signs each.
To process:

- Using ^ v select „Enter Ward Name" and confirm YES
- Enter or omit ID number
- Enter the name in selected line using numerical keys (like SMS) and ^ v
- Press YES to confirm entered name for selected line
- Press ESC to finish.

22.5. Ward Name

This function enables to read entered Ward Name.

22.6. Information

This function allows reading information about the pump stored in the memory.

- Press and hold MENU
- Using ▲ ▼ select „Information" and confirm YES.

The following will appear:

- Drug names — Information about drug library (name, version, creation date and modification date) entered using DRUG EDITOR.
- Pump — Pump data
- Statistics — Information about pump and battery working time

- Using ▲ ▼ select desired function and confirm YES.

22.6.1. Drug Names

This information will appear only when the drug library was created and sent using MEDIMA DRUG EDITOR (see p. 20.5, page 28). The information is very important as it enables to check weather the drug library in the pump is the proper one – the latest version and weather it was modified in the pump.

The following information will appear:

- Drug library name — given in DRUG EDITOR software
- Library version — given in DRUG EDITOR software
- Creation date — in DRUG EDITOR software
- Upload date — from DRUG EDITOR software
- Modify date — in DRUG EDITOR software or in the pump !!
- Drug changes locked — preset in DRUG EDITOR software

Use ▲ ▼ to review the information.

22.6.2. Pump

Here is information regarding pump identification:

- Serial number
- Prod. date
- Pump type
- Software — Software version e.g. V6.3.1
- WD — Watch dog version

Use ▲ ▼ to review the information.

22.6.3. Statistics

You can find the following information here:

Pump

- Inf. counter — Total number of infusion done by the device
- Infused vol. — Total volume infused by the device
- Working time — Total working time

Battery

- Working time — Total working time on battery
- Instal. date — Battery installation date
- Charge counter — Total number of recharges (see p. 24 “Internal Battery Operation”, page 40

Use ▲ ▼ to review the information.

22.7. Timer

Allows switching on the alarm after programmed time– **the pump remains switched off.**

- Press and hold MENU
- Using ▲ ▼ select „Timer” and confirm YES.

The following parameters will appear:

- time left — time left to the switch the alarm on
- time on — time when the alarm will be switched on

Enter one of the parameters – the second will be calculated.

22.8. Pump Tests

This function enables starting basic pump tests:

- Press and hold MENU
- Using ▲ ▼ select „Tests” and confirm YES.
- Using ▲ ▼ select a proper function and confirm YES.

For correct and safe operation the following tests should be carried regularly:

- Keyboard test — checks proper keyboard operation
- Display test — checks damages of display
- Alarm test — available also after pressing ✱ during infusion
- Clamp test — checks operation of syringe diameter measuring system. Compare result on display with the measurement taken with the slide calliper. The error cannot exceed ± 0,8 mm
- Batt. controller test — checks operation of battery controller system
- Battery test — indicates status of battery discharge
- Battery test-event log — enables to read results of four previous battery tests

Battery test takes even up to 15 hours as it is controlled discharge of battery. If the pump should be ready for patient transfer the battery test is not recommended.
The result of battery test below 80 % requires battery replacement as it means that rapid decrease of battery capacity is expected and the pump could not work unless connected to the mains. **The indicator of battery charge status will not show proper values!**

The following should be carried regularly:

- Control of power supply cable; in case of insulation damages the power supply cable should be changed.
- Inspections according to service manual carried by qualified personnel.
- Cleaning and disinfection of outer pump surface (see p. 23, page 39)

22.9. Service

These features are for the personnel of technical department only and are secured by password.

- Press and hold MENU
- ^ v to select „Service" and confirm YES
- Enter password 159.0 and confirm YES
- ^ v select right function and confirm YES

The following features are available:

• New battery	Function of battery recharge with reset of battery controller. It is recommended after batter replacement.
• Time to next technical inspection	Allows technical staff to plan next technical inspection. One can select period of time, amount of infusions, given volume and amount of battery recharges.
• Send drugs	Allows sending drug library to other pump. Requires a special cable (see p. 29, page 41).
• Send configuration	Allows sending configuration to the other pump for easy configuration of all the pumps at the ward in the same way. Requires a special cable (see p. 29, page 41)
• Delete drugs	Allows clearing drug library for example when unauthorized modification is suspected

22.9.1. New Battery

This function enables to charge a battery and to reset battery controller. It is always necessary after battery replacement as the charge status of the new battery is unknown.

Battery controller is scaled to use with MEDIMA battery type . Use of other than original battery can cause improper pump operation. This can cause danger to a patient's life.

22.9.2. Pump to Pump Drug Library Transfer

To transfer a drug library pump to pump:

- Connect both pumps to the mains: MEDIMA logo appears on display.
- Connect the pumps by special connection cord, using RS232 sockets.
- In the pump with demo drug library:
  - Press and hold MENU
  - ^ v to select „Service" and confirm YES
  - Enter password 159.0 and confirm YES
  - ^ v select function "Send drugs" and confirm YES; both pumps will display information about sent / received programs
- Check whether sent drugs library is correct.

The previous drug library is cleared by the next one, downloaded to the pump.

22.9.3. Pump to Pump Configuration Transfer

To transfer configuration pump to pump act the same way as with drug library, but select " Send configuration" instead of " Send drugs".

22.9.4. Clearing Drug Names Library

In case of the suspicion of unauthorized drug library modification it is recommended to clear it and to retransfer it from another pump or from MEDIMA DRUG EDITOR software.

23. CLEANING AND DISINFECTION

- Unload the syringe and switch the pump off
- Disconnect the pump from the AC power supply.
- Wipe the surface over with the cloth dampened with warm water and detergent solution.
- After cleaning, wipe the device with the dry cloth and wait until the surface is fully dried.
- Do not immerse the pump in any fluids as this may damage the pump and may cause electrical shock. Only the external parts of the pump should be cleaned.
- Do not steam autoclave or ethylene oxides sterilise.
- Disinfectants which could cause surface discoloration or degrade ABS are forbidden..

24. INTERNAL BATTERY OPERATION

- Internal rechargeable battery allows continued operation when the AC power is unavailable, for example during patient transfer or AC failure.
- The battery recharges automatically after connection the pump to the AC power supply. Infusion doesn't impact on battery charging speed.
- When operating on batteries a yellow lamp next to ⏻ flashes and an icon on the display appears. The icon also shows battery charge status and its precise value can be read in "Information" after pressing V INFO. (see p. 16.3 , page 18)
- Battery capacity will decrease in time. Battery tests should be carried every 2 – 3 months after one year of its use and in case of capacity drop up to 80% the battery should be replaced.
- Battery status can also be evaluated from information about the number of recharges in the pump's statistics (see p. 22.6.2 , page 36). The battery effective life time equals to 400 recharges. After exceeding this number quick battery capacity degradation could be expected.
- Due to configuration, replacement of battery should be done only by the trained technical personnel.
- To achieve optimum operation, ensure that the battery is fully recharged after full discharge periodically.

25. LONGER INTERRUPTION IN PUMP OPERATION

In case of expected interruptions in pump operation for longer period of time it is recommended:

- to clean an disinfect the device,
- to fully charge the battery,
- to recharge the battery regularly, every 3 months, or leave the pump connected to the electrical outlet.

26. NURSE CALL CONNECTION

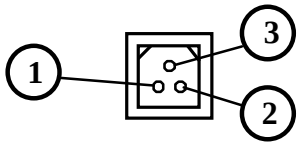
Nurse call alarm connection provides the communication remote backup to the internal audible alarm. Use of original connection lead is recommended. The connection is not needed when the pump is mounted in the docking station. Check the connection pressing 🔕 on the keyboard until test alarm occurs

1 / 2 COMM	Common output
3 / 4 NO	Output normally open with COMM and closed during alarm
5 / 6 NC	Output normally closed with COMM and open during alarm

Use of original connection is recommended.

27. CONNECTION LEAD 12V

Use of DC12 V connection allows operating the pumps in ambulances. Proper connection is signalized same as AC power connection.



1. ±12V
2. ±12V
3. NC

Use of original connection is recommended.

28. INTERFACE RS232C

Pumps are equipped with interface RS232C, which enables:

- Transmission of contains of event log to the outside PC, which allows review, printing and archiving of data about the previous infusions. To do this MEDIMA HISTORY FILE software is necessary which is not a standard delivery enclosure.
- Downloading a drug library to the pump's memory from MEDIMA DRUG EDIOR which is not a standard delivery enclosure.
- Pump to pump drug library transfer (see p. 22.9, page 38).
- Pump to pump configuration transfer or from/to PC .
- Upgrade of the pump's software.
- Visualization of the current infusion status (RS232 cable with battery is required). To visualize and archive information about infusion course it is recommended to use docking stations, that enables to connect to hospital / ward information system practically unlimited quantity of pumps via LAN Ethernet (see p. 34"Docking station", page 46).

Devices to transfer or receive digital data can be connected to pumps only by trained personnel. They must meet requirements of EN60950 specification and the whole system should comply to EN60601-1-1 specification. Connection of the pump which is at medical stand in a direct contact with a patient to PC is only possible by means of a special cable RS232 with isolation. Contact an authorized MEDIMA representative or the manufacturer directly to obtain an information.

29. ACCESSORIES

1. Power supply cord 12 V
2. Cable lead RS232 without isolation
3. Cable lead RS232 with isolation
4. Cable lead for pumps connection (for drug library and configuration transfer)
5. Converter USB/RS232
6. Docking station DS4(E)
7. Docking station DS6(E)

30. TECHNICAL DATA

Flow rate	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 0.1 – 400 ml/h for 5 ml syringe programmable by 0.1 ml/h
Volume of infusion	0.1 – 10 000 ml; in 0.1ml increments up to 999.9 and above in 1 ml increments
Time of infusion	1 min – 200 hours in 1 min increments
Bolus: Volume Rate	 from 0.1 ml up to syringe capacity, in 0.1 ml increments Minimal : 2 x flow rate, maximal : 2000 ml/h, in 1 ml/h increments
KVO rate	0 – 5.0 ml/h, programmable by 0.1 ml/h
Occlusion pressure - levels	1 0.2 kgf/cm2 (bar) ± 50 % 2 0.4 kgf/cm2 ± 40 % 3 0.6 kgf/cm2 ± 30 % 4 0.8 kgf/cm2 ± 25 % 5 1.0 kgf/cm2 ± 25 % 6 1.2 kgf/cm2 ± 25 %
Priming the extension line: Rate Volume	 500 – 1500 ml/h, programmable, default value 1000 ml/h or less, depending on the used syringe max. 5 ml, during priming the line pressure alarm is active
Pre-alarm time	1 – 30 min, programmable
Flow rate accuracy according to EN60601-2-24	Mechanical accuracy of pumps is ± 0.5 % Total accuracy of infusion including a syringe is ± 2% Flow rate accuracy depends on the quality of syringe.
Maximal volume infused during malfunction	0.5 ml for flow rate 2000 ml/h. 0.2 ml for flow rate below 500 ml/h 0.1 ml for flow rate below 100 ml/h
Battery	Ni-MH – 2000 mAh, Battery life: 20 hours / 5 ml/h, Recharging time: 5 hours (100%), Foreseen for about 400 recharges, 2 years
Memory retention	The memory of the unit will be retained for min. 5 years when not powered
Fuse	T 0.5 A / 250 V
Casing Material Protection class Dimensions	 ABS IP22 – according to EN60529 355 x 115 x 166 (W x H x D)– excluding pole clamp
Weight	Below 2.5 kg – without power supply cord

Password 13.46.79

Event log capacity	Minimal 2000 records of operation activities with date and time of event.
Power supply AC DC	 100 – 240 V AC, –15% +10%, 50/60 Hz, max. 15VA 12 – 16 V DC, max. 1 A
Classification	Type CF - protection against defibrillation, class I
Operating conditions	Temperature +5°C - +40°C, humidity maximum 90%
Transport conditions	Temperature -20°C - +50°C, humidity maximum 95%
Complies with safety standards	EN 60601 – 1, EN 60601 – 1 – 2, EN 60601 – 2 – 24, EN 1789, MDD93/42/EEC –IIB
Communication ports	• RS232C ,rate of transmission 38 kb • Infrared for communication with docking station
Drug Names Library	• Up to 120 drugs names. Drug names library can be transferred from pump to pump or from/to PC using RS232C.

31. LIST OF SYRINGES

Below you will find the list of syringes appropriate for use in syringe pumps S, S1, S2 and S-PCA. All the syringes are three- part (have a rubber plunger).

	Volume	**Name of syringe**
1.	5 ml	B.Braun Omnifix
2.	5 ml	BD Plastipak
3.	10 ml	B.Braun Omnifix
4.	10 ml	BD Plastipak
5.	10 ml	Monoject
6.	10 ml	Once
7.	10 ml	Terumo
8.	20 ml	B.Braun Omnifix
9.	20 ml	B.Braun Perfusor
10.	20 ml	BD Plastipak
11.	20 ml	Monoject
12.	20 ml	Once
13.	30 ml	B.Braun Omnifix
14.	30 ml	BD Plastipak
15.	30 ml	Monoject
16.	30 ml	Once
17.	30 ml	Terumo
18.	50 ml	B.Braun Omnifix
19.	50 ml	B.Braun Perfusor
20.	50 ml	BD Perfusion
21.	50 ml	BD Plastipak
22.	50 ml	Diprivan - vitreous
23.	50 ml	Once
24.	50 ml	Terumo

32. REPLACE OF AC FUSE

If the pump is connected to the AC power supply and the display shows: **NO MAINS**, the fuse can be broken. To replace it:

- Disconnect the AC power cord from the electric outlet.
- Open the drawer with the fuse, replace for identical one and close the drawer.
- Connect the power cable and check if the green lamp on the keyboard next to ⏻ will come on. If not, check the power supply cord and the outlet socket.

33. GRAPHS OF INFUSION ACCURACY

33.1. Start-up curves and trumpet curves

In syringe infusion pumps the action of the pumping mechanism and variations in individual syringes cause short-term fluctuations in rate accuracy. Knowledge of system accuracy may be important when choosing parameters of infusion depending on the drugs being administered, it solution and half life in patient body.
Below tests were performed in accordance with EN 60601-2-24 standards:

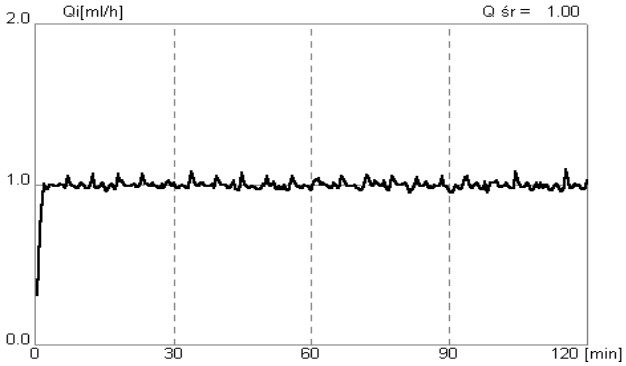
- start-up curves inform about the errors at the beginning of infusion depending on flow rate,
- trumpet curves inform about the accuracy of fluid delivery over various time period.

Start-up curves represent continuous flow versus operating time from the start of the infusion. The in onset delivery is caused by different factors. To reduce it:

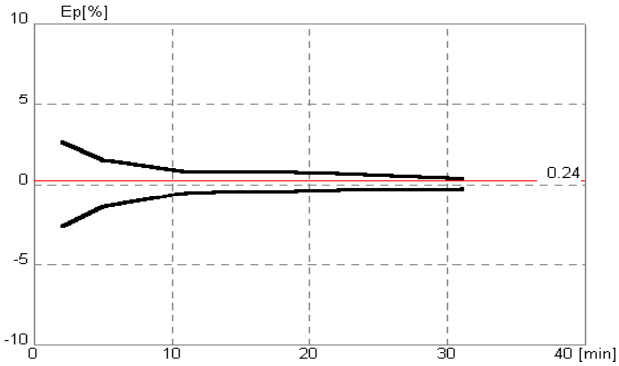
- always fill up the line after the syringe replacement,
- for low flow rate use the syringe of a small capacity,
- use possibly diluted drugs and higher rates.

Trumpet curves named for their characteristic shape, display discrete data averaged over particular time period or ‘observation windows’. Over long observation windows, short term fluctuations have little effect on accuracy.
This graphs show how large of uniformity errors can be expected depending on half-life of the drug and flow rate. For drugs of shorter half-life or for application were flow uniformity is a concern, possibly diluted drugs and flow rates of 1.0 ml/h or above and small syringe size are recommended.
Differences in factors such as size and plunger force in compatible syringes produced by the others manufacturers can cause variations in accuracy and trumpet curves as compared to those represented. Additional curves for compatible syringes are available upon request. Start-up and trumpet curves may not be indicative of operation under negative pressure.

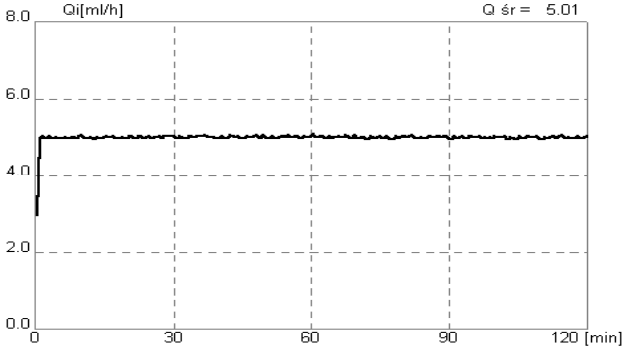
Tests taken using BD PLASTIPAK 50 ml syringe



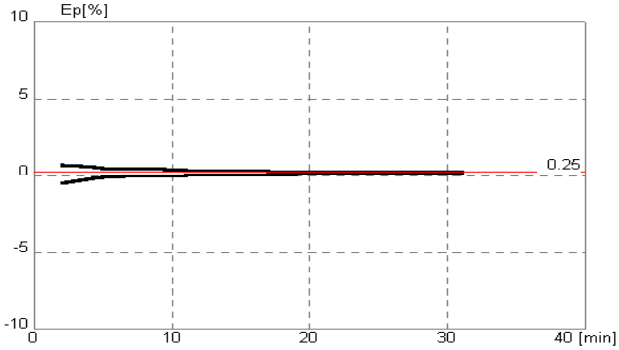
Start-up Curve
Nominal infusion rate r =1.0 [ml/h]
Testing time: 120 [min]
Sampling time: 30[s]



Trumpet Curve
Average terror 0.24%
Observation window: 2, 5, 11, 19, 31 [min]



Start-up Curve
Nominal infusion rate r = 5.0 [ml/h]
Testing time: 120 [min]
Sampling time: 30[s]



Trumpet Curve
Average terror 0.25%
Observation window: 2, 5, 11, 19, 31 [min]

33.2. Occlusion – Reaction Time and Residual Bolus

Pump reaction time for occlusion depends on many factors:

- Set pressure level - the lower the level, the sooner pump will signal occlusion in patient line.
- Flow rate - the higher the rate, the sooner the occlusion alarm will occur.
- Elasticity of extension line - the thicker the walls of the extension line, the sooner the occlusion alarm will occur.
- Length of extension line – the longer line will increase reaction time for occlusion.

When occlusion occurs the extension line will expand due to the pressure and more fluid will be accumulated within. The higher the pressure level set in the pump, the thinner the walls of the extension line and the longer the extension line will become more fluid will be accumulated.

Pressure	Time until alarm occurs at 1 ml/h	Time until alarm occurs at 5 ml/h	Residual bolus without Anti-Bolus-System	Residual bolus with Anti-Bolus-System
1 level	19 min	4 min 30 sec	0.21 ml	0.10 ml
2 level	33 min	7 min 30 sec	0.32 ml	0.12 ml
3 level	49 min	11 min 30 sec	0.45 ml	0.16 ml
4 level	1 hour 03 min	16 min 30 sec	0.60 ml	0.21 ml
5 level	1 hour 24 min	21 min 30 sec	0.78 ml	0.25 ml
6 level	1 hour 47 min	27 min 30 sec	0,96 ml	0,28 ml

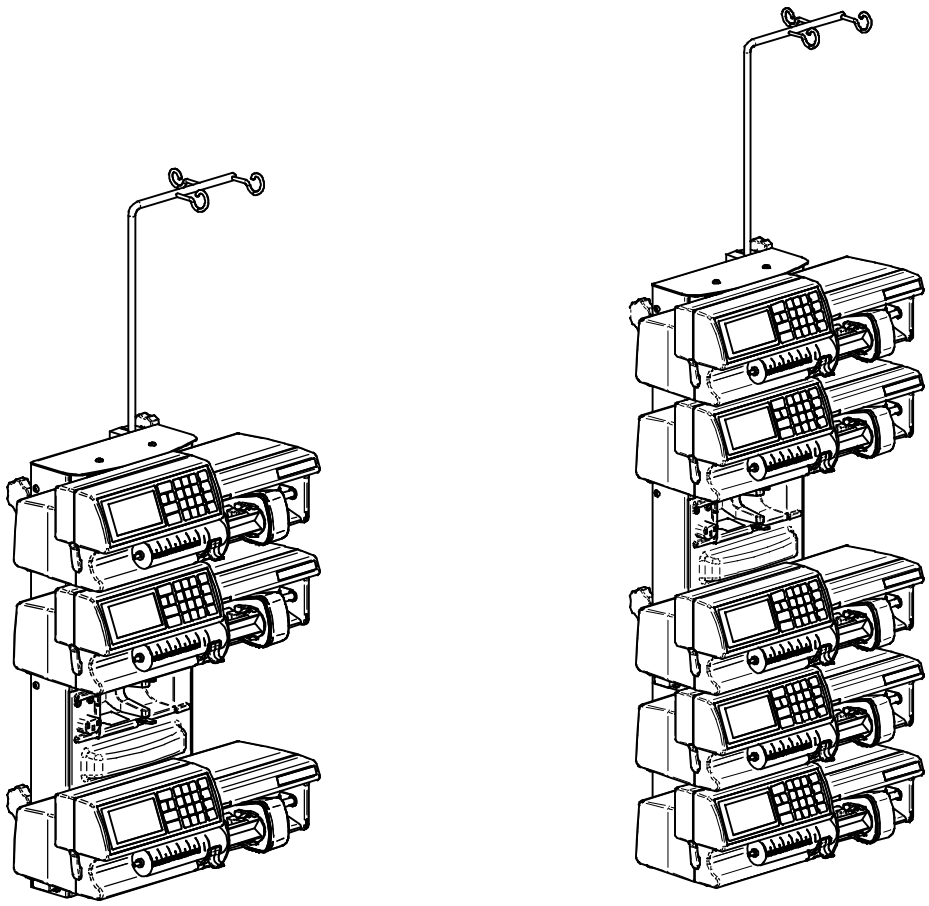
As can be observed the Anti-Bolus-System significantly reduces volume of fluid accumulated in the patient line. This volume is subtracted from the total volume received by the patient.
These measurements were taken using BD PLASTIPAK 50 ml and standard extension set of 2 m.

34. DOCKING STATION

The docking stations are recommended to save valuable space around the bedside:

- DS2 - for 2 pumps
- DS4 - for 4 pumps
- DS6 - for 6 pumps
- DS8 - for 8 pumps
- DS4E, DS6E, DS8E- version with Ethernet

They enable quick installation of pumps at the patient's bed and creation of sets required by actual therapy. Power supply and communications ports are connected automatically after mounting a pump into the docking station. In option there are communication modules that enable to connect a pump to the hospital information system. We offer software that enables observation of infusion in the real time at any PC, connected to LAN in the hospital ward. It also gives a possibility to transfer a drug library and configuration to all pumps mounted into docking stations.



35. INFORMATION ABOUT MANUFACTURER

MANUFACTURER:		REPRESENTATIVE:
MEDIMA Sp. z o.o	tel.: + 48223132266	
02-486 Warszawa	fax.: + 48223132269	
Al. Jerozolimskie 200		
POLAND	www.medima.com.pl	

Serial Number	Password	Hospital Ward Name

36. DOCUMENT HISTORY

Version	Date of Issue	Remarks	Software Version
1	2.2005	IO – 001 – 04.1	V5.6.xx
2	9.2006	IO – 001 – 04.2	V6.3.xx
3	10.2006	IO – 001 – 04.3	V6.3.xx

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