

SYRINGE INFUSION PUMP USER'S MANUAL

MODEL S1 MODEL S2



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.

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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. 19.7 , page 35)
- **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

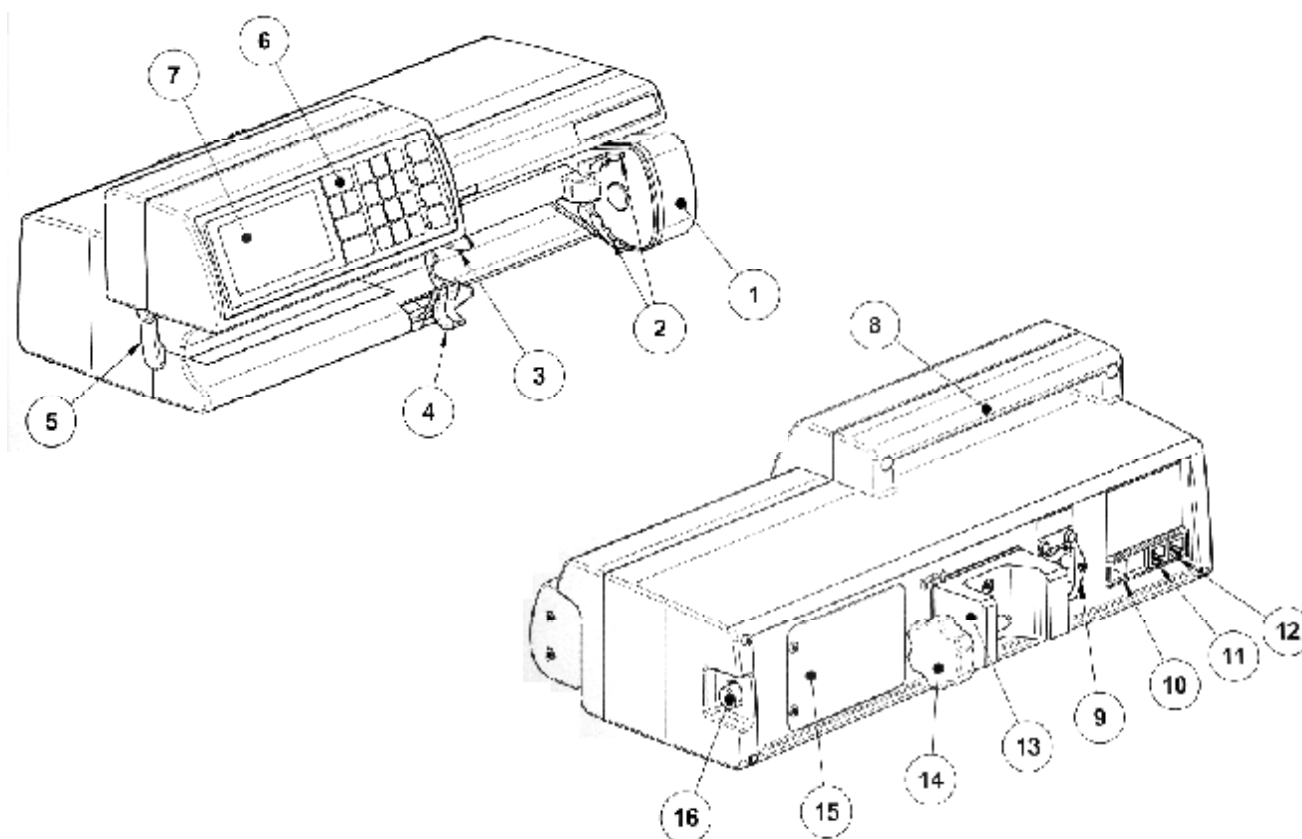
- For correct and safe operation the manufacturer recommends to carry out a technical inspection every two years.
- All maintenance work and repair should be done only by the personnel trained by the manufacturer. In case of any doubts concerning correct pump operation, the device should be removed from 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:

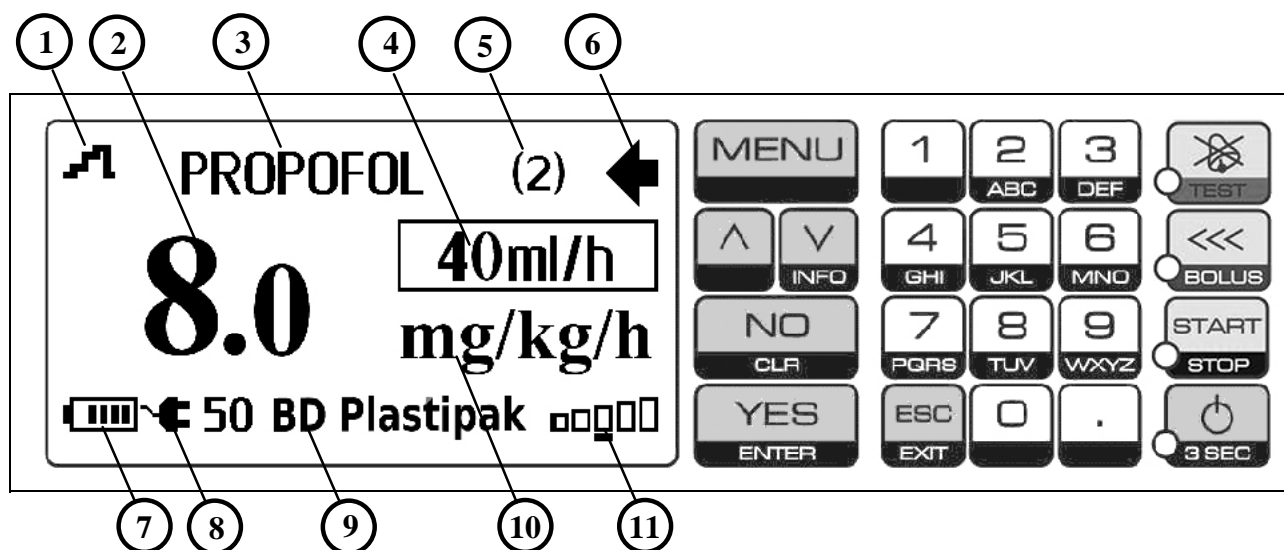
- Installation, operation and modification are performed in accordance with the user's manual and manufacturer's instructions.
- Inspections and repairs are made by authorized personnel trained by MEDIMA.
- Technical inspections of devices are carried out every two years.

5. PUMP CONSTRUCTION



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

5.1. Keyboard



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



Buttons used to select parameters or functions.

Review of the infusion parameters **V INFO**



Button used to confirm value or information displayed.



Button used to reset or reject information displayed.



Numeric keys for entering parameters and names



Button used to stop or exit selected window or entered data.



Starts / stops infusion

Infusion indicator – yellow, flashing



Acoustic alarm reset button. Longer pressing starts alarm tests.

Alarm – red, flashing.



Purge / bolus button

Bolus indicator – blue, flashing during bolus infusion



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

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 7) 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 7).

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 **▲** **▼** 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 the Value 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 **▲** **▼** 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 **▲** **▼** select the type of syringe, press **NO**; a list of syringes will appear.
- Using **▲** **▼** 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 41)

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.19.8 “Options - Additional Infusion Parameters”, page 36)
 - 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. 19.8“Options-Additional Infusion Parameters”, page 36) 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. 19.8 “Options-Additional Infusion Parameters”, page 36) 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 appropriate 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 **▼** 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. 19.8 “Options-Additional Infusion Parameters”, page 36) 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)

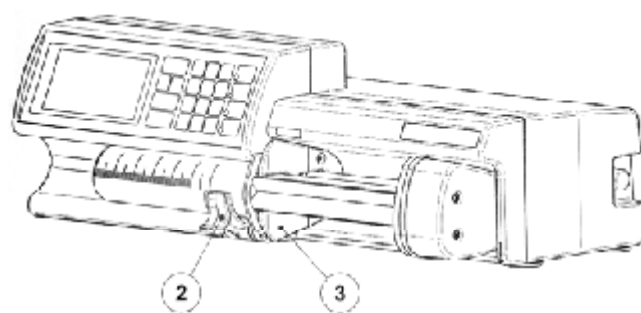
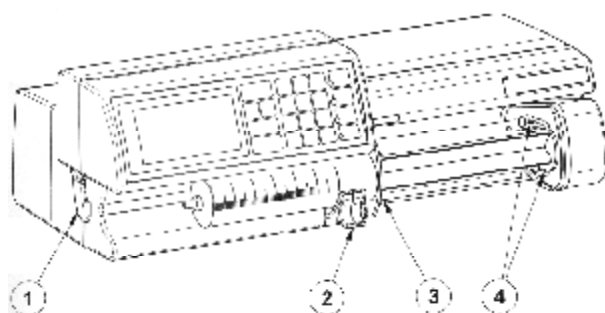
- Ensure the type and size of syringe on display is accurate. If not, choose the correct one.
- Clear rate of infusion (enter **0** or press **NO** and confirm **YES**).
- Enter volume of infusion and confirm **YES**.
- Enter time (hours & minutes) and confirm **YES**; the pump will calculate and show rate of infusion in ml/h.
- Enter, clear or omit BOLUS parameters.
- Using **▼** 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. 19.8 “Options-Additional Infusion Parameters”, page 36) 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

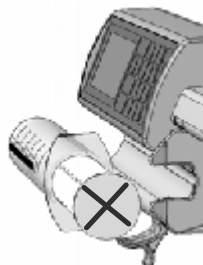
After proper entering infusion parameters the pump waits for a syringe to be loaded, displaying “**INSERT SYRINGE**”



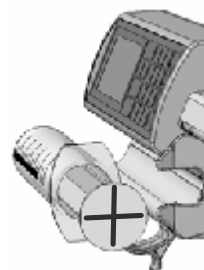
Never load a syringe to the pump if the extension set is connected to a patient. Uncontrolled infusion or back flow may occur and cause danger to the patient's life. For safety reason isolate the patient by closing the tap in the extension line. Check if there is air in the syringe and if yes, remove 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 18).

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 vein. 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 21):

16. INFUSION

Button **START/STOP** starts / stops the infusion

16.1. Induction Dose

Induction dose is a single dose delivered with high flow rate at the beginning of infusion. Delivery of induction dose in this mode begins automatically after start of infusion if this parameter has been programmed. A button **START/STOP** stops/restarts delivery of the dose. If you don't want infusion with induction dose cancel induction dose parameters or block it in "Options-Additional Infusion Parameters" (see p.19.8, page 36).

For safety reason before starting infusion the pump will require confirmation of delivery of induction dose that allows its omitting in justifiable cases.

Induction dose is not included in the programmed dose of infusion. It means that a patient will receive the sum of the programmed dose of the infusion and the induction dose. The total dose delivered to the patient can be read in information about infusion after pressing **INFO** (see p.16.4 "Review of Information about Infusion ", page 20).

16.2. 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

16.3. 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**
- **▲▼** Select „Parameters” and confirm **YES**: a window with parameters will appear
- **▲▼** 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.16.4 “Review of Information about Infusion “, page 20).

16.4. Review of Information about Infusion

- Press **V INFO**
- Review information using **▲ ▼**
- 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

16.5. 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 49) that starts alarm after expiry of the programmed time.

16.6. 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 17), 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 21).

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.

16.7. 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 17)
- Prime the extension line (see p.12 “Priming the Line, Start of Infusion”, page 17)
- 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**
- **▲ ▼** 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 **▲ ▼** 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.
 - **▲ ▼** 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	(Keep Vein Open)- 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
- Emptying 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 42.

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 47).

- Press **MENU** during infusion or during a pause in infusion
- Using **▲ ▼** 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 **▲ ▼** select „Information” and confirm **YES**.

The following will appear:


- Drug library Information about drug library (name, version, creation date and modification date) entered using DRUG EDITOR. (see p. 20.8, page 40)
- Pump Information about the pump (see p.22.6, on page 48)
- Statistics Statistical information about pump and battery working time.
(see p. 22.6, page 48)

17.8.1 Information about Drug Library Version

This information appears only if a drug library has been downloaded to the pump using MEDIMA DRUG EDITOR (see p. 20.8, page 40). The information is very important as it enables to check whether the drug library in the pump is the proper one – the latest version and whether it was modified in the pump. All the incompatibilities in the drugs protocols may cause significant infusion errors and danger to a patient’s life.

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	<ul style="list-style-type: none"> • Doesn't stop the infusion! • Regards both DC-12V and AC power
BATTERY LOW	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • INFUSION STOPPED (KVO also) • After muting the sound or after 3 minutes pump will switch off • Restart of operation possible on AC power.
OCCLUSION	<ul style="list-style-type: none"> • 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 23).
HIGH PRESSURE	<ul style="list-style-type: none"> • 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 46)
LINE DISCONNECTED	<ul style="list-style-type: none"> • INFUSION STOPPED (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 46) • Alarm will be activated only when the occlusion pressure is set above the 2-nd level
CHECK SYRINGE	<ul style="list-style-type: none"> • INFUSION STOPPED – 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	<ul style="list-style-type: none"> • 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 46)
INFUSION END	<ul style="list-style-type: none"> • INFUSION STOPPED – KVO active up to syringe unloading. • Occurs when volume / dose or infusion time is programmed.
5 MIN TO SYRINGE EMPTY	<ul style="list-style-type: none"> • 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 46)

SYRINGE EMPTY	<ul style="list-style-type: none"> • 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..
PAUSE	<ul style="list-style-type: none"> • Information about start of pause for intermittent infusion (KVO active) Alarm occurs when option “Cycle Alarm” is chosen (see p. 19.8.5, page 37)
PAUSE END	<ul style="list-style-type: none"> • Information about end of pause for intermittent infusion. Alarm occurs when option “Cycle Alarm” is chosen (see p. 19.8.5, page 37) • Infusion starts automatically if the syringe is loaded.
CYCLE END	<ul style="list-style-type: none"> • Information about end of cycle for infusion with profile; alarm occurs when option “Cycle Alarm” is chosen (see p. 19.8.5 , page 37) • Infusion starts automatically for the next cycle.
? ? ? (2 min)	<ul style="list-style-type: none"> • Occurs every two minutes when the switched on device is left without the infusion.
DRUG NOT ACTIVE	<ul style="list-style-type: none"> • Doesn't stop the infusion! • Warning about the degradation of drug's activity • After muting the alarm the red lamp is flashing until the syringe is unloaded.
MALFUNCTION XXX	<ul style="list-style-type: none"> • INFUSION STOPPED (KVO also)

19. ADDITIONAL POSSIBILITIES OF INFUSION (programming)

19.1. Advanced pump programming

Apart from the simple, basic infusion the pump also gives possibilities of programming other, more complicated infusions described below (see p.19.5 “Modes of Infusion”, page 29). Choose a proper mode and units of infusion and next enter necessary parameters (not all parameters have to be entered). A dosing procedure created in this way can be entered into a drug library (pump memory) named as a drug name (see p. 20 “Drug Library”, page 37). Next infusion of that medicine will not require the repetition of the same activities. Just choose it from the drug library list and modify dosage parameters if necessary. It is the quickest and the safest way of pump programming. To create a drug library MEDIMA DRUG EDITOR software is recommended (see p. 20.8, page 40).

19.2 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
- Drugs Drug library (dosing procedures) saved in the pump's memory (see p. 20.2, page 38)
- Save drug Allows recording a new dosing procedure in the drug library (see p. 20.1, page 38)
- Units Allows selecting flow rate units (see p.19.4, page 28)
- Infusion mode Allows selecting infusion mode (see p.19.5, page 29)
- Options Additional infusion parameters (see p.19.8, page 36)

19.3 . 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. This function is in particular useful when after the infusion composed of many parameters or taken from the drug library it is necessary to start a basic infusion in ml/h.

19.4. Units of Infusion

Flow rate can be programmed in the following mass units in all above mentioned modes of infusion:

- **ml/h, ml/min, ml/24h**
ml/kg/h, ml/kg/min, ml/kg/24h
- ng/h, ng/min, ng/24h
ng/kg/h, ng/kg/min, ng/kg/24h
- µg/h, µg/min, µg/24h
µg/kg/h, µg/kg/min, µg/kg/24h
- mg/h, mg/min, mg/24h
mg/kg/h, mg/kg/min, mg/kg/24h
- µU/h, µU/min, µU/24h
µU/kg/h, µU/kg/min, µU/kg/24h
- mU/h, mU/min, mU/24h
mU/kg/h, mU/kg/min, mU/kg/24h
- U/h, U/min, U/24h
U/kg/h, U/kg/min, U/kg/24h
- kU/h, kU/min, kU/24h
kU/kg/h, kU/kg/min, kU/kg/24h
- nmol/h, nmol/min, nmol/24h
nmol/kg/h, nmol/kg/min, nmol/kg/24h
- µmol/h, µmol/min, µmol/24h
µmol/kg/h, µmol/kg/min, µmol/kg/24h
- mmol/h, mmol/min, mmol/24h
mmol/kg/h, mmol/kg/min, mmol/kg/24h
- mol/h, mol/min, mol/24h mol/kg/h,
mol/kg/min, mol/kg/24h

Selection of flow rate units will cause the proper choice of unit for all other parameters of infusion (for conversion factors see p. 32, page 55).

19.4.1. Selection of Units of Infusion

(window with infusion parameters)

- Press **MENU**
- Using **▲▼** select UNITS and confirm **YES**
- Using **▲▼** select required unit and confirm **YES**
- If desired units are not on the list, select OTHER UNITS and press **YES**
- Using **▲▼ YES** create desired unit
- If you want to reject the changes, press **ESC**
- Come back to infusion in ml/h: choose units or use the function “ Clear Parameters”

19.5. Modes of Infusion

Three modes of infusion are available:

- Continuous Infusion – the most popular
- Intermittent Infusion
- Infusion with Profile

The choice of one of the mentioned modes of infusion will cause the appearance of proper parameters for this mode of infusion on the display.

19.5.1. Continuous Infusion



- Programmed volume over time – the pump automatically calculates the flow rate
- Programmed time or volume
- Programmed bolus and induction dose



19.5.2. Intermittent Infusion



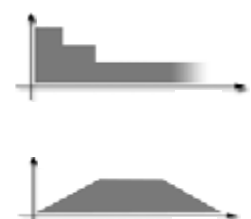
- Programmed volume over time – the pump automatically calculates the flow rate
- Programmed time of infusion and time of pause
- Programmed number of infusion – pause cycles
- Programmed bolus and induction dose
- Possible unloading of syringe during pause



19.5.3. Infusion with Profile



- Up to 24 cycles – each with flow rate and time or volume and time
- Programmed flow rate with possibility of ramp on/ramp off
- Programmed bolus and induction dose



19.5.4. Selection of Infusion Mode

(window with infusion parameters)

- Press **MENU**
- Using **▲ ▼** select **INFUSION MODE** and confirm **YES**
- Using **▲ ▼** select required infusion mode and confirm **YES**
- If you want to reject the changes, press **ESC**
- If you want to come back to continuous infusion: choose the proper mode of infusion or use the function “Clear Parameters”

19.6. Programming Examples

19.6.1. Continuous Infusion in mg/kg/h (or in other units)

Select:

INFUSION MODE continuous infusion (see p. 19.5.4, page 30)

UNITS for e.g. mg/kg/h (see p. 19.4.1, page 29)

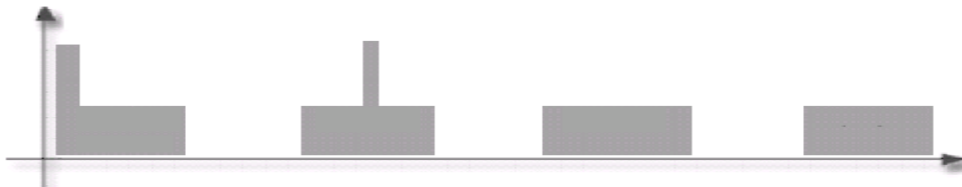
Parameters programming:

- Check whether the type and size of syringe on display is as required. If not choose the required one.
- Drug concentration – I-st way:
 - Use **▲ ▼** to select „Conc.” parameter
 - press **NO** shortly; a window for concentration counting will open
 - enter volume of dilution and confirm **YES**
 - enter drug dose and confirm **YES** (change of units possible). In order to do so:
 - press and hold **NO** until units field flashes
 - using **▲ ▼** or **NO** select required units and confirm **YES**
- Drug concentration – II-nd way:
 - Use **▲ ▼** to select „Conc.” Parameter
 - if required units not displayed, press and hold **NO** until units field flashes
 - using **▲ ▼** or **NO** create required units and confirm **YES**
 - enter drug concentration and confirm **YES**
- Enter patient weight and confirm **YES**
- Enter flow rate and confirm **YES** - you can change the units;
 - press and hold **NO** until units field flashes
 - using **▲ ▼** or **NO** create required units and confirm **YES**
- Enter total dose and confirm **YES**; entering this parameter is not obligatory. In this case alarm **INFUSION END** will not occur, only **EMPTY SYRINGE**. The dose units possible to change.

This parameter can be disabled if not used (see p. 19.8 “Options-Additional Infusion Parameters”, page 36).

- Enter, clear or omit BOLUS parameters. Entering:
 - press **NO** - a window for bolus will open
 - enter bolus dose and confirm **YES** (change of units possible)
 - enter time of bolus in seconds and confirm **YES** - rate will be counted automatically. Time can be omitted and rate entered only.
 - Bolus dose can be omitted (see p. 19.8 “Options-Additional Infusion Parameters” page 36)
- Enter, clear or omit induction dose parameters (if displayed; see p. 19.8 “Options-Additional Infusion Parameters”, page 36). The way of entering the same like for bolus.
- Dosing procedure can be stored in the pump memory for own drug library creation (see p.20, page 37)
- Using **YES** select „---Confirm---” and press **YES** -a window with parameters will be closed
- To come back to the parameters window and to review or modify the infusion parameters:
 - Press and hold **MENU** until a parameters window appears
 - or
 - Press **MENU**
 - Using **UP** **DOWN** select „Parameters” and confirm **YES**
 - Using **UP** **DOWN** review or modify parameters
 - Press **ESC** to finish

19.6.2. Intermittent Infusion in ml/h



I – st way

Select:

INFUSION MODE	intermittent infusion	(see p. 19.5.4, page 30)
UNITS	ml/h	(see p. 19.4.1, page 29)

Parameters programming:

- Check whether the type and size of syringe on display is as required. If not choose the required one.
- Enter **flow rate** and confirm **YES** - you can select units (ml/h, ml/min, ml/24h);
 - press and hold **NO** until units field flashes
 - using **UP** **DOWN** or **NO** select required units and confirm **YES**
- Enter **time** of infusion (hours & min.) of single cycle and confirm **YES**
- Enter time of pause (hours & min.) and confirm **YES**

- Enter number of cycles and confirm **YES**; entering this parameter is not obligatory. In this case the infusion will be continued until a syringe is empty and alarm END OF INFUSION will not occur. Number of cycles shows number of infusion – pause.
- Enter, clear or omit induction dose parameters (if enabled; see p. 19.8 “Options- Additional Infusion Parameters”, page 36)
- Enter, clear or omit BOLUS parameters (Bolus dose possible to be disabled (see p. 19.8 “Options- Additional Infusion Parameters”, page 36)
- The procedure of drug dosing can be entered into the pump’s memory creating this way an own drug library (see p. 20, page 37)
- Using **▼** select „---Confirm---” and press **YES** - a parameters window will be closed
- To come back to the parameters window and to review or modify the infusion parameters :
press and hold **MENU** until a window with parameters appears

II – nd way

Select:

INFUSION MODE	intermittent infusion	(see p. 19.5.4, page 30)
UNITS	ml + h	(see p. 19.4.1, page 29)

Parameters programming:

- Check whether the type and size of syringe on display is as required. If not choose the required one.
- Enter **volume** of single cycle and confirm **YES**
- Enter **time** of infusion (hours & min.) of single cycle and confirm **YES**
- Enter time of pause (hours & min.) and confirm **YES**
- Enter number of cycles and confirm **YES**; you can omit this parameter. In this case the infusion will be continued and alarm END OF INFUSION will not appear
- Enter, clear or omit induction dose parameters (if displayed)
- Enter, clear or omit BOLUS parameters (if displayed)
- The procedure of drug dosing can be entered into the pump’s memory creating this way an own drug library (see p.20, page 37)
- Using **▼** select „---Confirm---” and press **YES** - a parameters window will be closed.
- To come back to the parameters window and to review or modify the infusion parameters. Press and hold **MENU** until a window with parameters appears

It is recommended to use “Report” function for the infusion with the bigger quantity of cycles. The information about the infusion time and drug volume will be displayed if the number of cycles is entered.

- Press **MENU** (when a parameters window is displayed)
- Using **▲▼** select „Options” and confirm **YES**
- Using **▲▼** select „ Report” and confirm **YES** (or press **NO** to switch off)
- Press **ESC** to end

19.6.3. Intermittent Infusion in mg/kg/h (or in other units)

Select:

INFUSION MODE intermittent infusion (see p. 19.5.4, page 30)

UNITS for e.g. mg/kg/h (see p. 19.4.1, page 29)




Editing parameters and other remarks like in infusion in ml/h. Additionally will appear:

- Drug concentration
- Patient weight

See p. 19.6.1 “Continuous Infusion in mg/kg/h (or in other units)”, page 30

19.6.4. Infusion with Profile - Types

The following profile types can be programmed:

1. All parameters of profile cycles entered; after the infusion of programmed volume alarm INFUSION END will occur.
2. Not entered the time of the last profile cycle; the last cycle will last until the syringe is empty or infusion stopped (alarm INFUSION END will not occur). 
3. Not entered the flow rate of the first, last or both cycles; the flow rate of infusion will rise at the beginning and drop at the end (TPN). 
4. Not entered the flow rate of medium cycle; the flow rate of this cycle will change from the level of previous cycle the level of the next one. 
5. Entered zero for flow rate for chosen cycle; pause in infusion during this cycle will occur. KVO will also not be active.

All the above mentioned cases could be mixed and connected together to create desired infusion profile.

19.6.5. Infusion with Profile in ml/h

Infusion with profile - it is infusion with max 24 cycles. Flow rate (or volume) and time can be programmed. Actually delivered infusion cycle number is displayed.

I-st way:

Select:

INFUSION MODE	infusion with profile	(see p. 19.5.4, page 30)
UNITS	ml /h	(see p. 19.4.1, page 29)

Parameters programming:

- Check whether the type and size of syringe displayed is as required. If not choose the required one
- Enter number of profile cycles and confirm **YES**
- Enter **flow rate** of following cycle and confirm **YES** -you can select units (ml/h, ml/min, ml/24h);
- Enter **time** of infusion (hours & min.) of following cycle and confirm **YES**
- Enter, clear or omit induction dose parameters (if displayed)
- Enter, clear or omit BOLUS parameters (if displayed)
- The procedure of drug dosing can be entered into the pump's memory creating this way an own drug library (see p. 20, page 37)
- Using ☒ select „---Confirm---” and press **YES** - a parameters window will be closed.
- To come back to parameters window and to review or modify the infusion parameters : press and hold **MENU** until a window with parameters appears

II-nd way:

Select:

INFUSION MODE	infusion with profile	(see p. 19.5.4, page 30)
UNITS	ml + h	(see p. 19.4.1, page 29)

Parameters programming:

- Check whether the type and size of syringe displayed is as required. If not choose the required one
- Enter number of profile cycles and confirm **YES**
- Enter **volume** of following cycle and confirm **YES**
- Enter **time** of infusion (hours & min.) of following cycle and confirm **YES**
- Enter, clear or omit induction dose parameters (if displayed)
- Enter, clear or omit BOLUS parameters (if displayed)
- The procedure of drug dosing can be entered into the pump's memory creating this way an own drug library (see p.20, page 37)
- Using ☒ select „---Confirm---” and press **YES** - a parameters window will be closed.
- To come back to the parameters window and to review or modify the infusion parameters – press and hold **MENU** until a window with parameters appears.

19.6.6. Infusion with Profile in mg/kg/h (or in other units)

Select:

INFUSION MODE	infusion with profile	(see p. 19.5.4, page 30)
UNITS	mg/kg/h	(see p. 19.4.1, page 29)

Programming and remarks like for profile in ml/h; additionally will appear:

- Drug concentration (see p.19.6.1.”Continuous Infusion in mg/kg/h”), page 30)
- Patient weight

In the same way parameters of infusion in other units can be programmed.

19.7. Limits of Parameters Values (Model S2 only)

Model S2 enables to enter limits for each infusion parameter to warn the operator and makes infusion safer. The entering of the two different types of limits is possible:







- Soft limit (min & max) Only warn about the crossing of recommended values of parameter but doesn't block the entering the value. During programming the information about the recommended values of parameter will appear.
- Hard limit (min & max) Block the entering of parameter values exceeding the limit. During programming the information about the admissible values of parameter will appear.

Entering the limits makes infusion much safer and it is recommended when an own drug library is created (see p. 20, page 37). Not all drugs have to have the limits entered. Those which have them entered differ from the others by letter “L” before the drug name.

The sign “L” appears only when at least the limits for flow rate were entered. Missing of limits for that parameter will not activate the sign “L” even when the limits for other parameters were entered. If during infusion one of the entered limits for any of the infusion parameters is exceeded the sign “L” will not flash.

Not all four limits have to be entered, enter the needed ones only.

Entering the limits (a parameters window on the display):

- Using   select „Rate”
- Press and hold  until a window with limits for this parameter appears
- Review, enter, change or delete limit values. Units can be changed.
- Press  to close the window
- Using   select next parameter (for example Bolus dose) and repeat the procedure of limits entering
- When the parameter's value exceeds programmed limits an alert window will appear
- Save the drug in the drug library (see p. 20.1, page 38)
- Setting the same value for hard limits as minimum and maximum will limit the choice to this value only

19.8. 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 **▲ ▼** 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
 - Induction dose YES/NO induction dose enabled/disabled
 - Report YES/NO available for intermittent and infusion with profile only
 - Cycle Alarm YES/NO available for intermittent and infusion with profile only
 - Start time YES/NO start time enabled/disabled
 - Drug activity YES/NO drug activity enabled/disabled
- Using **▲ ▼** 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.

19.8.1 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.

19.8.2 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 46).

19.8.3 Induction Dose

If this option is enabled/disabled “Induction dose” parameter will appear/ disappear on the display. It is recommended to disable it if not required.

19.8.4 Report

This function enables displaying information about the total volume / dose and time of infusion at the end of parameters programming. Available only for:

- Intermittent Infusion - when the number of cycles entered
- Infusion with Profile - when the time of last cycle entered

19.8.5 Cycle Alarm

This option switches on/off the alarm after each infusion cycle for intermittent infusion or infusion with profile.

19.8.6 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.

19.8.7 Drug Activity

This function enables monitoring the time of drug degradation (increase of activity). After selecting this option time left to the DRUG NOT ACTIVE alarm will appear in the programming window. This parameter can be omitted; the alarm will not occur.

The time of drug activity is counted from the moment of syringe loading and not when infusion starts. Each syringe unloading resets the counter. Switching off the pump doesn't stop counting when a syringe is still loaded.

20. DRUG LIBRARY

Programmed earlier values of infusion parameters and options (additional parameters) and limits (Model S2) can be stored in the pump's memory under the created drug name. Collection of all stored dosing procedures creates a "Drug Library".

Creating drug library is recommended as it:

- Significantly increases safety of infusion; entering limits of infusion parameters reduces the risk of medicine's overdose.
- Checked and entered into the pump's memory dosing procedure doesn't require parameters entering before infusion but only their review or modification: it's enough only to select a required drug from the list and infusion parameters will be automatically fulfilled. This shortens infusion programming and reduces the probability of errors. Besides it is possible to disable a possibility of change of chosen parameters (for example: drug concentration, see p. 19.7, page 35).

- Increases safety of the pump operation: a drug name is always displayed during infusion. It is important in particular when many pumps are the patient bedside.

“MEDIMA DRUG EDITOR” software is recommended to create drug libraries (see p. 20.8, page 40).

20.1. Recording Drug Procedures- Drug Libraries Creation

- Select, enter and check all infusion parameters (infusion type, units, options). Not all parameters must be entered but check if the units of not entered parameters are correct. It is recommended to save parameters same for the most of infusions for the drug (like concentration, bolus). All other parameters may be omitted or typical values saved. In Model S2 all limits for all or most important parameters could be saved (see p. 19.7, page 35). It is also recommended to disable a bolus function, induction dose and other parameters in “Options” if they are not used (see p. 19.8, page 36).
- Press **MENU** when a parameters window is displayed
- Using **▲▼** select „Save drug” and confirm **YES**
- Enter a 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
 - entering 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
 - press **ESC** to cancel entering the name and revert to infusion parameters window.

If the entered drug name with the **same infusion name and type** already exists the warning will appear. The review of parameters of both programmes and cancelling one of them is recommended.

Saving the same dosing procedures under the same name is possible only when the type of infusion is different (continuous infusion, intermittent infusion, infusion with profile). Type of syringe and patient weight are not stored in the memory.

20.2. Dosing Procedures Recalling

- Press **MENU** when a parameters window is displayed
- Using **▲▼** select „Drugs” and confirm **YES** If the drug library was created with the use of DRUG EDITOR software (see p. 20.8, page 40) the name of drug library appears on the display.
- Using **▲▼** select a desired drug and confirm **YES**; instead of **▲▼** the numerical keys can be used to chose the first letter from drug name.

Recalled parameters should be checked and modified if needed. The name of drug will be displayed during infusion.

20.3. Review of Drug Parameters

When we are not sure about the chosen parameters they could be reviewed:

- Press **MENU** when a parameters window is displayed
- Using **▲▼** select „Drugs” and confirm **YES**
- Using **▲▼** select desired program and confirm **YES**; instead of **▲▼** the numerical keys can be used to choose the first letter from drug name.
- Press **MENU**
- Using **▲▼** select „Parameters” and confirm **YES**
- Using **▲▼** scroll the list of parameters – not all are visible on the display
- Press **ESC** to finish review

20.4 Delete Drug

- Press **MENU** when a parameters window is displayed
- Using **▲▼** select „Drugs” and confirm **YES**
- Using **▲▼** select desired program and confirm **YES**; instead of **▲▼** the numerical keys can be used to chose the first letter from drug name.
- Press **MENU**
- Using **▲▼** select „Delete drug ” and confirm **YES**
- Press **ESC** to exit

20.5. Change of Drug Name

- Press **MENU** when a parameters window is displayed
- Using **▲▼** select „Drugs” and confirm **YES**
- Using **▲▼** select desired program and confirm **YES**; instead of **▲▼** the numerical keys can be used to chose the first letter from drug name.
- Press **MENU**
- Using **▲▼** select „Change name” and confirm **YES**
- Enter the new drug name (see p. 20.1 “Recording Drug Procedures-Drug Libraries Creation”, page 38)
- Press **ESC** to exit

20.6. Creation of Concise Drug Library

A drug library can contain up to 120 dosing procedures, according to the requirements of a few wards or the specificity of application. To speed up choice of a drug from the list an operator can create an own concise drug library according to the requirements of a specified application.

- Press **MENU** when a parameters window is displayed
- Using **▲▼** select „Drugs” and confirm **YES**
- Again press **MENU**
- Using **▲▼** select „Create list” and confirm **YES**
- Using **YES NO** select required drugs
- Press **ESC** to exit. In your library you will find only selected drugs.

To revert to the full list of drugs act as above using a function “All drugs” instead of “Create list”.

20.7. 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 dosing procedures. Manual entering of many drugs procedures takes time and can cause errors. In such a case entering all procedures to one pump and transferring to all others is recommended.

A function “Send drugs” (see p. 22.9, page 50) enables to transfer of data by interface RS232. A special connection cord is needed (see p. 29, page 53).

Transfer of data between different models (S, S1 S2, S-PCA) is not allowed.

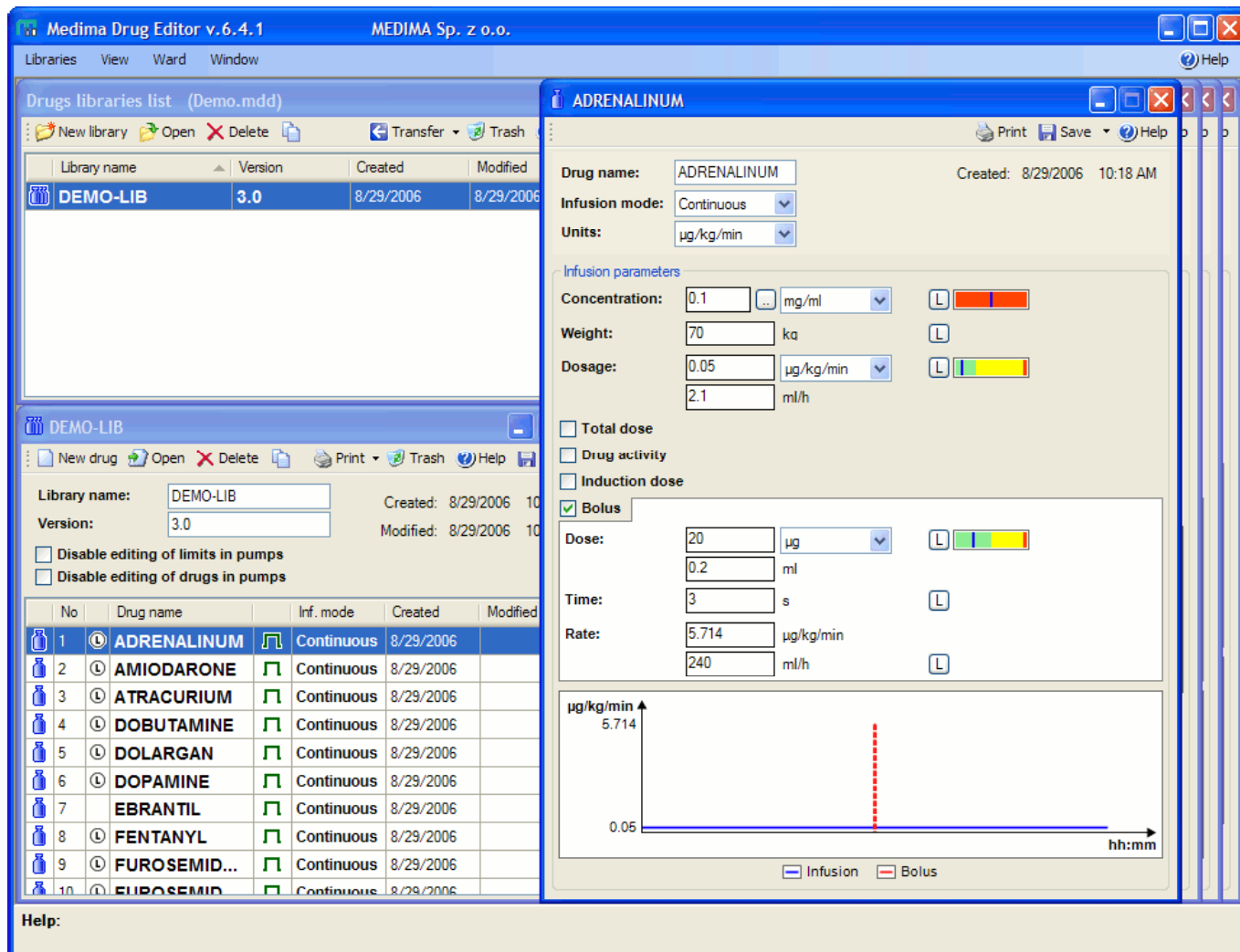
20.8. Drug Library Creation with the Use of DRUG EDITOR Software

Dosing procedures 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. All data are secured and modification of library is blocked.

If a drug library is downloaded to the pump from MEDIMA DRUG EDITOR software then in the function “Information” (see p. 22.6.1, page 48) will appear a library name, version, creation and modification. This information enables to check weather in all pumps in the hospital ward there is the latest drug library. Information about library name will also appear at the drug list headline (see p. 20.2, page 38).

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:

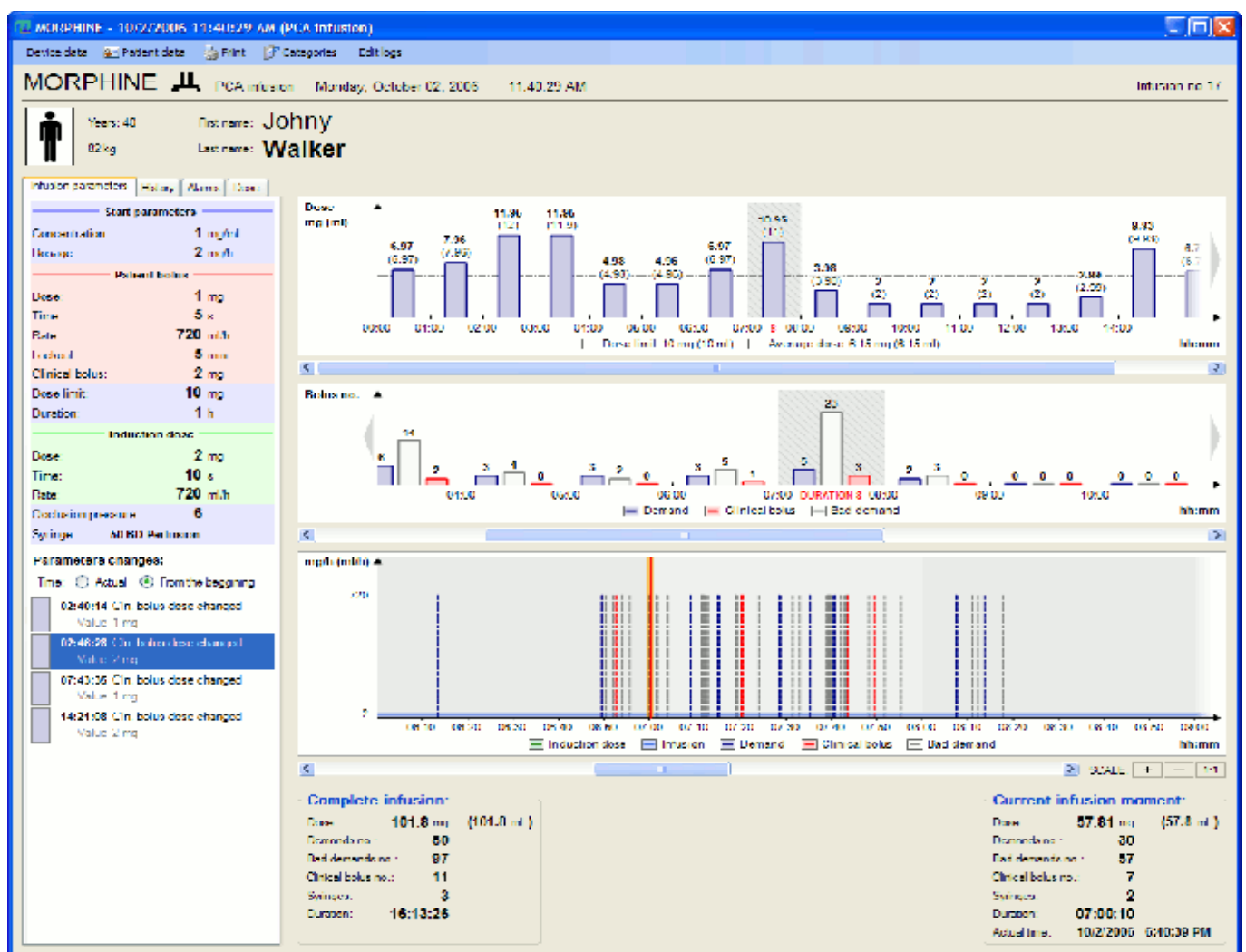
- Infusion parameters
 - Loading / unloading a syringe
 - Start / stop of infusion
 - Start, pause, end of the delivery of induction and bolus doses
 - Each change of parameters during infusion
 - All alarms including also these with moment of their muting by operators
 - Overridden limits values for infusion parameters- Model S2
-
- Press and hold **MENU**
 - Select „Event log” and confirm **YES**
 - Using **▲▼** 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 **▲▼** 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 **▲▼** select „Time, date” and confirm **YES**.
- Using **▲▼** 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 **▲▼** select „Date”, enter date and confirm **YES** (see p. 22.4.2 "Date format", page 45)
- 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 **▲▼** „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. 32, page 55 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 46).

- Using **▲▼** 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. 32, page 55.

To cancel the password:

- Using **▲▼** 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 **▲▼** 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:

- **▲▼** 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 (see p. 19.3, page 28) :

- 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 **▲▼** 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 **▲▼** 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 25) |
| • Line disconnected | YES/NO | Warning of pressure drop switch on/off (see p. 18, page 25) |

Entering the value:

- Using **▲▼** 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. 32, page 55 very carefully.

Setting security options:

- Pressing **YES** activate “Security” function
- Using **▲▼** 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 **▲▼** select „Enter Ward Name” and confirm **YES**
- Enter or omit ID number
- Enter the name in selected line using numerical keys (like SMS) and **▲▼**
- 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 library 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 library

This information will appear only when the drug library was created and sent using MEDIMA DRUG EDITOR (see p. 20.8, page 40). The information is very important as it enables to check whether the drug library in the pump is the proper one – the latest version and whether it was modified in the pump. All the incompatibilities in the drugs protocols may cause significant infusion errors and danger to a patient's life.

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 52)

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 $\pm 0,8$ 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 51)

22.9. Service

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

- Press and hold **MENU**
- **▲ ▼** to select „Service” and confirm **YES**
- Enter password 159.0 and confirm **YES**
- **▲ ▼** 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 53).
- 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 53)
- 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**
 - **▲▼** to select „Service” and confirm **YES**
 - Enter password 159.0 and confirm **YES**
 - **▲▼** 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 (see p. 20, page 37) but select “ Send configuration” instead of “ Send drugs”.



22.9.4. Clearing Drug 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  (see p. 16.4 , page 20)
- 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 48). 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 and 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

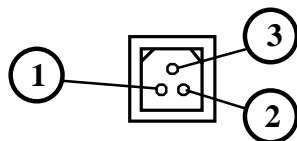
1 / 2	COMM	Common output
3 / 4	NO	Output normally open with COMM and closed during alarm
5 / 6	NC	Output normally closed with COMM and open during alarm

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. $\pm 12V$
2. $\pm 12V$
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 50).
- 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. 35 "Docking station", page 59).


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. 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.

31. 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	from 0.1 ml up to syringe capacity, in 0.1 ml increments
Rate	Minimal : 2 x flow rate, maximal : 2000 ml/h, in 1 ml/h increments
Induction dose	Parameters like for Bolus
KVO rate	0 – 5.0 ml/h, programmable by 0.1 ml/h
Occlusion pressure - levels	1 0.2 kgf/cm ² (bar) ± 50 % 2 0.4 kgf/cm ² ± 40 % 3 0.6 kgf/cm ² ± 30 % 4 0.8 kgf/cm ² ± 25 % 5 1.0 kgf/cm ² ± 25 % 6 1.2 kgf/cm ² ± 25 %
Priming the extension line:	
Rate	500 – 1500 ml/h, programmable, default value 1000 ml/h or less, depending on the used syringe
Volume	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	Total accuracy of infusion including a syringe is ± 2% Flow rate accuracy depends on the quality of syringe. Mechanical accuracy of pumps is ± 0.5 %

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	ABS
Protection class	IP22 – according to EN60529
Dimensions	355 x 115 x 166 (W x H x D)– excluding pole clamp
Weight	Below 2.5 kg – without power supply cord
Event log capacity	Minimal 2000 records of operation activities with date and time of event.
Power supply	
AC	100 – 240 V AC, –15% +10%, 50/60 Hz, max. 15VA
DC	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	<ul style="list-style-type: none"> • RS232C ,rate of transmission 38 kb • Infrared for communication with docking station
Drug Library	<ul style="list-style-type: none"> • Up to 120 drugs dosing procedures- drug names and all infusion parameters. In addition for Model S2 – parameters limits. • Drug library can be transferred from pump to pump or from/to PC using RS232C.

32. CONVERSION FACTORS

$$\begin{aligned}
 1.0 \text{ (g)} &= 1000 \text{ m(g)} & 1.0 \text{ m(g)} &= 1000 \text{ } \mu\text{(g)} & 1.0 \text{ } \mu\text{(g)} &= 1000 \text{ n(g)} \\
 1.0 \text{ } \mu\text{(g)/min} &= 60.0 \text{ } \mu\text{(g)/h} & 1.0 \text{ } \mu\text{(g)/h} &= 24.0 \text{ } \mu\text{(g)/24h} & 100 \% &= 1 \text{ g/ml} \\
 & & & & 1 \% &= 10 \text{ mg/ml}
 \end{aligned}$$

$$\begin{aligned}
 1.0 \text{ mg/kg/h} &\times 50 \text{ kg} / 1.0 \text{ mg/ml} = 50 \text{ ml/h} \\
 1.0 \text{ mg/kg/min} &\times 60 \times 50 \text{ kg} / 1.0 \text{ mg/ml} = 3000 \text{ ml/h} \\
 1.0 \text{ } \mu\text{g/kg/min} &\times 60 \times 50 \text{ kg} / 1.0 \text{ mg/ml} = 3.0 \text{ ml/h}
 \end{aligned}$$

Password 13.46.79

$$\text{(---)ml/h} = \frac{\text{(---)mg/kg/h} \times \text{(---)kg}}{\text{(---)mg/ml}} = \frac{\text{(---)} \mu\text{g/kg/h} \times \text{(---)kg}}{\text{(---)mg/ml} \times 1000} = \frac{\text{(---)} \mu\text{g/kg/min} \times 60 \times \text{(---)kg}}{\text{(---)mg/ml} \times 1000}$$

The example counts are shown for mass units. They are correct also for other units for example : U, mol.

33. 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).

Item no	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

34. GRAPHS OF INFUSION ACCURACY

34.1. 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, its 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.

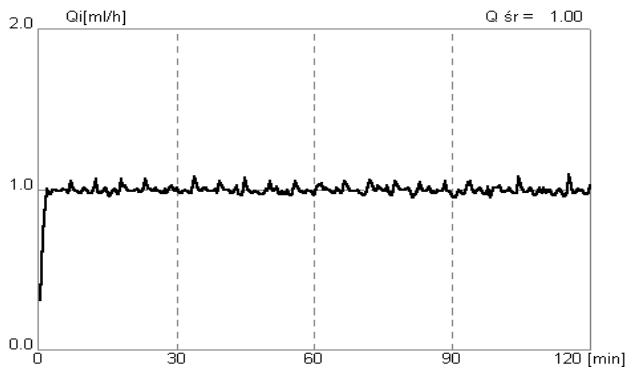
Start-up curves represent continuous flow versus operating time from the start of the infusion. The in onset delivery is caused by different factors. To reduce it:

- 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.

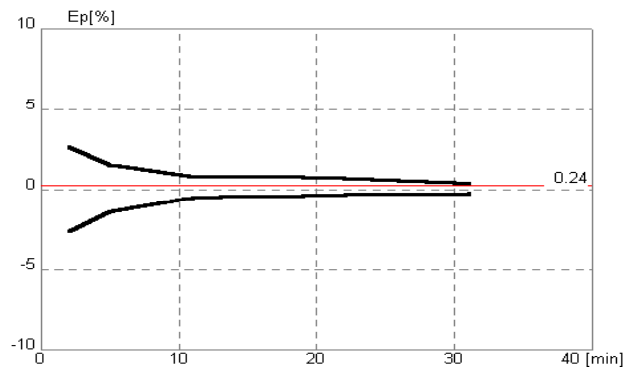
Trumpet curves named for their characteristic shape, display discrete data averaged over particular time period or ‘observation windows’. Over long observation windows, short term fluctuations have little effect on accuracy.

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 where flow uniformity is a concern, possibly diluted drugs and flow rates of 1.0 ml/h or above and small syringe size are recommended.

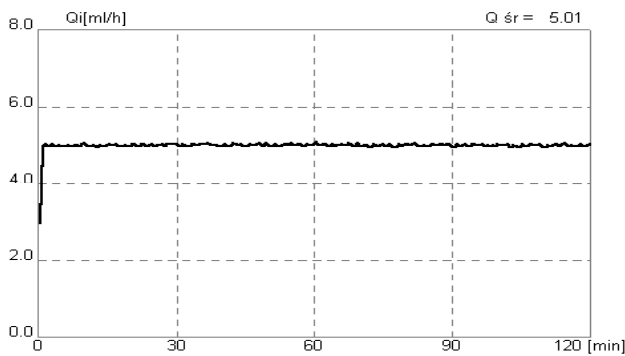
Differences in factors such as size and plunger force in compatible syringes produced by the others manufacturers can cause variations in accuracy and trumpet curves as compared to those represented. Additional curves for compatible syringes are available upon request. Start-up and trumpet curves may not be indicative of operation under negative pressure.



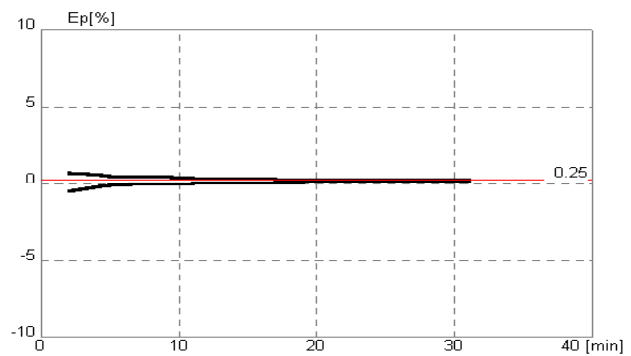
Start-up Curve
Nominal infusion rate $r = 1.0$ [ml/h]
Testing time: 120 [min]
Sampling time: 30[s]



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]

34.2. 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.

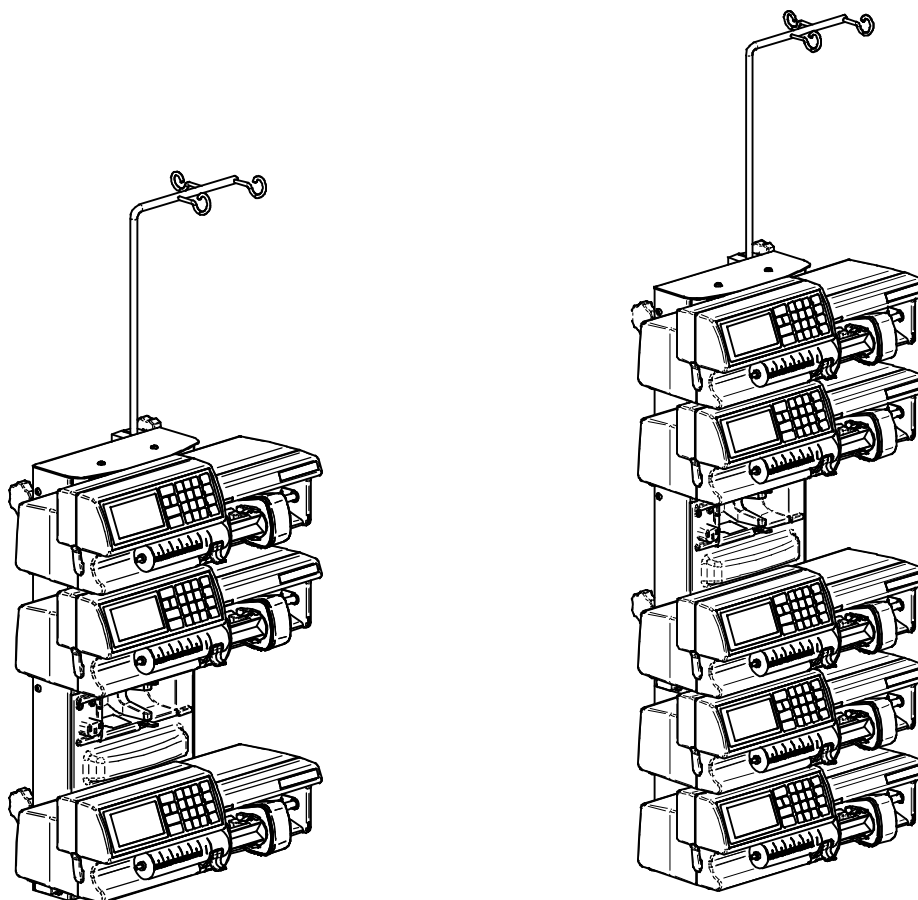
These measurements were taken using BD PLASTIPAK 50 ml and standard extension set of 2 m.

35. 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.



36. INFORMATION ABOUT MANUFACTURER

<div>MANUFACTURER:</div> <div> MEDIMA Sp. z o.o tel.: + 48223132266 02-486 Warszawa fax.: + 48223132269 Al. Jerozolimskie 200 POLAND www.medima.com.pl </div>	<div>REPRESENTATIVE:</div>
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Serial Number	Password	Hospital Ward Name

37. DOCUMENT HISTORY

Versi on	Date of Issue	Remarks	Software Version
1	2.2005	IO – 001 – 03.1	V5.6.xx
2	9.2006	IO – 001 – 03.2	V6.3.xx
3	10.2006	IO – 001 – 03.3	V6.3.xx

