

# Syringe Infusion Pumps S100, S200, S300



**User manual**

**medima**

**CE**  
1011





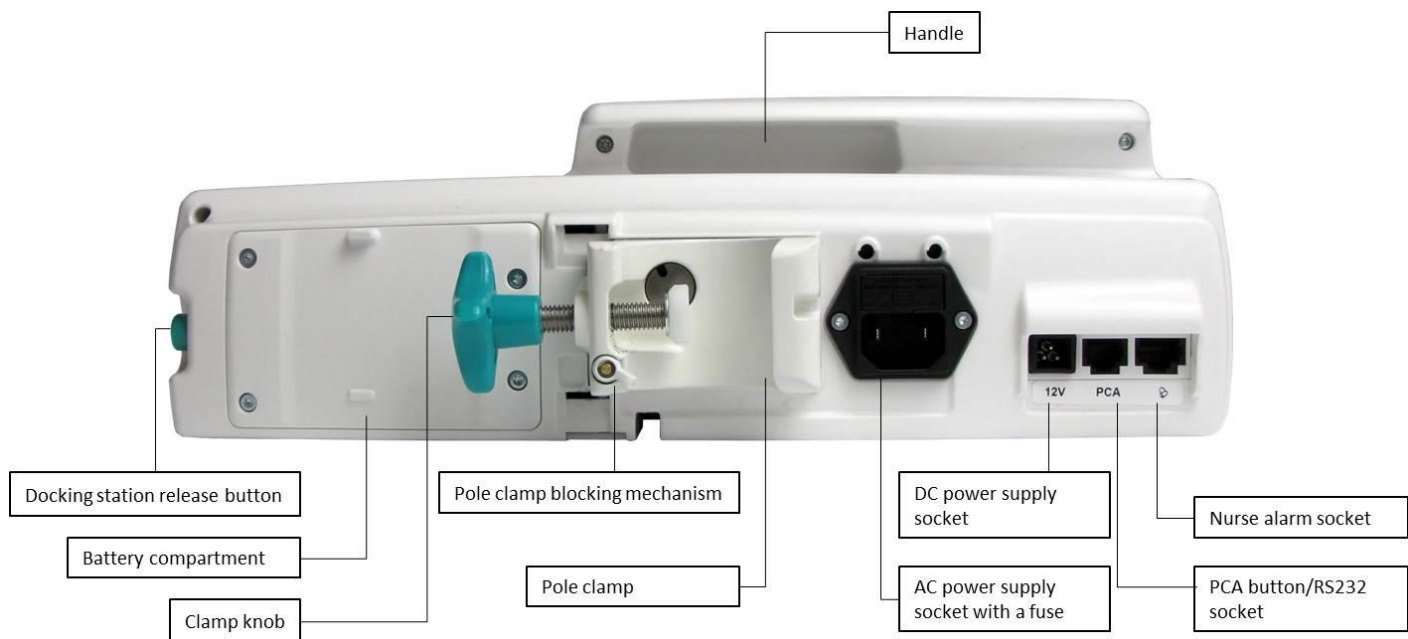
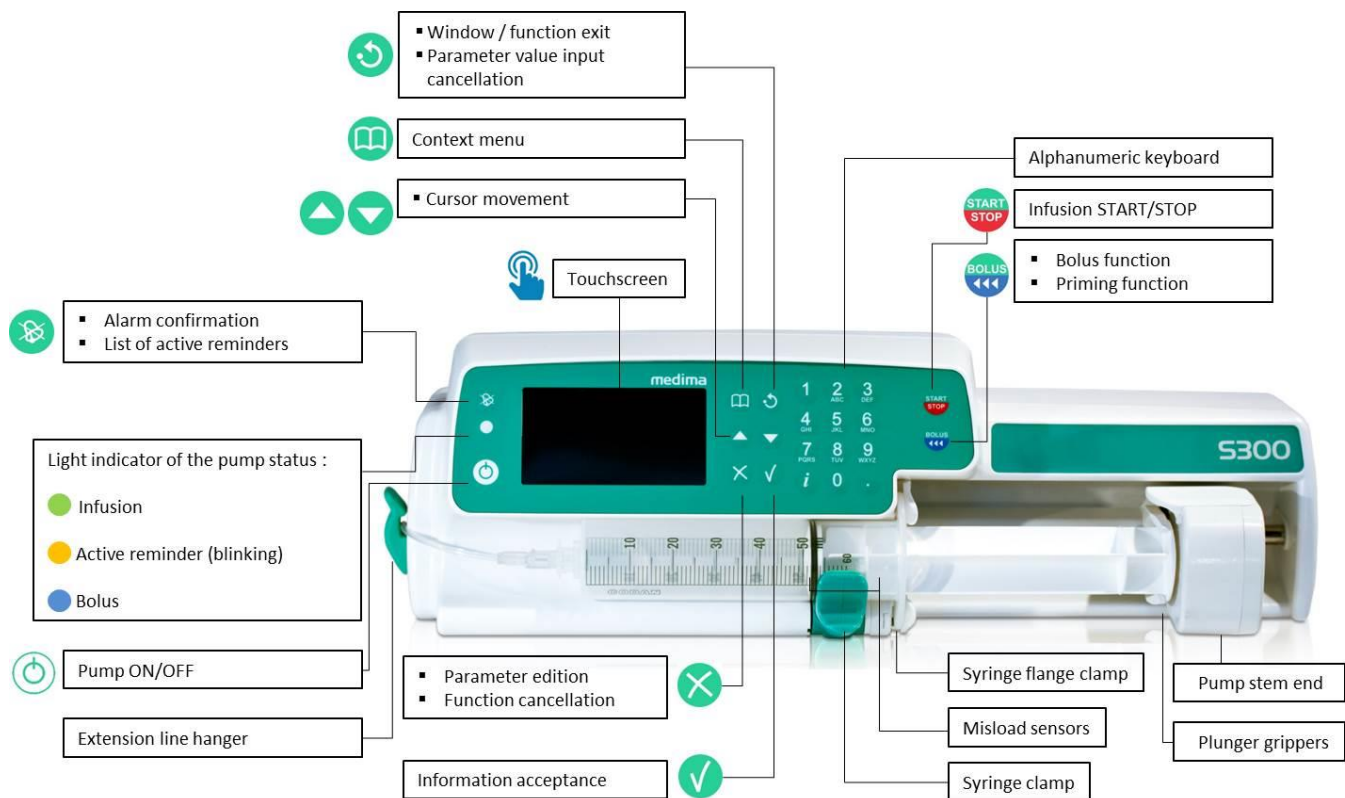


## Table of Contents

1	PUMP CONSTRUCTION .....	3
2	MOUNTING .....	4
2.1	Ways of pump mounting.....	4
2.2	Pump mounting to vertical column or horizontal rail .....	4
2.3	Pump mounting in docking stations.....	5
3	SYMBOLS .....	6
4	PATIENT SAFETY .....	7
4.1	Application .....	7
4.2	Warnings and precautions .....	7
5	DIFFERENCES BETWEEN MODELS .....	9
6	USER INTERFACE .....	10
6.1	Keyboard and touchscreen .....	10
6.2	Ways of data display .....	10
6.2.1	Presentation of parameters/functions to be chosen (menu) .....	11
6.2.2	Context menu .....	11
6.2.3	Colour marking of displayed digits.....	11
6.3	Navigation principles.....	12
6.3.1	Keyboard and touchscreen lock function .....	14
7	TURNING ON AND OFF THE PUMP .....	14
7.1	Turning ON the pump .....	14
7.2	Turning OFF the pump .....	15
7.2.1	Pump turned OFF – configuration and other options.....	16
7.2.2	Syringe exchange .....	16
7.2.3	Pump turned OFF – sleeping mode .....	16
8	SYRINGE INSTALLATION AND EXTENSION LINE PRIMING .....	16
8.1	Syringe installation .....	16
8.2	Extension line priming.....	21
9	SYRINGE RELEASE .....	23
10	INFUSION START.....	23
10.1	INFUSION MODE CHOICE .....	23
10.2	Infusion in mL/h .....	24
10.2.1	Flow rate only (fast infusion start).....	25
10.2.2	Flow rate and volume (Volume limit) .....	25
10.2.3	Flow rate and time (Time limit) .....	26
10.2.4	Infusion volume and time (Volume limit) .....	26
10.2.5	Infusion window in mL/h .....	27
10.3	Infusion in other units.....	28
10.3.1	Infusion programming in units.....	28
10.3.2	Infusion units choice.....	29
10.3.3	List of the units .....	29
10.3.4	Infusion window in units.....	29
10.4	Drug library .....	30
10.4.1	Drug library structure .....	32
10.4.2	Drug procedure choice from the drug library .....	33
10.4.3	LIMITS of parameters values .....	35
10.4.4	Drug library infusion window.....	36
10.5	Quick infusion flow/dose rate change .....	37
10.6	Bolus administration .....	38
10.6.1	Bolus in automatic mode .....	39
10.6.2	Bolus in manual mode .....	40
10.7	Infusion stop and restart.....	40
11	ADVANCED INFUSION OPTIONS.....	42
11.1	Additional parameters available in functions menu .....	42
11.1.1	Advisory Note .....	42
11.1.2	Options .....	42
11.1.3	Dose Done .....	43
11.1.4	Settings .....	43
11.2	Additional parameters available in infusion menu .....	43
11.2.1	Parameters .....	44
11.2.2	New Infusion.....	44
11.2.3	Dose .....	44
11.2.4	Dose Done .....	44

11.2.5	Occlusion.....	45
11.2.6	Security – Access restriction .....	46
11.2.7	Standby .....	48
11.2.8	Settings .....	48
11.2.9	Drug Lib. Info.....	48
11.2.10	Battery Info .....	48
11.3	Infusion status/progress information .....	48
11.4	ETTA bar .....	49
11.5	Infusion modes .....	49
11.5.1	Continuous infusion .....	50
11.5.2	Intermittent infusion.....	50
11.5.3	Profile infusion .....	53
11.5.4	TPN infusion (Total Parenteral Nutrition) .....	55
11.6	KVO .....	57
12	<b>CONFIGURATION SETTINGS, BASIC PUMP DATA .....</b>	<b>58</b>
12.1	Available configuration options.....	58
12.2	Settings .....	59
12.3	Infusion history .....	59
13	<b>USER NOTIFICATION AND ALARM SYSTEM.....</b>	<b>60</b>
13.1	Ways of notification and alarm signalling.....	60
13.2	Reminders and warnings .....	61
13.3	Alarm volume level .....	61
13.4	Alarm call system .....	61
13.5	List of alarms and reminders displayed by the pump.....	61
13.5.1	High importance alarms.....	61
13.5.2	Medium importance alarms.....	63
13.5.3	Low importance alarms.....	64
13.5.4	Reminders .....	64
13.5.5	Malfunctions .....	66
14	<b>INTERNAL BATTERY OPERATION .....</b>	<b>66</b>
15	<b>LIST OF SYRINGES.....</b>	<b>68</b>
16	<b>LONGER INTERRUPTIONS IN PUMP OPERATION .....</b>	<b>71</b>
17	<b>COMMUNICATION INTERFACES .....</b>	<b>71</b>
17.1	ALARM SOCKET .....	71
17.2	DC POWER SOCKET .....	72
17.3	RS232C INTERFACE .....	72
18	<b>INFUSION ACCURACY .....</b>	<b>73</b>
18.1	Start-up and trumpet curves .....	73
18.2	Occlusion – reaction time and occlusion bolus .....	74
19	<b>TECHNICAL DATA .....</b>	<b>75</b>
20	<b>ELECTROMAGNETIC RESISTANCE.....</b>	<b>78</b>
20.1	Manufacturer declaration.....	78
20.2	Recommended safe distance between radio devices and pumps.....	79
21	<b>PUMP UNPACKING AND PREPARATION.....</b>	<b>80</b>
21.1	Pump unpacking .....	80
21.2	Battery connection .....	80
21.3	Basic pump functioning check .....	82
22	<b>MAINTENANCE/CLEANING/DISPOSAL .....</b>	<b>82</b>
22.1	Maintenance .....	82
22.2	Cleaning and disinfection.....	83
22.3	Disposal.....	84
23	<b>MANUFACTURER'S RESPONSIBILITY .....</b>	<b>84</b>
24	<b>ADDITIONAL ACCESSORIES.....</b>	<b>84</b>
25	<b>MANUFACTURER.....</b>	<b>86</b>

# 1 PUMP CONSTRUCTION



## 2 MOUNTING

### 2.1 Ways of pump mounting



Without mounting, on desk  
(not recommended)

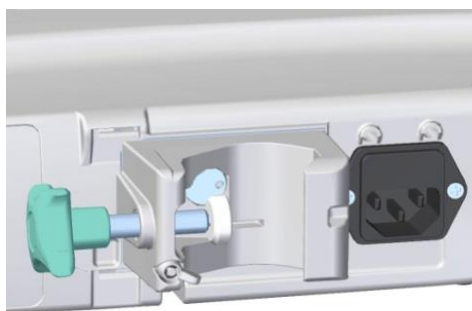


To vertical column or horizontal  
rail

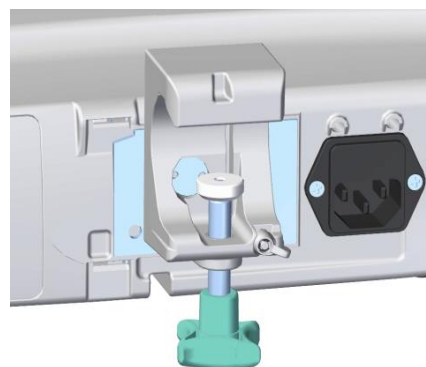


In docking stations

### 2.2 Pump mounting to vertical column or horizontal rail



Vertical column



Horizontal rail

In order to mount a pump proceed as follows:

- Set a pole clamp in the position adjusted to the vertical column or horizontal rail. The pole clamp turn is possible when the pole clamp blocking mechanism is released;
- Unscrew the clamp knob adjusting it to the rail or the medical stand diameter;
- Set the pump so as to column/rail is placed inside of the pole clamp;
- Tighten the mounting screw up to the limit in order to mount the pump to the column/rail;
- Connect mains power supply cord.

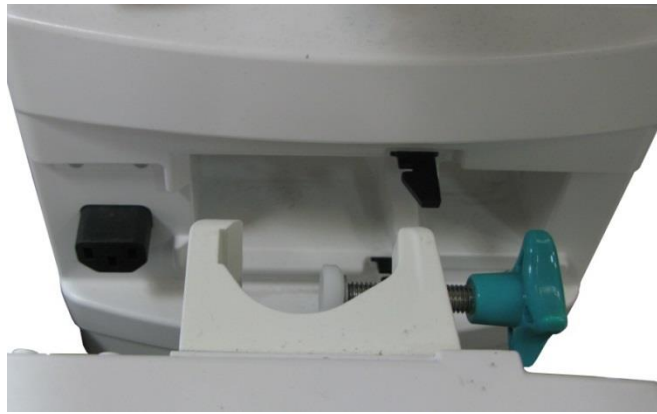


**Attention!**

Do not mount pumps on medical stands not providing enough stability.



## 2.3 Pump mounting in docking stations



**Attention!**

Pumps can be mounted in a docking station with a pole clamp set in the horizontal position. If prior to the pump installation in the docking station it was mounted on the horizontal rail then the pole clamp must be turned to the horizontal position.

Prior to the pump installation in the docking station, mains power supply cord must be disconnected from the pump.

In order to mount the pump in a docking station proceed as follows:

- Hold the pump horizontally and put it into the free slot so as to allow the clamp knob and the pole clamp be inside of a docking station's pocket;
- If the pump was not properly installed then 'Incorrect fixing in docking station' alarm would be activated. In this case the pump must be pushed stronger towards the docking station;
- Check if on the pump display (bottom left corner) the mains power supply socket icon has appeared (if not, check the mains power supply connection to docking station or pump mounting).

In order to release the pump from the docking station press the docking station release button on the right side of the cover and remove the pump from the docking station's slot.






Docking station release button



Pumps are allowed to be connected to mains with or without PE cable (Protective Earthing conductor). While docking stations are only allowed to be connected to mains with PE cable.

### 3 SYMBOLS

Symbols	Designation
	Manufacturer.
	Manufacture year.
	Do not throw into standard waste containers. The user is obliged to deliver the used equipment to the manufacturer or to a recycling collection point.
	Warning. For details concerning safe usage see user manual.
	Degree of resistance to electric shock - CF type. Defibrillation proof.
	Protection class II as per IEC 60601-1 standard. Device connection to sockets with or without PE cable.
	Compliance with Medical Devices Directive 93/42/EEC confirmed with the Notified Body number.
<b>IP 22</b>	Degree of protection against penetration by external factors. Protection against dripping water when casing tilted up to 15°.

Symbols	Designation
 <b>Attention!</b>	Important notifications for users.
	Touchscreen.
	Radio interference.

## 4 PATIENT SAFETY

### 4.1 Application

Syringe infusion pumps manufactured by Medima are designed for:

- accurate intravenous and intraarterial infusions,
- parenteral and enteral nutrition.

The pumps can be used in various clinical environments, including transportation, general profile wards, intensive care units, neonatology and paediatric units, operation theatres and postoperative wards, as well as medical rescue wards.

### 4.2 Warnings and precautions

- Medima pumps can only be used by the trained medical personnel aware of the hazards associated with the misuse of this kind of equipment and conscious of the consequences of acting against the provisions of this User Manual.
- Only syringes of volume, name and type, selected in infusion parameters can be used. Applying a syringe other than defined during the process of infusion parameters programming, even of the same volume, may cause significant infusion errors, control malfunction and endanger the patient. The list of recommended syringes has been entered into the pump and it is available during infusion programming. These are three-piece syringes with a rubber plunger or a rubber ring and a 'Luer Lock' or an 'ENFit' tip.
- In case of any enquiries concerning what syringe types can be applied, infusion errors or the pump's operation, please contact immediately with an authorized Medima representative or the manufacturer directly. The pumps should be properly marked and secured to prevent accidental use until the problem is solved.

- The extension set should be connected to the patient only after a syringe has been inserted into the pump and the extension line has been filled up with fluid. Otherwise, uncontrolled infusion or back flow may occur, which can cause a considerable risk to the patient's life. The air should be cleared out very carefully from all elements of the extension set. The pump cannot detect air in the extension line.
- Be sure that the infusion line is free of kinks.
- The syringe should be replaced only after the extension set has been disconnected from the patient. Every new connection to the patient is possible only after assurance that there is no air in the extension line and the syringe is properly fixed.
- An uncontrolled flow of medicine may occur when the syringe has been removed from the pump before the extension set has been successfully disconnected from the patient.
- It is not recommended to mount the pump higher than  $1\text{m} \pm 0.5\text{m}$  above the patient heart, as it may have a negative impact on the infusion stability.
- It is recommended to fix the pump as close to the level of the patient's heart as possible for most accurate pressure measurement.
- The pump should operate in a close distance from the patient so as to prevent a possible infusion stop by casual patient's movements.
- The patient must be informed that any attempt to manipulate the pump may cause a serious risk to his health or even life.
- It is very important to remember that simultaneous connection of many infusion devices to the same patient's line causes their interaction.
- Please note that simultaneous delivery of many medications by the same line may cause unwanted chemical interference affecting efficiency and safety of the treatment. For information about possible interference between different drugs, please check drug leaflets or contact directly the pharmaceutical company's representative.
- The pumps should be protected against infusion fluid spills. In particular, do not place containers with fluid directly above the pump. Any spills should be removed immediately. It is recommended to send the pump to the hospital technical department or to Medima service department
- The pumps cannot be used in the atmosphere containing flammable mixtures of anaesthetic gases or explosive fumes of volatile substances.
- The pumps meet electromagnetic compatibility requirements in accordance with EN 60601-1-2:2007 and EN 60601-2-24:2015 standards. Nevertheless, it is recommended to keep a safe distance between pumps and equipment emitting strong electromagnetic field (x-ray equipment, CAT scanners, diathermies devices,

mobile phones etc.). If the pump is affected by this external interference, it may stop the infusion and activate the alarm.

- If the pump is dropped or damaged in another way (pump displays message Malfunction XXX/System Code XXX/Damage XXX), it should be examined by the qualified service staff. In case of any doubts, please contact with an authorized Medima representative or directly with the manufacturer. The damaged device should be secured from an accidental use.
- Medima has reduced the risk associated with the use of the pumps to the level as low as possible but it is not possible to completely eliminate it. Therefore special care should be taken using the pump.

**Other components:**

- Mind to respect all manufacturer's data relating to possible incompatibilities of used equipment considering engagement of particular drugs.
- Only safe connectors in form of 'Luer Lock' or 'ENFit' regarding the infusion type in relation to disposables and working parts and accessories and equipment are suggested.

## 5 DIFFERENCES BETWEEN MODELS

### S100

Basic model which enables continuous infusion mode in mL/h only. It offers an option to calculate infusion rate based on volume and time.

### S200

Offers capabilities of the S100 model and allows to program infusion rate in all available units: g, mg, µg, ng, mL, L, kJ, J, kcal, cal, mol, mmol, kIE, IE, mIE, kIU, IU, mIU, Eq, mEq, µEq /-- , kg, m<sup>2</sup>/ min, h, 24h.

Available infusion modes: continuous, intermittent, profile and TPN.

### S300

Offers capabilities of the S200 model and allows to download a drug library consisting of up to 5000 drug procedures. The drug library can be divided into up to 40 wards (CCA - Clinical Care Area), up to 40 drug categories and up to 500 drug procedures for each CCA. Each procedure can contain, up to 10 fixed (predefined) and 1 variable (user defined) concentrations. It is possible to apply 'soft' and 'hard' limits to specific infusion parameters stored in a drug library.

## 6 USER INTERFACE

### 6.1 Keyboard and touchscreen

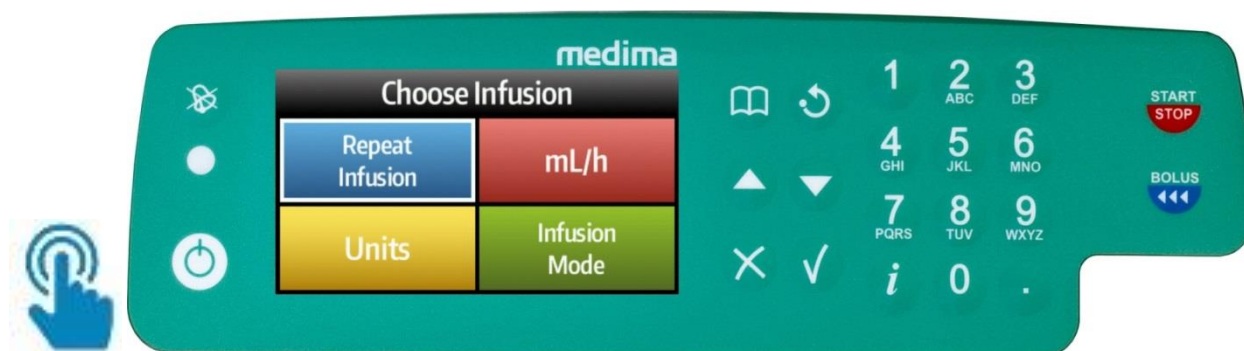
Pumps can be operated by using keyboard as well as touchscreen.

Due to the safety reasons some of the functions are only available by the alphanumeric keyboard use:

- ON/OFF function,
- Infusion parameters values input,
- Infusion START/ STOP,
- Priming the line,
- Bolus function activation.

Touchscreen option can be turned OFF in 'Settings' tile available in 'Infusion Menu' (see section 12.1). In the pump's configuration (the Medima Configurator software required) depending on the pump's application (for example in an ambulance), additional settings of touchscreen are available.

In this user manual, ability to use the touchscreen has been indicated in descriptions of particular display areas and marked by  icon.



### 6.2 Ways of data display

The high quality colour display has been implemented in the pumps. It provides comfortable reading under large angles scope. Interface colour has been linked in many areas with status of displayed data:

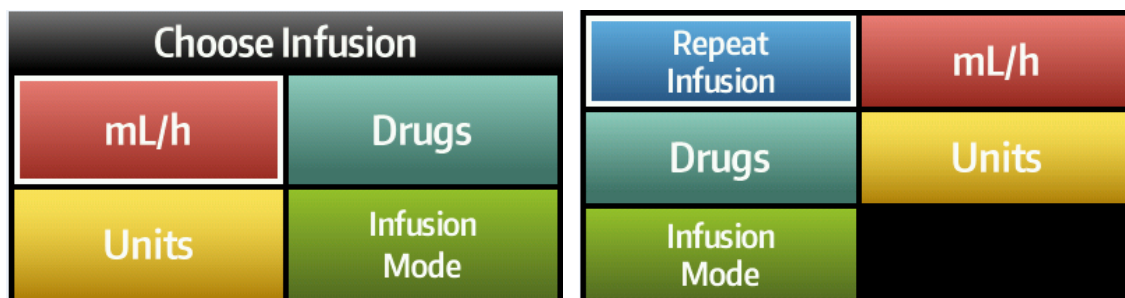
- green colour is associated with proper and safe functioning,
- yellow and orange colour are used in relation with warnings,
- red colour indicates alarm conditions.

This principle does not relate to tiles colours (see section below).

### 6.2.1 Presentation of parameters/functions to be chosen (menu)

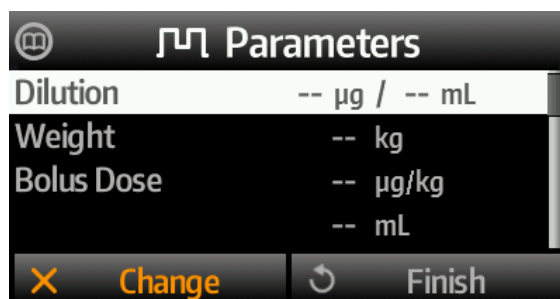
Two ways of functions or parameters display have been used in the pump interface:

- tiles



Currently chosen tile is marked by a white frame (on displayed examples, 'mL/h' and 'Repeat Infusion' tiles have been marked).

- list



Currently chosen list element is displayed on white background (on displayed example, 'Dilution' parameter has been marked).

In both cases slider bar placed on the right side of display indicates which part of available options is currently displayed.

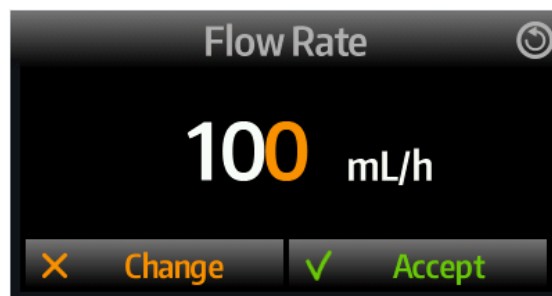
### 6.2.2 Context menu

Interface used in the pump has been designed to provide maximum of functionality and operation intuitiveness. Due to this fact particular functions are displayed only there, where they can be used (so called 'context menu').

### 6.2.3 Colour marking of displayed digits

In case of numerical parameters, colours are used only when:

- Input value refers to programmed limits (see section 10.4.3),
- Warning against casual digits repetition – next digits input within the same parameter are marked by orange colour. Short acoustic signal is an additional warning.














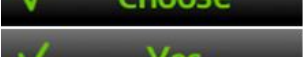













### 6.3 Navigation principles

In the pump interface following ways of navigation have been used:




- In windows with tiles:  
Function start linked with a tile begins after pressing it on touchscreen or after button pressing on the alphanumeric keyboard when the tile has been chosen. In order to change the tile, and buttons can be used. Window must be scrolled up or down if not all tiles can be displayed within the same displayed window.
- In windows with a list:  
 and buttons available on the alphanumeric keyboard enable navigation along the list. Parameter choice (moving to the next list element with current value acceptance or moving to lower list level) is made by button or by selecting the parameter by a finger on the touchscreen. **Finish** button available on the touchscreen or button on the alphanumeric keyboard enables to quickly accept or reject the parameters by pressing respectively 'Yes' or 'No' fields on the touchscreen or and buttons on the keyboard. 'Accept all parameters' line allows to accept the parameters if their minimum quantity allowing to start infusion has been set. If not then pump will inform which parameter must be filled up yet.
- Chosen parameter's value change:  
Chosen parameter edition or deleting of its value are made by pressing button on the alphanumeric keyboard or by pressing 'Change' button on the touchscreen. New value confirmation is made by pressing button.
- Edition resign/acceptance:  
In order to resign from parameter edition or quickly accept the edited parameters or return to a higher menu level, button on the alphanumeric keyboard or icon or **Finish** field on the touchscreen must be pressed.

Description of all buttons available on the alphanumeric keyboard and their touchscreen counterparts and their functionalities have been presented below:





Keyboard buttons	Touchscreen	Designation
	N/A*	Pump ON/OFF.
	N/A	<ul style="list-style-type: none"> <li>Alarm confirmation.</li> <li>Alarm test is activated by longer pressing.</li> <li>Active Reminders display (see sections 13.2 and 13.5.4).</li> </ul>
		Context menu display.
	N/A	<ul style="list-style-type: none"> <li>Parameter or function selection change.</li> <li>Tile selection change.</li> <li>Up/Down scrolling.</li> </ul>
		<ul style="list-style-type: none"> <li>Additional information.</li> <li>Help access button.</li> </ul>
	    	<ul style="list-style-type: none"> <li>Function start related with a chosen tile.</li> <li>Movement to a lower menu level for a chosen list position.</li> <li>Input value acceptance and edition closing.</li> <li>Acceptance of a chosen parameter on a list (with a movement on a next list element).</li> <li>'Check-box'  type element marking.</li> </ul>
	   	<ul style="list-style-type: none"> <li>Edition of a marked parameter.</li> <li>Cancellation of recently edited values.</li> <li>Suggested activity skipping.</li> </ul>
	N/A	Numeric or letter kind buttons.
	 	<ul style="list-style-type: none"> <li>Quicker parameters acceptance.</li> <li>Exit from current window.</li> <li>Return to a higher menu level.</li> <li>Function or new value input cancellation.</li> </ul>
	N/A	START/STOP of infusion.
	N/A	<ul style="list-style-type: none"> <li>Bolus function.</li> <li>Extension line priming.</li> </ul>

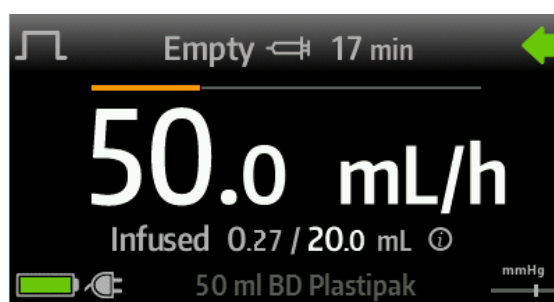
\*N/A – Not applicable.


 <p><b>Attention!</b></p>	<p> icon appearance means that during its display, detailed information relating to currently used pump functions is possible to be presented. Pressing this icon on touchscreen or pressing  button on the alphanumeric keyboard will allow to display for example Help, advisory note, value limits regarding the current context.</p>
--	---

### 6.3.1 Keyboard and touchscreen lock function

Keyboard and touchscreen can be protected against an accidental pressing by a lock function. Depending on pump configuration, this option can be started automatically by the pump after specified passage of time or manually by an operator by  button pressing and holding it for at least 2s.

The keyboard lock is indicated by a padlock icon  visible in the upper right corner of display. Similar icon is used by security function described in section 11.2.6.



In order to unlock the keyboard or the touchscreen,  button must be pressed and held for at least 2s. No password is required.

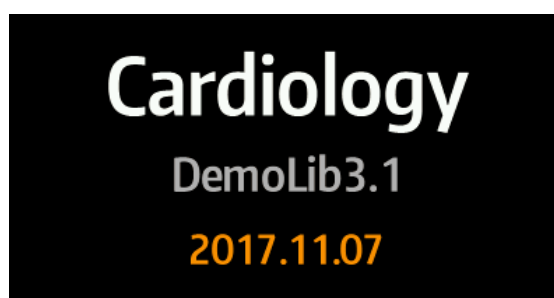
## 7 TURNING ON AND OFF THE PUMP



### 7.1 Turning ON the pump

In order to turn ON the pump 'ON/OFF' button  must be pressed.

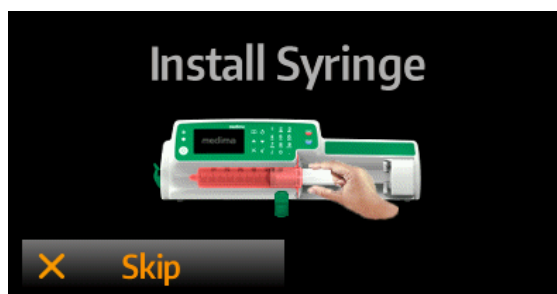
Starting process depends on a drug library presence in the pump (S300 model), status of a syringe installation and the previous infusion status.

- In case of S300 model with the drug library, window presenting ward name (CCA), drug library name and its creation time will be displayed for a short time.

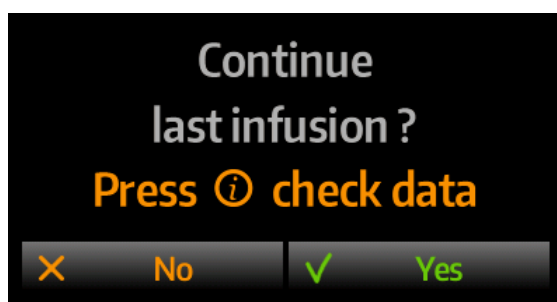


During window with a ward name (CCA) display, by pressing  button on the alphanumeric keyboard or by pressing  icon on the touchscreen, window with detailed drug library information will be displayed (see section 10.4).

- b) If a syringe has not been installed then window of the syringe installation will be displayed (see section 8 for syringe installation procedure).



- c) If the last infusion has not been finished before turning OFF the pump then window with 'Continue last infusion?' message will be displayed (see section 10.7).



- d) Window of infusion mode choice with tiles (S200 and S300 models) or window of Flow Rate parameter in mL/h (S100 model) (see sections 6.2.1 and 10.1).

All functions available after turning ON the pump have been described in detail in sections from 8 to 12.


## 7.2 Turning OFF the pump

In order to turn OFF the pump, 'ON/OFF' button  must be longer pressed.




Turning off the pump can be made at any moment also when infusion has already been started. After turning OFF the pump during started infusion and turning ON the pump again, message 'Continue last infusion?' will be displayed.



Pressing 'Yes' button on the touchscreen or pressing  button on the alphanumeric keyboard will allow to continue infusion with the same parameters.

### 7.2.1 Pump turned OFF – configuration and other options

When pump has been turned OFF but still connected to external power supply then pressing and holding  button will allow to move into a window with following options (see section 12.1):

- Standby,
- Infusion History,
- Settings,
- Device Info,
- Owner,
- Battery Info,
- Service.

### 7.2.2 Syringe exchange

If the pump is turned OFF then syringe exchange is possible (see section 9). Depending on the pump configuration settings (by the Medima Configurator), new syringe installation can turn the pump ON.


### 7.2.3 Pump turned OFF – sleeping mode

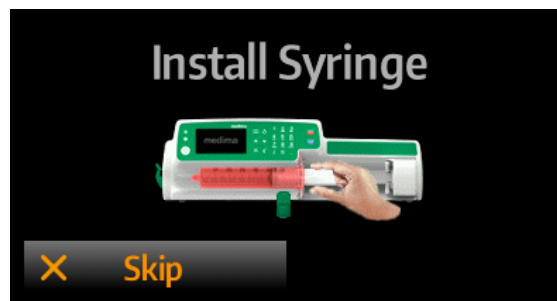
Pump is switching into a sleeping mode when external power supply has not been connected. This state is characterized by a complete switch OFF of the display.


Despite the sleeping mode, pump controls presence of installed syringe. Period during which pump can be left in the sleeping mode with installed syringe, depends on the pump configuration (by the Medima Configurator software) and has been set for 24 hours in the factory setting.

## 8 SYRINGE INSTALLATION AND EXTENSION LINE PRIMING

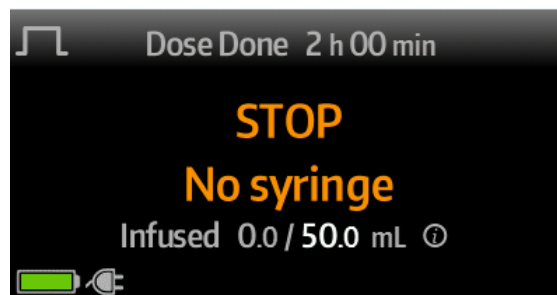
### 8.1 Syringe installation

**Step 1:** If syringe has not been installed yet, after turning ON the pump by pressing the  button, user will be asked to 'Install Syringe'. Displayed animation, simplifies syringe process installation.



**Skip:** Pressing the 'Skip' button on the touchscreen or pressing the  button on the alphanumeric keyboard allows for skipping the syringe installation process and directs to the 'Choose infusion' window (see section 10.1).

After infusion parameters setting finish, 'STOP No syringe' message will be displayed. Syringe installation process must started.



**Step 2:** In order to install the syringe properly proceed as follows:

- tilt the syringe clamp outwards and place the syringe horizontally in the pump



- place the syringe finger flange in the pump flange clamp. Allow the gripper plungers to grab the syringe end fitting and the syringe stem end to tighten the syringe end fitting.



Correct installation

Do not allow to mismatch the syringe finger flange against the pump syringe flange clamp. Remember that the syringe finger flange must be covered completely by the pump's syringe flange clamp.



Wrong installation

If the syringe installation has been made incorrectly then 'Improper fixing (Press syringe)' warning will be displayed.




In order to fix this problem, press syringe towards the pump pointed by a finger on the animated warning or remove the syringe and install it again.


Syringe infusion pump has been equipped with an automatic syringe detection system which automatically detects installed syringe and helps in choosing it correctly.

**Step 3:** Shortly after syringe has been placed in the pump, user will be asked to confirm volume and name of the detected syringe.




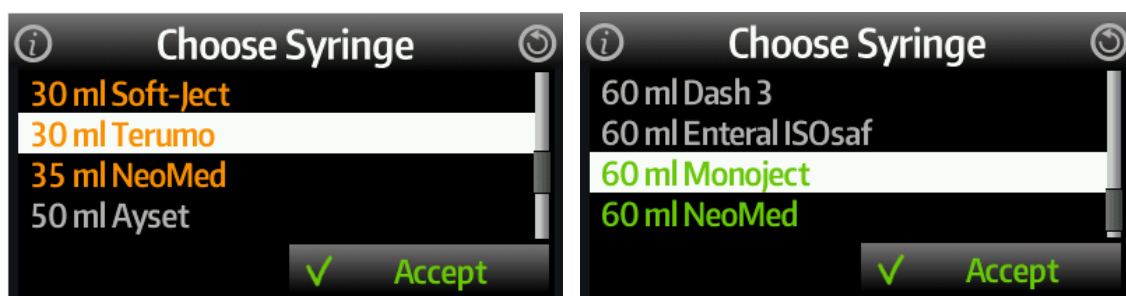
If both volume and name of the detected syringe are correct then press 'Yes' on the touchscreen or  button on the alphanumeric keyboard.

The window of 'Choose infusion' allowing to start the infusion process setting will be displayed as a result (see section 10.1).

If both volume and name of detected syringe are not correct according to the description on the installed syringe then press 'No' on the touchscreen or  button on the alphanumeric keyboard.



List of available syringes in the pump will be displayed. Due to safety reasons they have been marked in three colours:

- green – syringes have got very close parameters towards the one installed what means that they can be chosen. In order to ensure the infusion accuracy, installed syringe must be found on the list. Acceptance must be confirmed by 'Accept' button on the touchscreen or by  button on the alphanumeric keyboard.
- orange – syringes cannot be chosen, because they differ in volume towards syringe installed in the pump. Even if the choice has been made, warning of 'Incorrect syringe' will be displayed and pump will not allow to use it.
- white – syringes with the same volume as the one installed in the pump but having significant different parameters. Pump will not allow to start infusion by displaying 'Incorrect syringe' warning.



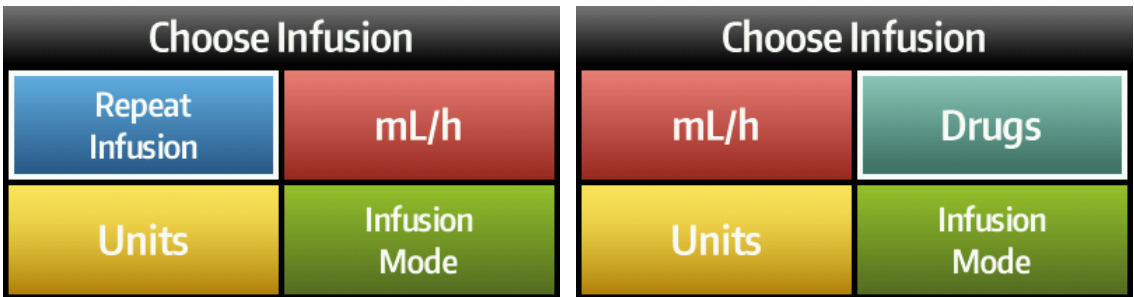
When wrong syringe has been chosen then ‘Incorrect syringe’ warning will be displayed. Pump will not allow to install it.



 <b>Attention!</b>	<p>Incorrect syringes use increase the risk of patient’s life due to different syringe parameters not defined by manufacturer. Full list of syringes available in the pump can be checked by Medima Configurator software.</p> <p>All syringes not included in the list can only be validated by Medima. In order to add not listed syringe, contact with your local representative or with Medima directly.</p>
 <b>Attention!</b>	<p>It is forbidden to install or release a syringe when connected to a patient. Uncontrolled drug infusion may happen as a result, causing risk of patient’s health or life loss.</p> <p>Connection to patient can be made being assured that there is no air in an installed syringe or in patient’s line.</p>

**Step 4:** Instantly after the correctness of syringe installation has been confirmed, question of ‘Prime the line?’ will be displayed (check section 8.2).

**Step 5:** If priming is fully accomplished or skipped then one of the following windows will be displayed.



**Step 6:** As the final step during syringe installation process, an extension line must be installed behind the extension line handle. It protects the extension line against an accidental pull.







## 8.2 Extension line priming

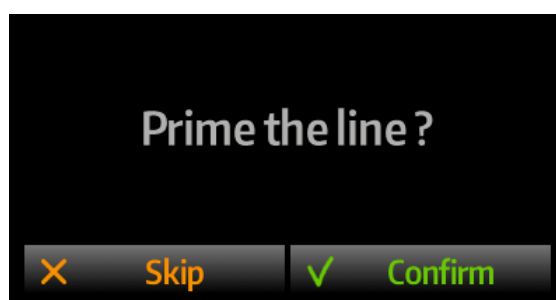
Syringe infusion pumps by Medima give possibility of the extension line priming.



Start of priming is possible under the following conditions:

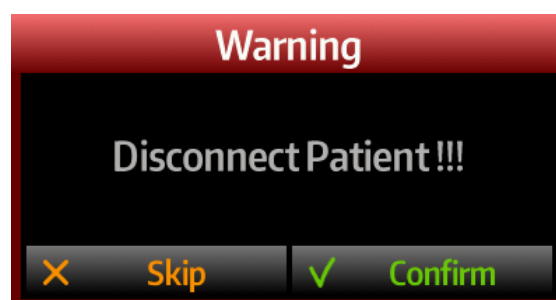
- immediately after finishing syringe installation ('Ask' setting in Medima Configurator).
- when infusion has not been started yet and the Bolus  button has been pressed ('Optional' or 'Ask' setting in Medima Configurator).

In order to start priming proceed as follows:

- As soon as syringe installation is finished, 'Prime the Line?' request will be displayed. Press the 'Confirm' button on the touchscreen or  button on the alphanumeric keyboard.



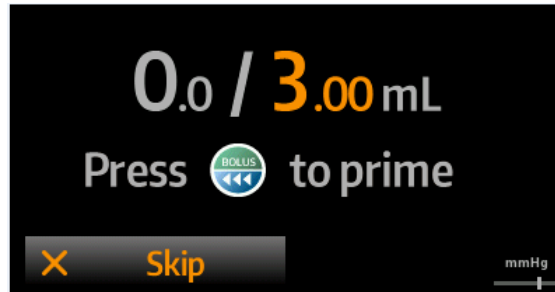
- 'Disconnect Patient!!!' warning will follow. Press 'Skip' or 'Confirm' button on the touchscreen or respectively press  or  button on the alphanumeric keyboard.





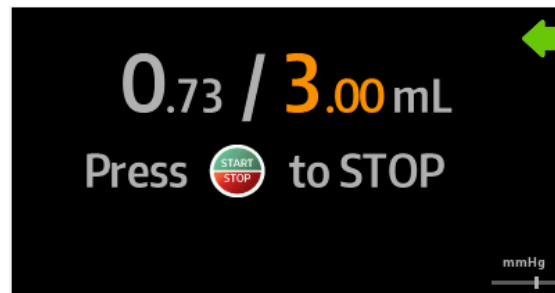


It is forbidden to prime the line connected to the intravascular or intraarterial blood system!

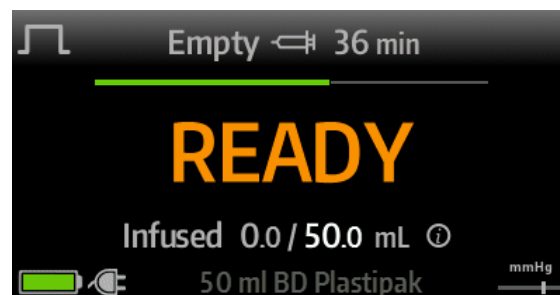
Following window will be displayed. Pump displays in yellow the priming volume. Its volume can be changed in the Medima Configurator software.



- Press Bolus  button to start priming. This activity can be stopped at any time by pressing START/STOP  button.



- After the priming process finish, following window informing about the pump being ready to have infusion started will be displayed.




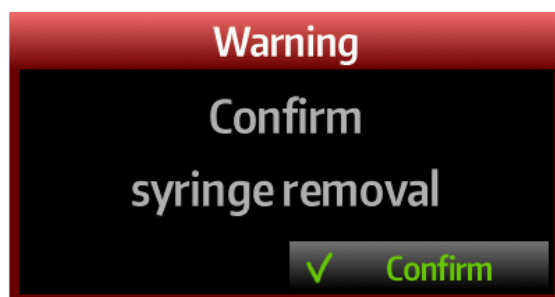
It is recommended to wait until the priming process is fully accomplished. Administered volume during priming is not added to the total infusion volume.

## 9 SYRINGE RELEASE

Depending on the pump configuration (implemented in the Medima Configurator software), removal of the syringe from the pump can be made either with required confirmation or instantly after the syringe clamp tilt.

In order to remove the syringe, proceed as follows:


1. Stop the infusion by pressing START/STOP  button.
  2. Disconnect patient!
  3. Tilt the syringe clamp out.
- The pump will display 'Confirm syringe removal' warning shortly before release if 'confirmation required' option has been chosen in the pump configuration. After 'Confirm' button has been pressed then syringe release takes place.




- If 'Auto' option of syringe release has been chosen in the Medima Configurator then warning will not be displayed when syringe clamp has been tilted out.

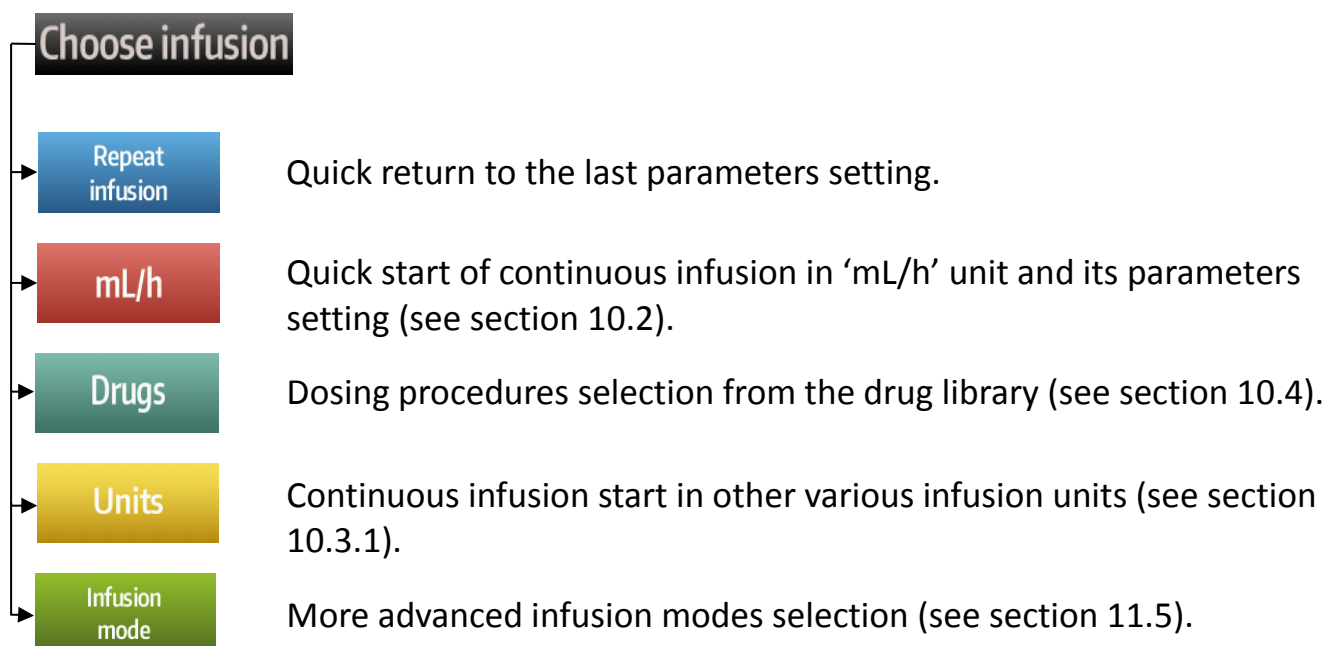
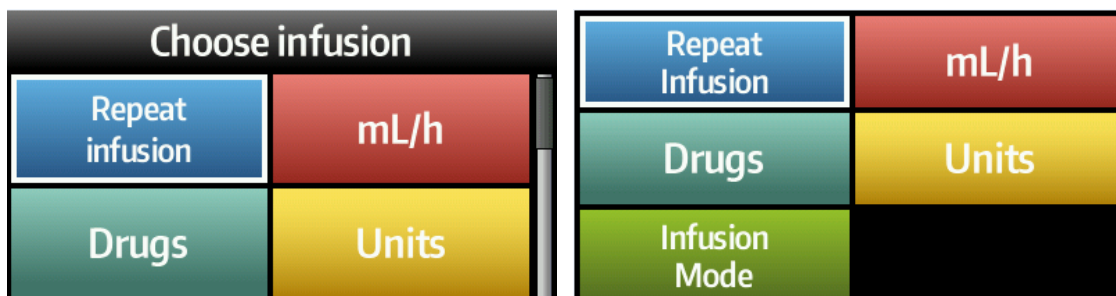
## 10 INFUSION START

Before starting the infusion programming proceed as follows:

- Ensure that the pump has been correctly installed (see section 2),
- Turn the pump ON by the ON/OFF  button,
- Choose infusion mode in 'Choose infusion' window (S200 and S300 pumps only),
- Ensure that the syringe has been correctly installed (see section 8) and the extension line primed (see section 8.2).

### 10.1 INFUSION MODE CHOICE

'Choose infusion' window appears shortly after the ON/OFF  button has been pressed and after syringe has been installed or its installation has been skipped.



## 10.2 Infusion in mL/h

Available in the following models:



The mL/h tile choice allows for continuous infusion setting in mL/h unit.

In the parameters setting window it is allowed to input:

- Flow rate,
- Volume (Volume To Be Infused),
- Time,
- Drug activity (optionally if it has been marked in infusion menu window (see section 11.1.2).

Setting of two parameters will mean automatic calculation of the third parameter.

The first three parameters are closely entwined with each other. If two of them are set then the third one will be calculated automatically.





**Attention!**

When value of every parameter has been set or changed, check if they are correct in accord with intentions.




### 10.2.1 Flow rate only (fast infusion start)

In order to start infusion proceed as follows:

- Input 'Flow Rate' parameter in mL/h and confirm it by pressing the 'Accept' button on the touchscreen or by pressing  button on the alphanumeric keyboard
- Start an infusion by pressing START/STOP  button




There is no volume limit set in this case.

This mode of setting is the fastest way to start the infusion and may be used if there is no need to input the rest of the parameters.

 <b>Attention!</b>	<p>START/STOP  icon appearance in the upper right corner of display indicates that minimum quantity of parameters have been entered in order to start infusion. Infusion can be started by pressing the START/STOP  icon from now on. It refers to all infusion modes.</p>
--	--

### 10.2.2 Flow rate and volume (Volume limit)

In order to start infusion proceed as follows:

- Input 'Flow Rate' parameter and press 'Accept' button on the touchscreen or press  button on the alphanumeric keyboard.
- Set 'Volume' parameter and press  button on the alphanumeric keyboard.  
'Time' parameter will be calculated automatically. Volume parameter will change its name to 'Volume limit'.
- Start infusion by pressing START/STOP  button

In this case the 'Volume' parameter becomes the infusion limit. After drug is dosed, infusion will be stopped and 'Dose Done' alarm will be activated.





If KVO (Keep Vein Open) parameter has been selected in configuration of the pump then infusion will be continued with the flow rate set in the pump's configuration (see section 11.6).

If Continue parameter has been selected in configuration of the pump then after volume limit is reached, infusion will be continued but without Volume/Dose parameter.

Infusion flow rate change during the infusion will result in Infusion 'Time' parameter change while 'Volume limit' parameter stays the same.

### 10.2.3 Flow rate and time (Time limit)

In order to start infusion proceed as follows:


- Input 'Flow Rate' parameter and press ,Accept' button on the touchscreen or press  button on the alphanumeric keyboard
- Skip 'Volume' parameter setting by pressing  or  button on the alphanumeric keyboard or by inputting no value.
- Set 'Time' parameter (Hr:min) and press ,Accept' button on the touchscreen or press  button on the alphanumeric keyboard.

'Volume' parameter will be calculated automatically. 'Time' parameter will change its name to 'Time limit' parameter.

- Start infusion by pressing START/STOP  button.



In this case the 'Time' parameter becomes the infusion limit. After set 'Time' parameter is finished, infusion will be stopped and 'Dose Done' alarm will be activated. If KVO (Keep Vein Open) parameter has been selected in configuration of the pump then infusion will be continued with the flow rate set in the pump's configuration (see section 11.6).

If Continue parameter has been selected in configuration of the pump then after volume limit is reached, infusion will be continued but without Volume/Dose parameter.


 <b>Attention!</b>	<p>Infusion Rate change during the infusion, cause change of the Volume parameter without changing the infusion Time. It may be confusing if this option was used to calculate the Volume parameter only.</p> <p>Please use this option carefully and if you want to set the Volume as an infusion limit please retype the volume calculated by the pump and confirm it with ,Accept' button. The Time limit will be replaced to the Volume limit.</p>
--	--

### 10.2.4 Infusion volume and time (Volume limit)


In order to start infusion proceed as follows:

- Skip 'Flow Rate' parameter by pressing ,Accept' field on the touchscreen or by pressing  button or by inputting no value.
- Set 'Volume' parameter and press ,Accept' field on the touchscreen or press  button on the alphanumeric keyboard.

'Volume' parameter changes its name to 'Volume limit' parameter.

- Set 'Time' parameter (Hr:min) and touch ,Accept' field or press  button.

'Flow rate' parameter will be automatically calculated.

- Start infusion pressing START/STOP  button.

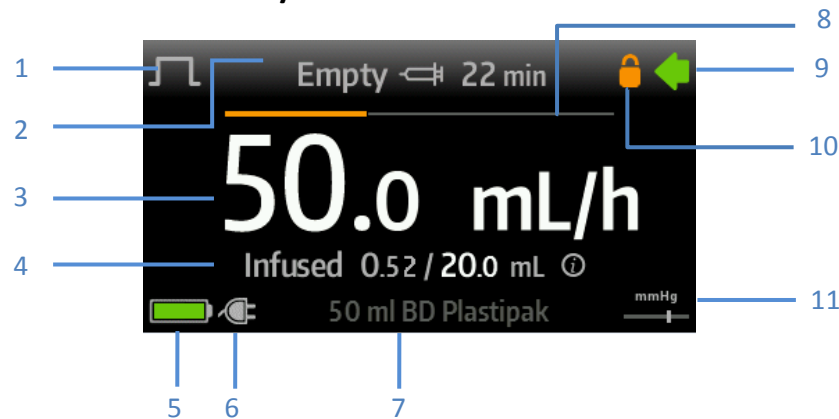
In this case the 'Volume' parameter becomes the infusion limit. After drug dose is done, infusion will be stopped and 'Dose Done' alarm will be activated.








If KVO (Keep Vein Open) parameter has been selected in configuration of the pump then infusion will be continued with the flow rate set in the pump's configuration (see section 11.6).


If Continue parameter has been selected in configuration of the pump then after volume limit is reached, infusion will be continued but without Volume/Dose parameter.

'Flow rate' change during infusion will change 'Time' parameter while 'Volume limit' parameter will stay the same.

### 10.2.5 Infusion window in mL/h



1. Infusion mode icon.
2. Drug name / Dose Done / Syringe empty / Remainder info.  
 Touch to open infusion menu window (see section 11.2).
3. Flow rate.  
 Touch to quickly change value (see section 10.5).
4. Infusion progress bar/status (see section 11.3).  
Press   to change information displayed.  
 Touch to open 'Infusion – Info' window or press  button on the Keyboard.
5. Battery charge level indicator.  
 Touch to see the battery status summary (see section 14).
6. Mains power supply connection icon.
7. Syringe volume, manufacturer and type.

8. ETTA bar (Estimated Time To Act).
  9. Infusion indicator – blinking during infusion.
  10. Security status level.
  11. Infusion pressure and selected occlusion level indicator.
-  Touch to change occlusion level (see section 11.2.5).

Only in case of enteral feeding when syringes designed for enteral nutrition have been installed and chosen from the syringes list in the pump, the following window in purple colour will be displayed:




### 10.3 Infusion in other units

Available in the following models:

S200

S300

S200 and S300 syringe pumps enable to program infusion in wide range of units. They can be chosen from a list prepared by Medima or can be created by a user.

 <p><b>Attention!</b></p>	<p>Some of the parameters are calculated on mL or mL/h. This function relates to all modes of infusion.</p>
--	---

#### 10.3.1 Infusion programming in units

In order to start infusion proceed as follows:

- Choose 'Units' tile in 'Choose infusion' window (see section 10.1),
- Choose predefined unit or create a new one (see section 10.3.3),
- Enter following infusion parameters:
  - Dilution,
  - Weight or Surface,
  - Dose Rate,
  - Dose,
  - Time.






For parameters Dose Rate, Dose and Time the same rules apply as described for parameters Flow Rate, Volume and Time in 'Infusion in mL/h' section (see section 10.2). According to the value entering sequence, 'Dose' may change to 'Dose Limit' and 'Time' may change to 'Time Limit'.

- Start infusion by pressing START/STOP  button.

### 10.3.2 Infusion units choice

'Units' tile choice results in displaying a list of the most popular units.

Use   buttons to switch between the units. To choose required unit press  button or touch specific unit tile.

### 10.3.3 List of the units

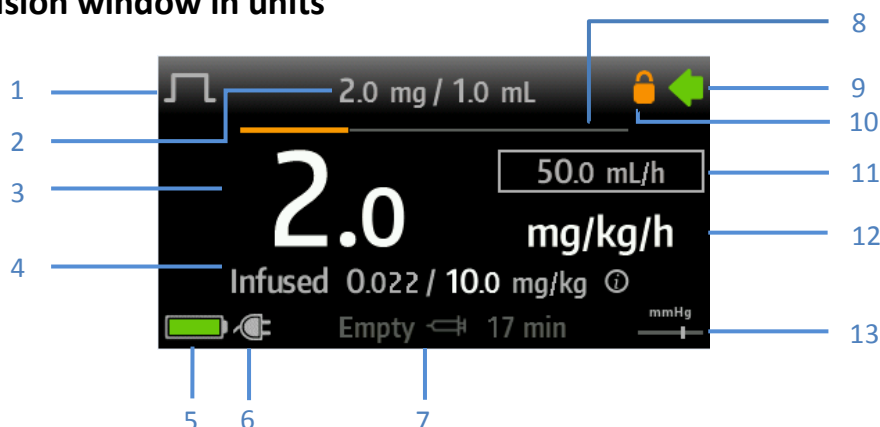
- Predefined units:**







mL/h, µg/kg/min, µg/kg/h, mg/kg/min, mg/kg/h, µg/min, µg/h, mg/min, mg /h, IU/h, Eq/h
---

- Variation of all possible units in 'Others' tile:**



kJ, J, kcal, cal, mol, mmol, kIE, IE, mIE, kIU, IU, mIU, Eq, mEq, µEq, g, mg, µg, ng, mL, L	--, kg, m²	min, h, 24h
---	------------	-------------

### 10.3.4 Infusion window in units

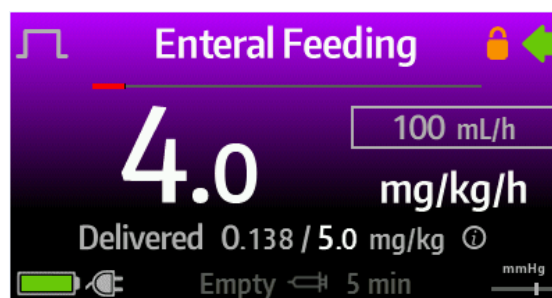


- Infusion mode icon.
- Drug name / Drug concentration / Remainder info.  
 Touch to open infusion menu window (see section 11.2).
- Dose rate.  
 Touch to quickly change value (see section 10.5).
- Infusion progress bar/status (see section 11.3).  
Press   to change information displayed.  
 Touch to open 'Infusion – Info' window or press  button on the

Keyboard.

5. Battery charge level indicator.
-  Touch to see the battery status summary (see section 14).
6. Mains power supply connection icon.
7. Dose Done or Syringe empty.
8. ETTA bar (Estimated Time To Act).
9. Infusion indicator – blinking during infusion.
10. Security status level.
11. Flow rate in mL/h.
12. Dose rate unit.
13. Infusion pressure and selected occlusion level indicator.
-  Touch to change occlusion level (see section 11.2.5).

Only in case of enteral feeding when syringes designed for enteral nutrition have been installed and chosen from the syringes list in the pump, the following window in purple colour will be displayed:



## 10.4 Drug library

Available in the following model:

S300

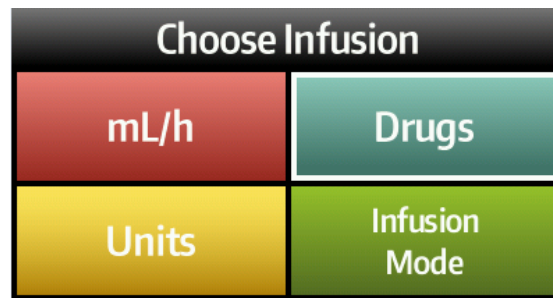
Drug library can be created in Medima Drug Editor software. It fundamentally influences on infusion safety increase and meets requirements of DERS (Dose Error Reduction System).



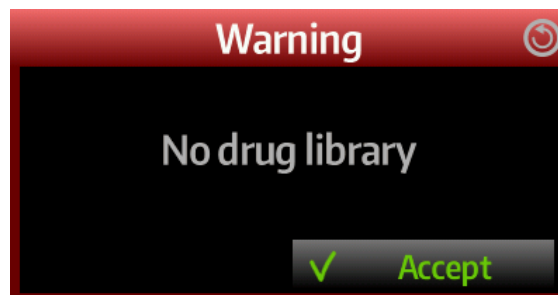
Attention!

Drug Library is not installed on the pump as a factory setting by Medima.

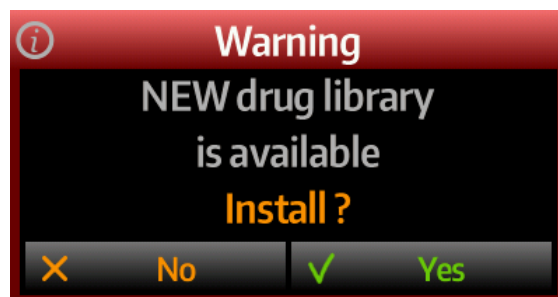
In S300 model in the window of 'Choose Infusion' the tile of 'Drugs' is visible even if a drug library has not been installed yet.



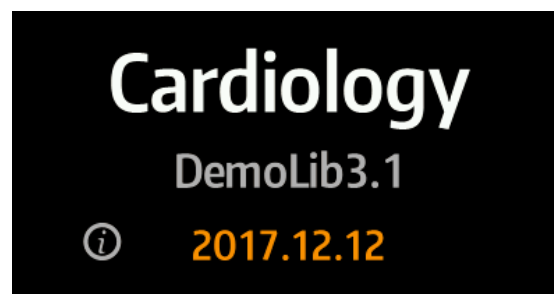
If no drug library is installed then after the 'Drugs' tile choice the following warning will be displayed:





If drug library has been uploaded into the pump. As soon as the pump is turned ON, the following request to install will be displayed:



Name of uploaded to pump drug library with ward (CCA - Clinical Care Area) name and date of its creation is displayed shortly after turning ON the pump.



More information concerning the uploaded library can be read by pressing  button or by touching  icon when window with name of the drug library is displayed. The 'Drug Library' information window is also available in infusion menu when 'Drug Lib. Info' tile is chosen.

Drug Library	
Name	DemoLib3.1
Version	v 1.00.00
Created	2017.12.12
Uploaded	2018.07.16
Activated	2018.07.19



**Attention!**

The most recent version of the drug library should always be used and the same drug library uploaded to all used pumps possibly at the same time. Name and version of the library should be checked. Check also name of selected CCA.

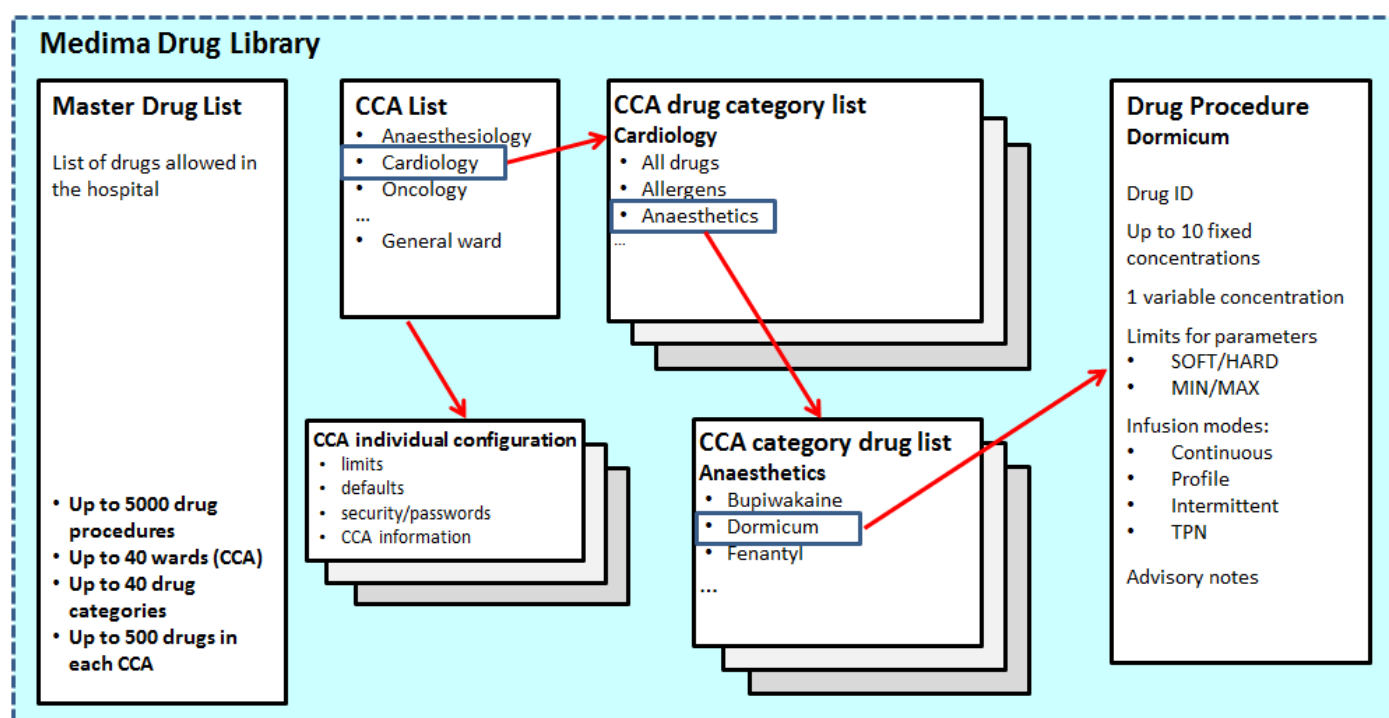
Drug dosing procedures placed in different CCA may significantly differ from one to another.

#### 10.4.1 Drug library structure

The drug library allows to store the list of up to 5000 drug dosing procedures allowed in the hospital. These drugs may be divided into 40 wards (CCA - Clinical Care Areas), each CCA may contain up to 40 drug categories. Each CCA may contain up to 500 drug dosing procedures.

Drug dosing procedure contains up to 10 fixed (predefined) drug concentrations and 1 variable (defined) drug concentration, hard and soft limits for infusion parameters, allowed infusion modes, boluses doses and rates and advisory notes.

The drug library structure has been presented on the drawing below:

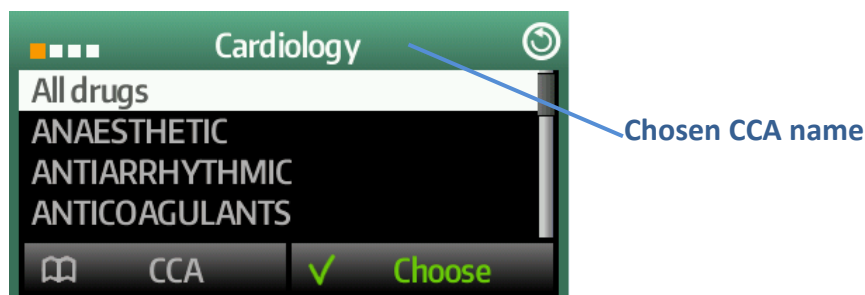




\* CCA – Clinical Care Area

### 10.4.2 Drug procedure choice from the drug library



In order to open drug library, go the 'Choose infusion' window and press 'Drugs' tile (see section 10.1).

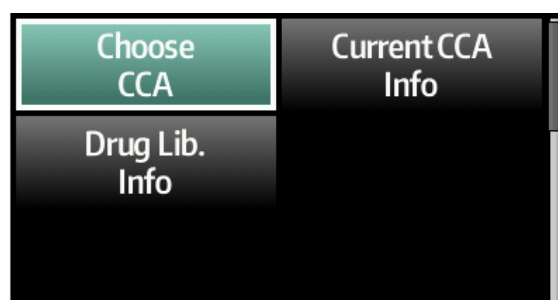
For easier navigation across the drug library, it has been divided into 5 levels of advancement. The first level is the definition of CCA.





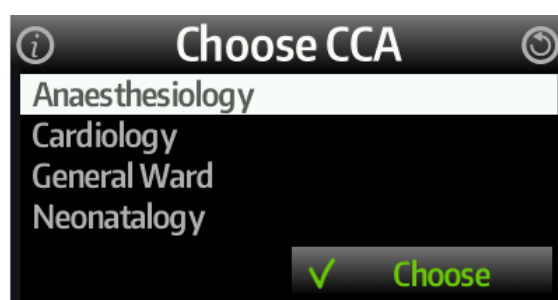
- **Level 1** - in order to choose or change CCA, touch  CCA field on the touchscreen or press  button on the alphanumeric keyboard.

Window enabling to choose one of three options will be displayed by the pump:

- Choose CCA – allows to open window of a specified CCA (details described below). Available names of CCAs can be scrolled up and down by   buttons.
- Current CCA info – it shares significant remarks about CCA choice.
- Drug Lib. Info – window of identification data about uploaded drug library will be displayed (see section 10.4).




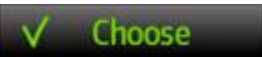

- Specified CCA choice can be chosen by pressing  **Choose** button on the touchscreen or  button on the alphanumeric keyboard.







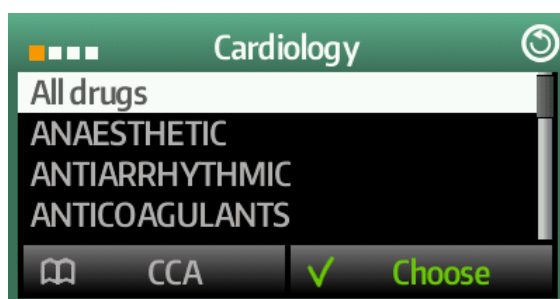






It is strongly recommended to set CCA in accord to the pump's application destination. Drug dosing procedures placed in different CCAs may significantly differ from each other therefore incorrect choice of CCA may result in serious patient's health or life loss risk.

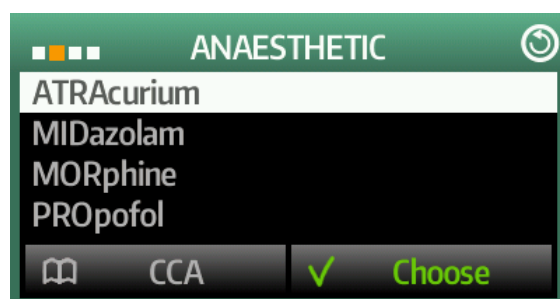
Next levels of the drug library structure are indicated by the  icon visible in the upper left corner of the screen.





In order to select the right drug procedure it is necessary to go through all levels confirming selection by  button on the touchscreen or by  button on the alphanumeric keyboard.

- **Level 2** – specific CCA's drug category list. Category choice can be done by   buttons and accepted by  button on the touchscreen or by  button on the alphanumeric keyboard.



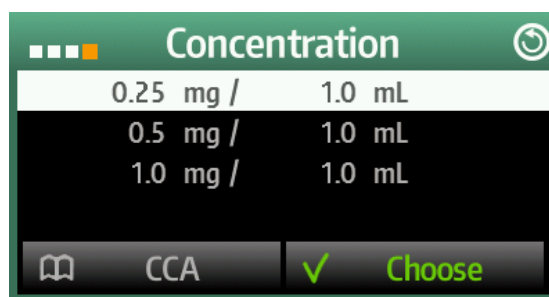
- **Level 3** –list of drugs in chosen category. Drug choice can be made by   buttons and accepted by  button on the touchscreen or by  button on the alphanumeric keyboard.



- **Level 4** – allowed infusion modes list for a specific drug. Infusion mode choice can be done by   buttons and accepted by  button on the touchscreen or by  button on the alphanumeric keyboard.

If only one infusion mode has been defined for the drug then this level is omitted in the drug library navigation structure.

- **Level 5** –drug concentration.



### 10.4.3 LIMITS of parameters values

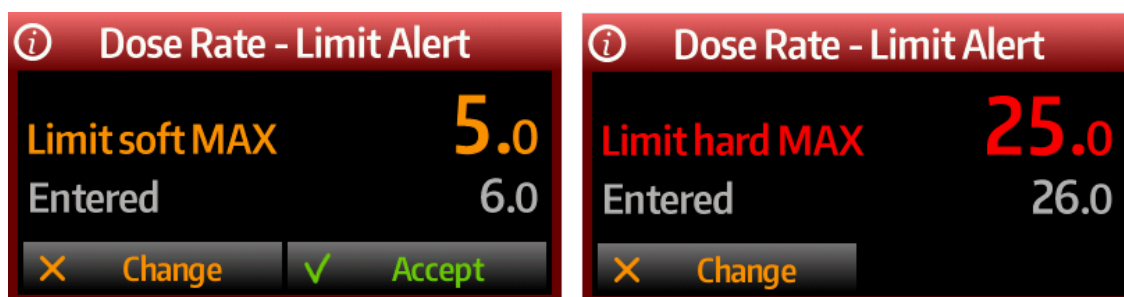
Syringe pumps manufactured by Medima have been equipped with advanced systems protecting against hazardous values input or warning user against exceeding defined standard values. Most of these pump settings due to safety precautions are not available from the pump level and can be configured by external software of Medima:


- Medima Configurator – allows for important pump parameters configuration settings with inclusion of minimum and maximum limits and default settings.
- Medima Drug Editor – enables the drug library creation for S300 pumps equipped with soft and hard limits, advisory notes, drug concentrations etc.

Two types of limits are possible to be input:

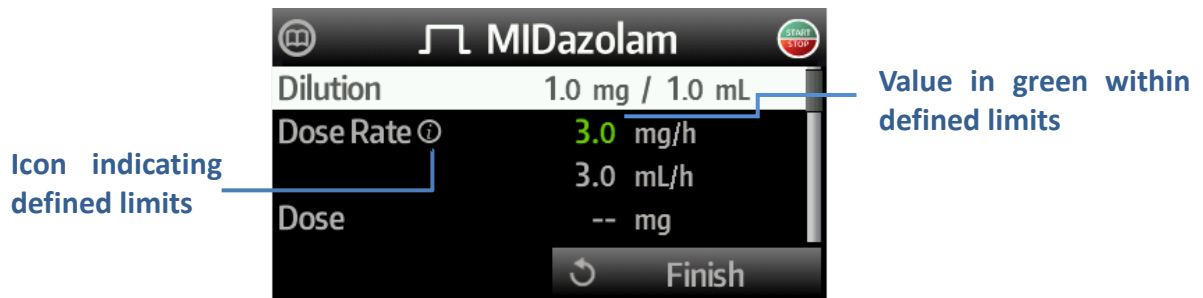
**Soft limits (min. and max)** Warn against exceeding recommended values of parameters but do not block entering values outside of their range. During programming warning and soft limit value predefined for the parameter will be displayed.

**Hard limits (min. and max)** Block entering values of the parameters outside of their range. During programming warning and hard limit value predefined for the parameter will be displayed.

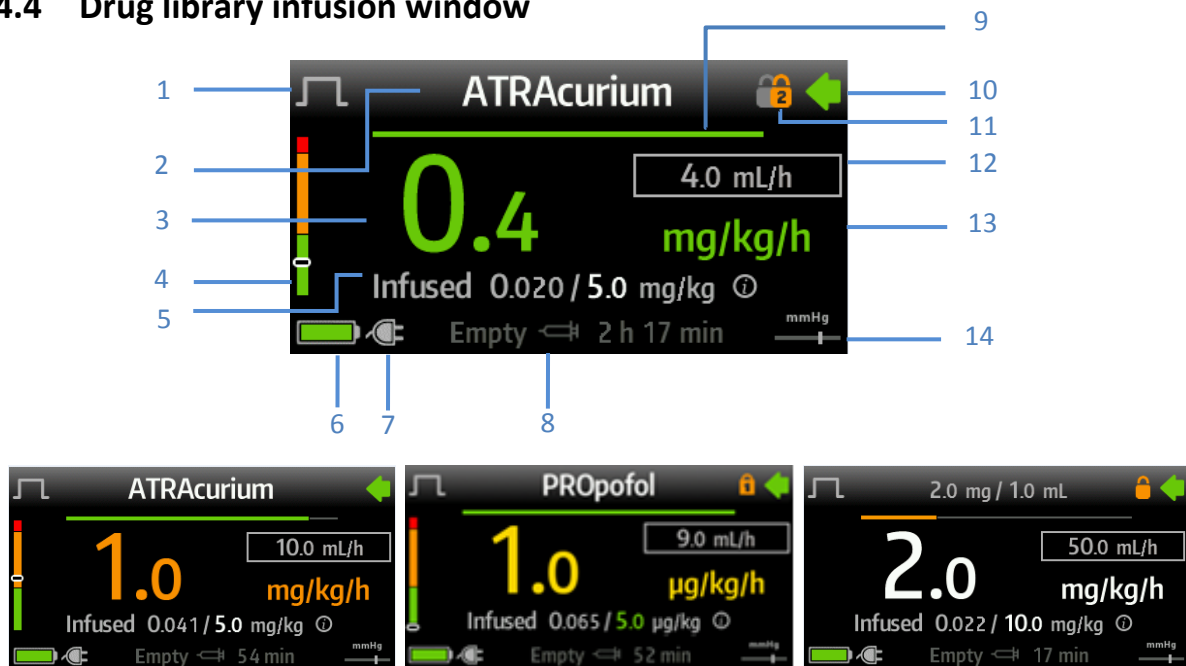


- ① icon displayed during entering of the parameter value or its name selection indicates that limits have been defined for this parameter. They can be checked by touching this icon or by pressing  button.
- ① The way how values of the parameters are displayed depends on how limits have been defined for them.

- White - no limits have been defined,
- Green - chosen value is within defined limits,
- Orange - chosen value is over defined soft limits (Limit soft MAX),
- Yellow – chosen value is below defined soft limits (Limit soft MIN).




#### 10.4.4 Drug library infusion window



1. Infusion mode icon.
  2. Drug name / Drug concentration / Remainder info.
  3. Flow or dose rate.
  4. Limits status bar with current value indicator.
  5. Infusion status/progress bar (see section 11.3).
  6. Battery charge level indicator.
  7. Touch to see the battery status summary (see section 14).
  8. Touch to open 'Infusion – Info' window or press **i** button on the Keyboard.
  9. Touch to quickly change value (see section 10.5).
  10. Touch to open infusion menu window (see section 11.2).
  11. Limits status bar with current value indicator.
  12. Flow or dose rate.
  13. Drug name / Drug concentration / Remainder info.
  14. Infusion status/progress bar (see section 11.3).
- Press **▲▼** to change information displayed.





7. Mains power supply connection icon.
  8. Dose Done or Syringe empty.
  9. ETTA bar (Estimated Time To Act).
  10. Infusion indicator – blinking during infusion.
  11. Security status level.
  12. Flow rate in mL/h.
  13. Dose rate unit.
  14. Infusion pressure and selected occlusion level indicator.
-  Touch to change occlusion level (see section 11.2.5).

In case of enteral feeding when syringes designed for enteral nutrition have been installed and nutrition specimen chosen from the drug library then delivery will be displayed with a window in a purple colour.

## 10.5 Quick infusion flow/dose rate change

In order to quickly change infusion's rate value during infusion two ways of input can be done:

- displayed value must be touched on the screen and the new one input.
- new value must be simply input on the alphanumeric keyboard. Pump will automatically open flow/dose rate window.

Confirm new value by pressing  button or by pressing  button on the alphanumeric keyboard.



**Attention!**

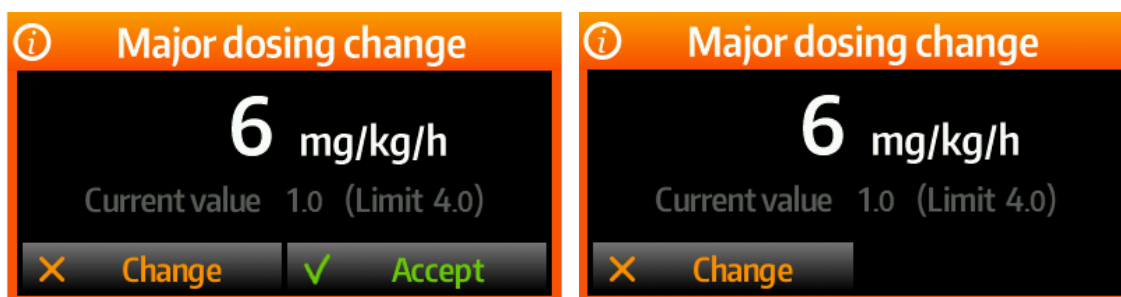
Touchscreen option may be disabled in the pump's configuration. If touchscreen does not respond to touching by a finger, check the configuration settings (see section 12.2).

In order to increase patient's safety, pump has been equipped with the mechanism of avoiding large infusion rate changes (titration).

Three types of setting are available:

- disabled – no additional limits. Only pump limits are defined.
- soft limits setting – exceeding those limits will activate 'Major dosing change' window. Input value can be accepted.
- hard limits setting – those limits cannot be exceeded. After 'Major dosing change' window display, input value will be blocked.

Titration mechanism configuration can be made in by the Medima Configurator software.



## 10.6 Bolus administration

Bolus can be administered to patient in two ways:

- automatic - with defined parameters of dose, time and rate,
- manual - with only rate parameter defined.

It must be remembered that bolus is administered at high infusion rate (most commonly higher than 200 mL/h). Depending on the diameter and length of the extension line, needle diameter and additional elements of infusion lines equipment such as infusion flow resistance, may be significant. In this case occlusion level set in the pump configuration (see section 11.2.5) may be too low as for standard infusion occlusion level setting and alarm of occlusion could be activated.

S100, S200 and S300 pumps have been equipped in mechanism of automatic adjustment of the bolus administration rate to the pressure in the patient's line. This mechanism can be enabled in the Medima Configurator software. If it is turned ON then bolus rate value during its administration is actively adjusted so as to pressure in the patient line did not exceed the defined occlusion level. The described mechanism allows for bolus administration despite high resistance in the patient line. Defined limits for bolus rate administration lowering mechanism can be set in the Medima Configurator software. If bolus rate adjustment cannot be made then occlusion alarm is activated.

Bolus can be administered multiple times during infusion. Each bolus dose is added to total infusion dose.



**Attention!**

Medima always recommends automatic bolus administration to avoid an overdose risk. If bolus rate is 2000 mL/h then 1 ml of the drug will be administered in time less than 2 sec.


At low bolus doses its administration errors cannot be excluded. It results from the start-up characteristics of the pump and patient's line tolerance.



Attention!

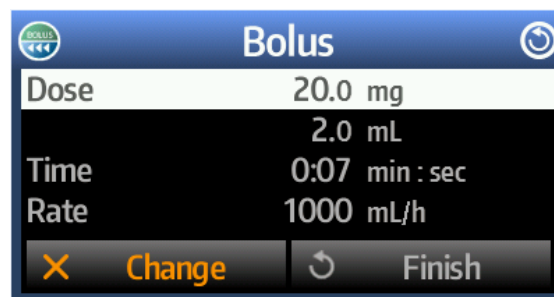
In the case when infusion has been programmed with 'Dose limit' parameter, bolus dose will be calculated to the infusion dose. It means that the patient will be administered only the dose of medicine which has been set regardless how many boluses have been administered.



In the case when infusion has been programmed with 'Time limit' parameter, bolus dose increases the total infusion dose administered to the patient but in the defined time. It can result in administration of increased drug dose in set time, higher than it was originally planned.

The total dose delivered to the patient is visible in infusion data available when  button is pressed.

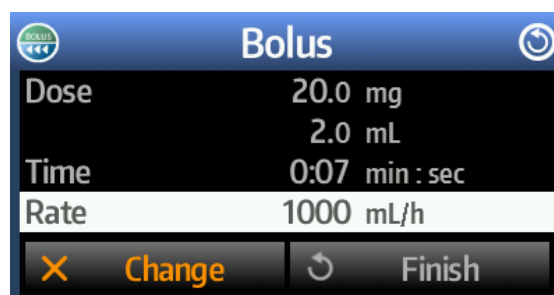
### 10.6.1 Bolus in automatic mode



- Press Bolus  button during infusion – 'Bolus' window will be displayed.



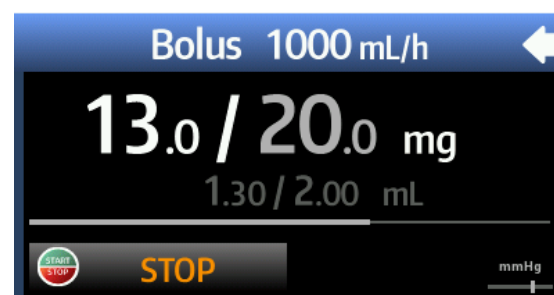
Bolus	
Dose	20.0 mg
	2.0 mL
Time	0:07 min : sec
Rate	1000 mL/h
	Change
	Finish


- Bolus dose or time must be set. Second parameter will be automatically calculated. Displayed bolus rate is a default value that can be defined in the pump configuration by the Medima Configurator software within predefined limits.




Bolus	
Dose	20.0 mg
	2.0 mL
Time	0:07 min : sec
Rate	1000 mL/h
	Change
	Finish


- In order to start bolus administration, bolus  button must be pressed.




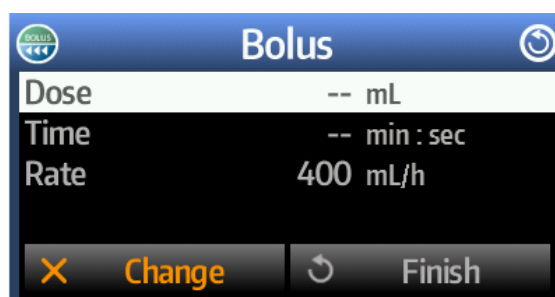
Bolus 1000 mL/h	
13.0 / 20.0 mg	
1.30 / 2.00 mL	
	STOP
mmHg	



- In order to stop bolus administration, START/STOP  button must be pressed.

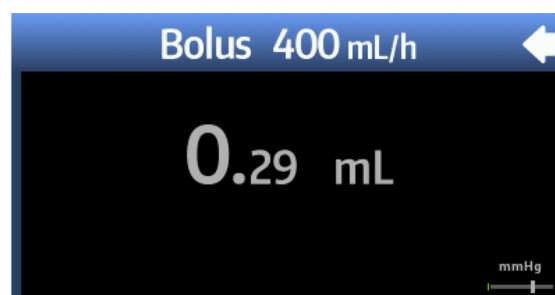
## 10.6.2 Bolus in manual mode


Manual administration can be turned OFF in the pump configuration. If it is turned ON then its administration is feasible when 'Dose' parameter value has not been defined or when 'Dose' parameter has not been calculated due to 'Time' parameter input. To erase previous value of dose, time or rate, null '0' value must be input and accepted by  button.

- Bolus window will be displayed during infusion shortly after bolus  button has been pressed.



- In order to start the manual bolus, user must wait about 2 sec. until the bolus icon  is displayed in the top left corner of the screen, then the bolus  button must be pressed and held. Displayed bolus 'Rate' is a default value that can be defined in the pump's configuration by Medima Configurator software, within predefined limits.



- In order to stop the manual bolus, holding of the bolus  button must be stopped. Window of already started infusion will be displayed again.

## 10.7 Infusion stop and restart


Stopping infusion is possible in one of two ways:

- Press START/STOP  button,
- Turn the pump OFF by ON/OFF  button.

To continue the stopped infusion when pump is still turned ON, proceed as follows:


- Press START/STOP  button.

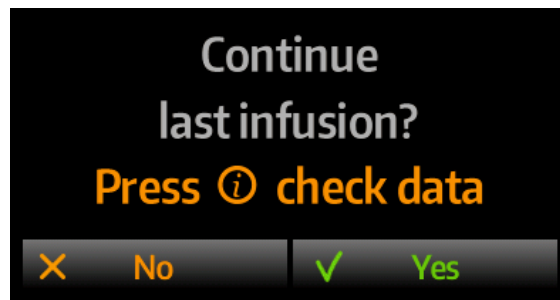
To continue the stopped infusion when pump has been turned OFF, proceed as follows:




- Turn the pump ON by pressing ON/OFF  button,

- Confirm displayed 'Continue last infusion?' message by pressing.



button on the touchscreen or by pressing  button on the alphanumeric keyboard.



All parameters of the last stopped infusion will be restored including administered dose/volume. Pressing  button enables to check the last infusion settings. When  button or  button is pressed again then 'Comments' window with recommendations when infusion should be continued or discontinued will be displayed.

Parameters	
Started	11:48
Rate	25.0 mL/h
Volume	10.0 mL
Infused	2.73 mL
Left	7.27 mL

PROpofol	
Started	15:23
Dose Rate	1.0 mg/kg/h
Dose	2.0 mg/kg
Infused	0.152 mg/kg
Left	1.85 mg/kg

- Press START/STOP  button



**Attention!**

**Use** the continue function if:


- infusion is to be administered to the same patient
- the same drug is to be administered in the same way
- you wish to sum up subsequent doses

**Do not use** the continue function if:

- infusion is to be administered to different patient
- different drug is to be infused
- you are not sure which drug has been infused recently

## 11 ADVANCED INFUSION OPTIONS

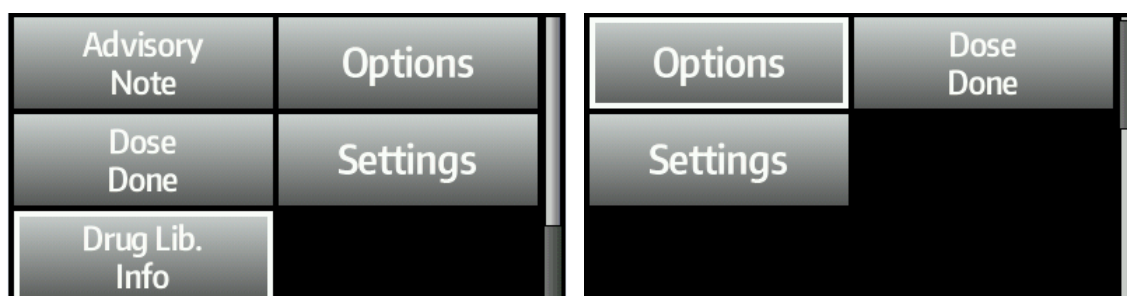
### 11.1 Additional parameters available in functions menu

Additional parameters may be chosen by pressing  button before the infusion start and before set parameters in the Parameters window have been accepted by 'Accept all parameters' line.

Default pump settings can be set by the Medima Configurator software.

Menu of additional functions consists of the following tiles:

- Advisory Note – available if the drug has a defined advisory note,
- Options,
- Dose Done,
- Settings,
- Drug Lib. Info - visible if the drug library was used for infusion setup.



#### 11.1.1 Advisory Note

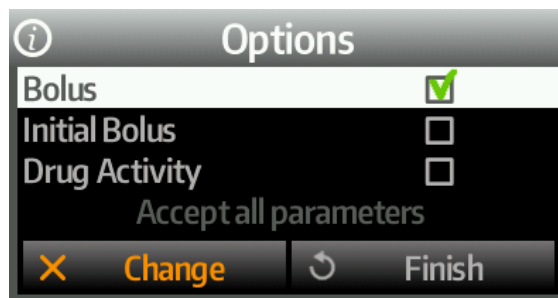
Information appears when infusion has been started from the drug library.

It contains detailed recommendations or contraindications relating to chosen drug.

#### 11.1.2 Options

'Options' function enables to turn ON/OFF the following parameters:

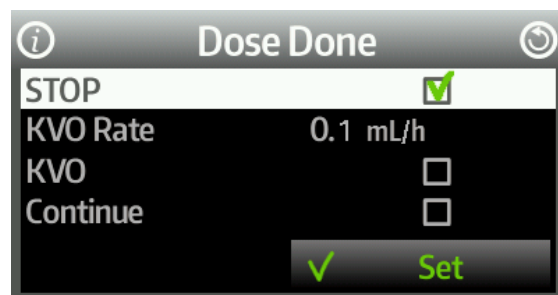
- Bolus – when turned ON then 'Bolus' administration is allowed during infusion. Bolus is available for continuous infusion only.
- Initial Bolus – when turned ON then 'Initial bolus' is allowed to be started at the beginning of infusion. Initial bolus is available for continuous infusion only.
- Drug Activity – drug activity is defined in Hr:min. Pump will activate 'Drug not active' alarm when defined time has been exceeded. The time is counted down from the moment a syringe has been installed in the pump.



### 11.1.3 Dose Done

'Dose done' tile consists of turn ON/OFF options of activities which will be taken by the pump after the programmed dose has been administered:

- STOP – infusion will be stopped.
- KVO Rate – value of the KVO rate can be set within the defined limits.
- KVO – pump will continue infusion at the rate defined in KVO parameters. For more information see section 11.6.
- Continue – pump will continue infusion at current rate but with no volume/dose defined. Option is only available for continuous infusion.




### 11.1.4 Settings

'Settings' function has been described in section 12.2.

## 11.2 Additional parameters available in infusion menu

Shortly before infusion start after acceptance of set parameters in the Parameters window by 'Accept all parameters' line or during ongoing infusion or when the infusion is stopped, the following context menu is available.



In order to open this context menu proceed as follows:

- Press  button,
- During ongoing infusion, press the title bar of the pump's display where CCA name, drug name, drug concentration and reminders are displayed.
- During infusion is stopped, press 'STOP' message field of the pump's display.

Following window will be displayed:



### 11.2.1 Parameters

The list of infusion parameters to be modified is displayed. In order to change any of available parameters,  button or  button must be pressed.

Parameters edition is made the same way as the initial parameters configuration.

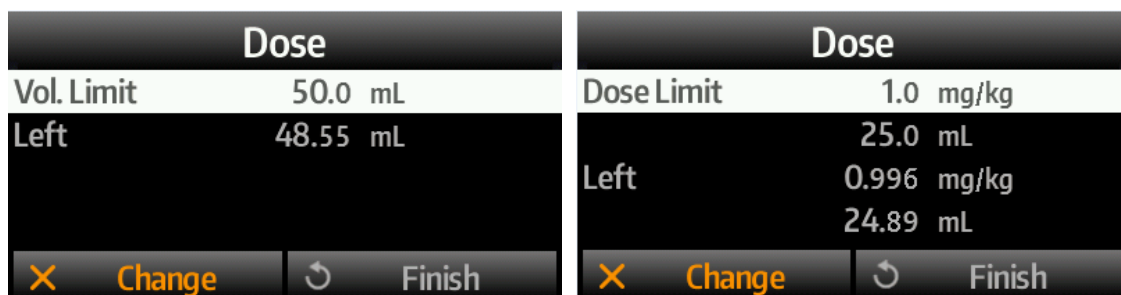
### 11.2.2 New Infusion

Function is available after the current infusion has been stopped. Start of new infusion with new starting parameters is possible. 'Choose infusion' window will be displayed (see section 10.1).

### 11.2.3 Dose

'Dose limit' or 'Volume limit' check or change is possible. 'Dose Limit' is visible in in the chosen unit and in mL/h. 'Left' parameter indicates how much dose/volume is yet to be administered.

User may modify both parameters 'Dose limit'/'Vol. limit' and 'Left' value. They are dependent on each other because changing one will automatically change the other.





### 11.2.4 Dose Done

Dose Done allows for defining how pump should behave after programmed dose has been administered. For more information see section 11.1.3.



### 11.2.5 Occlusion

At any moment of infusion it is possible to modify level of occlusion pressure by choosing the new level in range of 1 - 12 and confirmation by  **Accept** button on the touchscreen or by pressing  button on the alphanumeric keyboard.



1. Current pressure in line in defined unit.
2. Prealarm pressure level in defined unit.
3. Occlusion alarm pressure in defined unit and occlusion level.

Flow resistance depends on many factors such as:

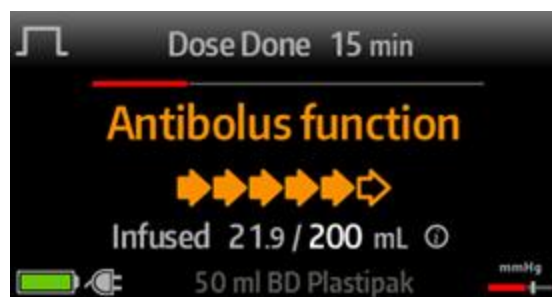
- Flow/dose rate,
- Fluid density,
- Inner diameter and length of the patient's line,
- Needle diameter,
- Additional equipment elements such as antibacterial filters increasing flow resistance as well as infusion time.

The mentioned flow resistance is difficult to evaluate and different in every case. It means that despite lack of occlusion, pump will activate an alarm at the lowest pressure levels. In such a case it is recommended to:

- increase the pressure level (see above),
- replace external filter (if present during infusion),
- replace a patient line for a new one.

The pump has been equipped with 'Antibolus' function reducing the occlusion bolus by fluid withdrawal from the patient's line until acceptable pressure level is reached.

This function also corrects counter of set drug volume/dose and starts automatically after 'Occlusion' alarm is activated or shortly after its confirmation.



'Antibolus' function may be configured by the Medima Configurator software. Following settings are available:

- Blocked,
- Start immediately,
- Start after alarm confirmation,
- Start after alarm confirmation and additional request confirmation.

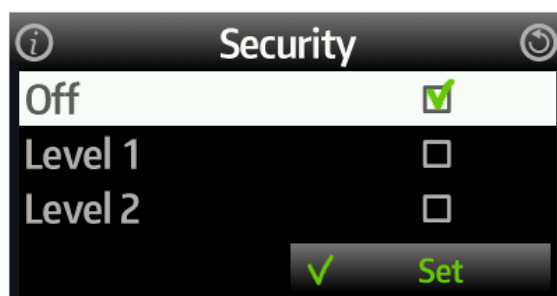
### 11.2.6 Security – Access restriction



S100, S200, S300 pumps have been equipped with function of settings security which protects pump against an unauthorized changes.

Passwords for particular security levels can be set in the Medima Configurator software. Additional protection options in the drug library can be configured by the Medima Drug Editor software (S300 pump only). Passwords cannot be changed in the pump.

In the 'Security' window one of two security levels can be chosen or any of them turned OFF:

- Off – no protection,
- Level 1,
- Level 2.



The specified security level must be chosen and then set by pressing  **Set** button on the touchscreen or by pressing  button. Removing security is possible by a password input.



Security level start is indicated by appearance of  or  icons in the upper right corner of display. Level of security is visible inside of the icon.


Table presenting what actions are password protected:



Function	Level 1	Level 2
Infusion parameters programming	Secured	Secured
Infusion start	Secured	Secured
Parameters change (during infusion)	Secured	Secured
Infusion stop		Secured ⚠
Infusion restart		Secured
Clinical bolus	Secured	Secured
Security turning OFF	Secured	Secured
Pump turning OFF		Secured ⚠

⚠ Because of safety reasons infusion stop is possible without entering a password. Nonetheless until the correct password is given, pump will keep activating a high priority alarm.

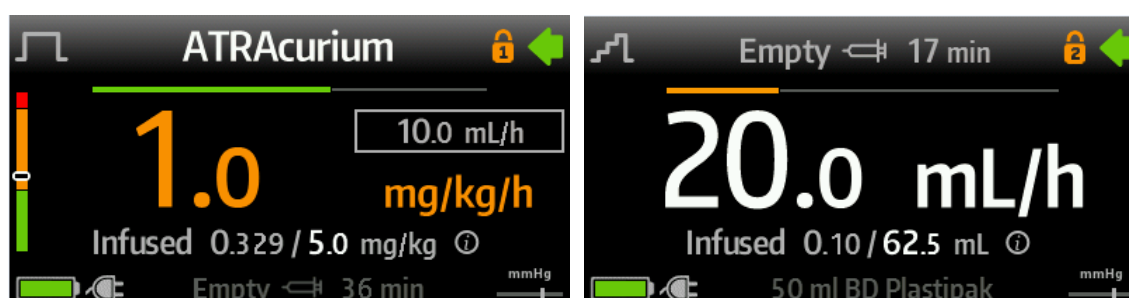
After security function has been started, an attempt to change the protected setting will result in a request to enter the password. Window additionally includes information whether the pump in infusion mode or it has been stopped.



 <b>Attention!</b>	<p>When asked for security level 1 password, security level 2 password can be input.</p>
--	--

Security function start influences how keyboard and touchscreen lock icon is displayed. Lock icon will be visible in this case as a grey padlock located next to the security function icon  or . Lock function start and disabling does not change comparing with its initial functionality (see section 6.3.1).

- Security level status without started lock of the keyboard and the touchscreen:



- Security level status with started lock of the keyboard and the touchscreen:



### 11.2.7 Standby

The 'Standby' function allows for temporary infusion stop without turning OFF the pump. 'No user activity' alarms will be activated then. 'Standby' tile is only available in menu when infusion has been stopped.

Time in format of Hr:min must be input and confirmed by pressing button on the touchscreen or by pressing button on the alphanumeric keyboard. Pump will start counting down the time and after its finish 'End of Standby' alarm will be activated.

### 11.2.8 Settings

'Settings' tile allows for basic pump settings input (see section 12.2).

### 11.2.9 Drug Lib. Info

Information concerning the uploaded drug library to the pump is displayed (see section 10.4).

### 11.2.10 Battery Info

Information of the battery status and a list of power supply reminders is displayed (see sections 14 and 13.2 and 13.5.4) This function is useful when touchscreen option has been turned OFF (see section 12.2).

## 11.3 Infusion status/progress information


Status/progress bar displayed during infusion gives important information about infusion status. Its content depends on the parameters defined before infusion. The sequence of appearance on the main infusion window depends on the setting made in the Medima Configurator software.

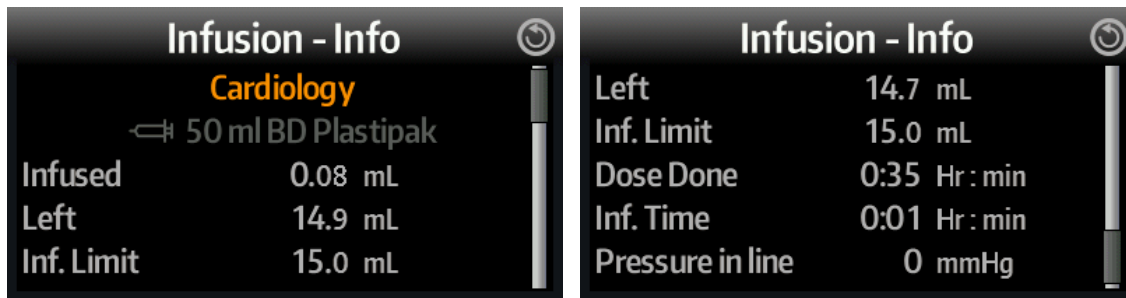
Selection of content can be made by pressing buttons.

Following parameters can be displayed on the bar:

- Infused – presents infused dose/volume,
- Left – presents dose/volume left to be administered,

- Dose done – presents time left for full dose administration.

Pressing  button during ongoing infusion or when the infusion is stopped enables to see summary of all parameters in the 'Infusion - info' window.

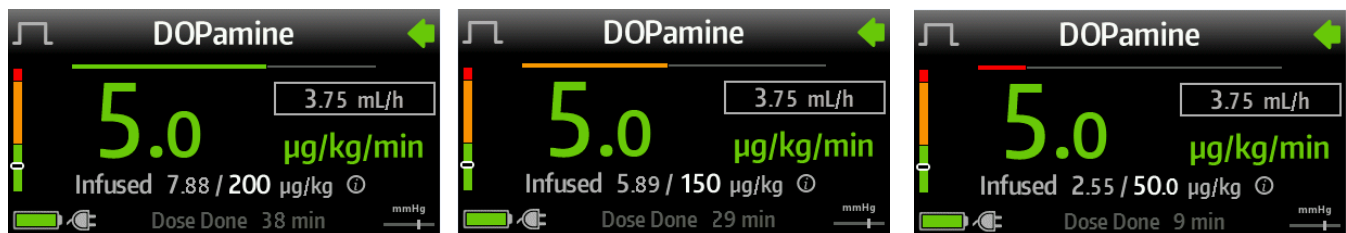


## 11.4 ETТА bar

Horizontal colour bar called the ETТА (Estimated Time To Act) bar located over the displayed rate value, graphically presents the time remaining for medical personnel to start the required action.

The ETТА bar can take the following colours:

- green – when time is longer than 30 minutes,
- orange – in time between 30 up to 15 minutes,
- red – when time is shorter than 15 minutes up to infusion end.



## 11.5 Infusion modes

In this section all available infusion modes have been described. Next to the infusion mode icon, models of pumps equipped with particular infusion mode have been added.

In order to choose any of available infusion modes, 'Infusion mode' tile in the 'Choose infusion' window must be pressed (see section 10.1).

11.5.1 Continuous infusion

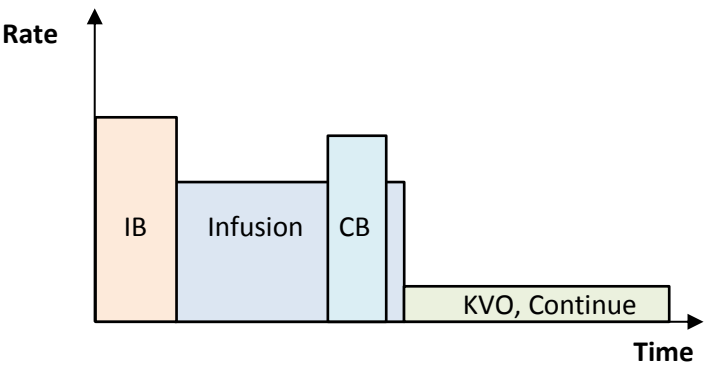
Available in the following models:

Continuous

S100

S200

S300



- IB Initial bolus (optional)
- CB Clinical bolus (optional)
- KVO, Continue (optional)

Continuous infusion is characterized by the constant rate value and can be limited by dose/volume or time parameters.

It can also be preceded by initial bolus (IB) with clinical boluses added during infusion as an option.

For more details how continuous infusion should be started see sections 10.2 and 10.3 and 10.4.

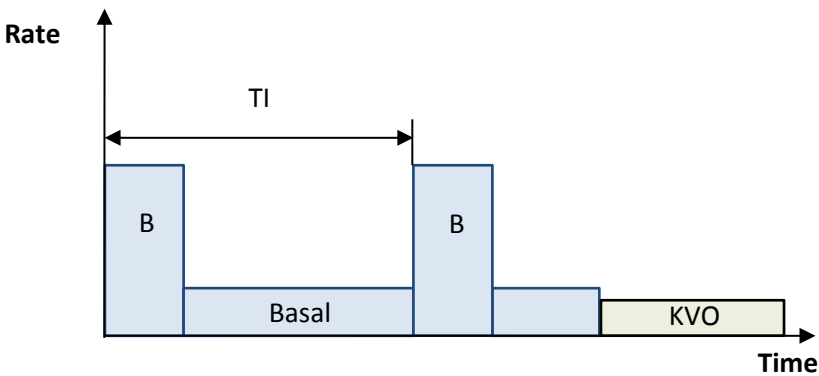
11.5.2 Intermittent infusion

Available in the following models:

Intermittent




S200

S300



- B Periodical bolus
- TI Interval time in between boluses

Basal      constant rate (in mL/h or in other units)  
 KVO      (optional)

 <b>Attention!</b>	<p>START/STOP  icon appearance in the upper right corner of display, indicates the minimum required set of parameters have been entered in order to start infusion. Infusion can be started by pressing the START/STOP  icon from now on.</p>
--	---

In order to start intermittent infusion proceed as follows:

1. In 'Infusion mode' window choose 'Intermittent' infusion tile (see section 10.1).
2. In 'Units' window the specified unit for intermittent infusion must be chosen.
3. Intermittent infusion programming:
  - a) Infusion in mL/h:



Press mL/h tile. Following parameters are to be defined:

- Bolus Volume (Bolus Vol.) (mL).
- Bolus Time (min:sec) – time during which bolus volume is administered.
- Bolus Rate (mL/h) – rate of bolus administration.

If two of three available parameters of Bolus volume, Bolus time, Bolus rate are set then the third parameter will be calculated automatically.



- Interval (Hr:min) – time of single bolus dose with following interval time.
- Basal Rate (mL/h) – constant drug administration between boluses
- Volume (mL) – after 'Time limit' setting, volume will be calculated automatically. If 'Volume' parameter is set first then it will change its name into 'Volume limit'. When reached, infusion will be stopped.
- Time (Hr:min) – after 'Volume limit' setting, time will be calculated automatically. If 'Time' parameter is set first with 'Volume' parameter omission then it will change its name into 'Time limit'. When reached infusion will be stopped.



Additional parameters can be set before infusion start by pressing  button on the touchscreen or by pressing  button on the alphanumeric keyboard (see sections 11.1 and 11.2).

b) Infusion in units:

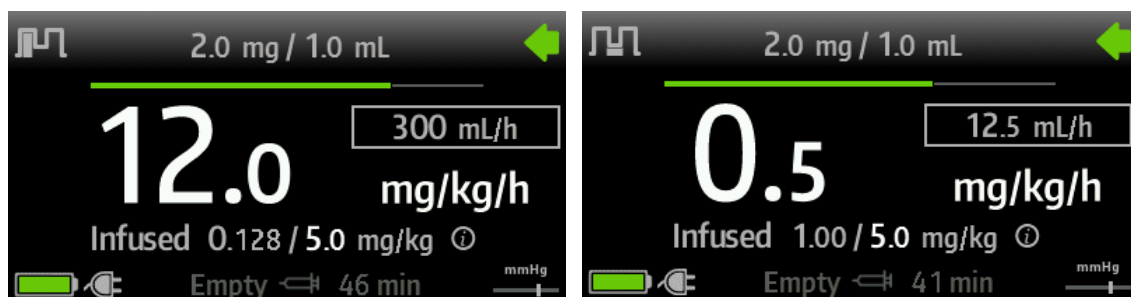
Choose any of predefined units tiles or create a new unit by choosing 'Others' tile. Following parameters are to be defined:



- Dilution - when  button is touched or  button is pressed then edition of Amount, Dilution volume and Concentration parameters must follow. If two of three available parameters are set then the third one will be calculated automatically.
- Weight (kg) or Surface (m<sup>2</sup>) – input patient weight or surface depending on the chosen unit.
- Bolus Dose.
- Bolus Time (min:sec) – time during which bolus dose is administered.
- Bolus Rate – rate of bolus administration.

If two of three available parameters of Bolus dose, Bolus time, Bolus rate are set then the third parameter will be calculated automatically.

- Interval (Hr:min) - time of single bolus dose with following interval time.
- Basal Rate – constant drug administration between boluses.
- Dose - after 'Time limit' setting, dose will be calculated automatically. If 'Dose' parameter is set first then it will change its name into 'Dose limit'. When reached, infusion will be stopped.
- Time - after 'Dose limit' setting, time will be calculated automatically. If 'Time' parameter is set first with 'Dose' parameter omission then it will change its name into 'Time limit'. When reached infusion will be stopped.

If time and dose have not been defined then boluses (B) will be administered in the same time intervals (TI) until syringe becomes empty or max. 200h time infusion, being the pump limit, is reached.

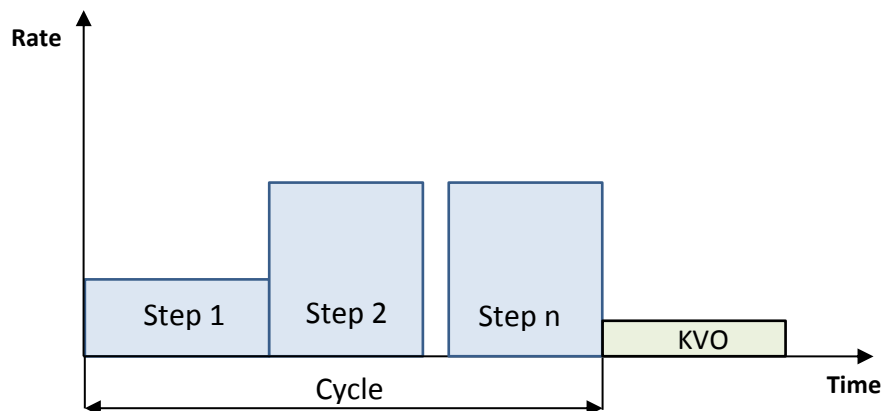


Additional parameters can be set before infusion start by pressing  button on the touchscreen or by pressing  button on the alphanumeric keyboard (see sections 11.1 and 11.2).






### 11.5.3 Profile infusion

Available in the following models:



KVO (optional)

 <p><b>Attention!</b></p>	<p>START/STOP  icon appearance in the upper right corner of display, indicates that the minimum required set of parameters have been entered in order to start infusion. Infusion can be started by pressing the START/STOP  icon from now on.</p>
---	--

In order to start profile infusion proceed as follows:



1. In 'Infusion mode' window choose 'Profile' infusion tile.
2. In 'Units' window specified unit for profile infusion must be chosen.
3. Profile infusion programming:


a) Infusion in mL/h:

Press mL/h tile. Following parameters are to be defined:

- Steps No. – max. 24 steps can be set.  
For each step at least two of three available parameters: Flow rate, Time and Volume must be set. The third parameter will be calculated automatically.
- Flow Rate (mL/h).
- Time (Hr:min).
- Volume (mL).
- Cycle Volume (mL) will be calculated automatically. 'Cycle volume' relates to summary volume of all steps volume parameters.



- Cycle Time (Hr:min) will be calculated automatically. 'Cycle time' relates to summary time of all steps time parameters.
- Cycles No. – if 'Cycle number' is set  $\geq 1$  then 'Volume limit' and 'Time limit' will be calculated automatically. 'Volume limit' will equal 'Cycle volume' multiplied by 'Cycles No.' while 'Time limit' will equal 'Cycle time' multiplied by 'Cycles No.'.
- Volume Limit (Vol.Limit) (mL) - summary volume of particular steps volume multiplied by the number of cycles.
- Time Limit (Hr:min) - summary time of particular steps times multiplied by the number of cycles.

Additional parameters can be set before infusion start by pressing  button on the touchscreen or by pressing  button on the alphanumeric keyboard (see section 11.1 and 11.2).

 <b>Attention!</b>	<p>If 'Cycle No.' counts 0 (null) then defined steps will be repeated as long as the syringe becomes empty or pumps limits will be reached.</p>
--	---

b) Infusion in units or in any other unit configured in 'Others' tile.



Following parameters are to be defined:

- Dilution - when  **Change** button or  button pressed then edition of Amount, Dilution volume and Concentration parameters must follow. If two of three available parameters are set then the third one will be calculated automatically.
- Weight (kg) or Surface (m<sup>2</sup>) – input patient weight or surface depending on the unit chosen.
- Steps No. – max. 24 steps can be set.
- Dose Rate.
- Time (Hr:min).
- Dose.

For each step at least two of three available parameters: Dose rate, Time and Dose must be set. The third parameter will be calculated automatically.

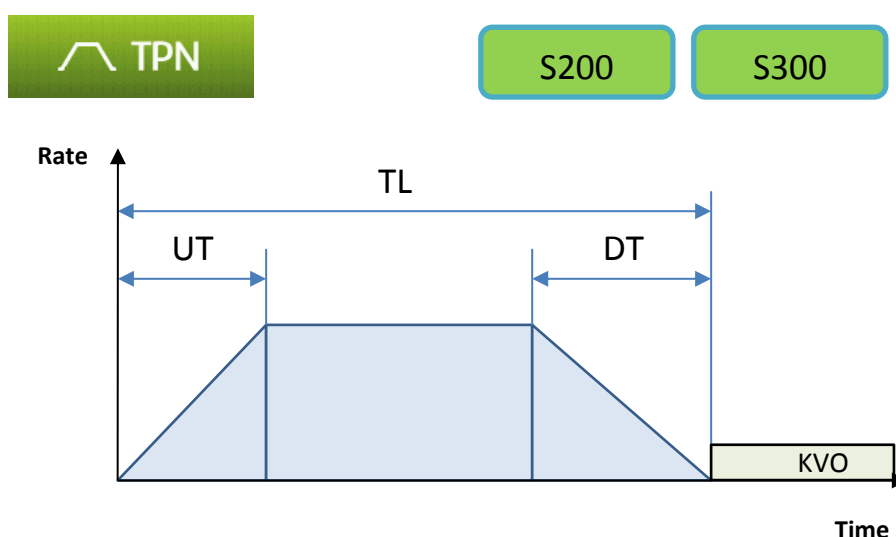
- Cycle Dose will be calculated automatically. 'Cycle dose' relates to summary dose of all steps doses parameters.
- Cycle Time (Hr:min) will be calculated automatically. 'Cycle time' relates to summary time of all steps time parameters.

- Cycles No. – this parameter indicates how many times all steps will be repeated. Its defining results in automatic calculation of ‘Dose limit’ and ‘Time limit’.
- Dose Limit – summary dose of particular steps doses multiplied by the number of cycles.
- Time Limit– summary time of particular steps times multiplied by the number of cycles.

Additional parameters can be set before infusion start by pressing  button on the touchscreen or by pressing  button on the alphanumeric keyboard (see section 11.1 and 11.2).

#### 11.5.4 TPN infusion (Total Parenteral Nutrition)



Available in the following models:



Time Limit (TL)	Complete infusion time
Up Time (UT)	Time of rate Increase
Down Time (DT)	Time of rate decrease
KVO	(optional)





**Attention!**

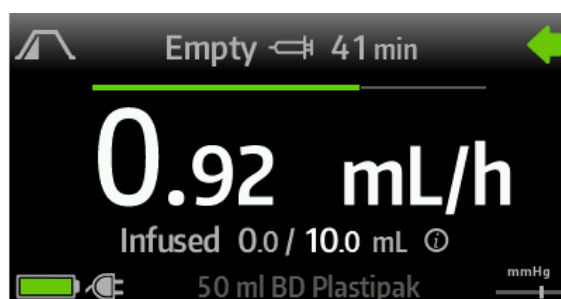
START/STOP  icon appearance in the upper right corner of display, indicates that the minimum required set of parameters have been entered in order to start infusion. Infusion can be started by pressing the START/STOP  icon from now on.



In order to start TPN infusion proceed as follows:

1. In ‘Infusion mode’ window choose ‘TPN’ infusion tile.
2. In ‘Units’ window specified unit for TPN infusion should be chosen.
3. TPN infusion programming:




a) Infusion in mL/h. Following parameters are to be defined:


- Volume (mL) – if 'Volume' parameter is entered first before 'Time' parameter then its name will change into 'Volume limit'.
- Time (Hr:min) – if 'Time' parameter is entered first before 'Volume' parameter then its name will change into 'Time limit'.
-  Increase Time (Hr:min) – indicates time during which infusion rate will increase until the Constant rate value is reached.
-  Decrease Time (Hr:min) – indicates time during which infusion rate will decrease from Constant rate value to zero.
- Constant Rate (ConstRate) (mL/h) will be calculated automatically after all parameters input or as a result of relation with other two parameters: volume and time.

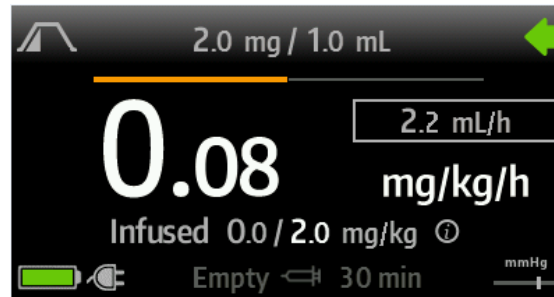




Additional parameters can be set before infusion start by pressing  button on the touchscreen or by pressing  button on the alphanumeric keyboard (see sections 11.1 and 11.2).

b) Infusion in units. Following parameters are to be defined:

- Dilution - when  button or  button is pressed then edition of Amount, Dilution volume and Concentration parameters must follow. If two of three available parameters are set then the third one will be calculated automatically.
- Weight (kg) or Surface (m<sup>2</sup>) – input patient weight or surface depending on the chosen unit.
- Dose - if 'Dose' parameter is entered first before 'Time' parameter then its name will change into 'Dose limit'.
- Time (Hr:min) - if 'Time' parameter is entered first before 'Dose' parameter then its name will change into 'Time limit'.
-  Increase Time (Hr:min) - indicates time during which infusion rate will increase until the Constant rate value is reached.

-  Decrease Time (Hr:min) - indicates time during which infusion rate will decrease from Constant rate value to zero.
- Constant Rate (ConstRate) will be calculated automatically after all parameters input or as a result of relation with other two parameters: dose and time.

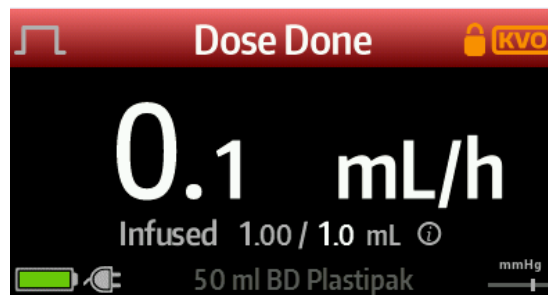


Additional parameters can be set before infusion start by pressing  button on the touchscreen or by pressing  button on the alphanumeric keyboard (see sections 11.1 and 11.2).

## 11.6 KVO

KVO (Keep Vein Open) indicates the rate value of a drug administration allowing to keep open flow in the patient's line. KVO administration starts when infusion ends.

Active KVO is indicated in the upper right corner of display by a blinking KVO icon.



- KVO is active until syringe is removed.
- KVO parameters are defined in the Medima Configurator software.
- KVO Rate parameter available in the Dose Done tile (see section 11.1.3) allows for defined KVO rate confirmation or change within the limits set in the Medima Drug Editor or Medima Configurator software.



When the infusion rate is lower than KVO then KVO will be infused at the rate of infusion.

## 12 CONFIGURATION SETTINGS, BASIC PUMP DATA

Syringe pumps by Medima can be characterized by very advanced configuration capabilities which allow to adjust their work to individual requirements of particular wards (CCAs). The most important of them are:

- Default settings of parameters and functions,
- Infusion parameters permissible range,
- Alarm options,
- Some programming options availability,
- Additional functions activation,
- Touchscreen and alphanumeric keyboard options.


Standard configuration settings of syringe pumps by Medima can differ depending on regional requirements. Contact with your Medima representative in order to decide on pump configuration details.

The Medima Configurator software is used for pump configuration. Some of the pumps settings can be overwritten by data taken from the drug library created in the Medima Drug Editor software (relates to the S300 model only). This option allows for creation of individual pump settings for the individual needs of every CCA.

### 12.1 Available configuration options

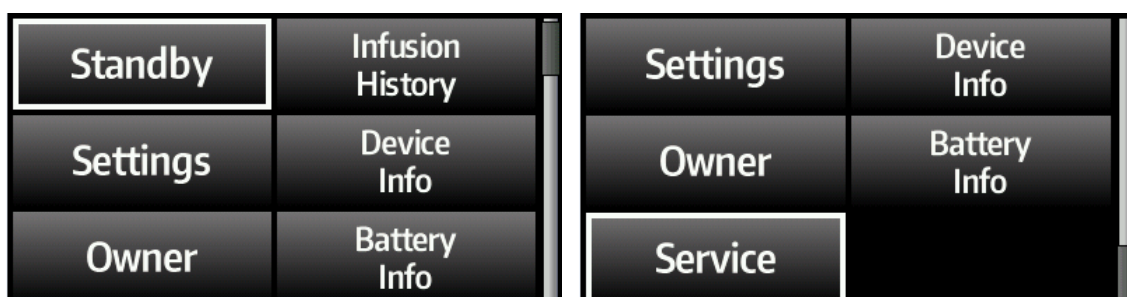
When the turned OFF pump is connected to the external power supply, then its display looks as follows.



Beginning this level of use, moving to options menu is possible by pressing  button on the alphanumeric keyboard. Functions as follows will be displayed:

- Standby – reminder of a stopped infusion or a planned user activity. Time is counted down to null and after its finish 'End of Standby' alarm will be activated.
- Infusion History – allows reading information about all infusions conducted so far by the pump (min. 2000 records of typical infusions).
- Settings – enables date, time, backlight brightness, touchscreen ON/OFF parameters setting and alarms volume.

- Device Info – provides identification information about the pump: model/serial number/production date data, software ID, drug library, configuration ID and license.
- Owner – data about a proprietor of the pump. Name of the hospital or a ward (CCA) for example.
- Battery Info – provides information about percentage value of the battery charge (status), time to full battery discharge (empty in), time needed for the full battery charge (full in) and displays list of active battery reminders (see section 14).
- Service – details about an authorised service: Contact, Maintenance date, Maintenance.



## 12.2 Settings



### Attention!




Date and time parameters setting should be done first before the pump use. It provides accuracy of recorded data interpretation relating to conducted infusions and alarms.

‘Settings’ function allows for following parameters modification:

- Date – setting of the date,
- Time – setting of the time,
- Display Brightness – pump display brightness can be set in one of five available levels. Full range of regulation is available in the Medima Configurator software,
- Touchscreen – allows for ON/OFF touchscreen option,
- Alarms Volume – enables daytime and nighttime alarms volume setting in range between 1 and 9.

## 12.3 Infusion history

The pump stores history of all user activities and conducted infusions.

In order to navigate between particular logs  and  buttons are used. Infusion choice is made by  button.



**Attention!**

History of min. 2000 typical infusions records can be stored in the memory of the pump. When the pump's memory becomes full, the pump starts to overwrite the oldest recordings.

Each event consists of date and time and additional parameters related with recording. Following data is stored:

- Infusion parameters,
- Syringe installation and release,
- Infusion START/STOP,
- Bolus administration start, stop and finish,
- Every parameter change during infusion,
- All alarms with their confirmation inclusion,
- Exceeding of values limits of infusion parameters.

## 13 USER NOTIFICATION AND ALARM SYSTEM

### 13.1 Ways of notification and alarm signalling

S100, S200, S300 pumps have been equipped with advanced user notification system informing about conditions requiring intervention. Alarm system consists three levels of defined notification priorities depending on the status of patient's risk.



**Attention!**

High level alarms always stop infusion.

The pump signals alarm condition occurrence by displaying a message and generating an acoustic notification. Alarms priority has been described in the table below.


Alarm confirmation is done by pressing  button on the alphanumeric keyboard.

Alarm level	Acoustic notification	Optical notification
High	10 tone melody repeated in 3 - 9 s time intervals (depending on dosed drug priority – S300).	Alarm's message displayed on a blinking black and red background.
Medium	3 tone melody repeated in 9 - 15 s time intervals (depending on dosed drug priority – S300).	Alarm's message displayed on a blinking black and orange background.
Low	3 tone melody repeated in 15 - 30s time intervals (depending on dosed drug priority- S300).	Alarm's message displayed on a constant orange background.



## 13.2 Reminders and warnings

Reminders appear only for some alarms. They are notified by the pump's status light indicator blinking in yellow in about every 2 seconds as well as generating a short acoustic signal repeated in every 15 seconds.

List of active reminders is displayed when an alarm confirmation button  has been pressed. Some very important reminders are displayed on red background during infusion in the title bar of the infusion window.

## 13.3 Alarm volume level

Volume level adjustment is not available on the pump. It can only be adjusted in the Medima Configurator software.



Attention!

It is recommended to adjust volume of acoustic notification according to application conditions. Too low volume setting could result in omission of possible dangerous patient health or life condition.

## 13.4 Alarm call system


Pump is equipped with interface enabling connection to hospital's ward call system. For proper connection, it is recommended to use CAL-01 cable (see section 24).

Notification to hospital ward call system is generated in time less than 1s starting from activation of alarm.



Attention!

By no means pump does not detect disability of connection to hospital ward call system and does not guarantee credibility of alarm's information transmission.

Connection can be checked by activating the test alarm by pressing and holding  button for at least 5 seconds (until test alarm is induced). For socket pin description see section 17.1.

## 13.5 List of alarms and reminders displayed by the pump

### 13.5.1 High importance alarms

Message	Possible alarm activation conditions	Recommended counteractions	Configuration*
Autoinfusion	<p>It may occur when:</p> <ul style="list-style-type: none"><li>▪ High underpressure in the patient's line,</li><li>▪ syringe is pulled out from the pump,</li><li>▪ plunger grippers did not manage to grasp the</li></ul>	Check syringe mounting and the extension line.	

Message	Possible alarm activation conditions	Recommended counteractions	Configuration*
	syringe plunger properly during syringe installation.		
Rapid Pressure Drop	Patient's line disconnection or damage.	Check the patient's line.	Yes
Dose Done	Programmed dose has been administered.	New infusion setting or turning off the pump.	Yes
Occlusion	<ul style="list-style-type: none"> <li>Pressure increase in the patient's line over defined level of occlusion.</li> <li>Patient's line, vein or needle clogging.</li> </ul>	<ul style="list-style-type: none"> <li>Check the patient's line and occlusion reason removal.</li> <li>Occlusion level change onto higher level (if it is safe for a patient)</li> </ul>	Yes
KVO End	KVO administration has ended.	New infusion setting or turning off the pump.	Yes
Infusion too long	Alarm occurs when: <ul style="list-style-type: none"> <li>summary infusion time exceeds 200h.</li> <li>summary dose volume exceeds 20L.</li> <li>number of logs recorded during infusion has exceeded 64000.</li> </ul>	New infusion setting or turning off the pump.	
Check syringe	<ul style="list-style-type: none"> <li>Misload buttons detecting syringe position have not been properly pressed.</li> <li>Syringe size change has been detected after its acceptance.</li> </ul>	Correction of syringe position in the pump or syringe reinstallation.	
No syringe	Syringe has not been installed in the pump while infusion has already been programmed.	Syringe installation or turning off the pump.	
Empty syringe	Alarm occurs when: <ul style="list-style-type: none"> <li>defined minimum fluid volume in syringe has been reached in a syringe (different depending on the syringe size)</li> <li>syringe has been completely depleted .</li> </ul>	Syringe installation or turning off the pump.	
Battery empty	Complete battery discharge. If external power supply is not restored then after 3 minutes alarm and pump will turn off.	<ul style="list-style-type: none"> <li>Connection of external charge source.</li> <li>Full battery discharge is recommended.</li> </ul>	
External reset	External reset condition has occurred.	If alarm repeats itself then contact with service	
Unexpected reset	Unexpected software reset has occurred.	If alarm repeats itself then contact with service.	

\* parameters which can be set in terms of value or occurrence in configuration settings. The Medima Configurator software enables to change configurational pump settings.

### 13.5.2 Medium importance alarms

Message	Possible alarm activation conditions	Recommended counteractions	Configuration*
HIGH pressure	Beginning of occlusion. Pressure has exceeded pre-alarm occlusion parameter (percent occlusion value set in the Medima Configurator).	<ul style="list-style-type: none"> <li>Check the patient's line</li> <li>Occlusion level change onto higher one (if it is safe for a patient).</li> </ul>	Yes
Pressure in line	Beginning of occlusion. Fluid flow decrease caused by patient's line kink or clogging.	<ul style="list-style-type: none"> <li>Check the patient's line</li> <li>Occlusion level change onto higher one (if it is safe for a patient).</li> </ul>	
(Time) to Dose Done	<ul style="list-style-type: none"> <li>Programmed dose is getting close (displayed time is counted to syringe depletion).</li> <li>Time of pre-alarm setting can be configured in the Medima Configurator software in range of 0 – 30min.</li> </ul>	If therapy is to be continued then new infusion start.	Yes
(Time) to empty syringe	<ul style="list-style-type: none"> <li>Syringe depletion is getting close (displayed time is counted to syringe depletion).</li> <li>Time of pre-alarm setting can be configured in the Medima Configurator software in range of 0 – 30min.</li> </ul>	If therapy is to be continued then new infusion start.	Yes
Battery low	Battery charge level has fallen under 15% with no external power supply connected.	External power supply connection. If message of 'Battery low' continues in form of a reminder then contact with service.	
No mains	Pump external power supply source has been disconnected or turned off.	Check external power supply source. If external power supply has been connected but alarm repeats itself then contact with service.	
Infusion wait time exceeded	Infusion wait time set in the Medima Configurator has been exceeded.	Syringe must be removed from the pump.	Yes
Incorrect fixing in docking station	Incorrect pump installation in the docking station.	Correction of the pump installation in the docking station or pump reinstallation in the docking station.	

\* parameters which can be set in terms of value or occurrence in configuration settings. The Medima Configurator software enables to change pump configurational settings.

### 13.5.3 Low importance alarms

Message	Possible alarm activation conditions	Recommended counteractions	Configuration*
No user activity	It occurs in every 2 minutes when turned-on pump is left without user activity. .	<ul style="list-style-type: none"> <li>▪ Infusion start,</li> <li>▪ Standby function start</li> <li>▪ Turn off the pump</li> </ul>	
Drug not active	Drug's activity has expired.	<ul style="list-style-type: none"> <li>▪ Syringe with a new drug should be installed.</li> <li>▪ Alarm will be automatically erased when syringe is released from the pump.</li> </ul>	Yes
End of standby	Time of standby has passed.	Infusion restart.	Yes
Supply voltage too low	Connected external power source does now allow the pump to work properly (pump partly uses battery).	<ul style="list-style-type: none"> <li>▪ Check parameters of external power supply.</li> <li>▪ If alarm repeats itself then contact with service.</li> </ul>	

\* parameters which can be set in terms of value or occurrence in configuration settings. The Medima Configurator software enables to change pump configurational settings.

### 13.5.4 Reminders

Message	Possible alarm activation conditions	Recommended counteractions	Title line notification**
Pressure in line	Pressure in patient's line has exceeded defined percent occlusion level in the Medima Configurator software.	<ul style="list-style-type: none"> <li>▪ Removal of occlusion reason in the patient's line.</li> <li>▪ Disconnect patient's line.</li> <li>▪ Occlusion level change onto higher one (if it is safe for a patient).</li> </ul>	
Near to empty syringe	Pump reminds about the incoming syringe depletion.	New syringe preparation or turning off the pump.	Yes
Near to Dose Done	Infusion end is close.	Prepare for next infusion or turning OFF the pump.	Yes
Dose done	Programmed dose has been administered.	New infusion start or turning off the pump.	Yes
KVO End	It takes place when KVO administration ends.	New infusion can be started or pump can be turned off.	Yes
Drug not active	More time has passed since syringe installation in the pump than defined drug activity time.	<ul style="list-style-type: none"> <li>▪ Infusion finish.</li> <li>▪ New syringe installation</li> <li>▪ Turning off the pump.</li> </ul>	Yes
Supply voltage too low	Connected external power source supplies too little energy. Pump partly uses battery.	<p>External power supply connection.</p> <p>If reminder still repeats itself then contact with service.</p>	


Message	Possible alarm activation conditions	Recommended counteractions	Title line notification**
No mains	No external power supply. Pump works from the battery.	External power supply connection.  If alarm repeats itself despite external power supply connection then contact with service.  Pump can be used.	
Battery low	No external power supply connected.  Battery charge level below 15%.	External power supply connection.	Yes
Battery empty	Battery is close to full discharge.  In time shorter than 3 minutes pump will turn off.  No external power supply is connected.	External power supply connection.  Reminder will turn itself off when battery charge level exceeds 5%.  Pump change for infusion.	Yes
Battery test recommended	Unknown battery status after exchange.  Recommended battery test time has passed.	Start the battery test.  Pump can be used for infusion but infusion break risk when external power supply disconnected exists.	
Battery test	Battery test is taking place.  Time to test finish is displayed.	It is not allowed to disconnect the pump from external power supply source.	Yes
Battery fault	Reminder is generated when following reasons have occurred: <ul style="list-style-type: none"> <li>▪ battery cable disconnection or its damage,</li> <li>▪ battery controller damage,</li> <li>▪ acceptable battery temperature has been exceeded (overheat).</li> </ul>	Contact with service.  Infusion can be started but pump can be supplied only from external power supply source.	Yes
Battery replacement recommended	Battery damaged or used.	Contact with Service.  Battery must be replaced for a new one.  Infusion is allowed to be started. Pump can work based upon battery in limited range.	
Disconnect mains!	Pump damage.  Displayed malfunction number informs about the damage type.	External power supply must be disconnected from the pump at once!  Contact with Service.  <b>Pump cannot be used.</b>	

Message	Possible alarm activation conditions	Recommended counteractions	Title line notification**
Disconnect battery!	Pump damage. Displayed malfunction number informs about the damage type.	Battery must be disconnected from the pump as soon as possible. Contact with service. <b>Pump cannot be used.</b>	
Date and time not set	Date and time not set.	Date and time must be set on the pump (see section 12.2). Infusion can be started.	
Service recommended	Service check overview period call is getting close or has passed.	Pump should be delivered to service for technical overview. Infusion can be started.	
Recommended repair	Pump displays an error number related with an internal technical problem.	Contact with service. Infusion can be started.	
Drug Library data corrupted	Installation of the drug library has failed.	Drug library must be uploaded again.	
User configuration corrupted	User configuration error has been detected.	Check if the pump's settings are correct. Infusion can be started.	

\*\* reminders display in the title line of the pump.

### 13.5.5 Malfunctions

In case the 'Malfunction XXX or Damage XXX' message is displayed the pump should be restarted (switched OFF and ON). If message is displayed again or displayed permanently, the pump should be examined by the qualified service staff.


In case of 'System Code XXX' alarm is displayed, it should be confirmed by the  button. If message is repeated then user should contact with technicians or service.


In case of any doubts contact with an authorized Medima representative or with the manufacturer directly.


The damaged device should be secured from possible accidental use.


## 14 INTERNAL BATTERY OPERATION

Built-in battery allows for infusion amid either of patient transport or external power supply malfunction.


Battery's charging starts automatically as soon as AC power supply is connected. Started infusion does not influence speed of battery charging from external power supply. Connection to the external power supply is indicated in the lower left corner of display by the plug  icon.

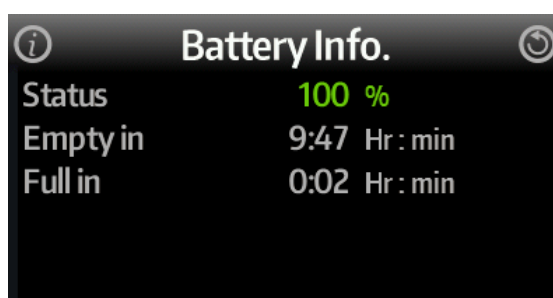
Battery status is displayed by a battery icon . The icon fill level is dependent on battery charge level. When battery charge level drops to 30% then the battery icon will be illuminated in orange colour. When it drops to 20% then the battery icon will change into red.

If displayed battery icon is blinking  after 1 minute time when mains power cord is connected check if battery has been connected. If problem continues, contact with local service representative or with manufacturer service directly.

Battery charge status can be checked by touching the battery icon  on the touchscreen as well as by opening the window of 'Battery info.' (see section 11.2.10).

'Battery info.' window displays following parameters:

- Status – percentage value of battery charge level (%). Its illumination colour can be green, orange or red depending on the charge level status, the same way as the battery icon does,
- Empty in – time to full battery discharge (Hr : min),
- Full in – time to full battery charge (Hr : min),
- List of battery active reminders also available by pressing alarm confirmation button  on the pump (see section 13.2 and 13.5.4).



When time passes capacity of the battery can lead to degradation. The more it discharges the fastest it degrades.

It is recommended to test battery status in every 3 months after the first year of use. When the capacity of battery drops below 70%, it is recommended to replace it for a new one. In case when pump is often used in medical transport it is recommended to carry out tests in every month after 6 months of use. Failure to follow these recommendations may result in unexpected stop of the pump work which may lead to health or life loss risk.

Effective lifetime of the battery equals 300 charging cycles. Quick degradation of the battery is expected after this time.

Due to configurational issues, exchange of the battery for a new one, can be made only by trained technical personnel.

For keeping optimal battery life, it is recommended to remember about periodic full discharge and charge cycles.

## 15 LIST OF SYRINGES

In attached table, list of tested and accepted syringes, which can be used with S100, S200, S300 pumps have been added. All these syringes are the three-part syringes (with a rubber plunger tip or a rubber ring around it) ended with Luer Lock or ENFit connector.

No.	Syringe volume [ml]	Syringe model
1	2	B.Braun Omnifix
2	2	Ecoject Plus
3	2	KD-JECT III
4	2	Soft-Ject
5	2.5	Terumo
6	3	B.Braun Omnifix
7	3	BD Plastipak
8	3	Codan Enteral
9	3	KD-JECT III
10	3	Monoject
11	3	Soft-Ject
12	5	Aryan
13	5	Ayset
14	5	B.Braun Enteral
15	5	B.Braun Omnifix
16	5	BD Plastipak
17	5	Codan
18	5	Codan Enteral
19	5	Ecoject Plus
20	5	Hayat
21	5	Ilam
22	5	KD-JECT III
23	5	Medset
24	5	Set Inject
25	5	Soft-Ject
26	5	Terumo
27	5	Vygon Nutrifit



No.	Syringe volume [ml]	Syringe model
28	6	NeoMed
29	10	Ayset
30	10	B.Braun Omnifix
31	10	BD Plastipak
32	10	Codan
33	10	Codan Enteral
34	10	Dash 3
35	10	Ecoject Plus
36	10	Hayat
37	10	Ilam
38	10	KD-JECT III
39	10	Medset
40	10	Set Inject
41	10	Soft-Ject
42	10	Soha
43	10	Terumo
44	10	Vygon Nutrifit
45	12	Monoject
46	12	NeoMed
47	20	Ayset
48	20	B.Braun Enteral
49	20	B.Braun Omnifix
50	20	B.Braun Perfusor
51	20	BD Plastipak
52	20	Codan
53	20	Codan Enteral
54	20	Ecoject Plus
55	20	Hayat
56	20	KD-JECT III
57	20	MEDICA
58	20	MEDICA M-JECT
59	20	Medset
60	20	Monoject
61	20	NeoMed
62	20	Polfa Lublin

No.	Syringe volume [ml]	Syringe model
63	20	Set Inject
64	20	Soft-Ject
65	20	Terumo
66	20	Vygon Nutrifit
67	20	Yazd
68	30	B.Braun Omnifix
69	30	BD Plastipak
70	30	Codan
71	30	Infuject
72	30	KD-JECT III
73	30	Monoject
74	30	Soft-Ject
75	30	Terumo
76	35	NeoMed
77	50	Ayset
78	50	B.Braun Enteral
79	50	B.Braun Omnifix
80	50	B.Braun Perfusor
81	50	BD Perfusion
82	50	BD Plastipak
83	50	Codan
84	50	Diprivan
85	50	Euromed
86	50	Exelmed F.Inject.
87	50	Exelmed Omnifix
88	50	Exelmed Perfusion
89	50	Exelmed Plastipak
90	50	Exelmed Terumo
91	50	Fres Injectomat
92	50	Hayat
93	50	Infuject
94	50	Janpol
95	50	Jiangsu
96	50	KD-JECT III
97	50	Khazar

No.	Syringe volume [ml]	Syringe model
98	50	MEDICA M-JECT
99	50	Margomed
100	50	Medset
101	50	Perfuject
102	50	Polfa Lublin
103	50	Set Inject
104	50	ShanChuan
105	50	Soft-Ject
106	50	Soft-Ject Perf.
107	50	Terumo
108	50	V.Med
109	60	BD
110	60	Codan Enteral
111	60	Dash 3
112	60	Enteral ISOsaf
113	60	Monoject
114	60	NeoMed
115	60	Vygon Nutrifit


## 16 LONGER INTERRUPTIONS IN PUMP OPERATION

In case of expected, longer stops in pump operation, it is recommended to:

- clean and disinfect the pump,
- fully charge the battery,
- charge the battery in regular periods of 3 months by connecting the pump to the external power supply or leave it permanently connected to the external power supply.

## 17 COMMUNICATION INTERFACES

### 17.1 ALARM SOCKET

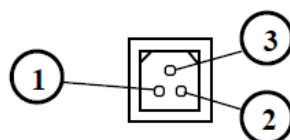
Alarm socket is used to connect the pump to the hospital ward call system. It is recommended to use the original CAL-01 nurse call cord. It is possible to check the connection quality by pressing and holding the alarm confirmation  button until the test alarm occurs.

Socket Pin	Description
<b>6/7 COMM</b>	Common output
<b>2/3 NO</b>	Output normally open with COMM and closed during alarm
<b>4/5 NC</b>	Output normally closed with COMM and open during alarm

## 17.2 DC POWER SOCKET

The DC socket allows to provide DC power supply when used in ambulances for example. The proper connection is signalled the same way as mains power connection.

	Description
<b>1</b>	$\pm$ DC
<b>2</b>	$\pm$ DC
<b>3</b>	Not Connected




It is recommended to use the original CDC-01 power supply cord.

## 17.3 RS232C INTERFACE

Pumps are equipped with RS232C interface, which enables to:

- upload drug library from the Medima Drug Editor (not a standard delivery enclosure),
- upload pump configuration parameters,
- upgrade software of the pump.

Pumps are equipped with RS232C optical connection , which enables to connect the pumps to MedimaNet software by docking stations of Medima.

 <b>Attention!</b>	<p>Devices used for digital data transfer/receipt can be connected to pumps only by trained personnel. The devices must meet EN60950 standard requirements.</p> <p>If the pump is in direct contact with the patient then it can be connected to a PC only with a RS232C cable with an opto-isolation barrier.</p>
--	--

## 18 INFUSION ACCURACY

### 18.1 Start-up and trumpet curves

In syringe pumps, errors in flow rate may occur as the result of the interaction of syringe and the mechanism of the pump. Knowledge of these errors may be important for the proper selection of infusion parameters for particular drugs, their dilutions and absorption time in the patient's body.

According to EN60601-2-24 norm, start-up and trumpet curves are used to present errors in infusion. They are shown on the below graphs.

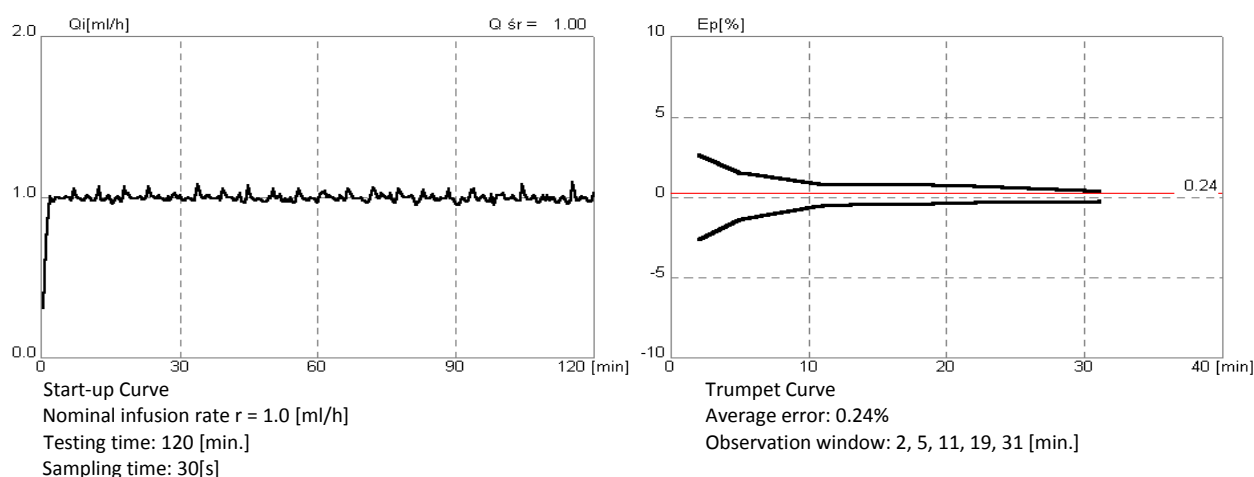
Start-up curve presents infusion course at the initial stage, just after its start. Delay in delivery is caused by many factors. To reduce it, one should use considerably diluted drugs and higher infusion rates.

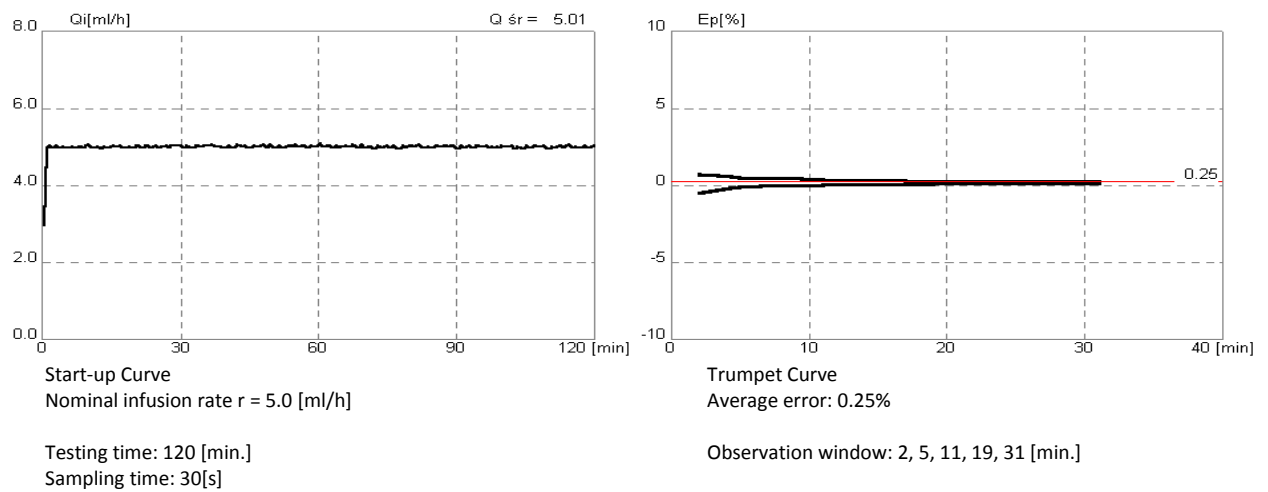
Trumpet curve named for its characteristic shape, displays the effect of discrete flow errors over infusion time. Flow rate instability observed over long time is less important than instability over short time; this trend is reflected by trumpet curve diagrams. Over a long time, the infusion error asymptotically nears to average value.

The diagrams show the expected size of transient infusion errors (instabilities), depending on the drug half-life and flow rate. **The conclusion is that drugs with short half time, or instances when flow uniformity is a critical parameter, should be infused when considerably diluted and at a higher flow rate.**

Charts presented below are only for general information purpose.

Measurements carried out for BD PLASTIPAK 50 ml syringe.





## 18.2 Occlusion – reaction time and occlusion bolus

Reaction time of the pump to occlusion depends on many factors:

- pressure level setting- the lower it is, the sooner occlusion will be detected in the patient's line,
- flow rate - the higher it is, the sooner occlusion alarm will be activated,
- patient's line elasticity - the thicker it is, the sooner the occlusion alarm will be activated,
- patient's line length – the longer it is, the longer reaction time to occlusion.

When occlusion occurs, some fluid will be accumulated due to extension capabilities of the patient's line. The higher the pressure level is set in the pump, the thinner the patient's line is, and the longer the patient's line is - the more fluid will be accumulated.

Pressure level	Time left to alarm at 1 ml/h	Time left to alarm at 5 ml/h
1	3 min 10 sec.	35 sec.
6	39 min.	5 min 20 sec.
11	67 min.	11 min 10 sec.

These measurements were taken for BD PLASTIPAK 50 ml and 2 m long patient's line.

## 19 TECHNICAL DATA

Flow Rate	<p>0.01 – 2000 ml/h for 50 ml syringe  0.01 – 1400 ml/h for 30 ml syringe  0.01 – 1000 ml/h for 20 ml syringe  0.01 – 600 ml/h for 10 ml syringe  0.01 – 400 ml/h for 5 ml syringe  0.01 – 200 ml/h for 2 ml syringe</p> <p>Increments:</p> <ul style="list-style-type: none"> <li>0.01 ml/h from 0.1 ml/h to 99.99 ml/h</li> <li>0.1 ml/h from 100ml/h to 999.9 ml/h</li> <li>1 ml/h from 1000 ml/h</li> </ul>
Infusion volume	<p>0.1 – 20 000 ml</p> <p>Increments:</p> <ul style="list-style-type: none"> <li>0.01 ml for dose from 0.1 ml to 999.99 ml</li> <li>0.1ml for dose from 1000 ml to 20000 ml</li> </ul>
Infusion Time	1 min – 200 hours
Bolus	<p>Automatic and manual bolus.</p> <p>Rate:</p> <ul style="list-style-type: none"> <li>max.: 2000 ml/h (depending on the syringe volume).</li> </ul> <p>Increments:</p> <ul style="list-style-type: none"> <li>0.01 ml/h from 0.1 ml/h to 99.99 ml/h.</li> <li>0.1 ml/h from 100ml/h to 999.9 ml/h.</li> <li>1 ml/h above 1000 ml/h.</li> </ul> <p>Bolus volume:</p> <ul style="list-style-type: none"> <li>0.1 - 50 ml (depending on syringe volume).</li> </ul> <p>Increments:</p> <ul style="list-style-type: none"> <li>0.01 ml from 0.1 ml up to syringe volume.</li> </ul> <p>Programmable volume (dose) and time or flow rate.</p>
KVO (KOR)	<p>0.1 – 5.0 ml/h, but not higher than the flow rate.</p> <p>Increments:</p> <ul style="list-style-type: none"> <li>0.1 ml/h</li> </ul> <p>If KVO is limited by the infusion flow rate then the increment of display is 0.01 ml/h.</p>

Priming	<p>Rate:</p> <ul style="list-style-type: none"><li>▪ programmable: 500 – 2000 ml/h.</li><li>▪ default: 1000 ml/h (the line priming rate depends on programmed syringe volume and cannot be bigger than the maximum possible flow rate for a specific syringe type).</li></ul> <p>Volume:</p> <p>max. 5 ml; pressure alarms are active during priming.</p>																																																																																			
Occlusion pressure levels	<ul style="list-style-type: none"><li>▪ 12 levels: 10 - 120 kPa (75 - 900 mmHg, 0.1 – 1.2 bar, 0.1 – 1.2 kG/cm<sup>2</sup>, 1.5 – 17 PSI).</li></ul> <p>Pressure measurement accuracy:</p> <ul style="list-style-type: none"><li>▪ ±15%, but not lower than 10 kPa (75 mmHg, 0.1 bar, 0.1 kG/cm<sup>2</sup>, 1.5 PSI).</li></ul> <table><tr><th rowspan="2">Occlusion level</th><th colspan="5">Occlusion pressure</th></tr><tr><th>bar</th><th>kG/cm<sup>2</sup></th><th>kPa</th><th>mmHg</th><th>PSI</th></tr><tr><td>1</td><td>0.1</td><td>0.1</td><td>10</td><td>75</td><td>1.5</td></tr><tr><td>2</td><td>0.2</td><td>0.2</td><td>20</td><td>150</td><td>2.9</td></tr><tr><td>3</td><td>0.3</td><td>0.3</td><td>30</td><td>230</td><td>4.3</td></tr><tr><td>4</td><td>0.4</td><td>0.4</td><td>40</td><td>300</td><td>5.8</td></tr><tr><td>5</td><td>0.5</td><td>0.5</td><td>50</td><td>380</td><td>7.2</td></tr><tr><td>6</td><td>0.6</td><td>0.6</td><td>60</td><td>450</td><td>8.7</td></tr><tr><td>7</td><td>0.7</td><td>0.7</td><td>70</td><td>530</td><td>10</td></tr><tr><td>8</td><td>0.8</td><td>0.8</td><td>80</td><td>600</td><td>12</td></tr><tr><td>9</td><td>0.9</td><td>0.9</td><td>90</td><td>680</td><td>13</td></tr><tr><td>10</td><td>1</td><td>1</td><td>100</td><td>750</td><td>15</td></tr><tr><td>11</td><td>1.1</td><td>1.1</td><td>110</td><td>830</td><td>16</td></tr><tr><td>12</td><td>1.2</td><td>1.2</td><td>120</td><td>900</td><td>17</td></tr></table> <p>Automatic reduction of occlusion bolus.</p> <p>Graphic presentation of infusion pressure and the set level (pictograms).</p>	Occlusion level	Occlusion pressure					bar	kG/cm <sup>2</sup>	kPa	mmHg	PSI	1	0.1	0.1	10	75	1.5	2	0.2	0.2	20	150	2.9	3	0.3	0.3	30	230	4.3	4	0.4	0.4	40	300	5.8	5	0.5	0.5	50	380	7.2	6	0.6	0.6	60	450	8.7	7	0.7	0.7	70	530	10	8	0.8	0.8	80	600	12	9	0.9	0.9	90	680	13	10	1	1	100	750	15	11	1.1	1.1	110	830	16	12	1.2	1.2	120	900	17
Occlusion level	Occlusion pressure																																																																																			
	bar	kG/cm <sup>2</sup>	kPa	mmHg	PSI																																																																															
1	0.1	0.1	10	75	1.5																																																																															
2	0.2	0.2	20	150	2.9																																																																															
3	0.3	0.3	30	230	4.3																																																																															
4	0.4	0.4	40	300	5.8																																																																															
5	0.5	0.5	50	380	7.2																																																																															
6	0.6	0.6	60	450	8.7																																																																															
7	0.7	0.7	70	530	10																																																																															
8	0.8	0.8	80	600	12																																																																															
9	0.9	0.9	90	680	13																																																																															
10	1	1	100	750	15																																																																															
11	1.1	1.1	110	830	16																																																																															
12	1.2	1.2	120	900	17																																																																															
Pre-alarm time	Programmable: 1 – 30 min or not set (pre-alarm blockade).																																																																																			
Flow rate accuracy according to EN60601-2-24	<ul style="list-style-type: none"><li>▪ Technical accuracy: ± 0.1 %.</li><li>▪ Total infusion accuracy taking a syringe into account: ± 2%.</li><li>▪ Flow rate accuracy depends on the syringe quality.</li></ul>																																																																																			
Maximal volume infused during single malfunction	<ul style="list-style-type: none"><li>▪ 0.5 ml for flow rate 2000 ml/h.</li><li>▪ 0.2 ml for flow rate below 500 ml/h.</li><li>▪ 0.1 ml for flow rate below 100 ml/h.</li></ul>																																																																																			
Battery	<ul style="list-style-type: none"><li>▪ Ni-MH battery capacity: 2000 mAh.</li><li>▪ Working time: 30 hours @ 5 ml/h.</li><li>▪ Full recharge time: ≤ 5 hours.</li></ul>																																																																																			
Time of data storage in memory	Min. 5 years after power supply disconnection.																																																																																			
Fuse	T 0.5 A / 250 V AC.																																																																																			




Casing <ul style="list-style-type: none"> <li>Material</li> <li>Protection class</li> <li>Dimensions</li> </ul>	ABS PC.  IP22 – according to EN 60529.  364 x 115 x 165 (W x H x D) – excluding pole clamp.
Weight	2.2 kg – without cabling.
Event log capacity	Min. 2000 typical infusions.
Power supply <ul style="list-style-type: none"> <li>AC</li> <li>DC</li> </ul>	100 (–15%) - 240 (+10%) V AC, 50/60 Hz, max. 20VA. 12.4 - 15.5 V DC, max. 1A.
Communication ports	RS232, transmission rate 115kbit/s. Optical connector to communicate with docking station.
Classification	CF Type, defibrillation resistance, class II, IP22.
Operating conditions	+5°C ~ 40°C, humidity max. 90%.
Transport conditions	-20°C ~ 50°C, humidity max. 95%.
Complies with safety standards	EN 60601–1, EN 60601–1–2, EN 60601–1-8, EN 60601-2-24, EN 1789, MDD93/42/EEC–IIb
Drug library	<ul style="list-style-type: none"> <li>Up to 40 CCA (Clinical Care Area, administration units).</li> <li>Up to 40 categories in CCA (depending on distributed drugs).</li> <li>Up to 500 drugs in one CCA.</li> <li>Up to 5000 drug dosing procedures (protocols) relating to dosing in the whole library.</li> <li>Up to 10 fixed (predefined) and 1 variable (user defined) concentrations for each drug dosing procedure.</li> <li>Soft and hard limits, max. and min. limits for parameters which may influence the infusion's safety.</li> <li>Titration with soft and hard limits.</li> <li>Additional limits for CCA.</li> <li>Advisory notes concerning drug dosing procedures.</li> <li>Uniform procedures for syringe and volumetric pumps.</li> <li>Possibility of procedures marking for all specified types of the pumps (syringe, volumetric, PCA).</li> <li>Drug library upload to the pump is automatic by LAN network connection without infusion interruption (pumps must be connected to MedimaNet software).</li> </ul>

## 20 ELECTROMAGNETIC RESISTANCE

### 20.1 Manufacturer declaration

S100/S200/S300 pumps are suitable to be used in the electromagnetic resistance environment as specified below. Pump user should provide work environment conditions meeting the following conditions:

Resistance test	Parameters of standard IEC 60601-1-2 IEC 60601-2-24	Result	Comment
Conducted radio frequencies IEC 61000-4-6	3 Vrms 150 kHz-80MHz	3 Vrms	<p>Devices which emit radio frequency waves should remain away from S100/S200/S300 pumps and their connection cords at a recommended distance depending on the power of the transmitter.</p> <p>Recommended protective distance can be calculated with formulas listed below, suitable for the following transmitter frequencies.</p> <p><math>D = 1,2 \sqrt{P}</math>, frequencies from 150 kHz to 80 MHz</p> <p><math>D = 1,2 \sqrt{P}</math>, frequencies from 80 MHz to 800 MHz</p> <p><math>D = 2,3 \sqrt{P}</math>, frequencies from 800MHz to 2,5 GHz</p> <p>where:</p> <p>P is the maximum output power of the transmitter in watts [W] specified by the manufacturer, and D is the recommended protective distance in metres [m]).</p> <p>The field intensity of stationary radio transmitters, as defined in the result of electromagnetic field measured locally, should be lower than the interference level.</p> <p>Interference can occur around devices marked with the following icon:</p> 
Emitted radio frequencies IEC 61000-4-3	10 V/m 80MHz-2,5GHz	10 V/m	
Resistance to electrostatic discharges (ESD) IEC 61000-4-2	+/- 8 kV contact discharge +/- 15 kV air discharge	Conformity with the standard	Flooring should be made of wood, concrete or ceramic materials. To obtain suitable humidity level, relative humidity should be at least 30%.
Resistance to fast transient states/impulses IEC 61000-4-4	+/- 2kV test voltage +/- 1kV for input-output	Conformity with the standard	Mains power supply quality should be suitable for standard home, business or hospital environment.
Resistance to surges IEC 61000-4-5	+/- 1kV difference mode +/- 2kV standard mode	Conformity with the standard	Mains power supply quality should be suitable for standard home, business or hospital environment.
Resistance to voltage swings, short power shortages and	< 5 % Ut (> 95% Ut) decrease / 0,5 cycle	Conformity with the standard	<p>Mains power supply quality should be suitable for standard home, business or hospital environment.</p> <p>Attention: Ut is the AC power supply voltage.</p>


Resistance test	Parameters of standard IEC 60601-1-2 IEC 60601-2-24	Result	Comment
voltage swings at power supply line IEC 61000-4-11	40 % Ut (> 60% Ut decrease) / 5 cycles		
	70 % Ut (> 30% Ut decrease) / 25 cycles		
	< 5 % Ut (> 95% Ut decrease) / 5 sec		
Resistance to magnetic field with mains frequency (50 / 60 Hz) IEC 61000-4-8	400 A/m	Conformity with the standard	The power supply magnetic field frequency should be on the level of standard power supply from the city mains or hospital power supply source.

## 20.2 Recommended safe distance between radio devices and pumps

S100/S200/S300 pumps are designed for use in an environment with controlled interference caused by the emission of radio frequencies. In order to prevent electromagnetic interferences when Medima pumps are used, keep recommended minimum distance between stationary and mobile radio connection devices, taking into account the maximum output nominal power of the transmitter.

Maximum output nominal power (W)	Protective distance related to the transmitter's frequency, in metres [m]		
	150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For maximum output power transmitters, not listed above, estimate the recommended protective distance 'd' expressed in meters [m] using an equation suitable for the transmitter's frequency, where 'P' is the maximum output power of the transmitter expressed in watts [W] as specified by the manufacturer of the transmitter.

 <b>Attention!</b>	<p>This guideline may not cover all circumstances.</p> <p>Electromagnetic propagation is affected by absorption and reflection from buildings, objects and persons.</p>
--	---

## 21 PUMP UNPACKING AND PREPARATION

### 21.1 Pump 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, the service staff or the manufacturer directly.

Complete set includes the following items:

- **syringe pump** – model according to the order,
- **mains power supply cord**,
- **user's manual**.

Before the first use of the device, see section of 'Battery connection' below.



**Attention!**

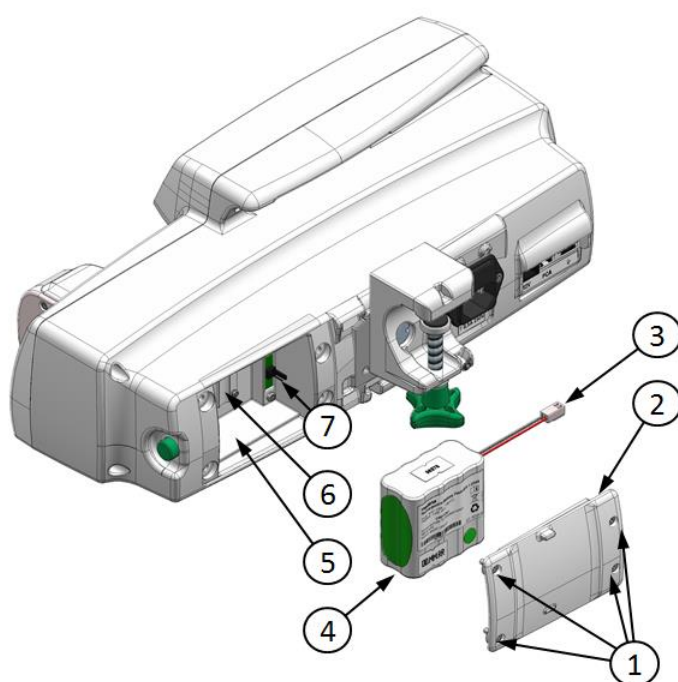
If the pump have been kept or transported in low temperature (below 0°C), it is recommended to leave it for a few hours at room temperature before connecting to the power supply.

If any steam condensation appears, do not connect the device to the mains for 4 – 8 hours until the casing surface is dry.

### 21.2 Battery connection



Before the first use of the pump, make sure that the battery is connected.

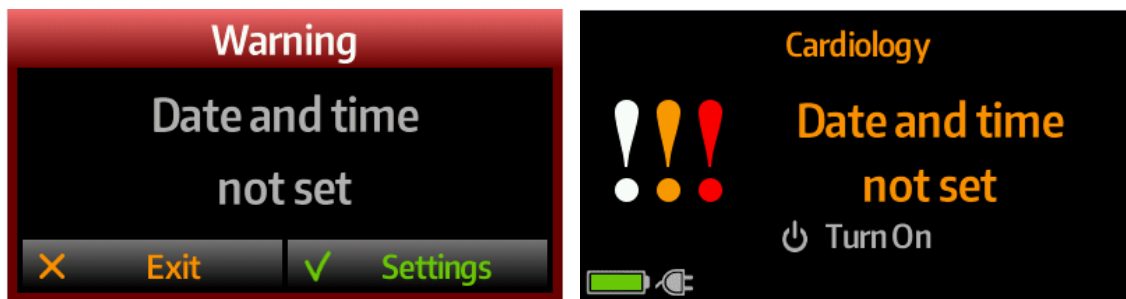
If it is impossible to switch the pump ON without connection to the external power supply, it may indicate that the battery is disconnected from the pump or discharged.






1. Battery cover mounting screws
2. Battery cover
3. Plug
4. Battery
5. Battery compartment
6. Temperature sensor
7. Connector


In order to connect the battery proceed as follows:

- Unscrew four battery cover mounting screws (1) and remove the battery cover.
- Remove the battery (4) from the battery compartment (5) in the casing.
- Connect the battery by connecting a plug (3) into the connector (7) – pump will display a warning of 'Date and time not set'. Press Settings  button in order to set date and time. If Exit  button is pressed then an active reminder of 'Date and time not set' will be displayed for a short time. After this, pump will switch into a sleeping mode (see section 7.2.3).



- Insert the battery into the battery compartment so that the part covered with thermally conductive paste adhere to the temperature sensor (6).
- Install the battery cover and tighten four screws.
- Connect the power cord to the pump and check whether the pump displays the Medima logo.
- If Exit  button was used in the warning window above, set the time and date before using the pump (see section 12.2).

 <b>Attention!</b>	<p>If displayed battery icon is blinking  after 1 minute time when mains power cord is connected check if battery has been connected. If after proper plug connection confirmation, blinking battery icon repeats itself then contact with local service representative or with manufacturer service directly.</p>
--	---

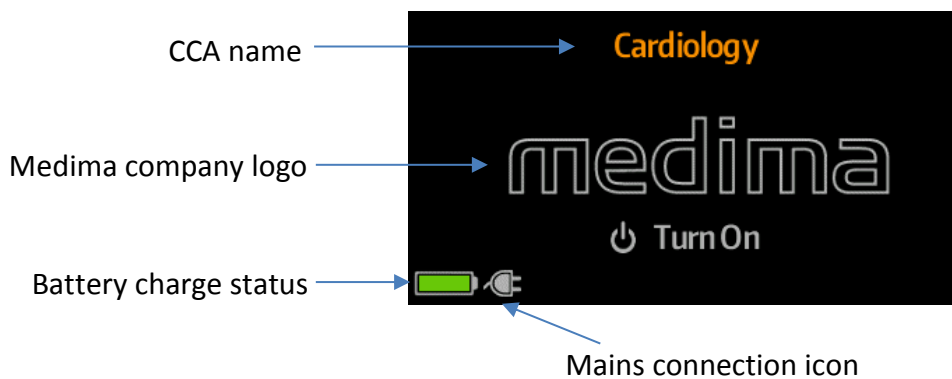
 <b>Attention!</b>	<p>Do not use the pump without battery connected, as there is a serious risk of interruption of current infusion in case of a breakdown in the power supply or accidental unplugging of the power cable.</p>
--	--

### 21.3 Basic pump functioning check

In order to check pump's functioning correctness, proceed with the following steps:


- Connect mains power supply cord to the pump and wait about 5 minutes.

Logo of Medima company should be displayed on the pump. Pump should not activate any alarm or 'Malfunction XXX'/'Damage XXX' (see section 13.5.5).



- Check correctness of date and time setting (date format display can be set in the Medima Configurator).


Date and time should be set according to local time according to section 12.2.

- Turn ON the pump by pressing ON/OFF  button. Skip infusion set installation. Turn OFF the pump. Pump should be started according to section 7.1.
- If after battery connection, battery reminders will be displayed by the pump then follow their recommendations (see table in section 13.5.4).

## 22 MAINTENANCE/CLEANING/DISPOSAL

### 22.1 Maintenance

#### Recommendations:

- For correct and safe pumps work, they must be technically overviewed in at least every 2 years. Pump has been equipped with a reminder function of recommended technical overview. Reminder is indicated by recommended technical overview date displayed on the screen. This message will appear every time the pump is turned on, beginning 14th day before a settled technical overview date, up to that specific date. Reminder about the recommended technical overview, does not obstruct the pump's functioning. When displayed message disappears or after pressing  button, further use is possible.



#### Attention!

According to EU law user realizing health benefits is obliged to keep made and planned documentation in agreement with user's manual of installation and repairs and maintenance and service and software updates and technical overviews and adjustments and calibrations and products' safety and quality checks containing precise dates and company's name which made those operations. Documentation should include operations' description and results and remarks about the product.

Documentation should be stored no shorter than 5 years beginning medical purpose product's usage discontinuation.

- in case of information labels removal or damage, pump must be delivered to Medima service unit,
- any service or repair operations can only be made by service previously trained by a manufacturer,
- in case of any doubts regarding pumps' work correctness they should be removed from usage as soon as possible, being protected against casual use. Contact with manufacturer or an authorized representative is highly recommended,
- before sending a pump to service, its cleaning and disinfection must be done
- original pump carton protecting against damage while transported is recommended.

## 22.2 Cleaning and disinfection

In order to clean and disinfect the pump proceed as follows:

- remove syringe and turn the pump off,
- disconnect the pump from the mains,
- wipe the outer pump surface with a cloth dampened with water detergent solution,
- after cleaning, wipe the device with a dry cloth and wait until the surface is fully dried.

Remarks:

- do not immerse the pump in any fluids as this may damage it and may cause electrical shock,
- only the external parts of the pump can be cleaned,
- do not sterilize pumps or their parts in steam autoclaves or by ethylene oxide,
- use only agents which do not damage the casing material (ABS).

## 22.3 Disposal

Pumps must be disposed in accordance with the country relevant regulations for disposal of used electrical and electronic products. The pumps can be returned to Medima or other designated collection point for discarded electrical and electronic products for further proper treatment.

The standard product lifecycle is 10 years.

## 23 MANUFACTURER'S RESPONSIBILITY

Manufacturer is responsible for safety and reliability and proper pump's functioning provided that following restrictions are kept:

- Installation, use, expansion, modification are made in accordance with delivered user manual or with specified manufacturer's remarks;
- service and repairs are made only by an authorized personnel trained by a manufacturer;
- pumps pass regular technical overviews according to the warranty conditions.

## 24 ADDITIONAL ACCESSORIES

For comfortable and safe mounting of the pump in the medical environment, it is recommended to use docking stations by Medima.

Power supply and communication ports are connected automatically after mounting the pump in the docking station. Docking stations with Ethernet module allow to connect pumps to MedimaNet network software.

### Docking stations

DS102/104/106/108	Docking stations for 2/4/6/8 pumps, which allow for quick mounting and mains power supply of Medima pumps.
DS202/204/206/208	Docking stations for 2/4/6/8 pumps, which allow for quick mounting and mains power supply of Medima pumps, but also displaying the status of installed pumps by light signals.
DS302/304/306/308	Docking stations for 2/4/6/8 pumps, which apart from DS10x, DS20x models' functions allow for pumps connection to the MedimaNet software by Ethernet network.
DS102A/DS102AC	Docking stations to be mounted in medical transport with an automatic power supply connection for Medima pumps.

S100, S200, S300 pumps are also compatible with older docking stations of DSx, DSxE, DSA generation.



## Infusion stands, holders, fixing systems

ST01	Mobile stand for safe transport of docking stations with pumps .
SM-03	Standard stand for bag infusions and infusion pumps (max 3 pcs).
TP2	Holder for mounting and transporting two pumps, power supply from a single cord.

## Accessories and tools

CAC-01	Mains power supply cord.
CDC-01	DC power supply cord.
CAL-01	Nurse call cord
SB-02	Medima ServiceBox - Medima calibration and technical overview tools set.

## Software

Medima User ToolBox	Medima software set includes: <ul style="list-style-type: none"><li>▪ Drug Editor to create, edit and upload drug libraries,</li><li>▪ Configurator to set and upload pumps' parameters,</li><li>▪ Loader for firmware upload.</li></ul>
Medima Service ToolBox	Medima software set includes: <ul style="list-style-type: none"><li>▪ Configurator to set and upload pumps' parameters,</li><li>▪ Loader for firmware upload.</li></ul>
MedimaNet	Software for central infusion monitoring.



**Attention!**

For more details and actual information about Medima offer, contact with the manufacturer directly or with a local representative.

## 25 MANUFACTURER

### **MEDIMA Sp. z o.o.**

Al. Jerozolimskie 200  
02-486 Warsaw  
Poland

Phone: (+48) 22 313 22 66

Fax: (+48) 22 313 22 69

E-mail: [medima@medima.pl](mailto:medima@medima.pl)

Website: [www.medima.pl](http://www.medima.pl)

Service centre:

Phone/Fax: (+48) 22 313 22 57

Phone/Fax: (+48) 22 313 22 49

E-mail: [serwis@medima.pl](mailto:serwis@medima.pl)

**Memo:**

Serial number	Password	Ward



Bear in mind that this manual may contain some typographical errors and incorrect information; therefore it is subject to correction. The corrections can be listed in the errata and included in the next issues of the manual. Due to evolution of standards, legal requirements and materials, characteristics included in this manual should be referred only to the devices mentioned in it. In order to obtain actual information about the products currently offered, please contact the manufacturer directly or the manufacturer’s local representative. Copying the manual in whole or in part without permission of the manufacturer is prohibited.











Medima Sp. z o.o.  
Al. Jerozolimskie 200  
02-486 Warsaw  
Poland  
Phone +48 22 313 22 66  
fax. +48 22 313 22 69  
e-mail: [medima@medima.pl](mailto:medima@medima.pl)  
website: [www.medima.pl](http://www.medima.pl)

