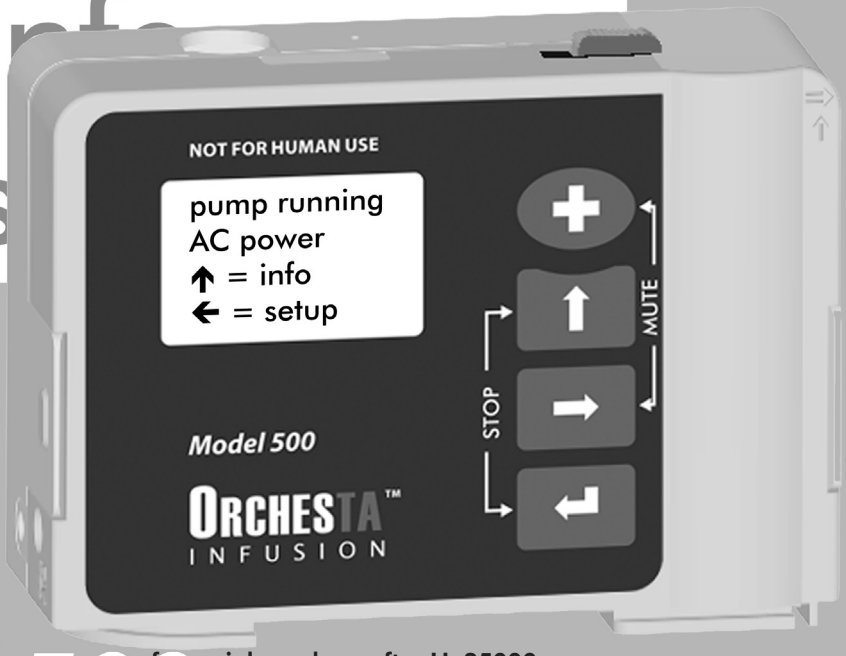
# Instruction manual




for serial numbers after LL-25000

## Infusion pump

*ORCHESTA™ Model 500*

CE

**NOT FOR HUMAN USE**

VENNER

*ORCHESTA* is a trademark of Instech Laboratories, Inc.

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# Contents

# Introduction

## Designated Use

*ORCHESTA*™ Model 500 is a portable, volumetric micro infusion pump for the administration of fluids for laboratory animal use only, not for human use. It can be used for multiple routes of administration.

The main accessories for the infusion pump are: *PEGA*® TUBE, *PEGA*® BAG, *PEGA*® LINE, *PEGA*® COMBI LINE, *PEGA*® SPIKE, *PEGA*® SET and *PEGA*® BOX.

*PEGA*® BAGs serve as containers for fluids and are connected when full to the inlet side of the *PEGA*® TUBE in the pump via a Luer-Lock connection.

The *PEGA*® BOX is provided for the *PEGA*® BAG in sizes of 50 ml, 100 ml and 150 ml.

*PEGA*® BOX with the *PEGA*® BAG is slid onto the side of the pump thereby creating a stable connection between the two.

*PEGA*® LINE and *PEGA*® COMBI LINE connect the pump to the animal. *PEGA*® SPIKE is used with infusion bags having a septum.

*PEGA*® SET is a complete catheter system comprising *PEGA*® BAG, *PEGA*® TUBE and *PEGA*® LINE.

*PEGA*® TUBE, *PEGA*® BAG, *PEGA*® LINE, *PEGA*® COMBI LINE, *PEGA*® SPIKE and *PEGA*® SET are all disposables.

## Notes on the use of the instruction manual

This manual is intended for technically instructed staff (**see p. 5, Items 2 and 3**).

International safety symbols are used in this instruction manual. Paying attention to these symbols will protect you from injury and avoid hazards. Please also note the key to the symbols on the back of this instruction manual.

⚠ Warning
Disregarding these instructions may result in serious damage to animal health or material damage.

⚠ Caution
Disregarding these instructions may result in material damage.

ⓘ Note
Additional information, which is not related to safety.

## ⚠ General Safety Information

1. Read the manual before setting up the system and be sure to observe the safety instructions.
2. *ORCHESTA*™ Model 500 may only be used with the supervision of personnel whose knowledge and judgement define the suitability of the pump for a particular infusion application. Disregarding this requirement will invalidate the warranty (**see p. 56**).
3. Using and changing the *PEGA*® TUBE, *PEGA*® BAG and *PEGA*® catheter systems (e.g. *PEGA*® LINE) may only be carried out by qualified staff.
4. Do not operate the pump higher than 1 m above the animal's heart.
5. Carry out the prescribed safety checks regularly. If use of the pump is continued beyond the next safety check date, the warranty will be invalidated and all product liability of the manufacturer will lapse.
6. In order to prevent risks, use only original *PEGA*® consumable materials and accessories (**see p. 55**).
7. Check that the pump is working and the unit is in proper condition each time before using it. To do this, a self-test must be carried out when starting up (**see p. 22**) with priming the pump (**see p. 33**).
8. *PEGA*® TUBE, *PEGA*® BAG and *PEGA*® catheter systems (e.g. *PEGA*® LINE) are disposable items in sterile packaging. Only use if the packaging is undamaged and unopened.
9. For optimal aseptic technique, consider replacing the *PEGA*® TUBE, *PEGA*® BAG and *PEGA*® catheter systems (e.g. *PEGA*® LINE) at the same time.
10. Only connect filled *PEGA*® BAGs to the pump in the primed state.
11. Dispose of disposable items according to local regulations.
12. During mains/AC operation, infusion therapy may be interrupted due to mains-borne interference. Such interference may occur if the network is overloaded by a lightning strike for example. In such a case, please follow the instructions in the operating

manual under the item “Start-up/Self-test” (**page 22/23**) to restart the infusion.

13. The field strength of stationary radio transmitters should be in compliance at all frequencies according to on-site tests. Interference is possible in the vicinity of equipment which carries the adjacent graphical symbol.

14. Do not use zinc carbon batteries as these may cause the unit to malfunction. Note the battery / rechargeable battery options shown in **Table 1 on p. 19**.
15. Never expose *ORCHESTA*™ Model 500 to X-rays (e.g. CT), strong magnetic fields (e.g. MRI) or ultrasound.
16. Defective units or units that are no longer required must not be disposed of in the household waste. Observe the specific disposal regulations for electrical equipment for your country.
17. Batteries and rechargeable batteries should be disposed of properly.

## Additional information

- *ORCHESTA*™ Model 500 has a splash-proof housing meaning that it will tolerate a small amount of water exposure.
- If a malfunction occurs, the pump will set off a visual and audible alarm, if enabled.
- The safety concept of the pump is designed in such a way that it reverts to the safe state if a fault occurs:

  If a fault occurs, infusion is stopped and a visual and audible alarm is signaled.

  If the power supply is interrupted during dosing, there is only an audible alarm. The visual alarm is switched off.

# Design and functional overview

## Hardware

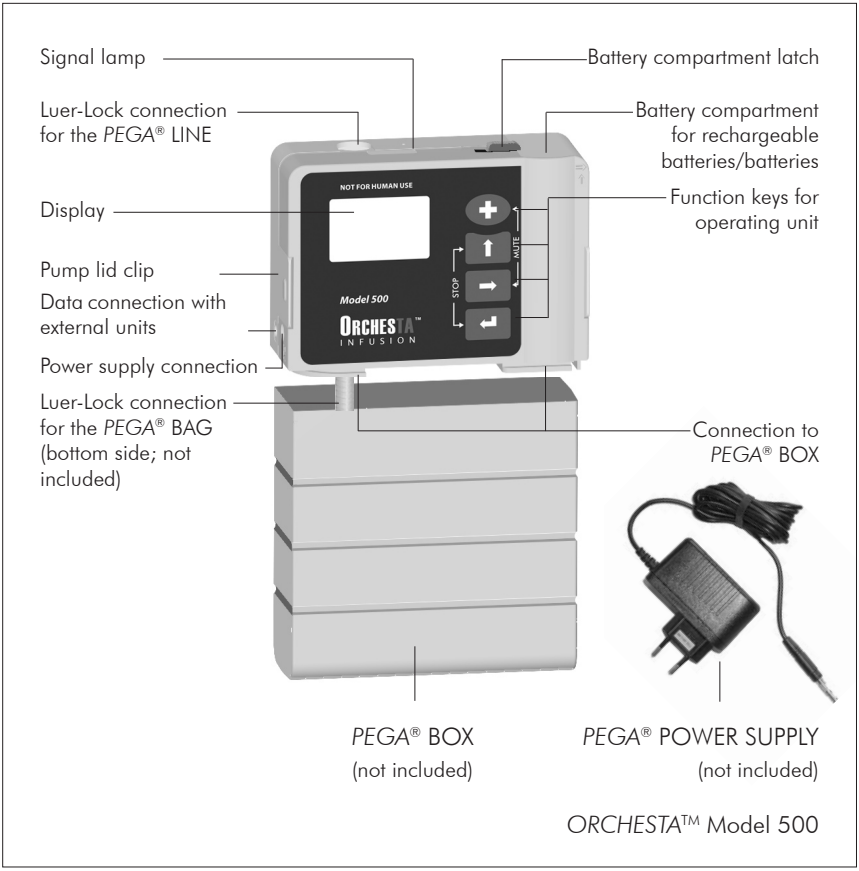



Figure A: View of pump, PEGA® BOX, and PEGA® BAG assembled

## Principle of operation

The *ORCHESTA*™ Model 500 infusion pump delivers fluids from a reservoir (e.g., *PEGA*® BAG) through a catheter system (e.g. *PEGA*® LINE) to the animal. In the filled state, the reservoir is connected to the bottom of the pump

by means of a Luer-Lock connection, and the catheter system is connected to the *PEGA*® TUBE by means of the Luer-Lock connection on the top of the pump (**see p. 16ff**). While pumping is in progress, a peristaltic drive, which is driven by a motor in the housing, ensures that the liquid is correctly pumped. Rechargeable or ordinary disposable batteries are used to provide power to the pump. The *PEGA*® POWER SUPPLY can also be used.

## Operating modes

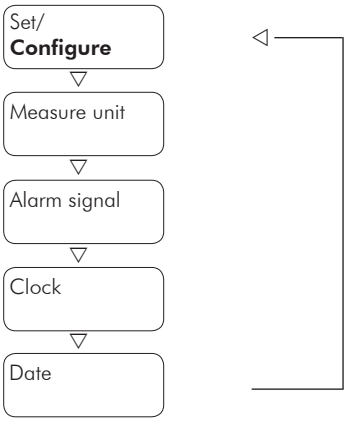
This manual will guide you through the continuous infusion mode only.

## Operational Menus

The *ORCHESTA*™ Model 500 has three operational menus. The settings menu 1 and 2 are secured by codes. The information menu is freely accessible.
The information menu differs depending on the unit of measurement set in settings menu 1. If in settings menu 1 no key is pressed for more than 30 minutes or the power supply is interrupted, all parameters must be reentered.

If in the information menu no key is pressed for about 15 seconds, the screen backlight switches off in order to save power. It can be switched on again by pressing any key.

**Settings menu 1**
**Code 1 - 9 - 2**




**Sub-menu A (Configure)**

**Selection:** Configure

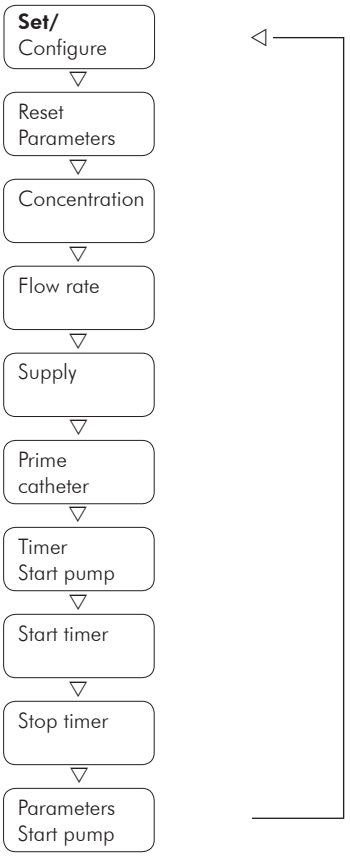
**Unit of measure:** ml/h, mg/h, µg/h

**Alarm signals:** select between different alarm signals (internal warning tones cannot be changed)

**Clock:** sets the current time

**Date:** sets the current date

**Settings menu 1**
**Code 1 - 9 - 2**




**Sub-menu B (set)**

**Selection:** Set

**Reset:** deletes all parameters set in this menu

**Concentration:** mg/ml, µg/ml (is only shown if mg/h or µg/h is set as the unit of measurement in sub-menu A "Configure")

**Flow rate:** rate at which fluid is continuously administered

**Supply:** amount of fluid with which the *PEGA*® BAG is filled; 1 ml - 1,000 ml in steps of 1 ml

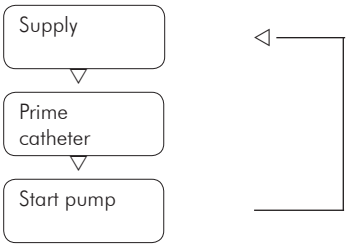
**Prime catheter:** filling the catheter system with the fluid; flow rate during priming: 100 ml/h

**Start timer:** set timer for scheduled pump start

**Stop timer:** set timer for scheduled pump stop

**Start pump:** terminates settings menu 1 and starts the pump with the parameters set

**Setings menu 2**
**Code 1 - 1 - 1**

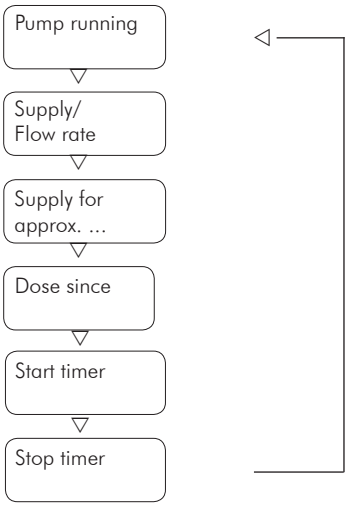



**Supply:** enter new amount of article after the *PEGA*® BAG has been changed

**Prime catheter:** filling the catheter system with the administration article; flow rate during priming: 100 ml/h

**End:** terminates settings menu 2, the pump returns to its previous state

**Information menu**
**No code**




**Unit of measure in ml/h**

**Supply/Flow rate:** current fluid amount in the *PEGA*® BAG/flow rate set

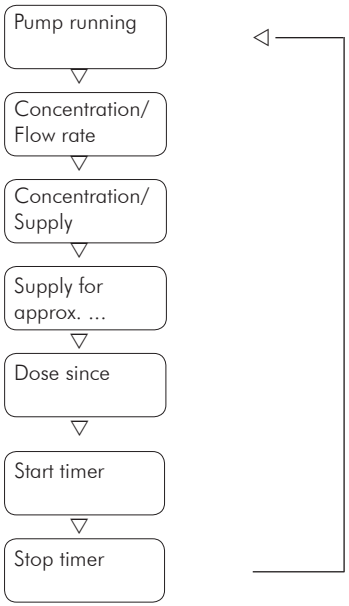
**Supply for approx. ...:** range of fluid supply in the *PEGA*® BAG

**Dose since...:** amount of fluid administered during the last 24 hours

**Start timer:** time for scheduled pump start (only if programmed)

**Stop timer:** time for scheduled pump stop (only if programmed)

**Information menu**
**No code**




**Unit of measure in mg/h or µg/h**

**Concentration/Flow rate:** concentration of the fluid (mg/ml or µg/ml)/set flow rate

**Concentration/supply:** concentration of the fluid (mg/ml or µg/ml)/current amount of the fluid in the *PEGA*® BAG

**Supply for approx. ...:** range of fluid supply in the *PEGA*® BAG

**Dose since...:** amount of fluid administered in the last 24 hours

**Start timer:** time for scheduled pump start (only if programmed)

**Stop timer:** time for scheduled pump stop (only if programmed)

## Function

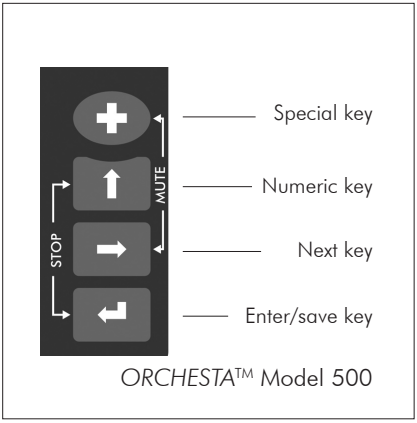



Figure B: Function keys

**Special key:** primes the catheter, re-starts an interrupted program

**Numeric key:** enters numerical values

**Next key:** displays the next message in the information or settings menu, selects the next numeral, prompts the information menu

**Enter/save key:** changes or saves/ deletes the entry, prompts the window for entering the code

**Stop**: Pressing the **Numeric key** and the **Enter/Save key** simultaneously stops the pumping process.

**Mute/Unmute**: Pressing the **Special key** and the **Next key** simultaneously in the Information menu mutes/unmutes the audible signals.

## Transport and storage

### Transport

Appropriately cover and protect the *ORCHESTA*™ Model 500 when placing in an animal jacket. When transporting the pump, use the plastic case with dedicated foam cutouts in which it was shipped originally.

### Storage

If you intend not to use *ORCHESTA*™ Model 500 for a long period of time, stop the pump, switch it off (**see p. 40**), remove the batteries or rechargeable batteries and store *ORCHESTA*™ Model 500 in its own case. The data will remain stored until the next safety check.

# Preparation for infusion

## Open infusion pump

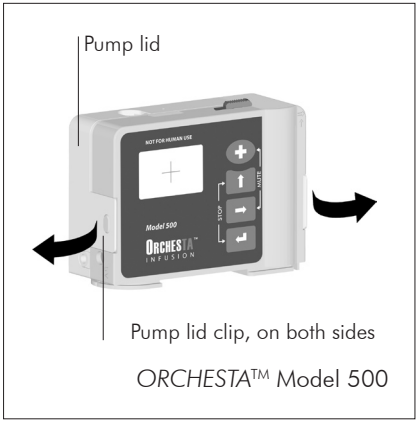



Figure C: Side view

⚠ Warning

The pump may only be opened for changing disposables. Further dismantling of the pump housing may lead to restrictions in the operation of the pump and will invalidate the warranty.

Procedure

1. Disconnect the *PEGA*® BOX if it is connected.
2. Place the *ORCHESTA*™ Model 500 on a flat surface.
3. Slightly bend the two pump lid clips outwards, one after the other.


Figure D: Side view with pump lid open

4. Lift the pump lid off away from you.

## Inserting the *PEGA*® TUBE

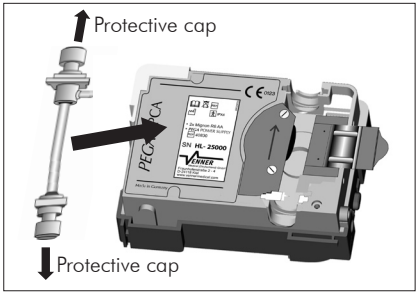



Figure E: Inserting the *PEGA*® TUBE 1

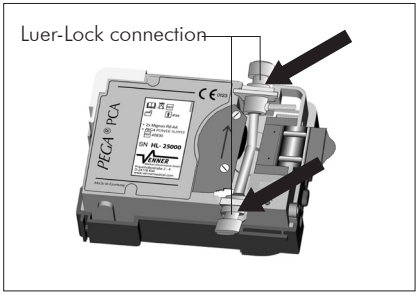



Figure F: Inserting the *PEGA*® TUBE 2

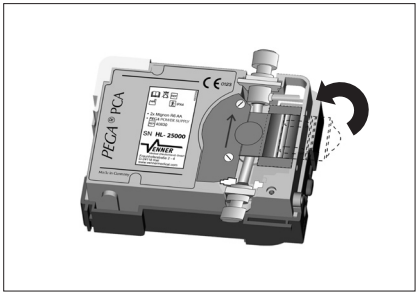


Figure G: Closing the blue locking clip

Procedure

1. It is essential to follow the general safety instructions (**see p. 5**).
2. Open the pump.
3. Open the locking clip.
4. Open the sterile packaging of the *PEGA*® TUBE.
5. Hold the *PEGA*® TUBE by the protective cap.(**Figure E**).
6. Insert the upper Luer connector in such a way that the lateral pressure tube is positioned inside the guides of the colored pressure sensor (**Figure F**).
7. Press the Luer connector of the *PEGA*® TUBE gently into the upper guide.
8. Pull the *PEGA*® TUBE gently and let the lower Luer connector of the *PEGA*® TUBE click into the lower guide.
9. If necessary, press the *PEGA*® TUBE downwards with your finger so that it rests deep in the shaft.
10. Close the blue locking clip. The tube is fixed firmly in the peristaltic drive by the pressure block. (**Figure G**).
11. Place the pump lid on the pump.
12. Close the pump. Make sure that the lid clips on the side engage fully into place.

Notes

- *ORCHESTA*™ Model 500 is only ready for operation and will only operate properly if the clips are correctly engaged.
- The *PEGA*® SET can also be used as an alternative to the individual disposables (**Figure H**).

Caution

In order to avoid contamination, do not open the protective cap of the *PEGA*® TUBE until the *PEGA*® BAG and *PEGA*® LINE are connected. Do not touch the Luer connections after removing the protective cap.

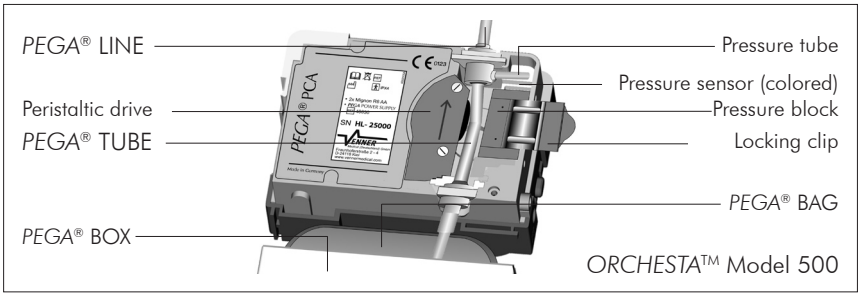



Figure H: Rear view without pump lid with *PEGA*® SET fitted

## *PEGA*® Disposables

To connect the *PEGA*® BAG and *PEGA*® catheter system (e.g. *PEGA*® LINE), please refer to the instructions enclosed with the disposable materials. You will find the steps needed for the pump operation on **page 36ff**.

## *PEGA*® BOX and soft cases

To accommodate the 50 ml, 100 ml and 150 ml *PEGA*® BAG connect the corresponding *PEGA*® BOX with the pump. Solomon Scientific offers stable pouches for using the infusion pump without the *PEGA*® BOX. They have been specially designed for this application and ensure a safe delivery without the *PEGA*® BOX.

# Power supply

To guarantee correct operation of the *ORCHESTA*™ Model 500, the pump should be operated using the batteries provided. However, it is also possible to use batteries (ordinary, disposable) or rechargeable batteries (Type R6, AA).

The *PEGA*® POWER SUPPLY is available for operating the pump from the mains supply. Solomon Scientific also provides an external charger with rechargeable batteries.

The life of normal batteries and rechargeable batteries (Type R6, AA) depends on their capacity and the flow rate set. The resulting approximate values for battery life are shown in Table 1 (battery/storage battery life) on **page 19**.

Notes

- The pump is unable to detect rechargeable batteries or normal batteries which are inserted during operation. Therefore disconnect from AC/mains power before inserting and confirming new batteries or rechargeable batteries.
- If the batteries have been removed by mistake before the pump has been stopped or switched off, an audible alarm will sound which can only be halted by re-inserting the batteries/rechargeable batteries or by connecting to AC power.

⚠ Caution

- Use only the separately available *PEGA*® POWER SUPPLY for supplying the unit with AC power.
- Do not use zinc carbon batteries as this may affect reliable operation of the pump.
- Rechargeable batteries and normal batteries have different voltage levels. After inserting, you must tell the pump which type of cell has been used when requested. This is necessary in order to guarantee correct operation of the pump and the internal monitoring functions and alarms.

## Inserting rechargeable battery pack/batteries, connecting the power supply unit

| Batteries | Capacity in mAh | at rate of 50 ml/h | | at rate of 100 ml/h | |
|---|---|---|---|---|---|
| | | Range | Life | Range | Life |
| **Lithium** | 3000 | 1000 ml | 20 h | 850 ml | 8.5 h |
| **Alkaline** | 2250 | 750 ml | 15 h | 650 ml | 6.5 h |
| **NiMH (ENELOOP)** | 2000 | 650 ml | 13 h | 550 ml | 5.5 h |
| **NiCd** | 1000 | 350 ml | 7 h | 300 ml | 3.0 h |

Table 1: Options of batteries/rechargeable batteries


*ORCHESTA*™ Model 500

Figure I: Battery compartment lid open

### Fitting/changing rechargeable batteries and normal batteries

Procedure

1. Pull out the AC plug if necessary.
2. Place the pump on a flat surface with the battery compartment lid upwards.
3. Release the latch of the battery compartment lid, push the lid up and move it sideways.
4. Remove any empty or defective batteries or rechargeable batteries.
5. Insert two new 1.5 V batteries or rechargeable batteries (Type R6, AA). Pay attention to the polarity (label in the battery compartment).
6. Fold the lid back over the compartment, gently press it downward and close the latch.


Figure K: Socket for power supply

### Operating with power supply unit

Procedure

1. Connect the power supply unit (*PEGA*® POWER SUPPLY) to the mains.
2. Plug the power supply unit into the socket on the infusion pump.
3. The unit is now working on AC power.

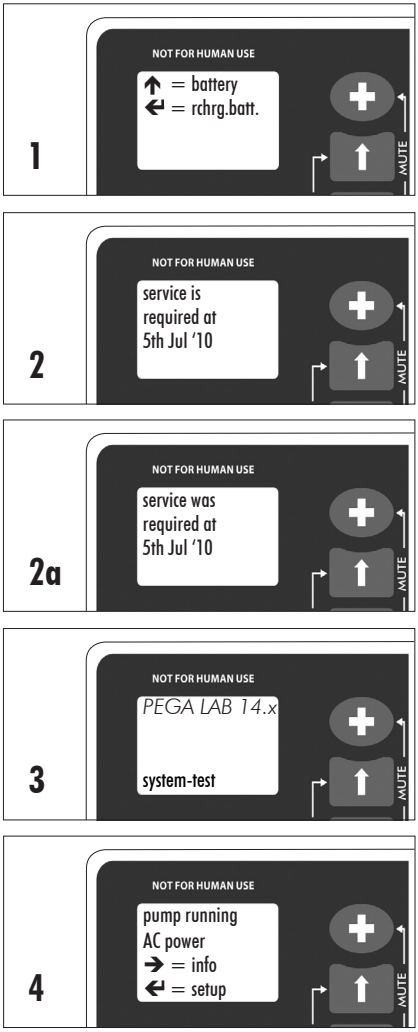
When power is supplied, *ORCHESTA*™ Model 500 starts operating.

If no batteries or rechargeable batteries are fitted, the pump will stop as soon as the mains plug is removed. Disconnect the mains connection at the infusion pump first.

### Remove the mains plug

Take hold of the knurled metal ring (**see Figure K**) and pull it back. The plug will be unlocked and can be easily removed.

## Start-up / system-test



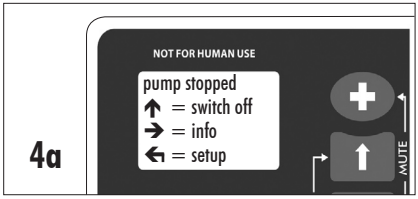

### Start-up

Procedure

1. If batteries or rechargeable batteries are inserted, **Figure 1** will automatically appear on the display.
2. Press the corresponding key. A short signal sounds.
3. A safety check must be carried out on the *ORCHESTA*™ Model 500 at regular intervals (**see p. 5**). If the date is within the next 4 weeks, **Figure 2** will appear on the display.
4. If the date has already passed, **Figure 2a** appears on the display.

> ⚠ Caution
> If the message appears or the date has already passed, send the pump immediately to the authorised technician or associate. If use of the infusion pump is continued beyond the next safety check date, the warranty expires and all product liability on part of Venner Medical (Deutschland) GmbH lapses.

5. **Figure 3** then appears on the display.
6. If any button is pressed, "system-test interrupted" will be shown briefly on the display and **Figure 4** will appear, for example.The system-test will continue to run in the background.





7. If the pump stops and the power supply has been interrupted, the display of **Figure 4a** appears after reinstatement of the power supply and the test.

8. If a fault or warning occurs, **see Table 5, p. 46**.

9. If you want to change the programming, press the Enter/save key. **Figure 5** appears on the display.

10. Enter the required code (**see p. 25**).

### Additional system-test

The *ORCHESTA*™ Model 500 carries out a system-test on start-up (insertion of rechargeable batteries/batteries or connection of *PEGA*® POWER SUPPLY) and thereafter in the background at hourly intervals.

An additional system-test can be initiated by the staff.

Procedure

1. Disconnect the unit from the mains.

2. Remove the batteries or the rechargeable batteries and reinsert them.

## Warnings, messages

**Messages on the display**

- **Rechargeable batteries or batteries weak:**
  indication of weak batteries/ rechargeable batteries
- **Rechargeable batteries or batteries empty:**
  red signal lamp lights up as soon as delivery stops (**see p. 59**).
- **Type of power supply:**
  additional information provided in the “Pump running” state

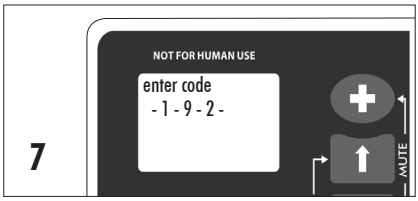
# Programming

All basic settings are made in settings menu 1 (Code 1 - 9 - 2). Settings menu 2 (Code 1 - 1 - 1) is only for setting the fluid supply when changing infusion accessories and when priming (for menu overview, **see p. 10-13**). The code protects against unintended or unauthorised changes to the settings.

*ORCHESTA*™ Model 500 is supplied with the following default settings:

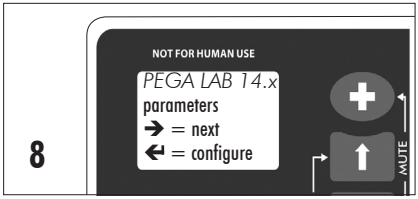
- Flow rate and supply: "0"

## Calling up settings menu 1 - entering code


Procedure

1. Press the Numeric key once.
2. Press the Next key.
3. Press the Numeric key nine times.
4. Press the Next key.
5. Press the Numeric key twice (**Figure 7**).
6. Confirm the code by pressing the Enter/save key.
7. The message, "enter code - okay - ", will appear on the display.

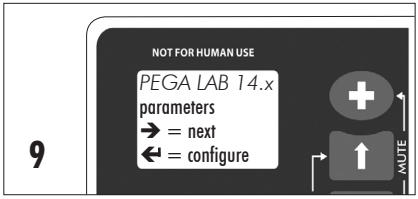



8. After 3 seconds, "service required on..." will appear for a short time.

The pump is now in programming mode (**Figure 8**).

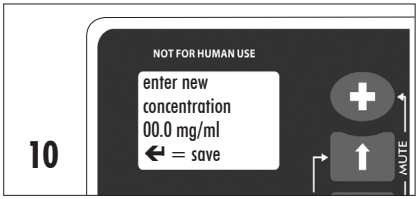
You can get to sub-menu B (Set) by pressing the Next key, and to sub-menu A (Configure) by pressing the Enter/save key.

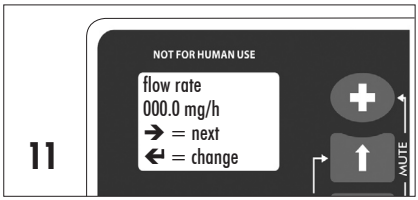
## Programming for continuous infusion




Procedure

1. Call up code entry.
2. Enter code 1 - 9 - 2.
3. Select sub-menu A (Configure) (**Figure 9**).




7. Repeated pressing of the Next key will lead you through the displays for setting the unit of measurement, the alarm signal, data transfer, pump clock and date.

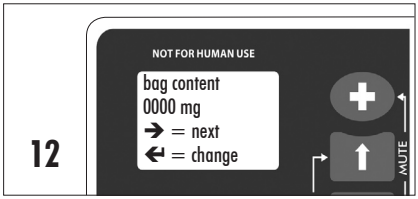
   When you have completed sub-menu A (Configure) in settings menu 1, you automatically switch to sub-menu B (Set).

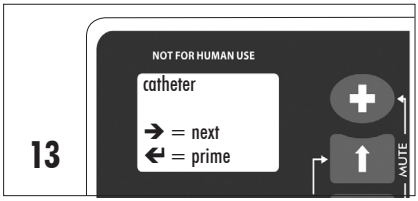
8. If you have set the pump for programming in mg/ml or µg/ml, enter the required value in the "concentration" window using the Numeric and Next keys (**Figure 10**).

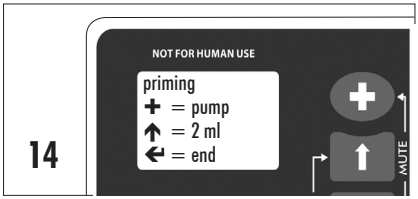
9. Confirm the change with the Enter/save key to save the value.

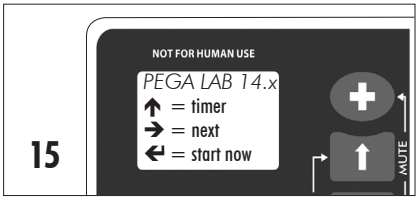
10. Press the Next key until you reach the menu item "flow rate" (**Figure 11**).

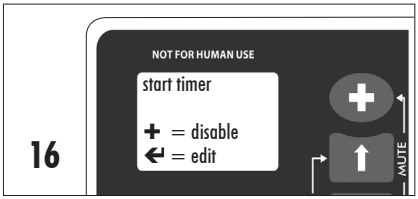
11. Set the required value using the Numeric and Next keys.



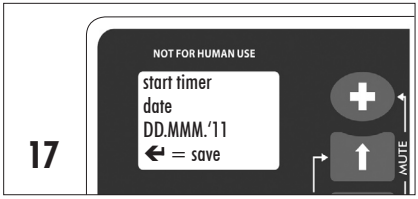



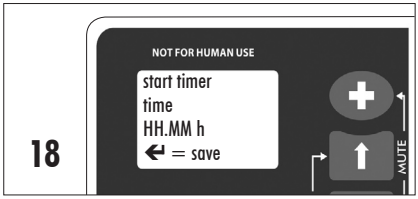



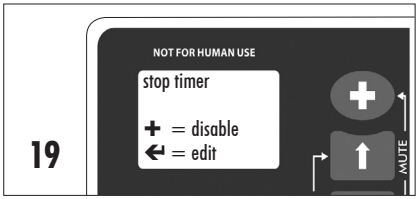



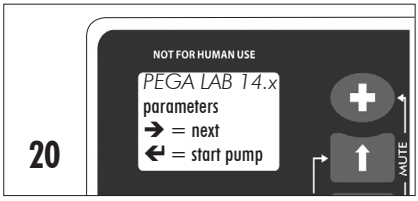




12. Press the Enter/save key to save the new value.
13. By pressing the Next key, you will reach the menu item "bag content" (**Figure 12**).
14. Set the required value using the Numeric and Next keys.
15. Press the Enter/save key to save the new value.
16. By pressing the Next key, you will reach the menu item "catheter" (**Figure 13**).
17. Press the Enter/save key in order to start the priming of the catheter system.
18. Press the Special key until the catheter system has been primed or...
    press the Numeric key. The pump will automatically deliver 2 ml (**Figure 14**).
19. If you press the Enter/save key, **Figure 15** appears.
20. By pressing the Next key, you will reach the enty point of the menu (**Figure 9**); using the Up key, you will reach the menu item "start timer" (**Figure 16**). To start the pump press the Enter key.




21. Press the Enter/save key in order to edit the date for scheduled pump start (**Figure 17**) or use the Special key to disable the timer.

22. Set the date using the Numeric and Next keys and press the Enter/save key to save the new value. **Figure 18** appears.

23. Set the time using the Numeric and Next keys and press the Enter/save key to save the new value. **Figure 19** appears.

24. Set the required values for the stop timer in a similar manner.

25. After timer values have been set, press the Next key until the menu item "parameters/start pump" appears (**Figure 20**).

26. Press the Enter/save key to start the pump or the Next key to scroll through the settings again.

27. If you want to delete parameters, proceed as described on **p. 29**.

### Changing values

You can view the menu items by using the Next key. Settings can be changed individually or combined. To do so, follow the instructions on the display.

Pay attention to the position of the cursor. The blinking cursor shows which numeral can be changed.

Procedure

1. Set the desired numeral using the Numeric key. 
2. Select the next numeral with the Next key. 
3. Set the desired numeral using the Numeric key. 
4. Repeat the procedure until all numerals have been selected.
5. Save your entries by pressing the Enter/save key. The saved value is displayed again. 
6. You can call up the next menu item by pressing the Next key. 

If date and time are changed, all parameters (if applicable, concentration, flow rate and supply) are automatically deleted.

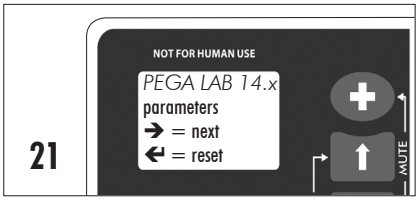
**Deleting all parameters**

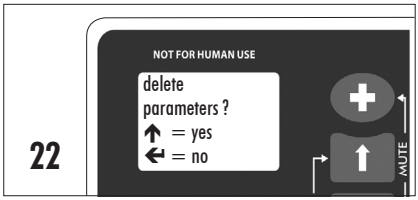
As the first step, any parameters set in the *ORCHESTA*™ Model

500 can be deleted. To do so, proceed as follows:

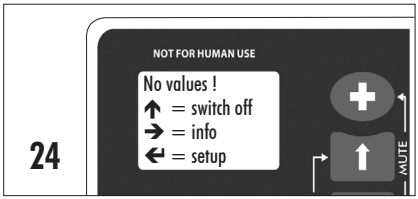
Procedure

1. Press the Next key. **Figure 21** appears on the display.
2. Press the Enter/save key. **Figure 22** appears on the display.
3. Confirm the following check by pressing the Numeric key (“yes”). Thus, all settings in settings menu 1, sub-menu A (Set), are reset to “0” (e.g. flow rate, if applicable, concentration). **Figure 23** appears.







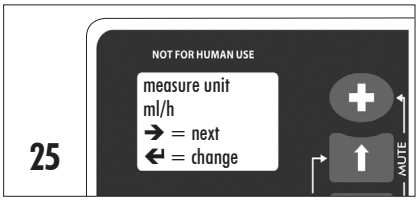

**Settings**

As long as the pump is switched on, you can run through settings menu 1 as often as you like.
If “0” has been entered for flow rate, the pump identifies this to be an unreasonable entry. **Figure 24** appears on the display.
The *ORCHESTA*™ Model 500 is switched off by pressing the Numeric key.

**Unit of measure**

Procedure

1. Call up code entry.
2. Enter code 1 - 9 - 2.



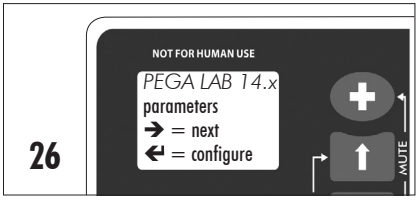

3. Select sub-menu A (Configure).
4. You are now in the menu item "measure unit" (**Figure 25**). The display shows ml/h, mg/h or µg/h. The unit of measurement can be changed by pressing the Enter/save key. ↵

   All further parameters are now shown in this unit of measurement. If you change between volumetric and gravimetric units, flow rate will be deleted.

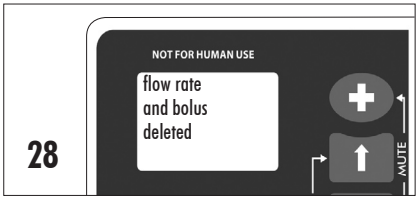
### Concentration

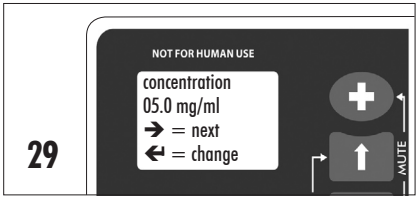
If mg/h or µg/h has been selected as the unit of measurement, the concentration of the fluid must be entered. To do so, proceed as follows:

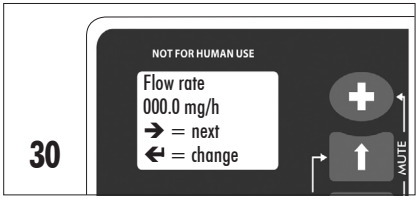
Procedure




1. Starting from the menu item "measure unit", press the Next key until **Figure 26** appears on the display. ➡
2. You can switch to sub-menu A (Set) by pressing the Next key. ➡
3. Press the Next key until you reach the menu item "Concentration". ➡


4. Enter the concentration using the Numeric and Next keys (**Figure 27**).

5. Complete the entry by pressing the Enter/save key. **Figure 28** appears briefly on the display.

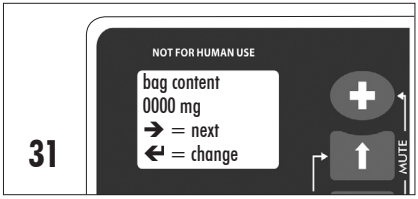
6. The new value is then displayed again, to check for correct entry. **Figure 29** appears on the display.

*ORCHESTA*™ Model 500 automatically computes the corresponding volume.

### Setting the flow rate

Procedure

1. Call up code entry.
2. Enter code 1 - 9 - 2.
3. Select sub-menu B (Set).
4. Press the Next key until you reach the menu item “flow rate” (**Figure 30**).
5. Press the Enter/save key to enter the flow rate.
6. Set the required value using the Numeric and Next keys.
7. Press the Enter/save key to save the new value.




## Setting supply

Procedure

1. Call up code entry.
2. Enter code 1 - 9 - 2.
3. Select sub-menu B (Set).
4. By pressing the Next key, you will reach the menu item "bag content" (**Figure 31**).
5. Set the appropriate value using the Numeric and Next keys.
6. Press the Enter/save key to save the new value.

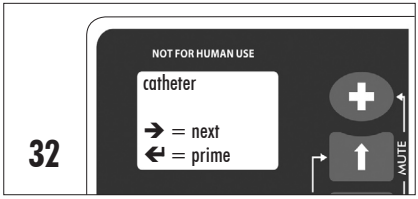
## Priming

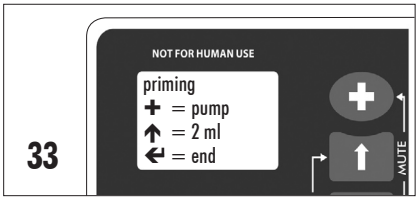
The infusion system must be primed before it is connected to the animal. The operation of the pump will be checked at the same time.

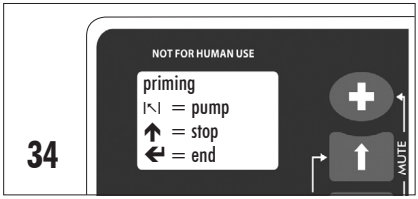
The priming function is available both in settings menu 1 (Code 1 - 9 - 2) and in settings menu 2 (Code 1 - 1 - 1).

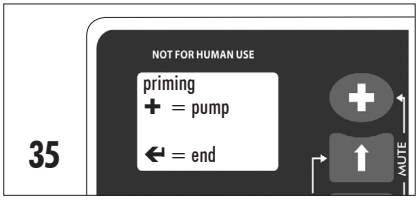
Procedure

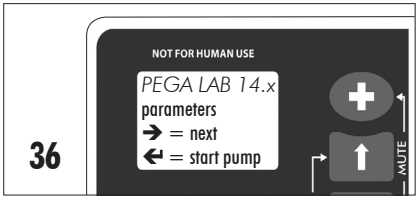
1. Call up code entry.
2. Enter the appropriate code.
3. If you are in settings menu 1, select sub-menu A (Set).




4. Press the Next key in the settings menu until **Figure 32** appears on the display. →

5. Press the Enter/save key. **Figure 33** appears on the display. ↵

6. Press the Special key until the catheter system has been primed or... +

   press the Numeric key. The pump will automatically deliver 2 ml (**Figure 34**). ↑

7. Press the Enter/save key. **Figure 35** appears. ↵

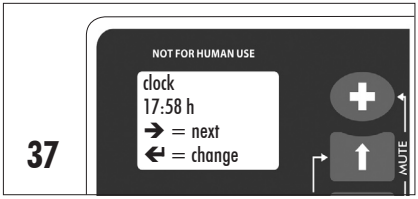
   If you press the Enter/save key again, it will take you back to **Figure 32**. ↵

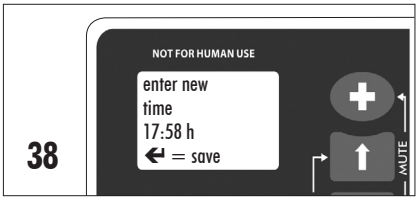
**Leaving settings menu 1 - starting pump**

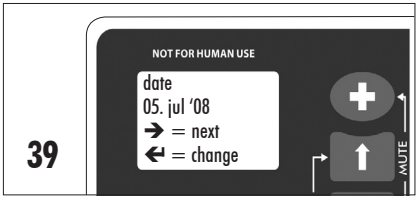
Procedure

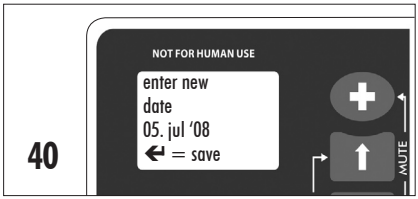
1. Press the Next key until **Figure 36** appears on the display. →

2. Press the Enter/save key to start the pump. ↵




## Setting pump clock and date

Procedure

1. Call up code entry.
2. Enter code 1 - 9 - 2.
3. Select sub-menu A (Configure).
4. Press the Next key until you reach the menu item "clock" (**Figure 37**).
5. Press the Enter/save key to change the time.
6. Set the appropriate value using the Numeric and Next keys (**Figure 38**).
7. Press the Enter/save key to save the new time.
8. Press the Enter/save key to change the date (**Figure 39**).
9. Set the appropriate value using the Numeric and Next keys (**Figure 40**).
10. Press the Enter/save key to save the new date.

⚠ Caution

When the time and date and changed, the parameters in sub-menu B (Set) are deleted and must be re-entered. This applies to flow rate and concentration.

# Brief instructions for daily care

## Replace *PEGA*® BAG and *PEGA*® disposables

Fluids and disposables must be inserted when starting a new infusion or regularly replaced when changing and resuming an existing infusion. The associated settings are made in settings menu 2 for technical staff (Code 1 - 1 - 1).

⚠ Warning

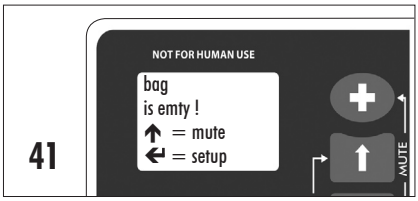
- It is essential to observe the general safety instructions (**see p. 5**).
- Check that the pump is working and the unit is in proper condition each time before using it.

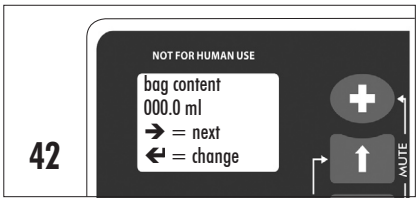
  To do this, a self-test must be carried out when starting up (**see p. 22**) and the pump primed (**see p. 44**).
- To avoid contamination, carry out all operations using proper aseptic techniques. Disinfect your hands before starting work and avoid touching the open Luer connections.
- Only use fluids or solutions which are compatible with the material of the disposable items.

ℹ Note

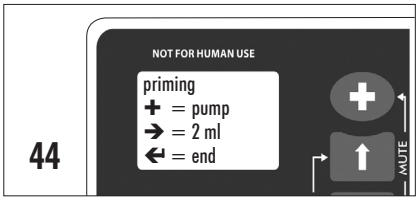
- If the fluid supply does not exceed two hours, the time remaining until the contents of the bag are exhausted is shown on the display.

  Between 8 a.m. and 8 p.m. this message is signalled every hour with a beeping tone (this is an artifact from human use).
- When the pre-set supply has been used up, the red signal lamp of the *ORCHESTA*™ Model 500 lights up, an alarm signal sounds and **Figure 36** appears on the display. By stopping the pump this alarm can be cut off and the pump may be switched off until it is used again (**see p. 40**).








## Setting supply and priming

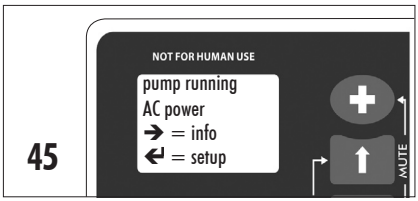
Procedure

1. Connect a pre-filled *PEGA*® BAG.
2. Press the Enter/save key. 
3. Enter code 1 - 1 - 1, **see p. 12**.
4. Press the Enter/save key.  **Figure 42** appears on the display.
5. Press the Enter/save key.  **Figure 43** appears on the display.
6. Set the supply using the Numeric and Next keys. 
7. Confirm your entry by pressing the Enter/save key. 
8. Press the Next key and **Figure 44** will appear on the display. Prime the infusion system. Exit settings menu 2 (Code 1 - 1 - 1) by pressing the Enter/save key. 

Note

- There is a restriction to 5 ml for 10 hours when priming in settings menu 2 (Code 1 - 1 - 1). If this volume is reached, the priming function is blocked.
- The priming process only works if a supply is set before priming.
- Care must be taken to ensure that there are no air bubbles in the catheter and the filter.
- If air bubbles are still seen during the priming process, gently flick your finger against the filter and the tube until all air bubbles have been flushed out.
- Continue the priming process until all air bubbles have been removed from the line.

## Connection with animal and starting the infusion



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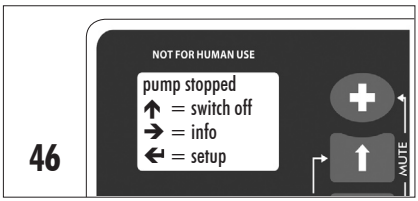

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If all the settings have been entered and preparations for the infusion completed, *ORCHESTA*™ Model 500 can be connected to the animal and started.

Procedure

1. Connect the catheter system and pump to the animal.
2. If you have called up settings menu 2 (Code 1 - 1 - 1) when the pump was running, the pump will start as soon as priming is completed (**Figure 45**).

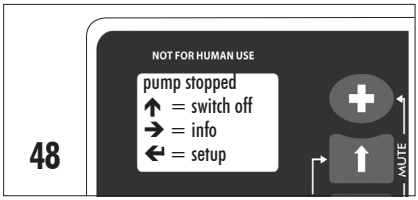
   If you have called up settings menu 2 (Code 1 - 1 - 1) when the pump was stopped, you will have to start the pump. Exit the menu by pressing the Enter/save key. **Figure 46** appears on the display. To start, **see p. 40**.
3. **Figure 47** will appear if the set supply is sufficient for 2 hours or less.

After starting, the *ORCHESTA*™ Model 500 pumps at the set flow rate.

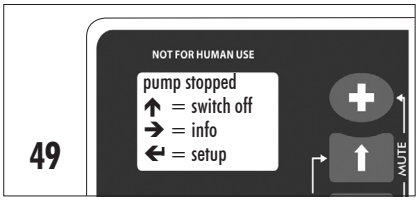
The green signal lamp blinks at regular intervals.

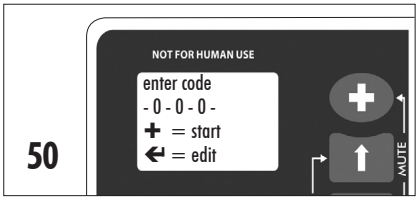
Pressing any key will take you back to the information menu.

## Stopping / switching off / re-starting the pump








### Stopping and switching off the pump

1. Press the Numeric key and the Enter/save key simultaneously. **Figure 48** appears on the display. The pumping process will stop.

2. Press the Numeric key again. *ORCHESTA*™ Model 500 will now switch off (**Figure 48a**).

   The values set remain saved.

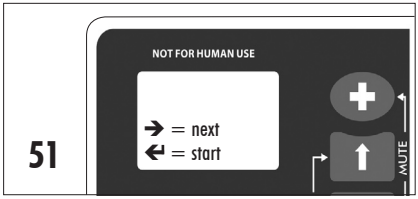
### Re-starting the pump

1. Press any key. **Figure 49** appears on the display.

   To check the set values, press the Next key. The information menu will appear (**see p. 42**).

2. Press the Enter/save key to enter the code 1 - 1 - 1: **Figure 50**.

   If you do not press a key, the screen will switch off again after a short time.



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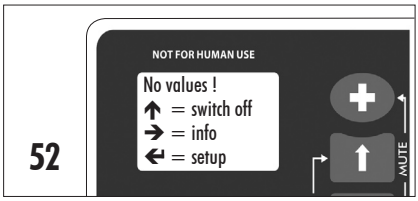
3. Press the Special key. **Figure 51** appears on the display.
4. Press the Enter/save key and the pump will start.

### Switching off the pump when infusion parameters have not been programmed

If you want to switch off the pump for an extended period without entered values, delete all parameters in Settings menu 1 (Code 1 - 9 - 2) (**see p. 29**).



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Note

If mg/h (µg/h) has been set for the pump in sub-menu A, a concentration must be entered before switching off.

**Figure 52** will appear on the display when restarting.

# Information menu

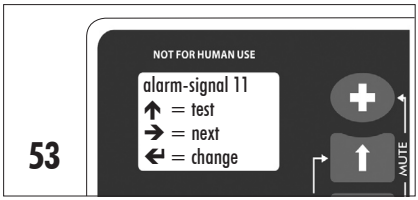
When the pump is operating all current values can be called up and checked at any time in the information menu. The information menu differs depending on whether the unit of measurement has been set to ml/h or mg/h or µg/h.

By pressing the Next key, you will reach the following items in succession: **see Table 2**.

| | **ml/h - version** | **mg/h or µg/h - version** |
|---|---|---|
| 1a | Supply/flow rate | Concentration/flow rate |
| 1b | | Concentration/supply |
| 2 | Range of supply | Range of supply |
| 3 | Amount of fluid administered since date/time | Amount of fluid administered since date/ time |
| 4 | Start timer | Start timer |
| 5 | Stop timer | Stop timer |

Table 2: Information menu

# Alarm and warning functions




53

## Setting alarm signals

Users can choose different tonal sequences to ensure that audible alarm signals can be heard more easily in the daily routine.

Procedure

1. Call up code entry.
2. Enter code 1 - 9 - 2.
3. Select sub-menu A (Configure).
4. Press the Next key until the "Set alarm signal" menu item appears (**Figure 53**).
5. Press the Enter/save key until you reach the desired tonal sequence.
6. Press the Numeric key to test the selected tonal sequence.
7. Press the Next key to confirm the selected signal tone.

Note
Internal warning tones cannot be changed.

## Signals

### Audible signals

- Every press of a key is followed by a beeping tone which confirms that the action was successful.

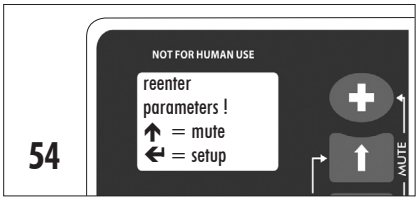
  In the event of malfunctions, signals sound in conjunction with a corresponding warning message on the display.

- In settings menus 1 and 2 a short beeping tone sounds every 15 seconds.

### Audible alarms

You can find the meaning of the audible alarms in the table below.

The audible warning can be suppressed for approx. 5 min in each case.




Procedure

1. For example, **Figure 54** appears on the display.
2. Press the Numeric key. The audible alarm is suppressed for approx. 5 min (the pump will not work during this time!).

| Audible alarm | Significance |
|---|---|
| Intermittent signal with 1 s tone / 1 s pause | No fluid supply left |
| Intermittent signal with 0.5 s tone / 1 s pause | Occlusion |
| Intermittent signal with 1 s tone / 10 s pause | All other alarms |

Table 3: Audible signals

### Mute/unmute audible alarms

For muting/unmuting all key tones an audible alarms, press Next key and Enter/save key in the Information menu at the same time. This setting will remain unchanged in case of switching off the device or changing the batteries.

### Audible alarm when power supply is interrupted (if not muted)

If the power supply is interrupted while the pump is running, an alarm tone (with lower frequency) sounds which differs from the above-mentioned tones. This alarm can continue for up to 15 min if the fault is not corrected.

### Visual signals

Audible and visual signals are complemented by corresponding messages and symbols on the display (exception: if the power supply is interrupted, there is only an audible alarm).

| Visual signal | Significance |
|---|---|
| Signal lamp flashes green | Pump running as programmed |
| Signal lamp not flashing | Pump not running |
| Signal lamp shining red | There is a fault and the pump is not running |

Table 4: Visual signals

## Tracing and correcting faults

*ORCHESTA*™ Model 500 offers maximum safety as the pump has built-in checking functions which constantly monitor the infusion settings. As soon as a malfunction occurs, the pump will set off a visual and audible alarm.

The following table shows which messages can occur and how you can correct the malfunctions.

Note

If you are unable to rectify a fault, send the pump and if necessary the *PEGA*® POWER SUPPLY in the pump case together with the fitted consumables to the authorised dealer. When dispatching, please observe the regulations for packing potentially contaminated goods.

⊗ Red signal lamp

| | Display | Cause | Correction |
|---|---|---|---|
| 1. | bag<br>is empty !<br>↑ = mute<br>↵ = edit ⊗ | *PEGA*® BAG empty | Change infusion system and restart pump or stop pump and switch off |
| 2. | BATT | Limited life in batteries | Insert new batteries or new rechargeable batteries or connect pump to AC/mains |
| 3. | battery<br>is weak !<br>➔ = next | 1. Limited life in batteries on start-up (max. 20% of capacity left)<br>2. Rechargeable batteries declared as batteries by mistake | 1. Insert new batteries<br>2. Refit rechargeable batteries and declare them correctly; connect AC/mains if necessary |

Table 5: Fault list

| | Display | Cause | Correction |
|---|---|---|---|
| 4. | battery<br>is empty ! ⊗ | Batteries used up. Infusion can stop any minute; not possible to start new infusion | Insert new batteries or new rechargeable battery pack or connect pump to AC/mains |
| 5. | **no display** | 1. Pump is switched off<br>2. No batteries or batteries empty; alarm tone (with lower frequency) for up to 15 minutes if power interrupted while pump is running<br>3. Technical fault in pump | Activate display and pump with any key or insert new batteries or rechargeable battery pack or connect pump to AC/mains; if this does not rectify the fault, return unit to authorised dealer |
| 6. | warning !<br>aux. battery<br>is empty ! | No internal storage power | Send pump back to authorised dealer |
| 7. | service<br>required<br>prematurely | Service required for technical reasons (e.g., max. delivery volume reached) | Send pump back to authorised dealer |
| 8. | pump stopped<br>↑ = switch off<br>→ = info<br>↵ = setup | Pump has stopped | Check values and re-enter if necessary; restart or switch off pump |

Table 5: Fault list

| | Display | Cause | Correction |
|---|---|---|---|
| 9. | reenter parameters ! ↑ = mute ↵ = edit  | When working in settings menu 1:<br>- No key pressed for 30 min<br>- The batteries have been removed | Check values in settings menu 1 and if necessary, re-enter |
| 10. | system error ! ↑ = mute ↵ = edit  | Pump has detected corrupted data in internal test | Call up settings menu, check settings and re-enter values |
| 11. | catheter occlusion ! ↑ = mute ↵ = edit  | Occlusion on animal's side (blockage):<br>Needle / filter is blocked or catheter system kinked | Check catheter system and remove occlusion, change catheter system if necessary; it is essential to open the pump lid and to release the pressure block by lifting the locking clip of the peristaltic insert. |
| 12. | please check *PEGA*® TUBE ! ↑ = mute ↵ = edit  | Check *PEGA*® TUBE; fault in pump/*PEGA*® TUBE | Change *PEGA*® TUBE |
| 13. | please close pump ! ↑ = mute ↵ = edit  | Housing clips have not clicked home or no *PEGA*® TUBE fitted | Fit *PEGA*® TUBE, close lid, engage pump lid clips, re-start pump |

Table 5: Fault list

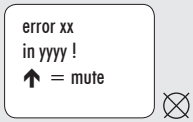
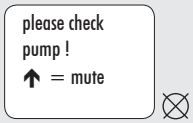
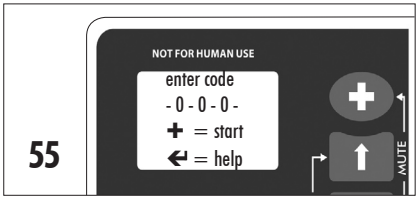
| Display | Cause | Correction |
|---|---|---|
| 14.   | Internal pump fault (coded fault message)<br>Technical fault in pump | Switch off power supply, re-start pump; if fault is not corrected, send pump to the authorised dealer |
| 15.   | Technical fault in pump | Switch off power supply, re-start pump; if fault is not corrected, send pump to the authorised dealer |

Table 5: Fault list

## Re-starting the pump




Procedure

1. If possible, correct the cause of the alarm.
2. Press the Enter/save key. **Figure 55** appears.

   Pressing the Enter/save key again causes a help text to be displayed.
3. Press the Special key and then the Enter/save key. The pump is re-started.

## What should I do if *ORCHESTA*™ Model 500 is dropped?

Examine the pump, pump lid and *PEGA*® BOX for external damage (cracks, etc.).

If the pump is damaged, send it to the authorised dealer.

Also check the disposables for damage and replace them if necessary.

If the *PEGA*® BOX is damaged, replace it.

If the pump is outwardly undamaged, proceed as follows:

Procedure

1. Press the Numeric key and the Enter/save key simultaneously (Stop).
2. Briefly interrupt the power supply (pull out the plug or remove batteries/rechargeable batteries and then re-insert them).

   *ORCHESTA*™ Model 500 will now carry out a system-test. If the system-test is successful, the pump is ready to operate and can be re-started. Otherwise, send the pump to the authorised dealer.

# Cleaning and safety check

## Cleaning

- Wipe the *ORCHESTA*™ Model 500 with a damp cloth.

  The pump is resistant to alcoholic disinfectants.

## Safety check

- For the *ORCHESTA*™ Model 500, this safety check must be carried out by a trained technician at least every five years or within one year after a delivery volume of 50 liters.
- The date of the next safety check is displayed in the settings menu. Within the final 4 weeks before the next service, this is notified on the display every time the batteries are inserted.
- If the service is due or the date has been exceeded, send the *ORCHESTA*™ Model 500 immediately to the authorised dealer.
- If use of the pump is continued beyond the safety check date, the warranty expires and all product liability on the part of Venner Medical (Deutschland) GmbH lapses.

# Dosing accuracy confirmation

| Rate | Time |
|---|---|
| 100 ml/h | 10 s |
| 50 ml/h | 20 s |
| 20 ml/h | 45 s |
| 10 ml/h | 1 m 30 s |
| 5 ml/h | 2 m 30 s |
| 1 ml/h | 10 m |
| 0.1 ml/h | 45 m |

Table 6: Delays before occlusion alarm

Dosing accuracy is continually checked and registered by a dual monitoring system of two microprocessors within the pump.

This ensures that an alarm is triggered at an inaccuracy of 195 µl (**check PEGA® TUBE**).

**Table 6** shows the maximum delay times before the occlusion alarm is activated.

An occlusion on the animal's side results in a bolus volume in the infusion system. After the occlusion has been removed, this volume is dispensed. The values in **Table 7** have been determined for the following *PEGA*® disposables:

| Designation | Max. bolus volume if occlusion occurs | |
|---|---|---|
| | 1400 hPa | 1800 hPa |
| *PEGA*® LINE 100 SF + *PEGA*® TUBE | 73 µl | 95 µl |
| *PEGA*® COMBI LINE 200 SF | 86 µl | 96 µl |

Table 7: Bolus volume for occlusion

The infusion systems are designed for a pressure p ≤ 2,000 hPa.

⚠ Caution

The use of consumables not approved by Venner Medical (Deutschland) GmbH, can endanger the animal, e.g.:

- no additional security against free-flow in the event of a malfunction
- no protection against air infusion
- larger bolus volume
- overdosage or underdosage of medication without alarm
- pressure stability not sufficient
- leaking of disposable items

# Compliance

This manual has been written with consideration to the requirements in the International Standard IEC 60601-1 for Medical Electrical Equipment.

The *ORCHESTA*™ Model 500 infusion pump is designed to comply with (among others) the following international safety and EMC requirements for medical electrical equipment:

- IEC 60601-1 (1988 with Amendments) medical electrical equipment, which classifies the *ORCHESTA*™ Model 500 as follows: **see table 9, page 54**.
- IEC 60601-1-2 (2001): Electromagnetic compatibility

# Technical data and accessories

## Technical data

| | |
|---|---|
| **Classification** | Typ BF |
| **Housing** | ABS, shock proof, splash proof protection degree IPX 4 |
| **Dimensions** | 87.0 x 64.2 x 33.0 mm |
| **Weight** | 170 g, without batteries |
| **Drive** | Linear peristaltic |
| **Batteries/ rechargeable batteries** | 2 x 1.5 V, Mignon, R6, AA (Lithium, Alkaline, NiMH, NiCd) |
| **Storage temperature** | -30 °C to +40 °C (-22 °F to 104 °F) |
| **Operating temperature** | +5 °C to +40 °C (3 °F to 104 °F) |
| **Relative humidity** | Between 30 % and 75 % |
| **Flow rate** | 0.1 ml/h to 100 ml/h adjustable in steps of 0.1 ml/h, similar setting options when programming in mg/h or µg/h |
| **Measure unit** | ml/h, mg/h, µg/h |
| **Supply** | 1 ml to 1,000 ml, adjustable in steps of 1 ml, similar settings in mg and µg |
| **Accuracy** | ± 5 % or ± 70 µl/h |
| **Pressure sensor** | Cut-out pressure for occlusion 1,600 ±200 hPa |
| **Max. delivery volume until next safety check due** | 50 liters, if last safety check more than one year ago |
| **Data transmission** | Compatible with *ORCHESTA*™ automated infusion system |

Table 8: Technical data

## Scope of delivery *ORCHESTA*™ Model 500

| Number | Contents |
|---|---|
| 1 | *ORCHESTA*™ Model 500 |
| 2 | Batteries (1.5 V, Mignon, R6 AA) |
| 1 | Pump case |

Table 9: Scope of delivery

## Further accessories, disposables

Accessories/disposables are listed on a separate leaflet.

# Appendix

## Warranty, claims and liability

Venner Medical (Deutschland) GmbH offers warranty against defects and damages as part of the following rules:

The warranty period is 24 months from delivery of the infusion pump by Venner Medical (Deutschland) GmbH. If there is a defect, Venner Medical (Deutschland) GmbH is entitled to choose between correcting the fault or replacing the unit.

If Venner Medical (Deutschland) GmbH is not prepared or able to correct the fault/replace the unit, in particular if the process of doing so exceeds reasonable time limits for reasons for which Venner Medical (Deutschland) GmbH is responsible, or if the attempt to correct the fault has failed twice, the buyer shall be entitled to choose between withdrawing from the contract or demanding a corresponding reduction in the purchase price.

Claims for compensation arising from breach of contract or unauthorised action are not permitted either against Venner Medical (Deutschland) GmbH or their various agents unless there is a case of deliberate or grossly negligent conduct. This also applies to claims for damages due to non-performance, but only in so far as compensation is demanded for indirect or consequential damages unless liability is based on the warranty which is intended to protect the buyer from the risk of such damages.

In the event that an important contractual obligation is not met, liability shall be limited to the foreseeable damages when the contract was concluded.

In order to claim the right to have a defect corrected or a replacement unit supplied, it is necessary to send the defective infusion pump to Venner Medical (Deutschland) GmbH or the responsible dealer. The buyer shall bear the carriage costs.

The warranty obligation shall not extend to faults which are due to...

- extraordinary or unavoidable events
- repairs carried out by unauthorised persons or to third party intervention
- improper operation and handling, in particular improper storage, dropping, immersion in liquid, unintended use and any disregard of the instructions for use
- the use of disposables that are not approved by Venner Medical (Deutschland) GmbH

## Trumpet curve (accuracy diagrams)

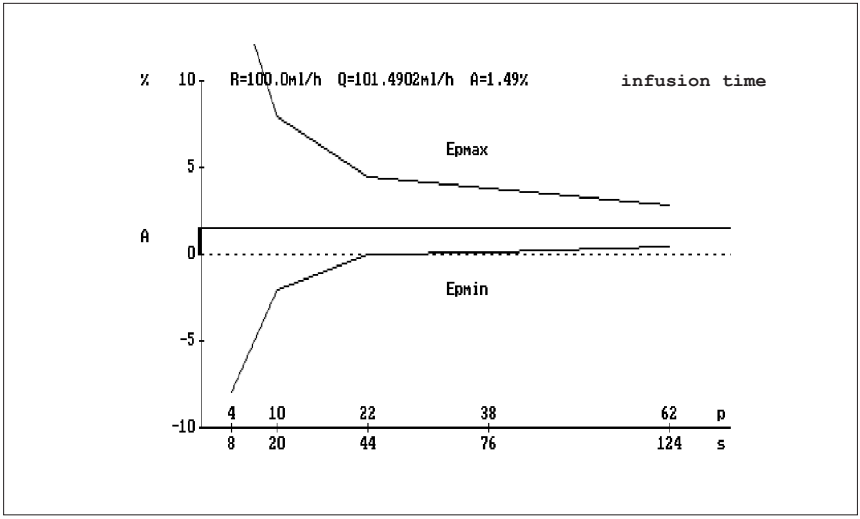



Figure J: Trumpet curve

The coordinate system of the trumpet curve shows the percentage deviation from the set flow rate on the y axis. The x axis shows the observation period. The possible deviation from the set flow rate can be seen from the trumpet curve for any observation period.

For example, for a flow rate of 100 ml/h: in an interval of 2 minutes, the maximum deviation, $E_{pmax}$ for the *ORCHESTA*™ Model 500 is approx. 2.5 %, and the minimum deviation, $E_{pmin}$ approx. 0.5 %. The total error is 1.5 %.

# Index

## Meaning of the symbols on the rating label and on the packaging

| | |
|---|---|
|  | Expiry date |
|  | Item for single use |
|  | Caution, consult accompanying documents |
|  | Batch |
| SN | Serial number |
|  | Date of manufacture |
|  | Sterilisation with ethylene oxide |
|  | Sterilisation by radiation |
|  | Compliant with product-specific European Directives |
| REF | Purchase code number |
|  | Open here |
|  | Protect against humidity |
|  | Storage temperature |
|  | Classification BF |
|  | Recycling |
|  | Dispose of pump, rechargeable batteries and batteries in accordance with the statutory regulations |
|  | Protect against direct solar irradiation |

Open the pump lid to see the rating label (**see p. 15**)

manufactured by:

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March 2011
*ORCHESTA*™ Model 500
E 4002001A