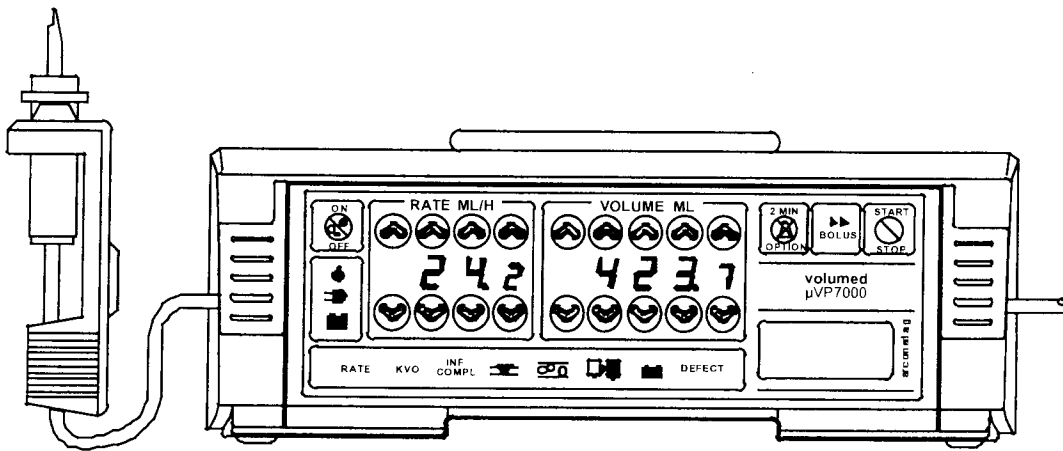


Instruction for use

Volumed[®] μ VP7000



Swiss Made

ARCOMED AG
8105 Regensdorf / Zürich

(an ISO 9001 company)

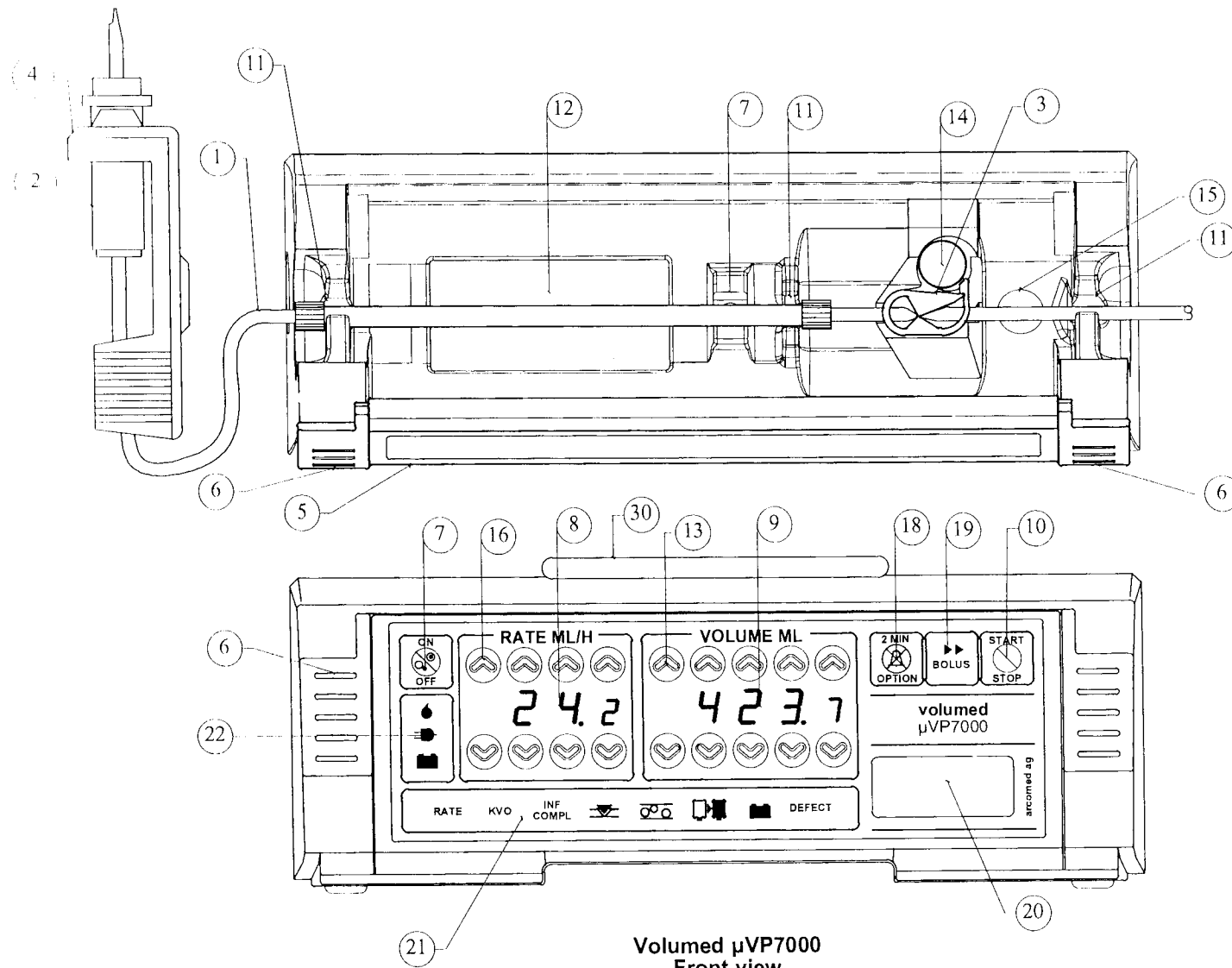
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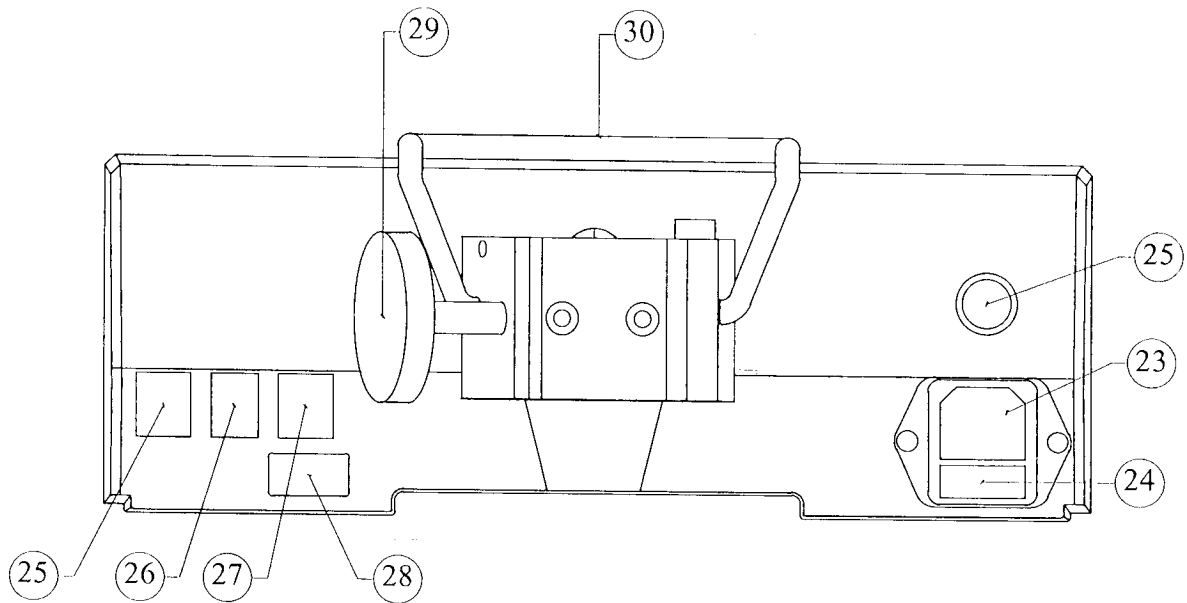
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Vomed μVP7000
Front view



Volumed μ VP7000
Rear view

1. Introduction

1.0 Introduction

The Volumed® μ VP7000 Volumetric Infusion Pump has been developed using the latest state-of-the-art technology. This microprocessor-controlled volumetric pump operates by pumping the infusate using a peristaltic system. The sterility of the infusate is not affected. The pump is designed to infuse drugs or other infusates into the patient by controlled means under pressure.

The Volumed μ VP7000 meets the performance requirements of the MDA (UK) for neonatal and high risk infusions. It can be used in both stationary and transportable applications as it has a battery life up to 6 hours duration. Applications include neonatology, intensive and cardiac care, paediatrics, gynaecology and obstetrics, surgery and general medicine. It can also be used in ambulances or for laboratory use. For infusions with very small rates and small volumes it is recommended to use a syringe pump such as the Syramed® μ SP6000 as the the remaining volume in the administration set can become significant compared to the infused volume.

The Volumed μ VP7000 meets the Medical Device Directive (MDD) requirements of the EC Guideline 93/42 EEC and is marked CE.

Classification: Class IIb

The manufacturer according to MDD is Arcomed AG, Althardstrasse 146, CH 8105 Regensdorf, Zurich, Switzerland. Responsible for the EC is Arcomedical Infusion Ltd., West Horndon, Essex CM13 3XL, UK.

The Volumed μ VP7000 may be operated only on mains power installed to DIN 57107 VDE 0107 or the appropriate national standards. If the integrity of the mains power supply protective earth system is in doubt, the pump should be operated on battery power. Mobile telephones should not be used anywhere near this equipment.

1.1 Mounting the pump

Check the pump and accompanying accessories for damage when unpacking. The pump must not be operated if damaged. Should the pump be damaged contact our Service Department.

Permitted mounting: positioned on a flat horizontal surface or pole mounted on an infusion stand or rail mounted.

The pump should normally be operated from a mains power supply. The internal batteries will automatically operate the pump in the event of a power failure.

CAUTION: This pump is not designed for use in areas where there is an explosion hazard. Environmental requirements as per IEC601-1-2 must be observed. Do not operate this pump in an environment with high levels of electromagnetic radiation such as surgical diathermy or mobile telephones. For further information contact the official distributor in your country or the Customer Service Department in Switzerland:

Switzerland: arcomed ag, Althardstr. 146, CH-8105 Regensdorf
Tel. ++41 (0) 43 388 90 30, Fax. ++41 (0) 43 388 90 40

United Kingdom: Arcomedical Infusion Ltd., 5J West Horndon Industrial Estate, West Horndon, Essex CM13 3XL
Tel. ++44 (1) 277'81'04'32 Fax. ++44 (1) 277'81'19'67

The technical manual and the list of spares and used materials can be requested from Arcomed.

1.2.1 Cleaning and disinfection

CAUTION: The pump must be switched off and disconnected from the mains power supply before cleaning and disinfecting.

The pump must be kept clean and dry. Remove any spillage immediately. The pump must not be placed in an autoclave.

The unit is disinfected by wiping over with a cloth which has been dampened slightly with an alcohol-based disinfectant. Take care when cleaning that no liquid enters the inside of the pump case. Wait at least 30 seconds after disinfecting before switching the pump on. Use only disinfectant that are compliant with:

- ABS, POM, stainless steel, PVC, aluminum, silicone

Please check with your supplier of disinfectant.

1.2.2 Annual safety check

Battery power is provided by a nickel metal hydride (NiMH) battery which must be checked annually. Battery condition is checked by connecting the pump to the mains power supply for 15 hours in a switched off condition so that the battery may be fully charged. Disconnect the mains power supply and switch the pump on using battery power. Determine the operating time when the low battery alarm activates. This should be at least 3 hours - if not the battery must be replaced. Repeated charging and discharging may in certain circumstances cause degeneration of the battery (memory effect).

Used batteries must be disposed of in an environmentally friendly manner or returned to the manufacturer.

Safety checks (see chapter 6) may be performed only by qualified staff.

1.3. Key to symbols

The pictograms and symbols shown on the reverse of the pump have the following meanings or functions:



Nurse Call



CF (cardiac floating) part



Empty bag detector



CAUTION: consult accompanying documents

12 VDC

External 12 VDC supply

IPX 1

Drip-proof

IR

Interface RS232
(Infrared Interface)



class I double insulated

2. Specifications

CE Mark	A23 02 04 07000 01
Classification	IIb
Software revision	1.xx
Flow rate range (ml/h)	0.1 - 999.0 ml/h, increments: 0.1 ml/h
Volume range (ml)	0.1 - 9999.9 ml, increments: 0.1 ml
Deviation in flow-rate with 8101P series administration set	typ. +/- 3% (Silicone insert)
Deviation in flow-rate with 3101P series administration set	typ. +/- 5% (PVC line)
Overinfusion in case of electrical or mechanical defect	1.5 ml max.
Keep vein open rate (KVO)	3.0 ml/h, adjustable
Bolus rate, Prime rate	1000 ml/h, adjustable
Infusion pressure min.	60 kPa / 450 mmHg / 0.6 bar
Infusion pressure max.	120-250 kPa / 900-1875 mmHg 1.5-2.5 bar (according to IV set)
Alarm pressure limit	0 - 999 mbar/mmHg
Bolus volume after occlusion	Automatic bolus reduction (see also 3.9)
Time to alarm after occlusion	Depending on rate, pressure limit setting and set, see also table below.
Air detection	ultrasonic
Sensitivity	typ. 100 µl, adjustable from 50 to 250 µl Cumulated 15 min adjustable from 500 to 5000 µl
Battery operation time (1.85Ah)	3 - 5 hrs (dependent on rate and mode)
Charging time	15 hours/20 hours
Supply voltage	230 VAC+10%-15%, 50/60 Hz
External power supply (optional)	12 VDC
Input power	9.3 VA
Mains fuse	T200 mA/IEC127/III/SEV 1064
Type of protection against electric shock	Class II
Protection against ingress of liquids	IPX 1, drip proof
Leakage current	< 40µA
Radio interference	CE-Class A
Nurse call, potential-free contact switch	24V/0.2A
Degree of protection against electric shock	CF (cardiac floating)
Dimensions	245x90x180 mm (WxHxD)
Housing	ABS plastic, UL listed
Weight	2.6 kg (approx.)

Max. storage period 3 months without charging
 Permitted temperature range (operation/storage) 15°C - 35°C / 0°C- 40°C
 Permitted relative humidity 20-90% max. (no vapor deposit)

Atmospheric pressure 500-1000 hPa
 Safety certification DIN IEC 601 Part 1
 EN55011 Radio interference
 IEC60601-1-2 Susceptibility
 IEC60601-2-24

Operating modes Continual, manual bolus, automatic bolus, priming.
 Labeling of the pump 12 alpha numeric characters.
 Configured through IR interface.

History Up to 1500 data logs with real time stamps.
 Read out and printout through IR interface and PC.

Time to alarm after occlusion (PVC set), volume of bolus **without** bolus reduction:

Pressure Rate	1.0 bar	500 mbar	100 mbar
1 ml/h	>60 min	45 min	8 min
20 ml/h	3.5 min	100 sec	20 sec
100 ml/h	50 sec	25 sec	5 sec
999 ml/h	6 sec	2.5 sec	0.5 sec
Bolus	0.9 ml	0.45 ml	0.09 ml

3. Operation

The figures in brackets refer to the illustrations of front and rear views shown in the appendices.


CAUTION: Use only approved disposable administration sets!
(cf. leaflet "Accessories and Consumables")

The performance of the pump depends on both pump and administration set. The volumed must only be used with the sets the pump has been calibrated to. The functional safety of the pump cannot be guaranteed if non-approved IV sets are used. The safety of the patient may be compromised as a result.

Disposable IV sets are for single-use only. Single-use needles carry an infection hazard and must be disposed of in accordance with local guidelines. The IV-set should be replaced every 24 hours.

3.1. Preparation and loading of the administration set

- a) If the pump is to be operated on an infusion stand, care must be taken that the pump is not positioned more than 1.4m above the ground to ensure stability. Ideally use an "Arco Luxe" or "Arco Standard" infusion stand. If several pumps are mounted one above the other the maximum permitted height from the floor must be observed and measures taken to **prevent instability**. The pump may be fixed to the infusion stand by means of the pole clamp (29) on the rear of the unit.
- b) Slot the **drip chamber** (2) into the empty container detector (4). Make sure that there are no large ribs or joints in the passage of the empty container detector and that fallen drops are detected by the drop-detector's light-barrier.
- c) Carefully purge the **infusion set** (1), without allowing any air bubbles to enter, until the drip chamber (2) is 1/4 to 1/3 full. If air has entered, repeat purge-procedure.
- d) Close the tubing **roller clamp**.
- e) Open the **pump door** (5) by pulling the **latch** (6).
- f) Pump with Robson Clamp:
Position the **Robson clamp** (3) on the tubing. In case of a silicon insert tubing, position the Robson clamp just left of the silicone segment. Close the Robson clamp. Hold the tubing with your right hand with your thumb positioned on the Robson clamp. Starting with the left side, insert the IV set into the left **tube guide** (11). Ensure that the flow direction of the pump from the left to the right is respected and the tubing is in a straight line. Put the Robson clamp with your thumb into the **Stop Flow device** (14) and insert the remaining tubing onto the right tube guide (11).
Pump with internal clamp:
Starting with the left side, insert the IV set into the left and right **tube guides** (11). Ensure that the flow direction of the pump from the left to the right is respected and the tubing is in a straight line. In case of a silicon insert tubing verify the correct position of the silicon insert as shown in the front view of this manual.
- g) Close the door (5) and push the **latch** (6) firmly against the pump. Open the tubing **roller clamp**.

- h) **Switch the pump on:** Press ON/OFF key () (10). The audible alarm beeps once together with the indication < ! > in the alarm window (21). The software version number (μVP7000, rx.xx) and the configuration of the pump (μVP7000, c.xxx) light up briefly.

Wait until the automatic **Stop Flow test** is terminated.

- i) Check if there is no free flow. Where possible mains power should be used. Plug the mains power cable into the connector socket (18) at the rear of the pump. The mains pictogram illuminates as soon as the mains supply is connected. The battery is charged automatically.
- j) The Volumed μVP7000 has the possibility to **prime** the line with the pump. Make sure the patient is always disconnected when priming:
Press the bolus key (19) until the LCD display (20) shows: *priming?* Press and hold the bolus key until the priming is finished. To terminate the priming mode press the Start/Stop key (10). Important: during priming both air alarm and empty bag alarm are ignored. The prime rate is displayed in the rate window (8).

- k) **Connect set to the patient.**

Important: Before the door is opened, close the roller clamp!

3.2. Setting rate (ml/h) and volume (ml)

Use the UP/DOWN keys (16) to select the required rate in ml/h indicated in the RATE display (8). Arrow up keys provide rate increase, arrow down keys provide rate decrease. Check that each key stroke changes one digit. The least significant digit (small size) indicates 0.1 (units).

If a specific volume (VTBI) is to be infused, the required volume in mls may be selected in the VOLUME window (10) using the UP/DOWN keys (13) before starting the pump (optional). Once the VTBI is reached, the pump gives an audible alarm and displays <INF COMPL> (infusion complete) in the Alarm window (21). The pump switches to the KVO rate.

Remark: With the empty bag detector (4) the pump stops automatically after the last drop in the bag. If no empty bag detector is used, the volume (VTBI) has to be set to stop before the bag is completely emptied. Otherwise the pump continues infusing until air is detected in the air detector (18). Hence, it is strongly recommended to use the empty bag detector.

3.3. Pump running

When the pump is running, the green drop symbol flashes (22). The VOLUME display now indicates the volume infused in mls. In order to display various data, such as pump condition, volume to be infused, infusion time, time to end of infusion, battery condition, pressure and pressure limit, press the OPTION key (18) sequentially and observe the LCD window (20) until the required data is displayed.

If a specific volume to be infused was selected the pump automatically switches to KVO operation when this volume has been infused and an audible and visual alarm (21) activates.

Press the ALARM SILENCE key (5) to silence the audible alarm for 2 minutes.

3.4. Resetting the volume infused

In order to reset the volume infused, stop the pump by pressing the STOP key (10). Press the OPTION key (18) for 2 seconds until the VOLUME display (9) flashes. When the LCD window (20) displays "000", confirm this by pressing the START/STOP key (10) to reset the volume infused to zero. If it is not desired to reset the volume infused, press the OPTION key (18) until the normal display appears.

3.5. Infusing a bolus

When the pump is infusing, a manual or an automatic bolus can be given.

To infuse a manual bolus:

Press the OPTION key (18) and the BOLUS key (19) together.

The bolus rate is displayed in the RATE window (8) and the bolus volume infused is displayed in the VOLUME window (9). The LCD window (20) indicates "Bolus manual". Keep the keys depressed until the required bolus volume has been infused. As soon as the keys are released the pump reverts to the normal infusion mode.

To infuse an automatic bolus:

Press the Bolus key (19) for 2 seconds until the display in the VOLUME window (9) flashes. The desired bolus volume in mls can then be preset in the VOLUME display using the VOLUME keys (13). Press the BOLUS key (19) to deliver the bolus automatically. If no bolus is required, press the OPTION key (18) to cancel.

During automatic bolus delivery, the RATE display (8) indicates the bolus rate and the VOLUME display (9) indicates the bolus volume infused. The LCD window (20) indicates "Bolus automatic".

To stop the pump at any time press the STOP key (10).

After the selected bolus volume has been delivered, the pump switches automatically to normal delivery mode.

Following bolus infusion, the bolus volume is added to the total ml infused.

3.6. IV container exchange

When changing the plastic container or bottle, infusion can be interrupted at any time by means of the 'Start/Stop' key (18) without affecting the set or displayed values. In this state, handling operations such as changing the container or IV set and rate changes can be implemented without activating the alarm. In the stop mode, 'KVO' operation is automatically activated.

If the pump remains in the stop mode for more than 4 minutes, the audible reminder alarm will sound.

3.7. Recall of previous data

If the pump has been accidentally switched off, data such as rate, volume to be infused and volume infused may be recalled during start up. Press the START/STOP key (10) and the ON/OFF key (7) together to recall all data.

3.8. Setting volume and time

If a specific volume is to be infused in a given time the RATE display must be left at zero. After inserting the IV set, closing the door and finishing the automatic test press and hold the OPTION key (18) until the RATE and VOLUME displays flash.

The time in hours and minutes may be selected in the RATE display (9) and the volume selected in the VOLUME display (9). The pump automatically calculates the infusion rate. Check this carefully in the LCD window (20) before starting the infusion.

3.9. Pressure system

The Volumed μ VP7000 has automatic pressure monitoring whereby the pressure in the system is measured via the pressure transducer. The alarm pressure limit can be set automatically or manually.

Automatic setting:

If the pump is configured for this mode, the alarm pressure limit is automatically matched to the set rate, the lower the rate, the lower the alarm pressure limit. The time to alarm can be viewed in the table of section 2.

Manual setting:

Press the OPTION key (18) sequentially to display pressure and alarm pressure limit in the LCD window (20). Hold down the OPTION key (18) until the VOLUME display (9) flashes "Lxxx". The pressure limit may be manually set using the VOLUME keys (17) in the VOLUME display (9) and the data in the LCD window changes accordingly. This can also be done while the infusion is in progress. NOTE: Manual setting of pressure deactivates the automatic pressure setting, i.e. the pressure remains at the current level independent of the rate selected.

If the pressure rises beyond the limit set, the pump stops and the stored bolus is automatically reduced to virtually zero volume. An audible and visual alarm is activated. Check the IV carefully for the cause of the alarm. Do not restart the pump until the occlusion is released.

3.10. Setting time and date

Press the OPTION key (18) sequentially to display date and time in the LCD window (20). Hold the OPTION key (18) down until the display flashes. The time may be set using the volume keys (17) in the Volume display (9), e.g. h9.45 = 9:45 am. This can also be done while the infusion is in progress.

The Volumed has the possibility to automatically adjust the daylight save time (summer time). The adjustments can be done as per EU, US or Australian regulations. If the text 'Clock !' should appear, replace the Lithium backup battery on the main PCB.

To set the date, first switch the pump off. Press the VOLUME 0.1 ml DOWN and VOLUME 100 ml DOWN keys (17) together whilst switching the pump on. This enables the Service Mode. Select the RATE display (8) according to the following table using the RATE keys (16). Then select the corresponding data in the VOLUME display (9) using the VOLUME keys (17). Press the START key (10) each time to confirm each setting:

<u>Rate display (9)</u>	<u>Volume display (10)</u>	<u>Function</u>
145	0 - 99	Year
144	1 - 12	Month
143	1 - 31	Date
142	1 - 7	Weekday (Monday = 1, Sunday = 7)

Press the ON/OFF key (7) to switch the pump off.

Note: Incorrect setting of date or time does not affect the correct functioning of the pump.

3.11. Different configurations

If a different configuration is required, please contact our Customer Service Department or the official ARCOMED distributor in your country.

3.12. Accessories and consumables

Accessories, expendable parts and single-use items may only be used if they comply with the appropriate international standard and national approvals. Sets, filters and extension sets must be CE marked. The ordering numbers can be found on the leaflet "Accessories and Consumables"

The Instructions for Use, the mains power supply cable and the empty bag detector (optional) are included as standard equipment with the Volumed µVP7000. For accessories see also 3.19.

3.13. START/STOP key (10)

The START/STOP key (10) is used to start the pump after the rate has been selected. The pump may be stopped at any time using this key. An additional function of this key is to confirm various parameters.

3.14. Prime / Bolus key (19)

The PRIME/BOLUS key (19) key is used to prime the extension set. It is also used to initiate a manual or automatic bolus (3.5).

3.15. AUDIBLE ALARM SILENCE/ OPTION key (18)

The audible alarm may be silenced for 2 minutes using the ALARM SILENCE/OPTION key (18). The audible alarm is re-activated after this period.

If there is no audible alarm, the key serves as an OPTION key which enables selection of any option.

3.16. ON/OFF \odot/\circ . key (7)

The pump may be switched off using the ON/OFF key (7) if the infusion has been completed. All data displayed (rate and volume) is lost when the pump is switched off. In order to avoid switching the pump off accidentally, the ON/OFF key (7) must be pressed for at least one second before the pump switches off.

If the pump is connected to the mains, the STANDBY mode will switch in when the pump is switched off. This means that the battery will be charged and the charge condition indicated in the LCD window.

3.17. Keep-Vein-Open (KVO) - Rate

The pump may be configured to infuse at the keep vein open rate when the volume to be infused has been delivered. The KVO rate is preset at 3.0 ml/h and may be set (by a technician) to suite individual requirements if necessary. If the set rate is smaller than than the KVO rate, this rate becomes the KVO rate.

Remark: The latest standard uses the new wording Keep-Open-Rate (KOR). The meaning is identical to the KVO-rate.

3.18. Using the pump in parallel or multiple infusions

If additional infusion systems are connected to the patient's vascular system, this may lead to complications e.g. infusion of air, reverse-flow, interruptions due to alarms and inaccurate flow.

To prevent such incidents, please observe the recommendations as stipulated in DIN VDE 0753, Part 5 or contact your distributor.

3.19. Options for external connection to the pump

Accessory equipment connected to the analog and digital interfaces RS232 interface (IR interface) must be certified according to the respective IEC standards (e.g. IEC 950 for data processing equipment and IEC 601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC 601-1-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC 601-1-1. If in doubt, consult the technical service department or your local representative.

- Use cable number 94070 to connect the Nurse call system. Important: The alarms on the pump have to be observed also when the nurse call is connected.
- If an external 12 VDC power supply is used and is linked to other equipment, ensure that the safety of the system complies with IEC60601-1. Use cable number 71630.
- Use only the external empty container detector Nr. 98502 (4)

Please contact the Customer Service Department of ARCOMED AG for details of the RS232 interface (IR interface) and how to link it to external systems.

4. Alarm system

4.1. Alarm causes

The electronic self-monitoring system continuously monitors the correct functioning of the pump and its displays whilst in operation. If a fault should occur, the infusion is stopped immediately and the alarm activates. The corresponding alarm symbol is illuminated continuously with a red colour and there is a continuous audible alarm. The nurse call alarm is activated at the same time.

The pump will not start:

- if no rate has been set (0 ml/h).
- if air is in the line
- if the door is open.
- if the IV set or the Robson clamp is not correctly installed.

During operation an audible alarm activates and the pump switches to the KVO rate if:

- the START/STOP key is operated.
- the VTBI is reached
- attempts are made to alter the rate during operation.

During operation an audible alarm activates and the pump stops if:

- the roller clamp is not opened.
- the bag is empty.
- battery capacity is low and the charge can no longer ensure controlled infusion.
- the infusion pressure exceeds the limit set.
- the door is opened.
- there is an internal defect.

With empty bag detector:

- if the detected drops do not correspond with the set tolerances.
- if the level in the drip chamber is too high.

4.2. Canceling the alarm condition

After rectifying the cause of the alarm or acknowledging the rate change, the alarm condition is canceled and infusion resumed by pressing the START/STOP - key (10).

4.3. Pressure limit/occlusion alarm

If the pressure in the system reaches the set pressure limit due either to a total or partial occlusion, the alarm activates and the occlusion alarm symbol and rate display flash. The LCD window displays "occlusion! check line!" The vein site should be checked to ensure there is no complication.

If the cause of the occlusion is removed, the occlusion symbol flashes and the pump may be started again.

4.3. Battery alarm

The pump may be operated independently of the mains power supply using the internal battery. If the mains power supply fails, the pump switches automatically to battery operation to continue the infusion without interruption.

Battery operation is indicated by illumination of the battery symbol (22). Battery capacity permits from 3 up to 6 hours operation (1.85 Ah battery) depending on the infusion rate set. After approximately 3 to 6 hours operation the battery symbol in the alarm display (21) illuminates and an audible alarm activates. Alarms are canceled automatically as soon as mains power is restored.

A low battery alert is activated approximately 30 minutes before the battery depleted alarm. The battery symbol (21) flashes and an audible alarm activates. To silence the audible alarm, press the ALARM SILENCE key (18). The battery symbol continues to flash until the pump is reconnected to the mains.

A cautionary alarm is activated if the pump is disconnected from the mains power supply whilst in operation. This alarm may be silenced using the ALARM SILENCE key (5).

4.4. Nurse call

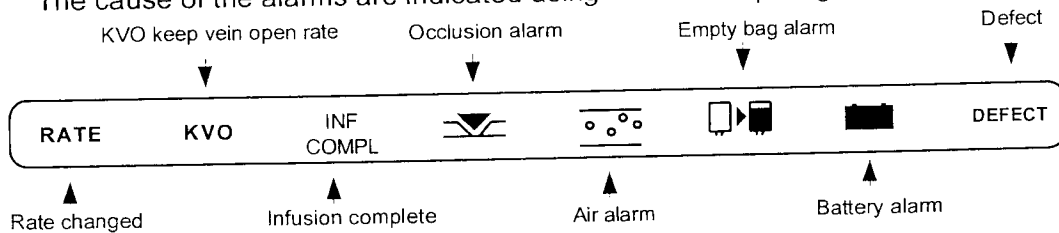
The pump may be connected to the external nurse call system via the connector (25) on the rear of the unit using cable part number 94070. All alarms are transmitted to the nurse call station. The normal pump alarms and displays continue to function.

4.5. Alarm silence

Audible alarms may be silenced for approximately 2 minutes using the ALARM/SILENCE key (18). The audible alarm is reactivated after this period.

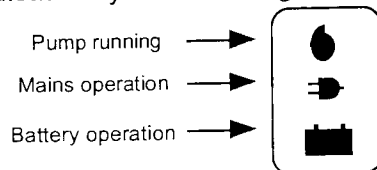
4.6. Alarm indicators (18)

The cause of the alarms are indicated using illuminated pictograms as shown:



4.7. Power and running indicators (22)

These are indicated by the following:



4.8. LCD window (20)

Various messages and infusion parameters are displayed in this window.

4.9. Technical description

The Volumed μ VP7000 is a microprocessor-controlled infusion pump with stepper motor drive and comprehensive software management function monitoring. The pump is operating range enables infusion rates from 0.1 ml/h to 1, 999 ml/h to be made. An internal rechargeable battery allows the unit to operate independently of the mains in emergencies or when used as a mobile unit. The mechanism is driven by a step motor via a toothed belt and friction spindle. All important operating parameters are clearly shown on an LED indicator. Setting the desired values is done via touch-pad keys. The unit is manufactured using the latest surface mounted control technology (SMD).

5. Warranty

Arcomed AG offers a twelve month warranty on each Volumed μ VP7000 volumetric pump effective from date of delivery.

The warranty covers the installation and replacement of faulty parts if caused by faulty assembly or materials. The warranty is rendered null and void if changes or repairs are carried out by persons who have not been authorized in writing to do so by Arcomed AG or Arcomedical Infusion Ltd and if the inspection and maintenance intervals are not observed.

The warranty does not cover the elimination of problems caused by incorrect operation, inappropriate handling or normal wear and tear,
The supplier only accepts responsibility for the safety, functional reliability and performance of the equipment providing that

- assembly, extension work, resetting, modification or installations are carried out by personnel authorized by him.
- the electrical system at the operating site meets IEC requirements.
- the unit is used in accordance with these Instructions for Use.

The information provided in this manual applies to the currently prevailing situation and is given in good faith. The manufacturer reserves the right to make modifications in the interest of technical progress.

5.1. Design changes

Arcomed AG endeavour to ensure that future improvements and modifications are compatible with earlier models.

NOTE: Always state the model, serial number and where applicable the colour of the unit in question when ordering spares.

**6. Inspection and maintenance intervals Volumetric Infusionpump
Volumed® μ VP7000 (according MDD)**

Interval: After 24 months or 10'000 h of use.

The following checks must be done by an engineer with sufficient technical background to comply with the safety regulations.

What to do	How / Equipment	Remarks	Result
Visual Check			
Housing		Physical damage	
External empty container detector (ECD) (Easy Clip)		Physical damage	
or Internal empty container detector (ECD) (especially spring)		Physical damage	
Door, door latch		Clean, function	
Stop-flow lever		Clean, function	
Cover for peristaltic blades		Physical damage	
Inscriptions, display		Readable, damage	
Display - LED		Function, display test	
Mains plug, fuses		Damaged, values	
Air in line		Physical damage	
Functional checks			
o <u>Spring plate</u>	manual	check free motion	
o <u>Pressure checks:</u>	IV-set filled with water, manometer & tubing		
o minimal mechanical pressure:	preload system with syringe to 0.7 bar	watch manometer	o alternative test PTD-7000
	4 min. at rate 5 ml/h (press. limit 999 mbar)	pressure always above 0.6 bar	p min =
o maximal mechanical pressure:	rate 400 ml/h (press. limit 999 mbar)	pressure always below 2.5 bar*	p max =
o <u>Pressure Sensor:</u>	rate 100 ml/h pressure limit 500 mbar make occlusion on set	alarm reaction within 20 sec \pm 10 sec	
o <u>Rate check:</u>	Rate 100 ml/h Total of 100 ml	\pm 5 % accuracy* Refer to trumpet curve (tech manual)	o alternative test VT-5000 % dev =
<u>while running on 100 ml/h</u>			
o simulate missing drops	Take out drop chamber of ECD detector	Visual and acoustic alarm	
o simulate Air in Line	Air bubble (eg reverse drip chamber) in the line	Visual and acoustic alarm	
o check nurse call	e. g. open door while pump is running	alarms and switching signal at connector	
o (External pump stop	only Option RS 232C)		
<u>Electrical safety according to IEC 601</u>	Safety Tester IEC 601	IEC 601.1, section 19	
o Leakage current	\leq 75 μ A		
o Resistance protective conductor	\leq 100 mOhm		

The rates of the fuses must comply with the rates recommended by arcomed (producer):
Conventional transformer 230V :100 mA/250V, toroid transformer 230V: 250 mA/250V,
toroid transformer 115V: 500mA T/250V (IEC127/III/SEV 1064).

Caution: After any work on the pump (e. g. adjustment of programming, change of parts, any opening of the pump) this inspection must be made and all checks must be documented with the serial number of the pump.
* depending on set: eg. 8101P PVC 2.5 bar \pm 5%; 8101P Silicone 1.5 bar \pm 3%

Serial Number:

Remarks:

Date /Signature:

7. Performance

7.1 Significance of trumpet curves for practical use

Trumpet curves indicate for 5 different observation windows the maximum and minimum mean values of the flow rate in ratio to the preset flow rate.

Known therefore is the discrepancy per time-window. For optimal use of the infusion pump Volumed® μ VP7000, the trumpet curve is an important factor in deciding whether the pump can be used with the prescribed drug.

Volatile drugs with short therapeutic half life demand high accuracy.

For a drug where the plasma-half life is e.g. 1 min. discrepancy of the flow rate of 15% per minute would mean the same discrepancy for the plasma level. Therefore, a predictable constant impact of the drug would not be guaranteed.

Example:

Intravenous infused Insulin has a therapeutic half life of 15 minutes. A flow deviation of $\pm 15\%$ within 40 minutes would have at least the same (rather twice as much) influence on deviation of the plasma level and therefore on its impact.

This is unacceptable to physicians and nursing personnel.

It is important to know that the deviation in a short observation window depends strongly on the preset rate. The Volumed® μ VP7000 has at a rate of 25 ml/h a deviation smaller than $\pm 2\%$ in a observation window of 2 minutes. With 5 ml/h the deviation in the same observation window is $\pm 7\%$, within 5 minutes it is $\pm 3\%$. Mean deviations are within $\pm 5\%$ (see also following table).

Table 1: Flow Accuracy of the Volumed® μ VP7000 (typical values)

Rate (ml/h)	2 min		5 min		Testzeit (h.min)	Messzeit (h.min)
	Max	Min	Max	Min		
5.0	+6.93%	-5.99%	+3.08%	-3.45%	2.00	1.00
25.0	+4.54%	-3.65%	+1.39%	-1.46%	2.00	1.00
100.0	+0.60%	-1.17%	+0.28%	-0.76%	2.00	1.00

Rate (ml/h)	eff. Rate (ml/h)	Abweichung (%)	Stand.-Abweichung (ml/h)	Testzeit (h.min)	Messzeit (h.min)
5.0	5.010	0.203	0.010	2.00	1.00
25.0	24.800	-0.399	0.200	2.00	1.00
100.0	101.182	1.182	1.182	2.00	1.00

File Name:

25ml/h IEC 7000

o Flow (2nd h):

25.788

o Error[%] (2nd h):

3.153

Reg. date:

11.2.2002

Rec. time:

10:54:24 Uhr

Rate (ml/h):

25.0

Evaporation:

0.00

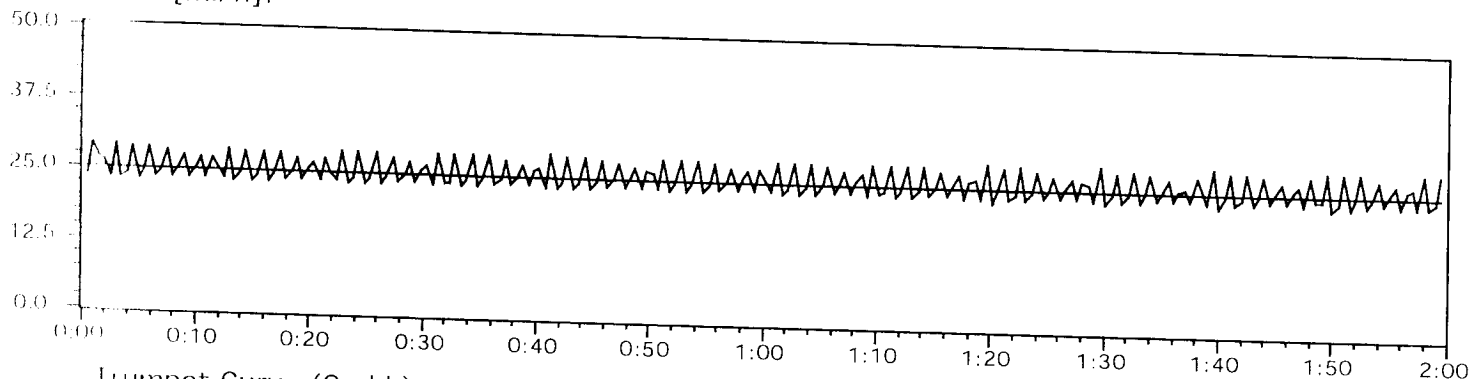
Scans:

240

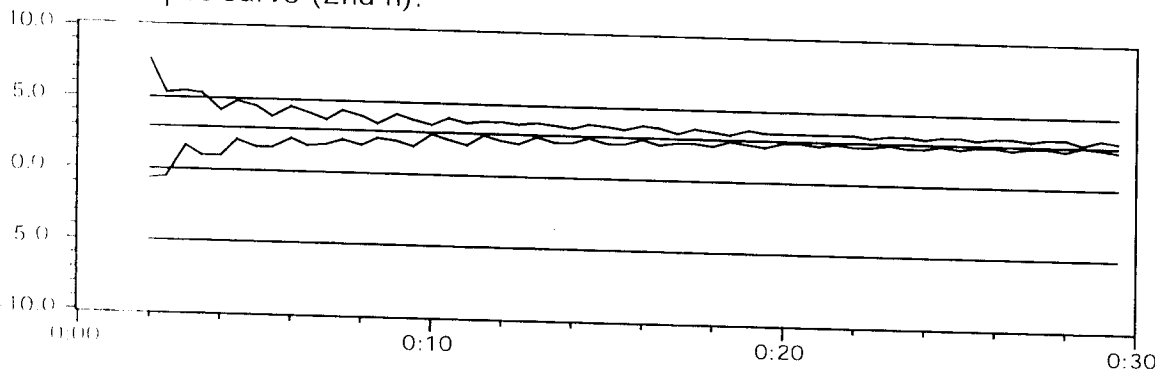
Interval (s):

30

Flow [ml/h]:



Trumpet Curve (2nd h):



2 Min (max): 2 Min (min):

4.54 -3.65

5 Min (max): 5 Min (min):

1.39 -1.46

11 Min (max): 11 Min (min):

0.60 -0.88

19 Min (max): 19 Min (min):

0.57 -0.37

31 Min (max): 31 Min (min):

0.28 -0.33

File Name:

5ml/h IEC 7000

Ø Flow (2nd h):

5.010

Ø Error[%] (2nd h):

0.203

Rec. date:

19.7.2002

Rec. time:

10:07:52 Uhr

Rate (ml/h):

5.0

Evaporation:

0.00

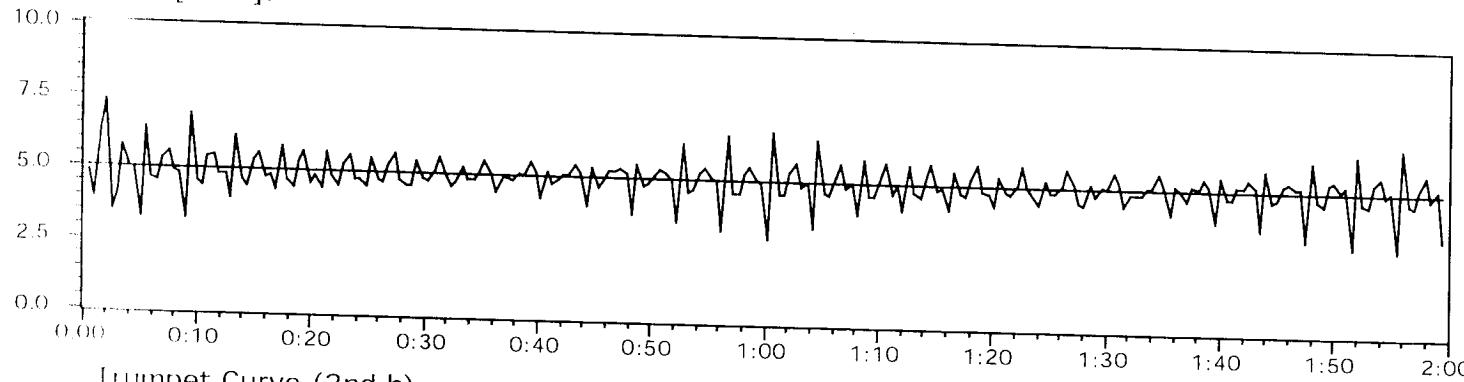
Scans:

240

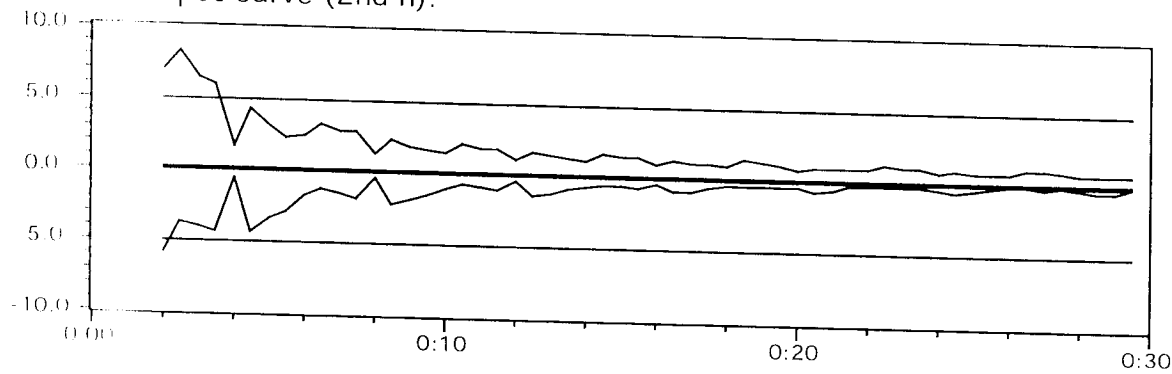
Interval (s):

30

Flow [ml/h]:



Trumpet Curve (2nd h):



2 Min (max):	2 Min (min):
6.93	-5.99
5 Min (max):	5 Min (min):
3.08	-3.45
11 Min (max):	11 Min (min):
1.77	-0.91
19 Min (max):	19 Min (min):
1.23	-0.52
31 Min (max):	31 Min (min):
0.71	-0.14