Smiths Medical Publications

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Users of the equipment must ensure that they have read and understood the contents of the complete manual including the warnings and cautions and have been trained in the correct use of the product.

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This publication maybe subject to revision and it is the users responsibility to ensure that the correct version of manual/ text/illustration is used in conjunction with the equipment.

ACCEPT REJECT

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Smiths Medical MD, Inc.,
1265 Grey Fox Road, St. Paul, MN 55112, U.S.A.

European representative:
Smiths Medical International Limited
Watford, Herts, UK, WD24 4LG
www.smiths-medical.com

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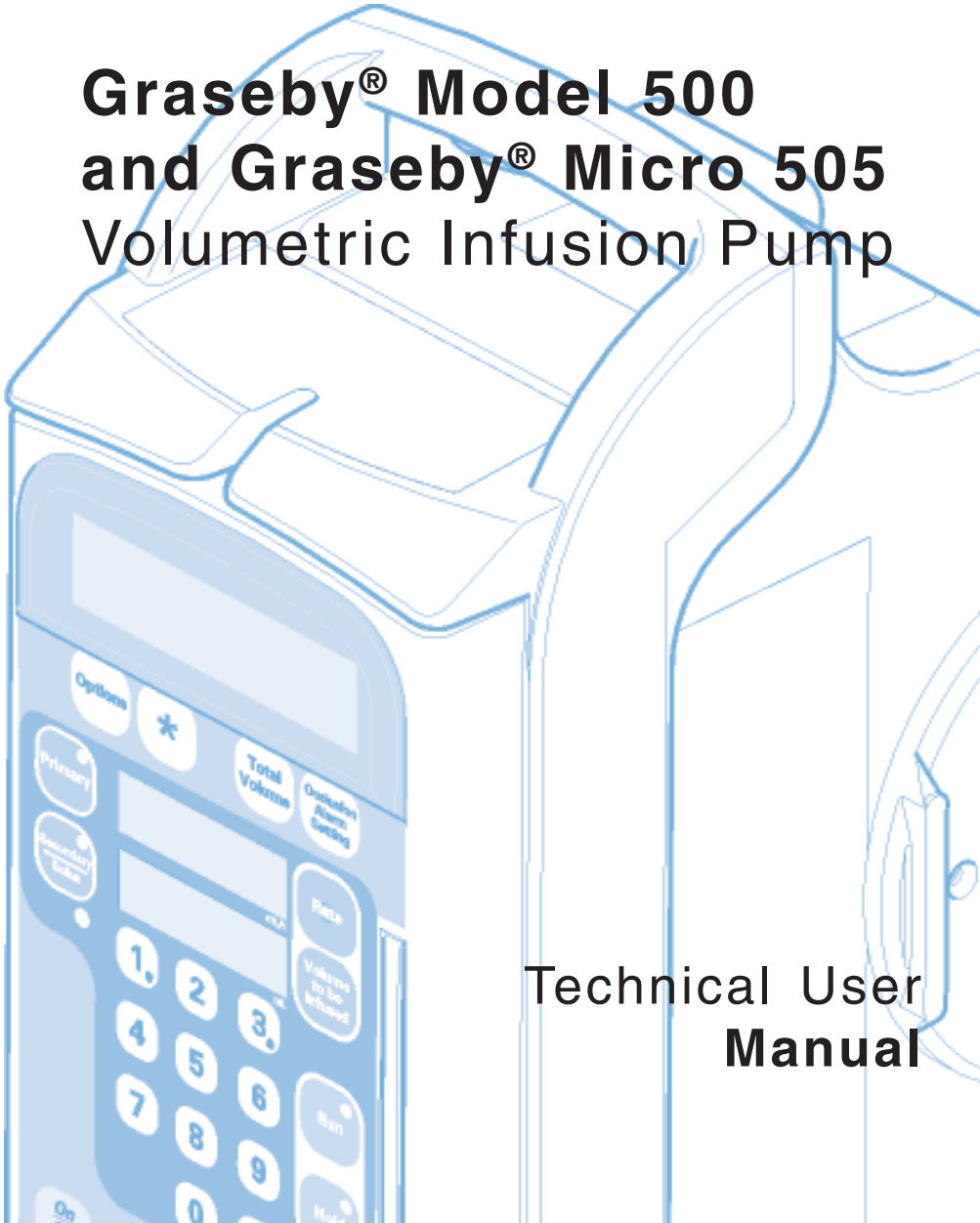
Graseby® Model 500 and Graseby® Micro 505
Volumetric Infusion Pump



Technical User **Manual**

Published by Smiths Medical MD, Inc.

Smiths Medical MD, Inc.
1265 Grey Fox Road, St. Paul, MN 55112, U.S.A.

European Representative:
Smiths Medical International Limited
Watford, Hertfordshire, UK, WD24 4LG

www.smiths-medical.com

Registered in England.

Company number 362847

Warnings

Warnings tell you about dangerous conditions, that could lead to death or serious injury to the user or patient, that can occur if you do not obey all of the instructions in this manual.

1. **WARNING: You should ensure that the performance offered by the pump is fit for the intended purpose. Failure to do so may result in compromised function of the product, patient injury or user injury.**
2. **WARNING: Do not use a faulty pump. If the pump detects a fault when it is first turned on, or if it develops a fault during operation then a continuous system alarm sounds. The pump must be referred to a suitably qualified technician or returned to Smiths Medical in order to have the fault rectified.**
3. **WARNING: Before using the pump, it should be inspected for physical damage. The pump should not be used if damage is evident, and should be returned to service personnel for repair before being returned to use. Failure to do so may result in compromised function of the product, patient injury or user injury.**
4. **WARNING: Do not use the pump if you detect any cracks, chips and loose or bent parts, or if the buttons do not move in and out freely when they are pressed. Failure to do so could cause inadvertent disconnection of the pumps.**
5. **WARNING: To avoid possible malfunction of the pump, do not expose the pump to X- rays, gamma rays or ionizing radiation, or to the RF interference or strong electric/magnetic fields emitted (for example) by diathermy equipment or mobile telephones. If the pump is used in the presence of, or in combination with Magnetic Resonance Imaging (MRI) machines it must be protected from the magnetic field emitted by such equipment. Malfunction of the pump can cause incorrect infusion or loss of infusion resulting in patient injury or death.**
6. **WARNING: Do not push or pull on the pumps, or the IV pole may tip over or the pumps fall to the floor. Do not try to remove modular connected pumps from the IV pole whilst they are joined together. Either of these could cause the administration set to separate from the fluid container thus spilling the medication, or the pumps themselves could be damaged.**
7. **WARNING: Correct entry of data is essential in order to ensure that the intended infusion is performed. Before confirming any displayed data when setting up an infusion, you should ensure that it is correct. Failure to do so may result in compromised function of the product, patient injury or user injury.**
8. **WARNING: Dose-rate calculation requires care in entering data. Refer to specific product drug labelling for information on appropriate administration techniques and dosages. Entering incorrect data may result in patient injury or death.**
9. **WARNING: When delivering drugs in the epidural space, use only those medications specifically indicated for epidural use. Epidural administration of other drugs could result in serious patient injury or death.**
10. **WARNING: The use of administration sets incorporating injection sites could lead to an improper or inappropriate infusion resulting in serious patient injury or death.**
11. **WARNING: Failure to clearly identify the pump and administration sets could lead to an improper or inappropriate infusion resulting in serious patient injury or death.**
12. **WARNING: Remove any air to prevent air embolism. The presence of air within the infusion can result in complications resulting in patient injury or death.**
13. **WARNING: To avoid over infusion, do not prime the infusion line when the administration set is connected to the patient. Over infusion can result in patient injury or death.**
14. **WARNING: The Occlusion alarm level must be checked before starting an infusion to ensure that it is appropriate for the infusion. Failure to do so may result in an unacceptably slow time to Occlusion alarm, resulting in patient injury or death.**
15. **WARNING: Prior to starting an infusion, inspect the fluid path for a closed clamp or any other obstructions or restriction. Failure to do so may result in the infusion not being delivered correctly, resulting in patient injury or death.**
16. **WARNING: If using a blood pressure cuff above the patient's venipuncture site take extra care in setting the Occlusion alarm pressures. Failure to do so may result in unnecessary Occlusion alarms, resulting in patient injury or death.**

17. **WARNING: The Occlusion detection system measures downline pressure in the administration set, but does not detect infiltration. In accordance with local protocol, you must periodically inspect the patient's infusion site for signs of infiltration. Failure to do so may result in an unacceptably slow time to Occlusion resulting in patient injury or death.**
18. **WARNING: If an Occlusion alarm occurs, immediately clamp the line to the patient. Then inspect the fluid pathway to determine what has caused the obstruction. An unintentional bolus of medication can result in patient injury or death.**
19. **WARNING: Do not run parallel infusion lines below the pump. Delivering a Secondary infusion means running a second line *above* the pump. Failure to do so may result in an inaccurate delivery of medication, resulting in patient injury or death.**
20. **WARNING: Check the Secondary set carefully, since an occlusion above the pump on the Secondary line could cause the Primary fluid to be delivered instead of the Secondary infusion. Administering the wrong medication may cause serious patient injury or death.**
21. **WARNING: The Secondary volume to be infused must match the amount of fluid in the secondary container. Primary flow resumes when the secondary container is empty. If the volumes do not correspond, the wrong infusion may be delivered which could cause serious patient injury or death.**
22. **WARNING: Delivery rate for secondary medication must not exceed 300 ml/hr, or fluid may be delivered from both primary and secondary container causing delayed delivery of secondary medication and unintended mixing of fluids. Failure to do so may result in patient injury or death.**
23. **WARNING: Correct management of battery charging, as described in this documentation is essential to ensure that the pump can operate on battery for the time specified. Failure to do so may result in compromised function of the product or patient injury.**
24. **WARNING: If a backup alarm sounds, the pump should be immediately removed from the patient and sent to be repaired by a Smiths Medical qualified technician. Failure to do so may cause patient injury or death.**
25. **WARNING: Failure to use the power cord retainer means that the pump may be accidentally or erroneously disconnected from the mains. Although there is a battery backup in case this happens, the battery may not be charged sufficiently. Consequently, there is a risk of the pump not functioning which could lead to patient injury or death.**
26. **WARNING: Do not open the pump housing. Refer all service faults only to qualified technical personnel. Opening the pump housing may cause electric shock leading to patient or user injury or death.**
27. **WARNING: When the pump is carrying out an infusion, to ensure that electrical safety is maintained, only items of equipment that conform to EN60950 are to be connected to the RS232 connector situated at the back of the pump, otherwise patient safety may be compromised.**
28. **WARNING: While Smiths Medical have taken all reasonable steps to ensure that the pump operates correctly while under remote control, it is the responsibility of the person who designs and implements the controlling device to ensure that the resulting system (pump and controlling device) is fit for its intended purpose. Failure to do so may result in compromised function of the product, patient injury or user injury.**
29. **WARNING: Use only Smiths Medical administration sets with this product. Failure to do so may result in compromised system accuracy leading to complications resulting in patient injury or death.**
30. **WARNING: Ensure that there is no clamp or other obstruction in the administration set above the pump. If the line is obstructed, there will be no flow of fluid and air back to the Primary fluid reservoir. In this case the pump cannot eliminate the air from the line above the pump and a pressure build-up may cause fluid leakage. Failure to observe this warning could lead to serious injury or death.**

Cautions

Cautions tell you about dangerous conditions that can occur and cause damage to the pump if you do not obey all of the instructions in this manual.

1. **CAUTION: Refer all service, repair and calibrations only to qualified technical personnel. Unauthorised modifications to the pump must not be carried out.**
2. **CAUTION: Do not autoclave, steam sterilize, ETO sterilise or subject the pump to temperatures in excess of 55° C (131° F). Excessive temperatures may cause damage to the pump.**
3. **CAUTION: To prevent serious damage to the pump it must not be immersed in any liquids or exposed to strong organic solvents. Wipe off spills immediately. Do not allow fluid or residues to remain on the pump. Additionally, the pump is not designed to allow it to be sterilised. Failure to observe these cautions may cause internal damage to the pump.**
4. **CAUTION: Carry out periodic cleaning following the detailed instructions in the *Volumetric Infusion Pumps Service Manual*. Do not use unapproved cleaning agents.**
5. **CAUTION: When turning the pump on, if screens similar to those illustrated are not displayed, do not use the pump, and send the pump to authorised service personnel.**
6. **CAUTION: Only carry the pump by the handle. Failure to do so may result in damage to the pump, or the pump may be dropped which could cause internal damage to the pump.**
7. **CAUTION: The backlight has a limited life and may, if used constantly, cause the light to dim. Eventually the message display may then need to be replaced. To preserve the life of the message display, you should only turn on the Message Display Light as described here if it is specifically required. Misuse of this feature could lead to both battery and LCD depletion.**

Contents

Introduction

This Technical User Guide accompanies pump software version 0.71 and above. The information in this guide supplements the Volumetric Infusion Pump Instruction Manual which is intended for anyone using the pump on a day-to-day basis. Technical issues, such as acceptance testing, configuring the pump and looking at technical information are not needed by most users, so they are separated into this stand-alone manual.

Apart from acting as a reference for use of the configuration menus, and providing technical details and a pump specification, this manual contains a summary of the initial setting up and acceptance testing of the pump. For more detailed information, see the Volumetric Infusion Pump Service Manual, available on request from Smiths Medical.

Who should read this manual

You should be familiar with the use of the Volumetric Infusion Pump before reading this manual in order to understand the effect of changes you should make with the configuration menus described in this manual.

As well as training in the use of the pump, this manual also assumes that you have appropriate experience of technical aspects of Volumetric pumps.

In order to understand the significance of the functions and features described in this manual, you should have read the Volumetric Infusion Pump Instruction Manual. You may also need to refer to it when using this manual.

You should read this manual if you fall into one of the following groups of people who need to configure the pump rather than using it to run infusions:

- a member of a Biomedical Engineering / Medical Physics department who is configuring the pump for use in a particular environment;
- a Technician servicing a pump;
- a member of a team setting up protocols for the use of a pump in a particular environment;
- a Clinician deciding how a pump should be configured for specialised use;
- a trainer who is setting up the pump.

Contents of the box

The box should contain the following items shown in the diagram below.

- two manuals:

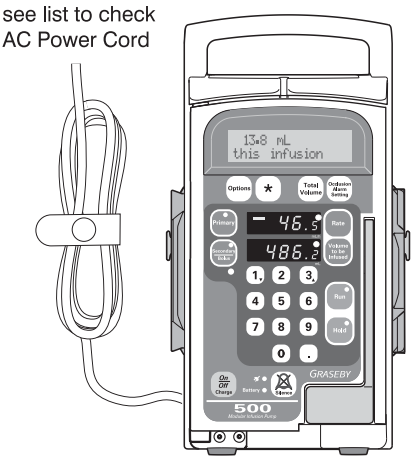
  an Instruction Manual
  and this Technical User Manual
- the Volumetric Infusion Pump
- an AC power cord fitted to the pump with a power cord retainer and screw.

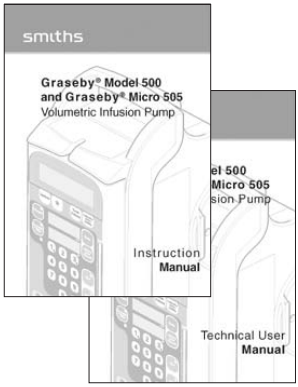
We suggest you keep the box in case you have to return the pump for servicing.

When you have unpacked the pump

When you have unpacked the items, do the following:

- Carry out the *Visual checks* described on page 4 to ensure that no damage has occurred during transit
- Set up, test and configure the pump as described on page 4.





Available AC Power cords

Voltage/country	Part number
120 V, USA, Pan Spanish, Japan, Canadian/French	78-8092-5142-0
240 V, Australian	78-8095-2485-9
240 V, English UK/International	78-8095-2486-7
220 V, European	78-8098-2208-9

GM0166_0012-GB-C

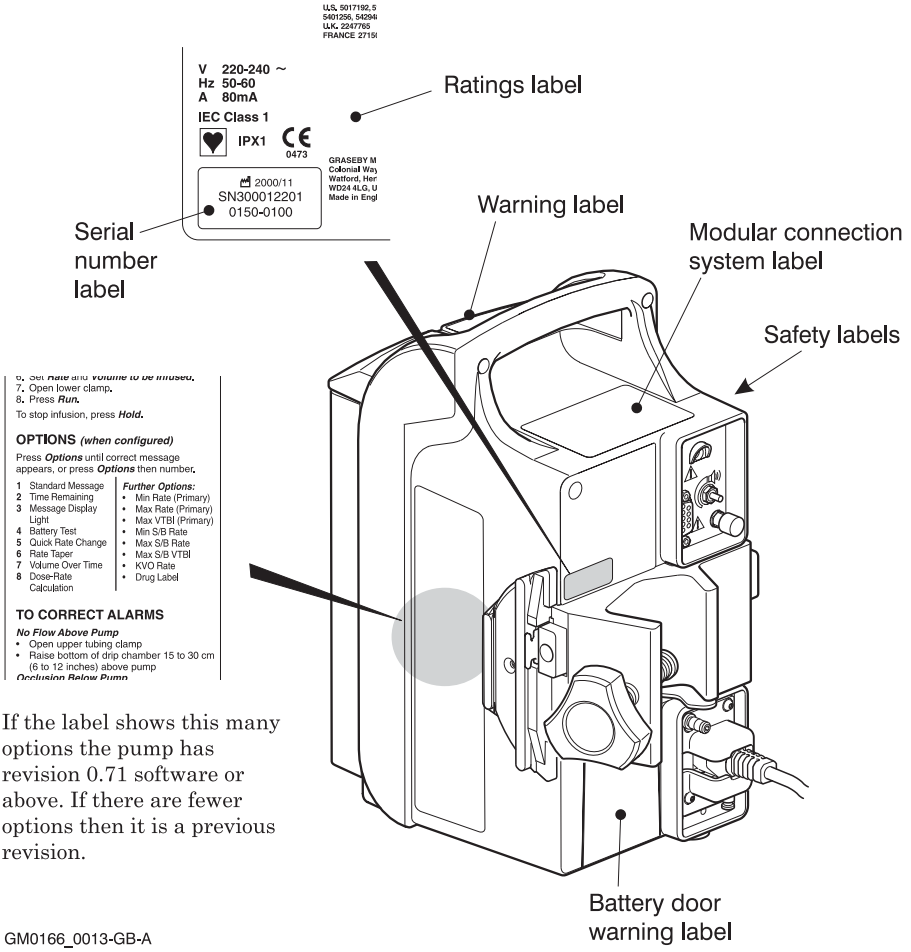
The pump should not be used if damage is evident. Contact your Smiths Medical Service Department

Checking labels and serial number

The pump has a number of labels which should be kept clean and legible. As shown in the diagram below, the instructions label on the right side of the pump can be used to identify the revision of the pump for ordering replacement parts.

Optional Labels

To help users to differentiate the pump and IV set being used for epidural delivery from those being used for other routes of administration, a yellow Epidural Label Set for the Volumetric Infusion Pump (part number TPF-00306) is available from Smiths Medical.



If the label shows this many options the pump has revision 0.71 software or above. If there are fewer options then it is a previous revision.

GM0166_0013-GB-A

Functional inspections and tests

Perform the following tasks when you have taken the pump out of the packaging or when following the regular testing described on page 9.

As you remove the parts from the packaging, check that the parts match the description on page 2.

Visual check

Check for damage:

- check for marks on the pump or other signs of mechanical damage;
- check the appearance of the LCD screen for damage, when the pump is switched off;
- check the serial number and the label as described on page 3.

If you are carrying out routine functional checking, repair or replace any parts that are damaged. Additionally, check for:

- chipping or cracking of the housing and the modular connector system;
- proper movement of the mechanical parts;
- damage to the sleeve or plug on the AC power cord;
- check that the AC power cord retainer is fitted to prevent the cord from being pulled out of the IEC socket.

WARNING: Failure to use the power cord retainer means that the pump may be accidentally or erroneously disconnected from the mains. Although there is a battery backup in case this happens, the battery may not be charged sufficiently. Consequently, there is a risk of the pump not functioning which could lead to patient injury or death.

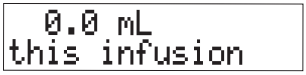
Power up and self test

Test that the pump is functioning correctly.

Switch on the pump and watch the screen and listen to the sounds made by the pump. You should observe the following:

Note: If the pump is switched off and connnected to AC power and the saftey keypad lockout feature is active, the pump cannot be switched on via the keypad. See Instruction Manual, *Safety keypad lockout*, page 2-22.

1. When the pump is connected to the AC mains supply, the green Mains LED lights up.
2. When you press the ***On/Off*** key on the keypad, you hear a click to indicate that you have pressed the key. The pump then performs a self test.
3. The LEDs on the ***Primary***, ***Secondary/Bolus***, ***Run*** and ***Hold*** keys light. The Battery LED also lights.
4. When the self test is complete, the LCD Message Display shows:

   Verify that the backlight is on.
5. Unplug the pump and verify that the mains LED goes out and that the battery LED lights.
6. Connect the pump to the AC mains supply again and, with the pump switched off, open the door. Verify that the pump turns on automatically, and that it does so with the LED on the ***Primary*** key lit.

7. Leave the door open for at least six seconds and verify that the pump does **not** sound the alarm. If it does, there is a fault.
8. Press the ***Secondary*** key and verify that the LED lights and the ***Primary*** key LED goes out.

Use the following checklist for errors that might occur in the above steps.

If any of the following faults occur with a new pump, contact your Smiths Medical Service Department.

- if **any LEDs** do not light in steps 1, 3 or 5;
- if **no sound** is heard in step 2;
- if **no display** appears in step 4;
- if **the backlight** does not come on in step 4.

LCD and LED tests

Run this test with the AC power cord connected to the AC mains supply.

Test the LCD and the LED ambient light sensor as follows. With the pump switched on, you should observe the following:

1. When you view the pump from the front at an angle of about 20 degrees, the LCD message screen should be clearly readable and have a minimum contrast.
2. Cover the ambient light sensor (which is just below the ***Secondary/ Bolus*** key) and verify that the LED display intensity decreases. When you uncover it the display should return to the original intensity.

If any of the following faults occur with a new pump, contact your Smiths Medical Service Department.

- if the **LCD message screen** is not clearly visible;
- if the **ambient light sensor** does not respond.

If there is a fault during a routine service check, repair or replace the faulty parts.

Load an administration set

Prepare a container of solution and prime a 'Standard Adult Set, 8C-820' (non-checkvalve 20 drop/mL) administration set Product Code 21-0346-25 for the following tests. Ensure that a suitable drain is provided for the expended solution.

Prime the administration set using the instructions in its accompanying leaflet.

Verify that the administration set can be loaded into the pump correctly.

Running checks

1. Press the ***Rate*** key and enter 12.3 mL/h. Verify that the correct rate appears in the rate display.
2. Press the ***Volume to be Infused*** key and enter 4567mL on the Model 500 or 456.7mL on the Micro 505. Verify that the correct volume appears in the Volume display.
3. Press the ***Occlusion Alarm Setting*** key and verify that the message display shows the occlusion alarm setting. If the pump is new it will display a Medium setting.
4. Press the ***Rate*** key and enter 890mL/h for a Model 500 pump or 89.0mL/h for a Micro 505. Press the ***Volume to be Infused*** key and enter 88.8mL. Ensure that the lower roller clamp is still closed and press the ***Run*** key. Verify that the

following message is displayed and an insistent alarm sounds:

```
Occlusion
below pump
```

5. Silence the alarm and open the lower roller clamp.
6. Press the ***Run*** key and then press the ***Options*** key. Verify that the message display shows the time remaining with a value like the following:

```
  0 hrs  6 mins
remaining
```

7. Close the upper tubing clamp or pinch the tubing above the pump and verify that the message display shows:

```
No flow
above pump
```

and the pump alarms. Silence the alarm and open the upper tubing clamp, or release the tubing.

8. Press the ***Run*** key. Tip the administration set drip chamber to introduce air into the line. When the air reaches the upper cassette chamber, verify that the pump alarms and the message display shows:

```
Air in cassette
```

Silence the alarm and clear the air as follows:
Ensure any upper clamp is open between the pump and reservoir, then close the lower roller clamp and open the door. Wait for the cassette to fill and then slowly close the door. The air should be expelled up the tube. If necessary repeat the process to clear the remaining air.

9. With pump on hold, press the ***Total Volume*** key and verify that the message display shows a volume and time like the following:

```
 31.5mL  00h 05m
Press * to clear
```

If you have a new pump and it does not behave as described here, contact your Smiths Medical Service Department.

If there is a fault during a routine service check, repair the pump as described in the Service Manual.

Lockout and safety checks

1. Press the ***Run*** key and then press the Keypad lock/unlock button on the lower right of the panel at the rear of the pump so that the screen momentarily shows

```
Keypad locked
```

2. Press each key, including the ***On/Off*** key, to verify that all keys are inactive and the above message appears when you press a key.
3. Press the Keypad lock/unlock button to enable the keypad again and press the ***Hold*** key and verify that the pump stops.
4. Press the ***Run*** key and then open the door. When the pump alarms and this message appears, silence the alarm.

```
Door open
```

5. Pull the safety clip from the slot and then, holding the tubing, pull the clip towards you so that the clip can be slid down the tubing.

Slide it down so that it is clear of the pump. Ensure that the cassette is firmly home on the pins and close the door.
When this message appears, silence the alarm and open the door:

```
Close clamp!
Load Safety Clip
```

6. Slide the safety clip up the tubing and push it into its slot. Close the clamp above the cassette. Then close the door and silence the alarm when this message appears:

```
Loading problem
Check tubing set
```

7. Open the roller clamp, open the door and close it again.
8. When the message disappears, press the Run key and verify that the pump is running. Then press the ***Hold*** key.

If the pump does not behave as in the description above, contact your Smiths Medical Service Department.

Audio alarm check

This test uses the Biomedical menu. Full details of this menu are given on page 17.

1. Switch the pump off. Then, while simultaneously holding the ***Options*** key, switch the pump on.
2. When the ID screen is displayed, enter the number **3031**, and then enter the password **7867**. If the Passwords screen does not come up, switch off and start again.
3. Press the ***Options*** key 9 times to display the alarm test screen:

```
Alarm Test
Press 1,2 or 3
```

4. Press 1 to test the non-insistent alarm, 2 to test the insistent alarm and 3 to test the continuous backup alarm. Press the alarm ***Silence*** key to stop each one.
5. Switch off the pump.

If you have a new pump and it does not behave as described here, contact your Smiths Medical Service Department.

If there is a fault during a routine service check, repair the pump as described in the Service Manual.

Further testing

The above tests are basic tests and are a subset of the acceptance tests described in the Service Manual. Carry out further tests as required by your internal acceptance protocol.

Instrument Care

Periodic cleaning of the pump housing and inside surface of the door is recommended. Unplug the power cord and use a sponge or cloth lightly dampened with a solution of warm water and a mild, non-staining disinfectant/cleaner. Do not use cleaning agents which could damage the outer pump housing.

The Service Manual contains information on which cleaning agents may or may not be used, and how to perform cleaning.

CAUTION: Carry out periodic cleaning following the detailed instructions in the *Volumetric Infusion Pumps Service Manual*. Do not use unapproved cleaning agents.

Setting up

Battery charging

Before using the pump for clinical use, connect the power cord to the AC mains supply and charge for at least 10 hours.

Pump configuration

With version 0.71 of the pump software, additional features can be configured. The complete list of parameters is shown in the table on page 12. The features which are enabled when the pump leaves the factory are the same as the ones enabled on previous versions of the pump. This allows you to run the pump as if it had been delivered from the factory as a previous version, without having to configure it.

When you have carried out the tests on pages 4 to 7, if you decide to use additional features, the pump must be configured. See the description of the Technician menu on page 12 for details of how to enable and disable features as required.

You may also need to set the date and time using the Service Functions menu as described on page 20.

Deciding on the configuration

In most cases, your hospital's protocol will have been agreed for the configuration settings for the use of the pump in particular locations.

When deciding on features to enable, bear in mind that to have too many features enabled may confuse the user and also that with more parameters enabled, it may take longer to reach the one required when pressing the ***Options*** key.

Enabling limits

When enabling limits, and deciding on the protocol to be used, you should be aware of the following:

- Primary limits can be enabled independently of Secondary limits; this is because rates for Secondary/ Bolus infusions may need to be higher than Primary limits;
- if limits are enabled, you should ensure that the clinical protocol includes checking and/or amending the values for the minimum and maximum rate and maximum VTBI limits using the ***Options*** key;
- if limits are enabled, the limits remain at the pump default values as described in the Specification unless the operator has set limits using the ***Options*** key;
- if limits are not enabled, then the pump VTBI/rate limits are as described in the Specification; the operator cannot alter them;
- only Primary limits are displayed during power up, even if both primary and secondary limits are enabled;

You cannot disable the ability to give a Secondary infusion, although you can disable the Bolus feature.

However, if Secondary infusions are not used in a particular environment, you could enable the Secondary limits on the Technician Menu and then set the Secondary max rate limit to 1mL/h. You cannot set a maximum of zero, but setting the lowest possible maximum can reduce the risk of a Secondary infusion being given.

Regular testing

In addition to the regular testing requirements listed below, Smiths Medical recommends that a qualified technician should carry out annual functional and accuracy checks on each pump as described in the Service Manual.

Requirements

After checking the following, you should decide whether the pump is fit for use.

1. The safety information and operating instructions on the side of the pump must be legible.
2. The mechanical conditions of the pump must allow safe operation.
3. The pump must be clean.
4. The safety fuses must be of the specified type and rating.
5. Ground impedance between the protective contact in the AC mains plug and the potential equalisation terminal must be ≤ 0.2 Ohm.
6. Ground impedance between the protective contact in the pump inlet and the potential equalisation terminal must be less than or equal to 0.1 Ohm.
7. The leakage current must meet the specification described on page S-3.
8. The functional inspections and tests described on page 4 are satisfactorily completed.

Menus

There are several menus on the pump, some of which have an overlap of features. This is to keep backwards compatibility with pump software versions before version 0.71.

Users familiar with previous versions of the pump software can continue to use a familiar menu to set up the features of pump that existed before version 0.71.

Which version of software is in the pump?

You know that a pump has version 0.71 software (or later), if:

- the Secondary infusion key appears as:

- the label on the right hand side of the pump, as shown on page 4, lists more than eight options;
- the Biomedical menu (menu item number 9) shows V0.71, for example:

```
Model 3000 V0.71
DB:3.65A MM:1.10
```

The Technician menu

This menu is only present on pumps with version 0.71 software and later.

You use the Technician menu to enable the features of the pump that have been introduced with version 0.71 software, as well as the features that existed in earlier versions. These features and their defaults are described on page 13.

The Biomedical menu

This menu is the one that also exists in versions of the pump before version 0.71. In previous documentation it has also been called the “Biomedical Special Functions”. As well as enabling or disabling features, it also displays data for fault finding and calibration.

Parameters on two menus

The common parameters on both the Technician and Biomedical menus are:

- Rate Taper
- Volume Over Time
- Dose Rate Calculation.

Which menu should you use?

For the parameters that are on both Technician and Biomedical menus, you can use either menu. In most instances, however, you will:

- use the Technician menu, where parameters for all the features appear, to configure the pump for the user;
- use the Biomedical menu only when you are servicing the pump.

The Service Functions menu

This menu contains a number of functions for servicing the pump. It is also where you set the time in the pump.

The Special Functions menu

This menu is used to initialise the pump when it is upgraded. A description of its use is included in the Service Manual and the Instruction Worksheet for the 500/3000 Volumetric Infusion Pump Software Upgrade Kit.

Technician menu

This menu allows you to define how the pump behaves by setting values or by disabling or enabling parameters.

Entering the Technician menu

To enter this menu, first switch off the pump if it is switched on.

Then press the ***Total Volume*** key while simultaneously pressing the ***On/Off*** key. When you take your fingers off the keys, the pump switches on and you are asked to enter the Technician menu ID.

Enter the numbers **0002**.

As you enter the digits, asterisks (*) are displayed for security protection. If you make a mistake, you must switch the pump off to enter the correct ID. When prompted:

Enter the password **2020**.

The Technician menu ID is always 0002 and the password is always 2020. These cannot be changed.

Using the Technician menu

When you enter the Technician menu, the first parameter is the one to enable or disable the display of the **Pump Identifier**. Move down the list by pressing the ***Options*** key. Use the ***** key to toggle a parameter. Thus if you see a screen like the following:

then the feature is disabled and you must press the ***** key to enable it.

You cannot move back through the menu. If you make a mistake, then you can continue to move through the list by continuing to press the ***Options*** key and the first item appears again when you reach the end. You may find it faster to switch off and start again.

To move through the list quickly, and avoid going past the item you want, you may also find it faster to count the number of times you press the ***Options*** key. The table on the next page has been numbered to help you do this.

Leaving the Technician menu

To exit from the menu, switch off the pump.

Technician parameters

The numbers on the left of this table show the number of ***Options*** key presses to reach the parameter. The default settings are the factory settings.

	Configuration Parameter	Operation	Default
	Pump Identifier	Enable or Disable	Disabled
1	Drug List	Enable or Disable	Disabled
2	Primary rate limits	Enable or Disable	Disabled
3	Primary Max VTBI	Enable or Disable	Disabled
4	Secondary/Bolus rate limits	Enable or Disable	Disabled
5	Sec / Bolus Max VTBI	Enable or Disable	Disabled
6	KVO rate entry	Enable or Disable	Disabled
7	Occlusion Default	High, Medium or Low	Medium
8	Secondary Stop	Enable or Disable	Disabled
9	Bolus	Enable or Disable	Disabled
10	Quick Rate	Enable or Disable	Enabled
11	Rate Taper	Enable or Disable	Enabled
12	Volume over Time	Enable or Disable	Enabled
13	Dose Rate Calculation (DRC)	Enable or Disable	Enabled
14	DRC Recovery	Enable or Disable	Disabled
15	Backlight	Enable or Disable	Enabled
16	Autolock Keypad	Enable or Disable	Disabled
17	GMT Timestamp	Enable or Disable	Enabled
18	Service Date	Review or Date Entry	00/00/00 (disabled)
19	Micrograms	Selection 1 (µg) or 2 (mcg)	2

Using Technician parameters

Most parameters enable or disable features that appear when the ***Options*** key is pressed. All only affect one feature, but for some you may need to think about making another setting at the same time. For example, if you enable Primary rate limits, you might also enable Primary Max VTBI.

See also page 8 for guidance on creating protocols for setting parameters.

Pump Identifier

If you enable this parameter, when you press the ***Options*** key to move to the next parameter you can edit the identifier text. When the pump leaves the factory, the identifier is set to the serial number of the pump.

You can change the identifier character by character by using the up and down keys (1 and 3) to cycle through alphanumeric values. Press the ***** key to move to the next character. Press the ***Options*** key when you are finished.

Drug list

Enabling this parameter gives the user the ability to change the displayed Drug label. If it is disabled, then the label is not displayed.

Minimum and maximum primary rate

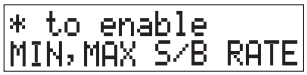
Enabling this parameter allows the user to define a range to limit the Primary rate.

Maximum primary VTBI

Enabling this parameter allows the user to set the maximum volume that can be infused for a Primary infusion.

Minimum and maximum secondary/ bolus rate

Enabling this parameter allows the user to define a range to limit the Secondary rate or Bolus rate.



Maximum secondary/bolus VTBI

Enabling this parameter allows the user to set the maximum volume that can be infused for a Secondary or Bolus infusion.

KVO rate entry

If this is enabled, then the user can set their own KVO rate. If it is disabled, the default KVO rate is used. KVO rate ranges and KVO default rates are in the Specification, see page S-7.

Occlusion default setting

Use this option to set the occlusion default setting that should be applied when the pump is switched on. Press * to change the default.

The user can press the ***Occlusion Alarm Setting*** key to change the occlusion level for a particular infusion regardless of this default parameter setting. However the default setting is reapplied when the pump is switched off and on again.

Secondary stop

With this parameter enabled, the pump stops when a Secondary infusion is completed. It sounds an insistent alarm and displays a message to say that the secondary infusion is complete:

If Secondary Stop is disabled, when a secondary infusion is complete, the pump sounds a non-insistent alarm twice and then automatically restarts the infusion at the primary rate.

This parameter is independent of the setting of the Bolus parameter and only affects a Secondary infusion; at the end of a Bolus infusion the pump always reverts to the previously programmed Primary rate.

Bolus

When this parameter is enabled, the user is given a choice of whether a Secondary or a bolus infusion is to be run when they press the ***Secondary/ Bolus*** key. If Bolus is chosen, the volume infused is deducted from the Primary VTBI. If Secondary is chosen, the Secondary volume infused is kept as a separate total and does not affect the Primary VTBI.

If Bolus is disabled, the user is not given a choice when they press the ***Secondary/Bolus*** key: they can only make settings for a Secondary infusion.

Quick Rate

The Quick Rate Change parameter was always enabled in software versions before version 0.71. From version 0.71, the parameter may be enabled or disabled on the Technician Menu.

Enabling this feature allows users to use the ***Options*** key to put the pump into a mode in which they can change the rate quickly while the pump is running or on hold.

Rate Taper

Enabling this parameter allows the user to taper the infusion rate, either up or down, for the administration of Total Parenteral Nutrition (TPN), Total Parenteral Admixture (Three-in-One) or other applicable therapies.

Volume Over Time

Enabling this parameter allows the user to set up an infusion using the volume to be infused and the total time, with the pump automatically calculating the infusion rate. This can be done with either Primary or Secondary infusions.

Dose-Rate Calculation

Enabling this parameter allows the user to set the dosing rate, patient weight, the drug amount in the fluid bag and the volume in the container, from which the pump then calculates the infusion rate.

Note: If you enable Dose-Rate Calculation, the Micrograms unit should also be set (using the Micrograms parameter on this menu) according to your protocol.

DRC Recovery

Enabling this feature allows a Dose-Rate Calculation mode infusion to be accessed quickly when the pump is switched on.

Backlight

This parameter sets the default for how the backlight behaves when the pump is switched on. With the parameter disabled, the backlight will go off after a minute of keypad inactivity.

If the parameter is enabled, the user can use the ***Options*** key to control whether the Message Display Light is permanently on or behaves as described above when the option is disabled.

Autolock Keypad

With this parameter enabled, the keypad will automatically lock one minute after a key was pressed.

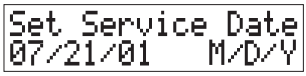
The user can unlock the keypad by pressing twice on the Keypad lock/ unlock button on the back of the pump.

GMT Timestamp

Enabling this parameter displays the message 'GMT' to the right of a time display.

Service Date

This parameter is used to set the service due date that is displayed during power up when the pump is switched on. You can set or clear the service date when this screen is displayed with the date flashing on the Technician Menu:



Enter the new date in the format MM/DD/YY, or to disable the Service Date feature, set the month, day and year to zeroes.

When the pump is in use, if the date set is reached or exceeded, then the following message is displayed with an insistent alarm when the pump is switched on:

The alarm must be silenced for the pump to work, as a reminder to the user that the pump should be serviced.

Micrograms

Use this feature to determine the units to be displayed as µg or mcg for the Dose-Rate Calculation. If you are not enabling Dose rate calculation, you can ignore this item.

Note: Since the pump does not confirm the chosen unit display, test that the display is set correctly. Switch the pump on normally and press the ***Options*** key until the Message Display asks you to set the Dose-Rate calculation. Then press * to examine the next screen.

CAUTION: The backlight has a limited life and may, if used constantly, cause the light to dim. Eventually the message display may then need to be replaced. To preserve the life of the message display, you should only allow the Message Display Light to be turned on as described here if it is specifically required. Misuse of this feature could lead to both battery and LCD depletion.

Biomedical menu

The Biomedical menu allows you to access technical information about the pump and carry out adjustments and tests.

System faults

If a fault occurs while the pump is infusing on a ward, an error code is recorded. An audio alarm sounds and the Message Display shows:

```
System check
Turn off then on
```

If the system error resulted from a temporary condition, turning the pump off then on, clears the alarm and allows you to continue the infusion. However, if the above message persists, the pump must be removed from the ward for service and repair.

Error codes resulting from system errors, can be viewed in the Message Display at a later time by entering the Biomedical menu and perusing the menu parameters described overleaf. The pump defaults to the screen displaying the error code.

Although the error codes are cleared when exiting the Biomedical menu, they are stored as a snapshot event.

Entering the Biomedical menu

To enter this menu, first switch off the pump if it is switched on.

Press the ***Options*** key while simultaneously pressing the ***On/Off*** key. When the keys are released, the pump switches on and you are asked to enter the Biomedical menu ID.

Enter the numbers **3031**.

As you enter the digits, asterisks (*) are displayed for security protection. If you make a mistake, you must switch the pump off to enter the correct ID. When prompted:

Enter the password **7867**.

The Biomedical menu ID is always 3031 and the password is always 7867. These cannot be changed.

Using the Biomedical menu

When you enter the Biomedical menu, the first screen you see depends on whether an error has occurred while the pump was running.

If no error has occurred

Entry into the Biomedical menu takes you directly into Snapshot screen-a (item 0 in the table on the next page).

If an error has occurred

If you enter the menu after a fault has occurred, system errors and warnings are displayed:

```
System error
 Service code 31
```

```
System warning
 Service code 01
```

Refer to the Service Manual for details of the codes. The codes are cleared on exiting from the Biomedical menu.

Navigate through the list by pressing the ***Options*** key.

The menu items are shown on the next page. Full details on their use are given in the Service Manual.

Leaving the Biomedical menu

Switch off the pump to exit the menu and switch on the pump for use.

Biomedical menu parameters

The numbers in the left hand column of this table indicate the number of ***Options*** key presses to reach the parameter.

	Screen	Use	Notes
	System error Service code 31 System warning Service code 01	These screens only appear when you enter the menu after a fault has occurred.	Decoding the errors is covered in the Service manual.
0	001 1023 1529 88 3000 00500 00000	Two snapshot screens are available: **a** (shown here) and **b**. Pressing * toggles between the two screens.	Decoding the screens is covered in the Technical Service Manual
1	14:18:50 GMT 10/23/00	This screen displays the time and date. It only displays the message GMT if this is enabled on the Technician menu.	To set the time and date, use the Service Functions menu as described on page 20.
2	Hrs 19 Liters 9 Load 22	The display shows: • cumulative running hours, • cumulative volume, • number of loading cycles.	
3	AC 18 Charge 73 Batt 2	The display shows the cumulative hours that the pump has been: • used on AC mains whilst switched on, • charging: plugged in but switched off, • run on batteries.	
4	Pressure calib. 452 0 0 0	Allows you to run a calibration test.	See the Service manual for full details on using this screen.

	Screen	Use	Notes
5	Baud rate: 9600 ↓ ↑ to change	Shows the current rate setting of the serial port. Use the scroll keys to set the rate.	Rates of 300, 600, 1200, 2400 and 9600 are available.
6	English ↓ ↑ to change	Displays the language installed in the pump.	Only one language is supplied in a pump.
7	Battery use 0.1 hr: 42	Displays the number of times a pump was used on battery for the number of hours indicated.	Use the scroll keys (1 and 3) to change the number of hours.
8	Model 3000 V0.71 DB:3.65A MM:1.10	Displays the model number and software revision.	See the Service manual for full details on using this screen.
9	Alarm Test Press 1,2 or 3	Use this screen to test the alarms by pressing 1, 2 and 3 on the keypad in turn.	
10	Rate Taper	Enable or Disable.	Also available on the Technician menu.
11	Volume Over Time	Enable or Disable.	Also available on the Technician menu.
12	Dose Rate Calculation	Enable or Disable.	Also available on the Technician menu.

Service Functions menu

The Service Functions menu allows you to set the date and time on the pump and to test some pump functions.

Entering the Service Functions menu

To enter this menu, first switch off the pump if it is switched on.

Then, press the ***Occlusion Alarm Setting*** key while simultaneously pressing the ***On/Off*** key. When you take your fingers off the keys, the pump switches on and you are asked to enter the Service Function menu ID.

Enter the numbers **7557**.

As you enter the digits asterisks (*) are displayed for security protection. If you make a mistake, you must switch the pump off to enter the correct ID. When prompted:

Enter the password **3796**.

The Service Function menu ID is always 7557 and the password is always 3796. These cannot be changed.

Using the Service Functions menu

When setting up the pump, the main use of this menu is to set the date and time.

Other parameters are shown in the table on the next page. Further details are given in the Service Manual.

Leaving the Service Functions menu

Switch off the pump to exit the menu and switch on the pump for use.

Service Functions menu parameters

	Screen	Use	Notes
1	Steps: 0 A/D: 0 0 0 0	Information for Smiths Medical Service Department use.	
2	14:18:50 GMT 10/23/00	Use this to set the time and date in the format MM/DD/YY	1. In order to set the date, you must enter the time. 2. GMT is only displayed if the Technician menu feature is enabled.
3	0 of event 1 Press ↓ ↑	The top line shows the number of times that each event code has occurred. Use the scroll keys (1 and 3) to select the snapshot event code to be displayed.	The event is the snapshot event in *Snapshot screen a* of the Biomedical Menu.
4	Sensors: DR0 CL0 CS0 PL0 ON0 JP0	The status of each sensor is displayed according to the table on the next page.	
5	Keys pressed:	Press a key to check each key one is functioning correctly. The key pressed shows on the second line of the screen.	Pressing the ***Options*** key will show that you have pressed that key. Pressing it again will take you to the next menu option.
6	ID: 300006212	Shows the serial number of the pump as on the back of the case.	If you need to enter the serial number on a pump that has been upgraded or had the main board changed, press * to enter the number.
7	Press * to clear pump history	Take care with this option, since the action is irreversible. You are given a chance to change your mind.	You can download history by using the Volumetric Infusion Pump History Download Kit.

Sensors screen

		Value = 0	Value = 1
DR	Door	Closed	Open
CL	Clip	Out	In
CS	Cassette	None	Fitted
PL	Keypad Lock	Unlocked	Locked
ON	On/Off key	Released	Pressed
JP	Jumper JP 10 on CPU board	500	505 (neonatal)

Specifications

General

Weight	5 kg (11 pounds).	
Dimensions	including pole clamp Height Width Depth	 28 cm (11 inches). 21.5 cm (8.6 inches). 23.5 cm (9.45 inches).
Temperature	Operating Storage	18° to 40° C (64° to 104° F) -25° to +55° C (-13° to 131° F).
Relative humidity	Operating Storage	30% to 75% (non-condensing). 30% to 75% (non-condensing).
Pressure range	Operating Storage	50 kPa to 106 kPa 19 kPa to 106 kPa
Immunity levels	Immunity levels are the full levels specified in EN60601-1-2 (radiated immunity is 3 V/m and ESD immunity is 3 kV contact and 8 kV air).	
Free flow protection	The pump mechanism operates the safety clip on the administration set.	
Head-height	*From bottom of drip chamber to top of pump*	
Model 500	15 cm (6 ins) minimum for flow rates <500 mL/h 30 cm (12 ins) minimum for flow rates >500 mL/h 30 cm (12 ins) when using 60 drops/mL sets 30 cm (12 ins) when using thick solutions*	
Micro 505	15 cm (6 ins) minimum 30 cm (12 ins) when using 60 drops/mL sets 30 cm (12 ins) when using thick solutions*	
	* certain cytotoxic agents, lipid-based fluids and other viscous solutions, for example Total Parenteral Nutrition.	
Self test	Dual microprocessors independently test each other.	

Maximum over infusion	Under a single-fault condition, the maximum over infusion which may occur is 12.5% over the selected flow rate. Larger inaccuracies are detected by the pump, and cause the pump to stop infusing and to alarm.
Air detect system	Air bubbles are detected by electronic opto-encoder detection device (with self-checking sensors) located on cassette housing.
Accuracy	± 2% of displayed rate and volume to be infused. The quoted accuracy is ±2% for a long-term infusion. Below rates of 1 mL/h this accuracy may not be achieved for a short-term infusion. During the total infusion time the accuracy averages out (see trumpet curves in this chapter).
Accuracy measurement equipment	50 mL glass measurement burette graduated in 0.1 mL increments and traceable to National Institute of Standards and Technology or appropriate international standards bureau.
Test solution	Sterile water or normal saline at room temperature (70°F ±5°/21°C ±3°). Smiths Medical standard (primary), 20 drops/mL, non-checkvalve administration set (8C820).
Testing conditions	
Model 500	Fluid level in the solution container 46 cm (18 inches) above top of the pump, rate set at 999 mL/h and volume to be infused of 49 mL.
Micro 505	Fluid level in the solution container 46 cm (18 inches) above top of the pump, rate set at 99.9 mL/h and volume to be infused of 25.0 mL.

Power

AC power supply	Internally configured for either 100-120 V AC, 200 mA, 50/60 Hz. or, 220-240 V AC, 80 mA, 50/60 Hz.
Battery type	Rechargeable, sealed lead-acid, 12 Volt, 1.3 Ah.
Battery operating time	6 hours at 100 mL/h (99.9 mL/h on **Micro 505**), with approximately 1/2 hour warning of discharged battery.
Battery recharge time	Approximately 10 hours, depending on the operating conditions. The batteries will be charging during an infusion.
Leakage current	100 to 120 V less than 20 microamps ungrounded or, 220 to 240 V less than 50 microamps ungrounded This is measured between the ground stud and the earth protective prong of the AC mains connector.

Over-current protection

Voltage	AC line fuse	Thermal fuse	Battery fuse
100 to 120 V	200 mA	130°	1.0 amp
220 to 240 V	2 x 80 mA	130°	1.0 amp
Note: All fuses are time delay fuses			

Primary and Secondary Infusions:

Rate range

Model 500	*Range*	*Increment*
	0.1 to 99.9 mL/h	0.1 mL/h
	1 to 999 mL/h	1 mL/h

Micro 505	*Range*	*Increment*
	0.1 to 99.9 mL/h	0.1 mL/h

Volume to be infused

Model 500	*Range*	*Increment*
	0.1 to 999.9 mL	0.1 mL
	1 to 9999 mL	1 mL

Micro 505	*Range*	*Increment*
	0.1 to 999.9 mL	0.1 mL

Rate Taper Infusions:

Rate range

Model 500	*Range*	*Increment*
	0.1 to 99.9 mL/h	0.1 mL/h
	1 to 400 mL/h	1 mL/h

Micro 505	*Range*	*Increment*
	0.1 to 99.9 mL/h	0.1 mL/h

Volume to be infused

Model 500	*Range*	*Increment*
	0.1 to 999.9 mL	0.1 mL
	1 to 4400 mL	1 mL

Micro 505	*Range*	*Increment*
	0.1 to 999.9 mL	0.1 mL

Time range

Model 500 & Micro 505	*Range*	*Increment*
	0 to 59 minutes	1 minute
	0 to 48 hours	1 hour

Volume Over Time Infusions:

Rate range

Model 500	*Range*	*Increment*
	0.1 to 99.9 mL/h	0.1 mL/h
	1 to 999 mL/h	1 mL/h

Micro 505	*Range*	*Increment*
	0.1 to 99.9 mL/h	0.1 mL/h

Volume to be infused range

Model 500	*Range*	*Increment*
	0.1 to 99.9 mL	0.1 mL
	1 to 9999 mL	1 mL

Micro 505	*Range*	*Increment*
	0.1 to 99.9 mL	0.1 mL
	1 to 999 mL	1 mL

Time range

Model 500 & Micro 505	*Range*	*Increment*
	0 to 59 minutes	1 minute
	0 to 48 hours	1 hour

Dose-Rate Calculation Infusions:

Dose range

	Range	*Increment*
	0.01 to 99.99	0.01
	0.1 to 999.9	0.1
	1 to 9999	1

Body weight range

Units	*Range*	*Increment*
Kilograms (kg)	0.10 to 99.99 kg	0.01 kg
	0.1 to 453 kg	0.1 kg
Pounds (lbs)	0.22 to 99.99 lbs	0.01 lbs
	0.2 to 999 lbs	0.1 lb.

Drug amount modes/range

Mode	*Range*	*Increment*
MG drug/bag	0.01 to 99.99	0.01
	0.1 to 999.9	0.1
	1 to 99999	1
Gm drug/bag	0.01 to 99.99	0.01
	0.1 to 99.9	0.1
	1 to 999	1
mcg drug/bag	0.01 to 9.99	0.01
	0.1 to 99.9	0.1
	1 to 9999	1
units/bag	0.01 to 99.99	0.01
	0.1 to 999.9	0.1
	1 to 99999	1

Rate range

Model 500	*Range*	*Increment*
	0.1 to 99.9 mL/h	0.1 mL/h
	1 to 999 mL/h	1 mL/h
Micro 505	*Range*	*Increment*
	0.1 to 99.9 mL/h	0.1 mL/h

Volume to be infused range

Model 500	*Range*	*Increment*
	0.1 to 999.9 mL	0.1 mL
	1 to 9999 mL	1 mL
Micro 505	*Range*	*Increment*
	0.1 to 999.9 mL	0.1 mL

Occlusion sensing

Alarm levels *(approximate values)*

Pressure units	Low	Medium	High
mmHg	103 mmHg	259 mmHg	517 mmHg
psi	2 psi	5 psi	10 psi
kPa	13.5 kPa	34.5 kPa	68.9 kPa

Time to occlusion

Maximum (measured +25%) delay times for activation of the "**Occlusion below pump**" alarm:

Rate	Low setting maximum time to alarm	High setting maximum time to alarm
1 mL/h	11 min, 5 sec.	1 hour, 10 min.
25 mL/h	15 sec.	2 min, 35 sec.

KVO rate

Default KVO rate

3.0 mL/h, or at the programmed rate if set at less than these values.

Configurable KVO rates

Model 500	0.1 to 10.0 mL/h
Micro 505	0.1 to 3.0 mL/h

Accessories

For a complete list of Administration Sets, please contact Smiths Medical or your local distributor.

Symbols used on the pump

Front panel symbols

Battery is charging/mains power applied.

Audio alarm silence button.

Side panel symbols

Use pump only in upright position.

Rear panel symbols

Attention: consult accompanying documents.

Data input/output.

CF Application (cardiac floating)

Audio alarm volume control.

Alternating current.

Nurse call option (only if option is fitted)

Inside battery door symbols

Attention: dangerous voltages, risk of electric shock if the housing is opened.

Equipotential point.

Internal battery.

Dispose of in an environmentally safe manner.

Battery symbols

Recycle battery

Dispose of in an environmentally safe manner.

Standards

Electrical Safety

Classified as Internally Powered Equipment
Class 1, Type CF (Cardiac Floating) insulation on all inputs.

Design Standards

EN 60601-1, EN 60601-1-2, IEC 601-2-24 (Draft).

Fluid Ingress Protection

IPX 1 Drip proof

CE Marking

CE 0473

The CE mark demonstrates that the pump conforms to the requirements in the European Council Directive 93/42/EEC concerning medical devices.

The number 0473 identifies the Notified Body under which the Quality Systems operated within Smiths Medical are assessed.

Disposal

When the time comes to dispose of the pump, its batteries, or any of its accessories, do so in the best way to minimise any negative impact on the environment.

You may be able to use special recycling or disposal schemes. To find out about these contact your local waste disposal service. Separate any other parts of the equipment where arrangements can be made for their recovery, either by recycling or energy recovery.

Important: Existing national or local regulations concerning waste disposal must take precedence over the above advice.

Patents

USA	5401256	*GB*	2247765
	5103214	*France*	2715073
	5429485		
	5017192		

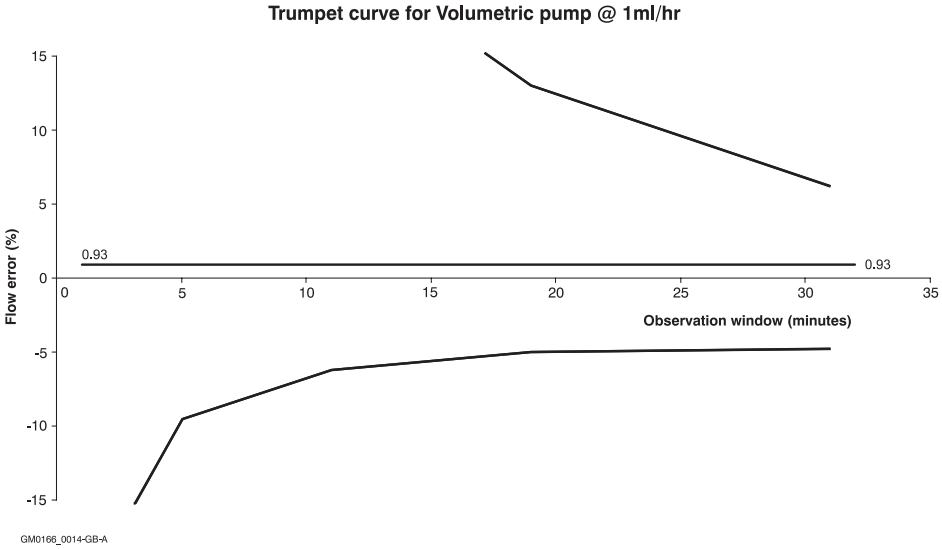
Trumpet curves

The curves were developed while testing the **Model 500** using a Smiths Medical *Standard Adult Set, 8C-820* administration set.

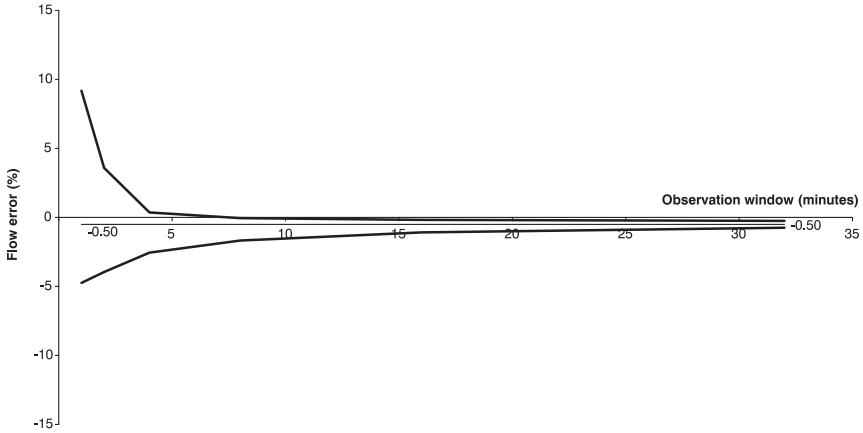
The curves for the **Micro 505** are identical since both pumps have the same pumping mechanism.

The trumpet curve represents the worst case rate error in any given observation window over the whole infusion period.

These trumpet curves were prepared according to the requirements of IEC 601-2-24.

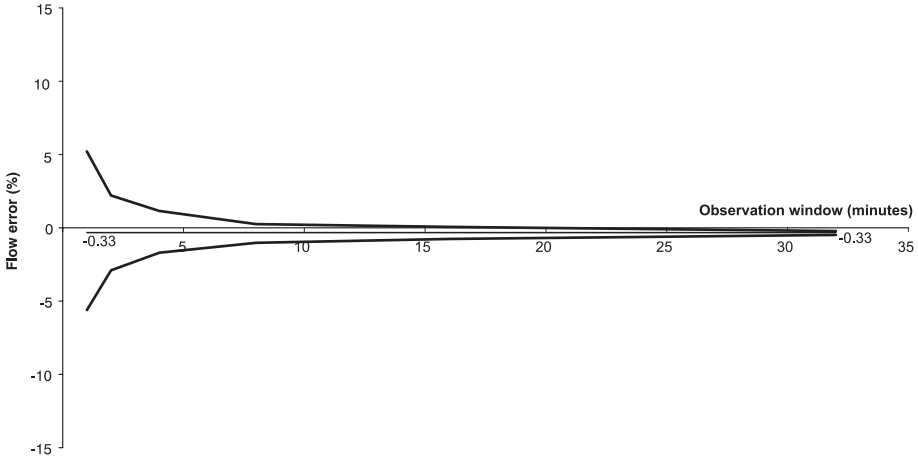


Trumpet curve for Volumetric pump @ 25 ml/hr



GM0166_0015-GB-A

Trumpet curve for Volumetric pump @ 100 ml/hr



GM0166_0016-GB-A

Index

K

L

M

N

O

P

Q

R

S

T

U

V

W

IN AN EMERGENCY CONTACT:

These products described are covered by one or more of the following Patent Nos. U.S. 5017192, 5103214, 5401256, 5429485, U.K. 2247765, FRANCE 2715073

smiths

CE 0473

Smiths Medical MD, Inc.
1265 Grey Fox Road, St. Paul, MN 55112, U.S.A.

European Representative:
Smiths Medical International Limited
Watford, Hertfordshire, UK, WD24 4LG
www.smiths-medical.com

Made in Malaysia

Part No. 0166-0202-D
Jan 2005

smiths
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