

MICROfuse

Dual Rate Infuser



O P E R A T O R M A N U A L

Important User Information

CAUTION: Do not autoclave, steam sterilize, EtO sterilize, or subject the MicroFuse Infuser to temperatures in excess of 400C (1040F).

CAUTION: No user-serviceable parts inside. Refer all service, repair and calibration to qualified technical personnel. Do not make unauthorized modifications.

CAUTION: USA Federal and Canadian laws restrict this device to sale by, or on the order of, a physician.

WARNING: Always ensure that medications delivered simultaneously by the pump are compatible. Refer to the drug manufacturers' labeling when selecting drugs for use.

WARNING: Always purge the infusion lines between infusions of two separate medications to avoid inadvertent infusion of medication contained within the administration set or to avoid inadvertent mixing of incompatible medications.

WARNING: Be sure that the syringe plunger is engaged by the syringe driver arm when MicroFuse Infuser is connected to a patient, to prevent siphoning.

WARNING: Purge the system of all air bubbles before administering any medication. Failure to follow this normal infusion procedure could result in patient injury.

WARNING: Do not expose the pump to X-rays, gamma rays, or other ionizing radiation, or to strong electric or magnetic fields.

WARNING: Do not operate the MicroFuse Infuser in the presence of flammable anesthetics mixed with air or oxygen or nitrous oxide.

Important User Information

WARNING: If an “OCCLUSION” alarm occurs; Immediately disconnect the administration set at or above the administration site to eliminate the possibility of a bolus being delivered to the patient. Inspect the administration set for kinks, closed stopcocks, clogged catheters, etc.

WARNING: Not for use with blood or blood products.

WARNING: Remember that the volume of fluid contained in the connecting tubing is a residual amount and will not be infused. Allow for this needed extra volume of fluid when initially filling the syringe.

WARNING: This device must not be used in the presence of Magnetic Resonance Imaging (MRI) machines.

WARNING: To prevent siphoning, make sure the flange of the barrel is inserted in the barrel flange slot.

WARNING: Use only the syringes listed in the specifications on page 14 of this manual. Failure to do so may result in inaccurate delivery.

IMPORTANT: Carefully read the entire contents of this manual before using the MicroFuse Infuser.

IMPORTANT: For safe disposal of administration sets and syringes, refer to facility protocol.

IMPORTANT: The release date is on the back cover. If the date is greater than two years, please contact Numia to see if additional information related to the this product is available.

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Overview

The MicroFuse® Infuser is intended for small volume infusion (SVI) of intravenous drugs. It is designed to deliver drugs that are diluted in 1 to 100 mL volumes and given intermittently over 1 to 120 minutes. Syringe infusion provides an alternative to gravity and minibag IV systems. The MicroFuse Infuser delivers reliable, fixed-rate infusion using less costly materials, reducing drug waste and setup and administration labor.

MicroFuse Infusers are:

- Durable – solid-body construction with secure motor attachment
- Easy-to-use – simple push-button controls
- Portable – lightweight and slender profile
- Reliable – low maintenance, with built-in safety features

Syringe Compatibility

The MicroFuse Infuser is compatible with Becton-Dickinson® (B-D), Monoject® and Terumo® disposable syringes in sizes from 5 to 140 cc. See the Reference Charts to determine the maximum fill volumes for different syringe sizes.

Description

The infuser operates on two standard alkaline C-cell batteries for an average life of 400 hours. The syringe holder secures the syringe in place. Once the infuser is turned ON, the syringe driver arm depresses the plunger at a fixed rate, administering the contents of the syringe through the extension tubing and into the patient access site. A microprocessor control operates at a constant delivery rate, and can infuse syringe contents against a back pressure of \pm 100 mm Hg.

The MicroFuse Infuser infuses at one of two pre-set flow rates. NORMAL rate infuses most therapies over 20 - 40 minutes. SLOW infuses most doses over 60 to 120 minutes.

Description (cont.)

The MicroFuse Infuser has a full complement of alarms that signal: end of infusion, occlusion detection, low battery, maintenance required, and internal malfunction. Alarms are indicated by flashing status lights and an audible chime.

NOTE: Audible alarms may be placed in MUTE mode by pressing Alarm Mute switch for two full seconds.



WARNING: Federal and Canadian law restricts this device to sale, distribution and use by, or on the order of, a licensed practitioner.

Applications

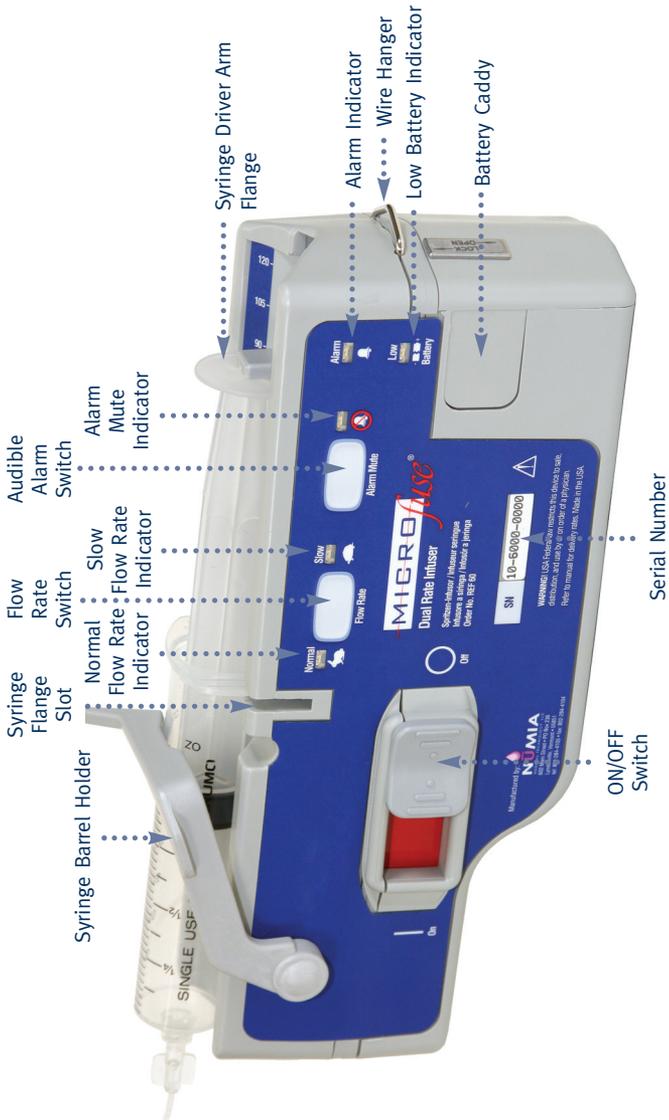
The MicroFuse Dual Rate Infuser may be used for the following types of intermittent infusion therapies:

1. Primary intermittent infusion through a heparin or saline lock.
2. Piggyback through a primary IV line. Primary line flow rate is not interrupted. The infuser extension set is attached to the primary line at the lower injection port or flashball site.
3. Piggyback with an IV controller or IV pump. No change is required for the pump or controller. The extension set is attached to the primary line at an injection port or a flashball site downstream from the primary infusion device.
4. Piggyback in combination with a volume control chamber (burette). Burette flow rate is not interrupted. The extension set is attached to the primary line at either the lower injection port or the flashball site.

Contraindications

The MicroFuse Infuser is not for use in the presence of explosive anesthetics.

Infuser Diagram



Features – Light Indicators

The MicroFuse Dual Rate Infuser uses five status indicator lights:

Indicator	Status
Normal Rate 	Flashes GREEN when Flow Rate is set to NORMAL
Slow Rate 	Flashes YELLOW when Flow Rate is set to SLOW
Low Battery 	Flashes RED when batteries need to be changed
Alarm 	Flashes RED when an alarm condition is detected
Alarm Mute 	Flashes YELLOW when the audible alarm is muted



NOTE: If the infuser detects an internal malfunction, the audible alarm always sounds, regardless of the Alarm Mute status.

Features—alarms

Condition	Light and Chime Indicators	Action Required
End of Infusion/ Occlusion	Slow flashing ALARM light with slow two-tone CHIME sound.	Turn infuser OFF, or leave infuser ON and press ALARM MUTE switch. If an alarm occurs, and infusion is not complete, the IV set or catheter may be occluded. If an occlusion occurs, clear it and restart the infuser.
Internal Malfunction	Rapid flashing ALARM light Rapid CHIME sound.	Turn infuser OFF, then ON. If alarm reappears, contact Customer Support. ALARM light remains lit when unit is OFF.
Low Battery/ First 10 hours	Multi-note CHIME when Power is first switched ON. LOW BATTERY light will continue to flash during an infusion when the batteries are low.	Change batteries as soon as possible.
Low Battery/ After 10 hours	Repeating multi-note CHIME and infuser will not function.	Batteries must be changed.



NOTE: The infuser will continue to operate for approximately 10 hours after a low battery condition is first detected. After 10 hours, the infuser will not function and will sound a repeating alarm.

Operating Procedures

Follow accepted IV therapy techniques and procedures when setting up and administering intermittent IV therapy with the MicroFuse Infuser.

A. Setup

- Eliminate any air from syringe.
- Connect an IV extension set to the drug syringe.

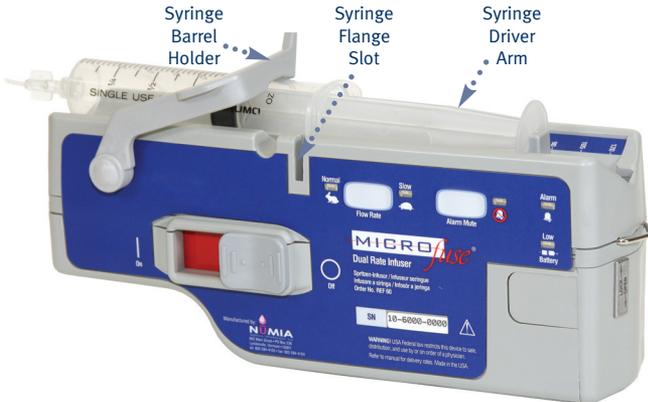


NOTE: Extension set should be 6 to 60 inches long with an internal diameter (ID) between 0.020 and 0.030 inches, except for 140 cc syringes – which require an ID of 0.05 inches. A tubing clamp is desired, but not required.

- Prime extension set to ensure that air is eliminated from the syringe and tubing.

B. Install Syringe

1. Load the syringe into the infuser by sliding it underneath the syringe barrel holder. Alternately, pull open the barrel holder and place syringe on the infuser.
2. Position the syringe barrel flange in the syringe barrel flange slot on the infuser body.
3. Position the syringe plunger in the slot on the syringe driver arm.



WARNING: The syringe driver arm can be moved only when the Power ON/OFF switch is fully in the OFF position. Syringe plunger must be secured in the slot of the syringe driver arm. If plunger is not properly secured, or unit is not completely turned OFF, gravity flow may occur when the infuser is hanging above the patient. Delay in delivery or failure to deliver may occur when the switch is placed in the ON position.

C. Select Flow Rate

Use the infuser scales to read an approximate time to infuse a specific dose. Check the Infusion Time Charts in the Technical Reference section for actual flow rates.

1. To check the infusion flow rate, press FLOW RATE switch. This can be done with the infuser power off.
2. To change rate, hold the FLOW RATE switch for two full seconds. NORMAL infuse will flash green, SLOW infuse will flash yellow. NORMAL rate infuses most doses over 20 to 40 minutes. SLOW rate infuses most doses over 60 to 120 minutes.

See page 16 for procedure to make the MicroFuse Infuser a single-rate infuser.

Administration

1. Attach the extension set to the patient infusion site.



NOTE: Excess force on the administration set (as low as 1.5 lb/0.7 kg in some directions) might separate the syringe from the infuser, causing infusion to stop.

2. Secure the MicroFuse Infuser to avoid unnecessary movement at the infusion site.
 - Hang the infuser from an IV pole using the attached wire hanger,
 - Attach the infuser to the IV pole using the optional IV Pole Clamp, or
 - Place the unit inside the optional “waist pack.”
3. Begin the infusion cycle by sliding the ON/OFF switch to ON.
4. When the infuser is turned ON it will:
 - Flash all alarm and status indicators.
 - Produce an audible CHIME.
 - Perform an internal self-check of the microprocessor and battery power level.
 - Rate indicator light will flash during the entire infusion.
5. Press the ALARM MUTE switch for two full seconds to deactivate the audible CHIME, if desired.



NOTE: If any malfunction or alarm condition is detected, a CHIME will sound. Refer to the Features section for detailed descriptions. If an alarm occurs, and infusion is not complete, the IV set or catheter may be occluded. If an occlusion occurs, clear it and restart the infuser.

Administration (continued)

6. When the infusion is complete, the ALARM flashes. A CHIME is sounded unless the ALARM MUTE switch is activated. Alarm verifies end of infusion/occlusion has been detected.
7. To leave the infuser in place until the next use:
 - Clamp the IV line and slide the ON/OFF switch fully to OFF. This turns off all alarm functions and releases the pressure on the syringe plunger.
8. To remove the syringe after infusion is complete, lift the syringe barrel holder and slide the syringe out of the infuser.



CAUTION: Releasing pressure on the syringe plunger can allow small amounts of the primary IV solution to be pumped back up the extension set and into the syringe. This situation can occur when the Infuser is OFF and an upstream infusion device is pumping the primary IV solution down the primary tubing. See notes on preventing fluid backflow.

Preventing Fluid Backflow

- Leave the infuser Power ON and press the ALARM MUTE switch. This will turn off audible alarms and leave the syringe driver arm locked in place.
- Clamp the MicroFuse Extension Set with the attached slide clamp.
- Use a primary tubeset with a back check valve prior to the secondary set attachment.

Procedural Notes:

- Always follow accepted IV therapy techniques when clearing occlusions and removing syringes and extension sets from the patient infusion site.
- Infuser may be turned OFF and infusion restarted at any time without affecting the infusion rate or accuracy.
- Administration set change interval should meet accepted facility policy.

Infusion Time Charts

These charts provide a simple method to determine: infusion time, solution volume, and syringe size.

To use the Charts:

1. Select the appropriate chart by defining the desired flow rate (NORMAL or SLOW) and the brand of syringe.
2. Select two of the three variables: solution volume, infusion time or syringe size.
3. Cross reference the two selections on the chart to locate the third unknown variable.

Example (Monoject® 20 cc syringe)

1. For a Monoject syringe, use Chart #1
2. Flow Rate: NORMAL
3. Solution volume: 20 mL
4. 20 cc indicates

Time to infuse: 27 minutes



NOTE: The infusion time labels located on the MicroFuse Infuser are approximate. The actual infusion time for a given solution volume and syringe size should be determined from the Infusion Time Charts.

Infusion Time Charts

Chart #1: Monoject Syringes – Normal Rate

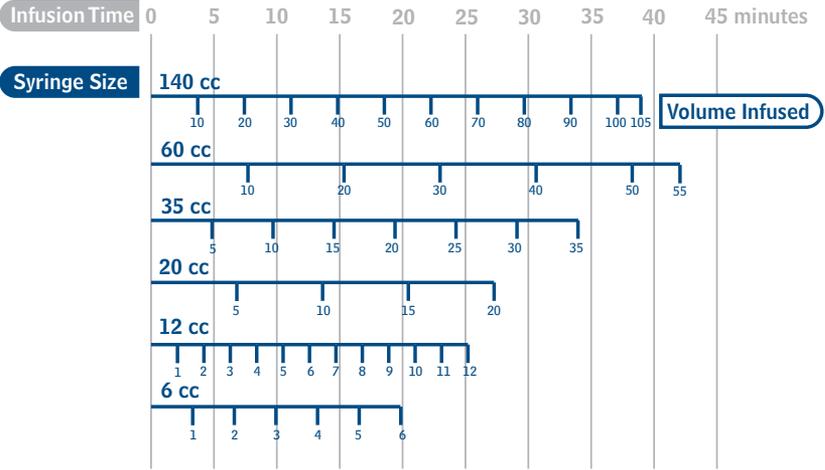
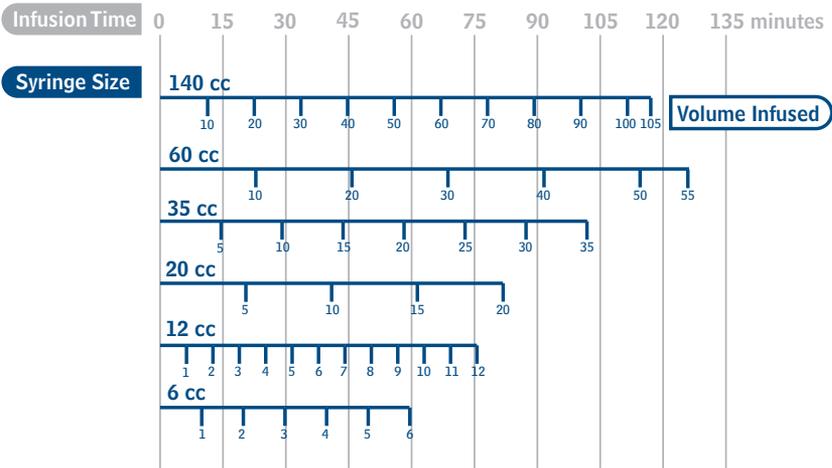


Chart #2: Monoject Syringes – Slow Rate



Infusion Time Charts

Chart #3: B-D Syringes – Normal Rate

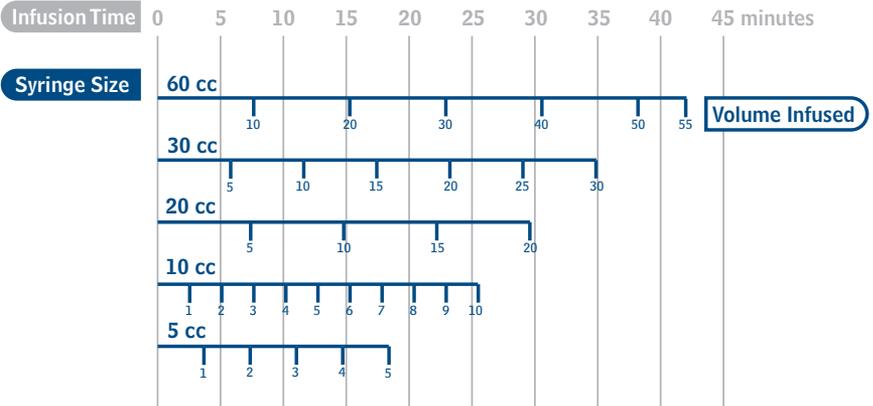
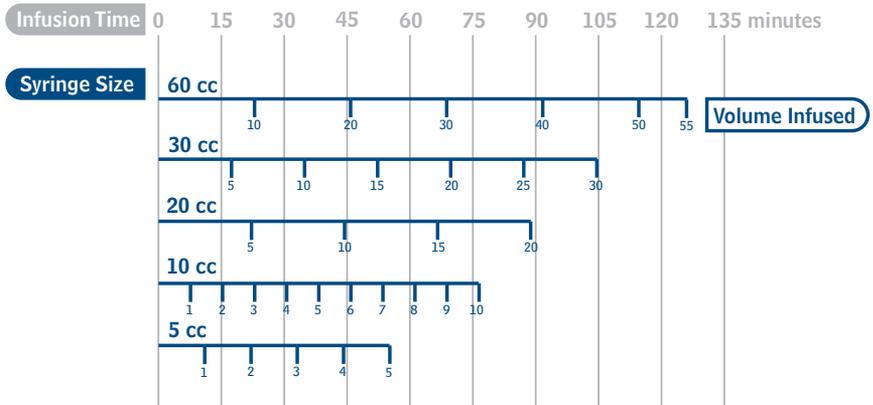


Chart #4: B-D Syringes – Slow Rate



Infusion Time Charts

Chart #5: Terumo Syringes – Normal Rate

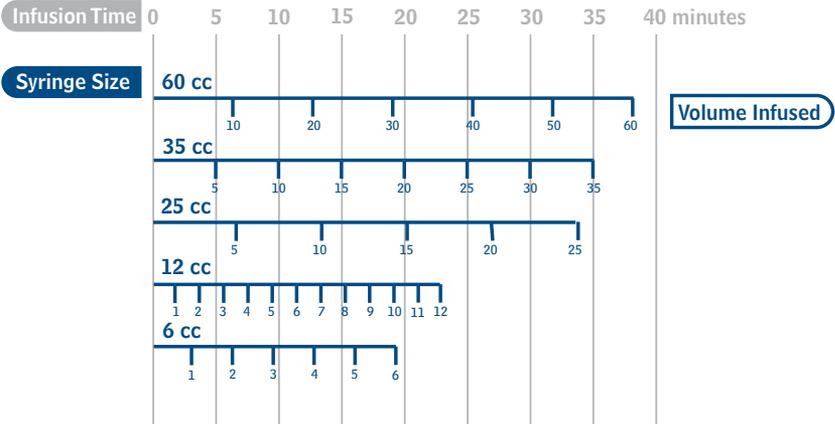
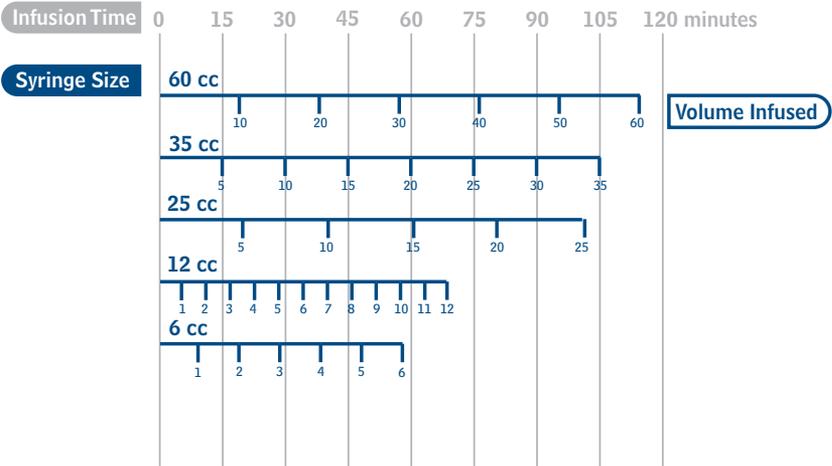


Chart #6: Terumo Syringes – Slow Rate



Occlusion Pressure Charts

These charts indicate the pressure exerted by the infuser when an occlusion alarm occurs. When the infuser is OFF, the pressure is released from the syringe driver arm.

To determine the typical occlusion pressures for a specific syringe:

1. Select the proper chart for brand of syringe.
2. Select the syringe size.
3. Read the resulting typical occlusion pressures from the table.

Occlusion Pressure Charts

Monoject Syringes

Syringe (cc)	Typical Pressure, psig
6	28
12	22
20	23
35	20
60	14
140*	9

* The Monoject 140 cc syringe requires the use of a smallbore (0.05") extension set to prevent false occlusion alarms.

Terumo Syringes

Syringe (cc)	Typical Pressure, psig
5	30
10	24
20	27
30	16
60	11

B-D Syringes

Syringe (cc)	Typical Pressure, psig
5	36
10	24
20	24
30	21
60	15



NOTE: Excessively viscous solutions (e.g., D25W) may cause false occlusion alarms under some delivery conditions.

Specifications

Size (L, W, H):	.9.6 in x 2.7 in x 4.0 in (24.4 cm x 6.9 cm x 10.1 cm)
Weight:	.25 oz. (0.7 kg) with batteries, 20 oz. (0.6 kg) without
Materials of Construction:	.Injection-molded plastic housing, battery cover, syringe driver arm, and syringe holder
Storage Temperature	.14°F to 149°F (-10°C to 65°C)
Compatible Syringes:	.BD, Monoject, and Terumo disposable syringes
Syringe Sizes:	.5 to 140 cc
Accuracy of Flow Rate:	.3% over 1.18 in (29.97 mm)
Power Requirement:	.3.0 V dc (battery only)
Battery Life:	.400 hours of operation typical, 10 hours typical at low battery indication.
Batteries:	.Two (2) C-cell, alkaline only
Infusion Rates:	.NORMAL: 5.5 in/hr, 14 cm/hr SLOW: 1.8 in/hr, 4.7 cm/hr
Delivery Times: (for most applications)	.NORMAL: 20 - 40 minutes SLOW: 60 - 120 minutes See the Infusion Time Reference Charts for flow rates with specific syringes.
Maximum Occlusion	
Detection Time:	.< 3 minutes at NORMAL rate
Occlusion Pressure:	.< 45 psi, (2327 mm Hg), See the Occlusion Pressure Reference Charts for typical occlusion pressures with specific syringe sizes.
Back Pressure Effect:	.None within 100 mm Hg pressure
Mounting Options:	.Built-in wire hanger or optional IV Pole Clamp
Alarms:	.Occlusion, end of infusion, low battery, and internal malfunction
Maximum Bolus Volume	
After Occlusion	.< 3 mL with 140 cc syringe
Maximum Infusion	
Upon Fault:	.Limited to volume of syringe

Maintenance

The MicroFuse Dual Rate Infuser is designed to require little maintenance. On activation, the infuser checks all major functions. Cleaning, disinfection and inspection should be performed according to users' standard protocols.

EMI Interference

The MicroFuse Infuser is designed to operate normally in the presence of most encountered electromagnetic field conditions. In the event of extreme levels of interference, normal operation may be disrupted.

Cleaning and Disinfection

Do not use harsh or aggressive cleaners such as concentrated bleach or ammonia. They may cause degradation of the unit and void the unit warranty! Exterior infuser surfaces may be cleaned using a damp cloth and mild detergent. Use either isopropyl alcohol 70% or dilute germicidal bleach to disinfect. The infuser cannot be immersed or flushed with any solution. Do not sterilize using EtO gas or steam autoclave.

Battery Replacement

The MicroFuse Infuser operates with two C-cell alkaline batteries. To access batteries, unlock caddy at the side of the unit and squeeze. Caddy will pull out. Load new batteries into the holders according to the orientation indicated. Replace the battery caddy.

Inspection

If the infuser has been dropped or damaged, inspect the unit before use.

- Look for visible cracks or breaks in the case.
- Inspect the battery housing for damage.
- Batteries must fit in the battery caddy, and the caddy must seat snugly into the infuser body.
- Turn power ON and verify that the syringe driver arm is locked into position.
- Run a Flow Rate Test to verify delivery accuracy.



CAUTION: Dropped infusers may incur internal damage. Refer to the instructions above to check for unit damage.

Flow Rate Test

The rate of travel of the syringe driver arm may be tested as follows:

1. Set the FLOW RATE switch to NORMAL.
2. Set the syringe driver arm as far toward the hanger as possible (maximum travel).
3. Slide the Power ON/OFF switch to ON.
4. Time until the End of Infusion alarm occurs. The time should be 44 to 47 minutes.



NOTE: Always replace both batteries at the same time with fresh batteries. Be careful to load both batteries in the correct orientation.

Rate Lockout

To restrict the MicroFuse Infuser to a single infusion rate: Set desired infusion rate using the FLOW RATE switch. Either NORMAL or SLOW rates can be locked. Release and remove battery caddy. Slide the LOCK/ UNLOCK switch in the battery compartment to LOCK. This fixes the FLOW RATE at the selected rate. Replace the battery caddy. Switch to UNLOCK to allow rate selection again.

Customer Support

During the warranty period, if the infuser malfunctions, or is defective for any reason, it should be returned to an authorized agent. Contact Customer Service (802-323-0101) for a Return Goods Authorization (RGA) number and shipping instructions. Please have the following information available:

- Infuser serial number
- Reason for the return

Freight is prepaid. Shipping weight: 2 lb. 2 oz. (when returned in the foam-lined infuser box). **Goods returned without an RGA will be refused.**

Ship to: Numia Medical Technology
84 Farrant Street
Newport VT 05855

Product Warranty

The Limited Warranty provided with the purchase of the MicroFuse Dual Rate Syringe Infuser covers defects in materials or workmanship for a period of 12 months from the date of purchase. This Warranty does not cover failures due to negligence or misuse.

Numia Medical Technology may, at their sole discretion, exchange the infuser for another that is in good working order. The MicroFuse Infuser is warranted to perform in accordance with published specifications and information.

This is an exclusive warranty. Any remedies under this warranty are restricted to replacement of defective product. Numia Medical Technology is in no way liable for incidental or consequential damages.

General Information

Trademarks

Monoject, B-D, and Terumo are trademarks of Sherwood Medical Co., Becton-Dickinson and Terumo, respectively.

New Product Program

Most of the products we offer were made because of customer suggestions. We welcome your suggestions for new products and improvements on existing products.

Ordering Information

To order MicroFuse Dual Rate Infusers and accessories:

Contact Numia Medical Technology:

Phone: 802-323-0101

Fax: 802-334-6971

Internet: www.numiamedical.com

Notes

Notes

Notes

Manufactured by:



Numia Medical Technology, LLC

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