

MICROfuse

Rapid Rate Infuser



Important User Information

CAUTION: Do not autoclave, steam sterilize, EtO sterilize, or subject the MicroFuse Infuser to temperatures in excess of 40°C (104°F).

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 hospital 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 this product is available.

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Overview

The MicroFuse® Rapid Rate Infuser is intended for intravenous infusion of adenosine. It is designed to deliver a “full” syringe dose (see NOTE below) over 6 minutes. The MicroFuse Rapid Rate Infuser delivers reliable, continuous infusion over the prescribed duration.

MicroFuse Rapid Rate 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 Rapid Rate Infuser is compatible with Becton-Dickinson® (B-D), Monoject® and Terumo® disposable syringes. Typical syringes for Adenoscan® (adenosine) are B-D 30 or 60 cc, Monoject 60 cc, or Terumo 30 or 60 cc.

Description

The infuser operates on two standard alkaline C-cell batteries. 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 ± 100 mm Hg.

The MicroFuse Rapid Rate Infuser infuses at one of two pre-set flow rates. RATE 1 infuses a “full” syringe over 6 minutes. RATE 2 infuses a “full” syringe over 8.4 minutes. If RATE 1 is set to deliver 140 mcg/kg/min of adenosine, RATE 2 will slow the dose to 100 mcg/kg/min.



NOTE: A “full” syringe is defined as having a syringe plunger extended 3.25 inches to accommodate the Rapid Rate Infuser fixed rates. Actual fixed rates are 0.533 inches per minute for RATE 1 and 0.381 inches per minute for RATE 2.

Description (cont.)

The MicroFuse Rapid Rate 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 law restricts this device to sale, distribution and use by, or on the order of, a licensed practitioner.

Contraindications:

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

NOTE: The MicroFuse Rapid Rate Infuser is designed exclusively for use with 30 to 60 cc syringes.

Features – Light Indicators

The MicroFuse Dual Rate Infuser uses five status indicator lights:

Indicator	Status
Rate 1 	Flashes GREEN when Flow Rate is set to Rate 1
Rate 2 	Flashes YELLOW when Flow Rate is set to Rate 2
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

Audible alarms accompany RED status indicator lights:

Condition	Light & 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/ approximately 15 doses remaining	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 15 doses	Repeating multi-note CHIME & infuser will not function.	Batteries must be changed.



NOTE: The infuser will continue to operate for approximately 15 doses after first detecting a low battery condition. After about 15 doses, 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 Rapid Rate Infuser. Refer to drug manufacturer's guidelines.

A. Setup

1. Remove air from syringe.
2. Calculate the correct volume of adenosine for a 140 mcg/kg/min dose, using the chart provided by Astellas Pharma Inc. or other manufacturer.
3. Draw up the adenosine solution in one of the following ways:
 - a. Use a B-D 30 mL or Terumo 30 mL syringe for doses up to 30 mL *For patients up to 231 pounds at 840 mcg/kg total dose using 3 mg/mL adenosine.*
 - b. Use a B-D or Monoject 60 mL syringe for 30 to 45 mL doses (may be used for all doses up to 45 mL by following step 4 below).
For patients up to 353 pounds at 840 mcg/kg total dose using 3 mg/mL adenosine.
 - c. Use a Terumo 60 cc syringe for doses up to 51 mL
For patients up to 400 pounds at 840 mcg/kg total dose using 3 mg/mL adenosine.
4. Add additional normal saline to the same syringe for:
 - a. 30 mL total volume in the B-D 30 mL syringe
 - b. 45 mL total volume in either the B-D 60 mL or Monoject 60 mL syringe
 - c. 51 mL total volume in the Terumo 60 cc syringe



NOTE: You must use one of the final diluted solution volume, syringe size AND manufacturer combinations for the Numia Rapid Rate Infuser to infuse over 6 minutes on Rate 1 (rabbit).

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. Set Up Tubing

1. Attach smallbore tubing to the syringe.
2. Prime the tubing.



NOTE: Administration set must have an internal diameter (ID) of at least 0.030 inches. A tubing clamp is desired, but not required. **Smaller set dimensions will cause a false occlusion alarm.**



CAUTION: Use of incompatible administration sets may cause false occlusion alarms, reduce infusion times, or increase prime and bolus volumes.

For Customer Support call 802-323-0101 • FAX 802-334-6971

D. 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. Rate 1 will infuse a full syringe over 6 minutes (0.533 inches per minute).
2. Rate 2 will infuse a full syringe over 8.4 minutes (0.381 inches per minute).



IMPORTANT NOTE: See definition of “full” syringe on page 2. Approximate time to infuse is indicated on the infuser and in the infuser Operator Manual.

E. Administration

1. Attach the administration 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 Rapid Rate Infuser to avoid unnecessary movement at the infusion site.
 - Hang the infuser from an IV pole using the attached wire hanger, or
 - Attach the infuser to the IV pole using the optional IV Pole Clamp.
3. Begin the infusion cycle by sliding the ON/OFF switch to ON.
 - a. Select Rate 1 (rabbit) to infuse at 140 mcg/kg/min.
 - b. Slide ON/OFF switch to ON.
4. To change infusion to 100 mcg/kg/min:
 - a. Leave the adenosine infusion running.
 - b. Press and hold flow rate switch for two full seconds to change to Rate 2 (turtle).

Administration (continued)

5. 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.
6. 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.

7. 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.
8. 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.
9. To remove the syringe after infusion is complete, lift the syringe barrel holder and slide the syringe out of the infuser.

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.
- Administrative procedures should follow drug manufacturers guidelines.

Advantages to Using the MicroFuse Rapid Rate Infuser for adenosine infusion:

- Ease of use
- Battery powered for portability
- No complicated programming, procedures or tubing systems

Safe

- Change infusion rates from 140 mcg/kg/min (Rate 1) to 100 mcg/kg/min (Rate 2) without turning off the infuser
- Rate accuracy of $\pm 3\%$
- Low battery light indicates when about 15 doses of battery operating life remain

Economical

- Low volume, 30" smallbore tubing minimizes drug waste
- Very low equipment cost compared to more complicated infusion devices
- Minimal drug waste

Reference : Vaishali KA, Kolling WM, Nardviriyakul N, Vander Kamp K and Wurster PE: Stability of undiluted adenosine at three temperatures in syringes and bags, *American Journal of Health-System Pharmacists*, 55: 466-470 (March 1) 1998.

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 (Rate 1 or Rate 2) 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 (B-D® 30 cc syringe)

1. For a B-D syringe, use Chart #3
2. Flow Rate: Rate 1
3. Solution volume: 30 mL
4. 30 cc indicates

Time to infuse: 6 minutes



NOTE: The infusion time labels located on the MicroFuse Rapid Rate 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 Syringe – Rate 1

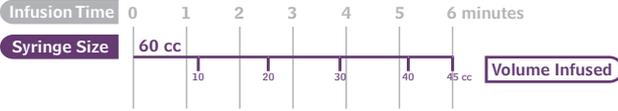


Chart #2: Monoject Syringe – Rate 2

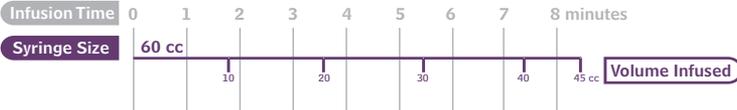


Chart #3: B-D Syringes – Rate 1

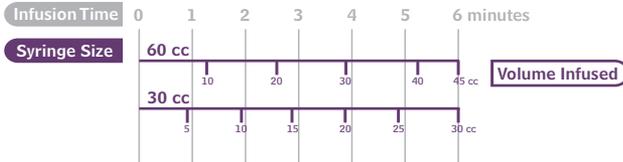


Chart #4: B-D Syringes – Rate 2

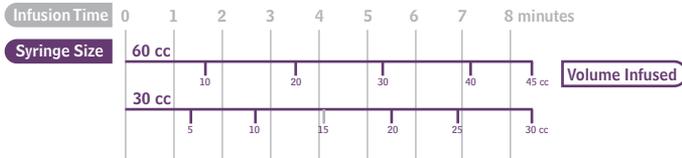


Chart #5: Terumo Syringe – Rate 1

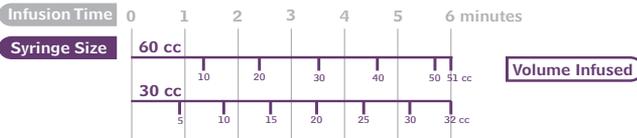
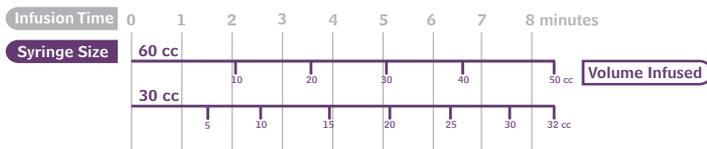


Chart #6: Terumo Syringe – Rate 2



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
60	14

B-D Syringes

Syringe (cc)	Typical Pressure, psig
30	21
60	15

Terumo Syringes

Syringe (cc)	Typical Pressure, psig
30	16
60	11

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
Storage Temperature	14°F to 149°F (-10°C to 65°C)
Materials of Construction:	Injection-molded plastic housing, battery cover, syringe driver arm and syringe holder
Compatible Syringes:	BD, Monoject, and Terumo disposable syringes
Syringe Sizes:	30 to 60 cc
Accuracy of Flow Rate:	± 3% over 1.18 in (29.97 mm)
Power Requirement:	3.0 V dc (battery only)
Batteries:	Two (2) C-cell, alkaline only
Infusion Rates:	Rate 1: 0.533 inches per minute Rate 2: 0.381 inches per minute
Delivery Times: (for full syringe)	Rate 1: 6 minutes Rate 2: 8.4 minutes See the Infusion Time Reference Charts for flow rates with specific syringes
Occlusion Pressure:	< 45 psi (2327 mm Hg) for approved syringes, 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, return for maintenance and internal malfunction

Maintenance

The MicroFuse Rapid 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 Rapid Rate 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 Rapid Rate 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 Rate 1. Fill 60 cc B-D or Monoject syringe to 45 cc.
2. Load the syringe onto the infuser (as described on page 7).
3. Slide the Power ON/OFF switch to ON.
4. Time for dose to infuse should be 6 minutes ($\pm 3\%$).



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

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 Numia (802-323-0101) for a Returned Material Authorization (RMA) 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 RMA will be refused.**

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

Product Warranty

The Limited Warranty provided with the purchase of the MicroFuse Rapid 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 may, at its 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 repair or replacement of defective product. Numia is in no way liable for incidental or consequential damages.

General Information

Trademarks

Numia, the Numia logo and MicroFuse are registered trademarks of Numia Medical Technology, LLC.

Monoject, B-D, and Terumo are trademarks of Sherwood Davis & Geck, Becton-Dickinson and Terumo, respectively.

Adenoscan is a registered trademark of Astellas Pharma Inc.

SmartSite is a registered trademark of Alaris Corporation.

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 Rapid Rate Infusers:

Contact Numia:

Phone: 802-323-0101

Fax: 802-334-6971

Internet: www.numiamedical.com

Notes

Notes

Manufactured by:

