

Freedom60™ Syringe Infusion System

Instruction Manual

Caution: Federal law (US) restricts this device to sale by or on order of a physician.

REPRO-MED SYSTEMS, INC 24 Carpenter Road Chester NY 10918
Tel: 800-624-9600 Outside US: 845-469-2042 Fax: 845-469-5518

(P.N. 337100, Rev. B, 5/98)

**FREEDOM60™ SYRINGE INFUSION SYSTEM
INSTRUCTION MANUAL**

TABLE OF CONTENTS

<u>Section</u>	<u>Item</u>	<u>Page</u>
1.	DEVICE DESCRIPTION	2
2.	INTENDED USE	2
3.	CONTRAINDICATIONS	2
4.	WARNINGS AND CAUTIONS	3
5.	MATERIALS SUPPLIED BY MANUFACTURER	4
6.	DISPOSABLE MATERIALS NOT SUPPLIED BY MANUFACTURER	4
7.	STORAGE	4
8.	DIRECTIONS FOR USE	
	A. Pharmacist Guidelines for Preparing Syringe and Tubing	5 6
	B. Description of the Freedom60 Pump System	7
	C. Loading the Freedom60 Pump with pre-filled syringe and starting the infusion	9
	D. Completing the infusion and removing used syringe and tubing	
9.	CARE AND MAINTENANCE	11
10.	SPECIFICATIONS	13
11.	LIMITATIONS	13
12.	REFERENCES	13
13.	WARRANTY	14
14.	MERCHANDISE RETURNS POLICY	15
15.	ORDERING INFORMATION	16

FREEDOM60™ SYRINGE INFUSION SYSTEM INSTRUCTION MANUAL

1. DEVICE DESCRIPTION

The Freedom60 Syringe Infusion Pump System consists of a reusable non-electric pump, Monoject or B-D 60cc syringe, and special rate-control extension tubing. The pump utilizes a constant force spring mechanism to apply pressure onto the syringe. The syringe is designed to be placed inside the pump with fluid amounts up to 60ml. The range of 10cc to 60cc is recommended. The constant force of the spring mechanism and the Freedom60 special rate-controlled extension tubing insures an accurate delivery rate and consistent flow profile. The syringe and rate-control extension tubing sets are supplied by Repro-Med Systems, Inc. The Freedom60 pump is designed to accept only Freedom 60® sets to operate as specified.

The Freedom60 Syringe Infusion Pump may be used for continuous or intermittent infusions and with most peripheral, midline, and central intravenous catheters, including peripherally inserted central catheters (PICCs)

2. INTENDED USE

The Freedom60™ Syringe Infusion Pump is intended for infusion of medications and intravenous solutions. The Freedom60 System allows the patient to be ambulatory and can be used in various settings, including home, hospitals, physician offices, outpatient clinics, ambulance, and nursing homes. The Freedom60 Syringe Infusion System may be used with fluids compatible with and recommended for use with the Sherwood Medical 60cc Monoject® syringes (mfg. reference no. 8881-560125) and Becton Dickinson & Co. 60cc B-D® Luer Lok® syringes (mfg. reference no. 309663).

3. CONTRAINDICATIONS

Use of the Freedom60 Syringe Infusion Pump is not indicated or approved for the delivery of blood or blood products.

4. WARNINGS AND CAUTIONS

Federal law (US) restricts this device to sale by or on order of a physician. Use the Freedom60 Syringe Infusion system only for patient for which the device is prescribed and only for its intended use.

Warnings:

1. Use only *Freedom60™* labeled tubing manufactured for Repro-Med Systems Inc, Chester, NY with Freedom60 pump. Use of any other tubing may cause excessive flowrate which can result in injury or death.
2. The tab which pushes on the plunger operates under high force. Do not place fingers on the tab or inside the clear syringe cover at any time. Do not attempt to interfere with the movement of this tab while pump is operating.

Cautions:

1. Prior to use, carefully inspect tubing package and syringe rigid package. Do not use tubing set if tubing package is opened or damaged. Do not resterilize Freedom60 tubing. Follow all syringe package instructions on handling and sterility. Do not resterilize syringes.
2. Carefully inspect the Freedom60 Infusion Pump prior to use. Verify that its condition is suitable for use. Test pump prior to use (follow procedures in Section 9 of this manual).
3. If repeated testing indicates that the pump is not operating at the appropriate rate of flow, immediately contact your nurse, physician, or pharmacist for assistance.
4. Inspect the syringe, syringe contents, and tubing before inserting syringe in pump, activating switch, or starting infusion.
5. Do not attempt to remove the syringe or remove or disconnect tubing without first placing the switch in the Stop/Wind (O) position and fully rewinding the pump.
6. Do not attempt to open pump housing or remove clear syringe cover.
7. Do not continue to use a pump which has been damaged, exposed to severe impact, or which has failed to test properly.
8. Storage of IV tubing with slide clamp or pinch clamp engaged will result in tubing deformation and may affect infusion rate.

5. MATERIALS SUPPLIED BY MANUFACTURER

The Freedom60 Syringe Infusion System is comprised of the Freedom60 pump, rate-control tubing and a standard 60cc syringe. An optional Accessory Travel Case adds to the convenience of the Freedom60 System. The rate-control tubing is available in various fixed flowrates. The complete Freedom60 Tubing & 60cc Syringe Set includes a standard Monoject 60cc syringe with luer lock tip. The Freedom60 tubing is also available separately for those customers who prefer to use standard B-D Luer Lok[®] 60cc syringes and purchase their syringes separately.

A complete listing of Freedom60 products is as follows:

1. Freedom60 Syringe Infusion Pump
2. Accessory Travel Case (optional)
3. Tubing & 60cc Syringe Set – 60ml/hr
4. Tubing & 60cc Syringe Set - 120ml/hr
5. Tubing - 60ml/hr
6. Tubing - 120ml/hr
7. Monoject[®] 60cc Replacement Syringe

Note: B-D 60cc syringes are not provided by Repro-Med directly.

6. DISPOSABLE MATERIALS NOT SUPPLIED BY MANUFACTURER

The following items are generally provided by the pharmacy for use with the Freedom60 Syringe Infusion System.

Item	Supplied by:
Prescription Medication	Pharmacy, appropriately diluted in intravenous solution.
Intravenous Solution Commonly used solutions include normal saline (NS), 5% Dextrose in Water (D ₅ W), and Sterile Water For Infusion (SWFI).	Pharmacy, typically pre-filled in syringe.
Intravenous Catheter Commonly used catheters are peripheral, midline, and peripherally inserted central catheters (PICC).	Inserted by nurse or physician or I.V. technician.

7. STORAGE

Store Freedom60 pump in a cool dry place as indicated on package. Prior to use, store packaged tubing and syringes at room temperature (approximately 16-30C or 61-86F).

8. DIRECTIONS FOR USE

8. A. PHARMACIST GUIDELINES FOR PREPARING SYRINGE AND TUBING

WARNING: Use only *Freedom60*TM labeled tubing manufactured for Repro-Med Systems Inc, Chester, NY with Freedom60 pump. Use of any other tubing may cause excessive flowrate which can result in injury or death. Note: as an additional safety feature, the Freedom60 pump is designed to reject the syringe, when pump is activated, if non-*Freedom60* labeled tubing is inadvertently attached.

The following guidelines are provided to assist a trained pharmacist in handling, filling, and storage of the Freedom60 syringe and tubing:

1. This is a conventional 60cc size syringe and should be handled and filled by the pharmacist (or other health care professional) using accepted protocols. Follow syringe package instructions for use. Maintain sterile procedure when filling syringe and attaching tubing.
2. The tubing is labeled to indicate the approximate flow rate when used with the Freedom60 Syringe Infusion System. The flowrate of the tubing is indicated in milliliters per hour (ml/hr).
3. Fill syringe to the appropriate level; do not exceed 60 ml. Remove air from the syringe by placing the syringe vertically, luer-end up, and expelling the air in the standard manner. Remove end-cap and attach female luer connector of the Freedom60 rate-control tubing to the syringe. After attaching tubing to syringe and removing both end-caps, remove remaining air from tubing and syringe. Re-cap the male-luer of tubing prior to packaging for patient and storage.
4. Following filling, the syringe, tip-capped or with capped restrictive tubing attached, should be immediately properly labeled for patient use by the pharmacist. Store filled syringes per established protocol following the syringe and drug manufacturers' recommendations.

CAUTION: Storage of IV tubing with slide clamp or pinch clamp engaged will result in tubing deformation and may affect infusion rate. Freedom60TM tubing is supplied with a non-vented end cap for resealing the male luer connector after filling. This end-cap is sufficient to prevent fluid loss during storage of filled sets. Do not use slide clamp or pinch clamp provided for this purpose. The clamp is provided only for momentary use in interrupting an infusion when pump is running.

A convenient storage tray is included with the Freedom60 sets. Each tray holds 4 filled syringe sets.

FOLLOWING ARE INSTRUCTIONS FOR USE OF THE FREEDOM60 SYRINGE INFUSION PUMP WITH PREFILLED FREEDOM60 TUBING/SYRINGE SETS. CHILDREN AND PEOPLE NOT ABLE TO UNDERSTAND AND FOLLOW THESE INSTRUCTIONS SHOULD BE CAREFULLY SUPERVISED WHEN USING THE FREEDOM60 SYRINGE INFUSION PUMP.

CAUTION: Inspect the syringe, syringe contents, and tubing before inserting syringe in pump, activating switch, or starting infusion.

Consult your pharmacist, physician, or nurse for instructions on how to inspect these items. Be sure to check that the tubing and syringe contents are free of bubbles, specks of material, or other particulate. Check the syringe and tubing for leaks, damage, or deformities. Check that the male luer-lock connector at the end of the tubing is covered with a small colored cap. Do not remove the cap at this time. A slide clamp or pinch clamp on the tubing set must be attached and the slide clamp or pinch clamp must be labeled with the proper flowrate (for example: 60ml/hr or 120ml/hr) and the word "Freedom60". Consult your pharmacist, physician, or nurse for proper flowrate information.

WARNING: Use only Freedom60™ labeled tubing manufactured for Repro-Med Systems Inc, Chester, NY with Freedom60 pump. Use of any other tubing may cause excessive flowrate which can result in injury or death.

8. B. DESCRIPTION OF THE FREEDOM60 PUMP SYSTEM

The Freedom60 Syringe Infusion Pump contains a constant force mechanism to press the plunger of a pre-filled standard Monoject or B-D 60 cc syringe with luer lock tip when mounted in the pump. A proprietary rate control tubing set, designed for a specific flow rate, is attached to the pre-filled syringe prior to mounting the syringe in the pump. The syringe is typically pre-filled with medicant and/or diluent by a pharmacist, physician, or nurse prior to patient use. The syringe has a maximum capacity of 60cc. The syringe can be filled (and the pump operated) at various levels, from 10cc to 60cc, dependent on physician and pharmacist recommendations. Adequate procedures are to be maintained to assure sterility of the fluid path during filling, storage, and use of the system. Following filling of syringe, the pharmacist, physician, or nurse either seals the syringe (typically with a sterile tip cap) or attaches a Freedom60 tubing set to the syringe prior to patient use. Immediately after attaching the Freedom60 tubing set and prior to patient use, the pharmacist, physician, or nurse will use the recommended procedure to evacuate air from both the syringe and tubing set. The female luer-lock end of the tubing should then be capped.

The Freedom60 pump consists of an opening for inserting the plunger of the pre-filled syringe, a special "nose-end" tip to help locate and secure the pre-attached proprietary tubing set and syringe during use, and a knob and switch for operating the pump. There is a large knob and a smaller round dark-color recessed switch located on the front surface of the pump. The knob is used to wind the pump, and the switch is a two position switch used to activate the pump. The switch rotates 90° or 1/4 turn and has two modes. The mode of the switch is indicated by the position of the arrow symbol (>) at either of the following 2 locations:

Stop/Wind, located by the symbol (O), or

Run, located by the symbol (|).

When the switch is positioned in the **Stop/Wind** mode, the pump mechanism, if running, will stop moving. In this position the pump can be wound. To wind the pump, the large knob is wound clockwise -- in the direction of the arrows on the knob. The winding of the knob moves the small plunger tab to the far end of its track in the pump. The small plunger tab locates and pushes on the plunger when the pump is in the **Run** mode. After full winding of the knob

(indicated by an overwind slip-clicking action) a used syringe and tubing can be easily removed from the pump. After fully winding the knob, a new pre-filled syringe with tubing attached can be inserted into the plunger opening and loaded in the pump. In the **Run** mode, the plunger tab will press on the syringe plunger, delivering the solution through the tubing to the patient's catheter. Note: during the **Run** mode the large knob may be rotated without interrupting the flow of the solution. For use in stopping the flow of solution, a standard slide clamp or pinch clamp is mounted on the tubing.

8. C. LOADING THE FREEDOM60 SYRINGE INFUSION PUMP WITH PRE-FILLED SYRINGE AND STARTING THE INFUSION

1. Before loading syringe check the following:

a) Check that the pump switch is in the **Stop/Wind** position, located by the symbol O. The pump switch is the small recessed dark-color disk on the front of pump.

b) Check that the small plunger tab is at the far end of its track in the pump. Simply wind the knob clockwise to move the small plunger tab to the far end of its track. Note: the small plunger tab locates and pushes on the plunger when the pump is in the **Run** mode.

It is recommended that the pump be stored fully wound with the small plunger tab at the far end of its track. Do not activate the switch without a pre-filled syringe securely mounted in the pump.

2. Insert the pre-filled syringe, with a Freedom60 tubing set pre-attached, into the Freedom60 Syringe Infusion Pump. Note, the pump has a bracket which matches the finger-flange design of both a Monoject and B-D 60cc syringe. This bracket secures the flange end of the syringe barrel and prevents rotation of the syringe in the pump. The proprietary micro-bore tubing set has a round blue-colored plastic disk located at the point where the tubing connects to the syringe. Be sure this disk is placed properly within the nose-end of the pump. The nose-end of the pump has a mating indentation which matches the shape of this blue disk and holds it in place. To insure proper operation of the pump this disk must be free from defects and properly located in the nose-end of the pump.

Note: the syringe has a numbered scale printed on one side of the syringe. This numbered scale is helpful to monitor the infusion and proper operation of the pump. For easy viewing, it is recommended that the syringe be placed in the pump with the numbered scale facing outward from the pump.

3. After properly loading the syringe with attached Freedom60 tubing in the pump, gently and carefully twist the colored cover cap counter-clockwise and remove cap from the male luer-lock at the end of the tubing. Retain cap. Use sterile handling of both the tubing and the cap.

4. Start pump and verify that fluid is flowing properly. Note: this procedure can also be used to eliminate bubbles that may have formed in the pre-filled syringe or tubing. Consult with your nurse, physician, or pharmacist on proper procedure for clearing bubbles.

To start pump and verify that fluid is flowing use the following steps.

a.) While holding the tubing, activate the pump by rotating the switch 90° or 1/4 turn, pointing the arrow symbol (>) at the **Run** position (|).

When you start the pump, with the syringe and tubing installed, you will immediately hear the following sounds: first the switch will **click** in place, then a **whirl** sound will be heard as the small plunger tab moves forward to the end of the syringe plunger, and finally, as the tab pushes on the plunger the pump will make a final **click** sound. This final **click** sound indicates that the tab is pressing on the plunger and fluid is being pumped through the tubing.

b.) After 3 - 5 seconds, drops of fluid should begin to flow consistently from the male luer-lock connector. Check that all air has been eliminated from the syringe and tubing and that only fluid is flowing from the connector. Stop the flow by attaching the small colored end cap provided for resealing.

Note: if you are removing air bubbles from the syringe, allow all air to be expelled from the syringe and tubing. After clearing all air from syringe and tubing, observe that drops of fluid flow consistently from the male luer-lock connector, and then stop the flow by attaching the small colored end cap provided for resealing.

The pump is now in the **Run** mode. During the **Run** mode the pump does not make any noise. In the **Run** mode, the plunger tab presses on the syringe plunger and, with the slide clamp or pinch-clamp open, delivers the solution in the syringe through the tubing to the patient's catheter.

5. Remove the small colored end cap provided for resealing and following instructions for care of and securing the patient infusion site and catheter, connect the tubing luer connector to the catheter and infusion site. Secure the tubing appropriately and begin infusion. Confirm that pump switch is in **Run** position (|). Begin monitoring the pump function and infusion rate.

Consult your pharmacist, nurse, or physician for instructions on the care of the patient infusion site and catheter and proper technique for connecting the tubing set to the infusion site and securing the tubing.

6. Periodically monitor the pump function, infusion rate, infusion site, and catheter throughout the infusion as instructed by your nurse, physician, or pharmacist.

To monitor the pump function, visually inspect the syringe movement to determine that it is supplying the syringe contents at the appropriate rate of flow. Note: the syringe is marked in two units of measure: cc (cubic centimeters) and oz (ounces). Note: for purposes of reading the pump infusion rate 1 ml (milliliter) equals 1 cc.

The approximate rate is printed on the Freedom60 slide clamp or pinch-clamp attached to the tubing. For example your slide clamp or pinch clamp may read: **60 ml/hr**. This means that the fluid should flow from the syringe to your catheter at a rate of approximately 60 milliliters (60 ml) per hour. When using tubing labeled **60 ml/hr**, the proper flowrate can be checked by verifying that the plunger moves 5cc in approximately 4 to 6 minutes. When using tubing labeled

120 ml/hr, the rate can be checked by verifying that the plunger moves 10cc in approximately 4 to 6 minutes.

These readings are approximate and may vary due to the specific temperature or viscosity of the fluids or medications you are using.

If the pump does not appear to be supplying the syringe contents at the appropriate rate of flow then immediately check to make sure the pump is in the **RUN** (|) mode and that the tubing is not “pinched” in the slide clamp or pinch clamp and that the infusion is not completed (syringe empty condition). Also check the condition of your catheter and infusion site. Correct any obvious problems, as instructed by your nurse, physician, or pharmacist. Make the necessary corrections or if no problems are found, repeat a second 5 minute test. **CAUTION: If repeated testing indicates that the pump is not operating at the appropriate rate of flow, immediately contact your nurse, physician, or pharmacist for assistance.** Do not attempt to diagnose or correct the problem further. If you have any concerns on the function or operation of your Freedom60 pump contact your nurse, physician, or home care agency immediately.

The Freedom60 pump may be worn by the patient using the travel pouch. Contact your Repro-Med representative for availability of this convenient accessory.

8. D. COMPLETING THE INFUSION AND REMOVING USED SYRINGE AND TUBING.

Continue to monitor the pump function, infusion rate, infusion site, and catheter periodically as instructed by your nurse, physician, or pharmacist (see instruction 8.c.6. above). Observe the position of the syringe plunger in the syringe. If the syringe plunger has advanced fully to the tubing-end of the syringe, the syringe is empty. Remove the empty syringe by completing the following steps:

- a) Following instructions for care of and securing the patient infusion site and catheter, apply the slide clamp or pinch clamp securely on the tubing to seal the tubing. Disconnect the micro-bore tubing set from the catheter or other infusion site connector. With syringe and tubing in place, briefly set the pump aside. Remove the used syringe from pump prior to storing the pump. Do not store the Freedom60 Syringe Infusion Pump with an empty syringe in place. See step c. below for safe removal of syringe from pump.
- b) Secure and care for the catheter and infusion site as instructed by your pharmacist, nurse, or physician.

c) Remove the used syringe and tubing from the syringe pump. To remove the syringe and tubing follow these steps:

1. Rotate the switch 90° or 1/4 turn “pointing” the arrow symbol (>) at the switch position **Stop/Wind** symbol (O). This will fully stop the pumping mechanism and allow you to wind the pump.
2. Wind the pump fully by turning the large knob clockwise -- in the direction of the arrows on the knob. After full winding of the knob, indicated by the overwind slip-clicking action, the used syringe and tubing can be easily removed from the pump.

CAUTION: Do not attempt to remove the syringe or remove or disconnect tubing without first placing the switch in the Stop/Wind (O) position and fully rewinding the pump. To prevent removal of the syringe and interruption of the infusion, the pump generates strong tension on the syringe and tubing connector when in the *Run* (|) mode. This strong tension can cause damage to the pump or injury if the syringe is incorrectly removed.

3. Remove the used syringe and tubing from the pump by doing the following:
Gently grasp the barrel of the syringe and gently pull the syringe downward and horizontal to the pump, moving it approximately 1/4 inch. This should free the blue tubing connector from the nose-end of the pump. Move the connector and tubing outward through the opening slot in the nose of the pump. When the connector is fully clear of the pump, gently remove the syringe and connector from the pump. Properly dispose of used tubing and used syringes as instructed by your nurse, physician, or pharmacist. Store the pump at room temperature and in a safe and secure place until next use.
4. After fully winding the knob and removing the used syringe, a new pre-filled syringe with tubing attached can be inserted into the plunger opening and loaded in the pump.

d) If a second pre-filled syringe is immediately required for your infusion complete the following steps. Note however that immediate use of a second pre-filled syringe is unusual and is only required with certain medications. Typically only one syringe is required for each infusion. If you are not certain concerning use of second syringe of medication then verify with your pharmacist, nurse, or physician before proceeding.

1. Inspect the second pre-filled syringe. Determine if a Freedom60 tubing set or tip cap is in place. If a Freedom60 tubing set is not in place, using sterile technique, replace the tip cap with a proper Freedom60 tubing set.
2. Complete the infusion by following the instructions in Sections 8. C. and D.

9. CARE AND MAINTENANCE

The internal mechanism of the Freedom60 Syringe Infusion Pump is not designed to be serviced or cleaned except by Repto-Med Systems at its factory. **CAUTION: Do not attempt to open pump housing or remove clear syringe cover.** Do Not attempt to service internal components of the Freedom60 Pump. Do not operate pump if clear syringe cover is removed. There are no user serviceable Freedom60 pump components. The pump internal mechanism operates under high tension and injury may occur if any attempt is made to open the pump.

CAUTION: Do not continue to use a pump which has been damaged, exposed to severe impact, or which has failed to test properly. Remove pump from service.

The Freedom60 Syringe Infusion Pump has been carefully engineered to operate reliably with minimal maintenance. Improper maintenance can result in contamination entering the pump which could damage the internal pump mechanism. Therefore, precautions should be taken to prevent contamination from entering the pump. Following are instructions for proper maintenance of the Freedom60 Syringe Infusion Pump:

1. Do not submerge the pump in solution. If any fluid is allowed to enter the pump, the pump should not be used and should be returned to the pharmacy for immediate replacement.
2. Clean the pump after every use. To clean, wipe surfaces with warm water and detergent. Wipe with clean water to rinse. Wipe with a cold sterilant to disinfect. Clean only with agents compatible with acetal-butyl-styrene (ABS) and polycarbonate (PC) plastics. Cleaning of the pump should be only to those areas that are exposed and external. No attempt should be made to clean any part of the pump which not easily accessible. The inside of the polycarbonate tube may be cleaned using a long swab or bottle brush and appropriate cleaning agents compatible with ABS and PC plastics. **WARNING: The tab which pushes on the plunger operates under high force. Do not place fingers on the tab or in the pump clear syringe cover at any time. Do not attempt to interfere with the movement of this tab while pump is operating.** Avoid the use of solvents or abrasive cleaning agents. Abrasive cleaning agents may mar the housing surface. If abrasive agents should enter the pump, the pump mechanism may be damaged or wear prematurely and not operate correctly.
3. The pump should be checked and tested following each use. The pump may be functionally tested by operating without a syringe in place. First fully wind the pump. Turn the switch to **RUN (|)** mode. The small plunger tab should then move smoothly the full length of the inside of the polycarbonate tube. When you start the pump you will immediately hear the following sounds: first the switch will click in place, a whirl sound will be heard as the small plunger tab moves forward to the end of the tube, and finally, as the tab reaches the end of its travel, the pump makes a short click sound. If the pump operates in this way the mechanism is operating normally. After the test, fully rewind the pump.
4. Examine the syringe placement area, and insure there is no debris or contamination. Test that the syringe tension spring-tab operates freely. The syringe tension spring-tab is the small 1 inch long blue-colored sliding tab located at the flange shaped entry to the clear syringe cover tube.
5. To test the flow accuracy of the pump use the following “bench test” procedure:

1. Fill a new Monoject 60cc syringe with SWFI. Fill the syringe to 60 cc and remove air bubbles. Attach a sterile 60 ml/hr labeled Freedom60 tubing to the syringe. Bleed tubing of air. A sterile 120 ml/hr labeled Freedom60 tubing can be used to accelerate testing.
2. Follow instructions in Section 8 for loading syringe and starting infusion.
3. Bench test pump flowrate by monitoring the plunger readings and elapsed time and deriving an approximate flowrate. Compare these test results to the range of test flowrates listed on the table below.

Label Flowrate	Bench-rated Flowrate ⁽¹⁾	Bench Test Range ⁽²⁾
60 ml/hr	72 ml/hr	61 - 83 ml /hr
120 ml/hr	134 ml/hr	113 - 154 ml /hr

Note: additional rate-control tubing may be available from Repro-Med Systems Inc. For information on the specific bench test flowrate ratings and test ranges on other tubing contact Repro-Med Systems Inc.

⁽¹⁾ The Freedom60 system design accounts for the effects on flowrate performance of standard clinical conditions providing the patient and pharmacist a "real-world" flowrate rating. Under bench test conditions, a 60 ml/hr labeled Freedom60 tubing is designed to generate a nominal infusion rate of 72 milliliters per hour. A 120 ml/hr labeled tubing will generate a nominal bench test rate of 134 milliliters per hour. The Freedom60 design generates nominal bench test rates higher than the application rate (label rate) accounting for the following standardized application criteria which affect the actual delivery rates under normal clinical circumstances.

	60 ml/hr Tubing	120 ml/hr Tubing
Bench Test Rate	72	134
less clinical criteria effects:		
Catheter gage (std 20 PICC)	-7	-8
Fluid viscosity (D ₅ W)	-2	-3
Venous pressure	-3	-3
Label flowrate	60	120

⁽²⁾ To assure consistent test results, keep pump and tubing at the same approximate horizontal plane and monitor flow for a minimum of 20 minutes. The Freedom60 system is factory rated to deliver infusions under strict test conditions over a large number of pumps tested within 8% of nominal with a 95% statistical confidence interval. Under varying bench testing and fluid conditions this range can be expected to vary within approximately 15% of nominal. For more accurate monitoring use a calibrated stop watch and finely-gradated burette of the appropriate size. Freedom60 pump testing is based on ANSI/AAMI National Standard, ID 26-1992, Infusion Devices, August 24, 1992.

If test results in the range indicated cannot be approximated under bench testing conditions, factory certification testing is available from Repro-Med Systems.

10. SPECIFICATIONS

Reservoir Volume 60 ml (maximum)
Residual Volume <1ml
Accuracy +/- 8%*
Maximum static pressure 14 psi
Flow Rates - selectable by rate-controlled microbore tubing
Height sensitivity +/- 3% per foot.
Weight approximately 14 ounces
Size 12.0" x 4.5" x 1.6"

* Flow rate data recorded at 22°C using 60 ml of 0.9% NaCl. An overall accuracy of +/- 8% is expected at these values. At higher temperatures due to the expected decrease in viscosity, a higher flow rate is anticipated to occur. The flow rate variation due to changes in temperature is approximately linear and would vary from -20% at 14C to +20% at 30C. Fluids considerably more viscous than 0.9% NaCl are expected to slow the flow rate and consequently may result in longer infusion times. More viscous fluids may be tested before patient use by following the bench test procedures in Section 9.5. of this manual and substituting the subject fluid(s).

11. LIMITATIONS

1. Do not use frozen or semi-frozen intravenous solutions.
2. Use of the Freedom60 Syringe Infusion Pump is not indicated or approved for the delivery of blood or blood products.
3. Rates of infusion vary significantly by pump placement 3 feet above or below the infusion site. Within three feet the maximum rate of error for infusion is approximately 3%/ft.

12. REFERENCES

1. Stuhmeier, Mainzer B. MD; Aspects of pressure build-up in the use of electronic infusion devices. II. Need for a pressure limit. *Anasth Intensivther Notfallmed* (1987 Aug.) 22(4) : 185-190.
2. *Anasth Intensivther Notfallmed* (1987 Aug.) 22(4): 181-184.
3. ANSI/AAMI National Standard, ID 26-1992, Infusion Devices, August 24, 1992

13. WARRANTY

Freedom60 Syringe Infusion System Warranty Statement

This warranty is given in lieu of all other warranties, expressed or implied, of merchantability, fitness for a particular purpose or otherwise.

No statement or claim about the product by any employee, agent, representative, or dealer of Repro-Med Systems, Inc. shall constitute a warranty by Repro-Med Systems, Inc. or give rise to any liability or obligation of Repro-Med Systems, Inc.

Subject to the next sentence, Repro-Med Systems, Inc. warrants that each Freedom60 product or part shall be free from defects in workmanship and materials, under normal use and with appropriate maintenance, for two (2) years from the date of delivery to the customer. For sterile or disposable parts or items, Repro-Med Systems, Inc. warrants only that each such part and item shall be free from defects in workmanship and materials at the time of shipment to the customer.

Repro-Med Systems, Inc.'s obligation for breach of this warranty, or for negligence or otherwise, shall be strictly and exclusively limited to the repair or replacement of the product or part. This warranty shall be void on any product on which the serial or lot number has been altered, defaced, or removed.

Repro-Med Systems, Inc. shall not be liable for any damage, injury, or loss arising out of the use of the product, whether as a result of a defect in the product or otherwise, if prior to such damage, injury, or loss, the product was: (1) damaged or misused; (2) repaired, altered, or modified by persons other than Repro-Med Systems, Inc.

UNDER NO CIRCUMSTANCES SHALL REPRO-MED SYSTEM, INC. BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES AS THOSE TERMS ARE DEFINED IN THE UNIFORM COMMERCIAL CODE.

14. MERCHANDISE RETURNS POLICY

A. RETURN GOODS POLICY

1. The following will not be accepted for credit:
 - Goods not in original, sealed package.
 - Goods not purchased directly from Repro-Med; contact your distributor if goods were purchased otherwise.
 - Goods without a Return Goods Authorization (RA number).
 - Merchandise more than 90 days old (from Repro-Med invoice date).
2. A 20% restocking charge will be deducted from the original purchase amount for all credits issued, except for return due to Repro-Med order entry error or warranty returns.
3. Return Authorization (RA) numbers are valid for returns received within 30 days after the date issued. Please forward merchandise promptly.
4. Except in the event of misshipment by Repro-Med, freight charges will not be credited.
5. Freight collect shipments are not accepted.
6. If merchandise is not salvageable, no credit will be issued.
7. All claims for damage or shortage occurring in transit must be made by the customer directly to the carrier.

B. WARRANTY RETURNS

1. Merchandise returned for warranty credit replacement must have been purchased from Repro-Med within the specified warranty period.
2. Defective items will, at Repro-Med's discretion, either be repaired or replaced with equivalent merchandise.
3. If merchandise is found not to be defective, the 20% restocking fee will be charged or merchandise returned to customer.
4. Freight charges to return defective merchandise to Repro-Med are not reimbursable. Freight charges to ship replacement or repaired merchandise to customer will be paid by Repro-Med.

C. CUSTOMER RETURN INSTRUCTIONS

Please follow the procedures outlined below so there is no delay of credit to your account. A Return Authorization (RA) number is required before returning any merchandise to Repro-Med. Credit may be issued only after merchandise is returned to and inspected by Repro-Med and determination is made that credit is due.

To Receive a Return Authorization (RA) Number:

1. Call your Customer Service Representative (800) 624-9600.
2. Be prepared to provide the following information:
 - a. Our invoice number and date and lot number (if applicable).
 - b. Product description, product number, and reason you wish to return merchandise.
3. Your Customer Service Representative will give you a RA number. The RA number authorizes our receiving department to accept the merchandise. Receipt of a RA number does not imply that credit will be extended.
4. Enclose a letter of explanation and a copy of our original invoice with return.
5. Any contaminated merchandise must be decontaminated prior to returning to Repro-Med

15. ORDERING INFORMATION

The following Freedom60 product reorder numbers and case quantity information are provided to assist ordering.

<u>Reorder Number</u>	<u>Description</u>	<u>Case Quantity</u>
F10050	Freedom60 Syringe Infusion Pump	1 each
F10090	Accessory Travel Case (optional)	1 each
Disposable Components:		
F60ML	Freedom60 Tubing & 60cc Syringe Set - 60ml/hr flowrate	100 per case
F120ML	Freedom60 Tubing & 60cc Syringe Set - 120ml/hr flowrate	100 per case
F60ML-250T	Freedom60 Tubing - 60ml/hr flowrate	250 per case
F120ML-250T	Freedom60 Tubing - 120ml/hr flowrate	250 per case
F60cc	Monoject® 60cc Replacement Syringe	100 per case

For availability of rate-control tubing in other flowrates contact your Repro-Med Systems representative.

(end page)

REPRO-MED SYSTEMS, INC 24 Carpenter Road Chester NY 10918
Tel: 800-624-9600 Outside US: 845-469-2042 Fax: 845-469-5518