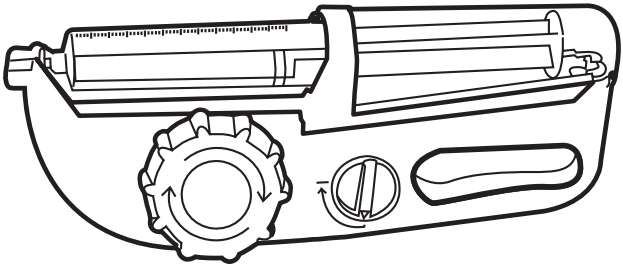
FREEDOM60®
Syringe Infusion System



Instructions For Use

Contents

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24 Carpenter Road Chester, NY 10918 USA

Introduction

The FREEDOM60® Syringe Infusion System is portable and easy to use, requiring no batteries or electricity. There are only two operating knobs and KORU Precision Flow Rate Tubing™ sets are used to control the flow rate.

The FREEDOM60 operates at a constant pressure, which automatically decreases the flow rate if there is an increase in resistance during the delivery. The system will find balance, known as Dynamic Equilibrium (or DynEQ®), between the increasing resistance and flow rate. It provides constant flow which tends to inhibit clots, and holds full pressure after an infusion is complete to prevent blood or drug return. The FREEDOM60 also eliminates concerns of a bolus, overflow, overdose or runaway infusion.

Indications for Use

The Freedom Integrated Syringe Infusion System is specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins when used according to the FDA approved biologic labeling: Cutaquig®, Immune Globulin Subcutaneous (Human) 16.5% Solution (manufactured by Octapharma®); Cuvitru®, Immune Globulin Infusion (Human) 20% (manufactured by Takeda®); Gammagard Liquid®, Immune Globulin Infusion (Human) 10% (manufactured by Takeda®); Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®); and Xembify®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by Grifols®) in the home, hospital, or ambulatory settings when administered according to the approved biologic or drug product labeling.

The Freedom Integrated Syringe Infusion System with the FREEDOM60® Syringe Driver and Precision Flow Rate Tubing™, is specifically indicated for the intravenous infusion of the following antibiotics when used according to the FDA approved drug product labeling: ertapenem, meropenem, oxacillin, and tobramycin.

The Freedom Integrated Syringe Infusion System consists of the following components:

- FREEDOM60® Syringe Driver
- Precision Flow Rate Tubing™
- HIgH-Flo Subcutaneous Safety Needle Sets™

The FREEDOM60® Syringe Driver is indicated for use with the BD® 50 ml syringe (US Reference number 309653).

MRI Safety Information

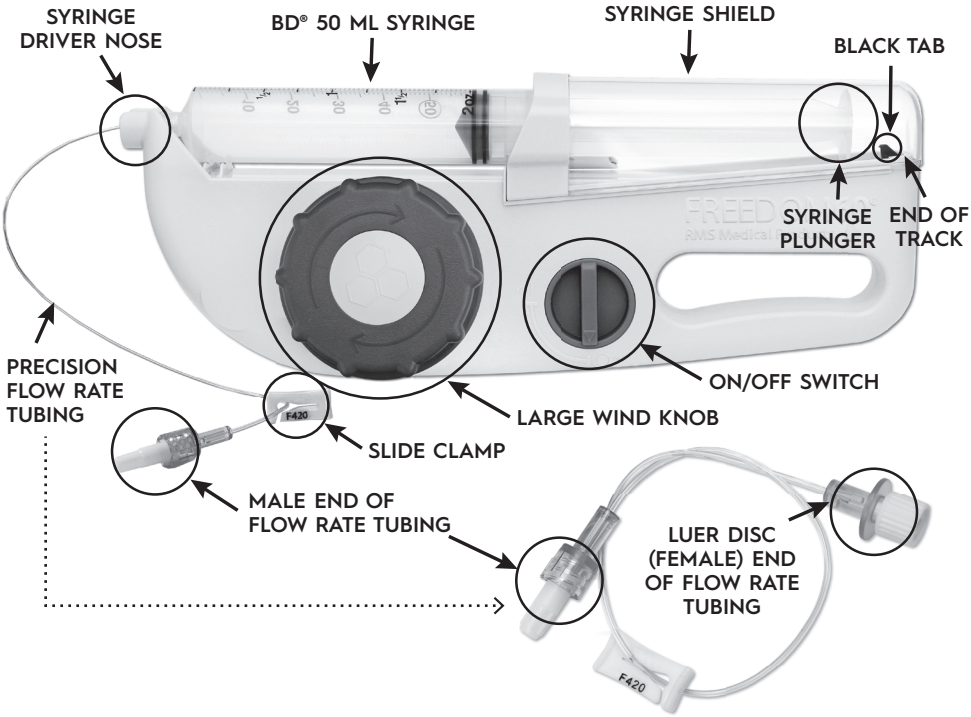
MR The Freedom Integrated Syringe Infusion System is MR Unsafe.

Do not use the Freedom Infusion System or its components, such as the Precision Flow Rate Tubing™, HIgH-Flo Subcutaneous Safety Needle Sets™ or Low Residual Volume Y-Connector, while undergoing MRI medical diagnostic procedures.

⚠ Caution

- Use the FREEDOM60® Syringe Infusion System only for the patient for whom the device is prescribed and only for its intended use.
- Use only Freedom System accessories manufactured by KORU Medical Systems. Use of off-brand products may result in unknown flow rates.
- Patient tolerability may vary. For patients experiencing discomfort, contact your healthcare provider to determine if a flow rate adjustment is necessary.
- Flow rates can be affected by multiple factors such as temperature, patient conditions, height differences between the system and infusion site, and variations in solution viscosity.
- Excessive motion during infusion may cause flow rate variability. Vigorous activity is not recommended.
- It is recommended to perform infusions while stationary or walking. Infusions with movement other than walking may result in faster, slower, or more variable flow rates than specified. Testing has been performed to simulate walking and its effect on flow rates, no other physical activity has been analyzed.
- Directly connecting extension tubing or HIgH-Flo needle sets (without the luer disc) to the syringe will cause it to eject from the FREEDOM60 and may eventually cause internal damage to the syringe driver.
- Use only BD® 50 ml syringes with the FREEDOM60.
- Before use, carefully inspect the tubing and needle set packaging. Do not use the set if the package is opened or damaged. Inspect the tubing and needle sets for damage. If damaged, replace and contact your healthcare provider.
- Do not re-sterilize tubing or needle sets.
- The slide clamp included on the Precision tubing and HIgH-Flo needle sets should only be used in the case of an emergency, to stop flow immediately. Use of the slide clamp may cause damage to the tubing and can affect the intended flow rate.
- The black tab that pushes on the syringe plunger operates under high force. Do not place fingers on the black tab or inside the syringe shield at any time. Do not attempt to interfere with the movement of the black tab at any time.
- Carefully inspect the FREEDOM60 before use. Discontinue use of a syringe driver that has been damaged, exposed to severe impact, or which fails to operate properly.
- Do not attempt to open the syringe driver housing or remove the syringe shield. Do not operate if the syringe shield has been removed.
- Avoid placing needles over a mole, tattoo, scar, muscle, hardened or bruised areas, where proper needle insertion could be difficult.
- To obtain maximum accuracy of the pump, verify that the height of the syringe driver relative to the needle site is positioned within ±3" both while in a stationary position and while in motion.
- Do not attempt to remove the syringe or disconnect the tubing set without first turning the syringe driver to the OFF position and fully winding the large knob clockwise until the black tab has reached the end of its track.
- The FREEDOM60 does not have an alarm, therefore no alarm will sound if an interruption to flow occurs. There is no display of infusion status.
- The syringe driver is not suitable for use with medication where delay or under-infusion could result in serious injury.
- If the syringe driver is submerged in any fluid, discontinue use and call your healthcare provider for a replacement.
- Do not autoclave the FREEDOM60 syringe driver.
- The FREEDOM60 Syringe Infusion System is not intended for blood transfusions.
- The FREEDOM60 Syringe Infusion System is not to be used during diagnostic procedures, such as MRI, x-ray, or CT scans.
- Federal law (USA) restricts this device to sale by or on the order of a physician.

FREEDOM60® Diagram



FREEDOM60 Product Line

Each FREEDOM60 includes a travel pouch and user instruction manual.

Product	Part #
FREEDOM60® Syringe Driver	F10050
Replacement Travel Pouch - Grey	345400
Pattern Travel Pouch - Zebra print	F10080

Syringe for use with the FREEDOM60

Becton Dickinson & Co. BD® Luer-Lok® 50 ml
(US Reference #309653, EU Reference #300865)

FREEDOM60® Preoperation Instructions

1. Examine the inside of the syringe shield and ensure it is free of debris or contamination. Should there be debris impacting normal functions, contact your healthcare provider.
2. Make sure that the syringe driver's ON/OFF switch is in the OFF position and that the black tab within the syringe shield is at the end of its track. If the black tab is not at the end of its track, fully wind the large knob clockwise.
3. Turn the syringe driver ON and watch that the tab moves smoothly along the full length of its track.

Step-by-Step Instructions for Subcutaneous Administration

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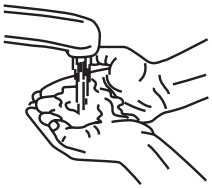
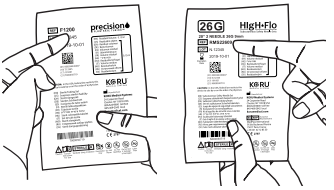
Before subcutaneous self-administration, patients and/or caregivers should be properly trained by a qualified healthcare provider.

Infusion Preparation:



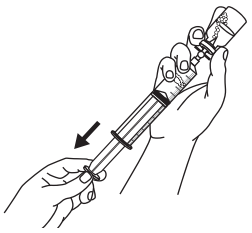
1. Gather Supplies & Sanitize

Clean your infusion work surface with antiseptic wipes or disinfecting solution. Wash your hands thoroughly and, if required, put on disposable gloves. Lay out your supplies.



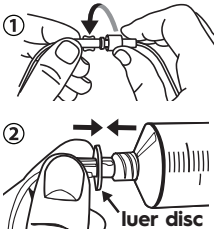
2. Verify Flow Rate Tubing & Needles

Verify that you are using the correct Precision Flow Rate Tubing and HIgH-Flo Needle Sets prescribed by your healthcare provider. Inspect tubing and needle sets for damage. If damaged, replace and contact your healthcare provider.



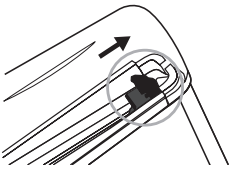
3. Prepare Syringe(s)

Ensure the medication is at room temperature (68-77°F or 20-25°C) before filling the BD® 50 ml syringe with your required dose. Refer to the drug manufacturer's instructions or ask your healthcare provider for detailed filling instructions.



4. Attach Tubing & Needles

Remove sterile caps from ends of the Precision Flow Rate Tubing set and HIgH-Flo Subcutaneous Needle set and connect, using care not to contaminate the ends. Remove cap from the **luer disc** end of the flow rate tubing set with aseptic technique and connect to the syringe.



5. Check Black Tab

Make sure the syringe driver is in the OFF position and the black tab inside the clear syringe shield is at the end of its track. If the black tab is not at the end of its track, wind the large knob clockwise.

6. Prime (Fill) Tubing

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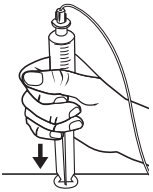
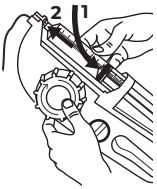
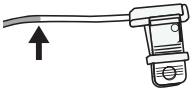
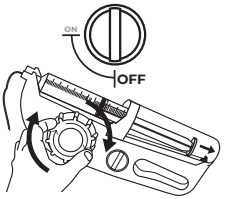
Always follow your healthcare provider's protocol. Priming can be done by hand or by using the syringe driver. Focus on a single needle and try to stop the flow when the fluid approaches the needle. Be careful not to prime to the needle tip.









Priming by hand: Push the syringe plunger and follow the medication as it flows through the tube. Release pressure from the plunger to stop the flow.

Priming by syringe driver: With syringe gradations facing up, load the assembled syringe into the syringe driver. Ensure the luer disc is fully seated in the driver's nose. Turn the syringe driver ON to prime (fill) the tubing.

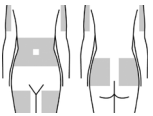
Watch the tubing fill as the medication approaches the needle. Turn the ON/OFF switch to the OFF position and immediately wind the large knob clockwise to release pressure on the plunger.

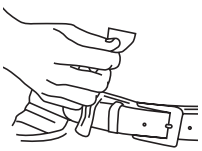
NOTE:

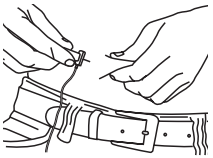
- You should not need to use significant force to load or remove the syringe. If you are having trouble, stop and make sure the black tab is at the end of its track.
- It is recommended to insert the needles dry to minimize site irritation.
- To best see the medication, we suggest priming the tubing against a dark, solid-colored surface in a well-lit area.

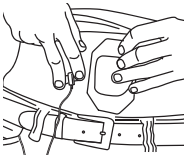
Insert Needles and Check for Blood Return:

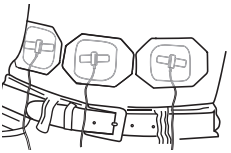
NOTE: Always refer to the drug manufacturer's prescribing information and recommendations from your healthcare provider for infusion site location(s). The most common areas for subcutaneous infusion include the abdomen, thighs, side of the upper hips and back of the arms.*





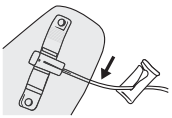






7. Prepare Sites

Select, clean and let site(s) dry before inserting needles. Carefully remove the shield from the needle tip, with care not to touch the needle.



8. Insert Needles

Pinch the skin and insert each needle into the subcutaneous tissue at a 90° angle.

9. Secure Needles

Peel the printed side from the dressing to expose adhesive. Secure the needle by placing the adhesive dressing in the center of the needle butterfly. Smooth it outward over skin.

10. Check for Blood Return

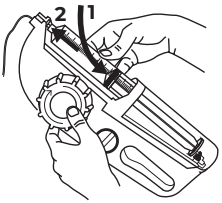
If you primed using the FREEDOM60, ensure that the black tab is at the end of its track and remove the syringe from the syringe driver. Check for blood return if instructed by your healthcare provider by gently pulling back on the syringe plunger. Watch to make sure no red/pink appears in tubing near your sites.

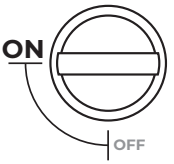
If blood return exists and if instructed by your healthcare provider, either clamp the flow to the needle site(s) or remove all needles, attach a new needle set, and start again from **Step 4**.

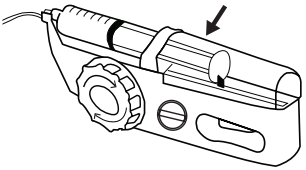
*Younger ME et al. J Inf Nurs. 2013; 36:58-64

Begin Infusion:

SC







11. Insert Syringe & Turn ON

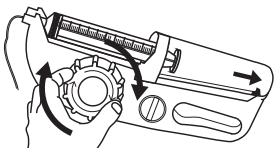
With syringe gradations facing up, insert the syringe back into the syringe driver. Turn the syringe driver ON. To reduce flow rate variability, try to keep the syringe driver level with your infusion sites.

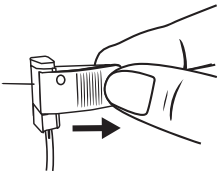
12. Check Infusion

Periodically check that the syringe driver is working properly by seeing that the syringe plunger is moving.

If using multiple syringes: Once the first syringe is empty, turn the syringe driver OFF and wind the black tab to the end of its track. Remove the syringe from the syringe driver and disconnect from tubing. With aseptic technique, connect the additional syringe to the luer disc end of the Precision tubing set. Load the prepared syringe into the syringe driver. Turn the syringe driver ON to continue infusion. Repeat until total dosage is complete.

End of Infusion:



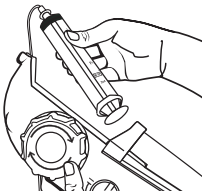


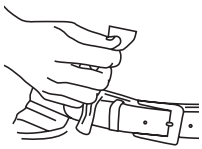
13. Turn OFF & Wind Back

When the syringe is completely empty and total dosage is administered, turn the syringe driver OFF. Wind the large knob until the black tab is at the end of its track.

14. Remove Needle(s)

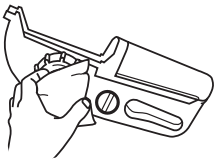
Holding the needle in place, peel back the surrounding adhesive dressing. Remove the needle in a straight motion, opposite of the direction you inserted it. To use safety feature, close wings over the needle and snap shut.





15. Remove Syringe & Cleanse Sites

Pull syringe away from the syringe driver's nose and remove. If needed, cleanse each site and cover with a bandage.



16. Discard Sharps & Clean

Discard all sharps and supplies as instructed by your healthcare provider.

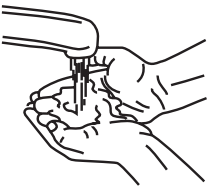
Remove visible soil as soon as possible after use of the device. Cleaning should be initiated as soon as possible after use of the device and delays between steps should be avoided. See **page 11** for full cleaning instructions.

Step-by-Step Instructions for Intravenous Administration

IV

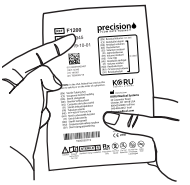
Before intravenous self-administration, patients and/or caregivers should be properly trained by a qualified healthcare provider.

Infusion Preparation:



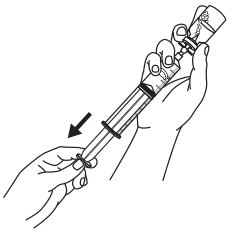
1. Gather Supplies & Sanitize

Clean your infusion work surface with antiseptic wipes or disinfecting solution. Wash your hands thoroughly and, if required, put on disposable gloves. Lay out your supplies.



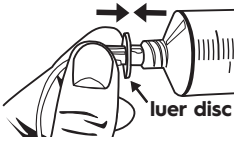
2. Verify Flow Rate Tubing

Verify that you are using the correct Precision Flow Rate tubing prescribed by your healthcare provider. Inspect the tubing set for damage. If damaged, replace and contact your healthcare provider.



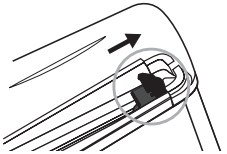
3. Prepare Syringe(s)

Fill the BD® 50 ml syringe(s) with your required dose. Refer to the drug manufacturer's instructions or ask your healthcare provider for detailed filling instructions.



4. Attach Tubing

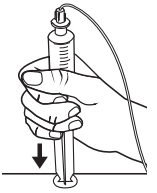
Remove cap from the **luer disc** end of the flow rate tubing set with aseptic technique and connect to the syringe.



5. Check Black Tab

Make sure the syringe driver is in the OFF position and the black tab inside the clear syringe shield is at the end of its track. If the black tab is not at the end of its track, wind the large knob clockwise.

6. Prime (Fill) Tubing



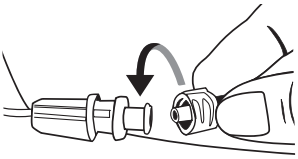
Always follow your healthcare provider's instructions. Loosen the cap on the Precision tubing set. Push the syringe plunger and follow the medicinal product as it flows through the tube. Release pressure from the plunger to stop the flow. When medication starts to drip, tighten the cap.

Starting & Ending Infusion:

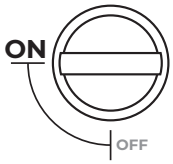
7. Begin Infusion

Follow the instructions of your healthcare provider for cleansing and preparing the vascular access device.

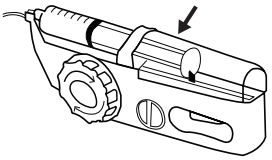
- Cleanse with alcohol – after 15 seconds scrub allow to dry completely.
- Aspirate for blood return to ensure the vascular access device is open and unobstructed before each access.



Uncap the Precision tubing set and connect to the vascular access device or needle-free connector.

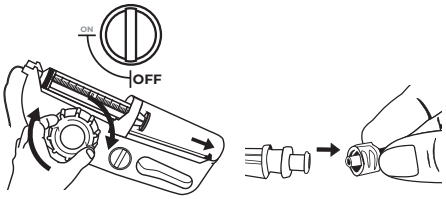


Insert the syringe into the syringe driver. Turn the syringe driver ON.



Periodically check that the syringe plunger is moving to ensure the syringe driver is working properly.

If using multiple syringes: Once the first syringe is empty, turn the syringe driver OFF and wind the black tab to the end of its track. Remove the syringe from the syringe driver and disconnect from tubing. With aseptic technique, connect the additional syringe to the luer disc end of the Precision tubing set. Load the prepared syringe into the syringe driver. Turn the syringe driver ON to continue infusion. Repeat until total dosage is complete.



8. End of Infusion

When the syringe is completely empty and the total dosage is infused, turn the syringe driver OFF. Wind the large knob until the black tab is at the end of its track. Pull syringe away from the syringe driver's nose and remove.

If instructed, close the clamp on the vascular access device. Disconnect Precision tubing from the vascular access device or needle-free connector.

9. Discard Supplies & Clean

Discard all supplies as instructed by your healthcare provider.

Remove visible soil as soon as possible after use of the device. Cleaning should be initiated as soon as possible after use of the device and delays between steps should be avoided. See **page 11** for full cleaning instructions.

10. Flush

Always follow the healthcare provider's instructions on flushing the vascular access device. Refer to the **SASH** technique below.*

S **Saline Flush:** Ensure the vascular access device is open and unobstructed.

A **Administer:** Administer the medication.

S **Saline Flush:** Clear the residual medication from the vascular access device and ensure the vascular access device is open and unobstructed.

H **Heparin** (If required for patency)**:** Minimize the potential of a blood clot forming inside the vascular access device.

*Hadaway L. Technology of flushing vascular access devices. Journal of Infusion Nursing. 29(3):129-145, May 2006.

Troubleshooting

If the suggestions in this section do not solve your problem, or if problems persist, discontinue use and consult your healthcare provider. Any serious incident should be reported to your healthcare provider and KORU Medical Systems at **+1 845-469-2042**.

Syringe will not load or remove from syringe driver:

NOTE: You should not need to use significant force to load or remove a syringe.

- Make sure the syringe driver is in the OFF position and that the black tab is at the end of its track. If the black tab is not at the end of its track, fully wind the large knob clockwise and try removing syringe again.
- Verify that you are using a proper recommended BD® brand 50 ml syringe.

Syringe will not stay inside in the syringe driver:

- Make sure you are using the proprietary Precision Flow Rate Tubing™ sets and that the luer disc end of the tubing has been connected to the recommended BD 50 ml syringe.
- Make sure the luer disc is seated properly in the nose of the syringe driver.
- **For subcutaneous use:** make sure you have not attached the syringe directly to the HIgH-Flo subcutaneous needle set.

No flow:

- Assure that the syringe driver is in the ON position.
- Make sure all the slide clamps are unclamped. If vascular access device is being used, make sure its clamps, if any, are open.
- Use aseptic technique as recommended by the healthcare provider; disconnect the tubing set from the needle set, vascular access device or needle-free connector, and check for medication drip. If the medication does not drip:
  - **Subcutaneous administration:** replace the tubing as it may be damaged.
  - **Intravenous administration:** check that the catheter is open and unobstructed.

Slow flow:

- If the slide clamp has been used, the tubing may be damaged.
- Ensure the syringe driver is level with the infusion sites. If the syringe driver is positioned lower than the sites, the flow rate may be slower than expected.
- **Subcutaneous administration:**
  - Administration may be slow based on how well the medication is absorbed through the tissue. Some infusions may be faster than others. The first infusions may take longer than expected because the body may need to adapt.
  - Avoid placing needles on top of scar tissue or muscle.
  - It is possible you may need more sites, longer needles or a faster flow rate tubing set. Talk to your healthcare provider.

Flow may continue even when the syringe driver is turned OFF:

- This is a normal function of the driver. The syringe driver is designed to maintain pressure during and after the infusion to prevent blood/drug return.
- To release pressure from the syringe plunger and to stop the flow, wind the large knob clockwise so that the black tab is at the end of its track.
- You can also use the slide clamp to cut off the flow immediately. This should only be done in the case of an emergency as use of the slide clamp can damage the tubing.

Medication (5 ml or less) left in the syringe:

- Verify that you are using a proper recommended BD® brand 50 ml syringe.
- If the syringe does not completely empty, contact your healthcare provider.

Subcutaneous swelling, pain or redness at the site:

- It is recommended to insert subcutaneous needles dry as the medication may irritate the skin.
- Assure that the needles are long enough to reach the subcutaneous layer. If the selected needle is too short, leaking at the site may occur.
- Assure that the needles are not too long, as they may hit muscle.
- Try a slower flow rate tubing set as the rate may be too fast.
- Rotate infusion sites if recommended by your healthcare provider. Periodically returning to sites that worked well in the past may provide best results.

Care, Maintenance and Reprocessing

The FREEDOM60® does not require any preventative maintenance. Since it works as a system, the tubing determines the flow rate, not the syringe driver; therefore the syringe driver needs no calibration. If you choose the correct tubing set, the proper flow rate will be achieved.

Between uses, the FREEDOM60 syringe driver needs to be first thoroughly cleaned, and then disinfected.

After cleaning and disinfection, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, and cracked seals and properly dispose any devices that fail the inspection.

Cleaning Procedure:

1. The FREEDOM60 may be cleaned with a soft cloth dampened with a weak mixture of mild detergent and warm water (minimum ratio of 1 part detergent to 50 parts water by volume).
2. Using the prepared detergent solution and a clean non-linting wipe or soft cloth, wipe all the external surfaces of the syringe driver, including the driver nose and syringe tray up to the syringe shield for at least one (1) minute. During the one (1) minute wipe, pay special attention to the ridges, crevices, raised lettering during wiping. Replace soiled cloths or wipes as needed, changing wipes when necessary to ensure that all surfaces are cleaned.

   Caution: Clean only those areas that are exposed and external. No attempt should be made to clean any part of the syringe drive that is not easily accessible.
3. Using a clean non-linting wipe or soft cloth wetted with room temperature tap water (wet but not dripping), wipe all the external surfaces of the syringe driver, including the driver nose and syringe tray up to the syringe shield. Pay special attention to the ridges, crevices, raised lettering during wiping. Continue wiping until all residue is removed to ensure the syringe driver is thoroughly clean. Replace or re-wet cloth or wipes as needed, changing wipes when necessary to ensure that all surfaces are rinsed.
4. Dry the device using a clean non-linting wipe or soft cloth.
5. Inspect the device for any visible soil after the cleaning steps (but before the disinfection steps) to ensure that the device is thoroughly cleaned between uses prior to disinfection. If the device has remaining visible soil following cleaning, repeat the cleaning steps (1 through 4).

Disinfection Procedure:

1. Wipe the outside surfaces of the FREEDOM60® syringe driver with 70% Isopropyl Alcohol (IPA) and a non-linting cloth or wipe, or pre-saturated IPA wipe.
2. Use pre-saturated IPA wipes, or non-linting wipes saturated with 70% Isopropyl Alcohol (IPA) (wetted but not dripping) to thoroughly wipe all exterior surfaces of the device. Ensure all external surfaces of the syringe driver, including the driver nose and syringe tray up to the syringe shield are wiped. Pay special attention to the ridges, crevices, raised lettering during wiping. Allow all surfaces to remain visibly wet for a minimum of five (5) minutes.

   Caution: Clean only those areas that are exposed and external. No attempt should be made to clean any part of the syringe drive that is not easily accessible.
3. During the five (5) minute contact time, use additional wipes to ensure all contacted surfaces remain wet for the full contact duration time.
4. Thoroughly dry the device using non-linting wipe(s) or allow to air dry.
5. Visually inspect the device for signs of damage or wear.

Storage:

The FREEDOM60® syringe driver and its components (Precision tubing sets and HIgH-Flo needle sets) are recommended to be stored in a cool, dry place at room temperature (approximately 68-77°F or 20-25°C).

Testing Flow Accuracy (if required by your local protocol):

1. Remove all air from a new BD® 50 ml syringe.
2. Fill the syringe with 50 ml of sterile water.
3. Attach a sterile F120 Precision Flow Rate Tubing™ set to the syringe.
4. Remove all air from the tubing set.
5. Load the syringe into the driver and keep the tubing and driver at the same horizontal level.
6. Using a stop watch or similar time tracking device, start the timer when the syringe driver is turned ON.
7. Monitor and stop the timer when 10 ml of water has left the syringe.
8. The elapsed time should fall between 3:45-5:15 minutes.

NOTE: If the test results fall outside the range indicated in Step 8, factory refurbishment and testing are available. Please contact KORU Medical Systems at **+1 845-469-2042**.

Technical Specifications

Testing was performed in a controlled test lab environment and as a result infusions should be administered within the same environmental conditions of 68-77°F (20-25°C) and atmospheric pressure of 1.01 bar (±0.09).

Syringe Driver:
Weight: 14 oz (0.4 kg)
Length: 12" (304 mm)
Width: 4.5" (114 mm)
Height: 1.6" (41 mm)

Syringe: Reservoir volume: 50 ml (BD® 50 ml syringe)

Target Operating Temperature: 68-77°F (20-25°C)

Height Sensitivity:

Vertical Height (inches)	% Variation From Target Flow Rate
±3 inches from infusion site	Equivalent to Level
±6 inches from infusion site	up to ±1.2% from target flow rate
±12 inches from infusion site	up to ±2.4% from target flow rate
±24 inches from infusion site	up to ±4.8% from target flow rate

System Max Operating Pressure:

Tubing/Needle Combo	Pressure at the Beginning of Needle Set (psi)	Measured Pressure at End of Needle Set (psi)
F60 + 24G	0.3 psi	0 psi
F2400 + 24G	7.7 psi	0 psi

Data represents pressure changes through the Freedom System (Freedom syringe driver, Precision Flow Rate Tubing™, and HIgH-Flo Subcutaneous Safety Needle Sets™) with the slowest flow rate parameter (F60) and the fastest flow rate parameter (F2400). The net effect: the pressure at the needle is significantly reduced from the initial head pressure.

Ancillary Supply Product Information

Precision Flow Rate Tubing™ Sets:

Description	Item #	Residual Vol.	p/Box
Very Low Flow	F0.5	0.09 ml	50
Very Low Flow	F1	0.08 ml	50
Very Low Flow	F2	0.10 ml	50
Very Low Flow	F3	0.09 ml	50
Very Low Flow	F3.8	0.09 ml	50
Very Low Flow	F5	0.08 ml	50
Very Low Flow	F8	0.08 ml	50
Very Low Flow	F10	0.14 ml	50
Very Low Flow	F15	0.11 ml	50
Low Flow	F30	0.13 ml	50
Low Flow	F45	0.11 ml	50

Description	Item #	Residual Vol.	p/Box
Low Flow	F60	0.14 ml	50
Low Flow	F120	0.16 ml	50
Low Flow	F180	0.13 ml	50
High Flow	F275	0.11 ml	50
High Flow	F420	0.10 ml	50
High Flow	F500	0.09 ml	50
High Flow	F600	0.09 ml	50
High Flow	F900	0.08 ml	50
High Flow	F1200	0.13 ml	50
High Flow	F2400	0.15 ml	50

Flow Rate Starter Kits:

Item Number	Description	Contents per Box
H20KT	High Flow Starter Kit	(2) F275, (5) F600, (5) F900, (4) F1200, (4) F2400
L20KT	Low Flow Starter Kit	(2) F30, (5) F45, (5) F60, (4) F120, (4) F180

KORU Related Accessories:

Item #	Description	Residual Vol.
LRVY	Low Residual Volume Y-Connector	0.14 ml
FEXT	24" Extension Set	0.4 ml

26G HIgH-Flo Subcutaneous Safety Needle Sets™:

Single-Needle Sets			
Length	**Item #**	**Residual Vol.**	**p/ Box**
4 mm	RMS12604	0.1 ml	20
6 mm	RMS12606	0.1 ml	20
9 mm	RMS12609	0.1 ml	20
12 mm	RMS12612	0.1 ml	20
14 mm	RMS12614	0.1 ml	20

Two-Needle Sets			
Length	**Item #**	**Residual Vol.**	**p/ Box**
4 mm	RMS22604	0.2 ml	10
6 mm	RMS22606	0.2 ml	10
9 mm	RMS22609	0.2 ml	10
12 mm	RMS22612	0.2 ml	10
14 mm	RMS22614	0.2 ml	10

Three-Needle Sets			
Length	**Item #**	**Residual Vol.**	**p/ Box**
4 mm	RMS32604	0.3 ml	10
6 mm	RMS32606	0.3 ml	10
9 mm	RMS32609	0.3 ml	10
12 mm	RMS32612	0.3 ml	10
14 mm	RMS32614	0.3 ml	10

Four-Needle Sets			
Length	**Item #**	**Residual Vol.**	**p/ Box**
4 mm	RMS42604	0.4 ml	10
6 mm	RMS42606	0.4 ml	10
9 mm	RMS42609	0.4 ml	10
12 mm	RMS42612	0.4 ml	10
14 mm	RMS42614	0.4 ml	10

Five-Needle Sets			
Length	**Item #**	**Residual Vol.**	**p/ Box**
4 mm	RMS52604	0.5 ml	10
6 mm	RMS52606	0.5 ml	10
9 mm	RMS52609	0.5 ml	10
12 mm	RMS52612	0.5 ml	10
14 mm	RMS52614	0.5 ml	10

Six-Needle Sets			
Length	**Item #**	**Residual Vol.**	**p/ Box**
4 mm	RMS62604	0.6 ml	10
6 mm	RMS62606	0.6 ml	10
9 mm	RMS62609	0.6 ml	10
12 mm	RMS62612	0.6 ml	10
14 mm	RMS62614	0.6 ml	10

24G HIgH-Flo Subcutaneous Safety Needle Sets™:

Single-Needle Sets			
Length	**Item #**	**Residual Vol.**	**p/ Box**
6 mm	RMS12406	0.4 ml	20
9 mm	RMS12409	0.4 ml	20
12 mm	RMS12412	0.4 ml	20
14 mm	RMS12414	0.4 ml	20

Two-Needle Sets			
Length	**Item #**	**Residual Vol.**	**p/ Box**
6 mm	RMS22406	0.7 ml	10
9 mm	RMS22409	0.7 ml	10
12 mm	RMS22412	0.7 ml	10
14 mm	RMS22414	0.7 ml	10

Three-Needle Sets			
Length	**Item #**	**Residual Vol.**	**p/ Box**
6 mm	RMS32406	1.1 ml	10
9 mm	RMS32409	1.1 ml	10
12 mm	RMS32412	1.1 ml	10
14 mm	RMS32414	1.1 ml	10

Four-Needle Sets			
Length	**Item #**	**Residual Vol.**	**p/ Box**
6 mm	RMS42406	1.4 ml	10
9 mm	RMS42409	1.4 ml	10
12 mm	RMS42412	1.4 ml	10

Selected Flow Rate Tables

The following section is to guide healthcare providers in selecting the Precision Flow Rate Tubing™ and HIgH-Flo Subcutaneous Safety Needle Sets™* to achieve the desired flow rate based on the selected medication and number of infusion sites.

*HIgH-Flo Subcutaneous Safety Needle sets are only to be used for subcutaneous administration.
*All flow rate tables are based on bench top testing which was performed with 0 psi of back pressure.

How to Use Flow Rate Tables for Subcutaneous Administration:

- Select prescribed medication and refer to its prescribing information for recommended infusion flow rate and infusion time.
- Select the subcutaneous needle type – 26G or 24G needle. Verify the correct flow rate table.
- Evaluate and select flow rate tubing and number of needles based on the infusion phase and flow rate.

Subcutaneous Flow Rate Table Contents:

Cutaquig® Flow Rate Combinations:

The following tables indicate the average (min-max) flow rates per site with HIgH-Flo Subcutaneous Safety Needle Sets™ (26G and 24G) when used in combination with KORU Precision Flow Rate Tubing™ and FREEDOM60® Syringe Infusion System with a 50 ml syringe for the subcutaneous use of Cutaquig.

To determine the appropriate flow rate tubing and subcutaneous needle configuration, please refer to drug package insert for the maximum indicated flow rate and volume per infusion site for initial and subsequent infusions.

HIgH-Flo 26G with Precision Tubing - Average (Min-Max) Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	10.0 (6.6-13.5)	12.6 (9.0-16.2)	17.3 (12.3-22.3)						
2 needles	5.5 (3.5-7.5)	7.1 (5.0-9.1)	10.2 (7.1-13.2)	14.3 (9.5-19.1)	16.2 (11.8-20.6)	18.4 (13.1-23.7)			
3 needles	3.8 (2.4-5.2)	4.9 (3.5-6.3)	7.2 (5.0-9.4)	10.4 (6.8-14)	11.9 (8.6-15.2)	13.7 (9.7-17.8)	19.4 (13.8-24.9)		
4 needles	2.9 (1.8-3.9)	3.8 (2.7-4.9)	5.6 (3.9-7.3)	8.2 (5.3-11.0)	9.4 (6.8-12.0)	10.9 (7.7-14.2)	15.9 (11.3-20.5)	18.4 (12.4-24.4)	
5 needles	2.3 (1.5-3.2)	3.1 (2.2-3.9)	4.6 (3.2-6.0)	6.7 (4.3-9.1)	7.8 (5.6-10.0)	9.1 (6.4-11.8)	13.4 (9.5-17.4)	15.7 (10.5-20.9)	
6 needles	2.0 (1.2-2.7)	2.6 (1.8-3.3)	3.8 (2.7-5.0)	5.7 (3.7-7.7)	6.6 (4.8-8.5)	7.8 (5.4-10.1)	11.7 (8.2-15.1)	13.7 (9.1-18.3)	

Exceeds drug manufacturer's maximum indicated flow rate.

Subsequent infusions after 6th infusion only.

HIgH-Flo 24G with Precision Tubing - Average (Min-Max) Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	11.7 (7.4-15.9)	15.2 (10.8-19.7)							
2 needles	6.0 (3.8-8.1)	7.8 (5.5-10.1)	11.8 (8.2-15.5)	17.8 (11.4-24.2)					
3 needles	4.0 (2.5-5.5)	5.3 (3.7-6.8)	8.0 (5.5-10.5)	12.1 (7.7-16.5)	14.2 (10.2-18.3)	16.9 (11.7-22.1)			
4 needles	3.0 (1.9-4.1)	4.0 (2.8-5.1)	6.0 (4.2-7.9)	9.2 (5.9-12.6)	10.8 (7.8-13.9)	12.9 (8.9-16.8)			
5 needles	2.4 (1.5-3.3)	3.2 (2.2-4.1)	4.9 (3.3-6.4)	7.4 (4.7-10.1)	8.7 (6.3-11.2)	10.4 (7.2-13.6)	16.5 (11.4-21.5)		
6 needles	2.0 (1.3-2.8)	2.7 (1.9-3.4)	4.1 (2.8-5.3)	6.2 (3.9-8.5)	7.3 (5.2-9.4)	8.7 (6.0-11.4)	13.9 (9.6-18.1)	16.9 (10.9-22.9)	

Exceeds drug manufacturer's maximum indicated flow rate.

Subsequent infusions after 6th infusion only.

Cuvitru® for Primary Immunodeficiency (PI) Flow Rate Combinations:

The following tables indicate the nominal predicted flow rates per site with HIgH-Flo Subcutaneous Safety Needle Sets™ (26G and 24G) when used in combination with KORU Precision Flow Rate Tubing™ and FREEDOM60® Syringe Infusion System with a 50 ml syringe for the subcutaneous use of Cuvitru for the treatment of Primary Immunodeficiency (PI).

To determine the appropriate flow rate tubing and subcutaneous needle configuration, please refer to drug package insert for the maximum indicated flow rate and volume per infusion site for initial and subsequent infusions.

HIgH-Flo 26G with Precision Tubing - Nominal Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle		10.4	14.0	18.5	21.0	22.7	27.3	28.6	35.3
2 needles				12.0	14.1	15.7	20.4	21.9	31.0
3 needles					10.6	12.0	16.3	17.7	27.6
4 needles							13.6	14.9	24.8

Outside of drug manufacturer's indicated flow rate (min/max).

Subsequent infusions after 6th infusion only.

HIgH-Flo 24G with Precision Tubing - Nominal Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	10.0	13.1	19.3	28.9	35.5	40.5	57.8		
2 needles			10.1	15.6	19.5	22.5	33.7	38.1	
3 needles				10.7	13.4	15.6	23.8	27.1	59.3
4 needles					10.2	11.9	18.4	21.0	48.0

Outside of drug manufacturer's indicated flow rate (min/max).

Subsequent infusions after 6th infusion only.

Gammagard Liquid® Flow Rate Combinations:

The following tables indicate the nominal predicted flow rates per site with 26G HIgH-Flo Subcutaneous Safety Needle Sets™ when used in combination with KORU Precision Flow Rate Tubing™ and FREEDOM60® Syringe Infusion System with a 50 ml syringe for the subcutaneous use of Gammagard Liquid.

To determine the appropriate flow rate tubing and subcutaneous needle configuration, please refer to drug package insert for the maximum indicated flow rate and volume per infusion site for initial and subsequent infusions.

40 kg and greater Body Weight

HIgH-Flo 26G with Precision Tubing - Nominal Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle									
2 needles	22.4	28.6							
3 needles	15.5	20.1	29.1						
4 needles	11.9	15.4	22.6						
5 needles	9.6	12.5	18.5	27.8					
6 needles	8.1	10.6	15.7	23.7	29.3				
7 needles	7.0	9.1	13.6	20.7	25.7	29.5			
8 needles	6.1	8.0	12.0	18.4	22.8	26.3			

▨ Exceeds drug manufacturer's maximum indicated flow rate.

☐ Subsequent infusions after 6th infusion only.

Under 40 kg Body Weight

HIgH-Flo 26G with Precision Tubing - Nominal Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle									
2 needles									
3 needles	15.5	20.1							
4 needles	11.9	15.4							
5 needles	9.6	12.5	18.5						
6 needles	8.1	10.6	15.7						
7 needles	7.0	9.1	13.6						
8 needles	6.1	8.0	12.0	18.4					

▨ Exceeds drug manufacturer's maximum indicated flow rate.

☐ Subsequent infusions after 6th infusion only.

NOTE: For Gammagard Liquid®, HIgH-Flo 24G is not recommended.

Hizentra® for Primary Immunodeficiency (PI) Flow Rate Combinations:

The following tables indicate the nominal predicted flow rates per site with HIgH-Flo Subcutaneous Safety Needle Sets™ (26G and 24G) when used in combination with KORU Precision Flow Rate Tubing™ and FREEDOM60® Syringe Infusion System with a 50 ml syringe for the subcutaneous use of Hizentra for the treatment of primary immunodeficiency (PI).

To determine the appropriate flow rate tubing and subcutaneous needle configuration, please refer to drug package insert for the maximum indicated flow rate and volume per infusion site for initial and subsequent infusions.

HIgH-Flo 26G with Precision Tubing - Nominal Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	8.2	10.2	13.7	18.1	20.6	22.2			
2 needles	4.6	5.8	8.3	11.7	13.8	15.3	20.0	21.4	
3 needles	3.2	4.1	5.9	8.6	10.4	11.7	16.0	17.4	
4 needles	2.4	3.1	4.6	6.9	8.4	9.5	13.3	14.6	24.3
5 needles	2.0	2.6	3.8	5.7	7.0	8.0	11.4	12.6	22.2
6 needles	1.6	2.2	3.2	4.8	6.0	6.9	9.9	11.1	20.3
7 needles	1.4	1.9	2.8	4.2	5.2	6.0	8.8	9.9	18.8
8 needles	1.2	1.6	2.4	3.7	4.7	5.4	8.0	8.9	17.4

▨ Exceeds drug manufacturer's maximum indicated flow rate.

☐ Subsequent infusions after 6th infusion only.

HIgH-Flo 24G with Precision Tubing - Nominal Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	9.8	12.8	18.9						
2 needles	5.0	6.6	9.9	15.2	19.1	22.0			
3 needles	3.4	4.5	6.7	10.4	13.1	15.2	23.3		
4 needles	2.5	3.4	5.1	7.9	10.0	11.7	18.0	20.6	
5 needles	2.0	2.7	4.1	6.4	8.1	9.4	14.7	16.8	
6 needles	1.7	2.3	3.4	5.4	6.8	7.9	12.4	14.2	
7 needles	1.5	1.9	2.9	4.6	5.8	6.8	10.7	12.3	
8 needles	1.3	1.7	2.6	4.0	5.1	6.0	9.4	10.8	

▨ Exceeds drug manufacturer's maximum indicated flow rate.

☐ Subsequent infusions after 6th infusion only.

Hizentra® for CIDP Flow Rate Combinations:

The following tables indicate the nominal predicted flow rates per site with HIgH-Flo Subcutaneous Safety Needle Sets™ (26G and 24G) when used in combination with KORU Precision Flow Rate Tubing™ and FREEDOM60® Syringe Infusion System with a 50 ml syringe for the subcutaneous use of Hizentra for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP).

To determine the appropriate flow rate tubing and subcutaneous needle configuration, please refer to drug package insert for the maximum indicated flow rate and volume per infusion site for initial and subsequent infusions.

HIgH-Flo 26G with Precision Tubing - Nominal Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	8.2	10.2	13.7	18.1	20.6	22.2	26.7	28.0	34.6
2 needles	4.6	5.8	8.3	11.7	13.8	15.3	20.0	21.4	30.3
3 needles	3.2	4.1	5.9	8.6	10.4	11.7	16.0	17.4	27.0
4 needles	2.4	3.1	4.6	6.9	8.4	9.5	13.3	14.6	24.3
5 needles	2.0	2.6	3.8	5.7	7.0	8.0	11.4	12.6	22.2
6 needles	1.6	2.2	3.2	4.8	6.0	6.9	9.9	11.1	20.3
7 needles	1.4	1.9	2.8	4.2	5.2	6.0	8.8	9.9	18.8
8 needles	1.2	1.6	2.4	3.7	4.7	5.4	8.0	8.9	17.4

☐ Subsequent infusions after 6th infusion only.

HIgH-Flo 24G with Precision Tubing - Nominal Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	9.8	12.8	18.9	28.3	34.8	39.7	▨	▨	▨
2 needles	5.0	6.6	9.9	15.2	19.1	22.0	33.0	37.3	▨
3 needles	3.4	4.5	6.7	10.4	13.1	15.2	23.3	26.5	▨
4 needles	2.5	3.4	5.1	7.9	10.0	11.7	18.0	20.6	47.0
5 needles	2.0	2.7	4.1	6.4	8.1	9.4	14.7	16.8	39.5
6 needles	1.7	2.3	3.4	5.4	6.8	7.9	12.4	14.2	34.0
7 needles	1.5	1.9	2.9	4.6	5.8	6.8	10.7	12.3	29.9
8 needles	1.3	1.7	2.6	4.0	5.1	6.0	9.4	10.8	26.7

▨ Exceeds drug manufacturer's maximum indicated flow rate.

☐ Subsequent infusions after 6th infusion only.

Xembify® for Primary Immunodeficiency (PI) Flow Rate Combinations:

The following tables indicate the average (min-max) predicted flow rates per site with HIgH-Flo Subcutaneous Safety Needle Sets™ (26G and 24G) when used in combination with KORU Precision Flow Rate Tubing™ and FREEDOM60® Syringe Infusion System with a 50 ml syringe for the subcutaneous use of Xembify for the treatment of Primary Immunodeficiency (PI).

To determine the appropriate flow rate tubing and subcutaneous needle configuration, please refer to drug package insert for the maximum indicated flow rate and volume per infusion site for initial and subsequent infusions.

HIgH-Flo 26G with Precision Tubing - Average (Min-Max) Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	6.5 (3.7-9.4)	8.1 (5.0-11.2)	11.2 (6.9-15.5)	14.8 (8.7-20.9)	16.3 (10.4-22.2)	18.0 (11.3-24.7)			
2 needles	3.6 (2.0-5.2)	4.6 (2.8-6.3)	6.6 (4.0-9.2)	9.3 (5.3-13.3)	10.5 (6.6-14.3)	11.9 (7.3-16.4)	16.1 (10.0-22.1)		
3 needles	2.5 (1.4-3.6)	3.2 (1.9-4.4)	4.7 (2.8-6.5)	6.7 (3.8-9.7)	7.7 (4.8-10.5)	8.9 (5.4-12.3)	12.5 (7.7-17.3)	14.3 (8.4-20.2)	
4 needles	1.9 (1.0-2.7)	2.4 (1.5-3.4)	3.6 (2.2-5.1)	5.3 (3.0-7.6)	6.1 (3.8-8.4)	7.1 (4.3-9.8)	10.2 (6.3-14.2)	11.9 (6.9-16.9)	
5 needles	1.5 (0.8-2.2)	2.0 (1.2-2.7)	2.9 (1.8-4.1)	4.4 (2.4-6.3)	5.0 (3.1-6.9)	5.9 (3.5-8.2)	8.7 (5.3-12.1)	10.2 5.9-14.5)	16.4 (9.4-23.3)
6 needles	1.3 (0.7-1.9)	1.7 (1.0-2.3)	2.5 (1.5-3.5)	3.7 (2.1-5.4)	4.3 (2.7-5.9)	5.0 (3.0-7.0)	7.5 (4.6-10.5)	8.9 (5.1-12.7)	14.7 (8.4-21.1)

Exceeds drug manufacturer's maximum indicated flow rate.

HIgH-Flo 24G with Precision Tubing - Average (Min-Max) Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	7.6 (4.2-11.0)	9.8 (6-13.6)	14.7 (8.8-20.5)						
2 needles	3.9 (2.1-5.6)	5.1 (3.1-7.0)	7.7 (4.6-10.7)	11.6 (6.4-16.8)	13.4 (8.4-18.5)	15.9 (9.5-22.2)			
3 needles	2.6 (1.4-3.8)	3.4 (2.1-4.7)	5.2 (3.1-7.3)	7.9 (4.3-11.5)	9.2 (5.7-12.7)	10.9 (6.5-15.3)	17.1 (10.3-23.8)		
4 needles	2.0 (1.1-2.9)	2.6 (1.6-3.6)	3.9 (2.3-5.5)	6.0 (3.3-8.7)	7.0 (4.3-9.6)	8.3 (5.0-11.7)	13.1 (7.9-18.3)	16.0 (8.9-23.1)	
5 needles	1.6 (0.9-2.3)	2.1 (1.3-2.9)	3.1 (1.9-4.4)	4.8 (2.6-7.0)	5.6 (3.5-7.8)	6.7 (4.0-9.4)	10.6 (6.4-14.9)	13.0 (7.2-18.8)	
6 needles	1.3 (0.7-1.9)	1.7 (1.0-2.4)	2.6 (1.6-3.7)	4.0 (2.2-5.9)	4.7 (2.9-6.5)	5.6 (3.4-7.9)	9.0 (5.4-12.6)	11.0 (6.1-15.9)	

Exceeds drug manufacturer's maximum indicated flow rate.

Warranty Information

This warranty and the rights and obligations hereunder, shall be construed under and governed by the laws of the State of New York, USA.

Limited Warranty: KORU Medical Systems ("Manufacturer") warrants the FREEDOM60® syringe driver to be free from defects in materials and workmanship under normal use. Warranty is limited to Original Purchaser and covers the FREEDOM60 for a period of two years from the purchase date. This warranty is not valid for any damage caused by the use of non-KORU products. The "Original Purchaser" is the person purchasing the syringe driver from the Manufacturer or Manufacturer's Representative. Warranty does not extend to subsequent purchasers. Subject to the conditions of and upon compliance with the procedures set forth in this limited warranty, the Manufacturer will repair or replace, at its option, any syringe driver, or part thereof, which has been actually received by the Manufacturer or Manufacturer's Representative within the two-year warranty period, and which examination discloses, to the Manufacturer's satisfaction, that the product is defective. Replacement product and parts are warranted only for the remaining portion of the original two-year warranty period.

KORU tests the FREEDOM60 using KORU accessories to ensure that the FREEDOM60 operates in accordance with published specification standards. If non-KORU accessories are used in conjunction with the FREEDOM60, KORU does not represent that the FREEDOM60 will operate in accordance with published specification standards. The FREEDOM60 warranty does not cover third-party products or accessories.

The following conditions, procedures, and limitations apply to the Manufacturer's obligations under this warranty:

- **Parties Covered by this Warranty:** This warranty extends only to the Original Purchaser of the syringe driver. This warranty does not extend to subsequent purchasers.
- **Warranty Performance Procedure:** Notice of the defect must be made in writing to Customer Support Department, KORU Medical Systems/Repro Med Systems, Inc., 24 Carpenter Road, Chester, NY 10918, USA. Notice to KORU Medical Systems/Repro Med Systems, Inc. must include the model and serial number, date of purchase, and description of the defect in sufficient detail to facilitate repairs. Authorization must be obtained by the Original Purchaser from the Manufacturer or Manufacturer's Representative prior to returning the product to the Manufacturer. The defective syringe driver must be properly packaged and returned to the Manufacturer, postage-prepaid. Any loss or damage during shipment is at the risk of the Original Purchaser.
- **Conditions of Warranty:** This warranty does not apply to any product, or part thereof, which has been repaired or altered outside of the Manufacturer's facility in a way so as, in Manufacturer's judgment, to affect its stability or reliability, or which has been subjected to misuse, negligence or accident.

- **Limitations and Exclusions:** Repair or replacement of a syringe driver or component part is the EXCLUSIVE remedy offered by the Manufacturer. The following exclusions and limitations shall apply:
  - No agent, representative, or employee of the Manufacturer has authority to bind the Manufacturer to any representation or warranty, expressed or implied, or to change this limited warranty in any way.
  - THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. THERE ARE NO WARRANTIES THAT EXTEND BEYOND THE DESCRIPTION ON THE FACE HEREOF.
  - Manufacturer's liability under this Limited Warranty Agreement shall noextend to special, indirect, or consequential damages.
  - The syringe driver can only be used under the supervision of medical personnel whose skill and judgment determine the suitability of the syringe driver for a particular medical treatment.
  - All recommendations, information, and descriptive literature supplied by the Manufacturer or its agents are believed to be accurate and reliable, but do not constitute warranties.

Definition of Symbols

	Caution		Use by YYYY-MM-DD or YYYY-MM
	Consult Instructions For Use		Manufacturer
EC REP	Authorized Representative in the European Community		Do Not Reuse
LOT	Batch Code		Do Not Resterilize
QTY	Quantity		Not Made with Natural Rubber Latex
REF	Catalog Number		Do Not Use if Package is Damaged
SN	Serial Number		MR Unsafe
STERILE R	Sterilized Using Irradiation	Rx ONLY	Prescription Only
MD	Medical Device	CE	European Conformity

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