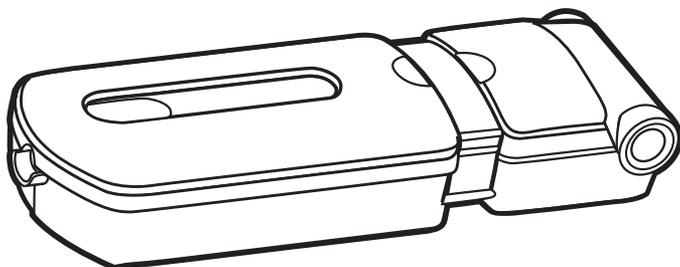


FreedomEdge[®]

Syringe Infusion System



Instructions For Use

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Introduction

The FreedomEdge® Syringe Infusion System is portable and easy to use, requiring no batteries or electricity. It starts to operate when the syringe driver is closed. KORU Precision Flow Rate Tubing™ sets are used to control the flow rate.

The FreedomEdge 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 FreedomEdge 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: 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 Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®) single-use prefilled syringe for subcutaneous administration 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 FreedomEdge 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 FreedomEdge Syringe Infusion System consists of the following components:

- FreedomEdge Syringe Driver
- Precision Flow Rate Tubing™
- HlgH-Flo Subcutaneous Safety Needle Sets™

The FreedomEdge Syringe Infusion System is indicated for use with the BD® 20 ml syringe (US Reference number: 302830), BD 30 ml syringe (US Reference number: 302832) and Hizentra® 20 ml prefilled syringe (NDC 44206-458-96).

MRI Safety Information



The Freedom Integrated Syringe Infusion System is MR Unsafe.

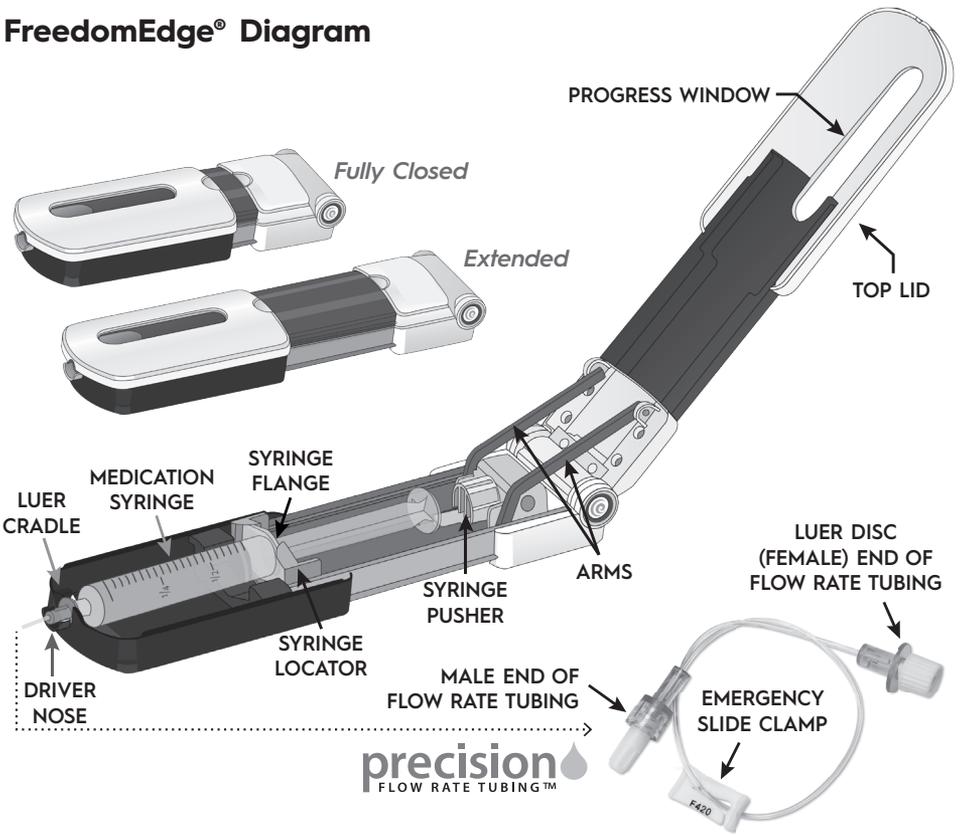
Do not use the Freedom Infusion System or its components, such as the Precision Flow Rate Tubing™, HlgH-Flo Subcutaneous Safety Needle Sets™ or Low Residual Volume Y-Connector, while undergoing MRI medical diagnostic procedures.



Caution

- Use the FreedomEdge® 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 may cause internal damage to the syringe driver.
- Use only BD® brand 20/30 ml syringes, or Hizentra® 20 ml prefilled syringes with the FreedomEdge.
- Using the same tubing set, BD 30 ml syringes will have slightly slower flow rates and slightly increased delivery times versus BD 20 ml syringes.
- Before use, carefully inspect the tubing and needle set packaging. Do not use the set if the package is opened or damaged. Inspect 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.
- Carefully inspect the FreedomEdge before use. Discontinue use of a syringe driver that has been damaged, exposed to severe impact, or which fails to operate properly.
- Do not place fingers inside while opening or closing the FreedomEdge.
- Do not attempt to interfere with the syringe pusher at any time.
- Do not attempt to open the rear housing.
- 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 $\pm 3''$ both while in a stationary position and while in motion.
- The FreedomEdge should be used at the same height as the user. If positioned higher than the infusion sites, the pressure will increase and can affect the flow rate. If positioned lower, the pressure will decrease and can affect the flow rate.
- Do not attempt to remove the syringe or disconnect the tubing set without first fully opening the top cover of the FreedomEdge.
- The FreedomEdge Syringe Infusion System 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 FreedomEdge.
- The FreedomEdge Syringe Infusion System is not intended for blood transfusions.
- The FreedomEdge 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.

FreedomEdge® Diagram



Product Line

Each FreedomEdge includes a travel pouch and user manual.

Product	Part #
FreedomEdge Syringe Driver	F10020
Replacement Travel Pouch	347400

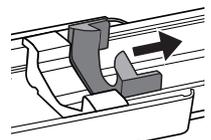
Syringes for use with the FreedomEdge

- Becton Dickinson & Co. BD® Luer-Lok® 20 ml (US Ref. Number: 302830)
- Becton Dickinson & Co. BD® Luer-Lok® 30 ml (US Ref. Number: 302832)
- Hizentra® 20 ml Single-Use Prefilled Syringe (NDC 44206-458-96)

Preoperation Instructions

The FreedomEdge Syringe Driver should be tested prior to any administration.

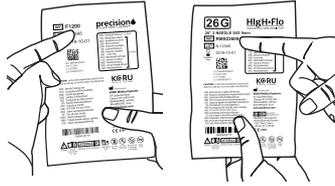
1. Examine the inside to ensure it is free of debris or damage.
2. Make sure the orange syringe locator moves freely by sliding it up and down the track with your finger.



Step-by-Step Instructions for Subcutaneous Administration

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

Infusion Preparation:

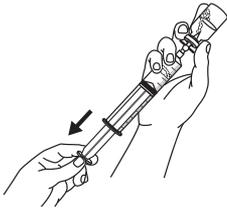


1. Gather Supplies & Sanitize

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.

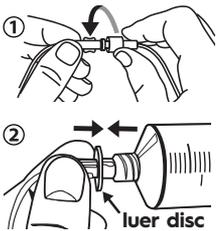
2. Verify Flow Rate Tubing & Needles

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)

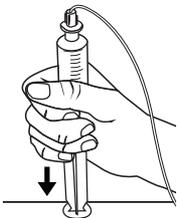
Ensure the medication is at room temperature (68-77°F or 20-25°C). Refer to the drug manufacturer's instructions or ask your healthcare provider for detailed filling instructions. If using a prefilled syringe, go to **Step 4**. If using vials, fill the BD 20 or 30 ml syringe(s) with the required dose.



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



5. Prime (Fill) Tubing

Always follow your healthcare provider's protocol. 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.

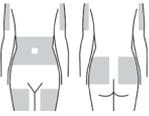
Push the syringe plunger and follow the medication as it flows through the tube. Release pressure from the plunger to stop the flow.

NOTE:

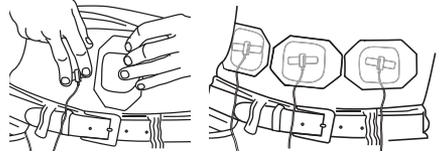
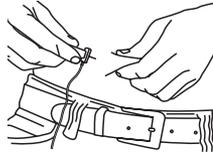
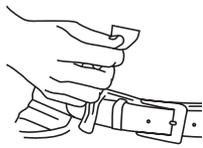
- It is recommended to insert the needles dry to minimize site irritation.
- To best see the medication, we suggest priming the tubing against a dark, solid-colored surface in a well-lit area.

Insert Needles and Check for Blood Return:

SC



NOTE: Always refer to the medical product 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.*



6. Prepare Sites

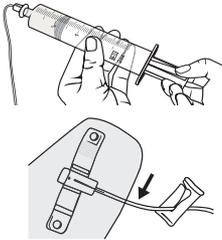
Select and clean site(s) before inserting needles. Carefully remove the shield from the needle tip, with care not to touch the needle.

7. Insert Needles

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

8. 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.



9. Check for Blood Return

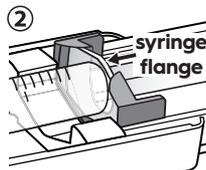
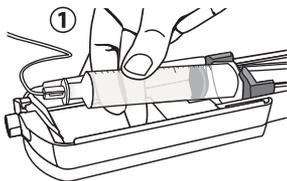
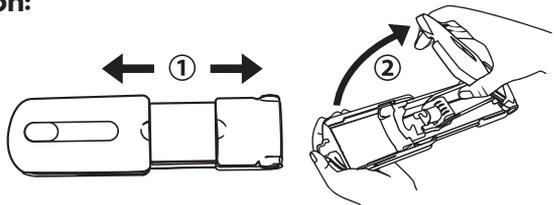
Check for blood return if instructed by your healthcare provider by gently pulling back on the syringe plunger. Watch to make sure no red/pink appears in tubing near your sites.

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**.

Starting & Ending Infusion:

10. Open Syringe Driver

1. Pull firmly to fully extend the syringe driver.
2. Then, open the syringe driver fully by lifting the top cover.



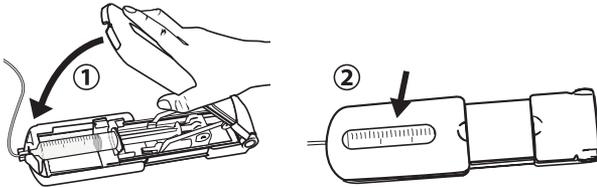
11. Load Syringe

1. With syringe gradations facing up, push the syringe flange against the orange syringe locator.
2. Make sure the syringe flange is seated within the front part of the orange syringe locator.
3. Verify that the Precision tubing (with the luer disc) is connected to syringe. Place the luer disc inside the syringe driver nose so that the syringe is firmly seated inside the syringe driver.

NOTE:



- You should not need to use significant force to load or remove the syringe. You can test proper fit by gently tugging on the syringe. It will stay in place if properly attached.
- When closing the syringe driver, make sure that the top lid is fully extended and aligns with the bottom portion.

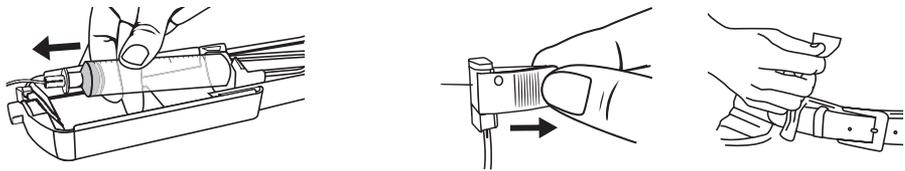


12. Begin Infusion

1. To start the infusion, close the top lid. The infusion will begin immediately. To reduce flow rate variability, try to keep the syringe driver level with your infusion sites.
2. Periodically monitor the infusion by checking the progress window, until syringe is empty.

To pause infusion: Simply open the syringe driver. To continue, re-close the top lid.

If using multiple syringes: Once the first syringe is empty, open the FreedomEdge. 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. Close the top lid to continue infusion. Repeat until total dosage is complete.

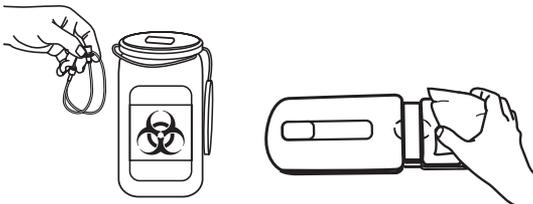


13. End of Infusion

When the syringe is completely empty and total dosage is administered, open the top lid of the syringe driver. Remove the empty syringe and its tubing.

14. Remove Needle(s) & Cleanse Sites

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.



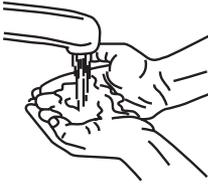
15. Discard Sharps & Clean

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

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

Infusion Preparation:

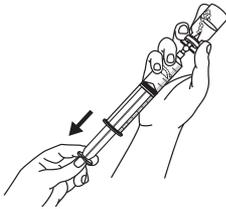


1. Gather Supplies & Sanitize

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

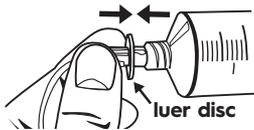
2. Verify Flow Rate Tubing

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.



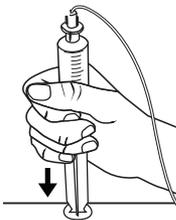
3. Prepare Syringe(s)

Refer to the drug manufacturer's instructions or ask your healthcare provider for detailed filling instructions. If using a prefilled syringe, go to **Step 4**. If using vials, fill the BD® 20 or 30 ml syringe(s) with the required dose.



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. Prime Tubing

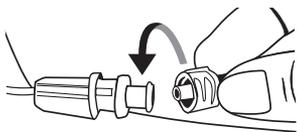
Always follow your healthcare provider's instructions. Loosen the cap on the Precision tubing set. Push the syringe plunger and follow the medication as it flows through the tube. When medication starts to drip, tighten the cap.

Starting & Ending Infusion:

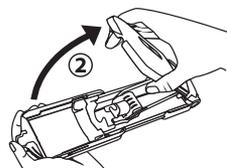
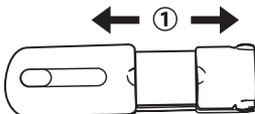
6. Begin Infusion

Follow the instructions of the 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.

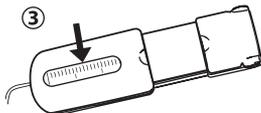
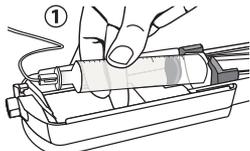


Uncap the Precision tubing set and connect to the vascular access device or needle-free connector.



Open the syringe driver:

1. Pull firmly to fully extend the syringe driver.
2. Then, open the syringe driver fully by lifting the top lid.



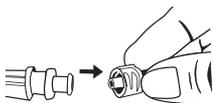
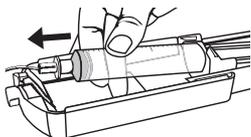
Load syringe and begin:

1. With syringe gradations facing up, push the syringe flange against the orange syringe locator.
2. Make sure the syringe flange is seated within the front part of the orange syringe locator. Place the luer disc inside the syringe driver nose so the syringe is firmly seated inside the syringe driver.
3. Close the top lid to start the infusion. Periodically monitor by checking the progress window, until syringe is empty. **To pause infusion:** Simply open the syringe driver. To continue, re-close the top lid.

NOTE:

- You should not need to use significant force to load or remove the syringe. You can test proper fit by gently tugging on the syringe. It will stay in place if properly attached.
- When closing the syringe driver, make sure that the top lid is fully extended and aligns with the bottom portion.

If using multiple syringes: Once the first syringe is empty, open the FreedomEdge. 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 and load back into the syringe driver. Close the top lid to continue infusion. Repeat until total dosage is complete.



7. End of Infusion

When the syringe is completely empty and the total dosage is infused, open the FreedomEdge and remove the empty syringe.

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

8. 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.

9. 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.

- Ensure the syringe driver is fully open, and that nothing is blocking the syringe locator.
- Confirm you are not overfilling the syringe (filling a 20 ml syringe with more than 20 ml of solution or a 30 ml syringe with more than 30 ml of solution), or using a syringe larger than 30 ml.
- If you still have difficulty, use one hand to slide the orange syringe locator all the way back, then place the 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 a BD® 20 or 30 ml syringe or a Hizentro® 20 ml prefilled syringe.
- Make sure the luer disc is seated properly in the nose of the syringe driver.
- Make sure the flange shape of the syringe is correctly seated into the shape of the orange syringe locator.

No flow:

- Open and close the lid to ensure the syringe pusher slides freely and does not bind.
- 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.
- Verify that you are using the proper syringe. 30 ml syringes will flow approx. 73% of the rate of a 20 ml syringe.
- 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.

Stopping the flow quickly:

- The syringe driver is designed to maintain pressure during and after the infusion to prevent blood/drug backflow.
- To stop the flow, fully open the top lid to relieve pressure from the syringe plunger.
- The slide clamp can be used in the case of an emergency.

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

- Verify that you are using a proper recommended syringe: BD® 20 or 30 ml, or Hizentra® 20 ml prefilled syringe.
- If the syringe does not completely empty, contact the 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 FreedomEdge® 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 FreedomEdge 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 FreedomEdge 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 driver 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 FreedomEdge® 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, syringe tray and top lid are wiped. Pay special attention to the ridges and crevices 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 driver 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 devices for signs of damage or wear.

Storage:

The FreedomEdge syringe driver and its components (Precision tubing sets and HigH-Flo needle sets) 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® 20 ml syringe with sterile water. Do NOT use a 30 ml syringe for this test.
2. Completely fill with 20 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 syringe driver.
6. Using a stop watch or similar time tracking device, start the timer when the top lid of the syringe driver is fully closed (flow will begin).
7. Monitor and stop the timer when 10 ml of water has left the syringe.
8. The elapsed time should fall between 3:50-5:11 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: 12 oz (0.34 kg)

Length:

Closed: 9" (229 mm), *Extended:* 11.75" (299 mm)

Width: 3.25" (83 mm)

Height: 1.5" (38 mm)

Syringe: Reservoir volume: 20/30 ml
(BD® brand 20/30 ml syringes or
Hizentra® prefilled 20 ml syringes)

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	Description	Item #	Residual Vol.	p/Box
Very Low Flow	F0.5	0.09 ml	50	Low Flow	F60	0.14 ml	50
Very Low Flow	F1	0.08 ml	50	Low Flow	F120	0.16 ml	50
Very Low Flow	F2	0.10 ml	50	Low Flow	F180	0.13 ml	50
Very Low Flow	F3	0.09 ml	50	High Flow	F275	0.11 ml	50
Very Low Flow	F3.8	0.09 ml	50	High Flow	F420	0.10 ml	50
Very Low Flow	F5	0.08 ml	50	High Flow	F500	0.09 ml	50
Very Low Flow	F8	0.08 ml	50	High Flow	F600	0.09 ml	50
Very Low Flow	F10	0.14 ml	50	High Flow	F900	0.08 ml	50
Very Low Flow	F15	0.11 ml	50	High Flow	F1200	0.13 ml	50
Low Flow	F30	0.13 ml	50	High Flow	F2400	0.15 ml	50
Low Flow	F45	0.11 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.

Hizentra®, Cuvitru® and Gammagard® Flow Rate Combinations:

The following tables indicate selected predicted flow rates with HigH-Flo Subcutaneous Safety Needle Sets™ (26G and 24G) when used in combination with KORU Precision Flow Rate Tubing™ and FreedomEdge® Syringe Infusion System for the subcutaneous use of Hizentra, Cuvitru, and 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.

Hizentra - FreedomEdge® with 20 ml syringe							
Drug volume (ml)	Flow Rate Tubing	HigH-Flo Needle Set*	Total Flow Rate (ml/hr)	Flow rate/site (ml/hr)	Vol/site (ml)	Time	NOTES:
10	F120	RMS12609	8.2	8.2	10	1:12	Suggested start Peds
10	F180	RMS12609	10.5	10.5	10	0:57	Suggested start Peds
20	F275	RMS22609	17.1	8.5	10	1:10	Suggested start Peds
20	F600	RMS22609	29.6	14.8	10	0:40	Suggested start Peds
40	F600	RMS32609	33.9	11.3	13.3	1:10	Suggested start Adult
40	F900	RMS32609	44.3	14.8	13.3	0:54	Suggested start Adult
60	F900	RMS42609	49	12.3	15	1:13	Suggested start Adult
50	F2400	RMS32609	72.2	24.1	16.67	0:41	6 th Infusion of biologic and beyond
100	F2400	RMS42609	85.5	21.4	25	1:10	6 th Infusion of biologic and beyond (NEEDS TWO SYRINGES)
Hizentra - with FreedomEdge® with 30 ml syringe							
20	F600	RMS22609	22.5	11.2	10	0:53	Suggested start Peds
30	F900	RMS22609	28.3	14.2	15	1:03	Suggested start Adult
30	F2400	RMS22609	41.9	20.9	15	0:42	6 th Infusion of biologic and beyond

Cuvitru - with FreedomEdge® with 20 ml syringe							
Drug volume (ml)	Flow Rate Tubing	HigH-Flo Needle Set*	Total Flow Rate (ml/hr)	Flow rate/site (ml/hr)	Vol/site (ml)	Time	NOTES:
10	F275	RMS12609	12.1	12.1	10	0:49	1 st Two Infusions patients under 40kg
20	F275	RMS12609	12.1	12.1	20	1:39	1 st Two Infusions patients under 40kg
20	F600	RMS22609	25.7	12.8	10	0:47	1 st Two Infusions patients under 40kg
50	F600	RMS22609	25.7	12.8	25	1:57	1 st Two Infusions patients over 40kg
60	F1200	RMS22609	37.1	18.6	30	1:37	Subsequent Infusions
60	F2400	RMS22409	110.5	55.4	30	0:32	Subsequent Infusions
60	F1200	RMS12409	55.3	55.3	60	1:05	Subsequent Infusions
100	F2400	RMS42409	132.8	33.2	25	0:45	Subsequent Infusions
Cuvitru - with FreedomEdge® with 30 ml syringe							
20	F500	RMS22609	12.9	12.9	20	1:32	1 st Two Infusions patients under 40kg
30	F900	RMS22609	24.6	12.3	15	1:13	1 st Two Infusions patients under 40kg
30	F2400	RMS12609	21.2	21.2	30	1:24	Maintenance Infusions
30	F1200	RMS12409	42.1	42.1	30	0:42	Maintenance Infusions

Gammagard Liquid - with FreedomEdge® with 20 ml syringe							
Drug volume (ml)	Flow Rate Tubing	HigH-Flo Needle Set*	Total Flow Rate (ml/hr)	Flow rate/site (ml/hr)	Vol/site (ml)	Time	NOTES:
20	F45	RMS12609	14.2	14.2	20	1:24	Patients under 40kg (Initial)
60	F120	RMS22609	39.8	19.9	30	1:30	Patients over 40kg (Initial)
100F	420	RMS42609	119.1	29.8	25	0:50	Patients over 40kg (maintenance infusions)
Gammagard Liquid - with FreedomEdge® with 20 ml syringe							
20	F120	RMS22609	30	15	10	0:40	Patients under 40kg (Initial)
30	F180	RMS22609	39.8	19.9	15	0:45	Patients over 40kg (Initial)
30	F120	RMS12609	27	27	30	1:06	Patients over 40kg (Maintenance)

*HigH-Flo needle sets: The first number refers to the number of needles, the next two numbers refer to the needle gauge, and the last two numbers refer to the needle length (mm).

Hizentra® 20 ml Prefilled Syringe for Primary Immunodeficiency (PI) Flow Rate Combinations:

The following tables indicate the average (min-max) predicted flow rates per site with HlgH-Flo Subcutaneous Safety Needle Sets™ (26G and 24G) when used in combination with KORU Precision Flow Rate Tubing™ and FreedomEdge® Syringe Infusion System with a 20 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.

HlgH-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	99 (70-129)	125 (97-154)	172 (131-212)						
2 needles	54 (38-71)	70 (54-87)	101 (76-126)	142 (101-182)	161 (126-196)	183 (140-225)			
3 needles	3.7 (2.6-4.9)	4.9 (3.7-6.0)	7.2 (5.4-8.9)	10.3 (7.3-13.3)	11.9 (9.3-14.5)	13.6 (10.3-16.9)	19.3 (14.8-23.7)		
4 needles	2.9 (2.0-3.7)	3.7 (2.9-4.6)	5.5 (4.2-6.9)	8.1 (5.7-10.5)	9.4 (7.3-11.5)	10.9 (8.2-13.5)	15.8 (12.1-19.5)	18.2 (13.3-23.2)	
5 needles	2.3 (1.6-3.0)	3.0 (2.3-3.8)	4.5 (3.4-5.7)	6.7 (4.7-8.7)	7.8 (6.0-9.5)	9.0 (6.8-11.2)	13.3 (10.2-16.5)	15.6 (11.2-19.9)	
6 needles	1.9 (1.3-2.5)	2.5 (1.9-3.2)	3.8 (2.9-4.8)	5.7 (3.9-7.4)	6.6 (5.1-8.1)	7.7 (5.8-9.6)	11.6 (8.8-14.4)	13.6 (9.8-17.4)	
7 needles	1.7 (1.1-2.2)	2.2 (1.7-2.7)	3.3 (2.5-4.1)	4.9 (3.4-6.4)	5.8 (4.5-7.1)	6.7 (5.1-8.4)	10.2 (7.7-12.7)	12.1 (8.6-15.5)	
8 needles	1.5 (1.0-1.9)	1.9 (1.5-2.4)	2.9 (2.2-3.7)	4.4 (3.0-5.7)	5.1 (4.0-6.3)	6.0 (4.5-7.5)	9.1 (6.9-11.4)	10.8 (7.7-13.9)	18.7 (13.2-24.2)

 Exceeds drug manufacturer's maximum indicated flow rate.

 Subsequent infusions after 6th infusion only.

HlgH-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	11.5 (8.0-15.1)	15.1 (11.5-18.7)							
2 needles	5.9 (4.0-7.7)	7.8 (5.9-9.6)	11.7 (8.7-14.7)	17.6 (12.2-23.0)					
3 needles	4.0 (2.7-5.2)	5.2 (4.0-6.5)	7.9 (5.9-10.0)	12.0 (8.3-15.7)	14.2 (11.0-17.4)	16.7 (12.5-21.0)			
4 needles	3.0 (2.0-3.9)	3.9 (3.0-4.9)	6.0 (4.5-7.5)	9.1 (6.3-11.9)	10.8 (8.3-13.2)	12.8 (9.5-16.0)			
5 needles	2.4 (1.6-3.1)	3.2 (2.4-3.9)	4.8 (3.6-6.1)	7.3 (5.1-9.6)	8.7 (6.7-10.7)	10.3 (7.7-12.9)	16.3 (12.2-20.4)		
6 needles	2.0 (1.4-2.6)	2.6 (2.0-3.3)	4.0 (3.0-5.1)	6.1 (4.2-8.1)	7.3 (5.6-8.9)	8.6 (6.4-10.8)	13.8 (10.3-17.2)	16.7 (11.7-21.8)	
7 needles	1.7 (1.2-2.2)	2.3 (1.7-2.8)	3.5 (2.6-4.3)	5.3 (3.6-6.9)	6.3 (4.8-7.7)	7.4 (5.5-9.3)	11.9 (8.9-14.9)	14.5 (10.1-18.9)	
8 needles	1.5 (1.0-2.0)	2.0 (1.5-2.5)	3.0 (2.3-3.8)	4.6 (3.2-6.1)	5.5 (4.2-6.7)	6.5 (4.9-8.2)	10.5 (7.8-13.1)	12.7 (8.9-16.6)	

 Exceeds drug manufacturer's maximum indicated flow rate.

 Subsequent infusions after 6th infusion only.

Hizentra® 20 ml Prefilled Syringe for CIDP 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 FreedomEdge® Syringe Infusion System with a 20 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-Average (Min-Max) Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	99 (70-12.9)	12.5 (9.7-15.4)	17.2 (13.1-21.2)	22.7 (16.7-28.7)	25.2 (19.9-30.5)	27.7 (21.6-33.9)	34.6 (27.3-42)	37.3 (28.8-45.9)	
2 needles	5.4 (3.8-7.1)	7.0 (5.4-8.7)	10.1 (7.6-12.6)	14.2 (10.1-18.2)	16.1 (12.6-19.6)	18.3 (14.0-22.5)	24.8 (19.2-30.3)	27.6 (20.7-34.6)	37.8 (28.7-46.9)
3 needles	3.7 (2.6-4.9)	4.9 (3.7-6.0)	7.2 (5.4-8.9)	10.3 (7.3-13.3)	11.9 (9.3-14.5)	13.6 (10.3-16.9)	19.3 (14.8-23.7)	22.0 (16.2-27.7)	32.3 (24-40.6)
4 needles	2.9 (2.0-3.7)	3.7 (2.9-4.6)	5.5 (4.2-6.9)	8.1 (5.7-10.5)	9.4 (7.3-11.5)	10.9 (8.2-13.5)	15.8 (12.1-19.5)	18.2 (13.3-23.2)	28.2 (20.6-35.8)
5 needles	2.3 (1.6-3)	3.0 (2.3-3.8)	4.5 (3.4-5.7)	6.7 (4.7-8.7)	7.8 (6.0-9.5)	9.0 (6.8-11.2)	13.3 (10.2-16.5)	15.6 (11.2-19.9)	25.0 (18.1-32)
6 needles	1.9 (1.3-2.5)	2.5 (1.9-3.2)	3.8 (2.9-4.8)	5.7 (3.9-7.4)	6.6 (5.1-8.1)	7.7 (5.8-9.6)	11.6 (8.8-14.4)	13.6 (9.8-17.4)	22.5 (16.1-28.9)
7 needles	1.7 (1.1-2.2)	2.2 (1.7-2.7)	3.3 (2.5-4.1)	4.9 (3.4-6.4)	5.8 (4.5-7.1)	6.7 (5.1-8.4)	10.2 (7.7-12.7)	12.1 (8.6-15.5)	20.4 (14.5-26.4)
8 needles	1.5 (1-1.9)	1.9 (1.5-2.4)	2.9 (2.2-3.7)	4.4 (3.0-5.7)	5.1 (4.0-6.3)	6.0 (4.5-7.5)	9.1 (6.9-11.4)	10.8 (7.7-13.9)	18.7 (13.2-24.2)

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	11.5 (8.0-15.1)	15.1 (11.5-18.7)	22.5 (16.8-28.2)	33.1 (23.2-43)	38.5 (29.9-47.1)				
2 needles	5.9 (4.0-7.7)	7.8 (5.9-9.6)	11.7 (8.7-14.7)	17.6 (12.2-23.0)	20.7 (16.0-25.4)	24.4 (18.2-30.5)	37.5 (28.3-46.7)		
3 needles	4.0 (2.7-5.2)	5.2 (4.0-6.5)	7.9 (5.9-10.0)	12.0 (8.3-15.7)	14.2 (11.0-17.4)	16.7 (12.5-21.0)	26.2 (19.7-32.7)	31.5 (22.2-40.9)	
4 needles	3.0 (2.0-3.9)	3.9 (3.0-4.9)	6 (4.5-7.5)	9.1 (6.3-11.9)	10.8 (8.3-13.2)	12.8 (9.5-16.0)	20.1 (15.1-25.2)	24.3 (17.0-31.7)	
5 needles	2.4 (1.6-3.1)	3.2 (2.4-3.9)	4.8 (3.6-6.1)	7.3 (5.1-9.6)	8.7 (6.7-10.7)	10.3 (7.7-12.9)	16.3 (12.2-20.4)	19.8 (13.8-25.8)	
6 needles	2.0 (1.4-2.6)	2.6 (2-3.3)	4.0 (3.0-5.1)	6.1 (4.2-8.1)	7.3 (5.6-8.9)	8.6 (6.4-10.8)	13.8 (10.3-17.2)	16.7 (11.7-21.8)	32.7 (22.0-43.4)
7 needles	1.7 (1.2-2.2)	2.3 (1.7-2.8)	3.5 (2.6-4.3)	5.3 (3.6-6.9)	6.3 (4.8-7.7)	7.4 (5.5-9.3)	11.9 (8.9-14.9)	14.5 (10.1-18.9)	28.6 (19.2-38.0)
8 needles	1.5 (1.0-2.0)	2.0 (1.5-2.5)	3.0 (2.3-3.8)	4.6 (3.2-6.1)	5.5 (4.2-6.7)	6.5 (4.9-8.2)	10.5 (7.8-13.1)	12.7 (8.9-16.6)	25.3 (17.0-33.7)

Exceeds drug manufacturer's maximum indicated flow rate.

Subsequent infusions after 6th infusion only.

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 syringe driver to be free from defects in materials and workmanship under normal use. Warranty is limited to Original Purchaser and covers the FreedomEdge® 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 FreedomEdge using KORU accessories to ensure that the FreedomEdge operates in accordance with published specification standards. If non-KORU accessories are used in conjunction with the FreedomEdge, KORU does not represent that the FreedomEdge will operate in accordance with published specification standards. The FreedomEdge 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 infusion 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, 24 Carpenter Road, Chester, NY 10918, USA. Notice to KORU Medical Systems 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 not extend 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
	Authorized Representative in the European Community		Do Not Reuse
	Batch Code		Do Not Resterilize
	Quantity		Not Made with Natural Rubber Latex
	Catalog Number		Do Not Use if Package is Damaged
	Serial Number		MR Unsafe
	Sterilized Using Irradiation		Prescription Only
	Medical Device		European Conformity

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