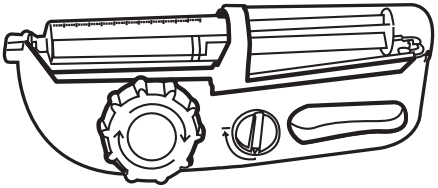

FREEDOM60®
Syringe Infusion System

EN International Instructions For Use

Contents

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Introduction

The Freedom Integrated Syringe Infusion System is designed for subcutaneous and intravenous infusions. It enables infusions to be done by patients in the comfort of their home, eliminating the need to go to a hospital or infusion suite and may also be used by healthcare providers in clinical settings. The FREEDOM60® Syringe Infusion System requires no batteries or electricity, is portable and is easy to use and train. Typical users include patients and caregivers, healthcare providers, nurses, and pharmacists.

This manual contains infusion instructions for all users and guides healthcare providers to select the most appropriate tubing and needle set for each patient and medicinal product. Patients and their caregivers will need to complete training provided with their qualified healthcare provider prior to self-administration.

Patients are advised to contact their healthcare provider for all questions related to their treatment.

The FREEDOM60 Syringe Infusion System operates at a constant pressure - the medicinal product's flow rate will automatically decrease in response to back pressure from resistance in the patient's body. This feature is known as Dynamic Equilibrium (or DynEQ®). Precision Flow Rate Tubing™ controls the maximum flow rate. Each tubing set provides a different level of flow restriction.

The system provides constant flow and holds full pressure after an infusion is complete to prevent blood or medicinal product return.

Indications for Use

The Freedom Integrated Syringe Infusion System is indicated for the subcutaneous infusion of immunoglobulins, electrolyte solutions, iron chelating agents, and infusible selective immunosuppressants requiring continuous delivery at controlled infusion rates when used according to approved medication labeling.

The Freedom Integrated Syringe Infusion System is indicated for the intravenous infusion of beta lactamase resistant penicillins, other aminoglycosides, and carbapenems requiring continuous delivery at controlled infusion rates when used according to approved medication labeling.

Contraindications

The Freedom Integrated Syringe Infusion System is not intended for the delivery of blood, critical* or life-sustaining medications, or for the delivery of insulin.

*Critical may be defined as medication requiring greater accuracy of delivery, such as CNS opiate depressants.

MRI Safety Information

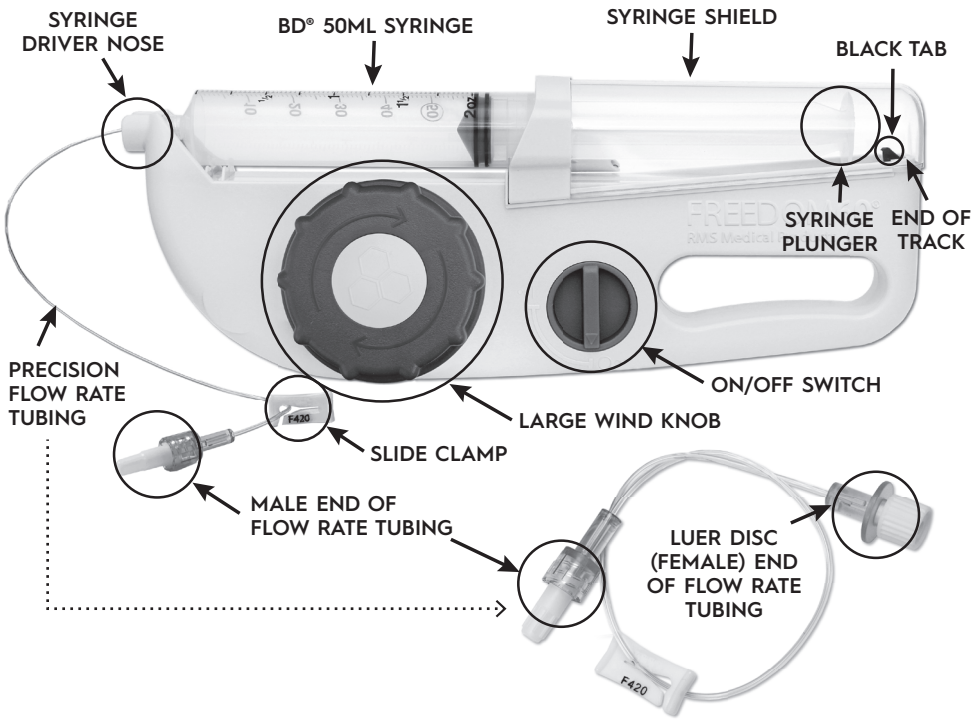
The Freedom Integrated Syringe Infusion System is MR Unsafe.

Do not use the FREEDOM60 syringe driver or components, such as the Precision Flow Rate Tubing™, HIgH-Flo Subcutaneous Safety Needle Sets™, 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® Plastipak™ 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, discard, 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, position the height of the syringe driver within ±7,6 cm (3") of the infusion site, whether infusing in a stationary position or in motion. If the syringe driver is positioned higher than the infusion sites, the pressure will increase and can increase the flow rate (decrease the infusion time). If the syringe driver is positioned lower than the infusion sites, the pressure will decrease and can decrease the flow rate (increase the infusion time).
- 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.

FREEDOM60® Diagram



FREEDOM60 Product Line

Each FREEDOM60 package includes a travel pouch and Instructions For Use.

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® Plastipak™ Luer-Lok® 50 ml
(EU Reference #300865, US Reference #309653)

Step-by-Step Instructions for Subcutaneous (SC) and Intravenous (IV) Administration

Healthcare providers select the medicinal product and infusion supplies to be used by patients and then train patients and/or caregivers on the infusion process. Patients will not select infusion supplies but can self-administer medicinal product after a qualified healthcare provider has confirmed that they are capable of doing so.

Testing the FREEDOM60® Syringe Driver:

The FREEDOM60 Syringe Driver should be tested prior to any administration.

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 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. Turn the syringe driver OFF and wind the large knob clockwise until the tab is at the end of its track.

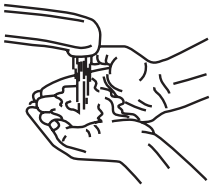
Step-by-Step Instructions for Subcutaneous Administration

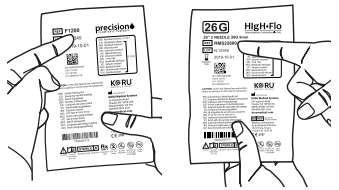
SC

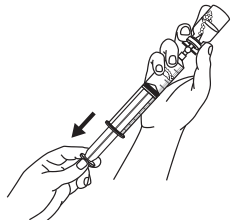
Before subcutaneous self-administration, patients and/or caregivers should be properly trained by a qualified healthcare provider.

Medicinal product may be stored in a vial or prefilled syringe. Healthcare providers will educate patients and caregivers on the correct handling of the medicinal product.

Infusion Preparation:







1. Gather Supplies & Sanitize

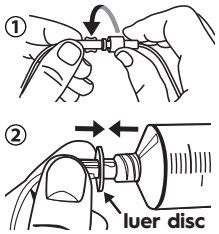
Clean your infusion work surface with antiseptic wipes or disinfecting solution. Wash your hands thoroughly. Lay out your supplies.

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 (20-25°C or 68-77°F). Refer to the medicinal product manufacturer's instructions or ask your healthcare provider for detailed filling instructions for vials or prefilled syringes. Fill the BD® 50 ml syringe(s) with the required dose.



4. Attach Flow Rate Tubing & Needle Set

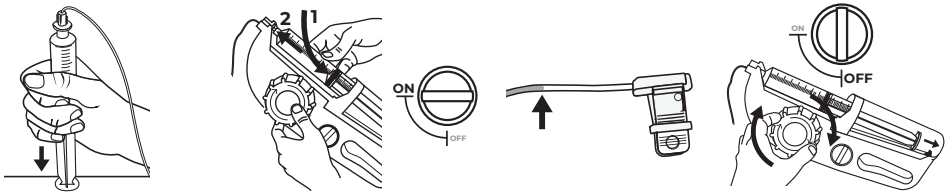
SC

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 Tubing

Always follow your healthcare provider's protocol. Priming or filling the tubing with medicinal product 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 medicinal product as it flows through the tube. Release pressure from the plunger to stop the flow.

Priming by syringe driver: Ensure 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.

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.

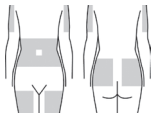
Watch the tubing fill as the medication approaches the needle. Turn the ON/OFF switch to the OFF position and immediately wind the large knob clockwise to release pressure on the plunger.

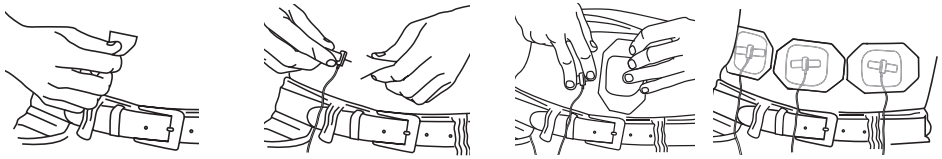
NOTE:

- 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 medicial 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.

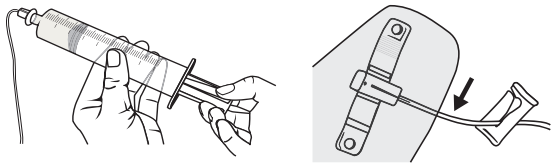
7. Insert Needles

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.

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



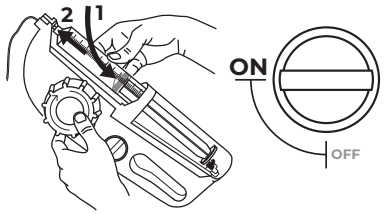
SC

9. Check for Blood Return

If you primed using the FREEDOM60, remove the syringe from the syringe driver. Check for blood return if instructed by the 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 the 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 5**.

Starting & Ending Infusion:

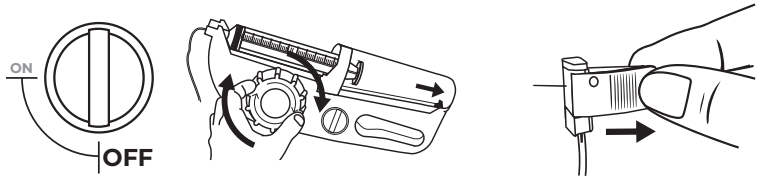


10. Begin Infusion

With syringe gradations facing up, insert the syringe back into the syringe driver. Turn the syringe driver ON.

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.

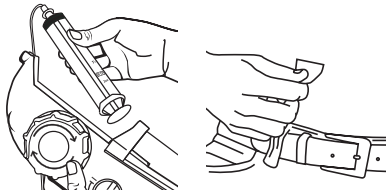


11. Turn OFF & Wind Back

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.

12. 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.



13. 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.

14. 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.

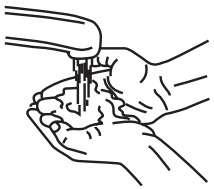
Step-by-Step Instructions for Intravenous Administration

IV

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

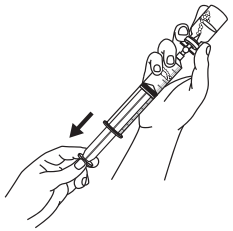
Medicinal product may be stored in a vial or prefilled syringe. Healthcare providers will educate patients and caregivers on the correct handling of the medicinal product.

Infusion Preparation:



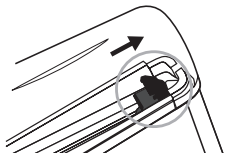
1. Gather Supplies & Sanitize

Clean your infusion work surface with antiseptic wipes or disinfecting solution. Wash your hands thoroughly. Lay out your supplies.



3. Prepare Syringe(s)

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

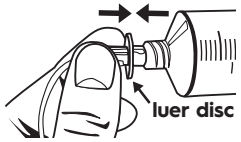


5. Check Black Tab

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.

2. Verify Flow Rate Tubing

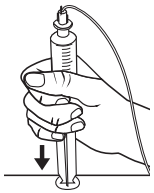
Verify that you are using the correct Precision Flow Rate tubing prescribed by your healthcare provider. Inspect the tubing set for damage. If damaged, replace and contact your healthcare provider.



4. Attach Tubing

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

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.

NOTE: To best see the medication, we suggest priming the tubing against a dark, solid-colored surface in a well-lit area.

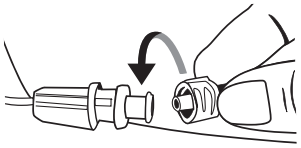
Starting & Ending Infusion:

IV

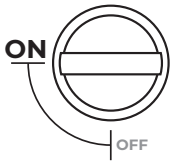
7. Begin Infusion

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

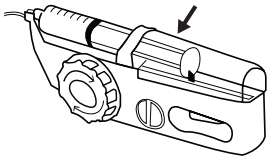
- Cleanse with alcohol – after 15 seconds scrub allow to dry completely.
- Aspirate for blood return to ensure the vascular access device is open and unobstructed before each access.



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



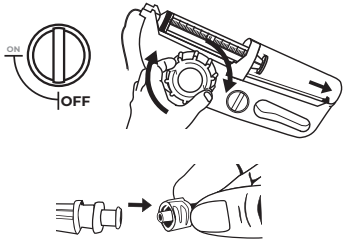
Insert the syringe into the syringe driver. Turn the syringe driver ON.



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. If instructed, close the clamp on the vascular access device. 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. If closed, open the clamp on the vascular access device. 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. 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 medicinal product.

S **Saline Flush:** Clear the residual medicinal product 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.

10. 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.

*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.

NOTE: Any serious incident should be reported to the local healthcare provider and KORU Medical Systems. Please contact KORU Medical systems at **+1 800-624-9600**.

Syringe will not load or remove from syringe driver:

- 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.
- Confirm you are not overfilling the syringe (filling a 50 ml syringe with more than 50 ml of solution), or using a syringe larger than 50 ml.

Syringe will not stay inside the syringe driver:

- Make sure you are using the proprietary Precision Flow Rate Tubing™ from KORU and that the luer disc end of the tubing has been connected to a BD® Plastipak™ 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 medicinal product 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.

Stopping the flow quickly:

- The syringe driver is designed to maintain pressure during and after the infusion to prevent blood/medicinal product 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.
- 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 BD® Plastipak™ 50 ml 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 medicinal product 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® syringe driver does not require any preventative maintenance or calibration. The flow rate tubing set determines the flow rate, not the syringe driver; therefore the syringe driver does not need calibration. If you choose the correct tubing set, the proper flow rate will be achieved.

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

Technical Specifications

NOTE: This section is intended for healthcare providers only.

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: 0,4 kg (14oz)
Length: 304 mm (12")
Width: 114 mm (4.5")
Height: 41 mm (1.6")

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

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

Height Sensitivity:

Vertical Height (cm)	% Variation From Target Flow Rate
±7,62 cm from infusion site	Equivalent to Level
±15,24 cm from infusion site	up to ±1,2% from target flow rate
±30,48 cm from infusion site	up to ±2,4% from target flow rate
±60,96 cm 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.

Factors that Affect Flow Rate:

It is important to understand that flow rates of infused medicinal products can be affected by multiple factors such as ambient temperature, patient conditions, height differences between the system and infusion site, and variations in solution viscosity.

Using a combination of HIgH-Flo Subcutaneous Safety Needle Sets™ and Precision Flow Rate Tubing™ not specified in the tables on the following pages may result in a flow rate outside of what has been approved for a specific medicinal product.

The total flow rate values presented in the following tables for subcutaneous administration are based on bench testing of combinations of either a 24G or 26G HIgH-Flo needle set connected to a Precision Flow Rate Tubing set. Testing was performed in a controlled test lab with temperatures ranging between 20-25°C (68-77°F).

The infusion times presented in the following table for intravenous administration are approximate. The flow rates shown in the table resulted from testing of distilled water performed in a controlled test lab with temperatures ranging between 20-25°C (68-77°F).

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 your local KORU Medical Systems distributor.

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

This 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 medicinal product and number of infusion sites.

Infusion parameters (flow rate and volume) are determined based on the medicinal product's prescribing information and the prescriber. The decision on the optimal flow rate tubing and subcutaneous needle configuration (if used) is solely made by the healthcare provider. Patient training by the qualified health-care provider needs to be completed before starting the self-administration of the prescribed medicinal product.

When using HyQvia®, please refer to prescribing information of the medicinal product for recommended flow rates and to the KORU Precision Flow Rate Controller Instructions for Use.

Contact the local distributor of KORU Medical Systems for any questions or for further assistance in determining which flow rate tubing and subcutaneous needle set to use.

NOTE: All flow rate tables are based on bench top testing which was performed with 0 psi of back pressure.

*HIgH-Flo Subcutaneous Safety Needle sets are only to be used for subcutaneous administration.

How to Use Flow Rate Tables for Subcutaneous Administration:

- Select prescribed medicinal product 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® (Immune Globulin Subcutaneous (Human) 16.5% Solution) Flow Rate Combinations:

The following tables indicate the average, minimum, and maximum 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 Cutaquig.

To determine the appropriate flow rate tubing and subcutaneous needle configuration, please refer to medicinal product labeling 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)	22,9 (15,6-30,2)	25,3 (18,6-32,0)	27,9 (20,2-35,6)	34,8 (25,5-44,1)	37,6 (26,9-48,3)	45,9 (33,4-58,5)
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)	24,9 (17,9-31,9)	27,8 (19,3-36,4)	38,1 (26,8-49,3)
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)	22,1 (15,1-29,2)	32,6 (22,4-42,7)
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)	28,4 (19,3-37,6)
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)	25,3 (16,9-33,6)
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)	22,7 (15-30,4)

Flow rates for initial infusions **(≤15 ml/hr/site)**

Flow rates for second and subsequent infusions **(≤25 ml/hr/site)**

Maximum for all sites combined **(≤80 ml/hr total)**

Exceeds medicinal product 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	11,7 (7,4-15,9)	15,2 (10,8-19,7)	22,7 (15,7-29,6)	33,4 (21,6-45,2)	38,7 (28,0-49,5)	45,1 (31,5-58,7)	66,4 (47-85,9)	77,5 (51,9-103,0)	123,6 (83-164,3)
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)	20,8 (15-26,7)	24,6 (17-32,1)	37,8 (26,4-49,1)	45,1 (29,6-60,7)	79,9 (51,7-108,1)
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)	26,4 (18,4-34,4)	31,8 (20,7-43)	59,0 (37,5-80,6)
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)	20,3 (14,1-26,5)	24,6 (15,9-33,3)	46,8 (29,4-64,2)

Flow rates for initial infusions **(≤15 ml/hr/site)**

Flow rates for second and subsequent infusions **(≤25 ml/hr/site)**

Maximum for all sites combined **(≤80 ml/hr total)**

Exceeds medicinal product manufacturer's maximum indicated flow rate

Cuvitru® (Immune Globulin Subcutaneous (Human), 20% Solution) 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 (±15%).

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

To calculate estimated infusion time, please use the formulas below		
Step 1	Flow rate per site, ml/h x Number of needles	Total flow rate, ml/h
Step 2	(Total medicinal product volume, ml / Total flow rate, ml/h) x 60 min = Total infusion time, min	Total infusion time, min

NOTE: The infusion is expected to last a maximum of two hours.

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	8,4	10,4	14,0	18,5	21,0	22,7	27,3	28,6	35,3
2 needles	4,7	6,0	8,5	12,0	14,1	15,7	20,4	21,9	31,0
3 needles	3,2	4,2	6,1	8,8	10,6	12,0	16,3	17,7	27,6
4 needles	2,5	3,2	4,7	7,0	8,5	9,7	13,6	14,9	24,8
5 needles	2,0	2,6	3,9	5,8	7,1	8,1	11,6	12,9	22,6
6 needles	1,7	2,2	3,3	4,9	6,1	7,0	10,2	11,3	20,7

Flow rates for initial infusion **(≤10 ml/hr/site)**

Flow rates for second infusion **(≤20 ml/hr/site)**

As per patient's tolerability

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	64,1	112,2
2 needles	5,1	6,8	10,1	15,6	19,5	22,5	33,7	38,1	77,6
3 needles	3,4	4,6	6,9	10,7	13,4	15,6	23,8	27,1	59,3
4 needles	2,6	3,4	5,2	8,1	10,2	11,9	18,4	21,0	48,0

Flow rates for initial infusion **(≤10 ml/hr/site)**

Flow rates for second infusion **(≤20 ml/hr/site)**

As per patient's tolerability

Gammanorm® (Human Normal Immunoglobulin, 165 mg/ml Solution) 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 Gammanorm (±15%).

To determine the appropriate flow rate tubing and subcutaneous needle configuration, please refer to medicinal product labeling 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	12,6	16,1	21,5	27,6	30,2	32,9	38,6	42,3	49,4
2 needles	7,1	9,3	13,1	18,0	20,2	22,7	28,6	32,9	42,3
3 needles	4,9	6,5	9,4	13,3	15,2	17,4	22,7	26,9	37,0
4 needles	3,8	5,1	7,4	10,6	12,2	14,0	18,8	22,7	32,9
5 needles	3,1	4,1	6,1	8,8	10,2	11,8	16,1	19,7	29,6
6 needles	2,6	3,5	5,1	7,5	8,7	10,2	14,0	17,4	26,9

Flow rates for initial infusion **(≤15 ml/hr/site)**

Flow rates for second and subsequent infusions **(≤25 ml/hr/site)**

Maximum for all sites combined **(≤100 ml/hr total)**

Exceeds medicinal product manufacturer's maximum indicated flow rate

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	15,2	20,5	30,2	43,8	50,7	58,8	80,2	98,0	146,9
2 needles	7,8	10,6	15,9	23,7	27,7	32,7	46,4	58,8	97,9
3 needles	5,3	7,2	10,8	16,2	19,1	22,6	32,7	42,0	73,4
4 needles	4,0	5,4	8,2	12,3	14,6	17,3	25,2	32,7	58,8

Flow rates for initial infusion **(≤15 ml/hr/site)**

Flow rates for second and subsequent infusions **(≤25 ml/hr/site)**

Maximum for all sites combined **(≤100 ml/hr total)**

Exceeds medicinal product manufacturer's maximum indicated flow rate

Hizentra® (Immune Globulin Subcutaneous (Human) 20% Liquid) 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 (±15%).

To determine the appropriate flow rate tubing and subcutaneous needle configuration, please refer to medicinal product labeling 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

Flow rates for initial infusion **(≤20 ml/hr/site)**

Flow rates for second and third infusions **(≤35 ml/hr/site)**

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	56,7	62,8	109,9
2 needles	5,0	6,6	9,9	15,3	19,1	22,0	33,0	37,3	76,0
3 needles	3,4	4,5	6,7	10,4	13,1	15,3	23,3	26,5	58,1
4 needles	2,5	3,4	5,1	7,9	10,0	11,7	18,0	20,6	47,0

Flow rates for initial infusion **(≤20 ml/hr/site)**

Flow rates for second and third infusions **(≤35 ml/hr/site)**

Flow rates for fourth and subsequent infusions (per patient's tolerability)

Xembify® (Immune Globulin Subcutaneous, Human-klhw) 20% solution) Flow Rate Combinations:

The following tables indicate the average, minimum and maximum 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.

To determine the appropriate flow rate tubing and subcutaneous needle configuration, please refer to medicinal product labeling 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)	22,4 (14,3-30,6)	24,2 (15,0-33,5)	29,6 (18,6-40,5)
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)	18,0 (10,8-25,2)	24,6 (15,0-34,2)
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)	21,1 (12,5-29,6)
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)	18,4 (10,8-26,1)
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)

Flow rates for initial infusion **(≤10 ml/hr/site)**

Pediatrics: Flow rates for the first two infusions **(≤20 ml/hr/site)**

Adults: Flow rates for the first two infusions **(≤25 ml/hr/site)**

Flow rates for subsequent infusions **(≤35 ml/hr/site)**

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)	21,7 (12,1-31,4)	25,0 (15,6-34,3)	29,1 (17,6-40,7)	42,9 (26,2-59,6)	50,2 (29,0-71,4)	80,1 (46,4-113,9)
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)	24,4 (14,8-34,1)	29,3 (16,5-42,1)	51,9 (28,9-75,0)
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)	20,7 (11,6-29,8)	38,4 (21,0-55,9)
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)	30,5 (16,5-44,5)
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)	25,3 (13,5-37,0)
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)	21,6 (11,5-31,7)

Flow rates for initial infusion **(≤10 ml/hr/site)**

Pediatrics: Flow rates for the first two infusions **(≤20 ml/hr/site)**

Adults: Flow rates for the first two infusions **(≤25 ml/hr/site)**

Flow rates for subsequent infusions **(≤35 ml/hr/site)**

Exceeds medicinal product manufacturer's maximum indicated flow rate

Desferal® (desferrioxamine mesilate) Flow Rate Combinations:

The following table indicates the nominal predicted infusion times with one (1) 26G HIgH-Flo Subcutaneous Safety Needle Set™ 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 Desferal (±15%).

Please refer to medicinal product labeling for maximum indicated flow rate, volume, and infusion time.

Infusion times are based on the standard subcutaneous concentration per medicinal product labeling. Higher concentrations may result in slower infusions, whereas lower concentrations may result in faster infusions.

HIgH-Flo 26G with Precision Tubing - Nominal Infusion Time for 50 ml BD Syringe

Tubing Set (Rate ml/h)	Syringe Volume (ml)			
	Time for 5 ml	Time for 10 ml	Time for 20 ml	Time for 30 ml
F0.5 (0,60 ml/h)	8 h 18 min	16 h 42 min	33 h 18 min	50 h 00 min
F1 (1,10 ml/h)	4 h 30 min	9 h 06 min	18 h 12 min	27 h 18 min
F2 (2,20 ml/h)	2 h 18 min	4 h 30 min	9 h 06 min	13 h 36 min
F3 (3,20 ml/h)	1 h 36 min	3 h 06 min	6 h 18 min	9 h 24 min
F3.8 (3,80 ml/h)	1h 18 min	2 h 36 min	5 h 18 min	7 h 54 min
F5 (5,40 ml/h)	0 h 54 min	1 h 54 min	3 h 42 min	5 h 36 min

Subcutaneous Hydration:

The following table indicates the nominal predicted infusion times with one (1) or two (2) 24G HIgH-Flo Subcutaneous Safety Needle Set™ 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 electrolyte solutions (±15%).

Typical infusion rate could be 1 ml/min (60 ml/h) with one needle. The volume can be increased by using 2 needles. Approximately 3 liters can be given in a 24-hour period at two separate sites.[1,2]

Please refer to medicinal product labeling for maximum indicated flow rate, volume, and infusion time. All indicated values as tolerated and at the direction of the prescribing healthcare provider.

HIgH-Flo 24G with Precision Tubing - 50 ml BD Syringe

Tubing Set (Rate ml/h)	Number of needles	Infusion time for 50 ml	Infusion time for 500 ml	Infusion time for 1000 ml	Infusion time for 1500 ml	Infusion time for 3000 ml
F60 (71,00 ml/h)	1 needle 24G	0 h 42 min	7 h 00 min	14 h 06 min	21 h 06 min	42 h 18 min
F60 (72,00 ml/h)	2 needles 24G	0 h 42 min	6 h 54 min	13 h 54 min	20 h 48 min	41 h 42 min

1 Caccialanza et al. J Parenter Enteral Nutr. (2018) 42:296–307.
2 The Health Technology Inquiry Service. October 2010. https://cadth.ca/sites/default/files/pdf/L0223_Hypodermoclysis_Final.pdf

How to Use Flow Rate Table for Intravenous Antibiotic Administration:

- Select prescribed medicinal product and refer to its prescribing information for recommended infusion flow rate and infusion time.
- Verify the expected infusion time and the syringe volume.
- Evaluate and select flow rate tubing based on the expected infusion time and the syringe volume.

Selected Infusion Times for Intravenous Administration:

The following table indicates the nominal predicted infusion times when used in combination with KORU Precision Flow Rate Tubing™ and the FREEDOM60® Syringe Driver with a 50 ml syringe for the intravenous use of meropenem, ertapenem, oxacillin, and tobramycin (±15%).

Please refer to medicinal product labeling for recommended infusion rates and times.

Tubing Set (Rate ml/h)	Syringe Volume (ml)					
	Infusion time for 10ml	Infusion time for 20 ml	Infusion time for 30 ml	Infusion time for 40 ml	Infusion time for 50 ml	Infusion time for 60 ml
F2 (2,23 ml/h)	4 h 30 min	9 h 00 min	13 h 24 min	17 h 54 min	22 h 24 min	26 h 54 min
F3 (3,20 ml/h)	3 h 06 min	6 h 18 min	9 h 24 min	12 h 30 min	15 h 36 min	18 h 48 min
F3,8 (3,86 ml/h)	2 h 36 min	5 h 12 min	7 h 48 min	10 h 24 min	13 h 00 min	15 h 36 min
F5 (5,48 ml/h)	1 h 48 min	3 h 36 min	5 h 30 min	7 h 18 min	9 h 06 min	10 h 54 min
F8 (8,12 ml/h)	1 h 12 min	2 h 30 min	3 h 42 min	4 h 54 min	6 h 12 min	7 h 24 min
F10 (10,15 ml/h)	1 hr 00 min	2 h 00 min	3 h 00 min	3 h 54 min	4 h 54 min	5 h 54 min
F15 (15,23 ml/h)	0 hr 42 min	1 h 18 min	2 h 00 min	2 h 36 min	3 h 18 min	3 h 54 min
F30 (35,53 ml/h)	0 hr 18 min	0 hr 36 min	0 hr 48 min	1 h 06 min	1 h 24 min	1 h 42 min
F45 (55,73 ml/h)	0 hr 12 min	0 hr 24 min	0 hr 30 min	0 hr 42 min	0 hr 54 min	1 h 06 min
F60 (73,09 ml/h)	0 hr 06 min	0 hr 18 min	0 hr 24 min	0 hr 30 min	0 hr 42 min	0 hr 48 min
F120 (135,58 ml/h)	0 hr 06 min	0 hr 06 min	0 hr 12 min	0 hr 18 min	0 hr 24 min	0 hr 24 min
F180 (182,74 ml/h)	0 hr 06 min	0 hr 06 min	0 hr 12 min	0 hr 12 min	0 hr 18 min	0 hr 18 min
F275 (275,00 ml/h)	0 hr 00 min	0 hr 06 min	0 hr 06 min	0 hr 06 min	0 hr 12 min	0 hr 12 min

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 syringe driver 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, 100 Corporate Drive, Mahwah, NJ 07430 USA. Notice to KORU Medical 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 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
EC REP	Authorized Representative in the European Community		Do Not Reuse
CH REP	Swiss Authorized Representative		Do Not Resterilize
LOT	Batch Code		Not Made with Natural Rubber Latex
QTY	Quantity		Do Not Use if Package is Damaged
REF	Catalog Number		MR Unsafe
SN	Serial Number	Rx ONLY	Prescription Only
STERILE R	Sterilized Using Irradiation	CE	European Conformity
MD	Medical Device		Importer

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CH REP Swiss Representative
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6302 Zug
Switzerland

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