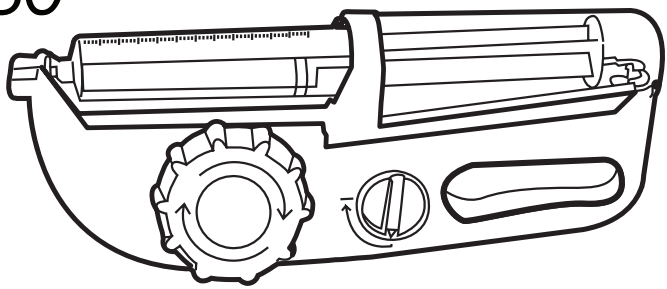
Freedom60®
INFUSION SYSTEM



# Instructions For Use

## User and Healthcare Provider Content


Introduction ....2
Indications For Use ....2
MRI Safety Information ....3
Warnings and Precautions ....4
Freedom60 Infusion System Diagram ....6
Compatible Syringes ....7

Instructions for Use ....7
Instructions for Freedom60 Prefilled Syringe Adapter ....8
Instructions for Subcutaneous (SC) Administration ....9
Instructions for Intravenous (IV) Administration ....16

Troubleshooting ....20
Care, Maintenance and Reprocessing ....23


## Healthcare Provider Content


Technical Specifications ....26
Ancillary Supply Product Information ....28
Selected Flow Rate Combinations ....30
Cutaquig® ....31
Cuvitru® ....32
Gammagard Liquid® ....33
Hizentra® for PID ....34
Hizentra® 50 mL Prefilled Syringe for PID ....35
Hizentra® for CIDP ....36
Hizentra® 50 mL Prefilled Syringe for CIDP ....37
Xembify® ....38

Warranty Information ....39
Definition of Symbols ....41



KORU™ MEDICAL SYSTEMS

KORU Medical Systems | korumedical.com | +1-800-624-9600
100 Corporate Drive, Mahwah, NJ 07430 USA

# INTRODUCTION

The Freedom60 Infusion System consists of the following components:

- **Freedom60® Infusion Pump** (referred to as "Freedom60" or "pump")
- **Precision™ Flow Rate Tubing** (referred to as "Precision tubing" or "tubing")
- **High-Flo™ Subcutaneous Safety Needle Sets** (referred to as "High-Flo needle set" or "needle set")

The Freedom60 Infusion System is mechanical, so no batteries or electricity are required for use. It is completely portable and may be used in a home or clinical setting by patients (adult, adolescent, and pediatric), caregivers, and healthcare providers. See page 6 for a complete system diagram and more details. This manual contains infusion instructions for all users and technical information for healthcare providers to select the most appropriate Precision tubing and High-Flo needle set for each patient and drug.

⚠ **CAUTION:** Patients and their caregivers must be trained by their qualified healthcare provider prior to self-administration. Patients are advised to contact their healthcare provider for all questions related to their treatment.

## Indications for Use

The Freedom60 Infusion System is specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins when used according to the FDA approved biologic labeling:

- Cutaquig®, Immune Globulin Subcutaneous (Human) 16.5% Solution (manufactured by Octapharma®);
- Cuvitru®, Immune Globulin Infusion (Human) 20% (manufactured by Takeda®);
- Gammagard Liquid®, Immune Globulin Infusion (Human) 10% (manufactured by Takeda®);
- Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®); and
- Xembify®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by Grifols®)

in the home, hospital, or ambulatory settings when administered according to the approved biologic or drug product labeling.

The Freedom60® Infusion System with the Freedom60 Infusion Pump and Precision Flow Rate Tubing™, is specifically indicated for the intravenous infusion of the following antibiotics when used according to the FDA approved drug product labeling:

- ertapenem,
- meropenem,
- oxacillin, and
- tobramycin.

The Freedom Infusion System consists of the following components:

- Freedom60® Syringe Driver
- Precision Flow Rate Tubing™
- High-Flo Subcutaneous Safety Needle Sets™
- High-Flo Super26™ Subcutaneous Needle Sets are specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins: Cutaquig®, Immune Globulin Subcutaneous (Human) 16.5% Solution (manufactured by Octapharma®); Cuvitru®, Immune Globulin Infusion (Human) 20% (manufactured by Takeda®); Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®); and Xembify®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Grifols®).

The Freedom Infusion System is indicated for use with the following syringes:

- BD® 50 ml syringe (US Reference number 309653)
- Medline 60 ml Syringe (US reference number SKU SYR160010)
- Hizentra 50 ml Prefilled Syringe

**Contraindications:** The Freedom60 Infusion System is not intended for the delivery of blood, critical or life-sustaining medications, or for the delivery of insulin. Note: “Critical” may be defined as medication requiring greater accuracy of delivery, such as CNS opiate depressants.

## MRI Safety Information


The Freedom Infusion System is MR Unsafe. Do not use the Freedom Infusion System in or around an MRI Machine.

## ⚠ WARNINGS

### For Users and Healthcare Providers:

- Patient tolerance may vary. If you are experiencing pain or discomfort, contact your healthcare provider.
- 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. Refer to the device technical specifications for information on device performance.
- Do not connect the High-Flo needle set directly to the syringe. Connecting the needle set directly without the tubing/luer disc may cause the syringe to eject from the Freedom60 Infusion Pump and may cause internal damage to the pump.
- Do not re-sterilize or reuse the Precision tubing or High-Flo needle set. Re-using a single-use device may result in infection or malfunction of the device.
- 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.
- Do not attempt to remove the syringe or disconnect the tubing set without first turning the pump to the OFF position and fully winding the large knob clockwise until the black tab has reached the end of its track.
- The Freedom60 Infusion Pump does not have an alarm. No alarm will sound if an interruption to flow occurs. There is no display of infusion status.
- If the Freedom60 Infusion Pump is submerged in any fluid, discontinue use and call your healthcare provider for a replacement.
- Do not sterilize the infusion pump. Always follow the cleaning and disinfection instructions on page 23.
- The Freedom60 Infusion System is MR-unsafe. Do not use the Freedom60 Infusion System in or around an MRI Machine.

### For Healthcare Providers:

- Do not use the Freedom60 Infusion System for blood transfusions or with medication where delay or under-infusion could result in serious injury.
- Patient tolerability may vary. Patients experiencing discomfort may require a flow rate adjustment. Refer to the device technical specifications for information on selecting appropriate infusion accessories. Always refer to the drug prescribing information for indicated flow rates

## ⚠ PRECAUTIONS

### Freedom60 Infusion System

- Federal law (USA) restricts this device to sale by or on the order of a physician. Use the Freedom60 Infusion System only for the patient for whom the device is prescribed and only for its intended use. Ensure that the patient and/or caregiver is trained by a qualified healthcare professional prior to use.
- Use only Freedom60 Infusion System components manufactured by KORU Medical Systems. Use of other products may result in unknown flow rates.
- Use only compatible syringes with the Freedom60 Infusion Pump. Using a different syringe may cause the syringe to eject from the pump or may result in unknown flow rates.
- Before use, carefully inspect the Precision tubing and High-Flo needle packaging. Do not use the set if the package is opened.
- Inspect tubing and needle sets for damage. If damaged, do not use - replace and contact your healthcare provider.
- The slide clamp included on the Precision tubing and High-Flo needle set should only be used to stop flow immediately in the case of an emergency. Use of the slide clamp may cause damage to the tubing and can affect the intended flow rate.
- Carefully inspect and test the functionality of the Freedom60 Infusion Pump before use. Discontinue use of a pump that has been damaged, exposed to severe impact, or which fails to operate properly. Inspect the device for signs of wear (including cracks, fractures, corrosion, discoloration, pitting, or cracked seals) and discontinue use if device is unacceptably deteriorated.
- Avoid placing High-Flo needle set over a mole, tattoo, scar, muscle, or hardened or bruised areas, where proper needle insertion could be difficult.
- Only 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; the Freedom60 Infusion System has not been tested with any other physical activity.
- If the pump is higher than the infusion site, flow rate may increase. If the pump is positioned lower than the infusion site, flow rate may decrease.
- Ambient temperature may impact the flow rate. For most accurate results, it is recommended to operate the device at a temperature of 20-25°C (68-77°F).

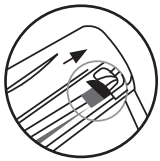
## ⚠ PRECAUTIONS

### Freedom60 Prefilled Syringe Adapter:

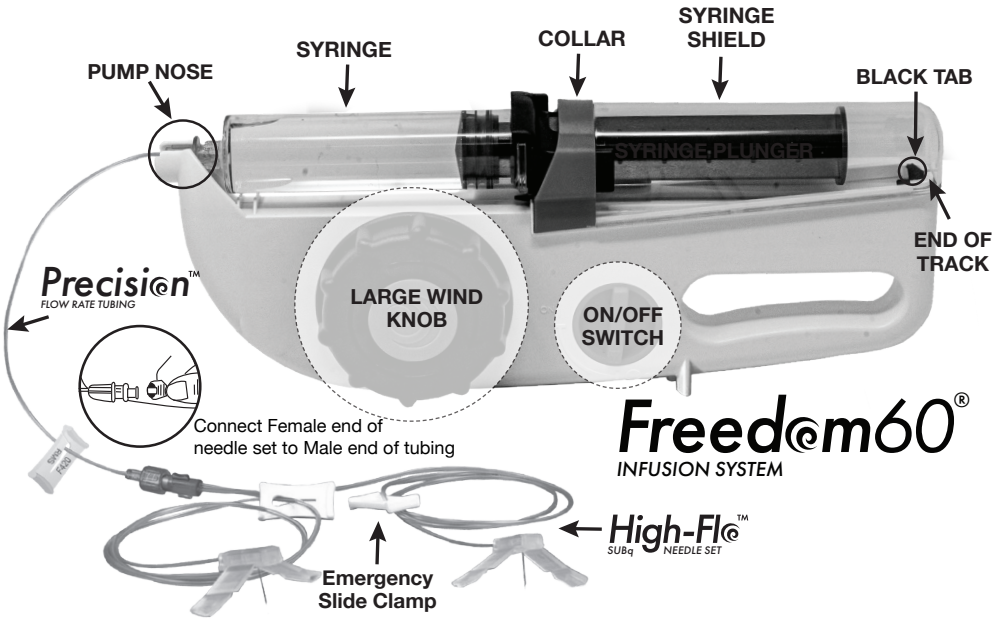
- Only use Hizentra 50 mL prefilled syringes with the Freedom60 Prefilled Syringe Adapter.
- Do not use BD 50 mL or Medline 60 mL syringes with the Freedom60 Prefilled Syringe Adapter.
- The Freedom60 Prefilled Syringe Adapter should be installed with the adapter placed into the pump collar and clicked into place as shown in the installation instructions on page 8. If the adapter is not assembled correctly, or the incorrect syringe is used, the syringe may be unintentionally expelled from the pump, and may cause injury to the end user.

### Freedom60® Infusion System Diagram

Luer Disc of Tubing connects to Syringe head and sits in pump nose

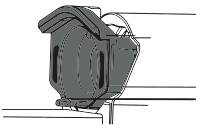


The Black Tab is wound to the end of the track before each infusion



### Compatible Freedom60 Syringes:

- Becton Dickinson & Co. BD Luer-Lok 50 mL (US SKU #309653; EU SKU #300865)
- Medline 60 mL Luer Lock Syringe (US SKU SYR160010)
- Hizentra® 50 mL Prefilled Syringe



**Freedom60 Prefilled Syringe Adapter**

Only for Hizentra® 50 mL prefilled syringes

### Freedom60 Prefilled Syringe Adapter

**For use with the following prefilled syringes:**

- Hizentra® 50 mL prefilled syringes

## INSTRUCTIONS FOR USE

**Before You Begin:**

**1.** Gather your supplies and sanitize by cleaning your infusion work surface with antiseptic wipes or disinfecting solution. Wash your hands thoroughly and, if required, put on disposable gloves. Then lay out your supplies.

**2.** Make sure that the infusion pump's ON/OFF switch is in the OFF position and that the black tab within the syringe shield is at the end of its track. If the black tab is not touching the end of its track, fully turn the large wind knob clockwise.

**3.** Turn the pump ON and watch that the black tab moves smoothly along the full length of its track. Once complete, be sure to fully turn the large wind knob clockwise so the black tab is at the end of its track and you are ready for infusion.

**4.** Examine the inside of the syringe shield and ensure it is free of debris or contamination.

**5.** Verify that you are using the correct Precision tubing and/or High-Flo needle set prescribed by your healthcare provider. Inspect tubing and/or needle set packaging. Check that the bag is intact (no rips, tears, or holes) and fully sealed along all edges of the bag. If the packaging is damaged, do not use. Replace and contact your healthcare provider.

**6.** Ensure the medication is at room temperature (68 - 77°F or 20 - 25°C).

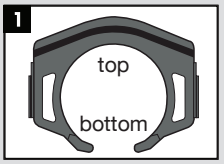
*Before subcutaneous self-administration, patients and/or caregivers must be trained by a qualified healthcare provider.*

⚠ **Contact your healthcare provider if your pump is not working, if the Precision tubing and/or High-Flo needle packaging is damaged, or if you see any debris or contamination inside of the syringe shield.**

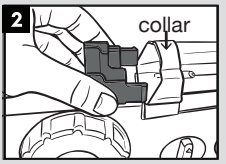
## If Using a Hizentra 50 ml Prefilled Syringe:

⚠ Do not use BD 50 mL or Medline 60 mL syringes with the Freedom60 Prefilled Syringe Adapter.

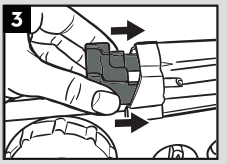
### Installation Instructions for the Freedom60 Prefilled Syringe Adapter



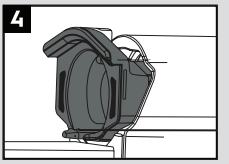

Make sure adapter is in the correct orientation, with opening at the bottom.




Line the adapter up with the collar of the Freedom syringe driver.

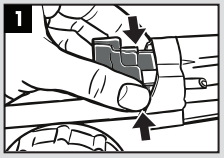



Lightly squeeze the sides of the adapter and begin to push it into the collar.

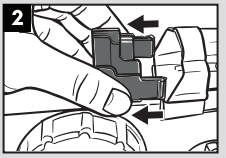



Continue pushing the adapter into the collar until it clicks into place.

### Removal Instructions for the Freedom60 Prefilled Syringe Adapter




Pinch the two retaining tabs inward by applying pressure to them.



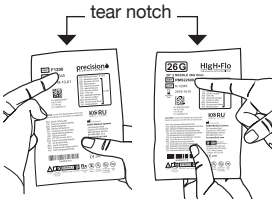

While pinching tabs, pull the adapter out of the collar, opposite the direction it was inserted.

## Step-by-Step Instructions for Subcutaneous Administration SC

## Part I – Prep System

### 1. Prepare Precision tubing & High-Flo needle set

Open the sterile package by tearing along the tear notch on the top of the package. Inspect needle set and tubing for damage. Check for bent needle set or damage to tubing. If damaged, replace and contact your healthcare provider.

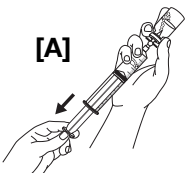



### 2. Prepare syringe(s)

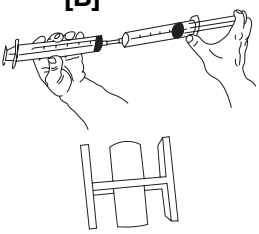
Refer to the drug manufacturer's instructions or ask your healthcare provider for detailed filling instructions.

- **Vial to syringe transfer:** fill required dose into compatible syringe(s), as listed on **page 7 [A]**
- **Prefilled syringe to syringe transfer:** fill required dose into compatible syringe(s), as listed on **page 7 [B]**
- **Hizentra® 50 mL prefilled syringe:** fits directly into pump with Freedom60 Prefilled Syringe Adapter, no transfers required. Refer to Freedom60 Prefilled Syringe Adapter Installation Instructions on **page 8**.

**[A]**



**[B]**

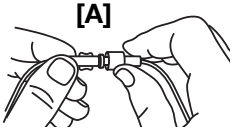


Refer to **page 8** for Installation instructions

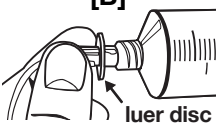
### 3. Attach Precision tubing & High-Flo needle set

Remove sterile caps from ends of the Precision tubing set and High-Flo needle set using care not to contaminate the ends. Connect the female end of the needle set to the male end of the tubing set **[A]**. Remove the cap from the female end of the tubing, without touching the end, and attach the female end with luer disc to the syringe **[B]**.

**[A]**



**[B]**



SC

## 4. Prime (fill) Precision tubing

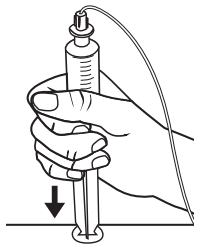
Always follow your healthcare provider's protocol.
There are two options for priming

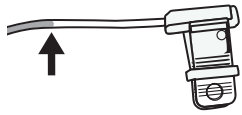
A. Priming by hand or
B. Priming by pump

Choose which option best suites you and follow the appropriate directions below.

### Option A – Priming by hand:

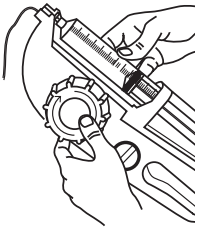
- Push the syringe plunger and follow the medication as it flows through the tube. When the medication is approximately 2-3 inches from the needle, release pressure from the plunger to stop the flow.
- Lay the Precision tubing and High-Flo needles on work surface and watch the tubing fills as the medication approaches the needle.
- 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.

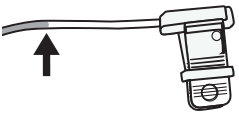




**Option B – Priming by pump:**

- Make sure the pump 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, turn the large wind knob clockwise.
- If using a Hizentra 50 mL prefilled syringe, be sure the Freedom60 Prefilled Syringe Adapter is installed prior to loading syringe into pump as directed below **(see page 8 for instructions)**. If not using a Hizentra 50mL prefilled syringe please be sure the Freedom60 Prefilled Syringe Adapter is removed before moving forward.
- With syringe gradations facing up, load the assembled syringe into the pump and ensure that the luer disc is fully seated in the pump nose.
- Lay Precision tubing and High-Flo needles on work surface. Turn the pump ON to prime (fill) the tubing and watch the tubing as the medication approaches the needle. When the medication reaches the desired point, turn the ON/OFF switch to the OFF position and immediately turn the large wind knob clockwise to release pressure on the plunger.

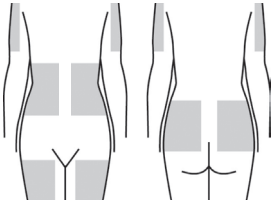




***Notes:***

- *It is recommended to insert the needles dry, meaning no medication is present in the needle, to minimize site irritation.*
- *To best see the medication in the tubing during priming, it is recommended to prime the tubing against a dark, solid-colored surface in a well-lit area.*
- *When priming by pump, 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.*

## 5. Prepare sites

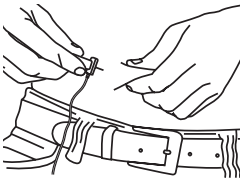


- Select, clean and let site(s) dry before inserting needles. Carefully remove the shield from the needle tip, with care not to touch the needle.
- **NOTE:** *Always refer to the drug manufacturer's prescribing information and recommendations from your healthcare provider for infusion site location(s). Common areas for subcutaneous infusion include the abdomen, thighs, side of the upper hips and back of the arms.**

⚠ Avoid placing needles over a mole, tattoo, scar, muscle, hardened or bruised areas, where proper needle insertion could be difficult.

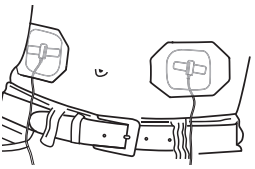
*Younger ME et al. J Inf Nurs. 2013; 36:58-64

## 6. Insert High-Flo Needles



- Pinch the skin and insert each needle into the subcutaneous tissue at a 90˚ angle. Secure the needle (following the instructions in Step 7) before inserting a needle in another site.

## 7. Secure High-Flo needles

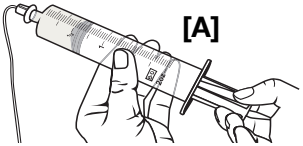


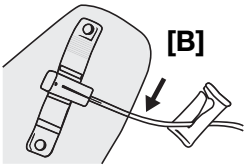
- Peel the printed side from the dressing to expose adhesive.
- Secure the needle by placing the adhesive dressing in the center of the needle butterfly. Smooth it outward over skin.
- Repeat for each infusion site.

## 8. Check for blood return

**Note:** If you primed by pump, first ensure that the black tab is at the end of its track and remove the syringe from the pump before moving forward.

- Check for blood return if instructed by your healthcare provider by gently pulling back on the syringe plunger **[A]**. 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) **[B]** or remove all needles, attach a new needle set, and start again from Step 3.




## Part III – Infuse

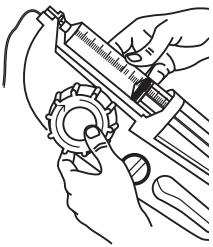
**When using the Hizentra 50 mL prefilled syringe,** be sure the Freedom60 Prefilled Syringe Adapter is installed prior to inserting the syringe into the pump. **When NOT using a Hizentra 50 mL prefilled syringe**, be sure to remove the Freedom60 Prefilled Syringe Adapter. **See page 8 for instructions.**

## 9. Insert syringe & turn ON

- Ensure the black tab is at the back of the pump. With syringe gradations facing up, insert the syringe back into the pump.
- Ensure the luer disc is fully seated in the driver's nose.
- Turn pump ON

**Note:** *To reduce flow rate variability, try to keep the pump level with your infusion sites.*

**Caution:** *if luer disc is not fully seated in pump driver nose it may eject from the pump.*

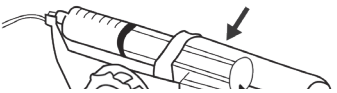


### 10. Infuse

- Periodically check that the pump is working properly by seeing that the syringe plunger is moving. If the pump is not functioning properly, reference the troubleshooting section on page 20 or contact your health care provider.

**If using multiple syringes:**

- Once the first syringe is empty, turn the pump OFF and wind the black tab to the end of its track. Remove the syringe from the pump and disconnect from tubing. Using care not to contaminate the ends, connect the additional syringe to the luer disc end of the Precision tubing.
- **When using the Hizentra 50 mL prefilled syringe,** be sure the Freedom60 Prefilled Syringe Adapter is installed prior to inserting the syringe into the pump (see page 8 for instructions).

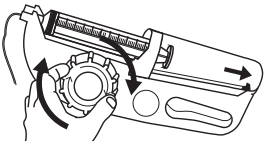


- **When NOT using a Hizentra 50 mL prefilled syringe,** be sure to remove the Freedom60 Prefilled Syringe Adapter (see page 8 for instructions).
- Load the prepared syringe into the pump. Turn the pump ON to continue infusion. Repeat until total dosage is complete.

## Part IV – Complete Infusion

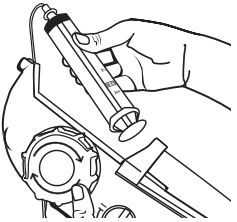
### 11. Turn off & wind back

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



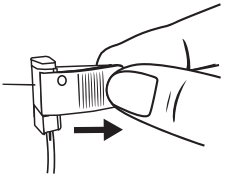
## 12. Remove syringe

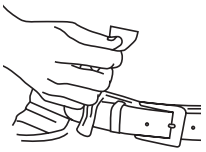
- Pull syringe away from the pump's nose and remove.



## 13. Remove High-Flo needles & cleanse sites

- Holding the High-Flo needle in place, peel back the surrounding adhesive dressing and remove.
- 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.
- Cleanse each site and cover with a bandage.



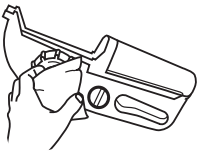


## 14. Discard of disposables

- Discard all sharps and non-reusable supplies, like tubing and needle sets, as instructed by your healthcare provider.

## 15. Clean and disinfect device

- Clean and disinfect the pump and adapter as soon as possible after use and avoid delays between cleaning/ disinfection steps. See page 14 for full cleaning and disinfection instructions.



## Step-by-Step Instructions for Intravenous Administration

**IV**

Always follow your healthcare provider's instructions on flushing the vascular access device prior to use. The SASH technique is detailed 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.

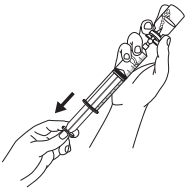
### Part I – Prep

#### 1. Verify Precision tubing

- Open the sterile package by tearing along the tear notch on the top of the package and inspect tubing set for damage. Check for damaged, bent, or occluded tubing, or any other issues that would prevent the proper function of the device. If the tubing or packaging is damaged, do not use. Replace and contact your healthcare provider.


#### 2. Prepare syringe(s)

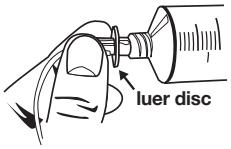
- Fill the compatible syringe(s) noted on **page 7** with your required dose. Refer to the drug manufacturer's instructions or ask your healthcare provider for detailed filling instructions.



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

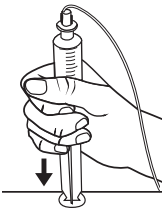
### 3. Attach Precision tubing

- Remove cap from the luer disc end of the Precision tubing, using care to not contaminate the ends, and connect to the syringe.



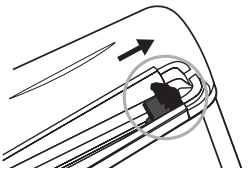

### 4. Prime (fill) Precision tubing

- Always follow your healthcare provider's instructions. Loosen the cap on the Precision tubing. 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.

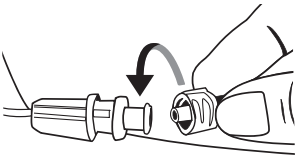


## 5. Begin Infusing

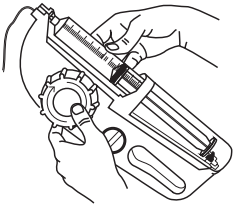
Follow the instructions of your healthcare provider for cleansing and preparing the vascular access device



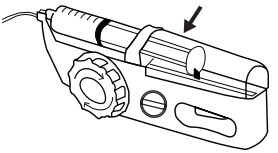
- Cleanse with alcohol – after 15 seconds scrub allow to dry completely.
- Aspirate for blood return to ensure the vascular access device is open and unobstructed before each access.



- Make sure the pump 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, turn the large wind knob clockwise.



- Uncap the Precision tubing and connect to the vascular access device or needle-free connector, using care not to contaminate the ends.
- With syringe gradations facing up, insert the syringe back into the pump.
- Ensure the luer disc is fully seated in the driver's nose. Turn the pump ON by rotating the switch clockwise.

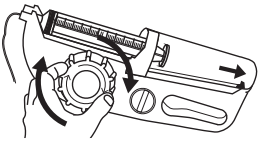


- Periodically check that the syringe plunger is moving to ensure the pump is working properly.

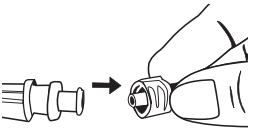
***Note - If using multiple syringes:***

- *Once the first syringe is empty, turn the pump OFF by rotating the switch counter clockwise and turn the large wind knob clockwise to move the black tab to the end of its track.*
- *Remove the syringe from the pump and disconnect from tubing.*
- *Using care not to contaminate the ends, connect the additional syringe to the luer disc end of the Precision tubing.*
- *Load the prepared syringe into the pump.*
- *Turn the pump ON to continue infusion. Repeat until total dosage is complete.*

## 6. End Infusion



- When the syringe is completely empty and the total dosage is infused, turn the pump OFF and turn the large wind knob clockwise 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.



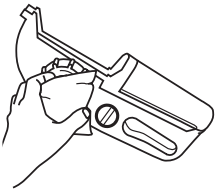
- Disconnect Precision tubing from the vascular access device or needle-free connector.
- Follow your healthcare provider's instructions on flushing the vascular access device if required.

## 7. Discard of disposables

- Discard all sharps and non-reusable supplies, like tubing, as instructed by your healthcare provider.

## 8. Clean and disinfect device

- Clean and disinfect the pump and adapter as soon as possible after use and avoid delays between cleaning/ disinfection steps. See **page 23** for full cleaning and disinfection instructions.



# 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 **+1-800-624-9600**.

If you are experiencing pain or extreme discomfort, stop use immediately and call your healthcare provider.

### Syringe will not load or remove from Freedom60 Infusion Pump:

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

- Make sure the pump is in the OFF position and that the black tab is at the end of its track. If the black tab is not at the end of its track, fully wind the large knob clockwise and try removing syringe again.
- Verify that you are using a compatible syringe (see **page 7** for details).
- If using a Hizentra© 50 mL prefilled syringe, ensure the Freedom60 Prefilled Syringe Adapter is installed prior to loading the syringe (see **page 8** for instructions)
- When NOT using a Hizentra 50 mL prefilled syringe, be sure to remove the Freedom60 Prefilled Syringe Adapter (see **page 8** for instructions)

### Syringe will not stay inside in the Freedom60 Infusion Pump:

- Make sure you are using a Precision Flow Rate Tubing™ set and that the luer disc end of the tubing has been connected to a compatible syringe (see **page 7** for details).
- Verify that you are using a compatible syringe (see page 7 for details).
- Make sure the luer disc on the tubing set is seated properly in the nose of the pump.
- *For subcutaneous use: Make sure you have attached the syringe directly to the Precision tubing and NOT directly to the High-Flo subcutaneous needle set.*

**Medication is not flowing through the tubing:**

- Make sure that the pump is in the ON position.
- For Subcutaneous use:
    - o Make sure all the tubing is not clamped.
    - o Using care not to touch or contaminate the ends, disconnect the tubing set from the needle set, and check for medication drip.
    - o If medication does not drip, replace the tubing as it may be damaged.
- For Intravenous use with a vascular access device:
    - o Make sure its clamps, if any, are open.
    - o Using care not to touch or contaminate the ends, disconnect the vascular access device or needle-free connector, and check for medication drip.
    - o If the medication does not drip, check that the catheter is open and unobstructed

**The flow is slow (infusion is taking longer than expected):**

- If the slide clamp has been used, the tubing may be damaged and should be replaced.
- Ensure the pump is level with the infusion sites. If the pump is lower than the infusion sites the flow rate may be slower.
- Only perform infusions while stationary or walking. Infusions with movement other than walking may result in faster, slower, or more variable flow rates than specified.
- For Subcutaneous use:
    - o Ensure that your medication is at room temperature and that the ambient temperature in your infusion space is between 68-77º F as temperature may impact flow rate.
    - o Flow rate can vary for each patient. Administration may be slow based on how well the medication is absorbed through the tissue.
    - o Some infusions may be faster than others. The first infusions may take longer than expected because the body may need to adapt.
    - o Avoid placing needles over a mole, tattoo, scar tissue, muscle, or hardened or bruised areas
    - o If you prefer a faster flow, you may need more sites, a different needle set and/or a faster flowrate tubing set. Talk to your healthcare provider.

### The flow is faster than expected (infusion is taking less time than expected):

- Ensure the pump is level with the infusion sites. If the pump is above than the infusion sites the flow rate may be faster.
- Only perform infusions while stationary or walking. Infusions with movement other than walking may result in faster, slower, or more variable flow rates than specified.
- For Subcutaneous use:
    - o Ensure that your medication is at room temperature and that the ambient temperature in your infusion space is between 68-77° F as temperature may impact flow rate.
    - o Flow rate can vary for each patient. Administration may be fast based on how well the medication is absorbed through the tissue.
    - o Some infusions may be faster than others. Subsequent infusions after initial dosing may flow faster as your body adapts to the infusions
    - o Ensure you have connected your Precision flow-rate tubing. If you connected your syringe directly to your High-Flo needles the medication will flow at a faster rate than expected.
    - o If you prefer a slower flow, you may need fewer sites, a different needle set and/or a slower flowrate tubing set. Talk to your healthcare provider.

### Flow is continuing even when the Freedom60 Infusion Pump is turned OFF:

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

### Medication (5 mL or less) is left in the syringe:

- Verify that you are using a compatible syringe (see **page 7** for details).
- If the syringe does not completely empty, contact your healthcare provider.

**There is swelling, pain or redness at the infusion site:**

- It is recommended to insert subcutaneous needles dry as the medication may irritate the skin.
- Make sure that the needles are long enough to reach the subcutaneous layer. If the selected needle is too short, leaking at the site may occur. Talk to your healthcare provider about using a longer needle.
- Make sure that the needles are not too long, as they may hit muscle. Talk to your healthcare provider about using a shorter needle.
- Ask your healthcare provider about trying 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® Infusion Pump does not require any preventative maintenance or calibration.
- Call your healthcare provider for a replacement if you notice your pump is damaged or broken, you drop the pump accidentally, or the pump is submerged in liquid.
- Clean and disinfect the Freedom60 Infusion Pump after every use.
- After cleaning and disinfection, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, and cracked seals.
- If you notice that your pump is damaged or deteriorated, call your healthcare provider for a replacement.

## Cleaning Procedure:

1. If the Freedom60 Prefilled Syringe Adapter is installed, follow removal instructions on page 7. Clean the adapter following the steps below.
2. Clean the pump 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).
3. Using the prepared detergent solution and a clean non-linting wipe or soft cloth, wipe all the external surfaces of the pump, including the pump nose and syringe tray up to the syringe shield for at least one (1) minute. During the one-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.
4. 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 pump, including the pump 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 pump is thoroughly clean. Replace or re-wet cloth or wipes as needed, changing wipes when necessary to ensure that all surfaces are rinsed.
5. Dry the pump using a clean non-linting wipe or soft cloth.
6. Inspect the pump for any visible residue and debris to ensure that the device is thoroughly cleaned. If the device has remaining visible residue and debris following cleaning, repeat the cleaning steps (1 through 4). Once all visible residue and debris is removed, disinfect pump per the noted disinfection procedure.

**Disinfection Procedure:**

**1.** Use pre-saturated IPA wipes, or a non-linting cloth or wipe saturated with 70% Isopropyl Alcohol (IPA) (wetted but not dripping) to thoroughly wipe all exterior surfaces of the Freedom60® Infusion Pump and Freedom60 Prefilled Syringe Adapter.

- Ensure all external surfaces of the pump and adapter, including the pump nose and syringe tray up to the syringe shield are wiped. Pay special attention to the ridges, crevices, raised lettering during wiping.
- **Caution:** Clean only those areas that are exposed and external. No attempt should be made to clean any part of the pump that is not easily accessible.
- Allow all surfaces to remain visibly wet for a minimum of five (5) minutes. During the five (5) minute contact time, use additional wipes to ensure all contacted surfaces remain wet for the full contact duration time.

**2.** Thoroughly dry the device using non-linting wipe(s) or allow to air dry.

**3.** Visually inspect the device for signs of damage or wear.

**Storage:** Store the Freedom60 Infusion Pump and accessories in a cool, dry place at room temperature (approximately 68-77F/20-25 C).

**THIS PAGE WAS INTENTIONALLY LEFT BLANK**

# INFORMATION FOR HEALTHCARE PROVIDERS

## 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).

**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 |

**Reservoir volume by syringe type:**

- Becton Dickinson & Co. BD® Luer-Lok® 50 mL = 50 mL
- Medline® 60ml Luer Lock Syringe = 60 mL
- Hizentra® 50 mL Pre-Filled Syringe = 50 mL

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

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

**NOTE:** If the test results fall outside the range indicated in Step 8, factory refurbishment and testing are available. Please contact KORU Medical Systems at **800-624-9600**.

## Ancillary Supply Product Information

**Compatible Infusion Accessories:** The Freedom60 Infusion Pump is designed to work together with the Freedom System accessories (Precision Flow Rate tubing, High-Flo Subcutaneous Safety Needles, Low Residual Volume Y-Connector, and Extension Set). Use only Freedom System accessories manufactured by KORU Medical Systems and compatible syringes. Use of other products may result in unexpected flow rates or damage to the Freedom60 Infusion Pump.

### 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 |

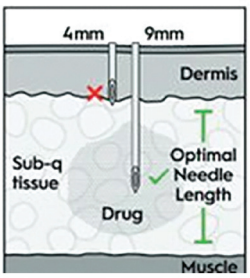
### Flow Rate Starter Kits:

| 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 |

**Selecting High-Flo Needle Sets:** Refer to the tables below for options. High-Flo needles are available in multiple lengths. Needles should penetrate into subcutaneous tissue. Select needle length based on patient size and infusion sites. The 24 gauge has a larger diameter and flows faster while the 26 gauge has a smaller diameter and flows slower.



## 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 |

# 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 backpressure.

**How to Use Flow Rate Tables for Subcutaneous Administration:**

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

**Subcutaneous Flow Rate Table Contents:**


| | |
|---|---|
| **Cutaquig®** | **Pg 31** |
| **Cuvitru®** | **Pg 32** |
| **Gammagard Liquid®** | **Pg 33** |
| **Hizentra® for Primary Immunodeficiency (PID)** | **Pg 34** |
| **Hizentra® 50ml Prefilled Syringe** | **Pg 35** |
| **Hizentra® for CIDP** | **Pg 36** |
| **Hizentra® 50ml Prefilled Syringe for CIDP** | **Pg 37** |
| **Xembify®** | **Pg 38** |

**Cutaquig® Flow Rate Combinations:** The following tables indicate the average (min-max) flow rates per site with High-Flo Subcutaneous Safety Needle Sets™ (26G and 24G) when used in combination with Precision Flow Rate Tubing™ and Freedom60® Infusion Pump with a 50 mL syringe for the subcutaneous use of Cutaquig.

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

**High-Flo 26G Needle with Precision tubing** - Average (Min-Max) Flow Rate Per Site (mL/hr/site)

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

Exceeds drug manufacturer's maximum indicated flow rate.

Subsequent infusions after 6th infusion only.

**High-Flo 24G Needle with Precision tubing** - Average (Min-Max) Flow Rate Per Site (mL/hr/site)

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

Exceeds drug manufacturer's maximum indicated flow rate.

Subsequent infusions after 6th infusion only.

**Cuvitru® for Primary Immunodeficiency (PID) 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 Precision Flow Rate Tubing™ and Freedom60® Infusion Pump with a 50 mL syringe for the subcutaneous use of Cuvitru for the treatment of PID.

**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 Needle with Precision tubing** - Average (Min-Max) Flow Rate Per Site (mL/hr/site)

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

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

☐ Subsequent infusions after 6th infusion only.

**High-Flo 24G Needle 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 | 13.1 | 19.3 | 28.9 | 35.5 | 40.5 | 57.8 | | |
| 2 needles | | | 10.1 | 15.6 | 19.5 | 22.5 | 33.7 | 38.1 | |
| 3 needles | | | | 10.7 | 13.4 | 15.6 | 23.8 | 27.1 | 59.3 |
| 4 needles | | | | | 10.2 | 11.9 | 18.4 | 21.0 | 48.0 |

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

☐ Subsequent infusions after 6th infusion only.

**Gammagard Liquid® Flow Rate Combinations:** The following tables indicate the nominal predicted flow rates per site with 26G High-Flo Subcutaneous Safety Needle Sets™ when used in combination with Precision Flow Rate Tubing™ and Freedom60® Infusion Pump with a compatible syringe for the subcutaneous use of Gammagard Liquid.

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

### 40 kg and greater Body Weight

**High-Flo 26G Needle with Precision tubing** - Average (Min-Max) Flow Rate Per Site (mL/hr/site)

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

Exceeds drug manufacturer's maximum indicated flow rate.

Subsequent infusions after 6th infusion only.

### Under 40 kg Body Weight

**High-Flo 26G Needle with Precision tubing** - Average (Min-Max) Flow Rate Per Site (mL/hr/site)

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

Exceeds drug manufacturer's maximum indicated flow rate.

Subsequent infusions after 6th infusion only.

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

**Hizentra® for Primary Immunodeficiency (PID) 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 Precision Flow Rate Tubing™ and Freedom60® Infusion Pump with a compatible syringe for the subcutaneous use of Hizentra for the treatment of PID.

**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 Needle with Precision tubing** - Average (Min-Max) Flow Rate Per Site (mL/hr/site)

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

Exceeds drug manufacturer's maximum indicated flow rate.

Subsequent infusions after 6th infusion only.

**High-Flo 24G Needle with Precision tubing** - Average (Min-Max) Flow Rate Per Site (mL/hr/site)

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

Exceeds drug manufacturer's maximum indicated flow rate.

Subsequent infusions after 6th infusion only.

**Hizentra® 50ml Prefilled Syringe for Primary Immunodeficiency (PID)**
**Flow Rate Combinations:** The following tables indicate average (min-max) predicted flow rates per site with High-Flo Subcutaneous Safety Needle Sets™ (26G and 24G) when used in combination with Precision Flow Rate Tubing™ and Freedom60® Infusion Pump with Freedom60 Prefilled Syringe Adapter for subcutaneous use with a Hizentra 50 mL prefilled syringe for the treatment of PID.

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

**High-Flo 26G Needle with Precision tubing** - Average (Min-Max) Flow Rate Per Site (mL/hr/site)

| | F120 | F180 | F275 | F420 | F500 | F600 | F900 | F1200 | F2400 |
|---|---|---|---|---|---|---|---|---|---|
| 1 needle | | | | | | | | | |
| 2 needles | 3.3 (1.3-5.3) | 4.1 (1.9-6.4) | 6 (2.6-9.3) | 8.4 (3.3-13.5) | 9.3 (4.1-14.5) | 10.6 (4.4-16.7) | 14.1 (5.8-22.4) | | |
| 3 needles | 2.3 (0.9-3.6) | 2.9 (1.3-4.5) | 4.2 (1.9-6.6) | 6.2 (2.5-9.9) | 6.9 (3.1-10.7 | 8 (3.4-12.5) | 11.1 (4.7-17.5) | 12.8 (5-20.5) | |
| 4 needles | 1.7 (0.7-2.8) | 2.2 (1-3.4) | 3.3 (1.4-5.1) | 4.9 (2-7.8) | 5.5 (2.5-8.5) | 6.4 (2.8-10) | 9.2 (3.9-14.4) | 10.7 (4.2-17.2) | |
| 5 needles | 1.4 (0.6-2.2) | 1.8 (0.8-2.8) | 2.7 (1.2-4.2) | 4 (1.6-6.4) | 4.5 (2.1-7) | 5.3 (2.3-8.3) | 7.8 (3.3-12.2) | 9.2 (3.6-14.8) | 14.6 (5.5-23.6) |
| 6 needles | 1.2 (0.5-1.9) | 1.5 (0.7-2.3) | 2.3 (1-3.5) | 3.4 (1.4-5.5) | 3.9 (1.8-6) | 4.6 (2-7.1) | 6.8 (2.9-10.6) | 8.1 (3.2-12.9) | 13.2 (5-21.4) |

☐ Exceeds drug manufacturer's maximum indicated flow rate.

☐ Exceeds drug manufacturer's maximum indicated flow rate and/or volume per site for initial infusion

**High-Flo 24G Needle with Precision tubing** - Average (Min-Max) Flow Rate Per Site (mL/hr/site)

| | F120 | F180 | F275 | F420 | F500 | F600 | F900 | F1200 | F2400 |
|---|---|---|---|---|---|---|---|---|---|
| 1 needle | | | | | | | | | |
| 2 needles | 3.6 (1.5-5.7) | 4.6 (2.1-7.2) | 7 (3.1-10.9) | 10.7 (4.4-17.1) | 12.3 (5.7-18.8) | 14.6 (6.5-22.6) | | | |
| 3 needles | 2.4 (1-3.9) | 3.1 (1.4-4.8) | 4.8 (2.1-7.4) | 7.3 (3-11.7) | 8.4 (3.9-12.9) | 10 (4.5-15.6) | 15.6 (7-24.3) | | |
| 4 needles | 1.8 (0.7-2.9) | 2.4 (1.1-3.6) | 3.6 (1.6-5.6 | 5.6 (2.3-8.9) | 6.4 (3-9.8) | 7.6 (3.4-11.9) | 12 (5.4-18.7) | 14.8 (6-23.6) | |
| 5 needles | 1.5 (0.6-2.3) | 1.9 (0.9-2.9) | 2.9 (1.3-4.5) | 4.5 (1.8-7.1) | 5.2 (2.4-7.9) | 6.2 (2.8-9.6) | 9.8 (4.4-15.2) | 12.1 (4.9-19.2) | |
| 6 needles | 1.2 (0.5-1.9) | 1.6 (0.7-2.4) | 2.4 (1.1-3.8) | 3.8 (1.5-6) | 4.3 (2-6.6) | 5.2 (2.3-8.1) | 8.2 (3.7-12.8) | 10.2 (4.1-16.2) | |

☐ Exceeds drug manufacturer's maximum indicated flow rate.

☐ Exceeds drug manufacturer's maximum indicated flow rate and/or volume per site for initial infusion

**Hizentra® for CIDP Flow Rate Combinations:** The following tables indicate the nominal predicted flow rates per site with High-Flo Subcutaneous Safety Needle Sets™ (26G and 24G) when used in combination with Precision Flow Rate Tubing™ and Freedom60® Infusion Pump with a compatible syringe for the subcutaneous use of Hizentra for the treatment of 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 Needle with Precision tubing** - Average (Min-Max) Flow Rate Per Site (mL/hr/site)

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

☐ Subsequent infusions after 6th infusion only.

**High-Flo 24G Needle with Precision tubing -** Average (Min-Max) Flow Rate Per Site (mL/hr/site)

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

☐ Exceeds drug manufacturer's maximum indicated flow rate.

☐ Subsequent infusions after 6th infusion only.

**Hizentra® 50ml Prefilled Syringe for Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Flow Rate Combinations:** The following tables indicate average (min-max) predicted flow rates per site with High-Flow Subcutaneous Safety Needle Sets™ (26G and 24G) when used in combination with Precision Flow Rate Tubing™ and Freedom60® Infusion Pump with Freedom60 Prefilled Syringe Adapter for subcutaneous use with a Hizentra 50 mL prefilled syringe for the treatment of CIDP.

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

**High-Flo 26G Needle 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 (2.4-9.5) | 7.3 (3.2-11.4) | 10 (4.2-15.7) | 13.2 (5.2-21.2) | 14.3 (6-22.5) | 15.7 (6.4-25) | 19.3 (7.8-30.9) | 21 (8.1-33.8) | 25.2 (9.5-40.9) |
| 2 needles | 3.3 (1.3-5.3) | 4.1 (1.9-6.4) | 6 (2.6-9.3) | 8.4 (3.3-13.5) | 9.3 (4.1-14.5) | 10.6 (4.4-16.7) | 14.1 (5.8-22.4) | 15.9 (6.2-25.6) | 21.3 (8.1-34.6) |
| 3 needles | 2.3 (0.9-3.6) | 2.9 (1.3-4.5) | 4.2 (1.9-6.6) | 6.2 (2.5-9.9) | 6.9 (3.1-10.7) | 8 (3.4-12.5) | 11.1 (4.7-17.5) | 12.8 (5-20.5) | 18.5 (7-29.9) |
| 4 needles | 1.7 (0.7-2.8) | 2.2 (1-3.4) | 3.3 (1.4-5.1) | 4.9 (2-7.8) | 5.5 (2.5-8.5) | 6.4 (2.8-10) | 9.2 (3.9-14.4) | 10.7 (4.2-17.2) | 16.3 (6.2-26.4) |
| 5 needles | 1.4 (0.6-2.2) | 1.8 (0.8-2.8) | 2.7 (1.2-4.2) | 4 (1.6-6.4) | 4.5 (2.1-7) | 5.3 (2.3-8.3) | 7.8 (3.3-12.2) | 9.2 (3.6-14.8) | 14.6 (5.5-23.6) |
| 6 needles | 1.2 (0.5-1.9) | 1.5 (0.7-2.3) | 2.3 (1-3.5) | 3.4 (1.4-5.5) | 3.9 (1.8-6) | 4.6 (2-7.1) | 6.8 (2.9-10.6) | 8.1 (3.2-12.9) | 13.2 (5-21.4) |

Exceeds drug manufacturer's maximum indicated flow rate.

Exceeds drug manufacturer's maximum indicated flow rate and/or volume per site for initial infusion

**High-Flo 24G Needle 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 (2.9-11.2) | 9 (4.1-13.9) | 13.5 (6-20.9) | 20 (8.2-31.9) | 22.7 (10.4-34.9) | 26.5 (11.7-41.4) | | | |
| 2 needles | 3.6 (1.5-5.7) | 4.6 (2.1-7.2) | 7 (3.1-10.9) | 10.7 (4.4-17.1) | 12.3 (5.7-18.8) | 14.6 (6.5-22.6) | 22.3 (9.9-34.6) | 26.9 (11-42.9) | |
| 3 needles | 2.4 (1-3.9) | 3.1 (1.4-4.8) | 4.8 (2.1-7.4) | 7.3 (3-11.7) | 8.4 (3.9-12.9) | 10 (4.5-15.6) | 15.6 (7-24.3) | 19.1 (7.8-30.4) | |
| 4 needles | 1.8 (0.7-2.9) | 2.4 (1.1-3.6) | 3.6 (1.6-5.6 | 5.6 (2.3-8.9) | 6.4 (3-9.8) | 7.6 (3.4-11.9) | 12 (5.4-18.7) | 14.8 (6-23.6) | 28.1 (10.9-45.3) |
| 5 needles | 1.5 (0.6-2.3) | 1.9 (0.9-2.9) | 2.9 (1.3-4.5) | 4.5 (1.8-7.1) | 5.2 (2.4-7.9) | 6.2 (2.8-9.6) | 9.8 (4.4-15.2) | 12.1 (4.9-19.2) | 23.4 (9.1-37.6) |
| 6 needles | 1.2 (0.5-1.9) | 1.6 (0.7-2.4) | 2.4 (1.1-3.8) | 3.8 (1.5-6) | 4.3 (2-6.6) | 5.2 (2.3-8.1) | 8.2 (3.7-12.8) | 10.2 (4.1-16.2) | 20 (7.8-32.2) |

Exceeds drug manufacturer's maximum indicated flow rate.

Exceeds drug manufacturer's maximum indicated flow rate and/or volume per site for initial infusion

**Xembify® for Primary Immunodeficiency (PID) 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 Precision Flow Rate Tubing™ and Freedom60® Infusion Pump with a compatible syringe for the subcutaneous use of Xembify for the treatment of PID.

**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 Needle with Precision tubing** - Average (Min-Max) Flow Rate Per Site (mL/hr/site)

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

☐ Exceeds drug manufacturer's maximum indicated flow rate.

**High-Flo 24G Needle with Precision tubing** - Average (Min-Max) Flow Rate Per Site (mL/hr/site)

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

☐ Exceeds drug manufacturer's maximum indicated flow rate.

# WARRANTY INFORMATION

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

**Limited Warranty:** KORU Medical Systems ("Manufacturer") warrants the Freedom60® Infusion Pump 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 pump 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 pump, 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 Infusion Pump using KORU accessories to ensure that the pump 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 pump. This warranty does not extend to subsequent purchasers.
- **Warranty Performance Procedure:** Notice of the defect must be made in writing to Customer Support Department, KORU Medical Systems/Repro Med Systems, Inc., 100 Corporate Drive Mahwah, NJ 07430 USA. Notice to KORU Medical Systems/Repro Med Systems, Inc. must include the model and serial number, date of purchase, and description of the defect in sufficient detail to facilitate repairs. Authorization must be obtained by the Original Purchaser from the Manufacturer or Manufacturer's Representative prior to returning the product to the Manufacturer. The defective pump 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 pump or component part is the EXCLUSIVE remedy offered by the Manufacturer. The following exclusions and limitations shall apply:
    - o 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.
    - o THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANT ABILITY AND FITNESS FOR A PARTICULAR PURPOSE. THERE ARE NO WARRANTIES THAT EXTEND BEYOND THE DESCRIPTION ON THE FACE HERE OF.
    - o Manufacturer's liability under this Limited Warranty Agreement shall not extend to special, indirect, or consequential damages.
    - o The pump can only be used under the supervision of medical personnel whose skill and judgment determine the suitability of the pump for a particular medical treatment.
    - o All recommendations, information, and descriptive literature supplied by the Manufacturer or its agents are believed to be accurate and reliable, but do not constitute warranties.

# DEFINITION OF SYMBOLS

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

**THIS PAGE WAS INTENTIONALLY LEFT BLANK**

**THIS PAGE WAS INTENTIONALLY LEFT BLANK**

KORU™
MEDICAL SYSTEMS

**+1-800-624-9600** | **korumedical.com** | **@korumedical**


Manufacturer
**KORU Medical Systems**
100 Corporate Drive
Mahwah, NJ 07430 USA
800 624 9600

EC REP European Representative
ICON (LR) Limited
South County Business Park,
Leopardstown, Dublin 18,
D18 X5R3, Ireland
+353 1 291 2000


CE 2797