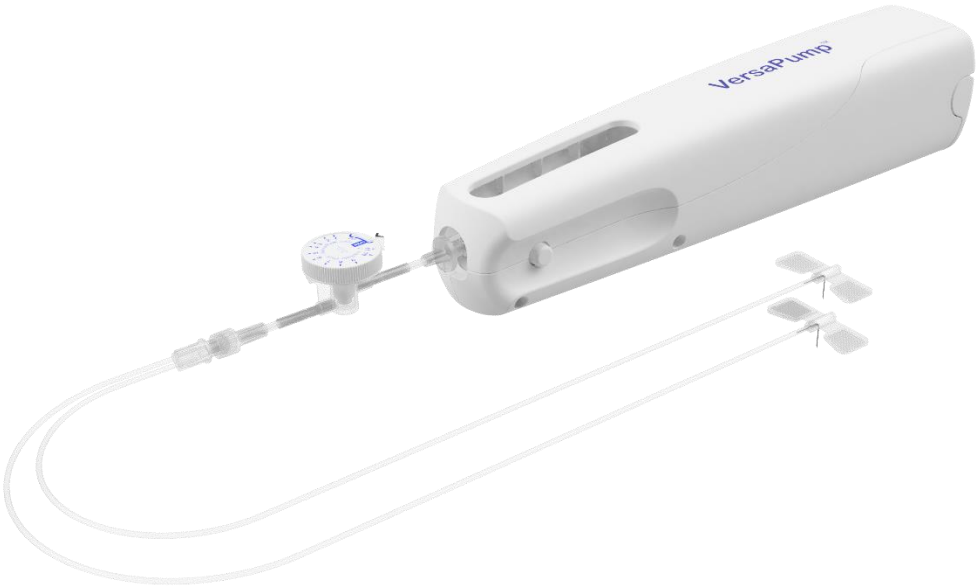
User Manual

VersaPump® Infusion System

USA Users



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NOTE:	In the event any serious incident occurs due to the use of this product, the healthcare provider, user or patient shall report the incident to EMED Technologies at +1-916-932-0071 and the competent authority in your region.

Contents

Important Information

Please contact EMED Technologies if you have any questions or concerns regarding the use of the VersaPump Infusion System.

Document Conventions

The below text and color code convention is used throughout this document to highlight warnings, cautions, and notes:

WARNING:	A **Warning** is an alert to a potential hazard which could result in serious personal injury or product damage if proper procedures are not followed.
CAUTION:	A **Caution** is an alert to a potential hazard which could result in minor personal injury or product damage if proper procedures are not followed.
NOTE:	A **Note** provides additional information or recommendation.

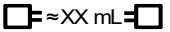
Terms and Abbreviations

The following terms are defined below and referenced throughout the document:

Defined Term	Meaning
Aseptic technique	Aseptic technique comprises specific, careful practices to minimize contamination by pathogens. Contact your healthcare professional for additional information and instructions.
Infuset	Infuset® flow control infusion set
Pump	VersaPump® Infuser
SUB-Q Set	Subcutaneous infusion set
VersaPump	VersaPump® Infusion System
VersaRate Plus	VersaRate® Plus variable flow control infusion set

Symbols

Some of these symbols below may be found on the VersaPump Infusion System labeling and packaging materials. A full glossary of symbols can be found at www.emedtc.com/support

Symbol	Definition	Symbol	Definition
	Approximate priming volume		Length
	Authorized Representative in the European Community / European Union		Manufacturer
	Batch code		Manufacturing date
	Catalogue number		Country of manufacture
	Caution		MR unsafe
	CE mark		Non-pyrogenic
	Consult instructions for use		Quantity
	Medical device		Refer to instruction manual/booklet
	Does not contain DEHP		Serial number
	Does not contain or has presence of natural rubber latex		Single patient, multiple use
	Do not re-use		Single sterile barrier system
	Do not use if package is damaged and consult instructions for use		Sterilized by Ethylene Oxide
	Fluid path		Temperature limit
	GTIN number	RxOnly	To sale by or on the order of a physician
	Importer		Use-by date

VersaPump® Infusion System

Introduction

The VersaPump Infuser consists of an infusion pump and a carrying case and is designed to be used as a system with recommended components purchased separately. The VersaPump Infusion System provides a portable and effective way to subcutaneously infuse prescribed fluids.

Description

The VersaPump Infuser is a reusable mechanical infusion pump and does not require batteries or any electrical source. The pump utilizes a spring as a source of energy to continuously deliver fluids at controlled flow rates when used as a system with the following components:

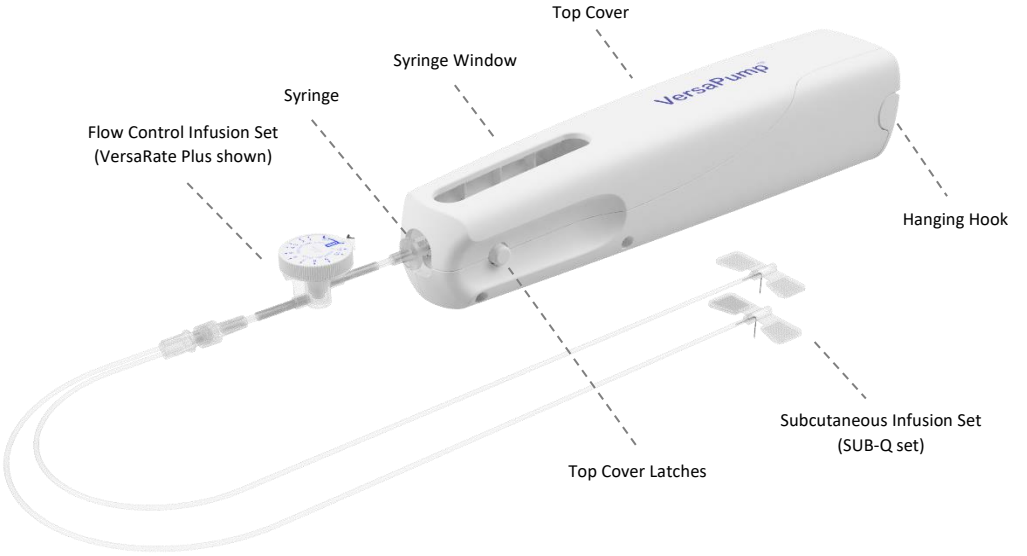
Component	Model Information
VersaPump Infuser with Carrying Case	FP-0010209
Syringe with Luer lock	20 mL BD syringe (302830) 20 mL Hizentra Prefilled Syringe (NDC 44206-458-96) 30 mL BD syringe (302832) 30 mL B. Braun syringe (4617304F) 35 mL Monoject syringe (1183500777 or 8881535762)
Flow Controller	Infuset® or VersaRate® Plus (See table below)
Subcutaneous Infusion Set (SUB-Q set)	OPTFlow®, SUB-, or SAF-Q set
AccuSert Needle Inserter	FP-0010033 (for OPTFlow infusion sets)

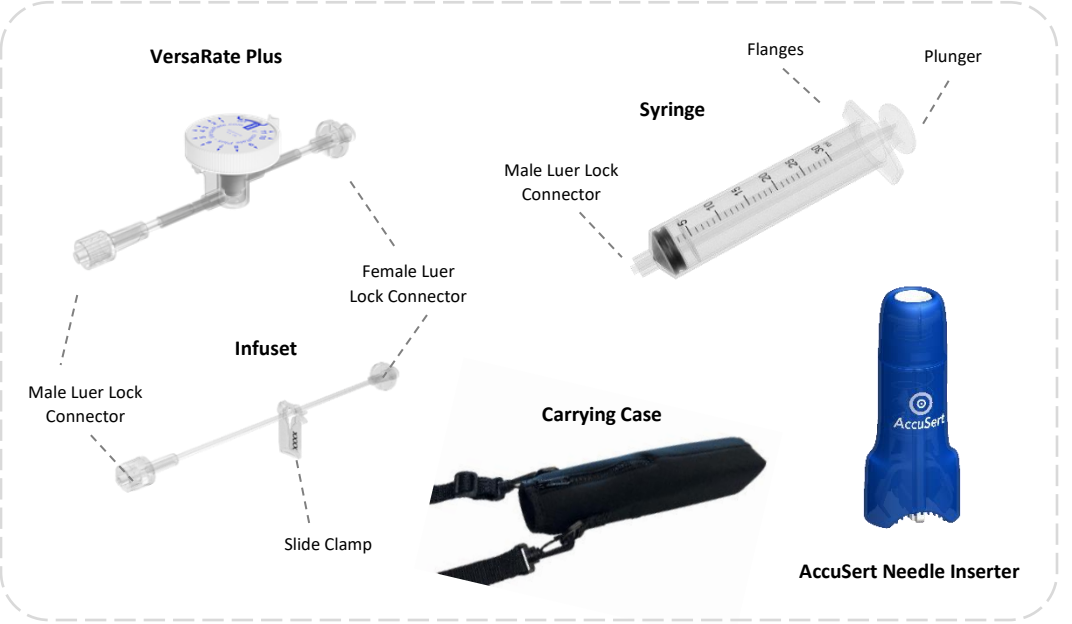
Syringes, flow controllers, subcutaneous infusion sets, and AccuSert needle inserters are sold separately. The syringe component is not manufactured by EMED and is available for purchase from the syringe manufacturer.

The flow control accessory regulates the fluid flow rate into the SUB-Q set. The flow control accessory should be selected based on the prescribing fluid's administration instructions, the prescribed fluid, the type of SUB-Q set being used, and patient factors. See section *How to choose a subcutaneous infusion set and flow controller* for additional information. The following flow controllers are available for use with the VersaPump Infusion System:

Description	Reorder Number
Infuset-45	FP-0010013
Infuset-80	FP-0010014
Infuset-120	FP-0010011
Infuset-190	FP-0010008
Infuset-290	FP-0010007
Infuset-430	FP-0010010
Infuset-650	FP-0010009
Infuset-820	FP-0010006
Infuset-930	FP-0010005
Infuset-1850	FP-0010004
Infuset-3200	FP-0010027
Infuset-4000	FP-0010028
Infuset-4300	FP-0010029
VersaRate Plus	FP-0010026

System Diagram





NOTE:	Images above are not representative of actual product sizes.

Indications for Use

The VersaPump Infusion System is intended for the subcutaneous infusion of indicated fluids for patients in the home or hospital environment when administered by an adult according to the indicated fluid's product labeling and with specified models of subcutaneous infusion sets, flow controllers, and syringes. The system is intended for single patient, multiple use only.

The VersaPump Infusion System is intended for adult and pediatric patients (2 years and older) that require subcutaneous infusion of fluid medication prescribed by a healthcare professional. The infusion system must be operated by an adult for use with pediatric patients.

The VersaPump Infusion System is indicated for the subcutaneous infusion of:

- 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%, manufactured by CSL Behring,
- Gamunex-C Immune Globulin Subcutaneous (Human) 10%, manufactured by Grifols Therapeutics
- Gammaked Immune Globulin Subcutaneous (Human) 10%, manufactured by Grifols Therapeutics
- Xembify Immune Globulin Subcutaneous (Human) 20%, manufactured by Grifols Therapeutics, and
- Cutaquig Immune Globulin (Human), 16.5%, manufactured by Octapharma AG.

Contraindications

Administration of indicated fluids is for subcutaneous infusion only. Infusion into other infusion sites, including blood vessels, should not be attempted.

Alarms

The VersaPump Infuser does NOT have alarms or indicators.

Limitations

The principle of operation of the VersaPump Infusion System is continuous infusion by applying a constant force to the syringe and regulating the fluid flow into the SUB-Q set using a flow controller. The system is passive and is therefore not able to compensate automatically for changes in environment or patient conditions. When using an Infuset flow controller, the rate is fixed and cannot be adjusted during infusion. When using a VersaRate Plus flow controller, the rate can be adjusted manually if needed. For more information, reference the *Factors that Affect Flow Rate* and *Troubleshooting* sections.

The VersaPump Infuser does not have any warning indications or alarms. The user or healthcare professional must always monitor the infusion progress and determine when the infusion is complete by verifying the remaining volume in the syringe.

Warnings and Precautions

Warnings:

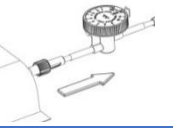
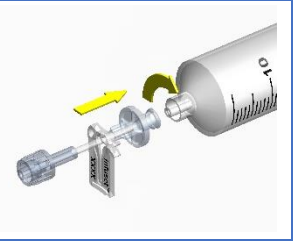
- Use the VersaPump Infusion System ONLY for its intended use and as prescribed by your healthcare professional.
- Read and follow all instructions for the VersaPump Infusion System and applicable components prior to use.
- Healthcare professionals and users should read the indicated fluid's contraindications, instructions, and warnings prior to initiating delivery of fluid.
- Pediatric patients should NOT use the VersaPump Infusion System without the aid of an adult.
- Use ONLY the listed SUB-Q sets, flow controllers, and syringes with the VersaPump Infusion System. Use of other infusion components may result in unsafe conditions for patient or deviation from desired infusion rates.
- Do NOT store the indicated fluid in the syringe prior to use. Prepare the VersaPump Infusion System and initiate therapy immediately after transferring indicated fluid to the syringe.
- Use aseptic technique when handling indicated fluids, syringes, flow controllers, and SUB-Q sets.
- Do NOT use flow controller, SUB-Q set, or syringe components more than once, as reuse may result in infection, cross contamination, or altered flow rate performance. Do NOT attempt to re-sterilize components, as doing so may cause serious personal injury.
- Do NOT use VersaPump Infusion System while undergoing medical diagnostic procedures, such as MRI, X-ray, or CT scans.
- Do NOT attempt to disassemble or tamper with the Infuser attempting to modify its function in any way other than its intended use. Serious injury may occur.

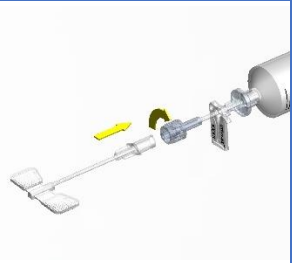
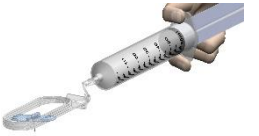
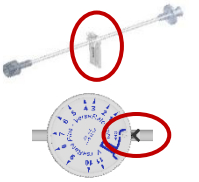
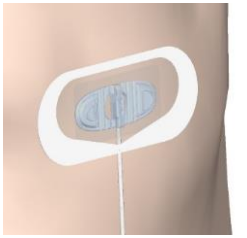
Cautions:

- U.S. Federal law restricts this device to sale by or on the order of a physician.
- Place the VersaPump infusion pump on a stable surface, or in the provided carrying case, or by using the rear hook.
- Avoid pinching the SUB-Q set or flow controller tubing.
- Syringe damage and fluid loss may occur if the VersaPump Infusion System is dropped while loaded.
- Do NOT continue to use a VersaPump Infuser that has been damaged, dropped, or if it has failed to perform as expected. If any damage is suspected, contact your healthcare professional.
- Avoid over tightening the Luer lock connections when attaching flow controllers to syringes and subcutaneous infusion sets to the flow controllers, as this may result in damage to the connectors.
- Do NOT subject the infuser to autoclaving or other similar methods of sterilization. Clean according to the instructions in the Maintenance section.
- Do NOT immerse the VersaPump infuser into fluid.
- Discontinue use of the VersaPump Infuser if it has been immersed or the internal mechanism has been exposed to fluid and cannot be cleaned, fails visual inspection, or shows signs of deterioration.
- Avoid exposing the VersaPump pump or carrying case to temperatures outside of recommended range of -5 to 40 °C (23 to 104 °F). See storage instructions in the Maintenance section.
- Using a combination of SUB-Q infusion set and Infuset or VersaRate Plus position not specified in the flow rate tables of this user manual may result in a flow rate outside of what has been approved for use.

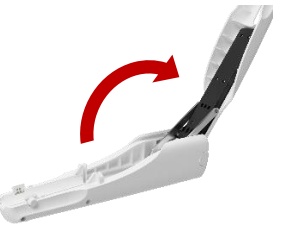
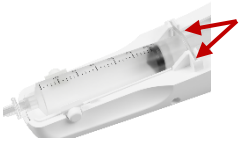
MR Safety Information

The VersaPump Infusion System is MR Unsafe.

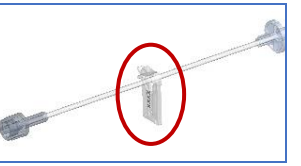
Step	Instruction	Image
	Prepare Infusion	
1	**WASH HANDS** thoroughly and dry before handling any supplies. Wear gloves if you have been instructed to do so. Disinfect the work surface. **WARNING**: Use aseptic technique throughout procedure.	
2	**VERIFY** you are using the correct flow controller, SUB-Q set, and syringe prescribed by your healthcare professional. **VERIFY** sterile component packaging is not damaged. **WARNING**: Read and follow all instructions for the indicated fluid and components prior to use.	
3	**REMOVE** flow controller, SUB-Q set and syringe from sterile packaging.	
4	For prefilled syringes, proceed to Step 5. For drugs in vials, **TRANSFER** indicated fluid from vial(s) to syringe according to the drug product labeling or as instructed by your healthcare professional. Immediately proceed to next step. **WARNING**: Do NOT store indicated fluid in the syringe prior to use. Follow the instructions of the indicated fluid.	
5	Remove sterile Luer lock caps from Infuset or VersaRate Plus using aseptic technique and **CONNECT** the syringe male Luer lock to Infuset or VersaRate Plus female Luer lock. **CAUTION**: Use aseptic technique and avoid over tightening the connection.	

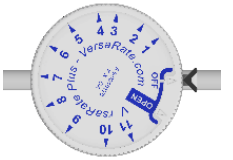
Step	Instruction	Image
6	Remove sterile Luer lock cap from the SUB-Q set using aseptic technique and **CONNECT** Infuset or VersaRate Plus male Luer lock to the SUB-Q set. **CAUTION**: Use aseptic technique and avoid over tightening the connection.	
7	**PRIME** the tubing by gently pushing on the syringe plunger to fill the tubing with fluid or as instructed by your healthcare professional.	
8	**CLOSE** flow controller. Use slide clamp provided with Infuset or select the 'OFF' position on the VersaRate Plus to prevent flow of fluid. **NOTE:** Failure to close the flow controller may lead to unintended start of infusion when top cover is closed (step 12).	
9	**PREPARE INJECTION SITES** by cleaning the skin with an alcohol swab as instructed by your healthcare professional. **REMOVE** the wing guards and needle guards from the SUB-Q set. **INSERT NEEDLES** according to the indicated medication package insert, specified SUB-Q set instructions, or as instructed by your healthcare professional. **OPTIONAL:** The AccuSert Needle Inserter can be used to insert the needles. **NOTE:** If instructed by your healthcare professional, before starting the infusion but after the needles are inserted, gently pull back on the plunger to make sure no blood is flowing back into the tubing. If blood is present, remove and discard the needle set.	 Optional:  Use AccuSert Needle Inserter

Load Pump

10	**OPEN** top cover fully. Place the pump on a stable surface. With one hand, hold the lower portion of the pump near the latches. Push both round buttons to release the top cover from the latches. With the other hand, grasp the top cover near the latches and pull firmly until the top cover is fully open. **NOTE:** A reasonable amount of effort is needed to open the top cover.	
11	**LOAD** syringe into pump with gradations pointing up. Ensure syringe flanges are horizontal and fully in the two slots.	
12	**CLOSE** top cover until latches are secured. An audible click should be heard as the top cover engages with the latches.	
13	**PLACE** the pump on a stable surface. Alternate placements (see images): • Use the carrying case accessory provided. The strap should be worn over or across the shoulder. • Use the hook at the rear of the product to hang the pump. Close hook when not in use. **CAUTION**: Avoid pinching SUB-Q set or flow controller tubing. Syringe damage and fluid loss may occur if the VersaPump Infusion System is dropped while loaded.	

Infusion

14	When using **Infuset**: a) To **START** infusion, release the **SLIDE CLAMP**, allowing fluid to flow. b) **MONITOR** infusion by viewing the syringe volume. c) To **STOP** infusion, **USE SLIDE CLAMP** as necessary during infusion session or when session is complete.	

	When Using **VersaRate Plus**: a) To **START** infusion, **TURN** dial to required flow position once pump is fully loaded and needles are inserted and secured. b) **MONITOR** infusion by viewing the syringe volume. c) To **STOP** infusion, **TURN to 'OFF'** position as necessary during infusion session or when session is complete.	

End of Infusion

15	When session is complete, **OPEN** the pump top cover and remove the syringe. **NOTE:** If the infusion protocol requires more than one syringe to be administered, repeat steps 3 – 15 in sequence. It is recommended to perform the infusions sequentially without a delay in time.	
16	**DISPOSE** of the syringe, flow controller, and SUB-Q set in an appropriate biohazard and/or sharps waste container according to your local regulations. **WARNING**: Read and follow all disposal instructions for the components.	
18	**CLEAN** and **STORE** pump and carrying case for next use. Instructions for cleaning and storage are described in the Maintenance section on the next page.	

Maintenance

The pump and carrying case are reusable parts of the infusion system and do not require any maintenance or calibration. Periodic cleaning of external surfaces is recommended.

Cleaning the infuser:

- External surfaces of the VersaPump Infuser may be cleaned with 70% isopropyl alcohol wipes or a soft cloth dampened with a weak solution of mild detergent and warm water (approximately 1 part detergent to 50 parts water by volume).
- Do not attempt to disassemble or clean any part of the VersaPump Infuser that is not easily accessible.
- Thoroughly clean exterior accessible surfaces by gently pressing onto the VersaPump Infuser and using circular motions with the alcohol wipe or damp cloth.
- Use a clean, dry cloth to dry the exposed and external portions of the device. Ensure that all areas are wiped until visibly clean.
- If needed, repeat the cleaning process until all areas are visibly clean and dry.
- Do not use heating devices to dry or expose infuser to high temperatures.
- If the device cannot be cleaned and fails the visual inspection (i.e. shows signs of deterioration such as corrosion, discoloration, cracks on plastic parts, illegible labels), safely dispose of the device.

Cleaning the carrying case:

- Only clean the surface with a clean damp cloth and let it air dry.
- Do not machine wash the carrying case as it could damage the materials.

CAUTION:	• Do NOT immerse the VersaPump infuser into fluid. • Discontinue use of the VersaPump Infuser if it has been immersed or the internal mechanism has been exposed to fluid and cannot be cleaned, fails visual inspection, or shows signs of deterioration. • Do not attempt to use an autoclave or dishwasher to clean or sterilize the VersaPump Infuser.

Storage

Store the pump and carrying case in a cool, dry place between the temperature range of -5 to 40 °C (23 to 104°F).

CAUTION:	Avoid exposing the pump or carrying case to temperatures outside of recommended range.

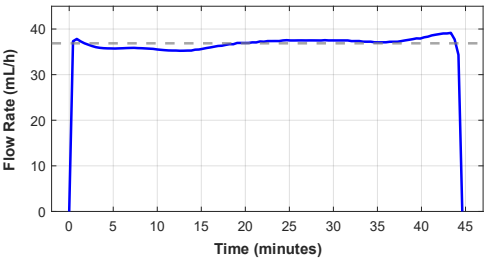
Disposal

The pump and carrying case should be disposed of in general waste collection and not disassembled prior to disposal. Please ensure compliance with local regulations.

The subcutaneous infusion set, flow controller, and syringe are single use only and should be disposed of in an appropriate biohazard and/or sharps waste container according to local and federal regulations.

WARNING:	• Safely dispose of the single-use components according to their instructions for use. • Do NOT attempt to disassemble or tamper with the Infuser attempting to modify its function in any way other than its intended use. Serious injury may occur.

Specifications

Compatible Syringe Models	**20 mL** BD syringe (302830) **20 mL** Hizentra Prefilled Syringe (NDC 44206-458-96) **30 mL** BD syringe (302832) **30 mL** B. Braun syringe (4617304F) **35 mL** Monoject syringe (1183500777 or 8881535762)
Infuser Mass (empty)	500 grams (1.1 lb)
Infuser Spring Force	36 N (8 lbf)
System Flow Rate Accuracy	Using **Infuset** and SUB-Q set: ± 30% Using **VersaRate Plus** and SUB-Q set: At settings 5 through OPEN: Up to ± 30% At settings 3 or 4: Up to ± 40% At settings 1 or 2: Not recommended. (Percent difference from the nominal flow rates listed)
Allowed Vertical Difference	± 30 cm (± 12 in) between Infuser and infusion site.
Flow Rate Vertical Sensitivity	Each 30 cm (12 in) **above** infusion site, up to 5% **increase** in flow rate. Each 30 cm (12 in) **below** infusion site, up to 5% **decrease** in flow rate.
Residual Volume	System residual volume depends on the combination of selected component residuals: Syringe: ≈ 0.2 mL in Luer tip, Flow Controller: 0.05 – 0.25 mL depending on model, SUB-Q set: 0.18 – 1.87 mL depending on model. See individual component information for specific residual values.
Infuser Useful Life	2,000 Cycles
Target Operating Temperature	Room temperature, 20 – 25 °C (68 – 77 °F)
Storage Temperature	- 5 to 40 °C (23 – 104 °F)
Alarms	None.
Noise	No audible noise during infusion.
Representative Flow Profile	 The figure shows the flow rate vs. time at 20°C – 25°C under laboratory conditions using BD 30 mL syringe filled with water, OPT12609, and Infuset-45. The mean flow rate was 37 mL/h. Although realized flow rates are determined by the combination of fluid type, syringe model, flow controller and SUB-Q set used, the flow rate profile remains the same due to the principle of action of the VersaPump Infusion System.

Factors that Affect Flow Rate

System flow rate can be affected by various environmental factors, patient factors, and infusion equipment used. The following table shows some of the factors that influence the flow rate. The compounded effect of these variables should be considered during use of the VersaPump Infuser and selection of the appropriate Infuset or VersaRate Plus accessories.

Factors That Affect Flow Rate:		
LARGE EFFECT	Flow Controller	The flow controller model and/or setting has a significant effect on flow rate. The flow controller model and/or setting should be selected from the flow rate tables provided in this manual.
	Subcutaneous Infusion Sets and Needle Gauge	The effect of the subcutaneous infusion set and needle size depend on the dimensions of the fluid path. Appropriate subcutaneous infusion set and needle gauge should be selected for specific clinical requirements, then the appropriate flow controller should be selected to achieve the desired flow rate.
	Ambient and Fluid Temperatures	Temperature of the fluid has a significant effect on drug viscosity, and therefore has a significant effect on flow rate. Ambient temperature may affect the fluid temperature given time to equilibrate. The system flow rate will change approximately 1 to 1.5% for each degree Fahrenheit temperature change of the fluid. Optimal operating temperate is between 20 – 25 °C (68 – 77 °F).
MODERATE EFFECT	Syringe Model	Different syringe models have different barrel diameter sizes. This results in different fluid pressure within the syringe thus has a moderate effect on flow rate. The flow controller model and/or setting should be selected from the flow rate tables based on the specific syringe model used.
	Patient Factors	• Tissue back pressure • Type of tissue and the absorption rate • Location of infusion site • Body Mass Index • Age • Health
SMALL EFFECT	Infuser Relative Height	Difference in relative height between the infuser and the infusion site has a minimal effect on flow rate.

How to determine approximate flow rate during infusion:

1. Record the starting volume and time.
2. Wait an appropriate amount of time for volume to infuse (Examples: 10 minutes or after 5 mL infused).
3. Record the elapsed volume in mL and elapsed time in minutes.
4. Calculate flow rate using the equation:

$$\text{Flow Rate [mL/h]} = \frac{\text{Volume [mL]}}{\text{Time [minutes]}} \times 60$$

How to determine per site flow rate:

$$\text{Flow Rate Per Site [mL/h/site]} = \frac{\text{Total Flow Rate [mL/h]}}{\text{Number of Needles}}$$

How to choose a subcutaneous infusion set and flow controller:

Visit **www.versarate.com** website for an electronic version of the flow rate information.

In the following pages you will find tables that can be used to identify the combination of the EMED subcutaneous infusion set and the Infuset model or VersaRate Plus position that will provide a flow rate that may accommodate the patient's need for infusion while falling within drug manufacturer's prescribing limits. Flow rate information for use with the Infuset and VersaRate Plus will be presented separately for each of the indicated fluids that are to be used with the VersaPump Infusion System. In the case of Hizentra, separate flow rate tables have been included for patients infusing for the treatment of Primary Immunodeficiency (PI) or Chronic Inflammatory Demyelinating Polyneuropathy (CIDP).

The flow rate values presented in the following tables are based on bench testing in a lab environment and controlled temperature range of 20 – 25 °C (68 – 77 °F) without the effect of the patient. It is important to understand that flow rates of infused immunoglobulin fluids can be affected by multiple factors. See previous section *Factors that Affect Flow Rate* for additional information.

To choose a system combination, first find the correct table according to the drug type and flow controller model. Select the table row that contains the needle gauge, SUB-Q set model, needle length, number of needle sites, and flow rate that best meets therapeutic needs and/or patient preferences.

Total flow rate values are presented in the following tables. Flow rate per site can be determined by dividing the total flow rate by the number of needle sites.

CAUTION:	Using a combination of SUB-Q infusion set and Infuset or VersaRate Plus position not specified in the tables on the following pages may result in a flow rate outside of what has been approved for use.

NOTE:	Please contact EMED Technologies at +1-916-932-0071 for additional information regarding selection of flow controllers with SUB-Q sets to obtain a desired flow rate.

Infusing Cutaquig

Tables 1a, 1b, and 2 show expected total flow rates for infusing Cutaquig using various combinations of subcutaneous infusion sets, flow controllers, and syringe models. Cells shaded in white are suitable for initial and maintenance infusions. Cells shaded in yellow are only suitable for maintenance infusions. Cells shaded in gray do not have values listed because testing has not been performed or the value may exceed the prescribing information flow rate limits.

Table Legend:

	Suitable for initial and maintenance infusions (Aged 2-16 years: up to 15 mL/h/site; Aged ≥ 17 years: up to 20 mL/h/site)
	Suitable for maintenance infusions only (Aged 2-16 years: up to 25 mL/h/site; Aged ≥ 17 years: up to 52 mL/h/site)
	No data available or may exceed prescribing information flow rate limits

Table 1a	Drug	Patient Information	Flow Controller
	Cutaquig	Patients aged 2-16 years	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller												
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
BD 30 (302832)	26G	OPT12604	4	1			8	15									
		OPT12606	6	1			8	15									
		OPT12609	9	1			8	15									
		OPT12612	12	1			8	15									
		OPT12614	14	1			8	15									
		OPT22604	4	2				17	23	37							
		OPT22606	6	2				17	23	37							
		OPT22609	9	2				17	23	37							
		OPT22612	12	2				17	23	37							
		OPT22614	14	2				17	23	37							
		OPT32606	6	3					24	39	53						
		OPT32609	9	3					24	39	53						
		OPT32612	12	3					24	39	53						
		OPT32614	14	3					24	39	53						
		OPT42606	6	4						40	56						
		OPT42609	9	4						40	56						
		OPT42612	12	4						40	56						
		OPT42614	14	4						40	56						
		OPT52606	6	5						41	57	79	83				
		OPT52609	9	5						41	57	79	83				
		OPT52612	12	5						41	57	79	83				
		OPT62609	9	6							58	81	86				
		OPT62612	12	6							58	81	86				
	27G	SAF-Q-109-G27	9	1				12	14								

Table 1a	Drug	Patient Information	Flow Controller
	Cutaquig	Patients aged 2-16 years	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller												
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
BD 20 (302830)	26G	OPT12604	4	1			10										
		OPT12606	6	1			10										
		OPT12609	9	1			10										
		OPT12612	12	1			10										
		OPT12614	14	1			10										
		OPT22604	4	2				21	29								
		OPT22606	6	2				21	29								
		OPT22609	9	2				21	29								
		OPT22612	12	2				21	29								
		OPT22614	14	2				21	29								
		OPT32606	6	3					30	49							
		OPT32609	9	3					30	49							
		OPT32612	12	3					30	49							
		OPT32614	14	3					30	49							
		OPT42606	6	4						51	72						
		OPT42609	9	4						51	72						
		OPT42612	12	4						51	72						
		OPT42614	14	4						51	72						
		OPT52606	6	5						52	73						
		OPT52609	9	5						52	73						
		OPT52612	12	5						52	73						
		OPT62609	9	6						53	75	104	110				
		OPT62612	12	6						53	75	104	110				
	27G	SAF-Q-109-G27	9	1			9	15	18								
B.Braun 30 (4617304F)	26G	OPT12604	4	1			8	15									
		OPT12606	6	1			8	15									
		OPT12609	9	1			8	15									
		OPT12612	12	1			8	15									
		OPT12614	14	1			8	15									
		OPT22604	4	2				16	22	36							
		OPT22606	6	2				16	22	36							
		OPT22609	9	2				16	22	36							
		OPT22612	12	2				16	22	36							
		OPT22614	14	2				16	22	36							
		OPT32606	6	3						38	52						
		OPT32609	9	3						38	52						
		OPT32612	12	3						38	52						
		OPT32614	14	3						38	52						
		OPT42606	6	4						39	55						

Table 1a	Drug	Patient Information	Flow Controller
	Cutaquig	Patients aged 2-16 years	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller												
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
		OPT42609	9	4						39	55						
		OPT42612	12	4						39	55						
		OPT42614	14	4						39	55						
		OPT52606	6	5						40	56	77	81				
		OPT52609	9	5						40	56	77	81				
		OPT52612	12	5						40	56	77	81				
		OPT62609	9	6							57	79	84				
		OPT62612	12	6							57	79	84				
	27G	SAF-Q-109-G27	9	1				11	14	18							
Monoject 35 (1183500777 or 8881535762)		OPT12604	4	1				12	16								
		OPT12606	6	1				12	16								
		OPT12609	9	1				12	16								
		OPT12612	12	1				12	16								
		OPT12614	14	1				12	16								
		OPT22604	4	2					18	28							
		OPT22606	6	2					18	28							
		OPT22609	9	2					18	28							
		OPT22612	12	2					18	28							
		OPT22614	14	2					18	28							
		OPT32606	6	3						30	41	55					
	26G	OPT32609	9	3						30	41	55					
		OPT32612	12	3						30	41	55					
		OPT32614	14	3						30	41	55					
		OPT42606	6	4							43	59	62				
		OPT42609	9	4							43	59	62				
		OPT42612	12	4							43	59	62				
		OPT42614	14	4							43	59	62				
		OPT52606	6	5							44	61	64				
		OPT52609	9	5							44	61	64				
		OPT52612	12	5							44	61	64				
		OPT62609	9	6								63	66				
		OPT62612	12	6								63	66				
	27G	SAF-Q-109-G27	9	1				9	11	14	17						

Table 1b	Drug	Patient Information	Flow Controller
	Cutaquig	Patients aged 17 years or older	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller											
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
BD 30 (302832)	26G	OPT12604	4	1			8	15	20	31							
		OPT12606	6	1			8	15	20	31							
		OPT12609	9	1			8	15	20	31							
		OPT12612	12	1			8	15	20	31							
		OPT12614	14	1			8	15	20	31							
		OPT22604	4	2				17	23	37	50	65	68				
		OPT22606	6	2				17	23	37	50	65	68				
		OPT22609	9	2				17	23	37	50	65	68				
		OPT22612	12	2				17	23	37	50	65	68				
		OPT22614	14	2				17	23	37	50	65	68				
		OPT32606	6	3					24	39	53	71	75				
		OPT32609	9	3					24	39	53	71	75				
		OPT32612	12	3					24	39	53	71	75				
		OPT32614	14	3					24	39	53	71	75				
		OPT42606	6	4						40	56	77	81				
		OPT42609	9	4						40	56	77	81				
		OPT42612	12	4						40	56	77	81				
		OPT42614	14	4						40	56	77	81				
		OPT52606	6	5						41	57	79	83				
		OPT52609	9	5						41	57	79	83				
		OPT52612	12	5						41	57	79	83				
		OPT62609	9	6							58	81	86				
		OPT62612	12	6							58	81	86				
	27G	SAF-Q-109-G27	9	1				12	14	19	22	24	24	30	31	31	31
BD 20 (302830)	26G	OPT12604	4	1			10	20	26								
		OPT12606	6	1			10	20	26								
		OPT12609	9	1			10	20	26								
		OPT12612	12	1			10	20	26								
		OPT12614	14	1			10	20	26								
		OPT22604	4	2				21	29	47	63						
		OPT22606	6	2				21	29	47	63						
		OPT22609	9	2				21	29	47	63						
		OPT22612	12	2				21	29	47	63						
		OPT22614	14	2				21	29	47	63						
		OPT32606	6	3					30	49	68	91	96				
		OPT32609	9	3					30	49	68	91	96				

Table 1b	Drug	Patient Information	Flow Controller
	Cutaquig	Patients aged 17 years or older	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller											
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
		OPT32612	12	3					30	49	68	91	96				
		OPT32614	14	3					30	49	68	91	96				
		OPT42606	6	4						51	72	98	103				
		OPT42609	9	4						51	72	98	103				
		OPT42612	12	4						51	72	98	103				
		OPT42614	14	4						51	72	98	103				
		OPT52606	6	5						52	73	101	106				
		OPT52609	9	5						52	73	101	106				
		OPT52612	12	5						52	73	101	106				
		OPT62609	9	6						53	75	104	110				
		OPT62612	12	6						53	75	104	110				
	27G	SAF-Q-109-G27	9	1			9	15	18	24	28	31	31	38			
B.Braun 30 (4617304F)		OPT12604	4	1			8	15	20	30	38						
		OPT12606	6	1			8	15	20	30	38						
		OPT12609	9	1			8	15	20	30	38						
		OPT12612	12	1			8	15	20	30	38						
		OPT12614	14	1			8	15	20	30	38						
		OPT22604	4	2				16	22	36	48	63	66				
		OPT22606	6	2				16	22	36	48	63	66				
		OPT22609	9	2				16	22	36	48	63	66				
		OPT22612	12	2				16	22	36	48	63	66				
		OPT22614	14	2				16	22	36	48	63	66				
		OPT32606	6	3						38	52	70	73				
	26G	OPT32609	9	3						38	52	70	73				
		OPT32612	12	3						38	52	70	73				
		OPT32614	14	3						38	52	70	73				
		OPT42606	6	4						39	55	75	79				
		OPT42609	9	4						39	55	75	79				
		OPT42612	12	4						39	55	75	79				
		OPT42614	14	4						39	55	75	79				
		OPT52606	6	5						40	56	77	81				
		OPT52609	9	5						40	56	77	81				
		OPT52612	12	5						40	56	77	81				
		OPT62609	9	6							57	79	84				
		OPT62612	12	6							57	79	84				
	27G	SAF-Q-109-G27	9	1				11	14	18	21	23	24	29	30	31	31

Table 1b	Drug	Patient Information	Flow Controller
	Cutaquig	Patients aged 17 years or older	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller											
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
Monoject 35 (1183500777 or 8881535762)	26G	OPT12604	4	1				12	16	24	30	37	38				
		OPT12606	6	1				12	16	24	30	37	38				
		OPT12609	9	1				12	16	24	30	37	38				
		OPT12612	12	1				12	16	24	30	37	38				
		OPT12614	14	1				12	16	24	30	37	38				
		OPT22604	4	2					18	28	38	50	52				
		OPT22606	6	2					18	28	38	50	52				
		OPT22609	9	2					18	28	38	50	52				
		OPT22612	12	2					18	28	38	50	52				
		OPT22614	14	2					18	28	38	50	52				
		OPT32606	6	3						30	41	55	58				
		OPT32609	9	3						30	41	55	58				
		OPT32612	12	3						30	41	55	58				
		OPT32614	14	3						30	41	55	58				
		OPT42606	6	4							43	59	62				
		OPT42609	9	4							43	59	62				
		OPT42612	12	4							43	59	62				
		OPT42614	14	4							43	59	62				
		OPT52606	6	5							44	61	64	182			
		OPT52609	9	5							44	61	64	182			
		OPT52612	12	5							44	61	64	182			
		OPT62609	9	6								63	66	200			
		OPT62612	12	6								63	66	200			
	27G	SAF-Q-109-G27	9	1				9	11	14	17	19	19	23	24	24	24

The majority of system configurations for Cutaquig with VersaRate Plus with worst-case tolerances considered exceed the Cutaquig administration requirements for patients aged 2 to 16 years. Therefore, no VersaRate Plus table is shown for patients aged 2 to 16 years, and Table 1a for Infuset should be used.

Table 2	Drug	Patient Information	Flow Controller
	Cutaquig	Patients aged 17 years or older	VersaRate Plus

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per VersaRate Plus position setting											
	Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
BD 30 (302832)	26G	OPT12604	4	1												
		OPT12606	6	1												
		OPT12609	9	1												
		OPT12612	12	1												
		OPT12614	14	1												
		OPT22604	4	2			64									
		OPT22606	6	2			64									
		OPT22609	9	2			64									
		OPT22612	12	2			64									
		OPT22614	14	2			64									
		OPT32606	6	3			70	86								
		OPT32609	9	3			70	86								
		OPT32612	12	3			70	86								
		OPT32614	14	3			70	86								
		OPT42606	6	4			75	94	150							
		OPT42609	9	4			75	94	150							
		OPT42612	12	4			75	94	150							
		OPT42614	14	4			75	94	150							
		OPT52606	6	5			77	97	158	192						
		OPT52609	9	5			77	97	158	192						
		OPT52612	12	5			77	97	158	192						
		OPT62609	9	6			79	101	168	207						
		OPT62612	12	6			79	101	168	207						
	27G	SAF-Q-109-G27	9	1			24	25	28	29	30	30	31	31	31	32
BD 20 (302830)	26G	OPT12604	4	1												
		OPT12606	6	1												
		OPT12609	9	1												
		OPT12612	12	1												
		OPT12614	14	1												
		OPT22604	4	2												
		OPT22606	6	2												
		OPT22609	9	2												
		OPT22612	12	2												

Table 2	Drug	Patient Information	Flow Controller
	Cutaquig	Patients aged 17 years or older	VersaRate Plus

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per VersaRate Plus position setting											
	Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
		OPT22614	14	2												
		OPT32606	6	3			89									
		OPT32609	9	3			89									
		OPT32612	12	3			89									
		OPT32614	14	3			89									
		OPT42606	6	4			96	120								
		OPT42609	9	4			96	120								
		OPT42612	12	4			96	120								
		OPT42614	14	4			96	120								
		OPT52606	6	5			98	124								
		OPT52609	9	5			98	124								
		OPT52612	12	5			98	124								
		OPT62609	9	6			101	129	215							
		OPT62612	12	6			101	129	215							
	27G	SAF-Q-109-G27	9	1			30	33	36	37						
B.Braun 30 (4617304F)		OPT12604	4	1												
		OPT12606	6	1												
		OPT12609	9	1												
		OPT12612	12	1												
		OPT12614	14	1												
		OPT22604	4	2			62									
		OPT22606	6	2			62									
		OPT22609	9	2			62									
		OPT22612	12	2			62									
		OPT22614	14	2			62									
		OPT32606	6	3			68	84								
	26G	OPT32609	9	3			68	84								
		OPT32612	12	3			68	84								
		OPT32614	14	3			68	84								
		OPT42606	6	4			73	92	147							
		OPT42609	9	4			73	92	147							
		OPT42612	12	4			73	92	147							
		OPT42614	14	4			73	92	147							
		OPT52606	6	5			75	95	155	188						
		OPT52609	9	5			75	95	155	188						
		OPT52612	12	5			75	95	155	188						
		OPT62609	9	6			77	98	164	202						
		OPT62612	12	6			77	98	164	202						
	27G	SAF-Q-109-G27	9	1			23	25	28	29	29	30	30	30	30	31

Table 2	Drug	Patient Information	Flow Controller
	Cutaquig	Patients aged 17 years or older	VersaRate Plus

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per VersaRate Plus position setting											
	Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
Monoject 35 (1183500777 or 8881535762)	26G	OPT12604	4	1												
		OPT12606	6	1												
		OPT12609	9	1												
		OPT12612	12	1												
		OPT12614	14	1												
		OPT22604	4	2			49	59								
		OPT22606	6	2			49	59								
		OPT22609	9	2			49	59								
		OPT22612	12	2			49	59								
		OPT22614	14	2			49	59								
		OPT32606	6	3			54	67	101							
		OPT32609	9	3			54	67	101							
		OPT32612	12	3			54	67	101							
		OPT32614	14	3			54	67	101							
		OPT42606	6	4			58	73	116	140						
		OPT42609	9	4			58	73	116	140						
		OPT42612	12	4			58	73	116	140						
		OPT42614	14	4			58	73	116	140						
		OPT52606	6	5			60	75	123	149	188					
		OPT52609	9	5			60	75	123	149	188					
		OPT52612	12	5			60	75	123	149	188					
		OPT62609	9	6			61	78	130	160	207	226				
		OPT62612	12	6			61	78	130	160	207	226				
	27G	SAF-Q-109-G27	9	1			18	20	22	23	23	24	24	24	24	25

Infusing Cuvitru

Tables 3 and 4 show expected total flow rates for infusing Cuvitru using various combinations of subcutaneous infusion sets, flow controllers, and syringe models. Cells shaded in white are suitable for initial and maintenance infusions. Cells shaded in yellow are only suitable for maintenance infusions. Cells shaded in gray do not have values listed because testing has not been performed or the value may exceed the prescribing information flow rate limits.

Table Legend:

	Suitable for initial and maintenance infusions (up to 20 mL/h/site or 80 ml/h total)
	Suitable for maintenance infusions only (up to 60 mL/h/site or 240 ml/h total)
	No data available or may exceed prescribing information flow rate limits

Table 3	Drug	Flow Controller
	Cuvitru	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller												
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
BD 30 (302832)	26G	OPT12604	4	1				8	11	17	21	26	27	44			
		OPT12606	6	1				8	11	17	21	26	27	44			
		OPT12609	9	1				8	11	17	21	26	27	44			
		OPT12612	12	1				8	11	17	21	26	27	44			
		OPT12614	14	1				8	11	17	21	26	27	44			
		OPT22604	4	2						20	27	36	37	79			
		OPT22606	6	2						20	27	36	37	79			
		OPT22609	9	2						20	27	36	37	79			
		OPT22612	12	2						20	27	36	37	79			
		OPT22614	14	2						20	27	36	37	79			
		OPT32606	6	3							29	39	41	99	115	131	132
		OPT32609	9	3							29	39	41	99	115	131	132
		OPT32612	12	3							29	39	41	99	115	131	132
		OPT32614	14	3							29	39	41	99	115	131	132
		OPT42606	6	4								42	44	120	144	170	173
		OPT42609	9	4								42	44	120	144	170	173
		OPT42612	12	4								42	44	120	144	170	173
		OPT42614	14	4								42	44	120	144	170	173
	27G	SAF-Q-109-G27	9	1					8	10	12	13	13	17	17	17	17
BD 20 (302830)	26G	OPT12604	4	1				11	14	22	27	34	35				
		OPT12606	6	1				11	14	22	27	34	35				
		OPT12609	9	1				11	14	22	27	34	35				
		OPT12612	12	1				11	14	22	27	34	35				

Table 3	Drug	Flow Controller
	Cuvitru	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller											
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
		OPT12614	14	1				11	14	22	27	34	35				
		OPT22604	4	2					16	26	35	46	48				
		OPT22606	6	2					16	26	35	46	48				
		OPT22609	9	2					16	26	35	46	48				
		OPT22612	12	2					16	26	35	46	48				
		OPT22614	14	2					16	26	35	46	48				
		OPT32606	6	3						27	38	50	53	127			
		OPT32609	9	3						27	38	50	53	127			
		OPT32612	12	3						27	38	50	53	127			
		OPT32614	14	3						27	38	50	53	127			
		OPT42606	6	4							40	54	57	154			
		OPT42609	9	4							40	54	57	154			
		OPT42612	12	4							40	54	57	154			
		OPT42614	14	4							40	54	57	154			
	27G	SAF-Q-109-G27	9	1				8	10	13	15	17	17	21	22	22	22
B.Braun 30 (4617304F)		OPT12604	4	1				8	11	16	21	26	27	43			
		OPT12606	6	1				8	11	16	21	26	27	43			
		OPT12609	9	1				8	11	16	21	26	27	43			
		OPT12612	12	1				8	11	16	21	26	27	43			
		OPT12614	14	1				8	11	16	21	26	27	43			
		OPT22604	4	2						20	27	35	36	77	87		
		OPT22606	6	2						20	27	35	36	77	87		
		OPT22609	9	2						20	27	35	36	77	87		
		OPT22612	12	2						20	27	35	36	77	87		
	26G	OPT22614	14	2						20	27	35	36	77	87		
		OPT32606	6	3							29	38	40	97	112	128	129
		OPT32609	9	3							29	38	40	97	112	128	129
		OPT32612	12	3							29	38	40	97	112	128	129
		OPT32614	14	3							29	38	40	97	112	128	129
		OPT42606	6	4								41	43	117	141	166	169
		OPT42609	9	4								41	43	117	141	166	169
		OPT42612	12	4								41	43	117	141	166	169
		OPT42614	14	4								41	43	117	141	166	169
	27G	SAF-Q-109-G27	9	1					8	10	12	13	13	16	17	17	17

Table 3	Drug	Flow Controller
	Cuvitru	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller											
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
Monoject 35 (1183500777 or 8881535762)	26G	OPT12604	4	1					9	13	17	20	21	34	36	38	38
		OPT12606	6	1					9	13	17	20	21	34	36	38	38
		OPT12609	9	1					9	13	17	20	21	34	36	38	38
		OPT12612	12	1					9	13	17	20	21	34	36	38	38
		OPT12614	14	1					9	13	17	20	21	34	36	38	38
		OPT22604	4	2						16	21	28	29	61	69	76	76
		OPT22606	6	2						16	21	28	29	61	69	76	76
		OPT22609	9	2						16	21	28	29	61	69	76	76
		OPT22612	12	2						16	21	28	29	61	69	76	76
		OPT22614	14	2						16	21	28	29	61	69	76	76
		OPT32606	6	3								30	32	77	89	101	102
		OPT32609	9	3								30	32	77	89	101	102
		OPT32612	12	3								30	32	77	89	101	102
		OPT32614	14	3								30	32	77	89	101	102
		OPT42606	6	4								33	34	93	112	132	133
		OPT42609	9	4								33	34	93	112	132	133
		OPT42612	12	4								33	34	93	112	132	133
		OPT42614	14	4								33	34	93	112	132	133
	27G	SAF-Q-109-G27	9	1						8	9	10	10	13	13	13	13

Table 4	Drug	Flow Controller
	Cuvitru	VersaRate Plus

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per VersaRate Plus position setting											
	Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
BD 30 (302832)	26G	OPT12604	4	1			26	30	38	41						
		OPT12606	6	1			26	30	38	41						
		OPT12609	9	1			26	30	38	41						
		OPT12612	12	1			26	30	38	41						
		OPT12614	14	1			26	30	38	41						
		OPT22604	4	2			35	42	61	69	81	84	87			
		OPT22606	6	2			35	42	61	69	81	84	87			
		OPT22609	9	2			35	42	61	69	81	84	87			
		OPT22612	12	2			35	42	61	69	81	84	87			
		OPT22614	14	2			35	42	61	69	81	84	87			
		OPT32606	6	3			38	47	72	84	101	108	112	119	124	
		OPT32609	9	3			38	47	72	84	101	108	112	119	124	
		OPT32612	12	3			38	47	72	84	101	108	112	119	124	
		OPT32614	14	3			38	47	72	84	101	108	112	119	124	
		OPT42606	6	4			41	52	83	99	124	133	140	151	160	
		OPT42609	9	4			41	52	83	99	124	133	140	151	160	
		OPT42612	12	4			41	52	83	99	124	133	140	151	160	
		OPT42614	14	4			41	52	83	99	124	133	140	151	160	
	27G	SAF-Q-109-G27	9	1			13	14	16	16	17	17	17	17	17	17
BD 20 (302830)	26G	OPT12604	4	1			33	38								
		OPT12606	6	1			33	38								
		OPT12609	9	1			33	38								
		OPT12612	12	1			33	38								
		OPT12614	14	1			33	38								
		OPT22604	4	2			45	54	78							
		OPT22606	6	2			45	54	78							
		OPT22609	9	2			45	54	78							
		OPT22612	12	2			45	54	78							
		OPT22614	14	2			45	54	78							
		OPT32606	6	3			49	61	92	108	130					
		OPT32609	9	3			49	61	92	108	130					
		OPT32612	12	3			49	61	92	108	130					
		OPT32614	14	3			49	61	92	108	130					
		OPT42606	6	4			53	66	106	127	158	170				
		OPT42609	9	4			53	66	106	127	158	170				
		OPT42612	12	4			53	66	106	127	158	170				
		OPT42614	14	4			53	66	106	127	158	170				
	27G	SAF-Q-109-G27	9	1			17	18	20	21	21	21	22	22	22	22

Table 4	Drug	Flow Controller
	Cuvitru	VersaRate Plus

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per VersaRate Plus position setting											
	Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
B.Braun 30 (4617304F)	26G	OPT12604	4	1			25	29	37	40	44					
		OPT12606	6	1			25	29	37	40	44					
		OPT12609	9	1			25	29	37	40	44					
		OPT12612	12	1			25	29	37	40	44					
		OPT12614	14	1			25	29	37	40	44					
		OPT22604	4	2			34	41	60	68	79	82	85			
		OPT22606	6	2			34	41	60	68	79	82	85			
		OPT22609	9	2			34	41	60	68	79	82	85			
		OPT22612	12	2			34	41	60	68	79	82	85			
		OPT22614	14	2			34	41	60	68	79	82	85			
		OPT32606	6	3			38	46	71	83	99	105	110	116	122	
		OPT32609	9	3			38	46	71	83	99	105	110	116	122	
		OPT32612	12	3			38	46	71	83	99	105	110	116	122	
		OPT32614	14	3			38	46	71	83	99	105	110	116	122	
		OPT42606	6	4			40	51	81	97	121	130	137	147	156	
		OPT42609	9	4			40	51	81	97	121	130	137	147	156	
		OPT42612	12	4			40	51	81	97	121	130	137	147	156	
		OPT42614	14	4			40	51	81	97	121	130	137	147	156	
	27G	SAF-Q-109-G27	9	1			13	14	15	16	16	16	17	17	17	17
Monoject 35 (1183500777 or 8881535762)	26G	OPT12604	4	1			20	23	29	32	35	35	36	37	38	40
		OPT12606	6	1			20	23	29	32	35	35	36	37	38	40
		OPT12609	9	1			20	23	29	32	35	35	36	37	38	40
		OPT12612	12	1			20	23	29	32	35	35	36	37	38	40
		OPT12614	14	1			20	23	29	32	35	35	36	37	38	40
		OPT22604	4	2			27	33	47	54	62	65	67	70	73	82
		OPT22606	6	2			27	33	47	54	62	65	67	70	73	82
		OPT22609	9	2			27	33	47	54	62	65	67	70	73	82
		OPT22612	12	2			27	33	47	54	62	65	67	70	73	82
		OPT22614	14	2			27	33	47	54	62	65	67	70	73	82
		OPT32606	6	3			30	37	56	65	78	83	87	92	96	113
		OPT32609	9	3			30	37	56	65	78	83	87	92	96	113
		OPT32612	12	3			30	37	56	65	78	83	87	92	96	113
		OPT32614	14	3			30	37	56	65	78	83	87	92	96	113
		OPT42606	6	4			32	40	64	77	96	103	108	116	124	153
		OPT42609	9	4			32	40	64	77	96	103	108	116	124	153
		OPT42612	12	4			32	40	64	77	96	103	108	116	124	153
		OPT42614	14	4			32	40	64	77	96	103	108	116	124	153
	27G	SAF-Q-109-G27	9	1			10	11	12	12	13	13	13	13	13	14

Infusing Gammagard

Tables 5a and 5b show expected total flow rates for infusing Gammagard using various combinations of subcutaneous infusion sets, flow controllers, and syringe models. Cells shaded in white are suitable for initial and maintenance infusions. Cells shaded in yellow are only suitable for maintenance infusions. Cells shaded in gray do not have values listed because testing has not been performed or the value may exceed the prescribing information flow rate limits.

Table Legend:

	Suitable for initial and maintenance infusions (Under 40 kg (88 lb) body weight: up to 15 mL/h/site; 40 kg (88 lb) and greater: up to 20 mL/h/site)
	Suitable for maintenance infusions only (Under 40 kg (88 lb) body weight: up to 20 mL/h/site; 40 kg (88 lb) and greater: up to 30 mL/h/site)
	No data available or may exceed prescribing information flow rate limits

Table 5a	Drug	Patient Information	Flow Controller
	Gammagard	**Patients under 40 kg (88 lb)**	**Infuset**

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller												
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
BD 30 (302832)	26G	OPT12604	4	1	10	15											
		OPT12606	6	1	10	15											
		OPT12609	9	1	10	15											
		OPT12612	12	1	10	15											
		OPT12614	14	1	10	15											
		OPT22604	4	2			24										
		OPT22606	6	2			24										
		OPT22609	9	2			24										
		OPT22612	12	2			24										
		OPT22614	14	2			24										
		OPT32606	6	3			24										
		OPT32609	9	3			24										
		OPT32612	12	3			24										
		OPT32614	14	3			24										
		OPT42606	6	4				48									
		OPT42609	9	4				48									
		OPT42612	12	4				48									
		OPT42614	14	4				48									
		OPT52606	6	5				49	68								
		OPT52609	9	5				49	68								
		OPT52612	12	5				49	68								
		OPT62609	9	6				49	69								
		OPT62612	12	6				49	69								
	27G	SAF-Q-109-G27	9	1	9	13											

Table 5a	Drug	Patient Information	Flow Controller
	Gammagard	Patients under 40 kg (88 lb)	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller												
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
BD 20 (302830)	26G	OPT12604	4	1	13												
		OPT12606	6	1	13												
		OPT12609	9	1	13												
		OPT12612	12	1	13												
		OPT12614	14	1	13												
		OPT22604	4	2		19	30										
		OPT22606	6	2		19	30										
		OPT22609	9	2		19	30										
		OPT22612	12	2		19	30										
		OPT22614	14	2		19	30										
		OPT32606	6	3			31										
		OPT32609	9	3			31										
		OPT32612	12	3			31										
		OPT32614	14	3			31										
		OPT42606	6	4													
		OPT42609	9	4													
		OPT42612	12	4													
		OPT42614	14	4													
		OPT52606	6	5				62									
		OPT52609	9	5				62									
		OPT52612	12	5				62									
		OPT62609	9	6				63	88								
		OPT62612	12	6				63	88								
	27G	SAF-Q-109-G27	9	1	12												
B.Braun 30 (4617304F)	26G	OPT12604	4	1	10	14											
		OPT12606	6	1	10	14											
		OPT12609	9	1	10	14											
		OPT12612	12	1	10	14											
		OPT12614	14	1	10	14											
		OPT22604	4	2			23										
		OPT22606	6	2			23										
		OPT22609	9	2			23										
		OPT22612	12	2			23										
		OPT22614	14	2			23										
		OPT32606	6	3													
		OPT32609	9	3													

Table 5a	Drug	Patient Information	Flow Controller
	Gammagard	Patients under 40 kg (88 lb)	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller												
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
		OPT32612	12	3													
		OPT32614	14	3													
		OPT42606	6	4				47									
		OPT42609	9	4				47									
		OPT42612	12	4				47									
		OPT42614	14	4				47									
		OPT52606	6	5				48	67								
		OPT52609	9	5				48	67								
		OPT52612	12	5				48	67								
		OPT62609	9	6				48	67								
		OPT62612	12	6				48	67								
	27G	SAF-Q-109-G27	9	1	9	13											
Monoject 35 (1183500777 or 8881535762)		OPT12604	4	1	8	11											
		OPT12606	6	1	8	11											
		OPT12609	9	1	8	11											
		OPT12612	12	1	8	11											
		OPT12614	14	1	8	11											
		OPT22604	4	2			18										
		OPT22606	6	2			18										
		OPT22609	9	2			18										
		OPT22612	12	2			18										
		OPT22614	14	2			18										
		OPT32606	6	3				37									
	26G	OPT32609	9	3				37									
		OPT32612	12	3				37									
		OPT32614	14	3				37									
		OPT42606	6	4				37	52								
		OPT42609	9	4				37	52								
		OPT42612	12	4				37	52								
		OPT42614	14	4				37	52								
		OPT52606	6	5					53								
		OPT52609	9	5					53								
		OPT52612	12	5					53								
		OPT62609	9	6					53								
		OPT62612	12	6					53								
	27G	SAF-Q-109-G27	9	1		10	15										

Table 5b	Drug	Patient Information	Flow Controller
	Gammagard	Patients over 40 kg (88 lb)	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller												
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
BD 30 (302832)	26G	OPT12604	4	1	10	15											
		OPT12606	6	1	10	15											
		OPT12609	9	1	10	15											
		OPT12612	12	1	10	15											
		OPT12614	14	1	10	15											
		OPT22604	4	2			24										
		OPT22606	6	2			24										
		OPT22609	9	2			24										
		OPT22612	12	2			24										
		OPT22614	14	2			24										
		OPT32606	6	3			24	48	66								
		OPT32609	9	3			24	48	66								
		OPT32612	12	3			24	48	66								
		OPT32614	14	3			24	48	66								
		OPT42606	6	4				48	68								
		OPT42609	9	4				48	68								
		OPT42612	12	4				48	68								
		OPT42614	14	4				48	68								
		OPT52606	6	5				49	68								
		OPT52609	9	5				49	68								
		OPT52612	12	5				49	68								
		OPT62609	9	6				49	69	116							
		OPT62612	12	6				49	69	116							
	27G	SAF-Q-109-G27	9	1	9	13	19										
BD 20 (302830)	26G	OPT12604	4	1	13	19											
		OPT12606	6	1	13	19											
		OPT12609	9	1	13	19											
		OPT12612	12	1	13	19											
		OPT12614	14	1	13	19											
		OPT22604	4	2		19	30										
		OPT22606	6	2		19	30										
		OPT22609	9	2		19	30										
		OPT22612	12	2		19	30										
		OPT22614	14	2		19	30										
		OPT32606	6	3			31	61									
		OPT32609	9	3			31	61									

Table 5b	Drug	Patient Information	Flow Controller
	Gammagard	Patients over 40 kg (88 lb)	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller												
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
		OPT32612	12	3			31	61									
		OPT32614	14	3			31	61									
		OPT42606	6	4				62	87								
		OPT42609	9	4				62	87								
		OPT42612	12	4				62	87								
		OPT42614	14	4				62	87								
		OPT52606	6	5				62	87								
		OPT52609	9	5				62	87								
		OPT52612	12	5				62	87								
		OPT62609	9	6				63	88								
		OPT62612	12	6				63	88								
	27G	SAF-Q-109-G27	9	1	12	17											
B.Braun 30 (4617304F)		OPT12604	4	1	10	14	22										
		OPT12606	6	1	10	14	22										
		OPT12609	9	1	10	14	22										
		OPT12612	12	1	10	14	22										
		OPT12614	14	1	10	14	22										
		OPT22604	4	2			23										
		OPT22606	6	2			23										
		OPT22609	9	2			23										
		OPT22612	12	2			23										
		OPT22614	14	2			23										
		OPT32606	6	3				47	65								
	26G	OPT32609	9	3				47	65								
		OPT32612	12	3				47	65								
		OPT32614	14	3				47	65								
		OPT42606	6	4				47	66								
		OPT42609	9	4				47	66								
		OPT42612	12	4				47	66								
		OPT42614	14	4				47	66								
		OPT52606	6	5				48	67	111							
		OPT52609	9	5				48	67	111							
		OPT52612	12	5				48	67	111							
		OPT62609	9	6				48	67	113							
		OPT62612	12	6				48	67	113							
	27G	SAF-Q-109-G27	9	1	9	13	19										

Table 5b	Drug	Patient Information	Flow Controller
	Gammagard	Patients over 40 kg (88 lb)	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller												
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
Monoject 35 (1183500777 or 8881535762)	26G	OPT12604	4	1	8	11	17										
		OPT12606	6	1	8	11	17										
		OPT12609	9	1	8	11	17										
		OPT12612	12	1	8	11	17										
		OPT12614	14	1	8	11	17										
		OPT22604	4	2			18	36									
		OPT22606	6	2			18	36									
		OPT22609	9	2			18	36									
		OPT22612	12	2			18	36									
		OPT22614	14	2			18	36									
		OPT32606	6	3				37	51								
		OPT32609	9	3				37	51								
		OPT32612	12	3				37	51								
		OPT32614	14	3				37	51								
		OPT42606	6	4				37	52	87							
		OPT42609	9	4				37	52	87							
		OPT42612	12	4				37	52	87							
		OPT42614	14	4				37	52	87							
		OPT52606	6	5					53	88							
		OPT52609	9	5					53	88							
		OPT52612	12	5					53	88							
		OPT62609	9	6					53	89	126						
		OPT62612	12	6					53	89	126						
	27G	SAF-Q-109-G27	9	1		10	15										

For Gammagard administration limits, there are no suitable flow rate system configurations with the VersaRate Plus, only with Infuset flow controller per Tables 5a and 5b.

Infusing Gamunex-C or Gammaked

Tables 6a, 6b and 6c show expected total flow rates for infusing Gamunex-C or Gammaked using various combinations of subcutaneous infusion sets, flow controllers, and syringe models. Cells shaded in white are suitable for initial and maintenance infusions. Cells shaded in yellow are only suitable for maintenance infusions. Cells shaded in gray do not have values listed because testing has not been performed or the value may exceed the prescribing information flow rate limits.

Table Legend:

	Suitable for initial and maintenance infusions For Adults: Up to 20 mL/h/site For Pediatrics: Under 25 kg (55 lb) body weight: up to 10 mL/h/site; 25 kg (55 lb) and greater: up to 15 mL/h/site
	Suitable for maintenance infusions only For Adults: Up to 20 mL/h/site For Pediatrics: Under 25 kg (55 lb) body weight: up to 10 mL/h/site; 25 kg (55 lb) and greater: up to 20 mL/h/site
	No data available or may exceed prescribing information flow rate limits

Table 6a	**Drug**	**Patient Information**	**Flow Controller**
	Gammunex-C and Gammaked	**Adults**	**Infuset**

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller													
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
BD 30 (302832)	26G	OPT12604	4	1	10	14											
		OPT12606	6	1	10	14											
		OPT12609	9	1	10	14											
		OPT12612	12	1	10	14											
		OPT12614	14	1	10	14											
		OPT22604	4	2			23										
		OPT22606	6	2			23										
		OPT22609	9	2			23										
		OPT22612	12	2			23										
		OPT22614	14	2			23										
		OPT32606	6	3													
		OPT32609	9	3													
		OPT32612	12	3													
		OPT32614	14	3													
		OPT42606	6	4				47									
		OPT42609	9	4				47									
		OPT42612	12	4				47									
		OPT42614	14	4				47									
		OPT52606	6	5				47	66								
		OPT52609	9	5				47	66								
		OPT52612	12	5				47	66								
		OPT62609	9	6					67								
		OPT62612	12	6					67								
	27G	SAF-Q-109-G27	9	1	9	13											

Table 6a	Drug	Patient Information	Flow Controller
	Gammunex-C and Gammaked	Adults	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller													
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
BD 20 (302830)	26G	OPT12604	4	1	12												
		OPT12606	6	1	12												
		OPT12609	9	1	12												
		OPT12612	12	1	12												
		OPT12614	14	1	12												
		OPT22604	4	2		19	29										
		OPT22606	6	2		19	29										
		OPT22609	9	2		19	29										
		OPT22612	12	2		19	29										
		OPT22614	14	2		19	29										
		OPT32606	6	3			30										
		OPT32609	9	3			30										
		OPT32612	12	3			30										
		OPT32614	14	3			30										
		OPT42606	6	4				60									
		OPT42609	9	4				60									
		OPT42612	12	4				60									
		OPT42614	14	4				60									
		OPT52606	6	5				60									
		OPT52609	9	5				60									
		OPT52612	12	5				60									
		OPT62609	9	6				61	85								
		OPT62612	12	6				61	85								
	27G	SAF-Q-109-G27	9	1	11												
B.Braun 30 (4617304F)	26G	OPT12604	4	1	9	14											
		OPT12606	6	1	9	14											
		OPT12609	9	1	9	14											
		OPT12612	12	1	9	14											
		OPT12614	14	1	9	14											
		OPT22604	4	2			22										
		OPT22606	6	2			22										
		OPT22609	9	2			22										
		OPT22612	12	2			22										
		OPT22614	14	2			22										
		OPT32606	6	3				45									
		OPT32609	9	3				45									
		OPT32612	12	3				45									
		OPT32614	14	3				45									
		OPT42606	6	4				46									

Table 6a	Drug	Patient Information	Flow Controller
	Gammunex-C and Gammaked	Adults	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller													
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
		OPT42609	9	4				46									
		OPT42612	12	4				46									
		OPT42614	14	4				46									
		OPT52606	6	5				46	65								
		OPT52609	9	5				46	65								
		OPT52612	12	5				46	65								
		OPT62609	9	6					65								
		OPT62612	12	6					65								
	27G	SAF-Q-109-G27	9	1	9	13											
Monoject 35 (1183500777 or 8881535762)		OPT12604	4	1		11											
		OPT12606	6	1		11											
		OPT12609	9	1		11											
		OPT12612	12	1		11											
		OPT12614	14	1		11											
		OPT22604	4	2			18										
		OPT22606	6	2			18										
		OPT22609	9	2			18										
		OPT22612	12	2			18										
		OPT22614	14	2			18										
		OPT32606	6	3				36									
	26G	OPT32609	9	3				36									
		OPT32612	12	3				36									
		OPT32614	14	3				36									
		OPT42606	6	4				36	51								
		OPT42609	9	4				36	51								
		OPT42612	12	4				36	51								
		OPT42614	14	4				36	51								
		OPT52606	6	5					51								
		OPT52609	9	5					51								
		OPT52612	12	5					51								
		OPT62609	9	6					52	86							
		OPT62612	12	6					52	86							
	27G	SAF-Q-109-G27	9	1		10	14										

Table 6b	Drug	Patient Information	Flow Controller
	Gammunex-C and Gammaked	Pediatrics over 25 kg (55 lb)	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller												
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
BD 30 (302832)	26G	OPT12604	4	1	10	14											
		OPT12606	6	1	10	14											
		OPT12609	9	1	10	14											
		OPT12612	12	1	10	14											
		OPT12614	14	1	10	14											
		OPT22604	4	2	10	15	23										
		OPT22606	6	2	10	15	23										
		OPT22609	9	2	10	15	23										
		OPT22612	12	2	10	15	23										
		OPT22614	14	2	10	15	23										
		OPT32606	6	3		15	23										
		OPT32609	9	3		15	23										
		OPT32612	12	3		15	23										
		OPT32614	14	3		15	23										
		OPT42606	6	4			23	47									
		OPT42609	9	4			23	47									
		OPT42612	12	4			23	47									
		OPT42614	14	4			23	47									
		OPT52606	6	5				47	66								
		OPT52609	9	5				47	66								
		OPT52612	12	5				47	66								
		OPT62609	9	6				47	67								
		OPT62612	12	6				47	67								
	27G	SAF-Q-109-G27	9	1	9	13											
BD 20 (302830)	26G	OPT12604	4	1	12												
		OPT12606	6	1	12												
		OPT12609	9	1	12												
		OPT12612	12	1	12												
		OPT12614	14	1	12												
		OPT22604	4	2	12	19	29										
		OPT22606	6	2	12	19	29										
		OPT22609	9	2	12	19	29										
		OPT22612	12	2	12	19	29										
		OPT22614	14	2	12	19	29										
		OPT32606	6	3		19	30										
		OPT32609	9	3		19	30										
		OPT32612	12	3		19	30										

Table 6b	Drug	Patient Information	Flow Controller
	Gammunex-C and Gammaked	Pediatrics over 25 kg (55 lb)	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller													
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
		OPT32614	14	3		19	30										
		OPT42606	6	4			30	60									
		OPT42609	9	4			30	60									
		OPT42612	12	4			30	60									
		OPT42614	14	4			30	60									
		OPT52606	6	5			30	60									
		OPT52609	9	5			30	60									
		OPT52612	12	5			30	60									
		OPT62609	9	6			30	61	85								
		OPT62612	12	6			30	61	85								
	27G	SAF-Q-109-G27	9	1	11												
B.Braun 30 (4617304F)		OPT12604	4	1	9	14											
		OPT12606	6	1	9	14											
		OPT12609	9	1	9	14											
		OPT12612	12	1	9	14											
		OPT12614	14	1	9	14											
		OPT22604	4	2		14	22										
		OPT22606	6	2		14	22										
		OPT22609	9	2		14	22										
		OPT22612	12	2		14	22										
		OPT22614	14	2		14	22										
		OPT32606	6	3			23	45									
	26G	OPT32609	9	3			23	45									
		OPT32612	12	3			23	45									
		OPT32614	14	3			23	45									
		OPT42606	6	4			23	46									
		OPT42609	9	4			23	46									
		OPT42612	12	4			23	46									
		OPT42614	14	4			23	46									
		OPT52606	6	5				46	65								
		OPT52609	9	5				46	65								
		OPT52612	12	5				46	65								
		OPT62609	9	6				46	65								
		OPT62612	12	6				46	65								
	27G	SAF-Q-109-G27	9	1	9	13											

Table 6b	Drug	Patient Information	Flow Controller
	Gammunex-C and Gammaked	Pediatrics over 25 kg (55 lb)	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller												
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
Monoject 35 (1183500777 or 8881535762)	26G	OPT12604	4	1	7	11											
		OPT12606	6	1	7	11											
		OPT12609	9	1	7	11											
		OPT12612	12	1	7	11											
		OPT12614	14	1	7	11											
		OPT22604	4	2		11	18										
		OPT22606	6	2		11	18										
		OPT22609	9	2		11	18										
		OPT22612	12	2		11	18										
		OPT22614	14	2		11	18										
		OPT32606	6	3			18	36									
		OPT32609	9	3			18	36									
		OPT32612	12	3			18	36									
		OPT32614	14	3			18	36									
		OPT42606	6	4				36	51								
		OPT42609	9	4				36	51								
		OPT42612	12	4				36	51								
		OPT42614	14	4				36	51								
		OPT52606	6	5				36	51								
		OPT52609	9	5				36	51								
		OPT52612	12	5				36	51								
		OPT62609	9	6				37	52	86							
		OPT62612	12	6				37	52	86							
	27G	SAF-Q-109-G27	9	1	7	10	14										

Table 6c	Drug	Patient Information	Flow Controller
	Gammunex-C and Gammaked	Pediatrics under 25 kg (55 lb)	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller												
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
BD 30 (302832)	26G	OPT12604	4	1													
		OPT12606	6	1													
		OPT12609	9	1													
		OPT12612	12	1													
		OPT12614	14	1													
		OPT22604	4	2	10	15											
		OPT22606	6	2	10	15											
		OPT22609	9	2	10	15											
		OPT22612	12	2	10	15											
		OPT22614	14	2	10	15											
		OPT32606	6	3		15	23										
		OPT32609	9	3		15	23										
		OPT32612	12	3		15	23										
		OPT32614	14	3		15	23										
		OPT42606	6	4			23										
		OPT42609	9	4			23										
		OPT42612	12	4			23										
		OPT42614	14	4			23										
		OPT52606	6	5													
		OPT52609	9	5													
		OPT52612	12	5													
		OPT62609	9	6													
		OPT62612	12	6													
	27G	SAF-Q-109-G27	9	1													
BD 20 (302830)	26G	OPT12604	4	1													
		OPT12606	6	1													
		OPT12609	9	1													
		OPT12612	12	1													
		OPT12614	14	1													
		OPT22604	4	2	12												
		OPT22606	6	2	12												
		OPT22609	9	2	12												
		OPT22612	12	2	12												
		OPT22614	14	2	12												
		OPT32606	6	3		19											
		OPT32609	9	3		19											

Table 6c	Drug	Patient Information	Flow Controller
	Gammunex-C and Gammaked	Pediatrics under 25 kg (55 lb)	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller												
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
		OPT32612	12	3		19											
		OPT32614	14	3		19											
		OPT42606	6	4			30										
		OPT42609	9	4			30										
		OPT42612	12	4			30										
		OPT42614	14	4			30										
		OPT52606	6	5			30										
		OPT52609	9	5			30										
		OPT52612	12	5			30										
		OPT62609	9	6			30										
		OPT62612	12	6			30										
	27G	SAF-Q-109-G27	9	1													
B.Braun 30 (4617304F)		OPT12604	4	1													
		OPT12606	6	1													
		OPT12609	9	1													
		OPT12612	12	1													
		OPT12614	14	1													
		OPT22604	4	2		14											
		OPT22606	6	2		14											
		OPT22609	9	2		14											
		OPT22612	12	2		14											
		OPT22614	14	2		14											
		OPT32606	6	3			23										
	26G	OPT32609	9	3			23										
		OPT32612	12	3			23										
		OPT32614	14	3			23										
		OPT42606	6	4			23										
		OPT42609	9	4			23										
		OPT42612	12	4			23										
		OPT42614	14	4			23										
		OPT52606	6	5													
		OPT52609	9	5													
		OPT52612	12	5													
		OPT62609	9	6													
		OPT62612	12	6													
	27G	SAF-Q-109-G27	9	1													

Table 6c	Drug	Patient Information	Flow Controller
	Gammunex-C and Gammaked	Pediatrics under 25 kg (55 lb)	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller												
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
Monoject 35 (1183500777 or 8881535762)	26G	OPT12604	4	1	7												
		OPT12606	6	1	7												
		OPT12609	9	1	7												
		OPT12612	12	1	7												
		OPT12614	14	1	7												
		OPT22604	4	2		11											
		OPT22606	6	2		11											
		OPT22609	9	2		11											
		OPT22612	12	2		11											
		OPT22614	14	2		11											
		OPT32606	6	3			18										
		OPT32609	9	3			18										
		OPT32612	12	3			18										
		OPT32614	14	3			18										
		OPT42606	6	4													
		OPT42609	9	4													
		OPT42612	12	4													
		OPT42614	14	4													
		OPT52606	6	5				36									
		OPT52609	9	5				36									
		OPT52612	12	5				36									
		OPT62609	9	6				37									
		OPT62612	12	6				37									
	27G	SAF-Q-109-G27	9	1	7												

For Gamunex-C and Gammaked administration limits, there are no suitable flow rate system configurations with the VersaRate Plus, only with Infuset flow controller per Tables 6a, 6b and 6c.

Infusing Hizentra for Primary Immunodeficiency (PI)

Tables 7 and 8 show expected total flow rates for infusing Hizentra for Primary Immunodeficiency using various combinations of subcutaneous infusion sets, flow controllers, and syringe models. Cells shaded in white are suitable for initial and maintenance infusions. Cells shaded in yellow are only suitable for maintenance infusions. Cells shaded in gray do not have values listed because testing has not been performed or the value may exceed the prescribing information flow rate limits.

Table Legend:

	Suitable for initial and maintenance infusions (up to 15 mL/h/site)
	Suitable for maintenance infusions only (up to 25 mL/h/site)
	No data available or may exceed prescribing information flow rate limits

Table 7	Drug	Flow Controller
	Hizentra (PI)	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller												
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
BD 30 (302832)	26G	OPT12604	4	1				9	12	18							
		OPT12606	6	1				9	12	18							
		OPT12609	9	1				9	12	18							
		OPT12612	12	1				9	12	18							
		OPT12614	14	1				9	12	18							
		OPT22604	4	2						22	29						
		OPT22606	6	2						22	29						
		OPT22609	9	2						22	29						
		OPT22612	12	2						22	29						
		OPT22614	14	2						22	29						
		OPT32606	6	3							32	42	45				
		OPT32609	9	3							32	42	45				
		OPT32612	12	3							32	42	45				
		OPT32614	14	3							32	42	45				
		OPT42606	6	4							33	46	48				
		OPT42609	9	4							33	46	48				
		OPT42612	12	4							33	46	48				
		OPT42614	14	4							33	46	48				
		OPT52606	6	5								47	49				
		OPT52609	9	5								47	49				
		OPT52612	12	5								47	49				
		OPT62609	9	6								48	51				
		OPT62612	12	6								48	51				
	27G	SAF-Q-109-G27	9	1					9	11	13	14	14	18	18		

Table 7	Drug	Flow Controller
	Hizentra (PI)	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller												
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
BD 20 (302830)	26G	OPT12604	4	1				12	16								
		OPT12606	6	1				12	16								
		OPT12609	9	1				12	16								
		OPT12612	12	1				12	16								
		OPT12614	14	1				12	16								
		OPT22604	4	2					17	28							
		OPT22606	6	2					17	28							
		OPT22609	9	2					17	28							
		OPT22612	12	2					17	28							
		OPT22614	14	2					17	28							
		OPT32606	6	3						29	41	54					
		OPT32609	9	3						29	41	54					
		OPT32612	12	3						29	41	54					
		OPT32614	14	3						29	41	54					
		OPT42606	6	4							43	58	61				
		OPT42609	9	4							43	58	61				
		OPT42612	12	4							43	58	61				
		OPT42614	14	4							43	58	61				
		OPT52606	6	5							44	60	63				
		OPT52609	9	5							44	60	63				
		OPT52612	12	5							44	60	63				
		OPT62609	9	6								62	65				
		OPT62612	12	6								62	65				
	27G	SAF-Q-109-G27	9	1				9	11	14	16	18					
B.Braun 30 (4617304F)	26G	OPT12604	4	1				9	12	18							
		OPT12606	6	1				9	12	18							
		OPT12609	9	1				9	12	18							
		OPT12612	12	1				9	12	18							
		OPT12614	14	1				9	12	18							
		OPT22604	4	2						21	29						
		OPT22606	6	2						21	29						
		OPT22609	9	2						21	29						
		OPT22612	12	2						21	29						
		OPT22614	14	2						21	29						
		OPT32606	6	3							31	41	44				
		OPT32609	9	3							31	41	44				

Table 7	Drug	Flow Controller
	Hizentra (PI)	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller												
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
		OPT32612	12	3							31	41	44				
		OPT32614	14	3							31	41	44				
		OPT42606	6	4							33	45	47				
		OPT42609	9	4							33	45	47				
		OPT42612	12	4							33	45	47				
		OPT42614	14	4							33	45	47				
		OPT52606	6	5								46	48				
		OPT52609	9	5								46	48				
		OPT52612	12	5								46	48				
		OPT62609	9	6									50				
		OPT62612	12	6									50				
	27G	SAF-Q-109-G27	9	1					8	11	13	14	14	17	18	18	18
Monoject 35 (1183500777 or 8881535762)		OPT12604	4	1					9	14	18						
		OPT12606	6	1					9	14	18						
		OPT12609	9	1					9	14	18						
		OPT12612	12	1					9	14	18						
		OPT12614	14	1					9	14	18						
		OPT22604	4	2						17	23	30	31				
		OPT22606	6	2						17	23	30	31				
		OPT22609	9	2						17	23	30	31				
		OPT22612	12	2						17	23	30	31				
		OPT22614	14	2						17	23	30	31				
		OPT32606	6	3							25	33	34				
	26G	OPT32609	9	3							25	33	34				
		OPT32612	12	3							25	33	34				
		OPT32614	14	3							25	33	34				
		OPT42606	6	4								35	37				
		OPT42609	9	4								35	37				
		OPT42612	12	4								35	37				
		OPT42614	14	4								35	37				
		OPT52606	6	5													
		OPT52609	9	5													
		OPT52612	12	5													
		OPT62609	9	6													
		OPT62612	12	6													
	27G	SAF-Q-109-G27	9	1						9	10	11	11	14	14	14	14

Table 7	Drug	Flow Controller
	Hizentra (PI)	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller												
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
Hizentra Prefilled 20 (NDC 44206-458-96)	26G	OPT12604	4	1			8	15									
		OPT12606	6	1			8	15									
		OPT12609	9	1			8	15									
		OPT12612	12	1			8	15									
		OPT12614	14	1			8	15									
		OPT22604	4	2				16	22	35							
		OPT22606	6	2				16	22	35							
		OPT22609	9	2				16	22	35							
		OPT22612	12	2				16	22	35							
		OPT22614	14	2				16	22	35							
		OPT32606	6	3						37	51						
		OPT32609	9	3						37	51						
		OPT32612	12	3						37	51						
		OPT32614	14	3						37	51						
		OPT42606	6	4						38	54	73					
		OPT42609	9	4						38	54	73					
		OPT42612	12	4						38	54	73					
		OPT42614	14	4						38	54	73					
		OPT52606	6	5							55	75	79				
		OPT52609	9	5							55	75	79				
		OPT52612	12	5							55	75	79				
		OPT62609	9	6							56	78	82				
		OPT62612	12	6							56	78	82				
	27G	SAF-Q-109-G27	9	1				11	14	18							

Table 8	Drug	Flow Controller
	Hizentra (PI)	VersaRate Plus

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per VersaRate Plus position setting											
	Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
BD 30 (302832)	26G	OPT12604	4	1												
		OPT12606	6	1												
		OPT12609	9	1												
		OPT12612	12	1												
		OPT12614	14	1												
		OPT22604	4	2												
		OPT22606	6	2												
		OPT22609	9	2												
		OPT22612	12	2												
		OPT22614	14	2												
		OPT32606	6	3			42	51								
		OPT32609	9	3			42	51								
		OPT32612	12	3			42	51								
		OPT32614	14	3			42	51								
		OPT42606	6	4			45	56								
		OPT42609	9	4			45	56								
		OPT42612	12	4			45	56								
		OPT42614	14	4			45	56								
		OPT52606	6	5			46	58								
		OPT52609	9	5			46	58								
		OPT52612	12	5			46	58								
		OPT62609	9	6				60	100							
		OPT62612	12	6				60	100							
	27G	SAF-Q-109-G27	9	1			14	15	17	17	18	18	18	18		
BD 20 (302830)	26G	OPT12604	4	1												
		OPT12606	6	1												
		OPT12609	9	1												
		OPT12612	12	1												
		OPT12614	14	1												
		OPT22604	4	2												
		OPT22606	6	2												
		OPT22609	9	2												

Table 8	Drug	Flow Controller
	Hizentra (PI)	VersaRate Plus

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per VersaRate Plus position setting											
	Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
		OPT22612	12	2												
		OPT22614	14	2												
		OPT32606	6	3												
		OPT32609	9	3												
		OPT32612	12	3												
		OPT32614	14	3												
		OPT42606	6	4			57									
		OPT42609	9	4			57									
		OPT42612	12	4			57									
		OPT42614	14	4			57									
		OPT52606	6	5			59	74								
		OPT52609	9	5			59	74								
		OPT52612	12	5			59	74								
		OPT62609	9	6			60	77								
		OPT62612	12	6			60	77								
	27G	SAF-Q-109-G27	9	1												
B.Braun 30 (4617304F)		OPT12604	4	1												
		OPT12606	6	1												
		OPT12609	9	1												
		OPT12612	12	1												
		OPT12614	14	1												
		OPT22604	4	2												
		OPT22606	6	2												
		OPT22609	9	2												
	26G	OPT22612	12	2												
		OPT22614	14	2												
		OPT32606	6	3			41	50								
		OPT32609	9	3			41	50								
		OPT32612	12	3			41	50								
		OPT32614	14	3			41	50								
		OPT42606	6	4			44	55								
		OPT42609	9	4			44	55								
		OPT42612	12	4			44	55								

Table 8	Drug	Flow Controller
	Hizentra (PI)	VersaRate Plus

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per VersaRate Plus position setting											
	Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
		OPT42614	14	4			44	55								
		OPT52606	6	5			45	57	92							
		OPT52609	9	5			45	57	92							
		OPT52612	12	5			45	57	92							
		OPT62609	9	6				59	98							
		OPT62612	12	6				59	98							
	27G	SAF-Q-109-G27	9	1			14	15	16	17	18	18	18	18	18	18
Monoject 35 (1183500777 or 8881535762)		OPT12604	4	1												
		OPT12606	6	1												
		OPT12609	9	1												
		OPT12612	12	1												
		OPT12614	14	1												
		OPT22604	4	2			29									
		OPT22606	6	2			29									
		OPT22609	9	2			29									
		OPT22612	12	2			29									
		OPT22614	14	2			29									
		OPT32606	6	3			32	40								
	26G	OPT32609	9	3			32	40								
		OPT32612	12	3			32	40								
		OPT32614	14	3			32	40								
		OPT42606	6	4			35	43	69							
		OPT42609	9	4			35	43	69							
		OPT42612	12	4			35	43	69							
		OPT42614	14	4			35	43	69							
		OPT52606	6	5				45	73	89						
		OPT52609	9	5				45	73	89						
		OPT52612	12	5				45	73	89						
		OPT62609	9	6					78	95						
		OPT62612	12	6					78	95						
	27G	SAF-Q-109-G27	9	1			11	12	13	13	14	14	14	14	14	15

Table 8	Drug	Flow Controller
	Hizentra (PI)	VersaRate Plus

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per VersaRate Plus position setting											
	Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
Hizentra Prefilled 20 (NDC 44206-458-96)	26G	OPT12604	4	1												
		OPT12606	6	1												
		OPT12609	9	1												
		OPT12612	12	1												
		OPT12614	14	1												
		OPT22604	4	2												
		OPT22606	6	2												
		OPT22609	9	2												
		OPT22612	12	2												
		OPT22614	14	2												
		OPT32606	6	3												
		OPT32609	9	3												
		OPT32612	12	3												
		OPT32614	14	3												
		OPT42606	6	4												
		OPT42609	9	4												
		OPT42612	12	4												
		OPT42614	14	4												
		OPT52606	6	5			74									
		OPT52609	9	5			74									
		OPT52612	12	5			74									
		OPT62609	9	6			76	96								
		OPT62612	12	6			76	96								
	27G	SAF-Q-109-G27	9	1												

Infusing Hizentra for Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Tables 9 and 10 below show expected total flow rates for infusing Hizentra for CIDP using various combinations of subcutaneous infusion sets, flow controllers, and syringe models. Cells shaded in white are suitable for initial and maintenance infusions. Cells shaded in yellow are only suitable for maintenance infusions. Cells shaded in gray do not have values listed because testing has not been performed or the value may exceed the prescribing information flow rate limits.

Table Legend:

	Suitable for initial and maintenance infusions (up to 20 mL/h/site)
	Suitable for maintenance infusions only (up to 50 mL/h/site)
	No data available or may exceed prescribing information flow rate limits

Table 9	**Drug**	**Flow Controller**
	Hizentra (CIDP)	**Infuset**

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller											
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
BD 30 (302832)	26G	OPT12604	4	1				9	12	18	23	28	29				
		OPT12606	6	1				9	12	18	23	28	29				
		OPT12609	9	1				9	12	18	23	28	29				
		OPT12612	12	1				9	12	18	23	28	29				
		OPT12614	14	1				9	12	18	23	28	29				
		OPT22604	4	2						22	29	39	40				
		OPT22606	6	2						22	29	39	40				
		OPT22609	9	2						22	29	39	40				
		OPT22612	12	2						22	29	39	40				
		OPT22614	14	2						22	29	39	40				
		OPT32606	6	3							32	42	45	107			
		OPT32609	9	3							32	42	45	107			
		OPT32612	12	3							32	42	45	107			
		OPT32614	14	3							32	42	45	107			
		OPT42606	6	4							33	46	48	130			
		OPT42609	9	4							33	46	48	130			
		OPT42612	12	4							33	46	48	130			
		OPT42614	14	4							33	46	48	130			
		OPT52606	6	5								47	49	140	171		
		OPT52609	9	5								47	49	140	171		
		OPT52612	12	5								47	49	140	171		
		OPT62609	9	6								48	51	154	192		
		OPT62612	12	6								48	51	154	192		
	27G	SAF-Q-109-G27	9	1					9	11	13	14	14	18	18	19	19

Table 9	Drug	Flow Controller
	Hizentra (CIDP)	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller											
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
BD 20 (302830)	26G	OPT12604	4	1				12	16	23	30	36	38				
		OPT12606	6	1				12	16	23	30	36	38				
		OPT12609	9	1				12	16	23	30	36	38				
		OPT12612	12	1				12	16	23	30	36	38				
		OPT12614	14	1				12	16	23	30	36	38				
		OPT22604	4	2					17	28	38	49	52				
		OPT22606	6	2					17	28	38	49	52				
		OPT22609	9	2					17	28	38	49	52				
		OPT22612	12	2					17	28	38	49	52				
		OPT22614	14	2					17	28	38	49	52				
		OPT32606	6	3						29	41	54	57				
		OPT32609	9	3						29	41	54	57				
		OPT32612	12	3						29	41	54	57				
		OPT32614	14	3						29	41	54	57				
		OPT42606	6	4							43	58	61				
		OPT42609	9	4							43	58	61				
		OPT42612	12	4							43	58	61				
		OPT42614	14	4							43	58	61				
		OPT52606	6	5							44	60	63	180			
		OPT52609	9	5							44	60	63	180			
		OPT52612	12	5							44	60	63	180			
		OPT62609	9	6								62	65	197			
		OPT62612	12	6								62	65	197			
	27G	SAF-Q-109-G27	9	1				9	11	14	16	18	19	23	23	24	24
B.Braun 30 (4617304F)	26G	OPT12604	4	1				9	12	18	23	28	29				
		OPT12606	6	1				9	12	18	23	28	29				
		OPT12609	9	1				9	12	18	23	28	29				
		OPT12612	12	1				9	12	18	23	28	29				
		OPT12614	14	1				9	12	18	23	28	29				
		OPT22604	4	2						21	29	38	39				
		OPT22606	6	2						21	29	38	39				
		OPT22609	9	2						21	29	38	39				
		OPT22612	12	2						21	29	38	39				
		OPT22614	14	2						21	29	38	39				
		OPT32606	6	3							31	41	44	105			
		OPT32609	9	3							31	41	44	105			

Table 9	Drug	Flow Controller
	Hizentra (CIDP)	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller												
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
		OPT32612	12	3							31	41	44	105			
		OPT32614	14	3							31	41	44	105			
		OPT42606	6	4							33	45	47	127			
		OPT42609	9	4							33	45	47	127			
		OPT42612	12	4							33	45	47	127			
		OPT42614	14	4							33	45	47	127			
		OPT52606	6	5								46	48	137	168		
		OPT52609	9	5								46	48	137	168		
		OPT52612	12	5								46	48	137	168		
		OPT62609	9	6									50	150	187		
		OPT62612	12	6									50	150	187		
	27G	SAF-Q-109-G27	9	1					8	11	13	14	14	17	18	18	18
Monoject 35 (1183500777 or 8881535762)		OPT12604	4	1					9	14	18	22	23				
		OPT12606	6	1					9	14	18	22	23				
		OPT12609	9	1					9	14	18	22	23				
		OPT12612	12	1					9	14	18	22	23				
		OPT12614	14	1					9	14	18	22	23				
		OPT22604	4	2						17	23	30	31	66			
		OPT22606	6	2						17	23	30	31	66			
		OPT22609	9	2						17	23	30	31	66			
		OPT22612	12	2						17	23	30	31	66			
		OPT22614	14	2						17	23	30	31	66			
		OPT32606	6	3							25	33	34	83	96	109	110
	26G	OPT32609	9	3							25	33	34	83	96	109	110
		OPT32612	12	3							25	33	34	83	96	109	110
		OPT32614	14	3							25	33	34	83	96	109	110
		OPT42606	6	4								35	37	100	121	142	144
		OPT42609	9	4								35	37	100	121	142	144
		OPT42612	12	4								35	37	100	121	142	144
		OPT42614	14	4								35	37	100	121	142	144
		OPT52606	6	5										109	133	160	162
		OPT52609	9	5										109	133	160	162
		OPT52612	12	5										109	133	160	162
		OPT62609	9	6										119	148	183	186
		OPT62612	12	6										119	148	183	186
	27G	SAF-Q-109-G27	9	1						9	10	11	11	14	14	14	14

Table 9	Drug	Flow Controller
	Hizentra (CIDP)	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller												
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
Hizentra Prefilled 20 (NDC 44206-458-96)	26G	OPT12604	4	1			8	15	20	29							
		OPT12606	6	1			8	15	20	29							
		OPT12609	9	1			8	15	20	29							
		OPT12612	12	1			8	15	20	29							
		OPT12614	14	1			8	15	20	29							
		OPT22604	4	2				16	22	35	47	62	65				
		OPT22606	6	2				16	22	35	47	62	65				
		OPT22609	9	2				16	22	35	47	62	65				
		OPT22612	12	2				16	22	35	47	62	65				
		OPT22614	14	2				16	22	35	47	62	65				
		OPT32606	6	3						37	51	68	72				
		OPT32609	9	3						37	51	68	72				
		OPT32612	12	3						37	51	68	72				
		OPT32614	14	3						37	51	68	72				
		OPT42606	6	4						38	54	73	77				
		OPT42609	9	4						38	54	73	77				
		OPT42612	12	4						38	54	73	77				
		OPT42614	14	4						38	54	73	77				
		OPT52606	6	5							55	75	79				
		OPT52609	9	5							55	75	79				
		OPT52612	12	5							55	75	79				
		OPT62609	9	6							56	78	82				
		OPT62612	12	6							56	78	82				
	27G	SAF-Q-109-G27	9	1				11	14	18	21	23	23	29	29	30	30

Table 10	Drug	Flow Controller
	Hizentra (CIDP)	VersaRate Plus

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per VersaRate Plus position setting											
	Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
BD 30 (302832)	26G	OPT12604	4	1			28	32								
		OPT12606	6	1			28	32								
		OPT12609	9	1			28	32								
		OPT12612	12	1			28	32								
		OPT12614	14	1			28	32								
		OPT22604	4	2			38	46	66							
		OPT22606	6	2			38	46	66							
		OPT22609	9	2			38	46	66							
		OPT22612	12	2			38	46	66							
		OPT22614	14	2			38	46	66							
		OPT32606	6	3			42	51	78	91	110					
		OPT32609	9	3			42	51	78	91	110					
		OPT32612	12	3			42	51	78	91	110					
		OPT32614	14	3			42	51	78	91	110					
		OPT42606	6	4			45	56	89	107	134	144				
		OPT42609	9	4			45	56	89	107	134	144				
		OPT42612	12	4			45	56	89	107	134	144				
		OPT42614	14	4			45	56	89	107	134	144				
		OPT52606	6	5			46	58	94	115	145	157	166	180		
		OPT52609	9	5			46	58	94	115	145	157	166	180		
		OPT52612	12	5			46	58	94	115	145	157	166	180		
		OPT62609	9	6				60	100	123	159	174	185	202	218	
		OPT62612	12	6				60	100	123	159	174	185	202	218	
	27G	SAF-Q-109-G27	9	1			14	15	17	17	18	18	18	18	19	19
BD 20 (302830)	26G	OPT12604	4	1												
		OPT12606	6	1												
		OPT12609	9	1												
		OPT12612	12	1												
		OPT12614	14	1												
		OPT22604	4	2			48	59								
		OPT22606	6	2			48	59								
		OPT22609	9	2			48	59								
		OPT22612	12	2			48	59								

Table 10	Drug	Flow Controller
	Hizentra (CIDP)	VersaRate Plus

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per VersaRate Plus position setting											
	Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
		OPT22614	14	2			48	59								
		OPT32606	6	3			53	66	100							
		OPT32609	9	3			53	66	100							
		OPT32612	12	3			53	66	100							
		OPT32614	14	3			53	66	100							
		OPT42606	6	4			57	72	115	138						
		OPT42609	9	4			57	72	115	138						
		OPT42612	12	4			57	72	115	138						
		OPT42614	14	4			57	72	115	138						
		OPT52606	6	5			59	74	121	147						
		OPT52609	9	5			59	74	121	147						
		OPT52612	12	5			59	74	121	147						
		OPT62609	9	6			60	77	128	158	204					
		OPT62612	12	6			60	77	128	158	204					
	27G	SAF-Q-109-G27	9	1			18	19	22	22	23	23	23	24	24	24
B.Braun 30 (4617304F)		OPT12604	4	1			27	31								
		OPT12606	6	1			27	31								
		OPT12609	9	1			27	31								
		OPT12612	12	1			27	31								
		OPT12614	14	1			27	31								
		OPT22604	4	2			37	45	64	73						
		OPT22606	6	2			37	45	64	73						
		OPT22609	9	2			37	45	64	73						
		OPT22612	12	2			37	45	64	73						
	26G	OPT22614	14	2			37	45	64	73						
		OPT32606	6	3			41	50	76	89	107					
		OPT32609	9	3			41	50	76	89	107					
		OPT32612	12	3			41	50	76	89	107					
		OPT32614	14	3			41	50	76	89	107					
		OPT42606	6	4			44	55	87	105	131	141				
		OPT42609	9	4			44	55	87	105	131	141				
		OPT42612	12	4			44	55	87	105	131	141				
		OPT42614	14	4			44	55	87	105	131	141				

Table 10	Drug	Flow Controller
	Hizentra (CIDP)	VersaRate Plus

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per VersaRate Plus position setting											
	Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
		OPT52606	6	5			45	57	92	112	142	153	162	176		
		OPT52609	9	5			45	57	92	112	142	153	162	176		
		OPT52612	12	5			45	57	92	112	142	153	162	176		
		OPT62609	9	6				59	98	121	155	170	181	198	213	
		OPT62612	12	6				59	98	121	155	170	181	198	213	
	27G	SAF-Q-109-G27	9	1			14	15	16	17	18	18	18	18	18	18
Monoject 35 (1183500777 or 8881535762)		OPT12604	4	1			22	25	32	34						
		OPT12606	6	1			22	25	32	34						
		OPT12609	9	1			22	25	32	34						
		OPT12612	12	1			22	25	32	34						
		OPT12614	14	1			22	25	32	34						
		OPT22604	4	2			29	35	51	58	67	71	73			
		OPT22606	6	2			29	35	51	58	67	71	73			
		OPT22609	9	2			29	35	51	58	67	71	73			
		OPT22612	12	2			29	35	51	58	67	71	73			
		OPT22614	14	2			29	35	51	58	67	71	73			
		OPT32606	6	3			32	40	60	71	85	90	94	99	104	
	26G	OPT32609	9	3			32	40	60	71	85	90	94	99	104	
		OPT32612	12	3			32	40	60	71	85	90	94	99	104	
		OPT32614	14	3			32	40	60	71	85	90	94	99	104	
		OPT42606	6	4			35	43	69	83	103	111	117	126	134	
		OPT42609	9	4			35	43	69	83	103	111	117	126	134	
		OPT42612	12	4			35	43	69	83	103	111	117	126	134	
		OPT42614	14	4			35	43	69	83	103	111	117	126	134	
		OPT52606	6	5				45	73	89	112	121	128	139	148	
		OPT52609	9	5				45	73	89	112	121	128	139	148	
		OPT52612	12	5				45	73	89	112	121	128	139	148	
		OPT62609	9	6					78	95	123	134	143	156	168	
		OPT62612	12	6					78	95	123	134	143	156	168	
	27G	SAF-Q-109-G27	9	1			11	12	13	13	14	14	14	14	14	15

Table 10	Drug	Flow Controller
	Hizentra (CIDP)	VersaRate Plus

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per VersaRate Plus position setting											
	Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
Hizentra Prefilled 20 (NDC 44206-458-96)	26G	OPT12604	4	1												
		OPT12606	6	1												
		OPT12609	9	1												
		OPT12612	12	1												
		OPT12614	14	1												
		OPT22604	4	2			61									
		OPT22606	6	2			61									
		OPT22609	9	2			61									
		OPT22612	12	2			61									
		OPT22614	14	2			61									
		OPT32606	6	3			67	82								
		OPT32609	9	3			67	82								
		OPT32612	12	3			67	82								
		OPT32614	14	3			67	82								
		OPT42606	6	4			72	90	144							
		OPT42609	9	4			72	90	144							
		OPT42612	12	4			72	90	144							
		OPT42614	14	4			72	90	144							
		OPT52606	6	5			74	93	152	184						
		OPT52609	9	5			74	93	152	184						
		OPT52612	12	5			74	93	152	184						
		OPT62609	9	6			76	96	161	198						
		OPT62612	12	6			76	96	161	198						
	27G	SAF-Q-109-G27	9	1			23	24	27	28	29	29	29	30	30	30

Infusing Xembify

Tables 11 and 12 show expected total flow rates for infusing Xembify using various combinations of subcutaneous infusion sets, flow controllers, and syringe models. Cells shaded in white are suitable for initial and maintenance infusions. Cells shaded in gray do not have values listed because testing has not been performed or the value may exceed the prescribing information flow rate limits.

Table Legend:

	Suitable for initial and maintenance infusions (up to 25 mL/h/site)
	No data available or may exceed prescribing information flow rate limits

Table 11	Drug: Xembify	Flow Controller: Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller											
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
BD 30 (302832)	26G	OPT12604	4	1			5	9	13								
		OPT12606	6	1			5	9	13								
		OPT12609	9	1			5	9	13								
		OPT12612	12	1			5	9	13								
		OPT12614	14	1			5	9	13								
		OPT22604	4	2				10	14	23	31						
		OPT22606	6	2				10	14	23	31						
		OPT22609	9	2				10	14	23	31						
		OPT22612	12	2				10	14	23	31						
		OPT22614	14	2				10	14	23	31						
		OPT32606	6	3					15	24	33	44	47				
		OPT32609	9	3					15	24	33	44	47				
		OPT32612	12	3					15	24	33	44	47				
		OPT32614	14	3					15	24	33	44	47				
		OPT42606	6	4						25	35	48	50				
		OPT42609	9	4						25	35	48	50				
		OPT42612	12	4						25	35	48	50				
		OPT42614	14	4						25	35	48	50				
		OPT52606	6	5						25	36	49	52				
		OPT52609	9	5						25	36	49	52				
		OPT52612	12	5						25	36	49	52				
		OPT62609	9	6							36	51	53				
		OPT62612	12	6							36	51	53				
	27G	SAF-Q-109-G27	9	1				7	9	12	13	15	15				
BD 20 (302830)	26G	OPT12604	4	1			6	12	16								
		OPT12606	6	1			6	12	16								
		OPT12609	9	1			6	12	16								
		OPT12612	12	1			6	12	16								

Table 11	Drug	Flow Controller
	Xembify	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller												
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
		OPT12614	14	1			6	12	16								
		OPT22604	4	2				13	18	29							
		OPT22606	6	2				13	18	29							
		OPT22609	9	2				13	18	29							
		OPT22612	12	2				13	18	29							
		OPT22614	14	2				13	18	29							
		OPT32606	6	3					19	31	42						
		OPT32609	9	3					19	31	42						
		OPT32612	12	3					19	31	42						
		OPT32614	14	3					19	31	42						
		OPT42606	6	4						32	45	61	64				
		OPT42609	9	4						32	45	61	64				
		OPT42612	12	4						32	45	61	64				
		OPT42614	14	4						32	45	61	64				
		OPT52606	6	5						32	46	63	66				
		OPT52609	9	5						32	46	63	66				
		OPT52612	12	5						32	46	63	66				
		OPT62609	9	6						33	47	65	68				
		OPT62612	12	6						33	47	65	68				
	27G	SAF-Q-109-G27	9	1			6	9	11	15	17						
B.Braun 30 (4617304F)		OPT12604	4	1			5	9	12								
		OPT12606	6	1			5	9	12								
		OPT12609	9	1			5	9	12								
		OPT12612	12	1			5	9	12								
		OPT12614	14	1			5	9	12								
		OPT22604	4	2				10	14	22	30						
		OPT22606	6	2				10	14	22	30						
		OPT22609	9	2				10	14	22	30						
	26G	OPT22612	12	2				10	14	22	30						
		OPT22614	14	2				10	14	22	30						
		OPT32606	6	3						24	32	43	46				
		OPT32609	9	3						24	32	43	46				
		OPT32612	12	3						24	32	43	46				
		OPT32614	14	3						24	32	43	46				
		OPT42606	6	4						24	34	47	49				
		OPT42609	9	4						24	34	47	49				
		OPT42612	12	4						24	34	47	49				
		OPT42614	14	4						24	34	47	49				

Table 11	Drug	Flow Controller
	Xembify	Infuset

Values shaded in yellow are only suitable for maintenance infusions according to the drug's prescribing information.

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per Infuset flow controller												
	Gauge	REF#	Length (mm)	# of Needles	Infuset-45	Infuset-80	Infuset-120	Infuset-190	Infuset-290	Infuset-430	Infuset-650	Infuset-820	Infuset-930	Infuset-1850	Infuset-3200	Infuset-4000	Infuset-4300
		OPT52606	6	5						25	35	48	51				
		OPT52609	9	5						25	35	48	51				
		OPT52612	12	5						25	35	48	51				
		OPT62609	9	6							36	49	52				
		OPT62612	12	6							36	49	52				
	27G	SAF-Q-109-G27	9	1				7	9	11	13	15	15	18			
Monoject 35 (1183500777 or 8881535762)		OPT12604	4	1				7	10	15							
		OPT12606	6	1				7	10	15							
		OPT12609	9	1				7	10	15							
		OPT12612	12	1				7	10	15							
		OPT12614	14	1				7	10	15							
		OPT22604	4	2					11	18	24	31	33				
		OPT22606	6	2					11	18	24	31	33				
		OPT22609	9	2					11	18	24	31	33				
		OPT22612	12	2					11	18	24	31	33				
		OPT22614	14	2					11	18	24	31	33				
		OPT32606	6	3						19	26	34	36				
	26G	OPT32609	9	3						19	26	34	36				
		OPT32612	12	3						19	26	34	36				
		OPT32614	14	3						19	26	34	36				
		OPT42606	6	4							27	37	39				
		OPT42609	9	4							27	37	39				
		OPT42612	12	4							27	37	39				
		OPT42614	14	4							27	37	39				
		OPT52606	6	5							28	38	40				
		OPT52609	9	5							28	38	40				
		OPT52612	12	5							28	38	40				
		OPT62609	9	6								39	41				
		OPT62612	12	6								39	41				
	27G	SAF-Q-109-G27	9	1				6	7	9	10	12	12	14	15	15	15

Table 12					Drug: Xembify											
					Flow Controller: VersaRate Plus											
Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per VersaRate Plus position setting											
	Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
BD 30 (302832)	26G	OPT12604	4	1												
		OPT12606	6	1												
		OPT12609	9	1												
		OPT12612	12	1												
		OPT12614	14	1												
		OPT22604	4	2												
		OPT22606	6	2												
		OPT22609	9	2												
		OPT22612	12	2												
		OPT22614	14	2												
		OPT32606	6	3			43									
		OPT32609	9	3			43									
		OPT32612	12	3			43									
		OPT32614	14	3			43									
		OPT42606	6	4			47	59								
		OPT42609	9	4			47	59								
		OPT42612	12	4			47	59								
		OPT42614	14	4			47	59								
		OPT52606	6	5			48	61								
		OPT52609	9	5			48	61								
		OPT52612	12	5			48	61								
		OPT62609	9	6			49	63	105							
		OPT62612	12	6			49	63	105							
	27G	SAF-Q-109-G27	9	1			15	16	18	18						
BD 20 (302830)	26G	OPT12604	4	1												
		OPT12606	6	1												
		OPT12609	9	1												
		OPT12612	12	1												
		OPT12614	14	1												
		OPT22604	4	2												
		OPT22606	6	2												
		OPT22609	9	2												
		OPT22612	12	2												
		OPT22614	14	2												
		OPT32606	6	3												
		OPT32609	9	3												

Table 12	Drug	Flow Controller
	Xembify	VersaRate Plus

Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per VersaRate Plus position setting											
	Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
		OPT32612	12	3												
		OPT32614	14	3												
		OPT42606	6	4			60									
		OPT42609	9	4			60									
		OPT42612	12	4			60									
		OPT42614	14	4			60									
		OPT52606	6	5			61	77								
		OPT52609	9	5			61	77								
		OPT52612	12	5			61	77								
		OPT62609	9	6			63	80								
		OPT62612	12	6			63	80								
	27G	SAF-Q-109-G27	9	1												
B.Braun 30 (4617304F)		OPT12604	4	1												
		OPT12606	6	1												
		OPT12609	9	1												
		OPT12612	12	1												
		OPT12614	14	1												
		OPT22604	4	2												
		OPT22606	6	2												
		OPT22609	9	2												
		OPT22612	12	2												
		OPT22614	14	2												
		OPT32606	6	3			43	52								
	26G	OPT32609	9	3			43	52								
		OPT32612	12	3			43	52								
		OPT32614	14	3			43	52								
		OPT42606	6	4			46	57								
		OPT42609	9	4			46	57								
		OPT42612	12	4			46	57								
		OPT42614	14	4			46	57								
		OPT52606	6	5			47	59								
		OPT52609	9	5			47	59								
		OPT52612	12	5			47	59								
		OPT62609	9	6			48	61	102							
		OPT62612	12	6			48	61	102							

Table 12					Drug: Xembify											Flow Controller: VersaRate Plus
Syringe Type (Model #)	SUB-Q Set				Total flow rate (mL/h) for ALL sites per VersaRate Plus position setting											
	Gauge	REF#	Length (mm)	# of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
	27G	SAF-Q-109-G27	9	1			14	15	17	18	18					
Monoject 35 (1183500777 or 8881535762)	26G	OPT12604	4	1												
		OPT12606	6	1												
		OPT12609	9	1												
		OPT12612	12	1												
		OPT12614	14	1												
		OPT22604	4	2			31									
		OPT22606	6	2			31									
		OPT22609	9	2			31									
		OPT22612	12	2			31									
		OPT22614	14	2			31									
		OPT32606	6	3			34	41								
		OPT32609	9	3			34	41								
		OPT32612	12	3			34	41								
		OPT32614	14	3			34	41								
		OPT42606	6	4			36	45	72							
		OPT42609	9	4			36	45	72							
		OPT42612	12	4			36	45	72							
		OPT42614	14	4			36	45	72							
		OPT52606	6	5			37	47	76	93						
		OPT52609	9	5			37	47	76	93						
		OPT52612	12	5			37	47	76	93						
		OPT62609	9	6			38	49	81	100						
		OPT62612	12	6			38	49	81	100						
	27G	SAF-Q-109-G27	9	1			11	12	14	14	15	15	15	15	15	15

Troubleshooting

Possible causes for the VersaPump Infusion System not performing as expected might be:

Problem	Possible Cause	Correction
Syringe not compatible	Use of non-recommended syringe model.	Use only recommended syringe model listed on page 13.
Experiencing pain during insertion of needles	Incorrect insertion technique is used.	Pinch the skin to tighten the site where needles are inserted according to needle set Instructions for Use or consult your healthcare professional (see step 9 on page 10).
	Incorrect insertion site chosen.	Ensure needle is inserted into an appropriate infusion site as instructed by your healthcare professional. Do not insert into a previous infusion site where scar tissue may exist or into muscle tissue.
	Needle is not inserted at a 90-degree angle.	Ensure SUB-Q set wings are aligned while holding the needle and that the needle penetrates the skin at approximately 90 degrees during the insertion step.
	Tip of the needle can get damaged if SUB-Q set is mishandled.	Handle SUB-Q set with care and only remove needle protector shortly before inserting into the skin. Do not use a damaged needle set.
Components will not connect	Incorrect assembly, incorrect components, or damage of components.	Verify the syringe is properly connected to the flow controller and that the flow controller is correctly connected to the SUB-Q set. Use only the recommended components with the VersaPump Infuser.
Syringe disengages from the pump when the top cover is closed	Syringe was not properly loaded in the pump.	Open the top cover fully. Ensure the syringe flanges are horizontal and fully seated in the flange slots (see step 11 on page 10). Close the top cover fully to engage the drive.
	Use of non-recommended syringe model.	Use only recommended syringe model listed on page 13.
Difficult to open	User must apply enough force to overcome the spring mechanism.	Place the pump on a flat surface. With one hand, hold the lower portion of the pump near the latches. With the other hand, grasp the top cover near the latches and pull firmly until the top cover is fully open.
Fluid leak	Incorrect assembly or damage of components.	Verify Luer connectors are properly tightened. Do not overtighten as it may result in damage.
NO fluid flow	Infuser drive is not completely engaged.	Close the top cover fully until the latches engage. Refer to IFU step 12.
	Infuset flow controller is blocked by slide clamp.	For the Infuset, make sure that the slide clamp is not blocking the flow.

Problem	Possible Cause	Correction
NO fluid flow	VersaRate Plus flow controller dial is in the OFF position.	For the VersaRate Plus, make sure that the dial is set to the intended position and not on the 'OFF' position.
	Subcutaneous infusion set is blocked by slide clamp or pinched or kinked.	Verify that no other slide clamp is blocking the flow and that the tubing is not pinched or kinked.
	Occlusion of fluid path	Use new flow controller or SUB-Q set.
	When using the VersaRate Plus at the lower position settings such as 1 to 3 to infuse 20% IG (viscous) fluids, it may result in slower than expected or stopped flow rate.	Monitor the fluid volume progress throughout the infusion. If the flow rate is slower than expected, adjust the VersaRate Plus dial to a higher position setting to obtain the desired flow rate. If the flow rate completely stops, turn the VersaRate Plus dial to the **OPEN** position for a few seconds or until the fluid starts to flow, then rotate the dial back to the original position setting and continue to monitor the infusion progress. If the flow rate continues to stop, use a different VersaRate Plus device, or switch over to the VersaRate or Infuset flow controller devices.
Flow rate is **FAST**	Incorrect combination of SUB-Q set with flow controller or flow controller setting for the prescribed fluid.	Verify that the correct combination of SUB-Q set and Infuset or VersaRate Plus position is being used. Consult the appropriate flow rate data sheet or calculator for expected flow rate.
		If using VersaRate Plus, turn the dial to a lower setting to reduce the flow rate.
	Patient or environmental factors	Refer to section *Factors that Affect Flow Rate*.
Flow rate is **SLOW**	Incorrect combination of SUB-Q set with flow controller or flow controller setting for the prescribed fluid.	Verify that the correct combination of SUB-Q set and Infuset or VersaRate Plus position is being used. Consult the appropriate flow rate data sheet or calculator for expected flow rate.
		If using VersaRate Plus, turn the dial to a higher setting to increase the flow rate.
	Patient or environmental factors	Refer to section *Factors that Affect Flow Rate* and verify factors are within intended limits.
	Storage of the flow controller or SUB-Q set with the slide clamp engaged for an extended period of time may temporarily deform the tubing and decrease flow rate.	Do not store with slide clamp engaged for long periods of time.
	Partial occlusion of fluid path	Use new flow controller or SUB-Q set.

Problem	Possible Cause	Correction
Flow does not **STOP**	Flow controller is not set to 'OFF' position or slide clamp is not clamped.	Verify that the slide clamp on the Infuset is fully closed or that the VersaRate Plus is in the 'OFF' position.
		If the flow controller fails to stop the flow, fully open the VersaPump top cover to stop fluid flow.

NOTE:	If any of the above conditions persist or the VersaPump Infusion System is not performing as expected, discontinue use and contact EMED Technologies +1-916-932-0071 and/or your healthcare professional.

Warranty

Parties Covered:

This warranty extends only to the Original Purchaser of the VersaPump Infuser, and it does not extend to subsequent purchasers or users. The "Original Purchaser" is the person purchasing the VersaPump Infuser from the Manufacturer or Manufacturers Representative.

Limited Warranty:

EMED Technologies Corporation ("Manufacturer") warrants the VersaPump Infuser to be free from defects in materials and workmanship for three (3) years from the date of original purchase when used as intended and under the direction of authorized medical personnel. Failure to comply with these conditions will result in a void warranty.

Use of accessories or components not specified in the VersaPump Infusion System User Manual may impact immunoglobulin solution flow rates, result in a flow rate outside of what has been approved for immunoglobulin solution, and is not recommended. The Manufacturer does not represent that the VersaPump Infusion System will operate in accordance with performance specifications if third party accessories are used.

Replacement:

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 discretion, any VersaPump Infuser, or part thereof, which has been received by the Manufacturer or Manufacturer's Representative within the three-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 three-year warranty period.

Notes:

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