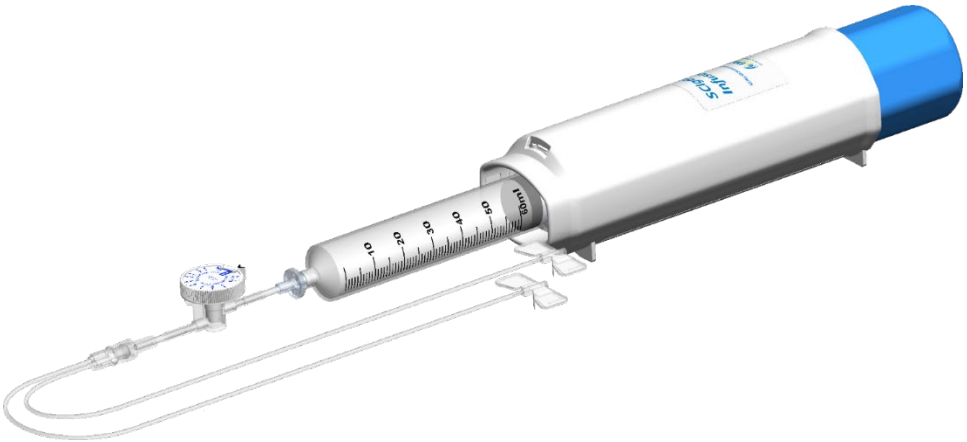
User Manual

SCIg60™ 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 SCIg60 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

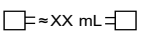
The following terms are defined below and referenced throughout the document:

Defined Term	Meaning
Infuset	Infuset™ fixed rate flow control accessory
IFU	Instructions for Use
Pump	SCIg60™ Infuser
SCIg60	SCIg60™ Infusion System
SUB-Q Set	Subcutaneous Administration Set
VersaRate	VersaRate® Variable rate flow control accessory
VersaRate Plus	VersaRate® Plus Variable rate flow control accessory

Symbols

EMED Symbol Glossary can be found at the following website: https://www.emedtc.com/support

The following symbols may be found on the SCIg60 Infusion System labeling and packaging materials:

Symbol	Definition	Symbol	Definition
	Caution		Manufacturer
	Read the instructions		EC Representative
	Medical Device		CE Mark
RxOnly	To sale by or on the order of a physician.		Importer
	Do not re-use		Reference number
	Don’t use if package is damaged		Serial number
	Sterilized by Ethylene Oxide		Manufacturing date
	Single sterile barrier system		Country of Manufacture
	This product is not made with latex		Batch number
	Is not made with di(2-ethylhexyl) phthalate (DEHP)		Expiration date
	Non-pyrogenic fluid path		Quantity
	Fluid Path		Length
	Storage temperature limits		Approximate priming volume

SCIg60™ Infusion System

Introduction

The SCIg60 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 SCIg60 Infusion System provides a portable and effective way to subcutaneously infuse prescribed fluids.

Description

The SCIg60 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:

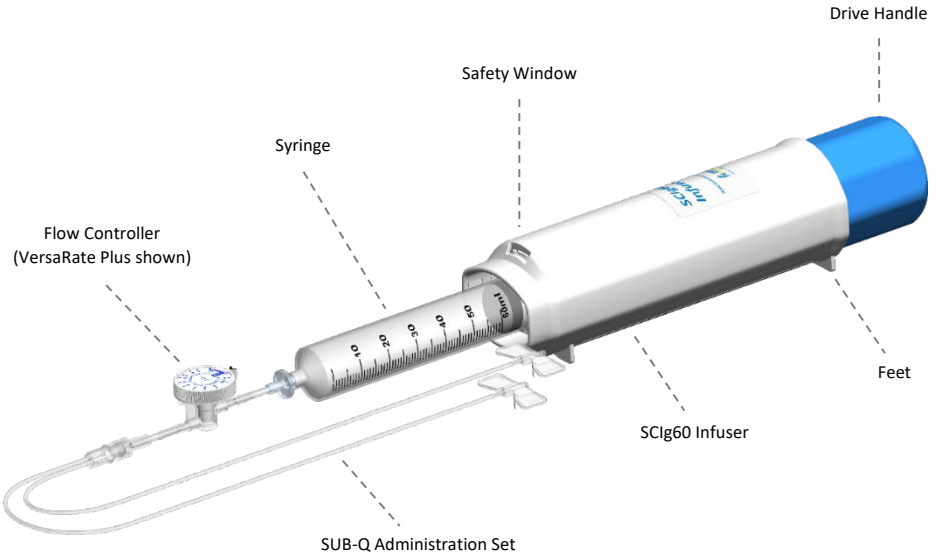
Component	Model Information
SCIg60™ Infuser with Carrying Case	FP-0010002
BD 50 mL Syringe	309653
Flow Controller	Infuset™, VersaRate®, or VersaRate® Plus (See table below)
Administration Set	SUB-Q, SAF-Q®, or OPTFlow®

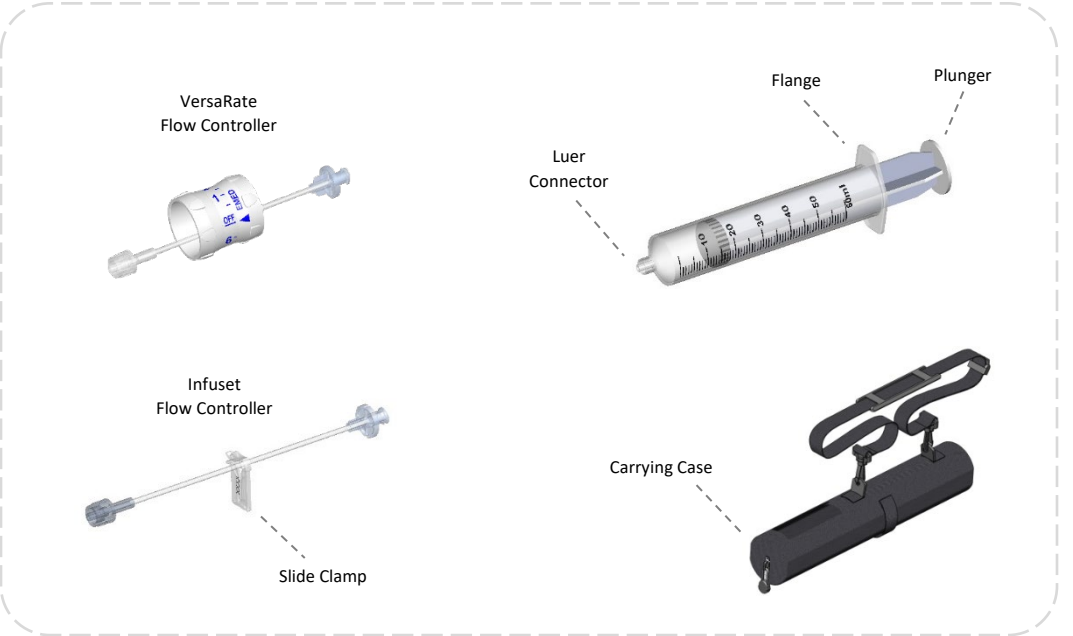
The syringe, flow controller and administration set are sold separately. The syringe component is not manufactured by EMED and is available for purchase from the manufacturer.

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 viscosity of the prescribed fluid, the type of SUB-Q administration set being used, and patient factors. See section *System Flow Rate Performance* for additional information. The following flow controllers are recommended for use with the SCIg60 Infuser 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	FP-0010003
VersaRate Plus	FP-0010026

System Diagram





Indications

The SCIg60 Infusion System is intended for use in the home or hospital environment for the subcutaneous infusion of:

- Cuvitru Immune Globulin Infusion (Human) 20%, manufactured by Takeda,
- Gammagard Liquid, Immune Globulin Infusion (Human) 10%, manufactured by Takeda, and
- Hizentra Immune Globulin Subcutaneous (Human) 20%, manufactured by CSL Behring,

with the BD 50 ml syringe (model no. 309653). The system is intended for single patient, multiple use only.

Contraindications

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

Alarms

The SCIg60 Infuser is a mechanical infusion pump which does NOT have alarms or indicators.

Limitations

The principle of operation of the SCIg60 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 flow controller, the rate can be adjusted manually if needed. For more information, reference the *Factors that Affect Flow Rate* and *Troubleshooting* sections.

The SCIg60 Infuser does not have any 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.

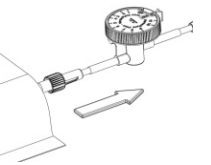
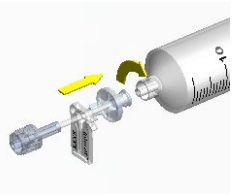
Warnings and Precautions

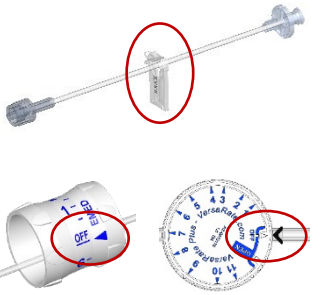
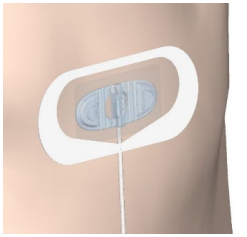
Warnings:

- Use the SCIg60 Infusion System ONLY for its intended use and as prescribed by your healthcare professional.
- Read and follow all instructions for the SCIg60 Infusion System and applicable components prior to use.
- Healthcare professionals and users should read the indicated immunoglobulin fluid's contraindications, instructions, and warnings prior to initiating delivery of fluid.
- Do NOT use SCIg60 Infusion System while undergoing medical diagnostic procedures, such as MRI, X-ray, or CT scans.
- Use ONLY the listed administration sets, flow controllers and BD syringe (Model No. 309653) with the SCIg60 Infusion System. Use of other infusion accessories may result in unsafe conditions for patient or deviation from desired infusion rates.
- Do NOT store indicated immunoglobulin fluid in the syringe prior to use. Prepare the SCIg60 Infusion System and initiate therapy immediately after transferring indicated immunoglobulin fluids to the syringe.
- Use aseptic technique when handling fluid, syringe, flow controller, and subcutaneous administration set.
- Do NOT insert or remove the syringe until the DRIVE HANDLE is fully opened, as instructed in the Instructions for Use section.
- Do NOT use flow controller, administration 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, doing so may cause serious personal injury.
- Do NOT open the Infuser or attempt to modify its function in any way other than its intended use.

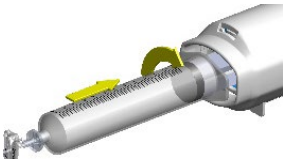
Cautions:

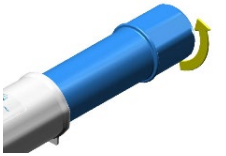
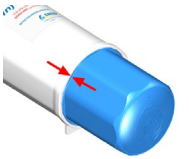
- U.S. Federal law restricts this device to sale by or on the order of a physician.
- Place the SCIg60 Infusion pump on a flat surface or in the provided carrying case during use. Syringe damage and fluid loss may occur if the SCIg60 Infusion System is dropped while loaded.
- Do NOT continue to use an SCIg60 Infuser that has been damaged, dropped, or if it has failed to perform as expected. If any damage is suspected, contact EMED Technologies.
- Do NOT subject the Infuser to autoclaving or other similar methods of sterilization. Avoid exposing the SCIg60 pump or carrying case to temperatures outside of recommended range.
- Do NOT use multiple flow control accessories at one time (e.g., connecting one Infuset to another, connecting an Infuset to a VersaRate, etc.) because the flow rates provided in this manual are for a single Infuset or VersaRate only.

Step	Instruction	Image
	Prepare Infusion	
1	**WASH HANDS** thoroughly and dry hands before handling any supplies. Wear gloves if you have been instructed to do so. **WARNING**: Use aseptic technique throughout procedure.	
2	**REMOVE** Flow controller, administration set and syringe from sterile packaging. **WARNING**: Read and follow all instructions for the components prior to use.	
3	**TRANSFER** indicated fluid from vial(s) to BD 50 ml syringe (model no. 309653) according to the package insert or as instructed by your healthcare professional. Immediately proceed to next step. **WARNING**: Do NOT store indicated immunoglobulin fluid in the syringe prior to use	
4	**CONNECT** syringe male Luer lock (MLL) to Infuset or VersaRate female Luer lock (FLL).	
5	**CONNECT** Infuset or VersaRate male Luer lock (MLL) to specified patient administration set female Luer lock (FLL).	

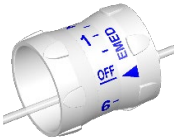
Step	Instruction	Image
6	**PRIME** the tubing by gently pushing on the syringe plunger to fill the tubing with fluid or as instructed by your healthcare professional.	
7	**CLOSE** flow control accessory. Use slide clamp provided with Infuset or select the 'OFF' position on the VersaRate to prevent flow of fluid.	
8	**PREPARE INJECTION SITES** and **INSERT NEEDLES** according to the indicated medication package insert, specified administration set instructions, or as instructed by your healthcare professional. **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 and tubing.	

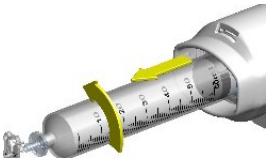
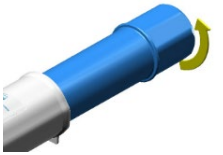
Load Pump

9	**OPEN** SCIg60 Infuser drive by turning the handle counterclockwise until it stops.	
10	**LOAD** syringe into SCIg60 Infuser by inserting the syringe plunger into the SCIg60 infuser.	
11	**LOCK** syringe into SCIg60 Infuser by turning the syringe clockwise until it stops.	

Step	Instruction	Image
12	**VERIFY** the syringe flange is visible in the safety window of SCIg60 Infuser to confirm the syringe is properly locked in place.	
13	**CLOSE** SCIg60 Infuser drive by rotating the handle clockwise until the base of the handle touches the body of the pump, as shown in the second image. **CAUTION:** **DO NOT ATTEMPT** to remove the syringe before performing STEP 16.	 
14	**PLACE** the SCIg60 Infuser, Infuset or VersaRate, and specified administration set on a stable, horizontal surface or use the Carrying Case Accessory (see Using the SCIg60 Infuser Carrying Case Accessory below for more details).	

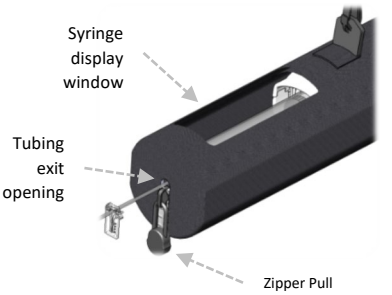
Start Infusion

15	When using **Infuset**: a) To **START** infusion, **USE SLIDE CLAMP** once pump is fully loaded and needles are inserted and secured. 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**: a) To **START** infusion, **TURN VersaRate to flow position** as directed by your healthcare professional once pump is fully loaded and needles are inserted and secured. b) **MONITOR** infusion by viewing the syringe volume. c) To **STOP** infusion, **TURN VersaRate To 'OFF'** position as necessary during infusion session or when session is complete.	 

Step	Instruction	Image
	Stop Infusion	
16	When session is complete, to remove the syringe **ROTATE** the handle counterclockwise until it stops, **THEN UNLOCK THE SYRINGE** by turning it counterclockwise. **NOTE:** If the infusion protocol requires more than one syringe to be administered, repeat steps 3 – 16 in sequence. It is recommended to perform the infusions sequentially without a delay in time.	 
17	**DISPOSE** of the syringe, Infuset or VersaRate, and SUB-Q set in an appropriate biohazard and/or sharps waste container according to your local regulations. **WARNING**: Read and follow all instructions for the components.	
18	**CLOSE** SCIg60 Infuser drive by rotating the handle clockwise until the base of the handle touches the body of the pump. **CLEAN** and **STORE** SCIg60 Infuser and Carrying Case for next use.	

NOTE:

- Instructions for Use also appear on the underside of the Infuser.
- During infusion, an intermittent clicking sound may occur as the spring extends. This is normal. See *Troubleshooting* section for additional information.

Step	Instruction	Image
	Insert	
1	Obtain the carrying case and place on a safe tabletop to prevent dropping.	
2	Open pouch by pulling the zipper.	
3	After loading the syringe and closing the inner drive per step 13 above, insert SCIg60 Infuser with syringe and flow controller into the pouch oriented with the syringe to show from the display window. The syringe should face away from the zipper pull, and the tubing should exit the Carrying Case through the small opening below the zipper. **CAUTION:** Use caution not to drop the device.	
4	Close the pouch with the zipper **CAUTION:** Use caution to prevent damage to the tubing.	
5	Use belt loop or shoulder strap to hold and carry the system on the body.	
	Remove	
6	Place the Carrying Case containing the SCIg60 system and place on a safe tabletop to prevent dropping	
7	Open the pouch by pulling the zipper.	
8	Remove the SCIg60 System from the pouch using caution not to drop the device.	
9	Close the Carrying Case zipper.	

Maintenance

The infuser 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 SCIg60 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).
- Clean exterior surfaces by gently pressing onto the SCIg60 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.

CAUTION:	• Clean only those areas that are exposed when the Infuser Drive Handle is completely screwed in. Do not attempt to clean any part of the SCIg60 Infuser that is not easily accessible. • Discontinue use of an SCIg60 Infuser that has been internally exposed to or immersed in fluid. • Do not use heating devices to dry or expose infuser to high temperatures. Damage to the infuser may occur.

Cleaning the carrying case:

Only clean surface with a clean damp cloth and let it air dry.

CAUTION:	Do not machine wash the carrying case as it could damage the materials.

Storage

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

CAUTION:	Avoid exposing the SCIg60 pump or carrying case to temperatures outside of recommended range.

Disposal

The SCIg60 Infuser Pump and Carrying Case can be disposed of in general waste collection systems. Please ensure compliance with local regulations.

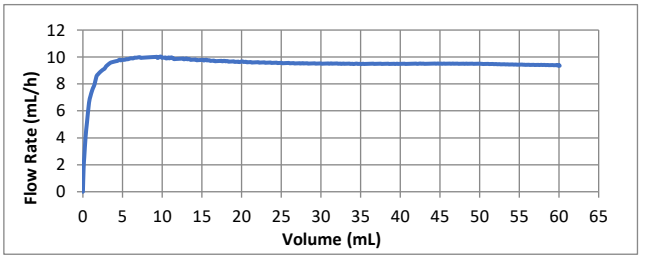
WARNING:	Do NOT open the Infuser or attempt to modify its function in any way other than its intended use.

The administration 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 regulations.

WARNING:	Read and follow all instructions for the components.

SCIg60™ Infusion System

Specifications

SCIg60 Infuser Length	26.0 cm (10.2 in.)
SCIg60 Infuser Width	6.5 cm (2.6 in.)
SCIg60 Infuser Weight	412 g (14.5 oz)
SCIg60 Infuser Alarms	None
Syringe Volume	50 mL (BD 50 mL syringe model no. 309653)
Maximum Operating Pressure	1.16 bar (16.8 psi)
Average Operating Pressure	1.0 bar (14.4 psi)
Storage Temperature	-5°C – +40°C (23°F – 104°F)
Target Operating Temperature	20°C – 25°C (68°F – 77°F)
Total System Accuracy: Using Infuset and SUB-Q set Using VersaRate and SUB-Q set: @ Position ½ @ Position 1 @ Position 2 @ Position 3 @ Position 4 @ Position 5 @ Position 6 Using VersaRate Plus and SUB-Q set: @ Position 1-2 @ Position 3-5 @ Position 6-10 @ Position 11-OPEN	**% Change from nominal flow rate:** ±15% Up to ±33% Up to ±37% Up to ±26% Up to ±22% Up to ±15% Up to ±15% Up to ±15% Up to ±41% Up to ±21% Up to ±20% Up to ±14%
Maximum Vertical Difference	±30.0 cm (±12 in.)
Vertical Sensitivity: Each 30.5 cm (12 in.) above infusion site Each 30.5 cm (12 in.) below infusion site	**% Change from nominal flow rate:** Up to +6% Up to -4%
Residual Volume	System residual volume depends on the combination of component residuals: Syringe: ≈ 0.2 mL, Flow Controller: ≈ 0.05 – 0.25 mL depending on model, SUB-Q set: ≈ 0.18 – 1.87 mL depending on model. See individual component instructions for specific residual values.
Useful Life	4200 cycles
Representative Flow Profile *The figure shows the Total Flow Rate vs. Infused Volume at 20°C – 25°C under laboratory conditions achieved with SUB-320 (3-needle, 27G 9-mm set) and FP-001008 (Infuset-190). Although realized flow rates are determined by the combination of Infuset and SUB-Q set used, the flow rate profile remains the same due to the design and principle of action of the SCIg60 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 SCIg60 Infuser and selection of the appropriate Infuset or VersaRate accessories.

Factors That Affect Flow Rate:		
LARGE EFFECT	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°C – 25°C (68°F – 77°F).
	Viscosity of Fluid	Differences in fluid viscosity significantly affect the system flow rate for a given system configuration. Various flow control accessories and SUB-Q set combinations are available to achieve flow rates according to specific clinical requirements.
MODERATE EFFECT	Administration Sets and Needle Gauge	The effect of the administration set and needle size depend on the dimensions of the fluid path. SCIg60 Infusion System is designed to work with a wide range of administration sets and needle gauges from 18 to 29G. Appropriate administration 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.
	Patient Factors	• Tissue back pressure • Tissue absorption rate • Body Mass Index • Age • Health
SMALL EFFECT	Infuser Relative Height	Difference in relative height between the infuser and the patient has a minimal effect on flow rate.
	Atmospheric Pressure	Difference in atmospheric pressure has 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:

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

System Setup for Infusion Rates

See **www.VersaRate.com** for an electronic version of the following information.

In the following pages you will find tables that can be used to identify the combination of the EMED administration needle set and the Infuset flow control accessory or VersaRate position that will provide a flow rate that may accommodates the patient's need for infusion while falling within drug manufacturer's recommended prescribing limits. Flow rate information for use with the Infuset, VersaRate and VersaRate Plus will be presented separately for each of the indicated immunoglobulin fluids that are to be used with the SCIg60 Infusion System. In the case of Hizentra, separate flow rate tables have also 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 of a single Infuset or a VersaRate at a single position and EMED SUB-Q infusion sets. Testing was performed between 20°C – 25°C (68°F – 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, needles model, needle length, number of needle sites, and/or 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 position not specified in the tables on the following pages may result in a flow rate outside of what has been approved for a specific immunoglobulin fluid.

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 Cuvitru

The tables below only include combinations that will provide both total and per site flow rates that are within Cuvitru dosage limits after system tolerances are applied. Cells shaded in gray do not have values listed because testing has not been performed or the value exceeds the dosage limits. Cells shaded in white are suitable for initial and maintenance infusions. Cells shaded in yellow are only suitable for maintenance infusions.

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

With Infuset:

Table 1: Cuvitru with Infuset*

Needle Set				Total mL/h vs. Infuset												
Gauge	REF#	Length (mm)	Number 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
24G	SUB-109-G24	9	1				11	14	17			31				
	SUB-112-G24	12	1				10	13	16			28	50			
	SUB-209-G24	9	2						20	32		42	94			
	SUB-212-G24	12	2						18	29		38	85	101		
	SUB-309-G24	9	3							35		45	118			
	SUB-312-G24	12	3							32		41	107			
	SUB-409-G24	9	4									49	145			
	SUB-412-G24	12	4									44	132			
	SAF-Q-106-G24	6	1				12	15	19			33				
	SAF-Q-109-G24	9	1				11	14	17			31				
	SAF-Q-309-G24	9	3							35		45	118			
26G	OPT12604	4	1					15	19	26		31	48			
	OPT12606	6	1					15	19	26		31	48			
	OPT12609	9	1					15	19	26		31	48			
	OPT12612	12	1					15	19	26		31	48			
	OPT22604	4	2							32		45	94			
	OPT22606	6	2							32		45	94			
	OPT22609	9	2							32		45	94			
	OPT22612	12	2							32		45	94			
	OPT32606	6	3									51	122			
	OPT32609	9	3									51	122			
	OPT32612	12	3									51	122			
	OPT42606	6	4									52	146	194		
	OPT42609	9	4									52	146	194		
	OPT42612	12	4									52	146	194		

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

With VersaRate:

Table 2: Cuvitru with VersaRate*									
Needle Set				Total mL/h vs. VersaRate #					
Gauge	REF#	Length (mm)	Number of Needles	1	2	3	4	5	6
24G	SUB-109-G24	9	1	11	17	26	35	47	
	SUB-112-G24	12	1	10	16	24	32	43	
	SUB-209-G24	9	2	11	20	33	50	87	
	SUB-212-G24	12	2	10	18	30	45	79	
	SUB-309-G24	9	3	11	21	35	58	107	
	SUB-312-G24	12	3	10	19	32	53	97	
	SUB-409-G24	9	4	12	23	37	65	141	
	SUB-412-G24	12	4	11	21	34	59	128	
	SAF-Q-106-G24	6	1	12	19	28	38		
	SAF-Q-109-G24	9	1	11	17	26	35	47	
	SAF-Q-309-G24	9	3	11	21	35	58	107	
26G	OPT12604	4	1	13	20	28	33	47	
	OPT12606	6	1	13	20	28	33	47	
	OPT12609	9	1	13	20	28	33	47	
	OPT12612	12	1	13	20	28	33	47	
	OPT22604	4	2		24	38	54	83	
	OPT22606	6	2		24	38	54	83	
	OPT22609	9	2		24	38	54	83	
	OPT22612	12	2		24	38	54	83	
	OPT32606	6	3			41	65	106	
	OPT32609	9	3			41	65	106	
	OPT32612	12	3			41	65	106	
	OPT42606	6	4			43	70	119	
	OPT42609	9	4			43	70	119	
	OPT42612	12	4			43	70	119	

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

With VersaRate Plus:

Table 3: Cuvitru with VersaRate Plus*

Needle Set				Total mL/h vs. VersaRate Plus #											
Gauge	REF#	Length (mm)	Number of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
24G	SUB-109-G24	9	1		17	31	41								
	SUB-112-G24	12	1		16	29	38	44	48	50	50				
	SUB-209-G24	9	2		21	50	72	88	98						
	SUB-212-G24	12	2		19	46	66	80	90	95	99				
	SUB-309-G24	9	3		25	61	89	113	131	145					
	SUB-312-G24	12	3		23	55	81	103	119	132	141	147			
	SUB-409-G24	9	4		29	59	92	126	158	187					
	SUB-412-G24	12	4		26	54	84	114	144	170	192				
	SAF-Q-106-G24	6	1		19	34	45								
	SAF-Q-109-G24	9	1		17	31	41								
	SAF-Q-309-G24	9	3		25	61	89	113	131	145					
26G	OPT12604	4	1	9	20	34	43	48	52	53					
	OPT12606	6	1	9	20	34	43	48	52	53					
	OPT12609	9	1	9	20	34	43	48	52	53					
	OPT12612	12	1	9	20	34	43	48	52	53					
	OPT22604	4	2		21	37	63	87	102						
	OPT22606	6	2		21	37	63	87	102						
	OPT22609	9	2		21	37	63	87	102						
	OPT22612	12	2		21	37	63	87	102						
	OPT32606	6	3		27	48	79	110	135	151	163				
	OPT32609	9	3		27	48	79	110	135	151	163				
	OPT32612	12	3		27	48	79	110	135	151	163				
	OPT42606	6	4			63	92	129	163	189	207	219			
	OPT42609	9	4			63	92	129	163	189	207	219			
	OPT42612	12	4			63	92	129	163	189	207	219			
27G	SUB-104-G27	4	1			15	17	18	19	20	20	20	21	21	21
	SUB-106-G27	6	1			14	16	17	18	19	19	19	20	20	20
	SUB-109-G27	9	1			13	15	16	16	17	17	18	18	18	18
	SUB-112-G27	12	1			12	13	14	15	15	16	16	16	16	17
	SUB-204-G27	4	2			29	34	37	40	41	42	43	44	45	47
	SUB-212-G27	12	2			23	27	30	31	33	34	34	35	35	37
	SUB-250	6	2			27	32	35	38	39	40	41	42	42	45
	SUB-260	9	2			25	30	33	34	36	37	38	38	39	41
	SUB-310	6	3			33	44	51	54	55	55	56	56	56	61
	SUB-312-G27	12	3			27	37	42	45	46	46	46	47	47	51
	SUB-320	9	3			30	41	47	49	50	51	51	51	51	56
	SUB-400	6	4			45	58	69	76	80	83	84	85	86	93
	SUB-410	9	4			41	53	63	70	74	76	77	78	79	85
	SUB-412-G27	12	4			38	49	58	64	67	69	70	71	72	77
	SUB-414-G27	14	4			35	45	54	59	63	65	66	67	67	72
	SAF-Q-106-G27	6	1			14	16	17	18	19	19	19	20	20	20
	SAF-Q-109-G27	9	1			13	15	16	16	17	17	18	18	18	18
	SAF-Q-112-G27	12	1			12	13	14	15	15	16	16	16	16	17
	SAF-Q-206-G27	6	2			27	32	35	38	39	40	41	42	42	45

Table 3: Cuvitru with VersaRate Plus*															
Needle Set				Total mL/h vs. VersaRate Plus #											
Gauge	REF#	Length (mm)	Number of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
27G	SAF-Q-209-G27	9	2			25	30	33	34	36	37	38	38	39	41
	SAF-Q-212-G27	12	2			23	27	30	31	33	34	34	35	35	37
	SAF-Q-306-G27	6	3			33	44	51	54	55	55	56	56	56	61
	SAF-Q-309-G27	9	3			30	41	47	49	50	51	51	51	51	56
	SAF-Q-312-G27	12	3			27	37	42	45	46	46	46	47	47	51
	SAF-Q-406-G27	6	4			45	58	69	76	80	83	84	85	86	93
	SAF-Q-409-G27	9	4			41	53	63	70	74	76	77	78	79	85
	SAF-Q-412-G27	12	4			38	49	58	64	67	69	70	71	72	77

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

Infusing Gammagard

The tables below only include combinations that will provide both total and per site flow rates that are within Gammagard dosage limits after system tolerances are applied. Cells shaded in gray do not have values listed because testing has not been performed or the value exceeds the dosage limits. Cells shaded in white are suitable for initial and maintenance infusions. Cells shaded in yellow are only suitable for maintenance infusions.

Table Legend:

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

With Infuset for patients under 40 kg (88 lb.):

Table 4a: Gammagard with Infuset for patients under 40 kg (88 lb.)*																
Needle Set				Total mL/h vs. Infuset												
Gauge	REF#	Length (mm)	Number 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
24G	SUB-109-G24	9	1	15												
	SUB-112-G24	12	1	14												
	SUB-209-G24	9	2		25	29										
	SUB-212-G24	12	2		23	26										
	SUB-409-G24	9	4			29										
	SUB-412-G24	12	4			26										
	SUB-512-G24	12	5				63									
	SUB-612-G24	12	6					95								
	SAF-Q-106-G24	6	1	16												
	SAF-Q-109-G24	9	1	15												
26	OPT12604	4	1	13												
	OPT12606	6	1	13												

Table 4a: Gammagard with Infuset for patients under 40 kg (88 lb.)*

Needle Set				Total mL/h vs. Infuset												
Gauge	REF#	Length (mm)	Number 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
26G	OPT12609	9	1	13												
	OPT12612	12	1	13												
	OPT22604	4	2	14	26											
	OPT22606	6	2	14	26											
	OPT22609	9	2	14	26											
	OPT22612	12	2	14	26											
	OPT32606	6	3			31										
	OPT32609	9	3			31										
	OPT32612	12	3			31										
	OPT42606	6	4			33	68									
	OPT42609	9	4			33	68									
	OPT42612	12	4			33	68									
	OPT52606	6	5			32	67									
	OPT52609	9	5			32	67									
	OPT52612	12	5			32	67									
	OPT62609	9	6				65									
	OPT62612	12	6				65									
27G	SUB-104-G27	4	1	15												
	SUB-106-G27	6	1	14												
	SUB-109-G27	9	1	13												
	SUB-112-G27	12	1	12												
	SUB-204-G27	4	2			28										
	SUB-250	6	2			27										
	SUB-260	9	2			25										
	SUB-212-G27	12	2			22										
	SUB-320	9	3				51									
	SUB-312-G27	12	3				47									
	SUB-414-G27	14	4					68								
	SUB-506	6	5				62									
	SUB-509	9	5				57									
	SUB-606	6	6					96								
	SUB-609	9	6					88								
	SAF-Q-106-G27	6	1	14												
	SAF-Q-109-G27	9	1	13												
	SAF-Q-112-G27	9	1	12												
	SAF-Q-206-G27	9	2			27										
	SAF-Q-209-G27	12	2			25										
	SAF-Q-212-G27	12	2			22										
	SAF-Q-309-G27	6	3				51									
	SAF-Q-312-G27	9	3				47									
	SAF-Q-509-G27	9	5				57									
	SAF-Q-609-G27	9	6					88								

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

With Infuset for patients over 40 kg (88 lb.):

Table 4b: Gammagard with Infuset for patients over 40 kg (88 lb.)*

Needle Set				Total mL/h vs. Infuset												
Gauge	REF#	Length (mm)	Number 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
24G	SUB-109-G24	9	1	15	24											
	SUB-112-G24	12	1	14	21	25										
	SUB-209-G24	9	2		25	29										
	SUB-212-G24	12	2		23	26										
	SUB-309-G24	9	3				57									
	SUB-312-G24	12	3				52									
	SUB-409-G24	9	4			29		94								
	SUB-412-G24	12	4			26		86								
	SUB-512-G24	12	5				63									
	SUB-612-G24	12	6					95								
	SAF-Q-106-G24	6	1	16	26											
	SAF-Q-109-G24	9	1	15	24											
	SAF-Q-309-G24	9	3				57									
26G	OPT12604	4	1	13	25											
	OPT12606	6	1	13	25											
	OPT12609	9	1	13	25											
	OPT12612	12	1	13	25											
	OPT22604	4	2	14	26	36										
	OPT22606	6	2	14	26	36										
	OPT22609	9	2	14	26	36										
	OPT22612	12	2	14	26	36										
	OPT32606	6	3			31	66									
	OPT32609	9	3			31	66									
	OPT32612	12	3			31	66									
	OPT42606	6	4			33	68									
	OPT42609	9	4			33	68									
	OPT42612	12	4			33	68									
	OPT52606	6	5			32	67	103								
	OPT52609	9	5			32	67	103								
	OPT52612	12	5			32	67	103								
	OPT62609	9	6				65	109	135							
	OPT62612	12	6				65	109	135							
27G	SUB-104-G27	4	1	15	23	25										
	SUB-106-G27	6	1	14	22	24										
	SUB-109-G27	9	1	13	20	22										
	SUB-112-G27	12	1	12	18	20										
	SUB-204-G27	4	2			28										
	SUB-250	6	2			27										
	SUB-260	9	2			25	47									
	SUB-212-G27	12	2			22	43									

Table 4b: Gammagard with Infuset for patients over 40 kg (88 lb.)*																
Needle Set				Total mL/h vs. Infuset												
Gauge	REF#	Length (mm)	Number 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
27G	SUB-310	6	3				56	77								
	SUB-320	9	3				51	71								
	SUB-312-G27	12	3				47	64								
	SUB-400	6	4					87								
	SUB-410	9	4					80								
	SUB-412-G27	12	4					72	103							
	SUB-414-G27	14	4					68	96							
	SUB-506	6	5				62									
	SUB-509	9	5				57		121							
	SUB-606	6	6					96								
	SUB-609	9	6					88								
	SAF-Q-106-G27	6	1	14	22	24										
	SAF-Q-109-G27	9	1	13	20	22										
	SAF-Q-112-G27	9	1	12	18	20										
	SAF-Q-206-G27	9	2			27										
	SAF-Q-209-G27	12	2			25	47									
	SAF-Q-212-G27	12	2			22	43									
	SAF-Q-306-G27	14	3				56	77								
	SAF-Q-309-G27	6	3				51	71								
	SAF-Q-312-G27	9	3				47	64								
	SAF-Q-406-G27	9	4					87								
	SAF-Q-409-G27	6	4					80								
	SAF-Q-412-G27	9	4					72	103							
	SAF-Q-509-G27	9	5				57		121							
	SAF-Q-609-G27	9	6					88								

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

With VersaRate for patients under 40 kg (88 lb.):

Table 5a: Gammagard with VersaRate for patients under 40 kg (88 lb.)*

Needle Set				Total mL/h vs. VersaRate #						
Gauge	REF#	Length (mm)	Number of Needles	½	1	2	3	4	5	6
26G	OPT42606	6	4	41						
	OPT42609	9	4	41						
	OPT42612	12	4	41						
	OPT52606	6	5	40	72					
	OPT52609	9	5	40	72					
	OPT52612	12	5	40	72					
	OPT62609	9	6		82					
	OPT62612	12	6		82					
27G	SUB-320	9	3	42						
	SUB-312-G27	12	3	38						
	SUB-400	6	4	51						
	SUB-410	9	4	47						
	SUB-412-G27	12	4	43	59					
	SUB-414-G27	14	4	40	55					
	SUB-506	6	5	46	77					
	SUB-509	9	5	42	71					
	SAF-Q-309-G27	9	3	42						
	SAF-Q-312-G27	12	3	38						
	SAF-Q-406-G27	6	4	51						
	SAF-Q-409-G27	9	4	47						
	SAF-Q-412-G27	12	4	43	59					
	SAF-Q-509-G27	9	5	42	71					

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

The VersaRate flow regulator has markings around the circumference of the rotating dial denoting position settings that reference flow rates. Six markings have been designated with sequential numbers 1-6, with additional demarcations between each number. These demarcations between the numbers represent additional reference points that can be used to assist in controlling flow rates between the numbered position settings. The first of these reference points between OFF and Position 1, will be referred to as Position ½.

With VersaRate for patients over 40 kg (88 lb.):

Table 5b: Gammagard with VersaRate for patients over 40 kg (88 lb.)*

Needle Set				Total mL/h vs. VersaRate #						
Gauge	REF#	Length (mm)	Number of Needles	½	1	2	3	4	5	6
26G	OPT22604	4	2	35						
	OPT22606	6	2	35						
	OPT22609	9	2	35						
	OPT22612	12	2	35						
	OPT32606	6	3	45						
	OPT32609	9	3	45						
	OPT32612	12	3	45						
	OPT42606	6	4	41	81					
	OPT42609	9	4	41	81					
	OPT42612	12	4	41	81					
	OPT52606	6	5	40	72					
	OPT52609	9	5	40	72					
	OPT52612	12	5	40	72					
	OPT62609	9	6		82	148				
	OPT62612	12	6		82	148				
27G	SUB-260	9	2	43						
	SUB-212-G27	12	2	39						
	SUB-310	6	3	46	66					
	SUB-320	9	3	42	60					
	SUB-312-G27	12	3	38	55					
	SUB-400	6	4	51	71					
	SUB-410	9	4	47	65					
	SUB-412-G27	12	4	43	59					
	SUB-414-G27	14	4	40	55					
	SUB-506	6	5	46	77					
	SUB-509	9	5	42	71					
	SAF-Q-209-G27	9	2	43						
	SAF-Q-212-G27	12	2	39						
	SAF-Q-306-G27	6	3	46	66					
	SAF-Q-309-G27	9	3	42	60					
	SAF-Q-312-G27	12	3	38	55					
	SAF-Q-406-G27	6	4	51	71					
	SAF-Q-409-G27	9	4	47	65					
	SAF-Q-412-G27	12	4	43	59					
	SAF-Q-509-G27	9	5	42	71					

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

With VersaRate Plus for patients under 40 kg (88 lb.):

Table 6a: Gammagard with VersaRate Plus for patients under 40 kg (88 lb.)*

Needle Set				Total mL/h vs. VersaRate Plus #											
Gauge	REF#	Length (mm)	Number of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
27G	SUB-320	9	3	46											
	SUB-312-G27	12	3	42											
	SUB-400	6	4	56											
	SUB-410	9	4	51											
	SUB-412-G27	12	4	47											
	SUB-414-G27	14	4	43											
	SUB-506	6	5	57											
	SUB-509	9	5	53											
	SUB-606	6	6	56											
	SUB-609	9	6	52	102										
	SAF-Q-309-G27	9	3	46											
	SAF-Q-312-G27	12	3	42											
	SAF-Q-406-G27	6	4	56											
	SAF-Q-409-G27	9	4	51											
	SAF-Q-412-G27	12	4	47											
	SAF-Q-509-G27	9	5	53											
	SAF-Q-609-G27	9	6	52	102										

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

With VersaRate Plus for patients over 40 kg (88 lb.):

Table 6b: Gammagard with VersaRate Plus for patients over 40 kg (88 lb.)*															
Needle Set				Total mL/h vs. VersaRate Plus #											
Gauge	REF#	Length (mm)	Number of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
27G	SUB-260	9	2	44											
	SUB-212-G27	12	2	40											
	SUB-310	6	3	50											
	SUB-320	9	3	46											
	SUB-312-G27	12	3	42											
	SUB-400	6	4	56											
	SUB-410	9	4	51	98										
	SUB-412-G27	12	4	47	90										
	SUB-414-G27	14	4	43	84										
	SUB-506	6	5	57	113										
	SUB-509	9	5	53	104										
	SUB-606	6	6	56											
	SUB-609	9	6	52	102	161									
	SAF-Q-209-G27	9	2	44											
	SAF-Q-212-G27	12	2	40											
	SAF-Q-306-G27	6	3	50											
	SAF-Q-309-G27	9	3	46											
	SAF-Q-312-G27	12	3	42											
	SAF-Q-406-G27	6	4	56											
	SAF-Q-409-G27	9	4	51	98										
	SAF-Q-412-G27	12	4	47	90										
	SAF-Q-509-G27	9	5	53	104										
	SAF-Q-609-G27	9	6	52	102	161									

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

Infusing Hizentra for Primary Immunodeficiency (PI)

The tables below only include combinations that will provide both total and per site flow rates that are within Hizentra dosage limits after system tolerances are applied for patients diagnosed with PI. Cells shaded in gray do not have values listed because testing has not been performed or the value exceeds the dosage limits. Cells shaded in white are suitable for initial and maintenance infusions. Cells shaded in yellow are only suitable for maintenance infusions.

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

With Infuset:

Table 7: Hizentra (PI) with Infuset*

Needle Set				Total mL/h vs. Infuset												
Gauge	REF#	Length (mm)	Number 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
24G	SUB-109-G24	9	1				12	16								
	SUB-112-G24	12	1				11	15	21							
	SUB-209-G24	9	2						26	35						
	SUB-212-G24	12	2						24	32						
	SUB-309-G24	9	3							39	49	51				
	SUB-312-G24	12	3							35	45	47				
	SUB-409-G24	9	4							39	48	52				
	SUB-412-G24	12	4							35	44	47				
	SUB-512-G24	12	5							39		52	100			
	SUB-612-G24	12	6							39	47	53	117			
	SAF-Q-106-G24	6	1				13	17								
	SAF-Q-109-G24	9	1				12	16								
	SAF-Q-309-G24	9	3							39	49	51				
26G	OPT12604	4	1				11	17	19							
	OPT12606	6	1				11	17	19							
	OPT12609	9	1				11	17	19							
	OPT12612	12	1				11	17	19							
	OPT22604	4	2						22	36						
	OPT22606	6	2						22	36						
	OPT22609	9	2						22	36						
	OPT22612	12	2						22	36						
	OPT32606	6	3							38		55				
	OPT32609	9	3							38		55				
	OPT32612	12	3							38		55				
	OPT42606	6	4							42		57				
	OPT42609	9	4							42		57				
	OPT42612	12	4							42		57				
	OPT52606	6	5									65				
	OPT52609	9	5									65				
	OPT52612	12	5									65				

Table 7: Hizentra (PI) with Infuset*																	
Needle Set				Total mL/h vs. Infuset													
Gauge	REF#	Length (mm)	Number 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
26	OPT62609	9	6									66				
	OPT62612	12	6									66				
27G	SUB-104-G27	4	1							16	18		20			
	SUB-106-G27	6	1							15	17		19			
	SUB-109-G27	9	1							14	15		17			
	SUB-112-G27	12	1							12	14		16			
	SUB-204-G27	4	2									29	34			
	SUB-250	6	2									27	32			
	SUB-260	9	2									25	30			
	SUB-212-G27	12	2									23	27			
	SUB-310	6	3									36	46			
	SUB-320	9	3									33	43			
	SUB-312-G27	12	3									30	39			
27G	SUB-400	6	4									40	53			
	SUB-410	9	4									37	49			
	SUB-412-G27	12	4									33	44			
	SUB-414-G27	14	4									31	42			
	SUB-506	6	5									46	63			
	SUB-509	9	5									42	57			
	SUB-606	6	6								44	46	76			
	SUB-609	9	6								41	42	70			
	SAF-Q-106-G27	6	1							15	17		19			
	SAF-Q-109-G27	9	1							14	15		17			
	SAF-Q-112-G27	12	1							12	14		16			
	SAF-Q-206-G27	6	2									27	32			
	SAF-Q-209-G27	9	2									25	30			
	SAF-Q-212-G27	12	2									23	27			
	SAF-Q-306-G27	6	3									36	46			
	SAF-Q-309-G27	9	3									33	43			
	SAF-Q-312-G27	12	3									30	39			
	SAF-Q-406-G27	6	4									40	53			
	SAF-Q-409-G27	9	4									37	49			
	SAF-Q-412-G27	12	4									33	44			
	SAF-Q-509-G27	9	5									42	57			
	SAF-Q-609-G27	9	6								41	42	70			

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

With VersaRate:

Table 8: Hizentra (PI) with VersaRate*									
Needle Set				Total mL/h vs. VersaRate #					
Gauge	REF#	Length (mm)	Number of Needles	1	2	3	4	5	6
24G	SUB-109-G24	9	1	14					
	SUB-112-G24	12	1	13					
	SUB-209-G24	9	2	15	27				
	SUB-212-G24	12	2	14	25	39			
	SUB-309-G24	9	3	17	27	50			
	SUB-312-G24	12	3	16	25	45			
	SUB-409-G24	9	4	17	30	49	80		
	SUB-412-G24	12	4	15	27	44	73		
	SUB-512-G24	12	5	16	31	49	79		
	SUB-612-G24	12	6	16	32	50	79		
	SAF-Q-106-G24	6	1	16					
	SAF-Q-109-G24	9	1	14					
	SAF-Q-309-G24	9	3	17	27	50			
26G	OPT12604	4	1	13	21				
	OPT12606	6	1	13	21				
	OPT12609	9	1	13	21				
	OPT12612	12	1	13	21				
	OPT22604	4	2		26	39			
	OPT22606	6	2		26	39			
	OPT22609	9	2		26	39			
	OPT22612	12	2		26	39			
	OPT32606	6	3		28	43			
	OPT32609	9	3		28	43			
	OPT32612	12	3		28	43			
	OPT42606	6	4			47	75		
	OPT42609	9	4			47	75		
	OPT42612	12	4			47	75		
	OPT52606	6	5			48	82		
	OPT52609	9	5			48	82		
	OPT52612	12	5			48	82		
	OPT62609	9	6				81		
	OPT62612	12	6				81		
27G	SUB-104-G27	4	1	11	14	17	18	20	21
	SUB-106-G27	6	1	11	13	16	17	19	20
	SUB-109-G27	9	1	10	12	15	16	17	18
	SUB-112-G27	12	1	9	11	13	14	16	16
	SUB-204-G27	4	2	12	19	26	32	36	42
	SUB-250	6	2	12	18	24	30	34	39
	SUB-260	9	2	11	17	22	28	31	36
	SUB-212-G27	12	2	10	15	20	25	28	33
	SUB-310	6	3	14	23	33	40	50	64
	SUB-320	9	3	13	21	30	37	46	59
	SUB-312-G27	12	3	11	19	27	33	42	54

Table 8: Hizentra (PI) with VersaRate*									
Needle Set				Total mL/h vs. VersaRate #					
Gauge	REF#	Length (mm)	Number of Needles	1	2	3	4	5	6
27G	SUB-400	6	4	14	26	37	51	66	80
	SUB-410	9	4	13	24	34	47	61	73
	SUB-412-G27	12	4	12	22	31	43	55	67
	SUB-414-G27	14	4	11	20	28	40	52	62
	SUB-506	6	5	16	26	37	53	73	94
	SUB-509	9	5	15	24	34	49	67	87
	SUB-606	6	6	16	28	40	58	82	117
	SUB-609	9	6	14	25	37	53	75	108
	SAF-Q-106-G27	6	1	11	13	16	17	19	20
	SAF-Q-109-G27	9	1	10	12	15	16	17	18
	SAF-Q-112-G27	12	1	9	11	13	14	16	16
	SAF-Q-206-G27	6	2	12	18	24	30	34	39
	SAF-Q-209-G27	9	2	11	17	22	28	31	36
	SAF-Q-212-G27	12	2	10	15	20	25	28	33
	SAF-Q-306-G27	6	3	14	23	33	40	50	64
	SAF-Q-309-G27	9	3	13	21	30	37	46	59
	SAF-Q-312-G27	12	3	11	19	27	33	42	54
	SAF-Q-406-G27	6	4	14	26	37	51	66	80
	SAF-Q-409-G27	9	4	13	24	34	47	61	73
	SAF-Q-412-G27	12	4	12	22	31	43	55	67
	SAF-Q-509-G27	9	5	15	24	34	49	67	87
	SAF-Q-609-G27	9	6	14	25	37	53	75	108

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

With VersaRate Plus

Table 9: Hizentra (PI) with VersaRate Plus*															
Needle Set				Total mL/h vs. VersaRate Plus #											
Gauge	REF#	Length (mm)	Number of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
24G	SUB-209-G24	9	2		36										
	SUB-212-G24	12	2		33										
	SUB-309-G24	9	3		40										
	SUB-312-G24	12	3		36	62									
	SUB-409-G24	9	4		34	76									
	SUB-412-G24	12	4		31	69									
	SAF-Q-209-G24-70	9	2		36										
	SAF-Q-212-G24-70	12	2		33										
	SAF-Q-309-G24	9	3		40										
	SAF-Q-312-G24-70	12	3		37										
	SAF-Q-409-G24-70	9	4		43	84									
	SAF-Q-412-G24-70	12	4		39	77									

Table 9: Hizentra (PI) with VersaRate Plus*

Needle Set				Total mL/h vs. VersaRate Plus #											
Gauge	REF#	Length (mm)	Number of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
26G	OPT12604	4	1	12											
	OPT12606	6	1	12											
	OPT12609	9	1	12											
	OPT12612	12	1	12											
	OPT22604	4	2	16	32										
	OPT22606	6	2	16	32										
	OPT22609	9	2	16	32										
	OPT22612	12	2	16	32										
	OPT32606	6	3		32										
	OPT32609	9	3		32										
	OPT32612	12	3		32										
	OPT42606	6	4		38	77									
	OPT42609	9	4		38	77									
	OPT42612	12	4		38	77									
	OPT52606	6	5			84									
	OPT52609	9	5			84									
	OPT52612	12	5			84									
	OPT62609	9	6				106								
	OPT62612	12	6				106								
27G	SUB-104-G27	4	1		15	17	18	20	20	21	21	21	22	22	
	SUB-106-G27	6	1		14	16	17	19	19	20	20	20	21	21	21
	SUB-106-G27-70	6	1		16	18	20	21	22						
	SUB-109-G27	9	1		13	15	16	17	18	18	18	19	19	19	19
	SUB-109-G27-70	9	1		15	17	18	19	20	21	22	22	22	22	
	SUB-112-G27	12	1		12	13	15	15	16	17	17	17	17	17	17
	SUB-112-G27-70	12	1		13	15	16	18	19	19	20	20	20	20	20
	SUB-204-G27	4	2		23	29	34	37	38	39	39	39	40	41	43
	SUB-250	6	2		22	28	32	35	36	37	37	37	38	38	40
	SUB-260	9	2		20	26	30	32	33	34	34	34	35	35	37
	SUB-212-G27	12	2		18	23	27	29	30	31	31	31	31	32	34
	SUB-310	6	3		27	37	44	50	54	56	58	58	58	58	63
	SUB-320	9	3		25	34	41	46	49	52	53	53	54	54	58
	SUB-312-G27	12	3		23	31	37	42	45	47	48	49	49	49	53
	SUB-400	6	4		34	47	57	65	70	74	77	79	82	85	
	SUB-410	9	4		31	43	52	59	64	68	71	73	75	78	82
	SUB-412-G27	12	4		28	39	48	54	58	62	64	66	69	71	75
	SUB-414-G27	14	4		26	37	44	50	55	58	60	62	64	67	70
	SUB-506	6	5		20	45	63	77	86	92	96	98	101	103	108
	SUB-509	9	5		19	41	58	70	79	84	88	90	92	95	99
	SUB-606	6	6		16	45	68	85	98	107	114	119	123	127	
	SUB-609	9	6		14	41	62	78	90	98	104	109	113	117	122
	SAF-Q-106-G27	6	1		14	16	17	19	19	20	20	20	21	21	21
	SAF-Q-109-G27	9	1		13	15	16	17	18	18	18	19	19	19	19
	SAF-Q-109-G27-70	9	1		15	17	18	19	20	21	22	22	22	22	
	SAF-Q-112-G27	12	1		12	13	15	15	16	17	17	17	17	17	17

Table 9: Hizentra (PI) with VersaRate Plus*															
Needle Set				Total mL/h vs. VersaRate Plus #											
Gauge	REF#	Length (mm)	Number of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
27G	SAF-Q-206-G27	6	2		22	28	32	35	36	37	37	37	38	38	40
	SAF-Q-209-G27	9	2		20	26	30	32	33	34	34	34	35	35	37
	SAF-Q-212-G27	12	2		18	23	27	29	30	31	31	31	31	32	34
	SAF-Q-306-G27	6	3		27	37	44	50	54	56	58	58	58	58	63
	SAF-Q-309-G27	9	3		25	34	41	46	49	52	53	53	54	54	58
	SAF-Q-312-G27	12	3		23	31	37	42	45	47	48	49	49	49	53
	SAF-Q-406-G27	6	4		34	47	57	65	70	74	77	79	82	85	
	SAF-Q-409-G27	9	4		31	43	52	59	64	68	71	73	75	78	82
	SAF-Q-412-G27	12	4		28	39	48	54	58	62	64	66	69	71	75
	SAF-Q-509-G27	9	5		19	41	58	70	79	84	88	90	92	95	99
	SAF-Q-609-G27	9	6		14	41	62	78	90	98	104	109	113	117	122

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

Infusing Hizentra for Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

The tables below only include combinations that will provide both total and per site flow rates that are within Hizentra dosage limits after system tolerances are applied for patients diagnosed with CIDP. Cells shaded in gray do not have values listed because testing has not been performed or the value exceeds the dosage limits. Cells shaded in white are suitable for initial and maintenance infusions. Cells shaded in yellow are only suitable for maintenance infusions.

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

With Infuset:

Table 10: Hizentra (CIDP) with Infuset*															
Needle Set				Total mL/h vs. Infuset											
Gauge	REF#	Length (mm)	Number 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
24G	SUB-109-G24	9	1				12	16	23	30		37				
	SUB-112-G24	12	1				11	15	21	27		33				
	SUB-209-G24	9	2						26	35	48	52				
	SUB-212-G24	12	2						24	32	44	48				
	SUB-309-G24	9	3							39	49	51				
	SUB-312-G24	12	3							35	45	47	124			
	SUB-409-G24	9	4							39	48	52	111			
	SUB-412-G24	12	4							35	44	47	101			

Table 10: Hizentra (CIDP) with Infuset*																	
Needle Set				Total mL/h vs. Infuset													
Gauge	REF#	Length (mm)	Number 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
24G	SUB-512-G24	12	5							39		52	100			
	SUB-612-G24	12	6							39	47	53	117			
	SAF-Q-106-G24	6	1				13	17	25	32		40				
	SAF-Q-109-G24	9	1				12	16	23	30		37				
	SAF-Q-309-G24	9	3							39	49	51				
26G	OPT12604	4	1				11	17	19	27		34				
	OPT12606	6	1				11	17	19	27		34				
	OPT12609	9	1				11	17	19	27		34				
	OPT12612	12	1				11	17	19	27		34				
	OPT22604	4	2						22	36		49				
	OPT22606	6	2						22	36		49				
	OPT22609	9	2						22	36		49				
	OPT22612	12	2						22	36		49				
	OPT32606	6	3							38		55				
	OPT32609	9	3							38		55				
	OPT32612	12	3							38		55				
	OPT42606	6	4							42		57	163			
	OPT42609	9	4							42		57	163			
	OPT42612	12	4							42		57	163			
	OPT52606	6	5									65	183			
	OPT52609	9	5									65	183			
	OPT52612	12	5									65	183			
	OPT62609	9	6									66	200			
	OPT62612	12	6									66	200			
27G	SUB-104-G27	4	1							16	18		20			
	SUB-106-G27	6	1							15	17		19			
	SUB-109-G27	9	1							14	15		17			
	SUB-112-G27	12	1							12	14		16			
	SUB-204-G27	4	2									29	34			
	SUB-250	6	2									27	32			
	SUB-260	9	2									25	30			
	SUB-212-G27	12	2									23	27			
	SUB-310	6	3									36	46			
	SUB-320	9	3									33	43			
	SUB-312-G27	12	3									30	39			
	SUB-400	6	4									40	53			
	SUB-410	9	4									37	49			
	SUB-412-G27	12	4									33	44			
	SUB-414-G27	14	4									31	42			
	SUB-506	6	5									46	63			
	SUB-509	9	5									42	57			
	SUB-606	6	6								44	46	76			
	SUB-609	9	6								41	42	70			

Table 10: Hizentra (CIDP) with Infuset*																		
Needle Set				Total mL/h vs. Infuset														
Gauge	REF#	Length (mm)	Number 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
27G	SAF-Q-106-G27	6	1							15	17		19			
	SAF-Q-109-G27	9	1							14	15		17			
	SAF-Q-112-G27	12	1							12	14		16			
	SAF-Q-206-G27	6	2									27	32			
	SAF-Q-209-G27	9	2									25	30			
	SAF-Q-212-G27	12	2									23	27			
	SAF-Q-306-G27	6	3									36	46			
	SAF-Q-309-G27	9	3									33	43			
	SAF-Q-312-G27	12	3									30	39			
	SAF-Q-406-G27	6	4									40	53			
	SAF-Q-409-G27	9	4									37	49			
	SAF-Q-412-G27	12	4									33	44			
	SAF-Q-509-G27	9	5									42	57			
	SAF-Q-609-G27	9	6								41	42	70			

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

With VersaRate:

Table 11: Hizentra (CIDP) with VersaRate*									
Needle Set				Total mL/h vs. VersaRate #					
Gauge	REF#	Length (mm)	Number of Needles	1	2	3	4	5	6
24G	SUB-109-G24	9	1	14	24	33			
	SUB-112-G24	12	1	13	22	30	40		
	SUB-209-G24	9	2	15	27	43	64		
	SUB-212-G24	12	2	14	25	39	58		
	SUB-309-G24	9	3	17	27	50	76	123	
	SUB-312-G24	12	3	16	25	45	69	112	
	SUB-409-G24	9	4	17	30	49	80	149	
	SUB-412-G24	12	4	15	27	44	73	136	
	SUB-512-G24	12	5	16	31	49	79	141	
	SUB-612-G24	12	6	16	32	50	79	156	
	SAF-Q-106-G24	6	1	16	26	36			
	SAF-Q-109-G24	9	1	14	24	33			
	SAF-Q-309-G24	9	3	17	27	50	76	123	
26G	OPT12604	4	1	13	21	30	38		
	OPT12606	6	1	13	21	30	38		
	OPT12609	9	1	13	21	30	38		
	OPT12612	12	1	13	21	30	38		
	OPT22604	4	2		26	39	59		

Table 11: Hizentra (CIDP) with VersaRate*									
Needle Set				Total mL/h vs. VersaRate #					
Gauge	REF#	Length (mm)	Number of Needles	1	2	3	4	5	6
26G	OPT22606	6	2		26	39	59		
	OPT22609	9	2		26	39	59		
	OPT22612	12	2		26	39	59		
	OPT32606	6	3		28	43	67	116	
	OPT32609	9	3		28	43	67	116	
	OPT32612	12	3		28	43	67	116	
	OPT42606	6	4			47	75	140	
	OPT42609	9	4			47	75	140	
	OPT42612	12	4			47	75	140	
	OPT52606	6	5			48	82	144	
	OPT52609	9	5			48	82	144	
	OPT52612	12	5			48	82	144	
	OPT62609	9	6				81	154	
	OPT62612	12	6				81	154	
27G	SUB-104-G27	4	1	11	14	17	18	20	21
	SUB-106-G27	6	1	11	13	16	17	19	20
	SUB-109-G27	9	1	10	12	15	16	17	18
	SUB-112-G27	12	1	9	11	13	14	16	16
	SUB-204-G27	4	2	12	19	26	32	36	42
	SUB-250	6	2	12	18	24	30	34	39
	SUB-260	9	2	11	17	22	28	31	36
	SUB-212-G27	12	2	10	15	20	25	28	33
	SUB-310	6	3	14	23	33	40	50	64
	SUB-320	9	3	13	21	30	37	46	59
	SUB-312-G27	12	3	11	19	27	33	42	54
	SUB-400	6	4	14	26	37	51	66	80
	SUB-410	9	4	13	24	34	47	61	73
	SUB-412-G27	12	4	12	22	31	43	55	67
	SUB-414-G27	14	4	11	20	28	40	52	62
	SUB-506	6	5	16	26	37	53	73	94
	SUB-509	9	5	15	24	34	49	67	87
	SUB-606	6	6	16	28	40	58	82	117
	SUB-609	9	6	14	25	37	53	75	108
	SAF-Q-106-G27	6	1	11	13	16	17	19	20
	SAF-Q-109-G27	9	1	10	12	15	16	17	18
	SAF-Q-112-G27	12	1	9	11	13	14	16	16
	SAF-Q-206-G27	6	2	12	18	24	30	34	39
	SAF-Q-209-G27	9	2	11	17	22	28	31	36
	SAF-Q-212-G27	12	2	10	15	20	25	28	33
	SAF-Q-306-G27	6	3	14	23	33	40	50	64
	SAF-Q-309-G27	9	3	13	21	30	37	46	59
	SAF-Q-312-G27	12	3	11	19	27	33	42	54
	SAF-Q-406-G27	6	4	14	26	37	51	66	80
	SAF-Q-409-G27	9	4	13	24	34	47	61	73
	SAF-Q-412-G27	12	4	12	22	31	43	55	67

Table 11: Hizentra (CIDP) with VersaRate*									
Needle Set				Total mL/h vs. VersaRate #					
Gauge	REF#	Length (mm)	Number of Needles	1	2	3	4	5	6
27	SAF-Q-509-G27	9	5	15	24	34	49	67	87
	SAF-Q-609-G27	9	6	14	25	37	53	75	108

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

With VersaRate Plus

Table 12: Hizentra (CIDP) with VersaRate Plus*															
Needle Set				Total mL/h vs. VersaRate Plus #											
Gauge	REF#	Length (mm)	Number of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
24G	SUB-109-G24	9	1		31	41									
	SUB-112-G24	12	1		28	38									
	SUB-209-G24	9	2		36	60	80								
	SUB-212-G24	12	2		33	54	73								
	SUB-309-G24	9	3		40	69	95	118							
	SUB-312-G24	12	3		36	62	86	107	126						
	SUB-409-G24	9	4		34	76	112	144	171						
	SUB-412-G24	12	4		31	69	102	131	155						
	SAF-Q-106-G24	6	1		33										
	SAF-Q-109-G24	9	1		31	41									
	SAF-Q-112-G24-70	12	1		29	42									
	SAF-Q-206-G24-70	6	2		39	66									
	SAF-Q-209-G24-70	9	2		36	60	79								
	SAF-Q-212-G24-70	12	2		33	55	72								
	SAF-Q-309-G24	9	3		40	69	95	118							
	SAF-Q-312-G24-70	12	3		37	73	105								
	SAF-Q-409-G24-70	9	4		43	84	123	159							
	SAF-Q-412-G24-70	12	4		39	77	113	146							
26G	OPT12604	4	1	12	24										
	OPT12606	6	1	12	24										
	OPT12609	9	1	12	24										
	OPT12612	12	1	12	24										
	OPT22604	4	2	16	32	57	71								
	OPT22606	6	2	16	32	57	71								
	OPT22609	9	2	16	32	57	71								
	OPT22612	12	2	16	32	57	71								
	OPT32606	6	3		32	74	92	126	135						
	OPT32609	9	3		32	74	92	126	135						
	OPT32612	12	3		32	74	92	126	135						
	OPT42606	6	4		38	77	103	152	160						
	OPT42609	9	4		38	77	103	152	160						
	OPT42612	12	4		38	77	103	152	160						

Table 12: Hizentra (CIDP) with VersaRate Plus*

Needle Set				Total mL/h vs. VersaRate Plus #											
Gauge	REF#	Length (mm)	Number of Needles	1	2	3	4	5	6	7	8	9	10	11	OPEN
26G	OPT52606	6	5			84	113	155	186	225					
	OPT52609	9	5			84	113	155	186	225					
	OPT52612	12	5			84	113	155	186	225					
	OPT62609	9	6				106	167	199	252	271				
	OPT62612	12	6				106	167	199	252	271				
27G	SUB-104-G27	4	1		15	17	18	20	20	21	21	21	22	22	22
	SUB-106-G27	6	1		14	16	17	19	19	20	20	20	21	21	21
	SUB-106-G27-70	6	1		16	18	20	21	22	23	24	24	24	24	24
	SUB-109-G27	9	1		13	15	16	17	18	18	18	19	19	19	19
	SUB-109-G27-70	9	1		15	17	18	19	20	21	22	22	22	22	22
	SUB-112-G27	12	1		12	13	15	15	16	17	17	17	17	17	17
	SUB-112-G27-70	12	1		13	15	16	18	19	19	20	20	20	20	20
	SUB-204-G27	4	2		23	29	34	37	38	39	39	39	40	41	43
	SUB-250	6	2		22	28	32	35	36	37	37	37	38	38	40
	SUB-260	9	2		20	26	30	32	33	34	34	34	35	35	37
	SUB-212-G27	12	2		18	23	27	29	30	31	31	31	31	32	34
	SUB-310	6	3		27	37	44	50	54	56	58	58	58	58	63
	SUB-320	9	3		25	34	41	46	49	52	53	53	54	54	58
	SUB-312-G27	12	3		23	31	37	42	45	47	48	49	49	49	53
	SUB-400	6	4		34	47	57	65	70	74	77	79	82	85	90
	SUB-410	9	4		31	43	52	59	64	68	71	73	75	78	82
	SUB-412-G27	12	4		28	39	48	54	58	62	64	66	69	71	75
	SUB-414-G27	14	4		26	37	44	50	55	58	60	62	64	67	70
	SUB-506	6	5		20	45	63	77	86	92	96	98	101	103	108
	SUB-509	9	5		19	41	58	70	79	84	88	90	92	95	99
	SUB-606	6	6		16	45	68	85	98	107	114	119	123	127	133
	SUB-609	9	6		14	41	62	78	90	98	104	109	113	117	122
	SAF-Q-106-G27	6	1		14	16	17	19	19	20	20	20	21	21	21
	SAF-Q-109-G27	9	1		13	15	16	17	18	18	18	19	19	19	19
	SAF-Q-109-G27-70	9	1		15	17	18	19	20	21	22	22	22	22	22
	SAF-Q-112-G27	12	1		12	13	15	15	16	17	17	17	17	17	17
	SAF-Q-206-G27	6	2		22	28	32	35	36	37	37	37	38	38	40
	SAF-Q-209-G27	9	2		20	26	30	32	33	34	34	34	35	35	37
	SAF-Q-212-G27	12	2		18	23	27	29	30	31	31	31	31	32	34
	SAF-Q-306-G27	6	3		27	37	44	50	54	56	58	58	58	58	63
	SAF-Q-309-G27	9	3		25	34	41	46	49	52	53	53	54	54	58
	SAF-Q-312-G27	12	3		23	31	37	42	45	47	48	49	49	49	53
	SAF-Q-406-G27	6	4		34	47	57	65	70	74	77	79	82	85	90
	SAF-Q-409-G27	9	4		31	43	52	59	64	68	71	73	75	78	82
	SAF-Q-412-G27	12	4		28	39	48	54	58	62	64	66	69	71	75
	SAF-Q-509-G27	9	5		19	41	58	70	79	84	88	90	92	95	99
	SAF-Q-609-G27	9	6		14	41	62	78	90	98	104	109	113	117	122

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

Troubleshooting

Possible causes for the SCIg60 Infusion System to not perform properly are:

Problem	Possible Cause	Correction
Syringe not compatible	Use of non-recommended syringe model.	Use only recommended syringe model (BD 50 mL syringe model no. 309653).
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 SCIg60 Infuser.
Syringe disengages from the infuser when the inner drive is closed	Syringe was not properly loaded in the infuser.	Unscrew the inner drive and properly position the syringe following the instructions for use steps #9-13. Ensure handle is fully closed.
	Use of non-recommended syringe model.	Use only recommended syringe model.
Clicking sound	During infusion, the spring readjusts as it extends and may intermittently produce sound.	No correction necessary. This is normal and does not impact the function of the pump.
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 closed.	Close inner drive by rotating the handle clockwise until the base of the handle touches the body of the pump. Refer to IFU step 13.
	Flow controller or administration set is in the OFF position or blocked by slide clamp.	For the Infuset, make sure that the slide clamp is not blocking the flow.
		For the VersaRate or VersaRate Plus, make sure that the dial is set to the intended position and not on the 'OFF' position.
		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 administration set.
	VersaRate Plus at low position settings with viscous fluids and factors that affect flow rate.	When using the VersaRate Plus at the low position settings such as 1 to 3 with fluids having a viscosity greater than 8 cP, it is recommended to continually monitor the volume infused throughout the therapy and adjust the VersaRate Plus setting accordingly.

Problem	Possible Cause	Correction
Flow rate is **HIGH**	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 position is being used. Consult the appropriate flow rate data sheet or calculator for expected flow rate.
		If using VersaRate or 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 **LOW**	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 position is being used. Consult the appropriate flow rate data sheet or calculator for expected flow rate.
		If using VersaRate or 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 administration set.
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 is in the 'OFF' position.
		If the flow controller fails to stop the flow, turn the Drive Handle counterclockwise fully to stop fluid flow.

NOTE:	If any of the above conditions persist or the SCIg60 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 SCIg60 Infuser, and it does not extend to subsequent purchasers or users. The “Original Purchaser” is the person purchasing the SCIg60 Infuser from the Manufacturer or Manufacturers Representative.

Limited Warranty:

EMED Technologies Corporation (“Manufacturer”) warrants the SCIg60 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 SCIg60 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 SCIg60 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 option, any SCIg60 Infuser, or part thereof, which has been actually received by the Manufacturer or Manufacturers 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.

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