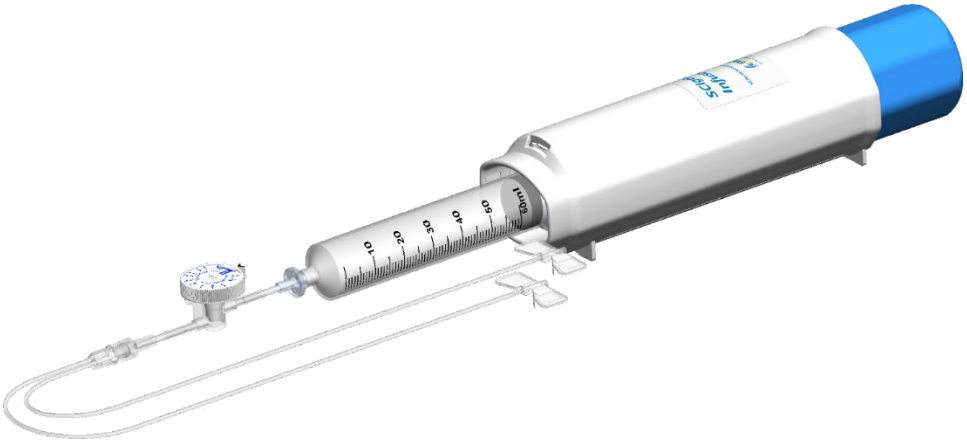
User Manual

SCIg60™ Infusion System

International 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.

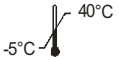
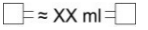
Terms and Abbreviations

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

Some of these 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
	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:

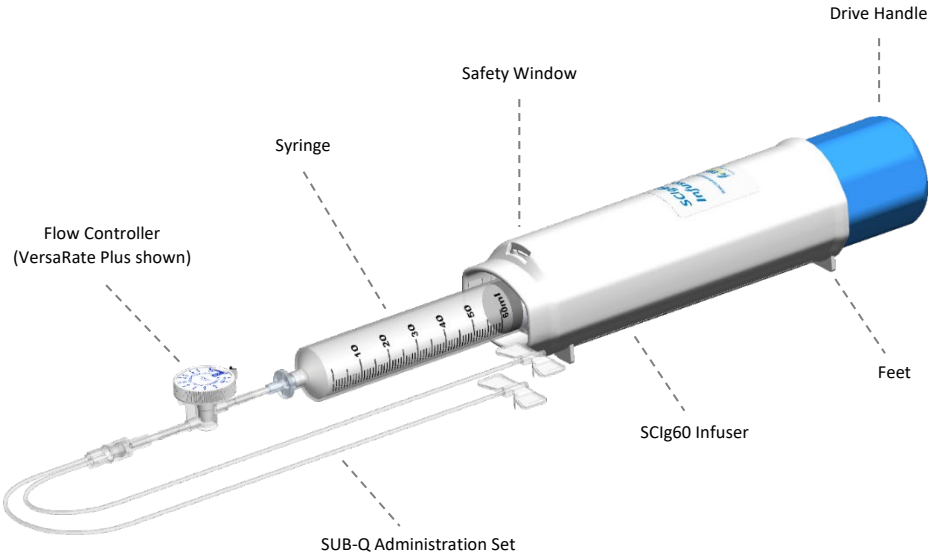
Component	Model Information
SCIg60™ Infuser with Carrying Case	FP-0010002
BD 50 mL Syringe	309653
Flow Controller	Infuset™, VersaRate®, or VersaRate® Plus (See table below)
Administration Set	SUB-Q, SAF-Q®, or OPTFlow®

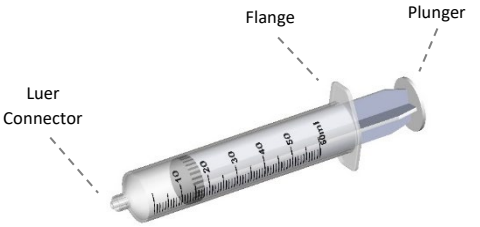
The syringe, flow controller and administration set are sold separately. The syringe component is not manufactured by EMED and is available for purchase from the manufacturer.

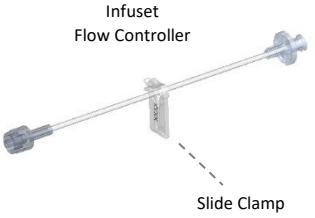
The flow control accessory regulates the fluid flow rate into the SUB-Q set. The flow control accessory should be selected based on the prescribing fluid's administration instructions, the viscosity of the prescribed fluid, the type of SUB-Q administration set being used, and patient factors. See section *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 immunoglobulin liquid medications with the BD 50 ml syringe (model no. 309653). The system is intended for single patient, multiple use only. The system is intended for single patient, multiple use only.

Contraindications

The SCIg60 Infusion System is not intended for delivery of whole blood or the infusion of insulin.

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.

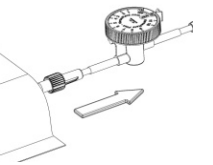
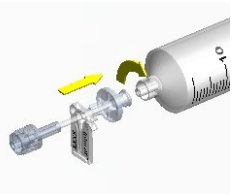
Warnings and Precautions

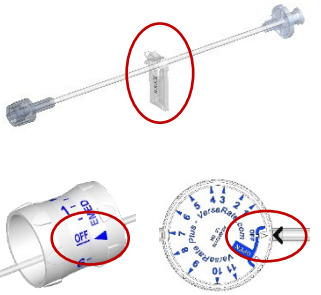
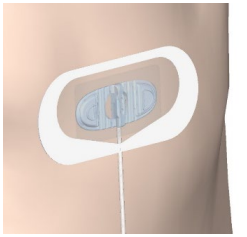
Warnings:

- 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.

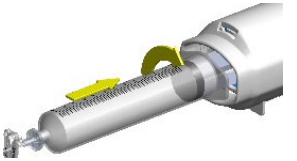
Cautions:

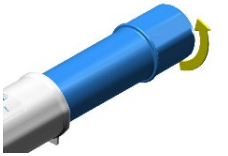
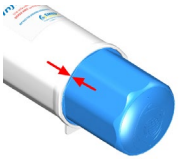
- U.S. Federal law restricts this device to sale by or on the order of a physician.
- Place the SCIg60 Infusion pump on a flat surface or in the provided carrying case during use. Syringe damage and fluid loss may occur if the SCIg60 Infusion System is dropped while loaded.
- Do NOT continue to use an 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.	

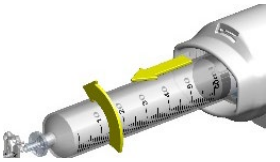
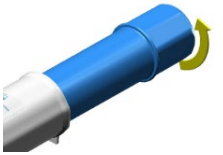
Load Pump

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

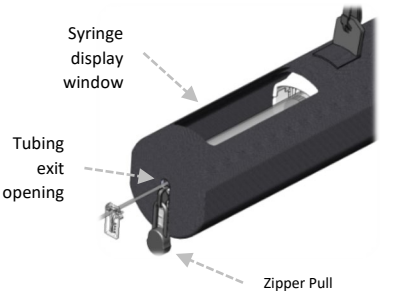
15	When using **Infuset**: a) To **START** infusion, **USE SLIDE CLAMP** once pump is fully loaded and needles are inserted and secured. b) **MONITOR** infusion by viewing the syringe volume. c) To **STOP** infusion, **USE SLIDE CLAMP** as necessary during infusion session or when session is complete.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

SCIg60 Carrying Case IFU

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.

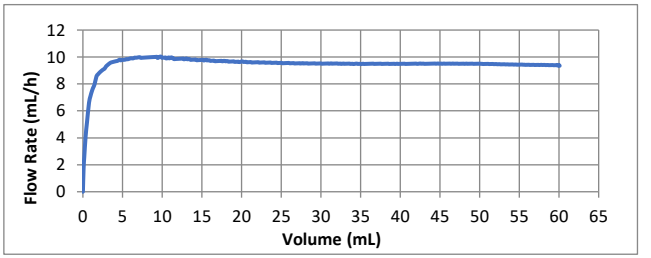
WARNING:	Do NOT open the Infuser or attempt to modify its function in any way other than its intended use.

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. It is the responsibility of the healthcare professional to determine a suitable system configuration flow rate based on the clinical requirements and the drug manufacturer's product labeling for your region.

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 show system total flow rates **without** system tolerance or other factors that may affect flow rate. Cells shaded in gray do not have values listed because testing has not been performed. Cells shaded in white may be suitable for initial and maintenance infusions. Values that are shaded in yellow may only be suitable for maintenance infusions Flow rates that exceed the prescribing information limits are shaded red and are for informational purpose only. Please confirm the drug manufacturer's prescribing information for your region.

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)
	May exceed the prescribing information (Exceeds 60 mL/h/site or 240 ml/h total)
	No data available

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	55			
	SUB-112-G24	12	1				10	13	16			28	50			
	SUB-209-G24	9	2						20	32		42	94	111		
	SUB-212-G24	12	2						18	29		38	85	101		
	SUB-309-G24	9	3							35		45	118		176	
	SUB-312-G24	12	3							32		41	107		160	
	SUB-409-G24	9	4									49	145			237
	SUB-412-G24	12	4									44	132			216
	SAF-Q-106-G24	6	1				12	15	19			33	60			
	SAF-Q-109-G24	9	1				11	14	17			31	55			
	SAF-Q-309-G24	9	3							35		45	118		176	
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	109		
	OPT22606	6	2							32		45	94	109		
	OPT22609	9	2							32		45	94	109		
	OPT22612	12	2							32		45	94	109		
	OPT32606	6	3									51	122	157		
	OPT32609	9	3									51	122	157		
	OPT32612	12	3									51	122	157		
	OPT42606	6	4									52	146	194		
	OPT42609	9	4									52	146	194		
	OPT42612	12	4									52	146	194		
27G	SUB-104-G27	4	1	3	4											
	SUB-106-G27	6	1	3	4											
	SUB-109-G27	9	1	2	4											
	SUB-112-G27	12	1	2	3											
	SAF-Q-106-G27	6	1	3	4											
	SAF-Q-109-G27	9	1	2	4											
	SAF-Q-112-G27	12	1	2	3											

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	60
	SUB-112-G24	12	1	10	16	24	32	43	55
	SUB-209-G24	9	2	11	20	33	50	87	125
	SUB-212-G24	12	2	10	18	30	45	79	114
	SUB-309-G24	9	3	11	21	35	58	107	211
	SUB-312-G24	12	3	10	19	32	53	97	192
	SUB-409-G24	9	4	12	23	37	65	141	296
	SUB-412-G24	12	4	11	21	34	59	128	269
	SAF-Q-106-G24	6	1	12	19	28	38	51	65
	SAF-Q-109-G24	9	1	11	17	26	35	47	60
	SAF-Q-309-G24	9	3	11	21	35	58	107	211
26G	OPT12604	4	1	13	20	28	33	47	63
	OPT12606	6	1	13	20	28	33	47	63
	OPT12609	9	1	13	20	28	33	47	63
	OPT12612	12	1	13	20	28	33	47	63
	OPT22604	4	2		24	38	54	83	124
	OPT22606	6	2		24	38	54	83	124
	OPT22609	9	2		24	38	54	83	124
	OPT22612	12	2		24	38	54	83	124
	OPT32606	6	3			41	65	106	180
	OPT32609	9	3			41	65	106	180
	OPT32612	12	3			41	65	106	180
	OPT42606	6	4			43	70	119	255
	OPT42609	9	4			43	70	119	255
	OPT42612	12	4			43	70	119	255

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	48	52	55	55	55	55	55	61
	SUB-112-G24	12	1		16	29	38	44	48	50	50	50	50	50	55
	SUB-209-G24	9	2		21	50	72	88	98	105	109	111	114	117	130
	SUB-212-G24	12	2		19	46	66	80	90	95	99	101	103	106	119
	SUB-309-G24	9	3		25	61	89	113	131	145	155	162	167	170	200
	SUB-312-G24	12	3		23	55	81	103	119	132	141	147	15	155	182
	SUB-409-G24	9	4		29	59	92	126	158	187	211	228	237	235	283
	SUB-412-G24	12	4		26	54	84	114	144	170	192	208	215	213	258
	SAF-Q-106-G24	6	1		19	34	45	53	57	59	60	60	60	60	66
	SAF-Q-109-G24	9	1		17	31	41	48	52	55	55	55	55	55	61
	SAF-Q-309-G24	9	3		25	61	89	113	131	145	155	162	167	170	200
26G	OPT12604	4	1	9	20	34	43	48	52	53	55	55	56	56	63
	OPT12606	6	1	9	20	34	43	48	52	53	55	55	56	56	63
	OPT12609	9	1	9	20	34	43	48	52	53	55	55	56	56	63
	OPT12612	12	1	9	20	34	43	48	52	53	55	55	56	56	63
	OPT22604	4	2		21	37	63	87	102	112	117	120	122	123	141
	OPT22606	6	2		21	37	63	87	102	112	117	120	122	123	141
	OPT22609	9	2		21	37	63	87	102	112	117	120	122	123	141
	OPT22612	12	2		21	37	63	87	102	112	117	120	122	123	141
	OPT32606	6	3		27	48	79	110	135	151	163	170	175	178	205
	OPT32609	9	3		27	48	79	110	135	151	163	170	175	178	205
	OPT32612	12	3		27	48	79	110	135	151	163	170	175	178	205
	OPT42606	6	4			63	92	129	163	189	207	219	227	232	277
	OPT42609	9	4			63	92	129	163	189	207	219	227	232	277
	OPT42612	12	4			63	92	129	163	189	207	219	227	232	277
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

Infusing Gammagard (Kiovig)

The tables below show system total flow rates **without** system tolerance or other factors that may affect flow rate. Cells shaded in gray do not have values listed because testing has not been performed. Cells shaded in white may be suitable for initial and maintenance infusions. Values that are shaded in yellow may only be suitable for maintenance infusions Flow rates that exceed the prescribing information limits are shaded red and are for informational purpose only. Please confirm the drug manufacturer's prescribing information for your region.

Table Legend:

	Suitable for initial and maintenance infusions (up to 20 mL/h/site or 160 ml/h total)
	Suitable for maintenance infusions only (up to 30 mL/h/site or 240 ml/h total)
	May exceed the prescribing information (Exceeds 30 mL/h/site or 240 ml/h total)
	No data available

With Infuset

Table 4: Gammagard 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	15	24	27										
	SUB-112-G24	12	1	14	21	25										
	SUB-209-G24	9	2		25	29	61									
	SUB-212-G24	12	2		23	26	56									
	SUB-309-G24	9	3				57	97	137							
	SUB-312-G24	12	3				52	89	125							
	SUB-409-G24	9	4			29		94	141							
	SUB-412-G24	12	4			26		86	128							
	SUB-512-G24	12	5				63		133							
	SUB-612-G24	12	6					95		183						
	SAF-Q-106-G24	6	1	16	26	30										
	SAF-Q-109-G24	9	1	15	24	27										
	SAF-Q-309-G24	9	3				57	97	137							

Table 4: Gammagard 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
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	62									
	OPT22606	6	2	14	26	36	62									
	OPT22609	9	2	14	26	36	62									
	OPT22612	12	2	14	26	36	62									
	OPT32606	6	3			31	66	98								
	OPT32609	9	3			31	66	98								
	OPT32612	12	3			31	66	98								
	OPT42606	6	4			33	68	105								
	OPT42609	9	4			33	68	105								
	OPT42612	12	4			33	68	105								
	OPT52606	6	5			32	67	103	136							
	OPT52609	9	5			32	67	103	136							
	OPT52612	12	5			32	67	103	136							
	OPT62609	9	6				65	109	135	227						
	OPT62612	12	6				65	109	135	227						
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	55	73								
	SUB-250	6	2			27	52	69								
	SUB-260	9	2			25	47	63								
	SUB-212-G27	12	2			22	43	58								
	SUB-310	6	3				56	77	113							
	SUB-320	9	3				51	71	104							
	SUB-312-G27	12	3				47	64	95							
	SUB-400	6	4					87	123	165						
	SUB-410	9	4					80	113	151						
	SUB-412-G27	12	4					72	103	137						
	SUB-414-G27	14	4					68	96	128						
	SUB-506	6	5				62		132	174						
	SUB-509	9	5				57		121	160						
	SUB-606	6	6					96		182	228					
	SUB-609	9	6					88		167	209					
	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	52	69								
	SAF-Q-209-G27	12	2			25	47	63								
	SAF-Q-212-G27	12	2			22	43	58								

Table 4: Gammagard 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-306-G27	14	3				56	77	113							
	SAF-Q-309-G27	6	3				51	71	104							
	SAF-Q-312-G27	9	3				47	64	95							
	SAF-Q-406-G27	9	4					87	123	165						
	SAF-Q-409-G27	6	4					80	113	151						
	SAF-Q-412-G27	9	4					72	103	137						
	SAF-Q-509-G27	9	5				57		121	160						
	SAF-Q-609-G27	9	6					88		167	209					

With VersaRate:

Table 5: Gammagard with VersaRate*										
Needle Set				Total mL/h vs. VersaRate #						
Gauge	REF#	Length (mm)	Number of Needles	½	1	2	3	4	5	6
24G	SUB-109-G24	9	1	44	61	110	142	196	262	355
	SUB-112-G24	12	1	40	55	100	129	179	239	323
	SUB-209-G24	9	2	49	64	132	194	280	421	727
	SUB-212-G24	12	2	45	59	120	177	255	383	661
	SAF-Q-106-G24	6	1	48	66	119	155	214	286	387
	SAF-Q-109-G24	9	1	44	61	110	142	196	262	355
26G	OPT12604	4	1	47						341
	OPT12606	6	1	47						341
	OPT12609	9	1	47						341
	OPT12612	12	1	47						341
	OPT22604	4	2	35	69					661
	OPT22606	6	2	35	69					661
	OPT22609	9	2	35	69					661
	OPT22612	12	2	35	69					661
	OPT32606	6	3	45	76					993
	OPT32609	9	3	45	76					993
	OPT32612	12	3	45	76					993
	OPT42606	6	4	41	81	143				1243
	OPT42609	9	4	41	81	143				1243
	OPT42612	12	4	41	81	143				1243
	OPT52606	6	5	40	72	144				1411
	OPT52609	9	5	40	72	144				1411
	OPT52612	12	5	40	72	144				1411
	OPT62609	9	6		82	148	228			1672
	OPT62612	12	6		82	148	228			1672

Table 5: Gammagard with VersaRate*										
Needle Set				Total mL/h vs. VersaRate #						
Gauge	REF#	Length (mm)	Number of Needles	½	1	2	3	4	5	6
27G	SUB-104-G27	4	1	41	50	67	84	98	109	120
	SUB-106-G27	6	1	38	47	64	80	93	103	113
	SUB-109-G27	9	1	35	43	59	73	85	95	104
	SUB-112-G27	12	1	32	40	53	67	77	86	95
	SUB-204-G27	4	2	50	65	90	121	153	199	232
	SUB-250	6	2	47	61	86	114	145	188	220
	SUB-260	9	2	43	56	79	105	133	173	202
	SUB-212-G27	12	2	39	51	71	96	121	157	183
	SUB-310	6	3	46	66	107	147	185	247	290
	SUB-320	9	3	42	60	98	135	170	226	266
	SUB-312-G27	12	3	38	55	89	123	155	206	242
	SUB-400	6	4	51	71	126	179	244	312	432
	SUB-410	9	4	47	65	116	165	224	286	397
	SUB-412-G27	12	4	43	59	106	150	204	260	361
	SUB-414-G27	14	4	40	55	99	140	191	243	337
	SUB-506	6	5	46	77	127	193	274	372	531
	SUB-509	9	5	42	71	117	177	251	342	487
	SAF-Q-106-G27	6	1	38	47	64	80	93	103	113
	SAF-Q-109-G27	9	1	35	43	59	73	85	95	104
	SAF-Q-112-G27	12	1	32	40	53	67	77	86	95
	SAF-Q-206-G27	6	2	47	61	86	114	145	188	220
	SAF-Q-209-G27	9	2	43	56	79	105	133	173	202
	SAF-Q-212-G27	12	2	39	51	71	96	121	157	183
	SAF-Q-306-G27	6	3	46	66	107	147	185	247	290
	SAF-Q-309-G27	9	3	42	60	98	135	170	226	266
	SAF-Q-312-G27	12	3	38	55	89	123	155	206	242
	SAF-Q-406-G27	6	4	51	71	126	179	244	312	432
	SAF-Q-409-G27	9	4	47	65	116	165	224	286	397
	SAF-Q-412-G27	12	4	43	59	106	150	204	260	361
	SAF-Q-509-G27	9	5	42	71	117	177	251	342	487

*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 Plus:

Table 6: Gammagard 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	SUB-104-G27	4	1	42											122
	SUB-106-G27	6	1	40											115
	SUB-109-G27	9	1	36											106
	SUB-112-G27	12	1	33											96
	SUB-204-G27	4	2	51	96										227
	SUB-250	6	2	48	91										215
	SUB-260	9	2	44	84										197
	SUB-212-G27	12	2	40	76										180
	SUB-310	6	3	50	99										334
	SUB-320	9	3	46	91										307
	SUB-312-G27	12	3	42	83										297
	SUB-400	6	4	56	107										426
	SUB-410	9	4	51	98										391
	SUB-412-G27	12	4	47	90										355
	SUB-414-G27	14	4	43	84										332
	SUB-506	6	5	57	113	178									528
	SUB-509	9	5	53	104	163									485
	SUB-606	6	6	56	112	175									593
	SUB-609	9	6	52	102	161									544
	SAF-Q-106-G27	6	1	40											115
	SAF-Q-109-G27	9	1	36											106
	SAF-Q-112-G27	12	1	33											96
	SAF-Q-206-G27	6	2	48	91										215
	SAF-Q-209-G27	9	2	44	84										197
	SAF-Q-212-G27	12	2	40	76										180
	SAF-Q-306-G27	6	3	50	99										334
	SAF-Q-309-G27	9	3	46	91										307
	SAF-Q-312-G27	12	3	42	83										279
	SAF-Q-406-G27	6	4	56	107										426
	SAF-Q-409-G27	9	4	51	98										391
	SAF-Q-412-G27	12	4	47	90										355
	SAF-Q-509-G27	9	5	53	104	163									485
	SAF-Q-609-G27	9	6	52	102	161									544

Infusing Hizentra

The tables below show system total flow rates **without** system tolerance or other factors that may affect flow rate. Cells shaded in gray do not have values listed because testing has not been performed. Cells shaded in white may be suitable for initial and maintenance infusions. Values that are shaded in yellow may only be suitable for maintenance infusions Flow rates that exceed the prescribing information limits are shaded red and are for informational purpose only. Please confirm the drug manufacturer's prescribing information for your region.

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)
	May exceed the prescribing information (Exceeds 50 mL/h/site)
	No data available

With Infuset:

Table 7: Hizentra 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	58			
	SUB-112-G24	12	1				11	15	21	27		33	53			
	SUB-209-G24	9	2						26	35	48	52	103			
	SUB-212-G24	12	2						24	32	44	48	94			
	SUB-309-G24	9	3							39	49	51	136			
	SUB-312-G24	12	3							35	45	47	124			
	SUB-409-G24	9	4							39	48	52	111	227		
	SUB-412-G24	12	4							35	44	47	101	206		
	SUB-512-G24	12	5							39		52	100	211		
	SUB-612-G24	12	6							39	47	53	117	263		
	SAF-Q-106-G24	6	1				13	17	25	32		40	63			
	SAF-Q-109-G24	9	1				12	16	23	30		37	58			
	SAF-Q-309-G24	9	3							39	49	51	136			
26G	OPT12604	4	1				11	17	19	27		34	55			
	OPT12606	6	1				11	17	19	27		34	55			
	OPT12609	9	1				11	17	19	27		34	55			
	OPT12612	12	1				11	17	19	27		34	55			
	OPT22604	4	2						22	36		49	109	124		
	OPT22606	6	2						22	36		49	109	124		
	OPT22609	9	2						22	36		49	109	124		
	OPT22612	12	2						22	36		49	109	124		
	OPT32606	6	3							38		55	138	178		
	OPT32609	9	3							38		55	138	178		
	OPT32612	12	3							38		55	138	178		
	OPT42606	6	4							42		57	163	225		
	OPT42609	9	4							42		57	163	225		
	OPT42612	12	4							42		57	163	225		

Table 7: Hizentra 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
26G	OPT52606	6	5									65	183	248		
	OPT52609	9	5									65	183	248		
	OPT52612	12	5									65	183	248		
	OPT62609	9	6									66	200	275		
	OPT62612	12	6									66	200	275		
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			
	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			

With VersaRate:

Table 8: Hizentra 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	44	57	77
	SUB-112-G24	12	1	13	22	30	40	52	71
	SUB-209-G24	9	2	15	27	43	64	101	169
	SUB-212-G24	12	2	14	25	39	58	92	153
	SUB-309-G24	9	3	17	27	50	76	123	244
	SUB-312-G24	12	3	16	25	45	69	112	222
	SUB-409-G24	9	4	17	30	49	80	149	307
	SUB-412-G24	12	4	15	27	44	73	136	279
	SUB-512-G24	12	5	16	31	49	79	141	300
	SUB-612-G24	12	6	16	32	50	79	156	354
	SAF-Q-106-G24	6	1	16	26	36	48	62	84
	SAF-Q-109-G24	9	1	14	24	33	44	57	77
	SAF-Q-309-G24	9	3	17	27	50	76	123	244
26G	OPT12604	4	1	13	21	30	38	53	64
	OPT12606	6	1	13	21	30	38	53	64
	OPT12609	9	1	13	21	30	38	53	64
	OPT12612	12	1	13	21	30	38	53	64
	OPT22604	4	2		26	39	59	90	142
	OPT22606	6	2		26	39	59	90	142
	OPT22609	9	2		26	39	59	90	142
	OPT22612	12	2		26	39	59	90	142
	OPT32606	6	3		28	43	67	116	218
	OPT32609	9	3		28	43	67	116	218
	OPT32612	12	3		28	43	67	116	218
	OPT42606	6	4			47	75	140	291
	OPT42609	9	4			47	75	140	291
	OPT42612	12	4			47	75	140	291
	OPT52606	6	5			48	82	144	335
	OPT52609	9	5			48	82	144	335
	OPT52612	12	5			48	82	144	335
	OPT62609	9	6				81	154	402
	OPT62612	12	6				81	154	402
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

Table 8: Hizentra with VersaRate									
Needle Set				Total mL/h vs. VersaRate #					
Gauge	REF#	Length (mm)	Number of Needles	1	2	3	4	5	6
27G	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

With VersaRate Plus

Table 9: Hizentra 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	50	58	63	67	70	72	72	73	73
	SUB-112-G24	12	1		28	38	46	52	58	61	64	65	66	66	67
	SUB-209-G24	9	2		36	60	80	97	112	123	131	136	139	148	157
	SUB-212-G24	12	2		33	54	73	89	102	112	119	124	126	134	143
	SUB-309-G24	9	3		40	69	95	118	138	155	169	179	186	189	227
	SUB-312-G24	12	3		36	62	86	107	126	141	154	163	169	172	206
	SUB-409-G24	9	4		34	76	112	144	171	194	214	232	247	260	310
	SUB-412-G24	12	4		31	69	102	131	155	177	195	211	224	236	282
	SAF-Q-106-G24	6	1		33	45	55	63	69	74	77	78	79	79	80
	SAF-Q-109-G24	9	1		31	41	50	58	63	67	70	72	72	73	73
	SAF-Q-112-G24-70	12	1		29	42	53	61	67	71	74	75	76	77	83
	SAF-Q-206-G24-70	6	2		39	66	86	103	115	123	129	134	137	140	152
	SAF-Q-209-G24-70	9	2		36	60	79	94	105	113	119	123	126	128	139
	SAF-Q-212-G24-70	12	2		33	55	72	86	96	103	108	112	114	117	127
	SAF-Q-309-G24	9	3		40	69	95	118	138	155	169	179	186	189	227
	SAF-Q-312-G24-70	12	3		37	73	105	134	159	181	199	213	223	229	254
	SAF-Q-409-G24-70	9	4		43	84	123	159	191	221	246	268	285	299	366
	SAF-Q-412-G24-70	12	4		39	77	113	146	176	202	226	246	262	274	336
26G	OPT12604	4	1	12	24	43	51								70
	OPT12606	6	1	12	24	43	51								70
	OPT12609	9	1	12	24	43	51								70
	OPT12612	12	1	12	24	43	51								70
	OPT22604	4	2	16	32	57	71	97							142
	OPT22606	6	2	16	32	57	71	97							142
	OPT22609	9	2	16	32	57	71	97							142
	OPT22612	12	2	16	32	57	71	97							142
	OPT32606	6	3		32	74	92	126	135						232
	OPT32609	9	3		32	74	92	126	135						232
	OPT32612	12	3		32	74	92	126	135						232
	OPT42606	6	4		38	77	103	152	160	196					300
	OPT42609	9	4		38	77	103	152	160	196					300
	OPT42612	12	4		38	77	103	152	160	196					300
	OPT52606	6	5			84	113	155	186	225					352
	OPT52609	9	5			84	113	155	186	225					352
	OPT52612	12	5			84	113	155	186	225					352
	OPT62609	9	6				106	167	199	252	271				411
	OPT62612	12	6				106	167	199	252	271				411
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

Table 9: Hizentra 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	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

Infusing Cutaquig

The tables below show system total flow rates without system tolerance or other factors that may affect flow rate. Cells shaded in gray do not have values listed because testing has not been performed. Cells shaded in white may be suitable for initial and maintenance infusions. Values that are shaded in yellow may only be suitable for maintenance infusions Flow rates that exceed the prescribing information limits are shaded red and are for informational purpose only. Please confirm the drug manufacturer's prescribing information for your region.

Table Legend:

	Suitable for initial and maintenance infusions (up to 20 mL/h/site or 30 ml/h total)
	Suitable for maintenance infusions only (up to 25 mL/h/site or 100 ml/h total)
	May exceed the prescribing information (Exceeds 25 mL/h/site or 100 ml/h total)
	No data available

With Infuset:

Table 10: Cutaquig 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
26G	OPT12604	4	1		8	11	19	26	34	45		60				
	OPT12606	6	1		8	11	19	26	34	45		60				
	OPT12609	9	1		8	11	19	26	34	45		60				
	OPT12612	12	1		8	11	19	26	34	45		60				
	OPT22604	4	2				21	27	41	60		84				
	OPT22606	6	2				21	27	41	60		84				
	OPT22609	9	2				21	27	41	60		84				
	OPT22612	12	2				21	27	41	60		84				
	OPT32606	6	3					29								
	OPT32609	9	3					29								
	OPT32612	12	3					29								
	OPT42606	6	4					35	42	69		101				
	OPT42609	9	4					35	42	69		101				
	OPT42612	12	4					35	42	69		101				
	OPT52606	6	5						41	72		106	300			
	OPT52609	9	5						41	72		106	300			
	OPT52612	12	5						41	72		106	300			
	OPT62609	9	6						43	69		105	321			
	OPT62612	12	6						43	69		105	321			
27G	SUB-104-G27	4	1				15	20	22	26						
	SUB-106-G27	6	1				15	19	21	25						
	SUB-109-G27	9	1				13	17	19	23						
	SUB-112-G27	12	1				12	16	18	21						
	SUB-204-G27	4	2					25	31	42						
	SUB-212-G27	12	2					20	24	33						
	SUB-250	6	2					23	29	39						
	SUB-260	9	2					22	27	36						
	SUB-310	6	3					26	35	51						

Table 10: Cutaquig 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	SUB-312-G27	12	3					22	29	43						
	SUB-320	9	3					24	32	47						
	SUB-400	6	4					27	37	53						
	SUB-410	9	4					25	34	49						
	SUB-412-G27	12	4					22	31	45						
	SUB-414-G27	14	4					21	29	42						
	SUB-506	6	5					28	40	59						
	SUB-509	9	5					25	36	54						
	SUB-606	6	6					29	39	60						
	SUB-609	9	6					27	36	55						
	SAF-Q-106-G27	6	1				15	19	21	25						
	SAF-Q-109-G27	9	1				13	17	19	23						
	SAF-Q-112-G27	12	1				12	16	18	21						
	SAF-Q-206-G27	6	2					23	29	39						
	SAF-Q-209-G27	9	2					22	27	36						
	SAF-Q-212-G27	12	2					20	24	33						
	SAF-Q-306-G27	6	3					26	35	51						
	SAF-Q-309-G27	9	3					24	32	47						
	SAF-Q-312-G27	12	3					22	29	43						
	SAF-Q-406-G27	6	4					27	37	53						
	SAF-Q-409-G27	9	4					25	34	49						
	SAF-Q-412-G27	12	4					22	31	45						
	SAF-Q-509-G27	9	5					25	36	54						
	SAF-Q-609-G27	9	6					27	36	55						

With VersaRate:

Table 11: Cutaquig with VersaRate

Needle Set				Total mL/h vs. VersaRate #					
Gauge	REF#	Length (mm)	Number of Needles	1	2	3	4	5	6
27G	SUB-104-G27	4	1	16	23	28			36
	SUB-106-G27	6	1	15	22	27			34
	SUB-109-G27	9	1	14	20	24			31
	SUB-112-G27	12	1	13	19	22			29
	SUB-204-G27	4	2		34	43	55		78
	SUB-212-G27	12	2		27	34	44		62
	SUB-250	6	2		32	41	53		74
	SUB-260	9	2		30	38	48		68
	SUB-310	6	3	23		52	72	89	103
	SUB-312-G27	12	3	19		43	60	74	86
	SUB-320	9	3	21		48	66	82	95
	SUB-400	6	4	24		60	89	115	154
	SUB-410	9	4	22		55	81	105	141
	SUB-412-G27	12	4	20		50	74	96	128
	SUB-414-G27	14	4	19		47	69	89	120
	SUB-506	6	5	26		68	94	138	187
	SUB-509	9	5	24		62	86	127	172
	SUB-606	6	6		47		102		227
	SUB-609	9	6		43		94		208
	SAF-Q-106-G27	6	1	15	22	27			34
	SAF-Q-109-G27	9	1	14	20	24			31
	SAF-Q-112-G27	12	1	13	19	22			29
	SAF-Q-206-G27	6	2		32	41	53		74
	SAF-Q-209-G27	9	2		30	38	48		68
	SAF-Q-212-G27	12	2		27	34	44		62
	SAF-Q-306-G27	6	3	23		52	72	89	103
	SAF-Q-309-G27	9	3	21		48	66	82	95
	SAF-Q-312-G27	12	3	19		43	60	74	86
	SAF-Q-406-G27	6	4	24		60	89	115	154
	SAF-Q-409-G27	9	4	22		55	81	105	141
	SAF-Q-412-G27	12	4	20		50	74	96	128
	SAF-Q-509-G27	9	5	24		62	86	127	172
	SAF-Q-609-G27	9	6		43		94		208

With VersaRate Plus

Table 12: Cutaquig 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	SUB-104-G27	4	1			30	31	31	32	32	33	33	34	34	36
	SUB-106-G27	6	1			29	29	30	30	31	31	32	32	32	34
	SUB-109-G27	9	1			26	27	27	28	28	29	29	29	30	31
	SUB-112-G27	12	1			24	24	25	25	26	26	26	27	27	28
	SUB-204-G27	4	2			45	49	58	66	69	70	71	71	71	73
	SUB-212-G27	12	2			36	39	46	52	55	56	56	56	56	58
	SUB-250	6	2			43	46	55	62	66	67	67	67	67	70
	SUB-260	9	2			39	42	50	57	60	61	62	62	62	64
	SUB-310	6	3			66	75	82	88	93	97	101	105	108	116
	SUB-312-G27	12	3			55	62	68	73	77	81	84	88	90	97
	SUB-320	9	3			60	68	75	80	85	89	93	96	99	107
	SUB-400	6	4			73	85	97	107	116	122	127	131	133	145
	SUB-410	9	4			67	78	89	99	106	112	116	120	122	133
	SUB-412-G27	12	4			61	71	81	90	97	102	106	109	111	121
	SUB-414-G27	14	4			57	67	76	84	90	95	99	102	104	113
	SUB-506	6	5			74	101	118	130	139	146	152	156	160	174
	SUB-509	9	5			68	93	109	120	128	134	139	143	147	160
	SUB-606	6	6			87	118	139	155	168	178	187	194	200	224
	SUB-609	9	6			80	108	128	142	154	163	171	178	184	206
	SAF-Q-106-G27	6	1			29	29	30	30	31	31	32	32	32	34
	SAF-Q-109-G27	9	1			26	27	27	28	28	29	29	29	30	31
	SAF-Q-112-G27	12	1			24	24	25	25	26	26	26	27	27	28
	SAF-Q-206-G27	6	2			43	46	55	62	66	67	67	67	67	70
	SAF-Q-209-G27	9	2			39	42	50	57	60	61	62	62	62	64
	SAF-Q-212-G27	12	2			36	39	46	52	55	56	56	56	56	58
	SAF-Q-306-G27	6	3			66	75	82	88	93	97	101	105	108	116
	SAF-Q-309-G27	9	3			60	68	75	80	85	89	93	96	99	107
	SAF-Q-312-G27	12	3			55	62	68	73	77	81	84	88	90	97
	SAF-Q-406-G27	6	4			73	85	97	107	116	122	127	131	133	145
	SAF-Q-409-G27	9	4			67	78	89	99	106	112	116	120	122	133
	SAF-Q-412-G27	12	4			61	71	81	90	97	102	106	109	111	121
	SAF-Q-509-G27	9	5			68	93	109	120	128	134	139	143	147	160
	SAF-Q-609-G27	9	6			80	108	128	142	154	163	171	178	184	206

Infusing Gammanorm

The tables below show system total flow rates without system tolerance or other factors that may affect flow rate. Cells shaded in gray do not have values listed because testing has not been performed. Cells shaded in white may be suitable for initial and maintenance infusions. Values that are shaded in yellow may only be suitable for maintenance infusions Flow rates that exceed the prescribing information limits are shaded red and are for informational purpose only. Please confirm the drug manufacturer's prescribing information for your region.

Table Legend:

	Suitable for initial and maintenance infusions (up to 10 mL/h/site)
	Suitable for maintenance infusions only (up to 20 mL/h/site)
	May exceed the prescribing information (Exceeds 20 mL/h/site)
	No data available

With VersaRate

Table 13: Gammanorm 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	19	28				100
	SUB-112-G24	12	1	17	25				91
	SUB-209-G24	9	2	20	34	48	72		173
	SUB-212-G24	12	2	18	31	44	66		157
	SUB-309-G24	9	3	21	39	60	110		254
	SUB-312-G24	12	3	19	35	54	100		231
	SAF-Q-106-G24	6	1	21	31				109
	SAF-Q-109-G24	9	1	19	28				100
	SAF-Q-309-G24	9	3	21	39	60	110		254
27G	SUB-104-G27	4	1	13	17	22	24	28	29
	SUB-106-G27	6	1	12	16	21	23	27	27
	SUB-109-G27	9	1	11	15	19	21	24	25
	SUB-112-G27	12	1	10	14	17	19	22	23
	SUB-204-G27	4	2	16	26	35	43	50	56
	SUB-212-G27	12	2	13	20	27	34	40	44
	SUB-250	6	2	16	24	33	41	48	53
	SUB-260	9	2	14	22	30	37	44	48
	SUB-310	6	3	17	30	41	53	69	73
	SUB-312-G27	12	3	14	25	34	44	58	61
	SUB-320	9	3	16	27	37	49	64	67
	SAF-Q-106-G27	6	1	12	16	21	23	27	27
	SAF-Q-109-G27	9	1	11	15	19	21	24	25
	SAF-Q-112-G27	12	1	10	14	17	19	22	23
	SAF-Q-206-G27	6	2	16	24	33	41	48	53
	SAF-Q-209-G27	9	2	14	22	30	37	44	48
	SAF-Q-212-G27	12	2	13	20	27	34	40	44
	SAF-Q-306-G27	6	3	17	30	41	53	69	73
	SAF-Q-309-G27	9	3	16	27	37	49	64	67
	SAF-Q-312-G27	12	3	14	25	34	44	58	61

With VersaRate Plus

Table 14: Gammanorm 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	SUB-104-G27	4	1	9	19	22	23	24	24	25	25	25	26	26	29
	SUB-106-G27	6	1	8	18	21	22	23	23	24	24	24	24	24	27
	SUB-109-G27	9	1	8	16	19	20	21	21	22	22	22	22	22	25
	SUB-112-G27	12	1	7	15	17	18	19	19	20	20	20	20	20	23
	SUB-204-G27	4	2	14	31	38	43	46	49	51	52	53	54	55	57
	SUB-212-G27	12	2	11	24	30	34	37	39	40	41	42	43	44	45
	SUB-250	6	2	14	29	36	41	44	46	48	49	51	52	52	54
	SUB-260	9	2	12	27	33	37	40	42	44	45	46	47	48	49
	SUB-310	6	3	16	34	49	62	69	73	76	77	78	79	79	82
	SUB-312-G27	12	3	13	28	41	52	58	61	63	65	65	66	66	69
	SUB-320	9	3	15	31	45	57	63	67	70	71	72	72	73	76
	SUB-400	6	4	19	44	61	73	82	88	94	98	101	104	106	113
	SUB-410	9	4	18	40	56	67	75	81	86	90	93	95	97	103
	SUB-412-G27	12	4	16	37	51	61	68	74	78	81	84	87	88	94
	SUB-414-G27	14	4	15	34	48	57	64	69	73	76	79	81	83	88
	SAF-Q-106-G27	6	1	8	18	21	22	23	23	24	24	24	24	24	27
	SAF-Q-109-G27	9	1	8	16	19	20	21	21	22	22	22	22	22	25
	SAF-Q-112-G27	12	1	7	15	17	18	19	19	20	20	20	20	20	23
	SAF-Q-206-G27	6	2	14	29	36	41	44	46	48	49	51	52	52	54
	SAF-Q-209-G27	9	2	12	27	33	37	40	42	44	45	46	47	48	49
	SAF-Q-212-G27	12	2	11	24	30	34	37	39	40	41	42	43	44	45
	SAF-Q-306-G27	6	3	16	34	49	62	69	73	76	77	78	79	79	82
	SAF-Q-309-G27	9	3	15	31	45	57	63	67	70	71	72	72	73	76
	SAF-Q-312-G27	12	3	13	28	41	52	58	61	63	65	65	66	66	69
	SAF-Q-406-G27	6	4	19	44	61	73	82	88	94	98	101	104	106	113
	SAF-Q-409-G27	9	4	18	40	56	67	75	81	86	90	93	95	97	103
	SAF-Q-412-G27	12	4	16	37	51	61	68	74	78	81	84	87	88	94

Infusing Subcuvia

The tables below show system total flow rates without system tolerance or other factors that may affect flow rate. Cells shaded in gray do not have values listed because testing has not been performed. Cells shaded in white may be suitable for initial and maintenance infusions. Values that are shaded in yellow may only be suitable for maintenance infusions Flow rates that exceed the prescribing information limits are shaded red and are for informational purpose only. Please confirm the drug manufacturer's prescribing information for your region.

Table Legend:

	Suitable for initial and maintenance infusions (up to 10 mL/h/site)
	Suitable for maintenance infusions only (up to 20 mL/h/site)
	May exceed the prescribing information (Exceeds 20 mL/h/site)
	No data available

With VersaRate

Table 15: Subcuvia 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	21	30				108
	SUB-112-G24	12	1	19	27				98
	SUB-209-G24	9	2	22	37	52	78		186
	SUB-212-G24	12	2	20	33	47	71		169
	SUB-309-G24	9	3	22	42	64	119		273
	SUB-312-G24	12	3	20	38	58	108		249
	SAF-Q-106-G24	6	1	23	33				117
	SAF-Q-109-G24	9	1	21	30				108
	SAF-Q-309-G24	9	3	22	42	64	119		273
27G	SUB-104-G27	4	1	14	19	23	26	30	31
	SUB-106-G27	6	1	13	18	22	24	29	29
	SUB-109-G27	9	1	12	16	20	22	26	27
	SUB-112-G27	12	1	11	15	19	20	24	24
	SUB-204-G27	4	2	18	27	37	46	54	60
	SUB-212-G27	12	2	14	22	29	37	43	47
	SUB-250	6	2	17	26	35	44	51	57
	SUB-260	9	2	15	24	32	40	47	52
	SUB-310	6	3	19	32	44	57	75	79
	SUB-312-G27	12	3	16	27	37	48	62	66
	SUB-320	9	3	17	30	40	53	68	72
	SAF-Q-106-G27	6	1	13	18	22	24	29	29
	SAF-Q-109-G27	9	1	12	16	20	22	26	27
	SAF-Q-112-G27	12	1	11	15	19	20	24	24
	SAF-Q-206-G27	6	2	17	26	35	44	51	57
	SAF-Q-209-G27	9	2	15	24	32	40	47	52
	SAF-Q-212-G27	12	2	14	22	29	37	43	47
	SAF-Q-306-G27	6	3	19	32	44	57	75	79
	SAF-Q-309-G27	9	3	17	30	40	53	68	72
	SAF-Q-312-G27	12	3	16	27	37	48	62	66

With VersaRate Plus

Table 16: Subcuvia with VersaRate Plus

Needle Set				Total mL/h vs. VersaRate Plus #											
Gauge	REF#	Length (mm)	Sites	1	2	3	4	5	6	7	8	9	10	11	OPEN
24G	SUB-109-G24	9	1	15	38	56	69	79	86	90	93	95	97	99	1081
	SUB-112-G24	12	1	14	34	51	63	72	78	82	85	86	88	90	98
	SUB-209-G24	9	2	12	49	81	108	132	151	167	179	187	192	194	212
	SUB-212-G24	12	2	11	44	73	98	120	137	152	162	170	175	177	193
	SAF-Q-106-G24	6	1	16	41	61	75	86	93	98	101	103	105	107	118
	SAF-Q-109-G24	9	1	15	38	56	69	79	86	90	93	95	97	99	108
27G	SUB-104-G27	4	1	10	18	22	24	25	25	26	26	26	26	26	28
	SUB-106-G27	6	1	10	17	21	22	23	24	24	25	25	25	25	26
	SUB-109-G27	9	1	9	16	19	21	21	22	22	23	23	23	23	24
	SUB-112-G27	12	1	8	14	17	19	20	20	20	21	21	21	21	22
	SUB-204-G27	4	2	12	28	40	48	54	57	59	59	60	60	62	66
	SUB-212-G27	12	2	9	22	32	38	42	45	46	47	47	48	49	52
	SUB-250	6	2	11	27	38	46	51	54	55	56	56	57	59	62
	SUB-260	9	2	10	24	35	42	47	49	51	51	52	52	54	57
	SAF-Q-106-G27	6	1	10	17	21	22	23	24	24	25	25	25	25	26
	SAF-Q-109-G27	9	1	9	16	19	21	21	22	22	23	23	23	23	24
	SAF-Q-112-G27	12	1	8	14	17	19	20	20	20	21	21	21	21	22
	SAF-Q-206-G27	6	2	11	27	38	46	51	54	55	56	56	57	59	62
	SAF-Q-209-G27	9	2	10	24	35	42	47	49	51	51	52	52	54	57
	SAF-Q-212-G27	12	2	9	22	32	38	42	45	46	47	47	48	49	52

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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