SCIg60
Infusion System

EMED Technologies
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CREATIVE THINKING

Caution: U.S. Federal Law restricts this device to sale by or on order of a physician.

Contents

United States User Manual

(Subcutaneous Infusion of Hizentra, Gammagard, and Cuvitru)

Introduction

The EMED SCIg60 Infusion system provides users with a portable way to subcutaneously infuse indicated human plasma-derived immunoglobulin solutions.

The SCIg60 Infuser is a reusable mechanical device and does not require batteries or any electrical source. The system utilizes a spring as a source of pressure that optimizes and controls the continuous delivery of the immunoglobulin fluids at desired flow rates using fixed rate (Infuset™) or variable rate (VersaRate and VersaRate Plus) flow control accessories.

Indications

The SCIg60 Infusion System is intended for use in the home or hospital environment for the subcutaneous infusion of Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid (manufactured by CSL Behring), Gammagard Liquid, Immune Globulin Infusion (Human) 10% (manufactured by Baxalta), and Cuvitru Immune Globulin Infusion (Human) 20% (manufactured by Baxalta) with the BD 60 ml syringe (model no. 309653).

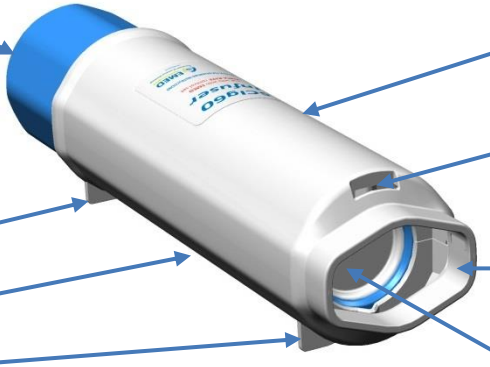
EMED SCIg60 Infusion System

- SCIg60 Infuser
- User Manual
- Carrying Case
- BD 60 ml syringe (model no. 309653)
- Infuset Flow Control Accessory (sold separately)
- VersaRate Variable Rate Flow Control Accessory (sold separately)
- EMED subcutaneous infusion administration sets (sold separately)

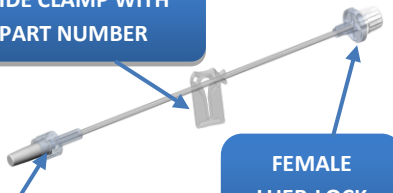
NOTE: BD 60 ml syringes (model no. 309653) are not provided and may be purchased separately.

Getting to know your SCIg60 Infusion System

SCIg60 Infuser

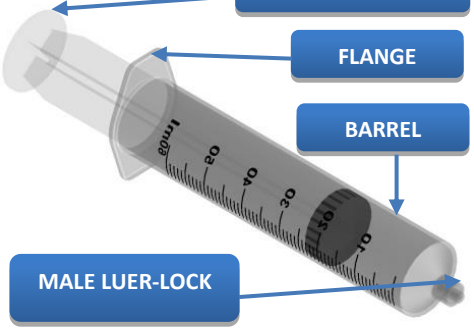


Infuset



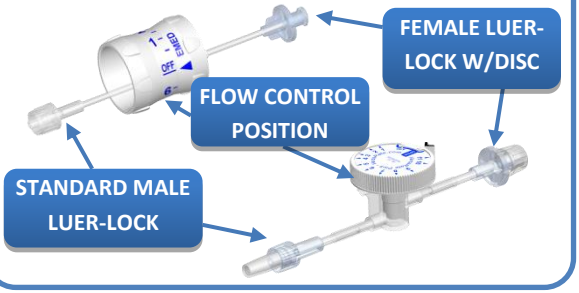
BD 60 ml syringe

(model no. 309653)



Administration Needle Set

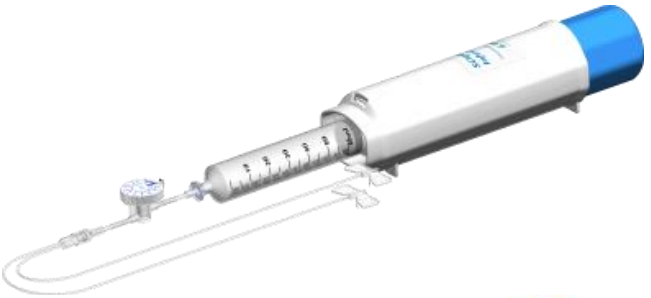
VersaRate and VersaRate Plus



Complete SCIg60 Infusion System

With VersaRate

With VersaRate Plus



With Infuset

SCIg60 Infusion System Carrying Case

Available Flow Control Accessories

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

NOTE: Please review *SCIg60 Infusion System Setup for Infusion Rates* section to determine which administration set is most appropriate for specific therapeutic needs and/or patient preferences.

Contraindications
Do not continue to use an SCIg60 Infuser that has been damaged, dropped, or if it has failed to perform as expected. If the infuser is dropped or damaged either in transit to you or during preparation for its use, or if any other damage is suspected, contact EMED Technologies.
Do not subject the Infuser to autoclaving or other similar methods of sterilization.
Do not use SCIg60 Infusion System while undergoing medical diagnostic procedures, such as MRI, x-ray, or CT scans.
Administration of indicated immunoglobulin fluids is for subcutaneous infusion only and infusion into other infusion sites, including blood vessels, should not occur.
Use only the listed administration sets for administration of indicated immunoglobulin fluids with the SCIg60 Infusion System to obtain specified flow rates. Use of other infusion accessories may result in flow rates that exceed ranges approved for each indicated immunoglobulin fluid.
Physicians and users should read the indicated immunoglobulin fluids contraindications and warnings prior to initiating delivery of indicated immunoglobulin fluids.

Warnings
Do not insert or remove the BD 60 ml syringe (model no. 309653) until the INNER DRIVE is fully opened, as indicated in the IFU section, steps 9 and 17 respectively.
Do not use flow control accessories, administration sets, or BD 60 ml syringes (model no. 309653) more than once, as reuse may result in infection, cross contamination, or altered flow rate performance.
Do not store indicated immunoglobulin fluids in the syringe prior to use. Prepare the SCIg60 Infusion System and initiate therapy immediately after transferring indicated immunoglobulin fluids to BD 60 ml syringes (model no. 309653).
Do not use multiple flow control accessories at one time (i.e. 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.
Do not open the Infuser or attempt to modify its function in any way other than its intended use.
DO NOT use any syringe other than the BD 60 ml (model no. 309653) syringe. Doing so may result in unsafe conditions for patient or deviation from desired infusion rates.
Do not re-sterilize Infuset or VersaRate flow control accessories, doing so may cause serious health effects to patient.

Important Information
Read all instructions for the SCIg60 Infusion System.
Read all instructions for the Infuset or VersaRate flow and specified administration set.
Use the SCIg60 Infusion System as prescribed by your healthcare provider and follow all the directions as prescribed.
Use aseptic technique when handling Infuset and VersaRate flow control accessories and specified subcutaneous administration set.
Place the SCIg60 Infusion pump on a flat surface or in the provided carrying case during use. BD 60 ml syringe (model no. 309653) damage and indicated immunoglobulin fluids loss could occur if system is dropped while loaded with syringe and indicated immunoglobulin fluids.
The SCIg60 Infusion System is intended for single patient use only.
Physicians and their patients should consult the Prescribing Information for the indicated immunoglobulin fluids to be sure that the immunoglobulin manufacturer's maximum recommended volume per infusion site is not exceeded.
Contact EMED if you have any questions regarding the use of the SCIg60 Infusion System.

SCIg60 Infusion System Instructions for Use (IFU)

Note: Instructions for Use also appear on the underside of the Infuser

1. **WASH HANDS** thoroughly and dry hands before handling any supplies, and wear gloves if you have been instructed to do so.

2. **REMOVE** Infuset or VersaRate, specified administration set and syringe from sterile packaging.

3. **TRANSFER** Immunoglobulin fluid from vial(s) to BD 60 ml syringe (model no. 309653) according to the package insert or as instructed by your healthcare professional, and immediately proceed to next step.

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).

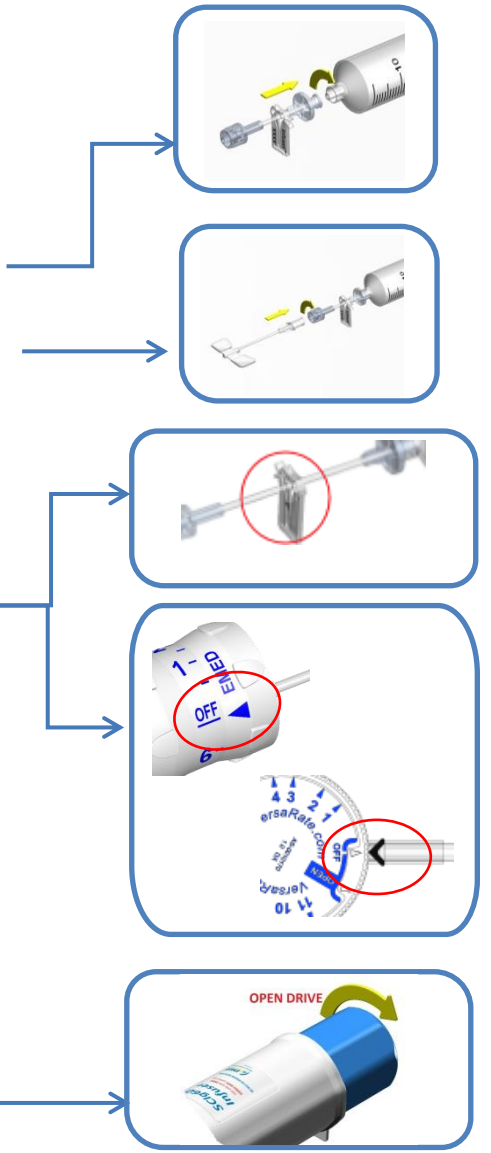
6. **PRIME** the tubing by gently pushing on the syringe plunger to fill the tubing with Immunoglobulin fluid, or as instructed by your healthcare professional.

7. Use slide clamp provided with Infuset or select the 'OFF' position on the VersaRate to prevent flow of Immunoglobulin fluid.

8. **PREPARE INJECTION SITES and INSERT NEEDLE**S according to the indicated Immunoglobulin fluid 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.

9. **OPEN** SCIg60 Infuser drive by turning the handle **counterclockwise** until it stops.



Instructions for Use (IFU) – Continued

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.

12. **VERIFY** the syringe flange is in the 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.

    CAUTION: DO NOT ATTEMPT TO REMOVE THE BD 60 ml syringe (model no. 309653) BEFORE PERFORMING STEP 17.

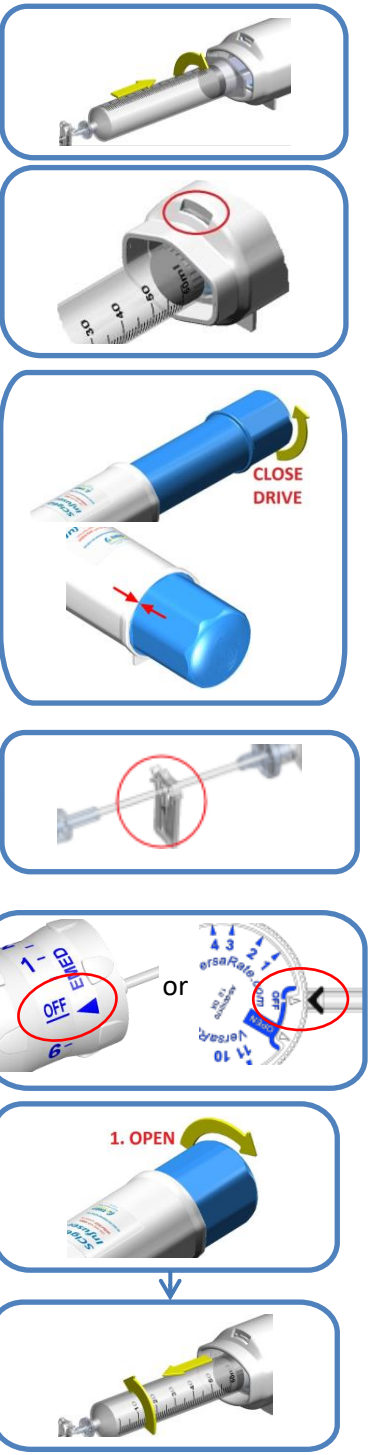
14. Place the SCIg60 Infuser, Infuset or VersaRate, and specified administration set on a stable, horizontal surface or use the Carrying Case Accessory (see *Using the SCIg60 Infuser Carrying Case Accessory* below for more details).

15. **For Infuset use**
    a) USE SLIDE CLAMP to start infusion once pump is fully loaded and needles are inserted and secured.
    b) USE SLIDE CLAMP to stop flow as necessary during infusion session or when session is complete.

16. **For VersaRate Use**
    a) TURN VersaRate to flow position as directed by your physician once pump is fully loaded and needles are inserted and secured.
    b) TURN VERSARATE TO 'OFF' position to stop flow as necessary during infusion session or when session is complete.

17. When session is complete, **REMOVE THE BD 60 ML SYRINGE (MODEL NO. 309653)** rotate the handle **counterclockwise** until it stops, then unlock the syringe by turning it **counterclockwise** (refer to steps 9 - 11 above).

18. **DISPOSE** of the BD 60 mL syringe (model 309653) , Infuset or VersaRate, and SUB-Q set in an appropriate waste container



SCIg60 Infusion System Instructions for Use (IFU) – Continued

Using the SCIg60 Infuser Carrying Case

Loading the SCIg60 System into the Carrying case

1. Obtain the carrying case and place on a safe table top 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 BD 60ml syringe (model no. 309653) and Infuset or VersaRate 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.

   Use caution not to drop the device.
4. Close the pouch with the zipper - Use caution to prevent damage to the tubing.
5. Use belt loop or shoulder strap to hold and carry the system on the body.

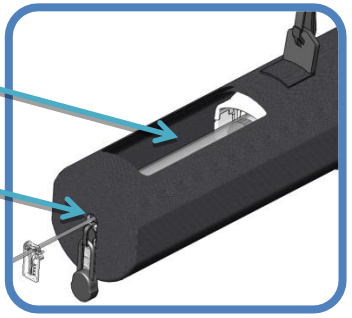
Removing the SCIg60 System from the Carrying Case

1. Place the Carrying Case containing the SCIg60 system and place on a safe table top to prevent dropping.
2. Open the pouch by pulling the zipper.
3. Remove the SCIg60 System from the pouch using caution not to drop the device.
4. Close the Carrying Case zipper.

Zipper Pull

Syringe display window

Tubing exit opening



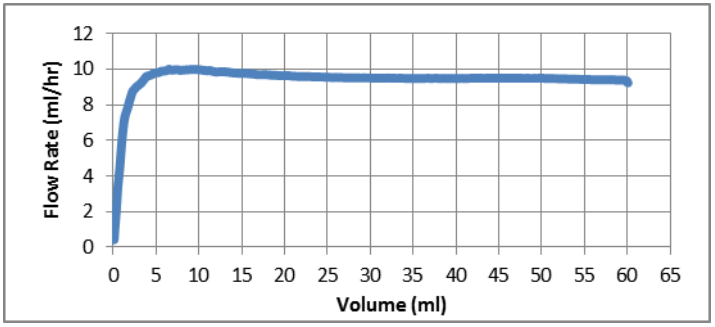
SCIg60 Infusion System Technical Information

Length	26.0 cm (10.2 in.)
Width	6.5 cm (2.6 in.)
Weight	412 g (14.5 oz)
Storage Temperature	-5°C to +40°C (23°F to 104°F)
Syringe Volume (BD 60 ml syringe (model no. 309653)	60 ml
Maximum Operating Pressure	16.8 psi
Average Operating Pressure	14.4 psi
Total System Accuracy	
(includes Infuset and SUB-Q set)	±15% from target flow rate
(VersaRate and SUB-Q set)	
@ Position ½	Up to ±33% from target flow rate
@ Position 1	Up to ±37% from target flow rate
@ Position 2	Up to ±26% from target flow rate
@ Position 3	Up to ±22% from target flow rate
@ Position 4	Up to ±15% from target flow rate
@ Position 5	Up to ±15% from target flow rate
@ Position 6	Up to ±15% from target flow rate
(VersaRate Plus and SUB-Q set)	
@ Position 1-2	Up to ±41% from target flow rate
@ Position 3-5	Up to ±21% from target flow rate
@ Position 6-10	Up to ±20% from target flow rate
@ Position 11-OPEN	Up to ±14% from target flow rate
Vertical Sensitivity	
Each 30.5 cm (12 in.) above infusion site	Up to +6% from target flow rate
Each 30.5 cm (12 in.) below infusion site	Up to -4% from target flow rate
Maximum Vertical Difference	±30.0 cm (±12 in.)
Target Operating Temperature	20°C - 25°C (68°F – 77°F)
Infuset Residual Volume	
Infuset-45	≈ 0.15 ml
Infuset-80	≈ 0.13 ml
Infuset-120	≈ 0.16 ml
Infuset-190	≈ 0.14 ml
Infuset-290	≈ 0.16 ml
Infuset-430	≈ 0.13 ml
Infuset-650	≈ 0.12 ml
Infuset-820	≈ 0.11 ml
Infuset-930	≈ 0.13 ml
Infuset-1850	≈ 0.10 ml
Infuset-3200	≈ 0.05 ml
Infuset-4000	≈ 0.06 ml

Infuset-4300	≈ 0.05 ml
VersaRate Residual Volume	
FP-0010003	≈ 0.20 ml
FP-0010026	≈ 0.25 ml
Needle Set Residual Volume	
Single needle, 27ga sets having tubing length of 27.6”	≈ 0.18 ml
Single needle, 27ga sets having tubing length of 36”	≈ 0.23 ml
Single needle, 24ga sets having tubing length of 27.6”	≈ 0.28 ml
Single needle, 24ga sets having tubing length of 36”	≈ 0.34 ml
Two-needle, 27ga sets having tubing length of 36”	≈ 0.40 ml
Two-needle, 24ga sets having tubing length of 27.6”	≈ 0.52 ml
Two-needle, 24ga sets having tubing length of 36”	≈ 0.66 ml
Three-needle, 27ga sets having tubing length of 36”	≈ 0.65 ml
Three-needle, 24ga sets having tubing length of 27.6”	≈ 0.75 ml
Three-needle, 24ga sets having tubing length of 36”	≈ 0.97 ml
Four-needle, 27ga sets having tubing length of 36”	≈ 0.80 ml
Four-needle, 24ga sets having tubing length of 27.6”	≈ 0.96 ml
Four-needle, 24ga sets having tubing length of 36”	≈ 1.30 ml
Five-needle, 27ga sets having tubing length of 36”	≈ 1.00 ml
Five-needle, 24ga sets having tubing length of 36”	≈ 1.57 ml
Six-needle, 27ga sets having tubing length of 36”	≈ 1.20 ml
Six-needle, 24ga sets having tubing length of 36”	≈ 1.87 ml
Syringe Residual Volume (BD 60 ml syringe (model no. 309653)	≈ 0.2 ml
Use-By Dating	5 years

Representative Flow Rate Profile

Total Flow Rate vs Infused Volume at 20°C – 25°C under laboratory conditions
Achieved with SUB-320 (3-needle, 27g 9mm set) and FP-001008 (Infuset-190)*



*NOTE: 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.

General - SCIg60 Infusion System Setup for Infusion Rates

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 Total Flow Rate that best accommodates each individual's needs for infusion comfort and convenience while falling within manufacturer's recommended dosage 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. Instructions for selecting the appropriate combination will also be provided for each indicated immunoglobulin fluid. 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 Total 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 subcutaneous tissue infusion sets. Testing was performed between 20°C - 25°C (68°F – 77°F). It is important to understand that flow rates of infused immunoglobulin fluids can be affected by multiple factors such as ambient temperature, patient conditions, large height differences between the Infuser and infusion site, and variations in solution viscosity.

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. Using more than one flow control accessory at a single time (i.e. connecting one Infuset to another, connecting an Infuset to a VersaRate, etc.) will impact resulting flow rates and is not recommended. Using other flow control accessories and/or subcutaneous tissue infusion sets may also result in a flow rate outside of what has been approved for a specific immunoglobulin fluid.

Please contact EMED Technologies at +1 (916) 932-0071 for additional information regarding selection of Infuset flow control extension sets or VersaRate positions with SUB-Q sets to obtain a desired flow rate.

Infusing with Infuset

Infuset with HIZENTRA (PI) - Setup for Target Infusion Rates

To choose a combination of Infuset and SUB-Q set, first find the correct table. Then find the table row that contains the needle gauge, number of needles, and/or Total Flow Rate that best meets therapeutic needs and/or patient preferences – these values are found in the first 3 columns of each table. Follow the row to the right to the Infuset Reorder Number and SUB-Q Set columns, where you will find the combination that will deliver the correct rate of Hizentra.

The first table only includes combinations that will provide flow rates that are within Hizentra dosage limits when prescribed for patients with Primary Immunodeficiency (PI) and who are infusing Hizentra for the **first time**. The second table includes combinations that will provide flow rates appropriate for subsequent **Standard Infusions** (those performed after the first infusion).

First Infusion of Hizentra indicated for PI: SUB-Q and Infuset Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset Reorder Number	SUB-Q Set
24	1	13	13	FP-0010008	SAF-Q-106-G24
	1	12	12	FP-0010008	SUB-109-G24 or SAF-Q-109-G24
	1	11	11	FP-0010008	SUB-112-G24
	2	24	12	FP-0010010	SUB-212-G24
	3	35	12	FP-0010009	SUB-312-G24
	4	39 48	10 12	FP-0010009 FP-0010006	SUB-409-G24
	4	35 44 47	9 11 12	FP-0010009 FP-0010006 FP-0010005	SUB-412-G24
	5	39 52	8 10	FP-0010009 FP-0010005	SUB-512-G24
	6	39 47 53	6 8 9	FP-0010009 FP-0010006 FP-0010005	SUB-612-G24
27	1	12	12	FP-0010009	SUB-112-G27 or SAF-Q-112-G27
	2	25	13	FP-0010005	SUB-260 or SAF-Q-209-G27
	2	23	11	FP-0010005	SUB-212-G27 or SAF-Q-212-G27
	3	36	12	FP-0010005	SUB-310 or SAF-Q-306-G27
	3	33	11	FP-0010005	SUB-320 or SAF-Q-309-G27

TABLE CONTINUES ON THE NEXT PAGE…

Infuset with HIZENTRA (PI) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

First Infusion of Hizentra indicated for PI: SUB-Q and Infuset Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset Reorder Number	SUB-Q Set
27	3	30	10	FP-0010005	SUB-312-G27 or SAF-Q-312-G27
	4	40	10	FP-0010005	SUB-400 or SAF-Q-406-G27
	4	37 49	9 12	FP-0010005 FP-0010004	SUB-410 or SAF-Q-409-G27
	4	33 44	8 11	FP-0010005 FP-0010004	SUB-412-G27 or SAF-Q-412-G27
	4	31 42	8 10	FP-0010005 FP-0010004	SUB-414-G27
	5	46 63	9 13	FP-0010005 FP-0010004	SUB-506
	5	42 57	8 11	FP-0010005 FP-0010004	SUB-509 or SAF-Q-509-G27
	6	44 46	7 8	FP-0010006 FP-0010005	SUB-606
	6	41 42 70	7 7 12	FP-0010006 FP-0010005 FP-0010004	SUB-609 or SAF-Q-609-G27

Standard Infusions of Hizentra indicated for PI: SUB-Q and Infuset Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset Reorder Number	SUB-Q Set
24	1	13 17	13 17	FP-0010008 FP-0010007	SAF-Q-106-G24
	1	12 16	12 16	FP-0010008 FP-0010007	SUB-109-G24 or SAF-Q-109-G24
	1	11 15 21	11 15 21	FP-0010008 FP-0010007 FP-0010010	SUB-112-G24
	2	26 35	13 18	FP-0010010 FP-0010009	SUB-209-G24
	2	24 32	12 16	FP-0010010 FP-0010009	SUB-212-G24
	3	39 49 51	13 16 17	FP-0010009 FP-0010006 FP-0010005	SUB-309-G24 or SAF-Q-309-G24

TABLE CONTINUES ON THE NEXT PAGE…

Infuset with HIZENTRA (PI) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for PI: SUB-Q and Infuset Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset Reorder Number	SUB-Q Set
24	3	35 45 47	12 15 16	FP-0010009 FP-0010006 FP-0010005	SUB-312-G24
	4	39 48 52	10 12 13	FP-0010009 FP-0010006 FP-0010005	SUB-409-G24
	4	35 44 47	9 11 12	FP-0010009 FP-0010006 FP-0010005	SUB-412-G24
	5	39 52 100	8 10 20	FP-0010009 FP-0010005 FP-0010004	SUB-512-G24
	6	39 47 53 117	6 8 9 20	FP-0010009 FP-0010006 FP-0010005 FP-0010004	SUB-612-G24
27	1	16 18 20	16 18 20	FP-0010009 FP-0010006 FP-0010004	SUB-104-G27
	1	15 17 19	15 17 19	FP-0010009 FP-0010006 FP-0010004	SUB-106-G27 or SAF-Q-106-G27
	1	14 15 17	14 15 17	FP-0010009 FP-0010006 FP-0010004	SUB-109-G27 or SAF-Q-109-G27
	1	12 14 16	12 14 16	FP-0010009 FP-0010006 FP-0010004	SUB-112-G27 or SAF-Q-112-G27
	2	29 34	14 17	FP-0010005 FP-0010004	SUB-204-G27
	2	27 32	14 16	FP-0010005 FP-0010004	SUB-250 or SAF-Q-206-G27
	2	25 30	13 15	FP-0010005 FP-0010004	SUB-260 or SAF-Q-209-G27
	2	23 27	11 13	FP-0010005 FP-0010004	SUB-212-G27 or SAF-Q-212-G27
	3	36 46	12 15	FP-0010005 FP-0010004	SUB-310 or SAF-Q-306-G27

TABLE CONTINUES ON THE NEXT PAGE…

Infuset with HIZENTRA (PI) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for PI: SUB-Q and Infuset Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset Reorder Number	SUB-Q Set
27	3	33 43	11 14	FP-0010005 FP-0010004	SUB-320 or SAF-Q-309-G27
	3	30 39	10 13	FP-0010005 FP-0010004	SUB-312-G27 or SAF-Q-312-G27
	4	40 53	10 13	FP-0010005 FP-0010004	SUB-400 or SAF-Q-406-G27
	4	37 49	9 12	FP-0010005 FP-0010004	SUB-410 or SAF-Q-409-G27
	4	33 44	8 11	FP-0010005 FP-0010004	SUB-412-G27 or SAF-Q-412-G27
	4	31 42	8 10	FP-0010005 FP-0010004	SUB-414-G27
	5	46 63	9 13	FP-0010005 FP-0010004	SUB-506
	5	42 57	8 11	FP-0010005 FP-0010004	SUB-509 or SAF-Q-509-G27
	6	44 46 76	7 8 13	FP-0010006 FP-0010005 FP-0010004	SUB-606
	6	41 42 70	7 7 12	FP-0010006 FP-0010005 FP-0010004	SUB-609 or SAF-Q-609-G27

Infuset with HIZENTRA (CIDP) - Setup for Target Infusion Rates

To choose a combination of Infuset and SUB-Q set, first find the correct table. Then find the table row that contains the needle gauge, number of needles, and/or Total Flow Rate that best meets therapeutic needs and/or patient preferences – these values are found in the first 3 columns of each table. Follow the row to the right to the Infuset Reorder Number and SUB-Q Set columns, where you will find the combination that will deliver the correct rate of Hizentra.

The first table only includes combinations that will provide flow rates that are within Hizentra dosage limits when prescribed for patients with Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) and who are infusing Hizentra for the **first time**. The second table includes combinations that will provide flow rates appropriate for subsequent **Standard Infusions** (those performed after the first infusion).

First Infusion of Hizentra indicated for CIDP: SUB-Q and Infuset Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset Reorder Number	SUB-Q Set
24	1	13	13	FP-0010008	SAF-Q-106-G24
	1	12 16	12 16	FP-0010008 FP-0010007	SUB-109-G24 or SAF-Q-109-G24
	1	11 15	11 15	FP-0010008 FP-0010007	SUB-112-G24
	2	26	13	FP-0010010	SUB-209-G24
	2	24 32	12 16	FP-0010010 FP-0010009	SUB-212-G24
	3	39 49	13 16	FP-0010009 FP-0010006	SUB-309-G24 or SAF-Q-309-G24
	3	35 45 47	12 15 16	FP-0010009 FP-0010006 FP-0010005	SUB-312-G24
	4	39 48 52	10 12 13	FP-0010009 FP-0010006 FP-0010005	SUB-409-G24
	4	35 44 47	9 11 12	FP-0010009 FP-0010006 FP-0010005	SUB-412-G24
	5	39 52	8 10	FP-0010009 FP-0010005	SUB-512-G24
	6	39 47 53	6 8 9	FP-0010009 FP-0010006 FP-0010005	SUB-612-G24

TABLE CONTINUES ON THE NEXT PAGE…

Infuset with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

First Infusion of Hizentra indicated for CIDP: SUB-Q and Infuset Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset Reorder Number	SUB-Q Set
27	1	16	16	FP-0010009	SUB-104-G27
	1	15 17	15 17	FP-0010009 FP-0010006	SUB-106-G27 or SAF-Q-106-G27
	1	14 15	14 15	FP-0010009 FP-0010006	SUB-109-G27 or SAF-Q-109-G27
	1	12 14 16	12 14 16	FP-0010009 FP-0010006 FP-0010004	SUB-112-G27 or SAF-Q-112-G27
	2	29	14	FP-0010005	SUB-204-G27
	2	27 32	14 16	FP-0010005 FP-0010004	SUB-250 or SAF-Q-206-G27
	2	25 30	13 15	FP-0010005 FP-0010004	SUB-260 or SAF-Q-209-G27
	2	23 27	11 13	FP-0010005 FP-0010004	SUB-212-G27 or SAF-Q-212-G27
	3	36 46	12 15	FP-0010005 FP-0010004	SUB-310 or SAF-Q-306-G27
	3	33 43	11 14	FP-0010005 FP-0010004	SUB-320 or SAF-Q-309-G27
	3	30 39	10 13	FP-0010005 FP-0010004	SUB-312-G27 or SAF-Q-312-G27
	4	40 53	10 13	FP-0010005 FP-0010004	SUB-400 or SAF-Q-406-G27
	4	37 49	9 12	FP-0010005 FP-0010004	SUB-410 or SAF-Q-409-G27
	4	33 44	8 11	FP-0010005 FP-0010004	SUB-412-G27 or SAF-Q-412-G27
	4	31 42	8 10	FP-0010005 FP-0010004	SUB-414-G27
	5	46 63	9 13	FP-0010005 FP-0010004	SUB-506
	5	42 57	8 11	FP-0010005 FP-0010004	SUB-509 or SAF-Q-509-G27
	6	44 46 76	7 8 13	FP-0010006 FP-0010005 FP-0010004	SUB-606
	6	41 42 70	7 7 12	FP-0010006 FP-0010005 FP-0010004	SUB-609 or SAF-Q-609-G27

TABLE CONTINUES ON THE NEXT PAGE…

Infuset with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

Standard Infusions of Hizentra indicated for CIDP: SUB-Q and Infuset Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset Reorder Number	SUB-Q Set
24	1	13	13	FP-0010008	SAF-Q-106-G24
		17	17	FP-0010007	
		25	25	FP-0010010	
		32	32	FP-0010009	
		40	40	FP-0010005	
	1	12	12	FP-0010008	SUB-109-G24 or SAF-Q-109-G24
		16	16	FP-0010007	
		23	23	FP-0010010	
		30	30	FP-0010009	
		37	37	FP-0010005	
	1	11	11	FP-0010008	SUB-112-G24
		15	15	FP-0010007	
		21	21	FP-0010010	
		27	27	FP-0010009	
		33	33	FP-0010005	
	2	26	13	FP-0010010	SUB-209-G24
		35	18	FP-0010009	
		48	24	FP-0010006	
		52	26	FP-0010005	
	2	24	12	FP-0010010	SUB-212-G24
		32	16	FP-0010009	
		44	22	FP-0010006	
		48	24	FP-0010005	
	3	39	13	FP-0010009	SUB-309-G24 or SAF-Q-309-G24
		49	16	FP-0010006	
		51	17	FP-0010005	
	3	35	12	FP-0010009	SUB-312-G24
		45	15	FP-0010006	
		47	16	FP-0010005	
		124	41	FP-0010004	
	4	39	10	FP-0010009	SUB-409-G24
		48	12	FP-0010006	
		52	13	FP-0010005	
		111	28	FP-0010004	
	4	35	9	FP-0010009	SUB-412-G24
		44	11	FP-0010006	
		47	12	FP-0010005	
		101	25	FP-0010004	

TABLE CONTINUES ON THE NEXT PAGE…

Infuset with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

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Standard Infusions of Hizentra indicated for CIDP: SUB-Q and Infuset Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset Reorder Number	SUB-Q Set
24	5	39 52 100	8 10 20	FP-0010009 FP-0010005 FP-0010004	SUB-512-G24
	6	39 47 53 117	6 8 9 20	FP-0010009 FP-0010006 FP-0010005 FP-0010004	SUB-612-G24
27	1	16 18 20	16 18 20	FP-0010009 FP-0010006 FP-0010004	SUB-104-G27
	1	15 17 19	15 17 19	FP-0010009 FP-0010006 FP-0010004	SUB-106-G27 or SAF-Q-106-G27
	1	14 15 17	14 15 17	FP-0010009 FP-0010006 FP-0010004	SUB-109-G27 or SAF-Q-109-G27
	1	12 14 16	12 14 16	FP-0010009 FP-0010006 FP-0010004	SUB-112-G27 or SAF-Q-112-G27
	2	29 34	14 17	FP-0010005 FP-0010004	SUB-204-G27
	2	27 32	14 16	FP-0010005 FP-0010004	SUB-250 or SAF-Q-206-G27
	2	25 30	13 15	FP-0010005 FP-0010004	SUB-260 or SAF-Q-209-G27
	2	23 27	11 13	FP-0010005 FP-0010004	SUB-212-G27 or SAF-Q-212-G27
	3	36 46	12 15	FP-0010005 FP-0010004	SUB-310 or SAF-Q-306-G27
	3	33 43	11 14	FP-0010005 FP-0010004	SUB-320 or SAF-Q-309-G27
	3	30 39	10 13	FP-0010005 FP-0010004	SUB-312-G27 or SAF-Q-312-G27
	4	40 53	10 13	FP-0010005 FP-0010004	SUB-400 or SAF-Q-406-G27
	4	37 49	9 12	FP-0010005 FP-0010004	SUB-410 or SAF-Q-409-G27

TABLE CONTINUES ON THE NEXT PAGE…

Infuset with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for CIDP: SUB-Q and Infuset Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset Reorder Number	SUB-Q Set
27	4	33 44	8 11	FP-0010005 FP-0010004	SUB-412-G27 or SAF-Q-412-G27
	4	31 42	8 10	FP-0010005 FP-0010004	SUB-414-G27
	5	46 63	9 13	FP-0010005 FP-0010004	SUB-506
	5	42 57	8 11	FP-0010005 FP-0010004	SUB-509 or SAF-Q-509-G27
	6	44 46 76	7 8 13	FP-0010006 FP-0010005 FP-0010004	SUB-606
	6	41 42 70	7 7 12	FP-0010006 FP-0010005 FP-0010004	SUB-609 or SAF-Q-609-G27

Infuset with GAMMAGARD - Setup for Target Infusion Rates

To choose a combination of Infuset and SUB-Q set, first find the correct table. Then find the table row that contains the needle gauge, number of needles, and/or Total Flow Rate that best meets therapeutic needs and/or patient preferences – these values are found in the first 3 columns of each table. Follow the row to the right to the Infuset Reorder Number and SUB-Q Set columns, where you will find the combination that will deliver the correct flow rate of Gammagard.

The first table only includes combinations that will provide flow rates that are within Gammagard's dosage limits for the **initial infusion of Gammagard for patients weighing less than 40kg** and the second table includes combinations that will provide flow rates appropriate for subsequent **Maintenance Infusions for patients weighing less than 40kg** (those performed after the first infusion). The third table provides combinations for **patients weighing 40kg or higher performing initial infusions with Gammagard**, and the fourth table is for those patients **performing maintenance infusions**.

Initial Infusion of Gammagard (patients weighing less than 40kg) – SUB-Q and Infuset Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset Reorder Number	SUB-Q Set
24	2	25	12	FP-0010014	SUB-209-G24
	2	23	11	FP-0010014	SUB-212-G24
	4	29	7	FP-0010011	SUB-409-G24
	4	26	7	FP-0010011	SUB-412-G24
	5	63	13	FP-0010008	SUB-512-G24
27	1	13	13	FP-0010013	SUB-109-G27 or SAF-Q-109-G27
	1	12	12	FP-0010013	SUB-112-G27 or SAF-Q-112-G27
	2	25	12	FP-0010011	SUB-260 or SAF-Q-209-G27
	2	22	11	FP-0010011	SUB-212-G27 or SAF-Q-212-G27
	5	62	12	FP-0010008	SUB-506
	5	57	11	FP-0010008	SUB-509 or SAF-Q-509-G27

Infuset with GAMMAGARD - Setup for Target Infusion Rates (continued)

Maintenance Infusions (patients weighing less than 40kg) – SUB-Q and Infuset Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset Reorder Number	SUB-Q Set
24	1	16	16	FP-0010013	SAF-Q-106-G24
	1	15	15	FP-0010013	SUB-109-G24 or SAF-Q-109-G24
	1	14	14	FP-0010013	SUB-112-G24
	2	25 29	12 15	FP-0010014 FP-0010011	SUB-209-G24
	2	23 26	11 13	FP-0010014 FP-0010011	SUB-212-G24
	4	29	7	FP-0010011	SUB-409-G24
	4	26	7	FP-0010011	SUB-412-G24
	5	63	13	FP-0010008	SUB-512-G24
	6	95	16	FP-0010007	SUB-612-G24
27	1	15	15	FP-0010013	SUB-104-G27
	1	14	14	FP-0010013	SUB-106-G27 or SAF-Q-106-G27
	1	13	13	FP-0010013	SUB-109-G27 or SAF-Q-109-G27
	1	12	12	FP-0010013	SUB-112-G27 or SAF-Q-112-G27
	2	28	14	FP-0010011	SUB-204-G27
	2	27	13	FP-0010011	SUB-250 or SAF-Q-206-G27
	2	25	12	FP-0010011	SUB-260 or SAF-Q-209-G27
	2	22	11	FP-0010011	SUB-212-G27 or SAF-Q-212-G27
	3	51	17	FP-0010008	SUB-320 or SAF-Q-309-G27
	3	47	16	FP-0010008	SUB-312-G27 or SAF-Q-312-G27
	4	68	17	FP-0010007	SUB-414-G27
	5	62	12	FP-0010008	SUB-506
	5	57	11	FP-0010008	SUB-509 or SAF-Q-509-G27
	6	96	16	FP-0010007	SUB-606
	6	88	15	FP-0010007	SUB-609 or SAF-Q-609-G27

Infuset with GAMMAGARD - Setup for Target Infusion Rates (continued)

Initial Infusion of Gammagard (patients weighing 40kg or more) – SUB-Q and Infuset Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset Reorder Number	SUB-Q Set
24	1	16	16	FP-0010013	SAF-Q-106-G24
	1	15	15	FP-0010013	SUB-109-G24 or SAF-Q-109-G24
	1	14	14	FP-0010013	SUB-112-G24
	2	25 29	12 15	FP-0010014 FP-0010011	SUB-209-G24
	2	23 26	11 13	FP-0010014 FP-0010011	SUB-212-G24
	4	29	7	FP-0010011	SUB-409-G24
	4	26	7	FP-0010011	SUB-412-G24
	5	63	13	FP-0010008	SUB-512-G24
	6	95	16	FP-0010007	SUB-612-G24
27	1	15	15	FP-0010013	SUB-104-G27
	1	14	14	FP-0010013	SUB-106-G27 or SAF-Q-106-G27
	1	13	13	FP-0010013	SUB-109-G27 or SAF-Q-109-G27
	1	12	12	FP-0010013	SUB-112-G27 or SAF-Q-112-G27
	2	28	14	FP-0010011	SUB-204-G27
	2	27	13	FP-0010011	SUB-250 or SAF-Q-206-G27
	2	25	12	FP-0010011	SUB-260 or SAF-Q-209-G27
	2	22	11	FP-0010011	SUB-212-G27 or SAF-Q-212-G27
	3	51	17	FP-0010008	SUB-320 or SAF-Q-309-G27
	3	47	16	FP-0010008	SUB-312-G27 or SAF-Q-312-G27
	4	68	17	FP-0010007	SUB-414-G27
	5	62	12	FP-0010008	SUB-506
	5	57	11	FP-0010008	SUB-509 or SAF-Q-509-G27
	6	96	16	FP-0010007	SUB-606
	6	88	15	FP-0010007	SUB-609 or SAF-Q-609-G27

Infuset with GAMMAGARD - Setup for Target Infusion Rates (continued)

Maintenance Infusions (patients weighing 40kg or more) – SUB-Q and Infuset Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset Reorder Number	SUB-Q Set
24	1	16 26	16 26	FP-0010013 FP-0010014	SAF-Q-106-G24
	1	15 24	15 24	FP-0010013 FP-0010014	SUB-109-G24 or SAF-Q-109-G24
	1	14 21 25	14 21 25	FP-0010013 FP-0010014 FP-0010011	SUB-112-G24
	2	25 29	12 15	FP-0010014 FP-0010011	SUB-209-G24
	2	23 26	11 13	FP-0010014 FP-0010011	SUB-212-G24
	3	57	19	FP-0010008	SUB-309-G24 or SAF-Q-309-G24
	3	52	17	FP-0010008	SUB-312-G24
	4	29 94	7 24	FP-0010011 FP-0010007	SUB-409-G24
	4	26 86	7 21	FP-0010011 FP-0010007	SUB-412-G24
	5	63	13	FP-0010008	SUB-512-G24
	6	95	16	FP-0010007	SUB-612-G24
27	1	15 23 25	15 23 25	FP-0010013 FP-0010014 FP-0010011	SUB-104-G27
	1	14 22 24	14 22 24	FP-0010013 FP-0010014 FP-0010011	SUB-106-G27 or SAF-Q-106-G27
	1	13 20 22	13 20 22	FP-0010013 FP-0010014 FP-0010011	SUB-109-G27 or SAF-Q-109-G27
	1	12 18 20	12 18 20	FP-0010013 FP-0010014 FP-0010011	SUB-112-G27 or SAF-Q-112-G27
	2	28	14	FP-0010011	SUB-204-G27
	2	27	13	FP-0010011	SUB-250 or SAF-Q-206-G27
	2	25 47	12 24	FP-0010011 FP-0010008	SUB-260 or SAF-Q-209-G27
	2	22 43	11 22	FP-0010011 FP-0010008	SUB-212-G27 or SAF-Q-212-G27

TABLE CONTINUES ON THE NEXT PAGE…

Infuset with GAMMAGARD - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Maintenance Infusions (patients weighing 40kg or more) – SUB-Q and Infuset Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset Reorder Number	SUB-Q Set
27	3	56 77	19 26	FP-0010008 FP-0010007	SUB-310 or SAF-Q-306-G27
	3	51 71	17 24	FP-0010008 FP-0010007	SUB-320 or SAF-Q-309-G27
	3	47 64	16 21	FP-0010008 FP-0010007	SUB-312-G27 or SAF-Q-312-G27
	4	87	22	FP-0010007	SUB-400 or SAF-Q-406-G27
	4	80	20	FP-0010007	SUB-410 or SAF-Q-409-G27
	4	72 103	18 26	FP-0010007 FP-0010010	SUB-412-G27 or SAF-Q-412-G27
	4	68 96	17 24	FP-0010007 FP-0010010	SUB-414-G27
	5	62	12	FP-0010008	SUB-506
	5	57 121	11 24	FP-0010008 FP-0010010	SUB-509 or SAF-Q-509-G27
	6	96	16	FP-0010007	SUB-606
	6	88	15	FP-0010007	SUB-609 or SAF-Q-609-G27

Infuset with CUVITRU - Setup for Target Infusion Rates

To choose a combination of Infuset and SUB-Q set, first find the correct table. Then find the table row that contains the needle gauge, number of needles, and/or Total Flow Rate that best meets therapeutic needs and/or patient preferences – these values are found in the first 3 columns of each table. Follow the row to the right to the Infuset Reorder Number and SUB-Q Set columns, where you will find the combination that will deliver the correct flow rate of Cuvitru.

The first table provides combinations for infusion at flow rates that are within Cuvitru dosage limits for a patient's **first two (2) infusions** and the second table includes combinations that will provide flow rates appropriate for **Subsequent Infusions**.

First 2 Infusions of Cuvitru – SUB-Q and Infuset Combinations

SUB-Q Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset Reorder Number	SUB-Q Set
24	1	12 15	12 15	FP-0010008 FP-0010007	SAF-Q-106-G24
	1	11 14 17	11 14 17	FP-0010008 FP-0010007 FP-0010010	SUB-109-G24 or SAF-Q-109-G24
	1	10 13 16	10 13 16	FP-0010008 FP-0010007 FP-0010010	SUB-112-G24
	2	20 32	10 16	FP-0010010 FP-0010009	SUB-209-G24
	2	18 29	9 14	FP-0010010 FP-0010009	SUB-212-G24
	3	35 45	12 15	FP-0010009 FP-0010005	SUB-309-G24 or SAF-Q-309-G24
	3	32 41	11 14	FP-0010009 FP-0010005	SUB-312-G24
	4	49	12	FP-0010005	SUB-409-G24
	4	44	11	FP-0010005	SUB-412-G24

Infuset with CUVITRU - Setup for Target Infusion Rates (continued)

Subsequent Infusions – SUB-Q and Infuset Combinations

SUB-Q Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset Reorder Number	SUB-Q Set
24	1	12 15 19 33	12 15 19 33	FP-0010008 FP-0010007 FP-0010010 FP-0010005	SAF-Q-106-G24
	1	11 14 17 31	11 14 17 31	FP-0010008 FP-0010007 FP-0010010 FP-0010005	SUB-109-G24 or SAF-Q-109-G24
	1	10 13 16 28 50	10 13 16 28 50	FP-0010008 FP-0010007 FP-0010010 FP-0010005 FP-0010004	SUB-112-G24
	2	20 32 42 94	10 16 21 47	FP-0010010 FP-0010009 FP-0010005 FP-0010004	SUB-209-G24
	2	18 29 38 85 101	9 14 19 43 50	FP-0010010 FP-0010009 FP-0010005 FP-0010004 FP-0010027	SUB-212-G24
	3	35 45 118	12 15 39	FP-0010009 FP-0010005 FP-0010004	SUB-309-G24 or SAF-Q-309-G24
	3	32 41 107	11 14 36	FP-0010009 FP-0010005 FP-0010004	SUB-312-G24
	4	49 145	12 36	FP-0010005 FP-0010004	SUB-409-G24
	4	44 132	11 33	FP-0010005 FP-0010004	SUB-412-G24

Infusing with VersaRate

VersaRate with HIZENTRA (PI) - Setup for Target Infusion Rates

To choose a combination of VersaRate and SUB-Q set, first find the correct table. Then find the table row that contains the needle gauge, number of needles, and/or Total Flow Rate that best meets therapeutic needs and/or patient preferences – these values are found in the first 3 columns of each table. Follow the row to the right to the VersaRate position and SUB-Q Set columns, where you will find the combination that will deliver the correct rate of Hizentra.

The first table only includes combinations that will provide flow rates that are within Hizentra dosage limits when prescribed for patients with Primary Immunodeficiency (PI) and who are infusing Hizentra for the **first time**. The second table includes combinations that will provide flow rates appropriate for subsequent **Standard Infusions** (those performed after the first infusion).

First Infusion of Hizentra indicated for PI: SUB-Q and VersaRate Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Position	SUB-Q Set
24	2	15	8	1	SUB-209-G24
	2	14 25	7 12	1 2	SUB-212-G24
	3	17 27	6 9	1 2	SUB-309-G24 or SAF-Q-309-G24
	3	16 25	5 8	1 2	SUB-312-G24
	4	17 30 49	4 7 12	1 2 3	SUB-409-G24
	4	15 27 44	4 7 11	1 2 3	SUB-412-G24
	5	16 31 49	3 6 10	1 2 3	SUB-512-G24
	6	16 32 50	3 5 8	1 2 3	SUB-612-G24
27	1	11	11	1	SUB-104-G27
	1	11	11	1	SUB-106-G27 or SAF-Q-106-G27
	1	10 12	10 12	1 2	SUB-109-G27 or SAF-Q-109-G27
	1	9 11	9 11	1 2	SUB-112-G27 or SAF-Q-112-G27

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate with HIZENTRA (PI) - Setup for Target Infusion Rates (continued)

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First Infusion of Hizentra indicated for PI: SUB-Q and VersaRate Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Position	SUB-Q Set
27	2	12 19 26	6 10 13	1 2 3	SUB-204-G27
	2	12 18 24	6 9 12	1 2 3	SUB-250 or SAF-Q-206-G27
	2	11 17 22	5 8 11	1 2 3	SUB-260 or SAF-Q-209-G27
	2	10 15 20 25	5 8 10 13	1 2 3 4	SUB-212-G27 or SAF-Q-212-G27
	3	14 23 33	5 8 11	1 2 3	SUB-310 or SAF-Q-306-G27
	3	13 21 30 37	4 7 10 12	1 2 3 4	SUB-320 or SAF-Q-309-G27
	3	11 19 27 33	4 6 9 11	1 2 3 4	SUB-312-G27 or SAF-Q-312-G27
	4	14 26 37 51	4 6 9 13	1 2 3 4	SUB-400 or SAF-Q-406-G27
	4	13 24 34 47	3 6 8 12	1 2 3 4	SUB-410 or SAF-Q-409-G27
	4	12 22 31 43	3 5 8 11	1 2 3 4	SUB-412-G27 or SAF-Q-412-G27

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate with HIZENTRA (PI) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

First Infusion of Hizentra indicated for PI: SUB-Q and VersaRate Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Position	SUB-Q Set
27	4	11	3	1	SUB-414-G27
		20	5	2	
		28	7	3	
		40	10	4	
		52	13	5	
	5	16	3	1	SUB-506
		26	5	2	
		37	7	3	
		53	11	4	
	5	15	3	1	SUB-509 or SAF-Q-509-G27
		24	5	2	
		34	7	3	
		49	10	4	
	6	16	3	1	SUB-606
		28	5	2	
		40	7	3	
		58	10	4	
	6	14	2	1	SUB-609 or SAF-Q-609-G27
		25	4	2	
		37	6	3	
		53	9	4	
		75	13	5	

Standard Infusions of Hizentra indicated for PI: SUB-Q and VersaRate Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Position	SUB-Q Set
24	1	16	16	1	SAF-Q-106-G24
	1	14	14	1	SUB-109-G24 or SAF-Q-109-G24
	1	13	13	1	SUB-112-G24
	2	15	8	1	SUB-209-G24
		27	14	2	
	2	14	7	1	SUB-212-G24
		25	12	2	
		39	20	3	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate with HIZENTRA (PI) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for PI: SUB-Q and VersaRate Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Position	SUB-Q Set
24	3	17 27 50	6 9 17	1 2 3	SUB-309-G24 or SAF-Q-309-G24
	3	16 25 45	5 8 15	1 2 3	SUB-312-G24
	4	17 30 49 80	4 7 12 20	1 2 3 4	SUB-409-G24
	4	15 27 44 73	4 7 11 18	1 2 3 4	SUB-412-G24
	5	16 31 49 79	3 6 10 16	1 2 3 4	SUB-512-G24
	6	16 32 50 79	3 5 8 13	1 2 3 4	SUB-612-G24
27	1	11 14 17 18 20 21	11 14 17 18 20 21	1 2 3 4 5 6	SUB-104-G27
	1	11 13 16 17 19 20	11 13 16 17 19 20	1 2 3 4 5 6	SUB-106-G27 or SAF-Q-106-G27
	1	10 12 15 16 17 18	10 12 15 16 17 18	1 2 3 4 5 6	SUB-109-G27 or SAF-Q-109-G27

VersaRate with HIZENTRA (PI) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for PI: SUB-Q and VersaRate Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Position	SUB-Q Set
27	1	9	9	1	SUB-112-G27 or SAF-Q-112-G27
		11	11	2	
		13	13	3	
		14	14	4	
		16	16	5	
		16	16	6	
	2	12	6	1	SUB-204-G27
		19	10	2	
		26	13	3	
		32	16	4	
		36	18	5	
		42	21	6	
	2	12	6	1	SUB-250 or SAF-Q-206-G27
		18	9	2	
		24	12	3	
		30	15	4	
		34	17	5	
		39	20	6	
	2	11	5	1	SUB-260 or SAF-Q-209-G27
		17	8	2	
		22	11	3	
		28	14	4	
		31	16	5	
		36	18	6	
	2	10	5	1	SUB-212-G27 or SAF-Q-212-G27
		15	8	2	
		20	10	3	
		25	13	4	
		28	14	5	
		33	16	6	
	3	14	5	1	SUB-310 or SAF-Q-306-G27
		23	8	2	
		33	11	3	
		40	13	4	
		50	17	5	
		64	21	6	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate with HIZENTRA (PI) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for PI: SUB-Q and VersaRate Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Position	SUB-Q Set
27	3	13	4	1	SUB-320 or SAF-Q-309-G27
		21	7	2	
		30	10	3	
		37	12	4	
		46	15	5	
		59	20	6	
	3	11	4	1	SUB-312-G27 or SAF-Q-312-G27
		19	6	2	
		27	9	3	
		33	11	4	
		42	14	5	
		54	18	6	
	4	14	4	1	SUB-400 or SAF-Q-406-G27
		26	6	2	
		37	9	3	
		51	13	4	
		66	17	5	
		80	20	6	
	4	13	3	1	SUB-410 or SAF-Q-409-G27
		24	6	2	
		34	8	3	
		47	12	4	
		61	15	5	
		73	18	6	
	4	12	3	1	SUB-412-G27 or SAF-Q-412-G27
		22	5	2	
		31	8	3	
		43	11	4	
		55	14	5	
		67	17	6	
	4	11	3	1	SUB-414-G27
		20	5	2	
		28	7	3	
		40	10	4	
		52	13	5	
		62	16	6	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate with HIZENTRA (PI) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for PI: SUB-Q and VersaRate Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Position	SUB-Q Set
27	5	16	3	1	SUB-506
		26	5	2	
		37	7	3	
		53	11	4	
		73	15	5	
		94	19	6	
	5	15	3	1	SUB-509 or SAF-Q-509-G27
		24	5	2	
		34	7	3	
		49	10	4	
		67	13	5	
		87	17	6	
	6	16	3	1	SUB-606
		28	5	2	
		40	7	3	
		58	10	4	
		82	14	5	
		117	20	6	
	6	14	2	1	SUB-609 or SAF-Q-609-G27
		25	4	2	
		37	6	3	
		53	9	4	
		75	13	5	
		108	18	6	

VersaRate with HIZENTRA (CIDP) - Setup for Target Infusion Rates

To choose a combination of VersaRate and SUB-Q set, first find the correct table. Then find the table row that contains the needle gauge, number of needles, and/or Total Flow Rate that best meets therapeutic needs and/or patient preferences – these values are found in the first 3 columns of each table. Follow the row to the right to the VersaRate position and SUB-Q Set columns, where you will find the combination that will deliver the correct rate of Hizentra.

The first table only includes combinations that will provide flow rates that are within Hizentra dosage limits when prescribed for patients with Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) and who are infusing Hizentra for the **first time**. The second table includes combinations that will provide flow rates appropriate for subsequent **Standard Infusions** (those performed after the first infusion).

First Infusion of Hizentra indicated for CIDP: SUB-Q and VersaRate Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Position	SUB-Q Set
24	1	14	14	1	SUB-109-G24 or SAF-Q-109-G24
	1	13	13	1	SUB-112-G24
	2	15 27	8 14	1 2	SUB-209-G24
	2	14 25	7 12	1 2	SUB-212-G24
	3	17 27 50	6 9 17	1 2 3	SUB-309-G24 or SAF-Q-309-G24
	3	16 25 45	5 8 15	1 2 3	SUB-312-G24
	4	17 30 49	4 7 12	1 2 3	SUB-409-G24
	4	15 27 44	4 7 11	1 2 3	SUB-412-G24
	5	16 31 49 79	3 6 10 16	1 2 3 4	SUB-512-G24
	6	16 32 50 79	3 5 8 13	1 2 3 4	SUB-612-G24

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

First Infusion of Hizentra indicated for CIDP: SUB-Q and VersaRate Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Position	SUB-Q Set
27	1	11	11	1	SUB-104-G27
		14	14	2	
		17	17	3	
	1	11	11	1	SUB-106-G27 or SAF-Q-106-G27
		13	13	2	
		16	16	3	
		17	17	4	
	1	10	10	1	SUB-109-G27 or SAF-Q-109-G27
		12	12	2	
		15	15	3	
		16	16	4	
		17	17	5	
		18	18	6	
	1	9	9	1	SUB-112-G27 or SAF-Q-112-G27
		11	11	2	
		13	13	3	
		14	14	4	
		16	16	5	
		16	16	6	
	2	12	6	1	SUB-204-G27
		19	10	2	
		26	13	3	
		32	16	4	
	2	12	6	1	SUB-250 or SAF-Q-206-G27
		18	9	2	
		24	12	3	
		30	15	4	
		34	17	5	
	2	11	5	1	SUB-260 or SAF-Q-209-G27
		17	8	2	
		22	11	3	
		28	14	4	
		31	16	5	
		36	18	6	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

First Infusion of Hizentra indicated for CIDP: SUB-Q and VersaRate Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Position	SUB-Q Set
27	2	10	5	1	SUB-212-G27 or SAF-Q-212-G27
		15	8	2	
		20	10	3	
		25	13	4	
		28	14	5	
		33	16	6	
	3	14	5	1	SUB-310 or SAF-Q-306-G27
		23	8	2	
		33	11	3	
		40	13	4	
		50	17	5	
	3	13	4	1	SUB-320 or SAF-Q-309-G27
		21	7	2	
		30	10	3	
		37	12	4	
		46	15	5	
	3	11	4	1	SUB-312-G27 or SAF-Q-312-G27
		19	6	2	
		27	9	3	
		33	11	4	
		42	14	5	
		54	18	6	
	4	14	4	1	SUB-400 or SAF-Q-406-G27
		26	6	2	
		37	9	3	
		51	13	4	
		66	17	5	
	4	13	3	1	SUB-410 or SAF-Q-409-G27
		24	6	2	
		34	8	3	
		47	12	4	
		61	15	5	
		73	18	6	
	4	12	3	1	SUB-412-G27 or SAF-Q-412-G27
		22	5	2	
		31	8	3	
		43	11	4	
		55	14	5	
		67	17	6	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

First Infusion of Hizentra indicated for CIDP: SUB-Q and VersaRate Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Position	SUB-Q Set
27	4	11	3	1	SUB-414-G27
		20	5	2	
		28	7	3	
		40	10	4	
		52	13	5	
		62	16	6	
	5	16	3	1	SUB-506
		26	5	2	
		37	7	3	
		53	11	4	
		73	15	5	
	5	15	3	1	SUB-509 or SAF-Q-509-G27
		24	5	2	
		34	7	3	
		49	10	4	
		67	13	5	
		87	17	6	
	6	16	3	1	SUB-606
		28	5	2	
		40	7	3	
		58	10	4	
		82	14	5	
	6	14	2	1	SUB-609 or SAF-Q-609-G27
		25	4	2	
		37	6	3	
		53	9	4	
		75	13	5	
		108	18	6	

VersaRate with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

Standard Infusions of Hizentra indicated for CIDP: SUB-Q and VersaRate Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Position	SUB-Q Set
24	1	16 26 36	16 26 36	1 2 3	SAF-Q-106-G24
	1	14 24 33	14 24 33	1 2 3	SUB-109-G24 or SAF-Q-109-G24
	1	13 22 30 40	13 22 30 40	1 2 3 4	SUB-112-G24
	2	15 27 43 64	8 14 22 32	1 2 3 4	SUB-209-G24
	2	14 25 39 58	7 12 20 29	1 2 3 4	SUB-212-G24
	3	17 27 50 76 123	6 9 17 25 41	1 2 3 4 5	SUB-309-G24 or SAF-Q-309-G24
	3	16 25 45 69 112	5 8 15 23 37	1 2 3 4 5	SUB-312-G24
	4	17 30 49 80 149	4 7 12 20 37	1 2 3 4 5	SUB-409-G24
	4	15 27 44 73 136	4 7 11 18 34	1 2 3 4 5	SUB-412-G24

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for CIDP: SUB-Q and VersaRate Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Position	SUB-Q Set
24	5	16	3	1	SUB-512-G24
		31	6	2	
		49	10	3	
		79	16	4	
		141	28	5	
	6	16	3	1	SUB-612-G24
		32	5	2	
		50	8	3	
		79	13	4	
		156	26	5	
27	1	11	11	1	SUB-104-G27
		14	14	2	
		17	17	3	
		18	18	4	
		20	20	5	
		21	21	6	
	1	11	11	1	SUB-106-G27 or SAF-Q-106-G27
		13	13	2	
		16	16	3	
		17	17	4	
		19	19	5	
		20	20	6	
	1	10	10	1	SUB-109-G27 or SAF-Q-109-G27
		12	12	2	
		15	15	3	
		16	16	4	
		17	17	5	
		18	18	6	
	1	9	9	1	SUB-112-G27 or SAF-Q-112-G27
		11	11	2	
		13	13	3	
		14	14	4	
		16	16	5	
		16	16	6	
	2	12	6	1	SUB-204-G27
		19	10	2	
		26	13	3	
		32	16	4	
		36	18	5	
		42	21	6	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for CIDP: SUB-Q and VersaRate Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Position	SUB-Q Set
27	2	12 18 24 30 34 39	6 9 12 15 17 20	1 2 3 4 5 6	SUB-250 or SAF-Q-206-G27
	2	11 17 22 28 31 36	5 8 11 14 16 18	1 2 3 4 5 6	SUB-260 or SAF-Q-209-G27
	2	10 15 20 25 28 33	5 8 10 13 14 16	1 2 3 4 5 6	SUB-212-G27 or SAF-Q-212-G27
	3	14 23 33 40 50 64	5 8 11 13 17 21	1 2 3 4 5 6	SUB-310 or SAF-Q-306-G27
	3	13 21 30 37 46 59	4 7 10 12 15 20	1 2 3 4 5 6	SUB-320 or SAF-Q-309-G27
	3	11 19 27 33 42 54	4 6 9 11 14 18	1 2 3 4 5 6	SUB-312-G27 or SAF-Q-312-G27

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for CIDP: SUB-Q and VersaRate Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Position	SUB-Q Set
27	4	14	4	1	SUB-400 or SAF-Q-406-G27
		26	6	2	
		37	9	3	
		51	13	4	
		66	17	5	
		80	20	6	
	4	13	3	1	SUB-410 or SAF-Q-409-G27
		24	6	2	
		34	8	3	
		47	12	4	
		61	15	5	
		73	18	6	
	4	12	3	1	SUB-412-G27 or SAF-Q-412-G27
		22	5	2	
		31	8	3	
		43	11	4	
		55	14	5	
		67	17	6	
	4	11	3	1	SUB-414-G27
		20	5	2	
		28	7	3	
		40	10	4	
		52	13	5	
		62	16	6	
	5	16	3	1	SUB-506
		26	5	2	
		37	7	3	
		53	11	4	
		73	15	5	
		94	19	6	
	5	15	3	1	SUB-509 or SAF-Q-509-G27
		24	5	2	
		34	7	3	
		49	10	4	
		67	13	5	
		87	17	6	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for CIDP: SUB-Q and VersaRate Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Position	SUB-Q Set
27	6	16	3	1	SUB-606
		28	5	2	
		40	7	3	
		58	10	4	
		82	14	5	
		117	20	6	
	6	14	2	1	SUB-609 or SAF-Q-609-G27
		25	4	2	
		37	6	3	
		53	9	4	
		75	13	5	
		108	18	6	

VersaRate with GAMMAGARD - Setup for Target Infusion Rates

To choose a combination of VersaRate and SUB-Q set, first find the correct table. Then find the table row that contains the needle gauge, number of needles, and/or Total Flow Rate that best meets therapeutic needs and/or patient preferences – these values are found in the first 3 columns of each table. Follow the row to the right to the VersaRate position and SUB-Q Set columns, where you will find the combination that will deliver the correct flow rate of Gammagard.

The first table only includes combinations that will provide flow rates that are within Gammagard's dosage limits for the **initial infusion of Gammagard for patients weighing less than 40kg** and the second table includes combinations that will provide flow rates appropriate for subsequent **Maintenance Infusions for patients weighing less than 40kg** (those performed after the first infusion). The third table provides combinations for **patients weighing 40kg or higher performing initial infusions with Gammagard**, and the fourth table is for those patients **performing maintenance infusions**.

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.

Initial Infusion of Gammagard (patients weighing less than 40kg) – SUB-Q and VersaRate Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Position	SUB-Q Set
27	4	43	11	½	SUB-412-G27 or SAF-Q-412-G27
	4	40	10	½	SUB-414-G27
	5	46	9	½	SUB-506
	5	42	8	½	SUB-509 or SAF-Q-509-G27

Maintenance Infusions (patients weighing less than 40kg) – SUB-Q and VersaRate Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Position	SUB-Q Set
27	3	42	14	½	SUB-320 or SAF-Q-309-G27
	3	38	13	½	SUB-312-G27 or SAF-Q-312-G27
	4	51	13	½	SUB-400 or SAF-Q-406-G27
	4	47	12	½	SUB-410 or SAF-Q-409-G27
	4	43 59	11 15	½ 1	SUB-412-G27 or SAF-Q-412-G27
	4	40 55	10 14	½ 1	SUB-414-G27
	5	46 77	9 15	½ 1	SUB-506
	5	42 71	8 14	½ 1	SUB-509 or SAF-Q-509-G27

VersaRate with GAMMAGARD - Setup for Target Infusion Rates (continued)

Initial Infusion of Gammagard (patients weighing 40kg or more) – SUB-Q and VersaRate Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Position	SUB-Q Set
27	3	42	14	½	SUB-320 or SAF-Q-309-G27
	3	38	13	½	SUB-312-G27 or SAF-Q-312-G27
	4	51	13	½	SUB-400 or SAF-Q-406-G27
	4	47	12	½	SUB-410 or SAF-Q-409-G27
	4	43 59	11 15	½ 1	SUB-412-G27 or SAF-Q-412-G27
	4	40 55	10 14	½ 1	SUB-414-G27
	5	46 77	9 15	½ 1	SUB-506
	5	42 71	8 14	½ 1	SUB-509 or SAF-Q-509-G27

Maintenance Infusions (patients weighing 40kg or more) – SUB-Q and VersaRate Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Position	SUB-Q Set
27	2	43	22	½	SUB-260 or SAF-Q-209-G27
	2	39	20	½	SUB-212-G27 or SAF-Q-212-G27
	3	46 66	15 22	½ 1	SUB-310 or SAF-Q-306-G27
	3	42 60	14 20	½ 1	SUB-320 or SAF-Q-309-G27
	3	38 55	13 18	½ 1	SUB-312-G27 or SAF-Q-312-G27
	4	51 71	13 18	½ 1	SUB-400 or SAF-Q-406-G27
	4	47 65	12 16	½ 1	SUB-410 or SAF-Q-409-G27
	4	43 59	11 15	½ 1	SUB-412-G27 or SAF-Q-412-G27
	4	40 55	10 14	½ 1	SUB-414-G27
	5	46 77	9 15	½ 1	SUB-506
	5 5	42 71	8 14	½ 1	SUB-509 or SAF-Q-509-G27

VersaRate with CUVITRU - Setup for Target Infusion Rates

To choose a combination of VersaRate and SUB-Q set, first find the correct table. Then find the table row that contains the needle gauge, number of needles, and/or Total Flow Rate that best meets therapeutic needs and/or patient preferences – these values are found in the first 3 columns of each table. Follow the row to the right to the VersaRate position and SUB-Q Set columns, where you will find the combination that will deliver the correct flow rate of Cuvitru.

The first table provides combinations for infusion at flow rates that are within Cuvitru dosage limits for a patient's **first two (2) infusions** and the second table includes combinations that will provide flow rates appropriate for **Subsequent Infusions**.

First 2 Infusions of Cuvitru – SUB-Q and VersaRate Combinations

SUB-Q Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Position	SUB-Q Set
24ga	1	12	12	1	SAF-Q-106-G24
	1	11	11	1	SUB-109-G24 or SAF-Q-109-G24
	1	10 16	10 16	1 2	SUB-112-G24
	2	11 20	5 10	1 2	SUB-209-G24
	2	10 18 30	5 9 15	1 2 3	SUB-212-G24
	3	11 21 35	4 7 12	1 2 3	SUB-309-G24 or SAF-Q-309-G24
	3	10 19 32	3 6 11	1 2 3	SUB-312-G24
	4	12 23 37 65	3 6 9 16	1 2 3 4	SUB-409-G24
	4	11 21 34 59	3 5 8 15	1 2 3 4	SUB-412-G24

VersaRate with CUVITRU - Setup for Target Infusion Rates (continued)

Subsequent Infusions – SUB-Q and VersaRate Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Position	SUB-Q Set
24ga	1	12	12	1	SAF-Q-106-G24
		19	19	2	
		28	28	3	
		38	38	4	
	1	11	11	1	SUB-109-G24 or SAF-Q-109-G24
		17	17	2	
		26	26	3	
		35	35	4	
		47	47	5	
	1	10	10	1	SUB-112-G24
		16	16	2	
		24	24	3	
		32	32	4	
		43	43	5	
	2	11	5	1	SUB-209-G24
		20	10	2	
		33	17	3	
		50	25	4	
		87	44	5	
	2	10	5	1	SUB-212-G24
		18	9	2	
		30	15	3	
		45	23	4	
		79	40	5	
	3	11	4	1	SUB-309-G24 or SAF-Q-309-G24
		21	7	2	
		35	12	3	
		58	19	4	
		107	36	5	
	3	10	3	1	SUB-312-G24
		19	6	2	
		32	11	3	
		53	18	4	
		97	32	5	
	4	12	3	1	SUB-409-G24
		23	6	2	
		37	9	3	
		65	16	4	
		141	35	5	
	4	11	3	1	SUB-412-G24
		21	5	2	
		34	8	3	
		59	15	4	
		128	32	5	

Infusing with VersaRate Plus

VersaRate Plus with HIZENTRA (PI) - Setup for Target Infusion Rates

To choose a combination of VersaRate Plus and SUB-Q set, first find the correct table. Then find the table row that contains the needle gauge, number of needles, and/or Total Flow Rate that best meets therapeutic needs and/or patient preferences – these values are found in the first 3 columns of each table. Follow the row to the right to the VersaRate Plus position and SUB-Q Set columns, where you will find the combination that will deliver the correct rate of Hizentra.

The first table only includes combinations that will provide flow rates that are within Hizentra dosage limits when prescribed for patients with Primary Immunodeficiency (PI) and who are infusing Hizentra for the **first time**. The second table includes combinations that will provide flow rates appropriate for subsequent **Standard Infusions** (those performed after the first infusion).

First Infusion of Hizentra indicated for PI: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	2	23	12	2	SUB-204-G27
	2	22	11	2	SUB-250 or SAF-Q-206-G27
	2	20 26	10 13	2 3	SUB-260 or SAF-Q-209-G27
	2	18 23	9 12	2 3	SUB-212-G27 or SAF-Q-212-G27
	3	27 37	9 12	2 3	SUB-310 or SAF-Q-306-G27
	3	25 34	8 11	2 3	SUB-320 or SAF-Q-309-G27
	3	23 31 37	8 10 12	2 3 4	SUB-312-G27 or SAF-Q-312-G27
	4	34 47	8 12	2 3	SUB-400 or SAF-Q-406-G27
	4	31 43 52	8 11 13	2 3 4	SUB-410 or SAF-Q-409-G27
	4	28 39 48	7 10 12	2 3 4	SUB-412-G27 or SAF-Q-412-G27
	4	26 37 44 50 55	7 9 11 13 14	2 3 4 5 6	SUB-414-G27

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with HIZENTRA (PI) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

First Infusion of Hizentra indicated for PI: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	5	20	4	2	SUB-506
		45	9	3	
		63	13	4	
	5	19	4	2	SUB-509 or SAF-Q-509-G27
		41	8	3	
		58	12	4	
	6	16	3	2	SUB-606
		45	7	3	
		68	11	4	
	6	14	2	2	SUB-609 or SAF-Q-609-G27
		41	7	3	
		62	10	4	
		78	13	5	
24	4	34	9	2	SUB-409-G24
	4	31	8	2	SUB-412-G24
	4	43	11	2	SAF-Q-409-G24-70
	4	39	10	2	SAF-Q-412-G24-70

Standard Infusions of Hizentra indicated for PI: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	1	15	15	2	SUB-104-G27
		17	17	3	
		18	18	4	
		20	20	5	
		20	20	6	
		21	21	7	
		21	21	8	
		21	21	9	
		22	22	10	
		22	22	11	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with HIZENTRA (PI) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for PI: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	1	14	14	2	SUB-106-G27 or SAF-Q-106-G27
		16	16	3	
		17	17	4	
		19	19	5	
		19	19	6	
		20	20	7	
		20	20	8	
		20	20	9	
		21	21	10	
		21	21	11	
		21	21	OPEN	
	1	13	13	2	SUB-109-G27 or SAF-Q-109-G27
		15	15	3	
		16	16	4	
		17	17	5	
		18	18	6	
		18	18	7	
		18	18	8	
		19	19	9	
		19	19	10	
		19	19	11	
		19	19	OPEN	
	1	12	12	2	SUB-112-G27 or SAF-Q-112-G27
		13	13	3	
		15	15	4	
		15	15	5	
		16	16	6	
		17	17	7	
		17	17	8	
		17	17	9	
		17	17	10	
		17	17	11	
		17	17	OPEN	
	1	16	16	2	SUB-106-G27-70
		18	18	3	
		20	20	4	
		21	21	5	
		22	22	6	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with HIZENTRA (PI) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for PI: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	1	15	15	2	SUB-109-G27-70 or SAF-Q-109-G27-70
		17	17	3	
		18	18	4	
		19	19	5	
		20	20	6	
		21	21	7	
		22	22	8	
		22	22	9	
		22	22	10	
		22	22	11	
	1	13	13	2	SUB-112-G27-70
		15	15	3	
		16	16	4	
		18	18	5	
		19	19	6	
		19	19	7	
		20	20	8	
		20	20	9	
		20	20	10	
		20	20	11	
		20	20	OPEN	
	2	23	12	2	SUB-204-G27
		29	15	3	
		34	17	4	
		37	18	5	
		38	19	6	
		39	20	7	
		39	20	8	
		39	20	9	
		40	20	10	
		41	20	11	
		43	21	OPEN	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with HIZENTRA (PI) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for PI: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	2	22	11	2	SUB-250 or SAF-Q-206-G27
		28	14	3	
		32	16	4	
		35	17	5	
		36	18	6	
		37	19	7	
		37	19	8	
		37	19	9	
		38	19	10	
		38	19	11	
		40	20	OPEN	
	2	20	10	2	SUB-260 or SAF-Q-209-G27
		26	13	3	
		30	15	4	
		32	16	5	
		33	17	6	
		34	17	7	
		34	17	8	
		34	17	9	
		35	17	10	
		35	18	11	
		37	19	OPEN	
	2	18	9	2	SUB-212-G27 or SAF-Q-212-G27
		23	12	3	
		27	13	4	
		29	15	5	
		30	15	6	
		31	16	7	
		31	16	8	
		31	16	9	
		31	16	10	
		32	16	11	
		34	17	OPEN	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with HIZENTRA (PI) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for PI: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	3	27	9	2	SUB-310 or SAF-Q-306-G27
		37	12	3	
		44	15	4	
		50	17	5	
		54	18	6	
		56	19	7	
		58	19	8	
		58	19	9	
		58	19	10	
		58	19	11	
		63	21	OPEN	
	3	25	8	2	SUB-320 or SAF-Q-309-G27
		34	11	3	
		41	14	4	
		46	15	5	
		49	16	6	
		52	17	7	
		53	18	8	
		53	18	9	
		54	18	10	
		54	18	11	
		58	19	OPEN	
	3	23	8	2	SUB-312-G27 or SAF-Q-312-G27
		31	10	3	
		37	12	4	
		42	14	5	
		45	15	6	
		47	16	7	
		48	16	8	
		49	16	9	
		49	16	10	
		49	16	11	
		53	18	OPEN	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with HIZENTRA (PI) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for PI: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	4	34	8	2	SUB-400 or SAF-Q-406-G27
		47	12	3	
		57	14	4	
		65	16	5	
		70	18	6	
		74	18	7	
		77	19	8	
		79	20	9	
		82	21	10	
		85	21	11	
	4	31	8	2	SUB-410 or SAF-Q-409-G27
		43	11	3	
		52	13	4	
		59	15	5	
		64	16	6	
		68	17	7	
		71	18	8	
		73	18	9	
		75	19	10	
		78	20	11	
		82	21	OPEN	
	4	28	7	2	SUB-412-G27 or SAF-Q-412-G27
		39	10	3	
		48	12	4	
		54	13	5	
		58	15	6	
		62	15	7	
		64	16	8	
		66	17	9	
		69	17	10	
		71	18	11	
		75	19	OPEN	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with HIZENTRA (PI) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for PI: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	4	26	7	2	SUB-414-G27
		37	9	3	
		44	11	4	
		50	13	5	
		55	14	6	
		58	14	7	
		60	15	8	
		62	15	9	
		64	16	10	
		67	17	11	
		70	18	OPEN	
	5	20	4	2	SUB-506
		45	9	3	
		63	13	4	
		77	15	5	
		86	17	6	
		92	18	7	
		96	19	8	
		98	20	9	
		101	20	10	
		103	21	11	
		108	22	OPEN	
	5	19	4	2	SUB-509 or SAF-Q-509-G27
		41	8	3	
		58	12	4	
		70	14	5	
		79	16	6	
		84	17	7	
		88	18	8	
		90	18	9	
		92	18	10	
		95	19	11	
		99	20	OPEN	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with HIZENTRA (PI) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for PI: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	6	16	3	2	SUB-606
		45	7	3	
		68	11	4	
		85	14	5	
		98	16	6	
		107	18	7	
		114	19	8	
		119	20	9	
		123	20	10	
		127	21	11	
	6	14	2	2	SUB-609 or SAF-Q-609-G27
		41	7	3	
		62	10	4	
		78	13	5	
		90	15	6	
		98	16	7	
		104	17	8	
		109	18	9	
		113	19	10	
		117	19	11	
		122	20	OPEN	
24	2	36	18	2	SUB-209-G24
	2	33	16	2	SUB-212-G24
	2	36	18	2	SAF-Q-209-G24-70
	2	33	16	2	SAF-Q-212-G24-70
	3	40	13	2	SUB-309-G24 or SAF-Q-309-G24
	3	36	12	2	SUB-312-G24
		62	21	3	
	3	37	12	2	SAF-Q-312-G24-70
	4	34	9	2	SUB-409-G24
		76	19	3	
	4	31	8	2	SUB-412-G24
		69	17	3	
	4	43	11	2	SAF-Q-409-G24-70
		84	21	3	
	4	39	10	2	SAF-Q-412-G24-70
		77	19	3	

VersaRate Plus with HIZENTRA (CIDP) - Setup for Target Infusion Rates

To choose a combination of VersaRate Plus and SUB-Q set, first find the correct table. Then find the table row that contains the needle gauge, number of needles, and/or Total Flow Rate that best meets therapeutic needs and/or patient preferences – these values are found in the first 3 columns of each table. Follow the row to the right to the VersaRate Plus position and SUB-Q Set columns, where you will find the combination that will deliver the correct rate of Hizentra.

The first table only includes combinations that will provide flow rates that are within Hizentra dosage limits when prescribed for patients with Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) and who are infusing Hizentra for the **first time**. The second table includes combinations that will provide flow rates appropriate for subsequent **Standard Infusions** (those performed after the first infusion).

First Infusion of Hizentra indicated for CIDP: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	1	15 17	15 17	2 3	SUB-104-G27
	1	14 16 17	14 16 17	2 3 4	SUB-106-G27 or SAF-Q-106-G27
	1	13 15 16 17 18 18 18	13 15 16 17 18 18 18	2 3 4 5 6 7 8	SUB-109-G27 or SAF-Q-109-G27
	1	12 13 15 15 16 17 17 17 17 17 17	12 13 15 15 16 17 17 17 17 17 17	2 3 4 5 6 7 8 9 10 11 OPEN	SUB-112-G27 or SAF-Q-112-G27

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

First Infusion of Hizentra indicated for CIDP: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	1	15	15	2	SUB-109-G27-70 or SAF-Q-109-G27-70
		17	17	3	
	1	13	13	2	SUB-112-G27-70
		15	15	3	
		16	16	4	
	2	23	12	2	SUB-204-G27
		29	15	3	
		34	17	4	
	2	22	11	2	SUB-250 or SAF-Q-206-G27
		28	14	3	
		32	16	4	
		35	17	5	
		36	18	6	
		37	19	7	
	2	20	10	2	SUB-260 or SAF-Q-209-G27
		26	13	3	
		30	15	4	
		32	16	5	
		33	17	6	
		34	17	7	
		34	17	8	
		34	17	9	
		35	17	10	
		35	18	11	
	2	18	9	2	SUB-212-G27 or SAF-Q-212-G27
		23	12	3	
		27	13	4	
		29	15	5	
		30	15	6	
		31	16	7	
		31	16	8	
		31	16	9	
		31	16	10	
		32	16	11	
		34	17	OPEN	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

First Infusion of Hizentra indicated for CIDP: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	3	27	9	2	SUB-310 or SAF-Q-306-G27
		37	12	3	
		44	15	4	
		50	17	5	
		54	18	6	
	3	25	8	2	SUB-320 or SAF-Q-309-G27
		34	11	3	
		41	14	4	
		46	15	5	
		49	16	6	
		52	17	7	
		53	18	8	
		53	18	9	
		54	18	10	
		54	18	11	
	3	23	8	2	SUB-312-G27 or SAF-Q-312-G27
		31	10	3	
		37	12	4	
		42	14	5	
		45	15	6	
		47	16	7	
		48	16	8	
		49	16	9	
		49	16	10	
		49	16	11	
		53	18	OPEN	
	4	34	8	2	SUB-400 or SAF-Q-406-G27
		47	12	3	
		57	14	4	
		65	16	5	
		70	18	6	
		74	18	7	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

First Infusion of Hizentra indicated for CIDP: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	4	31	8	2	SUB-410 or SAF-Q-409-G27
		43	11	3	
		52	13	4	
		59	15	5	
		64	16	6	
		68	17	7	
		71	18	8	
		73	18	9	
	4	28	7	2	SUB-412-G27 or SAF-Q-412-G27
		39	10	3	
		48	12	4	
		54	13	5	
		58	15	6	
		62	15	7	
		64	16	8	
		66	17	9	
		69	17	10	
		71	18	11	
	4	26	7	2	SUB-414-G27
		37	9	3	
		44	11	4	
		50	13	5	
		55	14	6	
		58	14	7	
		60	15	8	
		62	15	9	
		64	16	10	
		67	17	11	
		70	18	OPEN	
	5	20	4	2	SUB-506
		45	9	3	
		63	13	4	
		77	15	5	
		86	17	6	
		92	18	7	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

First Infusion of Hizentra indicated for CIDP: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	5	19	4	2	SUB-509 or SAF-Q-509-G27
		41	8	3	
		58	12	4	
		70	14	5	
		79	16	6	
		84	17	7	
		88	18	8	
		90	18	9	
	6	16	3	2	SUB-606
		45	7	3	
		68	11	4	
		85	14	5	
		98	16	6	
		107	18	7	
	6	14	2	2	SUB-609 or SAF-Q-609-G27
		41	7	3	
		62	10	4	
		78	13	5	
		90	15	6	
		98	16	7	
		104	17	8	
		109	18	9	
24	3	40	13	2	SUB-309-G24 or SAF-Q-309-G24
	3	36	12	2	SUB-312-G24
	3	37	12	2	SAF-Q-312-G24-70
	4	34	9	2	SUB-409-G24
	4	31	8	2	SUB-412-G24
	4	43	11	2	SAF-Q-409-G24-70
	4	39	10	2	SAF-Q-412-G24-70

VersaRate Plus with HIZENTRA (CIDP) - Setup for Target Infusion Rates

Standard Infusions of Hizentra indicated for CIDP: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	1	15	15	2	SUB-104-G27
		17	17	3	
		18	18	4	
		20	20	5	
		20	20	6	
		21	21	7	
		21	21	8	
		21	21	9	
		22	22	10	
		22	22	11	
		22	22	OPEN	
	1	14	14	2	SUB-106-G27 or SAF-Q-106-G27
		16	16	3	
		17	17	4	
		19	19	5	
		19	19	6	
		20	20	7	
		20	20	8	
		20	20	9	
		21	21	10	
		21	21	11	
		21	21	OPEN	
	1	13	13	2	SUB-109-G27 or SAF-Q-109-G27
		15	15	3	
		16	16	4	
		17	17	5	
		18	18	6	
		18	18	7	
		18	18	8	
		19	19	9	
		19	19	10	
		19	19	11	
		19	19	OPEN	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for CIDP: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	1	12	12	2	SUB-112-G27 or SAF-Q-112-G27
		13	13	3	
		15	15	4	
		15	15	5	
		16	16	6	
		17	17	7	
		17	17	8	
		17	17	9	
		17	17	10	
		17	17	11	
		17	17	OPEN	
	1	16	16	2	SUB-106-G27-70
		18	18	3	
		20	20	4	
		21	21	5	
		22	22	6	
		23	23	7	
		24	24	8	
		24	24	9	
		24	24	10	
		24	24	11	
		24	24	OPEN	
	1	15	15	2	SUB-109-G27-70 or SAF-Q-109-G27-70
		17	17	3	
		18	18	4	
		19	19	5	
		20	20	6	
		21	21	7	
		22	22	8	
		22	22	9	
		22	22	10	
		22	22	11	
		22	22	OPEN	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for CIDP: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	1	13	13	2	SUB-112-G27-70
		15	15	3	
		16	16	4	
		18	18	5	
		19	19	6	
		19	19	7	
		20	20	8	
		20	20	9	
		20	20	10	
		20	20	11	
		20	20	OPEN	
	2	23	12	2	SUB-204-G27
		29	15	3	
		34	17	4	
		37	18	5	
		38	19	6	
		39	20	7	
		39	20	8	
		39	20	9	
		40	20	10	
		41	20	11	
		43	21	OPEN	
	2	22	11	2	SUB-250 or SAF-Q-206-G27
		28	14	3	
		32	16	4	
		35	17	5	
		36	18	6	
		37	19	7	
		37	19	8	
		37	19	9	
		38	19	10	
		38	19	11	
		40	20	OPEN	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for CIDP: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	2	20	10	2	SUB-260 or SAF-Q-209-G27
		26	13	3	
		30	15	4	
		32	16	5	
		33	17	6	
		34	17	7	
		34	17	8	
		34	17	9	
		35	17	10	
		35	18	11	
		37	19	OPEN	
	2	18	9	2	SUB-212-G27 or SAF-Q-212-G27
		23	12	3	
		27	13	4	
		29	15	5	
		30	15	6	
		31	16	7	
		31	16	8	
		31	16	9	
		31	16	10	
		32	16	11	
		34	17	OPEN	
	3	27	9	2	SUB-310 or SAF-Q-306-G27
		37	12	3	
		44	15	4	
		50	17	5	
		54	18	6	
		56	19	7	
		58	19	8	
		58	19	9	
		58	19	10	
		58	19	11	
		63	21	OPEN	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for CIDP: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	3	25	8	2	SUB-320 or SAF-Q-309-G27
		34	11	3	
		41	14	4	
		46	15	5	
		49	16	6	
		52	17	7	
		53	18	8	
		53	18	9	
		54	18	10	
		54	18	11	
		58	19	OPEN	
	3	23	8	2	SUB-312-G27 or SAF-Q-312-G27
		31	10	3	
		37	12	4	
		42	14	5	
		45	15	6	
		47	16	7	
		48	16	8	
		49	16	9	
		49	16	10	
		49	16	11	
		53	18	OPEN	
	4	34	8	2	SUB-400 or SAF-Q-406-G27
		47	12	3	
		57	14	4	
		65	16	5	
		70	18	6	
		74	18	7	
		77	19	8	
		79	20	9	
		82	21	10	
		85	21	11	
		90	22	OPEN	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for CIDP: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	4	31	8	2	SUB-410 or SAF-Q-409-G27
		43	11	3	
		52	13	4	
		59	15	5	
		64	16	6	
		68	17	7	
		71	18	8	
		73	18	9	
		75	19	10	
		78	20	11	
		82	21	OPEN	
	4	28	7	2	SUB-412-G27 or SAF-Q-412-G27
		39	10	3	
		48	12	4	
		54	13	5	
		58	15	6	
		62	15	7	
		64	16	8	
		66	17	9	
		69	17	10	
		71	18	11	
		75	19	OPEN	
	4	26	7	2	SUB-414-G27
		37	9	3	
		44	11	4	
		50	13	5	
		55	14	6	
		58	14	7	
		60	15	8	
		62	15	9	
		64	16	10	
		67	17	11	
		70	18	OPEN	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for CIDP: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	5	20	4	2	SUB-506
		45	9	3	
		63	13	4	
		77	15	5	
		86	17	6	
		92	18	7	
		96	19	8	
		98	20	9	
		101	20	10	
		103	21	11	
		108	22	OPEN	
	5	19	4	2	SUB-509 or SAF-Q-509-G27
		41	8	3	
		58	12	4	
		70	14	5	
		79	16	6	
		84	17	7	
		88	18	8	
		90	18	9	
		92	18	10	
		95	19	11	
		99	20	OPEN	
	6	16	3	2	SUB-606
		45	7	3	
		68	11	4	
		85	14	5	
		98	16	6	
		107	18	7	
		114	19	8	
		119	20	9	
		123	20	10	
		127	21	11	
		133	22	OPEN	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for CIDP: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	6	14	2	2	SUB-609 or SAF-Q-609-G27
		41	7	3	
		62	10	4	
		78	13	5	
		90	15	6	
		98	16	7	
		104	17	8	
		109	18	9	
		113	19	10	
		117	19	11	
		122	20	OPEN	
24	1	33	33	2	SAF-Q-106-G24
	1	31	31	2	SUB-109-G24 or SAF-Q-109-G24
		41	41	3	
	1	28	28	2	SUB-112-G24
		38	38	3	
	1	29	29	2	SAF-Q-112-G24-70
		42	42	3	
	2	36	18	2	SUB-209-G24
		60	30	3	
		80	40	4	
	2	33	16	2	SUB-212-G24
		54	27	3	
		73	36	4	
	2	39	20	2	SAF-Q-206-G24-70
		66	33	3	
	2	36	18	2	SAF-Q-209-G24-70
		60	30	3	
		79	40	4	
	2	33	16	2	SAF-Q-212-G24-70
		55	27	3	
		72	36	4	
	3	40	13	2	SUB-309-G24 or SAF-Q-309-G24
		69	23	3	
		95	32	4	
		118	39	5	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with HIZENTRA (CIDP) - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Standard Infusions of Hizentra indicated for CIDP: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
24	**3**	36	12	2	SUB-312-G24
		62	21	3	
		86	29	4	
		107	36	5	
		126	42	6	
	3	37	12	2	SAF-Q-312-G24-70
		73	24	3	
		105	35	4	
	4	34	9	2	SUB-409-G24
		76	19	3	
		112	28	4	
		144	36	5	
		171	43	6	
	4	31	8	2	SUB-412-G24
		69	17	3	
		102	25	4	
		131	33	5	
		155	39	6	
	4	43	11	2	SAF-Q-409-G24-70
		84	21	3	
		123	31	4	
		159	40	5	
	4	39	10	2	SAF-Q-412-G24-70
		77	19	3	
		113	28	4	
		146	36	5	

VersaRate Plus with GAMMAGARD - Setup for Target Infusion Rates

To choose a combination of VersaRate Plus and SUB-Q set, first find the correct table. Then find the table row that contains the needle gauge, number of needles, and/or Total Flow Rate that best meets therapeutic needs and/or patient preferences – these values are found in the first 3 columns of each table. Follow the row to the right to the VersaRate Plus position and SUB-Q Set columns, where you will find the combination that will deliver the correct flow rate of Gammagard.

The first table only includes combinations that will provide flow rates that are within Gammagard's dosage limits for the **initial infusion of Gammagard for patients weighing less than 40kg** and the second table includes combinations that will provide flow rates appropriate for subsequent **Maintenance Infusions for patients weighing less than 40kg** (those performed after the first infusion). The third table provides combinations for **patients weighing 40kg or higher performing initial infusions with Gammagard**, and the fourth table is for those patients **performing maintenance infusions**.

Initial Infusion of Gammagard (patients weighing less than 40kg) – SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	4	47	12	1	SUB-412-G27 or SAF-Q-412-G27
	4	43	11	1	SUB-414-G27
	5	57	11	1	SUB-506
	5	53	11	1	SUB-509 or SAF-Q-509-G27
	6	56	9	1	SUB-606
	6	52	9	1	SUB-609 or SAF-Q-609-G27

Maintenance Infusions (patients weighing less than 40kg) – SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	3	46	15	1	SUB-320 or SAF-Q-309-G27
	3	42	14	1	SUB-312-G27 or SAF-Q-312-G27
	4	56	14	1	SUB-400 or SAF-Q-406-G27
	4	51	13	1	SUB-410 or SAF-Q-409-G27
	4	47	12	1	SUB-412-G27 or SAF-Q-412-G27
	4	43	11	1	SUB-414-G27
	5	57	11	1	SUB-506
	5	53	11	1	SUB-509 or SAF-Q-509-G27
	6	56	9	1	SUB-606
	6	52 102	9 17	1 2	SUB-609 or SAF-Q-609-G27

VersaRate with GAMMAGARD - Setup for Target Infusion Rates (continued)

Initial Infusion of Gammagard (patients weighing 40kg or more) – SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	3	46	15	1	SUB-320 or SAF-Q-309-G27
	3	42	14	1	SUB-312-G27 or SAF-Q-312-G27
	4	56	14	1	SUB-400 or SAF-Q-406-G27
	4	51	13	1	SUB-410 or SAF-Q-409-G27
	4	47	12	1	SUB-412-G27 or SAF-Q-412-G27
	4	43	11	1	SUB-414-G27
	5	57	11	1	SUB-506
	5	53 104	11 21	1 2	SUB-509 or SAF-Q-509-G27
	6	56	9	1	SUB-606
	6	52 102	9 17	1 2	SUB-609 or SAF-Q-609-G27

Maintenance Infusions (patients weighing 40kg or more) – SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	2	44	22	1	SUB-260 or SAF-Q-209-G27
	2	40	20	1	SUB-212-G27 or SAF-Q-212-G27
	3	50	17	1	SUB-310 or SAF-Q-306-G27
	3	46	15	1	SUB-320 or SAF-Q-309-G27
	3	42	14	1	SUB-312-G27 or SAF-Q-312-G27
	4	56	14	1	SUB-400 or SAF-Q-406-G27
	4	51 98	13 25	1 2	SUB-410 or SAF-Q-409-G27
	4	47 90	12 22	1 2	SUB-412-G27 or SAF-Q-412-G27
	4	43 84	11 21	1 2	SUB-414-G27
	5	57 113	11 23	1 2	SUB-506

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with GAMMAGARD - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Maintenance Infusions (patients weighing 40kg or more) – SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
	5	53 104	11 21	1 2	SUB-509 or SAF-Q-509-G27
	6	56	9	1	SUB-606
	6	52 102 161	9 17 27	1 2 3	SUB-609 or SAF-Q-609-G27

VersaRate Plus with CUVITRU - Setup for Target Infusion Rates

To choose a combination of VersaRate Plus and SUB-Q set, first find the correct table. Then find the table row that contains the needle gauge, number of needles, and/or Total Flow Rate that best meets therapeutic needs and/or patient preferences – these values are found in the first 3 columns of each table. Follow the row to the right to the VersaRate Plus position and SUB-Q Set columns, where you will find the combination that will deliver the correct flow rate of Cuvitru.

The first table provides combinations for infusion at flow rates that are within Cuvitru dosage limits for a patient's **first two (2) infusions** and the second table includes combinations that will provide flow rates appropriate for **Subsequent Infusions**.

First 2 Infusions of Cuvitru – SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	1	15 17	15 17	3 4	SUB-104-G27
	1	14 16 17	14 16 17	3 4 5	SUB-106-G27 or SAF-Q-106-G27
	1	13 15 16	13 15 16	3 4 5	SUB-109-G27 or SAF-Q-109-G27
	1	12 13 14 15 15 16 16 16 16 17	12 13 14 15 15 16 16 16 16 17	3 4 5 6 7 8 9 10 11 OPEN	SUB-112-G27 or SAF-Q-112-G27
	2	29 34	14 17	3 4	SUB-204-G27
	2	27 32	14 16	3 4	SUB-250 or SAF-Q-206-G27
	2	25 30 33	13 15 16	3 4 5	SUB-260 or SAF-Q-209-G27
	2	23 27 30 31 33	11 14 15 16 16	3 4 5 6 7	SUB-212-G27 or SAF-Q-212-G27

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with CUVITRU - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

First 2 Infusions of Cuvitru – SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	3	33	11	3	SUB-310 or SAF-Q-306-G27
		44	15	4	
		51	17	5	
	3	30	10	3	SUB-320 or SAF-Q-309-G27
		41	14	4	
		47	16	5	
		49	16	6	
	3	27	9	3	SUB-312-G27 or SAF-Q-312-G27
		37	12	4	
		42	14	5	
		45	15	6	
		46	15	7	
		46	15	8	
		46	15	9	
		47	16	10	
		47	16	11	
		51	17	OPEN	
	4	45	11	3	SUB-400 or SAF-Q-406-G27
		58	15	4	
		69	17	5	
	4	41	10	3	SUB-410 or SAF-Q-409-G27
		53	13	4	
		63	16	5	
	4	38	9	3	SUB-412-G27 or SAF-Q-412-G27
		49	12	4	
		58	14	5	
		64	16	6	
	4	35	9	3	SUB-414-G27
		45	11	4	
		54	13	5	
		59	15	6	
		63	16	7	
		65	16	8	
		66	16	9	
		67	17	10	
		67	17	11	
24	2	21	10	2	SUB-209-G24
	2	19	9	2	SUB-212-G24
	3	25	8	2	SUB-309-G24 or SAF-Q-309-G24
	3	23	8	2	SUB-312-G24
	4	29	7	2	SUB-409-G24
		59	15	3	
	4	26	7	2	SUB-412-G24
		54	13	3	

Subsequent Infusions of CUVITRU – SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	1	15	15	3	SUB-104-G27
		17	17	4	
		18	18	5	
		19	19	6	
		20	20	7	
		20	20	8	
		20	20	9	
		21	21	10	
		21	21	11	
		21	21	OPEN	
	1	14	14	3	SUB-106-G27 or SAF-Q-106-G27
		16	16	4	
		17	17	5	
		18	18	6	
		19	19	7	
		19	19	8	
		19	19	9	
		20	20	10	
		20	20	11	
		20	20	OPEN	
	1	13	13	3	SUB-109-G27 or SAF-Q-109-G27
		15	15	4	
		16	16	5	
		16	16	6	
		17	17	7	
		17	17	8	
		18	18	9	
		18	18	10	
		18	18	11	
		18	18	OPEN	
	1	12	12	3	SUB-112-G27 or SAF-Q-112-G27
		13	13	4	
		14	14	5	
		15	15	6	
		15	15	7	
		16	16	8	
		16	16	9	
		16	16	10	
		16	16	11	
		17	17	OPEN	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with CUVITRU - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Subsequent Infusions of CUVITRU: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	2	29	14	3	SUB-204-G27
		34	17	4	
		37	19	5	
		40	20	6	
		41	21	7	
		42	21	8	
		43	22	9	
		44	22	10	
		45	22	11	
		47	23	OPEN	
	2	27	14	3	SUB-250 or SAF-Q-206-G27
		32	16	4	
		35	18	5	
		38	19	6	
		39	20	7	
		40	20	8	
		41	21	9	
		42	21	10	
		42	21	11	
		45	22	OPEN	
	2	25	13	3	SUB-260 or SAF-Q-209-G27
		30	15	4	
		33	16	5	
		34	17	6	
		36	18	7	
		37	18	8	
		38	19	9	
		38	19	10	
		39	19	11	
		41	20	OPEN	
	2	23	11	3	SUB-212-G27 or SAF-Q-212-G27
		27	14	4	
		30	15	5	
		31	16	6	
		33	16	7	
		34	17	8	
		34	17	9	
		35	17	10	
		35	18	11	
		37	19	OPEN	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with CUVITRU - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Subsequent Infusions of CUVITRU: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	3	33	11	3	SUB-310 or SAF-Q-306-G27
		44	15	4	
		51	17	5	
		54	18	6	
		55	18	7	
		55	18	8	
		56	19	9	
		56	19	10	
		56	19	11	
		61	20	OPEN	
	3	30	10	3	SUB-320 or SAF-Q-309-G27
		41	14	4	
		47	16	5	
		49	16	6	
		50	17	7	
		51	17	8	
		51	17	9	
		51	17	10	
		51	17	11	
		56	19	OPEN	
	3	27	9	3	SUB-312-G27 or SAF-Q-312-G27
		37	12	4	
		42	14	5	
		45	15	6	
		46	15	7	
		46	15	8	
		46	15	9	
		47	16	10	
		47	16	11	
		51	17	OPEN	
	4	45	11	3	SUB-400 or SAF-Q-406-G27
		58	15	4	
		69	17	5	
		76	19	6	
		80	20	7	
		83	21	8	
		84	21	9	
		85	21	10	
		86	22	11	
		93	23	OPEN	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with CUVITRU - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Subsequent Infusions of CUVITRU: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
27	4	41	10	3	SUB-410 or SAF-Q-409-G27
		53	13	4	
		63	16	5	
		70	17	6	
		74	18	7	
		76	19	8	
		77	19	9	
		78	20	10	
		79	20	11	
		85	21	OPEN	
	4	38	9	3	SUB-412-G27 or SAF-Q-412-G27
		49	12	4	
		58	14	5	
		64	16	6	
		67	17	7	
		69	17	8	
		70	18	9	
		71	18	10	
		72	18	11	
		77	19	OPEN	
	4	35	9	3	SUB-414-G27
		45	11	4	
		54	13	5	
		59	15	6	
		63	16	7	
		65	16	8	
		66	16	9	
		67	17	10	
		67	17	11	
		72	18	OPEN	
24	1	19	19	2	SAF-Q-106-G24
		34	34	3	
		45	45	4	
	1	17	17	2	SUB-109-G24 or SAF-Q-109-G24
		31	31	3	
		41	41	4	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with CUVITRU - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Subsequent Infusions of CUVITRU: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
24	1	16	16	2	SUB-112-G24
		29	29	3	
		38	38	4	
		44	44	5	
		48	48	6	
		50	50	7	
		50	50	8	
	2	21	10	2	SUB-209-G24
		50	25	3	
		72	36	4	
		88	44	5	
		98	49	6	
	2	19	9	2	SUB-212-G24
		46	23	3	
		66	33	4	
		80	40	5	
		90	45	6	
		95	48	7	
		99	50	8	
	3	25	8	2	SUB-309-G24 or SAF-Q-309-G24
		61	20	3	
		89	30	4	
		113	38	5	
		131	44	6	
		145	48	7	
	3	23	8	2	SUB-312-G24
		55	18	3	
		81	27	4	
		103	34	5	
		119	40	6	
		132	44	7	
		141	47	8	
		147	49	9	
	4	29	7	2	SUB-409-G24
		59	15	3	
		92	23	4	
		126	31	5	
		158	39	6	
		187	47	7	

TABLE CONTINUES ON THE NEXT PAGE…

VersaRate Plus with CUVITRU - Setup for Target Infusion Rates (continued)

…TABLE CONTINUES FROM PREVIOUS PAGE

Subsequent Infusions of CUVITRU: SUB-Q and VersaRate Plus Combinations

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	VersaRate Plus Position	SUB-Q Set
24	4	26	7	2	SUB-412-G24
		54	13	3	
		84	21	4	
		114	29	5	
		144	36	6	
		170	43	7	
		192	48	8	

SCIg60 Infuser – Cleaning and Storage

- Outer surfaces of the SCIg60 Infuser may be cleaned with 70% isopropyl alcohol wipes or a soft cloth dampened with a weak mixture 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.
- Clean only those areas that are exposed when the Infuser Inner Drive 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.
- Use a dry cloth to dry the exposed and external portions of the device.
- Do not use heating devices to dry or expose infuser to high temperatures or damage to the infuser and its mechanism may occur.
- Storage temperature: -5°C to +40°C (+23°F to +104°F). Avoid exposing the SCIg60 Infuser to temperatures outside of this range.

SCIg60 Infuser Carrying Case – Cleaning and Storage

- Only clean surface with a clean damp cloth and let air dry.
- Do not machine wash the carrying case as it could damage the materials.
- Storage temperature: -5°C to +40°C (+23°F to +104°F).

Troubleshooting

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

- **SYRINGE POSITION**. Verify the syringe is properly positioned into the Infuser as instructed in the IFU section; the syringe should be parallel to the infuser with the syringe flanges properly engaged and seen in the safety check window (shown in the diagram). If syringe 'pops out' of Infuser when inner drive is closed/screwed in, it is an indication that the syringe was not properly positioned in the Infuser. Unscrew the inner drive and properly position the syringe following the instructions for use.
  Use only the BD 60 ml syringe (model no. 309653).
- **TUBING CONNECTORS**. Verify the BD 60 ml syringe (model no. 309653) is properly connected to the Infuset or VersaRate and that the Infuset or VersaRate is correctly connected to the specified subcutaneous administration sets.
- **NO FLOW**
  - If using the **Infuset**, check the slide clamp on the Infuset and make sure it is not blocking the flow. Verify that no other clamp is blocking the flow and that the Infuset or specified administration set is not kinked in any way.
  - If using the **VersaRate**, check to make sure the correct flow rate position is selected. Verify that no other clamp is blocking the flow and that the VersaRate or specified administration set is not kinked in any way.
- **FLOW RATE IS TOO HIGH**. Verify that the correct combination of SUB-Q set and Infuset or VersaRate position is being used.
- **FLOW RATE IS TOO SLOW**. Verify that the correct combination or SUB-Q set and Infuset or VersaRate position is being used, and that the flow rate controller or administration set is not kinked in any way.

  NOTE: Storage of the Infuset with the slide clamp engaged for an extended period of time may temporarily deform the tubing and decrease flow rate.
- **FLOW DOES NOT STOP**. Verify that the slide clamp on the Infuset is fully closed or that the VersaRate is in the 'Off' position.
- **BROKEN PARTS**. Inspect Infuser for any broken parts. If after following the instructions above the SCIg60 Infusion System does not appear to be working properly, or if you observe something unusual, discontinue use of the SCIg60 Infusion System and contact your healthcare provider or EMED Technologies Corporation.

If any of the above conditions persist or you feel the SCIg60 Infusion System is not performing as expected, please contact your healthcare provider or EMED Technologies Corporation.

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.

- **EMED Disposable items**: In the event that an EMED-branded disposable item is found defective, it will be replaced with a new disposable item by the Manufacture.

Contact Information

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EC REP **Emergo Europe**
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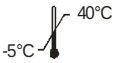
2514 AP The Hague
The Netherlands

CE 0459

Symbols Definition Table

Some of these symbols may be found on your device labeling and packaging materials:

SYMBOLS	DEFINITION	SYMBOLS	DEFINITION
	Warning		Quantity
	Read the instructions		Storage temperature limits
	Do not re-use	SN	Serial number
	Don't use if package is damaged	ø	Diameter
STERILE EO	Sterilized by Ethylene Oxide		Length
	Manufacturer	Rx ONLY	To sale by or on the order of a physician.
EC REP	EC Representative	≈ XX ml	Approximate priming volume
REF	Reference number	CE	CE Mark
	Manufacturing date	ID	Internal Diameter
LOT	Batch	OD	Outer Diameter
	Expiration date		Non-pyrogenic fluid path
DEHP Free	Is not made with di(2-ethylhexyl) phthalate (DEHP)	Latex Free	This product is not made with latex

International Markets User Manual

Introduction

The EMED SCIg60 Infusion system provides users with a portable and effective way to subcutaneously infuse immunoglobulin. The SCIg60 Infuser is a reusable mechanical device and does not require batteries or any electrical source. The system utilizes a spring as a source of pressure that optimizes and controls the continuous delivery of fluids at desired flow rates using Infuset precision tubing sets and *VersaRate*® variable flow rate controlling sets.

Indications

The SCIg60 Infusion System is intended for use in the home or hospital environment for the subcutaneous infusion of immunoglobulin liquid medicines with the BD 60 ml syringe (309653).

General Contraindications

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

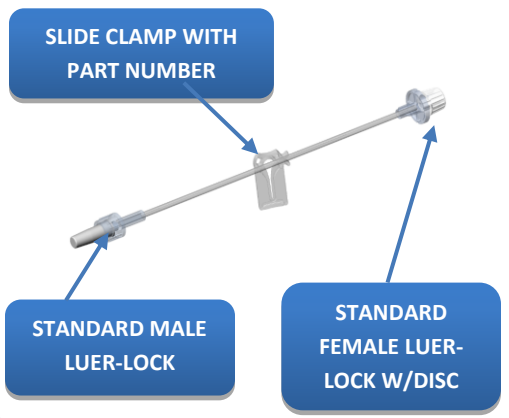
Getting to know your SCIg60 Infusion System

PACKAGE CONTENTS

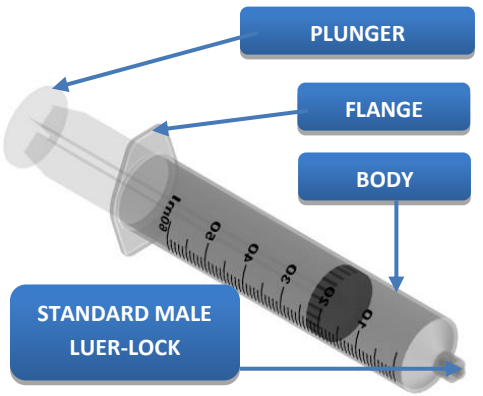
- SCIg60 Infuser
- User Manual
- Carrying Case
- (EMED Infuset and VersaRate® flow controllers are sold separately)
- (Syringe to be used: BD 60 ml Syringe Luer Lock Tip, product REF 309653)

SCIg60 Infuser

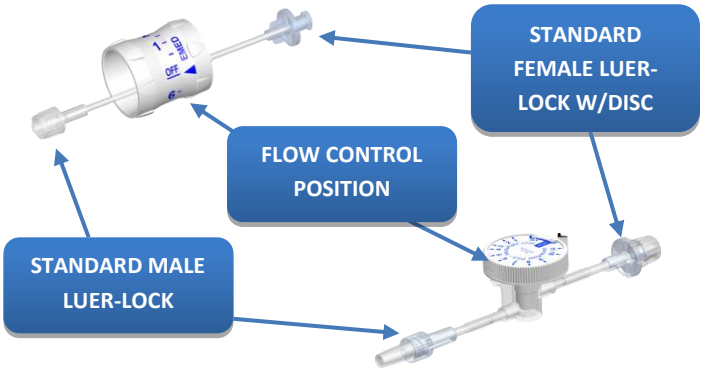
Infuset



Syringe



VersaRate® and VersaRate Plus

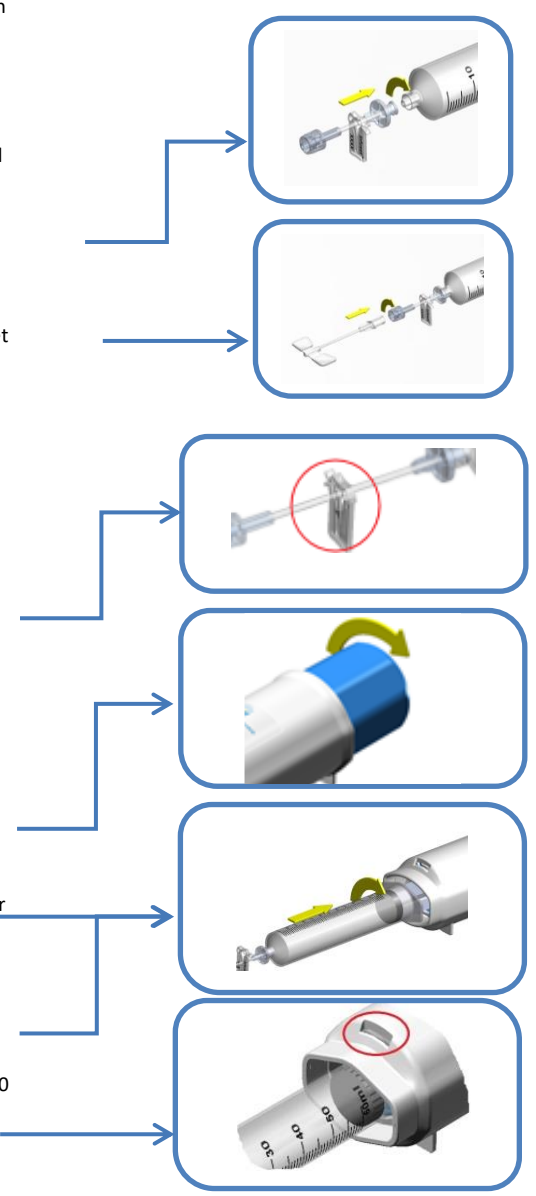


SCIg60 Infusion System

SCIg60 Infusion System Carrying Case

Instructions for Use (IFU): SCIg60 Infusion System with Infuset

1. WASH HANDS before handling any supplies.
2. **REMOVE** Infuset flow control infusion set, patient set and syringe from sterile packaging – Use caution to maintain the sterility of the fluid path.
3. **LOAD** syringe with medicine according to the immunoglobulin package insert or as instructed by your healthcare provider, and immediately proceed to next step.
4. **CONNECT** syringe male luer lock (MLL) to Infuset female luer lock (FLL).
5. **CONNECT** Infuset male luer lock (MLL) to patient set female luer lock (FLL).
   NOTE: see page 30 for instructions for using the *VersaRate®*
6. **PRIME** tubing per your pharmacy/ physician instructions.
7. Use slide clamp provided with Infuset to prevent flow of drug.
8. Select sites and insert needles as instructed by healthcare provider and/or SCIg patient set instructions.
9. **OPEN** SCIg60 Infuser drive by rotating the handle **counterclockwise** until it stops.
10. **LOAD** syringe into SCIg60 Infuser by completely inserting the syringe plunger into the SCIg60 Infuser until it stops.
11. **LOCK** syringe into SCIg60 Infuser by turning the syringe clockwise until it stops.
12. **VERIFY** the syringe flange is in the window of SCIg60 Infuser to confirm the syringe is properly locked.



Instructions for Use (IFU) – Continued

13. **CLOSE** SCIg60 Infuser drive by rotating the handle clockwise until the base of the handle touches the body of the pump.

    CAUTION: DO NOT ATEMPT TO REMOVE THE SYRINGE BEFORE PERFORMING STEP 17.

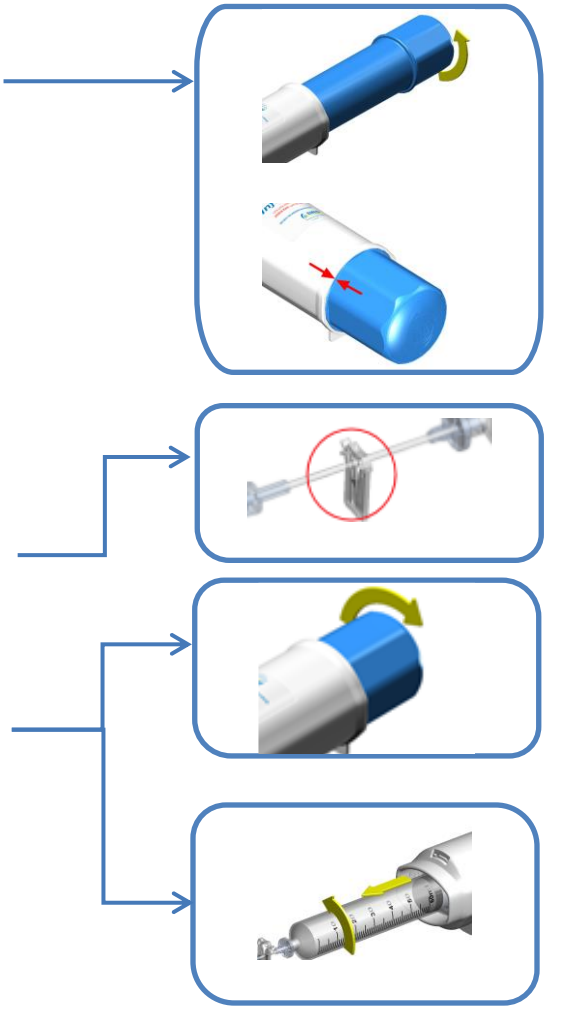
14. Place the SCIg60 Infuser, Infuset, and patient set on a stable, horizontal surface or use the Carrying Case Accessory (see *Using the Infuser Carrying Case Accessory* below for more details).

15. **COMPLETE INFUSION** as prescribed by your healthcare provider.

16. **USE SLIDE CLAMP** to stop flow as necessary during infusion session or when session is complete.

17. When session is complete, **REMOVE THE SYRINGE** by rotating the handle counterclockwise until it stops, then unlocking the syringe by turning it counterclockwise until it stops.

18. See next page for instructions on how to use the Carrying case.



SCIg60 Infusion System Instructions for Use (IFU) – Continued

Using the SCIg60 Infuser Carrying Case

Loading the SCIg60 System into the Carrying case

1. Obtain the carrying case and place on a safe table top 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 BD 60ml syringe (model no. 309653) and Infuset into the pouch oriented with the syringe to show from the display window.

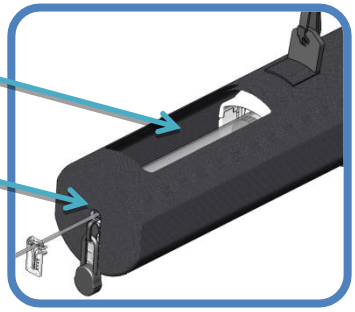
   The syringe should face away from the zipper pull, and the tubing should exit the Carrying Case through the small opening below the zipper.

   Use caution not to drop the device.
4. Close the pouch with the zipper - Use caution to prevent damage to the tubing.
5. Use belt loop or shoulder strap to hold and carry the system on the body.

Removing the SCIg60 System from the Carrying Case

1. Place the Carrying Case containing the SCIg60 system and place on a safe table top to prevent dropping.
2. Open the pouch by pulling the zipper.
3. Remove the SCIg60 System from the pouch using caution not to drop the device.

Zipper Pull



Syringe display window

Tubing exit opening

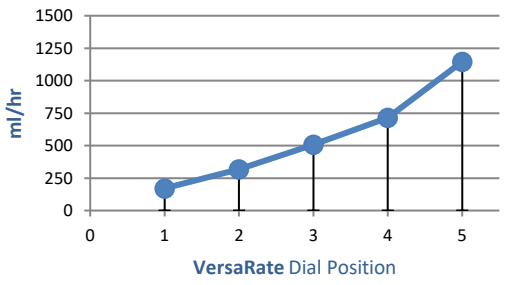
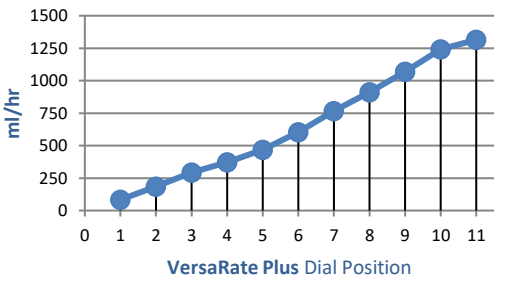
VersaRate® Adjustable Flow rate infusion set

Flow control dials have been used for decades to provide a means to improve flow rate control in Home and Hospital settings. EMED has designed *VersaRate™*, a proprietary flow regulator **that enhances the performance of mechanical and elastomeric infusers.** *VersaRate*® was designed to eliminate multiple infusion sets with limited flow rates required by this category of infusers.

The *VersaRate*® control set has a dial with a scale of 6 settings, and VersaRate Plus a dial with 12 settings. The scale has been selected to avoid the confusion experienced with other rate sets labeled in ml/hr that do not correspond to actual flow rates. The *VersaRate*® scale is correlated with flow rates for specific fluids viscosities that allow patients to adjust the desired flow rate without the use of multiple sets. Ambient conditions, equipment set up and patient parameters contribute to the actual flow rate during the use of mechanical and elastomeric infusion devices. *VersaRate*® provides a means to compensate for these factors by adjusting the settings to allow the clinician and patient to bring the actual flow rate to the desired level.

The chart below was developed based on 0.9% Sodium Chloride under controlled temperature conditions between 20°C - 25°C (68°F – 77°F) without a patient set. For specific fluid viscosities contact your healthcare provider.

Flow Rate charts (with 0.9% Saline solution and 15 PSI pressure)

VersaRate®	*VersaRate*® Plus
	
Note: *VersaRate*® Dial Position #6 is fully open.	*VersaRate*® Plus Dial Position #OPEN is fully open.

VersaRate® Instructions for Use (IFU)

1. **REMOVE** *VersaRate®* flow controller, patient set and syringe from sterile packaging – Using caution to maintain the sterility of the fluid path.

2 **LOAD** syringe with medicine according to the immunoglobulin package insert or as instructed by your healthcare provider, and immediately proceed to next step.

3 **TURN** *VersaRate®* control set to the **OFF** position to block flow. The *VersaRate™* is packaged in the open position for sterilization purposes.

4 **CONNECT** syringe male luer lock(MLL) to *VersaRate®* control set female luer lock (FLL)

5 **CONNECT** *VersaRate®* control set male luer lock (MLL) to patient set female luer lock (FLL).

6 **TURN** *VersaRate®* control set to the desired position to allow flow.

7 **PRIME** tubing per your pharmacy/physician instructions.

8 **TURN** *VersaRate®* control set to the **OFF** position to block flow.

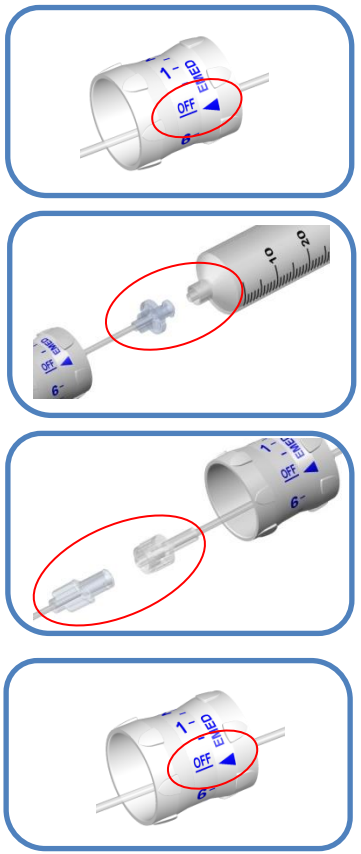
9 Select sites and insert needles as instructed by healthcare provider and/or SCIg patient set instructions.

10 **LOAD** syringe and prepare for infusion session by following steps 10 – 14 of the SCIg60 Infusion System with Infuset IFU.

11 **TURN** *VersaRate®* control set to the desired position to allow flow and begin infusion.

12 **COMPLETE INFUSION** as prescribed by your healthcare provider.

13 **TURN** *VersaRate®* control set to the **OFF** position to stop flow as necessary during infusion session or when session is complete.



Factors that Affect Flow Rate

The following are some of the factors that influence the flow rate of mechanical (non-electric) and elastomeric infusion devices. The compounded effect of these variables should be taken into account during use of the SCIg60 Infuser and selection of the appropriate Infuset or *VersaRate®* flow controller set.

FACTORS THAT AFFECT THE FLOW RATE	
Ambient temperature	Temperature has a significant effect on flow rate. The rate will change approximately 1 – 1.5% for each degree Fahrenheit in temperature changes.
Viscosity of solution	The SCIg60 Infusion System is designed to work with a wide range of fluid viscosities. The system was calibrated based on 0.9% Saline Solution. For specific data related to higher viscosities contact your healthcare provider.
Patient factors	➔ Venous Pressure / Sub-q tissue absorption ➔ Patient Body Mass Index (BMI), age and health
Catheters and needles	The effect of catheters and needles depends on their dimensions. SCIg60 Infusion System is designed to work with a wide range of gauges from 18 to 29.
Tubing obstruction	It is important to identify a comfortable position that prevents tubing obstruction.
Atmospheric pressure and infuser relative location	The force of gravity has a minimal effect on flow rate.

LARGE EFFECT	MODERATE EFFECT	SMALL EFFECT

SCIg60 Infuser Technical Information

Length	26.0 cm (10.2 in.)
Width	6.5 cm (2.6 in.)
Weight	412 g (14.5 oz)
Storage Temperature	-5°C to +40°C (23°F to 104°F)
Syringe volume (BD 60 ml syringe (model no. 309653)	60 ml only
Maximum operating pressure	16.8 psi
Average Operating Pressure	14.4 psi
Target Operating Temperature	20°C - 25°C (68°F – 77°F)
Use-By Dating	5 years
CE	0459

Infuset Flow Control Infusion Set Performance Information

Infuset Description	Reorder Number	Length	Residual Volume **(ml)**	Target Flow Rate (ml/hr) **(0.9% saline at 25°C)**	**Flow rate accuracy (ml/hr)** (0.9% saline at 25°C)
Infuset-45	FP-0010013	37.9" (96.2 cm)	≈ 0.15 ml	45	± 10%
Infuset-80	FP-0010014	22.4" (56.8 cm)	≈ 0.13 ml	80	± 10%
Infuset-120	FP-0010011	33.4" (84.8 cm)	≈ 0.16 ml	120	± 10%
Infuset-190	FP-0010008	22.0" (55.8 cm)	≈ 0.14 ml	190	± 10%
Infuset-290	FP-0010007	23.5" (59.7 cm)	≈ 0.16 ml	290	± 10%
Infuset-430	FP-0010010	14.5" (36.8 cm)	≈ 0.13 ml	430	± 10%
Infuset-650	FP-0010009	9.6" (24.5 cm)	≈ 0.12 ml	585	± 10%
Infuset-820	FP-0010006	7.9" (20.1 cm)	≈ 0.11 ml	750	± 10%
Infuset-930	FP-0010005	6.9" (17.5 cm)	≈ 0.13 ml	875	± 10%
Infuset-1850	FP-0010004	3.4" (8.7 cm)	≈ 0.10 ml	2100	± 10%
Infuset-3200	FP-0010027	2.6" (6.6 cm)	≈ 0.05 ml	2974	± 10%
Infuset-4000	FP-0010028	2.8" (7.0 cm)	≈ 0.06 ml	4084	± 10%
Infuset-4300	FP-0010029	2.3" (5.9 cm)	≈ 0.05 ml	4342	± 10%
		CE	**0459**		

Flow rates can be affected by various environmental factors, patient factors, and infusion equipment used. The above flow rates were determined at controlled room temperature between 20°C - 25°C (68°F – 77°F) without any downstream patient sets or additional tubing, and are intended as starting points to determine the flow rate for each application, as determined by a healthcare professional.

Please contact EMED for additional flow rate information specific to your therapeutic application.

VersaRate® Technical Specifications

	VersaRate (FP-0010003)	VersaRate Plus (FP-0010026)
Length and width	4.25" (10.8 cm) x 1.18" (3 cm)	4.69" (11.9 cm) x 1.24" (3.2 cm)
Tubing	Ø1.02mm ID x Ø2.4mm OD	Ø1.3mm ID x Ø3.2mm OD
Weight	0.45 oz / 13 g	0.44 oz / 12.4 g
Storage Temperature	-5°C to +40°C	-5°C to +40°C
Residual Volume	≈0.2 ml	≈0.25 ml
Maximum operating pressure	18.00 psi	18.00 psi
Flow rate range	Adjustable 0-2100 ml/hr	Adjustable 0-1250 ml/hr
CE	0459	0459

SCIg60 Infuser – Cleaning and Storage

- Outer surfaces of the SCIg60 Infuser may be cleaned with 70% isopropyl alcohol wipes or a soft cloth dampened with a weak mixture 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.
- Clean only those areas that are exposed when the Infuser Inner Drive is completely screwed in. Do not attempt to clean any part of the SCIg60 Infuser that is not easily accessible.
- Discontinue use of a SCIg60 Infuser that has been internally exposed to or immersed in fluid.
- Use a dry cloth to dry the exposed and external portions of the device.
- Do not use heating devices to dry or expose infuser to high temperatures or damage to the infuser and its mechanism may occur.
- Storage temperature: -5°C to +40°C (+23°F to +104°F). Avoid exposing the SCIg60 Infuser to temperatures outside of this range.

SCIg60 Infuser Carrying Case – Cleaning

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

Troubleshooting

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

- **SYRINGE POSITION**. Verify the syringe is properly positioned into the infuser as instructed in the IFU section; the syringe should be parallel to the infuser with the syringe flange properly engaged and seen within the safety check window (shown in the diagram). If syringe 'pops out' of infuser when inner drive is activated/screwed in, it is an indication that the syringe was not properly positioned in the infuser. Unscrew the inner drive and properly position the syringe following the instructions for use.
- **TUBING CONNECTORS**. Verify the BD 60 ml syringe (model no. 309653) is properly connected to the Infuset and that the Infuset is correctly connected to the specified patient sets.
- **NO FLOW.** Check the slide clamp on the Infuset and make sure is not blocking the flow, or if using the *VersaRate*® control set check to make sure it is not at the OFF position. If there is still no flow, verify the slide clamp is not closed on the patient tubing set and that the tubing is not kinked in any way.
- **FLOW RATE IS TOO HIGH**. Verify that the intended Infuset is being used or that the VersaRate dial is set to the intended position. If flow rate remains too high, contact your healthcare provider for alternative Infuset flow rate set, or if using *VersaRate*® control set, rotate the dial to a lower position or to the OFF position.
- **FLOW RATE IS TOO SLOW**. Verify that the intended Infuset is being used or that the *VersaRate*® dial is set to the intended position. If flow rate remains too slow, contact your healthcare provider for alternative Infuset flow rate set, or if using *VersaRate*® control set, rotate the dial to a higher position.
- **FLOW DOES NOT STOP**. Verify that the slide clamp on the Infuset is fully closed, or that the *VersaRate*® control set is fully turned to the OFF position. If flow does not stop disconnect the syringe from the SCIg60 Infuser by opening the Inner drive by rotating the handle counterclockwise until it stops.
- **BROKEN PARTS**. Inspect infuser for any broken parts. If this is the case contact EMED Technologies Corporation.

If after following the instructions above the SCIg60 Infusion System does not appear to be working properly, discontinue use of the SCIg60 Infusion System and contact your healthcare provider or EMED Technologies Corporation.

⚠ Contraindications/Warnings

DO	DO NOT
Read all instructions for the SCIg60 Infusion System and flow rate infusion set before use.	Do not use frozen solutions
Use only EMED Infusets or *VersaRate®* to control the flow; using any other device/tubing to control the flow rate will result in unsafe condition for patient.	Do not use Infuser if it is broken or damaged. If the infuser is dropped or damaged either in transit to you or during preparation for its use, or if water damage is suspected contact EMED Technologies.
Use the SCIg60 Infusion System as prescribed by your healthcare provider and follow all the directions as prescribed.	Do not subject the Infuser to autoclaving or other similar methods of sterilization
Use only BD 60 ml syringes (REF 309653) do not use any other syringe.	Do not open the infuser or attempt to modify its function in any way other than detailed in this User Manual.
If fluid source is disconnected during the infusion, stop the process and place a sterile non-vented cap on syringe and set	DO NOT use any other syringe. Doing so may result in unsafe conditions for patient or deviation from desired infusion rates
Use aseptic technique when handling Infuset and *VersaRate®* flow controllers	**Do not insert or remove the syringe** until the INNER DRIVE is fully opened, as indicated in the IFU section, step 17.
Place SCIg60 Infuser on a flat surface or in the provided carrying case during use. Syringe damage and drug loss could occur if system is dropped while loaded with syringe and drug.	Do not use this device if high accuracy is needed. Flow rates of all elastomeric or mechanical infusers are affected by multiple factors described in this manual. Alternative electronic infusers should be used in those cases
Use only one Infuset or VersaRate® at one time.	Do not use the Infuset, *VersaRate®*, or syringe more than once, as it may cause infection
Contact EMED if you have any questions regarding the use of the SCIg60 Infusion System.	Do not re-sterilize Infuset or *VersaRate®* flow controllers, doing so will cause serious health conditions to patient.

Caution: U.S. Federal Law restricts this device to sale by or on order of a physician.

Warranty

- **Parties Covered:** This warranty extends only to the Original Purchaser of the infusion infuser and it does not extend to subsequent purchasers or users. The "Original Purchaser" is the person purchasing the infusion 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 flow rates, result in unexpected flow rates, 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.

- **Disposable items**: In the event that an EMED-branded disposable item is found defective, it will be replaced with a new disposable item by the Manufacture.

Contact Information

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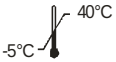
CE 0459

Symbols Definition Table

Some of these symbols may be found on your device labeling and packaging materials:

SYMBOLS	DEFINITION	SYMBOLS	DEFINITION
	Warning		Quantity
	Read the instructions		Storage temperature limits
	Do not re-use	SN	Serial number
	Don't use if package is damaged	ø	Diameter
STERILE EO	Sterilized by Ethylene Oxide		Length
	Manufacturer	Rx ONLY	To sale by or on the order of a physician.
EC REP	EC Representative	≈ XX ml	Approximate priming volume
REF	Reference number	CE	CE Mark
	Manufacturing date	ID	Internal Diameter
LOT	Batch	OD	Outer Diameter
	Expiration date		Non-pyrogenic fluid path
DEHP Free	Is not made with di(2-ethylhexyl) phthalate (DEHP)	Latex Free	This product is not made with latex