SCIg60
Infusion System

EMED Technologies
The power of creative thinking

The Power of
CREATIVE THINKING

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

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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.

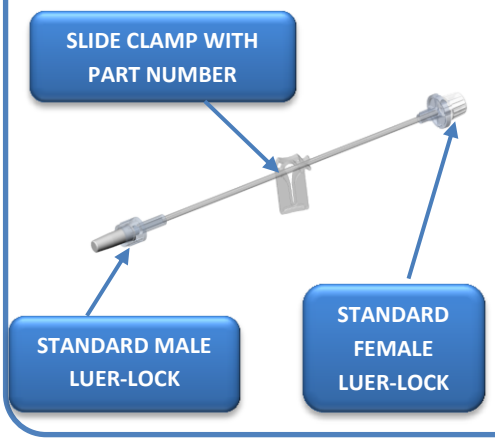
Getting to know your SCIg60 Infusion System

PACKAGE CONTENTS

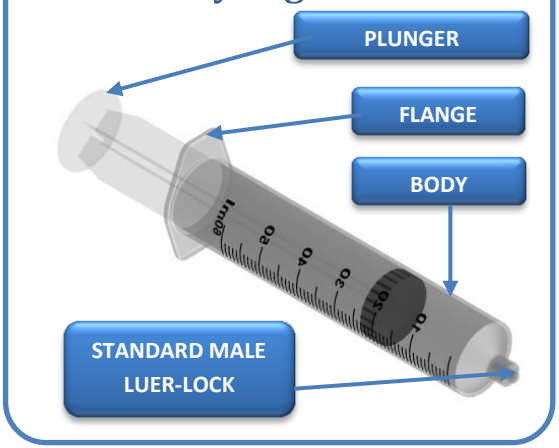
- SCIg60 Infuser
- User Manual
- Carrying Case
- (EMED Infuset and *VersaRate™* flow controllers are sold separately)
- (Syringe to be used: BD 60 ml Syringe Luer Lock Tip, product REF 309653)

SCIg60 Infuser

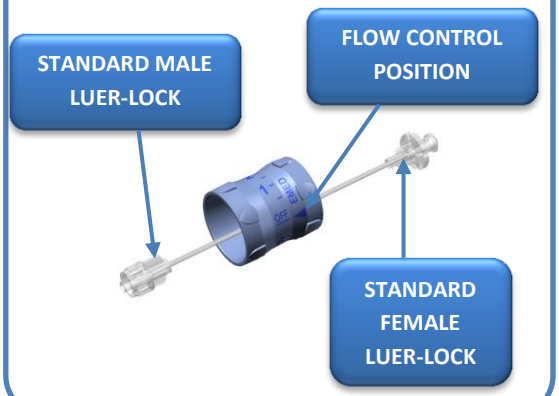
Infuset



Syringe



VersaRate™

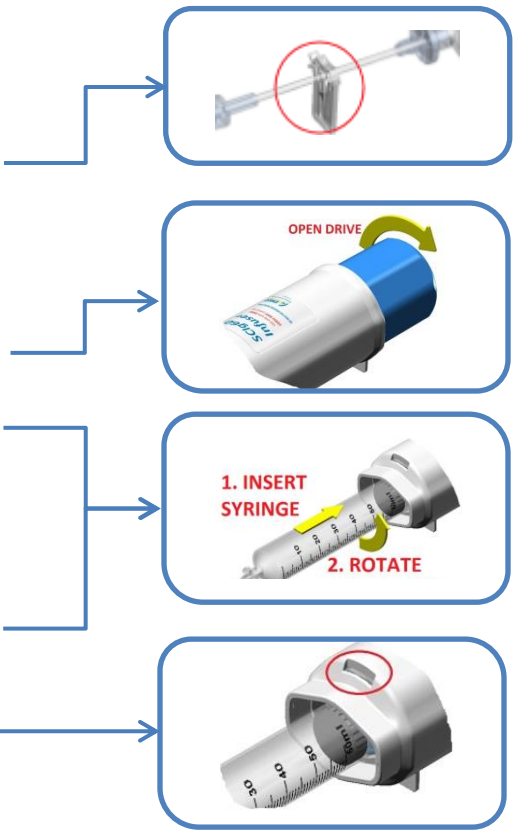


SCIg60 Infusion System

SCIg60 Infusion System Carrying Case

Instructions for Use (IFU) for SCIg60 Infusion System

1. **WASH HANDS** before handling any supplies.
2. **REMOVE** Infuset flow controller, patient set and syringe from sterile packaging – Use caution to maintain the sterility of the fluid path.
3. **LOAD** syringe with drug.
4. **CONNECT** syringe and patient set to Infuset controller set (see page 8 for instructions for using the *VersaRate™*)
5. **PRIME** set per your pharmacy/ physician instructions.
6. Use slide clamp provided with Infuset to prevent flow of drug.
7. Select sites and insert needles as instructed by healthcare provider and/or SCIg patient set instructions.
8. **OPEN** SCIg60 Infuser drive by rotating the handle **counterclockwise** until it stops.
9. **LOAD** syringe into SCIg60 Infuser by inserting the syringe plunger into the SCIg60 infuser.
10. **LOCK** syringe into SCIg60 Infuser by rotating the syringe 90° until you feel a click.
11. **VERIFY** the syringe flange is in the window of SCIg60 Infuser to confirm the syringe is properly locked.



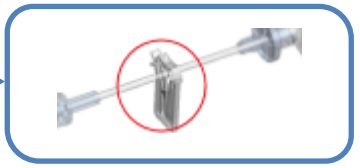
Instructions for Use (IFU) – Continued

12. **CLOSE** SCIg60 Infuser drive by rotating the handle clockwise until it stops.
CAUTION: DO NOT ATEMPT TO REMOVE THE SYRINGE BEFORE PERFORMING STEP 16.

13. 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).

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

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



16. To **REMOVE THE SYRINGE** rotate the handle counterclockwise until it stops, then unlock the syringe by turning it 90° (refer to steps 8 - 10 above).

Using the SCIg60 Infuser Carrying Case Accessory

Insert SCIg60 Infuser with syringe and Infuset or VersaRate™ into the pouch. Use the Velcro straps inside the pouch to secure the infuser in place.

Close the case with the zipper - Use caution to prevent damage to the tubing.

VersaRate™ Adjustable Flow rate infusion set

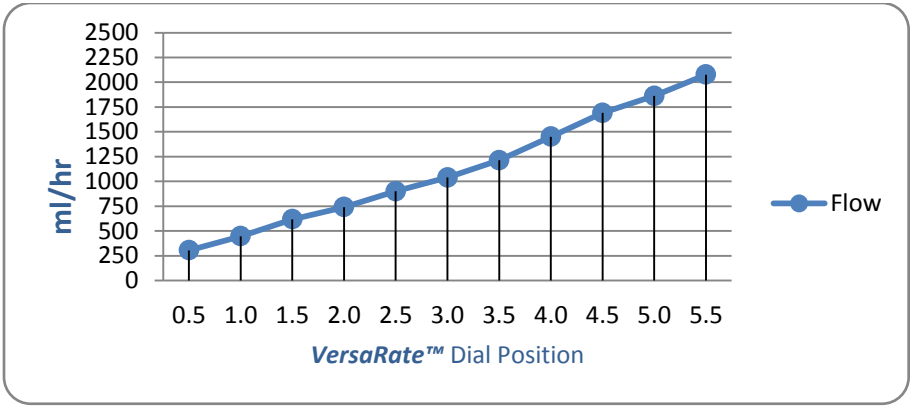
Flow control dials have been used for decades to provide a means to improve flow rate control in Home and Hospital settings. EMED has designed *VersaRate™*, a proprietary flow regulator **that enhances the performance of mechanical and elastomeric infusers.** *VersaRate™* was designed to eliminate multiple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

The *VersaRate™* control set has a dial with a scale from 1 to 6. 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 (71 degrees Fahrenheit) without a patient. For specific fluid viscosities contact your healthcare provider.

VersaRate™ Flow Rate chart (with 0.9% Saline solution and 15 PSI pressure)



Note: *VersaRate*™ Dial Position #6 is fully open.

VersaRate™ Instructions for Use (IFU)

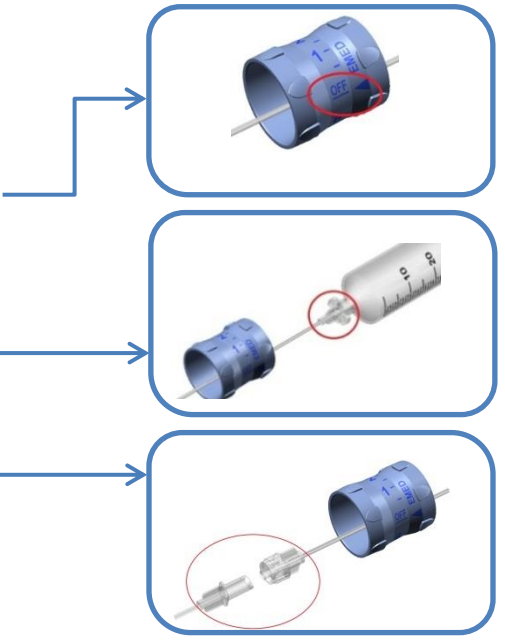
1. **REMOVE** *VersaRate™* flow controller, patient set and syringe from sterile packaging – Using caution to maintain the sterility of the fluid path.

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

3 **CONNECT** syringe (male luer lock) to *VersaRate™* control set (female luer lock)

4 **CONNECT** *VersaRate™* control set (male luer lock) to patient set (female luer lock).

5 **RESUME** with infuser Instructions.



Factors that Affect Flow Rate

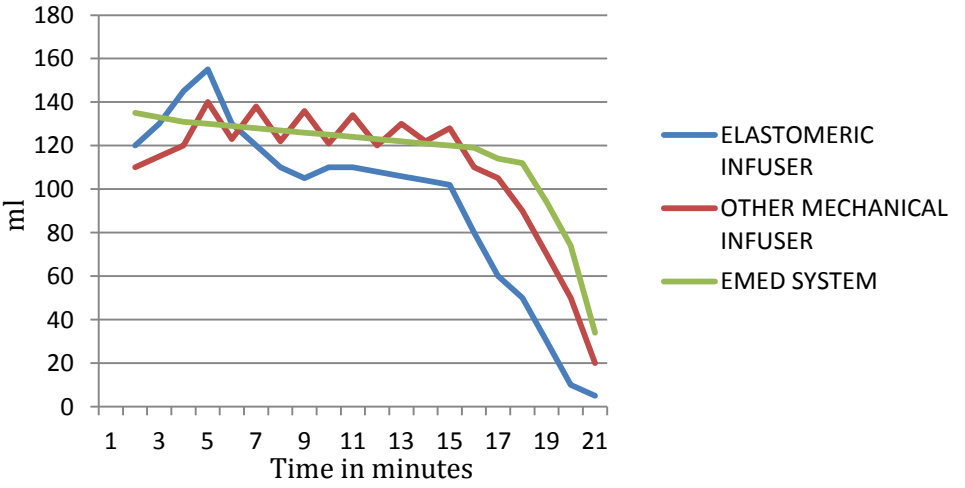
The following are some of the factors that influence the flow rate of mechanical (non-electric) and elastomeric infusion devices. The compounded effect of these variables should be taken into account during use of the SCIg60 Infuser and selection of the appropriate Infuset or *VersaRate™* flow controller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

FACTORS THAT AFFECT THE FLOW RATE	
Ambient temperature	Temperature has a significant effect on flow rate. Approximately the rate will change between 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

Different Infusion Systems Flow Profile

The chart below illustrates the variances between different infusion systems. This chart demonstrates that the SCIg60 Infusion System delivers a consistent flow rate throughout the infusion without the peaks and valleys found in other mechanical and elastomeric infusers.



SCIg60 Infuser Technical Information

Length	10.2" (26.0 cm)
Width	2.6" (6.5 cm)
Weight	14.5 oz / 412 gr
Storage Temperature	0°C to +40°C
Syringe volume	60 ml only
Maximum operating pressure	15.5 psi ± 10%
CE	0459

Infuset Flow Controller Performance Information

Infuset Part 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-190	22.0" (55.8 cm)	<0.2 ml	190	± 10%
Infuset-290	23.5" (59.7 cm)	<0.2 ml	290	± 10%
Infuset-430	14.5" (36.8 cm)	<0.2 ml	430	± 10%
Infuset-650	9.6" (24.5 cm)	<0.2 ml	585	± 10%
Infuset-820	7.9" (20.1 cm)	<0.2 ml	750	± 10%
Infuset-930	6.9" (17.5 cm)	<0.2 ml	875	± 10%
Infuset-1850	3.4" (8.7 cm)	<0.2 ml	2100	± 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 (20°C - 25°C) 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

Length and width	4.25" (10.8 cm) x 1.18" (3 cm)
Tubing	Ø1.02mm ID x Ø2.4mm OD
Weight	0.4 oz / 13 gr
Storage Temperature	0°C to +40°C
Residual Volume	<0.3 ml
Maximum operating pressure	18.00 psi
Flow rate range	Adjustable 0-2100 ml/hr
CE	0459

SCIg60 Infuser - Cleaning and Storage

- Clean the SCIg60 Infuser after each treatment using alcohol wipes, isopropyl alcohol, or mild detergent and hot water.
- Open inner drive by rotating the handle counterclockwise until it stops, then:
  - Clean all exposed surface of the SCIg60 Infuser.
  - Clean internal surface only if required to remove spilled liquids.

- If water or alcohol is in the infuser after cleaning, use a dry clean cloth and wipe the surface. Allow the infuser to dry at room temperature. 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: 0°C to +40°C. Avoid exposing the infuser, Infusets, or *VersaRate™* to temperatures outside of this range.
- 5 year shelf-life

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 seated 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 that all syringe-to-flow control set and flow control set-to-patient set connections are properly connected.
- **NO FLOW.** Check the slide clamp on the Infuset and make sure is not blocking the flow or when using the *VersaRate™* control set is at the OFF position, verify that the *VersaRate™* dial is turned to the desire position. If there is still no flow verify the slide clamp is not closed on the patient tubing set. If this condition is persists for more than one Infusion and patient set and there is still no flow, contact your healthcare provider or EMED Technologies Corporation.
- **FLOW RATE IS TOO HIGH**. Incorrect Infuset is being used; contact your healthcare provider for alternative flow rate set. Or, if using *VersaRate™* control set, rotate the dial to a lower or OFF position.
- **FLOW RATE IS TOO SLOW**. Incorrect Infuset is being used; contact your healthcare provider. If using the *VersaRate™* control set, rotate the dial to a higher position. Use of the Infuset slide clamp for an extended period of time may deform the tubing and cause decreased flow rate; switch to a new control set.
- **FLOW DOES NOT STOP**. Slide clamp on the Infuset is not fully closed. Or, if using *VersaRate™,* control set is not 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.	Do not use frozen solutions
Read all instructions for the flow rate infusion set	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 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 open the infuser or attempt to modify its function in any way other than detailed in this User Manual.
Use only BD 60 ml syringes (REF 309653) do not use any other syringe.	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 16.
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 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
Place SCIg60 Infusion pump 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 Infusets or *VersaRate™* more than once, as it may cause infection
	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 under normal use, if used in accordance with device operating instructions and under the direction of authorized medical personnel. Failure to comply with these conditions will result in a void warranty.
- **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 one 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 one-year warranty period.
- **Disposable items**: In the event that a disposable item is found defective, it will be replaced with a new disposable item.

EMED Technologies Contact Information

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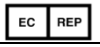
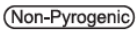
Symbols Definition Table

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

SYMBOLS	ENGLISH	SYMBOLS	ENGLISH
	Warning		Manufacturing date
	Read the instructions		Batch
	Single-use		Expiration date
	Don't use if package is damaged		Quantity
	Sterilized by Ethylene Oxide		Storage temperature limits
	Manufacturer		Serial number
	European Representative	Ø	Diameter
	Reference number		Length
	CE Mark	RxOnly	To sale by or on the order of a physician.
	This product is not made with di(2-ethylhexyl) phthalate (DEHP)		This product is not made with Natural Rubber Latex
	Fluid path of this product is non-pyrogenic		