SCIg60
Infusion System

EMED Technologies
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CREATIVE THINKING

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.

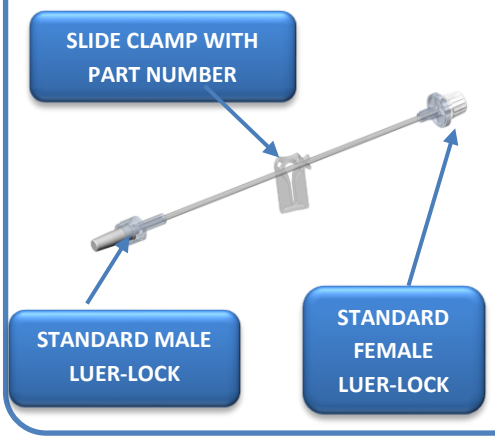
Getting to know your SCIg60 Infusion System

PACKAGE CONTENTS

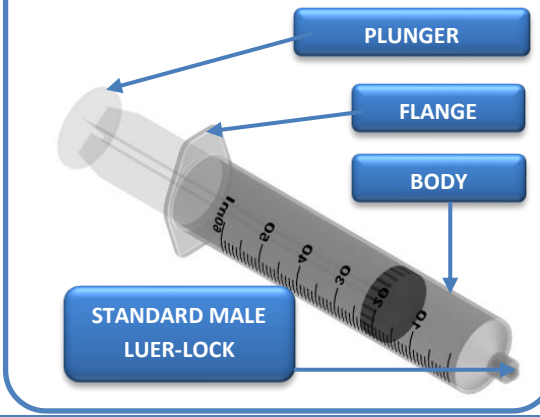
- SCIg60 Infuser
- User Manual
- Carrying Case
- (EMED Infuset and VersaRate® flow controllers are sold separately)
- (Syringe to be used: BD 60 ml Syringe Luer Lock Tip, product REF 309653)

SCIg60 Infuser

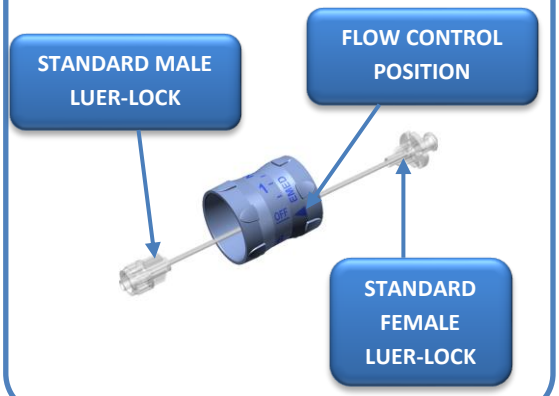
Infuset



Syringe



VersaRate®



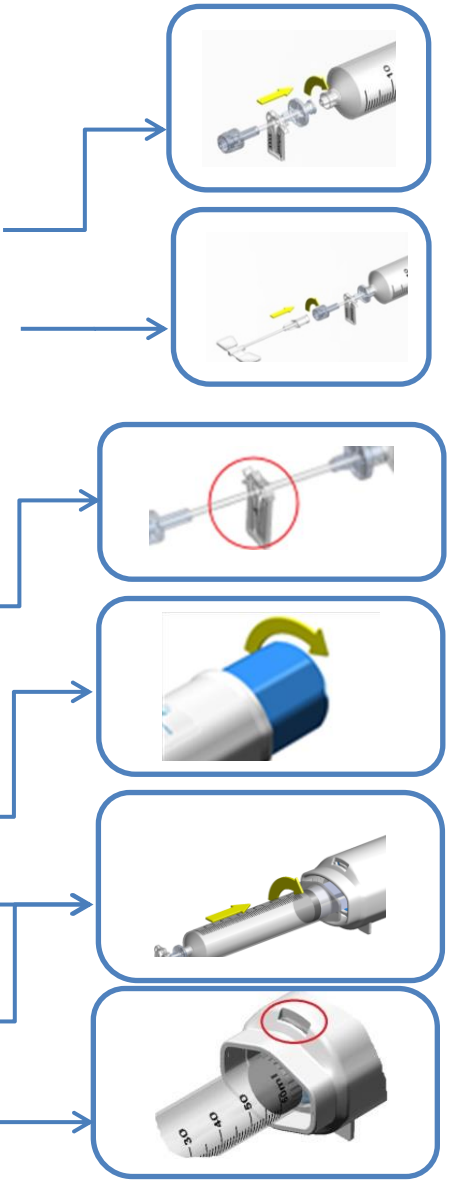
SCIg60 Infusion System

SCIg60 Infusion System Carrying Case

Instructions for Use (IFU): 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.

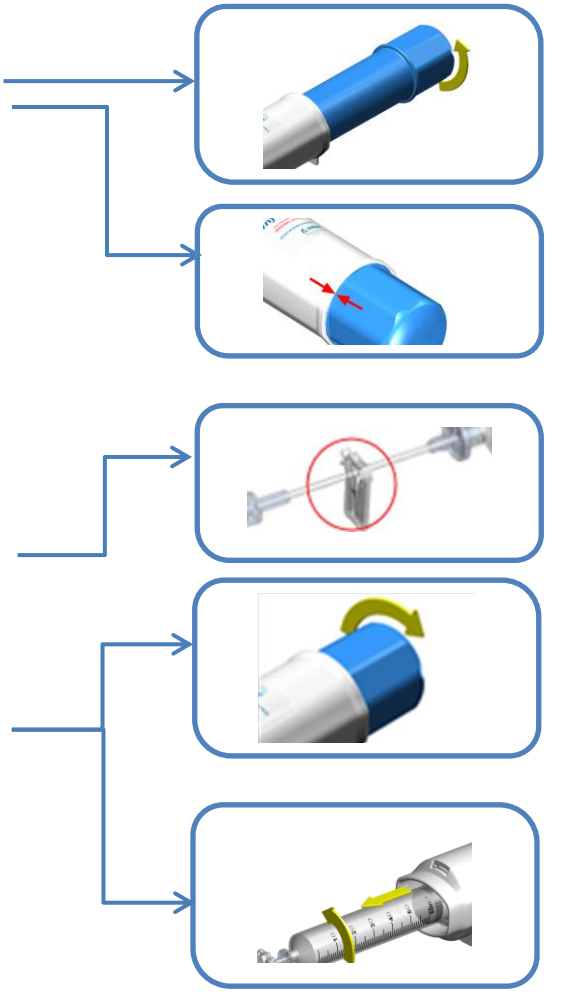
14. Place the SCIg60 Infuser, Infuset, and patient set on a stable, horizontal surface or use the Carrying Case Accessory (see *Using the Infuser Carrying Case Accessory* below for more details).

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.



Instructions for Use (IFU) – Continued

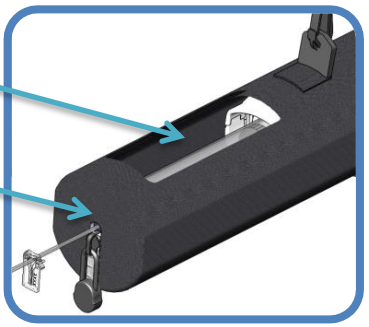
Using the SCIg60 Infuser Carrying Case

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.
4. Close the Carrying Case zipper.



VersaRate® Adjustable Flow rate infusion set

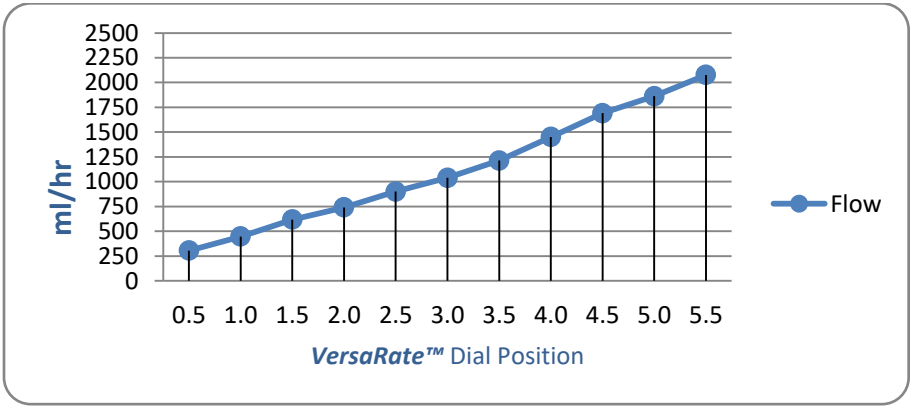
Flow control dials have been used for decades to provide a means to improve flow rate control in Home and Hospital settings. EMED has designed *VersaRate™*, a proprietary flow regulator **that enhances the performance of mechanical and elastomeric infusers.** *VersaRate*® was designed to eliminate multiple 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 between 20°C - 25°C (68°F – 77°F) without a patient set. 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.

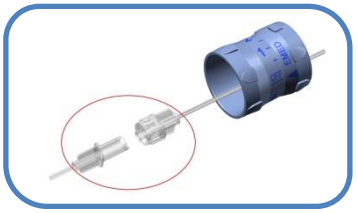
2 **LOAD** syringe with medicine according to the immunoglobulin package insert or as instructed by your healthcare provider, and immediately proceed to next step.

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

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	-5°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

- 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

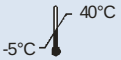
EMED Technologies
U.S.A. Headquarters
1264 Hawks Flight Court, Suite 200
El Dorado Hills, CA 95762
Tel. +1 (916) 932-0071
Fax: +1 (916) 932-0074
customerservice@emedtc.com
sales@emedtc.com
www.emedtc.com

EC REP Emergo Europe
Prinsessegracht 20
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	Non-pyrogenic fluid path
DEHP Free	Is not made with di(2-ethylhexyl) phthalate (DEHP)	Latex Free	This product is not made with latex