Edwards Lifesciences

Flow-Through Housing Model 93505

For single use only

Concept/Description

When used in conjunction with the Injectate Temperature Probe, the Flow-Through Housing (Model 93505) allows direct temperature measurement of the thermal indicator at the proximal lumen infusion site. Measurement of the injectate temperature at the infusion site helps reduce errors frequently encountered in standard injection techniques (for example, injectate warming caused by handling the syringe). The temperature of the injectate is fed directly by the injectate temperature probe into a patient monitor for curve analysis and determination of cardiac output. An appropriate computation constant must be entered into the computer to determine the correct cardiac output. A 3-way stopcock should be placed proximal to the flow-through housing (Figure 3) for standard catheter maintenance and fluid withdrawal.

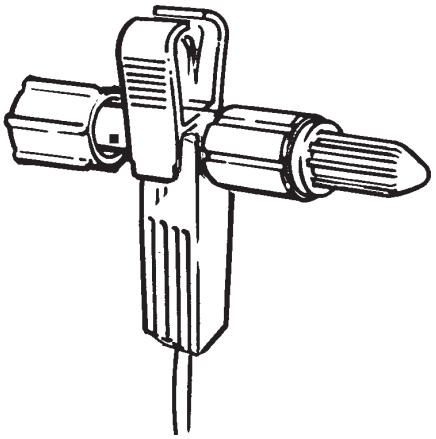

Figure 1 M5036-5

Instructions For Use

Connect Housing to Catheter and Patient Monitor (Figure 2)

Note: Use Aseptic Technique

1. Verify that the fluid path is completely free of air. Attach the flow-through housing to the catheter injectate lumen stopcock. (Figure 3)
2. Insert the reusable injectate temperature probe into the flow-through housing (Figure 4). Secure the system to minimize movement with respect to the patient.
3. Connect the injectate temperature probe cable to the "Injectate Probe" lead of the computer cable.

To Remove Flow-Through Temperature Probe (Figure 4)

Grasp the flow-through housing, gently press both tabs, and withdraw the temperature probe.

Prepare Patient Monitor for Operation

1. Select Injectate volume and catheter size on monitor to determine computation constant or enter a computation constant corresponding to injectate volume, temperature range, and catheter model being used.

   Note: Refer to the catheter's instructions for use for computation constants.
2. Prepare the monitor for operation according to the directions in the Operations Manual.

To Measure Cardiac Output

1. Attach a prefilled syringe (D_5W cold injectate) to the flow-through housing.
2. Turn the stopcock at the catheter injectate hub to close the IV flush and open the fluid path between the syringe and catheter.
3. Press start on patient monitor.
4. Immediately perform injections at a rate of at least 2.5 ml/sec.
5. Perform cardiac output determinations according to the instructions in the appropriate cardiac output computer operations manual.

   Note: To improve cardiac output reproducibility, space injections approximately 1 minute apart and increase injectate volume to 10 ml if not already doing so.
6. At the conclusion of measurements, return the catheter stopcock to its original (flush) position.

Injectate Temperature

Ensure that the injectate temperature falls within 6 °C to 16 °C for cold injectate and 18 °C and 25 °C for room temperature injectate.

Lower or higher injectate temperatures will affect cardiac output accuracy.

Precautions

Care should be taken to avoid air entrapment during setup and use. The flow-through housing and syringe should be secured to minimize movement with respect to the patient.

How Supplied/Recommended Use

This product is supplied sterile and nonpyrogenic, and will remain so as long as the package is unopened and undamaged. Do not resterilize. It is recommended for single patient use only. It is recommended that the product be changed (replaced) for each patient according to hospital procedures for changing tubing sets containing dextrose solutions.

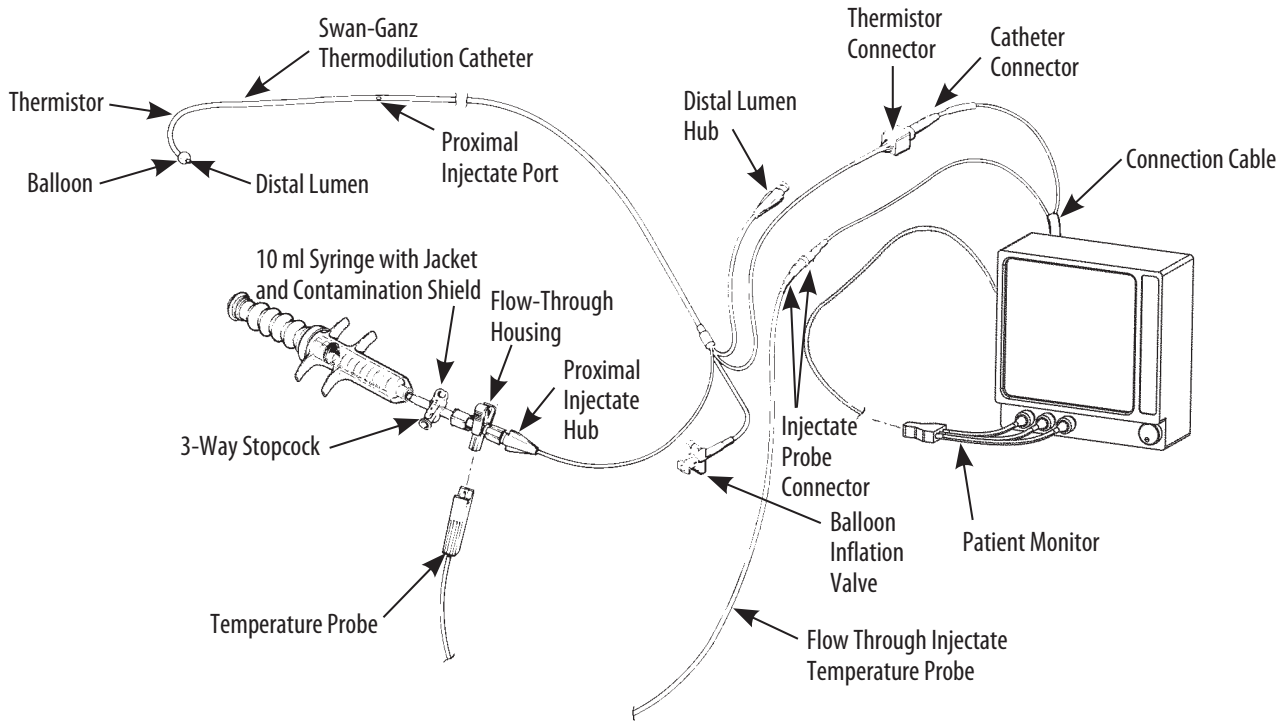

Figure 2. Flow-Through Housing and Temperature Probe M5036-24

Shelf Life

The recommended shelf life is as marked on each package. Resterilization will not extend the shelf life of this product.

Technical Assistance

For technical assistance, please call Edwards Technical Support at the following telephone numbers:
Inside the U.S. and Canada
(24 hours): 800.822.9837
Outside the U.S. and Canada
(24 hours): 949.250.2222
In the UK: 0870 606 2040-Option 4
In Ireland: . . . . . 01 8211012 Option 4

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Warning: This device is designed, intended, and distributed for single use only. **Do not re-sterilize or reuse this device.** There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing.

Because of continuing product improvement, prices, specifications, and model availability are subject to change without notice.

This product is manufactured and sold under one or more of the following US patent(s): US Patent No. 6,248,077; 6,336,902; and corresponding foreign patents.

Refer to the symbol legend at the end of this document.

Product bearing the symbol:

STERILE EO

has been sterilized using Ethylene Oxide.

Alternatively, product bearing the symbol:

STERILE R

has been sterilized using Irradiation.

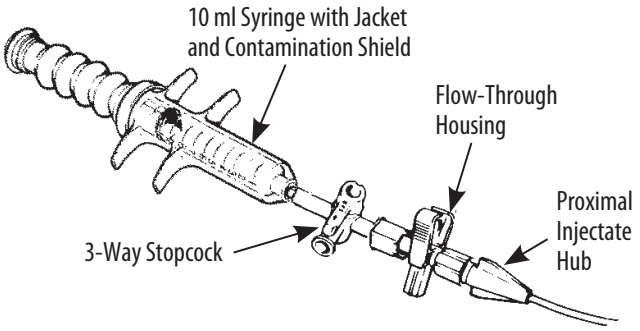

Figure 3. Flow-Through Housing Connected to Catheter Injectate Lumen

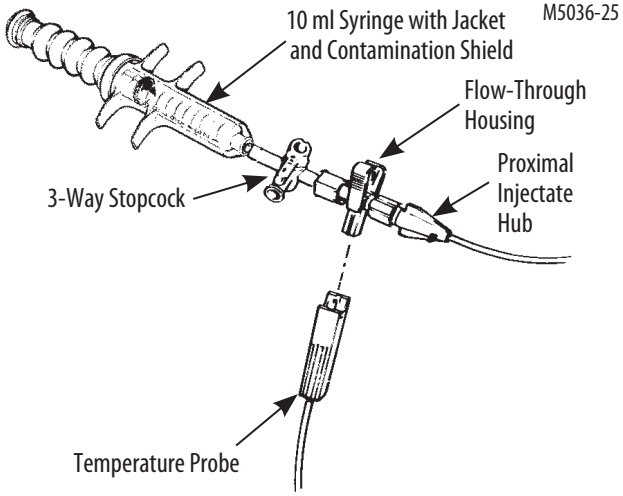

Figure 4. Temperature Probe and Flow-Through Housing

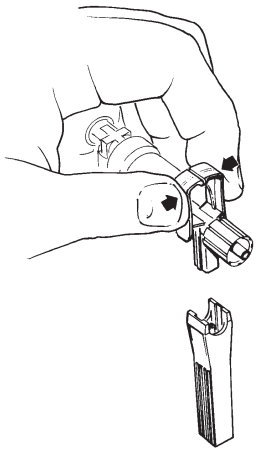

Figure 5. Removing the Temperature Probe from Housing

Computation Constants

Temperature (°C)	Injectate Volume (ml)	181F7 & 151F7	C144F7	All 7.5F Catheters	132F5	096F6
6 - 12	10	0.561	0.570	0.574	N/A	0.558
8 - 16	5	0.259	0.271	0.287	0.285	0.277
	10	0.608	0.585	0.595	N/A	0.607
18 - 25	5	0.301	0.287	0.298	0.307	0.301

Symbol Legend

	English		English
PHT DEHP	Contains or presence of Phthalates: bis (2-ethylhexyl) phthalate (DEHP)	EC REP	Authorized representative in the European Community/European Union
#	Model Number		Manufacturer
REF	Catalogue Number		Date of manufacture
	Do not re-use	LOT	Lot Number
40 °C 0 °C	Temperature limit	QTY	Quantity
90% 5%	Humidity limitation		Caution
	Keep dry		Consult instructions for use
Rx only	**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.		Non-pyrogenic
½" —1½" (12.7 mm —38.1 mm)	Bracket fits poles ½" to 1 ½" diameter		Do not use if package is damaged and consult instructions for use
CE 0123	Conformité Européenne (CE Mark)	2 STERILIZE	Do not resterilize
		STERILE EO	Sterilized using ethylene oxide
CE	Conformité Européenne (CE Mark)	STERILE R	Sterilized using irradiation
UDI	Unique device identifier		Use-by date
eifu.edwards.com + 1 888 570 4016	Consult instructions for use on the website	LATEX	Contains or presence of natural rubber latex
		NON STERILE	Non-sterile

Note: Not all symbols may be included in the labeling of this product.

COS1EM5x7.1

Edwards

Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614 USA

CE 0123

Made in Dominican Republic
CCT Critical Care Technologies, S.R.L.
Parque Industrial Itabo
Km 18.5 Carr. Sanchez
Haina, San Cristobal, Dominican Republic

08/25
60051652001B / DOC-0555323B

EC REP

Edwards Lifesciences GmbH
Parkring 30
85748 Garching bei München
Germany

Telephone 949.250.2500
800.424.3278
FAX 949.250.2525

Web IFU

For proofreading documentation only
For Internal Edwards Lifesciences Use Only.

Edwards	Title: eIFU, CO-SET, FLOW THRU HSG 93505, EM	Page: 7 of 7
	Label Item/Revision:	60051652001/B
	Visual Representation/Revision:	DOC-0555323/B
	Drawing/Specification:	N/A
	English Master/Revision:	N/A
	eIFU Visual Representation/Revision:	N/A
	Refer to supporting material for signatures.	