



USER: GRAY, ILKA K (ixg)

FOLDER: K991513 - 126 pages (FOI:08007474)

COMPANY: I-FLOW CORP. (IFLOW)

PRODUCT: SET, ADMINISTRATION, INTRAVASCULAR
(FPA)

SUMMARY: Product: HOMEPUMP C-SERIES AND
HOMEPUMP C-SERIES ONE-STEP KVO

DATE REQUESTED: Fri Nov 05 24:00:00 2010

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Note: Releasable Version

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JUN 21 1999



I-FLOW
CORPORATION

20202 Windrow Drive
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(800) 448-3569 (949) 206-2700
Fax (949) 206-2600

K991513

SUMMARY OF SAFETY AND EFFECTIVENESS

April 29, 1999

Trade Name: Homepump C-Series and Homepump C-Series One-Step KVO

Common Name: Elastomeric Infusion Pump

Classification Name: Pump, Infusion, Elastomeric

All questions and/or comments concerning this document should be made to:

Robert J. Bard, Esq., R.A.C.
Vice President of Regulatory and Legal Affairs

I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630

Telephone: 949.206.2700
Fax: 949.206.2600

1.0 GENERAL INFORMATION

1.1 Purpose of Submission

1.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow Corporation is adding two new optional components to the Homepump C-Series (K944692).

1.1.1.1 Regulator (optional)

1.1.1.1.1 The optional regulator controls the decreasing pressure (14 to 9 psi) of the Homepump C-Series to a fixed 6.0 psi.

1.1.1.2 Flow Indicator (optional)

1.1.1.2.1 An optional flow indicator component incorporates a flow status column indicator with the glass orifice flow restrictor.

Note: The PainBuster Infusion Kit (K980558 and K982946), the On-Q Infusion Kit (K980558 and K982946) and the Nerve Block Infusion Kit (K984502) use the Homepump C-Series infusion pumps in their kits. Neither the regulator nor the flow indicator components change the intended use of the Homepump C-Series when used in the PainBuster, On-Q or Nerve Block Infusion Kits.

1.2 Statement of Equivalence

1.2.1 The Homepump C-Series is substantially equivalent to the existing I-Flow Homepump C-Series (K944692) and the 3M IV Flow Regulator (K896907).

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTIONS

2.1 Description of Device

2.1.1 The Homepump C-Series is an elastomeric infusion pump with an integrated administration set.

2.1.2 The elastomeric membranes function as the fluid reservoir and the pressure source.

2.1.3 The pressure that pumps the fluid comes from the strain energy of the elastomeric membranes which are forced to expand when the pump is filled.

2.1.4 The incorporation of fixed diameter flow control tubing or glass orifice combined with the elastomeric pressure source produces the desired flow rate.

2.2 Product Configuration

2.2.1 Homepump C-Series models are available in fill volumes from 50 to 500 ml and flow rates from 0.5 to 10 ml/hr. The One-Step KVO models of the Homepump C-Series have an optional Y-site and optional check valve attached to the distal end of the administration set.

2.2.2 The following accessories are available: carry case, E-clip and power ring.

2.3 Components and Materials

All fluid path materials are in compliance with ISO 10993 Part 1.

2.4 Power Requirements

2.4.1 The Homepump C-Series is a mechanical device that utilizes elastomeric membranes for power. No additional external power is required.

3.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

3.1 Standard Operating Conditions:

Priming/Residual Volume: <= 10 ml for 500 ml volume pump
<= 9 ml for 270 ml volume pump
<= 4 ml for 125 ml volume pump
<= 3 ml for 65 ml volume pump
Operating Temperature: 31°C skin temperature (88°F)
Test Solution: 0.9% NaCl
Pressure Source: 6.0 psi
Head Height: 0"
Flow Rate Accuracy: ±10% at 95% confidence interval

3.2 **Flow Rate and Pressure Performance Data:** Testing occurred at standard operating conditions. All models produced an average flow rate and pressure within the ±10% accuracy claim.

3.3 Safety/Alarm Functions

- 3.3.1 The Homepump C-Series provides a fixed flow and as such is not subject to fluid runaway conditions similar to that of some electronic pumps.
- 3.3.2 This device contains no alarms for flow; however, each set may include an optional flow indicator component that indicates the flow status of the device.
- 3.3.3 This device contains no alarms or indicators to detect air in line or an occlusion; however, each set may include an optional, integrated air-eliminating filter.

4.0 BIOLOGICAL SPECIFICATIONS

4.1 Biological testing is in conformance with ISO 10993 Part 1 for all fluid path components.

5.0 CHEMICAL AND DRUG SPECIFICATIONS

5.1 Compatibility

5.1.1 There are no specific drugs referenced in the labeling for the Homepump C-Series.

6.0 INTENDED USE

- 6.1 The Homepump C-Series is intended for continuous infusion of medications for general infusion use, including chemotherapy and pain management. Routes of administration include intravenous, subcutaneous, intramuscular and epidural.
- 6.2 The KVO model of the Homepump C-Series is intended for general purpose drug and/or diluent delivery at a sufficient flow rate to maintain a patient IV line open (i.e. keep vein open). The Y adapter at the distal end of the administration set allows piggyback infusions. The routes of administration include intravenous, subcutaneous and intramuscular.

- 6.3 The Homepump C-Series is single patient use only.
- 6.4 The Homepump C-Series is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.
- 6.5 No testing has been conducted to determine the efficacy of Homepump C-Series for the delivery of blood, blood products, lipids or fat emulsions. The Homepump C-Series is not intended for the delivery of blood, blood products, lipids or fat emulsions.

7.0 STANDARDS

- 7.1 There are currently no performance standards established for elastomeric infusion pumps.

8.0 PACKAGING

- 8.1 Packaging is suitable for radiation or ETO sterilization.

9.0 STERILIZATION

- 9.1 The methods of sterilization are gamma radiation (cobalt 60) or ETO gas.

10.0 COMPARISON TO LEGALLY MARKETED DEVICES

- 10.1 The Homepump C-Series has the same intended use and routes of administration as the originally submitted Homepump C-Series. The optional regulator of the Homepump C-Series is similar to the 3M IV Flow Regulator.



JUN 21 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert J. Bard, Esq., R.A.C.
Vice President of Regulatory
and Legal Affairs
I-Flow® Corporation
20202 Windrow Drive
Lake Forest, California 92630

Re: K991513
Trade Name: Homepump C-Series and Homepump C-Series One-
Step KVO
Regulatory Class: II
Product Code: FPA
Dated: April 29, 1999
Received: April 30, 1999

Dear Mr. Bard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

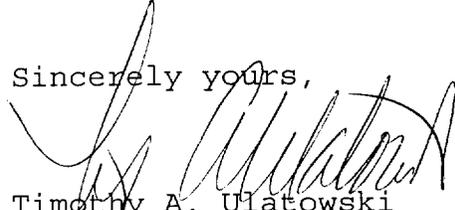
Page 2 - Mr. Bard

Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



20202 Windrow Drive
 Lake Forest, CA 92630
 (800) 448-3569 (949) 206-2700
 Fax (949) 206-2600

K991513

510(k) Number (if known): _____

Device Name: Homepump C-Series

Indications for Use:

1. The Homepump C-Series is intended for continuous infusion of medications for general infusion use, including chemotherapy and pain management. Routes of administration include intravenous, subcutaneous, intramuscular and epidural.
2. The KVO model of the Homepump C-Series is intended for general purpose drug and/or diluent delivery at a sufficient flow rate to maintain a patient IV line open (i.e. keep vein open). The Y-site at the distal end of the administration set allows piggy back infusions. The routes of administration include intravenous, subcutaneous and intramuscular.

Retucia Cicciolo

 (Division Sign-Off)
 Division of Dental, Infection Control,
 and General Hospital Devices
 510(k) Number K991513

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUED ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



JUN 21 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert J. Bard, Esq., R.A.C.
Vice President of Regulatory
and Legal Affairs
I-Flow® Corporation
20202 Windrow Drive
Lake Forest, California 92630

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Regulatory Class: II
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Page 2 - Mr. Bard

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Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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I-FLOW CORPORATION

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(800) 448-3569 (949) 206-2700
Fax (949) 206-2600

K991513

510(k) Number (if known): _____

Device Name: Homepump C-Series

Indications for Use:

1. The Homepump C-Series is intended for continuous infusion of medications for general infusion use, including chemotherapy and pain management. Routes of administration include intravenous, subcutaneous, intramuscular and epidural.
2. The KVO model of the Homepump C-Series is intended for general purpose drug and/or diluent delivery at a sufficient flow rate to maintain a patient IV line open (i.e. keep vein open). The Y-site at the distal end of the administration set allows piggy back infusions. The routes of administration include intravenous, subcutaneous and intramuscular.

Patricia Cuccinelli

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K991513

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUED ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Date: 6/17/99
From: Reviewer(s) - Name(s) Irene Naveau Mem

Subject: 510(k) Number K991513

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review 5/10/99.
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? YES NO

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class:

Additional Product Code(s) with panel (optional):

80/FPA/II/880.5440

Review: Pulcinella Cuencas
(Branch Chief)

6/17/99
(Branch Code)

6/18/99
(Date)

Final Review: _____
(Division Director)

[Signature]
(Date)

6/18/99
(Date)

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SE MEMO TO THE RECORD

510 (k) REVIEW

K991513

DATE: June 17, 1999
FROM: Irene Naveau

OFFICE: HFZ-480
DIVISION: DDIG/GHDB

COMPANY NAME: I-Flow Corporation
DEVICE NAME: Homepump C-Series; and Homepump C-Series One-Step KVO

NARRATIVE DEVICE DESCRIPTION

1. SUMMARY DESCRIPTION OF THE DEVICE UNDER REVIEW:

I-Flow Corporation intends to add two new components to the Homepump C-Series: an optional regulator that controls the decreasing pressure (14 to 9 psi) of the current Homepump C-Series to a fixed 6.0 psi. The new regulator creates a flow profile that (b)(4), (b)(5) than the original pumps, and results in a more (b)(4), (b)(5). The optional flow indicator replaces the distal glass orifice found in the predicate elastomeric pumps manufactured by I-Flow Corp, and provides the user with an accurate flow status of the pump. The Homepump C-Series is an elastomeric infusion pump with an integrated administration set. The Homepump C-Series pumps consist of a (b)(4), (b)(5) that (b)(4), (b)(5)

The pumps are contraindicated for delivery of blood, blood products or TPN.

The Homepump C-Series models include:

C060020: 50/65ml fill vol.-2ml/hr flow rate
C065005: 50/65ml fill vol.-0.5ml/hr flow rate
C100005: 100/125ml fill vol.-0.5ml/hr flow rate
C100010: 100/125ml fill vol.-1ml/hr flow rate
C100020: 100/125ml fill vol.-2ml/hr flow rate
C100050: 100/125ml fill vol.-5ml/hr flow rate
C100100: 100/125ml fill vol.-10ml/hr flow rate
C270005: 250/270ml fill vol.-0.5ml/hr flow rate
C270010: 250/270ml fill vol.-1ml/hr flow rate
C270020: 250/270ml fill vol.-2ml/hr flow rate
C270050: 250/270ml fill vol.-5ml/hr flow rate
C270100: 250/270ml fill vol.-10ml/hr flow rate
C500100: 500ml fill fol.-10ml/hr flow rate
C270020Y: 250/270 ml vol.-2mlhr flow rate, dual orifice with Y adapter
C000020Y: 2.0mlhr flow rate, dual orifice with Y adapter accessory

The Homepump C-Series One-Step KVO include:

EY060005: 50/65ml fill vol.-0.5ml/hr flow rate, with Y-site
EY110005: 100/125ml fill vol.-0.5ml/hr flow rate, with Y-site
EV060005: 50/65ml fill vol.-0.5ml/hr flow rate, with Y-site and

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check valve

EV110005: 100/125ml fill volume.-0.5ml/hr flow rate, with Y-site and check valve.

2. INTENDED USE: The Homepump C-Series: For continuous infusion of medications for general infusion use, including chemotherapy and pain management. Routes of administration include intravenous, subcutaneous, intramuscular and epidural.

The Homepump C-Series One-Step KVO: For general purpose drug and/or diluent delivery at a sufficient flow rate to maintain a patient IV line open. The routes of administration include intravenous, subcutaneous and intramuscular.

3. DEVICE DESCRIPTION:

- A. Life-supporting or life-sustaining: No
 B. Implant (short-term or long-term): No
 C. Is the device sterile? Yes

Method	Eto
Validation	ANSI/AAMI/ISO 11135-1994/EN550
SAL	10 ⁻⁶
Residues	(b)(4), (b)(5)
Pyrogenicity	LAL or USP Rabbit test

OR

Method	Gamma radiation (cobalt60)
Validation	ANSI/AAMI ST32-1991/EN 552 Method 1
SAL	10 ⁻⁶
Dosage	25-35 kGy (2.5-3.5 Mrad)
Pyrogenicity	LAL or USP Rabbit test

Packaging: Sealed Tyvek pouch

- D. Is the device for single use? Yes
 E. Is the device for prescription use? Yes. See labeling.
 F. Is the device for home use or portable? The Homepump C-Series is intended for use in the hospital, in the home environment or alternative care sites.
 G. Does the device contain drug or biological product as a component? No
 H. Is this device a kit? No
 I. Applicable standards to which conformance has been demonstrated (e.g., IEC, ANSI, ASTM, etc.): N/A
 J. Device(s) to which equivalence is claimed, manufacturer, and 510(k) number or preamendment status: Homepump C-Series, I-Flow Corp., K944692; IV Flow Regulator, 3M Corp., K896907.
 K. Submission provides comparative specifications a Yes performance data b Yes biocompatibility testing c YES
 K. Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Provide a summary about the devices design, materials, physical properties and toxicology profile if

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important.

The Homepump C-Series is identical to the original Homepump C-Series with two exceptions: optional regulator and optional flow indicator components. The optional regulator controls the decreasing pressure to a constant 6psi. The Homepump C-Series and the original Homepump C-Series use either a glass orifice or PVC tubing to control the flow rate, however, the optional flow indicator component establishes a flow status column in addition to the glass orifice flow restrictor.

The fluid path materials found in the Homepump C-Series are identical in formulation to other materials used in devices manufactured by I-Flow Corp. I-Flow Corporation certifies that all fluid path materials conform to ISO-10993 standards and are identical to similar, comparable legally marketed devices. (The 3M IV Flow Regulator membrane functions similarly to the Homepump C-Series diaphragm, but the membrane is (b)(4), (b)(5) (b)(4), (b)(5) as are the Homepump C-Series of this 510(k). The Homepump C-Series and the Homepump C-Series One-Step KVO conformed to ISO 10993 standards and have passed the following biocompatibility tests: cytotoxicity, sensitization, irritation, systemic toxicity, hemolysis, subchronic toxicity, pyrogenicity, and implantation.

The labeling is adequate for this device. I-Flow Corp. will add a statement to "Recap the valve with new sterile cap after each use" where there is no surface to swab.

Performance data consists of incremental flow rate profiles for fluids infused at 100mlx1ml/hr, 100mlx2ml/hr, 100mlx5ml/hr, 100mlx10ml/hr, 270mlx2ml/hr, 100mlx5ml/hr, 270mlx10ml/hr, and incremental pressure profiles for fluids infused at 100mlx1ml/hr, 100mlx2ml/hr, 100mlx5ml/hr, 100ml/10ml/hr, 270mlx2ml/hr, 270mlx5ml/hr, and 270mlx10ml/hr. Data shows the all during the flow time, the pressure holds stable at the 6.0 psi fixed rate.

I conferred with Hung Trinh, biomedical engineer, regarding the change from a pressure range of 8 to 18 psi created by the elastomer membrane to a constant pressure of 6.0 psi prior to clearing this device. We believed that the constant pressure would have no effect upon these elastomeric devices.

I corresponded with Mr. Bard of I-Flow Corporation to request information related to the possible effect the new regulator would have on the device by controlling the pressure flow from a decreasing pressure to a fixed rate. I questioned which models were included in this 510k and a demonstration of material conformance to ISO 10993 and/or a certification statement. I also suggested that the labeling should include using a sterile cap after each use of a needleless connector, when appropriate.

Based on the information provided in this premarket notification, I believe that these devices are substantially equivalent to the predicate devices listed in Section J. No new issues of safety and effectiveness exist for this device.

- M. Does the submission include a summary of safety and effectiveness information upon which an equivalence determination is based? Yes

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RECOMMENDATIONS:

I believe that this device is equivalent to: 80 MEB

Classification should be based on: External Elastomeric Infusion Pump

880.5725

Class: Unclassified

Irene Naveau 6/17/99
Irene Naveau

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"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K991513

Reviewer: Irene Naveau

Division/Branch: DDIGD/GHDB

Device Name: Homepump C-Series and Homepump C-Series One-Step KVO

Product To Which Compared (510(K) Number If Known): Homepump C-Series, I-Flow Corp., K944692; IV Flow Regulator, 3M Corp., K896907

	YES	NO	
1. Is Product A Device	X		If NO = Stop
2. Is Device Subject To 510(k)?	X		If NO = Stop
3. Same Indication Statement?	X		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?		X	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?		X	If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	x		If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision: SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use: The Homepump C-Series: for continuous infusion of medications for general infusion use, including chemotherapy and pain management. Routes of administration include intravenous, subcutaneous, intramuscular and epidural.

The Homepump C-Series One-Step KVO: for general purpose drug and/or diluent delivery at a sufficient flow rate to maintain a patient IV line open. The routes of administration include intravenous, subcutaneous and intramuscular.

2. Device Description: Refer to SE Memo dated June 17, 1999.

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5. Describe the new technological characteristics: A new (optional) regulator and a new (optional) flow indicator have been added to the device.
6. Explain how new characteristics could or could not affect safety or effectiveness: The new regulator creates a flow profile that is flatter than the original regulator on current pumps, and controls the pressure at a fixed rate of 6.0psi; result is a more controlled flow profile. The new flow indicator also replaces the distal glass orifice in predicate devices. It provides the patient and the caregiver with an accurate flow status of the pump.

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I-FLOW
CORPORATION

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Fax (949) 206-2600

June 15, 1999
VIA FACSIMILE

Ms. Irene Naveau
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd
Rockville, MD 20850

Re: K991513 HomePump C-Series and HomePump C-Series One-Step KVO

Dear Ms. Naveau,

This letter is being provided in response to your request for additional information for premarket notification K991513 (HomePump C-Series and HomePump C-Series One-Step KVO).

1. Biocompatibility

All fluid path materials of the devices are identical in formulation to materials currently being used in other I-Flow products and have a long history of use in devices used for the infusion of fluids.

I-Flow Corporation certifies that to the best of its knowledge all fluid path materials are exactly the same as in legally marketed devices and the conditions of use are comparable.

The devices are categorized as "Prolonged" (24 hrs to 30 days) based on ISO-10993-1 and FDA G95-1 Guidelines.

The HomePump C-Series and HomePump C-Series One-Step KVO are in conformance with ISO 10993-1 and FDA G95-1. The devices have been tested to and passed the following tests.

- a) **Cytotoxicity:** In-vitro cytotoxicity testing (MEM elution method using L-929 mouse fibroblast cells)
- b) **Sensitization:** Guinea Pig Maximization Tests Delayed Contact Sensitization Test (maximum method for biomaterial extracts).
- c) **Irritation:** USP/ISO Intracutaneous Test
- d) **Systemic Toxicity:** Acute systemic injection test
- e) **Hemolysis:** In vitro rabbit blood determination

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- f) **Subchronic Toxicity:** Subacute toxicity test
- g) **Implanation:** Rabbit implantation test
- h) **Pyrogenicity:** Material mediated pyrogenicity (rabbit test)

2. **Identified Devices**

All devices identified in premarket notification K991513 were released to commercial distribution by way of the listed 510(k)'s or are included in "Letters to the File" prepared by I-Flow.

3. **Mechanism of operation**

The addition of the flow regulator to the existing elastomeric devices creates a flow profile that is flatter than the original HomePump infusion pump. The regulator reduces the pressure range (8 to 18 psi) created by the elastomeric membranes to a constant pressure of 6 psi. The reduction in pressure seen by the flow control orifice results in a flatter more controlled flow profile.

The addition of the flow indicator has no effect on the operation of the elastomeric devices. The flow indicator is a direct replacement of the distal glass orifice that is currently found in the predicate elastomeric pumps produced by I-Flow. The addition of the flow indicator provides the patient and the healthcare professional with additional information about the flow status of the pump.

4. **KVO Y-site replacement cap**

A question was raised as to the need to add more information concerning a replacement cap for the Y-site.

A review of the labeling for the KVO and the devices that may be connected to the Y-site suggest that no additional statement is necessary.

On the third page of the KVO Directions for Use under the heading of "Medication Administration through the Y-Site of the One-Step KVO", Paragraph 3 states "When the medication infusion is complete, close the clamp on the intermittent medication line and disconnect from the Y-Site following your institutions protocol." This language was specifically included in the directions for use because of the various types of devices that might be connected to the Y-site.

I-Flow anticipated that the Y-site would be connected to various needleless connectors. In the majority of the cases, the disconnection of a needleless connector does not require a cap. The user is generally instructed to swab or clean the surface of the connector. In the case where there is no surface to swab or clean, the user is instructed to "Recap the valve with new sterile cap after each use" (taken from Directions for Use provided with the B. Braun device).

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Similarly, where a needle injection site is used, no cap is necessary and the users would normally follow standard practices for this type of device after the needle is removed.

We believe that based on the information provided in the Directions for Use included with the KVO device and the number of different types of devices that can be attached to the Y-Site, the user institution's clinical protocols are the most appropriate place to have information concerning the necessity for a sterile replacement cap.

Hopefully this information provided above is sufficient to complete the review of premarket notification K991513. If you should require additional information for the questions asked or other areas of the submission, please feel free to contact me at 800.448.3569 ext 2670.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert J. Bard".

Robert J. Bard, Esq., R.A.C.

Vice President, Regulatory and Legal Affairs

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USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*									
c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*									
d) Design Control Activities Summary									
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis									
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied									
iii) A declaration of conformity with design controls. The declaration of conformity should include:									
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met									
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.									

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted							

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below
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device
v) A specification of any deviations from each applicable standard that were applied
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:							
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:							
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with check in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening Yes No
 Date: 5/5/09

Reviewer: MS
 Concurrence by Review Branch: _____

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Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?		
6. Is the device exempt from 510(k) by regulation or policy?		
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.		

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Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

April 30, 1999

I-FLOW CORP.
20202 WINDROW DR.
LAKE FOREST, CA 92630
ATTN: ROBERT J. BARD

510(k) Number: K991513
Received: 30-APR-1999
Product: HOMEPUMP C-SERIES
AND HOMEPUMP
C-SERIES ONE-STEP
KVO

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff

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I-FLOW CORPORATION

20202 Windrow Drive
Lake Forest, CA 92630
(800) 448-3569 (949) 206-2700
Fax (949) 206-2600

K991513

Premarket Notification – 510(k)

Via Federal Express
April 29, 1999

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center HFZ – 401
9200 Corporate Blvd.
Rockville, Maryland 20850

Reviewing Staff:

In accordance with §510(k) of the Federal Food, Drug, and Cosmetic Act and in conformance with Title 21 CFR §807.81, I-Flow Corporation is submitting this premarket notification for the *Homepump C-Series* prior to the introduction into interstate commerce for commercial distribution.

I-Flow intends to make two component changes to the *Homepump C-Series* (K944692). The modified *Homepump C-Series* is substantially equivalent to the existing I-Flow Homepump C-Series (K944692) and the 3M IV Flow Regulator (K896907).

All questions and/or comments concerning this document should be made to:
Robert J. Bard, Esq., R.A.C.
Vice President Regulatory and Legal Affairs

I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630
Telephone: 949.206.2700
Fax: 949.206.2600

Sincerely,

Robert J. Bard, Esq., R.A.C.
Vice President Regulatory and Legal Affairs

FDA/CDRH/ODE/DMC
MAY 03 11 05 AM '99

SK
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HO
Page i

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission: 4/29/99

FDA Document Number:

Section A: Type of Submission

- | | | | |
|---|---|--|---|
| <input checked="" type="checkbox"/> 510(k) | <input type="checkbox"/> IDE | <input type="checkbox"/> PMA | <input type="checkbox"/> PMA Supplement - Regular |
| <input type="checkbox"/> 510(k) Add'l information | <input type="checkbox"/> IDE Amendment | <input type="checkbox"/> PMA Amendment | <input type="checkbox"/> PMA Supplement - Special |
| | <input type="checkbox"/> IDE Supplement | <input type="checkbox"/> PMA Report | <input type="checkbox"/> PMA Supplement - 30 day |
| | <input type="checkbox"/> IDE Report | | <input type="checkbox"/> PMA Supplement - Panel Track |

Section B1: Reason for Submission — 510(k)s Only

- | | | |
|--|---|---|
| <input type="checkbox"/> New device | <input type="checkbox"/> Additional or expanded indications | <input checked="" type="checkbox"/> Change in technology, design, materials, or manufacturing process |
| <input type="checkbox"/> Other reason (specify): | | |

Section B2: Reason for Submission — PMAs Only

- | | | |
|---|---|--|
| <input type="checkbox"/> New device | <input type="checkbox"/> Change in design, component, or specification: | <input type="checkbox"/> Location change: |
| <input type="checkbox"/> Withdrawal | <input type="checkbox"/> Software | <input type="checkbox"/> Manufacturer |
| <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Color Additive | <input type="checkbox"/> Sterilizer |
| <input type="checkbox"/> Licensing agreement | <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Packager |
| <input type="checkbox"/> Labeling change: | <input type="checkbox"/> Process change: | <input type="checkbox"/> Report submission: |
| <input type="checkbox"/> Indications | <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Annual or periodic |
| <input type="checkbox"/> Instructions | <input type="checkbox"/> Sterilizer | <input type="checkbox"/> Post-approval study |
| <input type="checkbox"/> Performance Characteristics | <input type="checkbox"/> Packager | <input type="checkbox"/> Adverse reaction |
| <input type="checkbox"/> Shelf life | | <input type="checkbox"/> Device defect |
| <input type="checkbox"/> Trade name | <input type="checkbox"/> Response to FDA correspondence (specify below) | <input type="checkbox"/> Amendment |
| <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Request for applicant hold | |
| <input type="checkbox"/> Change in ownership | <input type="checkbox"/> Request for removal of applicant hold | |
| <input type="checkbox"/> Change in correspondent | <input type="checkbox"/> Request for extension | |
| <input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Request to remove or add manufacturing site | |

Section B3: Reason for Submission — IDEs Only

- | | | |
|---|--|--|
| <input type="checkbox"/> New device | <input type="checkbox"/> Change in: | <input type="checkbox"/> Response to FDA letter concerning: |
| <input type="checkbox"/> Addition of institution | <input type="checkbox"/> Correspondent | <input type="checkbox"/> Conditional approval |
| <input type="checkbox"/> Expansion / extension of study | <input type="checkbox"/> Design | <input type="checkbox"/> Deemed approved |
| <input type="checkbox"/> IRB certification | <input type="checkbox"/> Informed consent | <input type="checkbox"/> Deficient final report |
| <input type="checkbox"/> Request hearing | <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Deficient progress report |
| <input type="checkbox"/> Request waiver | <input type="checkbox"/> Manufacturing | <input type="checkbox"/> Deficient investigator report |
| <input type="checkbox"/> Termination of study | <input type="checkbox"/> Protocol - feasibility | <input type="checkbox"/> Disapproval |
| <input type="checkbox"/> Withdrawal of application | <input type="checkbox"/> Protocol - other | <input type="checkbox"/> Request extension of time to respond to FDA |
| <input type="checkbox"/> Unanticipated adverse effect | <input type="checkbox"/> Sponsor | <input type="checkbox"/> Request meeting |
| <input type="checkbox"/> Emergency use: | <input type="checkbox"/> Report submission: | <input type="checkbox"/> IOL submissions only: |
| <input type="checkbox"/> Notification of emergency use | <input type="checkbox"/> Current investigator | <input type="checkbox"/> Change in IOL style |
| <input type="checkbox"/> Additional information | <input type="checkbox"/> Annual progress | <input type="checkbox"/> Request for protocol waiver |
| <input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Site waiver limit reached | |
| | <input type="checkbox"/> Final | |

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FDA Document Number:

Section C Product Classification

Product code: 80 MEB

C.F.R. Section: 880.5725

Device class:

- Class I Class II
 Class III Unclassified

Classification panel: General Hospital and Personal Use Device

Section D Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 80 MEB	2 80 FPA	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness data:

- 510(k) summary attached
 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K944692	1 Homepump C-Series	1 I-Flow Corporation
2 K896907	2 IV Flow Regulator	2 3M
3	3	3
4	4	4
5	5	5
6	8	8

Section E Product Information — Applicable to All Applications

Common or usual name or classification name:

Pump, Infusion, Elastomeric

Trade or proprietary or model name	Model number
1 Homepump C-Series and Homepump C-Series One-Step KVO	1
2	2
3	3
4	4
5	5
6	6

FDA document numbers of all prior related submissions (regardless of outcome):

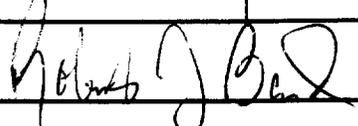
1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: Laboratory testing Animal trials Human trials

Indications (from labeling): 1. The Homepump C-Series is intended for continuous infusion of medications for general infusion use, including chemotherapy and pain management. Routes of administration include intravenous, subcutaneous, intra-muscular and epidural.
 2. The One-Step KVO model of the Homepump C-Series is intended for general purpose drug and/or diluent delivery at a sufficient flow rate to maintain a patient IV line open (i.e. keep vein open).

		FDA Document Number:	
Section F Manufacturing / Packaging / Sterilization Sites			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number: 2026095	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler
Company / Institution name: I-Flow Corporation			
Division name (if applicable):		Phone number (include area code): (949) 206-2700 ext. 2670	
Street address: 20202 Windrow Drive		FAX number (include area code): (949) 206-2603	
City: Lake Forest	State / Province: CA	Country: U.S.A.	ZIP / Postal Code: 92630
Contact name: Robert J. Bard, Esq., R.A.C.			
Contact title: Vice President of Regulatory and Legal Affairs			
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number:	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler
Company / Institution name:			
Division name (if applicable):		Phone number (include area code): ()	
Street address:		FAX number (include area code): ()	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number:	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler
Company / Institution name:			
Division name (if applicable):		Phone number (include area code): ()	
Street address:		FAX number (include area code): ()	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			

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				FDA Document Number:	
Section G Applicant or Sponsor					
Company / Institution name: I-Flow Corporation				FDA establishment registration number: 2026095	
Division name (if applicable):				Phone number (include area code): (949) 206-2700 ext. 2670	
Street address: 20202 Windrow Drive				FAX number (include area code): (949) 206-2603	
City: Lake Forest	State / Province: CA	Country: U.S.A.	ZIP / Postal Code: 92630		
Signature: 					
Name: Robert J. Bard, Esq., R.A.C.					
Title: Vice President of Regulatory and Legal Affairs					
Section H Submission correspondent (if different from above)					
Company / Institution name:					
Division name (if applicable):				Phone number (include area code): ()	
Street address:				FAX number (include area code): ()	
City:	State / Province:	Country:	ZIP / Postal Code:		
Contact name:					
Contact title:					

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply only to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

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I-FLOW
CORPORATION

20202 Windrow Drive
Lake Forest, CA 92630
(800) 448-3569 (949) 206-2700
Fax (949) 206-2600

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As required by 21 CFR 807.87(j))**

I certify that, in my capacity as the Vice President of Regulatory and Legal Affairs of I-Flow Corporation, I believe to the best of my knowledge, that all data and information submitted in the premarket notification for the Homepump C-Series are truthful and accurate and that no material fact has been omitted.


Signature

Robert J Bard, Vice President of Regulatory and Legal Affairs

Name	Title
<u>I-Flow Corporation</u>	<u>4/29/99</u>
Company	Dated

Premarket Notification (510(k) Number)

25



I-FLOW CORPORATION

20202 Windrow Drive
Lake Forest, CA 92630
(800) 448-3569 (949) 206-2700
Fax (949) 206-2600

510(k) Number (if known): _____

Device Name: Homepump C-Series

Indications for Use:

1. The Homepump C-Series is intended for continuous infusion of medications for general infusion use, including chemotherapy and pain management. Routes of administration include intravenous, subcutaneous, intramuscular and epidural.
2. The KVO model of the Homepump C-Series is intended for general purpose drug and/or diluent delivery at a sufficient flow rate to maintain a patient IV line open (i.e. keep vein open). The Y-site at the distal end of the administration set allows piggy back infusions. The routes of administration include intravenous, subcutaneous and intramuscular.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUED ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

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(Optional Format 1-2-96)

TABLE OF CONTENTS

1.0	GENERAL INFORMATION	Page 1
2.0	PHYSICAL SPECIFICATIONS AND DESCRIPTION	Page 1
3.0	OPERATIONS SPECIFICATIONS AND DESCRIPTION	Page 7
4.0	BIOLOGICAL SPECIFICATIONS	Page 9
5.0	CHEMICAL AND DRUG SPECIFICATIONS	Page 9
6.0	INTENDED USE	Page 9
7.0	LABELS AND LABELING	Page 10
8.0	STANDARDS	Page 10
9.0	PACKAGING	Page 10
10.0	STERILIZATION INFORMATION	Page 11
11.0	COMPARISON TO LEGALLY MARKETED DEVICES	Page 11

Appendix A – Homepump C-Series Drawings

Appendix B – Homepump C-Series Labeling

Appendix C - Homepump C-Series Performance Data

Flow Rate Profile	Pressure Profile
• Chart #1a – 100 ml Volume, 1 ml/hr flow rate	• Chart #1b – 100 ml Volume, 1 ml/hr flow rate
• Chart #2a – 100 ml Volume, 2 ml/hr flow rate	• Chart #2b – 100 ml Volume, 2 ml/hr flow rate
• Chart #3a – 100 ml Volume, 5 ml/hr flow rate	• Chart #3b – 100 ml Volume, 5 ml/hr flow rate
• Chart #4a – 100 ml Volume, 10 ml/hr flow rate	• Chart #4b – 100 ml Volume, 10 ml/hr flow rate
• Chart #5a – 270 ml Volume, 2 ml/hr flow rate	• Chart #5b – 270 ml Volume, 2 ml/hr flow rate
• Chart #6a – 270 ml Volume, 5 ml/hr flow rate	• Chart #6b – 270 ml Volume, 5 ml/hr flow rate
• Chart #7a – 270 ml Volume, 10 ml/hr flow rate	• Chart #7b – 270 ml Volume, 10 ml/hr flow rate

Appendix D – Predicate Labeling

- I-Flow Homepump C-Series
- 3M IV Flow Regulator

Appendix E – Summary of Safety and Effectiveness

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1.0 GENERAL INFORMATION

1.1 Purpose of Submission

- 1.1.1 Trade Name: Homepump C-Series and Homepump C-Series One-Step KVO.
- 1.1.2 Common Name: Elastomeric Infusion Pump
- 1.1.3 Classification Name: Pump, Infusion, Elastomeric
- 1.1.4 Product Code: 80 MEB
- 1.1.5 Device Classification: Class II, 880.5725
- 1.1.6 Classification Panel: General Hospital and Personal Use Device
- 1.1.7 This submission is intended to notify the Federal Food and Drug Administration that I-Flow Corporation is adding two new optional components to the Homepump C-Series (K944692).

1.1.7.1 Regulator (optional)

- 1.1.7.1.1 The optional regulator controls the decreasing pressure (14 to 9 psi) of the Homepump C-Series to a fixed 6.0 psi.

1.1.7.2 Flow Indicator (optional)

- 1.1.7.2.1 An optional flow indicator component incorporates a flow status column indicator with the glass orifice flow restrictor.

Note: The PainBuster Infusion Kit (K980558 and K982946), the On-Q Infusion Kit (K980558 and K982946) and the Nerve Block Infusion Kit (K984502) use the Homepump C-Series infusion pumps in their kits. Neither the regulator nor the flow indicator components change the intended use of the Homepump C-Series when used in the PainBuster, On-Q or Nerve Block Infusion Kits.

1.2 Statement of Equivalence

- 1.2.1 The Homepump C-Series is substantially equivalent to the existing I-Flow Homepump C-Series (K944692) and the 3M IV Flow Regulator (K896907).

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTIONS

2.1 Description of Device

- 2.1.1 The Homepump C-Series is an elastomeric infusion pump with an integrated administration set.
- 2.1.2 The elastomeric membranes function as the fluid reservoir and the pressure source.
- 2.1.3 The pressure that pumps the fluid comes from the strain energy of the elastomeric membranes which are forced to expand when the pump is filled.
- 2.1.4 The incorporation of fixed diameter flow control tubing or glass orifice combined with the elastomeric pressure source produces the desired flow rate.
 - 2.1.4.1 The delivery time characteristic is derived from the flow rate of the device which is in turn approximated by (b) (4)

(b) (4)

2 of

2.1.4.2

(b) (4)



REGULATOR ASSEMBLY
(UNSEATED CONFIGURATION)

2.2 **Regulator**

2.2.1 The Regulator is an optional component of the Homepump C-Series which regulates the pressure of the elastomeric reservoir.

(b) (4)

2.2.2

2.2.3

2.2.4

2.2.5



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2.3 Flow Indicator

(b) (4)



Fig. 1

Fig. 2

Fig. 3

2.4 Product Configuration

Homepump C-Series Models:

- 2.4.1 C060020: 50/65 ml fill volume, 2 ml/hr flow rate.
- 2.4.2 C065005: 50/65 ml fill volume, 0.5 ml/hr flow rate.
- 2.4.3 C100005: 100/125 ml fill volume, 0.5 ml/hr flow rate.
- 2.4.4 C100010: 100/125 ml fill volume, 1 ml/hr flow rate.
- 2.4.5 C100020: 100/125 ml fill volume, 2 ml/hr flow rate.
- 2.4.6 C100050: 100/125 ml fill volume, 5 ml/hr flow rate.
- 2.4.7 C100100: 100/125 ml fill volume, 10 ml/hr flow rate.
- 2.4.8 C270005: 250/270 ml fill volume, 0.5 ml/hr flow rate.
- 2.4.9 C270010: 250/270 ml fill volume, 1 ml/hr flow rate.
- 2.4.10 C270020: 250/270 ml fill volume, 2 ml/hr flow rate.
- 2.4.11 C270050: 250/270 ml fill volume, 5 ml/hr flow rate.
- 2.4.12 C270100: 250/270 ml fill volume, 10 ml/hr flow rate.
- 2.4.13 C500100: 500 ml fill volume, 10 ml/hr flow rate.
- 2.4.14 C270020Y: 250/270 ml volume, 2.0 ml/hr flow rate, dual orifice with Y adapter.
 - 2.4.14.1 The dual orifice set consists of a standard Homepump C-Series with dual orifice downstream from the Y adapter. Each orifice allows 2 ml/hr flow rate.
- 2.4.15 C000020Y: 2.0 ml/hr flow rate, dual orifice with Y adapter accessory.
 - 2.4.15.1 The Y adapter accessory may be connected to any Homepump C-Series model to split the infusion into two flow rates for multiple sites.
- 2.4.16 Each model above may have an optional Y-site and optional check valve attached to the distal end of the administration set. These models of the Homepump C-Series are marketed as the One•Step KVO devices. The models include the following:
 - 2.4.16.1 EY060005: 50/65 ml fill vol., 0.5 ml/hr flow rate, with Y-site.
 - 2.4.16.2 EY110005: 100/125 ml fill vol., 0.5 ml/hr flow rate, with Y-site.
 - 2.4.16.3 EV060005: 50/65 ml fill volume, 0.5 ml/hr flow rate, with Y-site and check valve.
 - 2.4.16.4 EV110005: 100/125 ml fill volume, 0.5 ml/hr flow rate, with Y-site and check valve.
- 2.4.17 Each model above contains a variable fill volume designated by the slash between the two numbers. For example, model C100005 may be marketed as a 100 ml fill volume pump but may be over filled to a maximum of 125 ml. This information is indicated on the Directions for Use in Appendix B.

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2.4.18 The following accessories are available for use with the Homepump C-Series:

Note: See Appendix A for drawings.

2.4.18.1 Carry Case: The carry case is used to hold the Homepump C-Series pump while delivering medication.

2.4.18.1.1 I-Flow part numbers 1400808 and 1400809.

2.4.18.2 E-clip: The E-clip is manufactured by I-Flow and is used to secure the Homepump C-Series pump to an arm, sling, clothing, etc.

2.4.18.2.1 I-Flow part number 2001318.

2.4.18.3 Power Ring: The Power Ring is fitted over a syringe to ease filling the Homepump C-Series pump.

2.5 Components and Materials

The Homepump C-Series is a disposable device intended for single patient use.

2.5.1 Non-fluid path:

2.5.1.1 Exterior Bag: PVC, (b) (4)

2.5.1.2 Outer Membrane: (b) (4)

Note: The Homepump C-Series pump contains three layers. The Exterior Bag, listed above, prevents the outer membrane from being in skin contact. The Inner Membrane, listed below under fluid path components, prevents the Outer Membrane from contacting the fluid path.

2.5.1.3 Snap Caps: (b) (4)

2.5.1.4 O-Rings (circumferential clamps): (b) (4)

2.5.1.5 Pinch Clamp: (b) (4)

2.5.1.6 Luer Caps: (b) (4)
(b) (4)
(b) (4)

2.5.1.7 Carry Case (accessory): Nylon, (b) (4) with (b) (4) strap.

2.5.1.8 E-Clip (accessory): Stainless Steel with (b) (4) strap, I-Flow (b) (4)

2.5.1.9 Power Ring (accessory): Stainless Steel, (b) (4)
(b) (4)

2.5.2 Fluid path components:

2.5.2.1 Fill Port (female luer lock): (b) (4)

2.5.2.2 Mandrel: (b) (4)

2.5.2.3 Fill Port Check Valve: (b) (4)

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- 2.5.2.4 **Check Band** (b) (4)
(b) (4)
- 2.5.2.5 **Inner Membrane:** (b) (4)
- 2.5.2.6 **Tubing (make-up):** (b) (4)
(b) (4)
- 2.5.2.7 **Tubing (flow control):** (b) (4)
(b) (4)
- 2.5.2.8 **Glass Orifice (optional):** (b) (4)
(b) (4)
- 2.5.2.9 **Flow Indicator (optional):** As an alternative to glass orifice.
 - 2.5.2.9.1 **Housing:** (b) (4)
(b) (4)
 - 2.5.2.9.2 **Sleeve:** (b) (4)
 - 2.5.2.9.3 **Restrictor:** (b) (4)
(b) (4)
- 2.5.2.10 **Filter (optional):** Manufactured by (b) (4) The filter is air eliminating with a nominal pore size of (b) (4) The membrane material is a (b) (4) The air vent material is (b) (4) The filter housing is clear (b) (4)
- 2.5.2.11 **Filter (optional):**
 - 2.5.2.11.1 **Manufactured by** (b) (4) The filter is air eliminating with a nominal pore size of (b) (4) The membrane material is a (b) (4) (b) (4) The air vent material is (b) (4) The filter housing is clear (b) (4)
 - 2.5.2.11.2 **Manufactured by** (b) (4) The filter is air eliminating with a nominal pore size of (b) (4) The membrane material is a (b) (4) (b) (4) The air vent material is (b) (4) supported (b) (4) The filter housing is (b) (4)
- 2.5.2.12 **Luer Adapters:** (b) (4)
(b) (4)
- 2.5.2.13 **Y Adapter (optional) for dual orifice set:** (b) (4)
(b) (4)
- 2.5.2.14 **Y-Site (optional):** The body is made of (b) (4) (b) (4) and the snap-on threads are made of (b) (4) The secondary injection fitting is a female luer. The distal fitting is a male luer adapter with rotating collar.

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2.5.2.15 Check Valve (optional), connects to Y-Site:

2.5.2.15.1 Body: (b) (4)

2.5.2.15.2 Valve: (b) (4)

2.5.2.16 Solvent Bonding: (b) (4)
 (b) (4)

2.6 Power Requirements

2.6.1 The Homepump C-Series is a mechanical device that utilizes elastomeric membranes for power. No additional external power is required.

3.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

3.1 Standard Operating Conditions:

Priming/Residual Volume: <= 10 ml for 500 ml volume pump
 <= 9 ml for 270 ml volume pump
 <= 4 ml for 125 ml volume pump
 <= 3 ml for 65 ml volume pump

Operating Temperature: 31°C skin temperature (88°F)

Test Solution: 0.9% NaCl

Pressure Source: 6.0 psi

Head Height: 0"

Flow Rate Accuracy: ±10% at 95% confidence interval

3.2 **Performance Data:** Testing occurred (b) (4)
 (b) (4)

(b) (4) See Appendix C for graphical representation of the following data.

3.2.1 Flow Rate Accuracy

	100 ml x 1 ml/hr	100 ml x 2 ml/hr	100 ml x 5 ml/hr	100 ml x 10 ml/hr	270 ml x 2 ml/hr	270 ml x 5 ml/hr	270 ml x 10 ml/hr
Average Flow Rate (ml/hr)	1.04	2.01	5.27	9.82	2.00	5.40	10.52
% Accuracy	104	101	105	98	100	108	105
Std. Dev.	0.06	0.06	0.05	0.30	0.13	0.15	0.27
N	(b) (4)						

100 ml x 1 ml/hr: A (b) (4) piece sample produced an average flow rate of 1.04 ml/hr. The faster infusion had an average flow rate of 1.13 ml/hr and the slowest infusion had an average flow rate of 0.98 ml/hr.

100 ml x 2 ml/hr: A (b) (4) piece sample produced an average flow rate of 2.01 ml/hr. The faster infusion had an average flow rate of 2.07 ml/hr and the slowest infusion had an average flow rate of 1.92 ml/hr.

100 ml x 5 ml/hr: A (b) (4) piece sample produced an average flow rate of 5.27 ml/hr. The faster infusion had an average flow rate of 5.33 ml/hr and the slowest infusion had an average flow rate of 5.20 ml/hr.

100 ml x 10 ml/hr: A (b) (4) piece sample produced an average flow rate of 9.82 ml/hr. The faster infusion had an average flow rate of 10.16 ml/hr and the slowest infusion had an average flow rate of 9.49 ml/hr.

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270 ml x 2 ml/hr: A (b) (4) piece sample produced an average flow rate of 2.00 ml/hr. The faster infusion had an average flow rate of 2.15 ml/hr and the slowest infusion had an average flow rate of 1.81 ml/hr.

270 ml x 5 ml/hr: A (b) (4) piece sample produced an average flow rate of 5.40 ml/hr. The faster infusion had an average flow rate of 5.64 ml/hr and the slowest infusion had an average flow rate of 5.26 ml/hr.

270 ml x 10 ml/hr: A (b) (4) piece sample produced an average flow rate of 10.52 ml/hr. The faster infusion had an average flow rate of 10.96 ml/hr and the slowest infusion had an average flow rate of 10.23 ml/hr.

3.2.2 Pressure Source Accuracy

	100 ml x 1 ml/hr	100 ml x 2 ml/hr	100 ml x 5 ml/hr	100 ml x 10 ml/hr	270 ml x 2 ml/hr	270 ml x 5 ml/hr	270 ml x 10 ml/hr
Average Pressure (psi)	5.79	5.81	6.18	6.14	6.05	6.21	5.67
% Accuracy	96	97	103	102	101	104	94
Std. Dev.	0.07	0.11	0.09	0.16	0.20	0.15	0.08
N	(b) (4)						

100 ml x 1 ml/hr: A (b) (4) piece sample produced an average pressure of 5.79 psi. The highest average pressure was 5.90 psi and the lowest was 5.72 psi.

100 ml x 2 ml/hr: A (b) (4) piece sample produced an average pressure of 5.81 psi. The highest average pressure was 5.92 psi and the lowest was 5.64 psi.

100 ml x 5 ml/hr: A (b) (4) piece sample produced an average pressure of 6.18 psi. The highest average pressure was 6.30 psi and the lowest was 6.07 psi.

100 ml x 10 ml/hr: A (b) (4) piece sample produced an average pressure of 6.14 psi. The highest average pressure was 6.34 psi and the lowest was 5.97 psi.

270 ml x 2 ml/hr: A (b) (4) piece sample produced an average pressure of 6.05 psi. The highest average pressure was 6.40 psi and the lowest was 5.88 psi.

270 ml x 5 ml/hr: A (b) (4) piece sample produced an average pressure of 6.21 psi. The highest average pressure was 6.31 psi and the lowest was 5.94 psi.

270 ml x 10 ml/hr: A (b) (4) piece sample produced an average pressure of 5.67 psi. The highest average pressure was 5.81 psi and the lowest was 5.61 psi.

3.2.3 Back Pressure (Head Height) Comparison: (b) (4)

(b) (4)

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3.3 Safety/Alarm Functions

- 3.3.1 The Homepump C-Series provides a fixed flow and as such is not subject to fluid runaway conditions similar to that of some electronic pumps.
- 3.3.2 The Homepump C-Series will not be recommended for any application that exceeds the minimum internal pressure of the system.
- 3.3.3 If for any reason the patient needs to stop his or her infusions, each administration set is supplied with a pinch clamp to stop the infusion.
- 3.3.4 This device contains no alarms for flow; however, each set may include an optional flow indicator component that indicates the flow status of the device.
- 3.3.5 This device contains no alarms or indicators to detect air in line or an occlusion; however, each set may include an integrated air-eliminating filter.

4.0 BIOLOGICAL SPECIFICATIONS

- 4.1 Biological testing is in conformance with ISO 10993 Part 1 for all fluid path components.
- 4.2 The Homepump C-Series is categorized as follows:
 - 4.2.1 Device Category: External Communicating Device.
 - 4.2.2 Body Contact: Blood Path, Indirect
 - 4.2.3 Contact Duration: Prolonged

5.0 CHEMICAL AND DRUG SPECIFICATIONS

- 5.1 Compatibility
 - 5.1.1 There are no specific drugs referenced in the labeling for the Homepump C-Series.
 - 5.1.2 The Homepump C-Series is intended for general purpose drugs and pain medication.
- 5.2 Drug Stability
 - 5.2.1 There are no specific drugs referenced in the labeling for the Homepump C-Series.

6.0 INTENDED USE

- 6.1 The Homepump C-Series is intended for continuous infusion of medications for general infusion use, including chemotherapy and pain management. Routes of administration include intravenous, subcutaneous, intramuscular and epidural.
- 6.2 The KVO model of the Homepump C-Series is intended for general purpose drug and/or diluent delivery at a sufficient flow rate to maintain a patient IV line open (i.e. keep vein open). The Y adapter at the distal end of the administration set allows piggyback infusions. The routes of administration include intravenous, subcutaneous and intramuscular.
- 6.3 The Homepump C-Series is single patient use only.

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- 6.4 The Homepump C-Series is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.
- 6.5 No testing has been conducted to determine the efficacy of Homepump C-Series for the delivery of blood, blood products, lipids or fat emulsions. The Homepump C-Series is not intended for the delivery of blood, blood products, lipids or fat emulsions.

7.0 LABELS AND LABELING

- 7.1 The proposed labeling changes include adding the optional flow indicator component of the administration set.
- 7.2 I-Flow Corporation believes the proposed labels and labeling, where appropriate, meets the requirements of 21 CFR Part 801 as it relates to a determination of intended use and adequate directions for use.
- 7.3 The Homepump C-Series Directions for Use labeling:
 - 7.3.1 Provides comprehensive directions for preparation and use for the Homepump C-Series.
 - 7.3.2 Describes the routes of administration as it relates to intended use.
 - 7.3.3 Contains warning information.
 - 7.3.4 Contains the prescription statement required under 801.109 (b)(1).
 - 7.3.5 Includes the specifications of the Homepump C-Series. The specifications include the priming volume, residual volume, accuracy and operating conditions.
- 7.4 Identification labels and labeling
 - 7.4.1 I-Flow has developed product identification labeling for the Homepump C-Series. Refer to Appendix B for examples.
- 7.5 Packaging labels
 - 7.5.1 Contains the prescription statement required under 801.109 (b)(1).
- 7.6 Appendix C contains predicate labeling for the Homepump C-Series.

8.0 STANDARDS

- 8.1 There are currently no performance standards established for elastomeric infusion pumps.

9.0 PACKAGING

- 9.1 The Homepump C-Series is packaged in a sealed Tyvek pouch, 24 pouches per case.
- 9.2 Packaging is suitable for radiation or ETO sterilization.
- 9.3 Package aging tests have been conducted on the Tyvek pouch. The results of bacterial dust challenge testing has determined that the Tyvek pouches used to package the disposable Homepump C-Series maintains sterility in excess of three years.

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10.0 STERILIZATION

10.1 The methods of sterilization are gamma radiation (cobalt 60) or ETO gas.

10.2 (b) (4)

10.3

10.4

10.5

11.0 COMPARISON TO LEGALLY MARKETED DEVICES

See Table 1 that follows this section for more specific information.

11.1 Intended Use

11.1.1 There is no change in intended use for the Homepump C-Series. The Homepump C-Series is indicated for:

11.1.1.1 Continuous infusion of medications for general infusion use, including chemotherapy and pain management. Routes of administration include intravenous, subcutaneous, intramuscular and epidural.

11.1.1.2 The KVO model of the Homepump C-Series is intended for general purpose drug and/or diluent delivery at a sufficient flow rate to maintain a patient IV line open (i.e. keep vein open). The Y adapter at the distal end of the administration set allows piggyback infusions. The routes of administration include intravenous, subcutaneous and intramuscular.

11.2 Comparison to the original Homepump C-Series

11.2.1 The Homepump C-Series is identical to the original Homepump C-Series with the exception of the regulator and flow indicator components.

11.2.2 The optional regulator component controls the decreasing pressure of the Homepump C-Series to a constant 6 psi.

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- 11.2.3 The optional flow indicator replaces the standard flow restrictor with a vertical chamber that indicates the flow status of the pump. See the directions for use in Appendix B for a detailed diagram of the flow indicator.
- 11.2.4 Note: The PainBuster Infusion Kit (K980558 and K982946), the On-Q Infusion Kit (K980558 and K982946) and the Nerve Block Infusion Kit (K984502) use the Homepump C-Series infusion pumps in their kits. Neither the regulator nor the flow indicator components change the intended use of the Homepump C-Series when used in the PainBuster, On-Q or Nerve Block Infusion Kits.

11.3 Comparison to the 3M IV Flow Regulator

- 11.3.1 The 3M IV Flow Regulator has a similar pressure regulator component as the Homepump C-Series.
- 11.3.2 Both regulator components control the variable pressure source to a fixed pressure to maintain a constant flow rate.
- 11.3.3 Both regulator components use (b) (4) to regulate the pressures.

11.3.3.1 (b) (4)

11.3.3.2

- 11.3.4 The Homepump C-Series diaphragm is pre-set to withstand pressures 6.0 psi or less. When the inlet pressure source is greater than 6.0 psi, the fluid flowing through the seat applies enough pressure to the exposed diaphragm to move the diaphragm towards the cap.

11.3.4.1 (b) (4)

11.3.4.2

- 11.3.4.3 The cycle repeats maintaining a constant 6.0 psi pressure.

- 11.3.5 The 3M IV Flow Regulator membrane functions similar to the Homepump C-Series diaphragm. The 3M membrane is not pre-set to a specific pressure. Instead, (b) (4)

(b) (4)

(b) (4)

The cycle then repeats as necessary.

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11.4 Specifications

11.4.1 The Homepump C-Series has the same flow rates and fill volumes as the original Homepump C-Series. The only specification change is that the optional regulator component establishes a constant 6 psi pressure source as opposed to a decreasing pressure source.

11.5 Flow Control

11.5.1 The Homepump C-Series and the original Homepump C-Series use either a glass orifice or PVC tubing to control the flow rate. The optional flow indicator component establishes a flow status column in addition to the glass orifice flow restrictor.

11.6 Materials

11.6.1 The Homepump C-Series uses the same fluid path materials as the original Homepump C-Series with the exception of the regulator and flow indicator components, see Table 1. All fluid path materials of the Homepump C-Series are in conformance with ISO 10993 Part 1.

11.7 Based upon the data presented in this section 11.0 and Table 1, I-Flow Corporation has determined that the Homepump C-Series is substantially equivalent to the original Homepump C-Series.

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Table 1
Comparison to Legally Marketed Devices

Comparison Element	Homepump C-Series with Regulator and Flow Indicator Components (subject device)	SE ¹ Homepump C-Series (K923875)	SE ¹ 3M IV Flow Regulator (K896907)
Intended Use	<p>To provide continuous infusion of medications for general infusion use, including chemotherapy and pain management. Routes of administration include intravenous, subcutaneous, intramuscular and epidural.</p> <p>The KVO model of the Homepump C-Series is intended for general purpose drug and/or diluent delivery at a sufficient flow rate to maintain a patient IV line open (i.e. keep vein open). The Y-site at the distal end of the administration set allows piggy back infusions. The routes of administration include intravenous, subcutaneous and intramuscular.</p>	<p>To provide continuous infusion of medications for general infusion use, including chemotherapy and pain management. Routes of administration include intravenous, subcutaneous, intramuscular and epidural.</p> <p>The KVO model of the Homepump C-Series is intended for continuous delivery through intravenous access devices. The Y-site at the distal end of the administration set allows piggy back infusions. Additional routes of administration include subcutaneous and intramuscular.</p>	<p>To provide continuous, fixed flow rate infusion of medications. Routes of administration include intravenous.</p>
Route of Administration	Intravenous, epidural, intramuscular and subcutaneous	Intravenous, epidural, intramuscular and subcutaneous	Intravenous
Contraindications	Not intended for delivery of blood, blood products, lipids or fat emulsions.	Not intended for delivery of blood, blood products, lipids or fat emulsions.	
Reuse Capability	Disposable, Single Patient Only	Disposable, Single Patient Only	Disposable, Single Patient Only
Description			
Flow Rates	0.5 to 10 ml/hr	0.5 to 10 ml/hr	variable
Pump Type	Elastomeric infusion pump	Elastomeric infusion pump	N/A
Pump Volume	50 to 500 ml	50 to 500 ml	variable IV bag volume
Power Requirements	None	None	None
Pressure Source	Strain energy of elastomeric membranes	Strain energy of elastomeric membranes	gravity
Fluid Reservoir	(b) (4)	(b) (4)	various IV bags
Administration Set	Integrated, flow control tubing	Integrated, flow control tubing	Accessory, flow control tubing
Flow Control	Consistent flow rate throughout the entire course of therapy is achieved by the combination of constant pressure and flow control tubing.	Consistent flow rate throughout the entire course of therapy is achieved by the combination of constant pressure and flow control tubing.	Consistent flow rate throughout the entire course of therapy is achieved by the combination of constant pressure and flow control orifice.
Safety / Alarm Functions	Fixed flow rate tubing prevents fluid runaway conditions. Each administration set is supplied with a clamp to stop the infusion if necessary.	Fixed flow rate tubing prevents fluid runaway conditions. Each administration set is supplied with a clamp to stop the infusion if necessary.	Fixed flow rate orifice prevents fluid runaway conditions. Each administration set is supplied with a clamp to stop the infusion if necessary.

¹SE = Substantially Equivalent

al

Table 1 (cont.)
Comparison to Legally Marketed Devices

Comparison Element	Homepump C-Series with Regulator and Flow Indicator Components (subject device)	SE ¹ Homepump C-Series (K923875)	SE ¹ 3M IV Flow Regulator (K696907)
Non-fluid Path Components			
Fill Port Cap	(b) (4)		
Exterior Bag			
Membrane (outer)			
Snap Cap			
O-Ring			
Distal Luer Cap			
Pinch Clamp			
Power Ring (optional)			
E-clip (optional)			
Carry Case (optional)			
Fluid Path Components			
Distal Luer Adapter	(b) (4)		
Fill Port Luer Adapter			
Membrane (inner)			
Mandrel			
Tubing (make-up)			
Tubing (flow control)			
Glass Orifice (optional)			
Orifice Sleeve			
Flow Indicator (optional)			
Housing			
Sleeve			
Fill Port Check Valve			
Check Band (optional)			
alternative to Fill Port Check Valve			
Filter (optional) 1.2µM			
Filter Housing			
Filter Membrane			
Filter Air Vent			
Filter (optional) 0.22µM			
Filter Housing			
Filter Membrane			
Filter Air Vent			

¹SE = Substantially Equivalent

JD

Table 1 (cont.)
 Comparison to Legally Marketed Devices

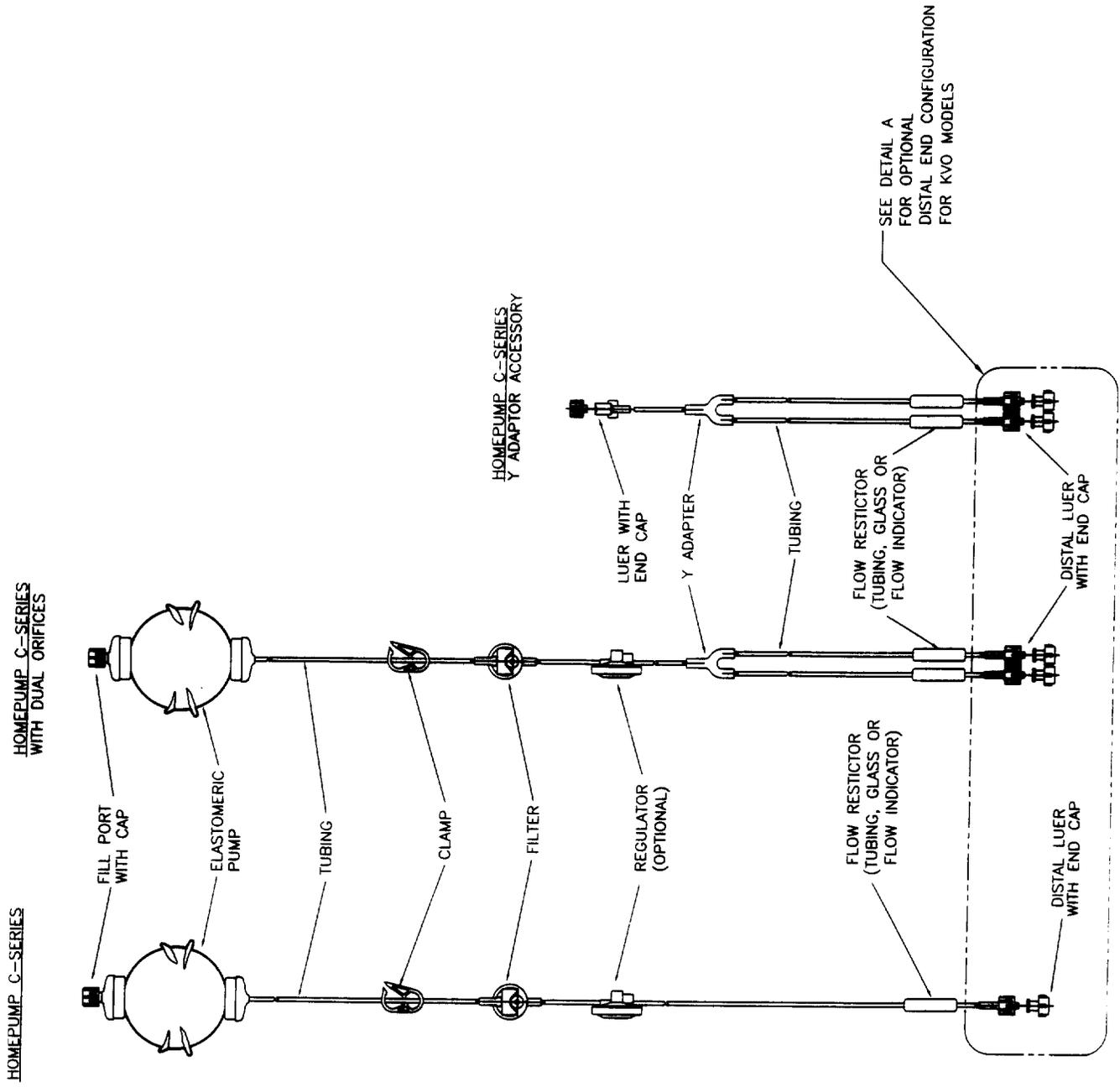
Comparison Element	Homepump C-Series with Regulator and Flow Indicator Components (subject device)	SE ¹ Homepump C-Series (K923875)	SE ¹ 3M IV Flow Regulator (K896907)
Y Adapter (optional) for dual orifice set	(b) (4)		
Y-Site (optional) alternative to distal luer adapter			
Check Valve (optional) attached to Y-Site			
Packaging (sterile)			
Sterilization	Gamma or ETO	Gamma or ETO	
Product Code	80 MEB	80 MEB	80 FPA

¹SE = Substantially Equivalent

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Appendix A
Homepump C-Series Drawings

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HOME PUMP C-SERIES
WITH DUAL ORIFICES

HOME PUMP C-SERIES

HOME PUMP C-SERIES
Y ADAPTOR ACCESSORY

FILL PORT
WITH CAP

ELASTOMERIC
PUMP

TUBING

CLAMP

FILTER

REGULATOR
(OPTIONAL)

FLOW RESTRICTOR
(TUBING, GLASS OR
FLOW INDICATOR)

DISTAL LUER
WITH END CAP

LUER WITH
END CAP

Y ADAPTER

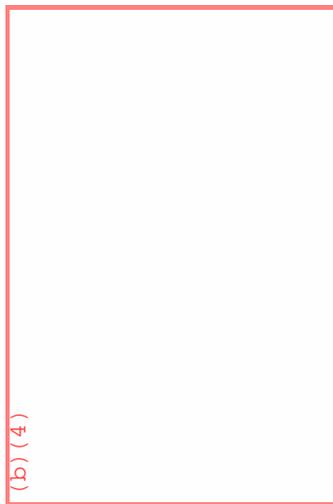
TUBING

FLOW RESTRICTOR
(TUBING, GLASS OR
FLOW INDICATOR)

DISTAL LUER
WITH END CAP

SEE DETAIL A
FOR OPTIONAL
DISTAL END CONFIGURATION
FOR KVO MODELS

OPTIONAL DISTAL END CONFIGURATION
FOR KVO MODELS



DETAIL A

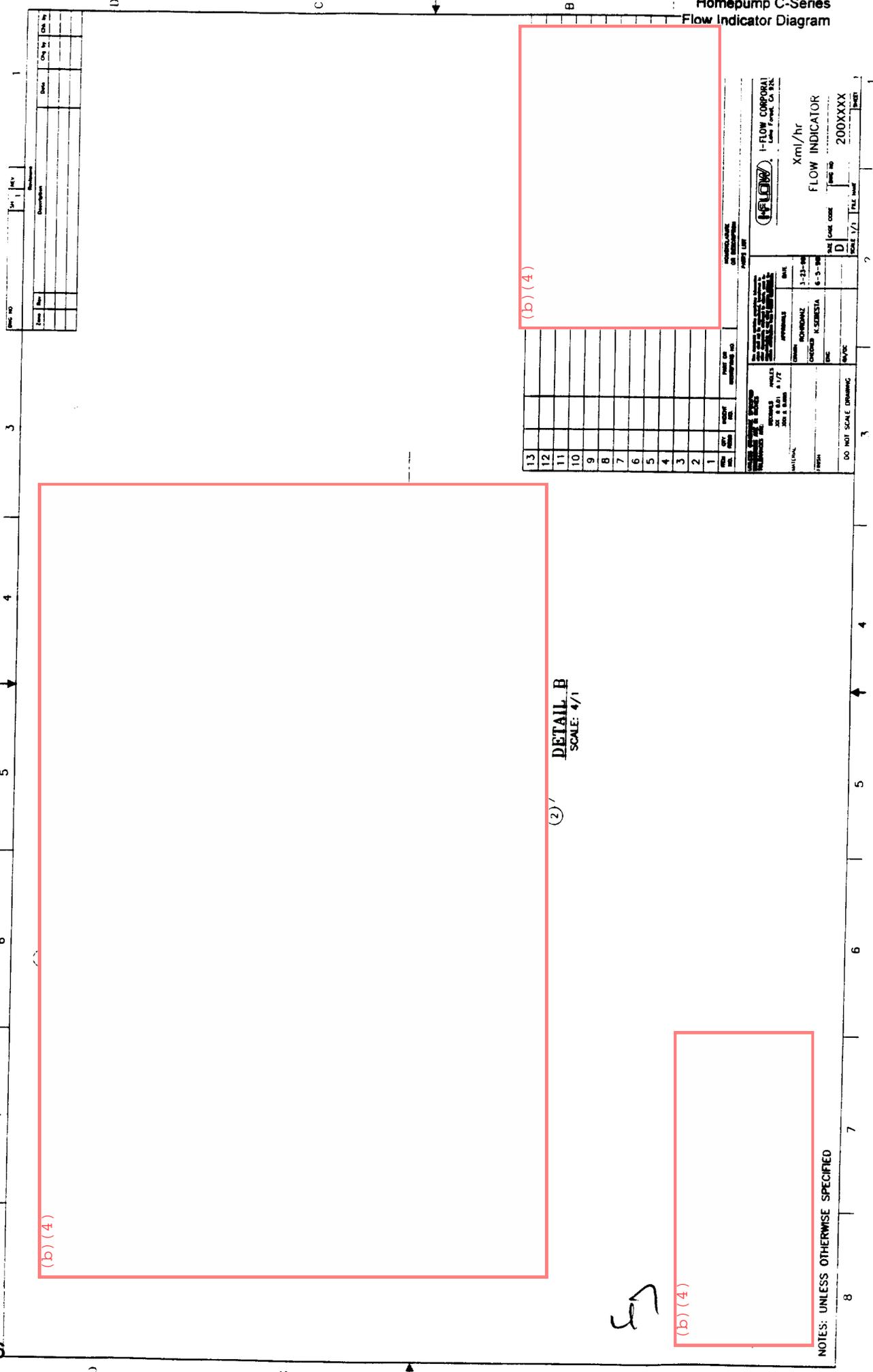
us



(b) (4)

REGULATOR ASSEMBLY
(UNSEATED CONFIGURATION)

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ITEM NO.	QTY.	DESCRIPTION	UNIT	PRICE	TOTAL
13					
12					
11					
10					
9					
8					
7					
6					
5					
4					
3					
2					
1					

FLOW I-FLOW CORPORATION
Flow Indicator Co. Inc.

Xm/hr
FLOW INDICATOR

DATE CODE: D
SERIAL NO: 200XXXX
SCALE 1/1

DO NOT SCALE DRAWING

② / **DETAIL B**
SCALE: 4/1

NOTES: UNLESS OTHERWISE SPECIFIED

1	2	3	4	1	2	3	4	1	
(b) (4)								(b) (4)	(b) (4)
(b) (4)								(b) (4)	

Revisions			
Zone	Rev.	Description	Date
	1	(b) (4)	

DWG NO. (b) (4)	SH	REV	1
-----------------	----	-----	---

I-Flow Corp	I-Flow Corp	I-Flow Corp	I-Flow Corp	I-Flow Corp	I-Flow Corp
DATE: 1/17/03	SCALE: 1/2" = 1'-0"	SHEET: 1 OF 1	REV: 1	DATE: 1/17/03	SCALE: 1/2" = 1'-0"

I-FLOW CORPORATION
 Labels Formed, CA 92530

CARRYING POUCH
 50-125ml ECLIPSE

DATE: 1/17/03

SCALE: 1/2" = 1'-0"

SHEET: 1 OF 1

REV: 1

DATE: 1/17/03

SCALE: 1/2" = 1'-0"

NOTES: UNLESS OTHERWISE SPECIFIED

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

(b) (4)

(b) (4)

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

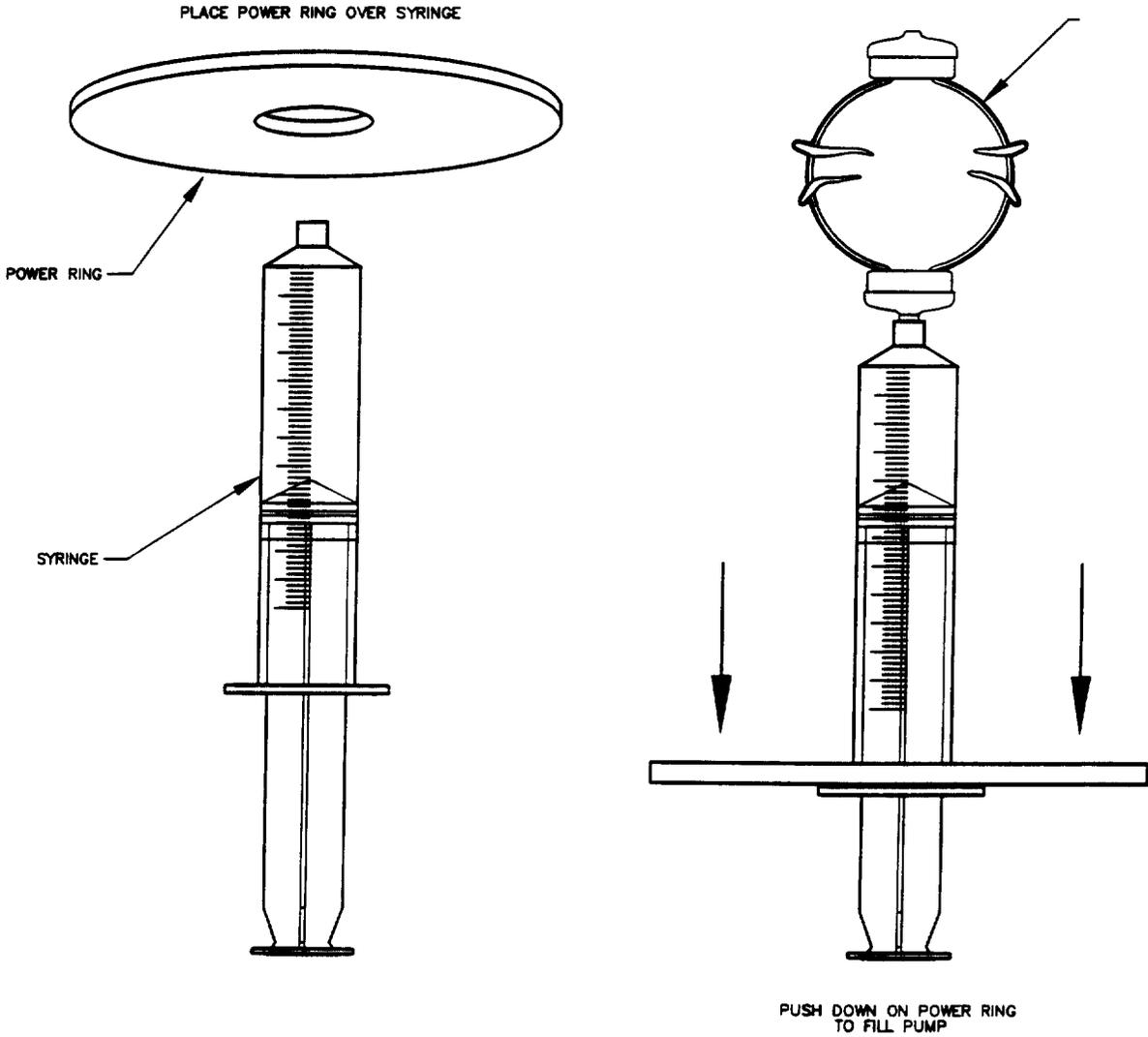
1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A

1	2	3	4	1	2	3	4
D	C	B	A	D	C	B	A



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Appendix B
Homepump C-Series Labeling

52



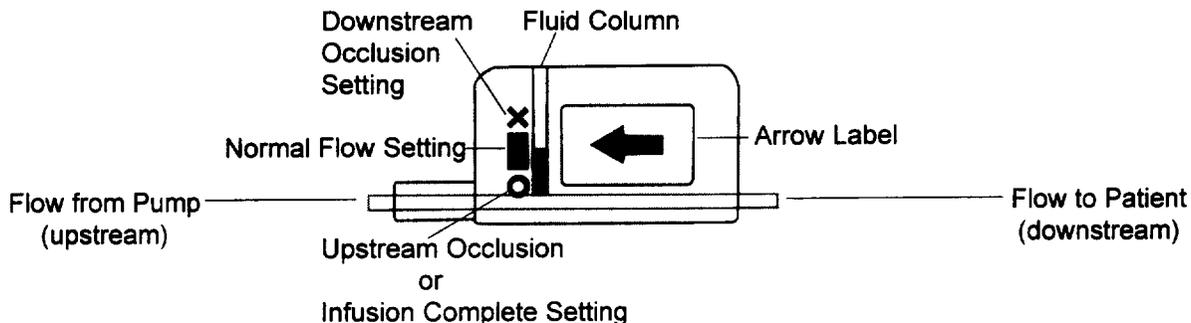
FlowView™ Indicator

**ELASTOMERIC PUMP
PRODUCT INSERT**

This product insert provides information on the FlowView indicator.
Refer to the Elastomeric Pump Directions for Use for complete instructions.

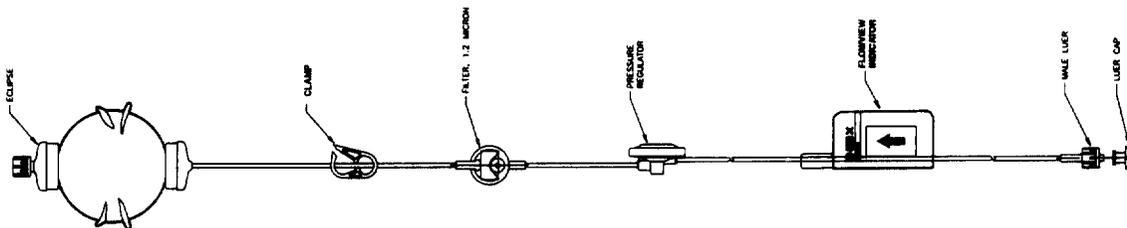
Description

The FlowView indicator provides an easy method to view the infusion flow status.
The indicator allows the patient or caregiver to determine if the Elastomeric pump is infusing or whether it has stopped infusing due to occlusions (both downstream and upstream) or completed delivery.



Securing FlowView

Secure the FlowView indicator against the patient's skin with arrow label facing up to ensure optimal flow rate. **Do not tape over FlowView indicator.**

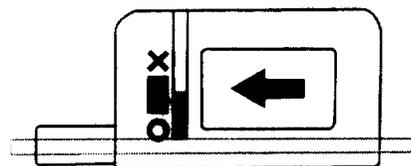


Reading Flow Status

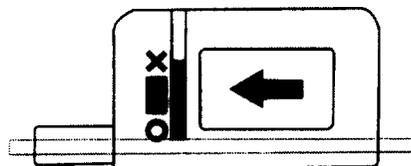
The fluid column in the FlowView indicator will move up or down depending on flow status.

Normal Flow

When the fluid column is within the normal flow setting (■) the pump is infusing.

**Downstream Occlusion**

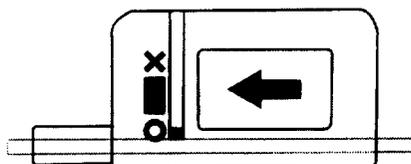
If the fluid column is in the downstream occlusion setting (x) flow has stopped due to an occlusion.



Check kinked tubing between the FlowView indicator and the patient access site. If no kinking is found or if unkinking does not return the fluid column to normal setting, the caregiver should be contacted.

Upstream Occlusion/Infusion Complete

When the fluid column is in the upstream occlusion setting (○), there may be an occlusion upstream or the infusion is complete.



Check for end of infusion. The infusion is complete when the pump is no longer full. A hard tube can be felt in the middle of the pump.

Upstream occlusion may occur due to:

- closed clamp (open clamp to resume flow)
- kinked tubing (unkink tubing to resume flow)
- clogged filter

To resume flow open clamp or unkink tubing as required. In the case of a clogged filter it will be necessary to change the pump.

Note

Towards the end of the infusion, the pump pressure will drop causing the FlowView fluid column to approach upstream occlusion or end of infusion setting. If the fluid level indicator on the pump is near empty, allow the infusion to continue until the elastomeric membranes are no longer extended.

For Customer Service
Call: 1.800.448.3569
949.206.2700
www.i-flowcorp.com



European Representative:
MPS Medical Product Service GmgH
Borngasse 20, 35619 Braunfels, Germany

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I-FLOW CORPORATION
LAKE FOREST, CA 92630
U.S.A.

DIRECTIONS FOR USE**Model Numbers**

C060020, C065005, C100005, C100020, C100050,
C270010, C270020, C270050, C270100

Homepump C-Series

INTENDED USE

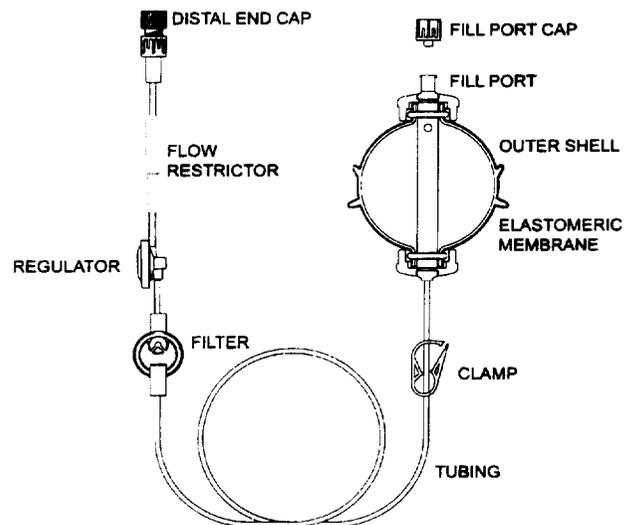
The Homepump C-Series is intended for continuous infusion of medications for general infusion use, including chemotherapy and pain management. Routes of administration include intravenous, subcutaneous, intramuscular and epidural.

CONTRAINDICATIONS

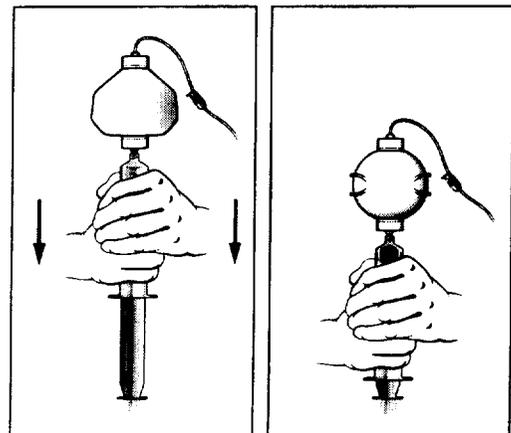
Not for blood, blood products, lipids or fat emulsions.

CAUTION

1. Do not use if package has been opened or is damaged or if either protector cap is not in place. The Homepump C-Series is sterile and non-pyrogenic.
2. Single Patient Use Only. Do not resterilize.
3. Do not overfill the pump.
4. Medications administered with this system should be used in accordance with instructions provided from the drug manufacturer.
5. It is recommended that the administration set be changed in accordance with established guidelines.
6. Epidural administration of analgesics is limited to use with indwelling catheters specifically indicated for either short-term or long-term analgesic drug delivery. Do not use Y adapter with epidural delivery.
7. If the device is to be used for epidural analgesic drug administration, it should be labeled to differentiate from other routes of administration. When using this device for epidural drug administration, make certain only drugs recommended for this route of administration are used.
8. Do not use while showering, bathing or swimming.
9. Do not microwave or submerge in water.

**DIRECTIONS FOR USE****Use Aseptic Technique****Filling the Elastomeric Pump**

1. Close clamp on tubing.
2. Remove protective cap from fill port. Do not discard cap.
3. Attach filled syringe to the fill port and inject fluid into pump. Repeat if necessary.
4. Do not over fill pump (refer to table on next page for applicable fill volumes).
5. Replace fill port cap.
6. Open the clamp and remove distal end cap to prime the tubing. Close the clamp until ready for use.
7. Attach the Homepump C-Series to the appropriate access site.



SS

STARTING THE INFUSION

1. Secure flow restrictor to skin and apply desired dressing.
2. Open the clamp to begin delivering medication.
3. When the elastomeric membranes are no longer extended, infusion is complete; disconnect and dispose of the Homepump C-Series as instructed by your healthcare provider.

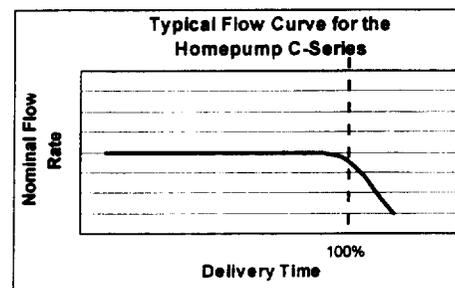
Delivery Time Information for the Homepump C-Series

	C060020	C065005	C100005	C100020	C100050	C270010	C270020	C270050	C270100
Nominal Flow Rate (ml/hr)	2	0.5	0.5	2	5	1	2	5	10
Nominal Volume (ml)	60	65	100	100	100	270	270	270	270
Maximum Volume (ml)	65	65	125	125	125	335	335	335	335
Retained Volume (ml)	<=3	<=3	<=4	<=4	<=4	<=9	<=9	<=9	<=9
Approximate Delivery Time		Fill Volume (ml)							
Hours	Days								
6									69
12	0.5	27		28	64				129
18		39		40	94				189
24	1	51		52	124			129	249
30		63		64				159	
48	2		27	100				249	
60	2.5		33	125					
72	3		39				153		
96	4		51				201		
120	5		63			129	249		
	6			76		153	297		
	7			88		177			
	8			100		201			
	9			112		225			
	10					249			
	11					273			
	12					297			

Delivery accuracy is $\pm 10\%$ (at a 95% confidence interval) of the labeled infusion period when delivering normal saline at 88° F (31°C).

NOTES

1. The infusion rate for each Homepump C-Series is labeled on the fill port. Delivery should be started immediately after filling. Storage of a filling Homepump C-Series unit for more than 8 hours prior to starting infusion may result in 10% longer delivery time.
2. If a filled Homepump C-Series needs to be stored in the refrigerator or freezer, for any reason, allow the unit to warm to room temperature before using:
 - If refrigerated: allow 4 hours for C060020, C065005, C100005, C100020, C100050; allow 12 hours for C270010, C270020, C270050, C270100.
 - If frozen: allow 8 hours for C060020, C065005, C100005, C100020, C100050; allow 24 hours for C270010, C270020, C270050, C270100.
3. Actual infusion times may vary due to:
 - fill volumes: See chart above.
 - positioning the Homepump C-Series above (increase) or below (decrease) the catheter site.
 - temperature: the flow restrictor (located distal to the filter) should be close to, or in direct contact with, the skin (31°C/88°F). Temperature will affect solution viscosity, resulting in shorter or longer delivery time. If the Homepump C-Series is used with the flow restrictor at room temperature (20°C/68°F), delivery time may increase by approximately 25%.
 - viscosity and/or drug concentration: The Homepump C-Series is delivery times are based on normal saline. Addition of any drug or use of another diluent may change viscosity and result in longer or shorter delivery time; use of D5W will result in a 10% longer delivery time.
4. This product uses DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the administration set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.



CAUTION

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

For Customer Service
Call: 1.800.448.3569
(949) 206.2700



European Representative:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

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I-FLOW CORPORATION
LAKE FOREST, CA 92630
U.S.A.

U.S. Patents: D324,911; 5,080,652; 5,284,481. U.S. and Foreign Patents Pending.

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REF C100100

I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

PART NO. 500XXXXX

HOMEPUMP C-SERIES

100 ml Vol x 10 ml/hr



STERILE



LOT

SEE DIRECTIONS FOR USE. CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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I-Flow Corporation
Lake Forest, CA 92630 U.S.A.



European Representative / Europäische Vertretung /
Représentant pour l'Europe / Representante Europeo:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

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CONTENU / CONTENIDO: 1



I-FLOW CORPORATION, LAKE FOREST, CA U.S.A. PART NO. 400XXXX

HOME PUMP C-SERIES

100 ml Vol x 10 ml/hr



STERILE



LOT

SEE DIRECTIONS FOR USE.
CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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Fabrique par / Fabricado por:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.

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European Representative / Europäische Vertretung /
Représentant pour l'Europe / Representante Europeo:
MPS Medical Product Service GmbH
Bomgasse 20, 35619 Braunfels, Germany

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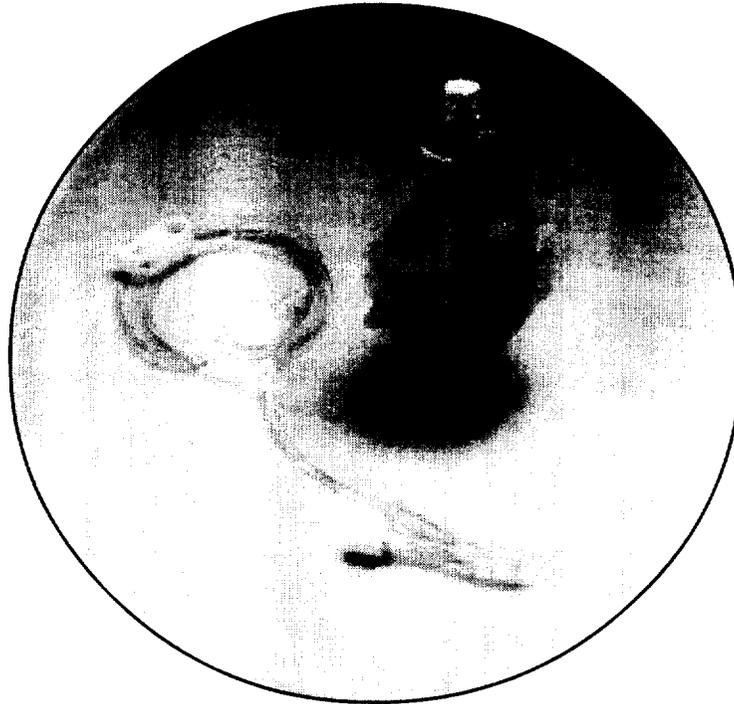
38

One-Step KVO™

DISPOSABLE ELASTOMERIC INFUSION SYSTEM

DIRECTIONS FOR USE

EY060005, EY110005
EV060005, EV110005



INDICATIONS FOR USE:

The One-Step KVO is indicated for general purpose drug and/or diluent delivery at a sufficient flow rate to maintain a patient IV line open (i.e. keep vein open). The Y-site at the distal end of the administration set allows piggy back infusions. The routes of administration include intravenous, subcutaneous and intramuscular.

Single Patient Use.

The One-Step KVO is sterile and non-pyrogenic. Do not resterilize. Do not refill.

CAUTION

- Do not use if package has been opened or is damaged or if either protector cap is not in place.
- Do not use while showering, bathing or swimming.
- Do not microwave or submerge in water.
- The One-Step KVO tubing is made of DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the IV administration set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.
- It is the responsibility of the healthcare professional to assure that the medication is prepared and administered in accordance with the drug manufacturer's package insert. It is the responsibility of the healthcare provider to assure that the patient is educated on the proper use of this product.
- Refer to established guidelines for specific recommendations regarding the usage of IV administration sets.

CONTRAINDICATION

- This product is not indicated for the delivery of blood, blood products or TPN.
- This device is not intended for the infusion of epidural or chemotherapy medications.

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DIRECTIONS FOR USE

Use Aseptic Technique
Do not remove from package
until ready to use.

FILLING INSTRUCTIONS

1. Remove the cap from the fill port.
2. The One•Step KVO can be filled with a syringe or similar device. After all air has been removed from the filling device, attach securely to the fill port.
3. The maximum fill rate is 10 ml/ second. Refer to your filling device instructions.
4. During the filling process, the tubing clamp on the One•Step KVO may be opened or closed. To expedite the priming of the tubing and filter of the One•Step KVO, leave the clamp open during filling and loosen the distal end cap.
5. Fill the One•Step KVO with no more than the maximum fill volume (refer to table on back page).
6. Remove the filling device from the fill port and securely replace the fill port cap.
7. To prime the distal end of the tubing and Y-Site during the filling process, open the tubing clamp and loosen the distal end cap. Fluid will slowly begin to fill the Y-Site. Invert and tap to remove any trapped air.

or

To expedite the priming process, remove the Y-Site cap, attach a filling device (or saline filled syringe) to the end of the Y-Site, loosen or remove the distal end cap, then flush the Y-Site, invert and tap the Y-Site to remove any trapped air.

8. Close the tubing clamp and tighten the distal end caps before transporting or storing the device.

NOTE

The following needleless devices have been tested with the One•Step KVO with Y-Site; Baxter Interlink®, ICU Medical Inc. Clave™ and the B. Braun Medical, Inc. SafeSite®. Follow the manufacturer's recommendations for their use.

Do not fill this device with fluids that are incompatible with the intermittent (piggyback) line medication.

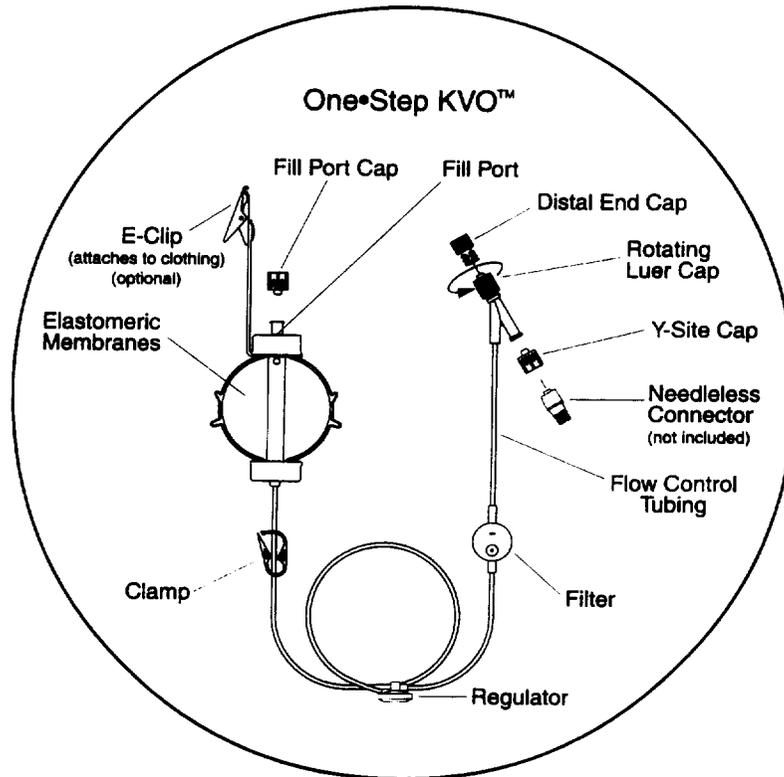
INFUSION INSTRUCTIONS

1. Allow the One•Step KVO to reach room temperature before using. For guidelines refer to the table on the back page.
2. Verify that the tubing clamp is closed.
3. If the tubing and Y-Site need to be primed, open the clamp and loosen the distal end cap of the Y-Site to allow air to escape.
 Note: The device will prime slowly.
4. To expedite priming the Y-Site, remove the Y-Site cap, then flush the Y-Site with a saline filled syringe or other filling device.
5. Replace the Y-Site cap, or attach a needleless connector or an injection port to the Y-Site.
6. Following your institutional protocol, check the patency of the IV access device. Do NOT attach the One•Step KVO if the IV catheter is NOT patent.
7. Connect the rotating distal Luer connector to the patient's IV access device. Position the Y-Site connector as necessary, then tighten the rotating Luer connector until it is secure.
 Note: The rotating Luer connector must be securely tightened to prevent leakage or disconnection from the IV access device.
8. Begin the infusion by opening the clamp — fluid delivery will start immediately. If the tubing is partially kinked, massage the tubing to promote flow.
 Note: The One•Step KVO can be attached to the patient's clothing using an E-Clip (optional) or carried in the Carrying Pouch (optional) to assist in patient mobility.
9. When the elastomeric membrane is no longer extended, the infusion is complete. Approximately 10 ml of fluid may remain in the membrane. Disconnect and dispose of the One•Step KVO according to your institution's protocol.

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Medication Administration through the Y-Site of the One-Step KVO

- To infuse medication, cleanse the injection site according to your institution's protocol.
- Connect the intermittent ("piggyback") medication line to the Y-Site connector using aseptic technique. Begin the intermittent infusion.
Note: Do not close the tubing clamp on the One-Step KVO.
- When the medication infusion is complete, close the clamp on the intermittent medication line and disconnect from the Y-Site following your institutions protocol.
- The One-Step KVO should remain connected to the IV access device until the One-Step KVO infusion is complete, or the IV therapy is discontinued.



Infusion delivery times for the One-Step KVO elastomeric infusion device are influenced by environmental conditions. The information below is provided to assist the healthcare provider in understanding these factors.

- The One-Step KVO can be filled with normal saline and stored for up to 8 weeks. However, storage of a filled One-Step KVO unit for more than 8 hours prior to starting infusion may result in a longer delivery time. Storage conditions other than the specified usage condition may affect delivery time.
- Each One-Step KVO is designed for the infusion tubing to be worn under the clothing, while the fluid reservoir can be worn in the manner most comfortable for the patient. The tubing below the filter should be close to, or in direct contact with, the skin (31°C/88°F). Temperature will affect the solution viscosity, resulting in a shorter or longer delivery time. If the One-Step KVO is used with the flow control tubing at room temperature (20°C/68°F), delivery time will be approximately 25% longer.
- The flow rate of 0.5 ml/hr may be decreased by infusion of more viscous fluids. Use of D5W will decrease the flow rate by approximately 8%.
- If the One-Step KVO is filled with more than the nominal volume it will infuse at a lower than nominal flow rate. A One-Step KVO filled with less than the nominal volume will infuse at a higher than nominal flow rate. Refer to the fill table on the back page for appropriate fill volumes.
- After priming the tubing set of the One-Step KVO, ensure that the distal end cap and Y-Site cap are tightened securely to prevent fluid evaporation and occlusion of the flow control tubing.
- Check for any tubing occlusion at the clamp site. After opening the clamp, if the tubing is partially kinked, squeeze the tubing to facilitate flow.
- Use extra care when handling frozen units.

Delivery Times and Fill Volumes

One • Step KVO					
		EY060005, EV060005	EY110005, EV110005		
Flow Rate (ml / hr)		0.5	0.5		
Nominal Fill Volume (ml)		60	110		
Maximum Fill Volume (ml)		65	125		
Retained Volume (ml)		10	10		
Accuracy		± 10%	± 10%		
Time to Reach Room Temperature		From Refrigerator:	6 hours	6 hours	
		From Freezer:	12 hours	12 hours	
Nominal Fill Volumes (ml)					
		Temperatures		Skin	Room
Approximate Delivery Times		31°C	20°C	31°C	20°C
2 days		29	23		
3 days		43	33		
			43		
5 days				70	54
6 days				83	63
					73
8 days				110	83
9 days					
10 days					

Fill Volumes account for device accuracy to ensure device will run for minimum stated time. Excess volume may remain at the end of the stated delivery time.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

For Customer Service
 Call: 1.800.448.3569
 949.206.2700
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 Bomgasse 20, 35619 Braunfels, Germany

U.S. Pat. Nos. D324,911;
 5,080,652; 5,284,481; and
 Foreign Pat. Pend.
 Assembled in Mexico

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USA

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CONTENTS / INHALT / CONTENU / CONTENIDO:



REF EY110005

I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

PART NO. 500XXXXX

ONE-STEP KVO 110 ml Vol x 0.5 ml/hr



STERILE



LOT

SEE DIRECTIONS FOR USE. CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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Lake Forest, CA 92630 U.S.A.



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I-FLOW CORPORATION, LAKE FOREST, CA U.S.A. PART NO. 400XXXX

ONE-STEP KVO

110 ml Vol x 0.5 ml/hr



STERILE



LOT

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04

PainBuster™

CONTENTS

- 1 each - PainBuster Infusion Pump
- 1 each - 16GA I.V. Catheter Needle
- 1 each - 20GA Epidural Catheter Set
- 1 each - Latex Free 60cc Syringe
- 1 each - Transparent Dressing
- 1 each - Medication Label
- 1 each - Dressing Clip (65/100 ml Vol)
or Carrying Case (270 ml Vol)

INTENDED USE

The PainBuster Pain Management System is intended to provide continuous infusion of a local anesthetic directly into an intraoperative site for postoperative pain management. Infusions may also be administered subcutaneously.

DO NOT USE IF PACKAGE HAS BEEN OPENED OR IS DAMAGED OR IF EITHER PROTECTOR CAP IS NOT IN PLACE. THE PAINBUSTER IS STERILE AND NON-PYROGENIC.

SINGLE PATIENT USE ONLY. DO NOT RESTERILIZE.

CAUTION

Do not overfill the pump.

Medications used with this system should be administered in accordance with instructions provided from the drug manufacturer.

CONTRAINDICATIONS

The PainBuster is not intended for intravenous, intra-arterial or epidural drug delivery.

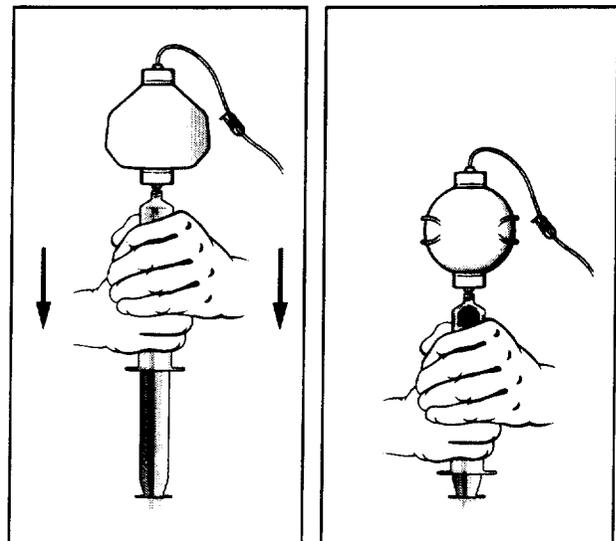
The PainBuster is not intended for the delivery of blood, blood products, lipids or fat emulsions.

DIRECTIONS FOR USE

Use Aseptic Technique

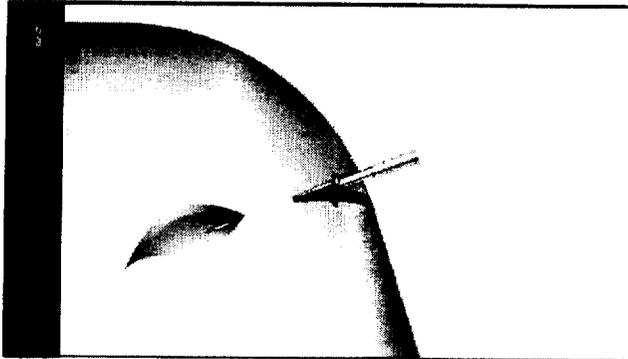
Filling the Elastomeric Pump

- Close clamp on tubing.
- Remove protective cap from fill port. Do not discard cap.
- Attach filled syringe to the fill port and inject fluid into pump (refer to diagram at right).
- Repeat if necessary.
- Do not overfill pump (refer to table on last page for applicable fill volumes).
- Replace fill port cap.
- Label with the appropriate pharmaceutical and patient information.
- Open the clamp and remove the distal end cap to prime the pump (up to 15 minutes). Close the clamp until ready for use.

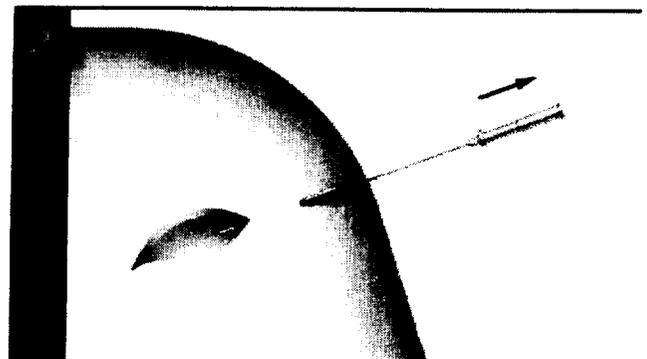


65

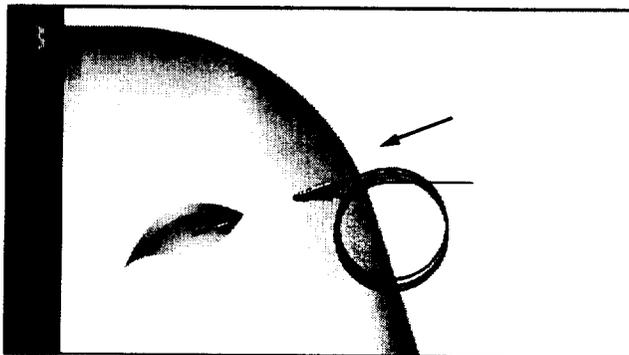
Placing the Catheter



Insert introducer needle through the skin (approximately 3-5 cm away from wound site) then push introducer needle into the surgical wound site.



Remove the needle from the introducer.



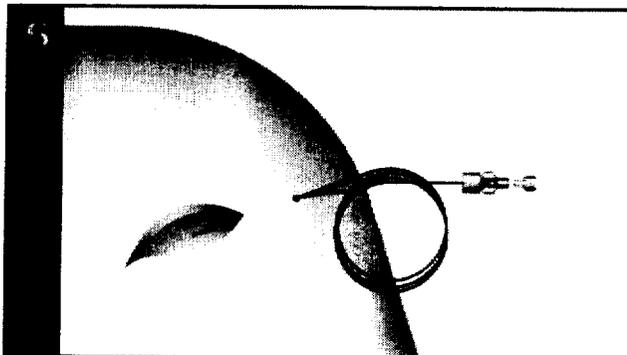
Insert the marked end of the catheter through the hub of the introducer into the wound site (approximately 5-8 cm).

CAUTION: Assure that the catheter tip is not in a vein or artery.



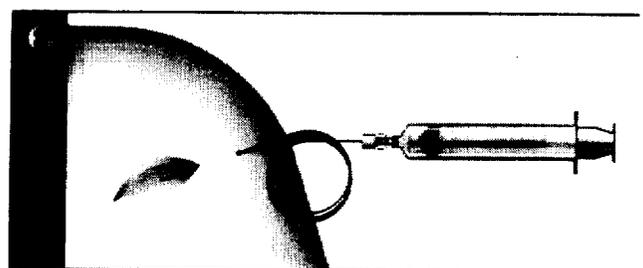
While holding catheter (a) tightly in place, remove introducer needle. Assure catheter placement in wound site.

NOTE: Catheter placement will vary depending on surgical procedure. Care should be taken during catheter placement such that occlusion will not occur during use and that catheter removal will not be impeded.



Attach the catheter connector to the unmarked end of the catheter. Tighten until catheter cannot be removed.

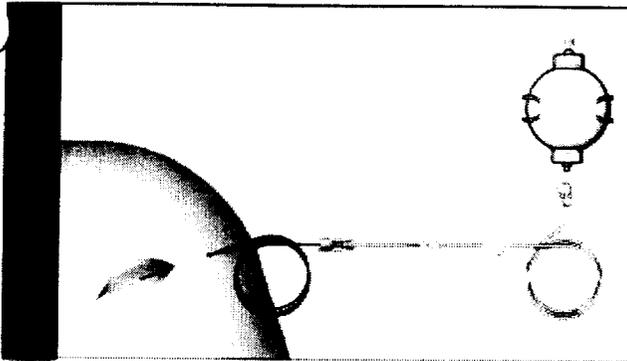
Catheter may need to be secured with tape to maintain catheter placement.



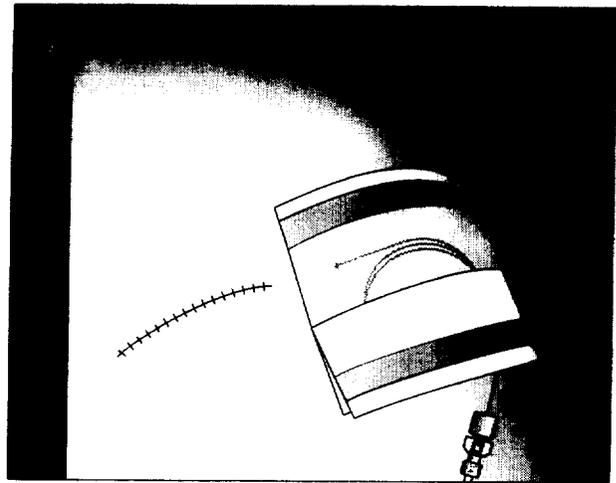
Attach syringe to catheter connector and prime catheter with local anesthetic.

WARNING: If catheter tip location cannot be verified before priming, draw back on the syringe to check for blood return. Blood return may indicate the catheter is in a vein or artery which is unsafe.

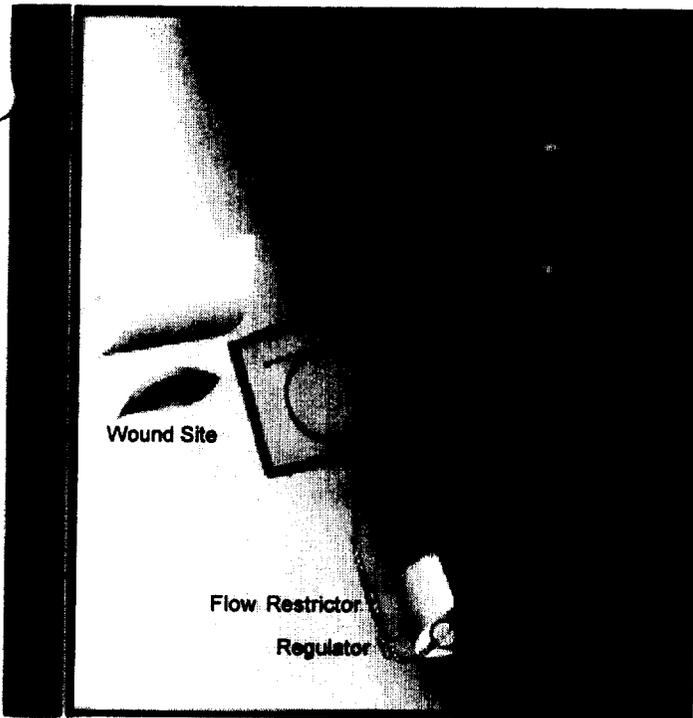
66



Attach the catheter connector to the pump tubing. Open the pump clamp to begin infusion.



Secure catheter by coiling close to insertion site. Remove backing from one-half of transparent dressing, center over insertion site and peel off backing. Then remove second half over coiled catheter and peel remainder of backing.



Assure that the edges of dressing are adequately sealed. Secure flow restrictor to skin. The flow restrictor must not be in contact with cold therapy pads.

Attach E-Clip to the top of the pump. Secure the PainBuster pump to the outer dressing, or to the patient's clothing, with tape or E-Clip as desired. 270 ml Vol includes carrying case instead of E-Clip.

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Delivery Time Information for the PainBuster

	65 ml Vol x 0.5 ml/hr pump	100 ml Vol x 2 ml/hr pump	270 ml Vol x 2 ml/hr pump	270 ml Vol x 5 ml/hr pump
NOMINAL FLOW RATE (ml/hr)	0.5	2	2	5
NOMINAL VOLUME (ml)	65	100	270	270
MAXIMUM VOLUME (ml)	65	125	335	335
RETAINED VOLUME (ml)	≤3	≤4	≤9	≤9
APPROXIMATE DELIVERY TIME	FILL VOLUME (ml)			
Hours	Days			
12	0.50		28	
18	0.75		40	
24	1		52	129
48	2	27	100	249
60	2.5	33	124	309
72	3	39		153
96	4	51		201
120	5	63		249

Delivery accuracy is $\pm 10\%$ (at a 95% confidence interval) of the labeled infusion rate when delivering normal saline at 88° F (31°C) against a back pressure of 40 cm of water.

NOTES:

- The nominal infusion rate for each PainBuster Pump is labeled on the fill port.
- Actual infusion times may vary due to:
 - viscosity and/or drug concentration.
 - positioning the PainBuster pump above (time decreases) or below (time increases) the catheter site.
 - temperature: the PainBuster flow restrictor (located distal to the filter) should be close to, or in direct contact with, the skin (88°F/31°C). Temperature will affect solution viscosity, resulting in shorter or longer delivery time. If the PainBuster is used with the flow restrictor at room temperature (68°F/20°C), delivery time may increase by approximately 25%.
- This product uses DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the administration set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.

CAUTION

Federal (U.S.A.) law restricts this device to sale by or on the order of a healthcare professional. Prompt removal of the catheter is advised after infusion is complete to reduce risk of infection. Infusion is complete when the PainBuster Pump is no longer inflated.

U.S. Patents: D324,911; 5,080,652; 5,284,481. U.S. and Foreign Patents Pending.

For Customer Service
Call: 1.800.448.3569
949.206.2700



European Representative:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

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CONTENTS / INHALT / CONTENU / CONTENIDO: 5



REF PB100100

I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

PART NO. 500XXXX

PAINBUSTER INFUSION KIT

100 ml Vol x 10 ml/hr



SEE DIRECTIONS FOR USE. CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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Lake Forest, CA 92630 U.S.A.



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CONTENTS / INHALT /

CONTENU / CONTENIDO: 1



REF PB100100

I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

PART NO. 500XXXX

PAINBUSTER INFUSION KIT 100 ml Vol x 10 ml/hr

CONTENTS: 1 each - 100 ml Vol, 10 ml/hr PainBuster Pump
1 each - 16GA I.V. Catheter Needle
1 each - 20GA Epidural Catheter Set
1 each - 60cc Syringe
1 each - Transparent Dressing



STERILE



LOT

SEE DIRECTIONS FOR USE

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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CONTENU / CONTENIDO: 1



I-FLOW CORPORATION, LAKE FOREST, CA U.S.A. PART NO. 400XXXX

PAINBUSTER PUMP

100 ml Vol x 10 ml/hr



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NOT FOR ORTHOPEDIC USE

ON-Q™

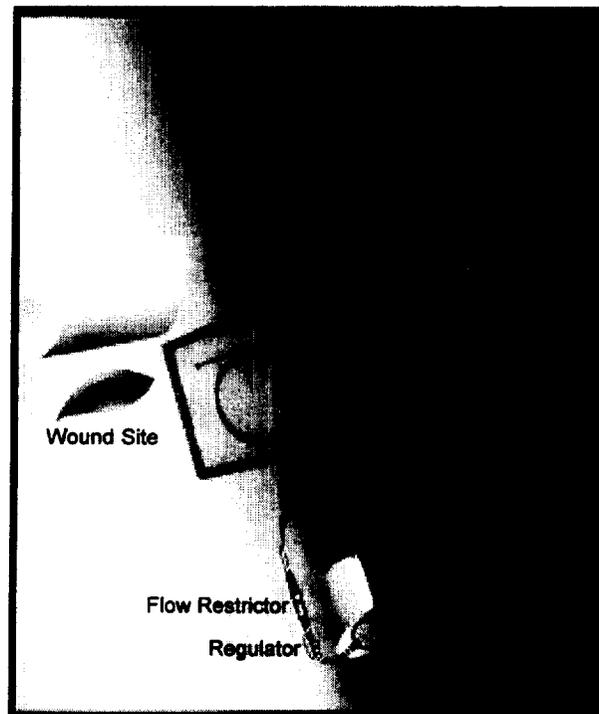
Pain Management System

CONTENTS

1 each - ON-Q Infusion Pump
 1 each - 16GA I.V. Catheter Needle
 1 each - 20GA Epidural Catheter Set
 1 each - Latex Free 60cc Syringe
 1 each - Transparent Dressing
 1 each - Medication Label
 1 each - Dressing Clip (65/100 ml Vol)
 or Carrying Case (270 ml Vol)

DESCRIPTION

The ON-Q Pain Management System is intended to provide continuous infusion of a local anesthetic directly into an intraoperative site for postoperative pain management. Infusions may also be administered subcutaneously.



DO NOT USE IF PACKAGE HAS BEEN OPENED OR IS DAMAGED OR IF EITHER PROTECTOR CAP IS NOT IN PLACE. THE ON-Q SYSTEM IS STERILE AND NON-PYROGENIC.

SINGLE PATIENT USE ONLY. DO NOT RESTERILIZE.

CAUTION

Do not overfill the pump.

Medications used with this system should be administered in accordance with instructions provided from the drug manufacturer.

CONTRAINDICATIONS

The ON-Q is not intended for intravenous, intra-arterial or epidural drug delivery.

The ON-Q is not intended for the delivery of blood, blood products, lipids or fat emulsions.

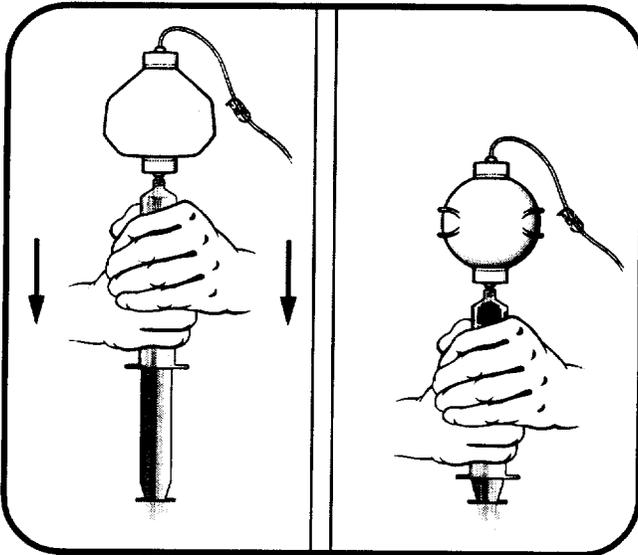
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DIRECTIONS FOR USE

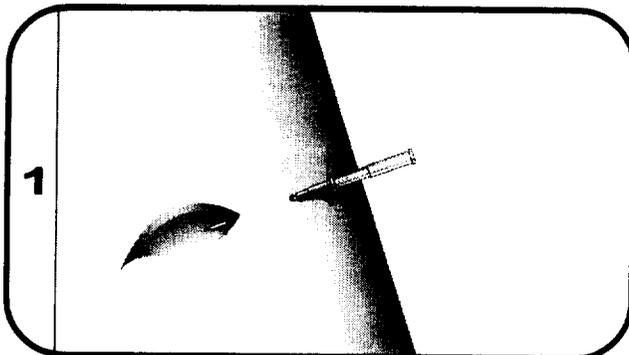
Use Aseptic Technique

Filling the ON-Q Pump

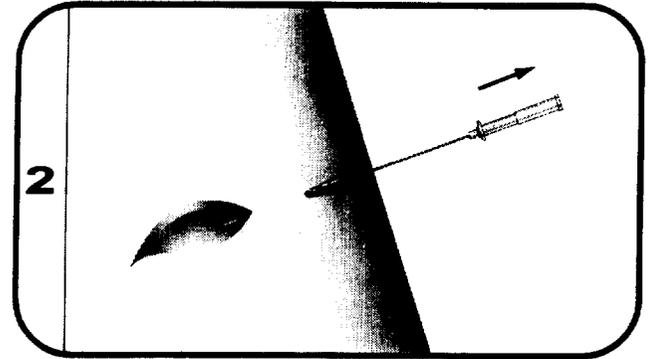
- Close clamp on tubing.
- Remove protective cap from fill port. Do not discard cap.
- Attach filled syringe to the fill port and inject fluid into pump (refer to diagram below). Repeat if necessary.
- Do not overfill pump (refer to table on next page for applicable fill volumes).
- Replace fill port cap.
- Label with the appropriate pharmaceutical and patient information.
- Open the clamp and remove the distal end cap to prime the pump (up to 15 minutes). Close the clamp until ready for use.



Placing the Catheter



Insert introducer needle through the skin (approximately 3-5 cm away from wound site) then push introducer needle into the surgical wound site.

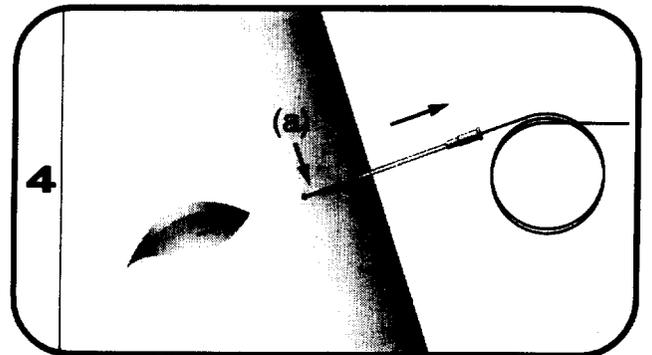


Remove the needle from the introducer.



Insert the marked end of the catheter through the hub of the introducer into the wound site (approximately 5-8 cm).

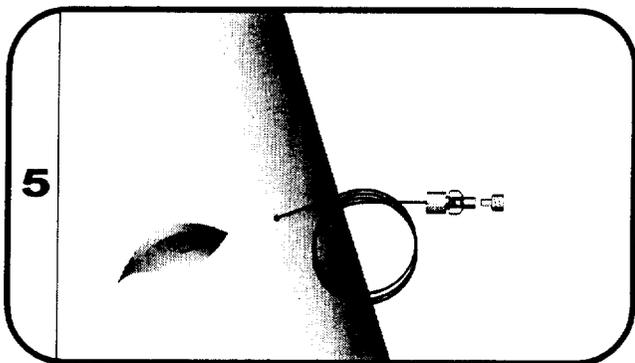
CAUTION: Assure that the catheter tip is not in a vein or artery.



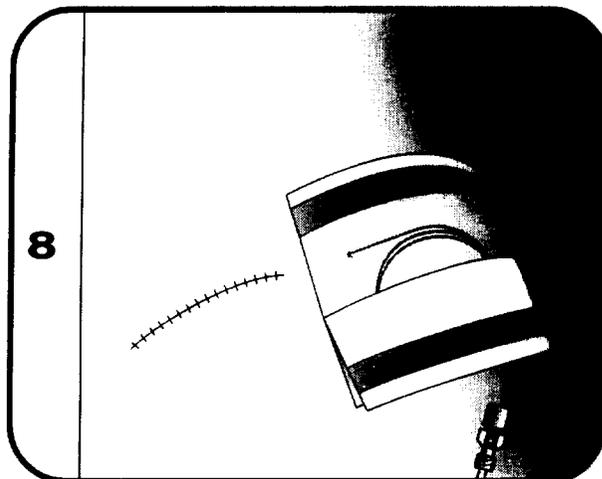
While holding catheter (a) tightly in place, remove the introducer. Assure catheter placement in wound site.

NOTE: Catheter placement will vary depending on surgical procedure. Care should be taken during catheter placement such that occlusion will not occur during use and that catheter removal will not be impeded.

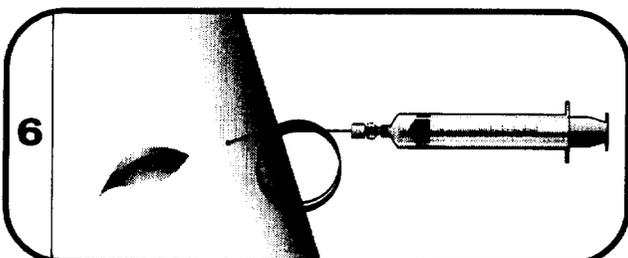
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Attach the catheter connector to the unmarked end of the catheter. Tighten until catheter cannot be removed. Catheter may need to be secured with tape to maintain catheter placement.

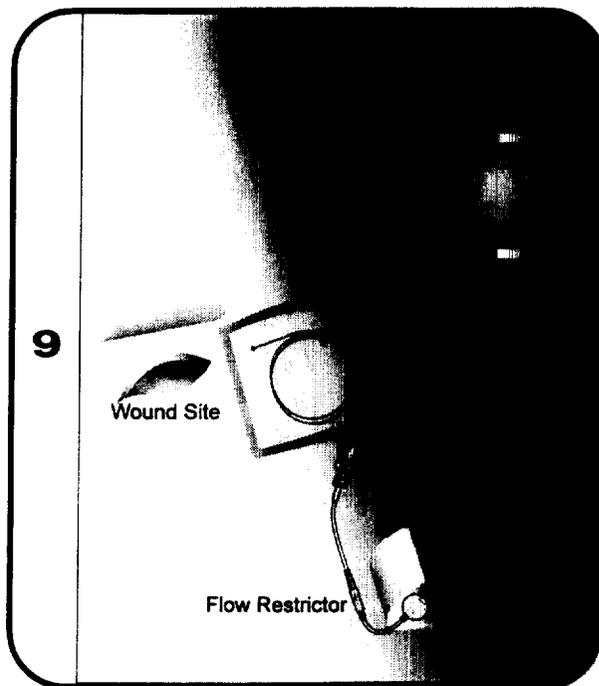


Secure catheter by coiling close to insertion site. Remove backing from one-half of transparent dressing, center over insertion site and peel off backing. Then remove second half over coiled catheter and peel remainder of backing.



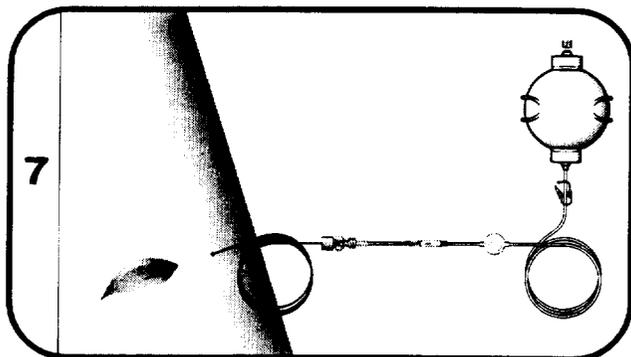
Attach syringe to catheter connector and prime catheter with local anesthetic.

WARNING: If catheter tip location cannot be verified before priming, draw back on the syringe to check for blood return. Blood return may indicate the catheter is in a vein or artery which is unsafe.



Assure that the edges of dressing are adequately sealed. Secure flow restrictor to skin. The flow restrictor must not be in contact with cold therapy pads.

Attach E-Clip to the top of the pump. Secure ON-Q pump to the outer dressing, or to the patient's clothing, with tape or E-Clip as desired. 270 ml Vol includes carrying case instead of E-Clip.



Attach the catheter connector to the pump tubing. Open the pump clamp to begin infusion.

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Delivery Time Information for the ON-Q Pain Management System

	Q065005	Q100020	Q270020	Q270050
NOMINAL FLOW RATE (ml/hr)	0.5	2	2	5
NOMINAL VOLUME (ml)	65	100	270	270
MAXIMUM VOLUME (ml)	65	125	335	335
RETAINED VOLUME (ml)	≤3	≤4	≤9	≤9
APPROXIMATE DELIVERY TIME	FILL VOLUME (ml)			
Hours	Days			
12	0.50		28	
18	0.75		40	
24	1		52	129
48	2	27	100	249
60	2.5	33	124	309
72	3	39		153
96	4	51		201
120	5	63		249

Delivery accuracy is ±10% (at a 95% confidence interval) of the labeled infusion rate when delivering normal saline at 88° F (31°C) against a back pressure of 40 cm of water.

NOTES:

1. The nominal infusion rate for each ON-Q Pump is labeled on the fill port.
2. Actual infusion times may vary due to:
 - viscosity and/or drug concentration.
 - positioning the ON-Q pump above (time decreases) or below (time increases) the catheter site.
 - temperature: the ON-Q flow restrictor (located distal to the filter) should be close to, or in direct contact with, the skin (88°F/31°C). Temperature will affect solution viscosity, resulting in shorter or longer delivery time. If the ON-Q is used with the flow restrictor at room temperature (68°F/20°C), delivery time may increase by approximately 25%.
3. This product uses DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the administration set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.

CAUTION

Federal (U.S.A.) law restricts this device to sale by or on the order of a healthcare professional. Prompt removal of the catheter is advised after infusion is complete to reduce risk of infection. Infusion is complete when the ON-Q Pump is no longer inflated.

U.S. Patents: D324,911; 5,080,652; 5,284,481. U.S. and Foreign Patents Pending.

For Customer Service
 Call: 1.800.448.3569
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CONTENTS / INHALT / CONTENU / CONTENIDO:
I-FLOW[®] REF **Q100100**
I-FLOW CORPORATION, LAKE FOREST, CA U.S.A. PART NO. **500XXXXX**

ON-Q INFUSION KIT
100 ml Vol x 10 ml/hr

SEE DIRECTIONS FOR USE. CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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CONTENTS / INHALT /
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REF Q100100

PART NO. 500XXXX

ON-Q INFUSION KIT 100 ml Vol x 10 ml/hr

CONTENTS: 1 each - 100 ml Vol, 10 ml/hr On-Q Pump
1 each - 16GA I.V. Catheter Needle
1 each - 20GA Epidural Catheter Set
1 each - 60cc Syringe
1 each - Transparent Dressing



STERILE



LOT

SEE DIRECTIONS FOR USE

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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CONTENU / CONTENIDO: 1

I-FLOW[®]

I-FLOW CORPORATION, LAKE FOREST, CA U.S.A. PART NO. 400XXXX

ON-Q PUMP
100 ml Vol x 10 ml/hr



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Nerve Block Infusion Kit

DIRECTIONS FOR USE

INTENDED USE

The Nerve Block Infusion Kit is intended to provide continuous infusion of a local anesthetic near a nerve for regional anesthesia and pain management for pre-operative, perioperative and postoperative general and orthopedic surgery. Additional routes of administration include percutaneous, subcutaneous, epidural and into the intraoperative site and synovial cavity.

CONTRAINDICATIONS

This system is not designed for intravenous or intra-arterial drug delivery. Not for blood, blood products, lipids or fat emulsions.

WARNINGS

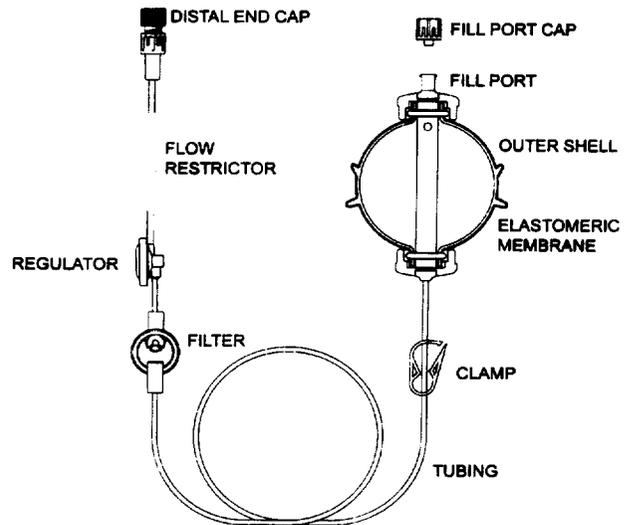
- Single Patient Use. Discard after use.
- Do not overfill pump.
- Medications administered with this system should be used in accordance with instructions provided from the drug manufacturer.

DIRECTIONS FOR USE

Use Aseptic Technique

FILLING THE ELASTOMERIC PUMP:

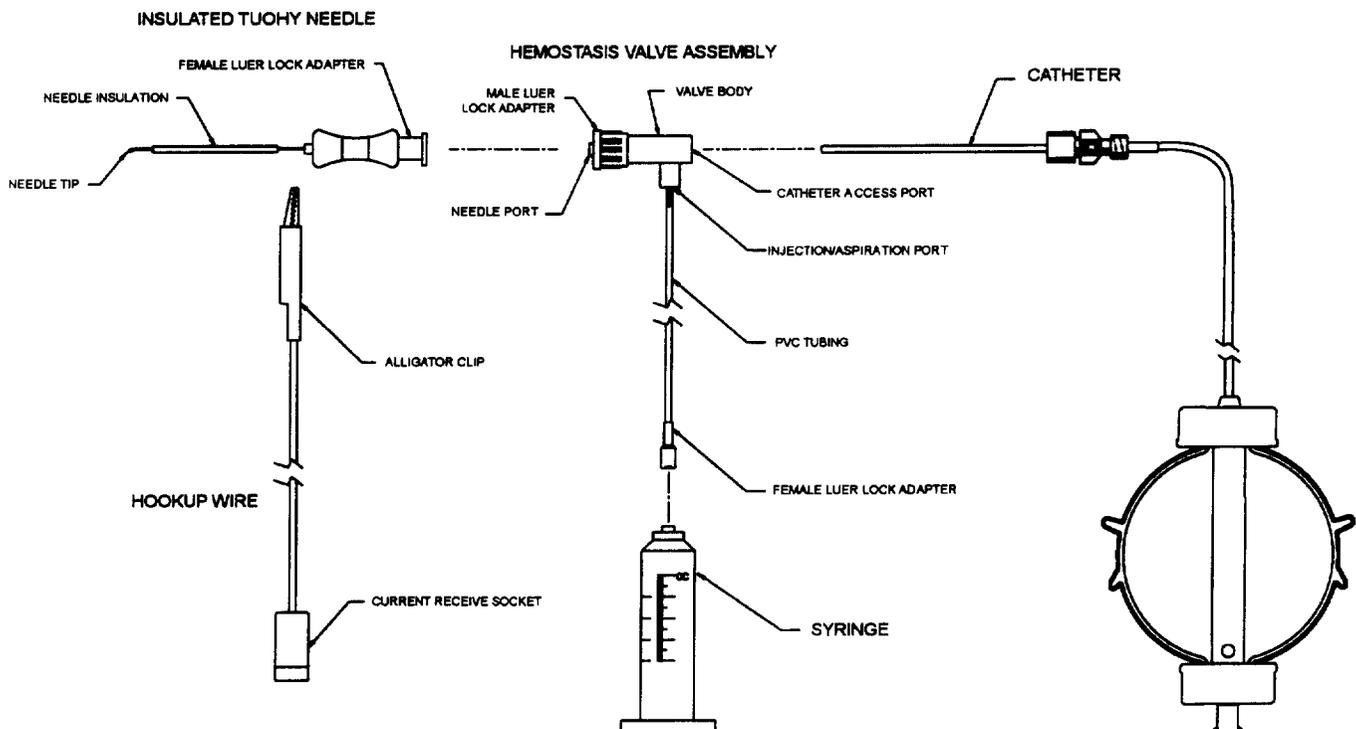
1. Close clamp on tubing.
2. Remove protective cap from filling port.
3. Attach filled syringe to the fill port and inject fluid into pump. Repeat if necessary. Do not over fill pump (refer to table for applicable fill volumes). Replace fill port cap.
4. To prime the tubing, open the clamp on the tubing and allow fluid to fill the tubing. Close clamp until ready for use.



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INTRODUCER NEEDLE DIRECTIONS:

1. Withdraw stylet from insulated needle and attach hemostasis valve assembly by rotating the luer lock collar clockwise onto needle hub. Orientation of hemostasis valve assembly tubing can be adjusted by loosening the luer lock collar, adjusting direction of tubing and re-tightening the collar.
2. Attach syringe filled with normal saline or anesthetic solution to proximal hub of hemostasis valve assembly tubing. Prime tubing, valve and needle with solution.
3. If a peripheral nerve stimulator is used, attach its electrode pin to the hookup wire connected to the insulated needle.
4. After raising a skin wheal with anesthetic agent, introduce the needle through the puncture site towards the targeted neurovascular bundle at an angle of about 30° (some authors suggest an angle of 10-20°).
5. Advance the needle in the direction of the nerve until visible muscle contractions occur in the innervated area. Reduce the current and optimize needle position until muscle contractions occur at lower current levels. The tip of the needle has reached an optimal position when noticeable contractions occur at a current of approximately 0.2mA (higher current levels may be required for certain lumbar blocks). Aspirate for possible intravascular placement.
6. Following negative aspiration, a test dose of local anesthetic can be injected through the extension tubing. Muscle contractions should cease within 5 to 10 seconds. Prior to indwelling catheter placement, the desired dose of anesthetic agent can be injected through the hemostasis valve assembly tubing.
7. The pink plastic threading assist guide should be removed from the indwelling catheter. The catheter should then be inserted through the hemostasis valve. It will continue through the valve and through the insulated Tuohy needle. Insert catheter to desired depth. Hold the catheter in place and slowly remove the insulated needle/ hemostasis valve assembly.
8. Introduce the proximal end of the catheter as far as possible in the central opening of the transparent screw cap of catheter connector. Tighten screw cap firmly until catheter can no longer be withdrawn (usually 2+ rotations).
9. Tape catheter(s) securely in place. Apply appropriate dressing to catheter site. Aspirate, prime and administer additional anesthetic as needed.



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STARTING THE NERVE BLOCK SYSTEM:

1. Open the clamp to begin delivering medication.
2. Secure flow restrictor to skin and apply desired dressing.
3. Secure Nerve Block pump to the outer dressing with tape or E-Clip as desired.

Delivery Time Information for the Nerve Block pump

	NB 060020	NB 065005	NB 100020	NB 100005	NB 125050	NB 270010	NB 270020	NB 270050	NB 270100	NB 500100
Nominal Flow Rate (ml/hr)	2	0.5	2	0.5	5	1	2	5	10	10
Nominal Volume (ml)	60	65	100	100	125	270	270	270	270	500
Maximum Volume (ml)	65	65	125	125	125	335	335	335	335	500
Retained Volume (ml)	<=3	<=3	<=4	<=4	<=4	<=9	<=9	<=9	<=9	<=10
Approximate Delivery Time		Fill Volume (ml)								
Hours	Days									
6									69	
12	0.5	27	28		64				129	
18		39	40		94				189	
24	1	51	52		124			129	249	250
30		63	64					159		310
48	2		27	100				249		490
60	2.5		33	124						
72	3		39				153			
96	4		51				201			
120	5		63			129	249			
	6			76		153	297			
	7			88		177				
	8			100		201				
	9			112		225				
	10					249				
	11					273				
	12					297				

Delivery accuracy is ±10% (at a 95% confidence interval) of the labeled infusion period when delivering normal saline at 88° F (31°C).

NOTES:

1. The infusion rate for each Nerve Block pump is labeled on the fill port. Flow rates from 0.5 ml/hr to 2 ml/hr are for small nerve block sites while flow rates from 5 ml/hr to 10 ml/hr are for larger sites.
2. Actual infusion times may vary due to:
 - viscosity and/or drug concentration.
 - fill volumes.
 - positioning the Nerve Block pump above (increase) or below (decrease) the catheter site.
 - temperature: the Nerve Block flow restrictor (located distal to the filter) should be close to, or in direct contact with, the skin (31°C/88°F). Temperature will affect solution viscosity, resulting in shorter or longer delivery time. If the Nerve Block pump is used with the flow restrictor at room temperature (20°C/68°F), delivery time may increase by approximately 25%.
3. This product uses DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the administration set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.

Infusion is complete when the Nerve Block pump is no longer inflated.

CAUTION

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

For Customer Service
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 (949) 206.2700



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REF NB100100
PART NO. 500XXXXX

I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

NERVE BLOCK INFUSION KIT

100 ml Vol x 10 ml/hr



STERILE



LOT

SEE DIRECTIONS FOR USE. CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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CONTENU / CONTENIDO: 1



REF NB100100

I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

PART NO. 500XXXX

NERVE BLOCK INFUSION KIT

100 ml Vol x 10 ml/hr

CONTENTS: 1 each - 100 ml Vol, 10 ml/hr Nerve Block Pump
1 each - 18GA x 2 inch Touhy Needle
1 each - 20GA Epidural Catheter Set
1 each - 60cc Syringe
1 each - Transparent Dressing
1 each - Hemostasis Valve Assembly
1 each - Hookup Wire



STERILE



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SEE DIRECTIONS FOR USE

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CONTENU / CONTENIDO: 1



I-FLOW CORPORATION, LAKE FOREST, CA U.S.A. PART NO. 400XXXX

NERVE BLOCK PUMP

100 ml Vol x 10 ml/hr



STERILE



LOT

SEE DIRECTIONS FOR USE.
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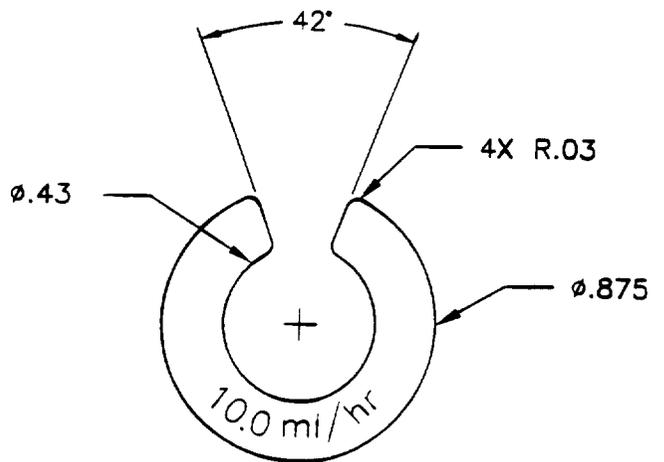
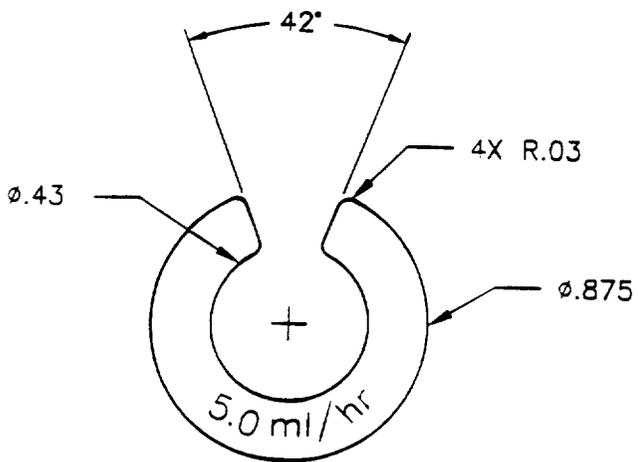
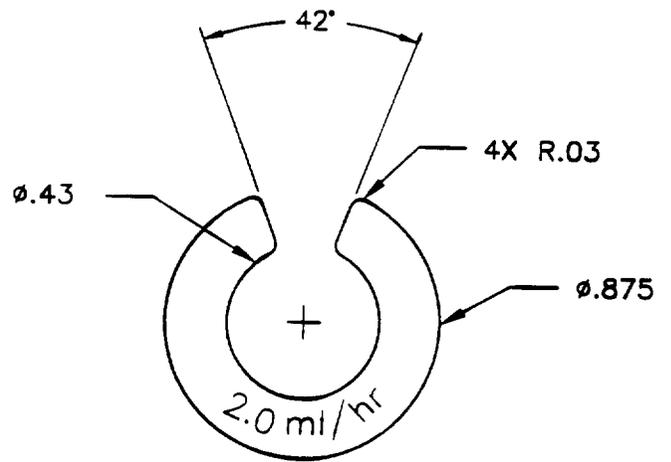
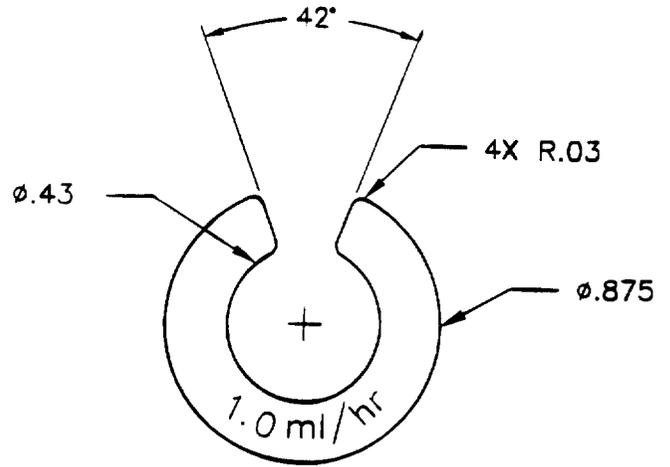
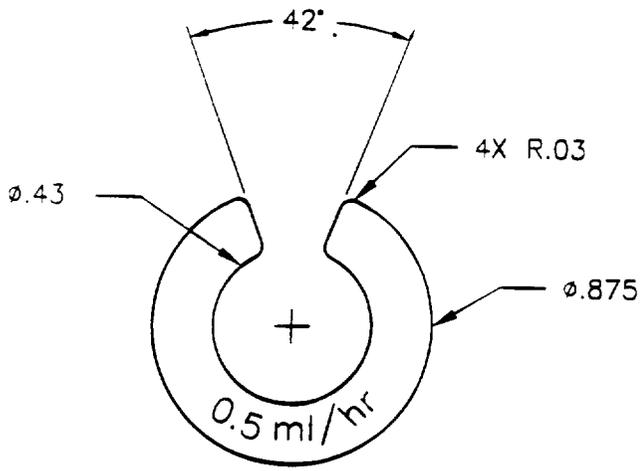
Manufactured by / Hersteller von /
Fabrique par / Fabricado por:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.

CE
0123

European Representative / Europäische Vertretung /
Représentant pour l'Europe / Representante Europeo:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

130XXXXA

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Appendix C
Homepump C-Series
Performance Data

86

Chart #1a
Homepump C-Series
Incremental Flow Rate Profile*
100 ml x 1 ml/hr (NS)

CUMULATIVE AVERAGE FLOW RATE AT 75 hrs*
1.01
1.04
0.98
1.12
1.08
0.98
1.12
5.00
1.05
0.06

*Incremental flow rate is the average flow rate (ml/hr) between time values.

**For QC test criteria, the average flow rate is measured at about [red box] the theoretical delivery time.

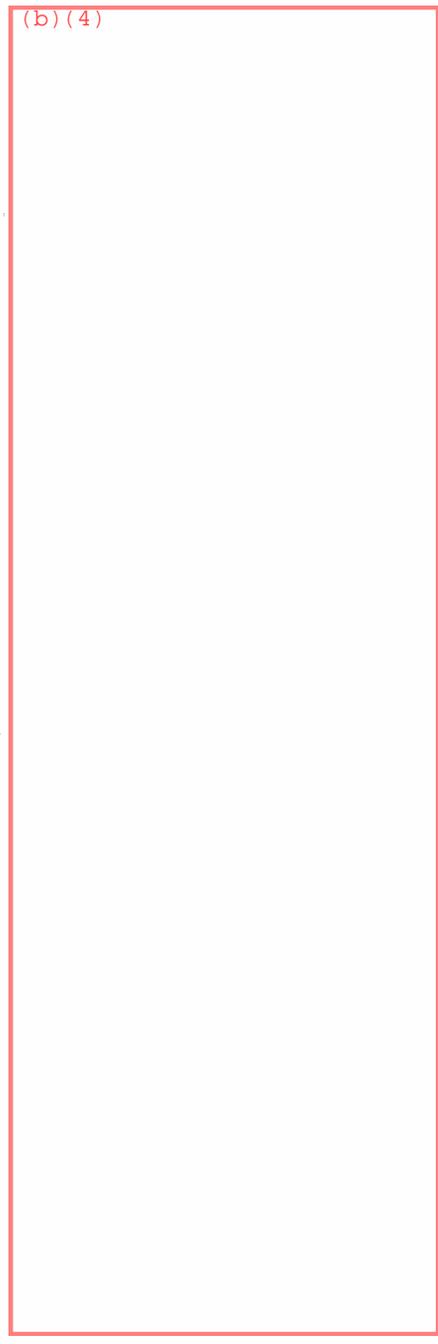
Time (hrs)



Sample # [red box containing (b) (4)]

Min
Max
N
Average
Std Dev.

Handwritten notes:
1.01
1.04
0.98
1.12
1.08



Incremental Flow Rate (ml/hr)

Time (hours)

← Average

87

Unit #2a
Homepump C-Series
Incremental Flow Rate Profile*
100 ml x 2 ml/hr (NS)

CUMULATIVE AVERAGE FLOW RATE AT 37.5 hrs*
2.04
1.99
1.93
2.08
2.01
1.93
2.08
5.00
2.01
0.06

*Incremental flow rate is the average flow rate (ml/hr) between time values.

**For QC test criteria, the average flow rate is measured at about (b) the theoretical delivery time.

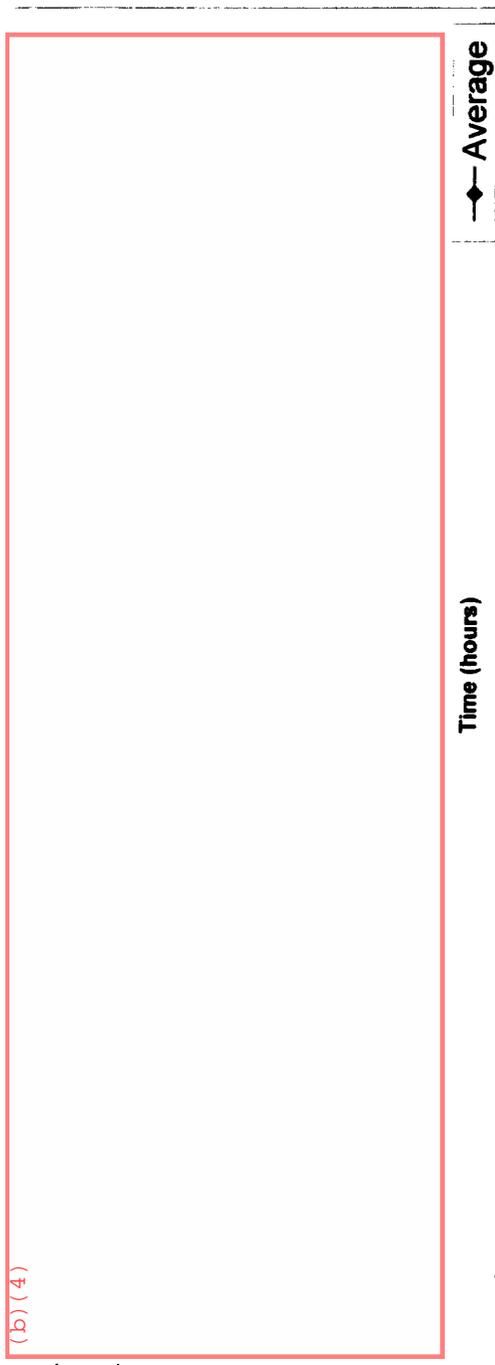
Time (hrs)



Sample #

(b) (4)

Min
Max
N
Average
Std Dev.



Incremental Flow Rate (ml/hr)

Time (hours)

◆ Average

88

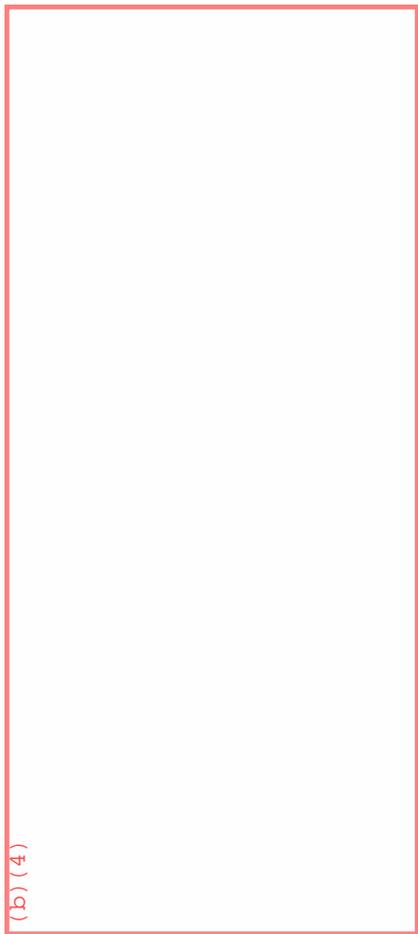
Chart #3a
Homepump C-Series
Incremental Flow Rate Profile*
100 ml x 5 ml/hr (NS)

CUMULATIVE AVERAGE FLOW RATE AT 15 hrs*
5.33
5.30
5.23
5.29
5.20
5.20
5.33
5.00
5.27
0.05

*Incremental flow rate is the average flow rate (ml/hr) between time values.

**For QC test criteria, the average flow rate is measured at about (b) the theoretical delivery time.

Time (hrs)



Sample #

(b) (4)

Min
Max
N
Average
Std Dev.

Incremental Flow Rate (ml/hr)

Time (hours)

◆ Average



Chart #4a
Homepump C-Series
Incremental Flow Rate Profile*
100 ml x 10 ml/hr (NS)

CUMULATIVE AVERAGE FLOW RATE AT 7.5 hrs*
9.97
10.16
9.49
9.97
9.51
9.49
10.16
5.00
9.82
0.30

*Incremental flow rate is the average flow rate (ml/hr) between time values.

**For QC test criteria, the average flow rate is measured at about (b) (4) the theoretical delivery time.

Time (hrs)



Sample # (b) (4)

Min
Max
N
Average
Std Dev.



Incremental Flow Rate (ml/hr)

Time (hours)

◆ Average

90

Unit #5a
Homepump C-Series
Incremental Flow Rate Profile*
270 ml x 2 ml/hr (NS)

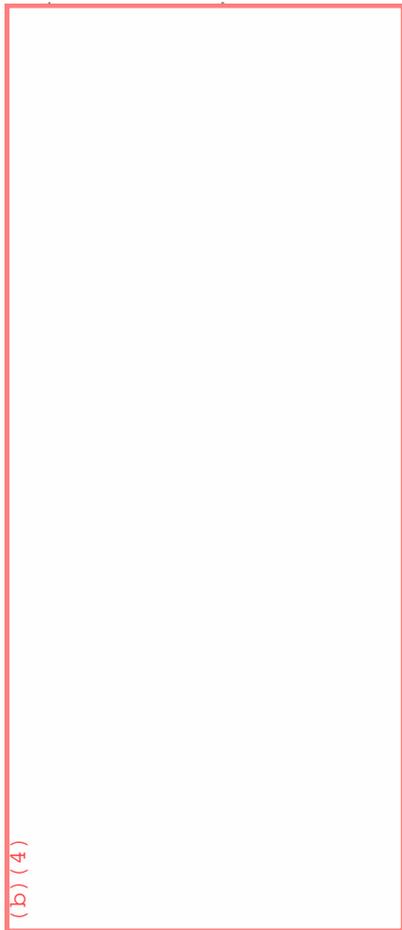
CUMULATIVE
AVERAGE
FLOW RATE AT
105 hrs*

2.06
1.81
2.15
2.00
2.01
1.81
2.15
5.00
2.00
0.13

*Incremental flow rate is the average flow rate (ml/hr) between time values.

**For QC test criteria, the average flow rate is measured at about the theoretical delivery time.

Time (hrs)



Sample #

(b) (4)

Min
Max
N
Average
Std Dev.



Incremental Flow Rate (ml/hr)

Time (hours)

◆ Average

Chart #6a
Homepump C-Series
Incremental Flow Rate Profile*
270 ml x 5 ml/hr (NS)

CUMULATIVE
AVERAGE
FLOW RATE AT
40 hrs*

5.30
5.14
5.25
5.51
5.18
5.14
5.51
5.00
5.28
0.15

*Incremental flow rate is the average flow rate (ml/hr) between time values.

**For QC test criteria, the average flow rate is measured at about (b) the theoretical delivery time.

Time (hrs)



Sample #

(b) (4)

Min
Max
N
Average
Std Dev.



Incremental Flow Rate (ml/hr)

Time (hours)

◆ Average

60

Chart #7a
Homepump C-Series
Incremental Flow Rate Profile*
270 ml x 10 ml/hr (NS)

CUMULATIVE AVERAGE FLOW RATE AT 19.5 hrs*
10.46
10.13
10.40
10.95
10.46
10.13
10.95
5.00
10.48
0.30

*Incremental flow rate is the average flow rate (ml/hr) between time values.

**For QC test criteria, the average flow rate is measured at about (b)(4) the theoretical delivery time.

Time (hrs)



Sample #

(b)(4)

Min
Max
N
Average
Std Dev.



Incremental Flow Rate (ml/hr)

◆ Average

Time (hours)

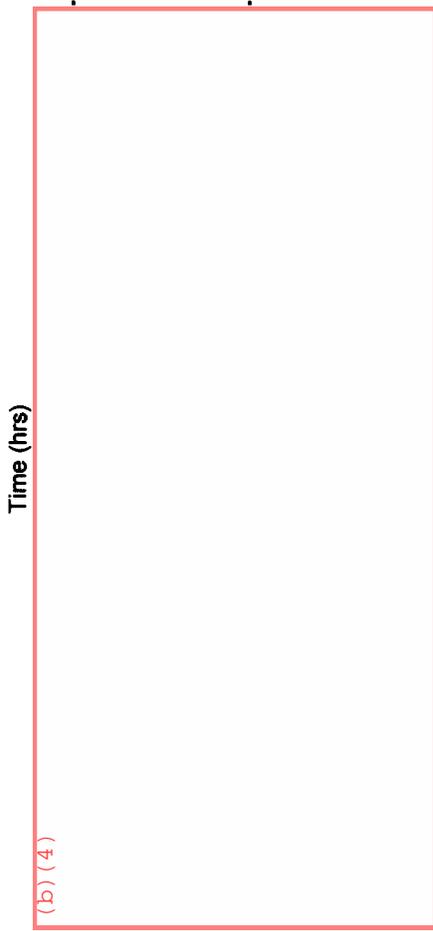
93

Chart #1b
Homepump C-Series
Incremental Pressure Profile*
100 ml x 1 ml/hr (NS)

AVERAGE PRESSURE from 0 to 75 hrs**
5.94
5.79
5.90
5.83
5.77
5.77
5.94
5
5.85
0.07

*Incremental pressure is the average pressure (psi) between time values.

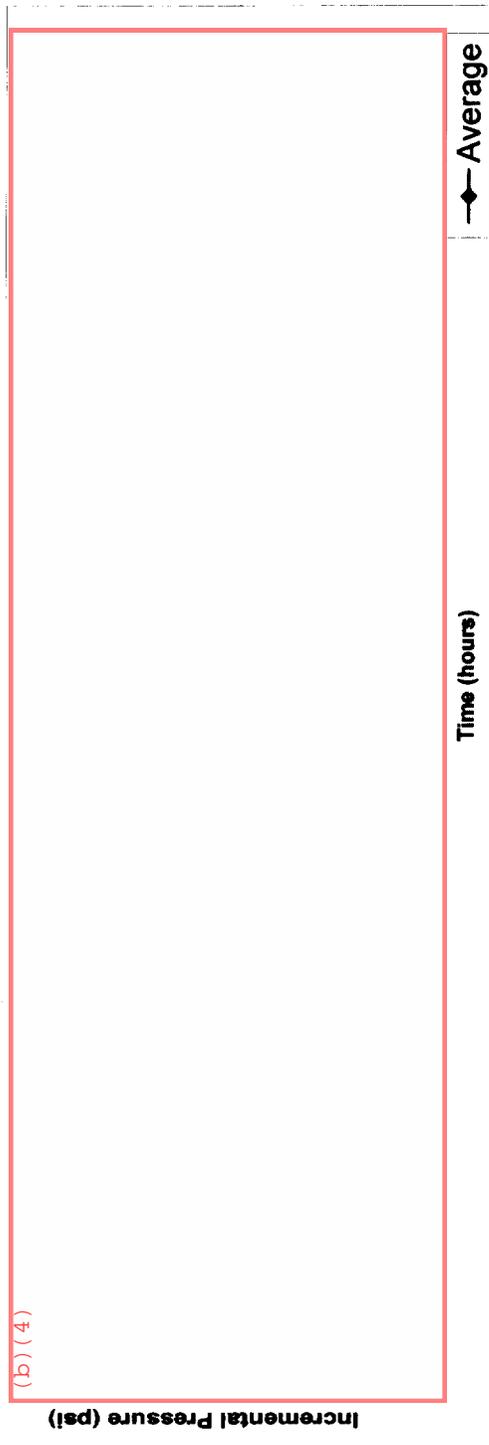
**For QC test criteria, the average pressure is measured over about (b) the theoretical delivery time.



Sample #

(b) (4)

Min
Max
N
Average
Std Dev.



◆ Average

Time (hours)

Incremental Pressure (psi)

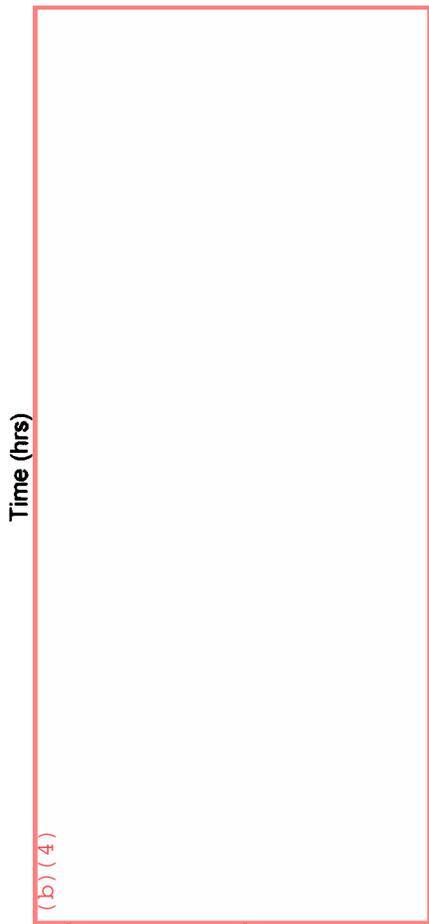
HP

Chart #2b
Homepump C-Series
Incremental Pressure Profile*
100 ml x 2 ml/hr (NS)

AVERAGE PRESSURE
from 0 to 37.5 hrs**
5.64
5.91
5.80
5.81
5.93
5.64
5.93
5
5.82
0.12

*Incremental pressure is the average pressure (psi) between time values.

**For QC test criteria, the average pressure is measured over about (b) the theoretical delivery time.

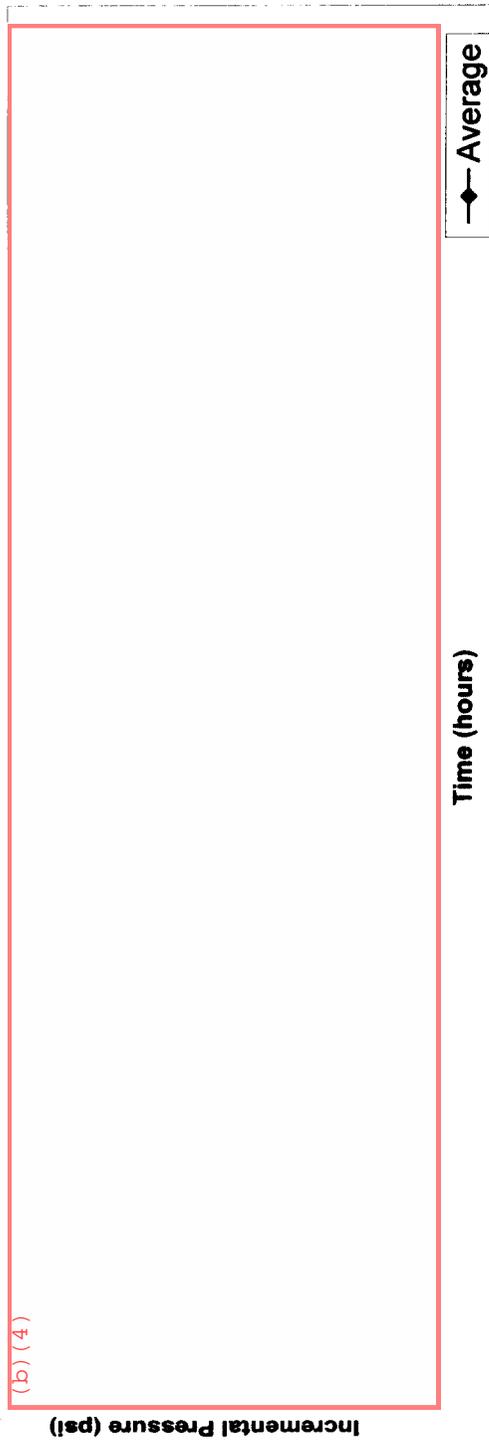


Time (hrs)

Sample #

(b) (4)

Min
Max
N
Average
Std Dev.



Incremental Pressure (psi)

Time (hours)

◆ Average

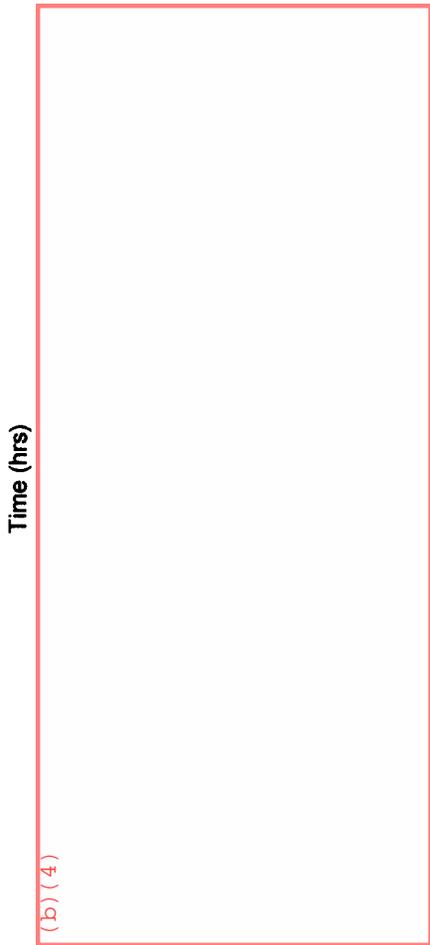
of

Chart #3b
Homepump C-Series
Incremental Pressure Profile*
100 ml x 5 ml/hr (NS)

AVERAGE PRESSURE from 0 to 15 hrs**
6.06
6.28
6.19
6.22
6.12
6.06
6.28
5
6.17
0.09

*Incremental pressure is the average pressure (psi) between time values.

**For QC test criteria, the average pressure is measured over about (b) the theoretical delivery time.



Sample # (b) (4)
Min
Max
N
Average
Std Dev.

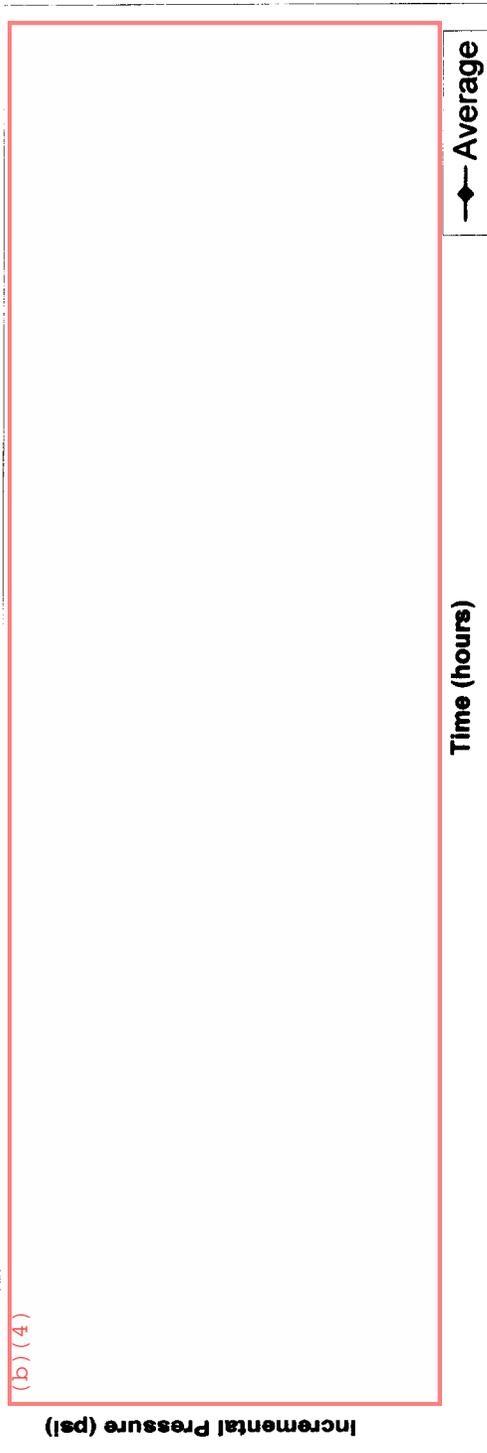
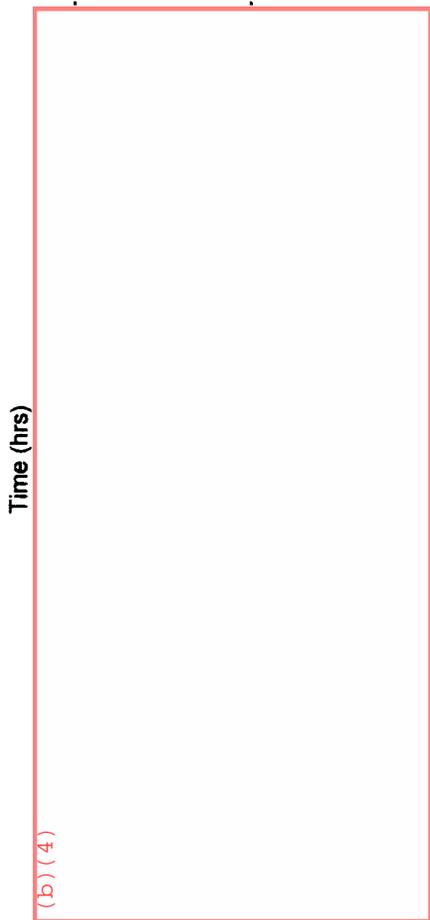


Chart #4b
Homepump C-Series
Incremental Pressure Profile*
100 ml x 10 ml/hr (NS)

AVERAGE PRESSURE from 0 to 7.5 hrs**
6.21
6.32
5.96
6.19
5.98
5.96
6.32
5
6.13
0.16

*Incremental pressure is the average pressure (psi) between time values.

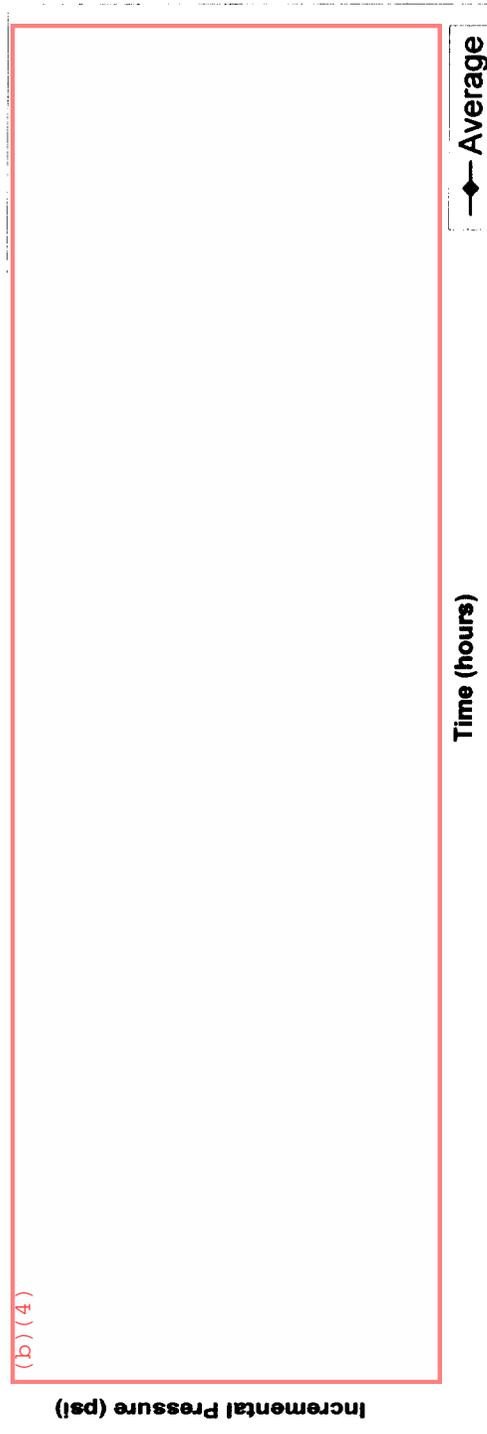
**For QC test criteria, the average pressure is measured over about (b) (4) the theoretical delivery time.



Sample #

(b) (4)

Min
Max
N
Average
Std Dev.



97

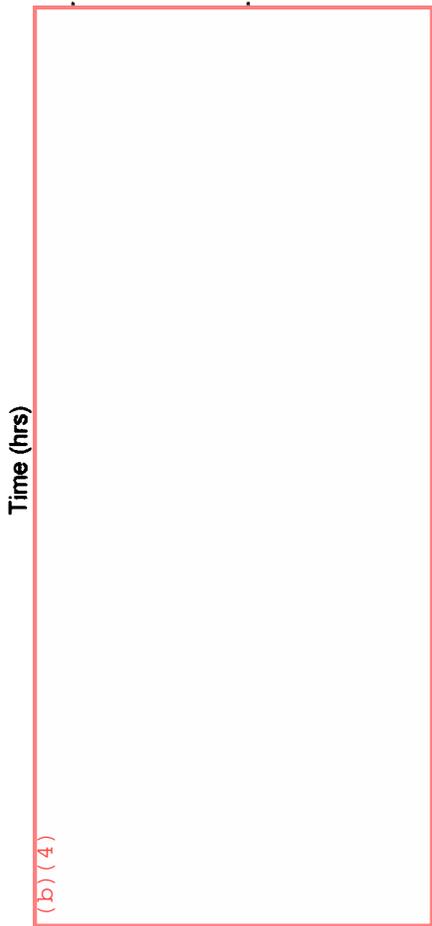
Chart #5b
Homepump C-Series
Incremental Pressure Profile*
270 ml x 2 ml/hr (NS)

AVERAGE
PRESSURE
from 0 to 105 hrs**

6.06
5.95
6.39
5.89
5.99
5.89
6.39
5
6.06
0.19

*Incremental pressure is the average pressure (psi) between time values.

**For QC test criteria, the average pressure is measured over about (b) the theoretical delivery time.



Time (hrs)

Sample #

(b) (4)

Min
Max
N
Average
Std Dev.



Incremental Pressure (psi)

Time (hours)

◆ Average

98

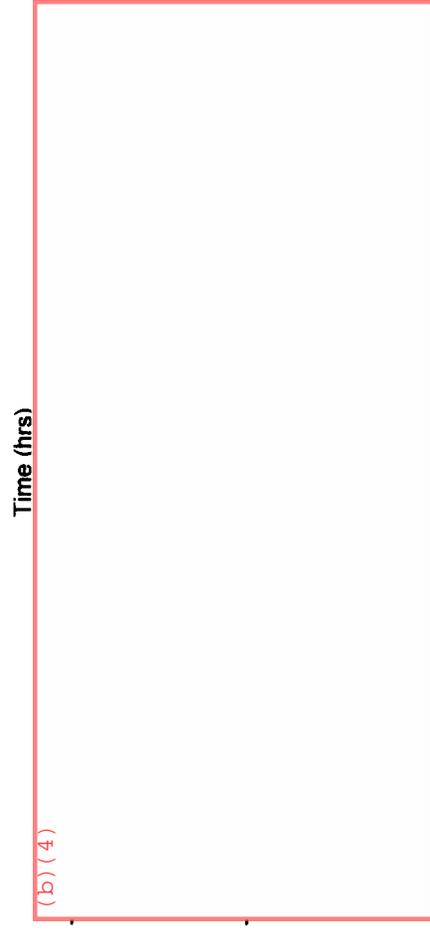
Chart #6b
Homepump C-Series
Incremental Pressure Profile*
270 ml x 5 ml/hr (NS)

AVERAGE
PRESSURE
from 0 to 40 hrs**

6.30
6.23
6.31
5.95
6.27
5.95
6.31
5
6.21
0.15

*Incremental pressure is the average pressure (psi) between time values.

**For QC test criteria, the average pressure is measured over about (b) the theoretical delivery time.



Sample # (b) (4)
Min
Max
N
Average
Std Dev.



◆ Average

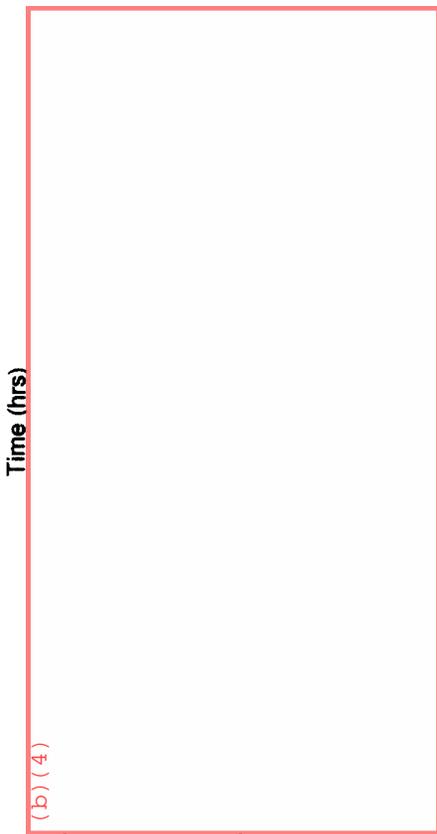
69

Chart #7b
Homepump C-Series
Incremental Pressure Profile*
270 ml x 10 ml/hr (NS)

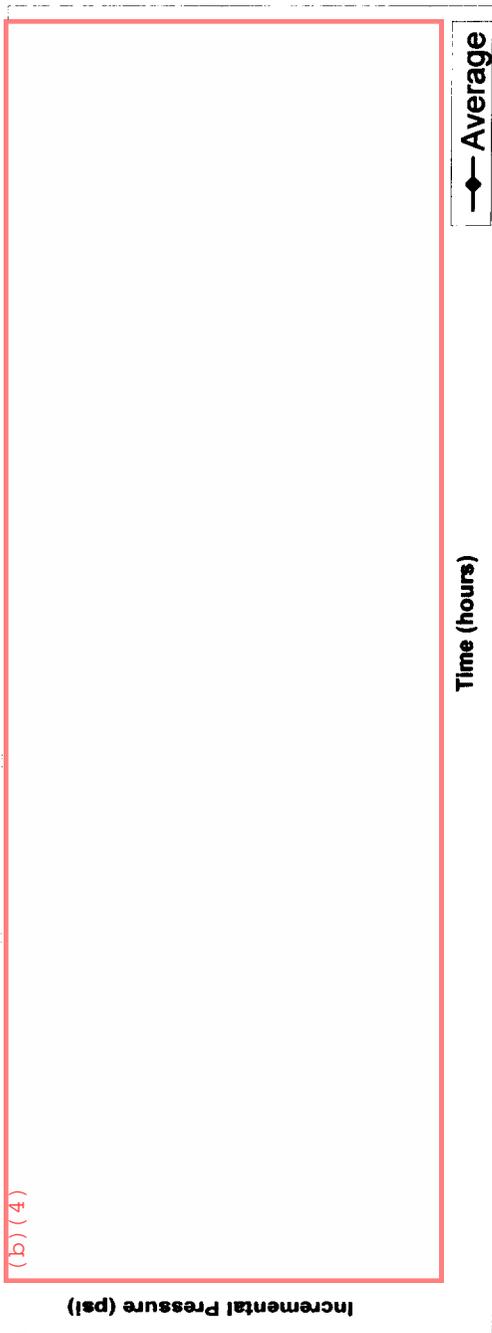
AVERAGE PRESSURE from 0 to 21 hrs**
5.63
5.62
5.82
5.68
5.65
5.62
5.82
5
5.68
0.08

*Incremental pressure is the average pressure (psi) between time values.

**For QC test criteria, the average pressure is measured over about (b) (4) the theoretical delivery time.



Sample # (b) (4)
Min
Max
N
Average
Std Dev.



00

Appendix D
Predicate Labeling

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Homepump C-Series Predicate Labeling

The following contents are example labeling from the Homepump C-Series 65ml Volume, 0.5 ml/hr flow rate model:

- P/N 111111 - Directions for Use
- P/N 1301712 - Flow Rate Label
- P/N 111112 - Pouch Insert
- P/N 1301758 - Pouch Label
- P/N 1301757 - Inner Box Label
- P/N 1301759 - Shipper Box Label

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HOME PUMP

DISPOSABLE ELASTOMERIC INFUSION SYSTEM

DIRECTIONS FOR USE

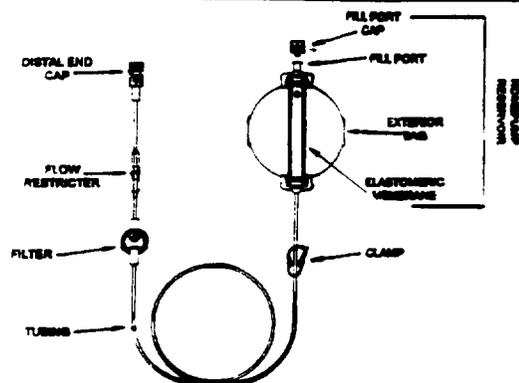
C-SERIES MODELS: C060020, C065005, C100020, C125050, C270010, C270020, C270100

- The Homepump Disposable Elastomeric Infusion System is designed for use by ambulatory patients.
- The Homepump is indicated for continuous delivery of medications through intravenous, intra-arterial, subcutaneous or epidural routes.
- The Homepump is not intended for the delivery of blood, blood products or TPN.
- The Homepump tubing is made of DEHP plasticized PVC.
- Epidural Administration:** Epidural infusion of analgesics is limited to use of indwelling catheters specifically designed for epidural delivery. To prevent infusion of drugs not indicated for epidural use, do not use IV set with additive ports. It is strongly recommended that devices used for administration of medication via epidural routes be clearly differentiated from all other infusion devices.
- Warning:** Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.
- It is the responsibility of the pharmacist to assure, that the medication is prepared and administered in accordance with the drug manufacturer's package insert. It is the responsibility of the healthcare provider to assure the patient is educated on the proper use of this product.
- Refer to Center for Disease Control Guideline for Prevention of Intravenous Therapy-related Infections for specific recommendations regarding the usage of IV administration sets.

- Do not use while showering, bathing, or swimming.
- Do not microwave or submerge in water.
- Do not reuse.

Use aseptic technique.

- Remove filled Homepump from protective plastic bag and verify that the clamp on the tubing is closed.
- Remove distal end cap from tubing. Open clamp. Fluid will fill the tubing set. When all air has been expelled from the tubing set, close clamp.
- Attach the Homepump tubing to the appropriate access site, as instructed by your healthcare provider.
- Begin infusion by opening the clamp.
- When the elastomeric membrane is no longer extended, infusion is complete; disconnect and dispose of the Homepump as instructed by your healthcare provider.



Effects of Environmental Factors (such as storage time, temperature, solution viscosity, backpressure, and/or fill volume) on Infusion Delivery Times

The information below will assist the healthcare provider in understanding these factors:

- C-Series Homepump delivery should be started immediately after filling. Storage of a filled Homepump unit for more than 8 hours prior to starting infusion may result in a 10% longer delivery time.
- If a filled Homepump unit needs to be stored in the refrigerator or freezer, for any reason, allow the unit to warm to room temperature before using: **if refrigerated**, allow 4 hours for C060020, C065005, C100020, C125050; allow 12 hours for C270010, C270020, C270100. **if frozen**, allow 8 hours for C060020, C065005, C100020, C125050; allow 24 hours for C270010, C270020, C270100.

Note: Delivery time can increase significantly as a result of extended storage time.

- The C-Series Homepump System is designed for the infusion tubing to be worn under the clothing, while the Homepump reservoir can be worn in the manner most comfortable to the patient. The Homepump flow restrictor (located distal to the filter) should be close to, or in direct contact with, the skin (31°C/88°F).

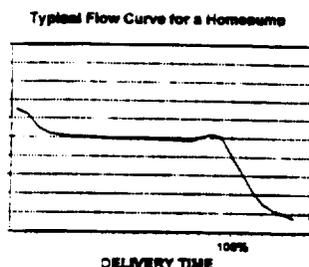
Temperature will affect solution viscosity, resulting in shorter or longer delivery time. If the Homepump is used with the flow restrictor at room temperature (20°C/68°F), delivery time will increase by 25%.

- Homepump delivery times are based on normal saline. Addition of any drug or use of another diluent may change viscosity and result in longer or shorter delivery time: use of D5W will result in a 10% longer delivery time.

- When administering through a central intravenous, arterial, or epidural catheter, follow the instructions provided by the catheter manufacturer. The length, diameter, and position (pressure at catheter tip) may affect delivery time.

- A Homepump filled with more than the nominal volume will infuse at a lower than nominal flow rate.

A Homepump filled with less than the nominal volume will infuse at a higher than nominal flow rate.



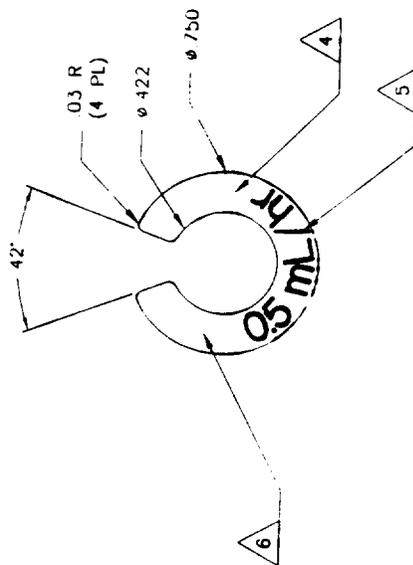
Delivery Time Information for C-Series Homepumps

	C060020	C065005	C100020	C125050	C270010	C270020	C270100
NOMINAL FLOW RATE (mL/h)	2	0.5	2	5	1	2	10
NOMINAL VOLUME (mL)	60	60	100	100	270	270	270
MAXIMUM VOLUME (mL)	60	60	100	100	290	290	290
MINIMUM VOLUME (mL)	2	2	2	2	0	0	0
APPROX. DELIVERY TIME	VOLUME (mL)						
0 h							60
10 h	20		30	75			100
15 h	42			100			200
24 h / 1 d	62		60	125			200
30 h	60						
40 h / 2 d		30	100				
60 h							
72 h / 3 d		40					170
90 h / 4 d		50					210
120 h / 5 d		60			100	200	
0 h					170	200	
7 d					190	220	
0 h					270		
0 h					200		
0 h					240		
11 d					200		
12 d					200		

A PRODUCT OF
I-FLOW
I-FLOW CORPORATION
LAKEFOREST, CA 92630

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REVISIONS		
REV	DESCRIPTION	DATE
A	PRODUCTION RELEASE PER DCO # 2803	5/21/92
		APPROVED <i>Ray</i>



CONTROL COPY
MAY 15 1998
MUST BE IN RED

MATERIAL: FMSH		APPROVALS: <i>[Signature]</i>		DATE: 05/27/97
UNLESS OTHERWISE NOTED ALL DIMENSIONS ARE IN INCHES		DATE: 5/27/97		DATE: 5/27/97
LINEAR: ±0.005		CONCENTRICITY: ±0.005		FLATNESS: ±0.005
ANGLES: ±0.5°		ROUNDEDNESS: ±0.005		
SEE NOTES		DO NOT SCALE DRAWING		
I-FLLOW CORPORATION 10855 Santa Bernarado Rd. CA 92127 (619) 618-7700		TITLE: FLOWRATE LABEL, SNAP CAP.		REV: A
SIZE: 0.5 ml/hr		DRAWING NO: 1301712		REV: A
SHEET: 2 OF 3		JOB NO: 1301712A		

(b) (4)

NOTES: UNLESS OTHERWISE SPECIFIED

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(4 7/8")

HOME PUMP®

DISPOSABLE ELASTOMERIC INFUSION SYSTEM

FOR SINGLE USE ONLY

- Fluid pathway and areas under undisturbed protective caps are sterile and nonpyrogenic.
- Do not remove from package until ready for use.
- Do not use if previously opened or damaged.
- See Directions for Use in the dispenser box.
- Storage: 10°-40°C, 10-90% relative humidity.

INFUSIONSGERÄT ZUR ENMALIGEN VERWENDUNG

- Auf Sterilität und Pyrogenfreiheit geprüft.
- Nicht verwenden, wenn Schutzkappen abgefallen oder geplatzt sind oder wenn Packung beschädigt ist.
- Bitte Gebrauchsanweisung in der Sammelpackung beachten.
- Lagerung: 10°-40°C, 10-90% Luftfeuchtigkeit.

DIFFUSEUR PORTABLE À USAGE UNIQUE

- Stérile, apyrógène.
- Vérifier l'intégrité du protecteur individuel avant usage.
- Se référer au mode d'emploi dans l'emballage de protection.
- Conserver à 10°-40°C, 10-90% humidité.

BOMBA DE INFUSION PARA UN SOLO USO

- Estéril, apirógena.
- No utilizar si el envase unitario no está íntegro.
- Consultar el modo de empleo en la caja dispensadora.
- Conservar a 10°-40°C, 10-90% humedad.

(6 1/2")

STERILE EO

A PRODUCT OF

 I-FLOW CORPORATION
 LAKE FOREST, CA 92630
 USA

CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on order of a physician.
 U.S. Pat. Nos. D324,911; 5,080,652; 5,105,983; and Foreign Pat. Pend.
 Assembled in Mexico 111112, Rev. B

TITLE: C-Series pouch insert			
DRWG NO:	111112	REV:	B
SHT	3	OF	4
		PRINTED AT	100 %

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PRODUCT OF / EINE PRODUKT VON / UN PRODUIT DE / UN PRODUCTO DE

CONTENTS / INHALT /



CONTENU / CONTENIDO: 1

I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

REF C065005
PART NO. 5001013

Homepump ECLIPSE® C-Series 65 ml Volume, 0.5 ml/hr

Assembled in Mexico



STERILE EO



LOT

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.
SEE DIRECTIONS FOR USE.

Manufactured by / Hersteller von /
Fabrique par / Fabricado por:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.

CE
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European Representative / Europäische Vertretung /
Representant pour l'Europe / Representante Europeo:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunsfels, Germany
13017568

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PRODUCT OF / ENE PRODUKT VON / UN PRODUIT DE / UN PRODUCTO DE 6
CONTENTS / INHALT / CONTENU / CONTENIDO:



I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

MODEL NO.: C065005

PART NO.: 5001013

Homepump ECLIPSE® C-Series 65 ml Volume, 0.5 ml/hr

Printed in U.S.A.

Assembled in Mexico



STERILE EO

LOT

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN. SEE DIRECTIONS FOR USE.

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Lake Forest, CA 92630 U.S.A.

European Representative / Europäische Vertretung /
Représentant pour l'Europe / Representante Europeo
MPS Medical Product Service GmbH
Bonnigasse 20, 35619 Braunfels, Germany



130175/A

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CONTENTS / INHALT / CONTENU / CONTENIDO: 24



A PRODUCT OF / EINE PRODUKT VON / UN PRODUIT DE / UN PRODUITO DE

REF C065005

PART NO. 5001013

I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

Homepump ECLIPSE® C-Series 65 ml Volume, 0.5 ml/hr

Assembled in Mexico



STERILE EO



LOT

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN. SEE DIRECTIONS FOR USE

Manufactured by / Hersteller von /
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European Representative / Europäische Vertretung /
Représentant pour l'Europe / Representante Europeo
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunsfels, Germany
13017588



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U.S. Food and Drug Administration

DETAILED INFORMATION

Device Classification Name	CONTROLLER, INFUSION, INTRAVASCULAR, ELECTRONIC
510(k) Number	K896907
Device Name	3M IV FLOW REGULATOR
Applicant	3M CO. 1120 RED FOX ROAD ST. PAUL, MN 55112
Contact	VON BUSCH
Product Code	LDR
Date Received	12/08/89
Decision Date	02/26/90
Decision	Substantially Equivalent
Classification Advisory Committee	General Hospital
Review Advisory Committee Type	General Hospital Traditional

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(Database Updated February 5, 1999)

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The 3M IV Flow Regulator



The accuracy of an electronic infusion device in a gravity IV flow regulator.

In clinical tests, the 3M IV Flow Regulator not only held the set rate throughout patient position changes far more successfully than other gravity flow devices tested, its rate accuracy was comparable to electronic infusion devices.

The 3M IV Flow Regulator is designed for use in gravity flow situations where the safety and security of a constant, accurate IV flow rate is desired, but the more specialized features of an electronic infusion device are not needed and available.

The 3M IV Flow Regulator features a unique patented oscillating membrane.

The pressure-sensitive membrane responds to fluctuations in pressure and compensates to provide constant volumetric output and maintain the set flow rate within $\pm 10\%$.

Saves you valuable time.

Set it once, and the rate remains constant. The proven accuracy of the 3M IV Flow Regulator frees you to concentrate on your patients, not their equipment. The 3M IV Flow Regulator offers easy, accurate gravity flow control that enhances safety and saves you valuable time.

Compensates for factors which affect gravity flow.

The 3M IV Flow Regulator is individually calibrated to existing patient conditions and fluid viscosity when the rate is set, and will self-adjust to compensate for factors that affect IV flow rate such as:

- patient movement
- ongoing patient venous pressure changes
- fluid head-height changes



Cross-sectional view of membrane

Set it once and the rate remains constant.

The 3M IV Flow Regulator features a unique oscillating membrane that automatically responds to changes in pressure. It eliminates the need to manually readjust flow settings to compensate for changes in pressure, such as those caused by patient movement.

Works in a wide variety of applications.

The 3M IV Flow Regulator's size, weight and design make it convenient for use with ambulatory patients in the hospital or home. It can be used for a wide range of clinical applications including antibiotics, chemotherapy and lipids with either peripheral or central lines.

With the 3M IV Flow Regulator working for you, you'll have more time to devote to other professional duties. The 3M IV Flow Regulator, flowing with advanced technology for superior patient care.

Specifications and Ordering Information for the 3M IV Flow Regulator

- Model Number 27000
- 18" extension set
- Kink-resistant tubing
- 1 Y-injection site
- 2 piece luer-lock
- 48 units/case

When the specialized features of an electronic infusion device are needed...

3M AVI offers a full line of infusion therapy products designed to meet your clinical needs. AVI Volumetric Infusion Pumps feature the unique AVI cassette and pumping mechanism, $\pm 2\%$ accuracy, easy upline air removal without violating the sterile fluid path, variable occlusion pressure detection with virtually no bolus, and continuous non-pulsatile flow.

For additional information, call:

1-800-336-7657 or write:
AVI, Inc.
3M Health Care
1120 Red Fox Road
St. Paul, MN 55112

In Canada, contact:

3M Canada, Inc.
P.O. Box 5757
London, Ontario N6A 4T1
1-800-265-0446

In clinical tests, the 3M IV Flow Regulator not only held the set rate throughout changes in patient position far more successfully than other gravity flow devices tested, its rate accuracy was comparable to electronic infusion devices.

The 3M IV Flow Regulator features a pressure-sensitive membrane that responds to fluctuations in pressure and automatically compensates to provide constant volumetric output and maintain the set flow rate within $\pm 10\%$.

Set it once and the rate remains constant.

The 3M IV Flow Regulator is individually calibrated to existing patient conditions and fluid viscosity when the rate is set, and will self-adjust to compensate for factors that affect IV flow rate such as:

- patient movement
- ongoing patient venous pressure changes
- fluid head-height changes

The 3M IV Flow Regulator's size, weight, and design make it convenient for ambulatory patients. It can be used for a wide variety of clinical applications including antibiotics, chemotherapy and lipids with either peripheral or central lines.

The 3M IV Flow Regulator features a unique oscillating membrane that rapidly and automatically responds to changes in pressure. It eliminates the need to manually readjust flow settings to compensate for changes in pressure, such as those caused by patient movement.

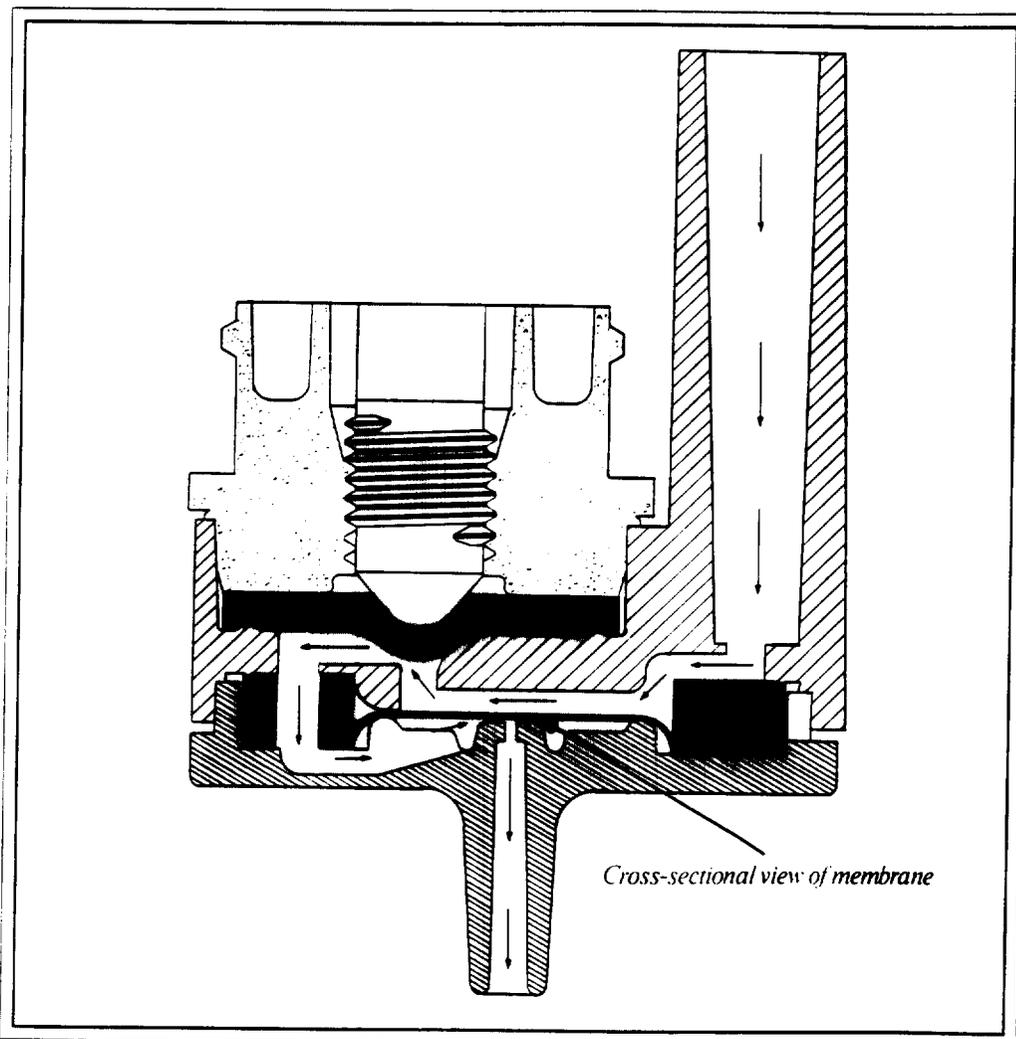
The accuracy of an electronic infusion device in a gravity IV flow regulator.

Proven accuracy helps you save time.

Most gravity flow rates can vary as much as 50%. And the time you spend checking and rechecking can add up to more than 15 minutes per patient, per shift.

With the 3M IV Flow Regulator you have accuracy you can count on. So you're free to concentrate on your patients, not on their equipment.

Whether hospital or home care, the 3M IV Flow Regulator offers easy, accurate gravity flow control that enhances safety and saves you valuable time.



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Appendix E
Summary of Safety and Effectiveness

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I-FLOW
CORPORATION

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Lake Forest, CA 92630
(800) 448-3569 (949) 206-2700
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SUMMARY OF SAFETY AND EFFECTIVENESS

April 29, 1999

Trade Name: Homepump C-Series and Homepump C-Series One-Step KVO

Common Name: Elastomeric Infusion Pump

Classification Name: Pump, Infusion, Elastomeric

All questions and/or comments concerning this document should be made to:

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Vice President of Regulatory and Legal Affairs

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1.0 GENERAL INFORMATION

1.1 Purpose of Submission

1.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow Corporation is adding two new optional components to the Homepump C-Series (K944692).

1.1.1.1 Regulator (optional)

1.1.1.1.1 The optional regulator controls the decreasing pressure (14 to 9 psi) of the Homepump C-Series to a fixed 6.0 psi.

1.1.1.2 Flow Indicator (optional)

1.1.1.2.1 An optional flow indicator component incorporates a flow status column indicator with the glass orifice flow restrictor.

Note: The PainBuster Infusion Kit (K980558 and K982946), the On-Q Infusion Kit (K980558 and K982946) and the Nerve Block Infusion Kit (K984502) use the Homepump C-Series infusion pumps in their kits. Neither the regulator nor the flow indicator components change the intended use of the Homepump C-Series when used in the PainBuster, On-Q or Nerve Block Infusion Kits.

1.2 Statement of Equivalence

1.2.1 The Homepump C-Series is substantially equivalent to the existing I-Flow Homepump C-Series (K944692) and the 3M IV Flow Regulator (K896907).

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTONS

2.1 Description of Device

2.1.1 The Homepump C-Series is an elastomeric infusion pump with an integrated administration set.

2.1.2 The elastomeric membranes function as the fluid reservoir and the pressure source.

2.1.3 The pressure that pumps the fluid comes from the strain energy of the elastomeric membranes which are forced to expand when the pump is filled.

2.1.4 The incorporation of fixed diameter flow control tubing or glass orifice combined with the elastomeric pressure source produces the desired flow rate.

2.2 Product Configuration

2.2.1 Homepump C-Series models are available in fill volumes from 50 to 500 ml and flow rates from 0.5 to 10 ml/hr. The One-Step KVO models of the Homepump C-Series have an optional Y-site and optional check valve attached to the distal end of the administration set.

2.2.2 The following accessories are available: carry case, E-clip and power ring.

2.3 Components and Materials

All fluid path materials are in compliance with ISO 10993 Part 1.

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2.4 Power Requirements

2.4.1 The Homepump C-Series is a mechanical device that utilizes elastomeric membranes for power. No additional external power is required.

3.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

3.1 Standard Operating Conditions:

Priming/Residual Volume: <= 10 ml for 500 ml volume pump
<= 9 ml for 270 ml volume pump
<= 4 ml for 125 ml volume pump
<= 3 ml for 65 ml volume pump

Operating Temperature: 31°C skin temperature (88°F)

Test Solution: 0.9% NaCl

Pressure Source: 6.0 psi

Head Height: 0"

Flow Rate Accuracy: ±10% at 95% confidence interval

3.2 **Flow Rate and Pressure Performance Data:** Testing occurred at standard operating conditions. All models produced an average flow rate and pressure within the ±10% accuracy claim.

3.3 Safety/Alarm Functions

3.3.1 The Homepump C-Series provides a fixed flow and as such is not subject to fluid runaway conditions similar to that of some electronic pumps.

3.3.2 This device contains no alarms for flow; however, each set may include an optional flow indicator component that indicates the flow status of the device.

3.3.3 This device contains no alarms or indicators to detect air in line or an occlusion; however, each set may include an optional, integrated air-eliminating filter.

4.0 BIOLOGICAL SPECIFICATIONS

4.1 Biological testing is in conformance with ISO 10993 Part 1 for all fluid path components.

5.0 CHEMICAL AND DRUG SPECIFICATIONS

5.1 Compatibility

5.1.1 There are no specific drugs referenced in the labeling for the Homepump C-Series.

6.0 INTENDED USE

6.1 The Homepump C-Series is intended for continuous infusion of medications for general infusion use, including chemotherapy and pain management. Routes of administration include intravenous, subcutaneous, intramuscular and epidural.

6.2 The KVO model of the Homepump C-Series is intended for general purpose drug and/or diluent delivery at a sufficient flow rate to maintain a patient IV line open (i.e. keep vein open). The Y adapter at the distal end of the administration set allows piggyback infusions. The routes of administration include intravenous, subcutaneous and intramuscular.

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- 6.3 The Homepump C-Series is single patient use only.
- 6.4 The Homepump C-Series is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.
- 6.5 No testing has been conducted to determine the efficacy of Homepump C-Series for the delivery of blood, blood products, lipids or fat emulsions. The Homepump C-Series is not intended for the delivery of blood, blood products, lipids or fat emulsions.

7.0 STANDARDS

- 7.1 There are currently no performance standards established for elastomeric infusion pumps.

8.0 PACKAGING

- 8.1 Packaging is suitable for radiation or ETO sterilization.

9.0 STERILIZATION

- 9.1 The methods of sterilization are gamma radiation (cobalt 60) or ETO gas.

10.0 COMPARISON TO LEGALLY MARKETED DEVICES

- 10.1 The Homepump C-Series has the same intended use and routes of administration as the originally submitted Homepump C-Series. The optional regulator of the Homepump C-Series is similar to the 3M IV Flow Regulator.

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