

**EUREKA™-IP
&
EUEKA™-LF
INFUSION PUMP
OPERATOR'S MANUAL**

Universal Medical Technologies Inc.



This guide applies to the EUREKA-IP™ INFUSION PUMP Catalog# 11016

This guide applies to the EUREKA-LF™ INFUSION PUMP Catalog# 11017

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EUREKA™ Infusion Pumps and EUREKA™ IV Administration Sets

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New Zeland - 295537
Singapore - 39680
Poland - 181 349
Russian Federation-2162345
European Union-pending

TECHNICAL ASSISTANCE

If you have any questions concerning the operation of the EUREKA™ Infusion Pump, Please call between 9AM and 5PM PST (Pacific Standard Time) and ask for clinical support. For 24 hour service please try our web site at **www.umtinc.com**.

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1.0 INTRODUCTION

The EUREKA™ INFUSION PUMPS are designed to provide intravenous drug therapy to patients in the hospital, home, clinic or surgery center settings. Health care clinicians (physicians, nurses, pharmacists and others) should be completely familiar with this manual before operating or dispensing this pump. The Eureka-IP and the Eureka-LF are designed and intended to be used with non emergency medications. They should be used with Antibiotic and Chemotherapy type drugs in Solution

2.0 GENERAL DESCRIPTION

The EUREKA™ INFUSION PUMPS are designed for intravenous infusions. The delivery rate of the IV solution container is determined by the selection of the EUREKA™ IV ADMINISTRATION SET. The EUREKA™ IV ADMINISTRATION SET is designed to deliver solution at a controlled flow rate. The EUREKA™ INFUSION PUMPS work by producing a constant pressure on the IV solution container placed in the pump chamber.

2.1 PHYSICAL DESCRIPTION

2.1.1 PUMP DESIGN

The EUREKA™-IP and EUREKA-LF INFUSION PUMPS are designed on the principle of displacement. The pumps are designed to maintain constant pressure on an IV solution container to evacuate all of its IV solution. Pressure is controlled and monitored by a sensor and logic controller integrated into the EUREKA™ INFUSION PUMPS. Restrictor tubing controls the flow rate of the IV solution.

2.1.2 PUMP PACKAGING

THE EUREKA™ INFUSION PUMPS are sold as follows

- 1- EUREKA™ INFUSION PUMP (IP or LF)
- 1- Operator Manual
- 1-Battery Recharger / Power Adapter 12V DC 1.25A
- 1-Nickel Metal Hydride Rechargeable Battery Pack 7.2V 1.3AH
- 1-EUREKA™ CARRY PAK

2.1.3 OPTIONAL ITEMS

- Pole Point
- Additional Battery Packs

2.2 IV SOLUTION CONTAINERS

The EUREKA™ INFUSION PUMPS will accommodate

Baxter 50 ml and 100 ml IV solution containers.
Abbott 50 ml and 100 ml IV solution containers

50 mls may be filled to a maximum volume of 58 mls
100 mls may be filled to a maximum volume of 110 mls

Typically these containers have overflow beyond their labeled volumes (typically 5%) and pharmacists must use caution when filling to be sure that additive drug/solutions not exceed the maximum volumes recommended.

Solutions tested for use include

D5W - Dextrose 5% in Water
NS - Normal Saline (.9% Sodium Chloride)

Flow rates vary between solution type. Typically Normal Saline will flow at higher infusion rates than Dextrose 5% in water. Other factors that may affect flow include catheter line type, additional filters and catheter patency. These factors should exert mostly minor flow variations.

Because the tubing has been designed and tested to flow at labeled rates using Normal Saline. Variations in the solution from normal saline to Dextrose 5% in Water will usually result in a slower rate of infusion than the labeled rate. Clinicians should be familiar with fluid osmolarity and viscosity when selecting IV solution.

2.3 INFUSION RATES AND VOLUMES

2.3.1 AVAILABLE FLOW RATES

Currently the Eureka-IP Administration Set flow rates are:

50 ml/hr EUREKA™ IV ADMINISTRATION SET
100 ml/hr EUREKA™ IV ADMINISTRATION SET
200 ml/hr EUREKA™ IV ADMINISTRATION SET

Currently the Eureka-LF Administration Set flow rates are:

1 ml/hr EUREKA™ IV ADMINISTRATION SET
2 ml/hr EUREKA™ IV ADMINISTRATION SET
5 ml/hr EUREKA™ IV ADMINISTRATION SET

2.3.2 EUREKA™ IV ADMINISTRATION SETS

The rates of infusion are determined by the EUREKA™ IV ADMINISTRATION SET specifically designed for the EUREKA™ INFUSION PUMPS. The restriction tubing determines the flow rate. Accuracy +/-12% of the labeled rate. The ring design on the IV spike allows for a firm and secure placement of the administration set and IV solution container in the EUREKA™ INFUSION PUMP.

**Caution: Flow rates at beginning and end of infusion will have flow rate variations.
(See tubing set labeling for graph)**

DO NOT USE ANY ADMINISTRATION SET OTHER THAN THE EUREKA™ IV ADMINISTRATION SET. ONLY THE EUREKA™ IV ADMINISTRATION SET WILL FUNCTION PROPERLY WITH THE EUREKA™ INFUSION PUMPS. ANY OTHER IV ADMINISTRATION SET MAY CAUSE DAMAGE TO THE EUREKA™ INFUSION PUMP OR CAN DELIVER MEDICATIONS AT UNCONTROLLED FLOW RATES.

2.3.3 FLOW RATE VARIABLES

The Eureka Administration Sets are designed to meet the labeled flow rates for use at room temperature of 68-75 degrees F using normal saline. Result between D5W and Normal Saline at room temperature are within normal flow rate accuracy (+/- 12%).

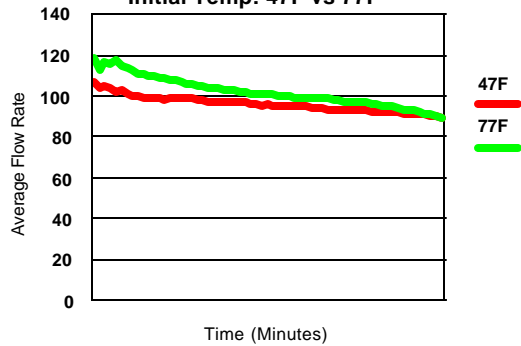
However, increases in fluid viscosity or decreases in solution temperature can result in a decreased (slower) fluid flow rate. Clinicians should be familiar with solution viscosity and temperature effects on viscosity and anticipate flow rate variations relative to these variables.

Effect of Temperature

Normal Saline 100 ml (Baxter)

100 cc/hr

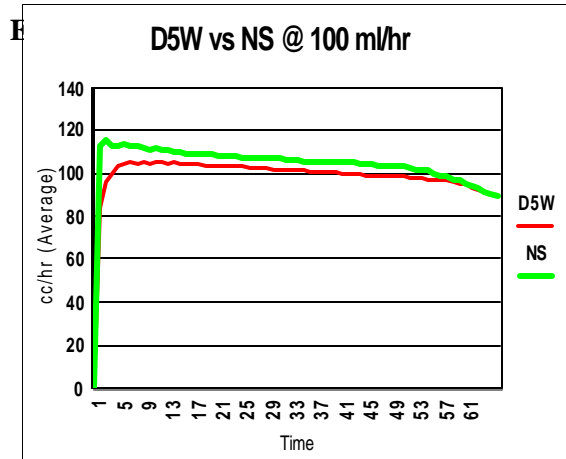
Initial Temp: 47F vs 77F



Flow Rate Effect of Temperature

NS 100cc volume @ 100cc/hr labeled rate

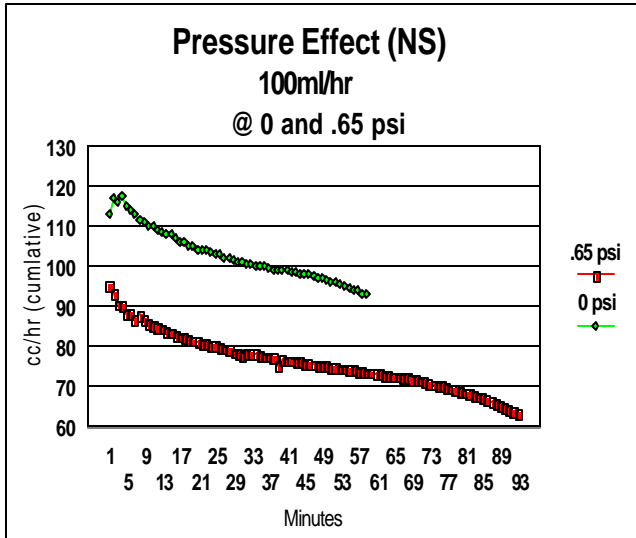
	47 F	77 F	
15 minutes	98	108.6	cc/hr
30 minutes	96.5	101.8	cc/hr
45 minutes	93.7	98.4	cc/hr
60 minutes	91.5	93.2	cc/hr



Flow Rate Effect of Viscosity

	NS	D5W	
15 minutes	113	105	cc/hr
30 minutes	108	102	cc/hr
45 minutes	105	100	cc/hr
60 minutes	98	95	cc/hr

Effect of Pressure (NS=Normal Saline)



**Flow Rate Effect of Pressure
(Static Back Pressure)
NS 100cc @ 100cc/hr**

	0 PSI	0.65 PSI
15 minutes	108.6	84.4 cc/hr
30 minutes	101.8	79.1 cc/hr
45 minutes	98.4	76.3 cc/hr
60 minutes	93.2	73.7 cc/hr

Tubing Set flow rate is not affected by normal venous pressure. This device is indicated for use under normal venous pressure (.18psi).

Flow rates may be affected by occluded catheters.

This device is NOT intended for arterial drug administration

3.0 OPERATING INSTRUCTIONS

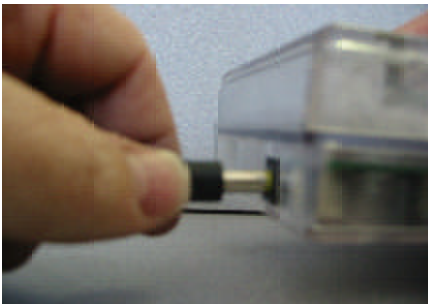
3.1 CHANGING BATTERIES / RECHARGING / DC ADAPTER



Slide open Battery Door.
(Pressing on Red Circle on bottom of case will make
slideing the battery door easier.)



When battery door is down., disconnect battery ca-
bling. Slide battery pack out to replace.



ADAPTER Connection
Charging Battery and connecting External
Power Supply: Plug into connector and
verify proper connection by checking
External Power light is Illuminated (Green).

Changing batteries is NOT likely to be required for most user as the Pump is designed for easy recharge without battery removal. Battery removal instructions are intended for clinicians and the occasional user who is instructed to change batteries by their clinician.

3.2 EXTERNAL POWER SUPPLY

Utilize Eureka supplied Power Adapter ONLY. Recharge time is between 30-60 minutes during non-operation. Charging during use may result in slightly longer times before full charge is achieved. Full charge can be determined when Battery Charged Light illuminates **WHILE** external power charger is connected

3.3 BATTERY INDICATORS

Battery Charged LED Illuminated means the Battery is charged

Battery Charged LED NOT Illuminated means Battery Charge Recommended

Battery Low LED Illuminated means Recharge immediately

Once the Battery Low has become activated unit should be recharged immediately.

While the unit may operate for up to 30 minutes more after the Battery low indicator alert first activates, it is required that the external power charger be connected as battery power will rapidly deteriorate.

It is recommended that the battery be charged when the charged indicator no longer illuminates after the completion of an IP infusion (50,100,200 ml/hr) and upon illumination when corresponding to an LF type infusion (1, 2, 5 ml/hr).

For Low Flow Infusions the unit can safely and easily be recharged during operation either for 30 minutes-1 hour or it can remain connected during nighttime by connecting to the Eureka Power Supply. For short Eureka-IP Infusions (15 min to 2 hour) it is recommended that the infusion be completed when the battery charged indicator no longer illuminates and after disconnecting the IV set from the patient the unit can be safely and easily charged. A new ambulatory infusion should not be initiated without the battery charged indicator on and fully recharging the unit prior to treatment is recommended. A low battery indicator requires immediate recharging attention within 15-30 minutes from the time the indicator first alarms as power will rapidly decrease from that point and our recommendation is a required connection

3.4 BATTERY LIFE (Typical Charge Times)

Initial charge time (average)	22 minutes
Subsequent charge times (range)	30 minutes- 60 minutes

“Conditioned Battery” Life (Typical Usage Time)

Battery Life typical time in each stage

Euerka-LF with LF Intravenous Administration Sets

Battery charged light illuminated	9 hrs Optimal
Battery illuminated alternates between On and Off	1 hrs Optimal
NO Battery charge LED No battery Low LED	5 hrs (Recharge Recommended)
No Battery LED alternates with Battery Low LED/Alarm	30 min (Must Recharge Immediately)
Battery Low LED Illuminates/Alarms Continuously	15 min (Not for Use)

Euerka-IP with IP Intravenous Administration Sets (typical continuous use)

Battery charged light illuminated	2.1 hrs Optimal
Battery illuminated alternates between On and Off	1/4 hr Optimal
NO Battery charge LED No battery Low LED	5-6 hrs (Recharge Recommended)
No Battery LED alternates with Battery Low LED/Alarm	30 min (Must Recharge Immediately)
Battery Low LED Illuminates/Alarms Continuously	15 min (Not for Use)

3.5 ENGAGING TUBING

Follow instructions on page 11.

Make sure Tubing set clamp is closed.

Spike IV Bag



3.6 PLACING BAG IN PUMP

Position Bag in Pump as follows:

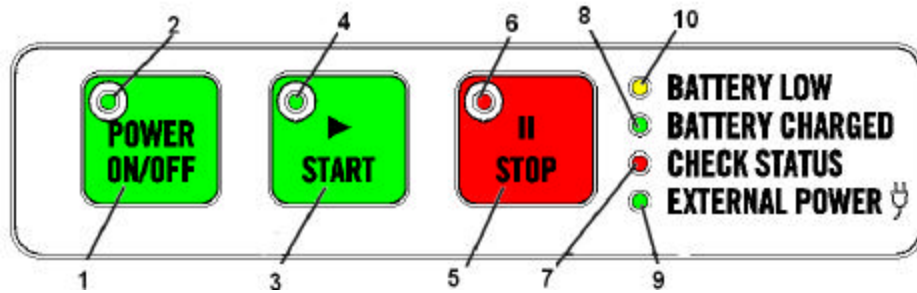
Place pump on flat surface. Place bag so that Spike Flange rests in slot before case outlet, and aligns with lever switch.



Close cover and slide Latch
Bar To Lock Cover Lid



3.7 PUMP OPERATIONS



3.7.1 USING THE EUREKA™ INFUSION PUMP

1. Engage EUREKA™ administration set and IV solution container per administration Set instructions.
 2. Turn EUREKA™ Infusion Pump on by depressing the POWER button (1). Power Light (2) will go on.
 3. Open Pump Lid- AVOID TOUCHING THE BLADDER AREA OF CAVITY CHAMBER.
 4. Place Bag in pump cavity.
 5. Secure EUREKA™ IV Administration Set spike and port securely in designated area.
 6. Close and latch Lid.
 7. Check Battery Low light (10). If light is illuminated then turn power off by pressing and holding Power button for 2-3 seconds, change or recharge battery and repeat step 1.
 8. Connect to patient IV access line.
 9. Begin Infusion by pressing START (3) and releasing clamp on Eureka™ Administration Set
Infuse GREEN Light (4) will illuminate and pump will begin
 10. Place pump in EUREKA™ Carry Pak or the EUREKA™ Pole Mount Holder or place in a secure area for infusion.
 11. Pump will cycle on till fully pressurized and then will cycle on and off at short intervals throughout infusion.
 12. When the pump cycle is off for 5 minutes then the RED Check Status Light (7) will Flash and an audible Tone will sound. This means:
 - a. Check time elapsed and solution container to verify appropriate infusion time has completed.
 - b. If time elapse is incorrect or solution remains then DOUBLE PRESS STOP (5). Check tubing for occlusions, kinks or closed clamps on Administration set or IV access site. Also check for clogged filter or other obstructions and correct problem
 - c. If the infusion is not complete and there are no line obstructions, call your clinician for further instructions
 13. When infusion is complete PRESS STOP (5) for 2-3 seconds. Close clamp on administration set.
 14. Disconnect per clinician instructions
 15. The pump can be operated using while charging with the Eureka Power Supply. While in operation with the power supply or while charging the External Power Light (9) will illuminate. When the battery has been fully charged the BATTERY CHARGED Light will illuminate (8).
- You should place the pump in a secure location The pump will automatically shut off when the not in use for 5 minutes. The Battery should be Recharged daily by connecting to the Eureka Power Supply.

3.7.2 WARNINGS AND ALARMS

1. **POWER** Light **GREEN** (2) indicates pump is ON when illuminated. **POWER** up sequence at powering ON of unit consists of a continuous tone and all lights illuminated for 1 second.
2. **START** Light (4) will illuminate **GREEN** when in infusion process. Press for 1 beep to initiate.
3. **STOP** Light (6) will blink **RED** while in stop mode or pause mode is activated. **STOP** must be pressed for 2 beeps to prevent accidental stoppages during an infusion and will emit 2 short beeps.
4. **CHECK STATUS** Light (7) will illuminate **RED** and 3 short intermittent audible tones will alarm. **CHECK STATUS** will indicate when an infusion is complete, an occlusion or error condition occurs.
5. **BATTERY LOW** Light (10) will illuminate **YELLOW** and a continuous audible tone will emit when pump is turned on and when battery power is insufficient for a complete infusion.
6. Initial audible and visual indicators will be activated when powering ON. A continuous audible tone will alarm and all Lights will illuminate for 1 second.
7. If the lid is not securely latched **and** the Spike is not properly in place when **START** key has been depressed, the **CHECK STATUS** Light (7) will illuminate and an audible tone will alarm.
8. When the Battery Charger/External Power Adapter is connected the **EXTERNAL POWER(9)** Light will illuminate **GREEN**. If light fails to illuminate then check plug connections. If problem still persists then call your clinician.
9. When the battery has reached a Full Charge with the External Power adapter connected the **BATTERY CHARGED** (8) Light will illuminate **GREEN**.
10. **BATTERY LOW** Light will illuminate **YELLOW** and beep (3 times) if battery power is insufficient for a complete infusion.
11. **POWER OFF** sequence of unit consists of a 2 beeps. Power off during infuse mode will Revert to Stop mode only. Complete **POWER Off** must be achieved from **STOP** mode

NOTES:

Removing the external Power connector prior to the Battery Charged cycle completion may result in a Battery Charged signal that indicates the battery is charged above its set point but not necessarily to its fullest potential.

A full battery charge will be obtained only when the external power charger is kept connected and then the Battery Charged light illuminates. Early removal of the External Power Adapter may still result in a Battery Charged signal but this may not signal a full charge only a partial charge.

Reconnecting the external power after the Battery has reached a full charge will result in a 6-12 minute delay of the Battery Charged indicator illuminating. This is due to the charging circuitry which runs tests of the battery prior to signaling that it has reached a full charge.

It is possible that the Battery charged LED will go on and off when the pump pressurizes each cycle. This indicates that the battery is at the low end of the charge cycle. When the Battery Charged indicator no longer goes on then it is recommended that the Battery Pack be recharged, as Battery life will rapidly deplete and a Low Battery condition will occur should a new infusion be started.

FUNCTION KEYS

START-Starts or restarts infusion cycle- Press once when Power is ON

STOP- hold press (2 seconds or 2 beeps) to stop or pause operation

POWER ON/OFF-Power ON (Press once)

Power OFF (hold press for 2 seconds/2 beeps)

Cover Release -Slide lid open latch while in STOP mode to open lid for removal or placement of IV solution container

Other Safety Features Include

1. Sensor for excessive pressure (over 6.5 psi) to prevent against hazards.
2. Tubing set in Place - Pump will not infuse without spike set in chamber Check Status Alarm will occur.
3. Lid Closed - Lid must secure spike set Inflation of pressure chamber will activate set removal alarm. Check Status Alarm will occur.
4. Battery Low indicator signals when power is too low for completion of a full infusion.

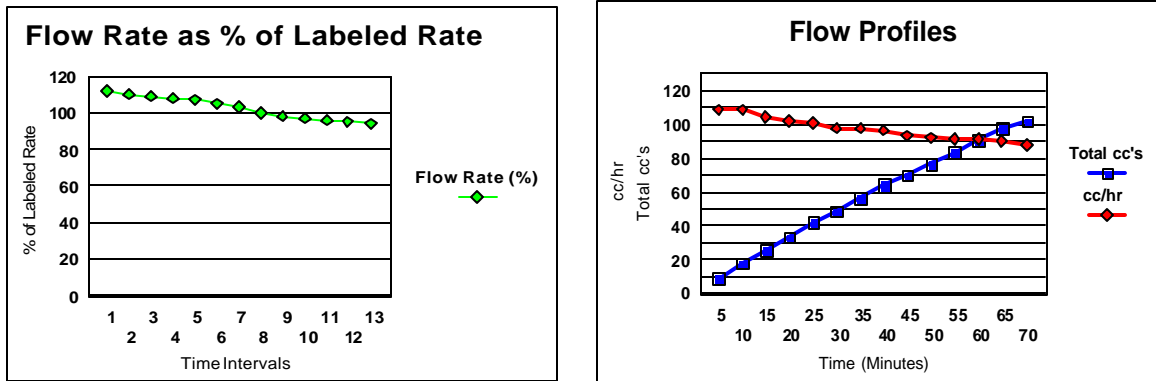
3.7.3 TROUBLESHOOTING

If a **Check Status** Alarm is activated

1. Check Infusion volume remaining
If infusion solution remains then
2. Check IV line for occlusion or Kinks
3. Restart Pump if necessary

3.8 FLOW RATE PROFILE and TOTAL VOLUME FLOW

EUREKA™ Infusion Pump Administration Set TYPICAL FLOW PROFILE



TYPICAL FLOW RATE RESULTS FOR ADMINISTRATION SET

Labeled Set Rate 100 ml/hr
 Max. fill capacity 110 mls
 Retained Volume 2-4 mls
 Tubing has accuracy rate of +/- 12% of labeled rate
 Tubing is connected with a pediatric 1.2 micron or 0.2 micron vented air eliminating filter
 Results for 100 ml IV solution Container (Piggyback) using .9% Sodium Chloride (Normal Saline)

Approximate delivery Time (Minutes)	Volume Delivered (mls)
15	26
30	52
45	76
60	99
65	103*

*-notes overflow commonly found in solution containers

3.9 DISPOSABLE Instructions (Typical)

Eureka™ IV Administration Set

Disposable

Delivery accuracy : +/- 12% based on 100 ccs Normal Saline Viaflex container

Fluid pathway is sterile and nonpyrogenic. Priming Volume is 1.2 ccs

For intravenous antibiotic delivery only

Caution: If end protector is missing or not in place then the sterility of this device is not guaranteed.

DO NOT use this device if end protector is either missing or not in place.

SINGLE Patient USE ONLY - DO NOT RE-STERILIZE

Not intended for use beyond 24hrs.

Use aseptic technique as instructed by clinician

DO NOT Use while showering, bathing or swimming

Use only with **EUREKA™** Infusion Pumps

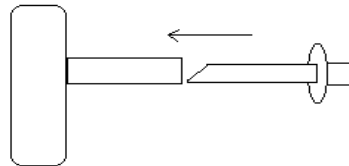
Warning : Flow control clamp must be closed before spiking IV infusion bag or fluid flow will start when spike and IV port are engaged.

To Use:

1. Remove IV tubing from package and clamp tubing line.



2. Remove tab from IV port on solution container.
3. Insert IV spike into IV port.
4. Squeeze Air from infusion bag by holding upright then C Pinch Clamp Note:(Filter is air eliminating once wet)



5. Place sterile connector on luer end of tubing as instructed by clinician.
6. Power on **Eureka Infusion Pump**

7. Properly Place infusion bag with attached infusion tubing into pump
(See **Eureka Pump Manual** for placement instructions)

8. Attach distal end of administration set or clave connector to patient's intravenous access injection site as instructed by clinician.

9. START INFUSION PER EUREKA™ PUMP INSTRUCTIONS

10. Open pinch clamp to allow drug fluid flow.



To Disconnect:

1. At pump signal of Check Status verify complete infusion.
 - a. If infusion has not completed then check the IV tubing line for crimping , closed clamps or obstructed tubing.
 - b. If infusion the time of infusion is finished then proceed to next step.
2. Clamp close tubing by closing clamp on tubing.
3. Disconnect from IV Site.
4. Remove bag and tubing from EUREKA™ INFUSION PUMP.
5. Dispose of IV bag and administration set in appropriate manner.



THE PUMP SHOULD BE REUSED

Caution: Certain solutions may be incompatible with the PVC used in the tubing. The PVC and acrylic plastics in the fluid path of the set meet Class VI Standards of the USP Biological Tests for Plastics. While some incompatibilities are apparent, be aware that subtle physical, chemical or pharmacological incompatibilities can occur. Medical literature, the drug insert and other available sources of information should be reviewed for a more thorough understanding of possible compatibility problems. Adherence to time and temperature limits for the storage and use of medication should be observed.

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

(February 2003)

4.0 REFERENCE SECTION

4.1 GLOSSARY

Administration Set- Tubing and spike attachment that connects solution container and patient's access device

Aspirate - To allow air to vent off. (Also see Purge)

Battery Charged - Battery has reached completion of charge cycle. **NOTE: A fully charged battery may take upto 10 minutes before the indicator signals that the charge cycle is complete.**

Conditioned Battery - a battery that has gone through its initial charge cycle and been fully depleted and then subsequently recharged.

Cycle - pressurization of IV container between high and low set points from maximum pressure (5.0psi) until sufficient fluid has infused to reduce IV container pressure to lower pressure (4.0 psi) at which point bladder pressure is restored to 5.0 psi

AC/DC Adapter- Electronic component that connects AC wall outlet and converts to DC power to operate pump or recharge NiCADD or NiMH batteries

Delivery Volume - The total amount of fluid in IV solution container this includes IV solution, overflow, and drug solution volume

Eureka - Latin for "I Found It"

Fluid path - The IV solution container, IV administration Set and Needle / Luer system all in connection to provide continuous movement of fluid from pump to patient

Infuse - Forward process of moving fluid from IV solution container towards patient

Luer - fitting that connects administration set and needle by means of twisting

Lo Batt- Low Battery Power signal to inform that battery should be changed or recharged or that DC power adapter may be used to recharge NiMH batteries.

LED (Light emitting Diode)- Light source on panel switch

Logic Controller - Electronic device that controls pump.

Prime - To allow small volume of solution through the fluid path from the solution container to the luer end in order to displace air in the IV line.

Purge - To allow air to vent off.

Residual Volume - amount of solution or medication that remains in IV solution container or IV Tubing Set when infusion is completed.

4.2 PUMP CLEANING & MAINTENANCE

Use soft damp cloth only.
Cloth may be dampened with one of the following solutions

Soap and water
70% Ethyl Alcohol
70% Chlorhexidine in Alcohol
70% Isopropyl Alcohol

DO NOT immerse pump in cleaning fluid or water
AVOID contact with bladder membrane
DO NOT UN-CAP needles until lid to Pump is closed.
This is to prevent a bladder puncture from needle sticks.

4.3 PUMP EXPOSURE TO RADIATION OR MAGNETIC RESONANCE IMAGING (MRI)

Pump should not be subject to direct irradiation. Exposure risks permanent damage to the pump electronic circuitry. It is recommended that pump not be in use and be removed during radiation treatments. In the event that the pump use not be discontinued then it should be shielded and following treatment it should be checked for proper function.

Magnetic fields produced by Magnetic Resonance Imaging (MRI) equipment may effect pump opera-

4.4 SPECIFICATIONS

Model - IP Catalog Number 11016 Eureka-IP Pump with Accessories (US)
Model - LF Catalog Number 11017 Eureka-LF Pump with Accessories (US)

Volume range 50-58 ml. for 50 ml. IV solution Container
100-110 ml. for 100 ml. IV Solution Container

Rate - EUREKA-IP based on IV set rates
50 ml/hr
100 ml/hr
200 ml/hr

EUREKA-LF based on IV set rates
1 ml/hr
2 ml/hr
5 ml/hr

Size- 6 7/8"(L) X 3 11/16(W) X 1 7/8"(H)
168 mm (L) x 92mm(W) x 43mm (H)

Weight - 370 gms without Battery
527 gms with Battery Pack
(Doesn't include IV medication container)

Pump Operations

Temperature Range - Recommended at room temperature 60-80 ° F
Accuracy Rate for Volume: 96% IV Solution Infused
Accuracy Rate for Flow Rates : Labeled flow rate +/- 12%
Power Source: 7.2V 1300mAH Rechargeable Battery Pack
Adapter/Recharger as specified for Eureka™ Infusion Pump

Storage

Store Pump at Room Temperature

4.5 ADDITIONAL WARNINGS

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

4.6 LIMITED WARRANTY INFORMATION

Universal Medical Technologies (UMT) warrants to the original purchaser that the Infusion Pump (not including accessories) is free from defects in materials and workmanship under proper use, if used in accordance with this manual, for a period of 90 days from the date of sale to original purchaser. An optional warranty extending this coverage till one year may be purchased at time of sale. Subject to the conditions of and upon compliance with these warranties the Manufacturer will repair or, replace at its option without charge (except for prepaid shipping and handling) any infusion pump which is defective during the warranty period.

The following conditions and limitations apply to the Manufacture's obligation under this warranty:

A. Parties covered by this warranty: This warranty extends only to the original purchaser of the infusion pump. This warranty does not cover purchaser of this device by sale under used condition. The original purchaser may be a patient, medical personnel, a hospital or institution which purchases the pump for patient care. The original purchaser should retain the invoice or sales receipt as record of purchase date.

B. Warranty Performance Procedure: Notice of any defect must be made in writing or by telephone to the customer service department, Universal Medical Technologies, PO Box 5155, Larkspur, CA 94977-5155; Telephone: 1(415)924-1133. Required information includes:

Date of purchase, copy of Invoice, model, and a description of defect. Authorization must be obtained prior to returning this device. The defective pump must be properly packaged and returned postage prepaid. Loss or damage during shipping shall be at risk of sender. It is recommended that pump be insured by carrier when shipped.

C. Conditions of warranty: Warranty shall be void if pump :

- 1) has been repaired by party other than UMT or it's authorized agent
- 2) altered in any way which it's reliability may be affected
- 3) misused
- 4) Damaged by negligence or accident

Misuse includes but is not limited to noncompliance with manual of infusion pump or approved accessories. This pump is a sealed unit, and the fact that the seal has been broken will be considered conclusive evidence that the pump has been altered or misused. Removal or damage to the serial number will invalidate this warranty.

D. Limitations and exclusions: Repair or replacement of infusion pump or component part is the EXCLUSIVE remedy offered by manufacture. The following exclusions and limitations may apply:

1. No agent, representative, or employee of the manufacturer has the authority to bind the manufacture to any representation or warranty implied or expressed.

THERE IS NO CLAIM OR WARRANTY FOR THIS DEVICE OTHER THAN FOR USES AS DESCRIBED IN THIS MANUAL.

2. The infusion pump can only be used under the supervision of medical personnel whose skill and judgement determine the suitability of the infusion pump for a claimed medical treatment.
3. All recommendations, information and descriptive literature supplied by the manufacturer or its agents are believed to be accurate and reliable, but do not constitute warranties.

E. Computer Program License:

1. The infusion Pump is intended to be used in conjunction with a particular Logic control set supplied by the manufacture as part of this unit. Any use of any other logic controller, or unauthorized modification of this logic controller shall void manufactured warranty as defined above.
2. The original purchaser and any users authorized by original purchaser are hereby granted a nonexclusive, non transferable license to use the logic controller only in conjunction with the individual pump supplied as a unit. The licensed logic control program is supplied only in machine readable object code form and is based upon Manufacturer's proprietary confidential information. No rights are granted under this license or otherwise to decompile, produce humanly readable copies of, reverse engineer, modify or create any derivative works based upon the licensed Computer Program.
3. All other terms and conditions of this Limited warranty shall apply to the licensed computer program.

The manufacturer disclaims responsibility for the suitability of the infusion pump for a particular medical treatment or for any medical complications resulting from the use of the infusion pump. The manufacturer shall not be responsible for any incidental damages or consequential damage to property, loss of profits, or loss of use caused by any defect or malfunction of the infusion pump. This warranty gives the original Purchaser specific legal rights, and the original Purchaser may have other legal rights which vary from state to state.

5.0 PRODUCT TRACKING FORM

Important: Distributors are required by the FDA to report to the manufacturer the purchase*, receipt in trade, return after sale, loss, destruction, or retirement from use of any tracked medical device. *If this is an initial purchase from Universal Medical Technologies, you may send a signed copy or fax of the packing list to Universal Medical Technologies in order to comply with your requirement to confirm receipt.

Universal Medical Technologies Inc. Attn: Device Tracking PO Box 5155 Larkspur, California 94977-5155 Telephone (415)924-1133 Fax: (415)924-3612	<h1>Tracked Medical Device Registration Form</h1>
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Distributor Information

			Phone
Address			Fax
City	State	Zip	Completed By

Distributor may list multiple devices from the same manufacturer in the space below. Multiple, sequential serial numbers of devices in the same transaction may be reported using a single entry listing the first and last serial number of the unbroken sequence. Use additional sheets as required.

Model Number	Serial/Lot Number	# of units	Date Received	Received From	Date of permanent Disposition (i.e. loss, destruction, retirement)

If this is a permanent sale to a patient, please report the following information.

Patient Information

Last Name		First Name		Middle Initial
Address			Telephone	
City	State	Zip	Social Security No.	Date Service Provided

Physician Information

Last Name		First Name		Middle Initial
Address			Telephone	
City	State	Zip	Specialty	

