Z-800 Infusion Pump

INSTRUCTIONS FOR USE

Zyno Medical LLC
177 Pine Street
Natick, MA 01760
1-508-650-2008
Fax: 1-508-650-2006
Web: www.zynomed.com

ZYNO MEDICAL

Zyno Medical LLC.
177 Pine Street
Natick, MA 01760
USA

Phone: 1-508-650-2008
Fax: 1-508-650-2006

⚠ **WARNING:**

Only use Zyno Medical provided IV sets with the Z-800 Infusion Pump. There are risks associated with using any IV Sets other than Zyno Medical IV Sets with this device. Zyno's warranty for its device will be null and void and Zyno will assume no responsibility for any incidents that may occur if the device is not utilized strictly in accordance with its product labeling.

SAFETY STANDARD

The Z-800 Infusion Pump meets all applicable safety standards for volumetric infusion pump devices, corresponding to IEC 60601-1 and IEC 60601-2-24.

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ACCESSORIES LIST

PART #	ITEM	Description	NOTE
6601B	Pump Pole Clamp	45 Degree Pole Clamp	Standard Accessory
6602A	Power Cord	Removable 8 feet Hospital Grade AC power cord	Standard Accessory
6617A	Power Cord	Removable 12 feet Hospital Grade AC power cord	Optional Accessory
6611B	Drip Sensor	Drip Chamber-Based Flow Sensor	Optional Accessory
6612B	Secondary Red Alarm/Warning Light	Secondary Red Alarm/Warning Light Visual Indicator (magnetic)	Optional Accessory
6638A	Secondary Blue Alarm/Warning Light	Secondary Blue Alarm/Warning Light Visual Indicator (magnetic)	Optional Accessory

INTRODUCTION

ABOUT THE DEVICE

The Z-800 Infusion Pump is intended to provide accurate delivery of parenteral fluids, blood, and blood products to a human patient when administered by a qualified health care professional.

User Qualification

The Z-800 Infusion Pump is intended for use at the direction or under the supervision of licensed physicians or certified healthcare professionals who are trained in the use of the Z-800 Infusion Pump and the administration of parenteral fluids and drugs, blood, and blood products. This training should emphasize patient safety and prevention of error.

This document provides directions for use of the Z-800 Infusion Pump. To ensure safe usage, please read the entire instruction manual before using the device.

The Z-800 Infusion Pump must only be operated utilizing Zyno Medical's proprietary administration sets. The sets are designed for use with the Z-800 Infusion Pump as well as for gravity-flow stand-alone use. For specific IV Administration Set instructions, refer to the Directions For Use provided with the set. For priming and loading instructions, refer to "Loading Primary Administration Set" and "Loading Secondary Administration Set" sections of this document.

Contraindication: None known.

APPROVED ADMINISTRATION SETS (Continued)

Blood Sets

PART #	ADMINISTRATION SET DESCRIPTION
A2-81071-D	104" Administration set with 1 Needle-less Access Port on the distal side; 2 spikes; drip chamber with 180 micron blood filter; roller clamp, male luer lock; non-DEHP tubing; Latex-free; Approximate priming volume 30 ml

FEATURES

Flow Rates
The Z-800 Infusion Pump flow rate range is from 1 to 1200 ml/h.

Free Flow Protection
The Z-800 Infusion Pump has a built in free flow clamp to prevent inadvertent free flow when the set is loaded in the pump.

⚠ **WARNING:** Some Z-800 IV Sets configurations do NOT have set based free-flow protection. Make sure to close the roller clamp before removing administration set from Z-800 Infusion Pump.

Occlusion Pressure
The Z-800 Infusion Pump provides 14 levels of adjustable downstream occlusion alarm thresholds between 4 psi and 30 psi.

Secondary Infusions
Secondary infusions may be delivered at a specified secondary delivery rate and secondary volume-to-be-infused (VTBI) independent of the primary infusion parameters. When secondary VTBI is greater than zero, the pump will always execute secondary infusion first. Automatic changeover occurs to the primary infusion parameters when the secondary infusion is complete. A Zyno Medical proprietary primary administration set with a back check valve must be used.

System Configuration
The system configuration mode allows qualified personnel to customize device settings.

Tamper Resist
The Tamper Resist feature provides a quick, one touch lockout of the front keypad.

Volume-To-Be-Infused (VTBI)
The volume-to-be-infused (VTBI) range is from 1 to 9999 ml in 1 ml increments.

APPROVED ADMINISTRATION SETS (Continued)

Primary Sets with Anti-Free-Flow Valve

PART #	ADMINISTRATION SET DESCRIPTION
A2-83071-D	105" Administration set with 1 Needle-less Access Port on the distal side; universal spike drip chamber (20 drops/ml); roller clamp, male luer lock; non-DEHP tubing; Latex-free; Anti-Free-Flow Valve; Approximate priming volume 16 ml
A2-83071-P	105" Administration set with 1 back check valve and 1 Needle-less Access Port on the proximal side; universal spike drip chamber (20 drops/ml); roller clamp, male luer lock; non-DEHP tubing; Latex-free; Anti-Free-Flow Valve; Approximate priming volume 16 ml
A2-83072	105" Administration set with 1 proximal Needle-less Access Port; 1 distal Needle-less Access Port; back check valve; universal spike drip chamber (20 drops/ml); roller clamp, male luer lock; non-DEHP tubing; Latex-free; Anti-Free-Flow Valve; Approximate priming volume 16 ml
A2-83070	105" Administration set with universal spike drip chamber (20 drops/ml); roller clamp, male luer lock; non-DEHP tubing; Latex-free; Anti-Free-Flow Valve; Approximate priming volume 16 ml

Primary Filter Sets

PART #	ADMINISTRATION SET DESCRIPTION
A2-80071-DF	105" Administration set with 1 Needle-less Access Port on the distal side; universal spike drip chamber (20 drops/ml); roller clamp, male luer lock; non-DEHP tubing; Latex-free; 0.22 micron IV Express® filter; Approximate priming volume 16 ml
A2-80072-F	105" Administration set with 1 proximal Needle-less Access Port; 1 distal Needle-less Access Port; back check valve; universal spike drip chamber (20 drops/ml); roller clamp, male luer lock; non-DEHP tubing; Latex-free; 0.22 micron IV Express® filter; Approximate priming volume 16 ml
A2-80070-F	105" Administration set with universal spike drip chamber (20 drops/ml); roller clamp, male luer lock; non-DEHP tubing; Latex-free; 0.22 micron IV Express® filter; Approximate priming volume 16 ml
A2-83071-DF	105" Administration set with 1 Needle-less Access Port on the distal side; universal spike drip chamber (20 drops/ml); roller clamp, male luer lock; non-DEHP tubing; Latex-free; 0.22 micron IV Express® filter; Anti-Free-Flow Valve; Approximate priming volume 16 ml
A2-83072-F	105" Administration set with 1 proximal Needle-less Access Port; 1 distal Needle-less Access Port; back check valve; universal spike drip chamber (20 drops/ml); roller clamp, male luer lock; non-DEHP tubing; Latex-free; 0.22 micron IV Express® filter; Anti-Free-Flow Valve; Approximate priming volume 16 ml

SYMBOLS

This CE symbol certifies that the product complies with the essential requirements of the Medical Device Directive 93/42/EEC Medical Device, including 2007/47/EC Amendment.

1282

Electrical Shock Protection Rating: Type BF.

IPX1 Protection against fluid ingress: Drip Proof.

Attention: Refer to accompanying documentation.

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

Fuse: 2X2TA.

APPENDIX

APPROVED ADMINISTRATION SETS

⚠ WARNING:
Use only administration sets labeled as Zyno Medical with the Z-800 Infusion Pump System. The use of any other set for use with Z-800 system may cause improper instrument operation, resulting in inaccurate fluid delivery or other potential hazards.

The following lists some of the most commonly used administration sets approved for use with the Z-800 Infusion Pump System. New administration sets configurations are added frequently. For complete administration set configurations, please visit Zyno Medical's web site at www.zynomed.com.

⚠ CAUTION:
It's recommended to replace Zyno Administration set within 72 hours.

Primary Needle-less Injection Port Sets

PART #	ADMINISTRATION SET DESCRIPTION
A2-80071-P	105" Administration set with 1 back check valve and 1 Needle-less Access Port on the proximal side; universal spike drip chamber (20 drops/ml); roller clamp, male luer lock; non-DEHP tubing; Latex-free; Approximate priming volume 16 ml
A2-80071-D	105" Administration set with 1 Needle-less Access Port on the distal side; universal spike drip chamber (20 drops/ml); roller clamp, male luer lock; non-DEHP tubing; Latex-free; Approximate priming volume 16 ml
A2-80072	105" Administration set with 1 proximal Needle-less Access Port; 1 distal Needle-less Access Port; back check valve; universal spike drip chamber (20 drops/ml); roller clamp, male luer lock; non-DEHP tubing; Latex-free; Approximate priming volume 16 ml
A2-80070	105" Administration set with universal spike drip chamber (20 drops/ml); roller clamp, male luer lock; non-DEHP tubing; Latex-free; Approximate priming volume 16 ml

Secondary Sets

PART #	ADMINISTRATION SET DESCRIPTION
A2-80075	40" Administration set with universal spike drip chamber (20 drops/ml); roller clamp, male luer lock; non-DEHP tubing; Approximate priming volume 8 ml

ALARM TESTING PROCEDURE (Continued)

Battery Test (Continued)

12. All pump configuration parameters are preserved.

13. All current infusion parameters are preserved.

14. If any one of the following is true, contact a qualified service personal to replace the battery:

  - Time interval between the Low Battery Warning and Battery Empty Alarm is less than 15 minutes.
  - Time interval between the Battery Empty Alarm and the pump shut down is less than 2 minutes.
  - Pump configuration setting changed after battery depletion.
  - Any of the current infusion parameters is not preserved.

GETTING STARTED

WARNINGS & CAUTIONS

The following Warnings and Cautions should be strictly followed to avoid harm to patients and pump operators:

⚠ **WARNING:** Zyno Medical assumes no responsibility for incidents that may occur if its product is not used in accordance with its product labeling.

⚠ **WARNING:** Only use Zyno Medical provided IV Sets with the Z-800 Infusion Pump.

⚠ **WARNING:** The Z-800 Infusion Pump operation is strictly limited to trained operators whose competency in safe Z-800 Infusion Pump operation and safe IV therapy practices has been tested and proven.

⚠ **WARNING:** Make sure the pump is stable by fastening securely to an IV Pole, or resting on a flat surface. IV Poles vary in quality and stability. Avoid fastening the pump too high on the pole, and test for stability before using.

⚠ **WARNING:** Prior to use, always verify the proper function of the display, audible and visual alarms.

⚠ **WARNING:** Verify there are no kinks in the tubing when loading into the pump.

⚠ **WARNING:** Always read and follow the instructions that accompany the fluid container and IV Administration Sets you are using. Carefully follow the instructions in this document for loading, removing, and reloading the IV Set. Adjust the pumping section of the IV Set every 24 hours, and replace the IV Set within 72 hours.

⚠ **WARNING:** To prevent free flow, make sure to load the IV Set in the Infusion Pump before connecting the IV set to a patient.

⚠ **WARNING:** To prevent free flow, make sure to disconnect the IV Set from the patient before unloading the IV set from the Z-800 Infusion Pump.

⚠ **WARNING:** Disconnect the IV Set from the patient before purging air bubbles out of IV Tubing.

⚠ **WARNING:** Some Z-800 IV Sets configurations do NOT have set based free-flow protection. Make sure to close the roller clamp before removing IV Administration Set from the Z-800 Infusion Pump.

⚠ **WARNING:** Do not over-program the VTBI. Program the actual amount of the fluid in the IV bag.

WARNINGS & CAUTIONS (Continued)

⚠ **WARNING:** After starting an infusion, make sure drops are falling in the Drip Chamber. If no drops are falling, make sure the Roller Clamp is open. If the Roller Clamp is open and still no drops are falling, replace and dispose of the IV Administration Set.

⚠ **WARNING:** The Air In-Line Sensor cannot recognize the introduction of air at 3-way Stopcocks, Infusion Ports, and other Lines/Tubes below the Infusion Pump.

⚠ **WARNING:** Do not operate this device in the presence of Flammable Anesthetics mixture with Air, Oxygen, or nitrous Oxide

⚠ **WARNING:** Do not expose the Z-800 Infusion Pump to X-Rays, Gamma Rays, or other Radiation, or to strong Electric or Magnetic Fields.

⚠ **WARNING:** The factory default settings should be used unless qualified clinical personnel determine that other customized settings are appropriate and safe.

⚠ **WARNING:** The manufacturer cannot assure the accuracy and/or safety of the Infusion Pump if it is not regularly maintained as recommended in the Z-800 Infusion Pump Instructions For Use Manual.

⚠ **WARNING:** Flow rate accuracy can be affected by one or a combination of the following factors: fluid viscosity; fluid temperature; head height; back pressure; incompatible IV sets or compatible set with unusually small or large diameters or unusually stiff materials.

⚠ **CAUTION:** Please read the entire contents of this manual before using the Z-800 Infusion Pump.

⚠ **CAUTION:** USA Federal and Canadian laws restrict this device to sale by or on the order of a physician.

⚠ **CAUTION:** There are no user serviceable parts inside. Refer all service, repair, and calibration to qualified technical personnel. Do not make unauthorized modifications.

⚠ **CAUTION:** To avoid mechanical or electronic damage, do not steam, autoclave, or immerse the pump in any fluids or cleaning solutions, and do not spray such fluids directly on the pump. Always disconnect electrical power cord from outlet before cleaning to prevent electrical shock. The IPX1 rating means that the pump is protected against vertical dripping water.

⚠ **CAUTION:** Do not attempt to infuse two fluids simultaneously using the Z-800 Infusion Pump.

ALARM TESTING PROCEDURE (Continued)

Battery Test

1. Connect the Z-800 pump to an approved AC power outlet for at least 18 hours to allow the battery to fully charge.

2. Unplug the power cord from the AC power. Turn on the device. Verify that the battery indicator 🔋 is ON.

3. Set a primary infusion with the following:
   - Pri RATE = 125 ml/h
   - Pri VTBI = 1000ml/h

4. Start the infusion. Record the infusion starting time.

5. Record the time when the Low Battery Warning is presented.

6. Verify the following:
   - Pump continues to operate during Low Battery warning.
   - The Battery indicator 🔋 turns red.
   - The warning audio tone and a visual message "Low Battery, Plug in AC power" displays every 10 seconds.

7. Record the time when the Battery Empty alarm displays. Record the VINF, Pri RATE and Pri VTBI parameters at the time of the alarm. Verify the following:
   - Battery Empty alarm continues to sound until user acknowledgement.
   - Infusion stops.

8. Allow the Battery Empty Alarm to continue to sound.

9. Record the time the pump shut itself off.

10. Connect the device to an approved AC power outlet.

11. Turn on the device. Verify 12-14 below.

LOW BATTERY

Plug in AC Power
Immediately

BATTERY EMPTY

Press STOP to confirm

WARNINGS & CAUTIONS (Continued)

⚠ **CAUTION:** Operating the Z-800 Infusion Pump near equipment that radiates high-energy radio frequencies (electrosurgical/cauterizing equipment, portable radios, cellular telephones, etc.) may cause false alarm conditions. If this happens, reposition the device away from the source of interference or use an appropriate clinical alternative.

⚠ **CAUTION:** Always verify displayed infusion parameters (Primary Rate, Primary VTBI, Secondary Rate, Secondary VTBI) with the prescription before starting infusion.

⚠ **CAUTION:** Grounding reliability can only be achieved when equipment is connected to an equivalent receptacle marked "hospital only" or Hospital grade.

ALARM TESTING PROCEDURE (Continued)

Occlusion Alarm Test

1. Program a primary infusion rate for 200 ml/h and VTBI for 50ml.

2. Press the **RUN/STOP** key to start the infusion.

```
ALARM
         OCCLUSION
Press STOP to confirm
```

3. Close the roller clamp on the administration set located directly at the distal side of the pump.

4. After a few seconds, the infusion status indicator will turn blinking red, audio alarm will sound, and the Main Display will show alarm screen with "Occlusion". The infusion will stop.

```
CONT  STP\INF0000mL 🔋
         PAUSED
* * *OCCLUSION* * *
                      PROG
```

5. Press the **RUN/STOP** key to acknowledge the alarm condition. The Z-800 Pump will be in PAUSE state. The "PAUSE" message will appear on the screen.

Ⓘ

6. Open the roller clamp to release pressure. Press the **RUN/STOP** key again to resume infusion.

Time Delay to Occlusion
The maximum time for activation of the downstream occlusion alarm at the minimum flow rate of 1ml/hr is around 5 minutes at the minimum occlusion threshold setting. It is more than 1 hour at the maximum occlusion alarm threshold setting.

The maximum time for activation of the downstream occlusion alarm at the intermediate flow rate of 25ml/hr is around 20 seconds at the minimum occlusion threshold setting. It is around 3 minutes at the maximum occlusion alarm threshold setting.

Occlusion Bolus Volume
The maximum bolus volume generated as a result of operation at 25 ml/hr and reaching the minimum downstream occlusion alarm threshold is 0.25ml.
The maximum bolus volume generated as a result of operation at 25 ml/hr and reaching the maximum downstream occlusion alarm threshold is 0.8mL.
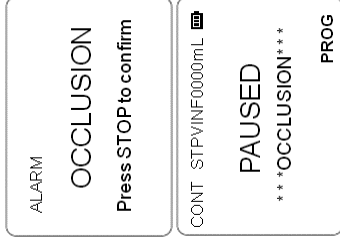
Note: At slower infusion rates, the occlusion alarm may take longer to trigger.

DEVICE DESCRIPTION

Pump Front View – Door Closed

Rate Display-When illuminated, indicates the current flow rate of the infusion

Main LCD Display

Pump Door

Data Entry Keys-When pressed, increases or decreases the value of the highlighted parameters with each key press

Handle

RUN/STOP Key-When pressed, resumes operation of a previously paused or alarmed infusion if the pump is stopped. When pressed during an infusion, temporarily stops the infusion.

Prime Key-When pressed, prompts user to prime by pressing and holding the left soft key. Release the soft key to stop the priming. Maximum prime volume= 10 ml

Infusion Status Indicator- When illuminated, indicates the on-going infusion status Infusing-Green Alarm-Red

Soft Keys-When pressed, allow selection of options or infusion parameters displayed in the Main Display

Home Key

Power Indicator- When illuminated, indicates the pump is connected to an AC power source

Battery Indicator- When illuminated, indicates the pump is operating on battery power

System On Key-When pressed, changes the pump from Standby to Operating mode

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APPENDIX

APPENDIX

ALARM TESTING PROCEDURE

Air-in-Line Alarm Test

ALARM
AIR-IN-LINE
Press STOP to confirm

CONT STPVINF0000mL
PAUSED
AIR-IN-LINE
PROG

1. Load an empty administration set into the pump. Close the pump door.

2. Program the primary flow RATE at 500 ml/h, and the primary VTBI at 100 ml.

3. Press the **RUN/STOP** key to start the infusion.

4. The infusion status indicator will turn blinking red, audio alarm will sound, and the Main Display will show "AIR-IN-LINE". The infusion will stop.

5. Press the **RUN/STOP** key again to acknowledge the alarm condition. The Z-800 Pump will be in PAUSE state. The "PAUSE" message will appear on the display screen.

6. Clear the Air-in-Line condition. Press the **RUN/STOP** key again to resume infusion.

Door Open Alarm Test

ALARM
DOOR OPEN!
Press STOP to confirm

CONT STPVINF0000mL
**PAUSED**
DOOR OPEN
PROG

1. Start a primary infusion. During operation, open the pump door.

2. The infusion status indicator will turn blinking red, the audio alarm will sound, and the Main Display will show "Door Open!". The infusion will stop.

3. Press **RUN/STOP** key to acknowledge the alarm condition. The Z-800 Pump will be in PAUSE state. The "PAUSE" message will appear on the display screen.

4. Close pump door. Press the **RUN/STOP** key again to resume infusion.
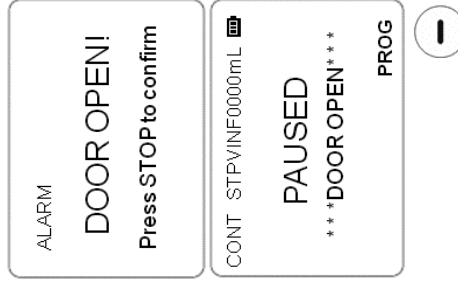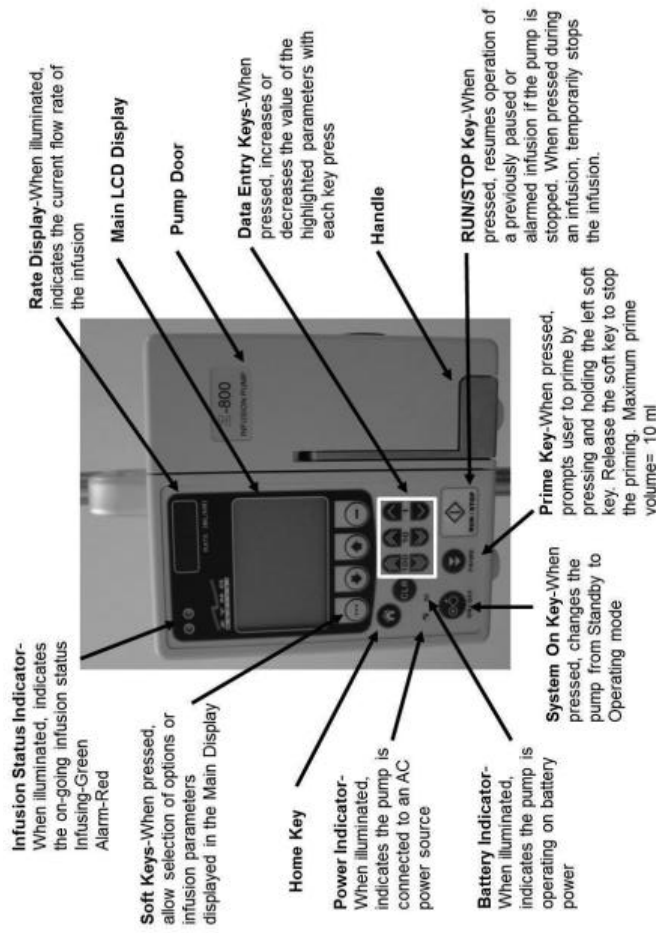
WARRANTY

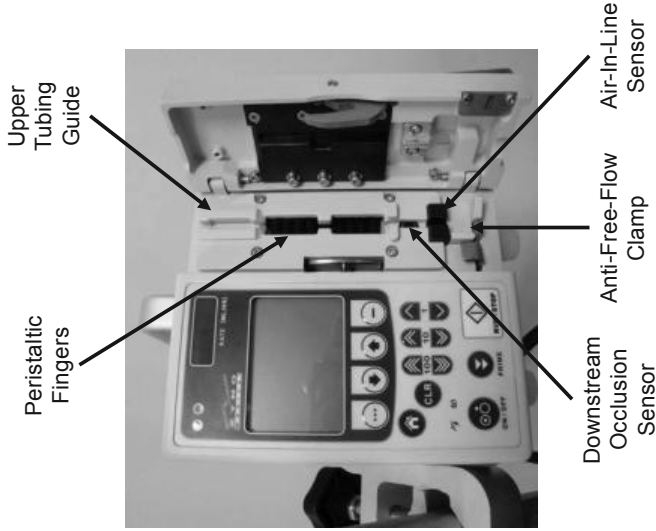Zyno Medical LLC. (hereinafter referred to as "Zyno Medical") warrants that:

A. Each new Zyno Medical Z-800 infusion pump is free from defects in material and workmanship under normal use and service for a period of one (1) year from the date of delivery by Zyno Medical to the original purchaser.

B. Each new accessory (including batteries) is free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by Zyno Medical to the original purchaser.

If any product requires service during the applicable warranty period, the purchaser should communicate directly with their relevant account representative to determine the appropriate repair facility. Except as provided otherwise in this warranty, repair or replacement will be carried out at Zyno Medical's expense. The product requiring service should be returned promptly, properly packaged and postage prepaid by purchaser. Loss or damage in return shipment to the repair facility shall be at purchaser's risk.

In no event shall Zyno Medical be liable for any incidental, indirect, or consequential damages in connection with the purchase or use of any Zyno Medical product. This warranty shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product. Furthermore, this warranty shall not apply to, and Zyno Medical shall not be responsible for, any loss or damage arising in connection with the purchase or use of any Zyno Medical product which has been:
(a) repaired by anyone other than an authorized Zyno Medical service representative;
(b) altered in any way so as to affect, in Zyno Medical's judgment, the product's stability or reliability;
(c) subjected to misuse or negligence or accident, or which has had the product's serial or lot number altered, affected, or removed;
(d) improperly maintained or used in any manner other than in accordance with the written instructions furnished by Zyno Medical.

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of Zyno Medical, and Zyno Medical does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of Zyno Medical any other liability in connection with the sale or use of Zyno Medical products.

Zyno Medical DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURCHASE OR APPLICATION.

DEVICE DESCRIPTION (CONTINUED)

Pump Front View - Door Open

Peristaltic Fingers

Upper Tubing Guide

Air-In-Line Sensor

Anti-Free-Flow Clamp

Downstream Occlusion Sensor

DEVICE DESCRIPTION (Continued)

Pump Back View

- Audio Speaker
- JAKT Communication Data Port
- Nurse Call Connector
- AC Power Cord Connector
- Fuse Container

SERVICE INFORMATION

If a Z-800 Pump fails to respond as described in this Instruction for Use and the cause cannot be determined, do not use the affected instrument. Contact qualified service personnel.

Within the United States, application and service information may be obtained by writing to Zyno Medical LLC. at:

Zyno Medical LLC.
177 Pine Street
Natick, MA 01760
ATTN: Instrument Service

Within the United States, information or assistance may be obtained by calling the Zyno distributor who provided the pump, or by calling Zyno Medical at (866)-395-1988.

Outside of United States, service information, applications, and manuals may be obtained by contacting your local Z-800 Infusion Pump distributor.

When submitting any request for service, include:
- A description of the difficulty experienced.
- Z-800 Pump serial number.
- Instrument settings and solution(s) used.
- Description, model and lot number(s) of the administration sets in use.
- Message displayed at the time of difficulty.

If it is necessary to return the instrument for service, obtain a return authorization number prior to shipment. Carefully package the instrument (preferably in the original packaging), reference the return authorization information, and return it to the appropriate service or distribution center. Zyno Medical does not assume any responsibility for loss of, or damage to, returned instruments while in transit.

Product complaints or adverse incidents should be reported to the Zyno Medical Quality Assurance Department at the above address. With each complaint, please include the pump serial number and a full description of the difficulty encountered, including all settings, types of fluids, times, and alarm messages. Return the administration set used if possible. Contact the Zyno Medical Customer Service Department for an RMA number prior to return.
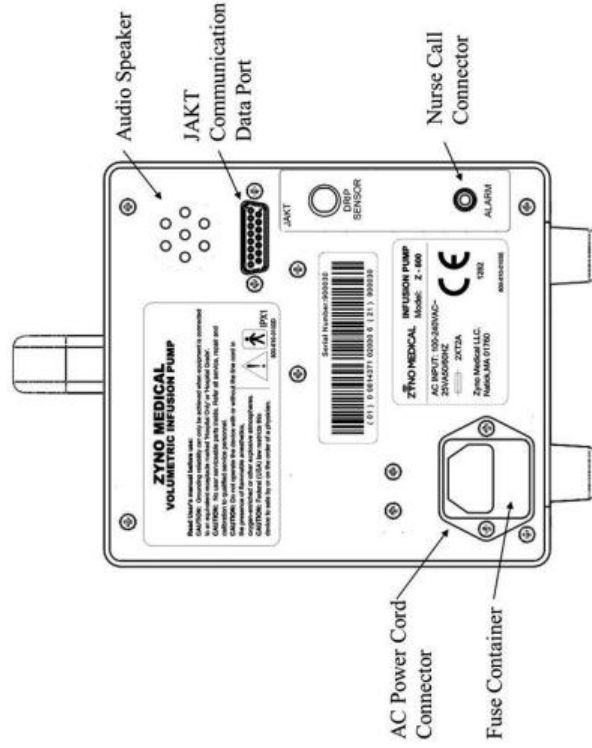
INSTALLATION PROCEDURE

UNPACK THE PUMP

The Z-800 Infusion Pump is supplied complete with
- A standard detachable, listed/certified IEC Hospital Grade electrical cord
- Pole Clamp pre-mounted at 45 degree angle to the pump
- Instruction for Use

1. Remove the pump module from its carton.
2. Inspect the pump.
3. Check to ensure the pump door operates freely.
4. Check for any loose parts.

NOTE: If any of the following conditions are observed, the Z-800 Infusion Pump must be removed from use and inspected by qualified personnel:
- Look for any signs of physical damage from shipping.
- LED segments are not illuminated during system power-on self-test.
- Indicator lights do not illuminate.
- Audio tone does not sound.
- Main Display does not appear backlit, appears irregular, or has evidence of a row of pixels not functioning properly.

MOUNT PUMP TO IV POLE

Attach the pump to an IV Pole by turning the knob on the pole clamp clockwise, or place the pump on a flat, stable surface.
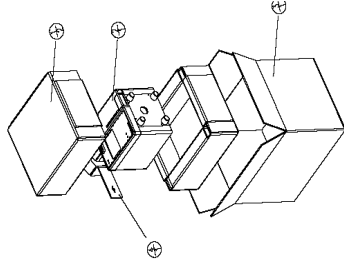
INSPECTION REQUIREMENTS (Continued)

```
SN: XXXXXXX    VXX.XXX
IV. SET        ZYNO-XX
PRESSURE       XX PSI
AIR            X.XX mL
P XXX  P4 XXX  P30 XXX
BATT XXXX  X. XX% XX%
                        QUIT
```

```
ODOMETER

     0001

                        QUIT
```

The value of the odometer is displayed at the "Information" section of the configuration menu. The "Information" section has multiple pages. The user needs to press the up/down arrow keys to navigate to different pages.

Loading the factory default will not change the value of the odometer. Only the Zyno qualified personnel can reset the odometer value.

Periodic preventive maintenance of the hardware (PM's) must only be performed by Zyno certified personnel, and are essential for assuring the accuracy and safety of the pump. PM's MUST BE PERFORMED AT LEAST ONCE PER YEAR, OR WHEN THE SCREEN DISPLAYS THE DUE FOR SERVICE MESSAGE, WHICHEVER COMES FIRST. A service agreement may be obtained from Zyno Medical for the performance of all required maintenance.

△ **WARNING: The manufacturer cannot assure the accuracy and/or safety of the pump if it is not regularly maintained as recommended in the Z-800 Instructions for Use Manual.**

PREPARING AN INFUSION

```
         ZYNO Z-800
==================
SN: XXXXXX    VX.X.XX
IV.SET        ZYNO-XX
PRESSURE      XX PSI
AIR           X.XXmL
==================
POST. . . .
```

Powering On the System

1. Connect the Z-800 Infusion Pump Power Cord to an AC power source.
2. Press and hold the **ON/OFF** key on the Z-800 Infusion Pump for 2 seconds.
3. System self-test begins:
   - The diagnostics test causes all LED display segments and Status indicator lights to illuminate briefly.
   - The Power Indicator illuminates.
   - An Audio tone sounds.
4. The Main Display shows the Zyno Medical Model Type, Pump Serial Number, Software Version and pump safety configurations during the system power-on self-test.
5. Upon completion of system power-on self-test, a New Infusion prompt screen will be displayed prompting the user to choose either resume a previously interrupted infusion or start with a new infusion.
6. If the user elects to resume the previously interrupted infusion, the pump will enter into the Programming screen of the previous selected infusion mode and with the previous infusion parameters populated.
7. If the user elects to start a new infusion, the pump will prompt user to main screen (see right image). For manual programming, the user should select PROGRAM. After selection, the pump will prompt user to select infusion mode. Upon selection, the pump will enter into the Infusion Programming screen of the selected Infusion Mode with all infusion parameters reset to zero. The user may choose one of the following infusion modes:
   - Continuous Mode with Rate/VTBI parameters
   - Continuous Mode with Time/VTBI parameters
   - TPN Auto Ramp Mode
   - 10 Step Mode Rate/VTBI
   - 10 Step Mode Time/VTBI
   - Intermittent
   - Blood Infusion

```
RESUME INFUSION
NEW INFUSION
SELECT
...
```

```
PROGRAM
PROTOCOL
SELECT
```

```
1.  CONT MODE R/V
2.  CONT MODE T/V
3.  TPN MODE
4.  10 STEP MODE R/V
5.  10 STEP MODE T/V
6.  INTERMITTENT
SELECT
```

INSPECTION REQUIREMENTS

To ensure the system remains in good operating condition, both regular and periodic inspections are required.

REGULAR INSPECTIONS:
Regular inspection consists of a visual inspection for damage and cleanliness, and performing the procedure described in the Start-Up Sequence section of this instruction for use before each usage of the instrument. Regular inspections are not covered under the contract or agreement offered by Zyno Medical and must be performed by the user.

REGULAR INSPECTIONS

PROCEDURE	FREQUENCY
INSPECTION FOR DAMAGE:	
Enclosure	Each usage
Power Cord	Each usage
CLEANING	As Required
START-UP SEQUENCE	Each usage

NOTE: If the instrument does not pass the regular inspection, the affected instrument must be removed from use and inspected by qualified service personnel.

PERIODIC PREVENTIVE MAINTENANCE:
The pump has a built-in maintenance cycle odometer. The odometer indicates how many liters of fluid can be accurately delivered before the pump must be serviced. This feature is designed to alert users for the required servicing timing for high-usage pumps.

When the value of the odometer approaches zero, the pump will display a warning message after power on, "Pump will be due for service. Please call 1-866-395-1988."

When the value of the odometer becomes zero or negative, the pump will display a warning message after power on, "Pump is due for service. Please call 1-866-395-1988."
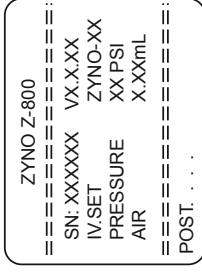
⚠ **WARNING:** Failure to perform these inspections and maintenance may result in improper instrument operation.

```
Pump will be due for
service soon. Please
call 1-866-395-1988
                QUIT
```

```
Pump is due for
service. Please
call 1-866-395-1988
                QUIT
```

LOADING PRIMARY ADMINISTRATION SET

Preparing the Primary Solution Container

Prepare the primary solution container in accordance with the manufacturer's directions for use.

Preparing the Primary Administration Set

Use only Zyno administration sets (refer to **Approved Administration Sets** section for a list of compatible sets). Open the administration set package, remove the set and close the roller clamp.

⚠ **WARNING: Some Z-800 IV sets configurations do NOT have set based free-flow protection feature. Make sure to close roller clamp before removing administration set from Z-800 pump.**

**Loading Primary Administration Set**

1. Insert the set spike into prepared fluid container following accepted clinical procedure, and hang the container approximately 20 inches above the Pump.
2. Fill the drip chamber to 1/3 full by squeezing it.
3. Open the roller clamp slowly to prime tubing. Invert and tap the back check valve and any Luer lock sites to clear the air from the administration set.
4. Close the roller clamp.
5. Close the pump door. Turn on the pump. After the pump has finished the power-on-self-test, open the pump door.
6. Using a fingertip, firmly push the tubing into the gap of upper tubing guides. (See picture "Step 6.")
7. Using a fingertip, firmly push the tubing into the gap of the tubing guides on the pumping fingers. (See picture "Step 7")
8. Using a fingertip, firmly push the tubing into the gap of the Air-in-Line Sensor. (See picture "Steps 8 & 9.")
9. Align the tubing on top of the gap of the Free Flow Clamp. Do not force the tubing into the clamp. The tubing will be loaded into the Free Flow Clamp automatically when the pump door is closed.
10. Close the pump door by pushing down the pump door handle (See picture "Step 10.")
11. Open the IV set roller clamp and confirm that there is NO FLOW in the IV set drip chamber. Connect the administration set to the patient's injection site.
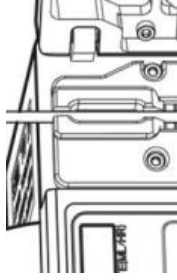
Step 6
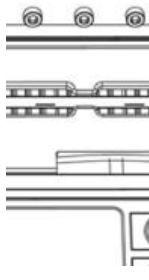
Step 7
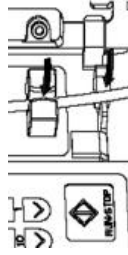
Steps 8 & 9

Step 10

CLEANING

DO NOT spray cleaning fluids directly onto the instrument or immerse the instrument in fluids.

DO NOT use solutions containing phosphoric acid (Foamy Q&A*), aromatic solvents (naphtha, paint thinner, etc.), chlorinated solvents* (Trichloroethane, MEK, Tuluene, etc.), ammonia, acetone, benzene, xylene or alcohol, other than as specified below.

DO NOT use hard or pointed objects to clean any part of the instrument.

Acceptable cleaning solutions are:
Warm water
Mild detergent (e.g., Manu-Klenz®)
** 10% bleach solution (1 part bleach to 9 parts water)
** Compublend™ II
** Envirocide®
** 2% Glutaraldehyde in water
** Hydrogen Peroxide 3%
** 70% Isopropyl Alcohol
** 2% Phenols in water (O-Syl 1:128, Pheno-Cen 1:256, Vesphene®
** 10% Providone Iodine (betadine™)
** Quaternaries 1:512
WEX-CIDE

1. Keep the instrument upright and do not allow any part of the instrument to become saturated with or submersed in fluid during the cleaning operation.
2. Use soft cloth dampened with warm water and a mild nonabrasive cleaning solution to clean all exposed surfaces. Do not spray any fluids directly on the instrument. For sanitizing or antibacterial treatment, use 10% bleach solution and water.

⚠ **WARNING:** Turn the instrument off and unplug the power cord from the AC power source before cleaning.
Do not spray fluid directly onto the instrument.
Do not steam autoclave, EtO sterilize, immerse the instrument or allow fluid to enter the instrument case. Failure to follow these instructions may result in an electrical hazard, damage to the instrument, and voided warranty coverage.

⚠ **CAUTION:** The solutions/solvents identified as NOT to be used can damage the surface of the instrument.

** After application, rinse all surfaces with a water-dampened soft cloth.

LOADING PRIMARY ADMINISTRATION SET (Continued)

LOADING IV SET INTO Z-800 PUMP

① Press tubing into upper tubing retainer

② Press tubing into tubing guide on top of the peristaltic pumping chamber.

③ Firmly push tubing toward back of Air-in-Line detector.

④ Align tubing on top of the opening of the Free Flow Clamp. (Do not force tubing into the gap of the Free Flow Clamp). Closing pump door will automatically load the tubing into the gap of the Free Flow Clamp.

⑤ Push door handle to close pump door.

⚠ **WARNING: Some Z-800 IV sets configurations do NOT have set based free-flow protection feature. Make sure to close roller clamp before removing administration set from Z-800 pump.**

BATTERY CARE AND MAINTENANCE (Continued)

Battery Care

The battery capacity should be checked at least once every 12 months.

If the Z-800 pump is to be stored at temperatures in excess of 86 °F (30 °C) for one or more months, the battery should be removed and placed in an environment between 50 – 86 °F (10-30 °C).

If the battery is to be stored for more than one year, it should be charged at least once per year to prevent leakage and deterioration in performance due to self-discharge.

When the battery is first being put into use, or has been out of use for one or more months, it will not have full capacity due to deactivation of reactants. Restore the battery to original performance by repeating one or two cycles of fully charging and fully discharging.

Some temporary reduction in capacity might become apparent if the battery is repeatedly discharged less than completely. One or two cycles of full discharge and full charge can restore full performance.

The Z-800 Pump is shipped with a battery in a discharged condition. Connect the power cord to an AC receptacle and allow the battery to charge for 18 hours.

Whenever possible, leave the power cord connected to an external AC power source while operating.

⚠ **CAUTION:** Battery replacement should be performed by qualified service personnel while the instrument is not in use.
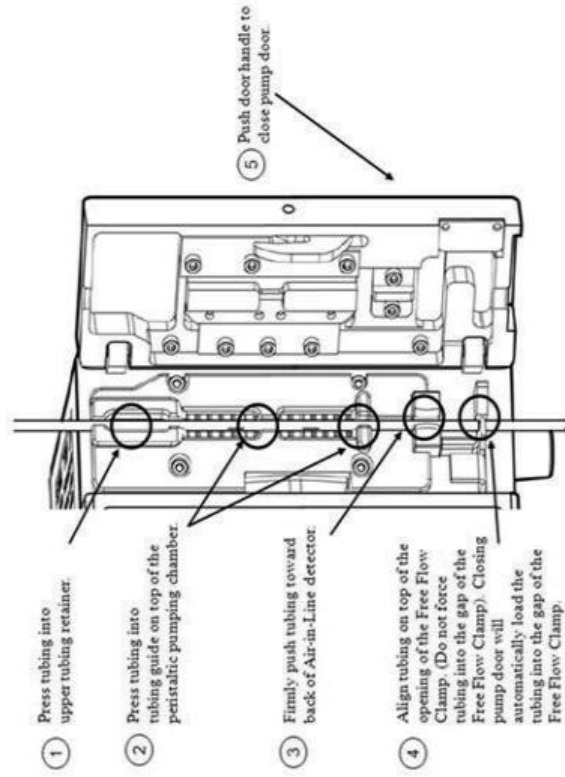
⚠ **CAUTION:** All pump configuration settings need to be verified and reset as needed after a complete discharge of battery.

⚠ **CAUTION:** DO NOT open, incinerate or short circuit battery. Worn out batteries must be disposed properly, according to local regulations.

BATTERY CARE AND MAINTENANCE (Continued)

Battery Operating Time

Battery run time is a function of the activity of the device. In the standard battery configuration of a 4500mAh battery, a fully charged new battery will provide approximately 8 hours of operation infusing at 125ml/h. As flow rate increases, the power consumption increases, the battery operating time will decrease accordingly. See _TABLE. Battery Operating Time_ on the right. In the standard configuration, a fully discharged battery will return to a fully charged capacity in 5-6 hours in an ambient temperature between 50 – 86 °F (10 – 30 °C).

Table: Battery Operating Time

Flow Rate	Run Time
1ml/hr	10hrs
25ml/hr	10hrs
125ml/hr	8hrs
1200ml/hr	6hrs

Battery Cycle Life and Aging

As batteries get older and go through many charge/discharge cycles, batteries "wear out," meaning that the chemicals and materials used to construct the cell break down. It is estimated that there will be a 30% capacity decrease of battery capacity over a 200 full discharge/charge cycles within 2 years of normal use. As the battery ages, the battery operating time will decrease.

Partial Discharge/Recharge

When a battery is partially discharged, then charged for less than the full time, differences between individual cell capacities result in cells completing charge at different times. If the full charge sequence is not then completed, the cell "mismatch" becomes progressively greater. This will be observed by user as low apparent run times and premature low battery warning and alarms. The lowered capacity is not permanent, but may require 2-3 full discharge/charge cycles to recover.

⚠ CAUTION: The battery capacity indicator display represents the total capacity of the battery measured by voltage. It only represents the percentage of battery capacity against its total capacity. As battery ages, the total capacity of the battery will decrease.

INFUSION MODE INFORMATION

CONTINUOUS MODE

CONTINUOUS MODE-PRIMARY INFUSION

Primary Infusion Programming Screen

The user may choose to program the continuous infusion either in RATE/VTBI or TIME/VTBI. The primary infusion programming screen contains the following display areas:

1. **Status Bar:** The Status Bar displays current operating mode, current pump state and volume infused.
   - **CONT:** Indicates the current application mode is Continuous Mode Operation
   - **VINF:** Indicates the Volume Infused during the current infusion
2. **Infusion Parameters:** -- Primary Flow Rate and Primary Volume to Be Infused
   - **Pri RATE:** Primary Flow Rate
   - **Pri VTBI:** Primary VTBI
3. **Keys:** Allows user to access pump configuration and secondary infusion programming screen
   - **CONFIG:** Access configurable settings
   - **SEC:** Access the secondary infusion programming
   - **Up/Down Arrows:** Select parameter items
   - **Home Key:** Access Infusion Mode menu

⚠ **WARNING: Do not over-program VTBI. Program the actual amount of the fluid in the IV bag.**

⚠ **WARNING:** Do not over-program VTBI. Program the actual amount of IV bag fluid.

(Screen display: Status Bar, Primary Infusion parameters, Soft keys, Battery meter — CONT VINF0000mL; Pri RATE 0000mL/H; Pri VTBI 0000mL; CONFIG Sec; Home Key, Clear Key, Data Entry Key)

Change Primary Flow Rate

Use Up/Down Arrow keys to highlight Pri RATE. Use the Data Entry keys to modify the corresponding digits of Pri RATE value.

Example: Programming Pri RATE = 125 mL/h

1. Use Up/Down Arrow keys to highlight Pri RATE.
2. Press the 100 Up data entry key ⟪100 once to increase the 100 digit of Pri RATE to 100.
3. Press the 10 Up data entry key ⟪10 twice to increase the 10 digit of Pri RATE to 20.
4. Press the single digit Up data entry key ⟨1 five times to increase the single digit of Pri RATE to 5.

(Screen display: CONT VINF0000mL; Pri RATE 0125mL/H; Pri VTBI 0000mL; CONFIG Sec)

CONTINUOUS MODE-PRIMARY INFUSION (Continued)

Change Primary VTBI

```
CONT     VINF0000mL  🔋
Pri RATE  0125 mL/H
Pri VTBI  0250 mL
CONFIG              Sec
```

Use the Up/Down Arrow keys to highlight Pri VTBI. Use the Data Entry keys to modify the corresponding digits of Pri VTBI value.

Example: Programming Pri VTBI = 250 ml
Use the Up/Down Arrow keys to highlight Pri VTBI.

Press the 100 Up data entry key ⟪100 twice to increase the 100 digit of Pri VTBI to 200.

Press the 10 Up data entry key ⟪10 five times to increase the 10 digit of Pri VTBI to 50.

Start Primary Infusion

Verify the displayed infusion parameter entries (Primary Rate, Primary VTBI). If a clamp is engaged, remove the clamp. Press **RUN/STOP** key to start the infusion.

Stopping and Resuming a Primary Infusion

Press the **RUN/STOP** key during infusion. The infusion will be paused. The **PAUSE** screen will be displayed.

From the **PAUSE** state, press the **RUN/STOP** key to resume infusion.

Titrate Flow Rate or VTBI During a Primary Infusion

From the **PAUSE** screen, press the **PROG** key; the pump will display primary infusion programming screen. The user is then able to modify the primary RATE and primary VTBI parameters.

```
CONT  STPVINF0000mL  🔋
         PAUSED
     Press RUN to resume
                    PROG
```

BATTERY CARE AND MAINTENANCE

Battery Type and Charging
The Z-800 can operate on internal rechargeable battery power, enabling continued infusion when the patient is being transferred or during electrical power failure.

When the pump runs on battery power, the POWER indicator 🔌 is off, and the BATTERY indicator 🔋 is on.

The Z-800 Pump is equipped with a standard configuration of 9.6 volt 4500mAh Nickel-Metal-Hydride battery. The battery charges whenever the pump is plugged into an AC outlet. The life expectancy of the battery is dependent on the amount of use, the depth of discharge, and the state of the charge that is maintained. Generally, the battery will have the longest life if the pump is always plugged in and the battery use is infrequent. Frequent use of battery power and insufficient battery charge cycles will significantly decrease the life of the battery. It is recommended that the battery be replaced after three years.

The quality of the battery is also a significant factor in determining battery life and runtime. The battery cannot be repaired and should not be opened. The battery may only be replaced with an approved battery from Zyno Medical. Use of any other brand may yield poor performance, and will invalidate the warranty.

The battery should be charged in a room with a temperature between 50 and 86 °F (10 – 30 °C) to minimize charge time and maximize battery life.

CONTINUOUS MODE-PRIMARY INFUSION (Continued)

Primary Infusion Execution

```
PRI    RUN    TL02:35  [battery]
RATE   0125 mL/H
VTBI   0585 mL
VINF   0345 mL
```

- During an infusion, the two Infusion Status Indicator LEDs will illuminate in green and toggle once per second.
- The primary infusion execution display contains the following contents:

Status Bar: The Status Bar displays the current operating mode, current pump state, and volume infused.
- **PRI**: Primary infusion
- **RUN**: Pump RUN state
- **TL**: Time Left in HH:MM format for the current infusion

Infusion Parameters: Current infusion parameters.
- RATE field displays primary flow rate.
- VTBI field counts down to show remaining VTBI.
- VINF field counts up to show volume infused.

- 3 minutes before infusion completes, a short audio prompt tone will sound twice. Along with the audio prompt, the screen will display "INFUSION NEAR END" message. This alert will repeat every 5 seconds until the infusion is complete.

- At completion of the infusion, an audio prompt sounds and the screen will display "INFUSION COMPLETE – KVO." This alert will repeat every 5 seconds until user intervention. During KVO state, the Flow Rate Indicator will change to display KVO flow rate.

Clearing the Volume Infused During a Primary Infusion:

Press the RUN/STOP key to PAUSE the primary infusion. Exit the PAUSE screen by pressing the PROG key. From the **Primary SETUP** screen, press and hold the **CLR** key. An audio/visual prompt will be presented requesting user confirmation to clear VINF. Press the **YSE** key to confirm. The VINF field will be reset to 0 ml. The user can press the **NO** key to abort the action.

NOTE: The VINF field will record cumulative infusion volume infused unless cleared by the user pressing the **CLR** key or turning the pump off/on and starting a new infusion.

STORAGE AND TRANSPORTATION

Store the pump away from excessive heat, cold, or humidity.

Keep the pump plugged into an AC outlet during storage, to ensure a fully charged battery when needed.

[plug icon] The AC indicator light pictured left will be on whenever the Z-800 Infusion Pump is plugged in.

When transporting the pump, please apply sufficient protection to the pump to prevent physical damages. It is recommended to use a box size of 10x10x12 for an individual pump. The upright orientation with lifting handle facing up is recommended during transportation.
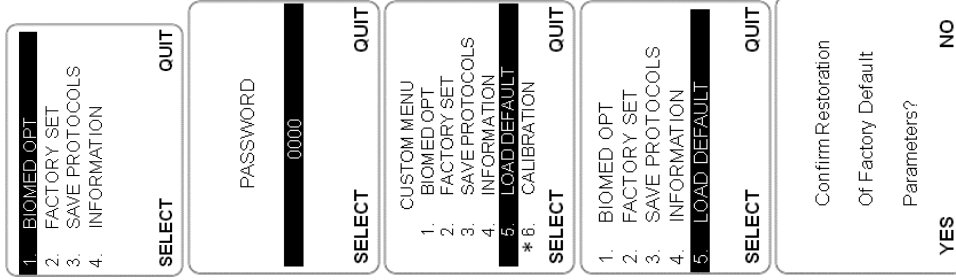
LOADING SECONDARY ADMINISTRATION SET

1. Program and start the primary infusion using a check-valve primary administration set, as previously described.

2. Open a secondary administration set package, remove the set and close the set roller clamp.

3. Insert set spike into a prepared fluid container and hang secondary container, following accepted clinical procedures.

4. Fill the drip chamber to 1/3 full.

5. Open a secondary set and prime the set. Close the set roller clamp.

6. Attach a secondary set to the upper injection site on the primary set.

7. Ensure that no air bubbles are in the line.

8. Hang the secondary fluid container at least 8 inches above the primary solution container.

⚠ **WARNING: Some Z-800 IV Administration Sets configurations do NOT have set based free-flow protection. Make sure to close roller clamp before removing administration set from Z-800 pump.**

⚠ **WARNING: The bottom of the secondary solution should be at least 19" above the top of the pump.**

⚠ **WARNING: A minimum height differential between primary and secondary solutions of eight inches is essential for the safe operation of a primary/secondary infusion.**

MAINTENANCE

CONFIGURABLE SETTINGS (Continued)

Load Factory Default

The user can load the factory default settings in the configuration menu.

From the configuration page, pressing CLR key and ⟫ key at the same time will bring out the customization authorization screen.

Enter the password "1111" by pressing ⟨ and ⟩ once and pressing ⟪ 11 times. Then press "SELECT". The pump will enter the customization page. Use the up/down ⟨ ⟩ arrow keys to move to the LOAD DEFAULT option. Use ⟨ or ⟩ to remove the "*" sign and shoose "SELECT" to save the changes and return to the configuration menu. Use the up/down ⟨ ⟩ arrow keys to move to the LOAD DEFAULT option and press "SELECT". A confirmation page will be displayed: "Confirm Restoration Of Factory Default Parameters?" Pressing "YES" would reset the pump to factory default parameters. Press "NO" to cancel the action.

1. **BIOMED OPT**	
2. FACTORY SET	
3. SAVE PROTOCOLS	
4. INFORMATION	
SELECT	QUIT

PASSWORD	
00000	
SELECT	QUIT

CUSTOM MENU	
1. BIOMED OPT	
2. FACTORY SET	
3. SAVE PROTOCOLS	
4. **INFORMATION**	
5. **LOAD DEFAULT**	
* 6. CALIBRATION	
SELECT	QUIT

1. BIOMED OPT	
2. FACTORY SET	
3. SAVE PROTOCOLS	
4. INFORMATION	
5. **LOAD DEFAULT**	
SELECT	QUIT

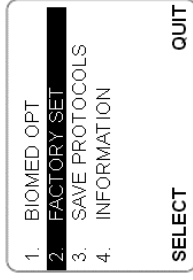|	
Confirm Restoration	
Of Factory Default	
Parameters?	
YES	NO

MAINTENANCE

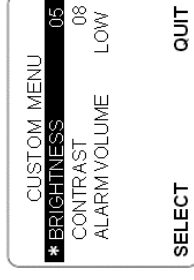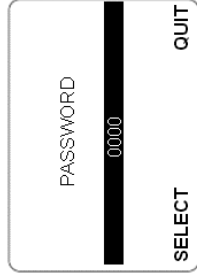## CONFIGURABLE SETTINGS (Continued)

Customize the FACTORY SET Menu

The user can choose to dislpay or hide certain items in the "FACTORY SET" menu.

In the configuration menu, select "FACTORY SET."

In the "FACTORY SET" page, pressing the CLR key and keys at the same time will bring out the customization authorization screen.

Enter the password "1111" by pressing keys and 100 once and pressing ≪ 11 times. Then press "OK." The pump will enter the customization page. The "*" sign before an item means that the item will not be displayed in the "FACTORY SET" page. Use ↓ and ► to toggle the "*" sign before each item. Use the up/down arrow keys to move to the selected item.

After the user has finished the customization, he or she can choose "SELECT" to save the changes and return to the "FACTORY SET" main page. Pressing "QUIT" will return to the "FACTORY SET" main page without saving the changes.

```
1.  BIOMED OPT
2.  FACTORY SET
3.  SAVE PROTOCOLS
4.  INFORMATION
SELECT            QUIT
```

```
      PASSWORD
        0000
SELECT            QUIT
```

```
    CUSTOM MENU    05
*BRIGHTNESS
 CONTRAST        08
 ALARM VOLUME    LOW
SELECT            QUIT
```

INFUSION MODE INFORMATION

CONTINUOUS MODE-SECONDARY INFUSION

Access Secondary Infusion Programming Screen

From the Continuous Mode Primary Infusion Programming screen, Press the Sec key to access the secondary infusion programming screen.

```
CONT     VINF 0000mL
Pri RATE  0125 mL/H
Pri VTBI  0250 mL
CONFIG            Sec
```

NOTE: The **SECONDARY INFUSION** option can be hidden if it is not required. To configure the Secondary Infusion options go to the **BIOMED OPT** Menu.

Secondary Infusion Programming Screen

Similar to the primary infusion programming screen, the secondary infusion programming screen contains the following display areas:
1. **Status Bar:** The Status Bar displays current operating mode, current pump state, and volume infused.
   • **CONT:** Continuous Mode Operation
   • **VINF:** Volume Infused for the current infusion
2. **Infusion Parameters:** Secondary Flow Rate and Secondary Volume to Be Infused.
   • **Sec RATE:** Secondary Flow Rate
   • **Sec VTBI:** Secondary VTBI
3. **Keys:** Allow user to access pump configuration and primary infusion programming screen.
   • **CONFIG:** Access pump configuration
   • **PRI:** Access primary infusion programming
   • **Up/Down Arrows:** Select parameter items

```
CONT     VINF 0000mL
Sec RATE  0000 mL/H
Sec VTBI  0000 mL
CONFIG            Pri
```

CONTINUOUS MODE-SECONDARY INFUSION (Cont.)

```
CONT      VINF0000mL
Sec RATE   0275 mL/H
Sec VTBI   0000 mL
CONFIG                Pri
```

Change Secondary Flow Rate

Use Up/Down Arrow keys to highlight Sec RATE. Use Data Entry keys to modify the corresponding digits of Sec RATE value.

Example: Programming Sec RATE = 275 mL/h

1. Use the Up/Down Arrow keys to highlight Sec RATE.

2. Press the **100 Up data entry** key [icon] twice to increase the 100 digit of Sec RATE to 200.

3. Press the **10 Up data entry** key [icon] seven times to increase the 10 digit of Sec RATE to 70.

4. Press the single digit Up data entry key [icon] five times to increase the single digit of Sec RATE to 5.

```
CONT      VINF0000mL
Sec RATE   0275  mL/H
Sec VTBI   0150 mL
CONFIG                Pri
```

Change Secondary VTBI

Use the Up/Down Arrow keys to highlight Sec VTBI. Use the Data Entry keys to modify the corresponding digits of Sec VTBI value.

Example: Programming Sec VTBI = 150 mL

1. Use the Up/Down Arrow keys to highlight Sec VTBI.

2. Press the **100 Up data entry** key [icon] once to increase the 100 digit of Sec VTBI to 100.

3. Press **10 Up data entry** key [icon] five times to increase the 10 digit of Sec VTBI to 50.

CONFIGURABLE SETTINGS (Continued)

Customize the BIOMED OPT Menu

The user can choose to dislpay or hide certain items in BIOMED OPT page.

In the configuration menu, select "BIOMED OPT."

```
1.  BIOMED OPT
2.  FACTORY SET
3.  SAVE PROTOCOLS
4.  INFORMATION
SELECT                QUIT
```

In the "BIOMED OPT" page, pressing the CLR key and [icons] keys at the same time will prompt the customization authorization screen.

```
          PASSWORD
           0000
SELECT                QUIT
```

Enter the password "1111" by pressing [icon] and [icon] once and pressing [icon] 11 times. Then press "OK." The pump will enter the customization page. The "*" sign before an item means that the item will not be displayed in the "BIOMED OPT" page. Use [icon] and [icon] to toggle the "*" sign before each item. Use the up/down [icon] [icon] arrow keys to move to the selected item.

```
        CUSTOM MENU
PRESSURE          24  PSI
AIR               0.01 mL
KVO RATE          05mL/H
NEAR END WARNING     NO
* DRIP SNESOR        NO
* CLAMP SENSOR       NO
SELECT                QUIT
```

After the user has finished the customization, he or she can choose "SELECT" to save the changes and return to the "BIOMED OPT" main page. Pressing "QUIT" will return to the "BIOMED OPT" main page without saving the changes.
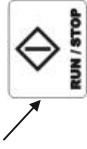
CONFIGURABLE SETTINGS (Continued)

Customize the Load Protocols Menu

Screen: PROGRAM / **PROTOCOL** / PATIENT QUERY — SELECT

The user can customize the protocol menu to dislpay or hide certain protocols .

In home page, select "**PROTOCOL**" .

Screen: LOAD PROTOCOLS — 1>P1 2>P2 3>P3 4>P4 5>P5 6>P6 — SELECT   QUIT

In the "**LOAD PROTOCOLS**" page, pressing the CLR key and [icon] at the same time will prompt the customization authorization screen.

Enter the password "1111" by pressing [icon] and [icon] once and pressing [icon] 11 times. Then press "OK." The pump will enter the customization page. The "*" sign before an item means that the item will not be

Screen: PASSWORD — 0000 — SELECT   QUIT

displayed in the "Protocol" page. Use [icon] and [icon] to toggle the "*" sign before each item. Use the up/down [icons] arrow keys to move to the selected item.

Screen: CUSTOM MENU — 1>P1 * 2>P2 3>P3 4>P4 5>P5 6>P6 — SELECT   QUIT

After the user has finished the customization, he or she can choose "SELECT" to save the changes and return to the "**LOAD PROTOCOLS**" main page. Pressing "QUIT" will return to the "**LOAD PROTOCOLS**" main page without saving the changes.

INFUSION MODE INFORMATION

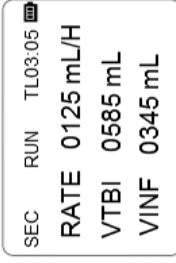## CONTINUOUS MODE-SECONDARY INFUSION (Cont.)

Start Secondary Infusion

Verify displayed infusion parameter entries (Primary Rate, Primary VTBI, Secondary Rate, and Secondary VTBI). If a clamp is engaged, remove the clamp. Press **RUN/STOP** key to start the infusion.

[RUN / STOP icon]

NOTE: Secondary infusion will be executed before primary infusion.

Secondary Infusion Execution

- The two Infusion Status Indicator LEDs will illuminate in green and toggle once per second.
- The secondary infusion execution display contains the following contents:

1. **Status Bar**: The Status Bar displays current operating mode; current pump state; and volume infused.
   - **SEC**: Secondary infusion
   - **RUN**: Pump RUN state
   - **TL**: Time Left in hours: minutes (HH:MM) format for the current infusion.

Screen: SEC   RUN   TL03:05 — RATE 0125 mL/H — VTBI 0585 mL — VINF 0345 mL

2. **Infusion Parameters**: Current infusion parameters
   - **RATE** field displays secondary flow rate.
   - **VTBI** field counts down to show remaining VTBI.
   - **VINF** field counts up to show volume infused.

- Upon completion of secondary infusion, a switchover audio alert sounds 4 short beeps. The Main Display will switch-over to **PRI (primary) State.**
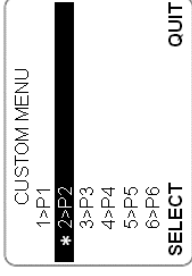
⚠ **WARNING: Do not over-program VTBI. Program the actual amount of the fluid in the IV bag.**

CONTINUOUS MODE-SECONDARY INFUSION (Cont.)

Stopping and Resuming a Secondary Infusion

Press the **RUN/STOP** key during infusion. The infusion will be paused. The **PAUSE** screen will be displayed.

From **PAUSE** state, press the **RUN/STOP** key to resume infusion.

Changing Rate or VTBI During a Secondary Infusion

From the **PAUSE** screen, press **PROG** key; the Z-800 Infusion Pump will enter secondary infusion programming screen. The user is able to modify the secondary RATE and secondary VTBI parameters.

```
CONT  STPVINF0035mL

        PAUSED
    Press RUN to resume

                        PROG
```

MAINTENANCE

CONFIGURABLE SETTINGS (Continued)

Customize the Infusion Mode Menu

The user can customize the infusion mode menu to dislpay or hide certain items.

Press the home key to access the infusion mode menu.
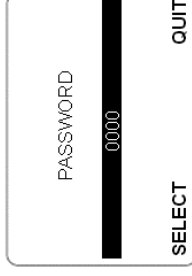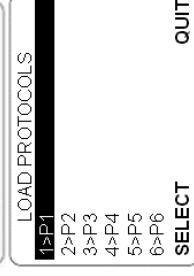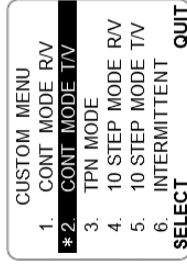
In the mode selection page, pressing CLR key and key at the same time will bring out the customization authorization screen.

Enter the password "1111" by pressing and once and pressing 11 times. Then press "SELECT." The pump will enter the customization page. The "*" sign before an item means that the item will not be displayed in the mode selection settings.

Use and to toggle the "*" sign before each item. Use the up/down arrow keys to move to the selected item.

After the user has finished the customization, he or she can choose "SELECT" to save the changes and return to the infusion mode menu. Pressing "QUIT" will return to the infusion mode menu without saving the changes.

```
1.  CONT MODE R/V
2.  CONT MODE T/V
3.  TPN MODE
4.  10 STEP MODE R/V
5.  10 STEP MODE T/V
6.  INTERMITTENT
SELECT              QUIT
```

```
        PASSWORD

          0000

SELECT              QUIT
```

```
    CUSTOM MENU
1.   CONT MODE R/V
*2.  CONT MODE T/V
3.   TPN MODE
4.   10 STEP MODE R/V
5.   10 STEP MODE T/V
6.   INTERMITTENT
SELECT              QUIT
```

TIME/VTBI PROGRAMMING

Access TIME/VTBI Programming Option

The Z-800 Infusion Pump provides TIME/VOLUME programming options for Continuous Mode Infusion. The user may choose the infusion programming parameter option in the pump Infusion Mode selection screen.

1. Press Home key to access the main page. If a confirmation page showing "Current infusion parameters will be lost. Want to continue?" is displayed, select YES to acknowledge. Note: Any unsaved parameters will be lost upon confirmation.

2. Select PROGRAM to access Infusion Mode menu.

3. In pump Infusion Mode menu, use the Up/Down Arrow keys to highlight **2. CONT MODE T/V** and press the **SELECT** key.

4. The display will switch to continuous mode primary infusion programming screen with TIME and VTBI parameters.

```
Current infusion parameters will be lost
Want to continue?
YES              NO
```

```
PROGRAM
PROTOCOL
SELECT
```

```
1. CONT MODE R/V
2. CONT MODE T/V
3. TPN MODE
4. 10 STEP MODE R/V
5. 10 STEP MODE T/V
6. INTERMITTENT
SELECT
```

CONFIGURABLE SETTINGS (Continued)

Customize the Configuration Menu

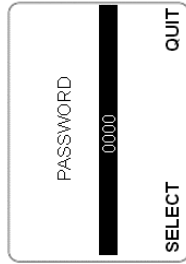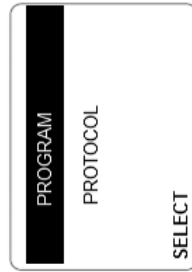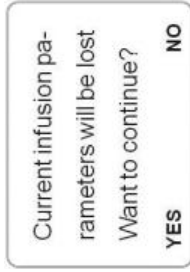The user can customize the configuration menu to dislpay or hide certain items.

From the configuration page, pressing CLR key and [100] key at the same time will bring out the customization authorization screen.
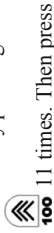
Enter the password "1111" by pressing [<] and [100] once and pressing [100] 11 times. Then press "SELECT". The pump will enter the customization page. The "*" sign before an item means that the item will not be displayed in the configuration settings. Use [<] and [>] to toggle the "*" sign before each item.

Use the up/down [<] and [>] arrow keys to move to the selected item.

After the user has finished the customization, he or she can choose "SELECT" to save the changes and return to the configuration menu. Pressing "QUIT" will return to the configuration menu without saving the changes.

```
1. BIOMED OPT
2. FACTORY SET
3. SAVE PROTOCOLS
4. INFORMATION
SELECT              QUIT
```

```
PASSWORD
0000
SELECT              QUIT
```

```
CUSTOM MENU
1. BIOMED OPT
2. FACTORY SET
3. SAVE PROTOCOLS
4. INFORMATION
*5. LOAD DEFAULT
*6. CALIBRATION
SELECT              QUIT
```

INFUSION MODE INFORMATION


```
CONT        VINF 0000mL
Pri TIME    00:00
Pri VTBI    0000mL
CONFIG                Sec
```

TIME/VOLUME Programming (Continued)

Programming in TIME/VTBI Option

Upon selection of the TIME/VTBI programming option, the continuous mode infusion programming screen will present Total Infusion Time and Total VTBI parameters. The TIME/VTBI infusion programming screen contains the following display areas:
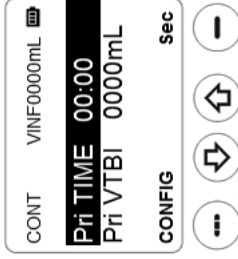
1. **Status Bar**: The Status Bar displays current operating mode, current pump state, and volume infused.
   - **CONT**: Continuous Mode Operation
   - **VINF**: Volume Infused for the current infusion

2. **Infusion Parameters**: Primary Infusion Time and Primary Volume to Be Infused.
   - **Pri TIME**: Primary Infusion Time
   - **Pri VTBI**: Primary VTBI

3. **Keys**: Allows user to access pump configuration and secondary infusion programming screen.
   - **CONFIG**: Accesses pump configuration.
   - **SEC**: Accesses secondary infusion programming screen. The Secondary Infusion Parameters will be presented as Sec TIME and Sec VTBI.
   - **Up/Down Arrows**: Select parameter items. Similar to the RATE/VTBI programming screen, the TIME/VTBI infusion parameters may be programmed by using the UP/DOWN arrow keys and Data Entry keys.

⚠ **WARNING: Do not over-program VTBI. Program the actual amount of the fluid in the IV bag.**

MAINTENANCE

CONFIGURABLE SETTINGS (Continued)

Adjusting the Alarm Volume

The Z-800 Infusion Pump is able to generate multiple audio alert tones to indicate a pump alarm, warning, error, or prompt.

Audio alarm volume may be adjusted by the user to Low, Mid or High setting.

2. From the configuration menu, Select 2. **FACTORY SET**

```
1.  BIOMED OPT
2.  FACTORY SET
3.  SAVE PROTOCOLS
4.  INFORMATION
SELECT                QUIT
```

3. In the **FACTORY SET** menu, highlight the **ALARM VOLUME** option by pressing the **Up/Down Arrow.**

```
        FACTORY SET
BRIGHTNESS          05
CONTRAST            08
ALARM VOLUME        LOW
SAVE              CANCEL
```

4. Press the ⌃ or ⌄ key to adjust alarm volume to LOW, MID or HIGH.

5. Press the **SAVE** ⊡ key to confirm the set value. Press the **CANCEL** key ⊖ to back out. Press the **QUIT** key ⊖ again to exit the CONFIGURATION menu.

INFUSION MODE INFORMATION

INFUSION COMPLETE

When the VTBI parameter of the current infusion decreases to zero, the pump determines that the infusion is completed and the pump automatically switches to KVO mode.

The Main display will present the "INFUSION COMPLETED – KVO" message and the KVO flow rate. An audio warning tone will sound every 5 seconds until the user presses the RUN/STOP key. If optional secondary alarm light is connected to the pump, this alarm light will turn solid (blue or red) during KVO mode until user presses the RUN/STOP key.

CONT KVOVINF1180mL 🔋

Infusion Completed

→KVO   5mL/H

The pump will continue infusing fluid into the patient with a "Keep Vein Open" rate of 5ml/h. The KVO rate of 5ml/h is also displayed in the Flow Rate LED.

Press the **RUN/STOP** key to acknowledge the infusion complete message. The pump will pause and the KVO infusion will be stopped.

⚠ **WARNING: Some Z-800 IV Administration Sets configurations do NOT have set based free-flow protection. Make sure to close roller clamp before removing administration set from Z-800 Infusion Pump.**

CONFIGURABLE SETTINGS (Continued)

Adjusting the Contrast

The Z-800 Main LCD Display's contrast level can be adjusted by the user.

1. From the configuration menu, Select 2. **FACTORY SET**

	BIOMED OPT	
1.		
2.	FACTORY SET	
3.	SAVE PROTOCOLS	
4.	INFORMATION	
SELECT		**QUIT**

2. In the **FACTORY SET** menu, highlight the **CONTRAST** option by pressing the **Up/Down Arrow.**

	FACTORY SET	
BRIGHTNESS		05
CONTRAST		08
ALARM VOLUME		LOW
SAVE		**CANCEL**

3. Press the ⌃ or ⌄ key to adjust Contrast from 00 to 09.

1. Press the **SAVE** ⊕ key to confirm the set value.

Press the **CANCEL** key ⊖ to back out. Press the **QUIT** key ⊖ again to exit the CONFIGURATION menu.

TPN MODE INFUSION

Access TPN Mode Infusion

The user may choose the TPN auto ramp infusion mode.

1. Press Home key to access the main page. If a confirmation page showing "Current infusion parameters will be lost. Want to continue?" is displayed, select YES to acknowledge.
   Note: Any unsaved parameters will be lost upon confirmation.

```
Current infusion pa-
rameters will be lost
Want to continue?
YES          NO
```

2. Select PROGRAM to access Infusion Mode menu.

```
PROGRAM

 PROTOCOL

SELECT
```

3. In pump Infusion Mode menu, use the Up/Down Arrow keys to highlight 3. **TPN MODE** and press the SELECT key.

```
1.  CONT MODE R/V
2.  CONT MODE T/V
3.  TPN MODE
4.  10 STEP MODE R/V
5.  10 STEP MODE T/V
6.  INTERMITTENT
SELECT
```

4. The pump will display the Programming screen of the TPN Mode infusion.

CONFIGURABLE SETTINGS (Continued)

Adjusting the LCD Brightness

The Z-800 Main LCD Display's brightness level can be adjusted by the user.

1. From the configuration menu, Select 2. **FACTORY SET**

```
1.  BIOMED OPT
2.  FACTORY SET
3.  SAVE PROTOCOLS
4.  INFORMATION

SELECT              QUIT
```

2. In the **FACTORY SET** menu, highlight the **BRIGHTNESS** option by pressing the **Up/Down Arrow.**

```
    FACTORY SET
BRIGHTNESS        05
CONTRAST          08
ALARM VOLUME    LOW

SAVE            CANCEL
```

3. Press the [ ] or [ ] key to adjust BRIGHTNESS from 00 to 09.

4. Press the **SAVE** key to confirm the set value. Press the **CANCEL** key to back out. Press the **QUIT** key again to exit the CONFIGURATION menu.

CONFIGURABLE SETTINGS (Continued)

Configuring Secondary Infusion Option

The Z-800 pump has the option to hide the Secondary Infusion option so that it is not selectable by the user. To hide or unhide this option select the **BIOMED OPT Menu**. When hiding the secondary infusion option, it will no longer be selectable by the user.
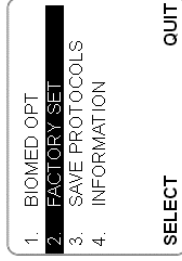
1. From the configuration menu, Select 1. **BIOMED OPT**.

2. In the **BIOMED OPT** menu, highlight the **HIDE SEC** option by pressing the **Up/Down Arrow**.

3. Press [↑] or [↓] key to switch between **YES** and **NO**.
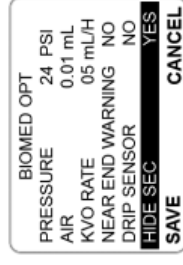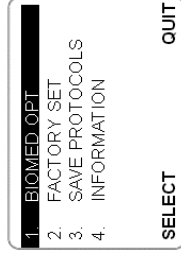
4. Press the **SAVE** key [−] to confirm the set value. Press the **CANCEL** key [−] to back out. Press the **QUIT** key [−] again to exit the CONFIGURATION menu.

NOTE: Hiding the secondary mode should be completed prior to starting an infusion for proper administration. When in manual continuous combined infusion, changing HIDE SEC to YES results in the infusion parameters being zeroed out. When in manual non-continuous infusion, changing HIDE SEC has no effect on selected infusion.

```
1.  BIOMED OPT
2.  FACTORY SET
3.  SAVE PROTOCOLS
4.  INFORMATION

SELECT              QUIT
```

```
        BIOMED OPT
PRESSURE          24 PSI
AIR              0.01 mL
KVO RATE         05 mL/H
NEAR END WARNING     NO
DRIP SENSOR          NO
HIDE SEC            YES
SAVE            CANCEL
```

TPN MODE INFUSION (Continued)

Programming TPN Mode Infusion

TPN infusion programming screen contains the following display areas:

1. **Status Bar**: The Status Bar displays current operating mode, current pump state, and volume infused.
   - **TPN**: TPN mode operation
   - **VINF**: Volume Infused for the current infusion
2. **Infusion Parameters**: TPN total VTBI and Total TIME of the infusion.
   - **TIME**: Total TIME of the infusion.
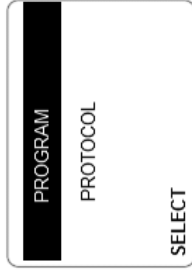   - **VTBI**: Total Volume to Be Infused.
3. **Keys**: Allow user to access pump configuration and TPN ramp programming screen
   - **CONFIG**: Accesses pump configuration
   - **RAMP**: Accesses TPN Ramp Up and Ramp Down Time parameter programming
   - **Up/Down Arrows**: Highlight the selected parameter item

The TPN infusion parameters may be programmed by using the UP/DOWN Arrow keys and Data Entry keys.

Access TPN Ramp Time Parameter Programming

From TPN programming screen, press RAMP Key to access TPN Ramp Parameter programming screen.

Programming TPN Ramp Time Parameters

The TPN Ramp Time parameters may be programmed by using the UP/DOWN Arrow keys and Data Entry keys.

⚠ **WARNING: Do not over-program VTBI. Program the actual amount of the fluid in the IV bag.**

```
TPN      VINF0000mL
TIME        00:00
VTBI       0000 mL
CONFIG          Ramp
```

```
TPN      VINF0000mL
UP TIME     00:00
DN TIME     00:00
CONFIG          VTBI
```

10-STEP MODE INFUSION

Access 10-STEP Mode Rate/Volume Infusion or 10-STEP Mode Time/Volume Mode Infusion

User may choose either 10 STEP infusion mode.

1. Press Home key to access the main page. If a confirmation page showing "Current infusion parameters will be lost. Want to continue?" is displayed, select YES to acknowledge.
   Note: Any unsaved parameters will be lost upon confirmation.

2. Select PROGRAM to access Infusion Mode menu.

3. In pump Infusion Mode menu, use the Up/Down Arrow keys to highlight **10 STEP MODE R/V or 10 STEP MODE T/V** and press the SELECT key.

4. The pump will display the Programming screen of the 10 STEP Mode infusion.

Current infusion parameters will be lost
Want to continue?
YES   NO

PROGRAM
PROTOCOL
SELECT

1. CONT MODE R/V
2. CONT MODE T/V
3. TPN MODE
4. 10 STEP MODE R/V
5. 10 STEP MODE T/V
6. INTERMITTENT
SELECT

CONFIGURABLE SETTINGS (Continued)

Enable/Disable Drip Sensor Option

The Z-800 pump has an optional external drip sensor, which may be used to detect a fluid container empty event. The user may enable or disable the drip sensor in the configuration menu. To enable or disable this option, refer to "**Customize the BIOMED OPT Menu**" page in this section. When enabled, the drip sensor will detect the absence of drips in the drip chamber, continue to infuse 8mL, then alarm, and stop the pump.

1. From the configuration menu, Select (1). **BIOMED OPT**.

2. In the **BIOMED OPT** menu, highlight the **DRIP SENSOR** option by pressing the **Up/Down Arrow.**

3. Press ⌃ or ⌄ key to switch between **YES** and **NO**.

4. Press the **SAVE** key ⊕ to confirm the set value.
   Press the **CANCEL** key ⊖ to back out. Press
   the **QUIT** key ⊖ again to exit the
   CONFIGURATION menu.

1. BIOMED OPT
2. FACTORY SET
3. SAVE PROTOCOLS
4. INFORMATION
SELECT   QUIT

BIOMED OPT
PRESSURE   24 PSI
AIR   0.01 mL
KVO RATE   05mL/H
NEAR END WARNING NO
DRIP SENSOR   NO
SAVE   CANCEL

10-STEP MODE RATE/VOLUME INFUSION (Continued)

Programming 10-STEP Mode Rate/Volume Infusion

Similar to the Continuous Mode infusion programming screen, the 10-STEP R/V infusion programming screen contains the following display areas:

1. **Status Bar**: The Status Bar displays current operating mode, current pump state, and volume infused.
   - **STEP01**: 10-STEP mode operation-Step01
   - **VINF**: Volume Infused for the current infusion
2. **Infusion Parameters**: Step01 Flow Rate and Step01 Volume to Be Infused
   - **RATE**: Current Step Flow Rate
   - **VTBI**: Current Step VTBI
3. **Keys**: Allow the user to access pump configuration and option setup screen.
   - **CONFIG**: Accesses pump configuration
   - **Up/Down Arrows**: Select parameter items and navigate between current step and previous/next step parameter programming

⚠ **WARNING: Do not over-program VTBI. Program the actual amount of the fluid in the IV bag.**

Navigate to Previous/Next Step

Use Up/Down Arrow keys to select current step parameters as well as change to previous or next step programming screen.

Similar to the Continuous Mode infusion programming screen, the 10-STEP R/V infusion parameters may be programmed by using the UP/DOWN Arrow keys and Data Entry keys. Simply continue to scroll down to program each step. The ten steps are a scrollable list that can be edited anytime during programming. Scroll and carefully review the steps you programmed before pressing **RUN/STOP** to begin the infusion. Pressing **RUN/STOP** to begin the infusion locks in the list. To edit the list after an infusion is underway, press **RUN/STOP** to pause, and then press the **PROG** key to edit the list.

```
STEP01   VINF0000mL
RATE  0000  mL/H
VTBI  0000  mL
CONFIG
```

CONFIGURABLE SETTINGS (Continued)

Enable/Disable NEAR END WARNING

The Z-800 Infusion Pump has a feature to detect that the current infusion is about to end in 3 minutes. The user may enable or disable the near end warning in the configuration menu. When enabled, the audio and visual warning message will appear every 5 seconds until infusion completion.

1. From the configuration menu, Select 1. **BIOMED OPT**.

2. In the **BIOMED OPT** menu, highlight the **NEAR END WARNING** option by pressing the **Up/Down Arrow.**

3. Press ⬆ or ⬇ key to switch between **YES** and **NO**.

4. Press the **SAVE** key ⊡ to confirm the set value. Press the **CANCEL** key ⊟ to back out. Press the **QUIT** key ⊟ again to exit the CONFIGURATION menu.

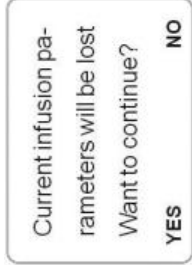⚠ **WARNING:** The factory default settings should be used unless qualified clinical personnel determine that other customized settings are appropriate and safe.

```
1. BIOMED OPT
2. FACTORY SET
3. SAVE PROTOCOLS
4. INFORMATION

SELECT              QUIT
```

```
        BIOMED OPT
PRESSURE          24 PSI
AIR               0.01 mL
KVO RATE          05mL/H
NEAR END WARNING  NO

SAVE              CANCEL
```

10-STEP TIME/VOLUME MODE INFUSION (Continued)

Programming 10-STEP Time/Volume Mode Infusion

Similar to the Continuous Mode infusion programming screen, the 10-STEP T/V infusion programming screen contains the following display areas:

1. **Status Bar**: The Status Bar displays current operating mode, current pump state, and volume infused.
   - **STEP01**: 10-STEP mode operation-Step01
   - **VINF**: Volume Infused for the current infusion
2. **Infusion Parameters**: Step01 Time and Step01 Volume to Be Infused
   - **TIME**: Current Step TIME
   - **VTBI**: Current Step VTBI
3. **Keys**: Allow the user to access pump configuration and option setup screen.
   - **CONFIG**: Accesses pump configuration
   - **Up/Down Arrows**: Select parameter items and navigate between current step and previous/next step parameter programming

Navigate to Previous/Next Step

Use Up/Down Arrow keys to select current step parameters as well as change to previous or next step programming screen.

Similar to the Continuous Mode infusion programming screen, the 10-STEP T/V infusion parameters may be programmed by using the UP/DOWN Arrow keys and Data Entry keys. Simply continue to scroll down to program each step. The ten steps are a scrollable list that can be edited anytime during programming. Scroll and carefully review the steps you programmed before pressing **RUN/STOP** to begin the infusion. Pressing **RUN/STOP** to begin the infusion locks in the list. To edit the list after an infusion is underway, press **RUN/STOP** to pause, and then press the **PROG** key to edit the list.
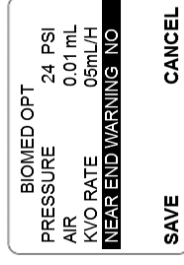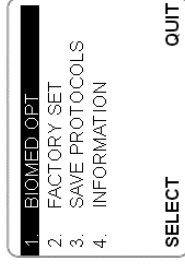
```
STEP01     VINF0000mL
TIME   00:00
VTBI   0000   mL
CONFIG
```

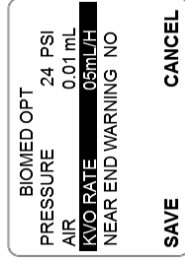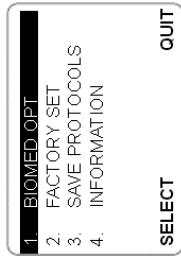⚠ **WARNING: Do not over-program VTBI. Program the actual amount of the fluid in the IV bag.**

CONFIGURABLE SETTINGS (Continued)

Adjusting the KVO RATE

The KVO rate can be adjusted in the configuration menu. The KVO rate can be adjusted by the user from 01ml/h to 20ml/h.

1. From the configuration menu, Select 1. **BIOMED OPT**.
2. In the **BIOMED OPT** menu, highlight the **KVO RATE** option by pressing the **Up/Down Arrow.**
3. Press ⌃ or ⌄ key to adjust the value.
4. Press the **SAVE** key to confirm the set value. Press the **CANCEL** key to back out. Press the **QUIT** key again to exit the CONFIGURATION menu.

⚠ **WARNING:** The factory default settings should be used unless qualified clinical personnel determine that other customized settings are appropriate and safe.

```
1. BIOMED OPT
2. FACTORY SET
3. SAVE PROTOCOLS
4. INFORMATION
SELECT              QUIT
```

```
        BIOMED OPT
PRESSURE        24 PSI
AIR             0.01 mL
KVO RATE        05mL/H
NEAR END WARNING  NO
SAVE            CANCEL
```

CONFIGURABLE SETTINGS (Continued)

Adjusting the Air-In-Line Alarm Threshold

The Z-800's Air-In-Line sensor detects an air bubble in the administration set tubing. Air-In-Line alarm threshold can be adjusted in the configuration menu. Alarm threshold can be adjusted to air bubble size from a volume of 2 micro-liters to 280 micro-liters. The Z-800's Air-In-Line Detector alarm threshold can be adjusted by the user.

1. From the configuration menu, Select 1. **BIOMED OPT**.

2. In the **BIOMED OPT** menu, highlight the **AIR** option by pressing the **Up/Down Arrow.**

3. Press ⬆ or ⬇ key to adjust the value.

4. Press the **SAVE** key ⦿ to confirm the set value.

   Press the **CANCEL** key ⦿ to back out. Press the **QUIT** key ⦿ again to exit the configuration menu.

⚠ **WARNING:** The factory default settings should be used unless qualified clinical personnel determine that other customized settings are appropriate and safe.
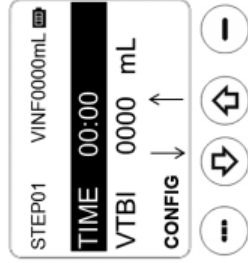
```
┌──────────────────────────────┐
│ 1.  BIOMED OPT               │
│ 2.  FACTORY SET              │
│ 3.  SAVE PROTOCOLS           │
│ 4.  INFORMATION              │
│                              │
│ SELECT              QUIT     │
└──────────────────────────────┘
```

```
┌──────────────────────────────┐
│      BIOMED OPT              │
│ PRESSURE          24 PSI    │
│ AIR              0.01 mL    │
│ KVO RATE        05mL/H      │
│ NEAR END WARNING  NO        │
│ SAVE             CANCEL     │
└──────────────────────────────┘
```

Z-800 Instructions for Use.
P/N 800-IFU-6651, Rev. I

INFUSION MODE INFORMATION

INTERMITTENT MODE INFUSION

Access Intermittent Mode Infusion

The user may choose the Intermittent Mode from Infusion Mode screen after entering a new infusion

1. Press Home key to access the main page. If a confirmation page showing "Current infusion parameters will be lost. Want to continue?" is displayed, select YES to acknowledge. Note: Any unsaved parameters will be lost upon confirmation.
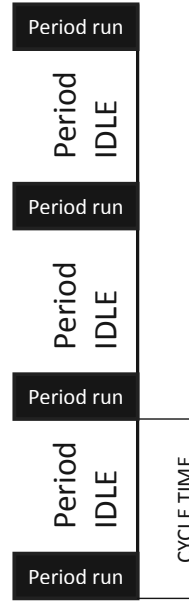
2. Select PROGRAM to access Infusion Mode menu.

3. In pump Infusion Mode menu, use the Up/Down Arrow keys to highlight 5. **INTERMITTENT** and press the SELECT key.

4. The pump will display the Programming screen of the intermittent mode infusion.

5. In intermittent mode, the pump runs for the period programmed, and then idles before the next period run. The sum of the "run" and the "idle" time is the cycle time, as illustrated below.

```
┌──────────────────────────────┐
│  Current infusion pa-        │
│  rameters will be lost       │
│  Want to continue?           │
│                              │
│  YES               NO        │
└──────────────────────────────┘
```

```
┌──────────────────────────────┐
│  PROGRAM                     │
│                              │
│  PROTOCOL                    │
│                              │
│  SELECT                      │
└──────────────────────────────┘
```

```
┌──────────────────────────────┐
│ 1.  CONT MODE R/V            │
│ 2.  CONT MODE T/V            │
│ 3.  TPN MODE                 │
│ 4.  10 STEP MODE R/V         │
│ 5.  10 STEP MODE T/V         │
│ 6.  INTERMITTENT             │
│     SELECT                   │
└──────────────────────────────┘
```

Period run	Period IDLE	Period run	Period IDLE	Period run	Period IDLE

CYCLE TIME

Z-800 Instructions for Use.
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MAINTENANCE

CONFIGURABLE SETTINGS

Adjusting the Occlusion Pressure Threshold

The pressure sensor detects down-stream occlusion in the IV sets. A user may specify the occlusion alarm pressure threshold in configuration screen. The occlusion alarm threshold can be adjusted between 4 psi and 30 psi

1. From the configuration menu, Select 1. **BIOMED OPT**.

```
1.  BIOMED OPT
2.  FACTORY SET
3.  SAVE PROTOCOLS
4.  INFORMATION

SELECT              QUIT
```

2. In the **BIOMED OPT** menu, highlight the **PRESSURE** option by pressing the **Up/Down Arrow**.

```
        BIOMED OPT
PRESSURE          24  PSI
AIR             0.01 mL
KVO RATE         05mL/H
NEAR END WARNING  NO

SAVE            CANCEL
```

3. Press ⌃ or ⌄ key to adjust the pressure.

4. Press the **SAVE** key ⊕ to confirm the set value. Press the **CANCEL** key ⊖ to back out.

Press the **QUIT** key ⊖ again to exit the configuration menu.

⚠ **WARNING:** The factory default settings should be used unless qualified clinical personnel determine that other customized settings are appropriate and safe.

INTERMITTENT MODE INFUSION (Continued)

Programming INTERMITTENT Mode Infusion

```
INTR        VINF0000mL
Total VTBI   0500mL
Cycle Time   00:60
CONFIG       PERIOD
```

INTERMITTENT infusion programming screen contains the following display areas:

1. **Status Bar**: The Status Bar displays current operating mode, current pump state, and volume infused.
   • **INTR**: INTERMITTENT mode operation
   • **VINF**: Volume Infused for the current infusion
2. **Infusion Parameters**: INTERMITTENT total VTBI and Cycle TIME of the infusion.
   • **Total VTBI**: Total Volume to Be Infused
   • **Cycle Time**: This displays the time for each cycle in Hour: Minute format. Cycle time should be programmed between 30 minutes and 24 hours. If the programmed Cycle Time is outside the range, pump alarms "Invalid Parameters."
3. **Keys**: Allow user to access pump configuration and INTERMITTENT ramp programming screen.
   • **CONFIG**: Accesses pump configuration
   • **PERIOD**: Accesses INTERMITTENT period parameter programming
   • **Up/Down Arrows**: Highlight the selected parameter item

The Total VTBI and Cycle Time parameters may be programmed by using the UP/DOWN Arrow keys and Data Entry keys.

Note: During idle period, the pump runs at KVO rate. Volume infused during idle period is counted. The pump alarms "Infusion Completed" once VINF (volume infused) equals programmed Total VTBI.
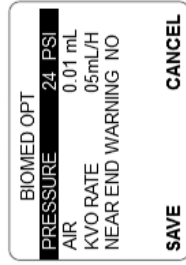
INTERMITTENT MODE INFUSION (Continued)

Programming INTERMITTENT Mode PERIOD parameters

INTERMITTENT infusion PERIOD programming screen contains the following display areas:

```
INTR        VINF0000mL  🔋
Period VTBI  0100mL
Period Time  00:30
CONFIG              TOTAL
```

1. **Status Bar**: The Status Bar displays current operating mode, current pump state, and volume infused.
   - **INTR**: INTERMITTENT mode operation
   - **VINF**: Volume Infused for the current infusion
2. **Infusion Parameters**: INTERMITTENT Period VTBI and Period TIME of the infusion
   - **Period VTBI**: Period Volume to Be Infused. The programmed value of this parameter has to be equal or less than the Total VTBI.
   - **Period Time**: This displays the time for each period run in Hour **:** Minute format. Period time has to be programmed between 10 minutes and 23 hours. If programmed Period Time is outside the range, pump alarms "Invalid Parameters".
3. **Keys**: Allow user to access pump configuration and INTERMITTENT TOTAL programming screen.
   - **CONFIG**: Accesses pump configuration
   - **TOTAL**: Accesses INTERMITTENT Total parameter programming
   - **Up/Down Arrows**: Highlight the selected parameter item

The Period VTBI and Period Time parameters may be programmed by using the UP/DOWN Arrow keys and Data Entry keys.

Example: To infuse total of 200mL drug intermittently, infuse 50mL (Period VTBI) every 6 hours (Cycle Time). The run time for each period is 10 minutes (Period Time); idle time in each cycle is 5 hours 50 minutes. The parameters can be programmed as follows:

Total VTBI: 200mL
Cycle Time: 06:00

Period VTBI: 50mL
Period Time: 10 minutes

SPECIFICATIONS (Continued)

Environmental Specifications:

Non-Operating Conditions (Transportation and Storage):

Temperature: -40°C to 55 °C (-13 °F to + 122 °F)

Humidity: < 93% R.H., non-condensing

Air pressure: 48kPa to 110kPa

Operating Conditions

The system may not meet all performance specifications if operated outside of the following conditions:

Temperature: +10°C to +40 °C (+59 °F to + 113 °F)

Humidity: 30 % to 75% R.H. at +40 °C, non-condensing

Air pressure: 70kPa to 106kPa

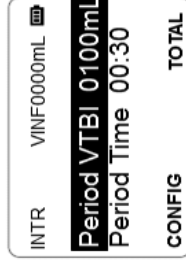IV Administration Set: Use only Zyno Medical approved Administration IV Sets.

Alarms:
Air-in-Line
Occlusion
Door Open
Battery Empty
No Drip (Optional)

Warnings:
Low Battery
Pump Unattended
Near End
Infusion Complete – KVO
Due for Service

Errors: System Error

BLOOD INFUSION

Access BLOOD INFUSION mode

The user may choose the BLOOD INFUSION Mode.

1. Press Home key to access the main page. If a confirmation page showing "Current infusion parameters will be lost. Want to continue?" is displayed, select YES to acknowledge.
   Note: Any unsaved parameters will be lost upon confirmation.

> Current infusion parameters will be lost
> Want to continue?
> YES   NO

2. Select PROGRAM to access Infusion Mode menu.

> PROGRAM
> PROTOCOL

3. In pump Infusion Mode menu, use the Up/Down Arrow keys to highlight **6. BLOOD INFUSION** and press the SELECT key.

> 2. CONT MODE T/V
> 3. TPN MODE
> 4. 10 STEP MODE R/V
> 5. 10 STEP MODE T/V
> 6. INTERMITTENT
> 7. BLOOD
> **SELECT**

4. The pump will display the Programming screen of the BLOOD INFUSION mode.

MAINTENANCE

MAINTENANCE

SPECIFICATIONS

Pumping Mechanism:	Linear Peristaltic
Flow Rate:	1 - 1200 ml/h in 1 ml increments
Priming Rate:	600 ml/h
Volume to Be Infused:	1 - 9,999 ml in 1 ml increments
Accuracy*:	± 5 %
Time Memory is maintained:	Permanent for previous infusion parameters.
Air-in-Line Detector:	Ultrasonic, 14-level configurable
Occlusion Detector:	Pressure sensor. 14-level configurable
Electrical Standard:	Class I, Type BF
Electrical Safety	Complies with: EN 60601-2-24:1998; EN 60601-1:2006/AC:2010; EN 60601-1-2:2007/AC:2010; EN 60601-1-6:2010; EN 60601-1-8:2007; EN 60601-1-11:2010, and EN 62366:2008.
Power Requirements:	100 – 240 VAC, 50-60 Hz
Power Consumption:	25 VA (at maximum flow rate)
Internal Battery:	Rechargeable Nickel-Metal-Hydride 9.6V; 4.5 Amp-hr (Replaceable by qualified service personnel only)
Battery Life at 125 ml/h:	8 hours
Battery Charging:	Automatic when pump plugged into an AC power source
Pump Housing:	Cast Aluminum & Sheet Metal
Weight:	3.2 kilograms, 7.0 lbs
Dimensions:	8.6"H x 5.7"W x 5.3"D
Standards:	Manufactured in a facility certified with ISO 13485: 2003

*The device is calibrated within flow rate accuracy specification under the following conditions:
- Test fluid is distilled water at room temperature (21+/-1°C) at ambient air pressure;
- Head height is set according to instructions in the IFU;
- Test set is Zyno proprietary set at specifications;
- Programmed volume during test is no less than 10 mL.

INFUSION MODE INFORMATION

BLOOD INFUSION (Continued)

Programming Blood Infusion Mode parameters

Blood infusion programming screen contains the following display areas:

1. **Status Bar**: The Status Bar displays current operating mode, current pump state, and volume infused.
   - **BLD**: BLOOD mode operation.
   - **VINF**: Volume Infused for the current infusion.
2. **Infusion Parameters**: BLOOD flow rate and Volume to Be Infused.
   - **RATE**: Blood flow rate
   - **VTBI**: Volume to Be Infused
3. **Keys**: Allow user to access pump configuration programming screen.
   - **CONFIG**: Access pump configuration
   - **Up/Down Arrows**: Highlight the selected parameter item

The RATE and VTBI parameters may be programmed by using the UP/DOWN Arrow keys and Data Entry keys.

BLD   VINF 0000mL

RATE   0500mL
VTBI   0100mL

CONFIG

ALARMS AND TROUBLESHOOTING

ERRORS

| Error	Meaning	Secondary Alarm/ Warning Light (optional)	Response
System Error	The system has detected an error in the pump. Infusion stops.	Continuously flashes (blue or red) notification until user acknowledgement.	Press **RUN/STOP** key to silence the alarm and to stop using the affected pump. The pump must be taken out of service until serviced by qualified service personnel.

MANAGING INFUSION

PRIME THE ADMINISTRATION SET USING PRIME KEY

The user can use the **PRIME** key to prime air bubbles out of the IV Administration Set from the distal end after it is loaded in the pump.

1. Press the **PRIME** key. The pump screen will display the PRIME warning message "Disconnect patient, then press and hold soft "Prime" key as indicated below." Confirm that the patient is not connected to the administration set. Press and hold the ⊖ key to prime.

> Disconnect patient, then press and hold soft "Prime" key as indicated below.
>
> **PRIME**

2. During the prime, the pump will run at the fixed prime flow rate of 600mL/hr. Both Air-In-Line sensor and Occlusion sensor are disabled.

3. Release the ⊖ key when the set is fully primed. While the ⊖ key is pressed, the pump screen will report the volume primed. The maximum prime volume is 10mL. Upon reaching the maximum prime volume, the prime will stop.

> PRIME
> 03ml

⚠ **WARNING: Patient must be disconnected before utilizing the PRIME key.**

ALARMS AND TROUBLESHOOTING

WARNINGS (Continued)

Infusion Complete – KVO	Infusion is completed. The pump automatically switches to KVO mode. The visual warning message will appear and the audio alarm will sound constantly until user acknowledgement.	Stays solid (blue or red) notification until user acknowledgement.	Press the RUN/STOP key. The Z-800 Pump will be paused.
Pump will be due for service soon.	The pump needs to be serviced soon.	N/A	Call 1-866-395-1988 to schedule the pump maintenance service.
Pump is due for service.	The pump must be serviced before use.	N/A	Stop using the pump. Call 1-866-395-1988 to schedule the pump maintenance service.

WARNINGS

Warning	Meaning	Secondary Alarm/ Warning Light (optional)	Response
Low Battery	Z-800 Infusion Pump is operating on battery power and low battery condition is detected. Battery has 30 minutes or less of power at current rates before operation will stop. The infusion continues. The audio and visual warning message will appear every 5 seconds.	Continuously flashes (blue or red) notification until user acknowledgement.	Plug the power cord into an AC power outlet. The audio warning will be silenced when AC power is detected.
Pump Unattended	The Z-800 Infusion Pump detects the current infusion is paused and there is no user input for more than 5 minutes. The audio and visual warning message will appear every 5 seconds until user acknowledgement.	Continuously flashes (blue or red) notification until user acknowledgement.	Press the **RUN/STOP key.** The Z-800 Pump will display the current infusion programming screen.
Near End	The Z-800 Infusion Pump detects the current infusion is about to end in 3 minutes. The audio and visual warning message will appear every 5 seconds until infusion completion.	Continuously flashes (blue or red) notification until user acknowledgement.	Prepare for completion of the infusion which will occur in 3 minutes.

MANAGING INFUSION

KEYPAD LOCKOUT

1. To lock keypad, press the CLR key and immediately after that the 10's DOWN data entry key. An audio prompt tone will sound and a "PANEL LOCKED" message will be displayed for 3 seconds.

2. During KEYPAD LOCKOUT, the user may only press and hold ON/OFF key for emergency shut off.

3. Any other key press will result a message display of "PANEL LOCKED" for 3 seconds.

4. To unlock the keypad, press the CLR key and immediately after that the 10's DOWN data entry key. An audio prompt tone will sound and a "PANEL UNLOCKED" message will be displayed for 3 seconds.

PANEL LOCKED

PANEL UNLOCKED

CLEAR VOLUME INFUSED

1. From primary or secondary setup state, user may elect to clear the current volume infused (VINF) parameter.

2. Press the RUN/STOP key to PAUSE the primary or secondary infusion during infusion.

3. Press the PROG key to return to programming page, press and hold CLR key, an audio prompt tone will sound and a confirmation screen will be displayed.

   - Press the YES key to confirm the action

   - Press the NO key to abort the action.

4. Upon user confirmation, the current VINF parameter will be reset to 0 ml.

NOTE: The VINF field will record cumulative infusion volume infused unless cleared by pressing the CLR key.

ALARMS AND TROUBLESHOOTING

ALARMS

Alarm	Meaning	Secondary Alarm/ Warning Light (optional)	Response
Air-in-line	Air has been detected in the set during an infusion. Infusion stopped.	Continuously flashes (blue or red) notification until user acknowledgement.	1. Acknowledge the alarm by pressing RUN/STOP key. 2. The infusion is paused. 3. Clear air from line and press the RUN/STOP key again to resume infusion.
Door Open	Pump door is opened during an infusion. The infusion is stopped.	Continuously flashes (blue or red) notification until user acknowledgement.	1. Acknowledge the alarm by pressing the RUN/STOP key. 2. The infusion is paused. 3. Close the pump door. Press the RUN/STOP key again to resume infusion.
Occlusion	Increased back pressure is sensed while infusing. Infusion is stopped.	Continuously flashes (blue or red) notification until user acknowledgement.	1. Resolve the cause of the occlusion. 2. The infusion will resume when pressure is reduced to below the alarm threshold.
No Drip	The drip sensor does not detect a fluid drop in the drip chamber (continues for 8mL, then alarms).	Continuously flashes (blue or red) notification until user acknowledgement.	1. Acknowledge the alarm by pressing RUN/STOP key. 2. The infusion is paused. 3. Verify that the fluid container is not empty. Press the RUN/STOP key again to resume infusion.
Battery Empty	The Z-800 pump is operating on battery power and battery is too low for pump operation.	Continuously flashes (blue or red) notification until user acknowledgement.	1. Plug the power cord into an AC power outlet. 2. Acknowledge the alarm by pressing RUN/STOP key. 3. The infusion is paused. Press RUN/STOP key again to resume infusion.

MANAGING INFUSION

POWERING OFF

Stop the Z-800 Infusion Pump by pressing the **RUN/STOP** key during an infusion.

Press and hold down the **ON/OFF** key for 2 seconds. The pump will turn off.

ALARMS AND TROUBLESHOOTING

ALARMS AND TROUBLESHOOTING

To enhance safety and ease of operation, the Z-800 Infusion Pump provides a full range of audio and visual alarms, warnings, and prompts.

DEFINITIONS

Error
An audio and visual signal indicates a failure has been detected. Immediate action is required.

The affected Z-800 pump needs to be replaced with an operational unit. The affected pump should be serviced by qualified personnel.

Alarm
An audio and visual signal indicates that a potentially unsafe condition is detected. Immediate action is required.

Under an alarm condition, the Z-800 Infusion Pump is in STOP state. The audio signal will sound until positive confirmation from user is delivered.

The Z-800 Infusion Pump will not allow the user to resume the infusion until the potentially unsafe condition is resolved.

Warning
An audio and visual signal indicates that a potentially unsafe condition is present. Immediate action is required.

Under a warning condition, the Z-800 Infusion Pump will continue to operate. The audio signal will not be silenced until the warning condition is resolved.

MANAGING PRIMARY SOLUTION CONTAINER

CHANGING PRIMARY SOLUTION CONTAINER

1. Stop the Z-800 Infusion Pump by pressing the **RUN/STOP** key during an infusion.

2. Close the Roller Clamp.

3. Remove the empty solution container.

4. Spike the new container.

5. Go to the primary infusion programming screen. Highlight Pri VTBI parameter. Use the data entry keys to enter desired VTBI.

6. Open the roller clamp.

7. Press the RUN/STOP key to resume infusion.

⚠ **WARNING: Some Z-800 IV Administration Sets configurations do NOT have set based free-flow protection. Make sure to close roller clamp before removing administration set from Z-800 pump.**
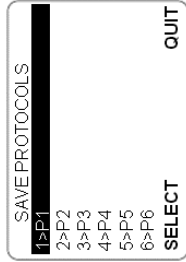

SAVE INFUSION PARAMETERS AS PROTOCOL

Turn on the pump; Select NEW INFUSION; Program an infusion.

Example:
1. Select **10 STEP MODE.** Program a 10 Step infusion with the following parameters.
   - **STEP 1:** RATE=50ml/h, VTBI=25ml.
   - **STEP 2:** RATE=100ml/h, VTBI=50ml.
   - **STEP 3:** RATE=150ml/h, VTBI=75ml.
   - **STEP 4:** RATE=200ml/h, VTBI=100ml.
   - **STEP 5:** RATE=250ml/h, VTBI=250ml.
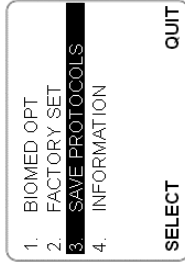
2. From the 10 STEP Programming screen, press the **CONFIG** key to access CONFIG screen. Select **3. SAVE PROTOCOLS**.

```
1.  BIOMED OPT
2.  FACTORY SET
3.  SAVE PROTOCOLS
4.  INFORMATION

SELECT              QUIT
```

3. Select one of the 8 protocols to be used to store the infusion parameters. Enter the name to be used for the protocol.

```
SAVE PROTOCOLS
1>P1
2>P2
3>P3
4>P4
5>P5
6>P6
SELECT              QUIT
```

   - Use the [100] or [100»] key to scroll through letter a through z.
   - Use the [10] or [»10] key to scroll through letter A through Z.
   - Use the [<] or [v] key to scroll through digit 0 through 9, SPACE and other special characters.
   - Use the Up/Down Arrow to move the cursor back and forth.

```
PROTOCOL 1 NAME

XXXXXXX

SAVE              CANCEL
```

4. Press **SAVE** key to associate the current programmed infusion parameters with the protocol name as entered.

NOTE: Loading factory default settings will delete all saved protocols. (Refer to Maintenance->Configurable settings->Load default on how to load factory default).

CHANGING AND RELOADING IV SET DURING INFUSION

Stop the Z-800 pump by pressing the **RUN/STOP** key during an infusion.

Close the roller clamp.

Disconnect the administration set from the patient.

Open the pump door.

Remove the administration set from the pump.

Prime and load a new administration set, as described in the Prepare Infusion section.

Close the pump door.

Open the roller clamp.

Press the RUN/STOP key to resume infusion.

⚠ **WARNING: Some Z-800 IV sets configurations do NOT have set based free-flow protection. Make sure to close roller clamp before removing administration set from Z-800 pump.**

PROTOCOL MODE INFUSION

Access Protocol Mode Infusion

A user may choose to save the current infusion parameters to the pump as a pre-defined protocol. The saved protocol can be retrieved in the future to automatically program a current infusion. This can eliminate repetitive programming for selected commonly used infusion regimens.
The Protocol infusion mode may be accessed after entering a new infusion.

RESUME INFUSION
NEW INFUSION

SELECT

1. Turn on the pump and select NEW INFUSION, or, if the pump is in infusion parameter programming screen, press Home key to access home page.

PROGRAM
PROTOCOL

SELECT

2. The home page should be displayed. Highlight **PROTOCOL** using Up/Down arrows and press **SELECT**.

LOAD PROTOCOLS
1>P1
2>P2
3>P3
4>P4
5>P5
6>P6
SELECT   **QUIT**

3. The pump will display the protocol names saved on the pump. There are up to 8 protocols that can be saved on the pump.

4. Choose one of the protocols by highlighting the name of the protocol. Press the SELECT key to program the highlighted protocol.

5. The pump will display the Programming screen of the pre-defined infusion mode with pre-defined infusion parameters populated.

Start Infusion

Verify the displayed infusion parameter entries (Primary Rate, Primary VTBI, Secondary Rate, and Secondary VTBI). If a clamp is engaged, remove the clamp. Press **RUN/STOP** key to start the infusion.

RUN/STOP key

RUN / STOP