

OPERATIONS MANUAL FOR ABC SYRINGE INFUSION PUMP MODEL 4100 (Software Version 1.15)

This manual is intended to be used with any pump whose software version is 1.15.



Atlanta BioMedical Corporation (ABC)

305 Shawnee North Drive
Suite 250
Suwanee, GA 30024
770-904-3766

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SECTION 1. INTRODUCTION and WARNINGS

1.1 INTRODUCTION

1.1.1 Indications for Use:

ABC Syringe Infusion Pump Model 4100 provides a continuous or bolus infusion in any area such as neonatal and pediatric intensive care, anesthesia, adult critical care or any other area where the pump use can be monitored or supervised by a trained healthcare professional where the precise administration of fluids including drugs, antibiotics, lipids, blood, blood products, enteral solutions, or other therapeutic solutions is required

Delivery routes include: Intravenous, arterial, epidural, spinal, enteral, and subcutaneous.

Delivery modes include: Continuous, volume /time, mass, body weight, and bolus.

1.1.2 Important Notices:

Delicate medical instrument, handle with care.

The notices having the symbol  contains important information that user needs to understand before operating the pump. It includes **WARNING, CAUTION, and IMPORTANT** notices. Also included are FDA-directed **Warnings and Precautions** notices. It is the user's responsibility to understand and follow these notices.

CAUTION:

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

IMPORTANT:

Prior to using any ABC pump it is the responsibility of the operator to be thoroughly familiar with the contents of this manual.

Carefully read the entire contents of this manual including all **CAUTIONS** and **WARNINGS** before attempting to use this pump.

Always verify that the SOFTWARE VERSION of the pump and operation manual are in agreement.

Only trained medical personnel approved by their institution should attempt to use this pump.

All medications should be delivered per their approved drug labeling.

There are five infusion modes: Body-Weight mode, Mass mode, Unit mode, Continuous mode, and Volume over Time mode.

- (1) Body-Weight Mode where mass units (e.g., MG or mcg) are delivered per weight (e.g., KG) per time (e.g., minute or hour). Rates for this mode would be programmed in MG/kilogram/minute or hour and mcg/kilogram/minute or hour.
- (2) Mass mode where mass units (e.g., MG or mcg) are delivered per time (e.g., minute or hour). Rates for this example would be programmed in MG per hour or minute or in mcg per hour or minute.

- (3) Unit Mode where milliunits or units (e.g., mU or U) are delivered per time (e.g. minute or hour). Rates for this example would be programmed in mU per hour or minute or in U per hour or minute.
- (4) Continuous mode where volume (e.g., ML) is delivered per time (e.g., hour or minute). Rates for this example would be programmed in ML per hour or minute.
- (5) Volume over Time mode where the total delivery volume in ML and the desired delivery time in hour and minutes are programmed.

1.2 WARNINGS

⚠ WARNING: Anyone operating this pump is responsible for knowing and using the information presented in this manual and in particular in this section.

The table below identifies many potentially **serious life and safety hazards**. Others such warnings are posted throughout this manual.

Users	This pump is for use only under the direction of qualified medical professionals.
High Negative Pressures	Do not use this pump where high negative pressures can occur. This includes on the inlet side of any Extracorporeal Membrane Oxygenation (ECMO) system.
Magnetic Fields	Do not expose the pump to strong magnetic fields as it may affect pump function.
Flammables	Do not use in presence of flammable anesthetics, explosive gases or oxygen enriched atmospheres.
Fluid Exposure Not Waterproof	Do not allow fluids to enter the pump housing. Immediately wipe off all spills.
Pump Performance	If the pump fails to perform as described herein, remove from service and consult the manufacturer.
Dropped or Damaged Pump	The pump must be thoroughly examined and tested to assure proper functioning prior to reuse.
Do Not Autoclave Or Gas Sterilize	Subjecting the pump to an autoclave or gas sterilization can cause serious pump damage.
Never Use Sharp Objects	Never use any sharp objects including sharp finger nails on the pump keypad. These can damage the operation of the keys.
Verify Syringe Manufacturer and Size	Verify that both the manufacturer of the syringe in use and the syringe size coincide with the information displayed on LCD display. Use of other manufacturers and sizes can lead to possible inaccurate delivery (over or under delivery). Use only the syringe types and sizes listed in the general specifications section of this manual.
Syringe Selection and Rate	To optimize delivery performance always select the smallest syringe size with the highest infusion rate for the intended infusion. Using a large syringe at low rates can increase infusion start-up times and increase the occlusion detection time.
Drug Manufacture Guidelines	Follow manufacturers precautions and guidelines for all medications or fluids infused. These fluids may interact with plastic components of the infusion set up (syringes, tubing, stopcocks, injection ports, etc.).

Syringe Labels	Do not place any labels on the syringe that will be covered by the syringe retainer clamp or between the syringe and the saddle. The syringe clamp must contact the syringe barrel without interference to ensure accurate syringe size sensing.
Verify Settings	Prior to using the pump always verify programmed settings by reviewing the 3 View Options pages.
Prevent Air Emboli	Purge all air from the syringe and infusion lines before connecting to patient.
Syringe Loading and Unloading	Make sure all fluid flow to the patient is turned OFF via clamping the tube, turning off a stopcock, etc. to eliminate the possibility of creating uncontrolled fluid flow to the patient.
Verify Proper Set up	Verify that the syringe and infusion lines are properly set up prior to beginning any infusion. Always verify that the syringe is mounted properly. The finger tabs should be secured by the syringe clamp and the syringe plunger end by the syringe driver retainer.
Syringe Pump Placement	Moving the syringe pump after it is connected to the patient can cause changes in hydrostatic pressure resulting in 1) over deliver if moved above the patient due to possibly bolusing and 2) under delivery if moved below the patient.
Priming	Never use the Prime function to deliver fluids directly to the patient.
Priming New Syringes	The PRIME function should always be utilized when mounting a newly filled syringe to remove any mechanical tolerances. Failure to do so may delay the delivery of the infusate (medication) and result in a falsely higher TOTAL DELIVERED read-out.
Check for Leaks	Periodically inspect the infusion fluid pathway for leaks.
Confirm Settings	Always confirm all settings prior to commencing any infusion.
Occlusion Alarm	When an occlusion alarm occurs and is corrected, there is a possibility of infusing the pressurized buildup of infusate. To avoid delivering an inadvertent bolus to the patient, relieve the pressure before restarting the infusion.
Communication Port	Used for Atlanta BioMedical diagnostic purposes only.
Safe Operation	To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth. Unplug the line cord to disconnect from supply mains.
Safe Operation	Do not modify this equipment without authorization of the manufacturer.
Battery Safe Operation	When the battery is removed from the unit, do not touch the battery terminals or the battery connections in the units housing and the patient at the same time.
Safe Operation	Do not place the pump in contact with the patient.

1.3 Warnings and Precautions

The following Warnings and Precautions are verbatim from an FDA notice to all syringe infusion pump manufacturers, for inclusion in the Operation Manuals:

Syringe Size and Selection

- Warning: Ensure syringe sizes and models are compatible with the syringe pump (refer to Section 2, General Specifications, for more information). Use of incompatible syringes can cause improper pump operation resulting in inaccurate fluid delivery, insufficient occlusion (blockage) sensing, and other potential problems.
- Warning: Use the smallest compatible syringe size necessary to deliver the fluid or medication; this is especially important when infusing high risk or life-sustaining medications at low infusion rates (e.g., less than 5 mL per hour, and especially flow rates less than 0.5 mL per hour). Using a larger syringe when infusing at low rates can lead to inadequate syringe pump performance including delivery inaccuracies, delay of therapy, and delayed generation of occlusion alarms. This is due to the increased friction and compliance of the syringe plunger tip with larger syringes.

Use of Accessory Devices

- Precaution: Use compatible components which have the smallest internal volume or “deadspace” to minimize residual volumes between the syringe and the patient when administering medications or fluids at low infusion rates (e.g., less than 5mL per hour, and especially flow rates less than 0.5 mL per hour). This reduces the amount of time it takes for fluid to reach the patient, maintains delivery accuracy, and reduces occlusion detection times. For example:
 - o **Tubing internal diameter:** Small bore or microbore tubing is recommended when infusing at low rates
 - o **Tubing length:** Tubing length should be minimized, when possible
 - o **Filters:** Internal volume (deadspace) of in-line filters should be minimized
 - o **Connection sites:** The number of connection sites such as stopcocks and Y-sites should be limited, and high risk or life-sustaining solutions should be connected as close to the intravenous access site as possible.
- Precaution: Avoid use of manifolds with ports containing high pressure valves. High pressure valves require additional pressure (e.g., 50-200 mmHg) to open and allow fluid flow. These high pressure valves may cause a significant delay in therapy followed by a sudden bolus once the valve is opened, particularly at low infusion rates (e.g., less than 5mL per hour, and especially flow rates less than 0.5 mL per hour).

Starting an Infusion or Changing a Syringe

- Precaution: Manually prime the syringe and tubing to remove all air, before connecting to the pump.
- Warning: **Electronically prime the syringe pump system before starting an infusion or after replacing a near-empty syringe with a replacement syringe.**
 - o Verify the fluid flow to the patient is OFF, and if available, use the prime (or purge) function on the syringe pump to remove any mechanical slack in the system.
 - o Using the syringe pump’s prime (or purge) feature engages the mechanical components of the pump and decreases the syringe’s friction and compliance (i.e., stiffness) to minimize startup delays and delivery inaccuracies, especially at low infusion rates.

o Failure to use the prime (or purge) feature on the syringe pump after every syringe change and/or tubing change can significantly delay the infusion delivery startup time and lead to delivery inaccuracies.

- Warning: During programming and prior to starting an infusion, verify that the syringe size and model on the syringe pump's display screen matches the syringe size and model loaded onto the syringe pump.

Height and Location of Syringe Pump System

- Warning: Ideally, the syringe pump should be level with distal tip of the catheter (e.g., the site of fluid delivery; if accessing a central line, the syringe pump should be at the level of the patient's heart). If the pump height is raised relative to the distal tip of the catheter (e.g., during patient transport), the increase in height of the syringe pump can result in a temporary increase in fluid delivery or bolus until the flow rate stabilizes. Alternatively, if the pump is lowered relative to the distal tip of the catheter, the decrease in height of the syringe pump may result in a decrease in delivery or under-infusion until the flow rate stabilizes.

- Precaution: If using multiple syringe pumps and it is not clinically feasible to have all pumps level with the distal tip of the catheter (or the site of fluid delivery), place the high risk or life-sustaining medications as close to level with the distal tip of the catheter as possible. When infusing multiple high risk or life-sustaining medications, consider placing the ones infusing at the lowest rates as close to the level with the distal tip of the catheter as possible.

- Precaution: Minimize the height difference between the pump and the patient and avoid changes in the height of the pump (e.g., during transport of critically ill patients) to prevent unintended fluctuations in the flow rate.

Occlusion Considerations

- Warning: To minimize the amount of time it takes the pump to recognize an occlusion (blockage) and generate an alarm while infusing at low rates (e.g., less than 5mL per hour, and especially flow rates less than 0.5 mL per hour):

- o Consider the plunger force or occlusion pressure threshold setting and adjust it, as necessary. The lower the plunger force setting or occlusion pressure threshold setting, the shorter the occlusion detection time. However, when infusing viscous or thick fluids (e.g., lipids), the plunger force or occlusion pressure threshold setting may need to be adjusted to reduce false alarms. Please refer to sub-section 7.7, Enhanced Pump Performance, for further detail.

- o Use the smallest compatible syringe size necessary to deliver the fluid or medication. This minimizes the amount of friction and compliance (i.e., stiffness) of the syringe plunger tip. Because syringe pumps infuse fluids by precisely controlling the plunger, smaller syringes provide more precise fluid delivery than larger syringes.

- o Use the prime (or purge) feature on the pump when changing a syringe and/or tubing.

- o Use accessory devices, which have the smallest internal volume or dead space (e.g., use microbore tubing when infusing at low rates, shorter length of tubing, etc.). See sub-section 7.7, Enhanced Pump Performance, for further detail.

- Warning: When addressing or clearing an occlusion:

- o **Ensure the fluid flow to the patient is OFF** to prevent administering an unintended bolus. An occlusion may pressurize the infusion tubing and syringe, which can result in an unintended bolus of drug when the occlusion is cleared. In order to prevent this additional bolus, disconnect the tubing, or relieve the excess pressure through a stopcock, if present. The health care professional should weigh the relative risks of disconnection with the risks of an unintended bolus of drug.

o Be aware that using larger size syringes on a high plunger force setting may produce a larger post occlusion bolus due to excessive syringe plunger tip compliance.

Note: Some of the **Warnings and Precautions** in this sub-section are duplicated in content and substance by the preceding sub-section, **1.2 WARNINGS**, there being no contradictions or counter-intuitive statements within these two sub-sections.

1.4 BATTERY DISPOSAL INSTRUCTIONS

- (1) The battery pack is user-replaceable and should be disposed by the user in an environmentally correct manner in accordance with local and governmental regulations.
- (2) At the end of useful life, the ABC 4100 device has several components which require environmentally correct disposal, e.g., the circuit boards and battery pack. The user should follow local and governmental regulations upon disposal of the device.
- (3) The battery pack has an estimated useful life of at least 500 cycles under normal conditions. The battery pack should be recharged if the pump is not used for 3-4 months to preserve its estimated useful life.

SECTION 2. GENERAL SPECIFICATIONS

Overall Size	9.5" wide × 3.95" high × 5.9" deep
Weight	4.99 Pounds
Accuracy	±3%, excluding syringe variations
Infusion Modes	<u>Body-Weight Modes</u> mcg/KG/min, mcg/KG/HR, MG/KG/min, MG/KG/HR <u>Mass Modes/Unit Modes</u> mcg/min, mcg/HR, MG/min, MG/HR mU/min, mU/HR, U/min, U/HR <u>Continuous Modes</u> ML/min, ML/HR, ML/DY <u>Volume/Time and Auto-Volume/Time Modes</u> dose volume / delivery time <u>Dose Modes</u> <i>DS/HR, DS/MN, DS/DY, DS/TM, DS/UT/HR, DS/UT/mn, DS/UT/DY, DS/UT/TM</i>
Flow Rate	Dependent on syringe size selected (see Appendix II)
Bolus	In Body-Weight, Mass, Unit, and Continuous Modes
Power	AC Power or DC Internal rechargeable batteries
Recharge Time	No longer than 4 hours
Battery Capacity	At 25 degrees C, 4 hour charge will operate the pump for approximately 12 hours at 5.0 ML/HR with a 60 ML syringe
Alarms/Alerts	Audio Volume Alarm: LOW, NORM, HIGH, or VLOW Battery Depleted Bolusing Check Track Check Plunger Loading Syringe Empty Delivery Limit Exceed Max Rate / Try New Number Enter Access Lock Invalid Number / Try New Number Invalid Size / Check Syringe Check Syringe Loading / Try Again / Press Enter Low Battery Near Empty Occlusion (Plunger) Out of Soft Limit Plunger Disengaged Syringe Dislodged System Malfunction / Error Code ## Temporary Delay Alarm: 2 to 60 minutes
Status Alerts	Battery Charging Battery Depleted Battery in use Deliver Priming / Don't Prime to Patient

Standby Mode
Stop/Program

Syringe Manufacturer

Becton Dickinson (B-D)	1, 3, 5, 10, 20, 30, 50/60 ML
Monoject (Mono)	1, 3, 6, 12, 20, 35, 60, 140 ML
Terumo (Teru)	1, 3, 5, 10, 20, 30, 60 ML
B-D Glass (B-D G)	1, 2.5, 5, 10 ML
ABC	140 ML
PS - RTI	3, 5, 10, 20, 30, 60
Custom Syringe	Contact ABC

Enteral Syringe Manufacturer

	Enteral Tip	ENFit Tip	
B-D	(ETBD)	---	1, 3, 5, 10, 20, 30, 50/60 ML
Mono	(ETMN)		1, 3, 6, 12, 20, 35, 60 ML
Mono	---	(ETMN)	x, x, 6, 12, x, 35, 60 ML
Avanos	---	(AVNS)	10, 20, 60 ML
NeoMed®	(NEOM)	(NEOM)	1, 3, 6, 12, 20, 35, 60, 100 ML
Ameritus®	(AMP)	(AMP)	1, 3, 5, 10, 20, 30, 60 ML
Vygon® C-Gon	(VYGO)	---	1, 2.5, 5, 10, 20, 35, 60 ML
Medela	(MDLA)	(MDLA)	5, 10, 30, 60 ML, and 140 ML (ENFit only)
Medicina	(MEDI)	---	5, 10, 20, 30, 60 ML
Custom Enteral Syringe			Contact ABC

Total Delivered	
from 0.01	To 99999 ML
from 0.01	To 99999 MG
from 0.01	To 99999 U

Becton Dickinson (B-D) is a trade mark of Becton Dickinson and Co.

Monoject is a trade mark of Medtronic Inc. (formerly Covidien, Kendall Company/Tyco Healthcare)

Terumo is a trade mark of Terumo Company

ABC stands for Atlanta BioMedical Corporation

Patient Safe is a registered trademark of Retractable Technologies Inc.

ETBD/ETMN are the same luer-tip B-D/MONO i.v. syringes with added enteral tip.

AVNS references Avanos Medical (formerly known as Halyard Health)

NeoMed® is a trade mark of NeoMed, Inc.

Ameritus® is a trade mark of Kentec Medical, Inc.

Vygon® is a trade mark of Vygon Corporation

MDLA references Medela Corporation

Power Rating: 120VAC, 115mA, 50/60Hz (240AC, 90mA, 50/60Hz available)

Safety Protection: Class I, Type BF  Equipment, against dripping water

⚠ WARNING: Accessories equipment connected to the communications port of this unit must be certified to the respective IEC/EN standards (i.e. IEC/EN 60950-1 for data processing equipment and IEC/EN 60601-1 for medical equipment.)

Furthermore, all configurations shall comply with the system standard IEC 60601-1-1.

⚠ WARNING: The maximum over-infusion which could occur in the event of a single-fault condition will not exceed 2 seconds of infusion at any infusion rate.

Operating Orientation: Pump is primarily designed for operating in horizontal position, but other orientations (e.g., 90° vertical) will not affect delivery accuracy.

Normal Operating Conditions

Temperature	5°C to 40°C (40°F to 104°F)
Relative Humidity	15 to 95% non-condensing
Ambient Pressure	70kPa to 106kPa (10.2 psi to 15.4 psi)
Infusion Back Pressure:	-100mmHg (-4.4ft H ₂ O) to +300mmHg (+13.4ft H ₂ O)

Storage Conditions:

Temperature:	0°C to 60°C (32°F to 140°F)
Relative Humidity:	5 to 95% non-condensing
Ambient Pressure:	70kPa to 106kPa (10.2 psi to 15.4 psi)

Guidance and manufacturer's declaration – electromagnetic emissions		
The ABC Model 4100 is intended for use in the electromagnetic environment specified below. The customer or the user of the ABC Model 4100 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The ABC Model 4100 used RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The ABC Model 4100 is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class D	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The ABC Model 4100 Syringe Infusion Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the ABC Model 4100 Syringe Infusion Pump should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic Discharge (ESD) IEC 61000-4-2 IEC 60601-2-24	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient/burst IEC 61000-4-4	+/- 2 kV or power Supply lines +/- 1 kV for input/output lines	+/- 2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	+/- 1 kV differential mode +/- 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) For 0,5 cycle 40% U_T (60% dip in U_T) For 5 cycles 70% U_T (30% dip in U_T) For 25 cycles <5% U_T (>95% dip in U_T) For 5 s	<5% U_T (>95% dip in U_T) For 0,5 cycle 40% U_T (60% dip in U_T) For 5 cycles 70% U_T (30% dip in U_T) For 25 cycles <5% U_T (>95% dip in U_T) For 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ABC Model 4100 requires continued operation during power mains interruptions, it is recommended the Model 4100 be powered from its battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 IEC 60601-2-24	400 A/m	400 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

SECTION 3. GENERAL DESCRIPTION/DIAGRAM, ALARM/ALERT

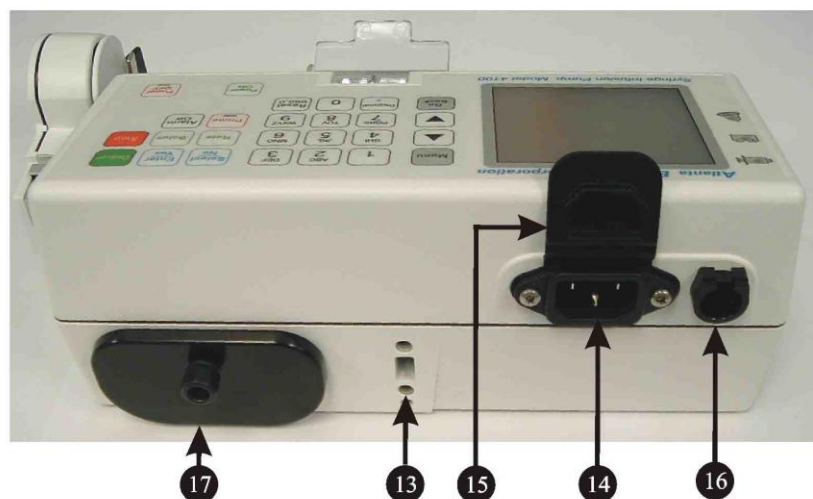
3.1 FRONT VIEW

- ① Alarm LEDs
- ② LCD Display Screen
- ③ Syringe Light (LED)
- ④ Disposable Syringe
- ⑤ Syringe Saddle
- ⑥ Syringe Clamp
- ⑦ Syringe Finger Tab Metal Retainer (Saddle Spring)
- ⑧ Clutch Lever
- ⑨ Syringe Driver
- ⑩ Plunger Retaining Bars
- ⑪ Keypad
- ⑫ Label Areas
- ⑬ Track



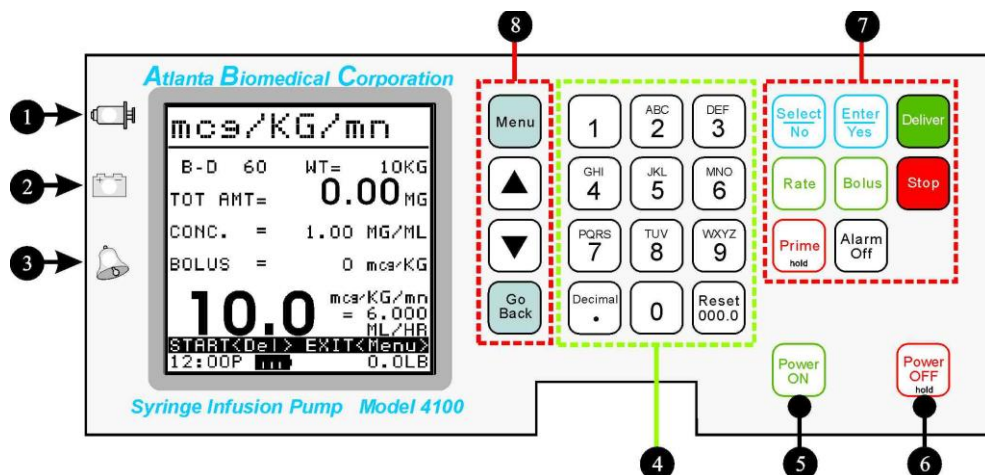
3.2 BACK VIEW

- ⑬ Handle Screw Holes
- ⑭ Power Cord Receptacle
- ⑮ AC Inlet Cover
- ⑯ Communication Port
- ⑰ Battery Pack



3.3 KEYPAD LAYOUT

- ① Syringe Alarm LED
- ② Battery Alarm LED
- ③ Malfunction LED
- ④ Number Keys
- ⑤ Power ON Key
- ⑥ Power OFF Key
- ⑦ Function Keys
- ⑧ Navigation Keys



3.4 SCREEN FORMAT

3.4.1 OPERATIONS SCREEN

(Body-Weight Mode shown)

- ① Rate Mode / Program
Displays the current selection of rate mode or program.
- ② Syringe Manufacturer and Size
Displays the current selection of syringe manufacturer and detected size.
- ③ Body Weight
Displays body weight of patient.
- ④ Total Amount Delivered
Displays total amount of infusate (medication) that has been delivered.
- ⑤ Concentration Lock ON
Displays the concentration of the infusate (medication).
- ⑥ Bolus
Displays the bolus amount to be delivered and delivery time.
- ⑦ Rate
Displays the current infusion rate and the equivalent rate in ML/HR.
- ⑧ Instruction/Status Lines
Two lines at the bottom of the screen that display the current status of the pump and instructions for the user, including:
 (1st line) Instructions (START EXIT<Menu>) or Near Empty alert message
 (2nd line) Time: *displays the present time.*
 Battery Symbol: *shows current battery charge condition*
 Plunger Force Graph or Reading: *indicates force detected at syringe plunger*

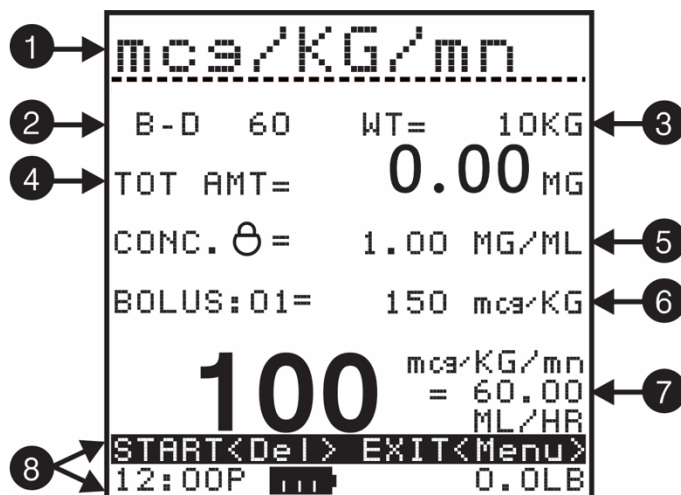


Figure 3.4.1: Operations Screen for Body Weight Mode

3.4.2 MENU SCREEN

- ① Menu Title
Displays current menu title.
- ② Selection Area
Displays options from which user can choose.
- ③ Instruction Area
Displays instructions for given menu.

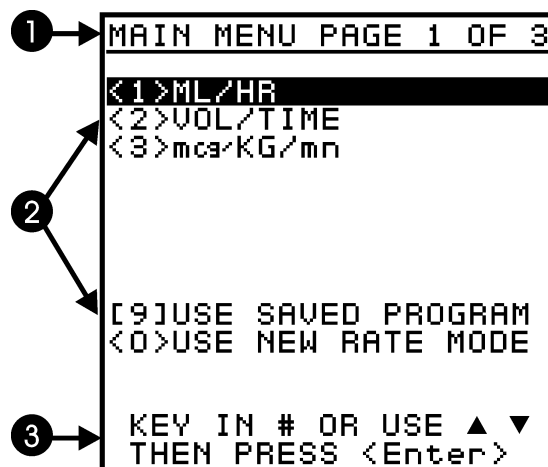


Figure 3.4.2: A typical menu screen displays the menu title (1), a selection area (2), and an instruction area (3).

3.5 ALARMS/ALERTS

LEDs There are three LEDs to the left of the LCD display:

 Syringe Symbol: can either be red or green.
RED: stop
GREEN: delivering
RED/GREEN: caution—near empty (blinks), etc.

 Battery Symbol: can be red, yellow or green.
RED: depleted battery
GREEN: charging
YELLOW: battery in use

 Malfunction Symbol
RED: system malfunction

Syringe LED – This front mounted LED can be red or green. It shows the same pattern as the syringe symbol LED.

LCD The LCD display will show written Error/Alert messages.

AUDIO An audio alert will sound to notify the user of various conditions:

Slow beeping: Indicates that the pump has stopped or is Near Empty
Fast beeping: Indicates error conditions
Continuous: Indicates system malfunction

SECTION 4. GETTING STARTED

4.1 TURNING ON THE PUMP

If AC Power is connected, the pump is automatically energized. The pump performs Self-Test and enters Power-off/Standby mode, the battery pack is charged if needed. However, if the battery pack is not inserted or is defective, REPLACE BATTERY is displayed. Press the **Power ON** key to turn on the pump.

If Battery Power is used, press the **Power ON** key to turn on the pump. Self-Test is performed after power-on. The LCD also displays the SW Version, SW date, and the S/N of the pump. It does not display the current date/time.

In both cases provided the option for USER ID and PATIENT ID are disabled, MAIN MENU PAGE 1 OF 3 is displayed, showing available Start-Up Rate modes (Refer to paragraph 8.1.1 for description of Start-Up Rate Modes).

The pump can be configured using special access codes for 3 master delivery modes – 1) Medela Enteral Only, 2) ABC IV Only, and 3) ABC Enteral Only.

NOTE: When multiple menus are available, use the **Menu** and **Go Back** keys to navigate (Refer to SECTION 8 for detailed explanation of Menu Structure).

If either USER ID and PATIENT ID or both are enabled as described in section 8.3.2.1.10 The operator will need to enter the appropriate ID information before reaching the Start-Up screen.

4.2 PROGRAM INFUSION SETTINGS

The infusion settings of the pump can be programmed in a menu-driven method. Brief instructions to guide the user are provided at the bottom of each menu. The following is a typical infusion setting programming sequence:

4.2.1 Select a Rate Mode (MAIN MENU PAGE 1 OF 3)

User can choose from the rate modes available on the Start-Up list; these modes are the most commonly used rate modes. User can also use option <8> To recall the last settings, <9> to choose from Saved Programs, or option <0> to choose from the list of other standard Rate Modes. (Refer to paragraph 6.1 for a detailed explanation of Rate Modes). The programming sequence varies slightly among the different Rate Modes. **Follow the menus and instructions to program the settings required for the selected Rate Mode.** The following example describes the programming sequence for ML/HR mode.

4.2.2 Select a Syringe Manufacturer

Use the **Select** or **▲ ▼** keys to scroll to the desired Syringe manufacturer. Press **Enter** key to confirm the selection. If Enteral syringe manufacturer is selected, manufacturer symbol is highlighted and a large highlighted “ENTERAL” will replace the rate mode name at the top of LCD display.

(Note: This step may be skipped if only one manufacturer is selected in PUMP DEFAULTS. Refer to paragraph 8.3.2.1.1).

⚠ IMPORTANT: If an Enteral syringe manufacturer is selected the only valid Rate Modes are ML/HR and Volume / Time. If any other Rate Mode is attempted to be used, **MFGER IS NOT ALLOWED!** will be displayed and the pump will return to MAIN MENU PAGE 1 OF 3.

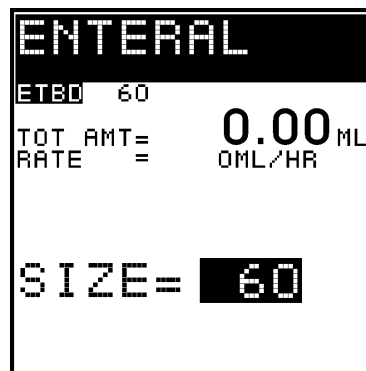


Figure 4.2.3 Enteral Syringe

4.2.3 Load Syringe

Syringe must be properly loaded (Refer to SECTION 5 for syringe loading instructions). Press **Enter** key and the syringe size is automatically detected and displayed. Make sure that the syringe size has been correctly recognized.

4.2.4 Program Delivery Limit

Program the Delivery Limit with the **number** or **up/down arrow** keys and use **Enter** key to confirm the number. If a Delivery Limit is not needed, enter 0.

(Note: This step may not be present if disabled in PUMP DEFAULTS. Refer to paragraph 8.3.2.1.3).

4.2.5 Program Automatic Bolus

Program the Bolus Amount with **number** or **up/down arrow** keys and use **Enter** key to confirm the number. If Bolus is not needed, enter 0.

(Note: This step may not be present if disabled in PUMP DEFAULTS. Refer to paragraph 8.3.2.1.4).

4.2.6 Program Manual Bolus

This step may not be present if disabled in PUMP DEFAULTS. Refer to paragraph 8.3.2.3.5

To Deliver a Manual Bolus press the Bolus key once then press and hold the Bolus Key until the desired amount has been delivered. If the Manual Bolus Duration Limit is reached the Bolus will stop. To continue repeat the previous steps.

If enabled the Manual Bolus is active in both the Stop and Delivery Modes.

The Manual Bolus Duration Limit is set in the pump defaults section (8.3.2.3.6).

4.2.7 Program Rate

Program the Infusion Rate with **number** or **up/down arrow** keys, press **Enter** key to confirm the rate.

The programming of the infusion settings is now complete.

4.3 PRIMING THE SYRINGE

WARNING:

Before starting a delivery, the syringe must be primed to remove any residual air inside the syringe tip and the infusion extension set and to eliminate any mechanical slack. **Make sure that the infusion line is not connected to the patient when priming.**

Press and hold the **Prime** key to start the priming process. Release the **Prime** key when all the air has been pushed out and fluid begins to flow out of the infusion line. The Prime key may be pressed multiple times if necessary. Now connect the infusion line to the patient (Refer to paragraph 7.5 for more details on Priming).

4.4 STARTING AND STOPPING DELIVERY

Press the **Deliver** key to start delivery. Use the **Stop** key to stop delivery (Refer to SECTION 7 for more details on Delivery).

4.5 TURNING OFF THE PUMP

Press and hold the **Power OFF** key to turn off the pump. If AC Power is used, the pump will go into Power-off/Standby mode. If Battery Power is used, the pump will shut down.

SECTION 5. SYRINGE LOADING INSTRUCTIONS

(1) Move the black CLUTCH LEVER toward the WHITE TAB.



(2) Pinch and hold together the CLUTCH LEVER/TAB, which releases the clutch.



(3) Pull the SYRINGE DRIVER outward until it reaches the end of its travel and then release the CLUTCH LEVER.



(4) Grasp the clear SYRINGE CLAMP, pull upward allowing room for the syringe in the SYRINGE SADDLE.



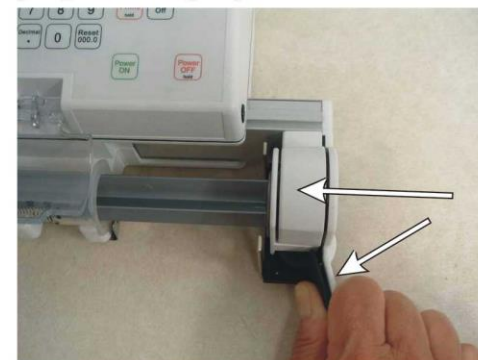
(5) Insert the syringe barrel first.



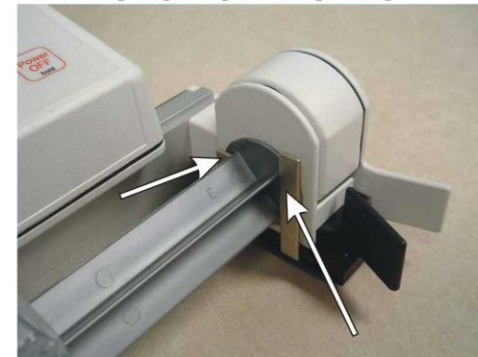
(6) Make sure the syringe finger tabs are retained by the METAL RETAINING SPRING and release the syringe clamp so that the syringe is held securely in the saddle.



(7) Pinch and hold together the CLUTCH LEVER/TAB and move the SYRINGE DRIVER forward until the SYRINGE DRIVER contacts the end of the syringe plunger and then gently release the CLUTCH LEVER.



(8) Make sure the RETAINING BARS secure the end of the plunger to prevent siphoning.



(9) Syringe is now properly loaded.

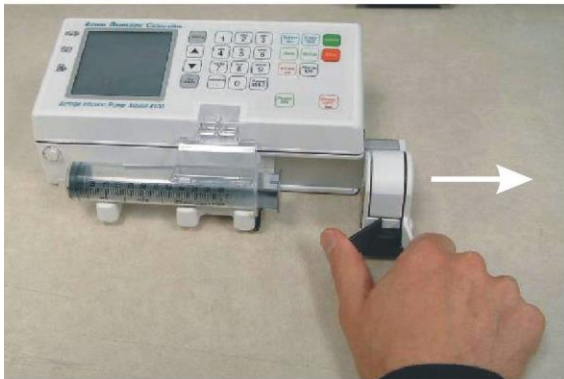


Unloading Syringe Instructions

1. Pinch and hold together the CLUTCH LEVER/TAB, which releases the clutch and the retainers.



2. Pull the SYRINGE DRIVER outward and then release the CLUTCH LEVER carefully.



3. Grasp the clear SYRINGE CLAMP, pull upward allowing room to remove the syringe from the SYRINGE SADDLE.



4. While holding the SYRINGE CLAMP up, remove the syringe.



5. Gently lower the SYRINGE CLAMP down.



SECTION 6. INFUSION SETTINGS

6.1 RATE MODES

Five Rate Modes are provided to match the preferred delivery method of a specific medicine. Some infusion settings, such as Syringe Manufacturer and Size, are the same for all Rate Modes. However, there are differences in the infusion settings required for different Rate Modes. Once a Rate Mode is selected, the pump will provide a sequence of menus to guide the user to enter the required infusion settings.

Once all the required infusion settings are entered, the user is allowed to change Rate or Bolus directly by pressing the **Rate** and **Bolus** keys respectively. However, other infusion settings such as Concentration, Delivery Limits, etc. must be programmed sequentially by pressing the **Select** key while in Stop Mode.

If the syringe is removed the user is asked to load a new syringe and press **Enter** key. The size of the new syringe is recognized. If a different size is detected, the Delivery Limit, Bolus, and Rate are reset to 0. A sequence of menus will guide the user to enter the required infusion settings.

If a different Rate Mode is desired, the user can press **Menu** key to return to MAIN MENU PAGE 1 OF 3 and select a new Rate Mode. The Total Amount Delivered and all other infusion settings are reset to 0 when a new Rate Mode is selected.

Some infusion settings (such as Bolus and Delivery Limit) can be disabled (i.e., programmed to not show up) by configuring PUMP DEFAULT options. The input unit for some infusion settings can also be customized with this option. (Refer to paragraph 8.3.2 for more details on configuring PUMP DEFAULTS).

The five types of rate modes are as follows:

6.1.1 Continuous Modes: ML/HR, ML/mn, ML/DY

Infusion settings to be programmed:

Delivery Limit, Bolus, and Rate.

Programming Sequence:

Syringe Manufacturer, Syringe Size, Delivery Limit, Bolus, and Rate.

After the initial programming sequence, Bolus and Rate can be modified directly by using the **Bolus** and **Rate** keys respectively. Delivery Limit can be modified with the **Select** key in Stop Mode. However, after the Delivery Limit is modified, the user is asked to confirm Bolus and Rate. Press **Enter** key to re-confirm the Bolus and Rate if no modification is needed.

If Rate Mode is ML/mn, then the equivalent rate in ML/HR is automatically calculated and displayed to the right of the ML/mn rate.

The syringe size determines the volume range (in ML) for Delivery Limit and Bolus, and the rate range (in ML/HR). (Refer to Appendix II for data).

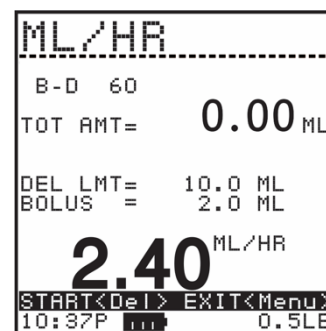


Figure 6.1.1: ML/HR
Stop Mode Screen

6.1.2 Volume/ Time and Auto-Volume/ Time Modes

Infusion settings to be programmed:

Delivery Volume and Delivery Time in Volume/Time
Confirm Volume and Program Time in Auto-Volume/Time.

Programming Sequence:

Syringe Manufacturer, Syringe Size, Delivery Volume, and Delivery Time.

Unlike in other rate modes, the **Rate** key in Vol/Time mode is used to modify both Delivery Volume and Delivery Time.

The equivalent Rate in ML/HR is calculated and automatically displayed.

The syringe size sets the allowable range for Delivery Volume (in ML) and Rate (in ML/HR). The allowable Delivery Time is determined by the programmed Delivery Volume and the syringes maximum and minimum rates (Refer to Appendix II for this data).

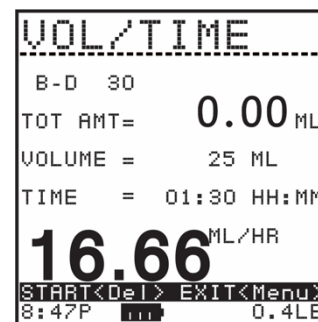


Figure 6.1.2: Vol/Time Stop Mode Screen

⚠ IMPORTANT: Program 1 hour and 30 minutes as 01:30 (HH:MM) or 00:90 (HH:MM).

6.1.3 Body-Weight Modes: *mcg/KG/mn*, *mcg/KG/HR*, *MG/KG/mn*, *MG/KG/HR*

Infusion settings to be programmed:

Body Weight, Concentration, Deliver Limit, Bolus, and Rate.

Programming Sequence:

Syringe Manufacturer, Body Weight, Concentration, Syringe Size, Deliver Limit, Bolus, and Rate.

Bolus and Rate can be modified directly by using **Bolus** and **Rate** keys respectively. The equivalent volume in ML for Total Amount and Bolus can be temporarily viewed by pressing **Enter** key.

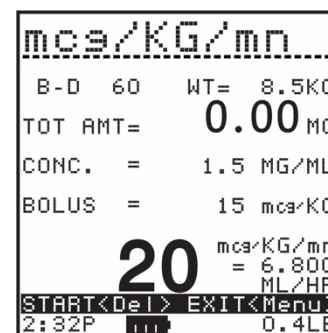


Figure 6.1.3: mcg/KG/mn Stop Mode

Normally, Body Weight and Concentration are not modified once they are programmed for a patient with a specific infusion regimen. However, if modification is needed, pressing the **Select** key in the Stop Mode will initiate the following programming sequence: Concentration, Body Weight, Syringe Size, Bolus, and Rate.

If Concentration is modified, the equivalent Total Amount Delivered in ML is displayed. Since the Total Amount in mass units is invalid for the new concentration, the user is prompted to record the previous Total Amount values and press the **Reset 000.0** key to reset the Total Amount. Bolus and Rate are also reset to 0.

The equivalent Rate in ML/HR is automatically calculated and displayed to the right of the Body-Weight Rate.

The syringe size sets the allowable volume range (in ML) for Bolus and the allowable Rate range (in ML/HR). The allowable ranges for Bolus and Rate in Mass/Body-Weight mode are calculated from the Appendix II with the data from the Programmed Weight and Concentration (Refer to Appendix I for calculations).

6.1.4 Mass Mode and Unit Mode:

Mass- **mcg/mn, mcg/HR, MG/mn, MG/HR**

Unit - **mU/mn, mU/HR, U/mn, U/HR**

The Infusion settings to be programmed are:

Concentration, Delivery Limit, Bolus, and Rate.

The Programming Sequence is:

Syringe Manufacturer, Concentration, Syringe Size, Delivery Limit, Bolus, and Rate.

Mass Mode/Unit Mode is similar to Continuous Mode, but with ML replaced by mass units or units.

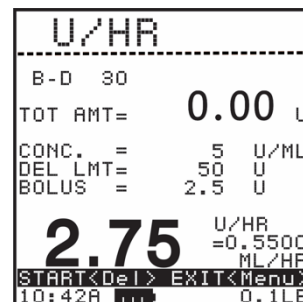


Figure 6.1.4: U/HR
Stop Mode Screen

Bolus and Rate can be modified directly by using the **Bolus** and **Rate** keys respectively. The equivalent volume in ML for Total Amount, Delivery Limit, and Bolus can be viewed temporarily by pressing the **Enter** key.

Pressing the **Select** key in Stop Mode will initiate the following programming sequence: Concentration, Syringe Size, Delivery Limit, Bolus, and Rate.

If Concentration is modified, the equivalent Total Amount Delivered in ML is displayed. Since the Total Amount in mass units is invalid for the new concentration, the user is reminded to record these total amount values and asked to press **Reset 000.0** key to reset Total Amount. Delivery Limit, Bolus and Rate are also reset to 0.

The equivalent Rate in ML/HR is automatically calculated and displayed to the right of the Mass Rate.

The syringe size sets the allowable volume range (in ML) for Bolus and the allowable rate range (in ML/HR) (Refer to Appendix II for values). The allowable ranges for Delivery Limit, Bolus and Rate in Mass Units are calculated from Appendix II with the Programmed Concentration data.

6.1.5 DOSE MODE:

Note: DS= Dose, TM = Time, UT = kg or M2

Concentration Units: mL, G, MG, mcg, U, mMol, mEq

Time can be in mn, HR, TM (HR:mn)

Dose can be: mL, G, MG, mcg, ng, U, mU, mM (mMol), mE (mEq)

mL = milliliters, G = grams, mcg = milligrams, ng = nanograms, U = units,

mU = milliunits, mM (mMol) = millimoles, mE (mEq) = milliequivalents

Dose - DS/HR, DS/MN, DS/DY, DS/TM, DS/UT/HR, DS/UT/mn, DS/UT/DY, DS/UT/TM

Table below show a summary of the possible allowable entries.

Mass	DS/HR	DS/mn	DS/DY	DS/TM	DS/UT/HR	DS/UT/mn	DS/UT/DY	DS/UT/TM
ML	ML/HR	ML/mn	ML/DY	V/T, ML/TM	ML/KG/HR	ML/KG/mn	ML/KG/DY	ML/KG/TM
G	G/HR	G/mn	G/DY	G/TM	G/KG/HR	G/KG/mn	G/KG/DY	G/KG/TM
G/MG	MG/HR	MG/mn	MG/DY	MG/TM	MG/KG/HR	MG/KG/mn	MG/KG/DY	MG/KG/TM
MG	MG/HR	MG/mn	MG/DY	MG/TM	MG/KG/HR	MG/KG/mn	MG/KG/DY	MG/KG/TM
MG/mcg	mcg/HR	mcg/mn	mcg/DY	mcg/TM	mcg/KG/HR	mcg/KG/mn	mcg/KG/DY	mcg/KG/TM
mcg	mcg/HR	mcg/mn	mcg/DY	mcg/TM	mcg/KG/HR	mcg/KG/mn	mcg/KG/DY	mcg/KG/TM
mcg/ng	ng/HR	ng/mn	ng/DY	ng/TM	ng/KG/HR	ng/KG/mn	ng/KG/DY	ng/KG/TM
U	U/HR	U/mn	U/DY	U/TM	U/KG/HR	U/KG/mn	U/KG/DY	U/KG/TM
U/mU	mU/HR	mU/mn	mU/DY	mU/TM	mU/KG/HR	mU/KG/mn	mU/KG/DY	mU/KG/TM
mM	mM/HR	mM/mn	mM/DY	mM/TM	mM/KG/HR	mM/KG/mn	mM/KG/DY	mM/KG/TM
mE	mE/HR	mE/mn	mE/DY	mE/TM	mE/KG/HR	mE/KG/mn	mE/KG/DY	mE/KG/TM

Select desired mode below:

DS/HR
DS/mn
DS/DY
DS/TM
DS/UT/HR
DS/UT/mn
DS/UT/DY
DS/UT/TM

Select Concentration Units follow pump prompts to complete programming.

Dose Mode programming sequence follows:

DS/HR, DS/MN, DS/DY

Conc Unit > Delivery Unit > Syr Mfger > Conc > Load Syr > Bolus > Rate

DS/TM

Conc Unit > Delivery Unit > Syr Mfger > Conc > Load Syr > Bolus > Dose > Time

Dose/UT/HR, DS/UT/mn, DS/UT/DY

Conc Unit > UT (KG or M2) > Syr Mfger > UT value > Conc > Load Syr > Bolus > Rate

DS /UT/TM

Conc Unit > Delivery Unit > UT (KG or M2) > Syr Mfger > UT value > Conc > Load Syr > Bolus > Dose > Time

Note: If the Bolus feature is NOT enabled it will not be offered during programming.

Note: On the LCD screen if DELIVERY UNIT mX = YES then MG becomes mcg, mcg becomes ng, U becomes mU.

6.2 SAVED PROGRAMS / EPROG

The pump provides a convenient feature for Creating and Retrieving Saved Programs. This feature allows users to save programs with a specific Rate Mode and infusion settings, for use in repeated infusions of the same medicine.

Programs can be created with option <3> of MAIN MENU PAGE 2 OF 3 (Refer to paragraph 8.2.2 for instructions on Creating a Program). Note that Weight and Delivery Limit values are not stored in the Saved Program.

Once a program is saved, it can be retrieved using option <9> of MAIN MENU PAGE 1 OF 3. Saved infusion settings are retrieved, but the user must enter values for Weight and Delivery Limit, as they are not stored.

The pump can store an EPROG. EPROG must be factory programmed. Directions for retrieving EPROG entries can be found in this Ops Manual for retrieving EPROG.

6.3 GENERAL RULES AND USEFUL TIPS FOR PROGRAMMING THE PUMP

- (1) As a general rule, during the programming of a parameter (when the number is blinking), the user must press **Enter**, **Stop**, or **Go Back** keys to conclude the data input. Pressing the **Enter** key accepts the programmed number. Using the **Stop** key abandons the programming process and leaves the current parameter unaltered. Pressing the **Go Back** key abandons the programming of the current parameter and goes back to the previous screen.

If the programming involves a sequence of infusion settings (such as the processes initiated by the **Select** key), the **Stop** key is active only if no change has been made to the infusion settings. In other words, the programming sequence can be abandoned only if nothing has been changed. Once a parameter has been changed, all other infusion settings must be reentered, and the **Stop** key is no longer valid.

- (2) On MAIN MENU PAGE 1 OF 3, the **Stop** key can be used to retrieve the most recently used Rate Mode and infusion settings. It serves as a “Retrieve Previously Used Rate Mode” function.

SECTION 7. DELIVERY

The pump has three types of fluid delivery:

NORMAL delivery, **BOLUS** delivery, and **PRIMING**

The infusion rate for NORMAL delivery is the programmed rate discussed in the previous section. The BOLUS (or PRIMING) delivery rate is the maximum rate the pump can deliver with the selected syringe size unless the rate is adjusted temporarily (Refer to paragraph 8.2.4 for more on the TEMPORARY ADJUST Option) or the USE BOLUS TIME default if enabled see 8.3.2.3.3.

The amount of fluid delivered in NORMAL or BOLUS delivery counts toward the Total Amount as well as the Running Amount. (Further discussed in paragraph 7.1.1 and 7.1.2 below) However, the amount of fluid pushed out of the syringe during PRIMING **does not** count toward the Total Amount and Running Amount (PRIMING is further discussed in paragraph 7.5).

7.1 STARTING NORMAL DELIVERY

All required infusion settings must be programmed before either delivery or priming can begin. Priming should always occur before beginning the actual delivery (Refer to paragraph 7.5 for more on Priming).

After the **Deliver** key is pressed, the pump checks if the Syringe is properly loaded. If the syringe is not properly loaded an audio alarm and LCD message will be actuated.

If a non-enteral syringe is selected or if Enteral Check in Pump Defaults is set to 0 MSG, **NORMAL delivery** will begin.

If the Enteral Check is set to 1 thru 7 MSGs in Pump Defaults and an enteral manufacturer is selected, immediately after pressing the Deliver key depending on the Pump Default a combination of questions must be confirmed prior to commencing delivery.

If selection 2 is enabled:

TRACE TUBING->PATIENT

PRESS<Enter> TO CONT. --- Pressing Enter initiates Delivery

or

If selection 7 is enabled:

(1) **VERIFY PATIENT I.D.**

PRESS<Enter> TO CONT. --- Press Enter

(2) **TRACE TUBING->PATIENT**

PRESS<Enter> TO CONT. --- Press Enter

(3) **VERIFY PUMP POSITION**

PRESS<Enter> TO CONT. --- Pressing Enter initiates Delivery

See section 8.3.2.2.6 to review all possible combinations.

When delivering the Syringe Status LED indicator is a **slow-blinking GREEN**.

The following are the only active keys during NORMAL Delivery:

- (1) **Stop** key stops any infusion, including BOLUS or NORMAL delivery.
- (2) **Rate** key allows user to change the NORMAL delivery rate.
- (3) **Bolus** key activates a process for confirming the bolus parameter. If the **Deliver** key is pressed while the bolus amount is blinking, the pump delivers the Bolus programmed. However, if **Enter** key is pressed, the pump saves any newly entered bolus value and returns to NORMAL delivery (Refer to paragraph 7.2 for more on BOLUS delivery.)
- (4) **Menu** key is used to toggle between detailed and simplified displays (further explained in paragraph 7.1.3).

7.1.1 Information Displayed during Normal Delivery

A comparison between the Stop and Delivery screens for Normal Delivery is shown below:

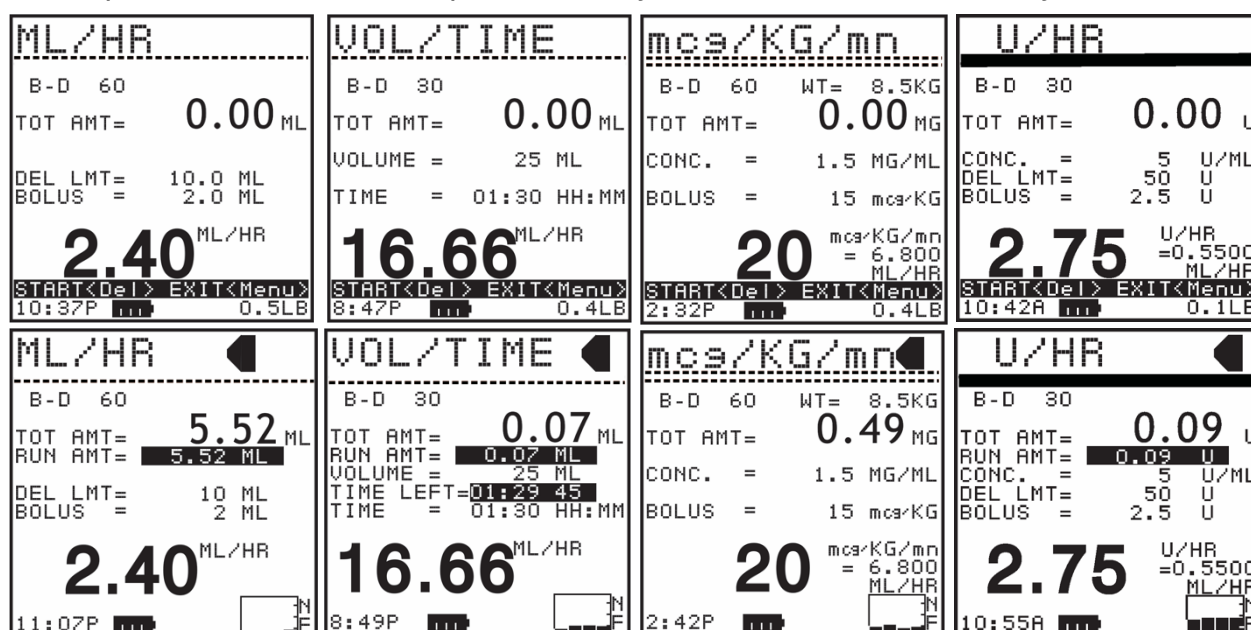


Figure 7.1.1: Stop (top) vs. Delivery (bottom) Screens for various Rate Modes

The following information is displayed on the LCD Screen during Normal Delivery:

- **Total Amount:**
This is the accumulated delivery amount since this amount was last reset. The Total Amount displayed can vary depending on the default setting and Rate Mode selected (8.3.2.3.2 TOTAL UNIT mX). To temporality display values in ML press the Enter Key during delivery.
- **Running Amount:**
This amount is displayed only if a nonzero Delivery Limit (or Delivery Volume) has been programmed. This is the accumulated amount for the current delivery session. The Running Amount will reset to 0 when its value reaches the Delivery Limit. (Running Amount is discussed further in paragraph 7.3, "Delivery Interruption and Resuming Delivery," of this section).
In Volume/Time mode, **Time Left** displays the amount of time remaining to complete the delivery.
- **Syringe Plunger Force (Occlusion) Chart:**



This chart is a representation of the force level trend detected at the Syringe Plunger for approximately the past 24 seconds. The right-hand side shows the most recent reading, and higher bars correspond to higher forces. The letter F on the right hand side of the chart stands for (plunger) Force, and 'L,' 'N,' 'M,' and 'H' stand for LOW, NORMAL, MIDDLE, and HIGH force threshold levels. The display shows that Normal Force is programmed.

- Moving Delivery Mark:

A moving delivery mark is displayed on the top of the screen. The speed of its movement corresponds with the delivery rate.



7.1.2 Changing Rate During Delivery

Except for in Volume/Time mode, the delivery rate can be modified without interrupting Normal Delivery by using the **Rate** key. Press **Rate** key to initiate the process and the pump will blink the current rate. Once the user enters a valid rate by either using the **numeric** or the **up and down** keys followed by **Enter** or **Deliver** key, the pump will switch to the new rate.

If the user does not enter a new rate within one minute, the pump continues to deliver at its previous rate. This existing rate can be immediately displayed by pressing the GO BACK Key.

For entries using mass units:

(In this example the Moving Soft Limit Multiplier was set to 1.5 and the Hard Limit set to 30 ml/hr.)

```

mcg/KG/mn
-----
B-D 60 WT= 70KG
TOT AMT= 1.05 MG
CONC. = 10 MG/ML
BOLUS = 1500 mcg/KG
25 mcg/KG/mn
= 10.50 ML/HR
START<Del> EXIT<Menu>
1:25P 1.2LB
  
```

This screen shows Normal stop screen with a valid rate.

```

mcg/KG/mn
-----
B-D 60 WT= 70KG
TOT AMT= 1.05 MG
CONC. = 10 MG/ML
BOLUS = 1500 mcg/KG
PROG OR DELIVER RATE
0080 mcg/KG/mn
= 10.50 ML/HR
EXCEED MAX 030 ML/HR!
TRY NEW NUMBER !!
  
```

This screen shows the Hard Alarm given when any rate greater than 30 ml/hr is entered. The maximum rate (Hard Limit) that can be programmed in ml/hr is displayed. Note the existing rate is also displayed (i.e. 10.50 ml/hr). The user must enter a rate in mcg/kg/mn that is equal to or less than 30 ml/hr (e.g. 71.42 mcg/kg/mn).

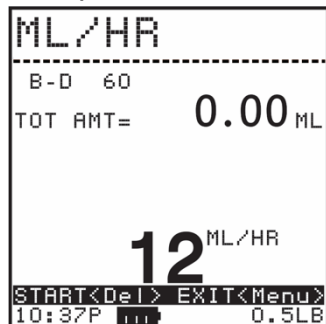
```

mcg/KG/mn
-----
B-D 60 WT= 70KG
TOT AMT= 1.05 MG
CONC. = 10 MG/ML
BOLUS = 1500 mcg/KG
PROG OR DELIVER RATE
037.6 mcg/KG/mn
MN=5953
MX=37.50
--OUT OF SOFT LIMIT--
PRESS <ENTER>CONFIRM
  
```

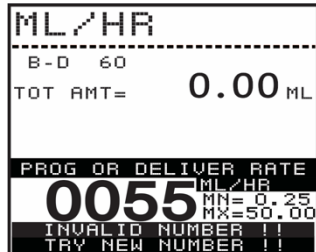
This screen shows the Moving Soft Limit Alert given when the rate was changed to more than 1.5 times the existing Rate (25 mcg/kg/mn times 1.5 = 37.5 mcg/kg/mn). To confirm new rate, press the ENTER key.

For entries using ml units:

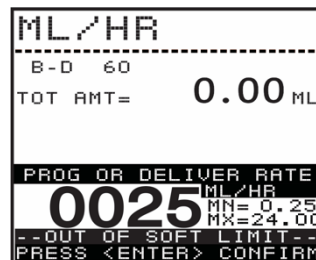
(In this example, the Moving Soft Limit Multiplier was set to 2.0 and the Hard Limit set to 50 ml/hr.)



This screen shows Normal stop screen with a valid rate.



This screen shows the Hard Alarm given when any rate greater than 50 ml/hr is entered. The values that can be programmed MN and MX are displayed. Only rates between 0.25 and 50.0 ml/hr can be programmed.



This screen shows the Moving Soft Alert given when an attempted rate change exceeded more than 2 times the existing Rate ($12 \times 2 = 24$ ml/hr). To confirm new rate, press the ENTER key. Otherwise the rate will not be changed and will deliver at its previous setting.

7.1.3 Simplified Display (Menu, Enter, Decimal keys)

The **Menu** key can be used to display or remove some of the detailed information from the display for easier viewing (See Figure 7.1.3). In V/T ENTERAL the following information is not normally displayed: Running Amount and Time Left. Pressing **Menu** again will display these parameters.

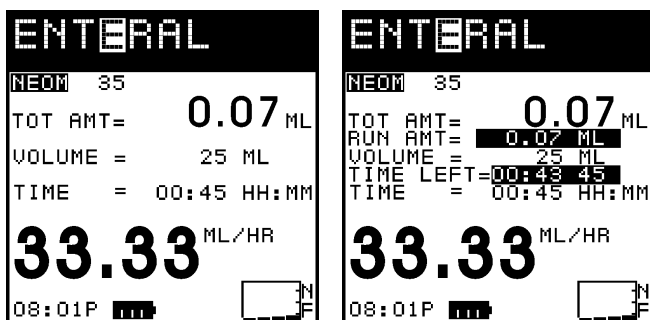


Figure 7.1.3 Normal simple display (left) versus complete display (right) for V/T

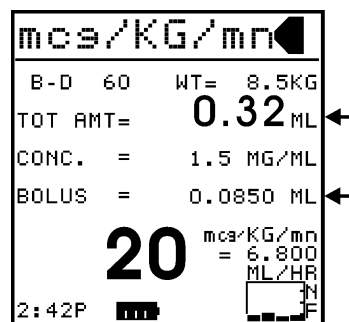


Figure 7.1.4 Alternate Unit Display Volume (shown) vs Mass

7.1.4 Alternate Unit Display

In the Body-Weight, Mass Rate, and Dose Modes, pressing the **Enter** key during delivery will temporarily display the equivalent in ML for the values on the display. (See Figure 7.1.4).

In the Body-Weight, Mass Rate, and Dose Modes once fully programmed, pressing the **Decimal** key will display the Total Amount in ML. Allows toggling the display between mass and volume.

7.2 BOLUS DELIVERY

Bolus can be delivered both automatically and manually in both the Stop or Delivery Modes.

7.2.1 Activating Automatic Bolus Delivery

If a non-zero Bolus has been programmed, **BOLUS Delivery** can be activated by pressing the **Bolus** key followed by the **Deliver** key.

The Syringe Status LED indicator becomes a **fast flashing GREEN** and the LCD display shows the BOLUS delivery screen (shown in Figure 7.2). The heading “BOLUSING” and the Bolus Amount being delivered are displayed.

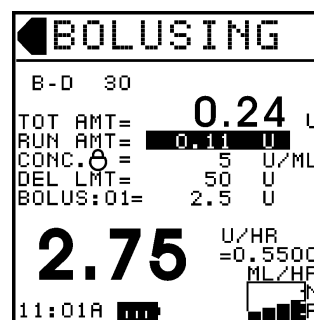


Figure 7.2: Bolus Delivery Screen
Bolus delivery time is 1 minute.
Concentration Lock is ON.

When the programmed bolus has successfully been delivered, an audio beep (if programmed in Pump Defaults) signals the completion of BOLUS Delivery and the LCD Screen returns to NORMAL delivery.

The following are the only active keys during BOLUS delivery:

- (1) **Stop** key stops any infusion, including BOLUS and NORMAL delivery.
- (2) **Deliver** key interrupts BOLUS delivery and resumes Normal Delivery.
- (3) **Menu** key simplifies the displayed information on the LCD screen (Refer to paragraph 7.1.3). Bolus Amount and Bolus are shown during simplified display.

If BOLUS delivery is interrupted by the **Deliver** key, and if BOLUS delivery is activated again after the interruption, the running Bolus Amount is reset to 0 and a completely new Bolus is delivered.

If the Delivery Limit is non-zero, the Bolus Amount is added to the Running Amount (not displayed) that counts towards the Delivery Limit. If the Delivery Limit is reached before BOLUS delivery is complete, the pump stops, displays the “DELIVERY LIMIT!” message, and sounds an alarm.

Pressing the **Bolus** key allows the user to adjust the bolus infusion settings. The pump will flash the current bolus amount and wait for user to enter a new bolus amount. User can then press either **Enter** or **Deliver** key:

- (1) If the **Enter** key is used, the Bolus is replaced with the new number and the pump continues NORMAL delivery.
- (2) If the **Deliver** key is pressed, the pump will immediately deliver the newly programmed Bolus.

If the user does not input a new Bolus within one minute, the modification process is terminated, and the original values will reappear. The existing bolus can be immediately displayed by pressing the GO BACK Key.

Bolus Delivery can also be activated directly from the Stop mode (without going through Normal Delivery) by pressing the **Deliver** key at the end of the Bolus programming process. The pump switches from Stop mode to BOLUS Delivery mode and returns to Stop mode after the programmed Bolus has been delivered.

If USE BOLUS TIME 8.3.2.3.3 is enabled, immediately following the program Bolus step as described above the user can program a bolus delivery time from 0 to 60 minutes in increments of 1 minute. Maximum rate is used if Bolus Time is set to 0.

The Bolus Time is not asked during delivery if there is no change to the Bolus. If the Bolus is changed the Bolus Time can be changed.

7.2.2 Activating Manual Bolus Delivery

The user can deliver a manual Bolus by pressing the Bolus Key once followed immediately by pressing and holding the Bolus Key down a second time until the desired amount is given or until the Manual Bolus Limit is reached. MANUAL BOLUSES can be given in both STOP and Delivery modes.

When a manual Bolus is being delivered the LCD will appear as described above with an M (BOLUS: xxM MANUAL BOL) in the bolus line. The Bolus will be delivered at the highest speed possible unless otherwise programmed in the temporary adjust setting.

7.3 DELIVERY INTERRUPTION and RESUMING DELIVERY

Both Normal Delivery and Bolus Delivery are interrupted when the **Stop** key is pressed, when the syringe is empty, or when the Delivery Limit has been reached. Delivery will also be interrupted if any of the following error conditions are detected:

- (1) Occlusion (Plunger force reading exceeds occlusion force threshold)
- (2) Depleted battery
- (3) Syringe dislodged
- (4) Plunger retainer is disengaged
- (5) Track has been moved incorrectly (Abnormal position sensor reading)
- (6) Questionable delivery accuracy due to internal check

If delivery is interrupted due to one of the error conditions listed above, NORMAL Delivery will resume if the **Deliver** key is pressed after the error condition is corrected. The accumulation of the Running Amount continues as if the delivery was not interrupted.

When any of the above events occur, the LCD will display ELAPSED TIME = HH:MM which is the time from occurrence until a key is pressed.

CAUTION:

If either the EMPTY SYRINGE or DELIVERY LIMIT condition occurs, or if any infusion settings besides the Normal Delivery Rate are changed after the interruption, pressing the **Deliver** key will RESTART a new NORMAL delivery and the Running Amount will be reset to zero. This is particularly important when a Delivery Limit is involved, as well as in Volume/Time Mode, because the Running Amount is used to stop the pump when the Delivery Limit or Delivery Volume is reached.

7.4 NEAR-EMPTY

A **Near-Empty** condition occurs at a preset time interval before the syringe reaches empty. The default Near-Empty time is five minutes.

A blinking message “NEAR EMPTY” will be displayed at the lower left corner of the LCD display. The Syringe Status LED alternates between a short RED flash and a long GREEN one. Three short audio beeps will sound once if programmed in PUMP DEFAULT.

The pump uses the Normal Delivery Rate to calculate the syringe plunger position where the Near-Empty alert is actuated. The Near-Empty time is defined in the PUMP DEFAULTS and can be changed by accessing PUMP DEFAULTS at option <3> of MAIN MENU PAGE 3 OF 3 (Refer to paragraph 8.3.2.4.8).

However, a **PHYSICAL fixed Near-Empty point** is used for BOLUS delivery and PRIMING. It is not determined by a certain time interval, but at a fixed distance before the syringe empty position. The Near-Empty alert is activated when the syringe plunger passes this position.

7.5 PRIMING

⚠ WARNING:

Priming should always occur before beginning infusion. **Priming fluid should never be delivered to the patient.**

When the **Prime** key is pressed, the Priming process will start only if all required infusion settings have been programmed and there is no error condition. The pump always uses maximum motor speed for the syringe in use during Priming.

The **Prime** key must be pressed and held continuously to maintain the Priming process. Priming sequence may be repeated.

PRIMING will stop if:

- (1) **Prime** key is released
- (2) An error condition is detected
- (3) **Prime** key is held down longer than 5 seconds

During Priming, the LCD screen displays the following (as shown in Figure 7.5):

- (1) "PRIMING" is shown at title line with Moving Delivery Mark
- (2) The accumulated Priming Volume in ML
- (3) Syringe Plunger Force Chart

The Syringe Status LED indicator becomes a **fast blinking RED**.

⚠ WARNING:

Fluid delivered during Priming does not count towards the accumulated Total Amount.

If the Priming process is interrupted due to the release of the **Prime** key or other error conditions (except Empty Syringe), pressing the **Prime** key again will RESUME the accumulation of the priming volume as though the process was not interrupted. However, the Priming Volume is reset to 0 if an Empty Syringe condition is encountered or if any parameter is reprogrammed.

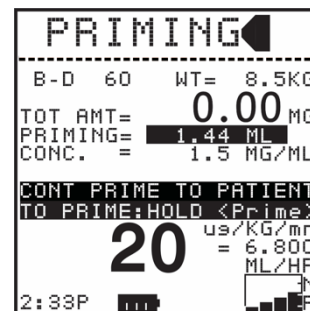


Figure 7.5: Priming Screen

7.6 STAND-BY AUTO and STAND-BY MANUAL

The pump offers a **STAND-BY feature** with a Stand-by timer for starting delivery at a programmed **later time**.

There are two types of Stand-by: **AUTO** and **MANUAL**. The user can choose between the types using PUMP DEFAULTS, option <3> of MAIN MENU PAGE 3 OF 3 (Refer to paragraph 8.3.2.1.5).

- (1) **Stand-by AUTO** - Normal Delivery will start automatically at the expiration of the standby timer.

- (2) **Stand-by MANUAL** - Pump does not start delivery automatically. An audio alert will sound, and the user must manually press the **Deliver** key to start Normal Delivery.

The pump must be programmed and ready to deliver before the activation of the Stand-by timer. Once the pump is programmed, the user can press the **Menu** key to access MAIN MENU PAGE 2 OF 3 and select option <5>, "SET STAND-BY TIMER," to activate the Stand-by feature. The user is prompted to program Stand-by time in HH:MM (Hours:Minutes). After the time is programmed, the pump is put into Standby Mode and shows the Stand-by screen (Shown in Figure 7.6). The remaining time in Stand-by is displayed in the title line.

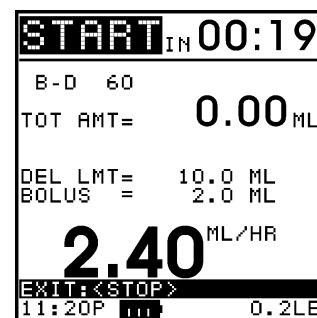


Figure 7.6: Stand-by AUTO Screen (In Stand-by MANUAL, "STBY ENDS" replaces "START" in title line).

During the Stand-by interval, the pump condition is continuously monitored. Any condition preventing the pump from being ready to deliver is detected. Normal Delivery will not start automatically if any error condition exists. Instead, an error alert will be given at the end of Stand-by.

Pressing the **Stop** key in Stand-by will cancel this function and return the pump to the Stop mode.

7.7 ENHANCED PUMP PERFORMANCE

⚠ IMPORTANT:

The user can maximize syringe pump performance by selecting the 1) correct syringe size for the given application. 2) optimizing the infusion line set up, and 3) programming the appropriate plunger (occlusion) force.

7.7.1 Program Appropriate Infusion Rate and Bolus Amount for Syringe Size

Always use the smallest syringe for the volume of fluid being given with the highest possible infusion rate.

The table below list the recommended lowest rate and smallest bolus for each syringe size.

Syringe Size	Lowest Recommended Rate	Smallest Recommended Bolus
140 ML	5.0 ML/HR	0.1 ML
60 ML	2.0 ML/HR	0.05 ML
30 ML	1.0 ML/HR	0.05 ML
20 ML	0.70 ML/HR	0.02 ML
10 ML	0.35 ML/HR	0.02 ML
5 ML	0.20 ML/HR	0.01 ML
3 ML	0.10 ML/HR	0.01 ML
1 ML	0.03 ML/HR	0.01L

7.7.2 Use Low Dead Space Infusion Set Ups

Always use components having the lowest deadspace (internal volume) to minimize the residual volume between the syringe pump and the patient.

For example, minimize:

- (1) Tubing internal diameter – small bore or microbore tubing (e.g. 0.020" ID)
- (2) Use thick walled kink resistant non-compliant tubing (e.g. 0.020" ID x 0.060" OD)
- (3) Tubing length – shorter is better
- (4) Number of stopcocks – minimize the number
- (5) Size of in line filters – small volume low deadspace filters
- (6) Y Sites – minimize number and use low volume sites

An infusion set up that is less compliant and has low deadspace can reduce both start-up time and occlusion detection time.

7.7.3 Selecting Appropriate Plunger (Occlusion) Force Setting

The pump monitors the pressure required for any infusion. The bar graph on the LCD displays the plunger force setting (Low, Norm, Mid, High) and the pressure trend for the infusion in process. See Appendix III for occlusion force pressures for each syringe.

The tables below displays the relative pressure for each setting for all syringes.

All Syringe Sizes (except 1 ML)

Code	Meaning	Relative Pressure (psi)
LF	Low	5
NF	Normal	10
MF	Mid	15
HF	High	20

Syringe Size 1 ML

Code	Meaning	Relative Pressure (psi)
LF	Low	7.5
NF	Normal	15
MF	Mid	22.5
HF	High	30

IMPORTANT:

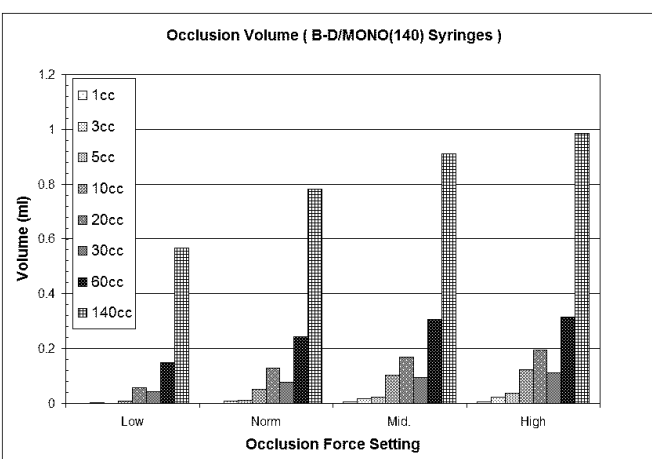
The lower the plunger force setting the faster the occlusion detection time.

7.7.4 Post Occlusion Bolus Reduction Option (option <5> (Motor Reverse) in Pump Defaults OPTIONS: PAGE 2 OF 2)

The pump can be programmed to minimize the amount of fluid released following an occlusion alarm. The table below shows the typical stored volume that is released post occlusion with this feature activated for Becton Dickinson 1,3,5,10,20,30, and 60 ML syringes.

NOTE: The Total Volume read out will be reduced slightly following an occlusion alarm if Motor Reverse is active.

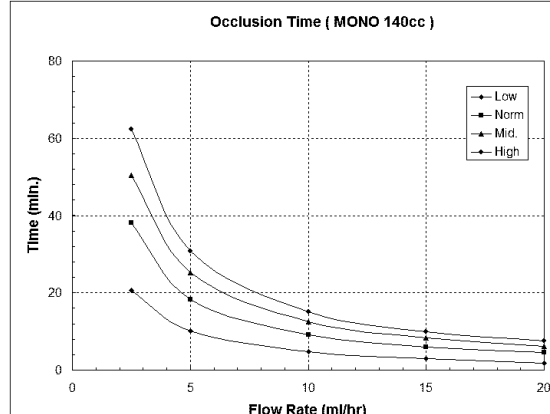
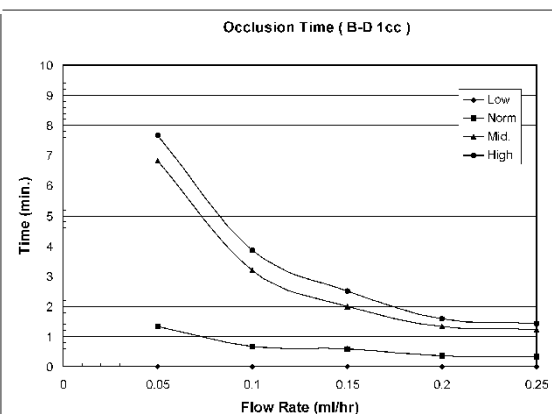
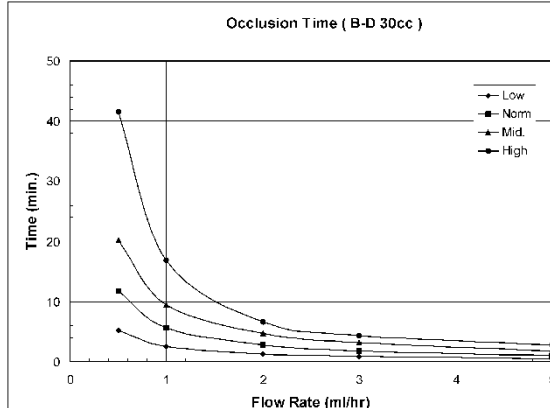
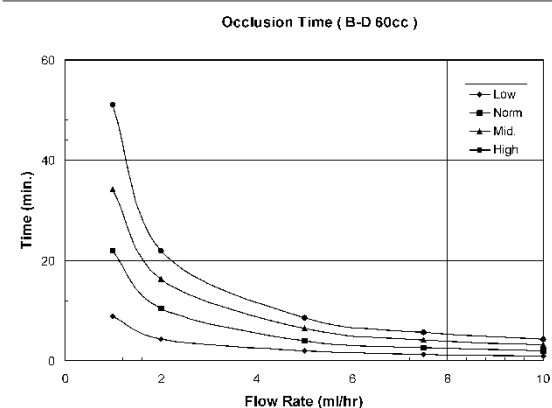
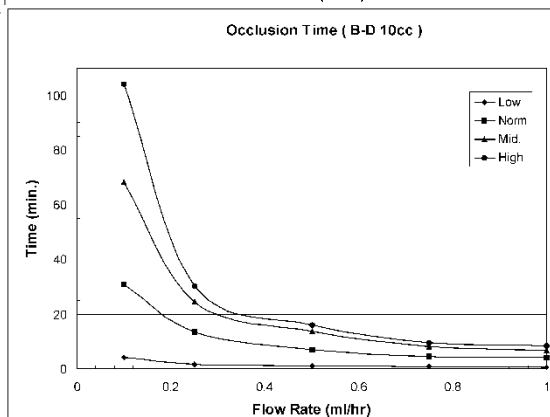
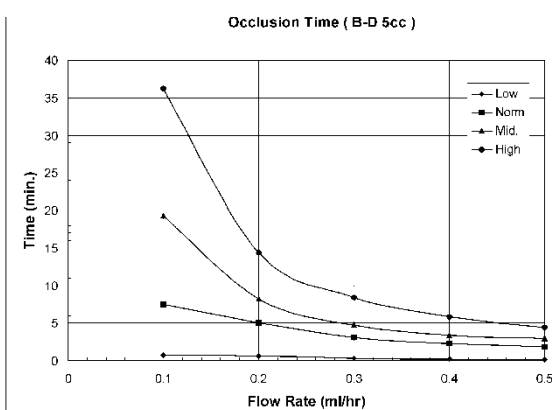
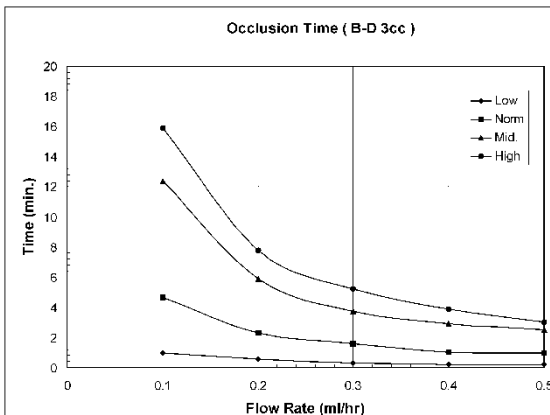
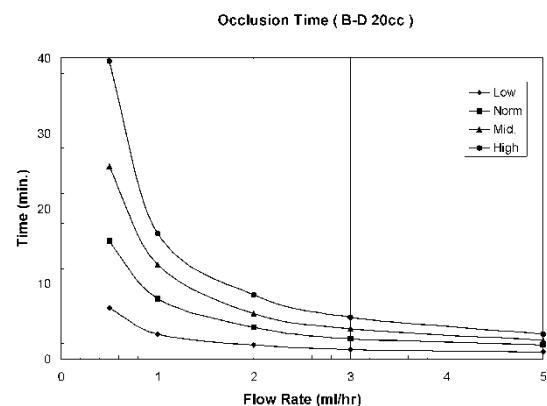
Force Settings	LF	NF	MF	HF
Syringe Size(ML)	Volume of Bolus (ML)			
BD 1	0	0	0	0.01
BD 3	0	0.01	0.02	0.02
BD 5	0.00	0.01	0.02	0.04
BD 10	0.01	0.05	0.10	0.12
BD 20	0.06	0.13	0.17	0.19
BD 30	0.04	0.08	0.10	0.11
BD 60	0.15	0.24	0.31	0.32
ABC/MONO140	0.57	0.78	0.91	0.99



The time required for a pump to detect an occlusion is primarily affected by the following factors:

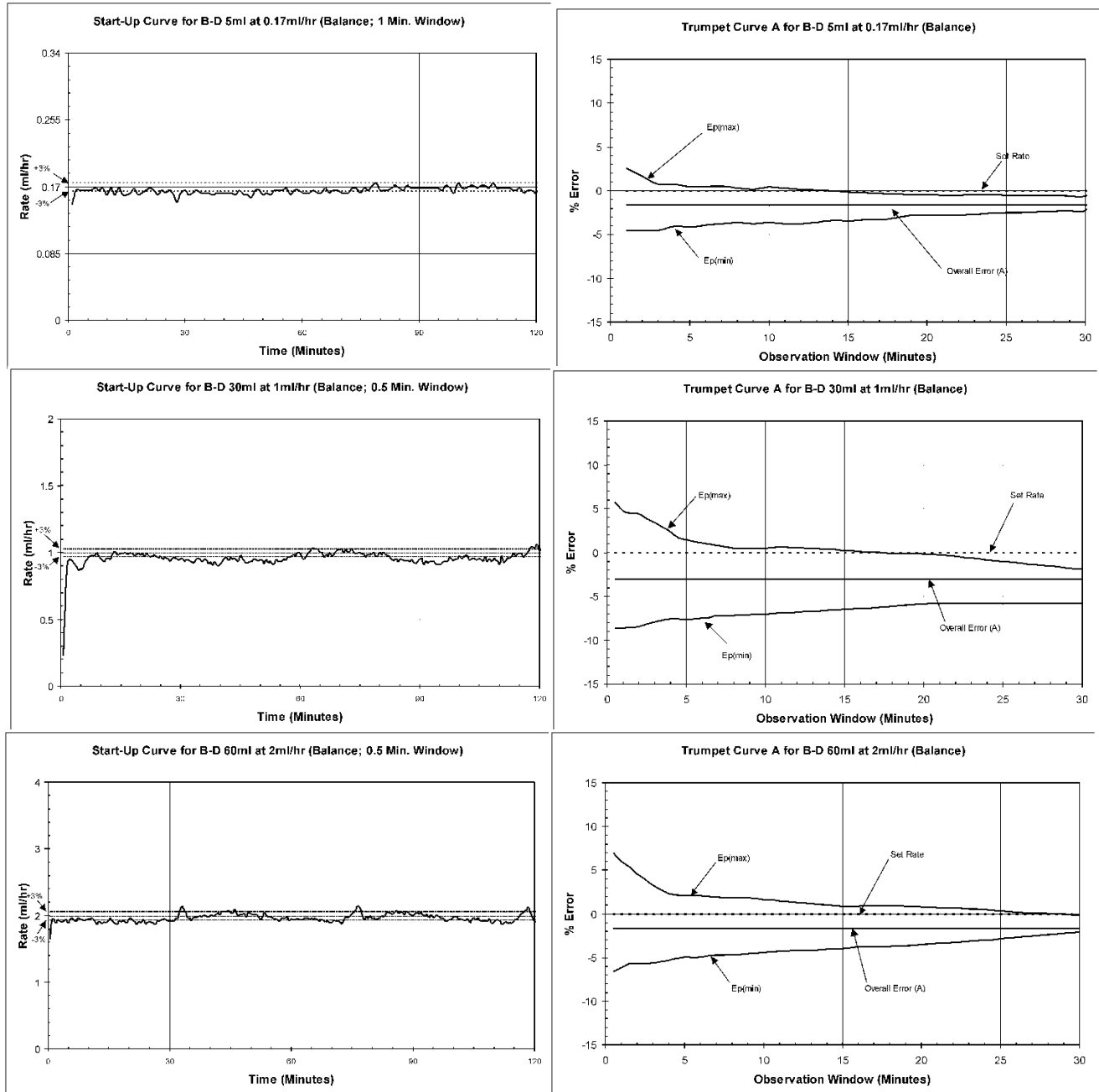
- (1) Occlusion Pressure Setting (Plunger Force)
- (2) Infusion Rate
- (3) Compliance and composition of the Infusion set up (i.e., Tubing and syringe tip softness, tubing internal diameter, existence of injection ports, filters, Y sites, etc.)

Below are typical time-to-occlusion graphs for several syringes. For best performance always select the smallest syringe size because smaller syringes at lower rates and plunger force settings have shorter occlusion times.



7.7.5 Start-up and Trumpet Curves

The flow delivery graphs below show the typical start-up times for select BD syringes. For best performance always select the smallest syringe size because smaller syringes at lower rates have faster start-up times compared to larger syringes at the same infusion rate.



SECTION 8. MENU STRUCTURE

To view the MENU screen, press the **Menu** key. There are 3 MAIN MENU screens. Use the **Menu** and **Go Back** keys to navigate through the MENU pages.

There are three general areas of each MENU screen (See Figure 3.4.2).

- (1) Menu Title at the top of the screen
- (2) Selection Area in the middle
- (3) Instructions at the bottom

In general, the selection area lists the available options. In order to make a selection, or, in some cases, to enter numeric data, follow the instructions at the bottom of the screen. In most cases, the **up/down arrow** keys, the **Select** key, or the **numeric** keys will be used. When an option is selected, it will become highlighted. Press the **Enter** key to confirm the selection.

To escape from a menu screen, press the **Stop** key.

MAIN MENU has 3 Pages:

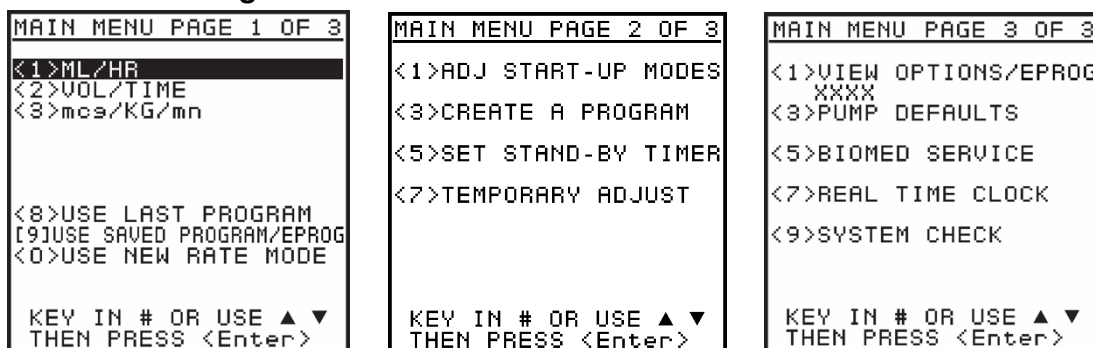


Figure 8.1: MAIN MENU pages 1 through 3

8.1 MAIN MENU PAGE 1 OF 3

This page allows the user to select a rate mode (Refer to paragraph 6.1 for more on rate modes).

8.1.1 Start-Up Modes

Options <1> through <7> (7 are shown) are called **Start-up Modes**. These are the most commonly used rate modes. The user can customize this list of Start-up Modes with ADJ START-UP MODES, option <1> of MAIN MENU PAGE 2 OF 3 (See paragraph 8.2.1).

NOTE: The location of each selection is denoted by one of three bracket styles.

<X> Indicates Standard Rate Mode

[X] Indicates Saved Program

{X} Indicates EPROG Program - EPROG entries also

have a solid box and a location number indicating the EPROG Area {XX}.

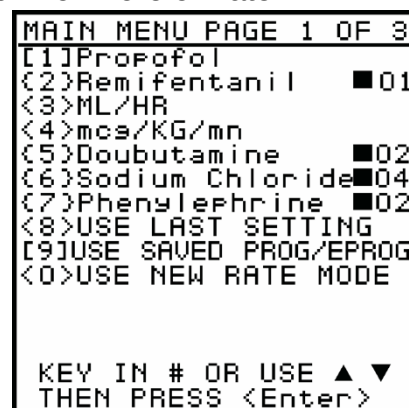


Figure 8.1.1 Sample Start Up Menu

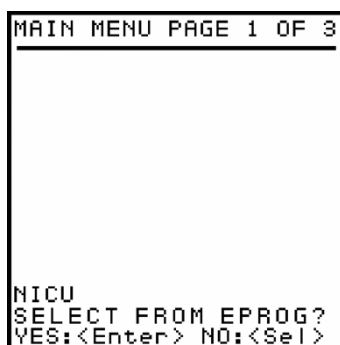
If the desired rate mode is not on the list of Start-up Modes, the user can select option <9> to choose from **Saved Programs/EPROG**, or option <0> for a list of **Standard Rate Modes**. Section 8.3.2.2.3 shows the available settings.

The user can also recall the last programmed settings by pressing <8> then enter. If multiple mfgrs are programmed the user will need to select the correct mfgr.

8.1.2 Select **USE SAVED PROG/EPROG** (Option <9> of MAIN MENU PAGE 1 OF 3)

The Saved Program provides the user ways to create programs with prestored settings and infusion limits from the keypad of the pump. The Extended Program (EPROG) **MUST** be factory programmed.

The LCD will offer a choice to use the SAVED PROG/EPROG (Extended Program) function selection [9].



Select NO to display any Saved Programs.

During Delivery Standard Mode entries have a dashed line below the Rate Mode, Saved entries have a double dashed line, and EPROG entries have a solid thick line (see Figure 7.1.1).

8.1.3 Using Saved Programs

To retrieve Saved Programs, press - NO: <Sel> (see Figure 8.1.4)

The pump provides a convenient feature for Creating and Retrieving Saved Programs. Saved Progs feature allows users to save programs with a specific Rate Mode, ~~and~~ infusion settings and options (i.e. Bolus Enabled, Bolus Time, Delivery Limit Enabled, Concentration Lock, Total Unit Display, and Rate Multiplier alert) for use in repeated infusions of the same medicine.

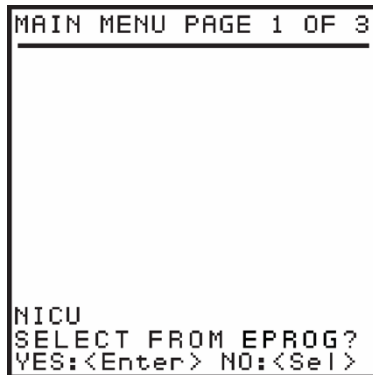
Up to 9 pages of customized Saved Programs can be stored in the pump. Only the page(s) with valid saved programs will be visible. If there are no Saved Programs already stored in the pump, "NO SAVED PROGRAMS !" will be displayed.

- (1) Use **Menu** and **Go Back** keys to navigate the pages.
- (2) Use **numeric** or **up/down** keys to select the desired Saved Program and confirm with **Enter** key.
- (3) Use the **Stop** key to abandon the selection process.

MAIN MENU PAGE 2 OF 3 option <3> allows user to CREATE A (SAVED) PROGRAM. (Refer to paragraph 8.2.2).

A Saved Program on the Start Up screen is identified with brackets [x].

8.1.4 To view the EPROG AREA(S) Select - YES: <Enter> (See Figure 8.1.4)



NOTE: If the pump contains an EPROG its name will be displayed on the LCD (e.g. NICU).

Figure 8.1.4 User can select EPROG or Saved Programs

Each EPROG contains 15 Areas and Each Area contains up to 40 drug entries. The only way to create/edit an EPROG entry is via a dedicated ABC PC Program.

The user can display any EPROG Areas that are enabled. The user selects the Area to display the drug entries. Each drug can have various preprogrammed options (i.e. Concentration, Conc. Lock, Starting Dose, Rate Mode, Bolus, Bolus Time, Manual Bolus with Time out, Zero Initial Rate, Delivery Limit, Total Unit Display, Hard and Soft Limits for Rate and Bolus, Soft Total Bolus and Hard Total Bolus)

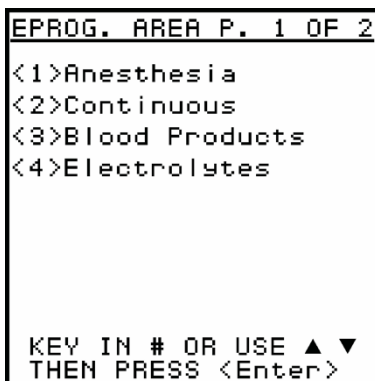


Figure 8.1.4.1 Shows 4 EPROG Areas. The maximum number of Areas is 15.

Select <1> then **Enter** to display the drug entries for this area (e.g. Anesthesia).

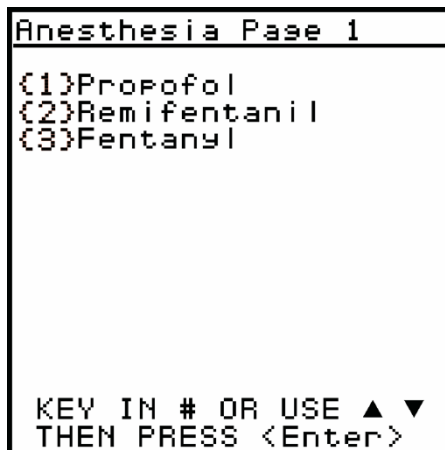


Figure 8.1.4.2 Three drugs located in the Area labelled Anesthesia. A total of 40 drugs can be placed in this area.

Select (2) Remifentanyl then **Enter** to display the EPROG settings for this drug.

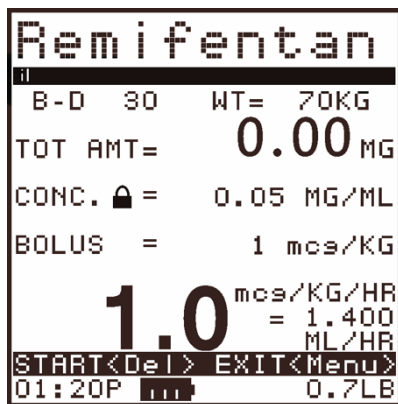


Figure 8.1.4.3 Shows drug with programmed settings.

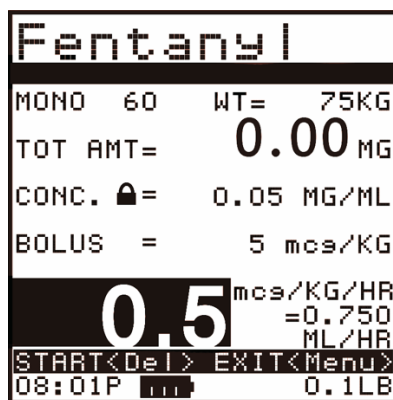


Figure 8.1.4.4 When a drug from the EPROG has the rate appear in a dark box, it indicates that rate limits have been programmed.

NOTE: If the drug name exceeds 10 characters all additional characters are displayed below in smaller size. A total of 20 characters can be displayed on the 2 lines.

NOTE: To view hard and soft limits while programming, press and hold the Menu key.
To view the limits once programmed, prior to delivery, press and hold the 9 key.

Solid Rate Mode line denotes EPROG.

8.1.5 USE NEW RATE MODE (Option <0> of MAIN MENU PAGE 1 OF 3)

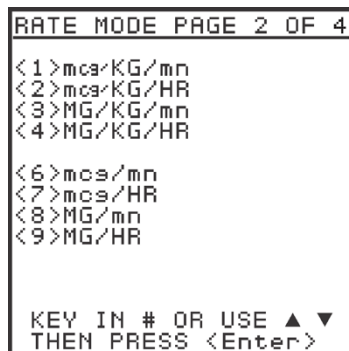
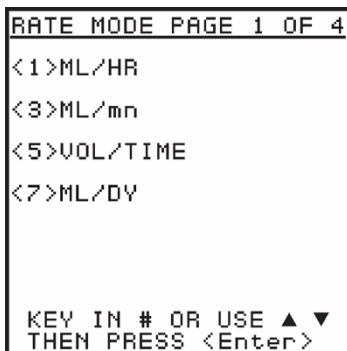
There are 43 pages of Standard Rate Modes (See Figure 8.1.5 3):

Page 1 - Continuous Modes and Volume/Time Mode.

Page 2 - Body-Weight Modes and Mass Modes (in mcg and MG)

Page 3 - Unit Modes (in mU and U)

Page 4 – Dose Modes per Time (HR, mn, DY, TM) and UT (KG of M2)



```

RATE MODE PAGE 3 OF 4
<1>mU/mn
<2>mU/HR
<3> U/mn
<4> U/HR

KEY IN # OR USE ▲▼
THEN PRESS <Enter>

```

```

RATE MODE PAGE 4 of 4
<1>DS/HR
<2>DS/mn
<3>DS/DV
<4>DS/TM
<5>DS/UT/HR
<6>DS/UT/mn
<7>DS/UT/DV
<8>DS/UT/TM

KEY IN # OR USE ▲▼
THEN PRESS <Enter>

```

NOTE: Dose can be in ML, G, MG, mcg, ng, U, mU, mM, mE

UT is KG, M2, or Blank

Figure 8.1.4.5: Menus 1 through 4 of “Use New Rate Mode,” Option <0> from MAIN MENU PAGE 1 OF 4

- (1) Use **Menu** and **Go Back** keys to navigate the pages.
- (2) Use **numeric** or **up/down** keys to select the desired rate mode and confirm with **Enter** key.
- (3) Use the **Stop** key to abandon the selection process.

8.2 MAIN MENU PAGE 2 OF 3

There are 4 options in MAIN MENU PAGE 2 OF 3:

- <1> Adjust Start-Up Modes (“ADJ START-UP MODES”)
- <3> Create a Program
- <5> Set Stand-By Timer
- <7> Temporary Adjust

NOTE: User access to each item in this section can be Locked (denying access) or Unlocked (allowing access) by programming selections in the PUMP DEFAULT OPTIONS SECTION (see section 8.3.2.)

8.2.1 Adjust Start-up Modes (Option <1> of MAIN MENU PAGE 2 OF 3)

Start-Up Rate Modes, the most commonly used modes, are available in the Selection Area of MAIN MENU PAGE 1 OF 3.

Using this utility (See Figure 8.2.1.1), the user can customize the list of Start-up Rate Modes. The maximum number of start-up modes is limited to 7 (only 3 selections are shown <1>, <2>, <3>).

There are two ways to customize the list:

(1) Add a rate mode to the Start-up list:

Additional rate modes can be added from the list of Standard Rate Modes (option <0>) or Saved Prog/EPROG (option <9>). A Rate Mode that is already included in the Start-up list will have a special marking on its item number and will be unavailable for selection, so as to prevent having two identical rate modes on the Start-up list.

(2) Delete or Re-Arrange the Rate Modes on the Start-up List:

- (A) Select the rate mode to be deleted or moved using the **number** or **up/down arrow** keys, followed by **Enter** key. Once this is done, the instructions at the bottom of the screen change (See Figure 8.2.1.2).

```

ADJ START-UP MODES
<1>ML/HR
<2>VOL/TIME
<3>us/KG/mn
[4]Propofol
<5>Remifentanyl

<9>USE SAVED PROGRAM/EPROG
<0>USE NEW RATE MODE

KEY IN # OR USE ▲▼
THEN PRESS <Enter>

```

Figure 8.2.1.1: ADJ START-UP MODES Main Screen

```

ADJ START-UP MODES
<1>ML/HR
<2>VOL/TIME
<3>mcg/KG/mn

DELETE MODE:<Reset>
UP:▲ DN:▼ EXIT:<Stop>

```

Figure 8.2.1.2: Deleting or Re-Arranging Start-up list Rate Modes

- (B) Per instructions on the menu, use the **Reset** key to delete the selected rate mode and/or the **Up/Down** keys to change the order of the rate mode on the list.
- (C) Press the **Stop** key to confirm the new arrangement and return to the option's main screen. Pressing **Stop** key again saves the new list and returns back to MAIN MENU PAGE 2 OF 3.

8.2.2 Create a Program (Option <3> of MAIN MENU PAGE 2 OF 3)

Up to 9 pages of customized Saved Programs can be stored in the pump. The steps for creating and saving a Program follow:

Step 1: Select the Page and Number where the new Program is to be stored:

Numbers that show “*Program with a number” are empty and available for storage (see Figure 8.2.2.1).

Use the **Menu** key to select a page for the new program.

Use the **number** or **up/down arrow** keys to select the number where the program will be saved. Press the **Enter** key, then proceed to step 2

NOTE 1: To delete an existing saved program select (highlight) the program and press **Reset** key. Press **Enter** key to confirm the selection.

NOTE 2: To move an existing saved program, select (highlight) the program and press **Prime** key. Highlight the page and program number of the new position and press Enter to move (Cut and Paste procedure).

If the moved program was on the Start Up Screen the screen will need to be reconfigured (See Section 8.1.1).

Step 2: Enter Program Name

(1) A screen will appear where the name of the program can be entered (See Figure 8.2.2.2).

(2) Use the **alphanumeric** keys to choose the desired letter/number. Pressing an **alphanumeric** key repeatedly (or using the **Up/Down** keys) allows the user to scroll through the corresponding lowercase and uppercase letters and numbers.

(3) Move to the next character using the **Select** key.

(4) When finished, press **Enter** key.

Step 3: Determine Rate Mode and the values for the infusion settings to be saved:

There are two options:

(1) Use Current Infusion settings:

If **Enter** key is pressed when “USE CURRENT SETTING?” is prompted (See Figure 8.2.2.3), then the current programmed infusion settings are saved to the Program. The pump returns to stop mode with the new program name displayed.

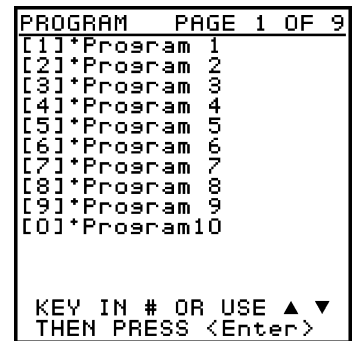


Figure 8.2.2.1: Select Page, Item Number, or Move to Store New Program



Figure 8.2.2.2: Entering Program Name

(2) Create new Infusion settings from scratch:

If the **Select** key is pressed when “USE CURRENT SETTING?” is prompted, the user must program a new set of infusion settings beginning with rate mode and followed by other associated infusion settings (Refer to paragraph 6.1). This new set of infusion settings and Program name is used as the current setting and saved in memory as a named Program.

Only the following infusion settings are stored into the Saved Program:

Continuous Mode: Rate Mode, Bolus, Rate

Options: Program Bolus, Use Bolus Time, Manual Bolus, Program Delivery Limit, Rate Multiplier, Prog Hard Rate Limit

Volume/Time Mode: Delivery Volume, Delivery Time

Options: Rate Multiplier, Prog Hard Rate Limit

Body-Weight Mode: Rate Mode, Concentration, Bolus, Rate

Options: Program Bolus, Use Bolus Time, Manual Bolus, Lock Concentration Total Unit mX, Rate Multiplier, Prog Hard Rate Limit

Mass Mode: Rate Mode, Concentration, Bolus, Rate

Options: Program Bolus, Use Bolus Time, Manual Bolus, Program Delivery Limit, Lock Concentration, Total Unit mX, Rate Multiplier, Prog Hard Rate Limit

NOTE 1: Weight and Delivery Limit are not stored and must be entered for each infusion.

NOTE 2: ALL saved program settings supersede any Default settings (e.g. Bolus Enabled. Use Bolus Time, Deliver Limit Enabled, Total Unit mX). Use Bolus Time option is available only when Bolus Enabled option is used.

NOTE 3: When a Hard Rate Limit is programmed the top line of the LCD will display a dark box on the right side (See figure 8.2.2.4).

NOTE 4: If a concentration is locked, a small lock icon  will appear at concentration display.

Once a program is saved, it can be retrieved using option <9> of MAIN MENU PAGE 1 OF 3 (Refer to paragraph 8.1.2).

Stored Programs can be repositioned using the cut and paste function by following the instructions at the bottom of the LCD display (See step 1 note 2 above).

NOTE: Drugs listed in the EPROG can also be placed on the Start-Up Screen (See Figure 8.1.1).

8.2.3 Set Stand-by Timer (Option <5> of MAIN MENU PAGE 2 OF 3)

(Refer to paragraph 7.6 for use of Stand-by Timer).

The pump must be completely programmed and ready to deliver before the Stand-by timer is activated. If the infusion settings are not properly programmed, an error message is given and the pump exits to MAIN MENU.

If the pump has been properly programmed, the user is prompted to program the Stand-by time in HH:MM (Hours:Minutes). See



Figure 8.2.2.3: Storing Current Infusion Parameters for the Saved

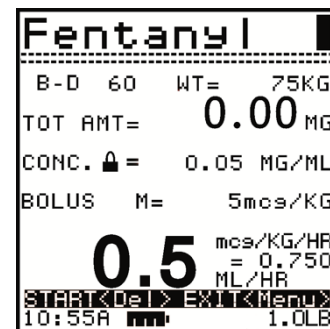


Figure 8.2.2.4: Dark box on right side of display is indicative of a Hard Rate Limit.



Figure 8.2.3: Setting Stand-By Timer

Figure 8.2.3. After the time is programmed, the pump goes into Stand-by Mode, which can be exited by pressing the **Stop** key.

8.2.4 Temporary Adjust (Option <7> of MAIN MENU PAGE 2 OF 3)

The Temporary Adjust feature can be used to eliminate a nuisance occlusion alarm by allowing the user to adjust both the Bolus Rate option <1> and Bolus Plunger Force option <3>. Normally, the infusion rate for Bolus Delivery is set at the maximum rate for the syringe in use and the plunger force threshold is the same as the default setting. In some situations, a false occlusion alarm can occur when the bolus is delivered into a small diameter tubing at a high rate. This adjustment is also applied to PRIMING.

This option allows the user to adjust both the bolus infusion rate and the plunger force threshold for the Bolus Delivery **Temporarily** (See Figure 8.2.4). The user can slow down the Bolus infusion rate and increase the occlusion threshold to overcome the problem.

```
TEMPORARY ADJUST.....
<1>BOLUS/PR RATE=HIGH
<3>BOLUS P.FORCE=NORM
<5>PLUNGER FORCE=NORM
<7>ALARM VOLUME =NORM

USE # TO SELECT ITEM
EXIT<Stop>
```

Figure 8.2.4: “Temporary Adjust” allows users to change Occlusion Force threshold, Bolus Delivery Rate, and Alarm Volume until the Pump is turned off

The values for both Bolus Rate and Prime Speed are reduced from the H setting by the following proportions – L = 1/4, N = 1/3, M = 1/2.

During Bolus delivery, a letter (L,N,M) is shown at the end of “BOL AMT= ” line to indicate the current setting of Bolus Rate. No letter is shown for default HIGH rate.

Temporary Adjust option <5> also allows the user to change the Plunger Force during Normal Delivery to select the best force setting for the given infusion.

Temporary Adjust option <7> allows the user to change the Alarm Volume for the existing delivery.

NOTE: Any temporary changes are cancelled when the pump is turned off.

- (1) Use the **number** keys to select the item to be adjusted.
- (2) Use the **Select** or **up/down arrow** keys to adjust the setting of the item. Press the **Enter** key to confirm the change.
- (3) Press the **Stop** key to exit to MAIN MENU PAGE 2 OF 3.

8.3 MAIN MENU PAGE 3 OF 3

MAIN MENU PAGE 3 OF 3 allows the user to view selected options, customize pump options and includes system maintenance. There are 5 options:

- <1> View Options (If EPROG is available, the name of the EPROG will be displayed below) / EPROG name e.g. NICU
- <3> Pump Defaults
- <5> Biomed Service
- <7> Real-Time Clock
- <9> System Check

8.3.1 View Options (Option <1> of MAIN MENU PAGE 3 OF 3)

This item allows the user to view all the Pump Default Options that have been selected without having to know the Access code (Option <1>).

(1) Use the **Menu** and **Go Back** keys to scroll through the option pages and view EPROGS.

(2) Use the **Stop** key to return to MAIN MENU PAGE 3 OF 3.

The user can review and verify all option defaults programmed but cannot change them (Figure 8.3.1 shows both the defaults that can be programmed and one possible Default settings). At the left side bottom (see arrow), on page one, are four digits that identifies the parameters programmed (CRC). The user can verify that another pump is programmed the exact same way provide the numbers are identical.

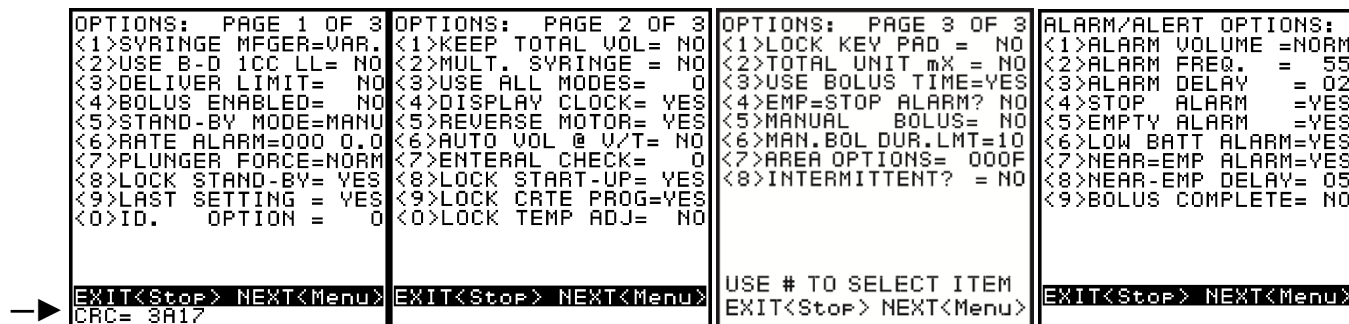


Figure 8.3.1: "Pump Defaults" has three pages of Pump Options (left three) and one page of Alarm Options (right)

```
WEIGHT LIMIT:      KG
MIN.= 0.0 MAX.= 0.0
RATE SOFT:      mcs/KG/HR
MIN.= 0.03 MAX.= 0.43
RATE HARD:      mcs/KG/HR
MIN.=0.02 MAX.= 0.55
BOLUS LIMIT:      mcs/KG
SOFT= 6.75 HARD= 8.75
TOTAL BOLUS LMT:mcs/KG
SOFT= 12.5 HARD= 17.5
CONC.= 0.05MG/ML
BOLUS==          mcs/KG B
RATE = 0.5mcs/KG/HR
Anesthesia      1:02
Fentanyl
EXIT<Stop> NEXT<Menu>
```

Note: Zero initial value(**Z**);
Manual Bolus(**M**);
Total Unit(**U**);
Reserved;
Bolus Time Enabled(**T**);
Enable Limit(**L**);
Enable Bolus(**B**);

Figure 8.3.2 All drugs in the EPROG along with their settings can be displayed sequentially. The drug name (e.g. Fentanyl) located in Drug Area # - 1 (e.g. Anesthesia) at Drug ID location # 2 are displayed at the bottom of the page.

Repeat pressing **Menu** Key to continue to review additional EPROG entries or **Stop** key to exit.

To change or program Pump Defaults, the user must enter the PUMP DEFAULTS option code as explained in the next section.

8.3.2 Pump Defaults (Option <3> of MAIN MENU PAGE 3 OF 3)

PUMP DEFAULTS contains 3 pages of Pump Options and 1 page of Alarm Options:

An Access Code is required to program the PUMP DEFAULTS. Please refer to Appendix IV.

⚠ IMPORTANT:

Some institutions may wish to limit user access to this code by removing the appendix or by blocking out the numerical code.

After entering the Access Code, the user can change Pump Defaults by doing the following:

Use the **Menu** key to navigate the option pages.

Use the **number** keys to select the item to be changed.

Use the **Select** or **up/down arrow** keys to scroll through the available options for the item or enter a number for the item.

Press the **Enter** key to confirm the change.

Repeat the same process for each item to be changed. Press **Stop** key to save the changes.

8.3.2.1 OPTIONS: PAGE 1 OF 3:

8.3.2.1.1 <1> SYRINGE MFGER (Manufacturer):

If only one syringe manufacturer is chosen, this will serve as the default syringe manufacturer and the user does not have to program the manufacturer setting.

If multiple manufacturers are chosen, PUMP DEFAULTS will show VAR. (for “variable”), and the desired manufacturer can be chosen from the list displayed.

NOTE: If BAXA is programmed and the operator loads a 20 or 35 mL BAXA enteral syringe onto the pump the user is required to manually PROGRAM SYRINGE SIZE by selecting <2> for 20 mL and <3> for 35 mL as stated on the LCD.

8.3.2.1.2 <2> USE B-D 1ML LL (luer lock): NO or YES

B-D 1ML luer lock syringe and B-D 3ML syringe have the same diameter syringe barrel. If B-D 1ML luer lock is enabled, the user must manually select B-D 1ML Luer Lock or B-D 3ML syringe.

8.3.2.1.3 <3> DELIVERY LIMIT: NO or YES

If YES is chosen, the pump will prompt user to enter limit. If NO is chosen, there is no prompt. Note if the option EMP=STOP ALARM is YES, the DELIVERY LIMIT AUDIO will sound like the STOP ALARM.

8.3.2.1.4 <4> BOLUS ENABLED: NO or YES

If YES is chosen, the pump will prompt user to enter Bolus. If NO is chosen, there is no prompt. See USE Bolus Time for more options.

8.3.2.1.5 <5> STAND-BY MODE: MANU (manual) or AUTO

User can program either Auto or Manu setting. Refer to paragraph 7.6 for the differences between Stand-by Modes.

8.3.2.1.6 <6> RATE ALARM: 0-999 and 0-9.9

The first entry is the RATE Hard Limit. Valid entries range from 0 to 999. This limits the maximum delivery rate for ALL Rate Modes. No maximum rate limit is in effect if 0 is programmed.

The second entry is the Moving Soft Limit Rate Multiplier (RATE MUL). Valid entries range from 0 to 9.9. Any attempt to enter a new rate that is outside the moving soft limit will prompt a warning –OUT OF SOFT LIMIT—PRESS <ENTER> CONFIRM. The Moving Soft Rate Limit is calculated by multiplying the existing rate by the multiplier. For example, if existing rate is 5.0 and multiplier is set to 2.0 the warning will appear for any rate greater than 10.0. Once entered, this new rate is then used to calculate the next warning. No multiplier is in effect if programmed to 0.

NOTE: Does not apply to BOLUS Rate

8.3.2.1.7 <7> PLUNGER FORCE: NORM, or LOW, MID, HIGH

Sets the threshold of the plunger (occlusion) force.

8.3.2.1.8 <8> LOCK STAND-BY= YES or NO

If NO is selected the user will be able to access this feature. If YES is selected the user will not be able to access this feature and the LCD will briefly flash "SETTING IS PROTECTED!" and return to MAIN MENU PAGE 1 of 3.

8.3.2.1.9 <9> LAST SETTING = YES or NO

If YES, the last valid infusion setting will be recalled. The user must confirm each setting prior to delivering. If NO, the message will not appear on the LCD.

8.3.2.1.10 <0> ID. OPTIONS: 0,1,2,3,4,5,6,7

If activated the operator will be asked to enter the choices shown below. Up to 10 alpha-numeric entries per selection are allowed

0 – Option is turned off

1 – USER, HCP. ID: ---> up to 10

2 -- PATIENT ID: ---> up to 10

3 – PATIENT ID AND USER (HCP) ID: ---> up to 10 each

4 – Option 0 above (no IDs) plus Enteral Formulary

5 – Option 1 (USER (HCP) ID) above plus Enteral Formulary

6 – Option 2 (PATIENT ID) above plus Enteral Formulary

7 – Option 3 (PATIENT ID AND USER (HCP) ID) above plus Enteral Formulary

All entries will be retained for subsequent infusions. The USER will need to either change or reconfirm the ID(s) before starting another infusion.

If options 4 thru 7 are selected the Start Up screen will display <9> ENTERAL FORMULARY. In addition, option 8.3.2.2.3 USE ALL MODES will be not be available.

If the USER selects ENTERAL FORMULARY, the pump will advance to the SAVED ENTERAL FORMULARY menu(s). Once a stored name is selected the USER will be able to select the desired RATE MODE - <1> ML/HR or <2> V/T.

8.3.2.2 OPTIONS: PAGE 2 OF 3:

8.3.2.2.1 <1> KEEP TOTAL VOL: NO or YES

If YES is selected the TOT AMT will accumulate until reset by the user.

If the pump is turned OFF and then ON, the user will be asked to reset or retain the TOT AMT. Active in ML modes only.

8.3.2.2.2 <2> MULT SYRINGE: NO or YES

If YES, the user will be able to use multiple syringes for an infusion. The user can program a VOL LIMIT that exceeds the syringe volume in order to deliver larger fluid volumes using multiple syringes (Helpful when larger fluid volumes need to be delivered at the same infusion rate) **OR** the user can load a syringe that contains a volume less than the VOL LIMIT. Once delivered the user can load another syringe and resume the infusion at the same rate until the VOL LIMIT is reached (Helpful if the user desires to flush the extension tubing dead space).

The user may use different syringe sizes if desired.

RESUME VOLUME LIMIT?: NO OR YES prompt appears - if YES allows the user to continue the infusion at the programmed rate until the VOLUME LIMIT is reached. If NO, the RUNNING Volume is reset to 0 and a new infusion begins.

8.3.2.2.3 <3> USE ALL MODES: Options: 0,1,2,3

Controls what appears on the last 2 lines of the startup screen.

0 Option deactivates this option

1 option <0> USE NEW RATE MODE will appear

2 option <9> USED SAVED PROGRAM will appear

3 option both <0> and <9> will appear

8.3.2.2.4 <4> DISPLAY CLOCK: YES or NO

If Yes, real-time clock will be displayed during normal operation.

8.3.2.2.5 <5> REVERSE MOTOR: YES or NO

If Yes, Motor will reverse briefly when occlusion is encountered. The motor reversal reduces post occlusion bolus it does not reduce the occlusion detection time.

8.3.2.2.6 <6> AUTO VOL @ V/T: NO or YES

If YES, when using V/T the pump will automatically sense the volume in the syringe and display it on the LCD. The user can confirm the volume and then enter the delivery time.

8.3.2.2.7 <7> ENTERAL CHECK: 0,1,2,3,4,5,6,7 MSGs

If 0 is selected the user is not required to confirm any statement(s):

0 – The user is not required to confirm any statement(s)

1 – VERIFY PUMP POSITION,

2 – TRACE TUBING-> PATIENT,

3 – TRACE TUBING-> PATIENT and VERIFY PUMP POSITION,

4 – VERIFY PATIENT ID,

5 – VERIFY PATIENT ID and VERIFY PUMP POSITION,

6 – VERIFY PATIENT ID and TRACE TUBING-> PATIENT,

7 – VERIFY PATIENT ID and TRACE TUBING-> PATIENT and VERIFY PUMP POSITION

Note these statements appear only when an enteral syringe manufacturer is selected.

8.3.2.2.8 <8> LOCK START –UP= YES or NO

If NO is selected the user will be able to access this feature. If YES is selected the user will not be able to access this feature and the LCD will briefly flash SETTING IS PROTECTED! and return to MAIN MENU PAGE 1 of 3.

8.3.2.2.9 <9> LOCK CRTE PROG =YES or NO

If NO is selected the user will be able to access this feature. If YES is selected the user will not be able to access this feature and the LCD will briefly flash SETTING IS PROTECTED! and return to MAIN MENU PAGE 1 of 3.

8.3.2.2.10 <0> LOCK TEMP ADJ= NO or YES

If NO is selected the user will be able to access this feature.

If YES is selected the user will not be able to access this feature and the LCD will briefly flash SETTING IS PROTECTED! and return to MAIN MENU PAGE 1 of 3.

NO (unlocked) - Allows the user to adjust several pump settings on a one-time temporary basis. Any change will be reset to the previous programmed setting once the unit is powered off.

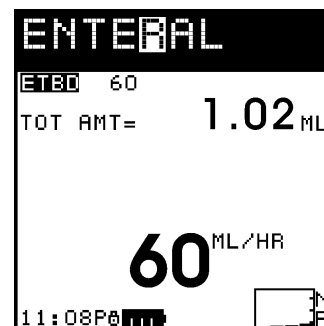
Settings that can be adjusted are <1> Bolus Prime Rate, <3> Bolus Prime Force, <5> Plunger Force, and <7> Alarm Volume.

8.3.2.3 OPTIONS: (PAGE 3 OF 3):

8.3.2.3.1 <1> LOCK KEY PAD: NO or YES

If NO, the Key Pad will not be locked. If YES, a code is required to unlock the key pad to make changes or starting infusion. All keys except “Stop”, “Alarm Off” and “Power Off” are inactive during delivery. When pump is stopped, and an attempt is made to change a setting the LCD will display ENTER ACCESS LOCK. The user must enter the password code to unlock the keypad. See Appendix IV for code. The user has 90 seconds to make any modifications before the keypad returns to its locked state.

When LOCKED a lock symbol (🔒) appears on the LCD near the battery symbol.



8.3.2.3.2 <2> TOTAL UNIT mX: NO OR YES

If YES, the user can view the TOT AMT (Total Volume Delivered) in mcg. To view the TOT AMT in ml the user can press and release the Enter Key during delivery.

8.3.2.3.3 <3> USE BOLUS TIME: NO OR YES

If YES, the user can program the Bolus delivery time in minutes. Valid entries are from 0 to 60 minutes in increments of 1 minute.

8.3.2.3.4 <4> EMP=STOP ALARM? NO OR YES

If YES, the EMPTY AUDIO ALARM and DELIVERY LIMIT AUDIO ALARM will sound like the programmed STOP AUDIO ALARM. This feature is useful when the HCP desires to have a slow beep audio alarm sound.

8.3.2.3.5 <5> MANUAL BOLUS: NO OR YES

If YES, the user can deliver a manual Bolus by pressing the Bolus Key once followed immediately by pressing and holding the Bolus Key down a second time until the desired amount is given or until the Manual Bolus Duration Limit is reached. A MANUAL BOLUS can be given in both STOP and Delivery modes.

8.3.2.3.6 <6> MAN.BOL DUR.LMT=: 10,15, 20, 25 (seconds)

Active only if the Manual Bolus Option is enabled. The Manual Bolus Duration Limit is universally applied to all Programs including any Saved Programs.

This feature limits the Bolus amount that can be delivered. As long as the Bolus Key is held down fluid will be delivered until the user releases the Bolus Key or until the programmed Duration Limit is reached. The user can give multiple Boluses by repeating the MANUAL BOLUS procedure.

8.3.2.3.7 <7> AREA OPTIONS= 000F

Allows user to select the Areas in the EPROG that will be available for use. Select any Area(s) desired by pressing the Enter key. The Areas selected can be viewed and utilized by the user.

8.3.2.3.8 <8> INTERMITTENT: *NO OR YES*

The Intermittent function allows for repeated intermittent infusions of the same infusion parameters. When enable the user can program the Stand-By Timer which is the time interval between infusions along with number of repeated deliveries for any desired infusions.

A Delivery Limit must be programmed, and the Bolus function is disabled.

Once all infusion parameters are programmed press Deliver to begin. The first infusion period will infuse until the Delivery Limit is reached, at which time the Start function will display the time until the beginning of the next infusion. The process will repeat until the number of deliveries is reached. Once reached the Delivery Limit Alarm will be activated.

The pump will return to display the initial base program. The user can elect to repeat the program by pressing Deliver.

When the pump is in its ready to deliver status the DEL LMT can be changed by pressing the Bolus Key.

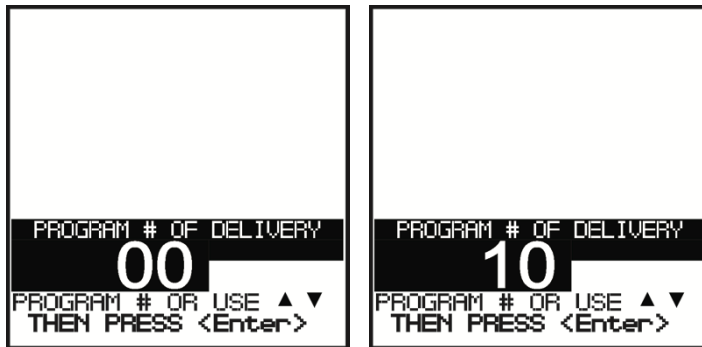
NOTE: If a fast infusion is desired, the Infusion Rate needs to be set to a high rate. When the infusion begins, it will run at the programmed rate until the DEL LMT is reached.

Program Stand-By time in HRS:MINS (e.g. 6 minutes). **Note:** If 00:00 time is entered, the Intermittent function is cancelled, and the infusion parameters can be entered as normal.



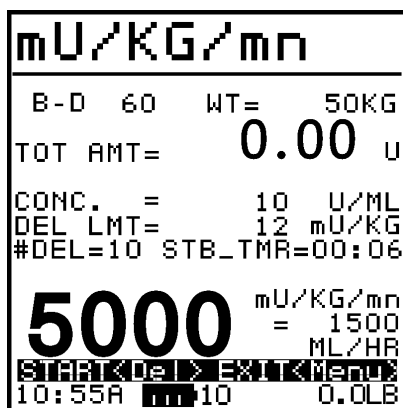
After Programming the Stand-By Time the total number of repeat infusions can be programmed.

This example shows 10 repeat infusions.

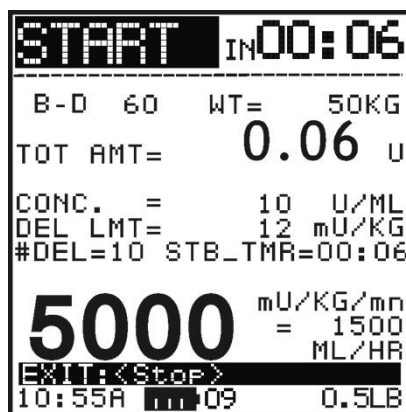


Once all of the infusion parameters have been programmed, the pump is in the ready to deliver status (far left display). Note: The # of DEL is 10 and the STB_TMR is set to 6 minutes and the total number of deliveries is displayed on the bottom line of the LCD (e.g. 10).

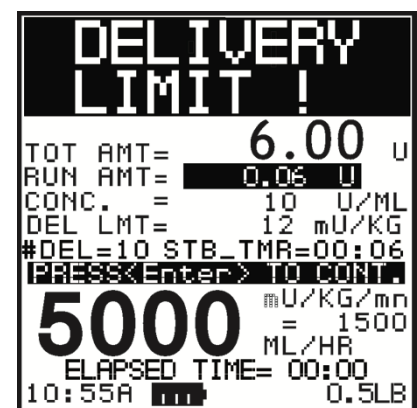
Initiate delivery by pressing Deliver. After the first delivery is complete, the LCD will show the time interval between deliveries (e.g. 6 minutes) and the total number of deliveries remaining is displayed on the bottom line of the LCD (e.g. 09) (middle display). After all 10 deliveries have been delivered (no more deliveries pending), the DELIVERY LIMIT ALARM will signal the end of the delivery program (far right display).



Ready to Deliver



After first delivery



End of Delivery Program

To change the DEL LMT:

Press STOP – Exit STBY TIMER enter Y

Press Bolus Key – Program new DEL LMT- Enter value

Press Deliver Key

The new program will begin the number of deliveries will resume and not reset.

To change other Infusion parameters:

Press STOP – Exit STBY TIMER enter Y

Press Select Key to cycle through the parameters to confirm or change –

Program STAND-BY TIMER – Program # of Deliveries- Restart Intermittent (Y/N)-
Program Concentration- Program Weight- Load Syringe-Program Delivery Limit-
Program Rate- Start or Exit

8.3.2.4 ALARM/ALERT OPTIONS (1 page):

8.3.2.4.1 <1> ALARM VOLUME: NORM, VLOW, LOW, or HIGH

Allows user to program audio volume settings. V denotes Very Low.

8.3.2.4.2 <2> ALARM FREQ. (frequency of sound):

Allows user to program audio alarm frequency from 00 to 99 in increments of 1. The audio alarm consists of two different frequencies; the first digit corresponds to the first frequency, and the second digit corresponds to the second frequency. The higher the digit, the higher the sound. For only one sound, set second digit to 0.

8.3.2.4.3 <3> ALARM DELAY: 2-60 minutes

Allows user to select the amount of time the audio alarm will be temporarily silenced after the ALARM OFF key is pressed.

8.3.2.4.4 <4> STOP ALARM: YES or NO

If NO, there will be no slow beep audio alarm in stop state.

If YES, there will be a slow beep. One can bypass the actuation of this alarm by pressing and holding the Stop key and then pressing the Alarm Off key. This is to temporarily silence the STOP ALARM before commencing the delivery. Once the delivery starts the normal STOP ALARM will activate when the delivery stops.

8.3.2.4.5 <5> EMPTY ALARM: YES or NO

If NO, there will be no audio alarm when the syringe is empty.

8.3.2.4.6 <6> LOW BATT (battery) ALARM: YES or NO

If NO, there will be no audio alarm when battery is low.

8.3.2.4.7 <7> NEAR-EMP (empty) ALARM: YES or NO

If NO, there will be no audio alarm when near-empty condition is detected.

8.3.2.4.8 <8> NEAR-EMP (empty) DELAY: 2-99 minutes

Allows user to adjust the amount of time before the syringe is emptied when a Near-Empty audio alarm is triggered.

8.3.2.4.9 <9> BOLUS COMPLETE: NO or YES

If NO, there will be no audio alarm when bolus infusion is completed.

8.3.3 Biomed Services (Option <5> of MAIN MENU PAGE 3 OF 3)

This item allows user to:

- (1) Perform calibration services for the analog sensors (Size, Position, and Force).
- (2) Duplicate the options configuration and saved programs from one device to another device.
- (3) Reset the pump to factory default settings.
- (4) Program pump delivery mode settings –1) Medela Enteral Only, 2) ABC IV Only, and 3) ABC Enteral Only. The pump will briefly display the mode setting when Powered On.

⚠ WARNING:

A special Access Code is required for BIOMED SERVICES. Only technically trained personnel should attempt to perform these functions.

Contact the manufacturer to acquire this code.

8.3.4 Real-Time Clock (Option <7> of MAIN MENU PAGE 3 OF 3)

⚠ WARNING:

A special Access Code is required for BIOMED SERVICES. Only technically trained personnel should attempt to perform this function.

This item allows the user to set up the Real-Time Clock. When the clock battery is replaced, the clock needs to be reset. The clock holds data of Year, Month, Day, Hour, Minute, and Second.

- (1) The data entered by the user is checked by the pump. For example, 30 is an invalid entry for Days in February, and 13 is an invalid entry for Hour, etc.
- (2) The current clock data is displayed (See Figure 8.3.4). All data must be entered. The **Stop** key aborts programming. The **Go Back** key can be used to return to the previous data entry.
- (3) The system returns to MAIN MENU when the clock data has been entered.

8.3.5 System Check (Option <9> of MAIN MENU PAGE 3 OF 3)

This item allows the user to inspect the readings of the system's major sensors in order to verify that they are functioning properly (See Figure 8.3.5). This menu can be used for Quality Control inspection. No Access Code is required.

The raw Analog to Digital Converter reading as well as the calibrated reading of the analog sensors are displayed. The **Stop** key is used to exit to MAIN MENU.

The following sensors are checked:

- (1) Position Sensor
- (2) Syringe Size Sensor
- (3) Battery Voltage
- (4) Plunger Force Sensor
- (5) Plunger Retainer Detector
- (6) To Load Battery
- (7) Test LED/Alarm

The operation of the LEDs and Audio Alarm can be tested by pressing the <Select> key. Once the <Select> key is pressed, all LEDs (except System Malfunction LED) and Alarm flash and sound for a brief moment. Immediately thereafter, the System Malfunction LED and audio alarm will flash and sound once.

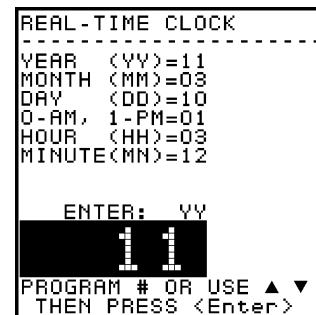


Figure 8.3.4: Real-Time Clock Set Up Screen

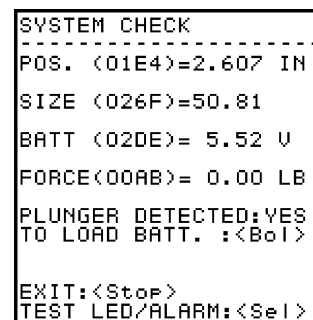


Figure 8.3.5: System Check allows user to verify that the system's major sensors are working properly

SECTION 9. BATTERY OPERATION

9.1 AC POWER / BATTERY OPERATION

The pump is designed to operate with AC power backed-up by battery power. The pump can operate with AC power only (i.e., battery pack is not installed or depleted) or with Battery Power only (i.e., AC power interruption or during patient transportation).

The pump automatically switches to battery power if AC power is interrupted during the pump operation. It will switch back to AC power as soon as the AC power is restored.

A battery pack is installed in each pump (See Back View figure - paragraph 3.2). The battery pack can be removed or inserted into the pump without any tool. A thumbscrew on the battery pack secures the battery pack in the pump. A rubber O-ring with the pack is compressed when the thumbscrew is tightened to prevent fluid from entering the battery compartment. Battery pack is comprised of AA NiMH cells. Replacement packs must be purchased from Atlanta BioMedical.

9.2 INSTALLING, CHARGING, AND REPLACING THE BATTERY PACK

The battery can be easily installed into the battery compartment of the pump without any tool.

When AC power is connected to the pump, the condition of the battery pack is assessed, and a charging process is initiated if necessary. Under normal conditions, a fast charging process will start immediately. If the pump motor is not running, it takes approximately 4 hours to fully charge the battery pack, depending on the battery condition.

If a battery pack is deeply discharged, with very low battery voltage, the pump will try to “Condition” the battery pack by pulsing energy into it until the battery voltage reaches a threshold to start fast charging. If the battery voltage cannot reach the threshold voltage after a preset time period, then “REPLACE BATTERY” is displayed. User can remove and re-insert the pack to try one more time. However, if the charging process fails again, the user must replace the battery pack.

If the battery pack is fully charged, the pump will not continue to charge it in order to prevent over-charging and prolong battery life. The pump will only continue charging if the battery pack voltage falls below a preset threshold or if the battery pack is removed from the pump and replaced. User can always manually trigger battery charging by removing and re-installing the battery pack while AC power is connected.

9.3 INDICATORS FOR BATTERY CONDITION

There are 3 indicators related to battery operation: Battery LED, LCD Battery Symbol, and audio alarm. The Battery LED is the main indicating source, since it is always visible.

9.3.1 Battery LED

The Battery LED is located on the left-hand side of the LCD display. The LED flashes different colors and speeds to indicate the battery condition:



- (1) GREEN indicates power coming from an AC source
 - (A) SOLID Green: Fully charged battery
 - (B) FAST BLINKING Green: Fast charging in progress
 - (C) SLOW BLINKING Green: Conditioning stage of battery charging
- (2) YELLOW indicates power coming from the Battery
 - (A) FAST BLINKING Yellow: Low battery condition
 - (B) SLOW BLINKING Yellow: Normal battery condition
- (3) RED indicates a battery alarm condition
 - (A) FAST BLINKING Red: Absent or Defective Battery, Depleted Battery

9.3.2 Battery Symbol on LCD display

The battery symbol is displayed in the middle of the “Status Line” when it is displayed (See Figure 9.1). The Status line appears on the bottom of the screen when the pump is in:

- (1) Stand-by charging state
- (2) Ready-to-Deliver state (when all infusion settings are programmed)
- (3) Delivery state, when pump motor is running

The following battery conditions are indicated during **AC power operation**:

- (A) Fast Charging: Fast moving block inside the battery symbol
- (B) Battery Conditioning: Slow moving block inside the battery symbol
- (C) Fully Charged Battery: Solid battery symbol
- (D) Absent or Defective Battery: Fast Blinking battery symbol

The following battery conditions are indicated during **Battery power operation**:

- (A) Solid battery symbol: More than 90% of battery energy remaining
- (B) Partially filled battery symbol: Proportional to % of energy remaining
- (C) Empty battery symbol: Depleted battery

9.3.3 Audio Alarm

The audio alarm sounds if the battery is low or depleted (this applies only if enabled in PUMP DEFAULTS—Refer to paragraph 8.3.2.4.6):

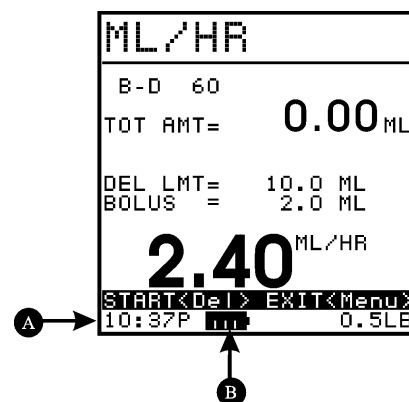


Figure 9.1: Status Line (A) and Battery Symbol (B) on LCD Display – Ready-to-Delivery State

- (A) Low Battery: distinct, low frequency slow beeping
- (B) Depleted Battery: fast beeping

9.4 BATTERY OPERATION PRECAUTIONS

- (1) Prior to battery pack replacement, put the pump in the stop delivery mode then turn off the power using the **Power Off** key. The programmed infusion settings are retained. After a new battery pack is installed, the user can resume normal operation by reconfirming the infusion settings with the **Enter** key after the pump is turned back on.

 **IMPORTANT:** Both the Total volume and Running volume are reset to 0.

- (2) Tightened battery thumbscrew by hand. DO NOT over-tighten, as this can cause breakage of the plastic thumbscrew.
- (3) The battery pack must be installed when cleaning the pump with disinfecting fluid to prevent liquid from entering the battery compartment.

SECTION 10. HANDLE and CLAMP (for IV POLE or RAIL mount)

A Handle is installed on each pump to facilitate carrying the pump. The Handle also is used to mount the Pump onto a Clamp (if available) for attachment to an IV Pole or Rail.

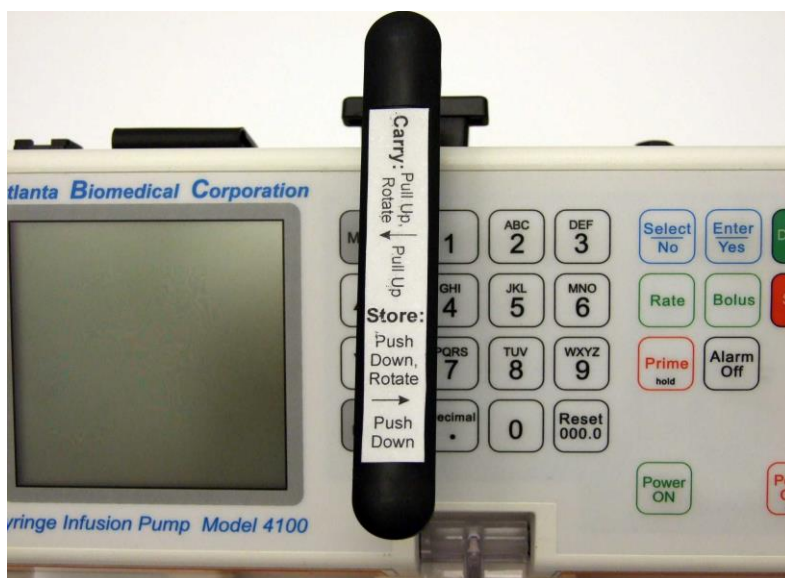
10.1 USING the HANDLE

To use the pump Handle, follow the directions provided on the label:



Handle shown in Store position.

To Carry - Pull the Handle up and rotate 90 degrees (see arrow).



Handle shown in the Carry position.

To return the Handle to the Store position – Push down and rotate 90 degrees (see arrow).

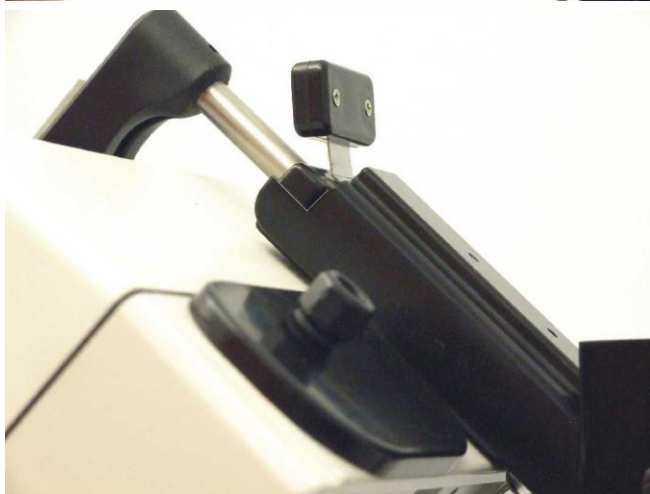
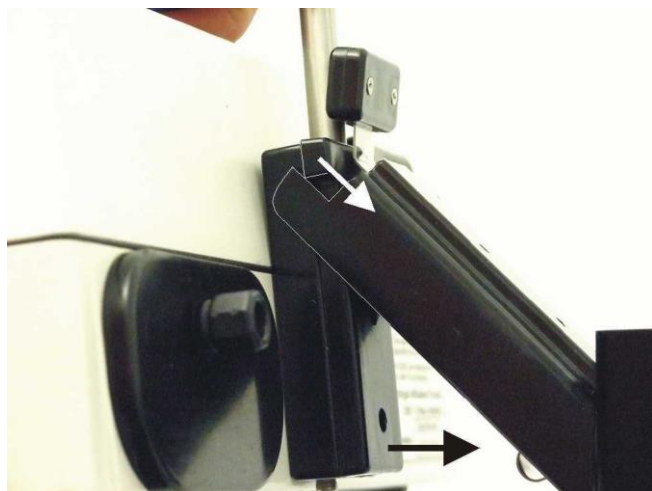
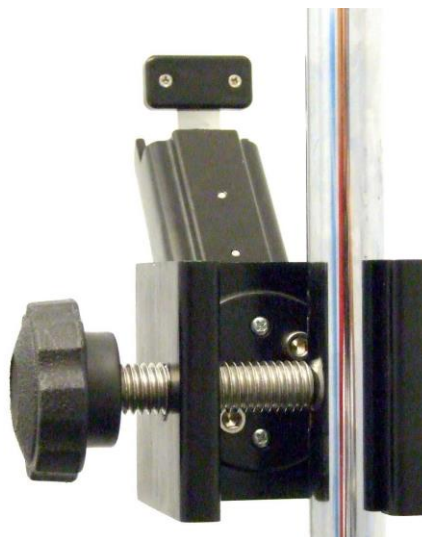
10.2 MOUNTING the PUMP onto an IV POLE (OR RAIL) (when a Clamp is available)

Step 1: Attach the Clamp

The Clamp can be easily mounted to a pole (or rail) by tightening the thumb screw Knob (turn clockwise) to capture the pole (or rail) in a selected position for use.

Step 2: Mount Pump to Clamp

To mount the Pump to the Clamp Receptacle, place the locking tabs into position and gently push down on the Handle to rock the Pump into the locked position. Return the Handle to the Store position.



Step 3: Pump Can Be Rotated

The Pump can be rotated 360 degrees in 90 degree increments in any direction (clockwise or counter-clockwise) by applying a gentle force in the desired direction.



10.3 REMOVING the PUMP from the CLAMP

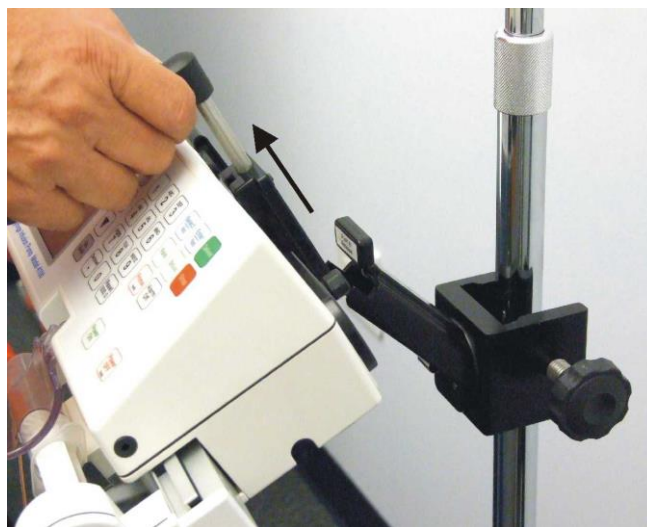
Step 1: Position the Handle

Place the Handle in the Carry Position

Step 2: Removing the Pump from Clamp



The Pump can be easily removed from the pole (or rail) Clamp by gently pushing on the Release Button while pulling up on the Handle.



The Handle is used to lift the Pump from the Clamp Receptacle.

SECTION 11. CLEANING

Follow your institutions guidelines for disinfecting and cleaning this pump.

The following solutions can be safely used:

- (1) Alcohol 70% isopropyl solution
- (2) Common bleach 10% solution
- (3) Sporidicin® solution
- (4) ASP® Cidex OPA solution
- (5) A mild water-soap solution
- (6) PDI® Super sani cloth
- (7) Metrex® cavi wipes
- (8) s BioMed, LLC STERIPLEX SD Wipes
- (9) AHP® Virox Accel TB Wipes

 CAUTION: To prevent possibility of serious damage

Do not use strong detergents, organic solvents or solutions containing ammonium chloride to clean any portion of the pump

Do not immerse.

Avoid spills and inadvertent entry of fluid in the pump housing.

Make sure that the battery pack is properly installed in the pump prior to cleaning.

SECTION 12. SERVICE AND WARRANTY

WARNING:

Other than cleaning, any repairs or maintenance must be performed by trained qualified biomedical personnel either at the institution or at the manufacturer.

Testing including all calibration checks should be performed at least yearly or whenever a pump has been dropped or damaged.

WARRANTY

Atlanta BioMedical Corp. (ABC) warrants to the purchaser that the Syringe Infusion Pump shall be free from defects in material and workmanship for a period of one (1) year from the date of purchase. Atlanta BioMedical Corp's sole obligation with respect to any such defect is limited to the repair, or at Atlanta BioMedical Corp's option, replacement of the Syringe Infusion Pump. Purchaser pays return freight charges.

This warranty is made on the condition that prompt notifications of a defect is given to Atlanta BioMedical Corp, within the warranty period, and that Atlanta BioMedical Corp shall have the sole right to determine whether a defect exists.

This warranty does not apply to Syringe Pumps that have been partially or completely disassembled, altered, subjected to misuse, negligence, or accident; or operated other than in accordance with the instructions provided by Atlanta BioMedical Corp.

This warranty represents the exclusive obligation of Atlanta BioMedical Corp, and the exclusive remedy of the purchaser regarding defects in a Syringe Infusion Pump. THIS WARRANTY IS GIVEN IN LIEU OF ANY EXPRESS OR IMPLIED WARRANTIES, INCLUDING THE WARRANTY OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE. No person is authorized to modify, in any manner, Atlanta BioMedical Corp's obligation as described above.

SECTION 13. DEFINITIONS

Alarm Temporary Delay Time: A custom programmed delay time of 2 to 60 minutes that is activated when the alarm off key is pressed once.

Alarm Volume: A program option in the pump default mode that allows programming of the alarm auditory volume to VLOW, LOW, NORM, HIGH.

Biomed Service: This mode is used by trained biomedical technicians to service the pump.

Body-Weight Mode: A level of pump operation that delivers either micrograms (μg , mcg) or milligrams (mg, MG) per kilogram (KG) per time (e.g., minute or hour).

Bolus: A level of pump operation during which a preprogrammed amount is delivered at the fastest rate possible for the syringe size in use by pressing the BOLUS key.

Continuous Infusion Mode: A level of pump operation that allows delivery of a specific fluid volume at a specified rate. Useful in delivery of a volume of medication at a specific constant rate.

Delivery Limit: The programmable preset volume the pump will deliver before stopping (Dose volume).

Delivery Mode: The level of pump operation during which the infusion occurs as initiated by pressing the DELIVER key and indicated by the blinking of the green DELIVER LED.

Delivery Time (DT): Time in hours and minutes for the programmed volume (dose) to be delivered.

Dose Volume (DV): Volume (ML) or dose size to be administered (the same as program volume in the volume/time mode). Also same as Delivery Limit in Continuous and Mass modes.

Invalid Number: A LCD parameter that indicates what has been programmed is not consistent with other values entered. A valid entry that is programmable will be displayed.

Kilogram: One kilogram (kg, KG) equals 1,000 (1×10^3) grams.

Light Emitting Diode (LED): A red, yellow or green light function signaled by the pump.

Liquid Crystal Display (LCD): The pump screen.

Infusion Saved Program: Stored information on a particular medication which when retrieved allows the user to deliver that medication in a quicker manner.

Microgram: One microgram (μg , mcg) equals 0.000001 (1×10^{-6}) grams.

Milligram: One milligram (mg, MG) equals 0.001 (1×10^{-3}) grams.

Prime: A level of pump operation that is only activated in the STOP mode after all other functions have been entered. Priming allows the fluid to be delivered to replace air in the tubing attached to the syringe. The actual priming volume can be verified on the prime volume counter of the LCD. The prime function also eliminates any mechanical tolerances whenever a newly filled syringe is loaded onto the pump. Never use the PRIME function to deliver infusate to a patient.

Pump Default Mode (PD): A level of pump operation that is limited in access by a lockout feature and generally only accessed by specially trained healthcare professionals or biomedical engineers to preprogram or customize the pump by selection of the syringe manufacturers, alarm delay time, alarm types, alarm volume, audio frequency, plunger force, near empty, volume limit, bolus capability, total unit and rate input.

Running Volume (RV): A recording of total volume delivered since the last dose volume reset. The Dose Volume minus running volume equals the volume yet to be delivered.

Total Delivered: Refers to the amount of medication actually delivered during the course of an infusion (Does not include the volume delivered in the priming mode).

User Mode: A level of pump operation that is available to the pump user. Level of operation can be limited by custom programming default settings.

Volume/Time Mode: A level of pump operations that delivers a specific volume (dose) over a specified delivery time (useful in delivery of a single dose over a specific time).

Symbols:



Manufacturer



Consult instructions for use



MR unsafe



Date of manufacture



Caution



Prescription only



Catalog number



Humidity limitation



Type BF applied part



Serial number



Atmospheric pressure limitation



Batch code



Temperature limits

APPENDIX I FLOW RATES AND CALCULATIONS

The following formulas are used to calculate various variables in the BODY-WEIGHT and MASS modes:

RATE MODE = mcg/KG/min

$$\text{RATE in mcg/KG/min} = \frac{(\text{Final conc in MG/ML}) (\text{ML/HR}) (1000)}{(60 \text{ min/HR}) (\text{Wt in KG})}$$

$$\text{RATE in ML/HR} = \frac{(60 \text{ min/HR}) (\text{Wt in KG}) (\text{mcg/KG/min})}{(\text{Final conc. in MG/ML}) (1000)}$$

$$\text{CONC. In MG/ML} = \frac{(60 \text{ min/HR}) (\text{Wt in KG}) (\text{mcg/KG/min})}{(\text{ML/HR}) (1000)}$$

RATE MODE = mcg/KG/HR

$$\text{RATE in mcg/KG/HR} = \frac{(\text{Final conc. in MG/ML}) (\text{ML/HR}) (1000)}{(\text{Wt in KG})}$$

$$\text{RATE in ML/HR} = \frac{(\text{Wt in KG}) (\text{mcg/KG/HR})}{(\text{Final conc. in MG/ML}) (1000)}$$

$$\text{CONC. In MG/ML} = \frac{(\text{Wt in KG}) (\text{mcg/KG/HR})}{(\text{ML/HR}) (1000)}$$

RATE MODE = MG/KG/min

$$\text{RATE in MG/KG/min} = \frac{(\text{Final conc. in MG/ML}) (\text{ML/HR})}{(60 \text{ min/HR}) (\text{Wt in KG})}$$

$$\text{RATE in ML/HR} = \frac{(60 \text{ min/HR}) (\text{Wt in KG}) (\text{MG/KG/min})}{(\text{Final conc. in MG/ML})}$$

$$\text{CONC. In MG/ML} = \frac{(60 \text{ min/HR}) (\text{Wt in KG}) (\text{MG/KG/min})}{(\text{ML/HR})}$$

RATE MODE = MG/KG/HR

$$\text{RATE in MG/KG/HR} = \frac{(\text{Final conc. in MG/ML}) (\text{ML/HR})}{(\text{Wt in KG})}$$

$$\text{RATE in ML/HR} = \frac{(\text{Wt in KG}) (\text{MG/KG/HR})}{(\text{Final conc. in MG/ML})}$$

$$\text{CONC. In MG/ML} = \frac{(\text{Wt in KG}) (\text{MG/KG/HR})}{(\text{ML/HR})}$$

RATE MODE = MG/HR

$$\text{RATE in MG/HR} = \frac{(\text{final conc. in MG/ML}) (\text{ML/HR})}{(\text{Final conc. in MG/ML})}$$

$$\text{RATE in ML/HR} = \frac{(\text{MG/HR})}{(\text{Final conc. in MG/ML})}$$

$$\text{CONC. In MG/ML} = \frac{(\text{MG/HR})}{(\text{ML/HR})}$$

APPENDIX II FLOW RATES and SYRINGE SIZES

Syringe Mfg	Syringe Size (ML)	Minimum Fill Volume (ML)	Minimum Rate ML/HR	Maximum Rate ML/HR
B-D / ETBD	1.0	0.01	0.01	46.85
MONO / ETMN	1.0	0.01	0.01	46.34
TERU	1.0	0.01	0.01	46.89
B-D Glass	1.0	0.01	0.01	45.54
NEOM	1.0	0.01	0.01	46.87
AMP	1.0	0.01	0.01	46.87
VYGO	1.0	0.01	0.01	43.92
B-D / ETBD	3.0	0.01	0.05	156.3
MONO / ETMN	3.0	0.01	0.05	166.7
TERU	3.0	0.01	0.05	169.9
B-D Glass	2.5	0.01	0.05	157.7
PS - RTI	3.0	0.01	0.05	191.3
NEOM	3.0	0.01	0.05	171.8
AMP	3.0	0.01	0.05	156.5
VYGO	2.5	0.01	0.05	160.6
B-D / ETBD	5.0	0.01	0.05	304.9
MONO / ETMN	6.0	0.01	0.05	336.7
TERU	5.0	0.01	0.05	358.6
B-D Glass	5.0	0.01	0.05	290.4
PS - RTI	5.0	0.01	0.05	331.3
NEOM	6.0	0.01	0.05	336.8
AMP	5.0	0.01	0.05	305.5
VYGO	5.0	0.01	0.05	331.5
MDLA	5.0	0.01	0.05	306.0
MEDI	5.0	0.01	0.05	325.7
B-D / ETBD	10.0	0.02	0.1	441.6
MONO / ETMN	12.0	0.02	0.1	517.7
TERU	10.0	0.02	0.1	529.6
B-D Glass	10.0	0.02	0.1	435.8
PS - RTI	10.0	0.02	0.1	477.1
AVNS	10.0	0.02	0.1	516.1
NEOM	12.0	0.02	0.1	516.3
AMP	10.0	0.02	0.1	439.9
VYGO	10.0	0.02	0.1	512.4
MDLA	10.0	0.02	0.1	447.9
MEDI	10.0	0.02	0.1	465.7
B-D / ETBD	20.0	0.02	0.25	770.0
MONO / ETMN	20.0	0.02	0.25	860.8
TERU	20.0	0.02	0.25	861.5
PS - RTI	20.0	0.02	0.25	773.6
AVNS	20.0	0.02	0.25	852.5
NEOM	20.0	0.02	0.25	874.3
AMP	20.0	0.02	0.25	774.0
VYGO	20.0	0.02	0.25	944.6
MEDI	20.0	0.02	0.25	771.6
B-D / ETBD	30.0	0.05	0.25	989.0
MONO / ETMN	35.0	0.05	0.25	1178
TERU	30.0	0.05	0.25	1132
PS - RTI	30.0	0.05	0.25	1117
NEOM	35.0	0.05	0.25	1171
AMP	30.0	0.05	0.25	989.9
VYGO	35.0	0.05	0.25	1181
MDLA	30.0	0.05	0.25	981.7
MEDI	30.0	0.05	0.25	1161
B-D / ETBD	50/60	0.05	0.25	1500
MONO / ETMN	60.0	0.05	0.25	1497
TERU	60.0	0.05	0.25	1796
PS - RTI	60.0	0.05	0.25	1820
AVNS	60.0	0.05	0.25	1500
NEOM	60.0	0.05	0.25	1501
AMP	60.0	0.05	0.25	1490
VYGO	60.0	0.05	0.25	1628
MDLA	60.0	0.05	0.25	1490
MEDI	60.0	0.05	0.25	1501
NEOM	100.0	0.10	0.5	2451
ABC/MONO	140.0	0.10	0.5	3055
MDLA	140.0	0.10	0.5	2933

NOTE: All syringes can be filled to their maximum stated syringe volume. The rates indicated are the mechanical Hard Rate Limits of the device.

APPENDIX III OCCLUSION FORCE

OCCLUSION FORCE: (All syringes except 1 ML) HIGH = 20PSI MID = 15 PSI NORM = 10 PSI LOW = 5 PSI
 1 ML syringe: HIGH = 30 PSI MID = 22.5 PSI NORM = 15 PSI LOW = 7.5 PSI

SYRINGE MFGR	SYRINGE SIZE (ML)	PLUNGER (OCCLUSION) FORCE (LB)			
		LOW	NORM	MID	HIGH
B-D / ETBD	1.0	0.2	0.4	0.61	0.81
MONO / ETMN	1.0	0.2	0.4	0.6	0.8
TERU	1.0	0.2	0.4	0.61	0.81
B-D Glass	1.0	0.2	0.39	0.59	0.78
NEOM	1.0	0.20	0.40	0.61	0.81
AMP	1.0	0.20	0.40	0.61	0.81
VYGO	1.0	0.19	0.38	0.57	0.76
B-D / ETBD	3.0	0.45	0.9	1.35	1.79
MONO / ETMN	3.0	0.48	0.96	1.43	1.91
TERU	3.0	0.49	0.98	1.46	1.95
B-D Glass	2.5	0.45	0.9	1.36	1.81
PS – RTI	3.0	0.5	1.0	1.6	2.2
NEOM	3.0	0.49	0.99	1.48	1.97
AMP	3.0	0.45	0.9	1.35	1.80
VYGO	2.5	0.47	0.93	1.40	1.87
B-D / ETBD	5.0	0.87	1.75	2.62	3.5
MONO / ETMN	6.0	0.97	1.93	2.90	3.86
TERU	5.0	1.03	2.06	3.09	4.11
B-D Glass	5.0	0.83	1.66	2.49	3.33
PS – RTI	5.0	0.9	1.8	2.8	3.8
NEOM	6.0	0.97	1.93	2.90	3.87
AMP	5.0	0.88	1.75	2.63	3.51
VYGO	5.0	0.95	1.90	2.85	3.80
MDLA	5.0	0.88	1.76	2.63	3.51
MEDI	5.0	0.93	1.87	2.80	3.74
B-D / ETBD	10.0	1.27	2.53	3.80	5.07
MONO / ETMN	12.0	1.49	2.97	4.46	5.94
TERU	10.0	1.52	3.04	4.56	6.08
B-D Glass	10.0	1.25	2.5	3.75	5.0
PS – RTI	10.0	1.4	2.7	4.1	5.4
AVNS	10.0	1.5	3.0	4.4	5.9
NEOM	12.0	1.48	2.96	4.44	5.93
AMP	10.0	1.26	2.52	3.79	5.05
VYGO	10.0	1.46	2.94	4.41	5.88
MDLA	10.0	1.29	2.57	3.96	5.14
MEDI	10.0	1.34	2.67	4.01	5.34
B-D / ETBD	20.0	2.21	4.42	6.63	8.84
MONO / ETMN	20.0	2.47	4.94	7.41	9.88
TERU	20.0	2.47	4.94	7.41	9.89
PS – RTI	20.0	2.2	4.4	6.6	8.8
AVNS	20.0	2.4	4.9	7.3	9.7
NEOM	20.0	2.51	5.02	7.52	10.03
AMP	20.0	2.22	4.44	6.66	8.88
VYGO	20.0	2.71	5.42	8.13	10.84
MEDI	20.0	2.21	4.43	6.64	8.85
B-D / ETBD	30.0	2.84	5.68	8.51	11.35
MONO / ETMN	35.0	3.38	6.76	10.15	13.53
TERU	30.0	3.25	6.50	9.74	13.0
PS – RTI	30.0	2.9	5.8	8.7	11.6
NEOM	35.0	3.36	6.72	10.08	13.45
AMP	30.0	2.84	5.68	8.52	11.36
VYGO	35.0	3.39	6.78	10.17	13.56
MDLA	30.0	2.82	5.63	8.45	11.27
MEDI	30.0	3.33	6.67	10.00	13.33
B-D / ETBD	50/60	4.31	8.61	12.92	17.22
MONO / ETMN	60.0	4.30	8.59	12.89	17.19
TERU	60.0	5.15	10.31	15.46	20.62
PS – RTI	60.0	5.2	10.5	12.9	20.9
AVNS	60.0	4.3	8.6	12.9	17.2
NEOM	60.0	4.31	8.61	12.92	17.23
AMP	60.0	4.27	8.55	12.82	17.10
VYGO	60.0	4.67	9.34	14.01	18.68
MDLA	60.0	4.27	8.55	12.82	17.10
MEDI	60.0	4.31	8.61	12.92	17.23
NEOM	100.0	7.03	14.06	21.10	28.13
ABC/MONO	140.0	8.77	17.53	26.3	31.0
MDLA	140.0				

Note: PSI is calculated by dividing the force (lbs) by the cross sectional area of the syringe in square inches.

APPENDIX IV PUMP DEFAULT PROGRAMMING CODE

IMPORTANT:

Many Institutions limit who has access to the following code to Biomedical Personnel or trained clinical specialist. If limited access is desired, then either remove this page or black-out the code number below or request a copy of the operation manual without the codes.

In order to program Pump Defaults, the following code must be entered 4321.

In order to unlock the keypad, the following password code (ACCESS LOCK) must be entered UNLK (8655).

To configure master delivery modes 1) Medela Enteral Only, 2) ABC IV Only, and 3) ABC Enteral Only, please contact ABC BioMedical Department.