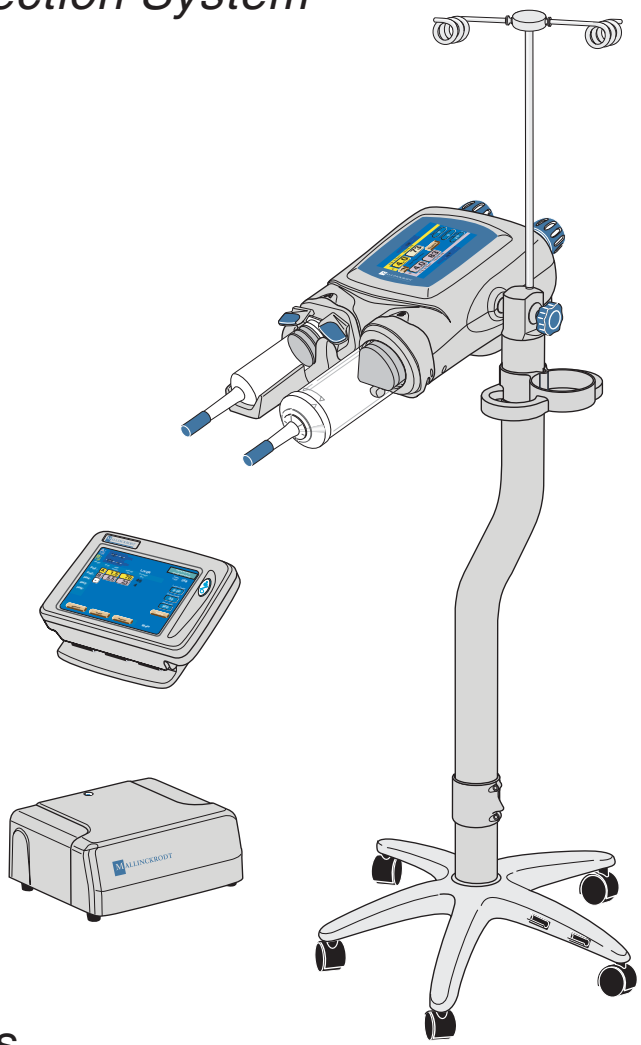
MALLINCKRODT

Liebel-Flarsheim

OptiVantage™ DH

Injection System



Operators Manual

844960-A

MALLINCKRODT

844960-A Feb. 2005

FOREWORD

Congratulations on the purchase of your OptiVantage™ DH Injection System. The OptiVantage DH represents our effort to provide a quality product to support better health care throughout the world.

Regardless of how well equipment is designed, misuse or abuse will deny its owner the expected quality of service. Misuse or abuse may occur unintentionally because the proper method of operating the equipment is unknown. Read this manual carefully before operating the OptiVantage DH. Retain this manual for future reference.

LIEBEL-FLARSHEIM TECHNICAL SUPPORT
Phone No. 1-800-877-0791

RECORDING MODEL NUMBER, PART NUMBERS, AND SERIAL NUMBERS

The model number (Mod. No.), part numbers (P/N), and serial numbers (S/N) must be supplied when requesting replacement parts or optional accessories. For convenience, record the requested information below:

Power Supply

Mod.No. ☐☐☐☐☐☐-☐

P/N ☐☐☐☐☐☐-☐

S/N **CI** ☐☐☐☐ **B** ☐☐☐

Powerhead

P/N ☐☐☐☐☐☐-☐

S/N **CI** ☐☐☐☐ **B** ☐☐☐

Console S/N

P/N ☐☐☐☐☐☐-☐

S/N **CI** ☐☐☐☐ **B** ☐☐☐

Date of Installation ☐☐/☐☐/☐☐

Installing Company_____

Address_____

Phone No. _____

TRADEMARK AND PATENT INFORMATION

OptiVantage™, Patency Check™, and Timing Bolus ™ are trademarks of Mallinckrodt, Inc. OptiBolus® and OptiRay® are Registered trademarks of Mallinckrodt, Inc.

The OptiVantage is protected under the following U.S. Patents:

5,279,569	5,300,031	5,451,211	5,456,669
5,658,261	5,662,612	5,681,286	5,758,659
5,928,197	6,315,758	6,635,030	6,659,979

Other U.S. and Foreign Patents Pending.

MEANINGS OF SYMBOLS

SYMBOLS LOCATED IN THE MANUAL

Please regard any message that follows a Danger, Warning, or Caution symbol.

⚠ DANGER! ⚠

DANGER!—Hazards which could result in severe personal injury or death.

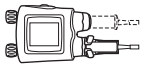
⚠ WARNING! ⚠

WARNING!—Hazards which could result in personal injury.

⚠ CAUTION! ⚠

CAUTION!—Hazards which could result in equipment or property damage.

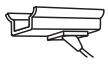
SYMBOLS LOCATED ON THE POWER CONTROL

Connection	Symbol	Definition
J1		Powerhead Cable Connector
J2		Startswitch Cable Connector
J3		Ethernet Port
J5	 RS232/ RS422	RS232/RS422 Port
J6		Universal Interface Connector
J10A		Console Cable Connector
J10B	OptiBolus™ 	OptiBolus™ Console Cable Connector
P4	**CAN**	Controller Area Network Port
		Equipment sensitive to Electrostatic Discharge. DO NOT TOUCH exposed connectors.
		ATTENTION! Consult User's/Service Manual.
		CAUTION! Risk of electrical shock. Do not remove cover. Refer servicing to qualified personnel.
	 250 V 4 AMP SLO-BLO	Controller Area Network Port
	Mod. No.	Model Number
	S/N	Serial Number
	P/N	Part Number
	V/A	Volts Amps

SYMBOLS LOCATED ON THE CONSOLE

Connection	Symbol	Definition
		Push Push ON/OFF
J1		Power Supply Cable Connector
J2		Handswitch Cable Connector

SYMBOLS LOCATED ON THE POWERHEAD

Connection	Symbol	Definition
		Manual Knob Light Status Flashing Blue: Injector Powering Up Solid Yellow/Purple: Enabled or injecting contrast (yellow) or saline (purple) Flashing Purple: Drip Mode injecting saline Flashing Yellow and Purple: Injector Paused Flashing Red: Alarm condition Flashing Blue quickly: Injector rotated vertically or 30 degrees below horizontal.
		A-side of Powerhead
		B-side of Powerhead
		Install pressure sleeve/Load syringe
		Lock pressure sleeve onto the powerhead/ Lock syringe into the pressure sleeve
		Heater Blanket Cable Connector
		Powerhead classified IEC 601-1, Type CF

CLASSIFICATION IN ACCORDANCE WITH EN 60601-1

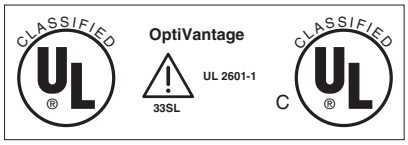
TYPE OF PROTECTION AGAINST ELECTRIC SHOCK
Class I equipment

DEGREE OF PROTECTION AGAINST ELECTRIC SHOCK
Type CF applied part.

DEGREE OF PROTECTION AGAINST INGRESS OF WATER
Ordinary Equipment

ELECTROMAGNETIC COMPATIBILITY
The OptiVantage meets the radiated emissions (Class B) and immunity standard IEC 60601-1-2 for medical devices

UL/CSA CLASSIFICATION



OptiVantage™ DH Injection System
CLASSIFIED BY UNDERWRITERS LABORATORIES INC.
WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1
33SL

OptiVantage™ DH Injection System
CLASSIFIED WITH RESPECT TO ELECTRIC SHOCK, FIRE MECHANICAL AND OTHER SPECIFIED HAZARDS ONLY IN ACCORDANCE WITH CAN/CSA C22.2 NO. 60601.1,
33SL

CE MARK INFORMATION

CE 0123

Conforms to the European Medical Device Directive (MDD)

Authorized EC Representative
TYCO HEALTHCARE UK LTD
154 FAREHAM ROAD
GOSPORT PO13 OAS UK

FCC/IC INFORMATION

All Radio type devices embedded in the OptiVantage DH Injector have met all qualifications for use under FCC Part 15.

Tyco Healthcare/Mallinckrodt
Model#: 844003 (OptiVantage DH Injector w/RFID)
IC: 3502A-844003
FCC ID: UEI844003

"This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation."

Note: The term "IC:" before the radio certification number only signifies that Industry Canada technical specifications were met.

Note: Changes or modifications to the OptiVantage DH Injector not expressly approved by Tyco Healthcare/Mallinckrodt could void the user's authority to operate the equipment.

This manual originally written in English.

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Table Of Contents


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1 SYSTEM OVERVIEW

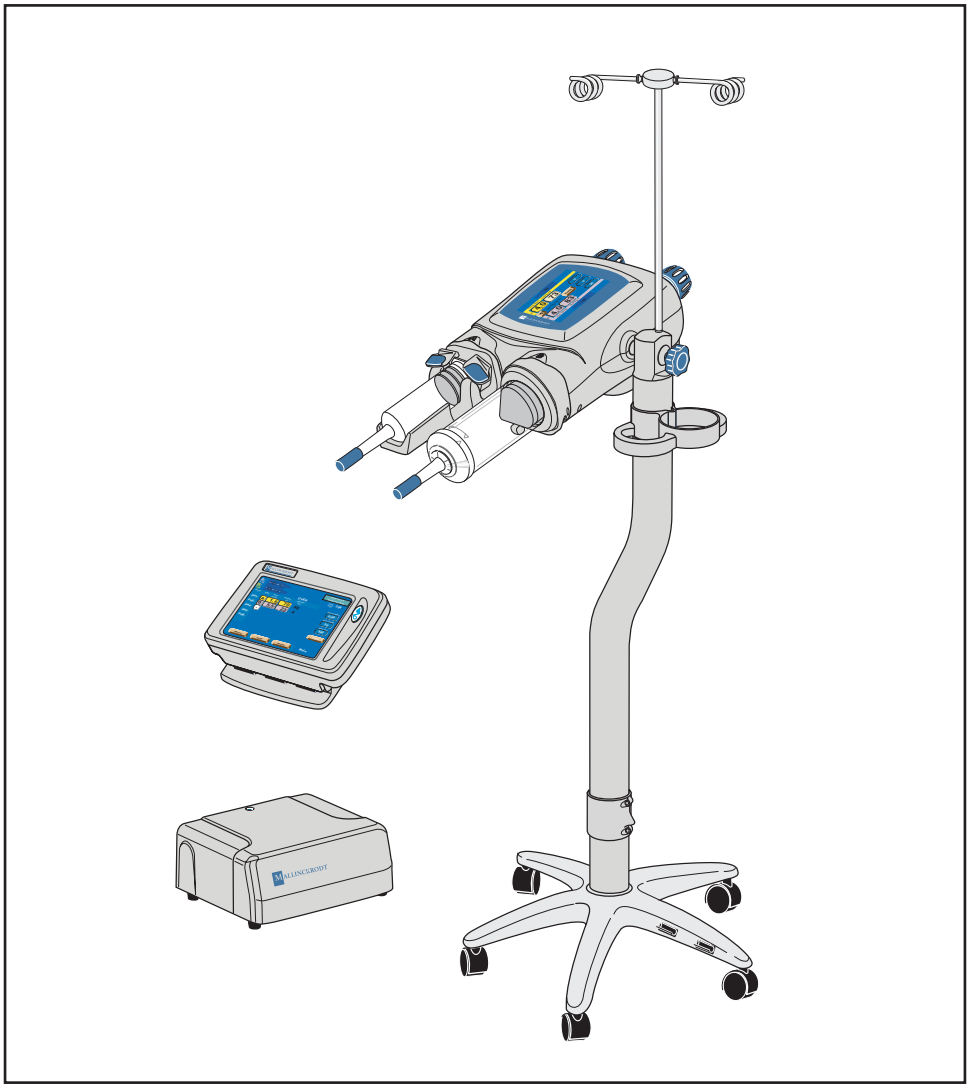


Figure 1-1-1 OptiVantage Injection System

1.1 INDICATIONS FOR USE

The OptiVantage Injection System is a contrast delivery system and is designed to inject radiopaque contrast media into a patient's vascular system to obtain diagnostic images when used with computed tomography (i.e. "CT") equipment.

1.2 USER QUALIFICATION

The OptiVantage Injection System should be operated ONLY by qualified personnel who:

- are completely familiar with the unit,
- have read and understood this Operator's Manual,
- have been trained concerning the process of how to stop an injection in the case of an emergency (described in Chapter 5 of this manual), and
- are otherwise properly trained in the use of equipment and procedures of this type.

Failure to follow these guidelines could result in serious injury to the patient or the operator.

⚠ CAUTION! ⚠

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

1.3 SYSTEM FEATURES

1.3.1 VERSATILITY

The injector is microprocessor-controlled and can perform injections within the following variable parameters:

- Flow Rate
- Volume
- Pressure Limit
- Inject Delay
- Scan Delay
- Phase Delays

1.3.2 TOUCH-SCREEN DISPLAYS

The console and powerhead both contain touch screen displays for operator interaction. Refer to Chapter 3-1-1 for detailed descriptions.

When using the touch screen displays, keep the following information in mind:

⚠ CAUTION! ⚠

Do not press on the touch screens with sharp or pointed items such as fingernails, pens or pencils. Using items of this type may cause damage to your screen, resulting in a nonworking unit. Do not allow objects, such as pens and pencils, to lay on the touch screen.

1.3.3 PROTOCOL MEMORY WITH PASSWORD PROTECTION

A convenient, user-friendly feature of the OptiVantage is its ability to store the parameters of as many as 40 protocols in its memory. Password protection is also available.

1.4 FEATURES

1.4.1 SAFETY

The OptiVantage has been designed to enhance the safety of both patient and operator. Specific safety features include:

Self-testing Design

When the OptiVantage is switched ON, it automatically performs a series of power-up tests to monitor the status of all systems. If a problem is detected, an appropriate message will appear in the system display. Also, during the enable process and during an injection, all necessary functions are constantly checked. If a fault is detected, the system will automatically shut down and an appropriate message will be displayed.

Patency Check™ Feature

Prior to the delivery of the main injection, a Patency Check--an injection of a small volume of saline--can be performed to determine the integrity of the I.V. site.

Timing Bolus™ Feature

Prior to the delivery of the main injection, a Timing Bolus injection--an injection of a small volume of contrast, followed by a small volume of saline--can be delivered to the patient to determine the optimal scan delay needed to capture the contrast agent in the area of interest.

Drip Mode Feature

Prior to the delivery of the main injection, a Drip Mode injection--a low flow rate injection of a small volume of saline--can be delivered to keep the fluid pathway open.

OptiBolus® Feature (Optional)

The OptiBolus feature is used to deliver an exponentially decaying flow rate injection that optimizes the contrast usage and provides an extended period of uniform enhancement of the area of interest. The End Flow Rate is automatically calculated by the OptiVantage and displayed only on the console Main screen.

Pointing Powerhead Downward prior to Starting an Injection

After completion of the Enable sequence, the [Enable] key is only active after tilting the powerhead to the downward position. Pointing the powerhead in the downward position allows any trapped air in the syringe to move to the plunger end of the syringe, away from the syringe tip, possibly preventing it from being inadvertently injected into the patient.

Start/Stop Key on Powerhead

Because the powerhead is near the patient during an injection, both the [Start] key and the [Stop] key are integrated into the powerhead for starting or quickly stopping an injection.

Remote Control Operation

Use of the remote handswitch allows the operator to perform injections from outside the area of direct radiation.

Electrically Isolated Syringe

All syringes are isolated from any electrical contact with the injector.

Syringe Clarity

Semitransparent syringes are used on the OptiVantage. Small air bubbles can be seen with careful observation.

Positive Positioning of the Powerhead

A preset friction device in the powerhead holds the syringe in the desired position during injection.

Physical Stability

The wide stance of the base of the pedestal assembly reduces the possibility of tipping. Two of the casters may be locked to prevent unwanted rolling and turning.

1.4.2 OPERATOR CONVENIENCE FEATURES

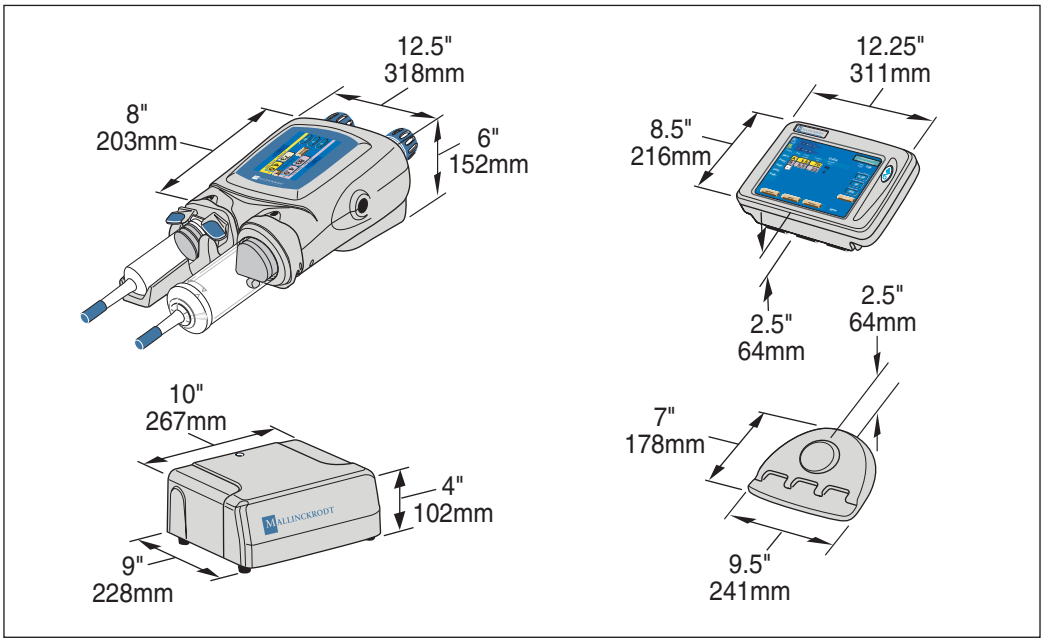
Auto-Fill Feature

This feature is designed to automatically fill the syringe while minimizing the introduction of air into the syringe. Upon loading a 200 ml syringe, the powerhead can automatically fill to 25 ml at 4 ml/s, expell to 0 ml at 10 ml/s, then fill to the operator programmed Auto-Fill Volume at 15 ml/s.

1.5 SPECIFICATIONS

1.5.1 DIMENSIONS

Console ..... 12.25 W x 2.5 H x 8.5 D inches
(311 W x 64 H x 216 D mm)
Console Base ..... 9.5 W x 2.5 H x 7 D inches
(241 W x 64 H x 178 D mm)
Powerhead ..... 12.5 W x 6 H x 8 D inches
(318 W x 152 H x 203 D mm)
Power Supply ..... 10 W x 9 D x 4 H inches
(267 W x 228 D x 102 H mm)



1.5.2 WEIGHT

Console w/Base ..... 5.8 lbs (2.6 kg)
Powerhead ..... 14.5 lbs (6.57 kg)
Power Supply ..... 6 lbs (2.7 kg)

1.5.3 POWER REQUIREMENTS

Standby ..... less than 1 A
Standard ..... 115 VAC, 4 A, 50/60 Hz
230 VAC, 2 A, 50/60 Hz

1.5.4 VOLTAGE REQUIREMENTS

Unit automatically adapts for input voltages from 100 to 240 VAC.

1.5.5 ELECTRICAL LEAKAGE

Chassis ..... less than 300 microamps

1.5.6 ENVIRONMENTAL

Transport and Storage Temperature: ..... -40° to +158° F (-40° to +70° C)
10% to 100% relative humidity

Operating Temperature: ..... 0° to +104° F (0° to +40°C)
30% to 75% relative humidity

Btu Output: ..... 510 Btu

Biohazard Disposal: Dispose of bioharzards in accordance with the requirements of your hospital, facility or local regulations.

Electromagnetic Compatibility (EMC): The OptiVantage meets EN60601-1-2 for level B conducted and radiated emissions and EMI immunity. **NOTE:** If any anomalies in the injector performance are noticed, identify devices within the immediate area that are capable of producing electromagnetic interference and call a qualified service representative.

⚠ DANGER! ⚠

Possible explosion hazard if used in the presence of flammable anesthetics. The unit is not designed for use in explosive environments.

⚠ WARNING! ⚠

The injector may only be operated in an area that is located beyond the 20 gauss limit. Operating the unit within magnetic fields that are higher than this limit may cause the unit to malfunction, resulting in operator or patient injury.

⚠ CAUTION! ⚠

Only the powerhead is considered spill proof. The console and power control are not spill-proof. Fluid spilled in these components can cause the unit to malfunction, resulting in patient or operator injury. If fluid is spilled on the console or power control, remove the unit from operation and contact your authorized service personnel.

1.5.7 SYRINGE SIZES

125 ml, 100 ml, 75 ml pre-filled

200 ml empty

1.5.8 SYRINGE HEATER

98° ± 6° F (37° ± 3° C) nominal. Maintains the temperature of pre-heated contrast.

1.5.9 FLOW RATE

Flow Rate Parameters ..... 0.1 – 10 ml/second adjustable in increments of 0.1 ml/second

Flow Rate Running Tolerance: ..... 0.2 ml/second or +/-20% whichever is smaller.

1.5.10 PEAK PRESSURE LIMIT

pounds per square inch (psi) ..... 50 – 325 adjustable in 5 psi increments

kPa ..... 345 – 2240 adjustable in 34 kPa increments

1.5.11 PHASE DELAY

Phase Delay Parameters ..... 0—600 seconds adjustable in increments of 1 second.

1.5.12 INJECT DELAY

Inject Delay Parameters ..... 0—600 seconds adjustable in increments of 1 second.

1.5.13 SCAN DELAY

Scan Delay Parameters ..... 0—600 seconds adjustable in increments of 1 second

The Scan Delay timer shall count down in one second increments. Three beeps (250 ms) occur when the timer reaches 10 seconds. Two beeps (440 ms) occur when the timer reaches 5 seconds. One beep (1000 ms) occurs when the timer reaches 0 seconds. A start signal is sent to the CT Scanner when the timer reaches 0 seconds.

1.5.14 TOTAL TIME

Total Time Display Parameters ..... 0—99:59 (minutes:seconds)

1.5.15 PROGRAMMABLE DRIP MODE PARAMETERS (SALINE SIDE)

- Flow Rate: 0.1 to 1.0 ml/s
- Volume: 0.1 to 3.0 ml
- Interval: 0 to 60 seconds

1.5.16 PROGRAMMABLE PATENCY CHECK PARAMETERS (SALINE SIDE)

- Flow Rate: 0.1 to 10 ml/s (defaults to maximum flow rate of protocol)
- Volume: 1 to 200 ml
- Default Volume: 1 to 200 ml

1.5.17 STORED PROTOCOLS

40 protocols can be stored and recalled.

NOTE: *Liebel-Flarsheim reserves the right to change product designs and specifications in the continuing effort to improve their products.*

1.6 CONSUMABLES

NOTE: The use of consumables not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include evidence that the safety certification of the consumables has been performed in accordance to the appropriate EN 60601-1 and/or EN 60601-1-1 harmonized national standard.

1.6.1 SYRINGES

Dual Head Procedures

- **P/N 844020** Multipack 200 ml OptiVantage Front Load Syringe w/Handi-Fil and 60" Coiled Y-Tube *w/No check valve*
- **P/N 844015** Multipack 200 ml OptiVantage Front Load Syringe w/Handi-Fil and 60" Coiled Y-Tube *w/Single check valve*
- **P/N 844021** Multipack 200 ml OptiVantage Front Load Syringe w/Handi-Fil and 60" Coiled Y-Tube *w/Dual check valves*
- **P/N 844022** DualPack (2) 200 ml OptiVantage Front Load Syringes w/(2) Handi-Fils and 60" Coiled Y-Tube *w/No check valve*
- **P/N 844016** DualPack (2) 200 ml OptiVantage Front Load Syringes w/(2) Handi-Fils and 60" Coiled Y-Tube *w/Single check valve*
- **P/N 844023** DualPack (2) 200 ml OptiVantage Front Load Syringes w/(2) Handi-Fils and 60" Coiled Y-Tube *w/Dual check valves*

Prefilled Contrast Syringes

- **P/N 1333-77** **50 ml** Optiray® 350 (Ioversol Injection USP 74%) 350 mgl/ml
- **P/N 1333-91** **75 ml** Optiray 350 (Ioversol Injection USP 74%) 350 mgl/ml
- **P/N 1333-83** **100 ml** Optiray 350 (Ioversol Injection USP 74%) 350 mgl/ml
- **P/N 1333-81** **125 ml** Optiray 350 (Ioversol Injection USP 74%) 350 mgl/ml
- **P/N 1323-77** **50 ml** Optiray 320 (Ioversol Injection USP 68%) 320 mgl/ml
- **P/N 1323-91** **75 ml** Optiray 320 (Ioversol Injection USP 68%) 320 mgl/ml
- **P/N 1323-83** **100 ml** Optiray 320 (Ioversol Injection USP 68%) 320 mgl/ml
- **P/N 1323-81** **125 ml** Optiray 320 (Ioversol Injection USP 68%) 320 mgl/ml
- **P/N 1332-83** **100 ml** Optiray 300 (Ioversol Injection USP 64%) 300 mgl/ml
- **P/N 1324-81** **125 ml** Optiray 350 (Ioversol Injection USP 51%) 240 mgl/ml

Single Head Procedures

- **P/N 800099** Multipack 200 ml Front Load Syringe w/Handi-Fil and 60” Coiled Tube
- **P/N 800096** Multipack 200 ml Front Load Syringe w/Handi-Fil

1.6.2 LOW PRESSURE TUBING

- **P/N 601195** 60” Coiled Tube
- **P/N 844010** 60” Coiled Y-Tubing *w/No check valve*, 5” Y-Legs
- **P/N 844011** 60” Coiled Y-Tubing *w/Single check valve*, 5” Y-Legs
- **P/N 844012** 60” Coiled Y-Tubing *w/Dual check valves*, 5” Y-Legs

1.6.3 CATHETERS, CONNECTORS AND TUBING

It is recommended that catheters, connectors and tubing used with the OptiVantage Injection System be rated for a minimum of 325 psi. If such products are rated at a pressure below 325 psi, it is the responsibility of the user to use manual mode to select a pressure limit that is appropriate for the product. The selection of manual mode is covered in section 3.1.6. Setting of the peak pressure limit is discussed in Sections 3.1.3 and 3.2.6 of this manual.

Use only safety-approved catheters suitable for connection to the LLN-K-A Luer male-threaded locking coupler (DIN 13 090).

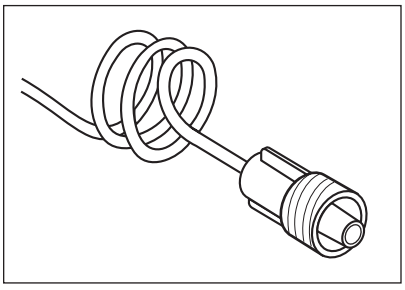


Figure 1-6-1
Luer Male-threaded Locking Coupler of the LF Spiral Extension Tubing

1.7 ACCESSORIES

A list of the accessories for use with the OptiVantage Injector is available through your Mallinckrodt sales representative.

NOTE: The use of accessories not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:

- use of the accessory in the patient vicinity
- evidence that the safety certification of the accessory has been performed in accordance to the appropriate EN 60601-1 and/or EN 60601-1-1 harmonized national standard.

2 POWER ON / POWER OFF

2.1 TURNING THE SYSTEM POWER ON

Refer to Figure 2-1-1.

1. At the rear of the power supply, place the switch to the ON position Ⓐ. The blue LED located on the top of the power supply will illuminate to indicate power is ON .

2. At the console, push the System ON/OFF button Ⓑ or press on the powerhead touchscreen. The ON/OFF button on the console will illuminate to indicate power to the console and powerhead is ON. The injector will perform a power-up check sequence, then display screens on the powerhead and the console to correctly position the rams for proper loading of the syringe(s).

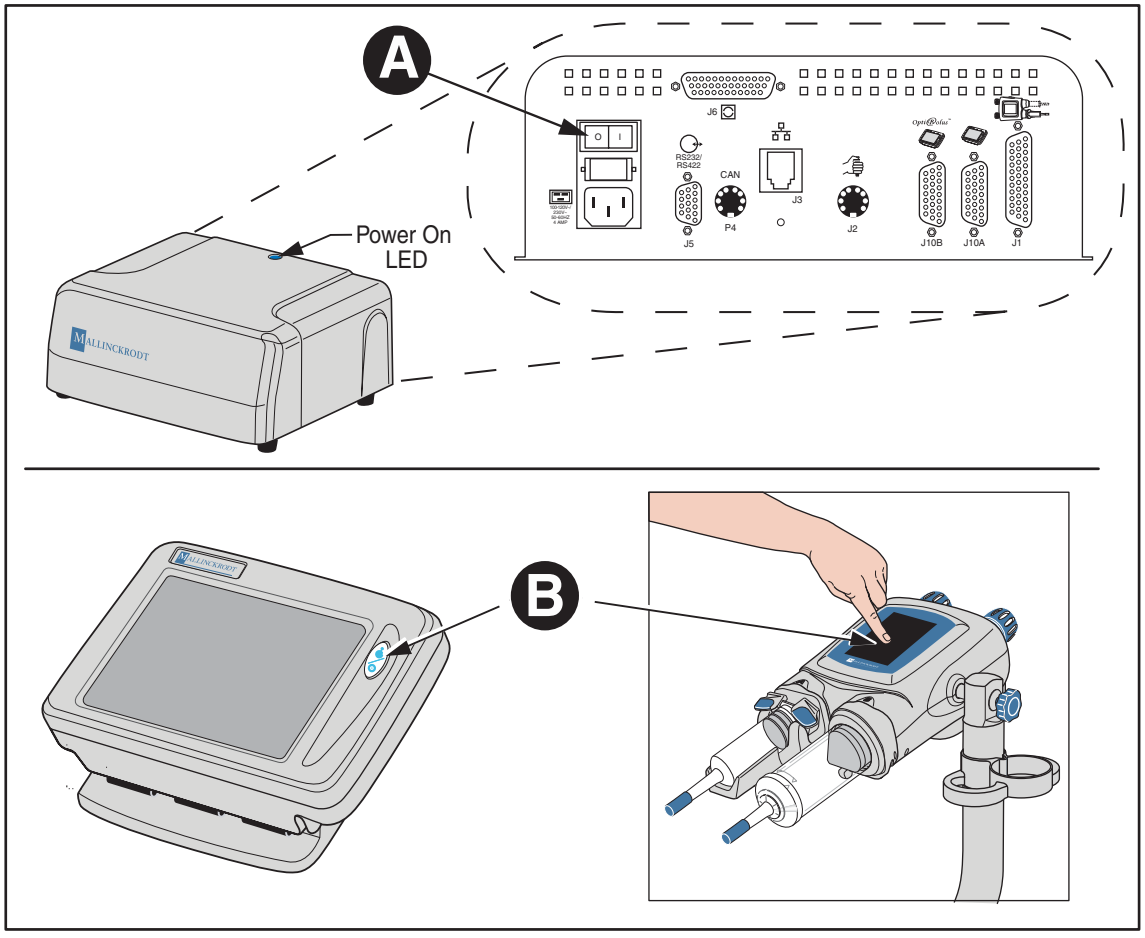


Figure 2-1-1 Switching the System Power ON

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2.2 HOMING THE RAMS

Each time power is cycled, the injector automatically performs a ram homing sequence to properly position the rams for loading of the syringes.

⚠ CAUTION! ⚠

Disconnect the tubing from all 125 ml syringes prior to performing the homing sequence. Retracting the ram during the homing sequence, while connected to tubing *not containing* a check valve, may cause inadvertent retraction of blood from the patient. Retracting the 125 ml ram during the homing sequence, while connected to tubing *containing* a check valve, will cause a vacuum in the syringe.

Remove all 200 ml syringes prior to performing the homing sequence. Expelling the ram during the homing sequence, when a 200 ml syringe is loaded, may cause inadvertent injection of contrast or saline into the patient.

Follow the instructions on the powerhead display to perform the homing sequence.

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2.3 TURNING THE SYSTEM POWER OFF

Refer to Figure 2-3-1.

At the console, push the ON/OFF button to switch the system OFF (B). The power supply can be left ON. This allows for quicker and easier restarts from the console.

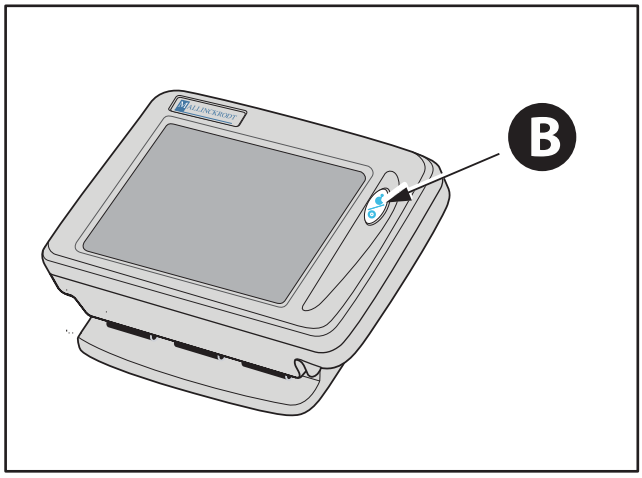

Figure 2-3-1 Switching the System Power OFF

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3 CONSOLE AND POWERHEAD

Operating the OptiVantage requires knowledge of the operator interfaces located on both the console and the powerhead. The console and powerhead both contain touch screen displays in order to interact with the operator.

Through use of the *console's touch screen display*, the operator can:

- enter protocol parameters
- save protocols
- delete protocols
- recall protocols
- enable/start/stop a Drip injection
- enable/start/stop an injection
- review achieved parameters of delivered protocols

Through use of the *powerhead's touch screen display*, the operator can:

- enter protocol parameters
- recall protocols
- fill/expel syringes
- enable/start/stop a Patency Check injection
- enable/start/stop a Drip injection
- enable/start/stop an injection

3.1 CONSOLE

3.1.1 CONSOLE POWER BUTTON

Refer to Figure 3-1-1.

Power Button/Power ON Indicator Ⓐ — The LED located on the power button glows to indicate that power is ON. With the power supply switch in the ON position, the injector system can be powered ON and OFF through use of the console power button.

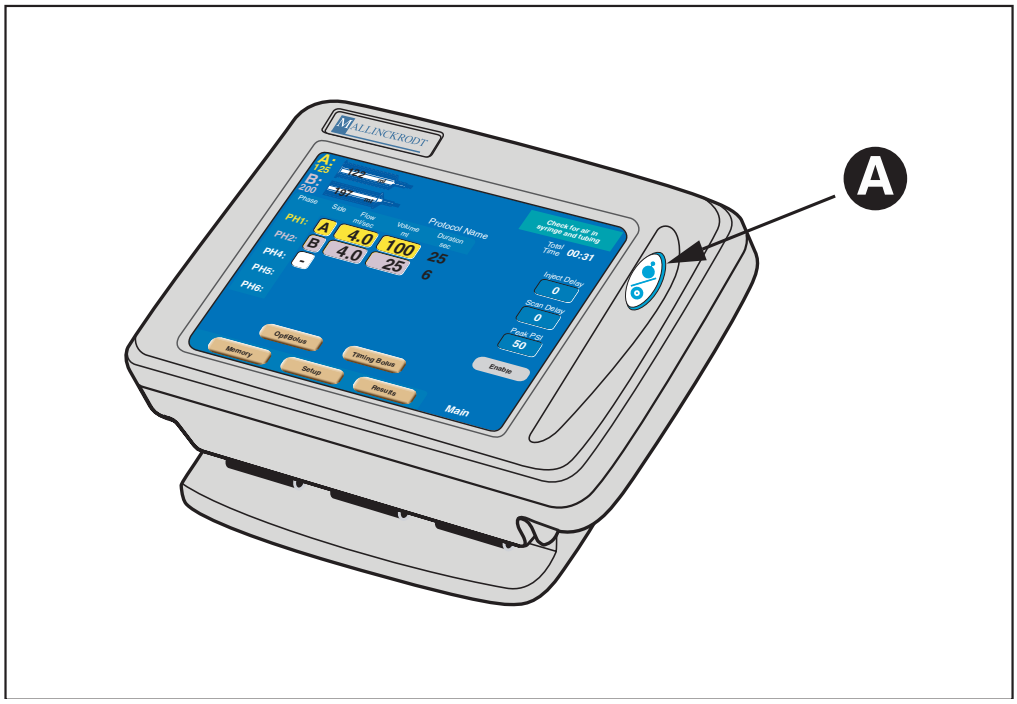

Figure 3-1-1 Console Power Button

3.1.2 CONSOLE DISPLAY MODES OF OPERATION

Refer to Figure 3-1-2.

Located along the lower portion of the console display are the following 4 keys: [Memory], [Setup], [Results] and [Main]. These keys allow access to their respective modes of operation.

Main Screen — Upon power-up, this screen is automatically displayed as shown in Figure 3-1-2. All protocol information needed by the injector is contained within the Main screen. To access the Main screen when displaying the Results screen, Setup screen or Memory screen, press the active [Main] key located on the lower right-hand side of the screen.

Enabled Main Screen — The Enabled Main screen allows for the delivery of the main protocol or a Drip Mode Injection.

Memory Screen — All stored protocol information is located within the Memory screen. Accessing this screen allows the operator to recall, store, rename and delete protocols. To access the Memory screen, press the [Memory] key Ⓑ located on the lower portion of the screen.

Setup Screen — Accessing this screen allows the operator to change the language, change the unit of measure for pressure, set the time, set parameter defaults, display the Alarm History, and access the service mode. To access the Setup screen, press the [Setup] key Ⓒ located on the lower portion of the screen.

Results Screen — All information pertaining to the results of a delivered injection is located within the Results screen. To access the Results screen, press the [Results] key Ⓓ located on the lower portion of the screen.

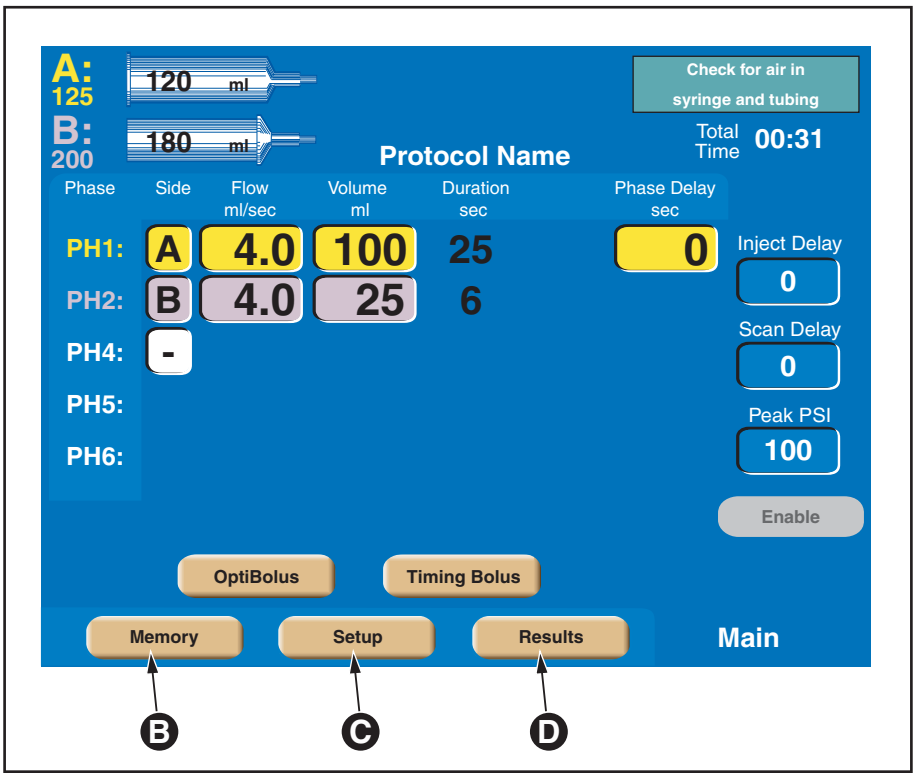

Figure 3-1-2 Console Main Screen with Location of Mode Keys

3.1.3 CONSOLE MAIN SCREEN

Refer to Figure 3-1-3 and Figure 3-1-4.

Protocol Name (E) — The name of the protocol currently displayed on the Main Screen is located in this area of the screen. An asterisk located at the end of the name indicates that the displayed parameters have been modified and no longer match the originally stored parameters.

A: Syringe Size (F) — This information indicates the size of the syringe currently installed in the A-side of the powerhead. Note that contrast parameters are indicated by the color yellow. Saline parameters are indicated by the color purple.

B: Syringe Size (G) — This information indicates the size of the syringe currently installed in the B-side of the powerhead. Note that contrast parameters are indicated by the color yellow. Saline parameters are indicated by the color purple.

Phase (H) — Within a protocol, up to six phases can be input. “PH” is the abbreviation of Phase.

Side (I) — These keys toggle among the following symbols: [A], [B], [-]. Pressing an [A] key will toggle the key to a [B] key, thus indicating injecting from the B-side. Pressing a [B] key will toggle the key to a white [-], indicating no injecting for and past that phase. Pressing a white [-] key will toggle the key to a [A] key, thus indicating injecting from the A-side.

Flow (J) — The values entered in this column indicate rate of delivery of the contrast medium and saline during each respective phase. Flow is expressed in milliliters/second.

Volume (K) — The values entered in this column indicate the volume of contrast medium and saline to be delivered during each respective phase. Volume is expressed in milliliters.

Duration (L) — The value in this column indicates the duration of a protocol phase (i.e., time to complete injection in seconds) based on the entered volume and flow rate values. Duration is displayed in the nearest whole second.

Phase Delay (M) — Phase Delay is a count down timer that delays the start of the next phase. The next phase will start when the phase delay counter reaches 0 (zero). Phase Delay is expressed in seconds. Phase Delay can also be set to pause the injection. Access the Pause feature by scrolling past either the 0 (zero) lower limit or the 600 (six-hundred) upper limit.

Total Time (N) — The Total Time field is an accumulation of all the calculated Duration and Delay fields for all phases. The total time field starts counting up from 0 (zero) after the injector receives a start signal. Total time continues to count after the injection is completed as long as the Results screen is displayed or up to 21 minutes. Total time is expressed in minutes:seconds.

Inject Delay (O) — Inject Delay is a count down timer that begins counting when the Start command is activated. The injection is started when the inject delay counter reaches 0 (zero). If Inject Delay is greater than 0 (zero), Scan Delay is automatically set to 0 (zero). Inject Delay is expressed in seconds.

Scan Delay (P) — Scan Delay is a count down timer that begins counting when the Start command is activated and stops when the counter reaches 0 (zero). The scan start signal will initiate once the timer reaches 0 (zero). If Scan Delay is greater than 0 (zero), Inject Delay is automatically set to 0 (zero). Scan Delay is expressed in seconds.

Peak PSI/Peak KPA (Q) — The value set in this key indicates the maximum allowable pressure that can occur during an injection. Pressure is expressed in either PSI or kPa. Refer to section *3.1.6 Setup Screen Parameters and Symbols* for more information about changing the unit of measure.

Enable (R) — **This key is only active when proper enabling sequence is followed and after the powerhead is tilted downward**. Pressing the active [Enable] key "enables" the injector (displays the [Start] key) for delivery of a protocol.

OptiBolus (optional) (S) — *This key is only active if a port-key is present at the OptiBolus port located on the rear of the power supply.* Pressing this key allows the operator to program an OptiBolus injection. The OptiBolus Mode delivers an exponentially decaying flow rate injection that optimizes the contrast usage and provides an extended period of uniform enhancement of the area of interest. Once the [Optibolus] key (S) is pressed, the screen shown in Figure 3-1-5 is displayed. Note the addition of the Optibolus symbol (V) to the left of the first phase along with the addition of End Flow Rate (W). End Flow Rate (W) is a function of the Optibolus mode and is automatically calculated by the OptiVantage for the entered parameters and is displayed only on the console Main screen.

Timing Bolus (T) — *This key is only active if turned ON at the Setup Screen and when 4 or less phases are programmed in a protocol.* Pressing this key allows the operator to program a Timing Bolus injection. A Timing Bolus injection--an injection of a small volume of contrast, followed by a small volume of saline--can be delivered to the patient to determine the optimal scan delay needed to capture the contrast agent in the are of interest. Once the [Timing Bolus] key (T) is pressed, the screen shown in Figure 3-1-6 is displayed. Note the addition of "Test" (X) to the left of the first and second phase.

Change Parameter Values via the Slide Bar (U) — To change the value of a parameter, select the desired parameter by touching its key. The key will highlight to indicate it is active and the slide bar will display at the bottom of the screen. Touch the slide bar at the value required, or use the left and right double arrows to decrease or increase the value. Use the left and right single arrows to decrease or increase the value in smaller increments.

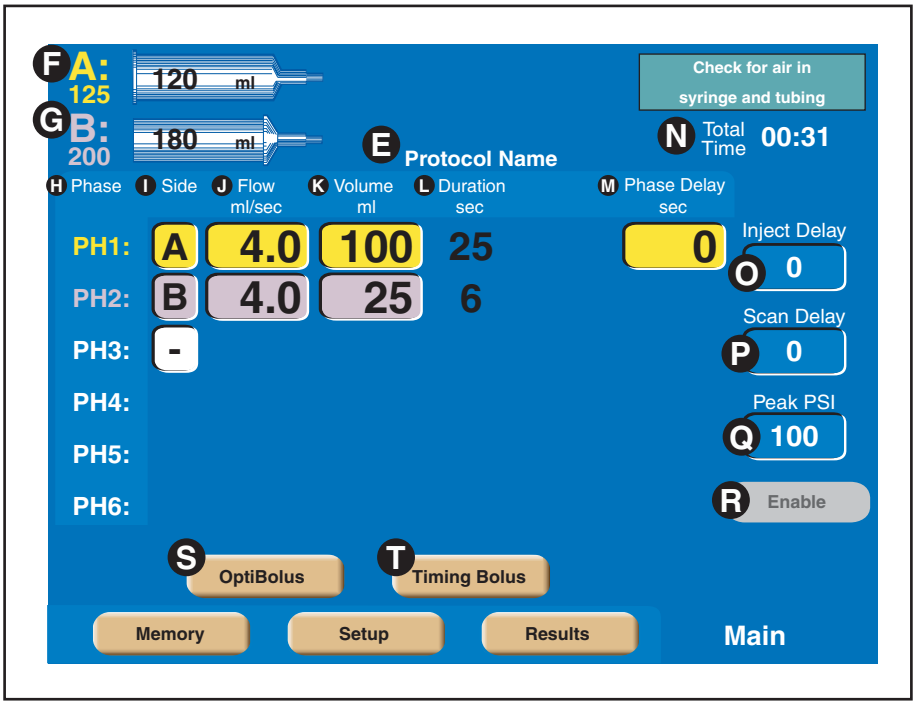

Figure 3-1-3 Console Main Screen

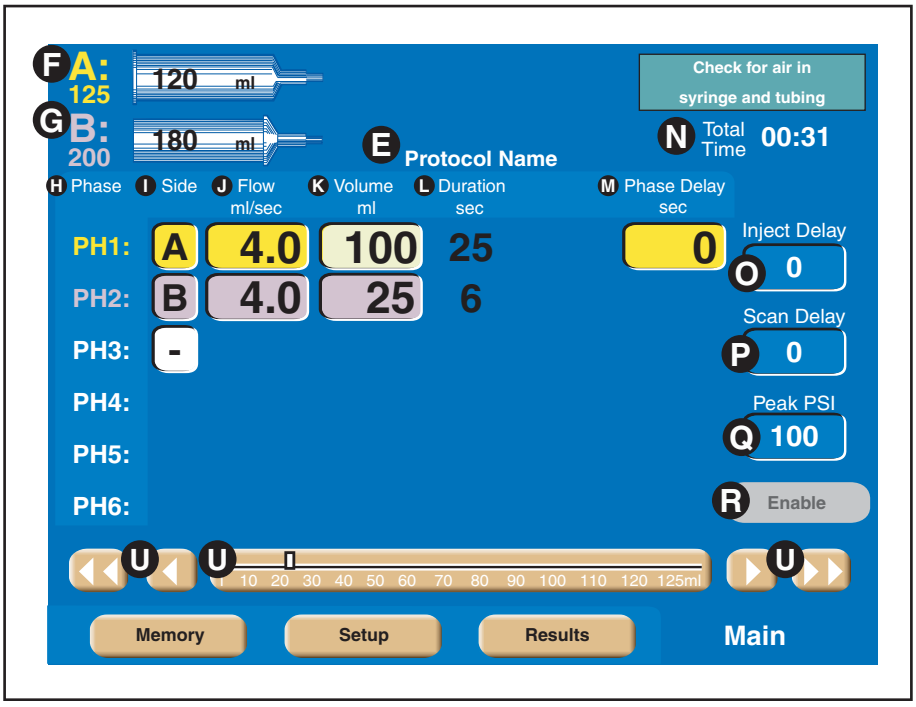

Figure 3-1-4 Console Main Screen with Active Slide Bar

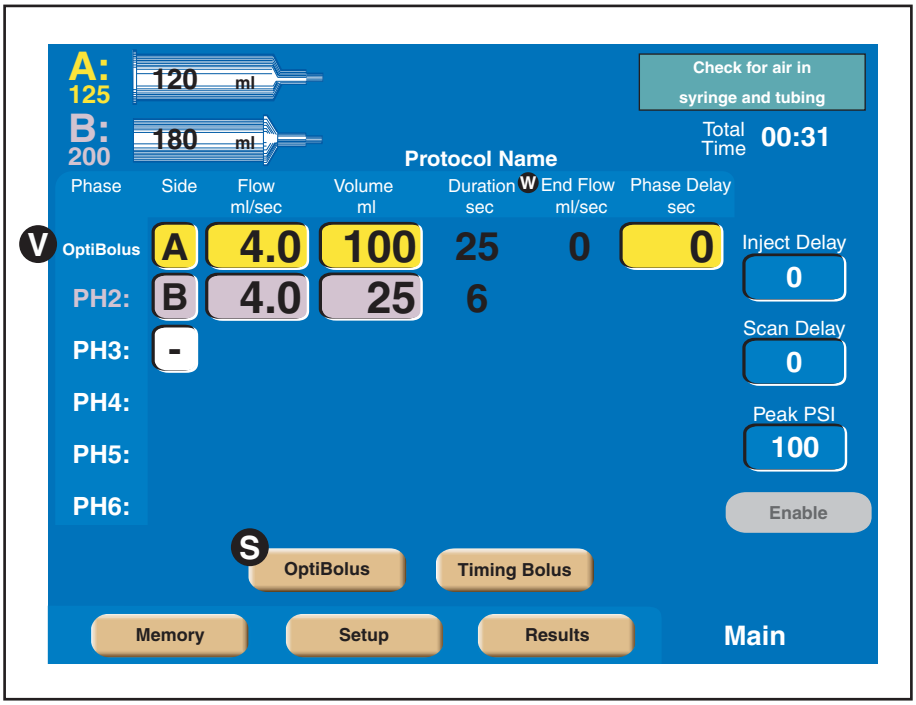

Figure 3-1-5 Console OptiBolus Injection Screen

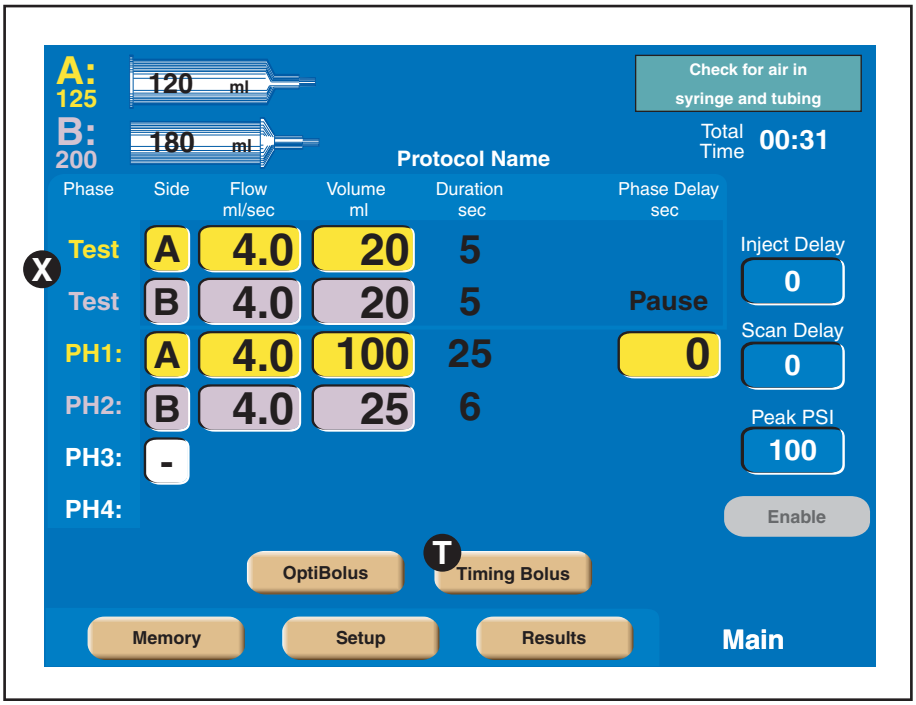

Figure 3-1-6 Console Timing Bolus Injection Screen

3.1.4 ENABLED CONSOLE MAIN SCREEN (START SCREEN)

Refer to Figure 3-1-7.

After pressing the active [Enable] key, the screen shown in Figure 3-1-7 is displayed. From this screen, the operator can change parameters, program an OptiBolus injection, program a Timing Bolus injection, enter the Drip Mode, or start the delivery of the protocol.

Start Y — This key starts the delivery of the programmed protocol. For more information about delivering injections, refer to Chapter 5.

Drip Z — *This key is active if turned ON at the Setup Screen and only displayed after the [Enable] key is pressed.* Pressing this key allows the operator to program a "drip" injection--a low flow rate injection of a small volume of saline delivered to keep the fluid pathway open. Refer to Figure 3-1-8.

Disable AA — This keys allows the injector to disable from the enabled mode.

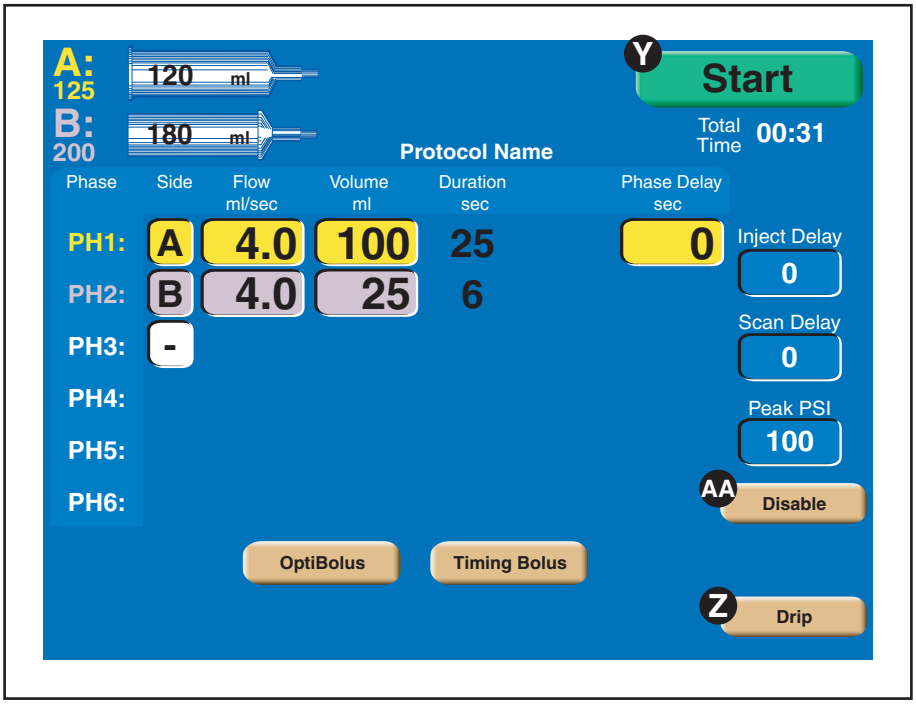

Figure 3-1-7 Enabled Console Main Screen

Drip Mode Screen

Refer to Figure 3-1-8.

The Drip Mode allows the injector to deliver a "drip" injection to keep the fluid path open during patient set up and between injections of contrast. The Drip Mode is accessible from either the Console Enabled Main Screen or the Powerhead Enabled Main Screen.

To access the Drip Mode screen as shown in Figure 3-1-8, press the [Drip] key Ⓩ located on the enabled Main screen (shown in Figure 3-1-7).

Side Ⓐ — The Drip injection can only be delivered from the saline side. (In Figure 3-1-8, the B-side is set up as the saline side.)

Drip Mode Flow Ⓑ — This value indicates rate of delivery of the saline. Drip Mode flow is expressed in milliliters/second.

Drip Mode Volume Ⓒ — This value indicates the volume of saline to be delivered during each drip injection. Drip Mode volume is expressed in milliliters.

Interval Ⓓ — This value indicates the amount of time the injector pauses between each delivery of drip injections. Drip Mode interval is expressed in seconds.

Change Parameter Values via the Slide Bar Ⓔ — To change the value of a parameter, select the desired parameter by touching its key. The key will highlight to indicate it is active and the slide bar will display at the bottom of the screen. Touch the slide bar at the value required, then use the left and right double arrows to decrease or increase the value. Use the left and right single arrows to decrease or increase the value in smaller increments.

Drip Time Ⓕ — Calculated automatically by the injector by using the programmed Flow, Volume and Interval values, this value indicates the amount of time the Drip Injection will require. Once the [Start Drip] key is pressed, the value counts down until it reaches zero. Once Drip Time reaches zero, an audible signal will indicate to the operator that the Drip Injection is complete.

Drip Volume Ⓖ — Calculated automatically by the injector by subtracting the programmed Volume of the main protocol (saline side) from the syringe volume (saline side), this value indicates the amount of saline the Drip Injection can inject. Drip Volume is expressed in ml.

Start Drip Ⓗ — This key starts the drip injection. For more information about delivering a drip injection, refer to Chapter 5.

Exit Ⓘ — This key disables the drip injection and displays the Enabled Main screen.

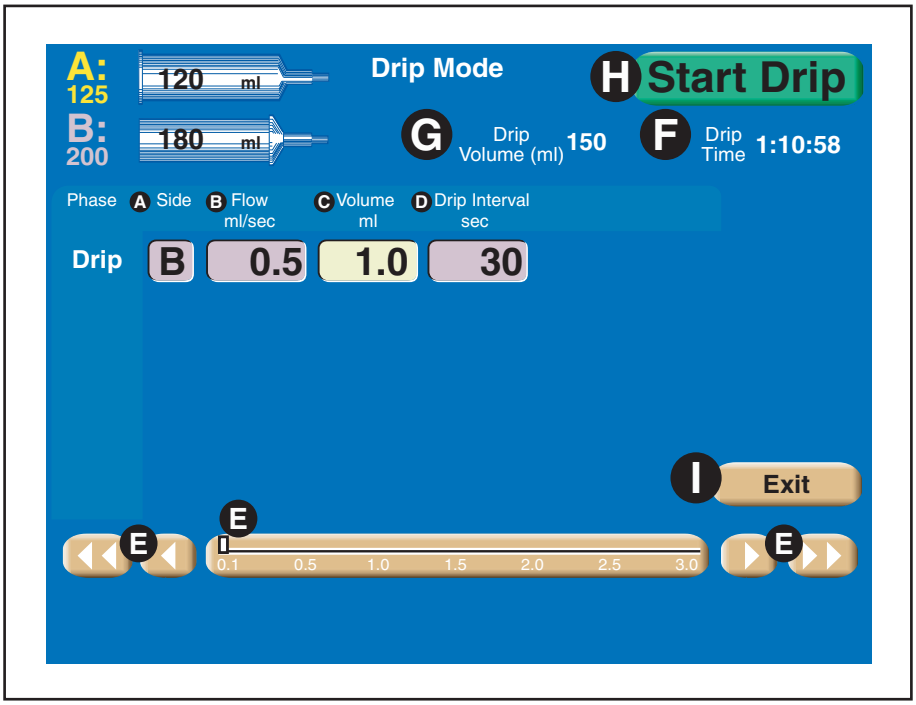

Figure 3-1-8 Drip Mode Screen

3.1.5 MEMORY SCREEN

Refer to Figure 3-1-9.

NOTE: If password protection is ON, moving, deleting, renaming or storing protocols is not permitted unless the correct password is entered.

Memory Location Ⓐ — The unit can store up to 40 six-phase protocols with 8 protocols listed per page. Each protocol can have a name consisting of up to 20 alpha-numeric characters. To display the protocol on the Main Screen, simply press the Protocol's corresponding key. OptiBolus protocols are indicated by the "OptiBolus" logo located on the key.

Protocol Parameters Ⓑ — Each protocol can contain up to six phases.

Current Values Ⓒ — The current values displayed on the Main screen are located in this area.

Memory Page Number Ⓓ — The memory screen contains five pages with eight protocols listed per page.

Move Ⓔ — This key allows the operator to move a protocol into a different slot or onto a different page.

Delete Ⓕ — This key activates the delete feature. Press the [Delete] key, then press the key of the protocol to be deleted.

Edit Ⓖ — This key allows the operator to edit the name of a protocol.

Store Ⓗ — This key stores the current values into a protocol memory slot.

Cancel (not shown) — This key is only displayed after pressing the [Move] key, the [Delete] key, the [Edit] key or the [Store] key and is used to cancel the feature.

Main Ⓘ — This key allows the operator to return to the Main screen.

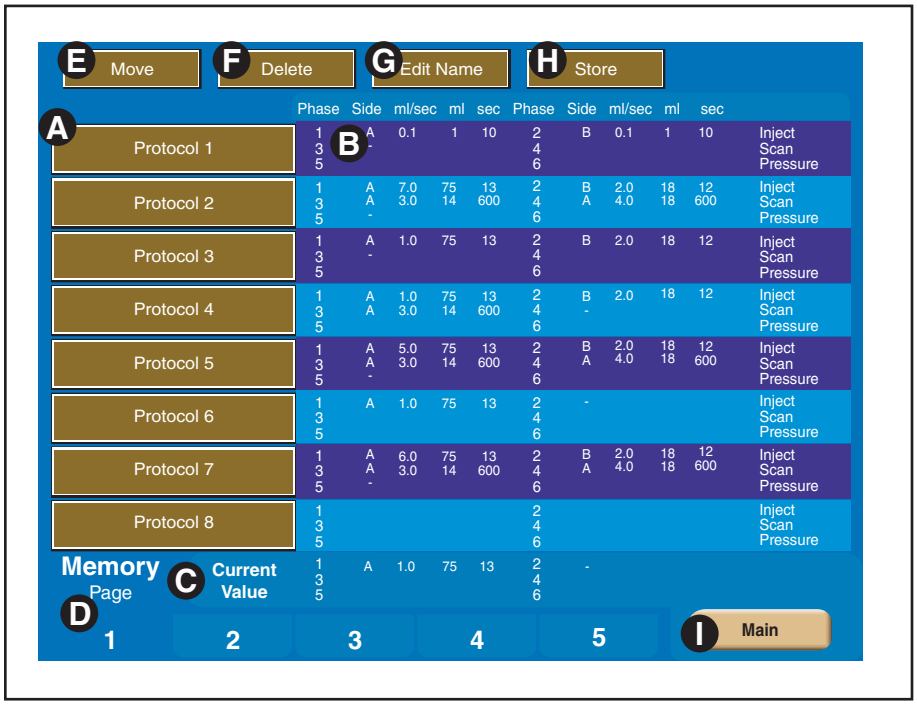

Figure 3-1-9 Memory Screen Keys and Definitions

Recall a Protocol

Refer to Figure 3-1-9.

1. Access the Protocol Memory menu by pressing the [Memory] key located on the bottom of the console Main screen.
2. Press the appropriate page (1, 2, 3, 4 or 5) D on which the Protocol is stored.
3. Press the key A of the desired Protocol Name. The protocol will be immediately displayed on both the powerhead display and the console display.

Store a Protocol in Memory

Refer to Figure 3-1-9 and Figure 3-1-10. This feature is only accessible from the console.

1. Enter all required parameters on the Main screen.
2. Access the Protocol Memory menu by pressing the [Memory] key located on the bottom of the console Main screen.
3. Press the appropriate page (1, 2, 3, 4 or 5) D on which to store the Protocol.
4. Press the [Store] key H. The display will prompt the user with "Select memory location."
5. Press the desired memory location key A. A keyboard will appear in order to name the protocol. Refer to Figure 3-1-10.
6. Enter the desired name using the keyboard. Press the keyboard [Enter] key J when finished. The protocol will be stored at the memory location selected.

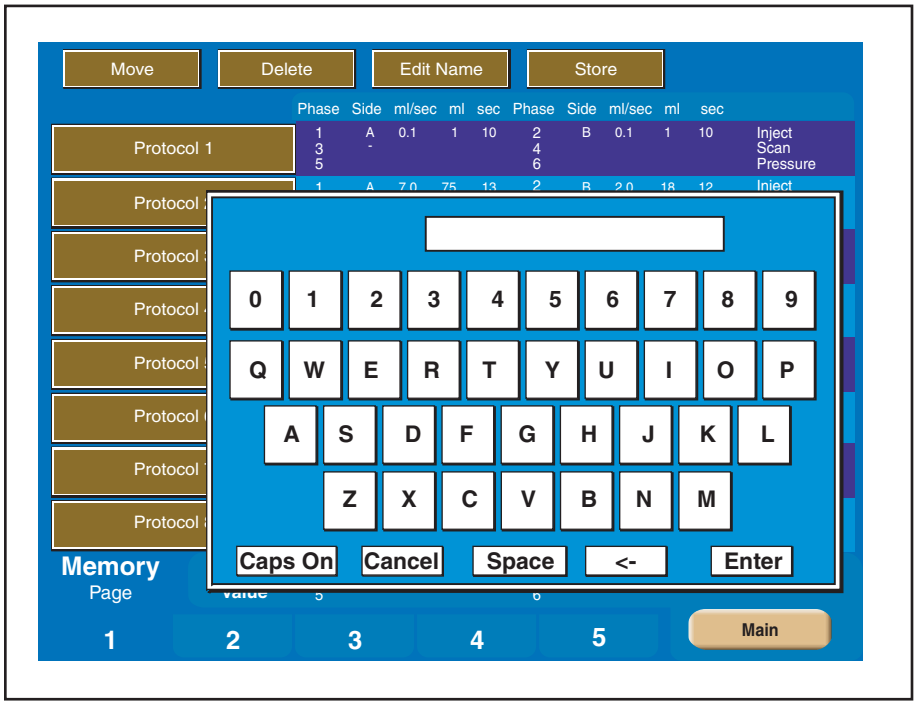

Figure 3-1-10 Memory Keyboard

Move a Protocol

Refer to Figure 3-1-9. This feature is only accessible from the console.

1. Access the Protocol Memory menu by pressing the [Memory] key located on the bottom of the console Main screen.
2. Press the appropriate page (1, 2, 3, 4 or 5) Ⓓ on which the Protocol is stored.
3. Press the [Move] key Ⓔ. The display will prompt the user with “Select protocol to move.”
4. Press the key of the protocol to be moved. The display will prompt the user with “Select position to insert moved protocol.”
5. Press the desired memory location key Ⓐ onto which the Protocol is to be relocated. The protocols will be shifted upwards or downwards to accommodate the new location of the moved protocol.

Delete a Protocol

Refer to Figure 3-1-9. This feature is only accessible from the console.

1. Access the Protocol Memory menu by pressing the [Memory] key located on the bottom of the console Main screen.
2. Press the appropriate page (1, 2, 3, 4 or 5) Ⓓ on which the Protocol is stored.
3. Press the [Delete] key Ⓕ. The display will prompt the user with "Select protocol to delete."
4. Press the key of the protocol to be deleted. The display will prompt the user with "Are you sure?" Pressing the [Yes] key deletes the protocol from memory. Pressing the [No] key returns you to the Memory screen without deleting the protocol from memory.

Rename (Edit Name) a Protocol Name or Page

Refer to Figure 3-1-9 and Figure 3-1-10. This feature is only accessible from the console.

1. Access the Protocol Memory menu by pressing the [Memory] key located on the bottom of the console Main screen.
2. Press the appropriate page (1, 2, 3, 4 or 5) Ⓓ on which the Protocol is stored.
3. Press the [Edit Name] key Ⓖ. The display will prompt the user with "Select protocol to rename."
4. Press the key of the protocol to be renamed and enter the new name using the displayed keyboard (shown in Figure 3-1-10). Press the keyboard [Enter] key Ⓙ when finished. The protocol will be stored under the new name at the same memory location.

3.1.6 SETUP

Refer to Figures 3-1-11 and 3-1-12.

Access the Setup screens by pressing the [Setup] key (Ⓑ on Figure 3-1-2) located on the Main Screen of the Console. Note: The Setup Screen and its features are not accessible from the Powerhead screen. Also, if password protection is ON, access to the Setup screens is not permitted unless the correct password is entered.

The Setup Screen allows the operator to adjust injection parameters, set the time and date, select the language, enter the service mode, and view the alarm history of the injector. Use the [< , >] keys Ⓒ to toggle between the two set up screens.

Date and Time Ⓐ — Indicates the Date and Time as set in item Ⓓ.

Software Versions Ⓑ — Indicates the software installed in the console, powerhead, and the current Scanner Interface software.

[< , >] keys Ⓒ — These keys allow the user to toggle between the two Set Up screens as shown in Figure 3-1-11 and 3-1-12.

[Time] key Ⓓ — This key allows the user to set the time and date. Refer to Figure 3-1-14.

[Language] key Ⓔ — This key allows the user to change the language of the injector. Refer to Figure 3-1-15.

[Service] key Ⓕ — This key allows service personnel access to the service screens. Note: The service screens are only accessible through use of a service key. Refer to the Service Manual.

[Alarm] key Ⓖ — The injector's alarm history is accessible through use of this key.

[Main] key Ⓗ — This key allows the user to exit the Set Up screens and return to the Main Screen.

OEM Interface Ⓘ — Select On or Off. Selecting "On" allows the OEM Interface to exercise limited control over the injector. Selecting "Off" disables the OEM Interface.

Timing Bolus Ⓙ — Select either On or Off. If On is selected, a [Timing Bolus] key will be made available on the Main screen to deliver a "Timing Bolus" injection to determine optimum image quality in order to determine the ideal scan delay.

Patency Check Ⓚ — Select either On or Off. If On is selected, a [Patency] key will be made available (after the injector is enabled) on the Powerhead to inject a small volume of saline at the maximum flow rate as the enabled protocol in order to check patency of the I.V. site.

Patency Check Volume (L) — The [Patency Check Volume] key allows the operator to set a default value for the Patency Check injection.

Drip Mode (M) — Select either On or Off. If On is selected, a [Drip Mode] key will be made available (after the injector is enabled) to deliver a "drip" injection (series of small volumes of saline) to keep the fluid path open.

Drip Flow Rate (N) — The [Drip Flow Rate] key allows the operator to set a default Flow Rate value for the Drip Injection.

Drip Volume (O) — The [Drip Volume] key allows the operator to set a default Volume value for the Drip Injection.

Drip Interval (P) — The [Drip Interval] key allows the operator to set a default value for the delay between Drip Injections.

Pause on Pressure Limit (Q) — Select either On or Off. Selecting "On" will cause the injector to automatically pause in the instance of a pressure limited injection. Selecting "Off" will allow the injector to continue injecting at a lower flow rate but will also display a message giving the operator the ability to either pause or continue.

Pressure Limit (R) — Select either Manual or Auto. Selecting "Manual" allows the operator to input a value for Peak Pressure Limit on the Main screen. Selecting "Auto" allows the injector to calculate a default value based on the highest flow rate of the displayed protocol. However, this value can be updated by the operator on the Main screen.

Pressure Units (S) — Select either PSI or kPa.

Auto-Fill (T) — Select either On or Off. If On is selected, the Auto-Fill feature is available to the operator to automatically fill a 200 ml syringe while minimizing the introduction of air.

Syringe Fluid A (U) — Select either Contrast or Saline to be used in the A-side syringe.

Syringe Fluid B (V) — Select either Contrast or Saline to be used in the B-side syringe.

Injection Duration Display (W) — Select either On or Off. Selecting Off removes the Injection Duration value (time to complete injection in seconds) from the Main Screen.

Phase Delay Display (X) — Select either On or Off. Selecting Off removes the [Phase Delay] key and its value from the Main Screen.

Console Brightness (display) (Y) — Select between Low or High.

Console Volume (display) (Z) — Select among Off, Low, Med or High.

Powerhead Brightness (display) **a** — Select between Low or High.

Powerhead Volume (display) **b** — Select among Off, Low, Med or High.

Auto Syringe Size Sense **c** — Select either On or Off. Selecting "On" allows the injector to determine the size of the installed pre-filled syringe.

Partial Prefills **d** — Select either On or Off. Select On if Partial Prefill syringes are to be used.

Password **e** — Once Password is set to ON, a keyboard, as shown in Figure 3-1-13, is displayed to enter and re-enter the password. When Password is set to ON, access to the Setup screens and Memory features is only available after entering the password.

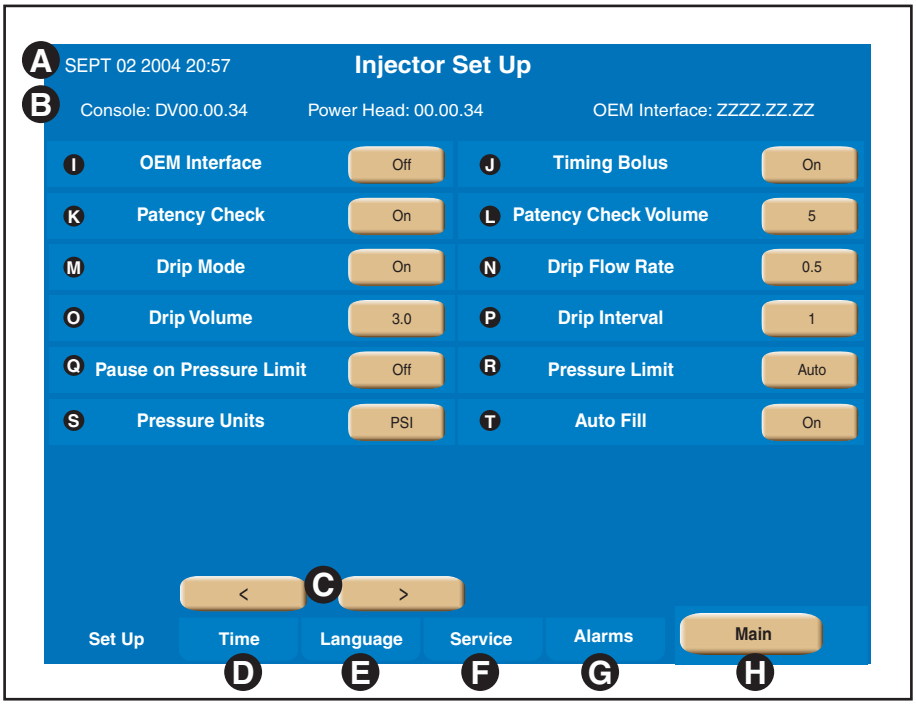

Figure 3-1-11 Injector Set Up 1 Screen

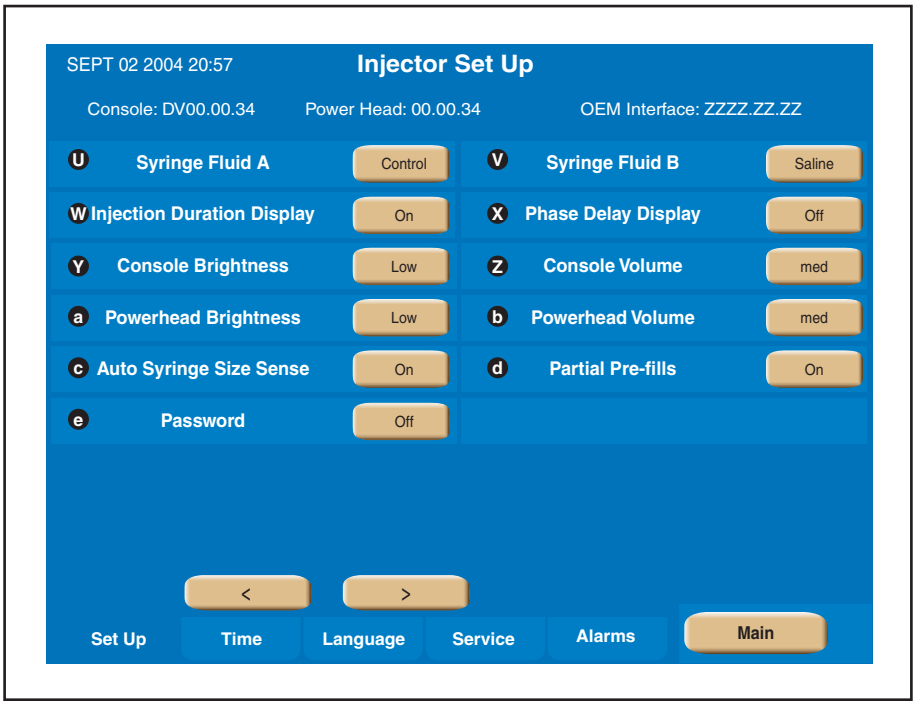

Figure 3-1-12 Injector Set Up 2 Screen

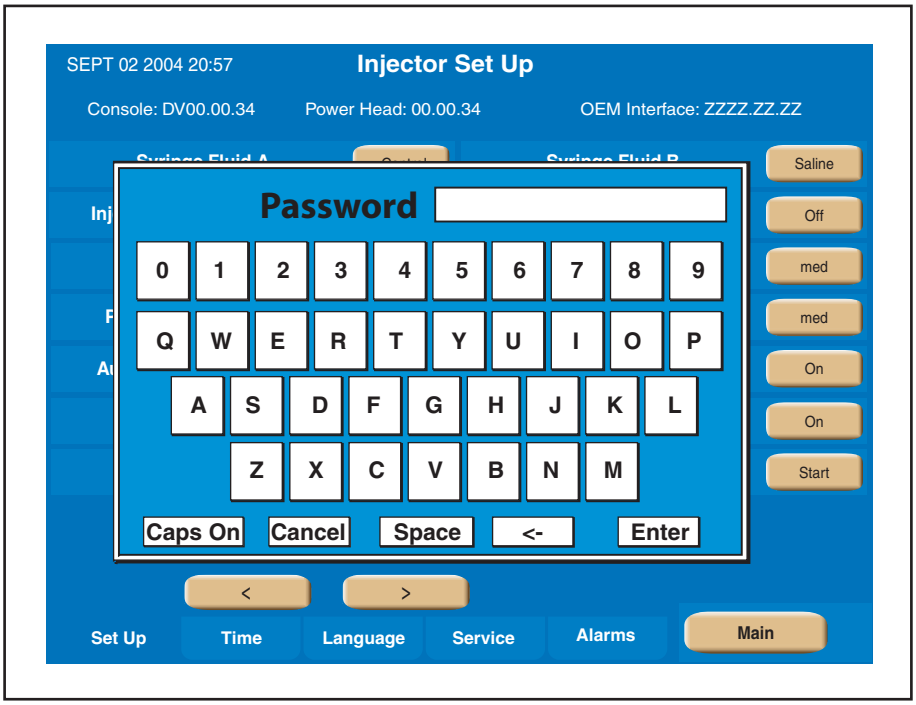

Figure 3-1-13 Enter Password

Time/Date

Refer to Figure 3-1-14.

Access the ability to set the Time and Date by pressing the [Time] key (D in Figure 3-1-10) .

Press the [Change Date] key i and/or the [Change Time] key j to update the date and time. Use the [▲▼] keys k to select the desired date and time.

After changing the Date and/or Time to the desired value, press the [Set Date] key l and/or the [Set Time] key m for the change to take effect.

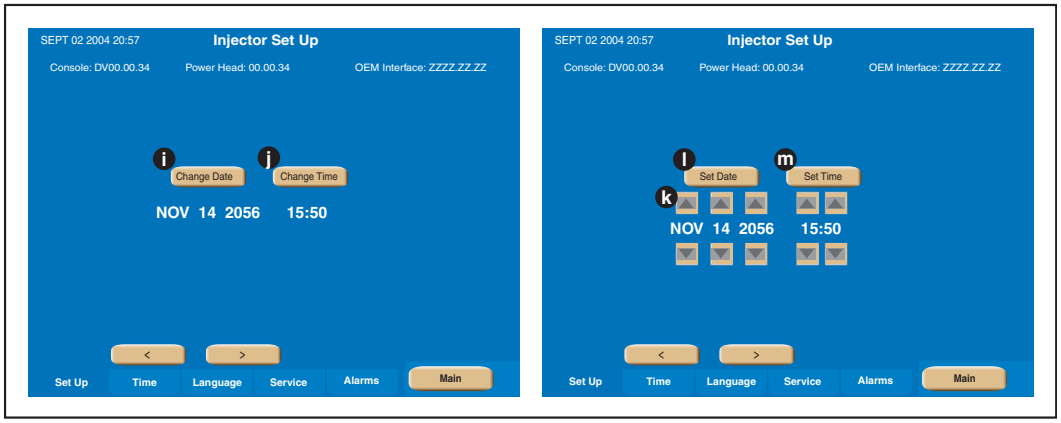

Figure 3-1-14 Setting the Time/Date

Language

Refer to Figure 3-1-15.

Select the Language from among the selections located under the [Language] key (Ⓕ in Figure 3-1-11)

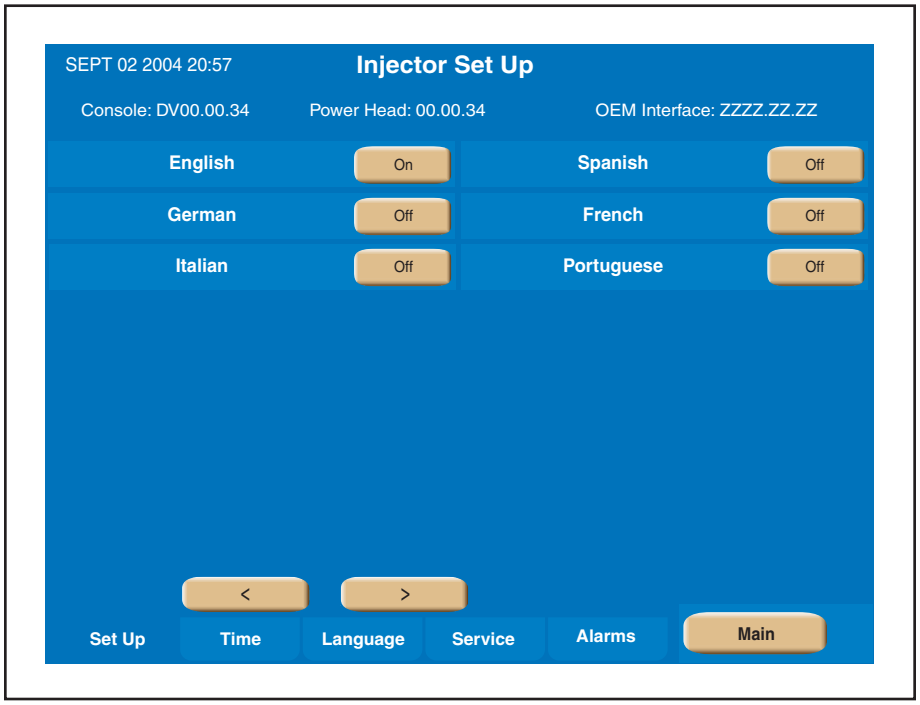

Figure 3-1-15 Selecting the Language

Alarms

Refer to Figure 3-1-16

Display the Alarm History screen by pressing the [Alarm] key (G in Figure 3-1-11) . Pressing the [<, >] keys (n in Figure 3-1-16), displays the most recent Alarms (up to 24) (on the console screen only) along with the protocol's settings at the time of the alarm.

Figure 3-1-16 Alarm Screen

3.1.7 RESULTS SCREEN PARAMETERS AND SYMBOLS

Refer to Figure 3-1-17 and 3-1-18

The Results Screen is automatically displayed after the delivery of an injection and only shows the achieved results of that injection. The Results screen is displayed for either 21 minutes or until the [Main] key is pressed. Refer to Figure 3-1-17.

Pressing the [Results] key (Ⓓ in Figure 3-1-2) , however, displays the results of the last 24 injections (on the console screen only) along with the protocol's settings. Refer to Figure 3-1-18.

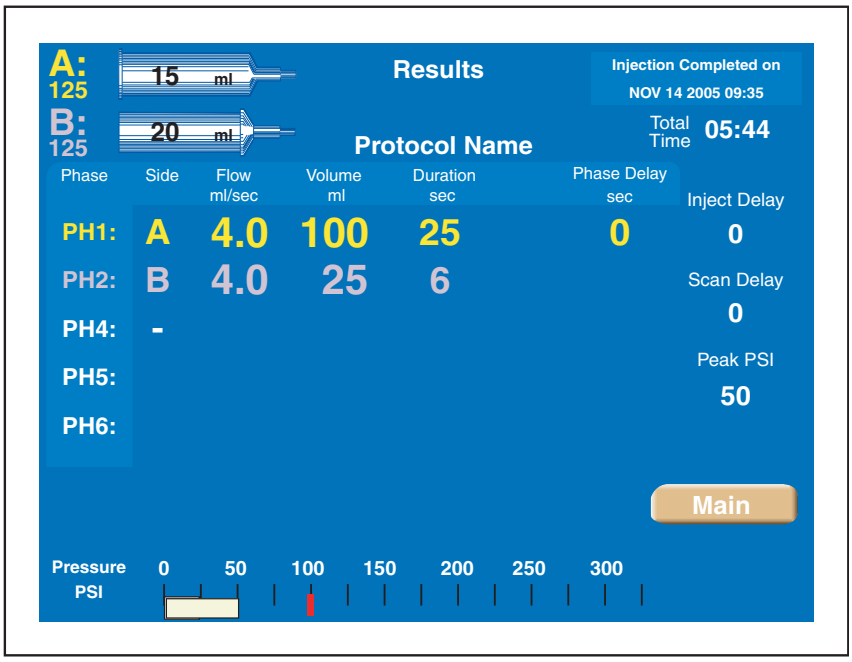

Figure 3-1-17 Results Screen displayed after delivery of an Injection

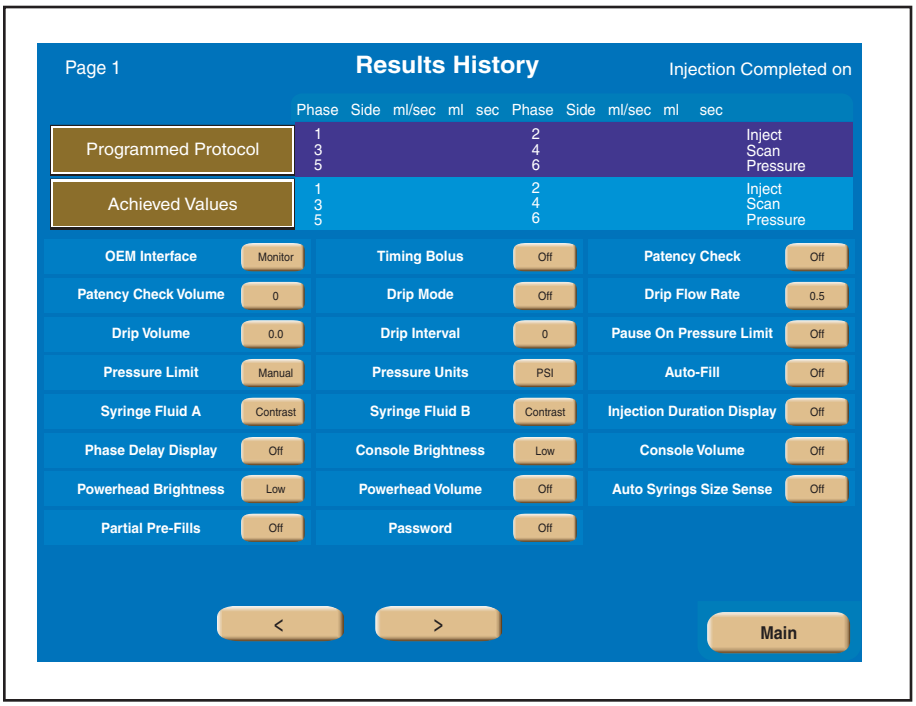

Figure 3-1-18 Results Screen displayed after pressing the [Results] Key

3.2 POWERHEAD

3.2.1 POWERHEAD POWER ON DISPLAY

Refer to Figure 3-2-1.

Power ON Display — With the power supply switch in the ON position, the powerhead display acts as a power ON switch. Simply press and hold down for 2 (two) seconds to turn the injector system ON.

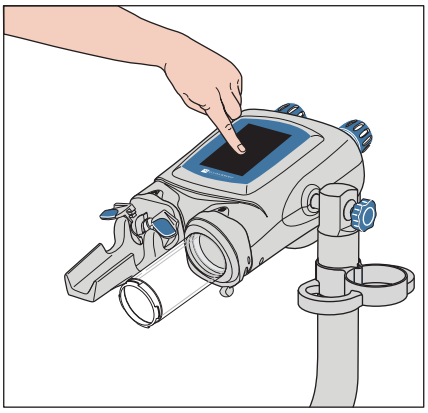

Figure 3-2-1 Powerhead Power ON Display

3.2.2 MANUAL KNOBS

Refer to Figure 3-2-2.

By turning either of the two knobs, the operator can move its respective ram/plunger. This is useful in the instance of purging air from the syringe and when drawing back blood to ensure proper venous placement of the catheter.

Turn the A-side manual knob Ⓐ clockwise to advance the A-side ram/plunger. Turn the B-side manual knob Ⓑ clockwise to advance the B-side ram/plunger. Turn the knobs counterclockwise to retract the ram/plunger. Refer to the following table for the manual knob light status.

Manual Knobs Light Status	Definition
Flashing Blue	Injector powering up.
Solid Yellow/Solid Purple	Enabled or injecting contrast (Yellow) or saline (Purple)
Flashing Purple	Injecting saline (Drip Mode)
Flashing Purple or Yellow	Injector paused
Flashing Red	Alarm Condition
Flashing Blue quickly	Injector rotated vertically or 30 degrees below horizontal.

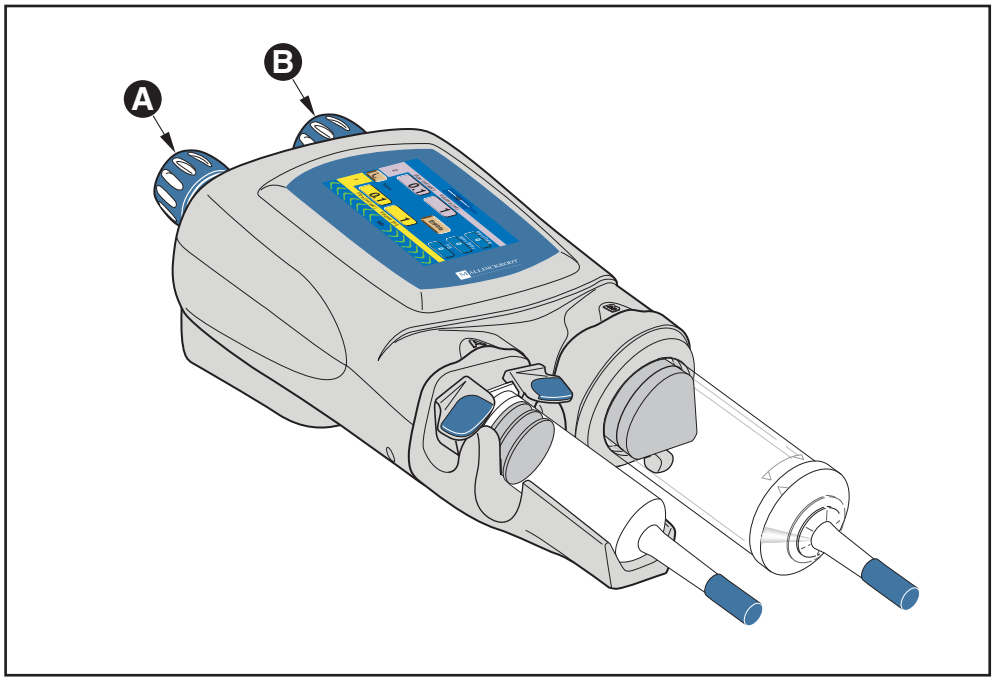

Figure 3-2-2 Powerhead A-side and B-side Indicators

3.2.3 POWERHEAD SYRINGE LOAD CLAMPS/LEVERS

Refer to Figure 3-2-3.

125 ml Syringe Clamp (A) — The clamps rotate open to allow loading of a 125 ml syringe. They rotate closed to secure the syringe in the cradle.

200ml Syringe Load Lever (B) — The lever rotates counterclockwise to allow loading of a 200ml syringe. Rotate the lever clockwise to lock the syringe in the pressure sleeve.

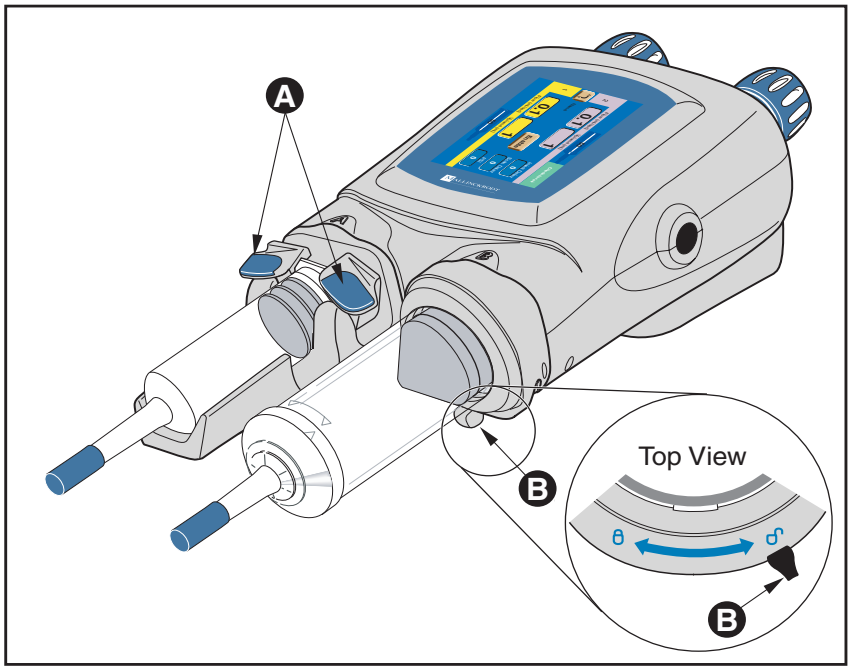

Figure 3-2-3 125 ml Syringe Load Clamps and 200ml Syringe Load Lever

3.2.4 HEATER BLANKET CONNECTION

Refer to Figure 3-2-4.

125 ml Syringe Cradle

The 125 ml syringe cradle (A) contains a built in heater to maintain the temperature of preheated contrast and sensors to read the size of the installed syringe. Connection of the heater blanket/syringe size sensor is as shown in Figure 3-2-4.

200ml Heater Blanket

The 200ml heater blanket (B) maintains the temperature of preheated contrast. Connection of the heater blanket is as shown in Figure 3-2-4.

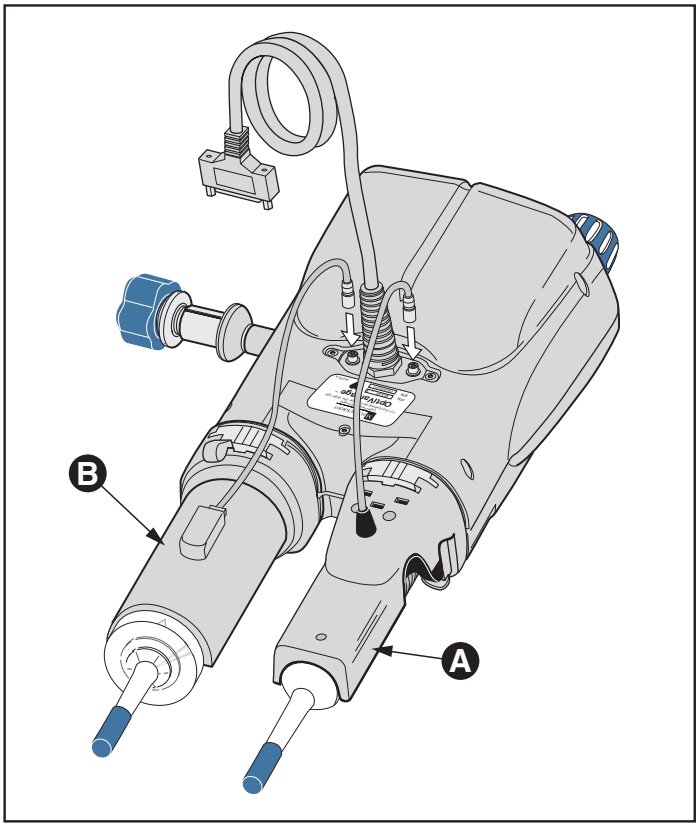

Figure 3-2-4 Location of the Heater Blanket Connections

3.2.5 POWERHEAD DISPLAY MODES OF OPERATION

Refer to Figures 3-2-5 and Figure 3-2-6.

Main Screen — The Powerhead Main screen Ⓐ is shown in Figure 3-2-5. Only the first phase of the A-side and the B-side is displayed on the Powerhead Main screen. The complete protocol is displayed on the expanded Protocol Parameter Entry screen Ⓒ.

Fill/Expel Arrows — Two [Syringe] keys Ⓑ, located in the upper and lower portion of the Main screen, change to the fill/expel arrows as shown in Figure 3-2-5.Press on the [Syringe] key to activate the fill/expel arrows.

Pressing on the active fill/expel arrows will retract/expel the ram at a rate that is proportional to the position touched in a range from 0.5 ml/sec to 15 ml/sec. Pressing the fill arrows for longer than 2 seconds will latch plunger movement. Once plunger movement has latched on, press anywhere on the powerhead display to cease plunger movement. Refer to Figure 3-2-6. Note: The fill/expel arrows do not appear if the injector is enabled.

Protocol Parameter Entry Screen Ⓒ — To access the Protocol Parameter Entry screen, press any parameter key Ⓓ located on the Powerhead Main Screen. The Protocol Parameter Entry screen allows modification of the parameters as well as access to the Memory screen. To access the Powerhead Main screen when displaying the Protocol Parameter Entry screen, press the [Main] key Ⓕ located on the lower portion of the screen.

Enabled Main Screen — The Enabled Main screen allows for the delivery of the main protocol, a Patency Check, or a Drip Mode Injection.

Memory Screen — All stored protocol information is located on the Memory screen. Displaying the Powerhead Memory screen allows the operator to only recall protocols. Storing, renaming and deleting protocols is only available on the console Memory screen. To access the Powerhead Memory screen, press the [Memory] key Ⓔ located on the lower portion of the Protocol Parameter Entry screen as shown in Figure 3-2-5. When the Memory screen is displayed, press the [Main] key Ⓕ to display the Main screen.

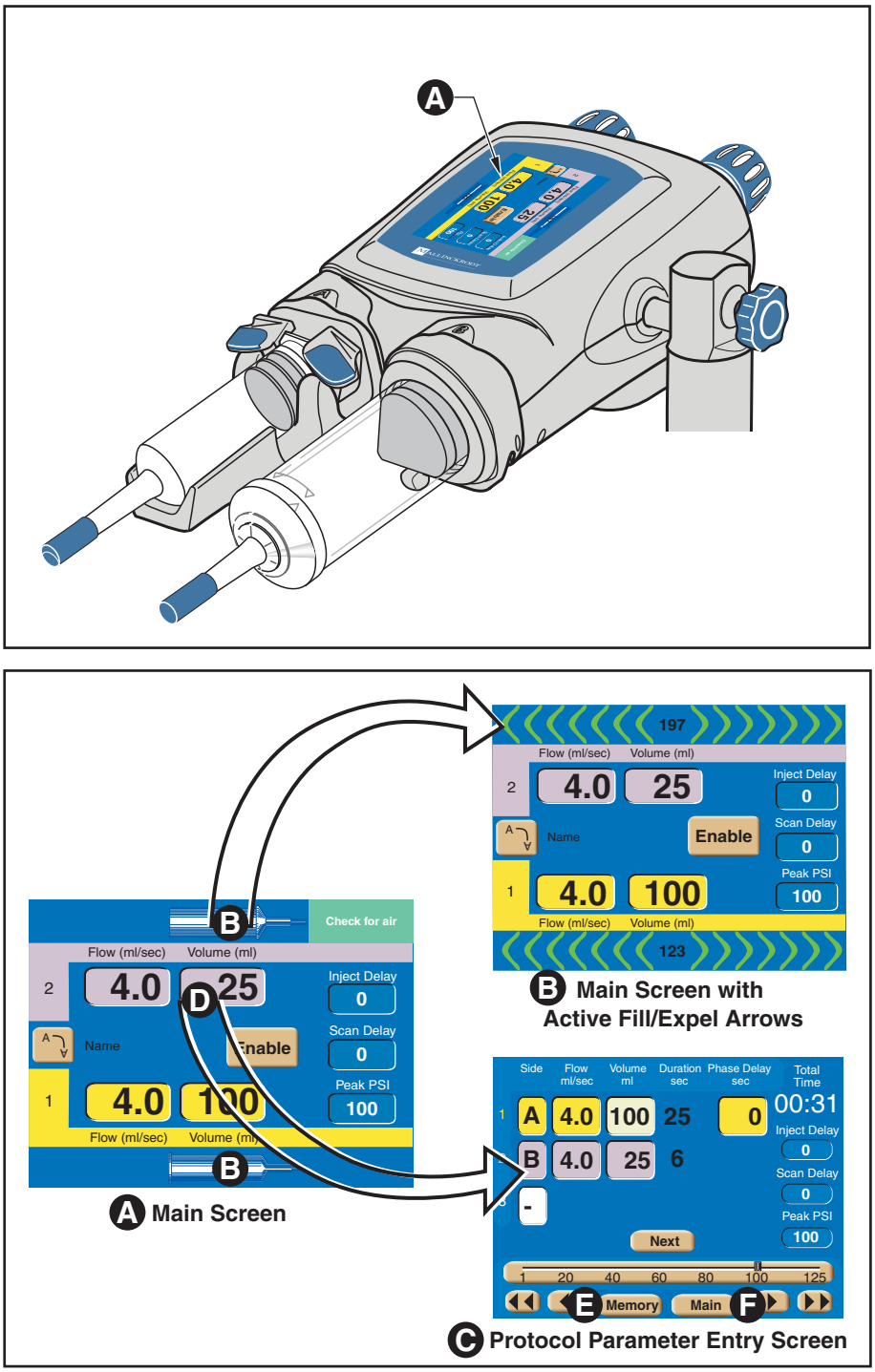

Figure 3-2-5 Powerhead Interfaces

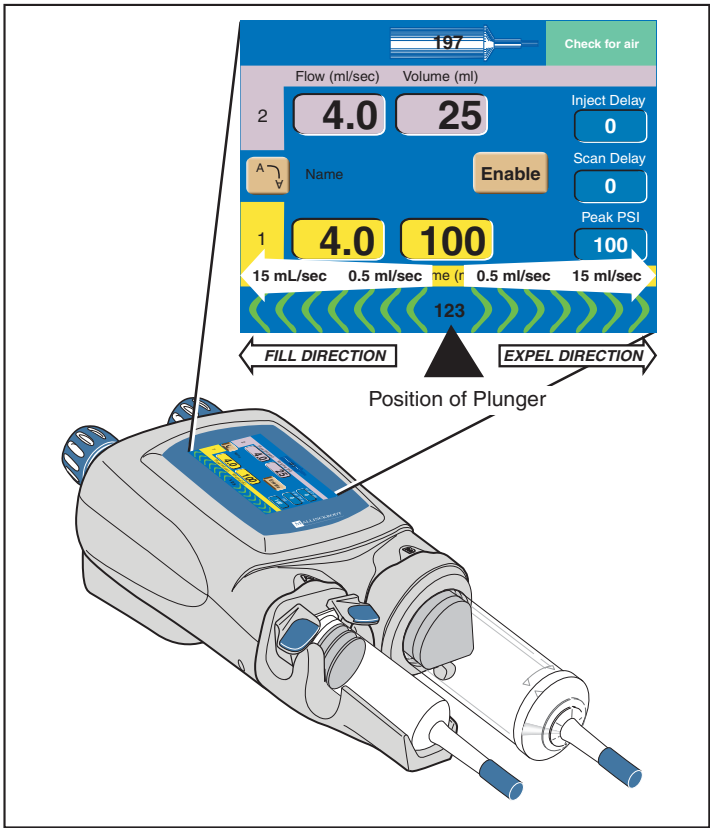

Figure 3-2-6 Fill/Expel Arrow Range of Speed

3.2.6 POWERHEAD MAIN SCREEN

Refer to Figure 3-2-7 and Figure 3-2-8.

A-Side Syringe (mL)/A-side Fill/Expel Arrows **A** — This symbol indicates the relative position of the plunger in the syringe thus indicating how much fluid may be in the A-side syringe. Pressing this key activates the A-side Fill/Expel arrows in order to move the ram/plunger.

B-Side Syringe (mL)/B-side Fill/Expel Arrows **B** — This symbol indicates the relative position of the plunger in the syringe thus indicating how much fluid may be in the B-side syringe. Pressing this key activates the B-side Fill/Expel arrows in order to move the ram/plunger.

Fill/Expel arrows — Upon pressing either the A-side **A** or B-side **B** [Syringe] keys as shown in Figure 3-2-5, the fill/expel arrows are activated. Pressing on the fill/expel arrows will retract/expel the ram at a rate that is proportional to the position touched in a range from 0.1 ml/sec to 15 ml/sec. Pressing the retract fill arrows for longer than 2 seconds will latch ram retraction movement. Once ram retraction movement has latched on, the arrows will turn green and have a white background. Press anywhere on the powerhead display to cease latched movement. See Figure 3-2-6.

1 (1st Phase) **C** — The 1 indicates the first phase of the protocol. Contrast parameters are indicated by the color yellow. Saline parameters are indicated by the color purple. To access the remaining protocol information, press any parameter key to display the Protocol Parameter Entry screen as shown in Figure 3-2-5.

2 (2nd Phase) **D** — The 2 indicates the second phase of the protocol. If only a one phase protocol is programmed, the 2 will revert to a B to indicate the B-side. Contrast parameters are indicated by the color yellow. Saline parameters are indicated by the color purple. To access the remaining protocol information, press any parameter key to display the Protocol Parameter Entry screen as shown in Figure 3-2-5.

Display Orientation **E** — To view the powerhead display from either the A-side or the B-side, the [Display Orientation] key allows the screen to flip as shown in Figure 3-2-8.

Flow **F** — The values shown in this column indicate rate of delivery during each respective phase. When delivering a protocol, the values reflect the flow rate of the current phase being injected. Flow is expressed in milliliters/second.

Volume **G** — The values entered in this column indicate the volume to be delivered during each phase. When delivering a protocol, the values reflect the volume of the current phase being injected. Volume is expressed in milliliters.

Protocol Name (H) — The name of the protocol currently displayed on the Main Screen.

Enable (I)— **Only active after proper enabling sequence is followed and when the powerhead is tilted downward**, pressing this key "enables" or readies the injector for delivery of a protocol.

Inject Delay (J) — Inject Delay is a count down timer that begins counting when the Start command is activated. The injection is started when the inject delay counter reaches 0 (zero). If Inject Delay is greater than 0 (zero), Scan Delay is automatically set to 0 (zero). Inject Delay is expressed in seconds.

Scan Delay (K) — Scan Delay is a count down timer that begins counting when the Start command is activated and stops when the counter reaches 0 (zero). The scan start signal will initiate once the timer reaches 0 (zero). If Scan Delay is greater than 0 (zero), Inject Delay is automatically set to 0 (zero). Scan Delay is expressed in seconds.

Peak PSI (L) — The value set in this key indicates the maximum allowable pressure that can occur during an injection. Pressure is expressed in either PSI or kPa. Refer to section *3.1.6 Setup Screen Parameters and Symbols for* more information about changing the unit of measure.

Check for Air message (M) — This message acts as a reminder to the operator to confirm no air exists in the syringe and tubing prior to enabling an injection.

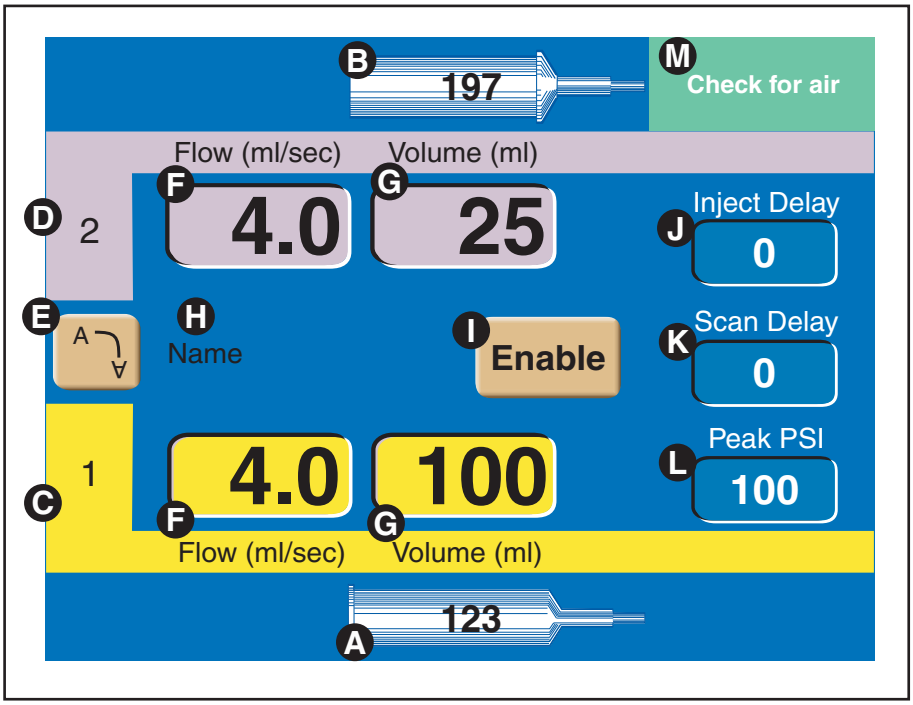

Figure 3-2-7 Powerhead Display Main Screen

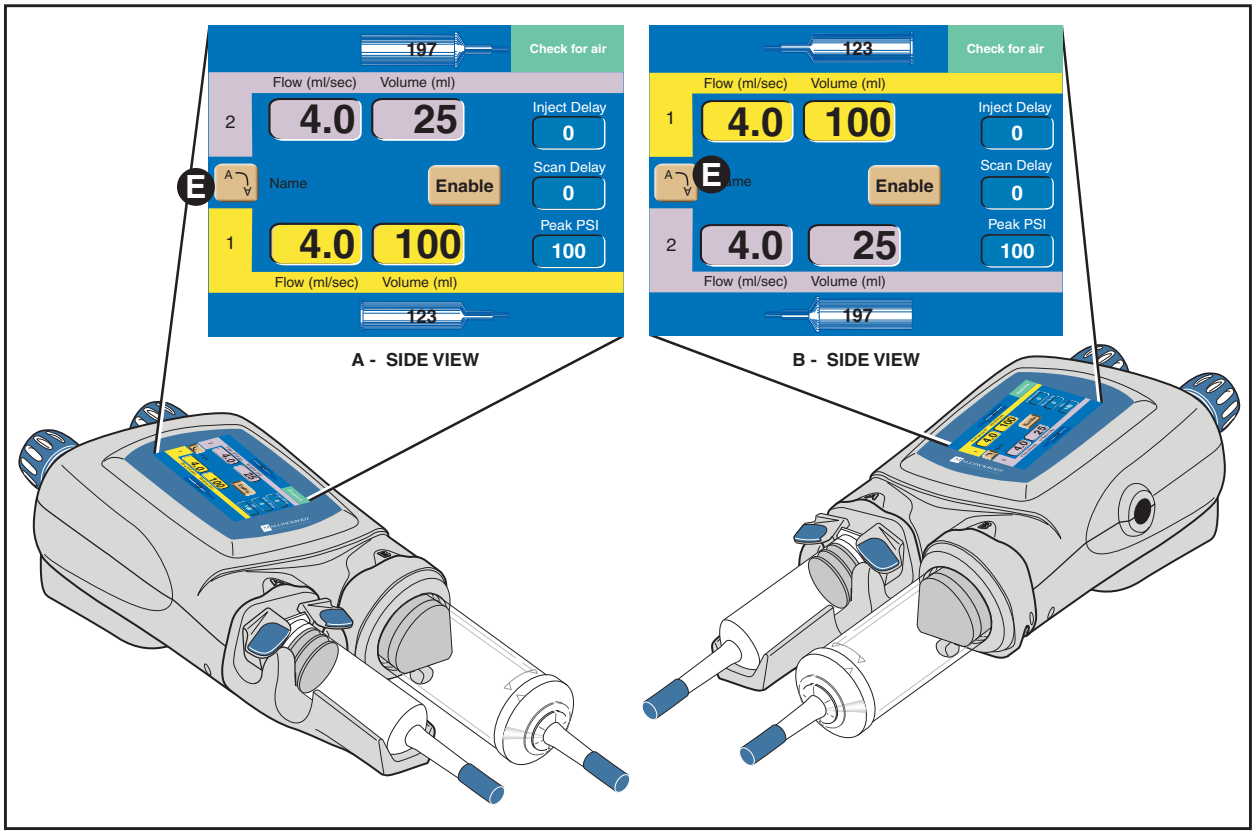

Figure 3-2-8 A-side Display or B-side Display using the [Display Orientation] Key.

3.2.7 POWERHEAD PROTOCOL PARAMETER ENTRY SCREEN

Refer to Figure 3-2-9.

All protocol information needed by the injector is contained within the expanded Protocol Parameter Entry screen. The Protocol Parameter Entry screen allows the parameters to be modified via the slide bar. To access this screen, press any parameter key located on the Main Screen as shown in Figure 3-2-5.

Phase Ⓐ — Within a protocol, up to six phases can be input. Press the [Next] key Ⓚ to view the next 3 phases.

Side Ⓑ — These keys toggle among the following symbols: [A], [B], [-]. Pressing an [A] key will toggle the key to a [B] key, thus indicating injecting from the B-side. Pressing a [B] key will toggle the key to a white [-], indicating no injecting for and past that phase. Pressing a white [-] key will toggle the key to a [A] key, thus indicating injecting from the A-side.

Flow Ⓒ — The values entered in this column indicate rate of delivery during each respective phase. Flow is expressed in milliliters/second.

Volume Ⓓ — The values entered in this column indicate the volume to be delivered during each respective phase. Volume is expressed in milliliters.

Duration Ⓔ — The value in this column indicates the duration of an injection (i.e., time to complete injection in seconds) based on the previously entered volume and flow rate values. Duration is displayed in the nearest whole second.

Phase Delay Ⓕ — Phase Delay is a count down timer that delays the start of the next phase. The next phase will start when the phase delay counter reaches 0 (zero). Phase Delay is expressed in seconds. Phase Delay can also be set to pause the injection. Access the Pause feature by scrolling past either the 0 (zero) lower limit or the 600 (six-hundred) upper limit.

Total Time Ⓖ — The Total Time field is an accumulation of all the calculated Duration and input Phase Delay fields for all phases. After the [Start] key is pressed, the total time field starts counting from 0 and continues to count after the injection is completed as long as the Results screen is displayed or up to 21 minutes. Total time is expressed in minutes:seconds.

Inject Delay Ⓗ — Inject Delay is a count down timer that begins counting when the [Start] key is pressed. When Inject Delay reaches 0 (zero), the injection is started. If Inject Delay is set with a value greater than 0 (zero), Scan Delay is automatically set to 0 (zero). Inject Delay is expressed in seconds.

Scan Delay Ⓘ — Scan Delay is a count down timer that begins counting when the [Start] key is pressed. The scan start signal will initiate once the timer reaches 0 (zero). If Scan Delay is set with a value greater than 0 (zero), Inject Delay is automatically set to 0 (zero). Scan Delay is expressed in seconds.

Peak PSI (J) — The value set in this key indicates the maximum allowable pressure that can occur during an injection. Pressure is expressed in either PSI or kPa. Refer to section *3.1.5 Setup Screen Parameters and Symbols* for more information about changing the unit of measure.

Next (K) *— This key is only active when more than 3 phases exist on the Protocol Parameter Entry screen.* Pressing this key displays the next 3 phases of the protocol. The key will then toggle to a [Previous] key to allow access to the first 3 phases of the protocol.

Change Parameter Values via the Slide Bar (L) — To change the value of a parameter, select the desired parameter by touching its key. The key will highlight to indicate it is active and the slide bar will appear at the bottom of the screen. Touch the slide bar at the value required, then use the left and right double arrows to decrease or increase the value. Use the left and right single arrows to decrease or increase the value in smaller increments.

Memory (M) — All stored protocol information is located within the Memory screen. Accessing this screen allows the operator to recall protocols. To access the Memory screen, press the [Memory] key located on the lower portion of the screen. For more information, refer to the section *Powerhead Memory Screen* in this chapter.

Main (N) — Pressing this key displays the Powerhead Main Screen.

OptiBolus (optional) (O) *— This key is only active if a port-key is present at the OptiBolus port located on the rear of the power supply.* Pressing this key allows the operator to program an OptiBolus injection. The OptiBolus Mode delivers an exponentially decaying flow rate injection that optimizes the contrast usage and provides an extended period of uniform enhancement of the area of interest. Once the [Optibolus] key (O) is pressed, the screen shown in Figure 3-2-10 is displayed. Note the addition of "O" (OptiBolus) (Q) to the left of the first phase. End Flow Rate is a function of the Optibolus mode and is automatically calculated by the OptiVantage for the entered parameters and is displayed only on the console Main screen.

Timing Bolus (P) *— This key is only active if turned ON at the Setup Screen and when 4 or less phases are programmed in a protocol.* Pressing this key allows the operator to program a Timing Bolus injection. A Timing Bolus injection--an injection of a small volume of contrast, followed by a small volume of saline--can be delivered to the patient to determine the optimal scan delay needed to capture the contrast agent in the are of interest. Once the [Timing Bolus] key (P) is pressed, the screen shown in Figure 3-2-11 is displayed. Note the addition of "T" (Timing Bolus) (R) to the left of the first and second phase.

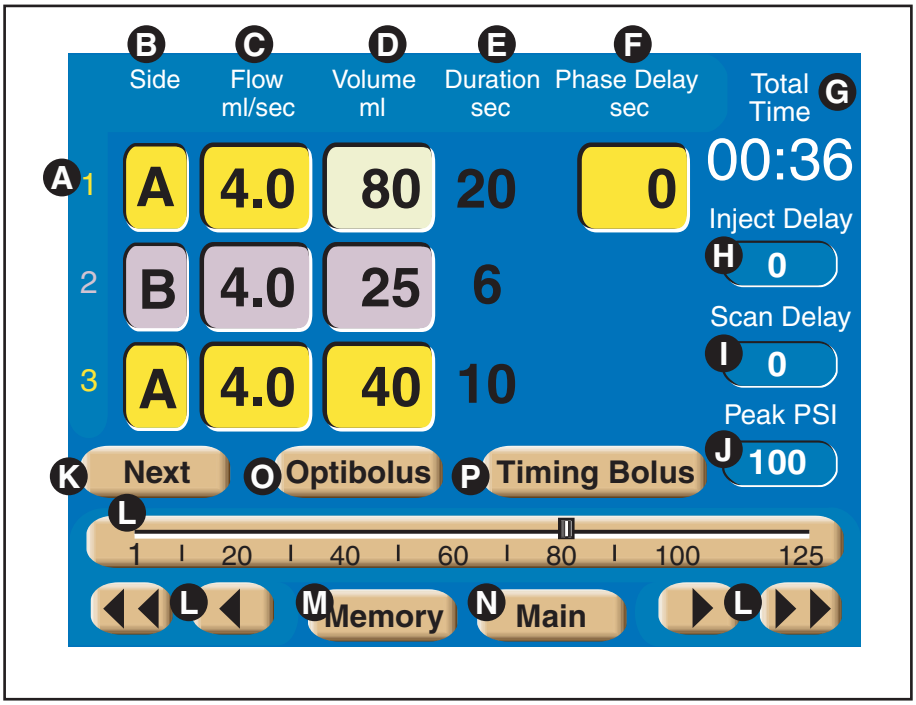

Figure 3-2-9 Powerhead Protocol Parameter Entry Screen

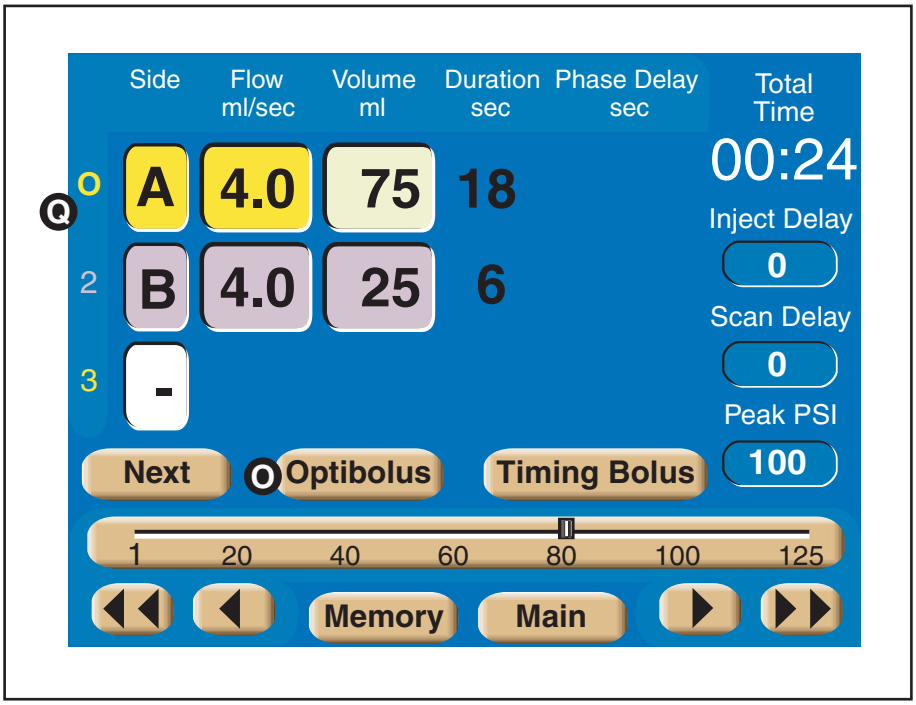

Figure 3-2-10 Powerhead OptiBolus Injection Screen

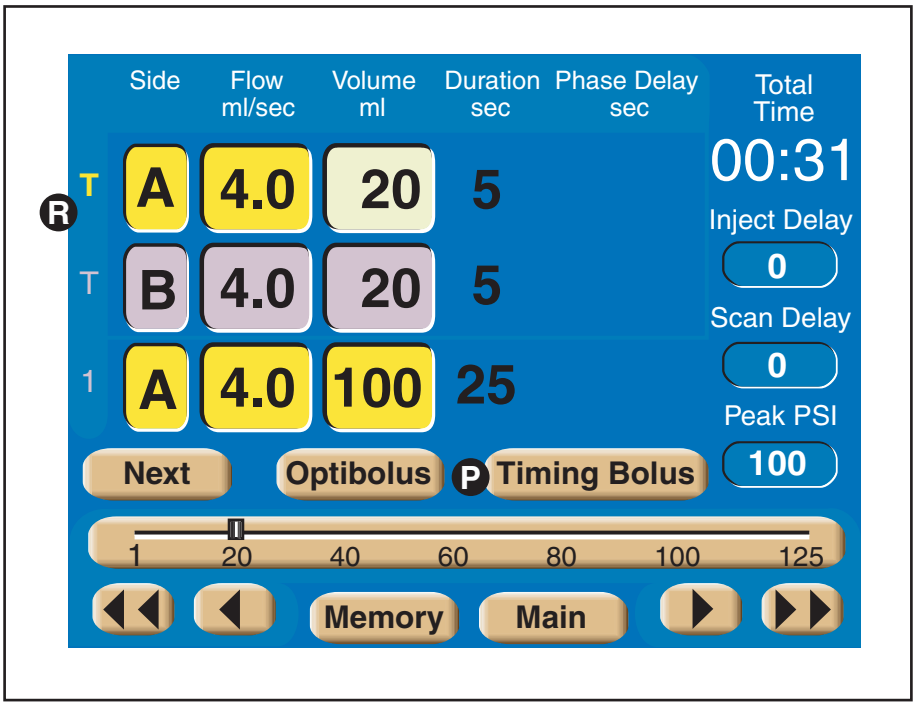

Figure 3-2-11 Powerhead Timing Bolus Injection Screen

3.2.8 ENABLED POWERHEAD MAIN SCREEN

Refer to Figure 3-2-12.

Once the [Enable] key is pressed, the Powerhead Main screen displays an Enabled screen as shown in Figure 3-2-12.

Start Ⓐ — Pressing the [Start] key begins the delivery of the protocol. This key is functionally interchangeable with both the [Stop] key and the [Start] key on the console and the optional Handswitch.

Disable Ⓑ —The [Disable] key disables the enabled injector.

Protocol Parameters Ⓒ — The protocol parameter entry keys are active and can be changed as needed without disabling the injector.

Patency Ⓓ *— This key is only active if turned ON at the Setup Screen.* The [Patency] key is available to deliver a Patency Check--an injection of a small volume of saline--to determine the integrity of the I.V. site. Refer to Figure 3-2-11.

Drip Ⓔ *— This key is only active if turned ON at the Setup Screen.* The [Drip] key is available to deliver a Drip Mode Injection--a low flow rate injection of a small volume of saline--to keep the fluid pathway open. Refer to Figure 3-2-14.

A-Side Syringe (mL) and B-Side Syringe (mL) Ⓕ — These symbols indicate the relative position of the plunger in the syringe thus indicating how much fluid may be in the syringes. Once the injector is enabled, the fill/expel arrows will not appear when the A-side Syringe symbol or the B-side Syringe symbol is pressed.

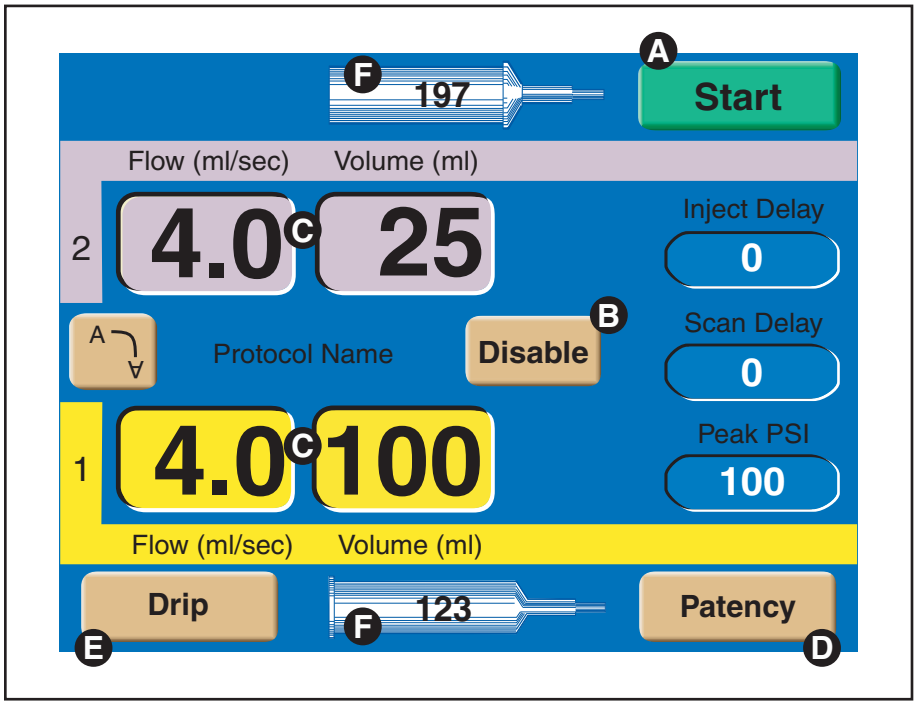

Figure 3-2-12 Powerhead Enabled Main Screen Keys and Definitions

Patency Check Screen

Refer to Figure 3-2-13.

Prior to the delivery of the main injection, a Patency Check--an injection of a small volume of saline--can be performed to determine the integrity of the I.V. site. The Patency Check feature is only accessible from the Powerhead Enabled Main Screen.

To access the Patency Check screen as shown in Figure 3-2-13, press the [Patency] key Ⓓ located on the Powerhead Enabled Main screen as shown in Figure 3-2-12.

B (side) Ⓐ — Patency check can only be delivered from the saline side. (In Figure 3-2-13, the B-side is set up as the saline side.)

Patency Check Flow Ⓑ — This value indicates rate of delivery of the saline. Patency check flow rate, expressed in milliliters/second, will automatically be set to the greatest value occurring in the enabled protocol. The value can be modified by the operator.

Patency Check Volume Ⓒ — This value indicates the volume of saline to be delivered. Patency check volume, expressed in milliliters, is initially set to the default value as defined in the Set Up screen. The value can be modified by the operator. If the value is set for an amount that compromises the enabled protocol, the [Patency Check Volume] key background wiil flash a magenta color and the [Start Patency] key will be removed from the screen.

Change Parameter Values via the Slide Bar Ⓓ — To change the value of a parameter, select the desired parameter by touching its key. The key will highlight to indicate it is active and the slide bar will display at the bottom of the screen. Touch the slide bar at the value required, then use the left and right double arrows to decrease or increase the value. Use the left and right single arrows to decrease or increase the value in smaller increments.

Start Patency Ⓔ — This key starts the patency check injection. For more information about delivering a patency check injection, refer to Chapter 5.

Exit Ⓕ — This key disables the patency check screen and displays the Enabled Main screen.

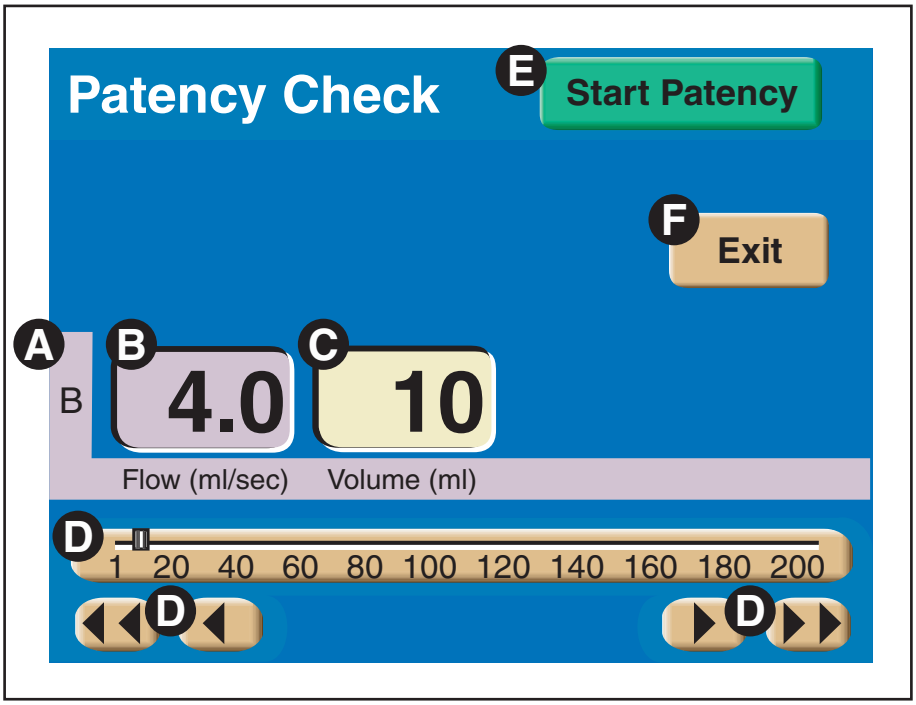

Figure 3-2-13 Powerhead Patency Check Screen

Powerhead Drip Mode Screen

Refer to Figure 3-2-14.

The Drip Mode allows the injector to deliver a “drip” injection to keep the fluid path open during patient set up and between injections of contrast. The Drip Mode is accessible from either the Console Enabled Main Screen or the Powerhead Enabled Main Screen.

To access the Drip Mode screen as shown in Figure 3-2-14, press the [Drip] key Ⓔ located on the Enabled Main screen as shown in Figure 3-2-12.

Side Ⓐ — The Drip injection can only be delivered from the saline side. (In Figure 3-2-14, the B-side is set up as the saline side.)

Drip Mode Flow Ⓑ — This value indicates rate of delivery of the saline. Drip Mode flow is expressed in milliliters/second. The value can be modified by the operator.

Drip Mode Volume Ⓒ — This value indicates the volume of saline to be delivered during each drip injection. Drip Mode volume is expressed in milliliters. The value can be modified by the operator. If the value is set for an amount that compromises the enabled protocol, the [Drip Mode Volume] key background wiil flash a magenta color and the [Start Drip] key will be removed from the screen.

Interval Ⓓ — This value indicates the amount of time the injector pauses between each delivery of drip injections. Drip Mode interval is expressed in seconds.

Change Parameter Values via the Slide Bar Ⓔ — To change the value of a parameter, select the desired parameter by touching its key. The key will highlight to indicate it is active and the slide bar will display at the bottom of the screen. Touch the slide bar at the value required, then use the left and right double arrows to decrease or increase the value. Use the left and right single arrows to decrease or increase the value in smaller increments.

Drip Time Ⓕ — Calculated automatically by the injector by using the programmed Flow, Volume and Interval values and the Drip Volume, this value indicates the amount of time the Drip Injection will require. Once the [Start Drip] key is pressed, the value counts down until it reaches zero. Once Drip Time reaches zero, an audible signal will indicate to the operator that the Drip Injection is complete.

Drip Volume G — Calculated automatically by the injector by subtracting the programmed Volume of the main protocol (saline side) from the syringe volume (saline side), this value indicates the amount of saline the Drip Injection can inject. Drip Volume is expressed in ml.

Start Drip H — This key starts the drip injection. For more information about delivering a drip injection, refer to Chapter 5.

Exit I — This key disables the drip injection and displays the Enabled Main screen.

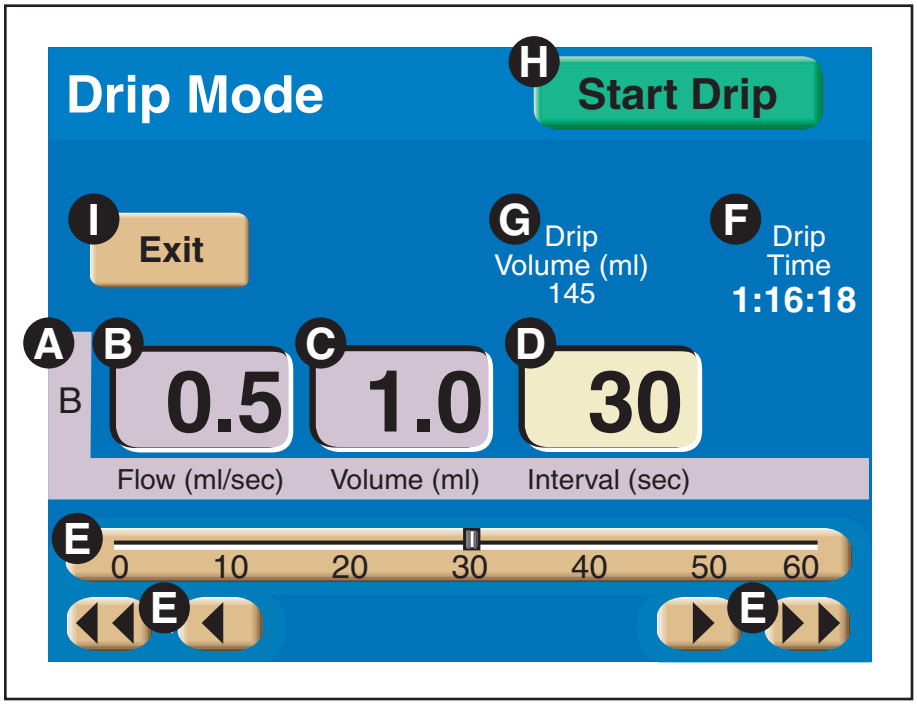

Figure 3-2-14 Powerhead Drip Mode Screen

3.2.9 POWERHEAD MEMORY SCREEN

Refer to Figure 3-2-15.

Memory Location Ⓐ — Eight protocols are listed per page. Each protocol can have a name consisting of up to 20 alpha-numeric characters. OptiBolus protocols are indicated by the "OptiBolus" logo located on the key.

Protocol Parameters Ⓑ — Each protocol can contain up to six phases. Once a protocol key is highlighted, the protocol parameters are displayed in this area.

Memory Page Number Ⓒ — The memory screen contains five pages with eight protocols listed per page.

Main Ⓓ — Pressing this key displays the Powerhead Main screen.

Recalling a Protocol

1. Access the Protocol Memory menu by pressing the [Memory] key located on the bottom of the powerhead Main screen.
2. Press the appropriate page (1, 2, 3, 4 or 5) on which the Protocol is stored.
3. Press the Protocol's corresponding key to highlight Ⓔ, then press the [Select] key Ⓕ. The protocol will be immediately displayed on both the powerhead display and the console display.

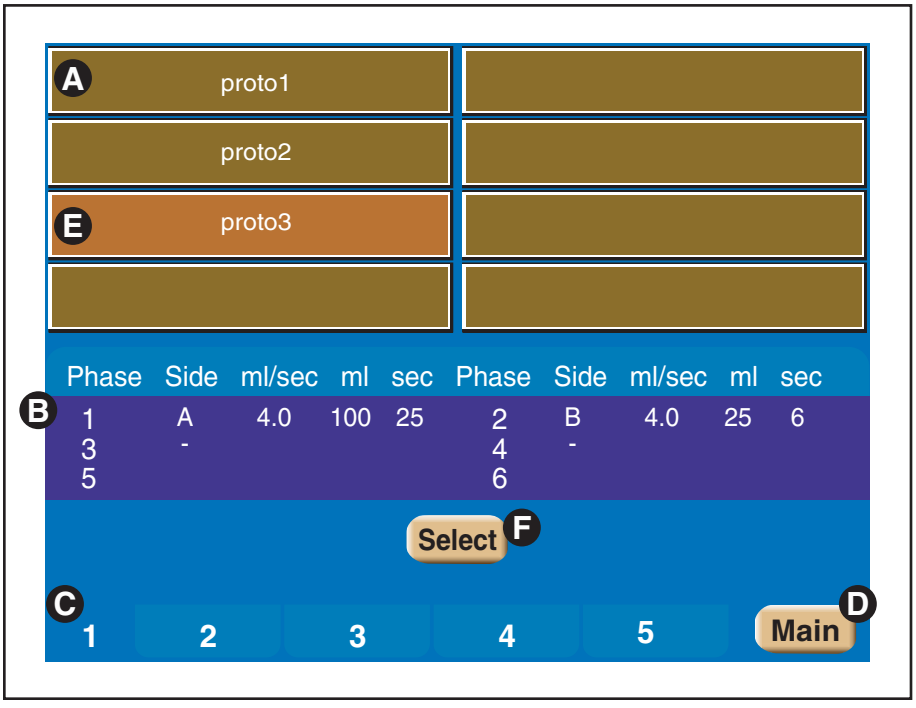

Figure 3-2-15 Powerhead Memory Screen Keys and Definitions

3.2.10 POWERHEAD RESULTS SCREEN

Refer to Figure 3-2-16.

The Results Screen as shown in Figure 3-2-16 is automatically displayed after the delivery of an injection and only shows the achieved results of that injection. The Results screen is displayed for either 21 minutes or until the [Main] key is pressed.

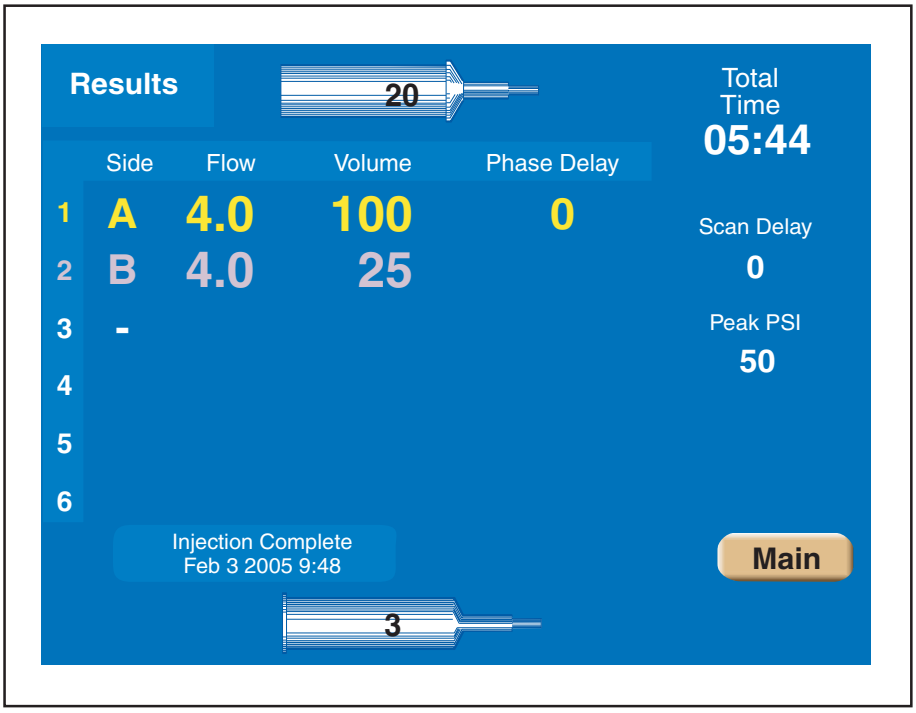

Figure 3-2-16 Results Screen displayed after delivery of an Injection

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4 ENABLING SEQUENCE

This chapter discusses the proper techniques for loading syringes, filling syringes, purging air from both the syringe and tubing, and priming the tubing.

4.1 ENABLING SEQUENCE

Refer to Figure 4-1-1.

The [Enable] key is only active when:

1. a new syringe(s) is loaded
2. the syringe is filled (200 ml only)
3. the powerhead is tilted up and air is purged from both syringes (plunger must move forward to expel a minimum of 1 (one) ml of contrast/saline)
4. the powerhead is rotated at least 30° below horizontal
5. there is sufficient volume in the syringes to perform the programmed injection.

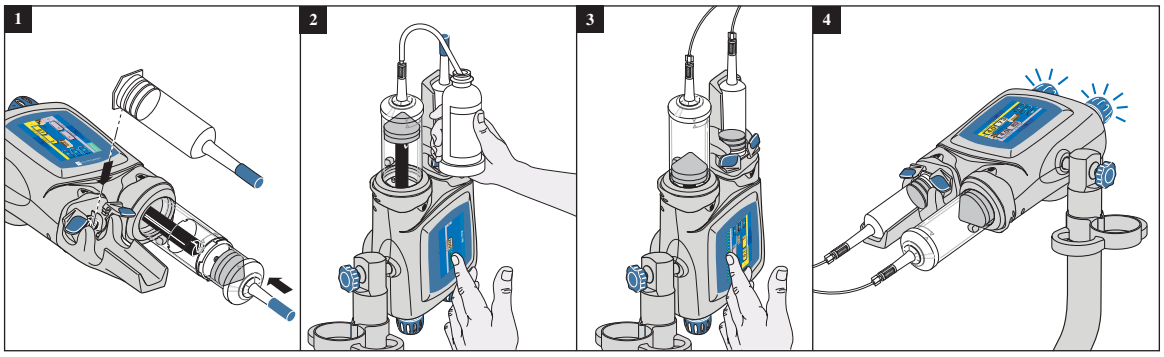

Figure 4-1-1 Enabling Sequence

4.1.1 DANGERS, WARNINGS, AND CAUTIONS

⚠ DANGER! ⚠

The danger of air embolism is always present when injecting into the circulatory system. The enabling sequence for the OptiVantage Injection System is designed to help prevent air injections. In order to enable the OptiVantage, the syringe load sequence and air purge sequence described in this chapter must be performed in order to ensure a safe injection. ***The enable sequence in itself does not guarantee that all air has been completely removed from the system. The operator is responsible for ensuring that all air has been completely evacuated from the syringe and tubing prior to delivery of the injection.***

⚠ DANGER! ⚠

Danger! Contamination Hazard!
Do not reuse syringe or other I.V. access components.

⚠ DANGER! ⚠

Danger! Air Embolism Hazard!
When filling an empty syringe, make sure a tight connection exists between the fill tube and syringe to ensure that air is not being drawn into the syringe. Entrapped air can cause patient injury or death if not properly removed prior to delivery of injection.

⚠ WARNING! ⚠

Warning! Infection Hazard!
Contamination of sterile-packed empty syringes is possible if proper precautions are not taken. Due to the risk of serious patient infection, do not touch the Linden-Luer adapter or the section of a fill tube that will be inserted into the contrast. Do not touch the interior of the syringe or expose the interior of the syringe to conditions which can cause contamination (coughing, sneezing, etc.). Immediately place syringe into injector sleeve to prevent contaminating the interior of the syringe.

⚠ CAUTION! ⚠

Install syringes containing the amount of contrast required by the procedure to be performed on the patient. Installing syringes containing more contrast than needed could result in the injection of excess contrast.

⚠ CAUTION! ⚠

Fill syringes only with the minimum amount of contrast required by the procedure to be performed on the patient. Filling syringes with more contrast than needed could result in the injection of excess contrast.

⚠ CAUTION! ⚠

PINCH POINT LOCATION. A pinch point may occur if the ram is extended while fingers are located in the area shown in Figure 4-1-2.

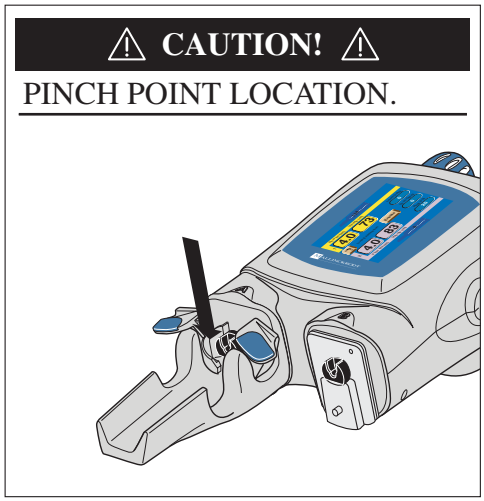

Figure 4-1-2 Pinch Point Location

4.1.2 NOTES

Preheating the contrast media will help in the removal of air bubbles.

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4.2 TYPES OF INJECTIONS

The OptiVantage has the ability to deliver an injection with or without a saline flush. Both the A-side and the B-side can accommodate either a 125 ml prefilled syringe, 125 ml partial prefilled syringe, or an operator filled 200 ml syringe.

Load 125 ml Syringe (Contrast side Only)

Refer to Figure 4-2-1.

1. If the ram is not home, move to the fully retracted position Ⓐ. Slide the 125 ml cradle Ⓑ onto the desired front plate mount of the powerhead (A-side is shown in Figure 4-2-1). Press the [Continue] key on the powerhead display to allow the ram to move forward to lock the faceplate in place and home the ram.
2. Inspect syringe and its contents for irregularities prior to loading. Open the 125 ml syringe clamps Ⓒ. Install the 125 ml syringe into the cradle Ⓓ.
3. Securely close syringe clamps Ⓔ.
4. Proceed to Section 4.1.4 Attach Tubing to Syringe(s).

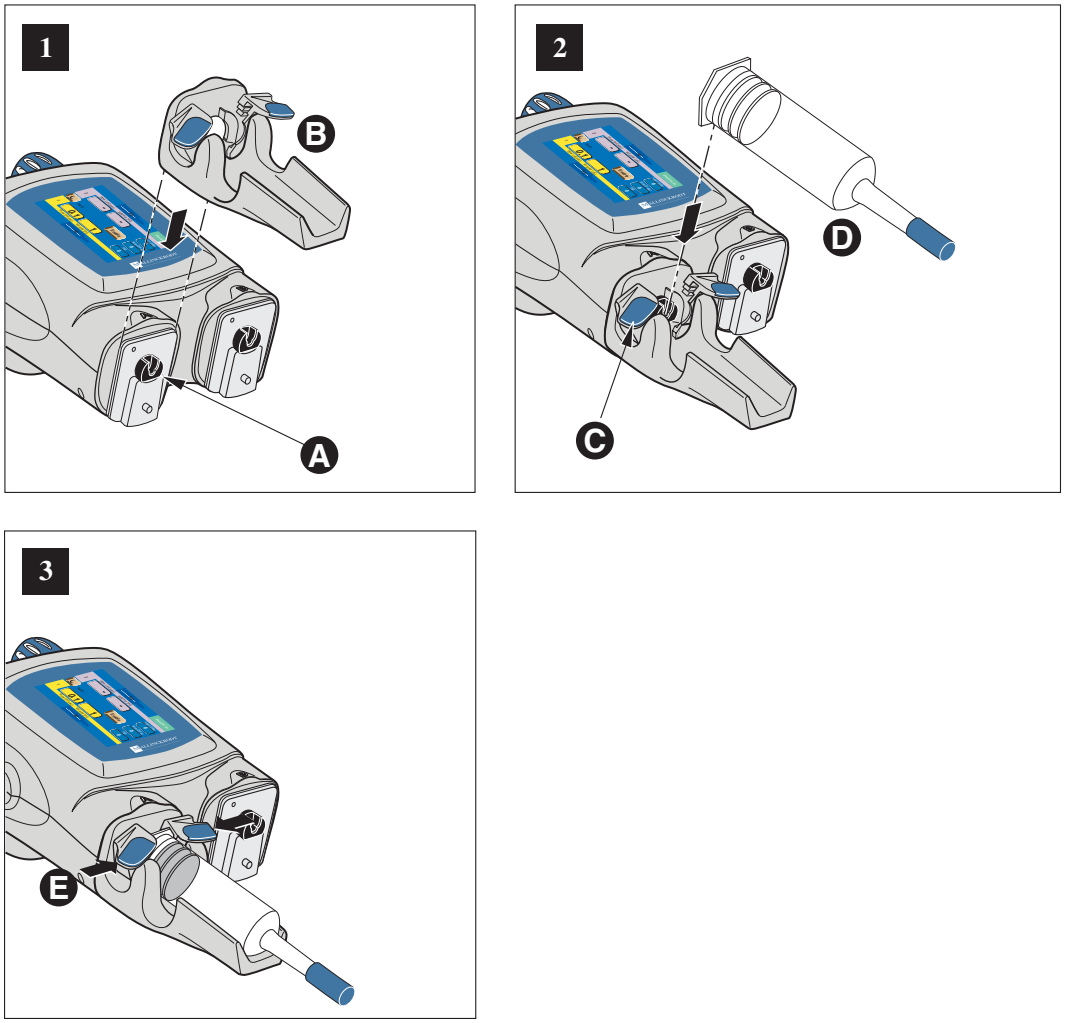


Figure 4-2-1 Load 125 ml Syringe (A-Side Only)

Load 200 ml Syringe (Contrast side Only)

Refer to Figure 4-2-2.

1. Move the desired ram to the fully retracted position Ⓐ (A-side is shown in Figure 4-2-2). Rotate the pressure sleeve lever to the unlock position. Slide the 200 ml pressure sleeve onto the front plate mount of the powerhead Ⓑ. Press the [Continue] key on the powerhead display to allow the ram to move forward to lock the faceplate in place and home the ram.
2. Extend the ram fully Ⓒ.
3. Using aseptic technique, remove the 200 ml syringe from its sterile packaging by grasping the umbrella cap Ⓓ. Inspect the syringe for irregularities prior to loading. Make sure the pressure sleeve lever is rotated to the unlock position. Insert the 200 ml syringe into the pressure sleeve by matching the load arrow on the syringe to the load arrow on the pressure sleeve Ⓔ.
4. Lock the syringe into place by either turning the pressure sleeve lever to the lock position or by rotating the umbrella cap clockwise until the load arrow aligns as shown Ⓕ. If the lever cannot be moved to the lock position, make sure the load arrow is aligned as shown Ⓔ, then gently push down on the umbrella cap. The lever should now lock easily. Leave the ram/plunger in the "fully expelled" or extended position in preparation to fill with contrast.
5. Proceed to section 4.3 Fill Syringe (200 mL Only).

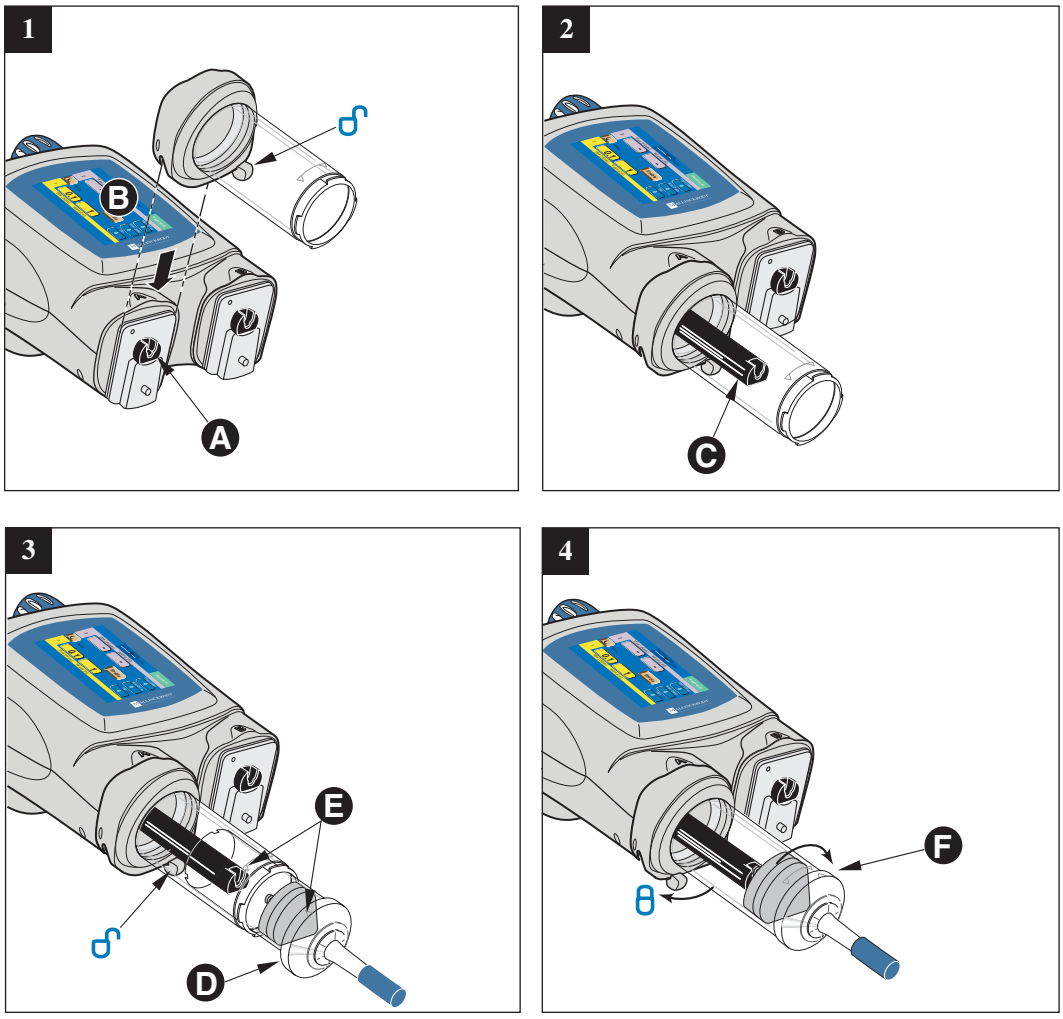
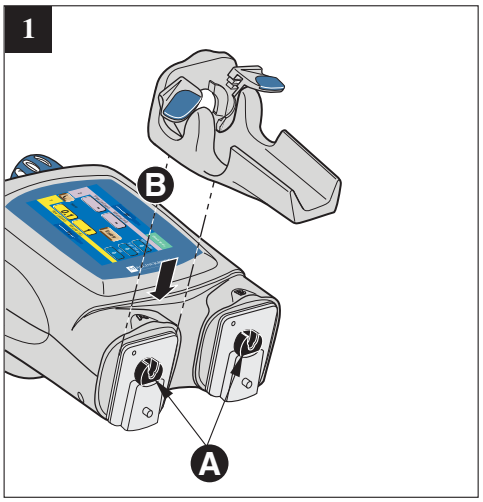


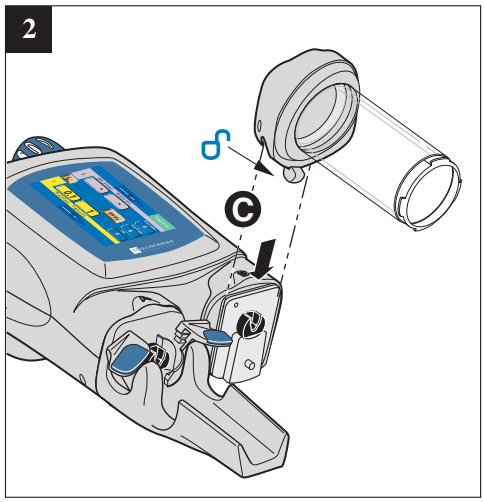
Figure 4-2-2 Load 200 mL Syringe (A-side Only)

Load 125 ml/200 ml Syringe

Refer to Figure 4-2-3.

1. Move the A-side and B-side ram to the fully retracted position Ⓐ. Slide the 125 ml cradle onto the A-side front plate mount of the powerhead Ⓑ. Press the [Continue] key on the powerhead display to allow the ram to move forward to lock the faceplate in place and home the ram.
2. Rotate the pressure sleeve lever to the unlock position. Slide the 200 ml pressure sleeve onto the front plate mount of the powerhead Ⓒ. Press the [Continue] key on the powerhead display to allow the ram to move forward to lock the faceplate in place and home the ram.
3. Inspect 125 ml syringe and its contents for irregularities prior to loading. Open the tabs Ⓓ and install the 125 ml syringe into the cradle
4. Close tabs to secure the 125 ml syringe Ⓔ.
5. Extend the B-side ram fully Ⓕ.
6. Using aseptic technique, remove the 200 ml syringe from its sterile packaging by grasping the umbrella cap Ⓖ. Inspect the syringe for irregularities prior to loading. Insert the 200 ml syringe into the 200 ml pressure sleeve by matching the load arrow Ⓗ on the syringe to the load arrow on the pressure sleeve.
7. Lock the syringe into place by either turning the pressure sleeve lever to the "lock" position or by rotating the umbrella cap clockwise until the load arrow aligns as shown Ⓘ. If the lever cannot be moved to the lock position, make sure the load arrow is aligned as shown Ⓗ, then gently push down on the umbrella cap. The lever should now lock easily. Leave the ram/plunger in the "fully expelled" or extended position in preparation to fill with contrast.
8. Proceed to section 4.3 Fill Syringe (200 ml Only).





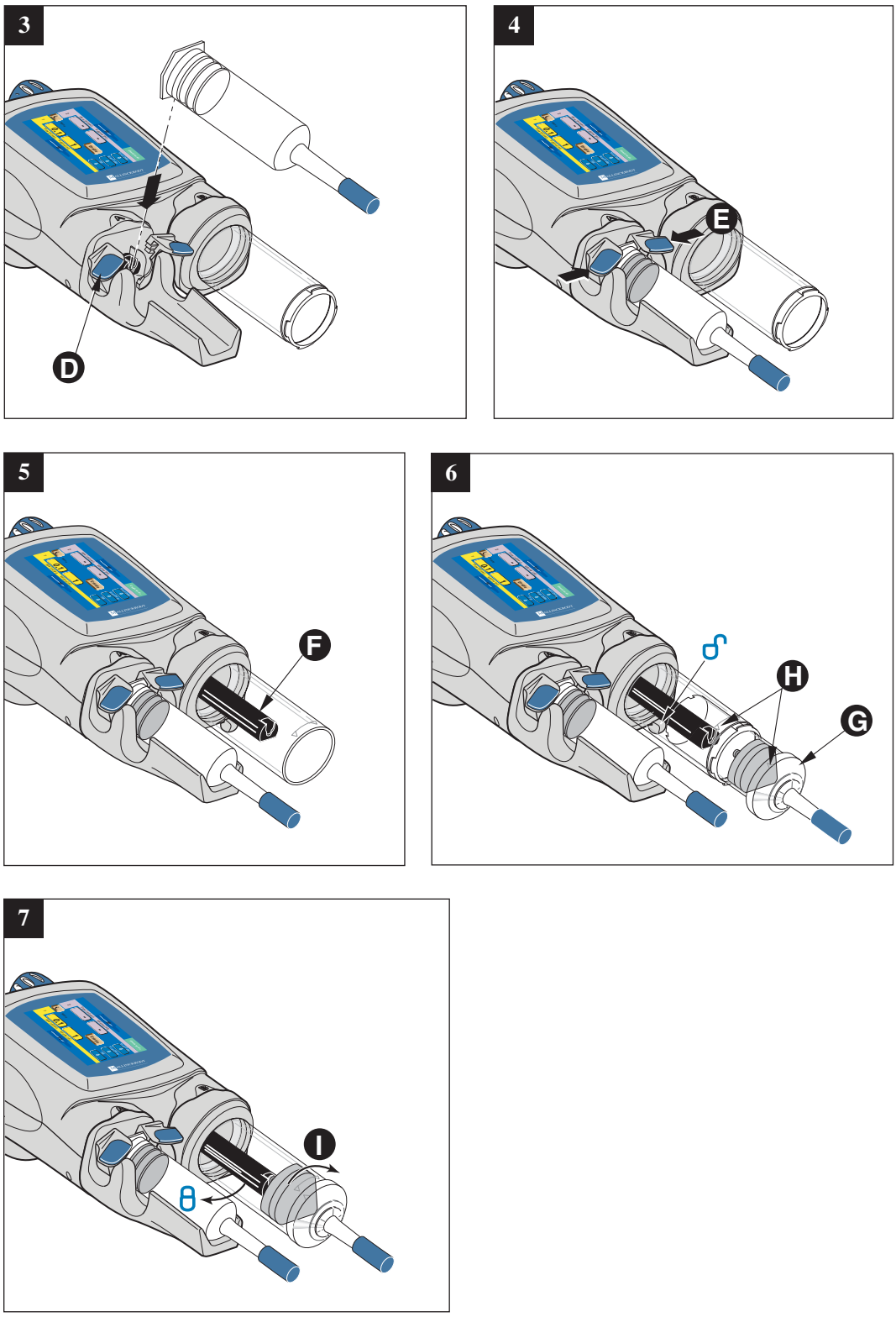


Figure 4-2-3 Load 125 ml/200 ml Syringe

Load 200 ml/200 ml Syringe

Refer to Figure 4-2-4.

1. Move the A-side and B-side ram to the fully retracted position Ⓐ. Rotate the pressure sleeve lever to the unlock position. Slide one of the 200 ml pressure sleeves onto the front plate mount of the powerhead Ⓑ. Press the [Continue] key on the powerhead display to allow the ram to move forward to lock the faceplate in place and home the ram. Slide the other 200 ml pressure sleeves onto the front plate mount of the powerhead Ⓑ. Press the [Continue] key on the powerhead display to allow the ram to move forward to lock the faceplate in place and home the ram.
2. Extend both rams fully Ⓒ.
3. Using aseptic technique, remove the 200 ml syringes from their sterile packaging by grasping their umbrella caps Ⓓ. Inspect the syringes for irregularities prior to loading. Insert a 200 ml syringe into each pressure sleeve by matching the load arrow on the syringe to the load arrow on the pressure sleeve Ⓔ.
4. Lock the syringes into place by either turning the pressure sleeve levers to the "lock" position or by rotating the umbrella caps clockwise until the load arrows align as shown. If the lever cannot be moved to the lock position, make sure the load arrows are aligned as shown, then gently push down on the umbrella cap. The lever should now lock easily. Leave the ram/plungers in the "fully expelled" or extended position in preparation to fill with contrast.
5. Proceed to section 4.3 Fill Syringe (200 ml Only).

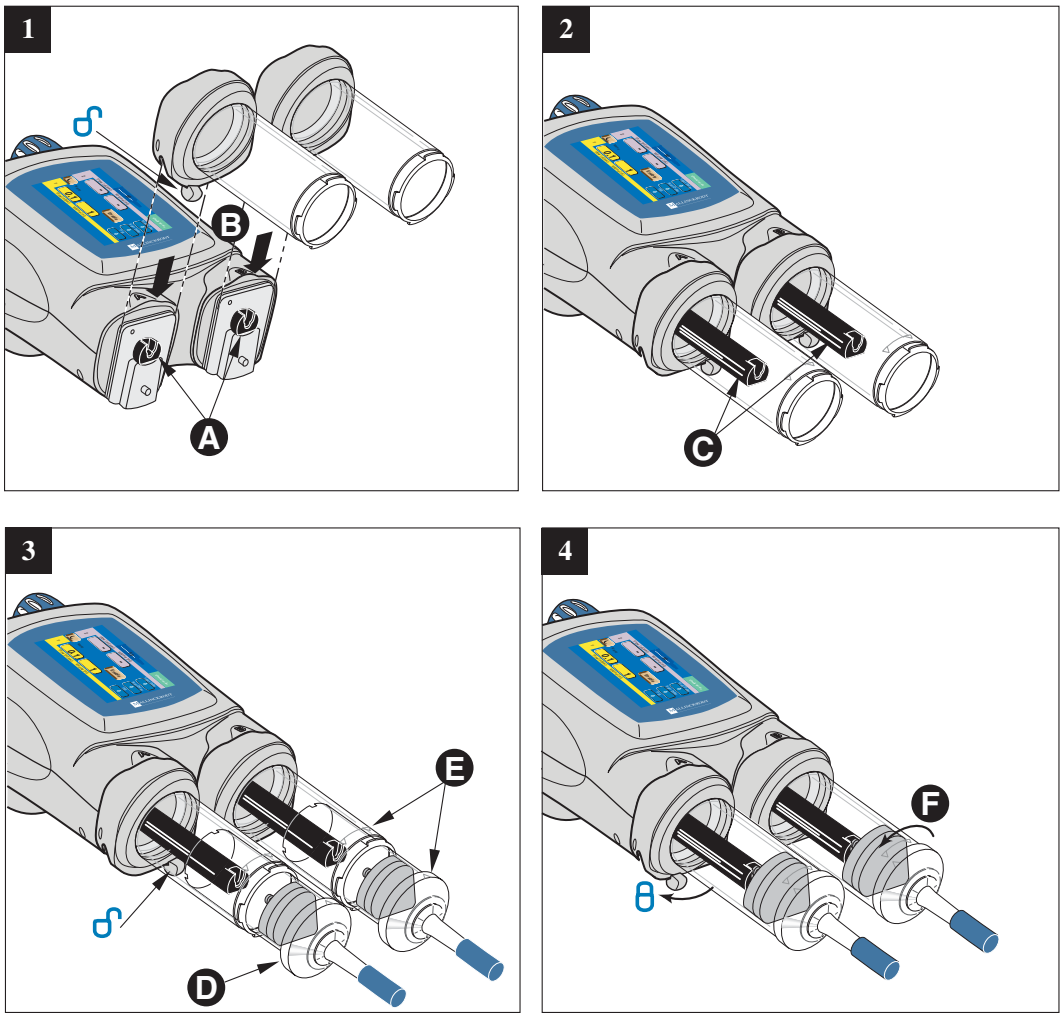


Figure 4-2-4 Load 200 ml/200 ml Syringe

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4.3 FILL SYRINGE (200 ML ONLY)

4.3.1 AUTO-FILL TECHNIQUE

Refer to Figure 4-3-1 and 4-3-2.

NOTE: This feature is only available if turned ON in the Setup screen.

The Auto-Fill feature has been designed to automatically fill the syringe while minimizing the introduction of air. To use the Auto-Fill feature:

1. Place the ram(s) in the "home" position (i.e. fully expelled), then load a 200 ml syringe into the pressure sleeve(s). If the powerhead is not in the vertical position, the following message will appear: *Rotate the Powerhead to the vertical position to activate Auto-Fill sequence.*
2. Rotate the powerhead to the vertical position. The screen shown in Figure 4-3-1 is displayed. NOTE: If the powerhead is utilizing a 200 ml syringe on both the A-side and the B-side, the Auto-Fill sequence will first fill the last installed syringe, then allow for filling the remaining empty syringe.
3. Set the desired Fill Volume (ml) by pressing the [Fill Volume] key **A** for either the A-side or the B-side (B-side is shown in Figure 4-3-1), then change the value via the slide bar keys **B**.
4. Remove the protective cap from the syringe tip and store in a safe place for reuse in step 9.
5. Using aseptic technique, slide the end of the shorter section of the fill tube over the syringe tip. DO NOT TOUCH THE TIP. Place the end of the longer section of the fill tube into the container of contrast media. To keep aeration to a minimum, verify that this end of the tube is in the media and is NOT drawing air.
6. Press and release the respective [Start Auto-Fill] key **C**. The injector will automatically retract the ram 25 ml at 4 ml/s, purge 25 ml at 10 ml/s, then retract to the Fill Volume at 15 ml/s. NOTE: Pressing the [Stop] key on the screen will disable the Auto-Fill feature.
7. Carefully remove the fill tube from the syringe tip by twisting while pulling off. NOTE: In order to prevent the contrast medium from spilling onto the syringe and pressure sleeve, make sure the curved portion of the fill tube is either completely empty or contains enough contrast medium so that the level in the longer end is slightly lower than the tip of the syringe. This will cause the fluid in the tube to return to the container.

8. Observe contrast medium to ensure all air bubbles are removed. If air bubbles are still clinging to the sides of the syringe, follow the steps outlined in the section 4.5 Purge Air/Prime Tubing.

9. To prevent contamination, replace the protective cap on the syringe tip. The powerhead should remain in the vertical position (to prevent leakage) until ready for injection.

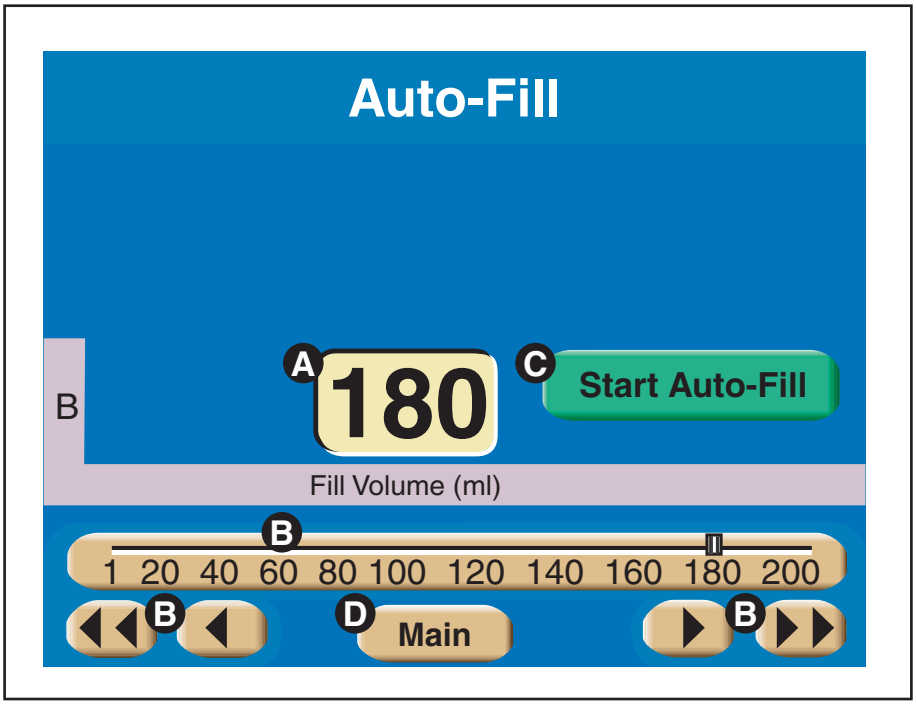

Figure 4-3-1 Auto-Fill Screen

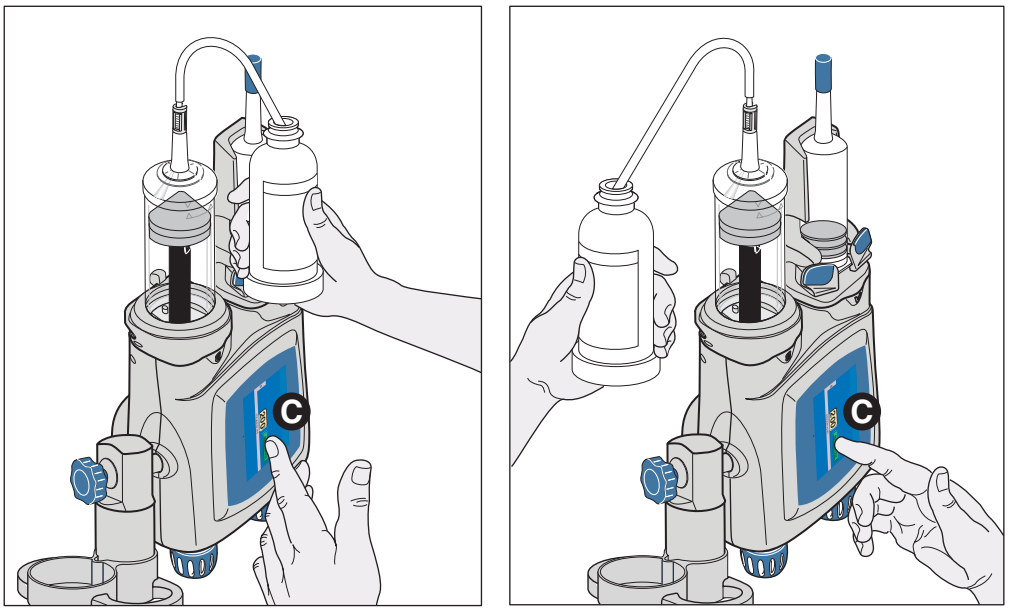

Figure 4-3-2 Fill Syringe Right-handed/Left-handed

4.3.2 MANUAL FILL TECHNIQUE

Upon loading a 200 ml syringe, the screen shown in Figure 4-3-1 is displayed (if Auto-Fill feature is turned ON in the Setup screen) to allow for automatic filling of the syringe. The Auto-Fill feature has been designed to automatically fill the syringe while minimizing the introduction of air. However, to manually fill the syringe:

1. Disable the Auto-Fill feature by pressing the [Main] key (Ⓓ in Figure 4-3-1) to display the Main screen.
2. Rotate the powerhead to the vertical position.
3. Remove the protective cap from the syringe tip and store in a safe place for reuse in step 9.
4. Slide the end of the shorter section of the fill tube over the syringe tip. DO NOT TOUCH THE TIP. Place the end of the longer section of the fill tube into the container of contrast media. To keep aeration to a minimum, verify that this end of the tube is in the media and is NOT drawing air.
5. Press the respective syringe key to display the fill/expel arrows. Retract the plunger to draw the desired volume of contrast medium into the syringe. NOTE: A retract flow of 10 ml/s or less is optimum to minimize the introduction of air.
6. Move the plunger in the “expel” direction, to expel all air from the syringe.
7. Carefully remove the fill tube from the syringe tip by twisting while pulling off. NOTE: In order to prevent the contrast medium from spilling down around the syringe and pressure sleeve, make sure the curved portion of the fill tube is either completely empty or contains enough contrast medium so that the level in the longer end is slightly lower than the tip of the syringe. This will cause the fluid in the tube to return to the container.
8. Observe contrast medium to ensure all air bubbles are removed. If air bubbles are still clinging to the sides of the syringe, follow the steps outlined in the section 4.5 Purge Air/Prime Tubing.
9. To prevent contamination, replace the protective cap on the syringe tip. The powerhead should remain in the vertical position (to prevent leakage) until ready for injection.

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4.4 ATTACH TUBING TO SYRINGE(S)

To attach the catheter or tubing to the 125 ml prefill syringe or the 200 ml disposable syringe, using aseptic technique, insert the hub **A** into the slot of the luer nut **B** and rotate the nut clockwise to tighten the hub onto the syringe tip. Refer to Figure 4-4-1.

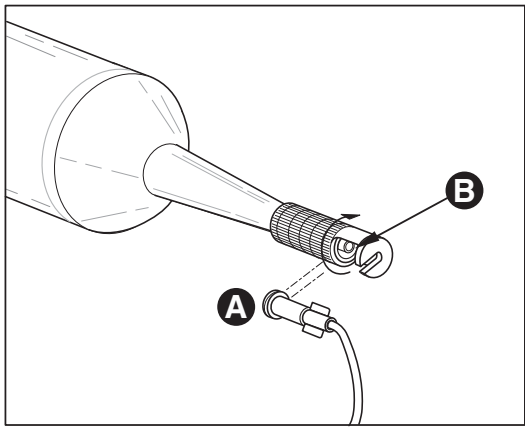


Figure 4-4-1 Attach Tubing to Syringe

4.5 PURGE AIR FROM SYRINGE

⚠ DANGER! ⚠

DANGER! AIR EMBOLISM HAZARD!
Air entrapped in the syringe and tubing can cause patient injury or death. Always verify that both the syringe and tubing have been properly cleared of air just prior to starting the injection! The OptiVantage Injection System does not have the capability to check for air in the syringe and tubing. ***The operator is responsible for removing all air from the system.***

4.5.1 PURGE AIR 125 ML PREFILL SYRINGE

NOTE: The instructions that accompany the prefill syringe should be followed.

1. The air pocket trapped in the syringe MUST be removed to prevent injection of an air embolism into the patient. Rotate the powerhead vertically to point the tip of the syringe upward to allow the air pocket to rise to the tip.
2. Advance the plunger to remove air from the syringe and tubing. The plunger must move forward to expel a minimum of 1 ml of contrast to indicate that an attempt was made to purge the air.
3. Verify that both the syringe and tubing have been properly cleared of all air.

4.5.2 PURGE AIR 200 ML DISPOSABLE SYRINGE

1. Air bubbles trapped in contrast media and saline MUST be removed to prevent injection of an air embolism into the patient. Rotate the powerhead vertically to point the tip of the syringe upward to allow the air bubbles to rise to the tip to form an air pocket.
2. Dislodge any air bubbles attached to the side of the syringe by gently tapping with the heel of the hand.
3. Using the expel arrows or the manual knob, advance the plunger to push the air pocket out the syringe tip and through the tubing. The plunger must move forward to expel a minimum of 1 ml of contrast to indicate that an attempt was made to purge the air.

4.6 PRIME TUBING

⚠ DANGER! ⚠

DANGER! AIR EMBOLISM HAZARD!
Air entrapped in the syringe and tubing can cause patient injury or death. Always verify that both the syringe and tubing have been properly cleared of air just prior to starting the injection! The OptiVantage Injection System does not have the capability to check for air in the syringe and tubing. ***The operator is responsible for removing all air from the system.***

4.6.1 PRIME TUBING WITH SALINE

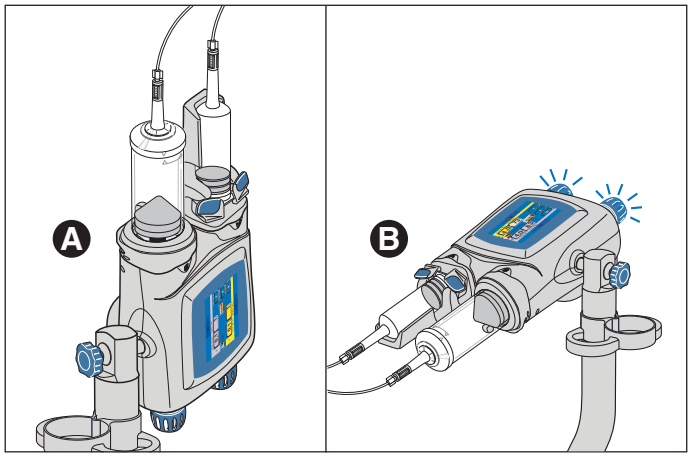
Priming the tubing with saline is necessary for the delivery of *Drip Mode injections, Patency Check injections and Timing Bolus injections*. Advance the saline plunger to push saline past the Y-intersection of the Y-tubing and out through the remaining tubing.

4.6.2 PRIME TUBING WITH CONTRAST

Prime the tubing with contrast if Drip Mode injections, Patency Check injections and Timing Bolus injections are not to be performed. Advance the contrast plunger to push contrast past the Y-intersection of the Y-tubing and out through the remaining tubing.

4.7 POWERHEAD IN VERTICAL POSITION

With all air removed and the tubing primed, the powerhead should remain in the vertical position **A** (to prevent leakage) until ready to inject. The [Enable] key will activate once the powerhead is rotated 30° below horizontal **B**.



5 DELIVERING AN INJECTION

This chapter instructs the operator on the steps taken to safely deliver an injection.

5.1 DANGERS/WARNINGS/CAUTIONS

⚠ DANGER! ⚠

DANGER! AIR EMBOLISM HAZARD!
Air entrapped in the syringe and tubing can cause patient injury or death. Always verify that both the syringe and tubing have been properly cleared of air just prior to starting the injection! The OptiVantage Injection System does not have the capability to check for air in the syringe and tubing. ***The operator is responsible for removing all air from the system.***

⚠ DANGER! ⚠

REMOVE SYRINGE AFTER COMPLETION OF INJECTION!
Disposable syringes are designed for single use only. Used syringes should be promptly removed from the injector after a procedure is completed to avoid accidental reuse of an empty syringe. Failure to remove the syringe after completion of a procedure may lead to an inadvertent injection of air. Injecting air can cause patient injury or death.

⚠ DANGER! ⚠

Follow all manufacturers guidelines and do not operate any part of the OptiVantage Injection System within 6 inches (15 cm) of a pacemaker and/or defibrillator.

⚠ WARNING! ⚠

This device has been approved for use with only the consumables listed in Chapter 1. Use of other consumables could result in patient injury, operator injury and/or equipment damage.

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5.2 RECALL/ENTER PROTOCOL PARAMETERS

Recall required protocol from memory or enter required parameters. For more information about recalling a protocol from memory or entering parameters, refer to Chapter 3.

⚠ CAUTION! ⚠

REVIEW PARAMETERS

Prior to delivering an injection, review all parameters thoroughly to ensure that they are correct and appropriate for the procedure. Also, ensure that contrast fluid is installed on the correct side of the powerhead.

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5.3 CONNECT TO PATIENT

⚠ WARNING! ⚠

Extravasation can be minimized through the following precautions:

- When choosing an I.V. site, use the largest vein possible.
- Use lowest flow rate practical to achieve enhancement.
- Use largest gauge teflon type catheter possible.
- Insure good backflow from catheter.
- Continue to monitor from remote location.
- Instruct patient to notify operator of any abnormal pain, pressure or swelling.

Follow proper venipuncture technique to connect the patient to the OptiVantage system.

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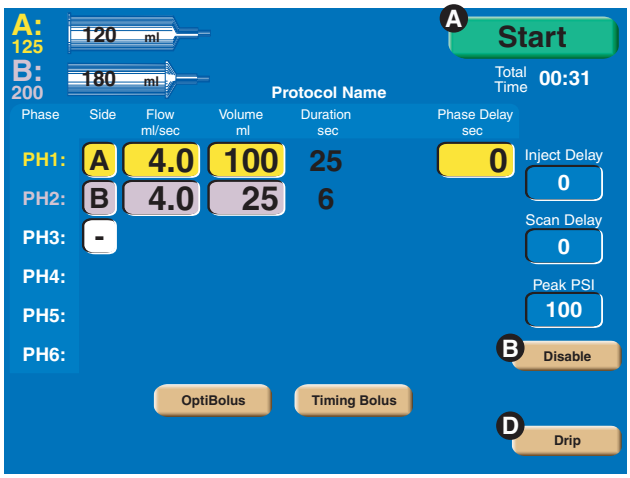
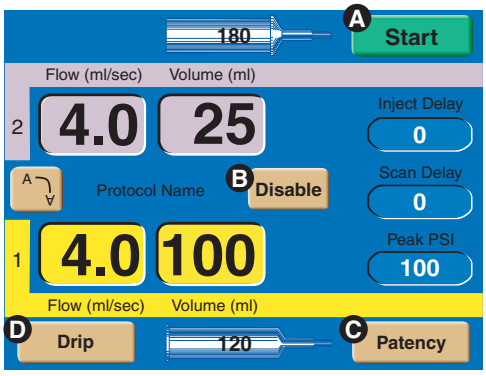
5.4 ENABLE INJECTOR

Refer to Figure 5-4-1.

1. ***The operator is responsible for ensuring that all air has been completely evacuated from the syringe and tubing prior to delivering the injection.*** Prior to enabling an injection, review all parameters thoroughly to ensure that they are correct and appropriate for the procedure. Also, ensure that the contrast fluid is installed on the correct side of the powerhead.
2. Follow the Enabling Sequence stated in Chapter 4 to properly load and fill syringes, purge air and prime the tubing.
3. Rotate the Powerhead at least 30° below horizontal. This safety precaution reduces the possibility of an air emboli. Any small remaining air bubbles will tend to float away from the tip and will not be injected into the patient.
4. Press the [Enable] key located on either the powerhead or console screen. A [Start] key Ⓐ will appear in the upper right-hand corner of both the console screen and the powerhead screen. The [Enable] key will change to a [Disable] key Ⓑ. The indicator lights on the powerhead will illuminate to signify the unit is now enabled for delivery of an injection.



Console Enabled Screen



Powerhead Enabled Screen

Figure 5-4-1 Enabled Screen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5.5 CHECK PATENCY OF I.V. SITE

⚠ WARNING! ⚠

Extravasation can be minimized through the following precautions:

- When choosing an I.V. site, use the largest vein possible.
- Use lowest flow rate practical to achieve enhancement.
- Use largest gauge teflon type catheter possible.
- Insure good backflow from catheter.
- Continue to monitor from remote location.
- Instruct patient to notify operator of any abnormal pain, pressure or swelling.

NOTE: The injector does not have the capability to prevent or detect an extravasation. Patency Check is only available when turned On in the Setup screen.

Two different techniques exist to check the patency of the I.V. site. Once a protocol is enabled, the [Patency] key is available on the powerhead display to inject a small volume of saline at the same flow rate as the enabled protocol. Also, the manual knob is available to manually check patency. Instructions for both techniques follow:

Check Patency Using the [Patency] key

Refer to Figure 5-5-1 and 5-5-2.

1. Press the [Patency] key (C on Figure 5-4-1) located on the powerhead's enabled screen. The screen as shown in Figure 5-5-1 appears.
2. Adjust Patency Check flow E and Patency Check volume F as desired using the slide bar G. Patency Check Volume can only be set to an amount that will not compromise the enabled protocol.
3. Press the [Start Patency] key H to start the injection and the screen as shown in Figure 5-5-3 will display. Monitor the site and instruct patient to notify operator of any abnormal pain, pressure or swelling.
4. Total Time J increments and syringe volume K decrements while injecting. The [Stop] key L is available to immediately stop the Patency Check injection at any time.
5. Once the Patency Check injection is delivered, the Enabled screen is displayed and the injector is ready to deliver the protocol or deliver another Patency Check.

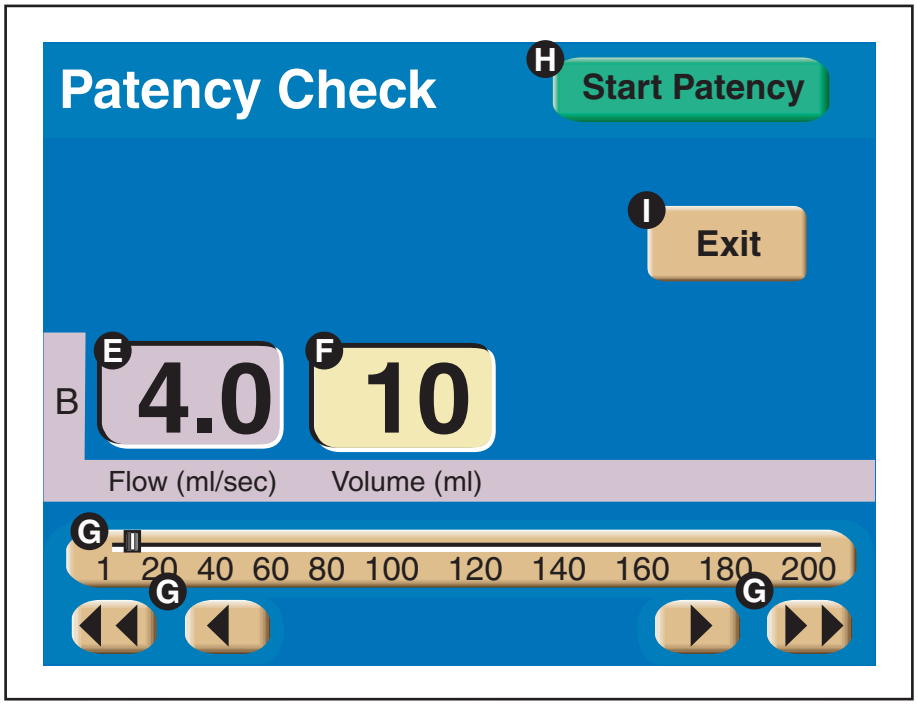

Figure 5-5-1 Patency Check Screen (Powerhead Only)

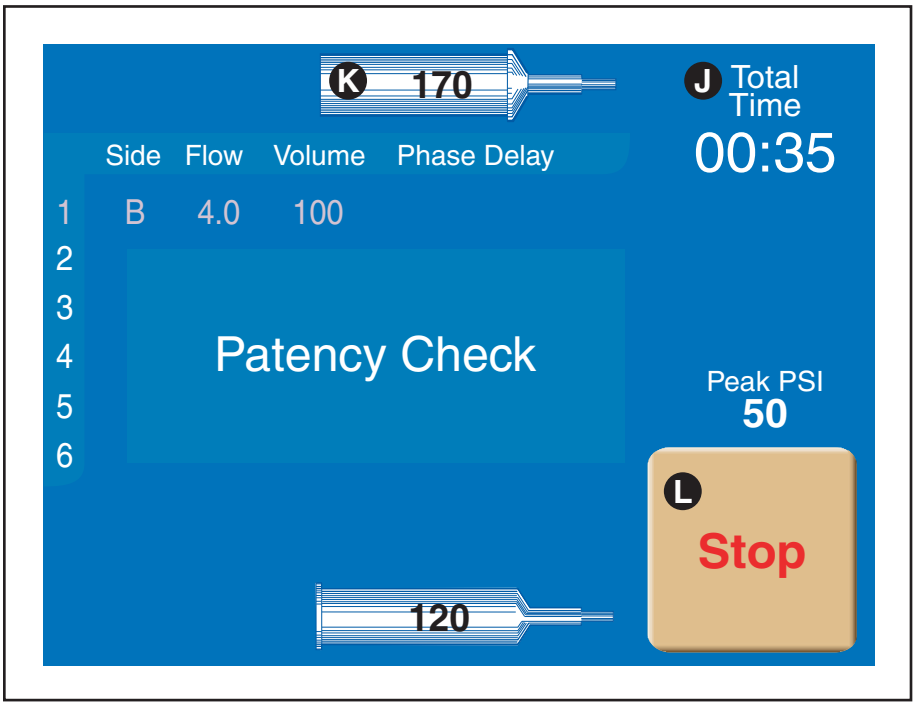

Figure 5-5-2 Patency Check Injecting Screen (Powerhead Only)

Check Patency Using the Manual Knob

⚠ DANGER! ⚠

DANGER! BLOOD CLOT HAZARD! Do not allow blood to remain in I.V. access line.

⚠ CAUTION! ⚠

Care should be taken when retracting the plunger using the manual knob so that the integrity of the vein is maintained.

NOTE: This technique can NOT be performed if the syringe is connected to tubing with a check valve. Using the manual knob of the saline side, retract the plunger in order to check the patency of the I.V. site. Do not allow blood to remain in the I.V. access line.

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5.6 DELIVERING A DRIP MODE INJECTION

Refer to Figure 5-6-1 and 5-6-2.

⚠ CAUTION! ⚠

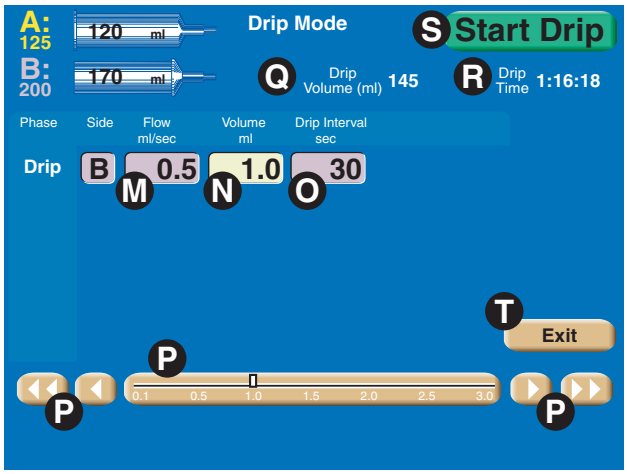
REVIEW PARAMETERS

The enabled protocol can be delivered via the Drip Mode injecting screen by pressing the [Start Protocol] key (X). If this feature will be utilized, prior to pressing the [Drip] key on the enabled main screen, review all protocol parameters thoroughly to ensure that they are correct and appropriate for the procedure. Also, ensure that contrast fluid is installed on the correct side of the powerhead.

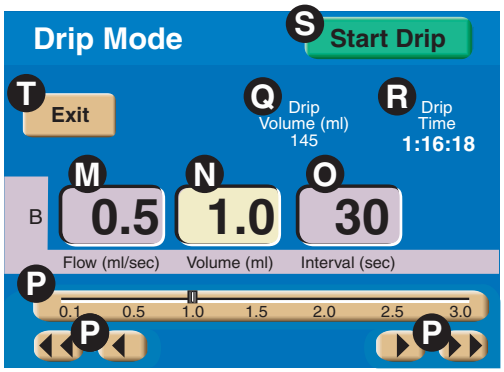
1. Press the [Drip] key ((D) on Figure 5-4-1) located on the powerhead's enabled screen. The screen as shown in Figure 5-6-1 appears.
2. Adjust Drip flow (M), Drip volume (N) and Drip interval (O) as desired using the slide bar (P). Drip volume can only be set to an amount that will not compromise the enabled protocol. Drip (injectable) Volume (Q) displays the amount of saline available for the Drip Mode injection. Drip Time (R) displays the amount of time the Drip Mode injection will require.
3. Press the [Start Drip] key (S) to start the injection and the screen as shown in Figure 5-6-2 will display. The [Exit] key (T) is available to exit the Drip Mode and return to the Enabled protocol screen.
4. While injecting, Drip Time (U) and syringe volume (V) decrement. The [Stop] key (W) is available to stop the injection at any time. Pressing the [Start Protocol] key (X) immediately starts delivery of the main protocol.
5. Once the Drip injection is delivered, the following message is displayed:

   WARNING!
   The Drip Mode Injection is complete.
   Start the Enabled Protocol.
   Press Close to return to the Start screen.

   Press the [Close] key and the Enabled protocol screen (Start screen) is displayed. The injector is now ready to deliver the main protocol. Adjustments to the protocol parameters can be made prior to starting delivery of the main protocol.

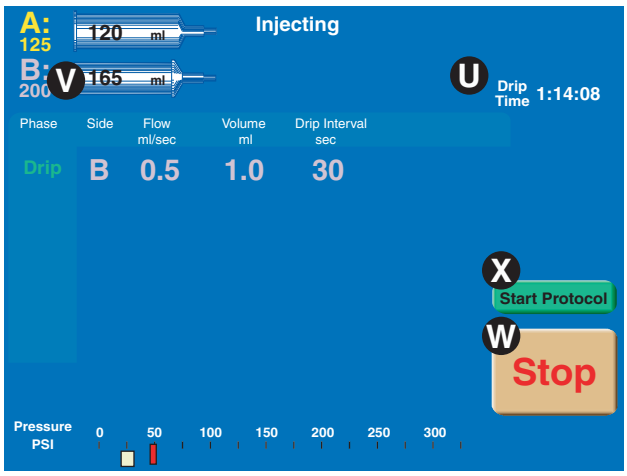


Console Drip Mode Screen

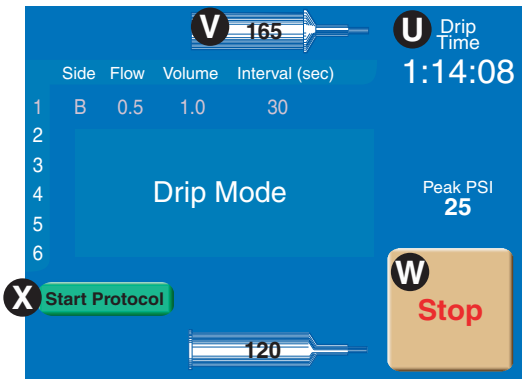


Powerhead Drip Mode Screen

Figure 5-6-1 Drip Mode Screen



Console Drip Mode Injecting Screen



Powerhead Drip Mode Injecting Screen

Figure 5-6-2 Drip Mode Injecting Screen

5.7 DELIVERING THE MAIN PROTOCOL

5.7.1 DANGERS, WARNINGS AND CAUTIONS

⚠ DANGER! ⚠

OPERATOR DUE DILIGENCE REQUIRED!
Delivering an injection to a patient requires due diligence on the part of the operator. Air entrapped in the syringe and tubing can cause patient injury or death. Always verify that both the syringe and tubing have been properly cleared of air just prior to starting the injection! The OptiVantage Injection System does not have the capability to check for air in the syringe and tubing. ***The operator is responsible for removing all air from the system.***

⚠ CAUTION! ⚠

REVIEW PARAMETERS
Prior to delivering an injection, review all parameters thoroughly to ensure that they are correct and appropriate for the procedure. Also, ensure that the contrast fluid is installed on the correct side of the powerhead.

5.7.2 STARTING DELIVERY OF THE MAIN PROTOCOL

Refer to Figure 5-7-1.

The protocol can be delivered by pressing the [Start] key (Ⓐ on Figure 5-4-1) either on the powerhead or the console or by pressing the remote handswitch. Once the injection is initiated, the Injecting screen, shown in Figure 5-7-1, is displayed, Total Time increments and syringe volume decrements. Note that the Peak PSI (pressure limit) parameter is indicated by the red line ⓐ. The current injecting pressure is indicated by the white bar ⓑ.

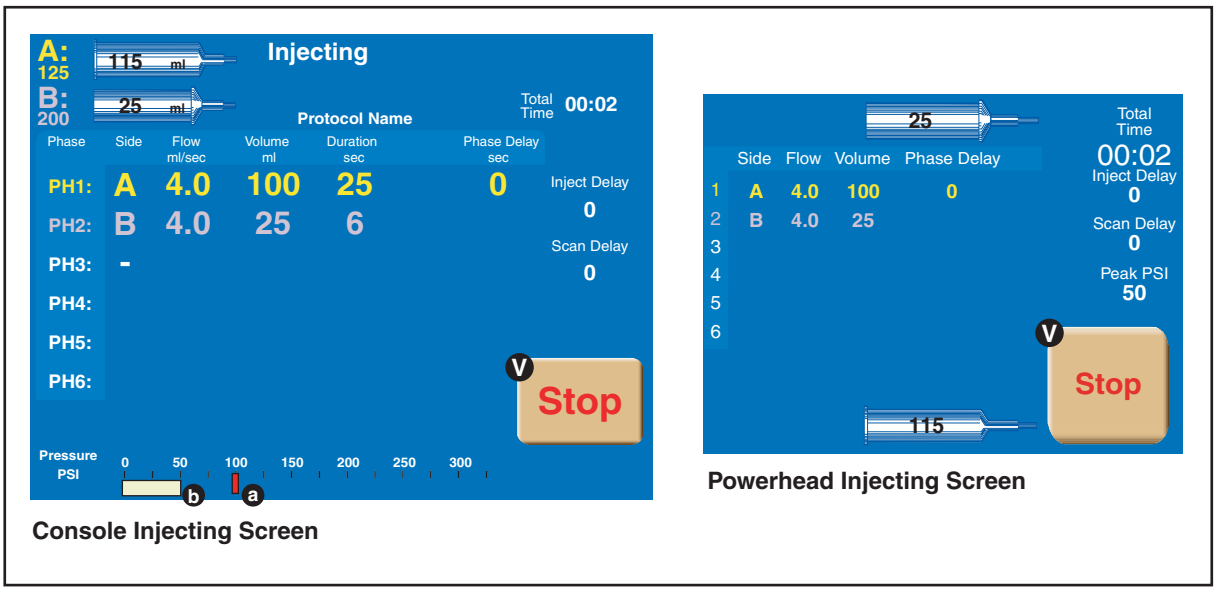


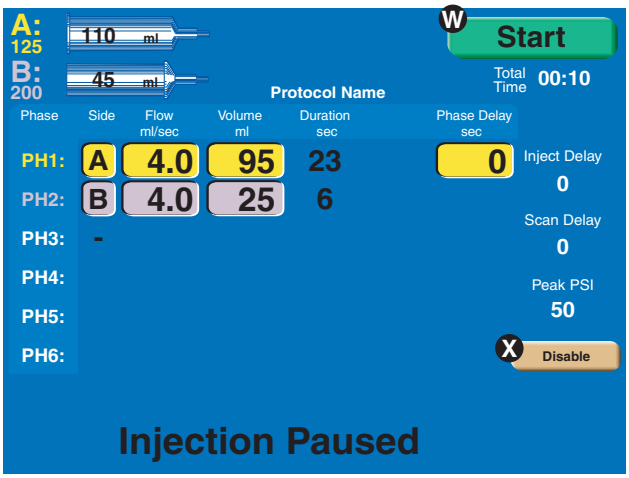
Figure 5-7-1 Injecting Screen

5.7.3 PAUSING AN INJECTION

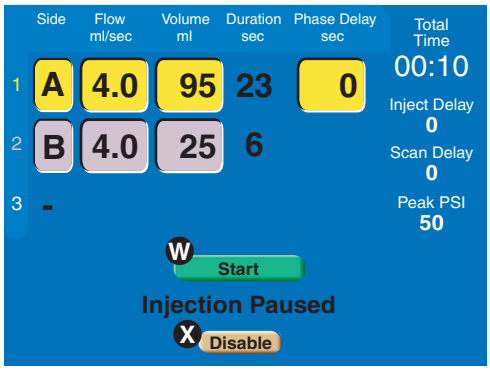
Refer to Figure 5-7-1 and Figure 5-7-2.

An injection may be immediately paused by pressing the [Stop] key (Ⓥ on Figure 5-7-1) on the console display or the powerhead display and also by depressing once on the handswitch. When the injector is paused, the screen shown in Figure 5-7-2 is displayed and the status lights on the console and powerhead will flash their respective color every 1/2 second.

While the injection is paused, the values for the flow rate, volume and phase delay can be changed on either the console screen or the powerhead screen. However, phases cannot be added or deleted when the injector is paused.



Console Paused Screen



Powerhead Paused Screen

Figure 5-7-2 Injection Paused Screens

5.7.4 RESTARTING A PAUSED INJECTION

Refer to Figure 5-7-2.

The injection can be restarted by pressing the [Start] key (W) on the console or the powerhead paused screens. The achieved values displayed on the Results screen after completion of the restarted injection represent the total volume delivered from the start of the injection and the average flow rate achieved since the restart.

5.7.5 TERMINATING AN INJECTION

Refer to Figure 5-7-1 and Figure 5-7-2.

Press the [Stop] key ((V) on Figure 5-7-1) then the [Disable] key ((X) on Figure 5-7-2) on the powerhead screen or console screen to terminate an injection.

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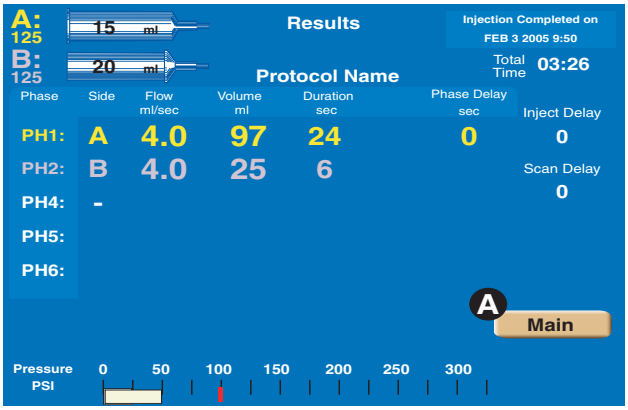
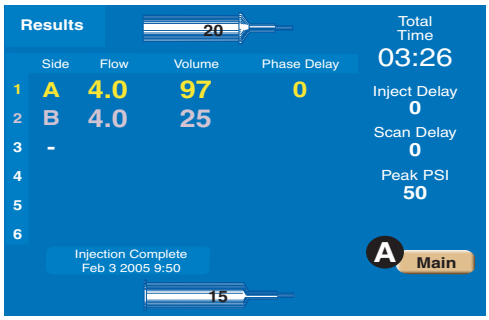
5.8 DISPLAYING RESULTS SCREEN

Refer to Figure 5-8-1.

Average flow rate, delivered volume and achieved pressure are displayed on both the console and the powerhead Results screen at the completion of the injection. Press the [Main] key (A) to display the Main screen.



Console Results Screen



Powerhead Results Screen

Figure 5-8-1 Results Screens

5.9 REMOVING 125 ML SYRINGES

After the completion of the injection, disconnect the tubing from Prefilled syringe(s) prior to retracting the ram(s). NOTE: Retraction of rams while 125 ml syringes are connected to tubing that contains check valves will create a vacuum in the syringe.

1. Using aseptic technique, disconnect patient from tubing.
2. Disconnect tubing from 125 ml syringe(s) and remove 200 ml syringe(s) from the injector. Discard according to hospital policy.
3. Retract 125 ml ram(s) and remove 125 ml syringe(s) and discard according to hospital policy.

6 SYSTEM GENERATED MESSAGES

This chapter contains instructions on responding to system generated messages. Messages are displayed on the powerhead and console screens in response to incorrect operator input or action and equipment status. These messages fall into two categories:

Operator Messages — Those messages that appear in response to incorrect operator input or to inform the operator of the status of the injector.

Alarm Messages — Those messages that appear when the OptiVantage's self-diagnostics detect a problem in the control circuitry.

6.1 OPERATOR MESSAGES

6.1.1 POWER UP MESSAGES

Hardware Initialization completed.

Message: Hardware Initialization completed. Searching for Power Control.

Occurs when: Upon power ON, the console displays this message to indicate the status of the injector.

Operator action: None.

6.1.2 PROGRAMMING MESSAGES

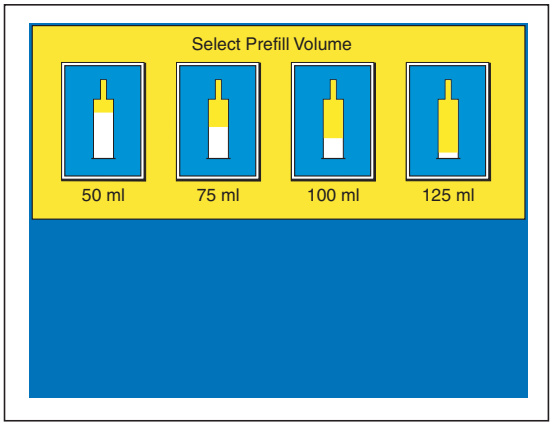
Auto-Fill in Progress

Message: Auto-Fill in progress. Please wait...

Occurs when: This message appears on the console screen when the powerhead is using the Auto-Fill feature to fill the syringe.

Operator action: None.

Automatic Prefill Syringe Size Sensor



Message: Select Prefill Volume 50 ml 75 ml 100 ml 125 ml

Occurs when: The injector's syringe size sensor has been unplugged or has failed.

Operator action: Plug in heater blanket/size sensor on underside of powerhead. Or, to use the injector without the sensor, press the corresponding graphic that matches the installed syringe size.

Changing Fluid Configuration

Message: The syringe fluid configuration has changed. This will prevent access to the stored protocols. Do you want to continue with these settings?

Occurs when: This message occurs when the operator updates the settings in the Setup screen changing the fluid configuration (i.e. A-side:contrast, B-side: saline changed to A-side:saline, B-side:contrast).

Operator action: This message is for informational purposes only in order to advise the operator that changing the fluid configurations will prevent access to stored protocols. Press the [Yes] key to continue with these settings. Press the [No] key to leave the fluid configuration unchanged.

Heater Blanket

Powerhead Message: Heater Blanket on this side of the injector has become disconnected or has failed. Check connection or call service. To continue without heater blanket, close window.

Console Message: The heater blanket on the A-side of the injector has become disconnected or has failed. Check connection or call service. To continue without heater blanket, close window.

Console Message: The heater blanket on the B-side of the injector has become disconnected or has failed. Check connection or call service. To continue without heater blanket, close window.

Occurs when: One of the 200 ml heater blanket connectors is unplugged or malfunctioning.

Operator action: Plug the heater blanket in or to use the injector without the heater blanket, press the [Close] key on the screen and continue. Contact your Service Department for corrective action regarding this message.

Insert Syringe SIDE A

Message 1: The syringe latch on side A is open. Please insert a CONTRAST filled syringe in side A of the injector and close the latch.

Occurs when: Message 1 occurs when the A-side is set up for contrast use and the 200 ml load lever or the 125 ml load clamps (dependent upon which faceplate is installed on the A-side) are in the load position.

Message 2: The syringe latch on side A is open. Please insert a SALINE filled syringe in side A of the injector and close the latch.

Occurs when: Message 2 occurs when the A-side is set up for saline use and the 200 ml load lever or the 125 ml load clamps (dependent upon which faceplate is installed on the A-side) are in the load position.

Operator action: This message is to advise the operator to load the correct syringe type into Side A.

Insert Syringe SIDE B

Message 1: The syringe latch on side B is open. Please insert a SALINE filled syringe in side B of the injector and close the latch.

Occurs when: Message 1 occurs when the B-side is set up for saline use and the 200 ml load lever or the 125 ml load clamps (dependent upon which faceplate is installed on the B-side) are in the load position.

Message 2: The syringe latch on side B is open. Please insert a CONTRAST filled syringe in side B of the injector and close the latch.

Occurs when: Message 2 occurs when the B-side is set up for contrast use and the 200 ml load lever or the 125 ml load clamps (dependent upon which faceplate is installed on the B-side) are in the load position.

Operator action: This message is to advise the operator to load the correct syringe type into Side B.

OptiBolus Key is not Installed

Message: OptiBolus Key is not installed. Insert OptiBolus Key and press Close to continue.

Occurs when: This message appears when the operator attempts to recall an OptiBolus protocol when the OptiBolus Key has been removed from the injector.

Operator action: To recall an OptiBolus protocol, the OptiBolus key must be installed at the rear of the power control. Install the OptiBolus Key, press the [Close] key on the screen and continue.

Patency Check in Progress

Message: Patency Check in progress. Please wait...

Occurs when: This message appears on the console screen when the powerhead is delivering a Patency Check injection.

Operator action: None.

Programmed to Deliver Contrast from both Side A and Side B

Message: Attention, the current protocol is programmed to deliver contrast on Side A and Side B. Press Close to continue.

Occurs when: The injector is set up for Contrast (A-side)/Contrast (B-side) delivery.

Operator action: This message is for informational purposes only in order to advise the operator to use caution when delivering more than 125 ml of contrast into a patient. Delivering more than 125 ml of contrast into one patient is not advised.

Protocol Modification in Progress at Console

Message: Protocol modification in progress at console. Please wait...

Occurs when: This message appears on the Powerhead display to inform the operator that Protocol modification is taking place at the Console display.

Operator action: The Powerhead display will refresh upon pressing the [Main] key on the Console.

Protocol Name Already Exists

Message: Protocol name already exists. Please change or cancel.

Occurs when: The operator enters an existing protocol name on the keyboard when trying to store a new protocol.

Operator action: Enter a new protocol name or press the [Cancel] key.

Protocol Name Not Valid

Message: Protocol name not valid. Please change or cancel.

Occurs when: The operator enters a protocol name that is blank or begins with a space.

Operator action: Enter a new, valid protocol name or press the [Cancel] key.

Setup to Deliver Contrast from A-side and B-side

Message: Settings on the Setup Screen will allow contrast to be injected from both sides of the injector. Contrast injections in excess of a single full syringe are possible. Do you want to continue with these settings? Yes/No

Occurs when: This message occurs when the operator updates the settings in the Setup screen for Syringe Fluid A: Contrast (A-side)/Syringe Fluid B: Contrast (B-side) delivery.

Operator action: This message is for informational purposes only in order to advise the operator to use caution when injecting more than one syringe of contrast into a patient. Injecting more than one syringe of contrast into one patient is not advised. Press the [Yes] key to continue with Contrast (A-side)/Contrast (B-side) delivery. Press the [No] key to change the setting for either Syringe Fluid A or Syringe Fluid B.

Unreadable Data on Powerhead or Console Display

Message: NO MESSAGE ASSOCIATED WITH THIS CONDITION.

Occurs when: Any single user display contains unreadable data.

Operator action: The injector can be used, with caution, if any single user display contains unreadable data. Cycle power to reset injector. If this condition persists, contact your Service Department for corrective action. If this issue persists, contact your Service Department for corrective action.

Volume Key Flashing a Magenta Color

Message: NO MESSAGE ASSOCIATED WITH THIS CONDITION.

Occurs when 1: The volume key(s) on the main screen will flash a magenta color to indicate that its value(s) is greater than the volume contained in its respective syringe.

Operator action: Lower the value of the applicable volume key(s) or fill the syringe(s) with an adequate amount of fluid.

Occurs when 2: The volume key on the Drip Mode screen or Patency Check screen will flash a magenta color to indicate that delivering this amount will compromise the volume available for the main protocol. Note that if the Volume key is flashing a Magenta Color, the [Start Drip] key or the [Start Patency] key will not appear.

Operator action: Lower the value of the volume key or fill the syringe with more fluid.

6.1.3 FACEPLATE MESSAGES

New Faceplate Installed

Message: A new Faceplate Adapter has been detected. Make sure the new Adapter is properly installed. Press Continue and the ram will automatically move forward to lock the faceplate.

Occurs when: A new faceplate is installed on the injector.

Operator action: Press the [Continue} key to allow the injector to automatically move the ram in order to lock the faceplate into place.

6.1.4 AUTO-FILL MESSAGES

Rotate the Powerhead to Activate Auto-Fill

Message: Rotate the Powerhead to the vertical position to activate Auto-Fill sequence.

Occurs when: This message occurs when a 200 ml syringe is installed [with the ram in the “home’ (fully expelled) position] but the powerhead is not oriented in the vertical position. The Auto-Fill screen is automatically displayed when 1) the ram is in the “home” position 2) a 200 ml syringe is installed and then 3) the powerhead is rotated to the vertical position.

Operator action: This message is for informational purposes only in order to advise the operator to rotate the powerhead to the vertical position in order to access the Auto-Fill feature.

6.1.5 SCANNER CONNECTIVITY

Scanner Interface Connection not Available

Message: The Scanner Interface connection is not available. To continue without the interface, close window.

Occurs when: When the OEM Interface on the Setup screen in set to On, but the OEM interface is not communicating with the injector properly, this message occurs.

Operator action: To continue without the OEM interace, press the [Close] key. Contact your Service Department for corrective action regarding this message.

6.1.6 ENABLE PROCESS MESSAGES

Enable sequence not completed

Console Message: The Enable sequence has not been completed at the Powerhead.

Powerhead Messages:

for 125 ml syringe/faceplate	*for 200 ml syringe/faceplate*
The Enable sequence is not complete.	The Enable sequence is not complete.
Install a new syringe.	Install a new syringe.
Tilt Powerhead up.	Tilt Powerhead up.
Purge syringe.	Fill syringe.
Tilt powerhead down.	Purge syringe.
	Tilt powerhead down.

Occurs when: As an additional precaution against the injection of an air embolism, the injector's software checks for a "Purge sequence" (125 ml syringe) and a "Fill/Purge sequence" (200 ml syringe) before allowing the injector to be enabled. If the Purge Sequence or Fill/Purge Sequence has not occurred and the [Enable] key is pressed, the console message will appear and the appropriate powerhead message [missed step(s)] will appear. If correct steps have been taken on either the A-side or the B-side, the message "This side ready." will appear.

Operator action: Follow the step indicated on the powerhead to allow the injector to be enabled. ***Note that it is the operator's responsibility to ensure the syringe and tubing does not contain air.***

Hand switch is closed.

Message: The hand switch is closed. Please check hand switch and press Close to continue.

Occurs when: As a safety precaution to prevent unintentional injections, the injector cannot be enabled if its hand switch is closed. If the hand switch is closed and the injector's enable key is pressed, this message appears.

Operator action: Check the appropriate switch to ensure that it is open. Once checked, press the [Close] key and continue the enable process. If you are unable to open the switch (as indicated by the return of this message), unplug the hand switch and continue. Contact your Service Department for corrective action regarding the hand switch.

Insufficient volume

Message: Insufficient volume to run this injection.

Occurs when: The [Enable] key is pressed when a volume key is flashing a magenta color. The volume key(s) on the main screen flash a magenta color to indicate that its value(s) is greater than the volume contained in its respective syringe.

Operator action: Lower the value of the applicable volume key(s) or fill the syringe with more fluid. ***Note that it is the operator's responsibility to ensure the syringe and tubing does not contain air.***

6.1.7 INJECTION STOPPED MESSAGES

Drip Expired

Message: WARNING! The Drip Mode injection is complete. Start the Enabled Protocol. Press Close to return to the Start screen.

Occurs when: This message appears when the Drip Mode injection is complete.

Operator action: Press the [Close] key to return to the Start screen to allow for delivery of the main protocol.

Injector Stalled

Message: Injector Disabled! Injector stalled. Check fluid path for obstructions. Press Close to continue.

Occurs when: This message appears if the injector has started an injection but cannot move the ram.

Operator action: Press the [Close] key and check the fluid path for any obstructions and remove them. Restart the Enable process.

Pressure Limiting

Message: Injection is pressure limiting! Do you want to continue or stop?

Occurs when: This message appears when the injector is injecting under maximum pressure limit conditions and cannot achieve the set flow rate.

Operator action: Press the [Continue] key to perform the injection under maximum pressure limit conditions. Press the [Stop] key to review the Flow Rate parameter to ensure it is not set too high for the procedure and also review the Pressure Limit parameter to ensure it is not set too low. Check the delivery system for closed stopcocks or kinked tubing. Under normal circumstances, the injection pressure should not reach the pressure limit. Reaching the pressure limit defeats the purpose of a flow rate injector.

Syringe Latch Open

Message: The injection has stopped. A syringe latch is open. Press Close to continue.

Occurs when: While the injector is enabled or injecting, the injector software checks to ensure the 125 ml syringe clamps and/or the 200 ml syringe levers are in the loaded (closed) position. If either are opened, the injector will immediately disable and display this message.

Operator action: Close the syringe clamps and/or levers. Press the [Close] key and re-enable the injector.

6.1.8 RESULTS SCREEN MESSAGES

Pressure Limited

Message: This injection was pressure limited.

Occurs when: This message appears on the Results screen if the injector injects under maximum pressure limit conditions but cannot achieve the set flow rate.

Operator action: This message is to advise the operator that the injection was delivered but under pressure limited conditions. Under normal circumstances, the injection pressure should not reach the pressure limit. Reaching the pressure limit defeats the purpose of a flow rate injector. Review the Flow Rate parameter to ensure it was not set too high for the procedure and also review the Pressure Limit parameter to ensure it was not set too low. Check the delivery system for closed stopcocks or kinked tubing.

6.2 ALARM MESSAGES

Refer to Figure 6-2-1.

The microprocessor control circuits in the OptiVantage continuously monitor all important functions from the moment that the unit is turned on. These checks, transparent to the operator, occur many times each second, monitoring the safe performance of the injector. If a fault is detected, the unit will lock into a fault mode and display an Alarm code.

Cycle power to reset the injector. If the alarm persists, contact your Service Department for corrective action regarding this alarm.

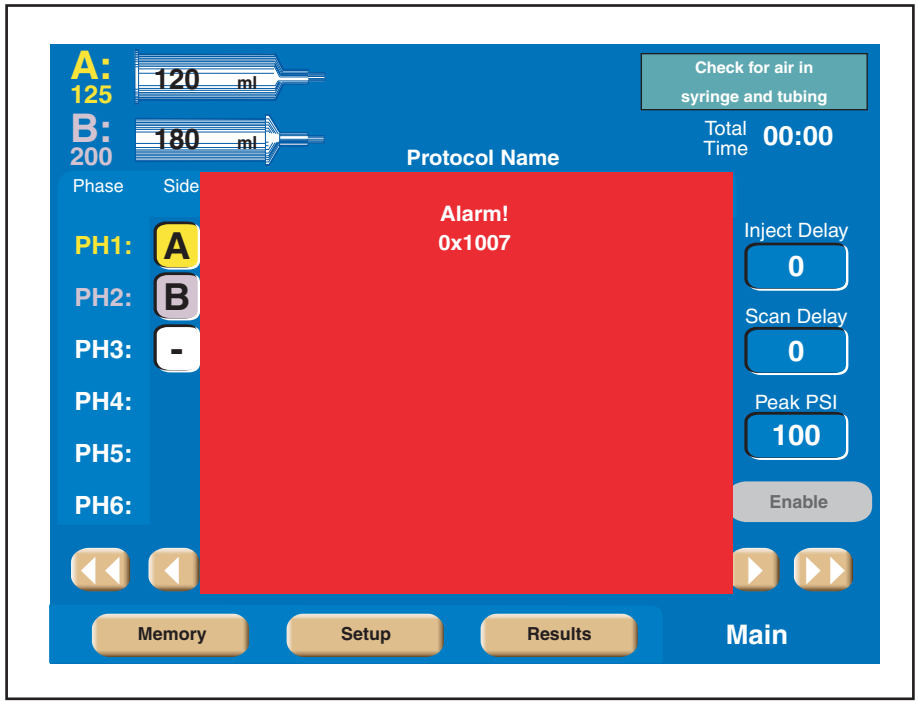


Figure 6-2-1 Alarm Message

7 CARE OF UNIT

NOTE: Preventive maintenance schedule and service procedures are in the Service Manual.

7.1 DAILY INSPECTION

7.1.1 200 ML PRESSURE SLEEVE

The 200 ml pressure sleeve has a limited life-span and must be replaced periodically. Its expected life-span may range from thirty (30) days or less to over two (2) years depending on pressures encountered, the number of injection cycles and the cleaning and sterilization techniques utilized. Check the 200 ml pressure sleeve(s) daily for signs of stress, crazing lines, or cracks and replace immediately when any of these symptoms are found.

⚠ WARNING! ⚠

CHECK PRESSURE SLEEVE DAILY!
Syringe pressure sleeves must withstand high pressures generated during injection delivery. Defective sleeves may shatter or explode under these conditions. Always inspect pressure sleeve closely before using injector. While viewing all areas; look for stress cracks (around the front or at the shoulder area), discard any pressure sleeve exhibiting signs of stress, crazing lines or cracks. The use of such parts may cause injury and/or an aborted injection.

7.2 CLEANING

7.2.1 200 ML PRESSURE SLEEVE AND BASE

On a daily basis, move the ram to the fully retracted position and wipe out the inside of the pressure sleeve with a damp (with water), lint-free towel.

NOTE: Do not autoclave the pressure sleeve. *Autoclaving will shorten the life of the pressure sleeve.*

The entire base and pressure sleeve may be placed or soaked in warm water with a mild soap to remove any hardened contrast. This procedure is also helpful if the locking lever is hard to rotate. *Do not use alcohol-based detergents. The water should not contain the following substances, even in trace amounts:*

- esters
- ethers
- ketones
- chlorides
- n-Alkyl
- alcohols (other than ethyl alcohol)
- cleaners and disinfectants (such as SaniZide and TB-Cide Quat)
- products containing: dimethyl benzyl, ammonium chlorides, and dimethyl ethylbenzyl

7.2.2 125 ML CRADLE ASSEMBLY

On a daily basis, move the ram to the fully retracted position and wipe out the inside of the cradle with warm water containing a mild soap. *Do not submerge the cradle in any liquid or damage to its internal components will occur.*

7.2.3 CONSOLE AND POWERHEAD

The console and powerhead may be dusted by using a lint-free cloth. To clean the touch screen, use a *nonabrasive* cloth towel and any commercially available *non-ammonia* window cleaner to regularly clean the surface. *The cleaning solution should be applied to the towel rather than the surface of the touch screen.* The touch screen has air vents and is not designed with water tight bezels so fluid ingress may occur from behind the panel if not cleaned carefully.

7.2.4 POWER SUPPLY

Clean the exterior of the power supply by spraying a cloth with an all-purpose household cleaner, then gently wipe clean.

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NOTES

Liebel-Flarsheim

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