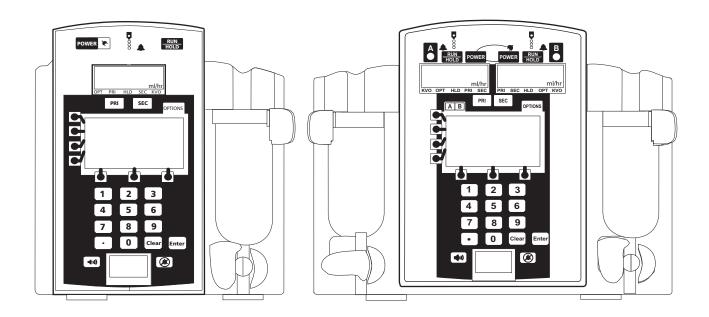
User Manual

Alaris® SE Pump

Models 7100/7130 and 7200/7230, Rev2.X

April 2011





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Introduction

This document provides directions for use for the Alaris® SE pump, Models 7100/7130 and 7200/7230. It is used in conjunction with:

- Instructions for Alaris® SE pump administration IV sets
- Drug product labeling
- Alaris SE pump Technical Service Manual
- Ground test equipment instructions
- ECG monitoring system instructions

The Alaris SE pump is intended for use in professional healthcare environments, including healthcare facilities, home care, and medical transport, that utilize infusion pumps for the delivery of fluids, medications, blood, and blood products. It is indicated for continuous or intermittent delivery through clinically acceptable routes of administration; such as, intravenous (IV), intra-arterial (IA), subcutaneous, epidural, enteral, and irrigation of fluid spaces.

The Alaris SE pump is available as either a single or a dual channel pump. The dual channel pump is a two-channel device intended to deliver multiple infusions to a single patient.

The Alaris SE pump uses a wide variety of administration sets for the AccuSlide® flow regulator. The 72 Series administration sets are designed for use with the instruments as well as for gravity-flow, stand-alone use. The unique, patented AccuSlide flow regulator has an integral flow control device that minimizes accidental free-flow when the set is removed from the instrument and provides accurate rate control during gravity administration.

Qualified service personnel can configure many features of the instrument to meet specialized needs. See *Configurable Options* on page *92* for a list of the configurable options and their default settings. Refer to the Technical Service Manual for the procedure on how to set selected configuration parameters.

Documentation provided with this product might reference product not present in your facility or not yet available for sale in your area.

WARNING

Read all instructions before using the Alaris SE pump.

CAUTION

ROnly

Getting Started Introduction

Introduction (Continued)

Administration Sets: See Administration Set Information on

page 14.

Alarms, Alerts, Prompts: See Alarms, Alerts, Prompts on

page 108.

Electromagnetic Environment: See Regulations and

Standards on page 119.

Contraindications: None known.

Warnings and Cautions:

Warnings and cautions provide information needed to safely and effectively use the Alaris SE pump. See *Warnings and Cautions* on page 73.

A **DANGER** is an alert to an <u>imminent</u> hazard which could result in <u>serious</u> personal injury and/or product damage if proper procedures are not followed.

A **WARNING** is an alert to a <u>potential</u> hazard which could result in <u>serious</u> personal injury and/or product damage if proper procedures are not followed.

A **CAUTION** is an alert to a <u>potential</u> hazard which could result in <u>minor</u> personal injury and/or product damage if proper procedures are not followed.

Getting Started Unpacking

Unpacking

- Remove instrument from carton.
- 2. IMPORTANT: Plug instrument into an AC outlet a minimum of 24 hours prior to use.

Maximum battery capacity, as well as gauge accuracy, is reached after several charge/discharge/recharge cycles in the refresh process. CareFusion recommends that the battery be fully charged/discharged/recharged, using the refresh cycle, before placing the instrument in use.

3. Perform regular inspections (see *Inspection Requirements* on page *116*).

See *Configurable Settings* on page 87 for a list of the configurable features.

WARNING

Failure to properly charge the battery results in an instrument malfunction. Biomedical personnel in the facility are responsible for unpacking the instrument and ensuring that the battery is fully charged before placing the instrument in use.

Check-In and Configuration

This is a quick reference procedure for check-in and configuration of new and recently serviced instruments.

- Rate Accuracy Qualification Test (Rate Verification)
- Set Sensor Check/Pressure Calibration Verification
- Functional Test
- Flow Stop Test
- Ground Current Leakage Test
- · Ground Resistance Test
- Instrument Configuration

WARNING

Instruments returned from the service depot might be set to factory defaults. Biomedical personnel in the facility are responsible for checking in the instrument and ensuring the current hospital-approved configurations are loaded.

CAUTION

Charge the battery for a minimum of 24 hours prior to performing the check-in and configuration procedures. Batteries without a full charge on initial use might become damaged and/or cause a malfunction.

Rate Accuracy Qualification Test

This procedure is to be used only when testing an instrument during a new instrument check-in or when just received from the service depot center. This test is to verify that damage or changes to the instrument did not occur during shipment and handling.

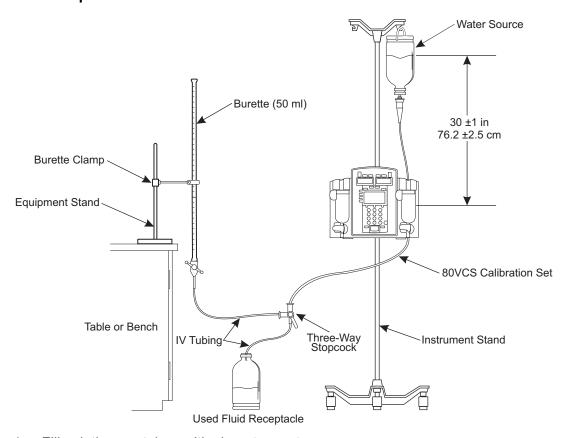
Rate accuracy should be tested using a Model 80VCS Calibration Set. The system is designed to produce overall accuracy of ±5% for rates greater than 1 mL/h and up to 999.9 mL/h, and ±6.5% for rates equal to or less than 1 mL/h, 95% of the time with 95% confidence (see *Trumpet and Start-Up Curves* on page *100* for additional information). The system performance with a calibration set produces a smaller variability. In order to ensure overall accuracy is achieved, new instruments are tested to an accuracy of ±3% with the Model 80VCS set during a new instrument check-in.

Due to the dynamic monitoring feature, the rate is varied during operation. For this reason, CareFusion does not recommend using automatic testers to check rate accuracy. Generally, these devices collect small samples and might cause the results to be incorrect, even though the instrument is accurate.

Do not use the Model 80VCS Calibration Set for more than 30 rate verification runs (15 rate calibration number changes). Keep track of the number of times the set is used by recording each use on the 80VCS insert or on a separate record.

Rate Accuracy Qualification Test (Continued)

Test Setup



- Fill solution container with clean tap water.
- 2. Close AccuSlide flow regulator clamp on 80VCS set and then insert spike into solution container.
- 3. Open AccuSlide flow regulator clamp and prime set. Ensure that all air is expelled from set.
- 4. Close AccuSlide flow regulator clamp.
- 5. Connect output of set to one side of three-way stopcock.
- 6. Load set into instrument and close latch.
- 7. Verify no fluid flow or drops falling in drip chamber.

Rate Accuracy Qualification Test (Continued)

- 8. Plug instrument into a properly grounded AC outlet.
- 9. Set stopcock to output into a class A or B burette.
- 10. Press **POWER** key to turn channel on.
- 11. Set primary infusion rate to 400 mL/h.
- 12. Set VTBI to 20 mL.
- 13. Ensure that instrument—both channels if dual channel—is set to **Pressure** mode. ¹
- Press RUN/HOLD key to start primary infusion. Infuse until tubing and burette are fully primed—approximately one minute.
- 15. Press **RUN/HOLD** key to stop infusion.
- 16. Adjust height of instrument and/or fluid container to attain a head height of 30 ±1 inches/76.2 ±2.5 centimeters between middle of pumping mechanism and fluid level in one of following sources: ²
 - bag or vented bottle (vent closed on administration set)
 - drip chamber (unvented bottle with vent open on administration set).
- 17. Adjust fluid level in burette until meniscus is level with zero mark on burette. ³

The factory default for the Monitoring Options mode is Pressure.

A 30-inch head height was used in the initial qualification of this
process and is the recommended head height for the Check-In
Rate Accuracy Test. Based on observed field use, a 24-inch
head height was also tested and verified for the Rate Accuracy
Specification.

^{3.} The instrument might need to be run to prime the line to the zero level of the burette (step 14).

Rate Accuracy Qualification Test (Continued)

- 18. Verify that primary infusion rate is 400 mL/h.
- 19. Reset VTBI to 40 mL and clear volume infused.
- 20. Press RUN/HOLD key to start primary infusion.
- Instrument will run approximately 360 seconds (six minutes) to complete delivery and then go into KVO mode.
 Stop instrument within one second of its entering KVO mode.
- 22. Make a note of volume collected in burette.
- 23. Note expected volume, as identified on 80VCS set insert.
- 24. Do not remove 80VCS set from instrument until one of following conclusions is determined:
 - Instrument passes rate verification and calibration is not needed.
 - Rate calibration number was changed and instrument now passes verification.
 - Mechanism replacement is required.
- 25. Calculate volume accuracy, as follows:

Volumetric Volume Accuracy Error Computation

Vcollected = volume in burette in milliliters

Vexpected = characterized volume printed on 80VCS set insert

Step 1: A = Vcollected ÷ Vexpected

Step 2: $B = A \times 100$

Step 3: % Error (round % Error to nearest tenth of a percent) = B - 100

A passing result is 0.0±3%.

Rate Accuracy Qualification Test (Continued)

- 26. If result is outside required range of ±3% from expected volume, perform one of following steps:
 - If result is inside a range of -5.5% to +7.0% from expected volume, perform rate calibration (refer to Technical Service Manual). Set rate calibration number to 0.0% before running rate test, to determine a new calibration number.
 - If result is outside a range of -5.5% to +7.0% from expected volume, return instrument to CareFusion for repair or replace mechanism.
- 27. Set stopcock to drain fluid in burette to zero level, in preparation for next test.

Alternative Rate Accuracy Qualification Test

This procedure is to be used only when testing an instrument during a new instrument check-in or when just received from the service depot center. This test is to verify that damage or changes to the instrument did not occur during shipment and handling.

Due to the dynamic monitoring feature, the rate is varied during operation. For this reason, CareFusion does not recommend using automatic testers to check rate accuracy. Generally, these devices collect small samples and might cause the results to be incorrect, even though the instrument is accurate.

Do not use the Model 80VCS Calibration Set for more than 30 rate verification runs (15 rate calibration number changes). Keep track of the number of times the set is used by recording each use on the 80VCS insert or on a separate record.

The test setup is the same as for the *Rate Accuracy Qualification Test* with the following exceptions:

- Burette and equipment stand are replaced with a digital scale, Acculab Vic-212 or equivalent, and 50 mL or 100 mL flask (plastic or glass).
- Three-way stopcock and used fluid receptacle are not needed.

Alternative Rate Accuracy Qualification Test (Continued)

- 1. Fill solution container with clean tap water.
- 2. Close AccuSlide flow regulator clamp on 80VCS set and then insert spike into solution container.
- 3. Open AccuSlide flow regulator clamp and prime set. Ensure that all air is expelled from set.
- Close AccuSlide flow regulator clamp.
- 5. Place flask in middle of scale.
- Load set into instrument and close latch.
- 7. Verify no fluid flow or drops falling in drip chamber.
- 8. Plug instrument into a properly grounded AC outlet.
- Place output of set so it drips into flask. Do not let set rest on flask.
- 10. Press **POWER** key to turn channel on.
- 11. Set primary infusion rate to 400 mL/h.
- 12. Set VTBI to 20 mL.
- 13. Ensure that instrument—both channels if dual channel—is set to **Pressure** mode. ¹
- 14. Press **RUN/HOLD** key to start primary infusion. Infuse until tubing is fully primed—approximately one minute.
- 15. Press RUN/HOLD key to stop infusion.

The factory default for the Monitoring Options mode is Pressure.

Alternative Rate Accuracy Qualification Test (Continued)

- 16. Adjust height of instrument and/or fluid container to attain a head height of 30 ±1 inches/76.2 ±2.5 centimeters between middle of pumping mechanism and fluid level in one of following sources:
 - bag or vented bottle (vent closed on administration set)
 - drip chamber (unvented bottle with vent open on administration set)
- 17. Zero reading on scale.
- 18. Verify that primary infusion rate is 400 mL/h.
- 19. Reset VTBI to 40 mL and clear volume infused.
- 20. Press RUN/HOLD key to start primary infusion.
- 21. Instrument runs approximately 360 seconds (six minutes) to complete delivery and then goes into KVO mode. Stop instrument within one second of its entering KVO mode.
- 22. Make a note of scale reading in grams.
- 23. Note expected volume, as identified on 80VCS set insert.
- 24. Do not remove 80VCS set from instrument until one of following conclusions is determined:
 - Instrument passes rate verification and calibration is not needed.
 - Rate calibration number was changed and instrument now passes verification.
 - · Mechanism replacement is required.

Alternative Rate Accuracy Qualification Test (Continued)

25. Calculate gravimetric accuracy as follows:

Gravimetric Volume Accuracy Error Computation

Vcollected = volume in flask in grams

Vexpected = characterized volume printed on 80VCS set insert

Step 1: A = Vcollected ÷ Vexpected

Step 3: $B = A \times 100$

Step 3: % Error (round % Error to nearest tenth of a percent) = B - 100

A passing result is 0.0±3%.

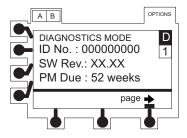
- 26. If result is outside required range of ±3% from expected volume, perform one of following steps:
 - If result is inside a range of -5.5% to +7.0% from expected volume, perform rate calibration (refer to Technical Service Manual). Set rate calibration number to 0.0% before running rate test, to determine a new calibration number.
 - If result is outside a range of -5.5% to +7.0% from expected volume, return instrument to CareFusion for repair or replace mechanism.
- 27. Empty flask and reset scale to zero, in preparation for next test.

Set Sensor Check/Pressure Calibration Verification

 Access **DIAGNOSTICS MODE** by pressing and holding upper left soft key on power-up. For details, refer to Technical Service Manual, *Troubleshooting* chapter for details, or contact CareFusion Technical Support.

XX.XX in illustrated display represents current software revision.

- 2. Advance to **D6** page and choose **Cal Pressure**—both Channel A and Channel B for dual channel instruments.
- 3. Verify that both **0 mmHg** and **500 mmHg** readings indicate **Pass**.



Set Sensor Check/Pressure Calibration Verification (Continued)

- 4. Install a standard set and close latch. Verify that reading is over 170, to confirm set sensor operation.
- Remove standard set and verify that **Sensor =** reading is in -80 mmHg to +30 mmHg range, to verify pressure calibration.

If reading is out of range, refer to Technical Service Manual, *Pressure Calibration* section, or contact CareFusion Technical Support for assistance.

Functional Test

- Turn instrument on without set installed. Verify that it beeps and that red alarm light flashes but does not stay lit.
- 2. Set infusion rate to 460 mL/h and VTBI to 100 mL.
- 3. With latch closed, press RUN/HOLD key, and rate and VTBI \neq 0 to cause **Set Out** and **Air In Line** messages.
- 4. Open latch.
- 5. Install primed administration set with latch open.
- 6. Verify that instrument displays **Air In Line** and **Latch Open** messages.
- 7. Close latch and verify that display returns to setup page.
- Perform Upstream Occlusion Test, as follows:
 - a. Verify that infusion rate is set to 460 mL/h.
 - b. With instrument on hold, or at start-up, verify that primary VTBI is set to greater than 100 mL.
 - c. Press RUN/HOLD key to begin infusion.
 - d. Clamp off IV line just above instrument—about two inches—to simulate an upstream occlusion.
 - e. Verify that instrument stops running, alarms, and displays **OCCLUSION UPSTREAM** within 60 seconds.

Functional Test (Continued)

- f. Press RUN/HOLD key to silence alarm and put instrument on hold.
- g. Release or open clamp and remove from tubing.
- h. Press **RUN/HOLD** key to resume infusion. Alarm should not reoccur.
- 9. Perform Downstream Occlusion Test, as follows:
 - a. Continue infusing (from step 8h).
 - b. Verify that rate is set to 460 mL/h.
 - c. Clamp off IV line just below instrument—about two inches—to simulate a downstream occlusion.
 - Allow instrument to run until it alarms OCCLUSION DOWNSTREAM. Verify that this occurs within 60 seconds.
 - e. Press **RUN/HOLD** key to silence alarm and put instrument on hold.
 - f. Release or open clamp and remove from tubing.
 - g. Press **RUN/HOLD** key to resume infusion. Alarm should not reoccur.
 - h. Press RUN/HOLD key to stop infusion.

Flow Stop Test

- 1. With an administration set primed and loaded in instrument, turn power off.
- With all tubing clamps open and fluid container two or more feet above instrument, verify that no fluid flows through set.
- 3. Open latch and remove set. Verify that no fluid flows through set.

Getting Started Storage

Check-In and Configuration (Continued)

Ground Current Leakage Test

Use a DNI Nevada Model 232D (or equivalent) to measure the ground leakage current. Refer to the test equipment's operation manual for the proper setup and measurement technique. Leakage current must be $\leq 100~\mu A$ for normal and reversed line polarity.

Ground Resistance Test

Use a DNI Nevada Model 232D (or equivalent) to measure the ground resistance. Measure resistance from the AC power plug ground pin to the screw for the power cord strap, or to the screw for the battery cover on the chassis. Refer to the test equipment's operation manual for the proper setup and measurement technique. Resistance must be $\leq 0.10\Omega$.

Instrument Configuration

Instrument configuration is set by qualified personnel in the Configuration and Diagnostics modes.

Storage

Plug the instrument into an AC outlet during storage to ensure that the battery is fully charged when needed. The * (AC indicator light) is green when the instrument is plugged in.

Close the latch(es) when the instrument is not in use.

Administration Set Information

General

The Alaris SE pump uses a wide variety of AccuSlide flow regulator administration sets. The sets dedicated for use with the Alaris SE pump are designed for use with the instruments as well as for gravity-flow stand-alone use. The unique, patented AccuSlide flow regulator has an integral flow control device that minimizes the risk of unintended flow when the set is removed from the instrument, and provides accurate rate control during gravity administration.

CAUTION

Do not connect the ground resistance probe to the pressure transducer.

General (Continued)

- For specific administration set instructions, refer to directions for use provided with set.
- Use aseptic technique when handling sets and syringes.
- Administration sets are supplied with a sterile and nonpyrogenic fluid path for one-time use. Do not re-sterilize or re-use.
- For administration set replacement interval, refer to facility protocol and/or government standards (such as: CDC guidelines in the United States) and see SmartSite® Needle-Free Valve on page 15.
- Discard administration set per facility protocol.
- For IV push medication, put instrument on hold and occlude tubing above injection port during administration.
- Flush port(s) per facility protocol.
- Place a sterile replacement cap on open end of tubing connector when not in use. Discard tubing when integrity has been compromised.

SmartSite® Needle-Free Valve

The SmartSite® needle-free valve is designed to permit injection and aspiration of fluids without the use of needles.

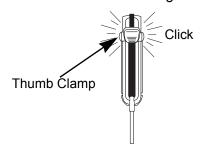
- Use proper hand-hygiene procedures. Wash hands with conventional antiseptic-containing soap and water or disinfect with waterless alcohol-based gels or foams.
- 2. Prepare SmartSite needle-free valve.
 - Always swab top of valve port, prior to every access, with sterile 70% isopropyl alcohol wipe and allow to dry.
 - For multiple syringes, swab prior to each syringe access.
 - Replace every 72 hours or 100 activations, whichever comes first.

Exception: For infusions of blood, blood products, or lipid emulsions replace every 24 hours.

Prepare Solution Container and Set

- 1. Prepare the primary solution container in accordance with the manufacturer's directions for use.
- 2. Slide AccuSlide flow regulator thumb clamp down until an audible click verifies that it is in fully closed position.

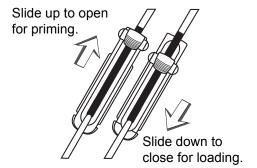
AccuSlide flow regulator



WARNING

- Use only sets dedicated for use with the Alaris SE pump. The use of any other set might cause improper instrument operation, resulting in an inaccurate fluid delivery or other potential hazard.
- Discard if packaging is not intact or protector caps are unattached.

- 3. Spike solution container.
- 4. Fill drip chamber to ²/₃ full.
- 5. If container requires venting, open vent cap on spike.
- 6. Invert AccuSlide flow regulator.
- 7. Slide AccuSlide flow regulator thumb clamp to open position to **slowly** prime set.
- 8. Close AccuSlide flow regulator clamp when priming is complete, as in Step 2. Verify that no fluid is flowing.
- 9. If desired, a gravity flow rate may be adjusted with AccuSlide flow regulator thumb clamp.

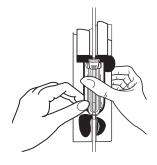


Load Set

- 1. Slide AccuSlide flow regulator thumb clamp down until an audible click verifies that it is in fully closed position.
- 2. Using both hands, press top and bottom of AccuSlide flow regulator into instrument until it snaps into place.
 - Verify that three gray fingers (clamp arms) on each side of pumping mechanism have engaged AccuSlide flow regulator.
 - b. Let go of set.

A properly loaded set stays in instrument.

- Press firmly just below blue thumb clamp on AccuSlide flow regulator while fully closing latch to left.
 - If resistance is met while closing latch, remove set, verify that AccuSlide flow regulator is fully closed, and then reinstall set.
 - Verify that thumb clamp has moved to open (up) position prior to starting infusion.
- 4. Attach set to patient's vascular access device.
- 5. Verify flow from IV container after starting infusion.



WARNING

After set installation, verify that no fluid is flowing through the set's drip chamber, to avoid free-flow.

CAUTION

Before operating the instrument, verify that the administration set is free from kinks and installed correctly in the instrument.



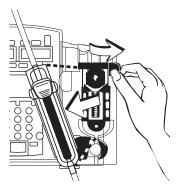
Remove Set

- Place channel on hold.
- 2. Open latch.

AccuSlide flow regulator automatically closes to prevent accidental unintended flow.



Press latch fully to right.Set is ejected from instrument.



Change Solution Container

- 1. Place channel on hold.
- 2. Remove empty solution container.
- 3. Spike new container.
- 4. Ensure that drip chamber is filled to ²/₃ full.

WARNING

Even though the instrument automatically closes the AccuSlide flow regulator, verify that the AccuSlide flow regulator is closed when the set is removed from the instrument, to prevent unintended flow.

CAUTION

Do not attempt to force the set from the instrument. Send the instrument to qualified service personnel.

References throughout this procedure to specific drugs and drug doses are for illustration purposes only. Refer to specific drug product labeling for information concerning appropriate administration techniques and dosages.

IMPORTANT:

- Prior to starting or restarting an infusion, verify that the prescribed therapy is displayed.
- Listen for audible tones.
- Observe the flow rate in the IV tubing drip chamber to verify the expected flow.

Displays: See *Features and Displays* on page *81* for a description of the displays and soft keys, and instructions on how to enter programming values.

Powering on and off: See *Power On and Off* on page 68 for instructions on how to turn the instrument on and off.

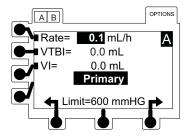
Maintenance Reminder: See *Respond to Maintenance Reminder* on page *70* for instructions on how to respond to a Maintenance Reminder message.

WARNING

Prior to initiating a RUN/HOLD, verify that all displayed programming parameters are correct.

Primary Infusion

- 1. Perform "Start-Up" steps (see Start-Up on page 67).
 - Primary setup page is displayed.
 - · Primary infusion rate is highlighted.



- Perform one of following steps:
 - If current primary infusion rate is appropriate, press ENTER key.
 - Enter new infusion rate and press ENTER key.

VTBI is highlighted.

Programming Primary Infusion

Primary Infusion (Continued)

- 3. Perform one of following steps:
 - If current primary VTBI is appropriate, press ENTER key. ¹
 - Enter new infusion rate and press ENTER key.

VI is highlighted.

- 4. If there is a **VI** value that needs to be cleared, press **CLEAR** key or press **0** (zero) key, and then press **ENTER** key.
- 5. Verify that all parameters are correct and press **run** soft key or **RUN/HOLD** key to start infusion.
- 6. To briefly view current profile from **RUN/HOLD** page or during a running infusion, press **v** soft key.

Pause and Restart Infusion

- An infusion may be paused temporarily by pressing RUN/ HOLD key.
 - Rate LED flashes while infusion is on hold.
 - After two minutes, "Hold Time Exceeded" visual and audio prompts begin. An additional two-minute period may be initiated by pressing hold soft key or RUN/ HOLD key.
- To restart infusion while on hold, press channel RUN/HOLD key.

Rate= 100.0 mL/h
VTBI= 0.0 mL
VI= 0.0 mL
Primary
Limit=600 mmHG

^{1.} If the flow sensor option is in use, VTBI can be turned off by selecting VTBI, pressing the CLEAR key, and then pressing the ENTER key. Or, the primary VTBI can be deleted from the primary mode setup page (see *Configurable Options* on page *92*).

Programming Primary Infusion

Primary Infusion (Continued)

Change Parameter During Infusion

Continuous infusion parameters (Rate or VTBI) may be changed without pausing the infusion, and VI may be cleared.

- Select applicable channel, as necessary.
- 2. Press soft key next to parameter to be edited.

Current value is highlighted.

- 3. Perform one of following steps:
 - To change rate or VTBI, enter a new value.
 - To reset VI to 0.0 mL, press CLEAR or 0 (zero) key.
- 4. To accept change, press ENTER key.

KVO Mode

When the primary VTBI reaches 0.0 mL, the instrument automatically switches to the configured KVO (keep vein open) rate, or remains at the current infusion rate, whichever is less.

- Programmed infusion rate continues to be displayed in Main Display.
- KVO flashes in infusion status bar.
- KVO alert tone sounds (may be silenced for two minutes using Silence key).
- VTBI=0 message flashes in Main Display.

Resume Infusion from KVO Mode

- 1. To place channel on hold, press RUN/HOLD key.
- Press VTBI soft key.

VTBI is highlighted.

- 3. Enter desired VTBI.
- 4. Press ENTER key.
- 5. To resume infusion, press **RUN/HOLD** key.

Primary Infusion (Continued)

Clear Volume Infused

The volume infused counter increments as fluids are infused through a given channel. All fluids infused in primary mode, all fluids infused in secondary mode, and all fluids infused in KVO mode are counted.

- To reset volume infused counter to 0.0 mL, press VI soft key.
- 2. Press CLEAR or 0 (zero) key and then press ENTER key.

Secondary Infusion

This mode is designed to support automatic secondary infusions (piggybacking) in the same channel. When the instrument is programmed and delivering in the secondary mode, the primary infusion is temporarily stopped and fluid is drawn from the secondary container.

The primary infusion must be programmed and on hold before a secondary infusion is programmed. The maximum rate for a secondary infusion is 270 mL/h.

When the secondary VTBI reaches zero, an audio tone sounds (if enabled), **Secondary Complete** message is briefly displayed, and the primary infusion rate automatically resumes. Delivery from the primary container also resumes when the fluid level in the secondary line is level with the fluid in the primary container.

For information regarding flow sensor use with secondary infusions, see *Flow Sensor* on page 79.

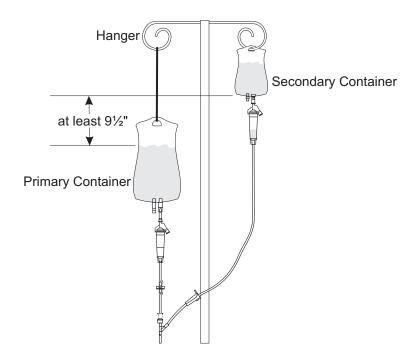
WARNING

- Secondary applications require the use of a check valve set on the primary IV line.
- The secondary solution container must be higher than the primary solution container.
- The secondary VTBI settings
 require consideration of variables;
 such as, factory overfill and
 medication additions.
 Underestimating the volume causes
 the remaining secondary solution to
 be infused at the primary rate;
 overestimating results in the primary
 solution being infused at the
 secondary rate. Multiple doses from
 a single container are not possible.
- The clamp on the secondary administration set must be opened. If the clamp is not opened, the fluid is delivered from the primary container.
- The secondary administration set must be primed prior to beginning the secondary infusion.
- Verify that the secondary systems are properly set up, to ensure that there is a proper flow.

Secondary Infusion (Continued)

Setup

- Open secondary administration set package, remove set, and close clamp.
- 2. Insert administration set spike into prepared fluid container and hang secondary container, following accepted hospital/facility procedure.
- 3. Fill drip chamber to ¾ full.
- 4. Open secondary administration set clamp and prime set.
- 5. Close clamp.
- 6. Attach secondary administration set to upper injection site on primary set.
- 7. Using hanger(s) provided with secondary administration set, lower primary fluid container until bottom of secondary container is at least 9½ inches above fluid level in primary container.



Secondary Infusion (Continued)

Infusion

- 1. Place primary infusion on hold by pressing **RUN/HOLD** key.
- 2. Press **SEC** key. ¹
 - · Secondary setup page is displayed.
 - Secondary rate is highlighted.
- 3. If current secondary infusion rate is appropriate, perform one of the following steps:
 - Press ENTER key.
 - Enter a new rate (maximum allowed rate is 270 mL/h) and then press ENTER key.
 - Secondary VTBI is highlighted.
- 4. If Secondary VTBI is appropriate, perform one of the following steps:
 - Press ENTER key.
 - Enter a new VTBI and then press ENTER key.
- 5. To start secondary infusion, press **RUN/HOLD** key.
- Verify that secondary clamp is open before proceeding and then press yes soft key.
- 7. To briefly view primary settings during secondary infusion press **Primary Settings** soft key.
 - Primary rate (Pri Rate), primary volume to be infused (Pri VTBI), and total volume infused (Total VI) are displayed.
 - Display returns to normal secondary page after six seconds.

The secondary mode must be set to ON in the instrument system configuration settings. If the secondary mode is OFF, an invalid keypress tone sounds and "Secondary Not Allowed" is displayed when the SEC key is pressed.

Secondary Infusion (Continued)

Infusion (Continued)

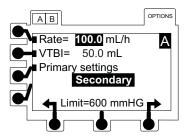
- To change Primary settings, press soft key for Pri Rate, Pri VTBI, or Total VI to freeze display and highlight desired value, and then edit as usual.
- 9. When secondary infusion is complete:
 - · An audio tone sounds (if enabled).
 - "Channel Secondary Complete" is briefly displayed.
 - Infusion automatically transitions to primary rate.

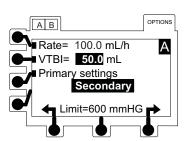
Change Parameters During Infusion

Change Secondary Parameters

- Select desired channel, as necessary. ¹
- 2. Press soft key next to parameter to be edited.

Current value is highlighted.





Enter a new value and press ENTER key.

Change Primary Settings

Select desired channel, as necessary.

The channel does not need to be on hold to change the rate or VTBI values.

Secondary Infusion (Continued)

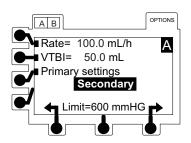
Change Parameters During Infusion (Continued)

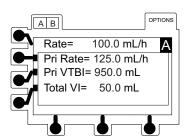
- 2. Press **Primary Settings** soft key.
 - Primary rate (Pri Rate), primary volume to be infused (Pri VTBI), and total volume infused (Total VI) are displayed.
 - Display returns to normal secondary screen after six seconds.
- 3. Press applicable soft key to freeze display and highlight value. 1
- 4. Enter a new value and press **ENTER** key

Clear Primary Volume Infused

- Press **Total VI** soft key.
 Current value is highlighted.
- 2. To reset volume infused to 0.0 mL, press CLEAR or **0** (zero) key.
- 3. To accept new value, press **ENTER** key.

Display returns to normal secondary screen after six seconds.





^{1.} If the flow sensor option is in use, VTBI can be turned off by selecting VTBI, pressing the CLEAR key, and then pressing the ENTER key. Or, the primary VTBI can be deleted from the primary mode setup page (see *Configurable Options* on page *92*).

Drug Specific Dose Rate Calculator (DRC)

This is an optional feature that is configured by the facility. It allows the clinician to select a drug name to calculate a volumetric rate or a dose rate for continuous drug infusions. The calculation is based on parameters such as drug dosage, patient weight, and concentration. When the calculation is complete, the instrument displays the drug name selected on the infusion screen. A generic calculation (**Drug?**) is provided for drugs not available on the drug list.

When the DRC VTBI has counted down to 0.0 mL, the channel switches to the preset KVO rate or remains at the current rate, whichever is less.

Qualified service personnel can turn the DRC feature on or off.

DRC notes:

- The patient weight, drug concentration, and diluent volume cannot be changed during infusion. Changes to any of these parameters while on hold recalculates the volumetric rate to maintain the dose rate.
- All drug names are generic. On a dual channel instrument, a drug name longer than ten letters scrolls when displayed on the split screen.
- The Drug? selection may be used for calculating when a particular drug name is not available on the drug list.
- When a drug amount is greater than 10,000 units (Un), a K is used to indicate a value multiplied by 1,000 (for example, 1,000,000 = 1,000K).
- DRC cannot be used in conjunction with secondary or other operating modes.

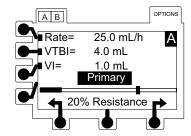
WARNING

Ensure the correct entry of all drug calculation infusion parameters.

Drug Specific Dose Rate Calculator (DRC) (Continued)

Program

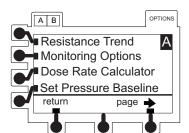
- 1. Select the desired channel, as necessary. 1
- 2. Press **OPTIONS** key.

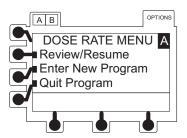


Press Dose Rate Calculator soft key.

.

4. Press Enter New Program soft key.





^{1.} The channel must be infusing in the primary mode or on hold in the primary mode, secondary mode, or a loading dose program.

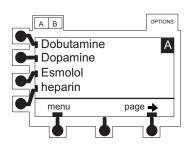
Drug Specific Dose Rate Calculator (DRC) (Continued)

Program (Continued)

5. Press soft key corresponding to applicable drug.

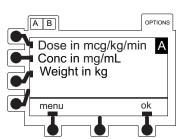
To view additional drug name selections, press **page** soft key.

- If desired drug name is listed, proceed to Drug Name Listed.
- If desired drug is not listed, proceed to *Drug Name Not Listed* on page *30*.



Drug Name Listed

- 1. Press soft key next to a drug name to select it. 1
- 2. To approve all displayed information and advance to first setup page, perform one of the following steps:
 - Press ok soft key.
 - To make changes, go to next step.
- 3. To change concentration, height, or weight units, press soft key next to a unit to select it. ²
 - soft key appears.



^{1.} Dose units cannot be changed.

^{2.} The weight and height unit selections are displayed only if they are appropriate for the selected drug.

Drug Specific Dose Rate Calculator (DRC) (Continued)

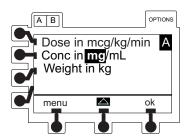
Program (Continued)

Drug Name Listed (Continued)

4. To scroll through available units, press and release soft key. When correct unit is displayed, press ENTER key.

Concentration: mcg, mg, gm, Un, mUn, mEq

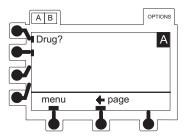
Weight: kg, lb Height: cm, inches



5. To approve all displayed information and advance to first setup page, press **ok** soft key.

Drug Name Not Listed

1. To use generic dose calculation feature, navigate using the **page** soft key and press the **Drug?** option.



- 2. To scroll through available units, press and release soft key.
 - Weight-based dosing versus non-weight-based dosing—perform one of following steps:
 - Weight-based dosing: Press ENTER key to advance to time segment.
 - Non-weight-based dosing: Press soft key to clear segment, and then press ENTER key (weight field disappears).

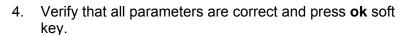
Drug Specific Dose Rate Calculator (DRC) (Continued)

Program (Continued)

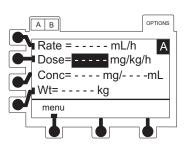
Drug Name Not Listed (Continued)

- Time unit—perform one of following steps:
 - If time unit is appropriate, press ENTER key to advance to concentration field.
 - Press soft key to scroll through available time unit choices. Press ENTER key when correct unit is displayed.
- Concentration unit—perform one of following steps:
 - If concentration unit is appropriate, press ENTER key to advance.
 - Press soft key to scroll through available concentration unit choices. Press ENTER key when correct unit is displayed.
- Weight—perform one of following steps:
 - If weight entry in kg (kilograms) is desired, press
 ok soft key to advance to programming page.
 - If weight entry in **Ib** (pounds) is desired, press soft key and then press ENTER key. Press ok soft key to advance to programming page. Patient weight in pounds is used to automatically calculate dose per kilogram per time.
- 3. Enter parameters, as needed.

Dose field is highlighted for first entry but soft keys can be pressed to highlight another parameter to be entered prior to a dose entry. To automatically calculate dose instead of rate, press **rate** soft key and enter a rate value. When all entries have been completed, dose or rate, as applicable, is automatically calculated.







Programming Loading Dose

Drug Specific Dose Rate Calculator (DRC) (Continued)

Program (Continued)

Drug Name Not Listed (Continued)

- 6. If there is a VI value that needs to be cleared, press **CLEAR** key or press **0** (zero) key, and then press **ENTER** key.
- 7. To continue programming, press **ok** soft key.
- 8. Verify that all parameters are correct and press **run** soft key or **RUN/HOLD** key to start infusion.
- 9. To briefly view current setup parameters from **RUN/HOLD** page or during a running infusion, press **▼** soft key.

Loading Dose

This is an optional feature that is configured by the facility. Options are enabled through the instrument configuration settings.

This feature allows an initial infusion rate to be set up for a specific volume, automatically followed by a maintenance rate (primary settings) from the same container. The primary VTBI and VI include the loading dose volumes. When the loading dose VTBI reaches zero, a transition tone sounds (if transition tone feature is enabled), **Load Dose Complete** message is briefly displayed, and the primary settings automatically take effect.

Verify that the primary mode parameters are correct prior to accessing the **Loading Dose** option.

Program

- Select desired channel, as necessary. Channel must be on hold in primary mode.
- 2. Press **OPTIONS** key.

WARNING

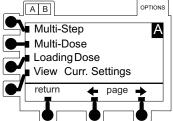
This mode is useful for delivering fluid challenges. This feature is for delivery from primary containers only. Using this feature with two separate containers might result in unintended flow rates.

Programming Loading Dose

Loading Dose (Continued)

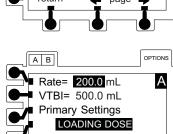
Program (Continued)

3. Press Loading Dose soft key.

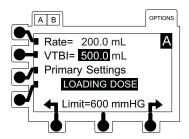


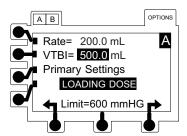
- 4. To program rate, perform one of following steps:
 - If current rate is appropriate, press ENTER key.
 - Enter a new rate and press ENTER key.
- To program VTBI (must be less than primary VTBI), perform one of following steps:
 - If current VTBI is appropriate, press ENTER key.
 - Enter a new VTBI and press ENTER key.
- 6. To start loading dose infusion, press **RUN/HOLD** key.
- 7. To briefly view current profile, press **▼** soft key.
- To change or briefly view primary settings during loading dose infusion, press **Primary Settings** soft key. To change settings, perform following steps:
 - a. Press soft key next to parameter to be edited.
 - b. Enter a new value.
 - To reset volume infused to 0.0 mL, press CLEAR or 0 (zero) key.
 - d. To accept new value and begin infusion, press ENTER key.

When loading dose infusion is complete, **Loading Dose Complete** is displayed and primary infusion resumes.



Limit=600 mmHG





Multi-Dose

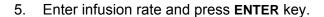
This feature allows 1 to 24 infusions to be preprogrammed with the same rate and volume, to be delivered at equally spaced intervals over a period of up to 24 hours. It also offers a delayed start option for up to 8 hours and a Dose Complete Alert Option. These features can be turned on or off.

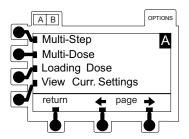
Programming a multi-dose infusion requires another infusing line to keep the vein open between programmed doses, because there is no KVO infusion between doses or following program completion.

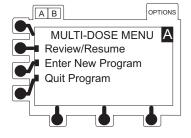
Program

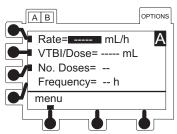
- Select desired channel, as necessary. Channel must be on hold in primary mode.
- 2. Press **OPTIONS** key.
- 3. Press **Multi-Dose** soft key.







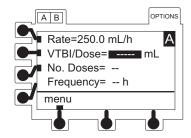




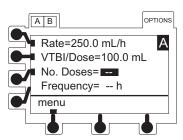
Multi-Dose (Continued)

Program (Continued)

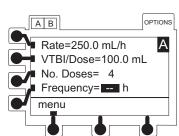
6. Enter VTBI/Dose and press ENTER key.



7. Enter number of doses and press **ENTER** key.

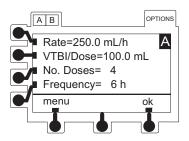


8. Enter dose frequency (time interval from start of one dose until start of next) and press **ENTER** key.

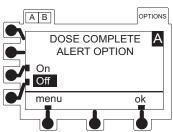


9. Verify that all parameters are correct then press **ok** soft key.

If Dose Complete Alert Option is enabled, **DOSE COMPLETE ALERT OPTION** page appears.



10. Press **On** or **Off** soft key, as applicable.



Multi-Dose (Continued)

Program (Continued)

11. To continue programming, press **ok** soft key.

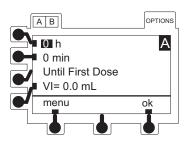
All doses must be programmed to start within 24 hours.

- To start first dose immediately, see Start First Dose Immediately.
- To delay start of first dose, see Delay Start of First Dose.

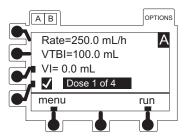
Start First Dose Immediately

A displayed time of 0 hours, 0 minutes identifies that first dose starts immediately after programming.

 To approve and advance to main hold page, press ok soft key.

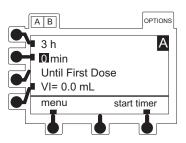


2. To start infusion, press RUN/HOLD key or run soft key.



Delay Start of First Dose

- 1. Enter number of hours until first dose and press **ENTER** key.
- 2. Enter number of minutes (0 to 59) until first dose and press **ENTER** key.

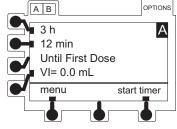


Multi-Dose (Continued)

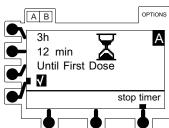
Program (Continued)

Delay Start of First Dose (Continued)

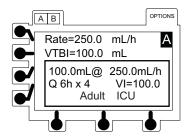
3. To advance to timer hold page, press **start timer** soft key.



- Hourglass icon flashes to indicate timer is counting down to start of dose.
- Dose automatically starts its infusion when timer reaches 0 hours, 0 minutes.

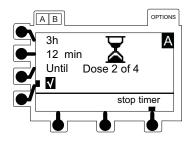


To briefly view multi-dose programmed information, press
 ✓ soft key.



Change Time Interval Until Next Dose

Press stop timer soft key.



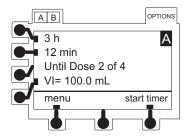
Multi-Dose (Continued)

Program (Continued)

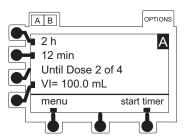
Change Time Interval Until Next Dose (Continued)

2. Press soft key next to value to be edited.

Return To Multi-Dose? page is displayed.



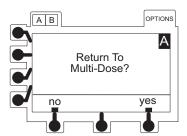
- 3. Enter new value and press ENTER key.
- 4. When editing is complete, press **start timer** soft key.



Resume an Interrupted Multi-Dose

- Select desired channel, as necessary.
 - Return To Multi-Dose? page is displayed.
- 2. Press **yes** soft key.

Pressing **no** soft key returns screen to primary setup page.



Multi-Dose (Continued)

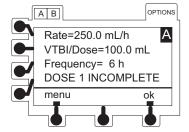
Resume an Interrupted Multi-Dose (Continued)

- To access setup parameters, press Review/Resume soft key.
 - If infusion was in progress when interrupted, see *Infusion in Progress When Interrupted*.
 - If infusion was not in progress when interrupted, see *Infusion Not in Progress When Interrupted*.

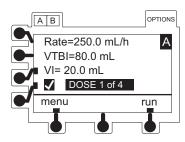
MULTI-DOSE MENU A Review/Resume Enter New Program Quit Program

Infusion in Progress When Interrupted

 To approve and advance to main hold page, press ok soft key.



2. To resume infusion, press RUN/HOLD key or run soft key.



Infusion Not in Progress When Interrupted

- 1. Press **ok** soft key.
- 2. Edit time to delivery of next dose, as necessary.
- 3. To begin timer's countdown to delivery of next dose, press start timer soft key.

When final dose is complete:

- Dose of Complete displays until user takes action.
- No Continuous Infusion or KVO Rate occurs.

Multi-Dose (Continued)

Quit Multi-Dose

The channel must be on hold or the last dose complete.

- 1. Press **menu** soft key.
- To return to primary setup page, press Quit Program soft key.

Primary setup page parameters might be different than those for the Multi-Dose program. Verify all settings prior to resuming an infusion.

Multi-Step

This is an optional feature that is configured by the facility. Options are enabled through the instrument configuration settings.

The Multi-Step feature allows a sequential drug delivery program (up to nine steps) to be set, delivering volumes of fluid at different rates during each step. This allows the instrument parameters to be set up once and to deliver a sequence, eliminating the need to change the rate and VTBI after each infusion step.

The infusion may be programmed in either rate and volume, or volume and time. At completion of the last programmed step, the channel switches to the preset KVO rate or remains at the current rate, whichever is less.

Program

- 1. Select desired channel, as necessary. Channel must be on hold in primary mode.
- 2. Press **OPTIONS** key.
- 3. Press Multi-Step soft key.
- Press Enter New Program soft key.

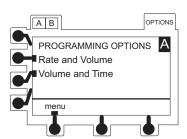
Multi-Step (Continued)

Program (Continued)

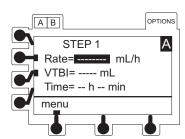
- 5. Determine applicable setup method, as follows:
 - Rate and Volume: Instrument calculates step infusion time. See *Program Rate and Volume* on page *41*.
 - **Volume and Time:** Instrument calculates rate. See *Program Volume and Time* on page *43*.

Program Rate and Volume

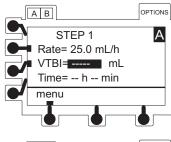
1. Press Rate and Volume soft key.



Enter a rate and press ENTER key.



- 3. Enter VTBI and press ENTER key.
 - Time in hours and minutes is automatically calculated and displayed.
- 4. To approve all displayed information and advance to **STEP 2** of infusion sequence, press **ok** soft key.



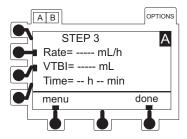
Multi-Step (Continued)

Program (Continued)

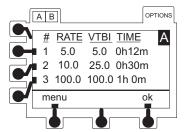
Program Rate and Volume (Continued)

- 5. To set up each additional step of infusion sequence, repeat steps 2 through 4.
- 6. When all steps have been entered and accepted, press **done** soft key.

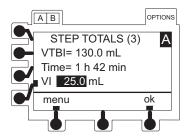
Review page displays three sequence steps at a time.



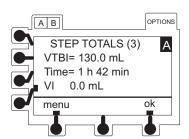
7. To approve and advance through review pages, press **ok** soft key.



8. To clear VI, if desired, press **CLEAR** or **0** (zero) key, and then press **ENTER** key.



9. To accept **STEP TOTALS** page, press **ok** soft key.

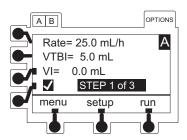


Multi-Step (Continued)

Program (Continued)

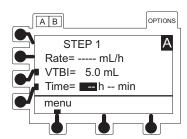
Program Rate and Volume (Continued)

 To start multi-step infusion, press run soft key or RUN/ HOLD key.

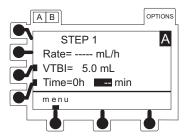


Program Volume and Time

- Press Volume and Time soft key
- 2. Enter a VTBI and press ENTER key.
- 3. Enter hours and press **ENTER** key.



If desired, enter minutes (0-59) and press ENTER key.
 Volumetric rate is automatically calculated and displayed.



- To approve all displayed information and advance to STEP 2 of infusion sequence, press ok soft key.
- 6. To set up each additional step of infusion sequence, repeat steps 1 through 5.
- 7. When all steps have been entered and accepted, press **done** soft key.

Review page displays three sequence steps at a time.

Multi-Step (Continued)

Program (Continued)

Program Volume and Time (Continued)

- 8. To approve and advance through review pages, press **ok** soft key.
- 9. To clear VI, if desired, press **CLEAR** or **0** (zero) key, and then press **ENTER** key.
- 10. To approve **STEP TOTALS** page, press **ok** soft key.
- 11. To start multi-step infusion, press **run** soft key or **RUN/ HOLD** key.

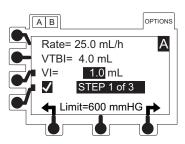
View Steps or Make Changes

Select the desired channel, as necessary.

Clear Volume Infused

The channel does not need to be on hold to clear the VI.

Press VI soft key.

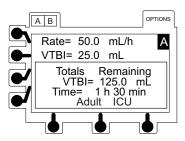


- 2. Press CLEAR or 0 (zero) key.
- 3. Press ENTER key.

View Totals Remaining

The channel does not need to be on hold to view the totals remaining.

Press soft key. Remaining time and VTBI are displayed for a short interval.



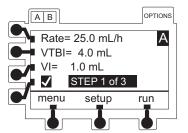
Multi-Step (Continued)

View Steps or Make Changes (Continued)

View or Edit

The channel must be on hold to view or edit the steps in the program.

- 1. To place channel on hold, press RUN/HOLD key.
- 2. To return to review page(s), press **setup** soft key.
 - A tick mark (I) next to a step on review page indicates it has not started.
 - Only steps having a I can be edited.
 - Completed steps, or a step in progress, do not have a I.
 - In-progress step number is highlighted.
- 3. To advance through review pages, press **ok** soft key.
- 4. To edit a parameter:
 - a. Press soft key next to applicable step.
 - b. Press soft key next to applicable parameter.
 - c. Enter new value and press ENTER key.
 - d. To accept changes, press **ok** soft key.
- 5. To approve review page and **STEP TOTALS** page, press **ok** soft key.
- 6. To resume infusion, press **run** soft key or **RUN/HOLD** key.



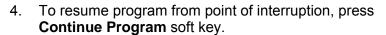
Multi-Step (Continued)

Resume an Interrupted Infusion

The channel retains its place in the program if the instrument is turned off. The program can be restarted from step 1 or be resumed where it left off.

- Select desired channel, as necessary.
 Return To Multi-Dose? page is displayed. ¹
- 2. Press **yes** soft key. ²

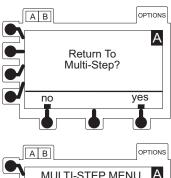




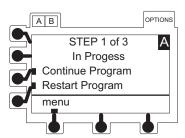
OR

To restart program at beginning of step 1, press **Restart Program** soft key.

5. Verify that all settings are correct. If a change is required, see *View Steps or Make Changes* on page *44*.







If resuming an infusion on a dual channel instrument with an infusion currently running, the display goes directly to **Return To Multi-Step?** during startup.

^{2.} Pressing **no** soft key returns screen to primary setup page.

Multi-Step (Continued)

Resume an Interrupted Infusion (Continued)

- 6. To approve review page and **STEP TOTALS** page, press **ok** soft key.
- To continue or restart program, press run soft key or RUN/ HOLD key.

Quit Multi-Step

The channel must be on hold or the last dose complete.

- 1. Press **menu** soft key.
- 2. To return to primary setup page, press **Quit Program** soft key.

Primary setup page parameters might be different than those for the Multi-Step program. Verify all settings prior to resuming an infusion.

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Dynamic Monitoring System

All features and options in this section are shown as enabled. Options are enabled through the instrument configuration settings.

The Dynamic Monitoring System provides the ability to monitor downstream pressure or resistance, allowing rapid detection of full and partial occlusions. Resistance monitoring eliminates the impact of patient elevation and flow rate to provide the most direct assessment of patency. Components of this system are:

- Monitoring Options—to select IV line/site monitoring modes of resistance, high resistance, and adjustable or fixed pressure.
- Auto Restart Plus Feature—allows instrument to automatically resume operation when specific instrument operating conditions are met.
- Adjustable Resistance Alert—to provide an early warning of increases in downstream flow resistance.
- Adjustable Pressure Alarm—to provide an early warning of increases in downstream pressure.
- Trend Graph—to display downstream pressure or flow resistance over time.
- Pressure Baseline—to provide a starting point from which to measure changes in system pressure.

WARNING

- The Alaris SE pump is designed to stop fluid flow under alarm conditions. Periodic patient monitoring must be performed to ensure that the infusion is proceeding as expected. It is a positive displacement delivery system, capable of developing positive fluid pressures to overcome widely varying resistances to flow encountered in practice, including resistances to flow imposed by small gauge catheters, filters, and intraarterial infusion. It is neither designed nor intended to detect infiltrations, and will not alarm under infiltration conditions.
- Before each use, verify that the pressure or resistance alarm limits are appropriate for the patient.
- Each time the instrument is turned on, verify and/or set the monitoring mode, and resistance alert and/or pressure alarm limit.
 If the monitoring mode, and resistance alert and/or pressure alarm limit are not verified, the instrument might not be operating with the desired occlusion detection parameter(s).

Monitoring Options—General

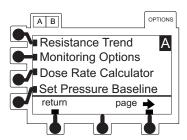
IV lines, catheters, and applications create various levels of resistance to flow. Monitoring mode options are available to meet each clinical need.

- Resistance—designed to monitor IV line/site resistance providing optimum sensitivity for most IV applications.
- High Resistance—designed to monitor IV line/site resistance with optimum sensitivity where higher resistance catheters are used.
- Adjustable Pressure—designed to monitor IV line/site pressure and provide user-adjustable pressure alarm limits. Used for Precision Flow mode or for high resistance systems; such as, infusion through transducers, into dialysis systems, and through highest resistance catheters. ¹
- Pressure—designed to monitor IV line/site pressure and alarm based on a fixed pressure limit. ¹

OPTIONS AB Rate= 125.0 mL/h Α VTBI= 1000.0 mL 0.0 mL 50% Resistance OPTIONS АВ 125.0 mL/h Rate= Α TBI= 1000.0 mL 0.0 mL Primary 450 mmHg

Select Monitoring Option

- Select applicable channel, as necessary.
 Bar graph and numeric displays are not available when split screen is displayed.
- 2. Press **OPTIONS** key.
- Press Monitoring Options soft key.

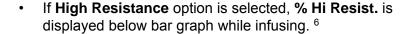


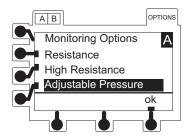
Precision Flow: In fixed and adjustable pressure modes, the Alaris SE pump provides enhanced flow continuity at rates below 50 mL/h.

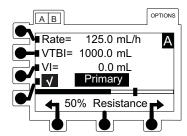
Monitoring Options—General (Continued)

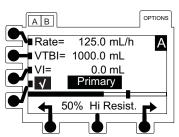
Select Monitoring Option (Continued)

- 4. Press soft key for applicable option. 1
- 5. Press **ok** soft key. ²
 - If Adjustable Pressure option is selected, pressure system accuracy may be enhanced by ensuring that no occlusion or other pressure source exists in IV line when activating RUN/HOLD. 3,4
 - If Resistance option is selected, % Resistance is displayed below bar graph while infusing.









- 1. If pressure limit adjustment is available, selection reads **Adjustable Pressure**; otherwise, it reads **Pressure**.
- 2. While the channel is on, the selected option, resistance alert, and pressure alarm thresholds remain in effect until changed.
- 3. Pressure alarm limits may be adjusted when operating in Adjustable Pressure mode using the soft keys located below the arrow symbols (see *Adjustable Pressure Alarm* on page *58*).
- 4. Maximum pressure limit settings may be configured by qualified service personnel.
- 5. Resistance alert limit may be adjusted using the soft keys located below the arrow symbols (see *Resistance Alert* on page *54*).
- 6. High Resistance alert limit may be adjusted using the soft keys located below the arrow symbols.

Monitoring Options—Resistance Mode

Detection of Downstream Occlusions

In the Resistance or High Resistance monitoring mode, a **RESISTANCE ALERT** condition occurs when the measured resistance reaches the alert limit.

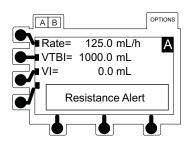
An **OCCLUSION DOWNSTREAM** condition is detected when one of the following conditions occurs:

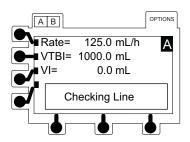
- The measured resistance reaches 100% of scale. For the Resistance mode, 100% results from a resistance producing 2 mmHg per mL/h of flow. For the High Resistance mode, 100% results from a resistance producing 6 mmHg per mL/h flow.
- The configured pressure limit is exceeded. This limit may be set, by qualified service personnel, from 1 mmHg to 600 mmHg (Pressure Limit, Maximum).

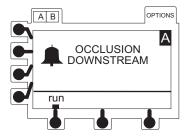
When a Downstream Occlusion is detected, one of the following responses occurs:

 If Auto Restart Plus feature is on, Checking Line message is displayed and audible tone sounds.

If Auto Restart Plus feature is off, OCCLUSION DOWNSTREAM alarm occurs.







Auto Restart Plus Feature

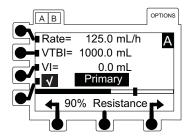
The Auto Restart Plus feature provides the ability to automatically continue an infusion if downstream resistance or pressure measurements indicate that an occlusion condition has cleared within a 40-second **Checking Line** period (excluding High Resistance Monitoring mode).

The **Checking Line** message and tone are presented when a resistance measurement exceeds the alarm threshold of 100%.

If resistance measurements initiate the **Checking Line** condition, the channel continues infusing in order to determine if the measured flow resistance has changed. If the measured flow resistance falls to any value below 100% within 40 seconds, the channel automatically resumes normal operating conditions (excluding High Resistance Monitoring mode).

Pressure measurements initiate the **Checking Line** period when the pressure exceeds the configured limit. If the pressure falls to less than one-third of the configured limit within 40 seconds, normal flow resumes. If the condition is not cleared, the **OCCLUSION DOWNSTREAM** alarm occurs and infusion stops until manually restarted.

This feature can be configured through the hospital configuration settings to allow from 1 to 9 **Checking Line** restarts. After the programmed number of restarts has occurred or the 40-second **Checking Line** period has been exceeded, the channel immediately alarms **OCCLUSION DOWNSTREAM** when resistance or pressure conditions indicate an occlusion.



Resistance Alert

The Resistance Alert provides an early warning of increasing flow resistance. The Resistance Alert marker can be set from 0% to 100% of scale in 5% increments. This feature can be enabled or disabled and a power-on default alert level is set through the hospital configuration settings.

To optimize the alert feature, it is advisable to set the alert level 20-30% higher than the initial displayed resistance. Read the resistance approximately two minutes after starting an infusion.

Set Alert Marker

To numerically display present alert level marker, press ◀ or ▶ soft key. Vertical line on resistance bar graph visually indicates the alert level.

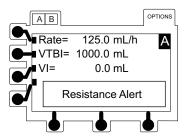
Each additional press of an arrow soft key increases or decreases the alert level marker and numeric value by 5%.

Rate= 125.0 mL/h VTBI= 1000.0 mL VI= 0.0 mL Primary Alert = 70%

Resistance Alert Message

If flow resistance exceeds the alert level marker, a **Resistance Alert** message is displayed and an alert tone sounds. The channel continues to infuse, and the message and tone continue until one of the following resistance levels occurs:

- IV line/site resistance falls below alert level marker.
- Resistance alert level marker increases above current measured resistance value.
- Resistance rises to 100%, initiating a Checking Line or OCCLUSION DOWNSTREAM condition.



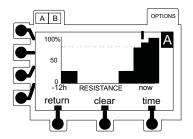
Resistance Trend Graphs

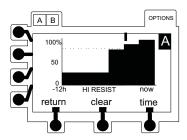
In Resistance and High Resistance monitoring modes, a trend graph displays flow resistance over time. Trend graphs of 15 minutes, 1 hour, 4 hours, and 12 hours are available during normal operation when enabled through the hospital configuration settings.

Downstream Occlusions are indicated by a tick mark (I) at the top of the trend screen.

View Graph

- Select applicable channel, as necessary.
 Trend graph is not available when the split screen is displayed.
- 2. Press **OPTIONS** key.
- 3. Press Resistance Trend soft key.
- 4. To change graph time frame, press **time** soft key.
 - A dashed horizontal line represents current resistance alert level.
 - Gaps in graph might indicate noninfusing conditions; such as turned off, on hold, in alarm.
 - If channel has been placed in Pressure Monitoring mode for some portion of a trend graph window, resistance data is not available and zero values are plotted.
 - A tick mark (I) at top of graph indicates an occlusion.
 - When viewing Resistance Trend Graphs in High Resistance mode, HI RESIST is displayed under graph.



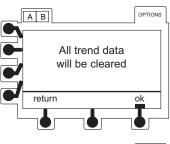


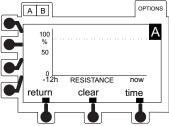
Resistance Trend Graphs (Continued)

Clear Graph

- 1. To clear graphed data, press **clear** soft key.
- 2. Press ok soft key.

All data is cleared from graphs.





Return to Normal Operating Screen

Press return soft key.

Normal operating screen appears.

The following events also turn off trend graph:

- Pressing RUN/HOLD key
- · An alarm
- Dual channel instrument:
 - Pressing split screen key (AB)
 - Replaced with a split screen display after one minute if both channels are infusing

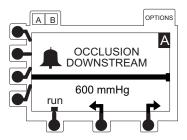
Monitoring Options—Pressure Mode

Downstream Occlusion Detection

When using the Adjustable Pressure monitoring mode, a pressure alarm limit may be varied from 25 mmHg to the maximum configured pressure limit, in 25 mmHg increments. When measured pressure exceeds this level, an **OCCLUSION DOWNSTREAM** condition occurs.

When a Downstream Occlusion is detected, one of following responses occurs:

- If Auto Restart Plus feature is on, a Checking Line message appears, along with an audible tone (see Auto Restart Plus Feature for further details.)
- If Auto Restart Plus feature is off, an OCCLUSION DOWNSTREAM alarm occurs.



Auto Restart Plus Feature

The Auto Restart Plus feature provides the ability to automatically continue an infusion if downstream pressure measurements indicate that an occlusion condition has cleared within a 40-second **Checking Line** period (excluding High Resistance Monitoring mode).

The **Checking Line** message and tone occur whenever a pressure measurement exceeds the selected alarm threshold. If the pressure falls to less than one-third of the alarm limit within 40 seconds, normal flow resumes. The Adjustable Pressure mode allows control of the pressure alarm limit. If the condition is not cleared, the **OCCLUSION DOWNSTREAM** alarm occurs and infusion stops until manually restarted.

Auto Restart Plus Feature (Continued)

This feature can be configured through the hospital configuration settings to allow from one to nine **Checking Line** restarts. After the programmed number of restarts has occurred or the 40-second **Checking Line** period has been exceeded, the channel immediately alarms **OCCLUSION DOWNSTREAM** when resistance or pressure conditions indicate an occlusion.

Adjustable Pressure Alarm

In the Adjustable Pressure monitoring mode, the pressure alarm limit may be varied from 25 mmHg to the maximum configured pressure limit, in 25 mmHg increments. A default alarm level and a maximum pressure limit are set through the hospital configuration settings.

Set Alarm Limit Marker

Pressing the ◀ or ▶ soft key changes the alarm limit by 25 mmHg in the corresponding direction. It is advisable to select an alarm limit appropriate for the flow rate. At lower flow rates, the alarm limit should be set lower, to shorten the time to alarm.

Automatic Baseline Calibration Used to Monitor Pressure

The auto pressure baseline calibration remains in effect until the instrument is turned off, the latch is opened, the set is reloaded, or the Set Pressure Baseline function is performed.

 The first activation of RUN/HOLD for a new infusion automatically establishes a pressure baseline based on current system pressure. An optimal baseline is maintained upon subsequent activations of RUN/HOLD, as follows:

Adjustable Pressure Alarm (Continued)

Automatic Baseline Calibration Used to Monitor Pressure (Continued)

- If current system pressure is same or higher than original baseline, pressure baseline does not change.
- If current system pressure is less than original baseline, system automatically resets to new system pressure value.
- The pressure measurement can be optimized, particularly at low flow rates (less than 3 mL/h), by pausing and restarting at least once every two hours (for example, when reprogramming VTBI). This allows the pressure baseline to calibrate based on current system pressure.
- Prior to activation, ensure that pressure has not built up in the IV line due to an occlusion or flow from other instruments through a common catheter. This results in a more accurate pressure measurement.
- When loading a set connected to a small diameter catheter, wait at least five seconds after loading the set before activating RUN/HOLD. This allows pressure generated by the loading process to dissipate and the sensor to stabilize. Very small PICC catheters, such as, 28 gauge/1.2 French, might require 60 seconds or more for stabilization.
- When multiple instruments are infusing through a common small diameter catheter, pressure measurement accuracy can be optimized by temporarily stopping all infusions, and then restarting all instruments beginning with the instrument delivering at the lowest rate.

Pressure Baseline

The Pressure Baseline feature, when enabled through the hospital configuration settings, provides a real-time bar graph and numeric display of line pressure.

The pressure limit might be reduced if the pressure in the line is high or changing. This results in the pressure limit being lowered from the selected setting. If this occurs, first try to remove or reduce the downstream pressure. Following that, try to reload the set, wait 15 to 30 seconds and then perform a Set Pressure Baseline operation. The pressure baseline might need to be set a second time, after the pressure readings have stabilized.

Manually Set Pressure Baseline While Operating in Adjustable Pressure Mode

For optimal results, set the baseline 15 minutes after starting an infusion. The pressure baseline can be optimized, particularly at low flow rates (less than 3 mL/h), by resetting the pressure baseline when the readings are negative. Check periodically for negative readings; for example, when programming VTBI. This allows the pressure baseline to calibrate based on current system pressure.

- Select applicable channel, as necessary.

 Pressure har graph is not shown when split screen
 - Pressure bar graph is not shown when split screen display is active.
- 2. Press RUN/HOLD key.

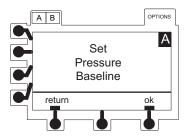
All infusions connected to channel being base-lined must be on hold.

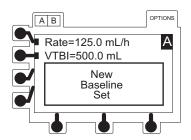
3. Press **OPTIONS** key.

Pressure Baseline (Continued)

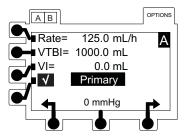
Manually Set Pressure Baseline While Operating in Adjustable Pressure Mode (Continued)

- Press Set Pressure Baseline soft key. ¹
 Set Pressure Baseline screen appears.
- 5. Verify that no pressure, due to occlusion or other infusions through a common line, is present in IV line.
- 6. For best results, verify that set outlet (for example, stopcock) is located at patient's heart level.
- 7. Press ok soft key.





8. Verify that pressure readout is 0 (zero) mmHg. ²



^{1.} To return to the normal screen without setting the baseline, press the **return** soft key.

True baseline pressure will be zero or within a few mmHg of zero.
If not, and the pressure is unstable, allow the pressure to drop to
the lowest level and then repeat the Set Pressure Baseline
process.

Pressure Baseline (Continued)

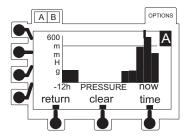
Manually Set Pressure Baseline While Operating in Adjustable Pressure Model (Continued)

9. To start infusion, press **RUN/HOLD** key. ^{1,2,3}

Pressure Trend Graphs

In Pressure Monitoring mode, a trend graph displays monitored pressure over time. Trend graphs of 15 minutes, 1 hour, 4 hours, and 12 hours are available during normal operation when enabled through the hospital configuration settings.

Downstream Occlusions, which occur in Pressure or Resistance modes, are indicated by a tick mark (I) at the top of the trend screen.



View Graph

- Select applicable channel, as necessary.
 Trend graph is not available while split screen is displayed.
- 2. Press **OPTIONS** key.
- 3. Press Pressure Trend soft key.

^{1.} The pressure baseline calibration remains in effect until the instrument is turned off, the latch is opened, the set is reloaded, or the set Pressure Baseline function is performed again.

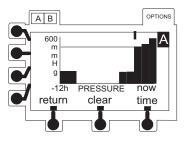
Setting the manual baseline overrides the auto baseline until the instrument is turned off, the latch is opened, set is loaded, or another manual baseline is set.

Setting a manual Pressure Baseline displays a horizontal realtime bar graph and numeric pressure readings. The vertical line on the pressure bar graph visually indicates the pressure alarm limit.

Pressure Trend Graphs (Continued)

View Graph (Continued)

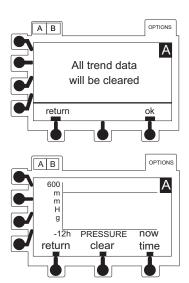
- 4. To change graph time frame, press **time** soft key.
 - A solid horizontal line represents current pressure alarm limit level.
 - Gaps in graph might indicate noninfusing conditions; such as, turned off, on hold, in alarm.
 - If channel has been placed in Resistance Monitoring mode for some portion of a trend graph window, pressure data is not available and zero values are plotted.
 - A tick mark (I) at top of graph indicates an occlusion.



Clear Graph

- 1. To clear graphed data, press **clear** soft key.
- Press ok soft key.

All data is cleared from graphs.



Pressure Trend Graphs (Continued)

Return to Normal Operating Screen

Press return soft key.

Normal operating screen appears.

Following events also turn off trend graph:

- Pressing RUN/HOLD key
- An alarm
- Dual channel instrument:
 - Pressing split screen key (AB)
 - Replaced with a split screen display after one minute if both channels are infusing

Upstream Occlusions Detection

If the flow pathway between the fluid container and the Pressure Sensor is obstructed due to kinked tubing, a closed clamp, or an improperly installed set, an **OCCLUSION UPSTREAM** condition exists.

Depending on where the upstream path is occluded, flow might continue for a fraction of a mL before the **OCCLUSION UPSTREAM** alarm is produced. At high infusion rates, the instrument takes relatively little time to alarm. At low infusion rates, a longer time elapses before the instrument detects the condition and alarms. In either case, some flow continues from the instrument during the time prior to the alarm, due to the elastic behavior of the tubing between the occlusion site and the pumping mechanism.

If an **OCCLUSION UPSTREAM** alarm occurs, investigate and remedy the cause before resuming the infusion. Ensure that the upstream flow path (such as tubing) is free of obstructions, that any clamp is open, and that the blue thumb clamp on the AccuSlide flow regulator is in the open (up) position.

Upstream Occlusions Detection (Continued)

When an upstream occlusion condition is detected:

- OCCLUSION UPSTREAM message appears.
- Audio alarm sounds and infusion stops.
- In certain conditions, upstream alarm system might briefly pause instrument and present **Checking Line** message for 10 seconds, to confirm or rule out presence of an occlusion. If occlusion condition is determined not to exist, flow resumes and no alarm is produced.

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General Setup and Operation

Start-Up

Secure to Pole

The uniquely designed pole clamp adapts to a wide variety of surfaces (such as poles and bed rails) to provide greater versatility and to simplify transports. ¹

It features:

- 360 degrees rotation in 90-degree increments
- · ergonomically designed knob
- accommodates diameters from 15 to 35 millimeters

When using multiple instruments, use care to evenly distribute the instruments, to ensure stability.

Change Pole Clamp Orientation

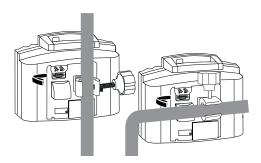
Press and hold rotation lever.

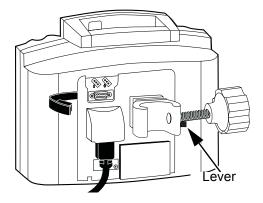
- 2. Reposition clamp.
- 3. Release lever at desired position.

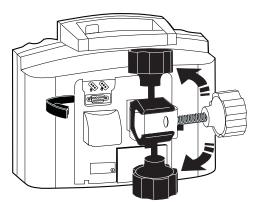
1. The illustrated pole clamp knob might not reflect the knob in use on the instrument.

WARNING

To ensure proper occlusion detection, do not operate the instrument tilted back more than 45 degrees from the upright position.



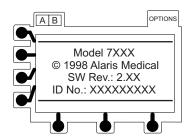




Start-Up (Continued)

Power On and Off

- 1. Press **POWER** key.
 - Instrument performs a self test.
 - All indicators and displays momentarily light.
 - · An audio tone sounds.
 - · Hold indicator flashes.
 - System startup page is briefly displayed. 2.XX in example display represents current software revision; ID No. is instrument serial number.



2. Press and hold POWER key until display turns off.

Audio Adjust

This feature allows the audio volume to be adjusted for alarms, alerts, and KVO tone to either High, Medium, or Low if all audio volume levels are enabled in the hospital configuration settings.

Press (4)) soft key next to lower LCD display.

Audio volume level displays in lower LCD display.

Low <> >>>>

Medium ◀ »»» »»»

 Instrument can be configured to enable only Medium and High, or High audio volume levels.

WARNING

Each time the instrument is turned on verify and/or set the monitoring mode, resistance alert, and/or pressure alarm limit. If the monitoring mode, resistance alert, and/or pressure alarm limit are not verified, the instrument might not be operating with the desired occlusion detection parameters.

CAUTION

- Appearance of lines and/or dots that remain on constantly when the instrument is powered on might indicate improper functioning of the Main Display. Although the instrument is functioning, return it to qualified service personnel.
- Inspect LCD for anomalies (improperly lit or unlit pixels).

Start-Up (Continued)

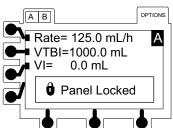
Tamper Resist—Panel Lock Feature

The panel lock feature helps prevent unauthorized changes to the instrument settings, including turning the instrument off. The panel lock feature must be set to **ON** in the hospital configuration settings. To make changes or respond to an alarm, the panel lock must be turned off. The panel lock key () is located behind the handle.

The panel lock feature is always off when the instrument is powered on because it must be off to power down the instrument.

- To turn panel lock feature on, press and hold appears in lower display.
 - Panel Locked appears in Main LCD Display if any other key is pressed.
 - Dual channel instruments: When panel lock feature is on, channel select and split screen keys can be used to view settings.
- To turn panel lock feature off, press and hold a until disappears from lower display.



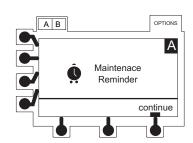




Respond to Maintenance Reminder

If the Preventive Maintenance Reminder option is enabled and the instrument is due for preventive maintenance, a **Maintenance Reminder** message appears at power up.

- 1. Notify appropriate facility personnel if a **Maintenance Reminder** message appears.
- 2. If necessary, press **continue** soft key to temporarily bypass reminder.



Nurse Call—7130/7230 Only

If the instrument is equipped with the optional nurse call feature, alarms and some alerts from the instrument are relayed to the hospital's existing nurse call system. No instrument operating features are changed. The instrument alarms with or without the nurse call installed.

Activate Nurse Call Feature

- Plug nurse call cable into RS-232 connector on instrument's rear panel. ¹
- Press POWER key.
 Instrument beeps briefly to signal proper operation.
- 3. Plug nurse call cable into nurse call system.
- 4. Operate instrument as described in this document. 2,3

^{1.} A false remote alarm might occur if the nurse call plug is not properly inserted.

All alarms and some alerts activate the nurse call system. The following alerts will not activate the nurse call system: Checking Line, Load Dose Complete, Secondary Complete.

Disconnecting the nurse call cable from the wall or turning off the instrument activates the nurse call system. Disconnecting the nurse call cable from the instrument will not activate the nurse call system.

Nurse Call—7130/7230 Only (Continued)

If an Alarm Occurs

- 1. Determine cause and appropriate corrective action (see *Alarms*, *Alerts*, *Prompts* on page *108*).
- 2. Reset nurse call system, as required.

RS-2323 Computer Link

The optional Computer Link feature allows a hospital/facility computer to interact with the instrument. The computer cannot start or stop the instrument, set the rate, or make any change in status. The feature may be enabled or disabled by qualified personnel in the instrument configuration settings. If the feature is enabled (On) the user may select **Monitor**, to allow the computer to receive information from the instrument, or **Off**. When **Off** is selected, the computer cannot communicate with the instrument.

To ensure continued electromagnetic compatibility performance, the communications cable attached to the instrument should be no longer than 3 feet 3 inches or 1 meter, have fully shielded connector housings, and have a 100% coverage braid/foil shield attached to the connector housings around the signal conductors with the cable jacket.

Connect to a Computer

- Press OPTIONS key.
- 2. To advance to next page, press page soft key.
- 3. Press Computer Link soft key.
- 4. Press Monitor soft key.
- Press ok soft key.

WARNING

- Use of any accessory or cable other than those specified might result in increased emissions or decreased Alaris SE pump immunity.
- The protective cover over the RS-232 connector must remain in place when the connector is not in use.
- Only equipment that complies with IEC EN 60601-1 or UL 1069 (approved medical or hospital signaling equipment) is to be connected to the RS-232 connector.

RS-2323 Computer Link (Continued)

Connect to a Computer (Continued)

- 6. Connect an RS-232 cable from hospital computer to RS-232 port on instrument's rear panel.
 - During communication between host computer and instrument, MNTR (Monitor Mode) appears in lower LCD. MNTR remains in lower display when mode is selected and communication with computer is established.
 - If communication is interrupted, MNTR flashes for 60 seconds.



Disconnect from a Computer

- 1. Press **OPTIONS** key.
- 2. To advance to next page, press page soft key.
- 3. Press Computer Link soft key.
- 4. Press Off soft key.
- 5. Press ok soft key.
- 6. Disconnect RS-232 cable from RS-232 port on instrument rear panel.

Warnings and Cautions



Explosion risk if used in the presence of flammable anesthetic agents or combustible vapors.

General

WARNING

- The Alaris SE pump is designed to stop fluid flow under alarm conditions. Periodic patient monitoring must be performed to ensure the infusion is proceeding as expected. It is a positive displacement delivery system, capable of developing positive fluid pressures to overcome widely varying resistances to flow encountered in practice, including resistances to flow imposed by small gauge catheters, filters, and intra-arterial infusion. It is neither designed nor intended to detect infiltrations, and will not alarm under infiltration conditions.
- Do not port the Alaris SE pump with a gravity flow infusion system. The use of positive displacement infusion devices ported together with gravity flow infusion systems into a common IV site can impede the flow of common gravityonly systems, affecting their performance. Hospital/facility personnel must ensure the performance of the common IV site is satisfactory under these circumstances.
- Each time the Alaris SE pump is turned on, verify and/or set the monitoring mode, resistance alert, and/or pressure alarm limit. If the monitoring mode, resistance alert, and/or pressure alarm limit are not verified, the instrument might not operate within the desired occlusion detection parameter(s).
- Before each use, verify that the pressure or resistance alarm limits are appropriate for the patient.
- A new alarm or alert reinstates the audio tone.
- Assess patient's condition before silencing an alarm. Do not silence alarm if patient safety might be compromised.
- Disconnect from main (AC) and battery power when performing maintenance.

General (Continued)

WARNING

- To disconnect from main (AC), unplug the power cord from the back of the instrument.
- Electrical shock hazard. Do not open case. Refer to qualified service personnel.

CAUTION

74

- The Alaris SE pump is not intended to replace supervision by medical personnel. The user must become thoroughly familiar with the Alaris SE pump features, operation, and accessories prior to use.
- Always use a grounded, three-wire receptacle. Where the integrity of the protective earth grounding system is in doubt, operate on internal battery.
- If an instrument or accessory is **dropped or severely jarred**, immediately remove it from use and have it inspected by qualified service personnel, to ensure its proper function prior to reuse.
- If an instrument appears **damaged**, contact CareFusion for authorization to return it for repair.
- Hyperbaric Chamber Operation:
 - The Alaris SE pump is not certified for use in oxygenenriched environments.
 - The healthcare facility's hyperbaric safety director is responsible for all equipment used in the hyperbaric chamber environment.

Administration Sets

WARNING

When priming:

- o Ensure that patient is not connected.
- Ensure that air is expelled from line prior to beginning infusion (unexpelled air in line could have serious consequences).

Failure to prime correctly can delay infusion delivery and cause the total volume to be infused to read higher than the actual total delivered to the patient.

- Discard if packaging is not intact or protector caps are unattached.
- Use only sets dedicated for use with the Alaris SE pump.
 The use of any other set might cause improper instrument
 operation, resulting in an inaccurate fluid delivery or other
 potential hazard.

CAUTION

Before operating the instrument, verify that the administration set is **free from kinks and installed correctly** in the instrument.

Epidural Administration

WARNING

- Epidural administration of drugs other than those indicated for epidural use might result in serious injury to the patient.
- It is strongly recommended that the source container, administration set, and Alaris SE pump used for epidural drug delivery be clearly differentiated from those used for other types of administration.

Epidural Administration (Continued)

WARNING

- The Alaris SE pump can be used for epidural administration of anesthetic and analgesic drugs. This application is appropriate only when using anesthetics and analgesics labeled for continuous epidural administration and catheters intended specifically for epidural use. Use only sets dedicated for use with the Alaris SE pump, without a 'Y' connector or injection port, for epidural infusions.
 - Epidural administration of anesthetic drugs: Use indwelling catheters specifically indicated for short-term (96 hours or less) anesthetic epidural drug delivery.
 - Epidural administration of analgesic drugs: Use indwelling catheters specifically indicated for either short-term or long-term analgesic epidural drug delivery.

Electromagnetic Compatibility

WARNING

- Do not use the Alaris SE pump near Magnetic Resonances Imaging (MRI) equipment, including Stereotaxis technology.
- Do not use the Alaris SE pump near Therapeutic
 Radiation equipment, such as Linear Accelerators.
- Use of any accessory, transducer, or cable other than those specified might result in increased emissions or decreased Alaris SE pump immunity.

CAUTION

 Do not use the Alaris SE pump adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, observe the Alaris SE pump to verify normal operation in the configuration in which it will be used.

Electromagnetic Compatibility (Continued)

- Portable and Mobile RF communications can affect Medical Electrical Equipment.
- The Alaris SE pump is intended for use under the supervision of healthcare professionals only. This is a CISPR 11 Class B device without the use of the Model 180 (Flow Sensor) and CISPR 11 Class A when the Model 180 (Flow Sensor) is used. In a domestic environment, this system might cause radio interference. Reorienting, relocating, or shielding the system, or filtering the connection to the public mains network, are examples of steps that can be taken to reduce or eliminate interference.

Battery Management System

The Battery Management System incorporates features that enhance battery maintenance in order to maximize the life of the battery, reduce associated costs, and increase instrument availability. The system provides the following features:

- Amber
 —flashes when instrument is operating on battery power.
- Automatic battery power—if instrument is unplugged or in the event of a power failure.
- Low battery alert—indicates battery depletion is imminent, beginning at least 30 minutes prior to a BATTERY DEPLETED alarm.

Maximum battery capacity, as well as optimal gauge accuracy, is reached after several complete charge/discharge/recharge cycles in the refresh process. It is recommended that the battery be fully charged/discharged/recharged, using the refresh cycle, before placing the instrument in use. Refer to the Technical Service Manual for detailed information on the refresh cycle.

Battery Management System (Continued)

Battery Power Gauge and Indicator

The gauge indicates approximate battery run time remaining under current operating conditions. It is located in the lower display and is always on. To ensure a more accurate battery gauge reading, review the remaining battery run time approximately five minutes after starting an infusion.

Battery run time might be affected by the operating mode, rate, monitoring options, and back pressure. The gauge accuracy is based on the last refresh cycle and is affected by the number of charge/discharge/recharge cycles. The instrument label and battery gauge are always displayed, even when the instrument is turned off; however, the battery gauge does not represent the battery time remaining when the instrument is turned off.



Battery Recharge

The battery recharges whenever the instrument is plugged into an AC outlet. The battery can be replaced when charging capacity gets too low.

All batteries gradually lose their capacity to hold a charge over time and use. To maintain optimal battery performance, ensure that the instrument is connected to AC power whenever possible, including when it is powered off or stored.

Battery Replacement and Disposal

Battery replacement should be performed by qualified service personnel while the instrument is not in use. Use only CareFusion batteries.

CAUTION

- Do not open, incinerate, or short-circuit the battery.
- Worn-out batteries must be properly disposed of according to facility protocol.

General Information Flow Sensor

Flow Sensor

If the flow sensor option is in use, VTBI can be turned off by selecting VTBI, pressing the **CLEAR** key, and then pressing the **ENTER** key. Or, primary VTBI can be deleted from the primary mode setup page (see *Configurable Options* on page *92*).

The optional flow sensor notifies users of empty containers and/or upstream occlusions. A handle cap accessory is available for storing the flow sensor when not in use.

The flow sensor is not used for the first 25 mL delivered when changing from secondary to primary. This is to account for overfill of secondary containers.

If a flow sensor is not connected to the instrument, ensure that protective plugs are installed at the connector site to prevent entry of foreign material.

1. Plug a Model 180 Flow Sensor into applicable channel connector on back of instrument.

WARNING

The protective cover over the RS-232 connector must remain in place when the connector is not in use.





- 2. Attach flow sensor to upper portion of drip chamber.
 - When using a flow sensor, correct placement is essential for proper operation.
 - Some administration set drip chambers have a flange to which a flow sensor can be attached. Attachment on flange ensures proper placement.
 - Upper surface of flow sensor should be slightly below dropforming orifice but above level of fluid in drip chamber.



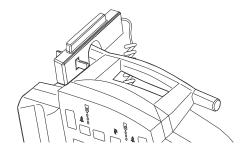
CAUTION

Infusing fluids which form smaller drops—through a 60 drops/mL set—at high rates might result in a **No Upstream Flow Detected** alarm.
This is because the small, rapidly falling drops form a continuous stream that does not trigger the flow sensor. In this event, unplug the flow sensor from the instrument.

General Information Flow Sensor

Flow Sensor (Continued)

- Ensure that drip chamber is at least ¾ full and sensor optics are clean. Fluid level in drip chamber must be checked/re–established after each empty container condition.
- When using flow sensor option while ambulating or transporting a patient from one area to another, use care to avoid excessive swinging of solution container.
- Attach flow sensor to instrument handle when not in use.



4. Routinely clean flow sensor with warm water while actuating slider, and then dry thoroughly.

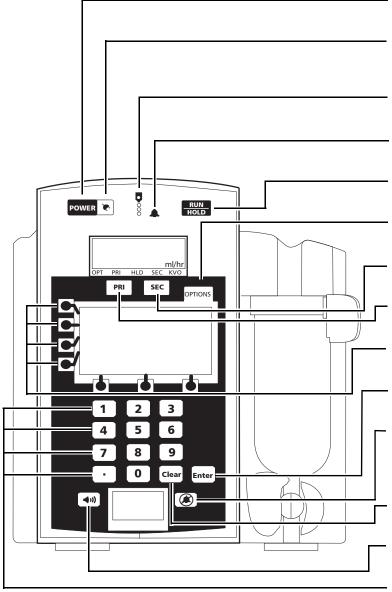
CAUTION

Do not use solvents or cleaning agents. Damage to plastic parts of the flow sensor might occur.

Features and Displays

Operating Features, Controls, Indicators

Single Channel Model



Power Key: Turns instrument on and off

Power Indicator:

Green = Plugged in and charging. Flashing Amber = Battery power.

Infusing Indicator: Indicates instrument is infusing.

Alarm Indicator: Indicates instrument is in alarm and has stopped infusing.

RUN/HOLD Key: Starts and stops infusion.

OPTIONS Key: Accesses additional features.

Secondary (SEC) Key: Selects secondary mode.

Primary (PRI) Key: Selects primary mode.

Soft Keys: See *Displays and Soft Keys* on page *84*.

ENTER Key: Accepts value or selection entered.

Silence Key: Silences audible alarm or alert for two minutes; message remains on screen. New alarm or alert reinstates audible tone.

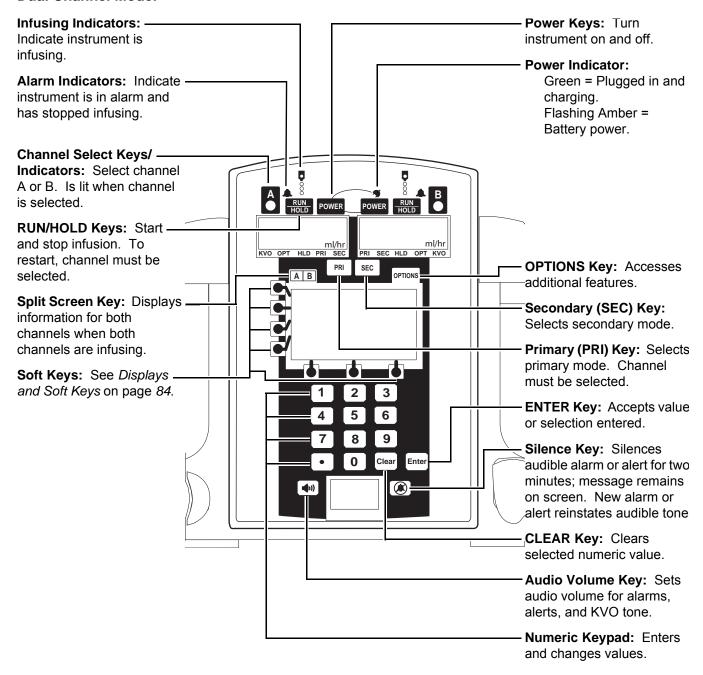
CLEAR Key: Clears selected numeric value.

Audio Volume Key: Sets audio volume for alarms, alerts, and KVO tone.

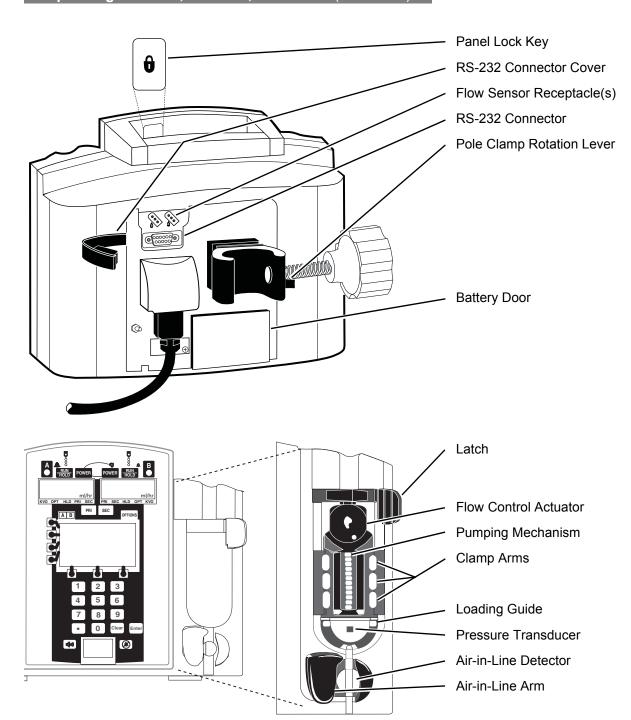
Numeric Keypad: Enters and changes values.

Operating Features, Controls, Indicators (Continued)

Dual Channel Model



Operating Features, Controls, Indicators (Continued)



Displays and Soft Keys

Main Display

The Main Display is backlit for easy viewing. The backlight dims when operating on battery power, as an energy-saving feature. Pressing any key automatically turns the backlight up again.

CAUTION

Appearance of lines and/or dots that remain on constantly when the instrument is powered on might indicate improper functioning of the Main Display. Although the instrument is functioning properly, return it to qualified service personnel.

Rate Display

The LED rate display is easily viewed from a distance. It indicates the current infusion rate(s) in mL/h and flashes to indicate a hold or alarm condition.

Single channel display:

The status bar indicates which mode the instrument is in: Optional Modes, Primary, Hold, Secondary, or KVO.



Dual channel display:

The status bar indicates which mode the instrument is in: KVO, Optional Modes, Hold, Primary, or Secondary.

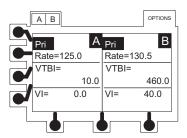


Split Screen (Dual Channel Only)

When both channels are infusing, a split screen showing programmed information for both channels is displayed automatically after one minute.

Press AB key to switch immediately to split screen.

Press $\frac{A}{O}$ or $\frac{B}{O}$ key to stop split screen.



Displays and Soft Keys (Continued)

Lower Display

The lower LCD display is backlit for easy viewing. The display dims when operating on battery power, as an energy-saving feature.

Displayed if panel lock is on. Audio Volume Indicator Indicates audio volume for alarms and alerts. Computer Mode Indicator Displayed if instrument is in computer monitor mode. Instrument ID Label Identifies selected configuration, ownership, location, and so forth. Battery Power Gauge

Indicates approximate battery time remaining under current infusing conditions.

The instrument label and battery power gauge are always displayed, even when the instrument is turned off; however, the battery power gauge does not represent the battery time remaining when the instrument is turned off. To ensure a more accurate battery power gauge reading, review the gauge approximately five minutes after starting an infusion. The gauge updates for each program change during an infusion. Battery run time might be affected by the operating mode, rate, monitoring options, and back pressure.

General Information Features and Displays

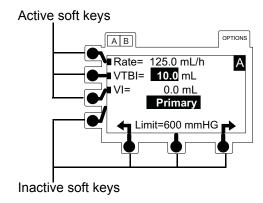
Features and Displays (Continued)

Displays and Soft Keys (Continued)

Soft Keys

Soft keys are the keys located on the left side and the bottom of the main LCD display. They serve a variety of functions, as indicated by the text in the display at the time.

A soft key is active if there is a tick mark (I) next to the key. If there is no tick mark next to the key, then it is not active and cannot be selected. Pressing an inactive key results in an invalid keypress tone.



Entering Programming Values

To enter or change a programming value, select the applicable parameter by pressing the corresponding soft key. Selecting a parameter highlights the field or existing value.

To enter a value, use the numeric keys. If the highlight is flashing, the entry is incomplete. When the entry is complete, press the **ENTER** key.

To clear an existing value, press the **CLEAR** key. To restore the value, press the **CLEAR** key a second time (before pressing the **ENTER** key). When the entry is complete, press the **ENTER** key.

When all parameters required on a programming setup screen have been programmed, press the **ok** soft key to confirm all entries and continue programming.

Configurable Settings

The configurable options are set in the configuration mode by qualified service personnel. If the configuration settings need to be changed from the factory default settings, refer to the Technical Service Manual or contact CareFusion Technical Support for technical, troubleshooting, and preventive maintenance information.

Definitions

Air-in-Line

Air-in-Line Threshold (microliters)

Sets the upper limit for a single bolus of air to pass without an alarm. In other words, it is the amount of air allowed to pass through the air-in-line detector before an air-in-line alarm sounds. One of four different air-in-line detection settings can be selected: 50, 100, 200, 500 mcL.

Air-in-Line Accumulator

Detects the presence of multiple air bubbles that are too small to be detected by a single bolus AIL detection limit. The accumulator feature, when enabled, looks for 10-15% of the downstream fluid path to be air before giving an ACCUMULATED AIR IN LINE alarm. The volume of air that trips the accumulated air detection alarm varies based on the current setting for a single air bolus.

Air-in-Line Reset

This allows the clinician to respond to an air-in-line alarm, assess its clinical significance, and choose whether or not to continue infusion without removing air. The reset feature allows only the current bubble to proceed without tripping an alarm.

Audio

Transition Tone (secondary to primary)

Provides an audible tone when the secondary VTBI reaches zero, to indicate the infusion has transitioned to a primary rate.

Volume

If all audio volume levels are enabled, the audio volume can be adjusted for alarms, alerts, and KVO tone to either High, Medium, or Low. The audio volume indicator in the lower LCD display indicates the selected audio volume. The instrument can be configured to enable only Medium and High, or only High audio volume levels if desired.

Configuration Name

Allows a 4-digit instrument ID label to appear in the lower LCD display.

Configurable Settings (Continued)

Definitions (Continued)

Dynamic Monitoring

Auto Restart Plus Part of the Dynamic Monitoring system, and designed to help minimize nuisance

"occlusion downstream" alarms. It allows the instrument to automatically continue an infusion following the detection of a downstream occlusion if downstream pressure falls to an acceptable level within a 40-second Checking Line period. It may be set to off (0 restarts) or to allow from 1 to 9 Checking Line restarts. If the allowable number of restarts is exceeded, or when resistance or pressure conditions

indicate an occlusion, an occlusion downstream alarm occurs.

Monitoring Options Dynamic monitoring allows one of the following monitoring modes to be selected:

Resistance mode, High Resistance mode, or Pressure mode. All of these modes offer an optional Auto-Restart Plus feature and optional trend graph display.

Trends Provides ability to display downstream pressure or flow resistance over time. Trend

graphs of 15 minutes, 1 hour, 4 hours, and 12 hours are available during normal operation. When Trends is enabled and the instrument is operating in pressure mode, a pressure trend graph is available. When Trends is enabled and the instrument is operating in resistance mode, a resistance trend graph is available.

Configurable Settings (Continued)

Definitions (Continued)

Dynamic Monitoring—Pressure

Adjustable pressure is designed to monitor IV line/site pressure and provide user-adjustable pressure alarm limits. It is used for Precision Flow mode or for high resistance systems; such as, infusion through transducers, into dialysis systems, and through highest resistance catheters. The pressure mode may be configured to operate with a fixed pressure alarm limit threshold so that it is not user-adjustable.

Manual Pressure Baseline Provides a real-time bar graph and numeric display of line pressure.

Pressure Alarm When Pressure Display is enabled, Pressure Alarm may be set to Adjustable

Pressure mode or Fixed Pressure mode.

Pressure Display In the Adjustable Pressure monitoring mode, the pressure alarm limit may be

varied from 25 mmHg to the maximum configured pressure limit, in 25 mmHg increments. The pressure display indicates the current pressure limit and provides the ability to adjust the limit by pressing the increase or decrease

arrows.

In the Fixed Pressure mode, the pressure limit of 600 mmHg is displayed, with no means of adjusting it. When Pressure Display is disabled, the instrument

automatically defaults to Fixed Pressure mode.

Pressure Limit, InitialDefault pressure alarm limit that is automatically set when the instrument is

powered on. The alarm level must be less than or equal to the maximum

pressure limit.

Pressure Limit, Maximum In Adjustable Pressure monitoring mode, the pressure alarm limit may be

varied from 25 mmHg to this maximum configured pressure limit, in 25 mmHg $\,$

increments. A value that exceeds this pressure limit cannot be selected.

Configurable Settings (Continued)

Definitions (Continued)

Dynamic Monitoring—Resistance

Resistance monitoring eliminates the impact of patient elevation and flow rate, to provide the most direct assessment of patency. It is designed to monitor IV line/site resistance, providing optimum sensitivity for most IV applications. High resistance is designed to monitor IV line/site resistance with optimum sensitivity where higher resistance catheters are used.

Default Resistance AlertDefault resistance alert level that is automatically set when the instrument

is powered on. The resistance alert marker can be adjusted up or down

from this default setting, as needed.

Resistance Alert Provides an early warning of increasing flow resistance. When enabled,

the resistance alert marker can be set from 0% to 100% of scale in 5% increments (Resistance Display must also be enabled). To optimize the alert feature, it is advisable to set the alert level 20% to 30% higher than the initial displayed resistance, which should be read approximately

two minutes after starting an infusion.

Resistance Display When enabled, provides a bar graph on the Main Display to indicate the

current % resistance on a scale of 0% to 100%. When disabled, the

resistance alert feature is unavailable.

Resistance Pressure Setting Provides an Occlusion Downstream alarm when the measured pressure

reaches the Resistance Pressure limit while operating in Resistance Mode. This threshold may be set from 1 mmHg to 600 mmHg in 1 mmHg increments. In other words, while operating in Resistance mode or High Resistance mode, an Occlusion Downstream condition can be detected in two ways: measured resistance reaches 100% of scale or configured

Resistance Pressure Setting is exceeded.

KVO Rate

KVO (keep vein open) mode automatically occurs when the primary VTBI has counted down to 0.0 mL. The channel switches to the preset KVO rate or remains at the current rate, whichever is less. The KVO rate may be set from 0.1 mL/h to 20 mL/h in 0.1 mL/h increments and cannot be adjusted by the clinician.

Configurable Settings (Continued)

Definitions (Continued)

Optional Modes

Optional modes include Loading Dose, Dose Rate Calculator, Multi-Step, and Multi-Dose. Each of these can be enabled or disabled. When disabled, they will not appear on the Options menu and cannot be accessed by the clinician.

Dose Rate Calculator Allows clinician to enter the flow rate or the drug dose rate for a continuous infusion.

The system then calculates the alternate parameter based on the drug

concentration and if used, the weight.

Loading DoseAllows the clinician to set up an initial infusion rate for a specific volume, to be

followed automatically by a maintenance rate (primary settings) from the same

container. This is useful for delivering fluid challenges.

Multi-Dose Allows 1 to 24 doses to be programmed at equally spaced intervals on the same

instrument over a 24-hour period. This mode allows delivery of multiple, equal doses from the same IV container at regularly scheduled intervals. Within this mode, a delayed start option allows the instrument to be programmed to delay the

infusion start for up to 8 hours.

Multi-Dose Alert When enabled, this feature alerts the clinician of the completion of each dose

delivered during a Multi-Dose program.

Multi-Step Allows a sequential drug delivery program (up to nine steps) to be set, delivering

volumes of fluid at different rates at each step. This allows the instrument parameters to be set up once and deliver a step profile, eliminating the need to change the rate and VTBI after each step of the infusion. The infusion may be

programmed in rate/volume or volume/time.

Rate, Maxin	num	

Maximum infusion rate may be set from 0.1 mL/h to 999.9 mL/h in 0.1 mL/h increments.

Configurable Settings (Continued)

Configurable Options

The following features can be customized by qualified service personnel in the Configuration or Diagnostic Modes.

Feature	Options	Default
Air-in-Line:		
Air-in-Line Accumulator Air-in-Line Threshold Air-in-Line Reset	On, Off 50, 100, 200, or 500 mcL On, Off	On 100 mcL Off
Audio:		
Transition Tone Volumes	On, Off Low/Med/Hi, Med/Hi, or Hi	On Low/Med/Hi
Computer Link:		
Baud Rate Mode Parity	300, 600, 1200, 1800, 2400, 4800, 9600 Monitor/Off, Off Even, Odd, None	9600 Off None
Configuration Name	four alphanumeric characters	GOLD
Instrument ID (a)	nine digits	00000000
KVO Rate	0.1 to 20 mL/h	5.0 mL/h
Language	Language: English	English
Monitoring Options:		
Auto Restart Plus Monitoring Options Trends	0 (Off) or 1 to 9 Resistance, High Resistance, Pressure On, Off	3 Pressure On
Optional Features:		
Multi-Dose Alert Panel Lock VTBI	On, Off On, Off On, Off	Off On On
Optional Modes:		
Dose Rate Calculator Loading Dose Multi-Dose Multi-Step	On, Off On, Off On, Off On, Off	Off On Off Off

Configurable Settings (Continued)

System Configurable Options (Continued)

Feature	Options	Default
PM Setup: (a)		
Maintenance Interval Maintenance Reminder	1 to 52 weeks On, Off	52 weeks On
Pressure Options:		
Manual Pressure Baseline Pressure Alarm Pressure Display Pressure Limit, Initial (Configuration Mode: Def Alarm) Pressure Limit, Maximum	On, Off Adjustable, Fixed On, Off 25 to 600 mmHg, 600 mmHg	On Adjustable On 600 mmHg
Pressure Sensor (a)		
Self Check Interval	1 to 52 weeks	12 weeks
Resistance Options:		
Default Resistance Alert Resistance Alert Resistance Display Resistance Pressure Setting	0 to 100% On, Off On, Off 1 to 600 mmHg	100% On On 600 mmHg
Rate, Maximum	0.1 to 999.9 mL/h	999.9 mL/h

a. This feature is configured in the Diagnostics Mode.

General Information Specifications

Specifications

Administration Sets Use only administration sets for Alaris SE pump.

Alarms Accumulated Air In Line Key Stuck
Air In Line Latch Open

Battery Depleted No Upstream Flow Detected Channel Malfunction Occlusion Downstream

Computer Link Failure Occlusion Upstream

Flow Sensor Unplugged Primary Flow Detected During Secondary

Hold Time Exceeded Set Out

Instrument Malfunction Set Up Time Exceeded

Battery Rechargeable nickel-cadmium. A single channel instrument operates for four hours

nominal and a dual channel instrument operates for three hours nominal, under following

conditions:

new, fully charged battery

• ambient room temperature, 73±7°F (23±4°C)

· resistance monitoring modes

rate: 100 mL/h on a single channel instrument and 50 mL/h on each channel

of a dual channel instrument

Battery run time is affected by operating mode, rate, monitoring options, and back

pressure (see Battery Management System on page 77).

Case Impact and flame resistant plastic.

Critical Volume Maximum incremental volume in case of single point failure does not exceed 1.0 mL at

999.9 mL/h.

Dimensions (nominal) <u>7100/7130</u> <u>7200/7230</u>

 Depth*
 5.0 in (12.7 cm)
 5.0 in (12.7 cm)

 Height
 8.6 in (21.8 cm)
 8.6 in (21.8 cm)

 Power cord
 10 ft (3 m)
 10 ft (3 m)

 Weight**
 6.6 lb (3.0 kg)
 8.4 lb (3.8 kg)

 Width
 7.6 in (19.3 cm)
 10.7 in (26.7 cm)

^{*} Without pole clamp.

^{**} Without power cord.

General Information Specifications

Specifications (Continued)

Downstream Occlusion

Time to Occlusion and Bolus Volume data tested to standards defined in AAMI ID26:1998, Section 51.101 b.

Time to Alarm

Time to Detect		Monitoring Options			
Downstream Occlusion (minutes)		Pressure		Resistance and High Resistance	
Threshold Settings		25 mmHg	600 mmHg	100% 25 mmHg	100% 600 mmHg
1 mL/h	Maximum	2	75	2	7
	Typical	0.6	30	0.6	4
25 mL/h	Maximum	1	25	1	3
	Typical	0.1	1	0.1	1

When occlusion alarm pressure limit is set to maximum threshold setting, maximum infusion pressure generated into a hard occlusion at 25 mL/h is 11.6±3.9 psi.

Bolus Volume

Bolus Volume Released		Monitoring Options			
Upon Correcting Downstream Occlusion (mL)		Pressure		Resistance and High Resistance	
Threshold S	Settings	25 mmHg	600 mmHg	100% 100% 25 mmHg 600 mmHg	
1 mL/h	Maximum	0.5	0.5	0.5	0.5
	Typical	<0.1	0.3	<0.1	<0.1
25 mL/h	Maximum	0.5	0.5	0.5	0.5
	Typical	<0.1	0.3	<0.1	0.3

Testing performed using Model 72003 administration set, at 68±8°F (20±4°C).

Environmental Conditions Operating Storage

Atmospheric Pressure 700 to 1060 hPa 500 to 1060 hPa

Relative humidity 20 to 90% 5 to 95%

Noncondensing Noncondensing

Temperature Range 41 to 104°F -40 to 140°F

(5 to 40°C) (-40 to 60°C)

Fluid Ingress Protection IPX1, Drip Proof

General Information Specifications

Specifications (Continued)

Flow Rate Range 0.1 to 600.0 mL/h in 0.1 mL/h increments (secondary mode)

0.1 to 999.9 mL/h in 0.1 mL/h increments (all other modes)

Ground Current Leakage Electrical leakage current, enclosure: <100 microamperes

Electrical leakage current, patient: <10 microamperes

KVO Flow Range 0.1 to 20.0 mL/h in 0.1 mL/h increments

Mode of Operation Continuous

Power Requirements 100-240 V~, 50/60 HZ (72 VA MAX), 3-wire grounded system

Class 1 with Internal Power Source

Rate Accuracy

CAUTION

Variations of head height, back pressure, time, monitoring mode option, pump tilt, or any combination of these might affect rate accuracy. Factors that can influence head height and back pressure are: Administration set configuration, IV solution viscosity, and IV solution temperature. Back pressure might also be affected by catheter type. See *Trumpet and Start-Up Curves* on page *100* for data on how certain factors influence rate accuracy.

For rates greater than 1 mL/h, up to 999.9 mL/h: ±5%, 95% of time with 95% confidence, under conditions listed below.

For rates equal to or less than 1 mL/h: $\pm 6.5\%$, 95% of time with 95% confidence, under conditions listed below.

Rate Accuracy Test Conditions:

Infusion rate range: 0.1 to 999.9 mL/h Head height: 24 ±1 in. (61±2.5 cm) Test solution: distilled water

Environment temperature: 68±8°F (20±4°C)

Back pressure: 0 psi Needle: 18 gauge Set Model: 72003

Minimum collection volume: 6 mL

Volume Infused Range

0.0 to 9999.9 mL in 0.1 mL increments

VTBI Range

0.1 to 9999.9 mL in 0.1 mL increments (Basic Infusion, Drug Library Primary Infusion, IV Fluid Infusion, and Multi-Step mode); 0.1 to 999.9 mL in 0.1 mL increments (all other

modes)

General Information Symbols and Terms

Symbols and Terms



Alarm indicator.



Caution: Refer to accompanying documentation.



Audio volume.



Approximate battery time remaining under current infusing conditions. Battery gauge does not represent battery time remaining when instrument is turned off.



Conformité Européenne [CE - Marking] notified body "0086": British Standards Institution.



Electrical shock protection rating: Type CF (a)



Type CF defibrillation-proof equipment. (a)



Explosion risk if used in presence of flammable anesthetics.



Flow sensor receptacle (optional), channel A.



Flow sensor receptacle (optional), channel B.



Infusing indicator.

IPX1

Indicates degree of protection, liquid ingress.



Manufacturing Date: Number adjacent to symbol indicates month and year of manufacture.



Nurse Call (optional for 7130/7230).



Consult operating instructions.

General Information Symbols and Terms

Symbols and Terms (Continued)



Panel lock.



Green = instrument plugged into AC power and battery being charged. Flashing amber = instrument running on battery power and battery being depleted.



RS-232 connector.



Caution: Federal (United States) law restricts this device to sale by or on the order of a physician.



Silence mode.



Split screen (dual channel instrument only).

Transition Tone

A brief tone during transition from one mode to another.



Canadian and United States Certification Mark: Products bearing this mark have been tested and certified in accordance with applicable United States and Canadian electrical safety and performance standards (CSA C22.2 No. 125).



Single-Use. Do not re-use.



DEHP in fluid pathway.



No DEHP in fluid pathway.



Product contains latex.



Product is latex free.



Drops per milliliter specification for product is identified on drop symbol.



Product incorporates SmartSite needle-free valve ports and should not be accessed by a needle.



Approximate set priming volume.

General Information Symbols and Terms

Symbols and Terms (Continued)



Expiration date for product is identified near hour glass symbol.



Do not use if package is damaged.



Electrostatic discharge (ESD).



Radio frequency (RF) transmission.

a. Depending on manufacturing and distribution timing, the Alaris SE pump might bear either the CF or CF Defibrillator-Proof symbol on the main rating label. The Alaris SE pump has been tested and complies with IEC 60601-1 Amendment 2, Clause 17 (h) for Defibrillator-Proof Equipment.

cm	centimeter	min	minute
gm	gram (g)	mL	milliliter
h	hour	mmol	millimole
HLD	infusion in hold mode	mUn	milliunit
in	inch	nan	nanogram (ng)
kg	kilogram	OPT	optional mode
KVO	keep vein open infusion rate mode	PRI	primary infusion mode
lb	pound	SEC	secondary infusion mode
mcg	microgram (μg)	Un	unit
mcL	microliter (µL)	VI	volume infused
mEq	milliequivalent	VTBI	volume to be infused
mg	milligram		

Trumpet and Start-Up Curves

In this instrument, as with all infusion systems, the action of the pumping mechanism and variations in individual administration sets cause short-term fluctuations in rate accuracy. The following graphs show typical performance of the system for both Pressure and Resistance modes in two ways:

- Accuracy during various time periods over which fluid delivery is measured (trumpet curves).
- Delay in onset of fluid flow when infusion commences (start-up curves).

Product operation is not affected by the selection of Resistance or High Resistance at 0.1 mL/h, 1.0 mL/h, and 25 mL/h; therefore, High Resistance graphs are not included.

Trumpet curves are named for their characteristic shape. They display discrete accuracy data averaged over particular time periods or observation windows, not continuous data versus operating time. Over long observation windows, short-term fluctuations have little effect on accuracy, as represented by the flat part of the curve. As the observation window is reduced, short-term fluctuations have greater effect, as represented by the mouth of the trumpet. Knowledge of system accuracy over various observation windows might be of interest when certain drugs are being administered. Because the clinical impact of short-term fluctuations on rate accuracy depends on the half-life of the drug being infused and on the degree of intravascular integration, the clinical effect cannot be determined from the trumpet curves alone. Knowledge of the start-up characteristics should also be considered.

The start-up curves represent continuous flow rate versus operating time for two hours from the start of the infusion. They exhibit the delay in onset of delivery due to mechanical compliance and provide a visual representation of uniformity. Trumpet curves are derived from the second hour of this data.

Tests were conducted in accordance with IEC 60601–2–24, "Particular requirements for safety of infusion pumps and controllers" and AAMI ID26–1998 "Medical electrical equipment - Part 2: Particular requirements for the safety of infusion pumps and controllers," using a Model 72003 Administration Set (includes Flow Regulator).

Trumpet and Start-Up Curves (Continued)

Flow Characteristics Under Varying Delivery Conditions

Effects of pressure variations:

Under conditions of +100 mmHg pressure, the Alaris SE pump typically exhibits a long-term accuracy offset of approximately -1.4% from mean values.

Under conditions of +300 mmHg pressure, the Alaris SE pump typically exhibits a long-term accuracy offset of approximately -1.5% from mean values.

Under conditions of -100 mmHg pressure, the Alaris SE pump typically exhibits a long-term accuracy offset of approximately -0.8% from mean values.

Resulting trumpet observation points typically track those of accuracy; therefore, no significant change in short–term variations result under these pressure conditions.

Effects of negative solution container heights:

With a negative head height of -0.5 meters, the Alaris SE pump typically exhibits a long–term accuracy offset of approximately -5.8% from mean values.

Resulting trumpet observation points typically track those of accuracy; therefore, no significant change in short–term variations result under negative head height conditions.

Effects of rate:

For applications where flow uniformity is a concern, use of the Pressure Mode at rates of 1.0 mL/h or above is recommended.

Trumpet and Start-Up Curves (Continued)

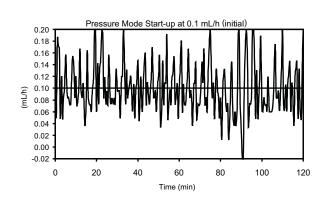
The plot range has been increased to ±100%, to allow visualization of the graph.

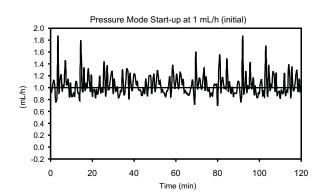
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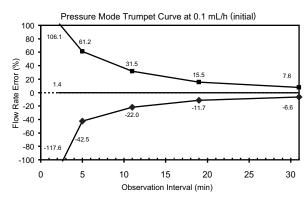
102

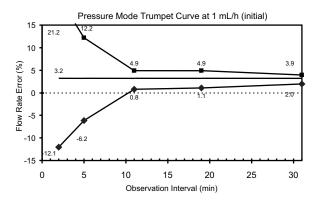
- Maximum rate error
- Overall rate error
- Minimum rate error

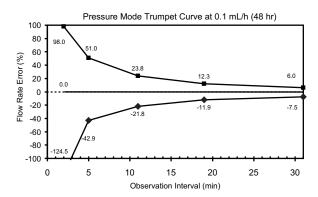
Pressure Mode

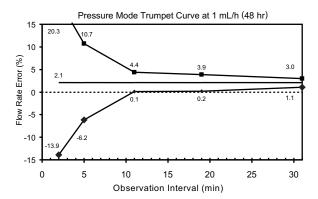




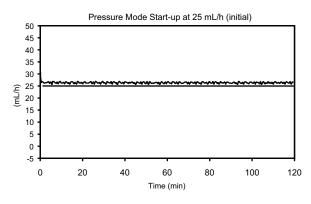


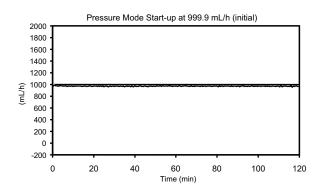


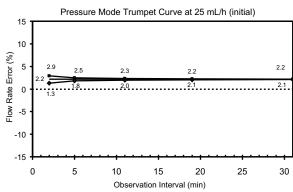


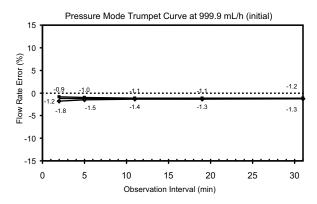


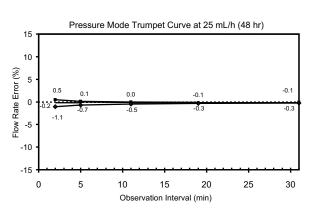
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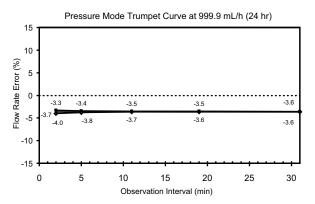




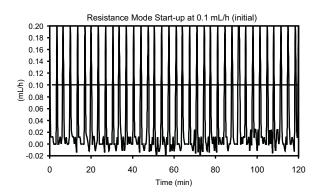


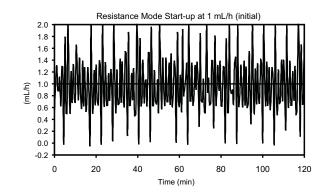


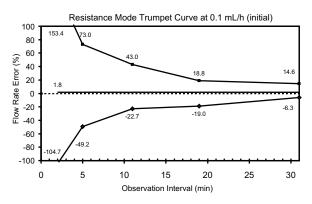


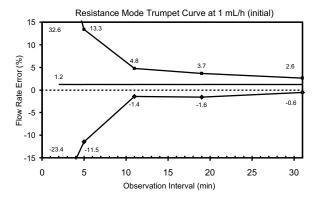


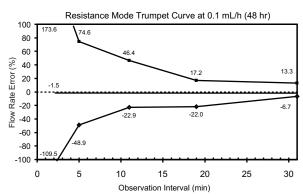
Resistance Mode

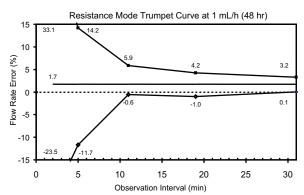




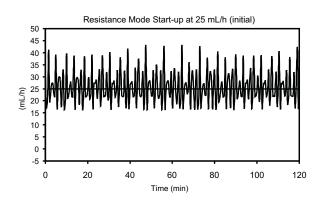


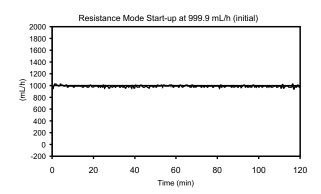


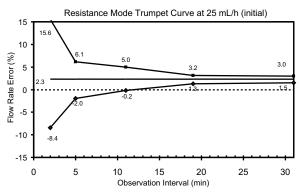


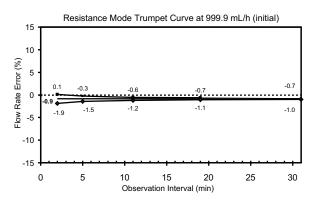


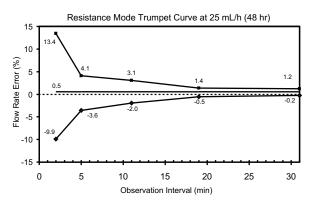
Resistance Mode (Continued)

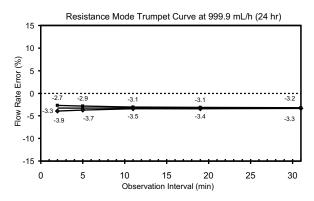




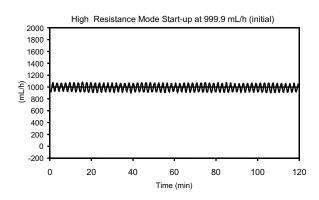


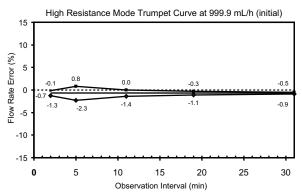


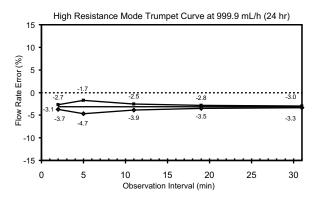




High Resistance Mode







Troubleshooting and Maintenance

The Alaris SE pump Technical Service Manual is available from CareFusion. It includes routine service schedules, interconnect diagrams, component parts lists and descriptions, test procedures, and other technical information, to assist qualified service personnel in repair and maintenance of the instrument's repairable components. Maintenance procedures are intended to be performed only by qualified personnel.

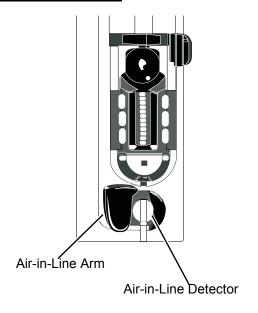
Artifacts: It is normal for an infusion device to produce nonhazardous currents when infusing electrolytes. These currents vary proportional to the infusion device flow rate. When an ECG monitoring system is not functioning under optimal conditions, these currents might appear as artifacts, simulating actual ECG readings. To determine if ECG abnormalities are caused by patient condition or the ECG equipment, place the Alaris SE pump on hold. If the ECG readings become normal, the ECG equipment requires attention. Proper setup of the ECG equipment should eliminate these artifacts. Reference the appropriate ECG monitoring system documentation for instructions on setup and maintenance.

Air-in-Line Assembly

The Air-in-Line Detection System provides clinicians the ability to detect inappropriate amounts of air in the IV line. The instrument is configurable to allow single bubble and accumulated air detection. Accumulated air detection is based on measurement of the average percentage produced by small air bubbles passing the detector.

Ensure that the tubing is properly inserted into the air detector to avoid false alarms. The tubing may be reshaped to ensure optimum contact with the sensors. Periodically clean the air-in-line detector to ensure a clear signal can be received (see *Cleaning* on page *116*).

Air is detected by an emitter (air-in-line arm) which rotates into position as the latch is closed. A receiver (air-in-line detector), opposite the arm and just below the pumping mechanism, sends the air-in-line information to the main processor.



Air-in-Line Assembly (Continued)

Qualified biomedical personnel may configure one of four possible sensitivity levels. The instrument is also configurable to permit the operator to clear (reset) any air registered in the instrument's memory.

Air Bubble Detection

- 1. To place channel on hold, press **hold** soft key.
- 2. Remove air per hospital protocol. 1
- To resume infusion, reinstall set and then press RUN/ HOLD key.
 - If air volume is clinically insignificant, press reset soft key or RUN/HOLD key, followed by run soft key or RUN/ HOLD key to resume infusion.
 - Subsequent air bubbles trigger alarm.

Alarms, Alerts, Prompts

Use this section in conjunction with the appropriate clinical practice of hospital procedure.

When using the dual channel instrument, some messages also display Channel A or Channel B, to indicate which channel is affected. Always verify that the channel is selected before making any changes.

ALARM—instrument or channel problem.

- infusion stops
- alarm bell icon illuminates
- alarm tone sounds
- · rate LED display flashes
- message appears in Main Display when channel is selected

^{1.} Opening the latch or turning the channel off clears air memory.

ALERT—possible change in infusion status.

- · channel continues to operate
- alert tone sounds
- message appears in Main Display

PROMPT—infusion status not changed.

Startup procedures were not completed or an invalid key was pressed.

Alarms

Alarm	Meaning	Response
Accumulated Air In Line	Air detector detected multiple small bubbles.	Press hold soft key. Open latch to remove set. Clear air per hospital protocol. Reinstall set. Press RUN/ HOLD to resume infusion. OR
		If reset key is active and air bubbles are clinically insignificant, press reset soft key and then press run soft key to resume infusion.
		Ensure air-in-line sensors are thoroughly cleaned.
Air In Line	Air detector detected an air bubble larger than configured threshold tolerance.	Press hold soft key. Open latch to remove set. Clear air per hospital protocol. Reinstall set. Press RUN/HOLD to resume infusion. OR
		If reset key is active and air bubbles are clinically insignificant, press reset soft key and then press run soft key to resume infusion.
		At flow rates of 1.0 mL/h and below, verify that upstream fluid path is unobstructed.
		Ensure air-in-line sensors are thoroughly cleaned.
Battery Depleted (Plug In)	Battery is too low to operate instrument.	Plug power cord into an AC outlet immediately. Press run soft key or RUN/HOLD to resume infusion.

Alarms (Continued)

Alarm	Meaning	Response	
Channel Malfunction (Dual channel instrument only.)	Channel malfunction.	Turn channel off and then on. If problem persists, do not use channel. Contact qualified service personnel.	
Computer Link Failure	RS-232 connection to computer was disrupted.	Check RS-232 connections.	
	Computer Link feature is in monitor mode.	Clearing this alarm automatically puts instrument in monitor mode. Re-establish infusion.	
Flow Sensor Unplugged	Flow sensor is unplugged from back of instrument.	Plug flow sensor into flow sensor receptacle.	
Hold Time Exceeded	Channel has been on hold for two minutes and no keys have been pressed.	Press hold soft key to return to hold mode.	
Instrument Malfunction	Instrument malfunction.	Turn instrument off and then on. If problem persists, do not use instrument. Contact qualified service personnel.	
Key Stuck	A key is stuck or was held down too long.	Release key. Turn instrument off and then on. If problem persists, do not use instrument. Contact qualified service personnel.	
Latch Open	Latch was opened during an infusion.	Check for proper set installation. Close latch fully to the left. Press run soft key.	
No Upstream Flow Detected	Flow is obstructed between container and instrument when using a flow sensor.	Check to see if container is empty, flow sensor is mispositioned or clouded, tubing is kinked, or air vent is closed. Verify correct set connections and open fluid path. Press run soft key to restart infusion.	
	Infusing fluids which form smaller drops through a 60 drops/mL set at rates might result in a No Upstream Flow Detected alarm—small, rap falling drops form a continuous stream that does not trigger the flow sensor. In this event, unplug the flow sensor from the instrument.		

Alarms (Continued)

Alarm	Meaning	Response
Occlusion Downstream	Pressure in IV line exceeded a pressure alarm threshold. Resistance has reached 100%.	Check administration set for probable cause (such as kinked tubing, closed stopcock, high resistance catheter). Press run soft key to restart infusion.
Occlusion Upstream	Flow is obstructed between fluid container and instrument's pressure sensor.	Check administration set for probable cause (such as kinked tubing, closed clamp). Verify that blue thumb clamp on Flow Regulator has moved to open (up) position. If not, reload set. Press run soft key to restart infusion.
Primary Flow Detected During Secondary	Instrument detected flow from primary container during secondary infusion. (Alarm can occur only when using an optional flow sensor.)	Verify that flow sensor is on Primary line and that setup is correct.
Set Out	Set was removed during an infusion.	Reinstall set. Press run soft key to restart infusion
Setup Time Exceeded	Instrument was turned on but no keys were pressed for ten minutes.	Press hold soft key to return to hold mode. Instrument turns off if left in alarm more than five minutes. If an audio alarm remains on, turn instrument on and then off.

Alerts

Alert	Meaning	Response
Battery Low	Battery has 30 minutes or less of charge remaining.	Plug power cord into an AC outlet as soon as possible.
Check Entry	Key press unclear.	Press CLEAR key to continue.
Checking Line	Flow is obstructed. Auto Restart Plus feature is on.	Auto Restart Plus feature must be on for downstream occlusion alerts (not required for upstream occlusion alerts). Check administration set for probable cause (such as kinked tubing, clogged filter).
Complete Entry	ENTER was not pressed to accept a new value.	Press ENTER key to confirm entry or press CLEAR key twice to return to previous settings. Note: Channel operates as previously programmed until ENTER key is pressed.
Resistance Alert	IV line resistance reached preset alert level. Resistance Alert feature is on.	Check downstream line and site. Raise resistance alert level, if appropriate.

Additional Alerts:

Additional alerts provide notification of program completion and/or transition to another mode: Dose Complete (Multi-Dose mode), Loading Dose Complete, Multi-Step Complete, Secondary Complete, Infusion in KVO or VTBI = 0.

Prompts

Prompt	Meaning	Response
Air In Line	Air detector detected air prior to starting infusion or is in poor contact with set.	Press continue soft key to allow infusion to continue. An alarm occurs if air detector detects an air bubble larger than configured threshold. Verify that set is loaded correctly. Prime and reload set or remove air. Reshape tubing to ensure optimum contact with sensor. Ensure air-in-line sensors are thoroughly cleaned.
Dose Out of Range	Calculated dose is outside allowable range.	Verify and reenter settings.
Entry Invalid	An invalid value was entered during programming.	Press CLEAR key or 0 key to clear entry. Enter appropriate value.
Instrument Self-check is Due Please Eject the Set	Instrument or channel did not perform self-check within programmed interval.	If set is loaded: Eject set, wait five seconds, and then reload set. If no set is loaded: Load set, wait one minute, and then eject set. Wait five seconds and then reload set.
Invalid Entry Rate Out of Range	Instrument calculated a rate less than 0.1 mL/h.	Verify and reenter settings.
Latch Open	Latch is open—prior to starting an infusion.	Close latch fully to left.
Maintenance Reminder	Periodic maintenance interval elapsed. Maintenance Reminder feature is on.	Notify Biomedical Engineering department. If desired, press continue soft key to temporarily bypass reminder.
New Baseline Set	A new Manual Pressure Baseline was successfully set. Manual Pressure Baseline feature is on.	Baseline remains set until a new manual baseline is set, instrument is turned off, or latch is opened.
Occlusion Downstream	A very high pressure exists in fluid line while baseline is being set. Pressure Baseline feature is on.	Remove source of high pressure and repeat setting of pressure baseline.

Prompts (Continued)

Prompt	Meaning	Response
Ok Entry	Attempt was made to go to another page before pressing ok soft key.	Verify that all parameters are correct and press ok soft key.
Panel Locked	A key was pressed. Panel lock feature is on.	Turn panel lock off to access panel controls. Panel lock key is located behind handle.
Place on Hold to Change	A key was pressed during KVO.	Channel must be on hold to make changes.
Place on Hold to Set Pressure Baseline	SET PRESSURE BASELINE function was selected while running. Pressure Baseline feature is on.	Place instrument on hold before performing manual SET PRESSURE BASELINE operation.
Press and Hold Key to Turn Off	POWER key was pressed.	Press and hold POWER key until display turns off.
Pressure Limit XXX mmHg (XXX represents configured maximum pressure)	An elevated pressure was present in fluid path when pressure baseline was established. This might reduce maximum available pressure range.	Reload administration set and verify that no obstruction exists which could cause excess pressure. If Pressure Baseline feature is on, repeat manual setting of pressure baseline. If Pressure Baseline feature is off, restart infusion to automatically set pressure baseline.
Pressure Limit Must Be Less Than or Equal to XXX mmHg (XXX represents configured maximum pressure)	Attempt was made to increase pressure alarm limit to a level higher than configured maximum pressure.	Choose a pressure alarm limit that is less than, or equal to, configured maximum pressure.
Pressure Unstable Cannot Set Baseline	Excessive variation in pressure due to motion, flow from other instruments, or blood pressure prevents accurate setting of pressure baseline. Pressure Baseline feature is on.	Reduce or temporarily remove sources of variation while performing manual baseline setting operation.

Prompts (Continued)

Prompt	Meaning	Response
Program Lost Re-Enter Setting	A memory or power failure was detected. Existing operating parameters were erased.	Press continue soft key and reenter all infusion settings. Configurable options are not affected.
Rate Out of Range	Instrument has calculated a rate less than 0.1 mL/h.	Verify and reenter settings.
Set Must Be Loaded	Flow Regulator segment is not loaded in selected channel during a manual pressure baseline setting operation. Pressure Baseline feature is on.	Load Flow Regulator segment in selected channel. Repeat manual pressure baseline setting.
Set Out	Flow Regulator segment is not installed correctly.	Reinstall Flow Regulator segment.
Set Pressure Baseline	Set Pressure Baseline was selected in options mode.	Press ok soft key to set Pressure Baseline or press return soft key to go to exit.
Set Pri VTBI	A primary VTBI was not programmed.	Enter a primary VTBI.
Set Pri VTBI > Loading Dose VTBI	Loading dose VTBI entered is greater than primary VTBI.	Raise primary VTBI or lower loading dose VTBI, as appropriate.
Stop Timer to Change	An invalid key was pressed while timer was running in Multi-Dose program.	Wait several seconds for popup to finish. Press stop timer soft key to make changes.
Time Out of Range	Programmed step time exceeds 24 hours and 59 minutes, or is less than 1 minute.	Verify and reenter settings.

Invalid Keypress During Programming:

The following Prompts might be seen if an invalid key is pressed during programming: Both A and B not Running, Channel Not On, Complete or OK Setup, No Numeric Entries, Select Channel.

Invalid Keypress During Infusion:

During an infusion, if an invalid key is pressed, the following prompts might be seen: Dose Rate Running, Loading Dose Running, Multi-Dose Running, Multi-Step Running, Pri Running, Sec Running, or Timer Running (Multi-Dose program).

Inspection Requirements

To ensure that the system remains in good operating condition, both regular and preventive maintenance inspections are required. Refer to the applicable Alaris SE pump service manual for detailed inspection instructions.

REGULAR INSPECTIONS

Procedure	Frequency
Inspect for Damage:	Each usageEach usageEach usage
Cleaning	As required
Start-Up	Each usage

WARNING

Failure to perform these inspections can result in improper instrument operation.

CAUTION

- Preventive maintenance inspections should only be performed by qualified service personnel.
- Inspect LCD for anomalies (improperly lit/unlit pixels).

Cleaning

Inspect and clean the Alaris SE pump as needed, typically between patient uses.

DO NOT use:

- Solutions containing phosphoric acid (Foamy Q&A¹), aromatic solvents (such as naphtha or paint thinner), chlorinated solvents¹ (such as Trichloroethane, MEK, Toluene), ammonia, acetone, benzene, xylene, or alcohol, other than as specified below.
- Hard or pointed objects to clean any part of instrument.
- Pressurized sprays on instrument.

Acceptable cleaning solutions are as follows (use per manufacturers' instructions): 10% bleach solution (one part bleach to nine parts water), Vesphene, Manu-Klenz, and warm water.

1. Unplug power cord from AC outlet before cleaning.

WARNING

Turn the instrument off and unplug the power cord from AC power **before cleaning**. Do not spray fluids directly onto the instrument or into any connector. Do not steam autoclave, EtO sterilize, immerse the instrument, or allow fluids to enter the instrument case. Failure to follow these instructions might result in an electrical hazard.

CAUTION

The **solutions/solvents** identified as NOT to be used can damage the surfaces of the instrument.

^{1.} Excluding 10% bleach solution in water.

Cleaning (Continued)

- 2. Verify that RS-232 connector is covered.
- 3. Use a soft cloth dampened with warm water and a mild, nonabrasive cleaning solution.
 - A soft-bristled brush may be used to clean narrow areas.
 - Use light pressure when cleaning pressure transducer and air-in-line detector areas of pumping channels.
- 4. Routinely clean flow sensor by running warm water over it while actuating slider, and then thoroughly dry it.

Service Information

If the instrument shows evidence of damage in transit, notify the carrier's agent immediately. Do not return damaged equipment to the factory before the carrier's agent has authorized repairs.

If the instrument fails to respond as described in this document and the cause cannot be determined, do not use the instrument. Contact qualified CareFusion service personnel.

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

Technical Support

Technical support, service information, applications, and manuals may be obtained by contacting a CareFusion representative. When submitting any request for service, include:

- model number
- a description of difficulty experienced
- instrument settings
- administration set/lot number
- solution(s) used
- message displayed at time of difficulty

WARNING

- The instrument case should only be opened by qualified personnel using proper grounding techniques. Prior to performing maintenance, disconnect the Alaris SE pump from AC power.
- During servicing, an instrument's configuration settings might be reset to the factory defaults. Qualified hospital/facility personnel are responsible for checking in the instrument and ensuring that the current hospital-approved instrument system configuration settings are correct.

Warranty

CareFusion warrants that:

- Each new Alaris SE pump is free from defects in material and workmanship under normal use and service for a period of one (1) year from the date of delivery by CareFusion to the original purchaser.
- The battery and each new accessory is free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by CareFusion to the original purchaser.

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

In no event shall CareFusion be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any Alaris SE pump product. This warranty shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product. Furthermore, this warranty shall not apply to, and CareFusion shall not be responsible for, any loss or damage arising in connection with the purchase or use of any Alaris SE pump product which has been:

- repaired by anyone other than an authorized CareFusion Service Representative;
- altered in any way so as to affect, in CareFusion's judgment, the product's stability or reliability;
- subjected to misuse or negligence or accident, or which has had the product's serial or lot number altered, effaced or removed; or
- improperly maintained or used in any manner other than in accordance with the written instructions furnished by CareFusion.

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

CAREFUSION DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

Refer to packing inserts for international warranty, if applicable.

Regulations and Standards

Compliance

Electromagnetic Environment

This system complies with part 18 of the FCC Rules. Operation is subject to the following two conditions:

- This system may not cause harmful interference.
- This system must accept any interference received, including interference that might cause undesired operation.

The digital apparatus does not exceed the Class B limits for radio noise emissions from digital apparatus set out in the radio interference regulations of the Canadian Department of Communications (DOC).

Le present appareil numerique n'emet pas de bruits radiolelectriques depassant les limites applicables aux appareils numeriques de la Classe A/B prescrites dans le reglement sur le brouillage radioelectrique edicte par le Ministere des Communications du Canada.

This system has been tested and found to comply with either the limits for a Class B digital device (without Model 180 Flow Sensor), or as a Class A digital device (with Model 180 Flow Sensor), pursuant to Part 18 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the system is operated in a commercial environment. This system generates, uses, and can radiate radio frequency energy. If it is not installed and used in accordance with the applicable directions for use, it might cause harmful interference to radio communications. Operation of this system in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at their own expense.

The authority to operate this system is conditioned by the requirement that no modifications will be made to the system unless the changes or modifications are expressly approved by CareFusion.

CAUTION

Any **changes or modifications** not expressly approved by the personnel responsible for compliance could void the user's authority to operate the system.

Electromagnetic Environment (Continued)

This Class A/B digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulation.

Cet appareil numerique de la Classe A/B respecte toutes les exigences du Reglement sur le materiel brouilleur du Canada.

Tables: The Alaris SE pump is intended for use in the electromagnetic environments specified in the following tables.

Table 1 Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment—Guidance
CISPR 11 RF Emissions	Group 1 Class A	The Alaris SE pump is suitable for use in all establishments, including domestic establishments and those directly connected to a public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following Caution is heeded.
		The Alaris SE pump is intended for use under the supervision of healthcare professionals only. This is a CISPR 11 Class A when the Model 180 (Flow Sensor) accessory is used and a CISPR 11 Class B when the Model 180 is not used. In a domestic environment, this system might cause radio interference. Reorienting, relocating or shielding the system, or filtering the connection to the public mains network, are examples of steps that can be taken to reduce or eliminate interference.
CISPR 11 RF Emissions	Group 1 Class B	The Alaris SE pump is suitable for use in all establishments, including domestic establishments and those directly connected to a public low-voltage power supply network that supplies buildings used for domestic purposes.
IEC 61000-3-2 Harmonic Emissions	Class A	
IEC 61000-3-2 Voltage Fluctuations Flicker Emissions	Complies	

Electromagnetic Environment (Continued)

Table 2 Electromagnetic Immunity

Emissions Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment— Guidance
IEC 61000-4-2 Electrostatic Discharge (ESD)	±6 kV contact ±8 kV air	±8 kV contact ^(a) ±15 kV air ^(a)	Floors should be wood, concrete, or ceramic tile. If the floors are covered with synthetic material, relative humidity should be at least 30%. If a connector testing exemption is used, the following ESD sensitivity symbol appears adjacent to each connector. "Do Not Touch"
IEC 61000-4-4 Electrical Fast Transient, Burst (EFT) (b)	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-5 Power Line Surge (b)	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-8 Power Frequency Magnetic Field (50/60 Hz)	3 A/m	400 A/m 50 Hz ^(a) 400 A/m 60 Hz ^(a)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

a. Compliance levels raised by IEC 60601-2-24.

b. Performed at the minimum and maximum rated input voltage.

Electromagnetic Environment (Continued)

Table 2 (Continued) Electromagnetic Immunity

Emissions Test	IEC 60601-1-2 Test Level (a)	Compliance Level ^(a)	Electromagnetic Environment— Guidance
IEC 61000-4-11 Voltage Dips, Short Interruptions, and	<5% <i>U</i> T (>95% dip in <i>U</i> T) for 0.5 cycle	<5% U T (>95% dip in U T) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If continued operation of the Alaris SE pump
Voltage Variations (b)	40% U T (60% dip in U T) for 5 cycles	40%~UT (60% dip in U T) for 5 cycles	is required during power mains interruptions, it is recommended that the Alaris SE pump be powered from an uninterruptible power aurable or a better.
	70% U T (30% dip in U T) for 25 cycles	70% U T (30% dip in U T) for 25 cycles	uninterruptible power supply or a battery. The Alaris SE pump does employ an internal short duration battery.
	<5% U T (>95% dip in U T) for 5 seconds	<5% U T (>95% dip in U T) for 5 seconds	

a. UT is the AC mains voltage prior to application of the test level.

b. Performed at the minimum and maximum rated input voltage.

Electromagnetic Environment (Continued)

Table 3Electromagnetic Immunity—Life Support Equipment

Emissions Test	IEC 60601-1-2 Test Level	Compliance Level ^(a)	Electromagnetic Environment— Guidance (b),(c)
IEC 61000-4-6 Conducted RF	3 Vrms 150 kHz - 80 MHZ	10 Vrms	Portable and mobile RF communications equipment should be used no closer to the
IEC 61000-4-3 Radiated RF	3V/m 80 MHZ - 2.5 GHz	10 V/m	Alaris SE pump (including cables) than recommended separation distance calculated from the equation applicable to frequency of transmitter.
			Recommended Separation Distance:
			12 d = [] \sqrt{P} 80 MHz - 2.5 GHz E ₁
			d = recommended separation distance in meters (m). (d)
			P = maximum output power rating of transmitter in watts (W) according to transmitter manufacturer.
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than compliance level in each frequency range. (e),(f)
			Interference might occur in the vicinity of equipment marked with the following symbol:

Electromagnetic Environment (Continued)

Table 3 (Continued)
Electromagnetic Immunity—Life Support Equipment

a. Compliance levels raised by IEC 60601-2-24.

b. At 80 MHz and 800 MHz, the higher frequency range applies.

c. These guidelines might not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

d. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz, and in the frequency range of 80 MHz to 2.5 GHz, are intended to decrease the likelihood that mobile/portable communications equipment might cause interference if inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

e. Field strengths from fixed transmitters (such as base stations for radio [cellular/cordless] telephones and mobile radios, amateur radio, AM/FM radio broadcast, TV broadcast) cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Alaris SE pump is used exceeds the applicable RF compliance level, the Alaris SE pump should be observed to verify normal operation. If abnormal performance is observed, additional measures might be necessary, such as reorienting or relocating the Alaris SE pump.

f. Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than [V₁] V/m.

Electromagnetic Environment (Continued)

Table 4Recommended Separation Distances

Reduce the potential for electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Alaris SE pump as recommended in this table, based on the maximum output power of the communications equipment.

For transmitters rated at a maximum output power not listed in this table, the recommended separation distance (d) in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) based on the transmitter manufacturer.

Rated Maximum Output Power of Transmitter (W)	Separation Distance Based on Transmitter Frequency (m) (a),(b),(c)				
	150 kHz - 80 MHz Outside ISM Bands	150 kHz - 80 MHz Inside ISM Bands	80 MHz - 800 MHz	800 MHz - 2.5 GHz	
	3.5 — d = [] √P V_1	12 — d = [] √P V_2	12 — d = [] √P E ₁	23 — d = [] √P E₁	
0.01	0.04	0.12	0.12	0.23	
0.1	0.11	0.38	0.38	0.73	
1	0.35	1.2	1.2	2.3	
10	1.11	3.8	3.8	7.3	
100	3.5	12	12	23	

a. At 80 MHz and 800 MHz, the higher frequency range applies.

b. These guidelines might not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

c. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz, and in the frequency range of 80 MHz to 2.5 GHz, are intended to decrease the likelihood that mobile/portable communications equipment might cause interference if inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

d. The ISM (Industrial, Scientific and Medical) bands between 150 kHz and 80 MHz are 6.765 to 6.795 MHz, 13.553 to 13.567 MHz, 26.957 to 27.283 MHz, and 40.66 to 40.70 MHz.

Standards

The Alaris SE pump has been assessed and complies with the following standards:

IEC EN 60601–1 / BS 5724, including amendments A1 and A2; IEC EN 60601–2–24; CISPR 11, Group 1, Class A/B Emissions; IEC EN 60601–1–2, UL 60601-1, CAN/CSA No. 601.1-M90

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