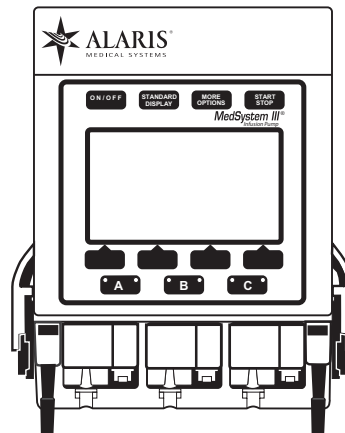


Directions for Use

MedSystem III® Infusion Pump Models 2865/2866

(With Advanced Dose Rate Calculation and Drug List Editor)

June 2006



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About MedSystem III® Infusion Pump

MedSystem III® infusion pump (instrument) with Drug List Editor is intended for use in today's growing professional healthcare environment, including healthcare facilities and home care, for use on adults, pediatrics and neonates.

Instrument is intended for facilities that utilize infusion pumps for the delivery of fluids, medications, blood and blood products using continuous or intermittent delivery through clinically acceptable routes of administration; such as, intravenous (IV), intra-arterial (IA), subcutaneous, epidural, enteral, or irrigation of fluid spaces.

Instrument is a multi-channel infusion pump intended to deliver multiple infusions to a single patient.

Instrument with Drug List Editor features:

- Three independent fluid delivery systems in the space of one.
- Compact size:
 - reduces bedside clutter
 - simplifies patient transport
- Easy to Setup and use, yet provides advanced features.
- Accommodates assorted container types.
- Multiple delivery methods:
 - Intravenous/Intra-arterial/Subcutaneous/Epidural
- Accurate delivery of a variety of fluids.
- Uses administration sets that provide free-flow protection.
- Six available Device Types with configurable parameters (maximum and minimum rates, maximum volumes, baseline and maximum pressures, and air-in-line thresholds) to achieve specific clinical applications:

- General Purpose
- Neonatal
- Controller Pressure
- Operating Room
- General Purpose II
- Operating Room II

About MedSystem III® Infusion Pump (Continued)

- Display infusion status for rate, volume remaining and volume infused.
- Infusions can be programmed to deliver at a specified rate or over a specified period of time.
- Secondary mode allows fluids and medications to be delivered at two different rates, sequentially.
- Dose Rate Calculator (DRC) feature performs volumetric rate and/or dose rate calculations.
- With DRC activated, instrument displays infusion status for rate, dosing regimen and drug name.
- Communications Protocol allows clinical monitoring, instrument configuration and maintenance.
- Field Maintenance Software (FMS) available for Biomed to configure, service and troubleshoot instrument.

Contraindications: None known.

Features

Multi-channel Fluid Delivery System

Combines three independent infusion channels in an unparallelled small size.

Lightweight/portable

Instrument with pole clamp weighs just over 5 pounds (2.3 kg) and is easy to transport.

Unique, rotating pole clamp

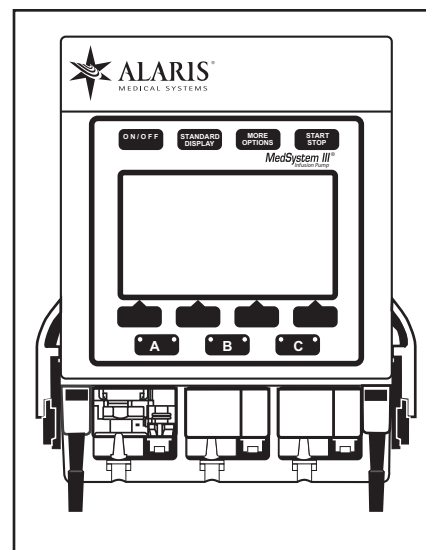
May be attached to a variety of surfaces.

Dose Rate Calculator (DRC)

Calculates a volumetric or dose rate based on values entered for patient weight, drug concentration (drug amount and diluent volume) and dosing parameters.

Drug List Editor (DLE)

Drug list can be customized using Drug List Editor software.



| | |
|-----------------------------|--------------------|
| A: Stopped | |
| DRUG? | Wt ---- KG= 0.0 LB |
| A:Conc | ----- mg/---- ml |
| A:Dose | ----- mcg/kg/min |
| A:Rate | ----- ml/h |
| A:VR | 1 ml (Vol Rem) |
| A:VI | 0 ml DI 0.0 mg |
| Press Select to choose line | |
| Select | ↑ ↓ Clear |

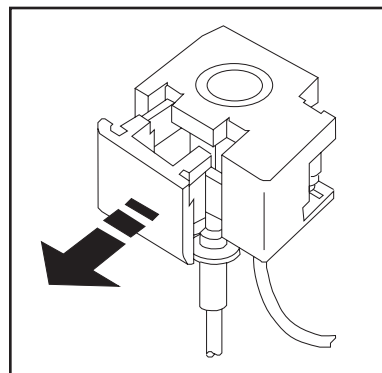
Six Device Types available

Six available Device Types with configurable parameters (maximum and minimum rates, maximum volumes, baseline and maximum pressures, and air-in-line thresholds) to achieve specific clinical applications:

| | |
|---------------------|--------------------|
| General Purpose | Operating Room |
| Neonatal | General Purpose II |
| Controller Pressure | Operating Room II |

Free-flow Protection

Administration Sets contain a cassette that provides protection from free-flow conditions. Upon removal of cassette from instrument, cassette's slide clamp is pulled to full extension, occluding the tubing and preventing fluid from flowing.

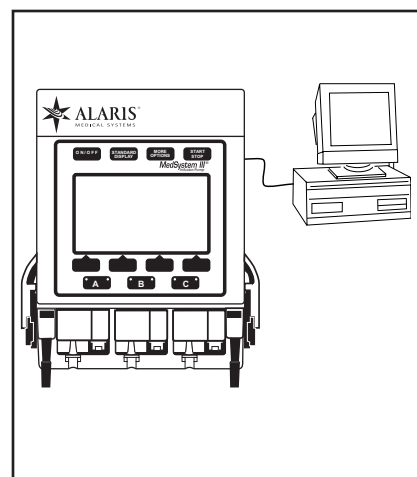


Monitoring System

Continuously monitors instrument conditions and alerts with adjustable audio tones and visual messages.

Data Monitoring

Can be configured to communicate with a remote computer, such as a centralized patient monitoring nurse's station. The COMM receptacle is compatible with RS-232 cabling. A communications manual that describes the programming and hardware involved is available.



Field Maintenance Software (FMS)

Can be modified to accommodate specialized clinical applications. The Device Type parameters, occlusion limit, and air-in-line threshold can be configured with the FMS software.

Features (Continued)

Secondary Mode

Allows user to program two different rates of infusion to run sequentially.

Syringe Delivery

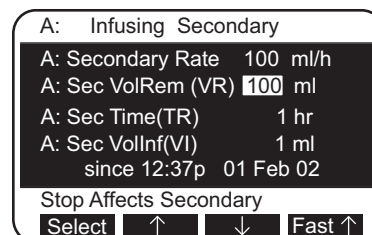
Accommodates 20cc to 60cc syringes.

Full Range of Delivery Rates

Rates from 0.1 to 999 milliliters per hour.

Battery Capacity

A new fully-charged battery provides 6 to 8 hours of operating time with rates at 125 ml/h per channel.



System Components

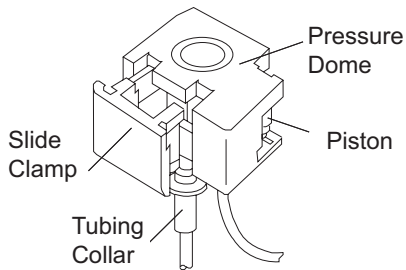
FRONT PANEL

- Instrument Keys
- Display Screen
- Softkey Pads
- Channel Indicator Lights
- Green:
- Steady - infusing on AC power
 - Flashing - infusing on battery power
- Red:
- Slow flashing - Advisory
 - Rapid flashing - Alert

Channel Select Keys

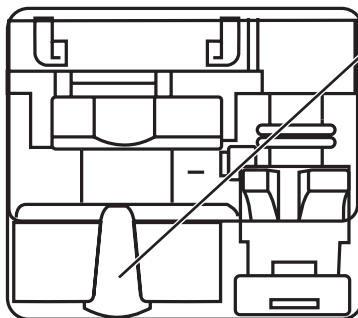
CASSETTE

Portion of administration set, inserts into cassette holder.



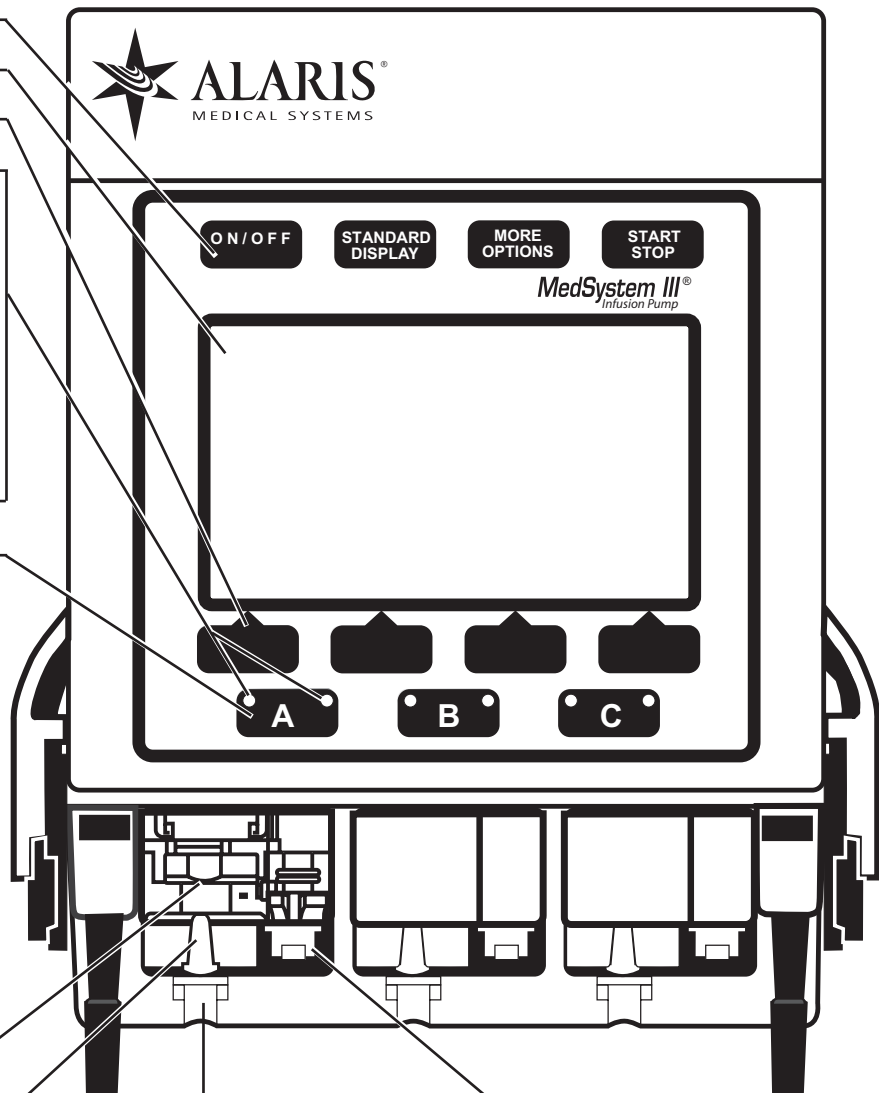
LOWER ASSEMBLY

3 Cassette Holders



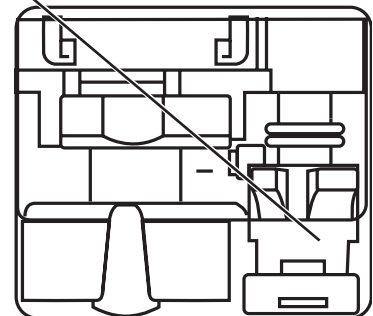
Air-in-Line Sensor

Detects bubbles of air during infusion.



Tubing Collar Recess

Holds tubing collar in place.

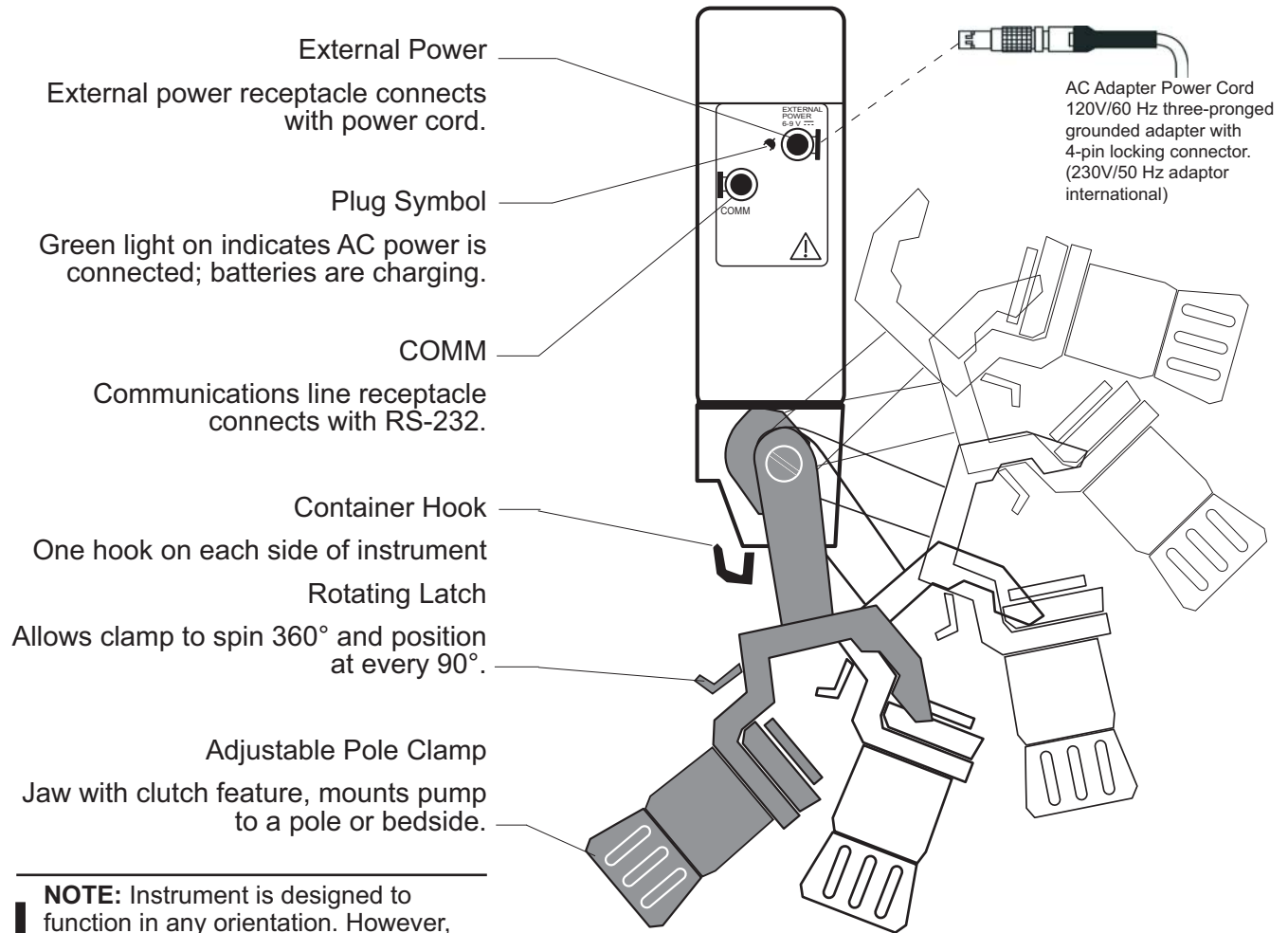


Pump Latch Mechanism

Drives the cassette piston to move fluid through the tubing.

CONNECTOR PANEL

NOTE: When inserting or removing connectors into or from receptacles, avoid excessive force or twisting. To remove AC adapter from pump first remove clip that is on connector.

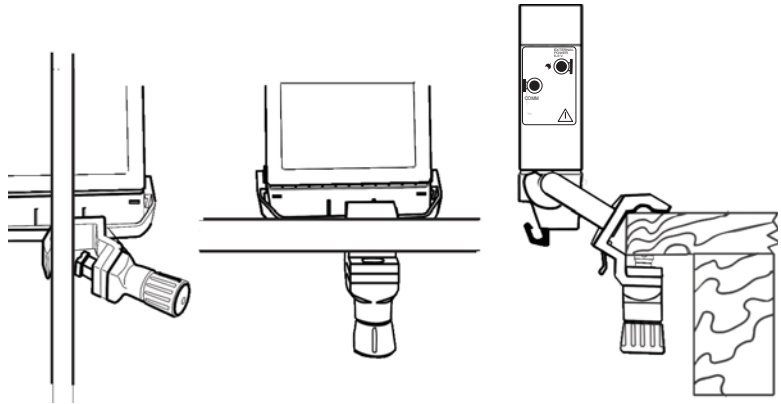


NOTE: Instrument is designed to function in any orientation. However, the effectiveness of the administration set air trap is diminished when instrument is in other than vertical position.

System Components (Continued)

Attaching Pole Clamp

To attach pole clamp, position clamp jaw over mounting surface and turn knob until the clamp is tightened and pump feels secure. When knob is as tight as possible, continued turning will make it click and spin freely without over-tightening.



Symbols



Canadian and U.S. Certification Mark: Products bearing this mark have been tested and certified in accordance with applicable U.S. and Canadian electrical safety and performance standards.

IPX1

Protection against fluid ingress: Drip Proof.



Caution: Refer to accompanying documentation.



U.S. Certification Mark: Products bearing this mark have been tested and certified in accordance with applicable U.S. electrical safety and performance standards (UL 544).



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



Consult operating instructions.



Explosion risk if used in presence of flammable anesthetics.

Symbols (Continued)



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

Single-Use



Single-Use. Do not reuse.



DEHP in fluid pathway.



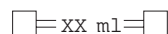
No DEHP in fluid pathway.



Product is latex-free.



Product incorporates SmartSite Needle-Free Valve ports and should not be accessed by a needle.



Approximate administration set, priming volume.



Drops per milliliter specification for product will be identified on drop symbol.



Expiration date for product will be identified near hour glass symbol.

NOTE: Although instrument is built and tested to exacting specifications, it is not intended to replace the supervision of IV infusions by medical personnel. The user should become thoroughly familiar with the features and operation of instrument and exercise vigilance in its utilization.

CAUTION

Rx Only

Warnings and Cautions

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

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

To ensure proper performance of instrument and to reduce potential injury, observe the following precautions:

Epidural Administration

Instrument can be used for epidural administration of anesthetic and analgesic drugs. This application is only appropriate when using analgesics and anesthetics labeled for continuous epidural administration and catheters intended specifically for epidural use. Use only a instrument, 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.

WARNING

The use of any accessory, transducer, or cable with instrument other than those specified may result in increased emissions or decreased immunity or electromagnetic compatibility performance of this device.

WARNING

Only connect equipment approved to IEC EN 60601-1 or UL 1069 approved medical or hospital signaling equipment

WARNING

Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.

WARNING

It is strongly recommended that instrument, source container and instrument Administration Set used for epidural drug delivery be clearly differentiated from those used for other types of administration.

Warnings and Cautions (Continued)

WARNING

Instrument is designed to stop fluid flow under alarm conditions other than Low Battery and KVO. Periodic patient monitoring must be performed to ensure the infusion is proceeding as expected.

WARNING

Instrument is a positive pressure 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.

WARNING

Hospital personnel must ensure compatibility of drugs as well as performance of each channel as part of the overall infusion. Potential hazards include drug interactions, inaccurate delivery rates, inaccurate pressure alarms and nuisance alarms.

WARNING

Use only Instrument 28 Series administration sets. The use of any other set may cause improper instrument operation, resulting in an inaccurate fluid delivery or other potential hazard.

WARNING

The use of positive displacement infusion devices ported together with gravity flow infusion systems into a common IV site may impede the flow of common "gravity only" systems, affecting their performance. Hospital personnel must ensure performance of common IV site is satisfactory under these circumstances

WARNING

References in this document to specific drugs and drug doses are for example only. Refer to specific drug product labeling for information concerning appropriate administration techniques and dosages.

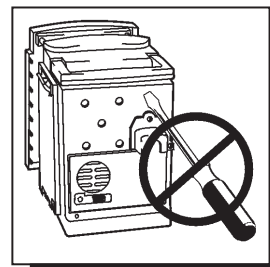
Warnings and Cautions (Continued)

Parallel Infusions

There are no contraindications regarding the use of an instrument with any other positive displacement infusion device when ported together into a common IV site location.

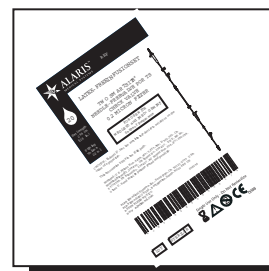
To ensure proper instrument performance and to reduce potential injury to the operator, observe the following precautions:

- Disconnect from mains (AC) and battery power when performing maintenance.
- To disconnect AC power, unplug power cord from back of instrument.
- Do not open instrument case. There are no user serviceable parts inside. The case should only be opened by qualified service personnel using proper grounding techniques. When the case is opened, an electrical shock hazard exists which can result in serious injury to persons and Instrument component damage.



Administration Sets

- A list of approved IV sets recommended by Cardinal Health, for use with instrument is listed on the Set Compatibility Card. The use of any other set may cause improper instrument operation, resulting in inaccurate fluid delivery.
- Before operating instrument, verify that the administration set is free from kinks and installed correctly.
- Instrument administration sets are disposable, have a sterile fluid path and are intended only for one time use. Do not resterilize.
- Always power on instrument before inserting the set.
- Do not insert a cassette into a channel with a SERVICE prompt.
- Remove any cassettes from channel(s) requiring service.
- Ensure the cassette is properly installed before starting infusions.



Warnings and Cautions (Continued)

- For set replacement interval, refer to facility protocol and/or government standards (such as CDC guidelines in the United States).
- For IV push medication (put Instrument on hold), clamp tubing above the port.
- Flush port(s) per facility protocol.
- Discard administration set per facility protocol.

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 the ECG monitoring system is not functioning under optimal conditions, these currents may appear as artifacts, simulating actual ECG readings. To determine if ECG abnormalities are caused by patient condition or the ECG equipment, place the infusion device 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.

Dropping/Jarring

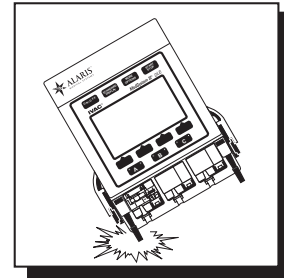
Should an instrument be dropped or severely jarred, it should be immediately taken out of use and inspected by qualified service personnel, to ensure its proper function prior to reuse.

Operating Environment

Not for use in the presence of flammable anesthetics.

Radio Frequency Interference

- This equipment system is intended for use by healthcare professionals only. This is a CISPR 11 Class B Group 2 Medical equipment system. In a domestic environment this equipment or system may cause radio interference, in which case it may be necessary to take adequate mitigation measures, such as re-orienting, relocating or shielding instrument or filtering the connection to the public mains network.



◀ DANGER ▶

Explosion risk if used in the presence of flammable anesthetics.



Warnings and Cautions (Continued)

- Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed, put into service and used according to the EMC information provided in the accompanying documents.
- Portable and Mobil RF communications can affect Medical Electrical Equipment.
- Operating the system near equipment which radiates high energy radio frequencies (electrosurgical/cauterizing equipment, portable radios, cellular telephones, etc.) may cause false alarm conditions. If this happens, reposition the device away from the source of interference or turn off the device and manually regulate the flow with the clamp and/or monitor the vital parameters using an appropriate clinical alternative.

Other Precautions

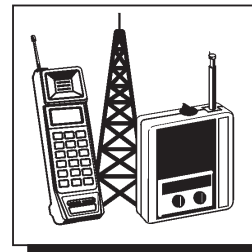
- The AC adapter must be connected to a properly grounded, 3-wire receptacle ("Hospital Use" or "Hospital Grade").
- Avoid excessive force or twisting of detachable power cords when inserting or removing connector terminals.
- Use AC adapter indoors only.
- Instruments should not be used adjacent to or stacked with other equipment, if adjacent or stacked use is necessary, instrument should be observed to verify normal operation in the configuration used.

Prepare solution container in accordance with the manufacturer's instructions.

- A syringe can be used as the container for the IV fluid to be infused. Syringe sizes from 20cc to 60cc of such as the B-D and Monoject brands can be used.

WARNING

Use of accessories or cables other than those specified may result in degraded electromagnetic compatibility performance of this device.



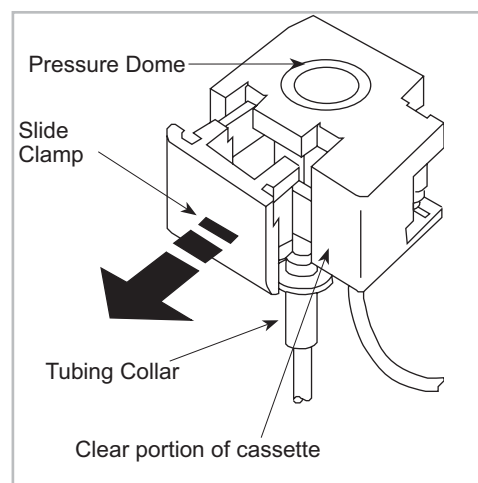
Preparing Infusion

Connect the container to the IV set.

Prime the Instrument administration set in accordance with the Administration Set Directions for Use.

It is important to prime the set properly to eliminate air bubbles.

NOTE: The Model 8631A Syringe Holder is available as an accessory that provides a convenient place to hold syringes while they are being used as containers for IV fluid. The Syringe Holder is designed to be easily installed and removed from the top of the pump and to support up to three syringes. Do not use the Syringe Holder as a handle to carry the pump.



Preparing Administration Set

Ensure the cassette slide clamp is pushed in completely so tubing is not occluded.

Invert the cassette so tubing is up. Slowly open the regulating clamp and establish fluid flow to fully prime the set. Gently tap the cassette and 'Y' sites as necessary to remove all air. Gently massage the pressure dome to ensure no air bubbles are trapped.

Close the regulating clamp before inserting and removing the cassette to reduce the risk of free flow.

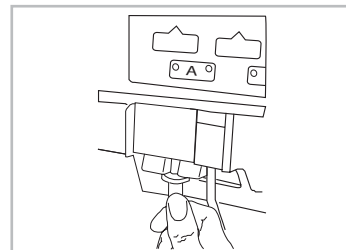
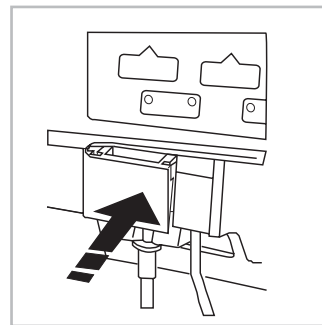
WARNING

An open regulating clamp and slide clamp can cause a free-flow condition and may result in serious injury to the patient.

Loading Set

1. Ensure cassette slide clamp is pulled out (in the closed position) prior to loading.
2. Press **ON/OFF** to turn pump on.
3. With tubing down, use a 45-degree upward motion to insert cassette into channel.
4. Push on clear portion of cassette until completely seated. Then push in slide clamp flush with entire cassette.
5. Pull down gently on tubing collar. Press with thumb to seat tubing collar in recess beneath cassette.

NOTE: Three beeps sound when inserted properly.



Front Panel Overview

Instrument Control Keys

ON/OFF Key

Turns the pump on and off.

STANDARD DISPLAY Key

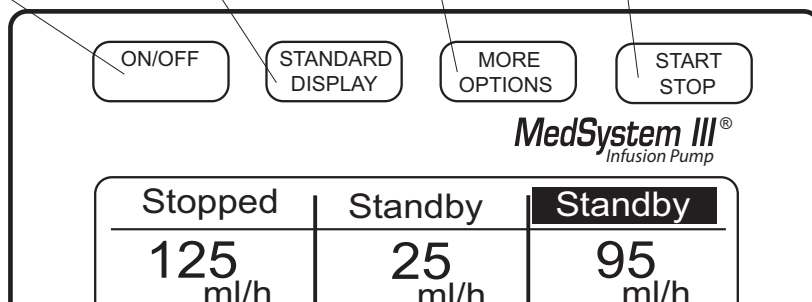
Allows the user to display Standard Display page to view infusion settings for all channels.

MORE OPTIONS Key

Allows the user to display additional softkey functions.

START/STOP Key

Starts or stops infusion on selected channel.



Front Panel Overview (Continued)

Standard Display Page

Status Line

Displays infusion status (Infusing; Stopped; Standby; KVO; ALARM; FAULT; SERVICE) for each channel.

NOTE: Status line in selected channel is highlighted.

Infusion Rate

Volume Remaining (ml)

Volume Infused (ml)

Prompt Line

Displays messages that prompt the user to make programming choices and/or take appropriate actions.

Softkey Prompts

Displays function of specific softkey.

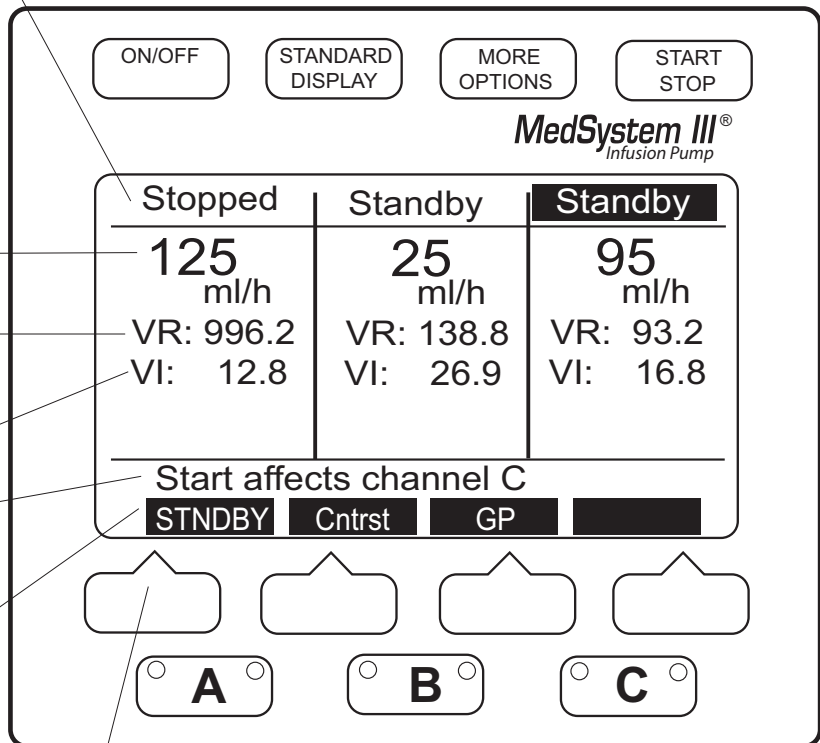
STNDBY Appears in softkey information line when **START STOP** is pressed during infusion.

Cntrst (Contrast) Brightens or dims display.

GP When pressed, indicates full name of selected Device Type on the prompt line.

NOTE: Additional softkey prompts are displayed by pressing **MORE OPTIONS**.

Softkey Pads (4)



Selected channel is indicated by the letter displayed at the beginning of the first five lines.

Status Line

Displays infusion status for selected channel.

Infusion Rate

Volume Remaining

Time Remaining

Volume Infused

Date/Time

Displays when volume infused was last cleared and infusion began.

Prompt Line

Displays messages that prompt user to make programming choices and/or take appropriate action.

Softkey Prompts

Displays function of specific softkey.

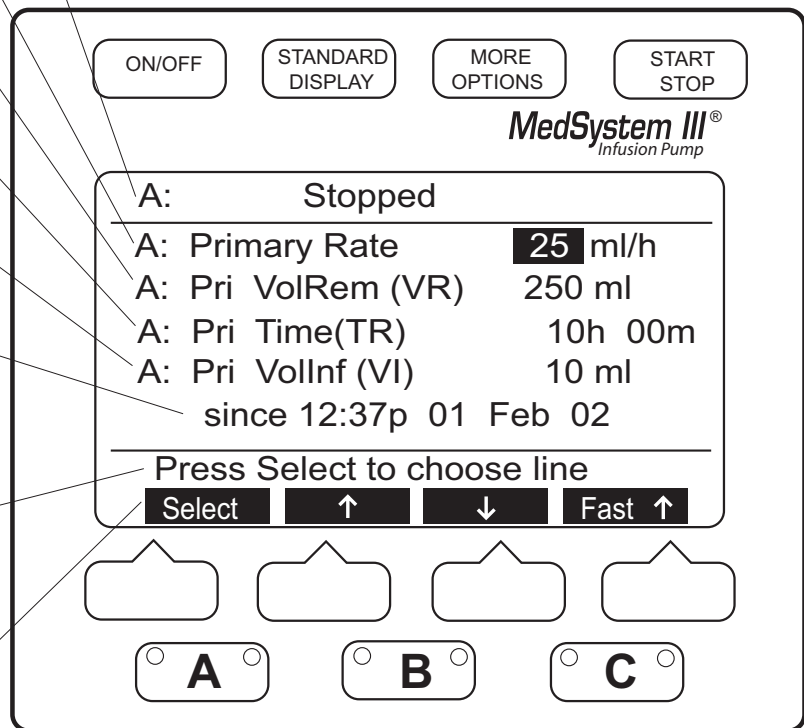
Select – Moves highlight bar through programmable infusion parameters.

↑ – Increases highlighted value.

↓ – Decreases highlighted value.

Fast↑ – Increases or decreases highlighted value at greater increments.

Fast↓



Programming Page (Continued)

To Turn Pump On

Press **ON/OFF**.

- Upon start-up, instrument performs an automatic self-test. Listen for a “beep” to ensure that the audio alarm transducer functions properly.
- Instrument information page is momentarily displayed.
- Continuing to hold down ON/OFF key will keep the Information page on the display.
- When the ON/OFF key is released, the Standard Display page is displayed.

To Turn Pump Off

Press and hold **ON/OFF**.

- Display disappears.
- Pump is turned off.

To View Infusion Settings For All Active Channels

Press **STANDARD DISPLAY**.

- Standard Display page is displayed.

To Activate Additional Standard Display Softkey Prompts

With the Standard Display page displayed:

Press **MORE OPTIONS** once.

- TotVol, Device, Config, and Note softkeys appear.

To Select Channel And Display Programming Pages

Press **MORE OPTIONS** again.



- Batlog and DemoWD softkeys appear.

Press **A**, **B** or **C**.

- Selected channel Programming Page is displayed.

To Program Infusion

With Programming Page displayed:

1. Press Select to choose value to change.
 - Value is highlighted.
2. Scroll through values using ↑, ↓, Fast ↑ or Fast ↓.
 - ↑ and Fast ↑ increase highlighted values in single or multiple increments.
 - ↓ and Fast ↓ decrease highlighted values in single or multiple increments.
 - Pressing ↑ or ↓ changes direction of the Fast ↑ or Fast ↓.
 - Highlight remains flashing until Enter is pressed. If Enter is not pressed, the entry incomplete advisory will sound.
3. Press Enter to accept new value.
 - Highlight moves to next programmable value if channel status is Stopped or Standby.
 - If status is Infusing, highlight remains on selected value.
4. To recall a previous value after a new value is introduced but not entered, press .
- Recall soft key appears.
5. Press Recall.
 - Number returns to previous value.
6. Press .
- Infusion starts or stops immediately, unless the channel's programming is incomplete, or if an advisory, alarm, or fault condition exists on selected channel.
- ALARM is displayed in affected channel status line
- Alarm condition is displayed on the Standard Display of the affected channel.

Programming Page (Continued)

To Access Alarm Information

Press affected channel **A**, **B** or **C**.

- Alarm Information page is displayed for that channel.

See the **ALARMS, ADVISORIES AND PROMPTS** section of this manual for more alarm information.

To Activate Additional Programming Page Softkeys

With the Programming Page displayed:

- Press **MORE OPTIONS**.
- Press 2° Sec to access Secondary page
OR
- Press CalcOn to access Dose Rate Calculation page.
- Press **MORE OPTIONS** and press CalcOff to discontinue use of the Dose Rate Calculator.

See the **GETTING STARTED** section of this manual for information on the use of the Dose Rate Calculator function.

Programming Primary Function

To Set Primary Rate

- Press **A**, **B** or **C**.
 - Programming Page is displayed.
 - Rate is highlighted.
- Press Select if current rate is desired
OR
- Press ↑, ↓, Fast ↑ or Fast ↓ to change rate.
 - Value flashes.
- Press Enter to confirm.
 - Highlight moves to volume remaining (VR)

| | |
|-----------------------------|------------|
| A: Stopped | |
| A: Primary Rate | 100 ml/h |
| A: Pri VolRem (VR) | 500 ml |
| A: Pri Time(TR) | 05h 00m |
| A: Pri VolInf(VI) | 1 ml |
| since 12:37p 01 Feb 02 | |
| Press Select to choose line | |
| Select | ↑ ↓ Fast ↑ |

Programming Primary Function (Continued)

To Set Primary Volume Remaining (VR)

1. Press Select if current VR is desired
OR
2. Press ↑, ↓, Fast ↑ or Fast ↓ to change VR.
 - Value flashes.
3. Press Enter to confirm.
 - Primary time remaining (TR) is calculated automatically based on VR and rate.
 - Highlight moves to volume infused (VI).

| | |
|-----------------------------|------------|
| A: Stopped | |
| A: Primary Rate | 100 ml/h |
| A: Pri VolRem (VR) | 500 ml |
| A: Pri Time(TR) | 05h 00m |
| A: Pri VolInf(VI) | 1 ml |
| since 12:37p 01 Feb 02 | |
| Press Select to choose line | |
| Select | ↑ ↓ Fast ↑ |

To Clear Primary Volume Infused (VI)

1. Press Select if current VI is desired
OR
2. Press Clear to reset volume infused to zero.
 - Date and time are cleared.
 - Clear softkey switches to Recall.
3. Press Enter to confirm
OR
4. Press Recall softkey to recall previous VI, date and time.
5. Open regulating clamp on administration set.
6. Press **START STOP** to begin infusion.
 - Channel starts infusing.
 - Current date and time are entered.
 - Green infusion light on channel key stays lit.
7. Press **STANDARD DISPLAY**
OR
 - Display reverts to Standard Display page after one minute.
8. Verify settings.
9. Verify solution flow from primary container.

| | |
|-----------------------------|----------|
| A: Stopped | |
| A: Primary Rate | 100 ml/h |
| A: Pri VolRem (VR) | 500 ml |
| A: Pri Time(TR) | 05h 00m |
| A: Pri VolInf(VI) | 800 ml |
| since 12:37p 01 Feb 02 | |
| Press Select to choose line | |
| Select | Clear |

| | |
|-----------------------|----------|
| A: Stopped | |
| A: Primary Rate | 100 ml/h |
| A: Pri VolRem (VR) | 500 ml |
| A: Pri Time(TR) | 05h 00m |
| A: Pri VolInf(VI) | 0 ml |
| since ----- | |
| Press Enter or Recall | |
| Enter | Recall |

Programming Primary Function (Continued)

To Titrate Or Change Primary Rate During Infusion

1. Press **A**, **B** or **C**.
 - Programming Page is displayed.
 - Rate is highlighted.
2. Press \uparrow , \downarrow , Fast \uparrow or Fast \downarrow to change Rate
 - Value flashes.
3. Press Enter to confirm.
 - New rate begins infusing immediately.

To Change Volume Remaining During Infusion

1. Press **A**, **B** or **C**.
 - Programming Page is displayed.
 - Rate is highlighted.
2. Press Select to highlight VR.
3. Press \uparrow , \downarrow , Fast \uparrow or Fast \downarrow to change VR.
 - Value flashes.
4. Press Enter to confirm.
 - Infusion continues with new volume remaining

To Clear Volume Infused During Infusion

NOTE: When the channel VI is cleared, that volume is not subtracted from the volume on the TotVol page.

1. Press **A**, **B** or **C**.
 - Programming Page is displayed.
 - Rate is highlighted.
2. Press Select to highlight VI.
3. Press Clear then Enter to reset volume infused to zero.
 - Date and time are cleared.
 - Clear softkey switches to Recall.

Programming Primary Function (Continued)

To Clear Volume Infused During Infusion (Continued)

4. Press Enter to confirm
 - Infusion continues with volume infused reset to zero.
 - Current date and time are entered
- OR
5. Press Recall softkey to recall previous VI value, date and time.

Making Changes While Infusing

To Simultaneously Clear Total Volume Infused For All Channels

1. Press **STANDARD DISPLAY**.
 - Standard Display page is displayed.
2. Press **MORE OPTIONS**.
 - TotVol, Device, Config and Note softkeys appear.
3. Press TotVol softkey.
 - Total Volume page is displayed
 - VI for each channel and total pump VI values are highlighted.
4. Press ClrTot to reset volume infused to zero.
 - Date and time are cleared.
5. Press Enter to accept clearing of all values
- OR
6. Press Recall softkey to recall the previous Total VI, date and time.

| Stopped | Stopped | Stopped |
|-----------------------------|---------|---------|
| TotVI A | TotVI B | TotVI C |
| Pri 20 | Pri 20 | Pri 20 |
| Sec 0 | Sec 0 | Sec 0 |
| = 20 | = 20 | = 20 |
| Total VI = 60 ml | | |
| since 03:25p 10 Feb 02 | | |
| Press ClrTot to clear TotVI | | |
| [Enter] [Recall] [ClrTot] | | |

| Stopped | Stopped | Stopped |
|-----------------------|---------|---------|
| TotVI A | TotVI B | TotVI C |
| Pri 0 | Pri 0 | Pri 0 |
| Sec 0 | Sec 0 | Sec 0 |
| = 0 | = 0 | = 0 |
| Total VI = 0 ml | | |
| since ----- | | |
| Press Enter or Recall | | |
| [Enter] [Recall] | | |

Making Changes While Infusing (Continued)

To Place A Channel On Standby During Infusion

NOTE: When a channel is Stopped for two minutes with a cassette in place, a Channel Not In Use advisory sounds. When a channel is on Standby, the advisory does not sound.

NOTE: Infusing channel should always be stopped prior to removing cassette.

1. Press appropriate channel **A**, **B** or **C**.
2. Press **START STOP** to stop infusion.
3. Press **STANDARD DISPLAY**.
 - Standard Display page is displayed.
4. Press STNDBY.

| | | |
|-------------------------|--------|----|
| Stopped | | |
| 100 ml/h | | |
| VR: 450 | | |
| VI: 50 | | |
| Start affects channel A | | |
| STNDBY | Cntrst | GP |

To Start An Infusion From Standby Status

1. Press appropriate channel **A**, **B** or **C**.
2. Press **START STOP** to start infusion.

Programming Option

To Setup An Infusion By Rate/volume Or Volume/time

1. Press **START STOP** if channel is infusing.
2. Press **STANDARD DISPLAY** if Standard Display page not already displayed.
3. Press **MORE OPTIONS**.
 - TotVol, Device, Config and Note softkeys appear.
4. Press Config softkey.
 - The first of five Instrument Settings pages is displayed.
5. Press Select to move the highlight to Setup Line Option.
6. Press ↑ or ↓ to choose Yes.
 - ↑ and ↓ will not be displayed if pump is infused.
7. Press Enter to enable programming option.
8. Press channel **A**, **B** or **C**.

| | |
|------------------------------|------------|
| Instrument Settings (1 of 5) | |
| * Audio Volume: | highest |
| Sec Complete Advisory: | No |
| Setup Line Option | No |
| Time: am/pm 02:16p 01 Jul 02 | |
| Press Stnd Display to Exit | |
| Select | ↑ ↓ NextPg |

Programming Option (Continued)

To Setup An Infusion By Rate/Volume Or Volume/time (Continued)

9. Press Select to move highlight to
Setup: Select VR and Time
OR
Setup: Select VR and Rate
10. If highlighted choice is not desired, press ↑ or ↓ to change setup choice.
 - Choice flashes.
11. Press Enter to accept.
 - Highlight moves to top of page.
 - Enter desired settings.

NOTE: Rate will highlight but cannot be changed if Volume/Time option is active. Time remaining selection will highlight but cannot be changed if Rate/Volume option is active.

| | |
|-----------------------------|---|
| A: | Stopped |
| A: Primary Rate | 100 ml/h |
| A: Pri VolRem (VR) | 500 ml |
| A: Pri Time(TR) | 05h 00m |
| A: Pri VolInf(VI) | 1 ml |
| | since 02:16p 01 Jul 02 |
| Setup: | Select VR and Time |
| Press Select to choose line | |
| Select | ↑ ↓ |

| | |
|-----------------------|------------------------|
| A: | Stopped |
| A: Primary Rate | 100 ml/h |
| A: Pri VolRem (VR) | 500 ml |
| A: Pri Time(TR) | 05h 00m |
| A: Pri VolInf(VI) | 1 ml |
| | since 02:16p 01 Jul 02 |
| Setup: | Select VR and Rate |
| Press Enter or Recall | |
| Enter | ↑ ↓ Recall |

KVO Status

To resume infusion when VR=0 (KVO)

With a channel infusing at KVO rate:


- Green light on channel key remains on.
 - Red light on channel key flashes.
 - Two toned advisory sounds.
1. Press appropriate channel A, B or C twice.
 - VR is highlighted.
 2. Press REPEAT to recall previous VR
OR
 3. Press ↑, ↓, Fast ↑ or Fast ↓ to change VR.
 - Value flashes.

| | | |
|---|--|--|
| KVO | | |
| 100 | | |
| Infusion Complete | | |
| VR = 0 | | |
| Alarm Info: Press A | | |
| | Cntrst | GP QUIET |

| | | |
|-----------------------------|--|----------|
| A: | KVO | 3.0 ml/h |
| A: Primary Rate | 100 ml/h | |
| A: Pri VolRem (VR) | 0 ml | |
| A: Pri Time (TR) | ---- | |
| A: Pri VolInf (VI) | 100 ml | |
| | since 12:37p 01 Feb 02 | |
| Press Select to choose line | | |
| Select | ↑ ↓ REPEAT | |

KVO Status (Continued)

To Resume Infusion When Vr=0 (KVO)

4. Press Enter to confirm.
5. Press  to resume infusion and stop KVO rate.

NOTE: If current infusion rate is set below KVO rate, channel will infuse at the lower rate.

Secondary Mode

This option allows two different rates of infusion to be administered sequentially. When secondary volume remaining reaches zero, primary infusion resumes automatically.

To avoid the possibility of concurrent flow during secondary delivery of intermittent medications, Setup the administration set as recommended below.

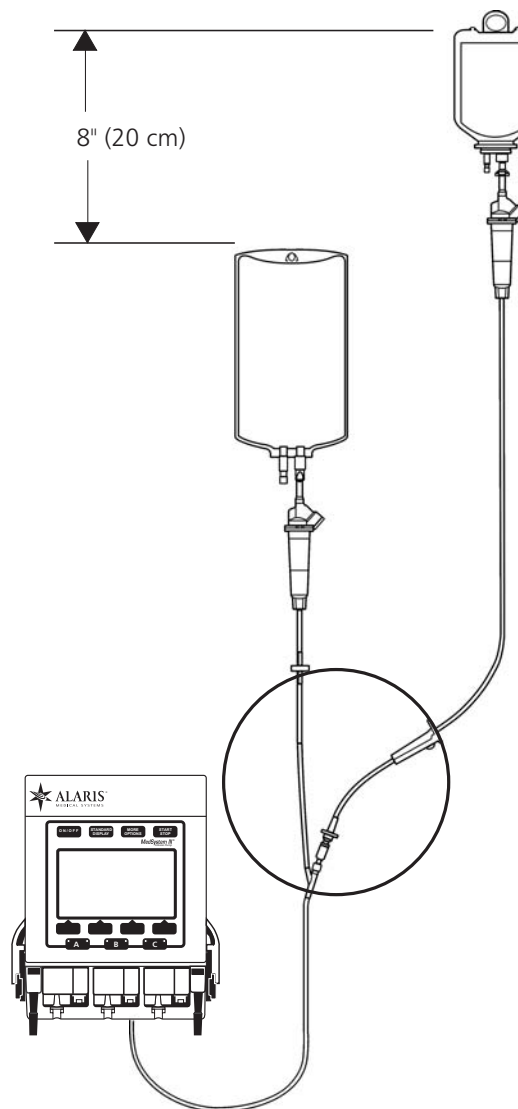
Secondary Mode (Continued)

Preparing The Administration Set And Container

- For Needle-Free sets, attach secondary to upper primary 'Y' site, below a check valve.
- Prepare the secondary IV container according to your institution's policy.
- Suspend secondary solution container at least 8 inches (20 cm) above primary solution container.
- Press **A**, **B** or **C** to select channel.

WARNING

Setting a secondary rate over 275 ml/h may result in concurrent flow with the primary container.



Secondary Mode (Continued)

Programming Secondary Infusion

1. Press **A**, **B** or **C**.
 - Primary Programming Page is displayed.
2. Press **MORE OPTIONS**.
3. Press 2° Sec softkey.
 - Secondary Programming Page is displayed.

NOTE: Secondary Programming Page is reverse highlighted.

| | |
|------------------------|---------------|
| A: Infusing Primary | |
| A: Primary Rate | 50 ml/h |
| A: Pri VolRem (VR) | 450 ml |
| A: Pri Time(TR) | 09h 00m |
| A: Pri VolInf(VI) | 50 ml |
| since 12:37p 01 Feb 02 | |
| Press desired function | |
| 2° Sec | CalcOn |

To Set Secondary Volume Remaining (VR)

1. Press Select to highlight secondary VR, if necessary.
2. Press REPEAT to enter the last VR selected
OR
3. Press ↑, ↓, Fast ↑ or Fast ↓ to change VR.
 - Value flashes.
4. Press Enter to confirm.
 - Secondary time remaining (TR) is calculated automatically, based on VR and Rate.
 - Highlight moves to secondary volume infused (VI).

| | |
|-----------------------------|---------------------------------|
| A: Infusing Primary | |
| A: Secondary Rate | 100 ml/h |
| A: Sec VolRem (VR) | 0 ml |
| A: Sec Time(TR) | ---- |
| A: Pri VolInf(VI) | 200 ml |
| since 12:37p 01 Feb 02 | |
| Start Switches to Secondary | |
| Select | ↑ ↓ Repeat |

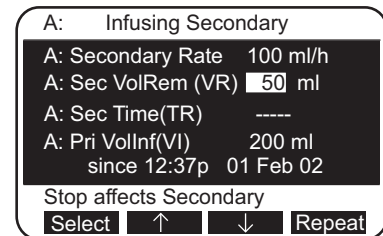
To Clear Secondary Volume Infused (VI)

1. Press Select if current VI is desired
OR
2. Press Clear to reset volume infused to zero.
 - Date and time are cleared.
 - Clear softkey switches to Recall.
3. Enter to confirm
OR
4. Press Recall softkey to recall previous VI value, date and time.

Secondary Mode (Continued)

To Set Secondary Rate

1. Press Enter to confirm
2. Press Select if current rate is desired
OR
3. Press ↑, ↓, Fast ↑ or Fast ↓ to change Rate.
 - Value flashes.
4. Press Enter to confirm.
5. Open regulating clamp on secondary administration set.
6. Press **START STOP** to begin infusion.
 - Four tones sound (if primary infusion is in progress).
 - Pump starts infusing at secondary rate.
 - Current date and time are entered.
7. Press **ON/OFF**
OR
 - Display reverts to Standard Display page after one minute.
8. Verify settings.
9. Verify solution flow from secondary container.



To Set Rate Of Infusion From A Time Entry

The infusion rate can be set with the volume remaining (VR) and time entry.

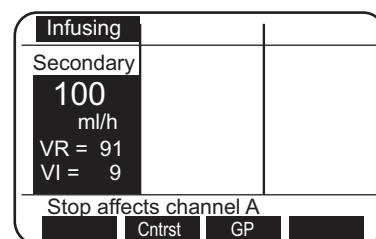
1. Press **MORE OPTIONS** from the Standard Display.
2. Press Config softkey at bottom of display.
3. Select Change Instrument Settings from menu.
4. Press ↑ or ↓, softkey to change Setup Line Option from NO to YES.
5. Return to the Standard Display and press a channel.
 - The display will read "Setup: Select VR and Rate".
6. Step down to "Set: Select VR and Rate".
7. Press Accept to set a time.
1. Press **A**, **B** or **C** .

Secondary Mode (Continued)

To Titrate Or Change Secondary Rate During Infusion

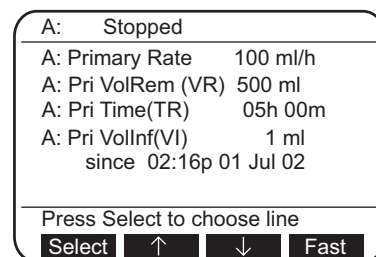
NOTE: Channel display on the Standard Display is reverse highlighted.

- Secondary Programming Page is displayed.
 - Rate is highlighted.
2. Press ↑, ↓, Fast ↑ or Fast ↓ to change rate.
 - Value flashes.
 3. Press Enter to confirm.
 - New rate begins infusing immediately.



To Review Or Change Primary Value(S) During Secondary Infusion

1. Press **A**, **B** or **C**.
 - Secondary Programming Page is displayed.
2. Press **MORE OPTIONS**.
 - 1° Pri and CalcOn softkeys appear.
3. Press 1° Pri softkey.
 - Primary Programming Page is displayed.
4. Press Select to highlight value(s) to change.
5. Press ↑, ↓, Fast ↑ or Fast ↓ to change value(s).
6. Press Enter to confirm.



Secondary Mode (Continued)

To Start Infusion Before Secondary Completes

1. Close regulating clamp on secondary infusion set.
2. Press **A**, **B** or **C** .
 - Secondary Programming Page is displayed.
3. Press **MORE OPTIONS** .
 - 1° Pri and CalcOn softkeys appear.
4. Press 1° Pri softkey.
 - Primary Programming Page is displayed.
5. Press **START STOP** to begin primary infusion and stop secondary infusion.
 - Four tones will sound.
 - Infusion starts at primary rate.

WARNING

Pressing **START STOP** will result in the remaining secondary medication being delivered at the primary rate if the regulating clamp on the secondary set was not closed.

Dose Rate Calculator (Drc) Programming Using A Specific Drug Name

NOTE: Dose Rate Programming Page will not display if channel is infusing. If infusing in secondary mode, switch to primary mode and stop infusion before proceeding.

NOTE: Pressing **A**, **B** or **C** at any time during DRC set-up, returns the highlight to the top of the page.

With this feature, instrument calculates a volumetric or dose rate based on values entered for patient weight, drug concentration (drug amount and diluent volume) and dosing parameters. If a dose is entered, the volumetric rate is calculated. If a volumetric rate is entered, the dose is calculated.

1. Press **A**, **B** or **C** .
 - Primary Programming Page is displayed.
2. If infusing, press **START STOP** to stop infusion.
3. Press **MORE OPTIONS** .
 - 2° Sec and CalcOn softkeys appear.

WARNING

Ensure correct entry of all drug calculation infusion parameters. Consult the drug manufacturer's labeling for information concerning appropriate administration guidelines and dosages.

| | | | |
|-----------------------------|---------|--------------|------------|
| A: | Stopped | | |
| DRUG? | Wt | --- | KG= 0.0 LB |
| A:Conc | ----- | mg/---- | ml |
| A:Dose | ----- | mcg/kg/min | |
| A:Rate | ----- | ml/h | |
| A:VR | 1 | ml (Vol Rem) | |
| A:VI | 0 | ml DI | 0.0 mg |
| Press Select to choose line | | | |
| Select | ↑ | ↓ | Clear |

Dose Rate Calculator (Drc) Programming Using A Specific Drug Name (Continued)

4. Press CalcOn.
 - Dose Rate Calculator Programming Page is displayed.
 - DRUG? is highlighted.

Programming Drug

NOTE: Changing drug name clears previous values and changes drug concentration and dose rate parameters to parameters appropriate for the selected drug.

1. Scroll using arrow softkeys to display alphabetized, abbreviated drug names.
 - ↓ moves A to Z.
 - ↑ moves Z to A.
 - Fast ↑ and Fast ↓ moves alphabetically through the drug name list. By default, Fast goes to the next letter of the alphabet.
2. Press Enter when desired drug name is highlighted.
 - Highlight moves to Wt.

Programming Weight

1. Choose patient's kilogram weight using the ↑, ↓, Fast ↑ and Fast ↓ softkeys.
2. Press Enter when desired weight is displayed.
 - Highlight moves to Conc.

| | |
|-----------------------------|--------------------|
| A: Stopped | |
| DOPAMINE | Wt 70.0 KG=154.3LB |
| A:Conc | 400 mg/ 250 ml |
| A:Dose | 5.0 mcg/kg/min |
| A:Rate | 13.1 ml/h |
| A:VR | 250 ml (Vol Rem) |
| A:VI | 0 ml DI 0.0 mg |
| Press Select to choose line | |
| Select | ↑ ↓ Clear |

Programming Concentration

1. Choose concentration using the ↑, ↓, Fast ↑ and Fast ↓ softkeys.
2. Press Enter when desired concentration is displayed.
 - Highlight moves to value for diluent volume.
3. Choose diluent volume using the arrow softkeys.

Dose Rate Calculator (Drc) Programming Using A Specific Drug Name (Continued)

Programming Concentration (Continued)

- Press Enter when desired volume is displayed.
 - VR is automatically set when the diluent volume value is entered but can be changed if desired.
 - Highlight moves to Dose.

NOTE: Calculated rates for infusion are fractional and will be displayed as a fraction on the Standard Display even if Device Type is set for whole numbers.

Programming Dose

NOTE: In Neonatal Device type, the concentration will always start at a numeric value of 0.1.

- Choose dose using the ↑, ↓, Fast ↑ or Fast ↓ softkeys.
- Press Enter when desired dose is displayed.
 - Volumetric rate is automatically calculated.
 - Highlight moves to Rate.

Changing Volumetric Rate

- Choose rate value using the ↑, ↓, Fast ↑ or Fast ↓ softkeys if dose rate is not as desired.
- Press Enter when desired volumetric rate is displayed.
 - When rate is changed, dose value is automatically calculated.
 - Highlight moves to VR.

| | | |
|------------------------|--------|----|
| Infusing | | |
| 131 | | |
| ml/h | | |
| 5.0 | | |
| mcg/kg/min | | |
| DOPAMINE | | |
| Stop affects channel A | | |
| | Cntrst | GP |

Changing Volume Remaining

- Change VR value using the ↑, ↓, Fast ↑ or Fast ↓ softkeys.
- Press Enter when desired VR is displayed.
 - Highlight moves to VI.

Dose Rate Calculator (DRC) Programming using a specific drug name (Continued)

Clearing the Volume Infused(VI) and Dose Infused(DI)

1. Press Clear then Enter to reset volume infused to zero.
 - Highlight moves to DI.
2. Press Clear then Enter to reset dose infused to zero.
3. Open regulating clamp.
4. Press **START STOP** to begin infusion.
 - Channel starts infusing.
5. Press **STANDARD DISPLAY**
OR
 - Display reverts to Standard Display page after one minute.
 - DRC parameters are displayed.
6. Verify settings.
7. Verify solution flow from solution container

NOTE: Stop infusion to make changes to the drug name, weight, or concentration.

Changing DRC values while infusing

1. Press **A**, **B** or **C**.
 - Dose Rate Calculator Programming Page is displayed.
 - Dose value is highlighted.
2. Press Select to scroll through values that can be changed.
3. When highlight is on value to be changed (Dose, Rate, VR, VI, DI), use ↑, ↓, Fast ↑ or Fast ↓ softkeys until desired value is displayed.
 - When dose is changed, rate is automatically recalculated.
 - When rate is changed, dose is automatically recalculated.
4. When highlight is on value for VI or DI, Clear softkey becomes active. Pressing the Clear softkey changes the value to 0.0.
5. Press Enter after each value change to accept the new value.
 - New rate begins infusing immediately.

Dose Rate Calculator (DRC) Programming using a specific drug name (Continued)

Changing DRC values while infusing (Continued)

6. Press STANDARD
DISPLAY.

OR

 - Display reverts to Standard Display page after one minute.
7. Verify settings.
8. Verify solution flow from solution container.

Dose Rate Calculator Programming with DRUG?

NOTE: Dose Rate Programming Page will not display if channel is infusing. If infusing in secondary mode, switch to primary mode and stop infusion before proceeding.

The DRUG? selection can be used to calculate a drug not listed in the pump or for an alternative dosing regimen.

1. Press A, B or C.
 - Primary Programming Page is displayed.
2. Press START
STOP if channel is infusing.
3. Press MORE
OPTIONS.
 - 2° Sec and CalcOn softkeys appear.
4. Press CalcOn.
 - Dose Rate Calculator Programming Page is displayed.
 - DRUG? is highlighted.
5. Press Select.
 - Highlight moves to Wt.

| | | | |
|-----------------------------|-------|--------------|------------|
| A: Stopped | | | |
| DRUG? | Wt | ---- | KG= 0.0 LB |
| A:Conc | ----- | mg/---- | ml |
| A:Dose | ----- | mcg/kg/min | |
| A:Rate | ----- | ml/h | |
| A:VR | 1 | ml (Vol Rem) | |
| A:VI | 0 ml | DI | 0.0 mg |
| Press Select to choose line | | | |
| Select | ↑ | ↓ | Clear |

Programming Weight

1. Choose patient's kilogram weight using ↑, ↓, Fast ↑ and Fast ↓ softkeys.
2. Press Enter when desired weight is displayed.
 - Highlight moves to Conc.

Dose Rate Calculator Programming with DRUG? (Continued)

Programming Concentration

1. Choose concentration using ↑, ↓, Fast ↑ and Fast ↓ softkeys.
2. Press Enter when desired concentration is displayed.
 - Highlight moves to concentration parameters.
3. Choose desired concentration parameters using ↑, ↓, Fast↑ and Fast ↓ softkeys.
4. Press Enter when desired parameter is displayed.
 - Highlight moves to value for diluent volume.
5. Choose diluent volume value using ↑, ↓, Fast ↑ and Fast ↓ softkeys.
6. Press Enter when desired volume is displayed.
 - VR is automatically set when the diluent volume is entered, but can be changed if desired.
 - Highlight moves to Dose parameters.

NOTE: In Neonatal Device type, the concentration will always start at a numeric value of 0.1.

Drug concentration parameters

Gm, mg, mcg, mMol, mEq, mUn, Un

Dose parameters

measure — Gm, mg, mcg, Ng, mMol, mEq, mUn, Un
weight — kg
time — min, h, or day

Programming Dose

1. Choose dose parameters (measure/weight/time) using ↑, ↓, Fast ↑ and Fast ↓ softkeys.
2. Press Enter when each desired dose parameter is displayed.
 - Highlight moves to next parameter each time Enter is pressed.
 - Highlight moves to Dose when Enter is pressed to accept time value.
3. Choose dose using ↑, ↓, Fast ↑ and Fast ↓ softkeys.
4. Press Enter.
 - Highlight moves to Rate parameters.

Dose Rate Calculator Programming with DRUG? (Continued)



Changing Volumetric Rate

1. Choose volumetric rate using arrow softkeys if dose calculation is not desired.
2. Press Enter when desired rate is displayed.
 - When rate is changed, dose is automatically calculated.
 - Highlight moves to VR.

Changing Volumetric Remaining

1. Choose VR value using the arrow softkeys.
2. Press Enter when desired VR is displayed.
 - Highlight moves to VI.

Clearing Volume Infused (VI) Or Dose Infused (DI)

1. Press Clear then Enter to change VI value to 0.
 - Highlight moves to DI.
2. Press Clear then Enter to change DI value to 0.
3. Open regulating clamp.
4. Press  to begin infusion.
 - Channel starts infusing.
5. Press 
OR
 - Display reverts to Standard Display page after one minute.
 - DRC parameters are displayed.
6. Verify settings.
7. Verify flow.

Editing Drug List

The Drug List Editor can be used to edit/customize drug list. See DFU for Drug List Editor (DLE).

Dose Rate Calculator Programming with DRUG? (Continued)

Discontinuing DRC Option

1. Press **A**, **B** or **C**.
 - Dose Rate Calculator Programming Page is displayed.
2. Press **START STOP** to stop if infusing.
3. Press **MORE OPTIONS**.
4. Press **CalcOff**.
 - Display reverts to primary Programming Page.
 - Volumetric rate, volume remaining and volume infused from DRC are carried over to the primary Programming Page.

| | | |
|-----------------------------|---------|----------------|
| A: Stopped | | |
| DOPAMINE | Wt 70.0 | KG=154.3LB |
| A:Conc | 400 | mg/ 250 ml |
| A:Dose | 5.0 | mcg/kg/min |
| A:Rate | 13.1 | ml/h |
| A:VR | 250 | ml (Vol Rem) |
| A:VI | 0 ml | DI 0.0 mg |
| Press Select to choose line | | |
| | | CalcOff |

Facts about DRC

- Drug name, patient weight, or drug concentration cannot be changed while infusing. Changes to patient weight or concentration will recalculate volumetric rate but maintain dose rate.
- Drug names may be abbreviated if the name contains more than eight letters.
- Weight can only be entered in Kg's but is displayed in Kg's and Lbs. Weight units can be switched to grams by pressing ↓ to value of 1Kg then repressing ↓. A two tone advisory sounds.
- If dose measurement parameters and concentration measurement parameters are unrelated, a volumetric rate will not calculate. Attempts to start will display a prompt message: Verify all dose settings.
- When a drug amount is 10,000 or greater, a K is used to replace 000th (i.e. 10,000=10K; 12,000=12K).
- If a recalculated dose results in a rate outside the rate ranges, a prompt message is displayed: Rate too High, reenter value or Rate too Low, reenter value.
- If a recalculated rate results in a dose outside the dose range, the channel will infuse at the entered rate but the dose will display the minimum or maximum allowable limit: (i.e. <0.1 or >999k).
- Secondary option cannot be used when the Dose Rate Calculator is enabled.
- If Instrument is off for more than five minutes, the DRC mode will revert to the primary mode.

Device

NOTE: The Device Type programming selection affects all three channels. It is not possible to program different Device Types for a channel independently.

There are six Device Types with preset parameters that accommodate specific clinical applications. They are:

| | |
|---------------------|--------------------|
| General Purpose | Operating Room |
| Neonatal | General Purpose II |
| Controller Pressure | Operating Room II |

When setting up the pump, select the device type that best suits your clinical needs. The abbreviated name of the Device Type appears as a softkey on the Standard Display page. Pressing the softkey displays the device type in non-abbreviated form on the prompt line.

Maximum rate, maximum volume, pressure and air-in-line threshold are configured at the factory. See Table 1 for a complete listing of preset parameters. Refer to the Config softkey section for programmable and configurable parameters.

These parameters can be modified to meet the institution's specific requirements using FMS software.

| | | |
|-------------------------|--------|----|
| Stopped | | |
| 100 ml/h | | |
| VR: 450 VI: 50 | | |
| Device: General Purpose | | |
| STNDBY | Cntrst | GP |

To Change Device Type

1. Press **STANDARD DISPLAY**.
2. Press **MORE OPTIONS**.
 - TotVol, Device, Config and Note softkeys appear.
3. Press Device softkey.
 - Currently selected Device Type has an asterisk and is highlighted.
4. Press Select to move the highlight through the list.
5. Press Enter when the desired device is highlighted.

If preset values are compatible with the newly selected device type,

- An asterisk appears next to the device name.

If channel is not infusing when device type is changed and preset values are not compatible with the newly selected device type,

| | | |
|------------------------|--------|-------------|
| Infusing | | |
| 100 ml/h | | |
| VR: 450 VI: 50 | | |
| Stop affects channel A | | |
| TotVol | Device | Config Note |

| | |
|----------------------------|--|
| Change Device Type | |
| General Purpose | |
| Neonatal | |
| Controller Pressure | |
| Operating Room | |
| *General Purpose II | |
| Operating Room II | |
| Press Stnd Display to Exit | |
| Select | |

Device (Continued)

To Change Device Type (Continued)

- The display switches to a notification screen.
- Incompatible Channel(s) indicated.
- Choice is given to continue.

If Yes,

- Incompatible values are cleared.
- Display reverts to Standard Display Page.
- New Device Type becomes active.

If No,

- Display reverts to Change Device Type page.

If channel is infusing when device type is changed and preset values are not compatible with the newly selected device type,

- The display switches to the notification screen.
- Incompatible Channel(s) is indicated.
- Choice is given to continue.

If No,

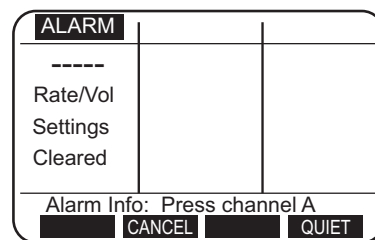
- Display reverts to Change Device Type page for user to select another device type.

If Yes,

- The pump will alarm.
- Infusion will stop on affected channel(s).
- Display reverts to Standard Display with Alarm indicated in affected channel.

6. Press affected channel ☐ A ☐ B or ☐ C .

7. Follow instructions displayed.



Device (Continued)

To Change Device Type (Continued)

Table 1

| Default Parameter | General Purpose | Neonatal | Controller Pressure | Operating Room | General Purpose II | Operating Room II |
|-----------------------------|-----------------|----------------|-----------------------|-----------------|--------------------|-------------------|
| Occlusion Detection Method | Baseline | Baseline | Absolute Threshold | Baseline | Baseline | Baseline |
| Occlusion Alarm Setting | Baseline+5 psi | Baseline+3 psi | 3 ft H ₂ O | Baseline +5 psi | Baseline +5 psi | Baseline +5 psi |
| Maximum Pressure | 15 psi | 15 psi | 3 ft H ₂ O | 15 psi | 15 psi | 15 psi |
| Air-in-line Alarm Threshold | 500 µl | 50 µl | 500 µl | 500 µl | 500 µl | 500 µl |
| KVO Rate* | 3 ml/h | 1.0 ml/h | 3 ml/h | 3 ml/h | 3.0 ml/h | 3.0 ml/h |
| Rate Range | 1 —999 ml/h | 0.1 —99.9 ml/h | 1 — 299 ml/h | 1 —999 ml/h | 0.1—999 ml/h | 0.1—999 ml/h |
| Maximum VR Setting | 9999 ml | 9999 ml | 9999 ml | 9999 ml | 9999 ml | 9999 ml |
| Pump Not In Use Advisory | Yes | Yes | Yes | No | Yes | No |
| ALL Setting for VR | N/A | N/A | N/A | Option | N/A | Option |

* Channel will infuse at the KVO rate shown in table or at the current infusion rate, whichever is lower.

NOTE: Values shown in table can be modified to meet the institution's requirements using FMS software. To review actual default parameters on a Instrument DLE. Select a Device Type and refer to Instrument Settings pages 2 through 5. An asterisk appears beside settings which are not factory default.

Config (Configuration)

The Config option allows the user to view and/or change some Instrument settings. There are five pages in this option. Items shown on page 1 of the Config option can be changed by the user (see Table 2). Pages 2 - 5 of the Config option can only be changed by qualified personnel using FMS software.

To Access Instrument Settings Information

1. Press **STANDARD DISPLAY**.
 2. Press **MORE OPTIONS**.
 - TotVol, Device, Config and Note softkeys appear.
 3. Press Config softkey.
 - The first of five Instrument Settings pages are displayed.
 - An asterisk indicates options that have been changed from factory settings.
 4. Pressing Select moves the highlight through the list.
 5. Press **↑** and **↓** to change a highlighted setting.
 - Select softkey changes to Enter and NextPg softkey changes to Recall when a setting is changed.
 6. Press Enter to accept new setting
- OR
7. Press Recall to recall previous setting.
 8. Press **ON/OFF** to exit instrument Settings page.

| | | |
|------------------------|--------|-------------|
| Infusing | | |
| 100 | | |
| ml/h | | |
| VR: 450 | | |
| VI: 50 | | |
| Stop affects channel A | | |
| TotVol | Device | Config Note |

| | |
|--------------------------------|------------|
| Instrument Settings (1 of 5) | |
| *Audio Volume: | low |
| *Sec Complete Advisory: | Yes |
| Setup Line Option: | No |
| Time: am/pm 9:56a 01 Feb 02 | |
| Press Stnd Display to Exit | |
| Select | ↑ ↓ NextPg |

Table 2

| Option | Choices | Description |
|-----------------------|----------------------------------|--|
| Audio Volume | low medium high highest | A tone accompanies each level to aid in determining volume choice. If an alarm is ignored, the volume will ramp to the highest audio unless disabled by FMS. Factory default is "highest." |
| Sec Complete Advisory | Yes No | Pump sounds two tones and displays advisory when secondary VR = 0. Factory default is "No." |
| Setup Line Option | No Yes | Enables infusion to be Setup as rate/ volume or volume/time. Stop infusion before modifying this line option. Factory default is "No." |
| Time | 24 hr am/pm | Allows pump to be set with a 12 or 24 hour clock. Factory default is "am/pm." |
| Hour/minutes | 0000-2359 | } Each item can be adjusted when highlighted. |
| Day | 1-31 | |
| Month | Jan-Dec | |
| Years | 00-99 | |

Note Soft Key

The Note soft key accesses the Special Note Message page. When a Note is programmed, it appears when the pump is turned on.

To Access NOTE(s)

1. Press **STANDARD DISPLAY**.
2. Press **MORE OPTIONS**.
 - TotVol, Device, Config and Note softkeys appear.
3. Press NOTE softkey.
 - NOTE information is displayed.
 - If no information has been programmed on the NOTE page, there will be a two tone advisory and the message There is no Special Note will display on the prompt line.

| | | |
|------------------------|--------|-------------|
| Infusing | | |
| 100 ml/h | | |
| VR: 450 | | |
| VI: 50 | | |
| Stop affects channel A | | |
| TotVol | Device | Config Note |

| | | |
|--------------------------|--------|-------------|
| Infusing | | |
| 100 ml/h | | |
| VR: 450 | | |
| VI: 50 | | |
| There is no Special Note | | |
| TotVol | Device | Config Note |

BatLog (Battery History Log)

To Access Battery History Log

The BatLog softkey accesses the Battery History Log page. This page is provided for the Biomedical Engineering staff to review and record battery history data.

1. Press **STANDARD DISPLAY**.
2. Press **MORE OPTIONS** twice.
 - BatLog and DemoWD softkeys appear.
3. Press BatLog softkey.
 - The Battery History page is displayed.
4. Press **ON/OFF** to exit Battery History page

OR

 - Display switches to Standard Display page after 1 minute.






| | | |
|------------------------|--------|--------|
| Infusing | | |
| 100 ml/h | | |
| VR: 450 | | |
| VI: 50 | | |
| Stop affects channel A | | |
| | BatLog | DemoWD |

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Alarms, Advisories, and Prompts

Use this troubleshooting information in conjunction with appropriate hospital procedures.

Responding to an advisory, alarm, or fault message

1. Press QUIET.
 - Audio tone stops.
 - Red light flashes on affected channel.
2. Press affected channel ,  or .
- Alarm Information page is displayed.
3. Take appropriate action(s) indicated on the display.
4. Press  to resume infusion.
 - Channel starts infusing.
5. Press 
OR
 - Display reverts to Standard Display after one minute.
6. Verify settings.
7. Verify flow.

Alarm Response Keys

NOTE: Channel's VR and VI values are updated with each press of ClrAir softkey.

NOTE: A  appears on Standard Display page to indicate CONFIRM has been pressed

QUIET Silences Advisories, Alarms, and Faults for two minutes. Softkey is accessible during alarm status.

CANCEL Clears alarm and advisory messages and stops tone. Use when alarm or advisory condition cannot be corrected or user chooses not to correct.

ClrAir Moves air bubbles past air-in-line sensor. Each press of the ClrAir softkey displaces approximately 0.2 ml of air/fluid. Three beeps indicate when air bubble is no longer in front of the air-in-line sensor.



CONFIRM Is present during Check Fluid Side alarms. Allows infusion to continue if no upstream occlusion is found.

RETRY Resets resumable fault conditions. Used when attempting to re-establish normal operation of a channel.

SERVICE Disables use of affected channel. Once pressed, servicing of instrument is required before channel can be used.


Advisories

Two beeps, slow flashing red light on infusing channel's channel key; infusion continues.



| Alarm | Meaning | Response |
|------------------------|--|---|
| Check Air Sensor | <p>At installation of cassette:</p> <p>a) air is detected in tubing;</p> <p>b) tubing collar is not properly seated;</p> <p style="text-align: center;">or</p> <p>c) air sensor is dirty or damaged.</p> | <p>Verify tubing collar is fully seated in air sensor recess.</p> <p>Verify tubing in air sensor recess is not damaged, twisted or dirty.</p> <p>Press ClrAir on channel's Alarm Information page. Three beeps indicate air bubble is no longer in front of air sensor.</p> <p>If air is still present, remove cassette and manually clear air according to hospital policy.</p> <p>If no air is present, clean air sensor recess as directed in cleaning instructions.</p> |
| Infusion Complete VR=0 | <p>VR has counted down to zero. Channel is infusing at KVO rate.</p> | <p>Enter new VR or, if same volume is desired, press REPEAT.</p> <p>Press Enter.</p> <p>Press  to resume primary infusion rate.</p> <p>Verify fluid flow.</p> |
| Low Battery | <p>30 minutes or less battery power remaining.</p> | <p>Connect AC adapter power cord to instrument.</p> <p>Plug into wall outlet.</p> |
| Channel Not In Use | <p>Two minutes have elapsed since cassette was installed or infusion was stopped.</p> | <p>Press STNDBY to place channel on Standby,</p> <p style="text-align: center;">OR</p> <p>Press  to start infusion,</p> <p style="text-align: center;">OR</p> <p>Remove cassette.</p> |

Alarms

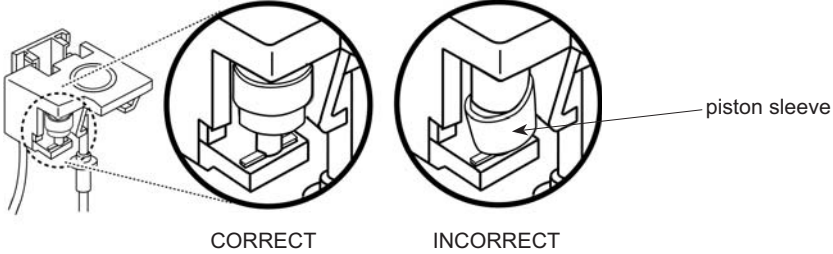
Four rapid-beeps, infusion stops, rapidly flashing red light on channel key.

| Alarm | Meaning | Response |
|---------------------|---|---|
| Air In Line | Air detected in fluid pathway during infusion, or air sensor is dirty. | <p>Verify tubing collar is fully seated in air sensor recess.</p> <p>Verify tubing in air sensor recess is not damaged, twisted or dirty.</p> <p>Press ClrAir softkey on channel's Alarm Information page. Three beeps indicate air bubble is no longer in front of air sensor.</p> <div> <p>NOTE: Each press of the ClrAir softkey displaces approximately 0.2 ml of air/fluid and updates channel's VR and VI values.</p> <p>If air is still present, remove cassette and manually clear air according to hospital policy.</p> <p>If no significant air is present, clean air sensor recess as directed in cleaning instructions.</p> <p>Setup instrument at or slightly below IV site to minimize formation of micro bubbles.</p> <p>Press  to resume infusion.</p> </div> |
| Air In Lower Tubing | <p>Air bubbles detected in fluid pathway with a total volume exceeding the air- in-line threshold setting.</p> <p>Possible outgassing and/or leaks in administration set.</p> | <p>Check administration set for leaks.</p> <p>Check lower tubing for multiple small air bubbles.</p> <p>Press ClrAir softkey on channel's Alarm Information page. Three beeps indicate air bubble is no longer in front of air sensor.</p> |




Alarms (Continued)

| Alarm | Meaning | Response |
|--------------------------------|---|--|
| Air In Line Tubing (continued) | | <p>NOTE: Each press of the ClrAir softkey displaces approximately 0.2 ml of air/fluid and updates channel's VR and VI values.</p> <p>If air is present, clear air according to hospital policy.</p> <p>Setup instrument at or slightly below IV site to minimize formation of micro bubbles.</p> <p>If no significant air is present, press  to resume infusion.</p> |
| Battery Depleted | Insufficient battery power. Instrument will shut down in 5 minutes. | <p>Connect AC adapter power cord to instrument and plug into wall outlet.</p> <p>Press  to resume infusion(s).</p> <p>NOTE: Drug List is lost if instrument battery is totally depleted. Drug List can be reloaded into the pump with FMS software only.</p> |

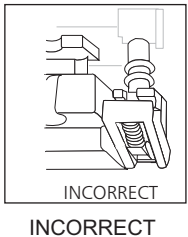
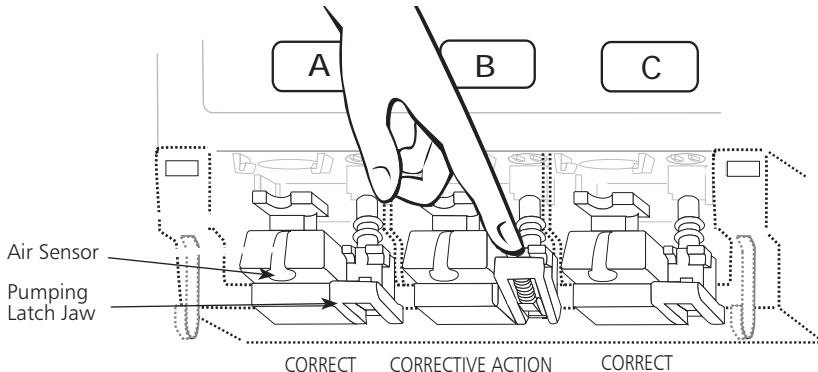
Alarms (Continued)

| Alarm | Meaning | Response |
|---|--|--|
| Cassette Jammed | Cassette piston is difficult to move or piston sleeve is loose. | <p>Remove cassette, check placement of soft, plastic piston sleeve and reposition, if necessary.</p> <p>If condition continues, try cassette in a different channel.</p> <p>Replace administration set if alarm recurs or if piston does not move freely.</p> <p>If alarm recurs with several cassettes, channel may need service.</p> |
|  | | |
| Cassette Not Latched | Cassette is partially disengaged or latching mechanism is dirty. | <p>Push cassette completely in. Ensure slide clamp is flush with entire cassette. Press START STOP to resume infusion.</p> <p>If condition continues, try cassette in a different channel. Replace administration set if alarm recurs.</p> <p>Clean lower assembly according to cleaning instruction described in MAINTENANCE section of this document.</p> |
| Cassette Removed | Cassette is removed from holder while channel is infusing. | <p>Reinstall cassette, and press START STOP to resume infusion</p> <p>OR</p> <p>Press Cancel.</p> |

Alarms (Continued)

| Alarm | Meaning | Response |
|---------------------|---|--|
| Check Fluid Side | Possible upstream restrictions to flow. | <p>Check tubing between container and instrument for a closed regulating clamp, closed vent (with unvented container), kinked tubing, empty syringe, or any restriction to flow.</p> <p>If NO occlusion is present, press CONFIRM.</p> <p>Press  to resume infusion.</p> <p>Verify fluid is flowing in drip chamber.</p> <p>A  appears on standard display to indicate Confirm has been pressed.</p> |
| Faulty Cassette | Cassette may be damaged or inoperable. Possible malfunction of cassette sensor located in holder. | <p>Reinsert cassette in another channel.</p> <p>If alarm recurs in second channel, replace administration set.</p> <p>If alarm recurs with two cassettes in the same channel, discontinue use and contact qualified service personnel.</p> |
| Fluid-Side Occluded | Upstream restriction to flow. | <p>Check tubing between container and instrument for a closed regulating clamp, closed vent (with unvented container), kinked tubing, empty syringe, or any restriction to flow.</p> <p>Clear occlusion.</p> <p>Press  to resume infusion.</p> <p>Verify fluid is flowing in drip chamber.</p> |

Alarms (Continued)

| Alarm | Meaning | Response |
|---|--|--|
| Patient-Side Occluded | Downstream restriction to flow. | <p>Check tubing between instrument and patient for kinks, closed clamps, closed stopcocks, clogged filters, site problems, etc.</p> <p>Clear occlusion or change infusion site.</p> <p>Press START STOP to resume infusion.</p> <p>Verify fluid is flowing in drip chamber.</p> |
| Pumping Latch Closed | Pumping latch jaw located to right of air sensor is closed or broken. | <p>Using only your finger, push down pumping latch jaw until it snaps open.</p> <p>If pumping latch jaw is visibly broken, contact qualified service personnel.</p> |
|  |  | <p>Re-enter settings as required.</p> <p>Press START STOP to resume infusion.</p> |
| Rate/Vol Settings Cleared | Rates and/or volumes are incompatible with newly selected Device Type. | |

Fault

Numeric message, European siren, rapid-flashing red light, infusion stops.

| Alarm | Meaning | Response |
|----------------------|--|--|
| Channel Out of Order | Safety checks built into software have detected a faulty channel. | CORRECTIVE ACTION for resumable faults only. |
| Fault Number | Safety checks built into software have detected a fault condition. | Press affected channel A , B or C . Follow instructions on channel's Alarm Information page. Press RETRY to clear fault. If fault recurs, press SERVICE and contact qualified service personnel. |

Watchdog

Blank screen, continuous tone red and green lights continuous, all infusions stop.

| | | |
|--------------|--|---|
| Blank Screen | Safety checks built into software have detected an instrument error condition. | Attempt to reset Instrument: Turn instrument off, then on again. Press START STOP to resume each channel that had been infusing. If Watchdog alarm recurs or instrument cannot be turned on, replace pump and notify qualified service personnel. |
|--------------|--|---|

Other Conditions

Screen is too light or dark to read with instrument on.


Press  .

Press Cntrst softkey to change screen contrast.

Instrument Shut Off: Low Power.

Instrument shut down after a Battery Depleted alarm had not been corrected.

Connect AC adapter cord to instrument and plug into wall outlet.

 next to External Power receptacle is lit green when AC power is properly applied.

Specifications

| | |
|-------------------------------|--|
| STANDARDS | UL 544, CSA C22.2, No. 125 |
| CASE MATERIAL | Impact resistant polycarbonate/ABS alloy |
| DIMENSIONS | Height 7.875 inches (20.00 centimeters) Width 6 inches (15.24 centimeters) Depth 2.10 inches (5.33 centimeters) |
| WEIGHT | Approximately 5.1 pounds (2.3 kilograms) including pole clamp |
| AIR-IN-LINE (DEFAULT) | 500 µl (except for Neonatal device type which is 50µl) |
| OCCLUSION PRESSURE (DEFAULT) | 15 psi except for Controller Pressure device type which is 3 ft H ₂ O |
| OPERATING TEMPERATURE | 50-104° Fahrenheit (10° - 40° Celsius) |
| TRANSPORT/STORAGE TEMPERATURE | -4 to +131° Fahrenheit (-20 to + 55°C) (<95°F or 35°C for optimum battery life) |
| RATE RANGE | 0.1 - 999 milliliter per hour (each channel) |
| VOLUME RANGE | 0.1 - 9999 milliliter (each channel) |
| KVO RATE RANGE | 0.1 - 20.0 milliliter per hour |
| RATE ACCURACY: | 1.0 - 999 ml/hr ±5% with a standard deviation of 1.96 under specified conditions.* 0.1 - 0.9 ml/hr ±10% with a standard deviation of 1.96. |
| ADMINISTRATION SETS | Use only Instrument Administration Sets |
| POWER CONSUMPTION | 6 watts AC power. Use only Instrument AC Adapter, Model 1555, or 1560A, ordered as part number 2861089. |
| BATTERIES | Main – Rechargeable NiCd Battery Pack Memory Back-up – Non rechargeable Lithium |
| | NOTE: Use only approved Cardinal Health Battery packs. |
| BATTERY CHARGE | A fully charged battery has a minimum of 6 hours running time with all channels running at 125 milliliters per hour and backlight usage of 2 minutes per hour. The main battery retains 80% of its capacity after 500 charging cycles, and retains 90% of its capacity after 3 months of continuous AC charging. NOTE: Replacement of both the main and memory backup batteries must be performed by qualified service technicians. |
| AC ADAPTER & CORD LENGTH | Model 1555, 7.5 Vdc @ 1 Amp with 10 ft cord. Model 1560A, 7.5 Vdc @ 1.65 Amp with 10.5 ft. cord. |

Specifications (Continued)

| | | |
|-----------------------|--------------------------|-------------------|
| AC POWER REQUIREMENTS | Voltage | 90 VAC to 132 VAC |
| | Frequency | 47 Hz to 63 Hz |
| FUSES | 3 amp fast-blow internal | |
| GROUND CONTINUITY | Maximum 0.1 ohm | |
| LEAKAGE CURRENT | Maximum 100 microamps | |

* Long-term accuracy specified, per IEC 60601-2-24, under the following conditions:

Head height: 30" (cm)

Test solution: Distilled water

Environmental: . . . Ambient temperature

Back pressure: . . . 18 gauge needle

IV set: Model 28034

Check-In

This is a Quick Reference Procedure for check-in and configuration of a new and recently serviced Instrument. The following check-in and configuration procedures are taken from the current service manual.

- Electrical Safety Test
- Power Tests
- Cassette and Sensor Test
- Patient-side Occlusion Detector Test
- Fluid-side Occlusion Detector Test
- Air-in-Line Test
- Volume Accuracy Test
- Watchdog Audio Test

References (used in conjunction with this document):

- Instrument models 2860 and 2863 Technical Service Manual.

Physical Inspection

Before unpacking, check the shipping container for damage that may have affected contents. Report any shipping damage to Customer Service.

Check to insure that all accessories are included in the package.

Check for any physical damage to the Instrument or accessories. If any is found report it to Customer Service.

Functional Test

Refer to your institutions policies for specific requirements regarding inspection and testing of incoming equipment before use. Recommended functional tests are given in the following pages. As a minimum, the following steps should be performed before use.

- Charge battery for 14 hours.
- Perform electrical safety checks.
- Turn Instrument on to verify normal power-up and operation of LEDS, display and audio.

Check-In (Continued)

Check-In Tests

Check-In tests are recommended prior to clinical use. When a test requires a primed cassette, it is recommended that clean tap water be used for such tests. If any of the functions are not as described in the check procedures, then the Instrument requires service. Refer to general contact information preceding the introduction of this manual.

NOTE: Upon completion of Check-In tests, reset the following: Volume Remaining, Time and Rate.

WARNING

For proper grounding, the AC adapter must always be connected to a three-wire outlet. Never operate the Instrument from a two-wire, ungrounded outlet.

WARNING

Do not perform any of the following tests while instrument is in use on a patient. Review all precautions in the DFU before performing these tests.

Electrical Safety Test

Equipment Required:

| NAME | MANUFACTURER | MODEL NUMBER |
|--------------------------|-----------------------------|----------------------|
| ELECTRICAL SAFETY TESTER | DALE TECHNOLOGY CORPORATION | LT544D OR EQUIVALENT |

This checks the ground continuity and leakage current of the AC adapter/Instrument, and can only be performed with the AC adapter connected to the Instrument.

NOTE: The pole clamp is isolated from the internal electronics and, therefore, is not grounded. It should not be used while performing the electrical safety test.

To perform Electrical Safety Test:

1. Refer to the operation manual for the electrical safety tester for the proper setup and measurement technique.
2. Connect the AC adapter to the MedSystem III® infusion pump.
3. Plug the AC adapter into the electrical safety tester.

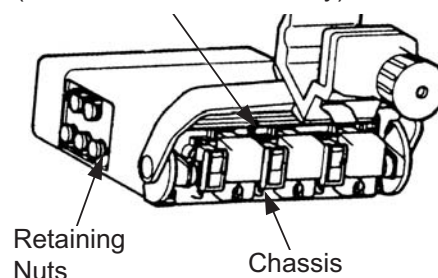
Check-In (Continued)

Electrical Safety Test (Continued)

4. Measure the ground continuity and leakage current. Any point of an instrument with an aluminum chassis can be used for testing. A black coated chassis can only be tested at the uncoated test point, located toward the back of the chassis under the lower housing. Verify the following:

- Ground continuity not to exceed 0.1 ohm.
- Leakage current not to exceed 100 μ A.

Test Point
(Black-coated Chassis only)



Power Tests

A. Power-Up Test

Charge the Instrument for at least one hour before performing this test. Proceed with the power-up test as follows:

1. Disconnect the AC adapter from instrument.
2. Remove any cassettes installed in instrument.
3. Turn instrument on and verify proper power-up.
4. Instrument performs initial self-test during power-up; and, if it detects any problems, it will indicate a fault.
5. Check audio and keypad operation by ensuring there is a soft beep for each key press.
6. Press any key and ensure the LCD backlight turns on.

NOTE: For a complete memory self-test, instrument should be turned on for a minimum of 18 minutes for the Models 2865 or 2866. It is not necessary for the unit to be pumping to perform this test. If operating on battery power, a cassette must be installed in at least one of the channels and that channel put in standby mode; otherwise, instrument will automatically shut off after five minutes of inactivity.

Check-In (Continued)

Power Tests (Continued)

B. AC Power Test

1. Turn on instrument without the AC adapter attached.
2. Install a primed cassette in each instrument channel.
3. Start all channels (at any rate). Verify the green LED on each channel blinks during operation.
4. Attach the AC adapter to instrument. Verify instrument beeps three times when the connector is properly installed. Verify that the green plug-shaped light on the side connector panel is lit and does not blink if connector is wiggled.
5. Verify that the green LEDs for each channel key (A, B and C) are steadily illuminated. If they are blinking, then the

Cassette and Sensor Test

Instrument is not recognizing that AC power is connected.

This test verifies the proper functioning of the cassette and latch sensors, as well as the latching mechanisms. Repeat the following procedures for all three channels (A, B and C).

1. With the Instrument off, remove any cassettes that are installed.
2. Turn on the Instrument.
3. Verify that the Instrument latch mechanism of each channel returns to the Home position at the top of the stroke (nearest to the chassis).
4. Press the channel select key (A, B or C), and then press the START/STOP key. A two-tone advisory will sound and the highlighted message Install Cassette will appear in the prompt line near the bottom of the screen.

Check-In (Continued)

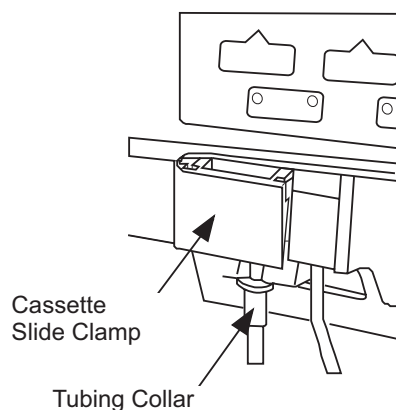
Cassette and Sensor Test (Continued)

5. Install a primed cassette into the appropriate channel (A, B or C), but do not push the cassette slide clamp into place. Ensure that there are no air bubbles.

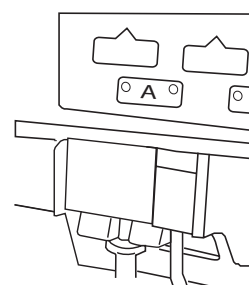
6. Press the START/STOP key again. A two-tone sound will be emitted, and the message Push Slide Clamp In will appear at the bottom of the page.

7. Push the cassette slide clamp in and seat the tubing collar in the recess below the cassette. Three beeps will sound to indicate correct cassette installation and fluid in the sensor pathway. The cassette should latch easily and smoothly. If the air-in-line sensor detects air when a cassette is installed, a Check Air Sensor advisory will be displayed.

8. Press the START/STOP key. The message Infusing will appear on the channel status line.
9. While the channel is pumping, pull out the cassette slide clamp. You will hear a repeating four-beep audio alarm and the red LEDs will blink. Infusion will stop and the display will indicate a Cassette Not Latched alarm.
10. Remove the cassette. The alarm display should read Cassette Removed. Reset the alarm by pressing the channel select key (A, B or C) for the channel in use, and press the CANCEL softkey.



Slide Clamp Not In Place



Slide Clamp In Place

Check-In (Continued)

Patient-side Occlusion Detector Test

This test verifies the proper functioning of the alarm which detects occlusion between the Instrument and the patient. Repeat the following steps for each of the three channels, A, B, and C.

1. Configure the Instrument in the Controller Pressure Device Type.
2. Prime a set, which contains no filters or check valves, and has macrobore tubing on the patient side.
3. Install the primed set into the Channel Under Test (CUT).
4. Set the infusion rate for 1 ml/h, for the CUT.
5. Press the START/STOP key to start infusion.
6. Raise the patient-side tubing 2' 2" (66.04 cm) above the cassette. The CUT should not sound an alarm.
7. Slowly raise the tubing outlet to 3' 8" (96.52 cm) above the cassette. The CUT should sound an alarm within 10 seconds.
8. After completing steps 1-7 for all three channels configure the Instrument in the General Purpose Device Type.

Fluid-side Occlusion Detector Test

This test verifies the proper functioning of the alarm which detects occlusion between the Instrument and the fluid container. Repeat the following steps for each of the three channels, A, B and C.

1. Install a primed set in the selected channel
2. Start the selected channel at 125 ml/h.
3. Close the roller clamp between instrument and fluid container. Occlusion should be detected within two minutes.

Check-In (Continued)

Fluid-side Occlusion Detector Test

4. The Standard Display screen will show an alarm for the channel under test and also the message *Fluid Side Occluded*. The red LED in the key for the test channel will blink, and an audible four-beep alarm will sound.
5. Open the roller clamp and press the START/STOP key to reset the alarm.

Air In Line Detector Test

This test verifies the proper functioning of the alarm which detects air in a line. Repeat the following procedure for each of the channels, A, B and C.

1. Disconnect the drip chamber from the solution bottle, or inject a large air bubble into the tubing via the upstream y-site.

NOTE: The injected air bubble size should be approximately twice the threshold value of the air detector plus one milliliter to fill the cassette air trap. For example, if the threshold is 500 microliters, then inject a 2-milliliter air bubble. To determine the threshold value, check the Clinical Configuration settings in instrument.

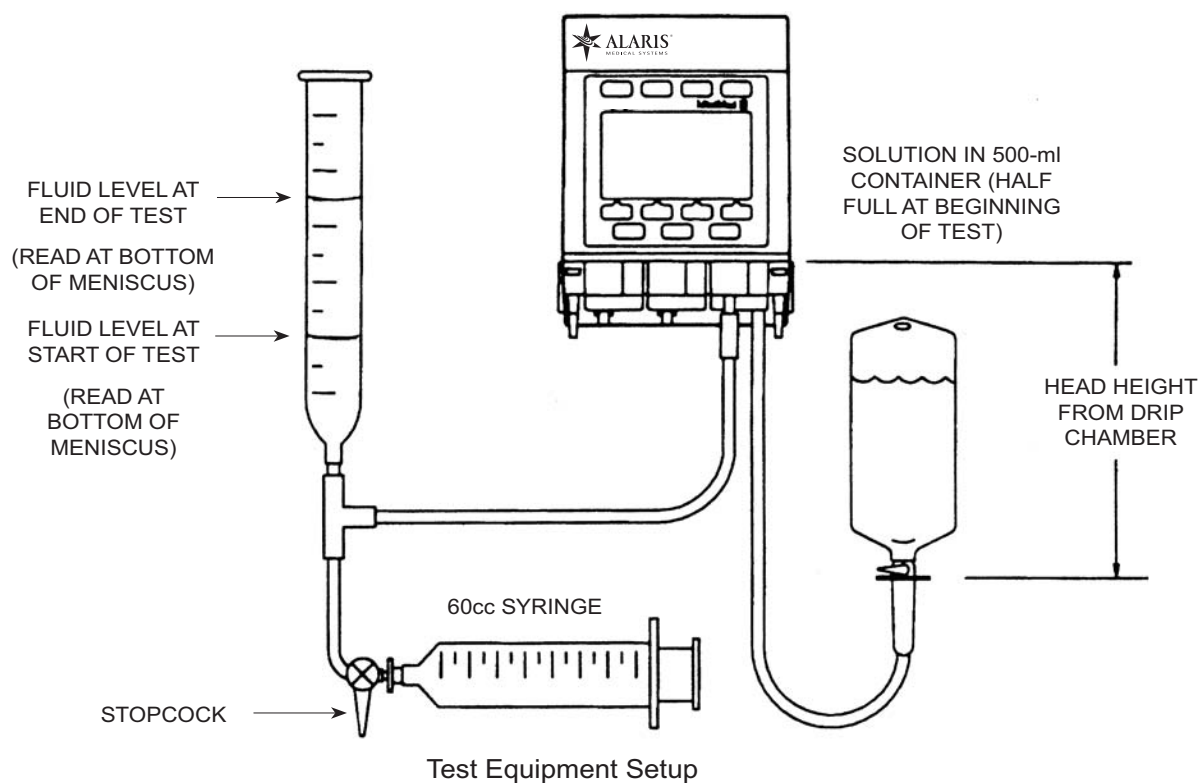
2. Press the START/STOP key on the selected cassette. When the bubble is pumped through the cassette, the Standard Display should show an alarm for the channel under test with the message, Air In Line. An audible four-beep alarm will sound and the red LEDs will blink.

New Instrument Volume Accuracy Test

Accuracy of fluid delivery is determined by measuring the volume of fluid delivered over a known time period and comparing this to the expected value. To ensure accurate measurements during the test, a volumetric glass burette (class A) must be used to collect the fluid. The infusion time interval must be 180 seconds or greater to minimize measurement errors. During a 180-second test, a one-second error by the operator results in an error of 0.6%.

A. Test Equipment Setup

1. Obtain a new administration set and connect it to a 500-milliliter container which is at least half full. Prime the set and eliminate all air.
2. Connect the apparatus as shown in Test Equipment Setup below. Use a volumetric burette marked in 0.1-milliliter increments (class A glassware).
3. Install the cassette to the channel to begin test.



New Instrument Volume Accuracy Test (Continued)

B. Test Procedure

1. Power up the Unit Under Test (UUT),
2. Press the MORE OPTIONS key.
3. Press the CONFIG soft key.
4. Press the SELECT soft key twice to highlight the Setup line option.
5. Press the ↑ arrow soft key to toggle setting to Yes.
6. Press the ENTER soft key to accept setting.
7. Set the meniscus level to 0 in the burette.
8. Press the A key to select Channel-A.
9. Press the SELECT soft key 4 times to highlight Setup option.
10. Press the ↑ arrow soft key to toggle setting to Select VR and Time.
11. Press the ENTER soft key to accept setting.
12. Press the SELECT soft key to highlight Pri VolRem (VR).
13. Press the ↑ arrow soft key until the (VR) is set to 18 ml.
14. Press the ENTER soft key to accept setting.
15. Press the SELECT soft key to highlight Pri Time (TR).
16. Press the ↓ arrow soft key until the (TR) is set to 00h 03m.
17. Press the ENTER soft key to accept setting.
18. Press the CLEAR soft key to set the "Pri Vol Inf (VI)" to 0ml.
19. Press the ENTER soft key to accept setting.
20. The Primary Rate should read 360 ml/h.
21. Press the START/STOP key to start Channel-A. Channel-A will run for 3 minutes.
22. Press the START/STOP key within 1 second after the channel goes into KVO alarm.
23. The volume collect will be between 17.1 ml and 18.9 ml.

Check-In (Continued)

New Instrument Volume Accuracy Test (Continued)

24. Repeat steps 7 - 23 for Channels B and C.
25. After testing all three channels repeat steps 1-6 with the exception in step 5 to toggle setting to No.

Watchdog Audio Test

Manually test the Watchdog Alarm Audio from the Standard Display. Press the More Options button two times until a softkey labeled Demo WD appears. Press this key and follow the directions on the screen for completing the Watchdog Test.

Cleaning

Clean the Instrument regularly to maintain proper working order and optimum performance.

- | | |
|--------|---|
| DO NOT | Invert instrument during cleaning or rinsing. |
| DO NOT | Clean instrument without first inspecting the condition of the housings for damage. |
| DO NOT | Use pressurized air to dry instrument, as the force may move fluid past the moisture seals. |
| DO NOT | Use organic solvents, ammonia, ammonium-based agents, and/or abrasive cleansers. |
| DO NOT | Damage valve actuators. |
| DO NOT | Use sharp or metallic tools to remove residue. |

WARNING

Turn the Instrument off and disconnect the power cord from the AC power source before cleaning. Do not spray fluids directly onto the rear case of the Instrument. Do not steam autoclave, EtO sterilize, immerse the Instrument or allow fluids to enter the Instrument case. Failure to follow these instructions may result in an electrical hazard.

NOTE: If the power cord is permanently attached to instrument, ensure cleaning solution does not enter the connector.

Cleaning (Continued)

Before Cleaning

1. Unplug the AC adapter power cord from the wall outlet.
2. Disconnect the power cord from the external power connector, on the side of instrument.
3. Inspect the Instrument's outside surfaces for damage.
 - Any cracks or punctures may allow fluid to enter.

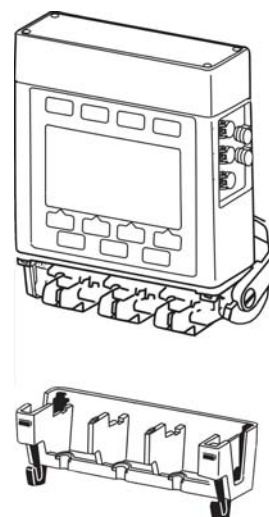
To Clean

For cleaning applications:

- Use solutions of non-abrasive, non-staining detergent (i.e., commercially available, alcohol-free, dish washing liquid) well diluted with warm water.
- Use either Cavicide or 10% chlorine bleach and water for disinfecting.
- Rinse with distilled or de-ionized water.
- Use soft, non-abrasive cloths, soft-bristled brushes and/or non-abrasive, lint-free swabs.

Instrument, lower housing, slide link and latch

1. Wipe instrument exterior using a cloth dampened with cleaning solution.
2. Remove the lower housing to access instruments lower assembly by pressing all four black, release tabs simultaneously while pulling straight down.
3. Set instrument upright.
4. Clean the slide link and instrument latch mechanism using a small soft-bristled brush (or lint free swab) dampened with the appropriate cleaning solution, as specified in the "Cleaning" section. If dried residue is difficult to remove, or the slide link or Instrument latch sticks, spray the cleaning solution on the residue and allow it to soak until it can be more easily removed.
5. After removing residue, rinse with a lint free swab dampened with water. Water may be sprayed on the cleaned surfaces to rinse areas that are difficult to reach with a swab.



Cleaning (Continued)

To Clean (Continued)

6. Dry with a lint-free swab or cloth, or allow to air dry.

Air Sensor Recess

NOTE: Air-in-line alarms may occur when dried residue builds up in the air-in-line sensor tubing recess.

1. Inspect the air-in-line sensor module to ensure that there is no separation or breakage of the glued seams.

NOTE: Defective air-in-line sensor modules must be replaced before using instrument.

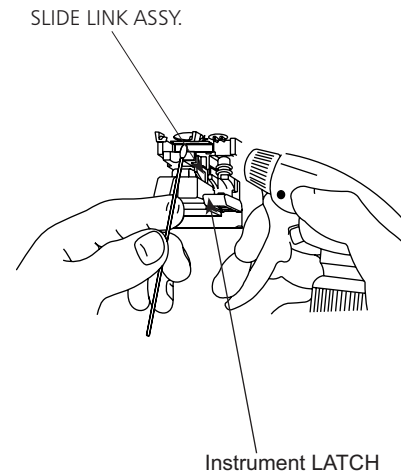
2. Place instrument in the upright position.
3. Clean the tubing recess (using a downward motion) with a lint free swab dampened with the appropriate cleaning solution, as specified in the “Cleaning” section.
4. Rinse with a lint free swab dampened with water.
5. Dry with a lint-free swab or allow to air dry.

Optomodule

1. Place the Instrument in the upright position.
2. Gently clean the optomodule using a lint-free swab dampened with the appropriate cleaning solution, as specified in the “Cleaning” section. The cleaning solution may be sprayed on difficult-to-remove residue to help wet and soften the residue for easier removal.
3. After removing residue, gently rinse with a lint-free swab dampened with water. Water may be sprayed on the cleaned surfaces to rinse areas that are difficult to reach with a swab.
4. Gently dry with a lint-free swab or allow to air dry.

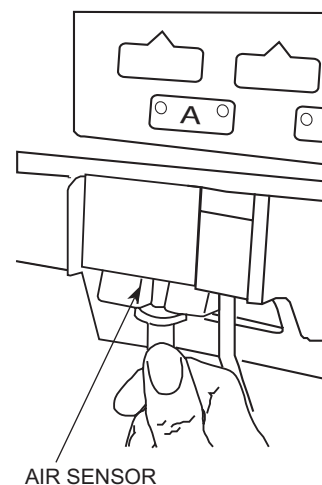
Valve Actuator

1. Place the Instrument in the upright position.
2. Gently clean the valve actuator and actuator seal using a lint-free swab dampened with the appropriate cleaning solution, as specified in the “Cleaning” section. The cleaning solution may be sprayed on difficult to remove residue to help wet and soften the residue for easier removal.



CAUTION

Use of abrasives or abrasive cleaners on air sensor recess may cause false Air-in-Line or Check Air Sensor alarms.



Cleaning (Continued)

To Clean (Continued)

3. After removing residue, gently rinse with a lint-free swab dampened with water. Water may be sprayed on the cleaned surfaces to rinse areas that are difficult to reach with a swab.
4. Gently dry with a lint-free swab or allow to air dry.
5. After cleaning, inspect the exposed tips of the valve actuators. A broken tip may be supported by the actuator seal and not appear defective. Lightly attempt to push the tips of the valve actuators from side to side with a dry lint-free swab. If a tip is not rigid, then it is broken and must be replaced before using the Instrument.

After cleaning

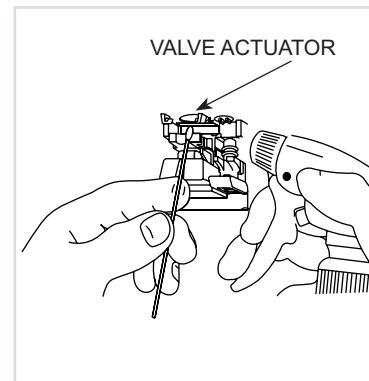
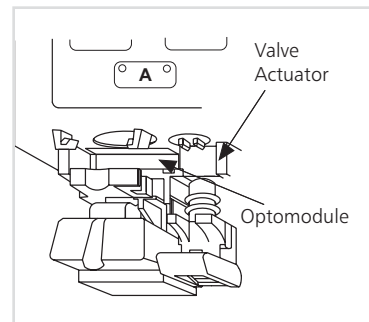
Inspect the exposed tips of the valve actuators for damage by lightly pushing the tips of the valve actuators side-to-side with a dry swab. If a tip is not rigid, it is broken and must be replaced before using instrument.

WARNING

Failure to perform these inspections may result in improper Instrument operation.

CAUTION

Do not use isopropyl alcohol on the optomodule.



WARNING

Care must be taken when cleaning the vicinity of the valve actuators to avoid damage and breakage of the actuator tips. Damage or breakage of the actuator tips could cause an uncontrolled flow condition.

CAUTION

Do not use isopropyl alcohol to clean the valve actuators.

Inspection Requirements

To ensure instrument remains in good operating condition, both regular and periodic inspections are required. Any instrument that does not meet listed specifications should be serviced.

Regular inspections consist of performing the procedures described in the Basic Operation and Cleaning sections of this manual before use of instrument. Regular inspections are not covered under any contract or agreement offered by Cardinal Health, and must be performed by the user.

When programming infusions verify that the display:

- Is complete and not blurred.
- Reads the same as described in this manual.
- Responds with the intended function for that key press.

NOTE: Detailed instructions for performing periodic inspections and maintenance can be found in the Technical Service Manual for the Instrument and in supplemental service bulletins.

Periodic inspections must be performed every 12 months. A service agreement may be obtained from Cardinal Health, for the performance of all required periodic inspections.

The periodic inspections must be performed in accordance with Cardinal Health, requirements and guidelines. Customers within the United States and Canada should note that these inspections are also intended to complement the intent of Joint Commission on the Accreditation of Healthcare Organizations requirements.

WARNING

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

Service Information

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

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

WARNING

- Instrument case should only be opened by qualified personnel using **proper grounding techniques**. Prior to performing maintenance, disconnect from AC power.
- During servicing, instruments **configuration settings** might be reset to the factory defaults. Qualified hospital/facility personnel are responsible for checking in the Instrument and ensuring the current hospital-approved data set is loaded.

Technical Support

Technical support, service information, applications, and manuals may be obtained by contacting a Cardinal Health 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

WARRANTY

Cardinal Health warrants that:

- A. Each new MedSystem III® infusion pump is free from defects in material and workmanship under normal use and service for a period of one (1) year from the date of delivery by Cardinal Health to the original purchaser.
- B. The battery and each new accessory is free from defects in material and workmanship under normal use and service for a period of 90 days from the date of delivery by Cardinal Health to the original purchaser.

If any product requires service during the applicable warranty period, the purchaser should communicate directly with Cardinal Health to determine the appropriate repair facility. Except as provided otherwise in this warranty, repair or replacement will be carried out at Cardinal Health'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 Cardinal Health be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any MedSystem III® infusion pump. 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 Cardinal Health shall not be responsible for, any loss or damage arising in connection with the purchase or use of any MedSystem III® infusion pump which has been:

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

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of Cardinal Health, and Cardinal Health does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of Cardinal Health any other liability in connection with the sale or use of MedSystem III® infusion pump.

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

See packing inserts for international warranty, if applicable.

Abbreviations, Acronyms, Units of Measure

| | |
|---------|--|
| 1° Pri | Primary infusion |
| 2° Sec | Secondary infusion |
| a | am |
| AAMI | American Association of Medical Instrumentation |
| ABS | acrylonitrile-butadiene-styrene |
| AC | alternating current (electrical power) |
| BatLog | Battery History Log |
| Calc | Calculator |
| CalcOff | Calculator Off |
| CalcOn | Calculator On |
| ClrAir | Clear Air |
| cm | centimeter |
| Cntrst | Contrast |
| COMM | Communications Port |
| Conc | Concentration |
| Config | Configuration |
| CP | Controller Pressure |
| CSA | Canadian Standards Association |
| DemoWD | Demonstrate Watchdog |
| DI | Dose Infused |
| ECG | Electro-cardiogram |
| ES | Electro-static |
| FMS | Field Maintenance Software |
| Gm | gram |
| GP | General Purpose |
| GP II | General Purpose II |
| h | hour |
| Hz | Hertz |
| in. | inch |
| I.D. | identification |
| IEC | International Electrotechnical Commission |
| Inf | infused |
| IV | intravenous |
| JCAHO | Joint Commission on the Accreditation of Health Care Organizations |
| K | 1,000 for numbers 10,000 or greater |
| KG; kg | kilogram |
| KVO | keep vein open |

Abbreviations, Acronyms, Units of Measure (Continued)

| | |
|-----------|---------------------------------|
| LB; lb | pound |
| mcg | microgram |
| mEq | milliequivalent |
| mg | milligram |
| min; mn | minute |
| ml | milliliter |
| mMol | millimole |
| mUn | milliunit |
| µl | microliter |
| N/A | not applicable |
| Neontl | Neonatal |
| NextPg | Next Page |
| Ng | Nanogram |
| NiCd | nickel-cadmium |
| OR | Operating Room |
| OR II | Operating Room II |
| p | pm |
| Pri | Primary |
| psi | pounds per square inch |
| Sec | Secondary |
| Stnd Disp | Standard Display |
| STNDBY | Standby |
| TotVol | Total Volume |
| TR | time remaining |
| UL | Underwriters Laboratories, Inc. |
| Un | unit |
| V | Volts |
| VI | volume infused |
| Vol | volume |
| VolRem | volume remaining |
| VR | volume remaining |
| Wt | weight |

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 curves show typical performance of the system in two ways: 1) the accuracy during various time periods over which fluid delivery is measured (trumpet curves), and 2) the delay in onset of fluid flow when infusion commences (start-up curves). 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 may 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.

Long-term accuracy of the Instruments in combination with the specified administration set is considered to be within 5 %.

FLOW CHARACTERISTICS UNDER VARYING DELIVERY CONDITIONS

Effects of Pressure Variations

Under conditions of +100mmHg pressure, the Instrument typically exhibits a long term accuracy offset of approximately -0.4%.

Under conditions of -100mmHg pressure, the Instrument typically exhibits no significant offset in long term accuracy.

Resulting Trumpet observation points typically track that of accuracy. Therefore, no significant change in short term variations result under negative solution container height conditions.

Effects of Negative Solution Container Heights

With a negative head height of -0.5 meters, the Instrument typically exhibits a long term accuracy offset of approximately -0.4%.

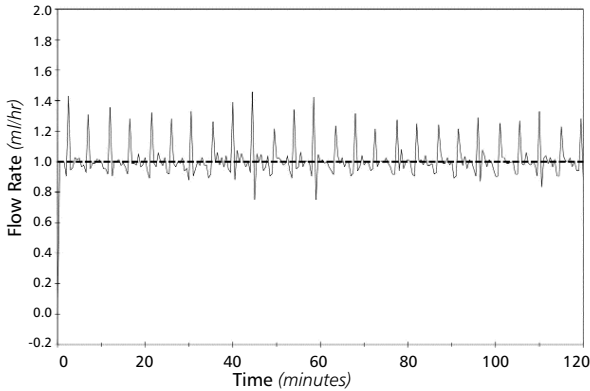
Resulting Trumpet observation points typically track that of accuracy. Therefore, no significant change in short term variations result under back pressure conditions.

The following graphs represent tests performed per IEC/FDIS 60601-2-24, "Particular Requirements for Safety of Instruments and Controllers" using Instrument with Model 28034 IV sets, 76cm of headheight and no back pressure.

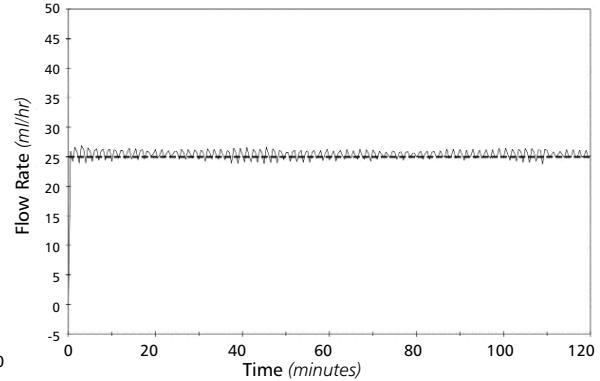
Trumpet and Start-Up Curves (Continued)

Pressure Mode

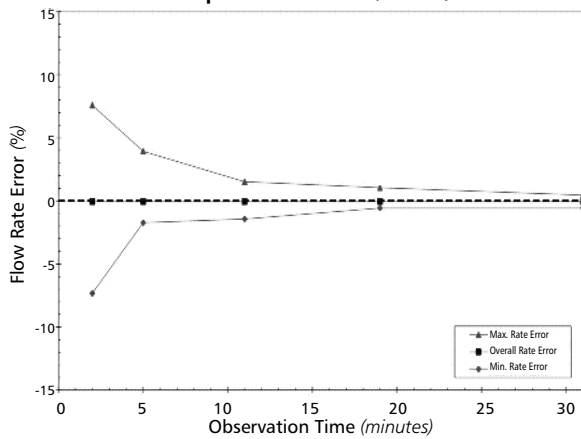
Start-up: 1 ml/hr



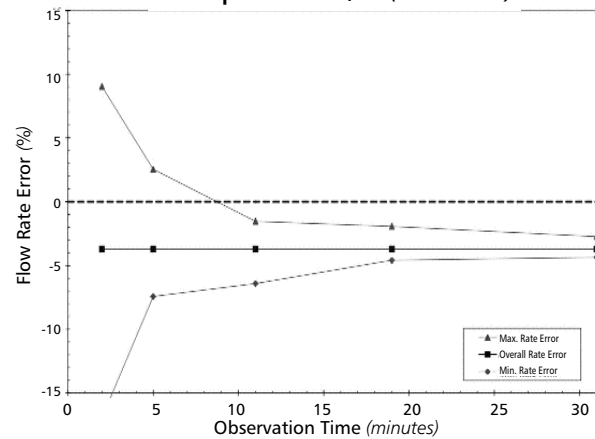
Start-up: 25 ml/hr



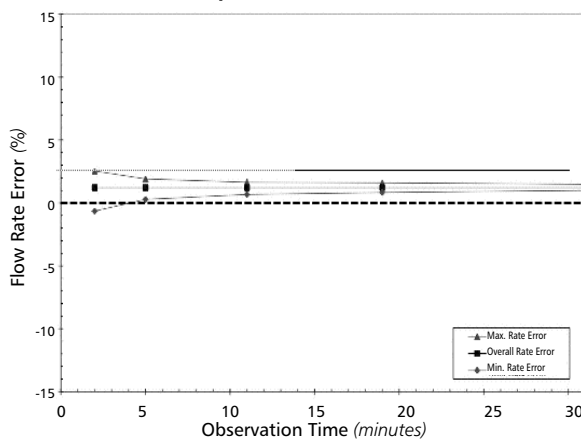
Trumpet: 1 ml/hr(Initial)



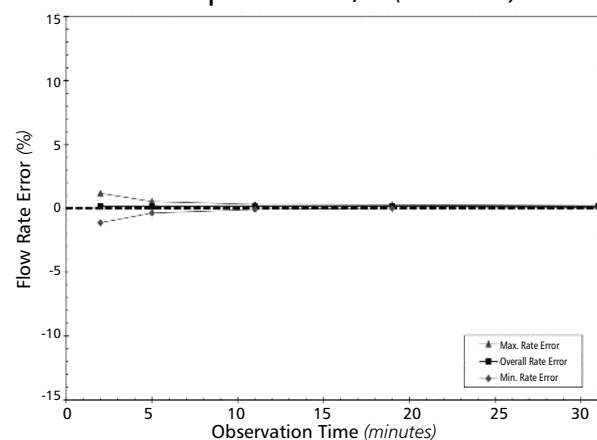
Trumpet: 1 ml/hr(48 Hours)



Trumpet: 25 ml/hr(Initial)




Trumpet: 25 ml/hr(48 Hours)



EMC Tables


The following information is to be provided to the User as directed by IEC 60601-1-2:2001, a Collateral Standard for Electromagnetic Compatibility. The information provided herein provide certain Warnings and Caution text that must be included into the Instructions for Use and the attached Tables of informative information as to the emission and immunity levels of the testing performed.

| Table 1 Guidance and Manufacturer's Declaration – Electromagnetic Emissions | | |
|--|-------------------|---|
| Instrument is intended for use in the electromagnetic environment specified below. Customer or user of instrument should assure that it is used in such an environment. | | |
| Emissions test | Compliance | Electromagnetic Environment – Guidance |
| CISPR 11 RF Emissions | Group 1 | <p>The Instrument uses RF energy only for its internal function in the normal product offering. An option is available for a low power wireless network card. If the following icon appears on the product, it has a low power RF transmitter installed, refer to the Instructions for Use for guidance.</p>  <p>RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</p> |
| CISPR 11 RF Emissions | Class B | Instrument is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| IEC 61000-3-2 Harmonic Emissions | Class A | |
| IEC 61000-3-3 Voltage Fluctuations, Flicker Emissions | Complies | |

EMC Tables (Continued)

Table 2
Guidance and Manufacturer's Declaration—Electromagnetic Immunity

Instrument is intended for use in the electromagnetic environment specified below.
Customer or user of instrument should assure that it is used in such an environment.

| Immunity Test | IEC 60601-1-2 Test Level | Compliance Level | Electromagnetic Environment— Guidance |
|---|---|--|--|
| IEC 61000-4-2 Electro-Static Discharge (ESD) | ±6 kV contact ±8 kV air | ±8 kV contact (NOTE2) ±15 kV air (NOTE2) | Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. If connector testing exemption is used, the following symbol for ESD sensitivity appears adjacent to each connector. "Caution – Do Not Touch".  |
| IEC 61000-4-4 Electrical Fast Transient, Burst (EFT) (NOTE 3) | ±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 (NOTE 3) | ±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 (NOTE2) 400 A/m 60 Hz (NOTE2) | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| IEC 61000-4-11 Voltage Dips, Short Interruptions, and Voltage Variations (NOTE 3) | <5 % U_T (NOTE 1) (>95 % dip in U_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 the user of the Instrument requires continued operation during power mains interruptions, it is recommended that the Instrument be powered from an uninterruptible power supply or a battery. The Instrument does employ an internal short duration battery. |
| | 40 % U_T (60 % dip in U_T) for 5 cycles | 40 % U_T (60 % dip in U_T) for 5 cycles | |
| | 70 % U_T (30 % dip in U_T) for 25 cycles | 70 % U_T (30 % dip in U_T) for 25 cycles | |
| | <5 % U_T (>95 % dip in U_T) for 5 sec | <5 % U_T (>95 % dip in U_T) for 5 sec | |

NOTE 1— U_T is the AC mains voltage prior to application of the test level.


NOTE 2—Compliance levels raised by IEC 60601-2-24.

NOTE 3 – Performed at the Minimum and Maximum Rated Input Voltage.

EMC Tables (Continued)

Table 3
Guidance and Manufacturer's Declaration—Electromagnetic Immunity
LIFE SUPPORT Equipment

Instrument is intended for use in the electromagnetic environment specified below.
Customer or user of instrument should assure that it is used in such an environment.

| Immunity Test | IEC 60601-1-2 Test Level | Compliance Level | Electromagnetic Environment—Guidance |
|--------------------------------------|------------------------------|----------------------|---|
| IEC 61000-4-6 Conducted RF | 3 V rms 150 kHz to 80 MHz | 10 V rms (NOTE 3) | Portable and mobile RF communications equipment should be used no closer to any part of the Instrument, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| IEC 61000-4-3 Radiated RF | 3 V/m 80 MHz to 2.5 GHz | 10 V/m (NOTE 3) | <p>Recommended Separation Distance</p> $d = \left[\frac{12}{V_2} \right] \sqrt{P}$ $d = \left[\frac{12}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{12}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 2.5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).^a</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^b should be less than the compliance level in each frequency range. ^c</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |

NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

NOTE 3—Compliance levels raised by IEC 60601-2-24.

^a The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is 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.

^b Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and 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 Instrument is used exceeds the applicable RF compliance level above, the Instrument should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Instrument.

^c Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

EMC Tables (Continued)

Table 4
Recommended Separation Distances For LIFE SUPPORT Equipment between
portable and mobile RF communications equipment and the Instrument

Instrument is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Customer or user of instrument can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and instrument as recommended below, according to the maximum output power of the communications equipment.

| Rated Maximum Output Power of Transmitter W | Separation Distance According to Frequency of Transmitter (m) | | | |
|--|--|--|--|---|
| | 150 kHz to 80 MHz Outside ISM bands $d = \left[\frac{3.5}{\sqrt{P}} \right] \sqrt{P}$ | 150 kHz to 80 MHz In ISM bands $d = \left[\frac{12}{\sqrt{P}} \right] \sqrt{P}$ | 80 MHz to 800 MHz $d = \left[\frac{12}{E1} \right] \sqrt{P}$ | 800 MHz to 2.5 GHz $d = \left[\frac{23}{E1} \right] \sqrt{P}$ |
| 0.01 | 0.35 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.12 | 0.38 | 0.38 | 0.73 |
| 1 | 0.35 | 1.20 | 1.20 | 2.30 |
| 10 | 1.11 | 3.80 | 3.80 | 7.30 |
| 100 | 3.50 | 12.00 | 12.00 | 23.0 |

For transmitters rated at a maximum output power not listed above, 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) according to the transmitter manufacturer.

NOTE 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2—The ISM (Industrial, Scientific, and Medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

NOTE 3—An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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