OMNI-FLOW 4000® PLUS

IV Medication Management System

For use with list 40051-04

System Operating Manual

Abbott Laboratories
North Chicago, IL 60064
USA

430-06371-C04 (Rev. 8/96)

VERSION

1.1

SERIES

Contents

Contents

Section 1

INTRODUCTION

The Omni-Flow 4000 Plus IV Medication Management System incorporates all the features of the Omni-Flow 4000, with added data communications capability and new data entry screens which incorporate automatic calculation, plus programming from alternate units of measure entry.

1.1
FEATURES OF THE IV MEDICATION MANAGEMENT SYSTEM

Incorporating microprocessor electronic design and safety features, the 4000 Plus represents a major advance in instrumentation for the delivery and management of intravenous therapy.

The 4000 Plus includes the following capabilities of the Omni-Flow 4000:

- ❑ Four-channel medication delivery through a single patient line
- ❑ Programmable
- ❑ Multi-dose containers
- ❑ Programmable automatic in-line dilution
- ❑ Programmable automatic flushing between incompatible medications
- ❑ Any combination of both continuous and intermittent infusions
- ❑ Real-time clock
- ❑ Infuses from combinations of bags, bottles, and syringes
- ❑ Automatic air detection and elimination
- ❑ Needleless connections

Additional capabilities of the 4000 Plus include:

- ❑ Programmable in Mcg/Kg/Min on all channels
- ❑ RS-232 communication (for printers)
- ❑ Date/time stamp (optional) of blood chemistry, hematology, vital signs, and other medication administration
- ❑ Detailed documentation, through the following printed reports (on demand):
  - Device Status Report:
    - Line status A, B, C, and D (ON, OFF, PGM, HLD, INF, DLY)
    - Dilution and flush data
    - Current infusion regimen details
    - Time and volume remaining in dose
  - IV Flow Sheet

- IV History Report:

    Line mode changes: off, on, intermittent infusion, hold, dilute, delay, flush, KVO, programmed

    Records details of infusion: as programmed, actual delivered, regimen changed

    Records non-infusion event documentation: blood, hematology, blood chemistry, vital signs

    All events date/time stamped

❑ Programming and memory retention following power OFF

❑ Selective hold for each medication line

❑ Advanced programming to preprogram all lines and place lines on hold until needed

❑ Automatic power prime of Line A for minimum solution waste

❑ Prioritized alarms stacked and presented sequentially for resolution

❑ Additional alarms: full collection bag, transfer to battery, external communications fault

❑ User selected power-up defaults:

    - Time: 12-hour AM/PM or 24-hour military format

    - KVO: 1.0 to 99.9 mL/hr

    - Patient line occlusion alarm - 1 to 12 psi (in 1 psi increments)

    - Units of temperature: degrees Centigrade or Fahrenheit

    - Callbacks

❑ Local display of IV History Report on LCD Display

1.2
SAFETY FEATURES

The 4000 Plus maximizes safety and reliability with the following features:

❑ The device automatically performs a self test of its electrical and mechanical components when the [ON/CHARGE] switch is placed in the ON position

❑ If the [ON/CHARGE] switch is turned to CHARGE during infusion, the device retains the most recent programming and infusion data in a nonvolatile memory. The data is reinstated during power up (see Section 3.1, Setup Procedures)

❑ The device maintains duplicate programming memory. If the duplicate programming information does not match, the device alarms

❑ A two-step procedure is required to remove the cassette from the device

❑ To change pumping instructions (rates, volume, stopping lines), two keys must be pressed in order

❑ A comprehensive self test identifies a variety of potential malfunctions within the device, cassette, and interface. This 36-second cassette test is activated every time the [PRIME PATIENT LINE] [ENTER] key sequence is pressed

Note: The user can bypass the cassette test; however, Abbott Laboratories recommends the routine use of this test.

1.3

WARNINGS, CAUTIONS, AND NOTES

Throughout this manual, three types of alert messages are used: warnings, cautions, and notes, as described below. Pay attention to all alert messages.

WARNING

A WARNING CONTAINS SPECIAL SAFETY EMPHASIS AND MUST BE OBSERVED AT ALL TIMES. FAILURE TO OBSERVE A WARNING IS POTENTIALLY LIFE THREATENING.

CAUTION: A CAUTION usually appears in front of a procedure or statement. It contains information that could prevent irreversible damage or hardware failure. Neglecting to pay attention to a CAUTION could result in serious injury.

Note: A Note highlights information that helps explain a concept or procedure.

1.4

INSTRUMENT INSTALLATION PROCEDURES

In order to fully utilize 4000 Plus capabilities, it is important to become thoroughly familiar with the System Operating Manual prior to use.

WARNING

PRODUCT DAMAGE MAY OCCUR UNLESS PROPER CARE IS EXERCISED DURING THE UNPACKING AND INSTALLATION PROCESS. THE BATTERY PACK MAY NOT BE FULLY CHARGED UPON RECEIPT. DO NOT PLACE THE DEVICE IN SERVICE IF IT FAILS THE SELF TEST.

Note: Instrument installation should be performed by qualified personnel only.

1.4.1

UNPACKING INSTRUCTIONS

Each shipping carton should contain the following items:

- ❑ Omni-Flow 4000 Plus IV Medication Management System with attached power cord
- ❑ Omni-Flow 4000 Plus System Operating Manual

Carefully remove the device from the shipping carton. The carton should be retained in the event the device needs to be shipped.

1.4.2
INSPECTION

Inspect the packing container for visible shipping damage. Should any damage be found, contact the delivering carrier immediately. Freight claims or insurance claims must be filed within seven days.

Inspect the device for damage. Do not use the device if it appears to be damaged; contact the Abbott Laboratories Technical Service Center.

CAUTION: If device appears to be damaged, do not operate; return for service.

Plug the power cord into a 110/120 volt AC outlet. The device is ready for immediate AC use. Do not operate the device on battery power until it has been plugged into an electrical outlet for at least 24 hours.

Locate the [ON/CHARGE] switch on the back of the device and toggle the switch to the ON position. Unlock the cassette locking lever and remove the shipping cassette. See *Section 3.5, Removing the Cassette from the Device*, for additional information on removing a cassette. Discard the shipping cassette; do not use.

1.4.3
4000 PLUS SELF TEST

Do not place the 4000 Plus in service until the self test has been conducted. See *Section 3.1, Setup Procedures*, for detailed information on the device self test.

1.4.4
PRINTER SETUP

The 4000 Plus allows the user to print history report information. The device works with several serial printers. The user should become thoroughly familiar with the system operating manual which is included with the printer. The following DIP switch configuration is for the Seiko DPU-411 printer. The printer operating manual should detail the printer DIP switch locations.

To set up the Seiko DPU-411 printer for use with the 4000 Plus, proceed as follows:

1. Set the printer DIP switch configuration as shown in the following display:
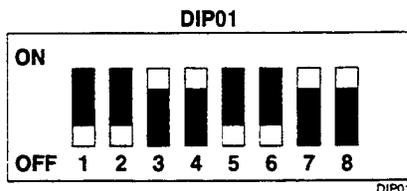
Note: DIP01 switches set input data format, number of columns, and characters.

DIP02

ON					
OFF| 1	2	3	4	5	6
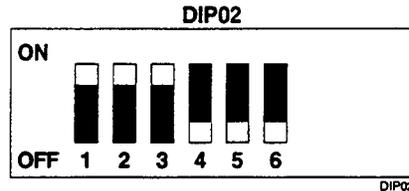
DIP02

Note: DIP02 switches are set for serial input.

2. Connect the printer cable to the serial port labeled RS-232 on the printer.

3. Connect the other end of the printer cable to the nine-pin serial port labeled RS-232 on the rear of the 4000 Plus. See *Figure 1-1, 4000 Plus, Rear View.*

4. Connect the AC power plug to the printer and the AC adapter to an AC outlet.

   Note: If necessary, the Seiko DPU-411 printer can be operated on battery power.

5. Turn the printer switch to the ON position. The LED power-on light is on, and the printer LED reads OFF-LINE. Press the printer [ON-LINE] switch, and confirm the ON-LINE LED is on.
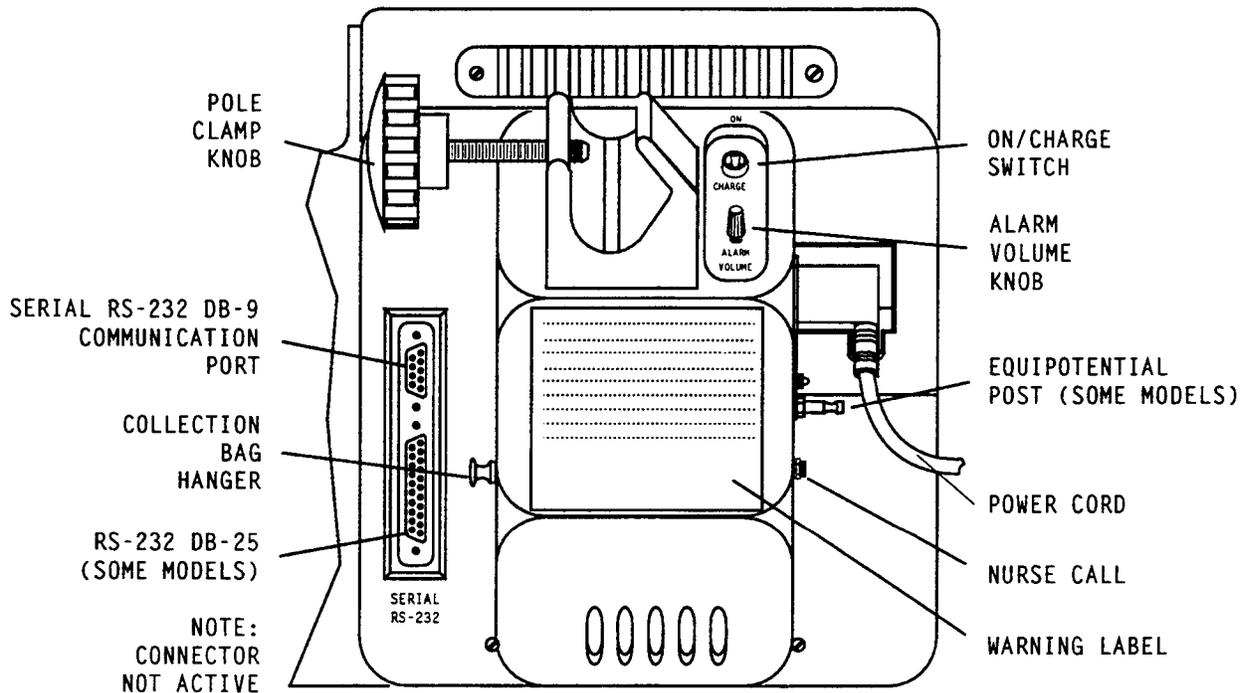
Figure 1-1. 4000 Plus, Rear View

Section 2

EQUIPMENT DESCRIPTION

The 4000 Plus incorporates a number of programming aids to simplify the setup and operation of the device. While performing setup or programming functions it may be helpful to refer to *Section 13, Keypad Description. Figure 13-1, 4000 Plus, Front View,* details the keypad.

Note: In-text references to device keypad are shown in uppercase letters; corresponding text on keypad may be in lowercase letters.

Note: Figures are rendered as graphic representations to approximate actual product; therefore, figures may not reflect the product exactly.

2.1

BACKLIT DISPLAY SCREEN

The 80-character display screen is backlit to aid visibility in dim or dark areas. The light comes on and stays on for two minutes when any key on the keypad is pressed. The display screen provides prompting messages, programming information, infusion status information, and alarm messages to aid in the setup and use of the device.

2.2

ESCAPE FUNCTION

The [ESCAPE] key can be utilized any time the user is unsure of the next step or is unable to exit a particular display screen. Press the [ESCAPE] key to return the display to the base screen and restart a programming sequence.

2.3

BASE SCREEN

The base screen appears during the normal device operation and shows which lines are ON, OFF, or programmed to start in the future (PGM); the current infusion rates of each line; and the cumulative infusion rate at that time.

```
A:OFF   B:OFF   C:OFF   D:OFF    TOTAL 12:30PM
   0       0       0       0       0   ML/HR
```

The base screen is the device status screen. During programming or operation, an intermittent beeping tone alerts the user that the device is not in the base screen. The beeping tone is a reminder to the user that a programming sequence is not complete. This reminder tone ceases upon return to the base screen.

The base screen utilizes the following indicators to assist in determining the pumping status of each individual line:

ON   Indicates the line is currently running in the *continuous* mode of operation.

INF   Indicates the line is infusing an *intermittent* dose to the patient. Also appears if Line A is running in the *maintenance* mode of operation.

DIL   Indicates that Line A is *diluting* a drug on another line.

FLS   Indicates that Line A is *flushing* the cassette and patient line after or before an intermittent infusion.

PGM   Indicates that an *intermittent* line is programmed to deliver a dose of medication sometime in the future,
         AND/OR
if line A is running in *maintenance* mode while another line is delivering an *intermittent* dose.

HLD   Indicates that line operation is *suspended* either due to an alarm condition or the user placing it on hold.

DLY   Indicates a programmed *intermittent* infusion (PGM) is being delayed due to a preceding *intermittent* infusion, being on hold (HLD), or due to a *flush*.

OFF   Indicates the line has been stopped and is OFF.

2.4
PROGRAMMING INPUT INDICATOR (CURSOR)

A flashing programming input indicator (cursor) automatically appears on the display screen at the first information entry point. The cursor must be moved to the next entry point on the screen. Press the [NEXT] key to move the cursor forward. To move to a previous entry point, press the [LAST] key to move the cursor backwards. To clear any entry where the cursor is flashing, press the [CLEAR ENTRY] key.

Note: Several programming screens do not allow an advance to the next screen if all the necessary programming information has not been entered on that screen (i.e., if a rate is entered, but not a total volume on a continuous infusion, the screen cannot be advanced). In these cases, the cursor automatically moves to the entry point which is missing the required programming information.

2.5
LED STATUS INDICATORS

The front panel LED indicators located next to the alphabetical line designations (A, B, C, D), indicate their status as follows:

- ❑ Off when the line is off
- ❑ Flashing when the line is infusing medication
- ❑ On steadily when the line is programmed to start at a future time or the infusion of a line is suspended (on hold).

The LED indicators located on the left side of the front panel indicate their status as follows:

- ❑ AC POWER - illuminated (green) when the device is operating on AC power.
- ❑ BATTERY - illuminated (yellow) when the device is operating on battery power.
- ❑ ALARM - illuminated (red) when the device is in an alarm condition.

See *Figure 13-1, 4000 Plus, Front View*, for location of the LED indicators.

2.6
NOTATION AREAS

The white area next to the alphabetical line designations (A, B, C, D) on the front panel are for making notations about the medication or the programming on that line. A non-permanent felt-tip pen or pencil should be used for these notations. This area can be cleaned with an alcohol swab or a soft eraser.

2.7

PRINTER

A printer (optional) can be attached to the 4000 Plus and used to print history report information. See *Figure 2-1, Seiko DPU-411 Printer (Optional)*. For more information on using the printer, refer to *Section 5.8.2, Accessing History Reports with a Printer*.
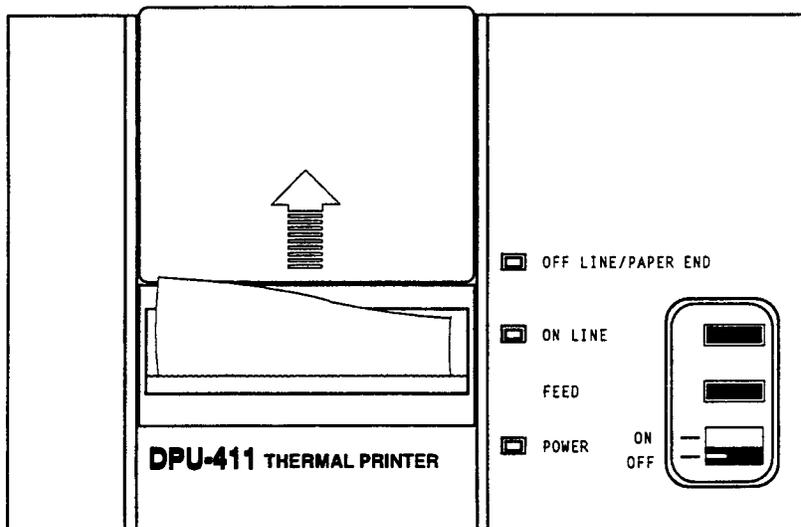
9216H002

Figure 2-1. Seiko DPU-411 Printer (Optional)

Note: The Seiko DPU-411 printer illustrated in *Figure 2-1* is one of several printers which can be used with the 4000 Plus.

Section 3

SETUP

The following sections detail setup and priming procedures for the 4000 Plus. See *Section 13, Keypad Description, Figure 13-1, 4000 Plus, Front View* and *Section 1, Introduction, Figure 1-1, 4000 Plus, Rear View*, for overview illustrations of the device.

Note: Prior to placing the 4000 Plus in service, fully recharge the battery by connecting the device to AC power for at least 24 hours.

3.1

SETUP PROCEDURES

WARNING

ARRANGE TUBING, CORDS, AND CABLES TO MINIMIZE THE RISK OF PATIENT STRANGULATION OR ENTANGLEMENT.

CAUTION: When programming the device, the confirmatory response beep should be clearly audible. If the confirmatory beep is inaudible, adjust the ALARM VOLUME knob located on the back of the device. If after adjustment the beep is still inaudible, contact Abbott Laboratories Technical Support Operations.

To set up the 4000 Plus, proceed as follows:

1. Use the pole clamp to attach the device to an IV pole.
2. Connect the power cord to a properly grounded 110/120 volt AC outlet.
3. Toggle the [ON/CHARGE] switch to the ON position.

   Note: A service code may be displayed if the device is turned on with a cassette locked in the cassette holster. If the service code appears, remove the cassette and cycle the power to the device (power the device off, then on by toggling the [ON/CHARGE] switch to CHARGE, then ON). The service code is cleared.

4. Confirm that the green AC POWER indicator is illuminated and that all other LED indicator lights are off.

At power on, the device performs its self-test diagnostics. The self test lasts approximately six seconds during which time the screen displays the following message:

```
>>>>>>>> SELF TEST IN PROGRESS <<<<<<<<
              ABBOTT 4000 PLUS
```

Upon successful completion of the self test, the *Restore Previous Programming* screen displays the following setup questions:

```
RESTORE PREVIOUS PROGRAMMING   Y/N?      NO
CLEAR IV HISTORY     Y/N?    NO        [ENTER]
```

Note: The *Restore Previous Programming* screen displays two setup questions. Select YES or NO to each query before pressing the [ENTER] key. The [ENTER] key enters all setup instructions into device memory.

3.1.1
RESTORE PREVIOUS PROGRAMMING

To restore previous programming at the *Restore Previous Programming* screen, proceed as follows:

1. Select YES to *Restore Previous Programming Y/N?*. Previous programming is restored to the device.

   When YES is selected to *Restore Previous Programming Y/N?*, the following data is restored:

   ❏ IV Flow Sheet
   ❏ Line Programming: Any lines that were not OFF are put on HLD

2. Select NO to *Clear IV History Y/N?*. Previous IV history is retained.

   Note: Select YES to *Clear IV History Y/N?* to remove previous patient IV history.

3. Press the [ENTER] key to enter all setup instructions into device memory.

Note: During a power shut down, programmed start times for lines are delayed for as long as the power is down. Upon power up and restoring previous programming, the user should review the programmed information before pressing the [RESUME] key to begin programmed infusions.

Note: To reduce the likelihood of restoring corrupted line programming after Service Code conditions occur, the *Restore Previous Programming* option is not available after the occurrence of certain Service Code alarms. In this case, the following screen is displayed after turning power on:

```
┌─────────────────────────────────────────────┐
│ INSERT CASSETTE AND LOCK IN PLACE            │
│ 4-JUN-92      PRESS [ENTER]      11:05 AM    │
└─────────────────────────────────────────────┘
```

3.1.2
INITIATE NEW PROGRAMMING

To initiate new programming at the *Restore Previous Programming* screen, proceed as follows:

1. Select NO to *Restore Previous Programming Y/N?*. Previous programming is removed from the device.

2. Press the [ENTER] key. The *Insert Cassette and Lock In Place* screen is displayed:

```
┌─────────────────────────────────────────────┐
│   INSERT CASSETTE AND LOCK IN PLACE.         │
│ 20-MAR-92     PRESS [ENTER]        11:30 AM  │
└─────────────────────────────────────────────┘
```

Confirm the correct date and time are displayed on the *Insert Cassette and Lock In Place* screen. If the date and time are correct, press the [ENTER] key. Proceed to *Section 3.2, Priming Procedures: Primary Administration Set.*

If the date and time are incorrect on the *Insert Cassette and Lock In Place* screen, press the [ESCAPE] key. The *Bypass Cassette Test* screen is displayed:

```
BYPASS CASSETTE TEST?   NO
                          PRESS [ENTER]
```

Press the [YES/NO] key to change NO to YES. Press the [ENTER] key. The base screen is displayed:

```
A:OFF   B:OFF   C:OFF   D:OFF   TOTAL    12:30PM
  0       0       0       0       0       ML/HR
```

Refer to *Section 5.4, Special Functions*, for detailed instructions on using [SPECIAL FUNCTION][1] to set date, time, and display format. When date and time are correct, cycle the device power by toggling the [ON/CHARGE] switch to CHARGE, then ON. Cycling the power returns the device to the *Self Test* screen, followed by the *Restore Previous Programming* screen.

Repeat Steps 1 and 2 as follows:

1. Select NO to *Restore Previous Programming Y/N?*. Previous programming is removed from the device.
2. Press the [ENTER] key. The *Insert Cassette and Lock In Place* screen is displayed. Confirm the correct date and time are displayed on the screen.
3. Proceed to *Section 3.2, Priming Procedures: Primary Administration Set*.

Note: Do not bypass the cassette test.

3.1.3
RESPONSE TO LOW BATTERY CONDITION

If a low battery condition is detected by the device self test, the *Current Time* screen is displayed:

```
CURRENT TIME   11:35 PM   24 HR TIME Y/N?   NO
DATE (DD-MM-YY): 30-MAR-92                [ENTER]
```

1. Confirm the correct date and time are displayed on the *Current Time* screen.
2. If the date and time are incorrect, use the [NEXT] key and [LAST] key to position the cursor as appropriate. Overwrite the old data with the new data.

   Note: Refer to *Section 5.4, Special Functions*, for more detailed information on setting date and time.
3. Upon data entry completion, press the [ENTER] key. The *KVO Rate* screen is displayed:

```
KVO RATE: 1.0ML/HR
MAX OCCLUSION:   10PSI                    [ENTER]
```

4. Confirm that the correct information displays on the *KVO Rate* screen.
5. If the default values are to be changed, use the [NEXT] and [LAST] keys to position the cursor as appropriate. Enter values for KVO and Maximum Patient Line Occlusion Pressure. The values entered become the default settings for the device.

   Note: Default settings remain in device memory when the device is turned off or on.

6. Press the [ENTER] key to accept the default values. The *Enable All Callbacks* screen is displayed:

```
ENABLE ALL CALLBACKS  Y/N?                 NO
TEMPERATURE UNITS     C:NO    F:YES    [ENTER]
```

7. Determine if the default settings shown on the *Enable All Callbacks* screen are appropriate.

8. To change the Callbacks or Temperature Units option, use the [NEXT] and [LAST] keys to position the cursor as appropriate. Press the [YES/NO] key to toggle to the desired setting.

9. Press the [ENTER] key. The *Insert Cassette and Lock in Place* screen is displayed:

```
INSERT CASSETTE AND LOCK IN PLACE.
30-OCT-92          PRESS [ENTER]       11:30 AM
```

3.2

PRIMING PROCEDURES: PRIMARY ADMINISTRATION SET

To prime the 4000 Plus with a primary administration set, proceed as follows:

1. Select the desired Omni-Flow Primary Set. Remove set from package, close the upper clamp for Line A, and confirm that all luer lock connections on cassette are secure.

   CAUTION: Use only Abbott Omni-Flow Primary Sets on the device. Refer to the administration package insert for complete instructions.

2. Prepare IV container: close all clamps, remove spike protector, insert spike through outlet hole in container, and squeeze drip chamber to adjust fluid level until approximately half full. Hang the container.

3. Confirm fluid level is correct. Grasp cassette so that the collection bag and patient line are at the top and the luer lock connectors are pointing to the right.

4. Confirm that the [ON/CHARGE] switch is ON, and the cassette lever is in the unlocked position. Insert cassette into holster located along the right side of device (*see Figure 3-1, Inserting the Cassette*). Slowly turn the cassette locking lever to the locked position. The cassette is locked in place. To secure, press down on the cassette lever (*see Figure 3-2, Locking the Cassette in Place*).

CAUTION: Turn the cassette locking lever slowly to lock cassette in place.

Note: Confirm the cassette locking lever is in the locked position. The cassette lever must be locked in place and properly secured before any operation can continue.

5. Open all clamps on the set and confirm no fluid is flowing in drip chamber. Attach collection bag to hanger located on the bottom right corner of the device (*see Figure 1-1, 4000 Plus, Rear View*).

9307A002

Figure 3-1. Inserting the Cassette.
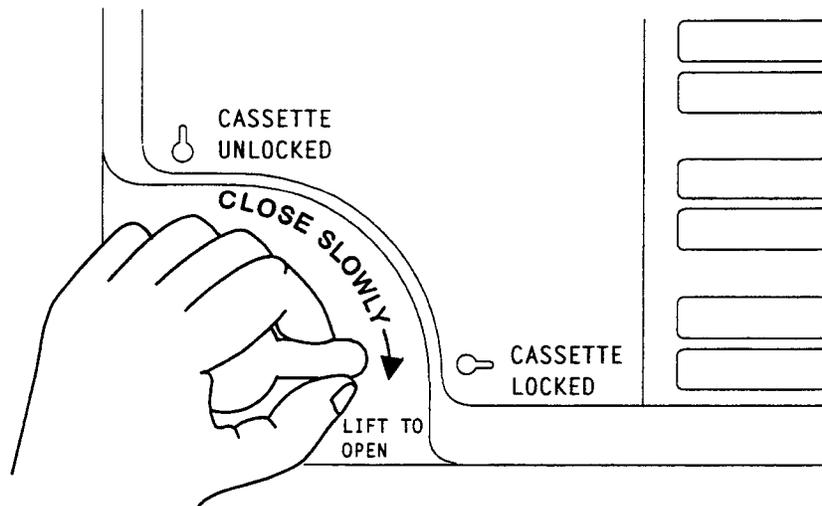
9216H004

Figure 3-2. Locking the Cassette in Place.

3.2.1
CASSETTE PRIMING MODES

The 4000 Plus has two priming modes: cassette power prime and cassette gravity prime. Line A can be primed using either mode.

When priming the cassette, the fluid goes into the collection bag.

```
HOLD DOWN [CASSETTE] KEY ON <A> TO PRIME
INTO COLLECTION BAG.        PRESS [ENTER]
```

3.2.1.1
CASSETTE POWER PRIME (LINE A)

When the prime cassette screen is displayed and the [PRIME CASSETTE] key is pressed and released, the pumping action of the system pulls fluid from Line A into the cassette. At each device stroke, the system measures cassette pressure; when cassette pressure is above threshold, it is fully primed. A device stroke limit of 25 is set in the event there is a cassette leak.

3.2.1.2
GRAVITY PRIME

When the prime cassette screen is displayed and the [PRIME CASSETTE] key is pressed and held, the system reverts to gravity prime. Gravity pulls fluid into the cassette until the [PRIME CASSETTE] key is released.

Note: See *Section 3.3, Priming Procedures: Secondary Administration Sets*, for information regarding priming secondary administration sets from the device.

3.2.2
PRIMING THE CASSETTE

The cassette is primed from lines B, C, and D by gravity flow as follows:

1. Press and hold the [PRIME CASSETTE] key on lines B, C, or D until solution enters the collection bag.

```
HOLD DOWN [CASSETTE] KEY ON <B> TO PRIME
INTO COLLECTION BAG.        PRESS [ENTER]
```

2. Press the [ENTER] key when priming is complete.

3.2.3
PATIENT LINE PRIMING MODES

The patient (distal) line may be primed either by power prime or by gravity prime.

WARNING
DO NOT CONNECT LINE TO PATIENT WHILE PRIMING PATIENT LINE.

Note: Priming the patient line can only occur when ALL lines are OFF.

3.2.3.1
PATIENT LINE POWER PRIME

When the *Prime Patient Line* screen is displayed and the [PRIME PATIENT LINE] key is pressed, then released, the pumping action of the system pulls fluid from Line A into the cassette. At each device stroke, the system measures cassette pressure; when cassette pressure is above threshold, it is fully primed. After reaching the pressure threshold, the patient line is opened and an additional 13 strokes are pumped, corresponding to 3 mL of fluid. This volume is sufficient to prime the entire microbore 60 inch patient line.

Note: When using power prime, confirm the patient line is fully cleared of all air before connecting to patient. Additional gravity priming may be required to fully clear air from the line.

Note: In the event of an occlusion alarm, use the appropriate aseptic techniques to remove the filter cap at the distal end of the patient line

3.2.3.2
PATIENT LINE GRAVITY PRIME

When the [PRIME PATIENT LINE] key is pressed and held, the system reverts to gravity prime. Gravity pulls fluid into the cassette until the [PRIME PATIENT LINE] key is released.

3.2.4
PRIMING THE PATIENT LINE

To prime the patient line from lines B, C, or D, proceed as follows:

1. Press and hold the [PRIME PATIENT LINE] key until all air is cleared from the patient line.

```
HOLD DOWN [PATIENT LINE] KEY ON <B> TO
PRIME PATIENT LINE.          PRESS [ENTER]
```

2. When priming is complete, press the [ENTER] key.

Note: When using the gravity flow prevention valve set, see *Section 3.3, Priming Procedures: Primary Administration Set With Gravity Flow Prevention Valve.*

3.2.5
CASSETTE TEST

The device performs a cassette test for approximately 36 seconds.

CAUTION: It is extremely important to always perform the cassette test when inserting a new cassette.

```
CASSETTE TEST IN PROGRESS
ABBOTT 4000 PLUS
```

When the cassette test is completed, one of two screens is displayed: *Possible Faulty Cassette* screen, or *Select Infusion Type* screen.

3.2.5.1
CASSETTE TEST FAILED

If the cassette fails the cassette test, the device alarms and the *Possible Faulty Cassette* screen is displayed:

```
-POSSIBLE FAULTY CASSETTE-
REPRIME OR REPLACE CASSETTE          [MUTE]
```

If the cassette fails the cassette test, proceed as follows:

1. Silence the alarm by pressing the [MUTE] key. To clear the alarm, press the [MUTE] key again. Check for air bubbles, and reprime if necessary.

2. Prime the cassette as described in *Section 3.2.2*. Prime the patient line as described in *Section 3.2.4*.

3. If it fails the cassette test again, replace cassette. Prime new cassette as described in *Section 3.2.2*. Prime the patient line as described in *Section 3.2.4*. If two cassettes fail in a row, send the device to clinical engineering.

3.2.5.2
CASSETTE TEST SATISFACTORY

If the cassette test is satisfactorily completed, the following screen is displayed:

```
            SELECT INFUSION TYPE
    PRESS [CONTINUOUS] OR [INTERMITTENT]
```

To prepare for connecting IV containers or syringes to the remaining three lines, press the [ESCAPE] key. The base screen is displayed.

THE DEVICE IS NOW READY FOR CONNECTING IV CONTAINERS OR SYRINGES TO THE REMAINING THREE LINES.

3.3
PRIMING PROCEDURES: PRIMARY ADMINISTRATION SET WITH GRAVITY FLOW PREVENTION VALVE

CAUTIONS: The gravity flow prevention valve protects the patient from free flow if the cassette is removed from the device without closing the clamps. The gravity flow prevention valve does not prevent mixing of drug lines. Close all clamps before removing cassette.

The gravity flow prevention valve requires pressure to open (1.5 to 5.0 psi). The device occlusion pressure setting may require adjustment to prevent nuisance occlusion alarms.

Note: These instructions offer an alternative priming procedure to those found on the package insert of the administration set. These instructions apply to the 4000 Plus only.

To prime the 4000 Plus with a primary administration set containing the gravity flow prevention valve, proceed as follows:

1. Remove the primary set from package, close the upper clamp for Line A, and confirm that all luer lock connections on the cassette are secure.

   CAUTION: Use only Abbott Omni-Flow Primary Sets on the device. Refer to the administration package insert for complete instructions.

2. Prepare IV container: close all clamps, remove spike protector, insert spike through outlet hole in container, and squeeze drip chamber to adjust fluid level until approximately half full. Hang the container.

3. Confirm fluid level is correct. Grasp cassette so that the collection bag and patient line are at the top and the luer lock connectors are pointing to the right.

4. Confirm that the [ON/CHARGE] switch is ON, and the cassette lever is in the unlocked position. Insert cassette into holster located along the right side of device (*see Figure 3-1, Inserting the Cassette*). Slowly turn the cassette locking lever to the locked position. The cassette is locked in place. To secure, press down on the cassette lever (*see Figure 3-2, Locking the Cassette in Place*).

CAUTION: Turn the cassette locking lever slowly to lock cassette in place.

Note: Confirm the cassette locking lever is in the locked position. The cassette lever must be locked in place and properly secured before any operation can continue.

5. Open all clamps on the set and confirm no fluid is flowing in drip chamber. Attach collection bag to hanger located on the bottom right corner of the device (*see Figure 1-1, 4000 Plus, Rear View*).

6. Prime the cassette using the Line A [PRIME CASSETTE] key until all air is cleared from the cassette into the collection bag. Press the [ENTER] key.

7. Attach any extension set or other devices to the gravity flow prevention valve located at the distal end of the patient line (do not attach to a venipuncture device).

8. Press the Line A [PRIME PATIENT LINE] key to power prime the patient line. The gravity flow prevention valve prevents gravity prime mode from priming the patient line.

   Note: If additional power primes are needed to prime the patient line, repeat Steps 9 and 10 until primed.

9. Press the [ESCAPE] key. When the Cassette Test Screen displays, enter YES to bypass the cassette test and return to the base screen.

10. When the base screen displays, press Line A [PRIME PATIENT LINE] to power prime the patient line.

11 Press the [ENTER] key when the patient line is fully primed. The device preforms a cassette test.

12. Determine if the venipuncture device is indwelling. If the venipuncture device is not indwelling, prepare and insert the venipuncture device in the patient per hospital procedure.

13. Attach the primed patient line to the venipuncture device.

THE LINE IS NOW READY FOR PROGRAMMING.

3.4
PRIMING PROCEDURES:
SECONDARY ADMINISTRATION SET

To prime the 4000 Plus with a secondary administration set, proceed as follows:

1. Select the desired Omni-Flow Secondary Set. Remove set from package; close clamp.

   CAUTION: Use only Abbott Omni-Flow Secondary Sets. Refer to the administration package insert for complete instructions.

2. Prepare IV container: close all clamps, remove spike protector, insert spike through outlet hole in container, and squeeze drip chamber to adjust fluid level until approximately half full. Hang container.

3. Confirm fluid level is correct. Remove distal cap from secondary set.

4. Remove the luer lock protector for the cassette line to be used. Connect secondary set to cassette.

   Note: An alternative method is to open the clamp and clear all air from the set by gravity prime prior to connecting the secondary set to the cassette.

5. Prime the line by pressing the appropriate [PRIME CASSETTE] key until no air bubbles are visible in the connection site or cassette.

THE LINE IS NOW READY FOR PROGRAMMING.

To prime the 4000 Plus with a secondary administration set while other lines are running, proceed as follows:

1. Put all lines on hold.
2. Connect and prime secondary set as described above.
3. Press the [RESUME] key, then the [ENTER] key.

CAUTION: Priming directs air and fluid out through the cassette and into the collection bag. Fluid originally in the cassette may be displaced into the collection bag by the priming sequence.

3.5
CONNECTING A SYRINGE TO THE CASSETTE

Note: For syringe infusions, only use 20 cc to 60 cc size syringes.

To connect a syringe to the cassette, proceed as follows:

1. Remove luer lock protector for the cassette line to be used. Connect an Omni-Flow compatible stop-cock or syringe support elbow into the cassette.
2. Connect the syringe to the stop-cock or elbow, with the syringe in a vertical position (*see Figure 3-3, Syringe Connected to the Cassette*). Open fluid pathway from syringe to the cassette.
3. If air bubbles are visible in the connection sight or cassette, prime the line by pressing the appropriate [PRIME CASSETTE] key.

Note: Syringes may not prime easily with gravity flow. Some force may be required on the plunger during cassette prime.

THE LINE IS NOW READY FOR PROGRAMMING.

8307A001
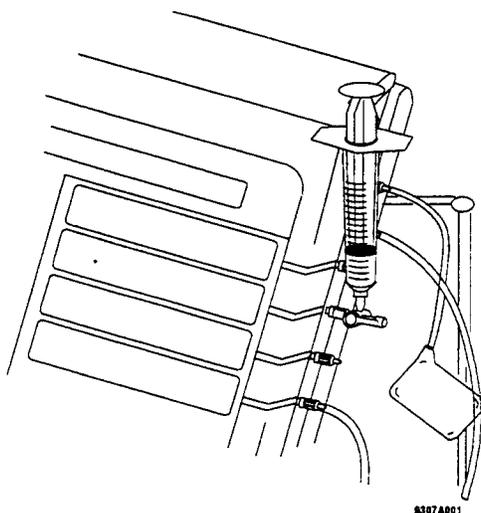
Figure 3-3. Syringe Connected to the Cassette

3.6

CONNECTING A SYRINGE AND SYRINGE ADAPTOR TO THE CASSETTE

A syringe adaptor serves to vent the syringe, making it less susceptible to plunger stopper resistance. When programming the 4000 Plus and using the syringe adaptor, it is recommended that the Syringe option be set to NO.

To attach a syringe and syringe adaptor to the cassette, proceed as follows:

1. Prepare the syringe using aseptic technique.

2. Attach the adapter to the syringe (see *Figure 3-4, Connecting Syringe and Syringe Adaptor to Cassette*).

3. Attach an Omni-Flow compatible stop-cock or a syringe support elbow to the adaptor (see *Figure 3-4*).

4. Prime the adaptor and stop-cock/syringe support elbow.

5. Remove the luer lock protection for the cassette line to be used. Connect primed stop-cock or syringe support elbow to the cassette.

THE LINE IS NOW READY FOR PROGRAMMING.
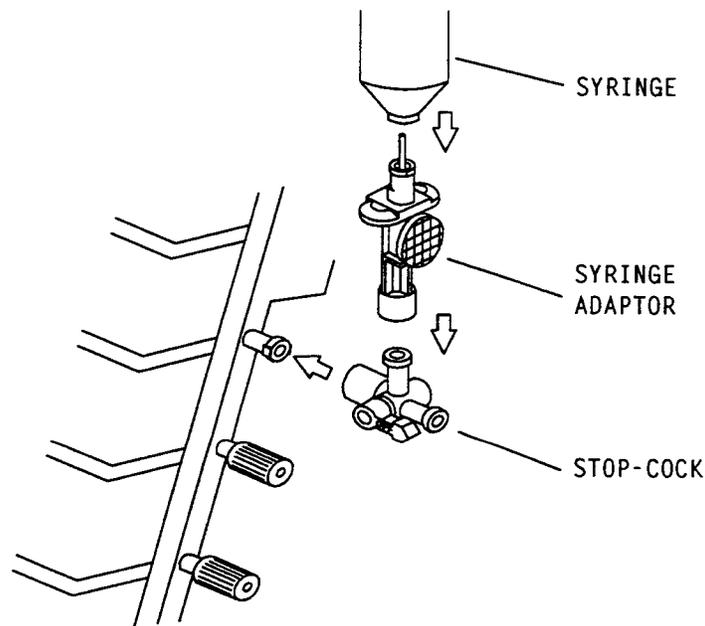
Figure 3-4. Connecting Syringe and Syringe Adaptor to Cassette

3.7

REMOVING THE CASSETTE FROM THE DEVICE

WARNING

REMOVING CASSETTE FROM DEVICE WITHOUT CLOSING LINE CLAMPS MAY RESULT IN UNRESTRICTED FLOW. All CLAMPS MUST BE CLOSED TO PREVENT FLOW TO PATIENT AND/OR MIXING OF DRUGS.

To remove a cassette from the 4000 Plus, proceed as follows:

1. Confirm that the [ON/CHARGE] switch is ON and all lines are OFF.
2. Close clamps on all lines to prevent free flow and/or mixing of drugs.
3. Lift cassette locking lever and turn counterclockwise. Allow approximately 3 seconds for the piston to retract.
4. Pull cassette from holster.

If a cassette becomes jammed or a Pump Service Code 0800 occurs while inserting or removing the cassette, proceed as follows:

1. Cycle the device power. Toggle the [ON/CHARGE] switch to CHARGE, then ON.
2. Push the cassette completely down in the holster until it is securely seated.
3. Confirm the self test completes.
4. Proceed with programming.

Section 4

PROGRAMMING

When programming the 4000 Plus, listen for the device response (audible confirmatory beep) during programming.

CAUTION: After programming the device, ensure that pumping has begun by verifying flow into the drip chamber on each appropriate fill stroke for each line in use.

4.1

MAINTENANCE INFUSIONS

The 4000 Plus can infuse on Line A in either the continuous mode of operation (device continues to deliver when an intermittent line is infusing) or in the maintenance mode (device stops delivering when an intermittent line is infusing and restarts when the intermittent line stops infusing).

If an intermittent with dilution programmed on Lines B, C, or D is put on hold, and a maintenance infusion was previously prgrammed on Line A, the dilution is put on hold and the maintenance programming on Line A continues.

To set up line A, proceed as follows:

1. Press the [MAINTENANCE INFUSION] key for Line A.

```
A> MAINTENANCE RATE:5.0ML/HR
     TOTAL VOLUME: 0 ML      [ENTER]
```

2. Set a rate using the numeric keys, then press the [NEXT] key.

   Note: If the line rate chosen exceeds the combined maximum rate of the device, a message appears on the display screen. Refer to *Section 12, Specifications*, for rate range specifications.

3. Set a Total Volume to be infused using the numeric keys, then press the [ENTER] key to start the line.

```
A> MAINTENANCE RATE:5.0ML/HR
     TOTAL VOLUME: 250ML      [ENTER]
```

The base screen is displayed:

```
A: INF B: OFF C: OFF D: OFF  TOTAL 12:30 PM
   5.0      0      0      0    5.0   ML/HR
```

Note: Maintenance or continuous rate on Line A can only be changed when Line A is not in the flushing or diluting mode. If Line A is flushing or diluting, the display only allows the entry of a new source container volume.

4.2

CONTINUOUS INFUSIONS

The 4000 Plus infuses up to four medications at the same time in the continuous mode and offers the user two methods of programming: ML/HR and MCG/KG/MIN.

Note: To change either the rate in MCG or mL/hr, or total volume on any line operating in the continuous mode, press the [CONTINUOUS INFUSION] key. Use the [NEXT] and [LAST] keys to move the cursor to the desired field that requires a change. Any change may be made while the line is operating; there is no need to stop the flow. After making a change, press the [ENTER] key and the device begins operating at the new rate and/or volume immediately.

Note: Continuous infusions may not be programmed over Maintenance or Intermittent infusions without first stopping the Maintenance or Intermittent infusion.

Note: Concurrent flow exists when two or more drugs are given simultaneously (*see Section 4.2.4, Concurrent Flow*).

Note: Continuous infusions are rate specific and alarm when dose is complete. The infusion does not stop. The device keeps pumping at programmed rate and does not go to KVO.

4.2.1

ML/HR INFUSIONS

The following sections detail the required steps to program an mL/hr infusion and the steps to change an mL/hr infusion.

4.2.1.1
PROGRAMMING OR CHANGING AN ML/HR INFUSION

To program a new mL/hr infusion, or change an existing mL/hr infusion, proceed as follows:

1. Press the [CONTINUOUS INFUSION] key for the line used. The following screen is displayed:

```
B> RATE: OML/HR    VOL:   OML WT: OKG
     OMCG/KG/MIN OMG IN OML [ENTER]
```

   Note: If [CONTINUOUS INFUSION] was pressed in error or there is a need to begin again, press the [ESCAPE] key to return to the base screen.

2. The cursor appears in the *RATE* field. Enter the delivery rate. Use the [NEXT] key to move the cursor to the *VOL* field. Enter the volume to be delivered.

   Note: If the line rate chosen exceeds the combined maximum rate of the device, a message appears on the display screen. Refer to *Section 12, Specifications, Delivery Rate Range*, for specifications.

3. Press the [ENTER] key to start the infusion.

4.2.1.2
CHANGING AN ML/HR INFUSION TO AN ALTERNATE UNIT OF MEASURE INFUSION

To change an existing mL/hr infusion to an alternate unit of measure infusion, proceed as follows:

1. Press the [CONTINUOUS INFUSION] key for the line used. For example, when using line B, the following screen is displayed:

```
B> RATE: 15.0ML/HR       VOL:   250ML WT:   0KG
       0MCG/KG/MIN       0MG IN       0ML      [ENTER]
```

2. Since the line has previously been programmed in mL/hr, the cursor will appear in the *ML/HR* field.

3. Use the [NEXT] key to enter the appropriate global body weight, if one does not already exist.

    Note: If programming in MCG/MIN is desired, enter a body weight of one (1).

4. Use the [NEXT] key to move the cursor to the *MCG/KG/MIN* field, and enter the MCG/KG/MIN rate.

5. Use the [NEXT] key to move the cursor to the *MG* field, and enter the medication dose.

6. Use the [NEXT] key to move the cursor to the *ML* field. Enter the diluent volume.

```
B> RATE: 16.9ML/HR       VOL:   250ML WT:   75.0KG
       3.00MCG/KG/MIN    200MG IN     250ML   [ENTER]
```

Note: If no entry is made in the *Volume* field, the volume entered in the *ML* field becomes the default container volume.

Note: The calculated delivery rate in ML/HR appears in the *ML/HR Rate* field.

7. To start the infusion, press the [ENTER] key. The following screen is displayed:

```
A:INF   B:ON   C:OFF   D:OFF   TOTAL 12:30PM
  35.0   16.9      0       0    51.9   ML/HR
```

In this example, the base screen shows Line A has been programmed as a maintenance at 35 mL/hr. Line B runs at 16.9 mL/hr in a continuous mode of operation and continues until stopped. (The mL/hr rate for Line B is the calculated result of the MCG/KG/MIN program.) The base screen only displays delivery rates in mL/hr.

4.2.2

ALTERNATE UNITS OF MEASURE (MCG/KG/MIN) INFUSIONS

The following sections detail the required steps to program an alternate unit of measure infusion and the steps to change a unit of measure infusion.

Note: The 4000 Plus will not accept MCG/KG/MIN programming unless all data fields are specified (non-zero); rate (MCG/KG/MIN), dose amount (MG), diluent volume (ML), and body weight (WT).

4.2.2.1

PROGRAMMING A NEW ALTERNATE UNIT OF MEASURE INFUSION

To program a new alternate unit of measure (MCG/KG/MIN) infusion, proceed as follows:

1. Press the [CONTINUOUS INFUSION] key for the line used. For example, when using line B, the following screen is displayed:

```
B> RATE:    0ML/HR       VOL:   0ML  WT:   0KG
            0MCG/KG/MIN   0MG IN       0ML  [ENTER]
```

2. The cursor is in the *ML/HR* field. Use the [NEXT] key to move the cursor to the *VOL* field, and enter the container volume.

   Note: If no entry is made in the *VOL* field, the volume entered in the *ML* field becomes the default container volume.

3. Use the [NEXT] key to move the cursor to the *WT* field and enter the appropriate global body weight, if one does not already exist.

   Note: If programming in MCG/MIN is desired, enter a body weight of one (1).

4. Use the [NEXT] key to move the cursor to the *MCG/KG/MIN* field and enter the desired rate.
5. Use the [NEXT] key to move the cursor to the *MG* field, and enter the medication dose.
6. Use the [NEXT] key to move the cursor to the *ML* field. Enter the diluent volume.

   Note: The calculated delivery rate in ML/HR appears in the *ML/HR Rate* field.

7. To start the infusion, press the [ENTER] key. The following screen is displayed:

```
A:INF B:ON C:OFF D:OFF  TOTAL 12:30PM
35.0   16.9    0      0   51.9   ML/HR
```

In this example, the base screen shows Line A has been programmed as a maintenance at 35 mL/hr. Line B runs at 16.9 mL/hr in a continuous mode of operation and continues until stopped. (The mL/hr rate for Line B is the calculated result of the MCG/KG/MIN program.) The base screen only displays delivery rates in mL/hr.

8. Repeat Steps 1 through 7 for each line to operate in a continuous mode of operation.

4.2.2.2
CHANGING AN ALTERNATE UNIT OF MEASURE INFUSION

To change an alternate unit of measure infusion (MCG/KG/MIN), proceed as follows:

1. Press the [CONTINUOUS INFUSION] key for the line used. For example, when using line B, the following screen is displayed:

```
B> RATE: 16.9ML/HR      VOL:   250ML WT:   75.0KG
    3.00MCG/KG/MIN      200MG IN     250ML   [ENTER]
```

2. Since the line has previously been programmed in Alternate units of Measure, the cursor will appear in the *MCG/KG/MIN* field. Confirm that global body weight is to remain unchanged.

   Note: If programming in MCG/MIN is desired, enter a body weight of one (1).

3. Enter new MCG/KG/MIN rate.
4. Use the [NEXT] key to move the cursor to the *MG* field, and enter the medication dose.
5. Use the [NEXT] key to move the cursor to the *ML* field. Enter the diluent volume.

   Note: If no entry is made in the *Volume* field, the volume entered in the *ML* field becomes the default container volume.

   Note: The calculated delivery rate in ML/HR appears in the *ML/HR Rate* field.

6. To start the infusion, press the [ENTER] key. The following screen is displayed:

```
A:INF   B:ON   C:OFF   D:OFF   TOTAL 12:30PM
 35.0    16.9      0       0    51.9    ML/HR
```

In this example, the base screen shows Line A has been programmed as a maintenance at 35 mL/hr. Line B runs at 16.9 mL/hr in a continuous mode of operation and continues until stopped. (The mL/hr rate for Line B is the calculated result of the MCG/KG/MIN program.) The base screen only displays delivery rates in mL/hr.

4.2.2.3
CHANGING AN ALTERNATE UNIT OF MEASURE INFUSION TO ML/HR INFUSION

To change an alternate unit of measure infusion to mL/hr, proceed as follows:

1. Press the [CONTINUOUS INFUSION] key for the line used. For example, when using line B, the following screen is displayed:

```
B> RATE: 16.9ML/HR      VOL:   250ML WT:   75.0KG
    3.00MCG/KG/MIN      200MG IN     250ML   [ENTER]
```

2. Since the line was previously programmed in alternate units of measure, the cursor will appear in the *MCG/KG/MIN* field.

3. Use the [LAST] key to move the cursor to the *WT* field. Press [CLEAR ENTRY] to clear the body weight.

4. Use the [LAST] key to move the cursor to the *VOL* field. Enter the volume to be delivered.

5. Use the [LAST] key to move the cursor to the *ML/HR* field and enter the desired rate.

   Note: If the line rate chosen exceeds the combined maximum rate of the device, a message appears on the display screen. Refer to *Section 12, Specifications, Delivery Rate Range,* for specifications.

6. Press the [ENTER] key to start the infusion.

4.2.3
CHANGING THE GLOBAL BODY WEIGHT

The global body weight is established when the first weight and concentration are entered on a continuous line. Entries in both fields are required to program in MCG. The patient weight must be consistent on all lines with the exception of 1 kg to program in MCG/MIN. If another weight is entered, the following screen is displayed:

```
GLOBAL BODY WEIGHT CANNOT BE CHANGED
WHILE LINES ARE INFUSING            [ESCAPE]
```

Global body weight can be changed only while lines are stopped or while no other line is running in MCG/KG/MIN. When a new body weight is entered, the following screen is displayed:

```
BODY WT. CHANGED FROM __KG TO__KG
[ENTER] TO ACCEPT   [ESCAPE] TO REVISE
```

Pressing [ENTER] starts the line and establishes a new global body weight. The [ESCAPE] key causes the line programming screen to appear with the cursor in the global body weight field.

When subsequent lines programmed in MCG are restarted, the new global body weight appears and the mL/hr rate is adjusted based on the *MCG/KG/MIN* field and new weight.

To accept the new global body weight and adjusted delivery rate for lines programmed in MCG, press the [CONTINUOUS INFUSION] key for the respective line, and then confirm the new setting by pressing the [ENTER] key.

If a line was previously programmed with a weight of 1 kg, its body weight is retained when the global body weight is changed.

If the global body weight is changed to 1 kg, or 1 kg is changed to global body weight, the *MCG/KG/MIN* and *Concentration* fields are erased as the cursor is moved from the *WT* field. The previous mL/hr value remains unchanged.

To change from MCG programming to mL/hr programming, enter a zero in the body weight field. When [ENTER] is pressed, or as the cursor is moved from the weight field, it erases the *MCG/KG/MIN* field and *Concentration* field values. The global body weight appears upon re-entry into this screen. The previous mL/hr value remains until changed.

4.2.4
CONCURRENT FLOW

Variation in patient response may occur when delivering certain short half-life drugs if the difference of the delivery rates between the lines is large. Drugs with a short half-life (approximately six minutes or less when given intravenously) include the following:

❑ Dobutamine   ❑ Nitroglycerine

❑ Dopamine   ❑ Nitroprusside

❑ Epinephrine   ❑ Norepinephrine

❑ Esmolol   ❑ Oxytocin

❑ Isoproterenol   ❑ Procainamide

❑ Lidocaine   ❑ Trimethaphan

Note: This list is not intended to be all-inclusive of drugs with a short half-life (critical drugs). Clinicians should be familiar with the pharmacodynamics of any critical drug before administration.

The following delivery rate guidelines represent a worst-case scenario of a nitroprusside infusion in combination with one or more drugs. This example represents an unlikely extreme since it considers a 20 second half-life for nitroprusside which is widely regarded as the drug with the shortest half-life in humans (reference the British Journal of Anesthesiology). These guidelines for nitroprusside would avoid variations in patient response in such an extreme case:

❑ If nitroprusside (with a 20 second half-life) is to be infused at a rate of less than 10.0 mL/hr, the combined infusion rate of drugs on the other three lines should be no greater than five times the critical drug (nitroprusside) rate.

❑ If nitroprusside (with a 20 second half-life) is to be infused at a rate of 10.0 to 20.0 mL/hr, the combined infusion rate of drugs on the other three lines should be no greater than 10 times the critical drug (nitroprusside) rate.

❑ If nitroprusside (with a 20 second half-life) is to be infused at a rate of 20.0 mL/hr or greater, the combined infusion rate of drugs on the other three lines can be programmed at any desired rate.

This information is presented to inform clinicians of a rare situation that could be misinterpreted if they are unfamiliar with this phenomenon.

CAUTION: When infusing short half-life drugs at a low flow rate, automatic air elimination interrupts the delivery of medication to the patient. This medication interruption is dependent upon the infusion rate and may cause a change in patient parameters.

4.3

INTERMITTENT INFUSIONS

The 4000 Plus can infuse as many as three intermittent medications. These medications can only be infused on Lines B, C, and D.

To set up lines B, C, and D as intermittent infusions, proceed as follows:

1. Press the [INTERMITTENT INFUSION] key on the line used.

```
B> EACH DOSE:   0ML OVER  0:00 (HRS:MIN)
   (RATE:   0ML/HR)   Q: 0 X: 1   [ENTER]
```

2. Input the volume of EACH dose infused.

```
B> EACH DOSE:50.0ML OVER  0:00 (HRS:MIN)
   (RATE:   0ML/HR)   Q: 0 X: 1   [ENTER]
```

3. Press the [NEXT] key. Input the total time EACH dose is to be infused.

```
B> EACH DOSE:50.0ML OVER  0:20 (HRS:MIN)
   (RATE: 150ML/HR)   Q: 0 X: 1   [ENTER]
```

Note: Rate has been automatically calculated.

Note: If the line rate chosen exceeds the combined maximum rate of the device, an alert message appears on the display. Refer to *Section 12, Specifications*, for delivery rate range specifications.

```
STARTING LINE WOULD CAUSE MAXIMUM RATE
TO BE EXCEEDED - REPROGRAM        [ENTER]
```

If this is a single dose, proceed to Step 6.

4. Press the [NEXT] key. Input the dosing frequency (Q) (the number of hours between doses).

```
B> EACH DOSE:50.0ML OVER   0:20 (HRS:MIN)
   (RATE: 150ML/HR)   Q: 6 X:0     [ENTER]
```

5. Press the [NEXT] key. Input the total number of doses to be delivered (X).

```
B> EACH DOSE:50.0ML OVER  0:20 (HRS/MIN)
   (RATE: 150ML/HR)   Q: 6 X: 4    [ENTER]
```

Note: A maximum of 24 hours of intermittent infusions can be programmed for a line; i.e., the total of the dosing frequency times the number of doses cannot exceed 24.

6. Press the [ENTER] key.

```
B> CALLBACK Y/N:  NO     SYRINGE Y/N:  NO
   DILUTION Y/N:  NO                 [ENTER]
```

The *Callback Y/N, Syringe Y/N*, and *Dilution Y/N* queries (as shown in the above screen) default to NO. If NO is correct, proceed to Step 7.

To answer YES to any of the queries (*Callback Y/N, Syringe Y/N,* or *Dilution Y/N*), press the [NEXT] key to move to the desired field. Press the [YES/NO] key to change the selection. When selections are correct, proceed to Step 7.

CALLBACK: To be called to the device each time the line starts and stops, select YES to *Callback Y/N.* When called to the device, stop the alarm by pressing the [MUTE] key twice. Callback can be canceled in two ways: stop the line, re-enter the screen, and select NO to *Callback Y/N*; or use [SPECIAL FUNCTION][5] (*see Section 5.4, Special Functions,* for more information about use of special functions).

SYRINGE: If infusing directly from a syringe, select YES to *Syringe Y/N.*

Note: Failure to select YES to *Syringe Y/N* may cause an occlusion alarm due to a sticking syringe plunger.

DILUTION: To dilute a concentrated medication with the solution running on Line A, select YES to *Dilution Y/N.*

All dilutions are made with the solution on Line A. The only infusions that can be programmed for dilution are intermittent infusions (B, C, or D). The screens necessary to perform a dilution are accessible during the programming of an intermittent infusion.

If YES is selected to *Dilution Y/N,* press the [ENTER] key. The following screen is displayed:

```
DILUTION VOLUME:    0ML FROM LINE A
DILUTION RATE:    0ML/HR           [ENTER]
```

Input either a per dose dilution volume or a dilution rate. The device calculates the other value automatically, based on the dose time previously entered. (Move cursor, if necessary, by pressing the [NEXT] key.)

7. To begin infusing immediately, press the [ENTER] key.

```
B>START AT 12:30 HR
   TIME NOW 12:30 HR               [ENTER]
```

Line B has begun to infuse its dose.

```
A:OFF B:INF C:OFF D:OFF TOTAL 12:30PM
    0   150     0     0   150   ML/HR
```

Note: To cancel the dilution of a particular line, STOP and reprogram the line being diluted by changing YES to NO. Recheck the number of doses remaining in the container and the start time of the next dose.

8. Alternately, to delay the start of the line up to 23 hours, input a start time using the keypad numeric keys.

Correct AM/PM, if necessary, by pressing the [NEXT] key once, then the [AM/PM] key.

```
B>START AT  4:00 PM
   TIME NOW 12:30 PM               [ENTER]
```

Line B now shows that it is programmed to start, but does not start infusing its first dose until the time set. Press [ENTER] to return to the base screen.

```
A: ON B:PGM C:OFF D:OFF TOTAL 12:30PM
   50.0   0    0    0     50.0 ML/HR
```

Note: The line must be OFF to re-enter the intermittent programming screen and make a change for a particular line. If it is currently infusing or programmed to start in the future, the line must be stopped before re-entering the programming screen.

Note: Lines which are currently programmed for intermittent or maintenance infusions must first be stopped before programming continuous infusions over these lines.

CAUTION: When restarting an intermittent line that has been stopped, the start time and dosing information for the next dose must be reset.

Note: If two or more intermittent infusions are scheduled to start at exactly the same time, the device infuses them in alphabetical order (Line B, then C, then D). Only one intermittent infusion can be infusing at a time. The schedule of doses rolls and begins from the time the first dose is given.

Note: Near the end of an intermittent infusion with dilution, delivery of the diluent may be completed before delivery of medication is completed (or vice versa), depending on the diluent/medication ratio. When this occurs, the rate for the completed line will be displayed as zero, until the full dosage/dilution programmed is delivered.

If an intermittent line is scheduled to start during the infusion delivery time frame of another intermittent line, its scheduled start and dose schedule is delayed until the current intermittent infusion has completed. This feature maintains the proper interval between scheduled intermittent doses.

Note: To program an automatic flush before or after any intermittent infusions, refer to the [SPECIAL FUNCTION][2] description in *Section 5.4, Special Functions*, for further information.

Note: If a flush is programmed to occur after an intermittent infusion, and the intermittent line is placed on hold while the intermittent infusion is running, and then stopped using the [STOP] key for that line (or [SPECIAL FUNCTION][4]) , the flush will not start. The flush will occur if the line is active when stopped using the [STOP] key for that line.

Note: Flushes increase the interval between intermittents by the amount of time allocated for the flush.

WARNINGS

WHEN ADMINISTERING CRITICAL MEDICATIONS, MONITOR DEVICE PERFORMANCE FREQUENTLY. THE USE OF THE CALLBACK FEATURE IS RECOMMENDED FOR INTERMITTENT INFUSIONS, DILUTIONS, AND FLUSHES. CALLBACK ALLOWS CONFIRMATION OF SUCCESSFUL COMPLETION OF THE INTENDED THERAPY.

NEAR THE END OF AN INTERMITTENT INFUSION WITH DILUTION, A SMALL AMOUNT OF MEDICATION MAY BE DELIVERED WITHOUT BEING DILUTED. THE DILUTION FROM LINE A MAY COMPLETE BEFORE THE MEDICATION. MEDICATION THAT COULD POTENTIALLY CAUSE PATIENT HARM IF DELIVERED UNDILUTED (E.G., POTASSIUM CHLORIDE), SHOULD BE DILUTED APPROPRIATELY BEFORE ADMINISTRATION.

Section 5

ADDITIONAL OPERATING FEATURES

Section 5 details emptying the collection bag, battery operation, and additional operating features of the 4000 Plus, including the following:

- ❑ Stopping the device lines
- ❑ Hold and resume
- ❑ Line status
- ❑ Special functions
- ❑ Automatic air detection and elimination
- ❑ Accessing history reports

5.1

TO STOP ANY OF THE LINES

To stop any of the device lines, proceed as follows:

1. Press the [STOP] key for the line to be stopped (either currently operational or programmed to start in the future), and the following screen is displayed:

```
TO STOP LINE <A>
                         PRESS [ENTER]
```

2. Press the [ENTER] key. The line turns OFF.

   Note: To restart a stopped line with the same drugs/fluid and delivery instructions, press the appropriate [INTERMITTENT INFUSION] or [CONTINUOUS INFUSION] key for that line. Recheck rate, total volume, and programming instructions, then press the [ENTER] key.

   CAUTION: If Line A is stopped while it is flushing, only the current flush is stopped. Reprogram subsequent intermittent doses. Any continuous infusion already programmed on Line A will restart; any maintenance infusion already programmed will restart after all currently infusing intermittents have completed.

5.2

HOLD AND RESUME FUNCTIONS

The [HOLD] key is used to place one or more operating lines on hold. The [HOLD] key function delays continuous and intermittent infusions in progress, and reschedules subsequent (future) intermittent infusions. All previous intermittent line programming is unaffected. Hold may be used while taking pressure readings, changing containers, or performing other tests.

5.2.1

HOLD INDIVIDUAL LINES OR ALL LINES

To place individual lines or all lines on hold, proceed as follows:

1. Press the [HOLD] key. A *Warning* screen is displayed:

```
-WARNING-   HOLD DELAYS OR RESCHEDULES
            INFUSIONS [ESCAPE] OR PRESS [ENTER]
```

Note: To cancel the hold operation, press the [ESCAPE] key, and the base screen returns to the display.

2. Press the [ENTER] key to continue the hold operation. The following screen is displayed:

```
HOLD LINES _, _, _      (USE STATUS KEYS)
OR TO HOLD ALL LINES PRESS        [ENTER]
```

To specify the lines to be put on hold, proceed as follows:

1. Press the [LINE STATUS] key and [NEXT] key for each line to be put on hold.
2. Press the [ENTER] key.

The lines selected, if currently infusing, are placed on hold. The HLD message appears on the base screen for all lines currently infusing.

To ensure that lines which have intermittent infusions with dilution will not be affected, Line A may only be placed on hold using the Hold All Lines option.

Note: To place all lines on hold, press the [ENTER] key without specifying individual lines. All lines currently infusing are placed on hold. The HLD message appears on the base screen.

A line programmed for future intermittent infusions is displayed as PGM on the base screen. If placed on hold, its programmed start time, and the start time for subsequent intermittent infusions is delayed. Start time is rescheduled to a time which is equivalent to the original start time plus the length of time the line was on hold. A DLY (delayed) status message appears on the base screen.

Lines placed on hold which were currently infusing (continuous or intermittent) are displayed as HLD (on hold) on the base screen. These lines also have subsequent intermittent infusions (if any) rescheduled to a time which is equivalent to the original start time plus the length of time the line was on hold.

5.2.2
RESUME INFUSIONS AFTER HOLD

To resume infusions after a hold, proceed as follows:

1. Press the [RESUME] key.
2. Press the [ENTER] key.

If the device is in hold for more than two minutes, it will alarm and the following *Warning* screen is displayed:

```
—WARNING—  MUTE/HOLD TIME EXCEEDED
              PRESS  [MUTE]  OR  [RESUME]
```

Resume infusions as detailed in Steps 1 and 2, or press the [MUTE] key to silence the alarm for two additional minutes.

5.3
LINE STATUS FUNCTION

At any time during the medication infusion, the programming status on each line can be obtained by pressing the appropriate [LINE STATUS] keys.

Note: The line status screens can be accessed only when the base screen appears on the display. To go from one line status screen to another, press the [LINE STATUS] key desired. Press the [ENTER] key or the [ESCAPE] key to return to the base screen.

Sample status screens for various operating conditions follow:

```
A> MAINTENANCE RATE:50.0ML/HR
   VOL REM:  85.0ML  TIME REM: 1HR  42MIN
```
Line A operating in a maintenance mode.

```
A> FLUSHING AFTER B    TOTAL FLUSH:5.0ML
   FLUSH REM:5.0ML  TIME REM:  0HR 1MIN
```
Line A operating in flush mode. Rate: 300 mL/hr.

```
A>DILUTING LINE C  TOTAL DILUTION:50.0ML
   DIL REM:25.0ML     TIME REM:  0HR 30MIN
```
Line A operating in dilution mode.

```
A> CONTINUOUS RATE: 100ML/HR
   VOL REM: 496ML  TIME REM:   4HR 58MIN
```
Line A operating in continuous mode.

```
A>      STOPPED
VOLUME REMAINING: 200ML
```
Line A in a stopped or off condition.

```
C> CONTINUOUS RATE: 100ML/HR
    VOL REM: 496ML  TIME REM:    4HR 58MIN
```
Continuous line infusing at 100 mL/hr.

```
B>DOSE REM:35.0ML TIME REM:0HR  18MIN CB
  EACH DOSE:50.0ML  Q: 6 X: 4  DIL:    0ML
```
Intermittent line currently infusing (dose in progress) a 50 mL dose with Callback.

```
C>DOSE:  50.0ML OVER  0HR 30MIN DIL: 0ML
NEXT DOSE  3:00 PM Q: 6 DOSES REM: 3  CB
```
Intermittent line programmed to start in the future with Callback.

```
D>     OFF
```
Lines not started.

5.4

SPECIAL FUNCTIONS

The 4000 Plus incorporates a number of special functions which can only be accessed from the base screen. Press the [ESCAPE] key at any time to return the display to the base screen. To access a special function, press the [SPECIAL FUNCTION] key, followed by the appropriate special function number (use keypad numeric keys). Press the [SPECIAL FUNCTION] key and the following screen is displayed:

```
   TO SELECT SPECIAL FUNCTION
PRESS APPROPRIATE NUMBER (0-9)
```

DESCRIPTION	FUNCTION KEY
External event recording	[0]
Sets or changes the current time and date	[1] *
Programs a flush either after or before any intermittent line infusion	[2]
Cancels all subsequent flushes	[3]
Stops all lines at once	[4]
Selects or cancels Callback	[5]

Selects or changes preset values of KVO   [6] *
rate, maximum occlusion pressure, units
of temperature, enables Callback, and allows
reset of these values to manufacturer's settings.

Selects the print (format) mode   [7]
definition

Selects preprogram function   [8]*

Clears IV Flow Sheet   [9]

Prints IV Flow Sheet   [AM/PM]

Displays purge totals for all lines   [IV FLOW SHEET]

Reset IV History   [CLEAR ENTRY]
(*All lines must be OFF to select this function.)

5.4.1
DESCRIPTION OF SPECIAL FUNCTIONS

The following subsections describe each special function and procedures for their use.

[SPECIAL FUNCTION][0]
Records external events.

The 4000 Plus documents certain external events by entering them into the battery backed-up memory with a date/time stamp, then printing them with the IV History Report. The event fields accept any values entered within the allowable spaces and print out the same.

The [YES/NO] key can be used to review the events available, or the number of the desired event may be entered.

```
PROC  1     BLOOD SAMPLE DRAW - CHEMISTRY
20-MAR-92    3:29 PM     [YES/NO] [ENTER]
```

Events are as follows:

1. Blood Sample Chemistry
2. Blood Sample Hematology
3. Blood Sample Other
4. Urine Sample
5. Oral Medication Administration
6. Y-Site Injection
7. Patient Temperature (value can be entered)
8. Pulse (value can be entered)
9. Respiration (value can be entered)
10. CVP (value can be entered)
11. Blood Pressure Reading (value can be entered)

Record an event by entering a value, date, and time of actual event (if different from current date and time); then, press the [ENTER] key. The device returns to the *Procedure 0* screen to allow selection of another event. Press the [ESCAPE] key to return to the base screen.

[SPECIAL FUNCTION][1]
Sets or changes date and time.

The device maintains date and time values when powered down. The time format may be based on 12-hour AM/PM or 24-hour (military) time as the default.

Note: The time and date can only be changed when ALL lines are OFF.

To change the date and time values, proceed as follows:

1. Press the [SPECIAL FUNCTION] key, followed by numeric key [1].

```
CURRENT TIME 12:00 PM 24HR TIME Y/N?  NO
DATE(DD-MMM-YY): 21-FEB-92        [ENTER]
```

2. Input the new time using the numeric keys:

```
CURRENT TIME 10:00 PM 24HR TIME Y/N?  NO
DATE(DD-MMM-YY): 21-FEB-92        [ENTER]
```

3. To change the display to AM/PM designation, press the [NEXT] key to move the cursor, then press the [AM/PM] key.

```
CURRENT TIME 10:00 AM 24HR TIME Y/N?  NO
DATE(DD-MMM-YY): 21-FEB-92        [ENTER]
```

Note: To display military (24 hour) time, press the [NEXT] key, then press the [YES/NO] key.

4. Set the date, month, and year by pressing the appropriate numeric key. Use the [LAST] and [NEXT] keys to position the cursor in the required field.

```
CURRENT TIME 10:00 AM 24HR TIME Y/N?  NO
DATE(DD-MMM-YY): 21-FEB-92        [ENTER]
```

After setting time and date, the display screen appears as follows:

```
CURRENT TIME 11:00 AM 24HR TIME Y/N?  NO
DATE(DD-MMM-YY): 20-MAR-92        [ENTER]
```

5. Press the [ENTER] key and the base screen is displayed:

```
A:OFF  B:OFF  C:OFF  D:OFF  TOTAL  11:00AM
    0      0      0      0      0   ML/HR
```

Note: If the battery pack has become fully discharged, cycle the device. Toggle the [ON/CHARGE] switch to CHARGE, then ON. Reset the time with the [SPECIAL FUNCTION][1] keys. The internal self check of the real time clock may have been missed while the battery pack was depleted.

3. To restart any line, press the infusion type key for the line. Press the [ENTER] key to page through and review the programming screens. Make changes as each screen is reviewed.

Note: If a flush is programmed to occur after an intermittent infusion and all lines are stopped using the [SPECIAL FUNCTION] [4] key, the flush will not start.

[SPECIAL FUNCTION][5]
Selects or cancels intermittent mode CALLBACK.

The 4000 Plus has the capability to call the user to the device as a line is starting and when it stops. This feature can only be used with intermittent infusions (B, C, or D). The feature can be selected during the programming of each of those lines.

To select or cancel intermittent mode CALLBACK, proceed as follows:

1. Press the [SPECIAL FUNCTION] key, followed by numeric key [5].

```
PROGRAM CALLBACKS Y/N? B: NO C: NO D: NO
                                     [ENTER]
```

2. Press the [YES/NO] key then press the [NEXT] and [LAST] keys to either select or deselect a CALLBACK on a line-by-line basis.

3. Press the [ENTER] key to return to the base screen.

[SPECIAL FUNCTION][6]
Selects or changes preset values.

The device maintains preset values when powered down. To select or change preset values, proceed as follows:

1. Press the [SPECIAL FUNCTION] key, followed by numeric key [6]. The following screen is displayed:

```
RESET TO MANUFACTURER'S
SETTINGS Y/N?    NO    [ENTER]
```

2. To reset the KVO rate, maximum occlusion pressure, enable callbacks and set temperature units to manufacturer's factory settings, use the [YES/NO] key to toggle the desired response. If YES is selected, press [ENTER] to reset the values and return to the base screen. Otherwise, press [ENTER] and proceed to Step 3.

3. Use the numeric keys to adjust the KVO rate from 1.0 to 99.9 mL/hr.

   Note: The device delivers at the KVO rate as a result of certain alarm conditions. See *Section 6, Alarm Conditions and Displays*, for further information regarding alarms.

4. Use the [NEXT] key to position the cursor in the maximum occlusion pressure field. Maximum occlusion pressure thresholds from 1 to 12 psi can be selected in 1 psi increment.

   Note: The maximum occlusion pressure threshold is the pressure at which the device reports a patient line occlusion. See *Section 6, Alarm Conditions and Displays*, for further information regarding alarms.

```
KVO RATE: 1.0 ML/HR
MAX OCCLUSION: 10 PSI[ENTER]
```

5. The default values set at the factory are 1.0 mL/hr for KVO rate, and 10 psi for maximum occlusion pressure. Press the [ENTER] key to accept these values.

   Note: Two asterisks (**) appear in the lower right corner of the base screen to indicate that either of these default values has changed.

   The following screen is displayed:

   ```
   ENABLE ALL CALLBACKS Y/N?      NO
   TEMPERATURE UNITS  C:NO  F:YES   [ENTER]
   ```

6. Use the [YES/NO] key to toggle the desired default. Select YES to *Enable All Callbacks Y/N?* and the 4000 Plus will callback after any line stops, starts or intermittent delivery is completed.

7. Press the [NEXT] key to position the cursor over the *Temperature Units C:NO F:YES*. Use the [YES/NO] key to toggle the desired units of temperature.

8. Press [ENTER] to accept the values displayed. The values are retained in memory.

   Note: Values are preserved when the device power is cycled, and the memory is checked when the device is powered ON. If it is determined that the device memory has been reset to default values due to an extreme low battery condition or power interruption, the *Preset Values* screen is displayed.

[SPECIAL FUNCTION][7]
Selects print mode.

To select print mode, proceed as follows:

1. Press the [SPECIAL FUNCTION] key, followed by numeric key [7]. The following screen is displayed:

   ```
   IV HISTORY Y/N? NO   DEV STATUS Y/N?   YES
           PRINT MODE DEFINITION      [ENTER]
   ```

2. Use the [YES/NO] key in the *IV History* field to change the response in the *Device Status* field and specify which printed report is desired. Use of the [NEXT] and [LAST] keys is not required and has no effect. The mode selection is preserved in memory and retained when the device is powered ON.

3. Press the [ENTER] key to enter the selections.

   Note: See *Section 5.8.2, Accessing History Reports with a Printer,* for a detailed description of the Device Status and IV History Report print modes.

[SPECIAL FUNCTION][8]
Selects preprogram function.

This function can only be selected when all lines are OFF. To select a preprogram function, proceed as follows:

1. Press the [SPECIAL FUNCTION] key, followed by numeric key [8].

   ```
   PREPROGRAM FUNCTION SELECTION Y/N?   NO
   [RESUME] TO START INFUSIONS        [ENTER]
   ```

Note: This screen shows the current status of the preprogram function. If enabled, the screen default response is YES.

2. Press the [YES/NO] key to select or deselect the preprogram function. Press the [ENTER] key again to return to the base screen.

Note: When selected, all lines and subsequent programming are placed in a hold condition as each line of programming is completed. A hold condition is indicated as follows: HLD for continuous infusions, DLY for intermittent infusions, PGM for a maintenance infusion. The hold condition remains in effect without the usual two-minute warning for lines on hold. The preprogram function should only be selected when all lines, including patient line, are primed. If at least one infusion has already been programmed, the preprogram function can be deselected by stopping all lines. If no infusions have been programmed, [SPECIAL FUNCTION][8] must be used to deselect preprogram mode.

3. To initiate infusion once lines have been preprogrammed, press the [RESUME] key, then the [ENTER] key.

[SPECIAL FUNCTION][9]
Records IV Flow Sheet data into IV History and clears the IV Flow Sheet.

To record IV Flow Sheet data into IV History and clear the IV Flow Sheet, proceed as follows:

1. Press the [SPECIAL FUNCTION] key, followed by numeric key [9].

```
CLEAR IV FLOW SHEET
                              [ENTER]
```

2. To clear the IV Flow Sheet, press the [ENTER] key.

[SPECIAL FUNCTION][AM/PM]
Prints IV Flow Sheet (requires AC power).

To print the IV Flow Sheet, proceed as follows:

1. Press the [SPECIAL FUNCTION] key, followed by the [AM/PM] key.

```
PRINT IV FLOW SHEET
                              [ENTER]
```

2. To print the IV Flow Sheet, press the [ENTER] key.

[SPECIAL FUNCTION][IV FLOW SHEET]
Displays purge totals for all lines.

To display purge totals for all lines, proceed as follows:

1. Press the [SPECIAL FUNCTION] key, followed by the [IV FLOW SHEET] key.
2. Press [ENTER] to return to the base screen.

[SPECIAL FUNCTION][CLEAR ENTRY]
Resets IV History for new patient.

To reset IV History for a new patient, proceed as follows:

1. Press the [SPECIAL FUNCTION] key, followed by the [CLEAR ENTRY] key.

2. Use the [YES/NO] key to select YES. All prior IV History information is cleared. This function prevents patient IV histories being combined.

```
CLEAR IV HISTORY Y/N? NO
                         PRESS [ENTER]
```

5.5

AUTOMATIC AIR DETECTION AND ELIMINATION

The 4000 Plus air-elimination system automatically detects and eliminates small air bubbles that might appear in the cassette during operation. Upon sensing air in the cassette (approximately 120 microliters), the device automatically clears the air into the collection bag portion of the Omni-Flow Primary Set by flushing the cassette with fluid from Line A. This process causes a temporary interruption of medication delivered to the patient. The device attempts to clear the air twice. Should there be more air present than can be cleared automatically, the device alerts the user with an air-in-line alarm. See *Section 6, Alarm Conditions and Displays*, for information on this alarm condition.

Note: If air-in-line or upstream occlusion occurs on Line B, C, or D, only the affected line is placed on hold (HLD). If no other lines are infusing, Line A infuses at the selected KVO rate. If the upstream occlusion is detected on Line A, all the lines currently infusing are put on hold. Subsequent intermittent infusions change from programmed (PGM) to delayed (DLY).

Note: If air has entered the cassette from a completely empty container, the device puts the line on hold and activates an air-in-line alarm. If the hold occurs on Line A, all lines go into the hold state.

CAUTION: When infusing short half-life drugs at a low flow rate, automatic air elimination interrupts the delivery of medication to the patient. This medication interruption is dependent upon the infusion rate and may cause a change in patient parameters.

5.6

EMPTYING THE COLLECTION BAG

It is important that during device operation the collection bag be checked periodically, and emptied or changed if necessary. The collection bag should be changed or emptied if more than half full or bulging.

Should the collection bag be completely filled during pumping, the following alarm condition results:

```
POSSIBLE FULL COLLECTION BAG
OR OCCLUSION LINE A         [RESUME]
```

To empty the collection bag, proceed as follows:

1. Close the collection bag tubing clamp.

2. Carefully remove the collection bag line from the cassette by turning the luer lock connector counterclockwise.

3. Dispose of the collected fluid as prescribed by hospital policy. The collection bag may be re-used, if permitted by hospital policy, by opening the tubing clamp and gently squeezing and emptying the contents.

4. Although it is recommended that the collection bag be replaced, it may be reused. Connect the collection bag line to the cassette by turning the luer lock connector clockwise. Open the tubing clamp and hang the collection bag on the collection bag hanger.

5.7
BATTERY OPERATION

Note: Prior to placing the device in service, fully recharge the battery by connecting the device to AC power for at least 24 hours.

The 4000 Plus is intended to be used on battery power only for emergency backup (i.e., AC power failure or inadvertent disconnection from AC power) or temporary portable operation (i.e., patient moving from one location to another).

The yellow battery indicator illuminates when the device is operating on battery power. The 4000 Plus can operate on battery power for up to five hours at a cumulative delivery rate of 125 mL/hr. Approximately 30 minutes prior to battery pack depletion, a LOW BATTERY alarm sounds and a *Warning* screen is displayed:

```
-WARNING-  LOW BATTERY, PLUG POWER
CORD INTO ELECTRICAL OUTLET OR [MUTE]
```

CAUTION: If the LOW BATTERY alarm sounds, connect the device to AC power immediately.

Press the [MUTE] key to silence the audible alarm for two minutes. After two minutes, the warning screen and alarm tone return. The device should not be operated on battery power after the LOW BATTERY alarm sounds. When the battery can no longer provide the necessary power to support the device, operation ceases.

Recharging occurs any time the device is connected to AC power. It takes 24 hours to fully recharge the battery pack when device operation has stopped. The [ON/CHARGE] switch does not have to be in the ON position for the battery pack to recharge. It is strongly recommended that the 4000 Plus be connected to AC power whenever possible to ensure a fully charged battery pack is available for patient ambulation or emergency power outage conditions.

If the device is used frequently for portable operation, battery life may be significantly reduced, and battery alarms may increase. Reduced battery life also increases the battery recharge time. As a general rule, the more often the battery is discharged and recharged, the sooner it need to be replaced. Leaving the battery in a less than a fully-charged state for any period of time is a primary cause of damage. Battery damage can occur in a matter of hours, resulting in a permanent loss of battery capacity.

Note: A permanently-damaged battery cannot be recharged to full capacity.

CAUTION: Do not operate a device with an insufficiently charged or depleted battery pack. If the device should be disconnected or if power fails, an insufficiently charged battery pack may not maintain device operation. Connect the device to AC power whenever practicable to assure maximum battery capacity during patient transport or ambulation.

WARNING

REPEATED OPERATION OF DEVICE TO LOW BATTERY CONDITION AFFECTS CHARGE CAPACITY OF THE BATTERY PACK. DEEP BATTERY DISCHARGE MAY RENDER THE BATTERY PACK UNUSABLE.

5.8

ACCESSING HISTORY REPORTS

Section 5.8 provides information on accessing history reports with and without a printer.

5.8.1

ACCESSING HISTORY REPORTS WITHOUT A PRINTER

History reports may be accessed without a printer through the use of the IV Flow Sheet.

The 4000 Plus tracks the total volume infused on each line and the cumulative total. Access to these totals is obtained by pressing the [IV FLOW SHEET] key. The following screen is displayed:

```
A:LOG  B:LOG  C:LOG  D:LOG  TOTAL   EDIT?   NO
  350   75.0      0   25.0    450        [ENTER]
```

To clear the entry of a specific line or the cumulative total, proceed as follows:

1. To edit line values, press the [YES/NO] key in the *Edit* field.

2. Use the [NEXT] key to position the cursor to clear each desired line and the total.

3. Press the [CLEAR ENTRY] key. Move cursor to next line and repeat. Clearing the individual lines does not automatically clear the total; the total must be cleared separately.

4. Press the [ENTER] key.

   Note: Resetting the IV Flow Sheet in this manner does not affect the programming information and/or performance of the device.

5. Alternately, to clear all lines and the cumulative total simultaneously, press the [SPECIAL FUNCTION][9] and [ENTER] keys. This special function feature automatically encodes the IV Flow Sheet information into the IV History and then clears all values to zero.

6. After turning the device ON, select NO to the RESTORE PREVIOUS PROGRAMMING query and the IV Flow Sheet information is cleared.

   Note: To use this feature, it is important to confirm the IV Flow Sheet log has been reset to zero for all values at the beginning of any period being monitored.

5.8.2
ACCESSING HISTORY REPORTS WITH A PRINTER

The 4000 Plus can provide printed reports of infusion status and infusion history, as well as certain time/date stamped external events. There are two standard reports for local or remote printing: Device Status Report and IV History Report. See *Section 1.4.4, Printer Setup*, for detailed information on printer setup. Confirm that the printer is connected to the 4000 Plus and turned on.

5.8.2.1
DEVICE STATUS REPORT

The device status is a snapshot of the current status and the programmed events on each line at the time the printed status report is requested. The Device Status Report includes the following information:

- ❏ Line status A, B, C, and D (ON, OFF, PGM, INF, DLY)
- ❏ Dilution and flush data
- ❏ Current infusion regimen details
- ❏ Time and volume remaining in dose

To obtain a Device Status Report, proceed as follows:

1. Press [SPECIAL FUNCTION], followed by numeric key [7].

```
IV HISTORY Y/N?  NO   DEV STATUS Y/N? YES
         PRINT MODE DEFINITION        [ENTER]
```

2. Select NO for *IV History Y/N?*. *Device Status Y/N?* automatically changes to YES.

3. Press [ENTER]. The 4000 Plus returns to the base screen.

```
A:OFF  B:OFF  C:OFF  D:OFF  TOTAL  12:30PM
   0      0      0      0      0    ML/HR
```

4. Confirm that the printer is connected to the 4000 Plus, has paper supply, is turned on, and is ready to print.

5. Press the [PRINT] key and the date and time is displayed for this print. Press [ENTER] and printing begins immediately.

   Note: If printer is not ready or is not properly connected, three beeps sound. This function requires AC power.

5.8.2.2
IV HISTORY REPORT

The IV History Report retains a minimum of 48 hours of the most recent historical data. Any portion of or all the data may be printed out at any time. When the historical data buffer is full, the oldest information is deleted first. The IV History Report includes the following information:

❑ Line mode changes (off, on, intermittent infusion, hold, dilute, delay, flush, KVO)

❑ Non-infusion event documentation (blood, hematology, blood chemistry, vital signs, etc.)

❑ Date/time stamp for all events

To obtain an IV History Report, proceed as follows:

1. Press [SPECIAL FUNCTION][7].

```
IV HISTORY Y/N? NO   DEV STATUS Y/N?   YES
      PRINT MODE DEFINITION        [ENTER]
```

2. With the cursor at *IV History Y/N?*, select YES and press [ENTER].

   Note: By answering YES to *IV History Y/N?*, *Device Status Y/N?* automatically changes to NO.

3. Press the [PRINT] key and the following screen is displayed:

```
IV HISTORY   FM:20-FEB-91 10:00AM
  117 EVENTS TO:23-FEB-91 11:00PM [ENTER]
```

4. Using the [NEXT] and [LAST] keys, move the cursor to the data fields to specify the range of events to print. The [YES/NO] key is used to select the month. The data keypad is then used to enter from and/or specific date and time, or number of events to print. It is only necessary to enter data into two of the three category fields to receive a report. Press [ENTER] to display the following screen.

```
SERIAL PORT Y/N? YES      DISPLAY Y/N?   NO
IV HISTORY DESTINATION           [ENTER]
```

5. To view the IV History on the display screen, select NO to *Serial Port Y/N?* (YES to *Display Y/N?*) and press the [ENTER] key. The first two lines of the most recent IV History event are displayed on the screen.

   Note: See *Table 5-1, Scanning IV History* for detailed scanning instructions.

6. To print the IV History Report, select YES to *Serial Port Y/N?* (NO to *Display Y/N?*) and press the [ENTER] key.

   Note: The display screen backlight flashes to distinguish it from the status screen.

Press the [ESCAPE] key to return to the base screen.

Table 5-1. Scanning IV History	
Key	**Function**
[NEXT->]	Scroll up display, display next line of IV History Report
[<-LAST]	Scroll down display, display previous line of IV History Report
[AM/PM]	Skip to start of next newer event or start of current event
[YES/NO]	Skip to start of next older event

Section 6

ALARM CONDITIONS AND DISPLAYS

Certain alarms may switch fluid delivery to KVO. In these situations, fluid and/or drug therapies are interrupted. The clinical consequences vary depending upon the particulars of the infusion(s) and the patient's clinical condition. Clinicians need to be cognizant of such particulars during alarm situations.

CAUTION: For those patients who are likely to be adversely affected by unintended operations and failures, including interrupted medication or fluid delivery from the device, close supervision and provision for immediate corrective action should be provided.

CAUTION: Should excessive alarms occur, remove the device from service.

Under most alarm conditions, the device stops operation and generates an alarm for corrective action. Corrective actions may include recycling the power; reprogramming the device; recharging the battery pack; replacing the device or cassette; or other procedures described in this manual.

As discussed in previous sections, the 4000 Plus is designed to sound an audible alarm and display an appropriate message should system checks identify a problem. The audible alarm and message display alerts the healthcare professional of operational problems and permits timely intervention to place the device back into operation quickly without undue risk to the patient.

Section 6 summarizes various alarm conditions and recommended corrective actions. Section 7 is a troubleshooting guide for failures which may occur but do not necessarily result in an alarm condition.

Note: Alarm events are added to the IV History, which retains a minimum of 48 hours of the most recent historical data. To aid in alarm analysis, the IV History can be reviewed or printed (*see Section 5.8, Accessing History Reports*).

Should an alarm sound, proceed as follows:

1. Press [MUTE] to temporarily silence the audible alarm (for a maximum of two minutes). The red alarm light remains ON. After two minutes, the audible alarm is reactivated.

   Note: In the Callback mode or if a faulty cassette alarm occurs, press the [MUTE] key a second time to completely cancel the alarm.

2. Observe the display and determine the cause of the alarm. It is possible to have multiple alarm conditions occur. Each alarm type is prioritized as to severity and chronology. The current alarm visual display is overwritten, but not lost, if a subsequent higher priority alarm occurs. The preceding alarm is placed on the alarm stack based on priority and time of occurrence. The first press of the [MUTE] key silences the audible alarm; subsequently pressing the [MUTE] key returns the user to the base screen.

3. Correct the identified problem and press the [RESUME] key, followed by the [ENTER] key, to resume all infusions. Using the *resume* function, stacked alarms are displayed by priority. Higher priority alarms are displayed first. If multiple alarms of the same priority exist, such as multiple *Upstream Occlusions*, the alarms are displayed in reverse chronological order, the most recent alarm displayed first.

Each stacked alarm displayed is accompanied by an audible alarm tone of two seconds duration. This tone is used to call attention to the alarm condition, but does not require pressing the [MUTE] key to silence the audible tone.

Note: When multiple alarms occur, the alarms are presented in order of severity and chronology.

Three distinct alarm severity classifications exist. These classifications are listed in the following tables, in order of priority.

6.1
FLUID DELIVERY ALARMS

A fluid delivery alarm causes ALL lines to be put on hold (HLD). The following table details conditions which may cause fluid delivery alarms.

ALARM MESSAGE	LINES PUT ON HOLD	CORRECTIVE ACTION
CASSETTE UNLOCKED - POSSIBLE GRAVITY FLOW	ALL	Make certain the cassette lever is locked and correctly seated
DEVICE SERVICE CODE - SERVICE REQUIRED	ALL	Turn power OFF, then ON. Restore previous programming and press [RESUME], then [ENTER]. If failure repeats, remove from service
OCCLUSION IN PATIENT LINE	ALL	Check patient line for closed clamp or kinks. **Note:** Low occlusion pressure settings may cause patient line occlusion alarms when infusing fluids through microbore tubing at higher rates
FULL COLLECTION BAG OR OCCLUSION ON LINE A	ALL	Check all lines for closed clamps or kinks. Check fill capacity of collection bag. Confirm IV bag is a minimum of 17 inches above the device
AIR-IN-LINE OR OCCLUSION LINE A	ALL	Check for air bubbles in cassette. Check Line A for closed clamp or kinks. Check IV container volume on Line A. Confirm IV bag is a minimum of 17 inches above the device

6.2
PUMPING ALARMS

The following table details conditions which may cause pumping alarms.

ALARM MESSAGE	LINES PUT ON HOLD	CORRECTIVE ACTION
AIR-IN-LINE OR OCCLUSION (Lines B, C, D)	ALARM LINE ONLY	Check for air in cassette. Check alarm line for closed clamp or kinks. Check IV container volume on alarm line. Confirm IV bag is a minimum of 17 inches above the device
UNABLE TO PUMP AT PROGRAMMED RATE	LINE A REVERTS TO KVO AND LINES B, C, AND D ARE ON HOLD	Check patient line for closed clamp or kinks. Check all lines for closed clamps or kinks. Confirm IV bag is a minimum of 17 inches above the device. **Note:** Pending alarms must be cleared before reprogramming over Line A, if an error or alarm causes Line A to revert to KVO

6.3
WARNING ALARMS

The following table details conditions which may cause warning alarms.

ALARM MESSAGE	LINES PUT ON HOLD	CORRECTIVE ACTION
POSSIBLE EMPTY CONTAINER	NONE	Check bag or syringe volume
LOW BATTERY WARNING	NONE	Connect device to AC power and recharge device for a minimum of 24 hours
MUTE/HOLD TIME EXCEEDED WARNING	NONE	[RESUME] or [STOP] for all lines on hold
POSSIBLE FAULTY CASSETTE	NONE	Reprime cassette and repeat test. If alarm recurs, replace cassette and repeat cassette test
CASSETTE TEST TIMEOUT	NONE	Press [ENTER] to repeat test Press [ESCAPE] to abort test

Section 7

TROUBLESHOOTING

Certain system operating conditions do not result in audible alarms; however, if not corrected, these conditions could cause device malfunction. These operating conditions are easily identifiable and correctable.

Refer to the Troubleshooting Guide for detailed information regarding no-alarm operating symptoms, probable causes, and corrective actions.

7.1

TROUBLESHOOTING GUIDE

The following table identifies probable causes specific to overdelivery or underdelivery in italics.

SYMPTOM	PROBABLE CAUSE	CORRECTIVE ACTION
SUSPECTED OVERDELIVERY: AMOUNT OF SOLUTION IN IV CONTAINER IS LESS THAN INDICATED BY IV FLOW SHEET AND LINE STATUS SCREEN TOTAL DELIVERY IS MORE THAN PROGRAMMED ACCORDING TO IV FLOW SHEET OR LINE STATUS SCREEN **SUSPECTED UNDERDELIVERY:** AMOUNT OF SOLUTION IN IV CONTAINER IS GREATER THAN INDICATED BY IV FLOW SHEET, AND LINE STATUS SCREEN TOTAL DELIVERY IS LESS THAN PROGRAMMED ACCORDING TO IV FLOW SHEET OR LINE STATUS SCREEN	OPERATOR PROGRAMMING ERROR	REVIEW THE PROGRAM SETTINGS AS ENTERED AND CORRECT ANY ERRORS
	SUSPECTED OVERDELIVERY: *EXCESSIVE AIR-IN-LINE WHICH CAUSES EXCESSIVE DELIVERY TO THE COLLECTION BAG*	CHECK TO ENSURE THAT LUER CONNECTIONS ARE SECURE
	SUSPECTED UNDERDELIVERY: *—INCOMPATIBLE ADMINISTRATION SET USED*	USE COMPATIBLE ADMINISTRATION SET
	—IV FLOW SHEET WAS CLEARED *—DELIVERY EXCEEDS 9,999 ML, CAUSING NUMBER ROLLOVER*	CYCLE POWER: TURN POWER OFF. TURN POWER ON. RESUME PREVIOUS PROGRAMMING AND RESTART INFUSION. IF THE RESTART DOES NOT CLEAR THE PROBLEM, REMOVE 4000 PLUS FOR SERVICING
	CASSETTE INLET PORTS ARE DAMAGED AND ARE LEAKING, WHICH CAUSE EXTERNAL LEAKAGE	IF DAMAGE IS SUSPECTED TO THE CASSETTE, REPLACE CASSETTE
	FLUID SPILL ACCUMULATIONS CAUSE VALVES TO FUNCTION IMPROPERLY	IF FLUID SPILL ACCUMULATION IS A PROBABLE CAUSE OF MALFUNCTION, REPLACE DEVICE. AFTER A FLUID SPILL, REMOVE DEVICE AS SOON AS POSSIBLE TO PERMIT CLEANING
	CASSETTE OR 4000 PLUS IS DAMAGED AND THE VALVES ARE NOT FULLY OPERATIONAL	IF CASSETTE OR 4000 PLUS RELIABILITY IS SUSPECT, STOP DELIVERY AND PERFORM A CASSETTE TEST —IF CASSETTE PASSES TEST, RESTART THE 4000 PLUS AND ESTABLISH CORRECT FLOW. MONITOR ALL LINES FOR PROPER OPERATION —IF CASSETTE FAILS TEST, REPEAT TEST. IF CASSETTE FAILS AGAIN, REPLACE CASSETTE SHOULD 4000 PLUS FAIL TO PERFORM CORRECTLY, REPLACE DEVICE
	CASSETTE LOCKING LEVER IS UNLOCKED WITHOUT FIRST CLOSING OFF ALL TUBING CLAMPS FOR EACH LINE	CLOSE TUBING CLAMPS ON ALL LINES BEFORE UNLOCKING CASSETTE LOCKING LEVER. GRAVITY DELIVERY AND/OR MIXING RESULTS IF MORE THAN ONE LINE IS OPEN
	CASSETTE LOCKING LEVER IS DAMAGED	REPLACE DEVICE
	IMPROPERLY FILLED IV FLUID CONTAINER RESULTING IN INCORRECT STARTING VOLUME	REPROGRAM INFUSION AND/OR RESTART A NEW CONTAINER

SYMPTOM	PROBABLE CAUSE	CORRECTIVE ACTION
FLUID BACKUP: FLUID IS BACKING UP ONE OR MORE OF THE LINES; THE DRIP CHAMBER IS FILLING	CASSETTE LOCKING LEVER AND ALL TUBING CLAMPS ARE NOT CLOSED	CLOSE TUBING CLAMPS ON ALL LINES BEFORE UNLOCKING CASSETTE LOCKING LEVER. GRAVITY DELIVERY AND/OR MIXING RESULTS IF MORE THAN ONE LINE IS OPEN IN GRAVITY MODE
	CASSETTE OR 4000 PLUS IS DAMAGED AND DEVICE CASSETTE VALVE INTERFACE IS NOT CLOSING DURING DEVICE DELIVERY STROKE	IF DAMAGE IS SUSPECTED TO THE CASSETTE, REPLACE CASSETTE IF CASSETTE OR 4000 PLUS RELIABILITY IS SUSPECT, STOP DELIVERY AND PERFORM A CASSETTE TEST —IF CASSETTE PASSES TEST, RESTART THE 4000 PLUS AND ESTABLISH CORRECT FLOW. MONITOR ALL LINES FOR PROPER OPERATION —IF CASSETTE FAILS TEST, REPEAT TEST. IF CASSETTE FAILS AGAIN, REPLACE CASSETTE SHOULD 4000 PLUS FAIL TO PERFORM CORRECTLY, REPLACE 4000 PLUS
	FLUID SPILL ACCUMULATIONS CAUSE VALVES TO FUNCTION IMPROPERLY	IF FLUID SPILL ACCUMULATION IS A PROBABLE CAUSE OF MALFUNCTION, REPLACE DEVICE. AFTER A FLUID SPILL, REMOVE DEVICE AS SOON AS POSSIBLE TO PERMIT CLEANING
EXCESSIVE PURGING: COLLECTION BAG IS FILLING TOO QUICKLY	EXCESSIVE AIR-IN-LINE WHICH CAUSES EXCESSIVE DELIVERY TO THE COLLECTION BAG	CHECK TO ENSURE THAT LUER CONNECTIONS ARE SECURE
	CASSETTE OR 4000 PLUS IS DAMAGED AND DEVICE CASSETTE VALVE INTERFACE IS NOT CLOSING DURING DEVICE DELIVERY STROKE	IF CASSETTE OR 4000 PLUS RELIABILITY IS SUSPECT, STOP DELIVERY AND PERFORM A CASSETTE TEST —IF CASSETTE PASSES TEST, RESTART THE 4000 PLUS AND ESTABLISH CORRECT FLOW. MONITOR ALL LINES FOR PROPER OPERATION —IF CASSETTE FAILS TEST, REPEAT TEST. IF CASSETTE FAILS AGAIN, REPLACE CASSETTE SHOULD 4000 PLUS FAIL TO PERFORM CORRECTLY, REPLACE 4000 PLUS
	LUER CONNECTIONS ARE NOT PROPERLY SEATED	CHECK TO ENSURE THAT LUER CONNECTIONS ARE SECURE
	FLUID SPILL ACCUMULATIONS CAUSE VALVES TO FUNCTION IMPROPERLY	IF FLUID SPILL ACCUMULATION IS A PROBABLE CAUSE OF MALFUNCTION, REPLACE DEVICE. AFTER A FLUID SPILL, REMOVE DEVICE AS SOON AS POSSIBLE TO PERMIT CLEANING
	SECONDARY TUBING IS RESTRICTING FLUID FLOW	USE ONLY ABBOTT OMNI-FLOW SECONDARY SETS

SYMPTOM	PROBABLE CAUSE	CORRECTIVE ACTION
FAILURE TO DETECT OCCLUSION: OCCLUDED LINE IS OBSERVED AND THE OCCLUSION ALARM HAS NOT BEEN ACTIVATED	OCCLUSION ALARM DELAYED BECAUSE LOWER DELIVERY RATE REQUIRES A LONGER TIME TO REACH THE OCCLUSION ALARM POINT	RESET RATE OR RESET OCCLUSION SETTING
	OCCLUSION SETTING IS SET HIGHER THAN USER EXPECTED	RESET OCCLUSION PRESSURE TO LOWER SETTING
	CASSETTE OR 4000 PLUS IS DAMAGED. THE DEVICE CASSETTE PRESSURE TRANSDUCER IS NOT MEASURING THE TRUE PRESSURE IN THE CASSETTE, OR A VALVE IS LEAKING	IF DAMAGE IS SUSPECTED TO THE CASSETTE, REPLACE CASSETTE IF CASSETTE OR 4000 PLUS RELIABILITY IS SUSPECT, STOP DELIVERY AND PERFORM A CASSETTE TEST —IF CASSETTE PASSES TEST, RESTART THE 4000 PLUS AND ESTABLISH CORRECT FLOW. MONITOR ALL LINES FOR PROPER OPERATION —IF CASSETTE FAILS TEST, REPEAT TEST. IF CASSETTE FAILS AGAIN, REPLACE CASSETTE SHOULD 4000 PLUS FAIL TO PERFORM CORRECTLY, REPLACE DEVICE
	FLUID SPILL ACCUMULATIONS CAUSE VALVES TO FUNCTION IMPROPERLY	IF FLUID SPILL ACCUMULATION IS A PROBABLE CAUSE OF MALFUNCTION, REPLACE DEVICE. AFTER A FLUID SPILL, REMOVE 4000 PLUS AS SOON AS POSSIBLE TO PERMIT CLEANING
BATTERY PACK IS DEPLETED: WHEN OPERATING ON BATTERY, THE SCREEN GOES BLANK WITH OR WITHOUT AN ALARM	THE BATTERY PACK HAS BEEN USED PAST ITS LIMIT	CONNECT UNIT TO AC CURRENT. CYCLE POWER: TURN POWER OFF. TURN POWER ON. RESUME PREVIOUS PROGRAMMING AND RESTART INFUSION ON AC CURRENT IF DAMAGE IS SUSPECTED TO THE BATTERY PACK, REPLACE DEVICE
	BATTERY PACK IS DEFECTIVE AND CANNOT BE RECHARGED	REPLACE BATTERY PACK
	BATTERY CHARGER CIRCUIT IS DEFECTIVE	IF BATTERIES DISCHARGE FREQUENTLY, REPLACE DEVICE
NO OPERATION ON AC OR BATTERY	4000 PLUS HAS BEEN EXPOSED TO EXCESSIVE VOLTAGE; FUSE IS OPEN; POWER BOARD IS DAMAGED	REPLACE DEVICE
CASSETTE TEST FAILS	CASSETTE VALVE DIAPHRAGM IS NOT FUNCTIONING PROPERLY	OPERATE THE CASSETTE LOCKING LEVER SEVERAL TIMES, THEN REPEAT CASSETTE TEST. IF FAILURE PERSISTS, REPLACE CASSETTE. IF SECOND CASSETTE FAILS TEST, REPLACE DEVICE
	4000 PLUS IS DAMAGED AND CASSETTE INTERFACE IS INADEQUATE	REPLACE DEVICE
KEYPAD FAILS TO RESPOND	KEYPAD IS DAMAGED	REPLACE DEVICE

Section 8

CLEANING AND DISINFECTING

CAUTIONS:
To avoid mechanical or electronic damage, do not immerse the device in any fluids or cleaning solutions.

Do not operate devices that contain residue from solution spills. Sticky or gummy residue can interfere with the free movement of the valve stems and/or the pressure-sensing mechanism. If the device cannot be completely cleaned, return it for service.

Certain cleaning and sanitizing compounds may slowly degrade components made from some plastic materials. Using abrasive cleaners or cleaning solutions not recommended by Abbott Laboratories may result in product damage. Do not use compounds containing combinations of isopropyl alcohol and dimethyl benzyl ammonium chloride.

Never use sharp objects such as fingernails, paper clips, or needles to clean any part of the device.

Do not sterilize by heat, steam, ethylene oxide (ETO), or radiation.

To avoid device damage, cleaning solutions should be used only as directed in Table 8.1, Cleaning Solutions. The disinfecting properties of cleaning solutions vary; consult the manufacturer for specific information.

It is important to ensure that the cassette channel and all plungers on the right side of the device are free of any material buildup or sticky substance. This area should be checked and cleaned frequently. Do not use acetone, alcohol, or abrasive cleaners on the device. Clean the device with a soft, lint-free cloth or swab dampened with soap and water, or a general nonstaining chemical disinfectant. Refer to hospital housekeeping, central service, or infection control for further information.

Note: Not all cleaning solutions are sanitizers. Check product labeling.

Table 8-1. Cleaning Solutions		
Cleaning Solution	**Manufacturer**	**Preparation**
Vesphene ® II se	Calgon Vestal Laboratories	Per manufacturer's recommendation
Manu-Klenz ®	Calgon Vestal Laboratories	Per manufacturer's recommendation
Formula C ™	Diversey Corporation	Per manufacturer's recommendation
Super Edisonite ®	S. M. Edison Chemical Co.	Per manufacturer's recommendation
Household bleach	Various	Per hospital procedures; do not exceed one part bleach in ten parts water
LifeCare ® Germicidal Towelette (subject to availability)	Manufactured for Abbott Laboratories	Per manufacturer's recommendation; use undiluted

SYMPTOM	PROBABLE CAUSE	CORRECTIVE ACTION
UNDEFINED PROBLEM: THE SCREEN HAS AN UNREADABLE MESSAGE UNIT IS STUCK IN ONE FUNCTION, I.E., FLUSH	CASSETTE OR 4000 PLUS IS DAMAGED	IF CASSETTE OR 4000 PLUS RELIABILITY IS SUSPECT, STOP DELIVERY AND PERFORM A CASSETTE TEST —IF CASSETTE PASSES TEST, RESTART THE 4000 PLUS AND ESTABLISH CORRECT FLOW. MONITOR ALL LINES FOR PROPER OPERATION —IF CASSETTE FAILS TEST, REPEAT TEST. IF CASSETTE FAILS AGAIN, REPLACE CASSETTE SHOULD 4000 PLUS FAIL TO PERFORM CORRECTLY, REPLACE 4000 PLUS
	4000 PLUS IS SUBJECTED TO AN EXCESSIVE ELECTROMAGNETIC FIELD OR ELECTROSTATIC DISCHARGE AND THE ELECTRONICS ARE DAMAGED	CYCLE POWER: TURN POWER OFF. TURN POWER ON. RESUME PREVIOUS PROGRAMMING AND RESTART INFUSION. IF THE RESTART DOES NOT CLEAR THE PROBLEM, REMOVE THE 4000 PLUS FOR SERVICING
UNRESOLVED SYMPTOM: 4000 PLUS PROBLEM COULD NOT BE RELATED TO CAUSE AND/OR CORRECTIVE ACTION DID NOT RESOLVE SITUATION	RANDOM INTERNAL SYSTEM FAILURE	IF CASSETTE OR 4000 PLUS RELIABILITY IS SUSPECT, STOP DELIVERY AND PERFORM A CASSETTE TEST —IF CASSETTE PASSES TEST, RESTART THE 4000 PLUS AND ESTABLISH CORRECT FLOW. MONITOR ALL LINES FOR PROPER OPERATION —IF CASSETTE FAILS TEST, REPEAT TEST. IF CASSETTE FAILS AGAIN, REPLACE CASSETTE SHOULD 4000 PLUS FAIL TO PERFORM CORRECTLY, REPLACE DEVICE
PRINTER (OPTIONAL) INOPERATIVE	PRINTER NOT SET UP CORRECTLY CABLING IS DAMAGED OR PRINTER IS DAMAGED	REFER TO PRINTER OPERATING MANUAL FOR TROUBLESHOOTING AND PRODUCT SERVICING INFORMATION CONFIRM PAPER IS LOADED; POWER IS ON; AND PRINTER IS ON-LINE

Section 9

WARNINGS, CAUTIONS AND PRECAUTIONS

Section 9 is a comprehensive listing of the warnings, cautions, and precautions detailed throughout this manual.

9.1

WARNINGS

Warnings contain special safety emphasis and must be observed at all times. Failure to observe a warning is potentially life threatening.

- ❏ Product damage may occur unless proper care is exercised during the unpacking and installation process. The battery pack may not be fully charged upon receipt. Do not place the device in service if it fails the self test.

- ❏ Do not connect line to patient while priming patient line.

- ❏ Removing cassette from device without closing line clamps may result in unrestricted flow. All clamps must be closed to prevent flow to patient and/or mixing of drugs.

- ❏ Continuous infusions are rate specific and alarm when dose is complete. The infusion does not stop. The device keeps pumping at programmed rate and does not go to KVO.

- ❏ When administering critical medications, monitor device performance frequently. The use of the callback feature is recommended for intermittent infusions, dilutions, and flushes. Callback allows confirmation of successful completion of the intended therapy.

- ❏ Near the end of an intermittent infusion with dilution, a small amount of medication may be delivered without being diluted. The dilution from line A may complete before the medication. Medication that could potentially cause patient harm if delivered undiluted (e.g., potassium chloride), should be diluted appropriately before administration.

- ❏ Repeated operation of device to low battery condition affects charge capacity of the battery pack. Deep battery discharge may render the battery pack unusable.

- ❏ A possible explosion hazard exists if the device is used in the presence of flammable anesthetics.

- ❏ Arrange tubing, cords, and cables to minimize the risk of patient strangulation or entanglement.

9.2
CAUTIONS

A caution usually appears in front of a procedure or statement. It contains information that could prevent irreversible damage or hardware failure. Neglecting to pay attention to a caution could result in serious injury.

❑ If device appears to be damaged, do not operate; return damaged devices for service.

❑ When programming the device, a confirmatory response beep should be clearly audible. If the confirmatory beep is inaudible, adjust the ALARM VOLUME knob located on the back of the device. If after adjustment the beep is still inaudible, contact Abbott Laboratories Technical Support Operations.

❑ Use only Abbott Omni-Flow Primary Sets on the device. Refer to the administration package insert for complete instructions.

❑ Use only Abbott Omni-Flow Secondary Sets on the device. Refer to the administration package insert for complete instructions.

❑ The gravity flow prevention valve protects the patient from free flow if the cassette is removed from the device without closing the clamps. The gravity flow prevention valve does not prevent the mixing of drug lines. Close all clamps before removing the cassette. The gravity flow prevention valve requires pressure to open (1.5 5p 5.0 psi). The device occlusion pressure setting may require adjustment to prevent nuisance occlusion alarms.

❑ Turn the cassette locking lever slowly to lock cassette in place.

❑ It is extremely important to always perform the cassette test when inserting a new cassette.

❑ After programming the device, ensure that pumping has begun by verifying flow into the drip chamber on each appropriate fill stroke for each line in use.

❑ When restarting an intermittent line that has been stopped, the start time and dosing information for the next dose must be reset.

❑ When infusing short half-life drugs at a low flow rate, automatic air elimination interrupts the delivery of medication to the patient. This medication interruption is dependent upon the infusion rate and may cause a change in patient parameters.

❑ If Line A is stopped while it is flushing, only the current flush is stopped. Reprogram subsequent intermittent doses. Any continuous infusion already programmed on Line A will restart: any maintenance infusion already programmed on Line A will restart after all currently infusing intermittents have completed.

❑ If the LOW BATTERY alarm sounds, connect the device to AC power immediately.

❑ Do not operate a device with an insufficiently charged or depleted battery pack. If the device should be disconnected or if power fails, an insufficiently charged battery pack may not maintain device operation. Connect the device to AC power whenever practicable to assure maximum battery capacity during patient transport or ambulation.

❑ For those patients who are likely to be adversely affected by unintended operations and failures, including interrupted medication or fluid delivery from the device, close supervision and provision for immediate corrective action should be provided.

❑ Should excessive alarms continue to occur, the device should be removed for service.

❑ To avoid mechanical or electronic damage, do not immerse the device in any fluids or cleaning solutions.

❑ Do not operate devices that contain residue from solution spills. Sticky or gummy residue can interfere with the free movement of the valve stems and/or the pressure-sensing mechanism. If it cannot be completely cleaned, return the device for service.

❑ Certain cleaning and sanitizing compounds may slowly degrade components made from some plastic materials. Using abrasive cleaners or cleaning solutions not recommended by Abbott Laboratories may result in product damage. Do not use compounds containing combinations of isopropyl alcohol and dimethyl benzyl ammonium chloride.

❑ Never use sharp objects such as fingernails, paper clips, or needles to clean any part of the device.

❑ Do not sterilize by heat, steam, ethylene oxide (ETO), or radiation.

❑ To avoid device damage, cleaning solutions should be used as directed in *Table 8.1, Cleaning Solutions*. The disinfecting properties of cleaning solutions vary; consult the manufacturer for specific information.

❑ Do not attempt to disassemble device or perform repairs.

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

❑ Use of radio frequency emitting devices such as cellular telephones and 2-way radios in close proximity of this device may affect its operation.

9.3
PRECAUTIONS

Before operating the 4000 Plus, the user should become thoroughly familiar with the proper use of the device as outlined in this manual. Precautions to be observed in operation of the 4000 Plus follow.

❑ Do not attempt to disassemble or repair the device. Refer all service to qualified and trained service personnel.

❑ A service code may be displayed if the device is turned on with a cassette locked in the cassette holster. If the service code appears, remove the cassette and cycle the power. Toggle the [ON/CHARGE] switch to CHARGE, then ON, to clear the service code.

❑ Turn cassette locking lever slowly to prevent sudden release of spring mechanism.

❑ It is recommended that the cassette test safety feature be routinely performed at each cassette insertion.

❑ For normal operation, the device must be connected to a hospital grade AC outlet.

❑ If quality of AC power source is in doubt, use battery power.

❑ To prevent flow interruption, it is necessary to plug the device into AC power immediately upon low-battery alarm.

❑ If the battery pack has become fully discharged, cycle the power. Toggle the [ON/CHARGE] switch to CHARGE, then ON, and reset the time with the [SPECIAL FUNCTION][1] keys. The internal self check of the real time clock may have been missed while the battery pack was depleted.

❑ After programming the device, ensure that pumping has begun by verifying flow into the drip chamber on each fill stroke.

❑ When infusing two or more medications, the user should confirm drug compatibility and program the device accordingly.

❑ When administering critical medications, monitor device performance frequently. The use of the Callback feature is recommended for intermittent infusions, dilutions, and flushes. Callback allows confirmation of successful completion of the intended therapy.

❑ Certain undiluted drugs are chemically reactive and may adversely affect plastics. These drugs should be diluted according to manufacturer's instructions prior to infusion.

❑ Unrestricted fluid flow occurs if the cassette locking lever is unlocked while the clamps to the IV fluid containers are open. Before unlocking cassette locking lever, all clamps must be closed to prevent flow to patient and/or mixing of drugs.

❑ For continual protection against risk of fire, replace fuse with a 250 VAC 0.6 A SB unit.

❑ Do not sterilize, autoclave, or immerse this device in any manner.

❑ The 4000 Plus is an electronic device with many components. Efforts have been made to ensure the quality and long life of these components; however, any component is subject to possible failure which may cause the 4000 Plus to malfunction and alarm. Backup systems to provide intravenous therapy should be available in the event of a device malfunction or failure.

❑ The 4000 Plus contains electrical components that may be affected by exposure to RF, X-ray, or MRI emissions. Caution should be exercised when the device operates in these environments. Shield the device from X-ray by a lead apron. If exposure to RF, X-ray, or MRI emissions does occur, cycle the power by turning the device off, then back on, to allow the self test to repeat. Return the device for service if there is any concern about reliability of operation.

❑ The 4000 Plus is not to be used in a hyperbaric chamber.

❑ A solution must be placed on Line A for the device to function properly. It is recommended that a neutral solution be placed on Line A.

❑ To cancel the dilution of a particular line, press the [STOP] key and reprogram the line being diluted by changing the YES to NO. Recheck the number of doses remaining in the container and the start time of the next dose.

❑ Nonhazardous, low-level electrical potentials are commonly observed when fluids are administered using infusion devices. These potentials are well within accepted safety standards, but may create artifacts on voltage sensing equipment such as ECG, EMG and EEG machines. These artifacts vary at a rate that is associated with the infusion rate. If the monitoring machine is not operating correctly or has loose or defective connections to its sensing electrodes, these artifacts may be accentuated so as to simulate actual physiological signals. To determine if the abnormality in the monitoring equipment is caused by the infusion device instead of some other source in the environment, set the infusion device so that it is temporarily not delivering fluid. Disappearance of the abnormality indicates that it was probably caused by electronic noise generated by the infusion device. Proper setup and maintenance of the *monitoring equipment* should eliminate the artifact. Refer to the appropriate monitoring system documentation for setup and maintenance instructions.

Section 10

SERVICE AND PERFORMANCE INFORMATION

If the 4000 Plus fails to respond to the operating or troubleshooting procedures listed in this manual, and the cause cannot be determined, discontinue use of the device.

CAUTION: Do not attempt to disassemble device or perform repairs.

Service and product performance information may be obtained by contacting:

Through January 5, 1997

Abbott Laboratories
Technical Support Operations
980 Linda Vista Avenue
Mountain View, California 94043

Effective January 6, 1997

Abbott Laboratories
Technical Support Operations
775 Jarvis Drive
Morgan Hill, California 95037

Product inquiries may be telephoned to the following number:

1-800-241-4002

Contact the Abbott Laboratories Technical Service Center to obtain authorization to return the device for repair. A Returned Goods Authorization must be obtained prior to the return of any 4000 Plus.

Carefully package the device (preferably in the original packing), and ship it prepaid to the Abbott Laboratories Technical Service Center with the Returned Goods Authorization (RGA) clearly identified.

Abbott Laboratories cannot assume any responsibility for loss or damage to returned instruments while they are in transit or for the unauthorized return of any instruments.

Note: Pre-authorization must be received prior to the return of any 4000 Plus.

4000 PLUS SETS

Use only Omni-Flow Primary Sets with the 4000 Plus. Primary Omni-Flow Sets can be used as a gravity administration set with the device. Sets are sterile and for single use only.

11.1

IV ADMINISTRATION SETS

The following table lists the intravenous administration sets for use with the 4000 Plus.

LIST NO.	DESCRIPTION
11167	Primary Macro-bore Device Set, convertible piercing pin 122 inches in total length with 72 inches of tubing from cassette to patient, collection bag, roller clamp, one "Y" injection site and luer lock adaptor.
11168*	Primary Micro-bore Device Set, convertible piercing pin approximately 80 inches in total length with 30 inches of micro-bore tubing from cassette to patient, collection bag, roller clamp, one "Y" injection site and luer lock adaptor.
11169*	Primary Micro-bore Device Set, convertible piercing pin approximately 110 inches in total length with 60 inches of micro-bore tubing from cassette to patient, collection bag, roller clamp, one "Y" injection site and luer lock adaptor.
11440	LifeShield® Primary Macro-bore Device Set, convertible piercing pin, approximately 118 inches in length, collection bag, roller clamp, two prepierced reseal "Y" injection sites.
11599*	LifeShield® Primary Micro-bore Device Set, convertible piercing pin, approximately 110 inches in total length with 60 inches of micro-bore tubing from cassette to patient, collection bag, roller clamp, two prepierced reseal "Y" injection sites.
11606*	Primary Micro-bore Device Set with gravity flow prevention valve, convertible piercing pin, approximately 110 inches in total length with 60 inches of Micro-bore tubing from cassette to patient, collection bag, roller clamp, one "Y" injection site and luer lock adaptor.
11681*	LifeShield® Omni-Flow Primary I.V. Pump Set with capped luer activated valve port at lower "y" injection site. Convertible piercing pin, approximately 110 inches in total length. Sixty inches of Micro-bore tubing (approx. 2 ml priming capacity), from cassette to patient; collection bag, and roller clamp.

11139	Secondary Set, convertible piercing pin approximately 40 inches in total length, clamp, luer lock adaptor.
40521	Colorgard® Midlength Secondary IV Set, 40 inches, orange striped tubing for line identification, and luer lock adaptor.
40522	Colorgard® Midlength Secondary IV Set, 40 inches, green striped tubing for line identification, and luer lock adaptor.
40524	Colorgard® Midlength Secondary IV Set, 40 inches, purple striped tubing for line identification, and luer lock adaptor.
11137	Nonvented Soluset, 150 x 15, 40 inches, with male luer lock adaptor.
11140	Low absorption proximal nitroglycerin set, vented, 40 inches, with male luer lock adaptor.
11141	Nonvented Y-type blood set with high capacity, bucket type nylon blood filter, 40 inches, with male luer lock adaptor.
11181	Mid-length secondary set with in-line IVEX .22 micron filter, 40 inches, with male luer lock adaptor.

* When infusing highly viscous solutions (i.e., 25% Dextrose) through micro-bore sets, at normal delivery rates, an occlusion pressure of twelve (12) psi should be set for the device. A maximum backpressure of approximately 1.5 psi (approximately 75 mmHg) is allowed. Exceeding these parameters may result in occlusion alarms.

11.2

ACCESSORY SETS

LIST NO.	DESCRIPTION
1736	Low absorption, distal nitroglycerin extension set, 60 inches, with male luer lock adaptor.
40500	Collection bag. Sterile nonpyrogenic fluid path. Single use only. Do not resterilize.
40055	Colorgard three-way stopcock. Omni-Flow compatible, for use with syringes or mid-length secondary sets.
11607	Gravity flow prevention valve, for use with the Omni-Flow medication management systems. Restricts gravity flow.
11441	Vented syringe adapter.

Note: This list may be updated without notice; contact the Customer Service Department for current listings.

Section 12
SPECIFICATIONS

Pumping Mechanism:	Piston Diaphragm
Dimensions:	Height: 11 1/4 inches Width: 12 inches Depth: 7 1/2 inches
Weight:	Approximately 15 lbs
Power Requirements:	50 Watts, 120 VAC, 50/60 Hz
Fuse:	Slow blow, 0.6 A, 250 VAC
AC Line Leakage:	Less than 20 Micro Amps
Plug:	Hospital Grade (3 pin)
Case Material:	Structural Foam
Battery Type:	12 Volt, Sealed Lead Acid, Rechargeable
Battery Life:	5 hours at 125 mL/hr (Low Battery alarm activated with 30 minutes of battery life remaining)
Battery Pack Recharge Time:	24 hours with device OFF

Delivery Rate Range: 1.0 mL - 100 mL per hour in 0.1 mL/hr increments up to 100 mL then in 1 mL/hr increments from 100-700 mL/hr (600 mL/hr maximum for 3-4 lines, 500 mL/hr maximum for single line with syringe)

Container Volume and Dose Range: 1.0 mL - 3000 mL in .1 mL increments up to 100 mL then in 1 mL increments from 100 - 3000 mL

KVO Rate: Preset at 1.0 mL/hr. Selectable from 1.0 mL -99.9 mL per hour

Fluid Types: All standard IV fluids including lipid emulsions, blood and packed cells

Nurse Call Jack: 1/4 inch phono jack

External Communications: RS-232, DB-9 connector set to 9600 baud

Note: RS-232 DB-25 connector not active on some models

Alarms: Cassette Unlocked
Air In Line/Upstream Occlusion
Occlusion in Patient Line
Possible Empty Container
Low Battery Voltage
Possible Faulty Cassette
Callback Requested
Device Failure/Service Required
Unable to Pump at Programmed Rate
Possible Full Collection Bag
Transfer to Battery Operation
Communications Fault

Occlusion Pressure: Preset at 10 psi
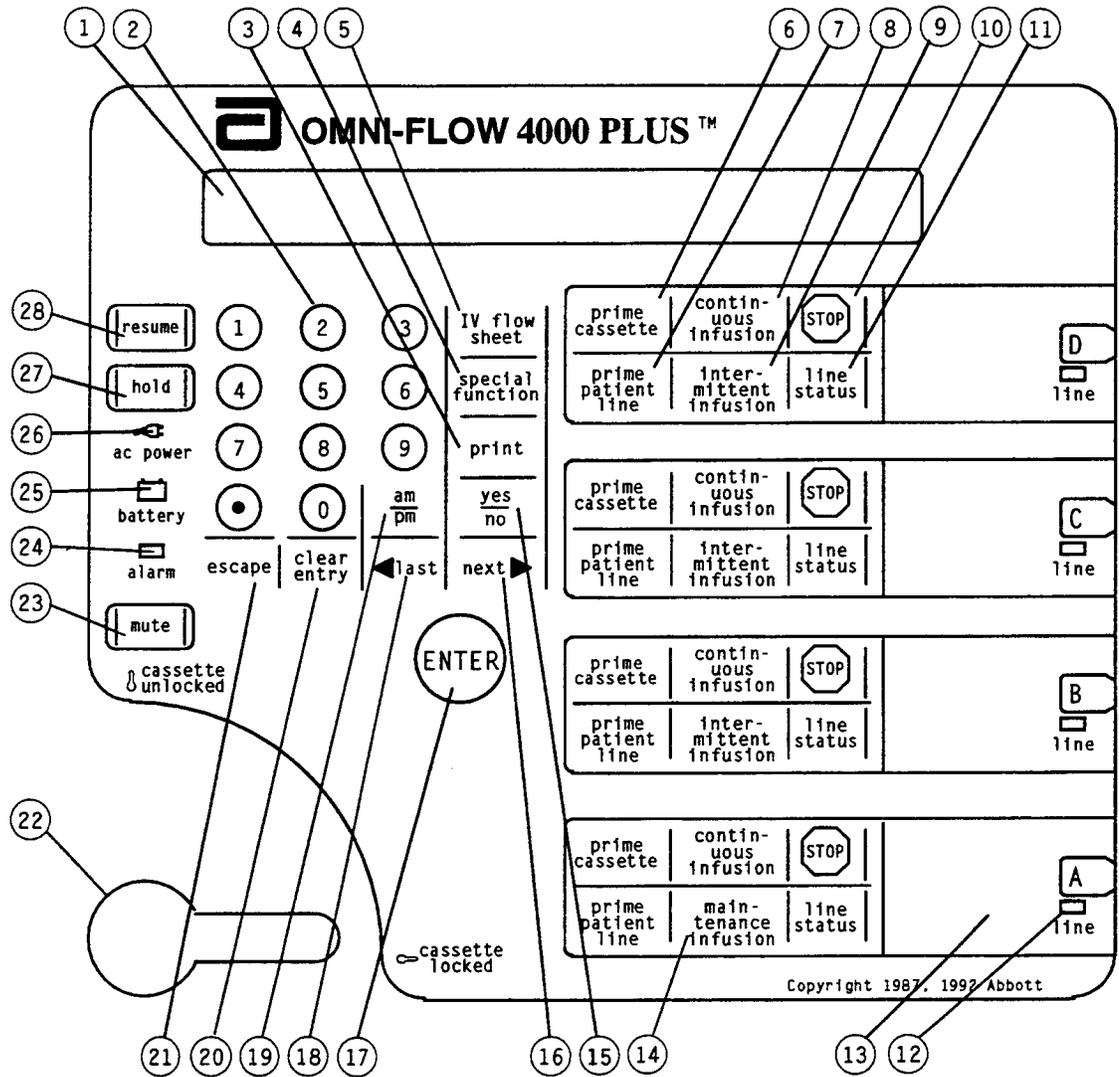User selectable from 1-12 psi

Section 13

KEYPAD DESCRIPTION

Section 13 describes the front panel of the 4000 Plus.

1. **DISPLAY SCREEN:** The 80-character, backlit, liquid crystal display provides instructions, programming information, alarm messages, and status information.

2. **[NUMERIC] KEYS 0-9:** Use these keys to input infusion rates, volumes, and times.

3. **[PRINT] KEY:** Press this key to print either the IV Flow Sheet or the IV History, selected with [SPECIAL FUNCTION][7].

4. **[SPECIAL FUNCTION] KEY:** Press this key (followed by the appropriate numeric key) to access any of the special functions.

5. **[IV FLOW SHEET] KEY:** Press this key to display a running total of the volume infused on each of the lines and the total volume for all four lines.

6. **[PRIME CASSETTE] KEY:** Press and hold this key to clear air from the upstream tubing and the cassette into the collection bag.

7. **[PRIME PATIENT LINE] KEY:** Press and hold this key to clear the patient line of all air. The patient line can be primed only when ALL lines are OFF.

8. **[CONTINUOUS INFUSION] KEY:** Press this key (on Lines A, B, C, or D) to program a continuous infusion on any line.

9. **[INTERMITTENT INFUSION] KEY:** Press this key (on Lines B, C, or D) to program an intermittent infusion of a medication.

10. **[STOP] KEY:** Press this key (on Lines A, B, C, or D), then press the [ENTER] key to stop the operation of any of the lines.

11. **[LINE STATUS] KEY:** Press this key (on Lines A, B, C, or D) to obtain the current programming information for each line. The information remains visible on the display screen until the [ENTER] or [ESCAPE] key is pressed.

12. **LINE INDICATOR LIGHTS:** On continuously when a line is programmed to start; flashing when a line is operating; off when a line is off.

13. **NOTATION AREAS:** These areas may be used to make notations concerning the medication and/or programming on each line. Clean with an alcohol swab or a soft eraser. Use a nonpermanent felt-tip pen or pencil.

14. **[MAINTENANCE INFUSION] KEY:** Press this key (on Line A only) to program a maintenance infusion on Line A. Line A stops when an intermittent infusion starts and restarts automatically when the intermittent line stops.

15. [YES/NO] KEY: Press this key to answer any of the programming questions on intermittent infusions or special functions.

16. [NEXT] KEY: Press this key to move the cursor to the next information entry point on a screen.

17. [ENTER] KEY: Press this key to enter programming information or to advance to another screen.

18. [LAST] KEY: Press this key to move the cursor back to the last information entry point on a screen.

19. [AM/PM] KEY: Press this key when changing the AM/PM time designation.

20. [CLEAR ENTRY] KEY: Press this key to clear information at the current cursor location.

21. [ESCAPE] KEY: Press this key to return to the base screen, or to return to the programming screen after certain message screens. Use the key to restart any time a particular programming sequence is unclear.

22. CASSETTE LOCKING LEVER: Move the cassette locking lever clockwise to lock the cassette in place. To unlock the cassette, lift up the cassette locking lever and turn counterclockwise.

23. [MUTE] KEY: Press this key to mute the audible alarm for a two-minute period or to cancel the Callback or Faulty Cassette Alarms.

24. ALARM LIGHT: This light illuminates when the device is in an alarm mode.

25. BATTERY LIGHT: This light illuminates when the device is disconnected from AC power, or when there is an AC power failure.

26. AC POWER LIGHT: This light illuminates when the device is connected to AC power.

27. [HOLD] KEY: Use this key to put currently operating lines on hold. Press the [HOLD] key, then press the [ENTER] key. All lines (including A) may be put on hold by pressing the [ENTER] key again. Any combination of Lines B, C, and D may be put on hold by pressing [LINE STATUS] keys. An alarm sounds after two minutes when lines are on hold.

28. [RESUME] KEY: Press this key to review pending alarms, then press the [ENTER] key to resume device operation following an alarm condition. Press the [RESUME] key, then press the [ENTER] key to resume device operation after a HOLD condition.

Figure 13-1. 4000 Plus, Front View

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