RB-82 INFUSION SYSTEM
USER'S GUIDE

Manufactured By:

RbM Services, LLC
101C Valley Court
Oak Ridge, Tennessee 37830
For
Bracco Diagnostics Inc.
107 College Road East
Princeton, NJ 08540

RbM Part Number 9300003-00
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Rev 07

Rb-82 Infusion System

Warranty

Bracco Diagnostics Inc. (BDI) warrants the Rb-82 Infusion System against any defects in materials or workmanship for a period of one year from the date of installation. BDI's warranty covers all parts, repair labor and its associated expenses for failures of the infusion system to perform to its specifications during the warranty period.

The Rb-82 Infusion System should only be serviced by authorized BDI- personnel. Any service by other than BDI-authorized personnel will void this warranty.

SAFETY SUMMARY

The "!" mark inside of a triangle as labeled on the Rb-82 Infusion System, as well as the label showing "a person looking at a book" is meant to reference the user to this User's Manual in order that the individual will understand the complete operation of the system and understand all safety precautions.

Radiation Safety

The Rb-82 Generator supplied by Bracco Diagnostics, Inc for use with the Rb-82 Infusion System emits radiation. All applicable radiation safety regulations should be followed by the user.

DANGER: EXPLOSION HAZARD. DO NOT USE IN THE PRESENCE OF FLAMMABLE ANAESTHETICS.

CAUTION!

To reduce the risk of electrical shock, do not remove. Refer servicing to qualified service personnel. Refer to Bracco Diagnostics, Inc. for servicing.

Power Source

This system can be set for 100/120/220/240V~ operation via the power entry module. For 230V~ operation use the 240V~ setting. To change this setting, ensure that the system is unplugged from its power source, and use a small flat screwdriver to remove the fuse drawer of the power entry module. Remove the small voltage selector card and rotate the card until the desired voltage is shown. Then replace the card and fuse drawer. Only use the fuse type and rating as indicated on the system label located near the power entry module. System power is 2.5A. The protective ground connection via the grounding conductor in the power cord is essential for safe operation.

Grounding the System

This system is equipped with a three-conductor ac power cord marked "Hospital Grade." The power cord must be plugged into an approved three-contact electrical outlet marked "Hospital Only" or "Hospital Grade" to assure a reliable ground. Use only a power cord that is in good condition.

Do not operate this system in an explosive atmosphere, such as, flammable gases or fumes.

The type B symbol refers to the fact that all applied parts of this system are categorized as Type B with regard to electrical shock per IEC 60601 Safety Standards for Medical Electrical Equipment.

Do Not Remove Covers or Panels

To avoid personal injury, do not remove or operate this system without all appropriate covers and panels in place. Refer all service to authorized personnel.

Fusing

To avoid fire hazard, use a fuse of the correct type, voltage rating and current rating as specified.

The following fuses and values are used in the system:

Power entry module: Use only the fuse type and rating as indicated on the system label located near the power entry module. **Internal fuses should only be replaced by qualified personnel.**

F1, Power chassis assembly (rear panel), ¼ x 1 ¼ T2, 5AL250V~ (2.5A, 250V~ time delay
F2, Power chassis assembly, ¼ x 1 ¼ T1, 5AL250V~ (1.5A, 250V~ time delay

Safety Compliance

The Cardiogen-82® Infusion System (Rubidium Rb 82 Generator) is compliant with IEC60601 and UL60601 Safety for Electronic Medical Equipment.

Service and Parts

Because of the danger of introducing additional hazards and personal injury, do not install substitute parts or perform any unauthorized modifications to the system. Refer to Bracco Diagnostics Inc. for all service and repairs to ensure that all safety features are maintained.

Preventive Maintenance

To ensure all safety features are maintained to system specifications, the system should have annual preventive maintenance service.

A preventive maintenance program is available through Bracco Diagnostics Inc.

TABLE OF CONTENTS

TABLE OF CONTENTS
(Continued)

LIST OF FIGURES

1. INTRODUCTION

The Rb-82 Infusion System is a complete system for the generation and delivery of Rb-82 from a CardioGen®-82 generator (Sr-82/Rb-82 generator) to a patient for cardiovascular nuclear medicine procedures. Rb-82 is a short-half-life (75 seconds) positron emitter and is a potassium biochemical analogue. For these reasons, Rb-82 is very useful for myocardial perfusion studies. The Rb-82 obtained from the Rb-82 Infusion System is eluted in sterile normal saline for direct injection into a patient.

Rb-82, with its 75-second half-life, offers some distinct advantages over radionuclides with longer half lives. The patient dose received for a given activity of Rb-82 is lower than the patient dose received from other, longer half-life positron emitters. Additionally, the rapid decay of Rb-82 (as well as the reduced patient exposure) permits multiple patient studies to be performed over a relatively short period of time.

2. GENERAL DESCRIPTION

2.1 Rb-82 Infusion System Overview

The Rb-82 Infusion System is a mobile, self-contained cart complete with a shield for a CardioGen®-82 generator, a waste bottle shield, a saline syringe pump, sterile tubing and valve components, a positron detector, and all of the support electronics necessary to administer controlled levels of Rb-82 activity to a patient. The system is illustrated in Figure 2.1.

The Rb-82 Infusion System delivers Rb-82 by pumping saline (which acts as an eluant) through a Sr-82/Rb-82 generator to produce the Rb-82 eluate. A diagram of the fluid system for the Rb-82 Infusion System is shown in Figure 2.2. Note that the Rb-82 generator eluate is assayed by a positron (beta) probe which consists of a plastic scintillator and a photomultiplier tube. This detector and its associated electronics are designed to reject the normally-occurring 511-keV gamma rays associated with positron annihilations while detecting the interaction of positrons in the detector's thin scintillator.

In addition to the syringe pump, the Sr-82/Rb-82 generator, and the positron detector, the fluid system contains a divergence valve for directing fluid flow in the Rb-82 Infusion System. This divergence valve (see Figure 2.2) is used to direct the low-level Rb-82 activity that initially leaves the Sr-82/Rb-82 generator to a shielded waste bottle. Once the Rb-82 activity leaving the Sr-82/Rb-82 generator reaches levels sufficient for patient injection, this valve directs the Rb-82 eluate to the patient.

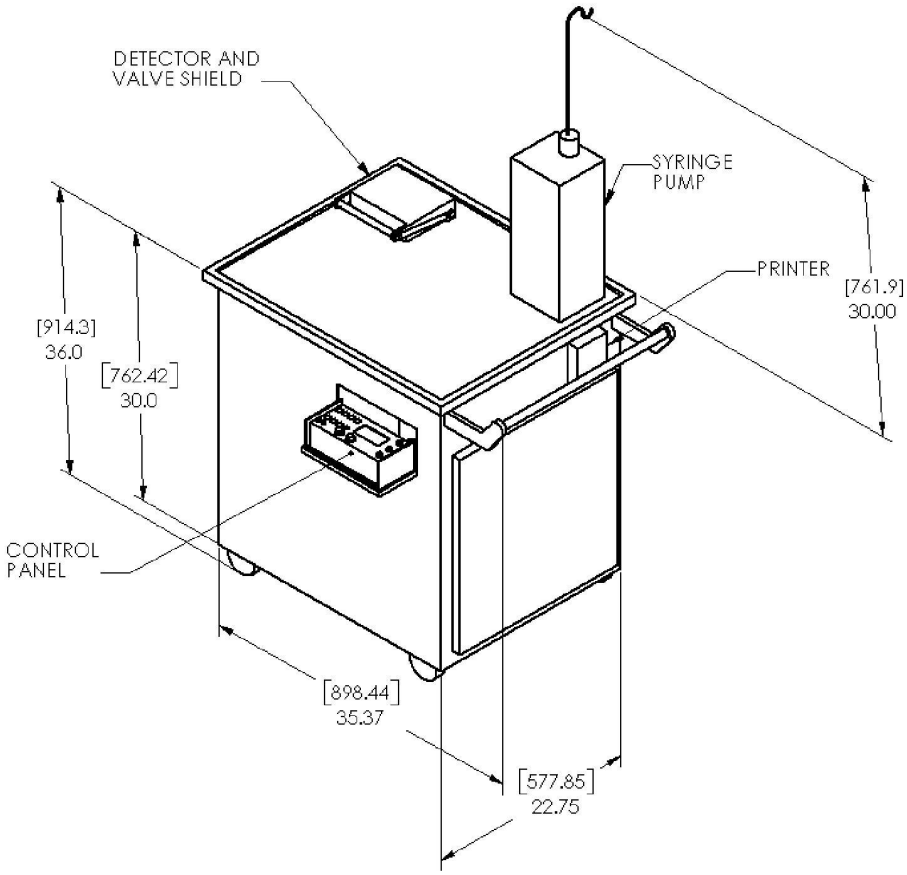


Figure 2.1 Rb-82 Infusion System Illustration

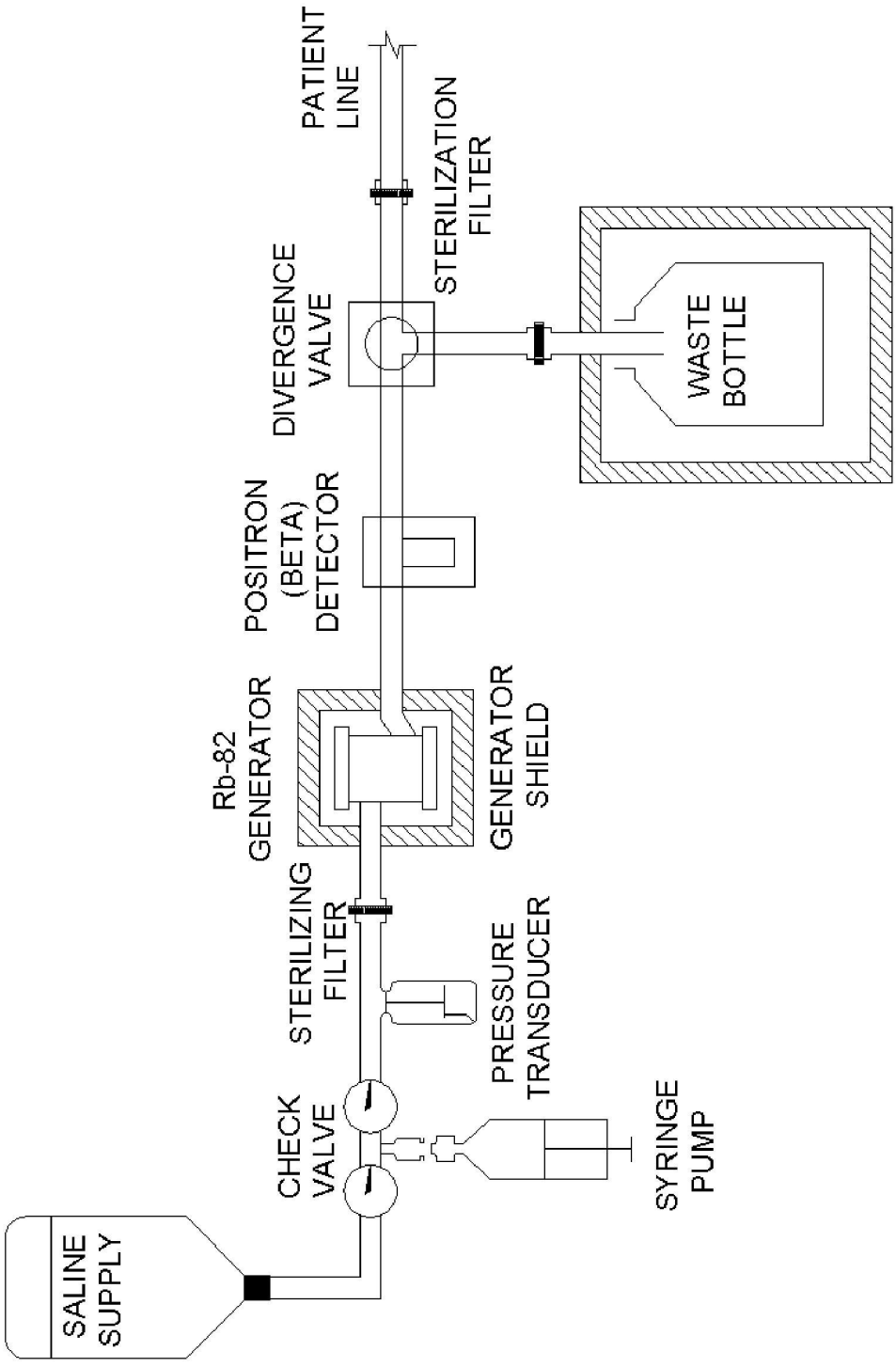


Figure 2.2 Rb-82 Infusion System Fluid-System Diagram

The Rb-82 Infusion System provides an AUTOMATIC INFUSION mode for automatic delivery of Rb-82 to a patient. Additionally, the system provides two purge modes, PURGE-GENERATOR-TO-WASTE and PURGE-GENERATOR-TO-PATIENT-LINE, for system setup and maintenance. The two purge modes are used to purge air out of the system tubing following the installation of a Sr-82/Rb-82 generator and the associated sterile tubing-component set. Detailed descriptions for all three operating modes are included in Section 4, and an overview of the AUTOMATIC INFUSION mode is contained in the following section.

2.2 Automatic Infusion Mode Overview

The AUTOMATIC INFUSION Mode is used for delivering a pre-selected quantity of Rb-82 eluate into the patient for myocardial perfusion studies.

To perform an automatic infusion operation, the operator selects the desired patient dose (the word dose is used to reflect common usage although the correct word is activity) in mCi and a flow rate of 50 ml/min in accordance with the CardioGen®-82 (Sr-82/Rb-82) package insert. Additionally, the operator selects a patient volume (ml) and an elution volume (ml) which are used as backup limits in the event of a detector failure. Note that patient volume is the volume administered to a patient, and elution volume is the total volume pumped through the generator during an infusion. Finally, the operator sets the dose-rate threshold, to 1.0 mCi/sec, which controls when the system will direct eluate (which initially is routed to the waste bottle) to the patient.

Once an automatic infusion is started, saline is pumped through the generator and the resulting eluate is routed to the waste bottle until its dose rate (mCi/sec) exceeds the pre-selected dose-rate threshold. It typically takes 10 to 18 seconds before eluate leaving the generator becomes sufficiently concentrated to reach the required dose-rate threshold of 1.0 mCi/sec. Once the dose-rate threshold is exceeded, the Rb-82 eluate is directed to the patient line and both the patient dose and patient volume are measured and displayed. The infusion continues and stops on whichever limit is reached first: patient dose, patient volume, or elution volume. As mentioned, the normal stopping limit is the patient dose.

Once the infusion is complete, the pump stops and the generator eluate is directed back to the waste bottle to vent any residual generator pressure. At this time, a complete report of the Rb-82 infusion is printed on the system printer and this same data is echoed out a RS-232C serial data port. The RS-232C port can be connected to the customer's computer for analysis or storage of Rb-82 infusion data.

3. GENERAL INFORMATION

3.1 General Precautions

- Use the Rb-82 Infusion System only with a CardioGen®-82 generator (Sr-82/Rb-82 generator) and the sterile tubing set provided with the generator.

- **For locations where the generator and infusion system remain in one location (i.e., hospital, physician office, or imaging center): The tubing set connected to the generator and the infusion system is to remain in place until a new generator is installed. A new tubing set will be provided with each new generator.**

  For locations where the generator and infusion system are transported from one location to a different location or Daily Use Customers (i.e., generator and infusion system are used and stored at a facility for one or more consecutive days and the following day the generator and infusion system are used by a different facility), the tubing set connected to the generator and the infusion system must be replaced. Prior to transporting the generator and infusion system to a different location, all tubing must be removed and discarded in accord with approved radiation safety and waste disposal procedures. Under no circumstances should the tubing used at one facility be used at a different facility. New tubing sets are available from Bracco Diagnostics, Inc., or the provider of the Daily Use program.

- Since the eluate obtained from the Sr-82/Rb-82 generator may be intended for intravenous administration to a human patient, aseptic technique must be strictly observed in all handling of the eluate and tubing set. In addition, care should be taken to ensure that the Rb-82 Infusion System is purged of air prior to each patient infusion.

- As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient consistent with proper patient management. Additionally, care should be taken to minimize the radiation exposure to attending personnel.

- Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides.

- To limit the exposure of personnel, the CardioGen®-82 generator (Sr-82/Rb-82 generator) must be installed in the lead shield provided in the Rb-82 Infusion System as a radiation safety precaution.

- Due to the short half-life of Rb-82, a time period of 10 minutes is sufficient to permit Rb-82 to decay before handling Rb-82 eluate. Hospital personnel should wait at least 10 minutes before handling Rb-82 eluate. Gloves should be worn when handling any of the generator, tubing, or waste bottle components.

- All components that may contain residual radioactivity must be stored and disposed of in accordance with the facility's radioactive materials license.

- Turn the power off the system and disconnect the power cord prior to cleaning the system. The system may be cleaned by using a cloth which has been dampened with alcohol. Do not use liquid cleaners on or near the power entry module or the display control panel.

3.2 System Specifications

OPERATING MODES: AUTOMATIC INFUSION
PURGE-GENERATOR-TO-WASTE
PURGE-GENERATOR-TO-PATIENT-LINE

AUTOMATIC INFUSION MODE:

Preset Elution Volume:	0-99 ml in 1 ml increments
Preset Patient Volume:	0-99 ml in 1 ml increments
Preset Patient Dose:	0-99 mCi in 1 mCi increments
Preset Dose Rate Threshold:	0.0 - 9.9 mCi/sec in 0.1 mCi/sec increments. The proper preset dose rate threshold for Rb-82 is 1.0 mCi/sec.
Flow Rate:	20, 35, 50, 65, and 80 ml/min (Flow rate for Rb-82 = 50 ml/min)
Rb-82 Delivery Accuracy:	(Generator Sr-82 Activity 30-120 mCi, Flow Rate 50 ml/min)

Generator Activity	Accuracy
>40 mCi:	+/- 10%
20 - 40 mCi:	+/- 10%
10 - 20 mCi:	+/- 15%
5 - 10 mCi:	+/- 20%

Patient Volume Delivery Accuracy: +/- 2 ml

Automatic Infusion Report:	The system printer prepares a detailed report following every automatic infusion. This report lists all system settings, measured infusion volumes and activities, and a history (in one-second intervals) of activity seen at the detector and patient port. Additionally, any error conditions are listed if an automatic infusion is unable to start or is terminated due to an error condition. Data identical to the system printout is provided on the RS-232C port.

SPECIAL SYSTEM MONITORING FUNCTIONS:

System pressure:	90 psig (+/- 5 psig) pressure limit sensor is provided along with a second, redundant pressure limit of 100 psig (+/- 10 psig) provided by the syringe pump.
Valve operation:	Valve position is continuously monitored. Additionally, the valve must transition between waste and patient positions in less than 2 seconds or an error will be detected.
Pump limit:	Syringe pump limits, both refill (nom. 128 ml) and pump limits (nom. 15 ml) are monitored.
Valve shield:	The valve shield is monitored to detect if it is open. Additionally, the valve shield remains locked for any purge or infusion operation and does not unlock until the detector measures a count rate less than 50 cps.
Monitoring function	Automatic infusion operations will not start if operation shield-open error is detected. Automatic infusion operations are terminated (if in progress) for all of the preceding conditions. Purge-generator-to-waste and purge-generator-to-patient-line operations will not start and will be terminated if in progress if a high-pressure error, valve

error, pump limit, or shield-open error is detected.

SYRINGE PUMP CAPACITY: Mechanically limited to ~130ml full capacity.

RS-232C PORT CHARACTERISTICS:

Description: The RS-232C port echoes out infusion report printout data for access by a remote computer. Although this port has a receive line, the Rb-82 Infusion System does not recognize incoming data.

RS-232C Port Interface Details:

Signal	DB25P Connector Pin
TX (transmit data)	(pin 2)
RX (receive data)	(pin 3) This signal is not used.
GND (signal ground)	(pin 7)

Data Format	Baud Rate
1 Start bit 1 Stop bit 8 Data bits No Parity	2400 bit/sec

SYSTEM POWER REQUIREMENTS:

System power is 2.5A max. This system can be set for 100/120/220/240V~ operation via the power entry module. To change this setting, ensure that the system is unplugged from its power source, and use a small flat screwdriver to remove the fuse drawer of the power entry module. Remove the small voltage selector card and rotate the card until the desired voltage is shown. Then replace the card and fuse drawer. Use only the fuse type and rating as indicated on the system label located near the power entry module.

System Weight:	650 lbs.
System Size:	See Fig. 2.1 on page 2
Shipping Weight:	875 lbs.
Shipping Size:	48"H x 31"W x 41"L

ENVIRONMENTAL CONDITIONS FOR OPERATION, TRANSPORTING AND STORAGE OF SYSTEM:

The system should be operated in a normal office environment, but can be safely operated, stored, and transported between temperatures of 40°F (4.4°C) - 110°F (43.3°C). This is primarily due to characteristics of the detector. Although no known problems have been encountered with storage and transport of the system below or above these temperatures, it would be best not to subject it to extreme high or low temperatures beyond this point for an extended period. Avoid condensing humidity conditions.

CLEANING:

Before performing any cleaning operations, turn off the system and unplug the power cord. The System Display Control Panel should only be cleaned with an alcohol-dampened cloth. Be very careful when wiping the mylar windows that cover the seven segment LED displays, so as not to puncture them. The top and sides of the system can be cleaned with normal household cleaners applied with a damp cloth. Use a sample test area on the plastic top of the system to verify the cleaner will not stain the plastic. **The interior of the system should only be cleaned by trained and qualified radiation and safety personnel. Observe all safety precautions noted in this manual.**

4.0 SYSTEM OPERATION

4.1 Introduction

This section of the Rb-82 Infusion System manual describes the display/control panel features and operating modes of the infusion system. The user, however, must refer to the specific operating procedures contained in Section 5 of this manual and to medical protocols for the CardioGen®-82 (Sr-82/Rb-82 generator) when performing system preparations, calibrations, breakthrough measurements, and infusions.

4.2 The Display/Control Panel

All displays and controls for the Rb-82 Infusion System, except for the CALIBRATION FACTOR switch, are located on the Display/Control Panel which is illustrated in Figure 4.1. This Figure should be referred to during the following discussion of the Display/Control Panel features.

4.2.1 POWER ON Switch

This momentary-contact, push-button-indicator switch is used to apply power to the infusion system. When the system is powered, this switch glows green. If AC power to the infusion system is interrupted, it is necessary to depress this switch to repower the system. When the system is turned off by the Power Off Abort switch, the system can only be turned back on by rotating the Power Off Abort switch clock-wise, until the Power Off Abort switch "resets" by popping up. If this Power Off Abort switch is not "reset," the Start switch is rendered disabled.

4.2.2 POWER OFF/ABORT Switch

Depressing this switch turns off the system. Please note that this switch does not turn off AC power to the system, and as long as the system's power cord is plugged into a live AC electrical outlet, there will be AC power to the system as indicated by the lighted AC Main LED indicator on the Display Control Panel. This switch also works as an emergency cutoff to stop the system in case of emergencies. In order to turn the system back on, the switch must be rotated clock-wise, until the switch "resets" by popping up. If this Power Off Abort switch is not "reset" the Start switch is rendered disabled.

4.2.3 MODE Switch

This rotary switch is used to select the operating mode of the infusion system. The modes available are

AUTOMATIC INFUSION,
PURGE-GENERATOR-TO-WASTE, and
PURGE-GENERATOR-TO-PATIENT-LINE.

4.2.4 MODE Display

The mode display is an illuminated flow diagram showing the routing of saline in the infusion system. The mode display shows the saline flow path for all operating modes of the infusion system.

Figure 4.1 Illustration of the Display/Control Panel

4.2.5 INJECT START/STOP Switch

This momentary-contact, indicator-push-button switch is used to start an automatic infusion. This switch glows red during an infusion and is extinguished once the infusion pumping operation is complete. This switch may be depressed during an infusion to stop the infusion.

4.2.6 PURGE Switch

This momentary-contact, push-button switch is used to purge the infusion system in the PURGE-GENERATOR-TO-WASTE or PURGE-GENERATOR-TO-PATIENT-LINE mode. It is necessary to continuously depress this switch during a purge operation.

4.2.7 REFILL Switch

This momentary-contact, push-button switch is used to refill the saline pump. To start a refill operation, depress the REFILL switch once. The pump will begin refilling and will stop when either the pump limit is reached or the operator depresses the REFILL switch a second time.

4.2.8 FLOW RATE Switch

This rotary switch is used to select the saline-pump flow rate used during infusion and purge operations. The available flow rates are

20 ml/min,
35 ml/min,
50 ml/min, (50 ml/min must be used for the CardioGen®-82, Sr-82/Rb-82 generator)
65 ml/min, and
80 ml/min.

4.2.9 ELUTION VOLUME Display and Limit Switch

This display and limit switch combination is used to display the total generator elution volume during an infusion operation and to set the elution volume limit for the infusion. Note that the ELUTION VOLUME display provides a running display of generator elution volume during an infusion and holds the total elution volume after the infusion operation is completed. Both the ELUTION VOLUME display and limit switch operate over the range of 0-99 ml.

4.2.10 PATIENT VOLUME Display and Limit Switch

This display and limit switch combination is used to display the patient elution volume during an infusion operation and to set the patient volume limit for the infusion. Note that the PATIENT VOLUME display provides a running display of patient elution volume during an infusion and holds the total patient elution volume after the infusion operation is completed. Both the PATIENT VOLUME display and limit switch operate over the range of 0-99 ml.

4.2.11 PATIENT DOSE Display and Limit Switch

This display and limit switch is used to display the patient dose during an infusion operation and to set the patient dose limit for the infusion. Note that the PATIENT DOSE display provides a running display of patient dose during an infusion and holds the total patient dose after the infusion operation is completed. Both the PATIENT DOSE display and limit switch operate over the range of 0-99 mCi.

4.2.12 DOSE RATE Display and Threshold Switch

This display and threshold switch combination is used to display the infusion-system dose rate during an infusion operation and to set the dose-rate threshold for the infusion. Both the DOSE RATE display and threshold switch operate over the range of 0.0-9.9 mCi/sec, where mCi/sec represents the amount of activity produced by the infusion system in a one-second time interval. For Rb-82 the proper setting is 1.0 mCi/sec.

4.2.13 PUMP LIMIT Indicator Light

This light glows yellow whenever the saline pump is at either the refill limit (pump fully extended) or at the pump limit (pump fully contracted). No infusion or purge operation can be started with the pump at the pump limit position. Additionally, if the pump reaches the pump limit position during an infusion or purge operation, that operation will be terminated automatically.

4.2.14 HIGH PRESSURE Indicator Light

This light glows red whenever the generator inlet pressure exceeds the preset high-pressure threshold. Infusion and purge operations cannot be started if there is a high-pressure error. Additionally, if a high-pressure error occurs during an infusion or purge operation, that operation will be terminated automatically.

4.2.15 VALVE FAILURE Indicator Light

This light glows red whenever the system has detected a valve error. The system detects valve positioning errors by measuring the time required for the valve to move from one position to the next position. Additionally, the system continuously tests the valve to ensure that it is in the correct position. Infusion and purge operations cannot be started if there is a valve error. Additionally, if a valve error occurs during an infusion or purge operation, that operation will be terminated automatically.

4.2.16 AC MAIN Indicator Light

This light glows green as long as the system's power cord is plugged into a live AC electrical outlet. This light indicates there is live AC power inside the system, even though the system is not "powered on."

4.3 The CALIBRATION FACTOR Switch

The CALIBRATION FACTOR switch contains a four-digit number which controls the calibration of Rb-82 delivery. This switch is adjusted only during calibration and is located away from the Display/Control panel to prevent accidental changing of its setting. The CALIBRATION FACTOR switch is located on the processing-electronics chassis front panel.

The CALIBRATION FACTOR switch is set by depressing the small buttons associated with each digit using a pointed object such as a writing pen.

4.4 System Activation

Depressing the POWER ON switch activates the infusion system and causes this switch to glow green indicating that the infusion system is powered. Note that the POWER ON switch is used in a power latching-relay system to prevent the infusion system from restarting following an AC power failure. If AC power to the infusion system is interrupted, or if the POWER OFF/ABORT switch is depressed, it is necessary to depress the POWER ON switch again to reactivate the infusion system.

Depressing the POWER OFF/ABORT switch shuts the infusion system off. This switch allows the operator to easily shut the system off during normal shutdown or in the event a problem is experienced.

4.5 Pump Refill Operation

The saline pump must be filled with saline solution before the Rb-82 Infusion System can be purged of air, or before an infusion can be performed. In order to refill the saline pump, the REFILL switch is depressed once and the pump will begin refilling. The refill operation can be stopped by the operator by depressing the REFILL switch a second time or by letting the pump reach its refill limit. It is, of course, important to ensure that the saline supply valve is open to permit the pump to accept saline from the saline supply.

4.6 Purge Modes

The Rb-82 Infusion System must be purged of air before an infusion can be performed. There are two purge modes used for purging the system: PURGE-GENERATOR-TO-WASTE, and PURGE-GENERATOR-TO-PATIENT-LINE. In the PURGE-GENERATOR-TO-WASTE mode, saline is pumped through the generator and is routed to the waste bottle by the automatic flow-control valve. In the PURGE-GENERATOR-TO-PATIENT-LINE mode, saline is also pumped through the generator, but is routed to the patient line instead of the waste bottle. The PURGE-GENERATOR-TO-PATIENT-LINE mode should not be used to purge the infusion system into a patient. Instead this mode is used to clear the patient line using a collection bottle to collect the purged eluate.

The operator activates the PURGE-GENERATOR-TO-WASTE mode by selecting PURGE-GENERATOR-TO-WASTE on the MODE switch and by continuously depressing the PURGE switch. The mode display on the Display/Control panel will show the routing of the saline solution through the Rb-82 Infusion System during the purge operation. The PURGE-

GENERATOR-TO-WASTE operation is summarized in Figure 4.2(a) which includes an illustration of the Display/Control mode display.

The operator activates the PURGE-GENERATOR-TO-PATIENT-LINE mode by selecting PURGE-GENERATOR-TO-PATIENT-LINE on the MODE switch and by continuously depressing the PURGE switch. The mode display on the Display/Control panel will show the routing of the saline solution through the Rb-82 Infusion System during the purge operation. The PURGE-GENERATOR-TO-PATIENT-LINE operation is summarized in Figure 4.2(b) which includes an illustration of the Display/Control mode display.

4.7 Automatic Infusion Mode

4.7.1 Description

The AUTOMATIC INFUSION mode is the normal infusion system mode for delivering a fixed dose of Rb-82 eluate to the patient. The operator initiates an automatic infusion by selecting AUTOMATIC INFUSION on the MODE switch and then depressing the INJECT START/STOP push-button switch. The infusion system then begins pumping saline through the generator at the flow rate selected by the FLOW RATE switch and the running generator elution volume is displayed on the ELUTION VOLUME display. The radioactive saline eluate from the generator is first directed to the waste bottle.

However, once the measured infusion dose rate (mCi/sec of infused activity as measured at the detector) exceeds the preset dose rate threshold (selected by the DOSE RATE THRESHOLD switch), the radioactive saline eluate from the generator is directed to the patient line. At this time, both the patient dose and the patient volume are measured and displayed on the PATIENT DOSE and PATIENT VOLUME displays.

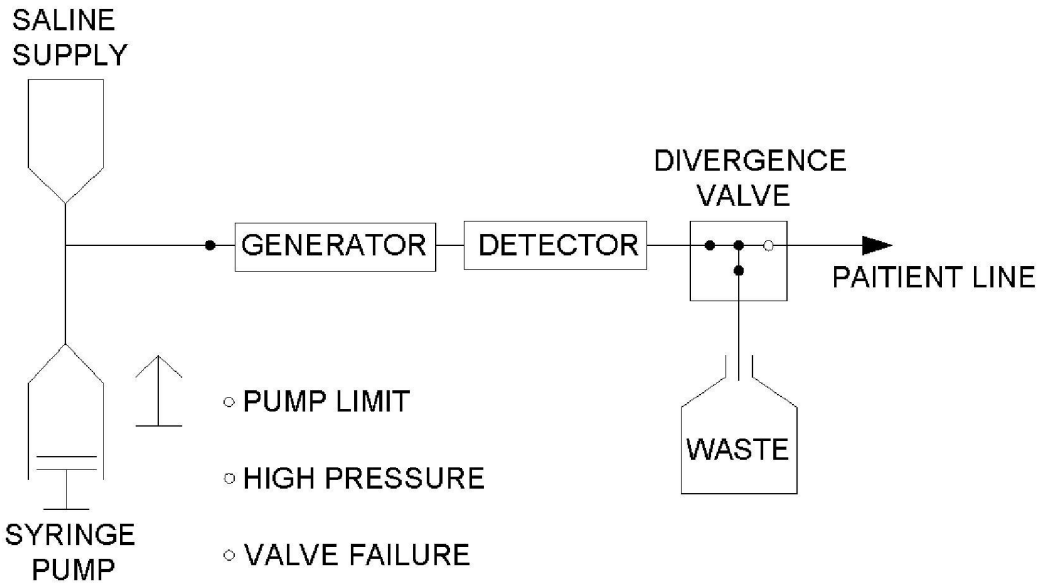
The radioactive eluate continues to be infused into the patient line until either the patient-dose limit, patient-volume limit, or elution-volume limit is reached. These limits are selected by controls on the Display/Control Panel. Once one of the preset infusion limits is reached, the saline pump is stopped and the INJECT START/STOP switch stops glowing red to indicate the conclusion of the infusion. At this time, the generator outlet is directed back to the waste bottle and the system printer begins printing out a report of the infusion. The infusion report includes setup parameters, measured infusion data, and a history of activity passing the detector port and the patient port in one-second time intervals. The printout data is also sent out the RS-232C port for access by a remote computer.

Note that reaching any of three independent parameter limits (the patient-dose limit, the patient-volume limit, or the elution-volume limit) will stop an infusion. Normally, the infusion is stopped when the patient-dose limit is reached. This is because the patient-volume and elution-volume limits are used as backup limits to stop an infusion should a detector failure occur. In normal operation, the patient-dose limit is selected and the patient-volume and elution-volume limits are set to values that slightly exceed the required volumes for the desired patient dose.

The AUTOMATIC INFUSION mode is summarized in Figure 4.3. Note that the Figure shows the Display/Control Panel mode display for the activity buildup cycle, the patient infusion cycle, and the infusion end cycle. Additionally, each cycle is described briefly in the Figure.

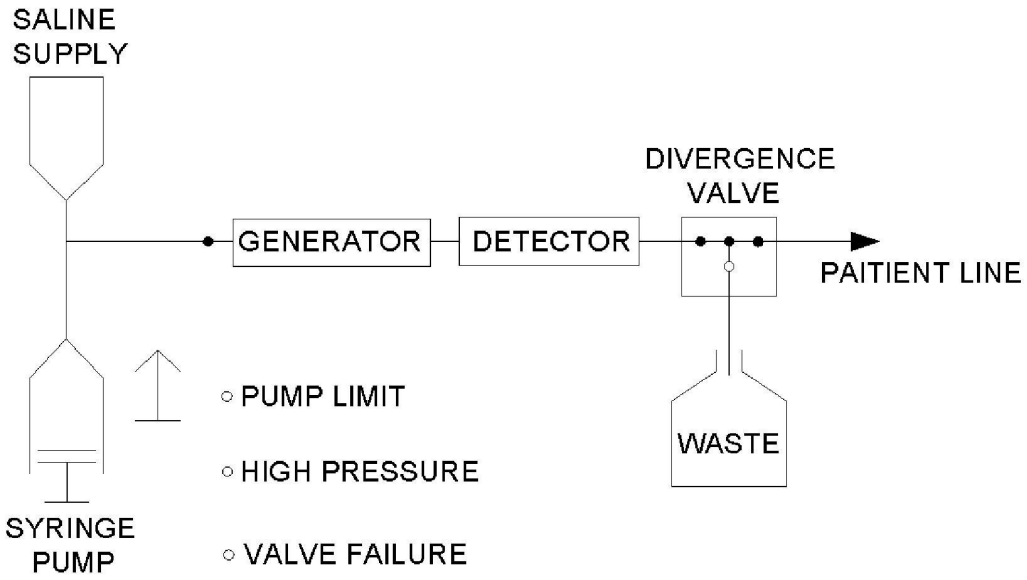
4.7.2 Report Printout

At the end of an infusion operation, a complete report of the Rb-82 infusion is printed on the system printer and this same data is echoed out the RS-232C serial data port. The RS-232C port can be connected to the customer's computer for analysis or storage of Rb-82 infusion data.



- Purge switch is depressed continuously during purge operation
- Generator eluate is purged into waste bottle.

(A) Purge Generator to Waste Mode



- Purge switch is depressed continuously during purge operation
- Generator eluate is purged into patient line.

(B) Purge Generator to Patient Line Mode

Figure 4.2 Summary of the PURGE Operations