LIFE FROM INSIDE

CardioGen-82®
INFUSION SYSTEM USER'S GUIDE

CE 0086

Manufactured By:

RbM Services, LLC

For
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RbM Part Number 9300003-00
July 3, 2007 – ECN 07-0703
Rev 11

CardioGen-82 Infusion System
Limited Warranty

ACIST Medical Systems, Inc. ("ACIST") warrants the CardioGen-82 Infusion System (the "Infusion System") against any defects in materials and workmanship for a period of one year from the date of installation. ACIST'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, subject to the following exceptions: (i) misuse, (ii) abuse, or (iii) alteration (without ACIST's express written consent).

Any part or component of the Infusion System that is judged to be defective by ACIST in material or workmanship during the warranty period will be repaired or replaced by ACIST at its sole option and its expense. Remedies available under this warranty are limited to repair or replacement of malfunctioning parts, system replacement, or refund of the purchase price with the specific remedy subject to election by ACIST in its sole judgment.

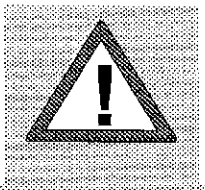
Application for a warranty remedy must be made to ACIST within (30) days of the apparent malfunction.

EXCEPT AS EXPRESSLY PROVIDED HEREIN, ACIST MAKES NO ADDITIONAL WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, WITH RESPECT TO THE INFUSION SYSTEM, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR USE OR PURPOSE.

ACIST SHALL UNDER NO CIRCUMSTANCES BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL OR EXEMPLARY DAMAGES OF ANY NATURE, WHATSOEVER, INCLUDING BUT NOT LIMITED TO, COMMERCIAL LOSS FROM ANY CAUSE, BUSINESS INTERRUPTION OF ANY NATURE, LOSS OF PROFITS OR REVENUE, REAL OR PERCEIVED LOSS OF USE, LOSS ARISING FROM A DEFECT IN DESIGN, MATERIAL AND/OR MANUFACTURE OR WORKMANSHIP, OR ARISING OUT OF THE PURCHASER'S FAILURE TO COMPLY WITH ALL OR ANY OF THE PROVISIONS OF THE INFUSION SYSTEM MANUAL AND/OR THE FAILURE OF THE INFUSION SYSTEM TO PERFORM AS SPECIFIED, EVEN IF ACIST SHALL HAVE BEEN ADVISED TO THE POSSIBILITY OF SUCH DAMAGES.

The Infusion System should only be serviced by personnel authorized by ACIST. Any service other than ACIST-authorized personnel will void this warranty.
For product complaints or questions regarding the operation and service of the system, please contact your assigned Bracco Representative.

SAFETY SUMMARY



The "!" mark inside of a triangle as labeled on the CardioGen-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 CardioGen-82 Generator supplied by Bracco Diagnostics, Inc for use with the CardioGen-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 ACIST Medical Systems, Inc. User Manual for servicing.

Power Source

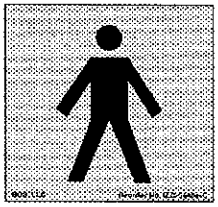
This system can be set for 100/120/220/240V~ operation via the power entry module. For 230V~ operation use the 240V~ setting. To change this setting, ensure that the system is unplugged from its power source, and use a small flat screwdriver to remove the fuse drawer of the power entry module. Remove 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.

The "Hospital Grade" detachable 10 foot power cord, supplied with this system, P/N 4040010-00, is recommended. The use of a cable other than the cable specified may result in increased emissions and decreased immunity of the CardioGen-82 Infusion System.

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

EMC Compliance

The CardioGen-82 Infusion System is compliant with EN/IEC 60601-1-2 Medical electrical equipment- Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility- Requirements and tests. Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual. CardioGen-82 Infusion System should be observed for normal operation when used with other electronic equipment. The Use of cables other than those specified may result in increased emissions and decreased immunity of this system. Portable and mobile communications equipment can and may affect Medical Electrical Equipment.

Guidance and manufacturer's declaration –electromagnetic emissions		
The CardioGen-82 Infusion System is intended for use in the electromagnetic environment specified below. The customer or the user of the CardioGen-82 Infusion System should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The CardioGen-82 Infusion System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	The CardioGen-82 Infusion System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies used for domestic purposes.

Guidance and manufacturer's declaration –electromagnetic immunity			
The CardioGen-82 Infusion System is intended for use in the electromagnetic environment specified below. The customer or the user of the CardioGen-82 Infusion System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [EQUIPMENT or SYSTEM] requires continued operation during power mains interruptions, it is recommended that the [EQUIPMENT or SYSTEM] be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A / m	3 A / m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration –electromagnetic immunity			
The CardioGen-82 Infusion System is intended for use in the electromagnetic environment specified below. The customer or the user of the CardioGen-82 Infusion System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the [EQUIPMENT or SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3,5}{3}\right]\sqrt{P}$ $d = \left[\frac{3,5}{3}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{3}\right]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as deter-mined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CardioGen-82 Infusion System is used exceeds the applicable RF compliance level above, the CardioGen-82 Infusion System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CardioGen-82 Infusion System. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the CardioGen-82 Infusion System

The CardioGen-82 Infusion System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CardioGen-82 Infusion System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CardioGen-82 Infusion System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = \left[\frac{3,5}{3}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{3}\right]\sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{7}{3}\right]\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.37	0.37	0.74
1	2.17	2.17	2.33
10	3.69	3.69	7.37
100	11.66	11.66	23.33

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

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

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

Safety Compliance

The CardioGen-82 Infusion System is compliant with EN/IEC 60601-1-2 Medical electrical equipment- Part 1-2:General requirements for safety – Collateral standard: Electromagnetic compatibility- Requirements and tests.

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 ACIST Medical Systems, Inc. User Manual 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 Diagnostic, Inc.

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1. INTRODUCTION

The CardioGen-82 Infusion System is a complete system for the generation and delivery of Rubidium-82 (Rb-82) from a CardioGen-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 CardioGen-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 CardioGen-82 Infusion System Overview

The CardioGen-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 CardioGen-82 Infusion System delivers Rb-82 by pumping saline (which acts as an eluant) through a CardioGen-82 Generator to produce the Rb-82 eluate. A diagram of the fluid system for the CardioGen-82 Infusion System is shown in Figure 2.2. Note that the CardioGen-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 CardioGen-82 Generator, and the positron detector, the fluid system contains a divergence valve for directing fluid flow in the CardioGen-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 CardioGen-82 Generator reaches levels sufficient for patient injection, this valve directs the Rb-82 eluate to the patient.

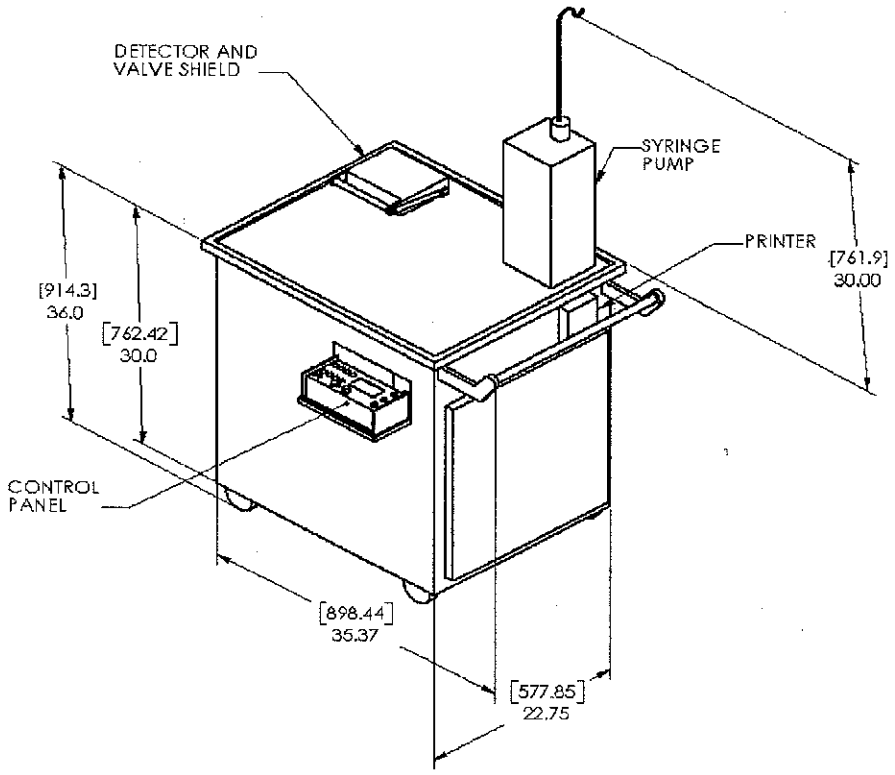


Figure 2.1 CardioGen-82 Infusion System Illustration

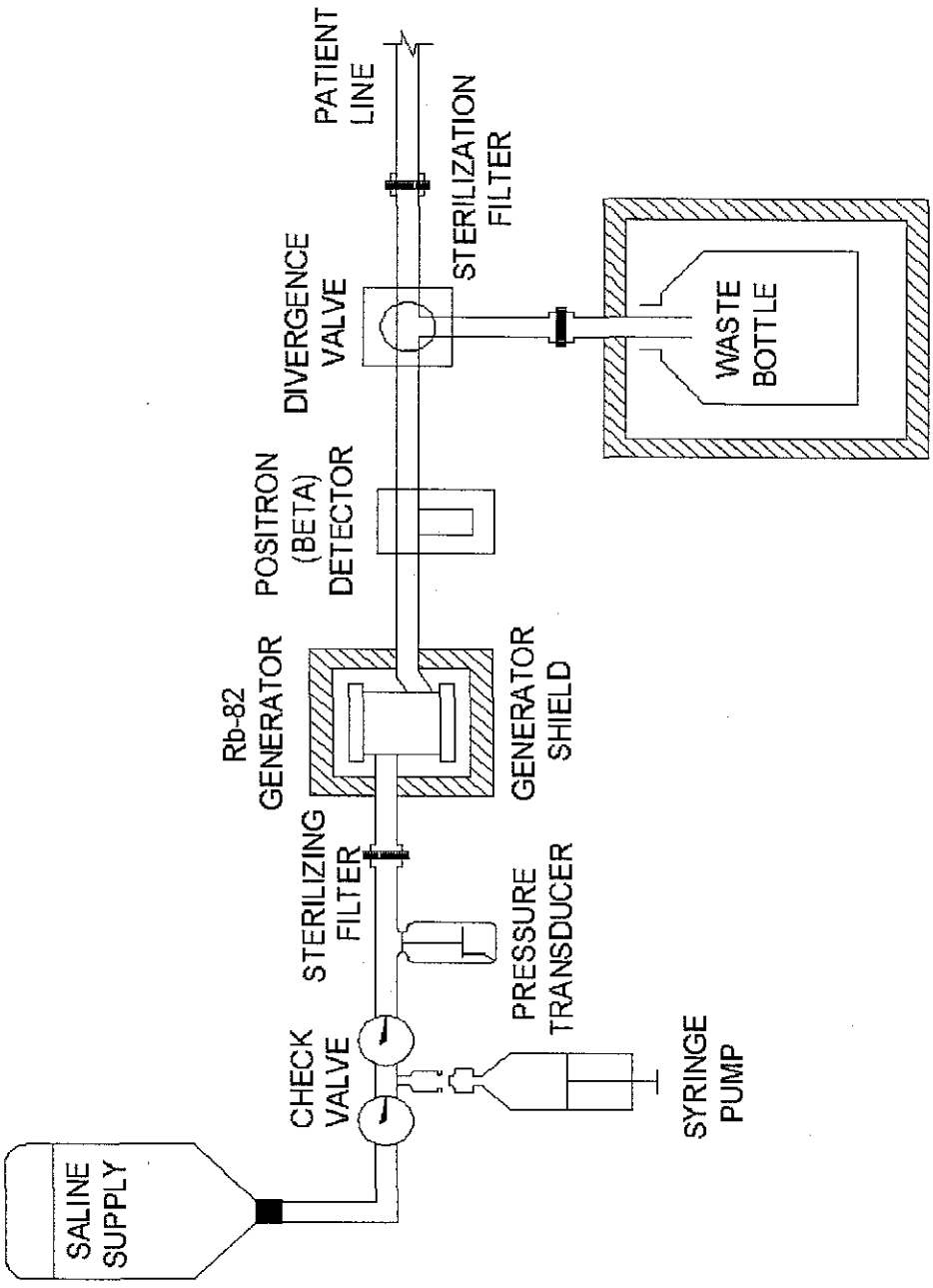


Figure 2.2 CardioGen-82 Infusion System Fluid-System Diagram

The CardioGen-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 CardioGen-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 package insert. Additionally, the operator selects a patient volume (ml) and 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 CardioGen-82 Infusion System only with a CardioGen-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 Diagnostic, Inc., or the provider of the Daily Use program.

- Since the eluate obtained from the CardioGen-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 CardioGen-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 must be installed in the lead shield provided in the CardioGen-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 CardioGen-82 Infusion System does not recognize incoming data.

RS-232C Port Interface Details:

The recommended RS-232 interface cable to be attached to the CardioGen-82 Infusion System should be a shielded type cable less than or equal to 10 feet long. If an RS-232 cable is attached to the CardioGen-82 Infusion System that exceeds the 10 foot length, the system should be observed to verify normal operation as well as other electronic equipment in the vicinity of the CardioGen-82 Infusion System. If abnormal operation is observed, it may be necessary to re-orient the RS-232 cable to the CardioGen-82 Infusion System.

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 CardioGen-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 Generator when performing system preparations, calibrations, breakthrough measurements, and infusions.

4.2 The Display/Control Panel

All displays and controls for the CardioGen-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.

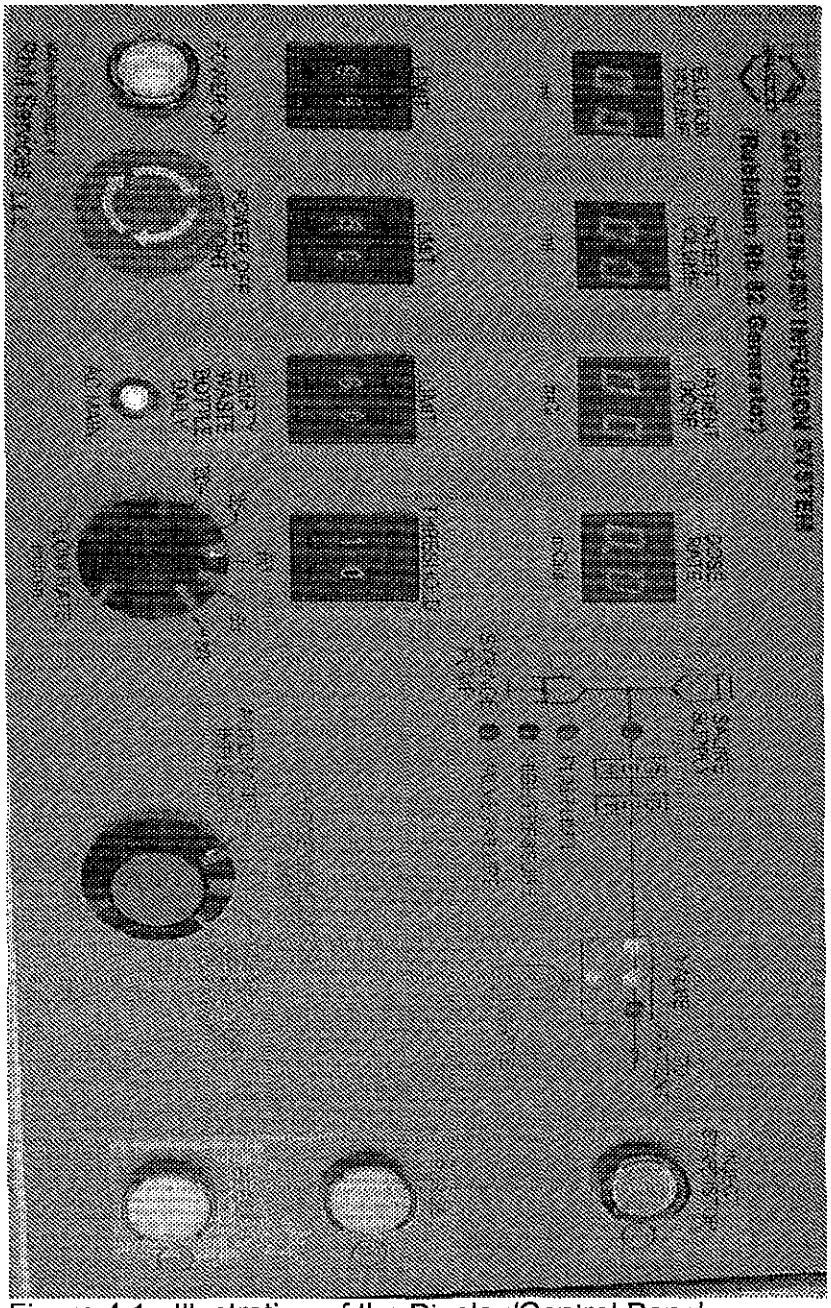


Figure 4.1 Illustration of the Display/Control Panel

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 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 CardioGen-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 CardioGen-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 <u>should not</u> 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 CardioGen-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 CardioGen-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.

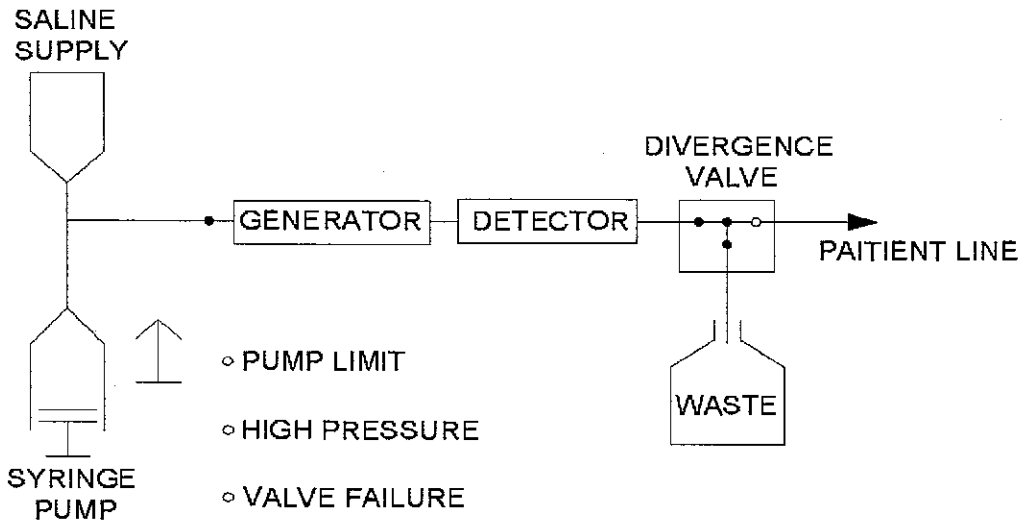
The radioactive eluate continues to be infused into the patient line until either the patient-dose limit, patient-volume limit, or elution-volume limit is reached. These limits are selected by controls on the Display/Control Panel. Once one of the preset infusion limits is reached, the saline pump is 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.

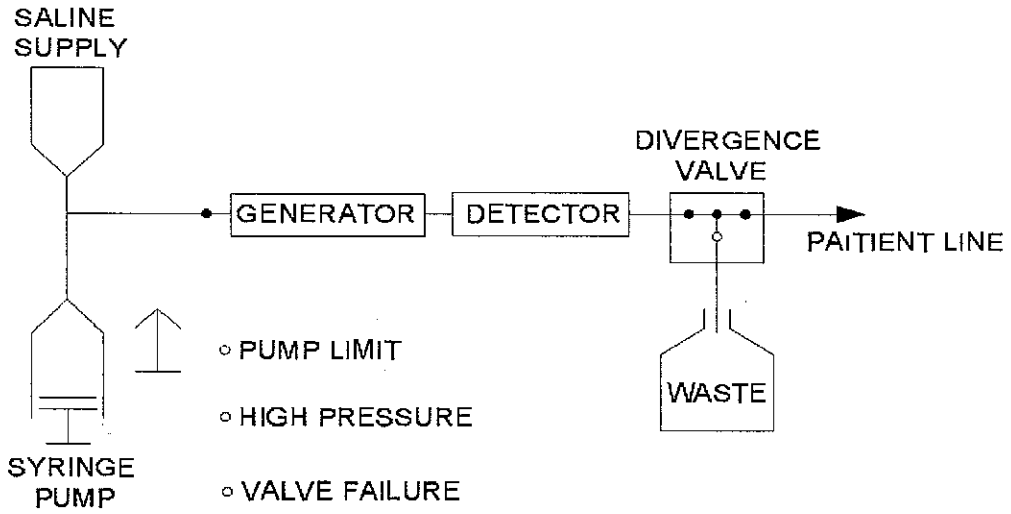
4.7.2 Report Printout

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

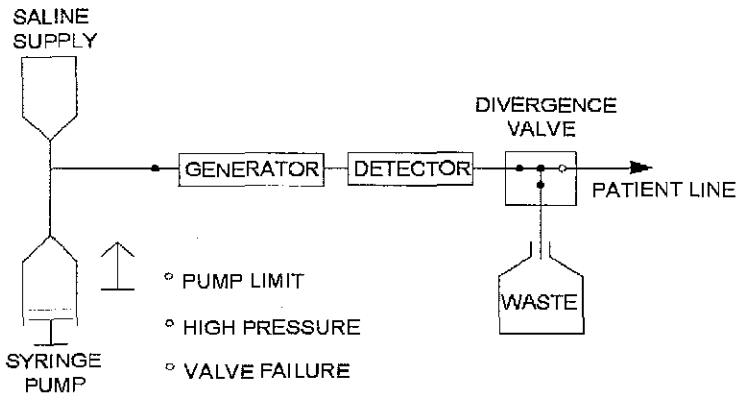
A sample automatic infusion printout is shown in Figure 4.4. Note that the first entry of the report contains status information. A normal infusion is indicated by the statement "INFUSION TERMINATED NORMALLY." If the infusion is unable to start or is interrupted in process, the detected error condition(s) is (are) printed out. Infusion error conditions are described in detail in the Section 6 of this manual.

The next entries in the infusion report are the set-points selected by the operator for the infusion. Elution volume, patient volume, patient dose, and dose-rate threshold set-points are listed in the report. Additionally, the selected flow rate and the selected calibration factor are listed.

The next entry in the infusion report is actual measured infusion data. The actual elution volume, patient volume, and patient dose are listed. Additionally, the activity present at end of infusion is listed. This activity is the activity that would be present in an infusion collection bottle at the end of an infusion. It is this activity value that is used for calibrations since on-going decay of the collected eluate is considered. Note that patient dose is the direct sum of activity leaving the patient port and does not consider on-going decay of the collected eluate. Finally, the activity present between detector and waste valve and the activity present between waste valve and patient are listed along with the corresponding saline volumes. This data is informational only and requires no user action as the infusion system automatically considers the effects of radioactivity stored in the tubing lines.

Finally, the infusion report contains an activity profile listing in one-second intervals. Both the activity measured at the detector and the activity calculated at the patient port are displayed for each one-second interval. This data should be interpreted as the amount of activity passing the detector and patient port in successive one-second time intervals. Note that the transit-time delay between the detector and the patient port can be readily observed in the sample infusion report.

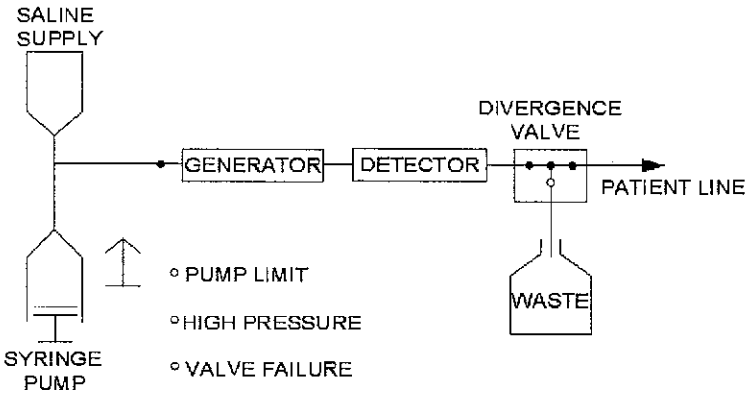
- The infusion operation is started by depressing the inject/start/stop switch.
- The saline pump is started.
- Low-Level activity is directed to the waste bottle.
- The running elution volume (volume through the generator) is displayed on the elution volume display.



(A) Activity Build Up Cycle

Figure 4.3.a Summary of the AUTOMATIC INFUSION Operation

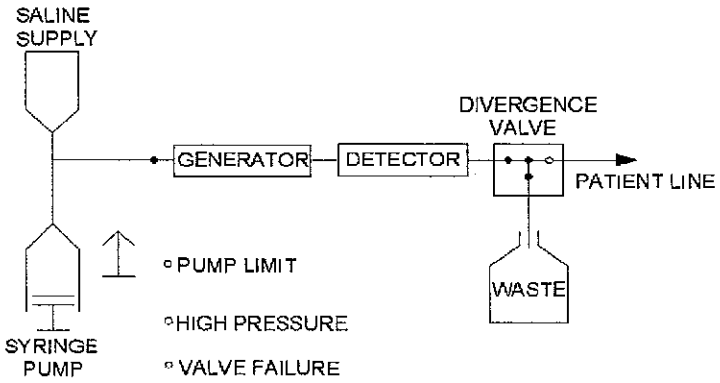
- Activity is directed to the patient line once the measured infusion dose rate exceeds the selected dose rate threshold.
- The running patient volume is dispayed on the patient volume display.
- The running patient dose is displayed on the patient volume display.
- The running elution volume continues to be displayed in the elution volume display.



(B) Patient Infusion Cycle

Figure 4.3.b Summary of the AUTOMATIC INFUSION Operation (continued)

- The saline pump stops when the patient-dose limit is reached. The elution-volume and patient volume limits serve as backup limits.
- The total elution volume, patient volume and patient dose is stored on the displays.
- The generator activity is directed to the waste bottle and patient line is diconnected form the generator.
- The printor begins to print out a report of the infusion.



(C) Infusion Ending Cycle

Figure 4.3.c Summary of the AUTOMATIC INFUSION Operation (continued)

INFUSION TERMINATED NORMALLY

SET-POINT VALUES:

Elution Volume = 40 ml
Patient Volume = 30 ml
Patient Dose = 50.0 mCi
Dose Rate Threshold. = 1.0 mCi/sec
Flow Rate = 50 ml/min
Calibration Factor = 926

ACTUAL INFUSION DATA:

Elution Volume = 26 ml
Patient Volume = 19 ml
Patient Dose = 50.1 mCi

Infused Activity Present
At End Of Infusion = 45.4 mCi

Activity Present Between
Detector and Waste Valve = 0.674 mCi
in Volume of 0.592 ml

Activity Present Between
Waste Valve and Patient = 3.23 mCi
in Volume of 2.75 ml

4.4 Sample of Infusion Report Printout

ACTIVITY PROFILE

Time sec	Detector mCi/sec	Patient mCi/sec
1	0.000	0.000
2	0.000	0.000
3	0.000	0.000
4	0.000	0.000
5	0.000	0.000
6	0.000	0.000
7	0.003	0.000
8	0.056	0.000
9	0.377	0.000
10	1.149	0.000
11	1.937	0.016
12	3.026	0.422
13	3.558	1.191
14	3.648	1.996
15	3.624	3.023
16	3.652	3.487
17	3.650	3.548
18	3.564	3.528
19	3.385	3.558
20	3.134	3.549
21	2.848	3.457
22	2.556	3.270
23	2.277	3.024
24	2.023	2.743
25	1.797	2.462
26	1.611	2.188
27	1.450	1.946
28	1.314	1.729
29	1.204	1.552
30	1.103	1.398
31	1.020	1.268
32	0.578	0.709

4.4 Sample of Infusion Report Printout (Cont'd.)

5.0 OPERATING PROCEDURE

5.1 General Notes

The sterility of each component must be preserved, be sure to wear protective gloves. Aseptic techniques must be strictly observed in all handling. Do not remove any luer-lock protective caps until instructed to do so. Additionally, do not allow any unprotected luer-lock fittings to make contact with anything other than its mating luer-lock fitting.

As system pressure can approach 100 PSI it is important that luer-lock fittings be connected tightly without stripping or otherwise damaging the fittings. Improper luer-lock connections will result in saline leaks that may be difficult to find and correct.

5.2 CardioGen-82 Generator and Sterile Components

Compare the CardioGen-82 Generator sterile disposable tray label's parts list, list 015100, with the actual components in the tray. If not correct, contact BDI Nuclear Medicine Customer Service at 1-800-447-6883.

5.3 CardioGen-82 Infusion System Preparation

Remove the syringe pump cover by loosening the three mounting thumb screws and carefully lifting the cover off the pump assembly. Activate the CardioGen-82 Infusion System by depressing the power switch and moving the mode switch to the **Purge Generator to Waste** position.

Raise the lid of the hinged valve shield cover to expose the inside of the valve shield assembly. Visually make sure there are no used disposables present in the system. If any of the used disposables are present they must be disposed of to prevent possible confusion with the new set-up. Close the valve cover.

Move the syringe pump to its upper end of the travel position by continuously depressing the purge switch while the system is in the **Purge Generator to Waste** mode. The pump will automatically stop when it reaches the upper end of the travel position. The LED pump limit light will come on.

5.4 Installation of the Syringe Pump Components

5.4.1 Pump Syringe Installation (Pump Syringe Package #1)

Loosen the 4 thumb screws; upper and lower on the pump syringe carriage. Install the 140 mL pump syringe with its luer-lock fitting facing

upward into its carriage in the pump assembly. Be sure to rotate the syringe so that the graduations face toward the operator. Tighten the upper and lower thumbscrews to secure both the syringe body and plunger into the carriage. Do not remove the protective cap on this syringe until directed to do so.

5.4.2 Pressure Sensor Syringe Installation (Inlet Assembly Package #2)

Install the 10 cc pressure sensor syringe by placing it with the luer-lock fitting facing upward into the carriage in the pump assembly. This is done by tilting the syringe into place with the plunger contacting the bottom of the carriage followed by pushing the top of the syringe back until it's locked in place. Be sure to rotate the syringe so the graduations face toward the operator. Do not remove the protective cap on the syringe until directed to do so.

5.4.3 Pump Cover Installation

Re-install the pump cover by carefully sliding it over the top of the pump assembly with the pump syringe and pressure sensor syringe protruding through the pump cover. Be sure the protective caps on the syringes protect the syringe luer-lock fittings from contacting the pump cover. Verify that the pump cover is fully seated on the pump assembly.

5.5 CardioGen-82 Generator Inlet Assembly Package

Remove the tubing assembly from its package and connect the check valve to the pump syringe. Tighten the luer-lock fittings but be careful not to damage the pump syringe connection.

5.5.1 Pressure Sensor Line Installation

Connect the shortest line of the inlet tubing assembly to the 10 mL sensor syringe. Tighten the syringe to the luer-lock connection, but be careful not to damage.

5.5.2 Generator Inlet Line Installation

Open the Valve shield. Take the longest line of the generator inlet tubing assembly and insert it down through the tubing shield so that it appears in the generator shield. Remove the generator shield lead lid and retrieve the free end of the generator inlet line. Approximately three to six inches of this line will now be in the generator shield with the luer-lock fitting and the cap on. Place the saline supply hook assembly back onto the pump assembly.

5.5.3 Generator Inlet Line Sterilizing Filter Installation

Take the filter from the generator inlet assembly package and connect the female luer-lock fitting of the Generator Inlet Sterilizing Filter to the male luer-lock fitting on the free end of the generator inlet line that is now located in the generator shield. Make sure that the luer-lock fitting on the other end of this filter remains in place until directed to do otherwise.

5.6 CardioGen-82 Generator Outlet Assembly (Package #3)

5.6.1 Divergence Valve Installation

If it is not already open, raise the lid on the valve shield assembly located on the top of the CardioGen-82 Infusion System and remove the valve retainer. Note: The lid cannot be raised if the CardioGen-82 Infusion System is unpowered or if the system detects activity within this shield. Take the divergence valve, (the white valve with the three arrows and the off sign) and orient it with the handle facing down toward the bottom of the CardioGen-82 Infusion System. Note: The shortest line of this connection will be facing towards the left end of the infusion system as you are looking at it. Finally, without changing the orientation of the valve, rotate the valve handle so that the valve can be dropped into its actuation carriage, to prevent it from being moved, with the "valve" arm fitting into the groove of the actuation carriage.

5.6.2 Generator Outlet Line Installation

Take the line with the red cap end and feed it through the hole in the valve shield assembly. Verify that the end of this line has entered the generator shield. There should now be two lines in the generator shield; the generator inlet line with its associated filter and the generator outlet line. Secure the end of the generator outlet line (located in the valve shield assembly) by inserting into the tubing slot near the detector and route the line past the detector; secure with detector cover.

5.6.3 Generator Waste Line Installation

Take the line from the outlet tubing assembly with the clear end and feed it down the opening of the valve shield assembly. There should now be three sets of tubing in the generator shield.

5.6.4 Generator Waste Line To Waste Shield

Take the line in the generator shield with the clear cap and feed it through the hole inside the generator into the waste shield. Tape the tubing in the generator shield so that the generator will not crimp the tubing.

5.6.5 Waste Bottle Preparation and Sterilizing Filter Installation

From the outlet assembly package take the short line with the filter on the end and connect it to the waste line inside the waste bottle shield. Once this connection has been made, take the waste bottle and connect the waste line to the top of the bottle *make sure you remove the cover from the needle under the bottle cap cover.* Verify that the waste bottle connections are correct. Carefully lower the waste bottle into the waste shield and route the extra waste line tubing to prevent any kinking or obstruction in the tubing. Place the lid on top of the waste shield.

The waste bottle should be emptied every morning prior to system use or at the end of system usage.

5.7 Patient Line Installation

Remove a patient line from its protective wrapping. Connect the female side of the luer-lock fitting, to the line on top of the infusion cart system which comes out the left side of the valve. This patient line contains its own sterilizing filter. This is the only part of the system that you must change as a new patient is being imaged. Make sure that the valve retainer is now over the valve and close the lid.

5.8 Saline Supply Installation

5.8.1 Installation of the Saline Supply

Take the remaining free tubing of the generator inlet line, which was the first kit you hooked up, pinch off valve and then carefully insert the spike into your bottle or bag of preservative-free, normal saline. Make sure the spike is fully inserted. Hang the saline supply on the saline supply hook located on top of the pump assembly.

5.9 CardioGen-82 Generator Installation

5.9.1 Installation Preparation

Look inside the generator shield, and verify that there are two lines available for connection:

- Generator inlet line and its attached filter with a male luer lock fitting.
- Generator outlet line with a female luer-lock fitting

Make sure the waste line that passes through the generator shield chamber is against the wall of the generator shield so that it does not interfere with the generator installation.

5.9.2 CardioGen-82 Generator Installation

Remove the generator from its shipping container, and unclip the outlet and inlet tubing, carefully lower it into the generator shield. Make sure that the generator does not interfere with the waste line that passes through the generator shield. Connect the inlet line on the generator (marked "inlet," and has a female luer-lock fitting on it) to the remaining fitting on the generator sterilizing filter and has a male luer-lock fitting on it. Connect the outlet line of the generator (marked outlet and has a male luer-lock fitting on it) to the remaining line in the generator shield which has a red cap on it. Carefully lower the generator shield lid **making sure that none of the lines are restricted.**

5.10 Purge Operation

5.10.1 Syringe Filling

Position the syringe pump to its limit if not already there, by continuously depressing the PURGE switch (in the PURGE GENERATOR TO WASTE mode) until the pump automatically stops. Open the saline supply pinch valve and depress the REFILL switch once. The syringe pump should begin drawing in saline and a stream of air bubbles should appear in the saline supply bottle. The refill operation can be stopped at any time by depressing the REFILL switch a second time. Otherwise, the pump will continue refilling until it reaches its refill limit and automatically stops. Unless problems are encountered, allow the pump to refill until it automatically stops on its refill limit.

5.10.2 Waste Line Purging

With the MODE switch in the PURGE GENERATOR TO WASTE position continually depress the PURGE switch to pump saline through the generator and into the waste bottle. A volume of 50 mL of saline should be sufficient to guarantee purging the waste lines of air. Note: The purge volume can be checked by observing the markings on the pump syringe. Lift the waste bottle shield cover and look for any signs of leakage. Correct any leaking connections before continuing to use the CardioGen-82 infusion system.

Note: It is recommended that leak testing be carried out by wipe test and radiation detection survey.

5.10.3 Pressure Sensor Line

Pinch off the saline bag valve, disconnect the pressure sensor line from the pressure sensor syringe and place it in a beaker. Depress the purge switch until liquid flows into the beaker. Reconnect the pressure sensor line to the pressure sensor syringe. Now unpinch the saline valve.

5.10.4 Patient Line Purging

Place the MODE switch in the PURGE GENERATOR TO PATIENT position. Connect the patient line to a shielded 50 mL vial and insert a venting needle. Continuously depress the PURGE switch until all the air has been expelled from the patient line into the vial. A volume of 20 mL should be sufficient to purge the patient line. The purge volume can be determined by observing the pump syringe markings.

Lift the generator shield cover and look for any signs of leakage. Correct any leaking connections before continuing to use the CardioGen-82 Infusion System.

Note: It is recommended that leak testing be carried out by wipe test and radiation detection survey.

5.10.5 Volumetric Flow Rate Verification

This is performed with the installation of a new generator.
Set the controls on the Display/Control Panel as follows:

• Mode Switch	=	Automatic Infusion
• Elution Volume Limit	=	99 mL
• Patient Volume Limit	=	50 mL

• Patient Dose Limit	=	99 mCi
• Dose Rate Threshold	=	1.0 mCi/sec.
• Flow Rate	=	50 mL/min.

Check for a 50 mL/min. flow rate using a stop watch.

5.11 Patient Administration

PATIENT ADMINISTRATION MAY BE PERFORMED ONLY AFTER SUCCESSFUL COMPLETION OF DAILY CALIBRATION, SR-82/85 BREAKTHROUGH PROCEDURES, AND FIRST WASH (ELUTION) DISPOSAL USING SAME SETTINGS AS SEEN ON SR-82/85 BREAKTHROUGH SHEET PAGE.

IN THE EVENT OF A POWER-FAILURE OR THE SYSTEM IS INADVERTENTLY SHUT DOWN, CALIBRATION SHOULD BE RECONFIRMED.

5.11.1 Replace the patient administration set for each new patient.

5.11.2 Purge all air out of the patient administration set and verify that all air is purged from the system. Refer to Installation Instructions, section 5.10.4.

5.11.3 Set the controls on the Display/Control panel as prescribed by the administering physician.

5.11.4 Verify that the syringe pump has been filled with saline. The syringe pump volume must at least equal the selected elution volume-set point plus 20 mL. This volume will cover the 15 mL nominal dead volume in the syringe.

5.11.5 Verify that the system printer is on and that approximately 1 inch of paper extends out of the printer. If the RS-232C port is being used for infusion data acquisition, the system printer can be turned off. Infusion report data is transmitted out the RS-232C port whether the system printer is powered or not.

5.11.6 Attach the CardioGen-82 Infusion System patient line to the patient's intravenous line.

5.11.7 Make sure that at least 10 minutes has elapsed following any purge or infusion operation. Start the infusion by depressing the INJECT START/STOP switch.

NOTE: The infusion can be terminated at any time by depressing the INJECT START/STOP switch a second time.

The running elution volume, patient volume, patient dose and dose rate will be registered on the control/display panel. Once the infusion operation is completed the INJECT START/STOP switch will stop glowing red and the infusion report data will be printed on the system printer and echoed out the RS-232C port.

5.11.8 Unless manually interrupted, the infusion will terminate when the number of mCi preset on the PATIENT DOSE LIMIT switch has been reached. As a safety precaution, the infusion will also terminate if the preset ELUTION VOLUME LIMIT or PATIENT VOLUME LIMIT are reached.

NOTE: THE CardioGen-82 GENERATOR ELUATE IS RADIOACTIVE AND SHOULD BE HANDLED WITH PROPER RADIATION SAFETY PRECAUTIONS.

NOTE: WAIT AT LEAST 10 MINUTES AFTER ANY PURGE OR INFUSION OPERATION BEFORE LIFTING THE GENERATOR SHIELD COVER, WASTE BOTTLE SHIELD COVER OR THE HINGED VALVE-SHIELD COVER. THIS WILL ALLOW ANY RB-82 ELUATE TO DECAY TO A SAFE LEVEL.

NOTE: THE HINGED VALVE-SHIELD COVER AUTOMATICALLY LOCKS IN THE CLOSED POSITION DURING ANY PURGE OR INFUSION OPERATION. THE COVER REMAINS LOCKED UNTIL THE DETECTED RADIOACTIVITY DECAYS TO A SAFE LEVEL. NO PURGE OR INFUSION OPERATION CAN BE STARTED UNLESS THE COVER IS CLOSED. ADDITIONALLY, THE COVER CANNOT BE RAISED UNLESS THE CardioGen-82 INFUSION SYSTEM IS POWERED.

NOTE: ALWAYS WEAR GLOVES BEFORE TOUCHING ANY OF THE TUBING, SYRINGE PUMP, VALVE OR COLLECTION BOTTLE SYSTEM COMPONENTS.

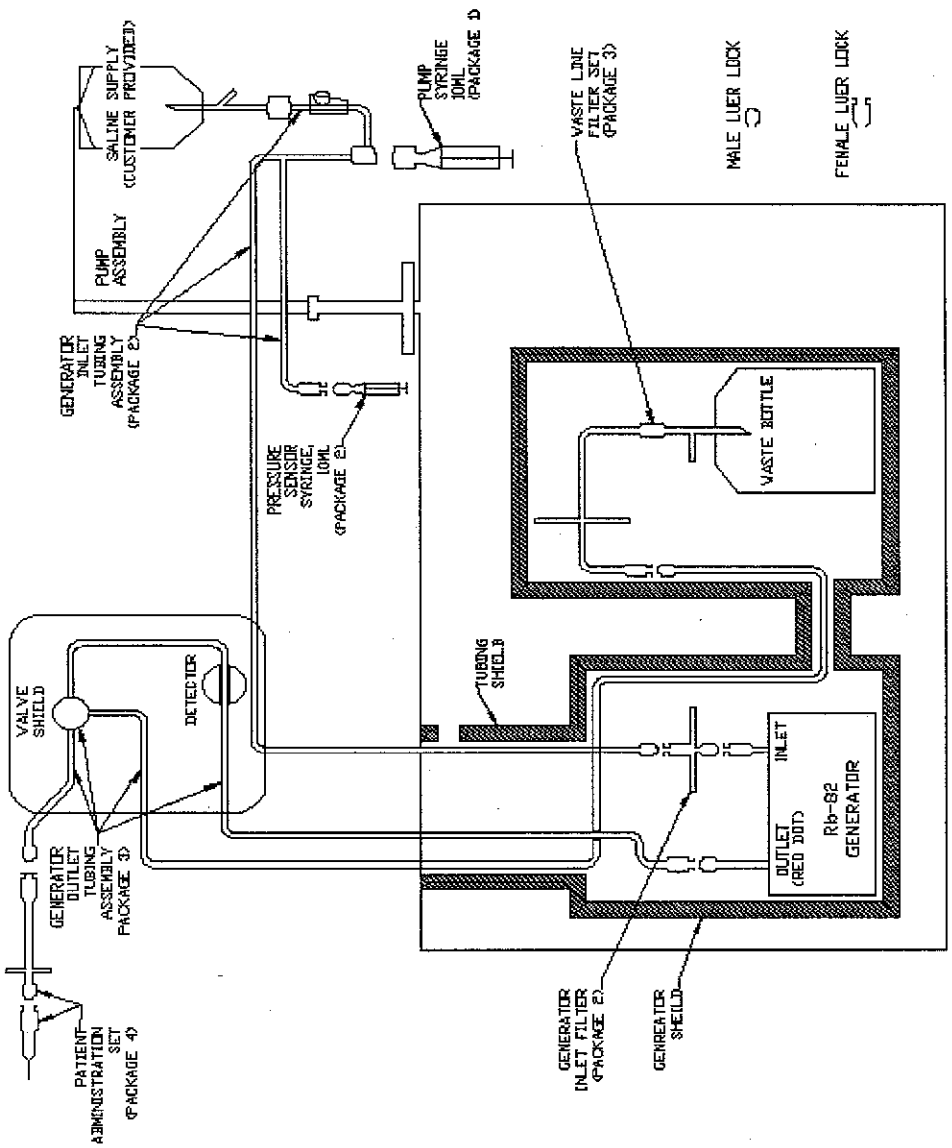


Figure 5.1 Tubing Diagram

CardioGen-82 Generator
Sr-82/85 Breakthrough Worksheet

Date _____

Infusion System Control Panel Settings

Mode Switch:	Automatic Infusion
Elution Volume:	99 mL
Patient Volume:	50 mL
Patient Dose:	99 mCi
Dose Rate:	1 mCi/sec.
Flow Rate:	50 mL/min.

Dose Calibrator Setting

504 (Capintec only) or
Co-60 setting then divide reading obtained by 0.548

---

1. Elute 50 mL of eluate into 50 mL vial using Infusion System Control Panel Settings as above. Note exact time at end of elution (EOE).

   Time when elution ended _____.

2. Set dose calibrator as above. Setting used: _____.

3. Measure Rb-82 activity in dose calibrator. Note exact time (minutes/seconds) when measurement is made.

   Rb-82 activity _____(mCi).
   Time of measurement _____.

4. Decay correct Rb-82 measurement to time when elution ended (EOE).

   (Note: If time between end of elution and measurement is allowed to be 150 seconds (2.5 minutes), multiply dose calibrator reading by a factor of 4).

   Decay correction factor_____.
   Rb-82 activity at EOE (mCi) _____.

5. Using same vial, let sample stand for 60 minutes to allow for complete decay of Rb-82.

6. Measure sample in dose calibrator.

7. Calculate amount of Sr-82 in sample using the following equation:

$$\text{Sr-82} = \frac{\text{dose calibrator reading (µCi)}}{\text{divisor (from sheet supplied with Generator)}}$$

Example:

$$\text{Sr-82} = \frac{0.5}{2.3} = .216$$

Sr-82 = .216 µCi

8. Determine Sr-82 Breakthrough by dividing µCi of Sr-82 by the mCi of Rb-82 at EOE

Example:

$$\frac{.216 \text{ µCi Sr-82}}{50 \text{ mCi Rb-82}} = .004 \text{ µCi Sr-82/mCi Rb-82}$$

Allowable Limit = .02 µCi Sr-82/mCi Rb-82

9. Determine Sr-85 Breakthrough by multiplying the result obtained in step 8 by the Sr-85/Sr-82 ratio from the data sheet supplied with the generator.

Example:

.004 x 1.48 = .00592

Allowable Limit = 0.2 µCi Sr-85/mCi Rb-82

CardioGen-82 INFUSION SYSTEM-CALIBRATION DATA SHEET

Infusion System Control Panel Settings

Mode Switch:	Automatic infusion
Elution Volume:	99 mL
Patient Volume:	50 mL
Patient Dose:	60 mCi
Dose Rate:	1 mCi/sec.
Flow Rate:	50 mL/min.

1. Date of Calibration or Calibration Verification: _____

2. Initial Generator Sr-82 Potency on calibration date: _____mCi

3. Generator Sr-82 Potency on present date: _____mCi

4. Present Calibration Factor: _____

5. Measured Rb-82 Activity from dose calibrator (corrected for decay): _____mCi

6. Printed Rb-82 Activity Present at the end of infusion: _____mCi

7. Ratio of Measured Rb-82 Activity and Printed Rb-82:

$$\frac{\text{Measured Rb-82 Activity}}{\text{Printed Rb-82 Activity}} = \text{Ratio}$$

8. Is the difference between Measured Rb-82 Activity and Printed Rb-82 .95 - 1.1?
_____ (If no, unit requires recalibration).

9. Calculated New Calibration Factor (if needed): _____

$$\text{New Cal. Factor} = \text{Initial Cal. Factor} \times \frac{\text{Measured Rb-82 Activity at End of Infusion}}{\text{Printed Rb-82 Activity Present at End of Infusion}}$$

Measured Rb-82 Activity at End of Infusion _____

Printed Rb-82 Activity Present at End of Infusion _____

10. Is new Calibration factor within 5% of old Calibration factor?

_____ (If no, repeat calibration).

Site Name_____ **Rb-82 Infusion System Calibration Log Sheet**

INFUSION SYSTEM SETTINGS			GENERATOR DATA
1. Patient Dose		mCi	1. Generator Lot Number
2. Flow Rate	50	ml/min	2. Initial Gen. Potency
3. Patient Dose Threshold	1.0	mCi/sec	3. Date

Decay Factor Table		
Measured Time		Factor
0 Min	0 Sec	1
1 Min	15 Sec	2
2 Min	30 Sec	4
3 Min	45 Sec	8
5 Min	0 Sec	16

CALIBRATION SHOULD ALWAYS BE DONE AT THE DESIRED PATIENT DOSE SETTINGS. THE FIRST ELUTION OF THE DAY MUST BE DISCARDED AND NOT USED FOR CALIBRATION. REFER TO SECTION 5.2 OF THE OPERATION MANUAL FOR INSTRUCTIONS.

A	B	C *	D	E	F	G	H **		I	J	K
Calibration Infusion (Date & Time)	Dose Reading From Dose Calibrator (mCi)	Corrected Dose (B/1) or (B/0.548) (mCi)	Dose Decay Time (min:sec)	Dose, Decay Corrected (C x Decay Factor) (mCi)	Printed Activity End of Infusion (mCi)	Ratio E to F (E/F)	Calib. ±5%? G = .95 to 1.05	Calib. ±10%? G = .90 to 1.10	Calib. Factor (from Rb-82 Printer)	New Calib. Factor	Operator Initials
Example: 9/28/85 8:00 AM	12.2	12.2	2:30	48.8	57.7	.855	No	No	1000	855	BGS
Example: 9/28/85 8:12 AM	13.8	13.8	2:30	55.2	55.7	.991	Yes	Yes	853	N/A	BGS

* Use the dose calibrator reading directly if an RB-82 calibration setting is used or divide the reading by 0.548 if a Co-60 Calibration setting is used.

** Calibration should be performed to ±5% (Ratio=0.95 to 1.05). Daily calibration checks should be within ±10% (Ratio=0.9 to 1.1). See Section 5.2 of the operation manual.

Figure 5.2 Rb-82 Infusion System Calibration Log Sheet

Site Name_____

CARDIOGEN® Rb-82 Generator
Sr-82 Breakthrough Log Sheet

INFUSION SYSTEM SETTINGS			GENERATOR DATA
1. Patient Dose	99	mCi	1. Generator Lot Number
2. Elution Volume		99 ml	2. Initial Gen. Potency
3. Patient Volume		50 ml	3. Date
4. Flow Rate		50 ml	
5. Patient Dose Threshold	1.0	mCi/sec	

Decay Factor Table		
Measured Time		Factor
0 Min	0 Sec	1
1 Min	15 Sec	2
2 Min	30 Sec	4
3 Min	45 Sec	8

THE FIRST ELUTION OF THE DAY MUST BE DISCARDED AND NOT USED FOR BREAKTHOUGH MEASUREMENT. REFER TO SECTION 5.3 OF THE OPERATION MANUAL FOR INSTRUCTIONS.

A	B	C*	D	E	F	G*	H	I	J	K	L
Breakthrough Infusion (Date & Time)	Rb-82 Reading From Dose Calibrator (mCi)	Corrected Rb-82 (B/1) or (B/0.548) (mCi)	Rb-82 Decay Time (min:sec)	Rb-82, Decay Corrected (C x Decay Factor) (mCi)	Break-through Reading from Dose Calibrator (μ Ci)	Break-through Corrected F/1 or F/0.548 (μ Ci)	Break-through Divisor from Gen. Data	Sr-82 Break-through G/H (μ Ci)	Ratio Sr-82 to Rb-82 I/E (μ Ci/mCi)	Ratio Sr-82 to Rb-82 <0.02 μ Ci/mCi?	Operator Initials
Example: 9/28/85 9:00 AM	12.1	12.1	2:30	48.4	0.8	0.8	6.43	0.124	0.0026	Yes	WLC

* Use the dose calibrator reading directly if an RB-82 calibration setting is used or divide the reading by 0.548 if a Co-60 Calibration setting is used.

Figure 5.3 CARDIOGEN®-82 GENERATOR SR-82 Breakthrough Log Sheet

6. TROUBLESHOOTING GUIDE

The table below describes possible purge and infusion error conditions that are displayed on the Control/Display panel. These errors are also listed in the infusion report printout. Suggested corrective action is provided in the table for each error condition.

For product complaints or questions regarding the operation and service of the system, please contact your assigned Bracco Representative.

This device has been tested for protection against electro-magnetic interference according to IEC 60601-1-2. However, the proximity of other devices that give off electro-magnetic radiation, such as X-ray machines, can interfere with the operation of this system.

TROUBLESHOOTING TABLE

Error Condition	Suggested Action
Automatic Infusion Errors (listed in infusion report printout)	
"Elution Volume Set-point = 0"	Select non-zero infusion set-points
"Patient Volume Set-point = 0"	Select non-zero infusion set-points
"Patient Dose Set-point = 0"	Select non-zero infusion set-points
"Valve Shield Open"	Close the valve shield
"Pump At Limit Position"	Refill syringe pump
"High Pressure Error"	Look for possible tubing constriction
"Valve Error"	Notify Bracco Diagnostic, Inc.
Automatic Infusion and Purge Errors (displayed on Control/Display panel)	
PUMP LIMIT	Refill the syringe pump, if necessary. Note that this display is also active if the pump is on the refill limit.
HIGH PRESSURE	Look for possible tubing constriction
VALVE ERROR	Notify Bracco Diagnostic,Inc.
Valve Shield Open (not displayed)	Close the valve shield for all purge and infusion operations

Contact Information

ACIST Medical Systems, Inc. (952) 941-3507
7905 Fuller Road
Eden Prairie, MN 55344
USA

Customer Service

Ordering Patient Kits	1-800-257-5181
Ordering Systems & Accessories	1-800-257-5181

Technical Support

Service, Parts, and Technical Support; *Bracco Professional Services*	1-800-257-5181

SYSTEM DIARY

Date:_____
Problem:_____
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Action Taken: _____
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Date:_____
Problem:_____
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