CRC®-712MH

RADIOISOTOPE DOSE CALIBRATOR

OWNER'S MANUAL

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PREFACE

Thank you for purchasing the Capintec, Inc. CRC®-712MH Radioisotope Dose Calibrator. Every effort has been made to insure that the information in this document is complete, accurate, and up-to-date. Capintec, Inc. assumes no responsibility for the results of errors beyond its control. Mention of products manufactured by other companies does not necessarily constitute endorsement by Capintec, Inc.

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SYSTEM DESCRIPTION

The CRC®-712MH Radioisotope Dose Calibrator consists of the following:

- Readout Unit
- Chamber(s)
- Power Cord
- Printer (optional)

ELECTROMAGNETIC INTERFERENCE POTENTIAL

This equipment generates radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to nearby devices. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference, the user is encouraged to try to correct the interference by one of the following measures:

- Increase the separation between the equipment and the affected device.
- Plug the unit into an outlet on a circuit different from that to which the affected device is connected.

If this fails to correct the problem, please contact Capintec's Authorized Service Center.

IMPORTANT SAFETY INFORMATION

The CRC®-712MH measurement system has been carefully designed to give you years of safe and reliable performance. As with all electrical equipment, however, there are basic precautions you must observe to avoid injuring yourself, the patient or damaging the equipment.

- ***Follow*** the unpacking and assembly instructions document, and ***read*** this manual carefully before using this equipment. Be sure to save all provided documents for future reference.
- ***Understand*** ***all*** warning and caution labels as explained in CHAPTER 1: SAFETY before operating this equipment.

CHAPTER 1

SAFETY

These warnings and instructions for use form an integral part of the CRC®-712MH and must therefore be kept available for consultation at all times. Precise compliance with the instructions is an essential condition for normal use, correct application and thus safety of the user.

SYMBOL DEFINITIONS

│	"ON" (power)
○	"OFF" (power)

WARNING AND CAUTION LABELS

Located on the back of the Readout Unit is a label, (Figure 1-1), providing the system power requirements, and the replacement fuse values for power line voltages.

Please reference CHAPTER 7: CLEANING AND MAINTENANCE for instructions on how to change the fuses and line voltage of the CRC®-712MH.

A fire hazard may exist if the wrong size of fuse is installed.

WARNING FIRE HAZARD!
For continued protection replace only with same type and rating of fuse.

Use slow blow fuse only.
1/4 AMP. for 115 Volts
1/8 AMP. for 230 Volts

Figure 1-1

Located on the Power Cord is a label, (Figure 1-2), indicating that the grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked hospital only or hospital grade..

FOR GROUNDING RELIABILITY
CONNECT TO A RECEPTACLE
MARKED HOSPITAL GRADE

Figure 1-2

Located on the chamber are 2 labels.

The first label (Figure 1-3) contains statements denoting not to remove the cover because there are no adjustments that the user can perform in the chamber.

CAUTION: DO NOT REMOVE COVER.
NO USER-SERVICEABLE PARTS INSIDE.
REFER SERVICING TO AUTHORIZED
SERVICE PERSONNEL. PN 7120-1205

Figure 1-3

The second label (Figure 1-4) is located in three places (on the bottom of the chamber, on the 150 Volt Battery pack inside the chamber & on the cover of the main power supply in the readout unit) and pertains to the electrical safety of the chamber and readout. It is necessary because of the high voltage present (approximately 150 volts) on the Battery board installed in the chamber and the line voltage inside of the readout. A screwdriver is necessary to remove the covers to both the chamber and the readout.

CAUTION
HIGH VOLTAGE

Figure 1-4

CAUTIONS AND NOTES

CAUTION

Only qualified/trained personnel should operate this unit.

CAUTION

If the equipment is used in a manner not specified in this manual, the protection provided by the equipment may be impaired.

CAUTION

No internal adjustments inside the chamber or readout that may be performed by the user within the conditions of the warranty. Due to the presence of high voltages, opening the cover with the system plugged in may be hazardous. Refer all servicing to qualified personnel.

CAUTION

Never use the calibrator without the well liner in place. Liners are inexpensive and easy to replace. A contaminated chamber is a very costly mistake. If the unit becomes contaminated remove the liner and clean the unit as stated in CHAPTER 7: CLEANING AND MAINTENANCE before operating.

CAUTION

Care must be exercised when moving the instrument or when maintenance is performed. The shielded cylinder is heavy (13.6 kg or 30 lb). In order to provide the required sensitivity, the wall of the ionization chamber is extremely thin and the chamber is filled with pressurized gas. It is therefore, essential to avoid mechanical shock or vibration of any kind.

CAUTION

When working with a heavy sample (especially a CapMac or Moly Assay Canister) always lower it gently into the chamber well. Dropping any heavy object into the well can cause permanent, expensive damage.

CAUTION

It is desirable to leave the unit powered at all times in order to prevent moisture absorption and to maintain the stability of the instrument (especially if the instrument is subjected to high humidity or low temperature).

CAUTION

The sensitivity of the chamber is somewhat dependent upon the vertical position of the sample within the well. All calibrations were done with a Standard Sample placed in the supplied sample holder (dipper). It should be noted that in this configuration, the sample is not quite at the bottom of the well. If, for any reason, you make a measurement without using the dipper, be sure that the sample is in the correct vertical position. Both the CapMac and the Standard Moly Assay Canister maintain the same position as the dipper.

CAUTION

Use of accessories not listed in this manual, may compromise the compliance of this product to IEC 60601-1. Therefore, only recognized accessories shall be used at all times. Also the Electromagnetic Interference (EMI) may be compromised which may affect other devices located in the same area as the CRC®-712MH or the CRC®-712MH may become susceptible to EMI.

CAUTION

The unit contains lead. Appropriate caution should be taken if the interior of the unit is exposed. The unit should be disposed of in accordance with local and national regulations.

CAUTION

The unit contains a Lithium Battery. This should be disposed of in accordance with local and national regulations.

CAUTION

The user should always verify the validity of any measurement or test result in order to minimize measurement errors.

NOTE

It is recommended that periodic re-calibration of the unit be performed by Capintec's Authorized Service Center to guarantee that the instrument's high reliability is maintained.

GENERAL SAFETY TIPS

- Unplug the equipment before cleaning it. Use only a damp cloth; do not use solvents or aerosol cleaners.
- To protect the equipment from overheating, do not use the equipment directly in front of a radiator or heat register.
- Do not use the equipment near water, or spill liquids of any kind into the equipment.
- Be sure that your power source matches the rating listed on the CRC®-712MH calibrator.
- The CRC®-712MH power cord has a grounded, 3-prong plug as a safety feature, and it will only fit into a grounded outlet. Do not use an adapter to defeat the grounding.
- To avoid damaging the power cord, do not place anything on it or place it where it will be stepped on. If the cord becomes damaged, replace it immediately.
- Aside from the routine maintenance described in this manual, do not try to service this equipment yourself. Do not make any adjustments other than those outlined in this manual, as you may in-validate the calibration or cause damage requiring extensive repair work. Refer servicing to qualified service personnel.

CHAPTER 2

FUNCTIONAL & TECHNICAL DESCRIPTION

FUNCTIONAL DESCRIPTION

The CRC®-712MH Radioisotope Dose Calibrator provides a precise, accurate, fast and very convenient method of measuring the activity of a radioisotope sample or radiopharmaceutical dose at the time and place of its application.

The CRC®-712MH Radioisotope Does Calibrator has been specifically designed for high activity radioisotopes measurements which are required for P.E.T centers, for radiopharmaceutical applications, research or other related activities.

When a sample of a known radioisotope or radiopharmaceutical dose is placed in the chamber well in the appropriate geometry and the proper calibration number is set, the activity of the sample will be displayed with the proper units on the Readout unit.

Note: *For a detailed description of the basic principles of the calibrator, see to APPENDIX I: PRINCIPLE OF THE CALIBRATOR.*

FEATURES

- Activity measurements are performed by state of the art electronic circuits in conjunction with a one atmosphere ionization chamber possessing extremely high sensitivity and stability.
- Curie or Becquerel units of measurement are selected by a rotary switch that can be locked in either position.
- An 8-button measurement range switch provides unambiguous manual selection or automatic selection of 6 activity measurement ranges. Manual range selection provides the shortest measurement time when numerous measurements are being taken in the same activity range. Automatic range selection provides the fastest measurement when the activity range of the sample is not known.
- Extra large 4-digit numeric readout display with a floating decimal point: 0.8” high (20 mm.). Back-lighted units of measurement symbols.
- Eight preset push-buttons are provided for quick selection of the calibration number of the most often used radioisotopes. The assignment of any of the eight push-buttons may be changed by the user for his or her particular requirements.
- Confirmation of the instrument functions and all the required adjustments can be made with fingertip operation. (Zero, Background, Bias Test)

- Reliable measurements with a resolution as low as .0001 millicuries (.01 mega-becquerels) and a top range of 80 Curies (2000 giga-becquerels) are provided for most radioisotopes.
- The calibration numbers for 12 radionuclides are provided in Appendix II of the owner's manual. The Calibration Potentiometer sets the gain for the specific radionuclide that is being measured. A 3-digit counter on the Potentiometer insures precise setting of the calibration number.
- The CRC®-712MH Model Calibrator can have a total of 5 remote Ionization Chambers connected to it. A 5 position Chamber Selector Switch is provided on the front panel of the calibrator to designate which remote Ionization Chamber is being used for the isotope measurement. After the initial CRC®-712MH order, additional Ionization Chambers may be installed by the customer up to the 5 chamber limit.
- The unique method of ion collection voltage application and the careful design of the instrument eliminates any possibility of shock hazard to the user.
- The 6cm diameter and 25cm deep Ionization Chamber well allows convenient measurements of virtually any radioisotope in clinical use, including whole generators.
- Critical positioning of the sample vial or corrections for container effects should not be required (except for X-ray, low energy γ-ray, or high energy β-ray emission dominant radioisotopes).
- The external shield of the Ionization Chamber protects users from exposure to intense radiation and reduces the effect from background radiation on low-level measurements. The optional Environmental Shield and Positron Shield lead ring sets are available to minimize the exposure received by the user during high level activity measurements.
- The Ionization Chamber sensitivity measurement and system calibration test were performed using Standards supplied by the U.S. National Institute of Standards and Technology (NIST) formerly the U.S. National Bureau of Standards (NBS).
- The use of the sealed 1 atmosphere chamber, filled with research grade pure argon gas, eliminates the need for temperature and barometric pressure corrections.
- The effects of the sample container, sample volume, and activity concentration are minimized by optimizing the counting geometries.

TECHNICAL DESCRIPTION

Warm Up Period

Approximately 30 minutes should be allowed for the instrument to stabilize. While the instrument is warming up, it is strongly recommended that you become familiar with the CRC®-712MH.

Note: *For optimum performance, the unit should be left powered at all times. This greatly reduces any errors that may be introduced by high humidity or low temperature and eliminates the wait of the required warm-up time (30 minutes)*

Environment Requirements

Operational

The instrument should be located where the level of the background radiation is as low and as constant as possible.

The instrument should be located where the temperature is stable within a range of +50°F to +85°F (+10°C to +30°C) and the maximum relative humidity is 90% non-condensing to warrant maximum reliability and accuracy.

The instrument should be located where the barometric pressure is within a range of 27 – 31 inches of mercury (91 – 105 kilopascals).

Storage

The instrument should be stored where the temperature is stable and the range is from +40°F to +115°F (+4°C to +43°C) and the maximum relative humidity is 90% non-condensing to warrant maximum reliability.

The instrument should be stored where the barometric pressure is within a range of 15 – 33 inches of mercury (51 – 112 kilopascals).

Note: *If these requirements are not followed, the instrument may display erroneous readings.*

Power Requirements

Line Voltage (Rear Panel Selectable)

90-130 VAC (Nominal 115 VAC), 50/60Hz, 0.11A, or
180-260 VAC (Nominal 230 VAC), 50/60Hz, 0.06A

Note: *For 230 volt application a NEMA type 6-15R 3 prong plug must be installed by the user.*

Circuit Protection

Power line filter, transient voltage suppresser, and power line fuse

Power Connector and Cable

A grounded 3-prong plug cord for the instrument that is approved for use at the user's site must be used.
Interconnection of devices must be made using the cables supplied with the instrument.

On/Off Switch

The on/off power switch (I = on, O = off) is located on the back of the instrument.

Dimensions

Readout

Height	15cm	(6in)
Width	32cm	(12.5in)
Depth	46cm	(18in)
Weight	6.8kg	(15lb)

Remote Chamber

Height	41.9cm	(16.5in)
Diameter	17.2cm	(6.76in)
Weight	13.6kg	(30lb)
Well Diameter	6.1cm	(2.4in)
Well Depth	25.4cm	(10.0in)
Cable Length	1.8m	(6ft)

Cables

Power	1.8m	(6ft)

Shielding (High Density)

Thickness	3.2mm	(1/8in)
Weight	9.1kg	(20lb)

Performance

Activity Range

There are six standard ranges whose full-scale values are as follows:

Curies	Becquerels
.1999 mCi	19.99 MBq
1.999 mCi	199.9 MBq
19.99 mCi	1.999 GBq
199.9 mCi	19.99 GBq
1.999 Ci	199.9 GBq
79.99 Ci	1999. GBq

Digital Readout

The activity measurement is displayed on a 4-digit, seven-segment (20mm. height) LED display with a floating decimal point. Measurement over-range is set for 80.00Ci (2000GBq) and is indicated by blanking of the display. Measurements above 20.00Ci (80GBq) have reduced accuracy and are indicated by display flashing. The analog to digital converter has an inherent uncertainty of, ±1 count on the least significant digit. The units of measurement are displayed as back-lighted measurement characters after the numeric display.

Iometer (Low Input Impedance Electrometer)

Accuracy: ±3% of reading.

Response time: 90% of full scale reading within 2 seconds for activity measurements of 2 millicuries (200GBq) or more.

Noise: RMS measurement fluctuations:
2 counts in the last digit for the top 3 mCi & Ci (GBq) ranges
6 counts in the last digit for 2mCi (20MBq) & 20mCi (200MBq & 2GBq) ranges
30 counts in the last digits of the .2000mCi (20MBq) range

Detector

Detector Linearity: chamber saturation 2% for 20Ci (740GBq) of Tc99m.

Detector Response: 25keV to 3MeV.
±2% of mean for radioisotopes with major photon radiation of over 0.1MeV (when chamber response is normalized for Co60 and Co57 radiations).

Shielding: Personnel Protection Shield of 3.2mm (1/8in) mechanically reinforced high density lead shielding; with 1Ci of Tc99m in the chamber, the exposure 50cm in front of the instrument is less than 0.5mR/min.

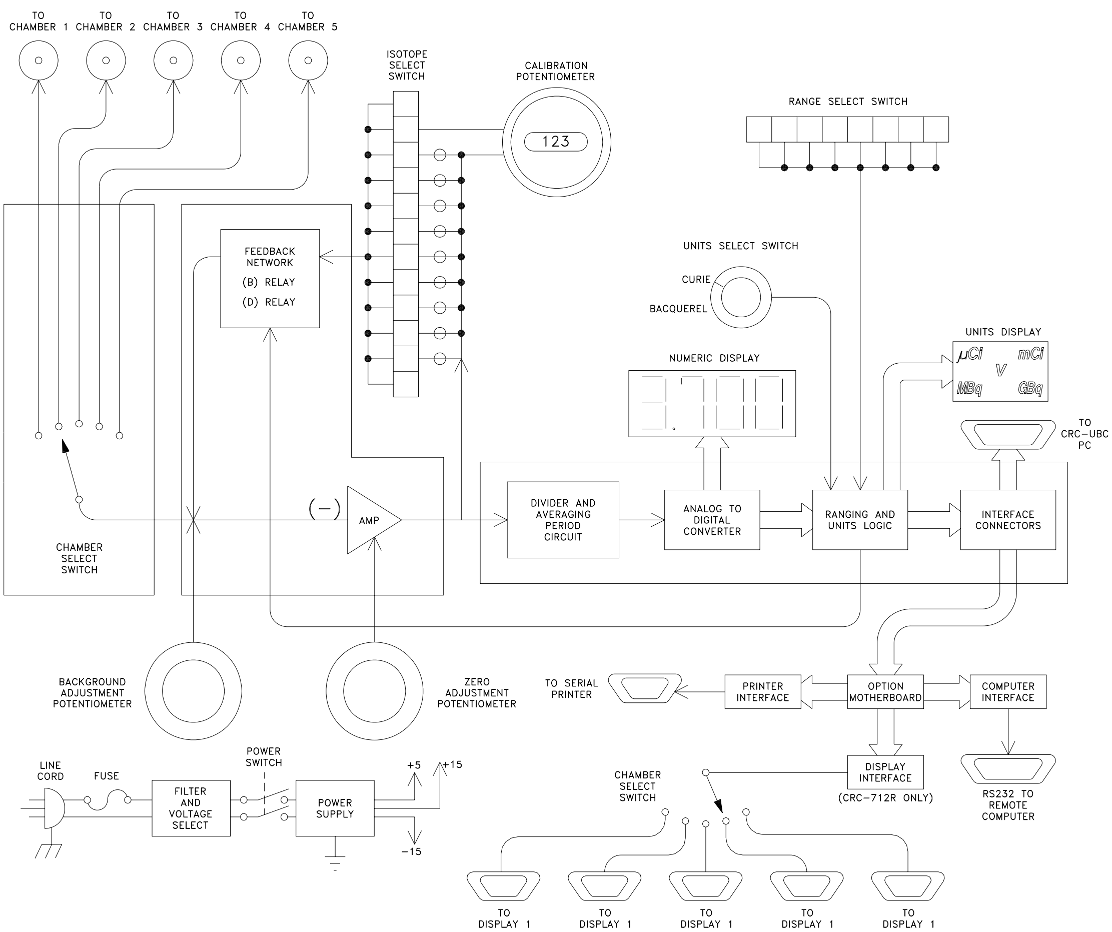
Overall Accuracy

Overall accuracy of the calibrator is determined by the accuracy of:

- specific source calibration
- chamber linearity and response
- iometer
- digital readout

Repeatability

Measurements will repeat to within, ±1% for a period of 24 hours during which time the instrument is maintained under constant temperature, humidity, and background radiation conditions, and is powered at all times.



Fig, 2-1 CRC®-712MH Simplified Block Diagram

CHAPTER 3

GENERAL OPERATING INSTRUCTIONS

GENERAL

This section describes the features and general operating procedures for the front panel controls and the back panel connectors.

PANEL DESCRIPTIONS

Front Panel

General selection and control functions are briefly described. The specific function of each control will be provided in the appropriate sections of this manual.

Range Selection Push-Buttons (A)

These 8 buttons manually or automatically set the activity measurement range. The display will be blanked if the push-button selected does not correspond to the units of measurement or if none of the push-buttons are selected. The correct measurement range will be automatically set if the **ZERO**, **BKG**, or **TEST** push-buttons are selected.

Digital Readout (B)

Chamber activity is presented to the operator on the four-digit, seven-segment numeric display and unit indicators. The placement of the decimal point and illumination of the proper units is done automatically. Blinking digits indicates an activity above the warning level. (Reference CHAPTER 2: FUNCTIONAL & TECHNICAL DESCRIPTION; SECTION: PERFORMANCE, DIGITAL READOUT)

TEST Push-Button (C)

When this button is pressed, the Ionization Chamber bias battery voltage is displayed. The reading should be between 140 and 180 volts. This also gives a general check of the system's functions.

ZERO Adjust (D)

This is a multi-turn potentiometer that compensates for the offset voltage of the amplifier in the chamber base. It is always active and therefore is equipped with a locking ring. Adjustments are made with the **ZERO** push-button depressed and the locking ring rotated counter-clockwise.

PRINT Push-Button (E)

When this button is pressed, the currently displayed activity measurement, units of measurement, selected isotope name, and the number of the Ionization Chamber selected is output serially from the calibrator.

Note: *The optional printer interface must be installed within the calibrator to obtain the above output data.*

Isotope Select Push-Buttons (F)

Eight preset calibration settings are provided for commonly used isotopes. These buttons are interlocked with the **BKG**, **OTHER**, **TEST** and **ZERO** push-buttons for one-at-a-time operation.

Background Adjust (G)

This multi-turn potentiometer electronically cancels the residual background activity detected by the Ionization Chamber. It is always active and therefore is equipped with a locking ring. Adjustments are made with the **BKG** push-button depressed and the locking ring rotated counter-clockwise.

Calibration for Other Isotopes (H)

To obtain a readout of any isotope, set this precision potentiometer to the calibration number for that isotope (obtained from the Calibration Card or the table in Appendix II) and press the **OTHER** push-button.

Calibration Card (I)

A list of calibration numbers for commonly used isotopes. Reference Appendix II for a more complete list of calibration numbers.

Curie or Becquerel Selector Switch (J)

Selects the units in which the activity will be displayed.

Chamber Select Switch (K)

A 5-position Chamber Selector Switch is provided on the front panel of the calibrator to designate which remote Ionization Chamber is being used for the isotope measurement.

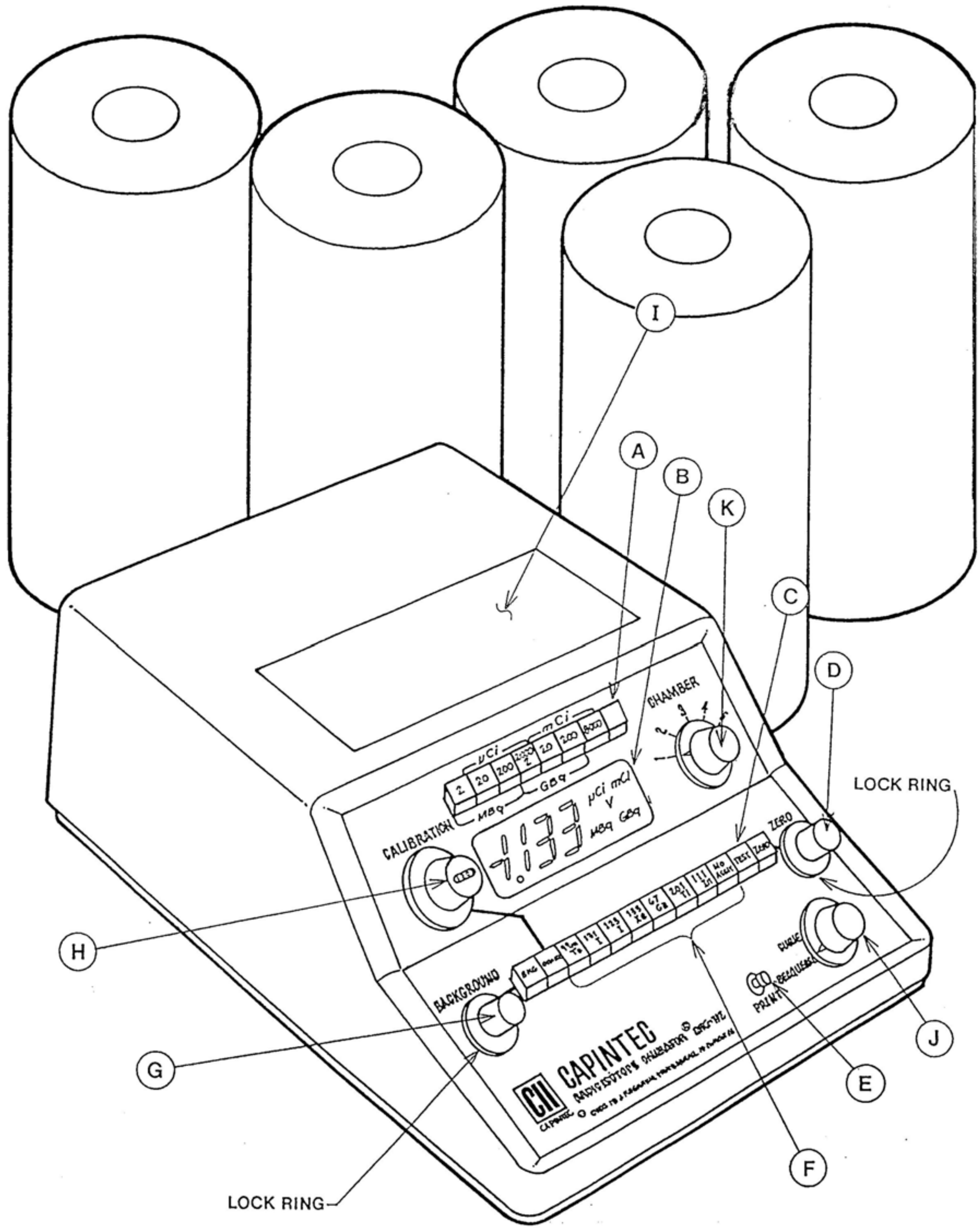


Figure 3-1 CRC-712MH Front Panel

Back Panel

Functional description of the features located on the back panel of the CRC®-712MH.

On/Off Switch

| = Power on position, ◯ = Power off position
For optimum performance, the unit should be left ON at all times.

Power Line (Mains) Connector

Provides connection for a power cord with a standard C-13 type receptacle. Attach the power cord provided for the appropriate line voltage.

Fuse

The primary circuit protection for the CRC®-712MH Readout unit. Replace only with 1/4 Amp Slow Blow fuse for 115 Volt power line or 1/8 Amp Slow Blow fuse for 220 Volt power line operation.

Line Voltage Selector

Must be set to indicate the correct power line voltage.

Locking Screw Storage

The Curie / Becquerel selector switch may be locked in either position to comply with local hospital operating procedures. This Screw is used to lock the selector switch in either position.

Remote Chamber Connector(s)

The CRC®-712M Model is provided with connectors for 5 remote Ionization Chambers.

Auxiliary Display Connector(s)

The CRC®-712M Model is provided with (5) connectors for 5 Remote Displays.

RS-232 Computer Interface Connector

Optional interface connector for the Computer Interface option.

Printer Connector

Optional interface connector for the Data Logging Printer option

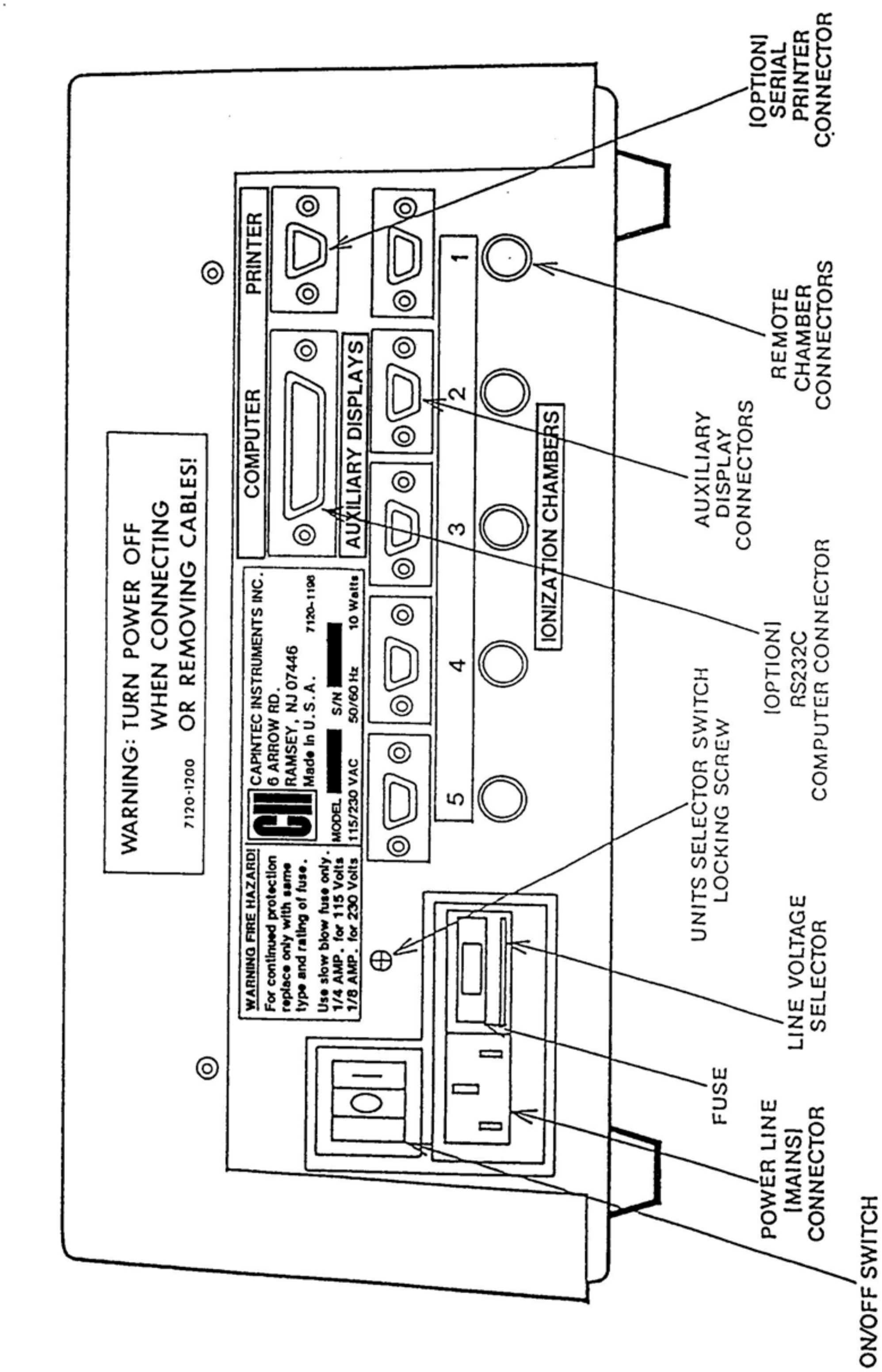


Figure 3-2 CRC-712MH Back Panel

CHAPTER 4

SYSTEM SETUP

GENERAL

Initial installation and checkout procedures are described in this section.

RECEIVING CONDITION EXAMINATION

Be sure to verify that the shipping carton is received in good condition, i.e., no damage should be visible and the box should be dry and clean.

Should the instrument be received in a damaged condition, save the shipping container and the packing material and request an immediate inspection by the carrier.

Capintec, Inc. is not responsible for the damage, which occurs during shipment but will make every effort to help obtain restitution from the carrier.

UNPACKING AND INSTALLATION

The instrument is packed and shipped as a complete unit. All the accessories and options are contained in their appropriate cartons. Optional equipment is shipped in separate cartons.

The instrument is shipped in a plastic bag in order to provide a dry and clean environment during shipment.

Remove all outer packing material and tapes. The shipping and packing material should be saved for future use. Be sure all tape and protective material is removed from the instrument prior to connecting to the power line.

The following equipment should be found upon unpacking the CRC®-712MH carton:

- Readout Unit
- Chamber
- Power Cord
- Owners Manual
- Chamber Well Liner
- Plastic Sample Holder

The following equipment should be found upon unpacking the optional Printer carton:

- Power Supply (If Roll printer ordered)
- Printer Ribbon
- Communications Cable
- Roll Paper (If Roll printer ordered)

Note: *If Test Sources are ordered, they will be shipped separately.*

ASSEMBLY

1. Verify that that the power switches for the Readout Unit and the printer are in the "OFF" or "0" position.

2. Connect the Chamber Cable(s) to the connector(s) at the rear of the CRC®-712MH Readout labeled "IONIZATION CHAMBER".

3. Attach the printer cable to the "PRINTER" Port connector at the rear of the CRC®-712MH Readout. Attach the other end to the Epson or Okidata printer.

4. For each printer type, verify that the correct paper is installed.

5. Attach the Power Cables to the Power Entry Module located on the back of the Readout Unit and to the printer (or power pack).

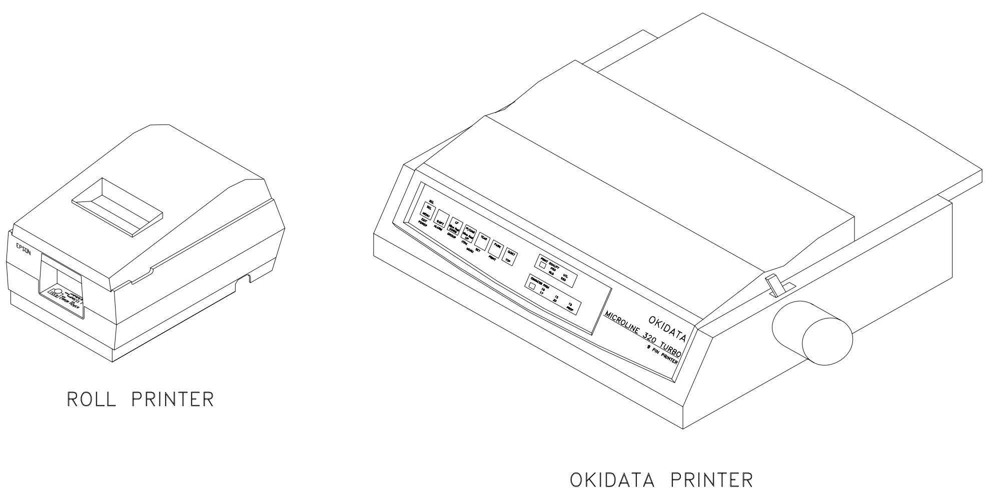


Figure 4-1 Printers

ENVIRONMENT REQUIREMENTS

The instrument should be located where the level of the background radiation is as low and as constant as possible.

The instrument should be located where the temperature is stable within a range of +50°F to +85°F (+10°C to +30°C) and the maximum relative humidity is 90% non-condensing to warrant maximum reliability and accuracy.

The instrument should be located where the barometric pressure is within a range of 27 – 31 inches of mercury (91 – 105 kilopascals).

CAUTION
If these environmental requirements are not followed,
the instrument may display erroneous readings.

POWER REQUIREMENTS

CAUTION
If the input voltage to the following items is not within the stated limits,
the unit may not function correctly or may be damaged.

Readout

Line Voltage (Rear Panel Selectable)

90-130 VAC (Nominal 115 VAC), 50/60Hz, 0.11A, or
180-260 VAC (Nominal 230 VAC), 50/60Hz, 0.06A

Note: *For 230 volt application a NEMA type 6-15R 3 prong plug must be installed by the user.*

Printers

Okidata Microline 320 (option)
120VAC, 60Hz, 900 mA or
230/240VAC, 50/60Hz, 500 mA

Epson TM-U200D Roll Printer (optional)
Input: 120VAC, 60Hz, 0.45A; ***Output***: 33VDC, 1.2A or
Input: 220VAC, 50/60Hz, 1.2A; ***Output***: +24VDC, 0.8A

INITIAL TURN ON PROCEDURES

1. Be sure the interconnecting cable from the Chamber assembly is properly plugged into the back of the Readout unit.
2. Confirm the power requirements of the instrument.
3. Be sure the power switch located at the rear of the unit is off.

CAUTION

Accidental connection of the power plug into a DC line or to an AC line that exceeds the specified voltage may result in damage to the instrument's circuits.

4. Plug the power cords into a grounded three-wire outlet of the specified power line.
5. Turn on the Readout using the power switch located at the rear of the unit.
6. Turn on the Printer or computer system.
7. The unit should now display numbers on the front panel.

   Note: *If numbers are not visible on the display, verify an Isotope push-button* ***and*** *a range button is selected.*

8. With an **optional printer** connected, press the **PRINT** button on the front panel and verify one line of "*measurement data*" is printed on the installed printer.
9. With a **computer connected**, start the communication program that is loaded on the computer.
   a. Select the "VT-100", "HyperTerminal", or other "generic" terminal emulation program.
   b. Use the "SETUP" menu to select the COM Port (1 or 2), 9600 Baud Rate, 1 Stop Bit, NO Parity Bit, and 8 Data Bits.
   c. Start the terminal emulation program on the computer.
   d. Set the "CAPS LOCK" key on the computer keyboard. ***ONLY CAPITAL LETTERS WILL BE RECOGNIZED***
   e. From the computer keyboard, type the letter **C** and verify one line of "*measurement data*" is displayed on the computer monitor.

If the communications program or the printer fails to operate, review the installation procedure in the Owners manual for the communication program or the printer.

If the problem persists, contact Capintec's Authorized Service Center for assistance.

ACCEPTANCE TESTING

For the initial Quality Assurance Acceptance Test, all of the quality assurance tests specified in CHAPTER 5: QUALITY ASSURANCE AND ACCEPTANCE TESTING; SECTION: ACCEPTANCE TESTING, ***MUST*** be performed before the CRC®-712MH can be used in normal operation.

GENERAL OPERATIONAL SETUP

Two configuration changes may be preferred or required for normal operation of the CRC®-712MH.

- **Locking** the Units of measurement in the Curie or Becquerel mode, and
- **Reassignment** of one or more of the preset isotope selection push-buttons.

Locking the Curie or Becquerel Mode of Operation

The CRC®-712MH provides radioisotope measurements in Curies (Ci) or Becquerels (Bq) as the selected units of measurement by the **CURIE / BECQUEREL** selector switch on the front panel of the instrument. This feature is particularly useful when a country is changing from the older unit of measurement the (Curies) to the currently recognized unit of measurement the (Becquerels). When this transition is complete, it may be desirable to permanently lock the selector switch in the Becquerel mode.

1. Facing the rear of the calibrator, locate the Unit's Selector Switch Locking Screw and remove it from its storage position (Refer to Figure 3-2).
2. Now moving to the front panel, rotate the Selector Switch to the desired unit of measurement.
3. Insert the locking screw and tighten. (Refer to Figure 4-2)

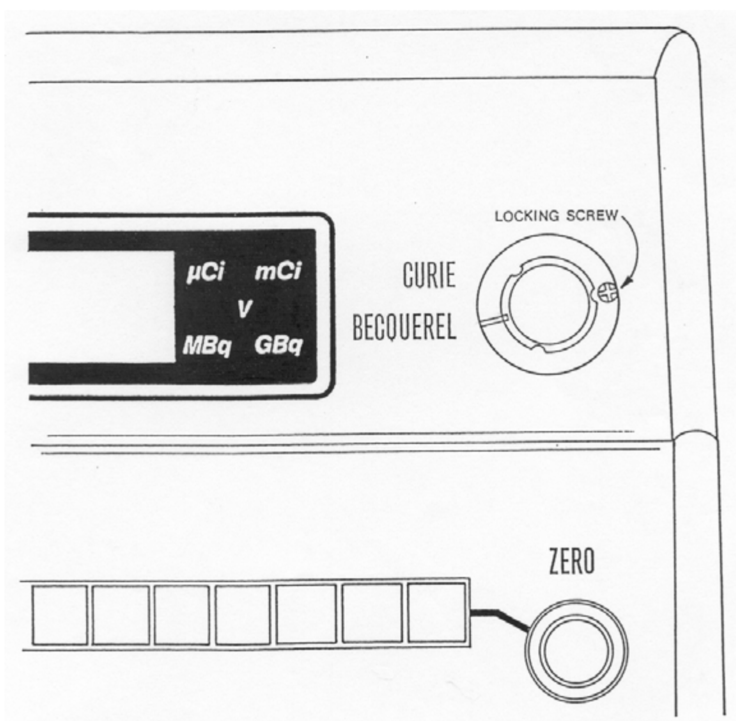


Figure 4-2

Reassignment of a Preset Push-Button

The calibrator provides eight preset radioisotope selection buttons for a quick setting of the most often used isotopes.

As users requirements are different for each nuclear medicine facility, the following procedure is provided to re-assign these preset buttons. (Refer to Figure 4-3).

1. Verify that the Zero and Background adjustments of the calibrator are within the specified limits. (Reference CHAPTER 5: QUALITY ASSURANCE AND ACCEPTANCE TESTING; SECTION: ACCEPTANCE TESTING.)
2. Press the **OTHER** push-button and set the Calibration Control to the calibration number assigned to the radioisotope being preset into the instrument. (obtained from the Calibration Card or the table in Appendix II)
3. Insert any radioisotope of substantial activity (enough to display 100µCi [3.7MBq] or higher; if possible, 0.5mCi [18.5MBq] or higher) into the calibrator well.
4. Record the activity displayed, including the decimal point and the units.
5. Remove the push-button being re-assigned by gripping it with pliers and pulling straight out.
6. Activate the switch being re-assigned by pressing the white “fingers” that held the button with a screwdriver.
7. With a small screwdriver, adjust the potentiometer directly above the button being re-assigned until the display coincides (to within, ±5%) with the activity recorded in Step 4.
8. Replace the re-assigned push-button with the correctly labeled button. (Replacement buttons are available from Capintec.)

Note: *If the RS-232 data-logging printer option is used, the program EPROM located in the readout unit will have to be changed. Consult Capintec’s Authorized Service Center concerning custom program EPROMs for the different isotope selections.*

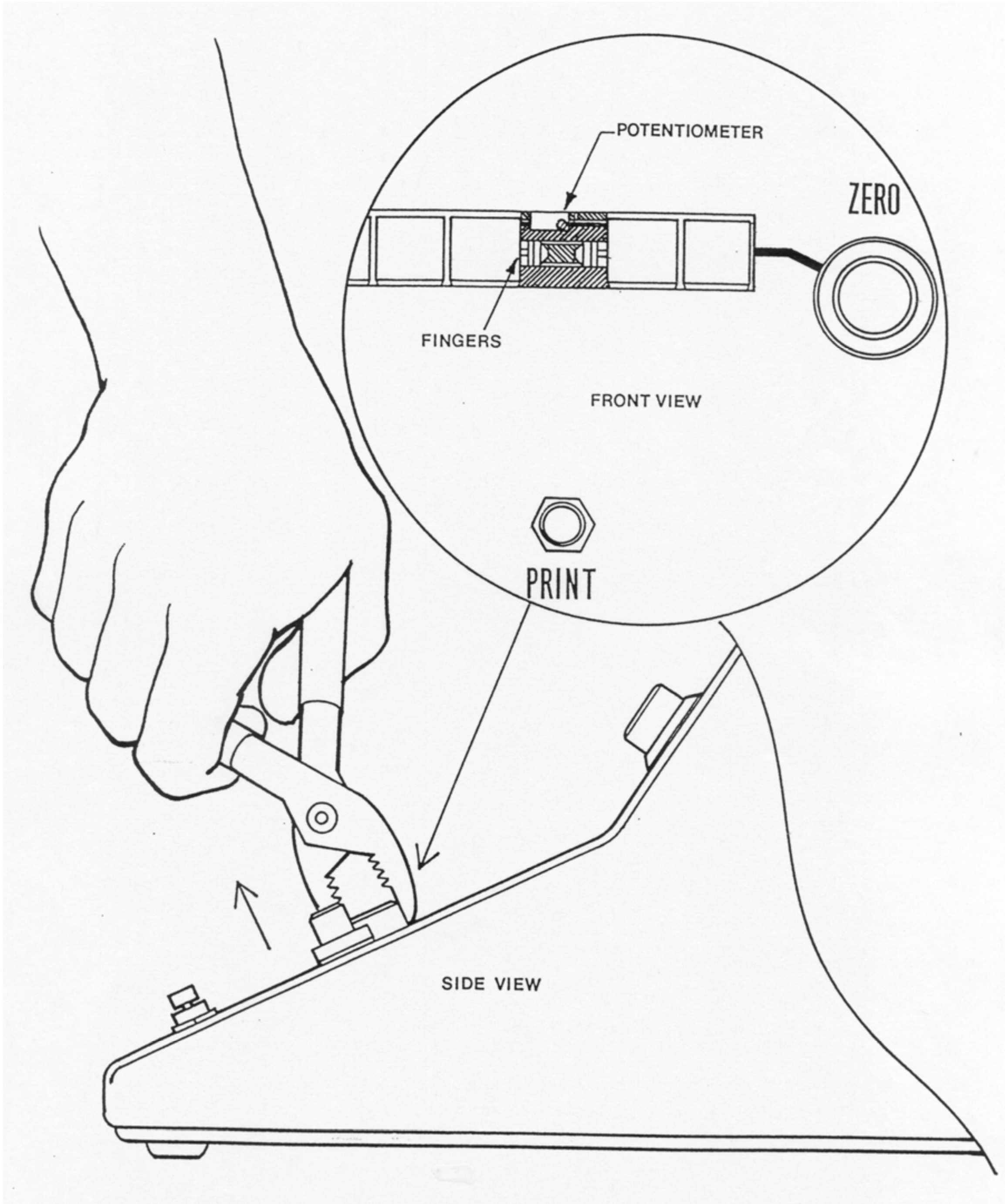


Figure 4-3

CHAPTER 5

QUALITY ASSURANCE & ACCEPTANCE TESTING

GENERAL

To insure proper operation of the CRC®-712MH, the following quality assurance tests should be preformed at the indicated intervals.

ACCEPTANCE TESTING

For the initial Quality Assurance Acceptance Test, all of the following tests must be preformed in the following order before the operational use of the CRC®-712MH in a nuclear medicine facility.

Geometry Test

The Geometry Test determines the effect of volume changes on the calibrator's accuracy.

This test should be performed using the syringe and container types used at your facility upon installation of the calibrator.

Daily Tests

The Daily Tests should be conducted at the beginning of each working day, prior to measuring any samples, which will be administered to patients. These tests consist of a Zero Adjustment, a Background Adjustment, an Instrument Functioning Test, a Contamination Test, and a Reference Source Test.

Zero Adjustment

This procedure should be performed at least once every day the instrument is used. The instrument zero should be verified (and adjusted if necessary) prior to each measurement.

1. Ensure that the instrument has been turned on for at least 30 minutes.
2. Press the **ZERO** push-button and verify that the display indicates zero within ±2 counts. If not, continue to Step 3.
3. Unlock the Zero Control Knob, adjust the zero control until the displayed reading is 0000 (±0002) and re-lock the control.

Background Adjustment

This procedure should be performed at least once every day the instrument is used. It is important to understand that this function does not provide a quantitative measurement of background radiation. The value indicated on the display when the **BKG** push-button is depressed is the relative change in background radiation since the last adjustment.

1. Ensure that there are no radioisotopes (especially the sample to be measured) or other radiation sources near the calibrator.
2. Press the **BKG** push-button and verify that the background level is satisfactory; if not, continue on with Step 3.
3. Unlock the Background Control Knob, adjust the background control until the displayed reading is 0000mCi (±0005) and re-lock the control.

Instrument Functioning Test (Battery Test)

1. Ensure that there are no unusual radiation sources near the instrument.
2. Press the **TEST** push-button. The display should indicate between 140 and 180 volts.

   Note: *On the CRC®-712MH, use the Chamber Selector Switch to verify the battery voltage for each chamber.*
3. Record the display reading.

The reading should be constant to within ±2 volts and never vary more than ±5 volts from one day to the next, under constant operating conditions. When the voltage decreases to below 140 volts the battery should be replaced.

Contamination Test (Sample Holder)

1. Remove the sample holder from the well.
2. Perform the Background Adjustment procedure.
3. Press the **OTHER** push-button and set the Calibration Control to **030**.
4. Insert the Sample Holder (empty) into the well and note the displayed reading.
5. If the reading exceeds .0010mCi (0.5MBq), the Sample Holder has been contaminated and should be replaced.
6. If the contamination is within allowable limits, perform the Background Adjustment (see step 2) to compensate for the activity of the Sample Holder.

Note: *The Chamber Well Liner should be tested similarly if contamination is suspected.*

CAUTION

Never use the calibrator without the well liner in place. Liners are inexpensive and easy to replace. A contaminated chamber is a very costly mistake. If the unit becomes contaminated remove the liner and clean the unit as stated in CHAPTER 7: CLEANING AND MAINTENANCE before operating.

Test with a Reference Source

It is recommended to use a source that has a long half-life such as Cs137 (approximately 100µCi [3.7MBq]) sealed in a plastic vial.

Always use the same Reference Source (i.e., Bench-mark Source).

1. Measure the activity of the Reference Source using the proper calibration setting and record the reading.
2. With the Reference Source in the calibrator well, press the eight preset isotope select buttons one by one and record the reading for each.
3. Press the **OTHER** push-button, set the Calibration Control to **112** and record the reading.
4. Set the Calibration Control to **990** and record the reading.
5. Similarly record the readings at all of the calibration settings of any radioisotopes, which are anticipated to be measured in the near future.

All readings should be consistent with previous readings to within ±2%. If a Cs137 Source is used as a Reference, the reading will decrease by 0.2% per month.

Quarterly Tests

The Quarterly Tests consist of:

- Daily Test
- Checking Preset Calibration
- Well Liner Contamination
- Linearity Test

Daily Tests

The normal Daily Tests as described above should be performed as a part of the Quarterly Tests.

Checking Preset Calibration

Any of the eight preset calibration numbers may be checked by the following procedure:

1. Verify that the Zero and Background Adjustments are within specifications.
2. Press the isotope push-button to be checked.
3. Insert a radioisotope of substantial activity (100µCi [3.7MBq] or higher) into the chamber well.
4. Record the displayed reading, including the decimal point and units.
5. Press the **OTHER** push-button.
6. Adjust the Calibration Control until the displayed reading coincides with the reading noted in Step 4.

7. Record the number appearing on the Calibration Control dial.

The number recorded in Step 7 should coincide with the calibration number assigned to the preset button used in Step 2. This can be checked by referring to the Calibration Card supplied with the unit or Appendix II of this manual.

Well Liner Contamination

The Ionization Chamber is protected from possible contamination by a plastic liner. This liner should be checked periodically for contamination (or any time it is suspect) in a similar manner to that detailed in the Contamination Test (Sample Holder) section.

Linearity Test

The linearity of the CRC®-712MH should be checked over the entire range of activities which are reasonably anticipated to be used. This can be done by any of several methods. The three most common methods are described below.

Decay Method

Start by measuring the activity of a sample of Tc99m or other nuclide of reasonably short half-life. The activity of the sample should be at least as large as the maximum assayed in normal use. At regular intervals, make repeated measurements of the same sample as it decays. Continue until the activity is below the minimum assayed in normal use.

CAUTION

Initially the activity of the Mo99 contamination in the sample will be insignificant compared to the activity of the Tc99m. However, Mo99 has a much longer half-life than Tc99m. If the test is continued down to very low levels, the activity of the Mo99 may become significant by the end of the test. If this is not taken into account, it may adversely affect the results of the test.

Sleeve Method

There are several manufacturers of sets of shielding “sleeves” that may be used for performing the linearity test. When testing by this method, follow the directions that come with the set. Be sure that you calibrate the sleeves first.

Proportional Method

The linearity can be confirmed by measuring the activity of a sample and then checking the activity of carefully measured portions of the sample. The activity of the initial sample should be at least as large as the maximum assayed in normal use. The ratio of the measured activities should be the same as the ratio of the measured weights or volumes. The weights or volumes must be measured to a degree of accuracy much greater than the expected linearity (i.e. ±0.5%)

Annual Tests

The Accuracy Test should be performed semi-annually (at least annually) to ensure the continued accuracy of the instrument.

Accuracy Test

The accuracy of the instrument should be verified using appropriate Reference Standard Sources such as Cs137, Co57 and Co60. The activity of these Standard Sources should be sufficient to obtain precise measurements at approximately those levels normally encountered.

The activity determined by the calibrator should coincide with the activity of the certified Reference Standard Source to within ±5%.

Should the activity reading for Co60 and/or Co57 be confirmed to be inaccurate by more than ±5%, the instrument should be repaired. Do not alter the system calibrations of the instrument unless the cause of the disagreement is found.

If the calibrator is used to determine a therapeutic dose for a patient, the accuracy of the measurement should be tested by all means possible.

CHAPTER 6

MEASUREMENT PROCEDURES

GENERAL

Instructions for the measurement of a radioisotope sample or a radiopharmaceutical dose are given in this section.

PRE-MEASUREMENT PROCEDURES

The Quality Assurance Daily Test needs to be performed each working day, prior to the measurement of any radioisotope sample or radiopharmaceutical dose that may be administered to a patient. The Daily Tests consist of the Zero Adjustment, the Background Adjustment, the Battery Test, the Contamination Test, and the Reference Source Test.

Refer to CHAPTER 5: QUALITY ASSURANCE AND ACCEPTANCE TESTING; SECTION: ACCEPTANCE TESTING to perform these test procedures.

PRESET ISOTOPE MEASUREMENT

The CRC®-712MH provides eight preset radioisotope selection buttons for a quick selection of the most often used isotopes.

As the user requirements are different for each nuclear medicine facility, the procedure to re-assign these preset buttons for other radioisotopes is provided in CHAPTER 4: SYSTEM SETUP; SECTION: REASSIGNMENT OF A PRESET PUSH-BUTTON.

To measure the activity of one of these 8 preset radioisotopes:

1. Verify that the Zero and Background adjustments of the calibrator are within the specified limits. (Reference CHAPTER 5: QUALITY ASSURANCE AND ACCEPTANCE TESTING; SECTION: ACCEPTANCE TESTING.)
2. Select the appropriate isotope and range push-buttons.

   Note: *If the activity range is not known, select the **AUTO-RANGE** push-button for the fastest measurement.*

   If numerous measurements are being made in the same activity range, select the specified range for the faster measurements.
3. Insert the sample into the Ionization Chamber well (with well liner), by means of the plastic Sample Holder.
4. Observe that the display stabilizes and the proper units are displayed.

5. Record the activity measurement on the appropriate form or press the **PRINT** button on the front panel to obtain a printout of the measurement (printer option required).

OTHER ISOTOPE MEASUREMENTS

The following procedure should be used for the other radioisotopes that do not have a preset push-button. This procedure may also be used to verify the accuracy of the preset radioisotopes.

1. Verify that the Zero and Background adjustments of the calibrator are within the specified limits. (Reference CHAPTER 5: QUALITY ASSURANCE AND ACCEPTANCE TESTING; SECTION: ACCEPTANCE TESTING.)
2. Locate the calibration number for the radioisotope to be measured, from the Calibration Card that is supplied with the unit or in Appendix II of this manual and make note of it.
3. Press the **OTHER** push-button.
4. Set the Calibration Control dial to the calibration number noted in Step 2. Select the appropriate activity range.

   Note: *If the activity range is not known, select the **AUTO-RANGE** push-button for the fastest measurement*

   If numerous measurements are being made in the same activity range, select the specified range for the faster measurements.
5. Insert the sample to be measured into the Ionization Chamber well by means of the plastic Sample Holder (dipper).
6. Observe that the display stabilizes and that the correct units are indicated.
7. Record the activity measurement on the appropriate form or press the **PRINT** button on the front panel to obtain a printout of the measurement (printer option required).

DOSE ASSAY PROCEDURE

Prior to administering a radiopharmaceutical dose to a patient, the following procedure should be performed.

1. Verify that the stock number and/or type of radiopharmaceutical agrees with what has been prescribed.
2. Determine the activity of the entire vial using the procedure in the PRESET ISOTOPE MEASUREMENT or OTHER ISOTOPE MEASUREMENTS section. Calculate the activity per unit volume. (It is assumed that the volume in the vial is known.)
3. Calculate the volume required for the prescribed radiopharmaceutical dose. If the dose is being prepared a significant time in advance of administration, the volume must be adjusted to compensate for half-life decay.

4. Withdraw the proper volume of the radiopharmaceutical into a syringe.
5. Place the filled syringe into the Ionization Chamber well and measure the activity. Verify that the measured activity corresponds to the desired radiopharmaceutical dose within the tolerance required for the particular procedure. (If necessary, adjust the amount of the radiopharmaceutical in the syringe to compensate for inaccuracies in step 2.)
6. If the syringe was prepared in advance, re-measure the activity in the syringe immediately prior to administration.
7. Ensure that the stock and/or the inventory information is updated.
8. Record the activity measurement on the appropriate form or press the **PRINT** button on the front panel to obtain a printout of the measurement (printer option required).

CAUTION

NEVER ADMINISTER A RADIOPHARMACEUTICAL TO A PATIENT WITHOUT MEASURING AND CONFIRMING THE ACTIVITY IMMEDIATELY PRIOR TO ADMINISTRATION.

ADDITIONAL CALIBRATION NUMBERS

Radioisotopes other than those whose calibration numbers are supplied by Capintec may also be measured by the calibrator. New calibration numbers may be derived by either “direct” calibration with Standard Reference Sources or by “intercomparison” of activity measurements using a standard 12 atmosphere CRC® Calibrator.

Direct Calibration with Certified Standard Sources

1. Verify that the Zero and Background adjustments of the calibrator are within the specified limits. (Reference CHAPTER 5: QUALITY ASSURANCE AND ACCEPTANCE TESTING; SECTION: ACCEPTANCE TESTING.)
2. Press the **OTHER** push-button.
3. Insert a Standard Source of the radioisotope whose calibration number is desired into the well. A Standard Source of 0.05 millicuries or stronger should be used.
4. Adjust the Calibration Control until the displayed activity matches the certified activity of the Standard Source.
5. Record the number appearing on the Calibration Control knob-dial. This number may now be used for all future measurements of the radioisotope of similar sample configuration.

Intercomparison Calibration with a 12 Atmosphere Chamber

1. Verify that the Zero and Background adjustments of the calibrator are within the specified limits. (Reference CHAPTER 5: QUALITY ASSURANCE AND ACCEPTANCE TESTING; SECTION: ACCEPTANCE TESTING.)
2. Insert a sample of the radioisotope, with adequate activity to display 100µCi or higher, into the chamber of the 12 atmosphere calibrator.
3. Select the **OTHER** push-button and adjust the Calibration Potentiometer to the value listed in Table II of the owner's manual for a standard CRC® Calibrator.
4. Record the displayed activity for the measured source.
5. Place the SAME source in the CRC®-712MH chamber.
6. Select the **OTHER** push-button and adjust the Calibration Control to obtain the same displayed activity as was recorded in step 4.
7. Record the number appearing on the Calibration Control knob-dial. This number may now be used for all future measurements of the radioisotope of similar sample configuration

PRINTING A RECORD OF THE MEASUREMENT

When an optional printer is connected to the CRC®-712MH readout, a printout of any current measurement may be obtain by pressing the **PRINT** button on the front panel of the readout unit.

CHAPTER 7

CLEANING AND MAINTENANCE

GENERAL

This chapter provides the information necessary for the user to perform the basic maintenance of instrument cleaning, fuse replacement, and general preventative maintenance. There are no internal adjustments or calibration settings that may be done by the user within the conditions of the warranty.

REFER ALL SERVICING TO A QUALIFIED SERVICE REPRESENTATIVE !

It is recommended that periodic (every five years) re-calibration of the CRC®-712MH be performed by Capintec's Authorized Service Center to guarantee the instrument's high reliability is maintained. Contact Capintec's Authorized Service Center in Pittsburgh for servicing or re-calibration at 1-800-227-6832.

CLEANING INSTRUCTIONS

WARNING !

TO AVOID ELECTRICAL SHOCK OR DAMAGING OF THE CRC®-712MH, NEVER GET WATER OR LIQUIDS INSIDE THE CHAMBER OR THE READOUT ENCLOSURE.

DO NOT USE AN AEROSOL DISPENSER TO SPRAY THE EQUIPMENT WITH ANY CLEANING SOLUTION OR LIQUID.

TO AVOID DAMAGING THE CASE OR DISPLAY SCREEN, DO NOT USE AROMATIC HYDROCARBONS, CHLORINATED SOLVENTS, OR METHANOL-BASED CLEANING SOLUTIONS.

If the CRC®-712MH Readout or Chamber requires cleaning, wipe down with a damp cloth; do not use solvents or aerosol cleaners.

For the printer (if included), refer to the printer owner's manual for proper cleaning procedures.

PREVENTATIVE MAINTENANCE

The Quality Assurance Tests described in CHAPTER 5: QUALITY ASSURANCE & ACCEPTANCE TESTING should be performed periodically as stated.

Tests must be performed in an environment where the temperature is stable within a range of +50°F to +85°F (+10°C to +30°C) and the maximum relative humidity is 90% non-condensing. The unit should be powered-up for at least one-half hour prior to performing any measurements. No other precautions need to be observed.

> ***CAUTION***
> *If these environmental requirements are not followed,*
> *the instrument may display erroneous readings.*

If the unit fails to pass any of the tests, the user **should not** attempt to perform any adjustments to the system. In this event, please contact Capintec for further assistance.

The Quality Assurance tests should be immediately performed if:

- The equipment has been subjected to extreme physical stress,
- Liquids enter the readout unit, and/or chamber, or
- Any cable shows signs of damage

SERVICING

The system is covered by a one year limited warranty, under normal conditions of use.

Other than the Readout Unit fuses (see LINE VOLTAGE SELECTION/FUSE REPLACEMENT in this chapter), there are no user serviceable parts contained in the system.

Every five years, the system should be returned to Capintec's Authorized Service Center for a complete verification.

CAPINTEC, Inc.
620 Alpha Drive
Pittsburgh, PA 15238
Phone (412) 963-1988, 1-800-227-6832
Fax (412) 963-0610

LINE VOLTAGE SELECTION/FUSE REPLACEMENT

Readout Fuses

> ***CAUTION***
> *For continued protection, replace only with*
> *same type and rating of fuse(s)*

The CRC®-712MH can be set to operate from either a nominal 115 volt or a nominal 230 volt AC power line. To check or change the setting: (refer to Figure 7-1)

1. Turn off the CRC®-712MH power switch and unplug the line cord from the power entry module.
2. Slide the clear plastic door to the left.
3. Pull the FUSE PULL lever and remove the fuse.
4. The number which is visible is the present setting.
5. To change the setting, use a small pair of pliers or a wire bent into a hook and remove the card. Rotate the card so that the desired voltage will be readable, and push the card back into place.
6. Install a fuse with the type and rating that is specified for the selected line voltage and slide the clear plastic door to the right.
    a. For the 115 volt power line, use a 1/4 Amp slow-blow type fuse.
    b. For the 230 volt power line, use a 1/8 Amp slow-blow type fuse.
7. Install a power cord that is specified for the selected line voltage.
    a. For the 115 volt power line, use a detachable power cord with a NEMA type 5-15R 3 prong plug similar to Belden 17250.
    b. For the 230 volt power line, use a detachable power cord with a NEMA type 6-15R 3 prong plug similar to Belden 17566.
8. Verify the CRC®-712MH System is functioning correctly by performing the Daily Test as specified in CHAPTER 5: QUALITY ASSURANCE & ACCEPTANCE TESTING.

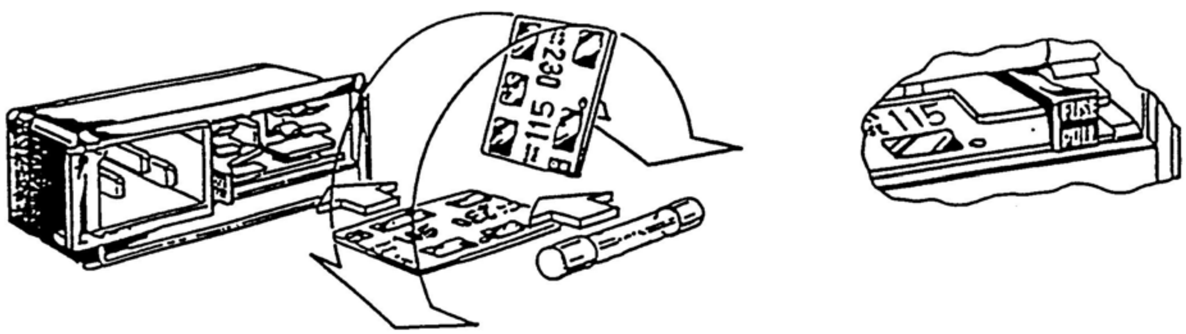


Figure 7-1

Printer Fuse

The printer fuse is not accessible from the outside of the printer case and must be replaced by a qualified service representative.

TROUBLESHOOTING

Some problems may be very easy to diagnose and correct in the field with little or no equipment. If a problem should occur, check here before you call for service. You may be able to save a considerable amount of time and money.

Nothing appears on the display

- Make sure calibrator is plugged into a live outlet and is turned on.
- Check fuse and replace if necessary. See: LINE VOLTAGE SELECTION/FUSE REPLACEMENT.

High background indication

- Chamber Well, liner, or dipper may have become contaminated. See: CHAPTER 5: QUALITY ASSURANCE & ACCEPTANCE TESTING, SECTION: CONTAMINATION TEST.
- Background may actually be high. Check by removing the dipper and placing a lead sheet over the top of the well.

Indication of significant negative activity

- Zero setting or Background level may have changed. Perform the Daily Test. See: CHAPTER 5: QUALITY ASSURANCE & ACCEPTANCE TESTING.

Printer will not respond

- Make sure printer is plugged into a live outlet, turned on, and “selected”.
- Make sure that either paper or a ticket is in the paper path.

ACCESSORIES AND REPLACEMENT PARTS

The following accessories and replacement parts are available from Capintec. Call Capintec's Authorized Service Center at 1-800-227-6832 for answers to your questions or to place an order.

- Dose Calibrator Reference Sources...CALL
- Shielded products for PET..CALL
- Calicheck Linearity Test Kit 5120-2144
- Ionization Chamber Well Inserts (liners).......................................7300-2004
- Plastic Sample Holders (dippers) 7300-2005
- Environmental Shield..7300-2450
- Flush Mount Mounting Flange 7310-2307
- Shielded Platform with 2mm shielded glass 5150-3010
- Shielded Platform with 4mm shielded glass 5150-3011
- Dosilift™ remote lowering/raising of syringes or vials 5120-2175
- Okidata 320 with Serial Board and cable 5110-1150
- Okidata 184 with Serial Board and cable 5430-0017
- Epson Roll Printer and cable. 5430-0058
- Printer Ribbons..CALL
- Additional copies of Owner's Manual 9250-0050
- Replacement 150 volt lithium battery 0500-2019

Note: *Circuit diagrams, component parts lists, descriptions and calibration instructions are available to appropriately qualified personnel.*

Environmental Shield

A set of eight, 4.1 cm (1.7 in.) thick lead rings that surround the chamber and reduce the effects of background radiation by more than a factor of 10.

Positron Shield

A set of eight, 6 cm (2.4 in.) thick lead rings that provide additional shielding for PET applications.

Hot Cell Chamber Mounting Flange

When the Capintec Ionization Chamber is used in a Laboratory Hot Cell, it is frequently advantageous to mount the chamber under an opening in the floor of the Hot Cell. For this application, Capintec provides a special mounting flange for the Ionization Chamber that matches the mounting hole provided in a Laboratory Hot Cell.

Data Logging Printer

The data logging printer option uses the RS-232C communication protocol with a serial printer and the print push-button as a simple measurement logging system. When the print button is pushed the current information displayed on the calibrator is printed. This option consists of a serial printer, cables, and an interface PC board.

RS-232C Computer Interface

The computer interface option is capable of outputting data to any computer with a standard RS-232C communication port. The measurement data can be had in 4 different formats and used as needed for different programming applications. As examples; the calibrator data can be used for dose computation or isotope inventory control. This option consists of a calibrator internal cable, an interface PC board, and a demonstration program disk.

Calicheck

A kit of 7 attenuating sleeves designed to perform the activity linearity test on a dose calibrator quickly and accurately. Each sleeve is coded with a colored band for identification. Each lead- lined sleeve varies in the thickness of lead so as to simulate various stages of radioactive decay.

SHIPPING

If for any reason the CRC®-712MH must be returned to Capintec, the shipping carton must contain the following or equivalent labeling as shown in Figure 7-2 and Figure 7-3. Label stipulating the maximum environmental conditions for safe storage and shipment.

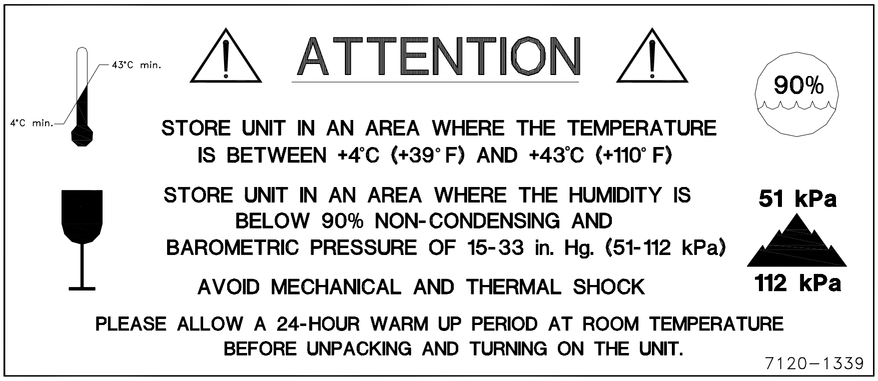


Figure 7-2

Figure 7-3

In order to ship this product, all appropriate Department of Transportation (DOT) and, if shipped by air, the International Aviation and Transportation Administration (IATA) requirements for the shipment of the pressurized (12 Atmosphere) Ionization Chamber Detector must be met.

APPENDIX I

PRINCIPLE OF THE CALIBRATOR

GENERAL

The definition of activity, the basic principle of the calibrator, and the detailed discussion on the calibration are presented in this section.

DEFINITION OF ACTIVITY

ACTIVITY

Activity is defined as:

The activity, A, of a quantity of a radioactive nuclide is the quotient of dN by dt, where dN is the number of spontaneous nuclear transformations which occur in this quantity in time interval dt.

$$A = \frac{dN}{dt}$$

The special unit of activity is Curie (Ci):

$1 \text{ Ci} = 3.7 \times 10^{10}$ s^{-1} (exactly)

Note: *The term “nuclear transformation” is meant to designate a change of nuclide of an isomeric transition. (ICRU REPORT 19, 1971)*

The SI (International System of Units) unit for activity is the reciprocal second, s^{-1}, and is named the Becquerel (Bq), i.e.;

1 Bq = 1 Nuclear Transformation per second

$1 \text{ Ci} = 3.7 \times 10^{10}$ Bq

Types of Transformations

α-decay

The nucleus emits a helium nucleus (α-particle).

Electron Capture (ε-decay)

The nucleus captures one of its own orbital electrons, usually from the K shell, and a neutrino is emitted.

β^- Decay

The nucleus emits an electron (β^- particle), and a neutrino.

β^+ decay

The nucleus emits a positron (β^+ particle) and a neutrino.

Nuclear Transition

A photon (electromagnetic radiation, γ-decay), electron (Internal Conversion Electron Emission, CE or electron-positron pair (Internal-pair emission, e±) is emitted by a nucleus in a transition from a higher to lower energy state. No nuclear transformation occurs if there is no change in the atomic number or the mass number. The de-excitation of a nucleus in its unstable state (metastable state) is, however, included in the definition of activity.

MEASUREMENT OF ACTIVITY

A Nuclear Transformation is always associated with one or more of the following types of radiation:

α, β^+, β^- and γ Photons

We can, therefore, measure activity by detecting one or more of the above radiations.

α-Particle Radiation

The most energetic α-particle emitted by a radionuclide has an energy of less than 10 MeV, which corresponds to a range of about 10 mg/cm^2 (8 cm in air). Because of its short range, an α-particle from a radionuclide cannot penetrate to the Ionization Chamber's sensitive volume and therefore, cannot be detected.

All α-decays, however, are accompanied by photon radiation as the daughter nucleus decays to its ground state. The activity of a nuclide that decays through a radiation can therefore, be measured by detecting the associated photon radiation.

β^+ Radiation

β^+ particle (positron) emitted from a nucleus comes to rest in the media by losing its kinetic energy mainly by direct ionization processes and then annihilates with an electron to produce two photons of 511 keV each. These photons are easily detected by the ionization chamber. De-excitation photons are also associated with β^+ decay.

β^- Radiation

The ejected electron loses kinetic energy in matter mainly by direct ionization.

The range of most emitted β's is very short. It should be noted that in β^+ and β^- emission, the emitted electron or positron has a continuous energy spectrum, which ranges from E_{max} to zero, where E_{max} is the maximum transition energy. β-rays (with the exception of a small portion of very high energy βs) will be stopped in the sample, in the chamber liner, and in the chamber wall.

As the electron decelerates, it also produces continuous low energy photon emission called Bremsstrahlung (stopping or braking radiation).

Many radionuclides which decay by β emission also emit de-excitation photons (x-rays, γ-rays), which can be detected by the ionization chamber.

Electron Capture

The actual electron capture process cannot be detected since the electron is not emitted but is captured by the nucleus. The capture of the orbital electron, however, leaves a vacancy in the atomic orbital shell, resulting in x-rays as the atom de-excites.

The energy of k x-ray is approximately

$$E_k \cong \frac{Z^2}{100} \quad \text{[keV]}$$

where Z is the atomic number of the daughter nucleus.

γ-rays are also often given off as the daughter nucleus de-excites.

Photon Radiation

Photon radiation is associated with most nuclear transformations. A high-energy photon interacts with matter very weakly. Photon intensity is therefore, not altered substantially by the surrounding media, i.e., measurement of activity can be accomplished with a minimum of disturbance from the sample configuration.

As can be seen from the above, in all cases we are detecting photons. We will therefore, discuss photons and their interactions with matter in detail.

PHOTONS

Photon is the general term for a quantum of radiation. Photons are classified according to their method of production.

γ-Rays

Photons resulting from nuclear transitions, nuclear reaction or annihilation of particles (e.g., electron-positron annihilation) are called Gamma-rays (γ-rays). Radioisotope sources (radionuclides) are the most common means of γ-ray production. Radioisotope γ-sources emit photons of one or more discrete energies.

X-Rays

X-rays are associated with the deceleration of electrons or with orbital electron transitions in atoms.

The radiation from a γ-source is often accompanied by characteristic x-rays from transitions of the orbital electrons in the daughter atom.

Bremsstrahlung

When very fast electrons are brought to rest in a medium (or pass through media) a continuous low energy photon spectrum occurs. This is called Bremsstrahlung (“stopping or braking radiation”).

The intensity and the energy spectrum of Bremsstrahlung are highly dependent upon the source configuration and media surrounding the sample. (See Appendix of this manual for more detailed discussion on Bremsstrahlung.)

In this manual, the term photon will be used when the method of production of the radiation has no bearing on the discussion.

Interactions of Photons with Matter

There are three mechanisms by which photons can interact with matter and, thus, deposit their energy. These mechanisms are: Photoelectric effect, Compton effect, and, pair production. The energy of the photon determines which process (or processes) is possible.

Photoelectric Effect

The photoelectric effect is an interaction between a photon and an electron that is bound to an atom. In the photoelectric process, the photon is absorbed by the atom and a bound electron is ejected. The kinetic energy of the ejected electron is equal to the photon energy minus the binding energy of the electron. The binding energy of an electron is the energy that must be supplied in order to remove the electron from the atom.

In nuclear medicine, we are interested in photon energies of 20 keV or greater. At these energies, all the electrons in the materials used for the chambers are able to participate in the photoelectric process. The photoelectric effect is the most important process at low energies. However, for photon energies much greater than electron binding energies, the processes described below become more important and the number of photoelectric interactions occurring becomes small. At a given energy, the number of photoelectric interactions per unit mass varies as the 4th power of the atomic number and is inversely proportional to the atomic weight of the medium (Z^4/A).

Compton Effect

The Compton Effect is a collision between a photon and an electron that can be considered unbound. An electron can be considered to be unbound (or “free”) if the energy of the incident photon is much greater than the binding energy of the electron. The kinetic energy of the scattered electron is not constant, but is a function of the angle through which it is scattered. The scattered photon must interact again in order to impart all of its energy to the medium.

The Compton effect is the dominant process for photon energies from 100 keV to about 10 MeV in the region of the atomic numbers for detector materials. At 100 keV, the maximum kinetic energy of the scattered electron is about 30 per cent of that of the incident photon; at 1 MeV, it is about 80 per cent; and at 10 MeV, it is about 98 per cent. The number of Compton interactions per unit mass varies directly as the atomic number and inversely as the atomic weight of the medium (Z/A).

Pair Production

The process of pair production is difficult to comprehend because it is strictly a relativistic quantum mechanical effect. What is observed to take place, is that in the presence of the electric field of a nucleus, the incident photon disappears and an electron and a positron appear. (A positron is a particle with the same properties as an electron, except that it has a positive charge.)

In order to produce an electron-positron pair, the incident photon must have an energy of at least twice the mass of an electron, i.e., 1.022 MeV. This process dominates for very high energies, that is, above about 10 MeV. The number of pair production interactions per unit mass is proportional to the square of the atomic number and inversely proportional to the
atomic weight of the medium (Z^2/A).

IONIZATION CHAMBER MEASURING PROCESS

An ionization chamber consists of two or more electrodes. The electrodes confine a volume of gas and collect the charge (ions) produced by radiation within the volume. Thus, ionization chambers can be used to measure radiation fields if the relationship between the radiation field and the charge produced is known.

The radiation enters the chamber through the chamber wall and interacts with the gas in the chamber or with the chamber wall. It must be pointed out that photons cannot produce ionization directly, but must first interact with the chamber material (gas and wall) producing electrons. That is, through a series of interactions, the photon transfers its energy to one or more electrons.

The electron is slowed down through collisions with the chamber gas (argon). The collisions knock electrons off the molecules producing positive ions (this is the ionization process).

The collection voltage across the chamber sets up an electric field. The positive ions will drift towards the negative electrode and the electron (and negative ions if they are formed) will drift towards the positive electrode, thus producing a current. The electronic circuitry then measures either the current or the total charge produced during the period of interest.

The number of ions produced in the chamber is directly related to the energy deposited in the chamber by the radiation.

DETERMINING CALIBRATION SETTING NUMBERS

A method of determining a calibration setting number is described in this section.[1]

RESPONSE and Sensitivity

It is very convenient to express the response of the detector to a radioisotope, A, relative to that of a standard reference material, e.g. Co60.

$$R_A \equiv \frac{\left(\dfrac{\text{Detector Output due to Sample A}}{\text{Activity of Sample A}}\right)}{\left(\dfrac{\text{Detector Output due to SRM Co60}}{\text{Certified Activity of SRM Co60}}\right)} \qquad (1)$$

The sensitivity of the detector for a photon of energy E_i is defined as:

$$S_i \equiv \frac{\text{Detector Output due to } 3.7\times10^{10} \text{ Photons of } E_i}{\text{Dtector Output due to one Curie of Co-60}} \qquad (2)$$

The detector response and the sensitivity have the following relation:

$$R_i \equiv \sum_i I_i S_i \qquad (3)$$

Where I_i is the intensity of the photon whose energy is E_i.

The procedure is to measure the response of the detector to all the available primary standard samples and to establish the sensitivity of the detector as a function of photon energy so as to satisfy equation (3) for all standards.

Once the sensitivity curve has been determined, the response of the detector to any radioisotope may be calculated using equation (3), provided that the decay data are known.

[1] See Suzuki, A., Suzuki M.N., and Weis A.M.: Analysis of a Radioisotope Calibrator; Journal of Nuclear Medicine Technology, Dec. 1976 for more detailed discussions.

The sensitivity curve of the high range 1 atmosphere Ionization Chamber is under development. As Calibration Numbers are determined, users will be updated.

Detailed Discussions

Effects of the Integral Shield

The advantage of the shield is the reduction of radiation exposure to the personnel handling the radioisotopes, as well as reduction of the background effects on the activity measurements.

It is important to note, however, that if a shield is placed around or near a calibrator, the sensitivity of the ionization chamber is enhanced due to backscattering of photons by the shielding. Above about 250 keV, the scattering of photons is mainly forward and at the low energy region, attenuation of photons by the outer wall of the chamber becomes significant. For a CRC® calibrator the backscattering effects are more significant for photons of energies between 70 keV and 250 keV than photons in other energy regions.

Effects of the Container

The radioactive standard materials in the ampoules now being provided by NIST are a good approximation to an assay of a radiopharmaceutical in a plastic syringe or in a glass syringe (a wall thickness of about 1.2 mm), even for radioisotopes that decay with a significant abundance of low-energy photons.

The user should select, whenever possible, a standardized procedure, volume, and container for all radioactivity measurements. The plastic syringe is convenient since it represents the delivery vehicle to the patient in most clinical situations.

Significant errors will occur in some instances, e.g., if the radioisotope is assayed in an appreciably different material and/or wall thickness than that of the standards.

The ampoules of recently available standards from NIST are uniform. Plastic syringes also have a rather uniform wall thickness and absorption is low. However, a random sampling of 5, 10, 25, 50, and 125ml size multi-injection dose vials from several sources indicated that the wall thickness varied randomly from 1 to 3 mm quite independently of the volume of glass vial.

The assay of radioisotopes having a significant abundance of low- energy gamma-, x-, and/or high-energy beta-ray radiation may be affected by changes in the sample configuration used to assay the radio-pharmaceutical if the samples are severely different from the standard source. In such cases, an independent check or determination of a calibration appropriate to a user's needs is advised. Fortunately, most radioisotopes can be accurately assayed independently of the sample size.

The radioisotopes most sensitive to source configuration and type of container are I125 and Xe133. Other radioisotopes that fall into this category are I123, Y169, Tl201, and other radioisotopes that decay with significant low-energy photon emission. It is not unusual to have a required correction factor of 2 if I125 is measured in a glass vial.

Effects of Impurities

An Ionization chamber itself does not have intrinsic energy- discrimination capability. The presence of radioisotope impurities will affect the reading of the instrument unless the effect of impurities is eliminated by photon filtration as is done with Mo99 breakthrough in Tc99m. However, the presence of low-level radionuclide impurity does not negate the usefulness of a radioisotope calibrator, if the user is aware of its presence and has an independently determined calibration including photons arising from the impurities.

APPENDIX II

TABLE OF CALIBRATION SETTING NUMBERS

CALIBRATION SETTING NUMBERS

The Calibration Setting Numbers in Table II are applicable to the Capintec Radioisotope Calibrator only for measurement of isotopes in NIST standard source ampoule geometry. Special configurations for Brachytherapy source measurements are listed in Table III.

If the calibration setting number is followed by a multiplication sign "×" or a division sign "÷" and a number, the meter reading with the Calibration Potentiometer Setting must be multiplied or divided by the number following the sign.

If the sample contains radioactive impurities, the meter indication will always be higher than the actual activity of the principal isotope. It will not, however, be the total activity of the principal isotope and the impurities.

If a Radium Needle is measured, the reading will be lower than the true activity in the needle due to the shielding effects (filtration) of the needle. To estimate the true activity in a needle, increase the reading obtained with a calibration number for Ra226 (790) by 2% for each 0.1mm of platinum wall thickness. For example, add 10% to the reading for a 0.5mm wall platinum needle and add 20% to the reading for a 1.0mm wall platinum needle to estimate the true radium activity.

ABBREVIATIONS USED IN TABLE II

Abbreviation	Meaning	Abbreviation	Meaning
eqb.	equilibrium	D	days
S	seconds	Y	years
H	hours	E	exponentiation, i.e.,
M	minutes		$3E5 = 3 \times 10^5$

UNCERTAINTY DUE TO SYRINGE CORRECTION

The Calibration Setting Numbers are given for approximately 5 grams of radioactive solution in a standard source ampoule made of about 0.6mm thick borosilicate glass. The standard radioactive source in the ampoule is, however, a good approximation for a radiopharmaceutical in a plastic syringe or a glass syringe (wall thickness about 1.2mm) for most radioisotopes.

In general, the attenuation of radiation by a plastic syringe is less than for the standard ampoule, while for most glass syringes, the attenuation will be greater than for the standard ampoule.

The anticipated syringe corrections are listed on Table II under the column "Uncertainty Due to Syringe Correction". For example, the required correction for I125 activity is estimated to be about ±25%. This means that you should add 25% to the meter reading if the I125 is in a glass syringe or subtract 25% if it is in a plastic syringe.

Since the attenuation of low energy radiation is very dependent upon the material of the container, the value given in the syringe correction column should be used mainly as a guide giving relative magnitude.

If a measurement of activity in a glass vial is anticipated, the container correction for low energy γ and/or x-ray emitting isotopes will be substantial. It could be about 3 to 5 times that for a syringe.

If no value is given in this column, the correction is not significant, except for a container differing greatly from the standard ampoule (e.g. Very thick glass container, vial made of glass which contains lead, etc.).

UNCERTAINTY DUE TO PUBLISHED DATA

This is the uncertainty on the value of the activity. From calibration numbers calculated from decay data, the uncertainty given is calculated using only the reported errors on the intensity of the γ and/or x-rays. For calibration numbers measured from NIST (formally NBS) standard reference materials (known as SRM's), the uncertainty given is the reported uncertainty on the activity of the SRM. For these numbers, the reference is given as NIST, and year of source.

HALF-LIFE

The number before the letter is the value of the half-life. The number following the letter is the reported uncertainty on the half-life.

Examples:

12.34	D1	means	12.34	days	±0.01	days
12.34	D11	means	12.34	days	±0.11	days
12.340	D1	means	12.340	days	±0.001	days
1.234	D1	means	1.234	days	±0.001	days

REFERENCES

This is the source of the data from which the calibration number was calculated. NIST, or NBS means that the calibration number was obtained by measuring a standard reference material (SRM).

NM75 (Nuclear Medicine 75): L.T. Dillman and F.C. Von Der Lage, Radionuclide Decay Schemes and Nuclear Parameters for Use in Radiation-Dose Estimation. NM/MIRD Pamphlet No. 10, 1975.

NDT70: M.J. Martin and P.H. Blichert-Toft. Radioactive Atoms: Auger-Electrons, α-, β-, γ-, and x-Ray Data. Nuclear Data Tables A, Vol. 8, Nos.1, 2. October, 1970

NCRP-58: National Council on Radiation Protection and Measurement, Report No. 58¸ A HANDBOOK OF RADIOACTIVITY MEASUREMENTS PROCEDURE.

K & S Associates Inc. Accredited Dosimetry Calibration Laboratory

TABLE I

CAL CARD

CRC®-______ Serial No. _________ Tested: ___/___/___ By: ____

Isotopes	Cal. Setting	Isotopes	Cal. Setting
Co-57	112	I-131	201
Co-60	990	Ba-133	555
Ga-67	113	Xe-133	194
Mo-99		Cs-137	260
Tc-99m	96	Tl-201	160
In-111	313	Ra-226	790
I-123	286		

These Cal Settings apply to the High Range and the Extra High Range Dose Calibrators **ONLY**.

The calibration numbers given in this table were obtained by intercomparison with NBS reference source measurements in a standard range dose calibrator having a 12 atmosphere chamber and a high range dose calibrator having a 1 atmosphere chamber. See Manual for details. 7120-1256

TABLE II

LISTING OF CALIBRATION NUMBERS FOR MEASUREMENT OF SOURCES IN NIST STANDARD SOURCE AMPOULE GEOMETRY.

CAUTION: The calibration numbers that are listed in this table with NIST reference were determined by direct measurement with NIST standard sources. The calibration numbers given in this table with NBS reference were obtained by intercomparison of a radionuclide source measurement in a standard range dose calibrator having a 12 atmosphere chamber and a high range dose calibrator having a 1 atmosphere chamber. However, no warranty of any kind can be made as to their accuracy, since there are many other uncontrollable factors (as well as the accuracy of the published data) involved in the determination of the overall accuracy of an assay. See previous sections of this manual for a discussion of some of the conditions under which the calibration numbers are valid.

Radioisotopes		Calibration Setting Number	Uncertainty Due To		Half-Life (NCRP-58)	Ref.	Comments
			Syringe Corr. %	Published Data %			
Co57	Cobalt	112		1.9	271.7 D 2	NIST91	
Co60	Cobalt	990		1.0	5.2714 Y 5	NIST90	
Ga67	Gallium	113		1.4	3.261 D 1	NBS78	*INTERCOMPARISON
Mo99	Molybdenum				65.92 H 2	NBS78	*INTERCOMPARISON
Tc99m	Technetium	96		2.0	6.007 H 1	NBS76	*INTERCOMPARISON
In111	Indium	313	10	1.36	2.805 D 1	NBS77	*INTERCOMPARISON
I123	Iodine	286	15	1.9	13.221 H 3	NBS77	*INTERCOMPARISON
I131	Iodine	201		1.65	8.021 D 1	NIST93	
Ba133	Barium	555	10	1.3	10.5 Y 1	NIST78	
Xe133	Xenon	194	12	1.95	5.243 D 1	NBS76	*INTERCOMPARISON
Cs137	Cesium	260		2.0	30.0 Y 2	NIST89	
Tl201	Thallium	160	2	2.0	72.91 H 2	NBS76	*INTERCOMPARISON
Ra226	Radium	790		0.5	1600 Y 7	NBS73	*INTERCOMPARISON

TABLE III

ADDITIONAL CALIBRATION NUMBERS THAT HAVE BEEN MEASURED FOR THE FOLLOWING 5 BRACHYTHERAPHY SOURCE CONFIGURATIONS.

One or more of the following sources were used to calibrate the CRC® one atmosphere chamber by the K & S Associates Inc.

ID	Isotope	Capsule	Mfgr	Description Lot / NIST uncertainty	Exposure Conversion Factor (mR•m^2)/(mCi•Hr)	Nominal Calibration Number
1	Cs137	20mm x 33mm dia st. steel	3M	Tube #6502(6D6C) NIST uncertainty=2%	0.3275	
2	I125	4.5mm x 0.8mm dia.	3M	#6702 (resin bead) NIST uncertainty=5%	0.145	
3	I125	4.5mm x 0.8mm dia	3M	#6711 (silver wire) NIST uncertainty=6%	0.145	
4	Ir192	3mm x 0.5mm dia st. steel	Best Industries	Seed in ribbon NIST uncertainty=2%	0.4596	
5	HDR Ir192	4mm x 1.1mm dia st. steel	Nucletron Mallinckrodt	ISO C53211 Welded to cable NIST Traceable uncertainty=2%	0.4596	

The exposure conversion factor for Iridium and Iodine are those quoted by the manufacturer.

APPENDIX III

MULTIPLICATION FACTORS FOR NON-EQUILIBRIUM RADIOISOTOPES

The activity in a non-equilibrium sample can be determined by using the following equation:

$$\text{Activity of "A"} = \frac{\text{Meter Reading with Cal. Number for Pure "A"}}{1 + F\dfrac{T_A}{T_A - T_B}\left[1 - \exp\left(-\dfrac{T_A - T_B}{T_A \times T_B} \times t \times 1n2\right)\right]\dfrac{R_B}{R_A}}$$

where “A” and “B” are parent and daughter nuclide respectively, T's are half lives, and R_A and R_B are the chamber responses to the isotopes A and B, “t” is the elapsed time after the pure parent isotope was produced, and “F” is the decay branching ratio.

The chamber response,”R,” may be obtained from the calibration number “N,” using the following equation:

$$R = \frac{N}{1075.8} + 0.0797$$

When the half-life of the parent nucleus (T_A) is much shorter than that of the daughter nucleus (T_R), the parent decays down to the daughter. After about 10 × T_A, we can assume that only the daughter is left (except if the original activity of the parent was exceptionally high). The equation above for the Activity of “A” can be used to obtain the activity of the parent while it has measurable activity.

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NEW PRODUCT WARRANTY

Conditions and Limitations

CAPINTEC warrants our products to be free from defects in material and workmanship for a period of 12 months after delivery to the original buyer (unless indicated otherwise). Our obligation under this warranty is limited to servicing or adjusting products returned to our factory for that purpose promptly upon any claim under this warranty, provided our examination discloses to our satisfaction that the affected parts were originally defective and have not been subjected to misuse, abuse, mishandling or improper operation. This warranty extends to every part of the product except batteries, fuses, ink, magnetic storage media, toner, transistors, tubes or any other normally consumable item. In no event shall we liable for transportation, installation, adjustment or any other expenses which may arise in connection with such products or their servicing or adjustment.

This warranty is expressly in lieu of any other express or implied warranties, and we make no warranty that the products sold herein are merchantable or are suitable for any particular purpose. The benefits of this warranty shall extend only to the buyer and to none other. We shall have no liability of any nature arising out of the use or application of the product in conformity with this warranty. If the product shall fail to perform in conformity with the warranty made herein, we shall be liable solely for the repair and replacement of the product as provided hereinabove, and shall have no other liability in respect of such failure or performance, or any consequences therefrom, including, without limitation, business impairment or loss, personal injury or property damage.

No agent, employee, or representative of ours has any authority to bind us to any representation or warranty concerning the product sold herein, and unless a representation or warranty made by an agent, employee or representative is specifically included herein, it shall not be enforceable by the buyer. No waiver, alteration or modification of the foregoing conditions shall be valid, unless made in writing and signed by an executive officer of our corporation.