



GE Medical Systems

P.O. Box 414, NB-917
Milwaukee, WI 53201-0414

17 March, 2000

NRC
Materials Safety Branch, Division of Industrial and Medical Nuclear Safety
White Flint North MS78F5
11545 Rockville Pike
Rockville, MD 20852

Dear Mr. Reviewer,

It is the intention of GE Medical Systems to market the Attenuation Correction Option (CoDe AC) for use on their dual head Nuclear Medicine Imaging Systems "Millenium VG gamma camera.

The application follows the format of the guide Consolidated Guidance about Materials Licenses: application for Sealed Source and device Evaluation Registration - NUREG-1556 Vol.3 dated July 1998.

A handwritten signature in cursive script that reads "James E. Beebe".

James E. Beebe, Ph.D.
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Dear Mr. Reviewer

It is intention of GE Medical Systems to market the Attenuation Correction Option (CoDe AC) for use on their dual head Nuclear Medicine Imaging Systems (*Millenium* VG gamma camera).

This option includes a collimator that incorporates a ^{137}Cs inside, the radiation is controlled by a On/Off mechanism which is a part of the collimator.

This application is submitted for the purposes of the NRC conducting a radiation safety evaluation and for registration of this device, which is designed to contain by-product material.

The information contained within this application follows the format of the guide Consolidated Guidance about Materials Licenses: Application for Sealed Source and Device Evaluation and Registration - NUREG-1556 Vol. 3 dated on July 1998.

Kindly contact me if you have any questions in this report.

Sincerely,

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Notes:

1. The pages in the application letter are numbered sequentially (19 pages).
2. The pages in appendixes A to I are numbered starting with the letter of the appendix, followed by the sequential page number.
3. The pages in Appendix B have a footer title 'Direction 2250060-100 Rev. A'
4. The pages in Appendix C have a footer title 'Direction 2250061-100 Rev. A'

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DEVICE TYPE: Attenuation Correction System

MODEL: CoDe AC Collimator Unit P/N **ASM000745**

MANUFACTURER: ELGEMS Ltd.

Mail Address: P.O.Box 170 - Tirat Hacarmel 30200 - ISRAEL

Location: Hayozma St. 10 -Tirat Hacarmel 30200 – ISRAEL

DISTRIBUTOR: GE Medical Systems
3000 North Grand View Blvd.
Waukesha, WI 53188
USA

SEALED SOURCE

MODEL DESIGNATION: 34-5-1

Manufactured by:

Isotope Products Laboratories

1800 Keystone Street

Burbank, California 91504

ISOTOPE:

MAXIMUM ACTIVITY

Cs¹³⁷

18x0.833 mCi = 15 mCi (0.55 GBq) ± 10%

LEAK TEST FREQUENCY: 6 Months

PRINCIPAL USE: (B) Medical Radiography

CUSTOM DEVICE : YES NO

CUSTOM USER: N/A - This device is not specifically designed or constructed to the order of a single licensee.

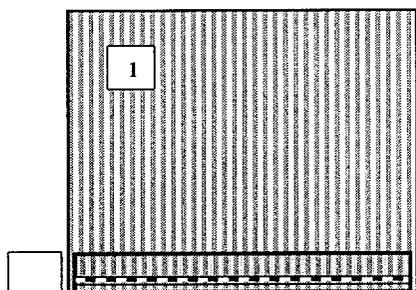
DEVICE TYPE: Attenuation Correction System

DESCRIPTION:

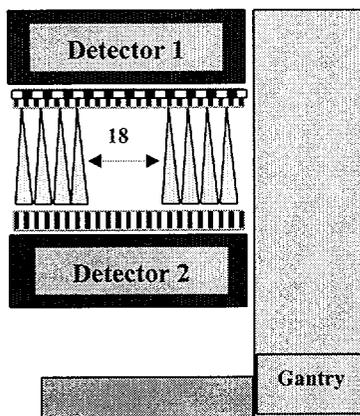
Introduction:

The purpose of this option is to provide attenuation information for a gamma camera operating in PET mode (coincidence mode). This information permits to reduce the body attenuation effect on the reconstructed image. The transmission source included in this device is a ^{137}Cs multipoint sources including 18 points of 0.833 mCi activity each, giving a total activity of 15 mCi.

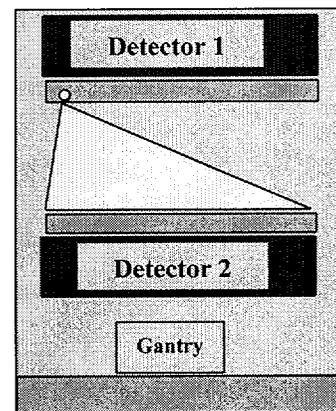
In Coincidence mode a septa collimator is used to reduce scattered and randoms events and to reduce the angles of incidence. The CoDe AC option is inserted in the septa collimator. It is a two parts Tungsten block, which contains the shielding, the sources, the collimation and the On/Off mechanism.



Face view of the septa collimator (1) with the source tungsten housing and the multipoint transmission line source (2).



Side view of the two detectors, the radiation field of each of the 18 collimated point sources and the two septa collimators on the detectors.



Face view of the two detectors, the fan beam radiation field profile and the two septa collimators on the detectors.

The septa collimator can be dismantled from the camera using a collimator cart, similar to other gamma camera collimators. The septa collimator is either mounted in the camera or it is stored on the collimator cart in the restricted area.

Detail of construction

The source used in the CoDe AC option is formed of 18 points sources with a total activity of 15 mCi, which are sealed in a high-grade 300 series Stainless Steel cylindrical tube, and positioned at fixed distances from each other in the tube. Between each point source there is an internal Tungsten shielding. Two Tungsten end pieces are affixed to the source by means of cement on one side and a spring pin on the other side. The Stainless Steel

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tube is inserted in a Tungsten block housing. This Tungsten block is formed of two main parts. The upper side of the Tungsten block source housing functions both as a shielding material and well as a collimator. The bottom side of the Tungsten block functions as a shielding material, preventing radiation leak and reducing background count rate on the supporting detector. The assembled parts form a rectangular block of 40.0 cm (length) x 6.3 cm (width) x 7.7 cm (height).

A third Lead part surround the two Tungsten parts and maintain the whole device to the septa collimator.

The upper side of the Tungsten housing has 25-mm thickness and the bottom side has 43-mm thickness.

The Tungsten material is a mixture of 95% Tungsten with density of 18.0 gr/cm³ + 5% of a mixture of Nickel and Iron. The effective Tungsten density for attenuation calculation is $\sim 0.95 \times 18.0 = 17.1$ gr/cm³ (not including the low attenuation coefficient of the 5% of Nickel and Iron).

Three screws maintain the two parts together and also to the Lead surrounding part. Four other screws maintain the surrounding Lead part to the septa collimator. The two end sides of the Tungsten block housing are formed of Tungsten preventing radiation leak. The device is an integral part of the septa collimator and requests no changes in the different interfacing parts of the septa collimator.

The device is positioned at the edge of the septa collimator (see the left face view of the above schematic drawing). The 18 collimated point sources create 18 asymmetric fan beams in the transverse plane of the gamma camera (see the right face view of the schematic drawing), covering exactly the opposite detector field of view. The 18 collimated point sources create narrow beams in the perpendicular plane (see central schematic drawing above). The Tungsten collimator opening determines the axial resolution and the spacing between the point sources determines the sampling uniformity (see the central drawing above). These two parameters define the overlap of the radiation profile.

The exposure of the multipoint sources is done manually without electrical power. The operator will push the push-button and the multipoint source will move by 1.07 cm, passing from the shielded position (between the Tungsten collimator openings) to the exposed position (under each 2.5 mm Tungsten collimator openings). The motion of the line source compress a spring. The source can be released from the exposed position to the shielded position at any time without electrical requirement. The compressed spring will push it back. In case of failure manual release is possible (see latter the radiation safety).

The product material is usually non-corrosive like Tungsten and Lead for shielding, and Stainless Steel in other parts

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Reference:

Details of construction, material and dimension can be found in Appendix A: Engineering Drawings p A-1, A-2.

Details of Assembly methods, QC and integrity verification can be found in Appendix I: Quality Assurance Program, Assembly and QC Test Instruction.

Description of radiation safety.

The source of the CoDe AC option is a ^{137}Cs long-lived collimated source. The source is formed out of 18 equally spaced point sources with a total maximal activity of 15 mCi (0.55 GBq). The 18 discrete ^{137}Cs ceramic elements are potted into a Tungsten core which is then welded into a high-grade 300 series cylindrical Stainless Steel tube. The active portion of the source is, in effect, triplely encapsulated. First the activity is encapsulated in ceramic. Then the ceramic elements are sealed into a Tungsten rod (internal shielding). Finally, the assembly is placed into the Stainless Steel tube. The ceramic encapsulation into the Tungsten rod provides additional mechanical resistance. Two Tungsten end pieces are affixed to the source by means of cement on one side and a spring pin on the other side.

This line of point sources is inserted into a Tungsten housing, which serves as a collimator for the radiation, as a shielding element, as a part of the On/Off mechanism and as a construction part.

When the line of point sources is manually shifted by 1.07 cm, each point source will be under the collimator opening, and when the line of point sources is shifted back by 1.07 cm, each point source will be shielded by the 25 mm Tungsten of the upper Tungsten block.

When the device is in use and the source exposed, the active area of the device is only the front part. The radiation dose in this case is 15 mR/h at a distance of 5 cm. When the source is not exposed the radiation dose is 3 mR/h at a distance of 5 cm.

The patient integrated dose coming from the option is 1 mRem for a complete scan of 36 minutes, which includes the transmission and the emission scan time (report name: Patient Exposure Test). The operator dose for a working day is 0.2 mRem, and for the installation is 0.03 mRem (report name: Radiation Exposure for Worker and Other Personnel).

The status indications are the following: a blinking LED will change his blinking color depending on the status of the source (blinking red for open position and blinking green for close position). Warning messages, which describe the source status will be displayed on the gantry display unit and on the computer monitor of the gamma camera (see "description of the on-off indicators and on-off mechanism").

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Warning label (see "label") are positioned on the side of the septa collimator and can be seen from any direction.

Reference:

Radiation leak information can be found in Appendix F: Radiation measurement.

Source information in Appendix D: Source NRC registration.

Status indication and warning label see latter "description of the on-off indicators and the on-off mechanism" and "label".

Securing the multipoint line source in the device:

The Tungsten housing is formed of two parts assembly like a sandwich, which are held together and to the surrounding frame by three screws. The line of 18 sealed point sources is inserted in a specific position, between the two parts. When the two parts are assembled the line is blocked in the Tungsten housing and cannot be extracted without dismounting the two main parts of the Tungsten housing. The upper part of the Tungsten housing is used for shielding or for collimation, depending on the point sources position (under or not the 2.5 mm opening). The sources are collimated with 18 parallel openings of 2.5 mm width and 25 mm height, spaced by 21 mm. The openings are created in the upper part of the Tungsten source housing in a conical form with an angle of 43 degrees.

The lower part is a plain block of Tungsten that is used for shielding purposes only. The thickness is 43 mm.

The CoDe AC unit is assembled inside the septa collimator by 4 screws that secure the device to the septa collimator frame.

The two-end flanges of the Tungsten housing are made of Tungsten. Two screws and a pin guide secure each end flanges.

Reference :

Appendix A, Engineering Drawings: p A-2,...,A-4

Appendix C, Service Manual: p 3-3, 3-4.

Radiation safety during installation of the device:

The source used in the CoDe AC option is a ^{137}Cs long lived source (30 years half life) and no exchange of the source is needed during the 10 years working life of the option.

The source supplier (IPL) will insert the ^{137}Cs multipoint line source in the CoDe AC Tungsten housing. The CoDe AC device will be sent by the source supplier (IPL) to the site in a shockproof package class A. The source position will be secured by two plastic bands which will prevent the motion of the multipoint line source in the Tungsten housing. This in addition to the spring, positioned at the end of the multipoint line source and which prevents the motion of the source from the close position to the exposed

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position. Two service personals will opened the CoDe AC shockproof package and checked the radiation level in the front direction. The maximal radiation level should be no more than 5 ± 0.5 mR/h at a distance of 5 cm from the front surface. They will remove the securing plastic bands, insert the option in the septa collimator and secure them by four screws. During the installation the integrated radiation dose will be 0.03 mRem (report name: Radiation Exposure for Worker and Other Personnel).

Reference:

Appendix C, Service Manual: chapter 1 and 3.

Description of the On-Off mechanism and On-Off indicators.

On-Off mechanism:

The On-Off mechanism of the option is completely manual and normally close. Change of the source position from close position to exposed position, does not request any electrical power. The motion of the multipoint line source is secured by a locker in order to prevent an unintentional exposition of the sources. For the activation of the system, the operator needs to open the locker located on the line source push-button with a special key. The push-button and only the push-button permits the motion of the multipoint line source. The sources are shifted by the operators by 1.07 cm, compressing a spring positioned at the end of the multipoint line source. The line moves from the initial position, between two adjacent openings and under the 25 mm of Tungsten shielding (the upper part of the Tungsten housing), to the exposed position, exactly under the openings. The shift is done until a lever (the release handle) locks the pin connected to the multipoint line source in this position. The shifted line source compresses a spring positioned at the end of the line source. The spring is intended to shift back the line source to the initial position when the operator releases the line source using the release handle. At this stage each point source will be positioned again between adjacent openings. The design of the option and the design of the multipoint line source permit a total motion of only 1.1 cm. The design constrains the starting motion position of each point source to be exactly between adjacent openings, under the 25 mm Tungsten shielding. A screw positioned at the end of the Tungsten housing calibrates the motion path to 1.07 cm. This calibration is needed to position the point sources just under the 2.5 mm openings, in exposed position.

When the septa collimator is removed from the camera and stored on the collimator cart, an additional mechanical stopper positioned on the collimator cart prohibits the inadvertently activation of the source.

In case of malfunction, the line source can be shifted back manually, using the source calibration position screw to push it back.

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Reference:

Appendix A, Engineering Drawing: p A-2, A-4, A-5, A-6.

Appendix B, Operation Manual: chapter 4, p 4-2.

Appendix C, Service Manual: chapter 3, p 3-3, ... , 3-10.

On-Off indicators

The indication is made in several ways:

1. Battery operated LED indicator for the multipoint line source position (red = exposed, green = closed). The LED is positioned on the side, and can be seen continuously by the operator, when the system is on the camera and when the system is on the collimator cart.
This independent and self-powered LED indication will be always activated, when the collimator is on the cart and when the collimator is on the camera.
The source position will be indicated by illuminating in blinking red for source in open position, and blinking green for source in closed position. When the push-button is pressed, and the multipoint source moves, a micro-switch is pressed from the third millimeter of this path. This micro-switch switches between the illumination options (blinking red or blinking green). The micro-switch is connected to the end of the Tungsten housing by two screws. A pin connected to the end side of the multipoint line source will press the micro-switch when the operators push the source from the closed position to the exposed position.
2. Indication on Acquisition station of the position of the multipoint source.
This indication receives its power through the gantry while the Septa collimator that contains the option is loaded onto the detector. When the CoDe AC option is activated a warning message appears on the Acquisition Station, which serves as the user interface to the gantry acquisition functionality only:

**Warning !
Transmission source is open**

3. When the CoDe AC option is activated and the transmission scan start, there is a blinking message on the gantry display unit:

**SOURCE
OPEN**

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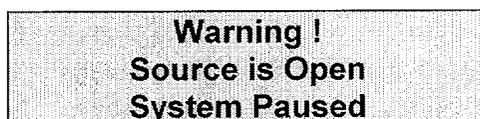
This message warns the operator that the source is open. If the acquisition is stopped or completed the warning message will be displayed on the screen till the user closes the source.

4. If the source is activated during other acquisition protocols, the system is paused and a warning message will be displayed on the gantry display unit:



A rectangular box with a black border containing the text "SOURCE" on the top line and "OPEN" on the bottom line, both in bold, uppercase letters.

And on the acquisition station monitor:



A rectangular box with a black border containing the text "Warning !" on the top line, "Source is Open" on the second line, and "System Paused" on the third line, all in bold, uppercase letters.

Reference :

Appendix A, Engineering Drawings: p A-5, A-6.

Appendix B, Operation Manual: p 4-2, 4-3.

Appendix C, Service Manual: p 3-10.

Source position mechanism:

The radiation beam is shielded by 25 mm of Tungsten when the multipoint line source is positioned in the closed position. The operator has to open the locker of the push button with a special key, and to push this push-button, which is concentric with the long axis of the multipoint line source. The release-handle hold back the pin which is connected to the multipoint line source end. At this stage the source is exposed. This motion compresses a spring, which will shift back the multipoint line source to the closed position, when the operator will presses the release handle.

In case of malfunction the multipoint line source could be shifted back manually, using the position calibration screw.

No electrical power is needed to expose or to close the multipoint line source of the CoDe AC option.

The radiation beam is accessible for human exposure when the multipoint line source is exposed.

Reference :

Appendix A, Engineering Drawings: p A-2.

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Testing for proper operation of On-Off mechanism and indicator.

See paragraph d) "Description of the on-off mechanism and on-off indicators". The On-Off mechanism is completely manual and does not require electrical power. In this case, test of the proper operation of the mechanism will be done automatically each time the operator activates the source. The operator had to push the line of point source with the push button till the release handle hold the source in the open position. In case of malfunction the operator will not be able to mechanically activate the source and to hold the source in the open position. The release handle can hold the source in the open position only if the source complete the full path of the motion (1.07 cm). When the operator will close the source he will press on the release handle, the source will be shifted back, pushing the push button back to the initial position. The blinking LED will change its color from red (open) to green (close). In case of partial back motion the blinking LED will not change its color, and the source will be considered as exposed.

Reliability and diagnostic test:

The report on the life test of the On-Off mechanism can be found in appendix G "Prototype Testing". The test was operated by a pneumatic push mechanism for a total life cycles of 62500 On/Off cycles (much higher then the total working life cycles which are calculated for 10 patients a day, during 365 days each year, and during 10 years, which is 36500 On/Off cycles). The data sheet of the micro-switch, which switches between the blinking LED color can be found in appendix G "Prototype Testing".

Reference:

Appendix C: Service Manual p. 3-10

Appendix G: Prototype testing p. G-24, ..., G-26.

Radioactive source classification according to the system in ANSI N542:

The radioactive sealed source used in this device has been tested by the manufacturer and has achieved ANSI (N542-1977) classifications of 77C43333.

Radioactive Source Model Designation:

Supplier: **Isotope Product Laboratories**
1800 Keystone Street
Burbank, California 91504

Model: 34-5

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NRC Registration: The request for registration was sent to NRC on the 9 august 1999.

Standards: N542-1977 ANSI class 77C43333

Radionuclides: ¹³⁷Cs (Cesium-137)

Maximal Activity: 100 mCi ± 15%.

Level of impurities: not detected

Form: Sealed form

Note: One source is used per system.

Reference :
Appendix D, Source NRC Registration.

LABELING:

a) description of the labeling for the device.

Each device will be labeled with the following information in accordance with 10 CFR 20.1901.

1. Label 1 – Warning Label p/n LBL000452

Warning: Radioactive Material Enclosed.
Universal Radioactive Symbol Label
Isotope ID (Cs137)
Activity Level in MBq
Reference Date (Month/Date/Year)

2. Label 2 - CoDe A/C option SER. No. Label p/n LBL000453

Manufacturer name and logo
Unit model name
Serial number

3. Label 3 – Open/Close Label p/n LBL000463

Open/Close (position of the push-button locker)

The sealed source will be labeled with the following information:

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4. Label 4- Sealed Line Source Label (provided by IPL)

Caution - Radioactive Material

Distributor Name:	Isotope Product Laboratories Burbank, CA 818-843-7000
Isotope:	Cs-137
Amount:	15 mCi
Ref. Date:	Day/Month/Year
Serial Number:	XX-XXXX
Model:	34-5

This label will be positioned on the front side of the Tungsten housing (the upper part) by the source supplier (IPL).

5. Engrave characters (0.060 high x 0.003 deep [inch]) on the sealed source:

IPL, MFG DATE, NUCLIDE, ACTIVITY, SERIAL NUMBER

Reference:

Appendix E, Labels.

Appendix D, Source NRC registration, p D-11.

How and where the labels are attached.

The CoDe AC manufacturer will affix the warning label (label 1) to the PSD side.

The CoDe AC manufacturer will affix the device identification and serial No label (label 2) to the PSD side.

The CoDe AC manufacturer will affix the Open Close label (label 3) on the PSD side, close to the locker which permits the motion of the push-button.

The source manufacturer will affix the Sealed Line Source label (label 4) to the source Tungsten housing (front side).

These Labels are made of Lexan and are attached to the device by Mac-Tac adhesive.

Label 5 will be engraved in the external tube of the multipoint line source.

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Reference:

Appendix B, Operation Manual: p 2-11, 2-12

Appendix C, Service Manual: p 1-11, 1-12

Appendix D, Source NRC Registration p. D-11.

Appendix E, Labels

DIAGRAMS: See appendix A – Engineering Drawings

Material description: p A-1

Engineering drawing: p A-2, ..., A-6

CONDITIONS OF NORMAL USE:

Describe the planned use of the device:

The CoDe Attenuation Correction system provides the operator with the means to measure and to correct the attenuation effects of the patient anatomy on the PET (Positron Emission Tomography) images.

The CoDe AC device, which includes the multipoint line sources, the Tungsten housing and the Tungsten collimator, is inserted in the septa collimator. The septa collimator is mounted on the head camera. The 661 keV gamma rays coming from the line of point sources, pass through the patient and became detected by the opposite head camera.

The radiation field cover exactly the field of view of the opposite head camera.

The transmission scan is a post-injected scan. The measurement is done on a range of 120 angles, between 0 and 360 degrees, during 4 minutes for the acquisition of the transmission data and during two more minutes, after closing the source, for impurity correction. The impurities come from the detection of the radiopharmaceutical agent in the ¹³⁷Cs energy window.

The acquisition is done in a continuous mode. This data is reconstructed to obtain attenuation coefficients in the transaxial sections.

Reference :

Appendix B, Operation Manual: chapter 3

Is it portable or installed in a fixed location?

The device is installed in the septa collimator of head camera n^o1, which is permanently mounted to a dual head Anger camera gantry, such as the *Millenium VG System*.

The device will not be use for a mobile van unit.

The device is fixed. Only authorized service personnel, or someone licensed by NRC or an Agreement State, may handle the device.

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Reference:

Appendix B, Operation Manual: Figure 1-1

Motion during use:

The CoDe AC device is permanently mounted to the septa collimator. The septa collimator rotate as well the detector head rotates during the tomography scan.

The operator does not have to remove, to attach or to set-up the device to the camera in order to use it for scan (it's a part of the septa collimator).

Reference:

Appendix A, Engineering Drawing: p. A-3, A-4.

Identify the extremes of environment and operating conditions.

The CoDe AC option is designed for use in controlled clinical conditions and should not be subjected to conditions exceeding those specified by ANSI 542.

The ¹³⁷Cs line of point sources will be inserted in the CoDe AC device by the source manufacturer (IPL). The CoDe AC device including the multipoint line source line, will be sent by the source manufacturer (IPL) to the user in a special container Model 75-7. The container meets all the requirements of the U.S Department of Transportation (DOT) regulations paragraphs 49CFR173.465, 49CFR173.411, 49CFR173.412, and of International Air Transport Association (IATA) regulations paragraphs 10.6.2.1, and 10.6.3.4.

Reference:

Appendix G, Prototype Testing: p G-9,...., G-23.

Types of users:

Physicians and other healthcare professionals.

Location of use:

Hospitals, clinics and other healthcare facilities.

Occasions when persons will be near the device:

Patients will be near the device when they undergo a PET scan procedure on a gamma camera on which the device has been installed.

Operators will be near the device during scan setup and patient positioning, and also when they dismount the septa collimators from the camera using the appropriate cart. The cart with the septa collimator will be positioned only in the restricted area.

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Service personnel will be near the device during installation and maintenance of the option.

Frequency of these occasions:

Patients will be near the device during the complete acquisition time: during 36 minutes (4 minutes for the transmission scan when the source is open, 2 minute scan for impurities correction, with the closed source, and 30 minutes for the emission scan when the source is closed).

Operators will be near the device before starting and at the end of each acquisition (total maximal time 5 minutes). Typical patient workload is 10 patients/day.

Service will be near the device at initial installation, planned preventive maintenance (every 6 months) and service visits.

Possibility that the device may be used as a component in other devices:

The device is designed to fit the current line of ELGEMS dual head cameras (*Millennium VG*) and may be used on future variants of these systems.

Expected useful life of the device:

10 years.

PROTOTYPE TESTING:

The completed prototype tests are discussed in Appendix G, Prototype Testing. The tests include:

CoDe AC On/Off Mechanism Test:

The purpose of the test is to check the reliability of the source On/Off mechanism. The test was done with a pneumatic push button for a total of 62500 On/Off cycles.

Test done by IPL the source manufacturer:

Test on the sealed multipoint line source:

The multipoint line source was tested at Isotope Products Laboratories between 8/2/99 and 8/6/99. All the test were performed in accordance with ANSI N542-1977. The raw data was documented in IPL notebook number 437 page 105 through 106. Temperature, external pressure, impact, vibration and puncture equipment was designed and built per ANSI standard N542-1977 paragraphs 7.2.1, 7.3.1, 7.4.1, 7.5.1 and 7.6.1 respectively. The source was leak tested by immersion in distilled water at 50⁰ C for no less than 4 hours. The soak water was then assayed by using a calibrated liquid

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scintillation counter. After each test the source was intact and found to be leak free.

Effect of Basic Transportation on the CoDe AC device Radiation Leakage:

The CoDe AC device including the multipoint line source, will be sent to the customer by the source manufacturer (IPL). It will be sent in a special container Model 75-7, which meets all the requirements of the U.S Department of Transportation (DOT) regulations paragraphs 49CFR173.465, 49CFR173.411, 49CFR173.412, and of International Air Transport Association (IATA) regulations paragraphs 10.6.2.1, and 10.6.3.4.

No significant shifting of internal packaging or contents was observed and no change in external radiation readings occurred. The radiation profile measurements were the same before and after the different tests, 2.0 mR/hr maximum on contact with the box.

Reference:

Enclosed in appendix G are the following documents:

- a) Source NRC registration including the source test: p G-2, ..., G-8.
- b) Report on the package different test: p G-9, ... , G-23.
- c) Life test of the CoDe AC On/Off mechanism: p G-24, ... , G-26.
- d) Data sheet on the micro-switch: p G-27, ..., G-31.

EXTERNAL RADIATION LEVELS:

CoDe AC Radiation Measurement were done with a calibrated radiation counter BICRON Micro Sievert™ (see report on Appendix F):

- a) Radiation leak test (maximal radiation level when the sources are not exposed) at 2 different distances 5 and 30 cm is 3 mR/h and 1 mR/hr respectively. At 100 cm distance there is no access.
- b) Radiation profile (maximal radiation level when the sources are exposed) at 2 different distances 5 and 30 cm is 15 mR/h and 5 mR/hr respectively. At 100 cm distance there is no access.
- c) The radiation dose outside the FOV of the opposite detector is lower than 0.2 mR/h.
- d) Method and instrumentation used to measure can be found in the report in appendix F "Radiation Leak Report".
- e) Dose to patient and worker:

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- Patient Exposure Test reports a radiation exposure rate of 7 mR/hr at a distance of 20 cm from the sources. The patient integrated dose is 1 mR for a complete scan.
The average effective dose from diagnostic nuclear medicine procedures is around 330 mR, which means that the additional dose from the transmission scan and the CoDe AC option is lower than 1% (1 mR / 330 mR).
- The exposure for worker and other personnel is 0.03 mR for the hands during the installation of the device and 0.2 mR during the working day of the operator:

The typical value of the radiation exposure for the worker from the transmission scan during the positioning of the patient is 0.12 mR/h (at 30 cm of the push-button). Assuming 5 minutes positioning for each patient and 10 patients a day we got $0.12 \text{ mR/h} * 5/60 * 10 = 0.1 \text{ mR}$. During the scan the typical value of the radiation exposure for the worker is 0.01 mR/h, and during a 10 hours working day the integrated dose will be $0.01 \text{ mR/h} * 10 = 0.1 \text{ mR}$. The total dose during a working day will be $0.1 \text{ mR} + 0.1 \text{ mR} = 0.2 \text{ mR}$. During a working year the additional dose will be $0.2 \text{ mR} * 250 \text{ days} = 50 \text{ mR}$

For radiation worker in a nuclear medicine department, the annual effective dose received is generally of the order of 412 mR for PET procedures. Specifically, the radiation dose to nuclear medicine technologists in PET procedure changes from 1.7 mR to 5.0 mR, with a mean value of 3.35 mR. The additional dose from the transmission scan is $0.2/3.35 \text{ mR}$ (mean value) which is 6%. The dose from both emission and transmission radiation is not exceed 10CRF Part 20 occupational and public dose limits.

Reference:

Appendix F, Radiation Measurements

Nuclear Medicine in Clinical Diagnosis and Treatment edited by Murray, second edition, 1998, vol. 2, p. 1670

QUALITY ASSURANCE AND CONTROL:

An overview of ELGEMS Quality Assurance Program (as it applies to the CoDe AC device), manufacturing, assembly and test procedures are included in appendix I.

Reference:

Appendix I, Quality Assurance Program.

DEVICE TYPE: Attenuation Correction System

LIMITATIONS AND OTHER CONSIDERATIONS OF USE:

- **Installation**

Installation procedure

Reference:

Appendix C, Service Manual: chapter 2 and 3

Installation personnel:

The CoDe AC Unit is to be installed by Service representatives of GE Medical Systems, or authorized personnel only.

Integrity inspection of the device received on the site:

The integrity of the device received at the site, is checked by GE personnel during the CoDe AC unit installation according to the following instructions in the *Millenium VG CoDe AC Service Manual* (appendix C):

1) Mechanical Installation, chapter 3, Section 3.2.1, Unpacking.

The camera is checked for radiation leaks after completing the installation. The test is performed according to the requirements of the American National Standard, Publication N542, Appendix A: Dry Wipe Test.

2) Mechanical Installation, chapter 3, Section 3.2.2, 3.2.3 and 3.2.4, Checking the CoDe AC option.

3) System calibration and adjustment, chapter 4 and quality control, chapter 5.

- **Radiological Safety Instructions**

Precautions or warning labels

All precautions or warning labels are discussed in Section Labeling

Specific instructions for safe operation and maintenance of the device

Reference:

Appendix B, Operation Manual, preface iii, chapter 2, chapter 4, p 4-2, chapter 5.

Leak testing instructions.

The source contained in the device shall be tested for leakage at time intervals not exceeding six months. Leak testing shall be in accordance with the individual

DEVICE TYPE: Attenuation Correction System

license requirements issued by the NRC or Agreement State. Leak test; American National Standard publication N542, Appendix A: Dry wipe test, should be performed by wiping all external surfaces of the CoDe AC device. The user has no access to the internal line of point source and to the CoDe AC device surface, but only to the surface of the septa collimator.

Surfaces measuring activity level less than 5 nCi are considered to be free from leakage.

Reference:

Appendix B, Operation Manual, p 5-4

Identify service operations not to be done by user.

Repair, installation, and training of the CoDe AC option will be conducted by representatives of GE Medical Systems only.

Reference:

Appendix B, Operation Manual, p 2-7, 4-3, 5-1, 6-1

Appendix C, Service Manual, p 1-4, 1-8, 3-1, 3-3

Procedures to control radiation hazards in damage or malfunctions.

- 1) The device is equipped with a built-in self-powered source position indicator. The indication will be done by a continuous blinking illumination of a LED. When the LED color is green, it indicates a safe mode (source close), when the LED color is red, it indicates a source in exposed position.

The self-powered source position indicator is intended to indicate the status of the source position while the collimator with the CoDe AC device is on the collimator cart, or on the camera.

The blinking LED will be activated continuously with a battery and will not depend on any electric power supplies.

- 2) When the CoDe AC device and the septa collimator are loaded on the camera, and the source push-button is pressed, the source status will be indicated on the gantry monitor by a blinking note:

**SOURCE
OPEN**

- 3) On the Acquisition Station, which serves as the user interface to the gantry acquisition functionality only, there will be a warning message:

**Warning !
Transmission source is open**

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This message warns the operator that the source is open and transmission photons are being acquiring.

- 4) Incorrect indication of the shutter position should not occur, due to the design of each part of the option. The micro-switch can be positioned only in one direction.

If any malfunction of the source position mechanism should occur, the mechanical position of the push-button will indicate the status of the source. It is mechanically possible to pull the push-button out and to change manually the source from the open position to the close position using the calibration position screw.

- 5) Damage to the outer Tungsten housing resulting in radiation leakage from the source or causing the source to be stuck in the exposure position, is unlikely. The source is entirely enclosed by the housing. The housing is made of Tungsten, and the overall construction of the unit is very rigid. In case the device is accidentally damaged during installation, specific instructions are described in the Operation and Service Manual.

Reference:

Appendix A, Engineering Drawing, A-2.

Appendix B, Operation Manual, p 1-3, 1-6, 2-9, 2-10, 4-2, 4-3

Appendix C, Service Manual, p 3-3, 6-1, 6-2

Caution against tampering with or modifying the device or unauthorized removal of the source contained in the device.

The source is contained within the device housing, which is held in place with structural screws. These screws are not intended to be unscrewed by the user or service engineer. The screws are secured with Loctite, to prevent unintended release of The screws. Warning instructions are specified in the safety chapter of the Operation Manual and the Service Manual, to discourage unauthorized access to the source.

Reference:

Appendix A, Engineering Drawing, p A-2.

Appendix B, Operation Manual, p 2-1, 2-7, 2-9, 4-3, 5-1, 6-1.

Appendix C, Service Manual, p 1-1, 1-4, 1-8.

Recommendations for disposal of the device (source).

The Cs137 source is designed to last for the extent of the life of the VG camera gantry. There is no need to replace the source during the life cycle of the system.

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Only GE personnel (trained in source handling), or someone licensed by the NRC or Agreement State, are responsible for disposal of their sources. Sealed sources used with the CoDe AC device should be returned to the supplier in the original package.

Reference:

Appendix C, Service Manual, p 1-4, 3-1

Appendix Source NRC registration, p D-3.

- **Servicing**

Type and extent of services to be offered to customer. Who is responsible for the following services:

	<u>Distributor</u>	<u>User</u>
Radiation survey.	X	X
Repair	X	
Leak test	X (installation)	X
Relocation	X	
Training	X	
Installation	X	
Maintenance	X	X
Calibration	X	

Note: Only GE personnel (trained in source handling), or someone licensed by the NRC or Agreement State may insert or remove the CoDe AC device. In case of malfunction the whole CoDe AC device will be sent to the source manufacturer (IPL) in its special shipping container Model 75-7.

Maintenance to be done by the user

The device maintenance activities to be done by the user are explained in the appendix B, *Millennium VG CoDe AC Option - Operator's Manual*, chapter 5 Maintenance as follows:

- 1) Radiation leak test

Maintenance to be done by the vendor

The device maintenance activities to be done by the vendor are explained in appendix C, *Millennium VG CoDe AC Option - Service Manual*, chapter 8 Planned Maintenance as follows:

- 1) On/Off Mechanism
- 2) Air frame profile test
- 3) Total Integral Counts Test

DEVICE TYPE: Attenuation Correction System

- 4) Battery Replacement
- 5) Radiation Leak Test (Dry Wipe Test)

SAFETY ANALYSIS SUMMARY:

The safety analysis of the CoDe AC option states the following:

1) CoDe AC unit Installation on the septa collimator :

The CoDe AC device including the line of point sources, will be sent to the customer by the source manufacturer (IPL). It will be sent in a shipping container Model 75-7, which meets all the requirements of the U.S Department of Transportation (DOT) regulations paragraphs 49CFR173.465, 49CFR173.411, 49CFR173.412, and of the International Air Transport Association (IATA) regulations paragraphs 10.6.2.1, and 10.6.3.4.

In the site the field service engineer (GE person) needs to perform the following steps:

- 1) Unload the device from the shipping container and check the radiation level.
- 2) Assemble the unit on a special SEPTA collimator, that is specifically designed for the CoDe AC option. The device is connected to the collimator by 4 screws that connect the Tungsten housing to the collimator frame.
- 3) Connect the electrical wiring for the source position indication, and test the source position mechanism, including the blinking LED source position indicator.
- 4) Adjust the collimator cart to the VG gantry, and load the collimator to the gantry.
- 5) Perform system calibration.

The process is described in details in the following appendixes:

Appendix A, Engineering Draw.

Appendix H, Source Packaging Information.

Appendix C, Service Manual.

Appendix D, Operation Manual.

2) Dose

Integrated radiation dose to patients for a typical attenuation correction procedure has being determined as being less than 1 mRem.

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Reference:

Appendix F, Radiation Measurements:

Report: Patient Exposure Test.

Radiation Exposure for Workers and other Personnel.

3) Source Shielding :

The device structure is made from two main parts, the collimator, and the bottom shield. Both parts are made from Tungsten, because of its good shielding performance, as well as good mechanical properties, that enable to use the Tungsten parts as the structure for the device.

The shielding that is achieved reduces the radiation levels to acceptable values from all sides of the device.

Reference:

Appendix F, Radiation Measurements.

4) Power failure:

The On/Off mechanism does not require electrical power. The push-button is released mechanically. In case of failure the multipoint line source can be released turning the calibration position screw.

The electrical power of the On/Off blinking LED status indicator is a battery. The LED will always blink (in red or in green depending on the source position). In case of battery power failure the LED will stop blinking, permitting an immediate detection of the failure.

Reference:

Appendix F, Radiation Measurements.

5) Caution and Labels:

Caution labels are affixed to the CoDe AC septa collimator.

Identification of the source is indicated by a label placed on the front of the CoDe AC device, by IPL.

An indication, and identification of the source and device, is printed on the PSD side of the septa collimator.

Caution/Warnings hazards are included in the Operation and Service Manuals .

Reference:

Appendix B, Operation Manual, p 2-11, 2-12.

Appendix C, Service Manual, p 1-11, 1-12.

Appendix E, Labels

DEVICE TYPE: Attenuation Correction System

6) Transmission Radiation On/Off indicators:

- 1) The device is equipped with a built-in self-powered source position indicator. The indication will be done by a blinking illumination of a LED. A green light indicate safe mode (source close), a red light indicate source exposed position.

The self-powered source position indicator is intended to indicate the status of the source position while the collimator with the CoDe AC device is on the collimator cart, or on the camera. The blinking LED will be activated with a battery and will not depend on any electric power supplies.

- 2) When the CoDe AC device and the septa collimator are loaded on the camera, and the source push-button is pressed, the source status will be indicated on the gantry monitor by a blinking note:

**SOURCE
OPEN**

- 3) On the Acquisition Station, which serves as the user interface to the gantry acquisition functionality only, there will be a warning message:

**Warning !
Transmission source is open**

This message warns the operator that the source is open and transmission photons are being acquiring.

Reference:

Appendix B: Operation Manual, p. 4-2, 4-3

Appendix C: Service Manual, p. 3-10

REFERENCES : no references

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: _____

Reviewer : _____
Name of 1st. Reviewer

Date: _____

Reviewer : _____
Name of 2nd. Reviewer

FDA 510(k) Number

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 10, 1999

ELGEMS, LTD.
P.O. BOX 170
TIRAT HACARMEL,
ISRAEL
ATTN: DAN LAOR

510(k) Number: K994167
Received: 09-DEC-1999
Product: CODE AC:
ATTENUATION
CORRECTION SYSTEM
FOR DUAL-HEAD

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

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Sincerely yours,


Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff

Appendix A

Engineering Drawings

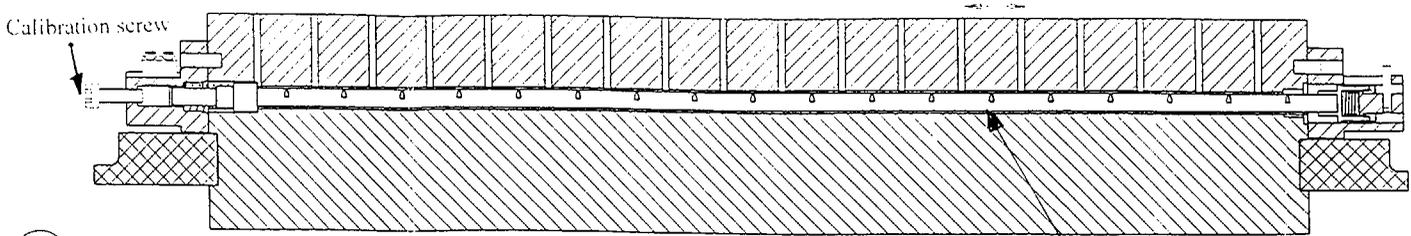
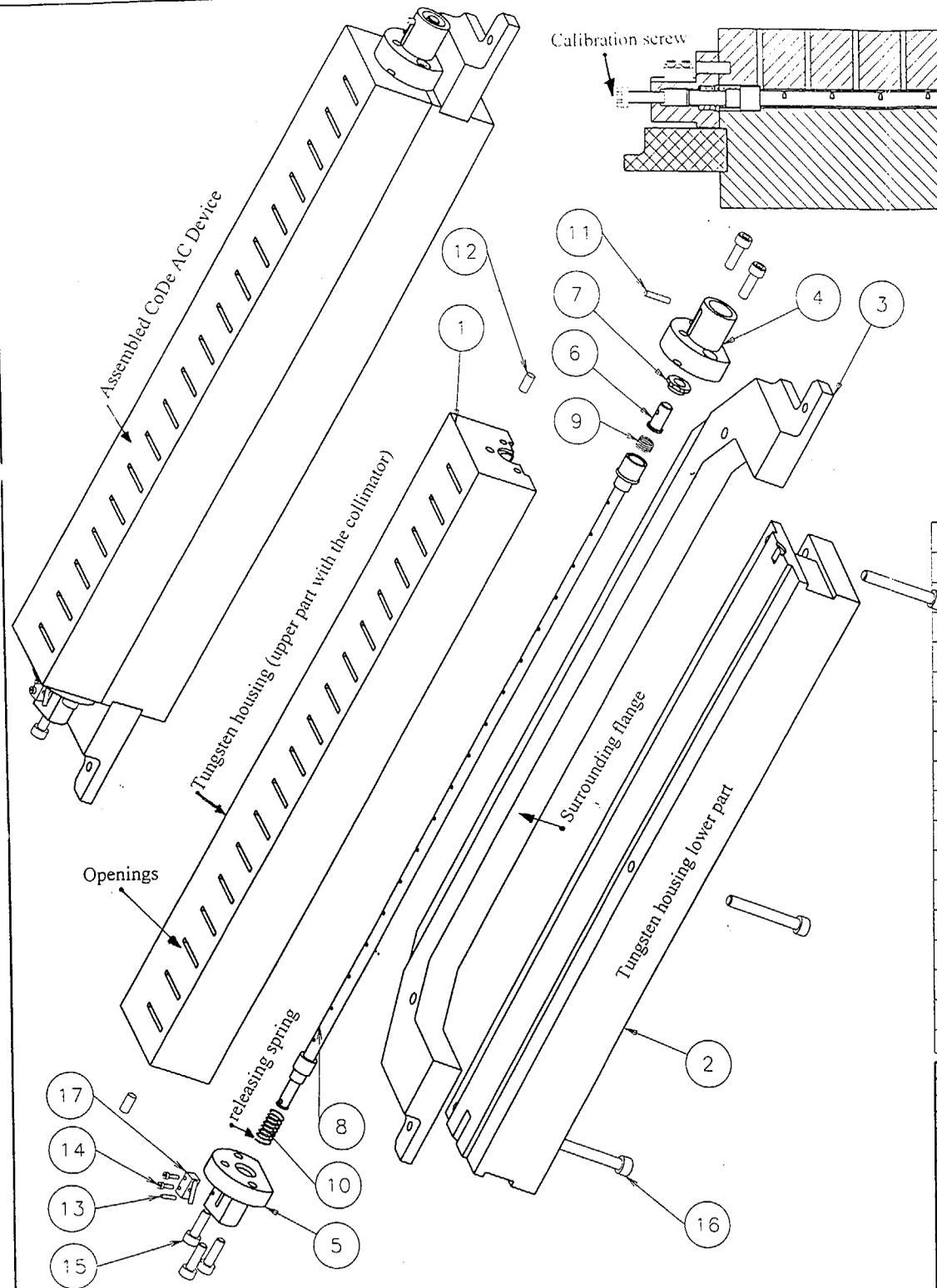
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MECHANICAL

MACHINED PART LIST

PART	MATERIAL	WEIGHT (Kg)
TUNGSTEN COLLIMATOR	TUNGSTEN	15
TUNGSTEN SHILED	TUNGSTEN	18.5
LEAD FLANGE	LEAD	4.5
HANDLE END FLANGE	TUNGSTEN	0.28
SCREW END FLANGE	STAINLESS STEEL 303	0.12
PISTON	STAINLESS STEEL 303	0.005
CORK	PH-BRONZE	0.0026
SOURCE : CESIUM SOURCE	TUNGSTEN	0.24
SCREW END	TUNGSTEN	0.02
HANDLE END	TUNGSTEN	0.017
ON FRAME		
PUSH HANDLE	STAINLESS STEEL 303	0.03
RELEASE HANDLE	STAINLESS STEEL 303	0.03
NEW SQR PIN RIGHT	STAINLESS STEEL 416	0.05



Multipoint line source in close position

STROKE 10.7

REMARKS or DWG. NO.	UNITS	QUANTITY	PARTNUMBER	DESCRIPTION	NO.
	pce	1.00	S 030000046	MICRO SWITCH	17
	pce	3.00	HS004006040	SCREW, M-6 L=40MM, CAP-HEAD	16
	pce	5.00	HS004005016	SCREW, M-5, L= 16MM, CAP-HEA	15
	pce	2.00	HS004002008	SCREW M2x8 CP-HEAD SKT STL12	14
	pce	1.00	HP023001210	DOWEL-PIN, D= 2.0MM, L= 10 M	13
	pce	2.00	HP023000511	DOWEL-PIN, D= 5.0MM, L= 10 M	12
	pce	1.00	HP023000320	DOWEL-PIN, D= 3.0MM, L= 20 M	11
	pce	1.00	HK00010009B	Spec co360-026-1120S	10
	pce	1.00	HK00010009A	Spec co360-032-0380M	9
	pce	1.00	DTP0000044	CoDe AC Cs Source	8
	pce	1.00	MEC005199	CORK	7
	pce	1.00	MEC005198	PISTON	6
	pce	1.00	MEC005196	SCREW END FLANGE	5
	pce	1.00	MEC005195	HANDLE END FLANGE	4
	pce	1.00	MEC005202	LEAD FLANGE	3
	pce	1.00	MEC005201	TUNGSTEN SHIELD	2
	pce	1.00	MEC005200	TUNGSTEN COLLIMATOR	1

DESIGNER: EREZ Y. 1.6.99		EUROPEAN PROJECTION: DEFAULT DIMENSIONS: MM.		EQUIPMENT: CESIUM		ASSEMBLY NAME	
DESIGN CONTROL: EREZ Y. 1.6.99		FINISH		SCALE: 1.0:2.5		NAME: Cs Holder Assy	
CHECKER: GUILAD B. 1.6.99		APPROVAL: YOSSI A. 1.6.99		TOL. NOT SPECIFIED:		DRAWING No. 2	
CONTENTS PROPERTY OF ELGEMS LTD. NO UNAUTHORIZED USE PERMITTED		ELGEMS R&D		LAST OP.		DRAWING No. ASM-000745-AA	
POB 170 Tirat Hacarmel 30200 ISRAEL		NEXT OP.		SHEET OF		VERSION	
Project: CESIUM, Item: CESIUM OPTION 2, 15-Jul-99 09:14				Old Partnumber: Cs Holder Assy			

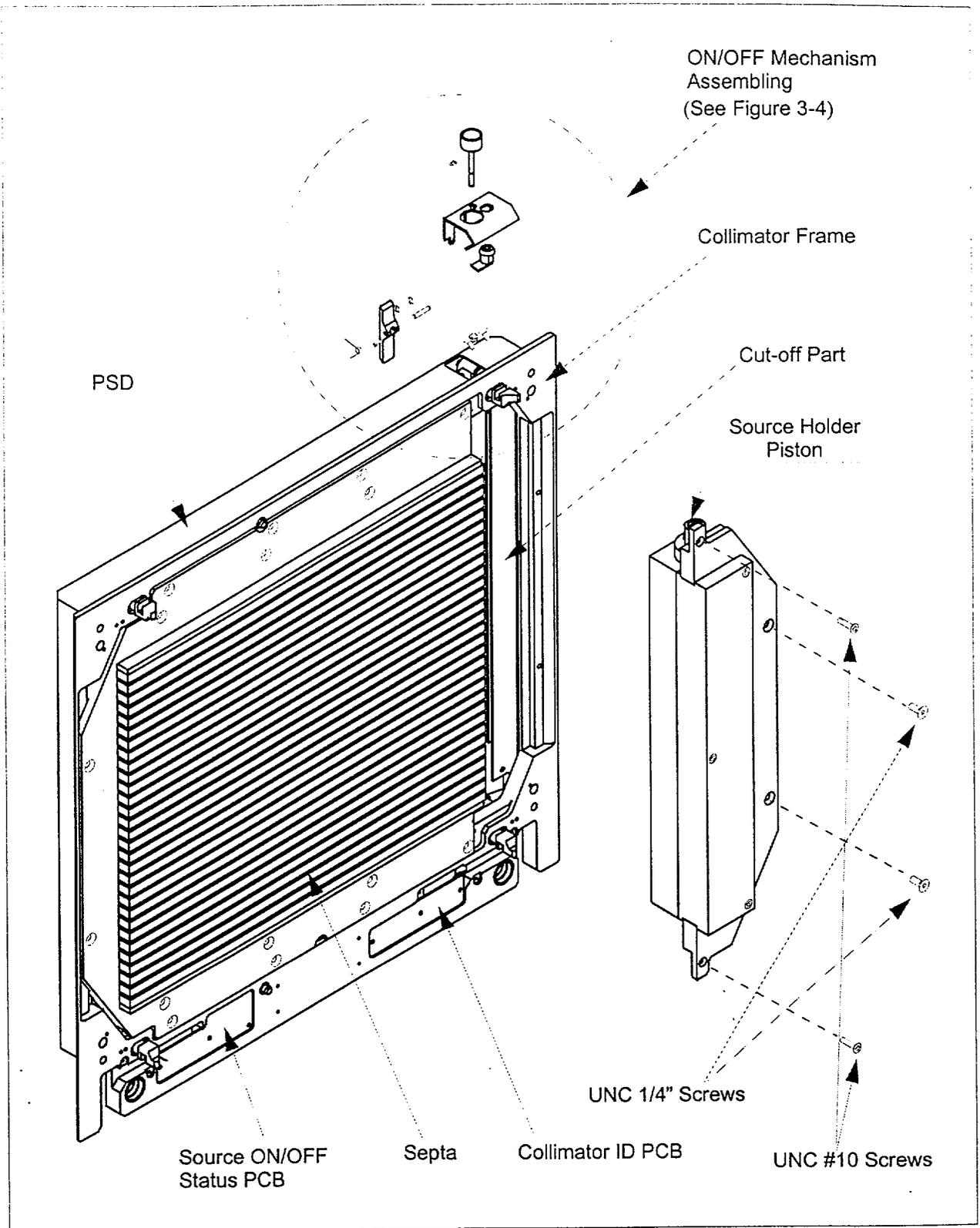
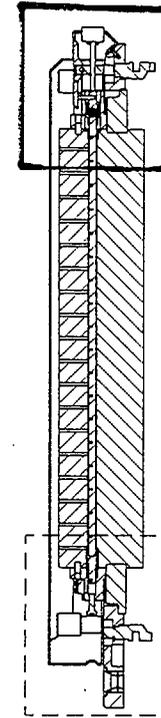
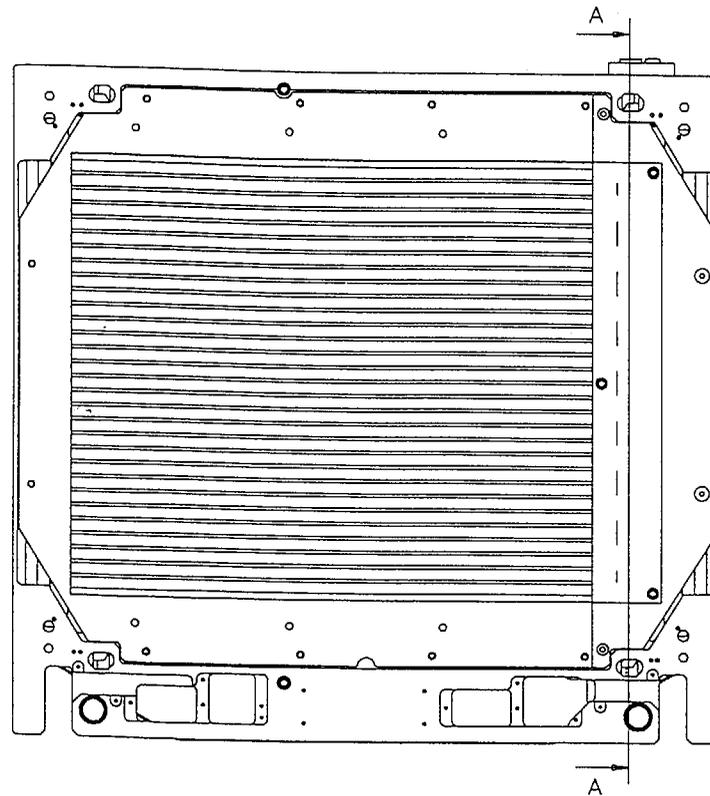
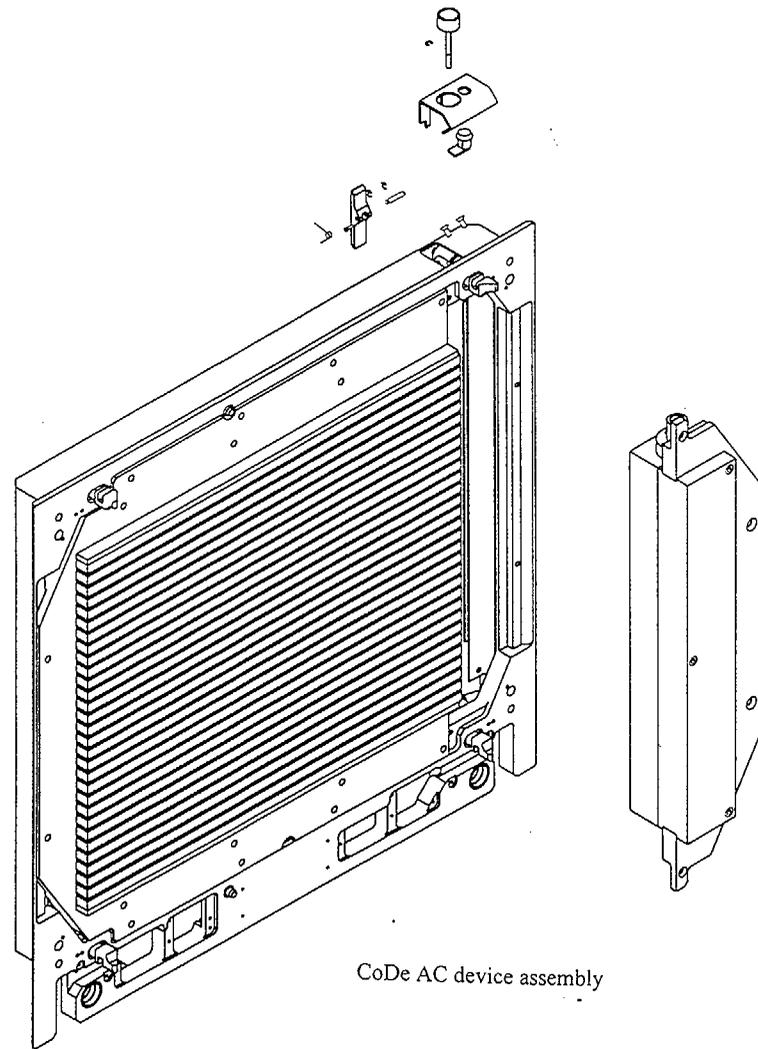


Figure 3-1. Assembling the CoDe AC Device

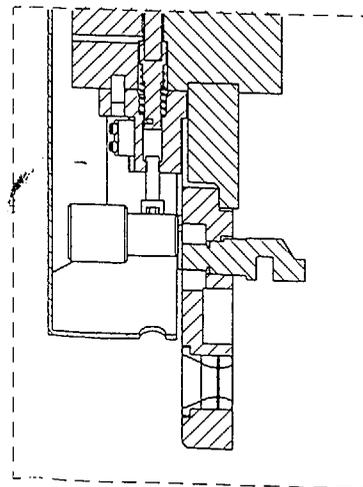
Back side of the septa collimator with the CoDe AC device



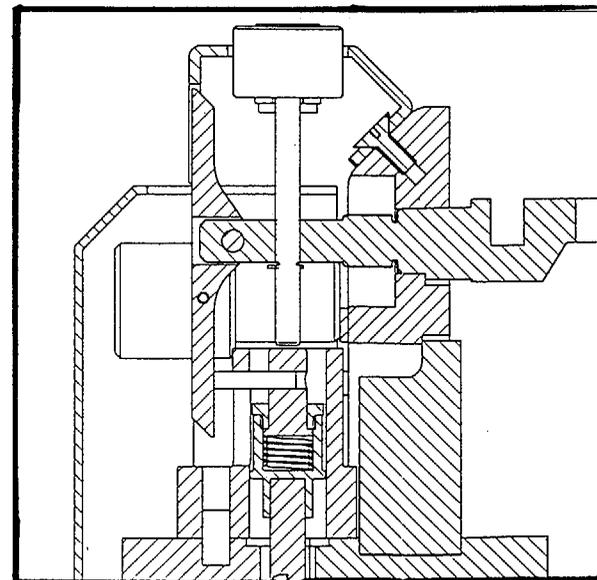
Profile of the CoDe AC device in the septa collimator



CoDe AC device assembly



Profile of the calibration screw side



Profile of the Push Button side

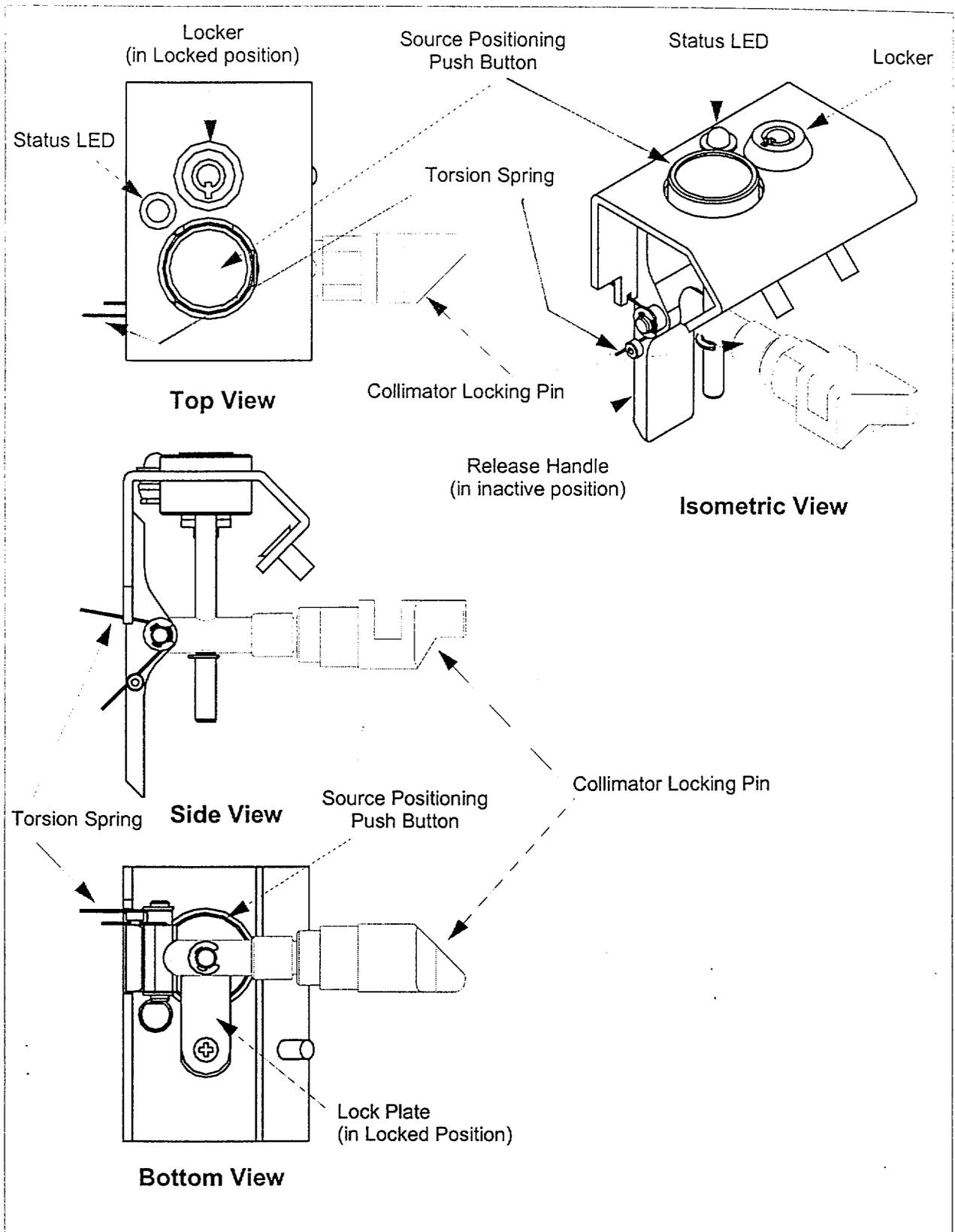
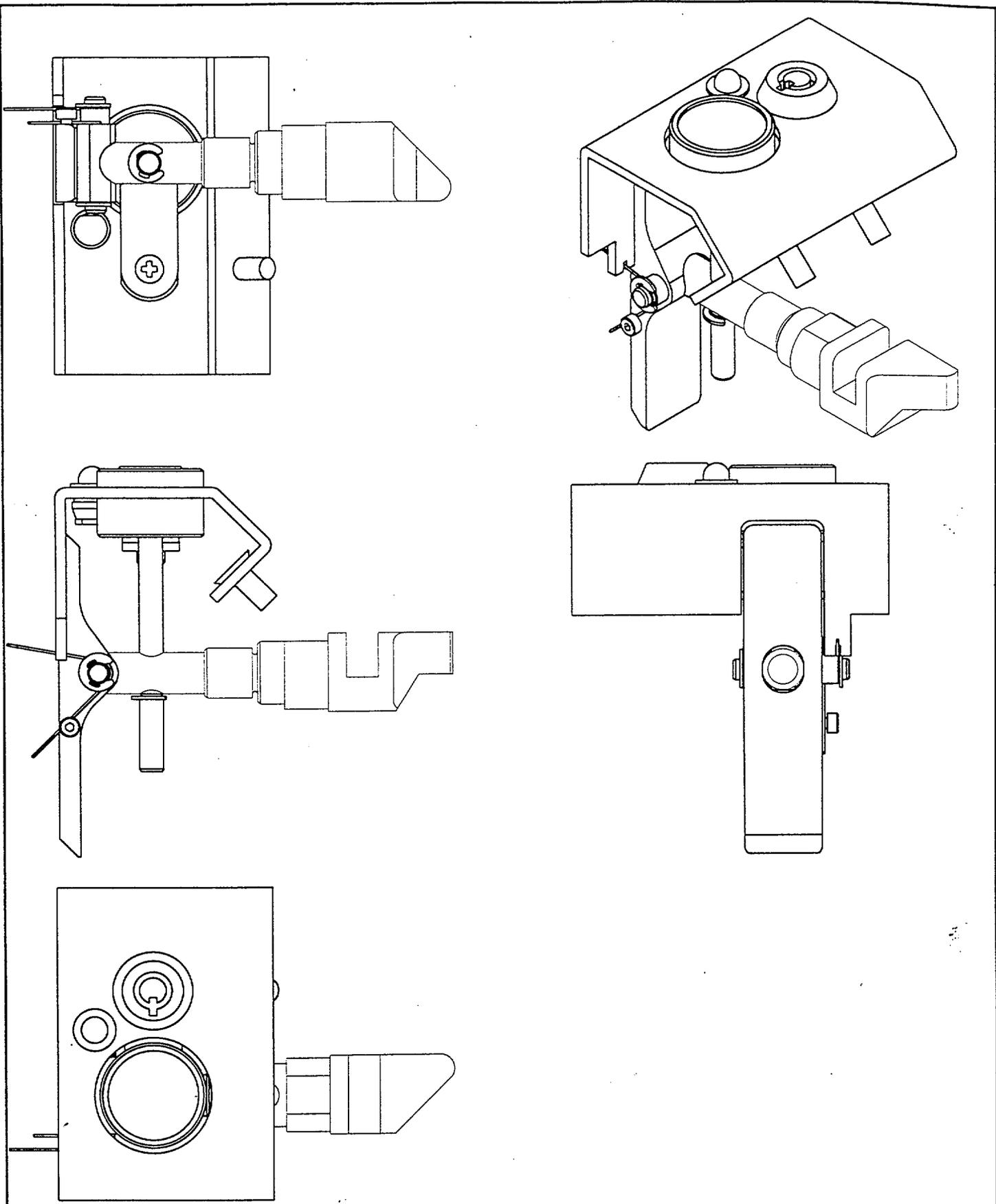


Figure 3-5. Assembled ON/OFF Mechanism - Different Views



	NAME	DATE	EUROPEAN PROJECTION. DEFAULT DIMENSIONS : MM.	EQUIPMENT CESIUM	ASSEMBLY NAME
DESIGNER	EREZ Y.	17.6.99	FINISH		No. 1
DESIGN CONTROL	EREZ Y.	17.6.99		SCALE	NAME
CHECKER			✓	1.0:1.0	KIT ASSEM
APPROVAL			TOL. NOT SPECIFIED :		
CONTENTS PROPERTY OF ELGEMS LTD. NO UNAUTHORIZED USE PERMIT				DWG. SIZE	DRAWING No.
				1	UGP-000625-
PCB 170 Tira! Hacarmel 30200 ISRAEL			LAST OP.		SHEET OF
			NEXT OP.		VERS CN

6

Appendix B

Operation Manual



GE Medical Systems

Technical Publications

Direction 2250060-100
Revision A

*Millennium*TM VG CoDe AC Option Operator's Reference Manual

Printed for



GE Medical Systems

GE Medical Systems: telex 3797371
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(Asia, Pacific, Latin America, North America)

GE Medical Systems - Europe: Telex 698626
283 rue de la Minière, B.P.34, 78533, Buc Cedex, France

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Preface

Coincidence imaging is an integral part of activating the CoDe AC option.

	WARNING
	The operator of the CoDe AC option must be well acquainted and fully understand how to perform Coincidence Imaging, as explained in the CoDe Operator's Manual, ELGEMS P.N. 490-3100-26 (MAN000036), Direction 2194379-100.

	WARNING
	The Safety section of Chapter 2 must be read <i>before</i> any attempt is made to operate the system.

This manual is a preliminary release of the Code AC option used to correct for attenuation while imaging with the dual-head, gamma camera.

- | | |
|------------------|--|
| Chapter 1 | describes the parts of the Code AC option on the dual-head camera. |
| Chapter 2 | provides Safety guidelines in general, with respect to the Code AC option in particular. |
| Chapter 3 | describe the theory of operation. |
| Chapter 4 | provides operation guidelines with respect to safety precautions and details the acquisition stages and the creation of Attenuation Maps. |
| Chapter 5 | details the maintenance procedures to be performed by the customer. |
| Chapter 6 | lists the faulty symptoms and error messages that the operator can encounter in the day-to-day operation of the system. In any case, the customer must call his/hers service office to repair the failure. |

Chapter 1 - Description

Overview

The Coincidence Attenuation Correction option for the Millennium VG camera referred to as CoDe AC, is a package used to correct for attenuation effects for PET acquisitions.

Gamma radiation emitted from the inspected organ is attenuated by the body tissues while passing to the Gamma Detector Head. Different body tissues absorb varying amounts of radiation, depending on their structure and thickness. Therefore, the actual attenuation varies, depending on the specific patient, his/her positioning and the angle of view.

Normal attenuation correction of images reconstructed from various views is based on a generic algorithm that does not consider the above factors.

The CoDe AC option is based on attenuation correction maps created individually for each projection. These maps are based on the degree of radiation originated by an external ^{137}Cs source, which is transmitted through the patient's body, and therefore referred to as the Transmission process.

The transmission gamma rays used to create the attenuation correction maps and the images generated by the emission of the internal radiation are acquired sequentially by the camera.

The transmission scan is acquired in two sequential steps: one scan with the source open, and the second one with the source close for impurity correction.

The attenuation correction maps contribute to more accurate reconstruction of PET images, which is the first step towards quantization accuracy.

The CoDe AC option consists of:

- Special Septa Collimator
- CoDe AC Device
- Acquisition Software

The CoDe AC device is assembled on the special Septa Collimator, forming an integrated unit. The Septa Collimator with the CoDe AC device is loaded on Head #1, while a standard Septa Collimator is loaded on Head #2.

When non-PET acquisitions are performed, the Septa Collimator with the CoDe AC device must be kept in a radiation restricted area.

Due to the physical design of the CoDe AC device, acquisitions are done while the Detectors are shifted two cm in the lateral axis. This off-center acquisition mode is reached by activating a special CoDe AC Home Position. See Figure 1-1 for the lateral shift performed to cover the Center of Rotation.

CoDe AC Acquisition consists of two sequential acquisitions: Transmission Acquisition followed by Emission Acquisition. Both acquisitions are performed in Continuous Mode, with rotations of 360°, while the Detectors are positioned in H-Mode.

The emission data is acquired by both Detectors while the Transmission data is acquired only by Head #2.

During CoDe AC Transmission acquisition, the on-line Center Of Rotation (COR) and Sensitivity corrections are turned off. COR correction is done off line, while sensitivity correction is done using an Air Frame, once a week.

CoDe AC Device

The CoDe AC device consists of a source housing made basically of Tungsten, a line of 18 ^{137}Cs point sources and an ON/OFF Mechanism. The line of point sources is inserted between the two parts of the source housing. One part of the Source Housing shields the Detector on which the Septa Collimator is mounted. The second part serves both for shielding and for collimating the 18 point sources.

The 18 ^{137}Cs point sources are positioned at equal distances in a Tungsten Rod and are sealed using a stainless steel tube.

The collimation ensures the transmission of a fan beam, which hits the opposite detector only in the Field Of View (FOV).

The ON/OFF mechanism consists of:

- **Source Position Push Button** - used to change the position of the point sources to the exposed (**open**) position. When the point source are shifted to the **open** position, the gamma radiation is transmitted toward the FOV of the opposite Detector.
- **Release Handle** - used to shift the line of point source back to the shielded (**close**) position.
- **Position Indicator** - a blinking LED (positioned on the Septa's Pressure Sensitive Device (PSD) close to the Source Positioning Push Button), which changes its color according to the position of the point sources. The LED blinks **green** when the sources are shielded (close), and blinks **red** when the sources are exposed (open).

Figure 1-1 provides a schematic front view of the Millennium VG with the CoDe AC option assembled, and shows the fan beam radiation field on Detector #2.

Figure 1-2 provides a schematic side view of the Millennium VG with the CoDe AC option assembled. The drawing shows the radiation fields of the point sources.

Figure 1-3 shows the Septa Collimator with CoDe AC option.

Figure 1-4 depicts the ON/OFF mechanism of the CoDe AC device.

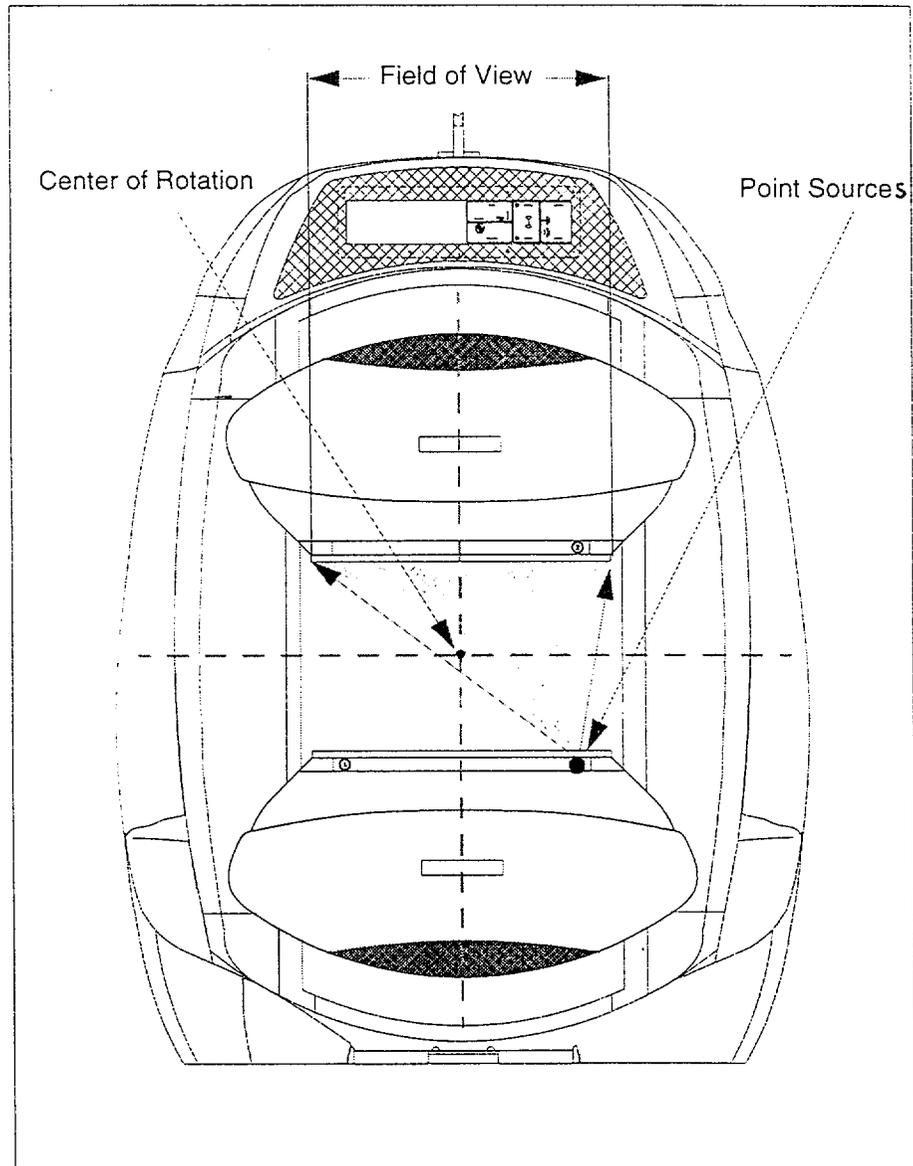


Figure 1-1. Millennium VG With CoDe AC - Front View

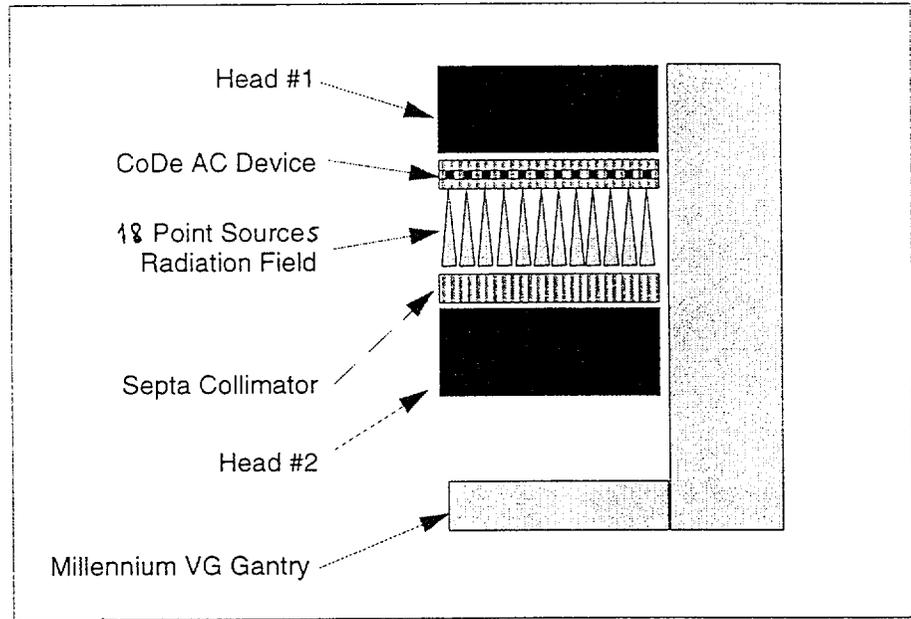


Figure 1-2. Schematic Side View of Millennium VG With CoDe AC

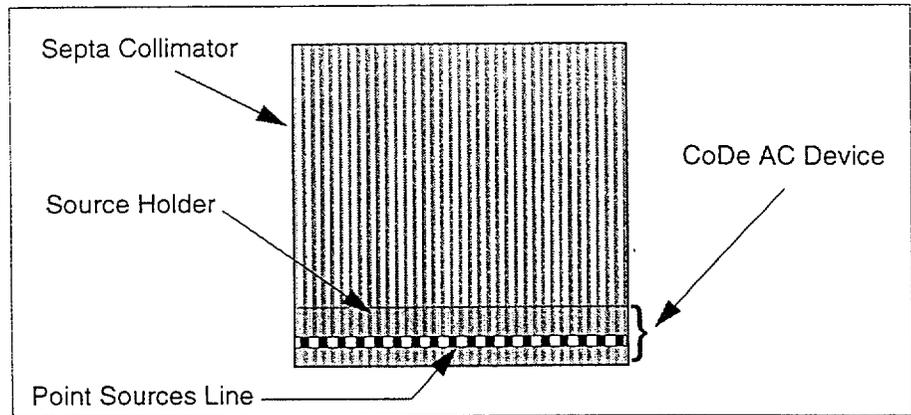


Figure 1-3. Schematic Septa Collimator with CoDe AC Device

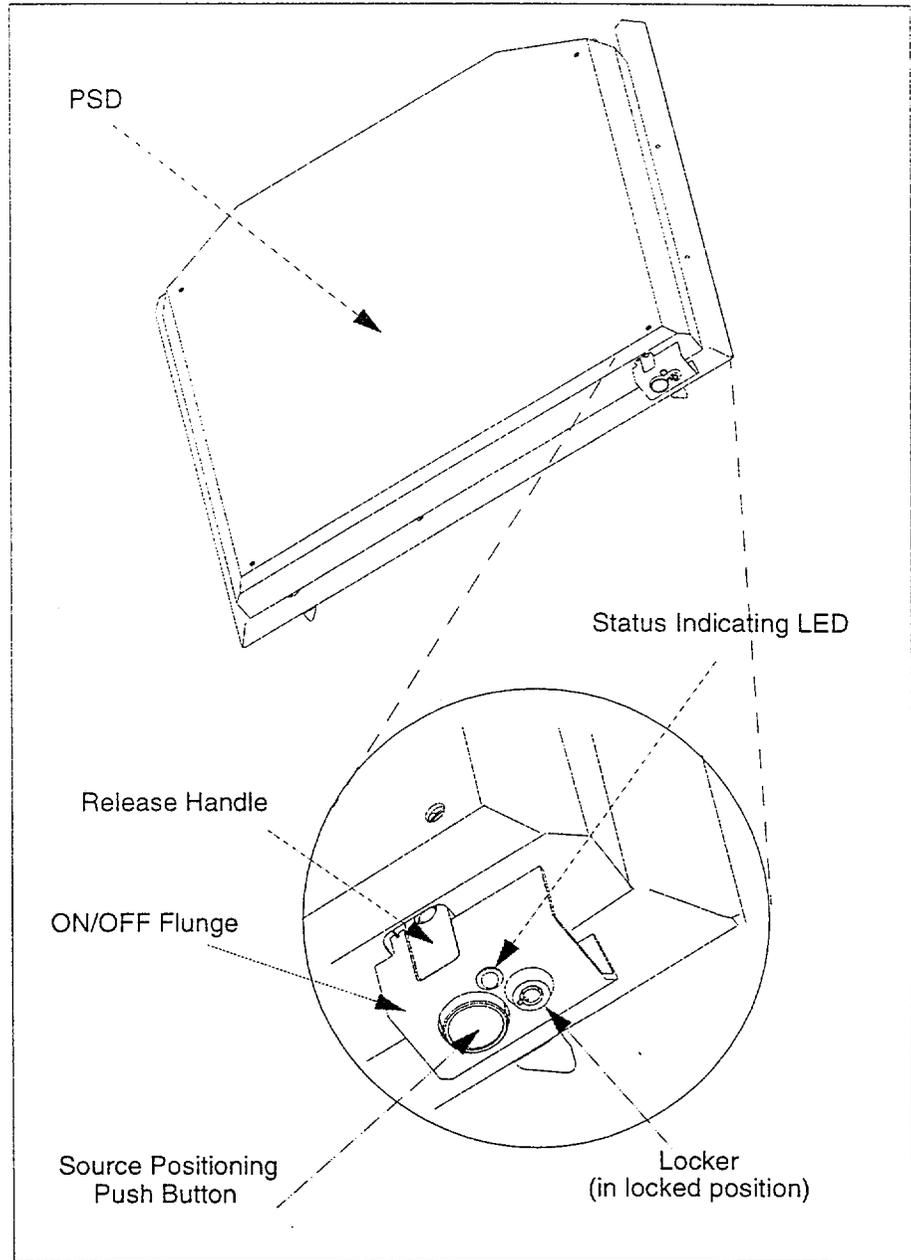


Figure 1-4. CoDe AC Option ON/OFF Mechanism

Chapter 2 - Safety

General Safety

1. This product was designed and manufactured to ensure maximum safety of operation. It should be operated and maintained in strict compliance with the safety precautions, warnings and operating instructions contained herein.
2. The system has been designed to meet all the safety requirements applicable to medical equipment. However, anyone attempting to operate the system must be fully aware of potential safety hazards.
3. There are no user serviceable parts in this system. The product should be installed, maintained and serviced by qualified service personnel according to procedures laid down in the product service manuals.
4. The system in whole or in part should not be modified in any way without prior written approval by ELGEMS Ltd.
5. The owner should make certain that only properly trained, fully qualified personnel are authorized to operate the equipment. An authorized operators list should be maintained.
6. It is important that this Manual should be kept at hand, studied carefully and reviewed periodically by the authorized operators.
7. The manufacturer or Vendor of the equipment makes no representation, however, that the act of reading this manual renders the reader qualified to operate, test or calibrate the system.
8. Unauthorized personnel should not be allowed access to the system.

9. If the product does not operate properly or if it fails to respond to the controls as described in this manual, the operator should:
- First ensure the safety of the patient and then the safety of the equipment, following the safety precautions as specified in this manual.
 - Freeze the situation and prevent any changes.
 - Immediately contact the service office, report the incident and await further instructions.
Tel: 1-800-437-1171 Fax: (901) 387-4110
10. The images and calculations provided by this system are intended as tools for the competent user. They are explicitly not to be regarded as a sole incontrovertible basis for clinical diagnosis. Users are encouraged to study the literature and reach their own professional conclusions regarding the clinical utility of the system.
11. The user should be aware of the product specifications and of system accuracy and stability limitations. These limitations must be considered before making any decision based on quantitative values. In case of doubt, please consult your sales representative.
12. **Electrical Shock Hazard** - do not remove or open system covers or plugs. Internal circuits use high voltage capable of causing serious injury.

An electrical hazard may exist if any light, monitor or visual indicator stays on after the system is turned off. To prevent possible injury, turn off the switch in the mains power supply box on the wall and contact your service office immediately.

Fuses blown within 36 hours of being replaced may indicate malfunctioning electrical circuits within the system. Have the system checked by qualified service personnel, and do **not** attempt to replace any fuse.

13. **Electrical Fire** - conductive fluids that seep into the active circuit components of the system may cause short circuits that can result in electrical fires. Therefore, do not place any liquid or food on any part of the system.
- To avoid electrical shocks or burns caused by the use of wrong type of fire extinguisher, make sure your fire extinguisher has been approved for use on electrical fires.

14. **Explosion Hazard** - do not operate the equipment in the presence of explosive liquids, vapors or gases. Do not plug in or turn on the system if hazardous substances are detected in the environment. If these substances are detected after the system has been turned on, do not attempt to turn off the unit or unplug it. Evacuate and ventilate the area before turning off the system.
15. **Overheating** - Do not block the ventilation ports of the electronic equipment. Always maintain at least 6 inches (12 cm) clearance around the ventilation ports to prevent overheating and damage to the electronic hardware.

Safety Definitions and Symbols Used

Safety Definitions

The safety instructions in this manual are used for the protection of the patient, operator and service personal. They identify hazards that will or may occur if instructions are ignored. The identified hazards are defined and classified as follows:

	<p style="text-align: center;">DANGER</p> <p>Danger is used to identify conditions or actions for which a specific hazard is known to exist which will cause severe personal injury, death or substantial property damage if the instructions are ignored.</p>
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	<p style="text-align: center;">WARNING</p> <p>Warnings are used to identify conditions or actions for which a specific hazard is known to exist, which may cause severe personal injury, or substantial property damage if the instructions are ignored.</p>
---	--

	<p style="text-align: center;">CAUTION</p> <p>Cautions are used to identify conditions or actions for which a potential hazard may exist, which will or can cause minor personal injury, or property damage if the instructions are ignored.</p>
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IEC Symbols Used

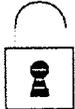
The system may have labels with one or more of the following symbols. These symbols indicate the IEC standards to which the system conforms.

All of these symbols in this section, IEC Symbols, are given in standard UL2601-1, Medical Electrical Equipment, Part 1: General Requirements for Safety, Second Edition, Clause 6. UL201-1 is the relevant Underwriters Laboratory standard for nuclear medicine equipment, including the labels. Compliance to the UL standard is recognized by the FDA as one of their requirements for FDA clearance (510(k)) to market the NM device in the USA.

Symbol	IEC Standard
	Alternating Current
	Protective Earthing Point
	ON / Power
	OFF / Power Off
	OFF (only for part of equipment)
	ON (only for part of equipment)
	Type B Equipment
	Input Power
	Output Power
	Functional Earth Ground
	Warning, Caution - consult accompanying documents
	Electrical Shock Hazard

System Specific Symbols

In addition to the standard IEC symbols used in the Millennium VG labels, as indicated in the Safety chapter of the Millennium VG Operator's Guide, the following Safety Symbols are used for the CoDe AC option.

Symbol	Meaning
	Radiation emission warning
	Source Positioning Push Button Locked
	Source Positioning Push Button Unlocked

Radiation Safety

Source Handling

The source is delivered to the customer when it is already inserted in the CoDe AC Tungsten housing. It is delivered in a drop proof packages class A.

1. No Source handling is needed. The line point source is an integral part of the CoDe AC option.
2. Only qualified service personnel is allowed to mount or dismount the CoDe AC device on/from the Septa Collimator.

	<p style="text-align: center;">WARNING</p> <p style="text-align: center;">It is prohibited to open the CoDe AC Device.</p>
---	---

3. When non-PET acquisitions are performed, the Collimator Cart with the Septa Collimators must be kept in a radiation restricted area.

Radiation Safety Mechanisms

The point sources are sealed within a tube, which is inserted in the CoDe AC Device. Thus, the point sources are shielded by the thick layer of Tungsten which comprises the CoDe AC Device. Exposure of the point sources is done manually by the operator. The mechanism used to open and close the line source is described in the CoDe AC Device section on page 1-3 and shown in Figure 1-4.

Radiation safety is ensured by the following components:

- **Source Tube** - the 18 ^{137}Cs point sources with a total activity of 15 mCi (555 MBq) are sealed within a stainless steel tube.
- **Source Housing** - the two thick Tungsten parts which seal off the Source Tube, providing the necessary shielding.
- **Collimator** - limits the radiation to the Field Of View of the opposite Detector, which minimizes the radioactivity dose to the patient.
- **Locking Key** - disables exposure of the point sources by unauthorized people or by accident. The Source Position Push Button can be pushed in only when the locker is released by using the special key.
- **Release Screw** - serves as backup for the **Release Handle** when it fails to return the point sources to the shielded position. It is used also to calibrate the position of the point sources.
- When the Septa Collimator with the CoDe AC Device is loaded on the Collimator Cart, the Release Handle is pressed and the Source can not be locked in the open position. When the Source Positioning Push Button is accidentally pushed in, the moment the pressure stops the source automatically returns to the close position.

Potential Radiation Hazard

The CoDe AC option contains a sealed line of 18 point sources with a total activity of 15 mCi (555 MBq).

	<p style="text-align: center;">WARNING</p> <p>When the user presses the Source Positioning Push Button, the sources are exposed, transmission radiation starts, and the color of the blinking Radiation Indicating LED changes from green (close position) to red (open position).</p>
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	<p style="text-align: center;">WARNING</p> <p>Tampering with or modifying the CoDe AC option, or removal of the source tube contained in the CoDe AC device may result in exposure to unnecessary levels of radiation.</p> <p>Only authorized and qualified service personnel are allowed to dismount the CoDe AC Device from the Septa Collimator.</p>
--	---

	<p style="text-align: center;">WARNING</p> <p>In the event of accidental damage to the CoDe AC option:</p> <ol style="list-style-type: none">1. Close the CoDe AC point sources by pressing the Release Handle.2. Verify that the Source Positioning Push Button is in Close position, as shown on the label attached to the PSD, and that the indicating LED blinks green.3. Lock the Source Positioning Push Button using the special key.4. Call a qualified service engineer authorized by the Vendor. <p style="text-align: center;">Tel: 1-800-437-1171 Fax : (901) 387-4110</p>
---	--

Radiation Indications

- LED Indication - located on the PSD of the Septa Collimator (next to the Source Positioning Push Button), signifies the status of the point sources by changing its color, as follows:
 - Green** - indicates that the Point Sources are closed
 - Red** - indicates that the Point Sources are open
- Warning Message "SOURCE OPEN" - appears on the Gantry Display during Transmission Acquisition
- Warning Message "Warning!! Transmission Source is Open" - is displayed on the Acquisition Station Monitor during Transmission Acquisition

Radiation Leakage Test

The camera should be checked for radiation leaks at least once every six months or earlier if stipulated by local safety regulations. The radiation leak test should be performed according to the requirements of the American National Standard, Publication N542, Appendix A: Dry Wipe Test. For instructions, refer to the **Radiation Leakage Test** in Chapter 5.

Patient Safety

For general patient safety information, refer to the Patient Safety Section in the Safety and Regulatory Chapter of the Millennium VG Operator's Guide.

Safety Status Labels

Figure 2-1 depicts the Septa PSD with the CoDe AC safety labels and the Status Label of the Source Push-button locker. The numbers used in the figure correspond to the numbers shown alongside the labels on the next page.

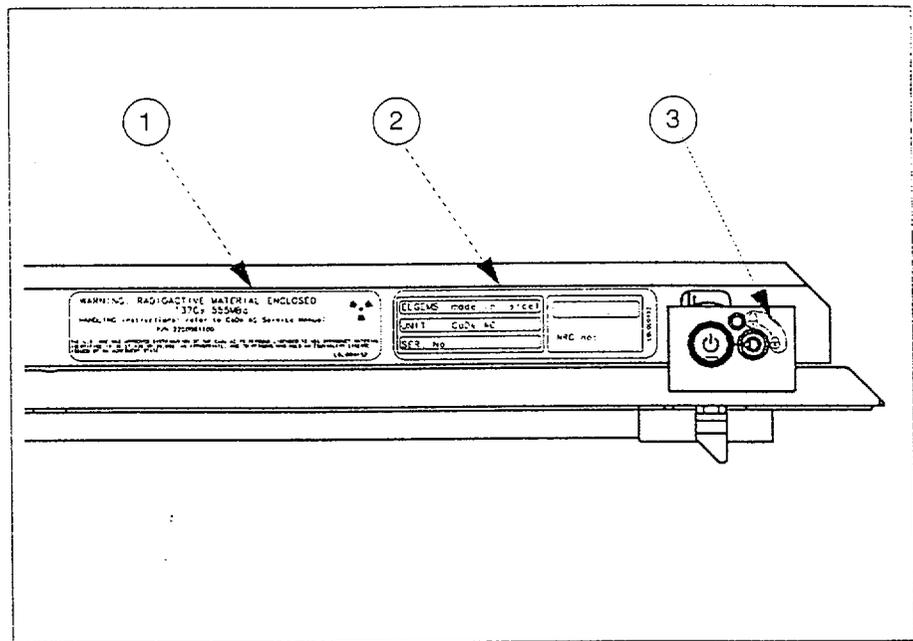
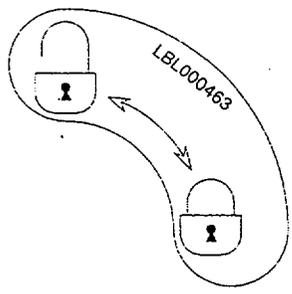


Figure 2-1. CoDe AC Device Safety Labels

<p>1</p>	<p>WARNING: RADIOACTIVE MATERIAL ENCLOSED </p> <p>Nuclide: ^{137}Cs Activity: 555 MBq Ref. Date: -----</p> <p>Handling Instructions: refer to CoDe AC Service Manual P/N 2250061-100</p> <p>THE U.S. NRC HAS APPROVED DISTRIBUTION OF THE CoDe AC TO PERSONS LICENSED TO USE BYPRODUCT MATERIAL IDENTIFIED IN 35.57, 35.400 OR 35.500 AS APPROPRIATE, AND TO PERSONS WHO HOLD AN EQUIVALENT LICENSE ISSUED BY AN AGREEMENT STATE</p> <p>LBL000452</p>		
<p>2</p>	<table border="1"> <tr> <td data-bbox="657 1029 1063 1228"> <p>ELGEMS made in Israel</p> <p>UNIT CoDe AC</p> <p>SER. No.</p> </td> <td data-bbox="1096 1029 1388 1228"> <p>NRC No:</p> <p>LBL000453</p> </td> </tr> </table>	<p>ELGEMS made in Israel</p> <p>UNIT CoDe AC</p> <p>SER. No.</p>	<p>NRC No:</p> <p>LBL000453</p>
<p>ELGEMS made in Israel</p> <p>UNIT CoDe AC</p> <p>SER. No.</p>	<p>NRC No:</p> <p>LBL000453</p>		
<p>3</p>	<p>Source Positioning Push Button Locking Status</p> 		

Chapter 3 - Theory of Operation

Overview

Gamma (or X-ray) radiation is attenuated when it passes through the body by absorption and scattering. In X-ray or CT imaging, different tissues are identified, based on the degree of attenuation of the X-ray photons passing through the body of the patient. Images are obtained by processing the differences measured between the incident x-ray flow and the flow detected after transiting through the body.

Nuclear Medicine imaging uses radiopharmaceuticals that emit radiation from within the body. Attenuation, the loss of emitted photons due to photon absorption or Compton scattering, is characteristic to this type of imaging as well.

The degree of attenuation differs as it depends on the thickness and density of the tissue that the radiation crosses on its way to the detectors. Therefore, the amount of radiation detected depends on the position of the camera with respect to the patient, and the size and shape of the patient.

The effect of attenuation is important when the relative intensity of the images (density of counts) is used for clinical analysis, as in PET imaging. Unless attenuation is taken into account, the emission activity from the organs near the body surface is overestimated comparatively to activity from deep within the body, which is underestimated.

The CoDe AC option is designed to correct for attenuation effects in coincidence imaging.

In thorax PET imaging, the attenuation of the body is highly non-uniform; lesions may appear deformed in uncorrected images and the lungs appear to contain more activity than they should. Attenuation correction reduces the artificial decrease in activity caused by attenuation, so that image of the radiopharmaceutical represents more accurately the actual activity distribution in the thorax.

Primary methods of attenuation correction are based on the Chang method and assume a uniform attenuation coefficient across the body. This approximation is acceptable in areas of uniform density such as the brain and provides a reasonable correction for attenuation in such cases.

However, within the thorax the attenuation coefficients vary greatly, from low degrees of attenuation in the lungs to high degrees of attenuation in soft tissues, and even higher in skeletal tissue such as the spine and sternum. Thus an accurate correction of photon attenuation in the thorax requires measuring the local attenuation coefficient in the body.

Application

The CoDe AC option provides the operator with the means to measure the attenuation effects of anatomy on patient images and correct for those effects, thereby reducing attenuation artifacts in coincidence (PET) images.

In order to correct for attenuation in the thorax, the shape and attenuation of the organs in the thorax cavity must be known. The lungs, breast tissue and myocardium are significantly different in their attenuation.

Attenuation is measured by detecting the photons from the a transmission source that travels through a patient. The transmission scan is acquired at a range of angles, using a protocol similar to that for a Step & Shoot SPECT acquisition. This data is reconstructed to obtain the attenuation coefficients.

The quantitative distribution of these attenuation coefficients across the patient is referred to as the Attenuation Map.

The CoDe AC option provides the most efficient way of acquiring PET data with attenuation correction. The fast acquisition of Transmission, using high rate SPECT acquisition ensures a timely acquisition of statistically significant data.

The CoDe AC Transmission source is permanently mounted on the Septa Collimator, and the operator does not have to spend time removing and attaching the device.

Transmission Fan-beam Scans

The transmission scan is done in H-Mode with a lateral shift of two cm to cover the center of rotation. This position defined as the CoDe AC Home Position will also be used for the acquisition of the coincidence emission data.

The 18 ^{137}Cs collimated point sources create 18 asymmetric fan-beams, which are limited exactly to the Field Of View (FOV) of the opposite Detector (Head #2). The angle of the fan-beams is constant and calculated for a defined radial value (28.0 cm), displayed on the Gantry Display.

The transmission acquisition is done before the emission acquisition, in Fast Mode, with an energy window of $\pm 10\%$ around the 662 keV full energy peak of ^{137}Cs .

A pile-up rejector is used to reduce the number of pile-up events coming from the FDG agent in the ^{137}Cs energy window.

A second transmission scan is done after the first one to correct for residual FDG impurity in the Cs energy window. This second scan is done with the point sources being closed.

During the scan, the sources do not move.

Main Features

The main features of CoDe AC are listed below.

1. The Transmission sources are an integral part of the Septa Collimator.
2. The Transmission source is a line of ^{137}Cs point sources at a fix position. They create asymmetric fan-beams which cover the opposite detector.
3. The transmission sources do not move during scans.
4. The transmission source is a long lived (30 years) solid sealed line of 18 ^{137}Cs point sources.
5. No Collimator exchange or setup is needed when passing from transmission to emission imaging.
6. The 662 keV transmission energy allows transmission scans to be performed for a patient already injected with FDG.
7. The FDG impurity in the Cs energy window is corrected.
8. Attenuation Corrected Reconstruction algorithm is installed as an upgrade to the processing features.

Method of Operation

Attenuation Correction with CoDe AC consists of three main steps:

1. Transmission and Emission Acquisitions

Three sequential acquisitions are performed on the Millennium VG, using a single acquisition template:

- a Transmission scan with Source Open, in which the opposite detector (Detector #2) acquires the 662 keV photons emitted by the line of point sources
- b Transmission scan with Source Close, performed for a shorter time.
- c Emission coincidence scan, in which images of the radio-pharmaceutical injected to the patient are acquired on both detectors. The emission data is automatically re-binned (for details, refer to the Operator's Manual of the CoDe Option).

2. Creation of Attenuation Maps

The Attenuation Map is created by the Millennium VG software as follows:

- a Correcting the transmission projections for FDG impurity in the Cs energy window.
- b Computing the attenuation coefficients of the transmission scan pixels according to the projections of the Average Air Frame acquired once per week (see Air Frame Creation, page 5-2).
- c Reconstructing the pixel attenuation coefficients to obtain the attenuation coefficient voxels which comprise the Attenuation Map of the scanned patient.

3. Attenuation Correction of Emission PET Data

The Emission Data set and the Attenuation Map are transferred to the Processing Station, which corrects the re-binned emission PET data according to the Attenuation Map. For details on attenuation correction and building of tomographic slice reports, refer to the CoDe AC processing documentation applicable for your processing workstation.

Chapter 4 - Operation

This chapter includes operations instructions arranged in the following breakdown:

- Safety Precautions
- Acquisition
- Creating the Attenuation Map

	<p style="text-align: center;">CAUTION</p> <p>Please note that acquiring the average Air Frame and checking its profile check must be done once a week (see Air Frame, page 5-1), to ensure the accuracy of the patient Attenuation Maps.</p>
---	--

Safety Precautions

Safety Precautions

To ensure maximum safety of operation, the line of point sources is fitted with numerous safety device:

- **Radiation Shield**

When the source is close:

Radiation Leakage \leq 3 mRem/h at 5 cm from the PSD surface

A warning label mentioning the source activity is attached onto the PSD.

- **On/Off Mechanism**

The radiation beam is controlled through the source motion in the Tungsten source holder. A mechanical spring ensures that the source stays in **Close** position when the source is not in use. This prevents unnecessary radiation emission. The ON/OFF mechanism is completely mechanical, and can be activated without power supply.

- **Locker**

The ON/OFF mechanism is secured by a locker. The locker prevents exposure of the source by non-authorized personnel, or accidental opening. The Locker locks the Source Positioning Push button and can be opened only by a special key.

- **On/Off Indication**

- A self powered blinking LED indicates the status of the source: red for open and green for close.
- A label with a drawing indicating the Locked / Unlocked status of the Source Push-button locker is attached close to the Source ON/OFF Mechanism on the PSD.

- o A warning message is displayed on the Gantry Display:

Source Open

- o A warning message is displayed on the Acquisition Station Monitor:

Warning! Transmission Source is Open

The system continuously monitors the source position to detect potential failure, whether or not the CoDe AC option is in use. In case of malfunction or mechanical failure, the system will halt and the following messages will be displayed on the Gantry Display and on the Acquisition Station Monitor:

Gantry Display

Source Open

Acquisition Station Monitor

**System Paused
Source is Open**

In this case, you must immediately **LOCK** the Source Positioning Push Button in the close position, as follows:

1. Power OFF the Gantry
2. Check the Source Positioning Push Button. If it is not in close position, press the Release Handle, then lock the Source Positioning Push Button.
3. Call a **qualified service engineer** authorized by GE.

	<p style="text-align: center;">WARNING</p> <p>Do not tamper with the Source Holders. All handling of CoDe AC Device, including: removal, replacement, installation and repair must be performed only by qualified service personnel authorized by GE.</p>
---	---

	<p style="text-align: center;">CAUTION</p> <ol style="list-style-type: none"> 1. Do not let the ¹³⁷Cs line sources remain open unnecessarily. 2. Avoid exposure to the ¹³⁷Cs irradiated area.
---	--

Acquisition

Acquisition Parameters

A single acquisition template is defined for the transmission and emission scans, in which the user may change the following parameters:

- Acquisition Time
- Acquisition Mode - Continues or Step & Shoot
- Zoom of emission scan
- Number of Steps in Step & Shoot or Continues acquisitions

Acquisition Procedure

1. If needed, perform Collimator Exchange to replace the currently mounted Collimators with the Septa Collimators.
2. Follow the Gantry initialization instructions displayed on the Gantry Display.
3. Verify that the Source Status Indication LED blinks green (source close).

Note

No protocol can be activated if the source is not in close position before opening the protocol.

4. Set the Gantry to **CoDe AC Home Position**, using the RCU. The following axes information will appear on the Gantry Display:
Lateral Shift = **2 cm**
Radials position = **28.0** for both Heads.
Rotation = **90°**

5. Help the patient to lie on the Table. The patient orientation should be **Legs IN** for **Torso** scans, and **Legs OUT** for **Brain** scans. For detailed instructions of patient positioning for brain scans, refer to Positioning Patient, page 3-10 in the Operator's Manual of the CoDe Option.
6. Position the patient as close as possible to the Center Of Rotation (COR), as follows:
 - a Position the patient at the center of the Detectors.
 - b Move the Table **2 cm up**..

Note

When the Gantry is set to CoDe AC Home Position, the center of the detectors is 2 cm lower than the COR, due to the lateral shift. See Figure 4-1.

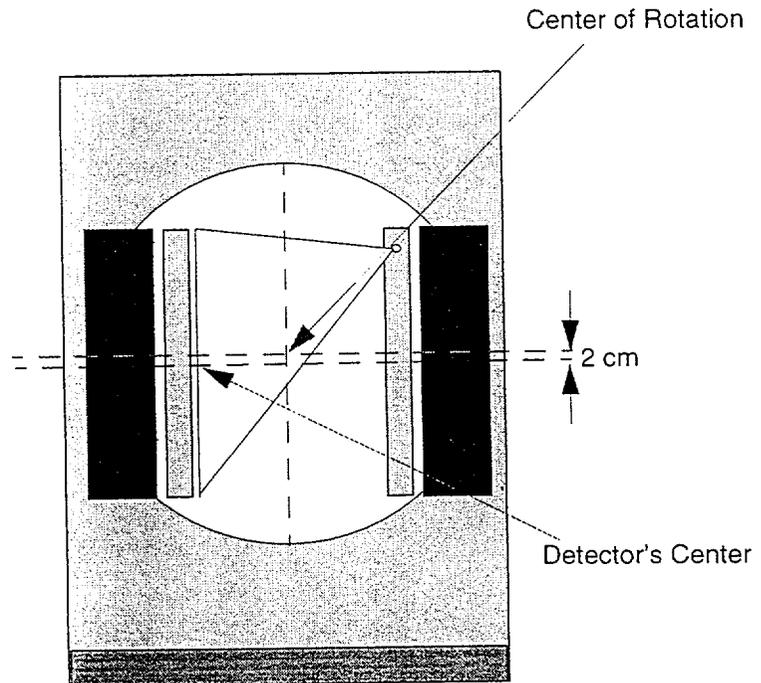


Figure 4-1. Center of Rotation & Detector Centers

7. Double click the desired **CoDe AC** icon residing in the **Tumor & Inflammation** or in the **Neurology** container, whichever applies.
8. Verify that the values of the transmission acquisition parameters are as follows:

Isotope:	Cs137
Head 2:	ON
Frame Size:	128
Zoom:	1
COR Correction:	OFF
Sensitivity Correction:	OFF
Rate:	Fast
Home Position:	CoDe AC
Rotation:	360°
Step:	3°
Mode:	Continuous
Time per Frame:	

2 s for Transmission Scan with Source Open
1 s for Transmission Scan with Source Closer.

Note

- The parameters of the transmission and emission protocols can be changed only **before** the transmission scans are started.
- The parameters of the emission scan are the same as used in the corresponding **CoDe** protocol.

9. Click the **[OK]** button and follow the displayed instructions.
10. When prompted, open the source by opening the Locker with the special key, and pressing the **Source Positioning Push Button**.



WARNING

The ¹³⁷Cs point sources are exposed. Keep clear from the radiation beam.

11. When prompted, press the RCU **<START/STOP>** key and the **<ENABLE>** lever concurrently to start the first transmission acquisition.

Note

The duration of the first transmission scan is four minutes.

12. Record the Study and Group numbers of the first transmission data.
13. When prompted, close the source by pressing the Release Handle and locking the Source Positioning Push Button with the special key.
14. When prompted, press the **<PAUSE/CONT>** key and the **ENABLE** lever on the RCU to continue the acquisition procedure.
15. When prompted, press the RCU **<START/STOP>** key and the **<ENABLE>** lever concurrently to start the second transmission acquisition.

Note

The duration of the second transmission scan is two minutes.

16. Record the Study and Group numbers of the second transmission data.
17. When the second transmission acquisition is completed, the system automatically enters the Coincidence Acquisition Mode, and the following message is displayed on the Acquisition Station Monitor:

For acquiring Emission Data, press start on the RCU.

Press the RCU **<START/STOP>** key and the **<ENABLE>** lever concurrently to start the Coincidence Acquisition.

18. Just following the Coincidence Acquisition, the image data is re-binned. When Coincidence Acquisition is completed, record the Study and Group numbers of the re-binned coincidence data.

Creation of Attenuation Maps

1. In the Command Line Window (CLW) type **CSPP <Enter>** to activate the Attenuation Maps Creation preset.
2. Enter the Study and Group numbers of the following scans:
 - Transmission With Source Open
 - Transmission With Source Close
 - Air Frame

Click **[OK]**.

The program creates the Attenuation Map applying to the patient and places it in the same study.

3. Transfer the Study which includes the Attenuation Map and the Emission data set to the processing station. At the processing station the emission data will be corrected for body attenuation.

Chapter 5 - Maintenance

	WARNING
	Tampering with or modifying the CODE AC line of point source, or unauthorized removal of the source container in this device may result with exposure to unnecessary levels of radiation. Handling of the CoDe AC Device, including: removal, replacement, installation and repair, must be performed <i>only by qualified service personnel</i> authorized by the Vendor.

Maintenance of the CoDe AC option includes:

- Air Frame Creation - performed once a week
- Radioactive Contamination Test

Air Frame Creation

a. Purpose

The Air Frame is used to compute the attenuation coefficients of the acquired transmission projections, which when reconstructed build the Attenuation Map.

The Air Frame is acquired for Head #2 only. It is acquired through a 40 minutes ECT scan of the transmission source with no patient or table between the source and the detector head.

b. b. Indications

- Following installation
- Once a week, following CoDe Weekly QC (for CoDe Weekly QC refer to Chapter 4 in the CoDe Option Operator's Manual).

c. Acquiring the Average Air Frame

1. Double click the **CSAIR** icon residing within the **Maintenance** container.
2. Verify that the values of the transmission acquisition parameters are as follows:

Isotope:	Cs137
Head 2:	ON
Frame Size:	128
Zoom:	1
COR Correction:	OFF
Sensitivity Correction:	OFF
Rate:	Fast
Home Position:	CoDe AC
Time per Frame:	20 sec
Rotation:	360°
Step:	3°
Mode:	Continuous

3. Click the [OK] button and follow the displayed instructions.
4. When prompted, open the source by opening the Locker with the special key, and pressing the **Source Positioning Push Button**.

	<p style="text-align: center;">WARNING</p> <p>The ¹³⁷Cs point sources are exposed. Keep clear from the radiation beam.</p>
---	--

5. When prompted, press the RCU <START/STOP> key and the <ENABLE> lever concurrently to start the first transmission acquisition.

Note

The duration of the Air Frame transmission scan is 40 minutes.

6. When prompted, close the source by pressing the Release Handle and locking the Source Positioning Push Button with the special key.
7. The program automatically creates one average Air Frame for Head #2. When the average Air Frame is created, the following message is displayed on the operator's console:

**Air Frame procedure is successfully completed
Air Frame is created !!!**

Record the Study and Group number of the average Air Frame.
You will need this information when creating of attenuation map for each CoDe scan.

Radioactive Contamination Test

The camera should be checked for radiation leaks at least once every six months or earlier if stipulated by local safety regulations. The radiation leak test should be performed according to the requirements of the American National Standard, Publication N542, Appendix A: Dry Wipe Test.

The radiation leak test is carried out as follows:

1. Ensure that the source is in close position and that the Source Positioning Push Button is locked.
2. Using dry filter paper, thoroughly wipe all surfaces of the PSD.
3. After wiping the PSD surface, check the filter paper.
4. If the radioactive content of filter paper is less than $5\eta\text{Ci}$ the CoDe AC Device is considered non-leaking.

In case of a higher radioactive content, immediately contact your service office.

Chapter 6 - Troubleshooting

Symptoms and Corrective Actions

When any of the symptoms listed in Table 6-1 below occurs, call you service office, describe the symptom and schedule the repair.

	WARNING
	Repair of CoDe AC malfunctions as well as removal, replacement and installation of the CoDe AC Device, must be performed <i>only by qualified service personnel</i> authorized by the Vendor.

Table 6-1: CoDe AC Malfunction Symptoms

#	Symptom	Possible Cause
1	Source Status Indicating LED is <i>not</i> blinking.	1. Bad LED Cable connection. 2. Faulty LED. 3. Discharged LED Batteries.
2	Source Status Indicating LED blinks green while the Source Positioning Push Button is pressed, and <i>no</i> SOURCE OPEN message is displayed.	1. Faulty Micro-Switch. 2. Defective Source Status PCB.
3	Faulty Air Frame	1. Incorrect Source Open position adjustment. 2. Faulty CoDe AC Device.
4	Source Locked in OPEN position.	1. Faulty Source Release Spring.

Error Message

Table 6-2 below, lists the CoDe AC error messages that may be displayed on the GAntry Display and on the Operator's Console, and the actions to be taken when they occur.

Table 6-2: Error Messages

Error Message		Description and Recommended Action
Gantry Display	Operator Console	
Error: Source Open	Error: Source Open System paused	<ol style="list-style-type: none"> 1. Press the Release Handle to close the source. 2. If the error message appeared after a Close Transmission scan, press the RCU <START/CONT> key for coincidence acquisition. Otherwise, carefully release the patient and call your service office. 3. If the error message persists, carefully release the patient and call your service office.

Appendix C

Service Manual

CoDe AC

Service Manual

Direction 2250061-100

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CHAPTER 1 SAFETY AND REGULATORY

1.1 SAFETY GUIDELINES

1.1.1 General

1. The CoDe AC option has been designed and manufactured to ensure maximum safety of operation. The equipment should be serviced in strict compliance with the safety precautions, warnings and operating instructions contained in this manual.
2. The product should be installed, maintained and serviced only by qualified service personnel according to procedures laid down in this manual. The owner should make certain that only properly trained, fully qualified service engineers are authorized to service the equipment.
3. The system has been designed to meet all the safety requirements applicable to medical equipment. However, anyone attempting to operate the system must be fully aware of potential safety hazards
4. CoDe AC is an option of the dual-head variable-angle Millennium VG gamma camera. The Service Engineer must be fully acquainted with the safety precautions and guidelines specified in the System Operation and Service Manuals, as well as those specified in the CoDe AC Operator's Manual.
5. The system in whole or in part should not be modified in any way without prior written approval by ELGEMS Ltd.
6. Do not leave the system with problems that may affect the safety of its operation. In case you have doubts concerning the system's safe operation, call the service office for further instructions and notify the customer that the system is not to be used until the problem is resolved.
7. Safe servicing requires that the field engineer has a thorough knowledge of all equipment controls and safety devices.
8. The CoDe AC option must be maintained according to the procedures described in the Planned Maintenance Chapter.

1.1.2 Transportation and Unpacking

1. Any damage discovered during shipment should be immediately reported to the Vendor.
2. During unpacking and installation, the option should be handled with great care, to avoid damage.
3. During unpacking and transportation, do not leave the equipment unsupervised.
4. Verify that all packages are empty after the unpacking process.
5. Before assembly, clear the area of packaging material, nails, hazardous metal pieces, dirt and rubbish.

1.2 SAFETY DEFINITIONS

Warnings, Cautions and Notes are used throughout this manual. The identified hazards are surrounded by a frame, and are used in the following way.

	DANGER
	Danger is used to identify conditions or actions for which a specific hazard is known to exist which will cause severe personal injury, or substantial property damage if the instructions are ignored.

	WARNING
	Warnings are used to identify conditions or actions for which a specific hazard is known to exist, which may cause severe personal injury, death or substantial property damage if the instructions are ignored.

	CAUTION
	Cautions are used to identify conditions or actions for which a potential hazard may exist, which will or can cause minor personal injury, or property damage if the instructions are ignored.

1.3 HAZARDS

1.3.1 General Hazards

1. Some repair/replacement procedures require the removal of protective covers, exposing parts at high temperatures or with pinch points. Read the safety/warning labels and follow the instructions in this manual to prevent burns or injuries.
2. Most servicing procedures direct you to remove power from the system. This is done using the Circuit Breaker located at the back of the Gantry.
3. If a procedure requires that power be maintained, you should disconnect or restrict access to all Hand-Held Controllers and the Acquisition Computer to prevent unexpected movement of the Gantry, Detectors or Table.

1.3.2 Electrical Hazards



Do not remove, or open, system covers or plugs, while the camera is powered *ON*. Some internal circuits operate at high voltage, capable of causing severe electric shock and/or serious injury.

1.3.3 Radiation Hazards



	<p>WARNING</p> <p>Handling of the CoDe AC option, including replacement, installation and repair must be performed <i>only by qualified service personnel</i>.</p>
--	---

	<p>WARNING</p> <p>When the Source Positioning Push Button is pressed, the sources are exposed, transmission radiation starts, the color of the blinking Radiation Indicating LED changes from green (close position) to red (open position).</p>
--	---

	<p>WARNING</p> <p>Tampering with or modifying the CoDe AC option, or removal of the source contained in the CoDe AC Device may result in exposure to unnecessary levels of radiation.</p>
--	--

	<p>WARNING</p> <p>In the event of accidental damage to the CoDe AC option:</p> <ol style="list-style-type: none"> 1. Close the CoDe AC point sources by pressing the Release Handle. 2. Verify that the Source Positioning Push Button is in <i>Close</i> position. 3. Verify that the indicating LED blinks green. 4. Lock the Source Positioning Push Button using the special key. 5. Call your Service Supervisor for instructions.
--	---

1.4 RADIATION SAFEGUARDS

1. The point sources have a fixed aperture and a limited radiation beam. The size of the radiation beam at the collimator plane of the opposite detector is less than the detector's field of view, ensuring that radiation is not emitted to the surrounding area during attenuation correction.
2. When the point source are in close position, the leakage dose at 5 cm from the collimator surface of the CoDe AC Device is less than 3 mRem/h.
The operator's exposure for 1 working day is calculated to be approximately 0.2 mRem and for the patient 1 mRem for one Study.

Note

1 Rad = 1 REM (Rad Equivalent Man). The maximum radioactive dose to which radiation workers may be exposed is: 5 Rem/year.

3. A blinking LED on the PSD side indicates the source position: red - open, green - close.
4. A Locker is used to secure the Source Positioning Push Button, preventing accidental opening.

A label on the ON/OFF flung displays symbols that indicate the state of the Locker, i.e.

Locked  or Unlocked  (see Figure 1-3 and Table 1-2).

5. The system continuously monitors the position of the sources in order to detect potential failures.

In the case of mechanical failure:

- a. Close point sources *manually* by screwing the Source Positioning Adjustment Screw inwards. This will push out the Source Securing Pin (see Figure 1-1).
- b. Lock the source in the close position by turning the Locking Key to the Locked Position to ensure that the source cannot be accidentally opened (see Figure 1-2).

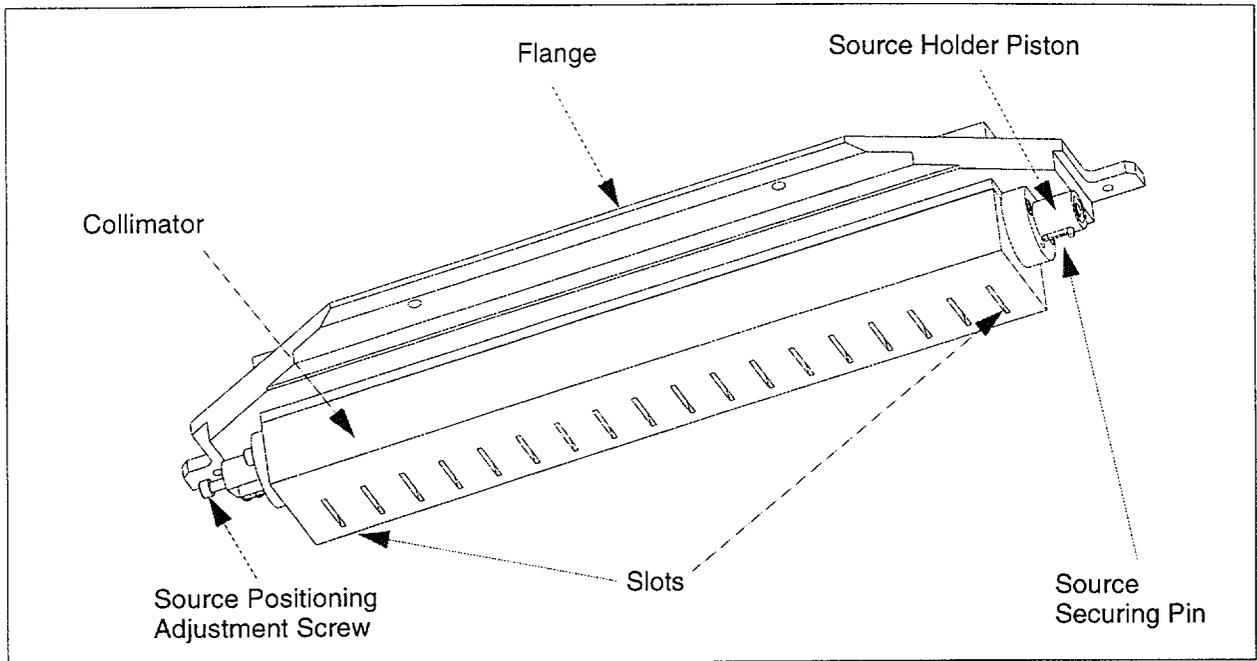


Figure 1-1. CoDe AC Device

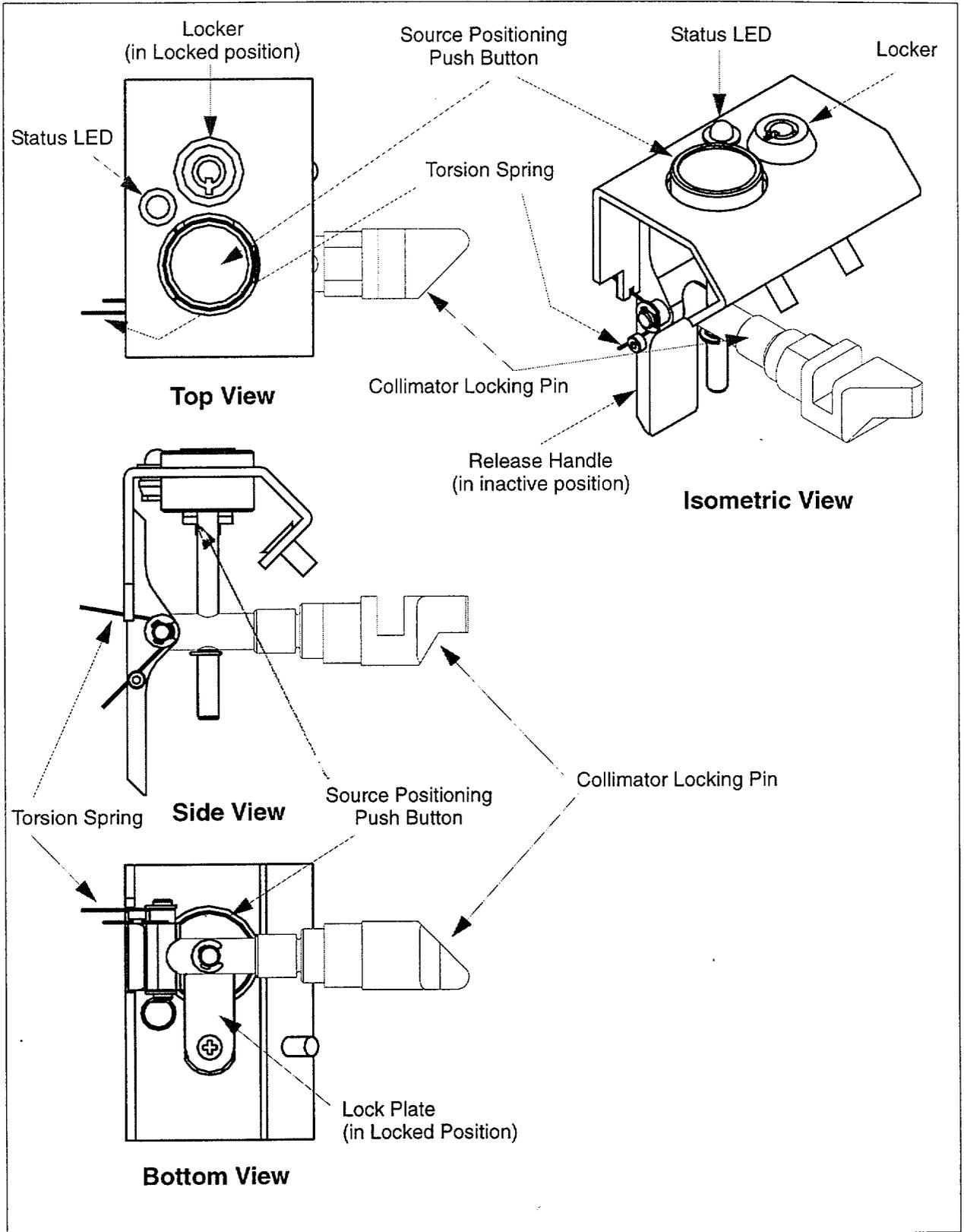
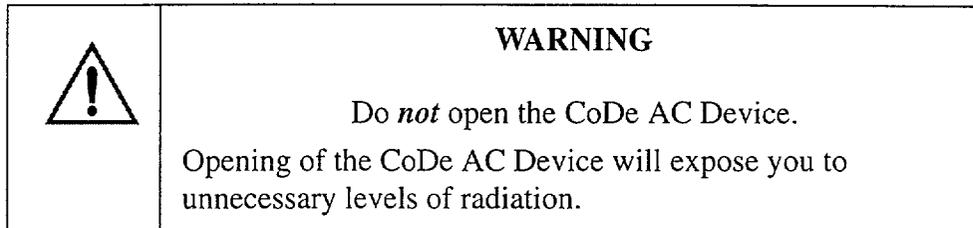


Figure 1-2. CoDe AC ON/OFF Mechanism

1.5 SOURCE HANDLING

The source is delivered to the customer when it is already inserted in the CoDe AC Tungsten holder. It is delivered in a drop proof packages class A.

No Source handling is needed. The line point source is an integral part of the CoDe AC option..



1.6 RADIATION LEAK TEST

The camera should be checked for radiation leaks at least once every six months or earlier if stipulated by local safety regulations. The radiation leak test should be performed by the user according to the requirements of the American National Standard, Publication N542, Appendix A: Dry Wipe Test. For instructions, refer to the **Radiation Leakage Test in Chapter 5 of the Operator's Manual**.

1.7 SYMBOLS USED

All of these symbols in section 1.7 subsection 1.7.1, IEC Symbols, are given in standard UL2601-1, Medical Electrical Equipment, Part 1: General Requirements for Safety, Second Edition, Clause 6. UL201-1 is the relevant Underwriters Laboratory standard for nuclear medicine equipment, including the labels. Compliance to the UL standard is recognized by the FDA as one of their requirements for FDA clearance (510(k)) to market the NM device in the USA.

1.7.1 IEC Symbols

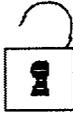
The system may have labels with one or more of the following symbols. These symbols indicate the IEC standards to which the system conforms.

Symbol	IEC Standard
	Alternating Current
	Protective Earthing Point
	ON / Power
	OFF / Power OFF
	OFF (only for part of equipment)
	ON (only for part of equipment)
	Type B Equipment
	Input Power
	Output Power
	Functional Earth Ground
	Warning, Caution - consult accompanying documents
	Electrical Shock Hazard

1.7.2 System Specific Symbols

The system has a label with the following symbols.

Table 1-1: Specific Symbols

Symbol	Meaning
	Source Positioning Push Button unlocked.
	Source Positioning Push Button locked.
	Radiation emission warning

1.8 SAFETY AND RATING LABELS

Figure 1-3 depicts the location of the CoDe AC safety and rating labels. The numbers used in the figures correspond to the numbers shown alongside the labels shown on the next page.

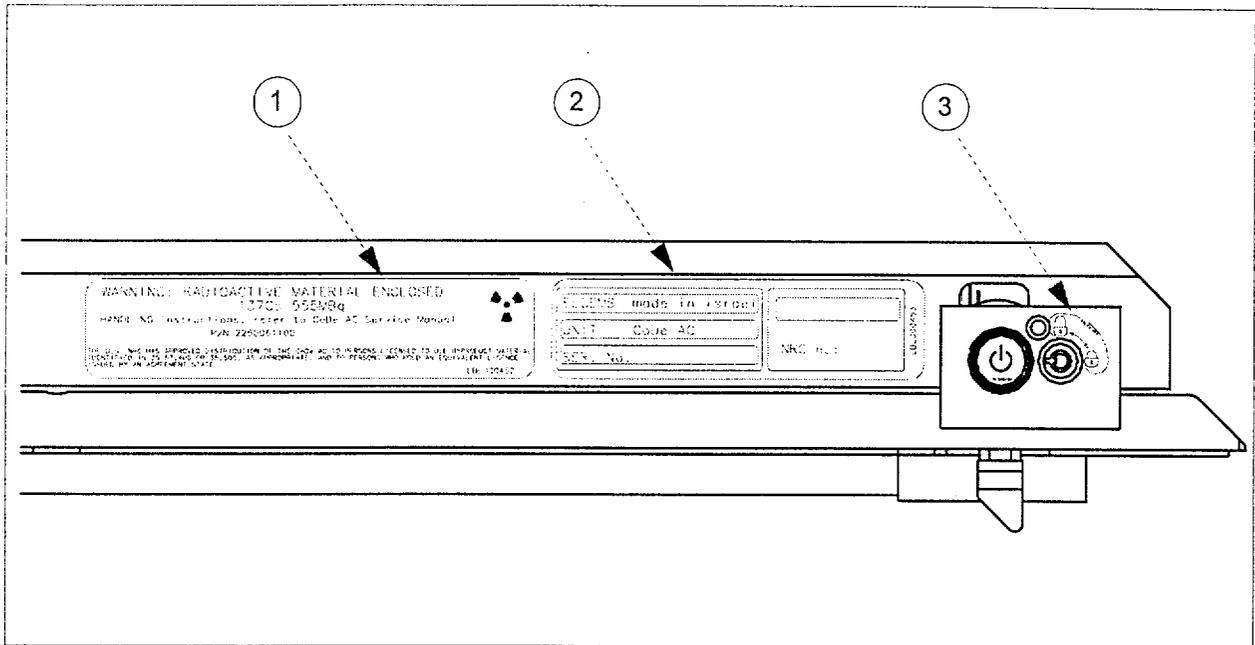
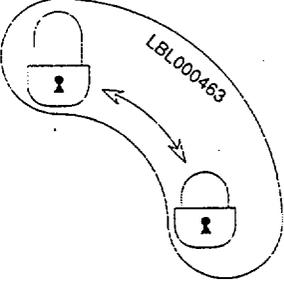


Figure 1-3. CoDe AC Safety and Rating Labels

Table 1-2. CoDe AC Safety & Rating Labels

1	<p>WARNING: RADIOACTIVE MATERIAL ENCLOSED </p> <p>Nuclide: ¹³⁷Cs Activity: 555 MBq Ref. Date: -----</p> <p>Handling Instructions: refer to CoDe AC Service Manual P/N 2250061-100</p> <p>THE U.S. NRC HAS APPROVED DISTRIBUTION OF THE CoDe AC TO PERSONS LICENSED TO USE BYPRODUCT MATERIAL IDENTIFIED IN 35.57, 35.400 OR 35.500 AS APPROPRIATE, AND TO PERSONS WHO HOLD AN EQUIVALENT LICENSE ISSUED BY AN AGREEMENT STATE</p> <p style="text-align: right;">LBL000452</p>
2	<div style="border: 1px solid black; padding: 5px;"> <div style="display: flex; justify-content: space-between;"> <div style="border: 1px solid black; padding: 2px;">ELGEMS made in Israel</div> <div style="border: 1px solid black; padding: 2px;"> </div> </div> <div style="border: 1px solid black; padding: 2px; margin-top: 2px;">UNIT CoDe AC</div> <div style="border: 1px solid black; padding: 2px; margin-top: 2px;">SER. No.</div> </div> <div style="border: 1px solid black; padding: 5px; margin-top: 5px;"> <p>NRC No:</p> <p style="text-align: right; font-size: small;">LBL000453</p> </div>
3	<p>Source Positioning Push Button Locking Status</p> 

1.9 REGULATORY INFORMATION

The equipment complies with the IEC 601-1 standard.

This equipment generates and can radiate radio frequency energy. The equipment may cause radio frequency interference to other medical and non-medical devices and to radio communications. To provide reasonable protection against such interference, the camera complies with the emission limits for a Group 1, Class A Medical Devices as stated in IEC 601-1-2. However, there is no guarantee that interference will not occur in a particular installation.

The manufacturer is not responsible for any interference caused by using other than recommended interconnect cables or by unauthorized change or modifications to this equipment.

Unauthorized change or modifications could void the user's authority to operate the equipment.

To comply with the regulations on electromagnetic interference for a Group 1, Class A Medical Device, all interconnect cables to peripheral devices must be shielded and properly grounded. Use of cables not properly shielded and grounded may result in the equipment causing radio frequency interference in violation of the local regulations.

Due to installation in less favorable environment, this equipment may be exposed to electromagnetic and electrostatic interference. To ensure a high level of reliability when exposed to such interference, this equipment complies with the immunity requirements as stated in IEC 601-1-2. for immunity Class 1. The operating conditions are classified on the basis of performance criteria as defined in IEC 801-2.

The equipment complies with the following standards:

10 CFR Part 19 "Notices, Instructions and Reports to Workers: Inspections and Investigations"

10 CFR Part 20 "Standards for Protection Against Radiation"

10 CFR Part 32 "Specific Domestic Licences to Manufacture or Transfer Certain Items Containing By-product Material"

10 CFR Part 35 "Medical Use of By-product Material"

CHAPTER 2 DESCRIPTION

2.1 OVERVIEW

The CoDe option consists of the CoDe AC Device, which is installed on a special Septa Collimator intended to be mounted on Head #1.

For a general description of the option, refer to Chapter 1 in the CoDe AC Operator's Manual.

The CoDe AC Device is shipped separately to the customer by IPL, the sub-contractor who inserts the sealed tube of ^{137}Cs point sources into the Device.

The CoDe AC Device is assembled in the field on the iron frame of the special Septa Collimator, while it is mounted on Head #1 via the Collimator Exchange procedure.

The special Septa Collimator consists of a Septa Collimator, where:

- Part of the Septa are cut off at one side to make space for the CoDe AC device
- The Body Contour (BC) Printed Circuit Board (PCB) is replaced by a new PCB, which provides the electronics required to detect the Close/Open position of the ^{137}Cs point sources and to pass this information to the Source Positioning Indicating LED, the Gantry Display and the operator's console.
- Two alkaline 1.5 V batteries used to power the Source Positioning Indicating LED are mounted beneath the above new board.
- Source ON/OFF mechanism assembled on the Frame of the Septa Collimator (in the Filed).

See Figure 2-1 and Figure 2-2 for the CoDe AC Device and the Septa Collimator with the mounted CoDe AC Device, respectively.

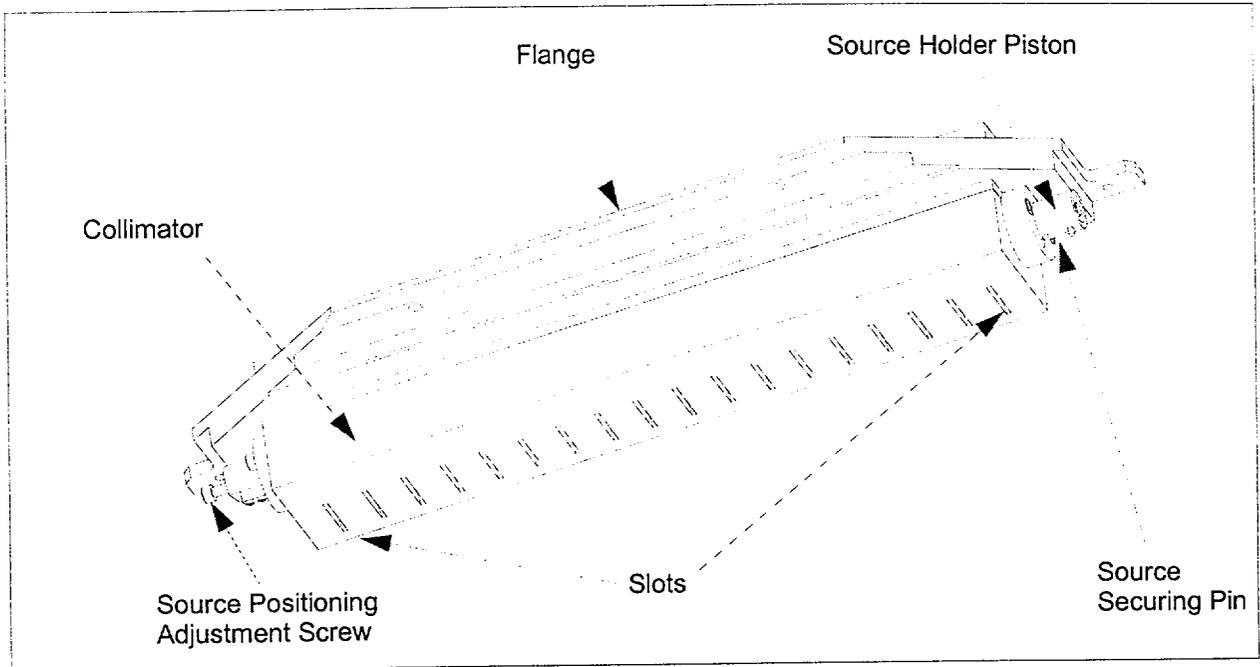


Figure 2-1. CoDe AC Device

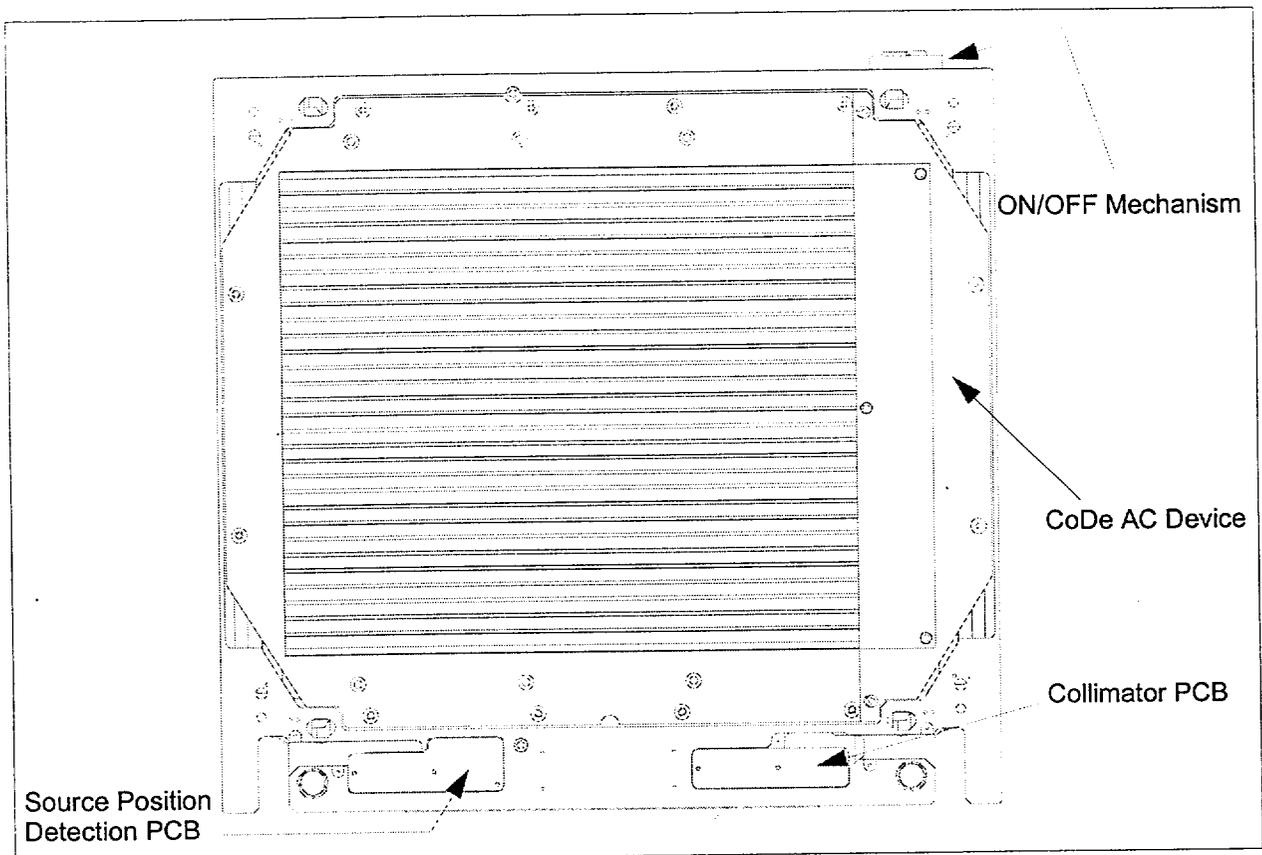


Figure 2-2. Septa Collimator with Mounted CoDe AC Device

2.2 PRE-REQUISITES

The pre-requisites for the CoDe AC options are:

- CDOC board: P.N. , Version TBD
- ADAM boards: P.N. , Version TBD
- CODE board: P.N. , Version TBD
- CED board: P.N. PCA000299, Version 01
- Acquisition Software Version 3.8, distributed on one CD, P.N. LSW000088

2.3 OPTION CONTENT

The Code AC option (P.N. OPT000239) consists of the following parts:

- CoDe AC Device, P.N. ASM000745 (shipped separately by the sub-contractor)
- Collimator Cart loaded two different Septa Collimators: one special and one regular Septa Collimator.
- CoDe AC Kit, P.N. UGP000625
- CoDe AC Operator's Manual, Direction 2250060-100
- CoDe AC Service Manual, Direction 2250061-100 (this manual)

2.3.1 Contents of the CoDe AC Kit

- ON/OFF Flung - P.N. MEC005249
- Locker - P.N. HH000100115
- Source Positioning Push Button - P.N. MEC005232
- Release Handle - P.N. MEC005233
- Release Handle Axis - P.N. MEC005234
- Torsion Spring - P.N. HK000300016
- External retaining Ring, P.N. HB70020040M
- Flat Screw NC- 1/4", 19 mm long P.N. HS11340412C
- Screw NC-10, Length 1/2" P.N. HS11349508C
- Screw M2, P.N. HS004002008
- Screw NC-8 10 mm long, P.N. HS11359406C
- Cs Warning Label, P.N. LBL000452
- Locker Position Label, P.N. LBL000463
- CoDe AC Serial Number Label, , P.N. LBL000453

2.3.2 Pioneer Kit

A Pioneer Kit has been designed to assist the service personnel in case of failures, and is mandatory for the installation.

One Pioneer Kit is required per geographic region of the field engineer.

Verify the presence of the complete kits *before* starting the installation.

Table 2-1. Pioneer Kit

Description	Part Number	Quantity
Full CoDe AC Option	OPT000239	1 per region

2.4 REQUIRED TOOLS AND EQUIPMENT

- Set of Allen Keys
- Philips flat Screwdrivers
- Circlip Pliers (retaining ring pliers)
- Blue Loctite glue
- Radiation Counter

2.5 INSTALLATION PROCEDURE

CoDe AC installation consists of the following steps, to be performed in the given order:

1. Mechanical installation - described in Chapter 3
2. Code AC Adjustment and Calibration - described in Chapter 4
3. Quality Control (QC) - described in Chapter 5

2.6 INSTALLATION SCHEDULE

The total time required to install the CoDe AC option and to calibrate the system is 7 hours, with the following breakdown:

- Mechanical installation - two qualified technicians for 1 hour
one qualified technician for an additional hour
- Creation of specific correction maps - 1 hour
- Adjusting the source position - 3 hours
- Air Frame Profile Test - 1 hour

CHAPTER 3 MECHANICAL INSTALLATION

	WARNING Installation of the CoDe AC option must be carried out <i>only</i> by a service engineer authorized by GE Medical Systems.
---	--

3.1 SHIPMENT

The CoDe AC option is shipped as follows:

- The **CoDe AC Device** is shipped to the site by the sub-contractor (IPL) in a drop-proof class-A package.
- The **Septa Collimators** mounted on the **Collimator Cart** are shipped in a wooden crate. The Septa Collimator of Head #1 has been cut to accommodate the CoDe AC Device, and the cut part is assembled to the Collimator Frame with four screws.

If the option is shipped from the factory, the ON/OFF mechanism is installed on the Septa Collimator of Head #1, and the documentation is included in the accessories box.

In case of field upgrade, the ON/OFF mechanism is shipped in a special cardboard box together with the Installation Kit.

- In case of field upgrade, the shipment includes a third cardboard box containing:
 - **ON/OFF Mechanism**
 - **Installation Kit**
 - **CoDe AC Operator's Manual** packed in nylon bag, to be inserted in the Operators Manual Binder
 - **CoDe AC Service Manual** (this manual) packed in nylon bag, to be inserted in the binder of Service Manual Volume II, under the Options Divider.

3.2 HARDWARE INSTALLATION

The mechanical installation of the CoDe AC option depends whether the option is shipped with the system or is field upgraded.

The mechanical installation procedure consists of the following steps, to be performed in the given order.

1. Unpacking, described in Section 3.2.1.
2. Assembling the CoDe AC Device, described in Section 3.2.2.
3. For field upgrade options only: assembling the ON/OFF Mechanism, described in Section 3.2.3.
4. Operational Checks, described in Section 3.2.4.
5. Proceed to Chapter 4 to calibrate the CoDe AC option.

3.2.1 Unpacking

1. Remove the Collimator Cart with the Septa Collimators from the wooden crate (for instructions, refer to the Millennium VG Installation Manual, Chapter 2), and wheel the cart into the site.
2. Bring the *packed* CoDe AC Device into the site.
3. Place the packed CoDe AC Device on a stable table, and open it carefully.
4. Check that the source is in close position, as indicated by the OUT position of the Source Securing Pin (see Figure 2-1).
Check with a radiation counter that the radiation level at the collimated surface of the CoDe AC Device is less than 5 mRem/hour ± 0.5 mRem/hour
5. Cut the two plastic ties that secure the Source Securing Pin in **OUT** position.

3.2.2 Assembling the CoDe AC Device

	WARNING If the CoDe AC Device is dropped down during installation: <ul style="list-style-type: none">• Place the CoDe AC Device into its original packing, seal it, and send it back to IPL. For IPL Address refer to Section 6.1.
---	--

1. Wheel the Collimator Cart with the Septa Collimator of Head #1 as close as possible to the table with the CoDe AC Device.
2. Lock the Collimator Cart wheels.
3. Remove the cut part of the Septa Collimator, removing it's four fastening screws. Keep the screws.
4. Together with a second technician, remove the CoDe AC Device form the package box and insert it into the Septa Collimator.
5. Fasten the CoDe AC Device to the frame of the Septa Collimator, using two of the four screws removed in Step 3, above (1/4 UNC), and two new screws (UNC #10) included in the ON/OFF Mechanism kit.
6. Place the cut part removed at Step 3 above into the CoDe AC package box and store it.

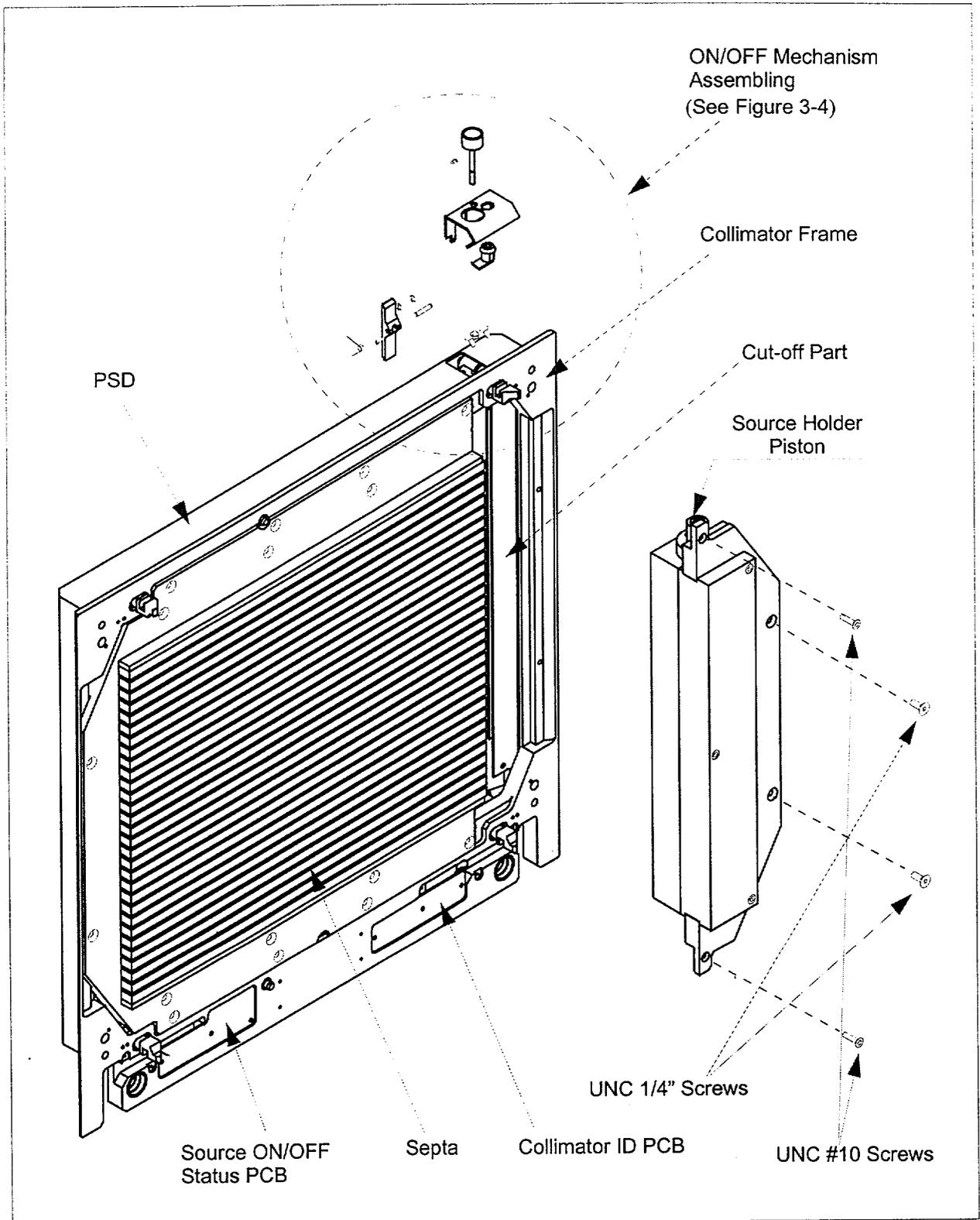


Figure 3-1. Assembling the CoDe AC Device

3.2.3 Assembling the ON/OFF Mechanism

1. Load the Septa Collimators on the Detector Heads using the Collimator Exchange procedure.
2. Set the Gantry to rotation angle of 180° (Head #1 down).
3. Move the Table to slanted position.
4. Remove the PSD of the Septa Collimator mounted on Head #1 (the collimator with the CoDe AC Device), by removing its four fastening Philips screws. See Figure 3-2. Be careful with the PSD cables.

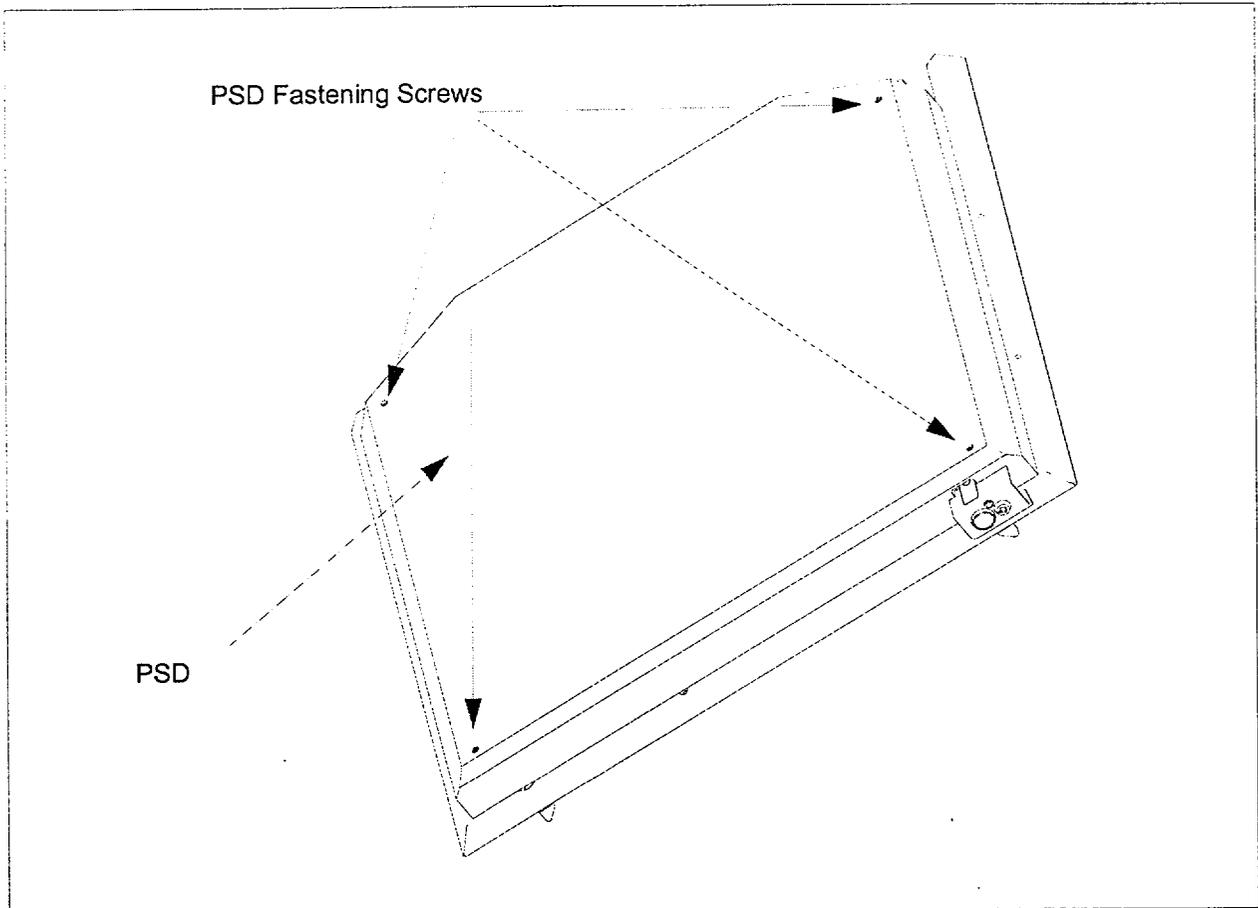


Figure 3-2. Septa Collimator with PSD

5. Referring to Figure 3-4, attach the ON/OFF Flange to the Collimator Frame and tight it with its two fastening screws.
6. Referring to Figure 3-4, insert the Source Positioning Push Button through its designated hole in the Flange and through the 4.5 mm diameter hole in the Collimator Locking Pin, and secure it with the retaining ring.

7. Verify that the M2 screw is assembled on the Release Handle (see Figure 3-4 and Figure 3-5).
8. Assemble the Release Handle.
9. Referring to Figure 3-4, insert the Axis Pin through the 4 mm diameter hole in the Collimator Locking Pin and through the Release Handle.
10. Insert the Torsion Spring onto the Axis Pin and lock it with two retaining rings one from each side, using the Retaining Ring Assembling Pliers.
11. Referring to Figure 3-3:
 - a. Disassemble the Locker Plate from the Locker, releasing its fastening screw. Unscrew the Locker's Nut.
 - b. Insert the Locker through its designated hole in the Flange and screw the Locker Nut to fix the Locker in place.
 - c. Assemble the locker plate and secure it with the Locker Plate Screw removed at Step 11, above, so that the Push Button is locked. Verify correct locking direction (see Figure 3-5) and secure it using locktite.

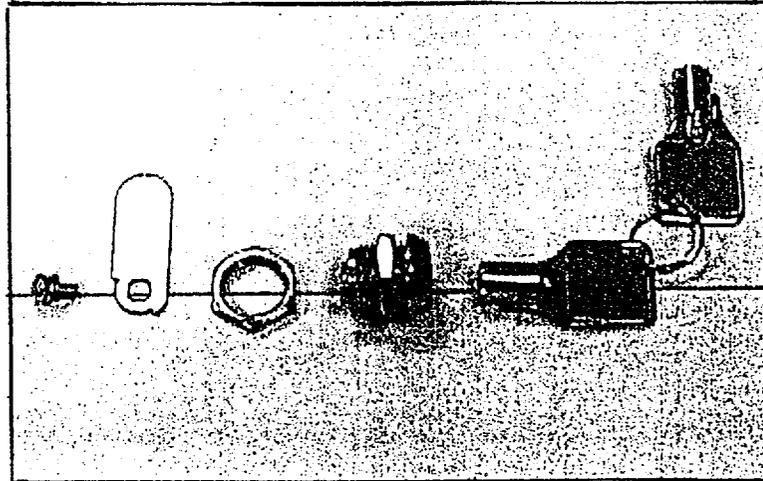


Figure 3-3. Locker Assembling / Disassembling

12. Connect the LED cable (attached to the Collimator Frame) to the LED Connector.
13. Connect the Source Micro-Switch (see Figure 3-6) cable to Connector XX on the Source ON/OFF Status PCB.
14. Re-assemble the PSD.

15. Attach the Warning Label and the Rating Label (supplied in the ON/OFF Mechanism Kit) to the PSD as per Figure 1-3.
16. Move the Table back to its normal position.

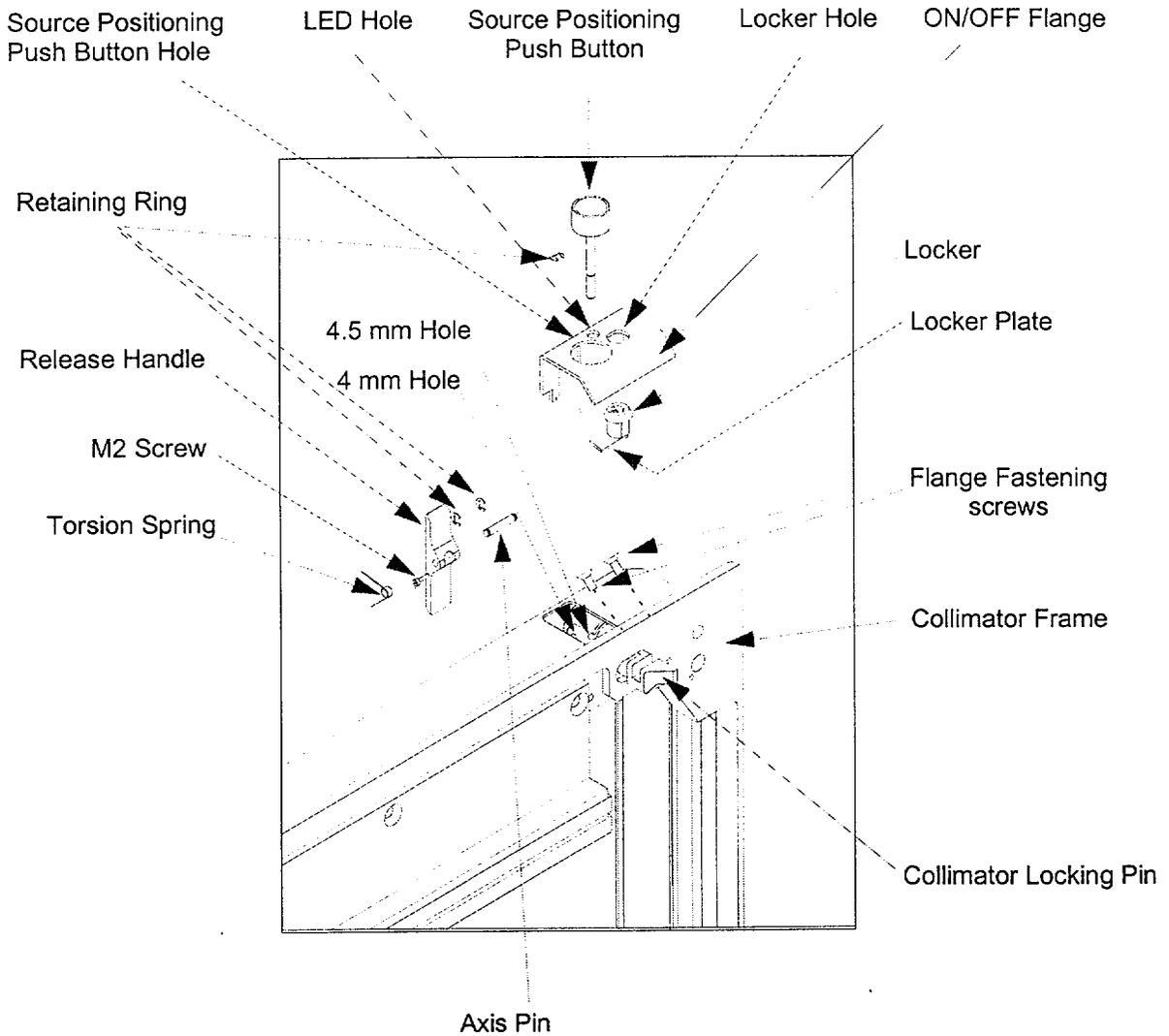


Figure 3-4. Assembling the ON/OFF Mechanism

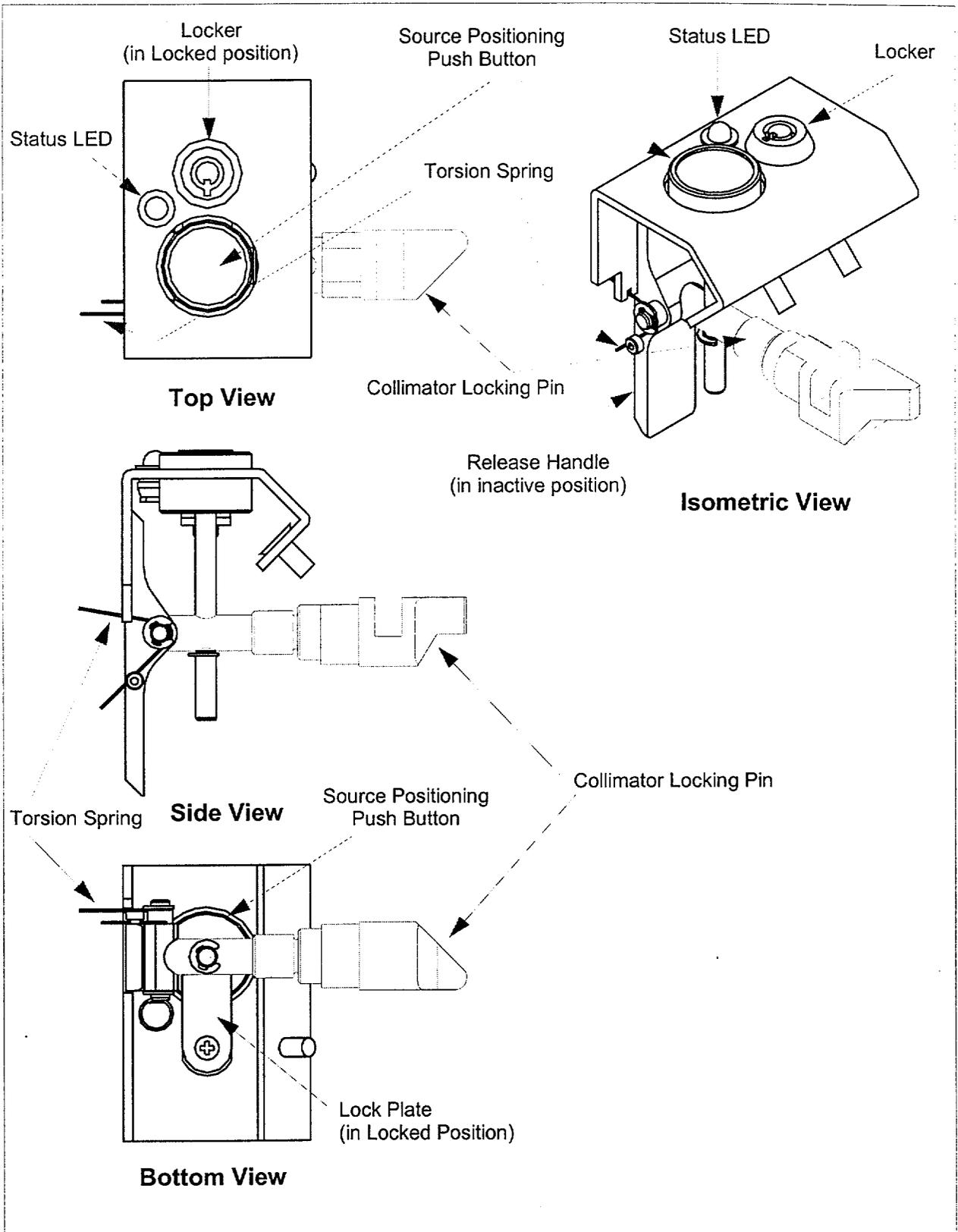


Figure 3-5. Assembled ON/OFF Mechanism - Different Views

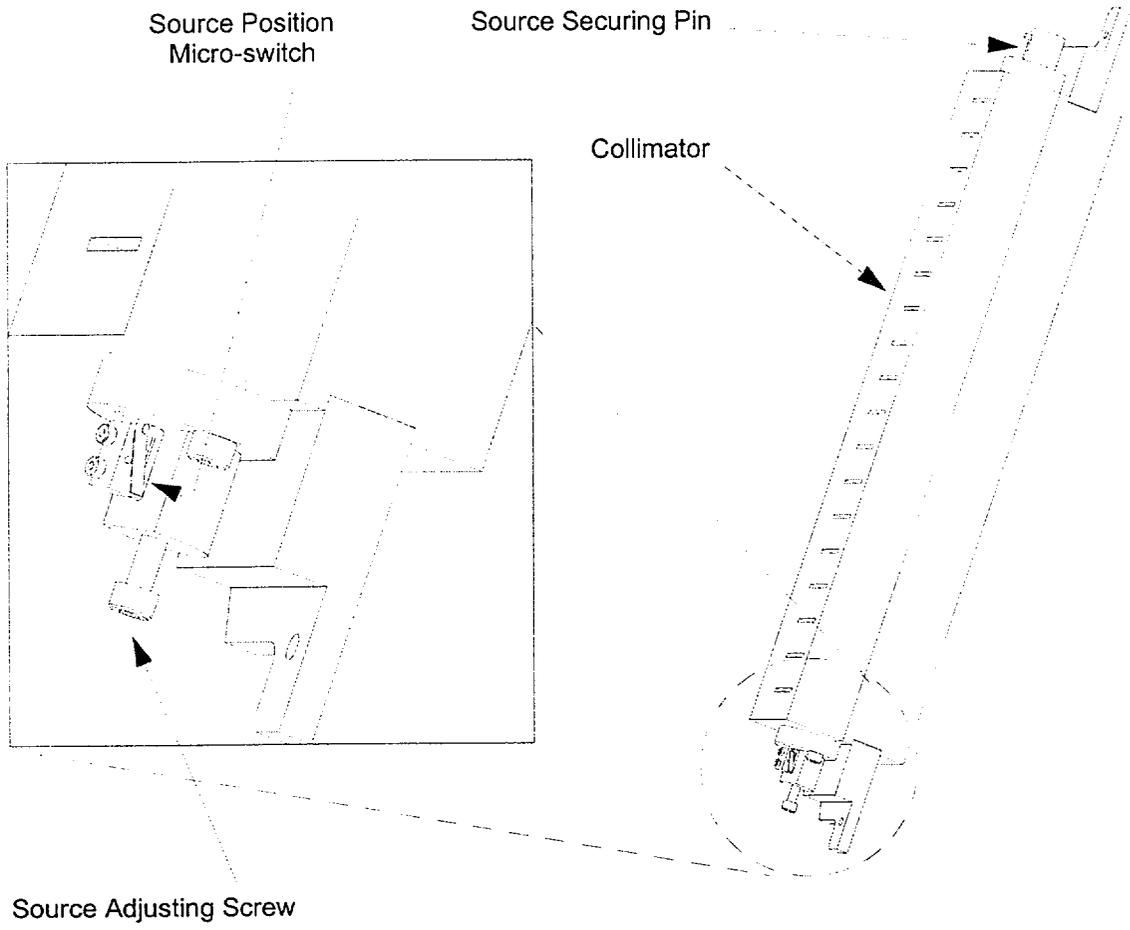


Figure 3-6. Source Position Micro-Switch

3.2.4 Checking the CODE AC Option

1. **Check the source motion and source open indications** as follows:
 - a. Press the Source Positioning Push Button and verify that the color of the blinking LED turns **red**.
 - b. Verify that the **SOURCE OPEN** message appears on the Gantry Display.
 - c. Verify that the following message appears on the operator's Console:
WARNING
Source is OPEN
System Paused
 - d. Check that Gantry rotation is disabled, by pressing the RCU **CW/CCW** key + the **Enable Lever**.
 - e. Press the Release Handle and verify that the color of the blinking LED turns **green**, and that the warning messages on the Gantry Display and on the Operator's Console disappear.
2. **Check the Lock** as follows:
 - a. Lock the Locker using the special key.
 - b. Press Source Positioning Push Button and verify that the source does not move to the Open Position.
3. Using a radioactive counter verify that the radiation dose at 5 cm from the PSD surface just above the CoDe AC device is less than 3 mRem/hour.
4. **Check CoDe AC acquisition** as follows:
 - a. Double click the **CoDe AC** icon residing in the **Maintenance** container.
 - b. In the opened acquisition notebook, click [**OK**].
 - c. When prompted, press the Source Positioning Push Button.
 - d. Verify that the **SOURCE OPEN** message appears on the GAntry Display.
 - e. Verify that on the operator's console appears the message:

WARNING!
Transmission Source is Open
 - f. Press the <**START/CONT**> key on the RCU together with the **Enable Lever**. Check that transmission acquisition starts and the GAntry rotates.
 - g. Abort the acquisition by clicking [**CANCEL**] on the Acquisition Window Control Panel.

CHAPTER 4 CALIBRATION

4.1 OVERVIEW

System calibration For CoDe AC consists of the following steps, to be performed in the given order:

- Center of Rotation (COR) Calibration, described in Section 4.2
- Creation of ^{137}Cs Energy Map, applicable for field upgrades only, described in Section 4.3
- Source Position Calibration, described in Section 4.4
- Air Frame Creation, described in Section 4.5
- Fan Beam Parameters Calibration, described in Section 4.6

4.2 COR CALIBRATING

1. Position a 100 μCi F^{18} (FDG) point source as close as possible to the center of the camera. Use the Daily QC point source if available. Use the CoDe Head Rest as the source holder, placing the source on the marked target.
2. Press the RCU <MODE> key to bring the Gantry to **CoDe AC** Home Position.
3. Activate **PHA** and verify that the peak is centered in the energy window (511 keV).
4. Observe the image. If needed, move the source to the center to remove any dark edge.

Rotate the Gantry to **90°** and observe the image again, and if needed, move the source to the center to remove any dark edge.

5. Update the COR correction values as follows:
 - a. In the CLW type **CORECREDIT SEPTA;'H'** and press <Enter>.
 - b. Change the values in column **A** of the **Xcor** raw as follows:
 $x(\text{H1}) = 150.0$
 $x(\text{H2}) = -150.0$

The values of all other parameters in columns A,B, C and D should be 0.0.
 - c. Click [**OK**].
6. Form the **Others** container, double click the **CoDe C.O.R.** icon.
Set COR Correction to **ON**.
7. Start acquisition by pressing the RCU <START/CONT> key together with the **Enable** Lever.
8. At the end of acquisition, when prompted, click [**OK**] to start COR data processing.
9. After a few minutes, a window will be opened. Write down the displayed information.
10. Update the COR correction values as follows:
 - a. In the CLW type **CORECREDIT SEPTA;'H'** and press <Enter>.
 - b. Add the values recorded in Step 9, above, to the current values of $x(\text{H1})$ and $x(\text{H2})$ in column **A**.
 - c. Click [**OK**].
11. Repeat Steps 6 through 10 above until the displayed COR correction values are:
 $x(\text{H1}) <0.2$
 $x(\text{H2}) <0.2$.

This takes usually three iterations.

4.3 CREATING THE CS ENERGY MAP

Acquire an Energy Correction Map for CoDe AC as follows (the linearity and sensitivity maps created for the CoDe option apply also to CoDe AC. See Section Section 3.3.2 and Section 3.3.3 in the CoDe Service Manual):

Note

¹³⁷Cs energy map is created only for Head 2.

1. In the CLW type **CISO** <Enter>. Scroll to the high energy isotope **CS137** and verify:

E	= 662 keV
Peak	= 1
Energy Range	= High
Energy Map Fast	= 137
Linearity Map Fast	= 25
Sensitivity Map Fast	= 25
Hardware Window	= Enabled
2. With the CoDe AC Septa Collimators mounted, type in the CLW **PHA** <Enter>.
3. Select the following parameters:

Head:	2
Energy Correction:	ON
Isotope:	TCHE
Mode:	FAST
4. Press the Source Positioning Push Button to expose the Cs point sources.
5. Measure the position of the ¹³⁷Cs full energy peak, and record it.
6. Press the Release Handle to close the source.
7. Close the **PHA** utility.
8. In the CLW type **TENTABF** <Enter>, and enter the following parameters.

Input map:	22
Output map:	137
T factor:	662.0/(full energy peak position with decimal point)
Head:	2
Isotope:	CS137

Click [**OK**].

Wait for the map to be created.

9. Re-activate **PHA** from the CLW with:

Head:	2
Energy Correction:	ON
Isotope:	CS137
Mode:	Fast

Check the new peak position.

10. Press the Source Positioning Push Button to expose the Cs point sources, and verify that peak position = **662.0 ± 2 keV**.
11. Press the Release Handle to close the source.

4.4 SOURCE POSITION CALIBRATION

When in **Open** position, the 18 Cs point sources should be positioned exactly in the middle of the collimator slots. This position is adjusted by means of the **Source Position Adjusting Screw** shown in Figure 2-1.

To adjust the position of the line of point sources do as follows:

1. Through the opening in the PSD, use a 4 mm Allen Key to screw the Source Position Adjusting Screw to the **maximum OUT** position, so that it is not pressed by the line of point sources when the Source Positioning Push Button is pressed.
2. Activate the **CoDe AC Static** protocol from within the **Maintenance** container and follow the displayed instructions.
3. Record the count rate on Head #2 in the $^{137}\text{Cs} \pm 10\%$ energy window.
4. Press the Release Handle to switch the source to the Close position.
5. Screw the Source Position Adjusting Screw inwards, turning it by a **quarter** of a turn.
6. Repeat Steps 2 through 5 above until the count rate starts to decrease. At this point, screw the Source Position Adjusting Screw a quarter turn **outward**, so that the point sources are set to their maximum exposure position when the Source Positioning Push Button is pushed.

Record the maximum count rate value. This value is used for Quality Control and must be kept in the system log book.

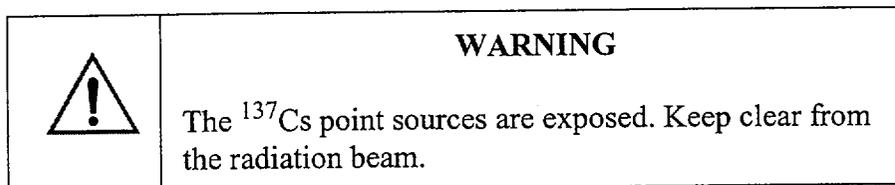
7. Lock the Source Position Adjusting Screw with locktite glue.

4.5 AIR FRAME CREATION

1. Double click the **CSAIR** icon residing within the **Maintenance** container.
2. Verify that the values of the transmission acquisition parameters are as follows:

Isotope:	Cs137
Head 2:	ON
Frame Size:	128
Zoom:	1
COR Correction:	OFF
Sensitivity Correction:	OFF
Rate:	Fast
Home Position:	CoDe AC
Time per Frame:	20 sec
Rotation:	360°
Step:	3°
Mode:	Continuous

3. Click the [**OK**] button and follow the displayed instructions.
4. When prompted, open the source by opening the Locker with the special key, and pressing the **Source Positioning Push Button**.



5. When prompted, press the RCU **<START/STOP>** key and the **<ENABLE>** lever concurrently to start the first transmission acquisition.

Note

The duration of the Air Frame transmission scan is 40 minutes.

6. When prompted, close the source by pressing the Release Handle and locking the Source Positioning Push Button with the special key.
7. The program automatically creates one average Air Frame for Head #2. When the average Air Frame is created, the following message is displayed on the operator's console:

**Air Frame procedure is successfully completed
Air Frame is created !!!**

Record the Study and Group number of the average Air Frame.

You will need this information when creating of attenuation map for each CoDe scan.

4.6 CALIBRATING THE FAN BEAM PARAMETERS

1. Set the system to CoDe AC Home Position via the RCU.
2. Place a lead rod on the Patient Table at a distance of 10 cm from Head #2, parallel to the rotation axis.
3. Activate the **Fan Beam Calibration** protocol residing in the **Maintenance** container.
4. Follow the displayed instructions.
The acquisition takes about 40 minutes.
When completed, write down the Study and Group numbers.
5. In the CLW type **FanBeamCal** <Enter>.
6. Enter the numbers of the **Fan Beam** study as recorded in Step 4, above and the number of the **Air Frame**, as recorded in Step 7, Section 4.6, at the relevant input fields.
7. Click **[OK]**.
The program computes the following fan beam parameters:

Focal Distance
Projection focal distance
Effective radius.

CHAPTER 5

QUALITY CONTROL

Quality control of the CoDe AC option consists of the following tests:

- Air Frame Profile Test, described in Section 5.1.
- Total Integral Counts Test, described in Section 5.2.

5.1 AIR FRAME PROFILE TEST

Purpose

To check the uniformity of line of 18 Cs point sources by checking the peak-to-valley ratio of the Air Frame image.

Procedure

1. In the CLW type **CsairProf SxGy** <Enter>, where SxGy corresponds to the last output group of the **csair** preset
2. Wait for the system to display the computed peak-to-valley ratio.
This value should be higher than **1.9**.
The Air Frame profile of the radiation distribution on Detector #2 is shown in Figure 5-1.

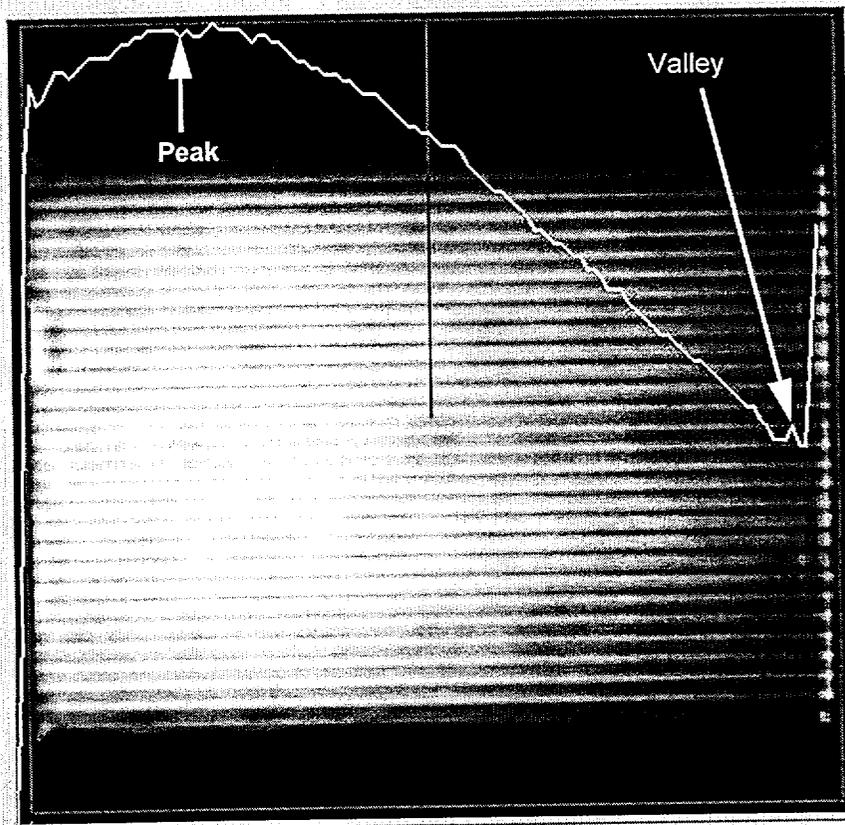


Figure 5-1. Air Frame Profile

5.2 TOTAL INTEGRAL COUNTS TEST

1. Activate the **CoDe AC Static** protocol from within the **Maintenance** container and follow the displayed instructions.
2. Record the count rate on Head #2 in the $^{137}\text{Cs} \pm 10\%$ energy window.
3. Press the Release Handle to switch the source to the Close position.
4. Compare the value recorded in Step 2, above with the maximum count rate available recorded in the system log book (see Section 4.4).
If the two values differ by more than 5%, re-adjust the Source Position Adjustment screw, as per Section 4.4.

CHAPTER 6 TROUBLESHOOTING

6.1 FAILURES AND CORRECTIVE ACTIONS

Table 6-1 details the failure symptoms and the corrective actions to be performed when they occur. For repair procedure instructions, refer to Chapter 7

The address of IPL to whom the CoDe AC Device must be shipped if instructed is:

IPL Isotope Product Laboratories,
1800 N. Keystone Str.
Burbank, California 91504

Table 6-1. Symptoms and Corrective Actions

#	Symptom	Possible Cause	Corrective Action
1	Source Status Indicating LED is <i>not</i> blinking.	1. Faulty LED connection. 2. Discharged LED Batteries. 3. Faulty LED.	1. Check the LED cable connection. 2. Replace the LED Batteries. 3. Replace the LED.
2	Source Status Indicating LED blinks green while the Source Positioning Push Button is pressed, and <i>no</i> SOURCE OPEN message is displayed.	1. Faulty Micro-Switch. 2. Defective Source Status PCB.	1. Replace the Micro-Switch of the CoDe AC Device. 2. Replace the Source Status PCB.
3	The Source is in open position and only one SOURCE OPEN message is displayed either on the Gantry Display or on the Operator Console.	1. Released Connector on Source Status PCB.	1. Remove the PSD and press in the relevant connector. 2. Replace the Source Status PCB.
4	Air Frame Profile Test failed.	1. Faulty CoDe AC Device.	1. Verify that the source is in close position, disassemble the CoDe AC Device and ship it to IPL in its original packing.

Table 6-1. Symptoms and Corrective Actions (Continued)

#	Symptom	Possible Cause	Corrective Action
5	Source Locked in OPEN position.	1. Faulty Source Release Spring.	1. Using a 4 mm Allen Key, screw in the M5 Source Position Adjusting Screw (see Figure 3-6) until the source moves to the close position (LED blinking turns green). 2. If the problem persists, set the source to close position as explained above, disassemble the CoDe AC Device and ship it to IPL in its original packing.
6	Total Integral Counts Test failed.	1. Incorrect adjustment of source position. 2. Faulty CoDe AC Device.	1. Re-adjust the Source Position Adjusting Screw. 2. Verify that the source is in close position, disassemble the CoDe AC Device and ship it to IPL in its original packing.

CHAPTER 7 REPAIR PROCEDURES

This chapter provides instructions for the following procedures:

- LED Batteries replacement, described Section 7.1 .
- Replacing the Source Status Indicating LED, described Section 7.2.
- Micro-Switch replacement, described in Section 7.3.
- Source Status PCB replacement, described in Section 7.4.
- CoDe AC Device replacement, described in Section 7.5.

7.1 BATTERIES REPLACEMENT

1. Using the special key, lock the source is in close position.
2. Remove the PSD, releasing its four fastening Philips screws.
3. Replace the old batteries with two new 1.5 V alkaline batteries.
4. Verify that the LED is blinking.
5. Re-assemble the PSD.

7.2 LED REPLACEMENT

1. Using the special key, lock the source is in close position.
2. Remove the PSD, releasing its four fastening Philips screws.
3. Disconnect the LED cable from its connector.
4. Screw out the LED Retaining Ring, and pull the LED out.
5. Insert the new LED into its designated hole and screw in the Retaining Ring removed above to secure the LED.
6. Connect the LED cable to the connector,
7. Re-assemble the PSD.

7.3 MICROSWITCH REPLACEMENT

1. Using the special key, lock the source is in close position.
2. Remove the PSD, releasing its four fastening Philips screws.
3. Disconnect the Micro-Switch cables.
4. Remove the two Philips screws that fasten the Micro-Switch and pull it out.
5. Assemble the new Micro-Switch using the two screws removed above.
6. Connect the Micro-Switch cables.
7. Re-assemble the PSD.

7.4 REPLACING THE SOURCE POSITION PCB

1. Using the special key, lock the source is in close position.
2. Unload the Septa Collimators onto the Collimator Cart.
3. Remove the XX philips screws that fasten the Source Position PCB to the Collimator Frame, and carefully pull out the board.
4. Disconnect all the connected cables by releasing their connectors .
5. Connect the cables to the new PCB
6. Assemble the new PCB with the xx screws removed above.

7.5 DISASSEMBLING THE CODE AC DEVICE

1. Using the special key, lock the source is in close position.
2. Unload the Septa Collimators onto the Collimator Cart.
3. Position the Collimator Cart next to a stable table.
4. Retrieve the original CoDe AC Device packing, place it on the table and open its cover.
5. Disassemble the CoDe AC Device by releasing its four fastening screws, and place it **together with another technician** in the original packing.
6. Instruct the customer to ship the CoDe AC Device to the sub-contractor ,following the local regulations for shipping radioactive devices.

CHAPTER 8 PLANNED MAINTENANCE

Planned Maintenance (PM) will be scheduled to be performed together with the general PM of the Millennium VG., just after the PM for the CoDe option.

The results are to be recorded in the CoDe AC Sheet in the Planned Maintenance Results Report.

PM of Code AC option includes these procedures:

- Test of the On/Off mechanism – to be performed every four month, according to the procedure described in section 3.2-4
- Air Frame Profile Test - to be performed every four month, according to the procedure described in Section 5.1.
- Total Integral Counts Test - to be performed every four month, according to the procedure described in Section 5.2.
- Batteries Replacement - to be performed once every two years, according to the procedure described in Section 7.1.

- Dry Wipe Test – to be performed every six month, according to the procedure described in operation manual p. 5-4.

Appendix D

Source NRC Registration

Contents

IPL description of the source, the sealing and the pollution safety	D-1
IPL commitment	D-3
IPL NRC registration source submission	D-4

IPL FAXDate May 24, 1999Number of pages including cover sheet 2TO: *Naor Wainer*
*ELGEMS LTD*Phone
Fax Phone *011 972 4 857-7662 4*FROM: *Michael Devine*
Isotope Products Laboratories
1800 N. Keystone St.
*Burbank, CA 91504*Phone *(818) 843-7000 x 101*
Fax Phone *(818) 843-6168*

CC:

REMARKS: Urgent For your review Reply ASAP Please Comment

Please see the following letter.

Ipl description of the
source, the sealing, and
pollution safety.

D-1



May 24, 1999

ELGEMS LTD
Attn: Naor Wainer, PhD.
P.O. Box 170
Tirat Hacarmel, 30200
Israel

Dear sirs:

Isotope Products Laboratories has designed and constructed its model 34-5 line source to satisfy the operational and safety requirements for a particular Elgems system. The source consists of upto 18 discrete Cs^{137} ceramic elements potted into a tungsten core which is then welded into a 304 Stainless Steel tube. The active portion of the source is, in effect, triply encapsulated. First the activity is encapsulated in ceramic. Then the ceramic elements are sealed into a Tungsten rod. Finally, the assembly is placed into a Stainless Steel tube which is plugged and hermetically welded. The Stainless Steel welded construction prevents accidental loss and dispersement of radioactive material under normal conditions and many accident conditions. The Ceramic encapsulation into the Tungsten rod provides additional damage resistance to mechanical factors such as vibration, puncture and impact. Following welding, the source is soak tested in accordance with ANSI 44.1-1973 "Integrity and Test Specifications for selected Brachytherapy sources". In addition, the sources are also wipe tested to check for external contamination and leakage. In both leak tests, the passing criterion is less than 1 nCi beta activity found in the soak liquid or the wipe media. The resultant source is exceptionally safe and rugged for the application for which it was designed. The safety of the source depends largely upon the materials of construction, which are corrosion resistant and durable, and upon the sealing method, which provides a tamper-proof, permanent encapsulation of the radioactive material. Other line sources manufactured by IPL in a similar manner are used in harsh environmental conditions and have passed severe puncture, pressure, impact, vibration, and temperature tests.

I believe the information provided herein is true and complete but if, however, you require additional information, please do not hesitate to call me.

Sincerely,



Michael Devine
Isotope Products Laboratories

• Page 1

RADIOACTIVE SOURCES • DEVICES • NUCLIDES



August 10, 1999

Naor Wainer, Ph.D.
Physics Department Manager
ELGEMS LTD
10 Hayozma St.
P.O. Box 170
Tirat Hacarmel 30200
Israel

Dear Dr. Wainer,

Isotope Products Laboratories will accept for return all Cs-137 line sources we provide to you without restriction. We must ask that transportation be paid in advance when the sources are returned, and that we will charge for the cost of recycle or disposal of those sources. As the return will be at an unknown future date we will send quotation for those costs at the time of return. Of course, the sources must be shipped in accordance with applicable transport regulations.

This commitment is contingent upon our licensing authorities continuing to allow our firm to accept these sources and no future restrictions by US or other customs authorities for their entry into this country.

If you need additional information to complete your regulatory submissions, please do not hesitate to call, fax, or e-mail me.

Sincerely,

Michael Devine
Director of Technical Services and IT
Isotope Products Laboratories

D-3



August 9, 1999

Radiologic Health Branch
Department of Health Services
State of California
Attn: David Wesley
601 North 7th Street
P.O. Box 942732
Sacramento, CA 94234-7320

Dear Mr. Wesley,

Please find our application for registration of our model 34-5 Gamma sources. These sources are manufactured by Isotope Products Laboratories and will be distributed by Isotope Products Laboratories. These sources have been tested in accordance with ANSI N542-1977 and meet the requirements for the classification of 77C43333. The summary data, source description, source use, test results, drawings, labeling and quality assurance are included in the following report.

If you have additional questions please feel free to call me at (818) 843-7000 x 119.

Sincerely,

A handwritten signature in cursive script, appearing to read 'Gary Zhou', written in black ink.

Gary Zhou

orate and
Laboratory
N. Keystone Street
ank, California
04
843-7000
818-843-6168

D-h

Summary Data

Date of Application: August 7, 1999

Applicant: Isotope Products Laboratories
1800 Keystone Street
Burbank, California 91504

Contact Person
Gary Zhou
Phone: (818) 843-7000 Extension: 119
Fax: (818) 843-6168

Sealed Source Type: Gamma Source

Model(s) 34-5

<u>Isotope</u>	<u>Maximum Activity</u>
Cs-137	100 mCi

Other Companies Involved: None

Leak Test Frequency: Six Months

Principal Use: Gamma Gauging
Code: D

Custom Source: No

Description:

The single encapsulated multipoint line source (Model 34-5-1) consists of the fusion welded capsule body and plug enclosing the internal tungsten shielding and the 18 active elements. The capsule body assembly is made of high-grade 300 series Stainless Steel and it has a cylindrical shape with following dimensions:

Capsule body: diameter 0.250" x length 15.749"
Wall Thickness: 0.028"

D-5

Two Tungsten end pieces are affixed to the source by means of cement on one side and a spring pin on the other side. The Tungsten pieces facilitate handling and mounting in a collimator device.

There are 18 active ceramic elements that are impregnated with Cesium-137 Chloride or Nitrate, dried, and sintered.

Source ANSI Classification: 77C43333

Labeling:

The following information will be engraved on the surface of the sources:

Distributor Name	-	IPL
Nuclide	-	Cs-137
Serial Number	-	XX-XXX
Manufacture Date	-	Day/Month/Year
Activity	-	XXmCi

Diagram:

See attached drawings.

Condition of Normal Use:

The source is designed to be permanently installed into a holder or device and used in laboratory, clinical, or field conditions for gamma gauging applications by trained personnel.

ANSI classification categories are the ceilings to which test prototypes have been subjected. Under no circumstances should the sealed sources be used in conditions which exceed the ANSI classification. If in doubt, contact the manufacturer for additional information.

The manufacturer of the sealed source indicates a recommended working life to the user of 15 years (half-life: 30.2y [Cs-137]).

Prototype Testing:

General Information: The line sources were tested at Isotope Products Laboratories between 8/2/99 and 8/6/99. All the tests were performed in accordance with ANSI N542-1977. The raw data was documented in IPL notebook number 437 pages 105 through 106. Temperature, external pressure,

impact, vibration, and puncture equipment was designed and built per ANSI standard N542-1977 paragraphs 7.2.1, 7.3.1, 7.4.1, 7.5.1, and 7.6.1 respectively. The sources were leak tested by immersion in distilled water at 50° C for no less than 4 hours. The soak water was then assayed by using a calibrated liquid scintillation counter.

Temperature: (desired: class 4) Initially, the sample source was subjected to the low temperature test at -40° C. The source was covered in crushed dry ice for more the 20 minutes. Then, the source was placed into an oven and heated at 400° C for one hour. For the thermal shock test, the source was heated up to 415° C and held at this temperature for 15 minutes. The source was transferred to water at 20° C within 10 second. The sample was visually examined and soak tested after the temperature test. The source was intact, and found to be leak free. The test capsule passed the class 4 temperature test.

External Pressure: (desired: class 3) The source was placed into a vacuum/pressure chamber and subjected to the test pressures for two periods of 5 minutes each. The low pressure test was conducted in air at 25 kN/m³, and the high pressure test was conducted in water at 2 MN/m³. The source was visually inspected and soak tested after the external pressure test. The source was intact and found to be leak free. The test capsule passed the class 3 pressure test.

Impact: (desired: class 3) The source was impacted with a 200 g weight dropped from 1m. The source was visually inspected and soak tested after the impact test. The source was intact and found to be leak free. The test capsule passed the class 3 impact test.

Vibration: (desired: class 3) The source was affixed to a vibration device and was tested from 25Hz to 80Hz in increments of 5Hz. The peak to peak amplitude was measured at minimum of 0.635mm. The duration of the test was 10 minutes, returning back to the initial frequency, and repeated for a total of three tests for two axes. The next test was for the 90Hz to 500Hz range with increments of 5Hz to 50Hz. The source was tested for 10 minutes at a constant of 10g. The test was repeated for a total of three times for two axes. Resonance frequencies were not found. The source was visually inspected and soak tested after the vibration test. The source was intact and found to be leak free. The test capsule passed the class 3 vibration test.

Puncture: (desired: class 3) The source was puncture tested with a 10 g weight dropped from 1m. The source was visually inspected and soak tested after the puncture test. The source was intact and found to be leak free. The test capsule passed the class 3 puncture test.

Results of the prototype testing indicate an ANSI classification of 77C43333.

External Radiation Levels:

The maximum exposure rates from distances of 5 cm, 30 cm and 100cm were calculated in accordance with the method described in Radiology Health Handbook. Cesium has a gamma factor of 3.3, and maximum dose rate at a distance can be calculated by using the formula: rate = gamma factor * (activity/distance²). The gamma factor is defined as $\Gamma = R\text{-cm}^2/\text{hr-mCi}$.

<u>Nuclide</u>	<u>Activity</u>	<u>Distance from Source</u>		
		<u>5 cm</u>	<u>30 cm</u>	<u>100 cm</u>
Cs-137	100 mCi	13.2 mR/h	0.367 mR/h	0.033 mR/h

Quality Assurance and Control

- a) **Program:** The IPL Quality Assurance Manual details the quality control of this source from raw materials to finished product. The program is designed to satisfy 10CFR Part 50 (B) and meets the requirements of ISO 9002 (IPL is ISO-9002 certified). The program covers drawing control, purchasing, training, calibration records, source numbering, incoming raw materials, assay quality control, leak testing, document control, confirming orders, and pre-production design review.

- b) **Activity:** Held to $\pm 15\%$ of nominal activity

- c) **Assay Procedures:** A calibrated pressurized re-entrant well-type ionization chamber is used to measure the activity of the source.

- d) **Radiopurity Determination:** Determined by gamma spectrometry of the source or the radionuclide batch.

- e) **Leak Test Procedures:** Sources are leak tested in accordance with ANSI N44.2-1973 paragraph A1.3. Criteria for acceptance are:

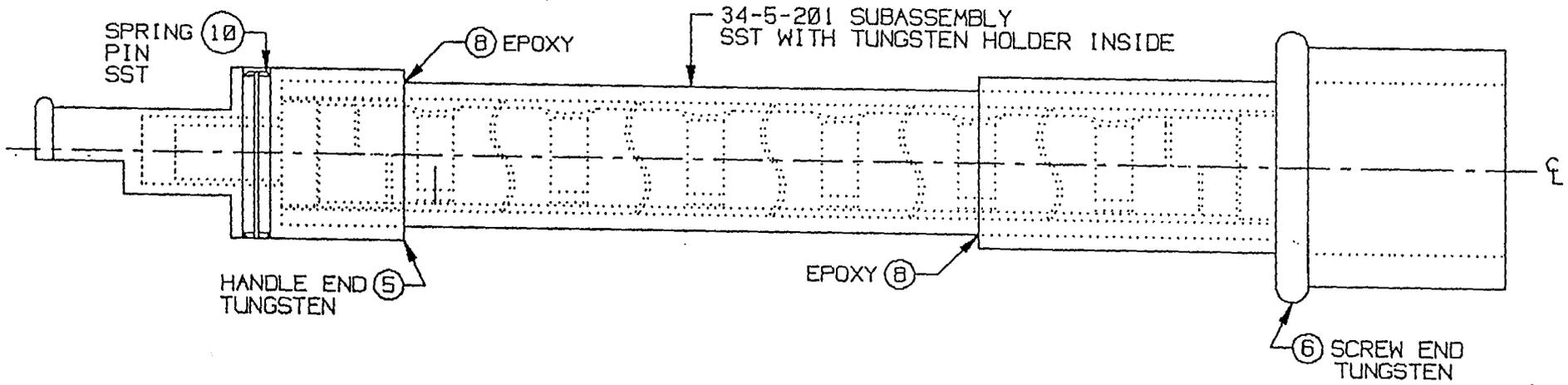
1.0 nCi removable beta/gamma
0.1 nCi removable alpha

Limitations and/or Other Consideration of Use

- a) **Distribution:** These sources shall be distributed to specific licensees of the NRC or Agreement States.

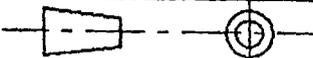
- b) **Leak Test:** These sources shall be leak tested at intervals not greater than six months. Such tests must be capable of detecting 0.005 μCi of removable radioactivity, and be performed by specific licensees of the NRC or agreement states.
- c) **Use:** These sources are intended to be used in gauging systems. These sources should not be subjected to conditions exceeding their ANSI rating of C43333.
- d) **Handling:** Remote handling tools and localized shielding should be used.
- e) **Storage:** Store in a clean, dry area. Shielding should be provided as necessary.
- f) **Cleaning:** Sources may be cleaned with a tissue moistened with any non-corrosive solvent.
- g) **Disposal:** Disposal of decayed or otherwise unusable sources must be made via the user's authorized radioactivity disposal method.
- h) The registration sheet and the information contained within the references shall not be changed or transferred without the written consent of the California Department of Health Services.

01-4



- 2. IDENTIFY PART NUMBER
 - 1. ASSEMBLE COMPLETE PER ENGINEERING DRAWING AND APPLY EPOXY AS REQUIRED
- NOTES: UNLESS OTHERWISE SPECIFIED

P/N: 34-5-1
 ASSEMBLY, 18 ACT ELEM x 2.14 cm APART

 ISOTOPE PRODUCTS LABORATORIES BURBANK, CALIFORNIA 91504	UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES		DESIGN JMD/RLT	DRAWING TITLE Cs-137 LINE SOURCE		
	TOLERANCES ON FRACTION DECIMAL ANGLE X XX XXX ±.5° ±1/64 ±.1 .01 .002		SCALE NONE	SERIES TITLE INDUSTRIAL SOURCES, LINE		
	THIRD ANGLE PROJECTION 		SIZE A	CAGE CODE 32993	REVISION 5	DRAWING NUMBER 34-5

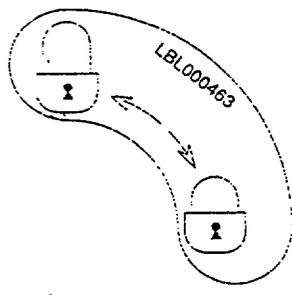
THIS DRAWING IS THE PROPERTY OF ISOTOPE PRODUCTS LABORATORIES AND MAY NOT BE USED, REPRODUCED, PUBLISHED OR DISCLOSED TO OTHERS WITHOUT EXPRESS AUTHORIZATION BY ISOTOPE PRODUCTS LABORATORIES.

Appendix E

Labels

Contents

Labels 1, 2 and 3	E-1
Label 1 and 2 (Drawing)	E-2
Label 3 (Drawing)	E-3
Label 4 (Drawing)	E-4

1	<p>WARNING: RADIOACTIVE MATERIAL ENCLOSED </p> <p>Nuclide: ¹³⁷Cs Activity: 555 MBq Ref. Date: -----</p> <p>Handling Instructions: refer to CoDe AC Service Manual P/N 2250061-100</p> <p>THE U.S. NRC HAS APPROVED DISTRIBUTION OF THE CoDe AC TO PERSONS LICENSED TO USE BYPRODUCT MATERIAL IDENTIFIED IN 35.57, 35.400 OR 35.500 AS APPROPRIATE, AND TO PERSONS WHO HOLD AN EQUIVALENT LICENSE ISSUED BY AN AGREEMENT STATE</p> <p style="text-align: right;">LBL000452</p>					
2	<table border="1" style="width: 100%;"> <tr> <td style="padding: 2px;">ELGEMS made in Israel</td> <td rowspan="3" style="padding: 2px; vertical-align: middle;"> <input style="width: 100%; height: 20px;" type="text"/> NRC No: </td> <td rowspan="3" style="padding: 2px; vertical-align: middle;">LBL000453</td> </tr> <tr> <td style="padding: 2px;">UNIT CoDe AC</td> </tr> <tr> <td style="padding: 2px;">SER. No.</td> </tr> </table>	ELGEMS made in Israel	<input style="width: 100%; height: 20px;" type="text"/> NRC No:	LBL000453	UNIT CoDe AC	SER. No.
ELGEMS made in Israel	<input style="width: 100%; height: 20px;" type="text"/> NRC No:	LBL000453				
UNIT CoDe AC						
SER. No.						
3	<p>Source Positioning Push Button Locking Status</p> 					

WARNING: RADIOACTIVE MATERIAL ENCLOSED

Nuclide: ^{137}Cs Activity: 555 MBq Ref. Date: _____

HANDLING instructions: refer to CoDe AC Service Manual
P/N 2250061100



THE U.S. NRC HAS APPROVED DISTRIBUTION OF THE CoDe AC TO PERSONS LICENSED TO USE BY-PRODUCT MATERIAL IDENTIFIED IN 35.57.400 OR 35.500, AS APPROPRIATE, AND TO PERSONS WHO HOLD AN EQUIVALENT LICENSE ISSUED BY AN AGREEMENT STATE

LBL000452

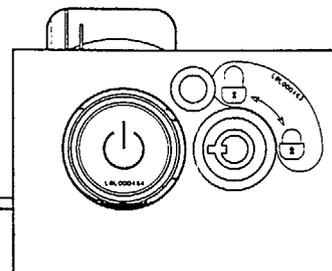
ELGEVS made in israel

UNIT CoDe AC

SER. No.

NRC no:

LBL000453



WARNING: RADIOACTIVE MATERIAL ENCLOSED

Nuclide: ¹³⁷Cs Activity: 555 MBq Ref. Date: -----

HANDLING instructions: refer to CoDe AC Service Manual
P/N 2250061100



THE U.S. NRC HAS APPROVED DISTRIBUTION OF THE CoDe AC TO PERSONS LICENSED TO USE BYPRODUCT MATERIAL IDENTIFIED IN 35.57.400 OR 35.500, AS APPROPRIATE, AND TO PERSONS WHO HOLD AN EQUIVALENT LICENSE ISSUED BY AN AGREEMENT STATE

LBL000452

MATERIAL-LEXAN 0.3m'm.
FONT-DARKGRAY PANTONE 446.
BACKGROUND LIGHT GRAY PANTONE 427.
ADHESIVE: MAC-TAC COVER BY PAPER.

Q.C.
Tests of 15 seconds rubbing with water, iso-propanol and methanol.
After adhesion inspect that the text is readable and clear, and
that the borders of the label are not folded.

	NAME	DATE	EUROPEAN PROJECTION. DEFAULT DIMENSIONS : MM.	EQUIPMENT CESIUM	ASSEMBLY NAME
DESIGNER	erez y.	14.7.99	FINISH	SCALE 1:0:1.0	NAME Warning Label
DESIGN CONTROL	erez y.	14.7.99			
CHECKER			TOL. NOT SPECIFIED :	DRAWING No.	VERSION
APPROVAL					
CONTENTS PROPERTY OF ELGEMS LTD. NO. UNAUTHORIZED USE PERMIT			0.5	1	LBL - 000452
			2DEG		
PCB 170 Eilat ha'armei 30200 ISRAEL			LAST OP.	SHEET OF	
			NEXT OP.		

E-2-A

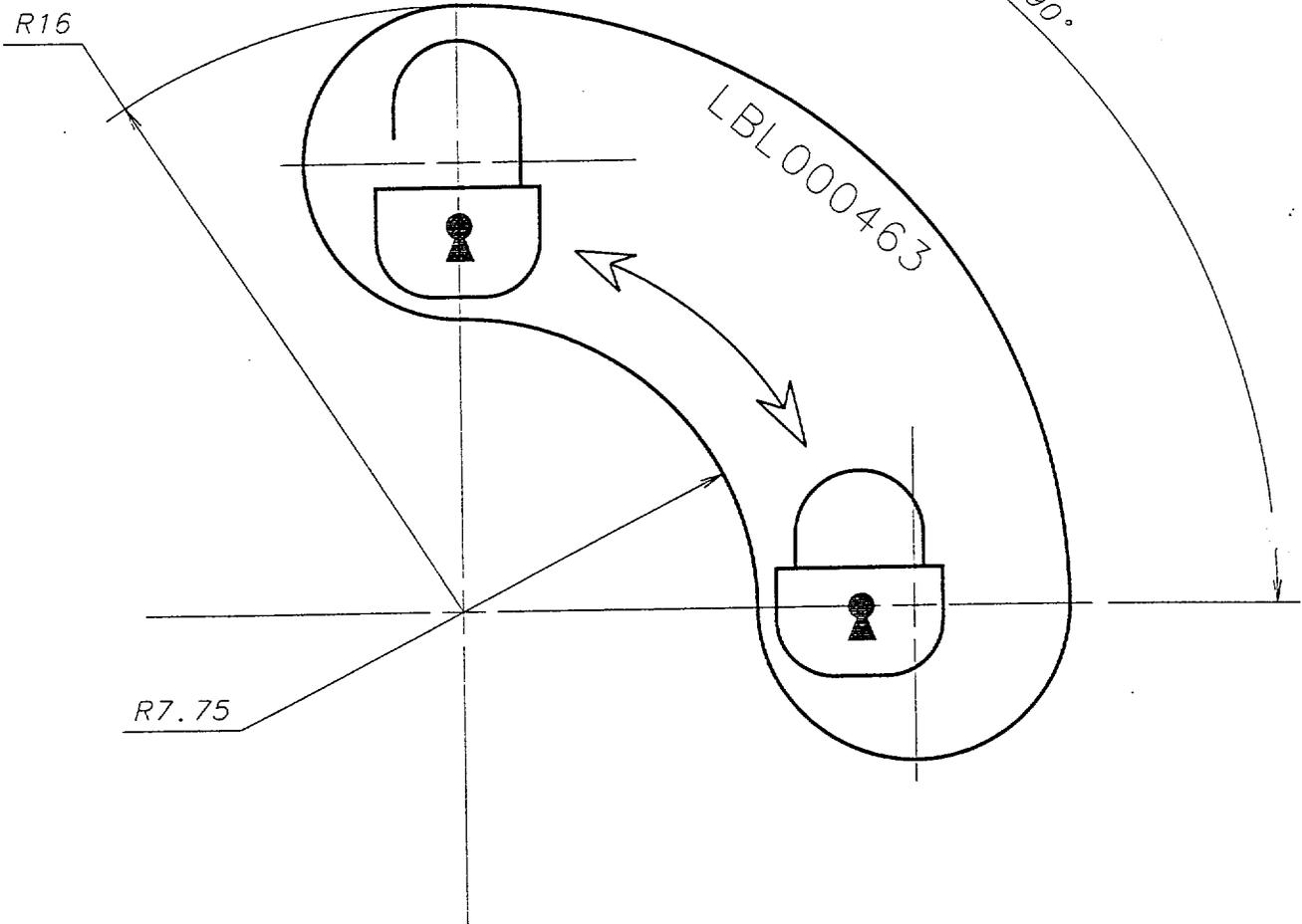
ELGEMS made in israel	LIBL000453
UNIT CoDe AC	
SER. No.	
NRC no:	

MATERIAL-LEXAN 0.3m^m.
 FONT-DARKGRAY PANTONE 446.
 BACKGROUND LIGHT GRAY PANTONE 427.
 ADHESIVE: MAC-TAC COVER BY PAPER.

Q.C.
 Tests of 15 seconds rubbing with water, iso-propanol and methanol.
 After adhesion inspect that the text is readable and clear, and
 that the borders of the label are not folded.

	NAME	DATE	EUROPEAN PROJECTION, DEFAULT DIMENSIONS : MM.	EQUIPMENT	ASSEMBLY NAME
DESIGNER	erez y.	14.7.99	FINISH	CESIUM	No. 1
DESIGN CONTROL	erez y.	14.7.99			
CHECKER			✓	SCALE	NAME
APPROVAL					
CONTENTS PROPERTY OF ELGEMS LTD. NO UNAUTHORIZED USE PERMITTED			TOL. NOT SPECIFIED :	1.0:1.0	Manufacturer Label
			0.5	DWG. SIZE	DRAWING No.
			<	2DEG	
Project: CESIUM.			15-Jul-99 07:57	LBL - 000453 SHEET OF _____ VERSION _____	

E-2-B

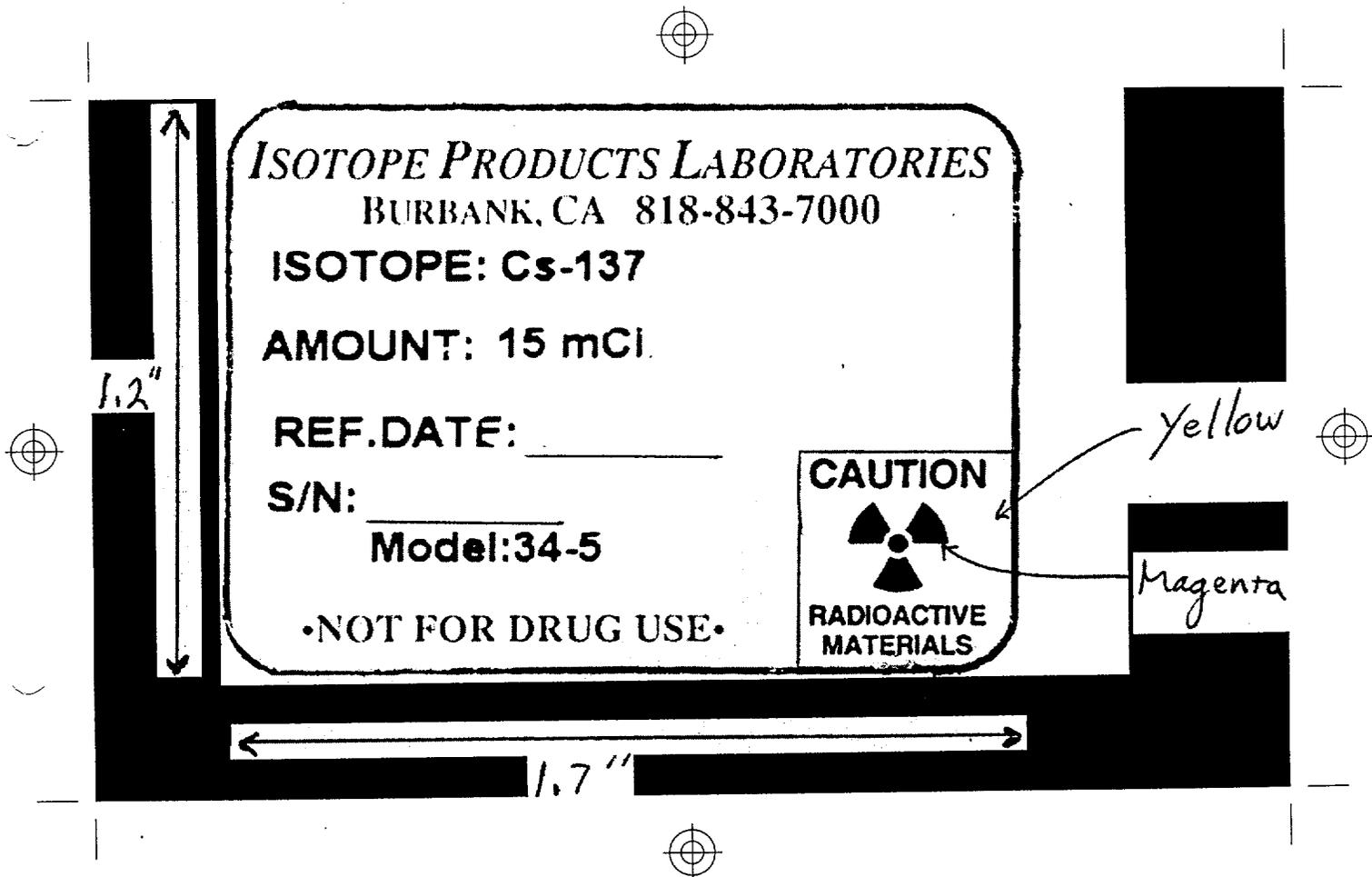


MATERIAL-LEXAN 0.3m*m.
 FONT-DARKGRAY PANTONE 446.
 BACKGROUND LIGHT GRAY PANTONE 427.
 ADHESIVE: MAC-TAC COVER BY PAPER.

Q.C.
 Tests of 15 seconds rubbing with water, iso-propanol and methanol.
 After adhesion inspect that the text is readable and clear, and
 that the borders of the label are not folded.

NAME		DATE	EUROPEAN PROJECTION, DEFAULT DIMENSIONS : MM.	EQUIPMENT	ASSEMBLY NAME
DESIGNER	erez y.	14.7.99	FINISH	CESIUM	No. 1
DESIGN CONTROL	erez y.	14.7.99			
CHECKER			TOL. NOT SPECIFIED :	SCALE	NAME
APPROVAL				5.0:1.0	Locking Position Label
CONTENTS PROPERTY OF ELGEMS LTD. NO UNAUTHORIZED USE PERMIT			0.5	DWG. SIZE	DRAWING No.
 POB 170 Tirat Hacarmel 30200 ISRAEL			2DEG	1	LBL-000463-
			LAST OP.		
Project : CESIUM Item : LOCKER LABEL, 15-Jul-99 07:57			NEXT OP.		SHEET OF
					Old Partnumber :

E-3



E-4



Appendix F

Radiation Measurements

Contents

Radiation Exposure for Workers and other Personnel
Patient Exposure Test
Radiation Leak Test

F-1
F-2
F-3

CoDe AC Project**Radiation Exposure for Workers and other Personnel****Report**

Wednesday, 30 June 1999

Patient Exposure Test of the 15 mCi ^{137}Cs line of point sources of the CoDe AC option was performed on 30 June 1999.

Test method:

The measurements were performed using BICRON Micro Sievert TM meter (Rate range - 1 $\mu\text{R/h}$... 200mR/h; Energy lower limit 17 keV). The leakage meter accuracy is $\pm 10\%$. The leakage meter was calibrated by BICRON on July 1998. Next calibration due July 1999.

Test results:

During the option installation two workers insert the option in the septa collimator. The maximal exposure to the hand of the workers (for 10 sec) is less than 0.03 mRem.

During the working day with the option, the maximal exposure is less than 0.2 mRem, coming from the CoDe AC option.

Jean-Paul Bouhnik, PhD
Physicist

J.P. Bouhnik

CoDe AC Project**Patient Exposure Test****Report**

Wednesday, 30 June 1999

Patient Exposure Test of the 15 mCi ^{137}Cs line of point sources of the CoDe AC option was performed on 30 June 1999.

Test method:

The measurements were performed using BICRON Micro Sievert™ meter (Rate range - 1 $\mu\text{R/h}$... 200mR/h; Energy lower limit 17 keV). The leakage meter accuracy is $\pm 10\%$. The leakage meter was calibrated by BICRON on July 1998. Next calibration due July 1999.

The radiation exposure rate measurements were carried out at a distance of 20 cm from the sources, respectively to the average absorption distance in the body.

Test results:

The result of the test demonstrate the radiation exposure rate of 7 ± 0.7 mRem/h at 20 cm from the source, when the source are exposed, and 1 mRem/h when the source are in close position.

The duration of the transmission scan is 4 minutes, the duration of the transmission with the closed source is 2 minutes and the emission scan, in which the sources are closed, is 30 minutes, giving a residual scan time of 32 minute after the transmission scan.

Patient Integrated Dose Estimation:

Assume: 4 minute scan, f factor of 1 (soft tissue, ICRU report 10d - NBS handbook 87, 1963), factor of 1 for conversion from Rad to Rem (gamma rays). After the transmission scan the source is closed but the patient scan continue for 32 minutes:

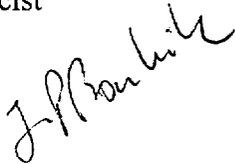
We get:

$$1 * 7 * 4/60 = 0.46 \pm 0.05 \text{ mRem.}$$

$$1 * 1 * 32/60 = 0.53 \pm 0.05 \text{ mRem}$$

The patient integrated dose is: 1 ± 0.07 mRem

Jean-Paul Bouhnik, PhD
Physicist



Test Report

Subject: Radiation Leak

Product: CoDe AC option **Division:** NM

Approved by	Bouhnik Jean-Paul
Position	Physicist
Date	30/6/99
Update	27/12/99
Signature	

<u>Contents</u>	<u>Page</u>
1. TEST PURPOSE.....	1
2 TEST SET-UP.....	1
3. TEST PLAN	1
4. TEST RESULTS.....	1
5. RESULTS ANALYSIS AND CONCLUSIONS.....	4

Test Equipment

Probe	Radiation counter Bicon
Source	Cs 137, 15 mCi
Collimator	Holder of the Cs + Septa

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Jean-Paul Bouhnik, Ph.D • Physicist • Tel: 972-4-8563673 • Email: Jean-Paul_Bouhnik@ELGEMS.COM

1. Test Purpose

The purpose was to check the radiation leak around the ¹³⁷Cs option.

2. Test Set Up

The option on a table and inserted in the septa collimator. The measurements were performed using BICRON Micro Sievert™ meter (Rate range - 1 microR/h --- 200mR/h; Energy lower limit 17 keV). The leakage meter accuracy is 10%. The leakage meter was calibrated by BICRON on July 1998. Next calibration due July 1999.

The holder had the 1 cm insert added to reduce the background on the detector supporting the option.

3. Test Plan

To measure the radiation dose of the option alone, the option inserted in the septa on the camera and the option inserted in the septa on the cart, for two different source positions: open and close.

4. Test Results

The measurement where done with a 15 mCi activity.

The option only not mounted on the septa:

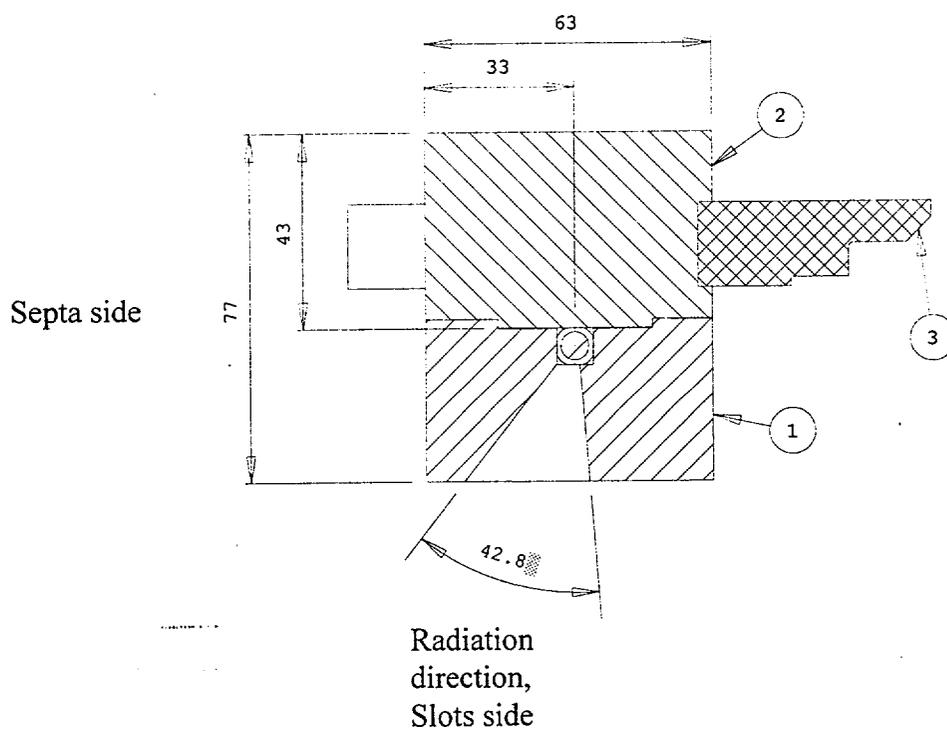


Figure 1: Profile of the CoDe AC device

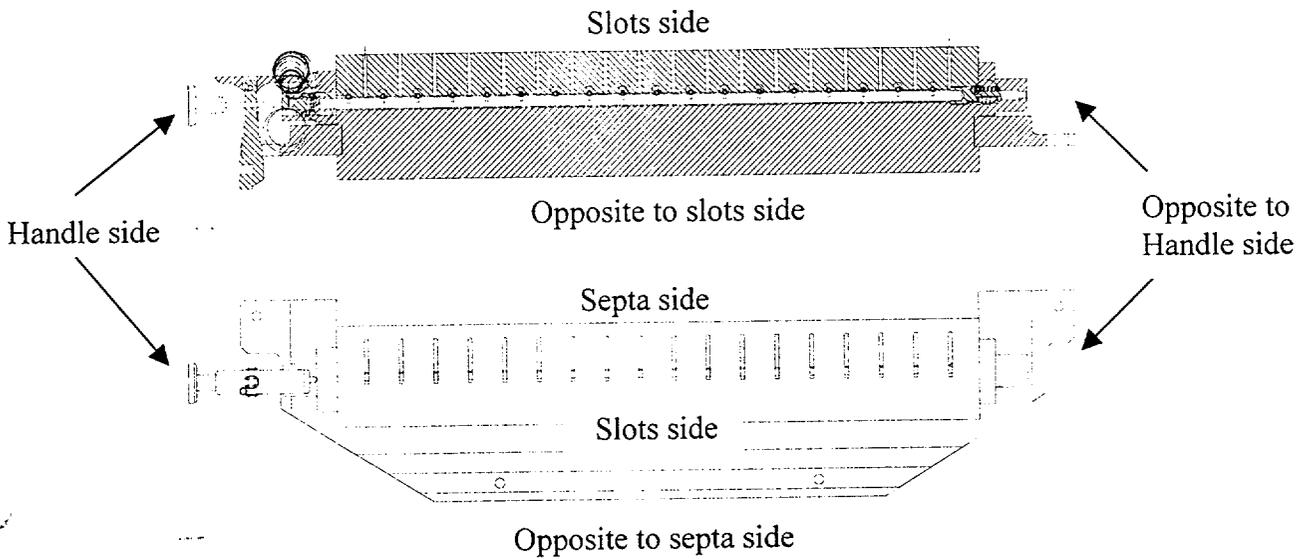


Figure 2: The CoDe AC device not inserted in the septa collimator

Radiation dose in mR/h for the option without the septa at the holder surface (error $\pm 10\%$ mR/h):

Distance [cm]	Slots side			Opposite to slots side			Handle side			Opposite to handle side		
	5	30	100	5	30	100	5	30	100	5	30	100
Open	15	5	X	0.2	0.03	Low	0.5	0.05	0.02	1.7	0.6	0.15
Close	5	1	X	0.2	0.03	Low	0.7	0.12	0.02	0.8	0.12	0.02

Distance [cm]	Septa side			Opposite to septa side		
	5	30	100	5	30	100
Open	5	1	0.2	4	0.7	0.12
Close	5	1	0.2	4	0.7	0.12

X = no access; Low = < 0.02 mR/h

Radiation dose in mR/h for the option with the septa assembled on the camera see figure 3:

Distance [cm]	Slots side, PSD plane			Opposite to slots, detector backside			Handle side			Opposite to handle side		
	5	30	100	5	30	100	5	30	100	5	30	100
Open	15	5	X	low	low	Low	0.5	0.05	0.02	0.4	X	X
Close	3	1	X	low	low	Low	0.7	0.12	0.02	0.7	X	X

Distance [cm]	Septa side			Opposite to septa side		
	5	30	100	5	30	100
Open	X	X	X	2	0.7	0.12
Close	X	X	X	2	0.7	0.12

X = no access; Low = < 0.02 mR/h

date: 27/12/99

file radiation_leak_cs.doc

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--	-----------------------------

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--	---

Jean-Paul Bouhnik, Ph.D • Physicist • Tel: 972-4-8563673 • Email: Jean-Paul_Bouhnik@ELGEMS.COM

Around the opposite detector there is no leak of radiation when the source is open. The radiation dose around the opposite detector is 0.2 mR/h.

On the collimator cart (two septa collimators face to face) the radiation dose is only 0.25 mR/h on the back side of the opposite septa, and 0.5 mR/h on the backside of the holder itself. The highest radiation dose on the cart is 2 mR/h.

5. Conclusions

The radiation dose level around the option, on the collimator cart, is lower than 0.5 mR/h. When the option is inserted in the septa collimator, on the camera, the radiation dose at 5 cm of the aperture side, is lower than 3 mR/h and lower than 15 mR/h in closed and exposed position respectively.

date: 27/12/99

file radiation_leak_cs.doc

Page 4 of 5

J 6

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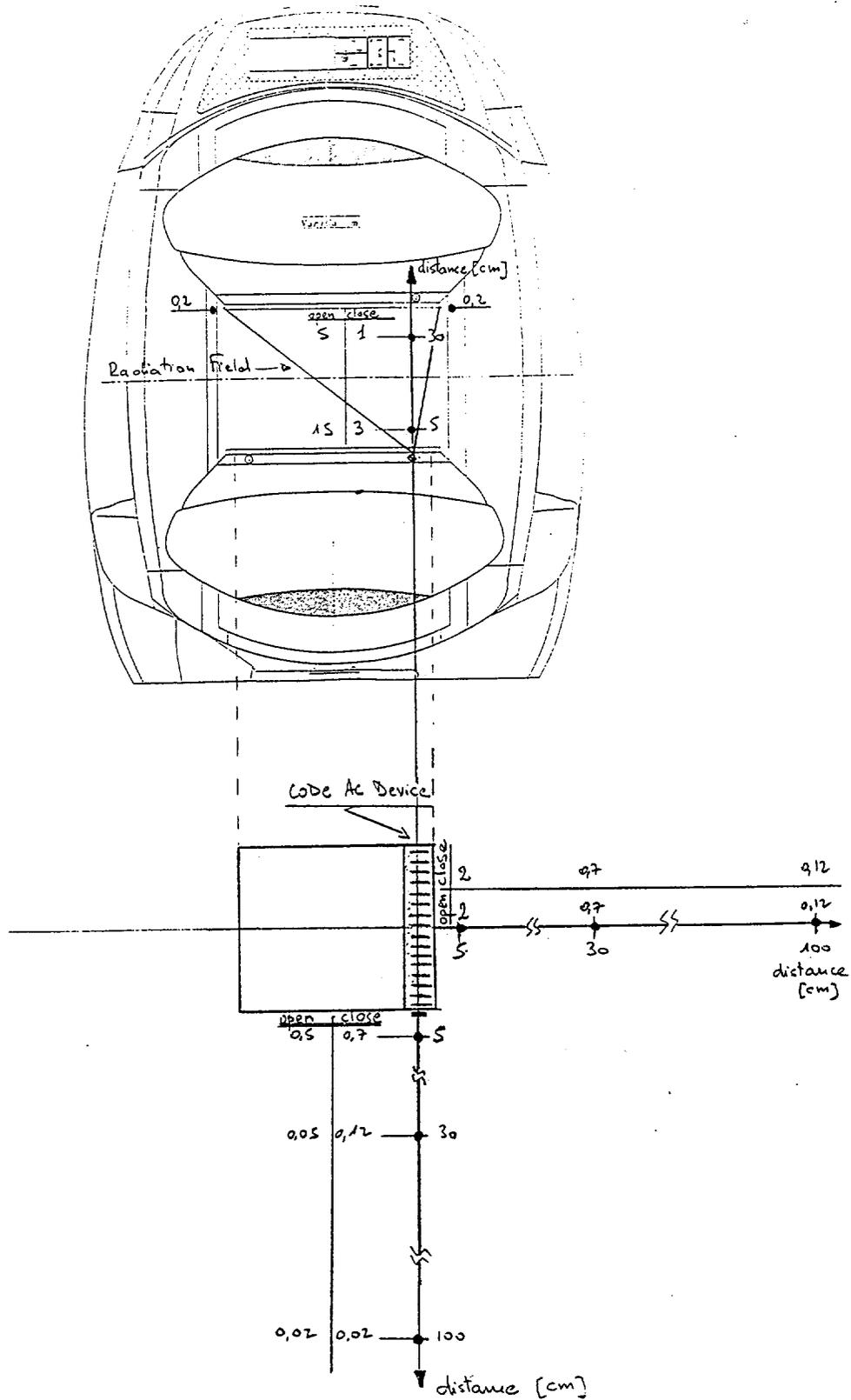


Figure 3: Radiation dose of the device inserted in the septa and positioned on the camera. UNIT [mR/h]

date: 27/12/99

file radiation_leak_cs.doc

Appendix G

Prototype Testing

Contents

Source prototype test for NRC source registration	G-1
Test report on the shockproof box Model 75-7	G-9
Shutter Mechanism Test	G-24
Data sheet on Micro-switch	G-27

Source prototype test for NRC source registration

Summary Data

Date of Application: August 7, 1999

Applicant: Isotope Products Laboratories
1800 Keystone Street
Burbank, California 91504

Contact Person
Gary Zhou
Phone: (818) 843-7000 Extension: 119
Fax: (818) 843-6168

Sealed Source Type: Gamma Source

Model(s) 34-5

<u>Isotope</u>	<u>Maximum Activity</u>
Cs-137	100 mCi

Other Companies Involved: None

Leak Test Frequency: Six Months

Principal Use: Gamma Gauging
Code: D

Custom Source: No

Description:

The single encapsulated multipoint line source (Model 34-5-1) consists of the fusion welded capsule body and plug enclosing the internal tungsten shielding and the 18 active elements. The capsule body assembly is made of high-grade 300 series Stainless Steel and it has a cylindrical shape with following dimensions:

Capsule body: diameter 0.250" x length 15.749"
Wall Thickness: 0.028"

Two Tungsten end pieces are affixed to the source by means of cement on one side and a spring pin on the other side. The Tungsten pieces facilitate handling and mounting in a collimator device.

There are 18 active ceramic elements that are impregnated with Cesium-137 Chloride or Nitrate, dried, and sintered.

Source ANSI Classification: 77C43333

Labeling:

The following information will be engraved on the surface of the sources:

Distributor Name	-	IPL
Nuclide	-	Cs-137
Serial Number	-	XX-XXX
Manufacture Date	-	Day/Month/Year
Activity	-	XXmCi

Diagram:

See attached drawings.

Condition of Normal Use:

The source is designed to be permanently installed into a holder or device and used in laboratory, clinical, or field conditions for gamma gauging applications by trained personnel.

ANSI classification categories are the ceilings to which test prototypes have been subjected. Under no circumstances should the sealed sources be used in conditions which exceed the ANSI classification. If in doubt, contact the manufacturer for additional information.

The manufacturer of the sealed source indicates a recommended working life to the user of 15 years (half-life: 30.2y [Cs-137]).

Prototype Testing:

General Information: The line sources were tested at Isotope Products Laboratories between 8/2/99 and 8/6/99. All the tests were performed in accordance with ANSI N542-1977. The raw data was documented in IPL notebook number 437 pages 105 through 106. Temperature, external pressure,

impact, vibration, and puncture equipment was designed and built per ANSI standard N542-1977 paragraphs 7.2.1, 7.3.1, 7.4.1, 7.5.1, and 7.6.1 respectively. The sources were leak tested by immersion in distilled water at 50° C for no less than 4 hours. The soak water was then assayed by using a calibrated liquid scintillation counter.

Temperature: (desired: class 4) Initially, the sample source was subjected to the low temperature test at -40° C. The source was covered in crushed dry ice for more the 20 minutes. Then, the source was placed into an oven and heated at 400° C for one hour. For the thermal shock test, the source was heated up to 415° C and held at this temperature for 15 minutes. The source was transferred to water at 20° C within 10 second. The sample was visually examined and soak tested after the temperature test. The source was intact, and found to be leak free. The test capsule passed the class 4 temperature test.

External Pressure: (desired: class 3) The source was placed into a vacuum/pressure chamber and subjected to the test pressures for two periods of 5 minutes each. The low pressure test was conducted in air at 25 kN/m³, and the high pressure test was conducted in water at 2 MN/m³. The source was visually inspected and soak tested after the external pressure test. The source was intact and found to be leak free. The test capsule passed the class 3 pressure test.

Impact: (desired: class 3) The source was impacted with a 200 g weight dropped from 1m. The source was visually inspected and soak tested after the impact test. The source was intact and found to be leak free. The test capsule passed the class 3 impact test.

Vibration: (desired: class 3) The source was affixed to a vibration device and was tested from 25Hz to 80Hz in increments of 5Hz. The peak to peak amplitude was measured at minimum of 0.635mm. The duration of the test was 10 minutes, returning back to the initial frequency, and repeated for a total of three tests for two axes. The next test was for the 90Hz to 500Hz range with increments of 5Hz to 50Hz. The source was tested for 10 minutes at a constant of 10g. The test was repeated for a total of three times for two axes. Resonance frequencies were not found. The source was visually inspected and soak tested after the vibration test. The source was intact and found to be leak free. The test capsule passed the class 3 vibration test.

Puncture: (desired: class 3) The source was puncture tested with a 10 g weight dropped from 1m. The source was visually inspected and soak tested after the puncture test. The source was intact and found to be leak free. The test capsule passed the class 3 puncture test.

Results of the prototype testing indicate an ANSI classification of 77C43333.

External Radiation Levels:

The maximum exposure rates from distances of 5 cm, 30 cm and 100cm were calculated in accordance with the method described in Radiology Health Handbook. Cesium has a gamma factor of 3.3, and maximum dose rate at a distance can be calculated by using the formula: rate = gamma factor * (activity/distance²). The gamma factor is defined as $\Gamma = R\text{-cm}^2/\text{hr-mCi}$.

<u>Nuclide</u>	<u>Activity</u>	<u>Distance from Source</u>		
		<u>5 cm</u>	<u>30 cm</u>	<u>100 cm</u>
Cs-137	100 mCi	13.2 mR/h	0.367 mR/h	0.033 mR/h

Quality Assurance and Control

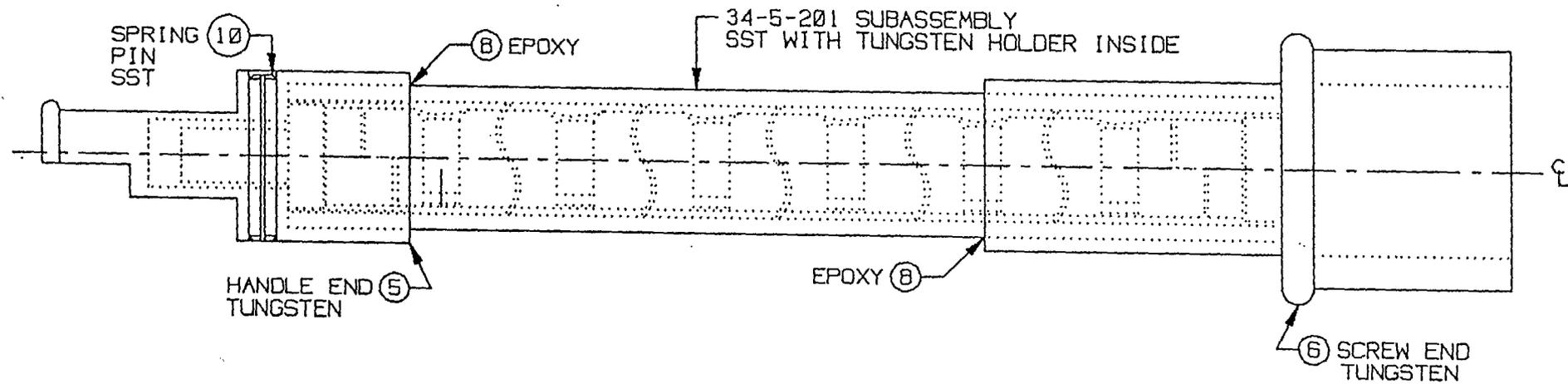
- a) **Program:** The IPL Quality Assurance Manual details the quality control of this source from raw materials to finished product. The program is designed to satisfy 10CFR Part 50 (B) and meets the requirements of ISO 9002 (IPL is ISO-9002 certified). The program covers drawing control, purchasing, training, calibration records, source numbering, incoming raw materials, assay quality control, leak testing, document control, confirming orders, and pre-production design review.
- b) **Activity:** Held to $\pm 15\%$ of nominal activity
- c) **Assay Procedures:** A calibrated pressurized re-entrant well-type ionization chamber is used to measure the activity of the source.
- d) **Radiopurity Determination:** Determined by gamma spectrometry of the source or the radionuclide batch.
- e) **Leak Test Procedures:** Sources are leak tested in accordance with ANSI N44.2-1973 paragraph A1.3. Criteria for acceptance are:

1.0 nCi removable beta/gamma
0.1 nCi removable alpha

Limitations and/or Other Consideration of Use

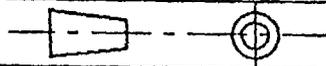
- a) **Distribution:** These sources shall be distributed to specific licensees of the NRC or Agreement States.

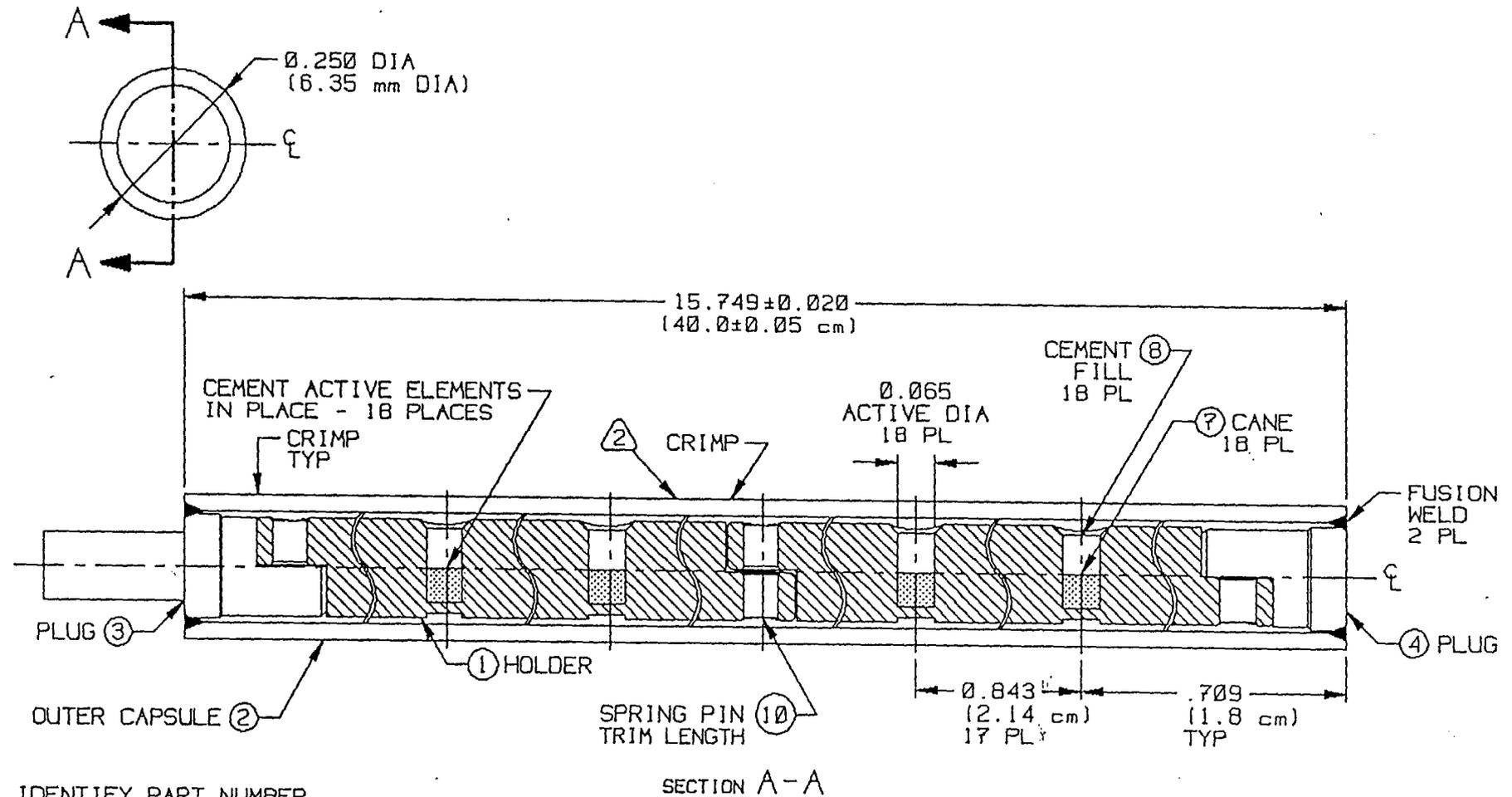
- b) **Leak Test:** These sources shall be leak tested at intervals not greater than six months. Such tests must be capable of detecting 0.005 μCi of removable radioactivity, and be performed by specific licensees of the NRC or agreement states.
- c) **Use:** These sources are intended to be used in gauging systems. These sources should not be subjected to conditions exceeding their ANSI rating of C43333.
- d) **Handling:** Remote handling tools and localized shielding should be used.
- e) **Storage:** Store in a clean, dry area. Shielding should be provided as necessary.
- f) **Cleaning:** Sources may be cleaned with a tissue moistened with any non-corrosive solvent.
- g) **Disposal:** Disposal of decayed or otherwise unusable sources must be made via the user's authorized radioactivity disposal method.
- h) The registration sheet and the information contained within the references shall not be changed or transferred without the written consent of the California Department of Health Services.



- 2. IDENTIFY PART NUMBER
 - 1. ASSEMBLE COMPLETE PER ENGINEERING DRAWING AND APPLY EPOXY AS REQUIRED
- NOTES: UNLESS OTHERWISE SPECIFIED

P/N: 34-5-1
 ASSEMBLY, 18 ACT ELEM x 2.14 cm APART

 ISOTOPE PRODUCTS LABORATORIES BURBANK, CALIFORNIA 91504	UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES		DESIGN JMD/RLT		DRAWING TITLE Cs-137 LINE SOURCE		
	TOLERANCES ON DECIMAL FRACTION X1 XX1 XXX $\pm 1/64$ $\pm .1$ $.01$ $.002$		ANGLE $\pm .5^\circ$		SCALE NONE		SERIES TITLE INDUSTRIAL SOURCES. LINE
THIRD ANGLE PROJECTION 		SIZE A		CAGE CODE 32993	REVISION 5	DRAWING NUMBER 34-5	SHEET 3 OF 11
THIS DRAWING IS THE PROPERTY OF ISOTOPE PRODUCTS LABORATORIES AND MAY NOT BE USED, REPRODUCED, PUBLISHED OR DISCLOSED TO OTHERS WITHOUT EXPRESS AUTHORIZATION BY ISOTOPE PRODUCTS LABORATORIES.							



3. IDENTIFY PART NUMBER

② ENGRAVE CHARACTERS 0.060 HIGH x 0.003 DEEP MAX
AS SHOWN: (BLACK FILL)
"IPL", MFG DATE, NUCLIDE, ACTIVITY, SERIAL NUMBER

1. ASSEMBLE COMPLETE PER ENGINEERING DRAWING
AND FUSION WELD AS REQUIRED.
CRIMP AS NECESSARY TO ARREST INTERNAL MOVEMENT.

NOTES: UNLESS OTHERWISE SPECIFIED

P/N: 34-5-201

SUBASSEMBLY,
18 ACT ELEM x 2.14 cm APART

THIS DRAWING IS THE PROPERTY OF ISOTOPE PRODUCTS LABORATORIES, AND MAY NOT BE USED, REPRODUCED, PUBLISHED OR DISCLOSED TO OTHERS WITHOUT EXPRESS AUTHORIZATION BY ISOTOPE PRODUCTS LABORATORIES.		UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES			THIRD ANGLE PROJECTION				
		TOLERANCES ON							
FRAC-TION	DECIMAL	ANGLE	DESIGN	SCALE					SIZE
±1/64	± .1 .01 .002	±.5°	JMD/RLT	NONE	A	32993	5	34-5	4 OF 11

TEST REPORT
FOR
MODEL 75-7 BOX
FOR
COLLIMATOR ASSEMBLY

1. Package Specimen Description
2. Test Protocol
3. Test Procedure
4. Test Results
5. Appendix

-copy of Department of Transportation (DOT) 49 CFR regulations paragraphs 173.411, 173.412, and 173.465.

-copy of International Air Transport Association (IATA) regulations (1999) 10.6.2.1, and 10.6.3.4

-drawings of package specimen designs

Package Specimen Description

Container Model 75-7 is offered in two options. The package consists of two options. Option 1 is a rugged rectangular package of riveted assembly construction with Aluminum alloy valences and 3/8" domestic plywood laminated with 035 fiberglass and upholstered with any combination of high density polyester and polyurethane foam. The sides of the package are made of fiberglass reinforced 3/8" thick plywood. The sides are joined together using 1/32" thick x 1 1/4" x 1 1/4" Aluminum alloy valences that are riveted to the sides of the package. The package is equipped with lifting handles and a locking latch. Ball corners provide additional reinforcement and shock absorption in the corner areas. Option 2 is a fiberboard box containing the rugged rectangular package described in Option 1. The fiberboard box of Option 2 has cutouts to permit lifting via the handles on Option 1 (the internal box). The fiberboard box is secured by means of fiberglass reinforced tape. The tape is used to seal all seams. The tape shall extend lengthwise a minimum of 2 inches onto an adjacent side.

The package with the collimator device and line source weighs approximately 110 pounds. The outer dimensions are approximately 9" high x 26" wide by 10" deep.

Test Protocol

Tests were performed as required in Department of Transportation (DOT) 49CFR173.465 governing transportation of hazardous materials and International Air Transport Association (IATA) (1999) guidelines governing international transportation of hazardous materials.

Test Procedure

Per DOT 49CFR173.465(a) - (b) and IATA 10.6.2.4(b) - (c) each package specimen was subject to a water spray test whereby a minimum of 2" of simulated rainfall was applied per hour over a one hour period no more than 2 hours before all subsequent tests were performed. Water spray was applied from five directions (top and four sides) simultaneously using a shower equipped with several miniature spray heads.

Per DOT 49CFR173.465(c)(1) and (4) and IATA 10.6.2.4(d) each specimen was dropped four feet (1.2 m) in a free drop test to inflict maximum damage. A different test specimen was dropped 1 foot (0.3 m) onto each corner. Heights were measured with a tape measure and were slightly over those required.

Per DOT 49CFR173.465(d) and IATA 10.6.2.4(e) each test specimen was subject to a 24 hour compression (stacking) test using a compressive load uniformly placed on two sides (one being the normal base_ at least 5 times the weight of the packages.

Per DOT 49CFR173.465(e) and IATA 10.6.2.4(f) each specimen was subject to a penetration test using a 1.25" diameter steel bar weighing 14 pounds (6.6 kg) with a hemispherical end. The bar was dropped onto the center of the test package from at least 40 inches (1.0 m) height.

As only solid materials will be shipped in this configuration, additional tests were not performed.

Test Results

Phase 1: On July 21, 1999 from 11:00 am to 12:10 pm, a test specimen loaded with a tungsten collimator containing a 15mCi Cs-137 line source was subjected to a simulated rain of 2" per hour minimum for 1 hour followed by two 5.0 foot drops. The first drop test was conducted such that the normal bottom of the package struck the concrete surface. The second drop test was conducted such that one of the handle ends struck the concrete surface. The test specimen had a maximum contact radiation reading of 2.0 mR/hr prior to the test and had a 2.0 mR/hr contact radiation reading following the test. Since there was no change in the radiation reading and no visible damage to the sources or the emitters, the package passed this phase of the type A test.

Phase 2: The same test specimen was used for this phase of the test which will include drops from a height of 1 foot onto each of the eight corners of the box following a simulated rain of 2 inches per hour for 1 hour. The box began the rain portion of the test at 2:30 pm on 7/21/99 and concluded the rain test at 3:35 pm 7/21/99. The box was immediately dropped onto each of the eight corners. The radiation reading prior to the test was 2.0 mR/hr on contact with the box (maximum) and was 2.0 mR/hr on contact with the box (maximum) following the drop test.

Phase 3: Immediately following the Phase 2 drop test, the penetration test was performed on the same specimen. The penetration test employed a 14 pound steel rod with a diameter of 1.25" and one hemispherical end. The rod was dropped from a height of 1 meter minimum onto the box which was placed onto a concrete slab. The rod left a circular mark on the top of the box. No other visible damage was apparent and the radiation measurements showed the same results as before, 2.0 mR/hr maximum.

Phase 4: Compression Test. On July 22, 1999, the compression test was conducted. The test specimen, the same package used in phases 2 and 3 above, was subjected to a 2" minimum simulated rainfall for 1 hour. The simulated rainfall struck all sides of the package simultaneously and began at 1:00 pm and was concluded at 2:15 pm. Following the rain test portion, the package was compressed with 600 pounds of lead bricks applied to the top of the package. The bricks were loaded onto the package at 3:30 pm on 7/22/99 and removed at approximately 4:30 pm on 7/23/99; total elapsed time was 25 hours. There was no visible deflection of the package due to the compressive load during the test. There was no visible damage to the package and the radiation profile measurements were the same as in earlier tests, 2.0 mR/hr maximum on contact with the box.

In conclusion, container Model 75-7 meets all the requirements of DOT 49CFR173.411, 49CFR173.412, and IATA 10.6.1.2 in that no loss or dispersal of contents occurred. No significant shifting of internal packaging or contents was observed and no change in external radiation readings occurred. Therefore, Model 75-7 meets all DOT 49CFR and IATA requirements for shipping solid materials up to the weights tested.

ISOTOPE PRODUCTS LABORATORIES
TYPE A CONTAINER CERTIFICATION

This is to certify that the shipping container described below was tested to and complies with the requirements and specifications as set forth in the following references:

-
1. Title 49 CFR U.S. Department of Transportation Regulations (DOT) Paragraphs 173.411 (General Design Requirements).
 2. Title 49 CFR U.S. Department of Transportation Regulations (DOT) Paragraphs 173.412 (Additional Design Requirements for type A Packages).
 3. Title 49 CFR U.S. Department of Transportation Regulations (DOT) Paragraphs 173.461- 173.465 (Compliance and Testing).
 4. International Air Transport Association (IATA) Dangerous Goods Regulations Paragraphs 10.6.1.2 (Requirements for Type A Packages).
 5. International Air Transport Association (IATA) Dangerous Goods Regulations Paragraphs 10.6.2.1 - 10.6.2.4 (Packaging Test Procedures).
-

Model: 75-7

Rectangular fiberglass and Aluminum reinforced wooden box for tungsten collimator with a 15 mCi line source

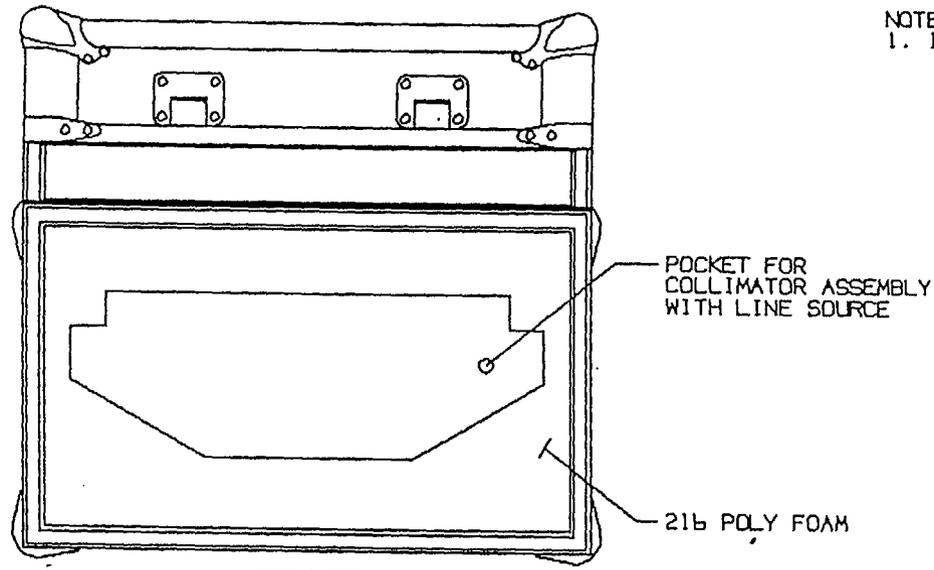
Drawing Number: 75-7 (attached)

Tested weight: 110 pounds

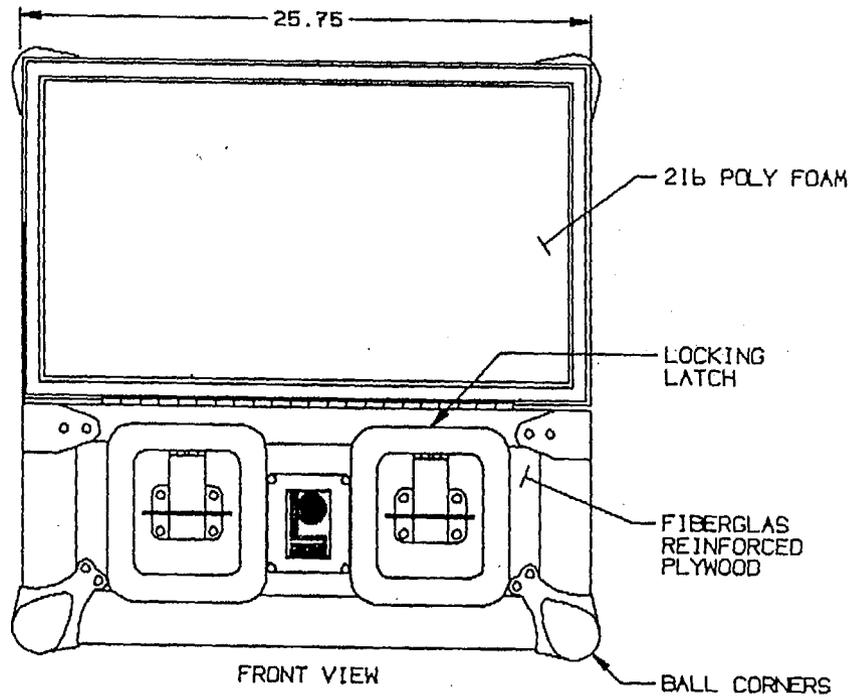


Authorized Signature

NOTES:
 1. INDICATED DIMENSIONS ARE APPROXIMATE.

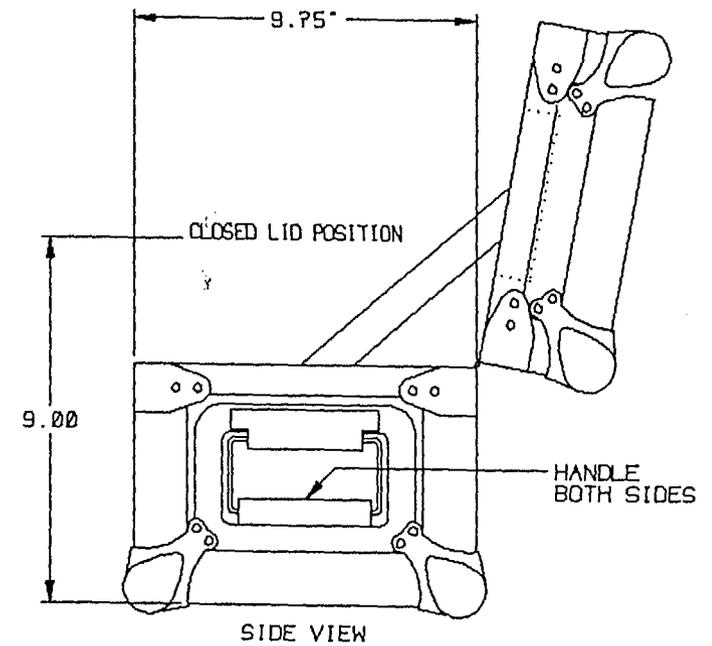


TOP VIEW



FRONT VIEW

SHIPPING/STORAGE CASE



SIDE VIEW

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DESIGN
 JMD/RLT

SCALE
 NONE

SIZE
 A

CAGE CODE
 32993

REVISION
 0

DRAWING NUMBER
 75-7

SHEET
 1 OF 1

set forth in § 173.465 or § 173.466, as appropriate.

(hh) *Type B packaging* means a packaging designed to retain the integrity of containment and shielding required by this part when subjected to the normal conditions of transport and hypothetical accident test conditions set forth in 10 CFR part 71.

(ii) *Uncompressed gas* means, for the purposes of this subpart, gas at a pressure not exceeding the ambient atmospheric pressure at the time and location the containment system is closed. All other radioactive gases are considered to be compressed.

(jj) *Unilateral approval* means approval by the competent authority of the country of origin only.

(kk) *Unirradiated thorium* means thorium containing not more than 10^{-7} grams uranium-233 per gram of thorium-232.

(ll) *Unirradiated uranium* means uranium containing not more than 10^{-6} grams plutonium per gram of uranium-235 and a fission product activity of not more than 0.25 millicuries of fission products per gram of uranium-235.

[Amdt. 173-162, 48 FR 10226, Mar. 10, 1983; 48 FR 13431, Mar. 31, 1983, as amended at 48 FR 31217, July 7, 1983; Amdt. 173-193, 50 FR 41898, Oct. 16, 1985; Amdt. 173-207, 53 FR 38274, Sept. 29, 1988; Amdt. 173-219, 54 FR 40069, Sept. 29, 1989]

§ 173.411 General design requirements.

Except for a package that contains a limited quantity or excepted instrument or article under §§ 173.421 through 173.424, each package used for shipment of radioactive materials shall be designed so that:

(a) The package can be easily handled and properly secured in or on a conveyance during transport;

(b) A package with a gross weight exceeding 10 kilograms (22 pounds) and up to 50 kilograms (110 pounds) has a means for manual handling;

(c) A package with a gross weight of 50 kilograms (110 pounds) or more can be safely handled by mechanical means;

(d) Each lifting attachment on the package, when used in the intended manner, with a minimum safety factor of three, does not impose an unsafe stress on the structure of the package.

In addition, the lifting attachment shall be so designed that failure under excessive load would not impair the ability of the package to meet all other requirements of this subpart. Each attachment or other feature on the outer surface of the packaging that could be used to lift the package must be removable or otherwise capable of being made inoperable for transport, or shall be designed with strength equivalent to that required for lifting attachments;

(e) The external surface, as far as practicable, may be easily decontaminated;

(f) The outer layer of packaging will avoid, as far as practicable, pockets or crevices where water might collect; and

(g) Each feature that is added to the package at the time of transport, and that is not a part of the package, will not reduce the safety of the package.

[Amdt. 173-162, 48 FR 10226, Mar. 10, 1983, as amended at 48 FR 31218, July 7, 1983]

§ 173.412 Additional design requirements for Type A packages.

In addition to meeting the general design requirements prescribed in § 173.411, each Type A packaging shall be designed so that:

(a) The smallest overall external dimension of the package is not less than 10 centimeters (4 inches);

(b) The outside of the packaging incorporates a feature, such as a seal, that is not readily breakable, and that, while intact, is evidence that the package has not been opened. In the case of packages shipped in exclusive use closed transport vehicles, the cargo compartment may be sealed instead of the individual packages;

(c) As far as practicable, the external surfaces are free from protrusions and are designed and finished so that they can be easily decontaminated;

(d) Containment and shielding would be maintained during transportation and storage in a temperature range of -40°C (-40°F) to 70°C (158°F) with account being taken of the possibility of brittle fracture;

(e) It is able to withstand the effects of any acceleration, vibration, or vibration resonance that may arise during normal transportation, without any deterioration of the effectiveness of clos-

ing devices or of the integrity of the package as a whole and without loosening or unintentional release of nuts, bolts, or other securing devices even after repeated use;

(f) It includes a containment system securely closed by a positive fastening device that cannot be opened unintentionally or by pressure that may arise within the package during normal transport. Special form, as demonstrated in accordance with §173.469 may be considered as a component of the containment system;

(g) The materials of the packaging and any components or structures are physically and chemically compatible with each other and with the contents, taking into account the behavior of each under irradiation;

(h) For each component of the containment system account is taken, where applicable, of radiolytic decomposition of materials and the generation of gas by chemical reaction and radiolysis;

(i) The containment system will retain its radioactive contents under the reduction of ambient pressure to .25 kilograms per square centimeter (3.5 pounds per square inch);

(j) Each valve through which the radioactive contents could otherwise escape is protected against damage and unauthorized operation and, except for a pressure relief device, has an enclosure to retain any leakage;

(k) Any radiation shield that encloses a component of the packaging specified as part of the containment system will prevent the unintentional escape of that component from the shield;

(l) Failure of any tie down attachment on the packaging under excessive load will not impair the ability of the package to meet other requirements of this subpart;

(m) When subjected to the tests specified in §173.465 or evaluated against these tests by any of the methods authorized by §173.461(a), the packaging will prevent:

(1) Loss or dispersal of the radioactive contents; and

(2) Any significant increase in the radiation levels recorded or calculated at the external surfaces for the condition before the test;

(n) Each packaging designed for liquids will:

(1) Meet the conditions prescribed in paragraph (m) of this section when subjected to the tests specified in §173.466 or evaluated against these tests by any of the methods authorized by §173.461(a);

(2) For any package with a liquid volume not exceeding 50 cubic centimeters (1.7 fluid ounces), have sufficient suitable absorbent material to absorb twice the volume of the liquid contents. The absorbent material shall be compatible with the package contents and suitably positioned to contact the liquid in the event of leakage; and

(3) For any package with a liquid volume exceeding 50 cubic centimeters (1.7 fluid ounces), either:

(i) Have sufficient absorbent material as prescribed in paragraph (n)(2) of this section; or

(ii) Have a containment system composed of primary inner and secondary outer containment components designed to assure retention of the liquid contents within the secondary outer components in the event that the primary inner components leak; and

(o) Each package designed for compressed or uncompressed gases other than tritium or argon-37 not exceeding 200 curies will be able to prevent loss of contents when the package is subjected to the tests prescribed in §173.466 or evaluated against these tests by any of the methods authorized by §173.461(a).

[Amdt. 173-162, 49 FR 10226, Mar. 10, 1983, as amended at 49 FR 31218, July 7, 1983]

§173.413 Requirements for Type B packages.

Each Type B(U) or Type B(M) package must be designed and constructed to meet the applicable requirements in 10 CFR part 71.

§173.415 Authorized Type A packages.

The following packages are authorized for shipment, if they do not contain quantities exceeding A₁ or A₂ as appropriate:

(a) U.S. Department of Transportation (DOT) Specification 7A (§178.350 of this subchapter) Type A general packaging. Each shipper of a Specification 7A package must maintain on file for at least one year after the latest

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 FEDERAL BUREAU OF INVESTIGATION
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§ 173.463 Packaging and shielding—
testing for integrity.

After each of the applicable tests specified in §§ 173.465 and 173.466, the integrity of the packaging, or of the packaging and its shielding, shall be retained to the extent required by § 173.412(m) for the packaging being tested.

§ 173.465 Type A packaging tests.

(a) The proposed packaging with proposed contents must be capable of withstanding the tests prescribed in this section. One prototype may be used for all tests if the requirements of paragraph (b) of this section are complied with.

(b) *Water spray test.* The water spray test must precede each test or test sequence prescribed in this section. The water spray test shall simulate exposure to rainfall of approximately 5 centimeters (2 inches) per hour for at least one hour. The time interval between the end of the water spray test and the beginning of the next test shall be such that the water has soaked-in to the maximum extent without appreciable drying of the exterior of the specimen. In the absence of evidence to the contrary, this interval may be assumed to be two hours if the water spray is applied from four different directions simultaneously. However, no time interval may elapse if the water spray is applied from each of the four directions consecutively.

(c) *Free drop test.* The free drop test consists of a fall onto the target in a manner that causes maximum damage to the safety features being tested, and:

(1) For packages weighing 5,000 kilograms (11,000 pounds) or less, the distance of the fall measured from the lowest point of the packaging to the upper surface of the target shall not be less than 1.2 meters (4 feet).

(2) For packages weighing more than 5,000 kilograms (11,000 pounds), the distance of the fall shall not be less than the distance specified in Table 11, for the applicable packaging weight:

TABLE 11—FREE-FALL DISTANCE FOR PACKAGINGS WEIGHING MORE THAN 5,000 KILOGRAMS

Packaging weight		Free-fall distance	
Kilograms	Pounds	Feet	Meters
>5,000 to 10,000 ...	>11,000 to 22,000 .	3	0.9
>10,000 to 15,000 .	>22,000 to 33,000 .	2	0.6
More than 15,000 ..	More than 33,000 .	1	0.3

(3) For Fissile Class II packagings, the free drop specified in subparagraph (1) or (2) of this paragraph shall be preceded by a free drop from a height of .3 meter (1 foot) on each corner. For cylindrical packagings, the .3 meter (1 foot) drop shall be onto each of the quarters of each rim.

(4) For fiberboard or wood rectangular packages not exceeding 50 kilograms (110 pounds) in weight, a separate specimen of the proposed packaging shall be subjected to a free drop onto each corner from a height of .3 meter (1 foot).

(5) For fiberboard cylindrical packages weighing not more than 100 kilograms (220 pounds) a separate specimen of the proposed packaging shall be subjected to a free drop onto each of the quarters of each rim from a height of .3 meter (1 foot).

(6) The target shall have a flat, horizontal surface of such mass and rigidity that any increase in its resistance to displacement or deformation upon impact by the specimen would not significantly increase the damage to the specimen.

(d) *Compression test.* The compression test shall last for a period of at least 24 hours and consists of a compressive load equivalent to the greater of the following:

(1) Five times the weight of the actual package; or

(2) 1300 kilograms per square meter (265 pounds per square foot) multiplied by the vertically projected area of the package. The compressive load shall be applied uniformly to two opposite sides of the packaging specimen, one of which must be the base on which the package would normally stand.

(e) *Penetration test.* For the penetration test the packaging specimen shall be placed on a rigid, flat, horizontal

§ 173.466

surface that will not move while the test is being performed. The test shall consist of:

(1) A bar of 3.2 centimeters (1.25 inches) in diameter with a hemispherical end, weighing 6 kilograms (13.2 pounds) being dropped with its longitudinal axis vertical, onto the center of the weakest part of the packaging specimen, so that, if it penetrates far enough, it will hit the containment system. The bar must not be deformed by the test; and

(2) The distance of the fall of the bar measured from its lower end to the upper surface of the packaging specimen shall not be less than 1 meter (3.3 feet).

[Amdt. 173-162, 48 FR 10226, Mar. 10, 1983, as amended at 48 FR 31219, July 7, 1983; Amdt. 173-16, 48 FR 50461, Nov. 1, 1983; Amdt. 173-196, 51 FR 5973, Feb. 18, 1986; Amdt. 173-224, 56 FR 66279, Dec. 20, 1991]

§ 173.466 Additional tests for Type A packagings designed for liquids and gases.

(a) In addition to the tests prescribed in § 173.465, Type A packagings designed for liquids and gases shall be capable of withstanding the following tests:

(1) *Free drop test.* The packaging specimen shall fall onto the target in a manner which will cause it to suffer the maximum damage to its containment. The distance of the fall measured from the lowest part of the packaging specimen to the upper surface of the target shall be not less than 9 meters (30 feet).

(2) *Penetration test.* The specimen must be subjected to the test specified in § 173.465(e) except that the distance of the fall shall be 1.7 meters (5.5 feet).

§ 173.467 Tests for demonstrating the ability of Type B and fissile radioactive materials packagings to withstand accident conditions in transportation.

Each Type B packaging or packaging for fissile material shall meet the test requirements prescribed in 10 CFR part 71 for ability to withstand accident conditions in transportation.

§ 173.469 Tests for special form radioactive materials.

(a) Special form radioactive materials must meet the test requirements

of paragraph (b) of this section. Each solid radioactive material or capsule specimen to be tested shall be manufactured or fabricated so that it is representative of the actual solid material or capsule which will be transported with the proposed radioactive content duplicated as closely as practicable. Any differences between the material to be transported and the test material such as the use of non-radioactive contents shall be taken into account. In addition:

(1) A different specimen may be used for each of the tests;

(2) The specimen must not break or shatter when subjected to the impact, percussion, or bending tests;

(3) The specimen must not melt or disperse when subjected to the heat test; and

(4) After each test, leaktightness or indispersibility of the specimen shall be determined by a method no less sensitive than the leaching assessment prescribed in paragraph (c) of this section. For a capsule resistant to corrosion by water, and which has an internal void volume greater than 0.1 milliliters, an alternative to the leaching assessment is a demonstration of leaktightness of 10^{-4} torr-l/s (1.3×10^{-4} atm-cm³/s) based on air at 25°C (77°F) and one atmosphere differential pressure for solid radioactive content, or 10^{-6} torr-l/s (1.3×10^{-6} atm-cm³/s) for liquid or gaseous radioactive content.

(b) Test methods. (1) *Impact Test.* The specimen must fall onto the target from a height of not less than 9 meter (30 feet). The target must be as specified in § 173.465(c)(6);

(2) *Percussion Test.* (i) The specimen shall be placed on a sheet of lead that is supported by a smooth solid surface, and be struck by the flat face of a steel billet so as to produce an impact equivalent to that resulting from a free fall of 1.4 kilograms (3 pounds) through 1 meter (3.3 feet);

(ii) The flat face of the billet shall be 25 millimeters (1 inch) in diameter with the edges rounded off to a radius of 3 millimeters ± 0.3 millimeters (.12 inch ± 0.12 inch);

(iii) The lead shall be of a hardness within 3.5 to 4.5 on the Vickers scale, and not more than 25 millimeters (1 inch) thick, and shall cover an area

greater than
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 used by
 (v) The
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 heated to

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(c) for Type B(M) Packages 10.6.2.2.12, and 10.6.2.2.13.

10.6.1.1.3 Excepted Package

An excepted package is a packaging containing radioactive material that is designed to meet the General Packing Requirements of 10.5.3.1 through 10.5.3.9 is an Excepted Package.

10.6.1.1.4 Industrial Package Type 1

An industrial package type 1 is a packaging or freight container containing LSA material or surface contaminated object (SCO) that is designed to meet the General Packing Requirements of 10.5.3. The smallest overall external dimension of the package must not be less than 100 mm.

10.6.1.1.5 Industrial Package Type 2

An industrial package type 2 is a packaging or freight container containing LSA material or surface contaminated object (SCO) that must meet the General Packing Requirements of 10.5.3. An Industrial Package Type 2 must also be designed to meet the requirements for an Industrial Package Type 1 as specified in 10.6.1.1.4 and, in addition, if it were subjected to the tests specified in 10.6.1.1.6 and 10.6.1.1.7 or alternatively to the tests for Packing Group III in Subsection 6.3, it would prevent:

- (a) the loss or dispersal of the radioactive contents; and
- (b) the loss of shielding integrity which would result in more than a 20% increase in the radiation level at any external surface of the package.

For freight container alternative see 10.6.1.1.7.

10.6.1.1.6 Industrial Package Type 3

An industrial package type 3 is a packaging or freight container containing LSA material or surface contaminated object (SCO) (see 9.3.10.7, 10.3.5, and 10.3.6) that must meet the General Packing Requirements of 10.5.3. An Industrial Package Type 3 must also be designed to meet the requirements for an Industrial Package Type 1 as specified in 10.6.1.1.4 and, in addition, the requirements specified in 10.6.1.1.1 and 10.6.2.1.1.1 through 10.6.2.1.1.6. For freight container alternative see 10.6.1.1.7.

10.6.1.1.7 Freight Container Alternative

Freight containers may also be used as Industrial Packages Types 2 and 3, provided that:

- (a) they satisfy the requirements for an Industrial Package Type 1 as specified in 10.6.1.1.4; and
- (b) they are designed to conform to the requirements prescribed in the ISO 1496-1:1990, "Series 1 Freight Containers — Specifications and Testing — Part 1: General Cargo Containers", and if they were subjected to the tests prescribed in that document they would prevent:
 - loss or dispersal of the radioactive contents, and
 - loss of shielding which would result in a more than 20% increase in the radiation level at any external surface of the freight containers.

10.6.2 Packaging Requirements

10.6.2.1 Requirements for Type A Packages

10.6.2.1.1 General

10.6.2.1.1.1 The smallest overall external dimension of the package must not be less than 100 mm.

10.6.2.1.1.2 The outside of every package must incorporate a feature, such as a seal, which is not readily breakable and which, while intact, will be evidence that the package has not been opened.

10.6.2.1.1.3 Any tie-down attachments on the package must be so designed that, under both normal and accident conditions, the forces in those attachments must not impair the ability of the package to meet the requirements of these Regulations.

10.6.2.1.1.4 The design of the package must take into account temperatures ranging from -40°C to +70°C for the components of the packaging. Special attention must be given to freezing temperatures for liquid contents and to the potential degradation of packaging materials within the given temperature range.

10.6.2.1.1.5 The design, fabrication and manufacturing techniques must be in accordance with national or international standards, or other requirements, acceptable to the competent authority.

10.6.2.1.1.6 If the package were subjected to the tests specified in 10.6.3.4 there must be no:

- (a) loss of shielding integrity which would result in more than a 20% increase in the radiation level at any external surface of the package; and
- (b) loss or dispersal of the radioactive contents.

10.6.2.1.2 Containment System

10.6.2.1.2.1 The design must include a containment system securely closed by a positive fastening device which cannot be opened unintentionally or by pressure which may develop within the package.

10.6.2.1.2.2 Special form radioactive material may be considered as a component of the containment system.

10.6.2.1.2.3 If the containment system forms a separate unit of the package, it must be capable of being securely closed by a positive fastening device which is independent of any other part of the packaging.

10.6.2.1.2.4 The design of any component of the containment system must take into account, where applicable, the radiolytic decomposition of liquids and other vulnerable materials and the generation of gas by chemical reaction and radiolysis.

10.6.2.1.2.5 The containment system must retain its radioactive contents under a reduction of ambient pressure to 25 kPa.

10.6.2.1.2.6 All valves, other than pressure relief valves, must be provided with an enclosure to retain any leakage from the valve.

10.6.2.1.2.7 A radiation shield which encloses a component of the package specified as a part of the containment system must be so designed as to prevent the unintentional

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release of that component from the shield. Where the radiation shield and such component within it form a separate unit, the radiation shield must be capable of being securely closed by a positive fastening device which is independent of any other packaging structure.

10.6.2.1.3 Additional Requirements for Type A Packages Designed to Contain Liquids

10.6.2.1.3.1 Type A packages designed to contain liquids must be adequate to meet the conditions specified in 10.6.2.1.1.6 if the package is subjected to the tests specified in 10.6.3.5.

10.6.2.1.3.2 Type A packages designed to contain liquids must be provided with sufficient absorbent material to absorb twice the volume of the liquid contents. Such absorbent material must be suitably positioned so as to contact the liquid in the event of leakage. Alternatively the package must be provided with a containment system composed of primary inner and secondary outer containment components designed so as to ensure retention of the liquid contents within the secondary outer containment components, even if the primary inner components leak.

10.6.2.1.3.3 The design of a package intended for liquid radioactive material must make provision for ullage to accommodate variations in the temperature of the contents, dynamic effects and filling dynamics.

10.6.2.1.4 Additional Requirements for Type A Packages Designed to Contain Gases

10.6.2.1.4.1 A package designed for compressed or uncompressed gases must prevent loss or dispersal of the radioactive contents if the package were subjected to the tests specified in 10.6.3.5. A package designed for contents not exceeding 40 TBq (1 000 Ci) of tritium or for noble gases in gaseous form with contents not exceeding A_2 , is excepted from this requirement.

10.6.2.2 Requirements for Type B Packages

10.6.2.2.1 A package must be so designed that, if it were subjected to the tests specified in 10.6.3.6 to 10.6.3.6.3.1, 10.6.2.1.1 and 10.6.2.1.2, it would retain sufficient radiation shielding to ensure that the radiation level at 1 m from the surface of the package would not exceed 10 mSv/h (1 rem/h) with the maximum radioactive contents which the package is designed to carry. For additional requirements for Type B(U) see 10.6.2.2.6 and for Type B(M) see 10.6.2.2.12.

10.6.2.2.2 A package must be so designed that, under the ambient conditions specified below, the heat generated within the package by the radioactive contents will not, under normal conditions of transport, as demonstrated by the tests in 10.6.3.4, adversely affect the package in such a way that it would fail to meet the applicable requirements for containment and shielding if left unattended for a period of one week. Particular attention must be paid to the effects of heat, which may:

(a) alter the arrangement, the geometrical form or the physical state of the radioactive contents or, if the material is enclosed in a can or receptacle (for example, clad fuel elements), cause the can, receptacle or material to deform or melt;

(b) lessen the efficiency of the packaging through differential thermal expansion or cracking or melting of the radiation shielding material; or

(c) in combination with moisture, accelerate corrosion.

For the purposes of 10.6.2.2.2, the ambient temperature must be taken as 38°C and the solar insolation conditions must be assumed to be as given by Table 10.6.A

TABLE 10.6.A
Type B Package Insolation Criteria
(10.6.1.3)

Form and location of surface	Insolation for 12 hours per day W/m ²
Flat surfaces transported horizontally:	
base	none
other surfaces	800
Flat surfaces NOT transported horizontally:	
each surface	200*
Curved surfaces:	400*

*Alternatively, a sine function may be used, adopting an absorption coefficient and neglecting the effects of possible reflection from neighbouring objects.

10.6.2.2.3 A package which includes thermal protection for the purpose of satisfying the requirements of the thermal test specified in 10.6.3.6.2 must be so designed that such protection will remain effective if the packaging is subjected to the tests specified in 10.6.3.4; 10.6.3.6.1.1 Drop Test 1 and 10.6.3.6.1.2 Drop Test 2 or 10.6.3.6.1.2 Drop Test 2 and 10.6.3.6.1.3 Drop Test 3, as appropriate. Any such protection on the exterior of the package must not be rendered ineffective by conditions commonly encountered in normal handling or transport, or in accidents, and which are not simulated in the tests referred to above, e.g. by ripping, cutting, skidding abrasion or other rough handling.

10.6.2.2.4 A package must be so designed that, if it were subjected to:

(a) the tests specified in 10.6.3.4, it would restrict the loss of radioactive contents to not more than $10^{-6} A_2$ per hour; and

(b) the tests specified in 10.6.3.6, 10.6.3.6.1.2 Drop Test 2, 10.6.3.6.2 and 10.6.3.6.3.1 and the test in either 10.6.3.6.1.3 Drop Test 3 when the package has a weight less than or equal to 500 kg, an overall density not greater than 1 000 kg/m³ based on the external dimensions, and radioactive contents greater than 1 000 A_2 not as special form radioactive material, or 10.6.3.6.1.1 Drop Test 1 for all other packages, it would restrict the accumulated loss of radioactive contents in a period of one week to not more than 10 A_2 for krypton-85 and not more than A_2 for all other radionuclides.

10.6.2.2.5 Where mixtures of different radionuclides are present, the provisions of 10.4.2.4 through 10.4.2.6.2 must apply except that for krypton-85 an effective A_2 value equal to 100 TBq (2 000 Ci) may be used. For 10.6.2.2.4(a), the



for adjusting certain test parameters, such as the penetrator diameter or the compressive load, must be taken into account.

(d) Calculation, or reasoned argument, when the calculation procedures and parameters are generally agreed to be reliable or conservative.

10.6.3.1.2 After the prototype or sample has been subjected to the tests, appropriate methods of assessment must be used to assure that the requirements of this subsection have been fulfilled in conformance with the performance and acceptance standards prescribed in 10.5.3, 10.6.1, 10.6.2 and 10.6.2.3.

10.6.3.1.3 All prototypes or samples must be examined before testing in order to identify and record faults or damage, including the following:

- divergence from the design;
- defects in construction;
- corrosion or other deterioration; and
- distortion of features.

10.6.3.1.4 The containment system of the packaging must be clearly specified. The external features of the specimen must be clearly identified so that reference may be made simply and clearly to any part of such specimen.

10.6.3.2 Testing the Integrity of the Containment System and Shielding and Evaluating Criticality Safety

After the applicable tests specified in 10.6.3.4, 10.6.3.5 and 10.6.3.6:

- (a) faults and damage must be identified and recorded;
- (b) it must be determined whether the integrity of the containment system and shielding has been retained to the extent required in 10.5.3, 10.6.1, 10.6.2 and 10.6.2.3 for the packaging under test; and
- (c) for packages containing fissile material, it must be determined whether the assumptions made in 10.6.2.3 regarding the most reactive configuration and degree of moderation of the fissile contents, of any escaped material, and of one or more packages are valid.

10.6.3.3 Target for Drop Tests

The target for the drop tests specified in 10.3.4.3.1, 10.6.3.4.3, 10.6.3.5.1 and 10.6.3.6.1 must be a flat, horizontal surface of such a character that any increase in its resistance to displacement or deformation upon impact by the specimen would not significantly increase the damage to the specimen.

10.6.3.4 Tests for Demonstrating Ability to Withstand Normal Conditions of Transport

The tests are: the water spray test, the free drop test, the stacking test, and the penetration test. Specimens of the package must be subjected to the free drop test, the stacking test and the penetration test, preceded in each case by the water spray test. One specimen may be used for all the tests, provided that the requirements of 10.6.3.4.1 are fulfilled.

10.6.3.4.1 Sequencing of Tests

The time interval between the conclusion of the water spray test and the succeeding test must be such that the water has soaked in to the maximum extent, without appreciable drying of the exterior of the specimen. In the absence of any evidence to the contrary, this interval must be taken to be two hours if the water spray is applied from four directions simultaneously. No time interval may elapse, however, if the water spray is applied from each of the four directions consecutively.

10.6.3.4.2 Water Spray Test

The specimen must be subjected to a water spray test that simulates exposure to rainfall of approximately 50 mm per hour for at least one hour.

10.6.3.4.3 Free Drop Test

The specimen must drop onto the target so as to suffer maximum damage in respect of the safety features to be tested.

(a) The height of drop measured from the lowest point of the package to the upper surface of the target must be not less than the distance specified in Table 10.6.B for the applicable weight. The target must be as defined in 10.6.3.3.

TABLE 10.6.B
Free Drop Distance for Testing Packages to Normal Conditions of Transport 10.6.2.4

Package weight (kilogram)	Free drop distance (metre)
5,000	1.2
≥5,000 to 10,000	0.9
≥10,000 to 15,000	0.6
≥15,000	0.3

(b) For packages containing fissile material, the free drop test specified above must be preceded by a free drop from a height of 0.3 m (1 ft) on each corner or, in the case of a cylindrical package, onto each of the quarters of each rim.

(c) For rectangular fibreboard or wood packages not exceeding a mass of 50 kg (110 lb), a separate specimen must be subjected to a free drop onto each corner from a height of 0.3 m (1 ft).

(d) For cylindrical fibre packages not exceeding a mass of 100 kg (220 lb), a separate specimen must be subjected to a free drop onto each of the quarters of each rim from a height of 0.3 m (1 ft).

10.6.3.4.4 Stacking Test

The specimen must be subjected, for a period of 24 hours, to a compressive load equal to the greater of the following:

- the equivalent of five times the weight of the actual package; or
- the equivalent of 13 kPa (0.13 bar or 2 lb/in²) multiplied by the vertically projected area of the package.

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The load must be applied uniformly to two opposite sides of the specimen, one of which must be the base on which the package would normally rest.

10.6.3.4.5 Penetration Test

The specimen must be placed on a rigid, flat, horizontal surface which will not move significantly while the test is being carried out. A bar of 32 mm (1.25 in) diameter with a hemispherical end and a weight of 6 kg (13 lb) must be dropped and directed to fall, with its longitudinal axis vertical, onto the centre of the weakest part of the package, so that, if it penetrates sufficiently far, it will hit the containment system. The bar must not be significantly deformed by the test performance. The height of drop of the bar measured from its lower end to the intended point of impact on the upper surface of the specimen must be 1 m (40 in).

10.6.3.5 Additional Tests for Type A Packages Designed for Liquids and Gases

A single package or separate packages must be subjected to each of the following tests unless it can be demonstrated that one test is more severe for the package in question than the other, in which case one package only must be subjected to the more severe test.

10.6.3.5.1 Free Drop Test

The specimen must drop onto the target so as to suffer the maximum damage in respect of containment. The height of drop measured from the lowest part of the package to the upper surface of the target must be 9 m (30 ft). The target must be as defined in 10.6.3.3.

10.6.3.5.2 Penetration Test

The specimen must be subjected to the test specified in 10.6.3.4.5 except that the height of drop must be increased to 1.7 m (67 in).

10.6.3.6 Tests for Demonstrating Ability to Withstand Accident Conditions in Transport

The specimen must be subjected to the cumulative effects of the tests specified in 10.6.3.6.1 and 10.6.3.6.2, in that order. Following these tests, either this specimen or a separate specimen must be subjected to the effect(s) of the water immersion test(s) as specified in 10.6.3.6.3.1 and, if applicable, 10.6.3.6.3.2.

10.6.3.6.1 Mechanical Test

The mechanical test consists of three different drop tests. Each specimen must be subjected to the applicable drops as specified in 10.6.2.2.4 and 10.6.2.2.5. The order in which the package is subjected to the drops must be such that, on completion of the mechanical test, the specimen will have suffered such damage as will lead to the maximum damage in the thermal test which follows.

10.6.3.6.1.1 Drop Test 1

The package must be dropped onto the target so as to suffer the maximum damage, and the height of the drop measured from the lowest point of the package to the upper surface of the target must be 9 m (30 ft). The target must be as defined in 10.6.3.3.

10.6.3.6.1.2 Drop Test 2

The specimen must be dropped so as to suffer the maximum damage onto a bar rigidly mounted perpendicularly on the target. The height of the drop measured from the intended point of impact of the package to the upper surface of the bar must be 1 m (40 in). The bar must be of solid mild steel of circular section 150 mm \pm 5 mm in diameter and 200 mm (8 in) long, unless a longer bar would cause greater damage in which case a bar of sufficient length to cause maximum damage must be used. The upper end of the bar must be flat and horizontal with its edges rounded off to a radius of not more than 6 mm (0.25 in). The target on which the bar is mounted must be as described in 10.6.3.3.

10.6.3.6.1.3 Drop Test 3

The package must be subjected to a dynamic crush test by positioning the specimen on the target so as to suffer maximum damage by the drop of a 500 kg weight from 9 m (30 ft) onto the specimen. The weight must consist of a solid mild steel plate 1 m \times 1 m (40 \times 40 in) and must fall in a horizontal attitude. The height of the drop must be measured from the underside of the plate to the highest point of the package. The target on which the specimen rests must be as defined in 10.6.3.3.

10.6.3.6.2 Thermal Test

The thermal test must consist of the exposure of a specimen fully engulfed, except for a simple support system, in a hydrocarbon fuel/air fire of sufficient extent in sufficiently quiescent ambient conditions to provide an average emissivity coefficient of at least 0.9, with an average flame temperature of at least 800°C (1,450°F) for a period of 30 minutes, or any other thermal test which provides the equivalent total heat input to the package. The fuel source must extend horizontally at least 1 m (40 in), and must not extend more than 3 m (10 ft), beyond any external surface of the package, and the package must be positioned 1 m (40 in) above the surface of the fuel source. After the cessation of external input, the package must not be cooled artificially and any combustion of materials of the package must be allowed to proceed naturally. For demonstration purposes, the surface absorptivity coefficient must be either 0.8 or that value which the package may be demonstrated to possess if exposed to the fire specified; and the convection coefficient must be that value which the designer can justify if the package were exposed to the fire specified. With respect to the initial conditions for the thermal test, the demonstration of compliance must be based upon the assumption that the package is in equilibrium at an ambient temperature of 38°C (100°F). The effects of solar radiation may be neglected prior to and during the tests, but must be taken into account in the subsequent evaluation of the package response.

10.6.3.6.3 Water Immersion Test

10.6.3.6.3.1 General

The specimen must be immersed under a head of water of at least 15 m (50 ft) for a period of not less than 8 hours in the attitude which will lead to maximum damage. For demonstration purposes, an external pressure of at least 150 kPa [gauge] (1.5 bar [gauge] or 22 lb/in² [gauge]) is considered to meet these conditions.

Test Report דו"ח בחינה

Subject Shutter Mechanism Test **נושא:**

Product Cesium option **מוצר** **Department** Mechanics **מחלקה**

Approved by	Yossi Aghion	אושר ע"י	Performed by	Erez Yehezkely	בוצע ע"י
Position	Mechanics Chief department	תפקיד	Position	Mechanic Engineer	תפקיד
Date	12.11.99	תאריך	Date	12.11.99	תאריך
Signature		חתימה	Signature		חתימה

תוכן העניינים - Contents

No.	Description	עמוד Page	תאור	מס'
1.	Test Purpose	2	מטרת הבחינה	.1
2.	Test Plan	2	תכנית הבחינה	.2
4.	Test Results	3	תוצאות הבחינה	.3
5.	Results Analysis & Conclusions	3	סיכום ומסקנות	.4

Appendices (Mark Relevant Box)

נספחים: (סמן תאים רלוונטיים)

Raw Material

חומר גלמי שנאסף במהלך הבחינה

Additional:

אחר. פרט:

ציוד הבחינה - Test Equipment

Instrument	Manufacturer / Model	Serial No.	Last Cal. Date
Cesium Option	Beta		
Pneumatic Actuation system: 1. Cyl 16x15 2. Cyl 12x10 3. 5x2 Solenoid valvex2 4. Controller	Conlog LTD		

Test Report No: _____ דו"ח מס': _____ Page 1 of 3

5. pneumatic accessories			
Collimator frame			

See additional Test Equipment list

ראה פירוט נוסף לציוד הבחינה

Test Purpose

The Cesium options posses a shutter mechanism, for the positioning and releasing of the rod containing the sources.

The Test Purpose is to assure life reliability of the shutter mechanism, estimated to be 35,000 cycles (push and release of the shutter).

Test Plan

The Cesium Option will be mounted upon a collimator's frame.

Sheet Metal bracket is mounted on the frame, containing pneumatic cylinder diameter 16mm stroke 15mm, pneumatic cylinder diameter 12mm stroke 10mm. The first for pushing the source rod to position (under cesium's collimator opening), the second to push the release handle, releasing the source rod to safe position.

The pneumatic cylinders are connected each to 5x2 valve – solenoid and spring actuated. The movement of for and back is continual.

Failure can be at the following:

- 1) Mechanism main spring.
- 2) Torsion spring of the release handle.
- 3) Spring of the source handle hand.
- 4) Dwell pin of screw end flange.
- 5) Dwell pin of source handle end.
- 6) Frictional stack of the system.
- 7) Wear due to alignment problems.
- 8) Parts coming apart due to tolerances, fittingness and loctite glue.
- 9) Microswitch malfunction.

Test Results

The Duty Cycle of the operation was set to be: 1cycle/sec (push and release).

The system run for **62,500** cycles, and showed no mechanical failure or deterioration.

Period of the test:

Date	Hour	Cycles
10.10.99	13:00-15:00 with stops	5000
	15:00-18:00	11200
11.10.99	08:00-11:00	10800
	14:00-19:00	15500
12.10.99	07:30-15:00	20000

total:62500

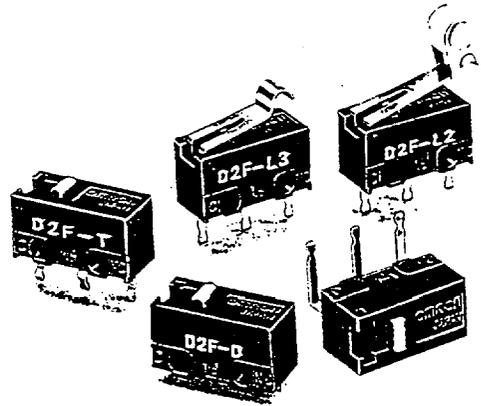
Results Analysis & Conclusions

The test bench had proved that the system could withstand the operational life minimal limits (35,000).

The most important thing is that the mechanism main spring didn't fail, and had the ability to place back the source rod back to safe place (no radiation), when the release handle was pushed.

A Variety of D2F-series Models Including Models Incorporating Simulated Hinge Lever and Hinge Roller Lever

- Subminiature switch (12.8 x 6.5 x 5.8 (W x H x D)) ideal for PCB mounting.
- Incorporating a reverse mechanism made with two highly precise split springs which ensures a long service life (1,000,000 operations).
- Two-stage bottom different in level and insertion terminals prevents flux penetration.
- PCB, self-standing, solder, and right angle terminals are available.
- Ideal for home electronics equipment, audio equipment, office machines, and communications equipment.



Ordering Information

Actuator	Terminals	Microvoltage/current load		Standard	
		0.1 A		1 A	3 A
		Low operating force (75 gf)	General-purpose (150 gf)	Low operating force (75 gf)	General-purpose (150 gf)
Pin plunger 	PCB terminals	D2F-01F	D2F-01	D2F-F	D2F
	Self-clinching terminals	D2F-01F-T	D2F-01-T	D2F-F-T	D2F-T
	Solder terminals	D2F-01F-D	D2F-01-D	D2F-F-D	D2F-D
	Right angle terminals	D2F-01F-A	D2F-01-A	D2F-F-A	D2F-A
Hinge lever 	PCB terminals	D2F-01FL	D2F-01L	D2F-FL	D2F-L
	Self-clinching terminals	D2F-01FL-T	D2F-01L-T	D2F-FL-T	D2F-L-T
	Solder terminals	D2F-01FL-D	D2F-01L-D	D2F-FL-D	D2F-L-D
	Right angle terminals	D2F-01FL-A	D2F-01L-A	D2F-FL-A	D2F-L-A
Simulated hinge lever 	PCB terminals	D2F-01FL3	D2F-01L3	D2F-FL3	D2F-L3
	Self-clinching terminals	D2F-01FL3-T	D2F-01L3-T	D2F-FL3-T	D2F-L3-T
	Solder terminals	D2F-01FL3-D	D2F-01L3-D	D2F-FL3-D	D2F-L3-D
	Right angle terminals	D2F-01FL3-A	D2F-01L3-A	D2F-FL3-A	D2F-L3-A
Hinge roller lever 	PCB terminals	D2F-01FL2	D2F-01L2	D2F-FL2	D2F-L2
	Self-clinching terminals	D2F-01FL2-T	D2F-01L2-T	D2F-FL2-T	D2F-L2-T
	Solder terminals	D2F-01FL2-D	D2F-01L2-D	D2F-FL2-D	D2F-L2-D
	Right angle terminals	D2F-01FL2-A	D2F-01L2-A	D2F-FL2-A	D2F-L2-A

Specifications

■ Ratings

OF max.		Standard		Microvoltage/current load	
		150 g	75 g	150 g	75 g
Item		Resistive load			
Rated voltage	125 VAC	3 A	1 A	---	
	30 VDC	2 A	0.5 A	0.1 A	

Note: Consult your OMRON representative before using the switch with inductive or motor loads.

■ Approved Standards

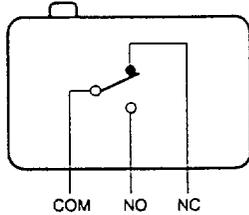
UL (File No. E32667)/CSA (LR21642)

D2F-01 series: 0.1 A at 30 VDC

D2F-F series: 1 A at 125 VAC, 0.5 A at 30 VDC (100,000 cycles)

D2F-□ series: 3 A at 125 VAC, 2 A at 30 VDC

Contact Form



■ Characteristics

Operating speed	1 to 500 mm/s (at pin plunger)
Operating frequency (at pin plunger)	Mechanical: 200 operations/min Electrical: 30 operations/min
Insulation resistance	100 MΩ min. (at 500 VDC)
Contact resistance	Standard: 30 mΩ max. (initial value) Microvoltage/current load: 100 mΩ max. (initial value)
Dielectric strength	600 VAC, 50/60 Hz for 1 min between contacts of the same polarity 1,500 VAC, 50/60 Hz for 1 min between current-carrying metal parts and ground, and between each terminal and non-current-carrying metal part
Vibration resistance	Malfunction: 10 to 55 Hz, 1.5-mm double amplitude
Shock resistance	Malfunction: 300 m/s ² (approx. 30G)
Life expectancy	Mechanical: 1,000,000 operations min. (OT value) Electrical: 30,000 operations min.
Ambient temperature	Operating: -25°C to 85° (with no icing)
Ambient humidity	Operating: 85% max.
Weight (at pin plunger)	Approx. 0.5 g

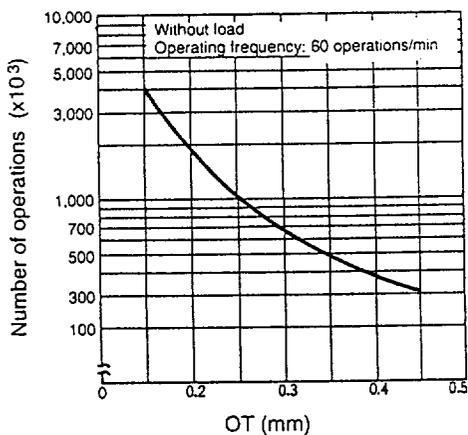
■ Operating Characteristics

Model	D2F□, D2F-01□	D2F-F□, D2F-01F□	D2F-L□, D2F-01L□	D2F-FL□, D2F-01FL□
OF max.	1.47 N (150 gf)	0.74 N (75 gf)	0.78 N (80 gf)	0.25 N (25 gf)
RF min.	0.20 N (20 gf)	0.05 N (5 gf)	0.05 N (5 gf)	0.02 N (2 gf)
PT max.	0.5 mm	0.5 mm	---	---
OT min.	0.25 mm	0.25 mm	0.55 mm	0.55 mm
MD max.	0.12 mm	0.12 mm	0.5 mm	0.5 mm
FP max.	---	---	10 mm	---
OP	5.5±0.3 mm	---	6.8±1.5 mm	---

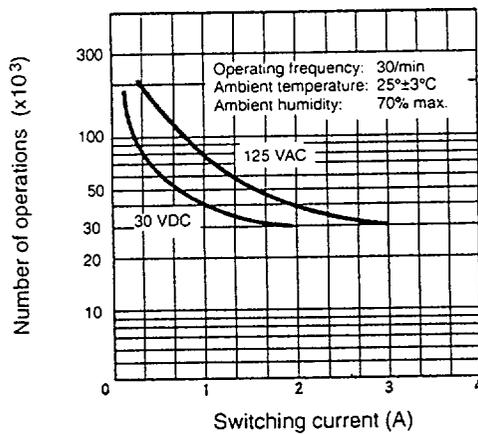
Model	D2F-L3□, D2F-01L3□	D2F-FL3□, D2F-01FL3□	D2F-L2□, D2F-01L2□	D2F-FL2□, D2F-01FL2□
OF max.	0.78 N (80 gf)	0.39 N (40 gf)	0.78 N (80 gf)	0.39 N (40 gf)
RF min.	0.05 N (5 gf)	0.02 N (2 gf)	0.05 N (5 gf)	0.02 N (2 gf)
OT min.	0.5 mm	0.5 mm	0.55 mm	0.55 mm
MD max.	0.45 mm	0.45 mm	0.5 mm	0.5 mm
FP max.	13 mm	---	16.5 mm	---
OP	8.5±1.2 mm	---	13±2 mm	---

Engineering Data

Mechanical Life Expectancy



Electrical Life Expectancy



Dimensions

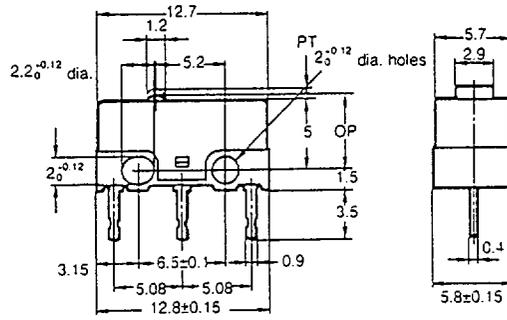
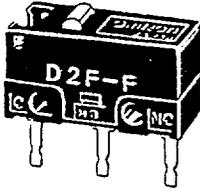
Note: *1. All units are in millimeters unless otherwise indicated.

2. Unless otherwise specified, a tolerance of ± 0.4 mm applies to all dimensions.

3. The following illustrations and drawings are for D2F models with PCB terminals. Self-standing, solder, and right angle terminals are omitted from the following drawings. Refer to page 118 for these terminals. When ordering, replace \square with the code for the terminal that you need.

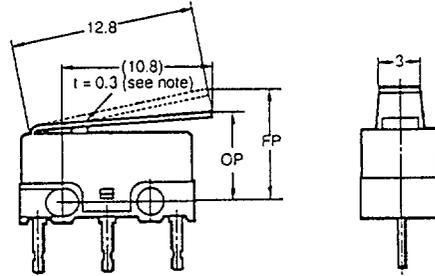
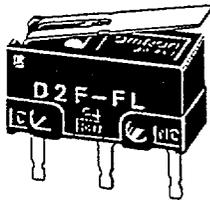
Pin Plunger

- D2F \square
- D2F-01 \square
- D2F-F \square
- D2F-01F \square



Hinge Lever

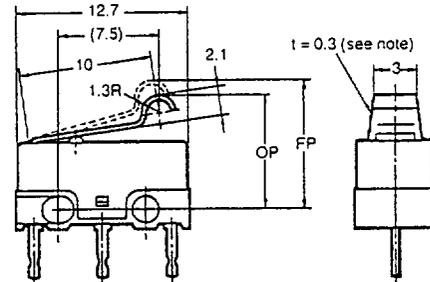
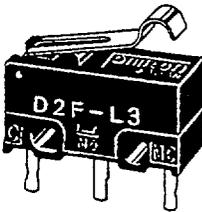
- D2F-L \square
- D2F-01L \square
- D2F-FL \square
- D2F-01FL \square



Note: Stainless steel lever

Simulate Hinge Lever

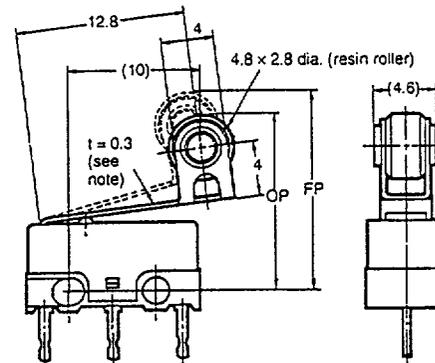
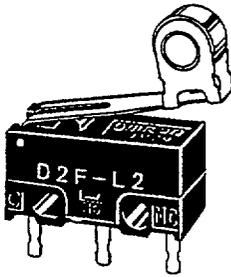
- D2F-L3 \square
- D2F-01L3 \square
- D2F-FL3 \square
- D2F-01FL3 \square



Note: Stainless steel lever

Hinge Roller Lever

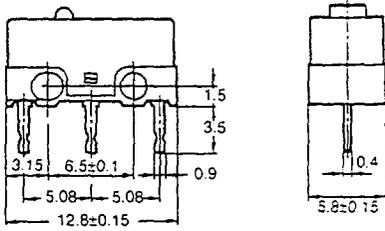
- D2F-L2 \square
- D2F-01L2 \square
- D2F-FL2 \square
- D2F-01FL2 \square



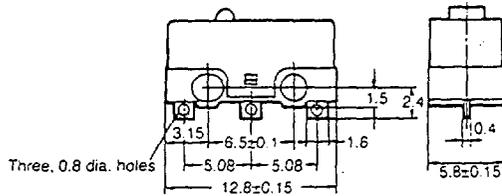
Note: Stainless steel lever

■ Terminals

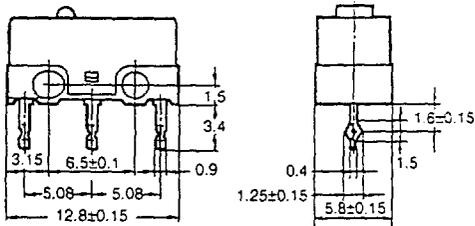
PCB Terminals
D2F



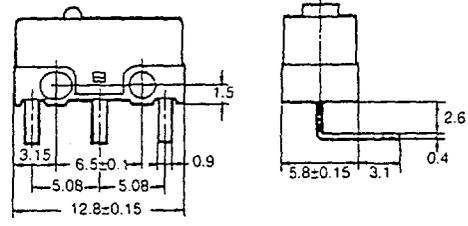
Solder Terminals
D2F-D



Self-clinching Terminals
D2F-T



Right Angle Terminals
D2F-A



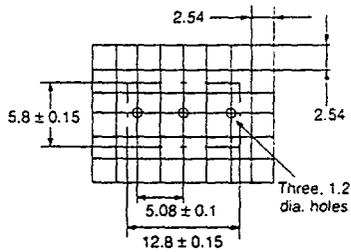
Precautions

Mounting

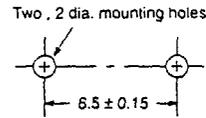
When mounting the switch to a PCB, refer to the following mounting dimensions. The gap between adjacent terminals is two pitches (2 x 2.54 cm).

Use M2 mounting screws with plain or spring washers to mount the switch. Tighten the screws to a torque of 0.08 to 0.1 N · m (0.8 to 1 kgf · cm).

Mounting Dimensions



Mounting Holes

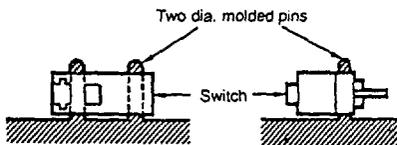


When soldering the relay terminals, use 6:4 solder and apply a soldering iron rated at 30 W and finish soldering within three seconds. After soldering, do not move the soldered terminals for at least one minute.

Make sure that each adjacent terminals of the switch are properly insulated from each other and the terminals and ground is properly insulated.

Use of molded fittings is recommended to secure the switch.

Mounting with Molded Pin



ALL DIMENSIONS SHOWN ARE IN MILLIMETERS.
To convert millimeters into inches, multiply by 0.03937. To convert grams into ounces, multiply by 0.03527.

Appendix H

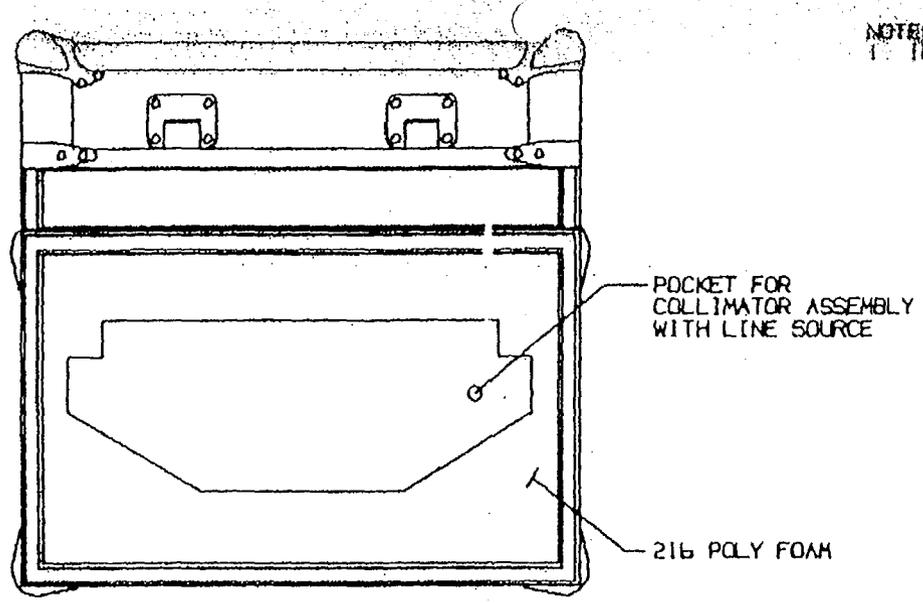
Source Packaging Information

Package Specimen Description

Container Model 75-7 is offered in two options. The package consists of two options. Option 1 is a rugged rectangular package of riveted assembly construction with Aluminum alloy valences and 3/8" domestic plywood laminated with 035 fiberglass and upholstered with any combination of high density polyester and polyurethane foam. The sides of the package are made of fiberglass reinforced 3/8" thick plywood. The sides are joined together using 1/32" thick x 1/4" x 1/4" Aluminum alloy valences that are riveted to the sides of the package. The package is equipped with lifting handles and a locking latch. Ball corners provide additional reinforcement and shock absorption in the corner areas. Option 2 is a fiberboard box containing the rugged rectangular package described in Option 1. The fiberboard box of Option 2 has cutouts to permit lifting via the handles on Option 1 (the internal box). The fiberboard box is secured by means of fiberglass reinforced tape. The tape is used to seal all seams. The tape shall extend lengthwise a minimum of 2 inches onto an adjacent side.

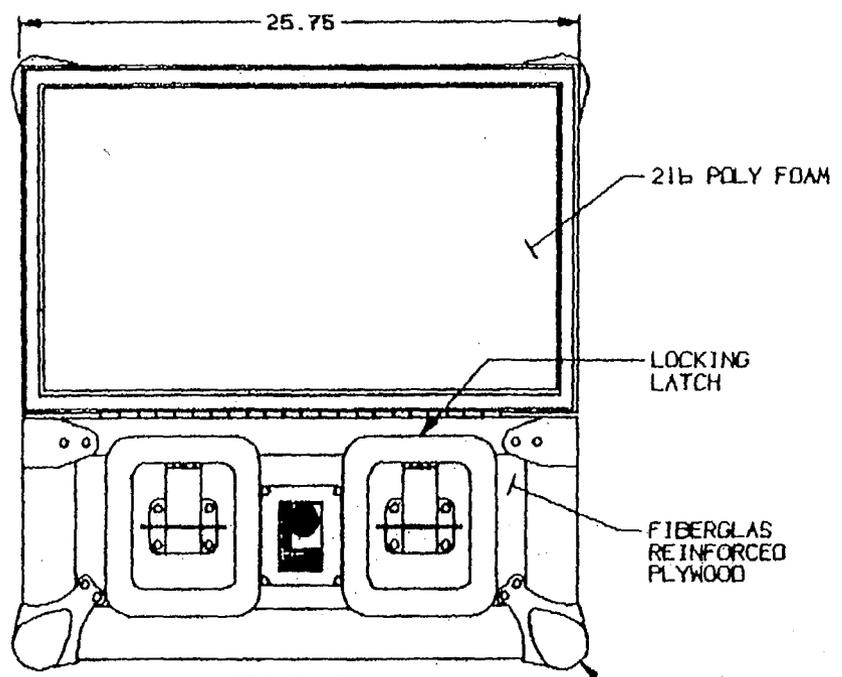
The package with the collimator device and line source weighs approximately 110 pounds. The outer dimensions are approximately 9" high x 26" wide by 10" deep.

NOTES:
 1. INDICATED DIMENSIONS ARE APPROXIMATE.

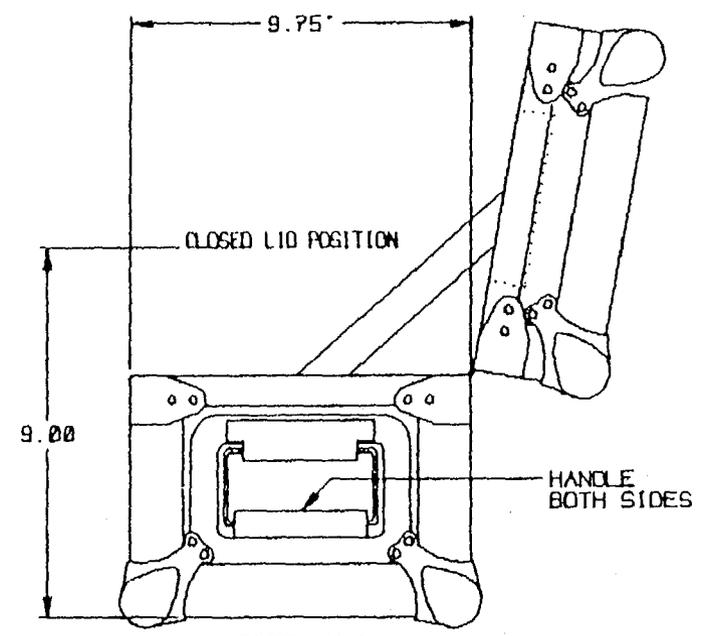


TOP VIEW

SHIPPING/STORAGE CASE



FRONT VIEW



SIDE VIEW

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DESIGN JMD/RLT	SCALE NONE	SIZE A	CAGE CODE 32993	REVISION 0	DRAWING NUMBER 75-7	SHEET 1 OF 1
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Appendix I

Quality Assurance Program

CoDe AC option

**Appendix I
Quality Assurance Program, Assembly
And QC Test Instructions**

Contents	Page
Quality Assurance Program	13-14
Assembly Instructions	15
QC Test Instructions	16

ELGEMS QUALITY PROCEDURES - OVERVIEW**Preface:**

ELGEMS is the GE division of research, development and production of nuclear medicine medical systems.

The ELGEMS products are sold and distributed to customers in the U.S. and others countries only by GE sales and marketing department.

ELGEMS products include GE's service and operation manuals with all the necessary instructions for use, inspection, installation and maintenance. These documents fully define the QA & QC program for this product.

The product installation and maintenance is done by GE field engineers according to the service and user manuals. These field engineers are technically trained by ELGEMS.

Procedures And Processes

Product processes and procedures are developed in accordance with FDA's Good Manufacturing Practices (GMP), ISO 9001 (quality system standard) and IEC 601-1 (quality system standard for medical devices). ELGEMS is ISO 9001 certified.

Design

Products are designed in accordance with Elgems Phase Review Discipline (PRD) , which is a product life cycle process. The PRD describes the steps and responsibilities required from initial product concept to end-of-product life. For product design and development, it describes design specifications, output, verifications, validation, transfer and changes. It also includes processes for regulatory compliance, safety, quality, marketing requirements and user instructions. New products and major modifications to existing products are developed in accordance with the PRD. Minor changes to products are completed via the Engineering Change Order (ECO) process.

Manufacturing

All products are manufactured and tested in accordance with FDA's Good Manufacturing Practices (GMP) , ISO 9001 (quality system standard) and IEC 601-1 (quality system standard for medical devices) . This includes :

- 1) Establishment of a Device Master Record including applicable drawings , list of parts and materials , assembly/test documents and shipping requirements.
- 2) Device History File containing assembly , test and inspection documentation per the Device Master Record for each device manufactured.
- 3) Defect tracking
- 4) Training of personnel.
- 5) Disposition of non-conforming material.
- 6) Handling , inspection and stocking of incoming and in-process parts, materials and devices.

Purchasing

Selection of suppliers (vendors) and purchasing of materials is conducted through the Sourcing Department per appropriate processes and procedures that comply with ISO 9001. Product , part and material specifications are defined by engineering.

User and Service Instructions

Operator and Service Manuals are written by Technical Publications staff, and reviewed by Engineering, Applications, Service and Legal Operations as appropriate. These manuals are developed per the PRD according to specific format guides, They contain the instructions required to safely and effectively use and service the device, including applicable safety warnings and regulatory statements.

Device Training

Training on the safe, effective use of the device is conducted by the Applications staff upon initial installation of the device and upon request of the user.

Service

Each device is supplied with a service manual that includes appropriate warnings for system and radiation safety. Product quality, safety or regulatory issues discovered during installation and servicing are forwarded to ELGEMS by our customers complaint handling systems. (Service records are maintained on all service visits by our customers GE and Elscint)

Complaints

Product quality, safety or regulatory complaints are forwarded to the ELGEMS complaint handling process where the issues are reviewed, investigated and resolved (as appropriate) per documented processes and procedures, in accordance with FDA requirements.

Product Changes

All changes to existing product are routed through the Engineering Change Order (ECO) process and approved by appropriate staff. Matters regarding safety and regulatory are reviewed and approved by members of the ECO committee. Validation is required prior to issuance of a change. The ECO process updates the Device Maser Record as appropriate.

Quality Systems Audits

The quality system of ELGEMS is audited periodically both internally and externally. Results of audits and resolution are documented and archived. These audits include (not an all-inclusive) review of processes, procedures and documentation for :

- 1) Design (including safety and regulatory requirements)
- 2) Manufacturing.
- 3) Sourcing
- 4) Material acceptance.
- 5) Complaint handling.
- 6) Product changes.
- 7) Non-conforming materials/devices.
- 8) Quality policy, quality manual, management reviews.
- 9) Personnel training (including radiation safety, as appropriate for the business)

Assembly Instructions

The assembly instruction of the CoDe AC option in the site are described in Chap. 3 of the service manual, page 3-1 to 3-9.

In this section we describe the assembly instruction of the CoDe AC Tungsten holder and the source. **The assembly is done by the subcontractor IPL.**

Assembly of the different parts of the CoDe AC Tungsten holder and source (figure 1)

See figure 1 page 7 and the list of part in figure 1.

The Source made of 4 parts:

- 1) Rod with 18 equally spaced point sources (part 8).
- 2) Tungsten shield + Lead Flange (part 2 and 3) and Collimator (part 1)
- 3) Screw End (part 5).
- 4) Handle End (part 4).

All are mounted together and supplied from the isotope producer IPL.

The Collimator (part 1) is placed on a table when the slot side is on the table face.

The Piston (part 6) and Cork (part 7) together with the Spring (part 9) are placed in the Source Handle End.

The Source (part 8) is placed on the Collimator (part 1), and the Tungsten Shield (part 1) + Lead Flange (part 3) are assembled together and placed on top.

Mounting screws (M6x3) (part 16) are placed through the Tungsten Shield and the Lead Flange (part 1 and part 3), into the Collimator. The Mounting screws hold the parts together, 2 of the side screws are passing through the Lead Flange.

Spring (part 10) is placed on the Source Screw End. Handle End Flange (part 4) and Screw End Flange (part 5) are being mounted on the Collimator by four M5 screws (part 15), and two Dowel-Pins (part 12)

Dowel-Pin (part 11) is pressed into the hole in the Piston through the Handle End Flange.

Dowel-Pin (part 13) is pressed into the hole in the Piston through the Screw End Flange.

The Micro Switch (part 17) is mounted with two screws (part 14).

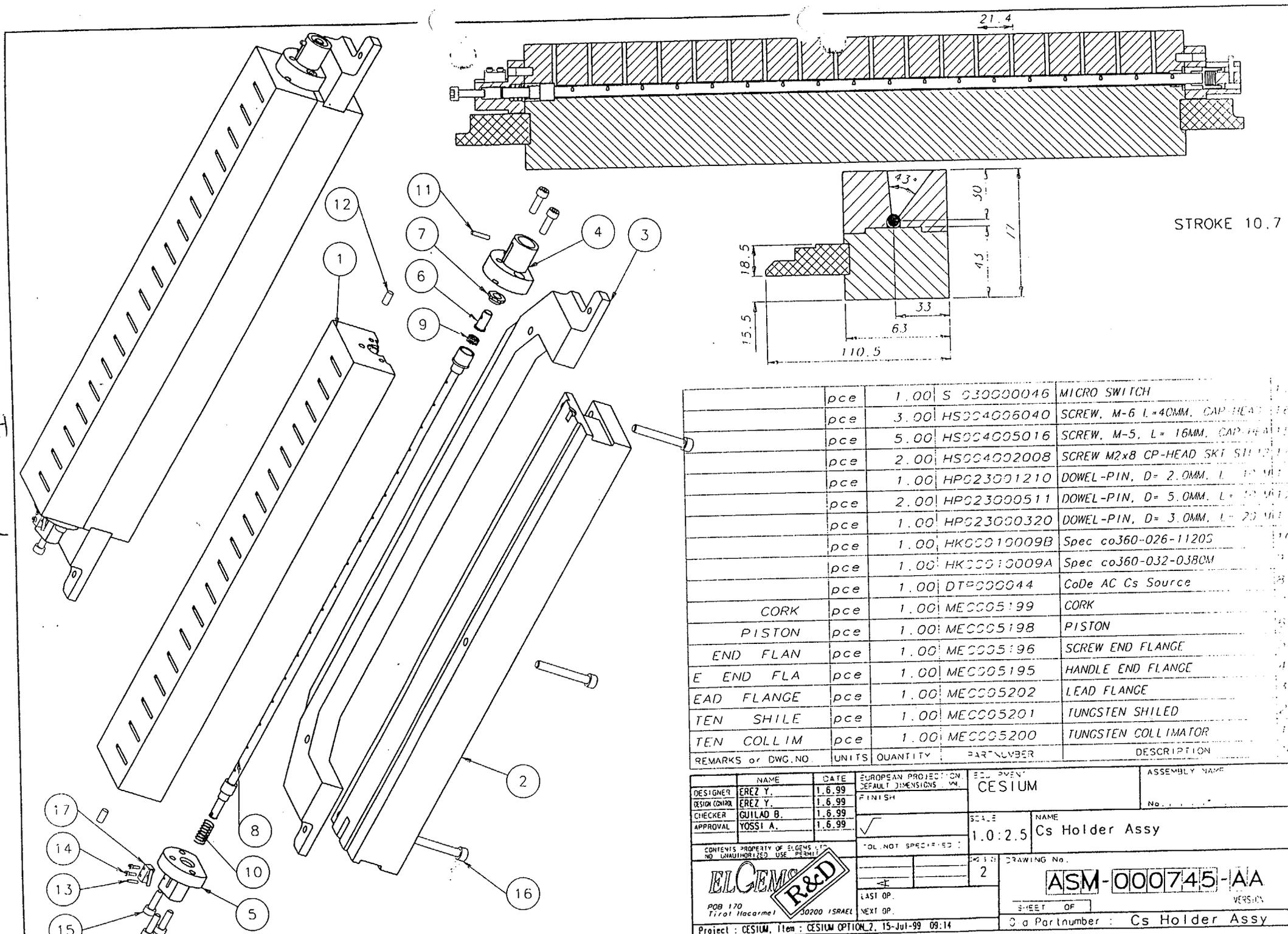
QC Test Instructions

The QC Test instruction for the CoDe AC option in the site are described in Chap. 3, page 3-10, and Chap. 5 page 5-1 to 5-3 of the Service Manual.

The QC Test instruction for the CoDe AC Device (Figure 1) by the source sub-contractor IPL are the following:

- After mounting the different parts respectively to the above description, test the motion of the line of point source in the Tungsten source housing.
- Test the radiation dose around the option. The radiation dose should be lower then 5 ± 0.5 mRem/h at 5 cm, in any direction around the device, when the source is in close position.

Figure 1



REMARKS or DWG. NO	UNITS	QUANTITY	PART NUMBER	DESCRIPTION
	pce	1.00	S 030000046	MICRO SWITCH
	pce	3.00	HS004006040	SCREW, M-6 L=40MM, CAP HEAD
	pce	5.00	HS004005016	SCREW, M-5, L= 16MM, CAP HEAD
	pce	2.00	HS004002008	SCREW M2x8 CP-HEAD SKT SH
	pce	1.00	HP023001210	DOWEL-PIN, D= 2.0MM, L= 10
	pce	2.00	HP023000511	DOWEL-PIN, D= 5.0MM, L= 10
	pce	1.00	HP023000320	DOWEL-PIN, D= 3.0MM, L= 20
	pce	1.00	HK00010009B	Spec co360-026-1120S
	pce	1.00	HK00010009A	Spec co360-032-0380M
	pce	1.00	DT0000044	CoDe AC Cs Source
	CORK	pce	MECC05199	CORK
	PISTON	pce	MECC05198	PISTON
	END FLAN	pce	MECC05196	SCREW END FLANGE
	E END FLA	pce	MECC05195	HANDLE END FLANGE
	EAD FLANGE	pce	MECC05202	LEAD FLANGE
	TEN SHILE	pce	MECC05201	TUNGSTEN SHILED
	TEN COLLIM	pce	MECC05200	TUNGSTEN COLLIMATOR

DESIGNER	EREZ Y.	DATE	1.6.99	EUROPEAN PROJECTION	DEFINITION	ASSEMBLY NAME	CESIUM
DESIGN CONTROL	EREZ Y.	DATE	1.6.99	FINISH		No.	
CHECKER	GUILAD B.	DATE	1.6.99	TOLERANCES		SCALE	1.0:2.5
APPROVAL	YOSSI A.	DATE	1.6.99	TOLERANCES		NAME	Cs Holder Assy
CONTENTS PROPERTY OF ELGEM LTD. NO UNAUTHORIZED USE PERMITTED				TOL. NOT SPECIFIED :		DRAWING No.	
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ELGEMS

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Specification for

**Application of EN ISO 9001 to
the manufacture of medical
devices**

The European Standard EN 46001 : 1996 has the status of a British Standard

ICS 03.120.10; 11.040.01

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/66, Quality systems for the manufacture of medical devices, upon which the following bodies were represented:

- Association of British Certification Bodies
- Association of British Health-care Industries
- Association of Consultants to the Bioscience Industries (ACBI)
- Association of Contact Lens Manufacturers
- Association of X-ray Equipment Manufacturers (BEAMA Ltd.)
- BLWA Ltd. – The Association of the Laboratory Supply Industry
- British Anaesthetic and Respiratory Equipment Manufacturers' Association
- British Dental Trade Association
- British In Vitro Diagnostics Association
- British Orthopaedic Association
- British Surgical Trades Association
- Dental Laboratories Association Limited
- Department of Health
- Electro Medical Trade Association Limited
- Guild of Hospital Pharmacists
- Institute of Quality Assurance
- Institution of Physics and Engineering in Medicine and Biology
- Medical Sterile Products Association
- Surgical Dressings Manufacturers' Association

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 February 1997

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First published January 1994
Second edition February 1997

The following BSI references relate to the work on this standard:
Committee reference CH/66
Draft for comment 90/56565 DC

ISBN 0 580 27045 9

Amendments issued since publication

Amd. No.	Date	Text affected

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S

National foreword

This British Standard has been prepared by Technical Committee CH/66 and is the English language version of EN 46001 : 1996 *Quality systems — Medical devices — Particular requirements for the application of EN ISO 9001*, published by the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC). It supersedes BS EN 46001 : 1994 which is withdrawn. BS EN 46001 supplements the requirements of EN ISO 9001 which, itself, has been implemented as BS EN ISO 9001.

Cross-references

Publication referred to	Corresponding British Standard
EN ISO 8402 : 1995	BS EN ISO 8402 : 1995 <i>Quality management and quality assurance. Vocabulary</i>
EN ISO 9001 : 1994	BS EN ISO 9001 : 1994 <i>Quality systems. Model for quality assurance in design, development, production, installation and servicing</i>

Compliance with a British Standard does not of itself confer immunity from legal obligations.

EUROPEAN STANDARD

EN 46001

NORME EUROPÉENNE

EUROPÄISCHE NORM

August 1996

ICS 03.120.10; 11.040.00

Supersedes EN 46001 : 1996

Descriptors: medical device, quality, quality system, quality audit, production, installation, detail, specification

English version

Quality systems — Medical devices — Particular requirements for the application of EN ISO 9001

Systèmes qualité — Dispositifs médicaux —
Exigences particulières relatives à l'application de
l'EN ISO 9001

Qualitätssicherungssysteme — Medizinprodukte —
Besondere Anforderungen für die Anwendung von
EN ISO 9001

This European Standard was approved by CEN/CENELEC on 1995-10-24. CEN/CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN/CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN/CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN/CENELEC members are the national standards bodies and national electrotechnical committees, respectively, of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN/CENELEC

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

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Ref. No. EN 46001 : 1996

Foreword

This European Standard has been prepared by the Joint CEN/CENELEC Coordinating Working Group on Quality Supplements with the cooperation of CEN/TC 205, 'Non-active medical devices', CENELEC/TC 62, 'Electrical equipment in medical practice', CEN/TC 140, 'In vitro diagnostic systems', and the Joint CEN/CENELEC Working Group on active implantable medical devices.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 1997, and conflicting national standards shall be withdrawn at the latest by February 1997.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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0 Introduction

EN ISO 9001 is intended to be a general standard defining quality system requirements. EN 46001 provides particular requirements for suppliers of medical devices that are more specific than the general requirements specified in EN ISO 9001.

In conjunction with EN ISO 9001, this European Standard defines requirements for quality systems relating to the design/development, production, installation and servicing of medical devices. It embraces all the principles of good manufacturing practice (GMP) widely used in the manufacture of medical devices. It can only be used in combination with EN ISO 9001 and is not a 'stand alone' standard.

There is a wide variety of medical devices and some of the particular requirements of this standard only apply to named groups of medical devices. These groups are described in clause 3, Definitions.

Particular requirements in a number of clauses of this standard are covered in detail in other European Standards. Suppliers should review the requirements and consider using national standards implementing harmonized European Standards in these areas.

To assist in the understanding of the requirements of EN ISO 9001 and EN 46001, a series of guidance standards are being prepared for various groups of medical devices (see annex A).

1 Scope

This European Standard specifies, in conjunction with EN ISO 9001, the quality system requirements for the design/development, production, and where relevant, installation and servicing of medical devices.

The field of application of EN ISO 9001 applies. In addition, this European Standard, in conjunction with EN ISO 9001, is applicable when a medical device supplier's quality system is assessed in accordance with regulatory requirements.

As part of an assessment by a third party for the purpose of regulatory requirements, the supplier may be required to provide access to confidential data in order to demonstrate compliance with this standard. The supplier may be required to exhibit these data but is not obliged to provide copies for retention.

2 Normative references

This European Standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN ISO 8402 : 1995	<i>Quality management and quality assurance – Vocabulary</i> (ISO 8402 : 1994)
EN ISO 9001 : 1994	<i>Quality systems – Model for quality assurance in design, development, production, installation and servicing</i> (ISO 9001 : 1994)

3 Definitions

For the purposes of this standard, the following definitions apply.

NOTE. Definitions 3.2 and 3.3 are taken from the Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC). Definitions 3.1 and 3.5 are taken from the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

3.1 medical device

Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception;

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

3.2 active medical device

Any medical device (see 3.1) relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.

3.3 active implantable medical device

Any active medical device (see 3.1 and 3.2) which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

3.4 implantable medical device

Any medical device (see 3.1) intended:

– to be totally or partially introduced into the human body or a natural orifice; or

– to replace an epithelial surface or the surface of the eye;

by surgical intervention, which is intended to remain after the procedure for at least 30 days and which can only be removed by medical or surgical intervention.

NOTE. This definition applies to implantable medical devices other than active implantable medical devices.

3.5 in vitro diagnostic device

Any device which is a reagent, reagent product, kit, instrument, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of samples derived from the human body with a view to providing information on the physiological state, state of health or disease, or congenital abnormality thereof.

3.6 non-active medical device

Any medical device (see 3.1) which is neither an active medical device (see 3.2) nor an in vitro diagnostic device (see 3.5).

sterile medical device

Any medical device labelled 'STERILE'.

NOTE. Requirements for labelling a medical device 'STERILE' appear in European Standards.

3.8 supplier

The organization that provides a product (see 3.11) to the customer [EN ISO 8402 : 1995].

NOTE 1. In a contractual situation, the supplier may be called the contractor.

NOTE 2. The supplier may be, for example, the producer, distributor, importer, assembler or service organization.

NOTE 3. The supplier can be either external or internal to the organization.

3.9 verification

Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled [EN ISO 8402 : 1995].

NOTE 1. In design and development, verification concerns the process of examining the result of a given activity to determine conformity with the stated requirement for that activity.

NOTE 2. The term 'verified' is used to designate the corresponding status.

3.10 label

All written, printed or graphic matter:

a) on a medical device or any of its containers or wrappers; or

b) accompanying a medical device;

relating to identification, technical description and use of the medical device but excluding shipping documents.

3.11 product

Result of activities or processes [EN ISO 8402 : 1995].

NOTE 1. A product may include service, hardware, processed materials, software, or a combination thereof.

NOTE 2. A product can be tangible (e.g. assemblies or processed materials) or intangible (e.g. knowledge or concepts), or a combination thereof.

NOTE 3. A product can be either intended (e.g. offering to customers) or unintended (e.g. pollutant or unwanted effects).

3.12 refurbishing

The processing or reprocessing to specified requirements of a medical device, which has been previously released.

NOTE. Refurbishing applies also to repacking and/or reesterilization of medical devices intended to be sterile medical devices, for example when a container that maintains sterility has been opened or damaged.

3.13 customer complaint

Any reported allegation, written or verbal, from a customer of deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device (see 3.1).

3.14 advisory notice

A notice issued to provide information and/or advice on what action should be taken in the use, modification, disposal or return of a medical device (see 3.1 and 3.15).

3.15 recall

When there is a risk of death or serious deterioration to the state of health:

- the return of a medical device to the supplier;
- its modification by the supplier at the site of installation;
- its exchange; or
- its destruction;

in accordance with the instructions contained in an advisory notice (see 3.14).

3.16 labelling

The process of combining labels (see 3.10) with medical devices.

4 Quality system requirements

4.1 Management responsibility

4.1 of EN ISO 9001 : 1994 applies.

4.2 Quality system

4.2.1 General

4.2.1 of EN ISO 9001 : 1994 applies.

Particular requirements for all medical devices:

The supplier shall establish and document the specified requirements.

NOTE. If this European Standard is used for compliance with regulatory requirements, the relevant requirements of the regulations should be included in the specified requirements.

4.2.2 Quality system procedures

4.2.2 of EN ISO 9001 : 1994 applies.

Particular requirements for all medical devices:

The supplier shall establish and maintain a file containing documents defining the product specifications, including complete manufacturing and quality assurance specifications for each type/model of medical device, or referring to the location of this information (see also 4.5.2 and 4.16).

4.2.3 Quality planning

4.2.3 of EN ISO 9001 : 1994 applies.

4.3 Contract review

4.3 of EN ISO 9001 : 1994 applies.

4.4 Design control

4.4.1 General

4.4.1 of EN ISO 9001 : 1994 applies.

4.4.2 Design and development planning

4.4.2 of EN ISO 9001 : 1994 applies.

4.4.3 Organizational and technical interfaces

4.4.3 of EN ISO 9001 : 1994 applies.

4.4.4 Design input

4.4.4 of EN ISO 9001 : 1994 applies

Particular requirement for all medical devices:

The supplier shall identify requirements that are related to the safety of the medical device and shall include such requirements as design input data.

4.4.5 Design output

4.4.5 of EN ISO 9001 : 1994 applies.

4.4.6 Design review

4.4.6 of EN ISO 9001 : 1994 applies

4.4.7 Design verification

4.4.7 of EN ISO 9001 : 1994 applies.

Particular requirement for all medical device

The supplier shall document and maintain records (see 4.16) of all design verification activities including those where clinical investigation was involved.

4.4.8 Design validation

4.4.8 of EN ISO 9001 : 1994 applies.

4.4.9 Design changes

4.4.9 of EN ISO 9001 : 1994 applies.

4.5 Document and data control

4.5.1 General

4.5.1 of EN ISO 9001 : 1994 applies.

4.5.2 Document and data approval and issue

4.5.2 of EN ISO 9001 : 1994 applies.

Particular requirement for all medical device:

The supplier shall define the period for which at least one copy of obsolete documents shall be retained. The period shall ensure that specifications to which medical devices have been manufactured are available for at least the lifetime of the medical device as defined by the supplier (see 4.16).

4.5.3 Document and data changes

4.5.3 of EN ISO 9001 : 1994 applies.

4.6 Purchasing

4.6.1 General

4.6.1 of EN ISO 9001 : 1994 applies.

4.6.2 Evaluation of sub-contractors

4.6.2 of EN ISO 9001 : 1994 applies.

4.6.3 Purchasing data

4.6.3 of EN ISO 9001 : 1994 applies.

Particular requirement for all medical device

To the extent required by the particular requirement for traceability in 4.8, the supplier shall retain copies (see 4.16) of relevant purchasing documents.

4.6.4 Verification of purchased product

4.6.4 of EN ISO 9001 : 1994 applies.

4.7 Control of customer-supplied product

4.7 of EN ISO 9001 : 1994 applies.

4.8 Product identification and traceability

4.8 of EN ISO 9001 : 1994 applies.

a) Identification:**Particular requirement for all medical devices:**

The supplier shall establish and maintain procedures to ensure that medical devices received for refurbishing are identified and distinguished at all times from normal production.

b) Traceability**Particular requirement for all medical devices:**

The supplier shall establish, document and maintain procedures for traceability. The procedures shall define the extent of traceability and facilitate corrective action (see 4.14.2).

Additional requirements for active implantable medical devices and implantable medical devices:

The extent of traceability shall include all components and materials used, and records of the environmental conditions (see 4.9Bd)), when these could cause the medical device not to satisfy its specified requirements.

4.9 Process control

4.9 of EN ISO 9001 : 1994 applies.

Particular requirement for all medical devices:**A) Personnel**

The supplier shall establish, document and maintain requirements for health, cleanliness and clothing of personnel if contact between such personnel and product or environment could adversely affect the quality of product.

Environmental control in manufacture of medical devices:

- a) that are supplied sterile; or
- b) that are supplied non-sterile and intended for sterilization before use; or
- c) where the microbiological and/or particulate cleanliness or other environmental conditions are of significance in their use; or
- d) where the environmental conditions are of significance in their manufacture;

the supplier shall establish and document requirements for the environment to which product is exposed.

If appropriate, the environmental conditions shall be controlled and/or monitored.

C) Cleanliness of product

The supplier shall establish, document and maintain requirements for cleanliness of product if:

- a) product is cleaned by the supplier prior to sterilization and/or its use; or
- b) product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and/or its use; or

c) product is supplied to be used non-sterile and its cleanliness is of significance in use; or

d) process agents are to be removed from product during manufacture.

If appropriate, product cleaned in accordance with a) or b) above need not be subject to the preceding particular requirements, i.e. A) Personnel and B) Environmental control in manufacture, prior to the cleaning procedure.

D) Maintenance

The supplier shall establish and document requirements for maintenance activities when such activities may affect product quality.

Records of such maintenance shall be kept (see 4.16).

E) Installation

If appropriate, the supplier shall establish and document both instructions and acceptance criteria for installing and checking the medical device.

Records of installation and checking performed by the supplier or his authorized representative shall be retained (see 4.16).

If the contract (see 4.3) allows installation other than by the supplier or his authorized representative, the supplier shall provide the purchaser with written instructions for installation and checking.

F) Special processes

The supplier shall ensure that the quality records of special processes (see 4.16 and note in 4.9 of EN ISO 9001 : 1994) identify:

- a) the work instruction used;
- b) the date the special process was performed;
- c) the identity of the operator of the special process.

Additional requirement for sterile medical devices:

The supplier shall subject the medical devices to a validated sterilization process and record (see 4.16) all the control parameters of the sterilization process.

4.10 Inspection and testing**4.10.1 General**

4.10.1 of EN ISO 9001 : 1994 applies.

4.10.2 Receiving inspection and testing

4.10.2 of EN ISO 9001 : 1994 applies.

4.10.3 In-process inspection and testing

4.10.3 of EN ISO 9001 : 1994 applies.

4.10.4 Final inspection and testing

4.10.4 of EN ISO 9001 : 1994 applies.

4.10.5 Inspection and test records

4.10.5 of EN ISO 9001 : 1994 applies.

Particular requirement for active implantable medical devices and implantable medical devices:

The supplier shall record (see 4.16) the identity of personnel performing any inspection or testing.

4.11 Control of inspection, measuring and test equipment

4.11 of EN ISO 9001 : 1994 applies.

4.12 Inspection and test status

4.12 of EN ISO 9001 : 1994 applies.

4.13 Control of nonconforming product

4.13.1 General

4.13.1 of EN ISO 9001 : 1994 applies.

4.13.2 Review and disposition of nonconforming product

4.13.2 of EN ISO 9001 : 1994 applies.

Particular requirements for all medical devices:

The supplier shall ensure that nonconforming product is accepted by concession only if regulatory requirements are met. The identity of the person authorizing the concession shall be recorded (see 4.16).

If product needs to be reworked, the supplier shall document the rework in a work instruction that has undergone the same authorization and approval procedure as the original work instruction.

4.14 Corrective and preventive action

4.14.1 General

4.14.1 of EN ISO 9001 : 1994 applies.

4.14.2 Corrective action

4.14.2 of EN ISO 9001 : 1994 applies.

Particular requirements for all medical devices:

The supplier shall establish and maintain a documented feedback system to provide early warning of quality problems and for input into the corrective action system.

If this European Standard is used for compliance with regulatory requirements which require post marketing surveillance, this surveillance shall form part of the feedback system.

All feedback information, including reported customer complaints and returned product, shall be documented, investigated, interpreted, collated and communicated in accordance with defined procedures by a designated person.

If any customer complaint is not followed by corrective action, the reason shall be recorded.

The supplier shall maintain records (see 4.16) of all complaint investigations. When the investigation determines that the activities at remote premises played a part in the complaint, a copy of the report shall be sent to those premises.

If this European Standard is used for compliance with regulatory requirements, the supplier shall establish, document and maintain procedures to notify the regulatory authority of those incidents which meet the reporting criteria.

The supplier shall establish, document and maintain procedures for the issue of advisory notices and the recall of medical devices. These procedures shall be capable of being implemented at any time.

4.14.3 Preventive action

4.14.3 of EN ISO 9001 : 1994 applies.

4.15 Handling, storage, packaging, preservation and delivery

4.15.1 General

4.15.1 of EN ISO 9001 : 1994 applies.

Particular requirements for all medical devices:

The supplier shall establish and maintain documented procedures for the control of product with a limited shelf life or requiring special storage conditions. Such special storage conditions shall be controlled and recorded.

If appropriate, special provisions shall be made for the handling of used product in order to prevent contamination of other product, the manufacturing environment or personnel.

4.15.2 Handling

4.15.2 of EN ISO 9001 : 1994 applies.

4.15.3 Storage

4.15.3 of EN ISO 9001 : 1994 applies.

4.15.4 Packaging

4.15.4 of EN ISO 9001 : 1994 applies.

Particular requirements for sterile medical devices:

The supplier shall establish and maintain procedures to ensure that:

a) the medical device is presented in a container which maintains the sterility of the medical device except for those medical devices for which only the inner surfaces of the medical device are sterile at the time the medical device is such that the sterility of the inner surfaces is maintained;

b) the medical device is capable of being presented in an aseptic manner, if its use so requires;

c) the package, or medical device if only the inner surface is sterile, clearly reveals that it has been opened.

Additional requirements for active implantable medical devices and implantable medical devices:

The supplier shall record the identity of persons who perform the final labelling operation (see 4.16).

4.15.5 Preservation

4.15.5 of EN ISO 9001 : 1994 applies.

4.15.6 Delivery

4.15.6 of EN ISO 9001 : 1994 applies.

Particular requirements for active implantable medical devices and implantable medical devices:

The supplier shall ensure that the name and address of the shipping package consignee is included in the quality records (see 4.16).

The supplier shall require that any authorized representative maintains records of distribution of medical devices and that such records are available for inspection.

4.16 Control of quality records

4.16 of EN ISO 9001 : 1994 applies.

Particular requirements for all medical devices:

The supplier shall retain the quality records for a period of time at least equivalent to the lifetime of the medical device defined by the supplier, but not less than two years from the date of dispatch from the supplier.

The supplier shall establish and maintain a record for each batch of medical devices that provides traceability to the extent required by 4.8 and identifies the quantity manufactured and quantity released for distribution. The batch record shall be verified and authorized.

NOTE. A batch may be a single medical device.

4.17 Internal quality audits

4.17 of EN ISO 9001 : 1994 applies.

4.18 Training

4.18 of EN ISO 9001 : 1994 applies.

Particular requirement for all medical devices:

The supplier shall ensure that all personnel who are required to work under special environmental conditions or who perform special processes (see 4.9) or functions are appropriately trained or supervised by a trained person.

4.19 Servicing

4.19 of EN ISO 9001 : 1994 applies.

4.20 Statistical techniques

4.20.1 Identification of need

4.20.1 of EN ISO 9001 : 1994 applies.

Particular requirement for all medical devices:

The supplier shall establish and maintain procedures to ensure that sampling methods are regularly reviewed in the light of the occurrence of nonconforming product, quality audit reports, feedback information (see 4.14) and other appropriate considerations.

4.20.2 Procedures

4.20.2 of EN ISO 9001 : 1994 applies.

Annex A (informative)

Bibliography

- EN 724 *Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices*
- EN 928 *In vitro diagnostic systems - Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for in vitro diagnostic medical devices*
- EN 50103 *Guidance on the application of ISO 9001 and EN 46001 and ISO 9002 and EN 46002 for the active (including active implantable) medical device industry*

Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices.

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Final draft Guidelines on a medical devices vigilance system, May 1993.

List of references

See national foreword.

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Medical electrical equipment

Part 1: General requirements for safety

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The dimension of the board shall be at least 1.5 times that of the EQUIPMENT and it shall lie flat on a rigid (concrete) base. The EQUIPMENT is dropped three times from each attitude in which it may be placed in NORMAL USE.

TABLE VIII

Drop height

Mass of EQUIPMENT (kg)	Drop height (cm)
Up to and including 10	5
More than 10 up to and including 50	3
More than 50	2

After the test EQUIPMENT shall comply with the requirements of this Standard.

***22. Moving parts**

22.1 Not used.

22.2 Moving parts which do not need to be exposed for the operation of EQUIPMENT and which, if exposed, constitute a SAFETY HAZARD shall:

- a) in the case of TRANSPORTABLE EQUIPMENT, be provided with adequate guards which shall form an integral part of the EQUIPMENT, or
- b) in the case of STATIONARY EQUIPMENT, be similarly guarded unless installation instructions provided by the manufacturer in the technical description require that such guarding or equivalent protection will be separately provided.

Compliance is checked by inspection of the accessibility of moving parts and the adequacy of possible protective measures, either forming an integral part of EQUIPMENT or being provided during installation of STATIONARY EQUIPMENT (see installation instructions).

22.3 Cords (ropes), chains and bands shall either be confined so that they cannot run off or jump out of their guiding devices, or a SAFETY HAZARD shall be prevented by other means. Mechanical means applied for this purpose shall be removable only with the aid of a TOOL.

Compliance is checked by inspection.

22.4 Movements of EQUIPMENT or EQUIPMENT parts which may cause physical injury to the PATIENT shall be possible only by the continuous activation of the control by the OPERATOR of these EQUIPMENT parts.

Compliance is checked by inspection.

22.5 Not used.

22.6 Parts subject to mechanical wear likely to result in a SAFETY HAZARD shall be accessible for inspection.

Compliance is checked by inspection.

22.7 — If an electrically produced mechanical movement could cause a SAFETY HAZARD, readily identifiable and accessible means shall be provided for emergency switching of the relevant part of EQUIPMENT.

Such means shall only be recognized as a SAFETY DEVICE if the emergency situation becomes obvious to the OPERATOR and his reaction time is taken into account.

- Operation of an emergency switching or stopping means shall not introduce a further SAFETY HAZARD nor interfere with the complete operation necessary to remove the original SAFETY HAZARD.
 - Devices for emergency stopping shall be able to break the full load current of the relevant circuit, taking into account possible stalled motor currents and the like.
 - Means for stopping of movements shall operate as a result of one single action.
- Compliance is checked by inspection.*

23. Surfaces, corners and edges

Rough surfaces, sharp corners and edges which may cause injury or damage shall be avoided or covered.

In particular, attention shall be paid to flange or frame edges and the removal of burrs.

Compliance is checked by inspection.

24. Stability in NORMAL USE

24.1 EQUIPMENT shall either not overbalance during NORMAL USE when tilted through an angle of 10°, or shall satisfy the requirements of Sub-clause 24.3.

24.2 Not used.

24.3 If EQUIPMENT overbalances when tilted through an angle of 10°, all the following requirements shall be met:

- EQUIPMENT shall not overbalance when tilted through an angle of 5° in any position of NORMAL USE, excluding transport.
- EQUIPMENT shall carry a warning notice stating that transport should only be undertaken in a certain position which shall be clearly described in the instructions for use or illustrated on the EQUIPMENT.
- In the position specified for transport, EQUIPMENT shall not overbalance when tilted to an angle of 10°.

Compliance is checked by application of the following tests, during which EQUIPMENT shall not overbalance.

a) EQUIPMENT is provided with all specified connection leads: the POWER SUPPLY CORD and any interconnecting cords. It is provided with the least favourable combination of possible detachable parts and ACCESSORIES.

EQUIPMENT having an APPLIANCE INLET is provided with the specified DETACHABLE POWER SUPPLY CORD.

The connection leads shall be laid down on the inclined plane (see tests b) and c)) in the position most unfavourable for stability.

b) If no special transport position with increased stability is specified, EQUIPMENT is placed in any possible position of NORMAL USE on a plane inclined at an angle of 10° to the horizontal plane.

If castors are present, they shall be temporarily fixed in their most disadvantageous position.

Doors and drawers and the like shall be placed in the most disadvantageous position.

28. Suspended masses

28.1 General

The following requirements concern EQUIPMENT parts suspending masses (including PATIENTS), where a mechanical defect of the means of suspension could constitute a SAFETY HAZARD.

Any moving part shall also comply with the requirements of Clause 22.

28.2 Not used.

28.3 Suspension system with SAFETY DEVICES

- Where the integrity of a suspension depends on parts, such as springs, which may, due to their manufacturing process, have hidden defects, or on parts having SAFETY FACTORS not complying with Sub-clause 28.4, a SAFETY DEVICE shall be provided, unless excess travel in the event of breakdown is limited.
- The SAFETY DEVICE shall have SAFETY FACTORS complying with Sub-clause 28.4.2.
- If EQUIPMENT can still be used after failure of suspension means and activation of a SAFETY DEVICE (for example a secondary rope), it shall become obvious to the OPERATOR that the SAFETY DEVICE has been activated.

28.4 Suspension systems of metal without SAFETY DEVICES

If a SAFETY DEVICE is not provided, the construction of the suspension shall comply with the following requirements:

- 1) The TOTAL LOAD shall not exceed the SAFE WORKING LOAD.
- 2) Where it is unlikely that supporting characteristics will be impaired by wear, corrosion, material fatigue or ageing, the SAFETY FACTOR of all supporting parts shall not be less than 4.
- 3) Where impairment by wear, corrosion, material fatigue or ageing is expected, relevant supporting parts shall have a SAFETY FACTOR not less than 8.
- 4) Where metal having a specific elongation at break of less than 5% is used in supporting components, the SAFETY FACTORS, as given in 2) and 3) above shall be multiplied by 1.5.
- 5) Sheaves, sprockets, bandwheels and guides shall be so designed and constructed that the SAFETY FACTORS of this sub-clause of the suspension system shall be maintained for a specified minimum life till replacement of the ropes, chains and bands.

Compliance with the requirements of Sub-clauses 28.3 and 28.4 is checked by inspection of the design data and any maintenance instructions.

*28.5 DYNAMIC LOADS

Not used.

28.6 Not used.