Technetium Tc 99m Generator For the Production of Sodium Pertechnetate Tc 99m Injection

DESCRIPTION: The Technetium Tc 99m Generator is prepared with fission produced molybdenum Mo 99 adsorbed on alumina in a lead-shielded column and provides a means for obtaining sterile pyrogen-free solutions of sodium pertechnetate Tc 99m injection in sodium chloride. The eluate should be crystal clear. With a pH of 4.5-7.5, hydrochloric acid and/or sodium hydroxide, may have been used for pH adjustment. Over the life of the generator, an elution will contain a yield of > 80% of the theoretical amount of technetium Tc 99m available from the molybdenum Mo 99 on the generator column.

Each eluate of the generator should not contain more than 0.0056 MBq, 0.15 μCi of Molybdenum Mo 99 per 37 MBq, 1 mCi of technetium Tc 99m per administered dose at the time of administration, and not more than 10 μg of aluminum per mL of the generator eluate, both of which must be determined by the user before administration.*

Since the eluate does not contain an antimicrobial agent, it should not be used after twelve hours from the time of generator elution.

PHYSICAL CHARACTERISTICS: Technetium Tc 99m decays by isomeric transition with a physical half-life of 6.02 hours. The principal photon that is useful for detection and imaging studies is listed in Table 1.

* Generators provided in Canada should meet the Canadian Regulatory limit of 1.1 kBq, 0.03 μCi of molybdenum Mo 99 per 37 MBq, 1 mCi of technetium Tc 99m.

Table 1. Principal Radiation Emission Data[1]

Radiation	Mean %/ Disintegration	Mean Energy (keV)
Gamma-2	89.07	140.5

[1] Kocher, David C., "Radioactive Decay Data Tables." DOE/TIC-11026. p. 108, (1981).

EXTERNAL RADIATION: The specific gamma ray constant for Technetium Tc 99m is 0.78 R/hr-mCi at 1 cm. The first half-value thickness of lead (Pb) for technetium Tc 99m is 0.017 cm. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of Pb is shown in Table 2. For example, the use of 0.25 cm of Pb will attenuate the radiation emitted by a factor of about 1,000.

Table 2. Radiation Attentuation by Lead (Pb) Shielding

Shield Thickness (Pb) cm	Coefficient of Attenuation
0.017	0.5
0.08	10^{-1}
0.16	10^{-2}
0.25	10^{-3}
0.33	10^{-4}

Molybdenum Mo 99 decays to technetium Tc 99m with a molybdenum Mo 99 half-life of 2.75 days. The physical decay characteristics of molybdenum Mo 99 are such that only 86.8% of the decaying molybdenum Mo 99 atoms form technetium Tc 99m. Generator elutions may be made at any time, but ihc amount of technetium Tc 99m available will depend on the time interval since the last elution. After six hours approximately 47% of maximum technetium Tc 99m is available. Ninety-five percent is reached after 24 hours. To correct for physical decay of each radionuclide, the fractions that remain at selected intervals of' time are shown in Table 3

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Table 3a. Physical Decay Chart Molybdenum Mo 99 (Half-Life 2.75 Days)

Days	Percent Remaining	Days	Percent Remaining	Days	Percent Remaining
-3+	213.2	4	36.5	11	6.3
-2+	165.6	5	28.4	12	4.9
-1+	128.7	6	22.0	13	3.8
0*	100.0	7	17.1	14	2.9
1	77.7	8	13.3	15	2.3
2	60.4	9	10.3	16	1.8
3	46.9	10	8.0		

* Calibration time

+ Applies only to 30.7 GBq, 61.4 GBq and 91.8 GBq generators shipped in advance of calibration.

Table 3b. Physical Decay Chart Technetium Tc 99m (Half-Life 6.02 Hours)

Hours	Percent Remaining	Hours	Percent Remaining
0*	100.0	7	44.7
1	89.1	8	39.8
2	79.4	9	35.5
3	70.8	10	31.6
4	63.1	11	28.2
5	56.2	12	25.1
6	50.1		

*Elution time

CLINICAL PHARMACOLOGY: The pertechnetate ion distributes in the body similarly to the iodide ion, but is not organified when trapped in the thyroid gland. Pertechnetate tends to accumulate in intracranial lesions with excessive neovascularity or an altered blood-brain barrier. It alsos concentrates in the thyroid gland, salivary glands, gastric mucosa, and choroids plexus. However, in contrast to the iodide ion, the pertechnetate ion is released unchanged from the thyroid gland.

After intravascular administration, the pertechnetate ion remains in the circulatory system for sufficient time to permit blood pool measurement, organ perfusion, and major vessel studies. It gradually equilibrates with the extravascular space. A small fraction is promptly excreted via the kidneys.

Following the administration of sodium pertechnetate Tc 99m injection as an eye drop, the drug mixes with tears within the conjunctival space.

Within seconds to minutes it leaves the conjunctival space and escapes into the inferior meatus of the nose through the nasolacrimal drainage system. During this process the pertechnetate ion passes through the canaliculi, the lacrimal sac and the nasolacrimal duct. In the event of any anatomical or functional blockage of the drainage system there will be a backflow resulting in tearing (epiphoral). Thus, the pertechnetate escapes the conjunctival space in the tears. While the major part of the pertechnetate escapes within a few minutes of normal drainage and tearing, it has been documented that there is some degree of transconjunctival absorption with a fractional turnover rate of 0.015/min. in normal individuals, 0.021/min in patients without any sac and 0.027/min. in patients with inflamed conjunctiva due to chronic dacrocystitis. Individual values may vary, but these rates are probably representative and indicate that the maximum possible pertechnetate absorbed will remain below one thousandth of that used in other routine diagnostic procedures.

INDICATIONS AND USAGE: Sodium pertechnetate Tc 99m injection is used IN ADULTS as an agent for: brain imaging including cerebral radionuclide angiography; thyroid imaging; salivary gland imaging; placenta localization; blood pool imaging including radionuclide angiography; urinary bladder imaging (direct isotopic cystography) for detection of vesico-ureteral reflux; and nasolacrimal draining system imaging (dacryoscintigraphy).

Sodium pertechnetate Tc 99m injection is used IN CHILDREN as an agent for: brain imaging including cerebral radionuclide angiography; thyroid imaging; blood pool imaging including radionuclide angiography; and urinary bladder imaging (direct isotopic cystography) for detection of vesico-ureteral reflux.

CONTRAINDICATIONS: None known.

WARNINGS: Radiation risks associated with the use of sodium pertechnetate Tc 99m injection are greater in children than in adults. In general, the younger the child, the greater the risk owing to greater absorbed radiation doses and longer life espectancy. these greater risks should be taken firmly into account in all benefit-risk assessments involving children.

PRECAUTIONS:

General

Technetium Tc 99m Generators received in advance of the calibration date and time will contain higher amounts of radioactive material. Care should be taken to assure that the generator is properly shielded. As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient consistent with proper patient management and to insure minimum radiation exposure to occupational workers.

Since the eluate does not contain an antimicrobial agent, it should not be used after twelve hours from the time of generator elution.

After the termination of the nasolacrimal imaging procedure, blowing the nose and washing the eyes with sterile distilled water or an isotonic sodium chloride solution will further minimize the radiation dose.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides, and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

The generator should not be used after 16 days from the date and time of calibration.

At time of administration, the solution should be crystal clear.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic potential, mutagenic potential, or whether technetium Tc 99m may affect fertility in males or females.

Pregnancy Category C

Animal reproductive studies have not been conducted with technetium Tc 99m. It is also not known whether technetium Tc 99m can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m should be given to pregnant women only if the expected benefits to be gained clearly outweigh the potential hazards.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Nursing Mothers

Technetium Tc 99m is excreted in human milk during lactation, and therefore formula feedings should be substituted for breast feedings.

Pediatric Use

See INDICATIONS AND USAGE, DOSAGE AND ADMINISTRATION. See also description of additional risk under WARNINGS.

ADVERSE REACTIONS: Allergic reactions including anaphylaxis have been reported infrequently following the administration of sodium pertechnetate Tc 99m.

DOSAGE AND ADMINISTRATION: Sodium pertechnetate Tc 99m injection is usually administered by intravascular injection, but can be given orally. For imaging the urinary bladder and ureters, (direct isotopic cystography), the sodium perytechnetate Tc 99m injection is instilled aseptically into the bladder via a urethral catheter, following which the catheter is flushed with approximately 200 mL of sterile saline directly into the bladder. The dosage employed varies with each diagnostic procedure. If the oral route is elected, the patient should fast for at least six (6) hours before and two (2) hours after administration. When imaging the nasolacrimal drainage system, instill the sodium pertechnetate Tc 99m injection by the use of a device such as a micropipette or similar method which will ensure the accuracy of the dose.

The suggested dose ranges employed for various diagnostic indications in average ADULT patients (70 kg) are (except as noted for VU imaging):

Indication	Megabequerels	Millicuries
Vesico-ureteral imaging (pediatric or adult)	18.5 - 37.0	0.5 – 1
Brain imaging	370.0 - 740.0	10 - 20
Thyroid gland imaging	37.0 - 370.0	1 - 10
Salivary gland imaging	37.0 - 185.0	1 - 5
Placenta localization	37.0 - 111.0	1 - 3
Nasolacrimal drainage system imaging	3.70 (max.)	0.100 (max.)
Blood pool imaging	370.0 - 110.0	10 - 30

In PEDIATRAIC patients:

Brain imaging:	5.2 – 10.4 MBq, 140-280 μCi per kilogram body weight
Thyroid gland imaging:	2.2 – 3.0 MBq, 60 – 80 μCi per kilogram body weight
Blood pool imaging:	5.2 – 10.4 MBq, 140 – 280 μCi per kilogram body weight. A minimum dose of 111.0 – 185.0 MBq, 3 – 5 mCi should be employed if radionuclide angiography is performed as part of the blood pool imaging procedure.
Vesico-ureteral imaging:	18.5 – 37.0 MBq, 0.5 –1.0 mCi

NOTE: Up to 1 gram of pharmaceutical grade potassium perchlorate in a suitable base or capsule may be given orally prior to administration of sodium pertechnetate Tc 99m injection. When sodium pertechnetate Tc 99m injection is used in children for

brain or blood pool imaging, administration of potassium perchlorate is especially important to minimize the absorbed radiation dose to the thyroid gland.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to the administration whenever solution and container permit.

The solution to be administered as the patient dose should be crystal clear and contain no particulate matter.

RADIATION DOSIMETRY: The estimated absorbed radiation doses[2] to an average ADULT patient (70 kg), from an intravenous injection of a maximum dose of 1100.0 MBq, 30 mCi of sodium pertechnetate Tc 99m injection distributed uniformly in the total body of subjects not pretreated with blocking agents such as pharmaceutical grade potassium perchlorate, are shown in Table 4. For placenta localization studies, when a maximum dose of 111.0 MBq, 3 mCi is used, it is assumed to be uniformly equilibrated between maternal and fetal tissues.

Table•4. Absorbed Radiation Doses (ADULTS)
Intravenous Administration

	(mGy/1110.0 MBq)	
Tissue	Resting Population	Active Population
Bladder Wall	15.9	25.5
Gastrointestinal tract: Stomach wall	75.0	15.3
Upper Large intestine wall	20.4	36.0
Lower large intestine wall	18.3	33.0
Red marrow	5.7	5.1
Testes	2.7	2.7
Ovaries	6.6	9.0
Thyroid	39.0	39.0
Brain	4.2	3.6
Whole body	4.2	3.3
Placenta	0.05	0.05
Fetus	0.05	0.05

Modified from: Summary of Current Radiation Dose Estimates to Normal Humans from ^{99m}Tc as Sodium Pertechnetate. MIRD Dose Estimates Report No. 8. *J Nucl Med* 17(1): 74-77, 1976.

NOTE: To convert the radiation dose from milligray (mGy) to rad units, divide the value in milligrays by 10.

Table 5. Absorbed Radiation Doses (ADULTS)
Dacryoscintigraphy

	Absorbed Radiation Dose	
Organ	mGy/3.7 MBq	mrad/100μCi
Eye Lens:		
If lacrimal fluid turnover is 16%/min.	0.140	14.0
If lacrimal fluid turnover is 100%/min.	0.022	2.2
If drainage system is blocked	4.020	402.0
Total Body	0.011	1.1
Ovaries*	0.030	3.0
Testes*	0.009	0.9
Thyroid*	0.130	13.0

*Assumes no blockage of drainage system. MIRD Dose Estimate Report No. 8. *J Nucl Med* 17(1): 74-77, 1976

In PEDIATRIC patients, the maximum radiation dose s when a dose of 185.0 MBq, 5 mCi of sodium pertechnetate Tc 99m injection is administered to a neonate (3.5 kg) for brain or blood pool imaging with radionuclidic angiography are shown in Table 6. When a dose of 37 MBq, 1 mCi of sodium pertechnetate Tc 99m injection is instilled directly into the urinary bladder for vesico-ureteral imaging in pediatric patients and retained for 30 minutes, the estimated absorbed radiation dose to the bladder wall and ureters is 0.3 mGy, 30 mrad and 0.04-0.05 mGy, 4-5 mrad to the gonads.[3]

Table 6. Absorbed Radiation Doses (PEDIATR1C)

	Absorbed Radiation	
Tissue	mGy/185.0 MBq	rads/5 mCi
Thyroid (without perchlorate)	230	23.0
Thyroid (with perchlorate)	48.5	4.85
Large Bowel (with perchlorate)	95.5	9.55
Testes	5.1	0.51
Ovaries	11.0	1.10
Whole Body	7.6	0.76

[3]Conway, JJ et al: Direct and indirect radionuclidic cystography. *J Urol* 113:689-693, May 1975.

Table 7. Generator Dosimetry Readings

TechnetiumTc 99m Generator

Front Side of Generator

Measurements at 8:00 A.M. prior to Elution

91 .8 GBq, 2480 mCi Generator with Internal Lead Shield

	µSv/hr		Mo 99	
Days from Calibration	2*	12*	GBq	mCi
-3	1552	247	226.4	6119
-2	1181	192	176.0	4756
-1	918	149	136.8	3696
O*	616	100	91.8	2480
1	554	90	82.6	2233
2	431	70	64.2	1735
3	336	55	49.9	1348
4	260	42	38.8	1048

Table 7. Generator Dosimetry Readings (continued)

TechnetiumTc 99m Generator

Front Side of Generator

Measurements at 8:00 A.M. prior to Elution

153.2 GBq, 4140 mCi Generator with Internal Lead Shield

	µSv/hr		Mo 99	
Days from Calibration	2*	12*	GBq	mCi
0*	1050	170	153.2	4140
1	810	140	137.9	3727
2	630	110	107.2	2897
3	490	80	83.3	2251
4	380	60	64.8	1750
5	300	50	50.3	1360
6	230	40	39.1	1057
7	180	30	30.4	821

Table 7. Generator Dosimetry Readings (continued)

614.2 GBq, 16600 mCi Generator with Internal Depleted Uranium Shield				
	μSv/hr		Mo 99	
Days from Calibration	2*	12*	GBq	mCi
0*	550	80	614.2	16600
1	430	60	553.0	14945
2	330	50	429.8	11615
3	260	40	334.0	9027
4	200	30	259.6	7016
5	160	20	201.8	5453
6	120	20	156.8	4238
7	90	10	121.9	3294

*Day of calibration at the time specified on generator label.

NOTE: To obtain equivalent generator dosimetry reading values in milirem units, divide the value of microsieverts (μSv) by 10.

Table 8. Elution Vial Radiation Dosimetry

423.3 GBqm 11440 mCi of Tc 99m Activity 20 cc Vial, 20 mL of Elution		
Vial Distance from Probe	Dosimetry Bare Vial	Dosimetry Shielded Vial*
Contact	4720 mSv/hr	40 μSv/hr
30.5 cm	130 mSv/hr	8 μSv/hr

Elution Vial Shield, Catalog No. 5074, shield 6.35 mm lead.

NOTE: to convert millisieverts (mSv) to millirem, multiply the value in millisieverts by 100. To convert microsieverts (μSv) to millirem, divide the value in microsieverts by 10.

HOW SUPPLIED: Sodium pertechnetate Tc 99m injection is supplied as a Molybdenum Mo 99/Technetium Tc 99m generator in sizes of molybdenum Mo 99 from 30.7 GBq up to 614.2 GBq, 830 mCi up to 16,600 mCi, as of the date and time of calibration specified on the generator label, in approximately 30.7 GBq, 830 mCi increments. The Technetium Tc 99m Generator consists of:

1. Sterile generator
2. Sodium Chloride Injection source
3. Sterile evacuated vials (10 and 20 cc sizes)*
4. Sterile needles
5. Elution vial shield (initial order only if needed)
6. Finished drug labels
7. Package insert

•Available only upon customer request.

the Technetium Tc 99m Generator should not be used after expiration date (see Expiration Date paragraph below). For multi-dose use, the eluate should be used within twelve (12) hours of the generator elution time. If the eluate is used to reconstitute a kit, the radio-labled kit should not be used after twelve (12) hours from the time of generator elution or six (6) hours after reconstitution of the kit, whichever is earlier.

Storage

Store generator at room temperature (18-25 °C).

CAUTION: Avoid freezing.

PREPARATION: The following instructions must be carefully followed for optimum prepartion of sodium pertechnetate Tc 99m injection.

The Technetium Tc 99m Generator is sterile and pyrogen-free at the time of shipment. Aseptic technique must be observed during the use of the generator to maintain a sterile and pyrogen-free system. Gloves should be worn during all elution procedures. The sealed column and fluid path MUST NOT be removed from the shielding system.

CAUTION: It is recommended that elution vial shields be used when eluting the generators, shielded syringes be used when preparing formulations, and appropriate vial shields be used for formulations.

FIRST ELUTION:

1. Remove generator system and accessories from carton. Place in auxiliary secondary shield*, if applicable.
2. Place an elution vial in the elution shield (Figure 1) and clean septum of elution vial with an alcohol swab and allow to dry. Position elution shield on dispensing platform (Figure 2).

NOTE: FIRST ELUTION ONLY

*generator secondary shield, catalogue nO. 5075, OR EQUIVALENT.

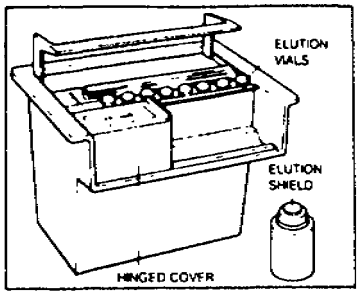

Figure 1

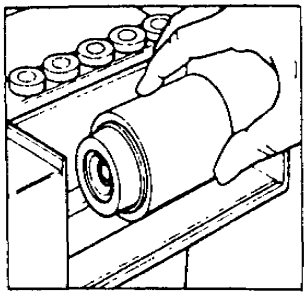

Figure 2

Figure 2

The elution volume obtained on the first elution will be approximately 15% less than the eluant volume stated on the evacuated vial. It is recommended that a 10 cc evacuated vial be used with generators ≤ 153.2 GBq, 4140 mCi and a 20 cc evacuated vial be used with generators ≥183.9-614.2 GBq, 4970-16,600 mCi.

3. Lift hinged cover exposing dispenser end. Remove protective cap from dispenser and attach a sterile needle-remove plastic needle cover (Figure 3). CAUTION: DO NOT OPEN THE “OPEN-CLOSED” LEVER.
4. SLide elution shield to far left position (Figure 4). the dispensing needle will pierce the septum of the evacuated elution vial. Move “Open-Closed” lever to the “Open” position. Lower hinge cover, the elution will begin immediately.

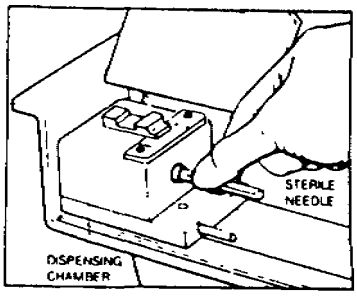

Figure 3

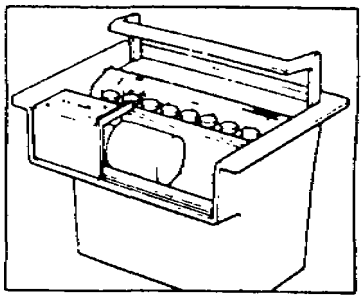

Figure 4

5. Step away to reduce you radiation exposure. Allow 3 to 5 minutes for complete elution. note: If vacuum in elution vial is lost, i.e. no eluate present in vial, discard vial and use a new elution vial.

6. When elution is complete, open hinged cover and move “Open-Closed” lever to “Closed” position. Slide elution shield to far right position. Remove elution shield containing vial with sodium pertechnetate Tc 99m injection from dispensing platform.
7. Replace dispensing needle with sterile needle with plastic cover in place. Do not remove cover from needle until next elution. Lower hinged cover.
8. Affix the pressure-sensitive label to the elution vial shield. Sodium pertechnetate Tc 99m injection is ready to use. Maintain adequate shielding of the radioactive preparation.

SUBSEQUENT ELUTIONS:

1. place an elution vial in the elution shield (Figure 1) and clean septum of elution vial with an alcohol swab and allow to dry. Position elution shield on dispensing platform (Figure 2).
2. Lift hinged cover exposing dispenser needle. Replace used needle with a new sterile needle-remove plastic needle cover (Figure 3).
3. Repeat steps 4 through 8.

The radioactive concentration of the final sodium pertechnetate Tc 99m preparation may be calculated by using the following formula:

C = A/V where C is the radioactivity concentration of the sodium pertechnetate Tc 99m injection (MBq/mL, mCi/mL).

A is the technetium Tc 99m activity added to the reaction vial (MBq, mCi) and

V is the total volume in the final mixture (mL).

TECHNETIUM Tc 99m ASSAY PROCEDURE:

1. Determine the equivalent technetium Tc 99m value for a Cobalt Co 57 standard by multiplyiny the number of MBq, mCi of the Cobalt Co 57 standard by the appropriate equivalence factor. This equivalent value of Cobalt Co 57 for the standard need be decayed only daily for use as a secondary standard.
2. Place the standard in the chamber and record μamp reading.
3. Transfer the technetium Tc 99m sample from the shield to the chamber. Record the μamp reading.
4. Calculate activity:

   $\frac{\mu\text{amps of Tc 99m}}{\mu\text{amps of Co 57 std.}}$ x MBq, mCi Co 57 std. = MBq, mCi Tc 99m+

   where MBq, mCi Cobalt Co 57 standard = the equivalent MBq, mCi value for Cobalt Co 57 from Step 1 above, corrected for decay.

DIRECT READOUT PROCEDURE: A direct readout dose calibrator is used.

1. Determine the MBq, mCi technetium Tc 99m value for Cobalt Co 57 standard using mehod 1. above. Correct MBq, mCi value for decay.
2. Place Cobalt Co 57 standard in chamber and adjust the calibrator to proper reading accotrding to the manufacturer’s instructions.
3. Transfer sample vial to chamber and read directly MBq, mCi.

MOLYBDENUM Mo 99 BREAKTHROUGH TEST:

1. Determine the amount of technetium Tc 99m eluted (MBq, mCi).
2. Place the technetium Tc 99m eluate in a lead container. Place lid on container and put the entire container in the chamber.
3. Record the amount of molybdenum Mo 99 (MBq, mCi) on the most sensitive scale.
4. Divide the MBq, mCi molybdenum Mo 99 by the MBq, mCi technetium Tc 99m. Correct for decay and shielding effects, if necessary.

The Molybdenum Mo 99/Technetium Tc 99m ratio should be determined at the time of elution prior to administration, and from that ratio. the expiration time (up to twelve hours) of the eluate mathematically determined. Each eluate should meet or exceed purity requirements of the current official United States Pharmacopeia.

Generators provided in Canada should meet the Canadian Regulatory limit of 1.1 kBq, 0.03 μCi of molybdenum Mo 99 per 37 MBq, 1 mCi of technetium Tc 99m.

EXPIRATION DATE: Technetium Tc 99m Generaotrs shipped on the day of calibration expire sixteen (16) days after calibration date and time. Technetium Tc 99m Generators of 30.7 GBq, 61.4 GBq and 91.8 GBq, 830 mCi, 1660 mCi and 2480 mCi may be shipped up to 72 hours prior to calibration and, if so, expire thirteen (13) days after calibration date and time.

The generator eluate expires twelve hours after elution.

DISPOSAL: Users should monitor the amount of radioactivity present prior to disposal of the unit. Storage and /or disposal of the Technetium Tc 99m Generator should be in accordance with the conditions of Agreement State or Licensing State licenses and regulations, or other regulatory agency authorized to license the use of radionuclides.

If in accordance with these regulation, vials and needles used for eluting may be discarded after two (2) days. The Technetium Tc 99m Generator should not be discarded in ordinary trashwithin 70 days of the calibration date. It is suggested that all identification labels be destroyed before discarding the generator or vials.

Technetium Tc 99m Generators of ≤153.2 GBq, 4140 mCi MAY be returned to the manufacturer, while those of 183.9-614.2 GBq, 4970-16600 mCi MUST be returned to the manufacturer. Please refer to the instructions included with each shipment.

This generator is licensed by the Illinois Department of Nuclear Safety for distribution to persons licensed pursuant to 32 Illimois Admin. Code 330.260(a) and Part 335, Subpart E, 335.4010, or under equivalent licenses of an Agreement State or a Licensing State.

THIS PRODUCT INFORMATION ISSUED MAY, 1997

Medi-Physics, Inc.,
Amersham Healthcare
2636 South Clearbrook Drive
Arlington Heights, Illinois 60005