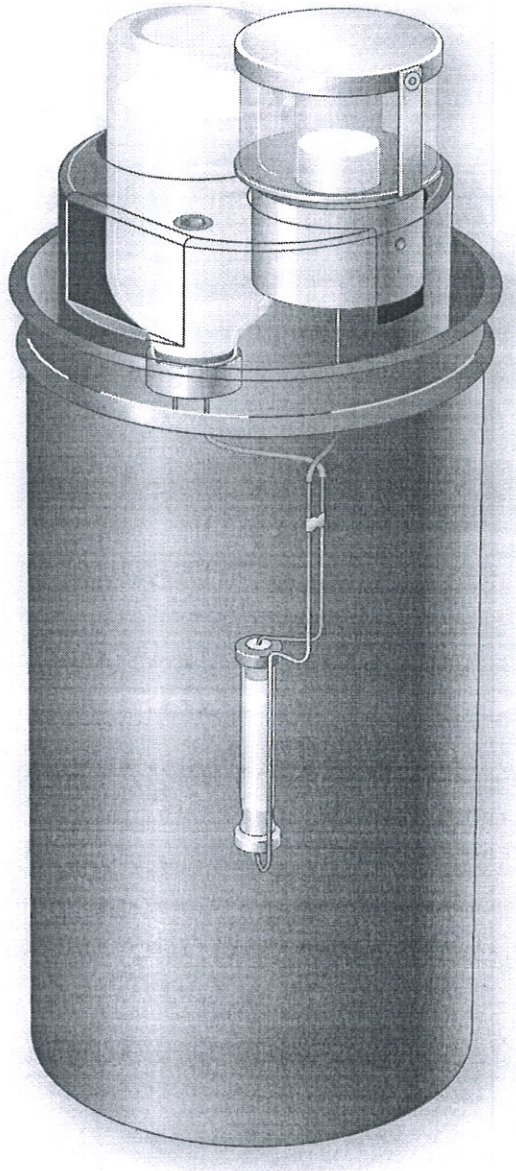
Mallinckrodt Pharmaceuticals

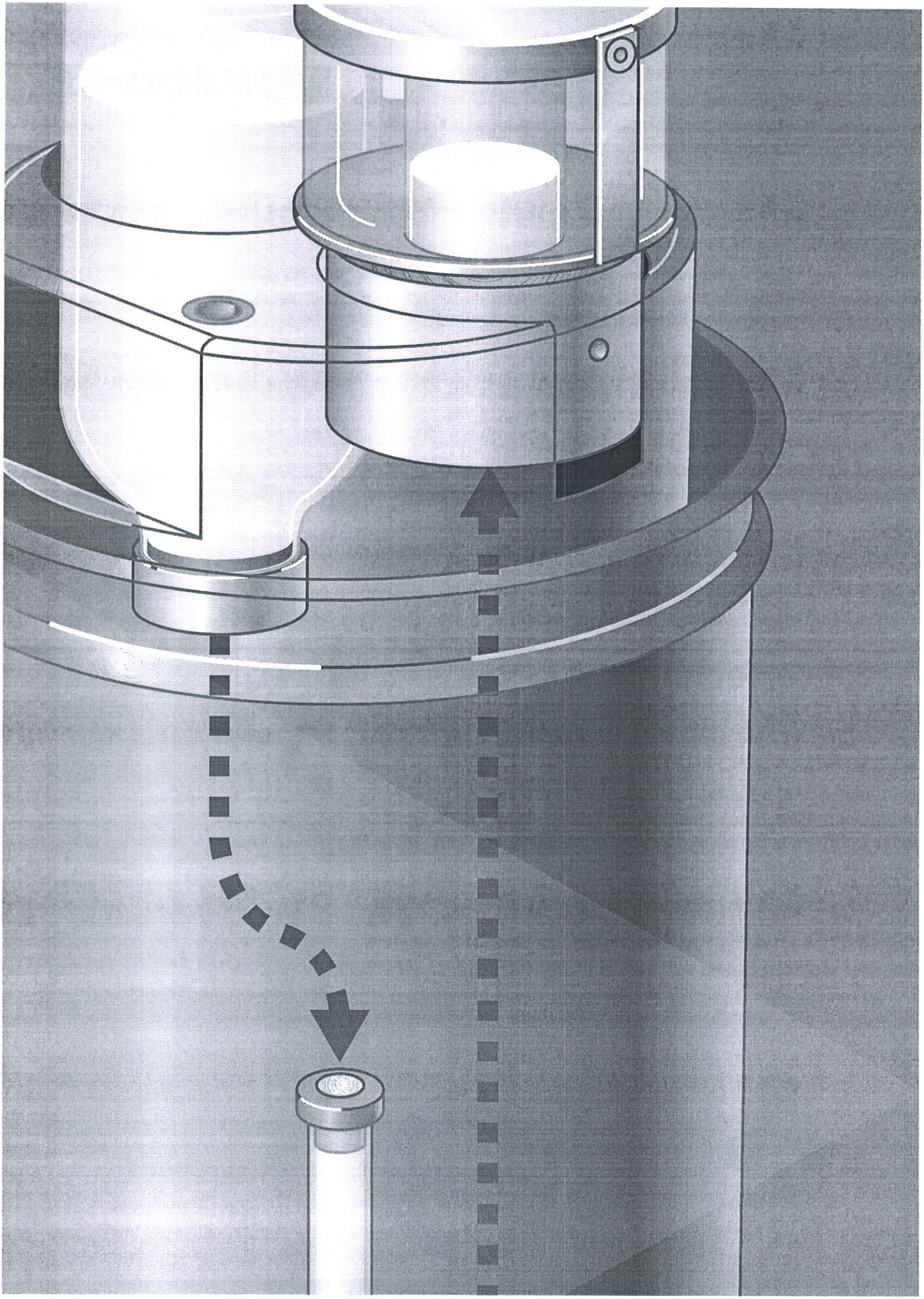
Ultra-Technekow™ FM

Mo-99/Tc-99m generator



Product Information

Vision. Value.
Vertical Integration.



Contents

Why choose
Ultra-Technekow FM?

Reliable Moly Supply

Mallinckrodt is the only supplier of Tc-99m generators that operates its own Molybdenum facility. The production plant in Petten, The Netherlands has been one of the largest investments in the history of our company. Mallinckrodt is one of the most reliable suppliers of Mo-99, assuring the delivery of your generator.

Daily Manufacturing

From Monday to Friday we produce and ship our generators every day of the week in a wide range of activities from 2,15 to 43,00 GBq. Standard Activity Reference Time (ART) is 7 days after shipment at 06:00 CET. We offer you optimal flexibility in choosing the right activity for your needs, combined with an excellent distribution network.

One Step Elution

Ultra-Technekow FM is very easy to operate. Elution starts by placing an evacuated vial in its appropriate shield on to the generator. This one step elution shortens handling time and consequently helps you in reducing exposure to radiation.

Variable Elution

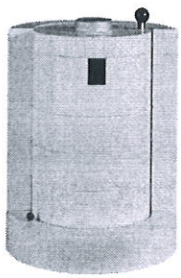
We offer three standard elution volumes: 5, 11 and 25 ml. In addition Ultra-Technekow FM is the only generator on the market to have a safe and dedicated system to perform a partial elution. Elution can be stopped at any time by turning the elution shield 90 degrees. Variable elution helps you to control the concentration of Tc-99m in the eluate to your own needs. Our concept of visible elution allows you to observe the process. We can provide you with a special Clear View shield for use in a cabinet and our Ultravial shield for use in our secondary lead shielding.

Consistent Yield

Analysis by our Research & Development Department demonstrates that the average Tc-99m yield efficiency is 89,5%, standard error 0,03%. This finding confirms what we hear from our customers: our generator produces a high and consistent yield of Tc-99m.

Quality of the Eluate

The generator yields a very pure eluate. It does not contain oxidizing agents and has less than 5 µg Al^{3+} per ml. The eluate is sterile, colourless and clear. pH of the carrier free, isotonic solution ranges between 4,0 and 8,0. We guarantee a radionuclidic purity > 99,9% and a radiochemical purity ≥ 99% as Pertechnetate.



Shielding

Ultra-Technekow FM contains integrated shielding around the column to provide safe handling and transport. An optimal balance between radiation protection and a minimal weight, determines the size of the shield. We can provide you with a secondary shield, for use in your department to contain one or two generators.

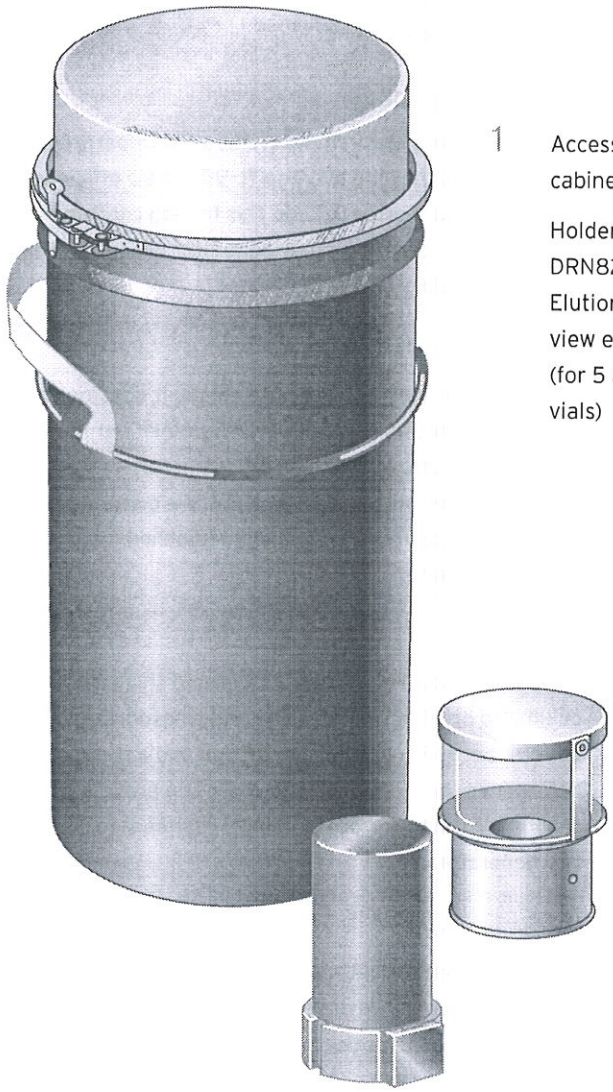
Environment

We feel it is our obligation to operate our production facilities with a minimum of waste. For this reason we recycle nearly all parts used in an Ultra-Technekow FM and its packaging.

How to use our Ultra-Technekow FM generator

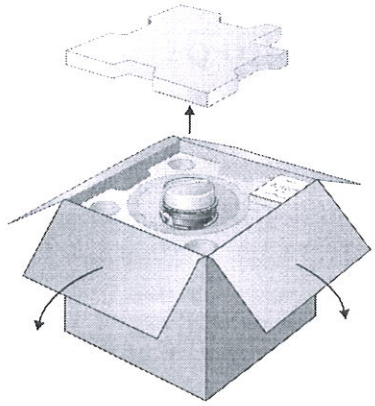
Start

Please make sure that you have all accessories to use Ultra-Technekow FM.



1 Accessories for use in a cabinet or isolator:

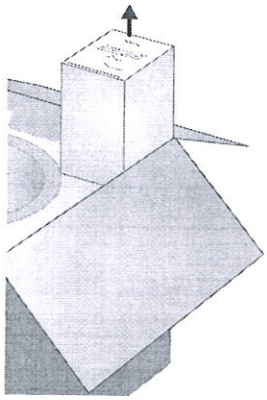
Holder for needle protector: DRN8262 Technestat shield
Elution shield: DRN8275 Clear view elution shield™ 11 ml (for 5 and 11 ml evacuated vials)

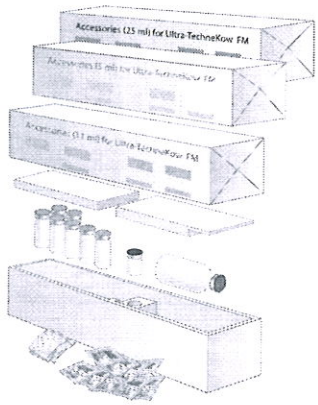


2 Accessories for use in one of our secondary safes (DRN8230 and DRN8260):

Holder for needle protector: DRN8265
Technestat shield
Elution shield: DRN8271 Ultravial shield™ 11 ml (for 5 and 11 ml sterile evacuated vial) or DRN8272 Ultravial shield™ 25 ml (for 25 ml sterile evacuated vial)

3 Ultra-Technekow FM is shipped in a transport box of w 40 x d 40 x h 40 cm





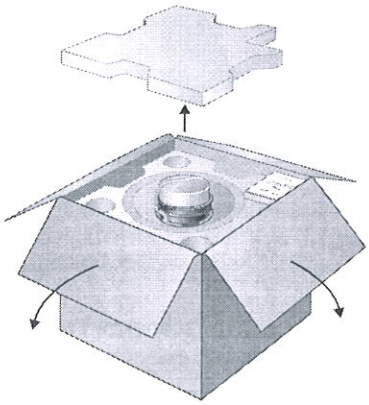
4 Each generator is shipped with a 5, 11 or 25 ml elution kit (DRN4345, DRN4347 or DRN4348)

5 An elution kit contains:

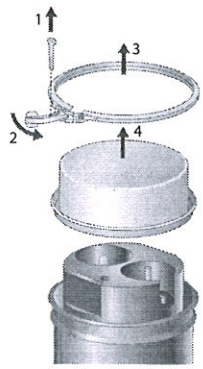
7x sterile evacuated vials (5, 11 or 25 ml)
1x 5 ml sterile needle protector
1x sterile eluent vial 100 ml NaCl 0,9%
7x disinfection swabs
7x radioactivity labels

How to use our Ultra-Technekow FM generator

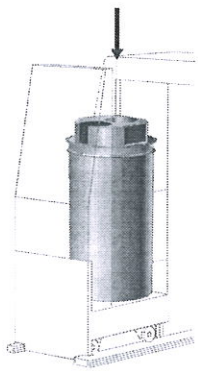
Preparation



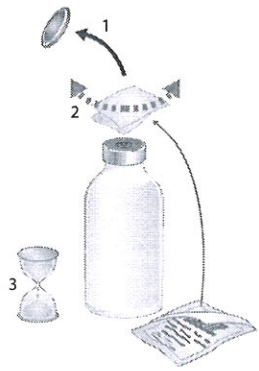
1 Take the generator out of the transport box
(and store the box and packaging materials for later use)



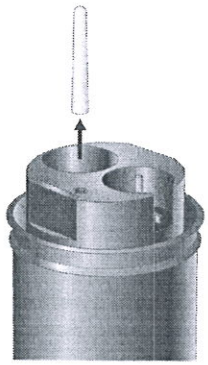
2 1 Pull out the seal
2-3 Open the closing ring and remove it
4 Take the top cover off
(and store for later use)



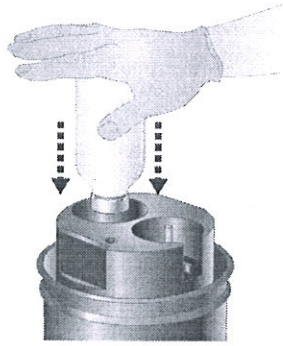
3 Put the Ultra-Technekow FM with the elution station facing forward in a lead castle or behind any other suitable laboratory shielding



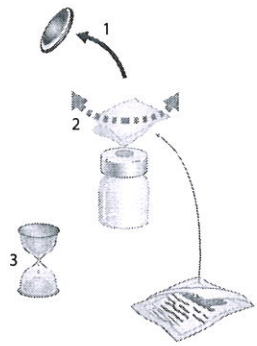
4 1 Remove the flip-off cover from an eluent vial
2 Disinfect the stopper
3 Let the disinfectant evaporate completely



5 Remove the plastic cover from the inlet needle (and store for later use)

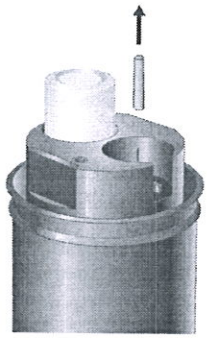


6 Lower the eluent vial gently and without turning on the inlet needle

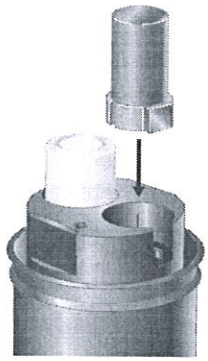


7
1 Remove the flip-off cover from a needle protector
2 Disinfect the stopper
3 Let the disinfectant evaporate completely

8 Place the needle protector in its holder



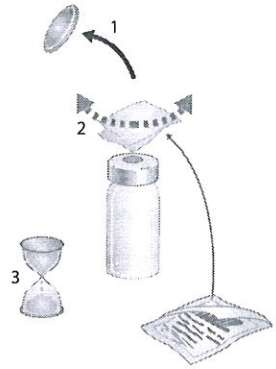
9 Remove the rubber cover from the outlet needle (and store for later use)



10 Lower the holder with needle protector on to the elution station

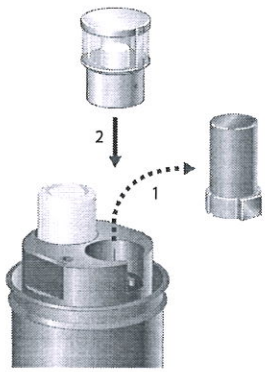
How to use our Ultra-Technekow FM generator

Elution

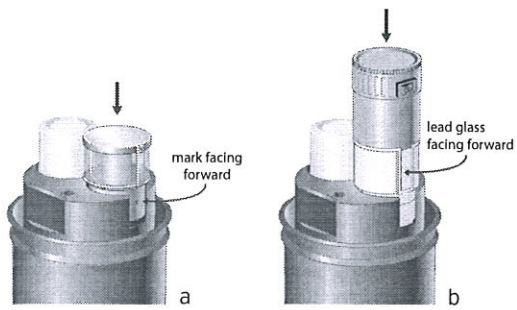


1 1 Remove the flip-off cover from an evacuated vial
2 Disinfect the stopper
3 Let the disinfectant evaporate completely

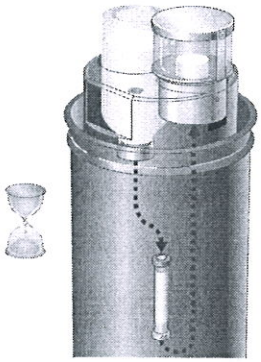
2 Place the evacuated vial in an elution shield



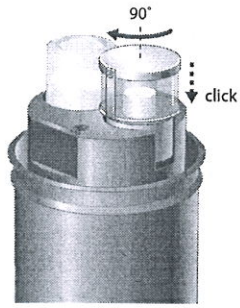
3 1 Replace the holder with needle protector
2 with the elution shield



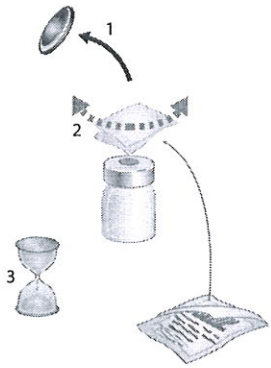
4 Lower the elution shield with evacuated vial
on to the generator
a Clear View: mark facing forward
or
b when using an Ultravial shield: lead glass facing forward



5 Elution starts

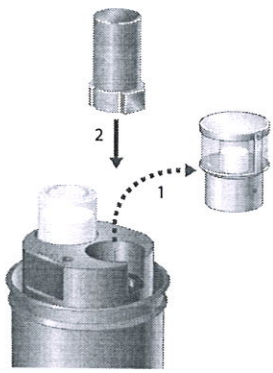


6 To stop the elution process
turn the elution shield 90 degrees



7
1 Remove the flip-off cover from a needle protector
2 Disinfect the stopper
3 Let the disinfectant evaporate completely

8 Place the needle protector in its holder



9
1 Replace the elution shield
2 with the holder with needle protector

For instructions on return of used generators please refer to page 27 'Return of the Ultra-Technekow FM generator'.

Variable elution to control Tc-99m concentration

an exclusive feature of Ultra-Technekow FM

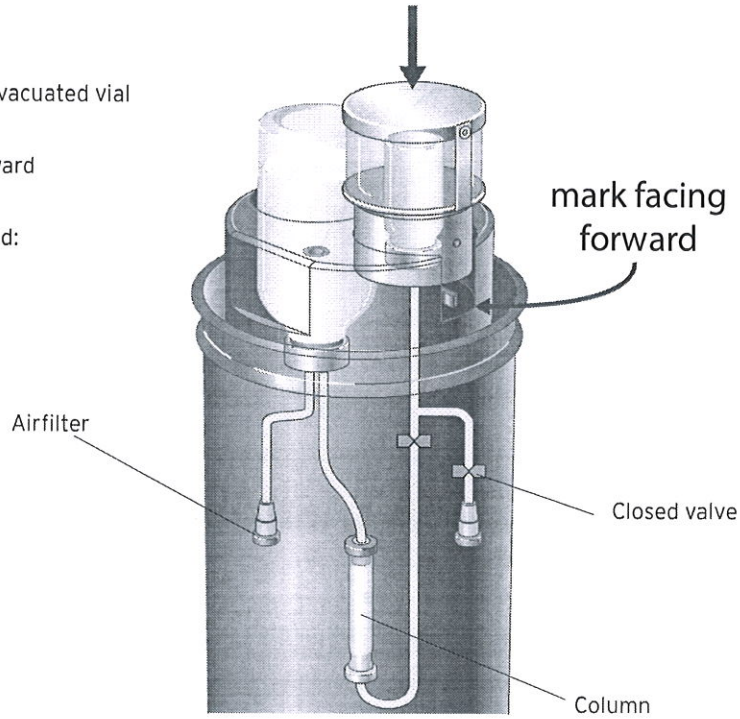
Elution can be stopped at any time by turning the elution shield 90 degrees. A variable elution volume helps to control the concentration of Tc-99m in the eluate to your own needs.

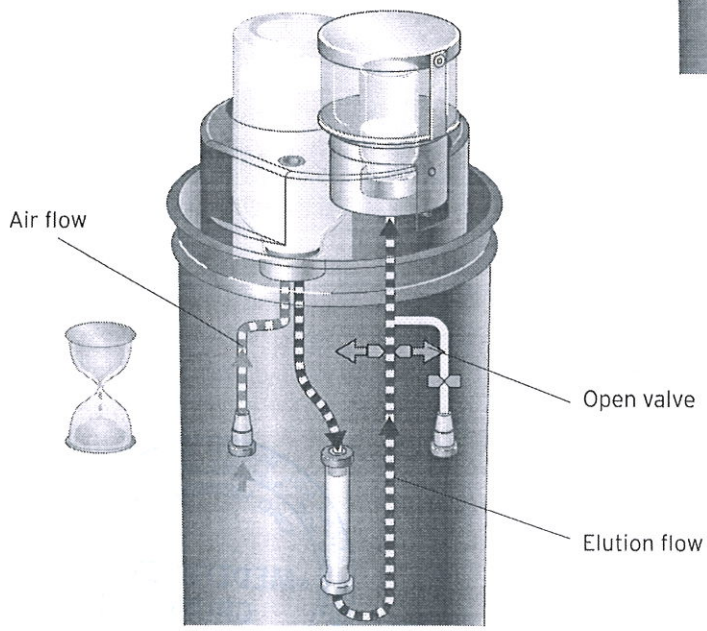
A Lower the elution shield with evacuated vial on to the generator

a Clear View: mark facing forward

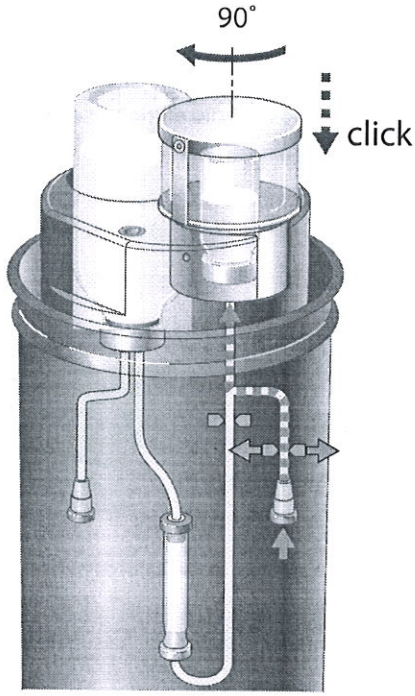
or

b when using an Ultravial shield: lead glass facing forward

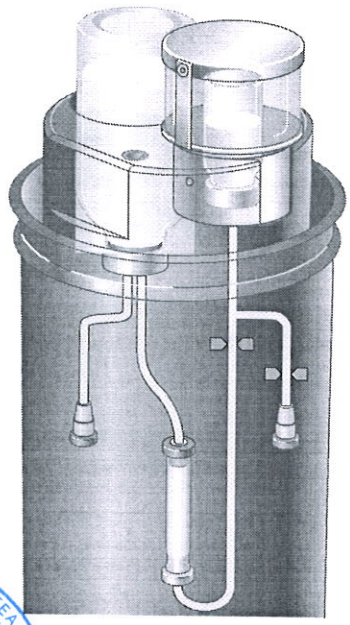




B The safety valve is now open: elution starts



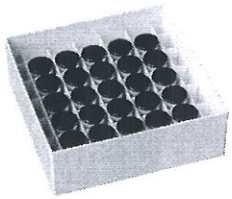
C To stop the elution process turn the elution shield 90 degrees either way
The technevial is now filled with sterile air



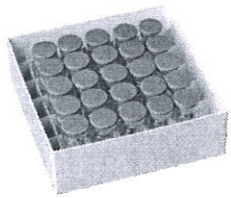
D There is equilibrium in the system: the elution shield can now be replaced by the holder with needle protector

Accessories
Vials

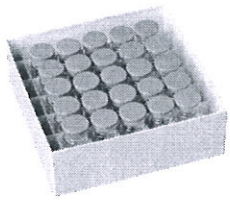
Needle protectors
DRN4349 Sterile elution needle protectors
25 vials in one box



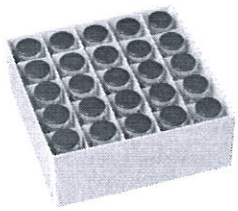
5 ml evacuated vials
DRN4373 5 ml sterile evacuated vials
25 vials in one box



11 ml evacuated vials
DRN4357 11 ml sterile evacuated vials
25 vials in one box

25 ml evacuated vials
DRN4370 25 ml sterile evacuated vials
25 vials in one box

Eluent vials

DRN4346 sterile eluent vials 100 ml NaCl 0,9%

10 vials in one box

Accessories
Shields

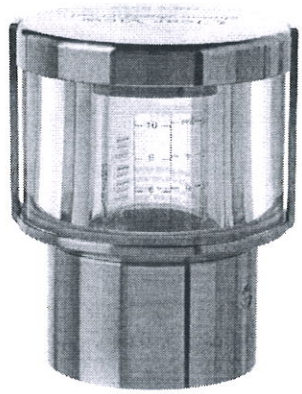
Clear view elution shield

DRN8275 Clear view elution shield™ 11 ml
Elution shield for 5 ml and 11 ml sterile evacuated vials
For use in a cabinet or isolator

With spherical lead glass possible to watch elution
Variable elution possible

14 mm lead glass (Pb equivalent 6 mm)
Stainless steel (grade 316, chromed) and lead
Surface dose rate: 0,043 ↔Sv/hr per GBq Tc-99m

Ø d 45/58 x h 76 mm
Weight 929 g



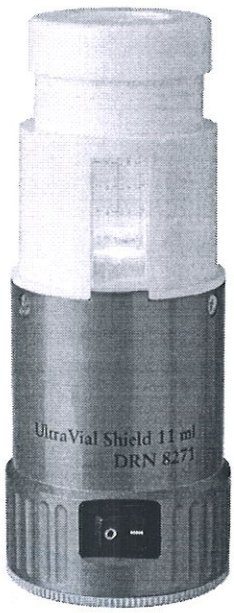
Elution shield 11 ml

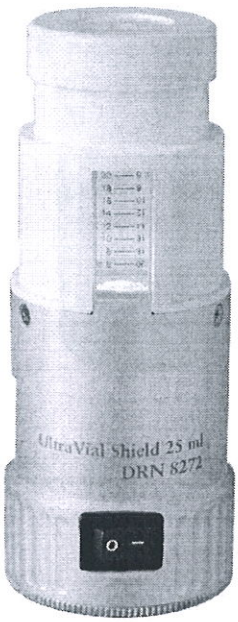
DRN8271 Ultravial shield™ 11 ml
Elution shield for 5 and 11 ml sterile evacuated vial
For use in one of our secondary safes (DRN8230 and DRN8260)

Watch the elution
With lead glass window and built-in light
Variable elution possible

Minimum diameter lead wall 4,5 mm
10 mm lead glass (Pb equivalent 4,5 mm)
Surface dose rate: 1,687 ↔Sv/hr per GBq Tc-99m

Ø d 45/62 x h 150 mm
Weight 1057 g
Needs 2x AA LR6 1,5V alkaline batteries





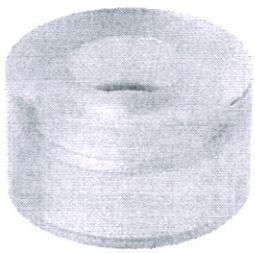
Elution shield 25 ml

DRN8272 Ultravial shield™ 25 ml
Elution shield for 25 ml sterile evacuated vial
For use in one of our secondary safes (DRN8230 and DRN8260)

Watch the elution
With lead glass window and built-in light
Variable elution possible

Minimum diameter lead wall 4,5 mm
10 mm lead glass (Pb equivalent 4,5 mm)
Surface dose rate: 2,214 ↔Sv/hr per GBq Tc-99m

Ø d 45/62 x h 150 mm
Weight 1047 g
Needs 2x AA LR6 1,5V alkaline batteries



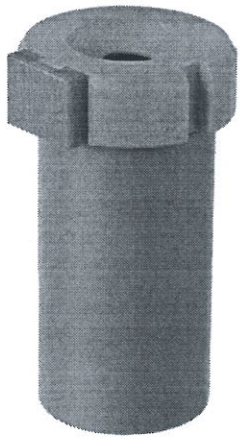
Adaptor ring

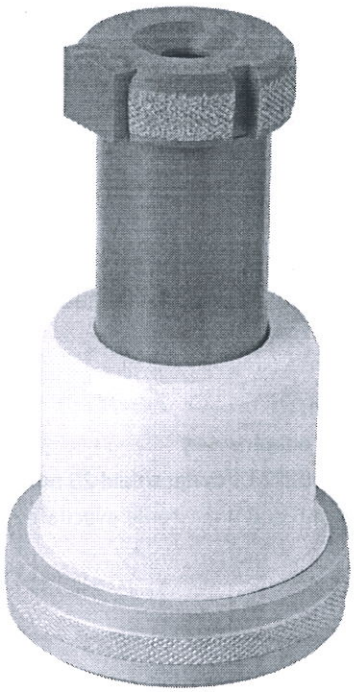
N311346 11 ml adaptor ring
For use in DRN8272 Ultravial shield 25 ml
To allow use of 5 and 11 ml sterile evacuated vials

Accessories
Shields

Holder for needle protector

DRN8262 Technestat shield without lead
Holds the sterile elution needle protector
For use in a cabinet or isolator





Shield for needle protector

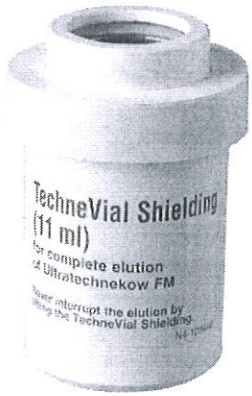
DRN8265 Technestat shield with lead
Holds the sterile elution needle protector
For use in one of our secondary safes
(DRN8230 and DRN8260)
Integrated lead shield

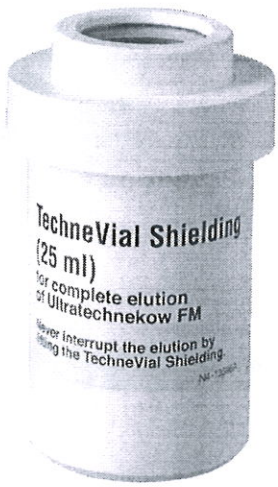
Vial shield 11 ml

DRN8263 Technevial 11 ml shield
Shield used to store 5 and 11 ml sterile evacuated vial

Suitable for elution
No variable elution possible

Diameter lead wall 7 mm
Surface dose rate: 0,006 ↔Sv/hr per GBq Tc-99m





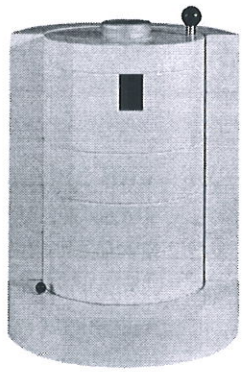
Vial shield 25 ml

DRN8264 Technevial 25 ml shield
Shield used to store 25 ml sterile evacuated vial

Suitable for elution
No variable elution possible

Diameter lead wall 3 mm
Surface dose rate: 0,215 ↔Sv/hr per GBq Tc-99m

Accessories
Secondary safes

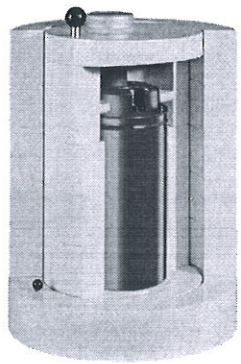


Mono safe

DRN8230 Lead castle FM™
Can store one generator

Lead castle remains closed during elution
Technestat shield with lead holds sterile elution needle protector in place (DRN8265)
Elution visible through lead glass by use of illuminated elution shield (DRN8271 or DRN8272)
Variable elution possible

Leadshielding
Top 42 mm
Around 50 mm
Ø d 344 x h 485 mm
Weight 250 kg

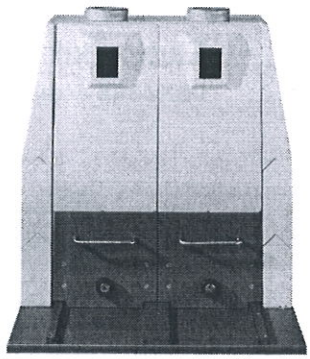


Surface dose

Dose rates	DRN8230 Lead castle FM™		
Lead wall mono safe	50		
Internal UTK lead shield	42	56	mm
Total lead shielding	92	106	mm
Surface dose rate	0,0665	0,0159	µSv/hr per GBq Mo-99
Dose rate at 1 meter	0,0020	0,0005	µSv/hr per GBq Mo-99

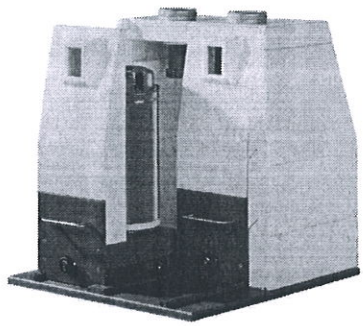
Duo safe

DRN8260 Ultra-Technekow safe™
Compact shield can store two generators



Lead castle remains closed during elution
Technestat shield with lead holds sterile elution needle protector in place (DRN8265)
Elution visible through lead glass by use of illuminated elution shield (DRN8271 or DRN8272)
Variable elution possible

Leadshielding
Top 50 mm
Around maximum 57 mm
w 455 x d 525 x h 522 mm
Weight 325 kg



Surface dose

Dose rates	DRN8260 Ultra-Technekow safe™		
Lead wall duo safe	57		
Internal UTK lead shield	42	56	mm
Total lead shielding	99	113	mm
Surface dose rate	0,0616	0,0148	µSv/hr per GBq Mo-99
Dose rate at 1 meter	0,0010	0,0002	µSv/hr per GBq Mo-99

Accessories
Elution kits

Elution kit 5 ml
DRN4345 Accessories kit 5 ml

Elution kit 11 ml
DRN4347 Accessories kit 11 ml

Elution kit 25 ml
DRN4348 Accessories kit 25 ml

An elution kit shipped with each generator contains:

7x sterile evacuated vials (5, 11 or 25 ml)
1x 5 ml sterile needle protector
1x sterile eluent vial 100 ml NaCl 0,9%
7x disinfection swabs
7x radioactivity labels

Yield

Technetium-99m (activities for one elution per day)

Elution at 07:00 CET (in GBq)

Nominal activity in GBq	2,15	4,30	6,45	8,60	10,75	12,90	17,20	21,50	25,80	30,10	34,40	43,00	Nominal activity in GBq
ART -6 days	7,07	14,14	21,22	28,29	35,36	42,43	56,58	70,72	84,86	99,01	113,15	141,44	ART -6 days
ART -5 days	5,95	11,91	17,86	23,81	29,77	35,72	47,62	59,53	71,44	83,34	95,25	119,06	ART -5 days
ART -4 days	4,63	9,25	13,88	18,50	23,13	27,75	37,01	46,26	55,51	64,76	74,01	92,51	ART -4 days
ART -3 days	3,59	7,19	10,78	14,38	17,97	21,57	28,75	35,94	43,13	50,32	57,51	71,89	ART -3 days
ART -2 days	2,79	5,59	8,38	11,17	13,96	16,76	22,34	27,93	33,52	39,10	44,69	55,86	ART -2 days
ART -1 day	2,17	4,34	6,51	8,68	10,85	13,02	17,36	21,70	26,04	30,38	34,72	43,40	ART -1 day
ART	1,69	3,37	5,06	6,75	8,43	10,12	13,49	16,86	20,24	23,61	26,98	33,73	ART
ART +1 day	1,31	2,62	3,93	5,24	6,55	7,86	10,48	13,10	15,72	18,34	20,97	26,21	ART +1 day
ART +2 days	1,02	2,04	3,05	4,07	5,09	6,11	8,15	10,18	12,22	14,25	16,29	20,36	ART +2 days
ART +3 days	0,79	1,58	2,37	3,16	3,96	4,75	6,33	7,91	9,49	11,08	12,66	15,82	ART +3 days
ART +4 days	0,61	1,23	1,84	2,46	3,07	3,69	4,92	6,15	7,38	8,61	9,84	12,29	ART +4 days
ART +5 days	0,48	0,96	1,43	1,91	2,39	2,87	3,82	4,78	5,73	6,69	7,64	9,55	ART +5 days
ART +6 days	0,37	0,74	1,11	1,48	1,86	2,23	2,97	3,71	4,45	5,20	5,94	7,42	ART +6 days
ART +7 days	0,29	0,58	0,87	1,15	1,44	1,73	2,31	2,88	3,46	4,04	4,61	5,77	ART +7 days

ART = Activity Reference Time | ART -7 days is production day

Tc-99m activities based on 89,5% average yield efficiency (standard error 0,03%)

Yield of a second elution

Hours after previous elution	% Tc-99m*
1	11%
2	20%
3	28%
4	36%
5	42%
6	48%
7	53%
8	57%
9	60%
10	64%
11	66%
12	69%

* Based on the values in the above table 'Technetium-99m (activities for one elution per day)'

Technical Information

Internal lead shields

Internal lead shield (mm)	Weight generator (kg)	Weight including box (kg)
42	12,0	15,6
56	18,0	21,6

Dimensions

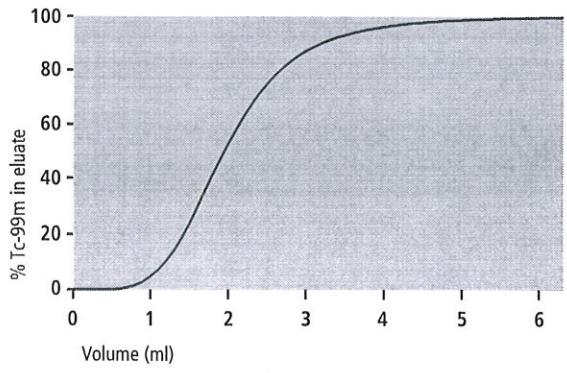
Dimensions	
Diameter Ultra-Technekow FM	135 mm
Height Ultra-Technekow FM	284 mm
Height Ultra-Technekow FM with Saline vial	325 mm
Height Ultra-Technekow FM with holder for needle protector DRN8262	344 mm

Elution speed

Evacuated vial	Time to complete elution (s)
5	60
11	38
25	82

Elution curve

Eluted volume (ml)	% Tc-99m eluted
0	0,0 %
1	4,9 %
2	52,8 %
3	87,1 %
4	96,3 %
5	98,8 %
6	99,7 %
7	100,0 %



Molybdenum-99

Mo-99 activity at 06:00 CET (in GBq)

Nominal activity in GBq	2,15	4,30	6,45	8,60	10,75	12,90	17,20	21,50	25,80	30,10	34,40	43,00	Nominal activity in GBq
ART -6 days	9,77	19,54	29,30	39,07	48,84	58,61	78,14	97,68	117,22	136,75	156,29	195,36	ART -6 days
ART -5 days	7,59	15,18	22,77	30,36	37,95	45,54	60,72	75,90	91,08	106,26	121,44	151,80	ART -5 days
ART -4 days	5,90	11,80	17,69	23,59	29,49	35,39	47,18	58,98	70,77	82,57	94,36	117,95	ART -4 days
ART -3 days	4,58	9,17	13,75	18,33	22,91	27,50	36,66	45,83	54,99	64,16	73,32	91,65	ART -3 days
ART -2 days	3,56	7,12	10,68	14,24	17,80	21,37	28,49	35,61	42,73	49,85	56,97	71,22	ART -2 days
ART -1 day	2,77	5,53	8,30	11,07	13,83	16,60	22,14	27,67	33,20	38,74	44,27	55,34	ART -1 day
ART	2,15	4,30	6,45	8,60	10,75	12,90	17,20	21,50	25,80	30,10	34,40	43,00	ART
ART +1 day	1,67	3,34	5,01	6,68	8,35	10,02	13,36	16,71	20,05	23,39	26,73	33,41	ART +1 day
ART +2 days	1,30	2,60	3,89	5,19	6,49	7,79	10,38	12,98	15,58	18,17	20,77	25,96	ART +2 days
ART +3 days	1,01	2,02	3,03	4,03	5,04	6,05	8,07	10,09	12,10	14,12	16,14	20,17	ART +3 days
ART +4 days	0,78	1,57	2,35	3,14	3,92	4,70	6,27	7,84	9,41	10,97	12,54	15,68	ART +4 days
ART +5 days	0,61	1,22	1,83	2,44	3,05	3,65	4,87	6,09	7,31	8,53	9,74	12,18	ART +5 days
ART +6 days	0,47	0,95	1,42	1,89	2,37	2,84	3,79	4,73	5,68	6,63	7,57	9,46	ART +6 days
ART +7 days	0,37	0,74	1,10	1,47	1,84	2,21	2,94	3,68	4,41	5,15	5,88	7,35	ART +7 days

ART = Activity Reference Time | ART -7 days is production day

Dose rates Ultra-Technekow FM generator

Dose rates Ultra-Technekow FM generator			
Internal lead shield	42	56	mm
Surface dose rate generator	85,1	20,6	µSv/hr per GBq Mo-99
Dose rate at 1 meter from generator	0,383	0,093	µSv/hr per GBq Mo-99

Delivery Information

Transport box

Type A package
Complies with international transport regulation of IAEA and related regulating organisations (ADR, IATA, ICAO, ICRP, IMO and CFR)
Dimensions of the box: w 40 x d 40 x h 40 cm
Includes elution kit
Box will be used for return shipment

Accessories

Each generator is shipped standard with the elution kit DRN4347 Accessories kit 11 ml
On request we can send a different elution kit than the standard one:
DRN4345 Accessories kit 5 ml, or
DRN4348 Accessories kit 25 ml (shipped with one extra eluent vial)

First time delivery

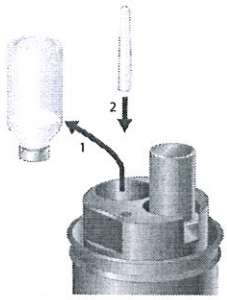
The first time an Ultra-Technekow FM is supplied, we will also supply:
Elution shield (DRN8271, DRN8272 or DRN8275)
Holder for needle protector (DRN8262 or DRN8265)

Return of used Ultra-Technekow FM generators

For return please use the same box in which the generator has been delivered. We will provide all necessary shipment documentation for return shipment. Before packing the generator for return shipment make sure to elute the remaining fluid from the generator. For instructions please refer to the following page 'Return of the Ultra-Technekow FM generator'. Depending on distribution planning we will exchange a used generator at the moment of a new delivery or regularly collect decayed generators.

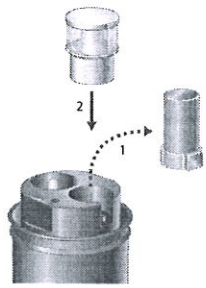
Our local Mallinckrodt representative is able to give you more information on deliveries. Please consult the competent authority in your country on handling of radioactive material.

Return of the Ultra-Technekow FM generator



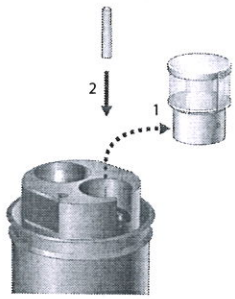
1 1 Remove the eluent vial
2 Place the original needle cover on the inlet needle

2 Place an evacuated vial in an elution shield

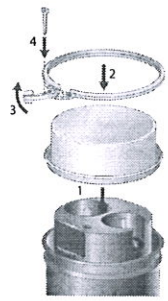


3 1 Replace the holder with needle protector
2 with the elution shield with evacuated vial

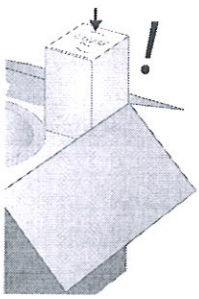
4 Elution starts



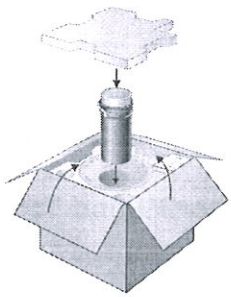
5 1 Replace the elution shield
2 with the original needle cover on the outlet needle



6 1 Close the generator with top cover,
2-3 closing ring and
4 seal



7 Place the used elution kit in the transport box

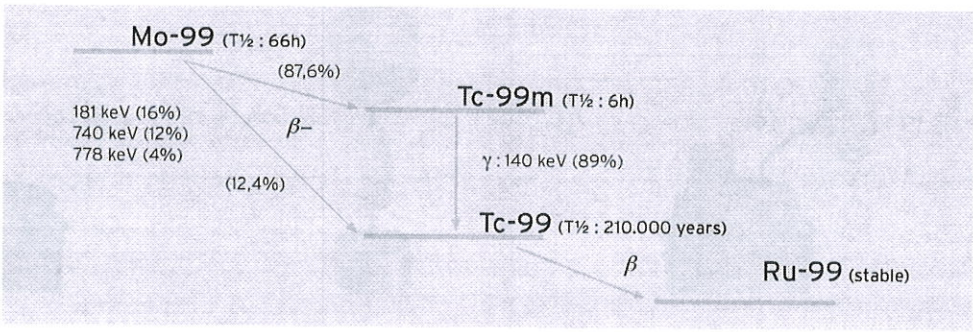


8 Place the used generator in its original shipping box and close off

Please store the generator in a suitable place for decay to a level acceptable for disposal.
Make sure to follow the relevant procedures for return of the generator in its transport box.

Physical Characteristics

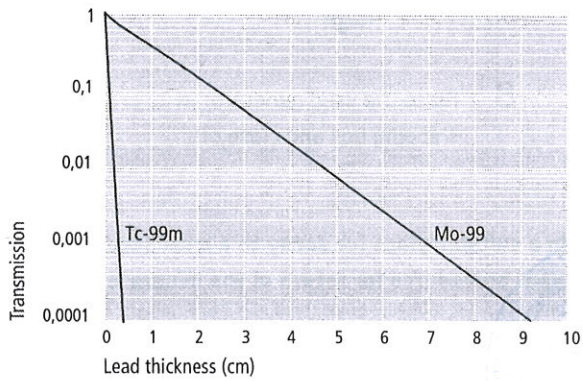
Decay schedule Mo-99



Decay factors

	Mo-99		Tc-99m
1d	0,7772	1h	0,8910
2d	0,6040	2h	0,7939
3d	0,4695	3h	0,7074
4d	0,3649	4h	0,6303
5d	0,2836	5h	0,5616
6d	0,2204	6h	0,5004
7d	0,1713	7h	0,4459
8d	0,1331	8h	0,3973
9d	0,1035	9h	0,3540
10d	0,0804	10h	0,3154
11d	0,0625	11h	0,2810
12d	0,0486	12h	0,2504
13d	0,0378	13h	0,2231
14d	0,0293	14h	0,1988

Transmission of Mo-99 and Tc-99m through lead



Units

Name	Symbol	Description	Conversion (often used)	SI / Traditional
Becquerel	Bq	1 Bq = 1 disintigration per second (dps)	1 Bq = 27 pCi	SI
Curie	Ci	1 Ci = roughly the activity of 1 gramme of the radium isotope Ra-226	1 Ci = 37 GBq	Traditional
Gray	Gy	unit of absorbed dose, physical effect of radation	1 Gy = 1 J/kg = 100 rad	SI derived
Rad	Rd	absorbed dose	1 rad = 1 x 10^{-2} J/kg	Traditional
Sievert	Sv	unit of dose equivalent, biological effect of radiation	1 Sv = 1 J/kg x W_r = 100 rem	SI derived
Rem	rem	röntgen equivalent man, dose equivalent	1 rem = 1 x 10^{-2} Sv	Traditional

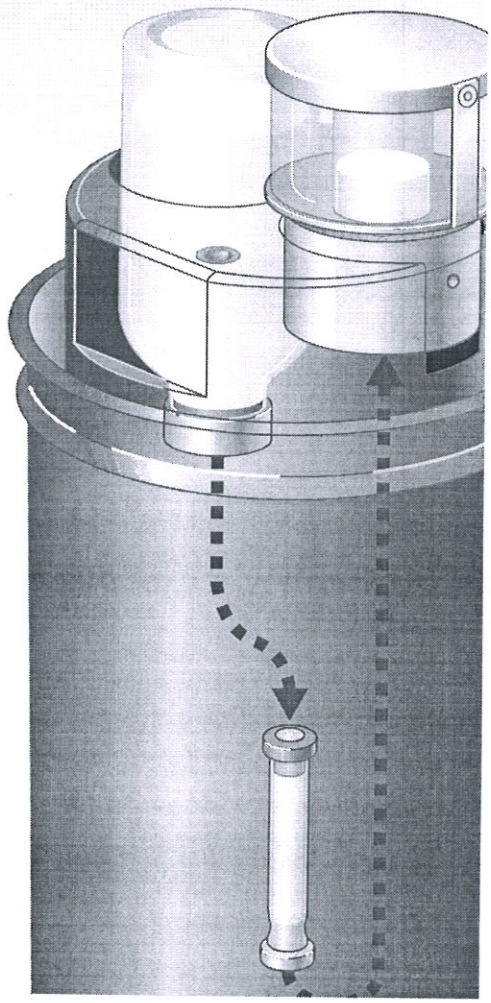
W_r = radiation weighting factor

Pre-fixes for SI units

Factor	Name	Symbol
10^{12}	tera	T
10^{9}	giga	G
10^{6}	mega	M
10^{3}	kilo	k
10^{-3}	milli	m
10^{-6}	micro	µ
10^{-9}	nano	n
10^{-12}	pico	p

Conversion table Bq <> Ci

Conversion table Bq <> Ci	
1 Bq = 27 pCi	1 nCi = 37 Bq
1 kBq = 27 nCi	1 µCi = 37 kBq
1 MBq = 27 µCi	1 mCi = 37 MBq
1 GBq = 27 mCi	1 Ci = 37 GBq



Notes

Notes

Availability

- Production and shipment every working day
- Range (activity in Mo-99): 2,15 / 4,30 / 6,45 / 8,60 / 10,75 / 12,90 / 17,20 / 21,50 / 25,80 / 30,10 / 34,40 / 43,00 GBq
- Activity Reference Time (ART): 7 days after production, 06:00 CET
- Expiry: 9 days after ART

Please consult your local Mallinckrodt representative to discuss our extensive distribution network.

Prescribing Information

Ultra-Technekow™ FM Mo-99/Tc-99m generator

COMPOSITION: A sterile generator containing the parent isotope ^{99}Mo, adsorbed to an aluminium oxide column. The ^{99}Mo on the column is in equilibrium with the formed daughter isotope ^{99m}Tc. PHARMACEUTICAL FORM: Radionuclide generator. THERAPEUTIC INDICATIONS: The eluate from the generator (Sodium Pertechnetate (^{99m}Tc) Injection Ph. Eur.) may be used as a reagent for labelling of various carrier compounds supplied as kits or administered directly in-vivo. Indications include: Thyroid scintigraphy; Salivary gland scintigraphy; Location of Meckel's diverticulum; Cerebral scintigraphy; Lacrimal duct scintigraphy: to assess patency of tear ducts. ^{99m}Tc-labelling of red blood cells: Cardiac and vascular scintigraphy; Diagnosis and localisation of occult gastrointestinal bleeding. POSOLOGY AND METHOD OF ADMINISTRATION: Sodium pertechnetate (^{99m}Tc) is normally administered intravenously at activities which vary widely according to the clinical information required and the equipment employed. Pre-treatment of patients with thyroid blocking agents or reducing agents may be necessary for certain indications. Children: The activity for administration to children may be calculated from the recommended range of adult activity and adjusted according to body weight or surface area. CONTRA-INDICATIONS: Hypersensitivity to the active substance or any of the excipients. SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE: Radiopharmaceutical agents should be used only by qualified personnel with the appropriate government authorizations for the use and manipulations of radionuclides. INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION: Drug interactions have been reported in brain scintigraphy where there can be increased uptake of (^{99m}Tc) pertechnetate in the walls of cerebral ventricles as a result of methotrexate-induced ventriculitis. In abdominal imaging drugs, such as atropine, isoprenaline and analgesics, can result in a delay in gastric emptying and redistribution of pertechnetate. PREGNANCY AND LACTATION: ^{99m}Tc (as free pertechnetate) has been shown to cross the placental barrier. When it is necessary to administer radioactive medicinal products to a woman of childbearing potential, information should always be sought about pregnancy. Radionuclide procedures carried out on pregnant women also involve radiation doses to the foetus. Only imperative investigations should be carried out during pregnancy, when the likely benefit exceeds the risk incurred by the mother and the foetus. Before administering a radioactive medicinal product to a woman who is breast-feeding, consideration should be given as to whether the investigation could be reasonably delayed until the mother has ceased breast-feeding and as to whether the most appropriate choice of radiopharmaceutical has been made. If the administration is considered necessary, breast-feeding should be interrupted for at least 12 hours and the expressed feeds discarded. Breast-feeding can be restarted when the activity level in the milk will not result in a radiation dose to the child greater than 1 mSv. UNDESIRABLE EFFECTS: Information on adverse reactions is available from spontaneous reporting. The reported reaction types are anaphylactoid reactions, vegetative reactions, as well as different kinds of injection site reactions. ^{99m}Tc-perchtechnetate from the Ultra-Technekow FM generator is used for radioactive labeling of a variety of compounds. These pharmaceuticals generally have a higher potential for side effects than ^{99m}Tc, and therefore the reported side effects are rather related to the labelled compounds than to ^{99m}Tc. The possible types of side effects following intravenous administration of a ^{99m}Tc-labelled pharmaceutical preparation will be dependent on the specific compound being used. Such information should be available from the manufacturer of the pharmaceutical which is to be radiolabelled. Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. For diagnostic nuclear medicine investigations, the current evidence suggests that these adverse effects will occur with low frequency because of the low radiation doses incurred. For most diagnostic investigations using a nuclear medicine procedure, the radiation dose delivered is less than 20 mSv EDE. Higher doses may be justified in some clinical circumstances. This product contains no excipients that have a recognised action or effect, or knowledge of which is important for safe and effective use of the product.

MANUFACTURED AND RELEASED BY: Mallinckrodt Medical B.V., Westerduinweg 3, 1755 LE, Petten, The Netherlands. DATE OF PREPARATION OF THIS INFORMATION: 18 SEPT 2013.

Product availability and Summary of Product Characteristics may differ from one country to another.

For your country's specific information, please contact your local Mallinckrodt Office or Representative.

Mallinckrodt Pharmaceuticals

MALLINCKRODT MEDICAL B.V.
P.O. Box 3, 1755 ZG Petten, the Netherlands

curium™
LIFE FORWARD

TEKCIS®

Proven quality in modern design

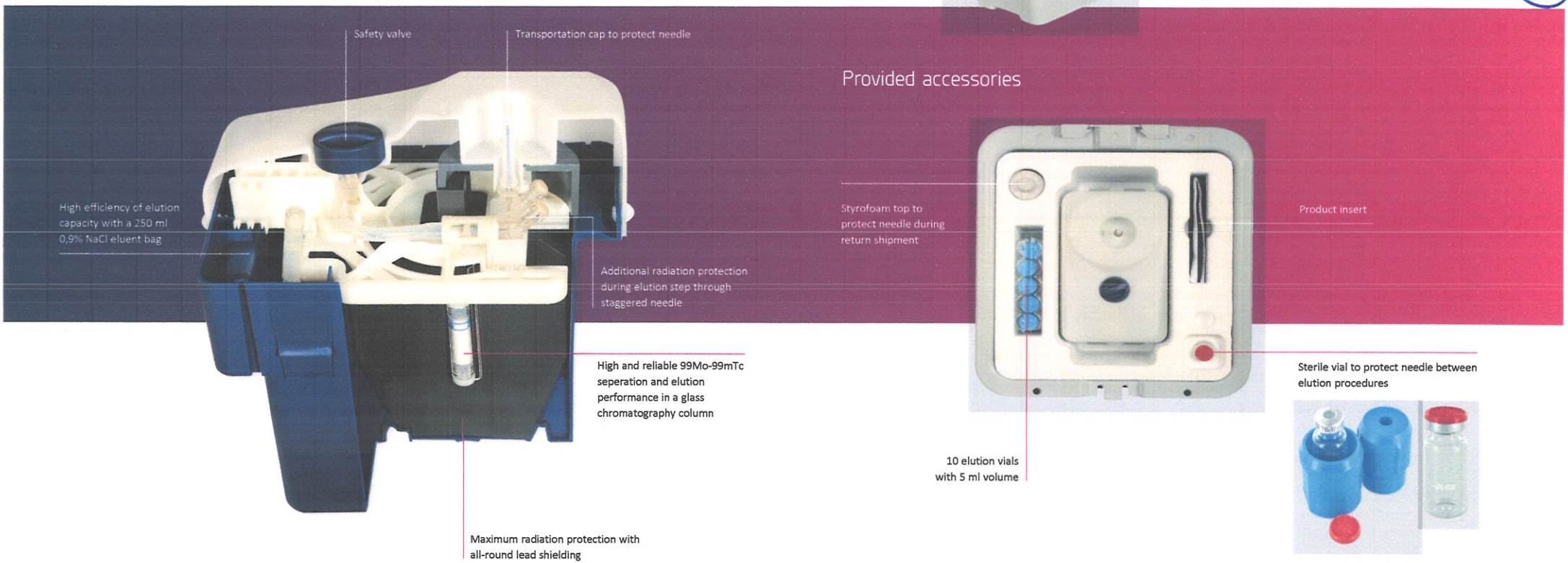
Mo-99/Tc-99m Generator

Features, that make a difference

TEKCIS®

Proven quality in modern design

TEKCIS is characterized by high reliability and easy and ergonomic handling. The profile shows elaborate composition and secured functionality of the generators.



Details of TEKCIS handling

TEKCIS will bedelivered in a type A package. The box is well-stackable.

Opening of packaging

Please withdraw fixing screw with rotary motion and store cap for return. Please press lateral holding down and push off top.

Provided accessories

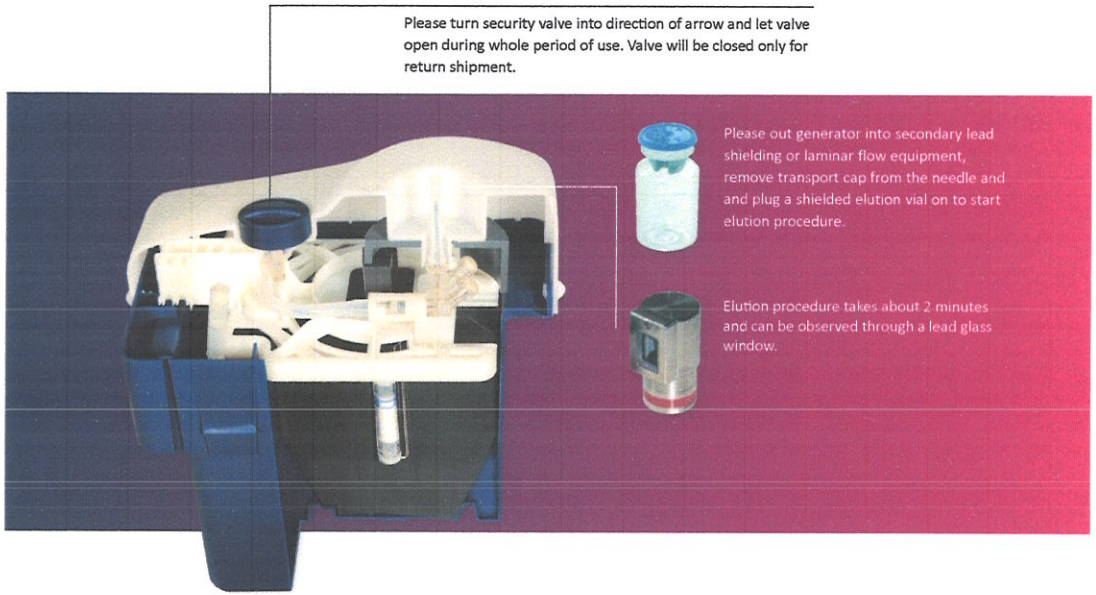
Sterile vial to protect needle between elution procedures

Sterile vial is used to protect needle between elution procedures. There is a shielding for this vial, that allows better handling and can be ordered with product code REF: 5001597- PROT-STE-ELU.

TEKCIS®

Proven quality in modern design

Before first elution



It is possible to use 5, 10 or 15 ml elution vials. Usually generator packages includes 10 vials with 5 ml elution volume.

After / between elutions

Please put sterile vial on the needle between elution procedures.

Needle has to be protected with styrofoam top **for return shipment**. Please put generator back into original transportation box and fill in transportation papers according to ADR requirements..

Yield Tables TEKCIS

Delivery Monday > Activity Reference Date Wednesday (at 12 am / data in GBq)

Activity Tc-99m	-2 Mon.	-1 Tues.	0 Wed.	+1 Thur.	+2 Fri.	+3 Sat.	+4 Sun.	+5 Mon.	+6 Tues.	+7 Wed.	+8 Thurs.
TEKCIS-2	3,3	2,6	2	1,6	1,2	0,9	0,7	0,6	0,4	0,3	0,3
TEKCIS-4	6,6	5,1	4	3,1	2,4	1,9	1,5	1,1	0,9	0,7	0,5
TEKCIS-6	9,9	7,7	6	4,7	3,6	2,8	2,2	1,7	1,3	1,0	0,8
TEKCIS-8	13,2	10,3	8	6,2	4,8	3,8	2,9	2,3	1,8	1,4	1,1
TEKCIS-10	16,6	12,9	10	7,8	6,0	4,7	3,6	2,8	2,2	1,7	1,3
TEKCIS-12	19,9	15,4	12	9,3	7,2	5,6	4,4	3,4	2,6	2,1	1,6
TEKCIS-16	26,5	20,6	16	12,4	9,7	7,5	5,8	4,5	3,5	2,7	2,1
TEKCIS-20	33,1	25,7	20	15,5	12,1	9,4	7,3	5,7	4,4	3,4	2,7
TEKCIS-25	41,4	32,2	25	19,4	15,1	11,7	9,1	7,1	5,5	4,3	3,3

Delivery Friday > Activity Reference Date Monday (at 12 am / data in GBq)

Activity Tc-99m	-3 Fri.	-2 Sat.	-1 Sun.	0 Mon.	+1 Tues.	+2 Wed.	+3 Thur.	+4 Fri.	+5 Sat.	+6 Sun.	+7 Mon.	+8 Tues.
TEKCIS-2	4,3	3,3	2,6	2	1,6	1,2	0,9	0,7	0,6	0,4	0,3	0,3
TEKCIS-4	8,5	6,6	5,1	4	3,1	2,4	1,9	1,5	1,1	0,9	0,7	0,5
TEKCIS-6	12,8	9,9	7,7	6	4,7	3,6	2,8	2,2	1,7	1,3	1,0	0,8
TEKCIS-8	17,0	13,2	10,3	8	6,2	4,8	3,8	2,9	2,3	1,8	1,4	1,1
TEKCIS-10	21,3	16,6	12,9	10	7,8	6,0	4,7	3,6	2,8	2,2	1,7	1,3
TEKCIS-12	25,6	19,9	15,4	12	9,3	7,2	5,6	4,4	3,4	2,6	2,1	1,6
TEKCIS-16	34,1	26,5	20,6	16	12,4	9,7	7,5	5,8	4,5	3,5	2,7	2,1
TEKCIS-20	42,6	33,1	25,7	20	15,5	12,1	9,4	7,3	5,7	4,4	3,4	2,7
TEKCIS-25	53,2	41,4	32,2	25	19,4	15,1	11,7	9,1	7,1	5,5	4,3	3,3

Delivery Wednesday > Activity Reference Date Saturday (at 12 am / data in GBq)

Activity Tc-99m	-3 Wed.	-2 Thur.	-1 Fri.	0 Sat.	+1 Sun.	+2 Mon.	+3 Tues.	+4 Wed.	+5 Thur.	+6 Fri.	+7 Sat.	+8 Sun.
TEKCIS-2	4,3	3,3	2,6	2	1,6	1,2	0,9	0,7	0,6	0,4	0,3	0,3
TEKCIS-4	8,5	6,6	5,1	4	3,1	2,4	1,9	1,5	1,1	0,9	0,7	0,5
TEKCIS-6	12,8	9,9	7,7	6	4,7	3,6	2,8	2,2	1,7	1,3	1,0	0,8
TEKCIS-8	17,0	13,2	10,3	8	6,2	4,8	3,8	2,9	2,3	1,8	1,4	1,1
TEKCIS-10	21,3	16,6	12,9	10	7,8	6,0	4,7	3,6	2,8	2,2	1,7	1,3
TEKCIS-12	25,6	19,9	15,4	12	9,3	7,2	5,6	4,4	3,4	2,6	2,1	1,6
TEKCIS-16	34,1	26,5	20,6	16	12,4	9,7	7,5	5,8	4,5	3,5	2,7	2,1
TEKCIS-20	42,6	33,1	25,7	20	15,5	12,1	9,4	7,3	5,7	4,4	3,4	2,7
TEKCIS-25	53,2	41,4	32,2	25	19,4	15,1	11,7	9,1	7,1	5,5	4,3	3,3

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Available activities*

Tc-99m activity Max. elutable activity at activity reference time 12:00 CET	2	4	6	8	10	12	16	20	25	50	GBq
Mo-99 activity at activity reference time 12:00 CET	2,5	5	7	9,5	12	14,5	19	24	30	60	GBq

Accessories TEKCIS

Product	Product Code	Package Unit
Elution Vials		
5 ml Evacuated vials	TC-ELU-5-10	10 Vials
10 ml Evacuated vials	TC-ELU-10-10	10 Vials
15 ml Evacuated vials	TC-ELU-15-10	10 Vials
Needle Protection		
Sterile vials	STE-ELU	5 Vials
Shielding		
For sterile needle protection vials	PROT-STE-ELU	1
Radiation Protection		
Lead-steel-shielding for elution vials	CONT-ELU	1
Lead shielding for generatorr	PROTEC-ELU	1

Data of secondary Lead Shielding PROTEC ELU

Door	Walls	Size	Weight
42 mm lead and steel	46 mm lead and steel	Height: 335 mm Depth: 315 mm Width: 380 mm	160 kg

Maximal Radiation Protection

Maximal dose rate can be reduced with secondary lead shielding by factor 100.

All activity details are based on internal data of our production plant in Saclay.

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Prescribing Information

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COMPOSITION: The radionuclide generator containing the parent isotope 99Mo, adsorbed to a chromatographic column, delivers sodium pertechnetate (99mTc) injection in sterile solution. The 99Mo on the column is in equilibrium with the formed daughter isotope 99mTc. **PHARMACEUTICAL FORM:** Radionuclide generator. **THERAPEUTIC INDICATIONS:** The eluate from the radionuclide generator (Sodium Pertechnetate (99mTc) Injection Ph. Eur.) is indicated for:Labelling of various kits for radiopharmaceutical preparation developed and approved for radiolabelling with such solution. Indications include: Thyroid scintigraphy; Salivary gland scintigraphy; Location of ectopic gastric mucosa (Meckel's diverticulum); Lacrimal duct scintigraphy. **POSOLOGY AND METHOD OF ADMINISTRATION:** Sodium pertechnetate (99mTc) is normally administered intravenously at activities which vary widely according to the clinical information required and the equipment employed. Other activities may be justifiable. The injection of activities greater than local DRLs (Diagnostic Reference Levels) should be justified. Pre-treatment of patients with thyroid blocking agents or reducing agents may be necessary for certain indications. Paediatric population: The use in children and adolescents has to be considered carefully, based upon clinical needs and assessing the risk/benefit ratio in this patient group. The activities to be administered to children and to adolescents may be calculated according to the European Association of Nuclear Medicine (EANM-May 2008) guidelines, by using the formula corresponding to the indication concerned and the relevant correction factor corresponding to the body mass of the young patient. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the excipients. **SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE:** Potential for hypersensitivity or anaphylactic reactions: If hypersensitivity or anaphylactic reactions occur, the administration of the medicinal product must be discontinued immediately and intravenous treatment initiated, if necessary. To enable immediate action in emergencies, the necessary medicinal products and equipment such as endotracheal tube and ventilator must be immediately available. Individual benefit/risk justification For each patient, the radiation exposure must be justifiable by the likely benefit. The activity administered should in every case be as low as reasonably achievable to obtain the required diagnostic information. Renal impairment: Careful consideration of the benefit risk ratio in these patients is required since an increased radiation exposure is possible. Paediatric population: For information on the use in paediatric population, see above Careful consideration of the indication is required since the effective dose per MBq is higher than in adults. Patient preparation: Pre-treatment of patients with thyroid-blocking agents or reducing agents may be necessary for certain indications. The patient should be well hydrated before the start of the examination and urged to void as often as possible during the first hours after the examination in order to reduce radiation. In Meckel's diverticulum scintigraphy, the patient should be fasting for 3 to 4 hours prior to examination, to keep the small bowel peristalsis low. After the procedure: Close contact with infants and pregnant women should be restricted during 12 h.Specific warnings: Sodium pertechnetate (99mTc) solution for injection contains 3.6 mg/mL of sodium. Depending on the time when you administer the injection, the content of sodium given to the patient may in some cases be greater than 1 mmol. This should be taken into account in patient on low sodium diet. When labelling kit, the sodium content of the dose administered must take into account the sodium derived from the eluate and the kit. Please refer to the package leaflet of the kit considered. **INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:** Atropine, isoprenaline and analgesics may cause a delay of gastric emptying and thereby cause a redistribution of (99mTc) pertechnetate in abdominal imaging. Administration of laxatives should be withheld since they irritate the gastrointestinal tract. Contrastenhanced studies (e.g. barium) and upper GI examination should be avoided within 48 h prior to administration of pertechnetate (99mTc) for Meckel's diverticulum scintigraphy. Many pharmacological agents are known to modify the thyroid uptake: Antithyroid agents (e.g. carbimazole or other imidazole derivatives such as propylthiouracil), salicylates, steroids, sodium nitroprusside, sodium sulfobromophtalein, perchlorate should be withheld for 1 week prior thyroid scintigraphy; phenylbutazone and expectorants should be withheld for 2 weeks; natural or synthetic thyroid preparations (e.g. sodium thyroxine, sodium liothyronine, thyroid extract) should be withheld for 2-3 weeks; amiodarone, benzodiazepines, lithium should be withheld for 4 weeks; intravenous contrast agents should not have been administered within 1-2 months. **FERTILITY, PREGNANCY AND LACTATION:** When an administration of radiopharmaceuticals to a woman of childbearing potential is intended, it is important to determine whether or not she is pregnant. Any woman who has missed a period should be assumed to be pregnant until proven otherwise. If in doubt about her potential pregnancy (if the woman has missed a period, if the period is very irregular, etc.), alternative techniques not using ionizing radiation (if there are any) should be offered to the patient. 99mTc (as free pertechnetate) has been shown to cross the placental barrier. Before administering radiopharmaceuticals to a mother who is breast-feeding, consideration should be given to the possibility of delaying the administration of radionuclide until the mother has ceased breastfeeding, and to what is the most appropriate choice of radiopharmaceuticals, bearing in mind the secretion of activity in breast milk. If the administration is considered necessary, breast-feeding should be interrupted for 12 hours post administration and the expressed feeds discarded. Close contact with infants should be restricted during this period. **UNDESIRABLE EFFECTS:** Information on adverse reactions is available from spontaneous reporting. The reported reaction types are anaphylactoid reactions, vegetative reactions, as well as different kinds of injection site reactions. Sodium pertechnetate (99mTc) from the Tekcis generator is used for radioactive labelling of a variety of compounds. These pharmaceuticals generally have a higher potential for side effects than 99mTc, and therefore the reported side effects are rather related to the labelled compounds than to 99mTc. The possible types of side effects following intravenous administration of a 99mTc-labelled pharmaceutical preparation will be dependent on the specific compound being used. Such information can be found in the SmPC of the kit used for radiopharmaceutical preparation. Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is 5.2 mSv when the maximal recommended activity of 400 MBq is administered these adverse reactions are expected to occur with a low probability. **MARKETING AUTHORIZAZION HOLDER:** CIS bio international, B.P. 32, F-91192 Gif sur Yvette Cedex. **DATE OF PREPARATION OF THIS INFORMATION:** 23 July 2018. **PRINTING DATE:** 23 July 2018

Product availability and Summary of Product Characteristics may differ from one country to another.
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