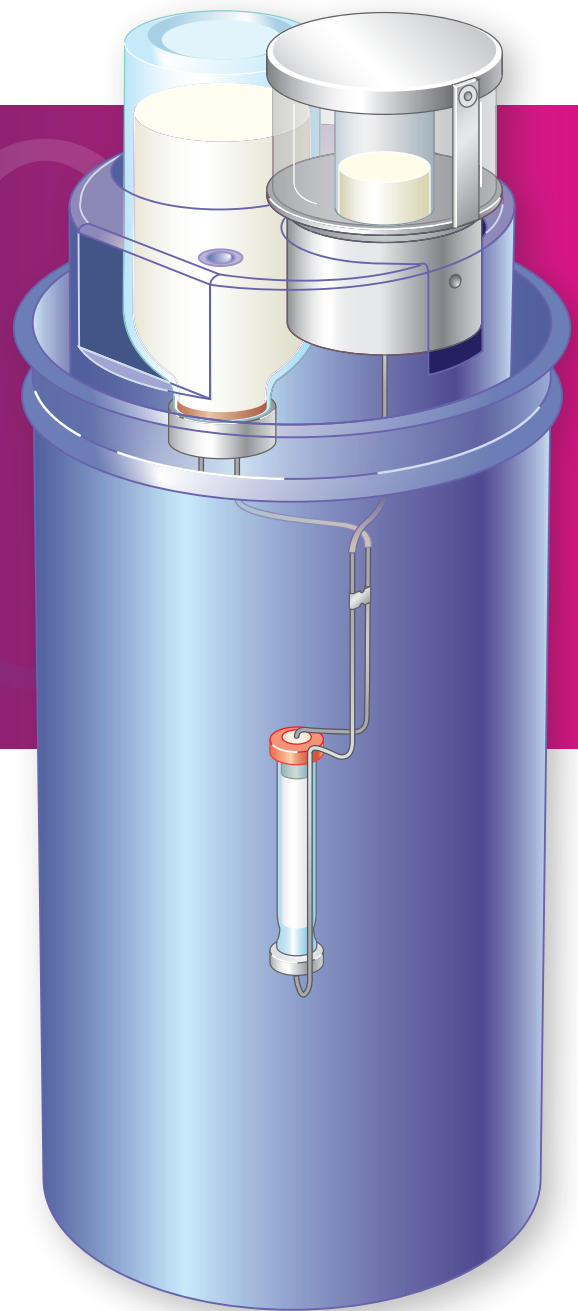
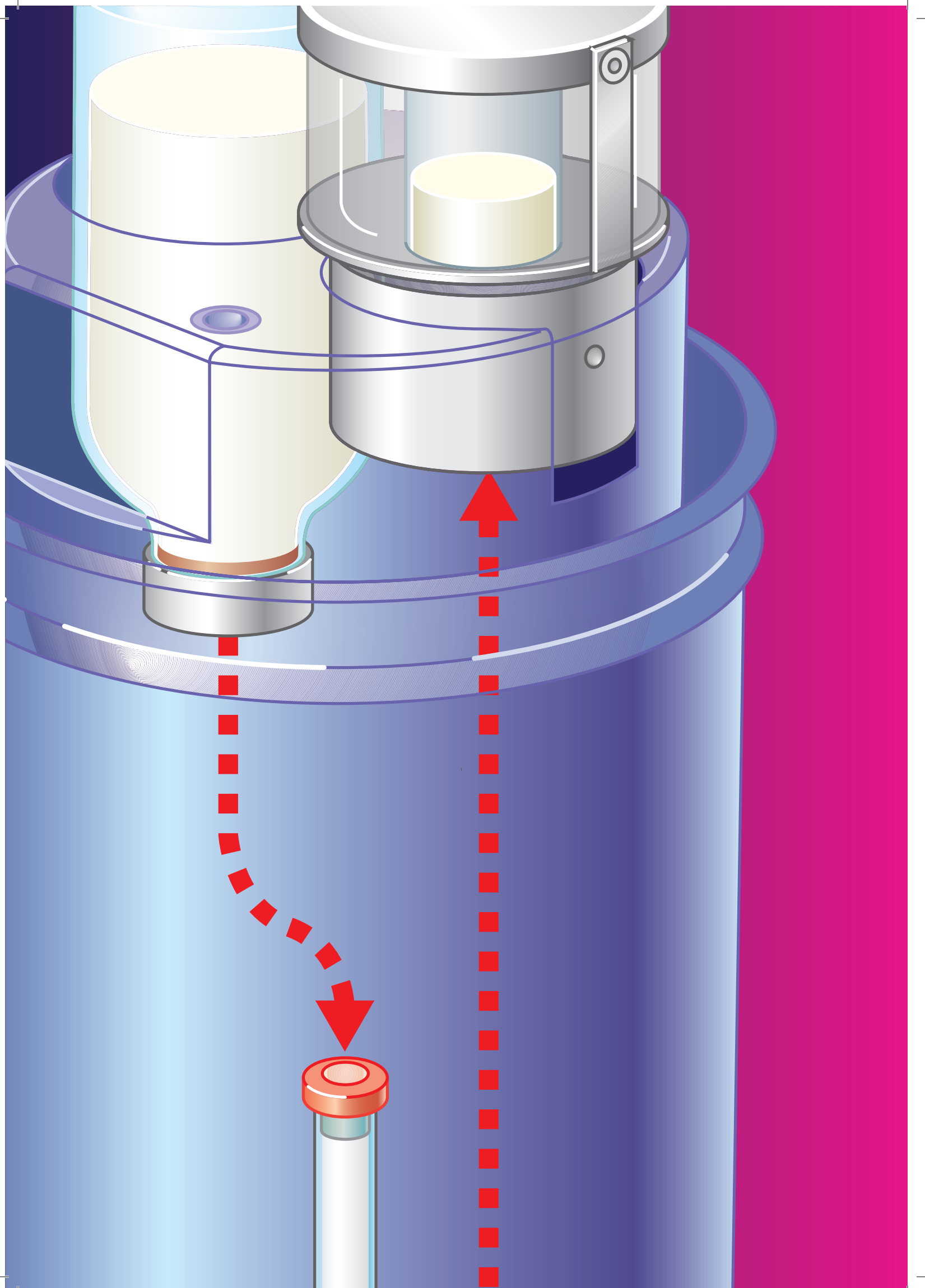


Ultra-Technekow™ FM

Mo-99/Tc-99m generator

Product Information



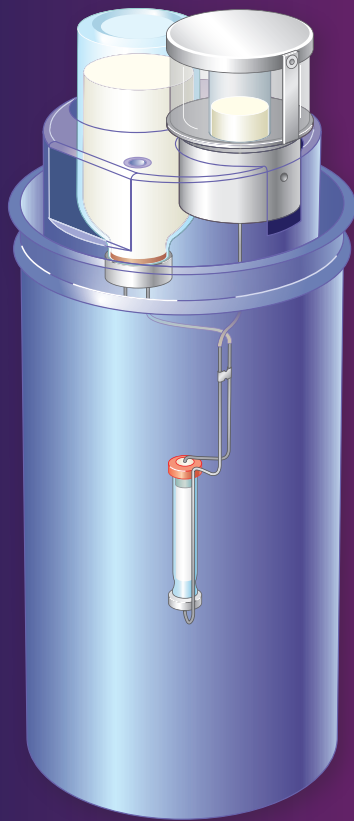


Content

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Why choose

Ultra-Technekow FM?



Reliable Moly Supply

Curium 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. Curium 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.

CURIUM™
LIFE FORWARD

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 Al³⁺ 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

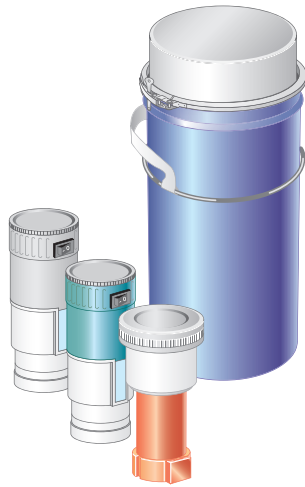
Start

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



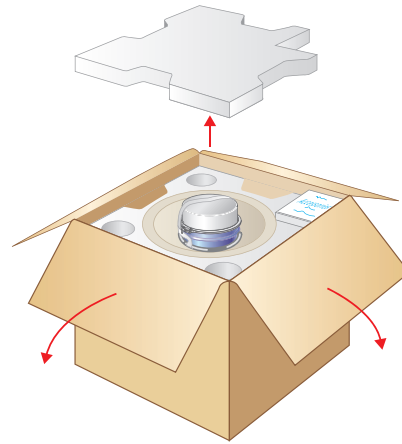
1 Accessories for use in a cabinet or isolator:

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

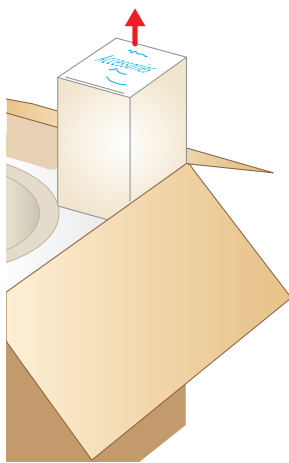


2 Accessories for use in one of our secondary safes (DRN8230 and DRN8260):

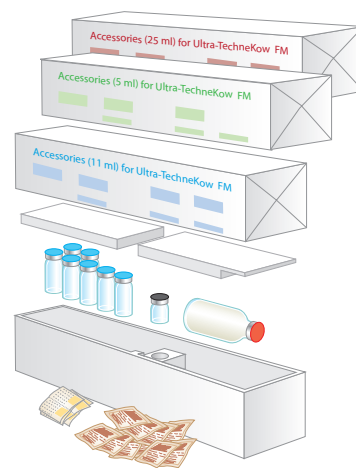
Holder for needle protector: DRN8265 Technestat shield
 Elution shield: DRN8271 Ultravial shield™ 11 ml (for 5 and 11 ml sterile evacuated vial) or DRN8272 Ultravial shield™ 25 ml (for 25 ml sterile evacuated vial).



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).

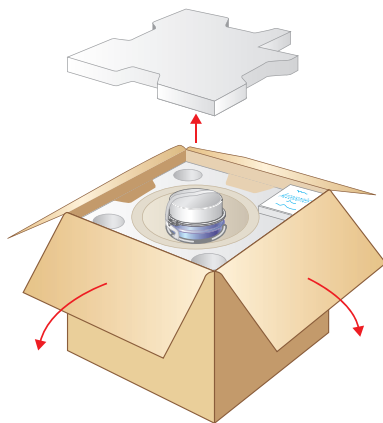


5 An elution kit contains:

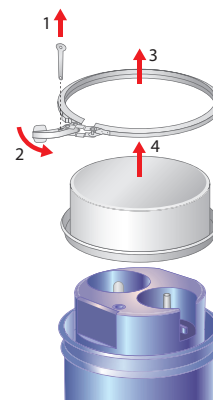
- 7x sterile evacuated vials (5, 11 or 25 ml)
- 1x 5 ml sterile needle protector
- 1x sterile eluent vial 100 ml NaCl 0,9%
- 7x disinfection swabs
- 7x radioactivity labels

How to use our Ultra-Technekow FM generator

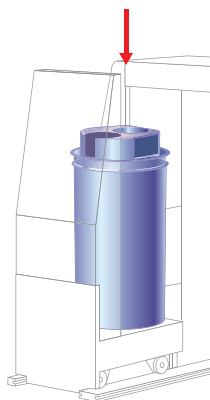
Preparation



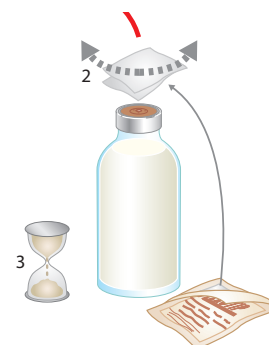
- 1 Take the generator out of the transport box (and store the box and packaging materials for later use).



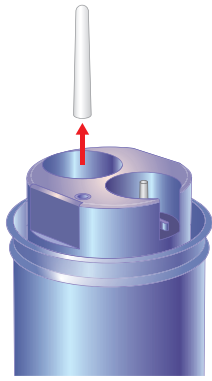
- 2
1 Pull out the seal
2-3 Open the closing ring and remove it
4 Take the top cover off (and store for later use)



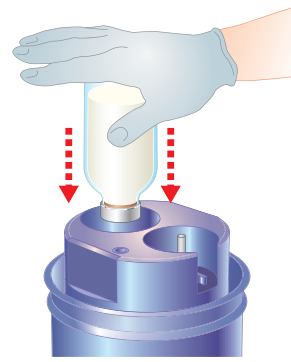
- 3 Put the Ultra-Technekow FM with the elution station facing forward in a lead castle or behind any other suitable laboratory shielding.



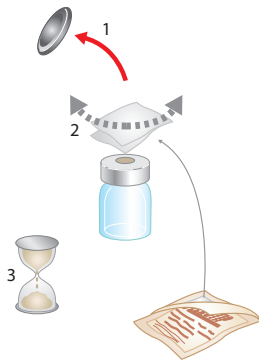
- 4
1 Remove the flip-off cover from an eluent vial
2 Disinfect the stopper
3 Let the disinfectant evaporate completely



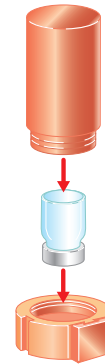
- 5 Remove the plastic cover from the inlet needle (and store for later use).



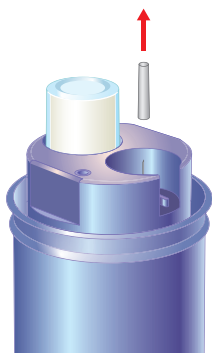
- 6 Lower the eluent vial gently and without turning on the inlet needle.



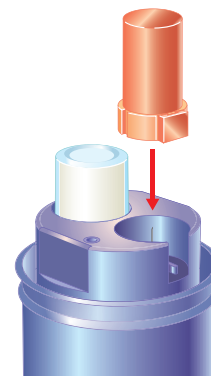
- 7
- 1 Remove the flip-off cover from a needle protector
 - 2 Disinfect the stopper
 - 3 Let the disinfectant evaporate completely



- 8 Place the needle protector in its holder.



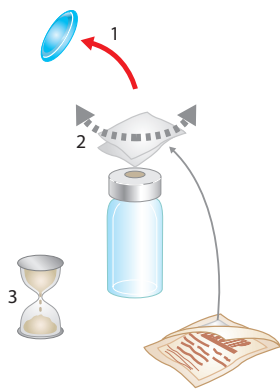
- 9 Remove the rubber cover from the outlet needle (and store for later use).



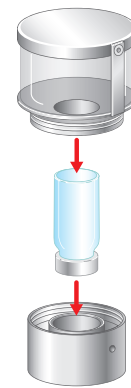
- 10 Lower the holder with needle protector on to the elution station.

How to use our Ultra-Technekow FM generator

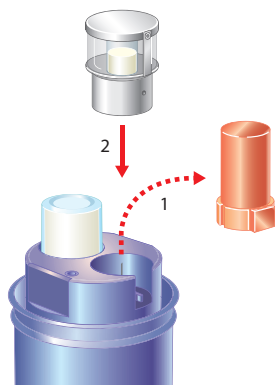
Elution



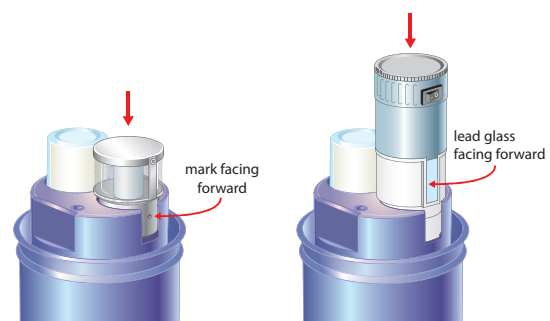
- 1 Remove the flip-off cover from an evacuated vial
- 2 Disinfect the stopper
- 3 Let the disinfectant evaporate completely



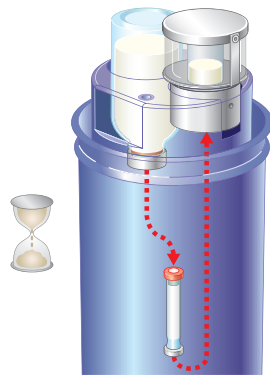
- 2 Place the evacuated vial in an elution shield.



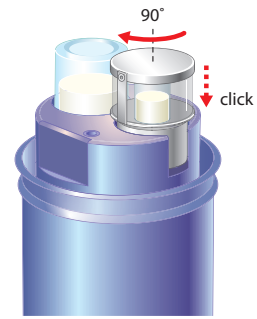
- 3
- 1 Replace the holder with needle protector with the elution shield
- 2



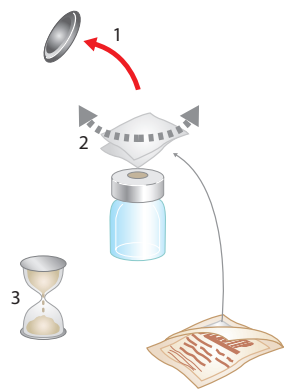
- 4 Lower the elution shield with evacuated vial on to the generator
 - a Clear View: mark facing forward **or**
 - b when using an Ultravial shield: lead glass facing forward



5 Elution starts.

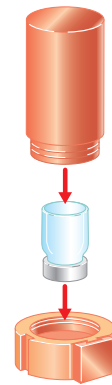


6 To stop the elution process turn the elution shield 90 degrees.

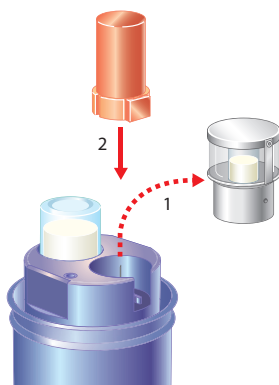


7

- 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

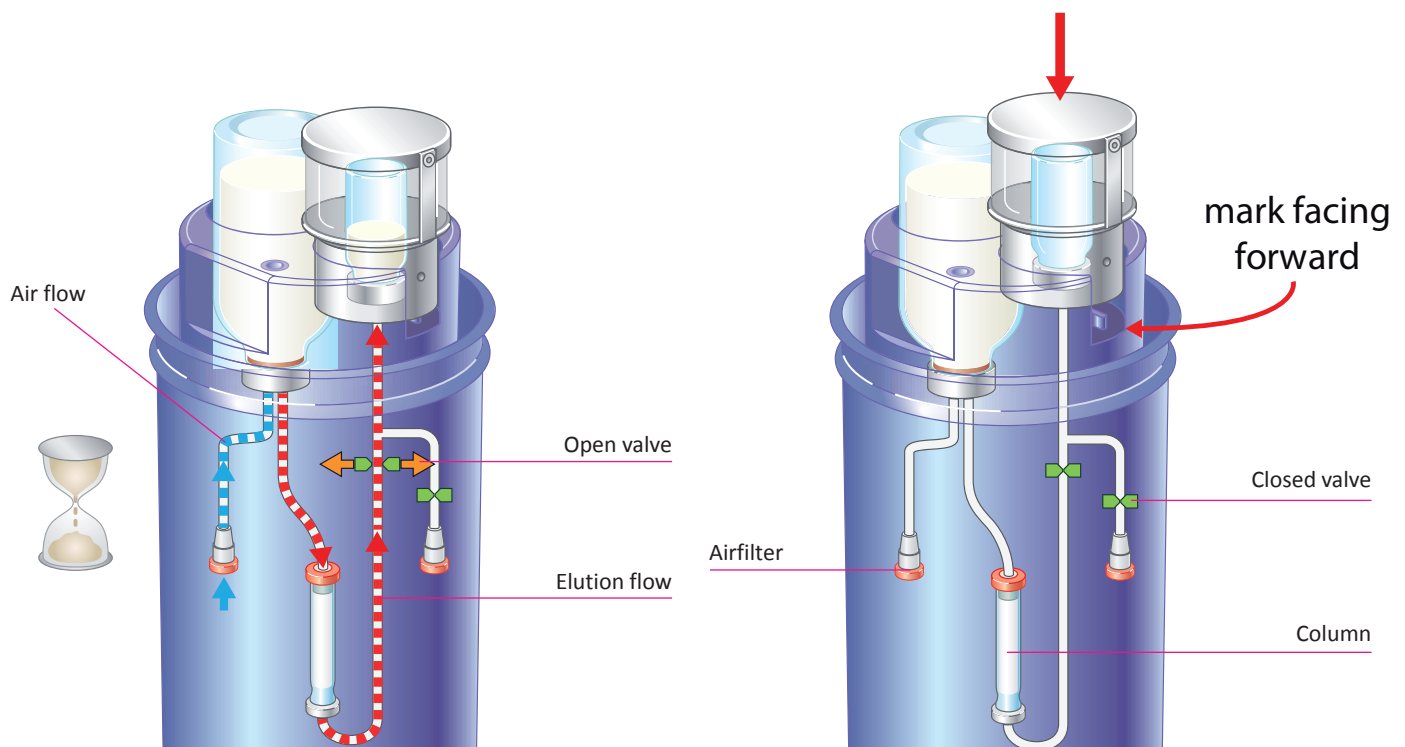
- 1 Replace the elution shield
- 2 with the holder with needle protector

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

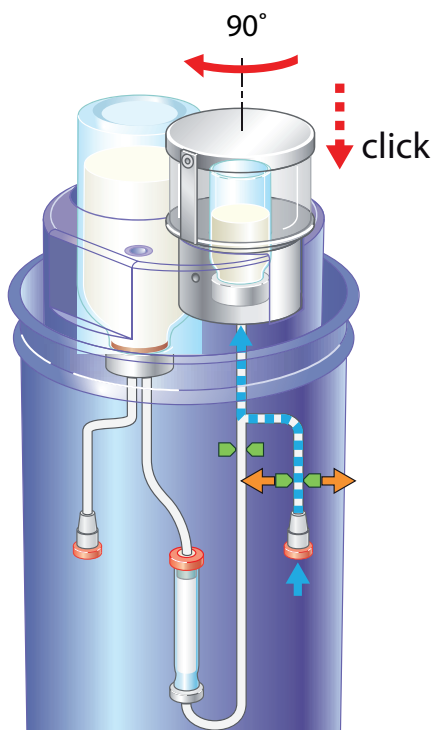
an exclusive feature of Ultra-Technekow FM

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.

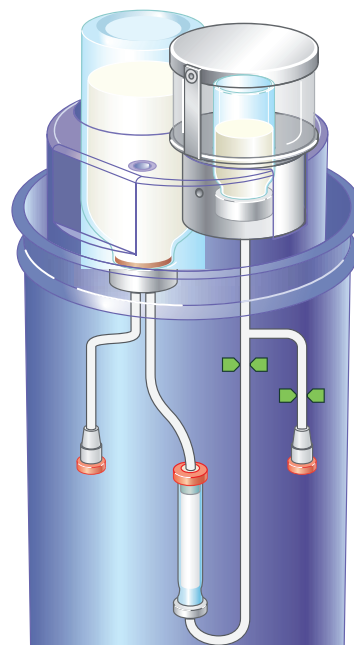


- A** Lower the elution shield with evacuated vial on to the generator
- a Clear View: mark facing forward or
 - b when using an Ultravial shield: lead glass facing forward

- 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 µSv/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 µSv/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 $\mu\text{Sv/hr}$ per GBq Tc-99m.

\varnothing d 45/62 x h 150 mm.

Weight 1047 g.

Needs 2x AA LR6 1,5V alkaline batteries.

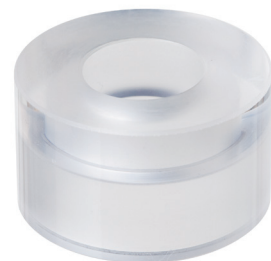


Adaptor ring

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 $\mu\text{Sv/hr}$ 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 $\mu\text{Sv/hr}$ 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

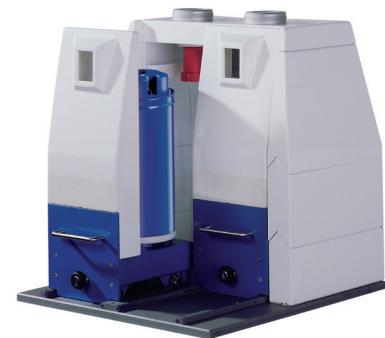
Dose rates	DRN8230 Lead castle FM™		
Lead wall mono safe	50	14,14	21,22
Internal UTK lead shield	42	56	mm
Total lead shielding	92	106	mm
Surface dose rate	0,0665	0,0159	µSv/hr per GBq Mo-99
Dose rate at 1 meter	0,0020	0,0005	µSv/hr per GBq Mo-99

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

Techneium-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

House 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

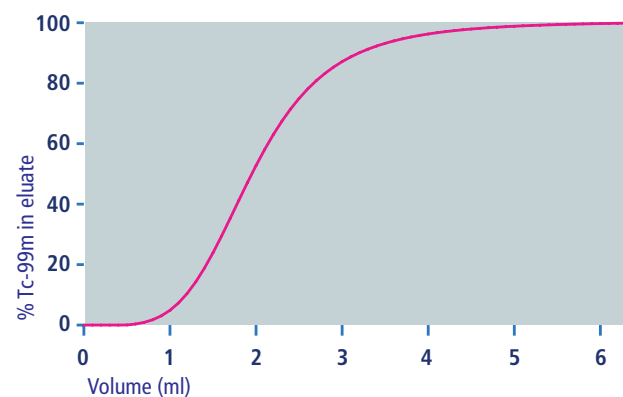
Dimensions	
Diameter Ultra-Technekow FM	135 mm
Height Ultra-Technekow FM	284 mm
Height Ultra-Technekow FM with Saline vial	325 mm
Height Ultra-Technekow FM with holder for needle protector DRN8262	344 mm

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)

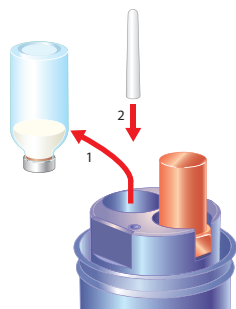
Holder for needle protector (DRN8262 or DRN8265)

Return of used Ultra-Technekow FM generators

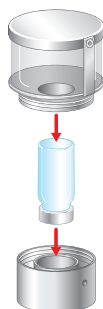
For return please use the same box in which the generator has been delivered. We will provide all necessary shipment documentation for return shipment. Before packing the generator for return shipment make sure to elute the remaining fluid from the generator. For instructions please refer to the following 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 Curium representative is able to give you more information on deliveries. Please consult the competent authority in your country on handling of radioactive material.

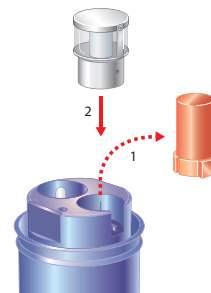
Return of the Ultra-Technekow FM generator



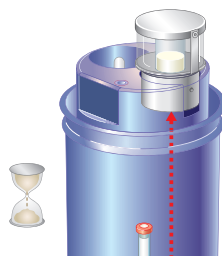
- 1 1 Remove the eluent vial
- 2 Place the original needle cover on the inlet needle



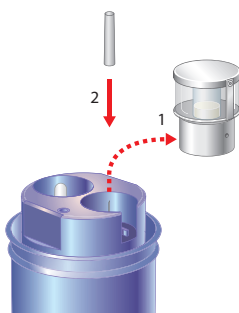
- 2 Place an evacuated vial in an elution shield.



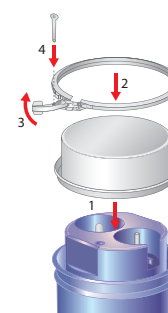
- 3 1 Replace the holder with needle protector
- 2 with the elution shield with evacuated vial



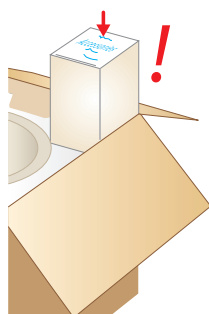
- 4 Elution starts.



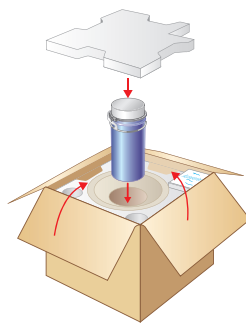
- 5 1 Replace the elution shield
- 2 with the original needle cover on the outlet needle



- 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



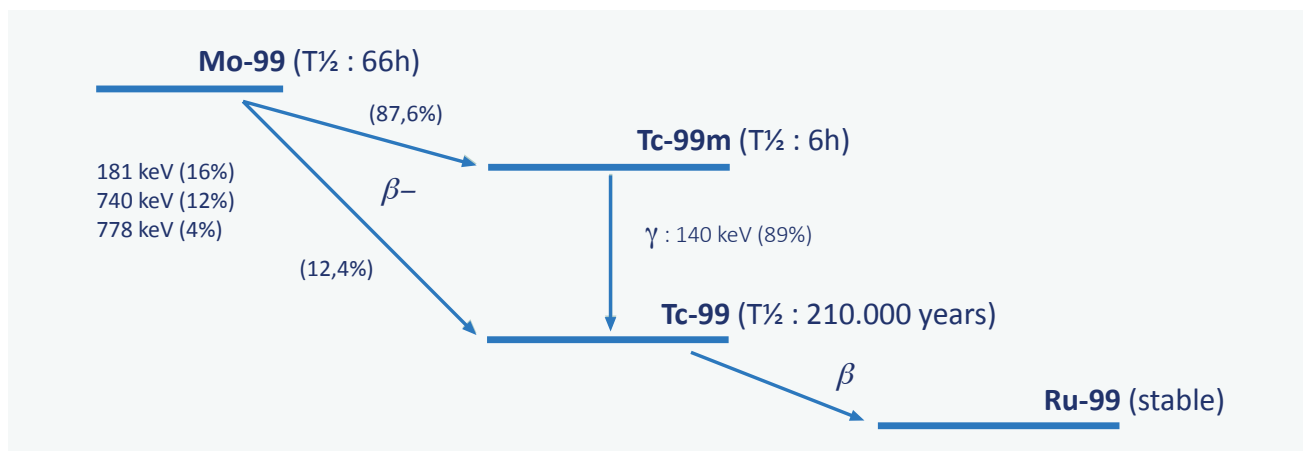
- 8 Place the used generator in its original shipping box and close off

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

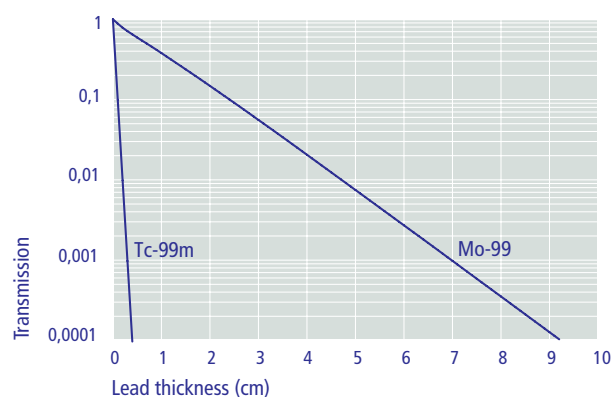
Decay schedule Mo-99



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 disintegration 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 radiation	1 Gy = 1 J/kg = 100 rad	SI derived
Rad	Rd	absorbed dose	1 rad = 1×10^{-2} J/kg	Traditional
Sievert	Sv	unit of dose equivalent, biological effect of radiation	1 Sv = 1 J/kg \times W_r = 100 rem	SI derived
Rem	rem	röntgen equivalent man, dose equivalent	1 rem = 1×10^{-2} Sv	Traditional

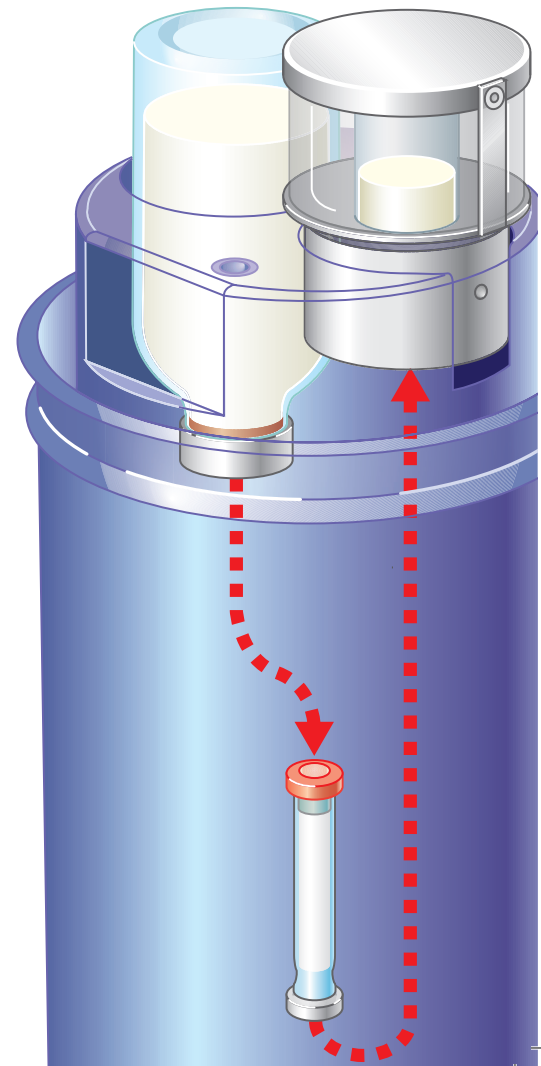
W_r = radiation weighting factor

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 μ Ci = 37 kBq
1 MBq = 27 μ Ci	1 mCi = 37 MBq
1 GBq = 27 mCi	1 Ci = 37 GBq



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 Curium 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 $^{99\text{m}}\text{Tc}$.

PHARMACEUTICAL FORM: Radionuclide generator. **THERAPEUTIC INDICATIONS:** The eluate from the generator (Sodium Perchnetate ($^{99\text{m}}\text{Tc}$) 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; Lacrimal duct scintigraphy. **POSODOLOGY AND METHOD OF ADMINISTRATION:** Sodium pertechnetate ($^{99\text{m}}\text{Tc}$) 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 must be adapted and may be calculated according to the recommendations of the European Association of Nuclear Medicine (EANM) paediatric dosage card. **CONTRA-INDICATIONS:** Hypersensitivity to the active substance or 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 section 4.2. Careful consideration of the indication is required since the effective dose per MBq is higher than in adults. Thyroid blocking is of special importance in the paediatric patient population except for thyroid scintigraphy. Patient preparation: Pre-treatment of patients with thyroid-blocking medicinal products 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. To avoid false positives or to minimise irradiation by reduction of pertechnetate accumulation in the thyroid and salivary glands, a thyroid blocking agent should be given prior to lacrimal duct scintigraphy or Meckel's diverticulum scintigraphy. Conversely a thyroid blocking agent must NOT be used before thyroid, parathyroid or salivary glands scintigraphy. Before the application of sodium ($^{99\text{m}}\text{Tc}$)pertechnetate solution for scintigraphy of Meckel's diverticulum the patient must keep an empty stomach for 3 to 4 hours to reduce intestinal peristalsis. After in vivo labelling of erythrocytes using stannous ions for reduction sodium pertechnetate ($^{99\text{m}}\text{Tc}$) is primarily built into erythrocytes, therefore Meckel's scintigraphy should be performed before or some days after in vivo labelling of erythrocytes. After the procedure: Close contact with infants and pregnant women should be restricted during 12 hours. Specific warnings: Sodium pertechnetate ($^{99\text{m}}\text{Tc}$) solution for injection contains 3.5 mg/mL of sodium. Depending on the time when the injection is administered, the content of sodium given to the patient may in some cases be greater than 1 mmol (23 mg). This should be taken into account in patient on low sodium diet. **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 ($^{99\text{m}}\text{Tc}$) pertechnetate in abdominal imaging. Administration of laxatives should be withheld since they irritate the gastrointestinal tract. Contrast-enhanced studies (e.g. barium) and upper gastro-intestinal examination should be avoided within 48h prior to administration of pertechnetate ($^{99\text{m}}\text{Tc}$) for Meckel's diverticulum scintigraphy. Many pharmacological medicinal products are known to modify the thyroid uptake. Antithyroid medicinal products (e.g. carbimazole or other imidazole derivatives such as propylthiouracil), salicylates, steroids, sodium nitroprusside, sodium sulfobromophthalein, 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. Administration of pertechnetate ($^{99\text{m}}\text{Tc}$) to a mother who is known to be pregnant should be justified by medical need and a positive individual benefit risk assessment for the mother and the foetus. Alternative non-irradiating diagnostic modalities should be taken into account. $^{99\text{m}}\text{Tc}$ (as free pertechnetate) has been shown to cross the placental barrier. Before administering a radiopharmaceuticals to a woman who is breast-feeding, consideration should be given of delaying the administration of radionuclide until the mother has ceased breast-feeding and as 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. $^{99\text{m}}\text{Tc}$ -perchnetate 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 $^{99\text{m}}\text{Tc}$, and therefore the reported side effects are rather related to the labelled compounds than to $^{99\text{m}}\text{Tc}$. The possible types of side effects following intravenous administration of a $^{99\text{m}}\text{Tc}$ 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. 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.

MANUFACTURED AND RELEASED BY: Curium Netherlandsl B.V., Westerduinweg 3, 1755 LE, Petten, The Netherlands. **DATE OF PREPARATION OF THIS INFORMATION:** 6 April 2017.

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

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

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www.curiumpharma.com

CURIUM NETHERLANDS B.V.
P.O. Box 3, 1755 ZG Petten, the Netherlands

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