Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Drytec 2.5-100 GBq radionuclide generator

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The mother nuclide is:

Sodium [^{99}Mo] molybdate 2.5-100GBq/generator
(no carrier added) at the activity reference date

The daughter nuclide is:

Sodium [^{99m}Tc] pertechnetate Variable

The quantity of Sodium Pertechnetate (^{99m}Tc) Injection that may be eluted from the generator at any one time is dependent on the quantity of sodium molybdate [^{99}Mo] present, the volume of eluate obtained and the lapsed time since the previous elution.

Technetium-99m is produced by means of a [^{99}Mo/^{99m}Tc] generator and decays with the emission of gamma radiation with a mean energy of 140keV and a half-life of 6 hours to technetium [^{99}Tc] which, in view of its long half-life of 2.13×10^5 years can be regarded as quasi stable.

Excipients with known effect:
Sodium: 3.54 mg/ml. This needs to be taken into consideration for patients on a controlled sodium diet.
For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Radionuclide generator.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

This medicinal product is for diagnostic use only.

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. When administered intravenously, the sterile sodium [^{99m}Tc]pertechnetate solution is indicated in adults and children as a diagnostic aid in the following:-

(a) Thyroid scintigraphy: direct imaging and measurement of thyroid uptake to give information on the size, position, nodularity and function of the gland in thyroid disease.

(b) Salivary gland scintigraphy: to assess salivary gland function and duct patency.

(c) Location of ectopic gastric mucosa: Meckel's diverticulum

(d) Cerebral scintigraphy: to identify breaches in the blood-brain barrier caused by tumour, infarction, haemorrhage and oedema, when no other methods are available.

When used in conjunction with pre-treatment with a reducing agent to effect technetium-99m-labelling of red blood cells:

(e) Cardiac and vascular scintigraphy

angiocardioscintigraphy for:

evaluation of ventricular ejection fraction

evaluation of global and regional cardiac wall motion

myocardial phase imaging.

organ perfusion or vascular abnormalities imaging

(f) Diagnosis and localisation of occult gastrointestinal bleeding

Following instillation of sterile sodium [^{99m}Tc]pertechnetate solution into the eye.

(g) Lacrimal duct scintigraphy: to assess patency of tear ducts

4.2 Posology and method of administration

Posology

Recommended activities are as follows:

Adults and the elderly:

Thyroid scintigraphy: 18.5-80 MBq
Scintigraphy performed 20 minutes after intravenous injection.

Salivary gland scintigraphy: 40 MBq

Scintigraphy performed immediately after intravenous injection and at regular intervals up to 15 minutes.

Meckel's Diverticulum scintigraphy: 400 MBq

Scintigraphy performed immediately after intravenous injection and at regular intervals up to 30 minutes.

Brain scintigraphy: 370-800 MBq

Rapid sequential images are taken immediately within the first minute after intravenous administration; static images 1 to 4 hours later. Thyroid and choroid plexus should be blocked to avoid non-specific technetium-99m uptake.

Cardiac and Vascular scintigraphy: 740-925 MBq
Red cells are labelled in vivo or in vitro by pretreating with a reducing agent. Dynamic images are taken in the first minute after intravenous administration, followed by regular images over 30 minutes.

Gastrointestinal Bleeding: 740-925 MBq
Red cells are labelled in vivo or in vitro by pre-treating with a reducing agent. Dynamic images are taken in the first minute after intravenous administration, followed by regular images at appropriate intervals for up to 24 hours.

Lacrimal duct scintigraphy: 2-4 MBq each eye

Drops are instilled into the eye and dynamic images are taken over 2 minutes, followed by static images at appropriate intervals over 20 minutes.

Paediatric population

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.

However, the Paediatric Task Group of European Association Nuclear Medicine recommends that the activity to be administered to a child should be calculated from the body weight according to the following table:

Fraction of adult dose:

3 kg = 0.1	22 kg = 0.50	42 kg = 0.78
4 kg = 0.14	24 kg = 0.53	44 kg = 0.80
6 kg = 0.19	26 kg = 0.56	46 kg = 0.82
8 kg = 0.23	28 kg = 0.58	48 kg = 0.85
10 kg = 0.27	30 kg = 0.62	50 kg = 0.88
12 kg = 0.32	32 kg = 0.65	52-54 kg = 0.90
14 kg = 0.36	34 kg = 0.68	56-58 kg = 0.92
16 kg = 0.40	36 kg = 0.71	60-62 kg = 0.96
18 kg = 0.44	38 kg = 0.73	64-66 kg = 0.98
20 kg = 0.46	40 kg = 0.76	68 kg = 0.99

In very young children (up to 1 year) a minimum dose of 20 MBq (10 MBq in thyroid scintigraphy) for direct administration or 80 MBq for red blood cell labelling is necessary in order to obtain images of sufficient quality.

The instructions for preparation of radiopharmaceuticals are given in section 12.

Method of administration
Sodium [^{99m}Tc]pertechnetate 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.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Information on contraindications when using a kit for radiopharmaceutical preparation should be sought in the pack insert of the kit for radiopharmaceutical preparation.

4.4 Special warnings and 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, exposure to ionising radiation must be justifiable on the basis of likely clinical benefit. The activity administered must be such that the resulting radiation is as low as reasonably achievable bearing in mind the need to obtain the intended diagnostic result.

Renal impairment, hepatic 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 (see section 11).

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. Thyroid blocking is of special importance when performing cerebral scintigraphy in the paediatric population.

Patient preparation
Premedication 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.
Before the application of Sodium [^{99m}Tc]pertechnetate-solution for scintigraphy of Meckel's diverticulum the patient should keep an empty stomach for 3 to 4 hours to reduce intestinal peristalsis.

In thyroid gland scintigraphy, salivary gland scintigraphy or location of ectopic gastric mucosa concomitant application of Sodium perchlorate is associated with reduced uptake of radioactivity in glandular tissue.

In cerebral scintigraphy there is also an uptake of Sodium Pertechnetate (^{99m}Tc) in the plexus choroideus that may be misinterpreted as misfunction of the blood-brain barrier (false-positive finding). To reduce the likelihood of misinterpretation and to reduce radiation exposure pre-treatment with Perchlorate is recommended as Perchlorate reduces uptake of Sodium Pertechnetate (^{99m}Tc) to the plexus choroideus.

In Shuntscintigraphy blocking of the thyroid gland to reduce radiation exposure is also necessary as with shunts with normal passability complete activity reaches the peritoneal cavity where it is absorbed and systemically distributed.

After in vivo labelling of erythrocytes using stannous ions for reduction Sodium Pertechnetate (^{99m}Tc) is primarily built into erythrocytes, therefore Meckel scintigraphy should be performed before or some days after in vivo labelling of erythrocytes.

Specific warnings
This medicinal product contains 0.15 mmol/ml (3.54 mg/ml) sodium. To be taken into consideration by patients on a controlled sodium diet.

4.5 Interaction with other medicinal products and other forms of interactions

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 [^{99m}Tc]pertechnetate.

Thyroid hormones, iodine, iodide, perchlorate, thiocyanate, aluminium containing antacids, sulfonamides and products containing stannous (II) ions may to increased concentrations of Sodium Pertechnetate (99mTc) in the vascular space, in the case of stannous (II) ions and sulfonamides the concentration of Sodium Pertechnetate (99mTc) in red blood cells may be increased, and there may be decreased accumulation in plasma and cerebral lesions. Such medicines should be discontinued several days before the procedure.
Iodine containing radiologic contrast media and perchlorate may decrease uptake of 99mTc-Pertechnetate to digestive mucous. Barium sulphate absorbs most of gamma radiation of the tracer. Scintigraphy of Meckel's diverticulum should therefore be performed at the earliest 2-3 days after application of these substances. Laxatives may increase transport of 99mTc-Pertechnetate from the stomach and the intestine and should not be taken before performing scintigraphy of Meckel's diverticulum.
The possible types of interactions following intravenous administration of a 99mTclabelled 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.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential
Where it is necessary to administer radioactive medicinal products to a woman of childbearing potential, information should always be sought about pregnancy. Any woman who has missed a period should be assumed to be pregnant until proven otherwise. Where uncertainty exists, it is particularly important that the radiation exposure should be the minimum consistent with achieving the desired clinical information. Alternative techniques which do not involve ionising radiation should be considered.

Pregnancy
Technetium-99m (as free pertechnetate) has been shown to cross the placental barrier. 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. Direct administration of 800 MBq sodium [^{99m}Tc]pertechnetate to a patient results in an absorbed dose to the uterus of 6.5 mGy. Following pre-treatment of patients with a blocking agent, administration of 800 MBq sodium [^{99m}Tc]pertechnetate results in an absorbed dose to the uterus of 5.3 mGy. Administration of 925 MBq technetium-99m labelled red blood cells results in an absorbed dose to the uterus of 4.3 mGy. Doses above 0.5 mGy should be regarded as a potential risk to the foetus.

Breast-feeding
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 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 1mSv.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have performed.

4.8 Undesirable effects

Summary of the safety profile:
Information on adverse reactions is available from spontaneous reporting. The reported reaction types are hypersensitivity or anaphylactoid reactions, unspecific systemic reactions, as well as injection site reactions.

Sodium pertechnetate (99mTc) from the Drytec radionuclide generator is used for radioactive labelling of a variety of compounds. These medicinal products generally have a higher potential for adverse reactions than 99mTc, and therefore the reported adverse reactions are rather related to the labelled compounds than to 99mTc.

Possible side-effects following the intravenous administration of 99mTc-labelled pharmaceuticals prepared by radiolabelling with Sodium (99mTc) Pertechnetate Solution will be dependent on the specific pharmaceutical being used. Such information can be found in the SmPC of the kit used for radiopharmaceutical preparation.

Tabulated list of adverse reactions
The frequencies of undesirable effects are defined as follows:
Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000) and not known (cannot be estimated from the available data)

Immune system disorders
Frequency unknown*: Anaphylactoid reactions (e.g. Dyspnoea, coma, urticaria, erythema, rash, pruritus, oedema at various location e.g. face oedema)

Nervous system disorders
Frequency unknown*: Vasovagal reactions (e.g. Syncope, tachycardia, bradycardia, dizziness, headache, vision blurred, flushing)

Gastrointestinal disorders
Frequency unknown*: Vomiting, nausea, diarrhoea

General disorders and administration site conditions
Frequency unknown*: Injection site reactions (e.g. Cellulitis, pain, erythema, and swelling)

* Adverse reactions derived from spontaneous reporting

Unspecific systemic reactions and gastrointestinal disorders are rather considered to be related to the examinational setting than to technetium (^{99m}Tc), especially in anxious patients.
Injection site reactions are related to extravasation of the radioactive material during the injection and may range from local swelling up to cellulitis.

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is 10.4 mSv when the maximal recommended activity of 800 MBq is administered these adverse reactions are expected to occur with a low probability.

For most diagnostic investigations using a nuclear medicine procedure, the effective dose is less than 20 mSv. Higher doses may be justified in some clinical circumstances.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL- Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

4.9 Overdose

In the event of the administration of a radiation overdose with sodium [^{99m}Tc]pertechnetate, the absorbed dose should be reduced where possible by increasing the elimination of the radionuclide from the body. Measures to reduce possible harmful effects include frequent voiding of urine and promotion of diuresis and faecal excretion.

Very little supportive treatment can be undertaken in the event of an overdose of technetium-99m labelled red blood cells since elimination is dependent on the normal haemolytic process.

The uptake in the thyroid, salivary glands and the gastric mucosa can be significantly reduced when sodium perchlorate is given immediately after an accidentally high dose of sodium pertechnetate (99mTc) was administered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: diagnostic radiopharmaceuticals, thyroid, technetium-99m pertechnetate,
ATC code: V09FX01

Pharmacodynamic effects
No pharmacological activity has been observed in the range of doses administered for diagnostic purposes.

5.2 Pharmacokinetic properties

Distruibution
The pertechnetate ion has similar biological distribution to iodide and perchlorate ions, concentrating temporarily in salivary glands, choroid plexus, stomach (gastric mucosa) and in the thyroid gland, from which it is released unchanged. The pertechnetate ion also tends to concentrate in areas with increased vascularisation or with abnormal vascular permeability,

particularly when pre-treatment with blocking agents inhibits uptake in glandular structures. Technetium-99m is selectively excluded from the cerebrospinal fluid.

Elimination
Following intravenous administration, [^{99m}Tc]pertechnetate is distributed throughout the vascular system from which it is cleared by three main mechanisms:

- rapid removal, depending on the diffusion equilibrium with interstitial fluid

- intermediate rate of removal, depending on the concentration of the pertechnetate in glandular tissues, mainly thyroid, salivary and gastric fundus glands which have an ionic pump mechanism

- slow removal, by glomerular filtration by the kidneys, dependent on rate of urinary excretion.

Plasma clearance has a half-life of approximately 3 hours.

Excretion during the first 24 hours following administration is mainly urinary (approximately 25%) with faecal excretion occurring over the next 48 hours. Approximately 50% of the administered activity is excreted within the first 50 hours.

When selective uptake of [^{99m}Tc]pertechnetate in glandular structures is inhibited by the pre-administration of blocking agents, excretion follows the same pathways but there is a higher rate of renal clearance.

When [^{99m}Tc]pertechnetate is administered in association with pre-treatment with reducing agents such as stannous/medronate which cause a "stannous loading" of red blood cells, up to approximately 95% of the administered activity is taken up by the red blood cells where it becomes bound within the cells. Any unbound [^{99m}Tc]pertechnetate is cleared by the kidneys; radioactivity in the plasma normally constitutes less than 5% of the intravascular activity.

The fate of the technetium-99m follows that of the labelled erythrocytes themselves and the activity is cleared very slowly. A small level of elution of activity from the circulating red cells is thought to occur.

5.3 Preclinical safety data

(a) There is no information on acute, subacute and chronic toxicity from single or repeated dose administration. The quantity of sodium [^{99m}Tc] pertechnetate administered during clinical diagnostic procedures is very small and apart from allergic reactions, no other adverse reactions have been reported.

(b) Reproductive Toxicity

Placental transfer of technetium-99mfrom intravenously administered sodium [^{99m}Tc]pertechnetate solution has been studied in mice. The pregnant uterus was found to contain as much as 60% of the injected technetium-99mwhen administered without perchlorate pre-administration. Studies performed on pregnant mice during gestation, gestation and lactation, and lactation alone showed changes in progeny which included weight reduction, hairlessness and sterility.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The technetium-99m is generated from sodium [^{99m}Mo] molybdate adsorbed onto an alumina column. The generator column is eluted with sodium chloride solution to produce the eluate, Sodium Pertechnetate (^{99m}Tc) Injection, which contains the following excipients:

Sodium Chloride.
Water for Injections.

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

The expiry date for the generator is 24 days from the date of manufacture. The reference and expiry dates are stated on the generator label.

The shelf life of the sodium chloride eluent is 3 years.

The generator eluate, Sodium Pertechnetate (^{99m}Tc) Injection, should be used within 8 hours of elution.

6.4 Special precautions for storage

Store the generator and the eluate, Sodium Pertechnetate (^{99m}Tc) Injection, below 25^{o}C. Do not freeze.

Store the sodium chloride eluent below 25°C. Do not freeze.

Storage should be in accordance with national regulations for radioactive materials.

6.5 Nature and contents of container

The Drytec generator comprises a neutral borosilicate glass column containing alumina on which is adsorbed sodium [^{99}Mo] molybdate. The column is sealed with a natural rubber closure and a pure gum closure and aluminium overseals. An air-vented inlet spike is connected by silicone tubing to the top of the column. A stainless steel outlet needle is connected to a sterilising filter, which is connected by silicone tubing to the bottom of the column. Three variants of the generator are supplied, which differ in the design of the column geometry and shielding materials. The type of generator is indicated by the generator weight which is given on the generator label. The column is surrounded by lead (11kg and 15kg generator) or depleted uranium and tungsten shielding (17kg generator).

The internal generator components are contained within a robust plastic casing fitted with a carrying handle.

To elute the generator a vial of sodium chloride solution is placed onto the inlet spike. The sodium chloride eluent is contained in a type I glass vial sealed with a bromobutyl rubber stopper and a plastic flip-top protected aluminium overseal. The eluent vials are packed in cartons. A range of different volumes of sodium chloride eluent can be supplied with the generator.. Collection of the eluate, Sodium Pertechnetate (^{99m}Tc) Injection, is achieved by placing a sterile evacuated elution vial comprising a clear glass vial sealed with a rubber closure and metal overseal onto the elution port.

Elution kits and accessories:

Elution kit provided with the generator
The following items are provided with the generator:

· Saline eluent vials each containing 0.9% sodium chloride solution.
· Evacuated vials for collection of the generator eluate.
· Sterile inlet spike protectors - to maintain sterility of the generator system if the saline vial is removed between elutions.
· Sterile closed cell foam collection needle protectors – to maintain sterility of the generator system between elutions.
· Spare sterile needles – to enable the user to replace the collection needle.
· Spare bactericidal sanitising swabs – to sanitise saline vial and collection vial closures prior to carrying out elutions.
· Vial labels – to record the activity, volume and time of elution.
· Technical leaflet
· Leaflet relating to the handling, use, storage and disposal of radiopharmaceuticals
· Information pack relating to the return of generators to GE Healthcare

Accessories available:

Saline eluent vials
The saline eluent is available in a range of different volumes to allow the generator eluate to be collected at varying radioactive concentrations.

Packs of vials containing 0.9% sodium chloride solution. Vials are packed in cartons.

Evacuated collection vials
Vials are packed in cartons.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

General warning
Radiopharmaceuticals should be received, used and administered only by authorised persons in designated clinical settings. Their receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licenses of the competent official organisation.

Radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.

For instructions on elution of the medicinal product before administration, see section 12.

If at any time in the preparation of this product the integrity of this generator is compromised it should not be used.

Administration procedures should be carried out in a way to minimise risk of contamination of the medicinal product and irradiation of the operators. Adequate shielding is mandatory.

The administration of radiopharmaceuticals creates risks for other persons from external radiation or contamination from spill of urine, vomiting etc. Radiation protection precautions in accordance with national regulations must therefore be taken.

After use, all materials associated with the preparation and administration of radiopharmaceuticals, including any unused product and its container, should be decontaminated or treated as radioactive waste and disposed of in accordance with the conditions specified by the local competent authority. Contaminated material must be disposed of as radioactive waste via an authorised route.

7 MARKETING AUTHORISATION HOLDER

GE Healthcare B.V.
De Rondom 8
5612 AP Eindhoven
Netherlands

8 MARKETING AUTHORISATION NUMBER

PA22734/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 August 1999

Date of last renewal: 23 August 2009

10 DATE OF REVISION OF THE TEXT

11 DOSIMETRY

The tables below show the dosimetry as calculated according to the publication 80 of the ICRP (International Commission on Radiological Protection, Radiation Dose to Patients from Radiopharmaceuticals, Pergamon Press 1998).

(i) Without pre-treatment with blocking agent

Organ	**Absorbed dose per unit activity administered (mGy/MBq)**				
	Adult	**15 Year**	**10 Year**	**5 Year**	**1 Year**
Adrenals	3.7E-03	4.7E-03	7.2E-03	1.1E-02	1.9E-02
Bladder	1.8E-02	2.3E-02	3.0E-02	3.3E-02	6.0E-02
Bone surfaces	5.4E-03	6.6E-03	9.7E-03	1.4E-02	2.6E-02
Brain	2.0E-03	2.5E-03	4.1E-03	6.6E-03	1.2E-02
Breast	1.8E-03	2.3E-03	3.4E-03	5.6E-03	1.1E-02
Gall Bladder	7.4E-03	9.9E-03	1.6E-02	2.3E-02	3.5E-02
GI tract					
Stomach	2.6E-02	3.4E-02	4.8E-02	7.8E-02	1.6E-01
SI	1.6E-02	2.0E-02	3.1E-02	4.7E-02	8.2E-02
Colon	4.2E-02	5.4E-02	8.8E-02	1.4E-01	2.7E-01
(ULI	5.7E-02	7.3E-02	1.2E-01	2.0E-01	3.8E-01)
(LLI	2.1E-02	2.8E-02	4.5E-02	7.2E-02	1.3E-01)
Heart	3.1E-03	4.0E-03	6.1E-03	9.2E-03	1.7E-02
Kidneys	5.0E-03	6.0E-03	8.7E-03	1.3E-02	2.1E-02
Liver	3.8E-03	4.8E-03	8.1E-03	1.3E-02	2.2E-02
Lungs	2.6E-03	3.4E-03	5.1E-03	7.9E-03	1.4E-02
Muscles	3.2E-03	4.0E-03	6.0E-03	9.0E-03	1.6E-02
Oesophagus	2.4E-03	3.2E-03	4.7E-03	7.5E-03	1.4E-02
Ovaries	1.0E-02	1.3E-02	1.8E-02	2.6E-02	4.5E-02
Pancreas	5.6E-03	7.3E-03	1.1E-02	1.6E-02	2.7E-02
Red Marrow	3.6E-03	4.5E-03	6.6E-03	9.0E-03	1.5E-02

Organ	**Absorbed dose per unit activity administered (mGy/MBq)**				
	Adult	**15 Year**	**10 Year**	**5 Year**	**1 Year**
Salivary glands	9.3E-03	1.2E-02	1.7E-02	2.4E-02	3.9E-02
Skin	1.8E-03	2.2E-03	3.5E-03	5.6E-03	1.0E-02
Spleen	4.3E-03	5.4E-03	8.1E-03	1.2E-02	2.1E-02
Testes	2.8E-03	3.7E-03	5.8E-03	8.7E-03	1.6E-02
Thymus	2.4E-03	3.2E-03	4.7E-03	7.5E-03	1.4E-02
Thyroid	2.2E-02	3.6E-02	5.5E-02	1.2E-01	2.2E-01
Uterus	8.1E-03	1.0E-02	1.5E-02	2.2E-02	3.7E-02
Remaining organs	3.5E-03	4.3E-03	6.4E-03	9.6E-03	1.7E-02
Effective Dose (mSv/MBq)	**1.3E-02**	**1.7E-02**	**2.6E-02**	**4.2E-02**	**7.9E-02**

(ii) With pre-treatment with blocking agent

Organ	Absorbed dose per unit activity (mGy/MBq) when blocking agents are given				
	Adult	15 Year	10 Year	5 Year	1 Year
Adrenals	2.9E-03	3.7E-03	5.6E-03	8.6E-03	1.6E-02
Bladder	3.0E-02	3.8E-02	4.8E-02	5.0E-02	9.1E-02
Bone surfaces	4.4E-03	5.4E-03	8.1E-03	1.2E-02	2.2E-02
Brain	2.0E-03	2.6E-03	4.2E-03	7.1E-03	1.2E-02
Breast	1.7E-03	2.2E-03	3.2E-03	5.2E-03	1.0E-02
Gall bladder	3.0E-03	4.2E-03	7.0E-03	1.0E-02	1.3E-02
GI tract					
Stomach	2.7E-03	3.6E-03	5.9E-03	8.6E-03	1.5E-02
SI	3.5E-03	4.4E-03	6.7E-03	1.0E-02	1.8E-02
Colon	3.6E-03	4.8E-03	7.1E-03	1.0E-02	1.8E-02
(ULI	3.2E-03	4.3E-03	6.4E-03	1.0E-02	1.7E-02)
(LLI	4.2E-03	5.4E-03	8.1E-03	1.1E-02	1.9E-02)
Heart	2.7E-03	3.4E-03	5.2E-03	8.1E-03	1.4E-02
Kidneys	4.4E-03	5.4E-03	7.7E-03	1.1E-02	1.9E-02

Organ	Absorbed dose per unit activity (mGy/MBq) when blocking agents are given				
	Adult	15 Year	10 Year	5 Year	1 Year
Liver	2.6E-03	3.4E-03	5.3E-03	8.2E-03	1.5E-02
Lungs	2.3E-03	3.1E-03	4.6E-03	7.4E-03	1.3E-02
Muscles	2.5E-03	3.1E-03	4.7E-03	7.2E-03	1.3E-02
Oesophagus	2.4E-03	3.1E-03	4.6E-03	7.5E-03	1.4E-02
Ovaries	4.3E-03	5.4E-03	7.8E-03	1.1E-02	1.9E-02
Pancreas	3.0E-03	3.9E-03	5.9E-03	9.3E-03	1.6E-02
Red Marrow	2.5E-03	3.2E-03	4.9E-03	7.2E-03	1.3E-02
Skin	1.6E-03	2.0E-03	3.2E-03	5.2E-03	9.7E-03
Spleen	2.6E-03	3.4E-03	5.4E-03	8.3E-03	1.5E-02
Testes	3.0E-03	4.0E-03	6.0E-03	8.7E-03	1.6E-02
Thymus	2.4E-03	3.1E-03	4.6E-03	7.5E-03	1.4E-02
Thyroid	2.4E-03	3.1E-03	5.0E-03	8.4E-03	1.5E-02
Uterus	6.0E-03	7.3E-03	1.1E-02	1.4E-02	2.3E-02
Remaining organs	2.5E-03	3.1E-03	4.8E-03	7.3E-03	1.3E-02
Effective Dose (mSv/MBq)	4.2E-03	5.4E-03	7.7E-03	1.1E-02	1.9E-02

The effective dose resulting from an administered activity of 800 MBq Sodium Pertechnetate (^{99m}Tc) Injection is 10.4 mSv. Following pre-treatment of patients with a blocking agent, administration of 800 MBq Sodium Pertechnetate [^{99m}Tc] Injection results in an effective dose of 3.36 mSv.

(iii) The radiation doses absorbed by a patient following intravenous injection of technetium-99m labelled red blood cells are as follows:

Organ	**Absorbed dose per unit activity administered (mGy/MBq)**				
	Adult	**15 Year**	**10 Year**	**5 Year**	**1 Year**
Adrenals	9.9E-03	1.2E-02	2.0E-02	3.0E-02	5.6E-02
Bladder	8.5E-03	1.1E-02	1.4E-02	1.7E-02	3.1E-02
Bone surfaces	7.4E-03	1.2E-02	1.9E-02	3.6E-02	7.4E-02
Brain	3.6E-03	4.6E-03	7.5E-03	1.2E-02	2.2E-02
Breast	3.5E-03	4.1E-03	7.0E-03	1.1E-02	1.9E-02
Gall bladder	6.5E-03	8.1E-03	1.3E-02	2.0E-02	3.0E-02
GI tract					
Stomach	4.6E-03	5.9E-03	9.7E-03	1.4E-02	2.5E-02
SI	3.9E-03	4.9E-03	7.8E-03	1.2E-02	2.1E-02
Colon	3.7E-03	4.8E-03	7.5E-03	1.2E-02	2.0E-02
(ULI	4.0E-03	5.1E-03	8.0E-03	1.3E-02	2.2E-02)
(LLI	3.4E-03	4.4E-03	6.9E-03	1.0E-02	1.8E-02)

Heart	2.3E-02	2.9E-02	4.3E-02	6.6E-02	1.1E-01
Kidneys	1.8E-02	2.2E-02	3.6E-02	5.7E-02	1.1E-01
Liver	1.3E-02	1.7E-02	2.6E-02	4.0E-02	7.2E-02
Lungs	1.8E-02	2.2E-02	3.5E-02	5.6E-02	1.1E-01
Muscles	3.3E-03	4.0E-03	6.1E-03	9.4E-03	1.7E-02
Oesophagus	6.1E-03	7.0E-03	9.8E-03	1.5E-02	2.3E-02
Ovaries	3.7E-03	4.8E-03	7.0E-03	1.1E-02	1.9E-02
Pancreas	6.6E-03	8.1E-03	1.3E-02	1.9E-02	3.3E-02
Red marrow	6.1E-03	7.6E-03	1.2E-02	2.0E-02	3.7E-02
Skin	2.0E-03	2.4E-03	3.8E-03	6.2E-03	1.2E-02
Spleen	1.4E-02	1.7E-02	2.7E-02	4.3E-02	8.1E-02
Testes	2.3E-03	3.0E-03	4.4E-03	6.9E-03	1.3E-02
Thymus	6.1E-03	7.0E-03	9.8E-03	1.5E-02	2.3E-02
Thyroid	5.7E-03	7.1E-03	1.2E-02	1.9E-02	3.6E-02
Uterus	3.9E-03	4.9E-03	7.4E-03	1.1E-02	1.9E-02
Remaining organs	3.5E-03	4.5E-03	7.3E-03	1.3E-02	2.3E-02
Effective dose (mSv/MBq)	**7.0E-03**	**8.9E-03**	**1.4E-02**	**2.1E-02**	**3.9E-02**

The effective dose resulting from an administration of 925 MBq technetium-99m labelled red blood cells is 5.78 mSv.

The radiation dose absorbed by the lens of the eye following administration of sodium [^{99m}Tc]pertechnetate for lacrimal duct scintigraphy is estimated to be 0.038 mGy/MBq. This results in an effective dose of less than 0.01 mSv for an administered activity of 4 MBq (ICRP 53, 1987).

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

This radiopharmaceutical may be received, used and administered only by authorised persons in designated clinical settings. Its receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licences of the local competent official organisations (see section 6.6)

The administration of radiopharmaceuticals creates risks for other persons from external radiation on contamination from spills of urine and vomiting. Radiation protection precautions in accordance with national regulations must therefore be taken.

Instructions for elution of the Drytec Generator
Safe handling

The weight of the generator depends on the shielding used. The approximate weights are:
45mm lead shielded generator = 11 kg
54mm lead shielded generator = 15 kg
Depleted uranium shielded generator = 17 kg

Consideration should be given to the safe lifting and carrying of the generators. Local manual handling operations regulations should be observed in order to reduce the risk of injury caused by manual handling activities.
Elution instructions – please also refer to the adjacent diagrams

The facilities used for elutions should comply with the appropriate regulations for safe radiological handling. Strict aseptic techniques should be used during the elution of the generator to ensure sterility of the generator eluate.

To avoid unsatisfactory performance it is important to adhere to the following sequence of elution steps.

First elution

1. Remove the generator and accompanying accessories from their packaging. Place the generator on a flat, level surface, in a suitably authorised and shielded location (Fig 1). **Do not remove** the spike and needle protectors until you are ready to carry out the first elution.

2. Select a saline vial containing the required volume of saline.

3. Remove the flip-top from the saline vial and swab the saline vial closure using a supplied bactericidal swab and allow to dry.

4. Remove the spike protector (Fig 2)

5. Place the saline vial onto the spike, ensuring that it is fully pushed to the bottom of the inlet well. Partial rotation will assist the positioning of the vial.

6. Select an evacuated collection vial and swab the collection vial closure using a supplied bactericidal swab and allow to dry. Prior to placing the collection vial inside the collection vial shield ensure that the vial contact surfaces of the shield have been swabbed using the bactericidal swab provided. Replace the collection vial shield screw-locked cap as shown (Fig 3). The collection shield push fit top is not required until the elution has been completed.

7. Remove the collection point protector by turning it anti-clockwise (Fig 4). Ensure that the luer type filter attached to the collection point protector is also removed. **Retain the collection point protector for use when returning the generator.** Immediately fit a collection needle provided in the accessory pack (Fig 5).
Do not remove the collection needle sheath until you are ready to place the collection vial on the needle.

8. Remove the collection needle sheath (Fig 6) and place the collection vial shield on to the collection needle, aligning the side location into its guide, and the window to the front. Push down to ensure that the vial is fully located on the collection needle (Fig 7).

9. Allow at least 3 minutes for the elution to proceed to completion.
Each elution is deemed complete when all vigorous bubbling has ceased inside the collection vial. **Do not remove either the saline vial or collection vial before the elution is complete.**

10. Slowly remove the collection vial shield to prevent damage to the collection needle (Fig 8) and replace the push fit top for added radiation protection.

11. Select a new collection needle protector from the accessory pack and push on to the collection needle to preserve sterility (Fig 8).

12. Leave the empty saline vial in place until the next elution to preserve sterility (Fig 9).

Subsequent elutions

Using a new sanitised saline vial of the required volume, repeat steps 5–12.

If the collection needle needs to be changed, simply remove the damaged needle, swab the collection well to ensure sterility is maintained and fit a new needle. Place a collection needle protector over the new needle.

Following expiry, the generator should be returned according to the return instructions in the accessory pack. A spare spike protector and the retained collection point protector should be used to cover the spike and collection point respectively (Fig 10).

Elution volume and yield of technetium-99m

Due to the elution characteristics of the different column designs, it is recommended that the minimum elution volume for lead shielded generators is 5ml. For depleted uranium shielded generators the minimum elution volume should be 10 ml. If 5ml elutions are used a higher radioactive concentration will be obtained, but a small yield reduction may be expected.

Drytec is calibrated in terms of the amount of molybdenum loaded on the column. The available technetium-99m at any time depends on the time before or after reference (due to the decay of molybdenum-99), the time elapsed since the previous elution (due to growth of technetium-99m) and on the decay characteristics of molybdenum-99 (86.2% of all decay yields technetium-99m). Factors listed in Tables 1 and 2 may be used to calculate the available technetium-99m activity using the following method.

First, multiply the stated reference activity by the appropriate factor from Table 1 (which allows for decay of molybdenum-99). Then multiply the product by the appropriate factor from Table 2 (which allows for the growth of technetium-99m and for decay characteristics of molybdenum-99).

The actual yield of technetium-99m will vary slightly due to variation in elution efficiency from generator to generator. It should typically be not less than 90% of the available technetium-99mactivity.

Disposal of expired generators

Expired generators containing lead shielding should normally be disposed of by the user as radioactive waste in accordance with the conditions specified by the local competent authority. If local regulations for disposal require that the generator should be dismantled, please contact GE Healthcare or its local representative. In certain markets, arrangements may be made for the return of lead shielded generators to GE Healthcare.

Generators containing depleted uranium and tungsten shielding must be returned to GE Healthcare after expiry.
Full instructions describing how the return of generators to GE Healthcare should be carried out are included with each generator. Users are reminded that all packaging, documentation and methods of transportation used must be in compliance with international transport regulations and all local regulations and codes of practice that relate to such matters.