HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use TECHNEGAS safely and effectively. See full prescribing information for TECHNEGAS.

TECHNEGAS® (kit for the preparation of technetium Tc 99m-labeled carbon inhalation aerosol), for oral inhalation use
Initial U.S. Approval: 2023

----------INDICATIONS AND USAGE----------
TECHNEGAS, when used with sodium pertechnetate Tc 99m in the Technegas Plus System, provides technetium Tc 99m-labeled carbon inhalation aerosol (Technegas Aerosol), a radioactive diagnostic agent for use in adults and pediatric patients aged 6 years and older for:
- visualization of pulmonary ventilation
- evaluation of pulmonary embolism when paired with perfusion imaging (1)

----------DOSAGE AND ADMINISTRATION----------
- For adult patients, the recommended activity of sodium pertechnetate Tc 99m injection to be loaded in the Technegas Crucible is 400 MBq to 1,000 MBq (10.8 mCi to 27 mCi) to achieve a lung count rate between 1,500 counts per second (cps) and 2,500 cps at the end of the last respiration. (2.2)
- For pediatric patients aged 6 years and older, a sufficient amount of Technegas Aerosol should be inhaled to achieve between 500 cps and 1,000 cps at the end of last respiration. The radioactivity to be loaded in the Technegas Crucible is a fraction of the recommended activity for adults adjusted by body weight. (2.2)
- Administer as soon as possible following preparation and complete inhalation within 10 minutes of preparation. (2.2)
- For drug handling, breathing techniques, preparation, and dosimetry information, see the full prescribing information. (2.1, 2.3, 2.4, 2.5)

----------DOSAGE FORMS AND STRENGTHS----------
TECHNEGAS (kit for the preparation of technetium Tc 99m labeled carbon inhalation aerosol) is a 1.25 gram single-use black to dark grey oval shaped graphite carbon crucible (Technegas Crucible). Upon addition of sodium pertechnetate Tc 99m injection, USP to the Technegas Crucible, the Technegas Plus System provides Technegas Aerosol for oral inhalation. (3)

----------CONTRAINDICATIONS----------
None (4)

----------WARNINGS AND PRECAUTIONS----------
Decreased Oxygen Saturation: Monitor oxygen saturation with continuous pulse oximetry. If clinically indicated, allow patients to breathe room air throughout the procedure and consider administration of supplemental oxygen before and at any time during the procedure. (5.1)
Radiation Exposure Risk: Ensure safe handling and preparation procedures to protect patients and health care providers from unintentional radiation exposure. (2.1, 5.2)

----------ADVERSE REACTIONS----------
The most common adverse reaction (≥ 1%) was hypoxia. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Cyclomedica Australia Pty Ltd at toll free phone number 1-888-8-586-4396 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------USE IN SPECIFIC POPULATIONS----------
Lactation: Temporarily discontinue breastfeeding. A lactating woman should pump and discard breastmilk for at least 4 hours after Technegas Aerosol inhalation to minimize exposure to the breastfed infant. (8.2)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 9/2023

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

TECHNEGAS, when used with sodium pertechnetate Tc 99m in the Technegas Plus System, provides technetium Tc 99m-labeled carbon inhalation aerosol (Technegas Aerosol), for use in adults and pediatric patients aged 6 years and older for:

- visualization of pulmonary ventilation
- evaluation of pulmonary embolism when paired with perfusion imaging

2 DOSAGE AND ADMINISTRATION

2.1 Radiation Safety – Drug Handling

Handle Technegas Aerosol with appropriate safety measures to minimize radiation exposure to the patient and healthcare providers. During preparation and handling, use waterproof gloves and effective shielding *[see Warnings and Precautions (5.2)].*

Radiopharmaceuticals should be used by or under the control of healthcare providers who are qualified by specific training and experience in the safe use and handling of radionuclides, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radionuclides.

2.2 Recommended Dose

The activity present in the lungs after each inhalation varies. Follow the pulmonary count rate during oral inhalation of Technegas Aerosol, using a gamma camera equipped with a standard collimator (low energy, low/medium resolution).

- For adult patients, the recommended activity of sodium pertechnetate Tc 99m injection to be loaded in the Technegas Crucible is 400 MBq to 1,000 MBq (10.8 mCi to 27 mCi) to achieve a lung count rate between 1,500 counts per second (cps) and 2,500 cps at the end of the last respiration. Discontinue Technegas Aerosol administration at that point.
- For pediatric patients aged 6 years and older, a sufficient amount of Technegas Aerosol should be inhaled until a lung count rate is obtained between 500 cps and 1,000 cps at the end of last respiration. Discontinue administration at that point. The radioactivity to be loaded in the Technegas Crucible for pediatric patients aged 6 years and older is a fraction of the recommended activity for adults, and is adjusted by body weight as listed in Table 1.

Table 1. Crucible Loading Activity of Sodium Pertechnetate Tc 99m Injection for Pediatric Patients Aged 6 Years and Older

Weight (kg)	Crucible Loading Activity MBq (mCi)
10	133 (3.6)
12	154 (4.2)
14	175 (4.7)
16	196 (5.3)

Weight (kg)	Crucible Loading Activity MBq (mCi)
28	315 (8.5)
30	336 (9.1)
32	357 (9.7)
34	378 (10)

Weight (kg)	Crucible Loading Activity MBq (mCi)
46	490 (13)
48	504 (14)
50	525 (14)
52-54	553 (15)

Weight (kg)	Crucible Loading Activity MBq (mCi)
18	217 (5.9)
20	238 (6.4)
22	259 (7)
24	270 (7.6)
26	301 (8.1)

Weight (kg)	Crucible Loading Activity MBq (mCi)
36	392 (11)
38	413 (11)
40	434 (12)
42	448 (12)
44	469 (13)

Weight (kg)	Crucible Loading Activity MBq (mCi)
56-58	588 (16)
60-62	623 (17)
64-66	658 (18)
68	686 (19)

2.3 Administration Instructions

Administer Technegas Aerosol by oral inhalation using an FDA-cleared radionuclide rebreathing system for Technegas Aerosol (e.g., Patient Administration Set from Cyclomedica) that connects directly to the Technegas Plus System (TP) as soon as possible following preparation and complete inhalation within 10 minutes of preparation.

Monitor oxygen saturation level in patients with an oximeter *[see Warnings and Precautions (5.1)].* Be prepared to allow patients to breathe room air during administration. Do not detach the patient administration set (PAS) from the patient to prevent residual aerosol from being released.

Prepare the patient in the imaging room or a preparation room before preparing Technegas Aerosol. For complete instructions on patient preparation, breathing techniques, and operation of the TP during administration, see the User Manual for the TP.

To facilitate uniform delivery of the aerosol from the apex-to-base of the lungs, perform the administration with the patient in the supine position.

Recommended Breathing Method

For adult patients, the recommended breathing method to inhale the aerosol is through the mouthpiece by slow deep breathing from the residual functional capacity (end of calm expiration), followed by a 5-second breath-hold.

For patients unable to hold their breath, normal breathing with deep inhalations without breath-holding can be used.

For pediatric patients aged 6 years and older, instruct the patient to inhale the aerosol through the mouthpiece or inhalation line by normal breathing with deep inhalations without breath-holding.

When the adequate pulmonary counts are achieved for imaging, the patient must continue exhaling air through the filter equipped exhalation circuit of the PAS for five breaths to six breaths to trap residual aerosol being exhaled.

The PAS is single use only and should be disposed of as radioactive waste.

2.4 Preparation of Technegas Aerosol

Important Preparation Information

- Prepare Technegas Aerosol in the Technegas Plus System (TP) using the supplied Technegas Crucible. See the User Manual for a comprehensive description of the setup, operation, and maintenance of the TP.
- Use Sodium Pertechnetate Tc 99m Injection, USP obtained from a commercially available technetium Tc 99m generator.
- **Only use ultra high purity (≥ 99.997% purity with less than 3 ppm oxygen) argon gas**. The presence of oxygen in argon gas during the process of formation of Technegas Aerosol may lead to formation of Pertechnegas Aerosol (instead of Technegas Aerosol), which may affect the image quality.
- Wear protective gloves, aprons, and masks for radiation protection and infection control.
- Handle Technegas Crucibles with forceps. Any oil from the skin will reduce connection efficiency and Technegas yield.
- Prepare Technegas Aerosol using the TP at 15° to 30°C (59° to 86°F) in a ventilated area that is suitable for using radioactive materials (e.g., Nuclear Medicine Department) near the patient, to enable timely (within 10 minutes) administration *[see Dosage and Administration (2.3)]*.
- The maximum use period for the TP is one year or 500 burn cycles, whichever occurs first. After this period, ask Cyclomedica to perform maintenance and recertify the TP for use.

Preparation:

1. Using forceps, remove a Technegas Crucible from its blister pack, inspect the crucible to ensure that it is free of chips or cracks, and place it on a clean flat surface. Store unused crucibles in the original packaging.
   (**Note**: When a blister pack of 10 crucibles is used for the first time, remove the tamper-proof seal to facilitate access to the crucibles. Then carefully remove one crucible (for preparation of each patient's dose) from the blister pack and reinsert the cardboard backing material to cover all remaining crucibles in their respective individual blister pockets. This prevents ingress of any contaminating material from the immediate environment and allows the crucibles to be securely stored).
2. Prepare the Alcohol, USP (i.e., 95% ethanol) wetted crucible. Using a 1 mL syringe, fill the crucible reservoir (approximately 0.1 mL) with Alcohol and then draw it back in the syringe.
3. Open the Technegas Plus System drawer and install the Alcohol wetted crucible between the support electrodes using forceps (see the Technegas Plus System User Manual for details on installation of the Technegas Crucible).
4. Rotate the crucible to ensure that good electrical contact is made with the support electrodes (Technegas Contacts); ensure the crucible reservoir is upright.
5. For adult patients, using a 1 mL syringe with needle, load 400 MBq to 1,000 MBq (10.8 mCi to 27 mCi) of Sodium Pertechnetate Tc 99m Injection, USP, in a volume of 0.1 mL while ensuring that the liquid meniscus does not exceed the height of the Crucible (the maximum crucible volume is 0.12 mL, and adding excess volume can lead to radioactive spill in the TP and may lead to formation of aerosol of free pertechnetate Tc 99m that may deteriorate image quality). For the recommended loading activity of Sodium Pertechnetate Tc 99m Injection in pediatric patients aged 6 years and older, refer to Table 1 *[see Dosage and Administration (2.2)].*
6. Close the drawer and run the SIMMER heating cycle to evaporate the liquid from the crucible reservoir. The process continues for 6 minutes, leaving a dry white residue of sodium pertechnetate Tc 99m and sodium chloride in the crucible. During this time the TP chamber is also completely filled with the argon gas (note: 100% argon atmosphere is necessary to prepare pure Technegas Aerosol). When the simmer is complete, the display will read: PRESS [START] TO INITIATE BURN.
7. Run the BURN heating cycle, during which the crucible containing the dry residue of sodium chloride and pertechnetate Tc 99m is heated to 2,750°C (4,982°F) for 15 seconds in TP, to

produce Technegas Aerosol. At the end of BURN cycle, the display will change to "DISCONNECT THE MAINS PLEASE".

(**Note**: At this time the argon gas supply is turned OFF and the argon gas line can be disconnected. The main power on the TP can be switched OFF. The TP will remain powered ON from an internal battery for Technegas Aerosol administration to the patient. The TP may be moved to the patient as required.)

8. Administer Technegas Aerosol as soon as possible following preparation and complete the inhalation within 10 minutes of its preparation. Do not use after 10 minutes of preparation. [See the TP User Manual for connecting the PAS to the patient and to the TP.]
9. The crucible is single use only. The TP breaks the crucible at the end of Technegas Aerosol production to prevent re-use. Crucible fragments are radioactive and should be disposed appropriately. Refer to the Technegas Plus System User Manual for detailed information.

2.5 Radiation Dosimetry

The estimated radiation absorbed doses to various organs are shown in Table 2. The dose limiting organ is the lungs at 0.11 mGy/MBq.

The effective dose resulting from an estimated inhaled activity of 40 MBq (1.08 mCi) in adults is 0.6 mSv. The effective dose in a 10-year old pediatric patient from estimated inhaled activity of 15 MBq (0.41 mCi) is 0.47 mSv.

Reference ID: 5253049

Table 2. Estimated Radiation Absorbed Dose from Inhalation of Technegas Aerosol

Organ	Absorbed Dose per Unit Activity Administered (mGy/MBq)			
	Adult	**15 Years**	**10 Years**	**5 Years****
Adrenals	0.0068	0.00911	0.013	0.02
Bone surfaces	0.0049	0.0063	0.0088	0.014
Brain	0.00025	0.00033	0.00058	0.00094
Breast	0.0067	0.0073	0.013	0.019
Gallbladder wall	0.0023	0.0032	0.0055	0.0084
Gastrointestinal tract				
Stomach wall	0.0044	0.0062	0.0088	0.013
Small intestines wall	0.00087	0.0013	0.0022	0.0039
Colon wall	0.0014	0.0019	0.0034	0.0059
Upper large intestines wall	0.0019	0.0025	0.0046	0.0077
Lower large intestines wall	0.00074	0.001	0.0018	0.0034
Heart wall	0.013	0.017	0.023	0.032
Kidneys	0.002	0.003	0.0046	0.0072
Liver	0.0057	0.0078	0.01	0.015
Lungs	0.11	0.16	0.22	0.33
Muscles	0.0028	0.0036	0.0049	0.0073
Esophagus	0.0082	0.01	0.015	0.019
Ovaries	0.00041	0.00055	0.0011	0.002
Pancreas	0.0052	0.0073	0.01	0.016
Red marrow	0.0033	0.0038	0.005	0.0066
Salivary glands	0.0028	0.0036	0.0063	0.0098
Skin	0.0012	0.0013	0.0022	0.0033
Spleen	0.0048	0.0063	0.0093	0.015
Testes	0.000061	0.000091	0.0002	0.00033
Thymus	0.0082	0.01	0.015	0.019
Thyroid	0.0029	0.0039	0.0069	0.011
Urinary bladder wall	0.00032	0.00045	0.00074	0.0012
Uterus	0.0003	0.00046	0.00083	0.0016
Remaining organs	0.0027	0.0035	0.0047	0.0068
Effective dose (mSv/MBq)	0.015	0.022	0.031	0.047

**Technegas Aerosol is not approved for pediatric patients younger than 6 years old *[see Indications and Usage (1)]*.

3 DOSAGE FORMS AND STRENGTHS

Technegas (kit for the preparation of technetium Tc 99m-labeled carbon inhalation aerosol) is a 1.25 gram single-use dark grey to black small oval graphite carbon crucible (Technegas Crucible). Upon addition of sodium pertechnetate Tc 99m injection, USP to the Technegas Crucible, the Technegas Plus System provides Technegas Aerosol in argon gas.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Decreased Oxygen Saturation

Decrease in oxygen saturation may occur during or after the inhalation of Technegas Aerosol. Oxygen saturation nadirs as low as 60% have been reported in a published study *[see Adverse Reactions (6.1)]*. In an efficacy trial, 79% of patients received supplemental oxygen or had the flow of Technegas Aerosol interrupted. Patients with compromised respiratory function may be at increased risk for decreased oxygen saturation. Monitor oxygen saturation with continuous pulse oximetry. If clinically indicated, allow patients to breathe room air throughout the procedure and consider administration of supplemental oxygen before and at any time during the procedure.

5.2 Radiation Exposure Risk

Technegas Aerosol contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer. Ensure safe handling and preparation procedures to protect patients and health care providers from unintentional radiation exposure.

5.3 Bronchospasm

As with other inhaled aerosol medications, Technegas Aerosol may result in acute bronchoconstriction, especially in patients with heightened bronchoreactivity, such as patients with asthma or other lung or allergic disorders. Monitor all patients for bronchospasm.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Decreased Oxygen Saturation *[see Warnings and Precautions (5.1)]*

6.1 Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The safety of Technegas Aerosol was evaluated in 291 patients undergoing ventilation studies with prospective data collection. Patients received an amount of Technegas Aerosol to achieve 1,500 cps to 2,500 cps by oral inhalation. The mean age of patients was 60 years (range:18 to 95 years); distribution by race was 92 % White, 7% Black or African American, 0.3 % Asian, and 0.3 % unreported; and distribution by ethnicity was 4% Hispanic/Latino and 96 % non-Hispanic/Latino.

Adverse reactions were reported in 10 patients (3.4%). The adverse reaction occurring at ≥ 1% in patients receiving Technegas Aerosol was hypoxia (1%).

Adverse reactions reported at < 1% were dizziness, dysgeusia, cough, dyspnea [not otherwise specified], throat irritation, and upper respiratory tract congestion.

In one published study, oxygen saturation was monitored in a series of patients undergoing Technegas Aerosol ventilation scintigraphy for suspected pulmonary embolism (n=28) or pulmonary disease (n=10). Of these 38 patients without pre-oxygenation, oxygen saturation fell to < 90% in 26 (68%) patients and < 85% in 15 (39%) patients. The recorded lowest value for each patient was usually observed after the first or second inhalation.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Available data with Technegas Aerosol use in pregnant women from several small retrospective studies are insufficient to evaluate for a drug associated risk for major birth defects, miscarriage, or other adverse maternal or fetal outcomes. The radiation dose to the fetus after inhalation of Technegas Aerosol has ranged from 0.007 mGy to 0.14 mGy *(see Data).* Animal reproduction studies have not been conducted with Technegas Aerosol. However, all radiopharmaceuticals, including Technegas Aerosol have the potential to cause fetal harm depending on the fetal stage of development and the magnitude of the radiation dose. If considering Technetium Aerosol administration to a pregnant woman, inform the patient of the potential for adverse pregnancy outcomes based on the radiation dose from Technetium Aerosol and the gestational timing of exposure.

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risks of major birth defects and miscarriage in clinically recognized pregnancies are 2% to 4% and 15% to 20%, respectively.

Data

Human Data

The radiation dose to the fetus after inhalation of Technegas Aerosol was calculated according to the stage of gestation, ranging from 0.007 mGy at the early stage through 3-months of gestation up to 0.011 mGy to 0.14 mGy at 6-months and 9-months of gestation, respectively. No adverse fetal effects or radiation-related risks have been identified for diagnostic procedures involving less than 50 mGy, which represents less than 10 mGy fetal doses.

8.2 Lactation

Risk Summary

There are no data on the presence of Technegas Aerosol in human milk, the effects of Technegas Aerosol on the breastfed infant, or the effects on milk production. Published case reports describe the presence of technetium-99 in human milk. Based on clinical guidelines, exposure of Technetium Aerosol to a breast fed infant may be minimized by advising a lactating woman to pump and discard breast milk for a minimum of 4 hours after administration of Technegas Aerosol. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Technegas Aerosol and any potential adverse effects on the breastfed child from Technegas Aerosol or from the underlying maternal condition.

8.4 Pediatric Use

The safety and effectiveness of Technegas Aerosol for lung ventilation imaging to visualize pulmonary ventilation and pulmonary embolism when paired with perfusion have been established in pediatric patients aged 6 years and older.

The safety and effectiveness of Technegas Aerosol with the patient administration set have not been established in pediatric patients less than 6 years of age.

8.5 Geriatric Use

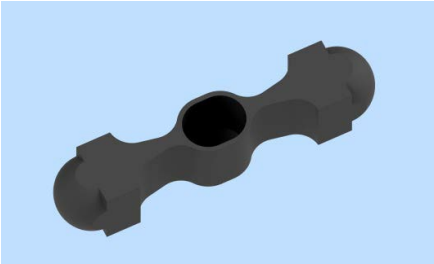
Of the total number of patients receiving Technegas Aerosol in clinical studies for lung ventilation imaging, 122 (41.9 %) were 65 years of age and older, while 58 (20 %) were 75 years of age and older. No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between elderly and younger patients.

11 DESCRIPTION

11.1 Chemical Characteristics

TECHNEGAS (kit for the preparation of technetium Tc 99m-labeled carbon inhalation aerosol) is a 1.25 gram black to dark grey graphite carbon crucible (Technegas Crucible). Graphite is a polymorph of the element carbon, appears opaque, and crystallizes in the hexagonal system. The crucible has the following appearance and physical dimensions:

Table 3. Physical Dimensions of Crucible



Length	31.25 to 32.75 mm
Wall Thickness	0.39 to 0.81 mm
Base Thickness	0.34 to 0.81 mm
Maximum volume capacity	0.12 mL

Technegas Crucible when used with sodium pertechnetate Tc 99m injection, USP in the Technegas Plus System (also commonly referred to as TechnegasPlus Technegas Generator or TP), provides technetium Tc 99m-labeled carbon inhalation aerosol in argon gas (Technegas Aerosol), a radioactive diagnostic agent for oral inhalation.

During the process of formation of technetium Tc 99m-labeled carbon inhalation aerosol, when dried pertechnetate Tc 99m in Technegas Crucible is heated to 2,750°C (4,982°F) for 15 seconds in the TP using the Alternate Current arc, both the technetium and a portion of the carbon crucible are volatilized. The reduction of pertechnetate Tc 99m results in elemental technetium Tc 99m that serves as a nucleation site for the condensing of the volatile carbon, producing hydrophobic particles made up of a technetium Tc 99m core surrounded by layers of carbon. More than 90% of the technetium Tc 99m activity is technetium Tc 99m-labeled carbon particles. More than 80% of technetium Tc 99m carbon aerosol particles are < 0.92 micrometer in size. The technetium Tc 99m carbon particles are suspended in argon gas as an aerosol for inhalation. The concentration of carbon labeled particles in argon depends on the amount of technetium Tc 99m used but is less than 98 mcg/liter in Technegas Crucible loading of 0.1ml of Sodium Pertechnetate Tc99m.

11.2 Physical Characteristics

Technetium-99m decays by isomeric transition with a physical half-life of 6 hours. The photon that is useful for imaging studies is listed in Table 4.

Table 4. Principal Radiation Emission Data for Technetium-99m

Radiation	Mean % per Disintegration	Mean Energy (keV)
Gamma-2	88.5	140.5

The specific gamma-ray constant for technetium Tc 99m is 5.23 $m^2 \cdot pGy \cdot (MBq)^{-1} \cdot s^{-1}$ [0.795 $cm^2 \cdot R \cdot (mCi)^{-1} \cdot h^{-1}$]. The first half-value thickness of lead for technetium-99m is 0.017 cm (Pb). A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from the interposition of various thicknesses of lead is shown in Table 5. For example, the use of 3 mm thickness of lead will decrease the external radiation exposure by a factor of 1,000.

Table 5. Radiation Attenuation by Lead Shielding

Lead Shield Thickness (mm)	Coefficient of Attenuation
0.25	0.5
1	0.1
2	0.01
3	0.001
4	0.0001

To correct for physical decay of this radionuclide, the fractions that remain at selected time intervals after the time of calibration are shown in Table 6.

Table 6. Physical Decay Chart of Technetium-99m, Half Life: 6 Hours

Hours	Fraction Remaining	Hours	Fraction Remaining
0*	1	7	0.447
1	0.891	8	0.398
2	0.794	9	0.355
3	0.708	10	0.316
4	0.631	11	0.282
5	0.562	12	0.251
6	0.501		

*Calibration Time

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

When the Technegas Aerosol particles are inhaled, they are mechanically deposited on the epithelium of ventilated pulmonary bronchioles and alveoli. Localization of the aerosol is not mediated by specific pharmacologic receptors; rather the distribution is determined by the aerodynamic function of the lungs.

12.2 Pharmacodynamics

Technegas Aerosol has no known pharmacological effects.

12.3 Pharmacokinetics

Distribution

After inhalation, Technegas Aerosol is adsorbed on the walls of pulmonary bronchioles and alveoli. The distribution within the lungs is determined by the size and aerodynamic properties of the individual particles. Following inhalation, the particles are retained in the lung. The redistribution of Technegas Aerosol following inhalation to human subjects has been monitored for as long as 70 hours without evidence of particulate translocation.

Elimination

There is no intravascular clearance, and the elimination of radioactivity occurs by the physical decay of the Technetium-99m. The Technegas Aerosol particles that are deposited in the mouth and along the mucociliary elevator are cleared by swallowing or expectoration. The particles that deposit in the alveolar region are cleared by alveolar macrophages.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic or mutagenic potential, or whether this drug affects fertility in males or females.

14. CLINICAL STUDIES

The safety and effectiveness of Technegas Aerosol were evaluated in two studies. Study 1 (NCT03054870) was a single-arm, fixed-sequence, prospective study comparing Technegas Aerosol and xenon Xe 133 ventilation imaging in 200 patients undergoing ventilation scintigraphy. Xenon Xe 133 imaging was performed first, followed by Technegas Aerosol imaging.

Mean patient age was 60 years (range: 20 years to 88 years) and 53% were male. Distribution by race was 89% White, 10% Black or African American, and 0.5% Asian; and distribution by ethnicity was 2% Hispanic/Latino and 98% non-Hispanic/Latino.

The images were interpreted in a randomized sequence by three independent readers blinded to clinical information. Each reader assessed six standardized lung regions for ventilation using a three-point scale. The study showed that the overall percent agreement between Technegas Aerosol and xenon Xe 133 ventilation scores on matched images exceeded the pre-specified threshold of 60%. The lower bounds of the 97.18% confidence interval (due to the reported interim analysis following O'Brien-Fleming boundary) were 72%, 66%, and 76% for readers 1, 2, and 3, respectively.

Study 2 was a prospective observational study in 100 patients with suspected acute pulmonary embolism (56% male, age range 50 years to 90 years). Each patient underwent technetium Tc 99m albumin aggregated (MAA) lung perfusion scintigraphy and Technegas Aerosol ventilation scintigraphy as well as reference standard imaging using computed tomographic pulmonary angiography (CTPA) within 24 hours. The observed percent agreement for the presence of pulmonary embolism between CTPA and Technegas Aerosol ventilation scintigraphy paired with perfusion scintigraphy was 95%.

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

TECHNEGAS (kit for the preparation of technetium Tc 99m-labeled carbon inhalation aerosol) is a 1.25 gram single-use black to dark grey oval shape graphite carbon crucible packaged into

thermoformed blister packs. Each carton contains five blister packs of 10 single-use Technegas Crucibles (NDC 73814-986-20).

The following components are supplied separately by Cyclomedica for the preparation of Technegas Aerosol:

- Patient Administration Sets (PAS)
- Technegas Contacts (replacement electrodes)
- Technegas Plus System

The following items are not supplied by Cyclomedica and are provided by the user:

- Sodium Pertechnetate Tc 99m Injection, USP
- Ultra-high purity (minimum 99.997% purity with less than 3 ppm of oxygen) argon gas
- Ethanol meeting requirements of Alcohol, USP.

Storage and Handling

Store Technegas Crucibles at 15°C to 30°C (59°F to 86° F). Store unused crucibles in the original package to prevent contamination of crucibles.

The Technegas Crucible and PAS are single use components. The crucible is split into pieces after use by the Technegas Plus System to prevent its reuse. Dispose of the radioactive crucible pieces and PAS as radioactive waste in accordance with applicable regulations.

The maximum use period for the Technegas Plus System is one year or 500 burn cycles, whichever occurs first. After this period, ask Cyclomedica to perform maintenance and recertify the Technegas Plus System for use.

This radiopharmaceutical is approved for use by persons under license by the Nuclear Regulatory Commission or the relevant regulatory authority of an Agreement State.

17 PATIENT COUNSELING INFORMATION

Pregnancy

Advise pregnant women of the risk of fetal exposure to radiation from a Technegas Aerosol ventilation imaging procedure *[see Use in Specific Populations (8.1)].*

Lactation:

Advise lactating women that pumping and discarding breast milk for a minimum of 4 hours after Technegas Aerosol administration may minimize exposure in the breastfed infant *[see Use in Specific Populations (8.2)].*

Manufactured by:
Cyclomedica Australia Pty Ltd
Unit 4, 1 The Crescent
Kingsgrove NSW 2208
Australia
Website: www.cyclopharm.com

Distributed by: To be determined.

MNL-0030

Technegas® Plus System

USER MANUAL

MNL-0009 Rev 10 US-EN

Manufactured in Australia by Cyclomedica Australia Pty Ltd

Reference ID: 5253049

1 Preamble

The information in this manual is for the **Technegas® Plus System, model number 25000**.

Cyclomedica Australia Pty Ltd reserves the right to change the content of this manual without prior notice.

You will be advised of any changes that may affect the use of your Technegas Plus System through your Cyclomedica authorized service partner.

The most recent version of the User Manual can always be found at http://www.cyclomedica.com/technegasplus-user-manuals/

The Technegas Plus System will meet the specifications described within when it is installed, operated, and maintained in accordance with this manual.

Caution: US Federal Law restricts this device to sale by or on the order of a physician.

1.1 Manufacturer's Trademark and Copyright

Technegas® is a registered Trademark of Cyclomedica Australia Pty. Ltd.

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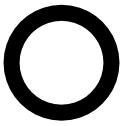
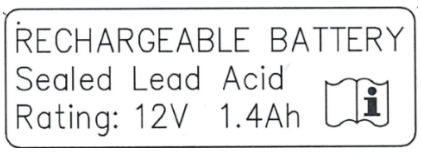
2 Table of Symbols and Abbreviations

Symbol	Description
	WARNING
	HOT SURFACE
	WARNING RADIATION
	WARNING HIGH VOLTAGE
	WARNING BIOHAZARD
	SINGLE USE ONY
	REFER TO INSTRUCTION MANUAL/BOOKLET
	CONSULT INSTRUCTIONS FOR USE
	OFF (POWER DISCONNECTION FROM THE MAINS) International Symbol for power OFF.
	ON (POWER CONNECTION TO THE MAINS) International Symbol for power ON
	SEALED LEAD ACID RECHARGEABLE BATTERY RATING 12V, 1.4AH This label is located on the chassis adjacent to the battery.

Symbol	Description
	DEPRESS PATIENT DELIVERY BUTTON TO A POSITIVE STOP This label is located on the TP top cover next to the PATIENT DELIVERY BUTTON.
	This label is located on the Low-Pressure argon Gas Regulator. It specifies that only ARGON gas be used with the TP.
	TYPE B APPLIED PART
TP	Technegas Plus System (also commonly referred to as TechnegasPlus Technegas Generator)
PAS	Patient Administration Set

3 Product Information

3.1 Description

Figure 1: Technegas Plus System (TP)

The Technegas Plus System (TP) is an automated module to prepare and administer Technegas Aerosol (technetium Tc 99m-labeled carbon inhalation aerosol) in argon gas from the supplied Technegas Crucible (kit for the preparation of technetium Tc 99m labeled-carbon inhalation aerosol) and the user supplied sodium pertechnetate Tc 99m injection, USP. The Technegas Aerosol is administered from the Technegas Plus System to the patient by oral inhalation using the supplied the Technegas Patient Administration Set (PAS).

3.2 Indications

Technegas Aerosol is a radioactive diagnostic agent indicated for use in adults and pediatric patients aged 6 years and older for:

- visualization of pulmonary ventilation
- evaluation of pulmonary embolism when paired with perfusion imaging

3.3 Contraindications

None.

3.4 Biocompatibility evaluation of breathing gas pathways

According to ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications, a typical exposure of a patient over a period of 3 minutes during the use of the TP has not been shown to result in any significant exposure to Volatile Organic Compounds; no toxicological effects are anticipated.

3.5 Principle of operation

3.5.1 Preparing the Technegas Aerosol in the TP

Technegas Aerosol is a solid in gas aerosol produced by reacting volatilized graphite carbon from the Technegas Crucible with technetium Tc 99m in an argon gas inert atmosphere in the TP steel chamber.

Technegas Aerosol is produced in the chamber of the TP by first drying the sodium pertechnetate Tc 99m solution (approximately 0.1 mL volume) in the Technegas Crucible at 70°C (158°F) for 6 minutes, which removes the water from the saline carrier solution. The chamber is purged of oxygen and filled with argon gas during this drying process. The TP then rapidly heats the crucible to 2,750°C ± 100°C (4,982°F ± 212°F) within 2 seconds and maintains this temperature for 15 ± 1 seconds. An optical sensor maintains the high temperature phase within the specified temperature limits.

During this process, both the technetium and a portion of the carbon crucible are volatilized and pertechnetate is reduced to elemental technetium. The elemental technetium serves as a nucleation site for the condensing of the volatile carbon, producing particles made up of a technetium core surrounded by layers of carbon. More than 90% of the technetium Tc 99m activity is technetium-labeled carbon particles. More than 80% of technetium carbon aerosol particles are < 0.92 micrometer in size. The technetium Tc 99m carbon particles are suspended in argon gas to provide aerosol for inhalation. The concentration of carbon labeled particles in argon depends on the amount of technetium Tc 99m used but is less than 98 microg/L.

See Section 9 “Preparation of Technegas Aerosol” for details.

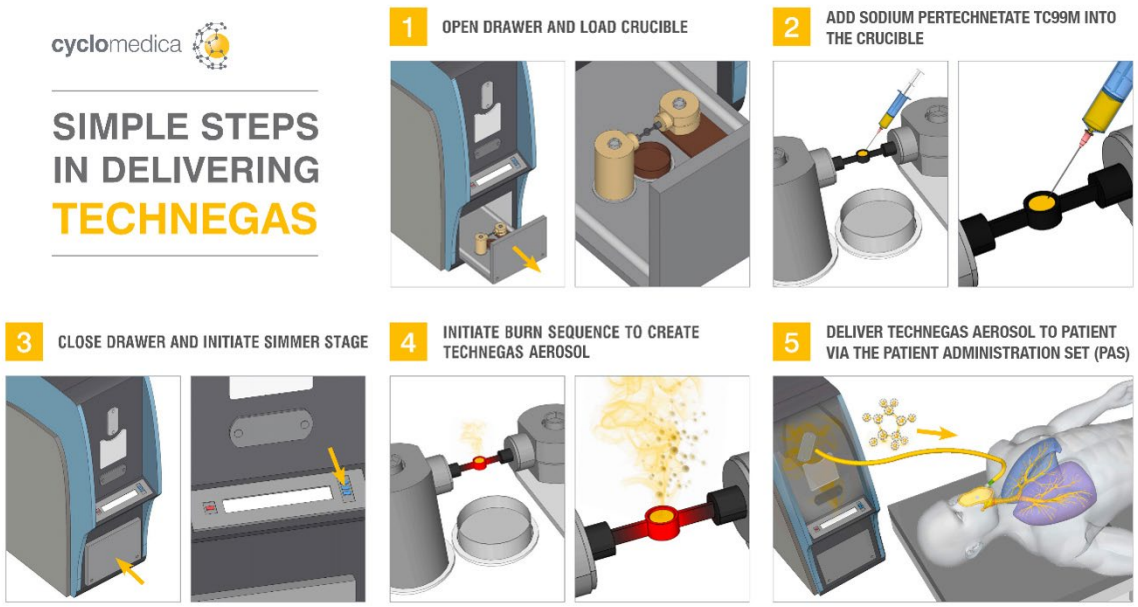


Figure 2: Technegas Aerosol generation and delivery summary

3.5.2 Administering the Technegas Aerosol to the patient

An operator controlled electrically actuated exit port in the chamber enables the patient to inhale Technegas Aerosol directly from the chamber via the PAS. Technegas Aerosol expires 10 minutes after it is prepared. To expedite the administration of the aerosol to the patient, the patient is prepared prior to or during the Technegas Aerosol preparation procedure. When the aerosol is ready for administration, the PAS tubing is attached to the chamber, the port is opened, and the patient directly inhales the aerosol from the chamber. To prevent accidental use of expired aerosol, the TP automatically closes the port after 10 minutes, which prevents delivery to the patient. The chamber is then automatically purged through a filter system to trap any residual activity.

See Section 10.3 “TP operation during administration” for details.

4 Operator Responsibility

Only personnel (Operators) specifically trained on the use of the TP should be allowed to use it.

Operators are responsible for understanding the contents of this manual, including:

- Measures to ensure safety
- Use of the TP according to the instructions provided in this manual
- Use of appropriate operating environment, as defined by the specifications in this manual
- Maintenance of the TP as per instructions in this manual
- Facilitating any periodic or required annual service with Cyclomedica authorized personnel
- Requests for repair from Cyclomedica should the TP become faulty
- Reporting any serious incident that occurs in relation to the TP to the manufacturer and their US Authorized Representative identified on page 2
- Reporting SUSPECTED ADVERSE REACTIONS to Cyclomedica Australia Pty Ltd at 1-888-586-4396 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

5 Precautions and Safety in Use

Technegas Plus System is for USE ONLY with Technegas Crucible.

To report SUSPECTED ADVERSE REACTIONS, contact Cyclomedica Australia Pty Ltd by telephone at 1-888-586-4396, or contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. For additional information refer to the TECHNEGAS *Prescribing Information* (PI).

Only use Sodium Pertechnetate Tc 99m Injection, USP in the TP.

Only use the brass Technegas Contacts (electrodes), manufactured by Cyclomedica Australia. The Technegas Contacts are critical accessories for the safe and effective performance of the TP.

The Technegas Patient Administration Set (PAS) is a SINGLE USE ONLY product. For safe and effective administration, only use the Technegas Patient Administration Set, manufactured by Cyclomedica Australia.

Each Technegas Crucible is a SINGLE USE ONLY product.

Unauthorized repairs and replacement of integral components will adversely affect the safe and effective operation of the TP; tampering with internal operating settings is a breach of the *Essential Principles of Safety and Performance of Medical Devices* outlined in international Medical Device Regulations.

5.1 Important safety in use

- Handle the Technegas Crucible with forceps with care. A contaminated crucible may lead to non-performing product. Prior to use inspect the Technegas Crucible for visible damage. Do not use a damaged crucible.
- Only use Alcohol, USP (95% ethanol) for rinsing and preparing the crucible.
- Use only high purity argon gas with minimum labeled purity of 99.997% (with NMT 3 ppm oxygen). Do not use industrial or welding grade argon with the TP.
- Do not allow repairs to be carried out on the TP by unauthorized personnel; tampering with a medical device breaches the *Essential Principles of Safety and*

Performance of Medical Devices outlined in the international Medical Device Regulations.

- Do not insert cleaning brushes or other foreign objects through the various valves, openings, or holes in the TP or its consumables. Resulting damage may render the TP unusable and unserviceable.
- Only open the Patient Delivery Valve when the Patient Administration Set (PAS) is connected to TP and the patient is breathing through the attached PAS. Keep the valve closed at other times.
- Ensure that the patient continues to breathe through the PAS while connected to the TP with the delivery button released for at least FIVE (5) breaths after the cessation of Technegas Aerosol inhalation. This clears the radioactive aerosol from the delivery tubing and the patient's conducting airways.
- **Do not leave the TP unattended while it is performing any operation**.

5.2 Radiation safety

When used correctly, the TP is shielded for Technetium Tc 99m radiation protection and contains self-contained filtration apparatus.

- Use radiation protection measures as TP and the PAS are radioactive during and after use.
- Wear protective gloves, aprons, and masks for radiation protection and infection control when using TP.
- Keep the Drawer closed when the TP is not in use, to prevent potential release of radioactive contamination.
- After use, the fragmented crucible pieces and the PAS are radioactive. Dispose of the radioactive crucible pieces and PAS as radioactive waste in accordance with applicable regulations.
- For radiation spills, refer to your radiation safety plan for site requirements on spill clean-up.

5.3 Moving the Technegas Plus System safely

- The TP weighs approximately 120 kg (265 lb), therefore appropriate care should be taken when moving it.
- To move the TP, disconnect it from the argon gas cylinder and disengage the wheel locks.
- After moving, re-engage the wheel locks and reconnect the cylinder.
- Exercise extra care when moving the TP over uneven or steep surfaces.
- Make sure that the wheel locks are engaged when the TP is stationary.
- Do not load heavy items such as the gas cylinder on the TP trolley for transport.

5.4 Warnings

- Argon is an asphyxiation hazard. Turn **OFF** the argon cylinder supply valve **when not connected** to the TP. Ensure that there is an oxygen sensor located in proximity where the argon gas is stored or that the facility's OH&S policy for storage and use of compressed gases is in place.
- The internal components of the TP may be hot and radioactive.
- Do not open or close the drawer if you suspect anything may obstruct normal operation.

Dispose of the used consumables as contaminated waste; both will be radioactive and biologically hazardous after use.

The patient must not touch the TP, only the PAS.

6 Operating Key Functions on the TP

6.1 Front and rear panel descriptions

1 – START button
2 – CLOSE button
3 – OPEN button
4 – Display
5 – Socket for Remote delivery button
6 – PAS connection behind metal cover
7 – Patient delivery button
8 – Drawer interlock button
9 – Easy Breather connection *(Easy Breather not available in USA)*
10 – CANCEL button
11 – Amber colored lead (Pb) shield
12 – TP Drawer

Figure 3: Front Panel of the TP

1 – Argon inlet connector
2 – Mains switch
3 – Mains power indicator light

Figure 4: Rear Panel of the TP

6.2 Operating the CANCEL button

To cancel an operation, the CANCEL button needs to be pressed TWICE within two seconds to activate a "CANCEL" operation. This eliminates the risk of cancelling an operation accidentally.

Throughout this manual, this operation is referred to as “DOUBLE CANCEL”.

6.3 Operating the Drawer

The Drawer is opened by pressing the OPEN button when the display reads

```
"    OPEN DRAWER TO      "
"    CHANGE CRUCIBLE     "
```

To close the Drawer from the open position, PRESS and HOLD the Drawer Interlock button at the top of the TP, then PRESS and HOLD the CLOSE button until the drawer is fully closed and an audible alert is sounded. The two buttons may then be released.

If either button is released before the Drawer has stopped moving it will immediately re-open. This ‘two-handed’ operation is a safety precaution.

The closing of the Drawer poses a finger and hand trapping hazard.

Issues with opening or closing of the Drawer may pose a radiation hazard if the TP has recently performed a Burn process. In this event, follow your site’s radiation safety plan and contact your Cyclomedica authorized service partner.

Keep the Drawer closed when the TP is not in use.

7 Installation and Operation Requirements

7.1 Installation information

The authorized Cyclomedica representative will unpack and install the TP. User should not install the TP. The Cyclomedica authorized representative will complete the installation checklist to be signed by the user representative.

7.2 Location for operation and storage

The TP must be stored and operated at 15° to 30°C (59° to 86°F) in an area that is suitable for using radioactive materials (e.g., Nuclear Medicine department). Prepare Technegas Aerosol near the patient to enable timely administration (within 10 minutes).

7.3 Power supply

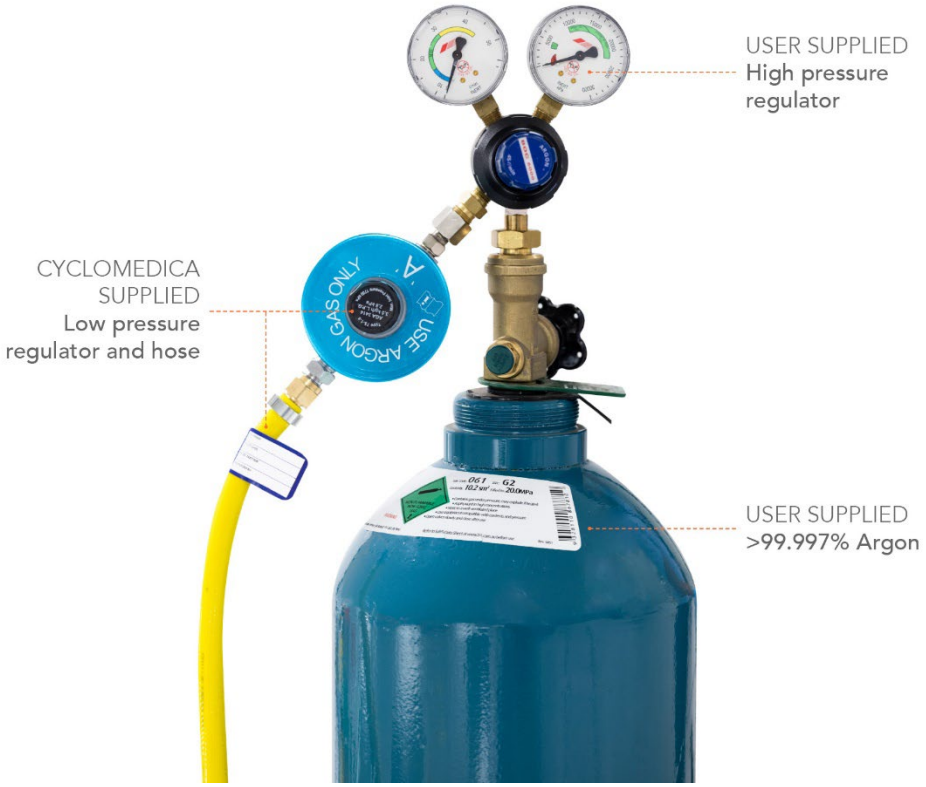
The TP is to be operated using the 20 Amps, 200 V to 240 V ±5%, 50 Hz or 60 Hz power. The Operator must provide an earthed mains power line dedicated for use with TP.

To avoid the risk of electric shock, the TP must only be connected to a supply mains with protective earth.

7.4 Argon gas supply and connection

The Operator must provide and use ultra-high purity grade argon (≥99.997% purity with less than 3 ppm oxygen) and the high-pressure argon regulator to the following specifications:

Maximum outlet pressure	150 kPa	1.48 Atm	21.75 PSI
Maximum flow output	45 L/min	11.88 US gallons/min	95 SCFH



The TP is designed for use with the supplied argon hose and the Cyclomedica argon low-pressure regulator.

Figure 5: Set up of argon supply

Secure the argon cylinder as per local regulations.

- Only ultra-high purity grade (≥ 99.997% purity with less than 3 ppm oxygen) argon gas must be used. Do not use industrial or welding grade argon.
- Ensure that the 'high' and 'low' pressure regulators are turned to the OFF position prior to setup.
- Ensure that the 'high' pressure regulator is firmly connected to the gas supply.
- Ensure that the 'low' pressure regulator is firmly connected to the high-pressure regulator.

Figure 6 (a, b): Connecting the argon supply hose

To connect the argon hose to the argon gas inlet of the TP, press the black cover on TP, insert the hose connector end into the socket, and pull the black cover back to engage the locking mechanism.

7.5 Oxygen sensor

Ensure that there is an oxygen sensor located in proximity where the argon gas is stored or that the facility's OH&S policy for storage and use of compressed gases is in place.

7.6 Battery charging

- The battery must be fully charged to administer the Technegas Aerosol to the patient.
- To charge the battery:
    - Plug the TP unit into the 20 Amp electrical power outlet and turn the switch button ON using the main switch located at the rear of the TP.
    - The green indicator light above the main switch will illuminate when the TP is powered on.
- **If there is insufficient battery power, the port required to deliver Technegas Aerosol will not open, and the patient will not receive Technegas Aerosol for inhalation.**
- **It is essential to leave the unit plugged in, powered on, and the Drawer closed when not in use to keep the battery fully charged.**
- The battery charging capacity will be assessed at least annually or during scheduled preventative maintenance, whichever is earlier.

7.7 External transportation

- Prior to moving the TP from or between facilities, contact Cyclomedica to prepare the TP for safe transport and subsequent optimal operation.

8 Patient Preparation

Prepare the patient for Technegas Aerosol administration in the imaging room or preparation room before starting preparation of Technegas Aerosol.

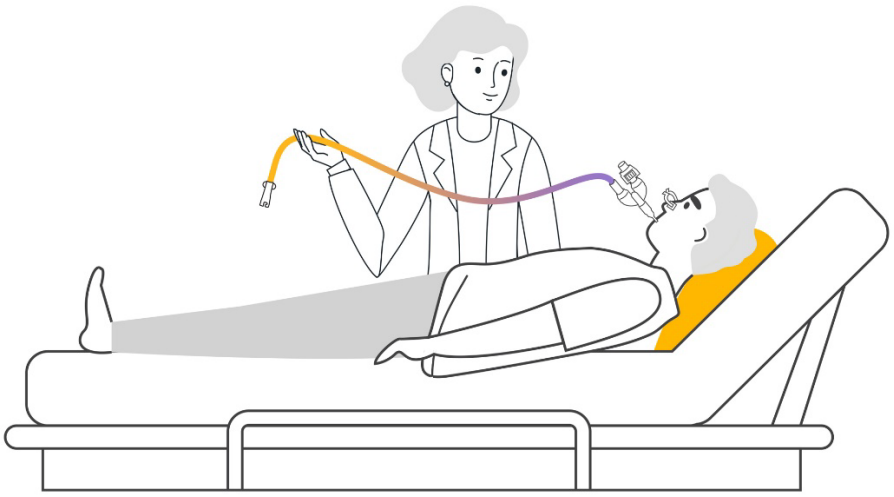


Figure 7: Patient preparation for the delivery of Technegas Aerosol

1. Prepare the patient in supine position.
2. Select the appropriate mouthpiece and attach it to the Y-section connector on the PAS.
3. Place the mouthpiece in the patient's mouth ensuring a total seal by their lips.
4. Place the nose clip on the patient's nose.
5. You may advise the patient to practice breathing with the mouthpiece and nose clip in place using one of the breathing methods detailed in Section 10.2 " Recommended breathing methods for Technegas Aerosol inhalation".

The PAS is constructed to allow the patient to breathe normal air from the room until the PAS is connected to the TP and the Patient Delivery Button or Remote Delivery Button is pressed during administration of Technegas Aerosol as described in Section 10.3 "TP operation during administration". The Patient Delivery and Remote Delivery Buttons **are not enabled** until the Patient Delivery sequence is reached.

9 Preparation of Technegas Aerosol

9.1 Safety and quality check

1. Wear gloves and exercise good radiation protection practice (ALARA principles).
2. Inspect the Technegas Crucible for visible damage.
3. Ensure that correct components (materials) (e.g., Alcohol, USP) are being used.
4. Perform a quick visual check of the TP:
    a. Check for visible damage to the TP exterior.
    b. Check that the TP trolley wheels are locked.
    c. Check the amber colored lead (Pb) shield is in place in front of the Drawer.
    d. Check that the argon gas supply is ultra-high purity grade (≥ 99.997% purity) and that there is positive pressure indicated on the regulator .
5. Check room oxygen sensor for alert or alarm, which may indicate a leak of argon gas from a source along its connection to the TP. If a leak is found or suspected, follow your workplace OH&S guidelines, since excessive levels of argon gas pose a risk of asphyxiation and death to bystanders.

USE ONLY Technegas Crucible for the Preparation of Technegas Aerosol

Do not leave the TP unattended while the argon supply is turned ON.

The TP releases argon to the room atmosphere during Purge Operation. When the TP is not in use, turn the argon Cylinder supply valve off.

The installation and use of an oxygen sensor in the room where the argon gas cylinder is located that alarms if the oxygen level falls below a safe level is strongly recommended.

9.2 Required items

To prepare and administer Technegas Aerosol using the TP, Cyclomedica provides the following items:

- Technegas Crucible
- Technegas Contacts (electrodes)
- Low pressure gas regulator and argon gas connecting hose
- Patient Administration Set (PAS)

Each Technegas Crucible and PAS are single use only and the Technegas Contacts are replaced every 50 Burn cycles (use).

The following items are provided by the user:

- Sodium pertechnetate Tc 99m injection, USP
- Ultra-high purity (minimum 99.997% purity with less than 3 ppm oxygen) argon gas supplied by the user. The following grade indicates a 99.997%: Grade 4.7 or greater from any medical gas provider. Please contact Cyclomedica if you require further clarification
- Alcohol, USP (≥95% ethanol)
- One 1 mL needleless syringe capable of dispensing 100 microliters
- One 1 mL syringe with needle capable of dispensing 100 microliters
- Disposable gloves
- Forceps
- A clean non-contaminated flat work surface
- Oxygen sensor or existing OH&S systems in place for handling compressed gases

9.3 Setting up the argon gas supply

The argon gas should be connected and turned ON (during use of the TP) using the following instructions prior to use:

Figure 8: Controlling Argon flow

1. Ensure the argon hose is connected to the TP as detailed in Section 7.4 “Argon gas supply and connection”.
2. Turn ON the argon supply at the cylinder.
3. Adjust the argon supply on the high-pressure regulator and set the flow rate to approximately 15 liters per minute.
4. The Cyclomedica supplied low-pressure regulator is fit-for-use and does not require adjustment.
5. Observe the argon high pressure regulator and check that the argon cylinder has positive pressure once cylinder valve is opened for preparing Technegas Aerosol.

9.4 Prepare the TP for use

1. Connect the Remote Delivery Button to the socket above the TP display panel.

Figure 9: The Remote Delivery Button

The remote delivery button is attached to an electrical cable approximately 1 m in length. Remote delivery may be used if the Operator wishes to position themselves either closer to the patient to assist the patient in the administration or further away to reduce occupational radiation exposure from the residual activity held within the Patient Administration Set or the activity emanating from the patient.

2. When not in use, the Remote Delivery Button may be placed in the dedicated holder on the sloping rear panel of the TP.
3. If necessary, switch ON the TP.

The display will show the name Cyclomedica Australia Pty Ltd and the current TP software version along with the date and time.

If a 'Purge' has not been carried out since the last Technegas Aerosol preparation, the TP will then check if the Drawer is closed and perform a Purge operation.

> **The Purge (through an internal filter) is to ensure that no residual Technegas Aerosol from a previous operation will escape into the atmosphere when the Drawer is opened.**

The display will then read:

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OPEN DRAWER TO
CHANGE CRUCIBLE
```

9.5 Open drawer and remove Technegas Crucible fragments

During and after Technegas Aerosol preparation, all internal components of the chamber and gas pathway leaving the chamber are radioactively contaminated. Use Good Radiation Protection Practices including wearing disposable gloves.

The internal components of the TP may be HOT!

1. Press the OPEN button to open the Drawer.
2. Remove any Technegas Crucible fragments from the Ash tray. The Ash tray is removable for ease of access and must be returned to position before continuing.

Figure 10: TP with Drawer open

In the case of an obstruction, the Drawer opening can be halted mid-way by pressing DOUBLE CANCEL.

9.6 Preparing the Technegas Crucible

Figure 11: Installing the Technegas Crucible into the TP Drawer

1. Using the forceps, pick up the Technegas Crucible from its packaging and place it on a clean flat surface.
2. To wet the Technegas Crucible, use a 1 mL syringe and fill the Technegas Crucible with Alcohol, USP (95% ethanol), then draw the ethanol back into the syringe.
3. Discard the syringe after use.
4. The Technegas Crucible should appear wet/moist. If the ethanol in the Technegas Crucible has evaporated and appears dry due to time elapsed between step 2 and step 11 below, repeat step 2 and 3.
5. Using the forceps, pick up the Technegas Crucible approximately at a 45° angle.
6. To enable fitting of the Technegas Crucible into the Technegas Contacts, press the lever below the left side of the Drawer (away from the operator) as shown in Figure 11.
7. Place the left end of the Technegas Crucible into the left Technegas Contact.
8. Align the right side of the Technegas Crucible with the right Technegas Contact and gently release the lever to connect the Technegas Crucible with both Technegas Contacts.
9. Rotate the Technegas Crucible gently backwards and forwards on its axis.

   Perform this procedure carefully, as the Technegas Crucible can fracture. Do not use a fractured crucible for preparing Technegas Aerosol.

10. Ensure the well of the Technegas Crucible is in the **upright position** as shown in Figure 12 below.

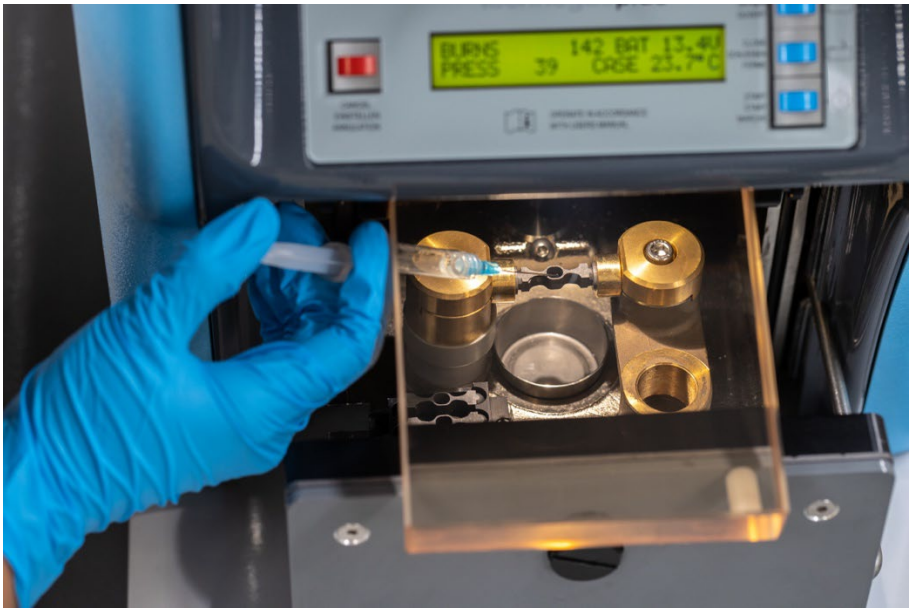

Figure 12: Loading Sodium Pertechnetate Tc 99m Injection, USP into the Technegas Crucible

11. For adult patients, using a new 1 mL syringe with needle, load the Technegas Crucible with 400 MBq to 1,000 MBq (10.8 mCi to 27 mCi) sodium pertechnetate Tc 99m injection in a volume of approximately 0.1 mL, while ensuring that the liquid meniscus does not exceed the height of the crucible. The maximum crucible volume is 0.12 mL, and adding excess volume can lead to radioactive spill in the TP and may led to formation of aerosol of free pertechnetate Tc 99m that may deteriorate image quality. For the recommended loading activity of sodium pertechnetate Tc 99m injection in pediatric patients aged 6 years and older, refer to *TECHNEGAS prescribing information.*

    Do not overfill the Technegas Crucible, the meniscus should not exceed the height of the crucible (as depicted in Figure 13).

Figure 13: Comparison of an incorrectly filled (Overfilled) crucible vs a correctly filled (≤0.12 ml) Crucible

Only USE Sodium Pertechnetate Tc 99m Injection, USP in the TP

Refer to the TECHNEGAS *Prescribing Information* for complete dosing and administration instruction.

12. To close the Drawer, PRESS and HOLD the DRAWER INTERLOCK button, then PRESS and HOLD the 'CLOSE' button. Keep both buttons depressed until the Drawer is fully closed.

Note: Store the Technegas crucibles in the original package.

When a blister pack of 10 Technegas crucibles is used for the first time, the tamper proof seal must be 'opened' to facilitate access to the crucibles. Carefully remove one crucible (for each Technegas Aerosol preparation) from the blister pack and reinsert the cardboard backing material to cover all residual crucibles in their respective individual blister pockets. This should effectively prevent ingress of any discernible material from the immediate environment and allows the crucibles to be securely stored in readiness for the next Technegas Aerosol preparation procedure.

9.7 Simmer process

The display will read:

```
PRESS START TO INITIATE
SIMMER
```

Press START to initiate the Simmer process, which heats the crucible to 70°C (158°F) for 6 minutes to evaporate the technetium Tc 99m solution. During this time the TP chamber is also completely filled with the argon gas (note: 100% argon atmosphere is necessary to prepare pure Technegas Aerosol). The Simmer Process may be aborted by pressing DOUBLE CANCEL.

When the simmer is complete, the display will read:

```
PRESS [START] TO
INITIATE BURN
```

9.8 Burn process

1. Press the START button to initiate the Burn process, which heats the crucible to 2,750°C (4,982°F) for 15 seconds to produce the aerosol.
2. When the Burn is complete the display will read:

   VERIFYING BURN

3. The display will then change to:

   DISCONNECT THE MAINS PLEASE

   Technegas Aerosol is now prepared and ready for inhalation by the patient within 10 minutes.

4. Turn OFF the argon supply and disconnect the power supply using the following sequence:
   a) Turn OFF the argon supply at the cylinder.
   b) Turn OFF the argon supply at the high-pressure regulator.
   c) Disconnect the argon hose from the TP.
   d) Switch OFF the mains power switch and disconnect the TP from the power supply. The TP will remain powered ON from an internal battery for Technegas Aerosol administration to the patient.
   e) The TP may be moved to the patient as required.

10 Administration of Technegas Aerosol

Use disposable gloves and conduct Good Radiation Protection Practice.

Do not press the Patient Delivery Button or Remote Delivery Button until the patient is being ventilated through the TP, as Radioactive Technegas Aerosol will be released.

The activity present in the lungs after each inhalation varies. Follow the pulmonary count rate during inhalation of Technegas Aerosol using a gamma camera equipped with a standard collimator (low energy, low/medium resolution). For adult patients, have them inhale Technegas Aerosol until a lung count rate of between 1,500 cps and 2,500 cps is obtained. Discontinue Technegas Aerosol administration at that point. Refer to the TECHNEGAS Prescribing Information for complete dosing instruction.

Do not touch the patient whilst attaching the PAS to the TP or touching the internal components of the TP Drawer.

10.1 Administration information

- For complete dosing and administration instructions see the TECHNEGAS *Prescribing Information* and Section 10.2 "Recommended breathing methods for Technegas Aerosol inhalation".
- Technegas Aerosol should be administered as soon as possible after being prepared and the administration must be finished within 10 minutes of its preparation.
- Patient posture affects the distribution profile of Technegas Aerosol in the lungs in response to the gravitational effect on blood distribution. Every effort should be made to ventilate the patient in the same posture as they will adopt for perfusion scanning.
- A method of monitoring the inhaled dose during Technegas Aerosol administration is required by using a gamma camera. Delivery of Technegas Aerosol is continued until a count rate of approximately 1,500 counts per second to 2,500 counts per second in adult patients is achieved.

10.2 Recommended breathing methods for Technegas Aerosol inhalation

Ensure the patient has their lips fully sealed around the mouthpiece and the nose clip is in place.

> **Operating tip:** Encouraging the patient to imitate sucking fluids through a straw can improve the efficiency of the inhalation.

For adult patients, the recommended breathing method to inhale the aerosol is through the mouthpiece by slow deep breathing from the residual functional capacity (end of calm expiration), followed by a 5-second breath-hold.

For patients unable to hold their breath, normal breathing with deep inhalations without breath-holding can be used.

For pediatric patients aged 6 years and older, instruct the patient to inhale the aerosol through the mouthpiece or inhalation line by normal breathing with deep inhalations without breath-holding.

When the adequate pulmonary counts are achieved for imaging, the patient must continue exhaling air through the filter equipped exhalation circuit of the PAS for five breaths to six breaths to trap residual aerosol being exhaled.

10.3 TP operation during administration

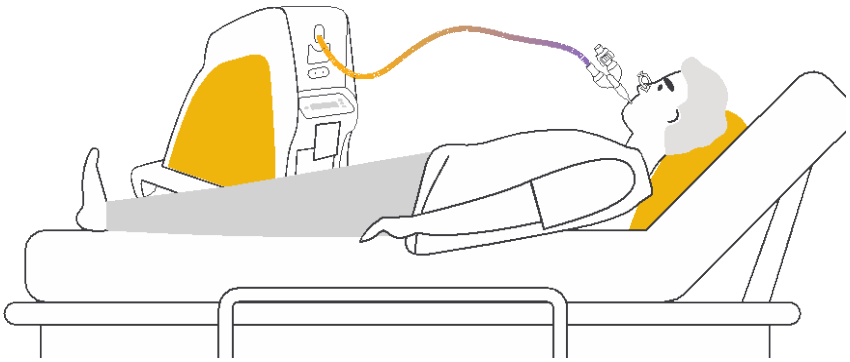

Figure 14: Supine administration of Technegas Aerosol

1. After placing the PAS mouthpiece and nose-clip on patient (see Section 8 “Patient Preparation”), attach the other end of the PAS to the TP by pushing the end of the hose into the PAS connection on the TP and rotating clockwise. Gently pull on the connection point to ensure secure connection.
2. Press the START button to open the chamber port to the PAS, which allows the Technegas Aerosol to be inhaled into the PAS and administered to the patient.

   The display will read:

   ```
   "   PRESS [CANCEL]       "
   "   IF FINISHED          "
   ```

3. Instruct the patient to perform the breathing method several times through the mouthpiece as practiced in Section 8.
4. When the patient ends exhalation, press and HOLD the Patient Delivery button or the Remote Delivery Button to allow delivery of Technegas Aerosol from the TP to the patient’s lungs.
5. On completion of patient first breath, RELEASE the Patient Delivery button or the Remote Delivery Button to allow the patient to breath room air via the PAS. Monitor the activity in the patient’s lungs.
6. Repeat Steps 4 and 5 until adequate pulmonary counts are achieved for imaging.
7. Release the Patient Delivery Button or the Remote Delivery Button. The patient must continue exhaling air through the filter equipped exhalation circuit of the PAS for five breaths to six breaths to trap residual aerosol being exhaled.
8. Press DOUBLE CANCEL and the TP will shut down and power off.
9. Remove the nose clip from the patient.
10. Remove the mouthpiece from the patient.
11. Disconnect the PAS from the TP.

12. Place the PAS into the PAS sleeve (as shown in Figure 15 below) and dispose in accordance with local and regulatory guidelines for biological and radioactive waste.

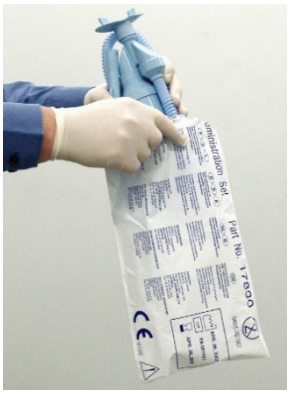

Figure 15: Disposal of the PAS

11 After Administration to the Patient

1. If required, return the TP to its designated operation and storage location.
2. Reconnect the TP to the argon supply and turn ON the argon supply.
3. Reconnect the TP to mains power and switch it ON at the mains switch at the rear of the TP.

The TP will perform an automated ‘Purge’ operation to clear the residual Technegas Aerosol from the internal chamber.

The display will read once the Purge operation is complete:

“….OPEN DRAWER TO CHANGE CRUCIBLE….”

4. Turn OFF the argon supply at the cylinder to minimize the risk of inadvertent leaks.
5. Turn OFF the argon supply at the high-pressure regulator.
6. **Leave the TP connected to mains power and powered ON** to keep the internal battery fully charged.

If the TP does not perform the automated Purge process after the Burn process, contact your Cyclomedica authorized service.

Do not leave the TP unattended while the argon supply is turned ON. Ensure the Drawer is closed and the argon supply is OFF when the TP is not in use.

The TP releases argon into the room atmosphere during the Purge Operation. While connected to the argon cylinder, operate, and store the TP in a well-ventilated room. Adhere to your local Safe Handling of Gas Practices/Guidance.

An oxygen sensor should be installed in the room where the argon gas cylinder is located. The sensor should alarm if the oxygen level falls below a safe level. If an independent oxygen sensor is not installed, the facility must be designed with controls to comply with OH&S requirements for using and storing compressed gases.

12 Disposal of Contaminated Items

12.1 List of contaminated items

- The Technegas Crucible
- The used Patient Administration Set (PAS)
- Technegas Contacts (replaced every 50 burns)
- Disposable gloves
- Used syringes

The Technegas Crucible and the PAS are single use items

- Always use disposable gloves when handling contaminated items.
- Treat the PAS and mouthpieces as radioactive and biological waste.
- Change the Technegas Contacts as specified in Section 13.3 "Changing the Technegas Contacts" and dispose of the old Technegas Contacts as radioactive waste.
- Handle any component removed or replaced from the internal systems as if it was contaminated with radioactivity.

12.2 Disposing of used Technegas Crucible

The TP breaks the Technegas Crucible automatically following Technegas Aerosol preparation and administration to prevent re-use. The fragments are collected in the Ash tray located beneath the Technegas Contacts; the fragments must be removed for subsequent use, prior to Technegas Aerosol preparation. Treat the crucible fragments as radioactive waste.

12.3 Disposal of radioactively contaminated items

Dispose of radioactive and infectious waste according to applicable national, state, and local regulations.

If advice on disposal is required, Cyclomedica recommends that Operators contact their local Competent Authority or Regulatory Body.

12.4 Cleaning of radioactive spills

If a radioactive spill occurs within the lower chamber, it may be left to decay as it is in a shielded environment before cleaning (surface wipe only with damp lint free wipe). Alternatively, refer to your radiation safety plan for your site's requirements on spill clean-up. Similarly, for spills on the exterior of the TP, refer to your radiation safety plan for your site's requirements on spill clean-up.

13 Maintenance

The TP must not be serviced or maintained while in use with a patient.

13.1 Operator maintenance

The Operator must:

- Replace the Technegas Contacts every 50 burns as described in Section 13.3 “Changing the Technegas Contacts”.
- Empty the Ash tray of Technegas Crucible fragments prior to preparation of Technegas Aerosol as described above in Section 12.2 “Disposing of used Technegas Crucible”.
- Keep the TP clean as described in Section 13.2 “Cleaning the TP”.
- See Section 13.6 “Authorized service and maintenance”.

13.2 Cleaning the TP

Clean the exterior panels of the TP, the Drawer, and the lower chamber as necessary with a damp, lint-free cloth while the TP is switched OFF at the mains switch and the power supply cord is unplugged from the wall, as per the instructions below.

1. Open the Drawer
2. Switch OFF the power at the mains switch
3. Clean the TP as required
4. Switch ON the TP and the following message will be displayed:

```
"CONTACTS    [OPEN ] = NO "
"CHANGED ??  [CLOSE] = YES"
```

5. Press OPEN button to select NO.

Allow to fully air-dry.

Do not use detergents or solvents such as alcohol, benzene, or thinners as they will damage the TP’s exterior.

13.3 Changing the Technegas Contacts

- The Technegas Contacts must be replaced every 50 Burns to ensure the safe and effective preparation of Technegas Aerosol.
- The TP automatically counts down the Burns remaining for each new set of Technegas Contacts installed.
- The TP will display the following message when the count reaches zero (0)

"……SWITCH OFF AND CHANGE CONTACTS……."

- Replace the Technegas Contacts by carrying out the instructions below:

1. Wear disposable gloves and use Good Radiation Protection Practice.
2. Open the Drawer
3. Switch OFF the power at the mains switch

The Technegas Contacts may be HOT!

Allow the TP to cool for at least 10 minutes prior to changing the Technegas Contacts

---

4. Use a 6 mm hex key (provided with TP) to loosen the Technegas Contact clamping screws on the two pedestals as depicted in Figure 16 below. The lever below the Drawer must be held in place to loosen the right-hand side pedestal screw.
5. Remove the 'old' Technegas Contacts and dispose of as radioactive waste.
6. Check that the brass surfaces of the Drawer pedestals and the new Technegas Contacts are clean. Wipe with a damp lint free cloth if not clean.
7. Fit the new Technegas Contacts into the two pedestals and slide the Technegas Contacts in as far as possible to provide good connection between the rear face of the Technegas Contact and the pedestal.
8. Firmly hand tighten the clamping screws on the pedestals with the supplied allen key which equates to approximately 5-15nm of force. The lever below the drawer must be held in place to tighten the right-hand side pedestal screw.

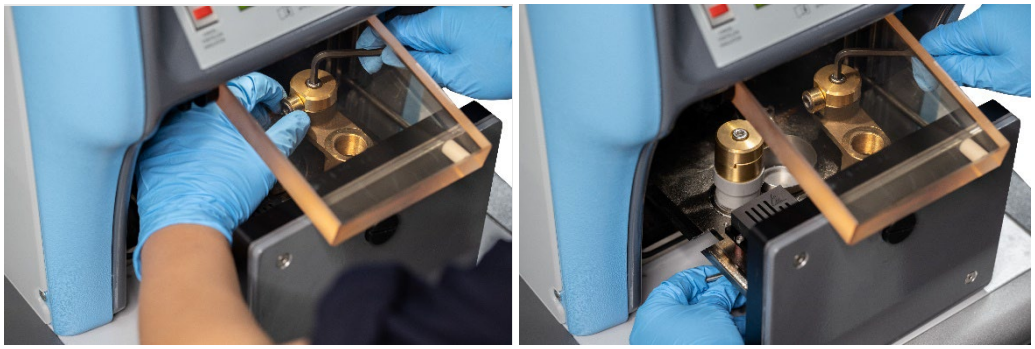

Figure 16: Replacing the Technegas Contacts

Do not over-tighten the screws as excessive force may damage the screw thread inside the brass pedestal.

9. Switch ON the TP and the following message will be displayed:

```
"CONTACTS    [OPEN ] = NO "
"CHANGED ??  [CLOSE] = YES"
```

10. Press CLOSE button to select YES. The TP will reset the Technegas Contacts counter to 50 remaining Burns.

Technegas Contacts are made from brass with a carbon inlay. Only Technegas Contacts supplied by Cyclomedica (as shown in Figure 17 below) must be used in the Technegas Plus System.

Figure 17: Technegas Contacts

13.4 Display language selection

The user interface language of the TP may be selected at installation or during a general service by the Cyclomedica authorized service partner. The default language of the TP is English.

13.5 Changing the clock on the TP

LCD MESSAGE	Meaning and actions required
ROUTINES	Indicates that the Clock Setting Routine has begun.
THE CLOCK HAS NOT YET BEEN SET	The TP detects that the clock has not been set and requests the operator to follow the clock setting routine.
CLOCK SETTING HOUR--	Indicates that the operator may set the Hour of the clock.
CLOCK SETTING MINUTE--’	Indicates that the operator may set the Minute of the clock.
CLOCK SETTING YEAR--	Indicates that the operator may set the Year of the clock.
CLOCK SETTING MONTH--	Indicates that the operator may set the Month of the clock.
CLOCK SETTING DAY--	Indicates that the operator may set the Day of the clock.

13.6 Authorized service and maintenance

There are no User modifiable or serviceable parts other than those described in Section 13.1 “Operator maintenance”.

- Only a Cyclomedica authorized service partner is authorized to carry out a general service of the TP.
- Only a Cyclomedica authorized service partner is authorized to replace the internal battery.
- The TP has a periodic maintenance schedule of a general service every 12 months or 500 burns, whichever is sooner. During this general service a Cyclomedica authorized service partner will test the performance of the TP and recertify the TP.
- If a fault arises in the operation of the TP, switch it OFF and contact a Cyclomedica representative for service. Do not operate the TP until the fault is resolved.

Please contact your Cyclomedica authorized service partner to request service for your TP.

14 Troubleshooting

14.1 Dead battery during administration period

If the battery dies during the administration period the release button will not function to open the patient valve. The user should contact a Cyclomedica authorized service partner to resolve the issue.

14.2 Accidental double cancel during administration period

If the user accidentally presses the double cancel during administration the TP will cancel its operation and shut down. The user should follow Section 11 “After Administration to the Patient” and then repeat the process from Section 9.4 “Prepare the TP for use”.

14.3 Low activity in inhaled dose

If the patient has a low inhaled dose or low activity count per minute after inhalation of 10 to 20 breaths or an accumulated one minute of inhalation with the patient delivery button depressed, this may be due to the TP producing a low yield of Technegas Aerosol. Contact your Cyclomedica authorized service partner to identify and resolve any issues related to the operation of the TP.

14.4 Argon flow monitor

Flow of argon into the unit is continuously monitored during the Simmer and Purge processes.

If the gas flow is too low (less than 8 L/minute) or too high (greater than 16 L/minute) because of an emptying cylinder or a valve not being fully open, the process will cease, and the unit will ‘beep’ while displaying the following message:

```
Gas Flow Too High/Low
```

When the cause of low or high gas pressure is rectified, the TP will resume the process.

14.5 Leak test errors

The TP performs a self-check for leaks during several of the internal operations. If an error message is reported, it is recommended that the Operator performs the following checks:

- There is sufficient supply of argon in the cylinder
- The high-pressure regulator on the cylinder is correctly set
- No foreign objects are preventing the Drawer from fully closing
- The gasket around the edge of the lower chamber is clean and free from debris

If the TP still reports an error message, contact your Cyclomedica authorized service partner.

14.6 Internal case temperature too high

The TP has a maximum duty cycle of two Technegas Aerosol preparations per hour. Do not use TP beyond its rated duty cycle.

If used more frequently, the internal components of TP may become too hot (greater than 49°C (120°F)) for effective use. In this scenario, a message is displayed to indicate to the Operator that they must wait for the TP to cool before continuing.

14.7 Tripping of the circuit breaker or fuse

If the TP trips the in-built circuit breaker or fuse, perform a visual inspection of the TP for damage to power supply cord and plug, or for other electrical hazards and remove any foreign objects from the Drawer and lower chamber.

Where possible, re-set the circuit breaker or replace the fuse. If the unit trips again, contact your Cyclomedica authorized service partner.

14.8 LCD messages

LCD MESSAGE	Meaning and Actions required
WAIT PURGING CHAMBER	The TP is purging (cleaning) the chamber prior to allowing the Drawer to be opened.
OPEN DRAWER TO CHANGE CRUCIBLE	The Drawer is ready to be opened to load a Technegas Crucible.
LOAD CRUCIBLE THEN CLOSE DRAWER	The Operator should install a Technegas Crucible, load the Technegas Crucible with sodium pertechnetate Tc 99m injection, and close the Drawer.
CHANGE CONTACTS OR CLOSE DRAWER	The Drawer can now be closed until it is a convenient time to change the contacts. If the Technegas Contacts are to be replaced, switch the power OFF with the Drawer open and refer to Section 13.3 "Changing the Technegas Contacts".
PRESS [START] TO INITIATE SIMMER	Indicates that the Operator should press the START button to begin the Simmer process.
CHECKING FOR ARGON GAS	No action is required. The TP is checking for connection to the gas supply.
CHECKING INLET & OUTLET VALVES	No action required. The TP is carrying out a self-test.
CHECKING FOR GAS LEAKS	No action required. The TP is self-testing for chamber seal.
WAIT SIMMERING AND PURGING	No action required. The TP is performing the Simmer process.
PRESS [START] TO INITIATE BURN	Indicates that the Operator should press the START button to begin the Burn cycle.
BURN VERIFIED	No action required. The TP is indicating that that a successful Burn has been carried out.
WAIT GENERATING GAS	No action required. The TP is in the process of generating Technegas Aerosol.
GAS READY TO USE WITHIN ---	Indication of time limit (minutes : seconds) within which the Technegas Aerosol must be delivered to the Patient.
DISCONNECT THE MAINS PLEASE	Indicates to the Operator that they must disconnect the mains supply and the argon.

LCD MESSAGE	Meaning and Actions required
[START] RELEASES THE GAS VALVE	Indicates to the Operator to press the START button to unlock the Patient Delivery Valve.
PRESS DRAWER INTERLOCK KNOB	If the CLOSE button is pressed without first pressing the DRAWER INTERLOCK button this message will be displayed along with an audible alert.
DRAWER MIDWAY OPEN OR CLOSE	Indicates the position of the Drawer. Press OPEN or CLOSE to continue.
NO CRUCIBLE OR BAD CONTACTS	Indicates that the TP has no Technegas Crucible installed or the Technegas Contacts may need to be replaced. If the Technegas Crucible is present, rotate the Technegas Crucible back and forth a few times. Next, try a new Technegas Crucible followed by replacing the Technegas Contacts.
SWITCH OFF AND CHANGE CONTACTS	Indicates that the Technegas Contacts have reached the end of their life and must be changed. The TP should now be switched OFF and the Technegas Contacts changed.
OPEN DRAWER AND CHANGE CONTACTS	This message occurs when 50 Burns on the Technegas Contacts have been completed. The Operator must replace the Technegas Contacts.
CONTACTS CHANGED?? OPEN=NO CLOSE=YES	This message is displayed when the power is switched back ON after changing the Technegas Contacts and also after turning TP off for cleaning. It confirms that the Operator has changed the Technegas Contacts and resets the Technegas Contacts counter. Pressing the appropriate button (OPEN or CLOSE) will allow normal operation.
THE CONTACT LIFE IS NOW 50 BURNS	Indicates the remaining lifetime of the newly installed Technegas Contacts.
SORRY THE GAS IS TOO OLD TO USE	This message is displayed after 10 minutes has elapsed from Technegas Aerosol production. The TP will switch itself OFF. No further action is required.
PRESS CANCEL TO EXIT OR TURN THE MAINS ON	This message is displayed at the end of the Delivery process. The Operator may press CANCEL or turn the mains switch ON. The TP will then perform a Purge.

LCD MESSAGE	Meaning and Actions required
THE DRAWER FAILED TO OPEN IN THE TIME ALLOWED	Indicates that there may be an issue with the Drawer. Try closing and opening the Drawer again. If this fails to fix the issue, then contact your authorized service partner for assistance.
THE DRAWER FAILED TO CLOSE IN THE TIME ALLOWED	Indicates that there may be an issue with the Drawer. Try closing and opening the Drawer again. If this fails to fix the issue, then contact your authorized service partner for assistance.
CHAMBER FAILED LEAK TEST	This indicates that the TP has detected a leak in the chamber. The most probable cause is that something has jammed between the Drawer and the lower chamber. Check this, then retry. If still in error, contact your authorized service partner for assistance.
BAD OUTLET VALVE	A fault has been detected in the Purge system. Try switching the mains switch OFF, then ON again. If still in error, contact your authorized service partner for assistance.
ERROR IN READING PRESSURE	A fault has been detected in the Purge system. Try switching the mains switch OFF, then ON again. If still in error, contact your authorized service partner for assistance.
CRUCIBLE FAILED TO REACH FULL TEMP	This message means that during the Burn, the temperature was incorrect and a low yield of Technegas Aerosol may have resulted. If low yields continue after checking/replacing the Technegas Contacts, contact your authorized service partner for assistance.
CRUCIBLE EXCEEDED ALLOWABLE TEMP	This message means that during the Burn, the temperature was incorrect and a low yield of Technegas Aerosol may have resulted. If low yields continue after checking/replacing the Technegas Contacts, contact your authorized service partner for assistance.

LCD MESSAGE	Meaning and Actions required
TRIAC FAILURE	Indicates that a failure has occurred in controlling the Technegas Crucible temperature. Contact your Cyclomedica authorized service partner for assistance.
TURN OFF AND TRY AGAIN	Indicates that the TP has detected a failure and requires the power to be switched OFF and then back ON again to reset the TP.
SWITCH OFF AND CALL MAINTENANCE	The TP has detected an error requiring service intervention. Contact your Cyclomedica authorized service partner for assistance.
PRESS CANCEL TO RESTART	Indicates that the Operator needs to press the CANCEL button. Press the CANCEL button twice within two seconds to cancel an operation and restart the TP.
CHAMBER OPEN OR NO ARGON GAS	Indicates that no pressure was detected in the TP chamber. This may mean that the argon is either not connected or not turned on. Other possible causes could be low pressure in the argon cylinder or something jammed between the Drawer and the lower chamber.
GAS FLOW IS TOO LOW	Indicates that the Operator should check the settings of their argon supply gauges, to ensure correct flow rate. The flow rate of argon into the TP is not sufficient. Replace the argon cylinder, if necessary.
GAS FLOW IS TOO HIGH	Indicates that the Operator should check the argon supply gauges and hose to the TP to ensure correct flow rate.
CASE TEMPERATURE TOO HIGH WAIT	The TP detects that its internal temperature is too high. Wait until the TP cools down to an allowable temperature. No more than two Burns operations per hour are specified.

15 Specifications

Further information may be found in the Cyclomedica Technegas Plus System Service Manual.

15.1 General

Supply Voltage	200 VAC to 240 VAC +/- 5% Transformer tapping set at installation.
Supply Frequency	50 Hz to 60 Hz
Mains Current –	Steady State < 0.2 A RMS
Mains Current -	Maximum – 17 sec. 20 A RMS
Circuit Breaker	10A, time-delay, resettable, two pole, single throw
Fuses	2x 500mA, time-delay, 250V
Fuse (Battery)	(Battery Charging) F1: Sub-Miniature Fuse Type: F (Quick Acting) Rating: 1 Amp.
Device Weight	120 Kg
Shipping Size	1100 mm x 630 mm x 1190 mm (L x W x H)
Floor Area	920 mm x 600 mm

15.2 Protection against electric shock

The TP must be connected to a dedicated earthed electrical supply.

As per IEC 60601-1 Ed. 3.1 (2012) the TP is rated as a Class 1 device for protection against electric shock. When assembled with the PAS, the PAS is a Type B applied part.

IEC 60601-1: 2015 – 8.11.1 – Isolation from the supply mains: The TP connects to the supply mains via a power cord; thus, the plug on the power cord serves as the isolation, or disconnecting device, to the supply mains.

15.3 Operating, transport, and storage conditions

Operating Temperature	15°C to 30°C (59°F to 86°F)
Storage Temperature	10°C to 30°C (59°F to 86°F)
Ambient Air Pressure	70 kPa to 106 kPa (700 mBar to 1,060mBar)
Ambient Humidity	15% to 90% relative humidity non-condensing
Duty Cycle	Two procedures per hour
Transport Standards Compliance	ASTM D4169-16

15.4 Consumables

15.4.1 Argon gas

- Argon Gas must be ultra high purity grade (≥99.997%) and must not contain more than 3 ppm oxygen (Grade 4.7 or greater).

15.4.2 Technegas Patient Administration Set (PAS)

- The Technegas Patient Administration Set (PAS) is for use with TP and is available from Cyclomedica or your local distributor.
- The PAS contains a filter to capture exhaled Technegas Aerosol to help prevent room contamination.
- The PAS is single use only.

15.4.3 Technegas Contacts (electrodes)

- One set of Technegas Contacts are supplied with a box of 50 PAS and 50 Technegas Crucibles.

These must be replaced as per the instructions in Section 13.3 "Changing the Technegas Contacts".

15.4.4 Technegas Crucible

- The Technegas crucibles are supplied with the PAS and the Technegas Contacts.
- The Technegas crucible is single use only. See the TECHNEGAS *Prescribing Information* for more details.

15.4.5 Purge filter life

The TP is fitted with a long-life Purge filter to capture remaining Technegas Aerosol during the Purge processes. The filter's lifetime is 3,000 operational cycles. The Purge filter is replaced periodically as required during the service of the TP. The Purge Filter is not accessible by the Operator and must only be replaced by a Cyclomedica authorized service partner as part of the preventative maintenance schedule.

15.5 Identifying the date of manufacture

The Serial Number for a TP is found on the Rear Panel of the device.

The serial number is "TP" followed by 6 numbers: **TPYYWWID**. Where **YY** represents the year of manufacture, **WW** represents the calendar week of manufacture, and **ID** represents the unique identifier for the device within the batch.

15.6 Electromagnetic compatibility

Guidance and manufacturer's declaration – electromagnetic emissions		
The TP is intended for use in the electromagnetic environment specified below. The User of the TP should assure that it is used in such an environment.		
Emissions Tests	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The TP uses RF energy only for its internal function. Its RF emissions are very low and are not likely to cause any interference in nearby electronic devices.
RF Emissions CISPR 11	Class A	The TP is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes. There may be potential difficulties in ensuring electromagnetic compatibility in domestic and those directly connected to the public low voltage power supply network that supplies buildings used from domestic purpose environments, due to conducted disturbances.
Harmonic Emissions IEC 61000-3-2	Not Applicable	
Voltage Fluctuations/flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The TP is intended for use in the electromagnetic environment specified below. The User of the TP should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	Complied 6 kV contact Complied 8kV air	Floors should consist of an inert cleanable material, such as epoxy, vinyl, concrete, or ceramic tile.
Radiated RF Fields IEC 61000-4-3	3 V/m 80 MHz – 2.7GHz 80% AM at 1 kHz	Complied	A minimum distance of 15 cm is recommended between sources of power frequency magnetic field and the TP.
Electrostatic fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	Complied 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV differential mode ± 2kV common mode	Complied 1 kV differential mode Complied 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The TP is intended for use in the electromagnetic environment specified below. The User of the TP should assure that it is used in such an environment.			
Immunity test			Electromagnetic environment - guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	< 5% Ur (> 95% dip in Ur) For 0.5 cycle 40% Ur (60% dip in Ur) For 5 cycles 70% Ur (30% dip in Ur) For 25 cycles < 5% Ur (> 95% dip in Ur) For 5 sec	Complied Complied Complied Complied	Mains power quality should be that of a typical commercial or hospital environment. If the user of the TP requires continued operation during power mains interruptions, it is recommended that the TP be powered from an uninterruptible power supply or battery.
Power frequency (50/50 Hz) magnetic field IEC61000-4-8	3 A/m	Complied < 3 A/m 50 Hz & 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: *Ur* is the A.C. mains voltage prior to the application of the test level.			

Use of the TP adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, the TP and the other equipment should be observed to verify that they are operating normally.

Note: *This is a mandatory warning for all medical electrical equipment in compliance with IEC60601-1-2*

Recommended separation distances between portable and mobile RF communications equipment and the TP			
The TP is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the TP can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TP as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{3}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{3}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{3}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.16	1.16	2.33
10	3.68	3.68	7.37
100	11.66	11.66	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer. NOTE 1 - At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

16 End of Life Decommissioning of the TP

- The TP has a recommended use life of 10 years from date of manufacture with required annual maintenance, which will recertify the TP for optimal performance.
- You must contact your local distributor or Cyclomedica for assistance with the decommissioning of the TP.
- Decommissioning of the TP may be subject to local regulations for medical devices.
- The TP contains lead (Pb) used as radiation shielding, which must be considered at decommissioning.
- Ensure that an appropriate decay period has elapsed before disposal. Cyclomedica suggests a minimum of 10 half-lives of Technetium-99m before disposal.

17 Contact Information

Order Information:

Email: orders@technegas.com

Phone: (888) 858-6439 or (888) 8-LUNGFXN

Servicing Contact Information:

Email: service@technegas.com

Phone: (888) 858-6439 or (888) 8-LUNGFXN

A full discussion of the Technegas technology and bibliography may be found at:
http://www.cyclomedica.com/clinical