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TechnegasPlus
Technegas™ Generator

USER MANUAL

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CE 0086

Manufactured in Australia by Cyclomedica Australia Pty Ltd

TECHNEGAS™
FUNCTIONAL LUNG IMAGING

1 Preamble

The information found in this manual is the latest information at the time of delivery for the **TechnegasPlus Technegas™ Generator, 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 TechnegasPlus Technegas™ Generator through your Cyclomedica authorised service partner.

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

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

1.1 Manufacturer's Trademark and Copyright

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2 Product Information

2.1 Device description

The TechnegasPlus Technegas™ Generator (TP) is an electrically powered medical device for creating hydrophobic Technetium-99m labelled carbon particles[1] dispersed in air as an aerosol with an activity median aerodynamic diameter of 200-430nm.[2]

Technegas™ is the brand name for the system of medical devices and pharmaceuticals used in the production of the Technetium-99m radio-labelled carbon aerosol also referred to as Technegas™.

The Technegas™ system comprises of the TP, Pulmotec™ (Crucible), the Technegas™ Contacts, the Technegas™ Patient Administration Set (PAS), and other proprietary components.

The system requires a general purpose 20 A electrical outlet, user supplied Technetium-99m (^{99m}Tc) as sodium pertechnetate ($Na\ TcO_4$) solution, pure non-denatured ethanol (≥ 95%), and high purity (≥ 99.997%) argon gas to create Technegas™.

2.2 Intended use

The nanoparticle size and hydrophobic properties of Technegas™ provide ideal characteristics for gaseous behaviour and alveolar deposition in the lungs.[3] This facilitates gamma-ray imaging of the functional ventilation distribution for diagnosing pathological processes.

Technegas™ is a ventilation agent for ventilation-perfusion imaging studies. In a few breaths and following gamma camera imaging, Single Photon Emission Computed Tomography SPECT) or SPECT/CT (Computed Tomography), the technologist/clinician can produce planar or 3D images providing information on lung function and pulmonary physiology.[4]

2.3 Indications for use

Technegas™ is safe and effective for use for functional lung ventilation imaging for the assessment of pulmonary embolism, pulmonary small airway disease including Chronic Obstructive Pulmonary Disease (COPD), lung resection surgery and other pulmonary ventilatory disorders.

Please refer to Pulmotec™ (Crucible) Product Information Leaflet.

2.4 Contraindications

There are no known contraindications for Technegas™.[4]

2.5 Maximum exposure

The maximum exposure of the TP to the patient via ventilation through the PAS is 3 minutes in a 24-hour period.

2.6 Principle of operation

Figure 1: TechnegasPlus Technegas™ Generator (TP)

The TP is a bespoke high temperature furnace; it is a Class IIb medical device. It uses a combination of graphite in the form of the Pulmotec™ (Crucible) and an inert atmosphere (argon) to reduce and then vaporise ^{99m}Tc generator eluate in a steel chamber.

It does this by first drying the eluate to remove the water from the saline carrier solution over 6 minutes, during which the chamber is purged of oxygen and filled with argon. The TP then raises the graphite Pulmotec™ (Crucible) to a temperature of 2750°C ± 100°C within 2 seconds and maintains this temperature for a period of 15 ± 1 second(s) to produce Technegas™. An optical sensor maintains the high temperature phase within the specified temperature limits. This validated process releases greater than 40% of the supplied ^{99m}Tc as Technegas™.

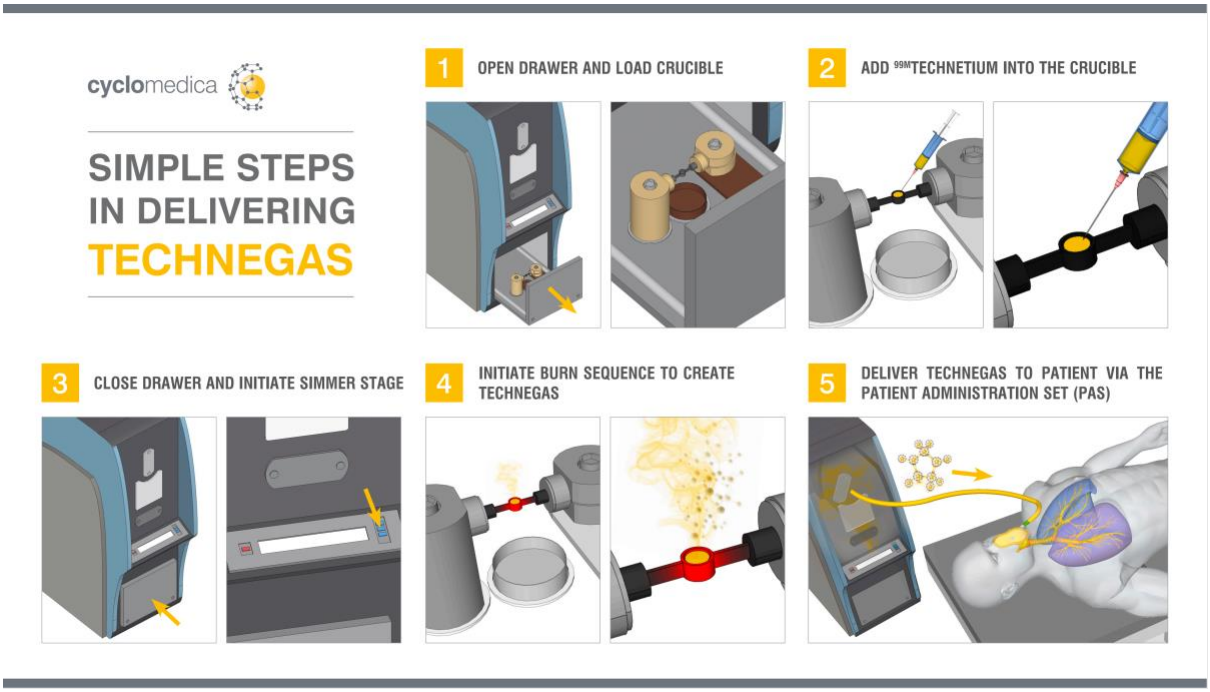


Figure 2: Technegas™ generation and delivery summary

An Operator controlled electrically actuated exit port in the chamber enables the patient to inhale Technegas™ via the PAS which, by depositing on the surfaces of the alveoli of the lung[2], enables the functioning airways distribution to be mapped by the standard nuclear medicine technology, namely a gamma camera.[3]

Prolonged storage of Technegas™ promotes aggregation into larger particles[3] and the migration of those particles to the walls of the TP chamber. As such, Technegas™ is intended to be administered to the patient within 10 minutes of its generation. To prevent accidental use of expired diagnostic agent, after 10 minutes, the TP inhibits the delivery to the patient and the chamber is automatically purged through a filter system to trap any residual Technegas™.

To expedite the administration of Technegas™ to the patient, the patient should be prepared during the Technegas™ generation process.

3 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, but not limited to:

- Measures to ensure their own safety
- The safety of others working in the vicinity of the TP system
- Patient safety
- Using the TP according to the instructions provided in this manual;
- Appropriate operating environment as defined by the specifications in this manual;
- Operator maintenance as per instructions in this manual;
- Facilitating periodic service with Cyclomedica authorised personnel;
- Informing Cyclomedica of complaints, mal-administrations, adverse events;
- Informing Cyclomedica requests for repair should the TP become faulty; and
- Any malfunction which results from the improper use, faulty maintenance, improper repair, damage, alteration, or modification by anyone other than an authorised Cyclomedica agent.

4 Precautions and safety in use

USE ONLY the Pulmotec™ (Crucible) with the TechnegasPlus Technegas™ Generator (TP).

The Pulmotec™ (Crucible) is the only registered carbon crucible drug product in Europe with marketing authorisation to be used for the production of Technegas™. No other carbon crucible has been authorised and validated for use with the TP.

USE ONLY a solution of Sodium Pertechnetate (Na TcO_4) of European or US Pharmacopoeia grade or equivalent, in the TP.

Only the brass Technegas™ Contacts, manufactured by Cyclomedica Australia, are validated to be used for the safe and effective performance of the TP and the production of Technegas™. The Technegas™ Contacts are critical accessories for the consistent and safe performance of the TP.

The Technegas™ Patient Administration Set (PAS) is a SINGLE USE ONLY product. Only the Technegas™ Patient Administration Set (PAS), manufactured by Cyclomedica Australia, is validated to be used for the safe and effective performance of the TP and the delivery of Technegas™.

The Pulmotec™ (Crucible) is a SINGLE USE ONLY product.

Unauthorised repairs and replacement of integral componentry will adversely affect the safe and efficacious 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.

4.1 Safety in use

- Handle the Pulmotec™ (Crucible) with care.
- Do not use methylated or denatured alcohol during the Pulmotec™ (Crucible) wetting process.
- Do not use industrial or welding grade argon with the TP.
- Inspect the Pulmotec™ (Crucible) for visible damage or defects.
- Do not allow repairs to be carried out on the TP by unauthorised 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. Damage may result which will make the TP unserviceable.
- Do not use the TP for any other purpose than that specifically indicated in this manual.
- Do not autoclave the TP or its consumables.
- Good Radiation Practice must be followed as the internal parts of the TP may be contaminated with ionizing radiation.
- The Patient Delivery Valve must not be opened unless the patient is breathing through the PAS and the PAS is affixed to the TP.
- Always ensure that the patient continues to breathe through the PAS whilst connected to the TP with the delivery button released for at least five (5) breaths after the cessation of Technegas™ inhalation. This clears Technegas™ (the aerosol) from the delivery tubing and the patient's conducting airways.
- If a patient is unable to use a mouthpiece adequately, Cyclomedica recommends that a face mask is used with the PAS mouthpiece. Such face masks are available from Cyclomedica.
- **Do not leave the TP unattended while it is performing any operation**.

4.2 Radiation safety

When used correctly, the TP is fully shielded appropriate for ^{99m}Technetium up to the recommended dosimetry and contains self-contained filtration apparatus.

- Disposable gloves must be worn when internal parts of the of the TP are handled.
- The Drawer must be closed when the TP is not in use, to prevent potential release of radioactive contamination.
- For radiation spills, refer to your radiation safety plan for site's requirements on spill clean-up.

4.3 Moving the TechnegasPlus Technegas™ Generator safely

- Inspect the wheels for damage before moving the TP.
- Do not move the TP over uneven or steep surfaces.
- To move the TP, disengage the wheel locks. Be sure to re-engage the wheel locks when the TP is stationary.
- Do not load the trolley with heavy items such as gas cylinders for transport.

4.4 Warnings

- Argon is an asphyxiation hazard. Always turn **OFF** the argon supply **when not connected** to the TP.

- The internal components of the TP may be hot.
- Do not open or close the Drawer if you suspect anything may obstruct normal operation.
- The TP weighs approximately 120kg (265lbs), therefore appropriate care should be taken when moving it.

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.

5 Operating key functions on the TP

5.1 Operating the CANCEL Button

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”.

5.2 Operating the Drawer

The Drawer may be 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.

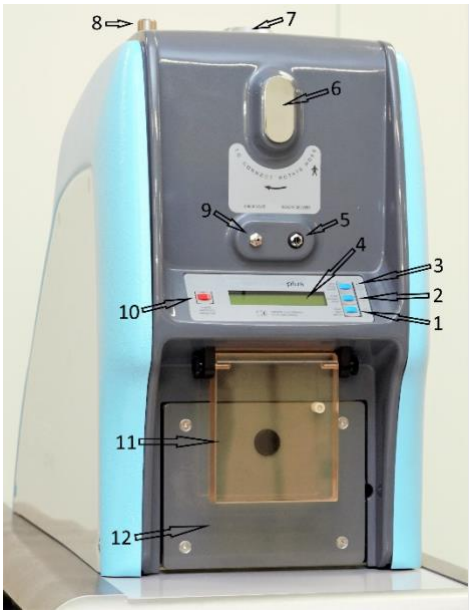
If either button is released before the Drawer has stopped moving it will immediately re-open. This ‘two-handed’ operation is a safety precaution.

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 authorised service agent.

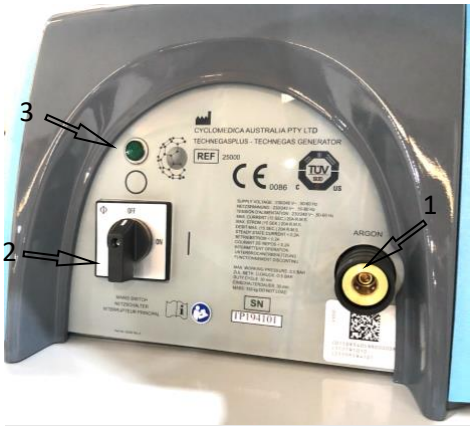
The Drawer must be closed when the TP is not in use.

5.3 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
10 – CANCEL button
11 – Amber coloured 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 Installation

6.1 Installation information

The unpacking of the TP from its carton, and the installation for use must be performed by a Cyclomedica authorised technician.

The Cyclomedica technician will complete the installation checklist to be signed by the Site Representative.

6.2 Location and storage

Assign an area within the Nuclear Medicine department, preferably near the imaging room, for the production of Technegas™ and storage of the TP.

The ambient operating conditions for the TP are 10-40°C, 70-106kPa (700-1060mBar), 15-90% relative humidity non-condensing.

Allow space for the safe storage of used Pulmotec™ (Crucibles) and PAS for a minimum of 10 half-lives before final disposal as non-radioactive waste or as per the regulations or licenses of your local Competent Authorities.

6.3 Power supply

The Operator must provide an earthed mains power line dedicated for use with the TP rated at 20 Amps, 200 - 240V ±5%, 50 or 60Hz.

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

6.4 Argon Gas supply

The Operator must provide high purity grade argon (≥99.997%) 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

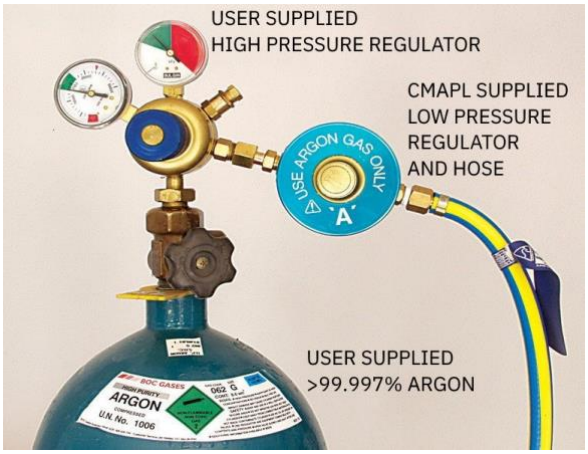


Figure 5: Set up of argon supply

Secure the argon cylinder as per local regulations.

- 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.

6.5 Connecting the argon gas

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

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

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

6.6 Battery charging

- Plug the TP unit into the 20 Amp electrical power outlet and switch ON using the main switch located at the rear of the generator.
- The green indicator light above the main switch will illuminate when the TP is powered on.
- Leave the unit plugged in, powered on, and the Drawer closed when not in use to keep the battery fully charged.

A flat battery will not be evident until you try to deliver Technegas™ to your patient.

6.7 Additional items required

- One 1mL needleless syringe capable of dispensing 135-300µL
- One 1mL syringe with needle capable of dispensing 135-300µL
- Disposable gloves
- Pure non-denatured ethanol (≥95%)
- A clean non-contaminated flat work surface e.g. a Petri Dish
- Forceps

6.8 External Transportation

- Prior to moving the TP from or between facilities, the TP requires a Cyclomedica authorised service agent to prepare the TP for safe transport.
- Contact your Cyclomedica authorised service partner or Cyclomedica for guidance/assistance.

7 Patient Preparation

Figure 7: Supine administration of Technegas™

- For the administration of Technegas™ to the patient, Operators should follow the details in the *Information for Use* for the Technegas™ Patient Administration Set (PAS) and the *Production Information Leaflet* for the Pulmotec™ (Crucible).
- Technegas™ should be administered to the patient as soon as possible after being generated, to enhance the quality of imaging.
- To expedite the administration of Technegas™, the patient should be prepared before or during the Technegas™ generation process.
- The patient may be prepared supine or upright.
- Patient posture affects the distribution profile of Technegas™ 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.

Note: Cyclomedica recommends that patients should be supine (lying down) and the gamma camera positioned for a posterior view. Body movement and breathing irregularities are reduced if your patient is in a comfortable but controlled supine position.

Figure 8: Patient preparation for the delivery of Technegas™

The patient may be prepared in the imaging room or a preparation room as required. A method of monitoring the inhaled dose during Technegas™ administration is required, for example by using the gamma camera or a Geiger counter.

1. Select the appropriate mouthpiece or facemask and attach it to the conical connector on the PAS.
2. Place the mouthpiece in the patient's mouth ensuring a total seal by their lips. Alternatively, attach or hold the facemask to the patient, ensuring that the nose and mouth are fully covered.
3. When using a mouthpiece, place the nose-clip on the patient's nose.
4. Advise the patient to relax and breathe normally.
5. You may wish to advise the patient to practice breathing with the mouthpiece and nose clip in place using one of the ventilation strategies detailed in Section 9 TECHNEGAS™ VENTILATION STRATEGIES (of this document).

Patients must be instructed not to breathe around the mouthpiece (e.g. not attempting to talk), as this would lead to low inhaled dose of Technegas™ and potential room contamination.

8 Dosimetry

Refer to the Pulmotec™ (Crucible) Product Information Leaflet for more information regarding dosimetry.

- The recommended activity to be loaded in the Pulmotec™ (Crucible) is between **200 - 900 MBq (5.4 mCi – 24.3mCi) of ^{99m}Tc sodium pertechnetate.**
- The recommended radioactive concentration for the Pulmotec™ (Crucible) 135µL is 1480 - 6670 MBq/mL (40 – 180 mCi/mL).
- The recommended radioactive concentration for the Pulmotec™ (Crucible) 300µL is 670 - 3000 MBq/mL (18 – 81 mCi/mL).
- If a high radioactive concentration eluate is not available, it is possible to carry out multiple Pulmotec™ (Crucible) loadings as described in section 10.5 PREPARING THE PULMOTEC™ (CRUCIBLE) or using the Pulmotec™ (Crucible) Simmer Plate as described in section 13 OPERATING THE SIMMER PLATE .
- The recommended inhaled dose of Technegas™ is between **20-50MBq (0.5 - 1.3 mCi)**, or as directed by the nuclear physician.

The inhaled dose of Technegas™ should be monitored while it is being administered to the patient.

9 Technegas™ ventilation strategies

There are three preferred ventilation strategies depending on the patient condition, these are summarised below. For more detail, refer to the Pulmotec™ (Crucible) *Product Information Leaflet*.

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

Strategy 1: Slow deep breathing from the residual functional capacity (i.e. the end of calm exhalation), followed by a 5-second pause breath-hold.

Strategy 2: Normal breathing with deep inhalation without breath-holding.

Strategy 3: Rapid and deep inhalation followed by a breath-hold of about 5 seconds at the end of the inhalation.

> **When the desired count rate is achieved, the patient must breathe through the TP and PAS for at least another FIVE (5) breaths to clear Technegas™ from the airways.**

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 as described in Section 11 ADMINISTRATION OF TECHNEGAS™ . The Patient Delivery and Remote Delivery Buttons **are not enabled** until the Patient Delivery sequence is reached.

10 Production of Technegas™ prior to administration

10.1 Safety and Quality check

1. Wear gloves and use Good Radiation Practice.
2. Inspect the Pulmotec™ (Crucible) for visible damage or defects.
3. Visually check that the ethanol used for wetting the Pulmotec™ (Crucible) is ≥ 95% pure and non-denatured.
4. Perform a quick visual check of the TP for major defects:
    a. Check for visible damage to the TP exterior;
    b. Check the TP trolley wheels are clean and in good working order;
    c. Check the amber coloured lead (Pb) shield is in place in front of the Drawer; and
    d. Check the argon gas supply is high purity grade (≥ 99.997%) and that sufficient supply is available for production of Technegas™.

USE ONLY PULMOTEC™ (CRUCIBLE) FOR THE MANUFACTURE OF TECHNEGAS™

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

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

The installation and use of an oxygen sensor in the room is strongly recommended.

10.2 Setting up the argon gas supply

The argon gas should be connected and turned ON using the following instructions prior to use:

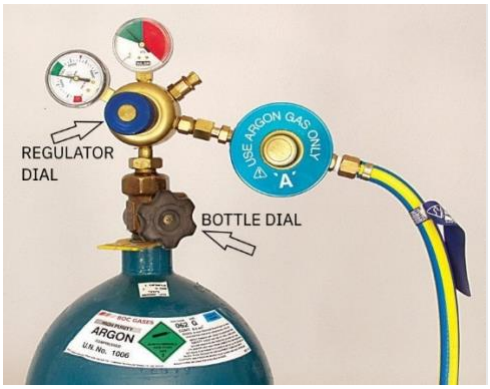


Figure 9: Controlling argon flow

1. Ensure the argon hose is connected to the TP as detailed in Section 6.4 ARGON GAS
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 15 litres per minute.
4. The Cyclomedica supplied low-pressure regulator is supplied fit-for-use and does not require adjustment.
5. Observe the argon high pressure regulator and check that the argon cylinder has sufficient supply of argon for the production of Technegas™.

10.3 Prepare the TP

1. Connect the Remote Delivery Button to the socket above the TP display panel.
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, the current TP software version and the date and time.

If a 'purge' has not been carried out since the last Technegas™ (aerosol) generation, 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™ from a previous operation will escape into the atmosphere when the Drawer is opened.**

The display will then read:

```
OPEN DRAWER TO
CHANGE CRUCIBLE
```

10.4 Open drawer and remove Pulmotec™ (Crucible) fragments

During Technegas™ generation all internal components of the chamber and gas pathway leaving the chamber are radioactively contaminated. Use Good Radiation 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 Pulmotec™ (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.

10.5 Preparing the Pulmotec™ (Crucible)

Figure 11 (a, b): Installing the Pulmotec™ (Crucible) into the TP Drawer

1. Using the forceps, pick up the Pulmotec™ (Crucible) from its packaging and place it on a non-contaminated flat surface.
2. To wet the Pulmotec™ (Crucible), use a 1mL syringe and fill the Pulmotec™ (Crucible) with 95% pure non-denatured ethanol, then draw the ethanol back into the syringe.
3. Using the forceps, pick up the Pulmotec™ (Crucible) approximately at a 45° angle.
4. To enable fitting of the Pulmotec™ (Crucible) into the Technegas™ Contacts, press the lever below the left side of the drawer forwards (away from the operator). Alternatively, pull the notch on the right-hand side backwards (towards the operator).
5. Place the left end of the Pulmotec™ (Crucible) into the left Technegas™ Contact.
6. Align the right side with the right Technegas™ Contact and gently release the lever to connect the Pulmotec™ (Crucible) with both Technegas™ Contacts.
7. Rotate the Pulmotec™ (Crucible) gently backwards and forwards on its axis.

Perform this procedure carefully, as the Pulmotec™ (Crucible) can fracture.

8. Ensure the well of the Pulmotec™ (Crucible) is in the **upright position** as shown in Figure 12 below.

Figure 12: Loading ^{99m}Tc sodium pertechnetate into the Pulmotec™ (Crucible)

Note: the Pulmotec™ (Crucible) must still be wet (from the ethanol) before the ^{99m}Tc sodium pertechnetate is added – if not, please repeat step 2 above.

9. Using a new 1mL syringe with needle, fill the Pulmotec™ (Crucible) with 200-900MBq (5.4 - 24.3 mCi) ^{99m}Tc sodium pertechnetate.

Do not overfill the Pulmotec™ (Crucible), the meniscus should be concave or flat as depicted above in Figure 12.

USE ONLY a solution of sodium pertechnetate (^{99m}Tc) of European or US Pharmacopoeia grade or equivalent in the TP

For further dosimetry information, refer to the Pulmotec™ (Crucible) Product Information Leaflet.

10. 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.

10.6 Simmer Process

The display will read:

PRESS START TO INITIATE
SIMMER

Press START to initiate the Simmer process. The Simmer Process may be aborted by pressing DOUBLE CANCEL.

10.7 Multiple loadings

To re-load the Pulmotec™ (Crucible) with more ^{99m}Tc sodium pertechnetate, press DOUBLE CANCEL when the Simmer Process is complete to return to 10.5.

- The Pulmotec™ (Crucible) does not require re-wetting with ethanol prior to refilling.
- The Pulmotec™ (Crucible) can be refilled with additional ^{99m}Tc sodium pertechnetate while fixed in the Technegas™ Contacts as detailed in 10.5 PREPARING THE PULMOTEC™ (CRUCIBLE) step 9.
- The Pulmotec™ (Crucible) sitting in the Pulmotec™ (Crucible) Simmer Plate may also be loaded with additional ^{99m}sodium pertechnetate at this stage as described in 13 OPERATING THE SIMMER PLATE .

10.8 Burn Process

1. Press the START button to initiate the Burn process.
2. When the burn is complete the display will read:

```
VERIFYING BURN
```

3. The display will then change to:

```
DISCONNECT THE MAINS PLEASE
```

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

4. Turn OFF the argon 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™ administration to the patient.
   e) The TP may be moved to the patient as required.

11 Administration of Technegas™

Use disposable gloves and conduct Good Radiation Practice.

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

The inhaled dose for an adult is usually about 20-50MBq (0.54-1.35mCi). Refer to the Pulmotec™ (Crucible) Product Information Leaflet for more information.

Do not touch the Patient whilst attaching the PAS to the TP or touching the internal components of the TP drawer.

1. Attach the PAS to the TP by pushing the end of the hose into the PAS connection on the TP and rotating clockwise.
2. Press the START button.

The display will read:

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

3. Whilst the patient is following a ventilation strategy, HOLD the Patient Delivery Button or the Remote Delivery Button and monitor the activity in the patient's lungs.
4. When the desired count rate is achieved as per the Pulmotec™ (Crucible) *Product Information Leaflet*, release the Patient Delivery Button or the Remote Delivery Button and allow the patient to breathe through the PAS and the TP for **at least another FIVE (5) breaths** to clear the Technegas™ from the conducting airways.
5. Press DOUBLE CANCEL and the TP will shut down and power off.
6. Remove the nose-clip from the patient.
7. Remove the mouthpiece from the patient.
8. Disconnect the PAS from the TP.
9. Place the PAS into the PAS sleeve (as shown in Figure 13 below) and dispose in accordance with local and regulatory guidelines for biological and radioactive waste.

Figure 13: Disposal of the PAS

12 After administration to the patient

1. If required, return the TP to the its designated operation and storage location.
2. Reconnect the TP to 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™ from the internal chamber.

Once the Purge operation is complete:

4. Turn OFF the argon supply at the cylinder.
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 authorised service agent.

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

Ensure the Drawer is left 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 bottle, operate and store the TP in a well-ventilated room. Adhere to your local Safe Handling of Gas Practices/Guidance.

The installation and use of an oxygen sensor in the room is strongly recommended.

13 Operating the Simmer Plate

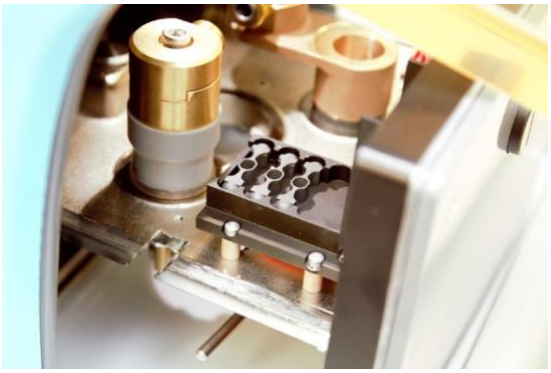


Figure 14: Simmer Plate set up

- The Drawer contains a Simmer Plate that allows simultaneous preparation of up to five Pulmotec™ (Crucibles) with multiple loadings of ^{99m}Tc sodium pertechnetate.
- The Simmer Plate is useful for sites performing multiple Technegas™ operations in a single day or institutions that do not have access to high activity ^{99m}Tc sodium pertechnetate.
- The Simmer Plate functions independently of the other TP operations and begins a 20-minute Simmer every time the Drawer is closed.

The Simmer Plate and Cover can be hot (up to 80°C) to touch.

---

1. Remove the Pulmotec™ (Crucible) from its packaging using the forceps and place it on a watch glass, Petri dish or a clean surface.
2. Using a 1mL syringe, fill the Pulmotec™ (Crucible) with 95% ethanol and then draw the ethanol back into the syringe.
3. Open the Simmer Plate lid using the forceps.
4. Using the forceps, pick up the Pulmotec™ (Crucible) as shown in Figure 15 below and place it in the Simmer Plate.

Figure 15: Loading the Simmer Plate

5. Using a 1mL syringe with needle, fill the Pulmotec™ (Crucible) with 200-900MBq (5.4 - 24.3 mCi) ^{99m}Tc sodium pertechnetate. The meniscus should be concave or flat.

6. Close the Simmer Plate lid using the forceps.

When ready to perform the production of Technegas™, carefully place the Pulmotec™ (Crucible) in the Technegas™ Contacts, using the forceps and continue to follow instructions, as detailed above in section 10 PRODUCTION OF TECHNEGAS™ PRIOR TO ADMINISTRATION.

The Operator may fill the Simmer Plate with as many Pulmotec™ (Crucible) as can be loaded (i.e. five) and refill the Pulmotec™ (Crucible) with additional ^{99m}Tc sodium pertechnetate throughout the day as required to reach the desired activity at the time of Technegas™ delivery.

The Pulmotec™ (Crucible) does not need to be re-wetted with 95% ethanol before additional loadings of ^{99m}Tc sodium pertechnetate.

14 Disposal of contaminated items

14.1 List of Contaminated Items

- The Pulmotec™ Crucible
- The used Patient Administration Set (PAS)
- Technegas™ Contacts
- Disposable Gloves

The Pulmotec™ (Crucible) and the PAS are single-use items

- Always use disposable gloves when handling contaminated items.
- Treat the PAS and mouthpieces as low-level radioactive and biological waste.
- Change the Technegas™ Contacts as specified in 15.3 CHANGING THE TECHNEGAS™ CONTACTS. and dispose of the old Technegas™ Contacts as low-level radioactive waste.
- Handle any component removed or replaced from the internal systems as if it was contaminated with radioactivity.

14.2 Disposing of used Pulmotec™ (Crucible)

The TP breaks the Pulmotec™ (Crucible) automatically following Technegas™ generation and delivery, to prevent re-use. The fragments are collected in the Ash tray located beneath the Technegas™ Contacts; the fragments must be removed prior to Technegas™ generation and treated as low-level radioactive waste.

14.3 Disposal of Radioactively Contaminated Items

The disposal of radioactive and infectious waste is subject to the regulations and the appropriate licenses of the local Competent Authority or Regulatory Body.

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

14.4 Cleaning of radioactive spills

If a spill occurs within the lower chamber, it is recommended that it is left to decay as it is in a shielded environment. 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 site's requirements on spill clean-up.

15 Maintenance

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

15.1 Operator Maintenance

The Operator must:

- Replace the Technegas™ Contacts every 50 burns as described in 15.3 CHANGING THE TECHNEGAS™ CONTACTS.
- Empty the Ash tray of Pulmotec™ (Crucible) fragments prior to production of Technegas™ as described above in 14.2 DISPOSING OF USED PULMOTEC™ (CRUCIBLE).
- Keep the TP clean as described in 15.2 CLEANING THE TP.

15.2 Cleaning the TP

Clean the exterior panels of the TP, the Drawer, the Simmer Plate, 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.

15.3 Changing the Brass Technegas™ Contacts

- The TP automatically counts down the remaining Burns for each new set of Technegas™ Contacts installed.
- The Technegas™ Contacts must be replaced every 50 Burns to ensure the safe and efficacious production of Technegas™.
- Wear disposable gloves and use Good Radiation Practice when replacing the Technegas™ Contacts.
- Replace the Technegas™ Contacts when the TP displays the following message and then carry out the instructions below

```
"    SWITCH OFF AND        "
"    CHANGE CONTACTS       "
```

1. Open the Drawer
2. 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

---

3. Use a 6mm hex key 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.
4. Remove 'old' Technegas™ Contacts and dispose as low-level radioactive waste.
5. Check that the brass surfaces of the Drawer pedestals and the new Technegas™ Contacts are clean.
6. 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.
7. Firmly tighten the clamping screws on the pedestals. 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.

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

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

9. Press CLOSE button to select YES. The TP will reset the Technegas™ Contacts counter to 50 remaining burns.

Warning: Only specially manufactured Technegas™ Contacts as shown in Figure 17 below, must be used in the Technegas™ Generator. The Technegas™ Contacts are medical device accessories as defined in international Medical Device Regulations (MDRs) and are vital to ensuring that the TP effectively facilitates the production of Technegas™.

Figure 17: Technegas™ Contacts made from brass with a carbon inlay.

15.4 Display Language Selection

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

The other available languages are:

- French
- German
- Spanish
- Italian
- Norwegian
- Turkish
- Portuguese.

15.5 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.

15.6 Authorised service & maintenance

There are no User modifiable or serviceable parts other than those described in 15.1 OPERATOR MAINTENANCE.

- Only a Cyclomedica authorised service agent is authorised to carry out a general service of the TP.
- Only a Cyclomedica authorised service agent is authorised 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.
- If a fault arises in the operation of the TP, switch it OFF and call your local distributor or Cyclomedica for service. Do not operate the TP until the fault is resolved.

Please contact your Cyclomedica authorised service partner to request a service for your TP.

16 Troubleshooting

16.1 Low activity in inhaled dose

If the patient has a low inhaled dose or low activity count per minute when imaged, this may be due to the TP producing a low yield of Technegas™. Contact your Cyclomedica authorised service partner to identify and resolve any issues related to the operation of the TP.

16.2 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 (<8 L/minute) or too high (>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
```

As soon as the fault is corrected, the TP will resume the process.

16.3 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:

- 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 authorised service agent.

16.4 Internal case temperature too high

The TP has a maximum duty cycle of two Technegas™ generations per hour.

Where used more frequently, the TP's internal components may become too hot (>49°C) 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.

16.5 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 authorised service agent.

16.6 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 Pulmotec™ (Crucible).
LOAD CRUCIBLE THEN CLOSE DRAWER	The Operator should install a Pulmotec™ (Crucible), load the Pulmotec™ (Crucible) with Technetium-99m 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 15.3 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™.
GAS READY TO USE WITHIN ---	Indication of time limit (minutes : seconds) within which the Technegas™ must be delivered.
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 Pulmotec™ (Crucible) installed or the Technegas™ Contacts may need to be replaced. If the Pulmotec™ (Crucible) is present, rotate the Pulmotec™ (Crucible) back and forth a few times. Next, try a new Pulmotec™ (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. 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™ 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.
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 authorised service agent for assistance.

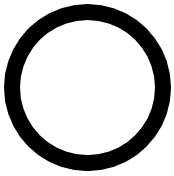
LCD MESSAGE	Meaning and Actions required
THE DRAWER FAILED TO CLOSE IN THE TIME ALLOWED	Indicates that there may be an issue with the Drawer. Try closing and opening the Drawer again. If this fails to fix the issue, then contact your authorised service agent for assistance.
CHAMBER FAILED LEAK TEST	This 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 authorised service agent 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 authorised service agent 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 authorised service agent 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™ may have resulted. If low yields continue after checking/replacing the Technegas™ Contacts, contact your authorised service agent for assistance.
CRUCIBLE EXCEEDED ALLOWABLE TEMP	This message means that during the Burn, the temperature was incorrect and a low yield of Technegas™ may have resulted. If low yields continue after checking/replacing the Technegas™ Contacts, contact your authorised service agent for assistance.
TRIAC FAILURE	Indicates that a failure has occurred in controlling the Pulmotec™ (Crucible) temperature. Contact your authorised service agent 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 authorised service agent for assistance.

LCD MESSAGE	Meaning and Actions required
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 is specified.

16.7 Label descriptions

REFER TO INSTRUCTION MANUAL/BOOKLET

CONSULT INSTRUCTIONS FOR USE

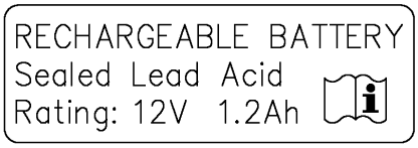


OFF (POWER DISCONNECTION FROM THE MAINS)

International Symbol for power OFF.

ON (POWER CONNECTION TO THE MAINS)

International Symbol for power ON

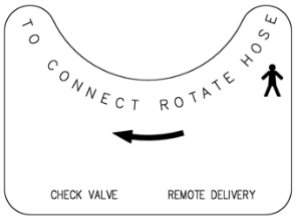


SEALED LEAD ACID RECHARGEABLE BATTERY RATING 12V, 1.2AH

This label is located on the chassis adjacent to the battery.

DEPRESS PATIENT DELIVERY BUTTON TO A POSITIVE STOP

This label is located on the TP top cover next to the PATIENT DELIVERY BUTTON.



ROTATE HOSE TO CONNECT

This label is located on the front of the TP Cover surrounding the Delivery Nozzle. It shows the direction of turn when connecting the Patient Administration Set to the TP.

USE ARGON GAS ONLY 'A'

This label is located on the Low-Pressure Argon Gas Regulator. It specifies that only ARGON gas be used with the TP.

HOT SURFACE

This symbol indicates the presence of a hot surface. Caution: Do not touch the hot surface as it may result in a burn injury.

TYPE B APPLIED PART

17 Specifications

Further information may be found in the Cyclomedica TechnegasPlus Technegas™ Generator Service Manual.

17.1 General

Supply Voltage	200-240 VAC +/- 5% Transformer tapping set at installation.
Supply Frequency	50-60 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 x 630 x 1190 mm (L x W x H)
Floor Area	920 x 600 mm

17.2 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.

17.3 Operating, transport, and storage conditions

Ambient Temperature	10 – 40°C
Storage Temperature	-25 – 60°C
Ambient Air Pressure	70 -106kPa (700 – 1060mBar)
Ambient Humidity	15% - 90% relative humidity non-condensing
Duty Cycle	Two procedures per hour
Transport standards compliance	ASTM D4169-16

17.4 Consumables

17.4.1 Argon Gas

- Argon Gas must be at least high purity grade (≥99.997%).

17.4.2 Technegas™ Patient Administration Set (PAS)

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

17.4.3 Technegas™ Contacts

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

These must be replaced as per the instructions in Section 15.3 CHANGING THE TECHNEGAS™ CONTACTS.

17.4.4 Pulmotec™ (Crucible)

- The Pulmotec™ (Crucible) are supplied with the PAS and the Technegas™ Contacts.
- The Pulmotec™ (Crucible) is single-use only.

17.4.5 Purge filter life

The TP is fitted with a long-life Purge filter to capture remaining Technegas™ during the Purge processes. The lifetime is 3000 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 approved service provider.

17.5 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.

17.6 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 TP.
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 be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF Fields IEC 61000-4-3	3 V/m 80 MHz – 2.7GHz 80% AM at 1 kHz	Complied	A minimum distance of 15cm 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	IEC 60601 Test level	Compliance level	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 & 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.			

18 End of Life decommissioning of the TP

- The TP has a recommended use life of 10 years from date of manufacture.
- 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.

19 Further reading

1. Lemb M, Oei TH, Eifert H and Günther B. Technegas: a study of particle structure, size and distribution. *Eur J Nucl Med* (**1993**); 20(7): 576-579
2. Irshad H, Kuehl P (Lovelace Biomedical). Aerosol Characterization of TechnegasPlus Generator. (**2017**). Internal Cyclomedica Australia Pty Ltd document; unpublished - commercial in confidence
3. Bajc M, Schümichen C, Grüning T, et al. EANM guideline for ventilation/perfusion single-photon emission computed tomography (SPECT) for diagnosis of pulmonary embolism and beyond. *Eur J Nucl Med Mol* (**2019**); 46(12): 2429-2451
4. Roach PJ, Schembri GP and Bailey DL. V/Q scanning using SPECT and SPECT/CT. *J Nucl Med (***2013**); 54(9): 1588-1596

The following European and Canadian clinical guidelines are suggested for further reading. These guidelines recommend Technegas™ as the best ventilation agent for the diagnosis of Pulmonary Embolism.

Guidelines of the European Association of Nuclear Medicine (EANM)

- Bajc M, Schümichen C, Grüning T, et al. EANM guideline for ventilation/perfusion single-photon emission computed tomography (SPECT) for diagnosis of pulmonary embolism and beyond. *Eur J Nucl Med Mol* (**2019**); 46(12): 2429-2451; https://link.springer.com/article/10.1007/s00259-019-04450-0

Guidelines of the Canadian Association of Nuclear Medicine (CANM)

- Leblanc M, Tessier M, Ollenberger and O'Brien Christopher. CANM guidelines for ventilation/perfusion (V/P SPECT) (**2018**); https://canm-acmn.ca/guidelines

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