

MESSENGER

News and Information from  Charter Main

Clarification of Recent 'Off-Label' Claims

I believe that it was Mark Twain who once said "Never let the truth get in the way of a good story."

We refer here (again) to the egregious, disparaging, misleading and scare-mongering attacks by the competition on our high quality product 'Vent-Medis Kit' registered in Australia as a Class IIb Medical Device (ARTG No 319260). Our product is designed, engineered and manufactured by Almedis Altmann in Germany and is highly cost effective.

The competition issued on June 16, 2020 a 'Safety Alert Notice' titled 'NON-PROPRIETARY CONTACTS RESULTING IN 'OFF-LABEL' USE OF Technegas (Trade Mark) GENERATORS.' The safety alert concludes that the mere use of contacts not manufactured by Cyclomedica essentially means that the Technegas (Trade Mark) Generator is being used 'off-label'. It further concludes that adverse Technegas (Trade Mark) production effects may result from the use of the non-proprietary pure graphite contacts. This is on the basis of two reported safety incidents in Germany where both incidents reported Technetium-99m Thyroid Uptake.

We need to add that Almedis Altmann has since 1992 to date placed in excess of a quarter of a million units in Germany with only these two reported incidences. The same safety record cannot be claimed by the competition. A simple survey of the Nuclear Medicine users and historical published literature to date discusses Thyroid Uptake when using this diagnostic modality with the competing product.

In reference to the blunt 'Off-Label' claim, we wish to present precise

definition of terms that are grounded in facts. The Australian Therapeutic Goods Administration (TGA), in its Website (<https://www.tga.gov.au/early-warning-system-health-professional-questions-and-answers#:~:text=The%20TGA%20is%20responsible%20for,as%20'off%20label'%20use>) states:

The TGA is responsible for ensuring that therapeutic products available

referring to 'off label' use is a misrepresentation.

for supply in Australia are safe and fit for their intended purpose (label use). Use of a medicine or a medical device outside the specified indication/s or intended purpose for supply is often referred to as 'off-label' use. For example, using a Medicine or a medical device:

- * for an indication or an intended purpose not specified in the product information or the package label,
- * in a different population to that intended (e.g., children or pregnant women),
- * at a different dose to that recommended,
- * via a different route of administration.

Based on the 'off-label' term definition above, it is clear from the face of the Safety Alert issued by Cyclomedica Pty Ltd on June 16th, 2020 and referring to 'off-label' use is a misrepresentation. According to the ARTG registration of the Technegas (Trade Mark) Generator, the Intended Purpose of the registered Medical Device is: 'An existing Device Used to Manufacture a Lung Imaging Agent, Technegas for use in the Diagnosis of Lung Disease'. Therefore, the listed 'label' use of the

Technegas (Trade Mark) Generator is for use in diagnosing generally 'Lung Disease'. Further, we must not confuse the 'Radioaerosol Administration Kit' with the intended label use of the Technegas Generator.

THE SCIENCE OF TECHNEGAS PRODUCTION

Further, the Technegas (Trade Mark) production process entails initial drying by evaporation of the pertechnetate eluate in an oxygen-free environment as the generator chamber is flushed and filled with Argon gas. Then, under high temperature the pertechnetate is instantaneously reduced to the Technetium metal, using carbon from the crucible as the reducing agent. This process is then followed by evaporation of the insoluble reduced metal simultaneously with spallating graphite nanoparticles into the device's chamber where the carbon particles/Technetium metal condense together and are subsequently available for inhalation by the patient.

The scientific basis for the occurrence of thyroid uptake during a Ventilation study using Technegas is as follows: The presence of any oxygen contamination within the generator combustion chamber will prevent complete reduction of the water soluble Pertechnetate ions and will yield a fraction of soluble Technetium-99m species adsorbed on the carbon nanoparticles. This fraction is the cause of the Tc-99m that is transported through the patient's alveoli into the blood stream and then is collected by the thyroid gland.

Any attempt at attributing thyroid uptake resulting from the administration of Technegas (Trade Mark) other than to the presence of a soluble fraction of Tc-99m (Pertechnetate ions) is mis-

leading and not based on science.

SOME RELEVANT HISTORY

Adding a bit of relevant history to this letter of information, the original Cyclomedica contacts were individually and manually made of cast gunmetal. They were machined to the required profile to fit the pedestal. This was an expensive process and so, they were retrieved from the customers and recycled to save costs. Brass was chosen because it was cheaper.

On a service trip to Germany in the nineties, it was discovered that solid carbon crucibles and contacts were manufactured and distributed by Altmann & Partner GmbH, the predecessor company of Almedis Altmann GmbH. These were produced by a highly qualified German manufacturer who analysed and verified their quality and consistency. They were brought back to Australia, analysed and tested and found to work with equal efficiency to the Tetley version. The solid, high-purity carbon contacts used today in the Charter Main vent-medis kits are the same quality and consistency as the original ones, quality controlled, validated and sold as a spare part, certified compliant by Almedis. During all of this time, since the nineties, there has never been any verifiable complaints of inferior image quality, which is surely the ultimate objective of performing the Ventilation scan.

Also, in the nineties again, when converting Technegas generators to conform to the accepted standard, it was discovered that state of the art HEPA filters were being used in the German Almedis purging and delivery filters as compared to resin-impregnated lambs-wool used by Vita Life. These, once again, were tested and validated and shown to be ideal.

THE FACTS

The only 'material' difference between the Cyclomedica contacts and the Almedis contacts is that there is no brass in the Almedis contacts. It is the carbon which is the critical element in the process of generating Technegas NOT the brass and to suggest otherwise is an attempt at creating an alternate reality.

And it is equally important that the crucibles can be heated to 2,750C within a very short rise-time of about

1 second. Almedis submitted actual service records to the TGA from its German customers which demonstrated a rise-time of less than 0.9 seconds thereby verifying that the solid carbon contacts were compatible with the Technegas generator. The contacts are very robust and up to 500 burns have been reported though it is still recommended that the 50 burn cycle be adhered to. It should also be noted that the Technegas generator only confirms a successful Burn-Process if the required Full-Burn Temperature is reached within a maximum of 2.5 seconds. If not, the generator provides an error message and ceases functioning. With the Almedis carbon contacts and large crucibles a rise-time of less than 1 second is achieved and remains within the generator specifications. In short, wrong contact would not be accepted by the device.

SUMMARY

So, let's all take a Bex, consider this rationally and think it through logically:

1. Technegas is trapped in the surfactant of the alveolus and does NOT cross into the circulation; the very premise of why a Ventilation image is done followed by a Perfusion image. The counts acquired in the Ventilation scan are ventilation counts and the counts acquired in the Perfusion scan are Perfusion counts and there are no Ventilation counts adding to the Perfusion counts.

2. There is no thyroid imaging since no Technegas gets to the thyroid via the circulation. (A different story if the patient is swallowing mucous).

3. Free pertechnetate readily crosses from the alveolus into the circulation and can thereby travel to the thyroid and if the field of view is large enough the thyroid will be imaged.

4. Stomach uptake can also be seen in some cases. This is largely due to Technegas being swallowed with mucous and ending up in the stomach. This can be prevented by proper patient instruction, drinking water prior to the exam and trying not to swallow during the exam.

5. How do you get free pertechnetate during the generation of Technegas?

6. Refer to Cyclomedica's User Manual for possibilities.

7. But in essence, free pertechnetate can be generated by:

i) Overfilling the 0.14 µl crucible. Excess Tc-99m could be blown off the crucible and not be heated to 2,750C in the burn resulting in free pertechnetate

ii) The burn is carried out in an atmosphere that contains as little as 3% oxygen. Again this can result in the production of Pertechnegas and thyroid imaging will be seen

iii) Old or damaged hoses and regulators

iv) 'Contaminated' Argon bottles

v) Improper attention to 'wetting' the crucible and ensuring the crucible if filled 'concave' PRIOR to generating Technegas. Drying out and overfilling WILL result in free pertechnetate and low Technegas yield

vi) Too low a simmer temperature to completely dry the large crucible (proper adjustment of the device is important when using larger crucibles)

8. So, IT IS FREE pertechnetate which causes thyroid uptake NOT the carbon in the crucible, NOT the carbon in the contacts, NOT the arbitrary introduction of brass to the contacts.

9. Thyroid uptake is the result of an imperfect burn which occurs for whatever reason and IS NOT THE RESULT of the quality, consistency or metal configuration of the contacts used in the production process.

We at Charter Main hope that this FACTUAL information would be considered by you when reading the conflicting and frankly erroneous information being circulated by ill-informed individuals who have no understanding of the processes which leads to the successful production of Technegas. With over 150 years of combined experience selling and marketing Technegas throughout the world, we at Charter Main, with the support, cooperation and research capabilities of our International partners, feel well qualified to provide this important information.

Your Charter Main Support Team

A Good News story.

Medical Consumables that are both Quality and Cost-effective.

Charter Main is a newly created medical device company established to provide consumables for the safe and efficient delivery of Technegas from a Technegas generator into your patient for a V/P S.P.E.C.T. lung scintigraphy scan. Charter Main can also provide your servicing needs on the Technegas generator and supply masks, and spare crucibles.

While the company is new, its support team is not, having over 150 years of global experience in servicing, maintaining, commissioning, decommissioning, training and repairing Technegas and TechnegasPlus generators.

The consumables work in the same way as those of the competitor. C.E. marked and fully approved by the responsible Australian regulatory authority, (ARTG No. 319260) for the efficient, safe and optimal generation and delivery of Technegas into a patients' lungs. Charter Main, however, offers a fully registered crucible with 0.3µl bowl capacity which is very convenient on low-activity days reducing the number of simmers required to achieve the activity desired for delivery to your patient.

Additionally, the generator can be efficiently serviced and maintained by our expert service engineers with over 35 years of experience, and its operating life cycle extended through routine servicing and regular attention to maintenance issues.

Current support for Charter Main's products and services include public and private hospitals in Victoria, N.S.W., Queensland and W.A. Testimonials as to reliability, equivalence, efficacy and cost-effectiveness can be provided upon request.

Visit the vent-medis web-site: <https://www.vent-medis.com> for further information and product updates.

So:

1. Discuss a cheaper, cost-effective service contract which will deliver all you expect from a service contract and is provided by our experienced team.
2. Prolong the life of your generator through expert servicing and maintenance.
3. Purchase your consumables at a significantly reduced cost per box saving your department money.

Your Charter Main Support Team

Vent-Medis disposable kit for Ventilation Scintigraphy

**Large 0.3 μ l
highest purity
graphite crucible**



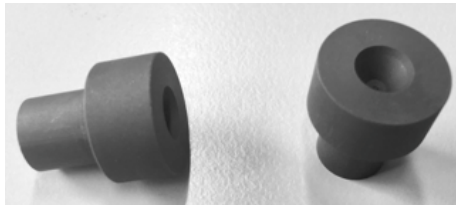
Vent-Medis Kits include the improved high-purity, high-volume carbon crucible with a 0.3 μ l bowl capacity. This crucible saves time and minimises multiple simmers allowing the use of dilute Tc-99m generator elutions thus reducing operator radiation exposure.

**Rugged design
smooth-bore
patient
delivery set**



The inhalation breathing unit contains a high efficiency HEPA, exhalation filter, T-piece with robust non-return valve, a robust one meter smooth-bore tubing with 15mm inner diameter and the special generator connection. A rigid mouthpiece and a nose clip complete the set.

**High purity
and long life
graphite
contacts**



With every Vent-Medis Box you get one pair of high-purity carbon contacts for 50 scintigraphic examinations. The carbon contacts are very robust and fit the Generator specifications with great contact reliability.

Vent-Medis Kits -

Larger volume crucible equals more efficient use of dilute Tc-99m eluate

High-Efficiency HEPA filter

Time and cost saving

Less radiation through reduced simmers

Improved and more reliable crucible contact

More rugged design

Improved packaging

TGA Certified

Reliability of supply

CE marked

Major price advantage

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 **Charter Main**
Medical Technology