Phase-Out of Older Technegas Generators

In June 2012, Cyclomedica’s registration of the Technegas generator (TG) was allowed to lapse owing to the availability of the new generation TechnegasPlus generator (TP).

I sent a letter to all customers to this effect but it seems that it created some misunderstandings. So I thought that I would restate the position with regard to Technegas generators once again.

Firstly, Cyclomedica can no longer sell or rent Technegas generators (TG’s). All generators currently in service, rented or owned, will be repaired, maintained, serviced, etc. to the best of our ability. Be aware, however, that Technegas generators 15 years and older, will be more difficult and more costly to repair as electronic componentry and parts have become obsolete and their production discontinued. Repairs may not be possible on every occasion.

Secondly, the TechnegasPlus generator (TP) is now available as a replacement. The Technegas generator was developed to address many of the suggestions made to Cyclomedica by its customers and to improve the functionality of the machine. For instance, the TechnegasPlus generator (TP) has a lower profile, is lighter and lacks sharp edges. This was done to improve manoeuvrability and customer safety.

An in-built crucible oven was added. On low-activity days it is now possible to pre-simmer several crucibles during the day rather than perform multiple simmers in order to get sufficient activity for the ventilation study saving the department time. Unused crucibles can be reused the next day.

Additionally, the purge filter no longer needs to be changed every 50 burns. The TechnegasPlus generator (TP) has a long-life filter which is usually changed after approximately 5,000 burns by the service engineer, providing further safety and confidence.

The EasyBreather, an option with the Technegas generator (TG) is now standard with all TechnegasPlus generators (TP’s). This feature ensures reliable and accurate delivery of Technegas to all patients, including comatose ones. (Not available in EU.)

I trust that this clears up any misconceptions. Rest assured that Cyclomedica will stand behind all of its Technegas generators (TG’s) and do its utmost to keep them all serviceable.

But like all capital equipment, Technegas generators (TG’s) have a duty cycle, considered not to exceed 15 years in the case of Technegas generators (TG’s).

If your generator is this vintage, I would exhort you to contact me and discuss upgrading.

Charles Buttigieg
Asia-Pacific Marketing & Sales Manager
Cyclomedica
“Functional Imaging with V/P Spect …”

In the last edition of Crucible we reported on a highly analytical airsways inhomogeneity measurement from a Swedish group using quantitative SPECT ventilation imaging that demonstrated the potential for a more sensitive marker than traditional lung function tests. Now Professor Bajc’s group have independently corroborated the finding of increased sensitivity to ventilation abnormalities in a study of 74 subjects. Grading obstructive lung disease using tomographic pulmonary scintigraphy in patients with chronic obstructive pulmonary disease (COPD) and long-term smokers. Bajc M, Markstad H, Jarenbäck L, et al: Ann Nucl Med (2015) 29:91–99

They concluded: “Functional imaging with V/P SPECT enables standardized grading of airway obstruction as well as reduced lung function, both of which correlate with GOLD stage [Crucible vol 7 #1 Feb 2014]. V/P SPECT shows that long-term smokers in most cases have signs of ventilatory impairment and airway obstruction not shown by spirometry.”

“…… stuck in a rut?”

Follow-up


The second response was from Harvey Zeissman from the Johns Hopkins in Baltimore, Maryland who has given Technegas very strong support: “Some of the data supporting these statements deserve further discussion. However, this letter will focus on one particular aspect, the ventilation agent used for SPECT. To support the thesis that SPECT should be standard, the editorial specifically references one prospective and two retrospective publications supporting the use of SPECT.

The ventilation agents used in the first two were 81Kr and 99mTc-Technegas (Cyclomedica Ltd.). Both are excellent ventilation agents; however, neither is available in the United States. The third publication did not use 99mTc-diethylenetriaminepentaacetic acid (DTPA) as stated in the editorial but rather evaluated 99mTc-macroaggregated albumin SPECT without a ventilation scan. Since 1986, there have been approximately 180 scientific publications about this radiopharmaceutical, with overwhelmingly positive sentiment and data on its safety and clinical efficacy. Anyone who has seen images of 99mTc-Technegas compared with 99mTc-DTPA aerosol or 133Xe readily appreciates the clear superiority of Technegas. The Australian manufacturer has been trying to obtain Food and Drug Administration (FDA) approval for Technegas in the United States for several years. However, the FDA has made this extremely difficult. Even though most imaging clinics in the United States use 99mTc-DTPA aerosol, the FDA will not allow a direct comparison between the two. The reason given is that the FDA never approved 99mTc-DTPA for ventilation studies. We presently use it on an off-label basis. Therefore, the FDA is requiring that Technegas be compared with 133Xe, even though 133Xe is used in a minority of imaging centers. In addition, the FDA has required a large multicenter protocol that must include at least 375 subjects with a final diagnosis positive for pulmonary embolism and 375 that are negative for pulmonary embolism. The protocol is complex, time-consuming, and expensive. As a result, the sponsor is having difficulty finding institutions willing to participate and patient accrual has been poor. Many predict that this study will never be completed and that we will not be able to use Technegas in the United States in the foreseeable future. The FDA is hindering good patient care in the United States and disregarding the extensive experience in Australia and Europe. A simple direct image comparison of Technegas with 133Xe or 99mTc-DTPA aerosol is all that should be needed. Its safety has already been demonstrated by the experience worldwide.

Currently, we really do not know much about the prognosis or the need for treatment of small emboli, and the only way this issue can be studied is by using V/Q SPECT. This is a significant point raised in the European Association of Nuclear Medicine guidelines (2). Once the significance of smaller pulmonary emboli is better established, V/Q SPECT guidelines will need to be refined to determine which patients need treatment. I agree that we need to try to convince the Food and Drug Administration to approve Technegas, but in the meantime we should move ahead with aerosol ventilation imaging and broadly adopt V/Q SPECT imaging”.

Bill Burch - February 2015

Bill Burch: who ‘discovered’ what he named Technegas in 1984 and developed it through the John Curtin School of Medical Research (JCSMR) of the Australian National University (ANU) where he was a Visiting Fellow from 1976-2008.

REVIEW

Medical Information and Adverse Reaction Reporting

Cyclomedica provide distributor and customer support with medical information queries on the products. Customers are advised to initially contact their local distributor, or they may contact Cyclomedica Australia direct using the contact details below. If you wish to report an adverse reaction to the product this can be done using the same contacts details.

Telephone +61 (0)2 9541 0411
Facsimile +61 (0)2 9543 0960 or Email: vigilance@cyclomedica.com.au
Konnichiwa to All.

It is interesting how the use of V/P SPECT imaging in general and the use of Technegas in particular varies around the world.

I thought I’d seen it all on my last trip to China but the recent trip to Japan exposed me to new and interesting concepts.

Technegas has been available in Japan for about 20 years. Over that time many papers have been written describing the use of Technegas in various diagnostic situations apart from P.E.: asthma, emphysema, pneumonia. In fact, V/P SPECT has been routine in ventilation/perfusion imaging for many years. P.E. is widely considered to be uncommon in Japan though this is disputed by the Japanese Society for Pulmonary Embolism Research (JaSPER). Nevertheless, C.O.P.D. is a common problem and there is considerable interest in Technegas V/P SPECT diagnosis to measure lung function particularly during exacerbations where spirometry cannot be used.

I was somewhat surprised to learn recently at the 7th Japanese Society of Respirology in Tokyo how widespread the use of Perfusion SPECT/CT was. Without the information provided by Ventilation imaging it must be difficult, if not impossible, to be sure that a normal perfusion scan or one showing a perfusion defect is a mismatch or mirrors a corresponding ventilation defect or, in fact, misses entirely a ventilation defect. Moreover, it has been shown that Perfusion SPECT/CT demonstrates many false positive findings for P.E. (Palmowski et al., Respiration 2014; 88:291-297). In particular, in C.O.P.D. assessment, V/P SPECT may offer the ability to assess lung impairments before they are detected by spirometry (viz. “healthy smokers”) and might show regional lung impairment during exacerbations; not possible with spirometry. Several physicians agreed that V/P SPECT with Technegas may be worth revisiting. It will be interesting to see what happens.

Have you visited www.spectlung.com? It is hoped that this will become a reference site for training. We particularly invite your submission of unusual or interesting cases for us to load onto the site. At the moment we have about 30 cases but realistically we need more than 100 to ensure that the dialogue box picks up enquiries. Please give this serious consideration and perhaps commission one of your staff to submit some cases. While on the subject, if you have interesting V/P SPECT cases you would like to have published in the newsletter send them in and we shall assess them.

I hope you enjoy this issue.

Charles

Charles Buttigieg
Asia-Pacific Marketing & Sales Mgr
Cyclomedica


TECH TIPS

**Labelling of Argon Bottles.**
A few instances of the use of incorrect grade Argon gas have come to our attention.
Best practice is to ensure that the Argon gas to be used in your Technegas Generator is high purity and NOT welding grade. The wrong purity may lead to poor image quality and the potential for the production of undesired by products in the Technegas generator. Please ensure ONLY high purity Argon gas is used at all times.

**Hose Connection**
A suggested good practice is to leave the gas bottle hose connected and locked to the Technegas generator when NOT in use. The reason for this is that there is a potential for the Argon gas bottle to empty if the bottle or regulator have been left on.

**Time to Move On?**
In servicing Technegas generators over the past year I have come across many ‘ancient’ machines. It might be time to consider trading in those old ones before they become costly and too difficult to repair. Parts and electronics are also becoming either obsolete and/or expensive to source. The new TechnegasPlus generator will offer many years of service. Please contact us to discuss a change-over.

Richard F Gotch
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**www.spectlung.com**
The information source for all aspects of lung imaging including Case Study examples of PE detection, Literature, Imaging Issues, Diagnostic Options, GP Info and Links to other sites.
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- Proven diagnostic accuracy - especially in presence of COPD
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