Cyclomedica Australia Pty Ltd
ABN 70 003 071 556
Unit 4, 1 The Crescent
Kingsgrove NSW 2208 Australia
T 61 2 9541 0411
F 61 2 9543 0960
www.cyclomedica.com.au

URGENT MEDICAL DEVICE
FIELD SAFETY NOTICE

28 Jun 2019

Product Field Action Number: FA-001-19

Description: TechnegasPlus Generator

Model/Part Number: TP 25000

Lot: See attached

Dear Customer,

Cyclomedica Australia Pty Ltd has initiated a voluntary medical device product field action relating to TechnegasPlus Generators model TP, part number 25000.

The intent of this letter is to describe all potential hazards with the below noted issue, and any risk mitigation factors associated with the use of the product.

Our records indicate that you have received the above referenced product. It is Cyclomedica Australia Pty Ltd's responsibility as a manufacturer to ensure that customers who have received this(these) affected product(s) also received this important communication.

We request that you read this notice carefully and reply via the included customer response form enclosed.

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Reason for the voluntary product field action:

On 24th May 2019, while performing electromagnetic compatibility (Specifically, conducted emissions certification testing) on the TechnegasPlus Generator to the requirements of the CISPR 11 standard, the TechnegasPlus Generator recorded a measurement above the upper limit for class A conducted emissions during the high temperature burn.

CISPR 11 is the international standard for electromagnetic compatibility (EMC) for industrial, scientific, and medical equipment. It is important that devices comply with these limits to ensure that equipment in the same environment won't malfunction when the device is working. For further information reference Appendix 1 of this document.

Potential Hazards may include:

- Conducted emissions are not considered to have an impact on the safety of users of the TechnegasPlus Generator or patients undergoing a Technegas examination or the performance of the product.

- While the conducted emissions of the TechnegasPlus Generator are above the Class A limit, medical devices in the same environment as the TechnegasPlus Generator and those connected to the same supply mains as the TechnegasPlus Generator are likely to be certified to the IEC 60601 standards so should be immune.

- IEC 60601 requires medical devices to be immune to conducted emissions at a higher limit than the measured conducted emissions generated by the TechnegasPlus Generator.; therefore, medical devices certified to the IEC 60601 standard should be immune to the TechnegasPlus Generator conducted emissions even though the measurements are above the Class A limit.

- However, depending on how the power supply network in the hospital or clinic is configured, the out of specification emission may cause other devices not certified to IEC 60601 that are connected to the same power supply in the healthcare facility to exhibit abnormal behaviour during the burn cycle,.

IEC 60601-1-2 is an internationally recognized standard concerning the requirements of medical devices with regards to electromagnetic compatibility. For further information reference Appendix 2 to this document.

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Follow up:

- Solutions are currently being investigated and verified and will be fitted, within 12 months of this notification, by Cyclomedica Australia Pty Ltd approved field service engineers. This solution will reduce the conducted emissions and result in the TechnegasPlus Generator Model TP-25000 meeting the CISPR 11 standard.

- In the interim standard use can continue as per TechnegasPlus Generator Model TP Part number 25000 user manual.

Required actions:

Our records indicate that you have received at least one of the subject devices and are therefore affected by this action. We request that you read this notice carefully and complete the following actions:

- Circulate this Field Safety Notice internally to all interested/affected parties.
- Maintain awareness of this notice internally until all required actions have been completed within your facility.
- Please inform Cyclomedica Australia Pty Ltd of any adverse events concerning the use of the TechnegasPlus Generator Model 25000. (Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority)
- Complete the attached customer response form.
- Return the completed form to the nominated Cyclomedica Australia Pty Ltd representative detailed below:

Your designated contact person for this action is given below.

Name: Niamh McAree

Position: Head of Quality and Regulatory

E-mail: nmcaree@cyclomedica.com.au

We request that you respond to this notice within 5 business days from the date of receipt.

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Should you have any queries concerning this matter please do not hesitate to contact your distributor. Please find below the contact details:

Name: _____

Address: _____

Tel: _____

Email: _____

We can confirm that this Field Safety Notification has been communicated appropriately to the National Competent Authority for your country.

On behalf of Cyclomedica Australia Pty Ltd we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be caused. We would like to reassure you that Cyclomedica Australia Pty Ltd is committed to ensuring our devices meet the highest standard of quality.

Sincerely,

_____

Niamh McAree

Head of Quality and Regulatory.

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URGENT MEDICAL DEVICE
FIELD SAFETY NOTICE – CUSTOMER RESPONSE FORM

Date: _____

Product Field Action Number: FA-001-19

Description: TechnegasPlus Generator

Model/Part Number: TP 25000

Lot: TPXXXXXXX

I have received the product field action notification from Cyclomedica Australia Pty Ltd, dated 28 Jun 2019, stating that the company has initiated a voluntary medical device product field action of the above referenced product.

_____ _____

Customer/Hospital Representative (Signature) Date

_____ _____

Customer/Hospital Representative (Print) Organisation/Hospital/Clinic Name

PLEASE COMPLETE THIS FORM WITHIN 5 BUSINESS DAYS AND RETURN IT BY USING THE EMAIL LISTED BELOW:

Email: nmcaree@cyclomedica.com.au

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Appendix 1: CISPR standard explained

CISPR 11 – Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement an international standard that deals with potentially harmful emissions of electromagnetic energy from a device. These emissions can be both in the of "conducted emissions" – emissions that are transferred through conductors of the electrical network and "radiated emissions" – emissions that are emitted through the air.

It is important that devices comply with these limits to ensure that nearby equipment won't malfunction when the device is working.

However, when assessing to compliance with CISPR 11, it is important to remember that CISPR 11 has different limits for devices which are connected directly to supply mains (like consumer electronics in households, which are called "Class B") and devices which are connected to another network, such as those that are used in a hospital ("Class A" devices). The TechnegasPlus Generator is not intended to be directly connected to public supply mains and is thus a "Class A" device.

The emissions requirements in CISPR 11 are largely harmonized with international law for devices that are connected directly to supply mains. However, because the TechnegasPlus Generator is a Class A device and is not intended to be connected directly to supply mains and is intended only for use in a professional health care environment, the legal implications aren't applicable.

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Appendix 2: IEC 60601-1-2 Standard explained:

IEC 60601-1-2 is an internationally recognized standard concerning the requirements of medical devices with regards to electromagnetic compatibility. Electromagnetic energy is used to perform many activities. Electricity is a type of electromagnetic energy used to power appliances, conducted through the mains power supply and delivered by wall outlets. Electromagnetic energy is also what allows devices to communicate wirelessly; it is what enables everything from WiFi networks to cell phones, radios and mobile communication. Because of the ubiquity of electromagnetic energy, it is important to ensure that medical devices both don't emit electromagnetic energy that may cause other devices to malfunction and ensure that devices don't malfunction because of the electromagnetic energy emitted by other devices in the environment.

International standards are a helpful tool for both industry and regulators to assess the safety of a device. While compliance is not always required by a regulatory authority, it often helps smooth the approval process. IEC 60601-1-2 is a widely recognized standard, and compliance is a de-facto requirement for most medical devices.

IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests, contains specific test requirements for medical devices. The test requirements both ensure that device doesn't emit electromagnetic radiation ("emissions") that may affect nearby equipment and won't harm patients or users when a device is exposed to electromagnetic radiation ("immunity"). While emissions requirements largely coincide with the regional regulations to ensure a safe electromagnetic environment, immunity requirements are tailored to the specific device and application in order to ensure safety of patients and users.