



## URGENT FIELD SAFETY NOTICE

**Commercial name of product:** Aeroneb Pro, Solo, USB and NIVO Nebuliser Systems

**FSCA-Identifier:** FSCA02SEP14

**Type of Action:** Exchange of Mains Power Adapters manufactured by FRIWO

**Date:** 2<sup>nd</sup> Sep 2014

**For the Attention of:**

Users of Aeroneb Pro, Solo, USB and NIVO Nebuliser Systems

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**Description of the Problem:**

Aerogen has received a small number of complaints in relation to the mains power adapter manufactured by FRIWO GmbH and used in the Aeroneb Solo, Pro, USB and NIVO Nebuliser systems. The complaints received identified that the power adapter cover had broken and dislodged from the body of the adapter prior to use. The reported incidents did not lead to any user injury as the failure was evident and adapter was unusable.

Additional investigation with the manufacturer FRIWO has identified that an unknown small quantity of adapters manufactured during the period of week 50/2013 and week 23/2014 could potentially fail in a similar manner whereby the plastic screw pillars can break and the adapter cover can open. FRIWO have confirmed that they received similar returns from other customers and all of the failures were observed prior to use. However it cannot be ruled out that the adapter may fail during use.

If the failure was to occur during use then the internal electrical components of the mains power adapter would become exposed to the user and therefore the following risk cannot be dismissed:

**Risk of Electrical Shock:** There is a potential risk of electric shock if the cover falls off during use, with mains power turned on, and the user makes contact with specific recessed components inside the adapter housing.

The risk is associated only with the power adapter and not with the Aerogen Nebuliser Systems.

**Details on affected devices:**

The mains power adapters manufactured by FRIWO and used in the Aeroneb Nebuliser systems are model number GPP10 FRIWO part number 1894699 and model number GPP USB FRIWO part number 1896343.

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These adapters are used in Aeroneb Nebuliser systems as follows:

- AG-AS3000-XX – Aeroneb Solo Starter Kit
- AG-AP6000-XX – Aeroneb Pro System
- AG-AP1500-XX – Aeroneb Pro Controller
- AG-AP1040-XX – Aeroneb Pro AC/DC Adapter
- AG-PX1000 –XX – Aeroneb Pro X Controller
- AG-UC1000-XX – USB Controller
- AG-UC1500-XX - Aeroneb Solo USB Controller Starter Kit
- 1079422 – NIVO Pro X Controller UK/IE
- 1082694 - NIVO Pro X Controller Southern Europe
- 1082693 - NIVO Pro X Controller Northern Europe

Note: XX is country/region designation e.g. SE is Southern Europe



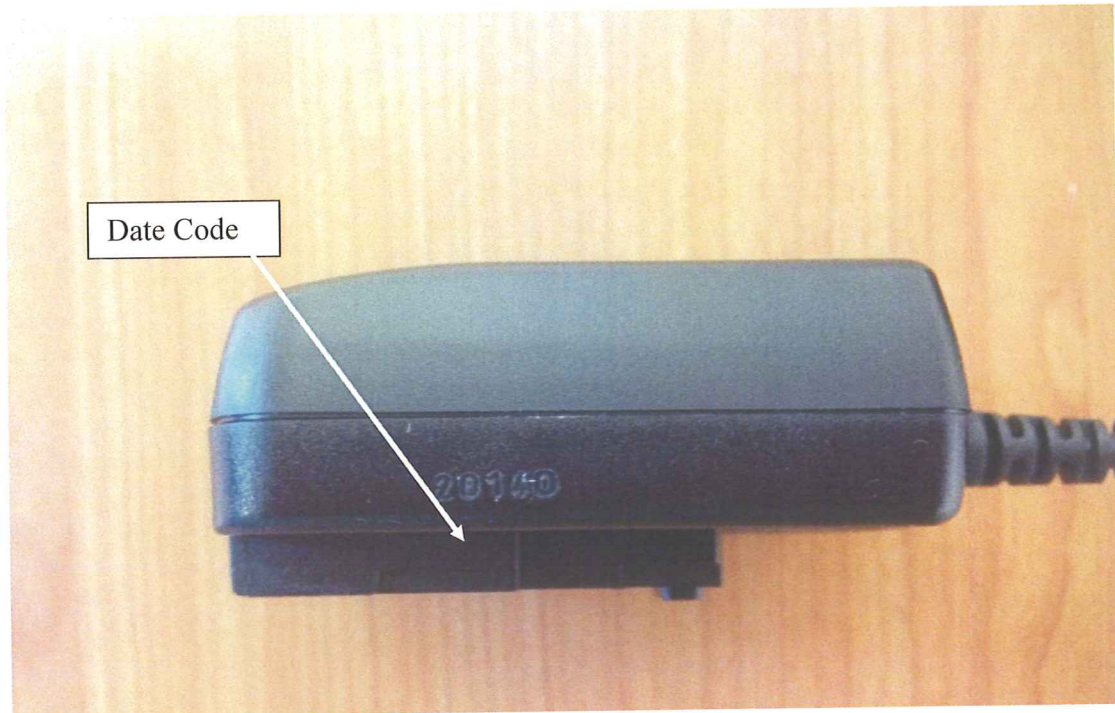
The fault outlined above could potentially occur in adapters with the following date code identification on the black adapter housing as per picture below:

**GPP10:**

4513O, 4613O, 4713O, 4813O, 5113O, 5213O, 0114O, 0214O, 0314O, 0414O, 0514O, 0614O, 0714O, 0814O, 0914O, 1014O, 1114O, 1214O, 1314O, 1414O, 1514O, 1614O, 1714O, 1814O, 1914O, 2014O, 2114O, 2214O, 2314O.

**GPPUSB:**

0214T, 0314T, 0414T, 0514T, 0614T, 0714T, 0214O, 0314O, 0414O, 0514O, 0614O, 0714O.



The manufacturer FRIWO has given Aerogen its assurance that the fault described above is not present in any other time period or date code than those identified above.

**Advice on action to be taken by the user:**

Please examine the mains power adapter supplied with your Aerogen Nebuliser System, if the power adapter has a date code as identified for the concerned adapters, please follow the instructions below:

1. In general you can continue to use the Aerogen Nebuliser system until a replacement is received if you inspect the power adapter prior to each use and there is no evidence of damage or separation of the housing and unplug the adapter after each use.

Do not use the power adapter if there is any evidence that the housing is not intact. If the housing was to fully separate in use, a person may come into contact with live parts and receive an electrical shock.

2. Please contact Aerogen or your appropriate Aerogen sales partner immediately so that we can replace your power adapter free of charge as soon as possible.



## URGENT FIELD SAFETY NOTICE

Aerogen is working actively with our sales partners to exchange all effected power supplies for the Aeroneb Solo, Pro, USB and NIVO Nebuliser Systems as soon as possible.

**Transmission of this Field Safety Notice:**

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred

**Contact Reference:**

Phone: 00353 91 540400

Address: Aerogen Ltd, Galway Business Park, Dangan, Galway , Ireland.

The undersigned confirms that the appropriate Regulatory Agencies have been notified.

We sincerely apologise for any inconvenience this may have caused, we are actively working to resolve this issue with the appropriate measures and thank you for your support and cooperation.

Signed :   
James Langan  
Aerogen QA/RA Director

Date: 2-Sept-2014