

SINGAPORE, 27 JULY 2012

## HSA UPDATES

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HSA UPDATES NO 6/2012

### HSA ALERTS PUBLIC ON FIELD SAFETY CORRECTIVE ACTION RELATED TO AFFECTED BATCHES OF NUVO / NUVO LITE OXYGEN CONCENTRATORS

The Health Sciences Authority (HSA) is overseeing the Field Safety Corrective Action (FSCA) for **Nuvo / Nuvo Lite Oxygen Concentrators (see picture below)** manufactured by Nidek Medical Products, Inc. and distributed in Singapore by Rainbow Care Pte Ltd. Only serial numbers **04210000 to 10209335** are affected by this FSCA. Please refer to the diagram in **Annex 1** for instructions on how to locate the serial number on the device.



#### Background Information

2. These devices are intended to supply supplemental oxygen to patients requiring low flow oxygen therapy. The reason for the field correction is due to a capacitor component inside the concentrators failing in some instances. This may lead to a loss of supplemental oxygen supply and potentially pose as a fire hazard. A capacitor is an energy storage component commonly found in electrical circuits.

3. Based on information provided by the product owner, Nidek Medical Products, Inc, the internal fire hazard can occur when an internal capacitor component fails in the oxygen concentrators. However, such occurrence is expected to be rare. There have been no reports of injury to date related to this issue locally.

4. The local distributor, Rainbow Care Pte Ltd, is in the process of arranging to supply replacement capacitors for affected devices. The replacement capacitors are expected to arrive in Singapore by end July.

#### HSA's Action and Advisory

5. HSA is overseeing the corrective actions taken by the local distributor, Rainbow Care Pte Ltd. This safety issue has also been communicated to the relevant healthcare institutions and healthcare professionals.

6. HSA advises that:
- i. Members of public / patients / healthcare professionals who have purchased a Nidek oxygen concentrator, should verify the model and serial number of their device to confirm if it is affected (i.e. serial numbers **04210000 to 10209335**) by the FSCA. If affected, members of public / patients / healthcare professionals should contact their supplier to arrange for the necessary device correction to be performed.
  - ii. Similarly, members of public / patients / healthcare professionals who have purchased the affected device from Rainbow Care Pte Ltd and have not had their device corrected as yet, should contact Rainbow Care Pte Ltd for further assistance as soon as possible. For those who might have purchased their devices from other sources / suppliers and require assistance to verify if their device will be affected by this FSCA should contact Rainbow Care Pte Ltd for further assistance.
  - iii. Members of public / patients/ healthcare professionals who are unable to arrange for a correction of their affected device should seek an alternative device for their oxygen therapy or consult their physician for further medical advice.
7. For further information on the corrective action and other additional information, members of the public are advised to contact Rainbow Care Pte Ltd, at Tel: 6223 0904 (operates from Monday to Saturday from 9am to 7pm) or email to [sales@rainbowcare.com.sg](mailto:sales@rainbowcare.com.sg).
8. HSA will continue to monitor the situation closely and take all appropriate actions to protect public health and safety.

**HEALTH SCIENCES AUTHORITY**  
**27 JULY 2012**

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• **About the Health Sciences Authority (HSA)**

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services, Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit <http://www.hsa.gov.sg/>. For more updates on public health and safety matters, follow us on Twitter at [www.twitter.com/HSAsg](http://www.twitter.com/HSAsg).

• **About HSA Updates**

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**Media representatives are welcome to send any queries to the Corporate Communications Department @ HSA.**

## Annex 1

### Location of serial number displayed on the oxygen concentrator

