Dräger

To our customers of the

Emergency and Transport Ventilator

Oxylog 3000 *plus*

May 2023

Important Safety Notice

Oxylog 3000 *plus* may not switch to mains supply following battery operation.

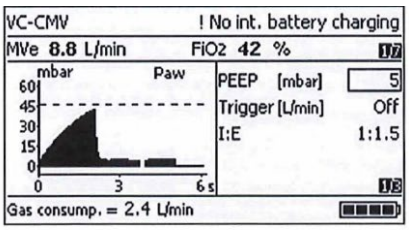
All Oxylog 3000 *plus* devices Part No 5704811 and 5704813,
Basic UDI DI 040486751304015FK19Z000XW, may be affected.

Dear Sir, Madam,

During the course of our global market surveillance activities, we have become aware of instances where emergency and transport ventilator Oxylog 3000 *plus* devices stopped ventilation due to a discharged battery. This happened despite the fact they were connected to a mains supply after prior battery operation.
In those cases, the battery status indication was correct at all times and the specified battery alarms (**"Charge int. battery"** and **"Int. battery discharged"**) were brought to the user's attention correctly. No serious injuries to patients have been reported as a result of this issue.

The root cause of the inability to switch to mains supply could be identified as a problem of the charging circuit which can occur in the following sequence of situations:

1. a prior battery issue indicated by the alarm **"No int. battery charging"** occurred during use on mains supply - see below



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Vorsitzender des Aufsichtsrats der
Drägerwerk AG & Co. KGaA und
Drägerwerk Verwaltungs AG:
...

and

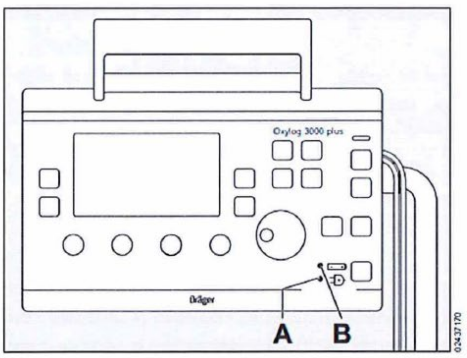
2. the internal battery is NOT removed and reinserted or replaced as recommended as remedy for this alarm message according to the Instructions For Use (IFU) and
3. the device is disconnected from mains supply (e.g., for patienttransport) and
4. the device is reconnected tomains supply.

Only if all the conditions are fulfilled and after the aforementioned alarms were given, ventilation could stop as soon as the battery charge was depleted.
Ventilation can be maintained using the manual resuscitator which needs to be ready according to the IFU.

Actions to be **taken:**

Please make sure that the battery is always removed and reinserted or replaced after occurrence of the **"No int. battery charging"** alarm message, without removing the device from mains supply.

Prior to a device being used on a battery supply, ensure the correct switchover by disconnecting from and reconnecting the device to a mains supply. Please verify the colors of indicators A and B as per the diagram below:



A should display a green light, and **B** should display a green or yellow light. If **B** displays a red light, you should disconnect and reconnect or replace the battery.

Your local Dräger Service representative or our service partner will contact you to arrange a date fora firmware update of the Printed Board Assembly Charger to be performed free of charge.

The devices can continue to be used safely as long as the aforementioned precautions and actions are taken.

Please ensure that all users and maintenance personnel of the above-mentioned products are made aware of this Important Safety Notice within your organization. If you have provided the products to third parties, please forward a copy of this information.

Please keep this information available until the indicated update measures have been completed.

The responsible authorities have been notified of this action.

Identification of the affected medical devices:

According to our records, you have received at least one Oxylog 3000 *plus*. All devices may be affected by this issue.

Contact:

If you have any questions, please do not hesitate to contact your local Dräger representative.

We apologize for any inconvenience caused by this measure.

With kind regards

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Head of Product Management
Care Area Intensive Care
Business Unit Therapy
Medical Division

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Director Post Market Surveillance
Quality & Regulatory Affairs
Medical Division

European Single Registration Number: DE-MF-000005329