Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 182 **dated** 30/12/2024 **Regarding SFDA Field Safety Corrective Action of Oxylog 3000 plus from (mfr: Draeger Medical, Inc).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DSC**
- **Director of Pharmacovigilance & Drug Information Dept, DSC**
- **Director of Drug Control Department, DSC**
- **Director of Pharmaceutical Licensing Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

DSC
مركز سلامة الدواء
Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

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Ministry of Health
Drug Safety Center
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سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

Circular No. 182 **/ 2024**

28 -06-1446 H
30 -12-2024

Field Safety Corrective Action of Oxylog 3000 plus from Draeger Medical, Inc.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/226
Product	Oxylog 3000 plus.
Manufacturer	Draeger Medical, Inc.
Local agent	Waleed Pharmacy & Stores LLC.
The affected products	All Oxylog 3000 plus devices Part No 5704811 and 5704813.
Reason	The Oxylog 3000 plus emergency and transport ventilators have stopped ventilation due to discharged battery if the alarm "No int. battery charging" was not handled according to the Instructions for Use (IFU) and a transport with the device was started.
Action	1. It has been decided by Dräger to update the Instructions for Use with the check described in the attachment of May 2023. This check, which must be performed prior to each transport, will avoid that a transport is started with an active alarm "No int.battery charging". A stop of ventilation due to a depleted battery because Oxylog 3000 plus does not switch to mains supply after battery operation would therefore not occur. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

Dräger

Technology for Life

Drägerwerk AG & Co. KGaA, 23542 Lübeck, Germany

To our customers of the
Emergency and Transport Ventilator
Oxylog 3000 *plus*

December 2024

Update on Important Safety Notice

Update: Oxylog 3000 *plus* may not switch to mains supply following battery operation.
IFU amendment

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

Dear Sir, Madam,

In May 2023 we informed you that we have become aware of instances where emergency and transport ventilator Oxylog 3000 *plus* devices stopped ventilation due to a discharged battery if the alarm "**No int. battery charging**" was not handled according to the Instructions for Use (IFU) and a transport with the device was started.

The preconditions for the stop and the check to be performed prior to transport were described in the Important Safety Notice.

We initiated and launched a firmware update of the Printed Board Assembly Charger for all Oxylog 3000 *plus* devices, designed to reduce the occurrence of situations in which the internal battery could not be charged.

Unfortunately, in the meanwhile we received a few reports of stopped ventilation of already updated devices in which the given alarm was not handled according to the IFU. No serious injuries of patients have been reported as a result of this issue.

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Swift-Code: NOLADE21SPL

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Commercial register:
Local court Lübeck HRB 7903 HL
General partner:
Drägerwerk Verwaltungs AG
Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7395 HL
UID-Nr. DE135082211

Dräger

Technology for Life

Dräger decided to update the Instructions for Use with the check described in the FSN of May 2023. This check, which must be performed prior to each transport, will avoid that a transport is started with an active alarm "**No int. battery charging**". A stop of ventilation due to a depleted battery because Oxylog 3000 *plus* does not switch to mains supply after battery operation would therefore not occur.

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

We apologize for any inconvenience caused by this measure and ask you to follow the attached IFU amendment.

With kind regards

Frank Ralfs

Head of Product Management

Care Area Intensive Care
Business Unit Therapy
Medical Division

Sonja Hillmer

Director Post Market Surveillance

Quality & Regulatory Affairs
Medical Division

European Single Registration Number: DE-MF-000005329

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.

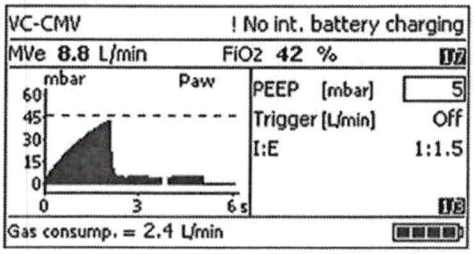
All Oxylog 3000 *plus* devices Part No 5704811 and 5704813,
Basic UDI DI 04048675130401 5FK19Z000XW, may be affected.

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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Swift-Code: NOLADE21SPL

Sitz der Gesellschaft: Lübeck
Handelsregister:
Amtsgericht Lübeck HRB 7903 HL
Komplementär: Drägerwerk Verwaltungs AG
Sitz der Gesellschaft: Lübeck
Handelsregister:
Amtsgericht Lübeck HRB 7395 HL

Vorsitzender des Aufsichtsrats der
Drägerwerk AG & Co. KGaA und
Drägerwerk Verwaltungs AG:
Stefan Lauer
Vorstand:
Stefan Dräger (Vorsitzender)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

and

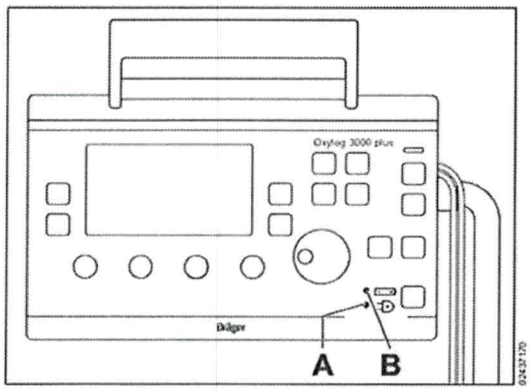
2. the internal battery is NOT removed and reinserted or replaced as recommended as remedy for this alarm message according to the Instructions For Use (IFU) and
3. the device is disconnected from mains supply (e.g., for patient transport) and
4. the device is reconnected to mains supply.

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 for a 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

[redacted]

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

[redacted]

Director Post Market Surveillance
Quality & Regulatory Affairs
Medical Division

European Single Registration Number: DE-MF-000005329