Drägerwerk AG & Co. KGaA, 23542 Lübeck

To the customers and users with Carbon dioxide (CO_2) / oxygen (O_2) terminal units - DIN standard

May 2017

Important safety notice!!!

Possible gas flow on DIN CO_2 connectors in DIN O_2 terminal units

Dear Sir/Madam,

As part of our global market monitoring we have become aware of individual cases in which temporary gas flow occurred due to improper insertion of a CO_2 connector into an O_2 terminal unit by inserting with excessive force.

Due to the temporary gas flow there is the risk that O_2 instead of CO_2 is applied to a patient during a minimally invasive procedure. There were no severe patient injuries in any of the known cases.

CO_2 terminal units are installed in healthcare facilities together with O_2 terminal units in selected functional areas such as operating theatres or endoscopy. A relevant risk of confusing the terminal units only occurs where the CO2 and O_2 Outlets are installed in direct proximity to each other.

In case of an improper insertion of a CO_2 connector into an O_2 terminal unit, the connector does not lock and is pressed out again by the gas pressure after a short period of time.

According to the applicable standard DIN 13260-2, the O_2 and CO_2 connector geometries are so similar that a CO_2 connector can also be inserted into an O_2 terminal unit. According to DIN EN ISO 9170-1, the distinctive feature of the coloured or colour-neutral version of the coupling is only the gas type symbol. According to the instructions for use, it must be ensured during application that the marking of the connector corresponds to the marking of the release sleeve of the terminal unit so that improper insertion can be avoided.

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Based on the findings of the investigation carried out, Dräger has developed an improved component for the O_2 terminal unit that reliably prevents gas flow even when a current, compliant CO_2 connector is accidentally inserted using excessive insertion force. In addition, the instructions for use have been updated and now include a more detailed description of the insertion process.

During the review of the events reported in the field, we discovered that also CO_2 connectors were used that do not comply with the current standard DIN 13260-2 any more. These connectors have a smaller internal diameter of 3.5 mm which can lead to a temporary gas flow due to the tight tolerance requirements of the previous standard in connection with the plug-in coupling (even after the update). As part of an adjustment of the standard in 2004, the internal diameter of the CO_2 connector was changed to 5.9 mm.

Please check the internal diameters of all CO_2 connectors in your healthcare facility. We recommend using only CO_2 connectors that comply with the current standard DIN 13260-2.

Please contact Dräger in order to update the affected O_2 terminal units. Within the warranty period or in case of regular service by Dräger, this is done free of charge. For this purpose, please complete the attached “Customer feedback and order” form and return it to us. We will then contact you to coordinate all required activities.

Please pay attention to the following points until the upgrade is carried out:

- The gas type label of connector and terminal unit must correspond
- The coloured gas type marking (if applicable) of connector and terminal unit must correspond
- The insertion of the connector into the terminal unit must be smooth
- Pay attention to the clicking sound when the connector locks.
- Slightly pull on the connector after it has locked to check the plug connection. The connector must not loosen.
- The connector must not be pressed in when in operating position.

We regret any inconvenience caused by this and would ask you to inform all personnel in your facility accordingly. Unfortunately, this activity is unavoidable as a preventive measure to increase patient and user safety.

The competent authorities have been informed about this activity.

With many thanks in advance for your support.

Yours faithfully,

Dr. V. Prapavat
Vice President Workplace Infrastructure
Product Management & Application Marketing
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Find attached:
Customer feedback and order
Supplementary sheet for the instructions for use