[Normal Priority] - H0637 : Air-Oxygen Blenders: Defective One-Way Inlet Valves May Cause Medical Gas Supply Concentration Inaccuracies [ECRI Exclusive Hazard Report]

Medical Device Hazard Report

Published: Thursday, August 13, 2020

UMDNS Terms:

- Compressed Gas Proportioners, Oxygen-Air [12876]

Geographic Regions: Worldwide

Suggested Distribution: Clinical/Biomedical Engineering, Pulmonology/Respiratory Therapy, Facilities/Building Management

Problem:

1. Defective air-oxygen blenders leaking oxygen into the air pipeline or air into the oxygen pipeline can lead to the following:
    1. Higher- or lower-than-expected oxygen concentrations being delivered to patients
    2. Serious injury (oxygen toxicity, not enough oxygenation)

ECRI Recommendations:

1. To prevent or reduce the risk of this problem occurring:
    1. Clinical Engineering staff should:
        1. Inspect the blenders annually and perform the operational verification procedure described in the manufacturer's service manual.
        2. Replace components such as O-rings and check valves at the frequency recommended by the manufacturer.
    2. Facilities staff should:
        1. Test medical gas pipelines (gas concentration, pressure, flow) at least annually.
    3. Clinical staff should:
        1. Use oxygen analyzers/monitors when blenders are used.
        2. Set high and low oxygen alarms on ventilators and oxygen monitors when available.
        3. When convenient, disconnect blenders from gas pipelines whenever they are not in use.

Background:

1. An ECRI member hospital reported oxygen leaking from blenders into their air pipeline.
    1. The facility's critical care unit discovered that the oxygen concentration in a ventilator was higher than the set amount, causing a high oxygen alarm.
    2. The same situation occurred the next day in another nearby unit.
    3. Clinical engineering staff measured the oxygen concentration at the wall air outlet and found that the oxygen concentration in the medical air pipeline was higher than 21%, leading them to conclude that oxygen was leaking into the medical air pipeline.
    4. Eventually, they found several air-oxygen blenders that were allowing oxygen backflow into the air inlets.
    5. All the faulty benders had worn duckbill one-way oxygen inlet valves.
    6. The problem was resolved after they replaced the parts in the two-year service kit, which includes new duckbill valves for both the air and oxygen inlets.
    7. Although the blenders were close to 10 years old, it does not appear that the hospital performed the yearly inspection procedure or the parts replacement per the manufacturer's recommended interval.
2. Manufacturer operational verification procedures usually include a backflow test to verify that neither air nor oxygen is leaking from the blender into the pipeline.
3. It the absence of a manufacturer verification procedure or if there is no backflow test in the manufacturer's verification procedure, clinical engineering personnel may follow ECRI's Biomedical Benchmark IPM for oxygen air proportioners (see link below).

References & Source Documents:

- ECRI Biomedical Benchmark IPM procedure for Oxygen-Air Proportioners

Comments:

- This alert is a living document and may be updated when ECRI receives additional information.

Source(s):

- 2020 Aug 11. ECRI Biomedical Benchmark IPM procedure for Oxygen-Air Proportioners; Procedure No. 444-20171208 Download

- 2020 Aug 11. ECRI Researched Report