الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Safety Communication letter

Ventilators in Isolation Rooms May Fail to Alert Clinicians of Critical Alarm Conditions

Safety Communication رسالة سلامة

Ventilators in Isolation Rooms May Fail to Alert Clinicians of Critical Alarm Conditions

Device Description:	Ventilators, Intensive Care
Manufacturer:	All
Problem:	With increase of ventilated patients in isolation for COVID-19, a patient's ventilator alarms were not heard, resulting in harm to the patient. Unique conditions contribute to the likelihood that ventilator alarms may not be heard, such as: 1. Ventilator patients require isolation with room doors closed. However, closed doors increase the risk that ventilator alarms not heard. 2. Because of isolation/high contagion of patients, staff are limiting the number of entries into the room to decrease exposure, conserve PPE, and bundle tasks. 3. Other equipment (e.g., IV pumps) is placed outside of the room. However, their alarms may mask ventilator alarms. 4. Staff-to-patient ratios may be inadequate for a surge in ventilated patients.
Recommendation/Actions:	• **Respiratory administrative recommendations** 1. Create/update surge plan annually for increased census and increase in ventilated isolation patients. This should include an adequate staffing plan and staff-to-patient ratios to provide safe care. 2. Educate and train appropriate personnel during employee orientation and during annual competencies in the use of all ventilator models used in the facility, including models that may be rented or borrowed for use during a patient surge. 3. Educate nursing as an additional resource in recognition and response to ventilator-related alarm conditions. • **Respiratory clinical recommendations** 1. Adjust ventilator alarm volume to the highest level. 2. Position the ventilator so that it is visible from outside the room, perform periodic visual checks of the ventilator, and/or check with manufacturer to see whether the ventilator monitor is detachable and able to be placed outside the room.

3. As part of routine ventilator checks, as defined by your facility, add documentation of information such as:
    - Alarm volume level
    - Power source–AC or DC
    - Battery level percentage—both primary and secondary if applicable
4. Keep ventilators connected to AC power when not in use on a patient to preserve battery power.

- **Recommendations to Multidisciplinary Team–Respiratory, Nursing, IT, Clinical Engineering**

A. Consider the following alternatives to enhance notification of ventilator alarms using these notification pathways, understanding that each has limitations:
    1- Nurse call system: Use the nurse call system to alert users to the presence of certain, but not necessarily all, ventilator alarms. The ventilator alarms that can be communicated in this manner will depend on the capabilities of the ventilator model and the nurse call system.
    1. Integrate ventilators with patient monitoring systems to allow notification of ventilator alarms via the associated central stations and ancillary displays.
    2. Use ancillary alarm notification/alarm integration systems to send specific alarms to end-user communication devices.

These systems can also be used to configure delays so that self-correcting conditions do not add to the alarm load. For example, configuring a delay for high-pressure alarms could reduce the number of alarms staff receive for transitory conditions, such as a patient cough.

B. With any of these approaches, it is important to test the systems before implementation to:
    1. Examine whether and how each alarm is communicated to the clinician.
    2. Understand the type of information (e.g., alarm type, priority level, and patient) that is and is not communicated.

If you think you had a problem with your device or a device your patient uses, please do not hesitate to report the problem to SFDA through:
NCMDR
Vigilance system
19999 unified call center