

[High Priority] - H0625 : [COVID-19] Ventilators in Isolation Rooms May Fail to Alert Clinicians of Critical Alarm Conditions [ECRI Exclusive Hazard Report]
Medical Device Hazard Report

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UMDNS Terms:

- Ventilators, Intensive Care [17429]

Geographic Regions: Worldwide

Suggested Distribution: Clinical/Biomedical Engineering, Critical Care, Nursing, Pulmonology/Respiratory Therapy, Information Technology

Problem:

1. Unique conditions during the COVID-19 pandemic 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 are 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.
 5. Staff members may not be familiar with alarm sounds and visual indicators on ventilator models that are not typically used in their area.
 6. Inability to monitor ventilator alarms with remote clinician notification platforms/solutions may lead to patient harm.

ECRI Recommendations:

Respiratory Department

1. 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.
2. Respiratory clinical recommendations:
 - a. Adjust ventilator alarm volume to the highest level.
 - b. 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 (GUI) is detachable and able to be placed outside the room.
 - c. 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
 - d. Keep ventilators connected to AC power when not in use on a patient to preserve battery power.

Clinical Engineering Department

1. Assist Respiratory Department personnel in adapting ventilator monitor (GUI) to be placed outside the room, if applicable.

Multidisciplinary Team—Respiratory, Nursing, IT, Clinical Engineering

1. Investigate and consider remote clinician notification solutions to align with NPSG.06.01.01—Use Alarms Safely. 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.
 2. Integrate ventilators with patient monitoring systems to allow notification of ventilator alarms via the associated central stations and ancillary displays.
 1. Check list of patient monitor—ventilator.

3. Use ancillary alarm notification/alarm integration systems to send specific alarms to end-user communication devices.
 1. 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.
2. 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, patient) that is and is not communicated. For additional information refer to [INTERFACING MONITORING SYSTEMS](#) .
3. While some alternative notification options are available to help improve staff awareness of activating ventilator alarms, these options all have limitations. For example:
 1. While nurse call systems can be used to provide an indication outside the patient's room of a ventilator alarm, they do not provide any indication of the cause or priority of the alarm. Additionally, users may not be able to distinguish this notification from other nurse call alarms, such as patient assist.
 2. Physiologic monitoring systems can be used as a pathway for ventilator alarms, but based on ECRI's experience, the systems may not provide adequate indication of the cause or priority of the alarm and may sometimes misrepresent alarms. For example, ECRI's testing showed that in some cases critical ventilator alarms were communicated as medium-priority alarms by the monitor.
 3. Alarm middleware systems offer extensive alarm management capabilities, but they can be an expensive option. In the absence of a server, middleware systems require proprietary hardware that must be connected to each ventilator to collect and distribute alarm data. For additional information, refer to [Ancillary Alarm Notification Systems](#) .

Background:

1. An ECRI member reported that during a surge in ventilated patients in isolation for COVID-19, a patient's ventilator alarms were not heard, resulting in harm to the patient.
2. Lack of integration to a remote clinician notification solution for alarm monitoring lead to critical ventilator alarms being missed.

Comments:

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

Source(s):

- 2020 Jun 22. ECRI researched report
- 2020 Jun 30. Interfacing Monitoring Systems with Ventilators [Download](#)
- 2020 Jun 30. Evaluation Background: Ancillary Alarm Notification Systems [Download](#)