

**[High Priority ] - H0624 : [COVID-19] Ventilators Obtained from Storage, Unknown Sources, or Accelerated Manufacturing Require Inspection before Patient Use [ECRI Exclusive Hazard Report] Medical Device Hazard Report**

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**UMDNS Terms:**

- Ventilators, Intensive Care [17429]
- Ventilators, Portable/Home Care [17423]
- Ventilators, Transport [18098]

**Geographic Regions:** Worldwide

**Suggested Distribution:** Anesthesia, Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, Nursing, Pulmonology/Respiratory Therapy, Risk Management/Continuous Quality Improvement, Staff Education, EMS/Transport, Materials Management

**Problem:**

1. A hospital's response to the COVID-19 pandemic may require an influx of ventilators from multiple sources and in unknown conditions that are quickly placed into use.
2. This could result in ventilators not performing as expected, potentially resulting in patient harm or death.

**ECRI Recommendations:**

*Clinical Engineering personnel, in close coordination with Respiratory Therapy personnel:*

1. Conduct acceptance checks on any incoming ventilators before placing them into service, irrespective of their source.
  - [ECRI IPM for intensive care ventilators](#) —includes incoming inspections and preventive maintenance
  - [ECRI IPM for transport ventilators](#) —includes incoming inspections and preventive maintenance
2. Perform preventive maintenance on ventilators known to be due for IPM, or those for which IPM history is unknown.
3. Obtain, if not already available at your facility, instructions for use (IFUs), quick-start guides, and maintenance manuals for incoming ventilators. Sources for these include:
  - Manufacturers
  - Public websites
    - [Frank's Hospital Workshop](#)
    - [iFixit](#)
    - [Ventilator Training Alliance](#)
  - ECRI IPMs for ventilators
    - [ECRI IPM for intensive care ventilators](#) —includes incoming inspections and preventive maintenance
    - [ECRI IPM for transport ventilators](#) —includes incoming inspections and preventive maintenance
4. Identify major performance and safety differences from ventilators currently used at the facility, and inform users of these differences.
5. Identify items needed to operate and maintain any incoming ventilators, and coordinate adequate supply with materials managers. These items include:
  - Filters
  - Breathing circuits
    - Single use
    - Reusable
  - Humidification devices
  - PM kits
  - Spare parts
6. Identify medical gas system requirements to supply the increased use of ventilators.
  - S0396: [\[COVID-19\] COVID-19 Emergency Response: Oxygen Supply Considerations \[ECRI Exclusive User Experience Network\]](#)
7. When inspecting and maintaining ventilators, use appropriate PPE.
8. When testing ventilators, use viral filters between the ventilator and test devices, such as test circuits, test lungs, and ventilator analyzers.
9. Use caution when removing and cleaning dust filters.
  - S0405: [\[COVID-19\] Medical Device Dust Filter Replacement Considerations during Pandemic \[ECRI Exclusive User Experience Report\]](#)

10. When borrowing or receiving devices from other facilities:
  - Check devices for sensitive information, and remove any such information before releasing them to clinical use.
    - H0616: [\[COVID-19\] The Transfer of Loaned Equipment during the COVID-19 Response Could Lead to Breach of Sensitive Information \[ECRI Exclusive Hazard Report\]](#)
  - Check devices for cybersecurity vulnerabilities.
    - H0615: [\[COVID-19\] The Use of Loaned or Warehoused Devices during the COVID-19 Response Could Pose Security Risk \[ECRI Exclusive Hazard Report\]](#)
11. Prioritize and allocate ventilation devices according to their capabilities.
  - S0398: [\[COVID-19\] Shortages of Intensive Care Ventilators—Strategies for Mitigation \[ECRI Exclusive Special Report\]](#)
12. Plan for the eventual removal from service for devices temporarily authorized under an FDA EUA.
  - S0399: [\[COVID-19\] Ventilators on FDA Emergency Use Authorization List : Hospitals Should Seek Clarity on Post-EUA Status Before Purchasing \[ECRI Exclusive Special Report\]](#)

**Background:**

1. ECRI has learned of cases in which:
  1. Ventilators received from the National Stockpile were not fully functional upon inspection.
  2. Member hospitals failed up to 30% of their incoming inspections of new ventilators obtained from manufacturers, mainly because of:
    1. Missing parts and accessories
    2. Physical damage caused by incomplete packaging
  3. Member hospitals reported not being able to receive timely on-site service, accessories, consumables, or repair parts for ventilators from manufacturers.
2. Devices authorized under FDA's EUA:
  1. May not have all the features and capabilities needed to provide full ventilation support, such as:
    1. Ventilation modes
    2. Measured parameters
    3. Alarms
    4. Alarm volume
    5. Must be taken out of service/repurposed after the EUA expires

**Comments:**

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

**Source(s):**

- 2020 Jun 11. ECRI researched report.