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Dear healthcare professional,

FDA Updates on Precautions with Audible Alarms on Ventilators

It has come to our attention that The U.S. Food and Drug Administration (FDA) issued an updated safety communication about the precautions on using audible alarms on ventilators.

Providing care to patients who require mechanical ventilation can be challenging due to factors such as the severity of the patient's illness and complexity of the equipment. Regarding to this, FDA advises healthcare professionals and care givers of paying immediate attention to the ventilators' built-in safety features—specifically their alarms.

In 2010, the FDA received over 2,500 adverse event reports associated with ventilator use. About a third of these events indicated an alarm-related issue. Although some of these alarm-related adverse event reports reflected deteriorating patient condition, indicating that the ventilator alarms had functioned appropriately, many indicated preventable audible ventilator alarm malfunctions or human error.

FDA recommends users to take the following steps to prevent serious ventilator alarm issues:

- Be familiar with the ventilators in your facility; not all ventilators have the same features or safety mechanisms, including alarms.
- Follow your facility's established protocols to ensure ventilator setting information is communicated to other staff members, especially during shift changes and patient admissions or transfers.
- At the beginning of your shift and as clinically indicated, confirm that ventilator settings are correct (as prescribed) and clinically appropriate and that alarms are appropriately set.
- Confirm that audible alarms can be heard in the intended environment of use (such as in the home or ICU, or during transport).
- Adjust audible alarm settings only when clinically necessary according to facility policy.
- When you hear a ventilator alarm, respond immediately by going to the patient's bedside.
- If possible, quickly identify the reason for the alarm and intervene appropriately.
- Immediately assess the patient to identify any deterioration in clinical status caused by the alarm situation, such as change in mentation, respiratory distress, decreased SpO₂, bradycardia, or hypotension.
- If patient compromise is identified, activate the rapid response team and manually ventilate the patient with a manual resuscitation bag. If the patient is unresponsive, apneic, and pulseless, call a code and initiate basic life support.
- Follow your facility's protocol for reporting ventilator adverse events and near-misses.

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For more details of FDA's recommendations to healthcare providers, patients and their caregivers, please refer to the following link:

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm270894.htm>

Thank you for your attention.

Yours faithfully,

A handwritten signature in black ink, appearing to be 'Addi Chan', written in a cursive style.

(Dr Addi CHAN)
for Director of Health