

Medical Safety Information

Pharmaceuticals and Medical Devices Agency



Extra issue No. 1 April 2020

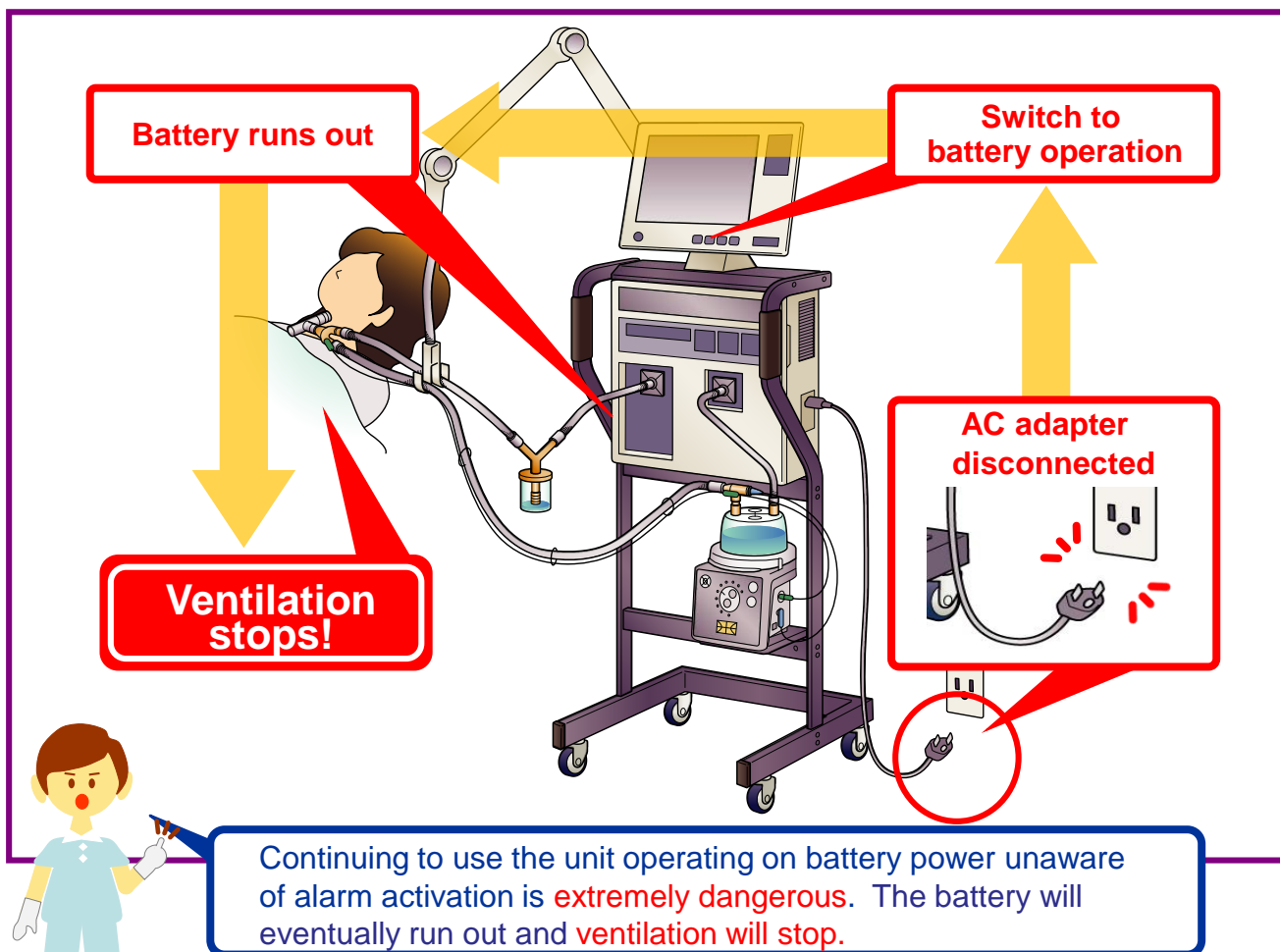
Reminder Series No. 1 (Precautions in Ventilator Use, etc.)

In response to the spread of COVID-19, use of ventilators is increasingly required in clinical settings. Key points for safe handling and use of ventilators in past issues of PMDA Medical Information have been extracted and organized as a reminder.

(Case 1) A ventilator was unintentionally switched to battery operation. After an empty battery alarm was activated, ventilation stopped. It was found that the AC adapter was disconnected.

1 Precautions for power source during use

- When using a ventilator, **always check indicators and/or messages to make sure** that AC power is being supplied.



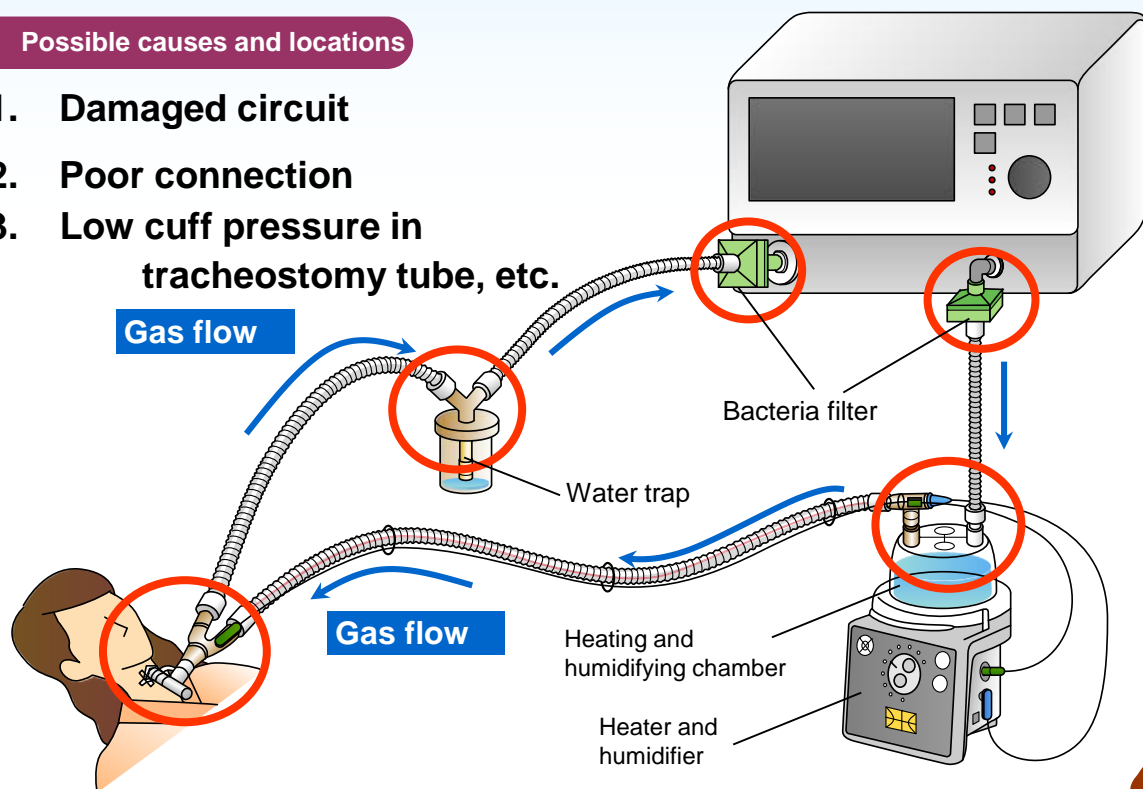
(Case 2) A ventilator's alarm sounded, and the patient was found in a cyanotic state. By correctly setting the water trap and the cup, the patient's respiratory status was recovered.

2 Points to be considered when a low-pressure alarm goes off

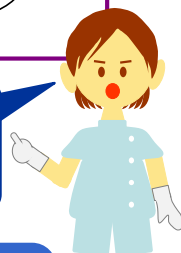
- A possible cause of a low-pressure alarm or a hypoventilation alarm is gas leakages from the circuit.

Possible causes and locations

1. Damaged circuit
2. Poor connection
3. Low cuff pressure in tracheostomy tube, etc.



Check that there are no “Loose connection”, “misconnection”, “respirator tube cracking or chamber damage,” etc. **Do not forget to check that there is a firm connection between the water trap and the cup !**

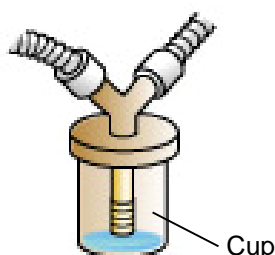


Gas leakage from the water trap



After draining water out of the water trap, make sure that there is a firm connection between the water trap and the cup !

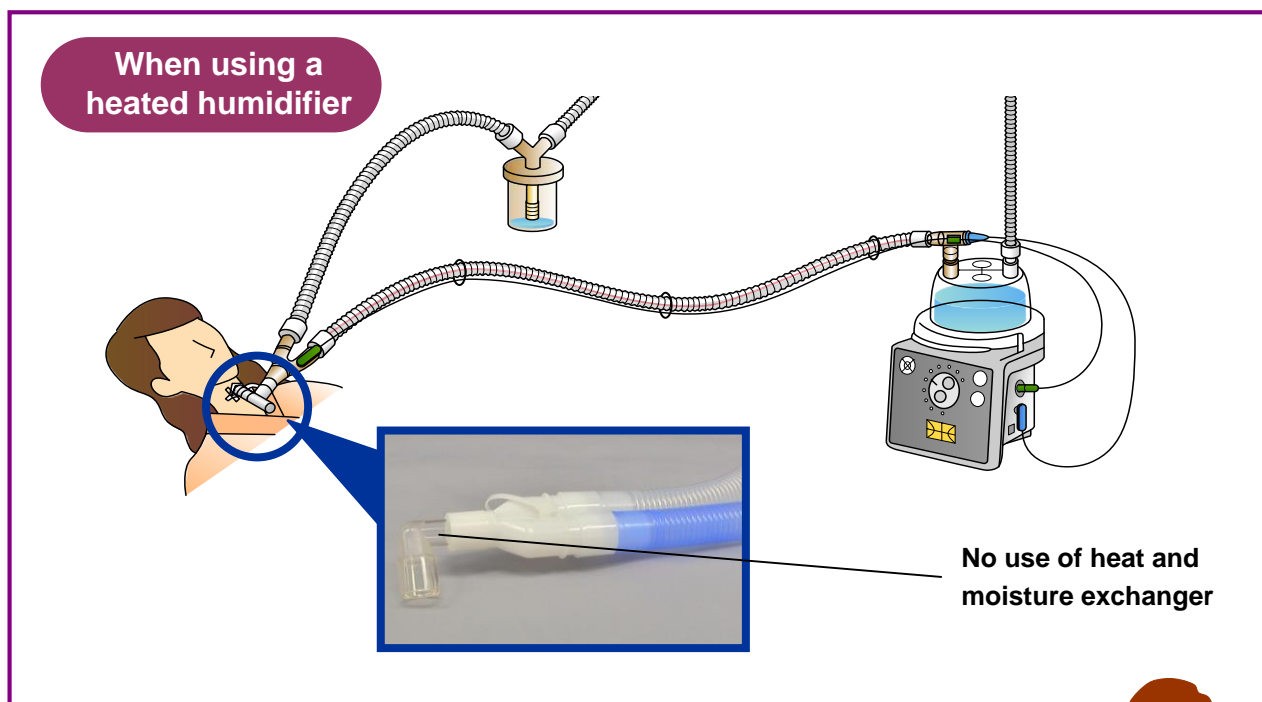
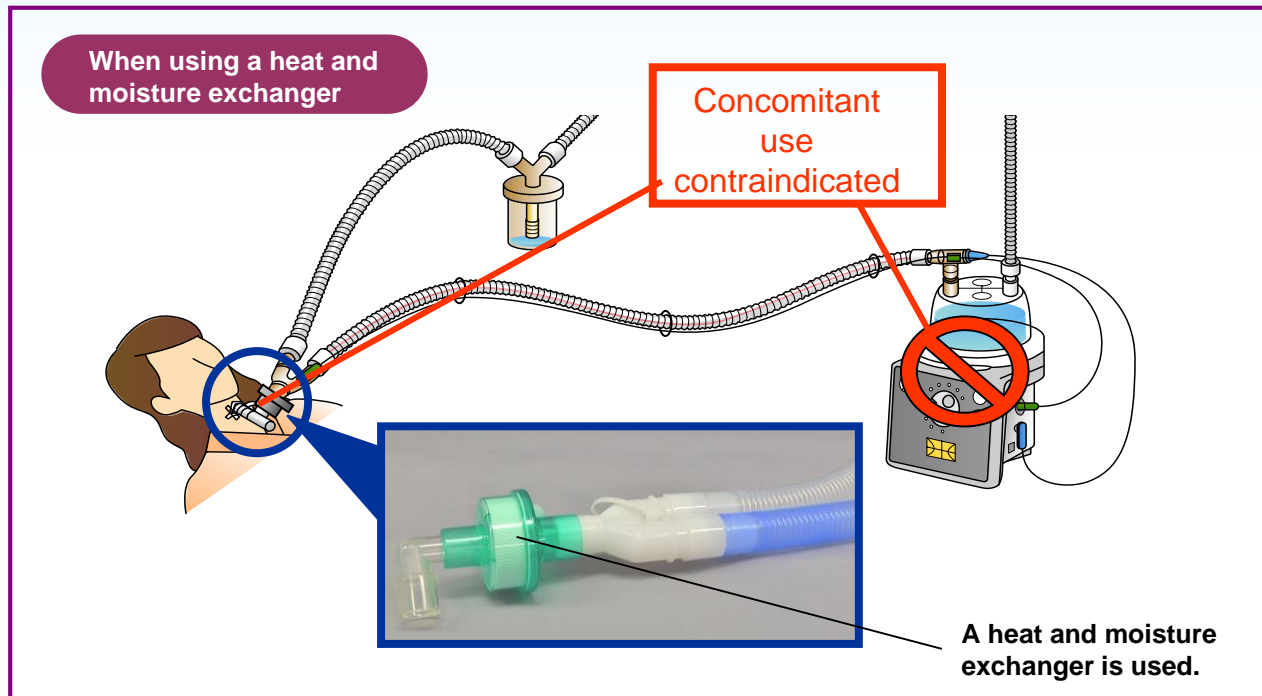
Examples of loose connection



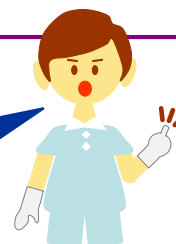
(Case 3) The patient was given mechanical ventilation with a heat and moisture exchanger. When it was switched to a heated humidifier, the heat and moisture exchanger was not removed and kept in place.

3 •Contraindication of concomitant use of a heat and moisture exchanger and heated humidifier

- Do not use a heat and moisture exchanger and a heated humidifier at the same time.
- Do not use a heat and moisture exchanger and a nebulizer at the same time.

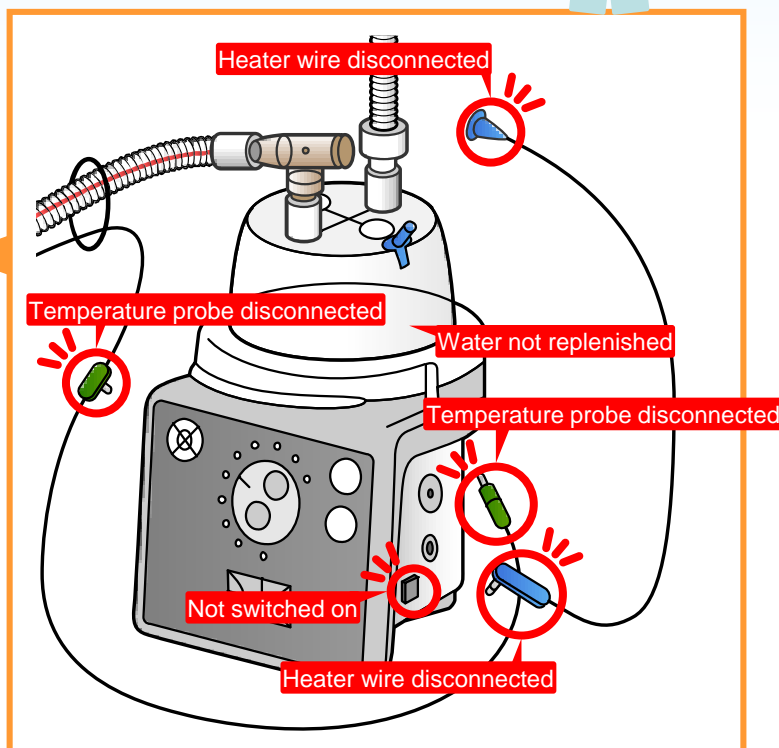
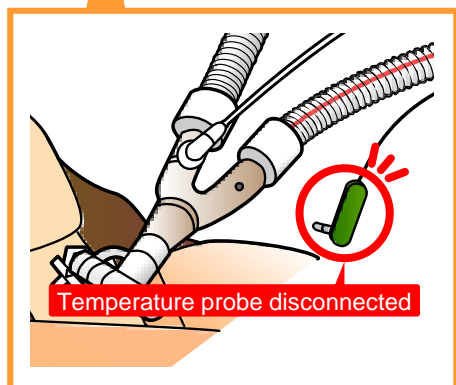
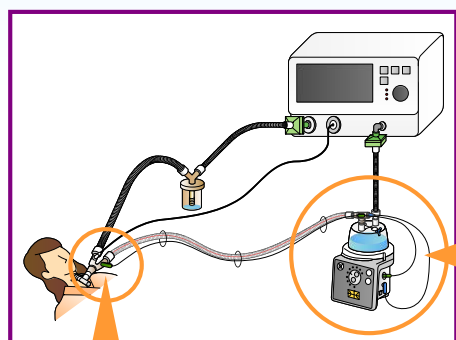


When a heat and moisture exchanger is used together with a heated humidifier or a nebulizer, excessive moisture may be absorbed, and airway clogging of the filter inside heat and moisture exchangers may occur making it difficult to ventilate.

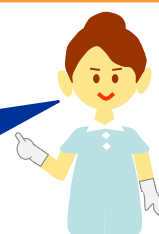


4 Other frequently reported incidents caused by heated humidifiers

Many of the reported “hiyari-hatto”(near-incidents) associated with ventilators are caused by heated humidifier issues.



Please confirm the guidelines and other materials on COVID-19 published by related academic societies !



Past related issues are as follows:

- PMDA Medical Safety Information No. 7 Precautions in Artificial Respiration (No. 1)
- PMDA Medical Safety Information No. 11 Precautions in Artificial Respiration (No. 2)
- PMDA Medical Safety Information No. 20 Precautions in Artificial Respiration (No. 2)

About this information

* PMDA Medical Safety Information is issued by the Pharmaceuticals and Medical Devices Agency for the purpose of providing healthcare providers with clearer information from the perspective of promoting the safe use of pharmaceuticals and medical devices. The information presented here has been compiled, with the assistance of expert advice, from cases collected as Medical Accident Information Reports by the Japan Council for Quality Health Care, and collected as Adverse Drug Reaction and Malfunction Reports in accordance with the Law on Securing Quality, Efficacy and Safety of Pharmaceuticals and Medical Devices.

* We have tried to ensure the accuracy of this information at the time of its compilation but do not guarantee its accuracy in the future.

* This information is not intended to impose constraints on the discretion of healthcare professionals or to impose obligations and responsibility on them, but is provided as a support to promote the safe use of pharmaceuticals and medical devices by healthcare professionals.

Access to the most up to date safety information is available via the PMDA medi-navi.

