

Medical Safety Information

Pharmaceuticals and Medical Devices Agency

pmda No. 7 January, 2009

Precautions in Artificial Respiration (No.1)

POINT Key points for safe use

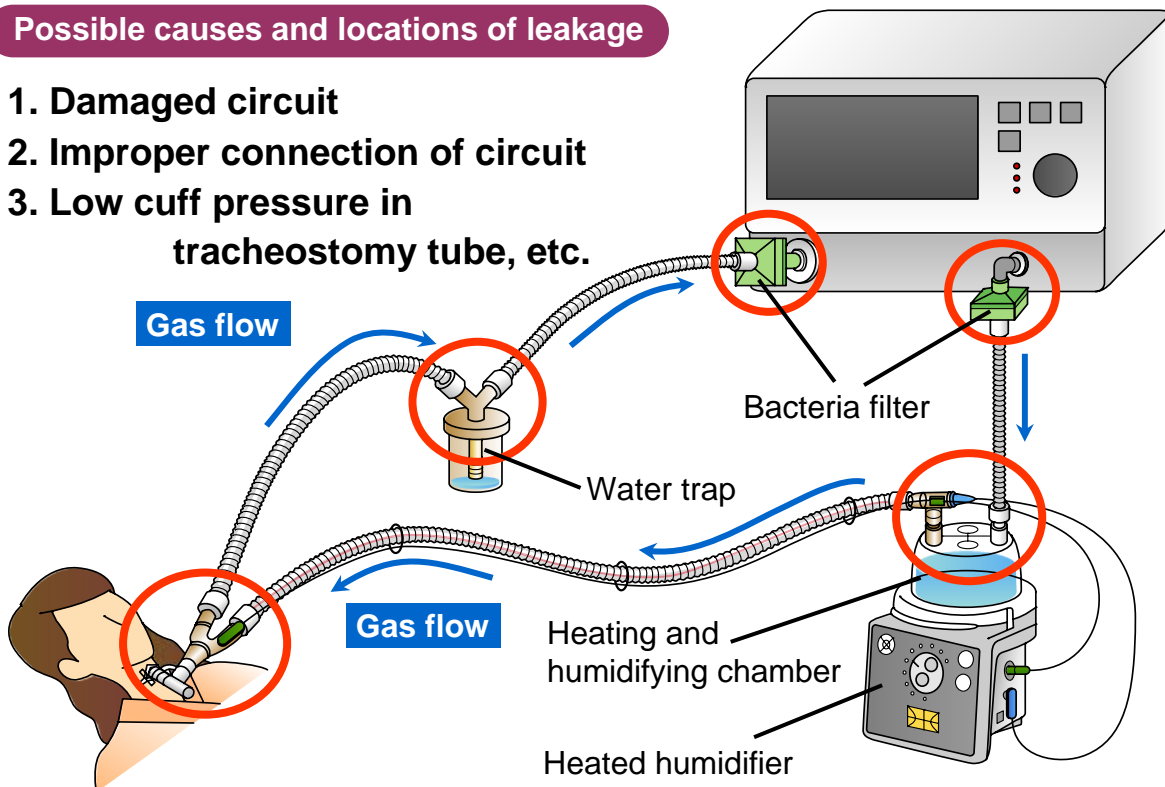
(Case 1) An artificial respirator's alarm sounded, and the patient was found in a cyanotic state. By correctly setting the water trap and the cup, the patient's respiratory status was recovered.

1 What should be checked when a low-pressure alarm occurs

- The possible causes of a low-pressure alarm or a hypoventilation alarm may be gas leakages from the circuit.

Possible causes and locations of leakage

- Damaged circuit
- Improper connection of circuit
- Low cuff pressure in tracheostomy tube, etc.



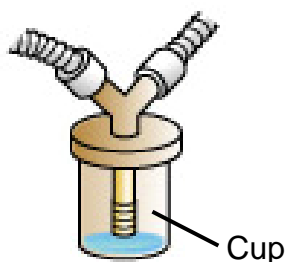
Check for no "Loose connection", "Misconnection", "Respirator tube cracking or chamber damages", etc. **Do not forget to check the firm connection of the water trap and the cup.**



Gas leakage from the water trap



After draining water out of the water trap, ensure a firm reconnection of the water trap.



Examples of loose connection



Connection of the water trap to the cup

- After water draining, make sure to have a firm connection of the water trap to the cup.

To avoid an improper connection, put caution labels on conspicuous places where possible leakage may exist.



Caution: Gas leakage



Caution: Gas leakage



Caution: Air leakage



Caution: Air leakage

Examples of label cautions

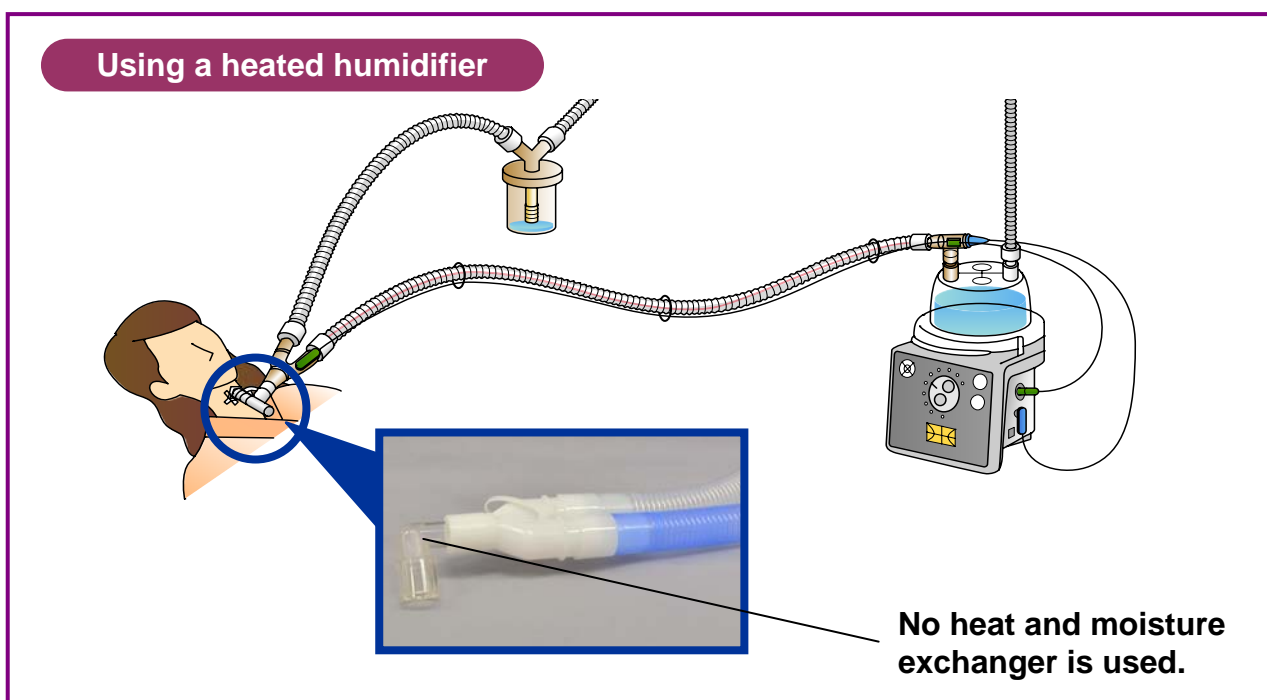
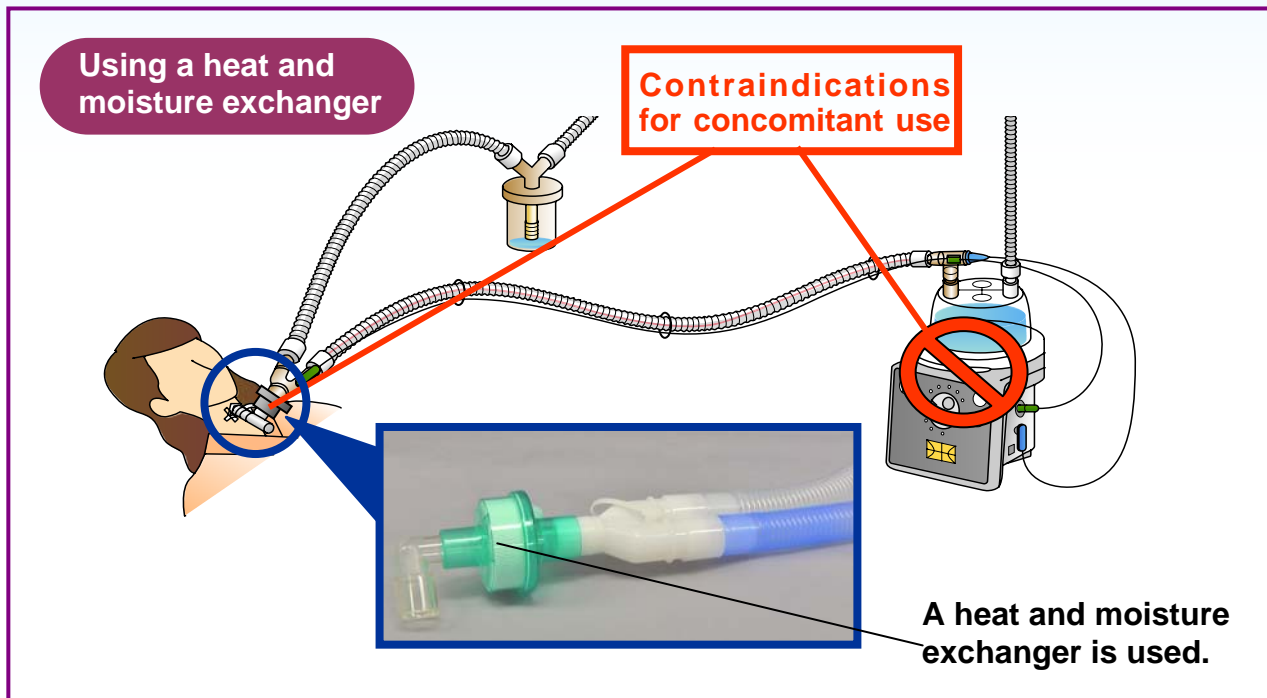


The caution labels must be visible from any direction, by putting multiple labels on the cup surface.



(Case 2) The patient was given an artificial respiration with a heat and moisture exchanger. When a changing to a heated humidifier was made, the heat and moisture exchanger was not removed and kept it setting.

2 Contraindications for concomitant use with a heat and moisture exchanger and a heated humidifier

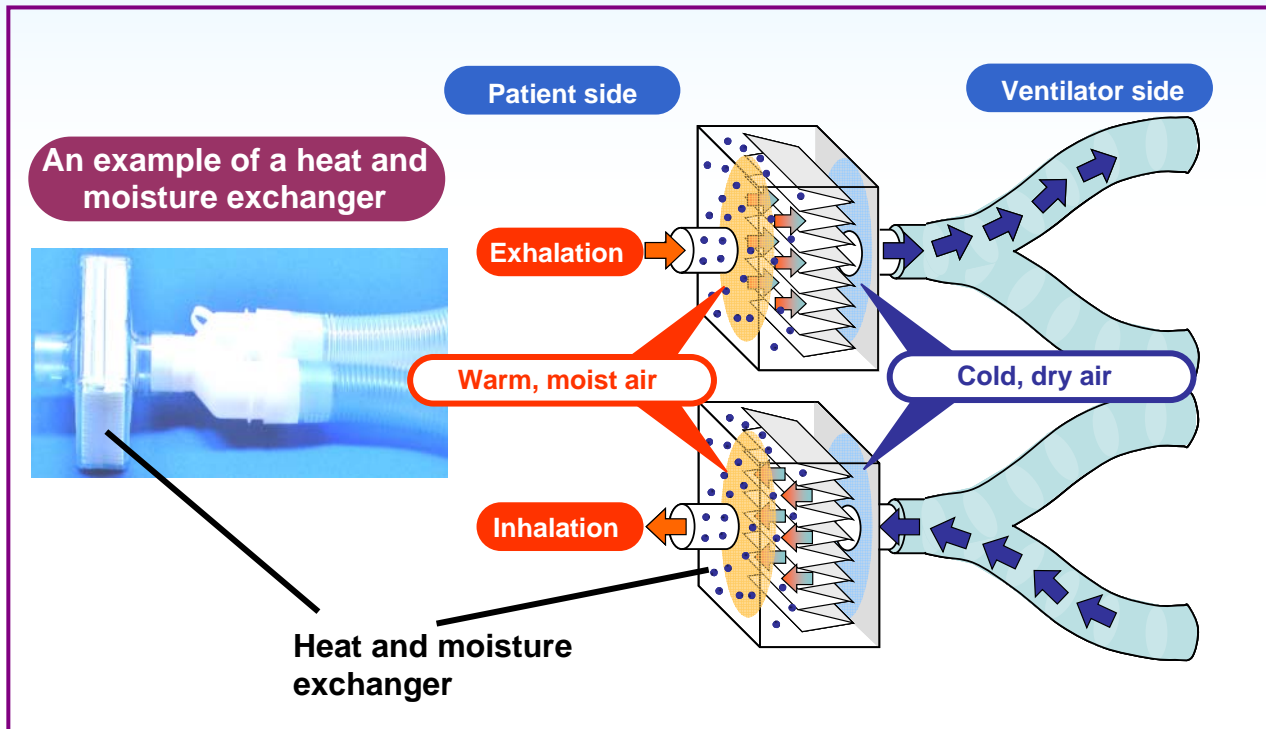


When a heat and moisture exchanger is used together with a heated humidifier or a nebulizer, excessive moisture may be absorbed, and **airway clogging of filter inside heat and moisture exchangers may occur and making it difficult to ventilate.**



Mechanism of a heat and moisture exchanger

- The heat and moisture exchanger capture heat and moisture contained in the exhalation from the patient side. The moisture and heat contained in the inhalation are supplied by the exchanger to the air from the ventilator.



The Ministry of Health, Labour and Welfare (MHLW) issued notification related to PMDA Medical Safety Information No. 7:

- "Self inspection, etc. of package inserts regarding combination use of a heat and moisture exchanger or a heated humidifier in a respiration circuit" (PFSB/ELD Notification No. 0911004 and PFSB/SD Notification No. 0911002)

Information on these notifications are available

at the Pharmaceuticals and Medical Devices Information website (in Japanese)
<http://www.info.pmda.go.jp/iryujiko/file/20080911.pdf>

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 Pharmaceutical Affairs Law.
- * We have endeavored to ensure the accuracy of this information at the time of its compilation but do not guarantee its accuracy into 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.