

Medical Safety Information

Pharmaceuticals and Medical Devices Agency

pmda No. 11 August, 2009

Precautions in Artificial Respiration (No. 2)

POINT Key points for safe use

(Case 1) When a low-pressure alarm was continuously sounding, it was first thought to be due to gas leakage from the circuit. After close inspection it was revealed that water had blocked the airway pressure tube, precluding accurate measurement of the airway pressure.

1 Precaution when connecting an airway pressure tube

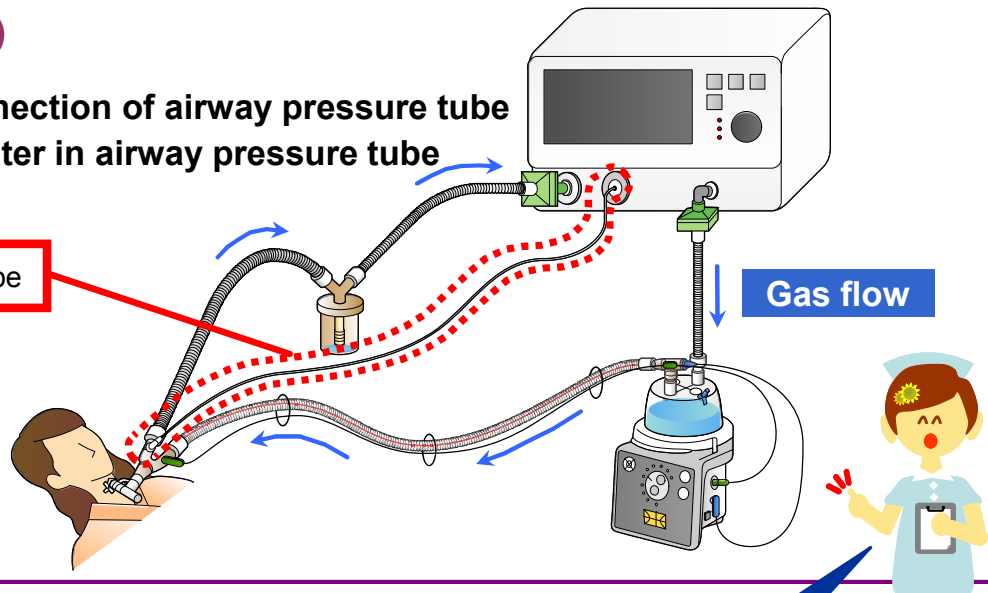
- Water blocking the airway pressure tube may be a possible cause of a low or high-pressure alarm.

Possible causes

1. Improper connection of airway pressure tube
2. Remaining water in airway pressure tube

Airway pressure tube

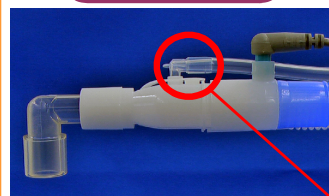
Gas flow



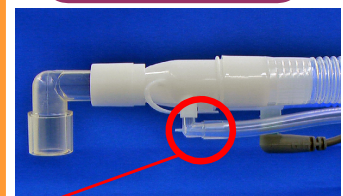
To prevent water from blocking the airway pressure tube, check the following:

1. **Keep the airway pressure tube connector at the top** to prevent water inflow.
2. **Immediately remove any water** remaining in the airway pressure tube.

Proper use



Improper use

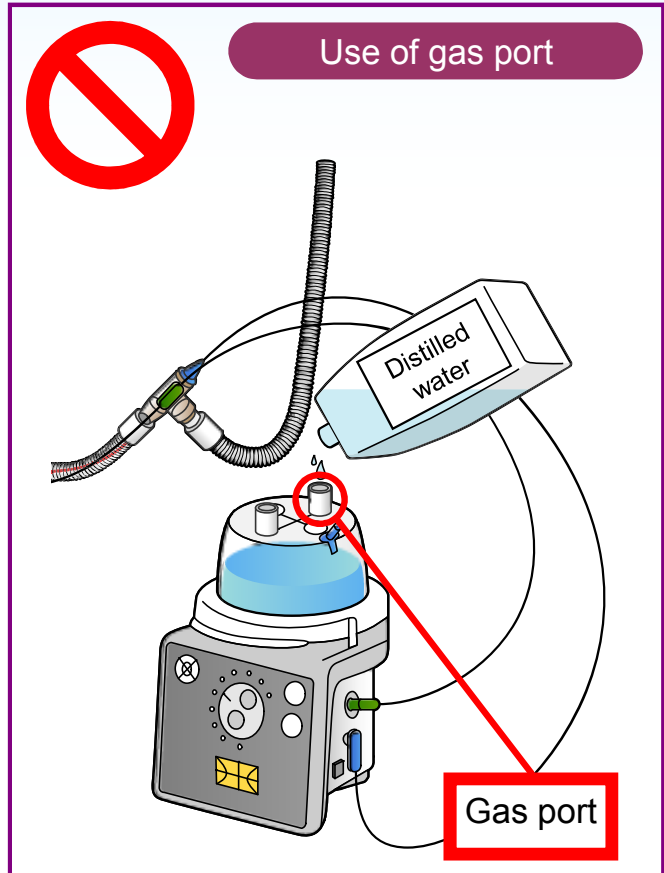
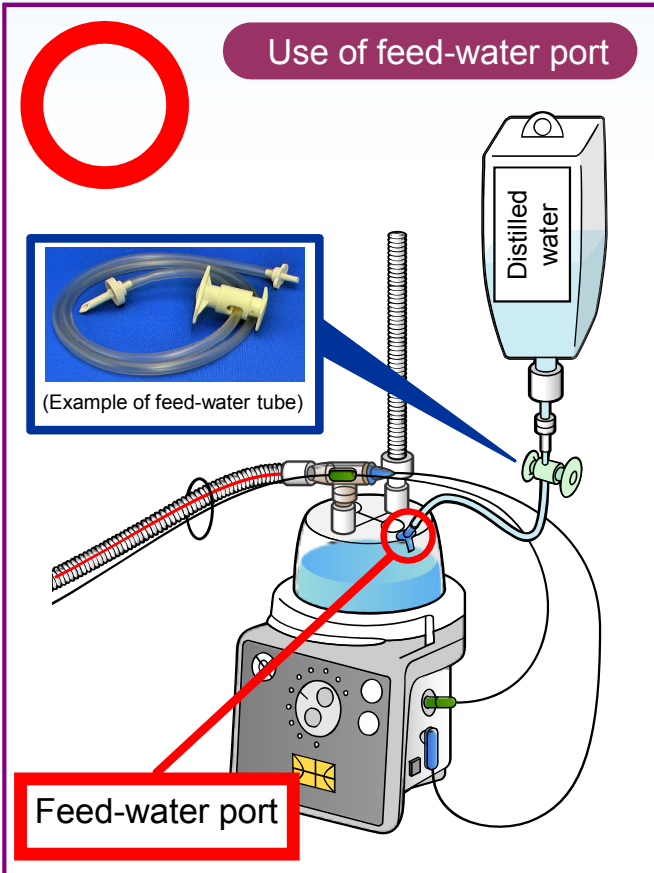


Airway pressure tube connector

(Case 2) After a heating and humidifying chamber was filled with water, by direct connection of the circuit to the chamber, via the gas port instead of through the feed-water port, reconnecting the gas tube to the chamber was forgotten.

2 Points for handling a heated humidifier

- Do NOT use the gas port to fill the heating and humidifying chamber with water.



[Contraindications/Prohibited Actions]
 9. Do NOT use the gas port to fill the humidifier with water. (This is to prevent incorrect connections and burns due to them, or contamination of the respiration circuit with microorganisms occurring from supplying water through the gas port.)

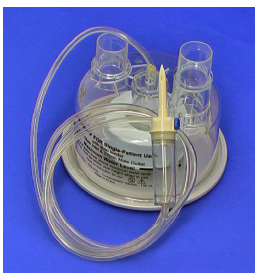
← Precautions such as shown on the left are described in package inserts of heated humidifiers and the like.

Excerpt from package insert of Heated Humidifier MR 850, Fukuda Denshi Co., Ltd.

*This part is indicated in Japanese.

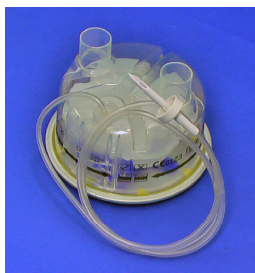
Water auto-feeding chambers

Pacific Medico Co., Ltd.



PMC-300AF

Fisher & Paykel Healthcare Ltd.



MR290



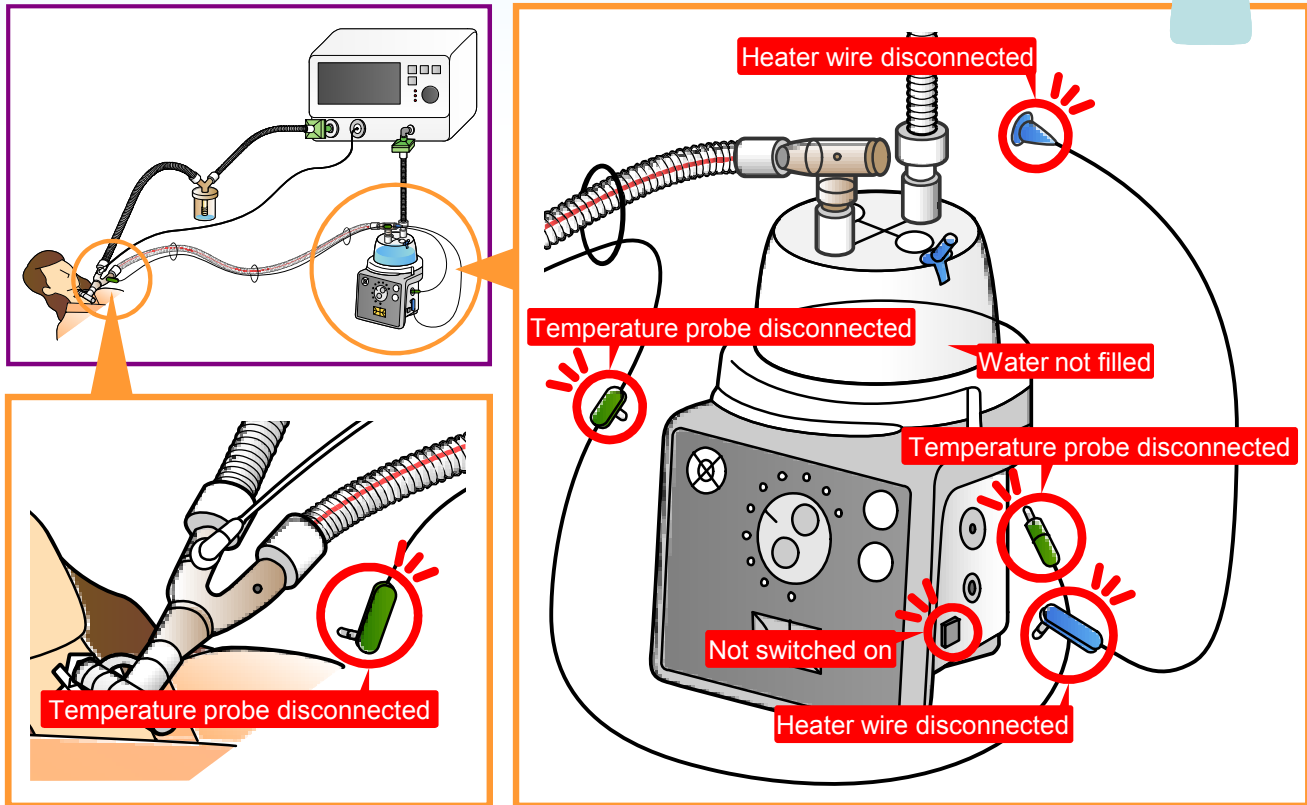
Note that water auto-feeding is inappropriate in some ventilation modes.

You can use **water auto-feeding chambers** that are continuously filled with distilled water to maintain a constant water volume.



Other frequently reported incidents

Numerous reported ventilator's incidents are caused by **heated humidifier issues.**



The Ministry of Health, Labour, and Welfare (MHLW) has issued notifications that are related to issues in this PMDA Medical Safety Information No. 11.

- "Revision of PRECAUTIONS regarding heated humidifiers" (PFSB/ELD Notification No. 1126009 and PFSB/SD No. 1126001 issued on November 26, 2004)
- "Self inspection, etc. of package inserts regarding airway pressure monitoring tubes in a respiration circuit" (PFSB/ELD Notification 0825 No. 2 and PFSB/MDIO Notification 0825 No. 6 issued on August 25, 2009)

Information on this notification is available

at the Pharmaceuticals and Medical Devices Information website (in Japanese)

<http://www.info.pmda.go.jp/mdevices/md2004-1126001.html>
<http://www.info.pmda.go.jp/mdevices/file/md2009-0825002.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.