

PMDA Medical Safety Information

Pharmaceuticals and Medical Devices Agency

pmda No. 63 March 2022

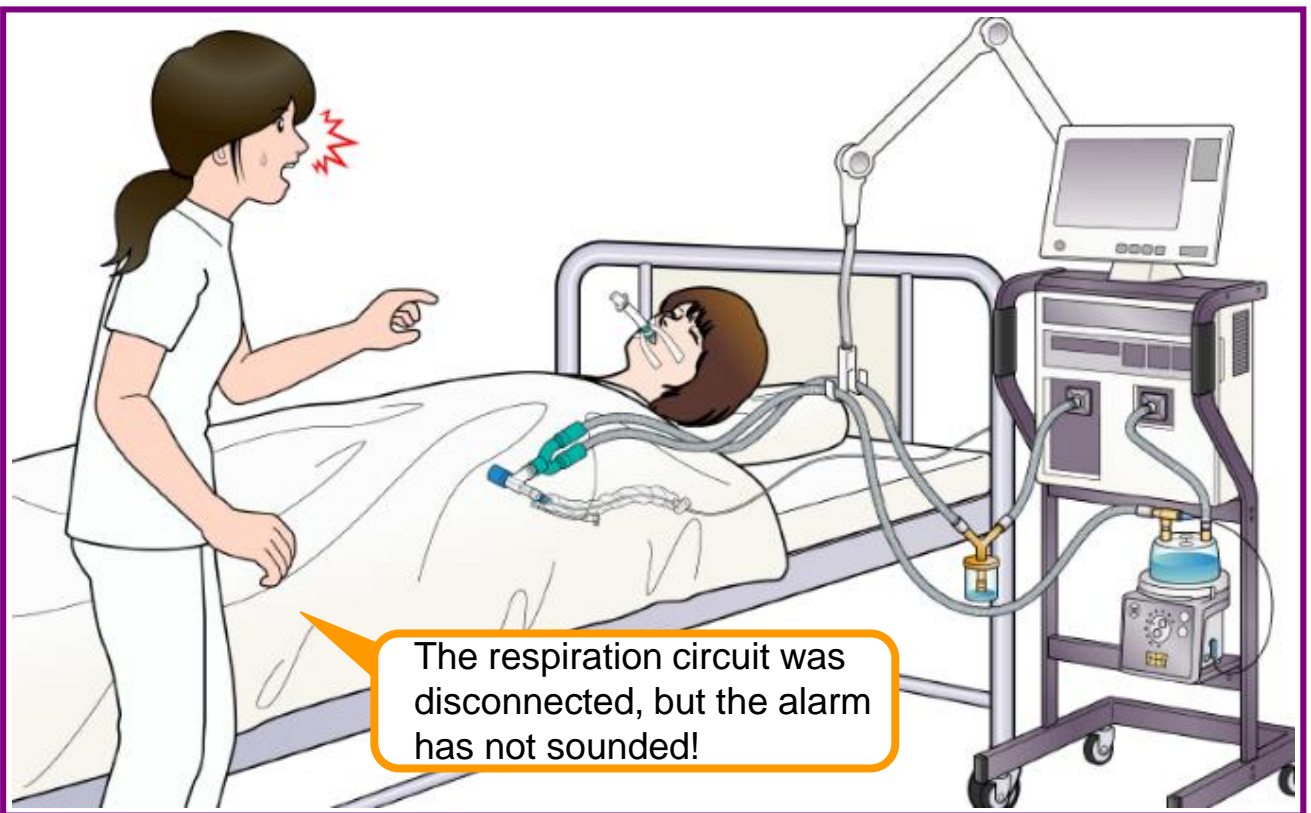
Precautions for the Pre-operational Check Prior to the Use of Ventilators

POINT Key points for safe use

(Case) When using a closed bronchial suction catheter connected between the ventilator circuit and the intubation cannula, the respiration circuit was disconnected, but an audible alarm did not sound.

1 Points to be considered when using closed bronchial suction catheters

- Before using a ventilator, confirm that an audio alarm is triggered if the circuit is disconnected.



There are products that can be connected to respiration circuits other than closed bronchial suction catheters. **See the next page for details!**

2 Precautions for products that can be connected to respiration circuits

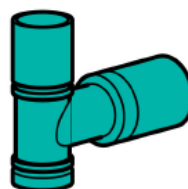
- Check in advance because an audio alert may not be triggered when a product not designated as a medical device to be used with the specific ventilator by marketing authorization holders is connected.

Examples of products that can be connected to respiration circuits

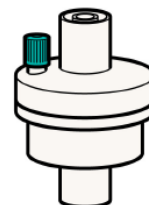
Does this combination trigger an appropriate alarm?



Elbow connector



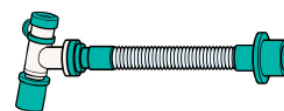
Heat and moisture exchanger



Closed bronchial suction catheter



Catheter mount



An example of confirmation procedures before connecting the unit to the patient



Assemble respiration circuits



Start ventilator operation



Remove the test lung



An audio alarm is triggered.




Before use with a patient, make sure to verify that **an audio alert for connection failure is triggered** with all the respiration circuits and connectable products connected.

3 The necessity of using medical monitors with an alert function and alert settings


- Considering the patient's respiratory status, use a medical monitor with an alert function and appropriate alarm settings.

Necessity of appropriate alert settings

What should be the alarm threshold of the pulse oximeter?

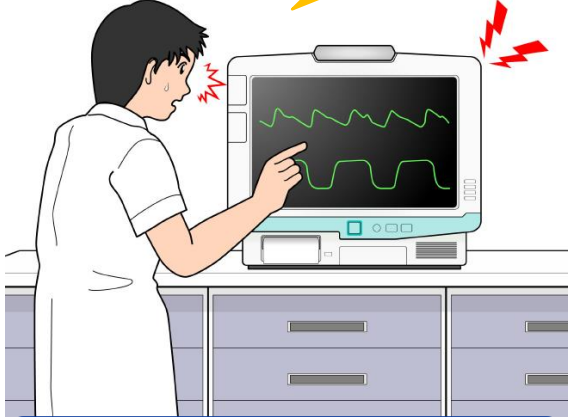


It is important for the team to discuss the alert settings, volume, etc., according to the patient's respiratory status.




Early detection of alerts

The patient's SpO₂ is falling.



Continuously monitoring a patient's condition enables rapid response of healthcare providers in the case of abnormalities.



◆ Package inserts of ventilators, etc. state the following.

The Important Precautions section, under the Precautions of the package insert

- If it is necessary to connect a product that is not designated to be connected to this device, before connecting the unit to the patient, always make sure that the alarm is triggered when the circuit is disconnected with all parts connected.
- Continuously monitor the percutaneous arterial oxygen saturation (SpO₂) or end-tidal carbon dioxide partial pressure (concentration) (EtCO₂) using medical monitors with an alarm function, depending on the use of this device.

The Ministry of Health, Labour and Welfare (MHLW) issued notification related to PMDA Medical Safety Information No. 63

- PSEHB/MDED Notification No. 1221-1, PSEHB/PSD Notification No. 1221-1 dated on December 21, 2020 Self-inspection, etc. of Ventilators concerning Products Used in Combination with Them

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.
- * 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.

Access to the most up-to-date safety information is provided via the PMDA Medi-navi service.

