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To: Commissioners of Prefectural Health Departments (Bureaus)

Director of Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare
(Official seal omitted)
Director of Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare
(Official seal omitted)

Self-inspection, etc. of Ventilators concerning Products Used in Combination with Them

Precautions for proper use of ventilators have been in place by the MSB Notification No. 248 Preventive Measures for Medical Accidents Associated with a Ventilator, which Is a Life-supporting Device, dated March 27, 2001 as well as the package inserts and instruction manuals prepared by the marketing authorization holders (MAHs).

Recently, when a closed bronchial suction catheter was connected between the circuit of the ventilator and the cannula to aspirate sputum in intubated patients, there was a case in which an alarm to notify the disconnection was not triggered when a leak occurred due to the disconnection between the bronchial suction catheter and the cannula. In this case, the bronchial suction catheter, which was not designated by the MAH of the ventilator as a medical device to be used in combination with the ventilator, was used. There may be situations in which a medical device not designated for specific uses has to be used due to lack of alternatives in clinical practice.

If the alarm is not triggered, medical personnel may not be able to detect the disconnection of the breathing circuit at an early stage, which may cause a serious health hazard to the patient due to dyspnoea, etc.

Commissioners of prefectural health departments or bureaus are requested to instruct the MAHs of ventilators under their jurisdiction to conduct a self-inspection, etc. of their products as shown below.

Of note, this notification has been informed to the professional organizations, the Pharmaceuticals and Medical Devices Agency (PMDA), and MAHs of ventilators.

1. Scope of this Notification

Ventilators and bilevel positive airway pressure units (hereinafter referred to as

"Ventilators, etc.)

2. Precaution regarding an inspection before use

The MAHs of Ventilators, etc. should confirm that the package inserts of their Ventilators, etc. contain a statement that it is critical to make sure before use that an audio alarm is triggered if the circuit is disconnected when using a product not designated by them (elbow connector, catheter mount, closed bronchial suction catheter, heat and moisture exchanger (HME), etc.) to connect the product comprising the respiration circuit with Ventilators, etc. If such a statement is not contained, the following language should be added to 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 in a state where all parts are connected.
- Continuously monitor the percutaneous arterial oxygen saturation (SpO2) or end-tidal carbon dioxide partial pressure (concentration) (EtCO2) with a physiological information monitoring system with an alarm function, depending on the use of this device.

3. Precaution regarding alarm operation

MAHs who have identified a combination of their own Ventilators, etc. and products that are highly likely to be connected with them in which the audio alarm is not triggered to detect a disconnection that may occur when connected with each other should promptly provide relevant information to the users.

4. Reporting self-inspection results

Responses to the instructions described in 2., above should be reported by January 31, 2021, or any combinations mentioned in 3., promptly when such combinations have been identified, to the Division of Safety for Medical Devices, Office of Manufacturing Quality and Vigilance for Medical Devices, PMDA.

5. Products under approval review

Regarding a ventilator under approval review, the applicant is required to inform the reviewer of the product at PMDA of its intention to make the addition to the package insert required in 2., and 3., above.