

Criteria for ventilator alarm

(July 30, 2001)

(MHLW Ministerial Announcement No. 264)

In accordance with provisions in Article 42, Paragraph 2 of the Pharmaceutical Affairs Act (Act No. 145 of 1960, hereinafter referred to as "Act"), the criteria for ventilator alarm shall be established as follows and applied from August 1, 2001. To ventilators pertaining to the permission actually granted on the said date under Article 12, Paragraph 1, Article 18, Paragraph 1 (including the cases where it is applied mutatis mutandis pursuant to Article 23 of the Act) or Article 22, Paragraph 1 of the Act, the provisions then in force shall remain applicable until July 31, 2002.

Criteria for ventilator alarm

1 Definition

- 1 A ventilator is a respiratory assist device that is intended to maintain human life and to operate artificial respiration by supplying air or a gas mixture containing oxygen as the main component into the lungs through the oral cavity, nasal cavity or air way, or other means, or to assist spontaneous respiration by continuously keeping only the air way under positive pressure.
- 2 A resuscitator is a ventilator that is designed to operate artificial respiration to save the life of a critically ill patient only in an emergency case.
- 3 An extracorporeal ventilator is a ventilator that is designed to operate artificial respiration by dilating the thorax under positive pressure against the extracorporeal environment.

2 Criteria

Ventilators (except for ventilators that assist spontaneous respiration by continuously keeping only the air way under positive pressure and resuscitators that are operated manually or by gas pressure) must conform to the following criteria. To extracorporeal ventilators and electrically operated resuscitators, the provisions in (1) to (3) shall not be applied; to ventilators used only for anesthesia, one in (2) shall not; and to ventilators operated by gas pressure, one in (4) shall not.

- (1) The ventilator shall issue a sound alarm in response to removal of the breathing circuit.
- (2) The ventilator shall have a function whereby a sound alarm is automatically issued within 2 minutes after temporarily muting the previous alarm that has been issued in response to removal of the breathing circuit.
- (3) The ventilator shall have a function whereby the sound alarm issued in response to removal of the breathing circuit cannot be stopped except for temporary muting.
- (4) The ventilator shall issue a sound alarm in response to power failure.
- (5) The switch to operate the main unit shall have such a structure or function that it is not readily turned off by contact, etc.