This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

14 April 1993 MS)

DRAFT EMERGENCY RESUSCITATOR GUIDANCE

868.5915 Manual Emergency Ventilator (Resuscitator) BTM
868.5925 Powered Emergency Ventilator (Resuscitator) BTL

A. GENERAL DEVICE DESCRIPTION

1) Manual (Operator Powered) Resuscitator

   a) Adult
   b) Pediatric
   c) Infant

2) Gas Powered Resuscitator

   a) Adult
   b) Pediatric
   c) Infant

B. DEVICE LABELING (Information to be provided by the manufacturer in the operating instructions for all types and sizes of resuscitators.)

*NOTE: Items 1, 2, 3, and 4 below should also be clearly labeled on the device itself or its packaging when applicable.

1) a persons who have received adequate training;

2) a warning regarding the hazards of using positive end-expiratory pressure (PEEP) if integral to the resuscitator;

3) a statement requiring the use of a manometer with the resuscitator if no pressure-limiting system (pop-off valve is encorporated in the device;

4) a statement requiring the use of a manometer to verify PEEP levels if integral to the resuscitator;

5) instructions on how to make the resuscitator operational in all intended modes of operation;

6) a list of device specifications including the following:

   a) the body mass range for which the resuscitator is suitable for use,
   b) range of ventilatory frequency,
   c) attainable delivery pressures,
   d) operating environmental limits,
   e) storage environmental limits,

f) delivered oxygen concentrations under various test conditions,
g) characteristics and/or dimensions of the gas inlet connection (the standard 15 mm x 22 mm fitting is recommended),
h) stroke-volume range for operator-powered resuscitators,
i) apparatus deadspace,
j) forward and backward leakage (where applicable),
k) expiratory and inspiratory resistance,
l) the amount of end-expiratory pressure generated by the resuscitator in normal use,
m) external dimensions of the resuscitator
n) mass of the resuscitator

C. ENVIRONMENTAL TESTING (for all resuscitator types and sizes)

1) Extreme Temperature and Humidity storage[1]

The resuscitator shall be operational, meeting all device specifications, after storage at temperatures of -40 and +60 degrees Celsius and at any relative humidity between 40 % and 95 % relative humidity.

2) Extreme Temperature and Humidity operation[1]

The resuscitator shall be operational, meeting all device specifications, throughout the temperature range from -18 to 50 degrees Celsius and a humidity range from 40 % to 90 % r.h.

3) Mechanical Shock[1]

For hand-carried resuscitators, it shall meet the performance requirements after a 1 meter drop onto a concrete floor.

For castor-mounted or wheeled resuscitatorq, it shall meet the performance requirements after being tipped over from its normal operating position onto a concrete floor.

4) Valve Function After Contamination with Vomitus[1]

When disabled by vomitus, the valve shall be capable of being restored to proper function within 20 seconds.

The effects of vomitus can be simulated by using a mixture of two parts baby food beef with vegetables and one part water. The total volume of this mixture should be 175 mL. This mixture should then be poured into the resuscitator at 30 breaths per minute for infant models and 12 breaths per minute for adult and child models for 30 seconds.

D. PERFORMANCE REQUIREMENTS

1) All Resuscitators

a) Expiratory Resistance[2]
In the absence of positive end-expiratory devices, the pressure generated at the patient connection port shall not exceed approximately 5 cmH_2O.

The expiratory resistance should be measured by introducing an air flow rate of 5 l/min for resuscitators suitable for use with patients with a body mass of up to 10 kg and an air flow of 50 l/min for all other resuscitators.

b) Inspiratory Resistance[2]
The pressure at the patient connection port shall not exceed approximately 5 cmH_2O below atmospheric pressure.

The expiratory resistance should be measured by connecting a vacuum source to the patient connection of the resuscitator. For resuscitators suitable for use with patients with a body mass of up to 10 kg, the vacuum source should produce an air flow of 5 l/min and 50 l/min for all other resuscitators.

c) Deadspace[1]
The deadspace of the resuscitator excluding the facemask shall not exceed 30 mL in equipment intended for use with adults, 15 mL in equipment intended for use with children, and 7 mL in equipment intended for use with infants.

d) All bag-valve resuscitators should have a self refilling bag that is easily cleaned and sterilized.[3]

e) All resuscitators should have a true bonrebreathing valve.[3]

2) Manual(Operator Powered) Resuscitators

a) Adult

(1) Frequency of ventilation[1]
The required tidal volume shall be achieved at a frequency of no less than 20 breaths per minute, and the length of inspiration shall not exceed the length of expiration.

(2) Delivered Oxygen concentration[1]
The resuscitator shall be capable, when an oxygen source is available, of delivering an inspired oxygen concentration of at least 40 % and with an attachment made available by the manufacturer, shall be capable of delivering at least 85 %.

(3) Tidal volume[1]
The resuscitator shall be capable of delivering no less than 600 mL into a test lung with a compliance of 0.02 L/cm/H_2O and a resistance of 20 cm H_2O/L/s.

(4) Pressure Limiting System(Pop-Off Valve)[1],3
ASTM F920 does not require a pressure-limiting system for adult operator-powered resuscitators. If a pressure-

limiting system is provided, it shall be capable of being readily overridden by the user according to the manufacturer's recommendations.

The Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiac Care published in JAMA, October 29, 1992 recommends against the use of pop-off valves in resuscitators suitable for use on adults.

(5) Resuscitator Valve Performance
The resuscitator shall be capable of flows up to 30 L/min without valve malfunction.

b) Pediatric

(1) Frequency of Ventilation[1]
The resuscitator shall be capable of delivering 30 breaths per minute at a tidal volume of 70 mL and 20 breaths per minute at a tidal volume of 300 mL. The length of inspiration shall not exceed the length of expiration.

(2) Delivered Oxygen concentration[1]
Resuscitators shall be capable, with an oxygen source, of 85 % oxygen concentration when the resuscitator is operated with a tidal volume of 70 mL at a frequency of 30 breaths per minute, with oxygen flows not exceeding 15 L/min.

(3) Tidal Volumes[1]
Resuscitators for use with children shall be capable of delivering a range of tidal volumes between 70 and 300 mL.

(4) Pressure-Limiting System[1,3]
The ASTM F 920 standard states that pressure-limiting systems for children's operator-powered resuscitators are mandatory and shall have an opening pressure of 40 cm H_2O + or - 10 cm H_2O. The standard further indicates that this pressure should not be exceeded under conditions of ventilation, but that an override mechanism may be provided. This override mechanism shall be so designed that its operating mode is readily apparent to the user.

The Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiac Care published in JAMA, October 28, 1992, recommend that ventilation bags used for resuscitation should have no pop-off valve. These guidelines further recommend that if a pop-off valve is present, it should be bypassed since pressures required for adequate ventilation during CPR may have to exceed pop-off limits. This is especially true during bag-mask ventilation of patients with poor lung compliance. In these patients the pop-off valve may prevent delivery of sufficient tidal volume.

(c) Infant

(1) Frequency of ventilation[1]
The resuscitator shall be capable of delivering ***60*** breaths per minute at a ***20*** **mL** tidal volume and ***40*** breaths per minute at a ***70*** **mL** tidal volume. The length of inspiration shall not exceed the length of expiration.

(2) Delivered Oxygen concentration[1]
Infant resuscitators shall be capable, with an oxygen source, of delivering from **21** % to **85** % oxygen when the resuscitator is operated with a tidal volume of **20** **mL** at a frequency of ***60*** breaths per minute with an input oxygen flow not to exceed 15 **L/min.**

(3) Tidal Volumes[1]
Resuscitators for use with infants shall be capable of delivering tidal volumes in a range between **20** and ***70*** **mL.** These devices shall be capable of delivering at least ***20*** **mL** tidal volume at ***60*** breaths per minute and a 70 **mL** tidal volume at **30** breaths per minute.

(4) **Pressure-Limiting System[1,3]**
ASTM ***F 920*** states that pressure-limiting systems for infant operator-powered resuscitators are mandatory and shall bave an opening pressure of ***40*** cm H_2O + or - 5 cm H_2O. The standard further indicates that this pressure shall not be exceeded under conditions of ventilation, but that an override mechanism may be provided. The override system shall be so designed that its operating mode is readily apparent to the user. ASTM F **920** further indicates that the override mechanism shall be capable of withstanding pressures up to ***70*** cm H_2O with a forward leak of less than 10 % of the delivered volumes.

3) Gas-Powered Resuscitators

a) Adult

(1) Pressure-Limiting system[1]
A pressure-limiting system shall be incorporated in **gas-**powered resuscitators such that airway pressure does not exceed 60 cm H_2O. An override mechanism shall be provided to enable the operator to select a higher pressure. However, automatic, pressure-cycled, gas-powered resuscitators shall not be equipped with any type of override mechanism.

(2) Delivered Oxygen **Concentration[1,2]**
ASTM ***F920*** and **ISO 8382** recommends that gas-powered resuscitators shall be capable of delivering at least **85** % oxygen. However, predicate devices exist that deliver oxygen concentrations between ***60*** **- 75** % in order to extend the **useable** life of the oxygen cylinder.

(3) Manually Triggered, Manually Cycled Gas-Powered

Resuscitators[1]

(a) Maximum Delivery Pressure
The maximum delivery pressure shall not exceed 55 cm H_2O over the range of supply pressures.

(b) Flow Capability
These resuscitators shall have a flow capability of at least 100 L/min at 20 cm H_2O and flows at 40 cm H_2O shall be stated in the labeling.

In addition, these resuscitators shall comply with the above mentioned tidal volume and frequency of ventilation requirements for adult operator-powered resuscitators.

(4) Automatic Time-Cycled, Gas-Powered Resuscitators

These resuscitators shall comply with the above mentioned tidal volume, frequency of ventilation, and delivered oxygen concentration requirements for adult operator-powered resuscitators.

(5) Volume-Cycled Resuscitators

These resuscitators shall be capable of delivering a tidal volume of 600 mL/cm H_2O at a frequency of 12 breaths per min. In addition, these resuscitators shall comply with the above mentioned requirements for adult gas-powered resuscitators.

(6) Time-Cycled Resuscitators

These resuscitators shall be capable of delivering a tidal volume of 600 mL at a frequency of 12 breaths per minute. In addition, these resuscitators shall comply with the above mentioned requirements for adult gas-powered resuscitators.

b) Child

(1) Pressure-Limiting system[1]
The pressure-limiting system for these resuscitators shall preclude airway pressures greater than 45 cm H_2O.

(2) Peak Flow[1]
These resuscitators shall be capable of peak flows of at least 18 L/min.

(3) Delivered Oxygen Concentration[1,2]
ASTM F920 and ISO 8382 recommends that gas-powered resuscitators shall be capable of delivering at least 85 % oxygen. However, predicate devices exist that deliver oxygen concentrations between 60 - 75 % in order to extend the useable life of the oxygen cylinder.

(4) Volume-Cycled Resuscitators
These resuscitators shall be capable of delivering a tidal volume throughout the range from **70** to **300** mL at a respiratory frequency in the range from **20** to **30** breaths per minute. In addition, these resuscitators shall comply with the above mentioned requirements for child gas-powered resuscitators.

(5) Time-Cycled Resuscitators
These resuscitators shall be capable of delivering a tidal volume throughout the range from **70** to **300** mL at a respiratory frequency in the range from **20** to **30** breaths per minute. In addition, these resuscitators shall comply with the above mentioned requirements for child gas-powered resuscitators.

c) Infant

(1) Pressure-Limiting System
The pressure-limiting system for these resuscitators shall preclude airway pressures greater than 45 cm H_2O.

(2) Peak Flow
These resuscitators shall be capable of a peak flow of at least 7 **L/min.**

(3) Delivered Oxygen **Concentration**[1,2]
ASTM F920 and **ISO 8382** recommends that gas-powered resuscitators shall be capable of delivering at least 85 % oxygen. However, predicate devices exist that deliver oxygen concentrations between **60** - 75 % in order to extend the **useable** life of the oxygen cylinder.

(4) Volume-Cycled Resuscitators
In addition to complying with the above requirements for infant gas-powered resuscitators, **these** devices shall be capable of delivering tidal volumes between 12 and **70** mL at **30** breaths per minute.

(5) Time-Cycled Resuscitators
In addition to complying with the above requirements for infant gas-powered resuscitators, these device shall allow a ventilatory rate of **60** breaths per minute at a tidal volume of **20** mL.

[1] Standard Specification for Minimum Performance and Safety Requirements for Resuscitators Intended for Use with Humans, ASTM F 920-85.

[2] International Standard on Resuscitators Intended for Use with Humans, ISO 8382, 1988.

[3] Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiac

Care, JAMA, **Oct.** 28, 1992 - **Vol.** 268, **No. 16.**