



Standard Specification for Minimum Performance and Safety Requirements for Resuscitators Intended for Use With Humans¹

This standard is issued under the fixed designation F 920; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

This standard has been approved for use by agencies of the Department of Defense.

INTRODUCTION

In January of 1989, ASTM Subcommittee F29.03.03 met in Boston with representatives of the American Heart Association and the U.S. Department of Defense to discuss the revision of this specification. It was unanimously determined that until a revised version of this specification that would be consistent with the American Heart Association's revised Standards and Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiac Care was available, ISO 8382-1988, should be used as the specific reference for manually-triggered gas-powered resuscitators. Shortly thereafter, the Subcommittee Chairman published a letter to this effect in the *Journal of the American Medical Association*.² The Subcommittee reaffirmed this stance at a subsequent meeting in March of 1990. This specification is therefore similar in content to ISO 8382.

1. Scope

1.1 This specification covers ventilatory resuscitators, that is, small portable ventilators intended to be used in emergencies both outside and inside hospitals. These devices are intended for use by medical personnel and for emergency use by personnel with varying degrees of training. They are intended to be used at the site of an emergency and during patient transport. Resuscitators intended for use on all age groups are included within the scope of this specification.

1.1.1 This specification does not intend to discourage or impede future innovation or development of resuscitators.

1.2 The effective and safe use of a resuscitator is determined not only by the performance of the resuscitator, but also by the skill of the operator. This specification does not describe the content of the training programs to develop such skill and does not state who should or should not use a resuscitator. This will be determined by the organizations involved in teaching resuscitation.

1.2.1 In certain countries, resuscitators are intended for use by nontrained personnel and lower pressure limits are set.

Some countries also reserve the use of automatic gas-powered resuscitators to trained individuals under medical supervision. This specification is not intended to conflict with these established practices.

1.3 Annex A1 details test methods, while Annex A2 provides tables of resistances and compliances required to set up the test lung. Annex A3 gives a rationale for various clauses in this specification and is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been given. Annex A4 and Annex A5 provide advice concerning materials to be used in resuscitators and face masks.

1.4 The values stated in SI units are to be regarded as the standard.

1.5 *This standard does not purport to address all of the safety problems, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 The following standards contain provisions that, through reference in this text, constitute provisions of this specification. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this specification are encouraged to investigate the possibility of applying the most recent editions of the standards listed below.

¹ This specification is under the jurisdiction of ASTM Committee F29 on Anesthetic and Respiratory Equipment and is the direct responsibility of Subcommittee F29.14 on Ventilators.

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² American Heart Association, "Standards and Guidelines for Cardiopulmonary Resuscitation (CPR) and Emergency Cardiac Care (ECC)," *Journal of the American Medical Association*, Vol 255, No. 21, June 6, 1986, pp. 2905-2984.

