ISO/TR 21954:2018-07 (E)

Guidance on the selection of the appropriate means of ventilation based on the intended patient, use environment, and operator

Contents

Page

Foreword v

Introduction vi

1 * Scope 1

2 Normative references 1

3 Termsanddefinitions 1

4 * Applications of means of ventilation 12
4.1 Critical care ventilator 12
4.1.1 Appropriate standard 12
4.1.2 Intended patient 12
4.1.3 Use environment 12
4.1.4 Intended operator 13
4.2 Ventilator for a ventilator-dependent patient in the home healthcare environment 13
4.2.1 Appropriate standard 13
4.2.2 Intended patient 13
4.2.3 Use environment 14
4.2.4 Intended operator 14
4.3 Ventilator for the emergency medical services environment 14
4.3.1 Appropriate standard 14
4.3.2 Intended patient 14
4.3.3 Use environment 15
4.3.4 Intended operator 15
4.4 Home healthcare environment ventilator for a patient with ventilatory insufficiency 15
4.4.1 Appropriate standard 15
4.4.2 Intended patient 15
4.4.3 Use environment 16
4.4.4 Intended operator 16
4.5 Home healthcare environment ventilator for a patient with ventilatory impairment 16
4.5.1 Appropriate standard 16
4.5.2 Intended patient 16
4.5.3 Use environment 17
4.5.4 Intended operator 17
4.6 Gas-powered emergency resuscitators 17
4.6.1 Appropriate standard 17
4.6.2 Intended patient 18
4.6.3 Use environment 18
4.6.4 Intended operator 18
4.7 Operator-powered resuscitators 18
4.7.1 Appropriate standard 18
4.7.2 Intended patient 18
4.7.3 Use environment 18
4.7.4 Intended operator 18
4.8 Sleep apnoea breathing therapy equipment 18
4.8.1 Appropriate standard 18
4.8.2 Intended patient 18
4.8.3 Use environment 19
4.8.4 Intended operator 19

Annex A (informative) Rationale and guidance 20

Annex B (informative) Comparison of the most important environmental characteristics 22

Annex C (informative) Applicable standard for the useenvironment 25

Annex D (informative) Comparison of the appropriate product standard to the intended patient, useenvironment and operator 27

Annex E (informative) Comparison of the categories of patient acuity to the appropriate product standard 29

Annex F (informative) Comparison of respiratory standards technical requirements 32

Annex G (informative)Terminology--Alphabetizedindexofdefinedterms 37

Bibliography 39