

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 | Terms and definitions | 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 |