ISO 16571:2024-03 (E)

Systems fo revacuation of plume generated by medical devices

Contents

Page

Foreword ... iv

Introduction ... v

1 Scope ... 1

2 Normative references ... 2

3 Terms and definitions ... 2

4 General requirements ... 7
- 4.1 Components ... 7
- 4.2 Systems ... 7
- 4.3 Capture device ... 8
- 4.4 Transfer tubing ... 9
- 4.5 Filtration subsystem ... 9
- 4.6 Control subsystem ... 9
- 4.7 Flow-generator ... 9
- 4.8 Exhaust subsystem ... 10
- 4.9 Colour coding ... 10

5 Portable and mobile system requirements ... 10
- 5.1 General requirements ... 10
- 5.2 Acoustic noise test ... 10
- 5.3 Ingress protection ... 12

6 Stationary and pipeline system requirements ... 12
- 6.1 Stationary plume evacuation systems ... 12
- 6.2 Design ... 12
- 6.3 Flow-generators ... 13
- 6.4 Exhausts ... 13
- 6.5 Flow-generator controls ... 13
- 6.6 Pipeline ... 14
- 6.7 Terminal units ... 14
- 6.8 Commissioning and testing ... 14

7 Endoscopic and laparoscopic system requirements ... 15
- 7.1 Active PESs ... 15
- 7.2 Passive PESs ... 15

Annex A (informative) **Rationale** ... 17

Annex B (informative) **Plume evacuation system implementation** ... 20

Annex C (normative) **Plume removal efficiency test method** ... 23

Annex D (normative) **Colour coding** ... 29

Annex E (normative) **Information to be supplied to the healthcare facility** ... 32

Annex F (informative) **Acoustic testing muffler design** ... 35

Bibliography ... 37