

# ISO 80601-2-80:2024-08 (E)

## Medical electrical equipment - Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency

---

<b>Contents</b>	<b>Page</b>
Foreword .....	v
Introduction .....	vii
201.1 Scope, object and related standards .....	1
201.2 Normative references .....	4
201.3 Terms and definitions .....	5
201.4 General requirements .....	24
201.5 General requirements for testing of ME equipment .....	28
201.6 Classification of ME equipment and ME systems .....	29
201.7 ME equipment identification, marking and documents .....	29
201.8 Protection against electrical hazards from ME equipment .....	37
201.9 Protection against mechanical hazards of ME equipment and ME systems .....	37
201.10 Protection against unwanted and excessive radiation hazards .....	39
201.11 Protection against excessive temperatures and other hazards .....	39
201.12 Accuracy of controls and instruments and protection against hazardous outputs .....	43
201.13 Hazardous situations and fault conditions for ME equipment .....	55
201.14 Programmable electrical medical systems (PEMS) .....	56
201.15 Construction of ME equipment .....	57
201.16 ME systems .....	58
201.17 Electromagnetic compatibility of ME equipment and ME systems .....	58
201.101 Gas connections .....	59
201.102 Requirements for the VBS and accessories .....	62
201.103 Spontaneous breathing during loss of power supply .....	63
201.104 Indication of duration of operation .....	64
201.105 Functional connection .....	64
201.106 Display loops .....	65
201.107 Ventilatory support equipment security .....	65
202 Electromagnetic disturbances -- Requirements and tests .....	66
206 Usability .....	67
208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems .....	69
211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment .....	71
Annex C (informative) Guide to marking and labelling requirements for ME equipment and ME systems .....	72
Annex D (informative) Symbols on marking .....	79
Annex AA (informative) Particular guidance and rationale .....	81
Annex BB (informative) Data interface requirements .....	102
Annex CC (informative) Reference to the IMDRF essential principles and labelling guidances .....	109
Bibliography .....	113
Terminology -- Alphabetized index of defined terms .....	116