

DIN EN ISO 10079-1:2019-06 (E)

Medical suction equipment - Part 1: Electrically powered suction equipment (ISO 10079-1:2015 + Amd 1:2018) (includes Amendment A1:201 9)

Contents

Page

European foreword	4
European foreword to Amendment A1	5
Anhang ZA (informative) Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered	6
Foreword	9
Foreword to Amendment 1	10
1 Scope	11
2 Normative references	11
3 Terms and definitions	12
4 General requirements	14
4.1 Risk management	14
4.2 Usability	15
4.3 Clinical investigation	15
4.4 Biophysical or modelling research	15
4.5 Test methods	15
5 Cleaning, disinfection and sterilization	15
6 Design requirements	16
6.1 Collection container	16
6.1.1 General	16
6.1.2 Container capacity	16
6.1.3 Container strength	16
6.2 Connections	16
6.2.1 Tubing connectors for collection containers	16
6.2.2 Inlet port	17
6.2.3 Exhaust port	17
6.3 Suction tubing	17
6.4 Vacuum level indicators	17
6.5 Spillage on electrical suction equipment	18
7 Operational requirements	18
7.1 Ease of operation	18
7.2 Dismantling and reassembly	18
7.3 Mechanical shock	18
7.4 Stability	18
7.5 Protective devices	19
7.5.1 Contamination protection	19
7.5.2 Overfill protection devices	19
7.5.3 Pressure protection	19
7.6 Noise	19
7.6.1 Low vacuum/low flowrate equipment	19
7.6.2 Suction equipment other than that specified in 7.6.1	19

7.7	Air leakage	20
7.7.1	Collection containers for general use	20
7.7.2	Collection containers for thoracic drainage	20
8	Physical requirements for suction equipment for field use	20
8.1	(*) Dimensions	20
8.2	Mass	20
9	Performance requirements for vacuum level and flowrate	20
9.1	High vacuum/high flowrate equipment	20
9.2	Medium vacuum equipment	21
9.3	Low vacuum/low flowrate equipment	21
9.4	Low vacuum/high flowrate equipment	21
9.5	Thoracic drainage equipment for adults	21
9.6	Intermittent vacuum equipment	21
9.7	Vacuum regulators with fixed setting	21
9.8	Vacuum regulators with variable setting	22
9.9	Equipment intended for pharyngeal suction	22
9.10	Battery powered transportable suction equipment	22
9.11	Interruption of the power supply	22
10	(*) Resistance to environment of suction equipment for field and/or transport use	22
10.1	Operating conditions	22
10.2	Storage	22
11	Information to be supplied by the manufacturer (labelling and instructions for use)	23
11.1	Information supplied by the manufacturer shall comply with EN 1041	23
11.3	Labelling of equipment	23
11.4	Instructions for use	24
Annex A	(normative) Test methods	26
Annex B	(informative) Rationale statement	37
Annex C	(informative) Lumen size and its effect on flowrate	38
Annex D	(informative) Schematic of suction equipment	39
Bibliography		40