

DIN EN ISO 10079-3:2014-09 (E)

Medical suction equipment - Part 3: Suction equipment powered from a vacuum or positive pressure gas source (ISO 10079-3:2014)

Contents		Page
Foreword		4
1	Scope	5
2	Normative references	5
3	Terms and definitions	6
4	General requirements	8
4.1	Risk management	8
4.2	Usability	9
4.3	Clinical investigation	9
4.4	Biophysical or modelling research	10
5	Cleaning, disinfection and sterilization	10
6	Design requirements	10
6.1	Collection container	10
6.2	Connections	11
6.3	Suction tubing	11
6.4	Vacuum level indicators	11
6.5	Supply connections	12
7	Operational requirements	12
7.1	Ease of operation	12
7.2	Dismantling and reassembly	12
7.3	Mechanical shock	12
7.4	Stability	13
7.5	Protective devices	13
7.6	Noise	13
7.7	Air leakage	14
8	Physical requirements for field and transport use suction equipment	14
8.1	(*)Dimensions	14
8.2	Mass	14
9	Performance requirements for vacuum level and flow rate	15
9.1	High vacuum/high flow rate equipment	15
9.2	Medium vacuum equipment	15
9.3	Low vacuum/low flow rate equipment	15
9.4	Low vacuum/high flow rate equipment	15
9.5	Thoracic drainage equipment for adults	15
9.6	Intermittent vacuum equipment	16
9.7	Vacuum regulators with fixed setting	16
9.8	Vacuum regulators with variable setting	16
9.9	Equipment intended for pharyngeal suction	16
10	(*)Resistance to environment of suction equipment for field and/or transport use	16
10.1	Operating conditions	16
10.2	Storage	16

11	Marking	16
11.1	Use of symbols	16
11.2	Equipment	17
11.3	Equipment or carrying case	18
12	Information to be supplied by the manufacturer	18
	Annex D (informative) Schematic of suction equipment	33
	Bibliography	36
	Annex A (normative) Test methods	20
	Annex B (informative) Rationale statement	31
	Annex C (informative) Lumensizeanditseffectonflowrate	32
ZAnnex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC		34