

# ISO 20789:2018 (E)

## Anaesthetic and respiratory equipment — Passive humidifiers

---

### Contents

	Foreword
	Introduction
1	* Scope
2	Normative references
3	Terms and definitions
4	General requirements for testing
4.1	Water level
4.2	Passive humidifier test conditions
4.3	* Gas flowrate and leakage specifications
4.4	* Passive humidifier testing errors
5	General requirements
5.1	Mechanical basic safety for all passive humidifiers
5.1.1	General
5.1.2	* Requirements for instability from unwanted lateral movement
5.1.3	* Requirements for audible acoustic energy
5.1.4	* Overflow
5.1.5	* Overpressure requirement
5.2	Compatibility requirement
5.3	General requirements for mechanical strength
6	Identification, marking and accompanying documentation
6.1	Legibility and durability of markings
6.1.1	Legibility
6.1.2	Durability
6.2	Markings on the outside of the passive humidifier or its parts
6.2.1	Identification
6.2.2	Additional requirements
6.2.3	Requirements for physiological effects
6.2.4	Requirements for packaging
6.2.5	Symbols
6.3	Units of measurement
6.4	Instructions for use
6.4.1	Identification
6.4.2	General requirements
6.4.3	* Requirements for warnings and safety notices
6.4.4	Requirements for installation
6.4.5	Requirements for start-up procedure
6.4.6	* Requirements for operating instructions
6.4.7	Requirements for cleaning, disinfection, and sterilization
6.4.8	Requirements for maintenance
6.4.9	Requirements for accessories, supplementary equipment and used material
6.4.10	Unique version identifier
6.5	Technical description
7	* Humidification output
8	Systems requirements

- 9           **Specific single fault conditions**
- 10          \* **Cleaning and disinfection**
  - 10.1        **General**
  - 10.2        **Home healthcare environment**
- 11          \* **Breathing system connectors and ports**
  - 11.1        **General**
  - 11.2        **Outlet connector**
  - 11.2.1      **Directly connected to the supply source**
  - 11.2.2      **Indirectly connected to the supply source**
  - 11.3        **Flow-direction-sensitive components**
  - 11.4        \* **Accessory port**
  - 11.5        **Monitoring probe port**
  - 11.6        **Oxygen inlet port**
    - 11.6.1      **Directly connected to the supply source**
    - 11.6.2      **Indirectly connected to the supply source**
  - 11.7        **Air inlet port**
    - 11.7.1      **Directly connected to the supply source**
    - 11.7.2      **Indirectly connected to the supply source**
  - 11.8        **Filling port**
- 12          \* **Requirements for the breathing system and accessories**
  - 12.1        **General**
  - 12.2        **Accompanying documentation**
  - 12.3        **Breathing tubes**
  - 12.4        **Liquid container level**
  - 12.5        **Filling cap**
- 13          **Compatibility with substances**
- 14          \* **Biocompatibility**
- 15          \* **Requirements for fire prevention**
- 16          **Usability**
- Annex A (informative) Rationale and guidance**
  - A.1        **General guidance**
  - A.2        **Rationale for particular clauses and subclauses**
- Annex B (informative) Symbols on marking**
- Annex C (normative) Determination of humidification output**
  - C.1        **General**
  - C.2        **Principle**
  - C.3        **Test conditions**
  - C.4        **Apparatus**
  - C.5        **Procedure**
- Annex D (informative) Reference to the essential principles**
- Annex E (informative) Terminology — Alphabetized index of defined terms**