

# DIN EN ISO 23747:2015-12 (E)

Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans (ISO 23747:2015)

---

## Contents

Page

|  |    |
|--|----|
| European foreword.....   | 3  |
| Introduction.....  | 4  |
| 1 Scope .....  | 5  |
| 2 Normative references .....   | 5  |
| 3 Terms and definitions .....  | 5  |
| 4 General requirements.....  | 7  |
| 4.1 Safety for a PEFM that utilizes electricity.....   | 7  |
| 4.2 Mechanical basic safety for all PEFMS.....   | 7  |
| 5 Identification, marking and documents.....   | 7  |
| 5.1 Marking of the scale or display .....  | 7  |
| 5.2 Marking of the PEFM or packaging.....  | 8  |
| 5.2.1 Marking of the PEFM.....   | 8  |
| 5.2.2 Marking of the PEFM packaging .....  | 8  |
| 5.3 Instructions for use.....  | 9  |
| 5.4 Technical description .....  | 9  |
| 6 PEFM measurement range.....  | 9  |
| 7 Performance requirements.....  | 10 |
| 7.1 Error of measurement.....  | 10 |
| 7.2 Linearity.....   | 10 |
| 7.3 Resistance to flow.....  | 10 |
| 7.4 Frequency response .....   | 10 |
| 8 Dismantling and reassembly .....   | 10 |
| 9 Effects of mechanical ageing .....   | 10 |
| 10 Effects of dropping a hand-held PEFM.....   | 11 |
| 11 Cleaning, sterilization, and disinfection .....   | 11 |
| 11.1 Reusable PEFM and parts.....  | 11 |
| 11.2 PEFM and parts delivered sterile.....   | 11 |
| 12 Compatibility with substances.....  | 11 |
| 13 Biocompatibility .....  | 11 |
| Annex A (informative) Rationale for tests and examples of test apparatus .....   | 12 |
| Annex B (normative) Determination of error, repeatability, and resistance to PEFM output .....                           | 15 |
| Annex C (normative) Determination of frequency response .....  | 18 |
| Annex D (normative) Test methods for determination of the effects of dismantling, ageing and dropping.....               | 20 |
| Annex E (informative) Environmental aspects .....  | 22 |
| Annex F (informative) Reference to the Essential Principles .....  | 24 |
| Annex G (informative) Terminology — Alphabetized index of defined terms.....   | 28 |
| Annex ZA (informative) Relationship between this Document and the Essential Requirements of EU Directive 93/42/EEC ..... | 29 |
| Bibliography .....   | 33 |