

# DIN EN ISO 15197:2013-09 (E)

In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus (ISO 15197:2013), German version EN ISO 15197:2013

---

| Contents                                                              | Page |
|-----------------------------------------------------------------------|------|
| Foreword .....                                                        | 3    |
| Introduction .....                                                    | 4    |
| 1 Scope .....                                                         | 5    |
| 2 Normative references .....                                          | 5    |
| 3 Terms and definitions .....                                         | 6    |
| 4 Design and development .....                                        | 12   |
| 4.1 General requirements .....                                        | 12   |
| 4.2 Metrological traceability .....                                   | 12   |
| 4.3 Safety and risk management .....                                  | 13   |
| 4.4 Ergonomics and human factors .....                                | 14   |
| 4.5 User verification requirements .....                              | 14   |
| 5 Safety and reliability testing .....                                | 14   |
| 5.1 General requirements .....                                        | 14   |
| 5.2 Protection against electric shock .....                           | 15   |
| 5.3 Protection against mechanical hazards .....                       | 15   |
| 5.4 Electromagnetic compatibility .....                               | 15   |
| 5.5 Resistance to heat .....                                          | 15   |
| 5.6 Resistance to moisture and liquids .....                          | 15   |
| 5.7 Protection against liberated gases, explosion and implosion ..... | 16   |
| 5.8 Meter components .....                                            | 16   |
| 5.9 Performance test .....                                            | 16   |
| 5.10 Mechanical resistance to vibration and shock .....               | 16   |
| 5.11 Equipment temperature exposure limits for storage .....          | 17   |
| 5.12 Equipment humidity exposure limits for storage .....             | 17   |
| 6 Analytical performance evaluation .....                             | 18   |
| 6.1 General requirements .....                                        | 18   |
| 6.2 Measurement precision .....                                       | 20   |
| 6.3 System accuracy .....                                             | 23   |
| 6.4 Influence quantities .....                                        | 29   |
| 6.5 Stability of reagents and materials .....                         | 34   |
| 7 Information supplied by the manufacturer .....                      | 34   |
| 7.1 General requirements .....                                        | 34   |
| 7.2 Performance characteristics .....                                 | 35   |
| 7.3 Options for supplying instructions for use .....                  | 35   |
| 8 User performance evaluation .....                                   | 35   |
| 8.1 General requirements .....                                        | 35   |
| 8.2 Acceptance criteria and evaluation of results .....               | 36   |
| 8.3 Selection and preparation of subjects .....                       | 36   |
| 8.4 Execution of study protocol .....                                 | 36   |
| 8.5 Glucose reference values .....                                    | 37   |

|                                                                                                                                                                                    |                                                 |           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|-----------|
| 8.6                                                                                                                                                                                | Human factors .....                             | 37        |
| 8.7                                                                                                                                                                                | Data analysis and presentation of results ..... | 37        |
| 8.8                                                                                                                                                                                | Evaluation of instructions for use .....        | 38        |
| <b>Annex A (informative) Possible interfering substances .....</b>                                                                                                                 |                                                 | <b>39</b> |
| <b>Annex B (informative) Traceability chain .....</b>                                                                                                                              |                                                 | <b>40</b> |
| <b>Annex C (informative) Rationale for the analytical performance requirements .....</b>                                                                                           |                                                 | <b>42</b> |
| <b>Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC <i>in vitro</i> diagnostic medical devices .....</b> |                                                 | <b>49</b> |
| <b>Bibliography .....</b>                                                                                                                                                          |                                                 | <b>51</b> |