Reference number
ISO 15197:2013
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International Standard
ISO 15197:2013
In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
Edition 2
2013-05

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Published (Edition 2, 2013)
This publication was last reviewed and confirmed in 2018. Therefore this version remains current.

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English
Format
CHF 181

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Abstract

ISO 15197:2013 specifies requirements for *in vitro* glucose monitoring systems that measure glucose concentrations in capillary blood samples, for specific design verification procedures and for the validation of performance by the intended users. These systems are intended for self-measurement by lay persons for management of diabetes mellitus.

ISO 15197:2013 is applicable to manufacturers of such systems and those other organizations (e.g. regulatory authorities and conformity assessment bodies) having the responsibility for assessing the performance of these systems.

General information

- Status
  : Published
  Publication date
  : 2013-05
  Stage
  : International Standard to be revised [90.92]
- Edition
  : 2
  Number of pages
  : 46
- Technical Committee :
  ISO/TC 212
  ICS :
  11.100.10
- RSS updates

Life cycle

- **Previously**

  Withdrawn

  ISO 15197:2003

- **Now**

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Published

ISO 15197:2013

A standard is reviewed every 5 years
Stage: **90.92** (To be revised)

- 00
  Preliminary
- 10
  Proposal
  - 10.99 2009-02-16
    New project approved
- 20
  Preparatory
- 30
  Committee
  - 30.99 2010-11-12
    CD approved for registration as DIS
- 40
  Enquiry
  - 40.00 2011-01-13
    DIS registered
  - 40.20 2011-01-27
    DIS ballot initiated: 12 weeks
  - 40.60 2011-06-29
    Close of voting
  - 40.99 2012-10-29
    Full report circulated: DIS approved for registration as FDIS
- 50
  Approval
  - 50.00 2012-10-29
    Final text received or FDIS registered for formal approval
  - 50.20 2013-02-07
    Proof sent to secretariat or FDIS ballot initiated: 8 weeks
  - 50.60 2013-04-09
    Close of voting. Proof returned by secretariat
- 60
  Publication
  - 60.00 2013-04-15
    International Standard under publication
  - 60.60 2013-05-14
    International Standard published
- 90
  Review
  - 90.20 2018-04-15
    International Standard under systematic review

        - 90.60 2018-09-05
          Close of review
        - 90.93 2018-10-24
          International Standard confirmed
        - 90.20 2023-10-15
          International Standard under systematic review
        - 90.60 2024-03-04
          Close of review
        - 90.92 2024-12-19
          International Standard to be revised
        - 90.93
          International Standard confirmed
        - 90.99
          Withdrawal of International Standard proposed by TC or SC
    - 95
      Withdrawal
        - 95.99
          Withdrawal of International Standard

- **Will be replaced by**

  Under development

  ISO/CD 15197

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