

PAS 2600:2025

Continuous glucose monitoring systems
– Design verification and validation of
performance – Specification



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Foreword

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It has been assumed in the preparation of this PAS that the execution of its provisions will be entrusted to appropriately qualified and experienced people, for whose use it has been produced.

Presentational conventions

The provisions of this document are presented in roman (i.e. upright) type. Its requirements are expressed in sentences in which the principal auxiliary verb is "shall".

Commentary, explanation and general informative material is presented in smaller italic type, and does not constitute a normative element.

Where words have alternative spellings, the preferred spelling of the *Shorter Oxford English Dictionary* is used (e.g. "organization" rather than "organisation").

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In particular, attention is drawn to the following specific Acts and regulations:

- Medical Devices Regulations 2002 [2]¹⁾;
- UK General Data Protection Regulation [3];
- Data Protection Act 2018 [4];
- Medical Device Regulation (EU) 2017/745 [5];
- Regulation for Electronic Instructions for Use of Medical Devices (EU) 2021/2226 [6];
- Radio Equipment Directive 2014/53/EU [7]; and
- Radio Equipment Regulations 2017 [8].

¹⁾ The regulations are being revised at the time of publication of this PAS and are expected to be published in due course.

Introduction

Continuous glucose monitoring (CGM) systems are designed to automatically measure glucose levels in interstitial fluid at frequent intervals over a period of time. A CGM system typically consists of a sensor, either worn on the body or implanted, and a digitally connected receiver. Some models also include a separate transmitter.

When used as intended, CGM systems allow users to frequently or continuously monitor their glucose levels. The glucose measurements can be used to guide treatment decisions aimed at managing the concentration of glucose present in the blood.

CGM systems are primarily used by individuals affected by diabetes mellitus to support diabetes management. Diabetes mellitus is a condition characterized by insufficient insulin production or insulin resistance, resulting in elevated blood glucose levels that can lead to both acute and long-term health complications.

CGM systems can also be used to manage other diseases or medical conditions relating to glycaemic control.

Some CGM systems incorporate configurable alerts and alarms to notify users of glucose levels outside clinically defined thresholds. These notifications, delivered via sound, vibration or visual cues, help enable timely user response to hypoglycaemia or hyperglycaemia and can be integral to system safety and usability depending on the system design and intended purpose.

As technology has evolved and CGM systems have become central to the management of diseases and medical conditions related to glycaemic control, it is critical for user safety to have robust clinical data to demonstrate the accuracy and clinical performance of the CGM system throughout the wear period. It is also critical for CGM systems to be designed to protect sensitive health data, safeguard systems from unauthorized access or misuse and preserve data integrity, particularly where CGM systems are digitally connected to mobile and cloud-based applications, and other medical devices, such as insulin pumps.

1 Scope

This PAS specifies requirements for continuous glucose monitoring (CGM) systems intended to be used alone, or in conjunction with, digitally connected medical devices for the purpose of managing diseases or medical conditions related to glycaemic control by lay persons and healthcare professionals.

In particular, requirements relate to:

- a) design verification and validation procedures for demonstrating safety and analytical and clinical performance of CGM systems;
- b) secure software lifecycle principles and the management of cybersecurity risks and threats to CGM systems; and
- c) the provision of information on CGM performance characteristics supplied by the manufacturer to CGM users.

This PAS does not:

- 1) provide a comprehensive evaluation of all possible factors that affect the performance of CGM systems;
- 2) pertain to glucose concentration measurement for the purpose of diagnoses of a medical condition or disease relating to glycaemic control, including diabetes mellitus;
- 3) address the medical aspects of diabetes mellitus management;
- 4) apply to in vitro blood glucose monitoring devices; or
- 5) apply to CGM systems that do not have a medical purpose, including products intended for wellness and fitness trackers.

NOTE *Although this PAS applies to CGM system safety and performance in the UK, it might be useful as a benchmark for other markets.*

The PAS is intended to be used by manufacturers of CGM systems, and is expected to be of interest to organizations (e.g. regulatory authorities and conformity assessment bodies) responsible for assessing the performance of these systems.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes provisions, or limits the application, of this document²⁾. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

BS EN 556-1, *Sterilization of medical devices. Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices*

BS EN 10993 (all parts), *Biological evaluation of medical devices*

BS EN 60601-1 (all parts), *Medical electrical equipment – Part 1: General requirements for safety*

BS EN 60601-1-6, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*

BS EN 60601-1-11, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

BS EN 62304, *Medical device software – Software life-cycle processes*

BS EN 62366-1, *Medical devices – Part 1: Application of usability engineering to medical devices*³⁾

BS EN IEC 81001-5-1, *Health software and health IT systems safety, effectiveness and security: Part 5-1: Security – Activities in the product life cycle*

BS EN ISO 11607-1, *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*

BS EN ISO 11607-2, *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*

BS EN ISO 11737-1, *Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products*

BS EN ISO 11737-2, *Sterilization of health care products – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*

BS EN ISO 14155, *Clinical investigation of medical devices for human subjects – Good clinical practice*

BS EN ISO 14971, *Medical devices – Application of risk management to medical devices*

BS EN ISO 15223-1, *Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements*

BS EN ISO 20417, *Medical devices – Information to be supplied by the manufacturer*

²⁾ Documents that are referred to solely in an informative manner are listed in the Bibliography.

³⁾ This PAS also gives an informative reference to BS 62366-1:2015+A1:2020.

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1.1 accuracy (of measurement)

closeness of agreement between a measured quantity value and a true quantity value of a measurand

[SOURCE: ISO/IEC Guide 99:2007, 2.13, modified – notes removed]

3.1.2 continuous glucose monitoring (CGM) system

glucose monitoring system with a sensor that measures glucose levels at regular and frequent intervals (e.g. every 15 min or less) over the wear period

NOTE CGM systems include intermittently scanned and “flash” systems.

[SOURCE: Clinical and Laboratory Standards Institute’s POCT05 [9], modified – note added]

3.1.3 interferent

substance that causes a false glucose reading detected by a continuous glucose monitoring (CGM) sensor

3.1.4 rate of change (RoC)

change in function value divided by the elapsed time

NOTE CGM glucose RoC is computed from the sequential CGM value closest to the time of the reference values, divided by the time interval between them.

[SOURCE: Clinical and Laboratory Standards Institute’s POCT05 [9], modified – note replaced]

3.1.5 secure by design

design principle that means technology products are built in a way that reasonably protects against malicious cyber actors successfully gaining access to devices, data, and connected infrastructure

[SOURCE: Cybersecurity and Infrastructure Security Agency’s *Secure by design* [10]]

3.1.6 state of the art

developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience

NOTE The term refers to what is currently and generally accepted as good practice in technology and medicine, but does not necessarily imply the most technologically advanced solution.

[SOURCE: PD ISO/IEC Guide 63:2019, 3.18, modified – in the note, “The state of the art embodies:” replaced with “The term refers to”; “The state of the art” replaced with “, but”; and final sentence removed]

3.1.7 usability

characteristic of the user interface that facilitates use and thereby establishes effectiveness, efficiency and user satisfaction in the intended use environment

[SOURCE: BS EN 62366-1:2015+A1 ©, 3.16]