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Health informatics — Personalized digital health — Digital therapeutics health software systems

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National foreword

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

As the healthcare sector evolves, there is an increasing demand for the production and appropriate use of digital health technologies (DHTs) across patient care settings. DHTs represent a broad spectrum of products ranging from clinician-facing electronic prescribing systems, telemedicine platforms, and decision support systems, to patient-facing wellness apps, diagnostic tools, monitoring products, digital biomarkers, and therapeutics.

Given the diversity of digital products available, it is important for patients, clinicians, and healthcare decision makers to have the ability to clearly distinguish between the numerous types of DHTs on the market. Without harmonized international guidance, healthcare decision makers and users are often unable to differentiate between, assess, and optimize the appropriate use of DHTs in practice based on the intended use of each product.

Digital therapeutics (DTx), as defined in this document, represent a type of medical product that can be used as standalone therapy, incorporated into a multi-functional DHT, or integrate into clinical care pathways alongside clinician-delivered therapies, pharmaceuticals, medical devices, or other DHTs.

Standards exist for various non-DTx DHT product categories and varying DTx product definitions, best practices, and country-level standards exist at the industry level (see Annex A), yet no DTx-specific international standards exist. This document centres on the ability of DTx to generate and deliver validated and measurable medical interventions directly to patients. It is relevant to patients, clinicians, healthcare decision makers, and product manufacturers.

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1 Scope

This document lists characteristics of a category of health software: digital therapeutics (DTx). DTx products generate and deliver medical interventions that are based on clinical evidence, have demonstrable positive therapeutic impacts on patient health, and produce real-world outcomes. Product use cases (see Annex B) demonstrate the variety of products represented in this quickly growing industry.

This document provides an overview of how DTx relates to other ecosystem constructs, including medical devices, software as a medical device (SaMD), software in a medical device (SiMD), and other digital health technologies (DHT). It also addresses relevant health and medical device software standards that have various degrees of applicability to DTx.

The focus of this document is on therapeutic products that are used in the context of a disease, disorder, condition, or injury for human use. It does not address products that are intended for veterinary use or for general wellbeing. Additional exclusions of this document include DTx market access pathways (i.e. prescription, non-prescription pathways), medical device requirements, product risk assessment, clinical evidence requirements, data security, patient privacy considerations, and product authorization pathways.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
digital health technology
DHT
system that uses computing platforms, connectivity, software, and sensors for healthcare and related uses

Note 1 to entry: These technologies span a wide range of uses, from applications in general wellness to applications as a medical device. They include technologies intended for use as a medical product, in a medical product, or as an adjunct to other medical products (devices, drugs, and biologics). They can also be used to develop or study medical products.

[SOURCE: BEST Resource[1]]

3.2
system
combination of interacting elements organized to achieve one or more stated purposes

[SOURCE: ISO/IEC/IEEE 15288: 2015, 4.1.46, modified — Notes to entry deleted.]

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