



BSI Standards Publication

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

National foreword

This Published Document is the UK implementation of [ISO/TR 11147:2023](#).

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its committee manager.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

This publication is not to be regarded as a British Standard.

© The British Standards Institution 2023
Published by BSI Standards Limited 2023

ISBN 978 0 539 20433 9

ICS 35.240.80

Compliance with a Published Document cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 30 June 2023.

Amendments/corrigenda issued since publication

Date	Text affected
------	---------------

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

*Informatique de santé — Santé numérique personnalisée — Systèmes
logiciels de santé pour la thérapie numérique*



Reference number
ISO/TR 11147:2023(E)

AVA Documents
Document Sharing Hub
© ISO 2023



COPYRIGHT PROTECTED DOCUMENT

© ISO 2023, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Context	5
5 Considerations	6
5.1 DTx Attributes	6
5.2 Impact on patient care	6
5.3 Relationship to SiMD	6
5.4 DTx in context of a DTx System	7
6 DTx in relation to ecosystem constructs	8
6.1 Existing ecosystem constructs	8
6.2 Medical device	9
6.3 Software as a Medical Device (SaMD)	9
6.4 Software in a Medical Device (SiMD)	10
6.5 Digital Health Technology (DHT) Frameworks	10
6.5.1 DHT Overview	10
6.5.2 Digital Therapeutics Alliance (DTA)	10
6.5.3 National Institute for Health and Care Excellence (NICE)	11
6.5.4 European Commission DG communications networks, content, and technology	12
7 Medical device software standards	13
Annex A (informative) Landscape analysis	14
Annex B (informative) DTx use cases	15
Bibliography	19

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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.

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.

This page deliberately left blank

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

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.]