PD CEN ISO/TS 82304-2:2021

BSI Standards Publication

Health software

Part 2: Health and wellness apps – Quality and reliability

Documents
Document Sharing Hub

Full document details: PD CEN ISO/TS 82304-2:2021

National foreword

This Published Document is the UK implementation of CEN ISO/TS 82304-2:2021. It is identical to ISO/TS 82304-2:2021.

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 2021
Published by BSI Standards Limited 2021

ISBN 978 0 539 05674 7

ICS 35.080; 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 31 August 2021.

Amendments/corrigenda issued since publication

Date	Text affected

Documents
Document Sharing Hub

Full document details: PD CEN ISO/TS 82304-2:2021

TECHNICAL SPECIFICATION

SPÉCIFICATION TECHNIQUE

TECHNISCHE SPEZIFIKATION

CEN ISO/TS 82304-2

August 2021

ICS 35.080; 35.240.80

English Version

Health software - Part 2: Health and wellness apps - Quality and reliability (ISO/TS 82304-2:2021)

Logiciels de santé - Partie 2: Applications de santé et de bien-être - Critères de qualité tout au long du cycle de vie - Code de pratique (ISO/TS 82304-2:2021)

Gesundheits- und Wellness-Apps - Qualitätskriterien während des gesamten Lebenszyklus - Verhaltenskodex (ISO/TS 82304-2:2021)

This Technical Specification (CEN/TS) was approved by CEN on 28 June 2021 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

© 2021 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

Ref. No. CEN ISO/TS 82304-2:2021 E

Documents
Document Sharing Hub

Full document details: PD CEN ISO/TS 82304-2:2021

European foreword

This document (CEN ISO/TS 82304-2:2021) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN websites.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this Technical Specification: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO/TS 82304-2:2021 has been approved by CEN as CEN ISO/TS 82304-2:2021 without any modification.

Documents
Document Sharing Hub

Full document details: PD CEN ISO/TS 82304-2:2021

Contents

Page

Foreword ... **iv**
Introduction ... **v**
1 Scope ... **1**
2 Normative references ... **1**
3 Terms and definitions ... **1**
3.1 General terms ... 1
3.2 Terms relating to apps ... 5
3.3 Terms relating to risk management ... 7
4 Health app assessment process ... **8**
4.1 Quality assessment ... 8
4.2 Quality requirements ... 8
4.3 Health app quality report ... 9
4.4 Health app quality evidence pack ... 9
4.5 Health app quality label ... 9
5 Quality requirements ... **9**
5.1 Product information ... 9
5.1.1 Product ... 9
5.1.2 App manufacturer ... 10
5.2 Healthy and safe ... 11
5.2.1 Health requirements ... 11
5.2.2 Health risks ... 14
5.2.3 Ethics ... 17
5.2.4 Health benefit ... 18
5.2.5 Societal benefit ... 23
5.3 Easy to use ... 24
5.3.1 Accessibility ... 24
5.3.2 Usability ... 26
5.4 Secure data ... 30
5.4.1 Privacy ... 30
5.4.2 Security ... 36
5.5 Robust build ... 42
5.5.1 Technical robustness ... 42
5.5.2 Interoperability ... 45
Annex A (normative) **Health app quality label** ... **47**
Annex B (normative) **Health app quality score calculation method** ... **54**
Annex C (informative) **Rationale** ... **58**
Annex D (informative) **Product safety and lifecycle process recommendations** ... **59**
Annex E (informative) **Application profile – Contact tracing apps** ... **67**
Annex F (informative) **Ethical considerations in health apps** ... **70**
Annex G (informative) **Potential uses of this document** ... **73**
Bibliography ... **75**

© ISO 2021 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD CEN ISO/TS 82304-2:2021

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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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*, in collaboration with Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC 62A, *Common aspects of electrical equipment used in medical practice*, and with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 82304 series can be found on the ISO website.

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.

© ISO 2021 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD CEN ISO/TS 82304-2:2021

Introduction

Context

Health and wellness apps are a fast-growing market, and there are now hundreds of thousands, with the most popular of these having many millions of downloads each. Some of these apps fall under medical devices regulations, most do not. These apps are often promoted directly to consumers through app stores without going through any formal evaluation. The apps often collect sensitive personal information yet do not have appropriate privacy controls, and provide advice on topics such as fertility, diet or activity that are not supported by any evidence. There are widespread concerns about the risks involved. At the same time, health apps that have proven to be effective and add to quality of life and even length of life, are not necessarily adopted at scale and reimbursed.

Many health organizations have projects to evaluate, endorse and procure apps that meet locally defined requirements. These activities are important for any app manufacturer who want to promote or sell their product to or through providers of health and wellness services, as providers want the reassurance that the apps they recommend to patients will be safe, reliable and effective. However, the cost of responding to different extensive sets of criteria and different evaluation regimes in each country, organization, or region is a barrier for app manufacturers wanting to make their products available in multiple markets. It is also a problem for those evaluating apps and maintaining libraries of health and wellness apps. They can miss out on products that effectively address health issues and health system inefficiencies, do not benefit from economies of scale of others evaluating the same apps and different evaluations can contradict one another, causing further confusion instead of trust. Because of the time investment involved, the vast majority of apps are not evaluated at all, although top 10 lists suggest otherwise.

There are several International Standards on health software related to product safety and lifecycle processes that are applicable to all health software, including health apps. This document provides quality requirements and health app quality labels as ways for app manufacturers and app assessment organizations to communicate the quality and reliability of health apps.

The working practice within app development is to deliver a focused piece of functionality, building on an existing platform - often with a small team doing the work who can be unfamiliar with health software development. This document includes Annex D to provide guidance specific to this community.

A vibrant transparent market for health apps will benefit individuals and programs across the world that are addressing issues such as aging population, unhealthy lifestyles, chronic diseases, affordability of or constrained budgets for health and care, unequal quality and access to health services, and shortages in health professionals.

This document makes no attempt to determine whether a health app is or should be regulated.

Development methodology

The quality requirements (Clause 5) and health app quality score calculation method (Annex B) have been developed with a Delphi consensus study. Further input was gathered with surveys, interviews, and review of existing standards and health app assessment frameworks. The health app quality label (Annex A) has been inspired by the EU energy label that is also used in more than 50 countries outside Europe, the Nutriscore and the FDA over-the-counter medicine label. Think-aloud testing of the health app quality label with people with low health literacy in the Netherlands and subsequently Egypt and Mexico was used to ensure adequate understanding in different contexts.

Outline

This document defines a set of questions and supporting evidence that can be used to clarify the quality and reliability of a health app. A health app quality label is defined to summarize this information in a visually appealing way.

© ISO 2021 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD CEN ISO/TS 82304-2:2021

The questions and evidence are listed under the following headings taking into account the need to be understood by those with low health literacy:

— Product information;

— Healthy and safe;

— Easy to use;

— Secure data;

— Robust build.

This document provides requirements for the specification for the health app quality label in Annex A, and a calculation method in Annex B to generate the quality score information that is displayed on the label.

This document also contains annexes covering the following:

— Annex C: the rationale for the scope of this document and content;

— Annex D: a walk through the relevant international health software products and process standards, providing recommendations and explanations, where appropriate, to help those developing or evaluating health and wellness apps to understand how the standards can be applied;

— Annex E: an example of how a profile of this document can be defined for the assessment of contact tracing apps. Similar profiles can be produced for other specific use cases;

— Annex F: ethical considerations for app manufacturers and evaluators to take into account;

— Annex G: a range of ways that this document can be used by different stakeholders throughout the lifecycle of a health app.

© ISO 2021 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD CEN ISO/TS 82304-2:2021

Health software —

Part 2:
Health and wellness apps—Quality and reliability

1 Scope

This document provides quality requirements for health apps and defines a health app quality label in order to visualize the quality and reliability of health apps.

This document is applicable to health apps, which are a special form of health software. It covers the entire life cycle of health apps.

This document is intended for use by app manufacturers as well as app assessment organizations in order to communicate the quality and reliability of a health app. Consumers, patients, carers, health care professionals and their organizations, health authorities, health insurers and the wider public can use the health app quality label and report when recommending or selecting a health app for use, or for adoption in care guidelines, care pathways and care contracts.

NOTE 1 Health apps can be subject to national legislation, such as for medical devices.

NOTE 2 See Annex C for additional details on the scope.

Outside the scope of this document are guidelines to comply to the medical device regulation.

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 terminological databases for use in standardization at the following addresses:

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

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

3.1 General terms

3.1.1
accessibility
extent to which products, systems, services, environments and facilities can be used by people from a population with the widest range of user needs, characteristics and capabilities to achieve identified goals in identified contexts of use

Note 1 to entry: Context of use includes direct use or use supported by assistive technologies.

[SOURCE: ISO 9241-11:2018, 3.2.2]

© ISO 2021 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD CEN ISO/TS 82304-2:2021

3.1.2
effectiveness
ability to produce the intended result

[SOURCE: ISO 81001-1:2021, 3.2.5]

3.1.3
efficiency
resources used in relation to the results achieved

Note 1 to entry: Typical resources include time, human effort, costs and materials.

[SOURCE: ISO 9241-11:2018, 3.1.13]

3.1.4
evidence
directly measurable characteristics of a process and/or product that represent objective, demonstrable proof that a specific activity satisfied a specified requirement

[SOURCE: ISO/IEC 21827:2008, 3.19]

3.1.5
health
state of complete physical, mental and social well-being and not merely the absence of disease or infirmity

[SOURCE: WHO 1948[53]]

3.1.6
health benefit
positive impact or desirable outcome of the use of health software on the health of an individual

3.1.7
health intervention
act performed for, with or on behalf of a person or population whose purpose is to assess, improve, maintain, promote or modify health, functioning or health conditions

[SOURCE: WHO 1948[53]]

3.1.8
health issue
representation of an issue related to the health of a subject of care as identified by one or more healthcare actors

Note 1 to entry: According to this definition, a health issue can correspond to a health problem, a disease, an illness or another kind of health condition.

EXAMPLE A loss of weight, a heart attack, a drug addiction, an injury, dermatitis.

[SOURCE: ISO 13940:2015]

3.1.9
health need
deficit in the current health state compared to aspects of a desired future health state

[SOURCE: ISO 13940:2015]

© ISO 2021 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD CEN ISO/TS 82304-2:2021

3.1.10
intended use
intended purpose
health-related use for which a product, process or service is intended according to the specifications, instructions and information provided by the manufacturer

Note 1 to entry: The intended health benefit, patient population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle are typical elements of the intended use.

Note 2 to entry: A health app has an intended use irrespective of whether it is a medical device. A concept of "intended use" is used in a more restrictive sense in some medical device regulations.

[SOURCE: ISO/IEC Guide 63:2019, 3.4, modified — Note 2 to entry added, "intended purpose added" as a preferred term.]

3.1.11
intended users
group(s) of people for whom a product is designed

Note 1 to entry: In many cases the actual user population is different from that originally intended by the manufacturer. The intended user group is based on realistic estimations of who the actual users of the product will be.

[SOURCE: ISO 20282-1:2006, 3.12]

3.1.12
interoperability
ability of two or more systems or components to exchange information and to use the information that has been exchanged

[SOURCE: IEEE standard computer dictionary: a compilation of IEEE standard computer glossaries. New York: Institute of Electrical and Electronics Engineers; 1990]

3.1.13
joint PII controller
PII controller that determines the purposes and means of the processing of PII jointly with one or more other PII controllers

[SOURCE: ISO/IEC 27701:2019, 3.1]

3.1.14
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one of more of the specific medical purpose(s) of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

— investigation, replacement, modification, or support of the anatomy or of a physiological process,

— supporting or sustaining life,

— control of conception,

— disinfection of medical devices,

— providing information by means of in vitro examination of specimens derived from the human body,

© ISO 2021 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD CEN ISO/TS 82304-2:2021

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means

Note 1 to entry: Products that can be considered to be medical devices in some jurisdictions but not in others include

— disinfection substances,

— aids for persons with disabilities,

— devices incorporating animal and/or human tissues, and

— devices for in-vitro fertilization or assisted reproductive technologies.

[SOURCE: ISO/IEC Guide 63:2019, 3.7]

3.1.15
personally identifiable information
PII
any information that (a) can be used to establish a link between the information and the natural person to whom such information relates, or (b) is or can be directly or indirectly linked to a natural person

[SOURCE: ISO/IEC 29100:2011/Amd.1:2018, 2.9, modified — Note to entry removed.]

3.1.16
privacy
freedom from intrusion into the private life or affairs of an individual when that intrusion results from undue or illegal gathering and use of data about that individual

[SOURCE: ISO/TS 27790:2009, 3.56]

3.1.17
processing of PII
operation or set of operations performed upon Personally Identifiable Information (PII)

Note 1 to entry: Examples of processing operations of PII include, but are not limited to, the collection, storage, alteration, retrieval, consultation, disclosure, anonymization, pseudonymization, dissemination or otherwise making available, deletion or destruction of PII.

[SOURCE: ISO/IEC 29100:2011, 2.23]

3.1.18
quality
degree to which a set of inherent characteristics of an object fulfils requirements

[SOURCE: ISO 9000:2015, 3.6.2, modified — Notes to entry removed.]

3.1.19
reliability
ability of a device or a system to perform its intended function under given conditions of use for a specified period of time or number of cycles

[SOURCE: ISO 14907-1:2020, 3.23]

3.1.20
safety
freedom from unacceptable risk

[SOURCE: ISO/IEC Guide 63:2019, 3.16]

© ISO 2021 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD CEN ISO/TS 82304-2:2021

3.1.21
satisfaction
extent to which the user's physical, cognitive and emotional responses that result from the use of a system, product or service meet the user's needs and expectations

Note 1 to entry: Satisfaction includes the extent to which the user experience that results from actual use meets the user's needs and expectations.

Note 2 to entry: Anticipated use can influence satisfaction with actual use.

[SOURCE: ISO 9241-11:2018, 3.1.14]

3.1.22
security
condition that results from the establishment and maintenance of protective measures that ensure a state of inviolability from hostile acts or influences

Note 1 to entry: Hostile acts or influences could be intentional or unintentional.

3.1.23
usability
extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use

[SOURCE: ISO 9241-210:2019, 3.13]

3.1.24
user
person who interacts with a system, product or service

Note 1 to entry: Users of a system, product or service include people who operate the system, people who make use of the output of the system and people who support the system (including providing maintenance and training).

[SOURCE: ISO 9241-11:2018, 3.1.7]

3.1.25
use error
reasonably foreseeable misuse

3.2 Terms relating to apps

3.2.1
app
software application that can be executed (run) on a computing platform

Note 1 to entry: Apps were initially established as a category of software developed to run on mobile platforms for a single or limited number of purposes. However, the distinction between apps and other software applications has become less clear as a wider range of computing platforms are marketed as supporting apps and app repositories, and as apps with a wider range of functions are developed.

Note 2 to entry: An example is a software application running on a handheld commercial off-the shelf computing platform, with or without wireless connectivity, or a web-based software application that is tailored to a mobile platform but is executed on a server.

[SOURCE: BS PAS 277:2015, 3.1.1, modified — 'and is typically a small application run or accessed on mobile devices' removed from the definition, Note 2 to entry modified.]

© ISO 2021 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD CEN ISO/TS 82304-2:2021

3.2.2
app assessment organization
organization that evaluates apps

Note 1 to entry: This can be done to inform the purchasing or recommendation of an app, or as part of a certification program.

3.2.3
health app
health and wellness app
app intended to be used specifically for managing, maintaining or improving health of individual persons, or the delivery of care

[SOURCE: IEC 82304-1:2016 3.6, modified — Changed 'software' to 'app' in term and definition, 'health and wellness app' was added as a term, notes to entry deleted.]

3.2.4
health software
software intended to be used specifically for managing, maintaining or improving health of individual persons, or the delivery of care

Note 1 to entry: Health software fully includes what is considered software as a medical device.

Note 2 to entry: The scope of IEC 82304-1 refers to the subset of health software that is intended to run on general computing platforms.

[SOURCE: IEC 82304-1:2016, 3.6]

3.2.5
health software product
combination of health software and accompanying documentation

[SOURCE: IEC 82304-1:2016, 3.7, modified — 'documents' changed to 'documentation'.]

3.2.6
manufacturer
app manufacturer
natural or legal person with responsibility for design and/or manufacture of a health app with the intention of making the health app available for use, under their own name; whether or not such a health app is designed and/or manufactured by that natural or legal person themselves or on their behalf by (an)other natural or legal person(s)

Note 1 to entry: This 'natural or legal person' has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the health app in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority within that jurisdiction.

Note 2 to entry: 'Design and/or manufacture' can include specification development, production, assembly, processing, packaging, repackaging, labelling, relabelling, installation, or remanufacturing of a health app, or putting a collection of apps, and possibly other products, together for a health purpose.

Note 3 to entry: Any natural or legal person who assembles or adapts a health app that has already been supplied by another person for an individual subject of care or wellbeing, in accordance with the instructions for use, is not the app manufacturer, provided the assembly or adaptation does not change the intended use of the health app.

Note 4 to entry: Any natural or legal person who changes the intended use of, or modifies, a health app without acting on behalf of the original app manufacturer and who makes it available for use under their own name, should be considered the app manufacturer of the modified health app.

Note 5 to entry: An authorized representative, distributor or importer who only adds its own address and contact details to the health app or the packaging, without covering or changing the existing labelling, is not considered an app manufacturer.

© ISO 2021 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD CEN ISO/TS 82304-2:2021

[SOURCE: ISO/IEC Guide 63:2019, 3.6, modified — 'medical device' replaced with 'health app', 'app manufacturer' was added as a term, Notes 2 and 7 to entry deleted.]

3.2.7
session management
process of securing repeated access of a user to the health app, once authentication has been established, e.g. automatic logout after a certain time of inactivity

3.2.8
validation
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

Note 1 to entry: The objective evidence needed for a validation can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The activities carried out for validation are sometimes called a qualification process.

Note 3 to entry: The word "validated" is used to designate the corresponding status.

[SOURCE: ISO 9000:2015, 3.8.13, modified — Notes 2 and 3 to entry have been changed.]

3.2.9
verification
confirmation through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The activities carried out for verification are sometimes called a qualification process.

Note 3 to entry: The word "verified" is used to designate the corresponding status.

[SOURCE: ISO 9000:2015, 3.8.12]

3.3 Terms relating to risk management

3.3.1
authentication
process of validating a user or process to verify that the user or process is not a counterfeit

Note 1 to entry: Methods to validate the identity of the user of a health app may include password, Face ID, Touch ID, Oauth2.

[SOURCE: ISO/IEC/IEEE 9945:2009+Cor 1:2013+Cor 2:2017, 3.31, modified — Note to entry added.]

3.3.2
authorization
process of verifying that a user or process has permission to use a resource in the manner requested

Note 1 to entry: To ensure security, the user or process would also need to be authenticated before granting access

[SOURCE: ISO/IEC/IEEE 9945:2009+Cor 1:2013+Cor 2:2017, 3.32, modified — Second sentence in the definition changed to Note to entry.]

3.3.3
harm
injury or damage to the health of people or damage to property or the environment

[SOURCE: ISO/IEC Guide 51:2014, 3.1]

© ISO 2021 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD CEN ISO/TS 82304-2:2021

3.3.4
hazard
potential source of harm

[SOURCE: ISO/IEC Guide 51:2014, 3.2]

3.3.5
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO/IEC Guide 51:2014, 3.9]

3.3.6
risk analysis
systematic use of available information to identify hazards and to estimate the risk

[SOURCE: ISO/IEC Guide 51:2014, 3.10]

3.3.7
risk control
process in which decisions are made and measures implemented by which risks are reduced to, and maintained within, specified levels

[SOURCE: ISO/IEC Guide 63: 2019, 3.12]

3.3.8
residual risk
risk remaining after risk control measures have been implemented

[SOURCE: ISO/IEC Guide 63: 2019, 3.9]

4 Health app assessment process

4.1 Quality assessment

The health app manufacturer shall provide answers to the questions defined in Clause 5 in order to conform with this document. The evidence defined in Clause 5 for each question is provided by the health app manufacturer to an app assessment organization.

Where the health app is available on different platforms and the answers to the questions defined in Clause 5 are not the same for each platform, then a separate set of answers shall be provided for the health app for each platform.

Annex G describes potential uses of this document for stakeholders including app assessment organizations.

4.2 Quality requirements

The quality requirement questions in Clause 5 are grouped under five sections, with 'Product information' and four aspects of quality:

— Healthy and safe;

— Easy to use;

— Secure data;

— Robust build.

© ISO 2021 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD CEN ISO/TS 82304-2:2021

The questions have different purposes that are indicated using the subheading 'PURPOSE':

— Label content: Question to capture information to be provided in the health app quality label. The answer does not impact the health app score;

— Requirements level: Question to establish which subsequent questions are to be asked;

— Colour coding: Question to establish a quality and reliability aspect of the health app. The answer affects the health app score (in Annex B) and colour in a particular quality aspect on the health app quality label (in Annex A). The colour coding questions shall be answered with 'Yes' or 'No' or, in some cases, 'Not applicable'. This way, the answers can be used to derive scores for the health app quality label;

— Filtering: Question to help app repository users to search and filter for relevant apps in a consistent way. The answer does not impact the health app score;

— App assessment: Questions to enable app evaluation. The response is provided to the app assessment organization only.

4.3 Health app quality report

The set of answers to the 'Label content', 'Requirements level', 'Colour coding' and 'Filtering' questions, excluding evidence provided to enable app assessment, form the health app quality report.

The health app quality report can be made available to potential customers and users of the health app to enable informed decision making.

4.4 Health app quality evidence pack

The health app quality evidence pack is the set of evidence as specified in Clause 5 that shall be made available to health app assessment organizations to enable the assessment process.

4.5 Health app quality label

The health app quality label enables consumers, patients, carers, health professionals, payers such as health insurers and health authorities to make informed decisions. The health app quality label enhances transparency concerning the quality and reliability of a health app.

The health app quality label is unrelated to any labelling requirements for medical devices.

The health app quality label shall conform to the requirements documented in Annex A, using quality scores calculated using the method defined in Annex B.

5 Quality requirements

5.1 Product information

5.1.1 Product

5.1.1.1 Which operating systems or platforms does the health app support?

PURPOSE: Label content, Filtering

© ISO 2021 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD CEN ISO/TS 82304-2:2021

RESPONSE OPTIONS: Android™[1] / iOS®[2] / Web app / Other (Multiple-choice)

If 'Other' is selected, provide the name(s) of the other operating system(s) or platform(s) for the label.

NOTE 'Health and wellness app' and 'health app' are synonyms.

5.1.1.2 What is the name of the health app?

PURPOSE: Label content

RESPONSE OPTIONS: Text

NOTE The name of the health app is the name used in the platform's digital marketplaces.

5.1.1.3 Provide the health app icon, if available.

PURPOSE: Label content

RESPONSE OPTIONS: Image file

NOTE The health app icon is the image that helps consumers to find and distinguish a specific app in, e.g. a platform's digital marketplace.

5.1.1.4 In which languages is the health app available?

PURPOSE: Filtering

RESPONSE OPTIONS: Multiple-choice (see ISO 639-3)

NOTE Language refers to the user interface languages of the health app, instructions for use and other user documentation relating to the health app, that are available for this version of the health app on this / these operating system(s) or platform(s).

5.1.1.5 Provide health app access instructions for the app assessment organization.

PURPOSE: App assessment

RESPONSE OPTIONS: Text

Login credentials should be included with the instructions if appropriate.

Test information input during app assessments should not affect normal use of the app or data derived from its normal use.

5.1.2 App manufacturer

5.1.2.1 What is the name of the health app manufacturer?

PURPOSE: Label content

1) Android ™ is a trademark of Google LLC. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

2) IOS® is the registered trademark of Cisco for a product supplied by Apple®. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

© ISO 2021 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD CEN ISO/TS 82304-2:2021

RESPONSE OPTIONS: Text

NOTE 1 App manufacturer refers to the legal or natural person that places the health app on the market and is responsible for the correct function according to applicable legislation. In some cases, the term for the responsible legal or natural person is app publisher.

NOTE 2 The name is provided in the health app quality label to help potential customers and users establish the identity of the app manufacturer.

5.1.2.2 Provide e-mail address and telephone number of the person who is authorized to represent the health app manufacturer.

PURPOSE: App assessment

RESPONSE OPTIONS: Text + Number

The contact details are for app assessment purposes only. As people can change roles, a role-based e-mail address and telephone number is recommended.

5.2 Healthy and safe

5.2.1 Health requirements

5.2.1.1 Who are the intended users of the health app?

PURPOSE: Label content (Benefit of the app), Filtering

RESPONSE OPTIONS: Anyone / Persons with, or at risk of, specific health issues / Informal carers / Health professionals / Researchers / Other (Multiple-choice + Text)

EVIDENCE: Screenshots of intended user specification communication and sources of the screenshots

If 'Other' is selected, provide a text description.

EXAMPLE 1 Informal carers include parents of underaged children and relatives who provide care.

EXAMPLE 2 Health professionals include clinicians, public health professionals, health policy workers, care workers and wellness professionals such as yoga teachers and personal trainers.

NOTE This is a multiple-choice question to allow for health apps that have more than one intended user type.

5.2.1.2 Are age restrictions of the intended users or subjects of care made clear to potential customers and users?

PURPOSE: Colour coding

RESPONSE OPTIONS: Yes/No/Not applicable

EVIDENCE: Screenshots of age restriction communication and sources of the screenshots (e.g. digital marketplace, section website)

Restrictions that apply to both supervised and unsupervised use should be specified.

NOTE 'Not applicable' indicates that the health app has no age restrictions.

5.2.1.3 For which health issue(s) and/or health need(s) is the health app intended?

PURPOSE: Label content (Benefit of the app), Filtering

RESPONSE OPTIONS: Text

© ISO 2021 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD CEN ISO/TS 82304-2:2021

EVIDENCE: Screenshots of health issues and/or health needs communication and sources of the screenshots

NOTE Health needs include engaging in health promotion and wellness objectives, such as fitness and mental wellbeing.

5.2.1.4 What is the intended use of the health app?

PURPOSE: Label content (Benefit of the app), Requirements level, Filtering

RESPONSE OPTIONS: System services / Inform / Simple monitoring / Communicate / Preventative behavior change / Self-manage / Research / Treat / Active monitoring / Calculate / Diagnose / Other (Multiple-choice + Text)

EVIDENCE: Screenshot for each intended use

If 'Other' is selected, provide a text description.

Table 1 provides examples of descriptions for intended uses.

Table 1 — Examples of descriptions of intended uses

Intended use	Description
System services	Health apps that improve health system efficiency. Unlikely to have direct and measurable individual health outcomes. Includes for example electronic prescribing systems, electronic health record platforms and ward management systems [45].
Inform	Health apps that provide information and resources to anyone or persons with, or at risk of, specific health issues. Can include information on specific health issues or about healthy living. Includes for example apps describing a health issue and its treatment, apps providing advice for healthy lifestyles (such as recipes), and apps that signpost to other services [45].
Simple monitoring	Health apps that allow users to record health parameters to create health diaries. This information is not shared with or sent to others. Includes for example health tracking information such as from fitness wearables, symptom or mood diaries [45].
Communicate	Health apps that allow two-way communication between anyone or persons with, or at risk of, specific health issues and health professionals, informal carers, third-party organizations or peers. Health advice is provided by a health professional using the app, not by the app itself. Includes for example instant messaging apps for health and social care, video conference-style consultation software, and platforms for communication with informal carers or health professionals [45].
Preventative behavior change	Health apps that are designed to change intended user behaviour related to, for example, smoking, eating, alcohol, sexual health, sleeping and exercise. Prescribed to intended users by a health professional. Includes for example smoking cessation apps, apps used as part of weight loss programs and apps marketed as aids to good sleep habits [45].
Self-manage	Health apps that aim to help persons with specific health issues to manage their health. Can include symptom tracking function that connects with a health professional. Includes for example apps that allow users to record, and optionally to send data to a health professional to improve management of their health issue [45].
Research	Health apps that generate data for research [56]: — measure the magnitude and distribution of a health problem; — create understanding of the diverse causes or determinants of the problem; — develop solutions or interventions that will help to prevent or mitigate the problem; — implement or deliver solutions through policies and programs; and/or — evaluate the impact of these solutions on the level and distribution of the problem.

© ISO 2021 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD CEN ISO/TS 82304-2:2021

Table 1 *(continued)*

Treat	Health apps that provide treatment for a specific health issue (such as CBT for anxiety), or guide treatment decisions. Includes for example apps for treating mental health or other conditions, and health professional-facing apps that advise on treatments in certain situations [45].
Active monitoring	Health apps that automatically record information and transmit the data to a health professional, informal carer or third-party organization, without any input from the user, to inform health management decisions. Includes for example apps linked to devices such as implants, sensors worn on the body or in the home. Data are automatically transmitted through the app for remote monitoring [45].
Calculate	Health apps that perform calculations that are likely to affect health care decisions. Includes for example apps for use by health professionals or users to calculate parameters pertaining to care, such as early warning system software [45].
Diagnose	Health apps that use data to diagnose a health issue in a person, or to guide a diagnostic decision made by a health professional. Includes for example apps that diagnose specified health issues using clinical data [45].

NOTE This is a multiple-choice question to allow for health apps that have more than one intended use.

5.2.1.5 Are assessments done to establish whether the health app is a medical device and if applicable is regulatory approval obtained before the app is made available in each country?

PURPOSE: Colour coding

RESPONSE OPTIONS: Yes/No

EVIDENCE: E.g. depending on the country 510(k) number, EUDAMED registration number and CE mark, device certification list issued by notified body, decision tree of applicable legislation with indications why this health app is not a medical device.

To determine if the health app is a medical device, the app manufacturer shall compare the intended use/intended purpose with the medical device definition applicable in each country the app is intended to be made available.

NOTE This assessment includes health apps that are part of, a component of or an accessory to a medical device.

5.2.1.6 Are health professionals involved in the development of the health app?

PURPOSE: Colour coding

RESPONSE OPTIONS: Yes/No

EVIDENCE: One paragraph describing the names of health professionals and professional associations involved, frequency and nature of their involvement and level of influence, with their acknowledgement

The health professionals shall be involved to establish an adequate understanding of health requirements, health risks, contexts and current health interventions. That understanding shall be used in the design of the health app.

If the health app is on the market in different countries, then involvement of local health professionals should be considered as contexts and health interventions can vary between countries.

5.2.1.7 Is appropriate peer reviewed scientific literature used in the development of the health app?

PURPOSE: Colour coding

RESPONSE OPTIONS: Yes/No

© ISO 2021 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD CEN ISO/TS 82304-2:2021

EVIDENCE: Appropriate peer reviewed scientific literature

To be appropriate, the peer reviewed scientific literature shall help establish an understanding of health requirements, health risks, contexts and/or current health interventions. The understanding shall be used in the design of the health app.

Where many resources cover the full range of health needs and health issues addressed by the app, provide the most important 5 to 10 peer reviewed articles used.

EXAMPLE A systematic review of existing publications, including academic research, on intended users' health requirements and current practices published in specialist magazines, conference proceedings and journals.

5.2.2 Health risks

5.2.2.1 Are the health risks of the health app analysed?

PURPOSE: Colour coding

RESPONSE OPTIONS: Yes/No

EVIDENCE: Risk analysis documentation

The manufacturer shall identify hazards and estimate the associated risks. Where appropriate, include situations where the health app can be configured and/or supports interfaces to other products (adapted from IEC 82304-1:2016, 4.1).

Information or data for estimating risks can be obtained (adapted from ISO 14971:2019, 5.5), for example, from:

— published standards;

— scientific or technical investigations;

— field data;

— usability tests employing typical users;

— clinical evidence;

— results of relevant investigations or simulations;

— expert opinion;

— external quality assessment schemes.

The health app manufacturer shall identify and document known and foreseeable hazards to intended users in both normal and fault conditions through the introduction and use of the health app (from Reference [44], section 4.3).

Health risks can include over-reliance, disproportionate attachment and addiction to the health app, or manipulation that affects human autonomy [32].

A hazard identification technique that can be used is Functional Failure Analysis, which takes a functional view of the health app and considers for each function what the potential safety consequences can be if the function is:

— lost, i.e. not available when it is required;

— wrong, i.e. is available but performs an unintended action;

— provided when not required, i.e. function performs as intended but not at the correct time or out of sequence.

© ISO 2021 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD CEN ISO/TS 82304-2:2021

(from Reference [44], appendix B.1]

Health risk analysis can be carried out by a multi-disciplinary group including a safety officer.

The risk management processes in ISO 14971:2019 are appropriate for medical devices and can be used for other health apps.

5.2.2.2 Are measures in place to control the health risks of the health app?

PURPOSE: Colour coding

RESPONSE OPTIONS: Yes/No/Not applicable

EVIDENCE: Overview control measures for specified health risks

The manufacturer shall determine risk control measures that are appropriate for reducing risks to an acceptable level. Risk control measures can reduce the severity or the probability of occurrence of the harm, or both (ISO 14971:2019, 7.1).

Risk control can be achieved through the application of one or more of the following measures:

— changes to the design or the inclusion of protective measures in the health app (adapted from Reference [44], section 6.1);

— health app verification and validation, for example testing. A testing program should address each of the hazards and thus provide a practicable demonstration that the claimed risk reduction has been achieved;

— administrative and implementation procedures, for example requiring users to register and checking whether they are indeed intended users;

— user and other stakeholder training and briefing;

— information for user safety, including warnings.

Warnings can include alerts to notify the user of potential faults that can cause inconvenience or harm to the user, e.g. low battery alerts, and notifications to the user in case of external interruptions or delays, for instance loss of network connection, database problem or lengthy operation [32].

NOTE 1 Risk control measures refer to risk mitigation.

NOTE 2 'Not applicable' indicates that the health app does not have any health risks.

5.2.2.3 Are the residual risks of using the health app found to be acceptable?

PURPOSE: Colour coding

RESPONSE OPTIONS: Yes/No/Not applicable

EVIDENCE: Overview residual risks and acceptability

The app manufacturer shall decide whether a health risk is acceptable; and take into account current values of society, as appropriate expressed in local, national or regional regulations (adapted from Reference [44], section 5.1).

When a residual risk is not acceptable and further risk control is not practicable, the manufacturer can gather and review data and literature to determine whether the benefits of the intended use outweigh this residual risk. When this evidence does not support the conclusion that the benefits outweigh the residual risk, the manufacturer can consider modifying the health app or its intended use. Otherwise, this risk remains unacceptable (adapted from ISO 14971:2019, 7.4).

NOTE 'Not applicable' indicates that the health app does not have any health risks.

Documents
Document Sharing Hub

© ISO 2021 – All rights reserved

Full document details: PD CEN ISO/TS 82304-2:2021

5.2.2.4 Describe when the health app requires approval from a health professional before use.

PURPOSE: Label content

RESPONSE OPTIONS: Text

If a Text response is given, the health app quality label will include: 'Check [here] when app requires approval from health professional before use'. If there are no circumstances in which a health professional's approval is required before use, a Text response is not required, and the message will not appear on the label.

5.2.2.5 Are potential customers and users of the health app made aware of the health risks, contra-indications and limitations of use?

PURPOSE: Colour coding

RESPONSE OPTIONS: Yes/No

EVIDENCE: Screenshots of communication on health risks, contra-indications and limitations of use, and sources of the screenshots

The app manufacturer shall document contra-indications, potential risks and limitations of use. For example, environmental or patient conditions under which apps or connected devices can be unreliable (e.g. tattoos that impact optical sensor, avoid usage when pregnant, avoid usage outside a temperature range) [32].

The contra-indications can include health issues and symptoms.

If the overall residual risk is judged acceptable, the manufacturer shall inform users of significant residual risks and shall include the necessary information in the product information in order to disclose those residual risks (adapted from ISO 14971:2019, Clause 8).

If the health app provides health recommendations (e.g. general guidelines), the health app manufacturer shall disclose the potential risks to patient safety and their controls. If the health app offers health advice (e.g. specific and personal health decision support), it should be stated that use of the health app does not replace the health professional-patient relationship or the recommendation, opinion or diagnosis of a health professional. Users should be warned of updates caused by possible errors in functionality, in health-related information or in any other sensitive data [32].

If research shows no-contra-indications, health risks or limitations of use are to be expected, or the type of health app makes health risks impossible and contra-indications and limitations of use not applicable, this shall also be made clear to potential customers and users of the health app.

5.2.2.6 Is a process to collect and review safety concerns and incidents for the health app maintained?

PURPOSE: Colour coding

RESPONSE OPTIONS: Yes/No/Not applicable

EVIDENCE: Screenshots of how users can report incidents or issues and sources of the screenshots, appropriate Standard Operating Procedure

This process extends beyond the health app itself and shall include the impact on users, related healthcare processes and any change in intended use (adapted from Reference [44], section 7.2). Dependent on the intended use it can include establishing a detection and response mechanism for undesirable adverse effects for the user [32].

© ISO 2021 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD CEN ISO/TS 82304-2:2021

The process shall (adapted from Reference [44], section 7.2):

— enable users of the health app to report incidents they have had or issues they consider can have an impact on patient safety;

— provide a communication mechanism;

— ensure appropriate and sufficient resources are allocated by the app manufacturer to manage and resolve the reported incident;

— enable customers and users to respond to any safety alerts or bulletins issued by the app manufacturer;

— include maintaining a record of safety incidents, including their management and resolution;

— include maintaining a record of potential hazards and their resolution.

The manufacturer shall review the information collected for possible relevance to safety, especially whether (from ISO 14971:2019, 10.3):

— previously unrecognized hazards or hazardous situations are present;

— an estimated risk arising from a hazardous situation is no longer acceptable;

— the overall residual risk is no longer acceptable in relation to the benefits of the intended use; or

— the generally acknowledged state of the art has changed.

The app manufacturer might not be able to communicate with users, unless the users opt in to receiving such information.

NOTE 1 Medical device manufacturers typically apply ISO 14971:2019 in risk management and ISO 13485:2016 to manage quality throughout the life cycle of a medical device.

NOTE 2 'Not applicable' indicates that the health app does not have any health risks.

5.2.3 Ethics

5.2.3.1 Are ethical challenges of the health app assessed with intended users and health professionals?

PURPOSE: Colour coding

RESPONSE OPTIONS: Yes/No

EVIDENCE: Names of users and health professionals and user and professional associations involved, ethical issues discussed, challenges and responses

Ethical challenges include discrimination, stigmatization, fairness, bias in data sets, algorithms and users' interpretation, human agency, liberty, dignity and environmental wellbeing.

Discrimination includes the unfair treatment on the basis of sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation (from Reference [40], FRIA1).

The assessment of ethical challenges is a form of continuous deliberation, critique, and inquiry between manufacturers, deployers, users and in some cases also the general public or policy makers at regional or national level [32].

The assessment of ethical challenges shall include measures to control the identified ethical challenges, testing and monitoring their effectiveness during development, deployment and use and correcting measures deemed not effective [32].

© ISO 2021 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD CEN ISO/TS 82304-2:2021

Ethical issues covered in the quality requirements are (adapted from Reference [40], FRIA1):

— technical robustness and safety;

— privacy and data governance;

— transparency (understand how the app achieves its decisions);

— individual and societal wellbeing;

— accountability.

NOTE 1 The "Health inequalities and eHealth" report[66] of the eHealth stakeholder group provides examples to consider in discussing ethical challenges for specific groups.

NOTE 2 Tables F.1 and F.2 provide a mapping of the ethical principles defined by the High Level Expert Group on Artificial Intelligence[40] with the relevant subclauses in this document

5.2.3.2 Is the health app approved by an independent ethics advisor or ethics advisory board?

PURPOSE: Colour coding

RESPONSE OPTIONS: Yes/No

EVIDENCE: Copy of approval or exemption documentation, which includes app name, date of assessment, considerations and resulting approval or exemption

NOTE 'Independent' means not being part of the design team.

5.2.4 Health benefit

5.2.4.1 Describe the health benefit of using the app.

PURPOSE: Label content

RESPONSE OPTIONS: Text

The described health benefit shall be consistent with health benefits mentioned in the product information and marketing materials.

EXAMPLE 1 With this app [see 5.2.1.1 for intended users] [see 5.2.1.3 for health issue or health need] [see 5.2.1.4 for intended use-specific benefit]. For instance:

— *Inform:* 'With this app, persons who aim to increase their fitness can learn exercises'

— *Simple monitoring:* 'With this app, persons with mood disorders can log goal attainment / symptoms / wellbeing'

— *Calculate*: 'With this app, health professionals can calculate drug dosages'

— *Active monitoring:* 'With this app, persons with diabetes (can) keep health professionals updated on blood sugar levels'

Where possible, this description should include measurable and testable relevant outcomes, which are supported by evidence. The word 'can' in the above examples is then replaced by the quantified information.

EXAMPLE 2

— *Diagnose:* 'With this app, 6 in 10 persons feel supported in identifying atypical moles that require contact with a dermatologist'

© ISO 2021 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD CEN ISO/TS 82304-2:2021

— *Treat:* 'With this app, 5 in 10 persons who have had a stroke return to work earlier and increase working hours with 10 % or more'

This description shall include the conditions for the health benefit to be realized.

EXAMPLE 3

— *Self-manage:* 'With this app, 8 in 10 persons with cancer increase quality of life and 6 in 10 prolong survival with on average 5 months, if the app is used on a weekly basis'

The description should be readable by a large audience and shall be no more than 200 characters long.

NOTE This health benefit is included in the health app quality label to help potential customers and users make informed decisions.

5.2.4.2 Are potential customers and users made aware of the health interventions applied to achieve the health benefit?

PURPOSE: Colour coding

RESPONSE OPTIONS: Yes/No/Not applicable

EVIDENCE: Screenshots of communication on the health interventions applied to achieve the health benefit and sources of the screenshots

The communication shall include naming the health interventions applied, such as Cognitive Behavioral Therapy, and describing any calculations used.

If there is human and/or automated interpretation of health-related content, the credentials of qualified health professionals and/or the algorithms shall be disclosed [32].

If the app contains algorithms that change through learning during use, the disclosure shall include:

— for what aspects and how the app changes during use, including its change dynamics and change boundaries;

— how the user can monitor and control change.

For apps that require tradeoffs between fairness and accuracy, the disclosure shall include:

— if and how this trade-off can be adjusted by the user.

Providing human oversight can for example be done through a stop or pause button, by enabling the user to return to an earlier version of the algorithm (roll back mechanism), by enabling a user to trace back which algorithm model or rules led to the decision or recommendation, or by providing a procedure to safely abort an operation when needed [32].

NOTE 'Not applicable' indicates that the health app does not include any health interventions.

5.2.4.3 Are potential customers and users made aware of all financial costs to achieve the health benefit?

PURPOSE: Colour coding

RESPONSE OPTIONS: Yes/No/Not applicable

EVIDENCE: Screenshots of financial costs communication and sources of the screenshots

This shall include providing details of any in-app purchases, services or other products that are needed to achieve the intended use health benefit, any recurring subscription or upgrade costs and how to end the agreement.

© ISO 2021 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD CEN ISO/TS 82304-2:2021