Technical Specification

ISO/TS 9166

First edition
2025-05

Health informatics — Guidelines for self-assessment questionnaire systems

Informatique de santé — Lignes directrices pour les systèmes de questionnaires d'auto-évaluation

iTeh Standards
(https://standards.iteh.ai)
Document Preview

ISO/TS 9166:2025
https://standards.iteh.ai/catalog/standards/iso/9339ebcc-5468-4b67-a0a6-c6a3c669dee7/iso-ts-9166-2025

Reference number
ISO/TS 9166:2025(en)

© ISO 2025

iTeh Standards
(https://standards.iteh.ai)
Document Preview

ISO/TS 9166:2025
https://standards.iteh.ai/catalog/standards/iso/9339ebcc-5468-4b67-a0a6-c6a3c669dee7/iso-ts-9166-2025

COPYRIGHT PROTECTED DOCUMENT

© ISO 2025

All rights reserved. Unless otherwise specified, or required in the context of its implementation, 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
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

iTeh Standards (https://standards.iteh.ai) Document Preview
ISO/TS 9166:2025
https://standards.iteh.ai/catalog/standards/sist/2839ebcc-5468-4b67-a0a6-c6a3c669dee7/iso-ts-9166-2025

© ISO 2025 – All rights reserved

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).

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.

iTeh Standards
(https://standards.iteh.ai)
Document Preview
ISO/TS 9166:2025
https://standards.iteh.ai/catalog/standards/iso/9339ebcc-5468-4b67-a0a6-c6a3c669dee7/iso-ts-9166-2025

© ISO 2025 – All rights reserved

Introduction

Self-assessment questionnaire systems utilising information technology can provide a series of questions through a survey or interview allowing the patients to check their health condition in non-clinical settings, such as at home or in the workplace, rather than in traditional point-of-care environments. During the COVID-19 pandemic, the necessity and effectiveness of self-assessment questionnaire systems have been recognised, leading to adoption and utilisation in many countries. These systems provide a convenient way for individuals to track their health and receive timely advice before visiting healthcare facilities.

With the advent of various personal health devices (PHDs), objective health measurement information is being collected from environments outside the medical domain, such as at home or in schools, aiding in monitoring patients on various health parameters. However, PHDs have limitations, as they are unable to capture subjective or qualitative health status, such as mood or discomfort. Therefore, there is a need for different methods, such as a survey-based approach, to express subjective health status.

Self-assessment questionnaire systems can store and record the individual's subjective conditions or moods to enable the patients to regularly monitor and assess their health condition. Through the compilation of the recorded data, it is possible to understand the health condition and identify potential health issues proactively. The qualitative data can ensure continuous care by healthcare providers and also enhance preventive medicine practices.

Through the analysis of the recorded data, the self-assessment questionnaire systems can provide guidelines on action, suitable healthcare needs, and information about local healthcare services. By aggregating inputs from numerous users, the self-assessment questionnaire systems can generate statistical information that is used in understanding the local disease trends and managing the supply of necessary medical resources, thereby contributing to public health.

Therefore, the self-assessment questionnaire systems contribute to traditional healthcare, self-care, preventive medicine, and public health. However, there is no standardized approach to the functional elements or management aspects. The lack of standardized guidelines on the systems and data exchange aspects leads to the fragmentation of personal/patient-centric health data, leading to difficulties in integrating personal/patient health records. This document aims to address these issues to establish standardized guidelines to ensure consistent configuration and interoperable data for self-assessment questionnaire systems.

iTeh Standards
(https://standards.iteh.ai)
Document Preview
ISO/TS 9166:2025
https://standards.iteh.ai/catalog/standards/iso/9339ebcc-5468-4b67-a0a6-c6a3c669dee7/iso-ts-9166-2025

© ISO 2025 – All rights reserved

iTeh Standards
(https://standards.iteh.ai)
Document Preview

ISO/TS 9166:2025
https://standards.iteh.ai/catalog/standards/iso/9339ebcc-5468-4b67-a0a6-c6a3c669dee7/iso-ts-9166-2025

Health informatics — Guidelines for self-assessment questionnaire systems

1 Scope

This document provides guidelines for the self-assessment questionnaire systems to be used for health. This document includes the following:

— structure and components of the self-assessment questionnaire systems;

— guidelines for administering and managing the self-assessment questionnaire systems;

— basic data elements for interacting with the self-assessment questionnaire systems.

This document does not define the contents of the self-assessment questionnaire specialised in healthcare domains or departments. The questionnaires themselves are out of the scope of this document since they are dependent on the intended purpose of the self-assessment questionnaire systems.

2 Normative references

There are no normative references in this document.

iTeh Standards
(https://standards.iteh.ai)
Document Preview

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

ISO/TS 9166:2025
https://standards.iteh.ai/catalog/standards/iso/[illegible]-a6a6-c6a3c669dee7/iso-ts-9166-2025

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

3.1
questionnaire
set of questions for a survey or a structured or semi-structured interview

Note 1 to entry: The questions may be closed (answerable by checking one of several predetermined answers) or open (requiring participants to answer in their own words).

Note 2 to entry: The questionnaire may be paper-based or in electronic form.

[SOURCE: ISO 21248:2019, 3.74]

3.2
self-assessment
process of critically reviewing the quality of one's own skills, knowledge, or confidence

Note 1 to entry: The reviewing is normally done through a paper-based or online *questionnaire* (3.1) where some or all of the questions require respondents to rate themselves on a scale.

[SOURCE: ISO 16439:2014, 3.62]

© ISO 2025 – All rights reserved