



BSI Standards Publication

Health informatics — Guidelines for self-assessment questionnaire systems

National foreword

This Published Document is the UK implementation of ISO/TS 9166:2025.

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.

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Published by BSI Standards Limited 2025

ISBN 978 0 539 30659 0

ICS 35.240.80

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This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 May 2025.

Amendments/corrigenda issued since publication

Date	Text affected



Technical Specification

ISO/TS 9166

Health informatics — Guidelines for self-assessment questionnaire systems

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

**First edition
2025-05**

Reference number
ISO/TS 9166:2025(en)

Full document details: PD ISO/TS 9166:2025

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Published in Switzerland

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Foreword

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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.

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.

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.

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 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]

3.3 self-assessment questionnaire systems SAQS

structured and interactive system that consist of a series of questions that enable *self-assessment* ([3.2](#)) and provide feedback and guidance

4 Symbols and abbreviated terms

CDA	clinical document architecture
COVID-19	coronavirus disease 2019
EHR	electronic health record
EMR	electronic medical record
FHIR	fast healthcare interoperability resources
GDPR	general data protection regulation
HIPAA	health insurance portability and accountability act
HL7	health level 7
IHE	integrating the healthcare enterprise
MPI	master patient index
OTC	over-the-counter
PDQ	patient demographic query
PHD	personal health device
PHR	personal health record
PIX	patient identifier cross-referencing
SAQS	self-assessment questionnaire system
XDM	cross-enterprise document media interchange
XDR	cross-enterprise document reliable interchange
XDS.b	cross-enterprise document sharing, profile b

5 Structure and components of self-assessment questionnaire systems (SAQS)

5.1 General

Self-assessment questionnaire systems (SAQS) utilising information technology provide a series of questions for users to assess their health condition, recognise the potential health concerns, and understand when to seek medical or health-related assistance in non-clinical settings, such as at home, in the workplace, or in schools. The questionnaires can be designed to help the user analyse the progress of their health condition and to find the necessary social and health services.

The user can record various complaints or discomforts such as fever, fatigue, moods, pain, chronic cough, digestive issues, and sleep disturbances on a daily basis. These compiled data can be used as a reference in subsequent clinical encounters or healthcare services. Distinct from conventional paper-based ad-hoc questionnaires, the questionnaire sequence within SAQS is designed to be dynamic and adaptable based

on the user's input. This adaptation serves to identify preliminary areas of concern and subsequently guide the user through more detailed queries tailored to their specific health-related queries. The questionnaire responses are stored in the data repository to be used to customise future interactions.

The statistically gathered results from the SAQS can be used for more general purposes such as medical research or to provide insights on health trends of the local community, including monitoring the spread of infectious diseases. For example, SAQS collects data on complaints such as cough and fever from the local community, enabling local pharmacies to effectively manage medical supplies.

5.2 Structure and components of SAQS

The structure and components of the SAQS are shown in [Figure 1](#).

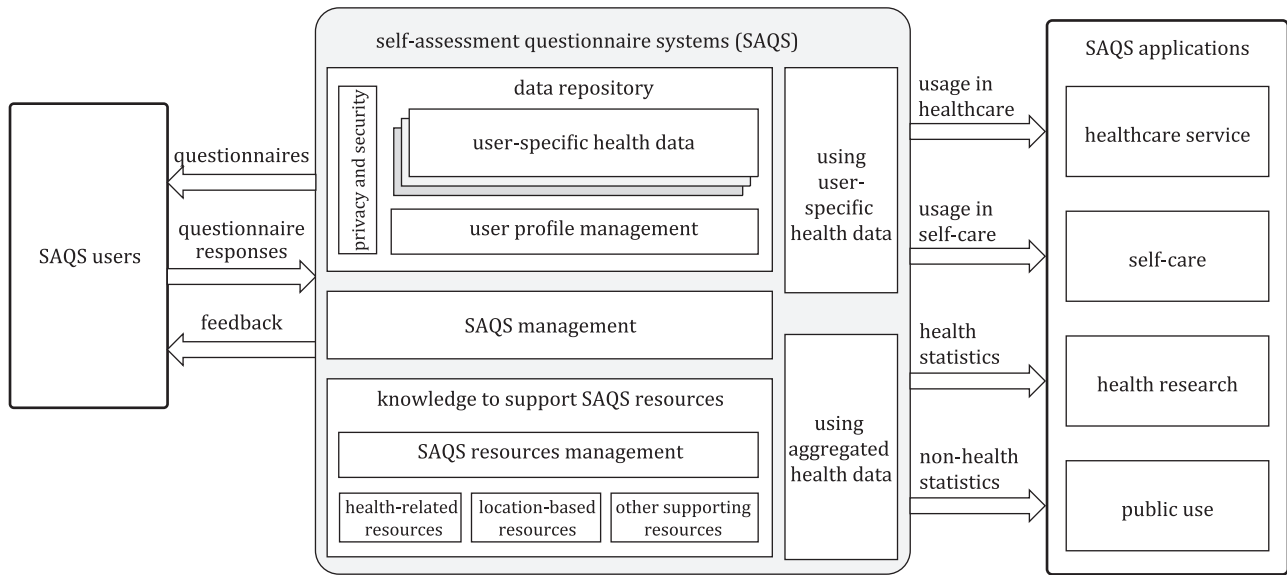


Figure 1 — Structure and components of self-assessment questionnaire systems

The structure consists of SAQS users, SAQS, and SAQS applications.

5.3 SAQS users

The SAQS users are individuals who interact with and utilise the SAQS for health-related purposes. The SAQS users respond to various questionnaires and receive feedback from the SAQS. The SAQS users may include patients, guardians, and caregivers. The guardians and caregivers interact with the SAQS on behalf of the patients.

5.4 Components of self-assessment questionnaire systems

5.4.1 General

This clause outlines the components of the SAQS. More detailed descriptions and examples can be found in [Annex A](#).

5.4.2 Data repository

5.4.2.1 General

The SAQS may store the interacted results of the self-assessment questionnaires for each SAQS user in the data repository.

5.4.2.2 User-specific health data

The user-specific health data component stores individual health data collected from self-assessment questionnaires for each SAQS user account. The types of information stored include questionnaire responses, personalised feedback, records of symptoms reported over time, notifications and reminders about health activities and upcoming check-ups, etc. The user-specific health data is used to monitor health changes and support personalised feedback. The user-specific health data can be integrated with PHRs or EHRs.

To ensure semantic interoperability, user-specific health data can be represented using international terminology systems such as SNOMED-CT, LOINC, and terminology defined by WHO.

5.4.2.3 User profile management

The user profile management involves administering and maintaining individual SAQS user accounts. This includes managing access to user-specific health data, maintaining user profiles, and ensuring user-specific health data is accurately recorded, securely stored, and appropriately utilised.

This component can integrate user-specific health data with medical information systems such as EMRs and PHRs. To facilitate this integration, a patient identifier cross-referencing (PIX) can be utilised, applying technologies such as IHE PIX and PDQ.

5.4.2.4 Privacy and security

The data exchanged between SAQS users and SAQS contains personal health data that is secured. This component ensures that all user-specific health data is protected against unauthorised access and breaches, maintaining strict privacy and security standards. The SAQS aligns its data repository and security practices with the applicable jurisdictions such as GDPR, HIPAA, etc.

5.4.3 SAQS management

The SAQS management component coordinates the various components of the SAQS. It ensures the quality and reliability of SAQS resources. It supports SAQS users by providing appropriate and adaptive questionnaires from the SAQS resources, and it generates practical and actionable feedback. It stores the questionnaire responses in the data repository. It analyses and processes the user-specific health data to be used by various SAQS applications.

5.4.4 Using user-specific health data

The user-specific health data can be used for both healthcare services and self-care. Healthcare professionals may utilise these collected data as a reference when making clinical decisions. The collected data can aid in self-care by tracking health changes or progress, helping users make necessary adjustments, or setting new health goals. They are used to provide appropriate feedback to the patients, encouraging prompt medical attention when needed.

The SAQS ensures data integrity and privacy protection when delivering user-specific health data to the SAQS applications.

5.4.5 Using aggregated health data

With the increased use of the SAQS, it is possible to aggregate user-specific health data for statistical purposes. The aggregated data can support clinical research enabling the study of specific phenomena, trend analysis, geo-plotting, etc. The SAQS should implement anonymisation or pseudonymisation measures, or both, to safeguard private data when generating statistical information. Consent from the SAQS user is obtained when using user-specific health data for statistical purposes, even if the private data have been deleted or anonymised.

5.4.6 Knowledge to support SAQS resources

5.4.6.1 General

This component is the foundational content for the questionnaires and includes relevant feedback based on the questionnaire responses. Examples of SAQS questionnaires can be found in [Annex B](#).

5.4.6.2 Location-based resources

The location-based resources are a collection of questionnaires and feedback that provide the patients with health-related information specific to the geographical location. These resources help SAQS users to obtain information about health-related conditions or to get assistance relevant to their current residence or a location they are planning to visit.

EXAMPLE Questionnaire on patient's current location, anticipated travel location, type of services needed, and methods for accessing health and healthcare services.

5.4.6.3 Health-related resources

The health-related resources are a collection of questionnaires and feedback focused on symptoms and primary health concerns. These tools assist SAQS users in identifying their health issues and provide guidance on how to address concerns. The SAQS users respond to health-related questions about symptoms and other chief complaints.

When designing health-related resources for SAQS, existing assessment scales and instruments should be used. This ensures consistency across different SAQS implementations and enables meaningful comparisons and integration.

EXAMPLE Health-related questionnaires include Short Form Health Survey (SF-36), Numeric Rating Scale (NRS), Patient Health Questionnaire-9 (PHQ-9), World Health Organisation Quality of Life (WHOQOL), etc.

5.4.6.4 Other supporting resources

Other questionnaires and feedback vary depending on the intended support of SAQS. There are types of resources that are not directly related to health but can affect self-assessment.

EXAMPLE Health-related jurisdiction, weather, traffic, living conditions.

5.4.6.5 SAQS resources management

The SAQS resources management component ensures that SAQS resources maintain consistency, accuracy, and compliance with local regulations.

5.5 SAQS applications

The gathered data from SAQS can be used for healthcare services or personal health checks. The collected data can also be utilised in medical research or for public use.

6 Recommended functionality of SAQS

6.1 Interface between SAQS users and SAQS

6.1.1 General

The following recommended functionality applies to the interaction between SAQS users and SAQS.

6.1.2 Providing questionnaires to SAQS users

- The SAQS should provide questionnaires based on the health status of the patient and various health-related context information.
- The SAQS should provide questionnaires based on previous questionnaire responses, feedback, and the context of the patient's concern.
- The SAQS may provide one-time questionnaires to support pre-screening and preventive measures. The responses to the one-time questionnaires should not be stored in the data repository but can be aggregated for statistical purposes.

EXAMPLE 1 For pre-screening, a questionnaire is used during immigration or when entering hospital rooms with patients who require absolute stability.

EXAMPLE 2 For preventative measures, questionnaires are used to enter symptoms that the individuals are experiencing to determine if a particular disease is suspected or if an encounter with the healthcare providers is needed.

- The SAQS may provide questionnaires to support the assessment of acute symptoms or intolerance. For feedback, it offers quick home remedies for relieving acute pain, guidance on managing symptoms, and recommendations for OTC medications. It may provide information on nearby healthcare facilities and contact details based on the patient's location.

EXAMPLE 3 Acute symptoms include acute headache, acute abdominal pain, high fever, severe bleeding, and fainting.

- The SAQS may provide questionnaires to support the assessment of diseases that require ongoing monitoring, such as chronic disease. The questionnaire responses should be stored with a timestamp to track changes and monitor the patient's condition over time.

EXAMPLE 4 Chronic diseases include diabetes, hypertension, asthma, arthritis, and depression.

- The SAQS may provide questionnaires to support the assessment of follow-up care and treatment.

NOTE Questionnaire covers the effectiveness and resolution of the symptoms from the use of the recommended prescription.

EXAMPLE 5 Follow-up care and treatment includes rehabilitation therapy, nutrition orders, post-surgery recovery, and medication adherence.

- The SAQS should provide security measures to protect questionnaires, responses, and feedback during interaction with the SAQS users.
- The SAQS should provide functions to interactively adjust the questionnaire content based on the response from the SAQS users.

EXAMPLE 6 In the smoking questionnaire, if the SAQS user indicates being a non-smoker, questionnaires about smoking become inactive or are omitted.

- The SAQS should provide user-friendly interfaces and seamless navigation that encourages regular engagement and a positive user experience.

The system's appeal should be strong enough to encourage regular user engagement. The collected user-specific health data remains meaningful and highly useful for various applications.

- The SAQS should support various types of input formats to accommodate different types of questionnaire responses.

EXAMPLE 7 Input format includes single selection, multiple selection, narrative text, scale ratings, yes/no options, date/time entries, dropdown menus, and sliders.

- The SAQS may guide how to handle incomplete or inaccurate user inputs to ensure data integrity.

EXAMPLE 8 SAQS users have the potential to mistype responses or misinterpret the questionnaire.

6.1.3 Storing user-specific health data

The following recommended functionality applies if the SAQS supports storing user-specific health data collected through interactions with questionnaires and responses.

- The SAQS should provide options for the user to choose whether to store the user-specific health data.

NOTE 1 The SAQS user can use the SAQS to obtain information about a particular disease.

- The SAQS should be able to support simple testing or verification for one-time users. In this case, the result should not be retained or stored.

The SAQS user should be informed that the information entered will not be stored. The user will need to re-type the same data when using the SAQS in the future.

- The SAQS should store the user-specific health data with consent from the SAQS user.

NOTE 2 The SAQS user can store the data to track the progression of the health condition.

- The SAQS user should be informed of the issues of privacy protection.
- The SAQS may provide recommendations for the optimal frequency and timing of usage to enhance user engagement and ensure information accuracy.
- The SAQS may use any telecommunication method, such as messaging, to send reminders to the SAQS user.
- The SAQS should consistently and historically manage questionnaires centred around the SAQS users.

EXAMPLE 1 For SAQS supporting smoking cessation, details such as the number of cigarettes smoked, the interval between smoking, and other related smoking behaviours are consistently recorded and stored. The SAQS changes the questionnaires interactively based on whether the SAQS user is adhering to the smoking cessation plan.

- The SAQS may store and manage the inputs from the SAQS user in a standardised format.

EXAMPLE 2 The standardised format includes HL7 FHIR, HL7 CDA, and ISO 13606.

- The SAQS should set the retention period for the questionnaire.

NOTE 3 Certain information can lose its significance after a certain period has elapsed. For example, travel records become irrelevant after a certain duration when dealing with infectious diseases.

- The SAQS should include a timestamp when storing data.

NOTE 4 Timestamps can be used for monitoring health progress.

- The SAQS may request permission from the SAQS user to access information relevant to the health concerns, such as family medical history, health check-up results, places visited, etc.

NOTE 5 The user can answer the questionnaire, or the SAQS can automatically import information from other systems.

6.1.4 Providing feedback

- The SAQS should provide personalised health-related recommendations.

NOTE Personalised health-related recommendations include dietary adjustment, exercise recommendations, smoking cessation, stress reduction, or chronic disease management.

- The SAQS should offer recommendations or suggestions on visits to the healthcare organisation.
- The SAQS may provide guidelines on the location of the healthcare organisation and what to expect during the visit.
- The SAQS may provide feedback by compiling information, including health monitoring data, medical history, and allergy information.

EXAMPLE 1 SAQS does not recommend hiking as a form of exercise to the patient with a fear of heights.

- The SAQS should integrate questionnaires and feedback from various SAQS resources enabling the SAQS users to receive advice from various healthcare professionals.
- The SAQS should be able to provide health-related feedback from the healthcare professionals.
- If the SAQS suspects specific diseases, the SAQS should provide recommended action for that disease and information on risk factors.

EXAMPLE 2 For infectious disease, outline direction for the patient and the close contacts, recommended self-isolation period, self-care advice during self-isolation, symptom relief, links to clinical assistance, etc.

6.2 Interface between SAQS application and SAQS

6.2.1 General

The following recommended functionality applies to the interaction between the SAQS application and SAQS.

6.2.2 Using user-specific health data

- The SAQS should inform the SAQS user of their rights regarding the ownership of their user-specific health data.
- The SAQS should provide a method for SAQS user to have full control over access to their health data, including the capability to grant or withdraw consent for sharing health data.
- The SAQS should not provide user-specific health data to SAQS applications without consent from the SAQS user.
- The SAQS should ensure the user health data is accurate and up-to-date.

NOTE 1 Providing accurate and up-to-date data is crucial for providing appropriate clinical care and avoiding potential clinical errors.

- The SAQS should provide relevant data protection mechanisms to support user privacy and confidentiality.

NOTE 2 There are regulations and standards that are compliant with jurisdiction, such as the Health Insurance Portability and Accountability Act (HIPAA), General Data Protection Regulation (GDPR), and Health Information Technology for Economic and Clinical Health (HITECH) Act.

- The SAQS should support integration with other healthcare systems using standardised protocols and data formats for interoperability.

EXAMPLE 1 The standardised protocol includes HL7 FHIR, IHE XDS.b, XDR, and XDM.

- The SAQS may integrate with EHRs to enhance the use of user-specific health data.
- The SAQS should support patient ID cross-referencing to ensure consistent and accurate sharing of user-specific health data across different platforms and healthcare service providers.

EXAMPLE 2 The SAQS uses MPI using IHE PIX, PDQ profiles.

- The SAQS should provide user-specific health data to SAQS applications that are relevant to patient care.
- The SAQS should enable care coordination by providing a comprehensive view of user-specific health data to the relevant healthcare service providers.
- The SAQS may combine other patient-related information to be used by the SAQS application.

EXAMPLE 3 Other patient-related information includes family history.

6.2.3 Using aggregated health data

The following guidelines apply if the SAQS supports statistical information utilising multiple user-specific health data.

- The SAQS should obtain consent from SAQS users when using their user-specific health data.
- The SAQS should support pseudonymisation and de-identification mechanisms for user-specific health data to ensure that aggregated health data cannot be traced back to individuals.

NOTE ISO 25237 can be adopted for pseudonymisation.

- The SAQS may support the analysis of aggregated data to identify trends to be used for public health strategies.
- The SAQS may use aggregated questionnaire responses based on demographics.
- The SAQS may use aggregated questionnaire responses on epidemiological data to track disease patterns and support public health.
- The SAQS may use aggregated questionnaire responses on lifestyle and behavioural factors.

EXAMPLE Lifestyle includes diet, exercise, sleep pattern, etc.

7 Recommended data elements for SAQS

7.1 General

The SAQS can provide questionnaires either upon request from a healthcare institution or healthcare provider for clinical purposes, or generated independently by the SAQS personalised for the patient. The content of the questionnaires depends on the clinical purposes and should be based on clinical information models such as ISO 13972. To ensure interoperability with other clinical systems, the questionnaires are delivered using HL7 FHIR questionnaire resources or HL7 CDA. An example of using HL7 FHIR questionnaire resources is in [Annex C](#).

This clause specifies the data elements exchanged by the components of the SAQS. The data elements described in this document are specialised for the SAQS. These include the questionnaires provided by the SAQS to the SAQS user, the questionnaire responses from the SAQS user to the SAQS, and the feedback from the SAQS to the SAQS user.

7.2 Data elements for questionnaires

7.2.1 Purpose of using SAQS

The self-assessment questionnaire may include the purpose of self-evaluation. The purposes include, but are not limited to, the following.

- Routine health management: SAQS users can use SAQS periodically to manage their health status. This can be done daily, weekly, or monthly. A “ROUTINE” may be assigned for this purpose.

EXAMPLE 1 Routine health management includes alcohol consumption, smoking, obesity, exercise, and nutrition.

EXAMPLE 2 In HL7 FHIR, “Questionnaire – purpose field” is assigned as “ROUTINE”. In ISO 13606, “Self-reported data – Description – Purpose” is assigned as “ROUTINE”, while “Self-reported data – Description – Keywords” is assigned as “questionnaire”.

- Specific symptom concern: SAQS users can use the SAQS when experiencing a sudden onset of specific symptoms before seeking healthcare services. The SAQS can provide health-related recommendations and feedback. “COMPLAINT” may be assigned for this purpose.