

ISO/TC 304 "Healthcare organization management"

Secretariat: ANSI

Committee Manager: Webster Lee Mr



Text for CD Ballot ISO 6028 Self-symptom checker

| Document type | Related content | Document date | Expected action |
|--------------------|---------------------------------------|---------------|---------------------------|
| | Project: ISO/CD 6028 | | |
| Ballot / Reference | Ballot: ISO/CD 6028 - Functional | 2021 11 16 | VOTE by 2022-01-12 |
| document | requirements for Self-symptom checker | | VOTE by 2022-01-12 |
| | (restricted access) | | |

ISO CD 6028:####(X)

ISO TC 304/WG 4

Secretariat: ANSI

Pandemic Response - Functional requirements for Self-symptom checker

CD stage

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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 304, Healthcare Organization Management.

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

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Introduction

On 3rd of March 2020, the WHO declared COVID-19 as a pandemic which has infected as of July 2020 more than 13 million people worldwide. It has devastated existing medical infrastructures in an alarming number of countries, as well as induced massive unemployment shaking the underpinnings of social and economic stability in the infected countries.

A self-symptom checker, hereinafter referred to as the Checker, for a pandemic enables individuals to record and report pandemic-related symptoms, to provide information on screening test sites and to offer consultation channels that link them to health experts for disease spread containment.

The Checker is qualified to act as a frontline defence that enables isolation and quarantine of potentially infected individuals.

This standard enables interested parties to build fully functioning mobile apps for individuals to monitor potential infection and for health authorities to respond as quickly as possible to those who may be infected. This standard is directly applicable for when continuous symptom checking is of critical import during a pandemic, from points of entry from overseas onward to quarantine and afterwards. This makes possible a timely response of available health services to those exhibiting symptoms; thus, effectively preventing disease spread.

Pandemic Response — Functional requirements for Self-symptom checker

1 Scope

This International Standard specifies functional requirements for a self-initiated disease symptom checker to be used for early screening and control of pandemics such as COVID-19.

There are four functional components specified in the standard: 1) self-registration; 2) symptom checking; 3) guidance on screening stations; and 4) health consultation.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

There are no normative references in this document.

3 Terms and definitions

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

3.1

confirmed case

person who has been confirmed to be infected with the infectious disease pathogen according to the diagnostic testing standard, regardless of clinical manifestations

[SOURCE: Korea Centers for Disease Control and Prevention [1]]

3.2

coronavirus

large family of viruses which may cause illness in animals or humans. In humans, several coronaviruses are known to cause respi ratory infections ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The most recently discovered coronavirus causes coronavirus disease COVID-19

[SOURCE: World Health Organization [2]]

3.3

COVID-19

infectious disease caused by the most recently discovered *coronavirus (3.2)*. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019

[SOURCE: World Health Organization [2]]

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3.4

isolation

separates sick people with a contagious disease from people who are not sick

[SOURCE: Centers for Disease Control and Prevention [3]]

3.5

pandemic

worldwide spread of a disease

[SOURCE: ISO PAS 45005:2020(en), 3.5 [4]]

3.6

quarantine

separates and restricts the movement of people who were exposed to a contagious disease to see if they become sick. These people may have been exposed to a disease and do not know it, or they may have the disease but do not show symptoms

[SOURCE: Centers for Disease Control and Prevention [3]]

3.7

reference architecture

list of functions and some indication of their interfaces (or APIs) and interactions with each other and with functions located outside of the scope of the reference architecture

[SOURCE: ISO/TR 24529:2008(en), 3.8^[6]]

3.8

self-symptom checker

tool that enables individuals to record and report pandemic-related symptoms, provide information on screening test sites, and offer consultation channels that link them to health experts for disease spread containment

[SOURCE: Korea Centers for Disease Control and Prevention, Self-symptom checker ^[7]]

4 Background

In 2005, the IHR declared that a global network of national health systems should be established that would facilitate coordinated defence against public health threats and that could ensure the security of international public health. Four areas of work to achieve the envisioned network have been established: 1) strengthening national prevention capacity 2) introduction of global alert & response mechanisms, 3) containment of specific threats, and 4) travel & transports.

With the first case reported on December 31, 2019, the WHO declared COVID-19 as a pandemic in March 2021. The lack of effective vaccines and treatment created a crisis that has seen a significant number of confirmed cases and deaths worldwide. The pandemic has imposed enormous pressure on, and paralyzed in some countries, public health systems, resulting in shortages of Personal Protective Equipments, ECMO, hospital beds and medical personnel.

Each country has implemented various measures to block infection spread at entry points to the country, which has required tremendous resources. It exacerbates the problem if there are many asymptomatic cases and that the disease has long incubation periods, which inevitably puts to test the administrative and public health faculties of the country.

To build or enhance the capacity to monitor and manage the spread of the disease at the points of entry and onward, the following considerations, at a minimum, should be taken:

- What efficient means are available to maintain timely communication with visitors/entrants?

It is an onerous task to contact entrants, due to unanswered calls and/or phones being offline. This incurs delayed quarantine and extra personnel to manage connection with entrants.

- What means are available to monitor the entrants' health status?

An entrant is subject to self-quarantine at a designated or self-reported residence for monitoring for a period set by the relevant health authorities (e.g., WHO or local authorities) of each country.

- What information technology (IT) and infrastructure are available at hand.

Technology can enhance our response to pandemic management in a very significant way. For example, it is possible for disease-pertinent symptoms of an entrant to emerge after clearance from the point of entry due to a latent state of the virus. With the help of, for example, a smart phone-based application, it is made possible to track, monitor and manage the health of the entrant.

Information technology-based applications such as the Checker described in this document increases the efficiency of disease containment. The Checker is designed to be applicable to a pandemic or epidemic.

5 Reference Architecture of the Checker

The reference architecture (Figure 1) describes the Checker in terms of a high-level set of functional components. Each functional component comprises a set of functions, each of which executes specific tasks (Figure 2).

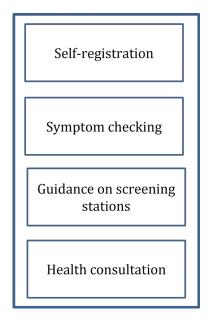


Figure 1. Functional components

Self-registration: after the Checker has been installed on the smartphone, tablet or personal computer of the individual, he/she shall register himself/herself to use the Checker.

Symptom checking: the individual shall record and report through the Checker any symptoms he/she has experienced.

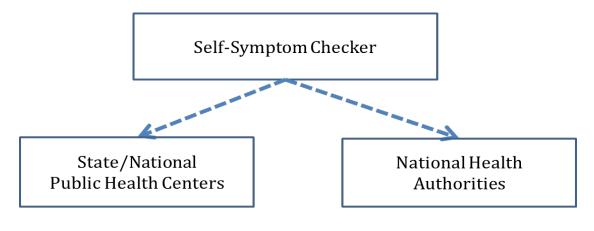
Guidance on screening stations: the individual may at any time search and contact nearby screening test sites, locations of which are determined by the GPS service of the device owned by the individual.

Health consultation: the individual may contact health experts through available communication channels, such as chatbot, mobile messaging application, or email.

6 External services/applications

The Checker is the central application upon which optional and/or external services and applications can operate (Figure 2).

For example, national health authorities, subject to user consensus, may gain access to demographic and symptomatic data about the individuals who have exhibited potential symptoms, and reach out pre-emptively to them for test and quarantine. State or national health centres may receive information about the individuals who have been exhibiting symptoms for 2 or more days consecutively and instruct them to visit a screening test site.



--->: Optional data link to external services and/or applications

Figure 2. External services and applications

7 Functional components of the Checker

7.1 Major components

This section serves as an introduction to the major functional components of the Checker, all of which are descried in greater detail in their relevant sub-sections. The current Checker defines four functional components: 1) self-registration; 2) symptom checking; 3) guidance on screening test stations; and 4) health consultation.

7.1.1 Self-registration

The Self-registration component is a required component that an individual uses to register himself/herself to the Checker. It principally initializes the Checker by validating user credentials. The sub-components are shown in Figure 3.

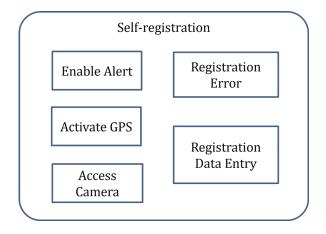


Figure 3. Self-registration component

7.1.2 Enable alert

The Enable Alert sub-component asks the individual to turn on the alerting function. Alerts including sounds and icons may be included in alert messages. The individual should be able to configure this feature as he/she sees fit. An example screenshot for the sub-component is shown in Figure 4.



Figure 4. Enable Alert

7.1.3 Activate GPS

The Activate GPS sub-component turns on the GPS service on the individual's device. Figure 5 shows an exemplary Enable Alert component for iOS and Android.

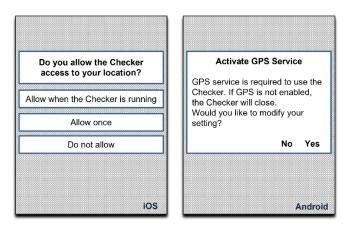


Figure 5. Activate GPS

7.1.4 Access Camera

The Access Camera sub-component enables the individual to take a picture of his or her ID such as passport number, social insurance number (SIN) or social security number (SSN).

7.1.5 Registration Error

The Registration Error sub-component enforces the user data requirements pertinent to the streamlined use of the Checker. Registration errors can also occur when entered user data are not properly handled, as in a network connection error that occurs while GPS data being transmitted to the server. When the required data elements, such as an identification number, are not entered by the individual, relevant registration error messages are issued to the individual.

7.1.6 Registration Data Entry

The Registration Data Entry sub-component has four sub-components (Figure 6).



Figure 6. Registration Data Entry component

7.1.6.1 ID Validation

The ID Validation sub-component validates user identification. Any unique identification can be employed, such as a social insurance number (SSN), social security number (SSN), a passport number. If technology permits, one may choose to use a photocopy of the user ID card. Validating identification requires a level of integration with external databases such as a national identification database. Hence, it may not be possible to validate the use identification number at the moment the individual enters it. Figure 7 shows a typical flow of activities involved in validating identification. Please note that the server in the figure has access to the collection of identification numbers. The format and location of the collection is outside the scope of this document.

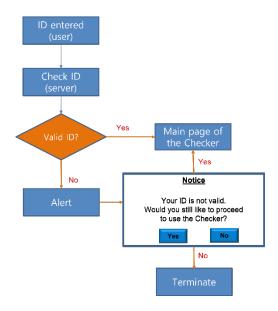


Figure 7. ID validation

7.1.6.2 Phone Number Verification

The Phone Number Verification sub-component verifies the user-entered phone number by calling it using cellular network, if available.

7.1.6.3 Visited Country

The Visited Country sub-component enables the individual to choose from a list of countries the countries he/she has visited 14 days prior to the entry. Multiple countries may be selected (Figure 8).

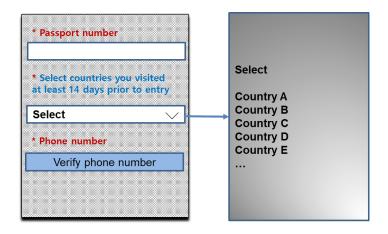


Figure 8. Countries visited prior to entry

7.1.7 Data elements for Self-registration component

Table 1 shows the minimum set of required and optional data elements for the Self-registration component.

| Element | Туре | Status | Definition |
|--------------------------|-------------------------------|----------|--|
| Identification number | string | required | A unique identification number; for example, a passport number, a social insurance number (SIN), social security number (SSN) |
| Name | string | required | Username |
| Phone number | number | required | Phone number |
| Address | string | optional | Local address |
| Visited countries | String (list of countries) | optional | Countries visited or lived 14 days prior to registration |

Table 1 – Data Elements for Self-registration

7.2 Symptom checking

The Symptom Checking functional component (Figure 9) provides capacity for the individual to record and report any symptoms related to the disease at hand. Please note that the symptoms used in this document are not exhaustive and thus may be extended or reduced as appropriate for the disease. Four common and symptoms are used in the document: fever, cough, sore throat, and dyspnea (shortness of breath).

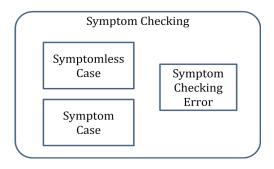


Figure 9. Symptom checking

7.2.1 Asymptomatic case

With the Asymptomatic Case sub-component, the individual can report that he/she has experienced no significant symptoms for the day, which is expressed by clicking the "No" buttons for each symptom (Figure 10). Alternatively, the individual may opt to check the "No symptom' checkbox for the same effect.

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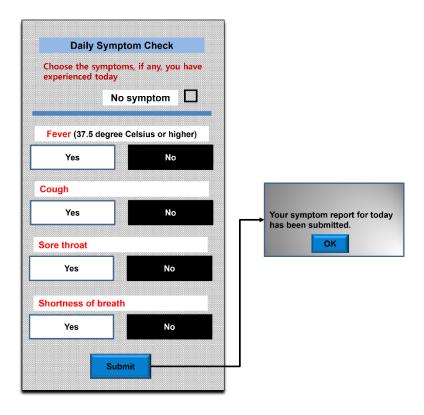


Figure 10. Asymptomatic case

7.2.2 Symptom case

The Symptom Case sub-component (Figure 11) is used to record and report any exhibiting symptoms the individual has experienced for the day. When a symptom, the individual is advised to call a help line, if available, to consult with health experts. The call function in the individual's device is activated when the individual presses the 'ok' button to make the call.

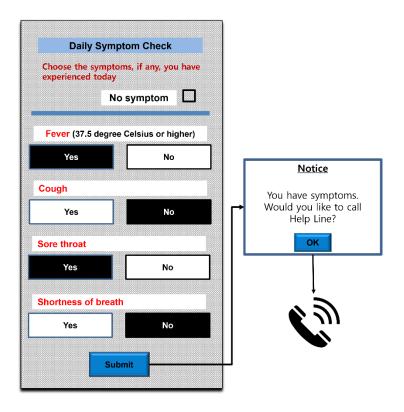


Figure 11. Symptom case

7.2.3 Symptom checking error

The Symptom Checking Error sub-component checks the integrity and correctness of the data entered by the individual when he/she uses the Symptom Checking component. For example, it issues an alert message when the individual neither chooses a symptom nor checks off the "No symptom" checkbox.

7.2.4 Data elements for Symptom-checking component

Table 2 shows the minimum set of required and optional data elements for the Symptom-checking component.

| Example element | Туре | Status | Definition |
|---------------------|---------|----------|--|
| fever | Boolean | optional | A binary value of yes or no. When the temperature of the individual reaches over a specific temperature (e.g., 37.3 degree Celsius or higher), the value is set to yes; otherwise, no. |
| cough | Boolean | optional | A binary of value of yes or no. When the individual experiences coughing, the value is set to yes; otherwise, no. |
| shortness_of_breath | Boolean | optional | A binary value of yes or no. When the individual has trouble in breathing, the |

| | | | value is set to yes; otherwise, no. |
|-------------|---------|----------|---|
| sore_throat | Boolean | optional | A binary value of yes or no. When the individual has a sore throat, the value is set to yes; otherwise, no. |
| no_symptom | Boolean | optional | A binary value of yes or no. When the individual shows none of the symptoms (fever, cough, shortness of breath, and sore throat), the value is set to yes; otherwise, no. When the individual experiences any symptom, the default value of this element should be set to 'no'. |

Table 2 – Data Elements for Symptom-checking

7.3 Guidance on screening stations

The Guidance on Screening Stations functional component (Figure 12) uses the GPS service of the individual's device to search and list a list of nearby screening stations in operation. The screening stations DB holds available screening test sites in the country. The DB is internally stored in the smartphone during installation of the checker and be updated whenever an update to the DB is made.

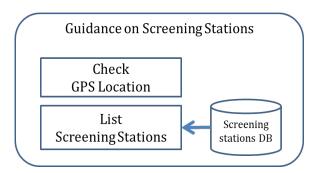


Figure 12. Guidance on screening stations

7.3.1 Check GPS location

The Check GPS Location sub-component activates the GPS service of the individual's device and retrieves his/her current location.

7.3.2 List screening stations

The List Screening Stations sub-component retrieves a list of nearby screening stations. The individual may also search screening stations based on keyword(s) entered (Figure 13).

| ScreeningStations | | | | |
|-------------------|-------|----------|---------------------------------|------------------|
| Seoul | | | Search | List All |
| # | City | District | Name | Tel |
| 1 | Seoul | Kangnam | Kangnam Public Health Center | 02-3423- 6705 |
| 2 | Seoul | Kangnam | Samsung Seoul Hospital | 02-3410- 2114 |
| 3 | Seoul | Kangnam | Yeonsei Severance Hospital | 02-2019- 3114 |

Figure 13. Display screening stations

7.3.3 Data elements for Guidance on screening stations component

Table 3 shows the minimum set of required and optional data elements for the Guidance on screening stations component.

| Element | Туре | Status | Definition |
|----------------|--------|----------|--|
| search_keyword | string | optional | A search keyword to find screening stations. |

7.4 Health consultation

The Health Consultation functional component (Figure 14) connects the individual to health experts online for consultation. The communication methods vary depending on the technology available, ranging from messaging app, email or chatbot.

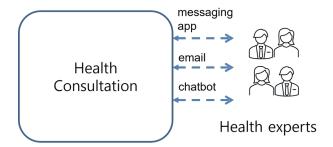


Figure 14. Health consultation

7.5 Application update

Application updates may happen over the course of the lifetime of the Checker. Installation of the mostupdate version of the Checker should incur no significant effect on the core functionalities of the Checker. There should be either a central or distributed server site where the Checker is connected to the most up-todate version of the application. Figure 15 shows example activity flows in which smartphone-based Checker is updated. The figure does not address any network errors that may occur during application updates, an issue that is not within the scope of this document.

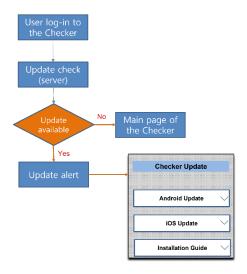


Figure 15. Application update

7.6 Termination of the use of the Checker

If the Checker is used by an individual who is quarantined for a specific period due to local quarantine requirements (i.e., 14 days after entry into a country), the Checker notifies the individual of the termination of the quarantine (Figure 16).

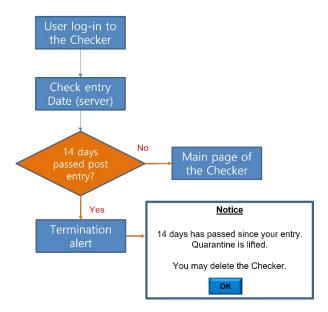


Figure 16. Post quarantine

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