Infermedica

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# Infermedica Triage

**(the device is also available under the following names: Symptom Checker, Healthform, Symptomate)**

**Instruction for use**

**ver. 2.**

Manufacturer:
Infermedica Sp. z o.o.
ul. Plac Solny 14/3
50-062 Wrocław
Poland

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# 1. Product information

## 1.1. Device name and classification

Infermedica Triage, also offered under the names: Symptom Checker, Healthform, is a piece of software registered in the European Union, meeting the requirements of the Council Directive No. 92/42/EEC of 14th June 1993 on medical devices and the Regulation of the European Parliament and of the Council (EU) 2017/745 of 5th April 2017 on medical devices. The software is also registered as a medical device in: Brazil, Great Britain and Ukraine.

It is a piece of software regulated by the Food and Drug Administration (FDA) as a "general wellness" product in the USA, for which FDA has not yet introduced any registration requirements.

The software is not a registered medical device in other countries that require registration, such as Canada or Australia, where this software should not be used.

Symptomate is a software version, registered as class I medical device in the European Union. It can be used freely in European Union member states and in Turkey.

Infermedica Triage, available in the "Symptomate" version, can be used in countries that do not require registering software as a medical device, such as Mexico and United Arab Emirates.

The software is also provided through clients of Infermedica using the iframe technology, i.e., a solution that allows for applications to be displayed to end users at the websites of clients.
The device version seen by the user may feature minor differences from the one described in this document. Whether a given variety features the functions described below depends on the character of cooperation between Infermedica Sp. z o.o., the

medical device manufacturer, and their client, i.e. the entity providing the application to you directly.  All the application versions have been tested in terms of security and provide the same quality of information obtained.

## 1.2. Intended use

The application is intended for conducting preliminary medical interviews, analysing the symptoms indicated by the user and then estimating preliminarily the probability of occurrence of specific diseases and providing recommendations for further procedure. The application is intended for supporting one's sense of well-being and promoting a healthy lifestyle.

## 1.3. User

The software can be used by any adult, without special qualifications or training. The application guides the user intuitively through the preliminary interview and provides them with necessary explanations, instructions and information required for conducting the interview correctly.

The user may conduct an interview for:

- themselves,
- another adult at their request,
- a child below the age of 18 for whom they are responsible under law

## 1.4. Characteristics of device functioning

The main function of the application is the preliminary medical interview during which the user answers questions regarding their sense of well-being and symptoms experienced. The answers provided
are analysed on a current basis. Within a few minutes the tool allows conducting the analysis of symptoms and notifies of their causes, severity and recommended level of medical care.

1. The application asks the user to provide basic information, such as age, sex, risk factors (e.g. bad habits or general health condition) and symptoms noticed.
2. On the basis of these answers, the preliminary medical interview asks questions adjusted to the user's case. These questions regard the intensity of symptoms, their occurrence and other, related symptoms.
3. The interview concludes with presentation of symptom analysis results and recommendation of the course of further procedure.
4. The decision regarding further procedure is left to the user.

Remember: an interview cannot replace a diagnosis. Please familiarise yourself with the warnings described in Item 1.9.

## 1.5. Expected clinical advantages

On the basis of the information provided by the user, the application provides a general assessment of health condition and recommendations for improving the sense of well-being. The application also contains general educational and informative content regarding health and healthy lifestyle.

## 1.6. Contraindications for use

**The user should not use the application when a sudden health hazard is suspected.** In such a situation, the user should immediately take action in order to obtain, as soon as

possible, medical assistance and commencement of rescue actions and treatment, e.g. by calling the emergency services or going to a hospital emergency room.

**What is sudden health hazard condition?**

It is a conditions consisting in sudden or anticipated imminent symptoms of worsening of health, the direct consequences of which may be a severe damage to bodily functions, body injury or loss of life, requiring immediate medical emergency actions and treatment to be commenced.

**Examples of sudden health hazard conditions:**

- consciousness disorders (e.g. loss of consciousness, sudden occurrence of attention disorder, cognitive process disorders, suddenly reduced capability of recognising the surroundings),
- convulsions (suspicion of epileptic seizure),
- slurred, incoherent speech, asymmetry of facial mimicry, the strongest headache ever experience, double vision, sudden paralysis, weakness, numbing of extremities (suspected stroke)
- sudden sharp pain in the chest, increased during exertion (suspected heart attack),
- cardiac rhythm disorders (sudden appearance and persistence of irregular heart palpitation in the chest),
- increased dyspnoea (sudden appearance and aggravation of breathing difficulties)
- acute stomach ache (sudden appearance and aggravation of pain)
- persistent vomiting (no possibility of oral rehydration and progressing weakness and dehydration),
- acute and intensified allergic reactions (rash, swelling, dyspnoea) resulting from taking a medicine or being bitten or stung by venomous animals,
- severe injuries of the body resulting from an accident, e.g., crushing, falling from height, suspected bone fractures, injuries of a lower extremity that make moving one one's own impossible,
- severe bleeding that is difficult to staunch, e.g., nosebleed, bleeding from alimentary tract (hematemesis, tarry stools), bleeding from reproductive tract, bleeding resulting from an injury,

- extensive wound resulting from an injury,
- extensive burns,
- rapidly progressing birth,
- poisoning with medicines, chemical agents or vapours,
- heatstroke (sudden increase in body temperature above 40°C, e.g., caused by becoming overheated in the sun)
- chilling of the body (suspected hypothermia, body temperature falling below 35°C),
- electric shock,
- submersion or drowning,
- aggression caused by mental illness,
- suicide attempt.

Next to the examples listed above, in any other situation where there is a suspicion of a sudden health hazard condition it is necessary to stop using the application and take immediate action aiming at obtaining appropriate medical help.

## 1.7. Technical requirements regarding product use

### Hardware requirements

The software works in web browsers on devices (computer, phone, tablet) that are connected to the Internet. Below you can find a list of minimum hardware requirements:

- Permanent connection to the Internet.
- Web browser:
    - Firefox - 5 last versions (counting from the most recent stable version),
    - Google Chrome - 5 last versions (counting from the most recent stable version),
    - Opera - 5 last versions (counting from the most recent stable version),
    - Safari - browser versions published within the last 2 years,
    - Samsung Internet - browser versions published within the last 2 years,

- Edge - browser versions published within the last 2 years.

PLEASE NOTE: The application does not run in the Internet Explorer browser.

## Installation

The application is available through two ways: web browsers or mobile applications.

In the case of web browsers it does not need to be installed. The user can use the application directly in the browser window.

In the case of mobile applications it is necessarily to install a given application. The application can be installed via App Store or Google Play services. The installation process should be carried out in line with the terms and conditions of a given service.

In the case of using an application through the Infermedica system of the client, an extra step may be necessary - signing in to the client's system. In such an event it is necessary to follow the instructions included there.

## 1.8. Symbols and information included on the label

| | |
|---|---|
|  | Medical Device |
|  | Manufacturer |
| 05 – 2022 | Application release date |
|  | Please familiarise yourself with the instruction for use prior to using the device |
|  | The application meets the requirements of the Directive 93/42/EEC regarding medical devices. |
|  | Warnings |
|  | Unique Device Identifier - Unique device identification code |

## 1.9. Warnings and information on safety measures

The application should not be used for medical purposes such as detecting, diagnosing, preventing, monitoring, managing, treating or mitigating any diseases or injuries.

No health-related information provided by this software
should be treated as medical advice.

Application limitations:

- The applications is not related to any medical system and does not impose any course of procedure on the user.
- The product is not intended as replacement for a doctor's opinion.
- The application is not intended as diagnostic support or medical segregation (triage) support for health care workers, nor is it a substitute for health care workers.
- The results of the interview, containing the recommendations regarding general health condition or lifestyle are of general nature, do not refer to the specific clinical situation of the user and are provided for information purposes only.
- It is expected that the users take advantage of all the reasonable decision making possibilities in order to arrive at an independent final decision regarding their health condition.

### 1.10. Consult a doctor

In any case when there is a suspicion of sudden health hazard condition regarding the user it is necessary to stop using the application and seek medical help immediately.

In cases that are not of emergency nature, the application can be used for preparing oneself
for the visit and improving the communication with the doctor.

## 2. Contact with the manufacturer

### 2.1. Reporting errors and complaints

- E-mail for contact purposes: support@infermedica.com
- Subject: Interview ID number (e.g.: CC00116842541)

- Content:
    - Problem description
    - Application version
    - Contact data, if the reporting party expects a response

In the event of any critical problems (where the functioning of the application may cause hazard to life or health of the users) the user should sent a report directly to the President of the Office for Registration of Medicinal Products, Medical Devices and Biocides via e-mail (address: incydenty@urpl.gov.pl), fax (No. +32 22 492 11 29), registered mail or courier service (Al. Jerozolimskie 181c, 02-222 Warszawa, Poland).

## 2.2. Opinions and suggestions

Any opinions and suggestions regarding new functions can be sent via e-mail to the following address: support@infermedica.com.