

# FR-03-01-05 Instructions for use Medical Guidance Platform

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# Instructions for Use

# Infermedica Medical Guidance Platform

Revision 1.

This version of the Instructions for Use applies to software versions 6.5 and later

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Manufacturer:

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# 1. Product information

## 1.1. Device name and classification

The Medical Guidance Platform is a modular Software as a Medical Device (SaMD). It collects and analyzes patient symptoms and medical history through a web application and API to provide information for pre-diagnostic decision-making. The application estimates possible conditions with associated probabilities and evaluates the necessity and urgency of medical attention using predictive AI algorithms.

The platform accommodates both adult and pediatric populations, allowing data entry on behalf of others as well as directly by yourself. It is intended for use by healthcare professionals and laypersons.

The platform enables you to collect detailed medical history, including chronic conditions, recent hospitalizations, and current medications, which can be forwarded to Electronic Health Record (EHR) systems before consultations with a clinician. It can also provide follow-up assessments to monitor your symptom progression. The platform supports your self-management by offering educational materials about symptoms and potential health condition mitigations.

The data exchange between the Infermedica Medical Guidance Platform and you involves several steps. First, you engage with the user interface. You input your personal health information, which the algorithm uses to ask relevant questions and analyze the data to estimate the likelihood of certain conditions. Based on this analysis, the device determines the urgency and appropriate level of care needed, recommending one of five levels of care:

Emergency (ambulance)	The reported symptoms are very serious and the patient may require emergency care. The patient should call an ambulance right now.
Emergency (ED, emergency department)	The reported evidence appears serious and the patient should go to an ED. If the patient can't get to the nearest ED, they should call an ambulance.

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Consultation 24	The patient should see a doctor within 24 hours. If the symptoms suddenly get worse, they should go to the nearest ED.
Consultation	The patient may require medical evaluation and may need to schedule an appointment with a doctor. If the symptoms get worse, they should see a doctor immediately.
Self care	The symptoms of the patient do not require medical care and they resolve on their own. The patient can try to manage the condition with home methods. If symptoms get worse or new symptoms appear, the patient should consult a doctor immediately.

The MGP offers additional functionalities that become accessible after the initial assessment is completed, namely Intake and Follow-Up. You can enter your medical history details, such as chronic conditions, specialist care, recent hospitalizations, existing medications, and allergies through the Intake flow. This information is then forwarded to EHR systems prior to a clinician consultation.

You can also request automated Follow-Up via the MGP; if you enroll in this service, you will receive a follow-up assessment which assesses the progress of your reported symptoms and captures new symptoms. Following the assessment, you can receive the recommended level of medical care, the list of possible conditions, and educational materials on the conditions provided.

Suitable for use in various settings, including clinics, hospitals, nursing facilities, help-lines, and home environments. This software is not intended for emergency situations or ongoing monitoring of chronic conditions without clinician oversight. It is designed to aid, but not replace, professional medical judgment.

The MGP App is designed to operate independently without requiring additional physical accessories, devices, or non-device products. Its autonomous design ensures functionality without external integrations. The software only needs a standard personal computer (PC) and Internet access to function effectively, making it accessible and user-friendly. There is no specific hardware required exclusively for this product, as it utilizes common technological platforms to facilitate easy integration into existing workflows without specialized equipment.

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The version of the Platform you are using may differ slightly from the description in this document. The features you see depend on the partnership between Infermedica and the provider offering it to you. Rest assured, all versions are thoroughly tested for safety and deliver high-quality health information.

## 1.2. Intended purpose

The MGP collects and analyzes patient symptoms and medical history through a web application and API to provide information for pre-diagnostic decision-making. The application estimates possible conditions with associated probabilities and evaluates the necessity and urgency of medical attention using predictive AI algorithms.

The platform accommodates both adult and pediatric populations, allowing data entry on behalf of others as well as directly by users themselves. It is intended for use by healthcare professionals and laypersons.

The platform enables the collection of basic medical history, including chronic conditions, recent hospitalizations, and current medications, which can be forwarded to EHR systems before consultations with a clinician. It can also provide follow-up assessments to monitor a patient's symptom progression. The platform supports patient self-management by offering educational materials about symptoms and potential health condition mitigations.

Suitable for use in various settings, including clinics, nursing facilities, help-lines, and home environments.

This software is not intended for emergency situations or ongoing monitoring of chronic conditions without clinician oversight. It is designed to aid, but not replace, professional medical judgment.

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# 2. Use specification

## 2.1. What can I use the Infermedica MGP for?

You can use the Platform to:

- assess initial symptoms
- get the list of the most probable conditions
- learn recommended care level (triage level)
- learn recommended specialist type
- learn recommended visit type
- learn more about the conditions and common care methods
- note medical history and prepare before a visit
- check progression of symptoms in time

## 2.2. How can I access the Infermedica MGP?

You can access the Infermedica MGP by various touchpoints, incl. webpages, mobile apps, chatbots, call centers, delivered to you by the provider of services you are using. The mobile version is available for download from the App Store or Google Play Store.

## 2.3. Who can use the Infermedica MGP?

The software can be used by any adult patient or an adult caregiver, without special qualifications or training. The intended patient population for the MGP includes children from birth to adulthood and adults aged 18 to 120 years old across diverse demographic and socioeconomic backgrounds. The software device is intended for users with varying levels of health literacy (at least 7-8 grade reading level) and is accessible to those familiar with basic smartphone or computer use. The MGP supports 24 different language users. The design ensures compliance with accessibility standards to serve patients with some disabilities effectively including visual or hearing impairments by compliance with accessibility WCAG (Web Content Accessibility Guidelines). Access to the electronic device is necessary, and a stable Internet is recommended for optimal functionality.

The user may conduct an interview for:

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Adult individuals for themselves, who are legally considered adults and are able to understand and respond to the questions posed by the MGP. This group is expected to be capable of conducting the interview autonomously, accurately reporting their symptoms, and understanding the guidance provided. Only in this case is the user and the patient the same person.

Caregivers of Adult Patients: These are individuals who may assist adult patients unable to use the software device themselves, due to physical or cognitive limitations. Caregivers can use MGP on behalf of the adult patients they are caring for.

Parents and/or Guardians of Minors: This group includes adults who are responsible for children under the majority age. Children cannot use MGP independently although they are included in the intended patient population.

The software can also be used by healthcare professionals with an officially recognized license to practice.

## 2.4. Who should not use the Infermedica MGP?

Do not use the Platform if:

- you are experiencing a medical emergency, you should not use the Infermedica MGP.
- you struggle to understand the questions in the symptom assessment – for example, if you do not have the required language skills or if your consciousness is impaired due to illness or intoxication.

People under the age of 18 are not allowed to use the Infermedica MGP themselves, but their legal guardian or a healthcare professional with an active license to practice can complete an assessment on their behalf.

## 3. The intended patient population

Infermedica MGP is:

- Suitable to assess health of children and adults from birth to 120 years old.

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- Suitable for people from various demographic and socioeconomic backgrounds from Western World Countries.
- For users with at least a 12-14 y.o. reading skills.
- Accessible to those who can use a smartphone or computer.
- Available in over 24 languages
- Designed to be accessible to people with disabilities, including those with visual or hearing impairments, following the Web Content Accessibility Guidelines (WCAG).

## 4. Device performance characteristic

The Platform uses an extensive Medical Knowledge Base that contains over 850 conditions that can be associated with declared symptoms and risk factors. The medical content is constantly being expanded with new medical concepts - symptoms, conditions, and risk factors.

### Adult Medical Content

Medical content	LINK
<b>Adult conditions</b> available in the medical knowledge base.	<a href="#">Adult conditions</a>
<b>Adult medical symptoms and signs</b> available in the medical knowledge base	<a href="#">Adult symptoms</a>
<b>Adult risk factors</b> available in the medical knowledge base	<a href="#">Adult risk factors</a>

### Pediatric Medical Content

Medical content	LINK
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<b>Pediatric conditions</b> available in the medical knowledge base.	<b>Pediatrics conditions</b>
<b>Pediatric medical symptoms and signs</b> available in the medical knowledge base	<b>Pediatrics symptoms</b>
<b>Pediatric risk factors</b> available in the medical knowledge base.	<b>Pediatrics risk factors</b>

The app guides you through a series of questions based on your signs and symptoms. Your responses help the MGP identify possible causes for your health concern. When the assessment is complete, you will receive your results, including a list of the most likely causes and a recommendation for the level of care you should seek. You can download the assessment results as a PDF document.

## 4.1. Technical Requirements regarding product use

### 4.1.1. Hardware requirements

The software works in web browsers on devices (computer, phone, tablet) that are connected to the Internet. 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.

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PLEASE NOTE: The application does not run in the Internet Explorer browser. The requirements might change depending on your service provider.

### **4.1.2. Installation**

The application can be installed through the App Store or Google Play services. The installation process should be conducted according to the terms and conditions of the respective service.

When using an application via Infermedica's system embedded on the client's website, an additional step may be needed: signing into the client's system. In this case, it is essential to adhere to the instructions provided.

### **4.1.3. IT Network Characteristics**

To ensure the smooth, secure functioning of the software, certain network conditions need to be met including:

- The internet connection should be stable and reliable
- The speed of the internet should be fast enough to send and receive information quickly, without any waiting or unexpected pauses.
- The time it takes for the software to respond to inputs (like clicking a button) should be very short, allowing users to have a conversation or get information without delays.

### **4.1.4. IT Security Measures**

To keep user's health information safe, the software includes several security features:

- Only people who are supposed to use the software can get in.
- Any information that goes in or out of the software is scrambled using special codes that are very hard to break. This keeps the user's data private and unchanged.
- The network itself is guarded by digital walls that keep out intruders and threats from the internet.

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- Software regularly gets updates and fixes to close any security gaps

## 4.2. Triage recommendations

Medical Guidance Platform provides five different levels of care recommendations based on the severity of symptoms and the urgency of medical attention required. Each level is designed to guide you towards the most appropriate course of action, ensuring timely and effective care while minimizing unnecessary medical visits.

### 5 levels of triage / care level recommendations:

Call an ambulance	Your symptoms are very serious, and you may require emergency care. Do not delay. Call an ambulance right now.
Go to the nearest emergency department	Your symptoms are worrisome and you may require emergency care. If you can't get to an emergency department, please call an ambulance.
Consult a doctor within 24 hours	Your symptoms may require prompt medical evaluation. If your symptoms suddenly get worse, go to the nearest emergency department.
Consult a doctor	Your symptoms may require medical evaluation. Schedule an appointment with your doctor. If your symptoms get worse, see a doctor immediately.
Self-care may be enough	Usually, symptoms such as these do not require medical care and they resolve on their own. You can try to manage your condition with home methods. If your symptoms get worse or new symptoms appear, consult a doctor immediately.

# 5. User safety

## 5.1. Software limitation

- The application does not replace a medical diagnosis made by a healthcare professional and it does not substitute professional medical advice.
- The accuracy of the assessment relies on providing detailed initial symptoms and on answering all questions precisely and truthfully. The initial symptoms provided should represent the main and most concerning issues for the user and should be as comprehensive as possible. False or inaccurate answers compromise the reliability of the assessment.
- The assessment is no longer valid if the user's health situation changes, for example, if new symptoms appear.
- The platform is not suitable for individuals with severe cognitive or learning impairments unless they have assistance.
- Children cannot use the platform independently, even though they are part of the intended patient population.
- The platform is not designed to assess multiple, separate health problems in one session.
- The platform is not intended for ongoing monitoring of chronic or pre-existing conditions.
- The MGP provides advice based on the latest evidence, but it may not cover all individual health aspects or symptoms, even for serious illnesses. The possible condition list at the end of an assessment is not exhaustive.
- The platform's features may vary depending on its configuration to meet specific use cases or the needs of different user groups.

## 5.2. When should you consult a healthcare professional?

Users should consult a healthcare professional in the following circumstances:

- If the symptoms worsen at any time or if new symptoms appear

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- If the symptoms continue despite following recommended care pathways, or if the user does not see an improvement in their condition within a reasonable amount of time suggested by the software.
- If experiencing symptoms that could indicate a serious or life-threatening condition, described in item 5.6 Contraindications for use
- If the user is unsure about the interpretation of their symptoms or the recommendations provided by the software.
- If the user has pre-existing health conditions that may complicate their situation or affect the triage outcome.
- If there are questions or concerns about medications, especially if new symptoms arise that may be related to recent medication changes or if there is confusion about medication instructions.
- Before making any significant changes to health routines, treatments, or before deciding on new treatments based on the software's recommendations.
- If the recommendations given by the software differ significantly from previous medical advice or common practice.
- If there are any malfunctions with the software, or if the user encounters any difficulties in using it which might affect the reliability of the results.

Even if the software does not indicate a need for medical attention, users should not replace regular check-ups and preventive care visits with the software's assessments.

### 5.3. Precautions

- The application is not related to any medical system and does not impose any specific course of action on the user.
- The product is not intended as a replacement for a doctor's opinion.
- 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.
- Accurate symptom reporting by the user is required for appropriate performance of the MGP.
- Users with significant comorbidities should be advised to use the device with caution and seek medical advice when in doubt.

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- The SaMD is intended to support, not replace, the professional judgment of the user's health condition. 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.
- While the MGP can provide advice based on the current evidence base, it does not account for all individual health aspects and variations in presentation. Even serious illnesses might cause unusual symptoms that the symptom checkers may not be able to recognise.

## 5.4. Warnings

- Do not use the Infermedica Medical Guidance Platform in an emergency situation.
- Stop using the Infermedica Medical Guidance Platform if symptoms get worse during an interview.
- Do not use it as a substitute for the advice of a healthcare professional.
- Do not use it to assess multiple, separate health problems in one interview.
- Users should not rely on the MGP as their sole source of medical advice.
- If the symptom checker's result does not correspond with the user's own idea of their situation, they should contact a health care professional in another way.
- Immediate medical attention should be sought if the user's condition worsens or if they experience new or changing symptoms.
- Medical attention should be sought if despite actions taken, their condition worsens or if they experience new or changing symptoms.

## 5.5. Indication for use

- The platform helps you assess your symptoms and provides a list of possible conditions with their likelihood. It also helps determine if you need medical attention and how urgent it is.
- The platform analyzes the health information you provide to suggest the best care options, making it easier to decide on the next steps for seeking healthcare.

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- It helps you prepare for conversations with healthcare providers, making it easier to explain your health concerns.
- Before seeing a healthcare professional, the platform helps you gather and assess your symptoms. It creates a summary that can be used by the healthcare provider before, during, and after your visit.
- The platform offers articles on over 200 diseases, including information about their causes, symptoms, diagnosis, and treatment. Each article includes references.
- The platform collects follow-up information about your progress and any changes in your symptoms after the initial assessment.

## 5.6. Contraindications for use

The Infermedica Medical Guidance Platform should not be used in cases of sudden health emergencies. If you suspect a serious health problem, you should immediately seek medical help. This means calling emergency services or going to a hospital emergency room right away.

**A sudden health emergency** is a situation where your health gets worse very quickly and could cause serious harm to your body or even be life-threatening. Immediate medical attention and treatment are needed in these cases.

Examples of sudden health emergencies<sup>1</sup>:

- changes in consciousness (e.g. loss of consciousness, sudden onset of attention disturbance, disturbances in cognitive processes, sudden decreased ability to recognize the surroundings)
- convulsions or seizures
- slurred speech, asymmetry of facial expressions, an extremely strong headache, double vision, sudden paralysis, weakness, limb numbness (suspected stroke)

<sup>1</sup> Sources:

<https://www.nhs.uk/nhs-services/urgent-and-emergency-care-services/when-to-call-999/>  
<https://www.emergencyphysicians.org/article/know-when-to-go/know-when-to-go-overview>  
[https://www.nfz-szczecin.pl/ncgch\\_stany\\_nagle\\_i\\_zagrozenie\\_zycia.htm](https://www.nfz-szczecin.pl/ncgch_stany_nagle_i_zagrozenie_zycia.htm)

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- chest pain, pressure, tightness or heaviness across the chest, chest pain radiating to the left arm or the jaw, chest pain that increases with exertion (suspected heart attack)
- heart rhythm disturbances (sudden onset, persistence of irregular palpitations in the chest)
- severe shortness of breath (increasing or persistent difficulty in breathing)
- Severe, persistent abdominal pain
- persistent vomiting (inability to be rehydrated via oral cavity, progressive weakness, and dehydration)
- acute and severe allergic reactions (rash, sudden rapid swelling of lips, mouth, throat or tongue, difficulty breathing) resulting from exposure to possible allergens such as taking medicine, bites, or stings by poisonous animals
- serious injuries resulting from an accident, e.g., crushing, falling from a great height, suspected bone fractures, leg injuries making it impossible to move independently
- profuse, difficult to stop bleeding, e.g., nosebleed, gastrointestinal bleeding (coffee-ground vomit, melaena), vaginal bleeding, bleeding resulting from an injury
- extensive wounds resulting from trauma
- extensive or specific (e.g. face, hands, eyes, crotch) burns
- labour (childbirth)
- intoxication with medicine, chemicals, or gasses
- heatstroke (sudden increase in body temperature above 40°C/104° F, e.g., from overheating in the sun)
- cold exposure (suspected hypothermia, body temperature drops below 35°C/95°F)
- electric shock
- half-drowning or drowning
- aggression caused by mental illness
- suicide attempt

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

Moreover, it is not suitable for use by individuals with severe cognitive or learning impairment without assistance.

Children cannot use MGP independently although they are included in the intended patient population.

MGP is not designed to assess multiple, separate health problems in one interview. The software device is not designed for the ongoing monitoring of chronic conditions (e.g., diabetes, hypertension, asthma), although it includes exacerbation symptoms and therefore can evaluate for acute exacerbations of chronic conditions. Further contraindications of use may be introduced based on the chosen configuration of the MGP to serve specific use cases or sub-populations.

## 6. Expected clinical benefits

Based on the information provided by the user, the application provides a general assessment of health conditions and recommendations for improving them. The application also contains general educational and informative content regarding health and healthy lifestyle. System provides:

- A list of possible conditions connected to declared symptoms.
- Recommendations for the appropriate medical level of care.

Benefits:

- Infermedica MGP provides users with immediate feedback on their health concerns, potentially guiding them to appropriate care settings (e.g., urgent care, primary care, or emergency services) based on the severity of their symptoms.

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- By assessing symptoms and suggesting possible conditions, the app can help prioritize patients according to the urgency of their conditions, thus optimizing the workflow in healthcare facilities and ensuring that those who need immediate attention receive it promptly.
- Empowering patients by providing them with information about their symptoms and possible conditions, encouraging them to take an active role in their health management.
- User education about their symptoms and potential health conditions, increasing awareness and understanding of health issues, which can promote healthier lifestyle choices and preventive measures.

## 7. Contact with manufacturer

### 7.1. Reporting errors and complaints

To report a safety concern that has occurred during the use of Infermedica MGP, please email Infermedica: [support@infermedica.com](mailto:support@infermedica.com)

- Subject: [Client's name]
- Content:
  - Interview session ID (e.g. SC00116842541) – if the problem concerns a specific session.
  - Problem description.

Serious incidents, i.e. death, serious deterioration of health, critical problems (where the functioning of the application may cause hazard to life or health of the users) shall be reported to the manufacturer and/or directly to the competent authority of the Member State in which the user and/or patient is established;

In case of Poland, the authority is The President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products via e-mail (address: [incydenty@urpl.gov.pl](mailto:incydenty@urpl.gov.pl)), fax (No. +32 22 492 11 29), registered mail or courier service (Al. Jerozolimskie 181c, 02-222 Warszawa, Poland).

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## 7.2. Opinions and suggestions

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

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