

Welcome to Kaiku Health, your digital cancer care companion!

Kaiku Health is a digital service that helps you let your care team know how you're doing when it comes to your cancer care. As you can use Kaiku Health on your computer, smartphone or tablet, you can do this at any time and in any place.

Kaiku Health gives you and your care team a sense of the symptoms and well-being changes that you may be experiencing during your cancer treatment.^{1,2,3,4}

¹ Basch E et al., Journal of Clinical Oncology 34.6 (Feb. 2016), pp. 557–565.

² Absolom K et al., BMC Cancer 17.1 (May 2017), p. 318.

³ Denis F et al., J. Natl. Cancer Inst. 109.9 (Sept. 2017).

⁴ Warrington L et al., J Med Internet Res 21 (1 2019), e10875



1. Starting to use Kaiku Health

A member of your care team will invite you to use Kaiku Health. You will receive an invitation email that allows you to register to the service.

You may have also received a link from your care team which you can use to register to Kaiku Health directly without an invitation email.

When registering, you may be required to enter a verification code which will be sent to your phone number by text message or automated voice call.

You will then be asked to fill in your personal details, such as name and date of birth. You will also need to set a personal password and accept the terms and conditions of the service. After this, you will be able to use Kaiku Health.

You can use your username (typically your email address) and password to log in to Kaiku Health.⁵ If you are using the mobile app, you can also enable biometric login (with fingerprint or facial recognition) if your device supports it.

⁵ For patients in Finland, Kaiku Health also supports log in via banking credentials or mobile identity (mobiilivarmenne).

2. Tasks and questionnaires

Once you have started using Kaiku Health, you will receive notifications when you have new tasks, such as questionnaires, in the service. These tasks are assigned to you by your care team.

Notifications are sent to you either by email or by push notification. You can always change the way you receive notifications by going to the "My information" page of your account.

Questionnaires 3

Dean Doctor would like you to do the following things today:



Symptom questionnaire for your cancer treatment

Knowing how your symptoms have developed over time helps your care team provide the best possible treatment. That's why it's important to fill the questionnaire even if you are not currently experiencing any symptoms.

[Fill in questionnaire](#)

Completing questionnaires only takes a few minutes. If needed, you can always stop and then continue completing the questionnaires later. It's important that you complete these questionnaires even if you're not experiencing any symptoms.

Please select groups of symptoms, which you have experienced within the last seven (7) days. We will ask about them in more detail in the next steps.

**Generic symptoms**

Cough, shortness of breath, nausea, vomiting, decreased appetite, fatigue, fever, abnormal bleeding, weight loss, numbness & tingling

**Head, eyes & vision, mouth & throat**

Headache, cough, taste changes

**Gastrointestinal**

Nausea, vomiting, diarrhea, decreased appetite, abdominal pain

**Mind & neurological**

With some of the questionnaires, you will first be asked to select from different symptom groups at the start of the questionnaire. You will only be asked about symptoms in those categories that you have selected. If you don't select any symptom group, you will be asked about all of the symptoms.

3. Feedback

Once you have completed a symptom questionnaire, Kaiku Health may provide you with guidance on how you can react to your symptoms. Your care team will also be able to see your questionnaire responses.



Kaiku Health is not monitored in real-time by the clinical staff, it is intended only for non-urgent communication. In urgent situations, contact your care unit or emergency number by phone.



At the end of the symptom questionnaires, you can receive three different types of feedback.

- Green means mild symptoms;
- Yellow means moderate symptoms, and;
- Red means severe symptoms.

CHEST PAIN



Please contact your care team immediately via telephone. If you cannot reach your care team right away, seek admission to the ER.

Remember to tell the clinical staff at the ER what treatment(s) you are receiving or have received.

If, after finishing a questionnaire, Kaiku Health tells you to contact your care team and/or emergency department, please do so without delay.

Here's what you can do yourself 

Cough is a common symptom in general and in association with some cancers and their treatments. Mild cough may be relieved to some extent by cough syrups or pastilles available from your local pharmacy without prescription.

Contact your care team without a delay in following situations:

- There appears blood in your cough
- Blood in your cough has increased
- Your cough gets worse than usual
- The cough occurs at the same time with shortness of breath

The feedback portion of Kaiku Health may also include self-care instructions to help you relieve your symptoms at home.



In some special cases the guidance and self-care instructions that Kaiku Health provides might not apply to you. If you have any questions regarding your care, or your symptoms and their management, we kindly ask you to contact your care team.

If you do not receive a response from your care unit within a reasonable time, please contact the care unit by phone.

FEEDBACK

**SYMPTOM QUESTIONNAIRE FOR
IMMUNOTHERAPY**

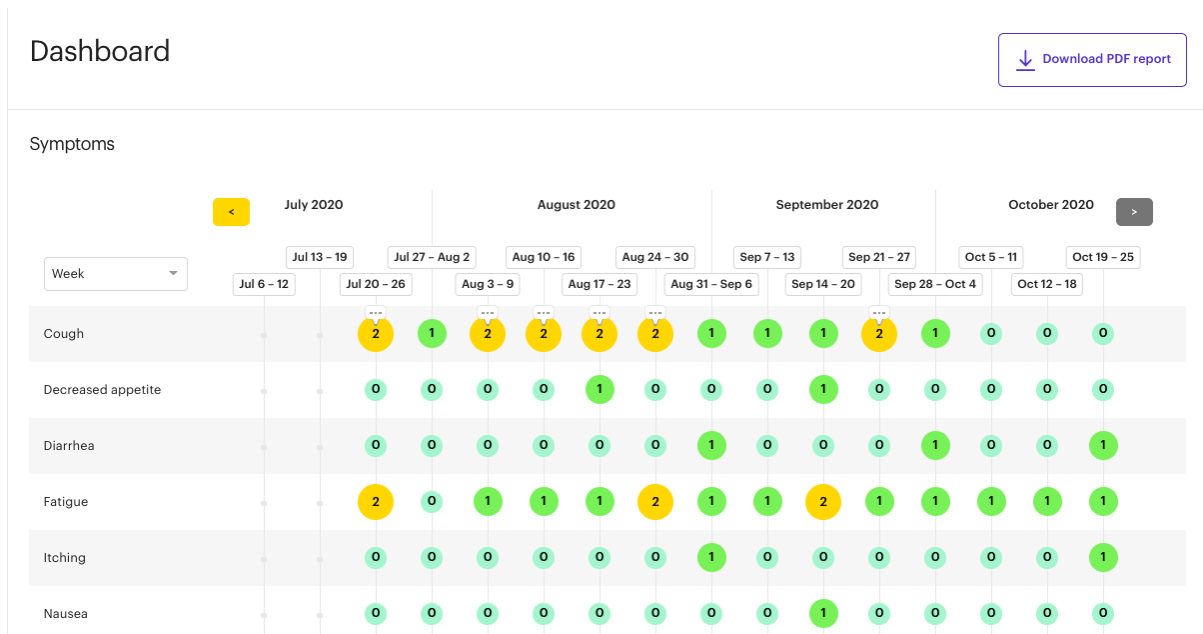
Feedback from the questionnaire you filled on
09/12/2020



If you want to go over any of the feedback that you have received from Kaiku Health, you can do so by navigating to the 'Feedback' portion of your Kaiku Health home page.

4. Dashboard

You can use the symptom dashboard to keep an eye on how your symptoms are changing over time. The symptom dashboard also lets you review any self-care instructions that you may have received from Kaiku Health.



5. Knowledge and support

Kaiku Health’s ‘Knowledge and Support’ section provides you with more information about the condition that you are dealing with, your treatment, and the symptoms that you may be experiencing.

Should you have any additional questions about Kaiku Health, your care, or any symptoms that you may be experiencing, please get in touch with your care team.

6. Communicating with your care team

Your care team automatically receives your responses to completed questionnaires. If your clinic has enabled the Conversations feature in Kaiku Health, you can use this feature to get in touch with your care team.



Kaiku Health is not monitored in real-time by the clinical staff, it is intended only for non-urgent communication. In urgent situations, contact your care unit or emergency number by phone.

If you do not receive a response from your care unit within a reasonable time, please contact the care unit by phone.

7. Frequently asked questions

7.1. On which devices and browsers can I use Kaiku Health?

Kaiku Health is available as an app for smartphones on iOS (version 11.0 and later) and Android (version 5.0 and later). You can install it through the App Store or Google Play.

You can also use Kaiku Health on a web browser on computers and smartphones. Kaiku Health is compatible with most modern web browsers. Having said that, we recommend that you use Kaiku Health on the newest version of Mozilla Firefox, Google Chrome, Microsoft Edge, or Apple Safari.

Using Kaiku Health on a web browser does not require you to install anything on your computer or mobile phone.

7.2. What is the intended use and indications of Kaiku Health?

Kaiku Health is intended for use in cancer care and follow-up for non-urgent communication between an adult patient and a medical professional and for collecting patient-reported data, displaying and analysing clinical and patient-reported data, and instructing the patient. The data processed by Kaiku Health are intended to be used in supporting treatment decisions and in supporting diagnoses.

Kaiku Health is indicated for all cancer diseases at all stages of treatment and follow-up.

7.3. Who can use Kaiku Health as patient?

To be able to use Kaiku Health, you need to give your consent for using the service. This consent is typically asked from you when you log in to Kaiku Health for the first time. Your consent may sometimes be asked in paper format outside of Kaiku Health, for instance if you are using Kaiku Health as part of a clinical trial or research activity.

As a patient user of Kaiku Health, you should be in the treatment or follow-up phase of a cancer disease.

You need to have access to an internet connection and a device that is compatible with Kaiku Health (see '**On which devices and browsers can I use Kaiku Health?**').

You can only use Kaiku Health if you, or another person acting on behalf of you, is physically and cognitively able to do so.

Kaiku Health should only be used by people aged 18 years or older. People who are older than 15 years may use Kaiku Health if they are judged by the clinical staff to be capable of using it.

7.4. Are there any situations where I should not be using Kaiku Health?

You should not use Kaiku Health in the following circumstances:

- You do not consent to use of Kaiku Health;
- You do not have Internet access or access to a device compatible with Kaiku Health;
- You are unwilling or unable (e.g., due to a medical condition) to comply with self-reporting duties and other use of Kaiku Health;
- You are not fluent enough in any language that Kaiku Health is offered in to be able to use Kaiku Health; or;
- You are younger than 15 years, or under 18 years and judged not capable to use Kaiku Health by the clinical staff.

It is important that the information which you send to your care team via Kaiku Health correctly reflects the symptoms you are experiencing.

Because of this, your care team should not invite you to use Kaiku Health if you are suffering from a physical or cognitive condition that would prevent you from using Kaiku Health (such as dementia). Use of Kaiku Health is contra-indicated in such a case.

7.5. Does Kaiku Health have any undesirable side effects or risks?

When used properly, Kaiku Health has no undesirable side effects or risks that relate to your safety.



Risks related to confidentiality, integrity and availability of the personal data processed by Kaiku Health cannot be completely eliminated. If you suspect that your personal data has been compromised, please contact support.

7.6. What should I do if I notice a problem with Kaiku Health?

If you are finding Kaiku Health difficult to use, please contact your care team to help you. You may also contact kaikusupport@elekta.com for technical support.

If you have improvement suggestions for Kaiku Health, you can give us feedback on our online [feedback form](#).

If you notice a serious incident in relation to Kaiku Health, please report it to the manufacturer and your local competent authority.

7.7. What should I do if I no longer want to use Kaiku Health?

If you do not want to use Kaiku Health anymore, please contact your care team and ask them to deactivate your Kaiku Health account. If you have used Kaiku Health via the mobile app, you can uninstall it from your device(s) using the normal uninstall process on iOS/Android. Kaiku Health does not store any of your health data on your devices.

7.8. What are the performance characteristics of Kaiku Health?

Clinical performance:

- Data processed and made available to the healthcare professional user by Kaiku Health can support treatment decisions and diagnoses through earlier detection of symptoms, signs and/or relapses. Patients using Kaiku Health are less likely to experience serious adverse events, ER visits, and hospitalisations that can be prevented or mitigated with appropriate medical intervention.

Safety performance:

- Use of Kaiku Health or a similar device does not cause any undesirable side effects.
- Use of Kaiku Health does not compromise integrity and confidentiality of personal data.
- Risks related to overgrading and/or undergrading may not lead to serious harm.
- Risks related to misscoring may not lead to serious harm.
- Risks related to instructions and information provided to the patient may not lead to serious harm.






Technical performance:

- Kaiku Health reduces therapy-related expenses and burdens on patients and their relatives and healthcare provider.
- Kaiku Health improves patient satisfaction.
- Kaiku Health improves coordination of treatment processes.
- Kaiku Health facilitates a good level of self-reporting adherence.
- Kaiku Health allows only authorised users to access and modify personal data.
- Kaiku Health supports personalising and automating the patient's follow-up based on the patient's indication and treatment modality by allowing patients to complete questionnaires assigned to them.
- Questionnaires completed by patients in Kaiku Health and clinical data imported from other systems are visible to the patient user and their assigned care team.
- Kaiku Health personalises symptom follow-up based on symptoms whose onset continuation is predicted to be likely by the machine learning models based on previously reported data.
- Medical staff and patient users can exchange text-based messages and file attachments in patient and care team specific conversations.
- Kaiku Health computes symptom severity grades based on the patient's responses to symptom questionnaires following configurable rule-based logic.
- Based on the graded symptoms and the patient's module, Kaiku Health provides prioritised alerts to healthcare professionals to assist focusing HCP's attention to patients in need.
- Where available, Kaiku Health computes composite scores for questionnaires per the scoring specification of the questionnaire.
- Kaiku Health displays self-management guidance to the patient based on the form the patient filled and the grading of the symptoms the patient reported.

- Kaiku Health displays general informational articles on the disease, treatment or similar topics to the patient user depending on their module.
- Kaiku Health displays self-management guidance to the patient on symptoms whose onset continuation is predicted to be likely by the machine learning models based on previously reported data

7.9. What are the symbols used in this document?

The symbols that are used in this document and their meaning is explained in the following table:

| Symbol | Symbol name | Symbol meaning |
|---|--|---|
|  | CE-marking with notified body identifier | CE marking indicates that a product has been assessed by the manufacturer and deemed to meet EU safety, health, and environmental protection requirements. It is required for products manufactured anywhere in the world that are then marketed in the EU. The notified body identifier indicates that the design of the medical device and its compliance with the Essential Requirements has been examined by a Notified Body. 2797 is the NB-identifier for BSI Group The Netherlands B.V. Netherlands. |
|  | Medical device | Symbol indicates that the product is a medical device, i.e., a device intended for medical purposes. |
|  | Warning | The symbol indicates that the information next to it pertains to warnings, precautions, contraindications, measures to be taken, or limitations of use regarding the device. |
|  | Manufacturer | The information associated with the symbol identifies the manufacturer of the device. |
|  | Swiss authorised representative | The information associated with the symbol identifies the name and address of the authorised representative's registered place of business |

7.10. What warnings are included in this document?

The following warnings concerning use of Kaiku Health are included in this document:

| Section | Warning |
|--|---|
| 3. Feedback | Kaiku Health is not monitored in real-time by the clinical staff, it is intended only for non-urgent communication. In urgent situations, contact your care unit or emergency number by phone. |
| 3. Feedback | <p>In some special cases the guidance and self-care instructions that Kaiku Health provides might not apply to you. If you have any questions regarding your care, or your symptoms and their management, we kindly ask you to contact your care team.</p> <p>If you do not receive a response from your care unit within a reasonable time, please contact the care unit by phone.</p> |
| 6. Communicating with your care team | <p>Kaiku Health is not monitored in real-time by the clinical staff, it is intended only for non-urgent communication. In urgent situations, contact your care unit or emergency number by phone.</p> <p>If you do not receive a response from your care unit within a reasonable time, please contact the care unit by phone.</p> |
| 7.5. Does Kaiku Health have any undesirable side effects or risks? | Risks related to confidentiality, integrity and availability of the personal data processed by Kaiku Health cannot be completely eliminated. If you suspect that your personal data has been compromised, please contact support. |

Contact information



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These Instructions for Use are applicable to Kaiku Health 8.0.0 and above.

Corresponding Instructions for Use for healthcare professionals: E060553 / 06

You are entitled to obtain a paper copy of the instructions for use at no cost within 7 calendar days. To order a paper copy, please email customersuccess@kaikuhealth.com with the following information:

- The document you are requesting (see document header for document identifier and revision number)
- Shipping address
- Desired language of the document

You may also access or download a copy of this document for printing via the Kaiku Health user interface, or via the kaikuhealth.com -website.

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2024-04-23