

# Welcome to Kaiku Health!

Kaiku Health is a digital service that helps patients to tell about their wellbeing to their care team during cancer care. You can use Kaiku Health on your computer, smartphone, or tablet.

Kaiku Health gives you information about patient reported symptoms and changes in their wellbeing during cancer care and follow-up.<sup>1,2,3,4</sup>

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

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

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

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



## 1. Starting to use Kaiku Health

Before Kaiku Health is available to your organization, the manufacturer's representative must perform a site installation. Medical and non-medical staff users must complete training provided by the manufacturer or by a staff user trained by the manufacturer before starting to use Kaiku Health.

Once you have received an invitation in your e-mail, you can login to the service. You can login with your username (usually your e-mail address) and password.<sup>5</sup> All alternative login methods are shown on the login page. 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.

After logging in, you will be directed to the staff home page.

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<sup>5</sup> If a patient user uses Kaiku Health in Finland, Kaiku Health supports login with internet banking credentials and mobile identity.

## 2. Inviting patients

On the staff home page, you can invite new patients by selecting “Invite a new patient” from the upper right corner.

When inviting a new patient, you will need to fill out at least the email of the patient.

When you have sent the invitation, the patient will get an invite to register to the given email address. The invite will include a link for signing up to the service.

After the first registration, the patient can continue to use the service with their username (email) and password.

## 3. Programs and care teams

When the invite has been sent, you need to set up the correct program for the patient. This program will determine which symptom and quality of life questionnaires will be asked from the patient.

You can also set a starting date and an end date for the program. The starting date will determine when the first questionnaire is sent to the patient. The end date will determine when the questionnaires will stop being sent to the patient.

After the program has been set, you need to set up the care team of the patient. Please remember to include all relevant personnel in the patient’s care team - all new notifications from filled symptom reports will be sent to the selected care team. You can also connect the care team directly to programs to automate the care team selection process.

Every patient must have at least one person in their care team.

Remember to always save the changes by selecting “Save changes” from the bottom of the page when you have modified the programs and care team information.

After saving the changes, you may continue inviting patients or go back to the home page.

## 4. Staff home page

Your home page view is divided to three parts: “New messages”, “New notifications”, and “Assigned tasks”.

When the patient has filled out a symptom questionnaire, a notification is raised to the patient’s care team.

- If automatic feedback was shown to the patient, you can see it by selecting “Show feedback”.
- You can view the questionnaire answers by selecting “Show form answer”.
- You can view the symptom report by selecting “Show symptom comparison”.
- You can assign the new symptom report notification to yourself or forward it to another staff user in the service by selecting “Assign to...” or “Assign to me”.
- When you have checked the patient’s symptoms, you can mark the task done by selecting “Mark done”.

Sometimes, depending on the selected program, if the patient has not reported symptoms or only mild symptoms, the care team will not get separate notification to the home page. Patients’ reported symptoms are always visible in “Overview” and “Symptom comparison” -views in Kaiku Health.

From the symptom comparison view,

- You can see the development of the patient’s symptoms during treatment.
- You can see the patient’s exact replies to the symptom questions by selecting the symptom grade (0–3).
- You can ask additional information of the patient’s symptoms by sending a message to the patient in the service by selecting “Go to the conversation” in the upper right corner.

Notifications of new activity will be displayed on your home page. In addition, Kaiku Health sends a daily summary of new symptom reports and messages to your email. A separate notification will be sent if a patient has reported severe symptoms, or if a notification has been assigned to you by your colleague.

## 5. Conversations

New messages sent by your patients are shown on the staff home page. You can read the whole conversation by selecting “Show conversation”.

You can also assign the task to someone else, assign the task to yourself, or mark it as done.

The conversation page shows all messages sent between the care team and the patient. The messages may also contain attachments and photos.

Every time the patient sends a new message, the patient’s care team members will receive a new notification to their home page.

## 6. Patient summary page

By selecting the patient’s name in any view, you will be redirected to the patient summary page. From the patient summary, you can see the patient’s symptom development and the notifications history in the service.

You can also edit the patient’s programs and care teams by selecting “Edit programs, forms and care team” from the left navigation bar. Patient information, such as phone number, can be edited by selecting “Edit information”.

You can also start a conversation with the patient by selecting “Go to the conversation” from the upper right corner.

## 7. Creating new users

In some cases, a user cannot be invited via e-mail. If this is the case, user credentials can be created by selecting “Create a new user” on the home page. This route can be used to create new patient users if the email invitation workflow is not possible, and sometimes, when the staff user has the rights to create other staff user accounts.

Select the new user’s type, name, language, and email address. Save these details by clicking on “Create user”. Kaiku will then inform you that “A new user was created successfully”.

New staff user accounts should be created by the non-medical staff user or by a staff user with administrative rights.

## 8. Absences -feature

The clinical staff can select a substitute for themselves for the duration of their absence. You can select a substitute for yourself by clicking on “Absences” at the top of the page.

You can then proceed to select your substitute. Enter the substitute’s name in the allocated field. You can also set a substitute for your colleague if they are on a sick leave, for example.

## 9. Management of patient user details

Patients who have registered into Kaiku are found under “Patients” in the top of the page. You can modify the personal details of users or manage their Kaiku programs and care team.

Under “Open invitations”, you can add yourself to a patient’s care team or re-send, modify, or remove the invitation.

## 10. Deactivating patient’s Kaiku Health user credentials

When a patient should no longer use or have access to Kaiku Health for any reason, their user account should be changed to “Inactive” status. This means that the patient can no longer log into the service and will no longer receive any prompts or reminders.

Locate the patient user whose credentials are to be inactivated by selecting “Patients” in the top of the page or by writing the name to the search bar. Select “Edit information” on the left navigation bar. Then change the “Status” from “Active” to “Inactive” and save the changes.

## 11. Programs

The programs -feature gives you some options for viewing program content and assigned patients, as well as to define a default care team for each program.

By accessing the “Programs” menu and clicking on a program name, you can view the questionnaires included in the program, their respective intervals, as well as which patients and care teams are currently in the program.

If you would like to assign a specific team of staff members to a certain program by default, you can do so by adding these staff members to the “Program staff”

on the page. These staff members will then be automatically assigned to any patient who is added to the program.

## **12. Creating user credentials for the clinical staff**

Click “Create new user” on the home page to create a new user for the clinical staff.

Select the new user’s type, name, language and email address. Save these details by clicking on “Create user”. Kaiku will then inform you that “A new user was created successfully”. The new user will receive an email with instructions on how to complete the registration.

## **13. Resetting clinical staff passwords**

Staff users’ passwords should be reset by your non-medical staff user.

By clicking on “Send password reset link” a password reset link will be sent to the user email address. A confirmation message will appear at the top of the page.

## **14. Deactivating staff user accounts**

Staff user accounts should be deactivated by your non-medical staff user.

To deactivate a user, select their name from the user list in the home page and change their status to “Inactive”. A confirmation message will appear on top of the page.

## **15. Frequently asked questions**

### **15.1. On which devices and browsers can I use Kaiku Health?**

Staff users can use Kaiku Health on a web browser on a computer and smart phones. 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.

## **15.2. 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.

## **15.3. Who can use Kaiku Health as staff or administrative user, or as a patient user?**

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.

You need to have access to an internet connection and a device that is compatible with Kaiku Health (see section 15.1).

As a staff user of Kaiku Health you should be a healthcare professional (nurse, doctor), who participates in provision of healthcare services related to the intended use of Kaiku Health (see section 15.2)

Your roles, responsibilities, educational background, and professional competence may depend on the general organization of cancer care at the hospital and the role of the individual user in it. Some level of computer literacy is expected, though it is expected to vary from user to user.

As an administrative user you are employed by hospitals who use Kaiku Health, and are responsible for managing user accounts (e.g., onboarding and offboarding healthcare professionals).

To be able to use Kaiku Health, a patient user needs to give their consent for using the service. This consent is typically asked from when the patient logs in to Kaiku Health for the first time.

A patient user should be in the treatment or follow-up phase of a cancer disease.



A patient user needs to have access to an internet connection and a device that is compatible with Kaiku Health.

A patient user can only use Kaiku Health if they, or another person acting on behalf of them, 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.

#### **15.4. Are there situations where a patient should not use Kaiku Health?**

A patient user should not use Kaiku Health in the following circumstances:

- They do not consent to use of Kaiku Health;
- They do not have Internet access or access to a device compatible with Kaiku Health;
- They are unwilling or unable (e.g., due to a medical condition) to comply with self-reporting duties and other use of Kaiku Health;
- They are not fluent enough in any language that Kaiku Health is offered in to be able to use Kaiku Health; or;
- They 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 information reported by patients by using Kaiku Health accurately correspond to the symptoms they experience.

Because of this, a patient should not be invited to use Kaiku Health if they are suffering from a physical or cognitive condition that would prevent them from using Kaiku Health (such as dementia). Use of Kaiku Health is contra-indicated in such a case.

### **15.5. 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.**

### **15.6. What should I do if I notice a problem with Kaiku Health?**

If you are finding Kaiku Health difficult to use, please contact your non-medical staff user to help you. You may also contact [kaikusupport@elekta.com](mailto: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 the relevant competent authority. Authority receiving the report is determined by the patient's location.

### **15.7. 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 administrative user and ask them to deactivate your Kaiku Health account. Kaiku Health does not store any of your health data on your devices.

## **15.8. 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

### 15.9. 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, contra-indications, 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

**15.10. What warnings are included in this document?**

The following warning concerning use of Kaiku Health is included in this document:

Section	Warning
15.5. 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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**Australia Sponsor Information**

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

Corresponding Instructions for Use for patient users: E060552 / 07

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](mailto: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

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