

# TD\_02\_00\_03\_Mika-Instructions for Use

Document control [🔗](#)

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Table of contents [🔗](#)

## 1 Changes [🔗](#)

Version	Changes
v1.0	<ul style="list-style-type: none"><li>initial UK version</li></ul>
v2.0	<ul style="list-style-type: none"><li>updated version adding<ul style="list-style-type: none"><li>Available regions and languages</li><li>Description of intended users</li><li>Section on security recommendations</li></ul></li></ul>
v3.0	<ul style="list-style-type: none"><li>Updated Manufacturer's address</li></ul>
v4.0	<ul style="list-style-type: none"><li>Updated the required compatible iOS version from 15 to 16</li></ul>
v5.0	<ul style="list-style-type: none"><li>Swiss rep details added</li></ul>
v6.0	<ul style="list-style-type: none"><li>Updated Basic UDI-DI</li><li>Updated manufacturer information to Outcomes4me Germany</li><li>Added Treatment management under 4.10 and 11</li></ul>

## 2 Symbols [🔗](#)

SYMBOLS	WHAT THESE MEAN FOR YOU
CE 0123	CE mark (Communauté Européenne). A product bearing a CE mark fulfils the requirements of the respective EU directive, i.e. of the valid European standard.

	<b>Manufacturer</b> <i>Information on the manufacturer of the medical device.</i>
	<i>Identifies a medical device.</i>
	<i>Please read the instruction manual.</i>
	<i>Caution!</i>
	Swiss rep

### 3 General information [🔗](#)



*Important! Please read the following information with care before you start using Mika and keep this document in a safe place for future reference.*

#### 3.1 Trade name of the medical device [🔗](#)

Mika

#### 3.2 Basic UDI-DI [🔗](#)

42700048958000JC

#### 3.3 Manufacturer's address [🔗](#)



**Outcomes4Me Germany GmbH**

c/o Cormoran GmbH

Am Zircus 2

10117 Berlin

Germany

#### **Contact**

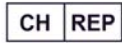
Email: [support@mika.health](mailto:support@mika.health)

Telephone: +49 3028484486

CE 0123 Mika is a medical device.



Year of production: 2019



QUNIQUE GmbH  
Bahnhofweg 17,  
5610 Wohlen,  
Switzerland

## Publication date of the instruction manual

v5.0, Date: 22 March 2024

The latest version of the instruction manual can also be found below:

- Germany: <https://www.mitmika.de/gebrauchsanweisung/>
- UK: [M User manuals - Mika Health](#)
- Switzerland: [ch.mika.health/gebrauchsanweisungen/](https://ch.mika.health/gebrauchsanweisungen/)

## 4 Device information

The Mika app aims to reduce symptoms related to psychological distress following a cancer diagnosis and associated treatment and with that to increase the quality of life.

To this end, Mika includes an evidence-based psychological distress test based on a clinically validated screening instrument. The test leads patients through guideline-compliant psycho-oncological interventions that consist of psychological education, relaxation techniques, strength and flexibility exercises as well as exercises to strengthen your coping skills with methods taken from cognitive behavioural therapy (CBT), acceptance commitment therapy (ACT) and creative therapy.

These resource-activating exercises seek to improve health-related behaviour, the way you manage psychological distress and how you deal with your condition. A personalised knowledge base offers further psychosocial and psycho-oncological support with compact information on individual types of cancer, guidelines and supportive health-related behaviour.

### 4.1 Intended Purpose

Mika is a digital health app to support the alleviation of psychic and psychosomatic effects related to a diagnosis or treatment of malignant tumors.

Mika achieves an alleviation of these effects by providing the means to document distress, symptoms and side effects as well as by providing resource activating patient education regarding the following topics:

1. Health Literacy
2. Stress Management
3. Physical Exercises
4. Nutrition

### 4.2 Intended Users

The intended users of the Mika app are oncological patients (at least 18 years or older) requiring support from psychosomatic effects related to a diagnosis or treatment of malignant tumors.

The patient must have the following capabilities to use Mika:

- The ability to use a smartphone
- The patient must not be visually impaired or a user suffering from polyneuropathy

Mika is not intended for use by vulnerable populations (pregnant and breastfeeding women, incapacitated subjects, and children < 18 years of age).

### 4.3 Intended Patient Population [🔗](#)

Mika is intended for patients requiring support from psychosomatic effects related to a diagnosis or treatment of malignant tumors.

### 4.4 Indications for use [🔗](#)

Mika is indicated for patients that are impacted by the condition: malignoma associated distress.

### 4.5 Contraindications [🔗](#)

The Mika app provides various physical exercises and techniques taken from the field of psychotherapy. The positive effects of these exercises, especially the physical exercises as well as relaxation, mindfulness and acceptance techniques, have been proven in clinical studies. Even so, these exercises should not be attempted if certain risks exist. Please therefore always observe the following information to ensure you use Mika safely without causing yourself any harm.

#### 4.5.1 Contra-indications and medical information on physical exercises [🔗](#)

Warnings, especially for physical exercises, apply for all patients.

Additionally, before you begin doing any physical exercises, please always check with your medical team whether you should be doing physical exercise at all and if so which restrictions apply.

The following limitations apply in general:

- They cannot replace first consulting your doctor.
- Following surgery, the surgical wound must have healed before any physical exercises can be attempted.
- If an implant has been fitted, your medical team must confirm that it is possible for you to lie face down again.
- In the case of bone metastases: if bone metastases put you at risk of breakage, certain exercises (depending on the location of any bone metastases) can be subject to restrictions that your medical team will have to discuss with you on an individual basis.
- In the case of orthopaedic restrictions: if certain exercises are not possible or only in restricted form, please refrain from attempting them.
- Physical exercise should be avoided if:
  - you are in severe pain and if exercise makes the pain worse,
  - you are running a fever or temperature of more than 38 °C,
  - you have an acute infection,
  - you are suffering with nausea or vomiting,
  - your cognitive functions are impaired or you are confused,
  - you are feeling dizzy or have problems with your cardiovascular system,
  - you are currently experiencing acute bleeding or are more prone to bleeding

Note: these contraindications do not prohibit all activity. Strenuous exercise should, however, be avoided. You can still go about your daily activities as usual.

#### 4.5.2 Contraindications and medical information on mindfulness, acceptance, and relaxation exercises [🔗](#)

Please do not attempt these exercises – or only if your medical team has confirmed that they are safe for you to attempt – if:

- you are currently experiencing severe psychological distress and you are not receiving professional psychotherapeutic support,
- you suffer with severe depression, psychoses or other severe mental health problems that could be made worse by relaxation and mindfulness techniques,

- you are in severe physical pain.

If any of the points mentioned above apply to you, please consult your doctor before attempting these exercises.

Even if none of the above points applies to you, it can happen that not every exercise offered by Mika is helpful at any given time in the course of your condition. Therefore, if you feel an exercise is causing you psychological distress or is not doing you good physically and/or emotionally, then please take a break from it. You can try again at a later point in time. If it still fails to do you any good or continues to cause you severe psychological distress, then please stop doing it altogether and do not attempt it again. If these feelings of psychological distress persist, please consult your medical team if necessary and inform us about the problem by sending an email to [support@mika.health](mailto:support@mika.health)

Exercise sessions cannot replace psychotherapy or psychiatric treatment. If your mood continues to be low over a longer period of time or if you are suffering with extreme panic attacks, are harming yourself, are thinking of taking your own life or have any other mental health symptoms, please consult your GP, medical specialist or a psychotherapist.

Help in acute crisis situations can be provided, for instance,

- Users in Germany can use the telephone helpline on 0800 111 0 111 (Internet: [TelefonSeelsorge® Deutschland | Sorgen kann man teilen. 0800/1110111 · 0800/1110222 · 116123. Ihr Anruf ist kostenfrei.](#) ) or the number against grief 116 111. In the event of acute suicidal thoughts or specific suicidal intentions, please contact the emergency number (112) immediately.
- Users in the UK can reach out to the Samaritans on 116 123 (How we can help ). If you are seriously considering or are intending to take your own life, please call 999 as a matter of urgency.
- Users in Switzerland can reach out to Association Suisse La Main Tendue on 143 ( [♥ Home | 143.ch Dargebotene Hand](#) ). If you are seriously considering or are intending to take your own life, please call 144 as a matter of urgency.
- Users in the USA can get urgent help in a crisis from the American Cancer Society by dialing \*\*1-800-227-2345\*\* (Internet: [🚑 End Cancer As We Know It](#) ) or call \*\*988\*\*, which is the number for the National Suicide Prevention Lifeline in the United States. This is a free and confidential service that connects users with a trained crisis counselor who can listen to you and provide support. Alternatively if users have urgent suicidal thoughts or planned suicidal intentions, call the emergency number \*\*911\*\* immediately.

## 4.6 Warnings [🔗](#)



### **General information**

1. Mika cannot replace a doctor or a therapist.
2. Mika cannot provide a diagnosis. This can only be supplied by the medical team in charge of your treatment.
3. The recommendations and instructions of your medical team always take precedence over any suggestions provided by Mika. You are urged to follow them – or risk damaging yourself and your health.
4. Please answer any questions asked by Mika carefully and truthfully, particularly with regard to your symptoms, medical indications such as diagnoses and treatment, physical limitations and capabilities as well as pain and any other symptoms. Entering wrong or incorrect information into Mika can result in the app offering you information and exercises that are not appropriate for your situation and current capabilities. Attempting exercises that are not appropriate for you can result in injury or other damage.
5. Before attempting any Mika exercises, please closely observe the written information flanking any audio and video instructions and then follow the instructions provided in the video or by the audio. These additional text-based details contain important information on counter-indications and exercise instructions. If you feel unsure about how to do an exercise, take a break from it and consult your medical team. Although these exercises are designed to be performed by you on your own, doing an exercise incorrectly can result in injury or emotional distress.
6. The Mika app provides various physical exercises and techniques taken from the field of psychotherapy. The positive effects of these exercises, especially the physical exercises as well as relaxation, mindfulness and acceptance techniques, have been

proven in clinical studies. Even so, these exercises should not be attempted if certain risks exist. Please therefore always observe the following information to ensure you use Mika safely without causing yourself any harm.

7. In case the Mika app fails or is working as unintended (e.g. app crashes or stops working; app shows wrong content; etc), please do not follow the recommendations and instructions. Please consult with your medical team and reach out to support@mika.health.

#### 4.7 Cybersecurity related recommendations [🔗](#)

- It is important to secure the device (E.g, password or a biometric login) on which Mika is installed since you would be storing health related information.
- It is recommended that you update Mika whenever a latest version is made available to adopt the latest security fixes.
- It is recommended that you set your device to allow automatic Mika updates in the background. This ensures you will always be using the latest Mika version.
- Please make sure that your device has the latest OS version that is compatible with Mika. Rooted devices on Android are not allowed.
- Please be aware that Mika cannot be used without a stable internet connection

#### 4.8 Data protection and data security [🔗](#)



***Please observe the following information to protect your personal data***

- Use a secure password that is known only to you. Please observe these basic rules: your password has to be at least 8 characters in length and will ideally contain a mixture of letters and numbers. Please do not use passwords that are easy to guess – such as ‘password’, your type of cancer or your name. Passwords consisting of only numbers are also inadmissible.
- Please use your password exclusively for Mika and not for any other apps. If you suspect that someone other than you may have gained knowledge of your password, please change the password as a matter of urgency.
- Please be aware, that you will be logged out after an inactivity period of 24 hours. If you want to use Mika after this period, you need to re-login with your email and password.
- Your data is stored on our backend in an encrypted form. In case a device is lost or changed, we could restore user data from our backend system.

#### 4.9 Side effects [🔗](#)

Using Mika is not associated with any known side effects.

#### 4.10 App functions [🔗](#)

**Check-up:** this guideline-compliant screening instrument lets patients measure their psychological distress levels on a weekly basis and make a note of areas causing psychological distress. Patients can make a daily record of any side effects of their treatment in a symptom diary with a graphical display of their development. Data can be exported and shared with your medical team for discussion, also with a possible view to adjusting medication-based treatment.

**Journeys** serve the purpose of training your psycho-oncological coping skills. This modular function contains practical exercises designed to reduce psychological distress.

**Discover** provides guideline-compliant and evidence-based information that is suitable for a lay audience on individual cancer diagnoses, current treatment options, nutritional knowledge, recipes, tips on dealing with physical restrictions as well as individual relaxation and physical exercises.

The **Treatment Management** module in Mika lets you record every medication you take at home and every therapy you receive at a clinic—in one place. Choose flexible intake schedules or appointment dates and set push notifications so you never miss a dose

or visit. A clear plan view lists all entries, while the Schedule tab shows upcoming events chronologically. You can edit or delete any item at any time via the pencil icon next to it.

#### Involvement of medical institutes and organisations in the development of the app

- Leipzig University Cancer Center (UCCL)
- Leibniz Institute for Resilience Research
- Charité – Universitätsmedizin Berlin

#### 4.11 Duration and frequency of use

Use the 'Check-up' **regularly** to assess how much psychological distress you currently feel.

If you are receiving treatment for your condition or are suffering with any long-term effects of your treatment, you are urged to **regularly** record any symptoms that arise and their severity. If necessary, this record of your symptoms can be used to adjust your medications in consultation with your medical team and so reduce any side effects.

To get the best out of the 'Journeys' therapy programme, you are recommended to complete the suggested exercises on a **regular basis**.

The information stored in the knowledge base is designed for use **as and when you need it**. This lets you access information on your condition and associated aspects to the degree that you find helpful in order to make decisions.

### 5 Description of application

#### 5.1 System requirements

Mika is currently compatible for use with operating systems upwards of Android 8.0 and iOS 16.

#### 5.2 Regions and languages

Mika is available for download in Germany, the UK and Switzerland. The app can be used in German or English language. The language used in the App is depending on the language settings of the device.

#### 5.3 Download and installation

Mika can be downloaded for Apple devices (iPhone and iPad) as well as for Android smartphones.

##### Mika from the Apple app store

<https://apps.apple.com/app/id1446551093>

##### Mika from Google Play



#### 5.4 Using the Mika app

Mika is a digital medical device that complies with the German law on medical devices. To make full use of Mika, you will need:

- a **partner code** (optional)
- a **Mika user account**.

##### 5.4.1 Information on the partner code

You may have received a partner code from your hospital, your doctor or a self-help group, which you can enter during initial installation of the app. Any additional or new codes can also be entered at any later time in the app's settings. This code is also referred to as a license key, activation code or registration code.

If you do not have a partner code, you can skip this step and continue without one. You will still be able to make full use of the Mika app even without a partner code.

#### 5.4.2 Information on your user account [🔗](#)

To make sure that only you will be able to access your data, which will be securely stored in a GDPR-compliant manner, and to let us contact you, you will have to set up a user account. All you need is a valid email address and a secure password. Setting up your account is entirely free of charge for you.

Your securely encrypted personal data will be stored on servers located in Germany. We will never sell your data, but will instead use it only to optimise Mika for you.

#### 5.5 Start and initial set-up (onboarding) [🔗](#)

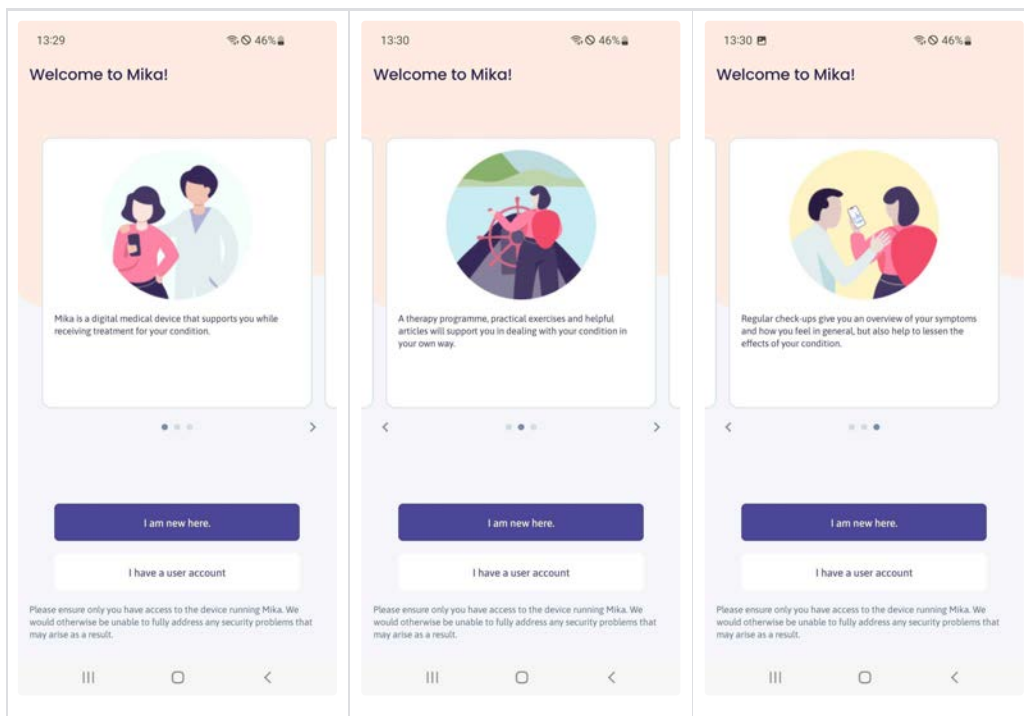
When you start Mika for the first time, you will be taken through a basic initial set-up (called onboarding).

You will first be asked to enter a partner code. If you have a valid code, your account will then be set up. But you will still be able to use Mika even if you don't have a partner code. Further information on the license key (or code) and your user account can be found in the 'Using Mika' section.

Once these formalities have been completed, you will be asked questions regarding your current status: your age, your gender, your diagnosis, whether you are currently receiving treatment, etc.. These details will be treated in the strictest of confidence and securely encrypted for storage. They serve the purpose of optimising Mika to suit your requirements. Any questions you would rather not answer can be skipped.

The individual steps you will encounter during your Mika onboarding are explained below.

##### 5.5.1 Logging in or new to Mika? [🔗](#)

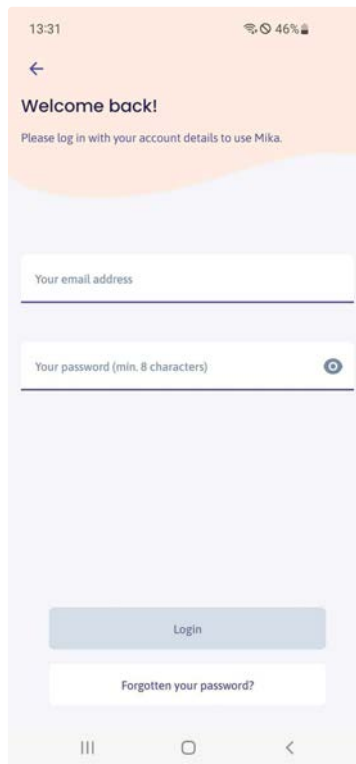


Once you have opened Mika, you can choose either to start as a new user or to log into an existing user account.

If you already have a Mika user account, please log in by tapping on 'I have a user account', after which a login window will open. If you are new to Mika and do not yet have a user account, please tap on 'I am new here'.



### 5.5.2 Logging into an existing user account [↗](#)



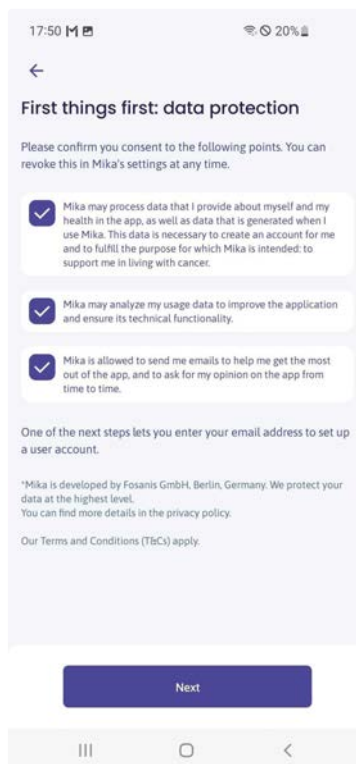
WelcomeBack screen

To log in please enter the email address you use for Mika and your password. All you have to do is tap on the fields underscored in blue and you can start typing straight away. If you have forgotten your password, please tap on 'Forgotten password'.

Please note: if your login attempt fails three times in a row, you will automatically be requested to reset your password (and then enter a new one).

If you used Mika in the past, but had not yet activated the app, you may – after logging in – be required to first activate Mika and/or to set up a user account. You can find further information on this in the 'Using Mika' section.

### 5.5.3 Declaration of consent/Data protection [↗](#)



Data Consent screen

If you are using Mika for the first time, you will be requested to allow us to process your data. Processing your data is necessary as Mika will otherwise fail to work. Please carefully read our Privacy Policy and our Terms and Conditions before granting consent, which you can revoke again at any time. Further information can be found in Mika's settings.

Your securely encrypted data will be stored on our servers in Germany. When you are ready, tap on 'Next'.

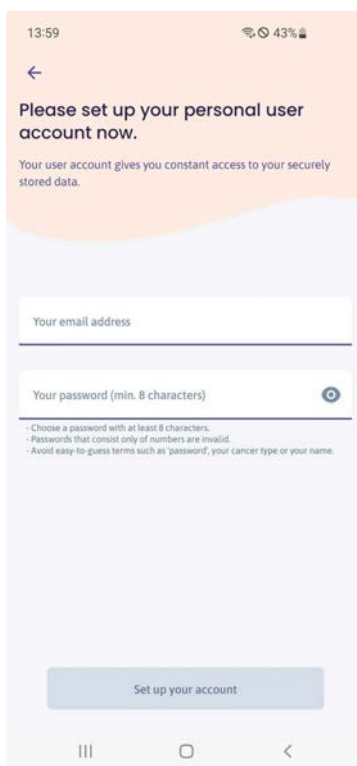
#### 5.5.4 Entering a partner code [🔗](#)



Code Input screen

Once you have agreed to your data being processed, you can then enter your partner code. Depending on the specific code, you will be given access to additional content, for example in the 'Discover' information section, or Mika will regularly ask you medically relevant questions that serve to monitor how your treatment progresses. You can enter partner codes at any time in Mika's settings.

### 5.5.5 Setting up a user account [🔗](#)



Create Account screen

Using Mika requires you to set up a user account, which not only lets you access your securely stored data at any time, but also allows Mika to contact you.

Please note: without setting up a user account, you will no longer have access to your data should you lose your smartphone, start using another device or delete Mika. Please use a valid email address that Mika can use for verification purposes. You will be sent an email with a confirmation link to the address specified.

Please set a secure password, which must consist of at least 8 characters. Further recommendations on setting a secure password can be found in the [‘Data protection and data security’](#) section.

### 5.5.6 Capturing personal and medical information [🔗](#)



*Please ensure the details you provide are accurate so you can be provided with information and content that correspond to your current situation.*

14:00 43%

← Skip

First, please provide some general details about yourself.

How would you like to be called?

First name

What's your date of birth?

DD/MM/YYYY

What is your gender?

Select

Next

||| ○ <

General Profile

17:52 19%

← Skip

What type(s) of cancer have you been diagnosed with?

Breast cancer

Prostate cancer

Bowel cancer

Lung cancer

Skin cancer

Anal cancer

Eye cancer

Pancreatic cancer

Pleural cancer (malignant mesothelioma)

Next

||| ○ <

Cancer Types

17:52 19%

← Skip

Which stage of your condition-related journey have you reached?

I have just received my diagnosis.

I am currently receiving treatment.

I have completed my treatment.

Next

||| ○ <

Cancer Phase

17:52 19%

← Skip

Do you have metastases?

No, I don't

Yes, I do

I don't know

Next

||| ○ <

Metastases

17:53 19%

← Skip

Which treatment(s) are you receiving?

Anti hormone therapy

Chemotherapy

Gene therapy

Immunotherapy

Surgery

Stem cell transplant

Radiotherapy

Targeted cancer treatment

Other

I don't (yet) know

Next

||| ○ <

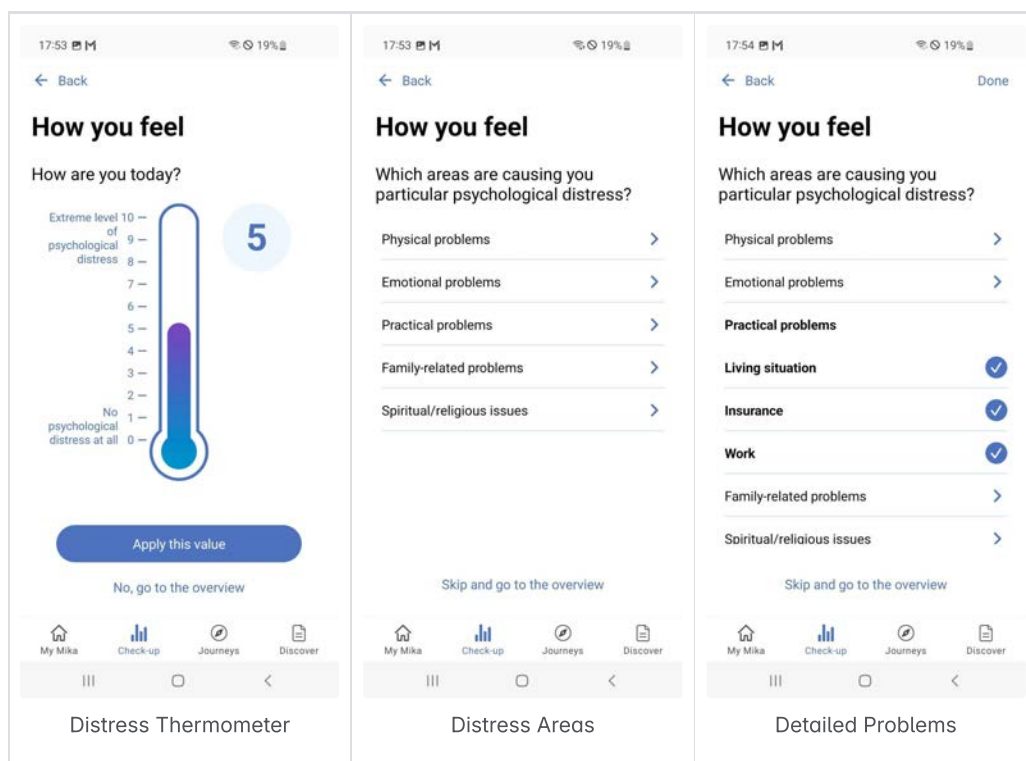
Therapy Type

In the following steps, Mika will ask you a number of questions about you (name, age, gender), the type(s) of cancer you have been diagnosed with, which phase you are currently in and your treatment. Tapping on 'Next' will take you to the next page. If you would rather not answer a question or do not know the answer, tap on 'Skip'.

Mika will use your data exclusively to provide you with personalised medical information, content and recommendations.

However, it is also absolutely fine if you would initially prefer not to share such details. You can edit or add to your data at any time in Mika's settings.

### 5.5.7 First check-up [🔗](#)



In the course of setting Mika up for the first time, you can also conduct a first partial check-up, during which Mika will ask you about your current health status and/or how psychologically distressed you feel. You can find detailed information on how exactly this check-up works in the [‘Check-up’](#) section.

## 6 Mika’s basic structure and functions [🔗](#)

Once you have completed the initial set-up, you will have all-area access to Mika.

Mika consists of four main areas that you can access at any time from the tab bar at the bottom of the screen. The following screenshots may differ from the display on your device depending on the Mika version and the operating system of your device.

**My Mika** is your personal start page. This is where you will find personalised messages, information and notes on using the app.

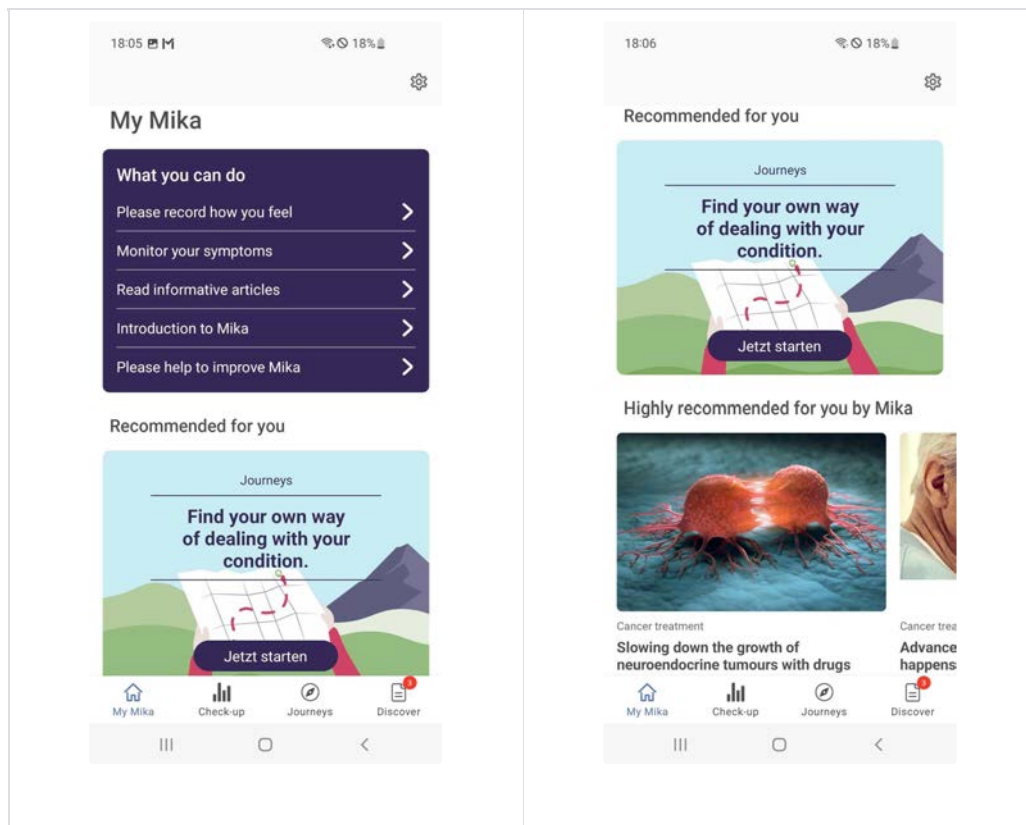
From here, you will also be able to access **Mika's settings** (tap on the cogwheel symbol on the start page).

**Check-up** is the area in which you can record your symptoms and keep track of the way you feel in general. This will give you a better overview of the course your condition is taking. In addition, you can pair Mika with your fitness tracker and/or your smartwatch.

**Journeys** offer you an extensive programme of exercises that are designed to help you deal with the emotional and psychological effects of your condition.

**Discover** provides you with information, physical exercises and practical tips that aim to help you live with your condition day to day. Content that is particularly relevant to you is highlighted automatically by Mika. In addition, the ‘Discover’ section lets you search for keywords or set bookmarks at any time.

## 7 My Mika [🔗](#)



'My Mika' is the central area from which you can access all Mika functions. The actual composition of 'My Mika' will gradually change over time as the app learns to better adapt to the way you use it and your interests.

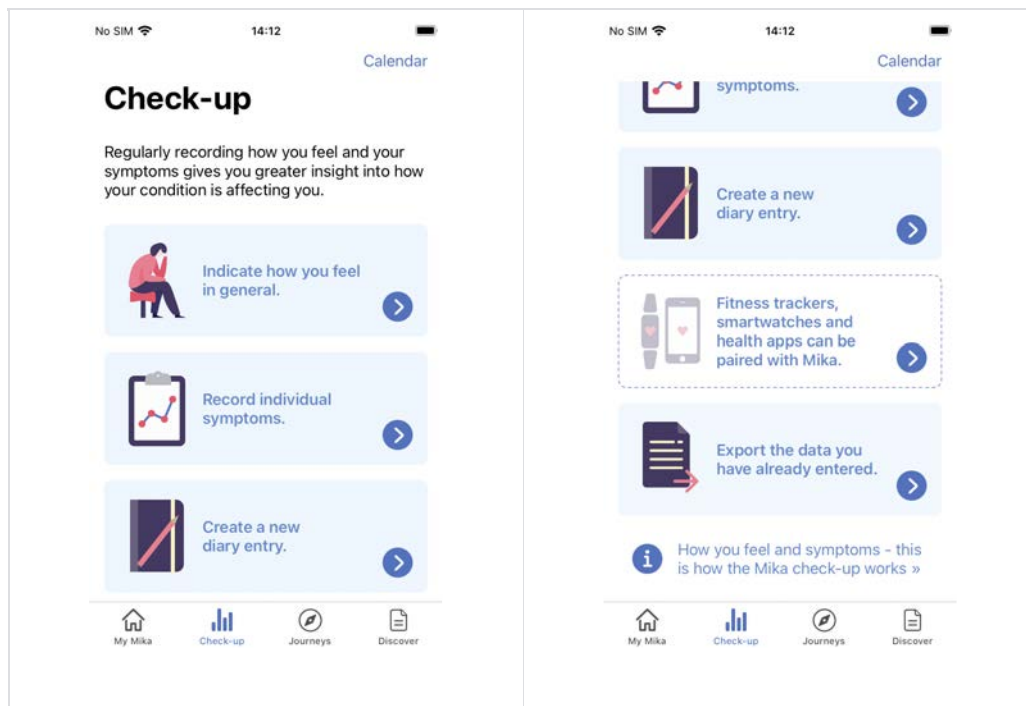
'My Mika' is divided into sections that will gradually change and/or be added to over time. At its most basic, which means when you first start using the app, Mika will display three sections:

The **What can you do?** box provides tips on which things you can do in your current situation. In the course of time, the composition of these tips will change depending on how you use Mika.

**Recommended for you** highlights content that Mika believes would be particularly relevant for you. In this regard, Mika may highlight new functions or content such as journeys, videos, texts or exercises.

Lastly, **Suggested for you** lists articles from the **Discover** section that were selected by Mika based on information provided by you. The composition of this section will change over time in the same way as the previously mentioned sections. Whenever you see anything that takes your interest, simply tap on it. Tapping on the **cogwheel symbol** at the top right will take you to **Mika's settings**.

## 8 Check-up [🔗](#)



The **Check-up** delivers an overview of *how you feel* and your *symptoms*. Regular and active observation of how you feel and your symptoms will help you to better understand the consequences of your condition. In addition, this data can provide your medical team with valuable information regarding your treatment.

**How you feel** seeks to find out what you would say if asked ‘How are you feeling?’. In Mika, you can indicate how psychologically distressed you currently feel on a sliding scale. If you are feeling really good, you will feel only a low level of psychological distress or even none at all. The slider would then be set to a lower value on the scale. If you are not feeling so good, you will be experiencing psychological distress – and the slider will rise on the scale. If you regularly record the way you feel, you will get a good idea of when and why you feel better or worse.

**Symptoms** can be of a physical, emotional or mental nature. In contrast to the way you feel, it is often necessary to specify and record symptoms in much more concrete terms. Such symptoms will mostly be a direct consequence of your condition and treatment. Depending on the symptom, Mika uses various scales that are designed to help you to evaluate the severity of any given symptom. Please note: not every person experiences the same symptoms. Select those symptoms from the list that you are actually experiencing. If a symptom is not listed, you can add it yourself.

Depending on the app version, the start page of the ‘Check-up’ section may offer further options:

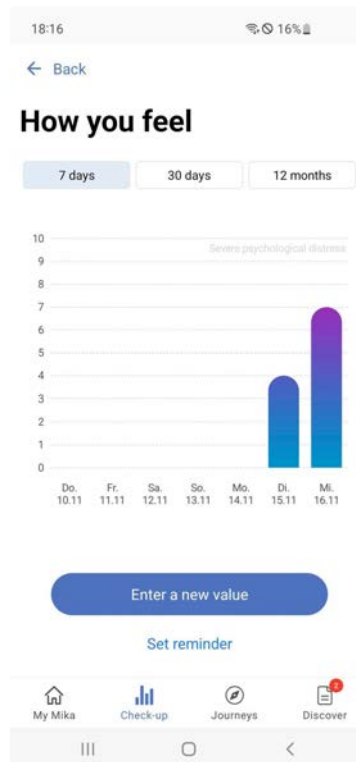
‘**Creating a new diary entry**’ (currently only on iOS devices). Tapping on this button will take you to the Mika diary, in which you can make a note of your thoughts and come back to them again at any time. Further details can be found in the ‘[Creating a diary entry](#)’ section.

‘**Pairing fitness trackers, smartwatches and health apps with Mika**’. Choosing this options lets you, for instance, export data from your fitness tracker for integration into the Mika app. Further details can be found in the ‘[Pairing other devices and services with Mika](#)’ section.

Under ‘**Exporting already recorded data**’ you can do just that. You can have all your previously captured data exported as a PDF or in machine-readable format for storage outside of Mika or you can share it, for instance, with your medical team.



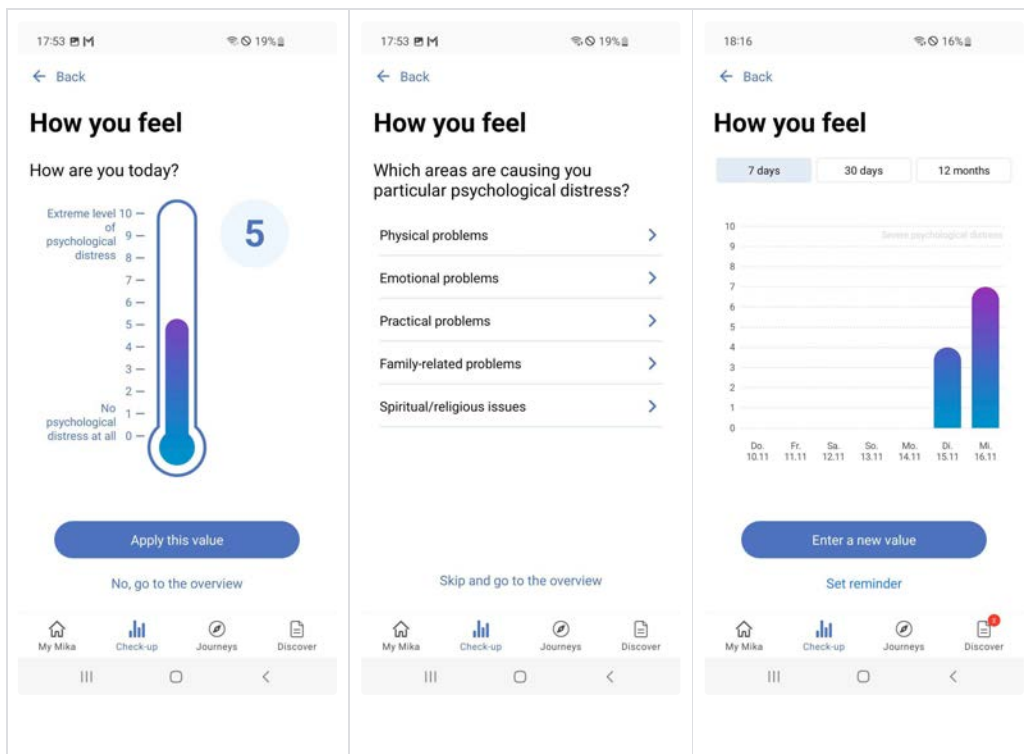
## 8.1 Overview of how you feel [🔗](#)



The **overview of how you feel** shows how the way you feel has developed over time. You can change the period of time for which data is displayed by using the segment switch to choose between 7 days, 30 days and 12 months. This lets you choose the time period you want to review yourself. When you first start using Mika, this overview page is likely to look rather empty. But making regular use of the Mika 'Check-up' will soon show you how the way you feel develops over time.

By the way, you can also export data previously captured by you as a PDF or in machine-readable format (in accordance with the FHIR standard). Simply go to the start page of the 'Check-up' section or go to Mika's settings and then to the 'Export data' subsection.

## 8.2 Recording the way you feel [🔗](#)



The **way you feel** is measured in the same way you would use a thermometer. Move the slider within the scale with your finger. The higher up the slider is on the scale, the more psychological distress you feel.

Choose a value that corresponds to the severity of your psychological distress level, in which 0 represents no psychological distress at all and 10 an extreme, maximum level of psychological distress. After you have set the value, tap on 'Next'.

In the following step, you can then specify the area(s) of life that you feel are causing you psychological distress.

Choose an **area of life** that is contributing to the way you currently feel. Tap on the respective area to be shown various aspects that you can additionally supplement if required. Tap on 'Done' at the top right to confirm your selection.

If you like, you can also add several areas of life and aspects. Please remember, though, that it makes sense only to select entries that correspond to actual contributing factors regarding anything you are currently dealing with.

Recording the way you feel and/or your current psychological distress levels serves to better understand which topics are especially important to you right now; it is less about extreme accuracy, rather it aims to 'take your temperature'. The idea behind it is to gradually make you more aware of when, for instance, physical and when practical problems are at the forefront. In this way, you will gain a better understanding of why you feel the way you currently do.

Please note: if clearly physical aspects are currently at the forefront, you should accurately record your symptoms. If you enter physical symptoms while recording the way you feel, these will also be added to your symptom list.

### 8.3 Symptom overview [🔗](#)



The **symptom overview** displays how your symptoms have developed over time. You can change the period of time for which data is displayed by using the segment switch to choose between 7 days, 30 days and 12 months. This lets you set the time period you want to review yourself.

To see the course of individual symptoms over time, simply tap on the blue symptom. If you recorded several symptoms, you will now be shown a list of all recorded symptoms.

Tap on 'Record a new value' if you wish to record existing or new symptoms.

By the way, you can also export data previously captured by you as a PDF or in machine-readable format (in accordance with the FHIR standard). Simply go to the start page of the 'Check-up' section or go to Mika's settings and then to the 'Export data' subsection.

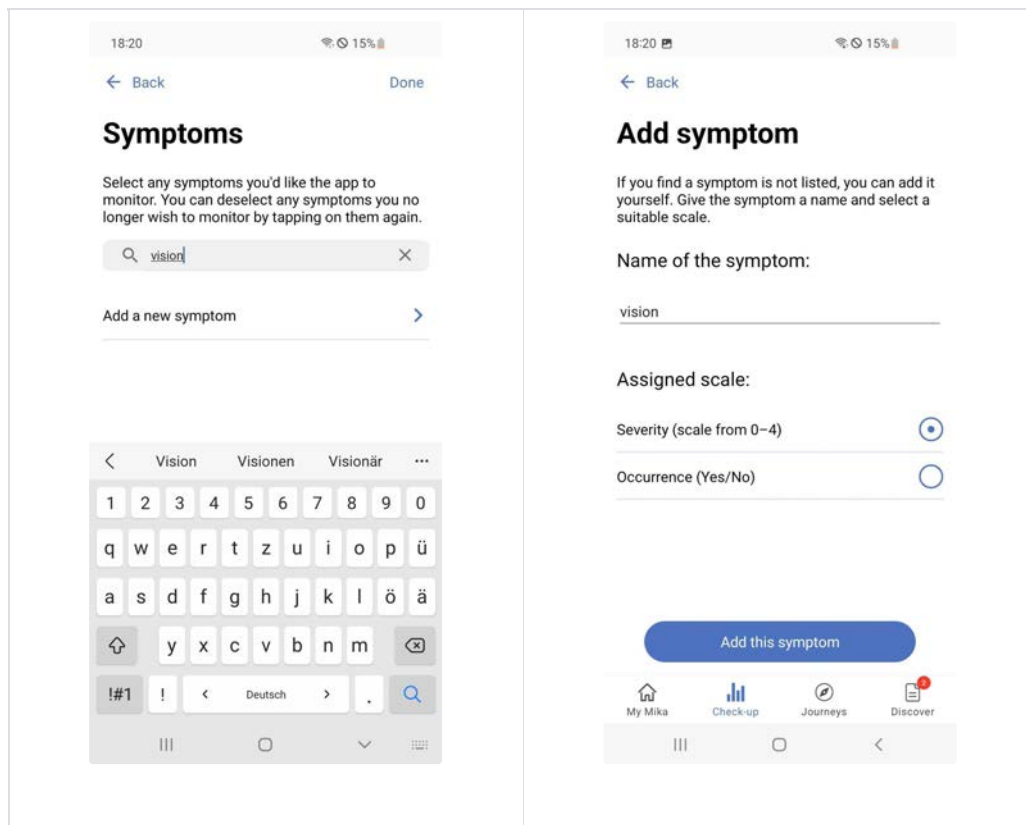
## 8.4 Recording symptoms [🔗](#)

It is recommended that you regularly record the severity of any symptoms you want the app to monitor over time. Mika lets you do this with ease.

Depending on the kind of symptom, you will be shown various scales, the principle of which always remains the same. Simply select the value that applies to you or the applicable description by tapping on it. Once you have updated all the symptoms you want to monitor in this way, tap on 'Apply values'.

To add a new symptom to your list of monitored symptoms or to delete a symptom from the list, tap on 'Add or delete a symptom'.

## 8.5 Recording new symptoms [🔗](#)



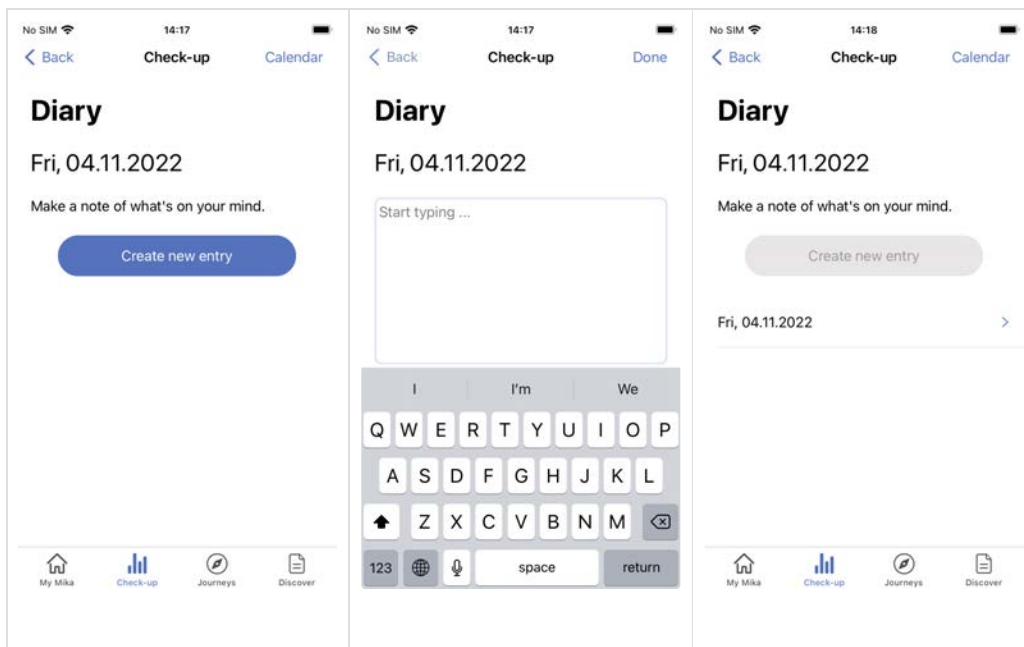
You can add new symptoms at any time in one of the following ways:

1. Select one or more symptoms from a standard symptom list.
2. Search for a specific symptom by entering it in the text input field.
3. Use the text input field to add a symptom that is not on the list.

To search for a symptom, simply tap on the text input field and start typing. After you have entered a few letters, you will often be shown a corresponding symptom. Tap on it and it will be added to your list. If the symptom has not yet been included in Mika, you can add it yourself. To do so, tap on 'Add new symptom'.

Please note: you are recommended to focus only on symptoms that you are currently actually experiencing. The course any health condition and its treatment takes will differ in every individual case and just because a symptom has been included on the standard list of symptoms does not automatically mean it has to apply to you.

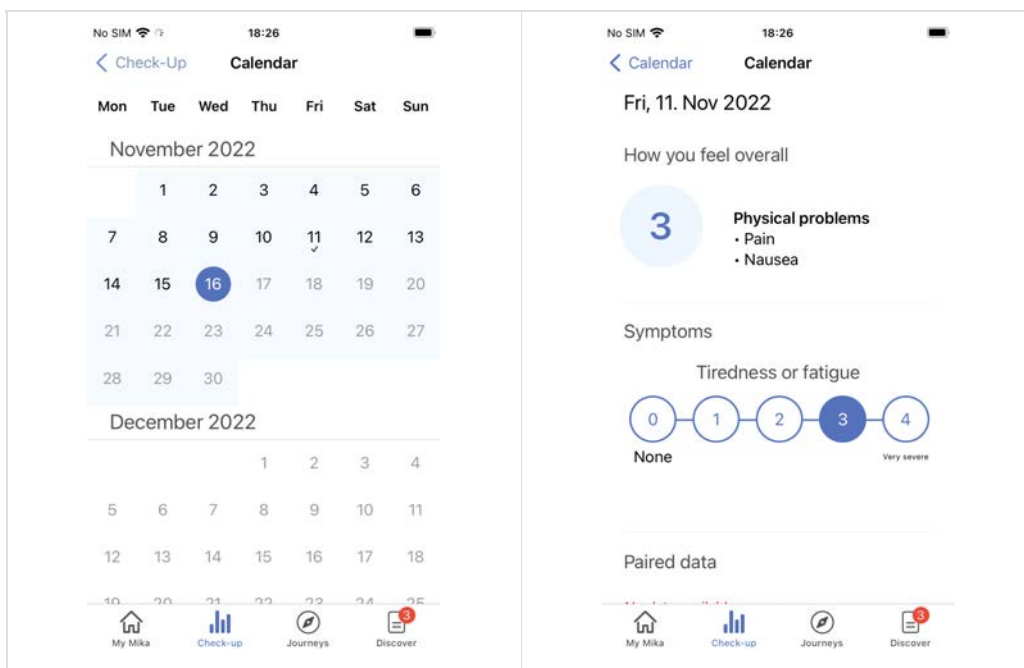
## 8.6 Creating a diary entry [🔗](#)



You can keep your own personal diary using Mika and simply make a note of things that are currently on your mind. You can also use the diary to make a record of additional information regarding the way you feel or about any treatment-related side effects. As a result, you will even be able to track the effects of any new medication, for instance, days later.

To create a new diary entry, simply tap on the 'Creating a new diary entry' tile on the start page of the 'Check-up' section. The overview page of your diary will then be displayed and you will see a list of all former entries made by you. A new entry can be made by tapping on the blue 'Create new entry' button. This will automatically create a new entry for the day in question and you can start typing straight away. Once you have finished, tap on 'Done' at the top right. The new entry will then appear in the overview. If you want to edit and/or change an entry, simply tap on the corresponding entry. You can then edit or even delete the entry if you want. All diary entries can also be accessed via the calendar. This is a quick way to check what was on your mind a few weeks ago.

## 8.7 Calendar [🔗](#)



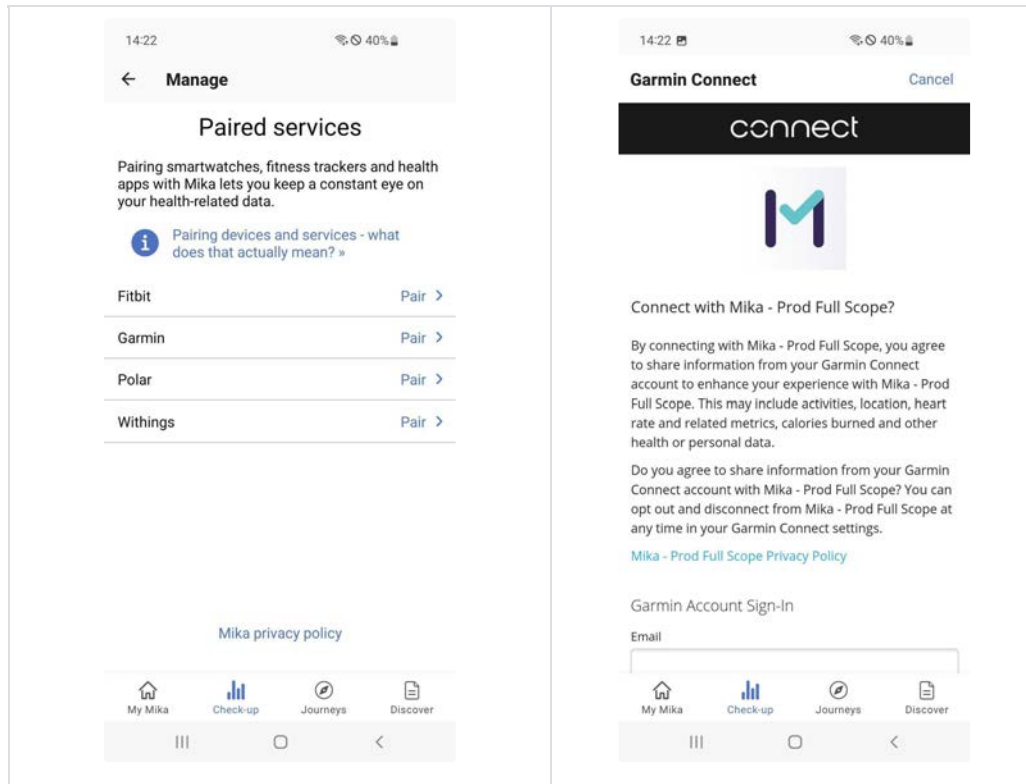
Mika includes a calendar that you can view in the 'Check-up' section by tapping on 'Calendar' at the top right.

The Mika calendar provides an accurate daily overview of your previously recorded data. Ticks placed in the overview indicate that data is available for these days. An overall overview is created for each day that displays all captured data at a glance:

- The way you felt and if applicable any aspects that contributed to the way you felt on this particular day.
- Symptoms observed by you.
- Any data captured by your smartwatch.
- The diary entry made on this day.

You can still edit some of the data at a later point in time by tapping on the pen symbol to the right of the section name.

## 8.8 Pairing other devices and services with Mika [🔗](#)



You can pair Mika with your fitness tracker, your smartwatch and with other health apps. To this end, you will have to allow the respective service to share data specified by you with Mika. This enables any values you recorded in Mika, e.g. symptom details, to be combined with data automatically recorded by your device. Please be aware that this process takes place in only one direction – values that you have recorded using the Mika app will never be transferred to other devices or services.

Sharing data with Mika is particularly useful if such data says something about your activity levels, for instance the number of steps taken per day or the average amount of sleep you get. Such values let Mika get to know you even better and enable the app to offer you specific content to match.

This is how it works:

1. Tap on the 'Pair fitness trackers, smartwatches and health apps with Mika' tile on the start page of the 'Check-up' section.
2. Select the manufacturer of your device from the overview shown and/or the service that you want to pair. If the manufacturer of your device is not included on the list, it is not yet possible to pair Mika with it. Please check back at a later point in time since new manufacturers are constantly being added to the list.
3. In the next step, you will be asked to log into your account with the manufacturer of your device (for instance your Garmin user account).

4. Now you can select data you want to share with Mika. Please note the following in this regard: when you have newly paired a device and/or service with Mika, you are likely not to see all the captured data to begin with since Mika continually 'learns' and will initially capture only simple values such as the number of steps you walk per day or the amount of time you spend asleep. Mika will gradually collate and add to this data.
5. Once you have confirmed your selection, your device and/or service will be paired.

Due to the synchronisation process, you may have to wait a few minutes before the overview displays your data.

The following fitness trackers, smartwatches and health apps can be paired with Mika:

- Apple Health (only iOS)
- Fitbit
- Garmin
- Polar
- Withings

#### **8.8.1 Viewing paired data** [🔗](#)

You can view data from paired devices in a new overview. For every category actively evaluated by Mika you will see a tile displaying the latest updated value in each case. Tapping on a tile included in the overview will display the details and you can track the way they developed during various time periods..

#### **8.8.2 Disconnecting paired devices and services** [🔗](#)

You can disconnect any pairings between your devices and Mika at any time. Simply go to the Mika settings, then to 'Manage paired devices and apps' under 'Paired services' and select which device/service you want to disconnect from Mika.

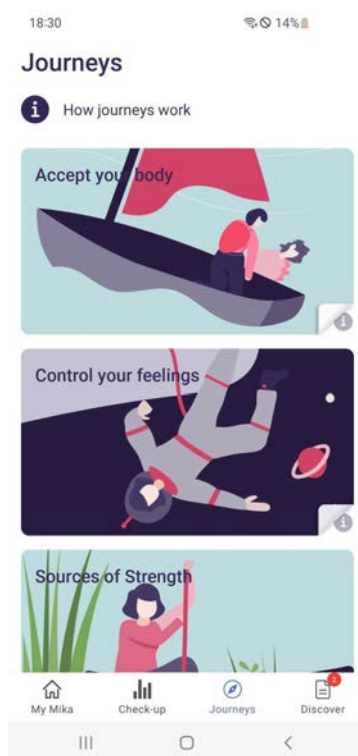
All previously captured data will be retained by Mika. You can view such data at any time via the 'Historical data' overview, which you can access from the 'Check-up' start page. Your data will be stored by Mika until you delete your user account. You can also export your captured data at any time for use in other applications.

#### **8.8.3 Information on data protection** [🔗](#)

To make sure that Mika can capture and interpret your data from another device, this data must first be translated into a format that Mika can understand. This happens automatically using a service called Thryve, with which we collaborate. This service works like a bridge between your fitness tracker and Mika. Since both have to communicate with one another, the following applies: the manufacturer of your device will gain knowledge that you use Mika. And Mika will know which device you use. However, the device manufacturer will never have access to your Mika data (symptoms, how you feel, progress made, etc.). What you do in Mika stays in Mika.



## 9 Journeys [🔗](#)



Mika's journeys are designed to help you to better deal with the emotional and physical consequences of your condition. These journeys were developed on the basis of scientific evidence and in close cooperation with experts.

The **list of journeys** shows you which topics are currently available. This list is added to on a continual basis and can also contain specific, treatment-related journeys that may not be relevant or visible for every user.

Every journey addresses a main topic. You only have to select the ones that interest you to embark on a fascinating and educational path. Simply tap on the respective tile.

Grouped into individual stages, journeys consist of various exercises and provide food for thought. As these stages build on each other, it is recommended to work through any given journey from beginning to end in the order suggested to ensure you get the most out of it.

### 9.1 Basic structure of a journey [🔗](#)


Every journey follows a clear structure that is designed to help you make sense even of more complex topics at your own pace:

Each journey is made up of individual **stages** that include certain exercises and together form a meaningful whole. Think of a stage as a chapter in a book. You will automatically progress from one stage to another.

Every stage begins with a **short introduction** to the respective topic that will tell you what it is about and what to expect.

After that, you will be asked for a **self-evaluation** that is intended to help you to establish where you are at present and what a good, achievable goal might be for you.

This is followed by various **exercises** that will help you to explore the respective topic. These include:



*Please read the 'Counter-indications and exclusions' section before using this section of the app.*

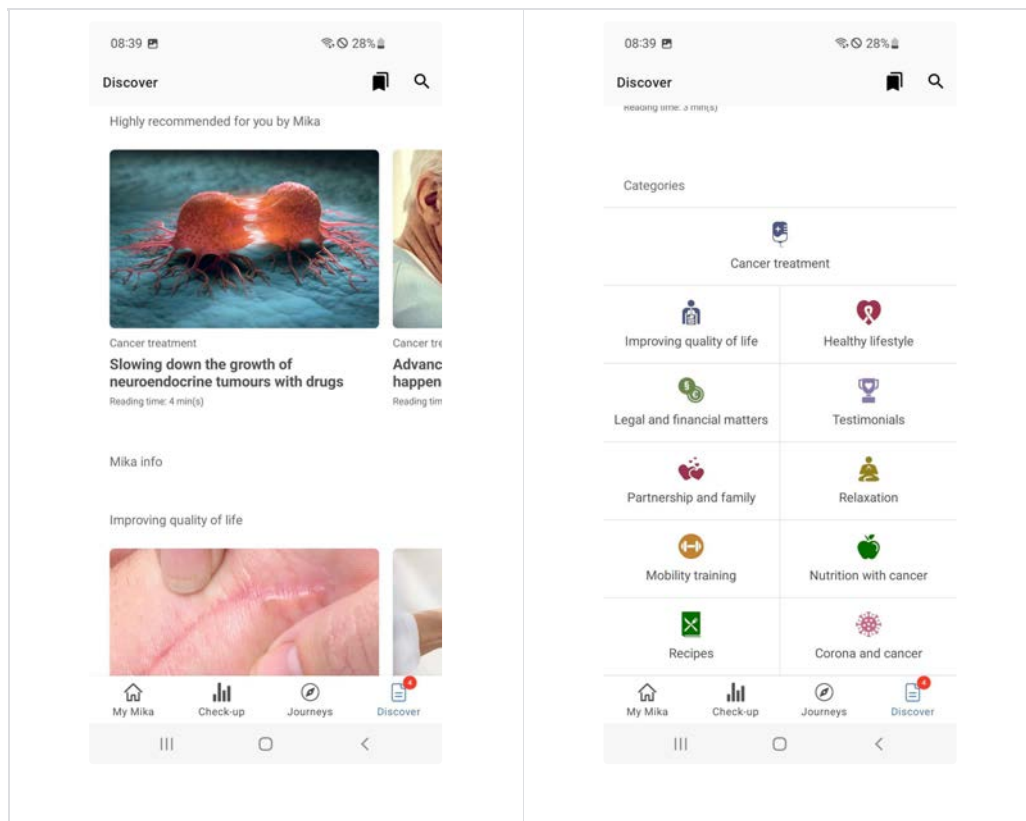
- **Mindfulness exercises** that aim to put your focus on being more aware of your body and your mind. These exercises are audio files and you will find them in various journeys as recurring exercises for completion every day.

- **Physical exercises** in the form of videos that are designed to strengthen your body. You can choose the degree of difficulty of these exercises.
- **Relaxation exercises** that are designed to help you find inner peace. These are longer audio files that, for instance, can help you fall asleep.
- **Journal exercises** that let you specifically reflect on challenges and order chaotic thoughts. These guided writing exercises are designed to be completed on your own on a daily basis.
- **Explanatory or informative content** that provides valuable background knowledge such as videos, diagrams or texts that let you learn something about yourself, your condition and/or its effects.

In addition, many journeys contain courses to be completed over several days that include exercises which you will ideally do on a daily basis. These can be mindfulness exercises, but can equally be physical exercises. Regardless of how long you may want to spend on the content of a journey, you will benefit greatly from actually doing the exercises on a regular basis. This will allow them to become a valuable part of your daily life and you will reap their full benefit.

To begin with, you can of course try various journeys until you find one you want to complete from start to finish. And: you can take a break from a journey at any time and come back to it again later.

## 10 Discover [🔗](#)



The 'Discover' section offers numerous interesting articles, videos and exercises. The composition of the content will gradually adapt to your needs and interests.

The **overview page** for the 'Discover' section is clearly and simply structured.

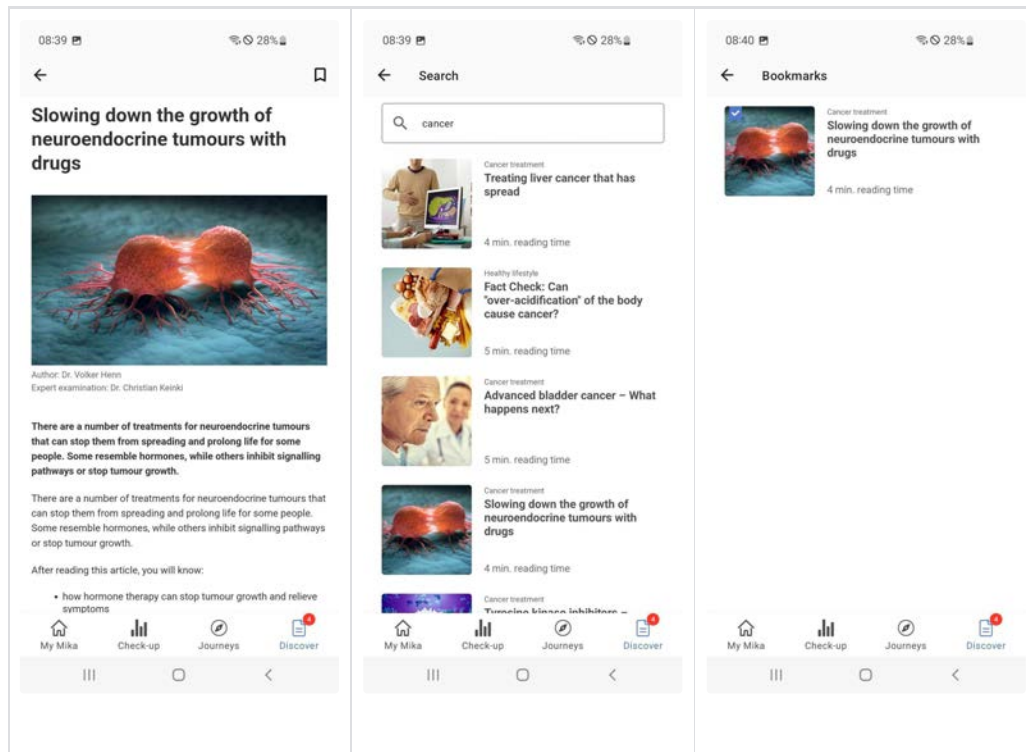
Bookmarks and the search function (more about that further down) can be found in the header. Below that you will find article tiles with images which are ordered in scrollable (movable) bands.

'Suggested for you' is just that – articles that Mika has highlighted for you based on your data. Depending on how you use Mika and how your treatment progresses, these suggestions will change.

You will then find this section contains numerous other articles, pre-sorted into categories.

At the end of the overview page you will then find all article categories again in an overview. Tap on the category that interests you to open a new page that will list all the content in the respective category.

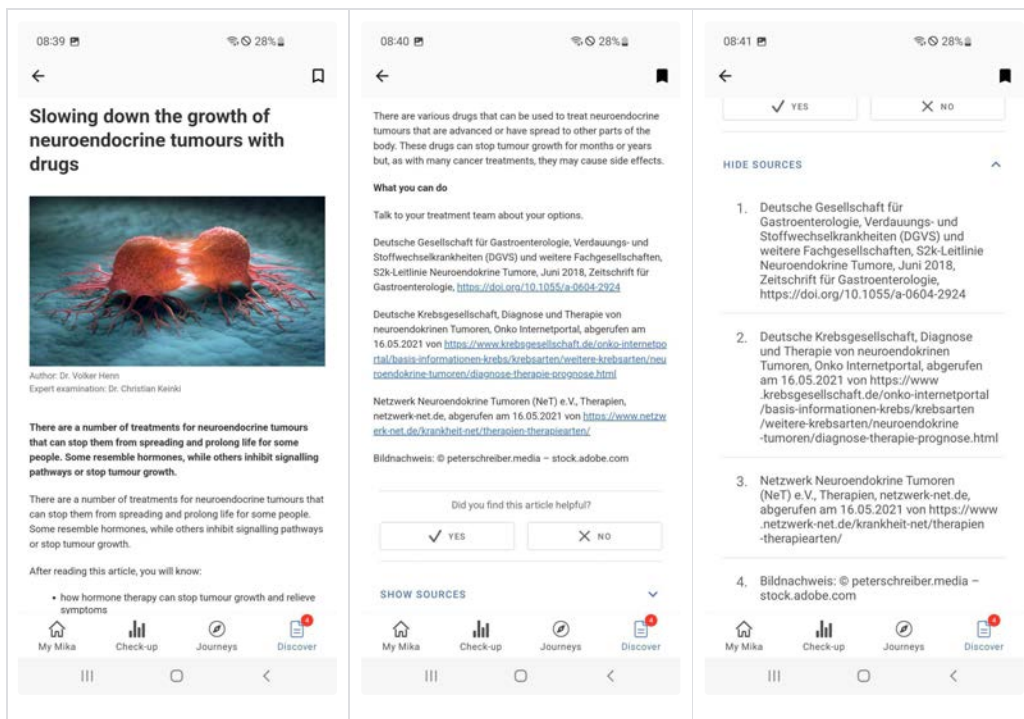
## 10.1 Bookmarks and search function [🔗](#)



Bookmarks are the place to which your articles are saved. A bookmark icon can be found in the page header of every article. Tap on the icon to add the article to the bookmark list. To access the bookmark list, simply tap on 'Bookmarks' at the top left of the header of the 'Discover' overview page.

If you know what you are looking for, you can also search for specific keywords. Just tap on the magnifying glass symbol at the top right of the 'Discover' overview page to enter your search term.

## 10.2 Articles [🔗](#)



In Mika, an article can be a text or a video. The following applies: each article was professionally checked by independent experts. If you want to check in detail on which basis an article rests, you can do so using the 'Show source' link, which is located underneath each article.

If you would like to save an article for later, simply bookmark it by tapping on the bookmark symbol at the top right of the header of each article page. You will then be able to find the bookmarked article at any time if you tap on 'Bookmarks' on the 'Discover' overview page. If you like, you can also rate articles. This will give Mika valuable feedback and the app will better be able to adapt to your specific needs.

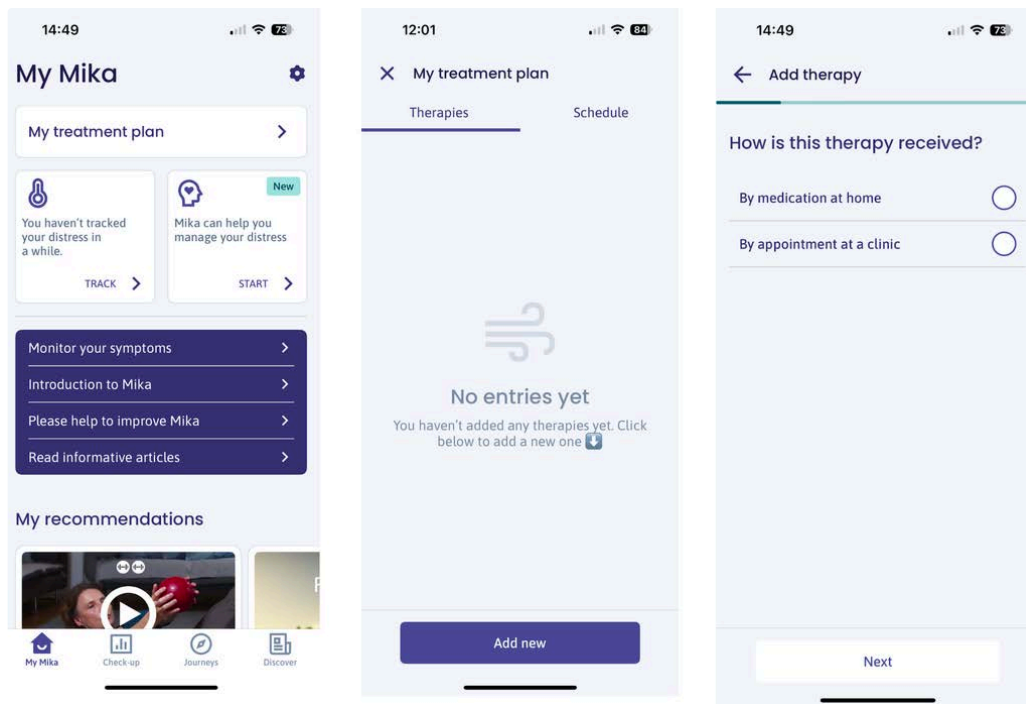
## 11 Treatment Management [🔗](#)

This feature is considered as an extension to the medication reminder feature. It provides you with an overview of your history of appointments and enables you to keep track of upcoming appointments. You can enter all of your ongoing or upcoming therapy details (name, type) and appointments in one place and get reliable push notifications. You can manage both:

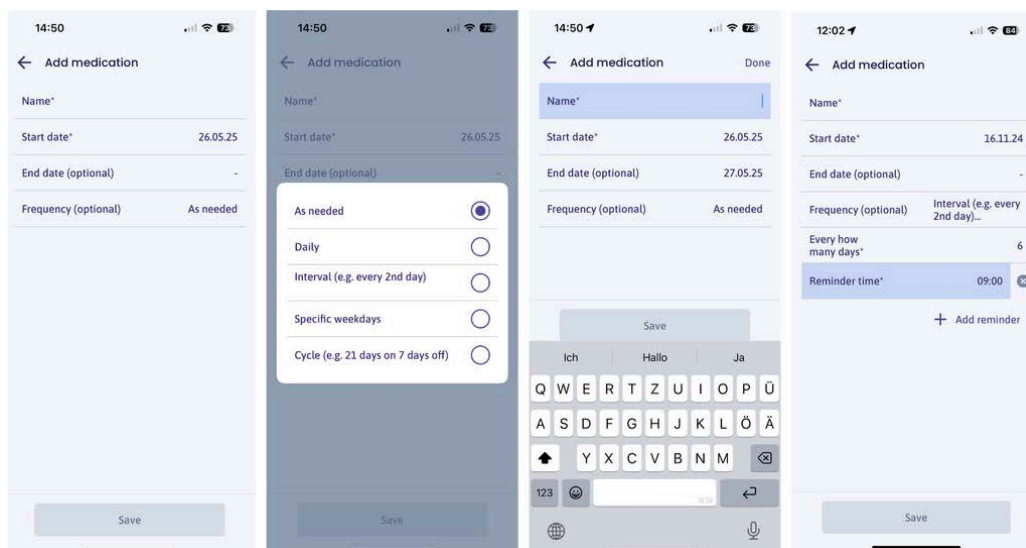
- medications you take at home, and
- therapies or appointments at a clinic (e.g. chemotherapy, radiation, surgery).

Flexible intake and appointment schedules are supported.

My **treatment plan** can be accessed from the Mika home. Here you can store the medication/therapy you are taking and schedule reminders for the medication intake/appointments. Tapping **Add new** under **Therapies** takes you to the **Add Therapy** page. Here you can choose how you receive therapy.



When you tap on **By medication at home**, you can enter the medication name, start date, and end date. **Frequency** lets you set Daily, Interval, Specific weekdays, Cycle or As needed for the frequency of the medication intake. Based on your selection, additional fields appear. Add reminder helps you to set one or more notification times. Once you've added all the information, tap 'save'.



By **appointment at a clinic** enables you to add therapies/treatments you receive at a clinic. You can choose the **Administration type** (e.g. Infusion, Injection or Radiation) and select the specific therapy type. When prompted, you can answer if you already receive this therapy. This helps Mika to show you articles relevant to your therapy type. Optionally, you can **enter the start date for your treatment**. In the next step you can enter **the date and time of your next appointment** for this therapy. You can add more appointments by answering **Yes** to 'Would you like to add more appointments to this treatment?' A summary of the therapy details is shown to you before you **Save**.

12:02

← Add therapy

How is this therapy received?

By medication at home

By appointment at a clinic

Next

14:50

← Add therapy

What will you be receiving at the clinic?

Infusion / Injection

Radiation

Surgery

Other

Next

14:52

← Add therapy

Infusion / Injection

Bone targeting agents

Chemotherapy

Anti hormone therapy

Immunotherapy

Stem cell/ Bone marrow transplantation

Systemic radiation

Targeted therapy

Gene therapy

Other

Next

14:50

← Add therapy

What will you be receiving at the clinic?

Infusion / Injection

Radiation

Surgery

Other

Have you received this treatment already?

Based on your answer, Mika can provide you meaningful tips in the Discover section.

No

Yes

12:03

← Add therapy

Skip

Enter the start date for your treatment

The date of the first administration of the treatment.

23.11.24

Next

12:03

← Add therapy

Skip

What is the date and time of the next appointment to receive this therapy?

23.07.25

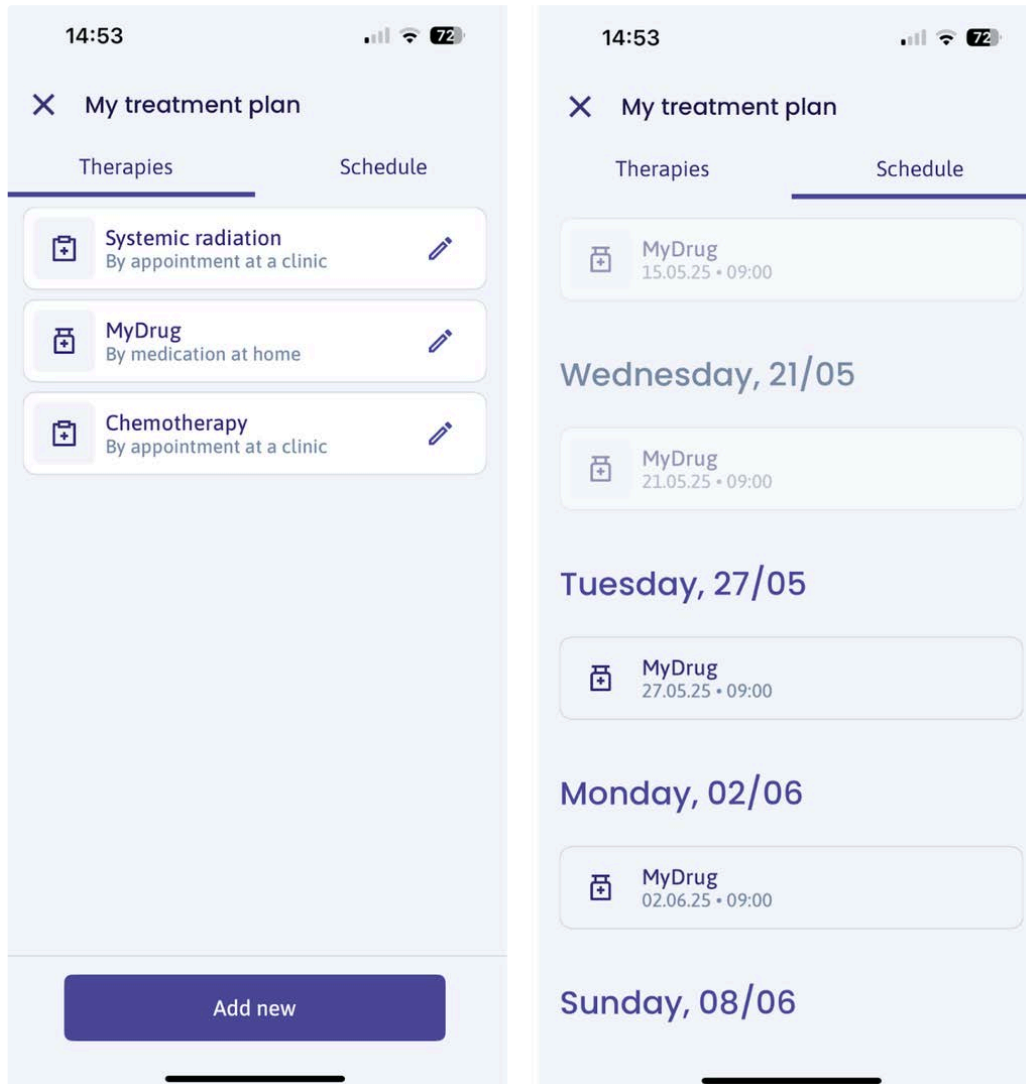
10:00

Next

**Therapies** tab shows an overview of all entries. By tapping on the pen icon, you can edit or delete any information that you've added.



**Schedule** tab displays all upcoming intakes and appointments in chronological order.



Push notifications appear at the chosen time on your lock or home screen. You can tap on the notification to mark the event as done. You can turn notifications on or off in your device settings.

## 12 Mika's settings [🔗](#)

You can access Mika's settings via the 'My Mika' start page. Simply tap on the cogwheel symbol at the top right. The settings can be seen as Mika's administrative centre. You can then edit or add to your personal data, set reminders, export your data in pre-processed format and much more. Mika's settings are grouped into logical sections. To edit or add to an entry, simply tap on the respective line. You will then be able to make your entries in the next window.

### Activating Mika

This section lets you enter a partner code if you have one, obtain information on how to obtain a code and read the FAQs.

### Personal data

Enter your personal details here. If you state your name, Mika will use it to communicate with you. Entering your age and gender will affect the suggestions that Mika provides you with.

### Medical data

As your medical data in particular can change over time, it is important that you update such details in Mika. This will ensure that Mika is working with correct data.

### **Your diagnosis**

Please enter the type of cancer you were diagnosed with here. If your specific condition is not listed, please choose 'Other type of cancer'. You can also select several types of cancer.

### **Status**

Status provides information on where you are at present: recently diagnosed, currently in treatment or already post-therapy.

### **Treatment**

The kind of treatment can also be subject to change. Please indicate here which kind(s) of treatment you are currently receiving.

### **Notifications**

Notifications can include the announcement of new functions and content-related improvements, just as personalised tips and recommendations for you.

### **Managing notifications**

This section lets you manage Mika's notification settings. You can en- or disable notifications at any time. Depending on your respective operating system (Android or iOS), you may have to access the central settings of your device if you en- or disable notifications.

### **Reminders**

In the 'Reminders' section, you can set automatic reminders for various Mika aspects. For example, to do repetitive exercise courses or to record your symptoms and how you feel at regular intervals.

### **Managing reminders**

This section lets you centrally manage any reminders you have set. As a result, you can see at a glance which reminders are active and can en- or disable them as required. If you have not yet set any reminders, you can set reminders for recording symptoms and how you feel without having to access the respective Mika sections.

### **User account**

This section lets you view the data stored in your user account.

### **Paired services**

This section lets you manage any devices you have paired with Mika such as fitness trackers or smartwatches. Pairings can be added or removed and you can export data captured by these devices to Mika.

### **Exporting data**

This section lets you export your medical data (how you feel, symptoms incl. type of cancer, status, kind of treatment) as a PDF or in machine-readable format (as a JSON file in acc. with the FHIR standard). You can also specify the data volume and the time period that you want to export. Leaving the standard settings will result in all data being exported.

### **Delete all data**

If you no longer want to use Mika, you can delete your user account and all your data.

Please note that **this step is irrevocable**. If you want to export your data, please ensure you do so before you delete your account and data.

### **Legal information**

Among other things, this section contains the Terms and Conditions (T&Cs), Privacy Policy and a link to the latest version of Mika's instruction manual. You are advised to carefully read these texts.

### **Technical matters**



This section is dedicated to several technical matters related to safeguarding product quality.

### App usage tracking

We will track usage of the Mika app to ensure that everything works as it should and you get the best possible user experience. If you would rather not have your usage of the app tracked, please disable the setting.

### Crash reporting

A so-called 'crash report' will be generated should anything ever go wrong with Mika and the app crashes. This technical report helps us to establish whether and where a possible technical problem has arisen. If you do not want your device to send crash reports, please disable the setting.

### App version

Mika is a work in progress and continually being updated. This section tells you which Mika version you are running.

## 13 Help [🔗](#)

You can obtain help for any questions or problems you encounter when using Mika on the Mika support page or by emailing [support@mika.health](mailto:support@mika.health)

Should there be any incidents, please email [Outcomes4Me Germany GmbH](mailto:Outcomes4Me.Germany.GmbH) at [support@mika.health](mailto:support@mika.health) and contact the local regulatory authority.

A printout of the document can be sent to you free of charge within 7 days. Please send your request to [support@mika.health](mailto:support@mika.health)

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### Change control [🔗](#)

Date	Version	IfU website version	Description of change
17.11.22	1.0	1.0	<ul style="list-style-type: none"><li>EN version of IfU for the UK launch</li></ul>
24.02.23	2.0	2.0	<ul style="list-style-type: none"><li>Adapting according to comments of TÜV for MDR certification</li></ul>
06.03.23	3.0	3.0	<ul style="list-style-type: none"><li>Updated manufacturer's address</li></ul>
04.05.23	4.0	3.0	<ul style="list-style-type: none"><li>Changed ownership</li><li>Update document classification</li></ul>
15.01.24	5.0	4.0	<ul style="list-style-type: none"><li>Updated the required compatible iOS version from 15 to 16</li><li>removed v11 from the "<a href="#">changed history</a>." as the change is for internal purpose only</li><li>added new column in the change control for the IfU version on the website</li></ul>
28.03.24	6.0	5.0	<ul style="list-style-type: none"><li>Added Swiss rep details</li><li>minor alignment changes</li></ul>
19.06.24	7.0	-	<ul style="list-style-type: none"><li>Reorganised sections 3 and 4 by clubbing more relevant articles together.</li><li>Added new section intended patient population to align it with other TD docs → Device description and CEP</li></ul>

			<ul style="list-style-type: none"> <li>• Added numbering to all sections</li> <li>• Separated contraindication and warnings into 2 sections</li> <li>• added a new warning related to malfunction (section 4.6)</li> <li>• removed claims from the section "Indications for use": depression, fatigue, anxiety</li> <li>• added vulnerable populations to the "Intended Users section"</li> </ul>
10.10.24	8.0	-	<ul style="list-style-type: none"> <li>• excluded vulnerable populations to the "Intended Users section"</li> </ul>
04.04.25	9.0	-	<ul style="list-style-type: none"> <li>• updated manufacturer details to Outcomes4Me</li> </ul>
12.06.25	10.0	6.0	<ul style="list-style-type: none"> <li>• Updated Basic UDI-DI</li> <li>• Added Treatment management under 4.10 and 11</li> </ul>