

# Instructions for use Kata



App Name: Kata Inhalation Coach

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These instructions for use contain information and safety instructions for your Kata app. Please read this manual completely and carefully before using the app.

In the event of a serious incident related to this app, please report it to the relevant authorities and VisionHealth.

## Content

1. Intended Use
2. Patient Groups
3. Compatibility
4. Liability
5. Warnings and Precautions
6. App explanations
7. Troubleshooting
8. Service
9. Explanation of symbols used

## 1. Intended Use

The Kata Inhalation app is a software app that is intended to monitor, inform about and improve inhalation therapy treatment. It collects and provides data of the inhalation manoeuvres to take decisions on the further proceeding of the treatment (therapy control and monitoring). Inhalation manoeuvres are guided through analysis and feedback, intended to reduce handling errors of patients and adjust therapy if required.

## 2. Patient Groups

The Kata app is suitable for patients aged 18 and over who have been prescribed an inhaler by their doctor. The patient must be able to perform the inhalation independently and on their own responsibility, or under the supervision of a healthcare professional.

Patients with impaired vision cannot use the Kata app.

## 3. Compatibility

### Compatible inhalation devices

For the following inhalers, Kata provides feedback on breathing manoeuvres and handling of the inhaler (inhalation coach):

- All metered dose inhalers
- Respimat
- Nexthaler
- Ellipta
- Turbohaler
- Easyhaler
- Breezhaler
- Diskus
- Handihaler

The reminder function and the device-specific step-by-step instructions are also part of the functional scope.

All other powder inhalers are considered with a basic function which, for example, reminds of inhalations and assists with the most important steps of the inhalation process.

## Compatible Smartphones

The Kata App can be used with operating systems of iOS from version 18 or Android from version 13 (API Level 33).

Smartphones should usually not be older than 3 years:

- Apple/iOS devices from iPhone 8
- Android devices are displayed as compatible or not compatible in the Google Play Store

In addition, there must be at least 2 GB of RAM and 1 GB of free main memory.

## 4. Liability

It should be expressly noted that the Kata App is intended solely for information and awareness purposes but cannot replace the consultation and diagnosis of a physician. Under no circumstances does VisionHealth give medical therapy recommendations or medical advice of any kind. For questions regarding illness and therapy, contacting a physician is recommended. The generated data will not be evaluated by VisionHealth GmbH in a person-related manner.

The proper entry of therapy plans (creation of inhalations in combination with reminder function) is the responsibility of the app user. Before using the inhalers, it is essential to read the package inserts of the medications and therapy products. It is also necessary for the app user to follow any instructions given by the doctor or pharmacist. The entry of all data, intervals, repetitions and quantities is the sole responsibility of the app user.

## 5. Warnings and Precautions

Please be sure to observe the following warnings and precautions:

Even if the inhalation assessment appears inadequate, do not under any circumstances repeat inhalation that has not been prescribed by a physician. If the ratings appear persistently poor, follow steps described in chapter 0 In the "Settings" section you can log out by tapping on "Log out".

If you no longer need the app, you can uninstall it at any time and/or delete your user account in the "Settings" section. Please note that when you delete your user account, all your data will be irretrievably deleted. Before uninstalling or deleting your account, you can export data as a PDF document.

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- For optimal use of the app, access to the camera functionality and microphone is necessary (image and sound are not transmitted or stored, but only processed by the artificial intelligence on the smartphone).
- The microphone of the smartphone must not be covered during the application, otherwise the results of the assessment may be incorrect.
- Ambient noise that is too loud can influence the result of the inhalation feedback.
- In case of doubtful results or deterioration of the health condition, it is essential to consult a doctor immediately.
- To ensure the functionality of the app, regular updates of the app are necessary. To ensure that no update is accidentally omitted, the regular updates from Google Play Store or Apple App Store should be activated in the settings of the smartphone.
- Regular Internet connections are necessary to store the generated data on a database. This ensures that they are not lost.
- The inhalation steps specified in the Inhalation Coach are the same as those in the package insert of the inhalers. If you notice that the steps for your inhaler are different from those in the app, this inhaler may only be used in accordance with the inhaler's instructions for use.
- To prevent unwanted changes or misuse of your entered data, please make sure that no one else is using your app.
- To ensure that all inhalations made are stored correctly and the reminder function works properly, please make sure that the app for one user account is installed and used on one smartphone only.
- To protect your entered data from manipulation and unauthorized access, we recommend using the authentication offered in the smartphone (PIN, pattern, fingerprint or facial recognition).
- To ensure the app works perfectly, please only use compatible smartphones.

## 6. App explanations

### Installation

You can install the app on your smartphone by yourself.

### Login (create user account)

Before you can use the app, you need to create your user account. This is done in the following steps:

- Enter email address
- Create and enter password
- Entry of personal data, such as, name, year of birth and gender, country
- Enter the information about your disease (asthma, COPD, cystic fibrosis or other)
- Input whether you smoke or not
- Read the terms of use and agree
- Read the privacy agreement and agree to the processing of personal data


Now you can unlock the app by entering your trial code.

After activation, the instructions for use are displayed.

Once the user account has been created, only the email address and password need to be entered to log in.

The data entered is subject to data protection and thus to strict legal requirements. In the integrated data protection agreement, you will find detailed information about which data is collected for which purpose.

### Setting up

	While you are setting up your inhalers, you can view the instructions for use by clicking on this icon (top right).
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#### Step 1: Set up inhaler

- Inhaler typ (MDI, Respimat, Ellipta, Flexhaler, Diskus etc.)
- Inhaler brand name (Note: Inhaler type and brand name must match. The app will display an error message if a mismatch is detected.)
- Usage type (Regular, As needed, Emergency use)
- For the “Regular” usage type:

- Inhaler name
- Frequency (applications per day)
- Number of sprays or inhalations per application
- Scheduled time (here you can additionally specify whether the app should remind you)
- For usage type “As-needed” and “Rescue Use”:
  - Inhaler name

If you are using an inhaler that is not available for selection in the Kata app, you can select the generic inhaler ("Other").

You can capture the inhaler type using your smartphone's rear camera. The app can automatically recognize supported inhalers based on the camera image. Place your inhaler on a table or another surface, or place it on the palm of your hand, or hold it between two fingers. Move the smartphone camera so that the inhaler is positioned within the white box on the display. After a short time, a pop-up will appear showing the result. You must then confirm that it is the correct inhaler type. In the pop-up, you can also repeat the scan or proceed to a manual selection. For optimal performance of this function, hold the smartphone steady and ensure the background is clear and free of distracting objects within the camera view.

## **Step 2: Medical values**

In this section you can specify the medical values to record and how often.

The following values are available for selection:

- PEF-Peak Flow – required information:
  - Personal best in l/min,
  - Frequency of recording

The following questionnaires are available:

- ACT (Asthma Control Test)
- CAT (COPD Assessment Test)

To set up a questionnaire it is necessary to specify the frequency of recording.

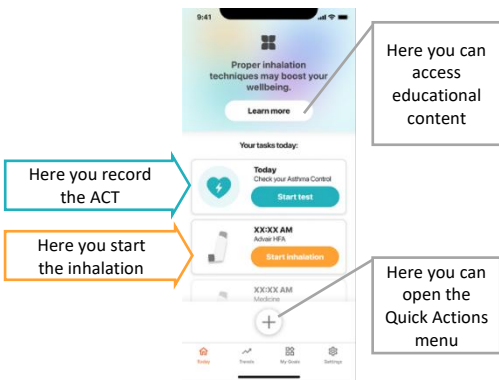
For the medical values, you can additionally specify whether the app should remind you to record the values at the entered frequency.

## Home Screen

After the setup, the home screen appears. Here you can read the instructions for use at any time under "Settings" (bottom right).

The home screen shows your tasks for today, based on your inhaler and medical value settings. If a task is greyed out, it's not yet time to perform it. Tasks disappear once completed.

The upper area of the home screen features content about respiratory and inhalation therapy and diseases. Tap the "Learn More" button for additional background information.



## Quick actions menu

By tapping on the “+” Symbol on the Home screen, the Quick actions menu will open.



Here you can start the Kata inhalation coach for your ‘As-needed’ and ‘Rescue’- inhalers (if any of these have been set up), by tapping on the “Start As-needed inhalation” field.

If you have missed to use Kata for any inhalation you can check-it off as done with the “Log Missed inhalation” field.

If you want to log any Peakflow measurements, you have to tap on the “Log Peakflow (PEF)” field.

If you want to edit any settings for inhalers or medical values, you have to tap on “Edit Inhaler settings” or “Edit Medical values”.

## Inhalation coach

The inhalation coach gives you important tips on how to use Kata during inhalation and general information about your inhaler. This can also be viewed in an integrated video. Tap "Start" to access a noise check where the app analyzes your surrounding noises. If noise levels are too high, you may be advised to find a quieter location. Perform inhalation in a quiet, windless area for optimal performance of the Kata inhalation coach. If the noise

exceeds 45 dB, the coach won't provide feedback but will guide you step-by-step through the process of your inhaler.

For the inhalation coach function, place your smartphone approx. 50 cm away from you. If the app requests access to the microphone or camera, allow Kata access. The app will now guide you through the necessary steps of the inhalation:

- Shake/activate (if necessary)
- Prepare (e.g. remove protective cap)
- Exhale
- Inhale (and if necessary, spray)
- Hold breath
- Exhale

Please follow the order given by the app.

Inhalations performed without Kata can be added later in the Quick Actions menu.

### Inhalation feedback

Depending on the inhaler you use, you will also receive detailed feedback from the Kata Inhalation Coach at the end of your inhalation. The following steps will be evaluated:

- Shake/activate (if necessary)
- Dose loading (if necessary)
- Exhale
- Inhalation (and triggering if necessary)
- Hold breath

If an inhalation error was detected by the coach, you'll see a short improvement tip, such as "Breathe in longer, fast, & deep." Tap the tip for a detailed explanation. The upper area of the feedback screen displays an overall inhalation score (1 = worst, 4 = best). To return to the home screen, tap "Close."

The inhalation feedback is based on a pre-trained deep learning model. This model was developed using quality-assured training data and supports evaluation through statistical pattern recognition. The system does not learn or change independently during use.

### Medical values

If you have set up PEF, ACT or CAT during onboarding or in medical settings, a 'Log' or 'Start Test' button will appear on the home screen based on your defined frequency. Tap it to enter your PEF value or complete the questionnaire.

## Mood

A pop-up will appear every 3 days, where you can record your today's mood.

## Trends

In the Trends section, you can view your inhalation results and recorded medical values for the last 4 weeks for each inhaler you have set up.

## Data export

### Physician Report

You can generate the report for your treating physician via the "Trends" – "Download" section. This will create a PDF document containing an overview of your inhalation performance, adherence, all recorded inhalations, medical values, and your recorded mood from a period of your choice (between 4 and 24 weeks in the past).

## My goals

In the "My Goals" section, you can customize the following:

- Inhalers (incl. applications per day)
- Medical values

## Uninstall and logout

In the "Settings" section you can log out by tapping on "Log out". If you no longer need the app, you can uninstall it at any time and/or delete your user account in the "Settings" section. Please note that when you delete your user account, all your data will be irretrievably deleted. Before uninstalling or deleting your account, you can export data as a PDF document.

## 7. Troubleshooting

Problem	Help
Logging into the app is no longer possible	Uninstall and reinstall the app, if data is still not available despite connection to the internet, contact User Support.

App can no longer be started	Uninstall and reinstall the app, if data is still not available despite connection to the Internet, contact User Support.
Message: Error "Your data could not be synchronized with the server. Do you want to try again?"	Please check your internet connection first. Then tap on "Yes" in the app -> message: Error "Your data still could not be synchronized with the server. Would you like to send us an email with error details for analysis?" -> tap on "Yes" -> Send email with precise details of the error message to "usersupport@kata-inhalation.com" -> The Kata team will take care of the matter.
Feeling that the state of health has deteriorated	In such cases, please always consult your doctor.
Feeling that displayed result is not correct (better or worse than expected)	<p>Ensure that:</p> <ul style="list-style-type: none"> <li>• the correct inhaler is entered.</li> <li>• the sound recording is possible.</li> <li>• the microphone is not covered.</li> <li>• the ambient noise is not too loud.</li> <li>• the smartphone with app is not too far away.</li> </ul> <p>In case of existing problem, please consult the user support and doctor.</p>
Feeling that the app is not working properly	To ensure the functionality of the app, regular updates of the app are necessary. To ensure that no update is accidentally omitted, the regular updates from Google Play Store or Apple App Store should be activated in the settings of the smartphone.
The shaking motion is poorly detected (MDI)	Please make sure that the ambient light is not too bright or too dark.
Password forgotten	Reset password by logging out of the app (in the settings area). Press the Login field and then select "Forgot password". Use the link in the email to set a new password.








Unknown error code	Consult user support and report the issue if possible
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## 8. Service

If you have any questions or need help, please contact us directly using the contact information above. Please let us know the version of the app you are currently using. You can find the version in "About" (-> Settings -> About > App Version). You can also contact us directly via the app (-> Settings -> Contact).

You can also find these instructions on our website. Should you require a printed copy of the instructions, we will provide them to you free of charge within 7 days of your request.

## 9. Explanation of symbols used

Symbol	Explanation
	Manufacturer
	This medical device complies with the obligations set out in Regulation (EU) 2017/745. Labeling indicating that the app is a medical device ("Medical Device")
	
	Please observe the instructions for use
	Please refer to the instructions for use, which indicate where the electronic instructions for use can be found.
	Unique product identification ("Unique Device Identification")
	Linking to the instructions for use within the app during set-up