

Instructions for Use



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

If a serious incident related to this app occurs, please inform VisionHealth and send a voluntary report (FDA Form 3500B) to MedWatch.

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1. Intended Use

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 maneuvers to take decisions on the further proceeding of the treatment (therapy control and monitoring). Inhalation maneuvers 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 all adult patients who have been prescribed an inhaler by their doctor. The patient must be able to perform the inhalation autonomously and under their own responsibility.

Patients with impaired vision cannot use the Kata app.

3. Compatibility

Compatible inhalation devices

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

- All metered dose inhalers
- Respimat
- Nexthaler
- Ellipta
- Flexhaler
- Easyhaler
- Neohaler

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 12.4 or Android from version 7.1.1 (API Level 25).

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 7 Troubleshooting.
- 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 anonymously 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).

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).

Step 1: Set up inhaler

Here you specify which inhaler(s) you use. For each inhaler you can enter the following information:

- For metered dose inhalers: Emergency medication (yes/no)
- Applications per day
- Number of sprays or inhalations per application
- Scheduled time (here you can additionally specify whether the app should remind you)

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

Step 2: Medical values

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

The following values are available for selection:

- PEF Peak Flow

- The following information is required for setup:
 - personal best value in l/min, frequency of recording.
- SpO2 (oxygen saturation)
 - The following information is required for setup:
 - Frequency of recording
- FEV1 (one second capacity)
 - The following information is required for setup:
 - Frequency of recording

The following questionnaires are available for selection:

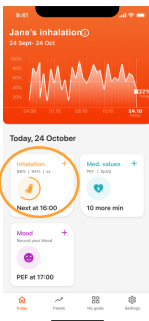
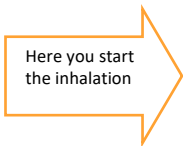
- ACT (Asthma Control Test)
- CAT (COPD Assessment Test)

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. There you can read the instructions for use at any time under "Settings" (bottom right).





Once you have completed all inhalations, this is indicated by a check mark with a full circle.

Inhalation process

In the inhalation area you can choose whether you want to start the inhalation with the inhalation coach or confirm the inhalation by check.



Tapping the "Inhalation" area takes you to the "Record inhalation" area.



If the planned inhalation has already been performed, a check mark can be set in the corresponding field (small circle symbol).

If you want to start the inhalation with the inhalation coach, tap on the "Begin inhalation" field.

The inhalation coach gives you important tips on how to use Kata during inhalation and general tips on your inhaler. This can also be viewed in an integrated video. The inhalation can be started via the "Begin inhalation" field.

For the "Record inhalation" function, place your smartphone approx. 50 cm (20 inch) 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 in the app. You should perform the inhalation in a quiet and windless place so that Kata's inhalation coach can hear you well.

Inhalations that were performed without Kata can be entered subsequently in the "Inhalation" area ('Record past' field).

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

The higher the % value achieved, the better. Afterwards you return to the inhalation area and can view the inhalations that are still planned and completed inhalations for today.

Medical values

In the Medical values section, you enter the previously specified values. You can also add or delete further values to be recorded.

Mood

In the Mood section, you indicate how you feel.

Data export

Physician Report

You can create the report for a treating physician via the "Trends" - "Export trend" section. This will generate a PDF document containing an overview of inhalation performance and adherence and 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 this case, please always consult your doctor.
Feeling that displayed result is not correct (better or worse than expected)	Ensure that: <ul style="list-style-type: none">• the correct inhaler is entered.• the sound recording is possible.• the microphone is not covered.• the ambient noise is not too loud.• the smartphone with app is not too far away. In case of existing problem, please consult the user support and doctor.
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	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 if possible






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 Kata" (-> Settings -> About Kata > Kata App Version).

You can also contact us directly via the app (-> Settings -> Contact).

You can also find these instructions on our website.

9. Explanation of symbols used

Symbol	Explanation
	Manufacturer
	Please observe the instructions for use
	Unique product identification ("Unique Device Identification")
	Linking to the instructions for use within the app during set-up
	Indication that the scheduled inhalations have been fully performed