

Instructions for Use



App name: My Acapella™

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Country: United States of America (US)



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ONLY

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This instructions for use contains information and safety instructions for the My Acapella™ app. Please read this manual completely and carefully before using the app.

If a serious incident related to the My Acapella™ app or the Acapella™ device occurs, please inform myacapella@icumed.com and send a voluntary report (FDA Form 3500B) to MedWatch.

My Acapella™ and Acapella™ are trademarks of ICU Medical, Inc. or its affiliates.

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1. Intended Use

The My Acapella™ app is a mobile medical app that is intended to be used together with the Acapella™ device for OPEP (Oscillating Positive Expiratory Pressure) therapy. The app helps patients to set up their therapeutic plan and reminds them to perform the OPEP therapy. Based on the generated data, the app shows the adherence score. The app also provides a step-by-step guide for the therapy with the Acapella™ device and provides educational information.

2. Patient groups

The My Acapella™ app is suitable for all adult patients who have been prescribed an Acapella™ device for OPEP therapy by their doctor.

Patients with impaired vision cannot use the app.

3. Compatibility

Compatible devices

The app is compatible with the following Acapella™ devices:

- Acapella™ DM Blue & DH Green – IFU: AS10018905
- Acapella™ DH Green Novaplus – IFU: AS10026697
- Acapella™ Choice Blue – IFU: AS10010097
- Acapella™ Choice Blue Novaplus – IFU: AS10026601

Compatible smartphones

The 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 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 therapeutic plans is the responsibility of the app user. Before using a PEP device, it is essential to read the package inserts of the device. It is also necessary for the app user to follow any instructions given by the doctor or pharmacist.

5. Warnings and precautions

For the My Acapella™ app, please be sure to observe the following warnings and precautions:

- In case of doubtful results or deterioration of the user's health condition, it is essential to consult a doctor immediately.
- Regular Internet connections are necessary to store the generated data anonymously on a database. This ensures that they are not lost.
- To ensure that all treatment data 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, please ensure that no one else is using your app. In addition we recommend using the authentication offered in the smartphone (PIN, pattern, fingerprint or facial recognition).

For the Acapella™ device, please be sure to observe the warnings and precautions indicated in the device IFU.

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
- Select your diagnosis
- 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 the valid trial code provided by the Clinician during your training.


After activation, the home screen of the application is shown.

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

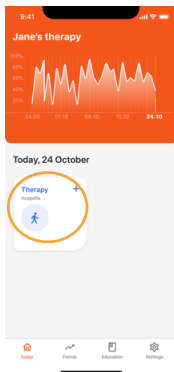
The data entered is subject to data protection and thus to strict legal requirements. In the integrated data protection agreement, you will find detailed information about which data is collected for which purpose.

Home Screen

From the home screen you can read the instructions for use at any time after tapping on “Settings” (bottom right) and then “Instructions for use”.



Here you set up your therapy plan and start the therapies

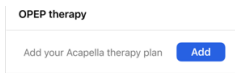




When you have completed all therapies for the day, it will be indicated by a check mark with a complete circle.

Set up therapy plan

After tapping on 'Therapy' widget, you can add your therapy plan by tapping on the 'Add' button.



For the setup you have to specify the following settings:

- Dial setting (1 to 4)
- Sets per session (1 to 4)
- Breathing cycles (5 to 10)
- Therapy frequency per day (1 to 3)
- Scheduled time (here you can additionally specify whether the app should remind you)

Therapy procedure

In the therapy widget you can choose whether you want to start the therapy with the Acapella™ coach or confirm the inhalation by setting a check mark.



Tapping the "Therapy" widget takes you to the "Record therapy" screen.



In case you want to indicate that a therapy session has been completed without using the coach, you can simply check it off by tapping on the small circle symbol.

In addition to the Acapella™ device IFU, the Acapella™ coach guides you through the steps of an Acapella™ OPEP therapy and gives you important information what to do at each step.

For the coach place your smartphone approx. 50 cm away from you so that you can still read the screen. The app will guide you through the necessary steps of the Acapella™ therapy after tapping on 'Begin therapy'.

- Set dial
- Get into position
- Place device in mouth
- Inhale
- Breath hold
- Exhale
- Huff
- Cough

Please follow the order given in the app. Dependent on the breathing cycles you defined in your therapy plan, the coach will repeat the steps Inhale, Breath hold and Exhale. If you have defined to do multiple sets per session in your therapy, the coach will repeat all the steps (except Set dial) until all sets are completed.

During the steps Inhale, Breath hold and Exhale you can pause the therapy by tapping on the 'Pause' button and start it again by tapping on 'Start'.

You can restart your therapy by tapping on 'Restart' (top right corner).

If you want to cancel a therapy without storing it as completed, you can tap on 'Cancel' (top left corner).

Education

In the 'Education' section you can find and read useful information related to OPEP therapy, e.g. patient organizations and how to huff-cough.

Trends

In the 'Trends' section you can view your weekly adherence score in the adherence graph diagram. You can also see for the last days whether you did the therapy with or without coach or whether you have missed any scheduled therapy.

Data export

Physician Report

You can create the report for a treating physician in the "Trends" using the export/share button in the top right corner. The app will generate a PDF document comprising an adherence graph, adherence statistics, trainer statistic and your Acapella™ settings.

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 myacapella@icumed.com
App can no longer be started	Uninstall and reinstall the app, if data is still not available despite connection to the Internet, contact myacapella@icumed.com
Message: Error "Your data could not be synchronized with the server. Do you want to try again?"	Please check your internet connection first. Then press "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?" -> Press "Yes" -> Send email with exact details of the error message to

	myacapella@icumed.com " -> The app 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 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.
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 myacapella@icumed.com 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" (-> Settings -> About > App Version).

9. Explanation of symbols used

Symbol	Explanation
	Manufacturer
	Please observe the instructions for use