

Instructions for use

AsthmaTuner App



AsthmaTuner



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1 General

1.1 Introduction

Welcome as a user of AsthmaTuner! Carefully read this manual to get important safety information and the best possible AsthmaTuner experience.

1.2 Intended Use

The intended use of AsthmaTuner is to improve asthma control. This is mainly done by providing information and treatment recommendations which is generated based on a patient's lung function, symptoms and physician prescribed treatment plan.

Furthermore, AsthmaTuner facilitates management of respiratory diseases by processing lung function and user reported data and by providing information.

The actual diagnosis shall be done by a healthcare professional so home use is only for indicative purpose.

1.3 Intended Users

Mainly indicated for asthma, Chronic obstructive pulmonary disease (COPD), Interstitial pulmonary fibrosis (IPF) and cystic fibrosis.

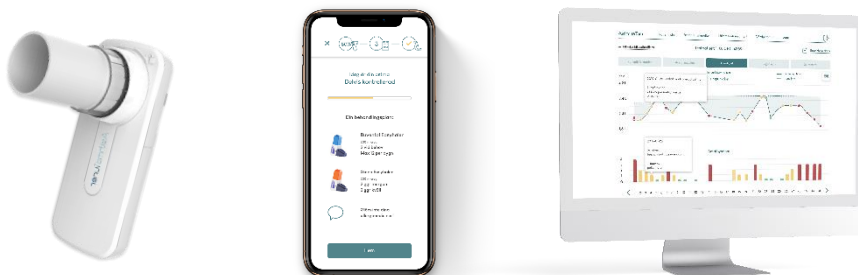
For use by trained users, healthcare providers and researchers.

AsthmaTuner is intended for use from the age of 6 onwards. All use by children and adolescents under the age of 18 must be under the supervision of their guardians. This means that children and adolescents must receive support, advice and information from guardians when needed while using AsthmaTuner.

Entering a treatment plan in AsthmaTuner must be done by qualified healthcare personnel. AsthmaTuner is currently available in Swedish, English, Danish and Norwegian and should be used by people who are fluent in these languages.

1.4 AsthmaTuner Components

1. Wireless spirometer
2. Smartphone app for iOS and Android
3. Careportal – web interface for caregivers



NOTE! The iOS and Android apps are very similar but may differ. Pictures in the manual illustrate the iOS app.



1.5 System requirements

To use the AsthmaTuner app, a smartphone with following requirements is needed:

- Bluetooth 4.0 or above
- iOS 14 or above
- Android 6 or above.
- In Sweden and Norway you need Mobile BankID or a relative with Mobile BankID to create an account

The AsthmaTuner Careportal is a web application than can be reached through a web browser on a computer. The approved browsers to reach the application include:

- Safari
- Internet Explorer IE11+
- Edge
- Firefox
- Google Chrome

The recommendation is to always use the latest version of the browser since functionality on older browsers might be affected. Unless stated otherwise the two latest major versions of the above listed browsers are supported.

1.6 Important information while using AsthmaTuner

- **Warning!** In case of emergency call 112
- **Warning!** Read these instructions before you start using AsthmaTuner
- **Warning!** Always inform your healthcare provider about which medicines you are taking together with your asthma medicines.
- **Warning!** Be sure to never exceed the maximum dose for your prescribed asthma medicine. Max-dose is stated on your prescription
- **Warning!** If the AsthmaTuner app or your phone for any reason do not work, follow the prescribed treatment (label on prescribed medicinal products) or contact your healthcare provider for information about your treatment.
- **Warning!** If you perceive that AsthmaTuner recommends a dose that is too high or too low in relation to how you feel, you should contact the healthcare provider that has prescribed your treatment plan and is responsible for it.
- **Note!** For patients with asthma, it is recommended to keep contact, be examined by and report any symptoms to the healthcare provider on a regular basis.
- **Note!** Check that your treatment plan is consistent with what you and your doctor have agreed upon, otherwise contact your healthcare provider. If your medicine is replaced by another medicine, contact your healthcare provider.
- **Note!** AsthmaTuner is not a surveillance / monitoring system. Users are responsible for seeking healthcare based on their needs.



1.7 Contraindications and complications of spirometry examination

Lung function tests should not be performed if patient, recently undergone surgery or myocardial infarction and aortic aneurysm. The assessment should be made individually by the responsible physician. This assessment should, in that case, be carried out individually and by the investigating doctor. Otherwise, complications are rare in spirometry examinations. Dizziness as well as various types of chest pain are very rare. In case of difficult dizziness, the examination is interrupted, and rest is recommended before re-examination.

2 Getting Started with AsthmaTuner

2.1 Download the AsthmaTuner app

Search for "AsthmaTuner" in App Store or Google Play and install the app

2.2 Create Account – adult with own BankID (Sweden and Norway)

1. Launch the app and choose create account (Figure 4)
2. Choose to create an account for yourself with your own BankID (Figure 5a)
3. Authenticate yourself with Mobile BankID
4. Fill in your account information and read through and accept terms of use
5. Read carefully and follow the instructions to get started

2.3 Create Account – Child without Own BankID (Sweden and Norway)

1. As an adult, you launch the app and choose to create an account (Figure 4)
2. Choose to create an account for someone without own BankID (Figure 5b)
3. First authenticate yourself with BankID, read and accept the terms of use
4. Then fill in the information of the person you are creating the account for.
They can then log in to another device with the information you entered



Figure 4

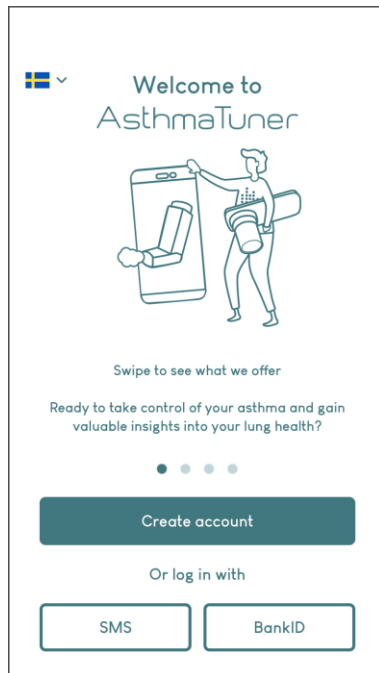


Figure 5a

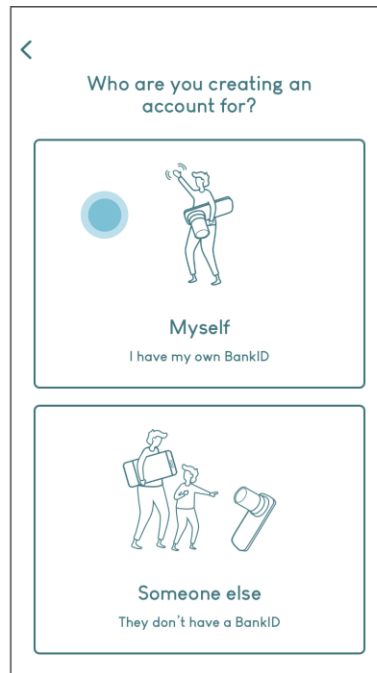
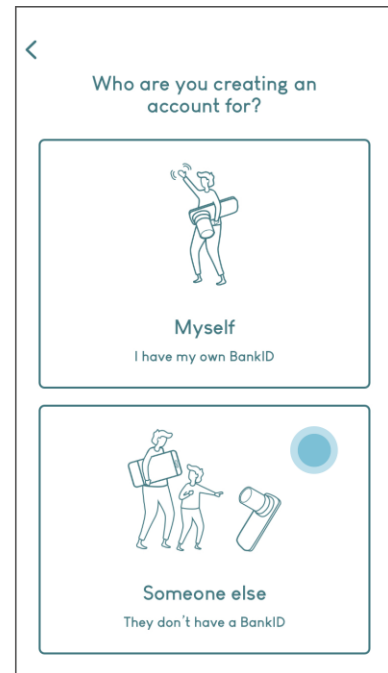


Figure 5b



2.4 Create Account – for countries that do not have BankID

In countries without BankID, your healthcare provider must invite you to create an account. You will then receive a code and link on SMS that you can use to create an account.

2.5 Login

2.5.1 Login with BankID

1. Choose log in with Mobile BankID and follow the instructions.

2.5.2 Log in with SMS

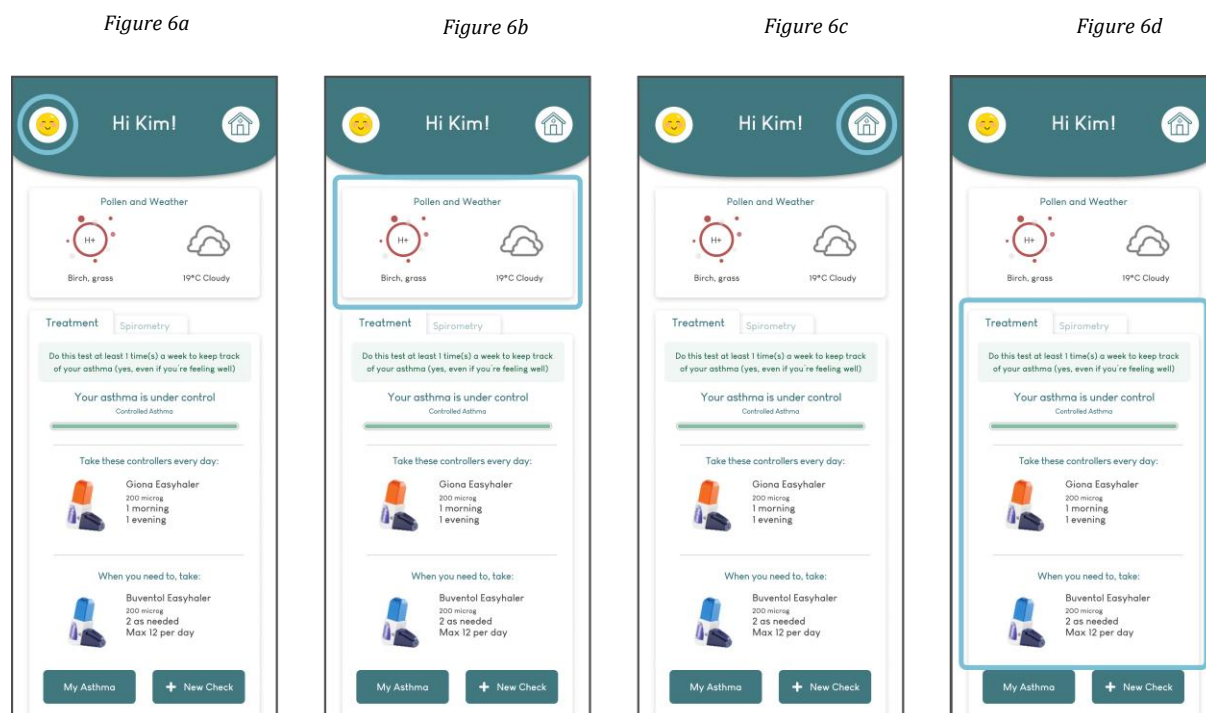
Logging in with SMS requires that you have entered your telephone number and entered a personal password in the menu or when relatives created your account.

1. Tap sign in with text message
 2. Enter your personal ID number and password – tap Continue
 - a. If you have forgotten your password, tap the "Forgot Password" link and follow the instructions
 3. Fill in the 4-digit code sent to you by text message and tap continue
- ➔ You are logged into the app



3 Navigate in AsthmaTuner

Navigation in the app starts from the app's home screen. Here you can access the app's menu (Figure 6a), get weather and pollen information (Figure 6b), get clinic connection information (Figure 6c), and use your asthma tools (Figure 6d). The home screen can be customized to your needs under asthma tools in the menu.



3.1 Menu - contents

3.1.1 Profile

To gain full access to all the features of the app and to provide your healthcare provider with information, your user profile should be complete. Click "Change" in the top right and fill in or update your user information.

NOTE! It is recommended that personal best FEV1 is set in consultation with healthcare personnel. It is recommended that personal best FEV1 is based on 3 independent measurements with the wireless lung function meter included with AsthmaTuner. If you blow a value that exceeds personal best FEV1, the app will ask if you want to update the saved value in the app and automatically do so if you answer yes.

3.1.2 Treatment Plan

If your healthcare provider has created a treatment plan for you, you will find it here. The treatment plan is defined for three different levels based on asthma status; green for controlled asthma, yellow for partially controlled asthma and red for uncontrolled asthma. Clicking on a level shows information about the specific level and the recommended treatment.

NOTE! Check that the treatment plan is in accordance with prescribed medications.



3.1.3 Connected Accounts

Here, you can create an account for a child and invite someone to follow your account. By clicking "change" in the right corner you can remove people you are following or who are following you.

When you follow someone, you can switch to their profile by clicking on their icon at the bottom of the app's home screen under the card called 'You are following these users'. You can then see their information but cannot change any information or do any new tests from their profile.

NOTE! You must be logged in with Bank ID (Sweden and Norway) in order to create a new account.

NOTE! For countries without a Bank ID, the child account is created by your care provider.

3.1.4 Asthma Tools

Here, you can control which functions you want to use and see on your home screen. Activating a tool will make it appear on the home screen. For more information on each feature, see sections for:

- Treatment Recommendation
- Evaluation of lung function
- Spirometry Testing

3.1.5 Spirometer

To gain full access to all features of the app, an AsthmaTuner spirometer should be paired with the app wirelessly via Bluetooth. The first time you do a new test, you get the opportunity to connect the spirometer. If you want to change spirometer at a later time, you can search for a new one via this menu entry.

Check that the batteries are properly inserted into the lung function meter. It has no ON/OFF button but is instead automatically activated when the phone searches for it. With normal use, the battery life is about 2 years. If the lung function meter is within reach, it is presented in the menu with a serial number. Verify that the number listed behind the battery cover of your lung function meter and that displayed in the app match. Click Connect.

NOTE! Make sure that Bluetooth is enabled on your phone before connecting

NOTE! Contact your healthcare provider if you have any questions about the lung function meter or how to do a proper lung function test with it

3.2 Reminders

Set reminders in the app so you don't forget to do a test or take your medicine.

NOTE! Make sure you've allowed the app to send you reminders. This can be done when installing the app, or later by going into settings in the phone.



3.3 Help

Under "Help" in the menu list you will find answers to frequently asked questions about AsthmaTuner. For technical questions you can always contact us at support@asthmaturer.com, medical questions are handled by your healthcare provider.

3.4 Password

To enable the SMS login option, you can enter their phone number in the profile and a personal password under the Password menu list. Here, you can also change your password.

3.4.1 Log out

By clicking "Log out" in the menu you can choose to log out of your AsthmaTuner

3.5 Instruction Card from your Caregiver

When you are connected to a clinic, your healthcare provider can send configure the tool selection in your app to ensure you are using the tools that are best suited for your condition. The instruction card at the top of the app home screen contains a message from your clinic with instructions about what the tools do and how they will help you keep track of your lung health.

3.6 Weather and Pollen

In AsthmaTuner, you can get weather- and pollen reports. A summary is displayed directly on the home screen and if you want more details you can click on the panel, a detailed view with more information will be shown.

NOTE! In order for us to give you information about weather and pollen we need access to your location. You approve this in the app. For more information on how your data is handled, see Privacy Policy.

3.7 Clinic Connection

To get full functionality of AsthmaTuner, it is recommended that you connect AsthmaTuner to a healthcare provider. Upon connection, your healthcare provider sends out a request to connect to your account. You accept this invitation in the app.

When you are connected to a clinic, your healthcare provider can see your data and create an individual treatment plan for you. You can also see more information about the clinic you are connected to.

3.8 Asthma Tools

AsthmaTuner has several tools that can be used to monitor your asthma, each different tool has its own tab in the app home screen. You and your healthcare provider should make a decision which tools that are right for you.

If you are connected to a clinic, your healthcare provider will choose the best tools for you and configure the app to show these tools. If you want to activate tools that your caregiver has not chosen for you, You can either choose which tools to activate when



you create a new account or at a later time you can find these under 'Asthma Tools' in the menu.

3.9 Treatment Check

This tool is created to support you in your self-management. With the help of our spirometer and symptom reporting you receive a suggestion of your asthma control. If you have a treatment plan from your healthcare provider, it will be linked to your control.

3.9.1 How often should I do a treatment check?

This is decided by your healthcare professional. To achieve optimal effect of AsthmaTuner, it is recommended to test yourself at least once a week, but preferably once a day.

3.9.2 How do I perform a treatment check to get a treatment recommendation?

AsthmaTuner's self-management is divided into a few steps, Lung function, Symptoms, Treatment Recommendation. Start by clicking new test on the home screen

Lung function

- Make sure the 'Treatment' tab is selected in the app's home screen
- Click "new check"
- Follow the instructions in the app to connect the lung function meter
- When connected, the test starts automatically
- Follow the on-screen instructions to perform a lung function test
- After completing the test, you can select "Retry" or "Save"
- **Important!** Be sure not to cover the turbine with your hand when doing a test, make sure you create a tight seal with your lips and blow out as hard as you can from the start.
- **Important!** If you blow a higher value than your previous tests, the app suggests updating your personal best value. This controls your treatment recommendation so only update it if you have correctly performed a test yourself.
- **NOTE:** If you have difficulties with or do not have a lung function meter, you can choose to skip directly to the next step.

Symptoms

Register your symptoms for the past week by answering Yes or No to the four symptom questions. If you would like to read more about what each question means, tap 'What do these asthma symptoms mean?' When you are satisfied with your answers, click 'Save'

Treatment recommendation

Based on your lung function and or reported symptoms, you now get a recommendation on which asthma control you have - green for controlled, yellow for partially controlled and red for uncontrolled. The treatment recommendation is dated and valid for 24 hours or until a new test is performed. The criteria for determining whether you have controlled, partially controlled or uncontrolled asthma follow international guidelines and are based on a comparison of personal best FEV1 with the current measured lung function value and by looking at the number of symptoms reported.



If you have a treatment plan from your doctor, you will also see which medicines to take and any further instructions from your healthcare provider.

Triggers

As a final step, you can choose to go directly to your home screen or add triggers. Choosing triggers gives you the opportunity to record what you think triggered your asthma and leave a comment.

3.9.3 My Asthma

On the home screen, you can click on 'My Asthma' to see your historical values. Information about asthma control, lung function, symptoms and registered triggers is shown here. You can choose to view triggers and other information for a specific time period.

3.10 Evaluation Tool

The evaluation tool is created to assess how your lung function varies over time. This can be an indication that will help for healthcare professionals to determine if you have asthma.

3.10.1 How long is an evaluation period and how many tests should I perform?

An evaluation period is normally 2 weeks. During these two weeks, you should test your asthma every morning, afternoon and when you experience symptoms.

The home screen shows how far you have come in your evaluation period. Only complete days with at least 2 tests are counted. If you miss a day, the evaluation period is extended.

Tip! Don't forget to set reminders so you remember to do your tests

Important! Duration of evaluation period and number of tests may vary. Discuss and follow your healthcare provider's recommendations.

3.10.2 Perform an evaluation test

A test consists of checking lung function and recording of complaints. Start the test by clicking on the new test on the home screen.

Evaluation test

- Make sure the 'Evaluation' tab is selected in the app's home screen
- Click "new evaluation test" Follow the instructions in the app to connect the lung function meter
- When connected, the test starts automatically
- Follow the on-screen instructions to perform a lung function test. You need to do 3 correct tests to proceed to the next step
- **Important!** Be sure not to cover the turbine with your hand when doing a test, be sure to create a tight seal with your lips and blow out as hard as you can from the start.

Register symptoms

- Answer all questions in order to save
- Select any symptoms you may have experienced



- You can also add additional information in free text

3.10.2.1 History

If you click on evaluation history, you will see a summary of the period with the highest and lowest test so far as well as details about all the tests. You can change previous comments by clicking on the text box during a test and then tapping save.

3.11 Spirometry Tool

The spirometry tool is another way for caregivers to assess a patient's lung function. This test provides caregivers with a larger set of values as well as a spirometry curve plotted in a graph. Forced Vital Capacity (FVC) is one of the values unique to this type of test.

When your caregiver requests this type of test, they can choose between two types of spirometry testing: with or without reversibility. Reversibility testing is a specific type of spirometry that is done specifically to evaluate the difference in lung function before and after taking asthma medication. Only caregivers can activate the reversibility feature from Careportal, it is not possible to do so from the AsthmaTuner app.

Important! Never perform a spirometry with reversibility unless a caregiver has specifically instructed you to do so and given you clear instructions for taking the asthma medication needed for this test.

3.11.1 Perform a spirometry test

Regular Spirometry Test

- Make sure the 'Spirometry' tab is selected in the app's home screen
- Click "new spirometry test" Follow the instructions in the app to connect the lung function meter
- When connected, select 'Start test'
- Follow the on-screen instructions to perform a spirometry test. It is recommended to do 3 correct tests in order to ensure acceptable test quality, but your caregiver may ask for fewer or more tests

Important! Be sure not to cover the turbine with your hand when doing a test, be sure to create a tight seal with your lips and blow out as hard as you can from the start.

Tip! It's common for patients to feel like your air runs out very early in the test, but don't remove the spirometer from your mouth until the ringing sound in the app stops.

Reversibility Test

- Make sure you have gotten clear instructions directly from your caregiver about which medication to take for this type of test and how to take it correctly. This is a vital part of the test and the app alone will not provide this type of information.
- Make sure the 'Spirometry' tab is selected in the app's home screen
- Click "new reversibility test" Follow the instructions in the app to connect the lung function meter
- When connected, select 'Start before-inhaler session'



- Follow the on-screen instructions. It is recommended to do 3 correct tests per session in order to ensure acceptable test quality but your caregiver may ask for fewer or more tests
- When you have completed the 'Before-inhaler session' it's time to take the caregiver recommended inhaler.
- Pressing "Taking inhaler now" will start a timer that allows 15 minutes for the medication to take effect.
- Wait until the timer runs out
- When the timer has run out, complete the "After-inhaler session" in the same way you did the previous session.
- Press "Save" - you have now completed the entire reversibility test

Tip! 15 minutes is a long time to wait between sessions. It's okay to leave the app while you wait but switch on notifications for the AsthmaTuner app to receive a reminder when it's time to continue the testLung function measurement and the spirometer

4 General about spirometry

Spirometry is performed for diagnosis of symptoms such as shortness of breath, protracted coughing and wheezing, and protracted respiratory symptoms. Furthermore, spirometry is performed to follow the effect of treatment and follow disease and for general control of the health of the lungs.

4.1 FEV1

FEV1 - "Forced expiratory volume measured in one second", is the volume of air that can be exhaled in one second with maximum force from fully filled lungs. Exhalation should start explosively with the highest speed from start to finish. This measure is used primarily in the treatment recommendation asthma tool, but also in the evaluation tool.

4.2 PEF

PEF - "Peak Expiratory Flow", is the peak flow measured during a test from fully filled lungs. Exhalation should start explosively with the highest speed from start to finish. This value is used primarily in the evaluation tool.

4.3 Mouthpiece

Place spirometer mouthpiece between the teeth without biting down on it. The lips should be closed tightly around the mouthpiece. The tongue is placed so it does not interfere with the airflow into the mouthpiece.

4.4 Posture

Seated position is the first choice at lung function test, but standing position is also allowed. Make sure your back is straight and lift the chin during the entire exhalation maneuver. Avoid a slouched position.



4.5 Nose clamp

The clinic recommends the use of a nose clamp, this is not a requirement for the use of AsthmaTuner.

4.6 Continuity

It is optimal if the spirometry assessment is performed in the same way every time. Repeated tests are ideal for every assessment.

4.7 Hygiene

Hygiene should be taken into account in a spirometry examination to minimize the risk of infection between individuals. AsthmaTuner's lung function meters are personal devices and should preferably not be shared between individuals. For further instructions on cleaning the mouthpiece and turbine see spirometer instructions.

4.8 Function control

AsthmaTuner's lung function meter is factory calibrated, so no further calibration is required. If you suspect that the AsthmaTuner lung function meter is not measuring correct values, the turbine should be cleaned. If this persists, contact AsthmaTuner.

