



medituner®

INSTRUCTIONS FOR USE

AsthmaTuner

MEDITUNER AB

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SWEDEN

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1. General

1.1 Introduction

Welcome as a user of AsthmaTuner! Carefully read this manual to get important safety information before using AsthmaTuner. For healthcare providers, please also read the manual for Careportal, which you can find on the AsthmaTuner website.

1.2 Intended Use

The intended use of AsthmaTuner is to improve asthma control for adults and children over the age of 6. This is done by providing information and treatment recommendations which are generated based on a patient's lung function, symptoms, and physician-prescribed treatment plan.

Furthermore, AsthmaTuner facilitates the management of respiratory diseases by processing lung function and user-reported data and by providing information to adults and children over the age of 6.

Any form of diagnosis of asthma or other respiratory diseases shall be done by a healthcare professional, so home use is only for indicative purposes.

1.3 Intended Users

Indicated for asthma, chronic obstructive pulmonary disease (COPD), interstitial pulmonary fibrosis (IPF) and cystic fibrosis.

For use by 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 any of these languages.

1.4 AsthmaTuner Components

- Bluetooth spirometer (Spirobank Smart or SmartOne by MIR)
- Smartphone app for iOS and Android
- Careportal – web interface for healthcare providers

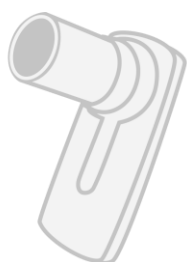


Figure 1. Spirometer



Figure 2. Smartphone app

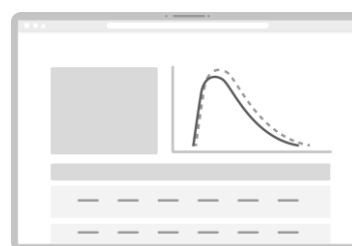


Figure 3. Careportal Web Interface

Note! The iOS and Android apps are very similar but may differ. Images in these instructions 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 14.5 or above.
- Android 8 or above.
- In Sweden and Norway, you need Mobile BankID or a relative with Mobile BankID to create an account.
- In regions outside of Sweden and Norway, you need to receive a code from your healthcare provider 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.

Note! The use of AsthmaTuner will always require a stable internet connection, to ensure tests and lung function measurements are saved correctly. When tests do not save, or are interrupted, try to change your internet connection to a more stable one.

1.6 Spirometer requirements

To measure lung function, the AsthmaTuner application works together with a Bluetooth spirometer. The AsthmaTuner application is set to work together with either the Spirobank Smart or SmartOne, manufactured by Medical International Research (MIR).

The spirometer should be running on the most recent firmware version to ensure correct functionalities within AsthmaTuner. You can update the firmware of the spirometer through the AsthmaTuner menu.

Note! Connect to the spirometer through the AsthmaTuner application instead of the system Bluetooth. If you connect through the system Bluetooth, the AsthmaTuner application might not recognize the connection to the spirometer and will prompt you to reconnect.

1.7 Important information while using AsthmaTuner

1.7.1 Notice for serious incidents

In the unlikely event that a serious incident occurs or is suspected to have occurred while using AsthmaTuner, please report this (suspected) incident immediately to MediTuner AB and the competent authority of your country. The competent authority per country:

- Sweden – Medical Product Agency (MPA)
- Norway – Norwegian Medical Products Agency (NOMA)
- Denmark – The Danish Medicines Agency

1.7.2 General warnings

- ⚠ **Warning!** AsthmaTuner is not a surveillance/monitoring system. Users are responsible for seeking healthcare based on their needs. In case of emergency call emergency services.

- ⚠ **Warning!** Read these instructions before you start using AsthmaTuner. If you are supervising a user under the age of 18, pay specific attention to the instructions for child accounts.
- ⚠ **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 medication. Max-dose is stated on your prescription. Check that your treatment plan is consistent with what you and your healthcare provider have agreed upon, otherwise, contact your healthcare provider. If your medicine is replaced by another medicine, contact your healthcare provider.
- ⚠ **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. The recommendations provided on the medication's label should always take precedence over any recommendations in the treatment plan. In cases of discrepancies between the two, always adhere to the instructions on the medication's label.
- ⚠ **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.

1.7.3 Other important general information

- **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!** AsthmaTuner is a personalized tool, and it is not recommended to have multiple people perform lung function tests with your device. This might influence your results.
- **Note!** If you have notifications disabled on your phone, AsthmaTuner will not be able to send medication or test reminders. Enable AsthmaTuner notifications in case you want to receive these reminders.

1.8 Contraindications and complications of spirometry examination

Recent surgery, heart attack, and aortic aneurysm are contraindications for pulmonary function tests.

During late pregnancy, users should consult their healthcare provider before using AsthmaTuner. Users who are not supposed to do strenuous activities should also consult

their healthcare provider. Users who experience dizziness and/or various types of chest pain should interrupt their tests and rest before starting a new test.

1.9 Using AsthmaTuner in a cyber-secure way

For your security and the protection of your personal health data, it's essential to safeguard your phone against unauthorized access. We strongly recommend the following measures:

- Use security features like PIN codes, fingerprint scanning, or facial recognition to lock and unlock your device. This is to ensure no person will enter the AsthmaTuner application without your permission.
- Ensure your phone's operating system and apps are regularly updated to benefit from the latest security patches.
- Be cautious with third-party apps. Only download apps from trusted sources and be wary of granting unnecessary permissions.

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)

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

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

- As an adult, you launch the app and choose to create an account (Figure 4)
- Choose to create an account for someone without own BankID (Figure 5b)
- First authenticate yourself with BankID, read and accept the terms of use
- 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

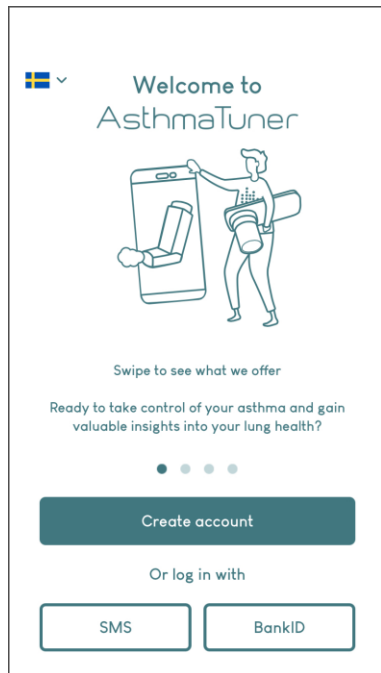


Figure 4

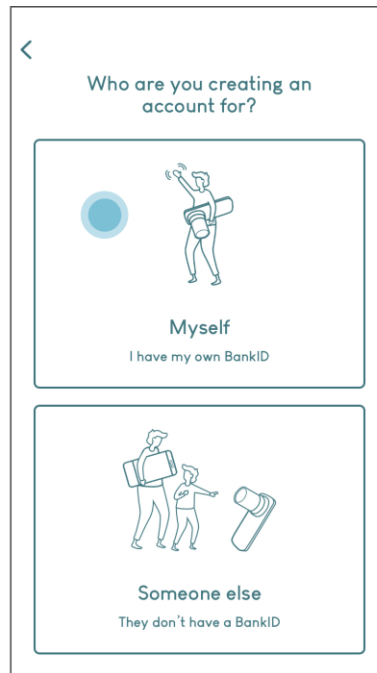


Figure 5a

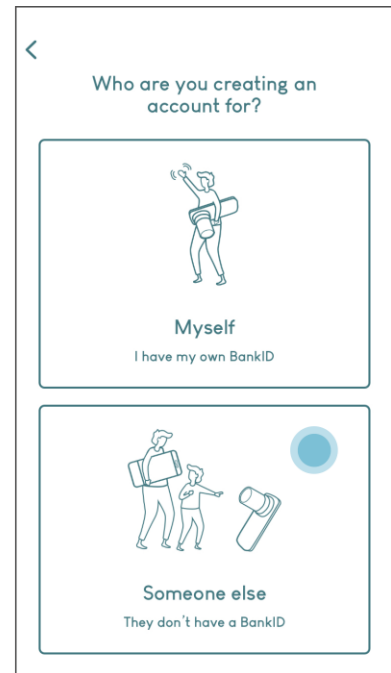


Figure 5b

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 via SMS that you can use to create an account.

2.5 Login

2.5.1 Log in with BankID

- Choose to log in with 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 someone else created your account.

- Tap sign in with text message
- Enter your user ID and password – tap Continue
- If you have forgotten your password, tap the "Forgot Password" link and follow the instructions

- 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 tools (Figure 6d). The home screen can be customized to your needs under asthma tools in the menu.

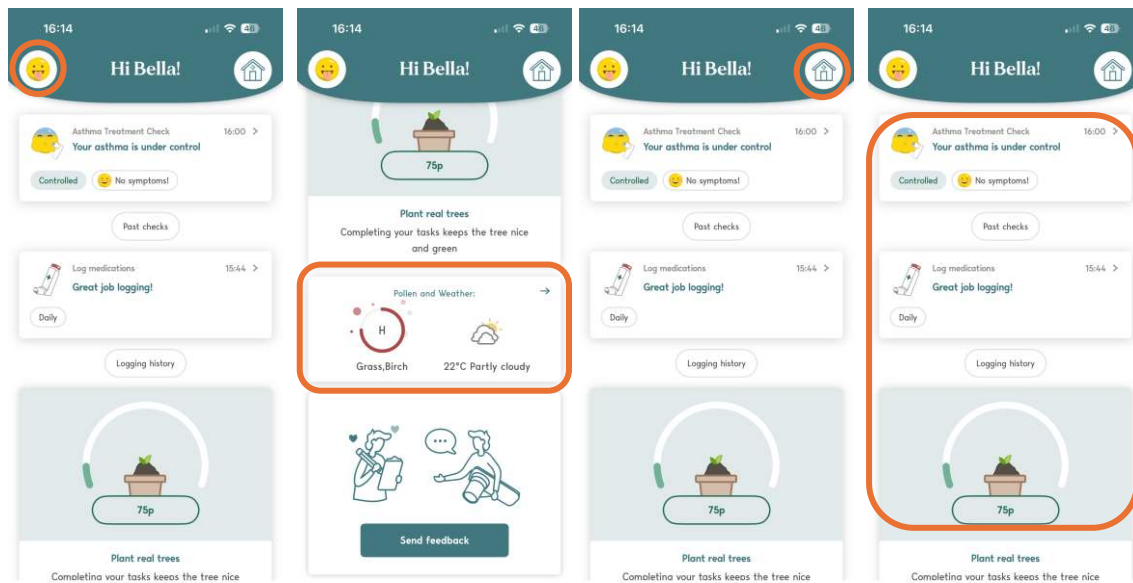


Figure 6a

Figure 6b

Figure 6c

Figure 6d

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 "Edit" 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 Bluetooth spirometer. 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 partly 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 under 18 and invite someone to follow your account. By clicking "Edit" 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) to create a new account for a child under 18.

Note! For countries without Bank ID, the child account is created by your healthcare provider.

3.1.4 Customize home view

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, a Bluetooth spirometer should be paired with the app. The first time you do a new test, you get the opportunity to connect the spirometer. If you want to change spirometer later, you can search for a new one via this menu entry.

Check that the batteries are properly inserted into the Bluetooth spirometer. 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 Bluetooth spirometer is within reach, it is presented in the menu with a serial number. Verify that the number listed behind the battery cover of your Bluetooth spirometer 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 Bluetooth spirometer or how to do a proper lung function test with it.

Note! Only the Bluetooth spirometer that you have received from your healthcare provider or pharmacy is compatible with the app.

3.1.6 Reminders

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

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

3.1.7 Help

Under "Help" in the menu you will find answers to frequently asked questions about AsthmaTuner. For technical questions, you can always contact the support email, which can be found in the "Help" section. Medical questions and questions about your medication are handled by your healthcare provider.

3.1.8 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.

Update password

Navigate to the menu (figure 6a) and select 'change password'. Here you will find instructions on how to change your password.

3.1.9 Log out

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

3.2 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.

3.3 Weather and Pollen

In AsthmaTuner, you can get weather- and pollen reports. Pollen reports are only available in Sweden. 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! 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 our Privacy Policy.

3.4 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 can accept this invitation in the app. When you accept this invitation, you agree to share your healthcare data with this clinic. No other clinics can see your healthcare data.

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

3.5 AsthmaTuner Tools

AsthmaTuner has several tools that can be used to monitor your condition, and each tool has its own tab in the app home screen. 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 healthcare provider has not chosen for you, you can find these under 'Asthma Tools' in the menu.

3.6 Asthma 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.

3.6.1 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. It's important to regularly monitor your asthma levels, even during periods of feeling well. Regular monitoring provides valuable insights into your asthma control.

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

The treatment check is divided into a few steps; Lung function, Symptoms, Triggers and Treatment Recommendation. Start by clicking "New check" on the home screen.

Lung function

- 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'
- **Note!** 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.
- **Note!** 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'.

Triggers

You can also add triggers. Choosing triggers gives you the opportunity to record what you think triggered your asthma and leave a comment.

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 partly 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, partly 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.

3.6.3 Past Checks - My Asthma

On the home screen, you can click on 'Past checks' 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.

3.7 Logging Medications

Note: This feature is only available in Sweden, Norway and USA

3.7.1 When and how often should I log medications?

While it isn't mandatory, it is best to log medications *after* you've done a treatment check. It can be a good idea to log your medications in the evening, or after your final dose for the day.

You should aim to log medications as a daily habit, doing this regularly will not only give you and your provider a more complete picture of your condition but also provide insights into the obstacles that could be getting in the way of taking your treatment as prescribed.

3.7.2 How do I create a medication log?

Start by tapping 'New log' on the app's home screen, you'll then answer the question 'How did you medicate today?' It is possible to select multiple options.

If you're unsure about what each option means, you can tap the information icons.

Daily medications

Select this option if you took medications that are shown under the 'Take daily' category of your treatment plan.

As needed medications

Select this option if you took medications that are shown under the 'As needed' category of your treatment plan. Taking as needed medications such as a reliever or allergy medications often could mean your daily medications are not enough.

Scheduled/other medications

Select this to log your scheduled medications or meds that are not in your treatment plan but still related to your respiratory condition (common examples are cortisone tablets, antibiotics or allergy meds)

Less/none

There's nothing to be ashamed of if you've taken less medication than you're supposed to. It's important to note why you took less, it helps you understand your habits better or if you need to find different medications

3.7.3 I want to log a medication that isn't in the list, what do I do?

If you search for a medication but don't get any results, the app will show you information on how to suggest a medication. Your suggestion will be reviewed by AsthmaTuner and added if it is relevant for respiratory conditions or allergies.

3.7.4 I skipped/forgot to take a dose today, is it still worth logging?

Yes! It's very important that you log when you skip or forget to take your medications. By documenting why it happened, it becomes easier to identify what's getting in the way of taking your medications as prescribed.

3.7.5 Viewing previous logs

Tap the 'Logging history' button on the app home screen to see a list of all your previous logs

Tap the arrow on the home screen's medication logging card to see your latest log. You can also replace your latest log by pressing 'Replace today's log', this can only be done within 24 hours of creating your initial log. It is not possible to log medications retroactively.

3.8 Evaluation Tool

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

3.8.1 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.

3.8.2 Perform an evaluation test

A test consists of checking lung function and recording of complaints. Start the test by clicking "New evaluation 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

History

If you click on evaluation history, you will see a summary of the period with the highest and lowest test result 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'.

3.9 Spirometry Tool

The spirometry tool is another way for healthcare providers to assess a patient's lung function. This test provides healthcare providers with a set of values as well as a spirometry curve plotted in a graph.

When your healthcare provider 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 to evaluate the difference in lung function before and after taking medication. Only healthcare providers can activate the reversibility feature from Careportal, it is not possible to do so from the AsthmaTuner app.

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

3.9.1 Perform a Spirometry test

- Scroll down to the Spirometry card in the app's home screen and tap 'New session'
- View the instructions for how to, and when not to do a spirometry test
- Update your personal information for correct reference values
- The spirometer will automatically connect when you start the test. If you're experiencing any issues, follow the instructions in the app to connect the Bluetooth spirometer.
- Follow the on-screen instructions to perform a spirometry test. It is recommended to do 3 approved tests to ensure acceptable test quality, but your healthcare provider may ask for fewer or more tests

Note! Be sure not to cover the turbine with your hand when doing a test. Create a tight seal with your lips around the mouthpiece and blow out as hard as you can from the start.

Note! It's common for it to feel like you run out of air very early in the test, but don't remove the spirometer from your mouth until the ringing sound in the app stops.

3.9.2 Perform a Reversibility Test

- Make sure you have gotten clear instructions directly from your healthcare provider 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 will not provide this type of information.
- Scroll down to the Spirometry card in the app's home screen and tap 'New reversibility session'.
- View the instructions for how to, and when not to do a spirometry test

- Update your personal information for correct reference values
- The spirometer will automatically connect when you start the test. If you're experiencing any issues, follow the instructions in the app to connect the Bluetooth spirometer.
- When connected, select 'Start before-inhaler session'
- Follow the on-screen instructions. It is recommended to do 3 approved tests per session to ensure acceptable test quality, but your healthcare provider may ask for fewer or more tests.
- When you have completed the 'Before-inhaler session' it's time to take the healthcare provider recommended inhaler.
- **Important!** Pressing 'Start 15-minute timer' will start a timer that allows 15 minutes for the medication to take effect.
- When the timer has run out, complete the 'After-inhaler session' in the same way you did the previous session.
- Press 'End session' - you have now completed the entire reversibility test

Note! 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 send a reminder when it's time to continue the test.

4 About lung function tests

Lung function tests, like spirometry and treatment checks, are performed for diagnosis of symptoms such as shortness of breath, protracted coughing, wheezing, and protracted respiratory symptoms. Lung function tests are also performed to follow the effect of treatment and for general control of the health of the lungs.

4.1 Common measurements

4.1.1 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 tool, but also in the evaluation tool.

4.1.2 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.

4.1.3 FVC

FVC - Forced Vital Capacity (FVC) is one of the values unique to spirometry tests. It is the amount of air that can be forcibly exhaled from your lungs, after taking the deepest breath possible.

4.2 Placement of the mouthpiece

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

4.3 Posture

A seated position is preferred when performing a 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. For consistent results, it is recommended that you perform your lung function tests in the same posture.

4.4 Nose clip

It is possible that your clinic recommends the use of a nose clip. However, this is not a requirement for the use of AsthmaTuner.

4.5 Continuity

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

4.6 Hygiene

Hygiene should be considered in a spirometry examination to minimize the risk of infection between individuals. AsthmaTuner's Bluetooth spirometers are personal devices and should preferably not be shared between individuals. For further instructions on cleaning the mouthpiece and turbine, see spirometer instructions.

4.7 Spirometer calibration

AsthmaTuner's Bluetooth spirometer is factory calibrated, so no further calibration is required. If you suspect that the AsthmaTuner Bluetooth spirometer is not measuring values accurately, the turbine might need to be cleaned. If problems with the Bluetooth spirometer persist, contact AsthmaTuner support.

5 Revision history

Revision	Description of changes	Date
1	First approved version	2023-12-13
2	Additional information regarding accessories provided Additional information about serious incidents Additional information to ensure the IFU refers to the IFU for professional users	2024-03-08
3	Updated to reflect MDR certification	2025-04-24
4	Updated to include scheduled treatments and adherence	2025-06-16
5	Updates the MediTuner address	2026-03-20

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Head of QA/RA - Karlijn van Herpen Fri Mar 20 13:53:16 GMT 2026

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5	Fri Mar 20 2026	Approved	Karlijn van Herpen
4	Tue Aug 19 2025	Superseded	Karlijn van Herpen
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