

myAir Patient self-monitoring software platform

ENGLISH

About myAir™

myAir is a mobile medical device and self-management application to support you throughout your sleep health journey by providing education, enabling home sleep testing, and providing encouragement to start and continue therapy. myAir allows patients who use a compatible ResMed device to:

- create and manage your myAir account profile, including therapy equipment information.
- view personal therapy usage data from your compatible ResMed device, including usage hours, mask on/off, mask seal, events per hour, and your myAir Score.
- view informational and coaching articles and videos to supplement their prescribed treatment (eg, using your flow generator, mask fitting, cleaning tips, and reminders).
- view help and support information for the myAir app.
- access Personal Therapy Assistant, which provides a step-by-step device setup tutorial for Air11™ devices and allows Air11 users to control the device via Bluetooth® wireless technology connection to simulate therapy before using their prescribed therapy settings with predetermined, scaled inspiratory pressures, known as Test Drive.
- pair with a compatible NightOwl™ home sleep test (HST) device over Bluetooth to record and upload sleep test data for diagnostic use by your healthcare provider.

⚠ CAUTION

In the US, Federal law restricts this device to sale by or on the order of a physician.

Indications for use

The myAir app is indicated for patients:

- prescribed with a compatible ResMed Air11 platform device to simulate therapy prior to using their device with their prescribed settings. It is an optional software accessory to allow patients to acclimate to their therapy device.
- prescribed with a NightOwl wearable device to provide the user interface to operate the connected device and aid in the home sleep testing process.

The device is intended for home and hospital use for:

- new and existing patients of ResMed Air10 and Air11 PAP therapy devices and
- new users who are prescribed a compatible NightOwl home sleep test (HST).

Intended use

The myAir mobile application is a patient-centric platform intended for the following:

- Simulate therapy on a prescribed compatible ResMed Air11 platform device before using their
 device with their prescribed settings. It is an optional software accessory to allow patients to
 acclimate to their therapy device.
- Self-tracking therapy usage data and receiving coaching (e.g., educational videos, tips) in a
 personal home or clinical setting.

 Connectivity and recording on/off operation of a prescribed compatible NightOwl device and transfer NightOwl diagnostic test data to the NightOwl cloud computing platform for subsequent processing by the NightOwl software.

Clinical benefits

The myAir app is a Patient Engagement application that supports patients in managing their Sleep-Disordered Breathing (SDB). The myAir app provides patients with educational tools, promotes positive behavior change, and allows patients to track their progress. For clinical benefits related to the NightOwl system, see the NightOwl accompanying documentation.

System requirements

- iOS™ 16.0 and later
- Android[™] 9.0 and later.

Compatible ResMed therapy devices

Air11

Other ResMed devices^a

Air10™

Note: Bluetooth features are only available on Air11. Not all compatible devices are available in all regions.

^a Other ResMed devices do not directly connect to or directly exchange data with the myAir app. The myAir app accesses therapy data indirectly through ResMed's secure cloud database, AirView.

Compatible ResMed pre-therapy devices

• NightOwl Mini

Security

Built-in security features, steps you take to protect your smart device against malware, and keeping up with software and firmware updates all help to safeguard your privacy, protect your smart device and ensure optimal performance.

The myAir app uses security features to help protect your privacy and prevent unauthorised access to your data. Security features include:

- Unique keys for Bluetooth pairing
- Application-level encryption for the transmission of data, in addition to Bluetooth security
- Data encryption
- Automatic email notification if there is suspicious authentication activity on your account

Protecting your smart device against malware helps keep your personal information and sleep data safe and secure. ResMed recommends the following:

- Use a strong account password and do not share it with anyone else.
- Enable personal identification number (PIN) or fingerprint security on your smart device. Refer to your smart device user instructions for information on enabling either feature.
- Avoid unsafe modification of the smart device's operating system.
- Consider enabling remote data wipe on your smart device. Remote data wipe is a function
 available on your smart device for remotely erasing personal data in the event that your device is
 lost or stolen. Refer to your smart device user instructions for information on enabling this
 feature.
- Keep your operating system and myAir application up to date with security patches.

If not already notified by your operating system, app store, or myAir itself, check your app store for new versions of myAir available for download. If there is a critical security patch, myAir may automatically update if permitted in your settings. Using the latest version of myAir ensures that your data is secure.

Getting started for pre-therapy

Setting up Bluetooth connection with the NightOwl device

If you are a first-time myAir user for sleep testing:

- 1. In the myAir app, select your device, and tap NightOwl Mini.
- 2. Follow the prompts on the app to activate your test.
- 3. Once activated, in the sleep testing dashboard, tap **Go to setup instructions**.
- 4. Follow the prompts on the app to complete the Bluetooth connection. Ensure that you give permission for myAir to access your Bluetooth connection. Once connected, you will see the **Connected** status on screen while you're setting up your test.

If you have already activated your test in myAir:

- 1. In the sleep testing dashboard, tap Go to setup instructions.
- 2. Follow the prompts on the app to complete the Bluetooth connection. Ensure that you give permission for myAir to access your Bluetooth connection.
- 3. Once connected, you will see the Connected status on the screen while setting up your test.

To exit the Bluetooth connection page

1. Tap the back arrow on the top left of the screen until you arrive at the myAir dashboard.

Starting/stopping a home sleep test with the NightOwl device

For attaching and positioning the NightOwl device, use the instructions in the myAir App or refer to the NightOwl device user guide.

Starting and stopping the recording:

- When you're ready, tap Start recording.
 The screen will update to a Goodnight message and a button to stop recording.
- 2. Record your whole night's sleep to ensure enough information is collected about your sleep.
- 3. When you start recording, you may then lock your smartphone and leave it at your bedside. Ensure that it is plugged into power. It is important to keep your smartphone within six feet of your bed whilst you sleep. This is to ensure the NightOwl device remains connected to your smartphone and enables the sleep test to be conducted.
- 4. If you need to go to the bathroom, do not remove the NightOwl device or stop the recording. There is no further action required when you go back to bed. The device may disconnect, but as long as you return near to your smartphone at your bedside it will automatically reconnect and continue recording.
- 5. If you tap **Stop recording** before the minimum number of hours that your provider has set, we will ask you to confirm cancelling the test, as we will not have sufficient data to conduct the test.
- When you wake up, unlock your smartphone and tap Stop recording. You will see the sleep testing dashboard screen and a processing status message to indicate that your test is being uploaded. This could take a few seconds.
- 7. After the upload, the test will be processed in our systems and you can continue with your day, using your smartphone as you wish. You will receive a notification when the processing has been completed. You will be informed on whether your test night has succeeded or failed.

Getting started for therapy

Setting up Bluetooth connection with the Air11 device

Make sure your Air11 device is powered on. For instructions on how to set up and power on your device, refer to the Air11 user guide.

If you are a first-time myAir user:

- 1. In the myAir app, follow the prompts on the app to create an account.
- 2. To select your device, tap Air11.
- 3. Follow the prompts on the app to complete the Bluetooth connection.

If you have an existing myAir account:

- 1. In the myAir app, tap Profile.
- 2. Tap My equipment.
- 3. Tap Pair Bluetooth.
- 4. Follow the prompts on the app to complete the Bluetooth connection.

The Air11 device is now connected to the myAir app. The Bluetooth connection symbol appears on the Air11 device status bar to confirm the connection between the device and the smartphone. Tap **Done** to finish

Disconnecting Bluetooth

- 1. In the myAir app, tap Profile.
- 2. Tap My equipment.
- 3. Tap Update device.
- 4. Tap Disconnect.
- 5. To exit the page, tap the back arrow icon.

Test Drive

Test Drive gives you an opportunity to try out what therapy feels like. It is designed to slowly acclimatise you to therapy by introducing you to low (4 cmH $_2$ O) pressure before moving you to higher (7 and 10 cmH $_2$ O) pressure. This feature requires an active Bluetooth connection to your Air11 device and your mask information.

Make sure you have an active Bluetooth connection. If the Bluetooth connection is inactive, see Setting up Bluetooth Connection with the Air11 device.

- 1. In the myAir app, tap Coaching.
- 2. Tap Library.
- 3. Tap Test Drive.
- 4. Tap the Let's go button.
- 5. Follow the on-screen prompts, Test Drive will slowly introduce you to higher pressure.

myAir score

myAir calculates your score by analyzing your nightly therapy data. The higher your score, the better. You get points based on the following four key categories.

Usage hours

The point system for usage is calculated in hours and minutes. If you use your therapy for 1 hour you get 10 points, or for 2.3 hours (2 hours, 18 minutes) you get 23 points. The more time you use your therapy, the more points you receive, up to a maximum of 70 points.

Mask seal

The better your mask seal, the more points you get. This category can help you know if you need to adjust or change your mask to get a better fit. If your mask seal is poor, it can affect your comfort and the quality of your treatment. Your score reduces as your mask leak increases. You can get up to 20 points for minimal mask leak, 10 to 15 points for moderate leak, and 0 to 10 points for higher leak.

Events per hour

The fewer breathing events you have each hour, the more points you get. These breathing events are also known as the apnea-hypopnea index (or AHI). myAir measures how many times your breathing partially or fully stops each hour. If you have minimal events, you get 4 to 5 points.

Mask on/off

The fewer times you take your mask on and off throughout the night, the more points you get. Everyone has to take their mask on and off one time during treatment. So, for example, if you remove your mask one or two times, you get 5 points. However, if you take your mask on and off several times, it can indicate a problem with mask fit or with your sleep in general.

Mask fitting issues

Throughout the Test Drive process, myAir will monitor for mask air leak issues. In the event that a mask air leak issue is detected, myAir will display mask troubleshooting tips specific to your mask.

Follow the on-screen prompts and instructions.

Once myAir detects the mask air leak issue has been resolved, you will be notified and returned to Test Drive.

Additionally, myAir will notify the user if Test Drive failed due to a device error. To understand and resolve the error, please refer to the front panel of your device and the Air11 user guide.

Troubleshooting

If you experience any problems, try the following suggestions. Also refer to your Air11 or NightOwl user guide. If you are not able to fix the problem, contact your care provider or ResMed.

If you experience problems with the Air11 device, do not open it.

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Problem/possible cause	Solution
I cannot establish a Bluetooth connection	
Bluetooth may be disabled.	Check your smartphone to determine whether Bluetooth is enabled $\ref{eq:condition}$.
	Reconnect and pair your device and smartphone. Refer to Setting up Bluetooth connection with the Air11 device or Setting up Bluetooth connection with the NightOwl device for more information.
	If these solutions do not resolve the issue, try restarting your smartphone.
Your Bluetooth connection may be poor.	Ensure that your device is placed away from potential sources of interference such as microwaves, wireless local area network (WLAN)

routers or cordless phones.

Problem/possible cause	Solution
Your device may be in airplane mode.	Turn off Airplane Mode.
	For instructions, refer to your Air11 user guide.
The device appears in the device list, but I cannot establish a connection.	Tap the device name in the device list to confirm that you want to connect to that device.

Further information

For information on cleaning your device, maintenance, troubleshooting, patient population, conditions, and technical specifications, please refer to your appropriate hardware device user guides.

Any serious incident that has occurred in relation to this device should be reported to ResMed and to the competent authority in your country. For incidents related to the NightOwl device, refer to the NightOwl accompanying documentation.



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