INSTRUCTIONS FOR USE

Rest Assure Elite

PATIENT COPY

℞ Only

Rest Assure®

by SomnoMed™

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Introduction to your Rest Assure device

Congratulations, you have been prescribed a Rest Assure - a comfortable oral device equipped with sensors for the treatment of Obstructive Sleep Apnea and/or snoring.

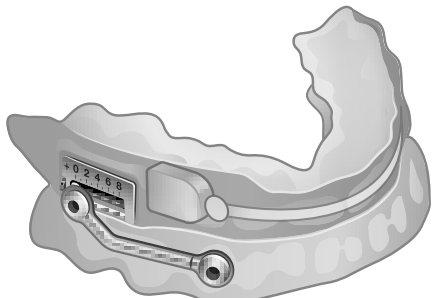
Your Rest Assure has been designed exactly to the shape of your teeth and jaw. Worn while you sleep, your oral device should fit snugly and comfortably over your upper and lower teeth. The device holds your lower jaw forward, helping to keep your airway open and allowing you to breathe normally.

In addition, your Rest Assure contains sensors that automatically monitor your sleep. Once you agree and connect to the Rest Assure patient App, you will be able to view details of your sleep time and sleep quality. Your sleep physician and dentist can also view this data and determine if an adjustment in your treatment and/or device is required.

To begin your journey to improved sleep and reduce the symptoms of sleep apnea such as daytime sleepiness, please read through these instructions. They explain how to use your Rest Assure device and connect to the app.

We look forward to helping you to a restful night's sleep.

The SomnoMed Team.



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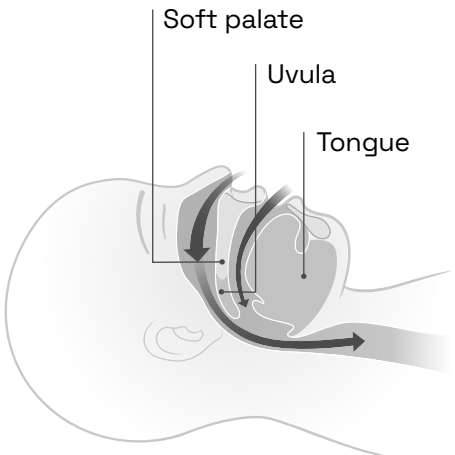
What is obstructive sleep apnea?

Obstructive Sleep Apnea (or OSA) is a medical condition affecting around 9% of women and 25% of men, or approximately one billion people globally.[1] Sleep apnea occurs when your throat muscles intermittently relax and block your airway during sleep, causing daytime sleepiness, excessive snoring and long-term cardiovascular (heart and artery) conditions.

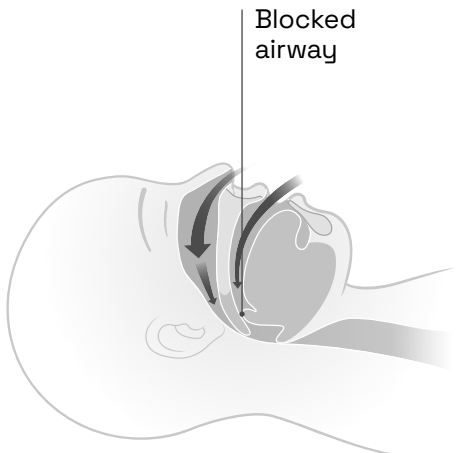
Rest Assure works by bringing your lower jaw and tongue forward during the night and unblocking your airway while you wear it. This device will encourage you to breathe through your nose, which will also decrease snoring. It is important for your ongoing therapy that you try and wear your Rest Assure device for the whole night.

IMPORTANT NOTICE Please read this user manual carefully before using your Rest Assure device and docking station and make sure to use the Rest Assure according to these instructions. Keep this manual with your Rest Assure for ongoing reference. If the user manual or the warning label on the docking station are damaged, contact SomnoMed for replacement.

Normal



Sleep Apnea



Warning labels on the device and used in this manual

To ensure Rest Assure can be used safely, SomnoMed use the following labels/symbols on the base of the docking station and in this manual:

Consult the user manual.

Caution, carefully read the safety precautions of this user manual.

This symbol indicates that as the Rest Assure device and docking station have electronic components, they should not be disposed of in regular household bins. Please take them to a center that deals with electronic waste.

IP42

The Rest Assure Docking Station is ‘splash-proof’ with an ingress rating of IP42 in accordance with IEC 60529.

5V ⎓ 500mA

The Rest Assure Docking Station input is 5VDC 500mA.

5°C 41°F 30°C 86°F

Permissible temperature range for docking station during use is 41°F to 86°F (5 to 30°C).

CE marking indicating that Rest Assure conforms with relevant EU regulations.

MD — Medical Device

Manufacturer

LOT — Manufacturing lot number of your docking station.

Follow instructions for use.

WARNING — Indicates a potentially hazardous situation which, if not avoided, could result in serious injury or possibly death.

CAUTION — Indicates a potentially hazardous situation which, if not avoided, may result in minor to moderate injury or damage to the Rest Assure device or docking station.

Note: 1.This manual is intended to be read up to 50cm in distance.
2.The Rest Assure device is intended to be used in a home environment.

Indications for use

Rest Assure is an intraoral device intended to be used in the treatment of snoring and mild to moderate obstructive sleep apnea in patients over 18 and has the capability to monitor parameters associated with obstructive sleep apnea treatment.

Contraindications

These devices are contraindicated for patients who:

» Have central sleep apnea
» Have severe respiratory disorders
» Have temporomandibular joint (TMJ) dysfunction
» Have loose teeth
» Have advanced periodontal disease
» Are under 18 years of age

Before first use

Before using your Rest Assure device for the first time, thoroughly clean your device by following the cleaning instructions in this manual on page 106.

Warnings

WARNING

» The Rest Assure device can be used if you have a pacemaker, and in a household where someone has a pacemaker. However, ensure the magnets in the Rest Assure device will not affect the function of the pacemaker by:
  » Keeping the docking station at least 6 inches or 15 cm away from a pacemaker
  » Keeping your Rest Assure device at least 1.2 inches or 3 cm away from a pacemaker
  » Do not put your Rest Assure device next to a pacemaker, such as in a shirt pocket

» Any changes or modifications to the Rest Assure device or docking station that have not been expressively approved by SomnoMed could void the user's authority to operate this equipment.
» The battery and electronic components of your Rest Assure device are completely enclosed within dental acrylic for your safety. Do not modify the device, as this may cause device fracture or damage to the electronics, and will void the manufacturers warranty. Do not attempt to remove electronics from the Rest Assure device. Removing the electronics may result in an electric shock and will permanently damage the device.
» Do not disassemble, crush, short-circuit or heat the battery in the Rest Assure device above 212°F (100°C) due to risk of fire, explosion and burns from the battery. Do not remove battery from the device or attempt to replace the battery due to risk of fire, explosion, and burns. In case of ingestion of an improperly removed battery, seek medical assistance immediately.
» Use of this device may cause tooth movement and changes in occlusion, TMJ pain or tenderness, obstruction of oral breathing, excessive salivation and gingival or dental soreness.
» If you have an allergic reaction to any material in this product, cease use of this product and contact your doctor or dental sleep professional.

choking, electric shock or swallowing some of the components. Return your Rest Assure device to your dentist for evaluation, repair, or replacement if it is broken or damaged.

» Regularly inspect your docking station and charging cable for signs of damage. If the docking station, cable or charging plug is damaged or broken it must NOT be used. This is to avoid electrical shock and other injuries. Please contact your sleep dentist or SomnoMed customer service at www.somnomed.com to organize a replacement docking station, cable or charging plug.

» Do not use the Rest Assure device in a scanner with magnetic resonance imaging (MRI).

» Your Rest Assure device contains a magnet, which may attract other things made of metal. Always store your Rest Device in the docking station when not in use to prevent this from occurring. Check there are no metallic objects attached to the magnet before placing the Rest Assure device in your mouth.

» Do not attempt to repair the Rest Assure Docking Station or remove any electronic components from the docking station. Removing the electronic components may result in an electric shock.

» Keep the cable, charging plug and electronics in the base of the Rest Assure Docking Station away from water to prevent the risk of electric shock.

Safety precautions

» Do not attempt to charge the Rest Assure device with unauthorized equipment, as this may result in battery damage, cell leakage, heat generation or fire.

» Portable Radio Frequency communication equipment such as a cordless phone should be used no closer than 12 inches (30 cm) to any part of the Rest Assure device or docking station, including the cable, to ensure the correct performance of this equipment. This precaution does not apply to your smartphone that is running the Rest Assure App.

» If your Rest Assure device is left uncharged for more than 1 month and does not recharge in the Rest Assure Docking Station, return it to your sleep dentist for a replacement.

» Only use the supplied Rest Assure Docking Station to charge your Rest Assure device. Use of other charging methods may result in permanent damage to the battery.

» Keep your Rest Assure device protected from direct sunlight to avoid degradation of the materials.

» Do not use the docking station in your bathroom, as the humid environment may cause the docking station to stop working.

» Store your Rest Assure Device and docking station between 5 to 45°C [41 to 113°F] while not in use and between 5 to 30°C [41 to 86°F] when the Rest Assure device is charging in the docking station.

» Keep your Rest Assure device away from pets & small children to avoid accidental swallowing.

» Never use hot or boiling water to clean your Rest Assure device as high temperatures may damage your device.

» Do not use toothpaste to clean your Rest Assure device, as it contains abrasives, and may damage your Rest Assure device.

» Use only a soft toothbrush to clean your Rest Assure device, a hard bristle toothbrush may damage your Rest Assure device.

» Do not use mouthwash to clean your Rest Assure device.

» Do not use ultrasonic cleaning to clean your Rest Assure device.

» Do not use denture cleaning tablets to clean your Rest Assure device, as these may contain abrasive substances that can damage your device. SomnoMed recommends using SomTabs, cleaning tablets specially formulated to clean oral devices, for 15 minutes twice a week. Immersion for longer than 15 minutes may damage the plastic or electronic components in the device.

» Always store your Rest Assure device in the docking station when not in use to allow it to charge and prevent accidental damage.

» Do not store your Rest Assure device or strap in water or any other liquid.

» To reduce the possibility of discoloration of the Rest Assure device, do not smoke or drink coffee, tea, colas, or wine with the Rest Assure device in your mouth. Always brush your teeth thoroughly before sleeping and using your Rest Assure device. Should discoloration of the material from issues outlined above occur it will not negatively affect the performance or longevity of the device.

Possible side effects

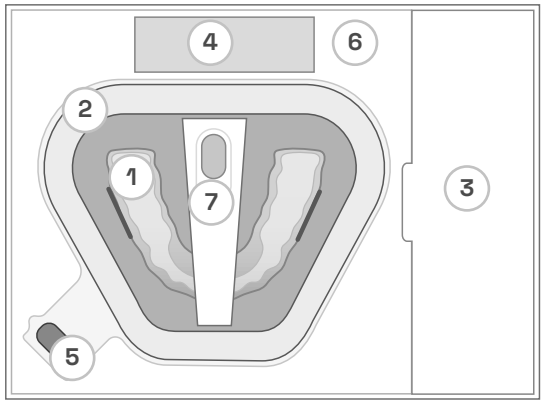
You may experience some temporary side effects such as sore jaw joints, increased salivation, dry mouth, sore teeth, irritation of the soft tissue in the mouth and/or a slight change in bite.

These possible side effects should diminish within an hour of removing your device. If any of these side effects continue, contact your dental sleep professional, and maintain regular dental check-ups.

Unpacking your Rest Assure device

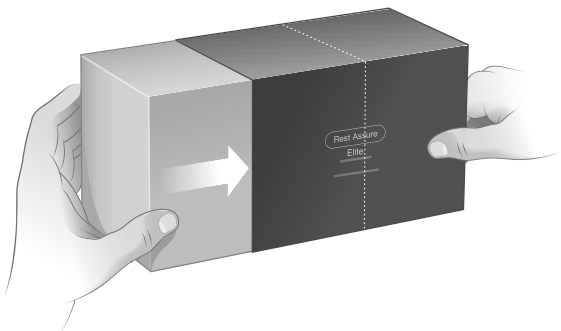
Your sleep dentist will provide you with your Rest Assure in the patient box, which looks like this when it has been opened:

1. Rest Assure device
2. Docking station
3. Accessories compartment
4. SomMorning Repositioner (available in certain markets)
5. Electrical plug
6. Docking station tray
7. Docking station lid vent



To start unpacking your Rest Assure, follow these steps:

1. Remove the blue sleeve by sliding it off either side of the box.



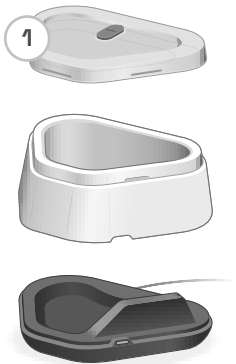
If your sleep dentist has used dental molds or impressions to make your device, you may also receive a separate small box with these enclosed.

2. Remove the pink lid from the blue box

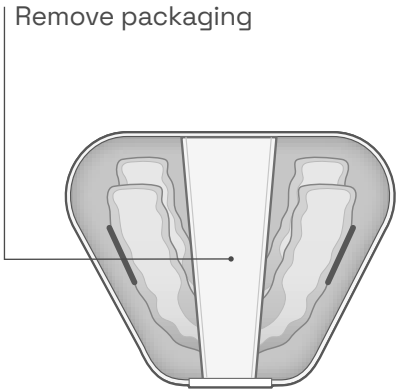
3. In the central compartment of the Rest Assure box, you will find the Rest Assure Docking Station. You will use this to charge your device when you are not asleep. When you place your device in the docking station, it will send the data from your last sleep period to a secure internet cloud via your smartphone.

TIP #1: Keep the Rest Assure box, in case you need to travel with your Rest Assure device and docking station in the future.

4 Inside the docking station you will find your Rest Assure device. To access the Rest Assure device, remove the clear lid, marked as number 1 in the picture below.



5 Remove the white shipping packaging before use.
It is recyclable, so it can be recycled with other paper-based materials.

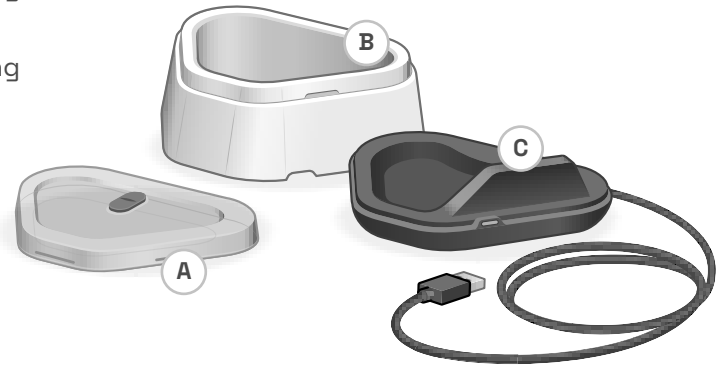


6 The Rest Assure Docking Station has three parts:

A Rest Assure Docking Station clear lid

B Rest Assure Docking Station cup

C Rest Assure Docking Station base

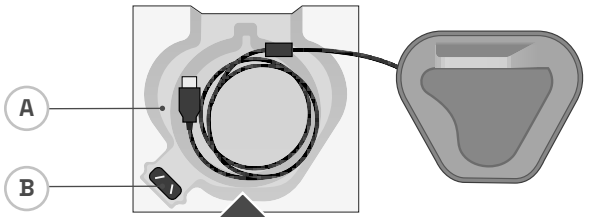


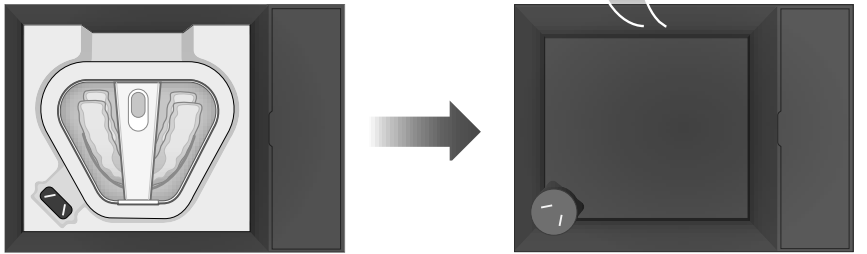
For more information about your Rest Assure device, refer to the section: **Getting to know your Rest Assure device** starting on page 24.

7 Remove the pulp tray in the central compartment, and you will find the electrical plug.

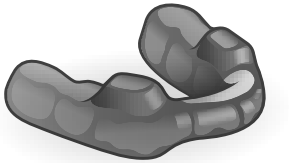
A Docking station tray

B Electrical plug



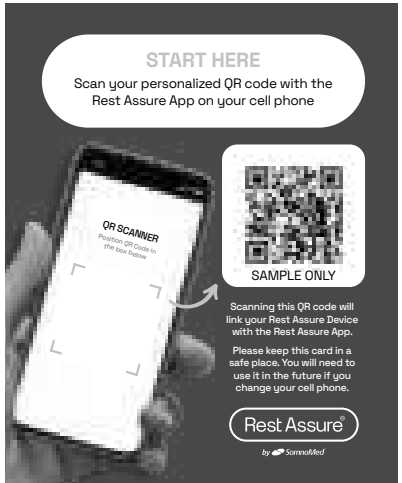


8 Your sleep dentist may have also ordered you a SomMorning Repositioner. If so, you will find it in this small box next to the docking station. Refer to your sleep dentist's instructions for how to use the SomMorning Repositioner.



In the right compartment of your Rest Assure box, you will find the following:

» **SomTabs**: SomTabs are used to clean your Rest Assure device. For more information on the use of SomTabs, refer to the section: **Cleaning your Rest Assure device** on page 106. Depending on where you live you may have a box of SomTabs like those in the picture on the right or a foil packet of SomTabs.



» This **Instructions for Use** Booklet.

» Other information that your dentist may provide

» A card containing your specific **QR code** for connecting your Rest Assure device to the Rest Assure App.

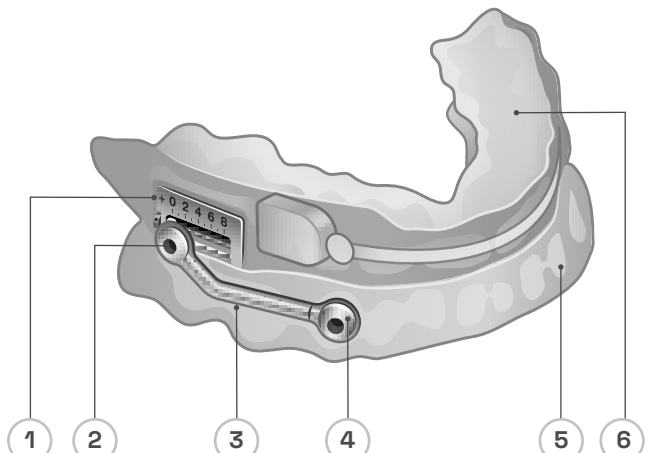
» Your Rest Assure Elite adjustment key and cleaning brush. For more information on how to use these, go to Adjusting your Rest Assure device on page 49.

TIP #2: Store this card in a safe place, as you may need it again if you want to connect your Rest Assure account to multiple Rest Assure devices.

Getting to know your Rest Assure device

These are the parts of your Rest Assure device:

1. Plus indicator
2. Hinge
3. Arm
4. Hinge
5. Lower arch
6. Upper arch

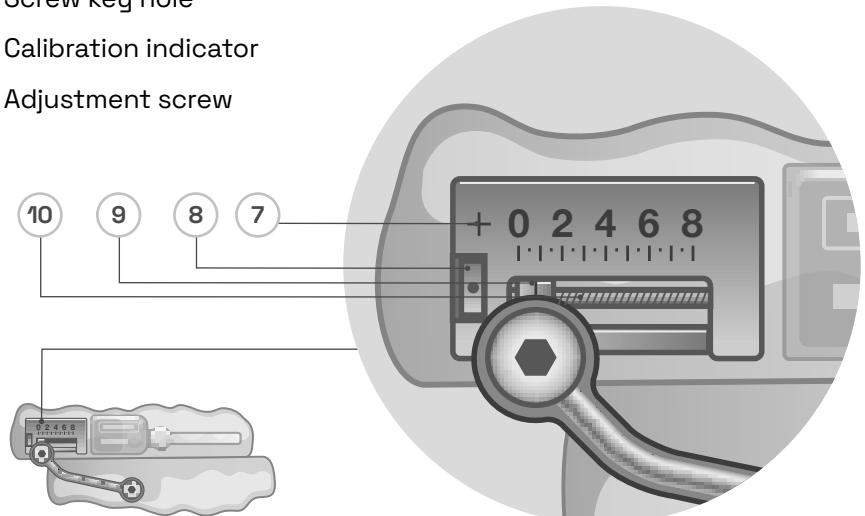


7 Plus “+” Indicator

8 Screw key hole

9 Calibration indicator

10 Adjustment screw



The Upper plate - fits onto your top teeth. The outside is made of dental acrylic and is resistant to breaking. It also has a soft inner liner called a b-flex comfort liner. The b-flex comfort liner cradles and supports each individual tooth, allowing you to comfortably wear your device all night, every night. The upper plate contains the battery and the sensors that are essential for the ongoing monitoring of your Rest Assure device.

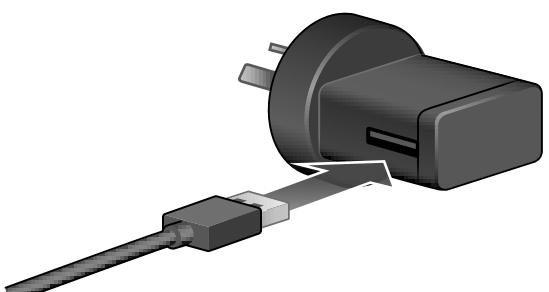
The Lower plate - fits onto your bottom teeth. It is made of dental acrylic on the outside, with a soft inner b-flex comfort liner on the inside. The arms will gently push the lower plate forward to bring your jaw and tongue forward and open your airway to reduce the number of apnea events you may experience during your sleep. The lower plate contains a small magnet used by the sensors in the upper plate.

The Rest Assure Elite arms- connect the upper and lower plates together and allow the lower plate to move forward independently of the top plate.

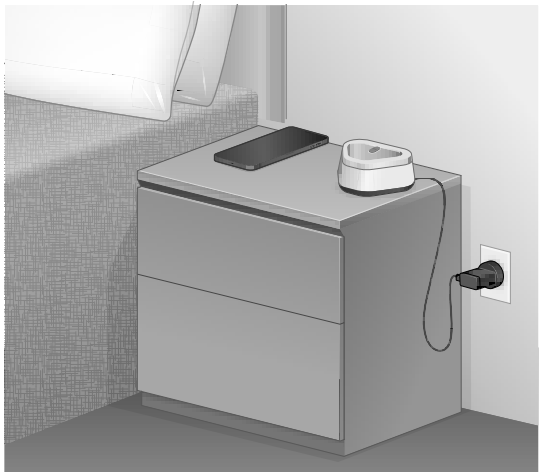
The Calibration Indicator - the Calibration indicator shows how far the lower plate has been advanced.

Setting up your Rest Assure Docking Station.

1. Connect the electrical plug to the USB cable attached to the docking station.



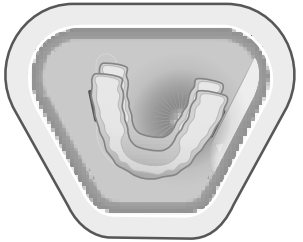
2. Connect the electrical plug to an electrical outlet in a place that will remind you to use your Rest Assure device every night, such as next to your bed. Your Rest Assure device should be placed in the docking station and be charging whenever you are not using it.



TIP #3: When you dock your Rest Assure device in the morning, it must be near your smartphone to allow the data to be transferred.

3. There is a blue light on the docking station. Turn on the power to your docking station and the blue light will briefly turn on to show you that it is connected.

4. Place your device in the docking station to charge for at least 5 hours. The light on the device will turn purple when it is charging, although for the first charge it may take up to 15 minutes for the purple light to illuminate.For information on how to place the device in the docking station, see **Downloading your sleep data** on page 55.



Connecting your Rest Assure device to the Rest Assure App

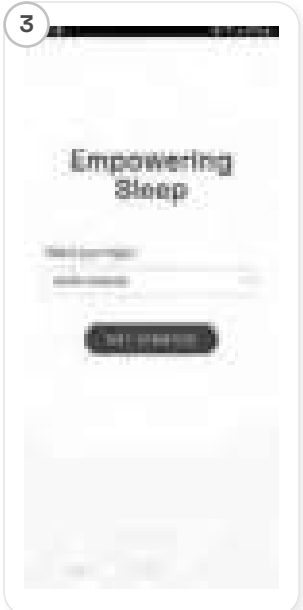
Your Rest Assure device is easy to connect to the Rest Assure App by following these steps:

1. Download the app from the App Store (if you have an Apple™ phone) or from Google™ Play (if you have an Android phone). Search **Rest Assure by SomnoMed** to find the app which looks like this:

Minimum smartphone requirements for the Rest Assure App: Android Version 10 (Samsung, Huawei, and Xiaomi handsets) and IOS (Apple) 15.

TIP #4: The patient should have the QR code card that came in the box with the Rest Assure device handy - it will be needed to complete the connection to the Rest Assure App.

2. Accept the terms and conditions from the App Store or the Google Play store.
3. Once installed on your phone, open the Rest Assure App and you will get to screen 3. Select your region (North America, Europe or Asia-Pacific) and then **Get Started**.
4. When you see the **Welcome back** screen, to create a Rest Assure account, click on **Sign up**.

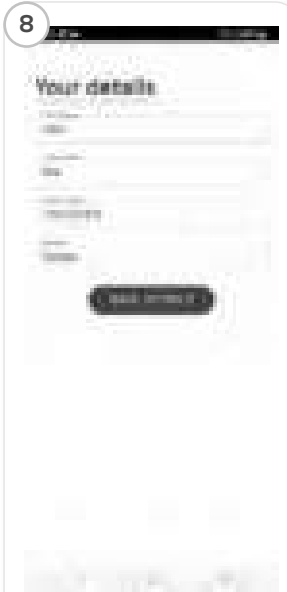


5. The following section will open a Rest Assure account for you. Enter the email address you would like to use for your Rest Assure account, and click **Send Verification Code**. Use a personal email account, as this email address provides access to your data and cannot be changed.
6. A six-digit verification code will be sent to your email to verify the email address. Enter the code and click **Verify Code**.
7. Enter the password you wish to use for the Rest Assure App and confirm this password. Enter your first name, last name, accept the terms and conditions and privacy policy, then click **Create Account**. If you would like to review the terms and conditions or privacy policy, click on the links to review or go to https://somnomed.com/en/rest-assure-terms-and-conditions/ or https://somnomed.com/en/privacy-policy/

8. Your first name and last name will populate in the fields. Enter your Date of Birth and Gender and click **Save Details**.

9. You have now created your Rest Assure account. The app will now take you to step 2 to link to your sleep dentist and sleep physician clinics. Click the arrow in the purple section to continue:

8



9

10. Click **Scan QR Code** to scan the QR code supplied with your Rest Assure device.

11. The Rest Assure App may ask you for permission to use the camera on your smartphone. If you see this screen, click **While using the app**.

10

11

12 The Rest Assure App will then open the camera app on your phone. Note the app will only use your smartphone to read the QR code that came with your Rest Assure device – Rest Assure does not activate the camera at any other time. Place the card with the QR code that came with your Rest Assure device on a flat surface.

13 Use the camera on your phone to position the QR code in the white box, as per the image on the right. As soon as the QR code is read by your smartphone's camera, your smartphone will advance to the next screen.

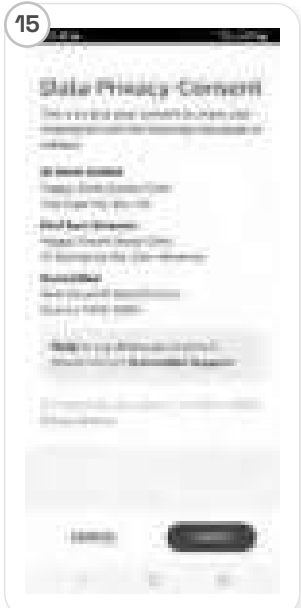
13

14 When you see this screen, you have successfully linked your Rest Assure account to display the physician and dental clinics that can review your sleep data.

14

15 The app will then display the physician and dental clinics that will be able to see your treatment information. Please consent for the team at these clinics to be able to see your Rest Assure data. You will also need to give consent to SomnoMed, the manufacturer of your Rest Assure device and operator of the Rest Assure system. Please review the data sharing terms and conditions by scrolling down the screen. Click **I Agree** to proceed. Note: if you do not proceed, the Rest Assure App cannot be used.

To review the privacy policy, click on the link in the app or go to: https://somnomed.com/en/privacy-policy/



16 The following screen shows that you have successfully set up your app.

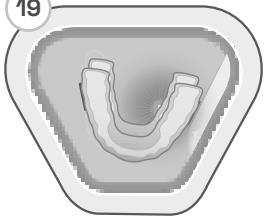
17 The final step is to pair your Rest Assure device with the Rest Assure App. To do this, you will need to unpack and set up the docking station. If you are ready to connect to the device now, click **Done**.

18 Click **Set Up Device**.

19 Place your Rest Assure device in the docking station to charge, so that the light on the Rest Assure device turns purple, green, or blue. Make sure your smartphone is no more than six feet (two meters) from the docking station.

18

19



20 The Rest Assure App uses the Bluetooth system on your smartphone to connect your Rest Assure device to the Rest Assure App. If you are using an Android-powered smartphone, click **Allow** to provide permission and then click **Connect Device**.

Please Note: If you are using a smartphone with IOS operating system, then you will need to go into the settings menu and allow the Rest Assure App to use Bluetooth.

20

21 If you are using a smartphone with an Android operating system, the Rest Assure App uses the location software on your smartphone to connect to the correct device. Click **Allow** to provide permission. Then click **Connect Device**.

22 If your Rest Assure device and docking station are in range, the app should briefly show **Connecting** on the next screen.

If the app does not proceed, check that your Rest Assure is in the docking station, the light on the Rest Assure device is on, and your phone is within six feet (two meters) of the docking station. Press the X in error screen to retry the connection step.

23 When you see this screen, you have successfully completed the set up of the Rest Assure App. Your Rest Assure is ready to record your next sleep period.

Using your Rest Assure device

» You may initially experience a mild plastic smell or taste. This will disappear with storage and use.

» To avoid injuries such as choking, or laceration do not use if any device components are damaged or broken.

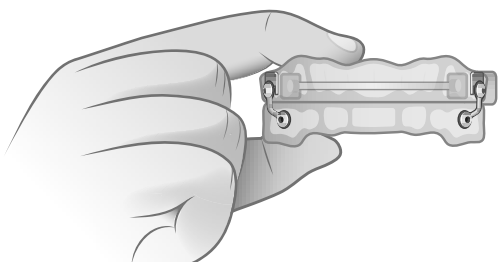
» For maximum longevity of the Rest Assure battery, the Rest Assure device should always be returned to the docking station when it is not being used.

» Always brush your teeth before using your Rest Assure device.

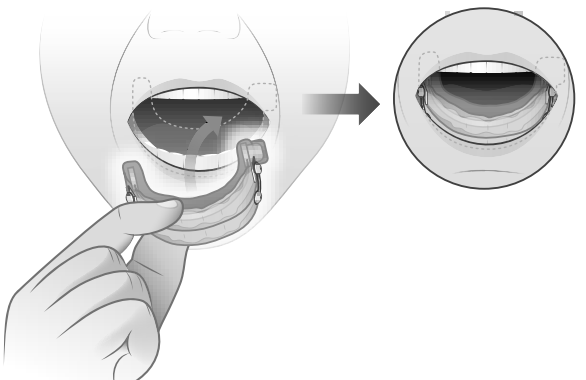
Fitting your Rest Assure device

Check that the upper and lower plates are attached before fitting your device.

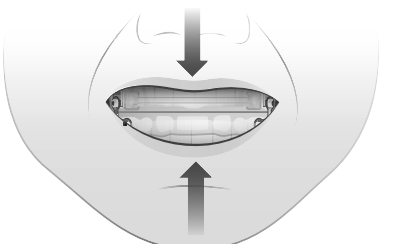
1. Hold the upper and lower plates together.



2 Gently place the lower plate onto your bottom row of teeth. Press down on both sides of the lower plate with your index fingers to ensure the fit is secure and comfortable.

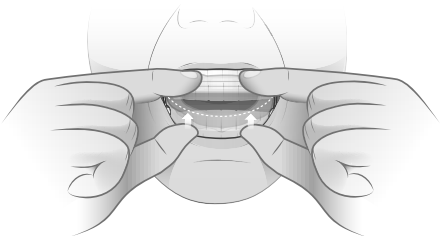


3 Once the lower plate is securely in place, bite down into the upper plate to secure it to your top row of teeth. Use your thumbs on both sides if required to push the upper plate onto your teeth.

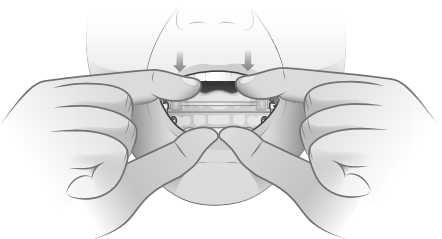


Removing your Rest Assure device

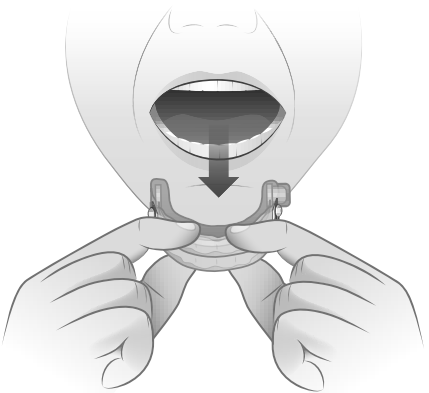
1. Disengage the lower plate from the teeth first. Use your thumbs on both sides to push the plate upwards.



2. Gently pull the upper plate down using both index fingers and thumbs.



3. Remove the entire device from your mouth in one motion.

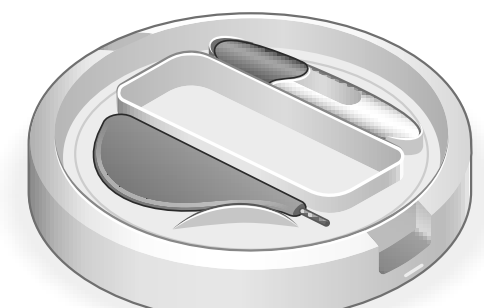


It is normal for some patients to experience a mild discomfort of the jaw and gums when you commence therapy with Rest Assure. This discomfort will reduce over a few days as you acclimate to Rest Assure therapy. If pain or discomfort persists, return to your dental sleep professional to assess the fit and settings of your Rest Assure device.

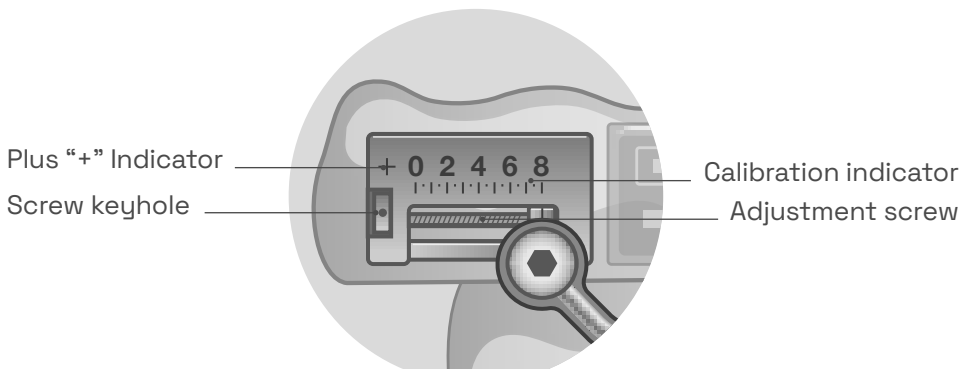
Adjusting your Rest Assure device

Your Rest Assure can be adjusted within an 8.0mm range, in 0.1mm steps. To adjust your device:

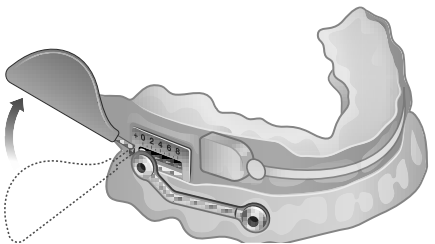
1. Find the calibration tool supplied in the Rest Assure box.



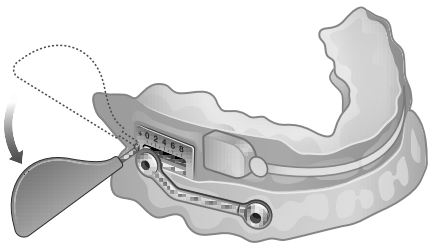
2. Locate the **Screw key hole** on the Right hand side of your device.



3 Place the small end of the calibration tool in the Screw key hole. To advance forward, rotate the screw key hole in the upwards direction. To reverse the movement, rotate the screw key hole in the downwards direction.



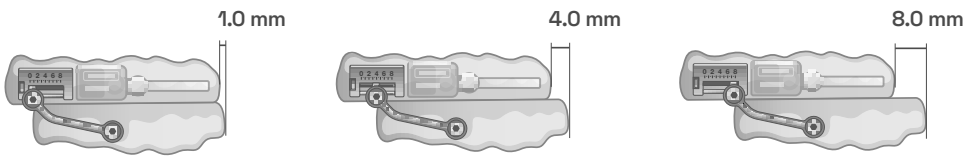
To move forward
Fit your calibration tool into the screw key hole and rotate upward, toward the plus indicator.



To move backward
Fit your calibration tool into the screw key hole and rotate downward, away the plus indicator.

4 The amount of advancement of the lower plate can be viewed on the Calibration indicator. In this example, the device is advanced 8mm. Always make sure you repeat the same calibration on both sides of the device.

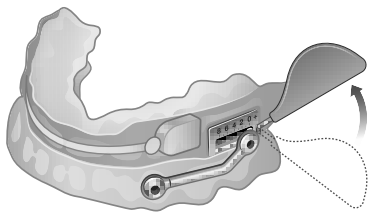
5 The image below shows the number of turns required to advance the lower plate by a given distance.



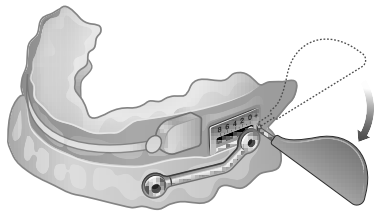
Reverse ← 1.0 → Forward

90° Turns	-10	-5	+5	+10	+15	+20	+25	+30	+35	+40	+45	+50	+55	+60	+65	+70
Adjustment (mm)	-1.0	-0.5	0.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0

6 Repeat the same adjustment on the left side of the device.



To move forward
Fit your calibration tool into the screw key hole and rotate upward, toward the plus indicator.



To move backward
Fit your calibration tool into the screw key hole and rotate downward, away the plus indicator.

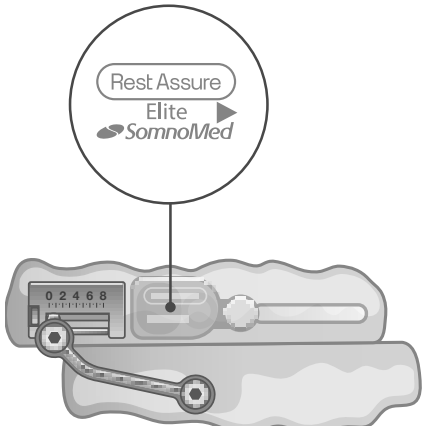
Important: Your sleep dentist will determine the advancement that is optimal for your therapy. He/she will advise when to adjust your Rest Assure device, taking into account both the mandibular advancement required and your comfort

Downloading your sleep data after each sleep

After every sleep when you have been wearing your Rest Assure, you will be able to download information about your sleep from your Rest Assure by following these simple steps.

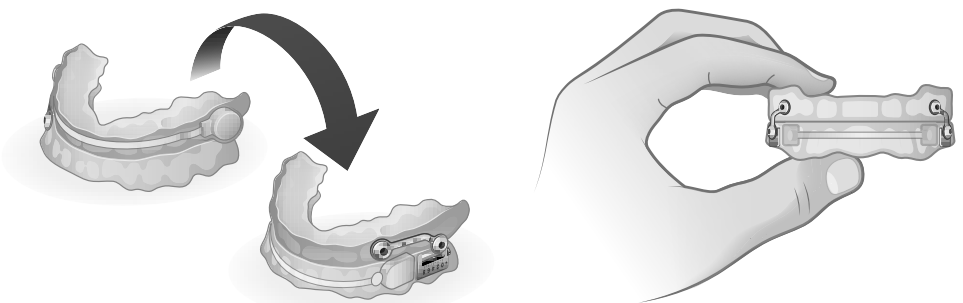
1. Ensure you have connected your Rest Assure device to the app on your smartphone by following the procedure detailed in **Connecting your Rest Assure device to the Rest Assure App** on page 30.
2. Ensure your docking station is plugged into a power outlet and set up correctly by following the procedure detailed in **Setting up your Rest Assure Docking Station** on page 27.
3. Place your smartphone within six feet (two metres) of the docking station. Ensure the Bluetooth function on your smartphone is turned on, and that the smartphone is charged and connected to the internet. If your smartphone has been inactive whilst you were sleeping, unlock your smartphone to ensure it is no longer in sleep/idle mode.

4. Clean your Rest Assure device as per **Cleaning and Maintaining your Rest Assure device** on page 106.
5. Remove the lid from the docking station. Locate the Rest Assure nameplate on the upper splint of your Rest Assure device that looks like this:

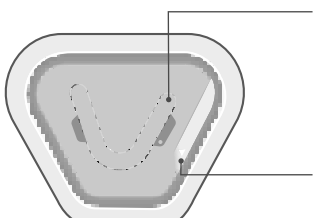


TIP #5: Data transfer should be performed with a dry docking station. When powered or plugged in, no water or liquid should be inside the docking station.

6 Hold your Rest Assure device as shown, with the upper plate on the bottom. The upper plate contains the white stripe.

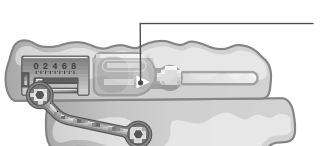


7 Find the arrow on the Rest Assure device. The arrow printed on the Rest Assure device should line up with the arrow on the Rest Assure Docking Station. The outline of the Rest Assure device on the bottom of the docking station shows the correct alignment.



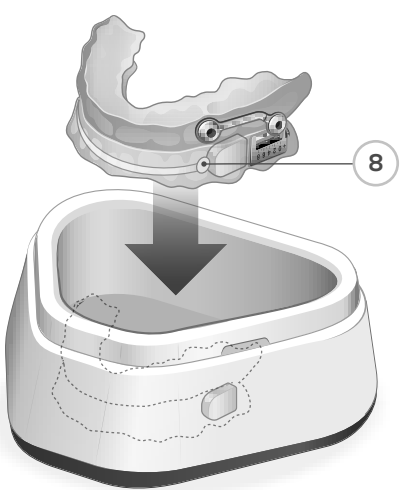
Outline of Rest Assure device printed on the base of the docking station cup shows the correct alignment of the Rest Assure device when in the docking station

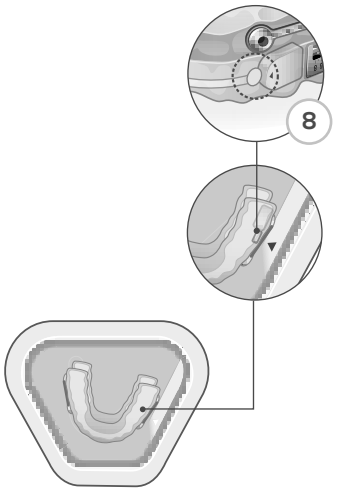
Arrow printed on the docking station. Align the arrow on the Rest Assure device with this arrow



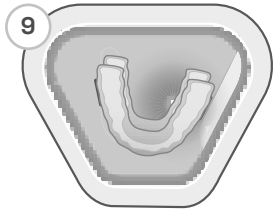
Arrow printed on the Rest Assure device.
You will hear a click when the device is in the correct position

8 The Rest Assure device will look like this in the correct position





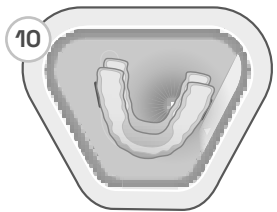
9 If the Rest Assure device is in the correct position, the light on the Rest Assure device will illuminate a purple light. The purple light indicates that charging has commenced. For the first use, or if you have not used your device for some time, it may take up to 15 minutes for this light to come on.



10 If your smartphone is within range, the light on your Rest Assure device will change from purple to blue in a matter of seconds.

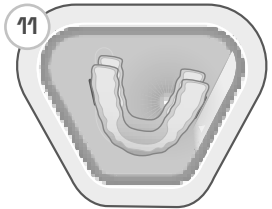
The blue light indicates that your smartphone is downloading the information from your Rest Assure device and uploading it to a secure cloud location.

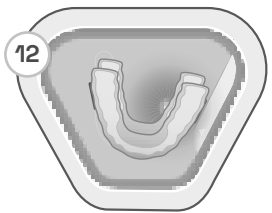
NOTE: Downloading the information from your Rest Assure device and uploading to the cloud will start automatically when you place your Rest Assure device in the docking station and your smartphone is in range.



11 If the data transfer process is interrupted (for example if you take your smartphone out of range), the light on your Rest Assure device will turn orange. When your smartphone is brought back within range, the light will automatically change back to blue, and the data transfer process will continue.

12 After about 5 minutes, the data transfer to the cloud should be complete. The light on your Rest Assure device will go back to purple. It is ok to take your smartphone away from the docking station after the light on your Rest Assure turns to purple.



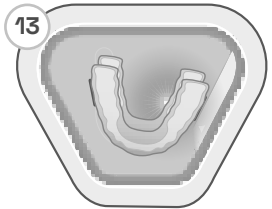


Quick reference chart for the status of your Rest Assure device.

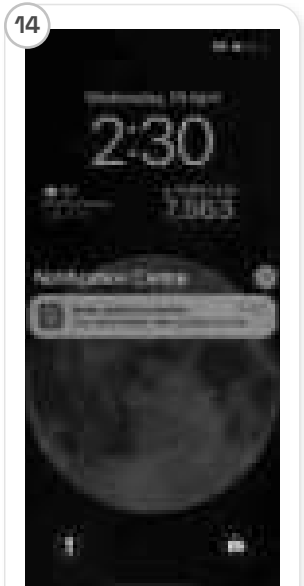
Status	Light on the Rest Assure device
Charging the Rest Assure device	● Purple
Downloading data from the device	● Blue
Error in downloading data from the Rest Assure device	● Orange
Device is charged, data is downloaded and ready for the next sleep.	● Green
Device is not connected properly in the docking station, or electronics are faulty.	○ Not illuminated

13 When the device is fully charged, and the data has been successfully transferred, the light on the Rest Assure device will turn green. The charging process typically takes up to 5 hours. Therefore, it is very important to return your Rest Assure device to the docking station after each use. The Rest Assure device should be stored in the docking station, with the power on, whenever it is not in use.

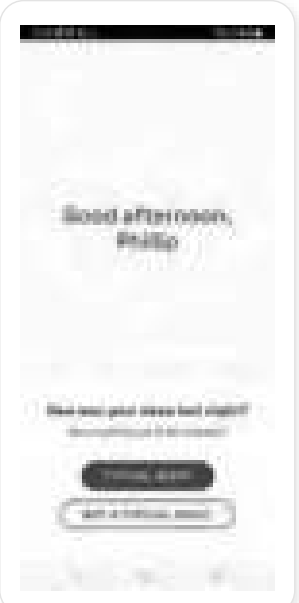
Following a full charge, your Rest Assure device will be ready for your next sleep. If your Rest Assure device does not charge, check that it is placed correctly in the docking station and leave to charge for 1 hour. If your Rest Assure device fails to charge after this period, contact the SomnoMed support center or your sleep dentist.



14 Your sleep data will now be processed by the Rest Assure cloud servers. Within 15 minutes, your app will alert you that your last sleep data is ready for review with a message on your smartphone that looks like this:



15 Click on the notification or open the Rest Assure App from your home screen. The Rest Assure App will briefly show the screen on the left, before asking you to rate your previous sleep period as per the screen on the right.



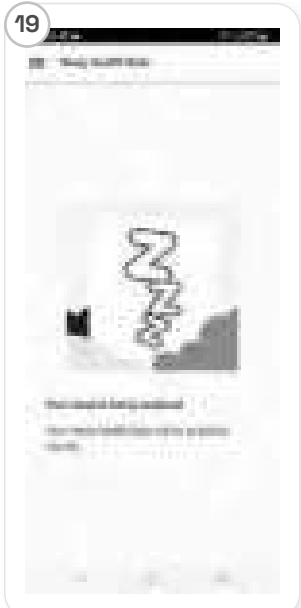
16 Click **Typical Night** to advance to the next screen if your last sleep period was similar to your normal sleep.

17 If you click **Not a typical night**, you can identify the cause of your non-typical night's sleep by clicking on one or more of the causes. When you have noted all the causes, click **Next**.

18 The sleep rating page will be shown as per the image on the right. Use the blue arrows to rate your sleep from 1 (a terrible night's sleep) to 10 (a perfect night's sleep). You can also use the slider to move your sleep rating up or down. When you have rated your sleep, click **Submit**.

Your sleep dentist and physician can view your sleep rating and the information about your sleep to assist you with improving your sleep.

19 If your last sleep is still processing, this screen will be displayed:



20 When your data is ready, this screen will be displayed. An explanation of the parameters on this screen can be viewed in the section **Understanding the data from your Rest Assure device** on page 78.

21 Repeat steps 1-20 every sleep period to provide your physician and sleep dentist with your most up to date sleep data.

Important information about downloading your treatment data:

» The Rest Assure App automatically downloads your data in the background mode of your smartphone. There is no need for you to open the app each morning to start the download process. To ensure the background sync will work on your phone, wake up your phone by logging in or opening any app on your phone when you wake up. It is also a good idea to charge your phone while your Rest Assure device is syncing, as some phones turn off syncing while using the battery to save power.

» If the internet is unavailable when you complete a sleep period, or you cannot keep your phone near the docking station for 5 minutes in the morning, do not worry. Place your Rest Assure device in the docking station to charge. When you come back to the Rest Assure Docking Station with your smartphone for your next sleep, your smartphone and Rest Assure device will connect, and download your data to the cloud then. Note that you and your sleep dentist/physician will only be able to see the treatment information for your last sleep when all the sleep data has been downloaded.

» Your Rest Assure device can only download data via the Bluetooth system on your smartphone when placed in the docking station. While the Rest Assure device is in your mouth, the wireless communication circuit is deliberately inactive, so other wireless communication devices cannot connect to your Rest Assure device.

» In addition to sending data about your sleep to the cloud, the Rest Assure App also transmits log files of app activity, such as the time when your Rest Assure started to download, to assist with troubleshooting any issues you may have with your Rest Assure device.

» Delete the Rest Assure App if you discard or sell your smartphone to prevent access to any data stored on your smartphone.

» If you have issues downloading the data from your Rest Assure device, please visit: [web address to be confirmed by region]

URL TBC

Troubleshooting and error messages.

1 Not connected to the Internet:

The Rest Assure App requires a connection to the internet. If the internet connection is lost, check that:

» Your smartphone is connected to the internet and is not in airplane mode.

» Your connection to the internet (via your home internet or your hotel internet if you are traveling) is active and working.

As soon as the internet is restored, then you will be able to continue with the app.

1

2 Location services on your smartphone are switched off.

The Rest Assure App needs a connection to the location services on your smartphone. If you see this error, turn on the location services on your smartphone.

3 Bluetooth is not switched on or has been disabled on your smartphone.

The Rest Assure App needs a connection to Bluetooth on your smartphone. If you see this error, turn on Bluetooth on your smartphone.

4 Something went wrong.

If you see this message, check that your internet connection is working. Close and reopen the app and see if this corrects the error. If the error persists, contact SomnoMed at:

Email:
restassuresupport@somnomed.com

Web:
www.somnomed.com/restassuresupport

Phone:
1800 Rest Assure.

To be updated by region

TBC

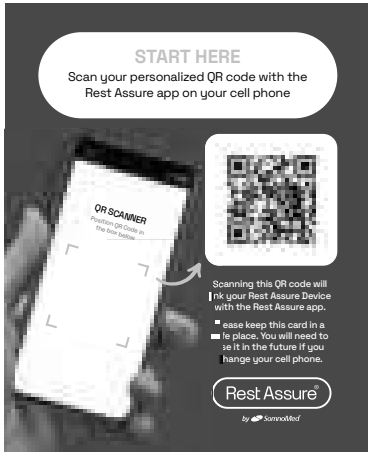
5 Other issues with your Rest Assure device, docking station or app.

Please contact SomnoMed customer support:

Email:
restassuresupport@somnomed.com

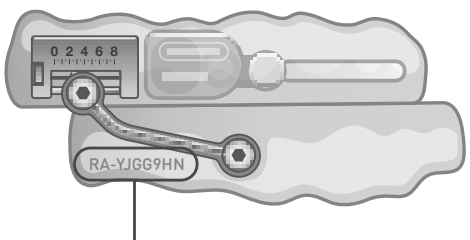
Web:
www.somnomed.com/restassuresupport

Phone:
1800 Rest Assure.



Please have the QR code that was sent with your device ready, so you can tell the customer support person the serial number of your device.

If you are unable to locate your QR card that came with your Rest Assure device, do not worry. Your serial number is also laser marked on your device. You will find it on the left-hand side of the device, on the lower plate that fits onto your lower teeth. In this example, the serial number is **RA-YJGG9HN**.



Serial number

Understanding the data from your Rest Assure device

After you have worn your Rest Assure device for at least one night, the data from your last sleep period will be displayed in the Rest Assure App on the Sleep Health Data page. This section will explain these measurements.

Once the data has been processed, your information will display on your Rest Assure App's Sleep Health Data page. Your previous sleep data period and your Rest Assure score will be displayed.

Your Rest Assure score for the previous sleep period is calculated using:

» The number of hours you slept during the night while wearing your Rest Assure device. The more hours you slept while wearing your device, the higher your score.

» The number of breathing events per hour that you experienced during the night. The lower the number of events, the higher your Rest Assure score.

» Your sleep position during the night. If you have breathing events while sleeping on your back, your score will be reduced.

» The number of times your sleep was interrupted during the night, for example by perhaps going to the bathroom or sitting up in bed. Taking your Rest Assure device out of your mouth during the night also counts as an interruption. The fewer sleep interruptions you have, the better your sleep and the higher your Rest Assure score.

Generally, a higher Rest Assure score may indicate that your treatment was more effective at reducing the symptoms of OSA such as daytime sleepiness. However, to confirm the effectiveness of your treatment, your physician or sleep dentist will need to complete a hospital or home sleep test.

There are many ways you may be able to increase your score over time, such as wearing your Rest Assure device all night (and every night), trying to sleep on your stomach instead of your back, and limiting drinking before bed - so you have less sleep interruptions during the night.

Understanding each element of the Rest Assure score

Sleep time

The Rest Assure score calculates both a usage time and a sleep time every time you use it. These periods are calculated as follows:

Usage time: is the time from when you put the Rest Assure device into your mouth until you take the Rest Assure device out of your mouth at the end of your sleep period.

You can take your Rest Assure out of your mouth if you need to during the night, for instance to take some medication. However, do not place your Rest Assure back in the docking station until you have finished sleeping. When you place your Rest Assure back in the docking station, this signals to the software that you have completed your night's sleep period.

Sleep time: is the time that you were wearing the device and you were asleep. Having at least 7-9 hours of sleep per night is associated with many health benefits.

Your sleep score is scored out of a total of 40 points. If you sleep 7 hours or more, your Rest Assure sleep time score will be 40 points. If you sleep less than 3 hours and 45 minutes, your Rest Assure score will be 0. If you sleep between 4 hours and 7 hours, generally every 15 minutes of sleep is worth 2 more points.

Note: If you do take a nap during the day, it is ok to wear your Rest Assure device. However, your nap time will not count towards your total sleep time. Rest Assure only counts the time you spent during your longest sleep period in 24 hours.

If you click on the Sleep time panel on the Sleep Health Data page, you will advance to this screen:

1. Your sleep time score is displayed here. You can click "ⓘ" on the to see how this score has been calculated.
2. Your usage time and sleep time (in hours) are displayed in a graph.
3. Your total usage time for your last sleep period is displayed as well as your average usage time for the previous week.
4. Your total sleep time for your last sleep period is displayed as well as your average sleep time for the previous week.

TIP #6: To maximize your Rest Assure score, wear your Rest Assure device every night and try not to miss any nights.

Breathing events

Breathing events per hour means the number of breathing events - called apneas and hypopneas - you experience each hour.

When you have an apnea event, your airway is completely blocked and air stops flowing to your lungs for 10 seconds or longer. A hypopnea is a partial blockage of the airway that lasts for 10 seconds or longer.

Your Rest Assure device monitors your apneas and hypopneas using the movements of your jaw that happen during these events.

Your Rest Assure breathing events score is calculated from a total of 40 points. Generally, the longer you sleep, and the smaller the number of breathing events, the better your Rest Assure breathing score will be. If you sleep 7 hours or more, and have less than 12 breathing events per hour, you will score 40 points. A sleep time of less than 4 hours and 16 or more breathing events per hour will result in a score of 0 for the breathing events score.

If you click on the Breathing events panel on the Sleep Health Data page, you will advance to this screen:

1. Your breathing events score is displayed here. You can click on the "ⓘ" to see how this score has been calculated.
2. Your breathing events are displayed in a graph for the entire night, showing the total number of breathing events for each hour of sleep in a bar graph. You will see the number of breathing events each hour while sleeping on your back. If you click on any of the bar charts, you will see the split of breathing events on your back and total events.

3. Your average breathing events per hour for your last sleep period and the number of breathing events per hour for the previous week are displayed.
4. Your average breathing events per hour while you were sleeping on your back for your last sleep period is displayed as well as an average number of breathing events per hour while you were sleeping on your back for the previous week.

TIP #7: If you can, try to minimize the time you sleep on your back, as sleeping on your back can increase breathing events.

Sleep position

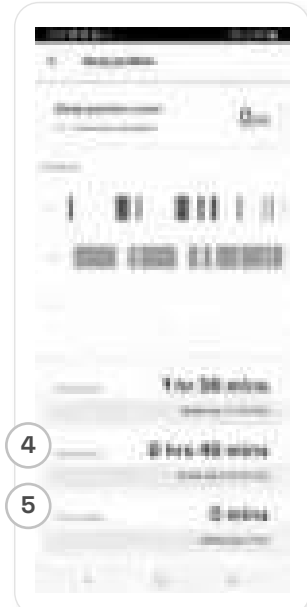
Rest Assure monitors your sleep position during the night. It records the time you spend sleeping on your back, on either side and on your front. Sleeping on your back may increase your breathing events.

Your Rest Assure Sleep position score is calculated from a total of 10 points. Generally, the longer you sleep on your side or front, the more points you will score. If you sleep on your back and have a low number of breathing events (<15 per hour), you can also earn 10 points.

If you click on the Sleep position panel on the Sleep Health Data page, you will advance to this screen:

1. Your sleep position score is displayed here. You can click on the "ⓘ" to see how this score has been calculated.
2. Your time in each sleep position is displayed in a graph showing the total sleep period. If you hover over any of the sleep periods, the app will show you the time periods that you were sleeping in that position.
3. Your average time sleeping on your back for this sleep period is displayed as well an average time spent sleeping on your back for the previous week.

4. Your average time sleeping on your side for this sleep period is displayed as well an average time spent sleeping on your side for the previous week.
5. Your average time sleeping on your front for this sleep period is displayed as well an average time spent sleeping on your front for the previous week.



Sleep interruptions

Rest Assure monitors your sleep interruptions during the night. A sleep interruption is counted when you sit up in bed, stand up, or if you take the Rest Assure device out of your mouth.

Your Rest Assure Sleep interruptions score is calculated from a total of 10 points. Generally, each interruption reduces your score by 2 points, and if you have 5 or more interruptions during the night, your Rest Assure sleep interruption score will be 0.

If you click on the Sleep interruptions panel on the Sleep Health Data page, you will advance to this screen:

1. Your sleep interruption score is displayed here. You can click on the "ⓘ" to see how this score has been calculated.
2. Your sleep interruptions and the time for each interruption are shown here. If you hover over any of the interruptions, the app will display the length of time that your sleep was interrupted. The Rest Assure App also shows the corresponding period when your sleep was not interrupted, i.e. you were sleeping or trying to sleep.

3. Your total sleep interruptions as well as a weekly average of the number of sleep interruptions are displayed.
4. Your total sleep interruption time and a weekly average of sleep interruption time is displayed.

TIP #8: Try to minimize the number of sleep interruptions per night, as these will reduce your Rest Assure sleep time score and your sleep interruption score.

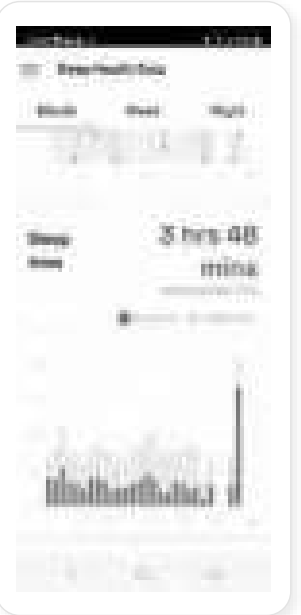
How can I see how my sleep is changing over time?

If you click on the **Week** or **Month** at the top of the Sleep Health Data page, the app will display your data for this period.

In the example shown here, the average weekly Rest Assure score is 54, with the individual night scores for the week graphed.

You can view data from other weeks by clicking on the arrows.

You can view your **Sleep Health Data** in monthly periods by clicking on the **Month** tab. Click on the arrows to view data from different months.



Your sleep physician and sleep dentist can also review this data and may discuss it with you on your next visit. Over time, your tongue and the muscles in your neck may relax and require your sleep dentist or physician to modify your treatment. Regularly wearing your Rest Assure device provides your specialists with the information that will help them treat your sleep apnea most effectively.

Additional functions in the Rest Assure App

From the Sleep Health Data screen in the app, you can access additional functions by clicking the 3 lines in the top left-hand corner of the screen:

This will take you to the information screen:

1. Your name and email address are displayed at the top of the screen.
2. Click here to find more details about your Rest Assure device.
3. Click here to find more details about your Rest Assure account.
4. The version of the Rest Assure App that you are using is displayed here.

If you click on **Device Info**, the type of Rest Assure device and the hardware and firmware versions are displayed:

1. Click **Instructions for use** tab to visit the web version of these instructions for use.
2. Click **Replace Device** tab if you want to change the Rest Assure device currently linked to your account.

On the Account page, your Rest Assure account information is displayed:

1. These details were added when you created your account.
2. The date shows the 1st time you used your Rest Assure to send data to the cloud.
3. Click here to visit the SomnoMed website to access support for Rest Assure.

4. Click here to delete your account. As required by Privacy laws, once your account is deleted, you, your sleep physician, and your sleep dentist will not be able to access your data. Your account cannot be re-instated once it has been deleted. *
5. Click here to log out of the app. You will need to log into the app again to continue downloading data from your Rest Assure and view your results.

   If you do log out of the Rest Assure App, any data that has not been synchronized with the cloud will be lost.

* Your data may still be held in database backups for 1 month after you delete your account. SomnoMed's data process will delete the data after 1 month and will delete the data if a backup is used to reinstate the Rest Assure database.

Frequently asked questions

This section answers common questions you might have regarding Rest Assure. Please also review the troubleshooting section for other technical questions.

What do I do if my Rest Assure does not fit my teeth properly?
Do not use it, return to your sleep dentist for adjustment or replacement.

Can I wear my Rest Assure and my Invisalign retainer?
No, advise your dentist/ orthodontist that you are wearing a device to treat your sleep apnea.

Do I take the device out when I go to the toilet at night?
There is no need to do this. Keep wearing the device and Rest Assure will keep measuring your sleep data when you go back to sleep.

I took my Rest Assure device out last night to take some medication and then forgot to wear it again. What should I do?
This happens sometimes. Your Rest Assure will measure your sleep for the period while you were wearing it. Put it in the docking station and wear it tonight.

If I forget to charge my device, should I not use it and instead leave it to charge?
Try to use your Rest Assure every night. If the battery is not charged, it will still help reduce your breathing events and improve your sleep.

Can I wear my device while watching TV or reading in bed?
Yes, the Rest Assure will include this in your usage time, but not your sleep time.

I dropped my device last night and this morning it is not working. What should I do?
Return your device to your sleep dentist. He/she will arrange for a replacement.

My smartphone only connects to my device when the app is open. Why?
Your smartphone may disable background tasks when on battery power. Either charge your smartphone when your Rest Assure device is in the docking station or turn off battery optimization for the Rest Assure App in your smartphone's settings (refer to your smartphone's manual for details).

My smartphone is not connecting to my device. What should I do?
Check that the Rest Assure App on your smartphone is running, location services are on and Bluetooth is on in the **settings** of your smartphone. Check that your Rest Assure device has a purple or orange light. If the light is blue or off, remove the device from the docking station and place it in again. Other common fixes:

» Force close the app and reopen the app.

» Move the smartphone closer to the device.

» If there are many electronic devices near the docking station, move your smartphone and docking station to a location with less electronic devices to minimize interference.

I am concerned about putting this device with a battery and sensors in my mouth.
SomnoMed has designed the Rest Assure to be safe. To protect the battery and sensors, they are enclosed inside the dental acrylic used to make your Rest Assure. Discuss your concerns with your sleep dentist.

Is my Rest Assure device transmitting while it is in my mouth?
No, Rest Assure is collecting the data while you are sleeping, with the data being stored in memory chip on the device. The wireless communication circuit is only active when you dock your Rest Assure in the docking station after you wake up.

Can my Rest Assure connect to the internet or radio?
No, it only connects to the Bluetooth service on your smartphone.

Where should I set up my docking station?
Somewhere that will remind you to wear the Rest Assure device every night. We recommend setting up on a bedside table so you can dock it easily when you wake up and it will be ready to use when you go to sleep. It is better not to set up your docking station in your bathroom as you might forget to wear your device when you go to sleep.

How often should I clean my Rest Assure device?
Clean your Rest Assure device every day with a soft toothbrush under lukewarm running water. See **Cleaning and maintaining your Rest Assure device** on page 106.

What should I do if I have tooth pain after using the Rest Assure?
Contact your sleep dentist.

What should I do if my Rest Assure device keeps coming off my teeth?
Contact your sleep dentist.

Who can see my sleep data?
Health Care Practitioners associated with your sleep dentist clinic and physician clinic or hospital can see your data, so they can help to improve your sleep. SomnoMed's customer service team can also see your data so they can help you if there are any issues with your device.

What do I do if I want a different sleep dentist or sleep physician to see my data?
Contact SomnoMed at contactrestassure@somnomed.com

Email TBC

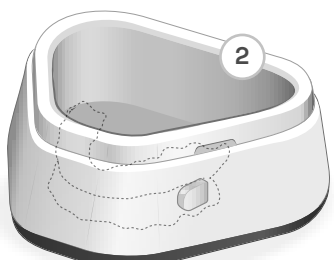
What do I do if I change my phone?
Log into the Rest Assure App on your new phone using your email and password, and all your recorded information will be available.

What do I do if I change my Rest Assure device for a new one?
Go to the account settings on the app. Click on **change device** and follow the steps to pair a new device.

How do I delete my Rest Assure account?
Go to the account settings on the app. Click on **delete account** and confirm that you want to delete the account. This cannot be undone.

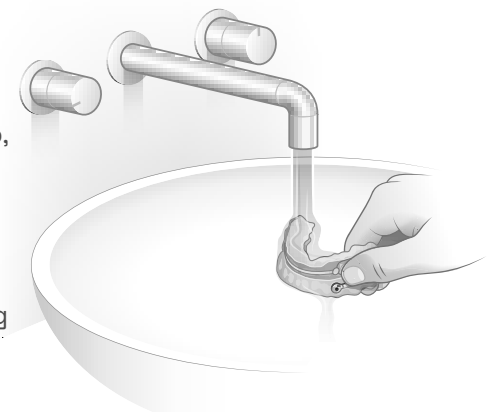
Cleaning and maintaining your Rest Assure device

Always clean your Rest Assure device in the morning immediately after you have removed it from your mouth by following these simple steps:



1. Remove the lid and place your Rest Assure device in the white removable cup that comes with your docking station (marked as number 2 in this picture) and replace the lid (marked as number 1).
2. Take the cup and lid to your bathroom and rinse in lukewarm water. The water temperature for cleaning should be no more than 113ºF (45ºC) to avoid damage to the Rest Assure device.

3. Clean device with a soft toothbrush and liquid soap.
4. Rinse your Rest Assure device thoroughly under lukewarm running water and dry it with a soft towel or tissue. Wipe any water from the cup, and place your Rest Assure device back in the cup and replace the lid.
5. Return the cup and lid to the docking station base beside your bed. Place the cup onto the docking station base and ensure the purple, green or blue light on the Rest Assure device is on.



6. Ensure the lid is securely placed on your docking station to reduce the risk of disturbing the device during the day. Open the vent of the lid to allow airflow. Always store your Rest Assure device in the docking station with the power on for maximum longevity of the battery.
7. SomnoMed recommends the use of a SomTab cleaning tablet twice per week. To clean your Rest Assure device with a SomTab cleaning tablet:
   a. Fill the cup of your Rest Assure Docking Station three quarters full of lukewarm water, or until your Rest Assure device is completely covered.
   b. Dissolve one SomTab into the water and leave for 15 minutes.
   c. After 15 minutes has elapsed, empty the water from the cup down the drain. Thoroughly rinse the Rest Assure device and the docking station cup under lukewarm running water, and then dry with a clean towel.
   d. Return the cup to the docking station base and ensure the purple, green or blue light is on the Rest Assure device, so the device will charge.

Cleaning your Rest Assure Docking Station

To clean your Rest Assure Docking Station, follow these steps:

» Detach the cup (2) and the lid (1) from the docking station base (3).

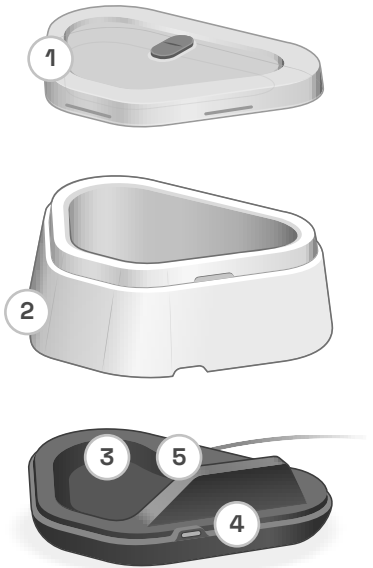
» Disconnect the docking station base from the power.

» Wipe the docking station base with a damp cloth only. Do not use any cleaning solutions on the base.

» Re-connect the docking station base after cleaning it. DO NOT SOAK the docking station base in water.

» Take care not to splash water near the charging light (4) or on the raised section of the docking station base (5). Exposure to water in these locations may cause damage to the docking station.

» The cup (2) and lid (1) of the docking station can be cleaned with soap and water. Do not put these or any components of the docking station in your dishwasher. Do not use any other chemical cleaners as these may damage the docking station.



Note: Your docking station is intended for use with your device only. Do not share docking stations with other Rest Assure device users.

Storing your Rest Assure device

Store the Rest Assure device in the docking station with the lid on. Do not store it in water or any other liquid and keep the temperature of your Rest Assure device between 41 to 113°F (5 to 45°C). Keep it away from direct sunlight and dusty environments. This will make sure it is ready for your next night's sleep.

If the Rest Assure device is not going to be used for any period of more than 2 weeks, charge the device at least weekly to maintain the lifetime of the battery.

Traveling with your Rest Assure device

Before traveling, thoroughly clean and dry your Rest Assure device and the cup of your docking station.

» Disconnect the docking station charging plug from the wall socket.

» Place your Rest Assure device inside inside the cup of the docking station.

» SomnoMed recommends you pack the Rest Assure device and Rest Assure Docking Station in the original packaging to ensure they are both protected during travel. If the original packaging is not available, ensure both the docking station and device are packed to prevent damage to either component.

» Keep the temperature of your Rest Assure device between 41 to 113°F (5 to 45°C) to retain the shape of your device and maximise the lifetime of the electronic components.

» At your destination, assemble your docking station as per the **Unpacking and setting up your Rest Assure device** procedure outlined on page 16 of these instructions.

Disposal of your Rest Assure device and docking station

The Rest Assure device and docking station should not be disposed of in regular household bins. Please take them to a center that deals with electronic waste in accordance with local regulations.

Limitation of liability

SomnoMed will not be liable for any lost revenue, profit, or data or special, indirect, consequential, incidental, or punitive damages, however caused regardless of the theory of liability, arising out of, or related to the use or inability to use the device, even if SomnoMed has been advised of such damage. In no event will SomnoMed's liability, whether in contract, torts (including negligence) or otherwise, exceed the amount paid for the device/service.

Technical specifications

The Rest Assure device monitors your sleep by collecting acceleration, magnetic field and temperature data from its sensors and transmits these via the Bluetooth Low Energy (BLE) function on your smartphone.

The Rest Assure device and docking station are designed for use in a residential property. It can also be used in hospitals except in environments with high intensity electromagnetic disturbances, such as an MRI room or near active high-frequency (HF) surgical equipment.

The Rest Assure device, docking station and charging plug are together a medical electrical system. You as the patient are the operator of this equipment. Other members of your household may be nearby while the device is in use.

The Rest Assure device has a type BF rating against electric shock, as per IEC60601-1. The docking station is an accessible part according to IEC60601-1.

	Rest Assure device	Rest Assure Docking Station
Dimensions	Specific to your jaw size and shape	143 x 117 x 66mm + cable
Weight	Generally around 15 to 40g	230g
Electrical Specification	Input: None Output: None (There is no wired connection to the oral device).	Docking station: Input: 5VDC 500mA Output: N/A Charging Plug: Input: 100-240Vac 50/60Hz 300mA Output: 5VDC 500mA
Connectivity	Wireless communication, 4.2 GHz	N/A
Compatibility	IOS 14+ and Android 10+ Use only CE marked smartphones	N/A

	Rest Assure device	Rest Assure Docking Station
Transport conditions	Temperature Range: -20 to 60°C Relative Humidity: 35-80%	Temperature range: -20 to 70°C Relative Humidity: 35-80%
Storage conditions	Temperature Range: 5 to 45°C [41 to 113°F] Relative humidity: 35-80%	Temperature range: -20 to 70°C [-4 to 158°F] Relative humidity: 35-80%
Operation conditions	Temperature Range: 5 -37°C [41 to 99°F] Relative Humidity: Any Atmospheric pressure: 700 - 1060 hPa [0.70 - 1.05 atm]	Temperature Range: 5-30°C [41 to 86°F] Relative Humidity: 35-80% Atmospheric pressure: 700 - 1060 hPa [0.70 - 1.05 atm]
Emissions class and group	Group 1, Class B	Group 2, Class B
Emission standard(s)	CISPR 11 (2015, AM2:2019); EN 55032 (2015)	CISPR 11 (2015, AM2:2019); EN 55032 (2015)
Ingress Protection (IP)	47	42

	Rest Assure device	Rest Assure Docking Station
Electrostatic discharge (IEC6100-4-2)	+/- 8kV (contact discharge), +/-2kV, +/-4kV, +/-f8kV, +/-15kV (air discharge)	+/- 8kV (contact discharge), +/-2kV, +/-4kV, +/-f8kV, +/-15kV (air discharge)
Radiated RF EM fields (IEC6100-4-3)	(10V/m) 80MHz to 2.7GHz for Home Healthcare Environment	(10V/m) 80MHz to 2.7GHz for Home Healthcare Environment
Rated power magnetic field (IEC6100-4-8)	30 A/m, 50Hz	30 A/m, 50Hz
BLE modulation	GFSK	N/A
BLE bandwidth	1MHz	N/A

	Rest Assure device	Rest Assure Docking Station
Frequency band(s) of operation:	Receiver: BLE 2.40GHz to 2.48GHz; WPT: 230kHz; Transmitter: BLE 2.40GHz to 2.48GHz	Receiver: None; Transmitter: WPT: 230kHz
Use only CE marked smartphones	Applicable	Not Applicable

FCC Compliance Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

» Reorient or relocate the receiving antenna.

» Increase the separation between the equipment and receiver.

» Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.

» Consult the dealer or an experienced radio/TV technician for help.

FCC ID: 2BBTC-1154412

Model: 1154412

Any changes or modifications to the Rest Assure device or docking station that have not been expressively approved by SomnoMed could void the user's authority to operate this equipment.

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation.

1. Benjafield et.al, Estimation of the global prevalence and burden of obstructive sleep apnoea: a literature-based analysis, Lancet Respir Med, 2019.

Note to treating sleep dentist: This instruction manual provides valuable information for your patient on how to use and care for their Rest Assure Elite. Please ensure this manual is provided to the patient with their device and docking station.

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