

# Instructions for Use

Flex®, Classic, Air & Air+ Devices



Classic®



AIR/AIR+



Flex®



Rx Only

[www.somnomed.com](http://www.somnomed.com)

## Introduction

The SomnoDent® is a medical device worn orally during sleep. The SomnoDent® device is comprised of an upper and lower dental splint that brings the lower jaw forward and improves the wearers' ability to breathe during sleep.

SomnoDent® devices may come with a Denti-Trac® micro-recorder embedded in the lower splint to record compliance with oral device therapy. The clinician may have decided to incorporate a Denti-Trac® micro-recorder into the SomnoDent® device to record compliance with oral device therapy in combination with the Denti-Trac® system. During scheduled visits, the data within the Denti-Trac® uploads to a web application for cloud-based reporting using a Denti-Trac® Base Station at the clinician's office. The Denti-Trac® micro-recorder monitors the wear time through oral temperature, as well as tracks movements and head position. The inclusion of the embedded Denti-Trac® micro-recorder provides additional information when used in combination with the Denti-Trac® System, but does not impact the operating principles or safety of the SomnoDent®.

*The SomnoDent® with Denti-Trac® Micro-Recorder will only capture and store patient compliance data. In order to view and use the data, a Denti-Trac® Base Station is required to extract the data and upload this information onto a cloud-based system.*

The Denti-Trac® Micro-Recorder captures and stores clinical usage data. To view and analyze this data, additional components of the Denti-Trac® system are required. A Denti-Trac® Base Station is used to extract the compliance data from the Denti-Trac® Micro-Recorder; this data is uploaded to a secure cloud-based system. Additionally, the clinician can view and create patient compliance reports from the cloud-based system via an internet account. The Denti-Trac® Base Station must be purchased separately.

## Caution

Take care to follow care instructions for the oral device (pg.4). Ensure the device is not exposed to extreme temperatures in excess of **45°C / 113°F** as this may damage the micro-recorder.

## Indications for Use

SomnoDent® devices are intended for the treatment of nighttime snoring and mild to moderate Obstructive Sleep Apnea in patients 18 years of age or older.

Optionally, if the Denti-Trac® micro-recorder is completely embedded into the SomnoDent® device, the micro-recorder is intended to measure patient compliance to oral device/appliance therapy in combination with the Denti-Trac® System.

## Contraindications

These devices are contraindicated for patients who:

- Have central sleep apnea.
- Have severe respiratory disorders.
- Have loose teeth.
- Have advanced periodontal disease.
- Are under 18 years of age.

## Precautions

Dentists should consider the medical history of the patient, including history of asthma, breathing, or respiratory disorders, or other relevant health problems and refer the patient to the appropriate healthcare provider before prescribing these devices.

## Regular inspection of your SomnoDent® devices with or without the Denti-Trac® micro-recorder

Regularly inspect the device for signs of damage, such as fractures and cracks. If the device is damaged or broken, the device must NOT be used any longer in order to avoid injuries, such as choking or laceration. If the device is damaged, immediately take it to a SomnoMed dental sleep provider who will arrange for it to be repaired by a SomnoMed laboratory.

*Repairs, including those under warranty, should be taken to a SomnoMed dental sleep provider, not sent directly to SomnoMed.*

## 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 tissues in the mouth and/or a slight change in your bite. These possible side effects should diminish within an hour of removing the device. If any of these side effects continue, contact your sleep dentist and maintain regular sleep dental check-ups.

## Cleaning & Storage

Always clean your device in the morning immediately after having removed it from your mouth.

After each use, rinse in cold or lukewarm water and clean with the brush provided or a soft toothbrush and mild detergent. Then rinse well. Avoid hot or boiling water as it will damage the device and/or micro-recorder. Water temperature for cleaning should be  $<45^{\circ}\text{C}/113^{\circ}\text{F}$  to avoid damage. Do not use mouthwash to clean device. Doing so will cause the material in the SomnoDent® to deteriorate. Do not use ultrasonic cleaning. Avoid organic solvents like ethanol, acetone etc. for cleaning.

Calibration tool and cleaning brush are located in the handy maintenance kit underneath the storage case.

Please store your SomnoDent® in clean water when not in use. Please store your Air + in dry storage when not in use.

### Caution:

Do not use toothpaste, as it contains abrasives, and may damage the device. **Never use hot or boiling water!** Hot or boiling water damages your SomnoDent® and/or micro-recorder. This will invalidate the warranty.

### Important

Keep your device away from sunlight.

Patients may initially experience a mild plastic taste. This will disappear with storage and use.

Some patients with amalgam fillings or users of Pyralvex (a solution for mouth ulcers and denture irritation) may over time notice discoloration in the lining of their SomnoDent®. Discoloration of the material will not adversely affect the performance or longevity of the device.

**Please note:** To reduce the possibility of discoloration do not drink coffee, tea or cola with the device in place. Always brush teeth thoroughly before use.

Visit [www.somnomed.com](http://www.somnomed.com) to learn more about cleaning your device.

## Inserting SomnoDent® devices

### Inserting the upper splint

Place the upper splint in your mouth as indicated in Fig. 1. Press up on both sides of the splint using your thumbs to ensure it fits securely and comfortably.

### Inserting the lower splint

Place the lower splint in your mouth. Press down on both sides of the splint using your index fingers to ensure it fits securely and comfortably.

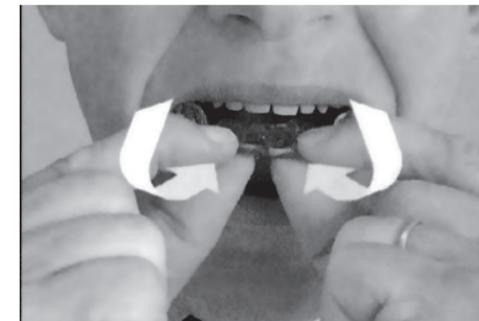


Fig. 1: Inserting the upper splint.

### Engaging the wings

Once the upper and lower splints are securely in position, bring your lower jaw slightly forward to allow the "wings" to engage. Slowly close your mouth until your lips lightly touch each other.

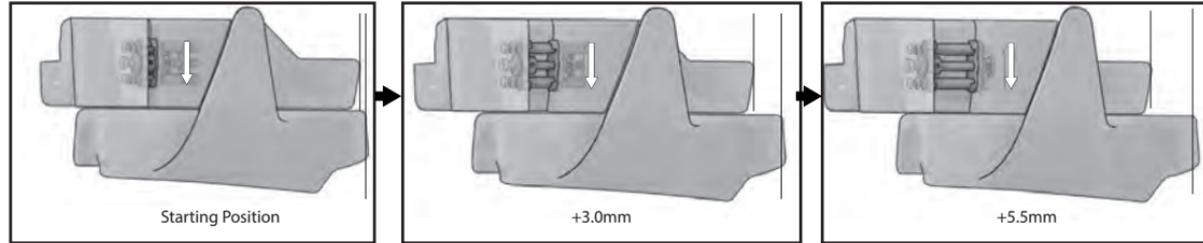
### Removal

Always remove the lower splint first. Using your thumbs on both sides, gently pull the lower splint in an upwards motion to remove as indicated in Fig. 2. Using both your index fingers and thumbs, gently pull the upper splint down and forwards to remove.



Fig. 2: Removing the lower splint

## ADJUST YOUR FLEX, CLASSIC, AIR DEVICE



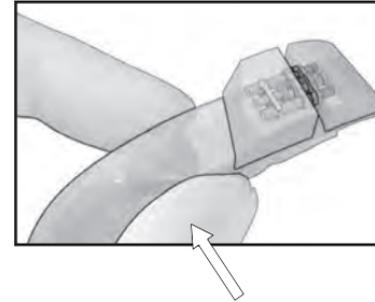
Reverse ←		→ Forward										
90° Turns	-5	1	5	10	20	25	30	35	40	45	50	55
Adjustment (mm)	-0.5	0.1	0.5	1.0	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.5

Your SomnoDent® Flex & Classic can be adjusted within a 6.0mm range, giving you control of your treatment and best possible fit.

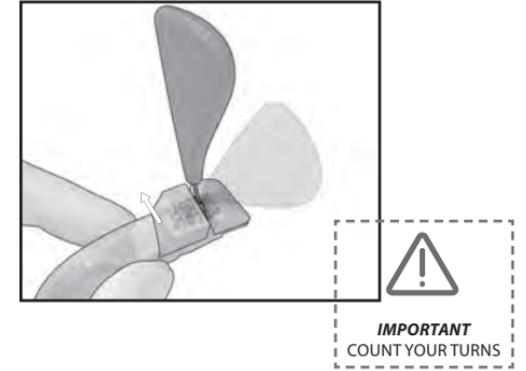
Simply fit the calibration tool into the Keyhole and rotate 90° for a precise 0.1mm adjustment.

## FORWARD ADJUSTMENT

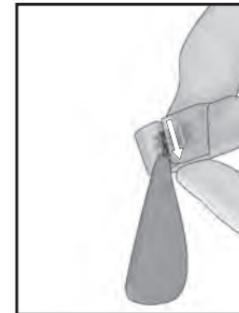
1 Hold Upper Tray with calibration screw facing toward you.



2 Fit your calibration tool into the adjustment keyhole and rotate 90° in the direction of the arrow.



## BACKWARD ADJUSTMENT



3 Rotate your calibration tool in the opposite direction of the arrow.

SomnoDent® Classic and Flex have an expected life of 3 years; Air/Air+ have an expected life of 1 year. For information on the SomnoMed warranty policy please reference the information on our site, [www.somnomed.com](http://www.somnomed.com).

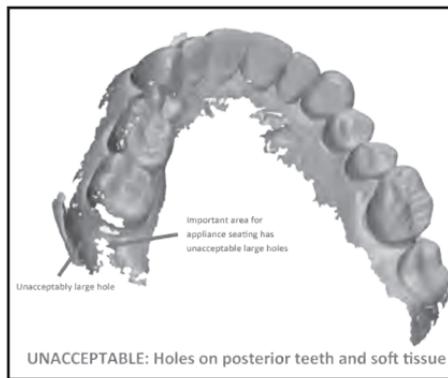
**SomnoDent® Case Requirements:** Should your case not meet the requirements for manufacturing; your case will be placed on hold and we will notify your office of what is needed and discuss what is required. This may result in a delay of your cases.

### I. Lab Form / Rx

- Fully completed SomnoDent® Lab Form with patient identifier, device type, device retention, and dentist signature. ([www.somnomed.com/orderform](http://www.somnomed.com/orderform))
- If no device is selected SomnoMed will place the case on hold and notify the office for device selection.
- If no retention is selected, SomnoMed will proceed with the case with SMH B-Flex as the retention type.

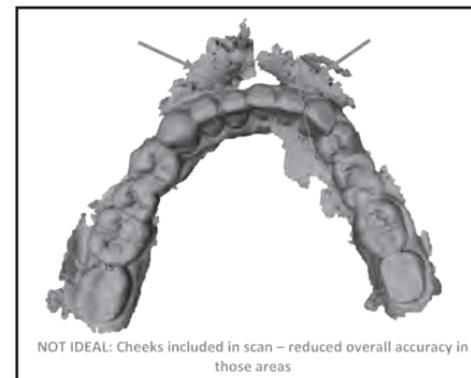
### II. Scan Quality – Intraoral Scanning

- No large holes (>0.5mm diameter) within scanned file mesh (Note: Some small holes (<0.5mm diameter) are normal and acceptable, but is at the labs discretion)
- Limit unnecessary details (e.g. lips, tongue, cheeks) (Note: Scans that include unnecessary details may have reduced accuracy in these areas)
- Should the dentist choose to proceed with scans containing holes > 0.5mm, SomnoMed will not warrant any fit / retention related events for that device



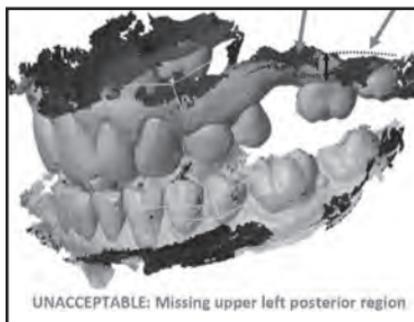
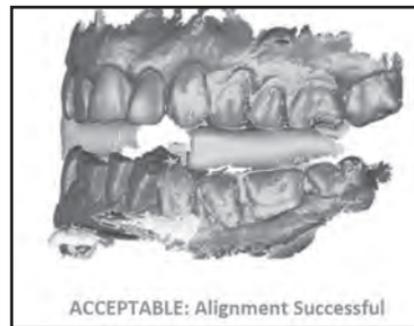
### III. Impression Coverage, Extension, and Distortion

- Coverage of all teeth including some portion of last teeth (Terminal molars)
- Soft tissue to 5.0mm beyond gingival margin at all lingual and buccal of molars
- Teeth and soft tissue to 2.0mm beyond gingival margin at facial surfaces of anterior and premolars
- No large voids, pulls, or drags (>1.0 mm diameter) (Note: Impressions / Models that include unnecessary details or do not include necessary details the record may have reduced accuracy in these areas)
- If doctor chooses to proceed with cases with large distortions / pulls or not enough gingival is captured, SomnoMed will not warrant any fit / retention related events for that device.



#### IV. Bite & Occlusion

- If midline shift is greater than 2.0mm and is unnoted on the order form, SomnoMed will hold the case and contact the office to verify the deviation.
- Minimum Occlusal Vertical Dimension (OVD) of 3.0mm clearance between the two closest teeth in opposing arches is required for production
- If dentist chooses to proceed with a bite that does not meet our required 3.0mm vertical clearance. SomnoMed will only offer a full warranty on device breakage and will not provide a warranty on device fit. Dental customer will pay full charge for a reset or replacement due to bite-related problems.



#### V. Optional Feature Requirements

The SomnoDent® device will be fabricated to cover to the mesial ½ of last available molar as standard protocol

- Distal Wrap - Soft tissue to 5mm beyond gingival margin for buccal of molars
  1. Minimum of 3.0mm clearance between two closest teeth in opposing arches (including distal of last present teeth)
- Metal Reinforcement of Occlusion - Minimum of 5.0mm clearance between two closest teeth in opposing arches is required.
- Breathing Hole - Minimum of 5mm clearance between two closest opening anterior teeth is required
- Denti-Trac® Compliance Recorder - Extension of 7mm in lower posterior regions on left side is required
- Edentulous - Coverage of entirety of Mx palate & Bite rims are needed
  1. Should any of the requirements not be met your case will be placed on hold and office notified.

#### Shelf Product and SomTabs Returns Timeframe:

- Shelf Products Return: SomGauge handles and forks, Product Demos and ALPHA devices, must be returned unused and unopened within 30 days in order to receive a full refund.
- SomTabs Returns: SomTabs returns are handled through amazon.com and their return policy, which may be accessed in their Help and Customer Service section of their website.

#### Denti-Trac® Compliance Recorder

The Denti-Trac® Compliance Recorder is covered by the Braebon Medical Corporation's 6-month warranty for the micro-recorder and 1-year warranty for the clinical base station under normal use conditions. The battery is expected to function for two years, based on a weekly upload. The battery is not rechargeable; if communications fail between the micro-recorder and the clinical base station, the Denti-Trac® must be removed from the oral appliance and replaced with a new one.

1. All SomnoDent® products have a 3 year warranty, with the exception of AIR and AIR+ which have a 1 year standard warranty, with additional warranty available for purchase.
2. In order to ensure a positive end-user experience, please remember that SomnoMed is responsible for the manufacturing of the device, and the clinician is responsible for the clinical suitability of the device.



### **Sleep and Comfort Diary**

Log your Sleep and SomnoDent® Comfort Rating in the diary provided on the following pages for the first 10 nights and discuss any issues with your sleep dentist. SomnoDent® works best when fitted correctly and should be snug yet comfortable in your mouth.

Continuous Open Airway Therapy is clinically validated as an effective treatment for mild to moderate obstructive sleep apnea, so make sure you start your treatment tonight, so you can experience restful nights and refreshing days!

### **Comfort Ratings**

**5 Excellent Comfort** – able to sleep entire night without a problem.

**4 Good Comfort** – able to sleep most of the night without discomfort.

**3 Fair Comfort** – able to wear it and sleep a little, but prefer to take device out.

**2 Poor Comfort** – wore my device but unable to sleep with it.

**1 Need Assistance** – unable to wear my device, even while awake.

<i>Night</i>	<i>Date</i>	<i>Sleep and Wearing Notes</i>	<i>Hours Worn</i>	<i>Comfort Level</i>	<i>Night</i>	<i>Date</i>	<i>Sleep and Wearing Notes</i>	<i>Hours Worn</i>	<i>Comfort Level</i>
<i>1</i>				<i>5 4 3 2 1</i>	<i>11</i>				<i>5 4 3 2 1</i>
<i>2</i>				<i>5 4 3 2 1</i>	<i>12</i>				<i>5 4 3 2 1</i>
<i>3</i>				<i>5 4 3 2 1</i>	<i>13</i>				<i>5 4 3 2 1</i>
<i>4</i>				<i>5 4 3 2 1</i>	<i>14</i>				<i>5 4 3 2 1</i>
<i>5</i>				<i>5 4 3 2 1</i>	<i>15</i>				<i>5 4 3 2 1</i>
<i>6</i>				<i>5 4 3 2 1</i>	<i>16</i>				<i>5 4 3 2 1</i>
<i>7</i>				<i>5 4 3 2 1</i>	<i>17</i>				<i>5 4 3 2 1</i>
<i>8</i>				<i>5 4 3 2 1</i>	<i>18</i>				<i>5 4 3 2 1</i>
<i>9</i>				<i>5 4 3 2 1</i>	<i>19</i>				<i>5 4 3 2 1</i>
<i>10</i>				<i>5 4 3 2 1</i>	<i>20</i>				<i>5 4 3 2 1</i>

## ***DEVICE REGISTRATION***

Please visit [somnomed.com](http://somnomed.com), click on the patients tab and choose Register Your Device to register your SomnoDent® device and share your SomnoDent® experience.

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