

# INSTRUCTIONS FOR USE



*SomnoDent*<sup>®</sup> HERBST ADVANCE<sup>®</sup> ELITE

*SomnoDent*<sup>®</sup> HERBST ADVANCE<sup>®</sup>

RxOnly    Medical Device



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\_\_\_\_\_

Name

\_\_\_\_\_

Physician

\_\_\_\_\_

Dentist

\_\_\_\_\_

Model

\_\_\_\_\_

Serial No.

\_\_\_\_\_

Date of Purchase

**My SomnoDent**  
SLEEP APNEA DEVICE

## Dear SomnoDent User

Thank you for selecting SomnoDent therapy.

Your SomnoDent Herbst Advance and SomnoDent Herbst Advance Elite is manufactured to the highest medical device standards. SomnoMed is recognized as the leading manufacturer of medical oral appliances for the treatment of sleep disordered breathing.

These instructions will provide you with useful information on the correct use and care of your SomnoDent device.

Please be sure to read this information carefully and should you have any questions, contact your qualified SomnoMed Sleep Professional.

**SomnoMed®**

**Restful Nights. Refreshing Days!**

## 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 improving the wearers' ability to breathe during sleep.

The SomnoDent line of devices are customized to each patient and offer superior comfort and quality. They are uniquely compliant and highly effective.

## What is obstructive sleep apnea?



### Normal

During normal sleep the muscles that control the tongue and soft palate hold the airway open.



### Snoring

When these muscles relax, the tissues of the upper airway vibrate as air passes over them, creating a snoring noise.



### Sleep apnea

If the muscles are too weak to hold the tongue and pharyngeal muscle in position, the airway may become obstructed and short respiratory arrests may occur.

### **Caution:**

Take care to follow instructions for the oral device (pg. 8). Ensure the device is not exposed to extreme temperatures in excess of 45°C / 113°F as this may damage the micro-recorder.

### **Inserting the upper plate**

Hold the upper and lower plates together and gently mount the upper plate to your teeth. Press up on the plate with both thumbs to ensure that it fits securely and comfortably.

### **Inserting the lower plate**

Once the upper plate is securely in place, insert the lower plate onto your teeth. Press down on both sides of the plate using your index fingers to ensure it fits comfortably.

### **Removal**

Always remove the lower plate first. Using your thumbs on both sides, gently pull the lower plate in an upward motion to remove. Using both your index fingers and thumbs, gently pull the upper plate down and forward to remove.

### **Cleaning**

Your calibration tool and cleaning brush are located in the handy maintenance kit underneath the storage container.

**Always** clean your device in the morning immediately after having removed it from your mouth. Use the brush provided or a soft tooth brush but do not use toothpaste as it contains abrasives.

In addition to cleaning your device every morning

we recommend that you use SomTabs to thoroughly clean your device once a week or as required.

SomTabs will thoroughly clean and disinfect the hard to reach areas of your device.

### **SomTabs Instructions**

SomTabs are recommended by SomnoMed for the gentle and thorough cleaning of SomnoMed devices. SomTabs thoroughly clean the hard-to-reach areas of your device.

**1.** Dissolve a SomTabs tablet in sufficient amounts of warm water in the storage case. (approx. 35°C/ 95 °F).

Never use hot water as hot water damages your device and will void the warranty.

**2.** Carefully place your SomnoDent device in the storage case. All parts must be completely immersed in the cleaning solution.

**3.** After about 15 minutes, remove the device and small parts from the storage case. Make sure not to lose any small parts! Empty the solution from the storage case.

**4.** After having removed the device from the the storage case, thoroughly brush it with a soft tooth brush and rinse it under cool running water.

**5.** Clean the metal components of the SomnoDent Flex, Edent, Classic or Herbst devices with a cleaning brush or tooth brush.

**6.** Dry all parts of the device and storage case carefully and thoroughly using a clean towel.

**7.** When not in use, the device should be stored as per your SomnoMed device instructions for use. (See pages 14 & 19.)

### ***Important***

Keep your device away from sunlight.

### ***Caution:***

Do not use toothpaste, as it contains abrasives, and may damage the device.

Do not put SomTabs tablets into the mouth.

Do not swallow the cleaning solution and do not use it as a mouthrinse.

### ***Contents***

Sodium Bicarbonate, Potassium Caroate, Citric Acid, Sodium Citrate, Sorbitol, Sodium Lauryl Sulfate, Sodium Percarbonate, CI73015.

### ***Ordering SomTabs refills***

Make sure you never run out of SomTabs to clean your device. Order your SomTabs refills in advance.

Place your order online at [www.somnomed.com/order](http://www.somnomed.com/order)

### ***Advice on cleaning***

Some patients with amalgam fillings or users of Pyralvex (a solution for mouth ulcers and denture irritation) may over time notice discolouration in the Flex lining of their SomnoDent.

Discolouration of the material will not adversely affect the performance or longevity of the device. Please note: To reduce the possibility of discolouration do not drink coffee, tea or cola with the device in place. Always brush teeth thoroughly before use.

Denture cleaning tablets dissolve to form active oxygen, an oxidizing agent, which may damage the metal components of your SomnoDent. Ensure that you use a “partial denture cleaner” and rinse in cold water after soaking for a maximum period of 15 minutes.

If you are using a partial denture cleaner, soak your Somnodent for 5 minutes only and then thoroughly rinse.

### **Never use hot or boiling water!**

Hot or boiling water damages your SomnoDent and this will invalidate the warranty.

### ***Storage instructions***

Always store your SomnoDent Herbst Advance and SomnoDent Herbst Advance Elite in the storage container with water when not in use. A storage container is included for your convenience. When traveling, protect your device by placing it inside the SomnoDent storage container.

### ***Regular inspection of your SomnoDent Device***

Regularly inspect the device for signs of damage and cracks. If the device is damaged, immediately take it to your SomnoMed dental sleep provider who will arrange for it to be repaired by SomnoMed.

Take your SomnoDent with you to your regular dental checkups.

### ***Repair of damaged devices***

Damaged or broken devices must not be used in order to avoid injury. Immediately contact your SomnoMed dental sleep provider, who will arrange for the device to be repaired by an expert.

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

### ***Warranty***

SomnoMed warrants all SomnoDents supplied to be free from defects in materials and workmanship for a period of 36 months from the date of invoice to the Providing Dentist. [SomnoMed gives no warranty that the SomnoDent will be efficacious in the treatment of snoring or Obstructive Sleep Apnea.]

a. The SomnoDent warranty is invalidated if the patient has subsequent substantial restorative work.

b. Additionally, the SomnoDent warranty is covered only for in-mouth breakage.

c. The warranty covers only repair of the device. If new casts or impressions are required, the warranty is void. In such cases SomnoMed offers to remake the device at a reduced cost.

d. Warranty repair work may only be completed by the authorized SomnoMed facility at which the SomnoDent was originally manufactured.

e. Repairs not covered under warranty include, but are not limited to: reset bites, acrylic fracture; clasp repair; wing repair; and other damage not caused by manufacturing defects. For example, repairs caused by defective or distorted models, defective or distorted bite records, calculus deposits and device modifications made by non SomnoMed authorized technicians.

## **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.

## **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.

## **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.

## **Warnings**

Use of these devices may cause:

- Tooth movement or changes in dental occlusion.
- Gingival or dental soreness.
- Pain or soreness to the temporomandibular joint.
- Obstruction of oral breathing.
- Excessive salivation.

## **SomnoDent Herbst Advance with Denti-Trac®**

***(The SomnoDent Herbst Advance Elite does not contain a Denti-Trac).***

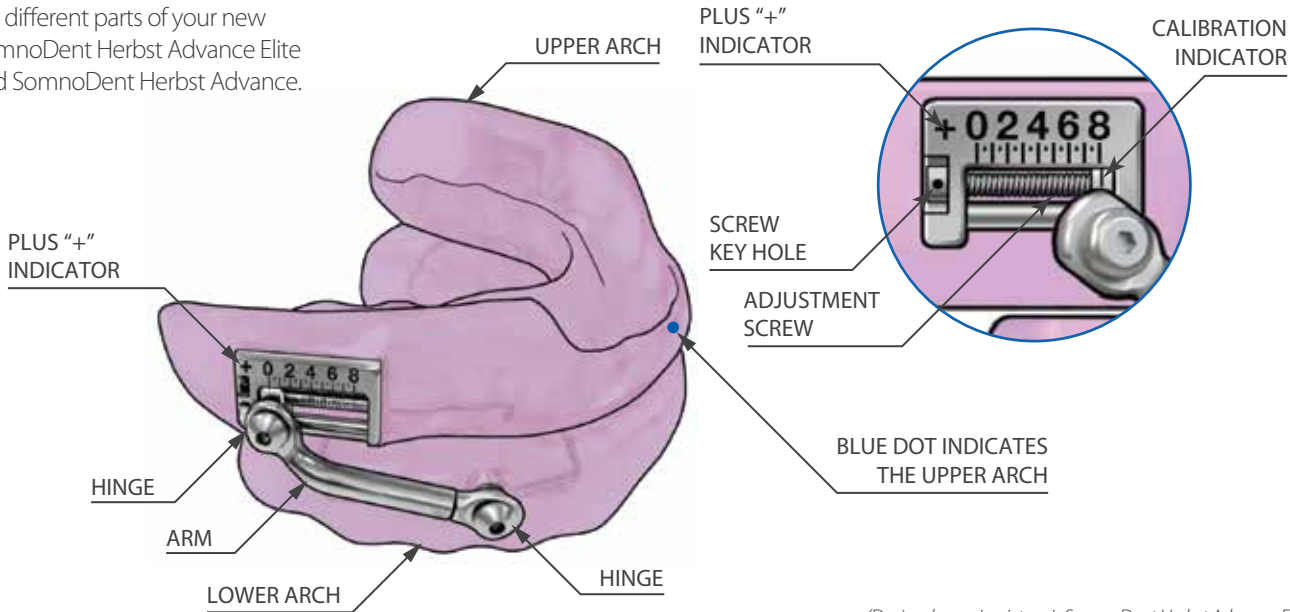
SomnoDent® Herbst Advance devices may come with a Denti-Trac® micro-recorder embedded in the lower splint to record compliance with oral device therapy.

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 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 Base Station must be purchased separately.

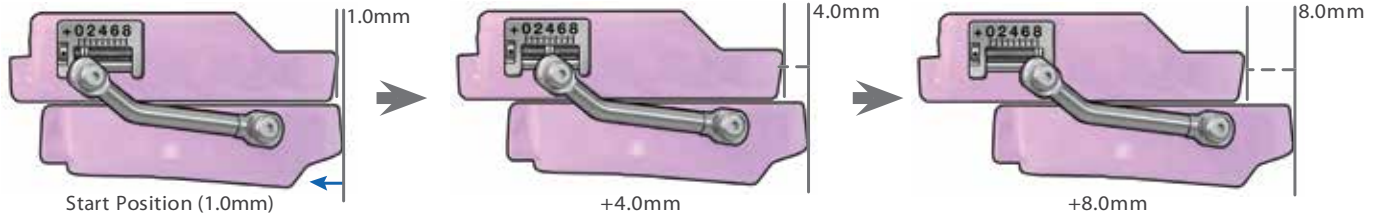


This Guide will help you identify the different parts of your new SomnoDent Herbst Advance Elite and SomnoDent Herbst Advance.



*(Device shown in picture is SomnoDent Herbst Advance Elite.)*

# CALIBRATION



|                 | REVERSE ← 1.0 |      | → FORWARD |     |     |     |     |     |     |     |     |     |     |     |     |     |
|-----------------|---------------|------|-----------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| 90° TURNS       | -10           | -5   | +5        | +10 | +15 | +20 | +25 | +30 | +35 | +40 | +45 | +50 | +55 | +60 | +65 | +70 |
| Adjustment (mm) | -10.0         | -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 |

Your SomnoDent can be adjusted within an 8.0mm range, in 0.1mm steps, giving you total control of your treatment and the best possible fit.

Use the calibration tool (shown on the following page) to visually calibrate your device, using the measurements indicated on the side.

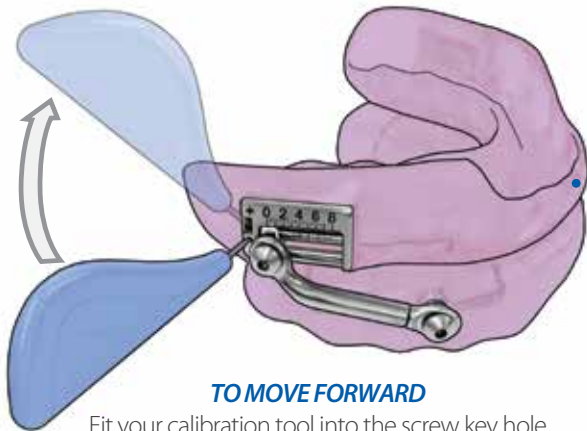
**Always make sure you repeat the same calibration on both sides of the device.**

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## ADJUSTMENT — RIGHT SIDE

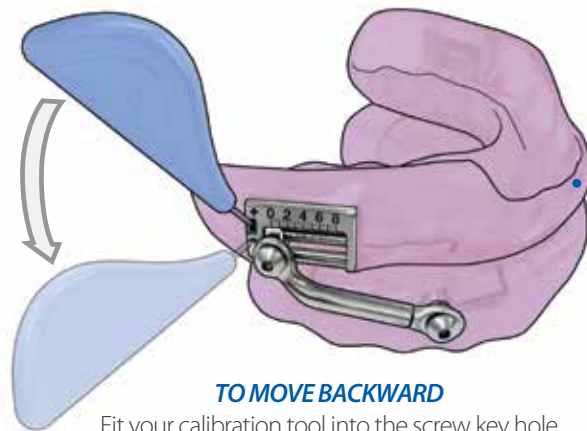
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Always repeat the same calibration on both sides of your device.



### **TO MOVE FORWARD**

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



### **TO MOVE BACKWARD**

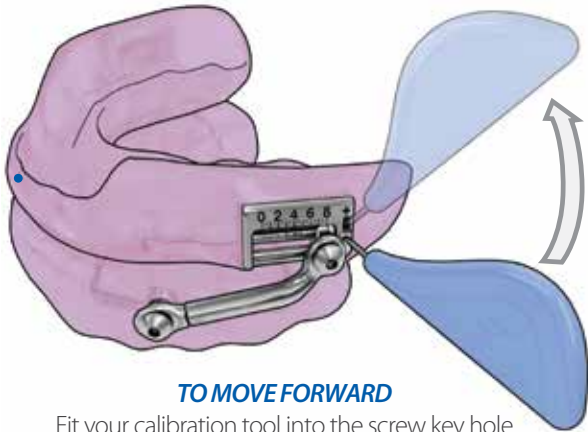
Fit your calibration tool into the screw key hole and rotate downward, away from the plus indicator.

---

## ADJUSTMENT — LEFT SIDE

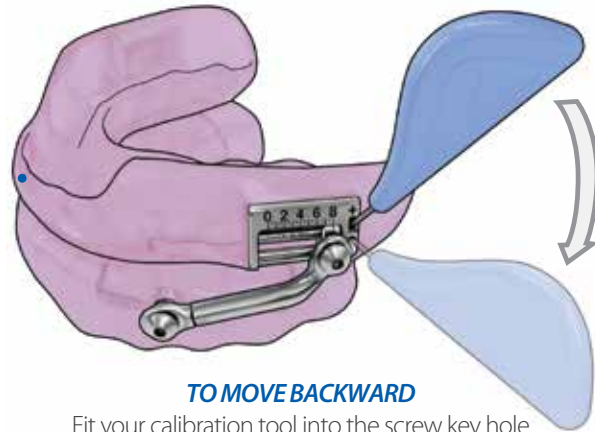
---

Always repeat the same calibration on both sides of your device.



### **TO MOVE FORWARD**

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



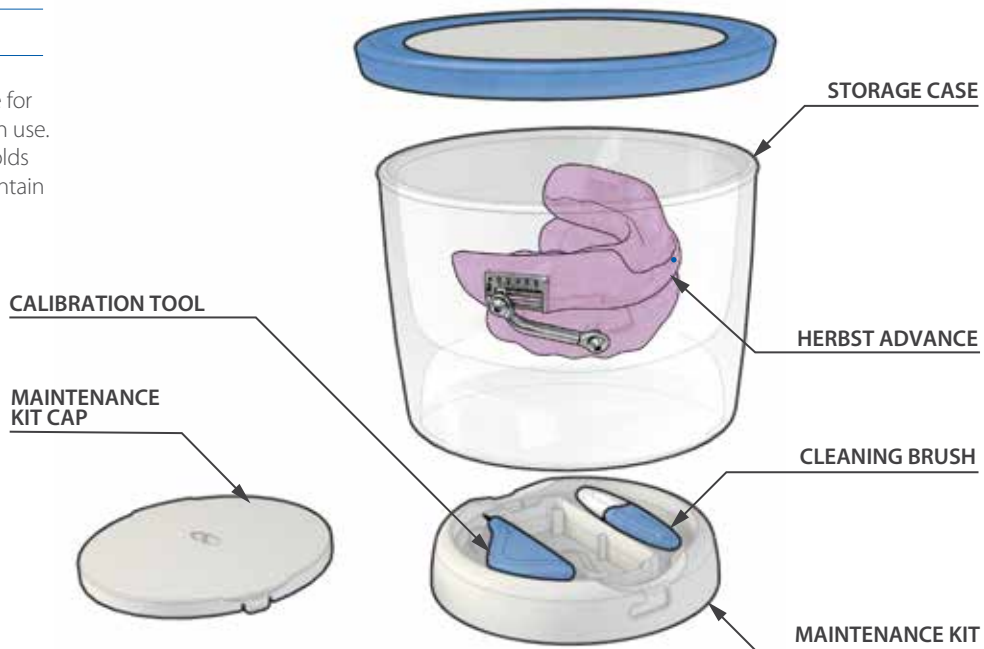
### **TO MOVE BACKWARD**

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

## ACCESSORIES

Place the device in the storage case for storage during the day or when not in use.

The maintenance kit in the base holds everything you need to use and maintain your SomnoDent.



## Keep a log of your SomnoDent Calibration settings.\*

| Date | Number of Millimeters |
|------|-----------------------|
|      |                       |
|      |                       |
|      |                       |
|      |                       |
|      |                       |

| Date | Number of Millimeters |
|------|-----------------------|
|      |                       |
|      |                       |
|      |                       |
|      |                       |
|      |                       |

\*Make sure you keep a Sleep Diary for the first 60 nights (located at the back of this User Guide).

## ***Sleep and Comfort Diary***

Log your Sleep and SomnoDent Comfort Rating in the diary provided on the following pages for the first 30 nights and discuss any issues with your sleep dentist.

SomnoDent works best when fitted correctly and should be snug yet comfortable in your mouth.

SomnoDent 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.

| Night | Date | Sleep and Wearing Notes | Hours Worn | Comfort Level | Doctor Setting Instructions |
|-------|------|-------------------------|------------|---------------|-----------------------------|
| 1     |      |                         |            | 5 4 3 2 1     |                             |
| 2     |      |                         |            | 5 4 3 2 1     |                             |
| 3     |      |                         |            | 5 4 3 2 1     |                             |
| 4     |      |                         |            | 5 4 3 2 1     |                             |
| 5     |      |                         |            | 5 4 3 2 1     |                             |
| 6     |      |                         |            | 5 4 3 2 1     |                             |
| 7     |      |                         |            | 5 4 3 2 1     |                             |
| 8     |      |                         |            | 5 4 3 2 1     |                             |
| 9     |      |                         |            | 5 4 3 2 1     |                             |
| 10    |      |                         |            | 5 4 3 2 1     |                             |
| 11    |      |                         |            | 5 4 3 2 1     |                             |
| 12    |      |                         |            | 5 4 3 2 1     |                             |
| 13    |      |                         |            | 5 4 3 2 1     |                             |
| 14    |      |                         |            | 5 4 3 2 1     |                             |
| 15    |      |                         |            | 5 4 3 2 1     |                             |



| Night | Date | Sleep and Wearing Notes | Hours Worn | Comfort Level | Doctor Setting Instructions |
|-------|------|-------------------------|------------|---------------|-----------------------------|
| 16    |      |                         |            | 5 4 3 2 1     |                             |
| 17    |      |                         |            | 5 4 3 2 1     |                             |
| 18    |      |                         |            | 5 4 3 2 1     |                             |
| 19    |      |                         |            | 5 4 3 2 1     |                             |
| 20    |      |                         |            | 5 4 3 2 1     |                             |
| 21    |      |                         |            | 5 4 3 2 1     |                             |
| 22    |      |                         |            | 5 4 3 2 1     |                             |
| 23    |      |                         |            | 5 4 3 2 1     |                             |
| 24    |      |                         |            | 5 4 3 2 1     |                             |
| 25    |      |                         |            | 5 4 3 2 1     |                             |
| 26    |      |                         |            | 5 4 3 2 1     |                             |
| 27    |      |                         |            | 5 4 3 2 1     |                             |
| 28    |      |                         |            | 5 4 3 2 1     |                             |
| 29    |      |                         |            | 5 4 3 2 1     |                             |
| 30    |      |                         |            | 5 4 3 2 1     |                             |

| Night | Date | Sleep and Wearing Notes | Hours Worn | Comfort Level | Doctor Setting Instructions |
|-------|------|-------------------------|------------|---------------|-----------------------------|
| 31    |      |                         |            | 5 4 3 2 1     |                             |
| 32    |      |                         |            | 5 4 3 2 1     |                             |
| 33    |      |                         |            | 5 4 3 2 1     |                             |
| 34    |      |                         |            | 5 4 3 2 1     |                             |
| 35    |      |                         |            | 5 4 3 2 1     |                             |
| 36    |      |                         |            | 5 4 3 2 1     |                             |
| 37    |      |                         |            | 5 4 3 2 1     |                             |
| 38    |      |                         |            | 5 4 3 2 1     |                             |
| 39    |      |                         |            | 5 4 3 2 1     |                             |
| 40    |      |                         |            | 5 4 3 2 1     |                             |
| 41    |      |                         |            | 5 4 3 2 1     |                             |
| 42    |      |                         |            | 5 4 3 2 1     |                             |
| 43    |      |                         |            | 5 4 3 2 1     |                             |
| 44    |      |                         |            | 5 4 3 2 1     |                             |
| 45    |      |                         |            | 5 4 3 2 1     |                             |

| Night | Date | Sleep and Wearing Notes | Hours Worn | Comfort Level | Doctor Setting Instructions |
|-------|------|-------------------------|------------|---------------|-----------------------------|
| 46    |      |                         |            | 5 4 3 2 1     |                             |
| 47    |      |                         |            | 5 4 3 2 1     |                             |
| 48    |      |                         |            | 5 4 3 2 1     |                             |
| 49    |      |                         |            | 5 4 3 2 1     |                             |
| 50    |      |                         |            | 5 4 3 2 1     |                             |
| 51    |      |                         |            | 5 4 3 2 1     |                             |
| 52    |      |                         |            | 5 4 3 2 1     |                             |
| 53    |      |                         |            | 5 4 3 2 1     |                             |
| 54    |      |                         |            | 5 4 3 2 1     |                             |
| 55    |      |                         |            | 5 4 3 2 1     |                             |
| 56    |      |                         |            | 5 4 3 2 1     |                             |
| 57    |      |                         |            | 5 4 3 2 1     |                             |
| 58    |      |                         |            | 5 4 3 2 1     |                             |
| 59    |      |                         |            | 5 4 3 2 1     |                             |
| 60    |      |                         |            | 5 4 3 2 1     |                             |

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