

SomnoMed® Return Materials Authorization Policy

Following FDA guidance, SomnoMed is unable to accept devices without a Return Materials Authorization (RMA).

Device Warranty Includes:

- SomnoMed® warrants SomnoDent® oral devices to be free from defects in materials and workmanship for up to 36 months.
- The warranty period begins from the original date of invoice from SomnoMed®
 - 3-Year Warranty Period: SomnoDent® CLASSIC; SomnoDent® FLEX; SomnoDent® HERBST ADVANCE; SomnoDent® HERBST ADVANCE ELITE; SomnoDent® AVANT
 - 1-Year Warranty Period: SomnoDent® AIR; SomnoDent® AIR+; SomnoBrux™ MICHIGAN; SomnoBrux™ TANNER; SomnoBrux™ GELB
 - 6-Month Warranty Period: SomnoMed® Morning Repositioner
 - Braebon Base Stations are covered under a 1-Year warranty for defects or malfunctions

Device Warranty Excludes:

- SomnoMed® does not warrant that the devices will be efficacious in the treatment of snoring or Obstructive Sleep Apnea.
- The SomnoDent® warranty does not cover adjustment, repair, or replacement due to but not limited to restorative dental work, orthodontics, dentures, partials, crowns, bridges, substandard or distorted models, insufficient or distorted bite records, physical damage, device staining, calculus deposits, pet damage, or use of harsh chemicals. The warranty is void if structural changes are made to the device by customer or patient.
- Repairs relating to reset to current position or bite, midline acrylic fracture, clasp repair, wing repair, and/or other damage not caused by manufacturing or material defect.
- The warranty does not include any incurred clinical costs relating to scheduling and or chair time required. A device must be shipped from and can be returned only to the treating provider. SomnoMed® cannot ship medical devices directly to a patient's address.
- If during the initial evaluation of your device it is determined that a repair is required due to a clinical error in original bite registration, impressions, scan files, or device selection, the repair may not be covered under this warranty.
- Warranty work may only be completed by an authorized SomnoMed® facility. SomnoMed® does not repair devices fabricated by other device manufacturers or dental labs.

NOTE: SomnoMed® does not warranty repairs or structural modifications made by the clinician. SomnoMed does not provide replacement parts and or components.

The Device Repair Process:

In the unlikely event a device is in need of repair, SomnoMed® will provide a no-obligation virtual device assessment to estimate the repair cost. There are two methods to receive a repair estimate:

- **SomACCOUNT:** on your SomACCOUNT dashboard, under the RETURNS selection, you will CREATE A RETURN. Here, you can provide details of the repair(s) needed. **NOTE: *this is the preferred method to create a return, which combines a seamless repair transaction with a 15% discount to the cost of the repair.***
- **Telephone:** contact the SomnoMed® Repairs Department at (888) 447-6673, ext. 4, to speak with a service technician, where you can provide any details of the repair(s) needed. Repair costs will be estimated at list price.

Whether creating a return in SomACCOUNT or through a telephone consultation, you will be provided an estimate of the repair. If you approve the repair estimate, a Return Materials Authorization (RMA) Courtesy Kit with an RMA order number will be shipped to your location, which is to be used to return the device to SomnoMed®. Upon device receipt and physical assessment, if it is determined that the needed repairs are more extensive than initially estimated, you will be contacted with a new estimate for approval before any repairs are performed.

IMPORTANT: following FDA regulations, SomnoMed cannot return devices received in a damaged or an altered condition that may pose harm if worn by a patient. Should you decide to opt out of the returns process after the SomnoMed® physical assessment of the device, we will honor your request to return the device so long as the device specifications comply with FDA patient safety regulations. You will be charged a \$19.95 shipping fee for the return of the device.

Steps to Return a Pre-Approved Device for Repair:

1. Returns must be generated according to this policy. Following FDA guidance, SomnoMed® is unable to accept devices without a Return Materials Authorization. **If any device is received outside of this policy, the device repair will be delayed while the RMA is manually generated. Additionally, a separate Repair Order Handling fee of \$50 will be added to the list price of the repair.**
2. To begin the Return Materials Authorization (RMA) process, create a return for device repair by either accessing your SomACCOUNT portal at www.somaccount.com or by contacting SomnoMed® at (888) 447-6673, ext 4.

3. Once the return order has been generated and approved, an RMA Courtesy Kit will be shipped to your location, containing return instructions, return packaging, and repair quote confirmation.
4. In the return packaging, include the original device and all device components such as wings, current strap, hinges, and any broken pieces. If applicable, include the original bite and impressions. If a new scan is required, please submit the scan via the scanner portal and reference the RMA sales order number generated when the device return was created.
5. **Do not include the storage case, brushes, keys, elastics, strap kits, SomTABS, or personal items as they cannot be returned.** SomnoMed® does not issue new accessories with device repairs.
6. If a replacement device is deemed necessary, manufacturing of the replacement device may begin prior to SomnoMed® receipt of the original device. FDA guidelines require that a device needing repair (or replacement) be returned to the manufacturer for evaluation, analysis, and traceability. **If SomnoMed® does not receive the original device within 30 days of shipping the replacement device, a new device fee will be charged to your account.**

Device Refunds:

SomnoMed® manufactures customized devices. Refunds will not be provided for any reason.

Product Refunds:

All product sales are final and non-refundable.

**Please direct questions to
SomnoMed® Repairs at (888) 447-6673, ext. 4.**

Som RMA Workflow

