

Comfort3D powered by ORB Innovations™

Instructions for Use

ENGLISH

Product Description

Comfort3D powered by ORB Innovations™ is a custom-fit, additive-manufactured device designed for comfortable nighttime wear as part of a user's sleep and wellness routine. Worn during sleep, the device is intended to support awareness of sleep and nightly habits, helping users establish a more consistent overnight experience.

Comfort3D powered by ORB Innovations is a full-coverage device designed to fit securely over all the upper teeth, allowing it to maintain a stable oral position while sleeping. Its custom fit is intended to support comfort throughout the night and ease of use, helping to minimize sleep disruption.

Integrated sensors within the device allow users to optionally view general, non-clinical wellness trends related to sleep and nightly routines through a companion smartphone application. These insights are provided for personal awareness only and are not intended to diagnose, treat, cure or prevent any medical or dental condition. The app-based wellness features are optional and may be enabled or disabled at any time without affecting the physical function or use of the device. When used without the app-based features the Comfort3D powered by ORB Innovations functions as a passive, night-worn sleep device.

Product Purpose

Comfort3D powered by ORB Innovations is intended for nighttime wear by adults as part of a personal sleep and wellness routine. The device is designed to be worn during sleep to provide optional, non-clinical metrics related to sleep and nightly habits through a companion smartphone application.

Comfort3D powered by ORB Innovations is intended for personal use only and is not intended to diagnose, treat, cure or prevent any medical or dental condition.

Limitations of Use

This device is intended for use only by individuals 18 years of age or older. It is not intended to diagnose or treat any medical condition. If users have or suspect they have sleep-related breathing disorders or other sleep conditions, they should consult a physician or qualified healthcare provider.

Safety Precautions

- DO NOT attempt to disassemble, grind, trim, or otherwise alter the device or the charging case. Do not adjust any surfaces on or near the area containing electronic components.
- DO NOT intentionally chew or bite down excessively on the device.
- DO NOT expose the device or the charging case to temperatures outside of the prescribed thresholds. (See Environmental Conditions).
- DO NOT use the device if it appears swollen, warped, or otherwise deformed.
- DO NOT use the charging case in a wet location, such as near a

sink or bathtub. Before charging, ensure that the charging case, charging port, cable, and surrounding area are completely dry. The charging case is NOT waterproof.

- DO NOT connect or disconnect the charging cable with wet hands.
- DO NOT submerge or rinse the charging case under liquid.
- Before charging, inspect the charging case, charging port, and cable for cracks, warping, corrosion, or other damage. Do not use or charge the device if any component is wet or damaged.
- Immediately disconnect the charging case from the power and discontinue use if it becomes unusually hot, emits smoke or an unusual odor, becomes discolored or deformed or otherwise appears to malfunction.
- Immediately discontinue device use and contact your dentist if device causes irritation including warmth or discomfort in the cheek.
- Store the charging case in a shaded well-ventilated area, out of direct sunlight.
- Use only the supplied USB-C charging cable (rated input: 5V, 1A) and a 5V USB wall charger that carries a UL, ETL/Intertek, CSA, or CE safety mark and provides double or reinforced insulation. Do not use any adapter supplying more than 5V.
- Keep out of reach of children and pets to prevent injury or damage.
- Intended for single-user use only. Reuse of the device on another user is not recommended due to the risks of improper fit and cross-contamination/infection.
- Regular dental check-ups are recommended to monitor for improper fit, device damage, allergic reaction, irritation, or discomfort.
- Soreness may occur after initial use and for several days thereafter. Soreness may be felt in the jaw, teeth, and gums. If soreness is excessive, stop using the device and contact your dentist.

Insertion and Removal

- Before each use, brush and floss your teeth, and thoroughly rinse your mouth with clean water. Visually inspect the device for cracks, punctures, exposed internal components, or other damage. Do not use a damaged device.
- If mouthwash is used, thoroughly rinse traces of mouthwash from your mouth.
- When inserting, begin at the front teeth and then seat it evenly on both sides of the arch. Do not bite down into place.
- If you gag, cough, or yawn, the device may move and need to be re-inserted.
- If the device becomes loose or tight, causes you any discomfort, or any part is broken or delaminated, contact your dentist.
- If any changes occur to your dentition, contact your dentist.

Comfort3D powered by ORB Innovations™

Cleaning Guidelines

- Clean the device with clean, cool water ONLY and let air dry. A soft toothbrush may be used.
- DO NOT clean or soak the device in mouthwash.
- DO NOT use denture cleanser or toothpaste.
- DO NOT use hot water for cleaning.
- DO NOT use alcohol, hydrogen peroxide, or chemical-based/acidic agents.
- DO NOT place the device in direct sunlight. Keep away from heat sources.
- Contact your dentist for any questions regarding cleaning.

Environmental Conditions

Environmental Condition	Temperature
Operating Temperature	50°F to 100.4°F (10°C to 38°C)
Charging Temperature	50°F to 95°F (10°C to 35°C)
Storage Temperature	-4°F to 95°F (-20°C to 35°C)
Transport Temperature	-4°F to 140°F (-20°C to 60°C)
Operating Humidity	15% to 95% RH, non-condensing
Storage Humidity	15% to 75% RH, non-condensing
Operating Altitude	0 to 3,000 m (0 to 9,843 ft)
Transport Altitude	0 to 10,000 m (0 to 32,808 ft)
Ingress Protection – Device	IPX7

Disposal

When the product reaches its end of life, do not dispose of the Comfort3D powered by ORB Innovations with household waste. The product contains a lithium-ion (LiPo) battery. Dispose of the device in accordance with applicable local regulations for lithium batteries. Dispose of the device and/or charging case in accordance with the local environmental laws and guidelines pertaining to electrical and electronic equipment.

Disclaimer of Liability

Comfort3D powered by ORB Innovations is warranted for six months with proper care. All warranty claims must include return of the device. PrismaTik Dentalcraft, Inc. is not liable for damages resulting from modification, misuse, or use outside of these instructions. The responsibility rests with the provider.

Compliance

Device contains FCC ID: 2BEPY-OSA-001. This device uses Bluetooth® Low Energy (BLE) 6.0 for wireless communication.

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.

NOTE: 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 into 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.

WARNING - Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

MPE/SAR/RF exposure information:

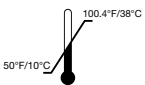
This device has been evaluated for and complies with the FCC RF exposure requirements for portable devices. Specific Absorption Rate (SAR) testing was performed at 0 mm separation in accordance with FCC KDB 447498. The reported SAR values are below the FCC limit of 1.6 W/kg averaged over one gram of tissue for general population / uncontrolled exposure.

This device includes a radio transmitter and receiver which is designed and manufactured not to exceed the emissions limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission (FCC). These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. These guidelines are based on the safety standards previously set by the U.S., Canada, and international standards bodies. The standards include a substantial safety margin designed to assure the safety of all persons, regardless of age and health.

The exposure standard for wireless RF devices employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6 W/kg averaged over any 1 gram of tissue. SAR values at or below that limit are considered safe for the general public.

Comfort3D powered by ORB Innovations™

Symbols Glossary

Symbol	Title – Symbol Description
	LOT Number – Indicates the manufacturer's component lot number so that the lot or batch can be identified.
	Serial Number – Indicates the manufacturer's serial number so that a specific device can be identified.
	Consult Instructions for Use – Indicates the need for the user to consult the instructions for use.
	Manufacturer – Indicates the device manufacturer.
	Date of Manufacture – Indicates the date (YYYY-MM-DD) when the device was manufactured.
	Caution – Indicates the user needs to consult the instructions for use for important cautionary information such as warnings and precautions.
	Temperature Range – Indicates the temperature limits to which the device can be safely exposed.
	Keep Away from Sunlight – Indicates a device that needs protection from light sources.
	Waste Electrical and Electronic Equipment – Indicates that separate collection for waste electric and electronic equipment (WEEE) is required.
	FCC Mark – Indicates that the electromagnetic radiation from the device is below the limits specified by the Federal Communications Commission and the manufacturer has followed the requirements of the Supplier's Declaration of Conformity authorization procedures.
	Keep Dry – Indicates a device that needs to be protected from moisture.