



## **Invisalign™ Ultrasonic Cleaning Station**

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**Instructions for use**

## **Intended use/ purposes; indications for use**

The Invisalign™ Ultrasonic Cleaning Station is an over-the-counter electronic appliance that is intended to clean Invisalign® System clear aligner orthodontic appliances and Invisalign® and Vivera™ retainers using ultrasonic vibrations.

## **Device description**

The Invisalign™ Ultrasonic Cleaning Station is a countertop device that cleans Invisalign® clear aligners and Invisalign® and Vivera™ retainers by transmitting high-frequency sound waves (also called 'ultrasonic vibrations') through a liquid medium, creating microscopic "scrubbing/scouring" bubbles which dislodge debris as they collapse. The device offers a convenient way to clean these removable orthodontic appliances at home in as little as five minutes using just plain tap water and with no additional chemicals.

In testing with water, the Invisalign Ultrasonic Cleaning Station removed 98.3% to 99.9% of the following odor-causing bacteria from Invisalign® clear aligners: *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Enterobacter cloacae* and *Escherichia coli*. Performance of bacteria removal for retainers has not been evaluated.

## **Compatible products**

- Invisalign® clear aligners including Invisalign® treatment with mandibular advancement featuring enhanced precision wings
- Invisalign® and Vivera™ retainers

## **Important safeguards**

When using electrical products, especially when children are present, basic safety precautions should always be followed, including the following:

**READ ALL INSTRUCTIONS BEFORE USING THE APPLIANCE**

**DANGER** - To reduce the risk of electrocution:

- 1. Do not place or store product where it can fall or be pulled into a tub or sink.**
- 2. Do not place or drop into water or other liquid.**
- 3. Do not reach for a product that has fallen into water. Unplug immediately.**
- 4. Do not use while bathing.**
- 5. Always unplug this product immediately after using.**
- 6. Do not submerge in water. Use and store away from water sources.**
- 7. Do not insert unintended objects in the opening for the cord. Use only with the 12v power adapter provided.**

**WARNING** - To reduce the risk of burns, electrocution, fire or injury to persons.

1. **A product should never be left unattended when plugged in.**
2. **Unplug this product before filling. Fill (reservoir) with water only unless otherwise specified by manufacturer. Do not overfill.**
3. **Close supervision is necessary when this product is used by, on, or near children or invalids.**
4. **Use only for intended purpose and in accordance with the instructions. Do not use attachments not recommended by the manufacturer.**
5. **Never operate this product if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into water. Return the product to a service center for examination or repair.**
6. **Do not place fingers or hands in the ultrasonic tank while in operation.**
7. **This equipment may cause radio interference or may disrupt the operation of nearby equipment.**
8. **Keep cord away from heated surfaces.**
9. **Store away from heated surfaces. Do not expose to extreme heat or cold.**
10. **Do not operate or use the product under high temperature or with heated liquids.**
11. **Never use while sleeping or drowsy.**
12. **Never drop or insert any object into any opening.**
13. **Do not use outdoors or operate where aerosol (spray) products are being used or where oxygen is being administered.**
14. **Never block air openings of the product or place it on a soft surface, such as a bed or couch, where air openings may be blocked. Keep air openings free of lint, hair, and the like.**
15. **Any serious incident that has occurred in relation to the product should be reported to the manufacturer (see back page of these instructions for user assistance information).**
16. **Do not tamper with product components. Changes or modifications to this unit could create a risk of injury to the user, render the product inoperable or ineffective, and will void any and all product warranties.**

### **Precaution:**

1. Do not operate the unit with no water or without sufficient water in the tank.
2. This cleaning station is for a single patient's use only. Cleaning multiple patients' aligners or retainers in one cleaning station causes a risk of infection.
3. The manufacturer is not responsible for any interference or damage caused by unauthorized modifications to this equipment.
4. Dispose of this product in compliance with national and local laws.
5. Do not use with Invisalign™ Cleaning Crystals or other chlorine-based cleaning agents as they may cause damage to the interior tank.

Not tested with Invisalign® compliance indicators or Invisalign Stickables™

### **Contraindication:**

1. Not intended for use by persons (including children) with reduced physical, sensory or mental capabilities without supervision.

### **Kit includes:**

- Invisalign™ Ultrasonic Cleaning Station
- 12v power adapter
- Instructions for use
- Warranty card

### **Set-up, cleaning, and maintenance of the product**

- Prior to each use: Fill the tank about ¼ full with water. Add a drop of dish soap. Wipe the inside of the tank with a clean, soft cloth. Pour out the soapy water. Rinse the tank with clean water and then dump out the water and dry.
- Always empty tank and dry product when not in use.
- Dispose of this product in compliance with national and local laws.

## Directions for use

1. Add tap water to the max level indicated in the tank. **(Figure 1)**

2. Place no more than two aligners/retainers in the tank at a time. Place them inside-up. Do not stack. **(Figure 2)**

⚠ For best results, make sure aligners/retainers are not touching and shake or tap off any air bubbles on the aligners/retainers.

3. Close the lid. Place the tank on a stable surface away from any water source, attach power adapter to the cleaning station, and plug it into outlet. **(Figure 3)** The “On/Off” button will quickly flash red, then blue, and a buzzer will sound.

⚠ Use caution when moving the product when it is filled with water; station is not water-tight and water may spill.

4. To start, place finger on touch-sensitive “On/Off” button once. **(Figure 4)** To cancel, press again.

- A blinking blue light indicates cleaning cycle is active. The blinking will speed up as it gets closer to the end of the cleaning cycle.

⚠ Do not remove aligners/retainers before the cleaning cycle is complete.

- The product will automatically turn off after 5 minutes. Open the lid to take out aligners/retainers. Rinse off aligners/retainers with fresh water.

5. Unplug the product and dump out the used water after every cleaning cycle and repeat the steps in the cleaning section.

- Use fresh water for each cleaning cycle.

- If the product is used two times consecutively, it will automatically enter a 5 minute cool down period before it can be restarted. A red light will flash if user attempts to start the product during the cool down period.

- Use daily as needed, up to 2 times/day. The product is expected to last for one year when used as directed.

- Ultrasonic cleaning does not replace regular aligner/retainer cleaning.

Figure 1

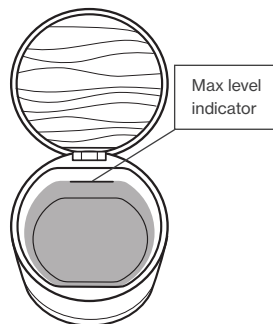


Figure 2

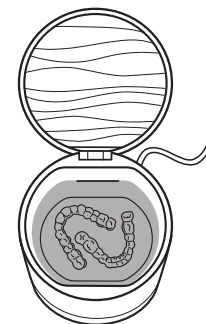


Figure 3

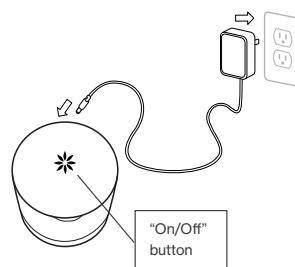
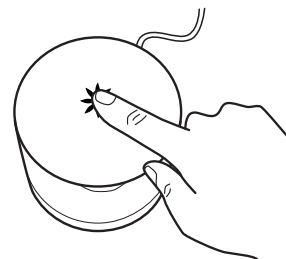


Figure 4



### On/Off button light:

- Quick flash red, then blue and beep: product is plugged in and ready to start.
- Blinking blue light: cleaning cycle is active. Blinking will speed up as it gets closer to the end of the cleaning cycle.
- Red flashing light: if user attempts to start the product during the cool down period.

## Product features

- 5-minute cycle time
- Unit will automatically enter a cool down cycle, followed by a 5-minute cool down period, after the unit is run for two consecutive 5 minute cycles

## Technical specifications

- Model: Invisalign™ Ultrasonic Cleaning Station S1.
- Power Supply: 100-240V AC 50/60Hz 0.65A.
- Ultrasonic Cleaning Station: 12V DC 2.0A.
- Dimensions: 112 x 114 x 90 mm.
- Net weight: 16 oz (1 lb).
- Operating temperature: 32-104 degrees F (0-40 degrees C).
- Storage temperature: 14-113 degrees F (-10-45 degrees C).

## Travel or international use

Electrical plug adaptor may be required when travelling internationally.

## Safety listings

CONFORMS TO UL1431, CSA C22.2 No. 68-18, ISO 10993 and ISO 11737-1

## Limited warranty

For complete terms and conditions, please see the included warranty.

















## FCC Compliance Statement

This product and its related accessories (the “Products”) comply with part 15 of the FCC Rules. Operation of each Product is subject to the following two conditions: (1) each Product may not cause harmful interference, and (2) each Product must accept any interference received, including interference that may cause undesired operation.

**NOTE:** The Products have been tested and found to comply with the limits for Class B digital devices, pursuant to Title 47 part 15 of the Code of Federal Regulations, which covers the rules of the Federal Communications Commission (FCC). These limits are designed to provide reasonable protection against harmful radio frequency energy, and if not installed and used in accordance with the instructions, the Products may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If the Products do 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 items.
- 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 technician for help.

## Symbols glossary

Symbol	Title	Explanation
	Manufacturer	Indicates the medical device manufacturer
	Date of manufacture	Indicates the date when the medical device was manufactured
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Catalogue Number	Indicates the manufacturer's Catalogue number so that the medical device can be identified
	Country of Manufacture	To identify the country of manufacture of products
	Model number	Indicates the model number or type number of a product. This symbol shall be accompanied by the model number of the product adjacent to the symbol.
	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	Keep away from sunlight	Indicates a medical device that needs protection from light sources
	Keep dry	Indicates a medical device that needs to be protected from moisture
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	Medical Device	Indicates the item is a medical device
	Unique device identifier	Indicates a carrier that contains unique device identifier information
	Single Patient Multiple Use	Indicates a medical device that may be used multiple times (multiple procedures) on a single patient
	FCC Mark of Conformity	Indicates a product that has been tested, evaluated, and found to be compliant with FCC rules.

Troubleshooting/User Assistance Information:  
For questions related to this product,  
please contact 1-833-212-8728  
or [invisalignaccessories@aligntech.com](mailto:invisalignaccessories@aligntech.com).

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