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Intended use/ purposes; indications for use

The Invisalign™ Ultrasonic Cleaner 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

With one touch your unit generates deep cleaning ultrasonic waves for 5 minutes. In a process known as cavitation, ultrasonic waves generated by the cleaner create small bubbles within the cleaning solution. These bubbles rapidly collapse, generating miniature shockwaves with sufficient force to help remove stains and debris. The cleaner may generate some noise during the cleaning cycle. This is a normal result of the interaction between ultrasonic waves and various materials.

Compatible products

- · Invisalign® clear aligners
- 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 DEVICE

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

- 1. Do not use or place the device near water sources
- 2. Do not retrieve the device from water. If immersed, disconnect immediately
- 3. Do not use the device while bathing
- 4. Do not leave the device unattended while powered
- 5. Stop using if the device is damaged or malfunctioning
- 6. Keep hands away from ultrasonic tank during operation
- 7. The device may cause radio disruptions
- 8. Do not allow water to enter the power inlet; do not use the device if this occurs
- 9. Avoid using the device if you have a pacemaker
- 10. Supervise the device when used around children or vulnerable individuals

Precaution:

- 1. Disconnect the device immediately after use
- 2. Use only the provided power supply
- 3. Do not insert foreign objects into the power outlet

- 4. Store in a dry, safe place
- 5. Disconnect the device before refilling and avoid overfilling
- 6. Follow intended use guidelines: do not use unapproved accessories
- 7. Keep the device away from hot surfaces
- 8. Use the device in safe temperature conditions
- 9. Only use cold water with the device
- Only use cold water with the device
 Operate the device on solid surfaces
- 11. Use the indicated amount of water in the device
- 12. Do not run the device without water in the tank
- 13. Alternations may affect functionality, void warranties and liabilities
- 14. We do not recommend cleaning appliances from multiple patients at the same time

Contraindication:

- 1. Supervise the device when used around children or vulnerable individuals
- This ultrasonic cleaner should not be used by individuals with cardiac pacemakers.
 The ultrasonic filed may interfere with pacemaker function

Kit includes:

- Invisalign™ Ultrasonic Cleaner (Lid, Base, 12v power adapter),
- Instructions For Use,
- · Warranty card
- Zima Dental Pod Tablets

Set-up, cleaning, and maintenance of the device

- Dispose of the device responsibly as per local and national regulations.
- Prior to use, fill the tank to the max fill line and run one cycle with the Zima Dental Tablets to ensure the device is clean
- Always empty tank and dry device when not in use.

Directions for use

- 1. Add tap water to the max level indicated in the tank.
- Place no more than two aligners/retainers in the tank at a time.
 Place them inside-up. Do not stack.
 - For best results, make sure aligners/retainers are not touching and shake or tap off any air bubbles on the aligners/retainers.
- 3. Place the device on a stable surface away from any water source, attach power

adapter to the device, and plug it into outlet.

- Use caution when moving the device when it is filled with water; device is not water-tight and water may spill.
- 4. To start, place finger on touch-sensitive "On/Off" button once. To cancel, press again.
- 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.
- 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.
- Ultrasonic cleaning does not replace regular aligner/retainer cleaning.

Product features

5-minute cycle time

Technical specifications

- Model: Invisalign™ Ultrasonic Cleaner
- Power Supply: 120-240V AC ~ 50/60Hz 0.60A
- · Ultrasonic Cleaner: 12V DC 1.5A
- Dimensions: 115 x 115 x 88 mm
- Net weight: 0.53 lbs
- Storage temperature: 14-113 degrees F (-10~45 degrees C).

Travel or international use

Electrical plug adaptor may be required when travelling internationally.

Limited warranty

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

FCC Compliance Statement

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

NOTE: The Devices 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 Devices may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If the Devices 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.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer or distributor (see back page of these instructions for user assistance information).

Symbols glossary

Symbol	Title	Explanation
ш	Manufacturer	Indicates the medical device manufacturer
M	Date of manufacture	Indicates the date when the medical device was manufactured
LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
REF	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
®	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
类	Keep away from sunlight	Indicates a medical device that needs protection from light sources
Ť	Keep dry	Indicates a medical device that needs to be protected from moisture
X	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
(]i	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use
Â	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 undestrable consequences
MD	Medical Device	Indicates the item is a medical device
F©	FCC Mark of Conformity	Indicates a product that has been tested, evaluated, and found to be compliant with FCC rules.



Ultrasonic Cleaner

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Manufactured for KP Dental LLC 1007 N Orange St. Wilmington, DE 19801











Distributed by Align Technology, Inc. 2820 Orchard Parkway San Jose, CA 95134











Country of Origin: China

Troubleshooting / User Assistance Information:

For questions related to this product, please contact the distributor support at invisaligncare@aligntech.com or 1-888-822-5446 M-F 5:00 am - 5:00 pm PST



Designed in London, UK by Zima Dental® Made in China zimadental.com | @zimadental

Warning - California Prop 65

This product can expose you to chemicals including acrylonitrile butadiene styrene (ABS), which is known to the State of California to cause cancer.

For more information, go to www.P65Warnings.ca.gov

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