



PROFESSIONAL USE ONLY



CAUTION, CONSULT DOCUMENTS



RE-USE NOT ALLOWED



HOT SURFACE



READ USAGE INSTRUCTIONS



AVOID SUNLIGHT



TEMPERATURE LIMITS: 10°C-25°C



CORROSIVE



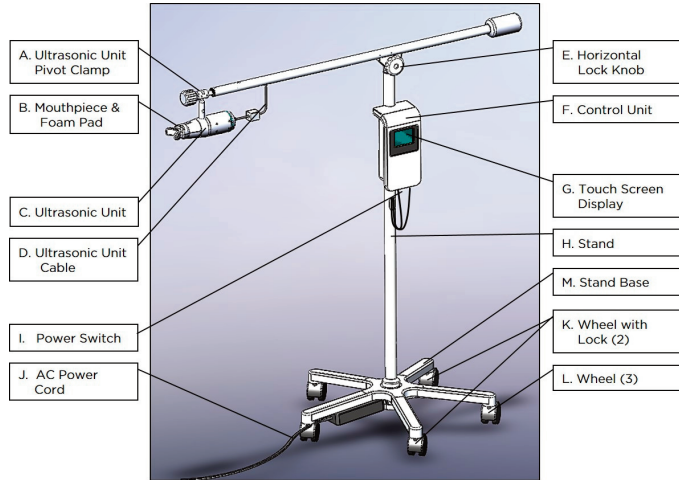
IRRITANT

uPhoria™
ULTRASONIC TEETH WHITENING SYSTEM

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION & INTENDED USE

The uPhoria Professional Teeth Whitening System is a reusable tooth whitening device for adults that is intended to be used as directed by a dental professional in a dental office. The single use treatment kit includes a hydrogen peroxide based solution which accelerates the process of intrinsic tooth whitening in an environment of ultrasonic vibration.



INDICATION FOR USE

Device and treatment are intended only for in-office use by a trained professional for whitening discolored natural teeth.

QUESTIONS

Call Dentovations Global Customer Service Center at: 617-737-1199.

TROUBLESHOOTING

If system does not operate as expected, please follow these instructions:

- Turn Power Switch to 'OFF', then disconnect the power supply for about 10 seconds. Then reconnect Power Supply.
- Remove and reconnect all cables.
- Error 1 means Mouthpiece is loose. Remove and replace Mouthpiece tightly.
- Turn the system back on; press the start button.
System should operate normally.

NOTE: If system still does not work: Replace the Mouthpiece with a different one. If fault persists, contact Dentovations customer service.

AUTHORIZED SERVICE

If troubleshooting instructions above are not successful to resume system use, then the system may require service by an Authorized Service Technician.

The System does not have any user serviceable parts; All device enclosures must be unopened with original Serial Number Label unaltered on the Control Unit and Ultrasonic Unit. This label has the unique date of production by the Manufacturer. Please have these serial numbers available when you call customer service.

Please call Dentovations Global Customer Service Center at: **617-737-1199**, email us at: info@4minutewhite.com or visit: 4minutewhite.com

CLEANING

- Both of the mating surfaces between Ultrasonic Unit and Mouthpiece must be cleaned daily with Isopropyl alcohol.
- After each treatment, disinfect entire device with an appropriate cleaning. Recommended cleaning agents:
 - Isopropyl alcohol (70% solution)
 - Hydrogen peroxide (3% solution)
 - Mild detergent according to the standard practice of care.
- Place Mouthpiece in Dental Autoclave equipment for cleaning and disinfection.

Before reusing Mouthpiece on a patient, it shall be sterilized and dried in a Dental Autoclave, then allowed to cool to ambient temperature as follows:

- Autoclave sterilization cycle duration shall be 60 minutes minimum, at 121°C (249.8°F).
- Autoclave Drying cycle shall be 60 minutes minimum.
- Allow 45 minutes minimum for Mouthpiece to cool to ambient temperature outside of the Autoclave equipment.

MAINTENANCE

- The device must be turned off at the end of each day.
- Device and Treatment Kit Storage Environment Requirements are as follows:
 - Storage temperature range shall be between 50° F (10° C) to 77° F (25° C)
 - Shipping temperature range shall be between 40° F (4.5° C) to 90° F (32° C)
- Treatment Kit disposal instructions:
 - Recycle according to local regulations.
 - Contains: Polymers, paper and fabric.
 - Discard according to local & institutional procedures.



1. **Determine SHADE** of patient's teeth.
2. **Liberaly apply Petroleum Jelly** to patient's lips.
3. **Rinse** with 10mL of Pre-rinse for 30 seconds (1/2 bottle).
4. **Attach Mouthpiece** onto Ultrasonic Unit – **MUST BE TIGHT**.
5. **Insert Gauze Pads**, place safety glasses and oral retractor.
6. **Soak Foam Pad** with 6mL of Whitening Gel.
7. **Place Foam Pad** onto sterile Mouthpiece by fitting straps behind arch.
8. **Align Ultrasonic Unit/Mouthpiece/Foam Pad** onto teeth
9. **Press START** to begin 2:00 minute treatment countdown. 3 tone chime indicates that treatment is complete.
10. **Move system, and remove first foam pad;** Repeat steps 6 to 9 with 2nd Foam Pad soaked with Gel placed onto Mouthpiece.
11. **Press START** for second 2 minute treatment. Rinse again to refresh.
12. **Determine POST treatment shade**, confirm results.
 - Position Stand, Ultrasonic Unit and Mouthpiece nearby, in advance.
 - Treatment may be paused to reposition Mouthpiece, as needed.
 - At START, blue light illuminates. Normal operation includes a pulsing hiss, a gentle warming, and a tingle feeling.
 - Foam Pad should gently press onto top and bottom teeth evenly.Instruct patient to hold top and bottom teeth in line, same as biting.

CONTRAINDICATIONS

Do not use this device for the following patient conditions:

- If you are pregnant, or a nursing mother, do not use this product without first consulting your doctor.
- Use on natural teeth only. Not recommended for use by patients with veneers, loose or damaged restorations or crowns with poor margins.

Not recommended for people with any of the following conditions:

- An allergy to hydrogen peroxide or taking photoactive medications.
- Gum disease or periodontitis, gingivitis, gum bleeding or severely receding gums.
- Active or fixed orthodontic appliances, restorations in the anterior dentition or tooth mobility crowns, bridges, or crowding involving the maxillary anterior teeth.
- Fluorosis, frank caries, tetracycline staining, or dark teeth due to loss of vitality.
- Self-reported dentinal hypersensitivity in the maxillary anterior region.
- It is recommended that patients with cavities or gum disease consult with their dentist prior to the use of this product.
- Not recommended for patients younger than 12 years of age.
- Excluded patient conditions as determined by the dental professional (i.e. existing caries, advanced periodontal disease, active orthodontics and or moving teeth).

WARNINGS

- Warning: Device is not sterile.
- Warning: Inspect device before each use.
- Warning: Device is to be used only by direction of a trained dental professional.
- Warning: Do not swallow any part of the solution, gel, or foam pad. Suction during treatment is recommended. Gel is to be used for teeth whitening only. If any problems or medical emergencies occur, contact a Poison Control Center immediately.

PIVOT CLAMP, ALIGNMENT OF MOUTHPIECE

- Loosen Ultrasonic Unit Pivot Clamp (UUPC) with 1 hand, so the Ultrasonic Unit (UU) is free to move 360°, and can be angled +30° to -30° any direction.
- While holding Ultrasonic Unit with 2nd hand, align and hold the UU so that Foam Pad gently touches the patient's top and bottom teeth.
NOTE: reaching over horizontal pole to hold Ultrasonic Unit can make it easier to position the device against the patient's mouth.
- When the Mouthpiece is aligned, tighten the UUPC firmly to hold the UU in desired position against the patient's teeth.
- The horizontal bar is balanced so it will stay in the desired position. If necessary, the Horizontal Position Lock Knob may be tightened.
- Adjust as required. The UUPC will index in & out about 2 inches as a final adjustment before START.

ORAL IRRITATION

- Patient may notice a subtle whitening of the gums near the teeth. If this happens, do not be alarmed. This condition normally disappears within 30 minutes. Wait a minimum of 24 hours before the next treatment.
- Prolonged contact with the Whitener Gel may cause moderate gum or lip irritation. If needed, rinse the exposed area with water. Typically, any irritation resolves within 48 hours.

POST TREATMENT INSTRUCTIONS

- To ensure lasting whitening, avoid the following items for 24 hours after treatment: Coffee, tea, wine and tobacco products.
- A whitening treatment is recommended after each prophylaxis treatment and or every 6 months.
- Follow tooth brushing, flossing and rinsing regimens to prolong the effect of the uPhoria treatment.

the Ultrasonic Unit, Mouthpiece and Foam Pad so that the Foam Pad presses gently onto patient's top and bottom teeth.

NOTE: Instruct patient to place top teeth in line with bottom teeth.

Mouthpiece should be positioned so that Foam Pad touches all teeth equally with a gentle pressure.

9. To begin treatment, press START button. The 2-minute treatment will complete with an audible tone and 'SMILE WITH CONFIDENCE' will appear on the display.

NOTE: Blue light should be ON. An audible pulsing hiss, a gentle rise in heat on the Mouthpiece, and tingling feeling caused by Hydrogen Peroxide activation are ALL part of normal operation.

10. Move Ultrasonic Unit away.
11. Repeat steps 6 to 9 above for the second treatment with a new Foam Pad placed onto Mouthpiece. Realign Mouthpiece onto teeth. Start the 2nd 2:00 minute treatment. Finally, repeat 10mL rinse to remove Gel residue.
12. Determine post treatment shade; Confirm results with patient.

PATIENT POSITION, STAND ALIGNMENT

- Patient should be comfortable, reclined slightly and not horizontal. It is best if the patient is upright to partly reclined.
- Stand should be placed near the dental chair, with access to a wall outlet.
- Stand is normally placed to the side of the chair in an operatory, and two casters are locked, so Stand is stationary. Unlock two casters to move system.
- To align mouthpiece to patient, Plunge UU Mount (against spring), then rotate so that arch of Mouthpiece is parallel to floor. This assembly can be indexed into a position every 45°.
- The UJPC can be moved 2" in or out. This adjustment may be used LAST to accurately press the Foam Pad onto the patient's teeth.

- Warning: Gel contains an irritant, hydrogen peroxide. Wear gloves. Avoid contact with eyes, Rinse eyes immediately if product comes into contact with them.1 Use protective eyewear or safety glasses during treatment. If irritation of the gums or the mouth occurs (such as redness, swelling or soreness), discontinue use.
- Warning: Device use will expose the soft tissues of mouth to heat. If patient has any discomfort in or around the mouth, remove the device and terminate the treatment immediately.
- Warning: Mouthpiece must be tight.

CAUTIONS

- Do not override normal procedures for use.
- Do not use this product if the patient is allergic to any of the ingredients, or if any of the patient medications could react with these ingredients.
- Do not use with orthodontic appliances such as braces.
- Device will only whiten natural teeth.
- Do not exceed more than one 2-cycle treatment per person, per day.
- Do not use device with any whitening agent other than the Gel in the uPhoria treatment kit, as directed by the physician.
- Composite restorations may require replacement since only natural teeth will whiten.
- Avoid spilling the whitening gel on fabric, clothing, or furniture as it may discolor them.
- If treatment causes a noticeable skin reaction: stop using the device, flush skin with water for 15 minutes and consult a physician immediately.
- Do not disconnect the Ultrasonic Unit Cable while system is in operation as this may cause damage to the system.
- Results depend upon anatomy, calcifications, age, tooth condition and hygiene.
- Review patient's current dental health and medical history.

COMPLETE TREATMENT INSTRUCTIONS

PREPARATION

- Connect all cables. Attach Mouthpiece, and turn ON power switch.
- Press START. Confirm normal operation: Ultrasonic Unit light turns ON, countdown begins, and vibration is evident on metal in Mouthpiece; Press PAUSE, then RESET.
- Mouthpieces should be steam sterilized by Autoclave. Attach Mouthpiece to Ultrasonic Unit.
- An oral prophylaxis, floss and brushing usually precedes this whitening treatment.
- Protective clothing, eyewear, bib and suction are recommended when using the uPhoria System.
- Inspect the distal area of Mouthpiece, and proximal area of Ultrasonic Unit. Clean with Isopropyl alcohol, if needed. (See pg. 10).
- Confirm Treatment Kit date of manufacture is acceptable.
- Read the Instructions for Use completely before using the uPhoria System.

SET-UP – STANDARD OPERATION

- Ensure the Control Unit Power Switch is turned OFF.
- Insert the Power Supply cable connector to the underside of the Control Unit oriented as shown on the panel.
- Connect the Ultrasonic Unit Cable to the Control Unit and Ultrasonic Unit. An audible click is evident with proper insertion.
- Plug the AC Power Cord into a suitable wall outlet.
- Turn ON the Control Unit; 'START' display is set to two (2) minutes.
- Timer may be reset to 2:00 by pressing RESET button at the bottom right corner of the display.

After pressing Start:

- The system will begin to countdown from 2:00 to 0:00.
- The Blue LED lights inside the Ultrasonic Unit will illuminate, indicating that the ultrasonic vibration is working as intended.
- Normally, an audible, pulsing hiss may be heard. If desired, operator may PAUSE treatment, reposition Mouthpiece on teeth and press START again.

- When PAUSE is pressed, the countdown stops, and the remaining treatment time is displayed.
- A Warning is displayed if the Ultrasonic Unit Cable is not properly connected; a notification signal will be heard until Cable is reconnected.
- Error display will be shown if the system malfunctions. (Contact customer service if this error is persistent).
- SMILE WITH CONFIDENCE is displayed when the 2 minute treatment has successfully completed.
- The display will automatically change to a slide show after 30 seconds. Touch display to return to START screen.

TREATMENT PROCEDURE

1. Determine the tooth shade of patient before treatment by following the standard practice of care using a shade guide.
2. Generously apply Vitamin E or petroleum jelly on the lips.
3. Patient rinses with 10 mL of Pre-rinse for 30 seconds.
NOTE: The rinse promotes balanced pH in the patient's mouth which improves the effect of the whitening treatment.
4. Attach Mouthpiece onto Ultrasonic Unit- MUST BE TIGHT.
NOTE: The Mouthpiece should FULLY ENGAGE onto the Ultrasonic Unit, and should be firmly tightened into position for the system to operate properly.
5. Roll & insert gauze pads on gums top and bottom; insert oral retractor into patient's mouth; place safety glasses on patient to protect the eyes.
NOTE: The 3rd gauze pad may be draped on bottom lip for comfort.
6. While patient is rinsing, soak Foam Pad with 6 mL of Gel.
NOTE: Inject Gel into individual Foam Pad zip-lock bag. Close bag and knead Gel into Foam Pad to evenly distribute in pad.
7. Place Foam Pad onto sterile Mouthpiece by fitting straps of foam pad behind arch of mouthpiece.
8. Position the stand and arm while holding the Ultrasonic Unit firmly. Then align