A Clinical Evaluation Pilot Study Evaluating Signs and Symptoms of Dry Eye Disease Following Tranquilvibes Moist-Heat Vibration Therapy

Sponsor: Eye Eco Inc.

Protocol: EETranquilvibes_010

Principal Investigator: Leslie O'Dell, OD

Questions about this study?
Contact Eye Eco Inc. at 888-730-7999 extension 600

A Clinical Evaluation Pilot Study Evaluating Signs and Symptoms of Dry Eye Disease Following Tranquilvibes Moist-Heat Vibration Therapy

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Protocol Number: EETranquilvibes_010

Phase: 4 - Pilot Study

Test Device: Moist-heat vibration therapy; Tranquilvibes™

Study Objectives: This pilot study is designed to determine the effects on signs and symptoms of Dry Eye following application of heat (between 102°F - 108°F) and vibration (180MHz) using the Class I Tranquilvibes™ moist-heat vibration therapy device.

Study Population: Up to 20 patients up to 85 years of age of any race and gender with demonstrated dry eye disease as documented in the TFOS DEWS II® report.

Study Design:

- **Structure:** Randomized, Study Observer Masked, Multi-Center
- **Duration:** Approximately 45 days
- **Number of Centers:** 2 or more
- **Control:** Randomized treatment option
- **Treatment Regimen:** In this randomized treatment option design, the patient will be assigned either tranquileyes XL or tranquilvibes treatment per randomization.
  - The non-masked investigator will provide randomized treatment selection and may also take Informed Consent, Demographic Medical History, VA and IOP measures as needed.
  - All objective study measures will be performed by the masked reader. This includes slit-lamp exam, tear breakup time (TBUT), corneal and conjunctival staining, Meibomian Gland Evaluation (MGE).

- **Summary of Visit Schedule:**
  - Visit 1: Day 0-Screening/Eligibility, baseline dry eye examination and symptom questionnaire, ocular surface evaluation
  - If eligible, patient will be randomly given either the tranquilvibes™ device or the tranquileyes XL (Control) device.
  - Visit 2: Day 30 (+ 3 days) – Study measures will be taken and the patient will exit
  - After study exit, patients will have the option to keep the device with an additional supply of items to continue therapy at home based on the physicians recommendations.
- Outcomes - to be measured at each visit
  - Efficacy:
    - Overall dry eye symptoms measured by SPEED & DEQ 5 (see Attachments 2 and 3)
    - Meibomian Gland Evaluation (MGE) evaluating meibomian gland function and secretion quality
    - Meibography for structure – grading atrophy using Pult Scale – see attached
    - Slit-lamp examination
    - Tear film break up time (NITBUT)
    - Corneal fluorescein staining after 3 minutes (superficial punctate keratitis, SPK)
    - Lissamine green staining 5 µL after 2 minutes to evaluate line of Marx
  - Safety Measures:
    - Best Corrected logMAR Visual Acuity
    - Intraocular pressure (IOP)
    - Adverse event (reported and observed)

Schedule Of Visits

Visit Schedule	Visit 1 (Day 0)	Home (Day 1-29)	Visit 2 (Day 30)
Procedures/Non-Procedure Description	Screening Measures 1st Treatment Measures	Tx's 2-30	Measures Get Data
Investigator Inclusion/Exclusion Criteria Review	X		
Informed Consent & HIPPA	X		
Review Medical History and Concurrent Medications	X		
Pregnancy test if patient indicates pregnancy	X		
SPEED Questionnaire	X		X
DEQ-5 Questionnaire	X		X
Best-corrected distance VA logMAR	X		X
Meibography (LipiView II)	X		X
Lipid Layer Thickness, LLT (LipiView II)	X		X
Meibomian Gland Evaluation (MGE), Number glands open	X		X
Meibomian Gland Evaluation (MGE), Grade secretion quality	X		X
Slit-lamp Examination	X		X
Tear Film Break up (NITBUT)	X		X
NaFL Corneal Staining (SPK)	X		X
Lissamine Green Staining	X		X
IOP	X		X
Subjective Efficacy Indicators	X		X
Tranquilvibes Procedure by Clinical Staff	X		
Manual Gland Expression	X		
Record Data	X	X	X
Start Home Therapy - Random XL or Vibes		X	

Inclusion Criteria

1. All subjects must meet the following criteria:
2. Subjects up to age of 85 years of age of any gender or any race.
3. The informed consent document must be read, signed, and dated by the subject or legally authorized representative before conducting the Screening Visit. Additionally, the informed consent document must be signed and dated by the individual obtaining consent from the subject, as well as signed and dated by a witness, if applicable.
4. Subjects must demonstrate the following to be included in the study.
   - Subjective and objective indicators for dry eye disease
   - SPEED score ≥ 8 / DEQ-5 score ≥ 6
   - Average TFBUT < 10 sec OU
5. Since this treatment does not use any systemic drugs, women will not be excluded or have a pregnancy test unless they indicate they are pregnant or nursing.
6. Subjects who are willing and able to appear at all scheduled in-office study visits.
7. Subjects able to follow instructions.
8. Subjects using artificial tears may be enrolled but they must remain on the same stable dosage regimen that they were on before Day 0 and remain on that dosage regimen throughout the study duration.
9. Subjects currently using RESTASIS® or Xiidra® may be enrolled if they have been on a stable dosage for 30 days prior to Day 0 and remain on a stable dosage regimen throughout the study duration.
10. Subjects who are taking systemic medications (including Vitamins A & B, and dietary omega-3 supplements) may be enrolled in the study if they have been on a stable dosing regimen for at least 30 days prior to the Screening Visit (Visit 0) and continue throughout the study duration.

Exclusion Criteria

1. Periorbital surgery or Rhytidoplasty in the past 6 months
2. Intraocular surgery in either eye within 3 months prior to the Screening Visit (Visit 1).
3. Evidence of active intraocular inflammation in either eye (i.e., cell/flare).
4. Evidence of severe Meibomian Gland Dropout (Grade 4 on meibography)
5. Ocular trauma within three months prior to the Screening Visit (Visit 0) in either eye, as determined by subject history and/or examination.
6. Evidence in either eye, as determined by subject history and/or examination within three months of the Screening Visit (Visit 0), of any of the following:
   - Herpes keratitis
   - Vaccinia virus
   - Active or recent varicella
   - Bacterial disease of the cornea, conjunctiva, or eyelids requiring treatment
   - Mycobacterial infection
   - Fungal disease
7. Chronic or recurrent uveitis or other inflammatory eye disease (e.g., scleritis) in either eye, as determined by subject history and/or examination.
8. Subjects with lid surface abnormalities that affect lid function.
9. Dry eye due to any of the following conditions:
   - Severe meibomian gland drop-out ($\geq$ 4)
   - Active Stevens-Johnson syndrome
   - Sjögren syndrome
   - Riley-day syndrome
   - Sarcoidosis
   - Leukemia
   - Ocular trauma
   - Chemical burns
   - Nerve paresis
10. Subjects with end stage salivary gland or lacrimal gland dysfunction, hepatitis C infection, HIV, or Graft vs. Host disease.
11. History of radiation therapy to the head above the angle of the jaw.
12. Subjects who are using systemic medications (including Vitamins A&B, and dietary omega-3 supplements) must be excluded from the study if they have not been on a stable dosing regimen for a minimum of 30 days prior to the Screening Visit (Visit 0). Subjects who are unwilling or unable to remain on this stable-dosing regimen for the duration of the study must be excluded.
13. Subjects using doxycycline will be excluded.
14. Therapy with another investigational agent or device within 30 days before the Screening Visit.
15. Subjects who are currently enrolled in another clinical trial.
16. Subjects who are unable to return for all in-office study visits as scheduled
17. Subjects who use the TrueTear® device.

18. Subjects who are pregnant or nursing.

Introduction

As stated in the TFOS DEWS II® Definition and Classification Report, “The last three decades have seen the awareness of dry eye disease (DED) rise considerably around the world. Through the mutual efforts of many organizations, much has been learned about the basis and impact of this disease in the continued attempt to improve clinical care for affected individuals.”

Tranquilvibes moist-heat vibration therapy is an FDA Class 1 medical device and indicated for use on closed eyelids. It has been shown to be well tolerated and safe. The device delivers sustaining temperatures between 102°F - 108°F for 5-20 minutes while applying gentle, safe vibration frequency of at 180 MHz (±5MHz) enhancing the controlled moist-heat therapy with peri-orbital vibration.

Materials and Methods

Patients with dry eye disease will be recruited for enrollment using the following criteria.

Enrollment Criteria:

- SPEED score ≥ 8
- DEQ-5 score ≥ 6 KCS, ≥ 12 suspect
- Measured by the LipiView 2 instrument using a cut-off value of < 75-nm lipid layer thickness for the detection of MGD, but its diagnostic contribution to DED has not been established [2]
- Non-Invasive Tear Breakup Time (NIBUT, < 10 seconds.

Screening Visit 1 Day 0:

Eligibility is determined and baseline study measures taken. After eligibility is determined, the treatment will be randomized whether they receive the Tranquilvibes or Tranquileyes device. The initial treatment and explanation will serve as education for the patient to continue to administer treatment on a daily regimen at home. The patient will be informed and responsible for completing a treatment tracking form logging the time and duration of the treatment as well as any other observations.

Time of treatment is approximately 15 minutes.

See Attachment 3 for Tranquilvibes™ directions for use.

Immediately following the moist heat therapy, the patient will undergo manual gland expression (on initial visit only).

Visits 2 Day 30:

Patients will return to the clinic and study measures taken. Patients will exit the study at this visit and no treatment will be done at this visit.

After exiting from the study, patients will be given the device, an additional supply of items to be able to continue therapy at home. The patient will be informed how to purchase additional supplies as they need them.

Primary Measures

- Symptom Questionnaire(s)
- Visual Acuity (UCVA / BCVA?)
- Corneal Staining
- Tear Film Instability (FBUT, TBUT, NITBUT)

Secondary Measures

- Meibography
- Lipid Layer Thickness (LLT)
- Meibomian Gland Evaluation (MGE)
    - Number of Glands Secreting
    - Grade Secretion Quality
- Slit-lamp Evaluation
- Lissamine Green Staining
- Ocular Surface Staining Staining (Fluorescence)
- Intraocular Pressure (IOP)
- Subjective Efficacy Indicators

Diagnostic Methodology

Since dry eye disease is so complex and mulit-factorial, the investigators of this study have outlined below the diagnostic methods to be used in this study based on the 2017 TFOS DEWS II® reports [1].

Visual Disturbance

Symptom Questionnaire

Questionnaire	Primary & Recent References	Dry Eye Screening Criteria	Type of Validation
5-Item Dry Eye Questionnaire (DEQ-5)	Primary: Chalmers et al. (2010) Recent: Camp et al. (2015) Galor et al. (2015) Fernandez et al. (2013)	≥ 6 KCS ≥ 12 suspect SS	Discriminant focus ADDE Subgroup Glaucoma Across post traumatic stress disorder, Depression
Standard Patient Evaluation of Eye Dryness (SPEED)	Primary: Blackie et al. (2009) Recent: Asiedu et al. (2016) Finis et al. (2014)	Concurrent with OSDI Concurrent with OSDI ≥ 8	Frequency & Intensity Better for MGD Dry Eye

Functional Tests

- Functional Visual Acuity (FVA)
- Slit-lamp Evaluation (SLE)

Test	Description
FVA	Functional visual acuity
SLE	Eyelashes (Anterior Blepharitis, Demodex infestation)
SLE	Eyelid (Palpebral conjunctiva for MGD, follicles/swelling)
SLE	Eyelid (bulbar conjunctiva for redness pattern, signs of swelling)
SLE	Cornea (ulceration, staining, trauma)
SLE	Anterior chamber for intraocular inflammation (presence of cells or flare)

Tear Film Stability

Ocular Surface Staining

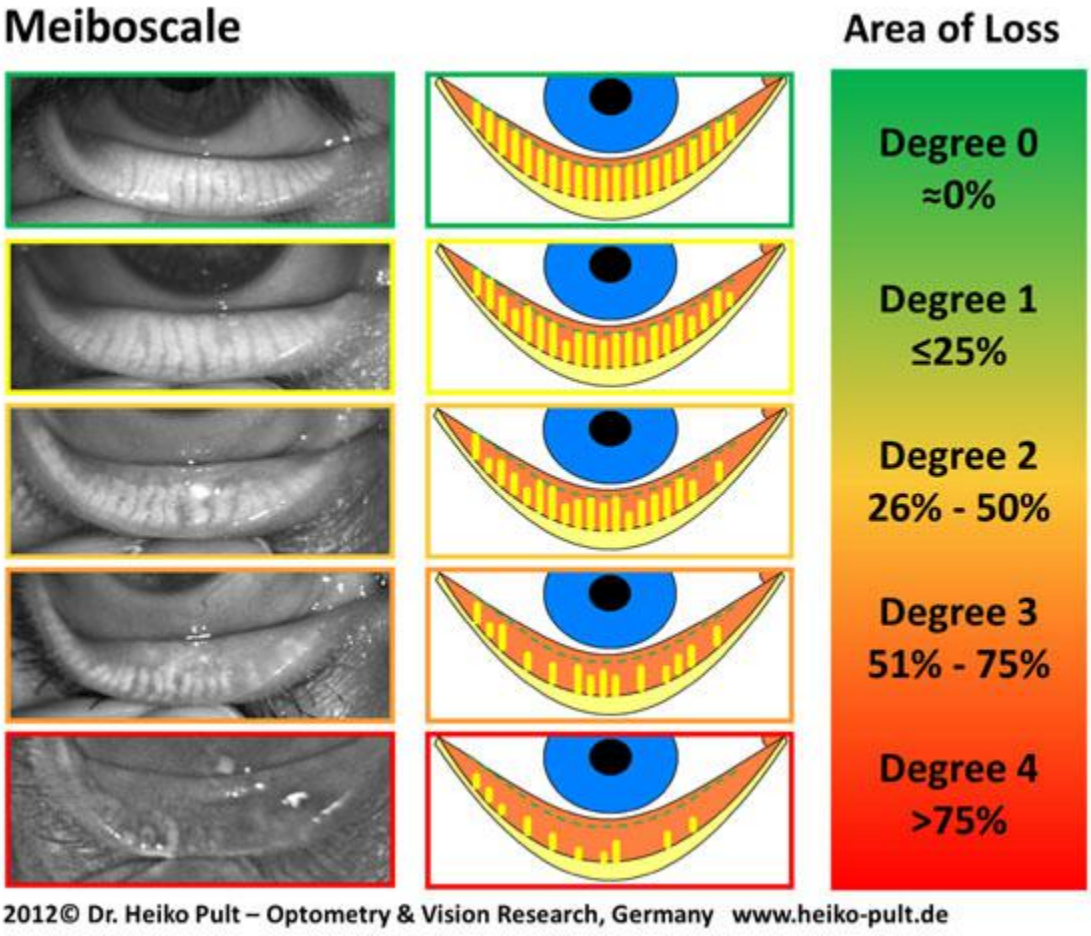
Test	Description
TBUT	Tear Break-Up Time
NIBUT	Using the Medmont topographer - Non-invasive breakup time should be performed with a method where as much of the naturally exposed cornea as possible is specularly illuminated with a light source allowing observation of breakup over the whole surface, after a blink. Objective methods are preferred, with three measurements being performed and the median value recorded. Following training, if a patient can no longer refrain from blinking before the tear film breaks up, this is typically counted as the breakup time for that measurement. The lower median breakup value of the two eyes should be considered in making the diagnosis. The cut-off for a positive finding can be as low as 2.7 s for automated algorithms, and up to 10 s for subjective observation techniques.
FBUT	FBUT can be considered when non-invasive techniques are not available, but due to its more invasive nature, **should follow after osmolarity measurement**. Fluorescein should be instilled at the outer canthus to avoid ocular surface damage with the excess saline on the strip shaken off, or a reduced area fluorescein strip used. For optimal results, viewing should take place between 1 and 3 min after instillation. A positive finding has been reported to be a value < 10 seconds although in some studies the average in healthy middle aged patients is noted to be lower than this.
SPK	Punctate staining of the ocular surface is a feature of many ocular diseases and instilled dyes are used extensively in the diagnosis and management of DED. The most frequently used dyes are sodium fluorescein, rose bengal, and lissamine green
Lissamine	A lissamine green strip will be wet using a drop of saline and the lissamine green vital dye will be applied the inferior temporal bulbar conjunctiva as the patient is instructed to look up. After 90 seconds, evaluation of the cornea and conjunctival tissues will be performed at the slit lamp. This is concurrent with the TFOS DEWS II® findings[1]
Fluorescein	Principally for assessing corneal damage, fluorescein should be instilled similar to lissamine, but with the excess saline on the strip shaken off to instill a minimal volume. Optimal viewing is between 1 and 3 min after instillation. A positive result is > 5 corneal spots.

Inflammation

Method	Description
Observation	Ocular/conjunctival redness

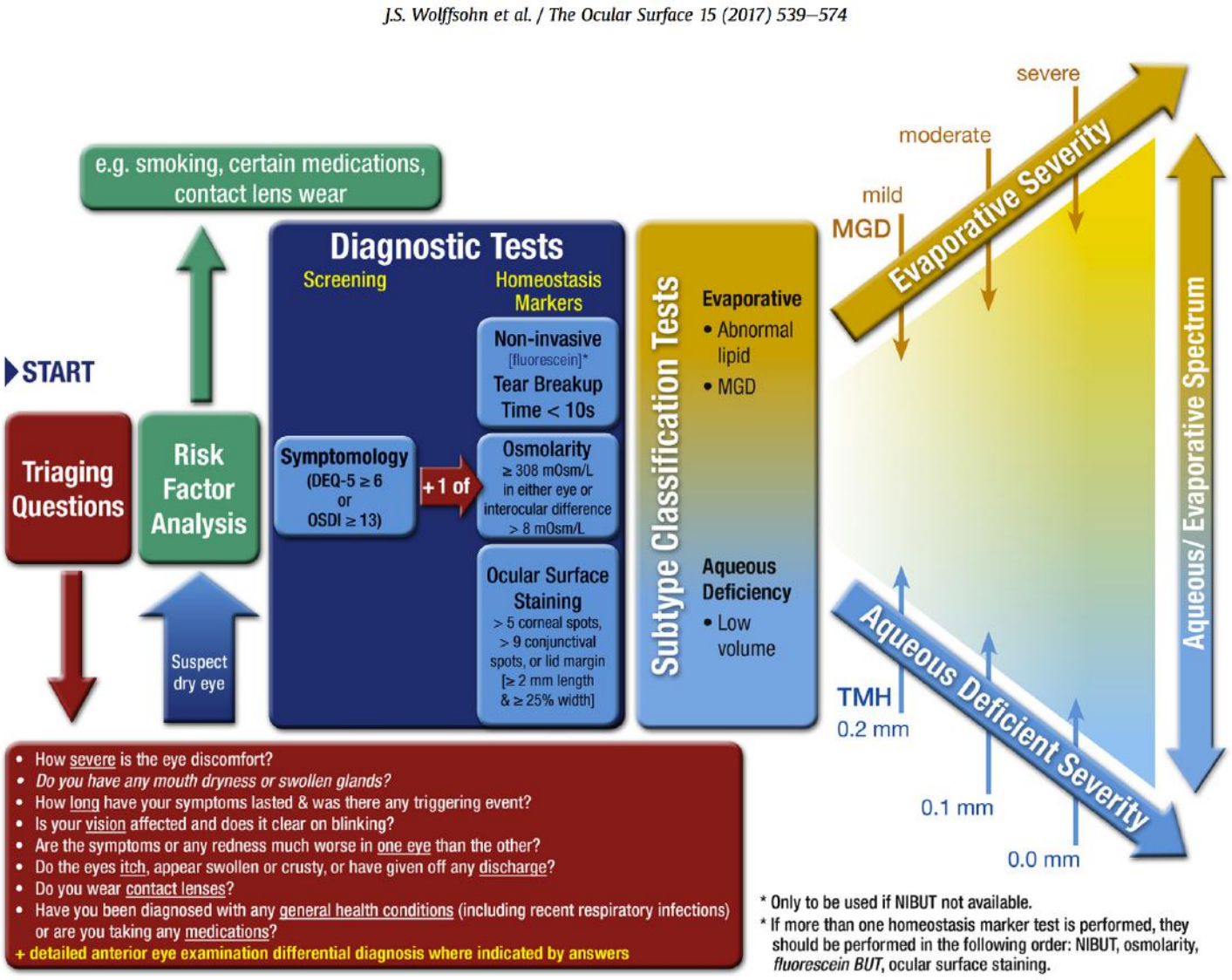
Eyelid

Method	Description
Interferometry	LipiView II
Meibography	observation of the silhouette of the meibomian gland morphological structure using LipiView II
MGE	Meibomian gland expressibility/duct assessment



- Meibomian gland expressibility/duct assessment

Clinical Protocol for dry eye diagnostic test battery (TFOS DEWS II®)



Protocol - Tranquilvibes™

PRE-PROCEDURE PREPARATIONS

1. **Gather Materials:**

Tranquilvibes™ materials:

- One (1) Tranquilvibes™ moist-heat vibration therapy device
- One (1) Soothing Eye Mist
- One hundred (100) Cotton liners (Single Use)
- Seven (7) sets of Thermoeyes™ Instants providing 1000+ treatments
- One (1) black USB Tranquilvibes™ power cord
- One (1) Tranquilvibes™ battery with white USB cord for charging
- One (1) Portable Tranquilvibes™ hands-free pouch
- One (1) Microfiber bag for storage
- Two (2) sets of fabric pockets

From Clinician's Office:

- List any items needed in clinicians office to perform study

2. **Patient Consent and Medical History Forms.**

PROCEDURE

1. **Tranquilvibes™ Instructions:**
    1. Plug black USB power cord into Tranquilvibes™ goggle.
    2. Moisten white fabric pockets in bottled water
    3. Activate blue Thermoeyes™ xl gel packs:
        - Hold gel pack in a vertical position lengthwise so the internal metal disc floats down to the narrow end of the gel pack.
        - Use thumb and forefinger of both hands to grasp the opposite edges of the disc.
        - Bend the disc back and forth and make the clicking sound until the fluid starts to crystallize and generates heat
    4. Insert activated gel pack into moistened fabric pocket
    5. Gently lift vibration ring up and place moistened pocket with activated gel pack into eye cup. Repeat on other side.
    6. Place disposable cotton liner over vibration rings.
    7. Moisten cotton liner with Soothing Eye Mist™
    8. Attach black USB cord to blue battery pack.
    9. Place battery pack into blue carrying pouch. Optionally, add a music source to pouch to enjoy during your Tranquilvibes™ treatment.
    10. Place pouch around neck.
    11. Set timer for 20 minutes in order to maintain therapeutic endpoint for 10-15 minutes.
    12. Place mask over closed eyelids and secure by slipping head strap over the back of the head.
    13. Relax and enjoy the vibes!
    14. Remove Tranquilvibes™ mask when timer goes off.
    15. Unplug black USB cord from blue battery pack.
    16. Dispose of cotton liner.
2. **Therapeutic Endpoint:** Based on patient tolerance and area treated, maintain between 102°F - 108°F for 10-15 minutes for the suggested treatment time. Slight erythema may be present at the end of treatment and will resolve within minutes after therapy.

See Attached PDF: Tranquilvibes™ Directions for use.pdf

Protocol - Tranquileyes™ XL

PROCEDURE

1. Moisten white fabric pockets in bottled water
2. Activate blue Thermoeyes™ xl gel packs:
   - Hold gel pack in a vertical position lengthwise so the internal metal disc floats down to the narrow end of the gel pack.
   - Use thumb and forefinger of both hands to grasp the opposite edges of the disc.
   - Bend the disc back and forth and make the clicking sound until the fluid starts to crystallize and generates heat
3. Insert activated gel pack into moistened fabric pocket
4. Place moistened fabric pocket with activated gel pack into the goggle eye cup. Repeat on other side.
5. Place Tranquileyes XL mask over closed eyelids and secure by slipping head strap over the back of the head.
6. Wear for up to 20 minutes.
7. Remove Tranquileyes XL mask

POST-PROCEDURE PREPARATIONS

1. Resetting Instant Thermoeyes™ XL - The XL instants need to be reset after each use. To reset:
   1. Submerge hardened Thermoeyes™ xl in boiling water. Boil for 3-5 minutes (do not leave. unattended).
   2. Carefully remove Thermoeyes™ xl with a spoon and place on towel to cool. Do not handle while cooling. The gel packs should be ready for reuse in approximately 30 minutes.
2. Tranquilvibes™ Precautions:
   1. Consult eye doctor prior to use.
   2. Do not use when operating equipment, machinery or while walking around.
   3. Do not microwave Thermoeyes™ xl.
   4. Discontinue use if you experience any eye irritations.
3. Cleaning Tranquilvibes™ - Hand wash white pockets with warm water and Gentle Tea Tree Cleanser after each use. Rinse well and air dry. Hand wash goggle the same way as needed.
4. Recharging Tranquilvibes™ - battery pack comes fully charged with 7 hours of use. To Recharge:
   1. Unplug Tranquilvibes™ goggle from battery pack.
   2. Plug white USB charging cord into battery pack.
   3. Insert USB end of cord into power box or computer.
   4. For a full charge, leave plugged in overnight.

Questionnaires

DEQ-5 Patient Questionnaire

1. Questions about **EYE DISCOMFORT**:
   a. During a typical day in the past month, **how often** did your eyes feel discomfort?
      0 Never
      1 Rarely
      2 Sometimes
      3 Frequently
      4 Constantly
   b. When your eyes felt discomfort, **how intense was this feeling of discomfort** at the end of the day, within two hours of going to bed?

Never have it	Not at all Intense				Very Intense
0	**1**	**2**	**3**	**4**	**5**

2. Questions about **EYE DRYNESS**:
   a. During a typical day in the past month, **how often** did your eyes feel dry?
      0 Never
      1 Rarely
      2 Sometimes
      3 Frequently
      4 Constantly
   b. When your eyes felt dry, **how intense was this feeling of dryness** at the end of the day, within two hours of going to bed?

Never have it	Not at all Intense				Very Intense
0	**1**	**2**	**3**	**4**	**5**

3. Question about **WATERY EYES**:
   During a typical day in the past month, **how often** did your eyes look or feel excessively watery?
      0 Never
      1 Rarely
      2 Sometimes
      3 Frequently
      4 Constantly

Score: 1a + 1b + 2a + 2b + 3 = Total
___+___+___+___+___= ____

Figure 3 The DEQ-5 (5-item Dry Eye Questionnaire), which is designed for patient self-assessment of dry eye severity on a typical day during the past month.
Notes: A composite score >6 suggests dry eye.

SPEED Patient Questionnaire

SPEED™ QUESTIONNAIRE

Name: _____ **Date:** ____/____/____ **Sex:** M F (Circle) **DOB:** ____/____/____

For the Standardized Patient Evaluation of Eye Dryness (SPEED) Questionnaire, please answer the following questions by checking the box that best represents your answer. Select only one answer per question.

1. Report the type of SYMPTOMS you experience and when they occur:

	At this visit		Within past 72 hours		Within past 3 months	
Symptoms	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
Dryness, Grittiness or Scratchiness						
Soreness or Irritation						
Burning or Watering						
Eye Fatigue						

2. Report the FREQUENCY of your symptoms using the rating list below:

Symptoms	**0**	**1**	**2**	**3**
Dryness, Grittiness or Scratchiness				
Soreness or Irritation				
Burning or Watering				
Eye Fatigue				

0 = Never **1** = Sometimes **2** = Often **3** = Constant

3. Report the SEVERITY of your symptoms using the rating list below:

Symptoms	**0**	**1**	**2**	**3**	**4**
Dryness, Grittiness or Scratchiness					
Soreness or Irritation					
Burning or Watering					
Eye Fatigue					

0 = No Problems
1 = Tolerable - not perfect, but not uncomfortable
2 = Uncomfortable - irritating, but does not interfere with my day
3 = Bothersome - irritating and interferes with my day
4 = Intolerable - unable to perform my daily tasks

4. Do you use eye drops for lubrication? ☐ **YES** ☐ **NO** **If yes, how often?** _____

Cornea. 2013 Sep;32(9):1204-10

13-ADV-123 A

For office use only
Total SPEED score (Frequency + Severity) = ____/28

Tranquilvibes Directions for Use

Page 1

DIRECTIONS FOR USE

1 Clean eyelids and surrounding skin as directed with enclosed Gentle 1% Tea Tree Cleanser. Rinse well with warm water.

2 Plug black USB power cord into tranquilvibes™ goggle.

3 Moisten white fabric pockets in bottled water.

4 Activate blue thermoeyes™ xl gel packs:
- Hold gel pack in a vertical position lengthwise so the internal metal disc floats down to the narrow end of the gel pack.
- Use thumb and forefinger of both hands to grasp the opposite edges of the disc.
- Bend the disc back and forth and make the clicking sound until the fluid starts to crystallize and generates heat.

5 Insert activated gel pack into moistened fabric pocket.

6 Gently lift vibration ring up and place moistened pocket with activated gel pack into eye cup. Repeat on other side.

7 Place disposable cotton liner over vibration rings.

8 Moisten cotton liner with Soothing Eye Mist™.

9 Attach black USB cord to battery pack.

10 Place battery pack into blue carrying pouch. Optionally, add a music source to pouch to enjoy during your tranquilvibes™ treatment.

11 Place pouch around neck.

12 Set a timer for 20 minutes.

13 Place mask over closed eyelids and secure by slipping head strap over the back of the head.

14 Relax and enjoy the vibes!

15 Remove tranquilvibes™ mask when timer goes off.

16 Unplug black USB cord from blue battery pack and tranquilvibes™ goggle.

17 Dispose of cotton liner.

3

CARE INSTRUCTIONS

RESETTING INSTANT THERMOEYES™ XL

THE XL INSTANTS NEED TO BE RESET AFTER EACH USE.
TO RESET:

1. Submerge hardened thermoeyes™ xl in boiling water. Boil for 3-5 minutes (do not leave unattended).

2. Carefully remove thermoeyes™ xl with a spoon and place on towel to cool. Do not handle while cooling. The gel packs should be ready for reuse in approximately 30 minutes.

Warnings:
Do not leave boiling water unattended.
Do not microwave.

Video instructions available online at eyeeco.com/watch-the-video.html

5

CLEANING TRANQUILVIBES™

Hand wash the white pockets with warm water and Gentle Tea Tree Cleanser after each use. Rinse well and air dry. Hand wash the goggle the same way as needed.

RECHARGING TRANQUILVIBES™

BATTERY PACK COMES FULLY CHARGED WITH 7 HOURS OF USE.
TO RECHARGE:

1. Unplug tranquilvibes™ goggle from battery pack.

2. Plug white USB charging cord into battery pack.

3. Insert USB end of cord into power box or computer.

4. For a full charge, leave plugged in for approximately 5-7 hours.

   a. Battery charge light will remain the same color when fully charged.

TRANQUILVIBES™ PRECAUTIONS

1. Consult eye doctor prior to use.
2. Do not use when operating equipment, machinery or while walking around.
3. Do not microwave thermoeyes™ xl.
4. Discontinue use if you experience any eye irritations.

WARRANTY & RETURNS

Our tranquilvibes™ product is guaranteed against manufacturer's defect (from date of purchase) for a maximum of six (6) months. Parts covered under the tranquilvibes™ Warranty will be replaced or repaired at Eye Eco's discretion. Some parts, such as the battery pack and USB cord, are not covered.
For information regarding tranquilvibes™ Warranty, as well the tranquilvibes™ Returns & Exchanges policy, please call us toll free at 1.888.730.7999 ext. 601 or email us at customerservice1@eyeeco.com – we are happy to assist you!

Patient Therapy Tracking Log

I am using: □ Tranquilvibes | □ Tranquileyes XL

Day	ID	Date	Time	Comments
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References

[1] James S. Wolffsohn, FCOptom, PhD et al. TFOS DEWS II® Diagnostic Methodology report. The Ocular Surface 15 (2017) 539e574

[2] Finis D, Pischel N, Schrader S, Geerling G. Evaluation of lipid layer thickness measurement of the tear film as a diagnostic tool for Meibomian gland dysfunction. Cornea 2013;32:1549e53.

[3] "General Controls for Medical Devices". *Medical Devices*. U.S. Food and Drug Administration. Retrieved 2010-10-15.

[4] "General and Special Controls". *Medical Devices*. U.S. Food and Drug Administration. Retrieved 2010-10-15.