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TearCare® System

Instructions For Use

TearCare® System

TEARCARE.COM

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1. INTRODUCTION

1.1 CONTACTING SIGHT SCIENCES

All questions or concerns about the TearCare® System products should be directed to:

Sight Sciences, Inc.
4040 Campbell Ave.
Suite 100
Menlo Park, CA 94025

Telephone: (877) 266-1144

Website: www.sightsciences.com

2. TEARCARE SYSTEM INFORMATION

2.1 INDICATIONS FOR USE

The TearCare® System is intended for the application of localized heat therapy in adult patients with evaporative dry eye disease due to meibomian gland dysfunction (MGD), when used in conjunction with manual expression of the meibomian glands.

2.2 CONTRAINDICATIONS

TearCare is contraindicated for patients with the following conditions. Use of the device in patients with these conditions may cause serious injury or exacerbation of the condition.

- Recent (i.e. within the last 90 days) surgical procedure to the eye or eyelid.
- Recent ocular injury.
- History of Herpes Simplex or Herpes Zoster of the eye or eyelid.
- Active ocular or periocular infection, inflammation or irritation.
- Diminished or abnormal facial, periocular, ocular, or corneal sensation.
- Ocular surface ulcers.
- Hordeolum, stye, or chalazion.
- Do not use TearCare in patients under the age of 22 years.
- Pacemakers or implantable cardiac defibrillators (ICD). Use of the TearCare System may affect the performance of pacemakers or ICD's due to electromagnetic interference (EMI). To avoid any potentially serious safety effects, patients with these implants should not be treated with the TearCare System.
- Known allergy to acrylate.
- Known allergy to silicone tissue adhesives.
- Known allergy to copper.

2.3 WARNINGS

- Do not use the TearCare System outside the instructions for use described in this manual. Doing so can result in unanticipated patient harm.
- Do not attempt to connect the SmartHub or SmartLid directly to an electrical outlet of any kind.
- Do not use the TearCare System in or near an MRI suite or near a magnetic field. Serious injury can occur to a patient or technician if a TearCare system is brought into an MRI suite.
- The TearCare System has not been tested in the presence of flammable anesthetics or other flammable agents in combination with air, nitrous oxide, or oxygen enriched environments.
- Do not apply SmartLids to non-intact skin (i.e., skin with active abrasion, cut, burn, rash, inflammation, redness, etc.)

2.4 PRECAUTIONS

- Use of the TearCare System in patients with eyelid abnormalities (e.g., entropion, ectropion, tumor, edema, blepharospasm, lagophthalmos, severe trichiasis, severe ptosis, etc.) may result in poor adhesion of the SmartLid to the eyelid and/or reduced benefit.
- Use caution when using the TearCare System in patients with ocular surface abnormalities (e.g. pterygium, pingueculum, corneal dystrophies, etc.) as the heat delivered by TearCare may aggravate these conditions.
- Remove contact lenses from the patient's eyes prior to use of TearCare. Patients should wait 60 minutes after the completion of the TearCare procedure before re-inserting contact lenses.
- Do not apply the SmartLids to any other part of the patient's body including the cornea. The SmartLids are only intended for application on the external surface of the patient's eyelids.
- It is important for patient to keep their eyes open (blinking is permitted) during treatment, to allow heat to dissipate off of the ocular surface.
- Effectiveness of the TearCare System has not been established in subjects for whom the treatment temperature is lowered from Warmth Level Setting #5 due to patient pain or discomfort.
- Do not reuse the SmartLids. Cross-contamination can occur if re-use is attempted.
- Do not use the TearCare System, its components, or accessories that appear damaged. Inspect all components for damage before each use.
- The safety and effectiveness of the TearCare System is not known in the following patient populations that were excluded in the OLYMPIA pivotal study: patients under 22 years of age, dry eye signs and symptoms other than meibomian gland dysfunction, severe signs and symptoms of dry eye due to meibomian gland dysfunction (OSDI > 79), mild signs and symptoms of dry eye due to meibomian gland dysfunction, and other study exclusions described in Section 2.7 "Clinical Study Summary."

2.5 POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of potential adverse effects that may be associated with use of the TearCare System. Adverse effects that occurred in the OLYMPIA pivotal clinical trial are indicated with an asterisk (*) and additional information regarding these adverse effects is summarized in Section 2.7 "Clinical Study Summary."

Potential adverse effects may include but are not limited to:

- Eyelid or eye pain requiring discontinuation of the treatment procedure
- Eyelid irritation or inflammation*
- Ocular surface irritation or inflammation*
- Ocular symptoms (such as burning, redness, tearing, visual disturbance, redness)
- Burning, erythema, or swelling of the eyelids
- Conjunctival infection (moderate or severe)
- Conjunctival abrasion
- Corneal abrasion
- Corneal deformation
- Allergic or inflammatory reaction to medical adhesive on the SmartLid device
- Formation of a chalazion or stye*

- Decline in visual acuity*
- Worsening of dry eye symptoms*
- Increased discomfort or pain of ocular surface (grittiness, foreign body sensation, etc.)
- Discomfort or pain of eyelids or orbit*

There is a potential risk of thermal injury to eye or eyelid based on the device design.

2.6 FOR PRESCRIPTION USE ONLY

Federal (USA) law restricts this device to sale, distribution, or use by or on the order of a physician. Physician training is required prior to use of the TearCare System.

2.7 CLINICAL STUDY SUMMARY

A prospective, multicenter, randomized, non-inferiority, masked, controlled clinical trial ("OLYMPIA") was performed to demonstrate the safety and effectiveness of a single TearCare System treatment compared to a single LipiFlow Thermal Pulsation System to treat adult patients with Meibomian Gland Dysfunction (MGD).

Study Design

This study was a prospective, randomized, single-masked, multi-center, non-inferiority, non-significant risk device study. Randomized subjects were followed for one month succeeding treatment with follow-up data collected at Day 1, Week 2, and 1 Month. A total of 235 subjects (470 eyes) from 10 investigative centers in the United States participated in the study, comprised of 169 female and 66 males, ages 22 to 91 years (mean = 55.9 ± 14.4 years). Subjects were randomized 1:1 to receive either a single TearCare System or LipiFlow System treatment. The TearCare treatment arm consisted of a 15-minute thermal procedure followed immediately (i.e., within 3 minutes) by manual expression of the meibomian glands using the Clearance Assistant. Study subjects were grouped into two cohorts to account for a SmartLid design change made during the study. There were 93 subjects in Cohort 1, comprised of 47 LipiFlow and 46 TearCare subjects treated with the prior SmartLid design. There were 142 subjects in Cohort 2, comprised of 73 LipiFlow and 69 TearCare subjects treated with the current SmartLid design. The effectiveness endpoints were assessed using data from Cohort 2 and the safety endpoints were evaluated separately for Cohort 1 and 2. The study procedures took place between March 2019 and February 2020.

Study Endpoints

The primary effectiveness endpoints included the mean change from baseline to 1-month in Tear Break-Up Time (TBUT) and Total Meibomian Gland Secretion Score (MGSS). Secondary effectiveness endpoints included the mean change from baseline to 1-month in Ocular Surface Disease Index (OSDI) score, corneal and conjunctival staining scores, Symptom Assessment in Dry Eye (SANDE) scores, Eye Dryness Score and meibomian gland health.

The primary safety endpoint was the incidence of ocular adverse events. The secondary safety endpoints included discomfort/pain during and after the procedure, change in Best Corrected Visual Acuity (BCVA), and change in intraocular pressure (IOP).

Description of Study Patients

To participate in the study, subjects were required to be at least 22 years of age with symptoms of dry eye in the past 3 months, regularly reported use of artificial tears or lubricants over the

past month to relieve dry eye symptoms, a Tear Break-up Time (TBUT) of ≤7 seconds in both eyes, an OSDI score of 23-79, and meibomian gland obstruction in both eyes based on a total Meibomian Gland Score ≤ 12 in each eye with at least 15 glands in each lower eyelid expressible with a sterile cotton swab at the Baseline visit.

Subjects could not participate in the study if they were using dry eye medications (such as lifitegrast, cyclosporine, antihistamines), or systemic medications (such as diuretics, anti-hypertensives) known to cause ocular dryness within specific timeframes prior to enrollment, prior dry eye treatments (such as laser, thermal pulsation, lid debridement, punctal plugs) within specific timeframes prior to enrollment, history of eyelid, conjunctiva or corneal surgery within the past year, use of bimatoprost, Retin A or isotretinoin, systemic diseases resulting in dry eye (such as Sjogren's syndrome, lupus, Grave's disease). Other exclusion criteria included history of ocular Herpes Simplex or Herpes Zoster, any active and clinically significant ocular or peri-ocular infection or inflammation or anterior blepharitis or eyelid abnormalities (such as entropion/ectropion, lagophthalmos) or dermatologic or cutaneous disease of the eyelid or periocular area or ocular surface abnormalities that may affect tear film distribution or treatment (such as pterygium, anterior membrane dystrophy) or conjunctivitis (such as allergic, vernal or giant papillary). Subjects were also excluded if they had corneal surface abnormalities (such as corneal epithelial defects, ulcers, dystrophies, keratoconus, ectatic disease), recurrent clinically significant eye inflammation (other than dry eye) or ocular trauma within 3 months prior to enrollment. Based on the clinical judgement of the investigator, subjects with meibomian glands having significant capping, atrophy or unable to be expressed were also excluded from the study.

Demographics

The mean age of all 235 enrolled and treated subjects was 55.9 ± 14.4 years. The gender of all randomized subjects was similar across treatment groups with a combined distribution of 169 (72%) female and 66 (28%) male subjects. The demographic of all study subjects was similar between the treatment groups. A summary of patient demographics is presented in Table 1.

Table 1. Baseline Demographics (Cohort 1 + Cohort 2)

	TearCare (n=115 subjects)	**Lipiflow (n=120 subjects)**	**Combined (n=235 Subjects)**
Age (years)			
n	115	120	235
Mean (SD)	57 (14.0)	55 (14.5)	55.9 (14.4)
Median	60	56.5	58.0
Range (min-max)	22 – 91	23 – 86	22 – 91
Gender n(%)			
Female	86/115 (74.8%)	83/120 (69.2%)	169/235 (71.9%)
Male	29/115 (25.2%)	37/120 (30.8%)	66/235 (28.1%)
Race, n(%)			
American Indian/ Alaska Native	2/115 (1.7%)	0/120 (0.0%)	2/235 (0.9%)
Asian	3/115 (2.6%)	5/120 (4.2%)	8/235 (3.4%)
Black or African American	4/115 (3.5%)	5/120 (4.2%)	9/235 (3.8%)

2. TEARCARE SYSTEM INFORMATION

	TearCare (n=115 subjects)	Lipiflow (n=120 subjects)	Combined (n=235 Subjects)
Indian	0/115 (0.0%)	0/120 (0.0%)	0/235 (0.0%)
Iranian	1/115 (0.9%)	0/120 (0.0%)	1/235 (0.4%)
Middle Eastern	0/115 (0.0%)	1/120 (0.8%)	1/235 (0.4%)
Spanish	1/115 (0.9%)	0/120 (0.0%)	1/235 (0.4%)
White	104/115 (90.4%)	109/120 (90.8%)	213/235 (90.2%)
Ethnicity, n(%)			
Non-Hispanic or Latino	94 (82.1%)	101/120 (84.2%)	195/235 (83.1%)
Hispanic or Latino	21 (18.3%)	19/120 (15.8%)	40/235 (17.0%)

Effectiveness Results

The primary effectiveness endpoints were defined as the change from baseline to 1 month for Tear Break-up Time (TBUT) and total Meibomian Gland Secretion Score (MGSS) for both treatment groups in Cohort 2. Subjects in both treatment groups demonstrated a statistically significant improvement in both endpoints and the TearCare arm of the study established non-inferiority relative to the LipiFlow arm for both TBUT and MGSS. Results are listed in Tables 2 and 3 below.

Table 2. Change in TBUT at 1 month compared to baseline (Cohort 2)

Visit Parameter Statistics	TearCare	LipiFlow
Baseline		
N (eyes)	134	136
TBUT		
mean(sd)	4.62 (1.19)	4.49 (1.05)
median	4.65	4.36
min, max	[1.12, 6.85]	[0.87, 6.92]
95% CI	[4.41, 4.82]	[4.32, 4.67]
Month 1		
N (eyes)	134	136
TBUT		
mean(sd)	7.64 (4.64)	7.08 (3.19)
median	6.59	6.39
min, max	[2.81, 32.50]	[2.94, 23.83]
95% CI	[6.84, 8.43]	[6.54, 7.62]
TBUT change-from-baseline		
mean(sd)	3.02 (4.41)	2.58 (3.28)
median	1.95	1.90
min, max	[-2.39, 28.00]	[-1.75, 20.79]
95% CI	[2.27, 3.78]	[2.03, 3.14]

Table 3. Change in MGSS at 1 month compared to baseline (Cohort 2)

Visit Parameter Statistics	TearCare	LipiFlow
Baseline		
N (eyes)	134	136
Total Meibomian Gland Secretion Score		
mean(sd)	6.54 (3.11)	6.29 (2.75)
median	7.00	6.00
min, max	[0.00, 12.00]	[0.00, 12.00]
95% CI	[6.01, 7.07]	[5.83, 6.76]
Month 1		
N (eyes)	134	136
Total Meibomian Gland Secretion Score		
mean(sd)	17.74 (11.63)	17.38 (11.08)
median	16.00	16.00
min, max	[0.00, 45.00]	[0.00, 41.00]
95% CI	[15.75, 19.73]	[15.50, 19.26]
Total Meibomian Gland Secretion Score change-from-baseline		
mean(sd)	11.20 (11.13)	11.09 (10.41)
median	8.00	8.00
min, max	[-8.00, 45.00]	[-8.00, 36.00]
95% CI	[9.30, 13.10]	[9.32, 12.85]

Results of the secondary endpoints for both treatment groups in Cohort 2 are presented in the following tables:

Table 4. OSDI – Mean change from baseline at 1-Month (Cohort 2)

Parameter	TearCare	LipiFlow
N (subjects)	67	68
Baseline (sd)	52.0 ± 14.4	51.1 ± 16.1
1-Month	24.2 ± 17.7	27.7 ± 19.6
change (sd)	-27.88 ± 20.5	-23.4 ± 17.7
min, max	-66.7, 35.0	-59.1, 30.2

Table 5. Change in Total Corneal Staining at 1 month compared to baseline (Cohort 2)

Visit Parameter Statistics	TearCare	LipiFlow
Baseline		
N (eyes)	134	136
Total Corneal Staining Score		
mean(sd)	2.51 (2.09)	2.51 (2.31)
median	2.00	2.00
min, max	[0.00, 9.00]	[0.00, 9.00]

Visit Parameter Statistics	TearCare	LipiFlow
Month 1		
N (eyes)	134	136
Total Corneal Staining Score		
mean(sd)	2.25 (2.19)	1.93 (2.16)
median	2.00	1.00
min, max	[0.00, 10.00]	[0.00, 9.00]
Total Corneal Staining Score change-from-baseline		
mean(sd)	-0.25 (1.98)	-0.57 (2.01)
median	0.00	0.00
min, max	[-7.00, 7.00]	[-7.00, 5.00]

Table 6. Change in Total Conjunctival Staining at 1 month compared to baseline (Cohort 2)

Visit Parameter Statistics	TearCare	LipiFlow
Baseline		
N (eyes)	134	136
Total Conjunctival Staining Score		
mean(sd)	4.08 (3.32)	4.85 (3.10)
median	3.00	4.00
min, max	[0.00, 18.00]	[0.00, 16.00]

Visit Parameter Statistics	TearCare	LipiFlow
Month 1		
N (eyes)	134	136
Total Conjunctival Staining Score		
mean(sd)	3.43 (2.75)	4.07 (3.96)
median	3.00	3.00
min, max	[0.00, 18.00]	[0.00, 18.00]
Total Conjunctival Staining Score change-from-baseline		
mean(sd)	-0.66 (2.26)	-0.78 (3.18)
median	-1.00	-1.00
min, max	[-7.00, 7.00]	[-8.00, 14.00]

Safety Results

The primary safety endpoint was defined as the incidence of ocular adverse events (AEs) and they are listed below in Table 7. No subject in either group experienced any serious adverse events or serious device related adverse events that required further management. There were 4 device related AEs in the TearCare group reported in 3 subjects (Chalazion-1, Superficial Punctate Keratitis-2, Blepharitis-1) and 7 device related AEs in the LipiFlow group reported in 4 subjects (Blepharitis-2, Foreign Body Sensation-3, Dry Eye Disease-2). In the TearCare group, the subject with chalazion required medication to resolve the event. In the LipiFlow group, one subject was prescribed warm compresses for blepharitis and another subject received medication to resolve

a foreign body sensation. The observed rate of device related AEs was 2.1% (n=2 AEs/92 eyes) and 2.1% (n=3 AEs/138 eyes) respectively in Cohort 1 and Cohort 2 of the TearCare group and 1.0% (n=1 AEs/94 eyes) and 2.1% (n=3 AEs/146 eyes) respectively in Cohort 1 and Cohort 2 of the LipiFlow group. There were 2.1% (n=1 subjects/46) of subjects in Cohort 1 and 4.3% (n=3 subjects/69) of subjects in Cohort 2 experiencing one or more device-related adverse events of the TearCare group and there were 2.1% (n=1 subjects/47) of subjects in Cohort 1 and 4.1% (n=3 subjects/73) of subjects in Cohort 2 of the LipiFlow group. The observed rate of ocular AEs of any type was 4.3% (4 eyes/92 eyes) and 3.0% (4 eyes/138 eyes) respectively in Cohort 1 and Cohort 2 of the TearCare group and 3.2% (3 eyes/94 eyes) and 3.4% (5 eyes/146 eyes) respectively in Cohort 1 and Cohort 2 of the LipiFlow group.

Table 7. Detailed list of ocular adverse events by treatment arm

Treatment Group	AE description	Relationship to Treatment	Serious	Action Taken	AE outcome
TearCare (Cohort 1)	Superficial Punctate Keratitis (SPK)	Probably Related	No	None	Resolved
	Superficial Punctate Keratitis (SPK)	Probably Related	No	None	Resolved
	Decrease in BCVA	Unlikely Related	No	None	Resolved
	Conjunctival Injection	Unlikely Related	No	None	Ongoing
TearCare (Cohort 2)	Chalazion	Definitely Related	No	Medication	Resolved
	Blepharitis	Possibly Related	No	None	Resolved
	Decrease in BCVA	Unlikely Related	No	None	Resolved
	Iritis	Definitely Unrelated	No	Medication	Resolved

Treatment Group	AE description	Relationship to Treatment	Serious	Action Taken	AE outcome
LipiFlow (Cohort 1)	Blepharitis	Possibly Related	No	Warm compresses	Unknown
	Epiphora	Unlikely Related	No	None	Ongoing
	Corneal Abrasion	Unlikely Related	No	Medication	Resolved
LipiFlow (Cohort 2)	Foreign Body Sensation	Possibly Related	No	Medication	Resolved
	Dry Eye Disease	Possibly Related	No	None	Resolved
	Foreign Body Sensation	Possibly Related	No	None	Resolved
	Decrease in BCVA	Definitely Unrelated	No	None	Ongoing
	Ocular Pain	Unlikely Related	No	None	Resolved

The secondary safety endpoints included measurement of study subject discomfort and pain during and after treatment, change in best corrected visual acuity (BCVA) and change in intraocular pressure (IOP).

There were subjects in both groups reporting pain and discomfort during and after the respective procedures. Subjects in the TearCare group initially reported higher pain/discomfort than LipiFlow subjects during and immediately following the procedure. However, by Day 1 the reported pain and discomfort was reduced and TearCare results were less than LipiFlow. Subjects were asked to indicate their level of pain and discomfort using a Visual Analog Scale with “0” indicating no pain/discomfort to “100” indicating worst or maximum pain/discomfort, as shown in Tables 8 and 9 below.

Table 8. Proportion of subjects reporting pain, stratified by treatment arm and cohort

	TearCare				LipiFlow		
Pain Thresholds	During Procedure N (%)	During Expression N (%)	After Procedure N (%)	1 day after procedure N (%)	During Procedure N (%)	After Procedure N (%)	1 day after procedure N (%)
	Cohort 1 (n=46)				**Cohort 1 (n=47)**		
0-39	43 (93.5%)	32 (69.6%)	44 (95.7%)	44 (95.7%)	45 (95.7%)	47 (100.0%)	45 (95.7%)
40-69	2 (4.3%)	12 (26.1%)	2 (4.3%)	1 (2.2%)	2 (4.3%)	0 (0.8%)	2 (4.3%)
70-100	1 (2.2%)	2 (4.3%)	0 (0.0%)	1 (2.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Cohort 2 (n=69)				**Cohort 2 (n=73)**		
0-39	63 (91.3%)	49 (71.0%)	65 (94.2%)	67 (96.5%)	72 (98.6%)	72 (98.6%)	70 (95.9%)
40-69	4 (5.8%)	16 (23.2%)	4 (5.8%)	2 (2.9%)	1 (1.4%)	1 (1.4%)	2 (2.7%)
70-100	2 (2.9%)	4 (5.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)

Table 9. Proportion of subjects reporting discomfort, stratified by treatment arm and cohort

	TearCare (n=115)				LipiFlow (n=120)		
Discomfort Thresholds	During Procedure N (%)	During Expression N (%)	After Procedure N (%)	1 day after procedure N (%)	During Procedure N (%)	After Procedure N (%)	1 day after procedure N (%)
	Cohort 1 (n=46)				**Cohort 1 (n=47)**		
0-39	34 (73.9%)	21 (45.7%)	42 (91.3%)	41 (89.1%)	37 (78.7%)	47 (100.0%)	40 (85.1%)
40-69	11 (23.9%)	17 (37.0%)	4 (8.7%)	4 (8.7%)	10 (21.3%)	0 (0.0%)	6 (12.8%)
70-100	1 (2.2%)	8 (17.4%)	0 (0.0%)	1 (2.2%)	0 (0.0%)	0 (0.0%)	1 (2.1%)

	TearCare (n=115)				LipiFlow (n=120)		
Pain Thresholds	During Procedure N (%)	During Expression N (%)	After Procedure N (%)	1 day after procedure N (%)	During Procedure N (%)	After Procedure N (%)	1 day after procedure N (%)
	Cohort 2 (n=69)				Cohort 2 (n=73)		
0-39	58 (84.1%)	36 (52.2%)	64 (92.8%)	61 (88.4%)	63 (86.3%)	71 (97.3%)	56 (76.7%)
40-69	9 (13.0%)	27 (39.1%)	5 (7.2%)	7 (10.1%)	9 (12.3%)	2 (2.7%)	13 (17.8%)
70-100	2 (2.9%)	6 (8.7%)	0 (0.0%)	1 (1.4%)	1 (1.4%)	0 (0.0%)	4 (5.5%)

One subject in the Cohort 1 and one subject in Cohort 2 of TearCare group and one in the Cohort 2 of LipiFlow group reported a decrease in visual acuity during the study. One subject treated in the Cohort 1 of TearCare group had a history of visual fluctuation in the right eye. The loss of visual acuity was reported at 2-weeks which was recovered at 1-month visit. A second TearCare study subject treated under Cohort 2 experienced loss of 10 letters at two weeks following treatment and the visual acuity further was reduced by 15 letters at one month compared to baseline. All other ocular findings for this subject were within the normal limits. The investigator suspects an error in visual acuity measurement and reported that it is highly likely that the uncorrected visual acuity was measured in place of best corrected visual acuity. Both AEs were categorized as “unrelated to device or procedure”. One subject treated in the Cohort 2 of LipiFlow group had a history of fluctuating vision in the left eye. The subject read 20 letters at baseline, 30 at 2-weeks and 10 at 1-month. The investigator did not consider this AE as device or procedure related. No other subjects reported any significant visual acuity change in either group compared to baseline.

The overall safety results are similar between the TearCare System subject device and the LipiFlow System predicate device with respect to the safety profile.

2.8 DEVICE DESCRIPTION

The TearCare System is designed to deliver controlled, precise heat to the tarsal plates and underlying meibomian glands of the eyelids for 15 minutes. The TearCare System is comprised of a re-usable SmartHub™ and accessories, and single use SmartLids®.

The TearCare System is comprised of the following components:

MODEL NUMBER	DESCRIPTION
5-116	TearCare SmartHub Kit, which includes:
5-101	TearCare SmartHub
VEP15US09	Charging Adapter (XP Power P/N VEP15US09)
5-102	Charging Nest
5-117	One (1) packaged pair of single-use TearCare SmartLids

The single use SmartLid pair comprises four flexible, sensor-controlled strips that adhere to each of the four eyelids. They contain flexible circuits, sensors and a microprocessor which provide accurate and precise thermal energy to the eyelids to melt oil in the meibomian glands. Medical grade adhesive on the skin-facing surface of the SmartLids allow them to be affixed to the external surface of the eyelids during the procedure and easily removed at the end of the procedure.

The SmartLids are connected to the SmartHub. When attached to the SmartHub, the SmartLids deliver thermal energy (i.e., heat) to the eyelids. Embedded software and a closed loop sensor system ensures that the temperature delivered at the eyelids is maintained within a precise range. The user can adjust the temperature using control buttons on the SmartHub.

2.8.1 TEARCARE SMARTHUB

The SmartHub, shown in Figure 1 below, is a battery-powered unit that powers and controls the SmartLids. It features a circuit board, microprocessor, ports for receiving the SmartLid connector(s), and a port for connecting to the charging nest. The SmartHub features a built-in rechargeable Li-ion battery that, when fully charged, supplies power for at least 4 therapies. The SmartHub may be used with one or two SmartLid devices connected. The SmartLid connectors are inserted into the SmartHub's device ports (6a, and/or 6b).

A control button on the center of the SmartHub (1) is used to turn the system on and off, and to initiate or discontinue the TearCare session. Two buttons, "+" and "-", on the SmartHub (2 and 5) allow the user to adjust the preferred temperature level. The SmartHub also has a display on the right side of its face that indicates how much time is left in the session (10 and 11).

2. TEARCARE SYSTEM INFORMATION

Figure 1. TearCare SmartHub Feature key

NOTE	FUNCTION
1.	Power button
2.	Warmth setting increase button
3.	Warmth setting indicator #4 (of 5)
4.	Active therapy indicator
5.	Warmth setting decrease button
6a.	SmartLid Port - left
6b.	SmartLid Port - right
7.	Charging Port
8a.	SmartLid error indicator - left
8b.	SmartLid error indicator - right
9.	Remaining Procedures (battery indicator)
10.	Timer complete indicator
11.	Timer indicators

2.8.2 TEARCARE SMARTLIDS

SmartLids are flexible, software and sensor-controlled, single-use heat treatment components. The SmartLids are connected via a 4 foot cable to the SmartHub, which provides power to heat and regulate the SmartLid temperature.

Each SmartLid is comprised of one cable, one temple pad, and two flexible curved elements. A Left and Right SmartLid are provided in a single package so that all four eyelids may be heated in a single session. The SmartLid delivers heat in a preset temperature range, and ramps from approximately 41°C to 45°C when the procedure is initiated. A thin adhesive holds the SmartLid on the patient's eyelids and temple. A clip is included with each SmartLid. This clip may be used to secure the cables behind the patient's head.

SmartLids are digitally marked as "used" during a session and cannot be re-used. The SmartHub will not allow initiation of a session with a used SmartLid in place.

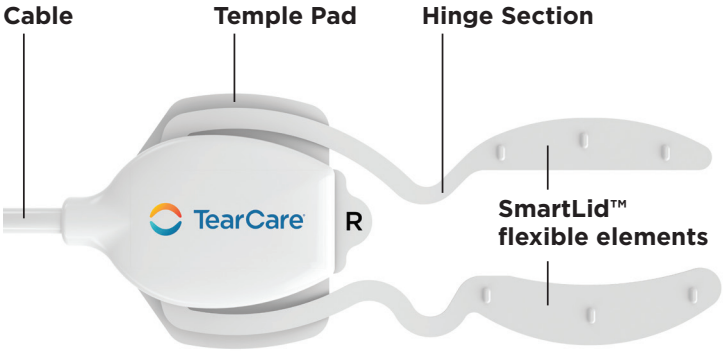

Figure 2. TearCare SmartLid

3. PERFORMING A TEARCARE PROCEDURE

3.1 UNPACKING AND CHECKING THE TEARCARE SYSTEM PRODUCTS

Warning: *Do not use any TearCare component if the component or its packaging appears damaged. Inspect all components for damage before each use.*

Caution: *Do not use SmartLids if they are expired (past the expiration date on the label).*

a) Tear the perforated strip off and remove the tray containing the Smarlids from the shelf carton.

b) Remove the SmartLids from the tray one at a time. Remove the cable first, starting with the connector, and carefully unwind the cable.

c) Turn on the SmartHub by pressing the “Power” button for 1 second.

   i. At least one of the Remaining Procedures (battery level) indicators should be lit to indicate the battery has sufficient charge to complete a procedure.

   ii. The amber “L” and “R” lights should be lit to indicate no cables are plugged in (Figure 3, left image).

d) Plug each cable into the SmartHub.

e) Confirm that the SmartHub recognizes the cables by observing the amber “L” and “R” lights going off (Figure 3, right image). If the amber light does not go off, refer to Troubleshooting (Section 7).

f) Unplug the cables from the SmartHub.

Figure 3. Status of SmartLids: No SmartLids plugged in (Left); Both SmartLids plugged in and functional (Right)

3.2 PREPARING THE PATIENT

Caution: *Ensure the patient’s skin is clean and free of make-up, oil or other contaminants. SmartLids are affixed to the eyelids with adhesive and will not adhere well to oily skin or make-up. Poor adherence of the SmartLids to the skin may result in an error message and temporary pausing of the procedure.*

a) Prior to applying the SmartLid, clean the patient’s eyelids and temples with a non-moisturizing make-up removal wipe to remove any make-up, oil, dirt or lotion.

b) After cleaning, ensure the patient’s skin is dry before applying any portion of the SmartLid.

Caution: *Eyelid cleansing may lead to skin irritation, which would put a patient at increased risk for thermal injury. If the patient is observed to have skin irritation, or if the patient complains of skin irritation after eyelid cleaning, do not proceed with the TearCare treatment.*

c) If the patient is wearing contact lenses, have them remove their lenses prior to the TearCare procedure.

3.3 APPLYING THE SMARTLID

Caution: *Remove the SmartLid adhesive liners slowly to ensure they do not become damaged during the application process.*

Caution: *Do not position the SmartLids on top of the eyelashes.*

Caution: *Ensure the SmartLids are fully installed, completely contacting the patient's eyelid skin, and stationary. The SmartHub may prevent/pause the procedure if the SmartLids are not fully in contact with the eyelid skin.*

a) The SmartLids are designed to fit either the left or right eyelids and are marked with an "L" or "R" next to the temple housing. Apply the SmartLid to the external eyelid surface one eyelid at a time, matching the "L" and "R" to the corresponding eyelid.

b) Applying the SmartLid to the Upper Eyelid:

i. Carefully remove the liner from the Upper SmartLid to reveal the adhesive. Peel from the temporal tab towards nasal and discard the liner.

ii. Ensure the SmartLids are adequately curved to conform to the patient's eyelid. To the extent needed, further curve the SmartLids by forming a bend at the distal tip, and another in the middle portion.

iii. Have the patient tilt their head slightly up, and look downward with eyes closed.

iv. The goal is to apply the upper SmartLid so that it is angled upward toward the center of the brow. It will straighten once the temple housing is attached.

v. Apply the nasal end of the upper SmartLid just lateral to the punctum, approximately 3-4 mm from the lid margin.

vi. Apply the lateral end about 1-2 mm from the lid margin.

c) Applying the SmartLid to the Lower Eyelid:

i. Carefully remove the liner from the Lower SmartLid to reveal the adhesive. Peel from the temporal tab towards nasal and discard the liner, ensuring not to disrupt upper lid.

ii. Have the patient tilt their head slightly down look upward with eyes closed.

iii. Apply the nasal end just lateral to the punctum.

iv. Apply the SmartLid parallel to the lid margin, approximately 1-2 mm from the margin.

v. Ensure that SmartLids are properly adhered to patient's eyelids

d) Applying the Temple Housing:

i. Have the patient look straight ahead.

ii. Carefully remove the liner from the temple pad and discard the liner. Apply the temple housing so the upper edge of the plastic portion is aligned with the lateral canthus (Figure 4).

NOTE: *Ensure that the housing is not applying tension to the SmartLid during liner removal or after placement on the patient as this could impair adhesion of the SmartLids to the eyelids or damage the devices.*

e) Figure 5 shows the SmartLids applied to all four eyelids.

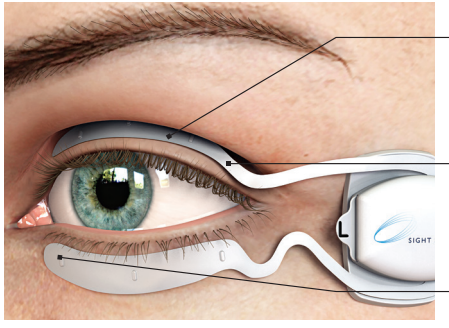

Figure 4. SmartLid positioning on patient eyelids

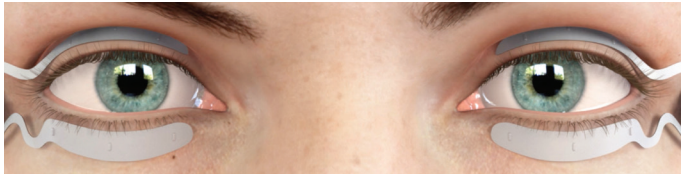

Figure 5. TearCare SmartLid attached to a patient's eyelid

3.4 PLUGGING THE SMARTLIDS INTO THE SMARTHUB

a) Position the cables behind the patient's head to minimize pulling/twisting of the temple housing.

b) If desired, use the clip on the SmartLid cable to join the two cables behind the patient's head. Adjust the clip position as desired for patient comfort and to secure the SmartLids in place.

c) Plug the cables into the SmartHub. Plug the left SmartLid into the port marked “L” and the right SmartLid into the port marked “R”.

Caution:

- *Only plug the SmartLid cables into the SmartHub provided by Sight Sciences, Inc.*
- *Ensure the SmartLid cables are free to move and not tangled. Constrained, tangled cables could place unintentional tension on the SmartLid.*

3.5 STARTING A TEARCARE PROCEDURE

Caution: *An eye care provider must be present during the entire heat treatment to ensure safe use of the device.*

The eye care provider should verbally instruct each patient to tell the eye care provider if they experience pain or discomfort, so that the eye care provider can lower the temperature to reduce the risk of patient harm.

a) Turn on the SmartHub by pressing the “Power” button momentarily (for approximately 1 second).

- When the SmartHub is powered on, it will check for the presence of the SmartLids, their prior use, and the patient’s skin temperature as well as display the number of procedures remaining before a required SmartHub recharge.

b) To initiate a procedure, press and hold the “Power” button until all the timer lights on the right-hand side of the SmartHub are lit, then release the button. The patient will immediately feel a warming sensation on their eyelids.

- The SmartHub will signal that the procedure has been initiated by illuminating the Active Procedure Indicator, then starting Timer lighting countdown sequence once the minimum session temperature is reached (Figure 6).
- The warmth setting will automatically increase every 30 seconds until the maximum setting is reached.

c) During the procedure, the patient may blink naturally.

Caution: *The eye care provider should verbally instruct each patient to keep their eyes open (including blinking naturally) during treatment, to allow heat to dissipate off of the ocular surface to reduce the risk of patient harm.*

d) The TearCare session will last for 15 minutes.

- The Timer Indicator lights on the right-hand side of the SmartHub will indicate how many minutes remain in the session in 3 minute intervals.

e) If an error is experienced any time during the session, refer to the Troubleshooting section (Section 7) to resolve the error.

f) At the end of the 15 minute session the SmartHub will automatically shut off the heat.

- The SmartHub will emit an intermittent tone, turn off the Active Procedure Indicator, and flash the “0” Timer Indicator to indicate the session is complete.

g) At the end of the procedure, carefully remove the SmartLid from the eyelids:

i. Unclip the two device cables behind the patient's head.

ii. Gently peel the temple pad from the ear toward the eyelid margin.

iii. Peel one or both heaters from the eyelids, moving in a temporal to nasal direction.

NOTE:

- *Pressing the "Power" button for longer than 7 seconds will turn the SmartHub off. If the power is turned off during the procedure, the SmartLid cannot be re-used.*
- *Keep the SmartHub stationary during the procedure by placing it on a nearby stable surface. This will prevent it from being dropped or the cable(s) from inadvertently being removed.*
- *During a procedure if the SmartLid cable is inadvertently removed from the SmartHub, the SmartHub will pause for up to 20 minutes. This will allow the user to re-install the cable, press the power button to clear the error and re-initiate the procedure by pressing the "Power" button for 2-5 seconds.*
- *Inadvertently removing the SmartLid cables from the SmartHub will pause the procedure and delay the procedure.*
- *Once a procedure has been initiated with SmartLids in a SmartHub, those SmartLids cannot be used in any other SmartHub*

Figure 6. Procedure initiated

3.6 ADJUSTING TEMPERATURE

a) The system warmth starts at level 1 and automatically increases one level every 30 seconds up to the maximum level 5. While the warmth is automatically ramping, the current warmth indicator(s) will be solid, and the targeted value will flash.

NOTE: *The TearCare therapeutic temperature operates to set points ranging 41-45°C (106-113°F), which correspond to the SmartHub warmth level settings of 1-5. The maximum allowable temperature is 47°C (117°F).*

b) Temperature ramping can be stopped by pressing the "-" button once, and reduced further with additional presses of the "-" button.

c) The warmth setting can be used to slightly vary the warmth during a session by pressing the "+" or "-" buttons.

NOTE: *The SmartHub uses a proprietary algorithm to ensure safe thermal exposure, and may reduce/restrict the target temperature. If the system cannot operate within its limits even at the lowest temperature setting, the user will be notified with a steady tone and blinking of the level 5 warmth indicator. In addition, delivery of heat will be paused. The application of the SmartLid should be checked for proper fit and adhesion (Refer to Troubleshooting Section for more information). If correction of fit and or adhesion does not result in permitting resumption of a procedure without further errors, return the potentially faulty SmartLid to Sight Sciences.*

3.7. TERMINATING A PROCEDURE EARLY

If the patient experiences any intolerable discomfort from the heat that cannot be resolved by adjusting the temperature, the TearCare session should be terminated immediately. This can be achieved in one of three ways:

a) Disconnect either SmartLid connector from the SmartHub, thus removing power to both the SmartLids; or

b) Hold the "Power" button on the SmartHub for at least 7 Seconds; or

c) Carefully remove the SmartLid(s) from the eyelids:

i. Unclip the two device cables behind the patient's head

ii. Gently peel the temple pad from the ear toward the eyelid margin

iii. Peel one or both heaters from the eyelids, moving in a temporal to nasal direction

Caution: *If the patient experiences extreme discomfort or pain, the procedure should be terminated immediately.*

3.8 EXPRESSING THE MEIBOMIAN GLANDS

a) Immediately (i.e., within 3 minutes) following the 15-minute thermal procedure, it is recommended that the clinician manually express the meibum from each of the eyelids with the TearCare Clearance Assistant device (provided separately). Safety and effectiveness of the TearCare System has not been established when used in conjunction with any other meibomian gland expressor. Effectiveness of the TearCare System has not been established when used without manual meibomian gland expression.

4. PRODUCT DISPOSAL

Caution: *The SmartLids are single use and should be disposed of after use.*

SmartLids should be disposed of in accordance with hospital policies, local laws, and regulations for equipment containing electrical and electronic parts.

At the end of SmartHub life, the SmartHub must be disposed of in accordance with hospital polices, local laws, and regulations for equipment containing electrical and electronic parts that contain lithium batteries.

5. CHARGING THE SMARTHUB

Caution:

- *Use only the charger supplied with the TearCare System. Use of other AC adapters may result in damage to the unit.*
- *Only plug the charging adapter into 120VAC electrical outlet.*

a) Attach the provided charging adapter to the charging nest.

b) Plug the charging adapter into a standard 120VAC electrical outlet.

c) To charge the SmartHub, place the SmartHub into the charging nest as shown below. The “Remaining Procedures” (battery level) lights and “Power” button will flash to indicate charging is in process.

d) When charging is complete, all four “Remaining Procedures” (battery level) lights, and the “Power” button will stay lit. A full charge may take up to four hours. The SmartHub battery has enough capacity to exceed 4 complete TearCare sessions, so the “Remaining Procedures” (battery level) lights may not change for several sessions after a full charge.

NOTE:

- *If the SmartHub does not attain sufficient charge for 4 procedures after one hour, remove the SmartHub from use and contact the Sight Sciences Customer Service Department (see Appendix B) or the Sight Sciences representative in your area.*

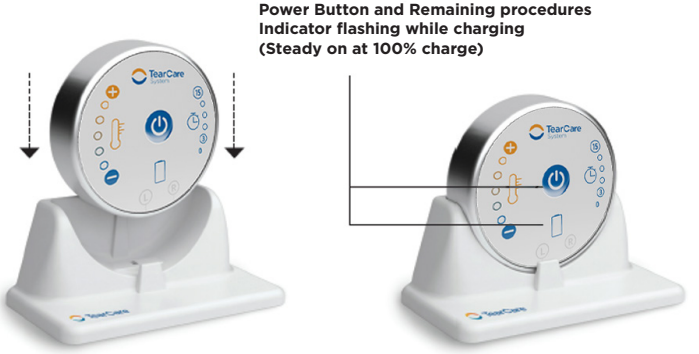

Figure 7. Charging nest connection and lighting.

6. USER MAINTENANCE

The SmartHub, Charging nest and adapter are designed for stable operation over their lifespan and, under normal circumstances, should not require technical maintenance. However, routine cleaning for these re-usable components is recommended. The section below discusses the prescribed cleaning method.

6.1 CLEANING THE SMARTHUB

If the SmartHub requires cleaning, use the following procedure:

a) If the SmartHub resides in the charging nest, remove it from the charging nest.

b) Ensure the SmartHub is off. If the SmartHub is on, press the power button for seven or more seconds to turn the SmartHub power off.

c) If SmartLids are connected to the SmartHub, remove them from the SmartHub.

d) Hand clean the SmartHub using standard hospital disinfectant wipes. Wipe all surfaces of the SmartHub.

e) Dry the SmartHub using a lint-free cloth.

f) Visually examine the SmartHub to ensure all contaminants have been removed.

g) Repeat the above cleaning process as required.

h) After cleaning is complete, inspect the System components for wear or damage.

Caution:

- *Do not clean the TearCare SmartHub while the system is on or while the SmartHub and SmartLids are attached to a patient.*
- *Do not clean the TearCare Charging nest while it is plugged into the wall adapter.*
- *Do not submerse in, or expose components to, free fluids.*
- *Do not clean the SmartHub while it is connected into the charger nest.*
- *Do not use abrasive cleaning agents or organic solvents on any of the TearCare™ System components.*
- *Use only recommended cleaning method to prevent damage to the device and components.*
- *Do not autoclave the TearCare System, its components, or accessories.*
- *After performing the cleaning method, ensure the SmartHub connector contacts are thoroughly dried to prevent possible malfunction.*

NOTE:

- *If the TearCare System presents an unresolvable error signal, remove the System from use and report the error to Sight Sciences, Inc.*

7. TROUBLESHOOTING

7.1 SMARTHUB TROUBLESHOOTING

The following may occur at SmartHub startup, or during procedure, with or without SmartLid connected.

Notes: *For audible tones, a momentary press of the "Power" button will mute the tone. For errors during a therapy, the error is cleared (if resolved) with a momentary press of the "Power" button after the audible tone stops.*

VISUAL CUE	AUDIBLE CUE	ERROR	SOLUTION
No LED indicators are lit on SmartHub	None	SmartHub is not turned on	Press the "Power" button.
	None	The battery charge is too low	Charge the SmartHub.
All lights turn on for approximately 0.5 seconds	None	None – Normal startup/ shutdown	(None)
Power button light flashing All 4 Remaining Procedures (battery level) indicators flashing, followed by auto shutoff.	Beeping, 10 seconds	SmartHub power error	Return SmartHub to Sight Sciences.
Status Indicator light(s) flashes before therapy	None	SmartLid below indicator is previously used	Remove/replace used SmartLid.
Status and Power lights flash before therapy	None	SmartLid below indicator is damaged	Return SmartLid to Sight Sciences.
Power button light flashing Warmth Setting 1 light flashing	None	All or some portion of SmartLid (s) is under normal body temperature indicating they are not applied to the patient properly	Check for proper placement and adhesion to skin surface. Check room temp is >20°C. Therapy may be resumed by following Step 3.5b.

VISUAL CUE	AUDIBLE CUE	ERROR	SOLUTION
Power button light flashing Warmth Setting 5 light flashing	None	All or some portion of SmartLid(s) is over normal body temperature prior to procedure	Check room temp is <26°C. Therapy may be resumed by following Step 3.5b.
Status Indicator on (steady) Warmth Setting 1 indicator flashing Active procedure indicator flashing Remaining timer counter increments flashing Power button light flashing	Steady tone 15 seconds	SmartLid(s) under minimum operating temperature during procedure	Check room temp is >20°C. Therapy may be resumed by following Step 3.5b.
Status Indicator on (steady) Warmth Setting 5 indicator flashing Active procedure indicator flashing Remaining timer counter increments flashing Power button light flashing	Steady tone 15 seconds	SmartLid(s) have detected the maximum temperature and time limits permitted during procedure	Check for proper placement and adhesion to skin surface. Therapy may be resumed by following Step 3.5b. If errors persist, replace SmartLid to continue. Return faulty SmartLid to Sight Sciences.
Status Indicator on (steady) Remaining timer counter increments flashing Power button light flashing	Steady tone, 15 seconds	An error has occurred communicating with the SmartLid(s) below the error indicator	Check that connector is fully inserted into the SmartHub port. Press the start button once to clear the error. If the error clears, therapy may be resumed by following Step 3.5b.

7. TROUBLESHOOTING

VISUAL CUE	AUDIBLE CUE	ERROR	SOLUTION
Status Indicator flashing Remaining timer counter increments flashing Power button light flashing	Steady tone, 15 seconds	An unresolvable error has occurred in the SmartLid below the status indicator	Replace SmartLid to continue. Return faulty SmartLid to Sight Sciences.
Warmth level reduces during therapy and cannot be increased	None	SmartLids are unevenly or partially applied to the skin	Disconnect SmartLid to pause treatment, and adjust fitment for even application over skin. Poor adhesion due to residual makeup may require replacement of the SmartLid. Press the start button once to clear the error. Therapy may then be resumed by following Step 3.5b.
SmartHub turns off during procedure	None	Connector shorted Excessive electrostatic discharge	Check ports for debris. Replace SmartLids to continue. Return faulty SmartLid to Sight Sciences. Determine and remove source of static charge.
SmartHub Resets during procedure	None	Excessive electrostatic discharge	Determine and remove source of static charge.

7.2 SMARTLID TROUBLESHOOTING

PROBLEM	POTENTIAL CAUSE	SOLUTION
SmartLid(s) do not become warm	The cable(s) is not completely inserted into the SmartHub	Check the SmartLid status indicators. Insert the cable securely into SmartHub. Therapy may be resumed by following Step 3.5b.
	SmartHub battery not charged	Check Remaining Procedures (battery level) indicators. If only one indicator light is on and flashing, charge the SmartHub as described in Section 5.
	SmartLid(s) is previously used	Check the SmartLid status indicators. If the indicator below the device is blinking, it has been previously used. Replace used SmartLid(s) with unused device. Therapy may be resumed by following Step 3.5b.
	SmartLid(s) is damaged	Check the device below the lit status indicator(s) for damage. Replace damaged SmartLid (s) with new device. Therapy may be resumed by following Step 3.5b.
	SmartHub Power error	Return SmartHub to Sight Sciences.
SmartLid(s) do not stick	Skin is not clean of dirt/oil/ makeup prior to application	Gently clean the patient's eyelids and temples before adhering the SmartLid(s).
	Adhesive liner has not been removed	Remove the adhesive liner on each patient applied surface prior to use.
SmartLid(s) Pull/Push eyelid	Temple pad position is incorrect	Apply the temple pad in a position that does not require pulling or pushing on SmartLid(s) when applying to the eyelids.

8. SPECIFICATIONS

8.1 THERMAL OUTPUT

SMARTLID DEVICE (APPLIED PART)	
Temperature limits during procedure	Temperature set point range: 41 – 45°C (106 – 113°F) Temperature accuracy: ±0.7°C (1.3°F) Maximum allowable temperature: 47°C (117°F).

8.2 PHYSICAL COMPONENTS

TEARCARE™ SYSTEM		
SmartHub	Dimensions	2.7” dia. x .9” ht. (68.6 mm dia. x 23 mm ht.)
	Weight	5.5 oz. (156 g)
SmartLid (left or right)	Dimensions	4’3” L x .25” H x .75” W (1295 mm L x 6 mm H x 19 mm W)
	Weight	1.5 oz. (43 g)

8.3 ENVIRONMENTAL CONDITIONS

ENVIRONMENTAL CONDITIONS FOR THE TEARCARE SYSTEM		
CONDITION	**STORAGE (PACKAGED/ UNPACKAGED)**	**OPERATING (UNPACKAGED)**
Temperature	-20°C to +55°C -4°F to +131°F	20°C to +26°C 68°F to +78.8°F
Humidity	15% to 95% non-condensing	10% to 95% non-condensing
Atmospheric Pressure Range	107 kPa to 50 kPa 803 mmHg to 375 mmHg 1.06 atm to 0.49 atm	107 kPa to 70 kPa 803 mmHg to 525 mmHg 1.06 atm to 0.69 atm

NOTES:

- Keep the SmartHub away from high electromagnetic fields.
- TearCare may not perform to specification if stored or operated outside the specified enviornmental conditions above.

8.4 STANDARDS COMPLIANCE

STANDARDS COMPLIANCE
CAN/CSA C22.2 No 601.1 M90 Part 1: General requirements for basic safety and essential performance
IEC 60601-1 Medical electrical equipment - Part 1: General requirements for safety
IEC 60601-1-2, Med. Elect. Equipment – Part 1-2: General requirements for safety – Collateral standard: EMC – Req. and tests
IEC 60601-1-6, Medical electrical equipment – Part 1-6: General requirements – Collateral standard: Usability
IEC 60601-1 Part 11: General requirements for basic safety and essential performance

Compliance with EMC Standards

All components of TearCare listed in the System Description section (Section 2.6), including the accessories, have been tested and found to comply with the limits of the standard for medical devices, IEC 60601-1-2:2014 +AMD1 2020. The limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy, and, if not installed and used in accordance with the manufacturer's instructions may cause harmful interference to other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation.

If TearCare causes interference with other devices, or if other equipment is causing interference with this equipment, which may be determined by turning the equipment off and on, the user is encouraged to try and correct the interference by one or more of the following measures:

- Reorient or relocate the device receiving the interference.
- Increase the separation between TearCare and the device receiving interference. (minimum 30cm is recommended)
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

8. SPECIFICATIONS

8.4.1 ELECTROMAGNETIC EMISSIONS

The TearCare System has been tested to the standards in the table below. To maintain proper function of the TearCare System as it pertains to EMC, all the instructions in this manual should be followed throughout the useful life of the product.

EMISSIONS (CLASS B, GROUP I)	CISPR 11:2016 (Radiated Emissions)
	CISPR 11:2016 (Conducted Emissions)
	IEC 61000-3-2:2014 - Harmonic Emissions
	IEC 61000-3-3:2013 - Flicker Emissions
IMMUNITY	IEC 61000-4-2:2008 - ESD
	IEC 61000-4-3:2006 - Radiated
	IEC 61000-4-4:2012 - EFT
	IEC 61000-4-5:2014 - Surge
	IEC 61000-4-6:2013 - Conducted
	IEC 61000-4-8:2009 - Magnetic
	IEC 61000-4-11:2004 - Voltage Dips and Interrupts

8.4.2 ESSENTIAL PERFORMANCE

The Essential Performance of the TearCare System is to provide controlled heat to a patient's eyelids. If the Essential Performance is lost or degraded due to electromagnetic disturbances, the operator can expect the following:

- Loss of temperature control resulting in a measured heater temperature exceeding 47°C that does not result in an "over temperature error."
- Loss of temperature control resulting in a measure heater temperature under 39°C, that is not signaled by an "under temperature error."
- A stalling of the treatment timer that results in a timing inaccuracy of more than ± 10 seconds over a 15-minute therapy.

8.4.3 EMC SUSCEPTIBILITY

Interference from electronic sources may result in the following observations or system notices. The operator should be aware of the following; however, they do not pose hazards to the patient or operator.

- Unit pauses therapy
- Unit restarts during use
- Unit shuts off during use
- Unit locks up requiring a restart

APPENDIX A

SYMBOLS

The following symbols are used on the TearCare System and component packaging. The symbols below comply with the international standard - ISO 15223-1:2021:

SYMBOL	TITLE OF SYMBOL	ISO 7000 REG. NO.	DEFINITION
	Warning	0434A	Indicates the need for the user to consult the instructions for use for important warnings.
	Caution	0424A	Indicates the need for the user to consult the instructions for use for important cautions.
	Non-sterile	2609	Indicates a medical device that has not been subjected to a sterilization process.
	Catalogue number	2493	Indicates the manufacturer's catalogue number so that the device can be identified.
	Batch code	2492	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Serial number	2498	Indicates the manufacturer's serial number so that a specific device can be identified.
	Do not reuse	1051	Indicates a device that is intended for one use.
	Use-by date	2607	Indicates the date (Year-month) after which the device is not to be used.

SYMBOL	TITLE OF SYMBOL	ISO 7000 REG. NO.	DEFINITION
	Manufacturer	3082	Indicates the device manufacturer.
	N/A	N/A	For prescription use only.
	Temperature limit	0632	Indicates the temperature limits to which the device can be safely exposed.
	Consult instructions for use	1641	Indicates the need for the user to consult the instructions for use.
	Keep dry	0626	Indicates a device that needs to be protected from moisture.

APPENDIX A

The symbols below comply with the international standards listed below, as applicable.

SYMBOL	TITLE OF SYMBOL	STANDARD	DEFINITION
	Type BF applied part	IEC 60601-1	Indicates the device has conductive contact with the patient.
	Separate Collection (disposal)	EU WEEE Directive	Indicates this device is designed for separate collection at an appropriate collection point. Do not dispose of as household waste.
IPXO	Not specially protected equipment for water/dust ingress	IEC 60601-1	Indicates the product may not operate as intended if dust or water gets inside of it.
Li-ion	Lithium-Ion battery	N/A	Indicates this product contains a lithium-ion battery.

APPENDIX B

PRODUCT RETURNS

In the event that a component needs to be returned, contact Sight Sciences at the Manufacturer address below for a Return Materials Authorization (RMA). Prior to shipping, ensure the components have been properly cleaned and the package has been labeled with the RMA number.

RESPONSIBILITY OF SIGHT SCIENCES

Sight Sciences is responsible for the effects on safety, reliability, and performance of the equipment only if:

1. Modifications or repairs are carried out by persons authorized by Sight Sciences, Inc. and
2. The equipment is used in accordance with the instructions for use.

ADVERSE EVENT REPORTING

Adverse events and/or potential patient injury complications that are reasonably associated with the use of the TearCare System should be reported to Sight Sciences, Inc. at the Manufacturer address below.

MANUFACTURER

Sight Sciences, Inc.
4040 Campbell Ave.
Suite 100
Menlo Park, CA 94025
Telephone: (877) 266-1144

PATENTS AND TRADEMARKS

This product and/or use of this product may be covered by U.S. patent(s) or patent application(s) available at: http://sightsciences.com/us/patents/


TearCare
System
15
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L
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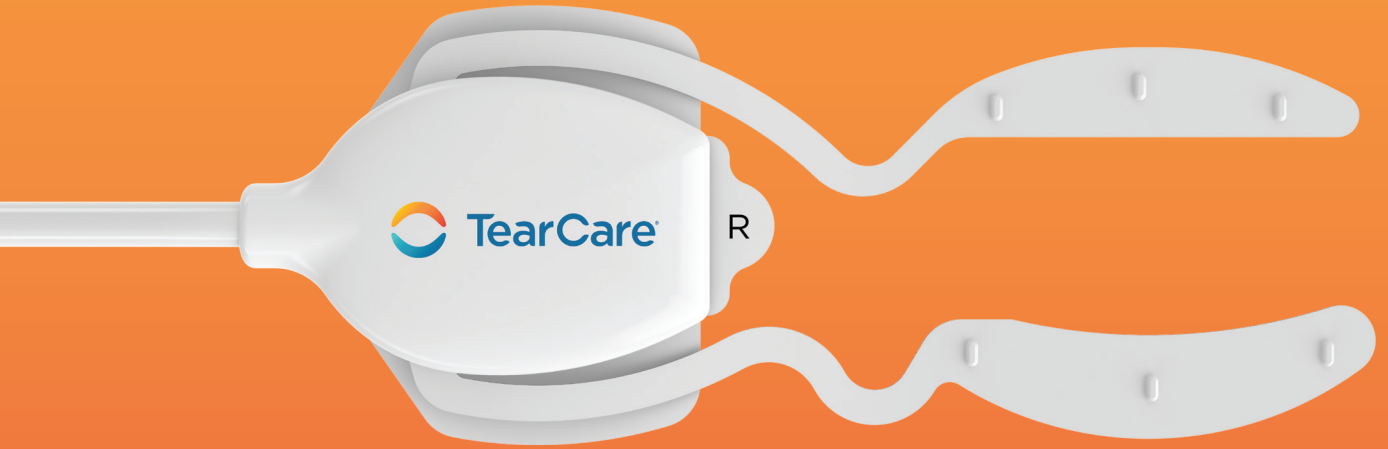
L
TearCare


TearCare
R


L
TearCare