A new method for

Tear Volume Measurement

SMTube®

Strip Meniscometry Tube

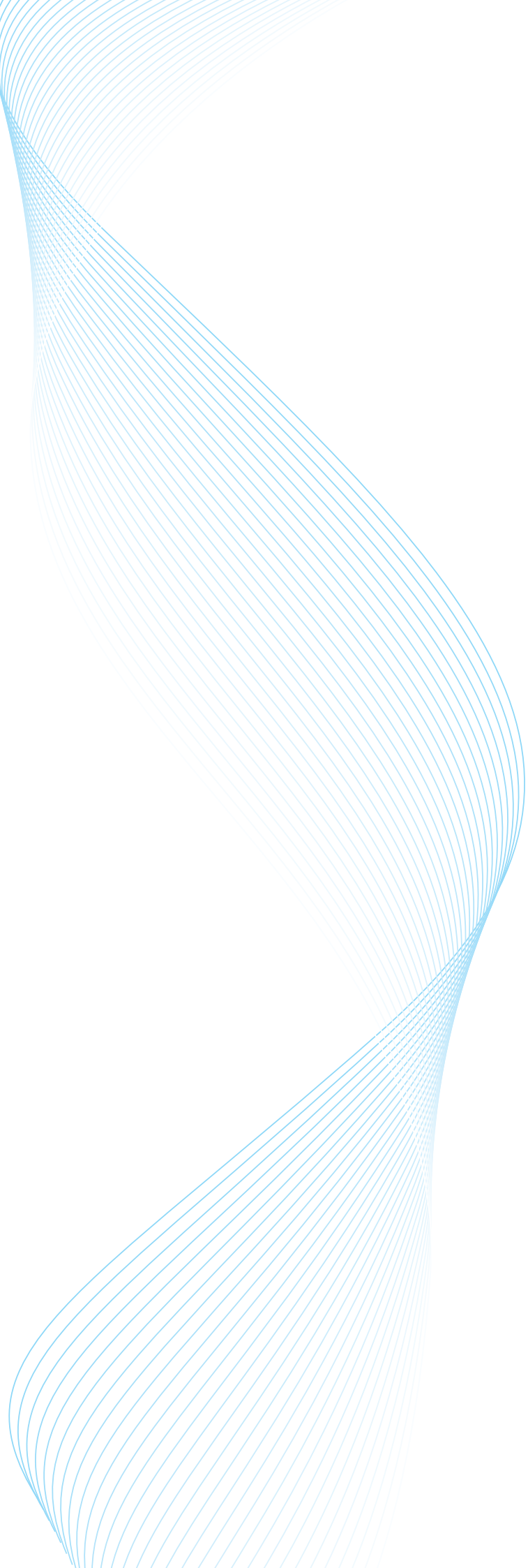
5 seconds

Dry eye screening

Five seconds quantification for the lower tear meniscus volume

SPIRIT

ECHO ELECTRICITY CO.,LTD.



The tear film stability is closely related to the tear volume. Thus, the tear volume is an important parameter to conduct tear-film-oriented-therapy properly, where the treatment of dry eye disease or the postoperative care for refractive and cataract surgeries are typical examples of such.

In this brochure, we would like to introduce our new diagnostic medical device, "Strip Meniscometry Tube (SMTube)", developed for a simple, accurate, swift and minimally-invasive assessment of tear volume. "Strip Meniscometry" is a term of a methodology for the tear volume evaluation, of which the original paper was published in 2006 (Dogru 2006). Then in 2011, it has been reported that the strip meniscometry testing was useful in the diagnosis of dry eye disease, showing a statistically significant correlation with other ocular surface examinations such as the Schirmer test, tear film breakup time measurement, and vital staining scores (Ibrahim 2011).
"SMTube" is a product to perform the strip meniscometry testing, developed with an appropriate standardization and mass-production techniques, with intent to help medical staff carry out the testing with ease and accuracy.

All you do is to immerse the tip of the SMTube strip into the tear meniscus of the lower eyelid for 5 seconds. And column will be stained with blue dye as the SMTube absorbs tears. The length of stained column quantifies the tear meniscus volume.
Since SMTube is used right on ocular surfaces, the safety is highly considered; The material and structure were carefully chosen and designed so that no damage ought to occur on the ocular surface in case the tip of the strip touches cornea or conjunctiva.

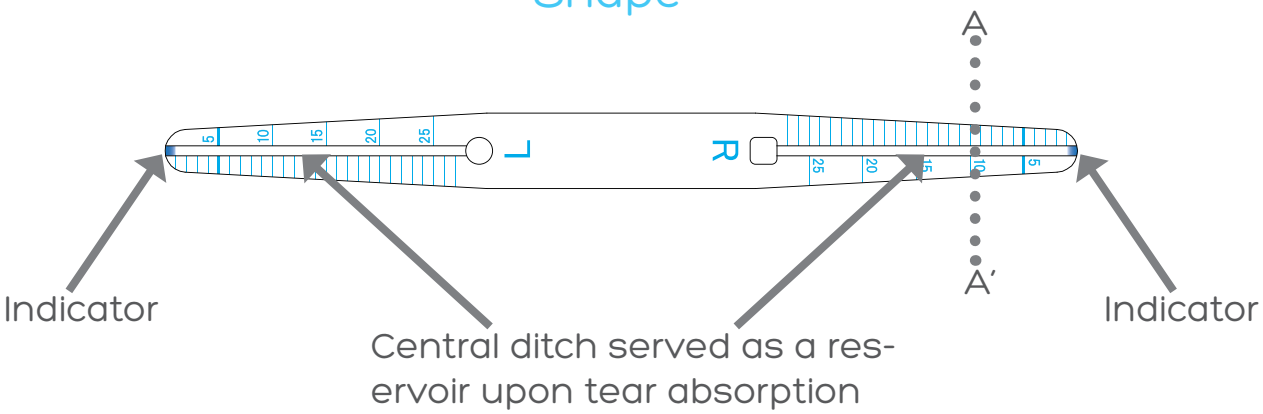
A number of reports have been published in terms of the use of SMTube in their clinical studies (please see the reference papers on page 9 of this brochure).

Here are some of the examples :
1. Quantitative measurement of tear meniscus volume during visual field testings using SMTube (Sagara et al.)
2. An efficacy of SMTube testing in a mass screening of dry eye disease during regular medical checkup (Ishikawa 2018)
3. A clinical efficacy of SMTube in the diagnosis of dry eye disease when combined with OCT examinations (Shinzawa 2018)

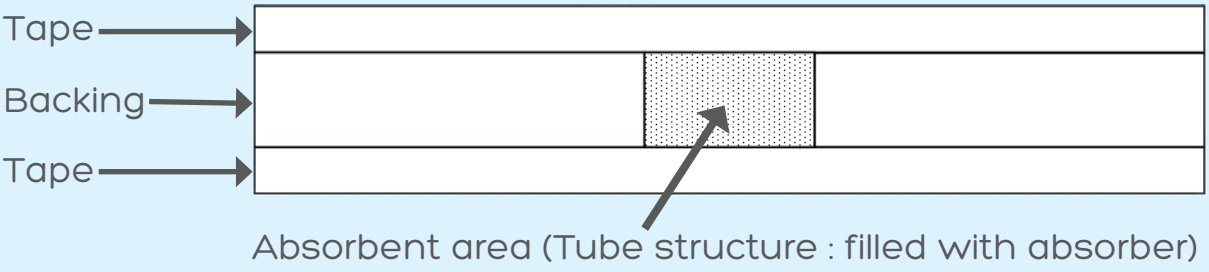
Configuration / Structure

SMTube is thin strip with a central ditch filled with absorber. Scale is printed on the both sides of absorber to measure the tear meniscus volume. Each SMTube is packaged individually in sterile pouch.

Shape



A - A' cross section



Size : Length : 85mm
Width : 7mm
Height : 0.3mm

Material : Indicator : Blue dye 1
Tape : Polyurethane, Polyester
Backing : Polyurethane
Absorber : Rayon, Pulp

When SMTube is applied to the tear meniscus in a lateral lower lid of an eye, it absorbs tears via the capillary action of absorber taking effect in the center of the strip. The indicator, placed at the end of the strip, is dissolved in the absorbed tear fluid. At the end of 5 seconds, the length of the stained tear column is marked and read to quantify the tear meniscus volume.

Single use only

Instruction for use

Without slitlamp (when used by paramedical staff)

Hold the center of SMTube strip. Do not touch a tip of strip to avoid potential infections.

Take the standing position with the patient as shown in the left photo. Fix the hand on the cheek of patient, so that the tip of SMTube is stabilized.

Immerse the tip of the L side into the tear meniscus of the left lower eyelid for 5 seconds to absorb tears.
Take extra care not to touch the conjunctiva nor the cornea with the tip of the strip.

Read the score (length of the column stained by blue colour). Mark with an oil pen if necessary.

Switch to the R side of the strip, and perform the testing on the right eye in the same manner as done on the left eye.

With slitlamp (when used by doctors)

Make sure to use the illumination with an essentially-minimum intensity to avoid the reflex secretion caused by the photostimulation. Use a diffuser if available.

Perform the testing on the left eye using the L side of the strip.

Read the score (length of the column stained by blue colour). Mark with an oil pen if necessary.

Switch to the R side of the strip, and perform the testing on the right eye. We recommend to fix the hand as shown in the left photo.

Hold a strip as follows

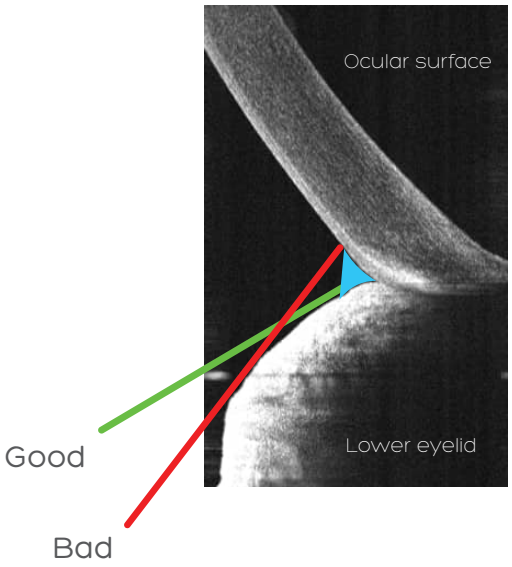
Make sure to hold the center part of SMTube during the examiniation. SMTube absorbs tears by capirally action, and holding the column parts or blocking the hole near the central of the strip (the end of the column) may distrurb the capirally action.

Angle of Instertion

The angle of insterion is highly importiant in order to evaluate tear meniscus volume correctly.

The good example shown in the picutre below is showing that stirip is inserted into tear menuscus, with correct anlge.

The bad example shown the picurre below is showing that the strip is appled with a too downward angle, which may cause the failure on absobtion, or inaccurate evaluation score.



Contraindications

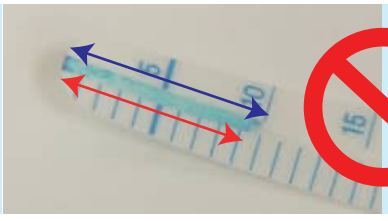
When taking out the strip, do not touch the tip of SMTube strip where the blue dye is impregnated.

Please note that when applying the strip, keep the appropriate angle near the horizontal.
In an example on the left, the strip is applied with a too upward angle.

Do not block the hole near the center of the strip (the end of the column) during the examination. Blocking the hole will disturb the capillary action.

Please note that when applying the strip, keep the appropriate angle near the horizontal.
In an example on the left, the strip is applied with a too downward angle.

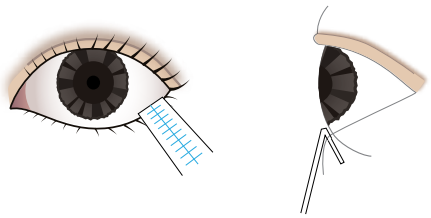
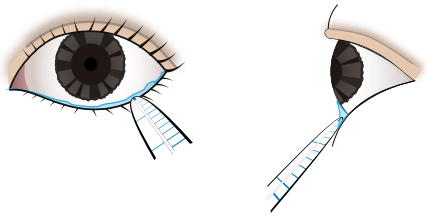
Never touch the cornea with the strip.



When reading the score, adopt the highest value (indicated by a blue arrow) instead of the shortest value (indicated by a red arrow) or so.

Do not deform or apply a pressure upon eyelid during the examination.

Comparison with the Schirmer's test

	 The Schirmer's test	 SMTube®
Usage	Inserting the Schirmer strip inside the lower eyelid (conjunctival sac)	Immersing the tip of SMTube strip into the tear meniscus
Required time	5 minutes	5 seconds x 2 (for both eyes)
Invasiveness	invasive	Minimally-invasive

SMTube has a high correlation with OCT

A clinical trial has proved that the SMTube testing has a high correlation with the Schirmer test, tear meniscus hight (TMH) and area (TMA) measurements using an optical coherence tomography (OCT), and tear film breakup time (BUT) measurement (Shinzawa 2015).

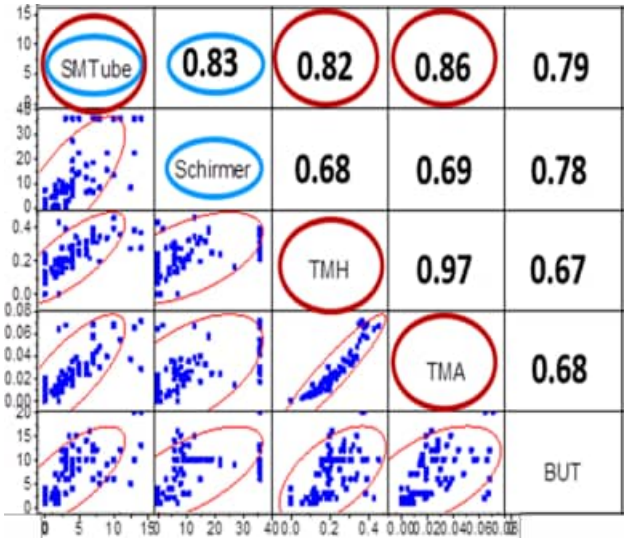
In this study, subjects were comprised of definite dry eye group and healthy control group. The detail is summarized in Fig.1 below.
Fig.2 below is a table demonstrating the correlation among the examinations. The diagonal cells are for the examination entries. The lower triangular cells exhibit scatter plots between the scores, and the upper triangular cells represent the correlation coefficients between the scores calculated by the Spearman's rank test.

Figure 1 : Summary of Subjects

Diagnosis	Subjects (eyes)	Gender *		Age Range (yrs)	Mean Age* (yrs)
		Men (eyes)	Women (eyes)		
DE	23 (45)	5 (10)	18 (35)	8-86	56.4±17.0
Normal Controls	29 (51)	7 (11)	22 (40)	7-82	53.6±18.4

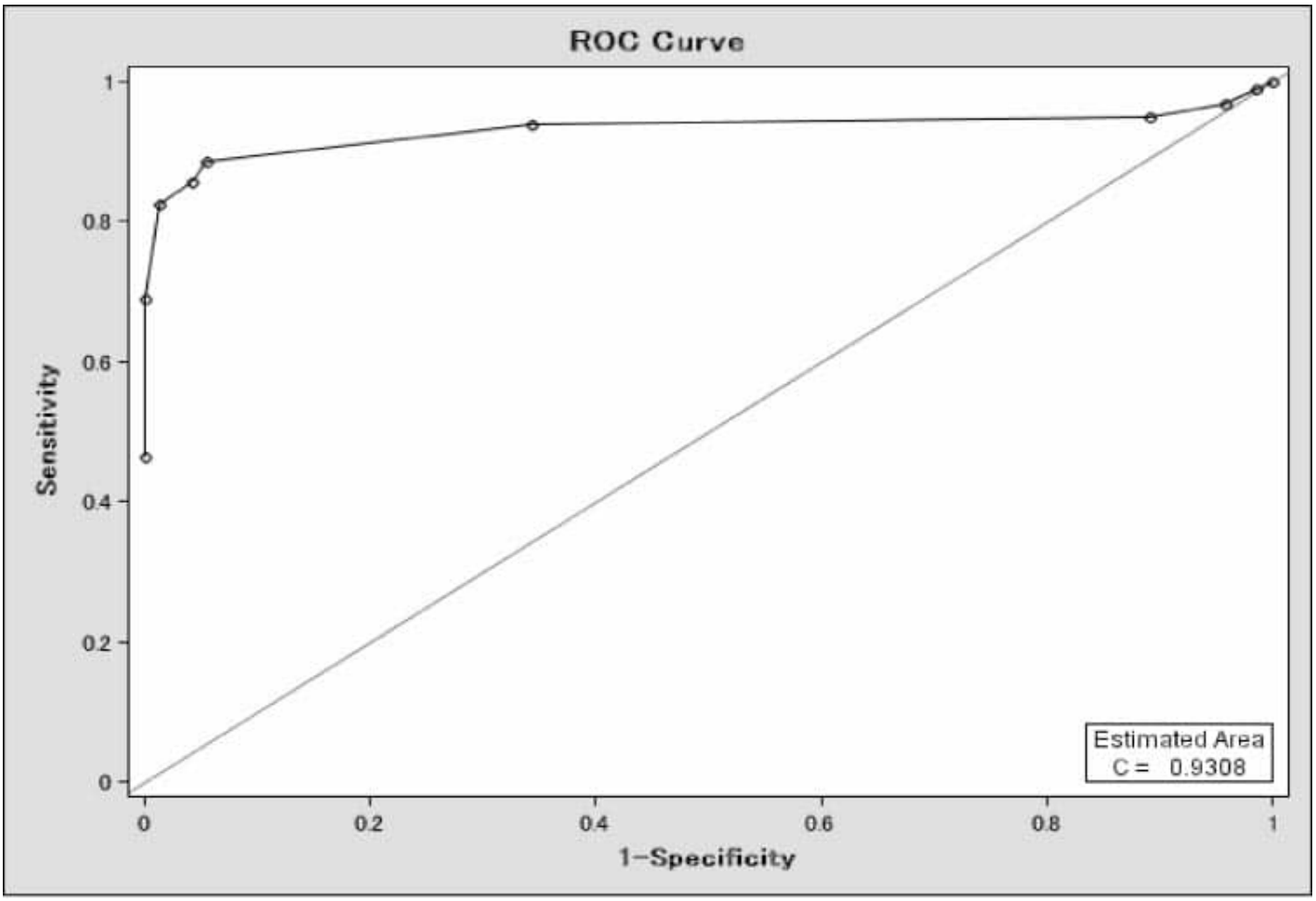
Subjects with dry eye symptoms, presence of a vital staining score of >3points, and decreased tear break-up time or tear quantity were diagnosed as having definite dry eye disease according to the 2006 Japanese Dry Eye Research Society Diagnostic Criteria.
*No statistically significant differences were found in terms of male-female ratio (P = 1.0 with Fisher's exact test, P = 0.90 with the chi-square test with Yates' correction) and the age distribution (P = 0.61 with Mann-Whitney U test).

Figure 2 : Correlation among SMTube and other ocular surface examinations



Tear meniscus assessment using OCT has recently attracted a lot of attention due to its non-invasiveness, swiftness and accuracy upon the evaluation of tear meniscus parameters including height, area, volume as well as curvature, where the tear meniscus volume is regarded to be the most essential. SMTube allows you to perform the tear meniscus volume evaluation without restrictions in terms of the cost, time, and place owing to its inexpensiveness and portability. An evidence of the high correlation between SMTube with OCT invokes that SMTube can be utilized for the tear volume measurement instead of using an expensive OCT instrument.

An estimate for cut-off length



Cut-off value (mm):	<1	<2	<3	<4	<5	<6	<7	<8	<10	>=10
Sensitivity:	0.46	0.69	0.82	0.86	0.89	0.94	0.95	0.97	0.99	1.00
Specificity:	1.00	1.00	0.99	0.96	0.95	0.66	0.11	0.04	0.01	0.00

The ROC graph showing the sensitivity and specificity of strip meniscometry test. (Dogru 2006)

Combinations of diagnostic tests may help to diagnose DE syndrome more accurately

The study demonstrated the efficacy, safety, and efficiency of SM and DEQS for the screening of DE syndrome during general medical checkup in a large population. The combination of SM and DEQS for diagnosis of DE yielded high sensitivity and specificity, indicating its feasibility for the screening of DE syndrome. (Ishikawa 2018)

Sensitivity and specificity of dry eye–related quality-of-life score, strip meniscometry score.

Examination (number of cases)	Sensitivity, %	Specificity, %
DEQS (n=54, DE group=28 normal group=26)	79	91
SM (n=70, DE group=24 normal group=46)	71	85
Single positive (DEQS or SM) (n=103, DE group=33, normal group=70)	97	77
Double positive (DEQS and SM) (n=28, DE group=20, normal group=8)	59	97

DE=dry eye, DEQS=dry eye–related quality-of-life score, SM=strip meniscometry.

Comparison of mean values of DED parameters (Shinzawa 2018)

Ocular Surface Test	DED, n=43 Eyes	Controls, n=49 Eyes
OSDI	36.0±27.2 (0–93.2)	11.4±13.0 (0–68.8)[a]
DEQS	34.9±22.0 (5–83.3)	9.8±13.6 (0–50.0)[a]
SMTube, mm	1.4±2.3 (0–13)	5.5±2.8 (2–14)[a]
OCT-TMH, mm	0.138±0.102 (0–0.426)	0.271±0.108 (0.132–0.685)[a]
OCT-TMA, mm^2	0.013±0.015 (0–0.067)	0.033±0.025 (0.007–0.152)[a]
BUT, sec	2.4±1.2 (1–6)	10.0±2.5 (6–16)[a]
Schirmer, mm	1.7±3.0 (0–11)	17.1±11.4 (6–36)[a]
FS	5.2±2.0 (1–9)	0.0±0.0 (0–0)[a]
LS	6.1±2.1 (3–9)	0.0±0.0 (0–0)[a]

Values are given as mean ± SD (range).

Statistically significant differences were found by Mann–Whitney *U* test ($P < 0.001$).

DED, dry eye disease; OSDI, Ocular Surface Disease Index; DEQS, Dry Eye–related Quality-of-life Score; SMTube, Strip Meniscometry Tube; OCT, optical coherence tomography; TMH, tear meniscus height; TMA, tear meniscus area; BUT, break-up time; FS, fluorescein; LS, lissamine green.

Application of SMTube

The advantage of SMTube is its swiftness and handiness in measuring tear volume without requiring special equipments. For this reason, SMTube is suitable for the first screening test of dry eye diagnosis, to differentiate true ADDE (Aqueous Deficient Dry Eye) from EDE (Evaporative Dry Eye). The applicable circumstance of exploiting the advantage of SMTube is not only for dry eye diagnosis. It can be applied not only as a "short-time" and "minimally invasive" tear volume measurement, but it can also be applied as a convenient tool for various purposes required in various clinical sites and researches.

1. Screening of a number of subjects such as group health checkup. (Ishikawa 2018)

2. Examining the amount of tears before and after a certain treatment and medication. (Ibrahim 2012, Kojima 2014, Okura 2015)

3. Monitoring the time-series variation of the tear volume, which is repeated in short period of time. (Kojima 2011, Hirayama 2013, Sano 2015, Ayaki 2019)

4. It is suitable for tear volume evaluation in pediatrics, owing to its minimal invasiveness.

5. Initial screening to rule out normal eyes from KCS in dogs. (Miyasaka 2019)

Product Information

Pouch : Each SMTube is individually sterilized

Package : 50 strips/box

- PCT patented
- MHLW Japan registered as Class I medical device

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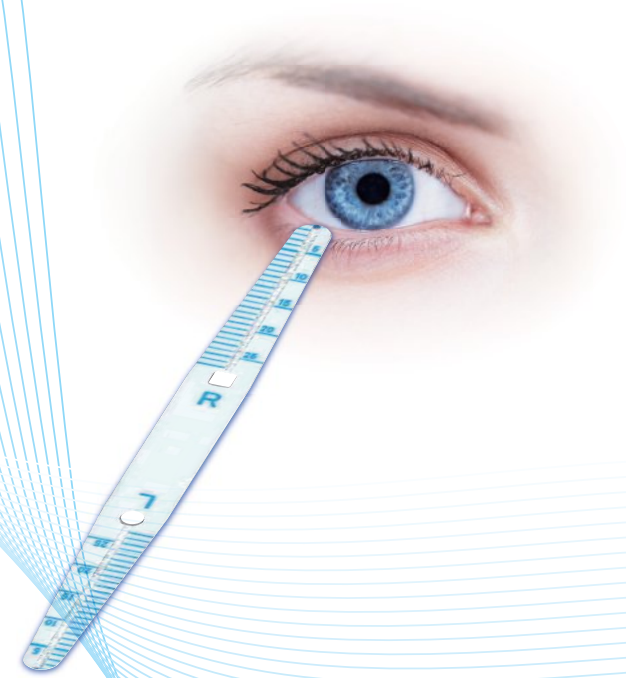
Thank you.



Our SMTube technical documents are available@

https://www.echo-mf.jp/en/smtube/product/

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- ISO 13485:2016 / JIS Q 13485:2018 certified
- Medical devices manufacturer licensed by MHLW Japan
- MHLW third-class medical devices marketing authorization holder

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Manufacture of LACRIMAL Tube
(Head office (Shirakawa Factory))

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