A new method for

Tear Volume Measurement

SMTube®

Strip Meniscometry Tube

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.

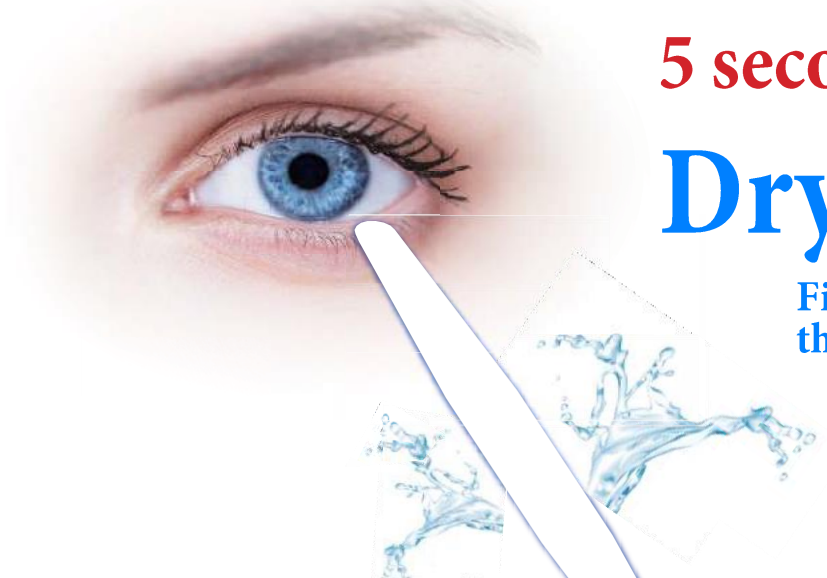
In this brochure, we would like to introduce our new diagnostic medical device, “Strip Meniscometry Tube (SMTube)”, developed for a simple, accurate, swift and minimally invasive assessment of tear volume. “Strip Meniscometry” is a term of a methodology for the tear volume evaluation, of which the original 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.

Several 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).



5 seconds

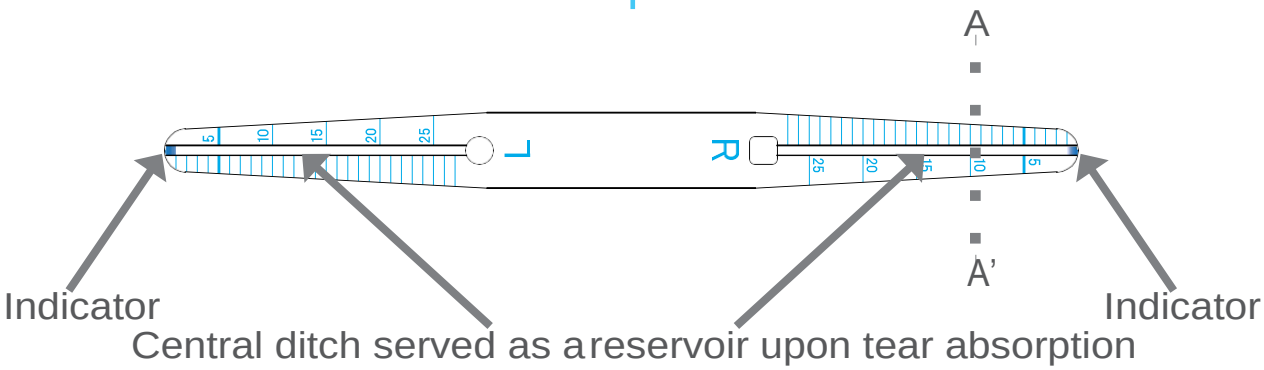
Dry eye screening

Five seconds quantification for the lower tear meniscus volume

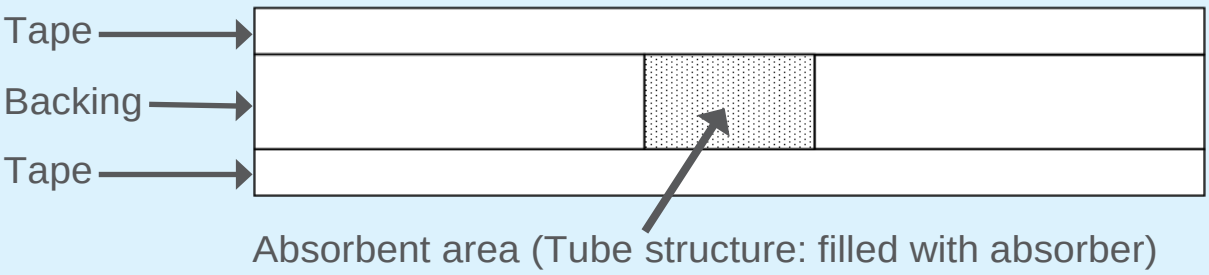
Configuration / Structure

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

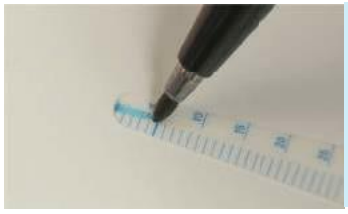
Instruction for use

Without slit lamp
(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 SM-Tube is stabilized.

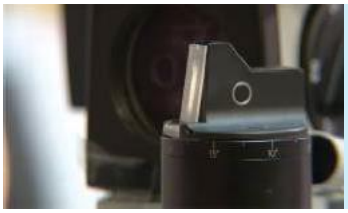
Immerse the tip of the L side into the tear meniscus of the left lower eyelid for 5 seconds to absorb tears.
Take extra care not to touch the conjunctiva nor the cornea with the tip of the strip.



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

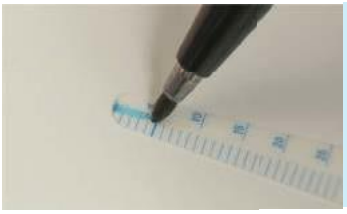
Switch to the R side of the strip and perform the testing on the right eye in the same manner as done on the left eye.

With slit lamp
(when used by doctors)



Make sure to use the illumination with an essentially minimum intensity to avoid the reflex secretion caused by the photo stimulation.
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 fixing the hand as shown in the left photo.

Hold a strip as follows

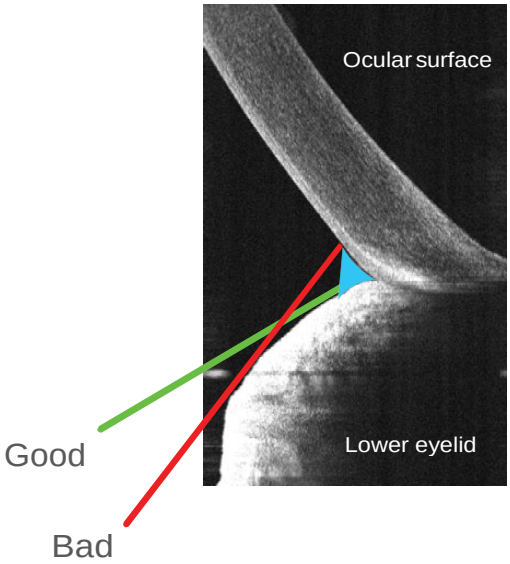
Make sure to hold the center part of SMTube during the examination. SMTube absorbs tears by capillary action and holding the column parts or blocking the hole near the central of the strip (the end of the column) may disturb the capillary action.

Angle of Insertion

The angle of insertion is highly important in order to evaluate tear meniscus volume correctly.

The good example shown in the picture below is showing that strip is inserted into tear meniscus, with correct angle.

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



Contraindications

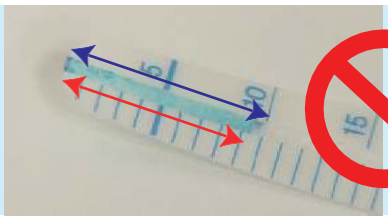
When taking out the strip, do not touch the tip of SMTube strip where the blue dye is impregnated.

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.

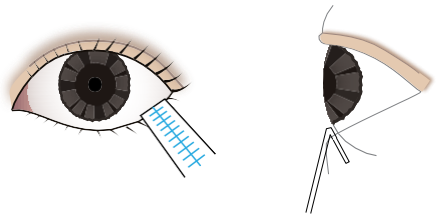
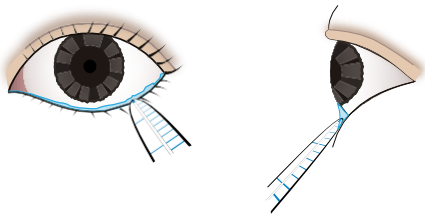
Never touch the cornea with the strip.



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 height (TMH) and area (TMA) measurements using an optical coherence tomography (OCT), and tear film breakup time (BUT) measurement (Shinzawa 2017).

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.

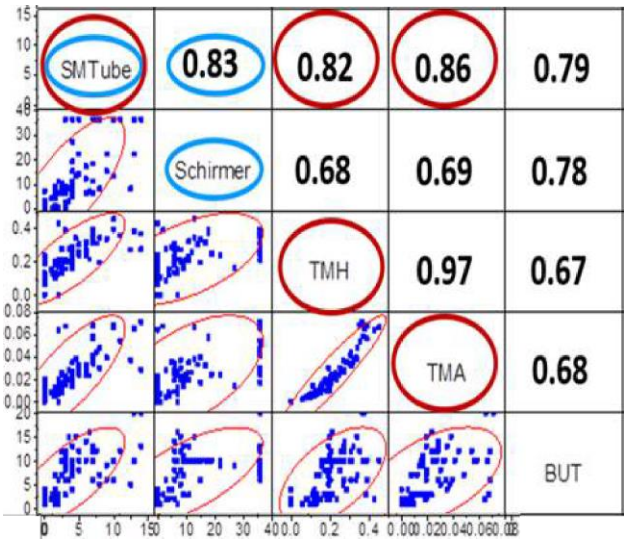
Figure 1: Summary of Subjects

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[4]

*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's 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.

Product Information

Pouch: Each SMTube is individually sterilized

Package: 50 strips/box

- PCT patented
- European Medical Device Directive 93/42/EEC, CE marked as Class I
- FDA device registered as Class I
- MHLW Japan registered as Class I medical device

Application of SMTube

The advantage of SMTube is its swiftness and handiness in measuring tear volume without requiring special equipment. For this reason, SMTube is suitable for the first screening test of dry eye diagnosis, to differentiate true ADDE(AqueousDeficientDryEye)fromEDE(EvaporativeDryEye).Theapplicable 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 several subjects such as group health checkup. (Ishikawa 2016)

2. Examining the number 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 multiple times in relatively short time. (Kojima 2011, Hirayama 2013, Sano 2015)

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

Carleton Optical

Making light work

Carleton Optical

Pattisson House, Addison Road, Chesham, Buckinghamshire HP5 2BD

Email: carleton@carletonltd.com

Sales: 01494 775 811