A novel method
For tear function test

SMTube®
Strip Meniscometry Tube

5 seconds
Dry eye diagnosis

ECHO ELECTRICITY CO., LTD.
We are pleased to introduce our novel medical instrument, “Strip Meniscometry Tube (SMTube)”, developed for a simple, accurate, swift and minimally-invasive assessment of tear volume. The SMTube enables very quick examination with minimized pain in eyes. All you do is immerse the SMTube into a tear meniscus for 5 seconds.

SMTube is a tube, developed to examine tear function by absorbing tear and is used as an examination and diagnostic method. It is the latest version of the SM test[*] strip with enhanced handiness and improved design for safety. Our in vitro experiments to assess tear-absorbing ability confirmed that the device error stayed within ±1.2 mm in the score, which is precise enough to evaluate the human tear volumes.

We carried out a clinical investigation to assure the safety of SMTube strip in vivo; None of the damages was found. The SM test using SMTube has proved strong correlation with other ocular surface tests on the basis of the Spearman’s rank correlation evaluations.

Configuration / Structure

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

Shape

Central ditch served as a reservoir for the tear absorption

A - A' cross section

Tape

Backing

Tape

Absorbent area (Tube structure: filled with absorber)

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 lateral lower lid tear meniscus of an eye, it absorbs tears via the capillary action of absorber present in the centre of the strip. The indicator, placed at the end of the strip, is dissolved in the absorbed tear. At the end of 5 seconds, the length of the stained tear column is marked and read to evaluate tear meniscus volume.
Instruction for use

Hold the centre of SMTube. Do not touch the dye area.

Immerse a tip of the SMTube to the lateral lower lid the tear meniscus in for 5 seconds. Take extra care so that the SMTube would not touch the patients’ conjunctiva nor the mucosa.

In 5 seconds, read the tear absorbing length and mark it by an oil-based pen.

Then the other eye in the same way.

Measure the length of the column stained by blue colour.
Comparison with an existing lacrimal test

<table>
<thead>
<tr>
<th>An existing method: Schirmer's test</th>
<th>SMTube®</th>
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</thead>
<tbody>
<tr>
<td><strong>Usage</strong></td>
<td>Inserting the Schirmer strip inside the lower eyelid (conjunctival sac)</td>
</tr>
<tr>
<td><strong>Required time</strong></td>
<td>5 minutes</td>
</tr>
<tr>
<td><strong>Algia</strong></td>
<td>invasive</td>
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</tbody>
</table>

Application of SMTube

Advantage of SMTube over the traditional Schirmer’s test is its swiftness and handiness in measuring tear volume. Applicable circumstance of exploiting the advantage of SMTube is not only for dry eye diagnosis. A variety of application in clinical research and experiments have been reported.

1. **Research tear volume changes associated with certain tasks (such as VDT work).**

2. **Time series variation of the amount of tears before and after a certain treatment and medication.**

3. **Screening of a number of subjects such as group health checkup.** [2]
   Please see page 7 for the Relevant papers.

4. **It is also suitable for tear volume evaluations in pediatrics, due to its minimal invasiveness.**
Product Information

Pouch: Each SMTube is individually sterilized

Package: 50 strips/box

- 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

Relevant papers

SMTube has been already introduced in an ophthalmic article.[1] Moreover, SM test using SMTube would be useful for rapid screening of the tear function. This advantage is more pronounced when a large number of examinees are involved in some specific examinations under specific situation.[2]


Thank you

Our SMTube technical documents are available at:

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- ISO 13485:2003, ENISO13485:2012 certified
- Medical devices manufacturer licensed by MHLW Japan
- MHLW third-class medical devices marketing authorization holder
- FDA registration