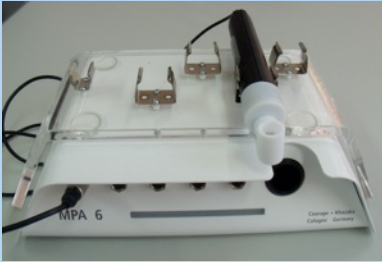




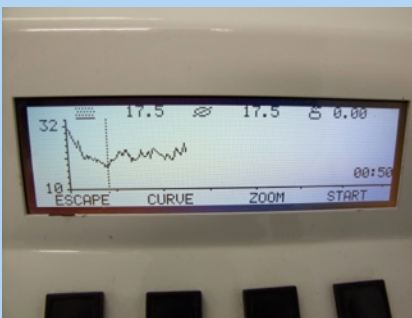
STEPS



1. INSTRUMENT



2. MEASUREMENT



3. READING OF RESULTS

Transepidermal Water Loss (TEWL)

A simplified explanation of the procedure for evaluating skin integrity with the TEWA Meter

Supportable Claims

- Improves skin barrier
- High barrier film
- Treats damaged skin

Technique

Skin respiration measurement is performed using a TEWA meter and is usually compared to the baseline (untreated) skin. Test subjects are pre-screened and those identified as having below normal skin i.e. dry skin types, are used in the test. Skin moisture measurement is performed using instruments which are designed to measure the relative humidity of the air directly above the skin surface.

How it Works

If the integrity of the skin, that is, its ability to protect from water transfer, decreases, the rate of evaporation at the skin surface will increase. This localised increase in Relative Humidity (R.H.) can be quantified. The probe of the instrument is held against the skin and the R.H. is measured by a very sensitive meter.

In Lab vs In-Use

Typically, effective products are occlusive in nature and will work even after only one product application, so it is possible to perform the test in controlled conditions in a clinical lab at say, 1, 2, 4, 7 hours.

Alternatively, in-use performance and improvement can be measured after several days or weeks of repeat applications, depending on intended

use and claims for the test product.

Regression

Normally, products do not continue to have an effect for an extended period of time after the last use and need to be reapplied at least once per day.

Analysis of Results - How Many Test Subjects?

When tested on test subjects, an effective formulation should provide at least 20 to 30% improvement. Provided there is not a high variability between individual test participants, A 10 person study should show significant results.

This test should not be confused with the measurement of moisturisation - it is determining water loss rate as a property of the treated skin.

References

1. Transepidermal Water Loss, Bioengineering of the Skin: Methods and Instrumentation, W. Courage, CRC Press 1995
2. Transepidermal water loss reflects permeability barrier status: validation in human and rodent in vivo and ex vivo models Joachim W. Fluhr, Kenneth R. Feingold, Peter M. Elias Experimental Dermatology Vol 15, No:7 pages 483-492, July 2006

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Transepidermal Water Loss (TEWL)

Transepidermal water loss using a Tewameter Model TM 210. This instrument measures the percentage relative humidity at the skin surface, using a sensing electrode encased in a chimney. Reduction in TEWL is an indicator of high barrier film integrity.

Experimental Design

Subjects: Panels of adult subjects, male and female, randomly selected or as specified by the client.

- Informed of the nature of the test including possible adverse reactions.
- Written informed consent documents signed by all participants prior to induction.
- Only subjects that are considered dependable and able to read, understand and follow directions will be requested to participate.
- Prior to initiation of a test, each subject will complete a medical history form. The subjects will not exhibit any physical or dermatological condition which would preclude application of the test material(s).
- Test subjects will refrain from applying moisturisers or other topical treatment or related products to the test area for 3 days prior to participation in the study.

Other Options

- a. Regression effects upon cessation of treatment.
- b. Incorporate a comparison product.

Method

There will be a pre-nominated wash out period, using Simple Soap prior to commencement of study. At commencement of the evaluation of each subject, the test area will be washed with Simple soap, followed by pat drying.

Dry skin zero state can be artificially induced by extra washings just prior to commencement of the study. After preparation, a period of 30 minutes will be allowed for equilibration, with the subject remaining in the test area.

For short term evaluation, subjects remain at the test facility for the duration of the test.

Temperature of the test area will be held between 18 and 22°C.

Humidity will be held at 50% R.H. +/- 5%.

All doors and windows will be closed during measurement.

The test product is weighed, so as to achieve an even coverage of the required number of milligrams/cm².

Generally this is in the region of 2mg/sq cm, or as specified by the client.

A series of measurements will be taken for each target area at each time point.

Mean and statistical significance will be reported.

Dermatest SOP DESOP 030 Procedure for Determining Transepidermal Water Loss using the Tewameter.