



## HOW TO EVALUATE SENSITIVE SKIN

The skin plays multiple roles of protection, perception, immunity, regulation or blood and lymphatic reservoir for the whole body. Thanks to several mechanical, chemical, or biological (sebum, biofilm ...) reactions, the skin ensures its integrity according to the various endogenous or exogenous environmental variations. Today, the increase in the fragile phenomena of skin is a major issue in the development of the dermocosmetics.

The concept of sensitive skin has been a topic of news for more than 30 years for the formulators of the cosmetic industry. Skin irritation, sometimes confused with allergic skin, results in redness, flaking, vesicles. Sensitive skin is often associated with a consumer's feelings. Since the years 90 there has been an evolution in the understanding of this skin mechanism in Europe that has led to the development of products specifically oriented towards this type of skin. The contribution of academic research in the fields of cutaneous innervation, intercellular communication, proteomics, or genomics has made it possible to better understand this skin and to develop products that are always more adapted and targeted.

Three mechanisms have been identified as potentially involved in the physiology of sensitive skins. There are:

- the disruption of the barrier function,
- the specific nervous system,
- the involvement of immune cells.

In fact, the **loss of the skin barrier function** causes a decrease in the protection of the cutaneous nerve fibers and exposes them to the external environment. The density of nerve fibers present in the skin can also play a role. Finally, neuronal hyperactivity is explained by the presence of receptors that no longer protect, **but induce sensations of pain, warmth and itching** in the sensitive skin.

## Fragile Skin characteristics

Thus, sensitive skin can affect all periods of life, ranging from infants to seniors. **Babies** are particularly prone to redness and irritation due to their **still immature skin barrier**. They have a lower hydrolipidic film, a thin dermis, a more permeable skin and almost non-existent protection against the sun and the heat. The skin of **teenagers** may also have a certain sensitivity because of aggressive cleansers uses, leaving the skin **hypersensitive**. **For mature skins**, these are particularly vulnerable to external aggression such as pollution, UV, blue-light and heat... The activity of the sebaceous glands slows over the years and the skin becomes thinner and more dehydrated.

The constant use of hydroalcoholic gel and soap on hands, becomes a new parameter to be taken into consideration in considering the sensitivity of the skin hand. The resulting change in the skin ecosystem is significant and can be akin to the dryness and the alteration of the skin barrier.

Called "**Dermatosis Invisible**", "**atopy**", or "**reactive skin**", **sensitive skin** is a recent phenomenon as it would have been described for the first time in the second half of the 20th century. This is a common disorder that now affects more than one European in two and is widespread throughout the world. Today we know that 1 French in 2 is affected, whereas in China and South Korea it is 62% of women who have sensitive skin. The causes of the higher prevalence in Asia compared to European countries would be due to overwork and stress, as well as to being exposed to pollution in large cities.

Clinical studies associated to biometrological assessments in vivo on human enables the observation of functional cutaneous signs and allow to describe the healthy skin and the different signs of sensitive demonstrations. The soothing effects are associated to respond to environment (water, wind, sun, pollution, cold) specific skin physiological conditions, internal factors, or lifestyle.



Formulations for sensitive skins generally contain few ingredients, (only the necessary, no superfluous ingredients), limited preservatives, adapted filters, and little or no fragrance. From these advances, some brands formulate skincare to avoid irritation or aggression from ingredients characterized by their low potential irritant or allergenic, coupled with moisturizing principles or constituents of the skin barrier. Others will provide a more symptomatology response with specialties designed to correct unrest and disorders found such as inflammation, discrete vasodilation and where the sensations of tingling and warming. After the Dewy wave, a new emerging trend coming from South Korea, the Skip Care, focusing on quality rather than the number of cosmetic products

used routinely. The goal is to return to a simpler beauty routine, identifying the essential ingredients in order to avoid any use of unnecessary products. To do this, we find multifunction products with for adage: less products for the same profits. The idea is to focus on two steps: cleaning and moisturizing. However, this is linked to the problematic of sensitive skins which only seek the strict necessary in formulas.

Thus, skin facial and body care products, **first protect, then restore the barrier function, strengthen the extracellular matrix, repair, soothe pruritus and limit itch, regenerate or calm irritations and redness**. They can also reduce the inflammation and help to treat both allergic contact and atopic dermatitis, even if it is not cosmetically correct to say it under some regulation latitudes.

Skinobs Clinical testing Platform lists more than 30 methods that meet this claim, in addition to other methods such as consumers testing, clinical scores, sensory analysis and neurosensorial studies.

### **How to Scientifically Evaluate the Emotions linked to Fragile Skin**

The study of emotions has won over cosmetics for a few years now with first the evaluation of well-being by quality-of-life questionnaires and self-evaluations of consumer tests. In the specific case of sensitive skin, emotions, complex physical and instinctive phenomena, cause unconscious bodily signals that can be instantly and objectively measured.

When it comes soothing claim, the multidimensional study of emotions makes it possible to evaluate a wide range of perceptions caused by the application of a product on sensitive skin and the improvements in self-representation as well as the physiological effects induced.

To scientifically objectify emotions, it is necessary to consider in the design of the protocols, the claim sought, the type of product studied, the sensitive type of skin and to integrate the combination of the 3 components of the perceptions:

- Expressive or behavioral: what modifies facial and postural expressions
- Physiological: what changes body parameters
- Subjective or cognitive: what can be verbalized.

The evaluation of ingredients, actives and finished products is at the heart of the activity of the cosmetics industry and feeds every stage of the product development. Subject to global regulations, influenced by the latest digital practices and new consumer habits, and inspired by AI, virtual reality and 3D printing technologies, the world of testing is challenged by the objectivation of the performance of skin care dedicated to the fragile skin.

Major innovations in the perception objectivation remain to come if it considers the latest research on **sounds, taste, smell, or vision receptors** present in the keratinocytes. In complementary ways, the testing innovations will be initiated with new active developments, without talking about the most promising role of cannabinoids in the treatment of itch. The more the mechanisms behind the sensitive skin phenomenon will be understood, the more cosmetic industries will be able to offer effective and durable solutions to treat sensitive skins, through the elaboration of formulations targeted specifically these mechanisms.

Anne Charpentier  
CEO  
Skinobs

## Our partners have the floor

We are glad to introduce the several topics presented by testing experts

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## **Managing Sensitive Skin and Inflammation by Validated Claim Support**

Jane Tervooren and Brian Ecclefield

Sensitive skin is a condition where the skin gets easily irritated and often turns red, itchy, and sore. This can happen because of things like changes in temperature, makeup, and stress. Many people have sensitive skin, and it's becoming more common worldwide. There are many potential causes of sensitive skin and things like genetics, the environment, and problems with the skin's barrier can often play a role. Sensitive skin is also linked to other skin conditions like eczema, rosacea, and atopic dermatitis that cause skin inflammation.

Inflammation can happen when the body's healing process starts after being irritated. When there is too much inflammation, it can harm the skin and make sensitive skin significantly worse. To treat sensitive skin, a variety of techniques can be used to fight the inflammation.

These treatments generally come in two forms: topical and systemic. Topical treatments are creams and ointments that are put directly on the skin. They work by reducing inflammation and soothing irritated skin.

Systemic treatments are often taken by mouth or through a vein and are used for more severe skin problems under a doctor's supervision.

When it comes to selecting skincare products for sensitive skin, it's important to choose products that have been tested and validated by scientific studies at appropriate regulatory approved or certified Clinical Testing Laboratories. Validated Claim Support can help support sensitive skin and anti-inflammatory claims using bio-instrumentation measurements and expert clinical grading. These studies use objective measurements and clinical assessments to determine the effectiveness of a product.

Instrumentation such as the Tewameter (TEWL) can measure the skin's barrier function, which is important for maintaining healthy skin. The skin barrier helps to protect the skin from environmental stressors and prevent water loss, which can lead to dryness and sensitivity. A compromised skin barrier can increase inflammation and sensitivity, so it's important to choose products that help to maintain and support the skin barrier.

Hydration is another important factor to consider when managing sensitive skin. The Corneometer, Novameter, and EpiD Moisture Meter are all instruments that can be used to

assess the hydration levels of the skin. Maintaining adequate hydration is essential for healthy skin, as it helps to prevent dryness and irritation.

In addition to bio-instrumentation measurements, expert clinical grading can provide valuable insights into the effectiveness of skincare products. Clinical grading involves the evaluation of skin by trained professionals to assess factors such as redness, dryness, and overall skin appearance. These assessments can help to identify areas of improvement and track changes in skin health over time.

It's also important to choose skincare products that are free from harsh chemicals, fragrances, and preservatives, and opt for products that contain natural, soothing ingredients such as aloe vera, chamomile, and calendula. Wearing protective clothing, such as hats and long sleeves, and using sunscreen with a high SPF can help to protect the skin from environmental stressors like pollution and UV radiation. Completely blocking UV radiation from ever reaching the skin will always be a more effective means of protection than creams and lotions, no matter how strong their SPF may be.

Maintaining healthy lifestyle habits can also contribute to healthy skin. Eating a balanced diet that is rich in fruits, vegetables, and healthy fats can provide the nutrients and antioxidants needed for healthy skin. Exercise, getting enough sleep, and managing stress can also help to support healthy skin.

Understanding the triggers of inflammation and sensitive skin and taking steps to minimize exposure to these triggers can help to reduce symptoms and promote healthy skin. Choosing skincare products that have been properly Validated by a reputable, FDA Registered lab and which contain natural, soothing ingredients is an important step towards maintaining your skin's natural barrier, and visibly fighting against the signs of aging.



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## **A Global and Multi-cultural Evaluation of Sensitive Skins by IEC Group**

Jean-Robert Campos – Scientific director

The terms "sensitive skin", "reactive skin", "irritable skin" are used for long years by the cosmetic industry to describe several symptoms which make it possible to distinguish these cutaneous conditions but which can also be combined with each other, sometimes being confused to precisely define the desired target

Since 2017, sensitive skin has an international consensus definition proposed by the IFSI [International Forum for the Study of Itch] which defines it as *"a syndrome manifested by the occurrence of unpleasant sensations (prickling, burning, pain, pruritus) in response to stimuli that would not normally cause such sensations. These unpleasant sensations cannot be explained by damage due to a specific skin disease. The skin may appear normal or be accompanied by erythema. Sensitive skin can occur in any skin location and especially on the face"*.

The "sensitive" skin syndrome linked to a hyper-reactivity of the skin may be favored in the presence of certain factors such as environmental parameters (temperature variation, pollution, cold, heat, wind...), chemical (cosmetics, pollution), psychological (stress), internal (hormones, alcohol, spices...)

In order to select volunteers with "sensitive" skin, it is possible to refer to the ARPP definition (July 2019) which takes into account, in particular, the declaration by subjects of a recent and repeated history of functional skin discomfort symptoms.

As sensitive skin being a subjective syndrome defined by the occurrence of sensations, diagnosis can be made by asking subjects about the sensations perceived and the mode of onset. Scales, such as the 10-question Sensitive Scale (Misery & al, 2014) is the most widely used to help diagnose sensitive skin, but some sponsors have also their own criteria for including subjects with sensitive skin.

Sensitive skin is very common since it affects about half of the French population, more often women (60%) than men (40%) (Misery & al. , 2018).

They mainly affect the face, although other areas may be affected such as the body and scalp.

An European study showed differences in the prevalence of sensitive skin between countries but also due to cultural and linguistic differences.

Sensitive skin is mainly found on the face (85%) but can also be present on the hands (57%), scalp (36%) and neck (27%).

The face is the area most often affected due to direct exposure to environmental factors (sun, wind, etc.) but also to the use of cosmetics and due to the high nerve density in this area.

Sensitive skin has an impact on quality of life, at least in its psychological dimension. Several quality scores show this significant relationship between the fact of having sensitive skin and the impairment of quality of life. This impact can be assessed by the generic questionnaire for studying quality of life in dermatology: Dermatology life Quality Index (DLQI) but also by a specific quality of life questionnaire for subjects with sensitive skin, the Burden of Sensitive Skin (BoSS) questionnaire.

In sensitive skin, the direct consequence of the alteration of the skin's barrier function and its lack of hydration is that the tolerance threshold is lowered: the skin becomes more sensitive to irritants and external stimuli. Indeed, as the skin's barrier function is less effective, the penetration of aggressors is facilitated. This results in an inflammatory response leading to the release of pro-inflammatory cytokines. This inflammatory mechanism explains the clinical signs such as redness and heat sensations.

In order to respond to the problem of skin sensitivity, which corresponds to a hyper-reactivity resulting from a lowering of the tolerance threshold, IEC can offer different protocols such as:

- A 21-day In Use Test on at least 20 subjects with "sensitive" skin according to the ARPP definition, combined with questionnaires and quality of life perception scales.
- Evaluation of the skin's barrier function [measurement of the Trans-Epidermal Water Loss] which, once restored, hinders the penetration of potentially irritating agents, thus increasing the skin's tolerance threshold.
- The measurement of certain neuro-mediators secreted by the superficial nerve endings and pro-inflammatory cytokines, the reduction of which corresponds to a reduction in skin reactivity.
- The scoring of the overall intensity of prickling [immediate or long-term effect] with the Stinging Test [lactic acid].

For a global multi-ethnic and cultural approach, these tests can be performed in our 8 test centers in France, Bulgaria, South Africa and Asia (Japan, Singapore, Korea and China).

The claims corresponding to this type of skin such as "suitable for sensitive skin", "short and/or long-term soothing effect" ..... must result in a reduction in the perception of discomfort, ideally associated with an improvement in the biometric parameters mentioned above. <https://www.iecfrance.com/>

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## Analyse inflammation with the C-Cube CR system by Pixience

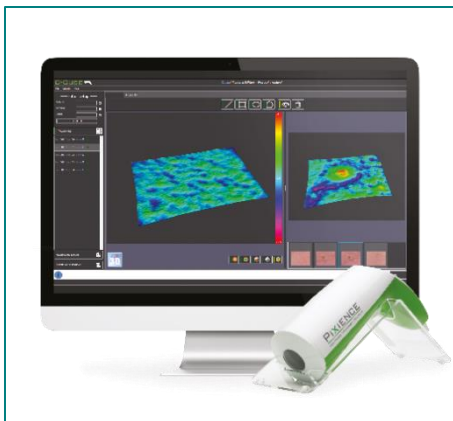
Sébastien Mangeruca – CEO

Sensitive skins naturally tend to be more inflamed than other skin types. This is the body's way of defending itself against internal and external aggressions on the skin barrier.

Local irritation can be initiated by contact with everyday substances. Inflammation can take many forms, and can result in red, rough skin, rashes and blemishes.

This way, many anti-inflammatory agents are incorporated into skincare products to improve skin tone and texture. Clinical trials are necessary to ensure that dermo-cosmetic products do not cause an inflammatory reaction or to test the effectiveness of your anti-inflammatory creams and treatments.

More than a chromameter, C-Cube CR 3 is a specific device for skin's color and surface analysis. It is specifically designed to be used in cosmetic clinical trials. French leader in digital dermoscopy, Pixience works closely with dermatologists and researchers to develop high quality products for skin and hair imaging and analysis.



An exclusive method of metric and color calibration makes the C-Cube CR 3 the only dermoscope to provide reproducible colors, correlated with a spectrophotometer. Thanks to its ease of use and flexibility, it integrates seamlessly and painlessly your clinical trials.

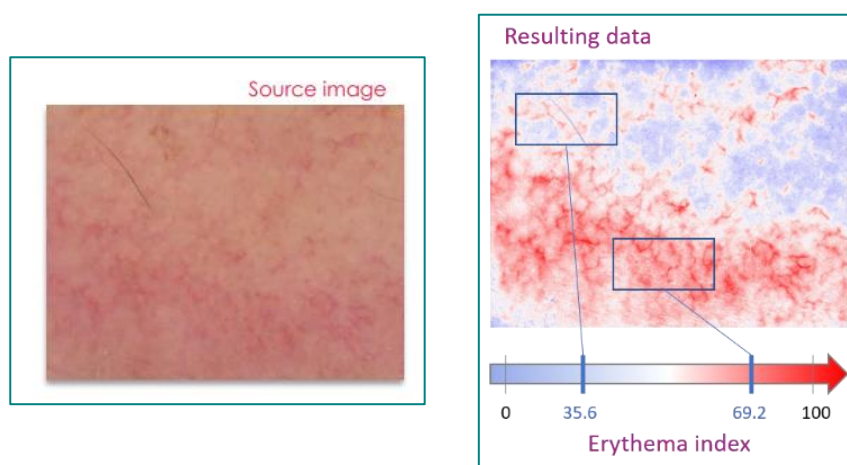
You improve your analysis sensibility by circling, or targeting, precise regions of interest directly on the very high-resolution photographs it produces.

With its CIE L\*a\*b\* COLOUR measurements, the C-Cube CR 3 allows you to image and measure the degree of effectiveness of your active ingredients on the skin and scalp. Thanks to the data contained in each pixel and the placement of the ROIs in the image, you ensure control and precision in your studies.

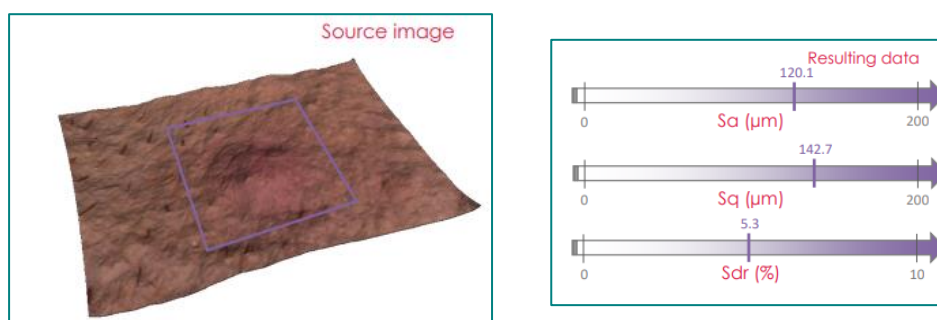
You can also make 3D acquisitions of skin's surface. Using a technique called photometric stereo, the C-Cube system analyses multiple images under different lighting conditions to estimate surface normals. 3D captures can be done in-vivo or using silicone replica in the Sample Reader. Combined with a geometric calibration the software produces elevation information at each pixel. 3D captures allow for exemple to visualise and analyze microrelief to evaluate his isotropy.

Accurate and reliable color measurements allow the evaluation of many of the skin's characteristics such as erythema, roughness, acne, and pigmentation evenness.

- **Erythema:** Observe the presence of erythema. The software allows you to obtain colour-mapped image of the study area (red for areas affected by erythema, blue for areas not affected). You can compare this image with an erythema index to characterise and locate it precisely.



- **Pigmentation evenness:** The C-Cube CR software provides the amount of melanin through an index called pigmentation index. It also provides the Individual Topology Angle (ITA) for the area. The C-Cube Clinical Research software also calculates the standard deviation for both pigmentation criteria.
- **Roughness:** Skin roughness can be analysed with C-Cube CR 3. Combined with a geometric calibration the software produces elevation information at each pixel and the roughness parameters Sa, Sq and Sdr. Sa and Sq represent the average distance (respectively arithmetic and quadratic) to the average elevation of the ROI. Sdr, is expressed as the percentage of additional surface area contributed by the texture as compared to the planar definition area.



- **Acne:** Pimple elevation is an important characteristic of the severity of the inflammation and may be reduced. The peak height (Sp) and total amplitude (Sz) of a ROI is processed and can be monitored to show product efficacy.

Conducting your clinical studies with the C-Cube CR 3 ensures that you can quantify all types of skin inflammation manifestations.

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## Human skin model to target sensitive skin and soothing effects by Syntivia

Claire Leduc - PhD, Head of R&D Business Unit

At pathophysiological level, sensitive skin is characterized by several phenomena: a defect in the cutaneous barrier, as well as increased inflammation and neuroinflammation. These phenomena lead to skin dryness, irritation and sometimes burning sensations.

At Syntivia, we are committed to providing studies that are as close as possible to *in-vivo* conditions and have chosen the skin explant as our favoured model. As the explant is obtained from surgically derived human skin, it is for us, the most representative of the complexity of human skin.

Despite its complexity, we can adapt the *ex-vivo* model to many cosmetic and dermatological applications to evaluate the biological effects of products under development or finish products.

**We are working on a human skin model with a barrier defect, dehydration and expressing the main markers of sensitive skin (figure 1).**

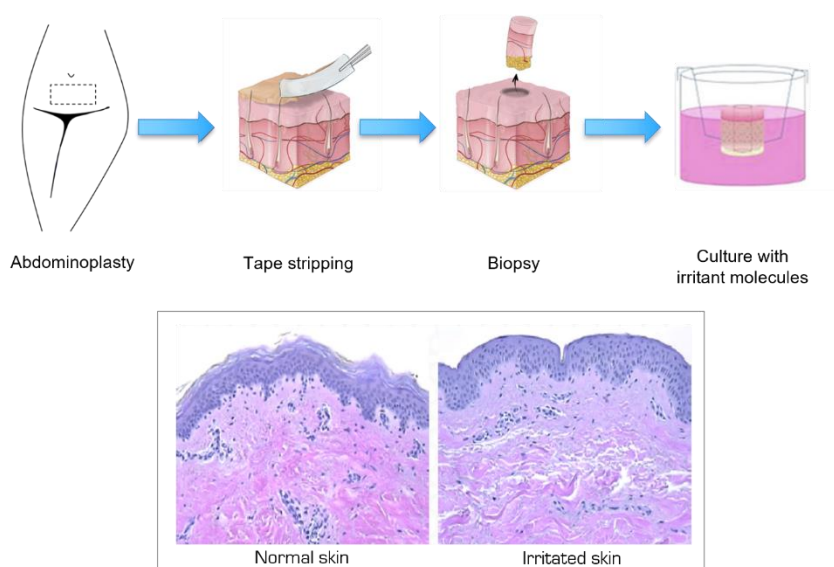


Figure 1: Preparation of a preclinical *ex-vivo* model of irritated skin and imaging after histological staining.

### Barrier defect and skin dehydration:

In addition to the **thinning of the stratum corneum** resulting from tape stripping (figure 1), the model shows a decrease in **the main markers of the stratum corneum** (figure 2):

- Filaggrin
- Ceramides
- Loricrin (not shown)
- Involucrin (not shown)

We also observe a significant **increase in TEWL** and a **decrease in the amount of glycerol** present in the skin (figure 2). Indeed, a low concentration of glycerol may lead to decrease the water content of both epidermal and dermal compartments, possibly leading to structural changes in the skin relief and increasing the TEWL.

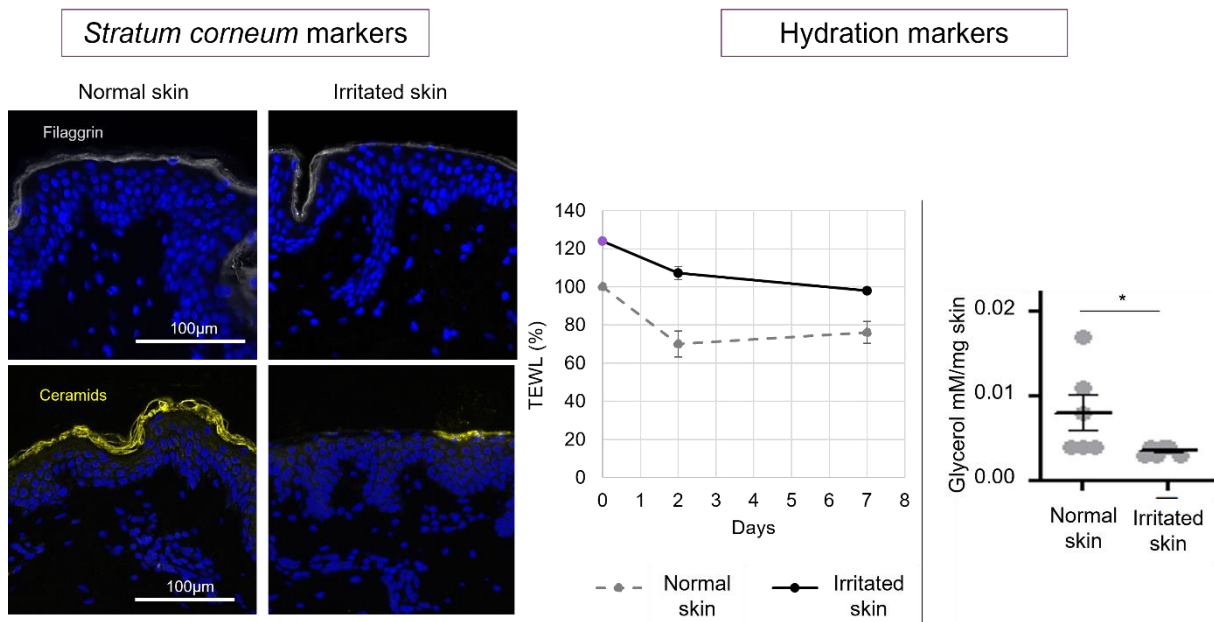


Figure 2 : Barrier alteration and skin dehydration in the preclinical *ex-vivo* model of irritated skin.

### Activation of inflammatory mediators:

The model we use is also characterized by the production of cytokines associated with non-specific inflammation: **Tumor Necrosis Factor  $\alpha$  (TNF $\alpha$ )** and **Prostaglandin E2 (PGE2)**, the latter being particularly associated with sensitive skin (figure 3).

Transient Receptor Potential, Vanilloid Family 1 (TRPV1) is a thermosensitive ion channel which reacts to noxious stimuli. TRPV1 is expressed among other on fibroblasts, mast cells and keratinocytes; activation results in pain or pruritus with a burning component. **TRPV1 expression is increased** in the skin model and probably upregulated by inflammatory mediators (Figure 3).

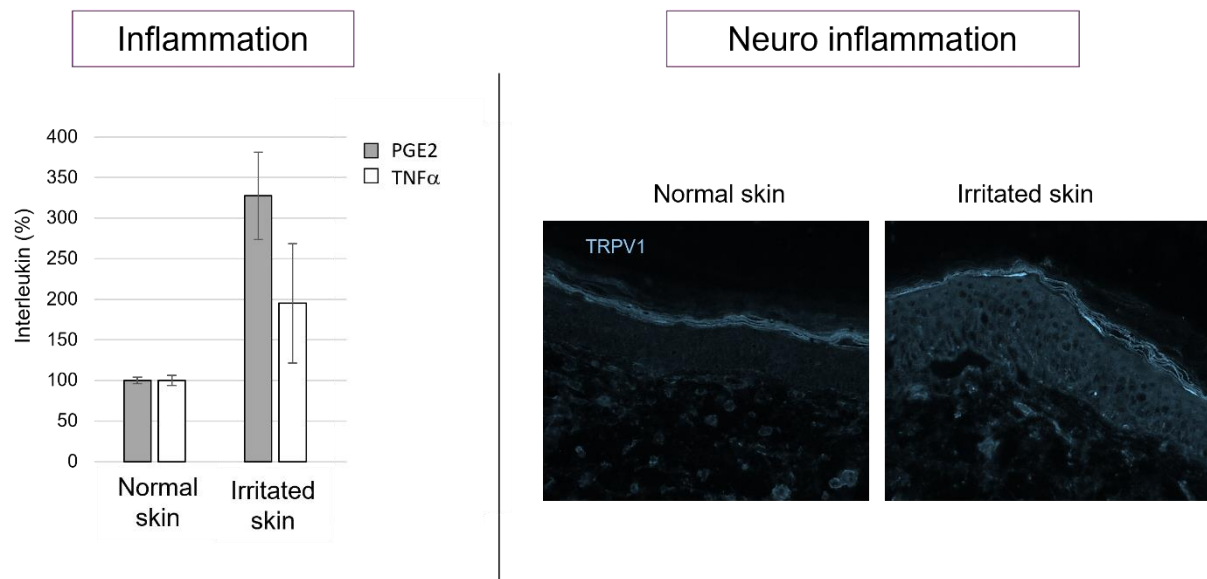


Figure 3 : Increase of markers associated to inflammation and neuroinflammation in the preclinical *ex-vivo* model of irritated skin.

In conclusion, this *ex-vivo* model, as a real human skin model of irritated skin, responds very closely to the *vivo* conditions, and perfectly bridges the gap between *in-vitro* activity and clinical studies, increasing the chances of success in clinical studies.

**The multiplicity of markers we can study means we can effectively screen products for their activity, highlighting both products that help reduce the signs of sensitive skin, and those that are potentially irritating.**

We are continuing our research to identify new conditions that can cause skin irritation through different external stresses (molecules, viruses, detergents...) to offer ever more evaluation possibilities for ever more reliable results.

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## Addressing Sensitive Skin: Challenges and Approaches in the Cosmetics Industry by SGS proderm

Sascha Faust – Marketing Director

Sensitive skin is a widespread concern, affecting nearly 50% of the global population, with a higher prevalence in women [1]. Factors such as environmental conditions, lifestyle choices, and physiological aspects can exacerbate symptoms. The characteristics of sensitive skin include overt sensory perceptions or decreased skin tolerance thresholds. Some individuals may experience sensations such as skin tightness, stinging, burning, tingling, pain, or itching. Objective perceptions observed by trained professionals include various cutaneous reactions such as erythema.

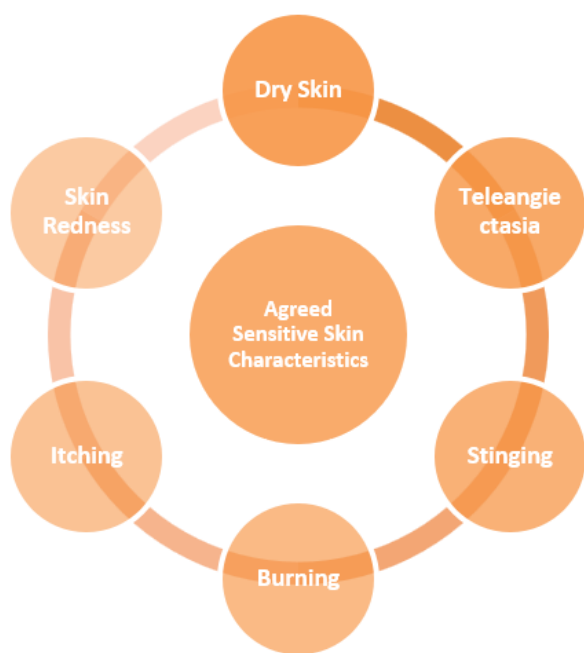
Defining sensitive skin is essential for the cosmetics industry to develop and market products that cater to this condition, but this remains a challenge, with no clear consensus on a definition of "sensitive skin" between consumers, dermatologists, scientists, and the cosmetics industry (see Figure 1, for the agreed sensitive skin characteristics). Sensitive skin remains by and large a self-diagnosed condition, however various research groups have defined different types of skin sensitivity (see Table 1) [2].

*Table 1 Classification of sensitive skin*

| Classification | Subgroups                 | Features  |
|----------------|---------------------------|---|
| Pons-Guiraud   | Very sensitive            | Reactive to a wide variety of both endogenous and exogenous factors with both acute and chronic symptoms with strong psychological component. |
|                | Environmentally sensitive | Comprises clear, dry, thin skin with a tendency to blush or flush and reactive to primary environmental factors.                              |
|                | Cosmetically sensitive    | Skin which is transiently reactive to specific and definable cosmetic products.   |
| Muizzuddin     | Delicate skin             | Characterized by easily disrupted barrier function not accompanied by rapid or intense inflammatory response.                                 |
|                | Reactive skin             | Characterized by a strong inflammatory response without a significant increase in permeability.   |
|                | Stingers                  | Skin with heightened neurosensory perception to minor cutaneous stimulation.  |

Inamadar AC, Palit A. Sensitive Skin. An overview. Indian J Dermatol Venereol Leprol 2013, 79:9-16

Figure 1 Sensitive skin characteristics which are agreed upon by the majority of experts



**Supporting sensitive skin claims**

To make sensitive skin claims, cosmetic products must meet global legislative requirements. Assessments and measurements on the appropriate test panel of subjects with sensitive are the key to a reliable and scientifically sound claim support.

**Volunteer selection and characterisation**

Volunteers in a clinical study should reflect the target population of the product under investigation. When a sensitive skin panel is required the main question is how the

sensitivity of the subjects is determined. Sometimes it may be enough to rely of the volunteer's self-perceived skin sensitivity (assessed via sensitive skin questionnaires where volunteers grade and score various sensitive parameters), other times it may be necessary to perform a chemical trigger test in order to further characterize their type of sensitivity (see Table 2) and there are also various biophysical methods for identification of sensitive skin (see section below on biophysical measurements).

Table 2 Characterization of Sensitive Skin According to Chemical Responses.

| Test                   | Test Site                 | Application                                      |
|------------------------|---------------------------|--|
| Lactic acid sting test | Nasolabial fold of cheeks | To elicit a stinging response                    |
| SLS occlusion test     | Forearm or back           | Erythema due to vasodilation                     |
| Capsaicin test         | Nasolabial fold of cheeks | Stinging and vasodilation                        |
| Methyl nicotinate test | Upper ventral forearm     | Erythema due to vasodilation                     |
| Histamine              | Forearm intradermal       | Pruritus (itch)                                  |
| Soap wash test         | Face                      | Tightness, burning, itching, stinging sensations |

**Accelerated sensitive skin volunteer panel recruitment**

Incorporating documentation of volunteer self-perceived skin sensitivity upon registration in the SGS Proderm databased ensures immediate access to more than 1,000 subjects with self-perceived skin sensitivity and more than 150 subjects with skin sensitivity determined in a Facial Stinging Test (stingers), vastly accelerating the recruitment process (see Figure 2, for the sensitive skin panels included in the SGS proderm database).

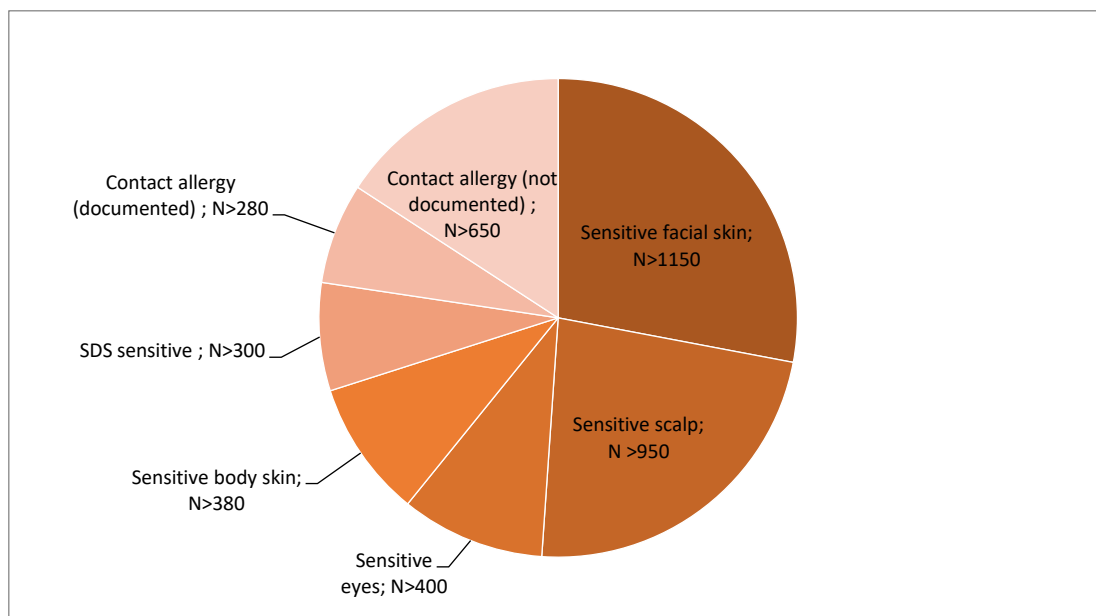


Figure 2 Sensitive skin panels at SGS Proderm. (N = number of volunteers in each panel)

### Methods for testing sensitive skin products

Sensitive skin product testing involves objective approaches, including tolerability assessments and efficacy assessments using biophysical and imaging parameters.

**Tolerability studies** aim to exclude irritation potential or skin discomfort during product usage. These studies often involve patch testing, in-use studies with expert grading and tolerability assessment, and facial stinging tests using lactic acid with subjective stinging severity grading. These studies are carried out on a defined "sensitive" panel of volunteers, who are either "Stingers" as determined by Lactic Acid Facial Stinging Tests or have sensitive skin as determined by Questionnaires or self-estimation.

Figure 3 Facial stinging test – Simultaneous application of two test products to the nasolabial folds of face of lactic acid stingers.



**Efficacy studies** should comprise both subjective and objective assessments as well as measurements where appropriate. They may include anti-facial stinging testing on "stingers" with subjective evaluation of stinging potential or the capsaicin / methyl nicotinate test on volunteers with sensitive skin and evaluation of erythema/stinging via a combination of subjective and objective assessments/measurements if applicable.

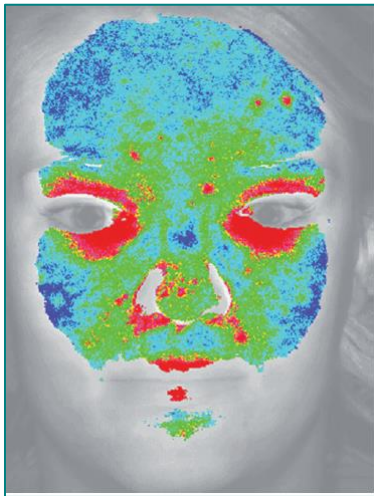
**Clinical photography** (with USR-CliP MacIS or Visia-CR) can be used in objective assessment of certain skin sensitivity parameters such as: skin redness or erythema; skin texture and surface roughness; pore size and distribution.

**Biophysical measurements** can be used to evaluate the physiological aspects of sensitive skin. These include transepidermal water loss (TEWL), skin hydration capacitance (corneometry), skin surface roughness (profilometry), skin redness (via chromametry), skin temperature (IR-Thermography), stratum corneum thickness (confocal microscopy) and skin elasticity (cutometer). Imaging measurements provide in-depth evaluations of vascular parameters, such as blood flow, using techniques like Full-Field Laser Perfusion



Imaging (FLPI). Additionally, itch sensations can be assessed experimentally using topical application or intra-dermal injections of various substances like histamine.

Figure 4 Full Field Laser Perfusion Imaging (FLPI) of facial blow flow.



**Quantitative Sensory Analysis (QSA)** can evaluate sensations like heat and cold pain using thermal cutaneous sensation testing. Methods like the thermo-sensory analyzer (TSA) measure the threshold for warm and cold sensation, as well as hot and cold pain. Touch-evoked sensitivity can also be assessed using Von Frey filaments.

Figure 5 Heated Thermode on the skin.

Measurement of Heat Pain Threshold (HPT) with a Thermal Sensory Analyser (TSA).



**Biomarker analysis** of inflammation markers and skin surface lipids offers insight into skin reactivity, irritation, and barrier function [3, 4]. Non-invasive methods can be used to collect these biomarkers for analysis with immune-assays or spectroscopic and chromatographic technologies. Dermal transcriptome analysis is possible with transdermal patches and next-generation sequencing [5].

In conclusion, to effectively support sensitive skin claims, it is essential to understand target consumers as well as regulatory requirements, while utilizing an appropriate sensitive skin volunteer panel in clinical studies. Combining both subjective and objective assessments as well as measurements ensures rigorous testing, ultimately helping build the necessary evidence for successful product development and marketing.

## References

Please contact SGS proderm for the cited literature.

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## **High quality standardized images for skin acne evaluation and product performance valorization by Newtonone Technologies**

Solène Trevisan – Clinical Image Analysis Pole Manager

Acne is a skin disease that often occurs during hormonal changes, particularly during adolescence and adulthood (50% of 20-29 years old and 4% of 40-49 years old are affected). Acne can have real psychological repercussions and alter the quality of life by inducing mood disorders, depression, alteration of self-image, relational difficulties... In severe cases, acne can also lead to the formation of scarring lesions causing, in the most serious cases, a grainy appearance of the skin.

Acne is characterized by different stages: a mild acne with open or closed comedones, a moderate acne characterized by papules or pustules, a severe acne with the presence of nodules or cysts.

Newtonone's challenge is to provide solutions to quantify the effect of different products on different acne lesions.

### **ColorFace®: focus on the holistic approach**

The face is the area most affected by acne. The ColorFace®, a full-face imaging system, allows a standardized image acquisition under 3 positions and different lighting (including UV) to highlight the different types of acne lesions. As the ColorFace® is a connected system, all the images of the study are recorded on the Newtonone server to view or analyze the images as soon as the acquisition is made even at the other side of the world! On these images, Newtonone offers image processing algorithms adapted to phototypes to extract open comedones, porphyrin, post inflammatory lesions (erythema and hyperpigmented lesions) and pores. These algorithms can highlight the cosmetic effects of products, especially since they can be correlated with the consumer perception. Newtonone also offers to follow the evolution of the gloss on the images in correlation with the production of sebum on the face.

### **SkinCam®: focus on the local lesion**

In addition to the face, the neck and back are areas prone to acne. With the SkinCam®, Newtonone offers a nomade system to make acquisitions of these areas. Its simple use allows the SkinCam® to be used in the laboratory as well as at home, so that the subject can acquire his lesions every day to study their evolution. In addition, for the analysis of the surface or the visibility of the lesion through its color, the SkinCam® offers 3D reconstructed images to evaluate the roughness of the analysis area or the depth of a scar for example.

### **PAHPI grading tool developed by Newtone:**

To evaluate the severity of post inflammatory pigmented spots, dermatologists use the acne hyperpigmentation index (PAHPI grading). This index is based on 3 criteria: the number of lesions, the mean size of the lesions and the mean intensity of the lesions. This scoring is performed directly on the subject. To upgrade this grading, Newtone has developed a digital tool allowing to perform the PAHPI grading on standardized images, thus facilitating the implementation since the dermatologist and the subject do not need to be present simultaneously. The obtained results are more robust than the ones *in vivo* because the grading can be done blindly without influence for the scorer. The tool is easy to use and can be made available to dermatologists.

To offer a complete service and to facilitate the implementation, Newtone offers the realization of PAHPI grading by its medical expert.

### **Innovative illustrations**

Thanks to its scientific and innovative visuals, Newtone can highlight the effect of visible products on the skin using data from imaging systems or not. With the Newtone average face technology, Newtone is able to extract the skin of a selected case from a study to apply it on an average face: it is now possible to scientifically illustrate before / after effects without the limitations of the right to image!



### **Contact**

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Discover Newtone Technologies profile on the Clinical Testing Platform: [Newtone Technologies](#)



## **New methods to evaluate the sensitive skin in vivo: a global assessment system using advanced methods by PhD Trials**

Pedro Contreiras Pinto – CEO

Sensitive skin is one of the major aspects that affect people in nowadays. In the recent Cosmetotest symposium a presentation shows that 40% of the inquired subjects express to have sensitive skin. Therefore, this is a major concern to the producers of cosmetic products, or cosmetic ingredients as some specific cosmetic products can help to reduce the main aspects of this affection.

Sensitive skin can be characterized by 4 main areas:

- 1) a **barrier impairment** expressed as a thinner stratum corneum,
- 2) a **higher reactivity**, expressed as a response to stinging substances such as lactic acid or capsaicin,
- 3) a change in the composition of the skin namely a **different NMF composition**, different water distribution in the skin layers and some filaggrin mutations and
- 4) a **high vascular response** expressed by a typical erythema or even a burning sensation due to the stimulation of some skin nociceptors.

At PhD Trials we developed a combined method that can evaluate the sensitive skin major aspects and express the result in a global value.

The method involves the **observation and calculation of the skin barrier thickness** by in vivo confocal microscopy. With this method we can calculate the Stratum corneum thickness and reconstruct in 3D the skin barrier, before and after the use of a product. The second targeting function is the detection of the main **skin components of the skin like NMF, Ceramides, Fatty acids and the calculation of the water profile** through the skin, using our new in vivo Raman spectroscope (gen2-SCA). With this method it's possible to precisely detect each of the components and to calculate precisely the stratum corneum thickness. Finally, by observing the Raman spectrums it is possible to detect **filaggrin mutations** which has been associated to some types of barrier impairment and therefore can be a specific marker.

Targeting the skin microcirculation, we use specific challenge procedures such as the **temperature response** and the histamine challenge to calculate the neural, muscular and local mediators' contribution to the vasodilation induced by those challenges. Techniques show different responses in normal vs sensitive skin subjects and can also be a marker for

the vascular response in those cases. Finally, to guarantee the continuity with old data, our method evaluates the **stinging response to lactic acid or capsaicin** and the standard calculation of the skin hydration, using the Corneometer and the skin barrier function using the trans epidermal water loss (TEWL), in this case using the new Tewameter Hex system.

The contribution of each part of the aspects of the sensitive skin is calculated and a final global assessment is obtained.

Contact PhD Trials to understand more how they can help your product to reduce the sensitive skin aspects.



## PhD Trials global sensitive skin assessment



Raman (gen2-SCA)

$$TEWL = B + I(e^{-K_{evap} \times t} - e^{-K_{hydr} \times t})$$


Movement of water from the deepest layers






## Contact

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## Study of the sensitive skin and the "anti-inflammatory" effects by Miravex Limited

Guido Mariotto, CEO

Sensitive skin is a common and frequently occurring skin disorder that may affect about 30–50% of the global population, which can be manifested as facial erythema accompanied by pruritus, burning or tingling sensation, and skin tightness.

The measurement of haemoglobin content and its distribution are important parameters to evaluate skin inflammation, and the Antera 3D is particularly well suited to perform these measurements.

Unlike traditional imaging techniques, where only three colour channels (red, green, and blue) are used, the Antera 3D® uses **reflectance mapping of seven different light wavelengths spanning the entire visible spectrum**. This allows for a more precise analysis of the skin colorimetric properties, which are mostly determined by two dominant chromophores: melanin and haemoglobin.

Acquired spectral images are transformed into skin spectral reflectance maps, and the skin surface shape is used to compensate for light intensity variation due to the varying direction of incident illumination. The reflectance data is transformed into skin absorption coefficients and used to quantify melanin and haemoglobin concentrations using mathematical correlation with known spectral absorption data of these chromophores<sup>1</sup>. The acquired spectral data is used to map the distribution and concentration of melanin and haemoglobin, providing a visual representation of their concentration and distribution in the skin. The result is repeatable measurements of spatially resolved haemoglobin/melanin.

The Antera 3D has been used extensively in many publications to measure vascular lesions, skin sensitivity and inflammation – a full bibliography is available at <https://miravex.com/publications/>. Here, we will briefly discuss a recent publication<sup>2</sup> that has proposed the Antera 3D as a method to objectively detect and quantitatively evaluate

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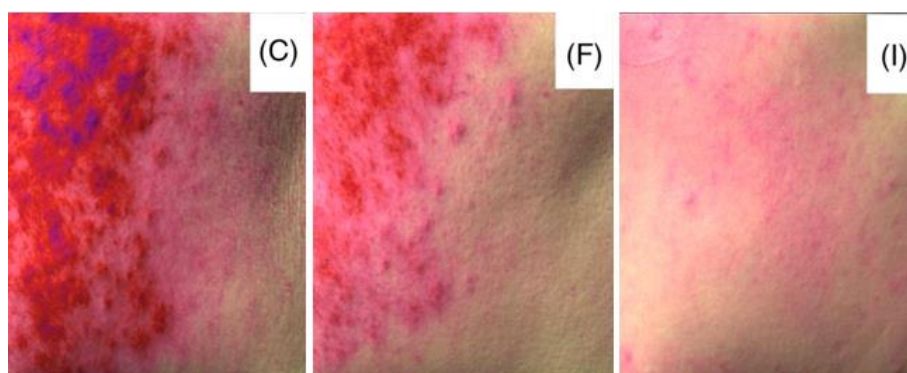
<sup>1</sup> R.R. Anderson and J.A. Parrish. "The optics of human skin". Journal of Investigative Dermatology, 77 (1981), pp.13–19

<sup>2</sup> X Ai'e et al., "Quantitative evaluation of sensitive skin by ANTERA 3D® combined with GPSkin Barrier®", Skin Res Technol. 2022;28:840–845.

sensitive skin by analyzing texture, hemoglobin concentration and the area of the vascular lesions.

In this study, 20 subjects with sensitive skin were treated with an anti-sensitive moisturizing tolerance-extreme cream which has anti-inflammatory and moisturizing effects, twice daily on the whole face for 28 days. Texture, haemoglobin, and influenced area (mm<sup>2</sup>) were recorded using ANTERA 3D. Subjects underwent skin tests and recorded changes at D0 and D28. 20 healthy participants were recruited and used as control.

Compared with controls, the hemoglobin concentration and influenced area of sensitive skin subjects – measured with ANTERA 3D – were significantly higher than healthy participants' data. Compared to D0, both a clear trend toward decreased hemoglobin and influenced area of sensitive skin subjects were seen at D28. It was also observed that the skin texture improved significantly at D28.



*Figure 3. ANTERA 3D images of sensitive skin subject at D0 (C), sensitive skin subject at D28 (F) and control subject (I).*

In conclusion, thanks to its repeatability, high specificity<sup>3</sup> (i.e. the ability to effectively separate the melanin and haemoglobin components from the reflectance spectra), and spatially resolved spectral response, the ANTERA 3D can be used to detect and quantitatively evaluate sensitive skin.

## Contact

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<sup>3</sup> Matial et al., "Skin colour, skin redness and melanin biometric measurements: comparison study between Antera" 3D, Mexameter" and Colorimeter", Skin Research and Technology 2015; 0: 1-17.



Skin, Hair, Nail Testing platforms

## The various choice of biometrological testing you can find on the platforms for clinical Testing

### Various clinical trials can be conducted under normal conditions

- **Consumer tests and self-assessments** including sensitive skin panel answering questionnaire such as **BoSS**, Burden of Sensitive Skin questionnaire.
- **Tolerance tests and expert score evaluation,**
- **Specific sensitive evaluation:**
  - **Stinging test:** testing the sensory answer in the nose wings lactic acid, capsaicin or dimethylsulfoxyde.
  - **Sensitivity test**
- **Sensory analysis and neurosensorial studies** with trained or naïve panels,
- **Biometrological tests** to measure the different parameters of skin physiology and in particular the evaluation of skin barrier such as: TEWL, colour, pH, redness, microcirculation, dryness, suppleness, softness, sebum...
- **The microbiota analysis:** quantitative analysis of the skin microbiota with the characterization of the species collected on the skin samples. The assays enable the taxonomic analysis of the bacteria, identifying what are the bacteria. Then the genome of the bacteria to better know their action. It gives answers relative to the effects of the cosmetics on functions and interactions of host and microbiome simultaneously.

### BIOMETROLOGICAL EVALUATION OF SENSITIVE SKINS

| Studied Effect                | Quantification and Visualization  |
|-------------------------------|---|
| Reduce the sensitivity        | Neurometer® CPT ( Neurotron), WEST-itech (FEI), Stinging test   |
| Decrease the redness          | Mexameter® MX 18 from (C+K), SkinColorCatch (Delfin), TiVi 70 Skin Colour (Wheelsbridge), C-Cube (Pixience)   |
| Improve the microcirculation  | TiVi 700 and TiVi 8000 Micro (Wheelsbridge), Lase Doppler Frequencer and Imager, RSOM Explorer (Ithera medical), Capillaroscope   |
| Decrease the dryness          | Corneometer and MoistureMap(C+K), DPM 9003, Moisturemeter SC/D/epiD (Delfin), Dermo, Epsilon (Biox), DermaLab...  |
| Improve the suppleness        | Indentometer IDM800 (C+K)   |
| Restore the barrier function  | TEWL measurement: Aquaflex (Biox) Vapometer (Delfin), Tewameter (C+K), Dermalab-TEWL...   |
| Improve the skin softness     | Frictiometer (C+K), Touchy Finger, Underskin and Waveskin (LTDS)  |
| Normalize the sebum           | Shotgun Massspectrometry , Quantiseb, Dermalab, Sebumeter (C+K), Sebum Scale (Delfin),  |
| Maintain the pH               | pHmeter (C+K)   |
| Respect the microbiota        | MS/MS-16srDNA-PCR genomics, proteomics, transcriptomics, metabolomics (Phylogene)   |
| Improve the skin surface      | <b>Quantitative &amp; semi-quantitative:</b> DermaTOP-HE-60 (Eotech), SpectraCam (Newtone Technologies), C-Cube (Pixience), Visioscan and MoistureMap MM 100 (C+K), TiVi 60 Skin Damage Visualizer (Wheelsbridge), Antera 3D (Miravex), Visia CR (Canfield), DermalTorqueMeter, SIAScope...<br><b>Visual &amp; imaging:</b> Videomicroscope, Dermlite DL100, Videometer Lab, VEOS DS3, DermaLab Videoscope... |
| Optimize the skin structure   | <b>Quantitative &amp; semi-quantitative:</b> LC-OCT, Antera 3D (Miravex), Vivascope, Vivosight , Dermascan, Dermcup, Sonde Raman...<br><b>Visual &amp; imaging:</b> Scanner: DUB@SkinScanner 50/22 (Eotech), Ultrasound WED-2018, Vivascope, Vivosight...   |
| Respect the molecular content | LC-OCT, Sonde Raman, FibroTX (Eotech), Raman spectroscopy gen2-SCA, Genomics, metabolomics, proteomics... (Phylogene)   |

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