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DermaLab Combo 4

Instructions For Use

CE

CORTEX TECHNOLOGY
Niels Jernes Vej 6B
9220 Aalborg, Denmark
www.cortex.dk cortex@cortex.dk

DERMALAB COMBO 4

INSTRUCTIONS FOR USE

Contents

1 Warnings

- If the unit is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

- The device shall only be powered using the power adaptor supplied with the device (Adapter Tech., ATM036T-P120). Do not use the power adaptor if it has been damaged.

- The unit is intended for indoor laboratory use only, at an altitude of less than 3048 m (10,000 feet) above sea level, within a temperature range of 10˚C to 35˚C and a relative humidity range of 10% to 90% non-condensing. If the instrument is stored outside these ranges, it should be left to stand until it equilibrates to within the above limits.

- The performance of this product may be affected if it is stored or transported outside the range -10°C to 50°C (14°F to 122°F).

- The performance of this product may be affected if it is being used outside the range 10°C to 35°C (50°F to 95°F).

- Keep the calibrator for the skin color probe out of direct sunlight. When not in use, the lid should be on to avoid degradation of the working standards by UV-radiation.

- When measuring with the skin color probe on skin where gels, lotions or ointments have been applied, make sure that excess material does not enter the measurement head. Foreign objects that enter the measurement head can be difficult to remove and may impair the performance of the probe.

- Do not use the device if it shows visible signs of damage or there are other reasons to believe that the device is not functioning correctly.

- Avoid exposure to water. If exposed to smaller amounts such as rain, allow for the device to completely dry and consider contacting Cortex support for aid in assessing if the exposure has affected the integrity of the device.

- Do not disassemble the device. There are no user accessible or serviceable parts inside the unit.

- The DermaLab® Combo 4 system does not require an internet connection for normal operation. If the Combo system is networked to other computer systems or exchange data with other systems, the device may be subject to computer virus attacks potentially harmful to the software environment and recorded data. To reduce such risk, the installation of proper virus scanner software is recommended.

- Before using any cleaning or decontamination method except those recommended by the manufacturer, users should check with the manufacturer that the proposed method will not damage the device.

2 Intended use and general description

2.1 Intended purpose

The DermaLab Combo is an investigational laboratory instrument for measuring skin parameters. Several probes can simultaneously be connected to the main unit to measure skin-related parameters such as TEWL, ultrasound, elasticity, hydration, pH, temperature, sebum, and skin color. In addition, a dermascope can be connected to the Windows-based computer system using a USB connector to capture optical images of skin.

The DermaLab Combo is intended to be connected using the supplied USB cable to a Windows-based computer system.

The DermaLab Combo does not serve a medical purpose and is not intended for diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease. The DermaLab Combo is not covered by annex XVI of the MDR (EU 2017/745).

2.2 General description

The DermaLab Combo system consists of the main unit, probes, and a medical grade power supply to provide power to the main-unit. The system is not a medical device and is designed to meet international safety requirements for measurement, control, and laboratory equipment (IEC 61010-1).

3 Installation and power-on

To ensure trouble-free and safe operation of the DermaLab Combo, including the installation of its software please follow the instructions for use and maintenance as laid down in this document.

3.1 Power supply

The power supply must be connected to a wall outlet providing a protective ground terminal to ensure electrical safety. It may be connected to input voltages from 100 - 240 VAC, 50/60 Hz. Do not use any other pow er supply than supplied by Cortex Technology (Adapter Tech., ATM036T-P120).

3.2 Main unit

Connect the main unit to the +12 V output cable from the power supply. The power input is located on the rear panel of the main unit (see Figure 1, connector 8).

To obtain the most stable readings it is advisable to let the unit and probes warm up for approx. 5 minutes prior to use.

3.3 Connection between the computer and the main unit

The main unit is connected to the computer with a USB cable (see Figure 1, connector 7).

3.4 Connection of probes

The TEWL, Skin Color, Ultrasound, Hydration, Elasticity, pH and Temperature probes are all connected to the rear panel of the DermaLab Combo 4 using various types of connectors.
When inserting the connectors: insert the connector and gently turn it. When the pins are correctly

aligned it clicks into the socket. To disconnect the probe, gently pull the outer ring of the connector and it will disengage (do not turn).

The TEWL, Hydration, Skin Color and Temperature probes may be connected to any of the 6 available inputs (1, 9, 10, 11, 12 or 13 in Figure 1)

The Dermascope is to be connected to a USB port on the Windows-based computer system.

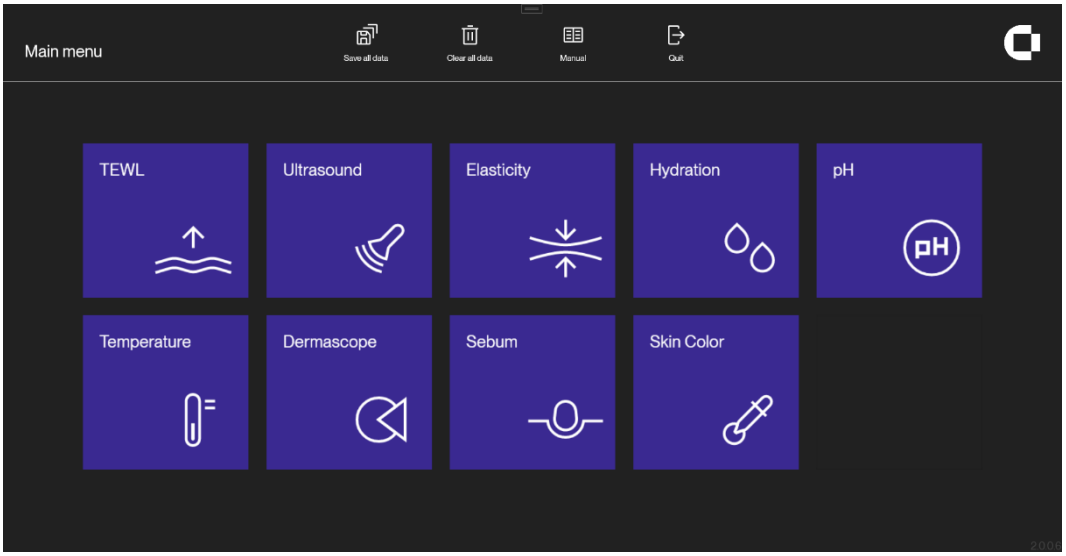
Figure 1: Connectors on the rear panel of the main unit. Table 1 lists how the probes are to be connected to the main unit. Connectors 1, 9, 10,11,12 and 13 are for the hydration, skin color, skin temperature, and TEWL probes. Connectors 2 and 3 are for the elasticity probe (both must be connected). Connector 4 is for the pH probe. Connectors 5 and 6 are for the ultrasound probes (standard and subcutaneous). Connector 7 is for the USB connection to a PC while connector 8 is for the power supply.

Table 1: Overview of how to connect probes, power supply, and USB cable to the main unit.

Connection type	***Icon***	***Figure reference (see*** Figure 1***)***
Hydration Probe (pin or flat)		*1, 9, 10, 11, 12, 13 (either one will work)*
Skin Color Probe		*1, 9, 10, 11, 12, 13 (either one will work)*
Skin Temperature Probe		*1, 9, 10, 11, 12, 13 (either one will work)*
TEWL Probe		*1, 9, 10, 11, 12, 13 (either one will work)*
Elasticity Probe		*2 and 3 (air intake). Both must be connected.*
pH Probe	pH	*4*
Ultrasound Probe (standard or subcutaneous)		*5 and 6 (either one will work)*
USB	-	*7 (USB-B male)*
Power	-	*8*

4 Main screen

After installing the SkinLab software package, turn on the PC and launch the SkinLab application. The main screen will appear, providing a series of buttons for navigation and interaction.



Main screen.

The **TEWL, Ultrasound**, **Elasticity**, **Hydration**, **pH**, **Temperature**, **Dermascope**, **Sebum** and **Skin Color** buttons are used to enter the specific measurement screens directly. See the following chapters for further details on each measurement function.

Parameters, for which probes are not connected, will appear dimmed except for PH and Elasticity.

The **Quit** button is used to exit the SkinLab application. After pressing **Quit,** the Windows desktop will appear, and it will be possible to launch other Windows applications - e.g. making backup of measurement data etc.

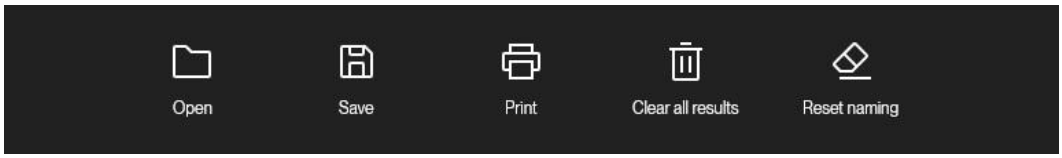
Save all data facilitates the saving of measurement data for all parameters by using just one **button**. Whether previously saved or not, all available measurement data for each parameter will be saved together in one file.
Please note that unless the internal memory has been cleared (see **Clear all data** below), the use of **Save all data** allows for unintended saving of new measurements together with previously saved measurements for other parameters.

Clear all data erases all measurement data for all parameters from the internal memory.

In addition to the global tools **Save all data** and **Clear all data,** measurements for each parameter may be individually saved and/or cleared from within the individual parameter screens – see section 5.

5 Introduction to the SkinLab Combo Screens

All individual measurement screens use common control buttons located at the lower left side of the screens. Note: Not all buttons are shown in all screens.



These buttons provide the following functions:

Open: Open (load) measurement data from a file. Only previously stored data for the specific skin parameter are loaded, other skin parameters remain unchanged. See 6.2. for specifics on opening ultrasound images.

Save: Save measurement data for a specific parameter to a file. See 6.2. for specifics on saving ultrasound images.

Print: Print measurement data on the default printer.

Clear all results: Delete all measurements on screen for the specific skin parameter. Other skin parameters remain unchanged.

Reset naming: Resets all measurement names.

6 High Resolution Ultrasound Imaging

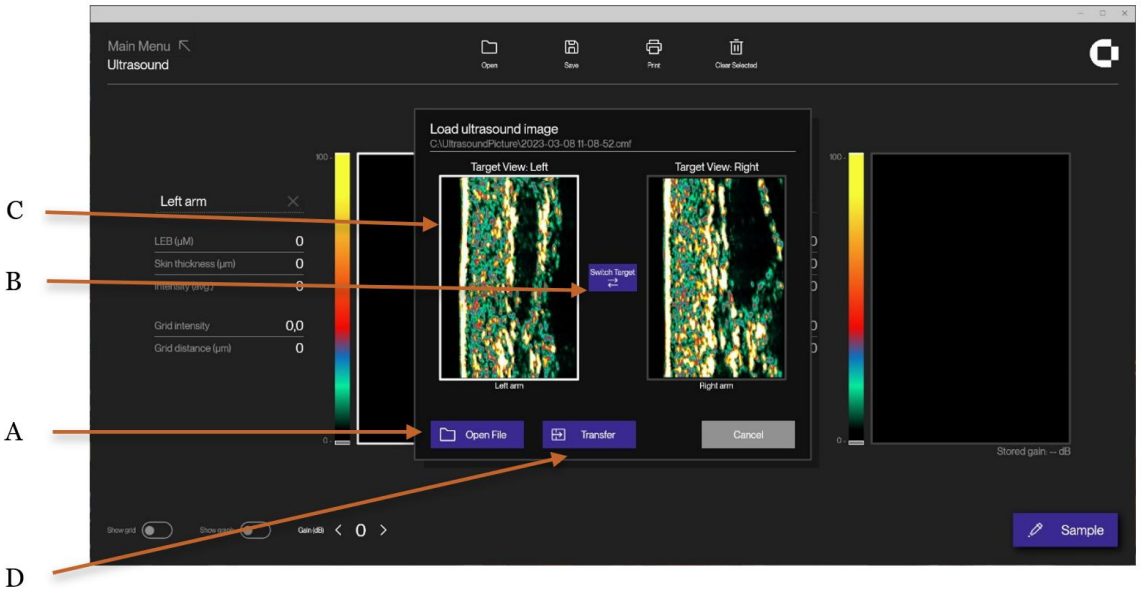
6.1 General principle

Ultrasound skin imaging is based on detecting the acoustic response from the skin and subcutaneous tissues when an acoustic pulse is transmitted into- and reflected from the skin. The energy of the acoustic pulse is very low and will not affect the tissue in any way.
When the emitted acoustic pulse hits the different structures of the skin, part of the pulse will be reflected, and part of the pulse will be transmitted further into the skin. The reflected signal is detected by the ultrasound transducer. After processing, the cross-sectional image visualized on the screen represents an intensity (amplitude) analysis of these reflected signals.

The intensity of the received signal refers to a color scale, where dark colors represent areas with low reflection (i.e. homogeneous composition) and bright colors represent areas with strong reflections (i.e. non-homogeneous composition, significant changes in structure density).

6.2 Saving and opening ultrasound images

Ultrasound images are saved and opened as sets of two images. Accordingly, if only one image is to be saved/opened, the other image position will be saved/opened as an empty image.



Ultrasound Open window, Standard probe.

The following applies to the use of any ultrasound probe:

When touching *Open* in the Ultrasound main screen, a new window will appear. Within this window select *Open file* (A) to show a list of image files. Select an image file to view the content. Once chosen, select the target position for the image(s) on the Ultrasound main screen (right or left, B), and then press to choose one or both images (indicated by the white borderline, C) to be transferred to the main screen by touching *Transfer* (D).
The content of the image file is now loaded into the Ultrasound main screen with the image(s) positioned as set by B.

6.3 Ultrasound unit selection

The DermaLab Combo offers two different ultrasound probes depending on the application:

- The **Ultrasound** probe features high resolution scanning specifically developed for skin imaging. It offers a good balance between resolution and penetration with a scan length of 17,6 mm and penetration depth of 3,37mm. As such it is the preferred probe for general purpose skin imaging. This probe provides a circular scan movement with a medium size footprint and a cross-sectional image perpendicular to the skin surface.

- The ***Subcutaneous*** unit is specifically designed to visualize subcutaneous structures – e.g., for follow-up on aesthetic procedures such as abdominal fat reduction. It provides a less detailed but deeper scan with a large size footprint, a max. penetration of 40 mm and a scan length of 50 mm. As the Ultrasound probe, this probe also provides a circular scan movement and a cross-sectional image perpendicular to the skin surface.

In the following the operation of each type will be explained in further detail.

6.4 The Ultrasound probe

6.4.1 Preparing the ultrasound probe

The Ultrasound Probe accommodates an internal water chamber. This chamber must be filled with de-ionized water or distilled water by following the instructions below.

6.4.1.1 Filling the water chamber

The required water quality is de-ionized water or distilled water. Plain tap water, or other liquids, must be avoided due to the risk of mineral deposits or contamination of the front of the transducer. Such deposits will lead to poor image quality or damage to the transducer element.

1.

Use a tip for easy filling of the chamber.

2.

Attach the tip to the syringe.

3.

Use the syringe with the attached tip to fill the chamber with water.

4.

Check for air bubbles (more information below).

5.

The Ultrasound Probe is ready for use.

Remove as much air as possible from the water chamber during filling. Minor air bubbles will typically not disturb the measurement.

If air bubbles adhere to the inside of the transparent window and cause shadowing effects in the image, they may be released by gently tapping the probe.

Otherwise, top up the probe with water as described above.

6.4.2 Using the probe

Dip the tip of the probe in a cup of de-ionized water or distilled water or apply a thin layer of gel on the skin before each scan. The thin layer of water on the probe will couple the ultrasound to the skin after positioning the probe.

Place the probe on the skin area to be scanned and spread the water with “massaging” movements of the probe (see figure).

Keep the probe steady and press the **probe** button. The probe will perform and present one scan on the screen.

6.4.3 Cleaning

The front piece parts may be cleaned in solutions of mild detergents suitable for plastics (Johnson-Diversey “DIVERSOL BX” or similar) or wiped off with alcohol for disinfection.

The water chamber can be cleaned by either using the syringe to empty it or by carefully unscrewing the front piece and wiping it down with a mild detergent or alcohol wipe. It is recommended to clean the water chamber at least every two weeks.

To empty the chamber:

1.

To empty the chamber, start by removing the valve.

2.

Use the syringe with the attached tip to empty the chamber.

3.

The front piece can be unscrewed carefully to clean the probe on the inside.

Warning ⚠

Take care not to use alcohol, detergent, or other solvents directly on the transducer as this may cause damage to the transducer element. The transducer head can be cleaned with a cotton swab if residue has built up on the front of the transducer.

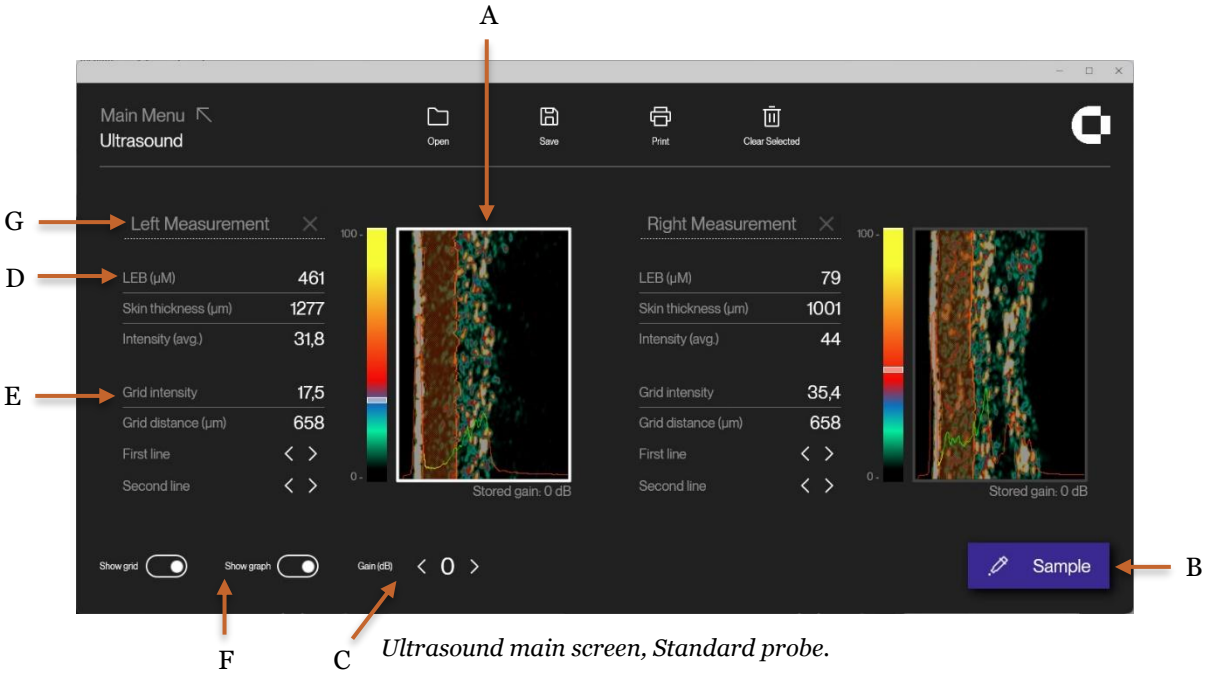
6.4.4 The Ultrasound probe screen

The screen facilitates simultaneous presentation of two images – e.g. a new image in comparison with a previously saved recording or two new recordings from different body areas.
One of the image positions is considered the active window, indicated by the white borderline of the frame (A). Select the active position by clicking inside the window. New recordings will appear in the active window.

Touching the **Sample** button (B) will record a new ultrasound image.

The gain (ultrasound sensitivity), used when recording the ultrasound image, may be adjusted using the up/down arrows (C).
Note: The new gain applies to the next image being recorded and will not change the already recorded and saved images. The gain used at the time of recording an image is displayed on the bottom of the images as “Stored Gain”.
Typical gain settings are 0 (zero).

Touch **Save** to save images. Previously saved images may be loaded using the **Open** button. All measurement data are saved together with the image for future reference.

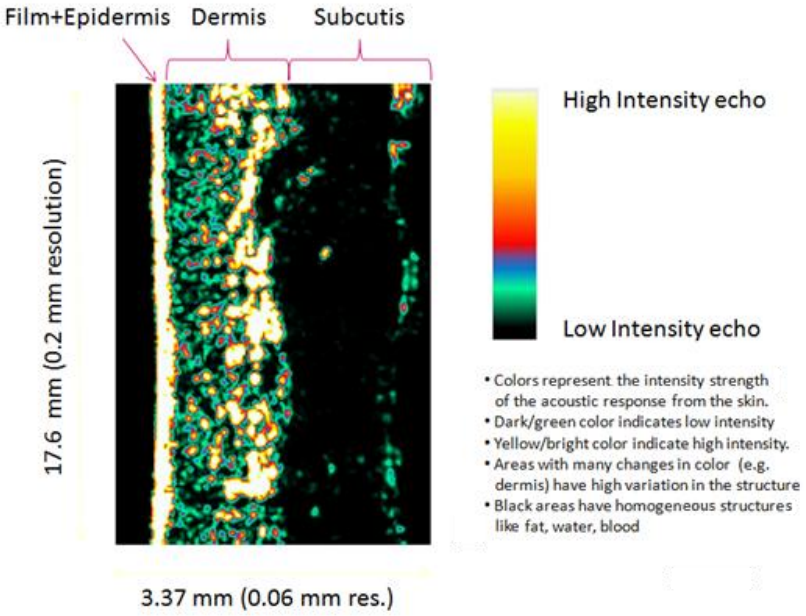


Ultrasound main screen, Standard probe.

Two sets of measurements (D, E) for each image relate to the use of the **Graph** and **Grid** buttons (F), which will be explained later in this section under Graph/Grid measurements respectively. Supportive text may be entered into the text fields (G).

6.4.5 Understanding the ultrasound image

By pressing **Sample**, an ultrasound image is recorded and visualized in the active window. In this image, the colors represent the intensity (strength) of the reflected ultrasound signal. Dark color represents low intensity and white (yellowish) represents a high intensity. The epidermis is highly reflective (white/yellowish) and the dermis is a mix of many colors. The subcutaneous fat and muscle fibers will return a low intensity signal (dark green and black). See below:

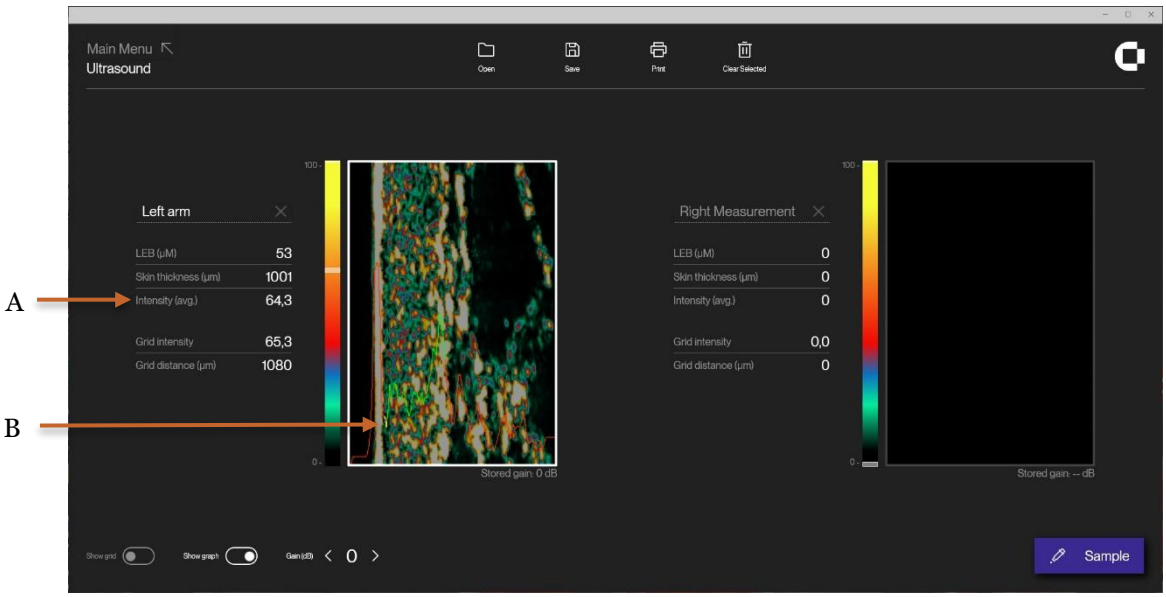


The Ultrasound Probe image – probe surface plus epidermis to the left followed by dermis and subcutis. The dermis is characterized by varying intensities (different colors), subcutis by low-intensity areas due to a homogenous composition.

6.4.6 Measurements

The Ultrasound probe screen features two sets of measurement data for each image. One set is fully automatic and requires no operator input. It relates to the use of the Graph button.
The other relates to the Grid button. It is semi-automatic and may require operator input.
The measurements automatically update upon capturing a new or loading a previously stored image.

Graph measurements (automatic) are based on the accumulated average of the total of 188 A-scans, which forms the cross-sectional ultrasound image, to generate a so-called *Super A-scan* (B).
As such, the *Super A-scan* is a graph showing the total average ultrasound intensity for all ultrasound responses in the image as a function of depth into the skin. It becomes visible as a superimposed red/yellow/green curve over the dimmed image by clicking the **Show Graph** button.



Curve - Ultrasound image with superimposed Super A-scan.

Interpretation of the Super A-scan:

The *red left* part of the curve indicates the intensity of the ultrasound passing through the water chamber in the probe. The high left peak originates from the combined probe surface/epidermal reflection.

The *yellow* part of the Super A-scan indicates the Low Echogenic Band (LEB) of the dermis (B, calculated in micrometers). In otherwise healthy skin the LEB may be a possible result of photo aging).

The *green* part of the curve indicates the more reflective part of the dermis (in otherwise healthy skin a possible result of the deeper dermis not being subject to photo damage). Together, the *yellow and green* part of the curve add up to the average *Skin Thickness* (calculated in micrometers), for which also the average *Intensity* (A) is calculated.

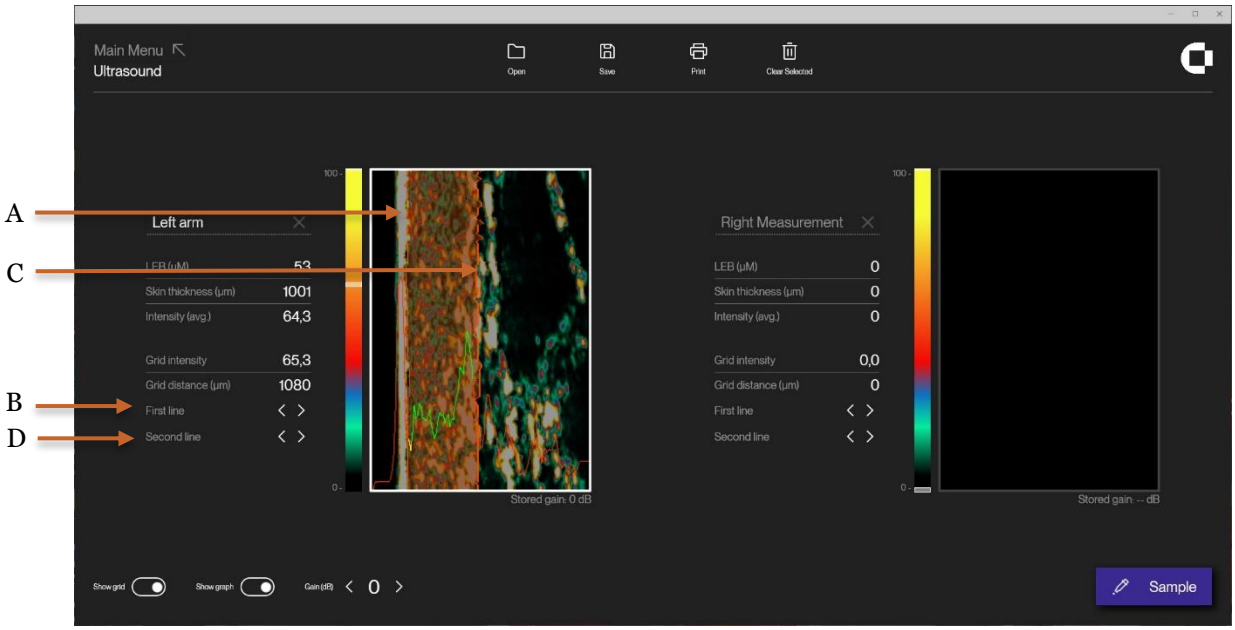
The *red right* part indicates the intensity of the ultrasound passing through the subcutaneous layers.

If the line is red all over, then the dermis and/or Low Echogenic Band is not clearly detected by the software and the automatic calculations are not performed or may be incorrect.
This may be a result of incorrect gain setting. It may also be a natural consequence of a physical skin condition – e.g. edema (fluid leads to less and weaker reflections/lower intensities).

Please note, that diseased skin may appear visually different not only to the naked eye but also in terms of ultrasound intensity patterns and levels.
In general, homogeneous areas and tissues are less reflective and appear dark (e.g. fluid, blood, fat, altered cell structures). Non-homogeneous structures - i.e. density changes in the tissue – cause reflections of varying intensities due to changing acoustical properties (e.g. healthy skin with intact collagen, elastin, connective tissue).

Grid measurements automatically adapt to the curvature of the skin surface to place a line, which follows the back side of the epidermis and becomes the left side of the grid (A). This line may be freely repositioned using the left/right arrows (B).
Maintaining the same curvature, a second line – the right side of the grid (C) – may be freely positioned using the left/right arrows (D).
The grid becomes visible over the dimmed image by touching the **Grid** button.

The Arrows used when moving the grid are only visible when the grid is enabled, as both grid intensity and grid distance is based on grid placement.



Grid - Ultrasound image with superimposed grid.

The measurement algorithm calculates the *Distance* between left and right side of the grid in micrometers as well as the average *Intensity* (ultrasound reflection strength) inside the grid. This may be used to quantify specific features within certain areas – e.g., in the upper or lower dermis.

Note 1: As a best estimate, the edge detection algorithm assumes identical curvatures for the skin surface and the dermis/subcutis tissue interface. Consequently, the left and right side of the grid are identically shaped.

Note 2: When pressing **Sample**, the software automatically detects the edge position of epidermis and updates the left grid position accordingly. This way, it is possible to automate measurements, so

the intensity is always measured at the same offset distance relative to the epidermis and with a constant width of the grid.

Note 3: The position of the grid relative to the epidermis is defined individually for each window. Every time a new image is recorded or loaded from the memory the curvature of the grid is aligned to the border between epidermis and dermis.

Note 4: The average intensity is updated even if the red grid is turned off.

6.5 The Ultrasound Subcutaneous unit

6.5.1 Preparing the Subcutaneous Ultrasound probe

Before use, the water chamber in the probe must be filled with water. Seal the chamber by applying the water barrier film, which is held securely in place by the black retaining ring attached to the probe tip. This ensures proper acoustic coupling and prevents leakage during scanning.

6.5.2 Mounting the water barrier

The water chamber in the probe must be filled with water, and the water barrier film is then used as a seal to ensure that the water will remain inside the probe, when used. The water barrier film is kept in place by a black ring which is attached to the tip of the probe.

1.

Black, press-fit ring holds the water barrier film in place.

2.

Inject water into the empty chamber. Gently shake the probe to eliminate air bubbles, top-up with water.

3.

Place film over the probe tip. Press the black ring down over the film

4.

off excess film with a quick downward movement.

5.

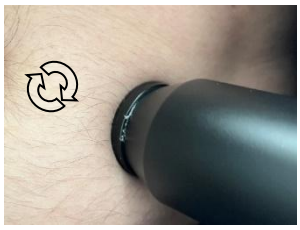
Final result. Check that the black fixation ring is correctly positioned

6.

The film shall present a smooth surface without wrinkles.

The ultrasound subcutaneous probe is now operational. Over time air bubbles may collect, however, when the probe is held correctly in an up-right position for scanning (probe front down/cable end up), air bubbles will normally not disturb.
If air bubbles adhere to the inside of the film causing shadowing effects in the image, they may be released by gently tapping the probe. Otherwise, replace the film after topping up with water.

6.5.3 Using the Ultrasound Subcutaneous probe



Before each ultrasound scan apply ultrasound gel to the skin. Place the probe on the skin area to be scanned and spread the gel evenly to the thinnest possible layer with “massaging” movements.

Alternative to the use of gel:
If gel is not available, then dip the tip of the probe in a cup of water. The thin layer of water on the probe will couple the ultrasound to the skin after positioning the probe.

6.5.4 Cleaning

After scanning, or at least after eight hours of operation, the water barrier film shall be removed disposing the water and the film and allowing the transducer to dry.

Arrange a container to collect the water coming from the probe head. The film can be peeled off after gently pulling off the black ring.

The front piece parts may be cleaned in solutions of mild detergents suitable for plastics or wiped off with alcohol for disinfection. Put the black ring back onto the scanning head without film for storage.

6.5.5 Ultrasound Subcutaneous imaging screen

The screen facilitates simultaneous presentation of two images – e.g., a new image in comparison with a previously saved recording or two new recordings from different body locations.
One of the image positions is considered the active window, indicated by the indicated by the white borderline of the frame (A). Select the active position by clicking inside the window.
New recordings as well as previously saved images being opened will appear in the active window.

Activating the **Sample** button (B) will record a new ultrasound image.

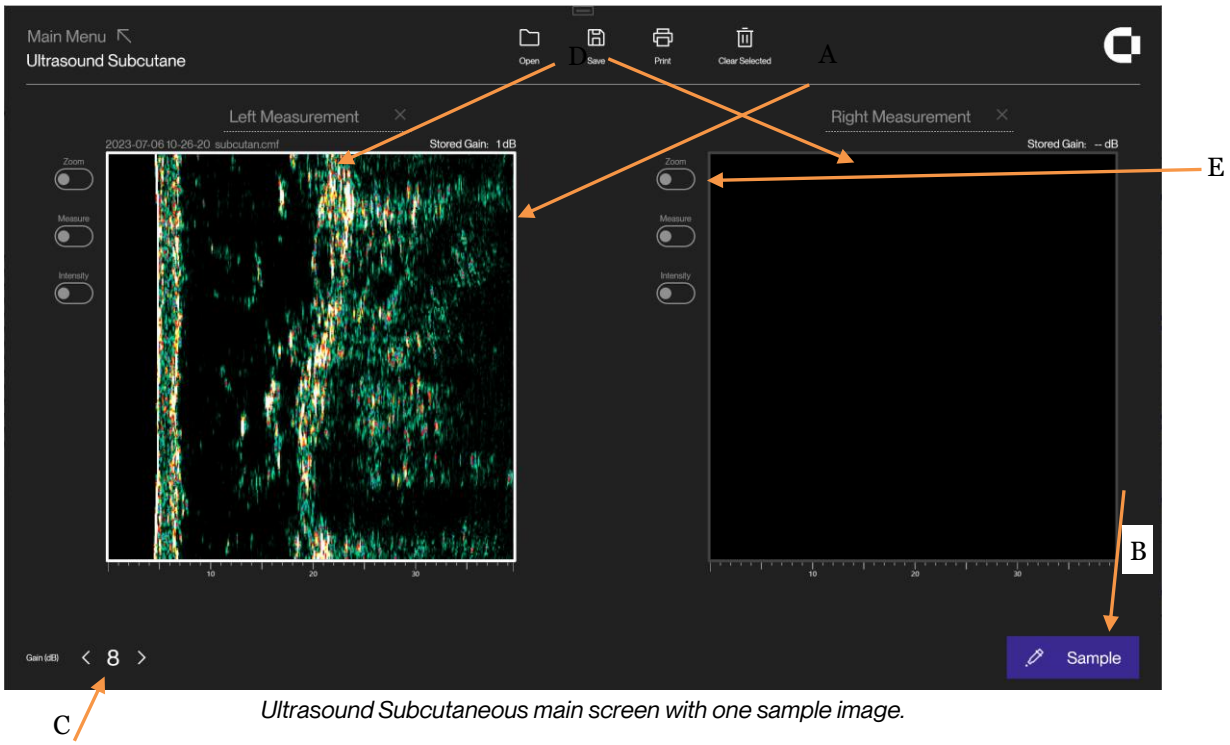
The **Gain** (ultrasound sensitivity), used when recording the ultrasound image, may be adjusted using the left/right arrows (C).
Note: The new gain applies to the next image being recorded and will not change already recorded and saved images. The gain used at the time of recording an image is displayed on top of the image as “Stored Gain”.

Supportive text may be entered into the text fields (D).

Zoom, Measure and Intensity can be enabled beside each individual image (E). further explained in Section 6.5.7.

Press **Save** to save images to the internal memory. All measurement data are saved together with the image for future reference.

Previously saved images may be loaded using the **Open** button.

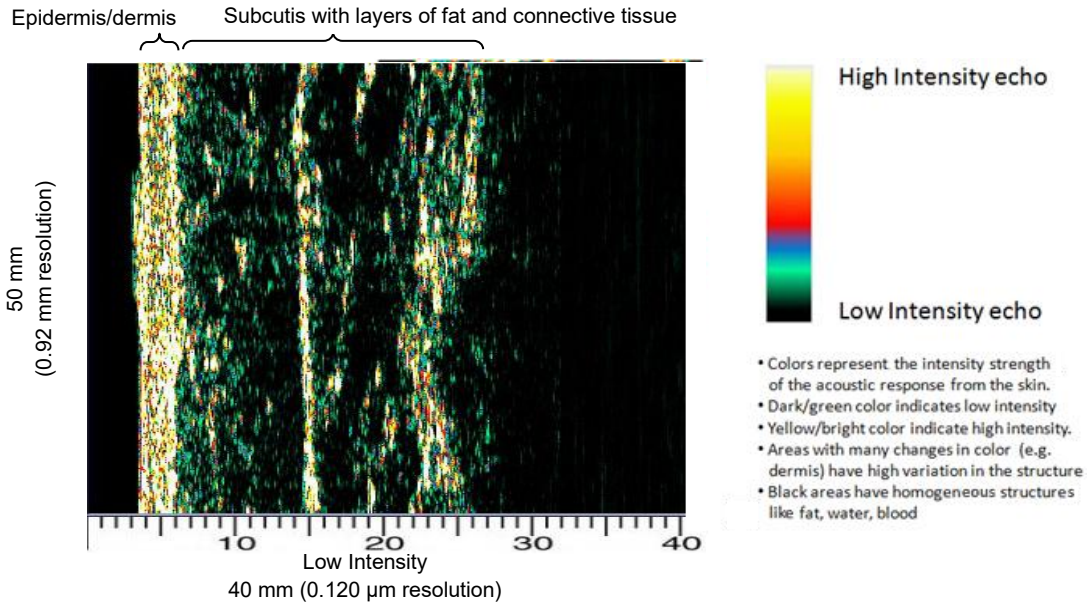


Ultrasound Subcutaneous main screen with one sample image.

Two sets of measurements for each image relate to the use of the **Measure** and **Intensity** buttons, which will be explained later in this section under section 6.5.7.

6.5.6 Understanding the subcutaneous ultrasound image

By clicking **Start**, an ultrasound image is recorded and visualized in the active window. In this image, the colors represent the intensity (strength) of the reflected ultrasound signal. Dark color represents low intensity and white (yellowish) represents a high intensity. The epidermis/dermis is highly reflective (white/yellowish). The subcutaneous fat and muscle fibers will return a low intensity signal (dark green and black). See example below:

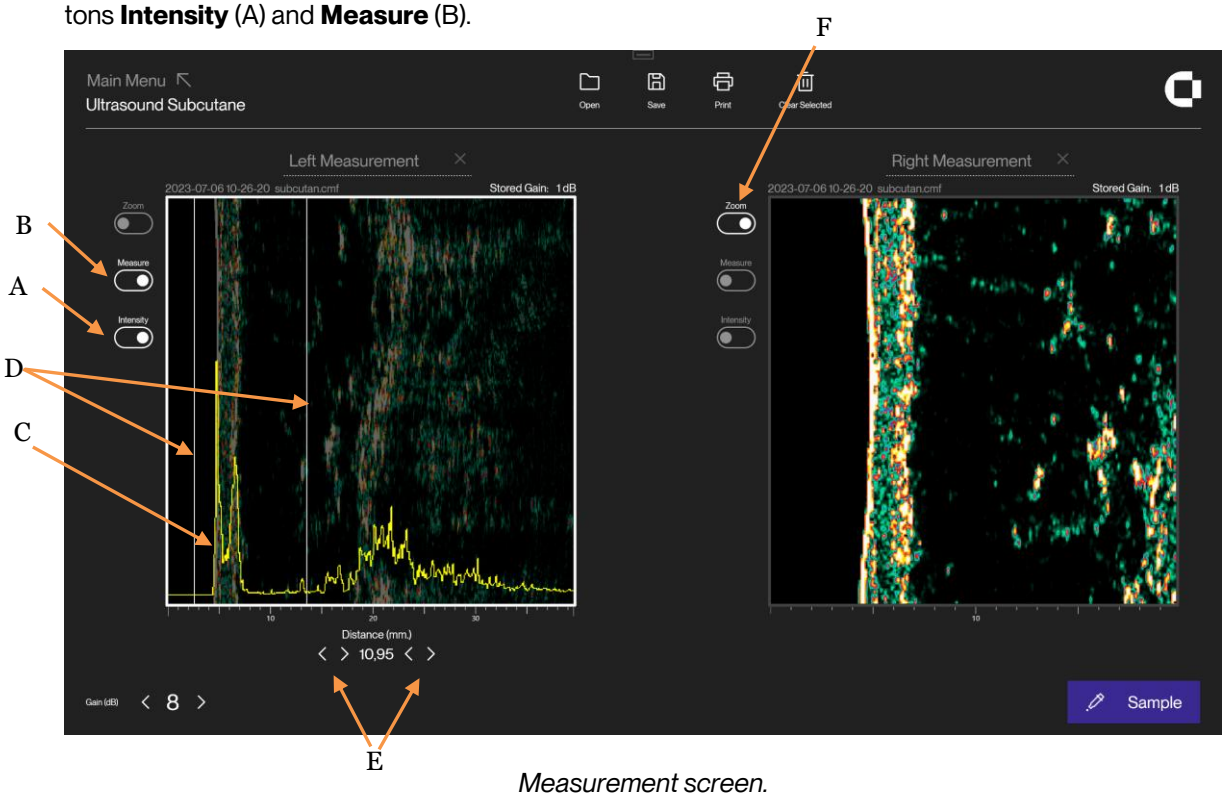


The Subcutaneous ultrasound image. Dermis is characterized by varying intensities (different colors), subcutis by

low-intensity (black/greenish) areas due to a homogenous composition separated by layers (vertical lines) of colored connective tissue.

6.5.7 Measurements

Subcutaneous Ultrasound features calculation of intensity and horizontal distance by use of the buttons **Intensity** (A) and **Measure** (B).



Measurement screen.

Intensity visualizes a superimposed yellow intensity curve based on the accumulated average of all ultrasound A-scans within the image – the so-called *Super A-scan* (C). No numbers are presented as a result, but a concentration of high intensities appears as peaks on the curve and this way serves as an indicator for the in-depth positioning of layers in the tissue.

Activate the **Measure** button to superimpose two white vertical cursor lines (D). With the arrows (E), these cursors may be positioned according to the position of peaks on the intensity curve to measure depth or distance between layers of tissue. The numerical display under the image updates accordingly.

The **Zoom** (F) button may be used to zoom the image to 20 mm width. Once zoomed, you can drag the image left or right.

6.6 The Ultrasound image

A good image delivers as much possible information in the best possible quality to the viewer in a given situation. In other words, what is seen on the image should be a result of tissue properties, not a result of artifacts.

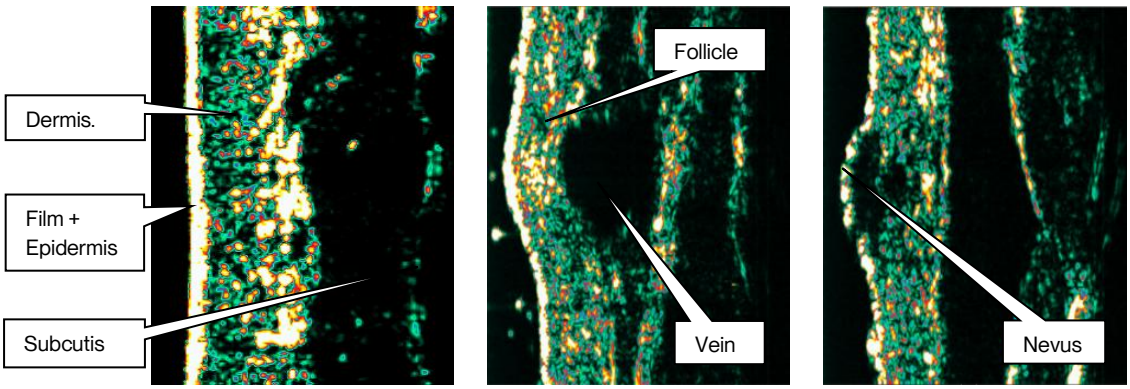
The properties and composition of the human skin and subcutaneous tissues vary throughout the body and between individuals because of many factors (e.g. genetics, age, sex, disease).

This section applies to the use and understanding of all DermaLab Combo ultrasound probes.
In the following examples obtained using the *Standard Probe* will be shown to establish a common understanding of what to expect as well as commonly seen artifacts and how to avoid them.

6.7 Understanding the ultrasound image

As the focused ultrasound beam propagates through the tissue, it travels through media with different densities. Such change in density will cause part of the ultrasound beam to be reflected, thus generating signals to be detected by the device, and part of the ultrasound beam to be transmitted further into the tissue. Every time a density change in the tissue causes a reflection, energy is lost in the transmitted part of the sound beam. Accordingly, the signal gets attenuated and eventually dies. The degree of attenuation depends on ultrasound frequency and tissue properties.

Tissue, which is homogeneous in structure, provides no or little density change and, accordingly, it will generate no or few and weak reflections – i.e. it appears black. As an example, blood, fat and muscle generate only few and weak reflections. The same is true for tumor mass in general, whereas normal skin contains a variety of structures with different densities - it appears as a visible area with varying intensities. In the below figures, the individual structures of a normal forearm image are identified.

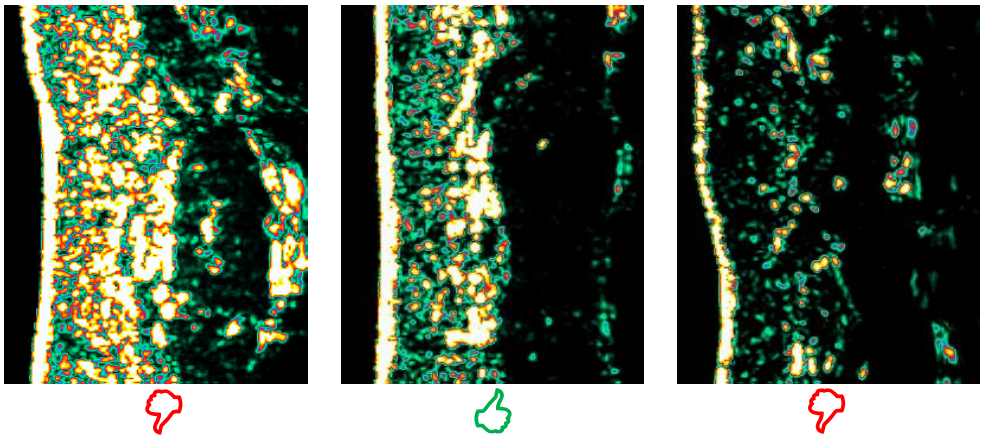


Ultrasound probe skin images.

6.8 How to record an ultrasound image

Setting the correct Gain
Most importantly, the amplification of the signal should be set correctly. As the focused sound beam travels through the tissue, it gets attenuated. Since attenuation increases with frequency, high frequency ultrasound is subject to a high degree of attenuation, which limits the penetration drastically.

Within certain limits, such attenuation can be compensated for by increasing the amplification (i.e. gain). In the DermaLab® Combo, this feature is referred to as *gain* control, which allows for individual setting of the gain level.



High gain image, blurred details.
Press Gain "arrow down" to lower intensity level.

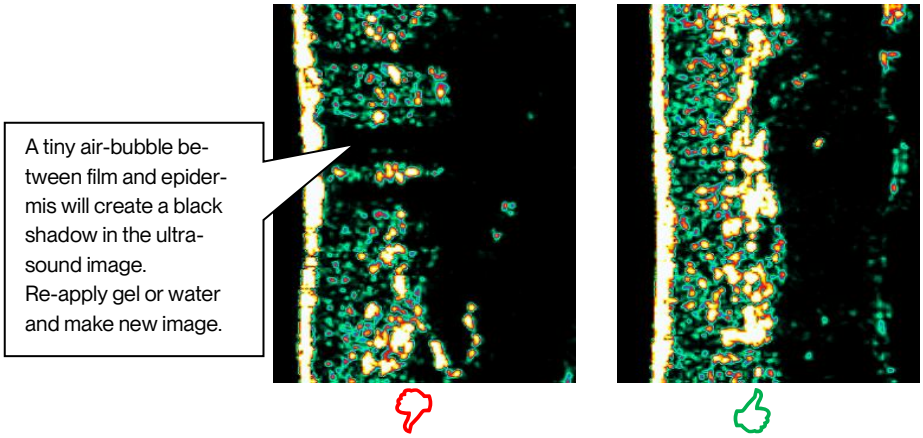
Normal gain image.
Good intensity level and distribution, many details, no Gain adjustment needed.

Low gain image, loss of details.
Press Gain "arrow up" to increase intensity.

A typical gain setting for scanning is 0 (zero). Scanning on the cheek typically requires a slightly higher gain to obtain a good image.

Avoiding Artifacts

The below figure to the left shows an ultrasound image, where gel at the tip of the probe has not been well distributed. This gives a horizontal shadow in the image because the acoustic ultrasound signal does not reach the skin. Such air bubbles will block the signal and cause horizontal shadows throughout the image.
To prevent this from happening, make sure the surface of the probe is clean.



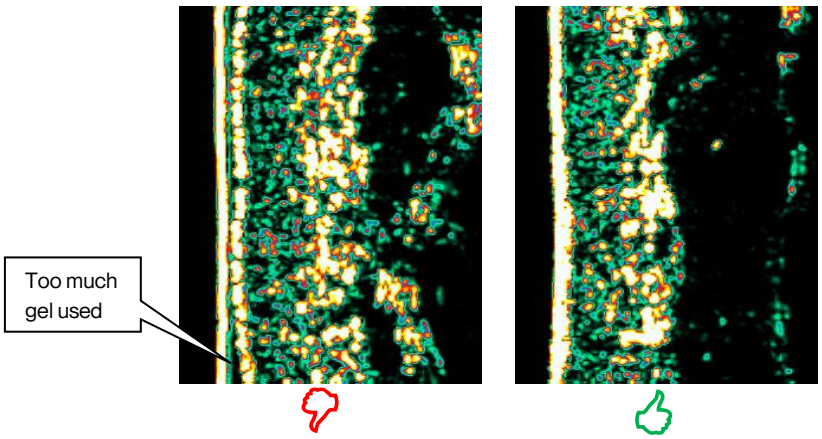
It is important to ensure a good acoustic contact between the tip of the probe and the skin.

Artifacts in the form of shadows may also be a result of collected air bubbles inside the water chamber. Such bubbles may often be released by gently tapping the probe.

Gel layer thickness

A thin gel layer secures good acoustical contact between the tip of the probe and the skin. Too much gel (left image below) results in a bright line in front of epidermis (i.e. two bright lines) with a black gel layer in between. This first bright line represents the acoustic echo from the surface of the probe and

the second line is the epidermis. Preferably, the layer of gel (or water) shall be so thin, that it is not possible to distinguish the acoustic echo from the film and epidermis. I.e. preferably they should be seen as one bright line (i.e. as one echo, right image below).



Avoid too much gel between the tip of the probe and the skin.

Preparation

It may facilitate the scanning procedure to apply a drop of water or a thin layer of gel on the skin area to be scanned. Gently distribute the water or gel in a thin layer – just enough to make the skin wet. This will help avoid air bubbles between the tip of the probe and the skin.

6.9 Maintenance

6.9.1 Ultrasound Probe maintenance

The daily maintenance of the Ultrasound Probe is limited to cleaning the outside of the probe, wiping any ultrasound gel off with a mild detergent.

Do not use solvents or hard objects to clean the transducer. Just gently wipe off any deposits with a cotton swab.

6.9.2 Ultrasound Subcutaneous Probe maintenance

The daily maintenance of the Subcutaneous Ultrasound probe is limited to the removal of film and water to reduce bacteria growth inside the water chamber, and to allow the transducer to dry. Always remove the plastic film overnight.

Do not use solvents or hard objects to clean the transducer - just gently wipe off the deposits with a cotton stick.

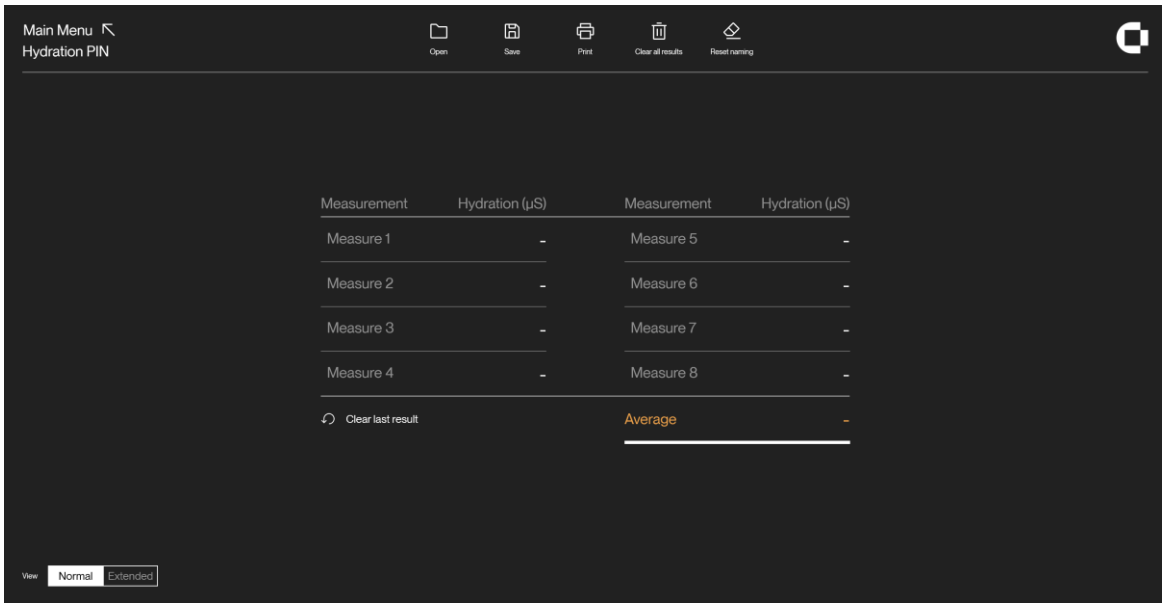
7 Hydration (Moisture)

7.1 Principle

The DermaLab Combo provides information about the hydration state by measuring the conducting properties of the very upper layers of the skin, when subject to an alternating voltage. Accordingly, the method is referred to as a conductance measurement and the output is presented in the unit of micro-Siemens (µS).

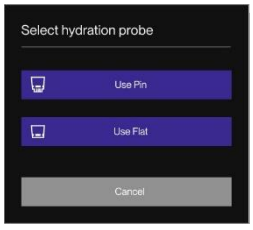
7.2 The Hydration probes

Depending on the application and personal preference, two different probe designs are available – PIN and FLAT probe.
If just one hydration probe is connected, the selection of **Hydration** in the main screen will automatically open the relevant parameter screen (PIN or FLAT) as indicated in the upper left corner.



PIN probe screen.

If both probes are simultaneously connected, the selection of **Hydration** in the main screen will open a new window in order to choose the correct probe for the application.



Selection of probe type.

Except for the indication in the upper left corner, the two probe screens are identical.

7.3 Pin probe

The PIN probe features eight contact pins and superior performance in dry skin applications, on uneven skin surfaces and on the scalp. Further, the pins and the ventilated design reduce occlusion, when applying the probe, thereby minimizing water accumulation in the skin covered by the probe.

The probe features spring-loaded action, which will initiate a measurement when the probe is pressed against the skin.

The probe comes with a ventilating spacer to facilitate application of constant measurement pressure and reduce accumulation of water in the measurement area.

Pin probe with ventilating spacer.

7.4 FLAT probe

The FLAT probe offers a traditional design with three concentric, circular electrodes. This flat design is convenient when measuring on larger areas of normal skin with no interference from hairs and scales etc.

the probe initiates the measurement when the probe is pressed gently against the skin.

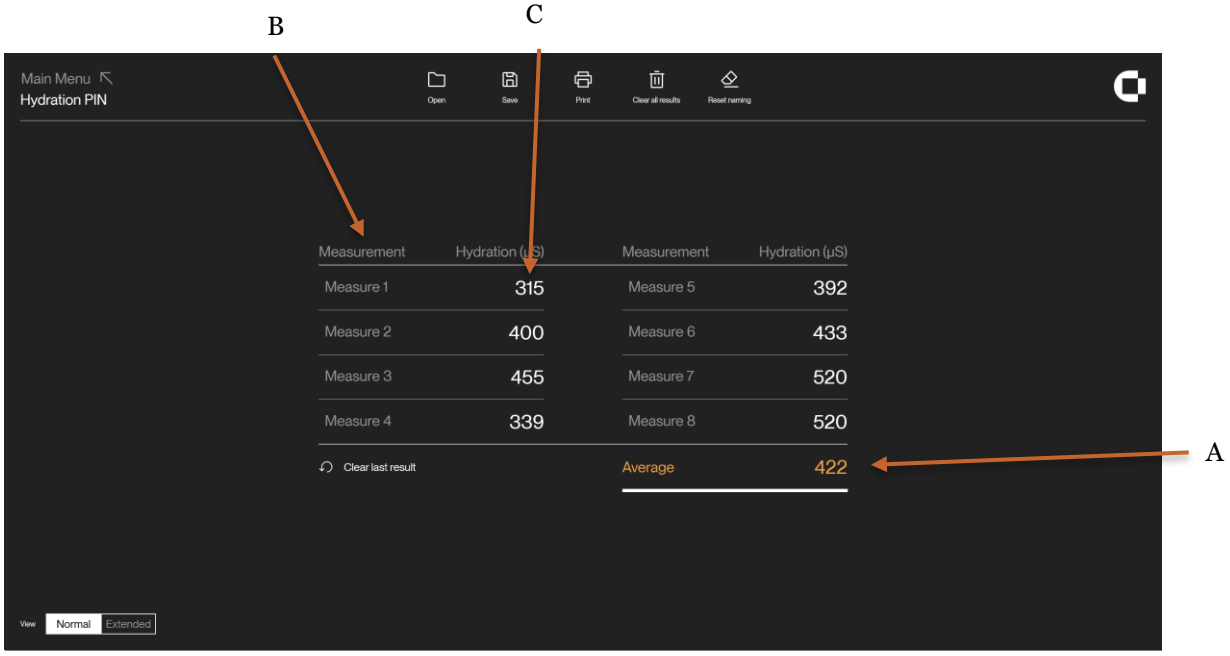
FLAT probe.

7.5 The Normal Hydration screen

Up to 8 measurements can be made with the average (A) being continuously updated for each new measurement. Hydration measurements may fluctuate, and an average of 3 to 8 measurements is recommended as the final result.

To perform a measurement, gently press the probe against the skin until the measurement is triggered, and the measurement result appears in the next empty field (C).

The text fields (B) can be used to label each measurement. Click on the label to enter text.

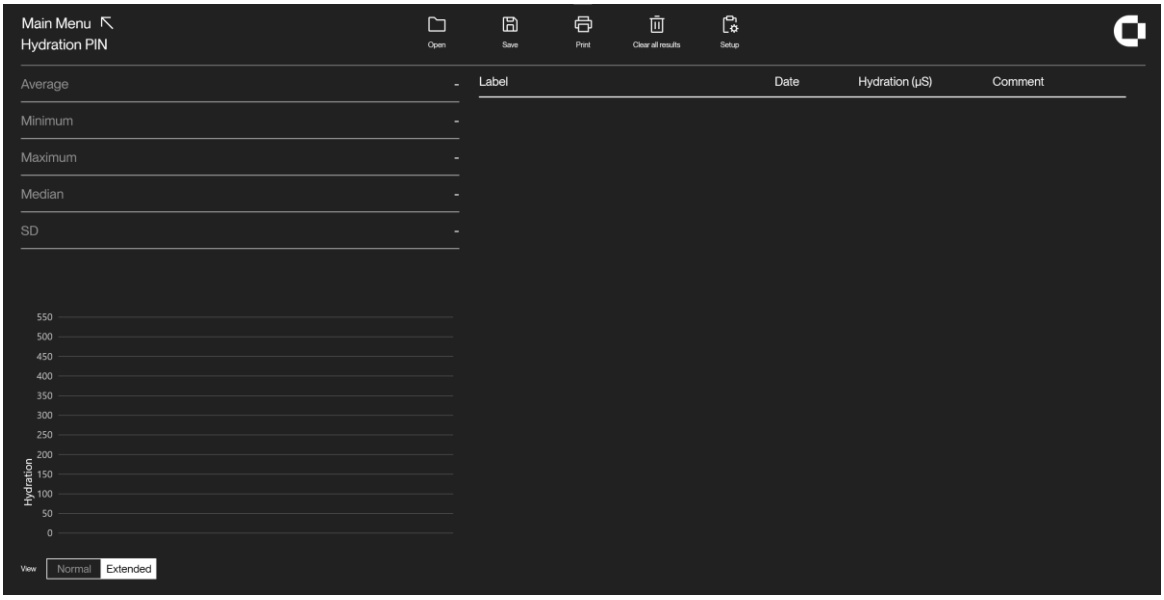


Hydration screen.

7.1 The Extended Hydration screen

Pressing the Extended button at the bottom of the hydration page will switch to the extended view.

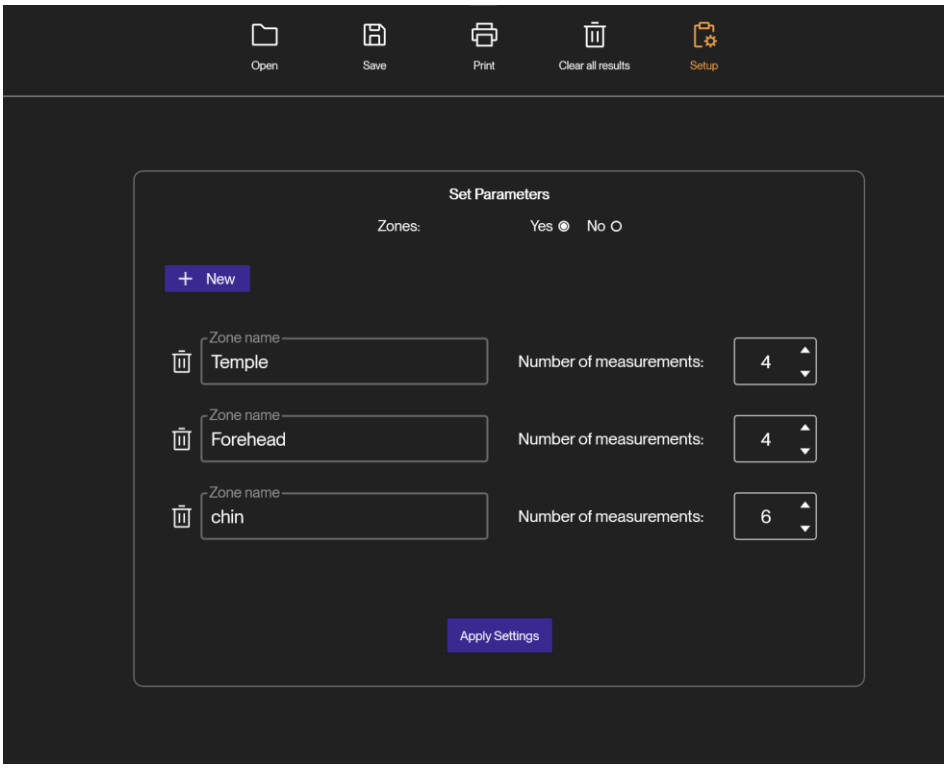
Measurements are not shared between views and will only be recorded in the screen currently shown.



Extended Hydration screen.

7.1.1 Setup

The extended view allows users to predefine a measurement protocol for hydration measurements.



Setup pop-up

Users can select to not use any grouping/zones which will allow for collecting up to 50

single measurements with no defined zone

Users can also choose to add zones which can be used to help guide measurement protocols.

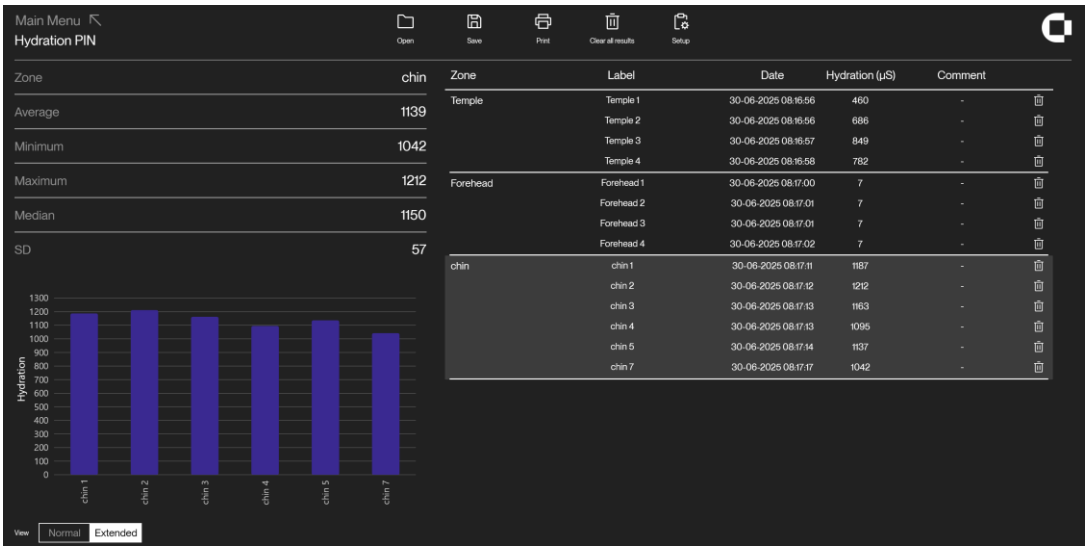
Measurement entries can be deleted and new measurement will fill the top-most available slot when recorded.

Setup cannot be changed with measurements already performed. Measurements must be cleared before changing setup.

Setup is stored between sessions but can be overwritten by loading a file using a different setup configuration.

7.1.2 Info panel

On the left side of the screen an info panel is shown summarizing performed measurements. If using zones each zone can be selected by clicking on it resulting in the info panel updating to reflect the selected zone. If no zone is selected information will reflect a collection of all measurements regardless of zones.



Extended page including infopanel and graphs

7.1.3 Graphs

Collected data will be shown for the selected zone, if no zone is selected a representation of average hydration will be shown in the graph for each zone.

If no zones are used the graph will reflect all individual measurements at all times.

7.2 Maintenance

Except for keeping the probes clean, there is no preventive maintenance associated with the use of the hydration probes. To clean the probe front, simply wipe it off using a dry cloth. Should more thorough cleaning be necessary, a drop of alcohol may be applied to the cloth.

Instrument performance in terms of calibration may be checked by obtaining an optional *calibration checker* (phantom). Press the phantom against the probe making sure to establish good electrical contact to the probe face (two pins in case of pin-probe) and perform a normal measurement. A moisture reading of 1000 ± 3% is considered normal.

8 Elasticity

8.1 Principle

The elasticity measurement of the DermaLab Combo 4 is based on suction applied to the skin surface. The probe provides a suction chamber and uses adhesive tape to prevent creeping and folding of the skin under the edge surrounding the measurement chamber. It is connected to the main unit, which accommodates an integrated negative pressure cylinder. This cylinder holds a preset negative pressure of 150/400/650 mbar reflecting the Soft/Normal/Firm setting in the software.
By pressing "**Sample**", this negative pressure is instantly applied to the skin surface and, consequently, the skin response is a direct function of the skin properties.

The suction method features an elevation phase and a retraction phase, the properties of which both contribute to the "feel" of the skin.
As an example, young and smooth delicate skin, which is well moisturized, will normally be relatively easy to elevate by applying suction, and it will retract rapidly.
Old and loose skin will also be easy to elevate, however, it will not retract rapidly. Therefore, what is usually considered to be skin elasticity (or smoothness, softness, firmness) is of a more complex nature and is best measured by taking both the elevation and retraction phase into account.

The DermaLab Combo offers three descriptive parameters for the skin elasticity:

1. Young´s elasticity modulus (E),
2. Skin retraction time (R)
3. ViscoElasticity (VE) combining both the elevation and retraction phase.

The three parameters are explained below. Which parameter(s) to choose may depend on study design and personal preference.

1) Young´s elasticity modulus.

Calculation of Youngs elasticity modulus (E) is based on measuring the distance the skin can be lifted, when applying a specific and preset vacuum to the skin inside the probe chamber. The Young's modulus is calculated using the following equation:

$$E = \psi \cdot p \cdot \frac{r^4}{\Delta x \cdot s^3}$$ where:

Δx = elevation of the skin measured at the middle of surface (in m)

ψ = constant (here set to 0.5)

p = surface pressure (in Pa)

E = elasticity modulus (in MPa)

r = radius of the surface (0.005 m)

S = thickness of surface (skin thickness, adjustable but set to 0.001 m by default)

Inserting reasonable assumptions, known probe constants and a default skin thickness of 1 mm leads to:

$$E = 0.3125 \cdot \frac{\Delta p}{\Delta x}$$

The elasticity modulus E depends entirely on the height Δx measured by the probe at the end of the elevation phase and the applied vacuum. Young´s modulus (E) carries the unit MPa (mega Pascal).

The instrument features 3 settings for the vacuum applied to the skin - Soft, Normal and Firm. The selection of the actual range should be made by the user before the measurement is started given the nature of the skin to be measured. For example, Soft is used when measuring the soft/loose skin under the eyes and Normal is used when measuring on an arm. Firm is used for measuring on thick and stiff skin - for example sclerotic skin or the palm of the hand.

2) Retraction time.

Retraction time (R) is the time in milliseconds it takes for the skin to retract from the peak elevation to 33% of the peak elevation. This is indicated in the red section of the graph on the elasticity screen.

3) Visco Elasticity.

Dividing the elasticity modulus by the retraction time provides a parameter (Visco Elasticity, VE), where both the elevation phase and the retraction phase contribute. R is normalized by a retraction time of 260 ms as a typical average of underarm readings (Caucasian skin, age 28 – 60).

$$VE = Young´s\ modulus/R_{normalized} \text{ where } R_{normalized} = R/260\ ms.$$

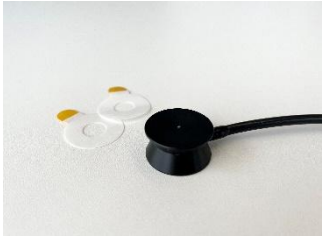
VE carries the unit MPa (mega Pascal).

8.2 The Elasticity Probe

The elasticity probe is connected to the input connector on the rear panel (electrical connector and Luer Lock air connector).

The use of double-sided adhesive rings on the probe surfaces in contact with the skin is required to obtain reproducible results. First mount the adhesive ring on the probe face, then pull off the adhesive cover before placing the probe firmly on skin. Prior to placing the probe, the skin surface should be clean and dry for the probe to adhere.

Exchanging the adhesive ring between measurements is highly recommended to obtain optimal adhesion and complete air tightness.

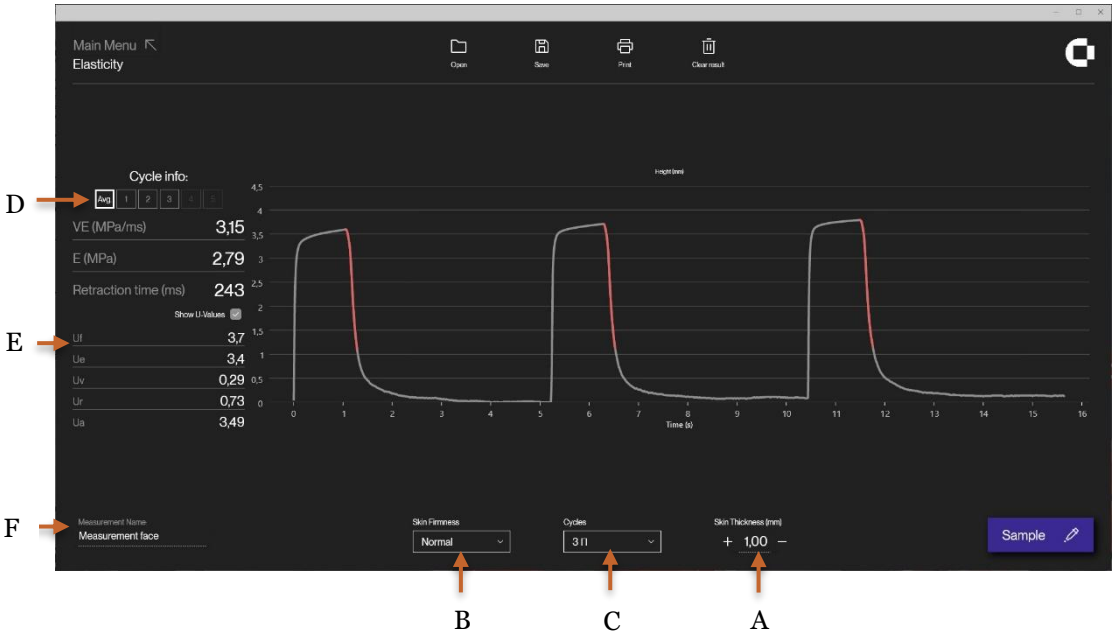


Elasticity probe with adhesive ring.

As the suction principle applies mechanical stress to the measurement site, the measurement cannot be immediately repeated in the exact same position. Allow 30 - 60 minutes between measurements at the same position for the skin to recover.

During the measurement, care should be taken to avoid body movement as muscle tension may impact the measurement. Also, do not touch the probe or pull the cables.

8.3 The Elasticity screen



Elasticity screen. The y-axis shows the elevation (mm), the x-axis is time (seconds).

The default skin thickness (A) is set to 1.00 mm. Optionally, it may be changed to the actual skin thickness as measured using the ultrasound probe (see section 6 above).

Before starting a measurement:
- select the type of skin (Soft, Normal or Firm) (B). The correct setting is facilitated by the graph fully utilize the dynamic range of the instrument. The optimal setting is a resulting skin elevation of min. 1 to max. 3.5 mm.

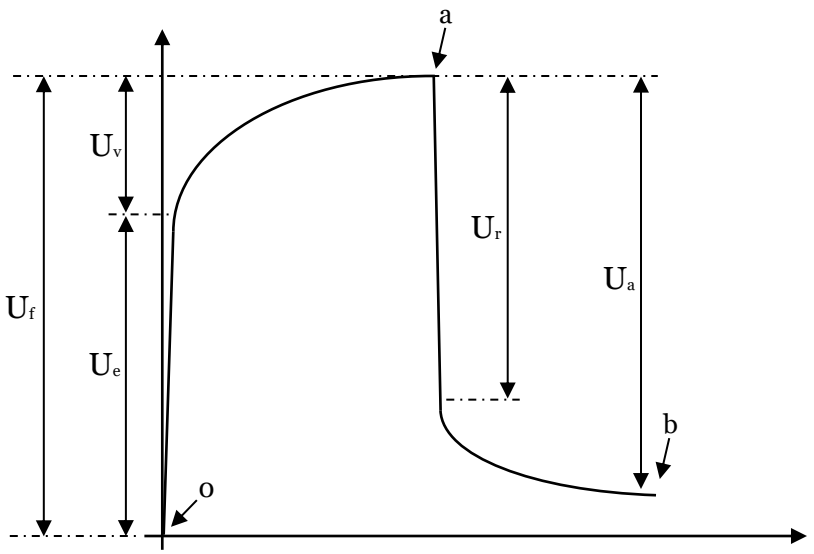
- select the number of elevation/retraction cycles for the measurements (1, 3 or 5) (C).
By selecting 1 cycle the skin will be exercised only once, and there will be no accumulated effect from repeated skin exercise.
By selecting 3 or 5 cycles the skin will be repeatedly exercised, which will introduce an accumulated effect. This can be seen as a slight elevation increase for each cycle as well as an increase in retraction time, which leads to a minor drop in E and VE for each cycle. The selection of 3/5 cycles may serve as a validity check for the correct application of the probe to the skin as any air leak can easily be identified on the curves.
When selecting 3/5 cycles, the results from each cycle as well as the total average may be displayed by using the buttons (D).
The setting of the number of elevation/retraction cycles may depend on the study design and personal preference.

Press **Sample** to initiate the elasticity measurement. The selected vacuum will be applied instantly, and the skin will immediately be lifted. On the graph, the actual height of elevation as a function of time can be seen. After a fixed time, the vacuum will be released, the elevated skin retracts, and Young's Modulus, Retraction time and Visco Elasticity is calculated for each cycle.

When all measurement cycles (1, 3 or 5) have been made, the average of the measurements is shown on the display. Use the buttons at the cycle counter (D) to select the specific measures for each cycle.

A further feature is the extraction of the U-values (E) from the suction/retraction curve. These values may be used for a more comprehensive analysis of the curve as explained in:

Calendula Extract: Effects On Mechanical Parameters Of Human Skin;
Akhtar et al, Acta Poloniae – Drug Research, Vol. 68 No. 5 pp. 693-701, 2011.



The figure shows how the U-values are extracted from the elasticity measurement. The immediate deformation or skin extensibility (Ue), delayed distension (Uv), final deformation (Uf), immediate retraction (Ur), and total recovery (Ua) are indicated in the figure together with point 0 (start), a (time at maximum elongation), and b (final elongation after returning to normal pressure). The Ue is the elongation 0.1 s after point 0 while Ur is the change in elongation 0.1 s after point a. The total recovery (Ua) is the difference between the elongation in point a and b.
Calendula Extract: Effects On Mechanical Parameters Of Human Skin;Akhtar et al, Acta Poloniae – Drug Research, Vol. 68 No. 5 pp. 693-701, 2011

Use **Measurement Name** (F) in case you want to name/label the measurement for future reference. This name will be archived in the saved- or printed measurements.

The **Clear Result** button clears all measurements.

8.4 Maintenance

Except for keeping the probe clean there is no preventive maintenance associated with the use of the elasticity probe. To clean the probe front, simply wipe it off using a dry cloth. Should more thorough cleaning be necessary, a drop of isopropyl alcohol may be applied to the cloth to remove residual glue.

CAUTION: Only use a dry cloth to clean the interior surfaces of the measurement chamber.

Probe cables are delicate. Do not apply any unnecessary force stretching the cable (e.g. do not pull the probe off the skin by pulling the cable or similar).

9 Sebum

9.1 Principle

The sebum screen provides an instrumental approach to quick and accurate measurement of surface sebum by means of a sebum collecting device (sebum collecting strip) and an integrated reader module. After applying the sebum collecting strip to the skin, the strip is inserted into the reader and the amount of sebum is measured based on the change in translucency of the film.

9.2 Sebum collecting strip

The sebum collecting material of the sebum collecting strip is a microporous film mounted on a light absorbing background, the color of which provides maximum absorbance of the light emitted from the light source in the reader module. Collected sebum changes the translucent properties of the film allowing more or less light to reach the background, where it is absorbed. Accordingly, the amount of reflected light varies according to the amount of sebum collected by the film.

Sebum collecting strips.

Each sebum collecting strip offers a sensitive area, and the film is mounted in a way, which greatly reduces wrinkling of the film, when inserted into the reader. The sebum collecting area is applied to the skin by pressing firmly on the backside of the area using the thumb. Press for a few seconds and make sure that the entire surface of the collecting area is in contact with the skin before reinserting the sebum collecting strip into the reader.

9.3 Tape Reader

The DermaLab Combo accommodates a reader module providing a slot for insertion of the strip in use. The slot is located on the right side of the main unit (see figures below), and the strip must be inserted with the absorbing film side (the text side) pointing down. Make sure the strip is fully inserted into the slot by pushing it until it goes no further. A slight resistance is felt as the strip goes in. This is intentional and a result of the strip being slightly bent in order to stretch the film and provide a smooth surface for measuring.

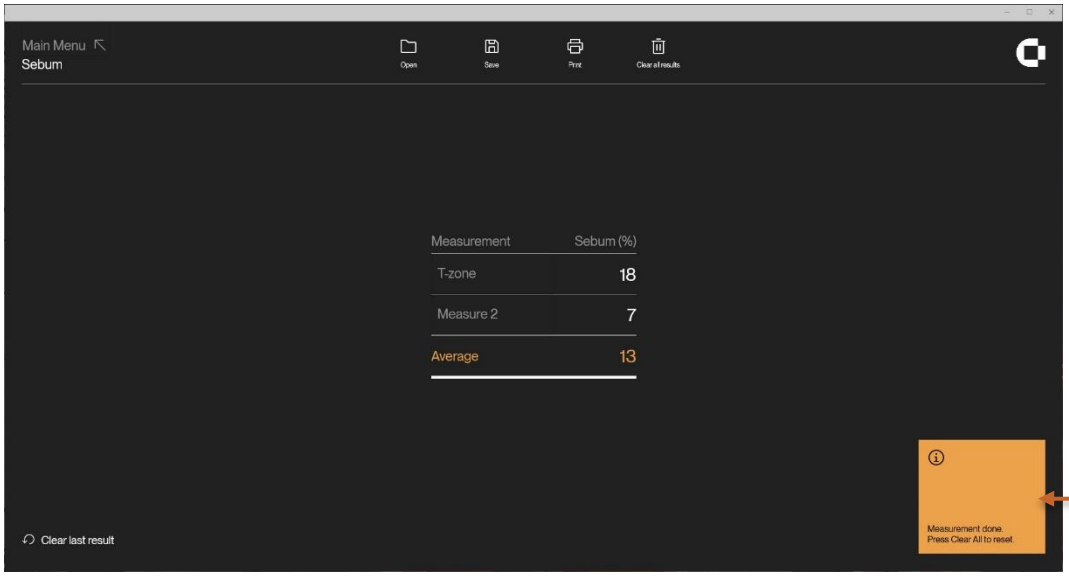
Strip insertion.

The strip fully inserted.

To eliminate the influence of batch to batch variation of the sebum absorbing film material, an initial offset calibration – a so-called “zero calibration” - is performed on the unexposed film prior to each skin application. Then, after application to the skin, the strip is re-inserted into the slot to measure the translucency changes of the film as a result of the absorbed sebum.

The measurement result is presented on the screen as a sebum score of saturation of the film from 0 to 99, where 99 equals very oily skin.

9.4 The Sebum screen and measurement procedure



Sebum screen

To perform a sebum measurement, proceed as follows:

1) Pick up an unused sebum collecting strip and insert it into the Tape Reader slot with the sebum collecting tape and the text side facing down. The device automatically detects the presence of the strip and performs an offset calibration before it prompts the user to perform the next step.

2) Remove the strip and place it on the skin. Apply firm pressure and make sure that the entire sensitive area is in contact with the skin by “rolling” a finger over the back side of the sensitive area for a few seconds.

3) Re-insert the exposed end of the strip into the reader and wait for the reading to automatically appear on the screen.

In the text box (**A**) instructions are given for the next step in the measurement sequence.

9.5 Maintenance

There is no preventive maintenance associated with the use of the Sebum reader.

10 Skin Color

10.1 Principle

The Colori Probe provides precise analysis of skin color and gloss characteristics for dermatological or cosmetic evaluation. The probe should be positioned gently and perpendicularly without applying pressure. External light interference must be minimized by using flat surfaces and avoiding direct sunlight. Correct matrix selection enhances measurement precision based on the application context.

10.2 How to perform a measurement

The measurement head is placed gently on the skin without applying force. If pressure is applied to the skin, the skin color may change because blood is forced away from the capillaries in the area. Depending on the amount of pigment, this may cause the skin to appear pale when compared to the surrounding skin (blanching). Measurements are optimally performed on as plane a surface as possible to avoid any external light from entering the measurement area. Because skin is translucent, measuring in direct sunlight may affect the measurement as light is passed through the skin.

When measuring gloss, it is also important to reduce the amount of force applied to the skin as any skin forced into the head of the probe head will result in non-optimal measuring conditions. Keeping the probe head away from the skin will also result in non-optimal readouts as outside sources of light can interfere with the measurement. The probe should be held steady and perpendicular to the surface without applying pressure to the skin.

10.3 Color-correction matrix

A Color correction matrix is used on the Colori Probe to ensure the most accurate readout based on what range of colors the Colori Probe is being used on.

10.3.1 Full Color

The full Color matrix is optimized for the entire color spectrum, attempting to provide the best possible readout no matter what color the measured area has.

10.3.2 Skin Optimized

The Skin optimized correction matrix is optimized for skin colors only, resulting in more accurate results when measuring on human skin tones (class I to VI). The average color difference when measuring on skin is generally lower when measuring using this matrix. The average color difference when measuring on non-conventional skin colors (e.g. blue or green), will be higher. Therefore, this matrix should not be used when measuring on anything other than skin.

10.4 Measurement mode and time

The Colori Probe has several measurement mode options. Depending on which option is chosen, each measurement may take a different amount of time to complete. Measuring only Color or Gloss will result in a faster measurement. Selecting any option enabling both gloss and color measurement will result in a longer amount of time for each total measurement to complete. It is therefore advised that if either color or gloss is not used, it should be disabled in the Colorimeter Colori Probe settings to increase the speed of future measurements.

Mode	Measurement time
Color	< 1 s

Gloss	< 1 s
Color + gloss	< 2 s

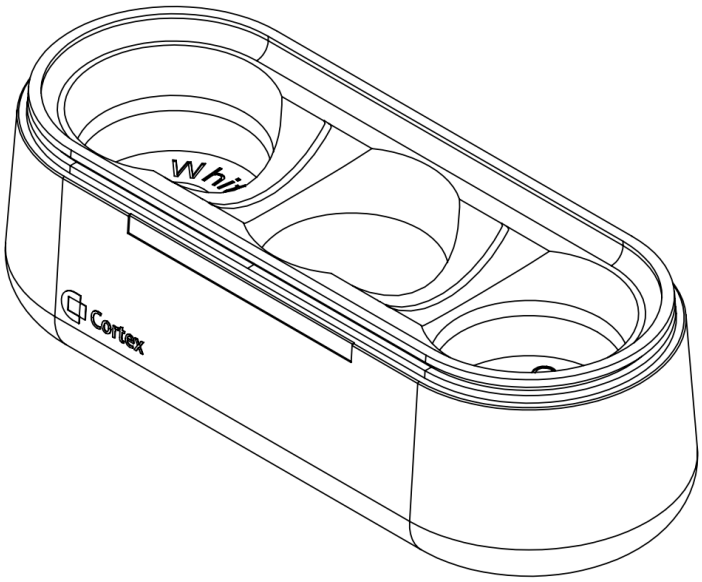
10.5 Calibration

Calibration is performed using the supplied *calibrator that contains working standards for w*hite, zero, and gloss.

It is not necessary to re-calibrate each time the unit is turned on. However, it is recommended to re-calibrate on a regular basis - e.g. daily or after 100 measurements.

Different parts of the calibrator are used based on what measurement mode is currently set for the Colori Probe. During a Calibration, the software will indicate which calibrator slot is to be used. Rejection of calibration can happen either due to dirty working standard or a bad measurement. If a measurement on the calibrator is rejected, the software will display a rejection message and not proceed with the calibration until a proper measurement has been performed.

Keeping the lid of the calibrator closed will protect the working standards from dust and scratches and prevent environmental light affecting the working standards.



10.6 Software

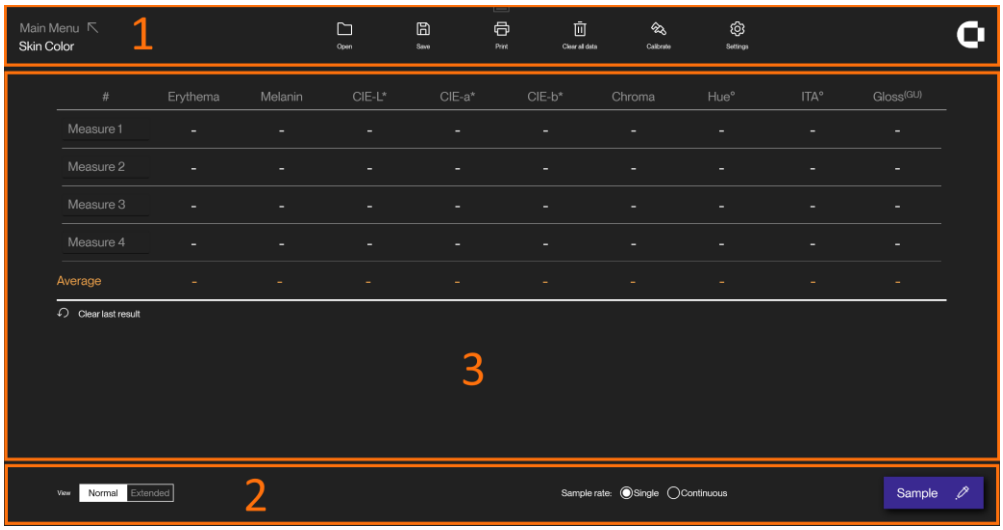
This section will give a brief description of available features in the Colori Probe software.

10.6.1 General

In the following figure, the main User-Interface has been divided into three areas for the purpose of this guide. Areas 1, and 2, annotated with orange numbers are general menus available at all times when using the Colori Probe.

The areas will henceforth be referenced as:

- Area 1 is the “top menu” covered in paragraph 10.6.2.
- Area 2 is the “bottom menu” covered in paragraph 10.6.2.7.
- Area 3 is the “Data View” covered in paragraph 10.6.3.
- The Settings is covered in 10.6.4.
- Documents generated from the software is covered in paragraph 10.6.5.

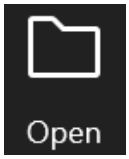


User-interface separated into 3 parts in orange

10.6.2 Top Menu

The top menu consists of buttons for general interaction with the software and Colori probes.

10.6.2.1 Open



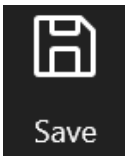
The Open button allows for importing any previously saved datafiles created using the Colori Probe software.

Only files with the .cmf file extension (Cortex Measurement File) generated by Cortex software can be opened this way.

Any data already open will be lost if not saved before importing new data. A warning will be shown if data will be deleted.

.cmf files will be opened in the currently active data view. Users will be warned if a file containing more than 4 measurements are attempted to be opened in Normal view.

10.6.2.2 Save



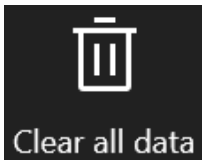
The Save button allows for saving of data collected with the Colori Probe software. Data is saved as a .cmf file containing all information presented in the user interface along with any metadata required to reopen the file later. .cmf files can be opened in any text editor and is compatible with excel or similar solutions.

Manipulation of Data in .cmf files can result in the files becoming unreadable by the software. Therefore, users are encouraged to create copies of saved files if any manipulation of data is needed.

10.6.2.3 Print

The Print button allows for printing of collected data. Pressing the print button will open a pop-up with options for printing. Printing options will be displayed based on currently installed printers on the system including options for printing directly to pdf. A maximum of 75 measurements can be printed this way at a time. A pop-up will warn the user if the number is exceeded. There is no max for how many measurements can be saved to a .cmf file.

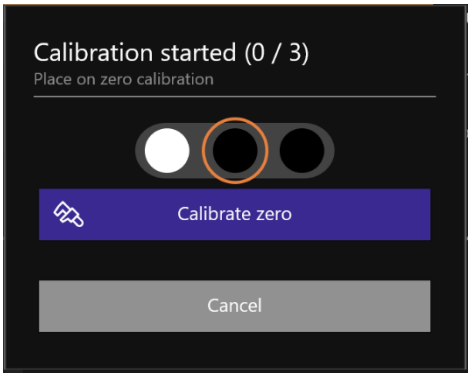
10.6.2.4 Clear Data



The “Clear all data” button will remove all collected data from both views.

10.6.2.5 Calibrate

The Calibrate button will initiate calibration of the probe. An example of the calibration process can be seen in the figure to the right. At any point, calibration can be canceled by pressing the Cancel button. Pressing cancel will discard any steps performed during current calibration and revert the probe to use calibration values from latest completed calibration. If a Calibration of the probe is due, the user will be informed and the Calibrate icon will change to orange until a calibration has been performed.



Example of calibration step

10.6.2.6 Settings

The Settings button will open the settings menu on the right side of the user-interface.

10.6.2.7 Bottom Menu

This section will cover the Bottom Menu layout. Items have been numbered in the figure below and will be explained in the following text.

Bottom Menu numbered for reference

10.6.2.8 Change view

1: The view type of the “Data View” can be changed here. The current view will be highlighted with a white background.

10.6.2.9 Change sample rate

2: If Single is selected, the system will make just one measurement. If Continuous is selected, multiple measurements will be made until stopped manually. Use the “Max” field to indicate the maximum number of measurements required while in continuous mode. During continuous sampling a new measurement will be taken roughly every 2 seconds. Continuous sampling can be stopped by either pressing the stop button, or by pressing the button on the side of the Colorimeter device.

10.6.2.10 Sample button

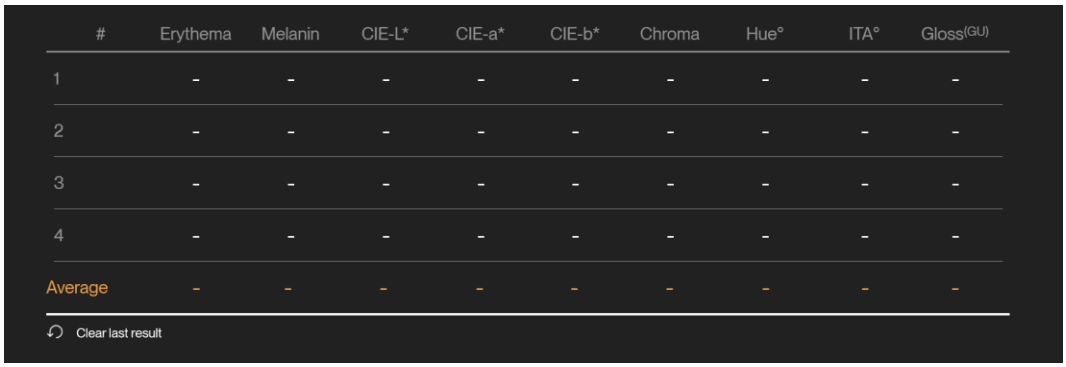
3: The sample button will initiate a measurement when pressed.

10.6.3 Data View

This section will cover the two types of views for presenting data in the user-interface. Several data points are presented in the data view independent of which view is enabled.

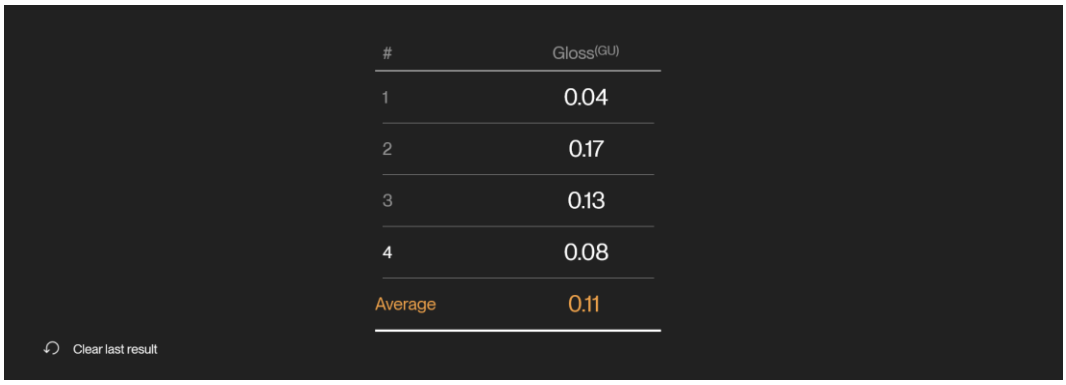
10.6.3.1 Normal View

Normal view allows for a maximum of 4 measurements to be presented at a time. An average of every measurement currently listed is available as well. The following 2 figures show the normal view without any data, and the same view after 4 measurements have been made. The last figure shows the same view changed to only display gloss values. The view can also be configured to show everything except gloss values. These settings will be described in section 10.6.4. Normal view includes the option to clear the last result as displayed in all 3 figures in the lower left. Pressing this button will delete the last measurement made. If 4 measurements are present in the window, no further measurements will be logged until space has been made by either clicking the clear last result button or clearing all data as described in section 10.6.2.4.



Normal view without any data

Normal view with data

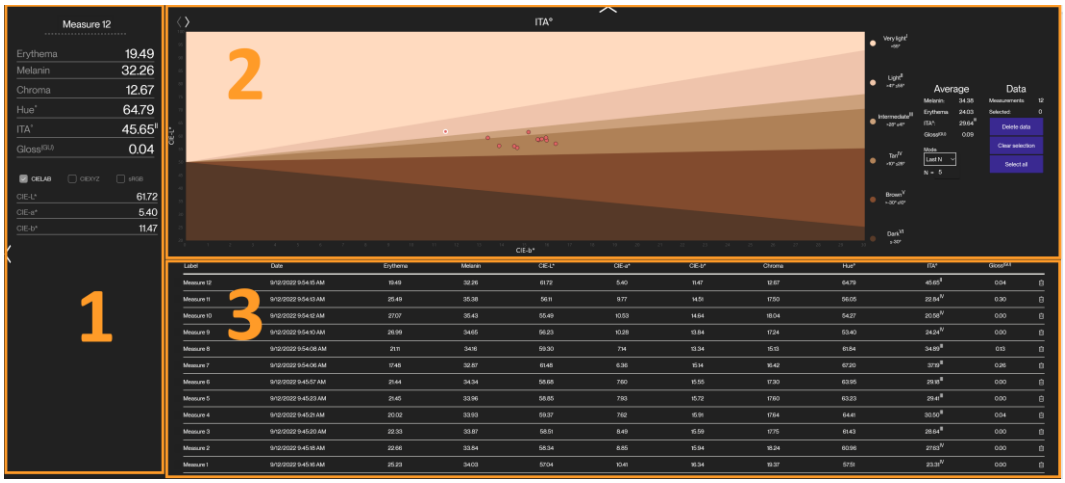


Normal View changed to only display Gloss values

10.6.3.2 Extended View

This section will cover the Extended view of the Colori Probe software user-interface which is seen in the following figure. The sections will be covered as follows:

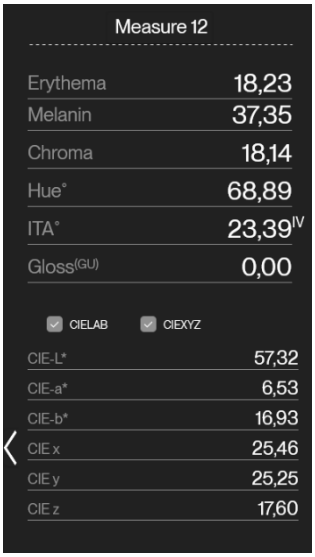
- 1: single measurement info panel
- 2: data presentation panel
- 3: Measurement list



Extended View split into 3 sections for reference

10.6.3.3 Single Measurement Info panel

The single measurement info panel covers info regarding a selected measurement as shown in 10.6.3.7.1. When a measurement is made it will automatically appear in the info panel until a new measurement is selected from the measurement list.



Single measurement info panel

The name of the measurement can be edited and will be reflected in the measurement list.

Gloss will be presented if gloss measurements are enabled.

The following data can be toggled on/off:

- CIELAB values
- CIEXYZ values

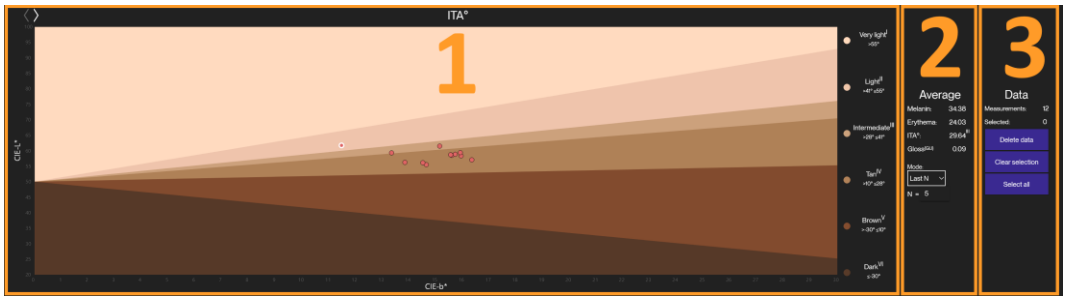
Toggling this data off can help make room on smaller screens. If the screen is too small to display all toggled data, the panel will become scrollable by mouse wheel.

If the single measurement panel is not needed, it can be minimized by pressing the arrow on the left side of the panel.

10.6.3.4 Data presentation panel

This section will cover the data presentation panel at the top of the Extended view. As several functionalities are present, the following figure shows the panel split into 3 sections that will cover the following:

- 1: Graphs covered in section 10.6.3.5
- 2: Average Calculator covered in section 10.6.3.6
- 3: Measurement List functions covered in section 10.6.3.7



Data presentation panel numbered for reference.

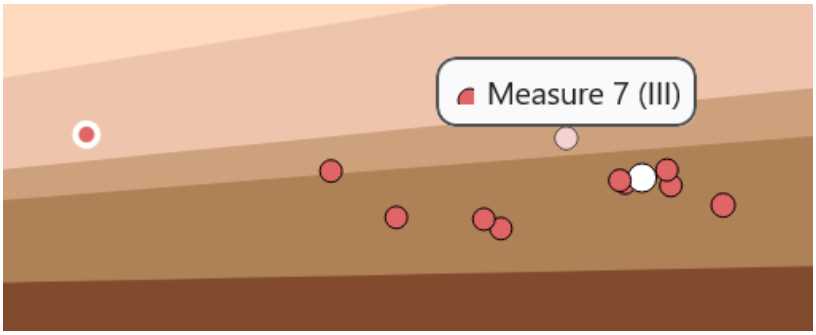
10.6.3.5 Graphs

Two graphs are available for displaying measurement data, ITA and color spectrum data. The graphs can be toggled by using the two arrows at the top left.

ITA Graph:

This is the default graph shown in the Colori Probe Software. All Measurements in the measurement list will be displayed in the graph if the measurement is within the margin for skin ITA. Any new measurement will be displayed as red circles. The Latest measurement performed will be highlighted by a

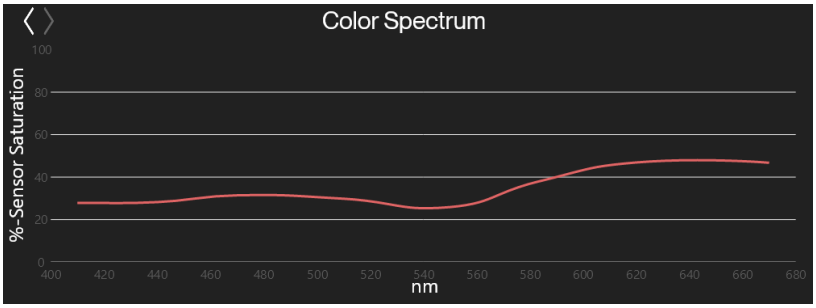
white ring, as shown in the following figure. Any measurements selected in the measurement list will be highlighted with a white circle instead. Hovering over a measurement in the ITA graph will also display the measurement name.



Highlighted measurements and label

Spectrum Graph:

The color spectrum graph will display a graph for the last selected measurement displaying the color spectrum, based on raw measurement data as seen in the following figure.

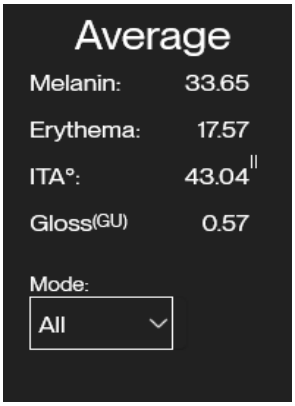


Color spectrum Graph

10.6.3.6 Average Calculator

The average calculator panel allows for different averages to be calculated based on what is selected by the user. The default state of the panel is “None” meaning that no average is calculated. Setting the mode to “Last N” will allow the user to input an N-Value (default value of 5) which will then be used to calculate a running average based on the last N measurement taken.

Setting the average type to be either “All” or “Selected” will calculate a running average of either all measurements or measurement selected respectively. The panel will then display average melanin, erythema, ITA and Gloss for all and selected measurements respectively.



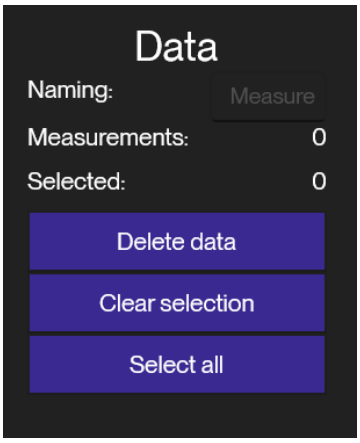
Average calculation panel

10.6.3.7 Measurement list functions

The measurement list function panel includes information regarding the total number of measurements as well as the total number of selected measurements in the measurements list.

By default, all new measurements will be named “Measure X” where X represents the total number of measurements with that naming scheme. However, this can be changed by overwriting the “Measure” listed in the measurement list functions with a new naming scheme. Numbering will reset from 1 when using a new naming scheme but will continue from the highest number if naming scheme matches any measurements in the current list.

Functions in this panel include selecting every measurement in the measurement list, clearing current selection, and deleting measurements.



Measurement List functions

Pressing the “Delete data” button will prompt the user to select what measurements to delete (everything, only selected measurements, or everything but selected measurements).

10.6.3.7.1 Measurement list

The measurement list panel offers a quick overview of every measurement performed as shown in the following figure. Much like the information in the single measurement data panel described in 10.6.3.3. this view can be changed from settings to only display data currently being measured by a probe. This setting is described in section 10.6.4. Besides measurement data, the date and time of the measurement is also available in this list. On the right side of the list, individual measurements can be removed by pressing the trash can icon.

Label	Date	Erythema	Melanin	CIE-L*	CIE-a*	CIE-b*	Chroma	Hue°	ITA°	Gloss(GU)	
Measure 13	8/31/2022 3:38:12 PM	22.98	31.83	59.72	10.06	9.33	13.72	42.84	46.18 II	1.51	
Measure 12	8/31/2022 3:38:10 PM	25.69	33.03	58.60	9.21	6.75	11.42	36.24	51.89 II	0.42	
Measure 11	8/31/2022 3:38:08 PM	23.53	33.43	58.85	9.69	8.47	12.87	41.16	46.28 II	1.17	
Measure 10	8/31/2022 3:38:06 PM	25.51	34.11	57.21	10.77	9.82	14.57	42.36	36.33 III	2.27	
Measure 9	8/31/2022 3:38:00 PM	14.31	36.67	60.59	4.78	12.74	13.61	69.43	39.75 III	0.33	
Measure 8	8/31/2022 3:37:53 PM	16.08	36.94	59.79	5.62	12.61	13.81	65.98	37.83 III	0.00	
Measure 7	8/31/2022	13.07	32.99	63.47	4.36	13.70	14.38	72.35	44.52 II	0.33	

Measurement list

Selected items in the list will be highlighted and a checkmark will appear in the left side of the list for each selected measurement as seen in the following figure.

	Label	Date	Erythema	Melanin	CIE-L*	CIE-a*	CIE-b*	Chroma	Hue°	ITA°	Gloss(GU)	
	Measure 13	8/31/2022 3:38:12 PM	22.98	31.83	59.72	10.06	9.33	13.72	42.84	46.18 II	1.51	
✓	Measure 12	8/31/2022 3:38:10 PM	25.69	33.03	58.60	9.21	6.75	11.42	36.24	51.89 II	0.42	
✓	Measure 11	8/31/2022 3:38:08 PM	23.53	33.43	58.85	9.69	8.47	12.87	41.16	46.28 II	1.17	
	Measure 10	8/31/2022 3:38:06 PM	25.51	34.11	57.21	10.77	9.82	14.57	42.36	36.33 III	2.27	
	Measure 9	8/31/2022 3:38:00 PM	14.31	36.67	60.59	4.78	12.74	13.61	69.43	39.75 III	0.33	
✓	Measure 8	8/31/2022 3:37:53 PM	16.08	36.94	59.79	5.62	12.61	13.81	65.98	37.83 III	0.00	
	Measure 7	8/31/2022	13.07	32.99	63.47	4.36	13.70	14.38	72.35	44.52 II	0.33	

Measurement list with selected measurements

10.6.4 Settings Menu

The settings menu can be opened by pressing the settings button.

10.6.4.1 Settings

The following settings can be changed in the settings menu:

10.6.4.2 Measurement type:

The following measurement types are available:

All:

This will show CIELAB and CIELCh values along with Erythema, Melanin, ITA and Gloss values from measurements.

No Gloss:

This type will display the same as “All” without the Gloss values. This will also decrease the time each measurement takes as the gloss measurement will not be performed.

Gloss Only:

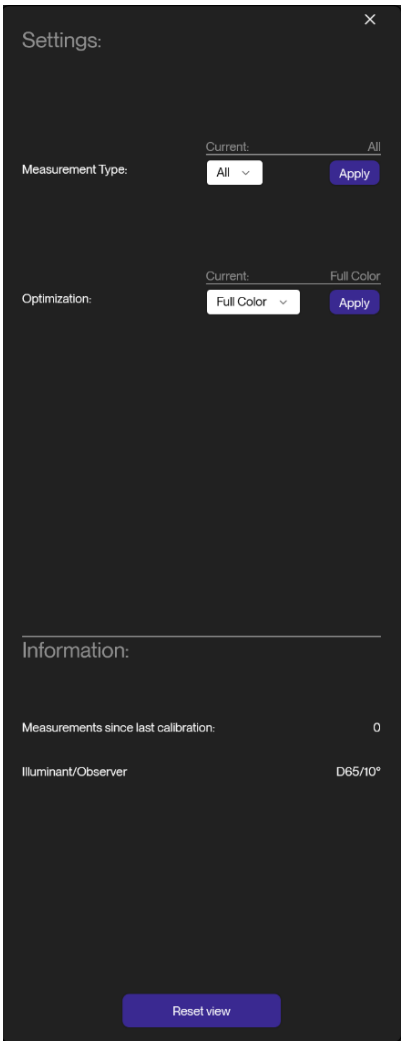
Only the Gloss value will be measured and displayed.

10.6.4.3 Optimization

This option allows the user to change the optimization of the Colorimeter Probe between “Full color” covering all visible colors to “skin optimized” which is more focused on only skin types, sometimes resulting in more precise skin measurements.

10.6.4.4 Reset view

Pressing the reset view button will reset any changes made to the user-interface layout.



Settings Menu

10.6.5 Generated documents

Two types of documents can be created using the Colori Probe software. A .cmf file is created when the save button is pressed. A .cmf file can be opened in any text editor or excel and similar. The layout is as shown in the following figure. .cmf files can be modified, but any modification can result in the file becoming unreadable by the Colori Probe software. Therefore, any modification to .cmf files should be made on copies.

Time	2025-05-15 13-04-43	Please do not modify original s	63,463;26, 00000;000	00000;000	Microsoft	3.2.0.7	da-DK	E										
Label	Date	Eryth.	Melanin	CIE-L*	CIE-a*	CIE-b*	X	Y	Z	Chroma	Hue	ITA	Gloss	CF1	CF2	CF3	CF4	CF5	CF6	CF7
Measure 8	15-05-2025 13:02	23,15	37,45	55,23	8,54	15,04	23,84	23,16	16,79	17,29	60,4	19,18	0	1115	2888	4510	5266	5377	7661	
Measure 7	15-05-2025 13:02	22,78	36,56	55,81	8,77	16,34	24,45	23,72	16,65	18,54	61,79	19,56	0	1116	2879	4527	5367	5536	7917	
Measure 6	15-05-2025 13:02	22,68	39,35	53,58	8,61	17,42	22,28	21,58	14,46	19,43	63,7	11,62	0	1002	2526	3954	4819	5204	7171	
Measure 5	15-05-2025 13:02	19,64	44,81	54	2,89	11,49	21,44	21,97	17,46	11,84	75,89	19,19	0,88	1116	2892	4542	5444	4923	6656	
Measure 4	15-05-2025 13:02	26,17	37,81	53,26	9,65	16,72	22,2	21,29	14,53	19,31	60	11,03	0	1008	2545	4014	4794	4976	7226	
Measure 3	15-05-2025 13:02	21,52	35,8	56,63	8,43	17,26	25,2	24,54	16,87	19,21	63,96	21	0	1127	2934	4606	5538	5798	8137	
Measure 1	15-05-2025 12:46	18,23	37,35	57,32	6,53	16,93	25,46	25,25	17,6	18,14	68,89	23,39	0	1144	3043	4741	5770	6036	8097	
Measure 1	15-05-2025 12:46	20,98	37,09	56,51	7,4	15,91	24,84	24,42	17,42	17,55	65,05	22,24	0	1136	3005	4708	5606	5700	7962	

.cmf data layout

Files for printing will be generated as shown in the figure below. Note that only files printed from normal view includes average values in the printing output.

As .cmf files can be edited and files in general can become corrupted, it may be advantageous to store file in a safe location and potentially create backups if needed.

Cortex Skin Color

Label	Date	Erythema	Melanin	CIE-L*	CIE-a*	CIE-b*	Chroma	Hue	ITA	Gloss
Measure 4	24-04-2023 13:12:39	0,00	58,38	59,96	-6,58	-24,83	25,68	255,16	-	0,06
Measure 3	24-04-2023 13:12:31	28,00	34,64	55,22	13,44	14,33	19,65	46,83	20,00	0,00
Measure 2	24-04-2023 13:12:26	29,21	34,84	54,19	13,99	13,00	19,10	42,91	17,84	0,00
Measure 1	24-04-2023 13:12:24	29,41	35,13	53,93	14,16	12,65	18,99	41,78	17,27	0,00

Printing layout

10.7 Maintenance

For normal cleaning use a dry lint free cloth. For more thorough cleaning the cloth can be soaked in a mild liquid detergent (soap). During cleaning of the probe, be careful not to introduce dirt or liquids into the opening in the probe head as any dirt in the internal parts may adversely affect device performance. Solvents should not be used on the display window as it may become less transparent and crack. When the device is not in use, it should be placed in its receptacle on the Combo 4 with the cable facing up to avoid any dust settling in the light guide.

10.7.1 Cleaning of the calibrator

For optimum performance, it is important to keep the working standards clean. Dust and other loose particles can be blown off the surface using an inert dusting gas. Do not touch the surface with your

fingers or use your mouth to blow on the surface. A clean cotton wipe or lens tissue soaked in a solvent can be used for cleaning.. Usable solvents are acetone, methylated spirit, and isopropyl alcohol (isopropanol). Read the safety data sheet carefully before using any solvents.

10.7.2 Cleaning of the measurement head

The measurement head can be cleaned and disinfected on the outer surface using an alcohol swab or cloth soaked in a disinfectant if needed. Do not insert a cotton swab (or any other object) into the measurement head.

11 Skin pH

11.1 Principle

The pH probe measures the pH potentiometrically on the skin surface using a glass probe especially developed for surface measuring.

11.2 The pH probe

The pH glass probe is fragile and will easily be destroyed if not handled carefully. The probe is made of different layers of glass and thereby it can easily break. Be careful making sure you never bend the probe or press on the side of the probe.

But most importantly be sure the probe is always stored in its holder and always covered by the KCl storage buffer solution. The tip of the pH probe must never dry out.

REMEMBER: If it dries it dies!

WWhen the pH Probe is not in use, it shall be inserted into the storage chamber holding the storage buffer solution. The cap on the storage chamber can be turned left/right to loosen/tighten the grip on the side of the probe. Loosen the cap when you wish to take out the probe for measurements and tighten again after placing the probe back into the chamber.

Cap on storage chamber. Loosen the cap before taking out the probe. Fasten again when the probe is not in use. This will ensure the storage buffer solution will not leak or evaporate.

Storage chamber. Make sure the storage chamber is filled with ample storage buffer solution. This will ensure the tip of the probe is fully submerged in the storage buffer solution.

When the pH probe is not in use, the probe - inserted in the storage chamber - should be placed in the main unit. This will ensure the probe tip is covered by the storage buffer solution. Remember to check from time to time that the probe tip is still covered by the storage buffer solution.

If the probe dries out, please try to recover it by placing the probe tip in a cup of tap water for 24 hours. This may recover the probe.

11.3 Calibration

The pH probe shall be calibrated regularly and at least:

- At first use.
- Every morning before use. Make a check pH measurement on the pH7 and pH4 reference solutions and make a new recalibration when the check measurement is outside your tolerance range for the pH measurement.

Except for the first time, the probe must be cleaned prior to calibration. Cleaning is done in the following way:

- Rinse the probe tip under fresh tap water.
- Fill a plastic cup with tap water and add a few drops of mild detergent (like dishwashing liquid) and gently stir the probe tip in the mixture.
- Rinse the probe tip under well running tap water to remove all remains of the detergent.

Calibrate the probe at the same operating temperature as the probe will be used at.

Always calibrate the probe at pH 7.0 first and then at pH 4.0.

One sachet with pH4 and one with pH7 reference solution are included with the pH probe. Before calibration, please empty the pH4 and pH7 sachet into two small plastic cups. A third plastic cup with tap water should be prepared for cleaning the probe before and in between the calibrations.

Note: Before dipping the probe in each calibration solution, it must be cleaned (see above).

The calibration is done by dipping the probe in the cup with a reference pH 7 solution and pressing the Calibrate pH7 button in the top right corner of the pH screen. The pH7 Calibrate button will then show an hourglass  during calibration. Keep the probe in the reference solution until the hourglass disappears, meaning that calibration has been completed.

This shall be followed by dipping the probe in the cup with a reference pH 4 solution and pressing the Calibrate pH4 button and wait for the button to get back to its original state.

Please note each calibration can take up to 20 seconds.

After calibration, the calibration values are stored in the DermaLab and will be used until the next time a calibration is performed.

Between the 2 calibrations and after the calibration the probe tip should be cleaned in the cup with tap water.

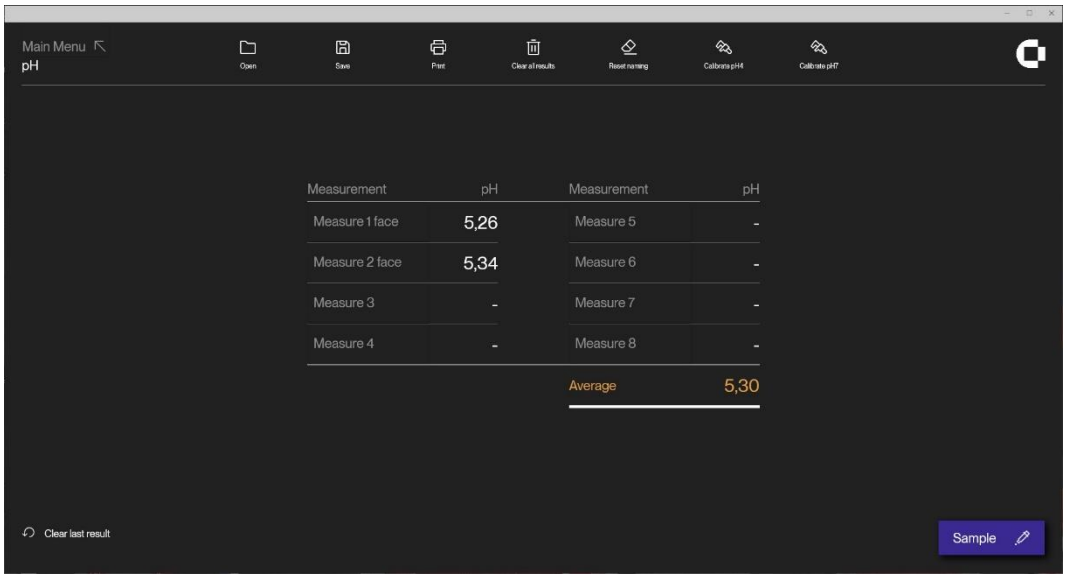
11.4 The pH screen

Up to eight pH measurements can be made with the average updated for each measure.

Each measurement is done by the following steps:

1. Take the pH probe out of its holder and out of the storage chamber.
2. Wipe the tip of the probe gently to remove the remains of the storage buffer solution.
3. Wet the probe in a cup of sterile water.
4. Wipe the tip of the probe once more to remove excess sterilized water, but make sure the probe is still wet at the end of the tip.
5. Apply the probe to the skin and press Start.
6. The measurement result will be written in gray color on the screen until the measurement has stabilized. Upon completion, the measurement color changes to white.
7. Remove the probe and insert it into the storage chamber and place it back in its probe stand with the tip fully covered by the storage buffer solution.

If multiple measurements are made in a short time, then only steps 3 to 7 are needed for each measurement as long as the probe is placed in its holder after all measurements have been done.



The pH screen.

11.5 Maintenance

To maximize the lifetime of the pH probe it is very important to make sure the probe is always in contact with the storage buffer solution when not in use. The probe shall always be placed in the holder and the tip of the probe shall be covered by the storage buffer solution. Be especially careful that the storage buffer solution does not dry out when the probe is stored for a long time, and please regularly check that the probe is covered by the storage buffer solution.

Even when making sure the probe is always kept in contact with the storage buffer solution, the pH probe will still wear out over time due to clogging of the small pores in the tip of the probe. I.e. the pH probe has a limited lifetime – even with careful maintenance – and one should expect to replace the probe regularly. The typical lifetime for a well-maintained pH probe is 2 years.

When the pH measurement takes a long time to stabilize then the probe is defective and needs to be replaced. A replacement pH probe can be purchased from Cortex Technology by contacting cortex@cortex.dk or your local Cortex distributor.

12 Temperature

12.1 Principle

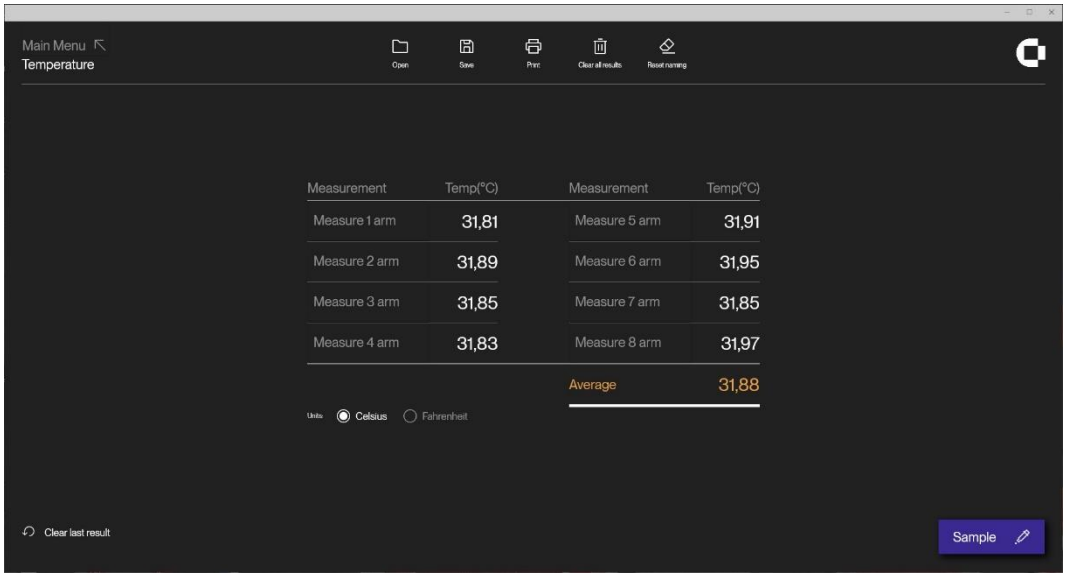
The temperature probe measures the skin temperature by infrared temperature sensing.

12.2 The Skin Temperature Probe

Infrared temperature measurement is a non-contact principle. Accordingly, the probe should not be placed on the skin but kept at a distance of approx. 1 – 3 cm.

To facilitate the measurement procedure an optional ventilating spacer is available.

12.3 The Skin Temperature Screen



The temperature screen.

Up to eight temperature measurements can be made with continuous update of the average for each measurement. Apply the probe to the skin and press Measure for each measurement.

It is possible to change between Fahrenheit and Celsius temperature scales.

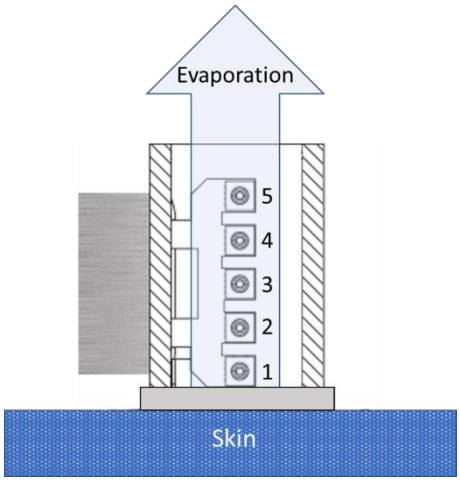
12.4 Maintenance

The temperature probe is maintenance-free.

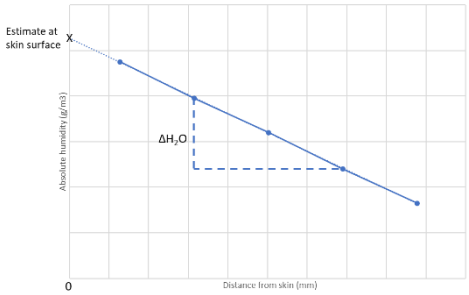
13 Trans Epidermal Water Loss (TEWL)

13.1 Principle

Water loss as measured by the DermaLab Combo is based on Nilsson's Vapor Pressure Gradient method, which is an open chamber method with minimal impact on the skin being examined and, accordingly, very low bias to the reading.



Ten temperature/humidity sensors are arranged in the center of a cylindrical measurement chamber at 5 different heights above the skin surface (5 layers). The measurement chamber is open to allow the skin to "breathe" freely, and the evaporation rate follows Fick's Law of Diffusion when a steady state has been reached.



The TEWL probe measures the relative humidity and temperature in 5 layers inside the chamber using two sensor pairs in each layer and calculates the density gradient of the water evaporation from the skin which can be converted into a TEWL value in g/m^2/hour when the physical sensor arrangement and the geometry of the measurement chamber are considered. Assuming linearity of the vapor pressure gradient inside the chamber, it is possible to estimate the absolute humidity at the skin surface in g/m^3. Only two sensor pairs were used to calculate the TEWL in the previous version of this product. By adding additional sensors, it is possible to reduce the measurement uncertainty and get more information about the pressure gradient in the measurement chamber. It also allows linearity of the pressure gradient (steady state) to be used as a stop criterion for the measurement.

To obtain comparable and reproducible results when measuring trans epidermal water loss, standardized measurement procedures are strongly recommended. Guidelines have been published by *The Standardization Group of the European Society of Contact Dermatitis*:

Guidelines for trans epidermal water loss (TEWL) measurement

J. Pinnagoda, R.A. Tupker, T. Agner, J. Serup
Contact Dermatitis 1990: 22: 164-178

13.2 The TEWL X Probe

The probe is connected to the input connector on the rear panel.

Place the probe on the skin as indicated by the arrow on the front of the probe. The arrow indicates which side of the measuring chamber shall point towards the skin. Do not press the probe too hard against the skin - apply light to moderate pressure.

To minimize possible cross-contamination, a disposable TEWL-probe protector is available to be placed on the skin side of the probe.

The sensors in the probe are delicate, *do not touch* and handle the probe carefully. The sensors inside the probe shall not get in close contact with volatile chemicals such as solvents or other organic compounds used for e.g. cleaning or disinfection.

13.3 The TEWL screen

Normal view showing the TEWL measurement in g/m²/h (B, C), ambient conditions (D), and history of the latest 8 measurements (E).

Extended view showing additional details, such as stop criteria (F), and sensor data (G, I).

Pressing (A) toggles between normal and extended view. Detailed settings are only shown in extended view. Touching the **Sample** button initiates the TEWL measurement, and the graph for the TEWL is shown in g/m^2/h as a function of time. After the TEWL has stabilized after typically 30 – 40 sec., the measurement stops automatically upon reaching a preset *stop-criterion* (F). Several stop criteria can be active at the same time. A green color will indicate which stop criterion stopped the measurement. The stop-criteria includes a preset standard deviation, a preset time, or linearity of the vapor gradient (slope target). By default, the stop-criterion is set to a standard deviation of 0.2.
In rare cases, where the standard deviation during the measurement does not exceed the preset stop-criterion due to very low evaporation (indicated by a fully horizontal curve), the automatic stop function will not be activated. If so, the measurement can be stopped by pressing **Stop**.
The TEWL main result is presented as the mean value over the last 5 seconds. In normal view, the history of the last measurements is shown (E). This makes it more convenient to do several measurements on the same subject.

In the extended view, the sensor data and absolute humidity are shown for all 5 layers (I). Selected data is visualized (G) by clicking on the desired parameters (H). These sensor values form basis for the calculation of TEWL and may provide useful information.

The environmental conditions are shown on the screen. Initially, they are measured by the layer 5 sensors when entering the TEWL screen. It is possible to make a new measurement by pressing “Measure Ambient” (D). The **Clear last result** button deletes the last measurement while **clear all results** clears all measurements.

13.4 Maintenance

There is no maintenance associated with the use of the TEWL module besides cleaning. To clean the probe front, simply wipe it off using a dry cloth. Should more thorough cleaning be necessary, a drop of alcohol may be applied to the cloth. However, care should be taken not to touch the sensors inside the measurement chamber.

The sensors inside the probe shall not get in close contact with volatile chemicals such as solvents or other organic compounds. Especially high concentration and long exposure must be avoided. Ketenes, Acetone, Ethanol, Isopropyl Alcohol, Toluene, etc. are known to cause drift of the humidity reading – irreversibly in most cases. Strong acids or bases, ozone in high concentration, or H_2O_2 may affect the sensor irreversibly. Applying cleaning agents directly to the sensors inside the measurement chamber may lead to drift of the reading or complete breakdown of the sensor.

The sensors show best performance when operated within the temperature and humidity range of 5 °C – 60 °C and 20 %RH – 80 %RH, respectively. Long-term exposure to conditions outside this range, especially at high humidity, may temporarily offset the RH signal (e.g. +3%RH after 60h kept at >80%RH). After returning to the normal temperature and humidity range the sensor will slowly come back to calibration state by itself. Alternatively, a re-conditioning procedure can be used: (80-90°C [176-194°F] at < 5%RH for 24h (baking) followed by 20-30°C [70-90°F] at > 74 %RH for 48h (re-hydration). Prolonged exposure to extreme conditions may accelerate ageing.

13.5 Calibration

The probe sensors may, depending on use, need re-calibration at regular intervals. To ensure the best performance and interchangeability of your probe, it is strongly recommended to return probes for *factory re-calibration* regularly. When doing so, both the humidity and temperature sensors are calibrated in a climate chamber that has been calibrated in an ISO/IEC 17025 accredited calibration laboratory (NIST traceable).

Re-calibration is recommended at a 1-year interval depending on the use of the probe - a shorter interval if the probe is used extensively in very wet conditions (RH>80%), or longer intervals at lower RH values. Within normal RH/T operating range, the typical long-term humidity drift of the sensors is <0,25 %RH/year, while the maximum long-term drift of the temperature sensors is <0,03 °C/year.

14 Dermascope

14.1 Principle

The Dermascope probe provides a magnified surface image of the skin using polarized or non-polarized white LED light as the light source.

The Dermascope probe needs to be connected to an USB connector on the computer.

14.1.1 Magnification

The probe provides two focus ranges. The screen of the SkinLab Software provides an adjustable magnification of 10x to 50x. The black turn-dial on the side of the probe is used to focus the image in one of these two focus points.

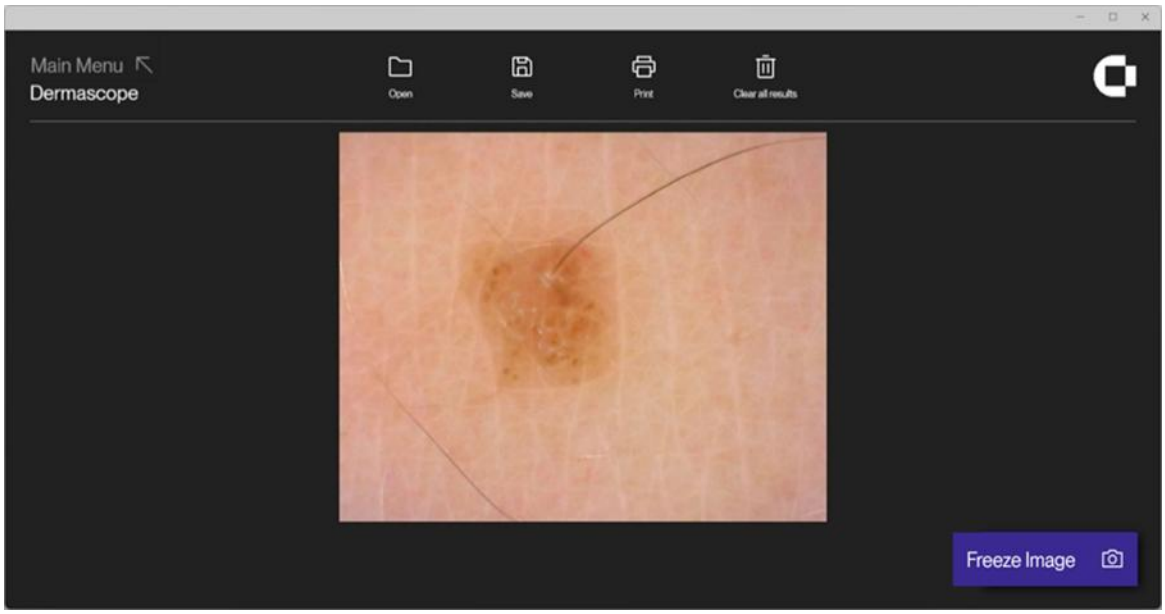
14.1.2 Polarizer

Close to the tip of the probe a black turn-dial can be found, which has two positions for setting the polarization of the white light:

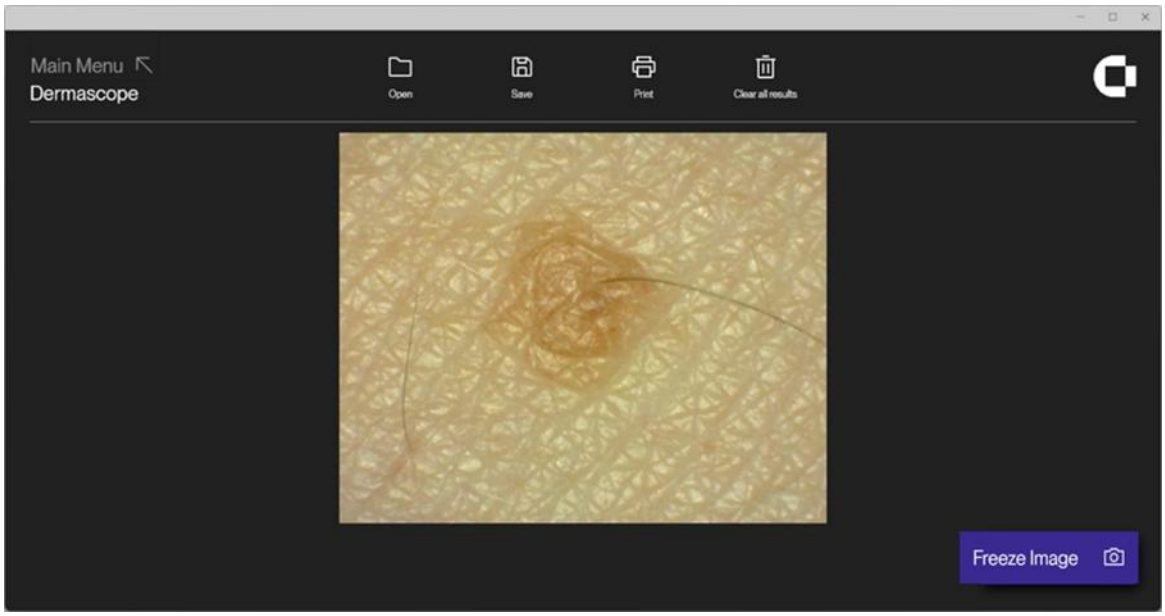
- polarized: turn the clear dial fully clockwise when looking into the probe tip.
- non-polarized: turn the clear dial fully anticlockwise when looking into the probe tip.

The polarized light setting facilitates the elimination of surface reflections similar to oil-microscopy but without the need for applying oil.

It is also possible to use the Dermascope for conventional oil-microscopy by mounting the clear plastic cap supplied with the probe in front of the clear plastic probe tip. Then apply oil to the skin surface and use the non-polarized light setting.



Polarized (surface reflections are eliminated).



Non-polarized (surface reflections – typically fine lines - are visible).

14.2 The Dermascope Probe

When using the probe bring the image in focus at one of the two focus areas by turning the black dial on the side of the camera. Once the image is in focus at the desired magnification, press **Freeze Image** to capture the image on the screen. The captured image can then be saved.

Press **Unfreeze** to start updating the image on the screen again.

14.3 Maintenance

Except for keeping the probe clean, there is no preventive maintenance associated with the use of the Dermascope probe.

15 Files and Formats of Saved Data

When pressing the **Save** button in the measurement screens SkinLab proposes to save the data at the folder used last time for saving data. It also proposes a default filename with the actual date and time (a time stamp). Pressing OK will save the data to the selected folder.

Pressing **Save** in any menu will save all measurement data for all kinds of measurements done. So wait to press **Save** until all measurements have been done.

All measurement data are set to 0 (zero) at startup of the SkinLab application.

When saving measurement data, SkinLab always saves up to 15 different files with the same filename - but using different file type extension:

- **Filename.cmf**: The .cmf file is the Cortex Measurement File. It is an ASCII text file with all measurement data separated by the horizontal TAB character (ASCII value 09). The .cmf file can be imported to Excel or other spread sheet programs or opened in any word processing editor (e.g. Notepad, WordPad, Word etc). This is the file used by SkinLab, when the user presses **Open** to load the data in to SkinLab again.
- **Filename.crd**: The .crd file holds the graph of the elasticity curve, saved in readable text as coordinates of time from the start and the elevation height.
- **Filename_L.crf and filename_R.crf**: These .crf files are the Cortex Raw Files and contain the raw data for the left and right Ultrasound images.
- **Filename_chart.tcd**: These .tcd files are the TEWL Chart Data and contain the raw data for the TEWL X chart.
- **Filename_TEWL-X_data.txd**: These .txd files are the TEWL X Data and contain stored measurements for each perform TEWL measurement (1-2 pr. Second).

The .bmp file stores the ultrasound image from an ultrasound measurement. For all other kinds of measurements an empty (=black) image is stored. The image is stored as a bit map image of 256 x 376 pixels (512 x 376 for the Subcutaneous image). A .bmp file can be opened by any image processing program like Paint, GIMP or inserted in Excel, Word or Power Point files etc.

- **Filename_L. bmp and filename_R. bmp**: These .bmp files contain the left and right Ultrasound images.
- **Filename.jpg.** This is the image captured from the Dermascope (if any).
- **Filename _TEWL-X_graph_nr.bmp** is a picture of the TEWL graph. The nr used in the file name references the nr in software (1-8)
- **Filename _ela_graph.bmp** is a picture of the elasticity graph.

*NOTE: It is important to always keep all the files for each measurement together in the same folder. If a measurement needs to be moved or copied to another folder all the files (filename.****) must be moved or copied to the new folder.*

16 Data extractor

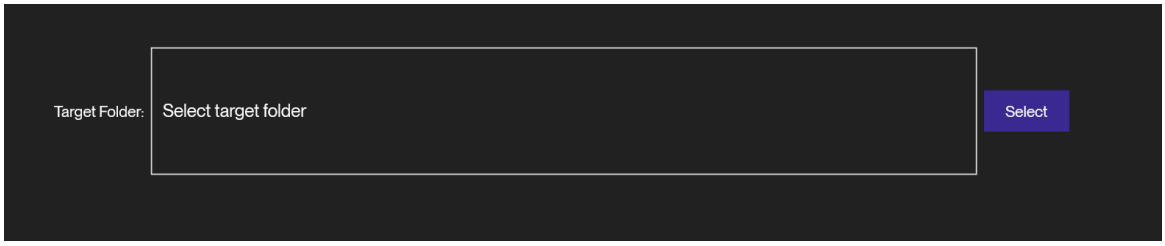
DermaLab SkinLab version 2.2.5.0 and onwards provides built-in capabilities for extracting data from several cortex measurement files and combining the results into a .csv file.

The Data extractor can be accessed on the main menu by clicking “Extract data” in the top row of the screen.

The data extractor page consists of 4 parts:

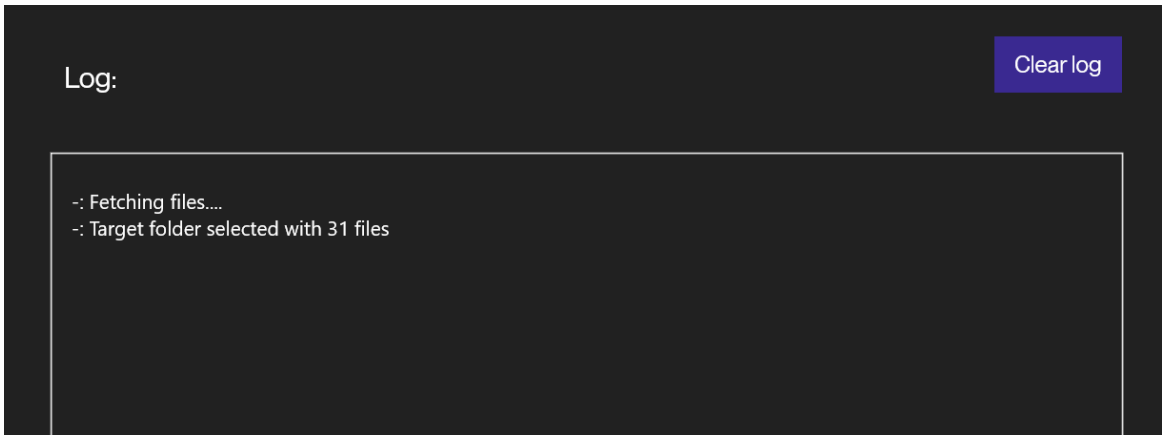
Folder selection

Select which folder the data extractor should look for .cmf files in. The search for .cmf files will be performed on the selected directory and all subdirectories within the selected folder.



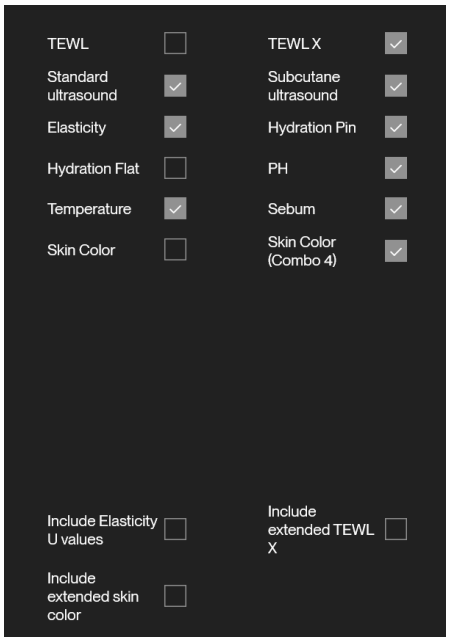
Log

The log will provide information regarding the currently selected folder and the extraction process once started. The log can be cleared by clicking “Clear log”.



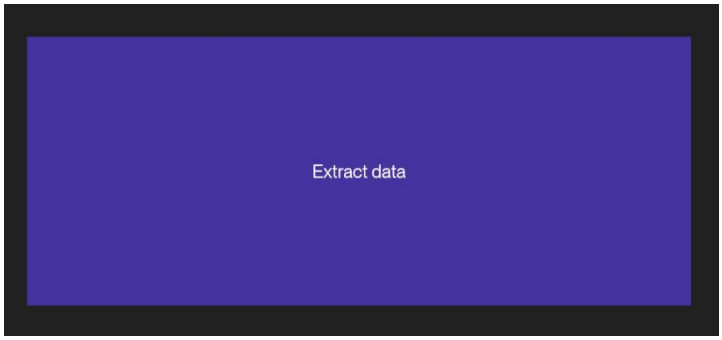
Data Filtering

Before starting the data extractor, it is possible to filter what information should be included in the output file. Only selected measurement types and related information will be included in the output file.



Extracting data

When folder and filters have been selected, click the “Extract data” button to begin the process.

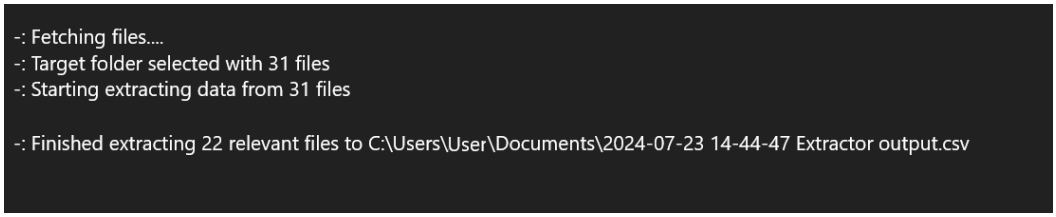


The log will be updated to include any relevant information regarding the process.

Process times may vary depending on the hardware running the DermaLab SkinLab and the number of files selected for extraction.

Extraction is possible from network drives, however this may increase processing time.

Once complete the user will be prompted to select a name and a save destination for the output file. Afterwards the log will update with the number of files extracted to the output file.



16.1 Extractor output

The output of the data extractor is a file in the format .csv (comma separated file).

This file can be imported into Excel or similar software for easy viewing of data.

When importing using Excel or similar software, note that the output file is separated using Semicolon ";" and should be imported as such in the software.

The output file always contains 4 headers:

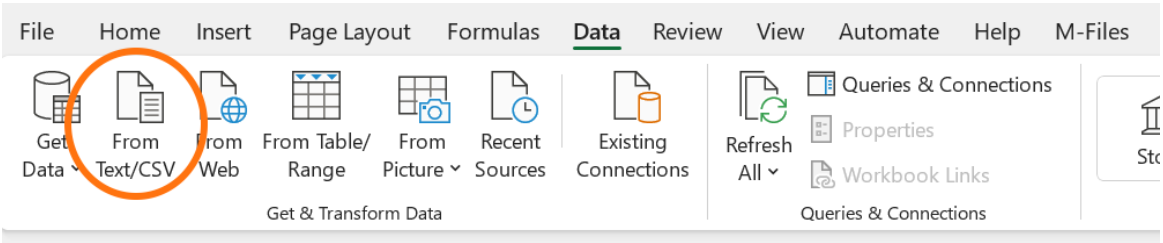
- Path: the location of the file
- File: the name of the file
- Time: the document date saved within the file
- Software version: the software version (if available) contained within the file.

Any other header-values are determined by the filters selected before importing.

Path	File	Time	Software V	Elasticity skin thickness	Elasticity cycles	Elasticity skin type	Elasticity ve avg.	Elasticity e avg.	Elasticity retraction time avg.	Elasticity ve 1
C:\The\File\Path	2024-07-23 11-29-11.cmf	2024-07-23 11-29-13 9201.2.5.0								
C:\The\File\Path	TewIX.cmf	2024-07-23 11-29-27 9201.2.5.0								
C:\The\File\Path	50 year male 20220203.cmf	2022-02-03 09-25-42								
C:\The\File\Path	2024-06-11 14-59-37.cmf	2024-06-11 14-59-37								
C:\The\File\Path	foto kontrol.cmf	2019-06-15 08-08-27		1.3	1	Normal	4.06	1.94	124	4.0611
C:\The\File\Path	2019-04-05 15-25-23 tewl 1.cmf	2019-04-05 15-25-23		1.3	1	Normal	6.12	2.36	100	6.1248
C:\The\File\Path	2019-04-05 15-26-19 tewl 2.cmf	2019-04-05 15-26-19		1.3	1	Normal	6.12	2.36	100	6.1248
C:\The\File\Path	2019-04-05 15-26-49 tewl 3.cmf	2019-04-05 15-26-49		1.3	1	Normal	6.12	2.36	100	6.1248
C:\The\File\Path	2019-04-05 15-27-17 hydration 1, 2, 3.cmf	2019-04-05 15-27-17		1.3	1	Normal	6.12	2.36	100	6.1248
C:\The\File\Path	2019-04-05 15-28-00 video.cmf	2019-04-05 15-28-00		1.3	1	Normal	6.12	2.36	100	6.1248
C:\The\File\Path	2019-04-05 15-29-24 US 1 og 2, gain 4 og 2.cmf	2019-04-05 15-29-24		1.3	1	Normal	6.12	2.36	100	6.1248
C:\The\File\Path	2019-04-05 15-30-12 elasticitet 1.cmf	2019-04-05 15-30-12		1.3	1	Normal	10.59	3.38	83	10.595
C:\The\File\Path	2019-04-05 15-30-31 elasticitet 2.cmf	2019-04-05 15-30-31		1.3	1	Normal	10.56	3.29	81	10.5648
C:\The\File\Path	2019-04-05 15-30-48 elasticitet 3.cmf	2019-04-05 15-30-48		1.3	1	Normal	10.5	3.27	81	10.5012
C:\The\File\Path	2019-04-05 15-31-21 temp 1, 2 ,3.cmf	2019-04-05 15-31-21		1.3	1	Normal	10.5	3.27	81	10.5012
C:\The\File\Path	2019-04-05 15-32-04 colour 1, 2 ,3.cmf	2019-04-05 15-32-04		1.3	1	Normal	10.5	3.27	81	10.5012
C:\The\File\Path	2019-04-05 15-17-37 tewl 1.cmf	2019-04-05 15-17-37								
C:\The\File\Path	2019-04-05 15-18-09 tewl 2.cmf	2019-04-05 15-18-09								
C:\The\File\Path	2019-04-05 15-18-56 tewl 3.cmf	2019-04-05 15-18-56								
C:\The\File\Path	2019-04-05 15-19-22 hydration 1, 2, 3.cmf	2019-04-05 15-19-22								
C:\The\File\Path	2019-04-05 15-19-55 video.cmf	2019-04-05 15-19-55								
C:\The\File\Path	2019-04-05 15-21-01 US 1 og 2 gain 2 og 4.cmf	2019-04-05 15-21-01								
C:\The\File\Path	2019-04-05 15-22-45 elasticitet 1.cmf	2019-04-05 15-22-45		1.3	1	Normal	6.06	2.38	102	6.06
C:\The\File\Path	2019-04-05 15-23-00 elasticitet 2.cmf	2019-04-05 15-23-00		1.3	1	Normal	6.13	2.36	100	6.134
C:\The\File\Path	2019-04-05 15-23-12 elasticitet 3.cmf	2019-04-05 15-23-12		1.3	1	Normal	6.12	2.36	100	6.1248
C:\The\File\Path	2019-04-05 15-23-52 temp 1, 2, 3.cmf	2019-04-05 15-23-52		1.3	1	Normal	6.12	2.36	100	6.1248
C:\The\File\Path	2019-04-05 15-24-33 colour 1, 2, 3.cmf	2019-04-05 15-24-33		1.3	1	Normal	6.12	2.36	100	6.1248
C:\The\File\Path	2019-04-05 15-39-46 tewl 1.cmf	2019-04-05 15-39-46		1.3	1	Normal	10.5	3.27	81	10.5012
C:\The\File\Path	2019-04-05 15-40-48 tewl 2.cmf	2019-04-05 15-40-48		1.3	1	Normal	10.5	3.27	81	10.5012
C:\The\File\Path	2019-04-05 15-41-21 tewl 3.cmf	2019-04-05 15-41-21		1.3	1	Normal	10.5	3.27	81	10.5012
C:\The\File\Path	2019-04-05 15-41-50 hydration 1, 2 ,3.cmf	2019-04-05 15-41-50		1.3	1	Normal	10.5	3.27	81	10.5012
C:\The\File\Path	2019-04-05 15-43-06 video.cmf	2019-04-05 15-43-06		1.3	1	Normal	10.5	3.27	81	10.5012
C:\The\File\Path	2019-04-05 15-44-19 US 1 og 2, gain 2 og 4.cmf	2019-04-05 15-44-19		1.3	1	Normal	10.5	3.27	81	10.5012
C:\The\File\Path	2019-04-05 15-45-42 elasticitet 1.cmf	2019-04-05 15-45-42		1.3	1	Normal	6.05	2.33	100	6.0516
C:\The\File\Path	2019-04-05 15-46-01 elasticitet 2.cmf	2019-04-05 15-46-01		1.3	1	Normal	5.81	2.24	100	5.8124
C:\The\File\Path	2019-04-05 15-46-16 elasticitet 3.cmf	2019-04-05 15-46-16		1.3	1	Normal	5.72	2.22	101	5.7161
C:\The\File\Path	2019-04-05 15-46-48 temp 1, 2 , 3.cmf	2019-04-05 15-46-48		1.3	1	Normal	5.72	2.22	101	5.7161
C:\The\File\Path	2019-04-05 15-47-23 colour 1, 2, 3.cmf	2019-04-05 15-47-23		1.3	1	Normal	5.72	2.22	101	5.7161
C:\The\File\Path	2019-04-05 15-48-07 tewl 1.cmf	2019-04-05 15-48-07		1.3	1	Normal	5.72	2.22	101	5.7161
C:\The\File\Path	2019-04-05 15-49-43 tewl 2.cmf	2019-04-05 15-49-43		1.3	1	Normal	5.72	2.22	101	5.7161
C:\The\File\Path	2019-04-05 15-50-12 tewl 3.cmf	2019-04-05 15-50-12		1.3	1	Normal	5.72	2.22	101	5.7161
C:\The\File\Path	2019-04-05 15-51-15 video.cmf	2019-04-05 15-51-15		1.3	1	Normal	5.72	2.22	101	5.7161
C:\The\File\Path	2019-04-05 15-52-04 US 1 og 2, gain 2 og 4.cmf	2019-04-05 15-52-04		1.3	1	Normal	5.72	2.22	101	5.7161
C:\The\File\Path	2019-04-05 15-52-50 elasticitet 1.cmf	2019-04-05 15-52-50		1.3	1	Normal	5.46	2.12	101	5.4574
C:\The\File\Path	2019-04-05 15-53-10 elasticitet 2.cmf	2019-04-05 15-53-10		1.3	1	Normal	5.09	2.02	103	5.0948

16.2 Importing extractor output into spreadsheet software

To import the data into Excel or any similar software open the software. Locate the option to import from Text/CSV.



Select output from extractor. When prompted to select delimiter select Semicolon and import file.

This should import the complete output file to any spreadsheet software.

17 General maintenance

Maintaining the main unit is limited to cleaning the exterior of the instrument as necessary. Check the cables and connectors regularly to ensure trouble-free operation.

Maintenance of application probes is described in the relevant application module chapter.

17.1 Calibration & Performance Check Certificates

An increasing demand for documentation to verify that all parts of the equipment are up to spec and calibrated in accordance with our client's internal quality assurance procedures has led to the implementation of a special Calibration & Performance Check service.

As a result, all relevant items are marked with a suggested recalibration/check date at time of shipping. Items returned to Cortex Technology for such service are thoroughly checked, adjusted and recalibrated as appropriate, and each item is returned with a verification/calibration certificate.
Please contact your local distributor or Cortex Technology for further information.

All probes come pre-calibrated and can be exchanged without any need for recalibrating the main unit. Please contact your local distributor or Cortex Technology (www.cortex.dk or cortex@cortex.dk) for requests of service and repair.

18 Service

Service and repair of the DermaLab Combo is only to be performed by authorized personnel or by Cortex Technology.

> ***Disclaimer:*** *In case the DermaLab is sent for repair at Cortex, please note: Although we will do our outmost to prevent or minimize loss of data, Cortex Technology does not warrant that saved measurement data can be recovered. Please make sure to backup measurement data regularly.*

19 Safety

The external power supply for the DermaLab Combo forms an integral part of the electrical safety features of the device and must not be tampered with. Do not use any other power supply than provided by Cortex Technology.

Cortex Technology Aps cannot be held responsible for any damage or loss caused by improper installation or incorrect use of the device.

20 Warranty

The DermaLab® Combo, probes and other accessories are covered by a one-year warranty against material and manufacturing defects, except

- Due to the nature of the pH probe, the warranty period is 6 months.

- Due to the nature of the humidity sensors used in the TEWL probes and the use of these probes, re-calibration may be needed within the one-year warranty period. Such re-calibration is not covered by the warranty.

21 Technical specifications

21.1 Main Unit

- IP-class: IP20 (EN60529)
- Environment: Indoor use
- Temperature: 10 to 35 °C
- Relative humidity: 10 to 90 percent relative humidity, non-condensing
- Altitude: 3048 m (10,000 feet) maximum
- Dimensions: 452x106x131 mm
- Power requirement: 12VDC, 20W (external power supply included).
- Integrated probe holder.

21.2 Colori probe

- 45°/0° colorimeter with full visible spectrum color sensor (10° standard observer)
- Diffuse reflectance spectroscopy color measurement (Specular Component Excluded)
- Light Source: D65 illuminant (CRI > 98).
- Measurement aperture: 8 mm (50 mm^2 area).
- Color space: CIE L*a*b*, L*C*h, XYZ
- Pigmentation (melanin): 0.0 – 99.9.
- Erythema (redness, hemoglobin) 0.0 – 99.9.
- Ceramic (white) and polished black glass (gloss) working standards
- Gloss: 60° specular gloss (GU)
- $\Delta E^*_{ab} \leq 2$ (Average measured on 14 CSSII* ceramic color tiles)
- $\Delta E^*_{00} \leq 1$ (Average measured on 14 CSSII* ceramic color tiles)

* The CCSII is a set of standards for checking the consistency of operation and accuracy of color measuring instruments over long periods.

21.3 Ultrasound probe

- Ultrasound scanner using a rotating single element transducer.
- Bandwidth (MHz): 14-26 Key figure
- Center frequency: 20 MHz, focused ultrasound.
- Resolution: 60 µm x 200 µm (axial x lateral).
- Image depth (max): 3.4 mm. key figure
- Rotating scan diameter: 11 mm.
- Gain-range: Adjustable +/- 10dB.

21.4 Ultrasound Subcutaneous probe

- Ultrasound scanner using a rotating single element transducer.
- Bandwidth (MHz): 14-26 Key figure
- Center frequency: 20 MHz, focused ultrasound.

- Resolution: 60 µm x 200 µm (axial x lateral).
- Image depth (max): 6 mm. key figure
- Rotating scan diameter: 11 mm.
- Gain-range: Adjustable +/- 10dB.

21.5 TEWL X

The trans epidermal water loss (TEWL) probe measures water evaporation from the skin using 10 temperature and 10 humidity sensors placed centrally in an open chamber. The TEWL value is calculated in g/m²/h and is an important parameter for assessing skin barrier function.

- Range: 0–250 g/m²/h
- Resolution: 0.1 g/m²/h
- Sample rate: 14 samples pr second
- 10 sensor pairs organized in 5 layers centrally inside an open measurement chamber
- Standard uncertainty: 2.5%
- Stop criteria: standard deviation, time, and linearity of the vapor gradient (slope target) of moving average filtered data (5 s window).
- Recommended operating conditions: 18-26°C
- Certificate shows the deviation of the relative humidity before and after calibration.
- The temperature and humidity at the skin surface is calculated based on the vapor gradient inside the measurement chamber.

21.6 Hydration Probe

The hydration probe measures the hydration level of the stratum corneum down to around 15 micrometers using the conductance method.

- Two variants: Flat faced or pin electrodes
- Conductance: 0 – 9999 µS (1 µS resolution).
- Measurement frequency: 100 kHz for hydration flat and 300 kHz for hydration pin.
- 1 second measurement time
- Factory calibrated and linearized within the entire measurement range.
- Optional calibration checker available.
- Measurement uncertainty: ±5%

21.7 Elasticity Probe

The elasticity probe utilizes a well-established method to evaluate the (visco)-elastic properties of the skin using controlled mechanical deformation. The measured elevation/retraction curves provide information about skin aging and the collagen/elastin content of the skin.

- Measurement of air pressure-induced skin elevation and subsequent retraction time.
- Settings: Adjustable pressure (150, 400, and 650 mbar) and skin thickness (in mm).
- Measurements: Young's Modulus, Retraction Time, and Viscoelasticity.
- 10 mm diameter suction area.
- Ultra-low weight (approx. 7 grams) for minimum measurement bias.
- Adheres to the skin by double sided adhesive tape.

21.8 Temperature Probe

- Range: 0 – 50 ˚C/ 32 – 122 ˚F.
- Measurement uncertainty: ±0.1°C (@ 36°C-39°C surface temperature & 20°C-30°C ambient temperature)
- Resolution: 0.1 ˚C.
- Display Mode: Degree Celsius or degree Fahrenheit.

21.9 pH Probe

- Probe type: Standard gel-filled surface type probe.
- Range: 1.00 – 11.00 pH.
- Calibration liquids included (4 and 7 pH)

21.10 Dermascope Probe

Handheld digital microscope

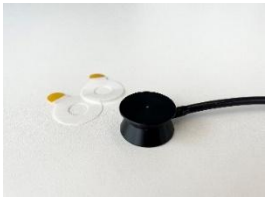
- Readout: Digital image 1.3M pixels (SXGA).
- Magnification: 10x-50x
- Save format: jpeg.
- Illumination: 8 x white LED.
- Selection between diffused and polarized light source.
- Medical Device Class 1 – Medical Devices Regulation (EU) 2017/745

21.11 Sebum Strip Reader

- Principle: Optical assessment of collected sample.
- Sebum collector: Microporous polymer film mounted on light absorbing substrate.
- Sebum score: 0 – 99.

22 Combo parts

Name	Picture	Item number
Combo Main		C64000.xx
Colori probe		C09600.xx
Calibrator for Colori probe		D22214.xx
Ultrasound probe		C08645.xx
Ultrasound probe head		C08601.xx
Ultrasound Subcutaneous probe		C01044.xx
Film for Subcutaneous ultrasound probe		V01005.xx

Elasticity probe		C05440.xx
Elasticity double adhesive patch		V02001.xx
Hydration flat probe		C03440.xx
Moisture flat calibrator		C03006.xx
Hydration pin probe		C06440.xx
Hydration pin calibrator		C06006.xx
Stand-off for hydration pin		M21010.xx
Dermascope		C10002.xx
pH probe		C07444.xx
Buffer for pH probe (4 and 7 pH + storage)		C17441.xx (pH 4) C17443.xx (pH 7) C17442.xx (storage)

Sebum strips		V02002.xx
Skin temperature probe		C02440.xx
TEWL X probe		C04445.xx
TEWL probe protectors		M20009.xx
Power supply (Adapter Tech., ATM036T-P120)		C44701.xx

23 FAQ

In the FAQ below please find answers to questions not to be found elsewhere in this manual.

General:

Q: *In the main screen, some buttons are lit although no probe is connected.*
A: - Some parameters require a probe as well as an internal module. The internal module is recognized even though the probe is not connected (elasticity, sebum, and ph).

Specifically TEWL:

Q: *Why does the measurement not stabilize and stop?*
A: - There may be a leak between probe and skin surface. Reposition the probe to align with skin surface.
- Environmental conditions may be unstable. Check the environment for open doors, windows, direct light (sensors are light sensitive), heat sources, ventilation equipment etc.

When does the TEWL measurement stop?
Q: - When the measurement is stable, it stops automatically. The default stop criteria is a standard dev. of
A: 0.2. if no stop criteria is set, the measurement will not stop.

What are the individual sensor values used for?
Q: - The sensor values ($T_{upper/lower}$, $RH_{upper/lower}$) may provide “diagnostic” information for troubleshooting in
A: case the TEWL value behaves unexpectedly.

When and how are the environmental measurements done?
Q: - The environmental T and RH is measured by one of the sensor pairs in the probe upon entering the
A: TEWL application. As the same sensor pair is used during the TEWL measurement procedure, it is important to document the environmental conditions prior to initiating skin measurements.

Specifically Ultrasound:

Q: *The probe scans, but there is no or just a very weak image on the screen?*
A: - The probe lacks water. Check the membrane for holes and replace if necessary. Refill the probe.
- Too low gain setting. Adjust the gain.

Q: *Why not use tap water in the probe?*
A: - Tap water quality varies, and it may leave mineral deposits in the probe mechanics and on the transducer front, which may lead to malfunction and/or poor image quality. Use deionized water.
- Fresh tap water contains many tiny air bubbles, which impacts the ultrasound signal transmission.

Q: *What does the image colors mean?*
A: - Colors are not tissue specific but relate to the reflected signal strength – black is minimal strength, white is maximum.

Q: *Should I use water or gel as the coupling medium?*
A: - The use of water or gel is a matter of personal preference. Water spreads evenly and more easily, gel stays on the skin but is more likely to collect air bubbles. NB! The use of gel does not apply to the Ultrasound Narrow probe.

Q: *Why do I get horizontal black lines across the image?*
A: - Horizontal black lines are caused by air bubbles in the gel/water used as a coupling medium. Renew the gel/water after wiping off residuals left on the probe front and the skin.

Specifically Hydration:

Q: *The DermaLab Combo measures skin conductance. What is the difference to skin capacitance?*
A: - Skin conductance is the skin’s ability to conduct an electrical, alternating current as opposed to skin capacitance, which is the ability to accumulate an electrical charge.
As the cell fluids of the live epidermis are highly conductive, the dynamic range of the conductance measurement is mainly impacted by the water binding capacity of the stratum corneum. Accordingly, the conductance measurement is more superficial and well defined compared to the capacitance principle, which goes deeper and to a higher extent incorporates both stratum corneum and live epidermal cells.

Specifically Sebum:

Q: *Why is offset calibration on each strip necessary?*
A: - The offset calibration eliminates batch-to-batch variation on the strip in order to increase accuracy/reproducibility.

Q: For how long do I need to press the sebum collecting strip against the skin?
A: - The time is less important as long as all of the absorbing area on the strip is exposed. Spend a few seconds to roll your thumb over the back side of the absorbing strip, when pressed against the skin with moderate pressure.

Specifically Elasticity:

Q: *The elasticity screen allows for adjusting the skin thickness – why?*
A: - Skin thickness is a parameter in the equation for calculating elasticity. By default it is preset to 1 mm, but if the real thickness is known, it is possible to obtain a more correct elasticity measurement by adjusting this setting. Depending on configuration, the DermaLab Combo features high resolution ultrasound to accurately measure skin thickness.

Q: *Why change between soft/normal/firm skin?*
A: - Depending on the body location and skin condition the mechanical properties of the skin varies. This setting allows for adapting the device to the body site and actual skin condition in order to fully utilize the dynamic range of the device, thus obtaining more precise and sensitive readings.

Specifically DermaScope:

Q: *Why use polarized light?*
A: - Using polarized light mimics the use of oil on the skin to eliminate surface reflections.

A. List of symbols

The following symbols are used:

WARNING or CAUTION information to avoid personal injury or damage to the product.

ELECTRICAL SHOCK HAZARD. Indicates that an electrical shock could or might occur.

Class 2 equipment (IEC 60601-1).

Alternating current, single phase.

Direct current.

Waste Electrical and Electronic Equipment (WEEE). This product complies with the European Union's Waste Electrical & Electronic Equipment (WEEE) Directive 2012/19/EU.

B. Declaration of Conformity

EC – DECLARATION OF CONFORMITY

We hereby declare that the product mentioned below conforms to the requirements of:

- Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to *electromagnetic compatibility*.
- Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits.
- Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on *waste electrical and electronic equipment* (WEEE).
- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
- Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH). We confirm that, to the best of our knowledge and based on the information provided by our suppliers, the products we supply do not contain any substances listed on the REACH Candidate List of Substances of Very High Concern (SVHC) or release any restricted substances under normal or reasonably foreseeable conditions of use.

Name of product:

Dermalab® Combo 4

Name and address of manufacturer:

Cortex Technology Aps,
Niels Jernes vej 6B
9220 Aalborg Ø,
Denmark
Tel.: +45 98574100
E-mail: cortex@cortex.dk

Implemented standards:

DS/EN 61000-6-1:2019
DS/EN 61000-6-3:2021
DS/EN 61010-1:2010 + AMD1:2016
DS/EN 61187:1995
DS/EN 50419:2022

Place and date: Aalborg 2024/09/17 Signature: