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DermaLab® Single

Instruction Manual

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DermaLab® Single

Instruction Manual

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 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.

- 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 a 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 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).

- The DermaLab® Single system does not require an internet connection for normal operation. If the DermaLab® Single 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.

- 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.

- 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 use

The DermaLab® Single is an investigational laboratory instrument for measuring skin parameters. DermaLab® Single offers units for the measurement of the following parameters:
Skin hydration (two different units – PIN and FLAT), skin elasticity, Transepidermal Water Loss (TEWL), and skin ultrasound (two different units – Standard and Subcutaneous).

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

2.2. General description

Each of the six available units consists of a main unit dedicated to a specific handheld probe – i.e. main units and probes are not interchangeable.

The main unit is connected to a Windows based PC (e.g. a tablet or laptop) via a USB cable. It is possible to connect multiple main units to the same PC if several USB ports are available. The dedicated software will automatically detect and update the main screen according to the number and type of connected units.

3. Installation and power-on

To ensure trouble-free and safe operation of the DermaLab® Single please follow the instructions for use and maintenance as laid down in this manual.

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 power supply than supplied by Cortex Technology.

3.2. Main unit

Connect the main unit to the +12 V output cable from the power supply. The power input is located at the rear panel of the main unit.

To obtain the most stable readings it is advisable to let the main-unit and probe warm up for approx. 5 min. prior to use.

3.3. Connection between the computer and main unit

The DermaLab® Single main unit is connected to the computer with a USB cable. Please use the USB cable delivered with the device.

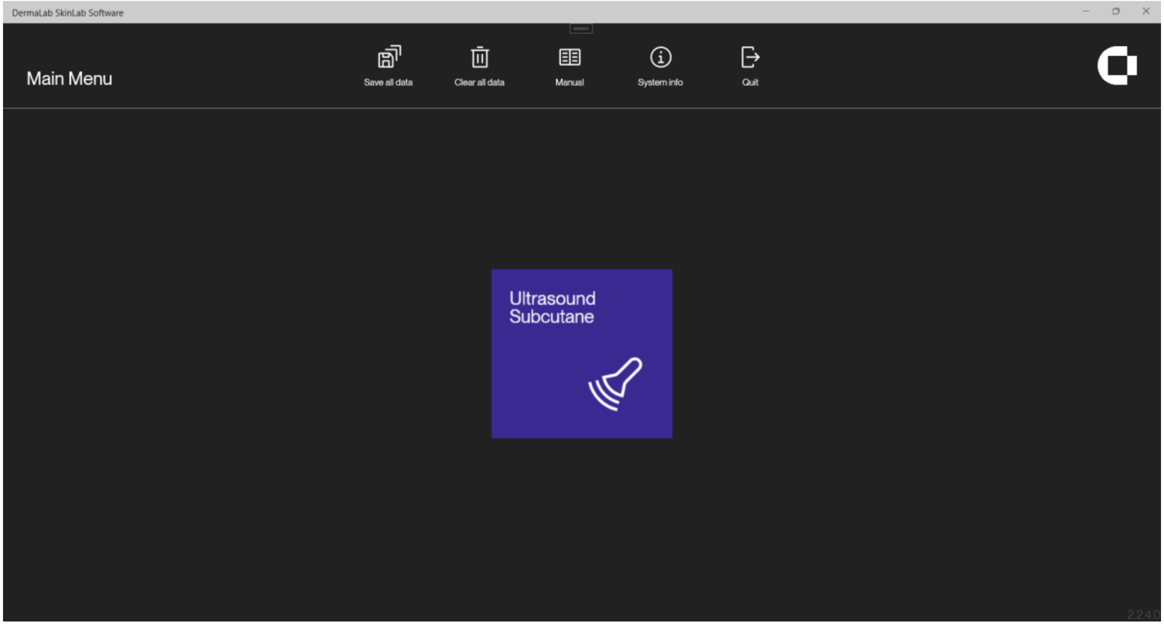
3.4. Connection of the probes

The Ultrasound, TEWL, Hydration and Elasticity probes are all connected at the rear panel of the DermaLab® Single main unit using various types of connectors. It is only possible to connect the probe to a main unit made for the particular type of probe.

When inserting the connectors: insert the connector and gently turn it. When the pins are cor-rectly 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).

4. Main screen

Turn on the tablet/PC, activate the DermaLab® SkinLab software, and the main screen appears. The main screen provides buttons to be activated.



Main screen showing connection to Ultrasound Subcutane unit.

Only parameters, for which probes are connected, appear on the main screen (here Subcutane Ultrasound).

The **Quit** button is used to exit the SkinLab software. 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 DermaLab® Single Software screens

All individual measurement pages use common control buttons located at the top of the page. Note: Not all buttons are shown in all pages and some buttons may only occur on 1 measurement screen. In these cases, buttons will be explained under the section covering that page.

The buttons provide the following functions:

Open: The Open button allows for importing previously saved datafiles. Only previously stored data for the specific skin parameter are loaded, other skin parameters remain unchanged. See 6.1.1. for specifics on opening ultrasound images.

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.

.cmf files can be opened in any text editor and is compatible with excel or similar solutions.

Save: Save measurement data for a specific parameter to a file. See 6.1.1. for specifics on saving ultrasound images.

The Save button allows for saving of data collected with the 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.

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.

Print: Print measurement data on the default printer.

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.

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

Reset naming: Resets naming of all measurement on page to use default naming scheme

Pressing the button 

will Exit the measurement page and return to the main-screen.

Pressing the 

Button on any page will clear the last measurement performed.

6. High Resolution Ultrasound Imaging

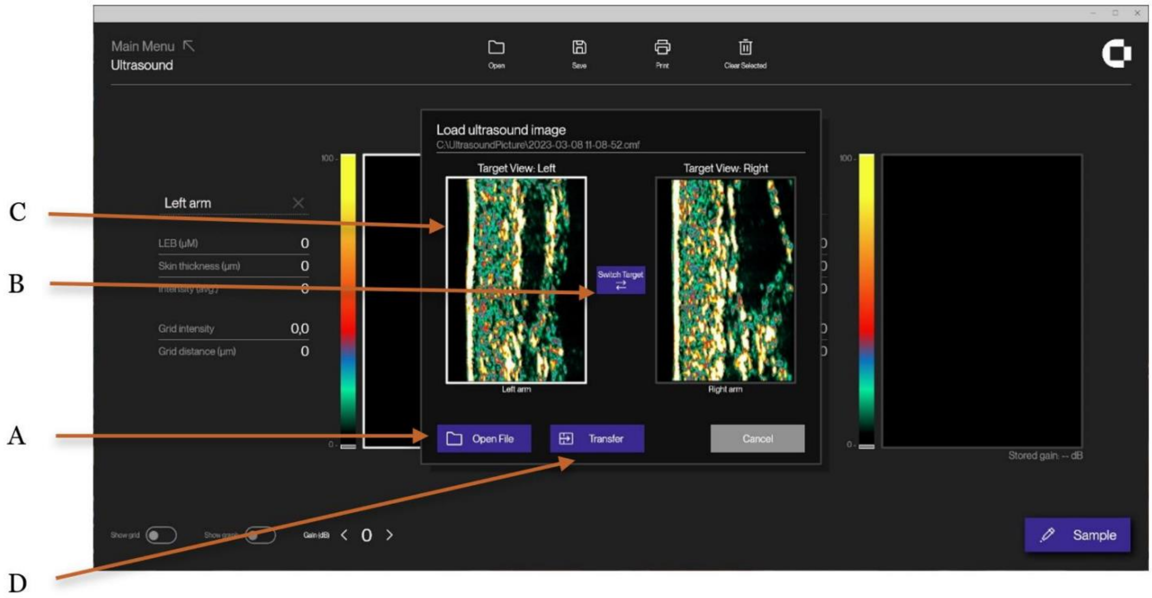
6.1. General principle

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 (see above). 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® Single offers two different ultrasound probes depending on the application:

- The ultrasound ***Standard*** 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. 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 crosssectional image perpendicular to the skin surface.

- The ultrasound ***Subcutane*** 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 50 mm and a scan length of 50 mm. As the Standard, 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 Standard probe

6.4.1. Preparing the Probe

Water is selected as the ultrasound transmission medium to provide minimal attenuation of the acoustical signal. Consequently, the scanning heads accommodate an internal water chamber ("water path"). For the operator's convenience and the comfort of the client the ultrasound probe features an integrated disposable water barrier to prevent spillage.

The water barrier is made of a special plastic film-material, which allows high freq. ultrasound to pass with minimal attenuation and without compromising the image quality. This water barrier is intended to be disposed of between recordings to minimize the risk of cross-contamination.

The water chamber is designed as an open chamber to reduce the risk of permanent contamination of the water. The recommended water quality is de-ionized water or distilled water. Plain tap water should be avoided due to the risk of mineral deposits on the front of the transducer. Such deposits will lead to poor image quality.

6.4.2. 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 during use.
The water barrier film is kept in place by a black ring which is attached to the tip of the probe.

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

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

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

Snap off excess film with a quick downward movement.

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

The film shall present a smooth surface without wrinkles.

The ultrasound 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 and disappear by gently tapping the probe. Otherwise, please replace the film after topping up with water.

6.4.3. Using the probe

Dip the tip of the probe in a cup of water 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 **Sample** button. The probe will perform and present one scan on the screen.

6.4.4. Cleaning

After each scanning, or at least after eight hours of operation, the water barrier film shall be removed disposing the water and the film, thereby allowing the transducer to dry. 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 using 70% isopropyl alcohol as a disinfectant. When disinfecting the probe, please be careful not to wipe the ultrasound transducer inside of the water chamber with alcohol, as this may cause damage to said transducer.

After emptying the water chamber and cleaning the probe, the black ring can be put onto the scanning head without film for storage.

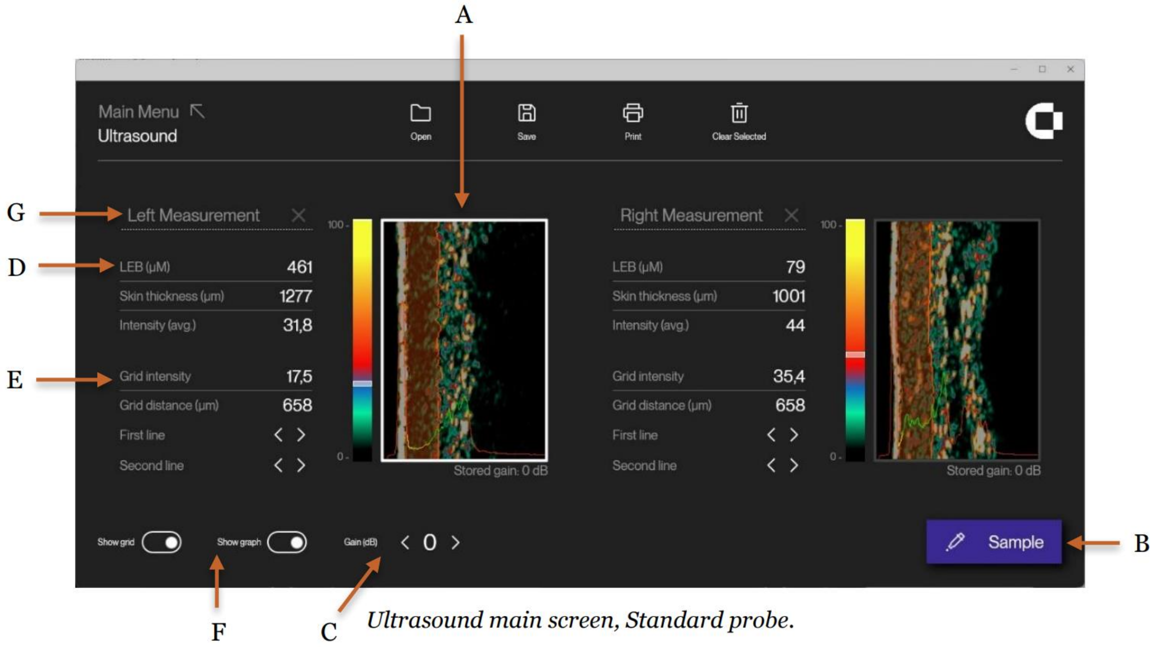
6.4.5. The Ultrasound Standard probe screen

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 **Start** 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 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) for scanning on the forearm and 4 on the temple.

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.

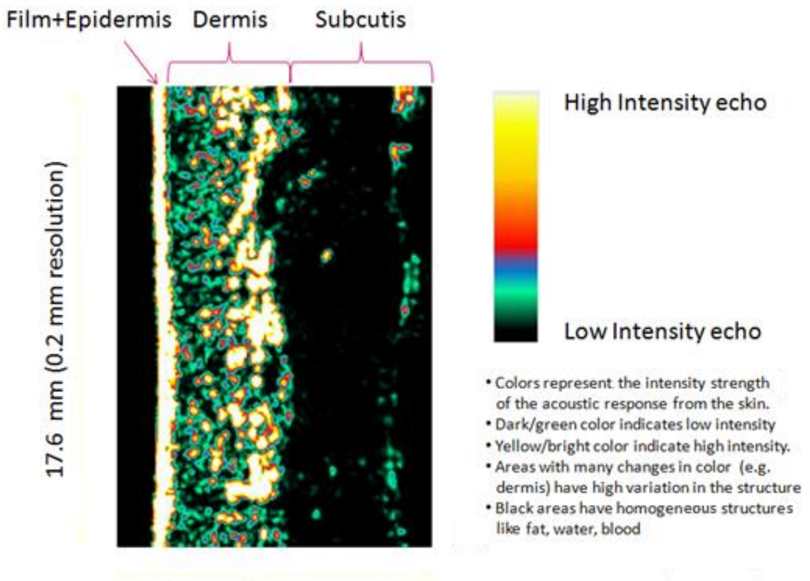


Ultrasound main screen, Standard probe.

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).

6.4.6. 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 a mix of many colors. The subcutaneous fat and muscle fibers will return a low intensity signal (dark green and black). See below:

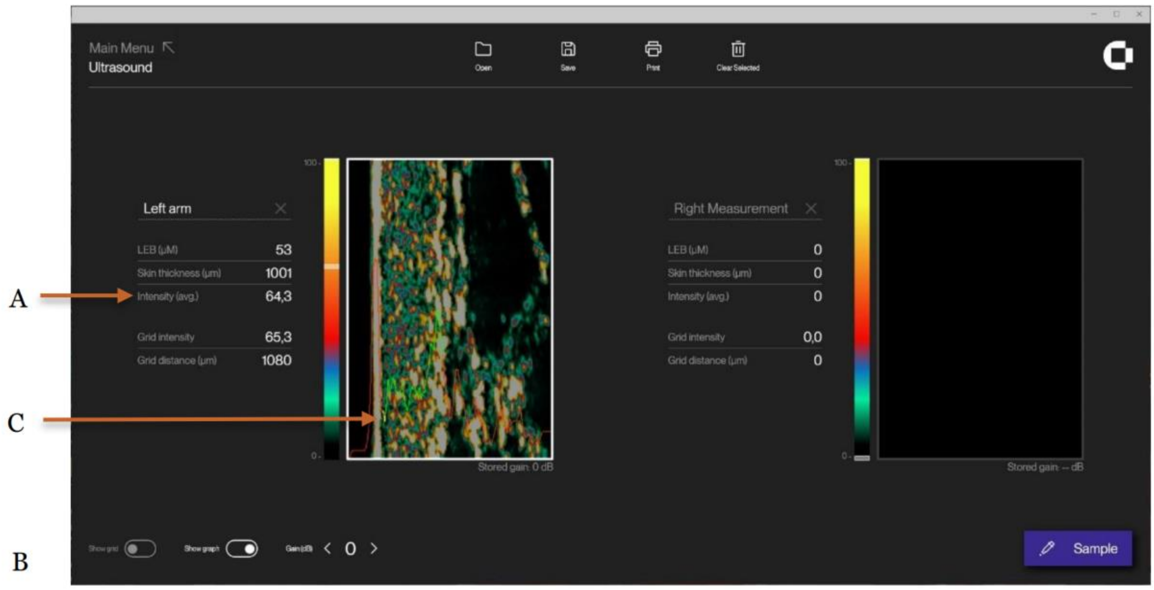


The Standard Probe ultrasound image – film plus epidermis to the left followed by dermis and subcutis. The dermis is characterized by varying intensities (different colors), subcutis by low-intensity areas due to a homogenous composition.

6.4.7. Measurements

The Ultrasound Standard 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 film/epidermal reflection.

The *yellow* part of the Super A-scan indicates the Low Echogenic Band (LEB) of the dermis (C, 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 S*kin 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.

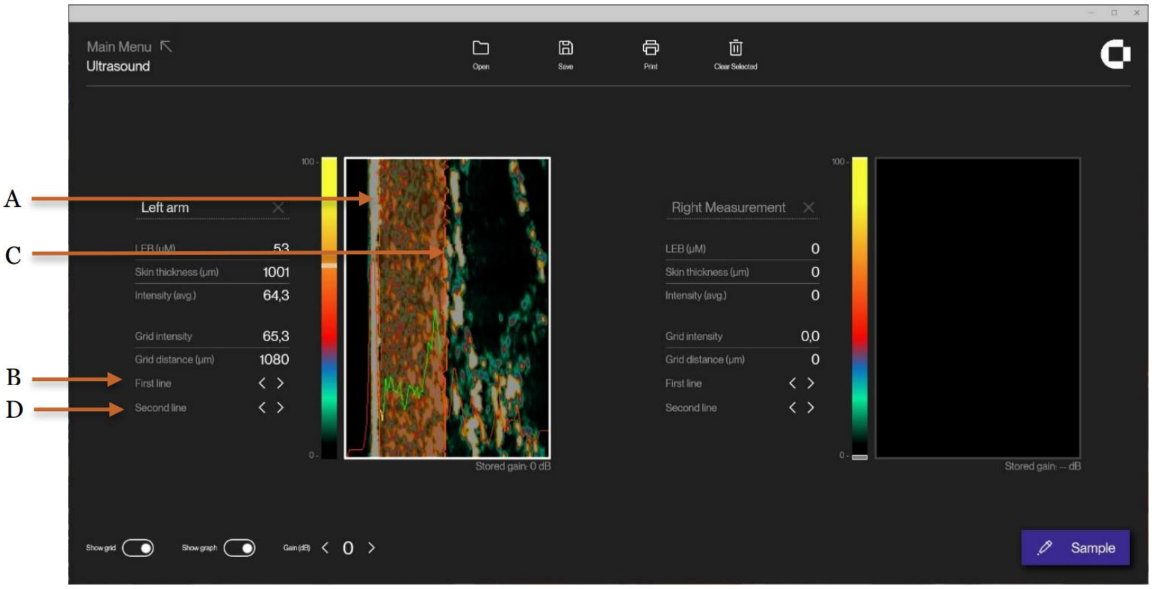
If the line is red all over, then the dermis and/or Low Echogenic Band is not clearly detected by the software and the automatic calculations are not performed or may be incorrect.
This may be a result of incorrect gain setting. If so, then change the gain 1-2 steps and record a new image. Please refer to 6.6 – “The ultrasound image”.
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). The 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 clicking the **Grid** button.

The arrows used when moving the grid are only visible when the grid in 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

Except for the physical dimensions and choice of transducer, the basic design of the *Subcutaneous Probe* is similar to the design of the *Standard Probe* and, accordingly, the preparations are the same – please refer to section 6.4. “The Ultrasound Standard probe”.

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.

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

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

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

Snap off excess film with a quick downward movement.

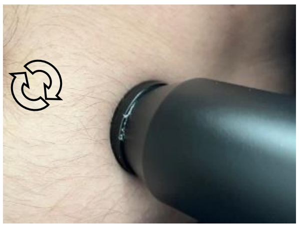
Final result. Check that the black fixation ring is correctly positioned.

The film shall present a smooth surface without wrinkles.

The ultrasound 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 and disappear by gently tapping the probe. Otherwise, please replace the film after topping up with water.

6.5.3. Using the Subcutaneous Ultrasound probe

Before each ultrasound scan apply ultrasound gel to the film. 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

Please refer to cleaning of the *Standard Probe* section 6.4.4.

6.5.5. The Subcutaneous Ultrasound 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 light green top bar (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 **Start** button (B) will record a new ultrasound image.

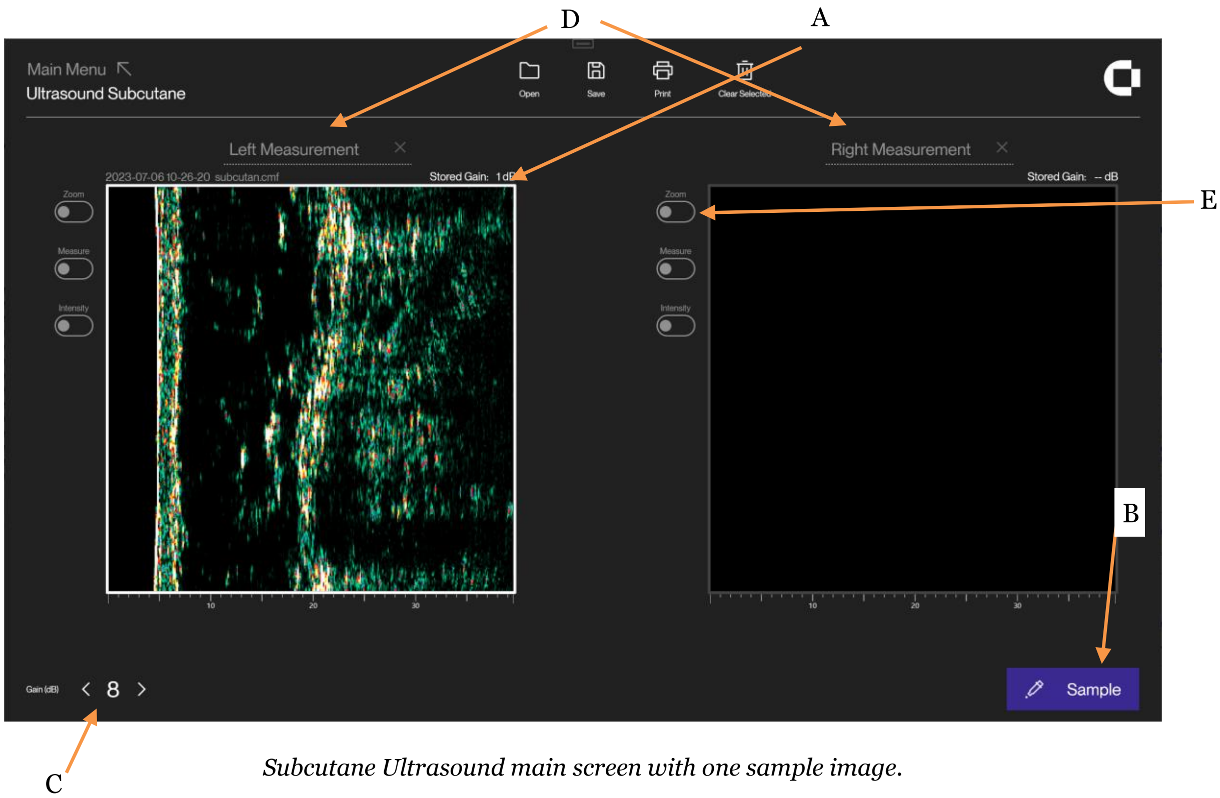
The **Gain** (ultrasound sensitivity), used when recording the ultrasound image, may be adjusted using the left/right arrows (C).
Note: The new gain applies to the next image being recorded and will not change already recorded and saved images. The gain used at the time of recording an image is displayed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

Touch **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.

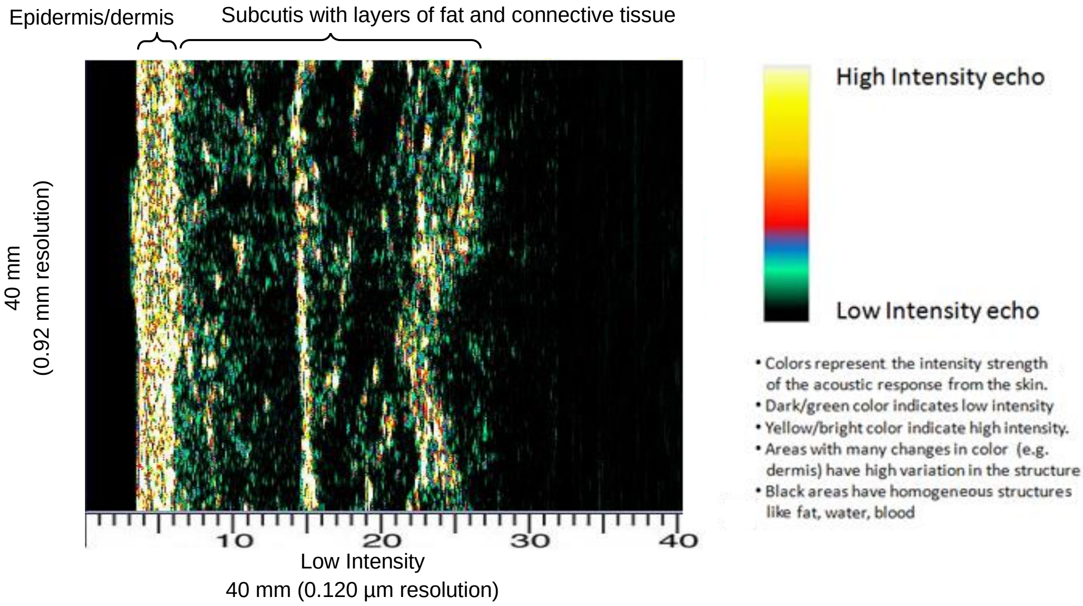


Subcutane Ultrasound main screen with one sample image.

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

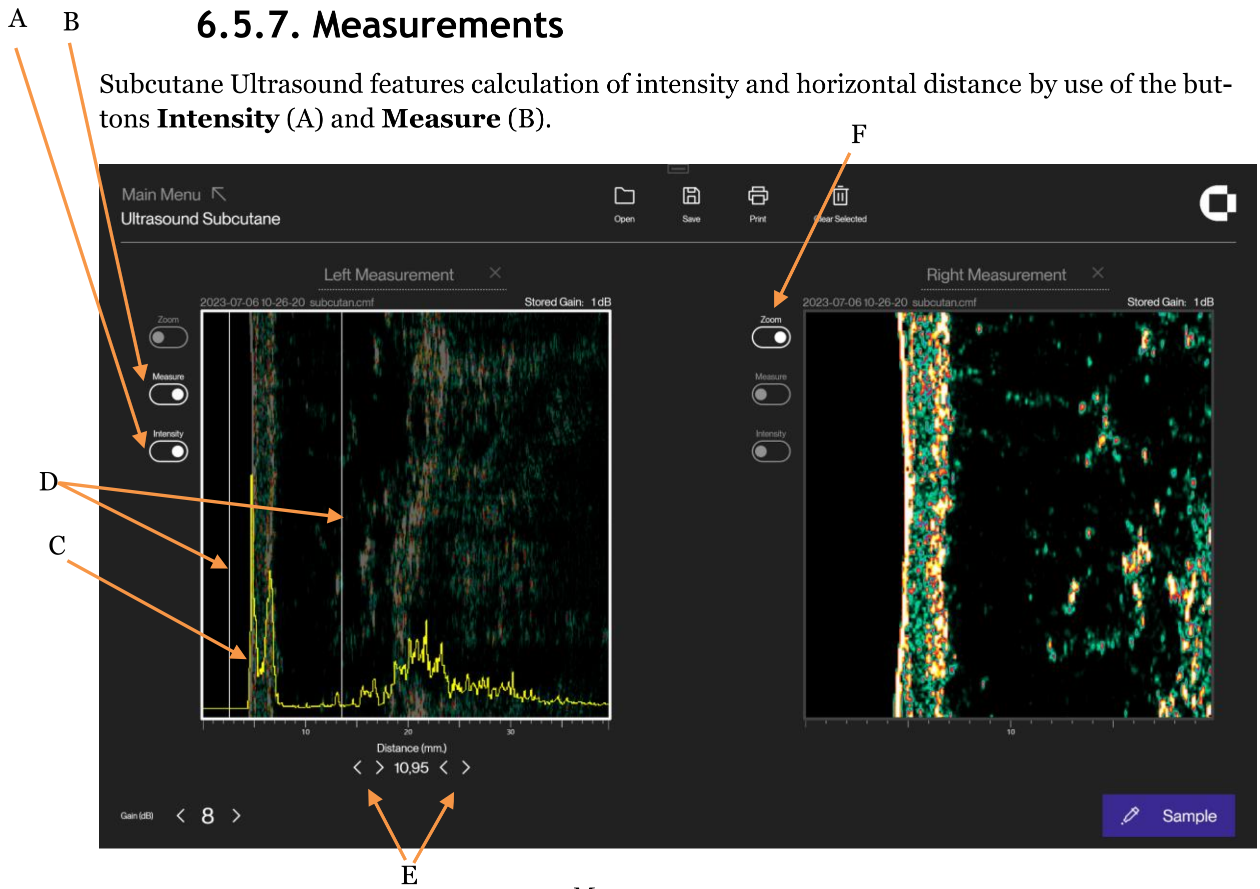
By clicking **Start**, an ultrasound image is recorded and visualized in the active window. In this image, the colors represent the intensity (strength) of the reflected ultrasound signal. Dark color represents low intensity and white (yellowish) represents a high intensity. The epidermis/dermis is highly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



The Subcutane 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

Subcutane 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 25 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 being seen on the image should be a result of tissue properties, not a result of artifacts.

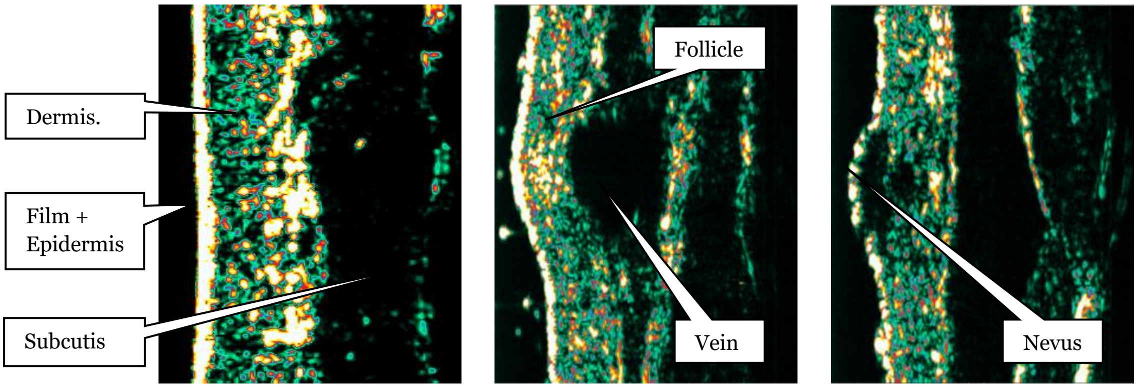
The properties and composition of the human skin and subcutaneous tissues vary throughout the body and between individuals as a result of many factors (e.g. genetics, age, sex, disease).

This section applies to the use and understanding of all DermaLab® Single 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.

6.6.1. Understanding the ultrasound image

As the focused ultrasound beam propagates through the tissue, it travels through medias 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 generates 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.



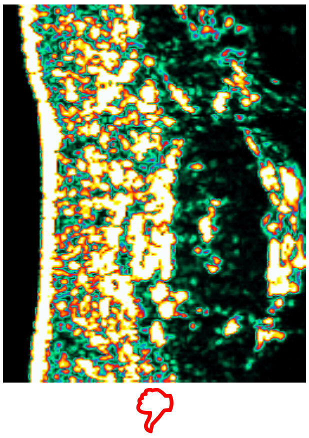
Standard probe ultrasound skin images.

6.6.2. How to record an ultrasound image

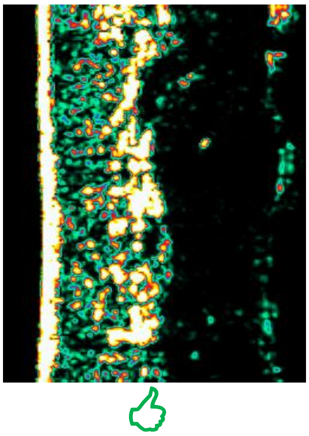
Setting the correct Gain

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 the frequency, high frequency ultrasound is subject to a high degree of attenuation, which limits the penetration drastically.

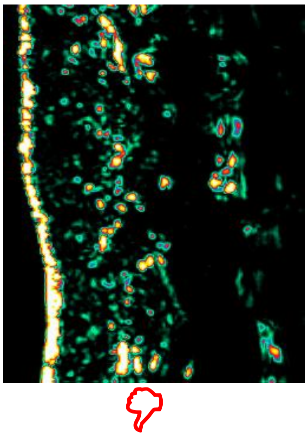
Within certain limits, such attenuation can be compensated for by increasing the amplification (i.e. gain). In the DermaLab® Single, this feature is referred to as *gain* control, which allows for individual setting of the gain level.



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.

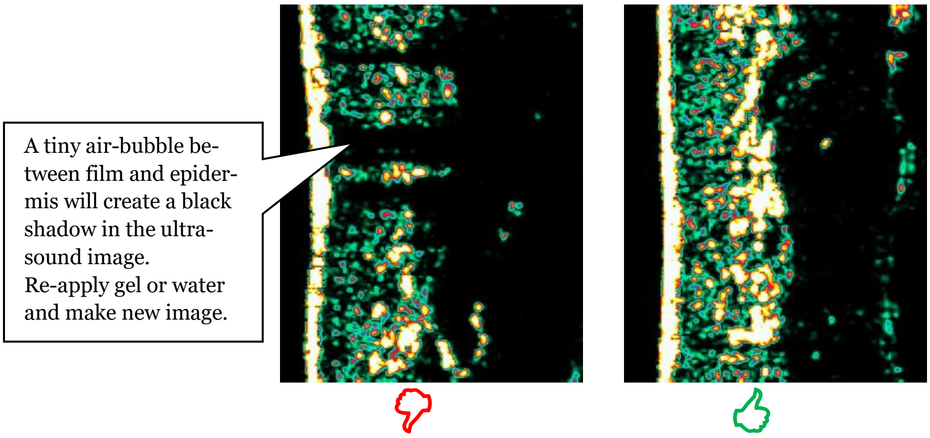


Low gain image, loss of details. Press Gain "arrow up" to increase intensity.

A typical gain setting for scanning on the arm is 0 (zero) and for scanning on the temple 4. Scanning on the cheek typically requires a gain of 6 to obtain a good image.

Avoiding Artifacts

The below figure to the left shows an ultrasound image where the 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 outside of the film on the probe is clean and has a thin layer of well distributed gel or a thin layer of water before making the scan.

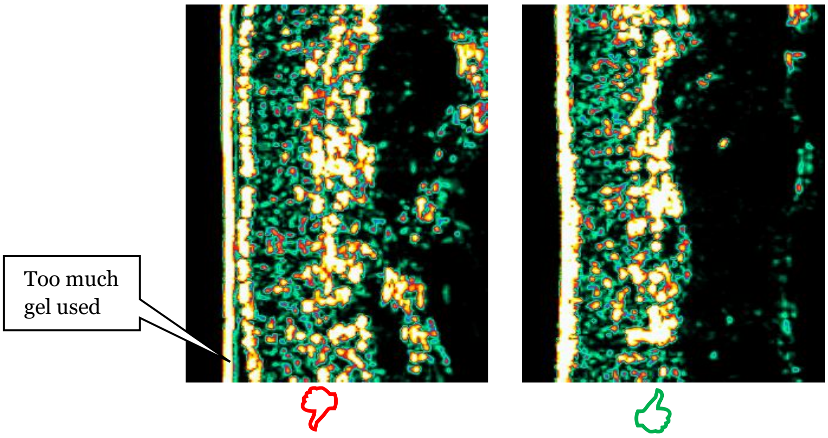


It is important to ensure a good acoustic contact between the tip of the probe and the skin.

Artifacts in the form of shadows may also be a result of collected air bubbles inside the water chamber. Such bubbles adhering to the film may often be released by gently tapping the probe. If unsuccessful, the film may be replaced after topping up with water.

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 plastic film at the tip 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 avoiding air bubbles between the tip of the probe and the skin.

6.7. Maintenance

The daily maintenance of DermaLab® ultrasound scanning probes 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)

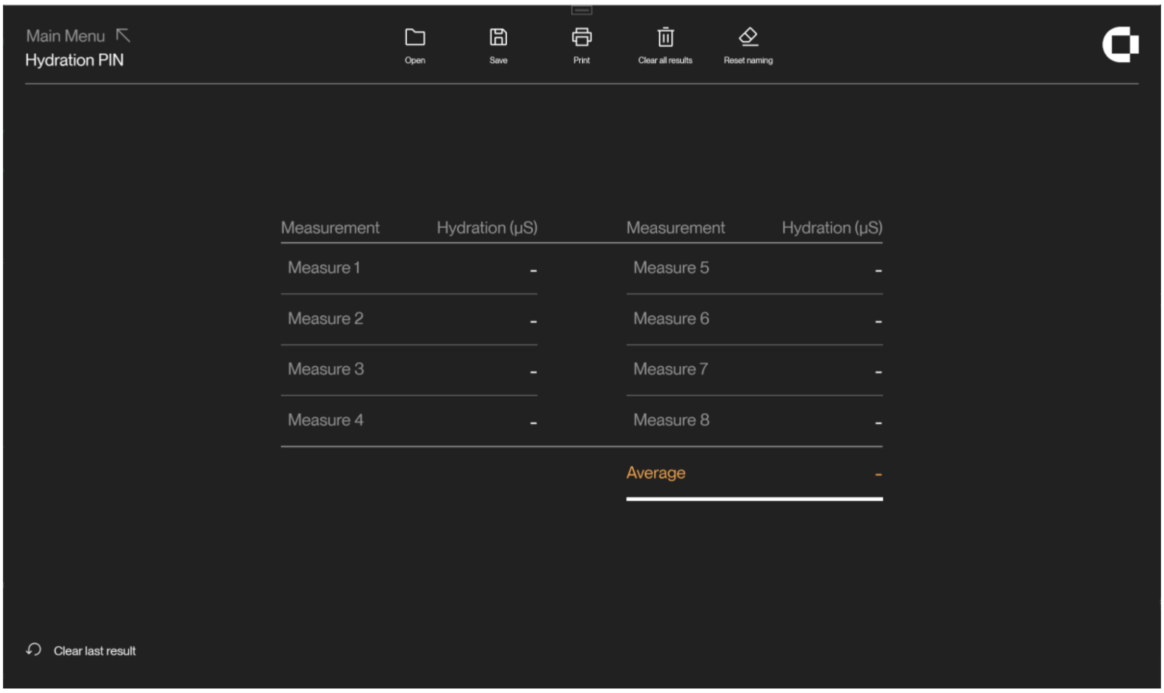
7.1. Principle

The DermaLab® Single 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 to choose the correct probe for the application.

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

7.2.1. 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.

7.2.2. 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.

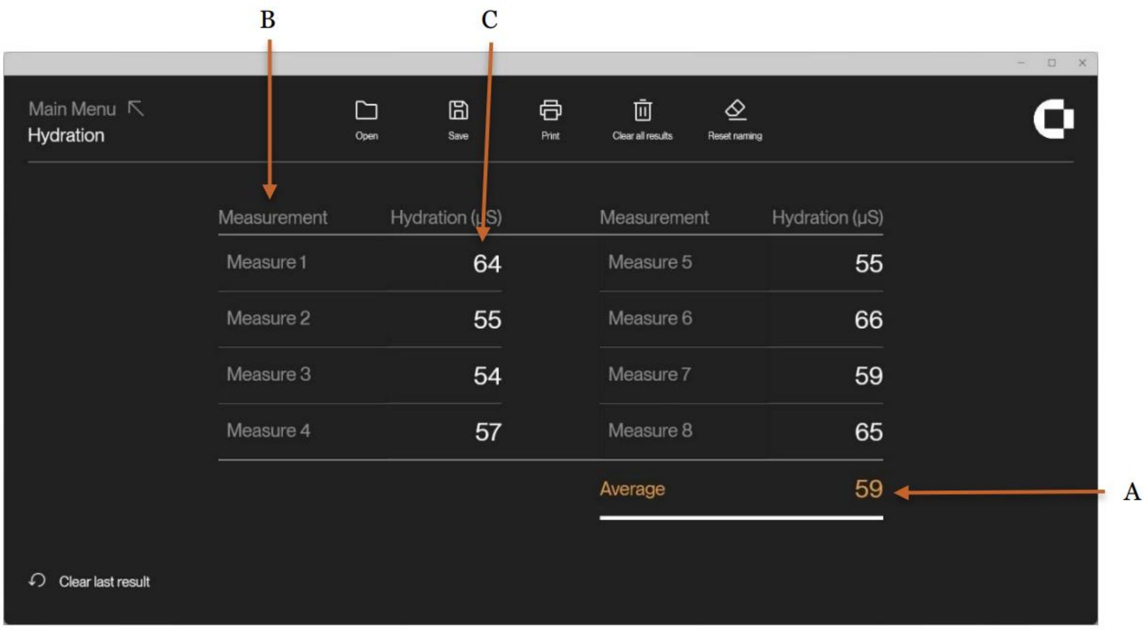
Spring loaded action initiates the measurement when the probe is pressed gently against the skin.

7.3. The 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 the average of 3 to 8 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

7.4. Maintenance

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.

Except for keeping the probes clean there is no preventive maintenance associated with the use of the hydration probes.

To disinfect the Hydration Pin probe, a cloth can be wettened using isopropyl alcohol, onto which the probe is placed. Ensure all pins are wiped. The steel casing can be wiped down using any type of alcohol disinfectant.

The Hydration Flat Probe can be disinfected by carefully wiping the tip, using isopropyl alcohol. The steel casing can be wiped down using any type of alcohol disinfectant.

8. Elasticity

8.1. Principle

The elasticity measurement of the DermaLab® Single 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® Single 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:

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

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) ViscoElasticity.
Dividing the elasticity modulus by the retraction time provides a parameter (ViscoElasticity, 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).

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

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.

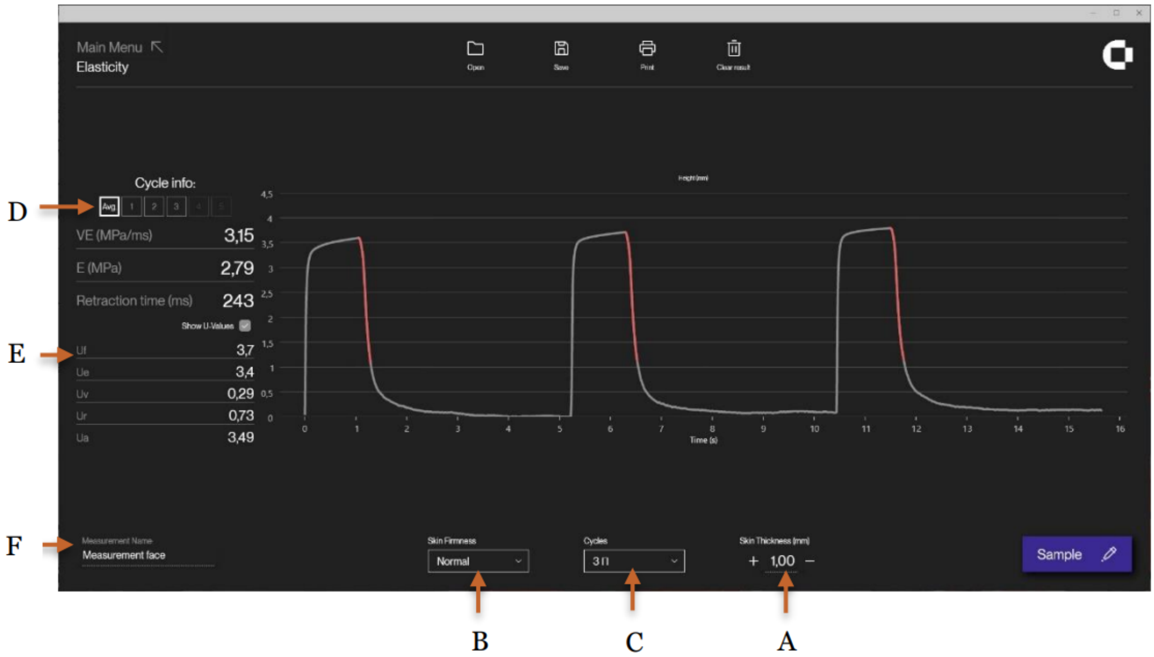
Exchanging the adhesive ring between measurements is highly recommended to obtain optimal adhesion and complete air tightness.

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 to 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).

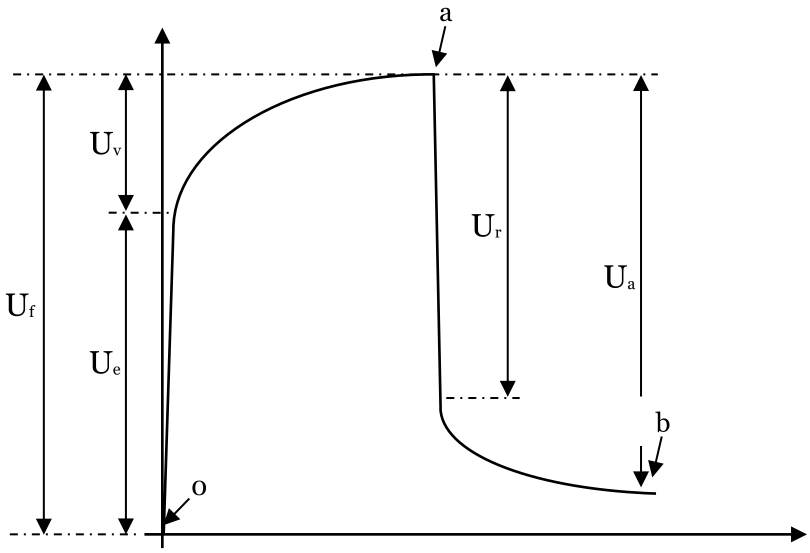
By selecting 1 cycle the skin will be exercised only once, and there will be no accumulated effect from repeated skin exercise. By selecting 3 or 5 cycles the skin will be repeatedly exercised, which will introduce an accumulated effect. This can be seen as slight elevation increase for each cycle as 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 ViscoElasticity is calculated for each cycle.

When all measurement cycles (1, 3, or 5 cycles) 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.

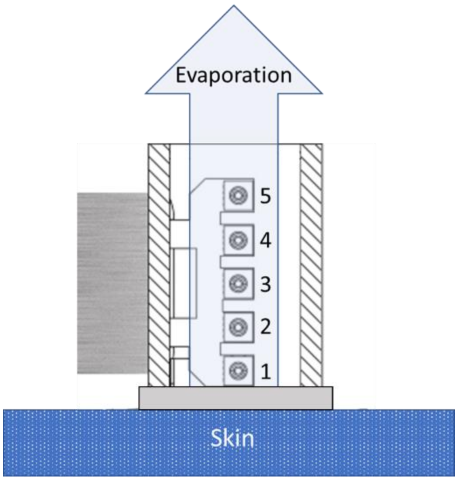
CAUTION: Only use a dry cloth to clean the interior surfaces of the measurement chamber.

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).

Ensure, that the probe is completely dry before applying the adhesive ring. The adhesive ring must be changed with every use.

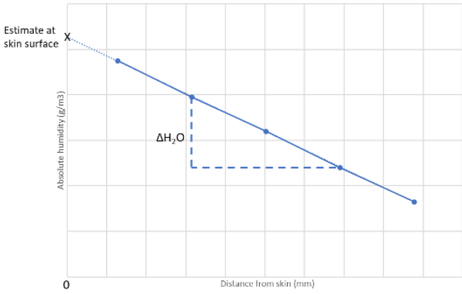
9. Trans Epidermal Water Loss (TEWL)

9.1. Principle



Water loss as measured by the Dermalab® Single 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/m²/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/m³. 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 transepidermal water loss (TEWL) measurement

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

9.2. The TEWL X Probe

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

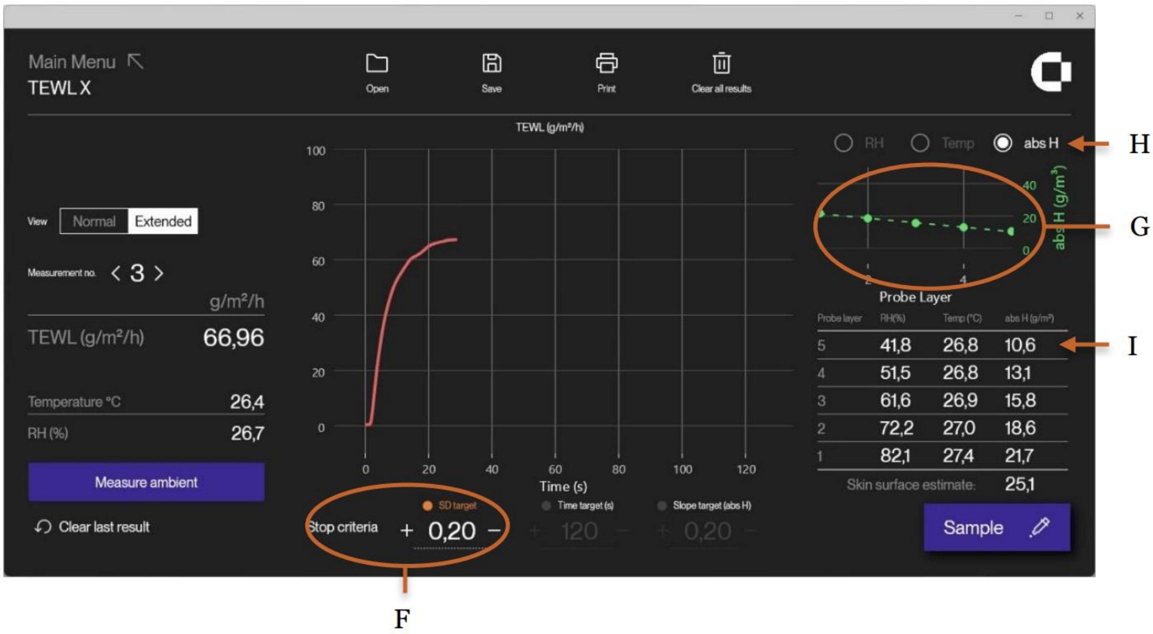
Place the probe on the skin as indicated by the arrow on the front of the probe. The arrow indicates which side of the measuring chamber shall point towards the skin. Do not press the probe too hard against the skin - apply light to moderate pressure.

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.

9.3. 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.

9.4. Maintenance

There is no maintenance associated with the use of the TEWL probe besides cleaning. The TEWL probe is recommended to be used with the corresponding disposable TEWL-probe protector, which eliminates the direct contact of the probe and skin, thereby minimizing potential cross-contamination.

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. 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 into 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.

9.5. 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.

10. Files and Formats of Saved Data

When pressing the **Save** button in the measurement screens the DermaLab® Single 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 pressing **Save** until all measurements have been done.

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

When saving measurement data, the DermaLab® always saves up to 14 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 the DermaLab, when the user presses **Open** to load the data in to the DermaLab 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 performed TEWL measurement (1-2 pr. Second)

- **Filename_SubC_L.crf and filename_SubC_R.crf**: These .crf files are the Cortex Raw Files and contain the raw data for the left and right Ultrasound Subcutane images.

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_SubC_L. bmp and filename_SubC_R. bmp**: These .bmp files contain the left and right Ultrasound Subcutane images.

- **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.*

11. Data extractor

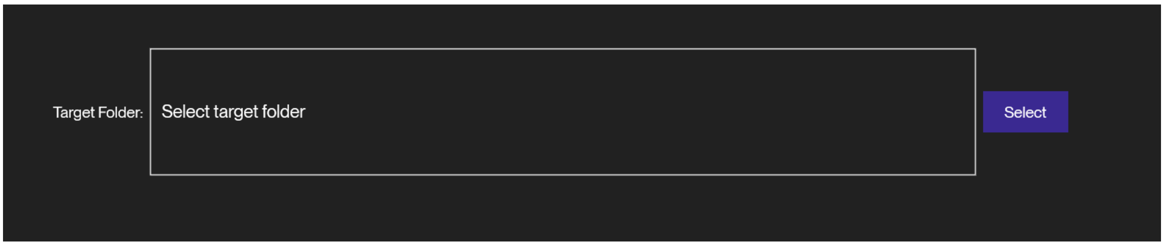
DermaLab SkinLab version 2.5.0.0 and onwards provides built-in capabilities for extracting data from several cortex measurement files and combining the results into a .csv file.

The Data extractor can be accessed on the main menu through the respective button in the top row of the screen.

The data extractor page consists of 4 parts:

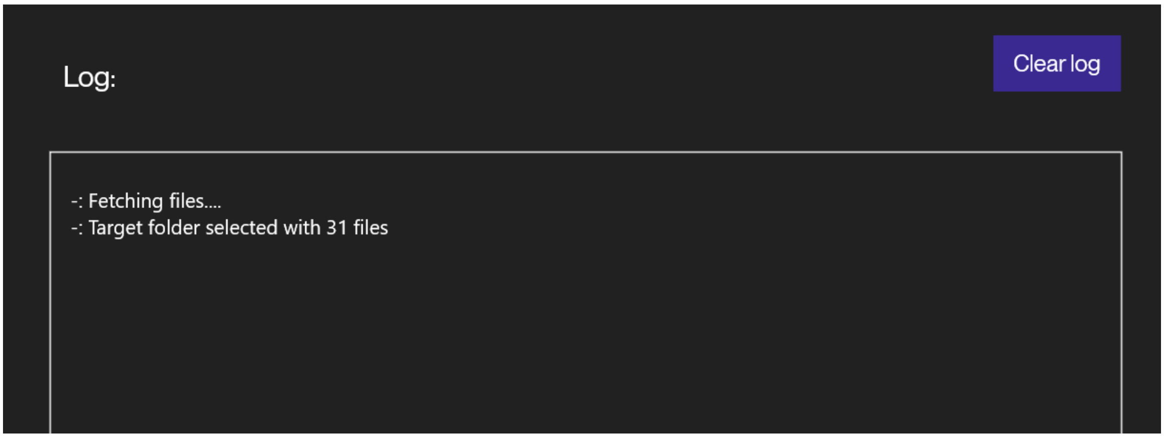
Folder selection

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.



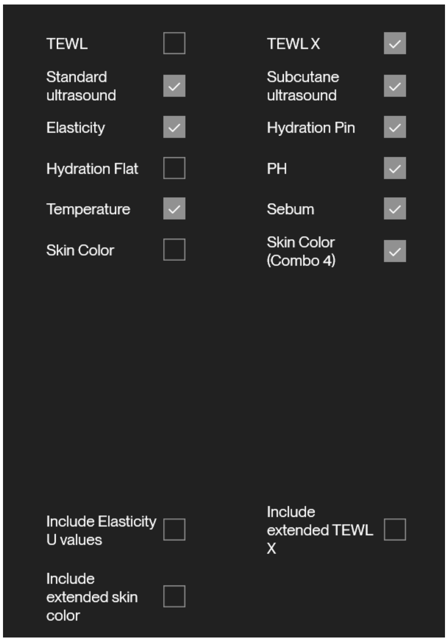
Log

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”.



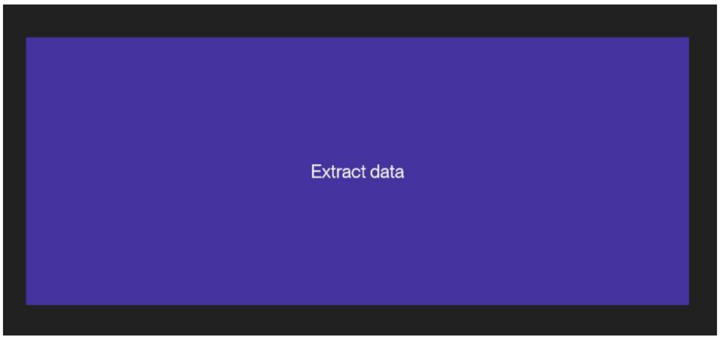
Data Filtering

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.

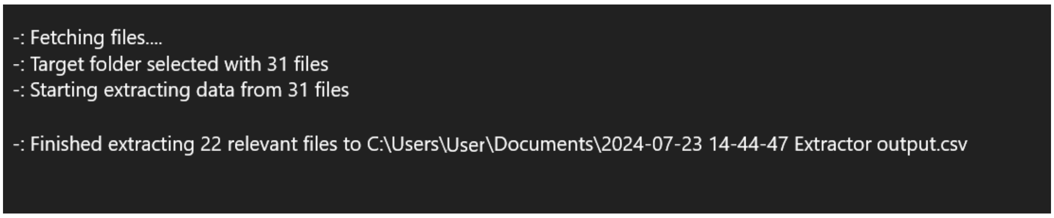


The log will be updated to include any relevant information regarding the process.

Process times may vary depending on the hardware running 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.



11.1. 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:

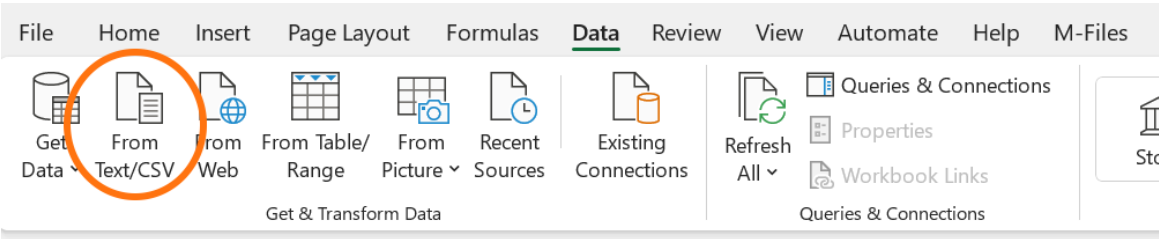
- Path: the location of the file
- File: the name of the file
- Time: the document date saved within the file
- Software version: the software version (if available) contained within the file.

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	E
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	TewlX.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 elastictet 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	

11.2. 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.

12. 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.

12.1. 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.

13. Service

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

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.

> ***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.*

14. Safety

The external power supply for the DermaLab® Single 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.

15. Warranty

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

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

16. Technical specifications

- 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: 195 x 123 x 90 mm
- Power requirement: External 12 V DC power supply (included).
- Integrated probe holder.

16.1. Ultra-High Frequency Ultrasound probe

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

16.2. TEWL X probe

The transepidermal 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 $g/m^2/h$ and is an important parameter for assessing skin barrier function.

- Range: 0–250 $g/m^2/h$
- Resolution: 0.1 $g/m^2/h$
- 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.

16.3. 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 entire measurement range.

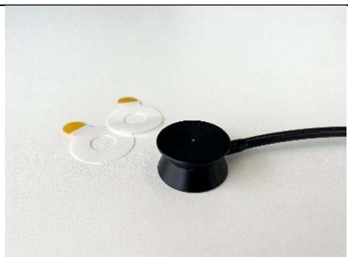
- Optional calibration checker available.
- Measurement uncertainty: ±5%

16.4. 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.

17. DermaLab Single parts

Name	Picture	Item number
Dermalab Single		C02228.05
Elasticity probe for DermaLab® Single		C05600.xx
Elasticity double adhesive patch		V02001.01
Hydration flat probe for DermaLab® Single		C03600.xx
Moisture flat calibrator		C03006.01
Hydration pin probe for DermaLab® Single		C06600.xx
Hydration pin calibrator		C06006.02

Stand-off for hydration pin		M21010.01
TEWL X probe		C04600.0x
TEWL probe protectors		M20010.01
Ultrasound standard probe		C08900.xx
Ultrasound subcutaneous probe		C01660.xx
Film for ultrasound probe		V01005.01
Outer ring for foil		M09007.01

Power supply (Adapter Tech., ATM036T-P120)		C44703.01

18. FAQ

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

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.

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

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

Q: *When and how are the environmental measurements done?*
A: - The environmental T and RH is measured by one of the sensor pairs in the probe upon entering the 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 more easily, gel stays on the skin but is more likely to collect air bubbles.

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 Single measures skin conductance. What is the difference to skin capacitance?*
A: - Skin conductance is the skins 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 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 Single features high resolution ultrasound to accurately measure skin thickness.

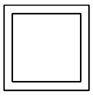
Q: *Why change between soft/normal/firm skin?*
A: - Depending on the body location and skin condition the mechanical properties of the skin varies. This setting allows for adapting the device to the body site and actual skin condition in order to fully utilize the dynamic range of the device, thus obtaining more precise and sensitive readings (see 8.3).

Appendix A – List of symbols

The following symbols are used:

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

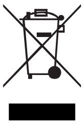
ELECTRICAL SHOCK HAZARD. Indicates that an electrical shock could or might occur.



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.