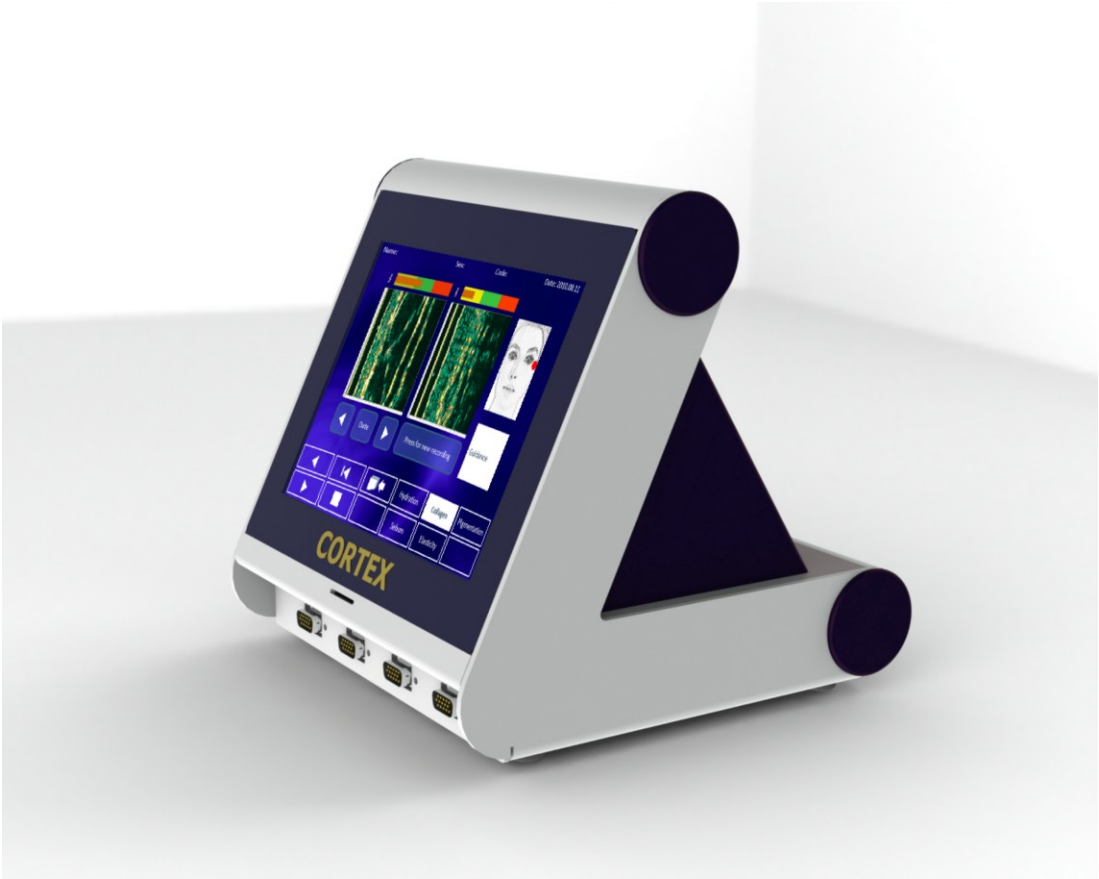
DermaLab® Series
Clinique Combo

Instruction Manual



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DERMALAB® SERIES
CLINIQUE COMBO

INSTRUCTION MANUAL

Contents

1. Warnings

- Read this entire manual before using or showing to others how to use the DermaLab® Combo.

- Do not use the DermaLab® Combo if the device shows visible signs of damage or there is other reason to believe that the device is not functioning correctly.

- 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® Combo is a fully self-contained device. However, if networked to other computer systems or exchanging 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.

- Operation of the device requires administrator rights and, consequently, the operator may be able to change the settings of the operating system. Do not alter basic settings of the operating system (e.g. power options, user accounts).
  Changes to these settings cannot lead to risk of personal injury, but may lead to malfunction or lack of performance, which may or may not recognized by the operator.

- The DermaLab® Combo as a system consists of the main-unit, and handheld probes and a medical grade power supply to provide power to the main-unit, and it is designed to meet international safety requirements.
  If external peripheral devices are connected to the main-unit it shall be observed, that such devices meet and are connected to mains in accordance with current legal safety requirements for the particular application of the device.

2. Installation and power-on

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

2.1. Power supply

The power supply must be connected to a wall outlet providing a protective ground terminal in order to ensure electrical safety. It may be connected to input voltages from 100 - 240 VAC, 50/60 Hz. Do never use any other power supply than supplied by Cortex Technology.

2.2. Main unit

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

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

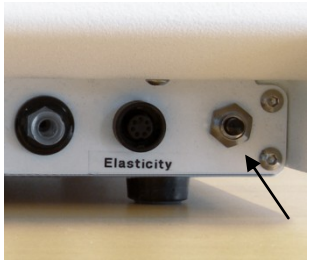
2.3. Connection of probes

The TEWL, Skin Color, Ultrasound, Hydration and Elasticity probes are all connected at the front of the DermaLab Combo® using various types of connectors. Probes using USB connectors (e.g. the Videoscope) are connected to one of the USB connectors at the rear side of the main-unit.

The connectors for the probes are all of different types so it is not possible to connect the probes wrongly to the main-unit. But please note: When connecting the black connectors to the front panel of the main unit, the turn able lock on the connector at the probes has to be turned as far as possible to the left before attaching the connector to the socket of the main-unit. When the connector has been inserted in the socket the lock shall be turned to the right to lock the connector in place.

2.4. Power On

The DermaLab Combo is powered on by pressing the power-on button on the front of the DermaLab Combo located right of the probe connectors under the display.



Power-on button

3. Intended use and general description

3.1. Intended use

The DermaLab® Combo is a measurement instrument mainly for laboratory use. The DermaLab® Combo is not intended for medical use and serves no diagnostic purpose.

3.2. General description

The DermaLab® Combo is based upon a built-in Windows XP embedded PC with a touch screen display.

The application software is implemented in LabView (National Instruments) and is pre-installed on the DermaLab® Combo unit, which is using Windows XP Embedded as operating system.

4. Main screen

Turn on the DermaLab Combo by pressing the small button on the on the front of the DermaLab Combo just right of the probe connectors. When the DermaLab® Combo is turned on the main screen will be shown. The main screen has the following soft buttons, which can be pressed by touching the button with the tip of a finger or using a stylus.

Main screen

The **Ultrasound**, **TEWL, Hydration**, **Elasticity**, **Sebum**, **Skin Color** and **Video scope** buttons are used for entering the specific measurement screens. See the following chapters for further details on each measurement screen.

With the **Open file** button it is possible retrieve measurements previously captured for a client. The specific measurement results will be available in all the measurement screens, and it will be possible to compare the captured measurements to new measurements.

The **Clear All** button is used to clear all measurement data in the measurement screens. When starting a new session of measurements with a client, pressing the **Clear All** button will make sure no old measurements from a previous client are available in the measurement screens of the DermaLab® Combo. It is recommended to press this button every time a new measurement session is started with a client.

Pressing the button **Client info** opens a screen where info about the client and comments about the measurement can be stored. This info is stored with the measurement data and will be available later on when the measurement date are retrieved using the **Open File** button.

The **Summary** button can be used to see an overview of all measurements made. As well it is possible to print a short report on a printer.

The **Quit** button is used to shut down the DermaLab® Combo application. After shut down the Windows XP Embedded desktop will appear and it will be possible to launch other Windows applications - for example making backup of measurement data to a USB stick, install a printer driver etc.

Shut down Windows XP Embedded to turn off the power for the DermaLab® Combo. This is done by clicking at the left-bottom of the display calling up the hidden Windows START menu.

5. Introduction to the DermaLab® Combo Screens

All the individual measurement screens in the DermaLab® Combo are using a number of common control buttons which are located at the lower left side of the screens.

The buttons have the following functions:

Delete last measurement

Delete all measurements on the current screen

Save measurement data to a file

Exit the measurement screen

Show pop-up touch screen keyboard for entering text into text fields

Hint: In case an external USB keyboard is connected to one of the USB-ports of the DermaLab the pop-up of the on-screen keyboard can be permanently disabled by renaming the application file: c:\program files\clik-n-type\click-n-type.exe to click-n-type-no-pop-up.exe.

Note: A “right mouse click” on the touch screen can be made by pressing the touch screen for one second or longer at the same position. The use of right clicks can be an advantage when operating Windows XP because it will often open a small menu with a selection of options. This may be useful for example when backing up measurement files to a USB memory stick.

5.1. Loading and saving measurement data

The DermaLab® Combo can save all measurements for a client to a single data-file. This file can then later be recalled by using **Open File** in the main screen. In this way it is possible to compare new and previous measurements and see the progress of treatments. Previous measurement are always shown in the left side of the measurement screens. New measurements are always show to the right in the screens.

Measurement data can be saved in all the measurement screens and as well in the summary screen. When measurement data are saved to a data-file then please note all measurements and the client info are saved into one file. I.e. it is not necessary to save to the data-file between measurements. Just remember to save the measurement when having finished all measurements.

6. High resolution Ultrasound Skin-Imaging

6.1. Principle

Ultrasound skin imaging is based on measuring the acoustic response from the skin, when an acoustic pulse is sent into the skin. The energy of the acoustic pulse is very low and will not affect the skin in any way. When the transmitted acoustic pulse hits the different borders in the structures of the skin a part of the transmitted pulse will be reflected and the signal will travel back and be picked up by the ultrasound probe. The cross-sectional image as visualized on the screen represents an intensity (amplitude) analysis of these returned signals.

The intensity of the received signal refers to a color scale, where dark colors represent areas of the skin with low reflection (i.e. none or small changes in density between the structures in the skin) and bright colors represent areas with strong reflections (i.e. significant changes in density between structures).

6.2. The ultrasound probe

The DermaLab® Combo ultrasound probe is scanning in a circle and in a single plane into the skin, the so-called B-mode.

6.2.1 Preparing the probe

Water has been selected as the ultrasound transmission medium to provide minimal attenuation of the acoustical signal from the probe to the skin and back. As a result, the scanning heads have an internal water chamber ("water path"), and for the operator's convenience and the comfort of the client the ultrasound probe has an integrated disposable water barrier to prevent spillage.

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

The water chamber inside the scanning head 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.

6.2.2. Mounting the water barrier

The ultrasound probe is using a closed water chamber, which means the water chamber in the probe has to be filled with water and a water barrier film has to be used as a seal making sure the water will not flow out of the probe when used.

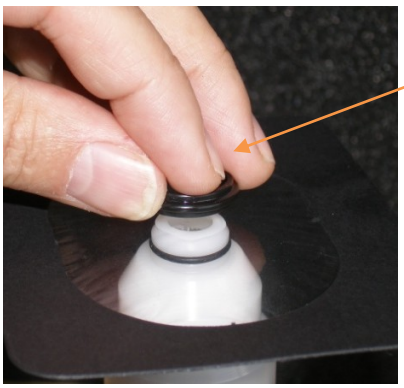
The water barrier film is fixated and kept in place by a black ring which is attached to the tip of the probe.

Press fit black ring holds the water barrier film on the tip of probe

Tip of probe

Inject water into the chamber.

Shake the probe to get all air bubbles out and top-up again with water



Place a film over the probe tip and hold it firm to the probe.

Press the black ring down over the film and onto the tip of the probe

Wrap the film down and peel off excess film

Mounting the water barrier is done in 6 easy steps.

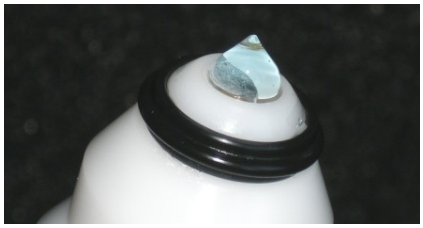
1) Make sure the black ring holding the water barrier film is removed from the probe tip.
2) Hold the probe up-right and inject water into the chamber. Fill the chamber, then cover the opening with the thumb and shake the probe to release any air bubbles trapped in the chamber.
3) Top up with water so the probe is completely full.

4) Place the water barrier film gently on the probe tip. No air bubbles must be visible.
5) Press the black ring down over the film.
6) Peel off excess film around the probe

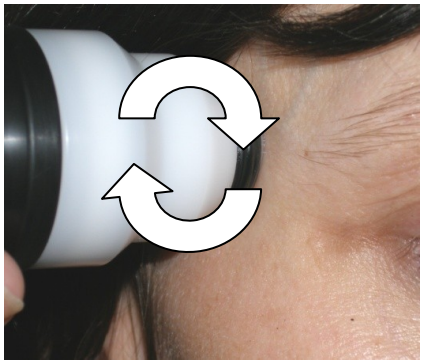
The ultrasound probe is now ready for use. In the event that air bubbles become visible under the film, it is advisable to gently remove the film and top up with water before mounting a new film. A tiny bubble with an area of less than approx. 1 mm^2 will not disturb the recording and may be tolerated.

6.2.3. Using the probe

Before each ultrasound scan apply a little drop of gel to the film. See the figure below:



Place the probe on the skin area to be scanned and spread the gel evenly to the thinnest possible layer with “massaging” movements of the probe (see figure).



Distribute the gel evenly to a thin layer.

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 then couple the ultrasound from the probe to the skin.

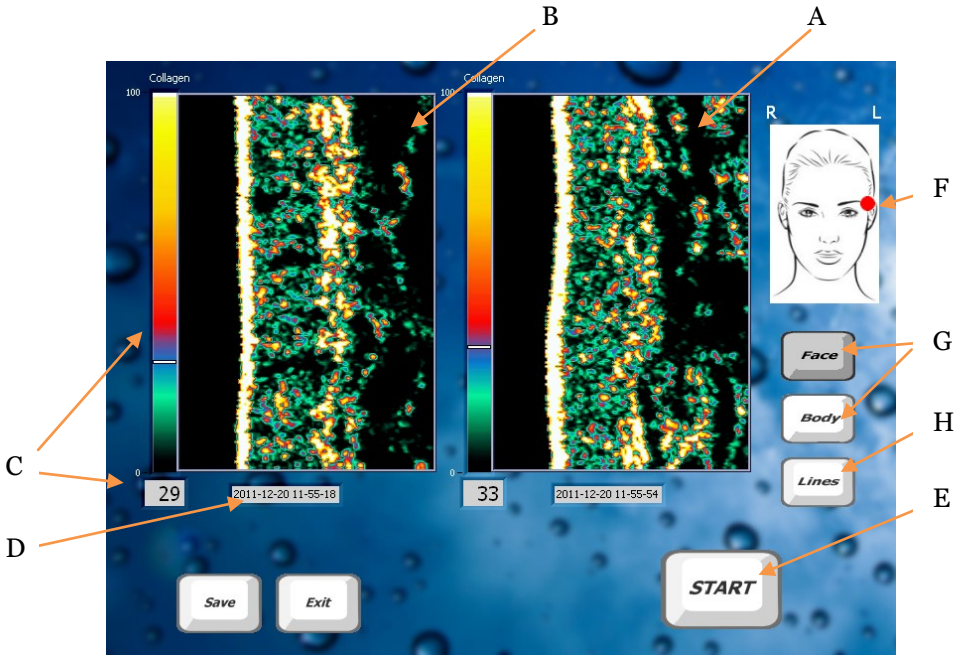
6.2.4. Cleaning

After scanning, or at least after eight hours of operation, the water barrier film should 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.

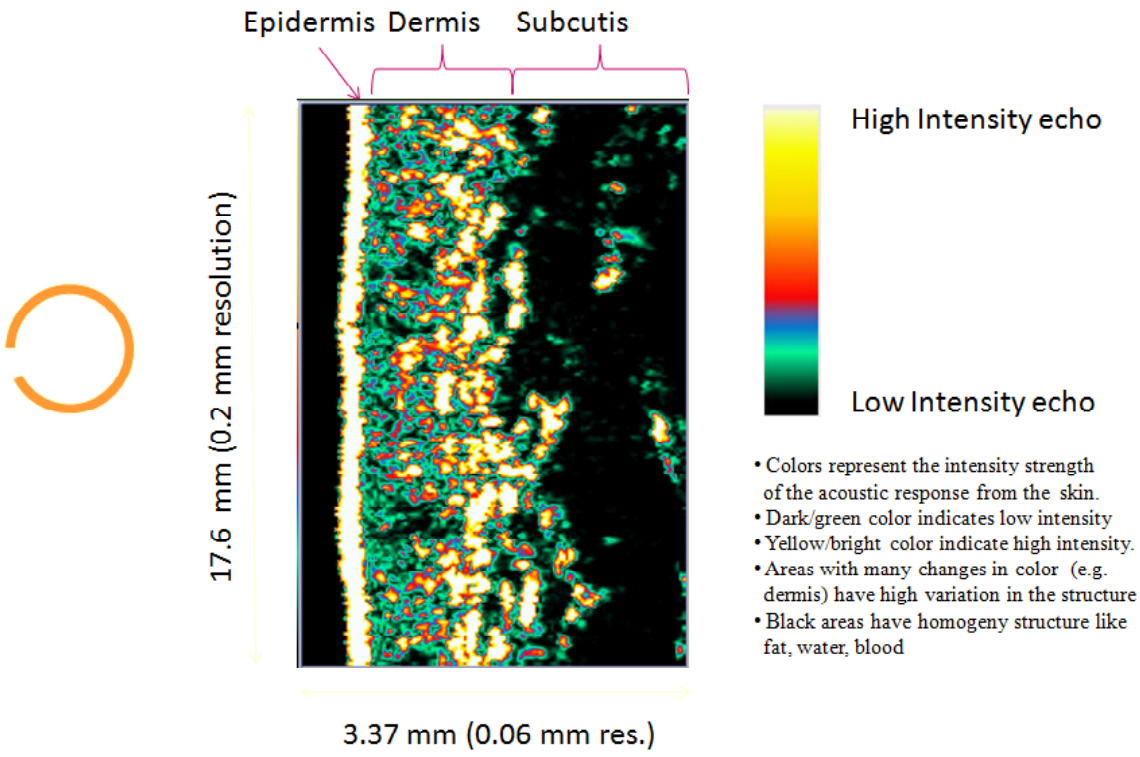
The front piece parts can be cleaned in solutions of mild detergents suitable for plastics (Scan-Diversey “DIVERSOL BX” or similar) or wiped off with alcohol for disinfection. Put the black ring back onto the scanning head without film for storage. The water chamber inside the scanning head can be cleaned by gently flushing with the same, mild solutions intended for use with rubber and plastics.

6.3. The Ultrasound skin imaging screen



Ultrasound screen

In the ultrasound image the colors represent the intensity (strength) of the reflected ultrasound signal. Dark color represents low intensity and white (yellowish) represents a high intensity. Typically the epidermis gives a high intensity (white/yellowish) and the dermis a mix of many colors. The subcutaneous fat and muscle will return a low intensity signal (dark green and black). See figure below:



The ultrasound image - 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.

A is the location for the active ultrasound image which is refreshed every time an ultrasound recording is made by pressing the **Start** button (**E**).

B is a previously stored ultrasound image loaded by **Open File** in the main screen. (If no file is opened then this image will be empty).

C holds the Collagen score, which is the average intensity of the area inside the red grid visible right after the ultrasound image is made - and when pressing the Lines button (**H**). The Collagen score is also indicated on the vertical bar to the left of the ultrasound image.

D is the date/time stamp for the ultrasound image.

The red spot (**F**) on the pictogram represents the suggested scan position.

The FACE/BODY buttons (**G**) are used to choose between two sensitivity levels for the ultrasound receiver. The skin in the face is often thicker and more difficult to penetrate for the ultrasound, so when measuring in the face press the FACE button (it becomes dimmed) to increase the sensitivity of the ultrasound receiver before pressing the Start button (**E**). Press the Body button when measuring any other body site – like arms and neck.

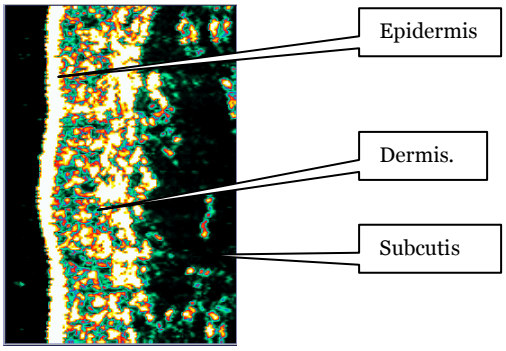
6.4. The good ultrasound image

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).

In the following examples will be shown to establish a common understanding of what to expect as well as commonly seen artifacts and how to avoid them.

6.4.1. Understanding the ultrasound image



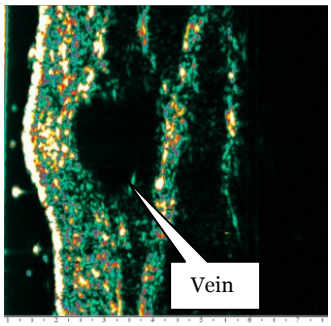
Normal ultrasound skin image

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 received by the device, and part of the ultrasound beam to be transmitted further into the tissue.

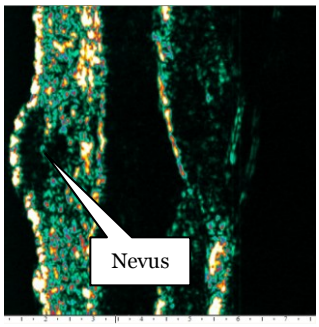
Tissue, which is homogeneous in structure, provides no or little density change and, accordingly, it will generate no or few and weak reflections – it appears black. As an example blood, fat and muscle generates only few and weak reflections. The same is true for tumor mass in general, whereas normal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

In the above figure the individual structures of a normal forearm image are identified.

The figures show examples of less reflective material – vein and nevus.



Normal skin over vein



Intradermal nevus

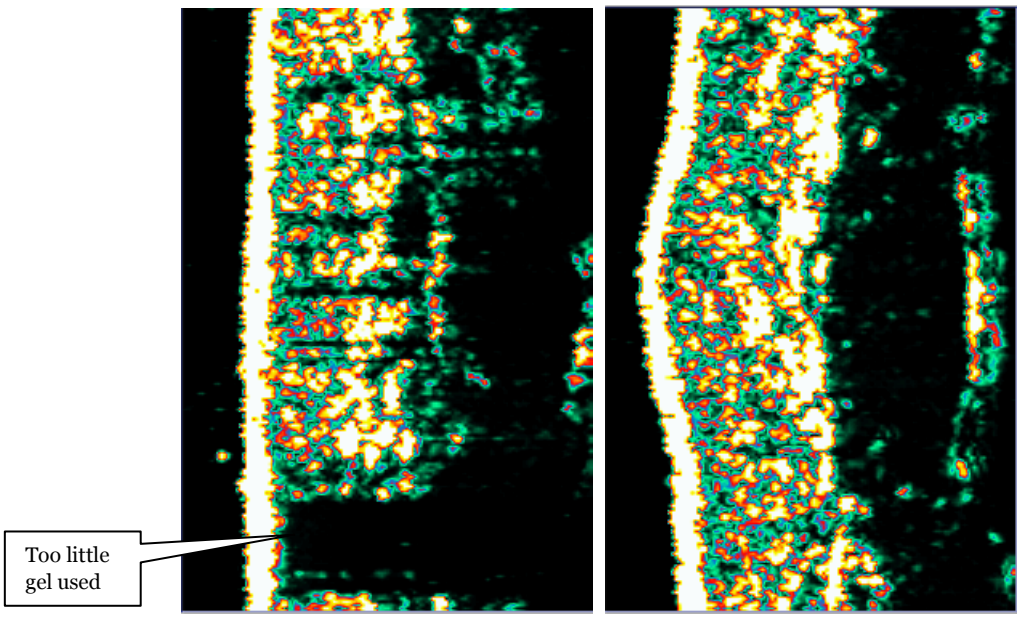
6.4.3. How to record a good image

Avoiding Artifacts

The left image below shows an ultrasound image where the gel (or water) at the tip of the probe has not been distributed well. This gives a shadow in the image because the acoustic ultrasound

signal does not reach the skin. Such air bubbles will block the ultrasound signal and cause horizontal shadows throughout the image.

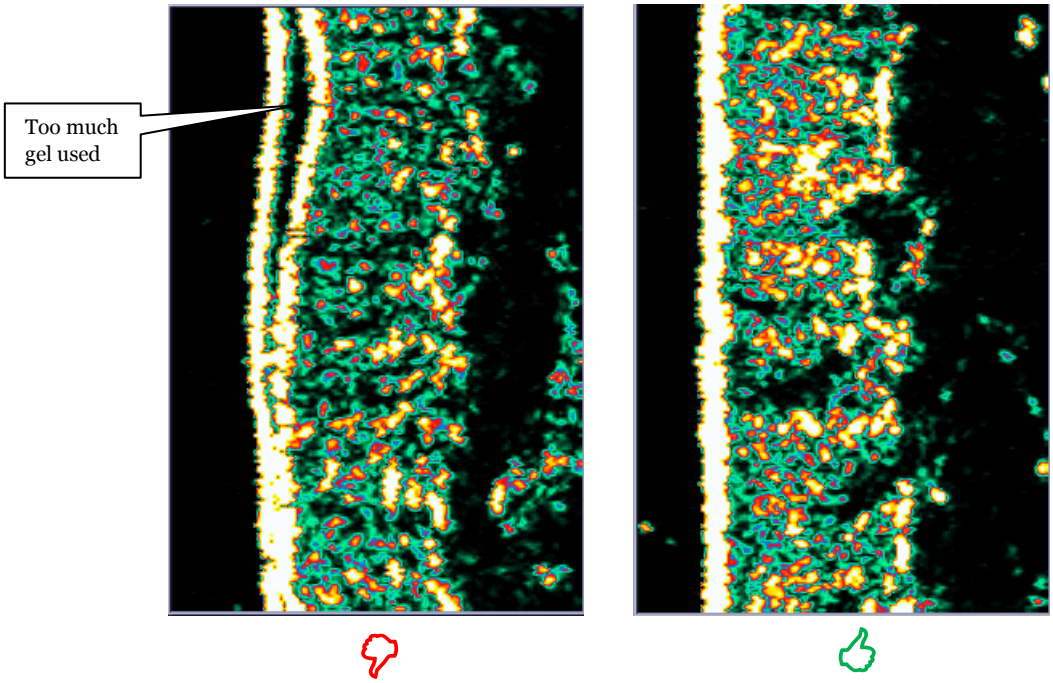
To prevent this from happening make sure the outside of the film on the probe is clean and having a thin layer of well distributed gel or a thin layer of water before making the scan.



It is important to make sure there is good acoustic contact between the tip of the probe and the skin

Gel layer thickness

The gel layer secures good acoustical contact from the tip of the probe to 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 appear as one bright line (i.e. as one echo) - see the right image below.



It is preferable to avoid too much gel between the tip of the probe and the skin

6.4.4. 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.

6.5. Maintenance

The daily maintenance of the ultrasound scanning probe is limited to the removal of water to reduce bacteria growth inside the water path and to allow the transducer to dry. Always remove the plastic film over night.

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 Moisture Module provides information about the hydration state by measuring the conducting properties of the very upper layers of the skin, when subjected to an alternating voltage. Accordingly, the method is referred to as a conductance measurement and the output is a hydration score from 0 to 99.

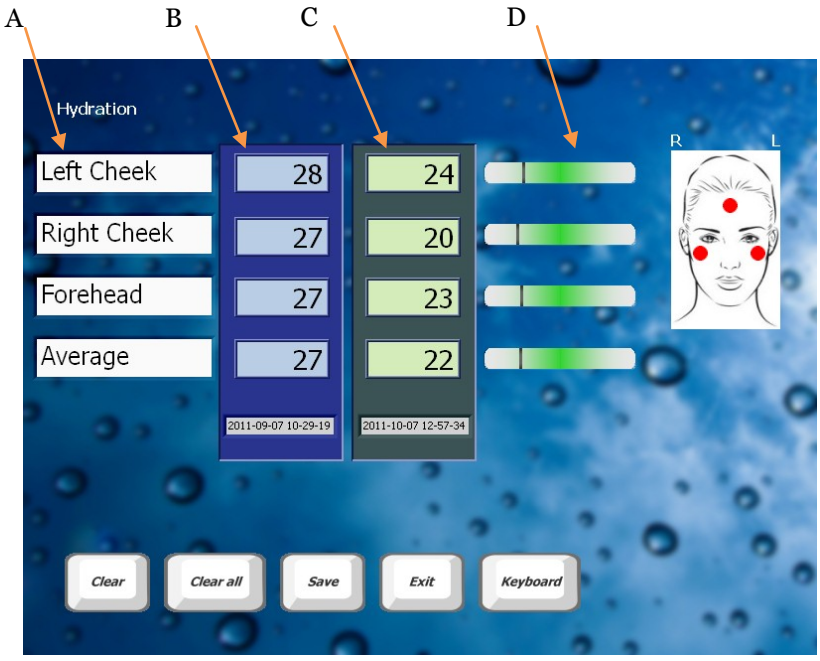
7.2. Moisture pin-probe

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 reduces occlusion, when applying the probe, thereby minimizing water accumulation in the skin covered by the probe.
The probe has a spring-loaded action, which will initiate a measurement, when the probe is pressed against the skin.

Pin probe with ventilating spacer

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

7.3. The Hydration screen



Hydration screen

A. The text fields can be used to label the places on the body where the hydration measurement is made. Pres **Keyboard** to get access to a touch screen keyboard.

B. The stored measurement and the date/time of the measurement can be seen in this column.

C. In this column the new hydration measurements are displayed together with a date/time stamp.

D. On the bars the measurement is indicated on a bar-scale.

7.4. Maintenance

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

8. Elasticity

8.1. Principle

The elasticity measurement of the DermaLab® Combo unit is based on suction applied to the skin surface. The probe provides a vacuum chamber and uses adhesive tape to prevent creeping and folding of the skin under the edge surrounding the measurement chamber.

The suction method features an elevation phase and a retraction phase. 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 retract slowly.

The DermaLab® Combo measures the skin retraction time as an indicator for the skin elasticity. The retraction time is defined as the time it takes for the skin to retract 1.5 mm from full elevation. The retraction time is displayed as an Elasticity score from 0 to 99, where a high score represents a very elastic skin with a short retraction time.

8.2. The Elasticity Probe

Connect the probe to the input connector on the front 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 the 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.

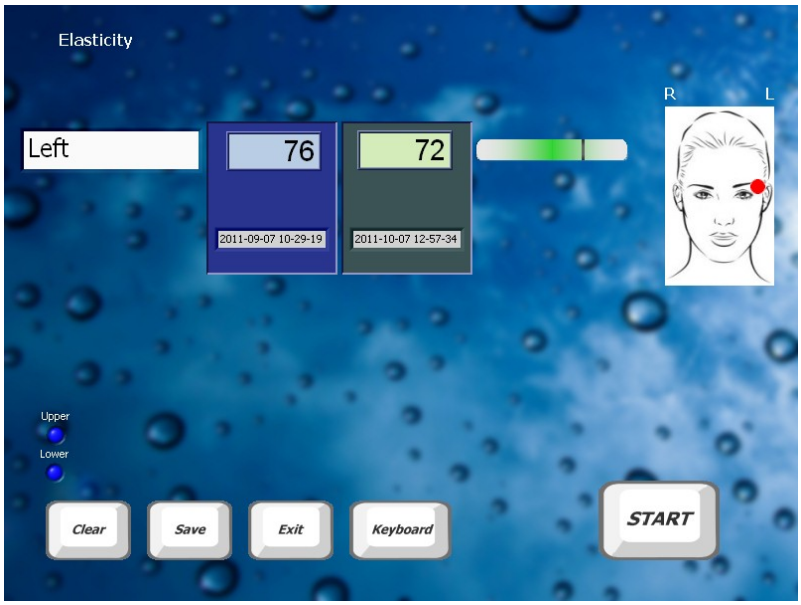
The adhesive ring shall be changed between measurements.

Elasticity probe with adhesive ring

As the suction principle applies mechanical stress to the measurement site, attention should be paid to the fact that 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. Do not touch the probe or pull the cables as this will influence the measurement.

8.3. The Elasticity screen



Elasticity screen

Press **Start** to start the elasticity measurement. A vacuum pump will start lifting the skin to its maximum extension of 2.5 mm. Then the neg. pressure will be relieved and the elevated skin will retract. Two internal detectors in the probe are positioned 1.5 mm apart and will be triggered as the skin retracts, thereby measuring the time needed for a retraction of 1.5 mm.

If air is leaking between the probe and skin (e.g. if the application of the adhesive tape is not fully tight), then the vacuum pump will not be able to lift the skin. If this happens then press 

to stop the measurement, change the adhesive tape and repeat the measurement.

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: Do not use other than isopropyl alcohol to clean the interior surfaces of the measurement chamber. Doing so may irreversibly damage the optical light guides within the probe.

The probe cables are delicate. Do not apply any unnecessary force to the cables (e.g. pulling the probe off the skin by the cable).

9. Sebum

9.1. Principle

The DermaLab® Combo sebum screen provides an instrumental approach to quick and accurate measurement of surface sebum by means of a sebum collecting device (Sebum Collector) and a DermaLab® Combo interface module (Tape Reader). Subsequent to applying the Sebum Collector 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 Collector 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 Collector offers a sensitive area, and the film is mounted in a way, which greatly reduces wrinkling of the film, when it is 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 Collector into the reader.

9.3. Tape Reader

The DermaLab® Combo interface accommodates a Tape Reader module providing a slot for insertion of the strip in use. The slot is located on the front side of the DermaLab® Combo 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 in till it will go 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

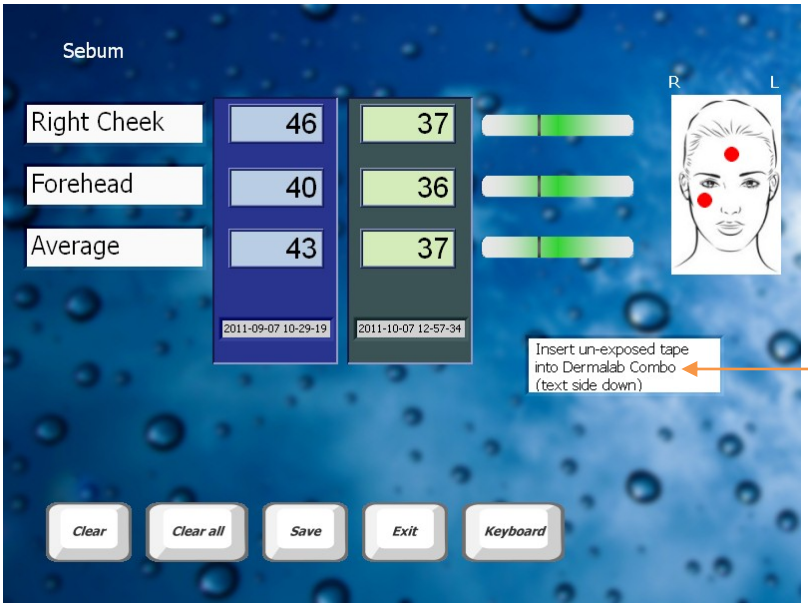
The strip fully inserted

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 colleting 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 measurement of skin color is based on an active color detecting chip measuring the Melanin) (pigmentation) and Erythema (redness) of the skin. Illumination is provided by two high intensity white LED´s.

The DermaLab® Combo measures the Melanin and Erythema value as an index. The higher the index the higher the pigmentation and redness of the skin.

10.2. Skin Color Probe

Pigmentation probe

The handheld probe accommodates the color sensor, filters, optics and light source. Light is provided by two high intensity white LED´s, and a unique feature is the guiding light, which illuminates the target during the positioning of the probe.
Once the probe is in place the measurement is triggered by pressing **Measure** and the LED´s will flash at full power to illuminate the target area.

Internal reflections and the influence of unwanted light through the clear probe front are eliminated by optical focusing on the 6 mm diameter target area.

10.3. The Skin Color screen

Pigmentation screen

Place the probe on the skin and press **Start** to perform the pigmentation measurement.

10.4. Maintenance

The DSM II ColorMeter probe is maintenance-free. However, please keep the calibrator out of direct sunlight. Preferably it should be stored in a dark place to prevent color change due to UV-radiation.

10.5. Calibration

Calibration is performed on the white surface on the supplied *calibrator*. Hold the probe against the white surface, then press the **Cal.** button. Once calibrated, the display will show a zero value.

It is recommended to re-calibrate on a regular basis - e.g. once a week or every time a new measurement session is started.

Calibrator

11. Video scope

11.1. Principle

The video scope probe is able to magnify and visualize the surface of the skin using polarized or non-polarized white light as the light source.

11.1.1. Magnification

The probe provides two focus ranges. Magnification depends on the screen size: the built-in screen provides magnification of approx. 15x and 50x, using an external screen magnification to approx. 200x may be obtained. The dial on the side of the probe is used to focus the image in one of these two focus points.

11.1.2. Polarizer

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

- polarized: turn the dial fully clockwise when looking into the probe tip
- non-polarized: turn the dial fully anti-clockwise when looking into the probe tip

With polarizer (surface reflections eliminated)

Without polarizer (visible surface reflections)

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

11.2. Probe

When using the probe bring the image into focus at one of the two focus areas by adjusting the dial on the side of the camera. Once the image is in focus at the desired magnification, take a picture by double clicking on the image on the screen or touching the small touch-button on the top of the probe.

The captured image will then be displayed in the picture scroll list located to the left on the screen from which any captured image may be selected for display on the main screen.

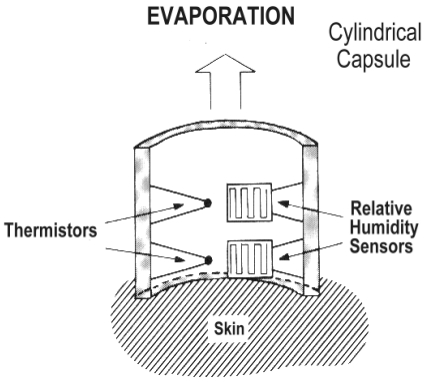
11.3. Maintenance

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

12. Trans Epidermal Water Loss (TEWL)

12.1. Principle

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



Two sets of temp./humidity sensors are mounted in a measurement chamber at different hights above the skin surface. The measurement chamber is open to allow the skin to "breathe" freely., and the evaporation rate follows Fick's Law of Diffusion:

$$Rate = P \times (c1 - c2) / T$$

where P = permeability coefficient of membrane, (c1 - c2) = concentration gradient, T = thickness of membrane.

To obtain comparable and reproducible results when measuring transepidermal 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

12.2. The TEWL Probe

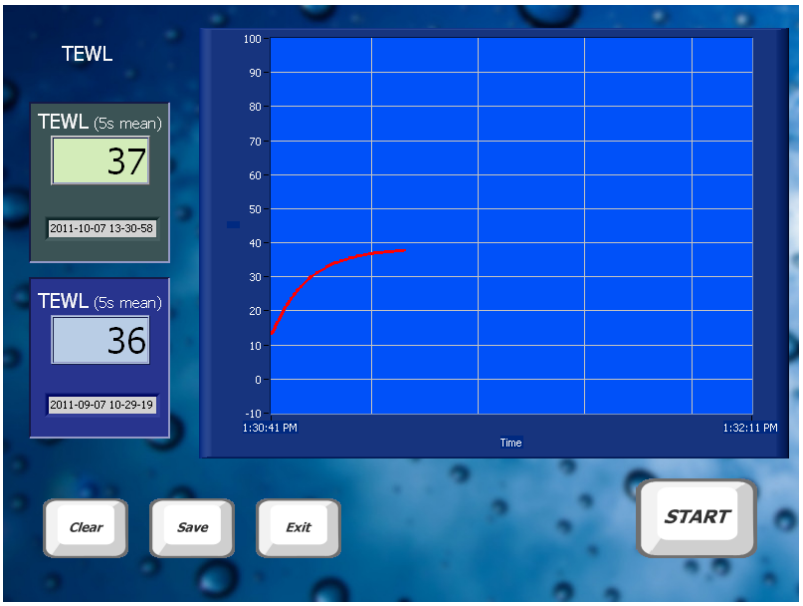
The probe is connected to the input connector on the front panel.

Place the probe on the skin with the perforated foam up and the open end of the measuring chamber pointing towards the skin. Do not press the probe too hard against the skin, apply light to moderate pressure.

To minimize possible cross-contamination, optional and disposable TEWL-probe protectors are available to be placed on the open end of the probe.

The two sensors in the probe are delicate, *do not touch* and handle the probe carefully.

12.3. The TEWL screen



TEWL screen

On the TEWL screen the graph for the trans-epidermal water loss as is shown as a function of time. After pressing **Start** the graph will show the trans-epidermal water loss until it stabilizes after typ. 30 – 40 sec. The measurement stops automatically and the 5 sec. mean value of TEWL is displayed.

12.4. Maintenance

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

The probe is delicate. Care should be taken not to touch the sensors inside the measurement chamber.

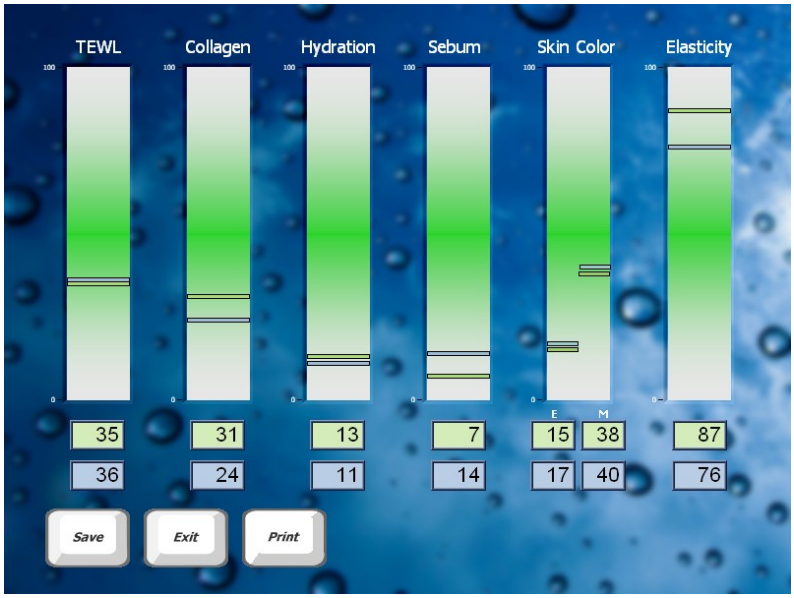
12.5. Calibration

The sensors of the probe may, depending on the use of the probe, 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. By doing so, both the humidity and temperature sensors are calibrated at probe level in a standardized setup.

Re-calibration is recommended at 3-12 month intervals depending on the use of the probe - short intervals if the probes are used extensively in very wet conditions (RH>80-90%), longer intervals at lower RH values.

13. Summary screen

The Summary screen provides a quick overview all measurements currently in the memory.



Summary screen

The upper (green) line of measurements represents the new measurements and the lower (blue) line of measurements represents the measurements loaded by the Open File button in the main screen.

Pressing the 

button will print a report on a connected printer (the Windows default printer), which can be handed to the client or saved for reference.

14. 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.

15. Service

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

However, if necessary the following spare parts may be ordered separately for replacement:

- External power supply
- Ultrasound probe
- TEWL probe
- Hydration probe
- Elasticity probe
- Pigmentation probe
- Video scope

All probes come pre-calibrated and can be exchanged without any need for recalibrating the main unit.

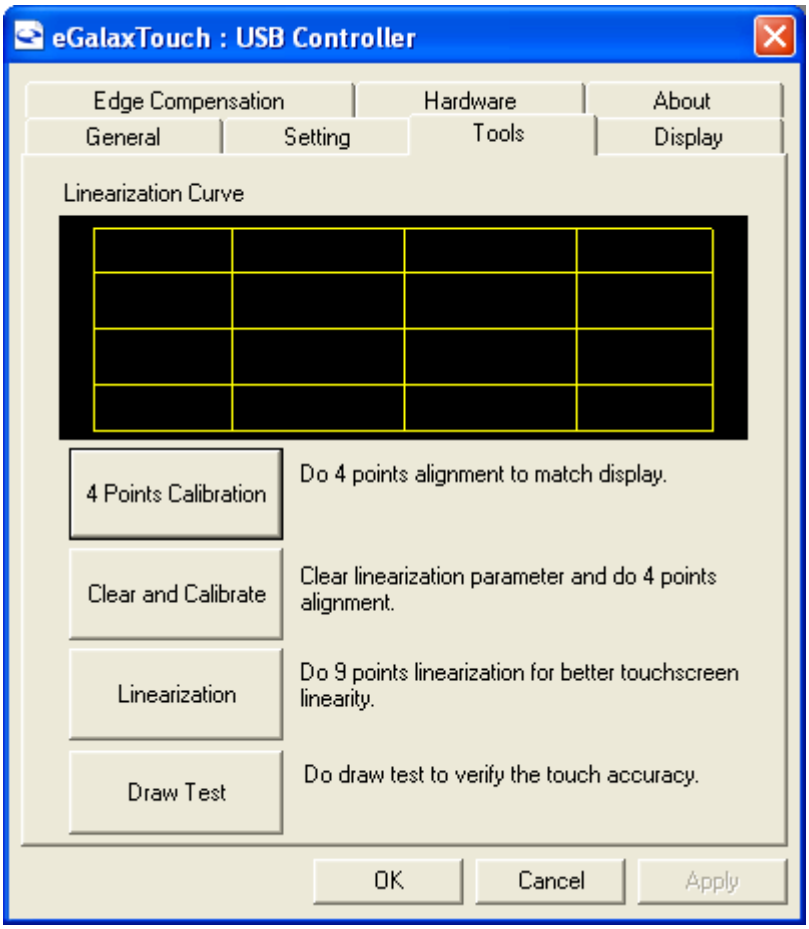
Please contact your local distributor or Cortex Technology (www.cortex.dk or cortex@cortex.dk) for requests of service and repair.

15.1. Calibration of the Touch Screen

If the touch screen has drifted out of calibration (i.e. if the cursor on the screen do not exactly show up under the point where you point), then the touch screen can be recalibrated by clicking the “eGalaxTouch” short cut on the Windows XP desktop screen.

After starting the eGalaxTouch application, select “TOOLS” followed by “4-Points Calibration” (see figure below).

A red ring will be shown in the lower-left corner of the display. Please touch the dot at the center of the ring with the stylus. There after a red ring will be shown at the lower right corner of the screen. Touch the center of this ring as well with the stylus and continue until all four corners have been calibrated. Thereafter the calibration has been finished and you can exit the eGalaxTouch application.



Screen shot from the eGalaxTouch application used for calibrating the touch screen on the main unit

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

17. Warranty

The DermaLab® Combo, probes and other accessories are covered by a one-year warranty against material and manufacturing defects. Due to the nature of humidity sensors as 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.

Appendix A – List of symbols

The following symbols are used in accordance with the harmonized standard EN60601-1:

Attention, consult accompanying documents. Where applicable, this symbol can be found on the following pages.

Class 2 equipment.

Alternating current, single phase.

Waste Electrical and Electronic Equipment (WEEE).

Appendix B – Declaration of Conformity

EC – DECLARATION OF CONFORMITY

We hereby declare that the products listed below conform to the requirements of directive 89/336/EØF "Council Directive of 3rd May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility" and 73/23/EØF "Council Directive of 19 February 1973 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits":

DermaLab® Combo

Manufacturers name and address:

CORTEX TECHNOLOGY,
Smedevaenget 10,
9560 Hadsund,
Denmark.
Tel.: +45 9857 4100 Fax: +45 9857 2223

Implemented standards:

EN 61000-6-1
EN 61000-6-3
EN 61000-3-2
EN 61000-3-3
EN 61010-1
EN 61187
EN 50419

Place and date: Hadsund 2010/10/29 Sign.:

Gunnar Svendsen
Managing Director