



DermaLab[®] Aesthetic

Instructions for Use



DermaLab Aesthetic

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1 Before you start



1.1 Warnings

- If the unit is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.
- 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.
- The unit is intended for indoor 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. The performance of this product may be affected if it is being used outside this range. If the instrument is stored outside these ranges, it should be left to stand until it equilibrates to within the above limits.
- The performance of this product may be affected if it is stored or transported outside the range -10°C to 50°C (14°F to 122°F).
- Avoid exposure to water. If exposed to smaller amounts such as rain, allow for the device to completely dry and consider contacting Cortex support for aid in assessing if the exposure has affected the integrity of the device.
- Do not disassemble the device. There are no user accessible or serviceable parts inside the unit.
- The DermaLab Aesthetic system does not require an internet connection for normal operation. If the DermaLab Aesthetic 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, you should check with the manufacturer that the proposed method will not damage the device.

1.2 Intended purpose

The DermaLab Aesthetic is electrical equipment for investigational measurement of skin parameters. Several probes can simultaneously be connected to the main unit to measure skin-related parameters such as collagen, elasticity, moisture (hydration), pH, and skin oiliness (sebum).

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

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

1.3 General description

The DermaLab Aesthetic system consists of the main unit, a Windows-based computer system, probes, and a medical grade power supply to provide power to the main unit. The system is not a medical device, and it is designed to meet international safety requirements for measurement, control, and laboratory equipment (IEC 61010-1:2010 / A1:2019).

2 Getting started

To ensure trouble-free and safe operation of the DermaLab Aesthetic please follow the instructions for use and maintenance as described in this document. The following figure shows the connectors on the rear panel of the main unit.



Figure 1. Connectors on the rear panel of the main unit. Table 1 lists how the probes are to be connected to the main unit. Connectors 1 and 2 are for the elasticity probe (both must be connected). Connector 3 is for the aesthetic ultrasound probe. Connector 4 or 5 is for the hydration probe (either port will work). Connector 6 is for the pH probe. Connector 7 is for the power supply while connector 8 is for the USB connection to a PC.

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

Connection type	Icon	Figure reference (Figure 1)
Elasticity probe		1 and 2 (air intake). Both must be connected.
Ultrasound probe		3
Hydration probe		4 or 5 (either one will work)
pH probe		6
Power	-	7
USB	-	8 (USB-B male)

2.1 Connect power supply

Connect the power supply 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 (Adapter Tech., ATM036T-P120).

2.2 Connect main unit

Connect the main unit to the +12 V output cable from the power supply. The power input is located on the rear panel of the main unit (Connector 7 on Figure 1).

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

2.3 Connect computer to main unit

Connect the main unit to the computer with the supplied USB cable (USB-A male to USB-B male).

2.4 Connect probes

The Collagen, Hydration, Elasticity, and pH probe are all connected at the rear panel of the DermaLab Aesthetic using various types of connectors according to Figure 1.

When inserting the connectors: Insert the connector and gently turn it. When the pins are correctly aligned it clicks into the socket. To disconnect the probe, gently pull the outer ring of the connector and it will disengage (do not turn).

The aesthetic hydration probe may be connected to either port 4 or 5 as shown in Figure 1. The pH, Elasticity and Ultrasound probes must be connected to their respective inputs on the main unit as shown in Figure 1.

2.5 Install DermaLab Aesthetics Software

If installation of the DermaLab Aesthetics software is necessary on a PC not included in the purchase, it will be provided along with the DermaLab Aesthetics hardware.

2.5.1 Software Requirements

The DermaLab Aesthetics Software is only available for Windows operating systems and will require Windows 10 or later. The DermaLab Aesthetics Software is only compatible with Windows x64 architecture. The software is NOT compatible with x64_ARM architecture..

Any PC running Windows 10 or later, with minimum an i3-processor, should have no issue running the DermaLab Aesthetics software. However, the quantity of measurements stored in the software will impact the required amount of storage.

For optimal use, a screen resolution of minimum 1366x768 is required. Unconventional aspect ratios or resolutions are not supported. A display scale up to 200% is supported in software.

2.5.2 Software installation instructions

To install and run the DermaLab Aesthetics Software, run the DermaLab Aesthetics software installation exe package provided with the DermaLab Aesthetic.

On first install, you will be asked to install USB-drivers to access the DermaLab Aesthetic hardware, this needs to be installed for the hardware to communicate with the software. The driver installer will open during the installation of the software.

3 How to use the software

When starting the software, the first page presented is the “Client menu” as shown in Figure 2.

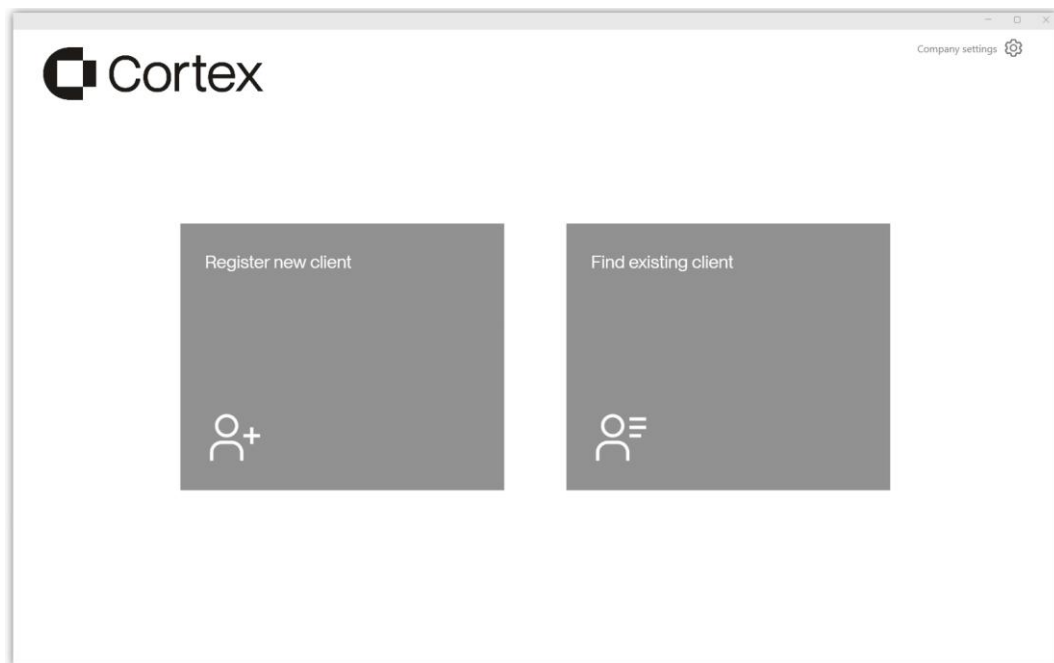


Figure 2 The “Client menu”

At first startup, you will be prompted to input company information. Access the Company settings page through the “Company settings” button in the top right corner. The “Company settings” are further described in section 3.1.

When Company information has been entered, the “Client menu” will provide you with options to either register a new client or access an already existing client. These options are further described in sections 3.2 and 3.3 respectively.

3.1 Company settings

From the “Client menu”, you can enter the “Company settings” page by pressing the top right corner button. On the “Company settings” page you can add company information and access other settings.

3.1.1 Company information

Before using the DermaLab Aesthetics software, the company name must be set. Company address, phone and email address can be omitted.

Apply your own company logo by clicking the “Change company logo” button. Your logo image must be in one of these image formats .png, .jpeg. or .bmp. The image will scale to fit the top menu and can require external editing.

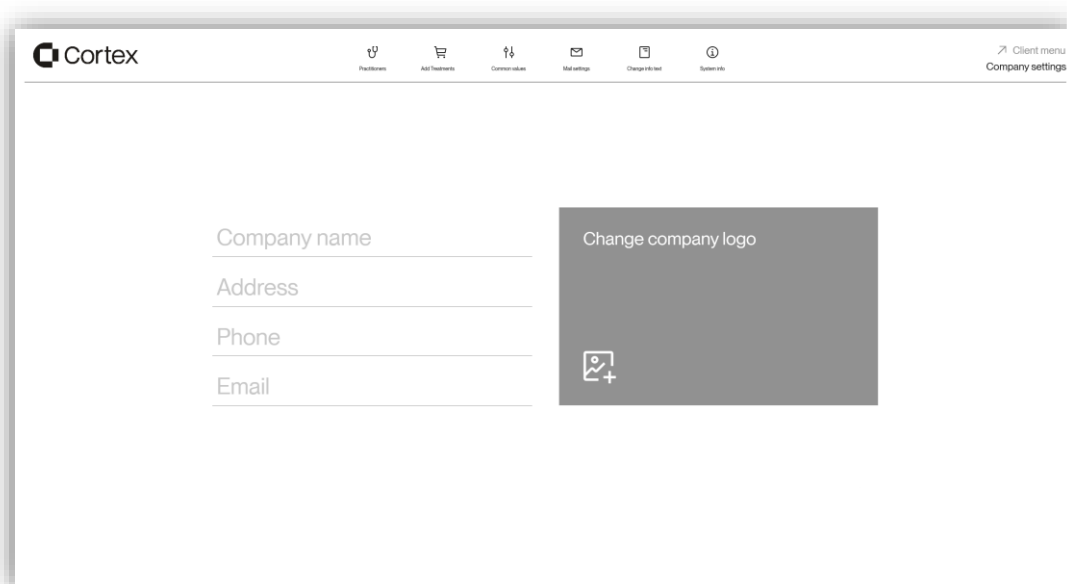


Figure 3 The “Company settings” page

3.1.2 Company and system settings

From the top menu you can access further settings and information regarding the system.

3.1.3 Change info text

This page allows you to change the text of the about sections that each of the measurement pages contain. There is also a button that allows you to restore the default text. The about text on each measurement page is in the top right corner, represented by an “i” symbol with a circle around it.

3.1.4 Email settings

From this page you can enable or disable the ability for the software to send mails. You can also change the default text shown in the email client when sending an email from the software. These can all remain blank if you prefer to enter this information in the email client. You can also choose if you want the software to minimize when sending a mail or not.

3.1.5 Practitioners

The “Practitioners” page is where you can add / delete practitioners. A list of added practitioners is available. To delete a practitioner, simply press the trashcan icon. Pressing the top right corner will navigate you back to the “Company settings” page.

3.1.6 Treatments

The “Treatments” page allows you to add and remove treatments in the software, see Figure 4. These treatments will be made available in the treatment recommendations part of a session, further described in 3.4.4.

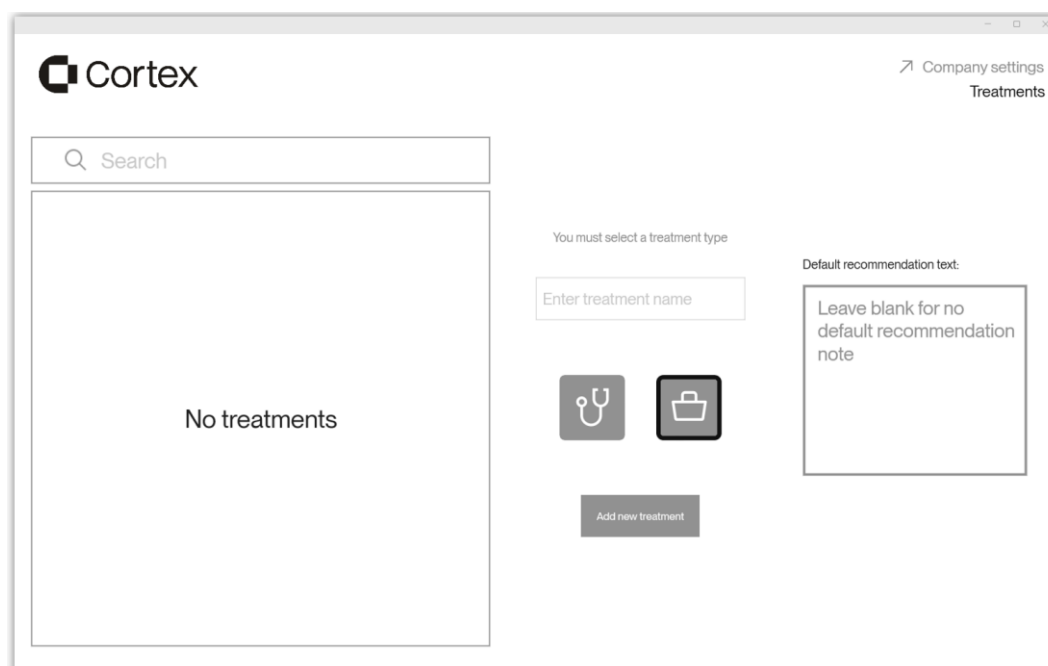


Figure 4 The “Treatments” page

The page is divided into three sections:

- “Search”: Search for treatments that have been added.
- “Add treatment”: Give the treatment a name and select the icon that would match the treatment.
- “Default recommendation”: Specify the default text for recommendations whenever a new session is started.

Pressing the button in the top right corner will bring you back to the “Company settings” page.

3.1.7 Common values

Common values are used to indicate the common area on measurement indicators displayed in the “Main menu”, described in section 3.4.2. These values are initially set by Cortex Technology, based on research studies.

As common areas can be different depending on use-case or target group, the software allows you to edit these values to better fit your own preferences and client base. However, values cannot be modified outside the total range of measurements. Modifying the common area will result in a disclaimer on the final printout stating that common values have been set by your company.

Common values can be reset by clicking “Restore default”.

The common values set by Cortex Technology are shown in Figure 5.

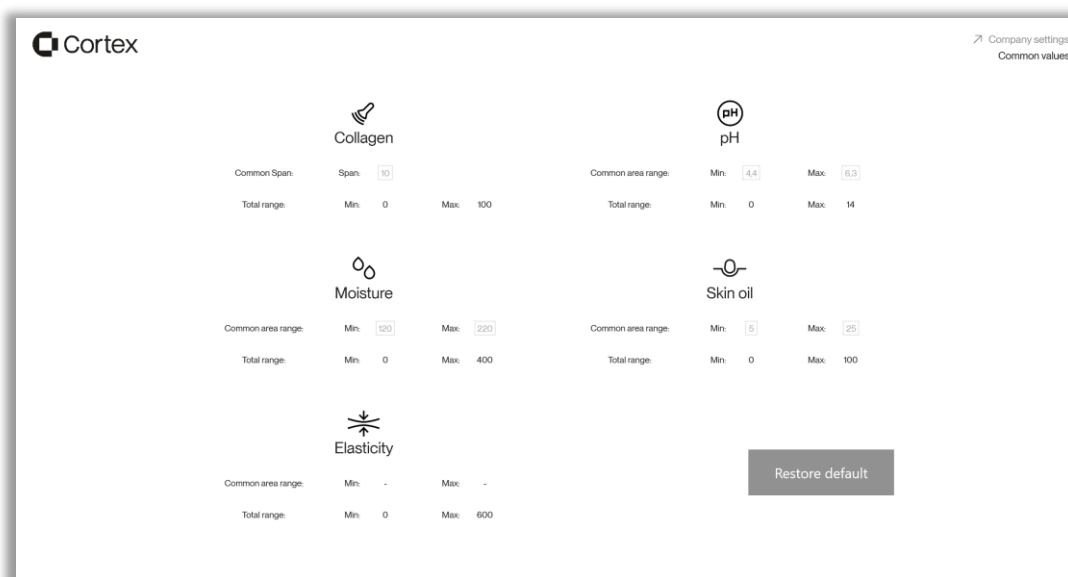


Figure 5 The “Common values” page

pH: The common value for pH is based on multiple research studies using the pH Probe from Cortex Technology and is between 4.4 and 6.3^{1,2}.

Moisture: The moisture score ranges from 0 to 400 μ S. The common value for moisture is between 120 and 220 μ S. This is based on numerous research articles using the Hydration Probe from Cortex Technology^{1,3,4}.

Skin oil: The sebum score ranges from 0 to 99, where 99 equals very oily skin. The common value for sebum is between 5 and 25^{4,5} which is based on numerous research articles using the Sebum Module from Cortex Technology.

Elasticity: Common values for skin elasticity are not supplied by Cortex Technology, as literature regarding normal skin elasticity is not available. The Common values can be set in the menu as described above. Shorter retraction time (R) means the skin has higher elasticity.

- 1) Mehta HH, Nikam VV, Jaiswal CR, Mehta HB. A cross-sectional study of variations in the biophysical parameters of skin among healthy volunteers. *Indian J Dermatol Venereol Leprol.* 2018 Jul-Aug;84(4):521. DOI: [10.4103/ijdv.IJDVL_1151_15](https://doi.org/10.4103/ijdv.IJDVL_1151_15). PMID: 29491191.
- 2) Yüksel YT, Sonne M, Nørreslet LB, Gundersen G, Fazli MM, Agner T. Skin barrier response to active chlorine hand disinfectant—An experimental study comparing skin barrier response to active chlorine hand disinfectant and alcohol-based hand rub on healthy skin and eczematous skin. *Skin Res Technol.* 2022; 28: 89–97. <https://doi.org/10.1111/srt.13096>
- 3) Hadi H, Awadh AI, Hanif NM, Md Sidik NF, Mohd Rani MR, Suhaimi MS. The investigation of the skin biophysical measurements focusing on daily activities, skin care habits, and gender differences. *Skin Res Technol.* 2016 May;22(2):247-54. doi: 10.1111/srt.12257. Epub 2015 Sep 3. PMID: 26333416.
- 4) Hua W, Fan LM, Dai R, Luan M, Xie H, Li AQ, Li L. Comparison of two series of non-invasive instruments used for the skin physiological properties measurements: the DermaLab® from Cortex Technology vs. the series of detectors from Courage & Khazaka. *Skin Res Technol.* 2017 Feb;23(1):70-78. doi: 10.1111/srt.12303. Epub 2016 Sep 16. PMID: 27637867.
- 5) Sakuma TH, Maibach HI. Oily skin: an overview. *Skin Pharmacol Physiol.* 2012;25(5):227-35. doi: 10.1159/000338978. Epub 2012 Jun 20. PMID: 22722766.

3.1.8 System info page

The “System info” page provides a list of devices and probe information, along with the option to change the language, which will take effect when the “Apply” button is pressed. You can also backup your database or import a database by pressing the buttons. Furthermore, you can restore the default logo in the top left corner. The default logo is the Cortex logo shown in Figure 6.

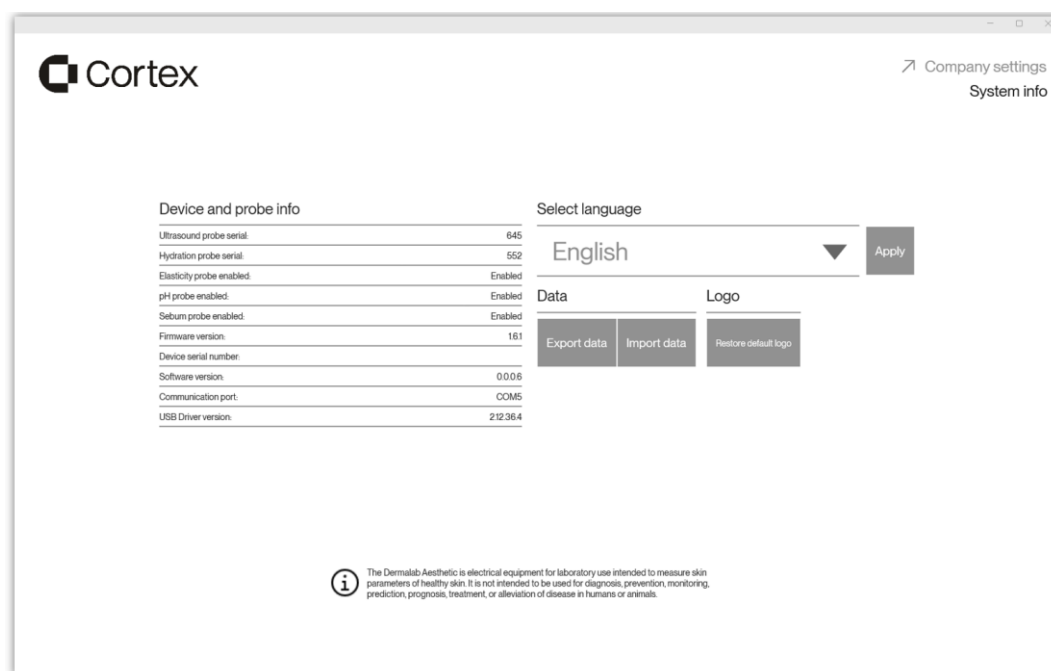


Figure 6 “System info” page

This page is useful when you are concerned about whether a probe is enabled, if you want to ensure that you have the latest version of the software, etc.

The company settings page also provides options to export and import data further described in section 3.1.8.1.

In the top right corner, the button will take you back to the “Company settings” page.

3.1.8.1 Exporting and importing data

It is recommended to perform regular backups of collected data, as all data is inherently contained within the software installation and will be deleted if the DermaLab Aesthetics software is uninstalled or if the PC data is corrupted.

To export data, click the “Export data” button and select a folder to export to. Exporting may take a few seconds depending on amount of data on the system.

A folder will be created within the folder selected using the following naming scheme: “yyyy-MM-dd_hh-mm-ss_DermaAdviser_Backup”. The exported data will be placed within this folder as a “.realm” file.

To import data, click the “Import data” button. Pressing this button will open a menu as shown in Figure 7.

When importing data, the user can select what data to import and how the import should be done.

Users can select the following data for import:

- Company info
 - Company information listed on the company information screen along with company logo and default treatment recommendation text.
- Clients and session.
 - All clients and their respective sessions
 - If practitioners and treatments are not selected for import, any practitioner or treatment related to client or sessions will not be transferred.
- Practitioners
 - All practitioners
- Settings

- Any settings related to common values or language selection
- Treatments
 - All treatments
- All Data
 - All of the above

Before importing, users will also have to select the import method:

- Overwrite
 - Any data selected for import will overwrite current values on system (e.g. if clients and sessions are selected, only client and session from importing database will be present after import)
- Merge
 - Any data select for Import will be merged into current system data (e.g. if clients and sessions are selected, all clients and sessions from both databases will be present after import)
 - If Practitioners, Treatments or clients exist with the same name (not capital letter sensitive) These will be merged into each other as well, basing values such as age or capitalization of name on the entry with the most recent change.
 - Example: Given a system with a client named “John Smith” with 3 related sessions, merge-importing data from another system with a client named “john smith” with 2 related sessions, will result in a single client named after the newest of the two clients and containing 5 sessions unless some session already exist (i.e. same date, results, practitioner etc.)

When data and import method has been selected, clicking the “Import” button will prompt the user to select a “.realm” file for import. When a file has been selected, import will begin. When import is complete a status will be shown in the lower left corner if import was successful.

Import data

Company info	Clients & sessions	Practitioners	Settings	Treatments	All data
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Import Method

Overwrite

☐

Merge

☐

Please select import method

Cancel

Import

Figure 7 Import data menu

3.2 Register new client

Press the “Register new client” shown in Figure 2 to enter the “Register new client” page.

Here you can enter the client ID (as assigned by you), age and gender of the client, and you can register the practitioner. Any information besides a client ID is optional.

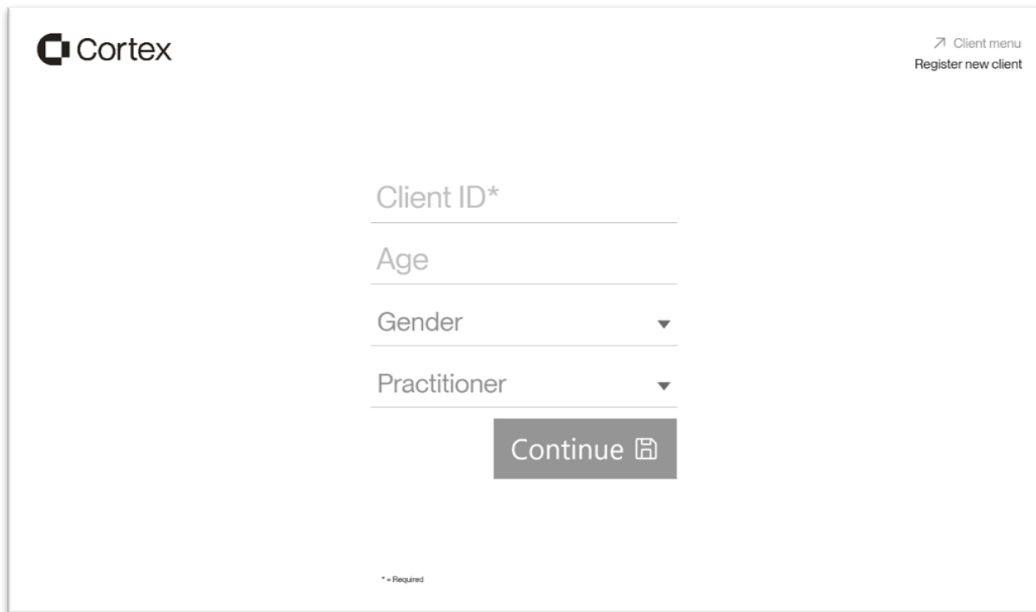


Figure 8 The “Register new client” page

Pressing the top right button “Client menu” will take you back to the previous page.

By pressing the “Continue” button, the client will be stored, and a new session will be started as described in section 3.4.

3.3 Existing client

Pressing the “Find existing client” button shown in Figure 2, opens the “Existing client” page, where you can select previously registered clients.

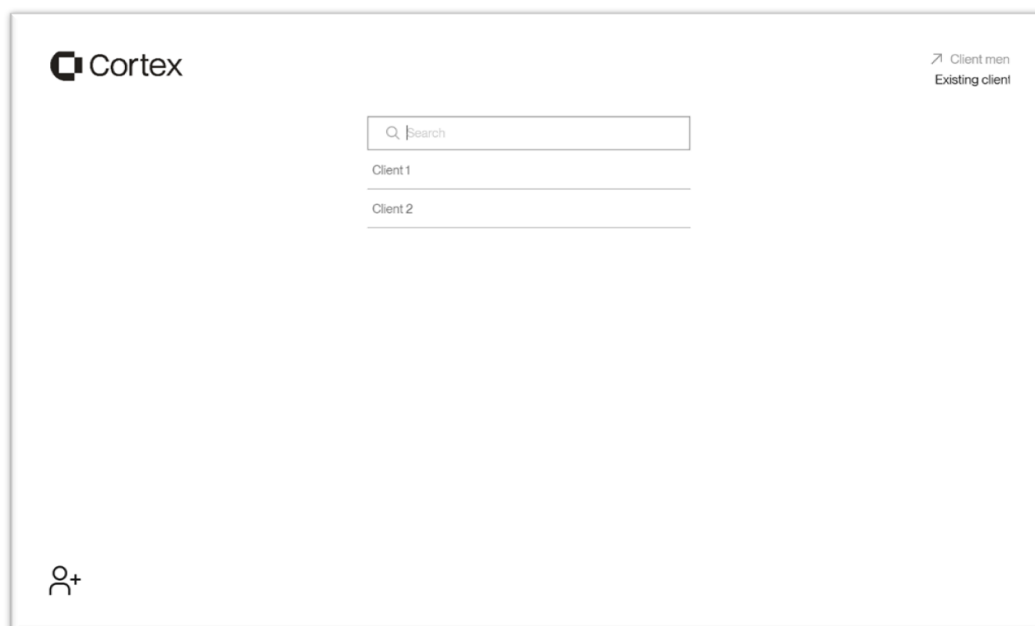


Figure 9 The “Existing client” page

Click on a client name to navigate to their “Client profile” page, as illustrated in Figure 10.

If the client is not present in the list and needs to be registered as a new client, click the button in the bottom left corner to go to the “Register new client” page.

On the “Client profile” page, you will find information about the client, including age, gender, and details about previous sessions. See Figure 10.

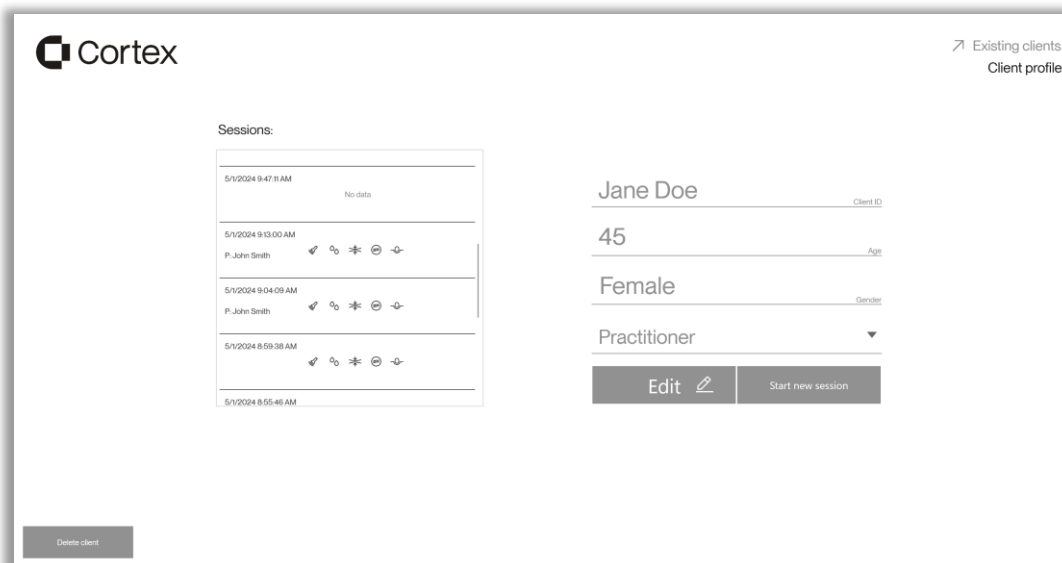


Figure 10 The “Client profile” page

You can choose to edit the client ID, age, gender and view previous sessions. You can also delete the client completely, which also will delete the sessions that have been created for that client. Here you can also reopen any session that has been closed within the last 12 hours. This helps you to resume the work if the accidentally closed.

Hovering over a measurement icon on a previous session will present any note stored for that session.

Pressing the “Client menu” button at the top of the page will take you back to the “Client menu”.

3.4 Sessions

Start a new session by selecting a client and pressing "Continue". The "Main menu" will open, displaying the five parameters of skin analysis, see Figure 11.

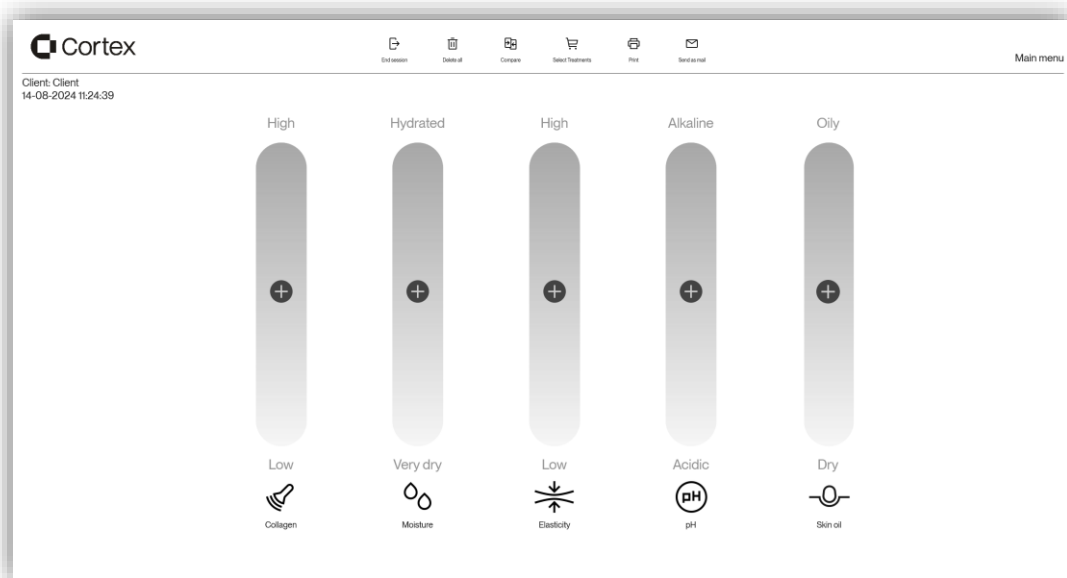


Figure 11 The "Main menu" page with no measurement data

3.4.1 Session options




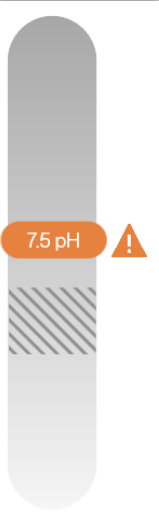
You can start measurements by clicking on the measurement indicators on the screen. More information about each measurement can be found in section 4.

The top menu of the "Main menu" provides functionalities for the session:

- "End session" will complete the session
- "Delete all" will remove all data from the session and none of the collected data is stored
- "Compare" provides access to a comparison feature, allowing you to compare new and previous measurements, as detailed in section 3.4.3
- "Treatment" provides access treatment recommendations, detailed further in section 3.4.4
- "Print" provides access to printing functionalities, detailed further in 3.4.5.

3.4.2 Understanding measurement indicators

When the respective measurements are completed, data will be displayed on the "Main menu". Below, the various measurement indicators that you may encounter are explained.

	<p>Probe is present.</p> <p>Measurement is not yet performed.</p> <p>Measurement indicator will highlight when hovering.</p> <p>Measurement menu can be entered by clicking the measurement indicator.</p>		<p>Probe is not connected.</p> <p>Insert probe to enable measurement type.</p> <p>Measurement indicator will not react to cursor hover.</p>
	<p>Measurement has been completed in measurement menu.</p> <p>Results are within common area.</p>		<p>Measurement has been completed in measurement menu.</p> <p>Results are outside common area.</p> <p>Note:</p> <p>In cases such as Hydration measurements, more than one result indicator may be present.</p> <p>Orange text will not always appear outside common area. (i.e. Hydration is only presented as orange when values are lower than common values or outside indicator range).</p>

3.4.3 Compare measurements

Measurement results from previous sessions can be compared on the “Compare results” page shown in Figure 12.

Baseline values can be enabled or disabled using the switch in the lower left corner.

Select the individual measurements you want to compare in the right menu.

To toggle all measurements on/off click the checkmark besides “Select files”.

A printout can be made from the “Compare results” page by clicking the “Print” button, further described in section 3.4.5.

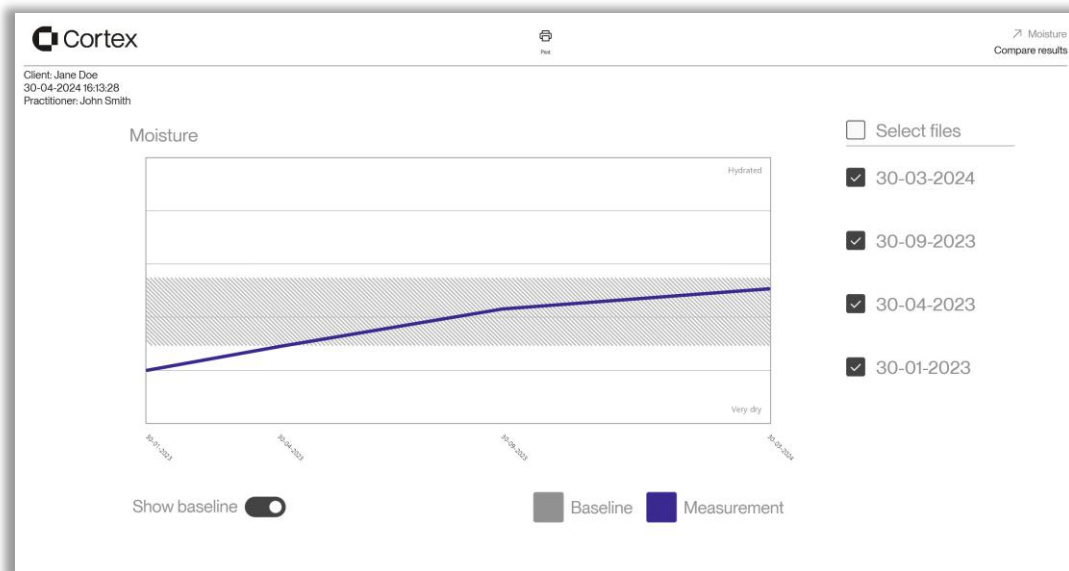


Figure 12 The “Compare results” page

3.4.4 Treatment recommendations

After conducting the skin analysis on your client, you can select the treatments you would recommend based on the analysis, and you can attach notes to your recommendations. This is done on the “Treatments” page. Access this page through the “Treatments” button on the “Main menu” shown in Figure 11.

The selected treatment recommendations and notes will be displayed on a printout page that you can share with your client along with the measurements. Read more in chapter 3.4.5.



Figure 13 The “Treatment selection and recommendations” page.

In the “All treatments” section, you can view all the treatments you have added in “Company settings”.

Select a treatment by clicking on the treatment in the section “All treatments”. The treatment will then be displayed in the “Selected treatment” section. You can also remove a treatment from the “Selected treatments” section by clicking on it.

If you want to move all treatments at once, you can use the three arrow buttons between the sections:

- The button with an arrow pointing **right** moves all the treatments to “Selected treatments”.
- The button with arrows pointing **both directions** switches the columns, transferring all treatments from 'All treatments' to 'Selected treatments' and vice versa.
- The button with an arrow pointing **left** moves all the treatments to “All treatments” and will clear the “Selected treatments” section.

By pressing the button “Select last saved”, you will add all the treatments that was selected for this specific client and saved at the previous session.

In the section “Selected treatments” the treatments you have selected for recommendation will be displayed.

The box to the right is the note area where you can write notes for the client, notes about the treatment recommendations, etc. This box is by default empty, unless you have entered a default text in “Company settings”, read more in section 3.1.6. The “Clear text” button deletes all the text in the note area.

3.4.5 Printing

Printing is available for measurements, treatment recommendations and compare results.

Clicking the “Print” button on the “Main menu” will present the pop-up shown in Figure 14.

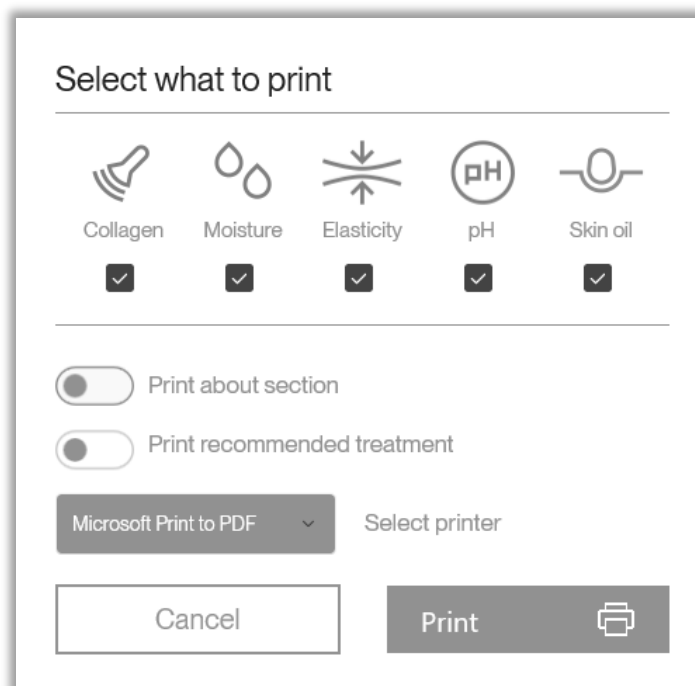


Figure 14 Print settings.

From print settings, you can choose which measurements to include in the printout.

You can choose to include:

- The relevant about sections, which is a short text that explains each measurement.
- The selected treatment recommendations and your notes for the client.

Select format and printer for printout and press “Print”. The default printer selection will be the default Windows printer on the system.

Examples of printout can be seen in Figure 15, Figure 16, Figure 17 and Figure 18.

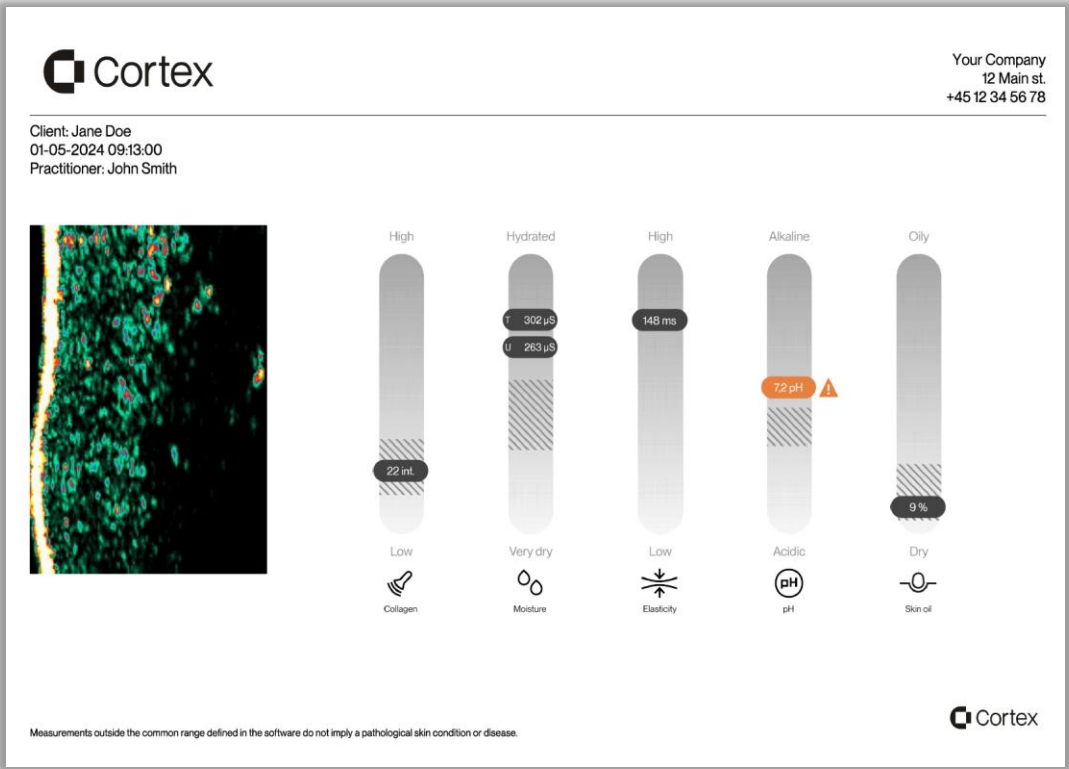


Figure 15 Printout with all measurements

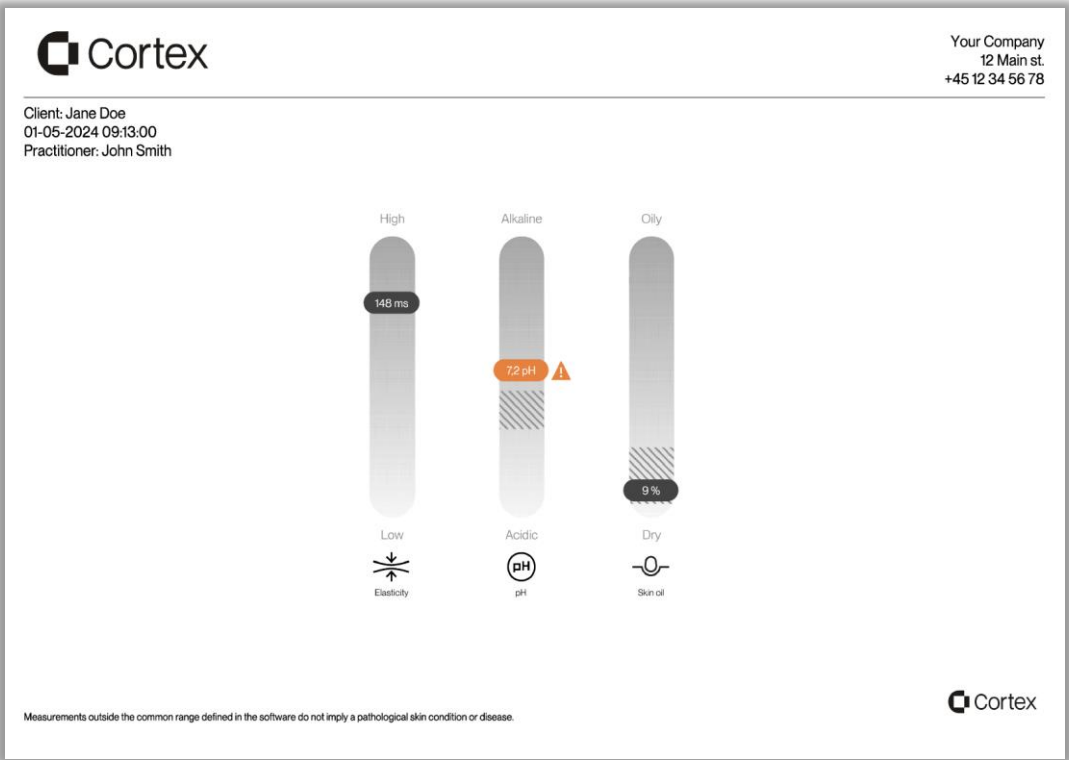


Figure 16 Printout with only 3 measurements selected.

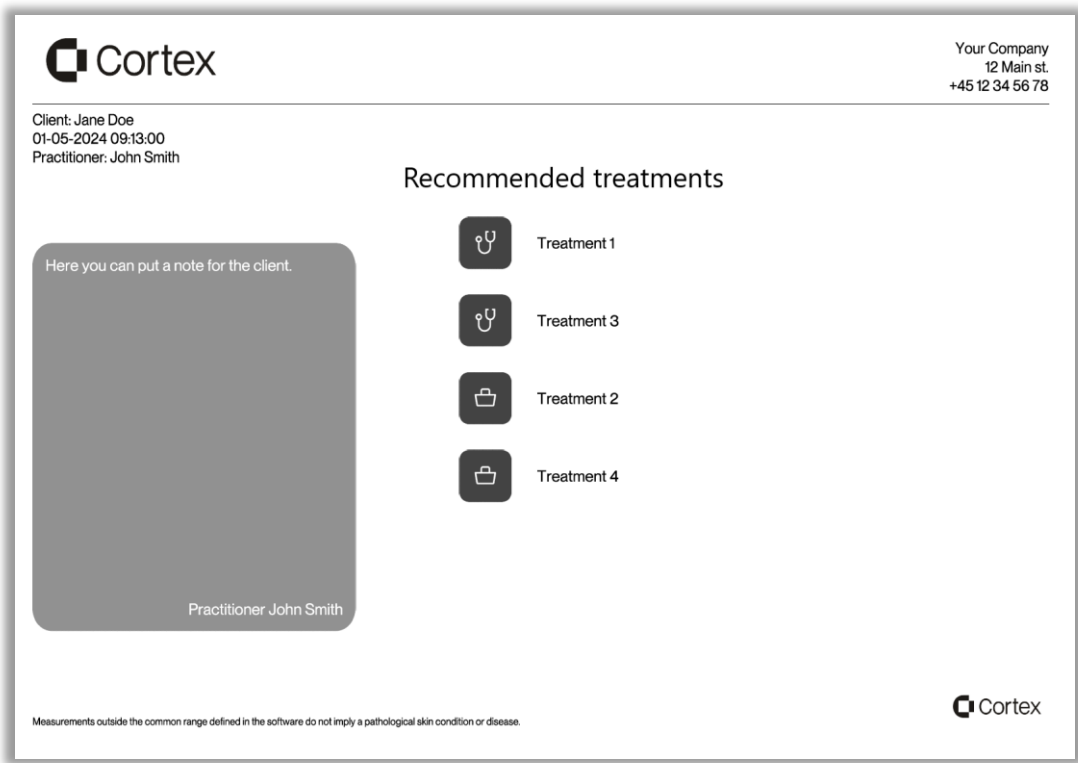


Figure 17 Treatment recommendations printout.

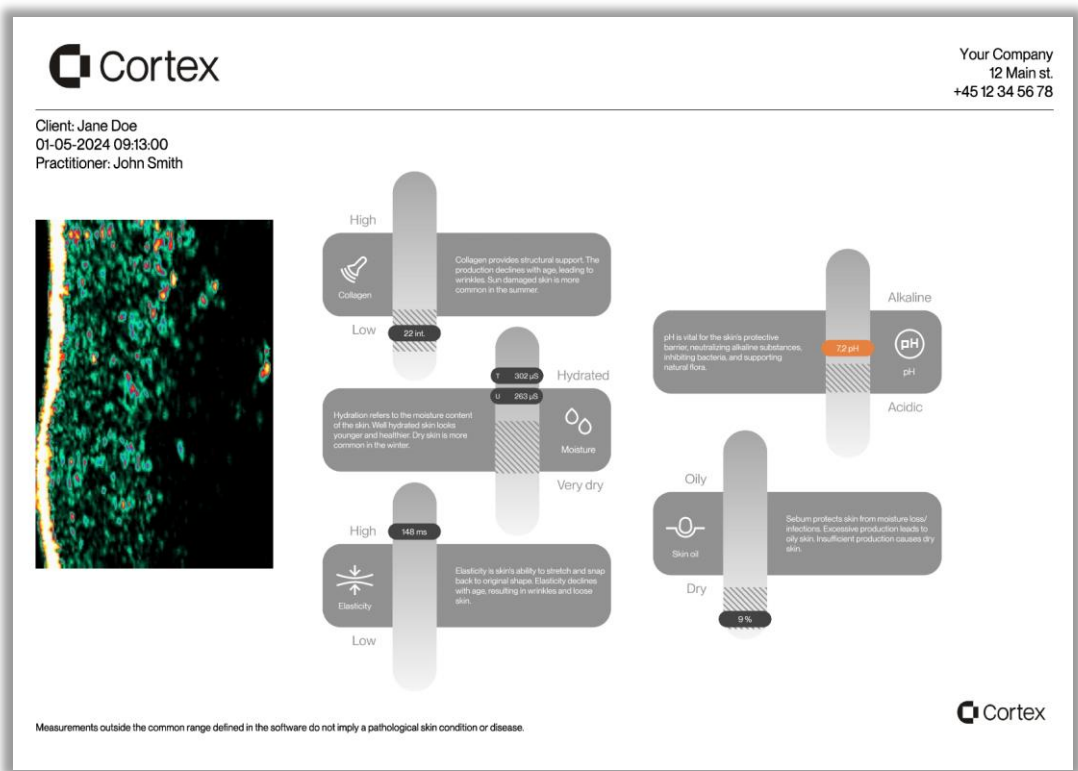


Figure 18 Printout with all measurements - including information about sections.

Printing from the “Compare results” page will include all measurements selected for comparison. Baseline values will only be present in the printout if selected beforehand.

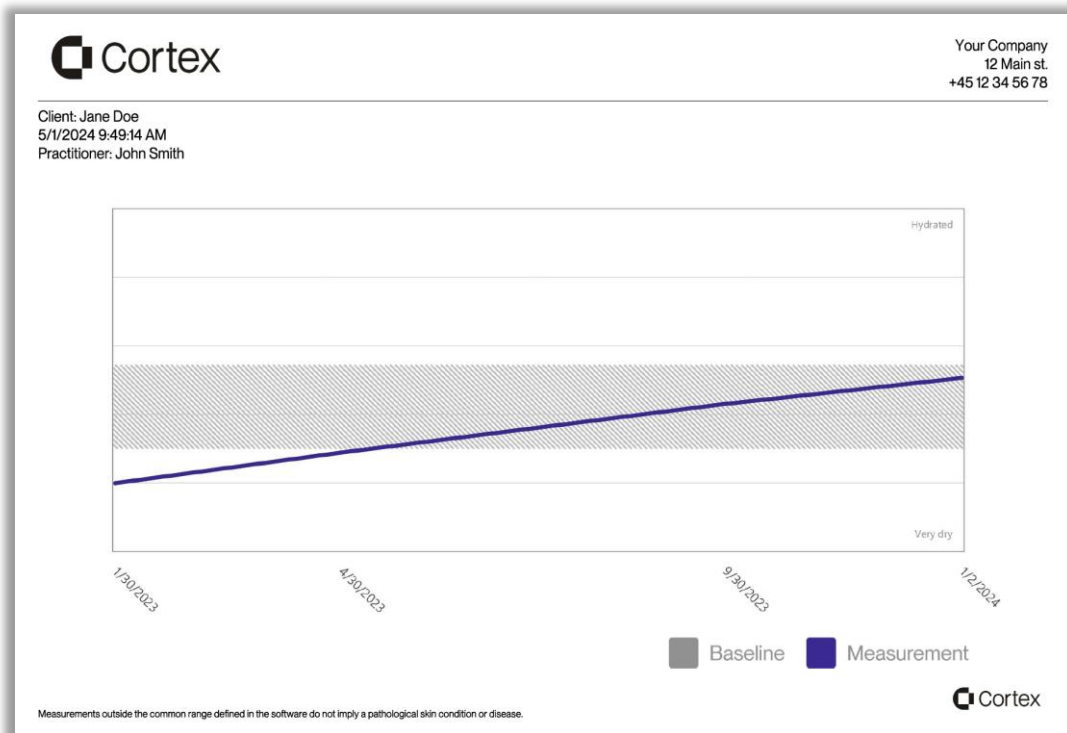


Figure 19 “Compare results” printout.

3.4.6 Sending email

Dermalab Aesthetics software allows you to send an email to the client containing the same data that can be printed. When you choose to send an email, the software generates a .PDF file with the report and attaches it to the email. Your default email client will open automatically, allowing you to send the email with the attached file.

3.4.6.1 Email setup

Go to the “Mail settings” to set up the email system before use. On this page, you can define default content for the emails you will send to the clients along with their reports. You have the option to set a default subject and add default CC or BCC recipients – this is useful if the practitioner wants to keep a copy in their own mailbox. You can also specify a default email body, including a general message and a signature.

Test mail system

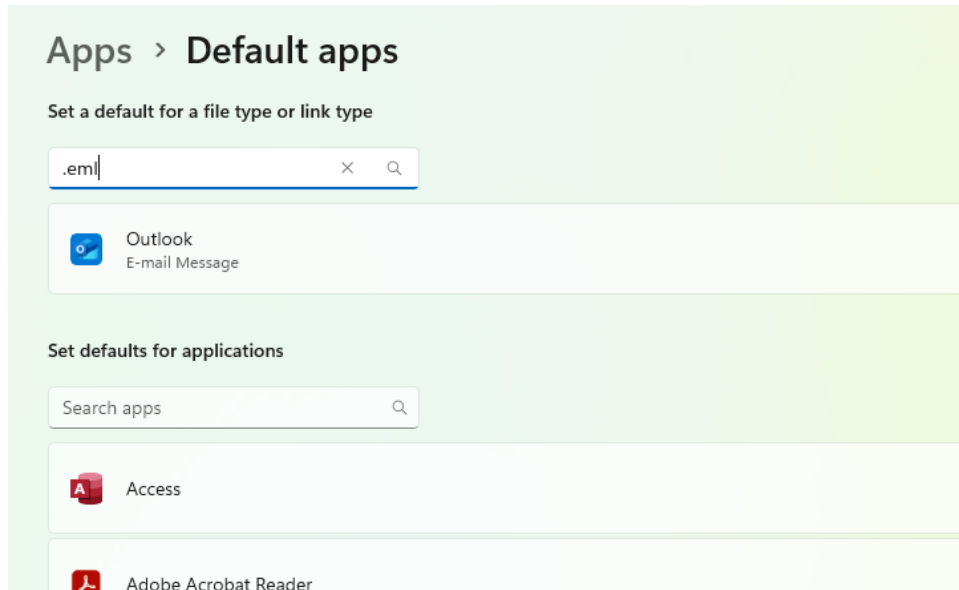
To make sure the mail system works correctly, it is recommended that you test it before use:

- Press the “Test Mail” button on the “Mail settings” page.
- A popup will appear with the question: “Did the mail client open correctly?”
 - If the mail client opened a new email with the text “This is a Test Mail”, the mail system is working correctly. Click “Yes” to confirm, and the function will be ready for use.
 - If the mail client did not open, you need to change the default .eml handler in Windows. Click “No” and follow the instructions below to set up the mail system.

Setup the email system (the default .eml handler)

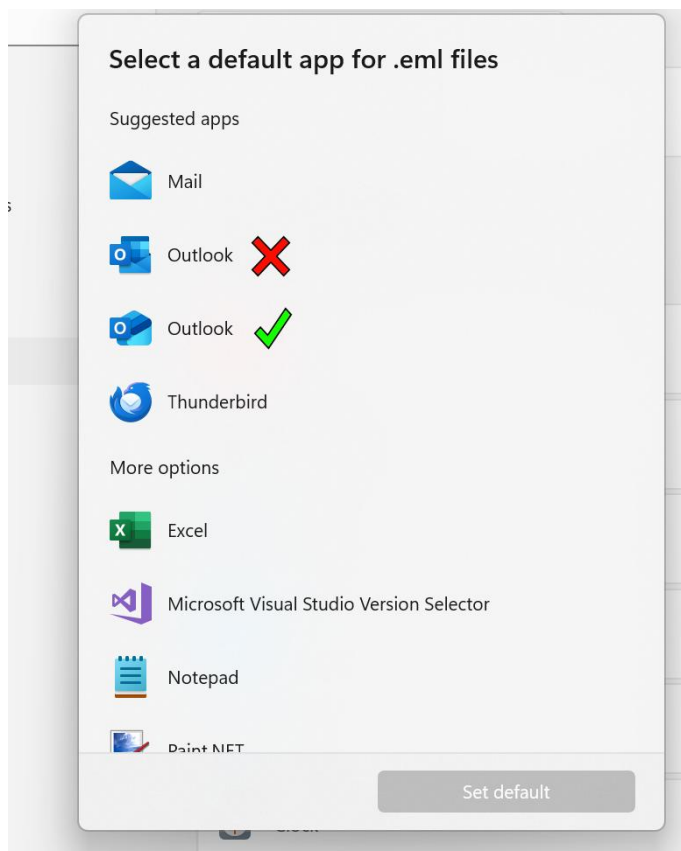
- A new pop up will appear with the message “Change default mail settings”

- Press “Yes” and the “Default apps” settings will open (see below).



- In the search field at the top, type “.eml” (remember the dot) to search for your mail client.
- Choose “Outlook” and a new pup up will appear with the headline: “Select a default app for .eml files” (see below).
- Select the default mail client and press “Set default”.

Please note: Two versions of Outlook may appear. It is important to choose the correct outlook client. We recommend using Outlook (new).



- After selecting the default mail client, click 'Test Mail' again to confirm that the email opens correctly

with the test message.

4 How to perform measurements

From the "Main menu" you can access each of the five measurement pages where you can perform measurements.

Each measurement page includes an about section available in the top right corner marked with an "i". Press this to view a pop-up with a short description of the measurement.

To add notes to a measurement, press the "Add note" button in the top menu. The note will then be viewable on the "Client profile" page by hovering over the relevant measurement icon, read more in section 3.3.

Pressing the "Compare" button will open the "Compare" page described in section 3.4.3.

To return to the "Main menu" click the button in the top right corner.

Session data is automatically stored for later use after each measurement.

4.1 Collagen

Collagen level (intensity) is measured with the Ultrasound Probe.

A collagen measurement comprises two reference measurements and two actual measurements. The reference measurements are conducted on the inside of the client's arm to establish the baseline collagen level as this skin area has minimal sun exposure, indicating an optimal collagen level for each individual client. The actual measurements are conducted on the client's temple, providing the current collagen level.

Collagen level is calculated based on the first 500µm behind the epidermis.

4.1.1 Preparing the ultrasound probe

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

4.1.2 Filling the water chamber

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

1.

Use a tip for easy filling of the chamber.



2.

Attach the tip to the syringe.



3.

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



4.

Check for air bubbles (more information below).



5.

The Ultrasound Probe is ready for use.



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

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

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

4.1.2.1 Cleaning

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

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

To empty the chamber:

1.

To empty the chamber, start by removing the valve.



2.

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

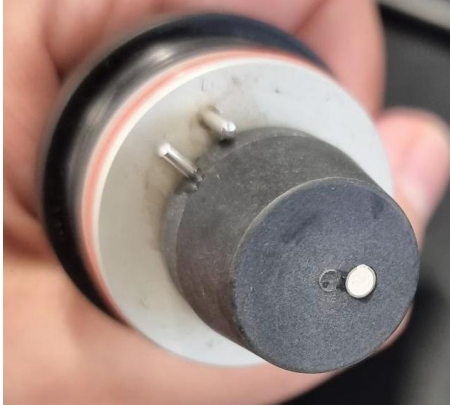


3.

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



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



*Figure 21 Probe with no button
Transducer head*



*Figure 20 Probe with Button Transducer
head*

The transducer is inside the probe and is in the compartment that is filled with water. In the probe without the button (Figure 21), the transducer should be wiped gently with the cotton swab at the end of daily use. For the probe with the button (Figure 20) the compartment with water does not need to be emptied every day, and the transducer should only be gently wiped every time the water is replaced.

4.1.3 Performing a collagen measurement

Measurements are performed in order from left to right, beginning with the reference measurements. See Figure 22.

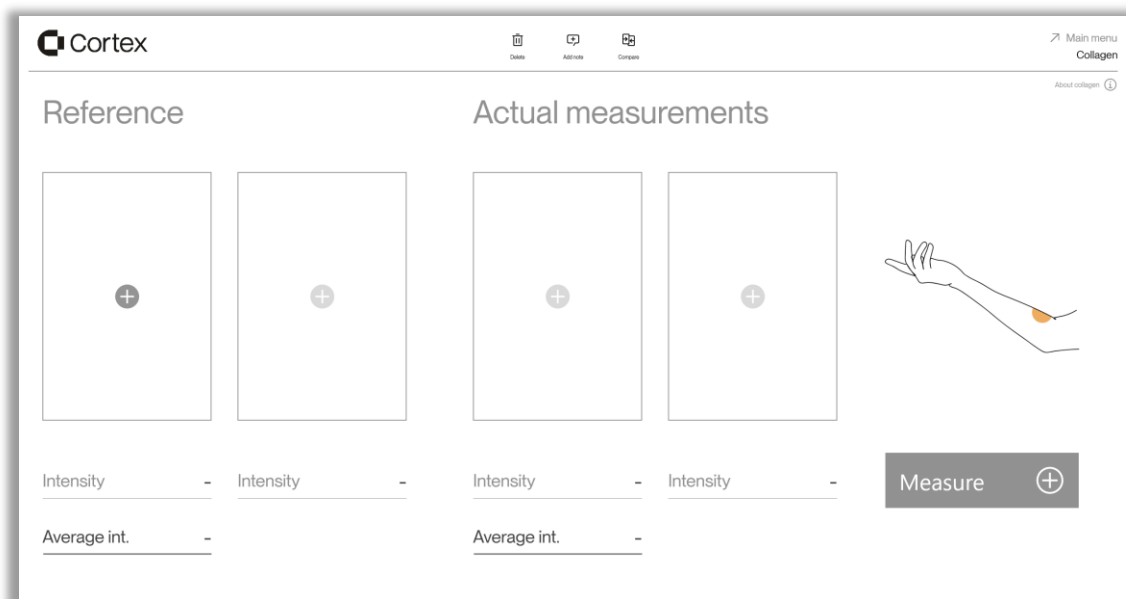


Figure 22 “Collagen” page with no measurements.

Apply ultrasound gel on the tip of the probe before each scan to couple the probe to the skin.

Place the probe on the skin and spread the gel with “massaging” movements of the probe

Keep the probe steady and use the button on the probe to start a measurement.

You can also start a measurement by pressing the “Measure” button in the software or clicking the “+” icon on the available measurement area.

When a measurement is performed an ultrasound image is visualized in the measurement area as seen in Figure 23. An individual intensity score will be displayed beneath each ultrasound image, along with the average intensity score for both the reference and actual measurements, respectively.

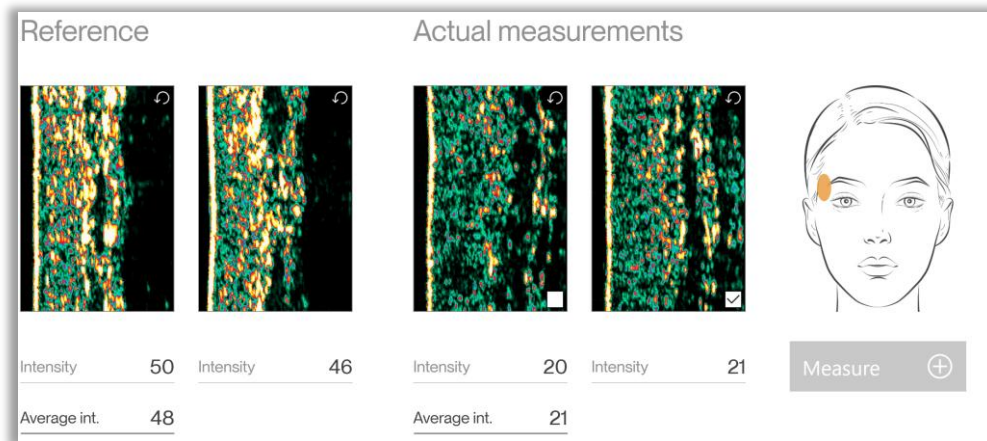


Figure 23 Collagen measurement.

To retake a measurement, click the “Retake” button available in the top right corner of each measurement area.

The average intensity of the measurements will be presented on the “Main menu”.

4.1.4 Understanding the collagen measurement

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. The epidermis is highly reflective (white/yellowish), and the dermis is a mix of many colors. The subcutaneous fat and muscle fibers will return a low intensity signal (dark green and black), see Figure 24.

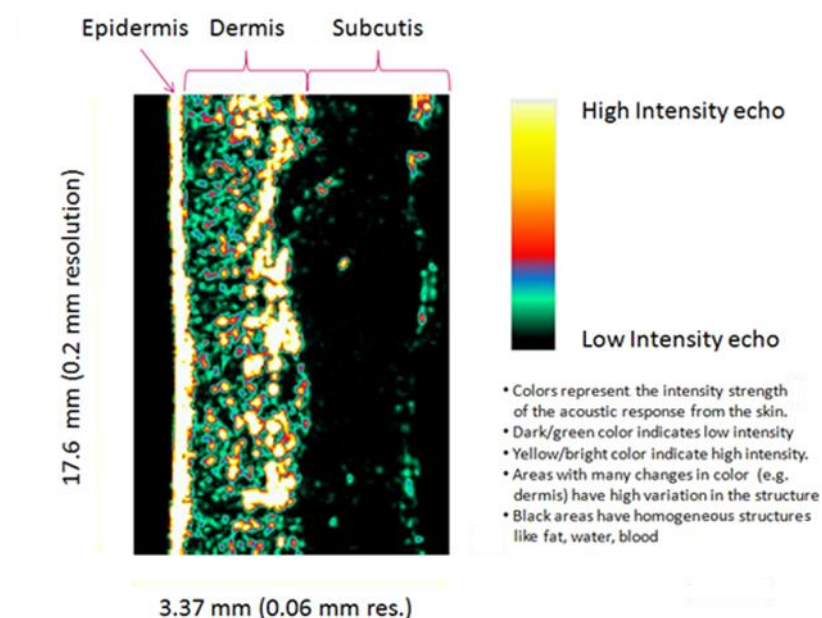


Figure 24 Explanation of ultrasound image

In the ultrasound image you can see the window and 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.

4.1.5 Avoiding Artifacts

Figure 25 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 window on the probe is clean and has a thin layer of well distributed gel or a thin layer of water before making the scan.

shows an ultrasound image with well distributed gel.

Air bubbles between the probe tip and epidermis will create a black shadow in the ultrasound image. Re-apply gel or water and make new image

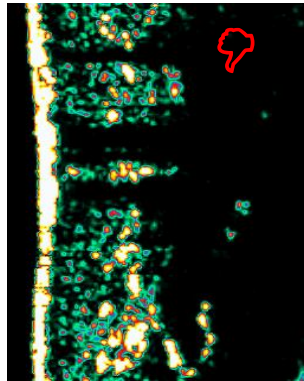


Figure 25

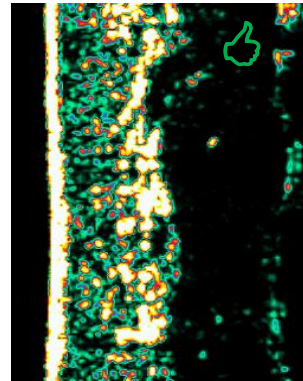


Figure 26

It is important to ensure 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 window may often be released by gently tapping the probe.

4.1.6 Gel layer thickness

Avoid too much gel between the tip of the probe and the skin. A thin gel layer secures good acoustical contact between the tip of the probe and the skin.

Too much gel results in a bright line in front of epidermis (i.e. two bright lines, see Figure 28) with a black gel layer in between. The first bright line represents the acoustic echo from the plastic window at the tip of the probe and the second line is the epidermis.

Preferably, the gel (or water) layer should be so thin that the acoustic echo cannot be distinguished from the window and epidermis, resulting in the image displaying only a single bright line (See Figure 27).

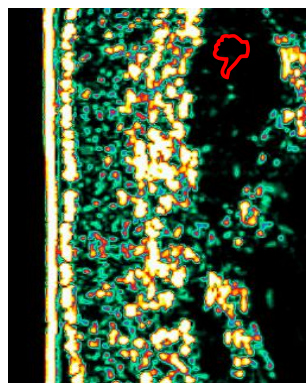


Figure 28 Too much gel used

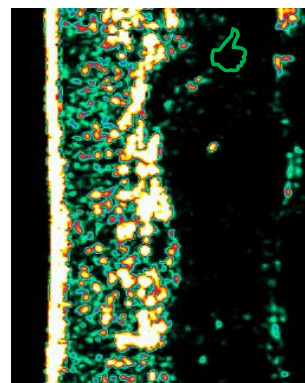


Figure 27 Appropriate gel layer

4.1.7 Maintenance

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

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

4.2 Moisture

The skin's moisture level is measured by using the Hydration Probe. This probe provides information about the hydration state of the skin 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).

The higher the hydration value is, the more hydrated is the skin. Several factors can influence the skin's hydration measurement. The amount of water intake has an influence on skin hydration as well as the use of any moisturizing cream.

A Moisture measurement consists of 3 measurements performed on the T-zone of the client and 3 measurements performed on the U-zone of the client, see Figure 29, and Figure 30.

4.2.1 Performing a measurement

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

Position the probe on the skin, exerting gentle pressure until a reading appears on the screen. Begin by measuring the T-zone (See Figure 29) followed by the U-zone (See Figure 30). All measurement results including the calculated averages for the two zones will be displayed on the "Moisture" page.

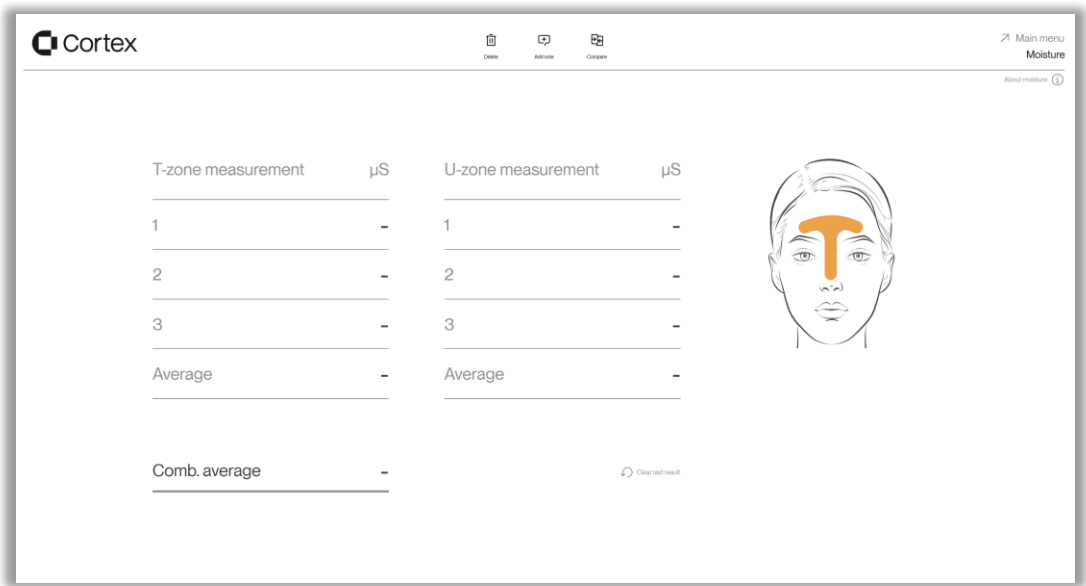


Figure 29 "Moisture" page with T-zone measurement indicator.

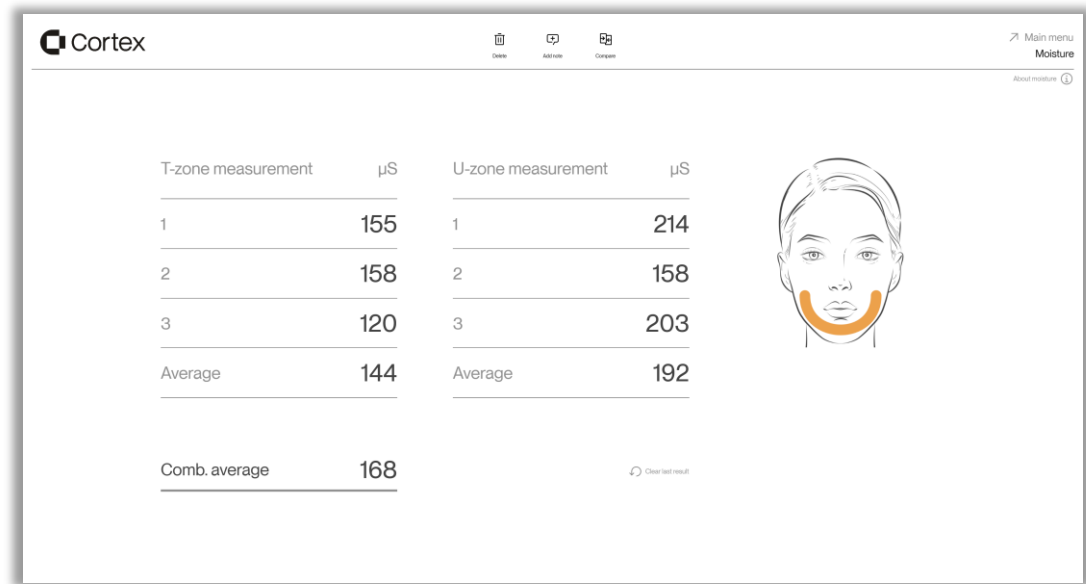


Figure 30 "Moisture" page with U-zone measurement indicator.

All results can be cleared by clicking "Delete" in the top menu. The last measurement performed can be cleared by clicking "Clear last result".

The two calculated averages will be displayed on the "Main menu" when measurements are done. If the two averages are close to each other, the combined average will be displayed on the "Main menu" instead.

4.2.2 Maintenance

To clean the Hydration Probe front, simply wipe it off using a dry cloth. Should more thorough cleaning be necessary, a drop of alcohol may be applied to the cloth.

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

4.3 Elasticity

The Elasticity Probe provides information regarding the skin's elasticity by measuring the retraction time of the skin.

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 blue section of the graph on the elasticity screen. The shorter the retraction time (R) is, the more elastic is the skin. The retraction time increases with age, as the skin loses its elasticity.

4.3.1 Performing a measurement

A measurement should optimally be performed on the client's temple.

The use of double-sided adhesive rings on the probe surfaces in contact with the skin is required to obtain reproducible results. See the probe and the adhesive rings in Figure 31. 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.

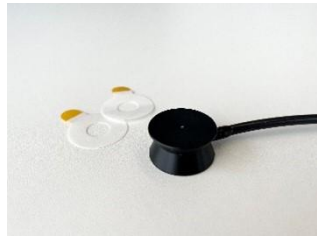


Figure 31 Elasticity probe and adhesive rings

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.

The elasticity measurement consists of 3 cycles and then outputs the average retraction time of the skin. See Figure 32. Results can be cleared by clicking "Delete" in the top menu. A new measurement can also be started overwriting the last by pressing the "Measure" button again. The average result will be displayed on the "Main menu".

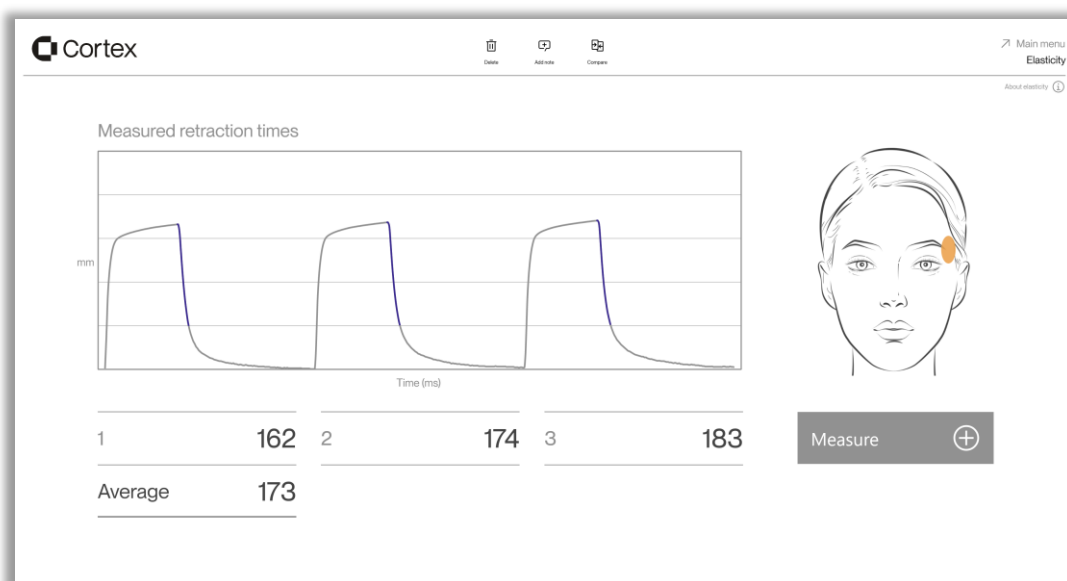


Figure 32 The "Elasticity" page.

4.3.2 Maintenance

Except for keeping the Elasticity Probe clean there is no preventive maintenance associated with the use of the 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).

4.4 Skin oil (sebum)

The “Skin oil” measurement is based on an instrumental approach to quick and accurate measurement of surface sebum by means of a sebum collecting strip and an integrated sebum reader module in the DermaLab® Aesthetic main unit.

After applying the Sebum collecting strip to the skin to gather sebum, insert the strip into the reader to measure the amount of sebum based on the film's translucency change.

4.4.1 Performing a measurement

The Sebum Module is placed on the right side of the DermaLab® Aesthetic main unit. This is where you need to insert the sebum strip.

For each measurement, a new sebum collecting strip is used, see Figure 33



Figure 33 Sebum collecting strips

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 before each skin application.

To perform the zero calibration, pick up an unused sebum collecting strip and insert it into the strip reader with the absorbing film side (the text side) facing down, See Figure 34 and Figure 35. The device automatically detects the presence of the strip and performs an offset calibration before it will ask you to perform the next step.



Figure 34 Strip insertion



Figure 35 The strip fully inserted

To perform the measurement, remove the strip from the strip reader and place it on the skin (e.g. in the T-zone, see Figure 29). Press firmly for a few seconds 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.

Re-insert the exposed end of the strip into the strip reader to measure the translucency changes of the film as a result of the absorbed sebum.

Wait for the reading to automatically appear on the screen.

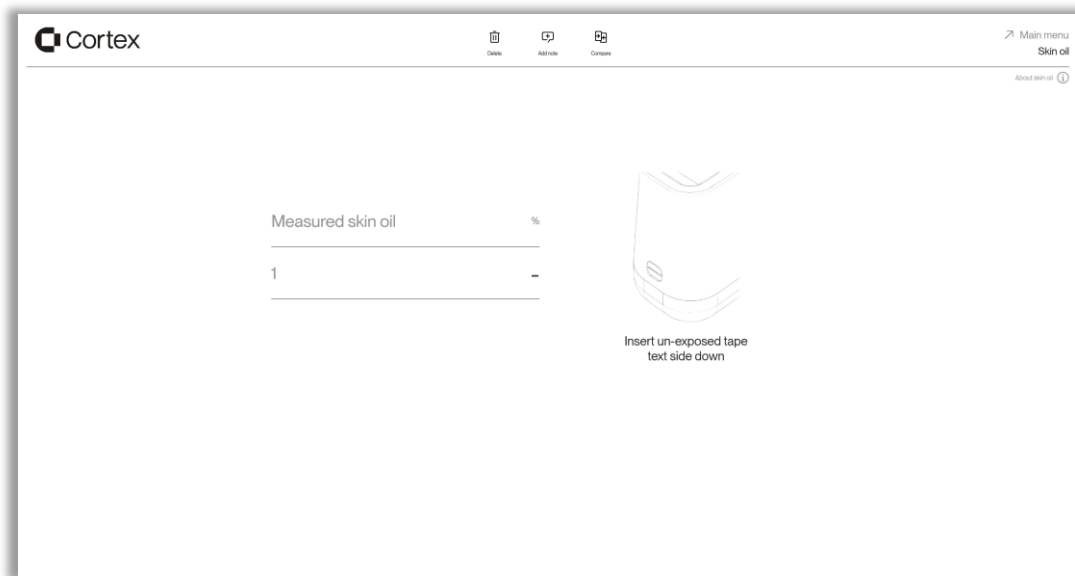


Figure 36 The "Skin oil" page.

The measurement result is presented on the screen as a sebum score of saturation of the film from 0 to 100, where 100 indicates very oily skin. See Figure 36.

A new measurement can be performed by pressing "Delete" in the top menu.

The result will be displayed on the "Main menu".

4.4.2 Maintenance

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

4.5 Skin pH

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

4.5.1 Performing a measurement

Each measurement is done by the following steps:

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

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

Results can be cleared by clicking "Delete" in the top menu. The result will be displayed on the "Main menu".

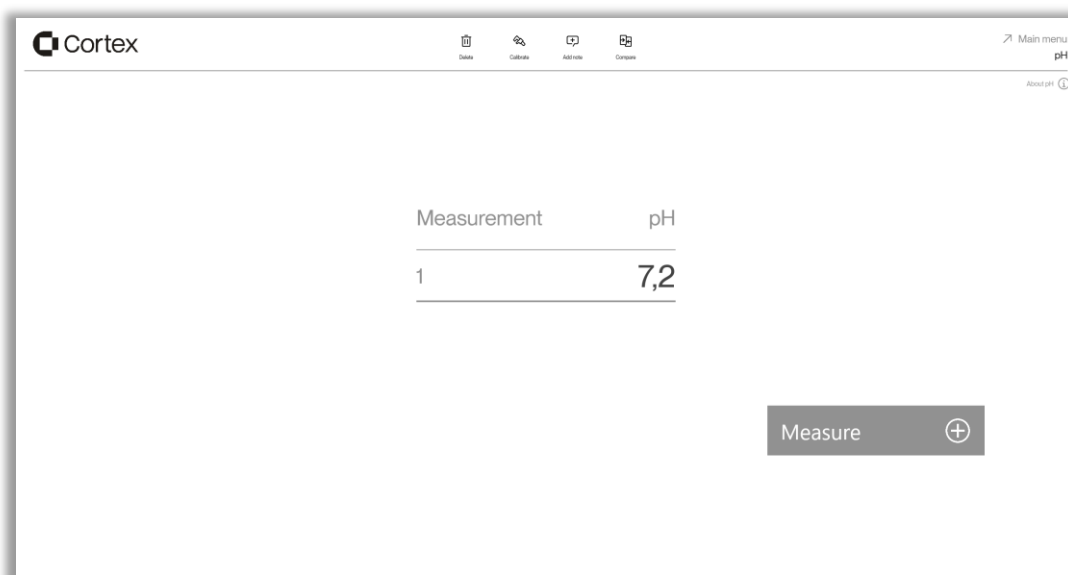


Figure 37 The “pH” page.

4.5.2 Calibration

A Calibration can be Initialized by pressing the “Calibrate” button at the top of the “pH” page and a pop-up will appear as shown in Figure 38.

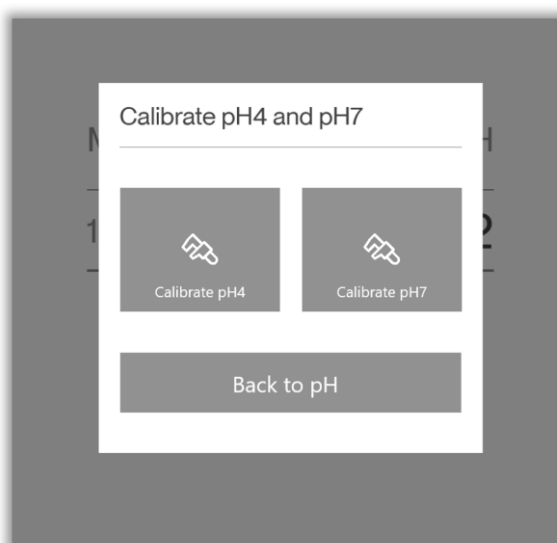


Figure 38 pH calibration screen.

The pH Probe should be calibrated regularly, at minimum:

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

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

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

- Calibrate the probe at the same operating temperature as the probe will be used at.
- Always calibrate the probe at pH 7.0 first and then at pH 4.0.

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

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

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

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

Please note each calibration can take up to 20 seconds.

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

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

4.5.3 Maintenance

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



Figure 39 The pH Probe properly stored in buffer solution

Most importantly be sure the probe is always stored in its holder and always covered by the KCl storage buffer solution. The tip of the pH probe must never dry out. See Figure 39.

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

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

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

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

If the probe dries out it may be recovered by placing the probe tip in a cup of tap water for 24 hours.

5 Data Storage

All data is stored locally on the pc. Data has been encrypted and cannot be used outside of the DermaLab Aesthetics Software.

Uninstalling the software will delete any stored data.

It is recommended to do regular backups through the system info page described in section 3.1.8.1.

6 Maintenance and service

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.

6.1 Calibration & Performance Check Certificates

Cortex Technology offers a special Calibration & Performance Check service to ensure that you can verify and document that all parts of the equipment are up to spec and calibrated in accordance with your internal quality assurance procedures.

Therefore, 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.

6.2 Service

Service and repair of the DermaLab® Aesthetic 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® Aesthetic is sent for repair at Cortex Technology, please note: Although we will do our utmost 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.*

7 Safety



The external power supply for the DermaLab Aesthetic 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.

8 Warranty

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

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

9 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: 266 (L) x 105,84 (W) x 138,53 (H) mm
- Power requirement: External 12 V DC power supply (included)
- Integrated probe holder.

9.1 Ultrasound Probe

- Ultrasound scanner using a rotating single element transducer
- Bandwidth (MHz): 14-26 MHz bandwidth
- 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.

9.2 Hydration Probe

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

- Method: pin electrodes
- Conductance: 0 – 9999 µS (1 µS resolution).
- Measurement frequency: 300 kHz
- 1 second measurement time
- Factory calibrated and linearized within the entire measurement range.
- Optional calibration checker available.
- Measurement uncertainty: ±5%

9.3 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: 400 mbar and skin thickness (in mm)
- Measurements: Retraction Time
- 10 mm diameter suction area
- Ultra-low weight (approx. 7 grams) for minimum measurement bias
- Adheres to the skin by double sided adhesive tape.



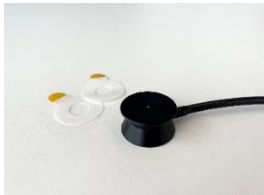


9.4 pH Probe

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

9.5 Sebum Module

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

10 DermaLab Aesthetic parts

Name	Picture	Item number
DermaLab Aesthetic main unit		C65001.xx
Elasticity Probe for DermaLab Aesthetic		C05600.xx
Elasticity double adhesive patch		V02001.xx
Hydration Probe for DermaLab Aesthetic		C06445.xx
Hydration pin calibrator		C06006.xx
Stand-off for hydration pin		M21010.xx
pH Probe		C07444.xx
Buffer for pH Probe (4 and 7 pH + storage)		C17441.xx (pH 4) C17443.xx (pH 7)

		C17442.xx (storage)
Sebum strips		V02002.xx
Aesthetic Ultrasound Probe		C08600.xx
Ultrasound Probe Head		C08601.xx
Ultrasound Probe Fill Valve		M26038.xx
Filling adapter		M08610.xx
O-ring for Ultrasound Probe Head		N16032.xx

Power supply (Adapter Tech., ATM036T-P120)		C44703.xx
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11 FAQ

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

General:

Q: *In the "Main menu", some buttons are greyed out and it is not possible to perform a measurement.*

A: - If a probe is not correctly attached, the related bar with the plus sign and the icon is greyed out indicating that the probe is not attached.

Specifically, regarding the Ultrasound Probe:

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.

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 demineralized water.

Q: *What does the image colors mean?*

A: - Colors are not tissue specific but relate to the energy of the reflected signal – black is minimal energy while white is maximum (high reflection).

Q: *Should I use water or gel as the coupling medium?*

A: - The use of water or gel is a matter of personal preference. Water spreads evenly and more easily, gel stays on the skin but is more likely to collect air bubbles.

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, regarding the Hydration Probe:

Q: *The DermaLab® Aesthetic measures skin conductance. What is the difference to skin capacitance?*

A: - Skin conductance is the skin's ability to conduct an electrical, alternating current as opposed to skin capacitance, which is the ability to accumulate an electrical charge.

As the cell fluids of the live epidermis are highly conductive, the dynamic range of the conductance measurement is mainly impacted by the water binding capacity of the stratum corneum.

Accordingly, the conductance measurement is more superficial and well defined compared to the capacitance principle, which goes deeper and to a higher extent incorporates both stratum corneum and live epidermal cells.

Specifically, regarding the Sebum Module:

Q: *Why is offset calibration on each strip necessary?*

A: - The offset calibration eliminates batch-to-batch variation on the strip to increase accuracy/reproducibility.

Q: *For how long do I need to press the sebum collecting strip against the skin?*

A: - The time is less important if all of the absorbing area on the strip is exposed. Spend a few seconds to roll your thumb over the back side of the absorbing strip, when pressed against the skin with moderate pressure.

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.



The crossed-out bin symbol indicates that the product, at the end of its life, should not be disposed of with other household waste. To protect human health and the environment it should be handed over to a designated collection point for the recycling of waste electrical and electronic equipment (WEEE).

B. Declaration of Conformity

EU – DECLARATION OF CONFORMITY

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

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

Name of product:

DermaLab® Aesthetic

Name and address of manufacturer:

Cortex Technology Aps,

Niels Jernes Vej 6B

9220 Aalborg Ø,

Denmark.

Tel.: +45 98574100

E-mail: cortex@cortex.dk

Implemented standards:

DS/EN 61000-6-1:2019

DS/EN 61000-6-3:2021

DS/EN 61010-1:2010 + AMD1:2016

DS/EN 61187:1995

DS/EN 50419:2022

Place and date: Aalborg 2024/04/19 Signature:



