

Dermus SkinScanner-U

User Guide



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Attention!

Please regularly check if there is an updated version of this document. The up-to-date version is always available on the following link (also accessible using the QR code on the label of the device): dermus.app/manual.

Manufacturer

Company name: Dermus Ltd. Address: Kanizsai utca 2-10 C/11, H-1114 Budapest, Hungary Website: www.dermusvision.com

ISO 13485 compliance

Dermus Ltd. has established and maintains a comprehensive quality control system according to the requirements of the EN ISO 13485: 2016 + A11: 2021 standard.

This system and the technical documentation are reviewed periodically.

Certification body: DNV, Oslo, Norway, which participates in the conformity assessment.

EMC compliance

This device can generate and radiate radio frequency energy. The device can generate radio frequency noise to other radio frequency communication equipment.

The *Dermus SkinScanner-U* (hereafter: *SkinScanner*) complies with the rational limitations of the standards listed below.

Conducted and radiated RF emission	EN 60601-1-2:2015,
	EN 55011:2016+A1:2017, Class A

If this device is installed in a more unfavorable environment, it may be subjected to electromagnetic interference.

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Symbol descriptions

Symbols used in this User Guide

Special	It draws attention to situations that, if not avoided, could result in an
attention!	injury or damage to the user, subject, subject data, or the device.

Attention! It draws attention to situations that, if not avoided, could affect the usability and applicability of the device, but do not affect the safety of the investigator, subject, subject data, or of the device itself.



Mandatory action.

It draws attention to an action that must be taken in order to avoid a hazard.



Prohibition.

It draws attention to a prohibited action to avoid a hazard.



Warning.

It draws attention to a hazard or information about proper operation.

Safety precautions

Attention!

Make sure that the device is not subjected to strong mechanical impact (e.g. dropping). If the device is damaged, does not work according to the specification, or becomes dangerous, disconnect the device from the host (power source), suspend its use and notify the manufacturer's authorized service person immediately.

Implementation of the ALARA principle: Since shielding is irrelevant for ultrasound imaging of the skin with the *Dermus SkinScanner* device, and a fixed minimal distance of 19 mm is structurally kept between the ultrasound transducer surface and the surface of the skin, the ALARA principle is implemented and maintained by keeping the number of inspections on a specific skin area of a specific patient as low as reasonably achievable, as cautioned in the Contraindications (see below).



Special Attention!

In the case of any serious incident that has occurred in relation to the device, report it to the manufacturer.

General cautions



Special attention!

Direct mechanical radiation emitted by the device can be dangerous to the eye.



Special attention!

Do not use the device to inspect the skin of the eyelid.



Special attention!

Do not use the device to check bleeding or purulent skin surfaces. Do not touch the device to such surfaces.



Special attention!

Avoid unnecessary usage of the device.



Special attention!

Keep the number of inspections on a specific skin area of a specific subject as low as practically possible.

1. Introducing Dermus SkinScanner

1.1. See Deeper. Care Better

Dermus SkinScanner is a portable skin ultrasound imaging device. The device is capable of creating a depth image of a skin section positioned with the aid of real-time optical image guidance showing the surface of the skin area to be inspected. Imaging is based on the high-frequency ultrasound reflection properties of the structures of the tissue.

1.2. Intended use

The *Dermus SkinScanner* is intended to visualize the layers and lesions of skin tissues.



Special attention!

The *Dermus SkinScanner-U* is a device for research purposes only, not a medical device. It cannot be used for diagnostic purposes on human subjects.

1.3. Principles of operation and role of software component

The ultrasound imaging of the Dermus SkinScanner relies on the well-documented pulse-echo principle. The high-frequency, single-element transducer is moved by a motor to produce full-frame images. Optical guidance of the scanning is achieved by an LED-illuminated camera looking at the same position where the ultrasound imaging works. The device is USB-powered, and the main image processing is carried out on a third-party host computer (ie. Android-based device). Dermus SkinScanner technically comprises a web application software component as a display and annotation interface (dermus.app/capture), which was developed to receive ultrasound- and optical- frame pairs and cine-loops from the device through USB. It displays the captured skin record pairs and the user is able to step between the framepairs.

Note: while the *Dermus.app/capture* web-application is an essential component of the device to achieve its main function as an image displaying tool, it can be executed on any computing device with a browser and internet connection. It works in such a way that network connection is necessary only to load the software, while captured data remains in the memory, without a bi-directional network communication. To archive the captured data, the user can download it from the memory as still images, cine-loop video or a pdf report. Alternatively, the user can export and upload to a different image catalog and cloud storage software, called SkinAid, which is not part of this device, but an optional accessory.

Since the software component of Dermus SkinScanner is not offering cloud storage (but the separate *SkinAid* application), we do not store any data for long term in this product, image archiving is only achieved by exporting the data. In this way, captured images can be rewatched in this application only after the live capturing (inspection), before starting a new capturing session. Furthermore, this software component is not storing any sensitive information or personal data.

No special network-connection- or cybersecurity-related compliance obligations apply (such as IEC 80001-2-2:2012) regarding the software component (Capture app) of Dermus SkinScanner.

1.4. Device parts, packaging and recommended accessories

The parts and recommended accessories of the product are presented in the scheme (figure) below.

The *Dermus SkinScanner* device itself, including its removable applied part, and its display and management tool: *dermus.app/capture* web-application. These parts are physically or technically separable from the recommended accessories and from the catalog system web application (*skinaid.app*).

The packaging of the device, including the labels of the packaging, are standardized and tested to maintain safe shipping and storage of the device and its recommended accessories. The recommended accessories (see Section 1.5 below) which are intended to be used in combination with the device are not parts of the device but can be parts of the package sent to a user.



Parts of the device



Button functionalities

The user can provide the following control inputs via pressing the buttons of the device:

- Short press of the "start/freeze" (top) button: Scanning starts or stops (freeze).
- Short press of the "navigation" buttons (left and right): Select the previous (left button) or next (right button) frame for display.
- Long press of the "navigation" buttons (left and right): Step multiple frames back (left button) or forth (right button) for display. The speed of stepping increases with the time the button is being pushed for.
- Short press of the "save frame" button (bottom): Select the frame (currently on display) for saving. (Please note that the selected frame will actually be saved only upon completion of the saving procedure described in Section 3.5. Saving results into *SkinAid Catalog* below.)

Feedback light states

The color of the feedback light (placed beside the control panel) provides visual feedback to the user about the state of the device:

- Cyan light: The device is currently connecting to the MCU (Mobile Computing Unit, see Section 1.7 below), and getting power from the MCU.
- Green light: Scanning is in progress.
- Blue light: Scanning is frozen (stopped).
- Magenta light: Firmware update mode (indicates critical phases of firmware update; make sure that the cable connection between the device and the MCU is stable during this part of the firmware update).



Special attention!

Make sure that the cable connection between the device and the MCU is stable during firmware update (especially during the part of the update indicated by the red color of the feedback light).

1.5. Recommended accessories

Additional accessories needed to use the device:

- MCU as host device (Mobile Computing Unit) e.g. exclusively prepared host smartphone, bearing an USB connector complying at least USB 3.0 standard, optionally with a magnetic phone case for physical attachment. Host device is a user interface and energy source to be able to use and control the SkinScanner device and display the results of imaging. For required certifications, please see Section 1.7.
- **USB cables** (USB C-C) complying at least USB 3.0 with standard USB-C male connector is required to connect the device to the host.
- **Refillable flask** with **distilled water** to fill the water chamber of the device.
- **Ultrasound gel** CE marked, biocompatible and non-expired; for conducting the ultrasound inspection.
- Water refill stand to guarantee convenient water refilling process.
- Cardstock **quick start guide** one-pager handout, to help the user during first use of the device.
- Paper box, with foam insert (for storage and transport) / **Textile bag** to facilitate device storage and in-house transport.
- **Paper towel** and **alcohol** to clean the device (usually not included).

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Note that the above recommended accessories are separate devices from the Dermus SkinScanner, and are certified in their own right.

1.6. Packaging

Dermus Ltd. provides proper durable packaging, which also functions as a case. The user can use this case for storing and carrying the device until the end of its lifetime.

The user can also use the textile bag as a recommended accessory for carrying the device.

1.7. Host (MCU) device

A host device or MCU (e.g. exclusively prepared host smartphone) is referred to a device that includes USB connection, power supply, user interface, internet connection and a WebUSB-compliant web-browser access (e.g. Google Chrome, Microsoft Edge).

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Although it is technically possible to use several types of smartphones, personal computers or tablets as host devices of the SkinScanner, it is strongly recommended to use the MCU (Mobile Computing Unit, a dedicated, prepared smartphone) provided by Dermus Ltd for the most reliable and best user experience.



Attention!

For reliable user experience, the recommended host device to be used is the MCU provided by Dermus Ltd.

The host device can be connected to SkinScanner through USB port A or B (see the second figure – Parts of the device – in Section 1.4). Host devices with a port that can also be used for charging the device (e.g. smartphones, tablets) shall always be connected to port A of SkinScanner. Other devices (e.g. most personal computers) can be connected either via port A or port B.



Attention!

MCU host devices shall always be connected to port A. (Port B is kept primarily for service purposes.)

It is not mandatory to use the host device and the SkinScanner as a compact unit. It is possible to place the host device apart from the SkinScanner body (with USB connection maintained) and perform the imaging in that way. The physical attachment of a smartphone MCU host device is an option for enhanced point-of-care usability and portability.



Attention!

Do not plug any charger into any of the USB-C ports of the SkinScanner device.

Minimum requirements for the MCU (or other) host devices:

- USB 3.0 certified connector
- Android 10 or later (Windows 7 or later)
- Web browser with WebUSB compliance (e.g. Google Chrome, Microsoft Edge, Samsung Internet, Opera)
- Internet connection
- max 7nm octa-core Snapdragon (Intel Core i5-5300U CPU or similar)
- 4 GB of RAM
- Min. FHD (1920x1080p) display resolution
- Certified according to IEC 60950 and/or IEC 62368

2. Filling the water chamber

The chamber behind the inspection window needs to be filled with distilled water for acoustic coupling required for proper ultrasound wave propagation. The water filling needs to be performed at the beginning of each day of use, before the first use of the device on that day, and the water shall be removed (poured out) at the end of each day of use, after the last use of the device on that day.

It is important to always use distilled (or demineralized) water. Using saline or regular water can damage the ultrasound transducer. Also, always empty the water chamber at the end of the day to prevent growth of biological contamination that could blur the lens and ruin the optical image.



Attention!

Please perform the water filling process at the beginning of each day of use, and remove the water from the device at the end of each day of use.



Attention!

Please always use distilled (or demineralized) water for filling the chamber.



Attention!

If the casing contacts with a significant amount of water outside of the inspection window area (patient part), disconnect the device from the host (power source), suspend its use and notify the manufacturer's authorized service person.

Tools and materials used for bubble discharge

Tools:

- Dropper bottle
- Device stand

Material:

• Distilled (demineralized) water

Bubble discharge process

The dropper bottle is intended to refill the inner chamber with distilled water.

The device stand is meant to hold the device securely in parallel to the ground as shown in the image below.





1. After placing the device on the stand, remove the applied part cap closing the water chamber by turning it counter clockwise by ~45°.



2. Use the dropper bottle for refilling. Aspirate approximately 18 ml of deaerated (as treated with a vacuum chamber or via boiling) distilled water. Be slow and patient while filling, as rushing may cause foaming that would lead to out-of-focus bubbles appearing in the optical image.



Attention!

Air bubbles could stick under the internal glass plate. Take care of removing all visible bubbles from the water chamber as they can degrade optical and ultrasound image quality. Removal is also possible via rotating the device a bit during the first half of the refilling process.

3. Distilled water should be added to the inner chamber until a dome-shaped pool of water forms on top.



4. You may apply a small amount of gel around the edges of the chamber as a lubricator to eliminate friction of the cap while closing the vent.

5. If there are no more bubbles in the chamber, close the vent by carefully fitting and tightening the cap via turning it 45° clockwise.

Put on the cap while applying a mild pressure with your finger on the membrane to prevent any bubbles from being trapped inside.





6. Turn the device around to check for hidden bubbles. Small bubbles (smaller than approximately 1/4th of the window) are acceptable. If you see any larger bubbles, unscrew the cap, add a little more water, and close the cap again as instructed.

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A few drops of water might trickle out when closing the water chamber. This will not damage the device, as the casing is drop-resistant.

However, pay attention to not let water trickle into the USB port of the device.

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Attention!

At the end of each day, please remove the water from the chamber. Leaving water inside for an extended period of time can cause image quality degradation.

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Attention!

Let the water chamber of the device dry out after removing the water. For an extended period of inactivity, please store the device with an empty and dry water chamber.

3. Recording Workflow

The SkinScanner device uses a web application as a user interface. This interface needs user registration. Both the *SkinAid Catalog* and the SkinScanner Capture products of Dermus Ltd. use a web application user interface, and both software products can be used with the same user profile logged into the system. For more detailed instructions regarding user registration and login, please refer to Section 2 of our **SkinAid User Guide**.

The registration is made via the *SkinAid Catalog* web application (**skinaid.app/signup**). Users already registered on our *SkinAid Catalog* platform can log in to the user interface software with their credentials.

3.1. Steps prior to inspection

In order to use either the SkinScanner Capture or the *SkinAid Catalog* applications you need to be logged in to the system. You can log in to the system via either of them.

 Please access our web application via the pre-installed shortcut icon on the MCU home screen or by pressing the "SkinScanner" shortcut button (see the button highlighted by a yellow circle on the image below) in the SkinAid Catalog user interface (www.skinaid.app) or via the URL https://www.dermus.app/capture.



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It is recommended to always open the application via the shortcut button. Use the URL only if the shortcut is not yet created. 2. If you are not logged in yet, log in to the SkinScanner Capture application by selecting the 'Login' button on the screen. A dialog will be presented where e-mail address and password can be entered.



3. Plug in your device and click on the button with the 'Pair Dermus Camera' text.



4. Select 'Dermus Camera' and click 'Connect' on the pop-up window.

DE	https://www.dermus.app wants to connect	
10	Dermus Camera	
(e)		
٢	Get help Connect	
	PAIR DERMUS CAMERA PAIR DERMUS ULTRASOUND	

5. Click 'OK' to allow Chrome access to Dermus Camera.

DD	Please plug in your Dermus device and allow access to Dermus <u>Camera</u> and	
	<u>Ultrasound</u> .	
	Chrome	
•	Allow Chrome to access Dermus Camera?	•
	CANCEL OK	
4	PAIR DERMUS CAMERA PAIR DERMUS ULTRASOUND	

6. Repeat steps 3-5 for 'Dermus Ultrasound' connection.

DE	https://www.dermus.app wants to connect	
10	Dermus Ultrasound	
La La		
٢	Get help Connect	
•	PAIR DERMUS ULTRASOUND	
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DD	Please plug in your Dermus device and allow access to Dermus <u>Camera</u> and <u>Ultrasound</u> .	
	Chrome	
٢	Allow Chrome to access Dermus Ultrasound?	•
•	PAIR DERMUS ULTRASOUND	

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Note that steps 4–6 (and the related action of step 5) are needed to be performed each time when connecting the device to a smartphone MCU.

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Note that the order of connecting the 'Dermus Camera' or the 'Dermus Ultrasound' first does not matter.

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While the Capture screen (**dermus.app/capture**) is on display, it puts the screen of the host device into 'always on' mode. The host device screen will not turn off automatically while the capture is open.

Attention!

Please always make sure that the host device is charged to at least 20% before taking inspections.

3.2. Capture screen layout

The Capture screen displays an optical (surface) and an ultrasound (depth) image of the skin, next to each other. The screen also contains a navigation bar (left side), a taskbar (right side) and other functionalities and information.



Capture screen during an ongoing recording process.



Capture screen after stopping a Recording (Frozen state).

Contents of the user menu

The user menu can be opened by clicking on the user button (with the user's initials) at the top of the navigation bar on the left. It is marked as '1 User menu' on the first figure of Section 3.2 above).

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profile	
[→	
logout	

The 'profile' option redirects to the Profile page (https://www.skinaid.app/settings) where it is possible to delete the profile of the user, change the password of the account, or change the email address of the account.

The 'Logout' button logs the user out of both the SkinScanner Capture and the *SkinAid Catalog* applications.

Contents of the hamburger menu

The hamburger menu is located at the bottom top of the navigation bar on the left. It is marked as '4 Other tools' on the first figure of Section 3.2.



About

This button redirects to the About screen, where information about the connected device and the application itself is provided. The following links and documents are available:

- User Guide of SkinScanner
- Terms and Conditions
- Privacy Policy
- Release notes of the SkinScanner application
- The webpage of Dermus Ltd
- Technical information about the connected SkinScanner device

TD	About		
10	User Guide		
	Terms and Conditions	Privacy Policy	
Þ.	Connected Device		
	Serial number: N/A	Current Firmware Version: N/A	•
	Current version of this web app: R2403 About Dermus	Release notes	
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Feedback

It is possible to send direct feedback to the Support team of Dermus Ltd. through the application. Use this option to report any issues which arise during using our products.

This is by far the most efficient way of reporting issues.

When the 'Feedback' button is pressed, a screenshot about the current status of the application is made, which is by default automatically attached to the feedback. Although there is an option to not include the screenshot to the feedback report, it is strongly recommended to keep it included for any kind of feedback. Please also fill out the 'Description' and 'Conditions' fields to your best knowledge so that our Support Team can address the issue as accurately and quickly as possible. In the 'Description field, please describe your feedback or issue or ask. In the 'Conditions' field, please write a few notes about the circumstances (e.g. what has been done before this issue appeared; any environmental conditions that may be of relevance; did it appear uniquely and unexpectedly or is it a recurring experience; etc.).

As it can be seen on the feedback screen, additional metadata are also logged and sent to our Support Team to facilitate discovering the circumstances and finding the best solution as soon as possible.

TD	Send feedback	We will automatically log the following data:
NOII Die	Description Please describe your issue in a few sentences. Was this a one-off issue, or recurring?	Date: 23.04.2024. 13:07:57 Logged in user: Test Dermus Test App version: R2403 Serial number: Firmware version: Operating system: Windows 10 Browser version: Chrome 124.0.0.0
	Conditions Please describe what you were doing before this happened.	Include screenshot
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To finish, click on the 'Submit' button to send the feedback.

Support

Clicking on this button opens the Dermus Academy (https://dermus.atlassian.net/wiki/spaces/DOC) page on a new tab. See Section 4.3. 'Support Options' for more information.

Preferences

Selecting this opens the User Preferences screen where settings of options regarding the behavior of the web application are available. These options belong to one of three categories:

- General behavior
- Annotation
- Capture screen

ET	User preferences	
	General behaviour	Capture screen
i) about	 Set all dialog visibilities Dynamic ruler coloring Include Opt-US guideline in downloaded 	Pan up ultrasound image to hide membrane
æ	images	0,0 between 0 and 5 (mm)
feedback	🗹 Include Header in downloaded images	* virtual effect without deleting data
⑦ support	Annotation Show RGB/intensity values on annotation	Recorded loop length
preferences		Preset gain on modalities
		optical
full screen		ultrasound
=		✓ sharpen optical image ☐ display ultrasound image center

Here is a detailed explanation of the contents of the three categories:

- General behavior
 - **Set all dialog visibilities:** show/hide the following dialogs:
 - dialog asking to start Capture from the current level or from scratch (not assigned to any patient/lesion), see Section 3.6 (Access to capture screen directly from SkinAid);
 - dialog asking to rotate the phone on the Capture screen if it's held vertically (it is expected to start the recording with the MCU screen held horizontally).
 - **Dynamic ruler coloring:** adjust the color of the rulers on images for better visibility. (If selected, parts of the ruler will appear in either black or white color depending on the local image background being brighter or darker than a certain threshold, to give the highest contrast available.) Note that this might slow down the application.

- Include Opt-US guideline in downloaded images: set whether to show or not the red line on the optical image and the red triangle on the ultrasound image (both indicating the relative spatial position between the ultrasound and the corresponding optical image) on the downloaded images. This affects only the image download functionality, see "Download images" in Section 3.4 Other functionalities. Note that it is recommended to set this option On to have this information on the downloaded image pairs.
- **Include Header in downloaded images:** set whether to include or not the header with timestamp and optional patient data on the optical and ultrasound images exported using the direct download function. This affects only the image download functionality, see "Direct download" in Section 3.4 Other functionalities. Note that it is recommended to set this option On to have this information on the downloaded image pairs.

• Annotation

• Show RGB/intensity values on annotation: allows for displaying pixel intensity values using the annotation tool (for the use of this tool, see "Annotation" in Section 3.4 Other functionalities). Note that this is an advanced tool, not part of the default tool set. If selected, the echo intensity values or the RGB (red/green/blue channel) values will be displayed in a field on the image for all of the points selected by annotation marks of the ultrasound or optical images, respectively.

• Capture screen

- **Pan up ultrasound image to hide membrane:** the ultrasound image on the Capture screen is panned up by default with the given amount. This tool can be used for example to hide the reflections from the membrane or to look at a deeper region within the subject by default (when starting the scan).
- **Recorded loop length:** offers an option to raise the limit of recorded frames in a cine-loop from the default 100 to 300. The higher number of frames may be needed for longer inspections (eg. lesion margin inspection) whereas the default limit ensures easier stepping between individual frames when reviewing the recording using the frame slider and also ensures quicker saving of the loop.
- **Preset gain on modalities:** these default gain settings will be applied to the images on the Capture screen. Please note that the images will be recorded with the gain settings presented here or altered during the scanning. Please refer to "Image adjustments during data acquisition" in Section 3.3 for further information about gain settings.

- **Sharpen optical image:** apply a sharpening algorithm to the optical image for better image quality.
- **Display ultrasound image center:** offers an option to display the centerline of the ultrasound image and the corresponding point on the optical image (middle marker on red positioning line) during and after recording. This further aids orientation and precise positioning.



Full screen mode

It is recommended to use the platform in 'Full screen' mode. Doing so, not only the images will be displayed in larger frames, but the MCU will be disabled from going into 'screen saving' mode during scanning. In order to enter / exit 'Full screen' mode, press the button located in the hamburger menu (item 4 on the layout image).



3.3. Skin ultrasound image recording

The recording process is as follows:

1. For good recording quality, apply an at least ~0.5 cm thick layer of ultrasound gel to the membrane of the device's inspection window, covering the whole circular window.

Special attention!

Use only CE marked, biocompatible and non-expired ultrasound gel.



Attention!

Use only clear - optically fully transparent - ultrasound gel.



Attention!

Be careful not to let any air bubbles in the gel crossing or touching the red line on the optical image displayed on the recording screen while scanning. If you see a bubble near the line and you are unable to reposition or remove it, repeat the application of the gel to the membrane of the inspection window.

2. Place the ultrasound-gel-lubricated inspection window of the device to the skin area to be inspected so that the area between the inspection window and the skin surface is completely filled with the gel.

3. Start recording either by clicking on the 'Unfreeze' button in the application (located at the top right, on the taskbar) or by pushing the top 'Start/Freeze' button on the physical control panel of the device. Notice the feedback light turning into green while scanning/recording (see Section 1.4. 'Device parts, packaging and accessories').



Use the real-time optical image displayed on the screen to position the device so that the top view axis of the depth section to be inspected is aligned with the optical-ultrasound guideline (red line) on the optical image as shown in the images below.



The optical ultrasound guideline is not aligned with the lesion yet. (Note also the reflection from the air bubble at around the middle of the red positioning line and the acoustic shadow beneath it on the ultrasound image.)



The optical-ultrasound guideline is aligned with the lesion, so the lesion can be seen on the ultrasound image as well.

4. After aligning the red line on the lesion to be inspected on the display, click on the red 'Freeze' button either in the navigation taskbar (top right) of the web application screen (top right) or on the control panel of the device (top button).Notice the feedback light turning into blue while scanning/recording is stopped/'frozen' (see Section 1.4. 'Device parts, packaging and accessories').

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Note that the maximum number of image frame pairs to be shown on display (to be stored in the loop, and to be saved at a later stage) is 100. A frame counter appears below the ultrasound image during scanning. From and above 80, the number turns red to draw the attention of the user into soon reaching the limiting 100. Above 100, new frames are still being recorded, but overwriting the first frames so that the last 100 frame pairs will be retrieved/recorded.

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Note that the optical and ultrasound images may have different frame rates. The frame counter and the slider both reflect the numbers of ultrasound images. For each frame pair, the optical image recorded closest in time is assigned to the given ultrasound image frame.

Internet connection during inspection

If the internet access is lost during the data acquisition process, the following message will appear at the bottom of the screen.



If the connection is restored, the following message will appear. The message will automatically disappear after 6 seconds of successful internet connection establishment, however you can manually close the message before that by clicking on the 'x' button at the right end of the message window.




Attention!

New recordings can be started only if the host device is connected to the internet.



Special attention!

Make sure to implement both hardware and software firewalls to protect your network from unauthorized access.



Special attention!

Use reliable antivirus and antimalware programs to detect and remove malicious software on your host device (MCU).



Special attention!

Secure your Wi-Fi network with a strong password and encryption, and consider using a Virtual Private Network (VPN) for secure internet browsing.



Special attention!

Keep your operating system, applications (web browser), and firmware up to date to protect against vulnerabilities.



Special attention!

Do not use any browser extensions on your host device without consultation with Dermus.



Special attention!

It is strongly recommended to not leave the host device alone with the Dermus applications in a logged-in state. It is recommended to log out before leaving the device on a site, where unauthorized persons can access it.

Image Adjustments during data acquisition

In order to perform an image adjustment, please click on the Gain adjustment button (located top right, next to the ultrasound image frame). Please note that both the Ultrasound and the Optical Images can be adjusted, separately. Select the modality you want to make adjustments on by clicking on it. The selection is indicated by a thin light blue frame around the selected image. Note that the Ultrasound image is selected by default whenever you start image adjustments. If you would like to adjust the brightness of the Optical image, please select the Optical image before moving the slider.



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Note that these image adjustments will be applied globally, for every frame of the actual recording.

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Note that the image adjustments can be performed either during or after scanning, but with different outcomes. When adjusted during scanning, the Optical image gain will set the exposition time of the camera and record the images accordingly. When adjusted after scanning, the gain setting adjusts the brightness for display of the given image information.



Attention!

Be aware that the Optical gain setting has different effects during and after scanning. During scanning it affects the data themselves; while after scanning, it only adjusts the display. Make sure to perform the scanning with the desired setting.



Brightness level / gain can be modified for both the Ultrasound and the Optical image. It can be modified using the slider, for one of them (the one highlighted with a thin light blue frame) at a time. It can be increased or decreased by moving the slider up or down on the scale having 9 levels in total.



Gain adjustment on the ultrasound image.



Gain adjustment on the optical image.

The default level of brightness/gain can be set in the User Preferences (dermus.app/userpreferences). See "Preferences" in Section 3.2 above for more information.



Color Switch

By pressing the "Color switch" button, the display of the Ultrasound image can be switched between colorized and grayscale representation.

(The colormap switch function is specific for – only applicable on – the Ultrasound image.)



Echo Intensity

It is possible to display or hide the echo intensity label of the Ultrasound image by pressing the button at the bottom of the adjustment panel.

(The echo intensity label is again specific for the Ultrasound image.)



High Resolution / High Depth imaging

There is an option to switch between high resolution ('HR') and high-depth data ('HD') recording. 'HR' results in an image with greater resolution and more details in the more superficial areas of the skin, but does not provide as much information about deeper layers; 'HD' allows the visualization of deeper structures but with lower resolution.

To use this functionality, click on the 'HR'/'HD' button on the bottom of the page during an active scan. Note that 'HR' is the default recording mode.

Every recording has an 'HR'/'HD' flag on its ultrasound image(s) indicating the mode in which their data have been recorded.



Recording with high resolution ultrasound image



Recording with high depth ultrasound image

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Please note that when the imaging mode is changed, the frames made in the previous mode will be lost and the frame counter is reset. A loop of images can be recorded in either 'HR' or 'HD' mode (being applied for all of the frames of the recording).



Attention!

Make sure to perform the scanning in the desired ultrasound imaging mode. (The data recorded in one of the modes can not be changed afterwards.)

Highlight a modality

The modality highlight feature makes it possible to view only one of the modalities, such that the selected modality is enlarged over the screen.

Click on the 'Expand'/'Collapse' button in the top right of either the Optical or the Ultrasound image to enlarge it. Click on the button again to return to normal view.



Zooming and panning the images

The images can be zoomed, and when zoomed in, panned for more precise inspection the following ways:

- on touchscreen: zoom and pan by two-finger gestures
- with a mouse: zoom by scrolling with the wheel of a mouse, pan by pressing the wheel of the mouse and moving the mouse

• with a touchpad of a laptop: zoom with two fingers, pan by pressing down the Ctrl key then double-tapping on the touchpad with one finger (or holding down the left 'mouse' button), then moving your finger.

The ultrasound image can be panned up and down even when it is not zoomed in, because a 12 mm depth is recorded, but only 10 mm of it is shown at a time. To change the default position of the 10 mm window that is displayed of the 12 mm data, use the "Pan up ultrasound image" setting in the User Preferences (see "Preferences" in Section 3.2 above).

3.4. Other functionalities

As shown on the first figure in Section 3.2 Capture screen layout, image analysis tools can be found below the Optical image. These tools are also available in the *SkinAid Catalog* platform, so that you will be able to make analysis on the images later, if they were saved. The results of image analysis can be saved and shown in *SkinAid Catalog* if the corresponding frame pair is saved.





Note that the active image analysis tool is always indicated by showing its icon in red.



Annotation

The user can mark out lesion borders or any other structures in the given image by using the annotation functionality of our software. You can make annotations on both the Optical and the Ultrasound images.



In order to select annotation points, tap the 'Annotation' button, then select points on the Optical or on the Ultrasound image. Selected points are indicated with markers. When a point is selected on the Ultrasound image, a corresponding marker (projection) appears on the red Ultrasound image slice position indicator line of the Optical image. It is possible to simultaneously have up to seven annotation points on the same Optical and also up to seven annotation points on the Ultrasound image.

Results of annotation made on a particular frame can be hidden and displayed again by tapping on the 'Annotation' button.

Annotation results can be modified by dragging, moving and dropping the annotation markers.

Any annotation marker can be deleted by dragging and dropping it onto the bin icon which appears whenever a marker is moved.



The results of annotation will be saved in the *SkinAid Catalog* database and can be viewed on the Record Review page if you save that particular frame (see Section 3.5 for uploading frames).

Distance measurement

This option contains two sub-filters: distance measurement and volume estimation, and it is available for optical-ultrasound frame pairs and cine-loops.

Upon clicking on the Distance Measurement button in the filter toolbar, the distance measurement will become active, by default. Switching to volume estimation mode can be done by clicking on the button located on the upper right corner of the ultrasound image. A second click on that button switches back to distance measurement mode.



Distance measurement mode is active, the button switches to volume estimation

Volume estimation mode is active, the button switches to distance measurement

Making distance measurement

This option allows the user to measure the distance between two specified points on the ultrasound image or on the optical image, independently from each other. Note that the results are demonstrated in three different values: True Distance, Vertical and Horizontal projections (components) in millimeters. (The display of these projection metrics facilitates the measurements of thickness or lateral dimension of skin structures without the need for perfectly aligning measurement points vertically or horizontally.)



In order to execute the measurement, tap the 'Distance measurement' button, then select two points (by tapping / clicking) on the Optical or on the Ultrasound image. The distance measurement results can be displayed simultaneously for both the Optical and the Ultrasound image. It is possible to simultaneously have up to three measurements on the same optical or ultrasound image. Distance measurements can be modified by dragging and dropping the markers that indicate the selected points.

The numerical results of distance measurements are displayed in panels on the modalities they were made on. Results of a measurement made on a particular frame can be hidden and displayed again by tapping on the 'Distance measurement' button.

Any distance (thickness) measurement result can be deleted by dragging the marker of either of its two points onto the bin icon which appears when a marker is moved.



The results and coordinates of the last three performed (and not deleted) distance measurements will be saved in the memory, and can be downloaded locally, or uploaded to the *SkinAid Catalog* database (separate product) and can be viewed on the Lesion page if you save that particular frame (see Section 3.5 for uploading frames).

Making volume estimation

This functionality allows you to estimate the volume of a lesion, by taking the extent of the lesion into account on both modalities.

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Please note that this functionality is not intended to give you a precise measurement of the volume of any structure of the skin. It is an estimate, calculated for an imaginary ellipsoid, based on the distance inputs selected on the optical-ultrasound image pair.

To make a volume estimation, two pairs of points have to be selected on the Ultrasound image and one pair of points on the Optical image. One of the selections (pair of points) made on the Ultrasound image should be aimed to represent the thickness of the structure of interest, the other the lateral length of it, while the third selection, the one performed on the Optical image, should be aimed to represent the length of the structure in the perpendicular direction to the Ultrasound image plane.

The selected pairs of points will be connected with a line. When the two selections are made on the ultrasound image, two markers appear on the registration line on the optical image, which correspond to the selection with the longer horizontal extent. The estimated volume appears in a panel in the bottom right corner of the ultrasound image.

Previous volume estimations can be modified and deleted the same way as distance measurements.



The results and coordinates of the last performed (and not deleted) volume estimation will be saved in the *SkinAid Catalog* database and can be viewed on the Record Review page if you save that particular frame (see Section 3.5 for uploading frames).

Free text note

With this tool, a free text note can be added to the optical and/or the ultrasound image separately.



To add notes, first tap on the 'Notes' button, then select a modality. When a modality is selected, the notes will be displayed in editing mode. There are separate text panels for the optical and the ultrasound image. The modality which was selected will be automatically active in the editing window, but the other note can also be modified by tapping on the pencil icon in its bottom left corner.

Changes made in the notes can be confirmed or discarded by selecting the check mark and the x button, respectively.



The free text notes will be saved to *SkinAid Catalog* and can be viewed and edited on the Record Review page if you save that particular frame (see Section 3.5 for uploading frames).



Please note that Notes, Annotation and Distance measurement results of a frame can be viewed simultaneously, but only one of them can be edited at a time. The button corresponding to the currently active (editable) tool is displayed in red, and the others in black.



Multiple filter results are displayed simultaneously.

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Please note that image analysis tools and gain adjustment cannot be used simultaneously. If one or more image analysis tools are active when the gain adjustment panel is opened, the image analysis tools will be closed (hidden), and vice versa.

Direct download

The recordings and their metadata can be downloaded locally to the host device in three formats:

- 1. Optical and ultrasound images of a single frame pair can be saved as '.png' files. In order to do that, press the 'Save frame' button when the desired frames are on display.
- 2. A section of a cine-loop (or the whole loop) can be downloaded in '.mp4' format. Use the crop markers located on the frame slider to select a section if desired.
- 3. Selected frame pairs, along with metadata can be exported to a report in '.pdf' format.

After selecting the desired frame pairs and/or cine-loop range, press the download button.

Buttons which can be used in the download process: crop marker, frame selector, frame saving button, download button.

When the download button is clicked, an overlay is displayed, where it is possible to select which download formats to use, and optional patient data (name and/or insurance number) can also be included. These, along with other metadata (date and time), will appear in a header on the images, if the 'Include Header in downloaded images' checkbox is set to 'On' in the user Preferences (see "Preferences" in Section 3.2 Capture screen layout).

After pressing the 'Save' button, the selected images, video and report will be downloaded in a zip file.

	Choose what to download: loop as MP4 video PDF report Note: longer loops may take some time to download.	Optional: Include the following patient data Note: we do not store this patient data. This information will only be stored in the downloaded file(s) Name of the current patient Patient's Insurance Nr. Send PDF report in email Device	\$.↓
		A Chintensity L1% 2.0% 3.3%	
=) 10 19 28 37 46 55 64 73	

The PDF report can also be sent in email. This is possible by pressing the 'send PDF report in email' text, providing an email address in the pop-up window and pressing 'Send'.

TD NON De	Choose what to download: Selected frame(s) as PNG Coop as MP4 video DF report Note: longer loops may take son download.	Optional: Include the following patient data Note: we do not store this patient data. This information will only be stored in the downloaded file(s) Email PDF report Enter email	
=		Back Send Save	

Contents of downloaded images

The downloaded '.png' images contain:

- The actual gain/brightness settings at the time of the download;
- The image analysis filters applied to the images, if they are set to be visible at the time of the download (distance measurements, annotations, notes);
- The optical-ultrasound guideline, if this option is turned on (not turned off) in User Preferences;
- Scale markers on the sides of the images;
- The whole 12 mm depth of the ultrasound image, not just the displayed section.

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You can use the above download functionalities for exporting image data from the system.

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If you wish to avoid saving the recordings into *SkinAid* (our anonymized Cloud-based data storage, catalog and skin image analysis system), you can choose to download the images with or without your analysis filters into your local storage.

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The download functionality is also useful for exporting data into image, video, or PDF document formats for use in presentations, publications, or sharing with patients or colleagues. Note that this functionality is available in *SkinAid* as well.

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To make it possible to further analyze your recorded data, we recommend saving all recording results into the *SkinAid* catalog and skin image analysis system.

3.5. Saving results into SkinAid Catalog

The user can save the recordings frame-by-frame and/or save the whole series of frames ('cine-loop') into the database of the *SkinAid Catalog* system, using the following buttons with the following functionalities:

Select a frame for saving

It is possible to select any of the recorded frames for saving either using the 'Frame selection for saving' button of the screen or with the corresponding physical (bottom) button on the control panel of the device. It is possible to deselect the previously selected frame by pushing either of these buttons again when that particular frame is on display.

When a frame is selected, the 'Frame selection for saving' button of the application will be displayed in red, and if it is deselected, the button will be displayed in gray again.

Please note that pressing this button only *selects* the frame for saving. The frame will be saved after closing the exam successfully (see *Close Exam* below).

Save cine-loop

Selecting the cine-loop for saving is possible in the 'Close Exam' step. You can select the whole cine-loop or only a section of it for saving. Cropping of the cine-loop can be done by moving the two markers (start and end marker) located on the slider below the image pair. The start marker is located at the beginning of the slider, and the end marker is located at the end of the slider by default. They can be moved by dragging and moving. Move the start marker to the position of the first, and the end marker to the position of the last frame you want to include in the cine-loop segment selection (cropped segment).

Buttons related to the saving process:

crop marker, frame selector, frame selection for saving button, cloud upload button.

Close Exam

After pressing the 'Cloud upload' button of the Capture screen, the savings dialog is initiated with a split screen. The left side represents the *Dermus Capture* application, with the data selected for saving. The right side represents the *SkinAid Catalog* system, here is where the records to be saved can be (and needs to be) assigned to a lesion of a patient (either a previously added or a newly added patient/lesion), with the addition of the diagnosis information as well.

You can see the number of single frames selected for saving and can select or deselect the cine-loop for saving. Note that the "multi-frame (cine-loop)" option will always appear on this window, and is selected by default if the cine-loop was cropped.

The 'n selected frames' option shows the number of individually selected frames. If no individual frames were selected, it offers to select the actual frame (the one on display at the time of pressing the 'Cloud upload' button) for saving.

Note that the selected items will be saved only after successfully designating the recording to a specific lesion of a patient, filling in the required diagnosis information, and making sure that the saving is attained (uploading progress bar reaches 100%).

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It is generally considered good practice to save all of the valuable data by saving the whole or a cropped cine-loop, and to save a few selected frames in addition. In this way, it will be easier to review cases in the future while retaining all potentially useful data and the scanning flow.

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Note that any number of frames and parts of the cine-loop can be exported from a saved cine-loop in the *SkinAid Catalog* system at any time.

Saving frames/cine-loop (records) to a lesion of a patient

Data can be saved into the *SkinAid Catalog* system which has a structure of three levels: patients, lesions, records. You need to select a patient and then a lesion of that patient to which the recordings will be saved. Either existing patient/lesion can be selected or a new one can be added.

In summary, there are three options for assigning patient/lesion to recordings (single frames/cine-loop) to be saved:

- Select an existing patient and its existing lesion (in your database);
- Select an existing patient and add a new lesion to him/her;
- Add a new patient with a new lesion.

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Note that there are two tabs on the patient selection interface. The human patient selection tab is selected by default, however you have the option to switch to the other tab where animal-type patients can be selected (for preclinical inspections).

Add records to an existing lesion

1. Select a specific patient from the Patients list.

2. By selecting the lesion of choice the saved frames/cine-loop will be assigned to that lesion.

GC	Choose which records to add to the database.	🎧 🛛 🍰 1561	ơ" │ 📋 1990	
NON	☑ 1 selected frame ☑ multi-frame loop	Lesions	+ < = ⊞	
۵.,	Note: all measurements and notes made on the above frames will be exported into the new records.		06 Burn scar (1 week 0 06.05.24. 16:41:46 05 Vessel 0 06.05.24. 16:32:08	
			04 Vessel	
			06.05.24. 16:26:23 02 Scar	
			01 Vein	
≡	Cancel Back		06.05.24. 16:52:25	

Add records to a new lesion of an existing patient

1. Select a specific patient from the Patients list.

2. Add a new lesion by clicking on the red plus sign icon in the header of the lesion list.

3. After selecting the lesion area on the following body schematic, the saved frames/cine-loop will be assigned to that newly created lesion.

Add records to a new patient

1. Add a new patient by clicking on the plus sign icon in the header of the patient list.

GC	Choose which records to add to the database.	Your patients $(+) \ \ = \blacksquare$
	 I selected frame multi-frame loop Note: all measurements and notes made on the above 	6 1561 ★ ♂ 1990 (☆ 06.05.24. 16:52:25 Vein, Scar, Tendon + vessel, Vessel, Vessel, 1562 ★ ♂ 1983 (☆ 06.05.24. 16:16:06 Vein
	frames will be exported into the new records.	1 1557 o" 1989 [m] 03.05.24.12:16:50 Nevus 3 1555 ★ o" 1989 [m] 02.05.24.14:52:22 Nevus, paper towel, nevus 4 1275 0.1891 [m] 28.04.24.17:01:13
		 15/3 * 103 L_Q 20.04.24. (7.01.10) nevus, Burn (1 day ago), Burn (1 day ago), R 1538 ★ σ[*] 1990 L^Q_Q 16.04.24. 13:55:57 JB45.Y (Other specified infections of breas
=	Cancel	1536 ★ ♂ 2024 to 10.04.24. 13:09:35 Nevus

2. Provide details of the patient.

GC	Choose which records to add to the database.	New patient
NON De	I selected frame multi-frame loop Note: all measurements and notes made on the above	Human Animal Birth year 1992
	frames will be exported into the new records.	Sex \$ @ \$ \$ \$ \$
=	Cancel Back Next	

3. Register a lesion to the patient. After selecting the lesion area on the following body schematic, the saved frames/cine-loop will be assigned to the newly added lesion and patient.

GC	Choose which records to add to the database.	New lesion
NOT L,	 I selected frame multi-frame loop Note: all measurements and notes made on the above frames will be exported into the new records. 	Select the area on the body image.
=	Cancel Back Next	

Providing diagnosis information

After selecting or registering a patient and a lesion, the application asks to provide information about the diagnosis of the inspected lesion. A dialog appears with an ICD code search field and a free text field to describe the diagnosis, and radio buttons to select the basis of the diagnosis. You have the options to either give the ICD code or fill the free text field or do both (supplementing each other).

GC	Choose which records to add to the database.	
	1 selected frame	Property note
	Note: all measurements and notes made on the above	Select from the list
¥.	frames will be exported into the new records.	Specify the diagnosis.
		Search for ICD code
		Add your own notes
		Basis of diagnosis
≡	Cancel Back Next	o prelim. O final o histological

If a new lesion is registered, the fields in the dialog are empty and none of the radio buttons is selected. If the recordings are saved to an already existing lesion, previously saved diagnosis information is displayed in the dialog. In the latter case, you are free to either update it, or leave it as is.

After you start typing an ICD code in the search field, options will be displayed in a drop-down menu and you can choose one by clicking on it. It is possible to provide additional information in the free text field.

GC	Choose which records to add to the database.	
NO	⊠1 selected frame ⊠multi-frame loop	Property note
Ny,	Note: all measurements and notes made on the above frames will be exported into the new records.	Specify the diagnosis.
		Nae naevus, unspecified
		2F20.1 Atypical + [Details] melanocytic nae vus
		EC20.03 Keratinopathic [Details] ichthyoses
≡	Cancel Back Next	clinical clinical

If you click the 'Save' button, the application saves the recordings and the corresponding diagnosis information to the selected lesion.

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Please note that it is mandatory to choose a basis of diagnosis and to fill in at least one of the ICD code field and the free text field.

Special attention!

You shall avoid to input and save any identifiable patient data (such as name, social security number, exact birth date) in any of the fields of the software.

Feedback about saving and option to cancel saving

After you click 'Save', the uploading of the recordings will start automatically. The application provides feedback about the progress of saving by displaying a progress bar in a pop-up window.

Above the progress bar, a text is displayed about the number of frame pairs and/or about cine-loop being under uploading.

If the uploading of the optical-ultrasound frame pairs is finished and the uploading of the cine-loop is still in progress, the text changes to 'We are uploading the cine-loop (*n* frame pairs are already uploaded)'.

Uploading data	
We are uploading the cine-loop(6 frame pairs are already uploaded) 100%	
CANCEL CINE-LOOP SAVING	

There is an option to cancel the saving of the recordings by clicking the button with the text 'Cancel saving' at the bottom of the pop-up window. The text on the button changes to 'Cancel cine-loop saving' If the uploading of the optical-ultrasound frame pairs is finished and the uploading of the cine-loop is still in progress. If the saving is canceled at this point, previously selected single frames will be uploaded and the cine-loop will be discarded.

If the 'Cancel' button is clicked, the saving stops and only those records will be uploaded to *SkinAid Catalog* for which the uploading was finished before the 'Cancel' button has been clicked. The application returns to the Capture screen where the results of the previous inspection are displayed and the frame and/or cine-loop selections are still present. Recordings that got fully uploaded to *SkinAid Catalog* will remain saved, other recordings will not be saved.

Finishing the saving workflow

When the uploading is finished, the application presents three options for the user:

- 1. Check the saved recordings: the application progresses to the *SkinAid Catalog* system where the uploaded recordings can be viewed. From here, there is no returning to the Capture screen with the previous recording on display. Nevertheless, new recording may be initiated for the selected lesion (see Section 3.6 below) or 'from scratch'.
- 2. Return to current recording: the application returns to the Capture screen with the recording being in frozen state, as left when the 'Upload' button was pushed. The results of the previous inspection are displayed and the frame and/or cine-loop selections are still present.
- 3. Start new from scratch: the application returns to the Capture screen, but the previous recording will not be displayed anymore.

DD				
	Success! Your work is saved.			
2,,				
				•
	Check The Saved Recording	Return To Current Recording	Start New From Scratch	
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3.6. Access to Capture Screen directly from SkinAid

By selecting the SkinScanner icon in the navigation bar, on any level of the *SkinAid Catalog* system, it is possible to start a recording session directly from the screen of a patient or a lesion. If dialog visibilities are turned on in User Preferences (https://www.skinaid.app/userpreferences), a message at the bottom of the screen will ask whether you want to add new recordings to the currently viewed catalog page or make new recordings from scratch (without assignment to any patient / lesion yet).

If the 'This level' option is used, the recordings will be automatically assigned to the patient or lesion from which the capture was initiated. If the capture was initiated from the level of a patient, then a lesion still has to be selected during the saving process.

Also, the selected patient ID and lesion ID will be displayed at the top of the screen once Capture is opened.

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Please note that for captures initiated from a certain level of *SkinAid Catalog* with the above 'This level' option, the saving workflow is different from that described in Section 3.5 (Saving Results into SkinAid Catalog). After closing the capture session (see Close Exam above), the dialogue will only ask to confirm or update the diagnosis information. The new recordings will be automatically saved to the lesion from which the recordings were initiated.

Using the 'From scratch' option opens the capture screen without any patient / lesion associated, and the saving workflow goes as described in Section 3.5.

3.7. Completing the inspection

Steps to follow each patient inspection:

- 1. Remove the gel from the inspection window
- 2. Clean the inspection window

Special attention!

After inspecting each patient, remove the gel from the inspection window of the device and clean it.

3.8. Interpretation of the ultrasound images

The ultrasound images recorded of the skin by the *Dermus SkinScanner* usually present reflections from the following structures:

- Structures of the imaging window:
 - o Membrane
- Structures of the skin:
 - o Epidermis
 - o Dermis
 - o Subcutis
 - o Lesion
- There is ideally a reflection-free gel area in between the membrane of the imaging window and the epidermis of the skin.

Reflections seen in the gel area are usually representing hair or air bubbles, both of which may also cause an acoustic shadow in the image of the skin. Note that these shadows are always presented in the direction of the ultrasound wave propagation (vertical direction) on the Dermus SkinScanner ultrasound images, and below a highly reflective structure (such as an air bubble).

4. Troubleshooting and support

4.1. Common troubleshooting steps

If the connection between the device and the host is lost or in other cases of the device not working properly, please reset the connection between the device and the host via the following steps:

- 1. Unplug the device from the host.
- 2. Wait for 5 seconds.
- 3. Plug in again the USB connector to the host device.
- 4. Refresh the Capture screen of the web application (**dermus.app/capture**) via a downward gesture on the MCU screen or via closing and reopening the application.

Multiple failed connection attempts

An error message will appear after multiple unsuccessful connection attempts. The message will show an option to reset the device so that it can be used normally again.

Optical / ultrasound image not appearing or freezing

If either the optical or the ultrasound image freezes for several seconds or does not appear on the screen, please stop the recording (freeze) and restart it (unfreeze). In most of the cases, both the optical and the ultrasound images should appear after restarting the recording.

If the issue still occurs and the two images do not appear simultaneously after the recording has been restarted, please do the steps of physical reconnection of the device and reopening of the application as described in the beginning of this section.

If the issue still occurs after multiple reconnection attempts, please contact the support team of the manufacturer, preferably via the Feedback functionality described in Section 3.2 above.

4.2. Firmware updates

How to view firmware versions in the web application

In case our support team is asking for such information, you can check the actual firmware versions of your device by opening **dermus.app/usb-settings** on a host device connected to it. The versions are listed under the title "Current device version table".

The About screen when the firmware of the device is up to date

How to update the firmware of the device

Note that the updates of the SkinScanner capture software (and also of the *SkinAid Catalog* software) are realized automatically, with no need for user interaction. However, the firmware updates of the device require a simple user interaction. You will always be notified by the application when there is an update available. It is always possible to skip the update for later while it is recommended to perform them as soon as possible.

There are two ways to access the firmware update:

 Simply connect the device with the outdated firmware to a host and open the SkinScanner application. A warning will be displayed about the firmware version of the device if it is out of date. The warning contains a button 'Install', and the firmware update can be started by pressing this button.

	Device connected. <u>Unsuppor</u> Please start the scanning by right of this sc Alert Your device's strongly recoversion. This update	ted environment de pressing the "Unfree s firmware is out of d pmmended you insta might take a few min	tected. System m ze" button on the : ate. It's II the new nutes.	ight not work properly. scanner or on the top	O
		Later	Install		
=					

2. Open the About screen (**dermus.app/about**) and connect the device. There is an 'Update' button next to where the most recent available firmware version is displayed. Press this button to start the update.

TD	About		
10	User Guide		
	Terms and Conditions	Privacy Policy	
∑J ₆	Connected Device		
	Serial number: 230512	Current Firmware Ver	sion: R2401H3
		R2403H3 available	Update
	Current version of this web app: R2403 About Dermus	Release notes	
≡			

When the 'Install'/'Update' button is pressed, a warning will be displayed drawing your attention to avoid disconnecting the device during the installation/update.

TD	About		
26	User Guide		
	Terms and Condition	Important	
24	Connected Device	This update might take a few minutes. Do not close this window or unplug th	ie
	Serial number: 23051	device; otherwise, the device may be damaged.	онз
		Later In	stall
	Current version of thi		
	About Dermus		

Place the device on a table to ensure undisturbed USB connection between the device and the host (MCU). Press 'Install' (again) to start the update.

During the update, a progress bar is displayed, and the status of each firmware component update is shown under the progress bar.

There are 4 different firmwares running on the device (Main Fx3, Camera Fx3, STM32, FPGA). A specific update may affect only some of them. There are critical parts of the firmware update indicated by the feedback light of the device flashing in magenta. Maintaining stable USB connection between the device and the host (MCU) during this period is crucial. Note that there may be updates not affecting this critical part (no flashing magenta light). Note that if the connection fails during another phase of the update, the process can be restarted without consequences.

TD	Updating firmware to version R2403H3
D ₁ ,	Updating firmwares STM32, Main Fx3, FPGA are up-to-date
	Camera Fx3 : 25%
	Do not close this window or unplug the device; otherwise, the device may be damaged.
≡	

When the update is finished, please unplug and reconnect the device if you wish to use it again.

TD	Updating firmware to version R2403H3	
1011 D.p.	The update is finished. You can exit SkinScanner or start Capture. Please, reconnect the device.	
=		

Attention!

Do not disconnect the device and do not close the application while the update is not finished. Doing so may damage the device and it will no longer be usable.

Attention!

Place the device on a table during firmware updates to ensure undisturbed USB connection.

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Note that the critical part of the firmware update is indicated by the flashing of the feedback light of the device in magenta. If the device and the host disconnects in another part of the update, it may be started over again.
4.3. Support options

If the above steps do not solve the problem, or in any other cases of malfunctions, please contact our Support Team. You may write directly to **support@dermusvision.com**, however we strongly recommend to use the in-built Feedback functionality of the application as a first channel whenever applicable. See "Feedback" in Section 3.2 above.

How to access 'Support page' from Capture Screen

The instructions below will help you to locate our support page.

- 1. Open the application (dermus.app/capture).
- 2. Click on the menu at the bottom of the sidebar

Three options will appear: 'About', 'Feedback', 'Support', and 'Preferences'.

- 3. Click on the 'Support' button.
- 4. The Dermus Academy page (Dermus Academy) opens, which contains
 - a. information about the SkinScanner device and the *SkinAid Catalog* software
 - b. training materials
 - c. list of publications related to the development or use of the device
 - d. contact information of our support team.



5. Storage and maintenance

5.1. Storage

The safe use and storage of the device requires a dry place at room temperature, protected from direct sunlight.

Temperature range permitted for max one week delivery time: 0... +45 °C

Special attention!

Do not expose the device to direct sunlight, strong heat or temperatures below 10 °C, and avoid any direct contact with water.

Attention!

Empty out the water chamber of the device before putting it into storage.

5.2. Maintenance

Dermus SkinScanner is maintenance-free in addition to cleaning and water filling and discharging (described in Section 2). Do not leave the same distilled water in the chamber for more than 1 day. It could cause significant degradation in the optical and ultrasound image quality.

For safety reasons, it is important to maintain the integrity of the device.



Disassembly or unauthorized modification of the device may lead to electrical shocking of the user or to a loss of functionality of the device.



Special attention!

If the device needs to be repaired or the safety of the device becomes uncertain, place the device in the storage case, notify the manufacturer and return the device to the manufacturer.

If any malfunction occurs or safe use of the device is not certain anymore for any reasons, please contact the manufacturer forthwith.

5.3. Disposal

In the case of an intended disposal, the user should send the device back and Dermus Ltd. will dispose of the device properly.



Special attention!

Do not dispose of the device.



Special attention!

In the case of an intended disposal, please contact the manufacturer and return the device. The manufacturer will take the responsibility to dispose of the components of the device properly.

5.4. Cleaning the device

Agents and tools used for cleaning

Agents: ethanol or isopropyl alcohol (at least 95% concentration)

Tools: paper towel

Process of cleaning:

The imaging window and its neighborhood (the parts being in indirect contact with the patient, through ultrasound gel) should be cleaned in the following way, after finishing the inspection of each patient.

- 1. Remove the gel completely from the relevant parts of the device surface (imaging window and its neighborhood, if necessary) using a paper towel.
- 2. Cover the entire area that was previously in contact with the gel preferably using a spray of the cleaning agent. In the absence of spray, use a paper towel instead to evenly distribute the cleaning agent on the surface area.
- 3. Leave the surface area treated with the cleaning agent untouched for 2–3 minutes. During this time, the alcohol substance exerts its effect, the majority of the alcoholic component evaporates, and the cleaning finishes.



Special attention!

After checking each patient, remove the gel from the inspection window of the device and clean it.



Special attention!

Paper towels are disposable. After each use, place the paper towels with the gel and potential contaminants on it in a suitable waste container.



Special attention!

Cleaning should be performed using no other cleaning agents than the ones listed above (ethanol or isopropyl alcohol).

5.5. Environmental condition

Application and long-term storage

Temperature range: +10 ... +45 °C

Relative humidity: 0 ... 100% non-condensing

Short-term (< 24 hours time) ratings for storage and transport

Temperature range: +5 °C ... +50 °C

Relative humidity: 0 ... 100% non-condensing

6. Technical data

6.1. Working principle

The *Dermus SkinScanner* uses high-frequency ultrasound waves for imaging of the subsurface structures of human skin. The ultrasound pulses generated by the device get scattered and reflected on the inhomogeneities of the structural elements of the skin. The reflected waves are received and their data are processed by the device. The device uses a one-element transducer moved on a linear stage by a stepper motor. The data are converted into two-dimensional images by recognition of stepper motor position (for forth and back movement as well). During capturing the ultrasound image, optical imaging aids the guidance of where the ultrasound image should be taken. The relative spatial position of the ultrasound image cross-section is indicated with a red line superimposed on the optical image. A series of corresponding optical-ultrasound image frame pairs can be recorded of which a number of selected frame pairs or the whole loop of frames can be saved for storage and further analysis.

6.2. Technical specification

1. General device specifications:	
Device connector	USB type C
Rated voltage	5 V
Rated input current	800 mA

Average power consumption	4 W
Rated output voltage during charging (on port A)	5 V
Rated output current during charging (on port A)	900 mA
2. Imaging specifications:	
Ultrasound frequency range	20-40 MHz
Ultrasound penetration depth	up to 10 mm
Ultrasound field of view	10 mm (depth) x 12 mm (lateral)
Mechanical index (MI):	<0.59 ±13%
Soft tissue thermal index (TIS):	<0.12 ±27%
Optical field of view	12 mm x 12 mm
Frame rate	1+ Hz (for both optical and ultrasound)
3. Software specifications:	
Web browser	Any browser with web-USB support (e.g. Google Chrome, Microsoft Edge)