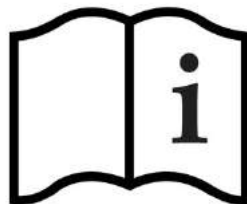




SkinVision

Instructions for Use version 5.0




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1. Introduction


This document is the user guide for **SkinVision**, a device designed by **SkinVision B.V.** Company. It is recommended that you read this instruction manual carefully before use.


Please, read carefully the precautions with  symbols, to ensure that the software is used in best conditions.

1.1

1.2 Conventions

This document has identified two types of danger level, and in this document you can find safety instructions about these.

	ATTENTION
	Hazardous situation which calls the attention on the facts that the customer shouldn't do when using this software.

	WARNING
	Hazardous situation which can cause serious/ fatal injury.


1.3 Intended use

The SkinVision Online Assessment software module assesses skin lesions for possible signs of irregular patterns.


2 Precautions


2.1 Compliant Use

Before using the software please read our terms and conditions presented in this guide and check the safety instructions of the software.

	ATTENTION
	You shall not: <ul style="list-style-type: none"> - Install the SkinVision app on a non-original (fake) iOS or Android device - Install the SkinVision app on a jailbroken iOS or Android device

2.2 Safety instructions

	ATTENTION
	<p>You shall not:</p> <ul style="list-style-type: none"> - Upload or transmit any communications or content of any type that may infringe or violate any rights of any party; - Use this app for any purpose in violation of local, state, national or international laws; - Use this app as a means to distribute advertising or other unsolicited material to any third party; - Use this app to post or transmit material that is unlawful, obscene, defamatory, threatening, harassing, abusive, slanderous, hateful or embarrassing to any other person or entity; - Attempt to disable, "hack" or otherwise interfere with the proper functioning of this software.

	WARNING
	<p>Electronic communication is not appropriate for all health issues, particularly those of an urgent nature, and SkinVision B.V. makes no guarantee of any particular response time to any inquiry you may make, accordingly, if you are experiencing a medical emergency, you should not rely on this guide for assistance, but should instead seek appropriate emergency medical assistance.</p> <p>Before using SkinVision check if the device is working normally and unobstructed.</p> <p>Do not cover in any way the flashlight source or the camera during the image acquisition!</p>

2.3 Malfunction


In case of malfunction:

- Try to identify or eliminate the cause using the description in this document (section Error messages, Troubleshooting).
- If it is not possible to identify or eliminate the cause using this document, contact **SkinVision B.V.**

2.4 Privacy and security

2.4.1 Privacy

Please read our Privacy Policy to understand how SkinVision is committed to protecting your online privacy. We feel it is important for you to know how we handle the information we receive from you via the internet. You can visit www.skinvision.com without revealing any personal information.

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However, you are required to provide an email address to subscribe to a newsletter or obtain personalized information and services. Information communicated electronically may be incorporated and retained in the SkinVision medical record and may be disseminated as part of an authorized release of a copy of the medical record.

2.4.2 Security

This security of any data you submit via this app is very important to us. This software uses encryption technology, and we constantly review our security practices to help ensure that your data is maintained securely. However, no system can perfectly guard against risks of intentional intrusion or inadvertent disclosure of information sent to us. Moreover, when you transmit information via the internet, your information will be transmitted over a medium that is beyond our control, and therefore the security of the transmission may be compromised before it reaches us. Accordingly, SkinVision B.V. makes no guarantee as to confidentiality or security. IN ADDITION, YOU HEREBY EXPRESSLY AND SOLELY ASSUME THE RISK OF ANY UNAUTHORIZED DISCLOSURE OR INTENTIONAL INTRUSION, OR OF ANY DELAY, FAILURE, INTERRUPTION OR CORRUPTION OF DATA OR OTHER INFORMATION TRANSMITTED IN CONNECTION WITH YOUR USE OF SKINVISION ONLINE SERVICES. Your username and password should be kept confidential. Failure to do so may also compromise the confidentiality of your information.

3 User Manual

If you are using this software for the first time please consult our Installation Manual, where you can find information about how to install/uninstall the software.

3.1 *Intended use*

The Online Assessment within the SkinVision application is for individuals to assess skin lesions for potential signs of irregular patterns. The imaged lesions can be melanocytic and non-melanocytic, pigmented or non-pigmented lesions, with the restrictions mentioned under the next paragraph.


3.2 *Contra-indications*

The Online Assessment is intended to determine unnatural growth in skin lesions. However, if a user wants to analyze a lesion, we advise the user not to use the Online Assessment if:

- a. The user has dark skin (skin type V and VI per Fitzpatrick scale) or the skin is sun burnt;
- b. The lesion has been previously traumatized (excised/biopsied);
- c. The skin surrounding the lesion is not intact (open sores, ulcers, bleeding);
- d. The lesion is under the nail(s);
- e. The lesion is very close to a (visible) area with scar(s);
- f. The lesion and surrounding skin (<5cm) contain foreign matter (e.g. marker, tattoo, sunscreen, skin cream, powder, etc.);
- g. The lesion is surrounded or covered by a significant amount of hair;
- h. The lesion is on mucosal surfaces (e.g., lips, genitals)
- i. The lesion is in a skinfold.

3.3 *Risk Factors*

Picture quality too low to be analyzed

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The user is notified via a dialog message that he must retake the picture of a higher quality.

The user cannot provide adequate lighting conditions for the picture to be visible

In this case, taking the picture should be postponed until proper conditions are available.

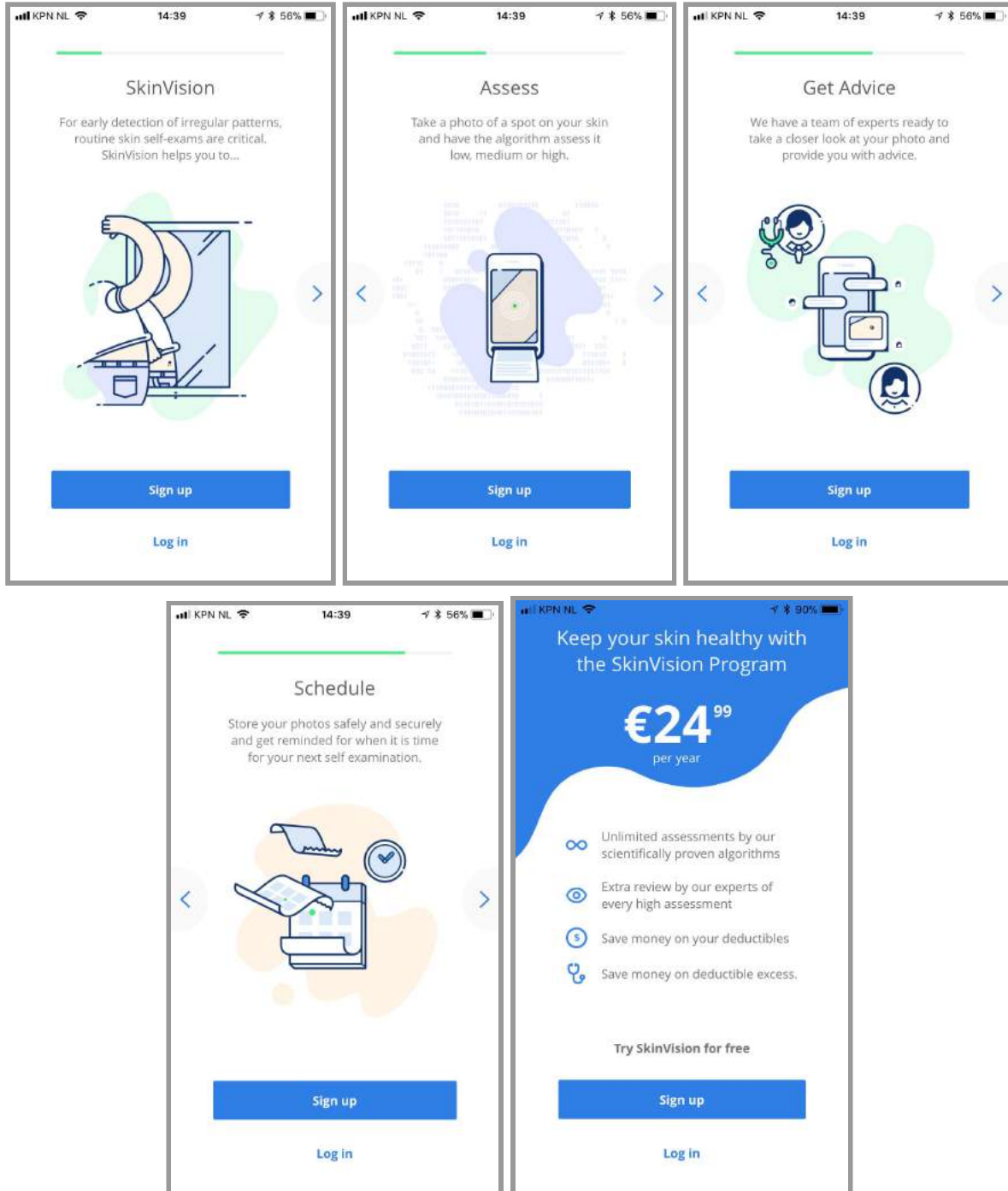
The user wants to take a picture of a lesion from an area of his body he cannot reach


In this case it is required to request the assistance of another person or physician.

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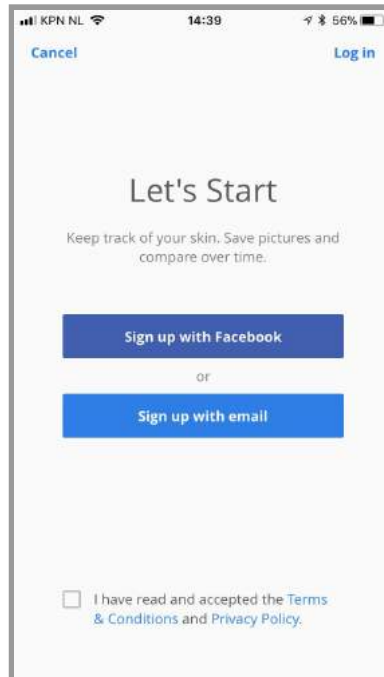
3.4 Getting started

When the app is loaded for the first time or when a user is logged out, a set of onboarding screens is shown that give a short introduction to the SkinVision service. The signup/login procedure can be started at any time from either of these screens.

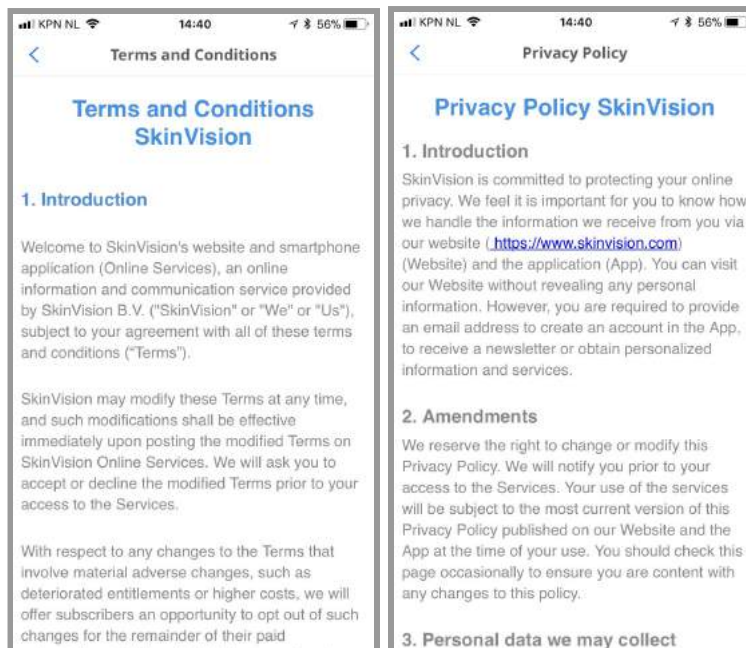



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If you are new to SkinVision you can create a new account by using the 'Sign up' button. The following screen will appear, which lets you choose whether you want to sign up using your personal facebook account or through an email address:

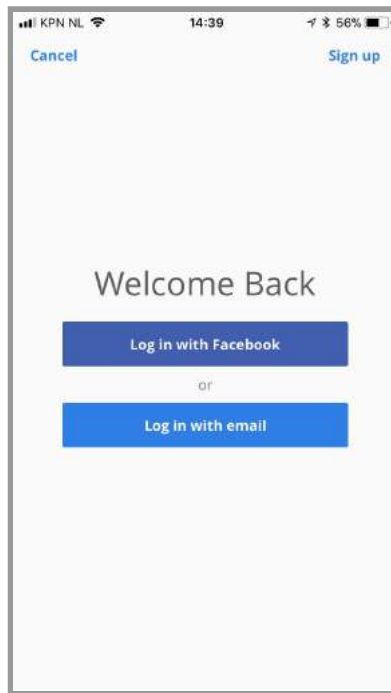



Before you can sign up for a new account, you will have to accept the Terms and Conditions and the Privacy Policy of SkinVision. These can be read by pressing the corresponding links in the signup screen. If you agree and want to make an account, tick the box next to it.



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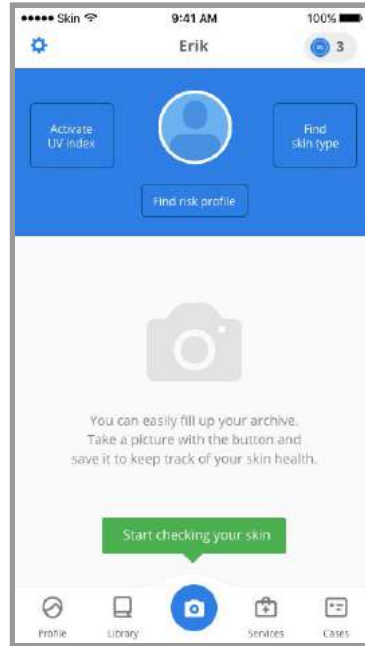
If you have used SkinVision before, you can login using your personal facebook account or through your email address and password:



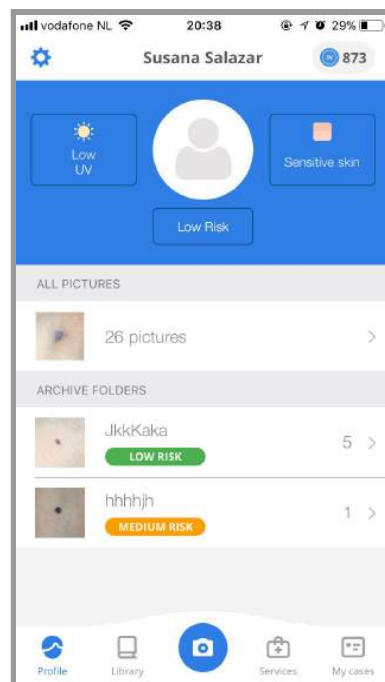
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3.5 Taking a picture of a lesion and assessing it

If you are new to the SkinVision App, you will see the following screen with a popup message guiding you towards the camera to make your first assessment:

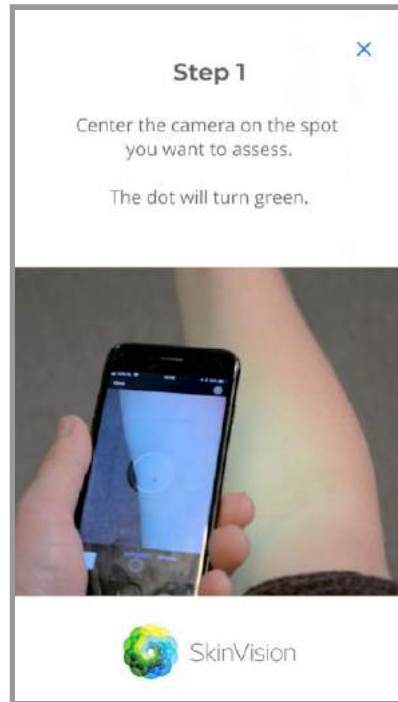


As an existing user, open the camera by pressing the camera button on the bottom menu. Previous assessments and pictures are accessible from the archives in the homescreen:

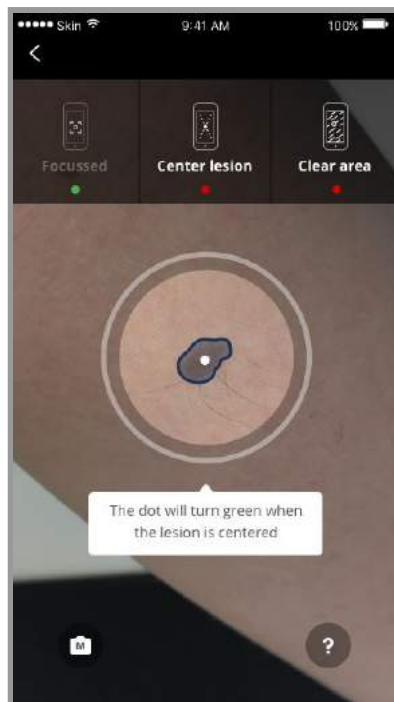



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In case you need more help, you can view the camera tutorial by pressing the question mark button on the top right. This will show a video explaining the camera.

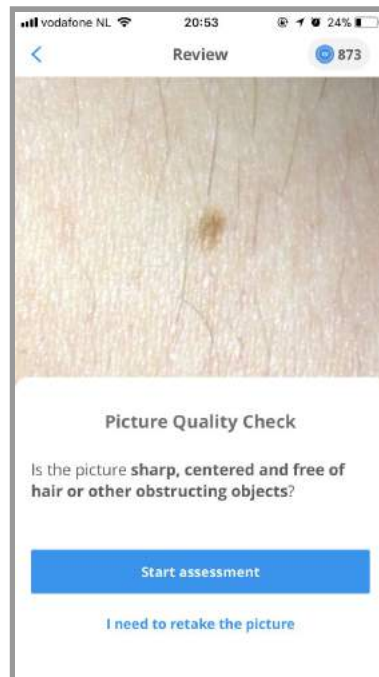


To take an automatic picture point the center of the camera on the lesion and make sure the area around the lesion does not contain too much hair or shadows. The circle will turn blue when automatic pictures are taken:

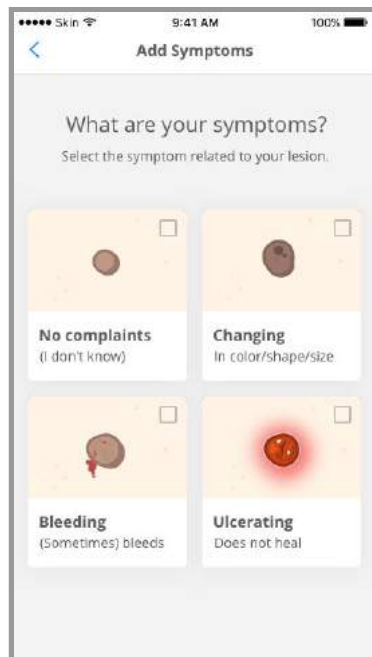



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After successfully taking a picture using the automatic camera, you will have to confirm that the taken picture is of sufficient quality and is indeed the right skin spot you want to have assessed:

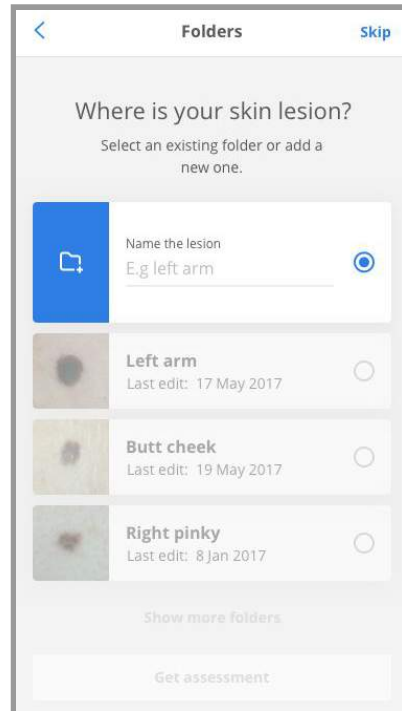


In order for the SkinVision algorithm to make a proper assessment, you need to answer a question about possible symptoms of the skin spot you want to have assessed:

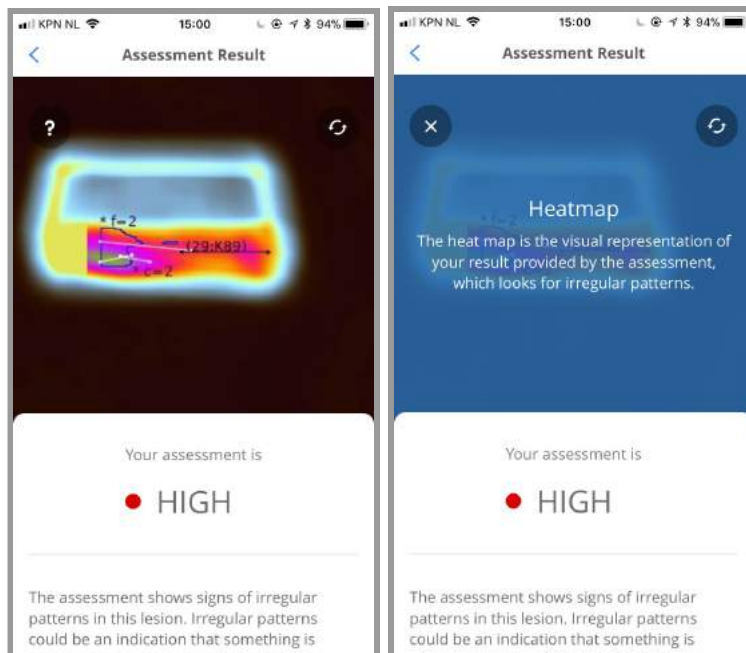



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After answering the questionnaire, you get the option to save the picture to your account in a folder. This can be a new folder or an existing one. The folders can be accessed in your personal gallery from the homescreen of the App (section 3.6):

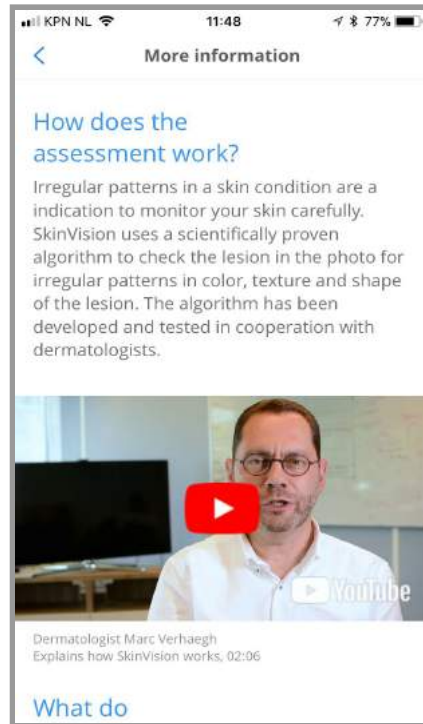


After answering the question, the assessment will come back with an outcome of Low, Medium or High:

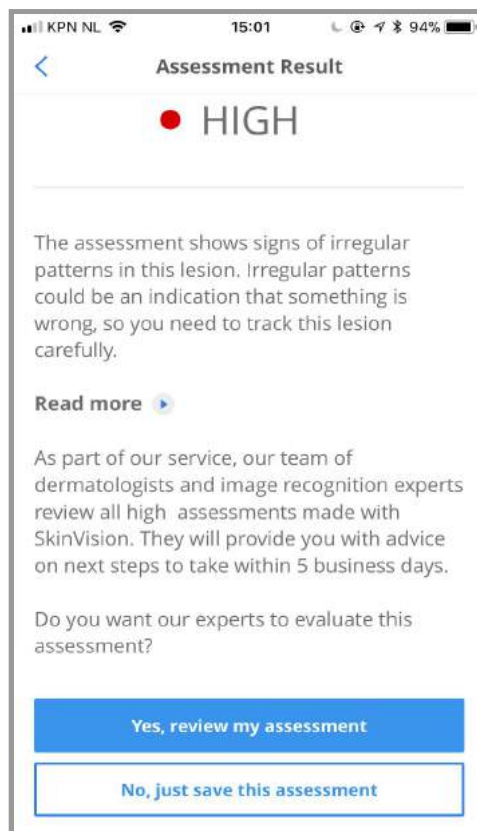



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To read further advice, please press the Read More button:



After getting the result, you can choose whether you want to send the picture for an Expert Review or to just save it to your account:



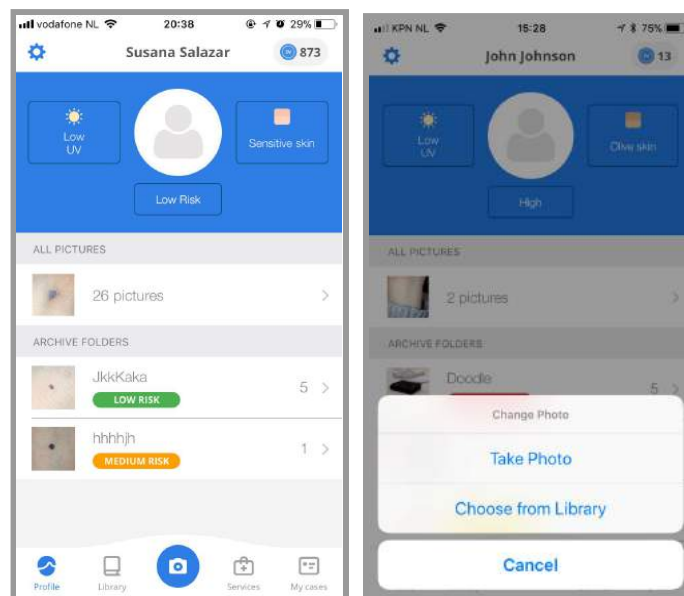
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In case the automatic camera does not allow you to take a picture, there is also a manual camera that allows you to take a picture, the same way you are used to with your device. Pictures taken with the manual camera can not be sent for assessment and are only for tracking changes over time:



3.6 *Managing your Profile*

Press the profile icon in the center to change your profile picture. You can take a new picture, select one from your camera roll or delete the existing one if there is one. Deleting the profile picture will default it to the placeholder icon.

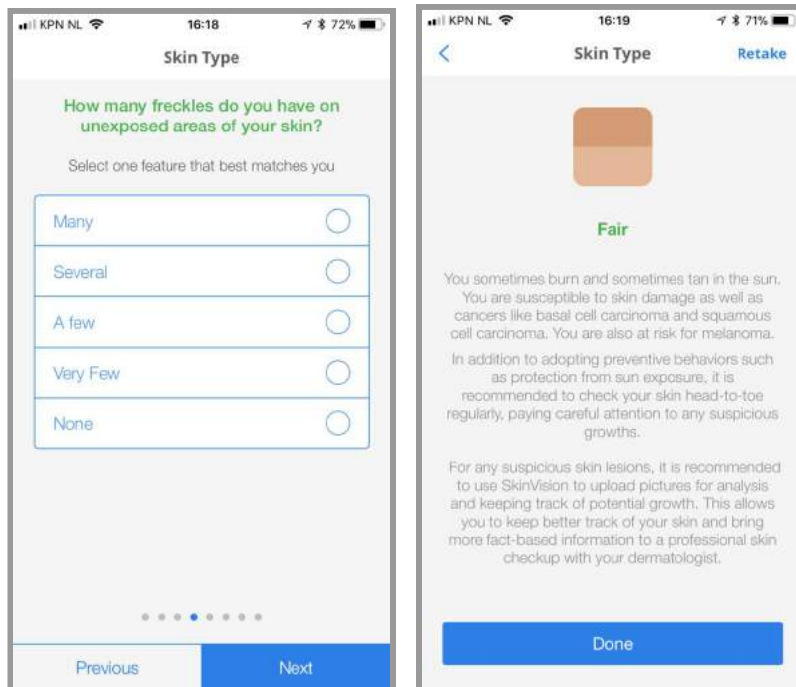



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Press the UV index button to view information about the current UV index. You need to have the 'Location' service activated for SkinVision in order for this feature to work:

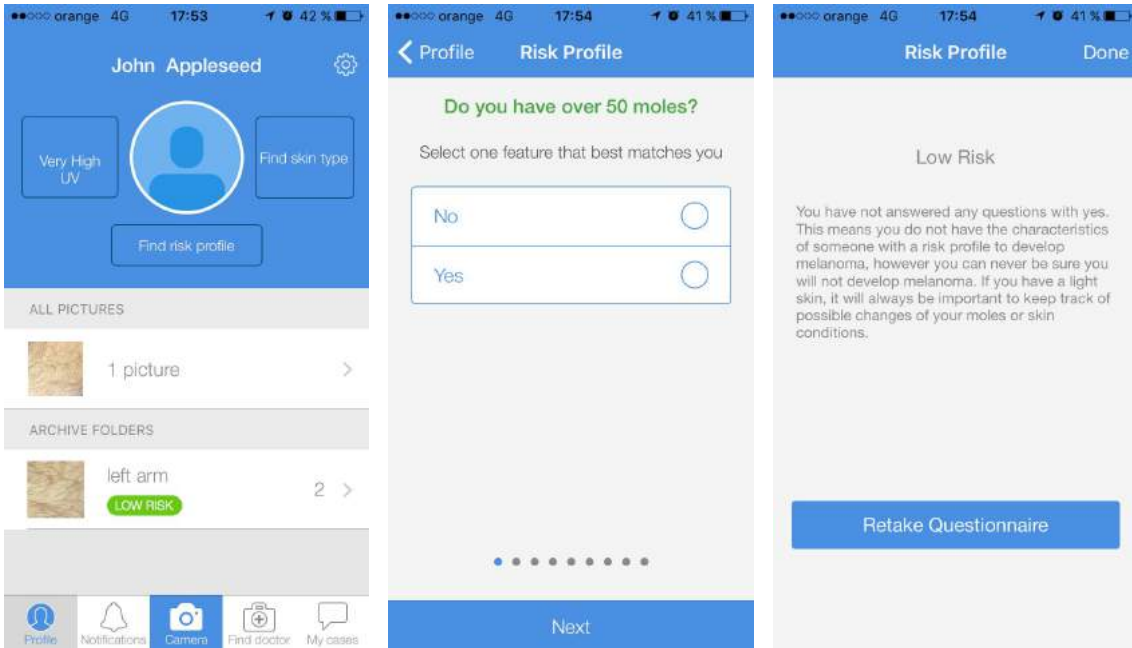


Press the 'Find skin type' button to start the Skin Type evaluation. This questionnaire will give you more information regarding your skin type:

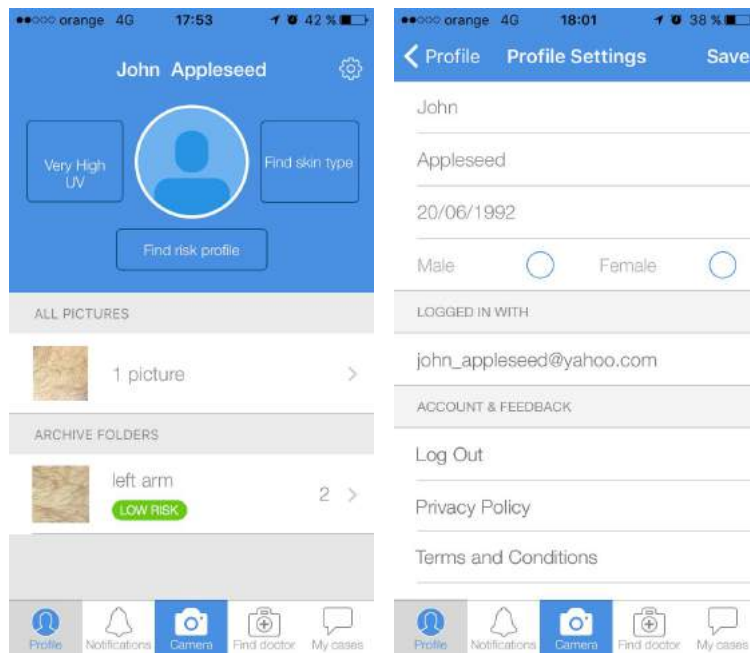



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Press the 'risk profile' button to start the Risk Profile evaluation.



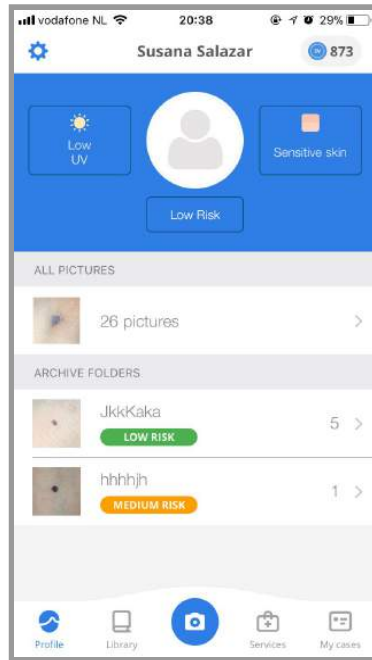
Press the cog button to access the Settings screen. See more for Settings in § 3.13.



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3.7 *Managing your Archive*

While you are in your Profile section, you can scroll down to see the contents of your Archive.

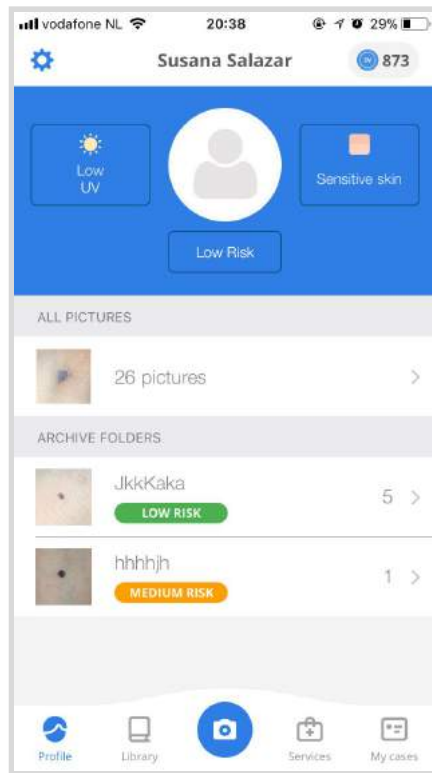


Open the 'All Pictures' folder to find all your uncategorized pictures in one place. These are automatically saved pictures that weren't manually archived by you.

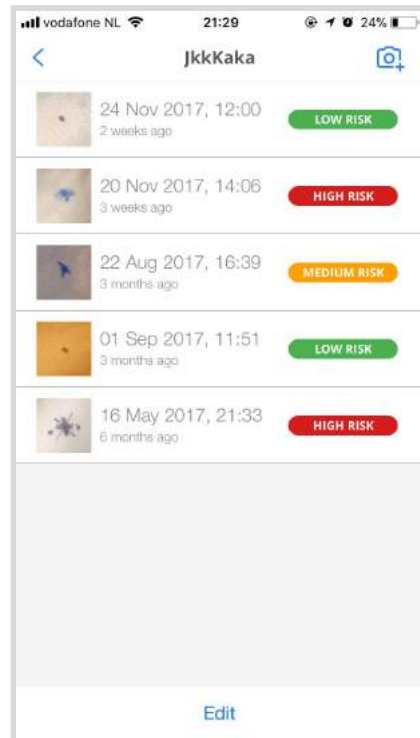



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Each folder shows the latest picture taken, the dominating risk assessment result in that folder, and number of pictures.

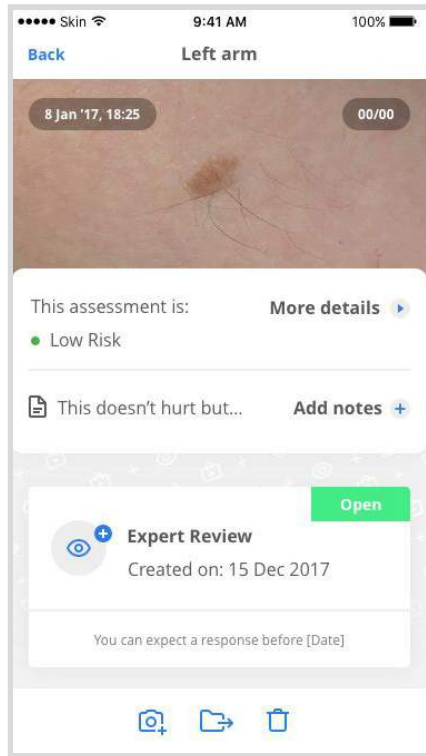


Press a folder to see the content. From here you can edit the folder's properties, or delete it.

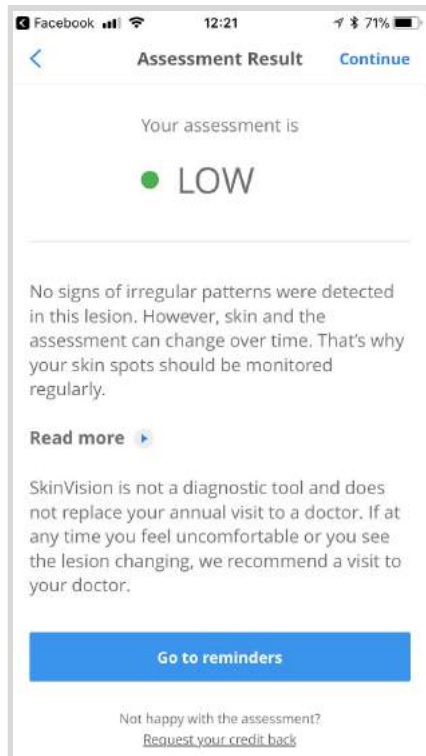



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To see details about each picture, press a picture from this view.

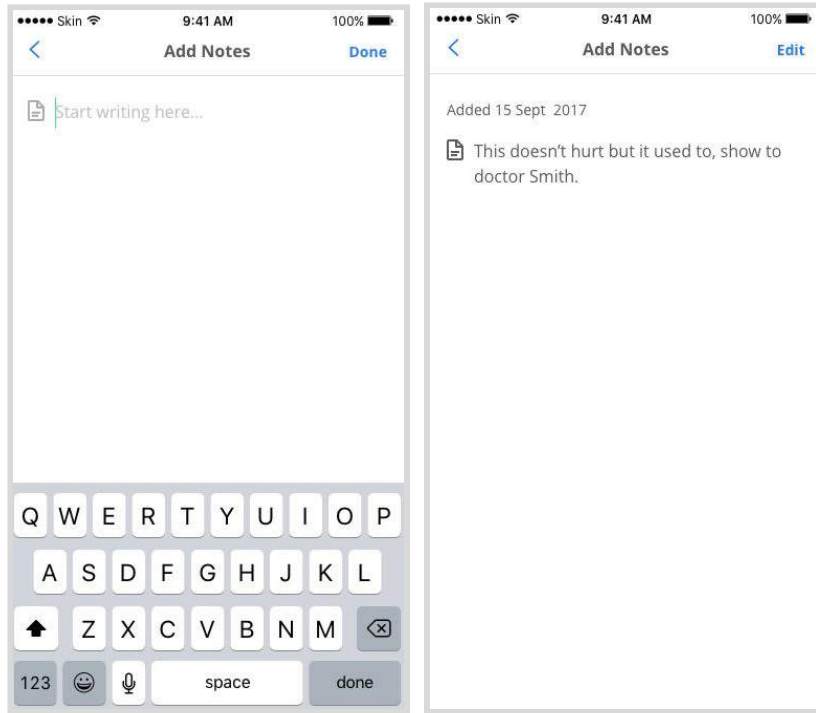


Press on the colored risk label to see more information about the assessment result.

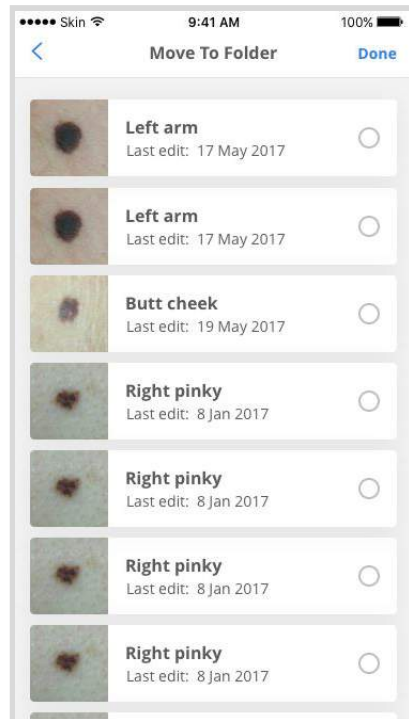



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Press the 'Notes' button to view, add or edit notes related to this picture.

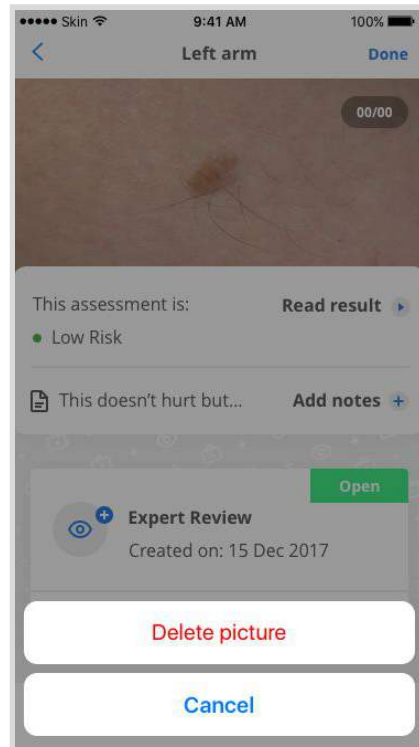



Press the Folder-image button on the bottom bar to move this picture to another folder. You will be shown the list of available folders other than the one you are moving the picture from.



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Press the Trash-image button on the bottom bar to delete this picture and its assessment.

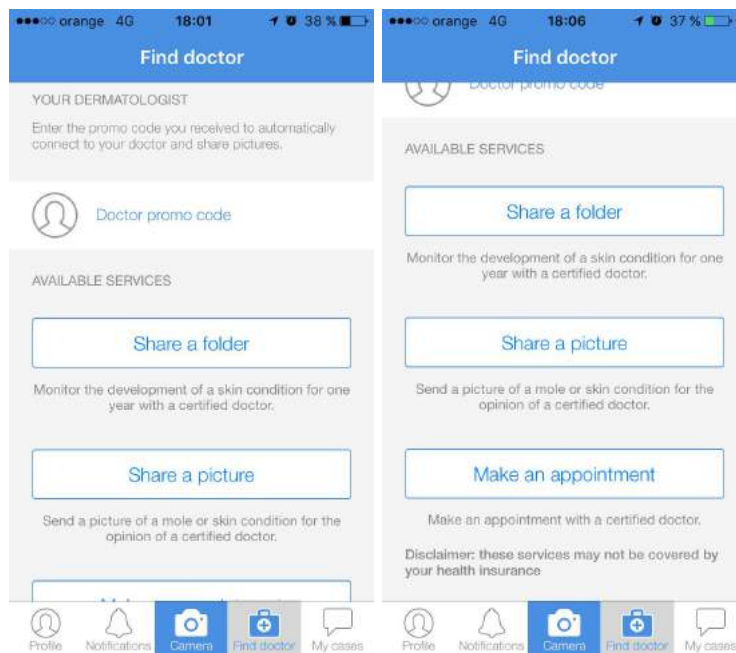



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3.9 *Contacting a doctor & creating a case*

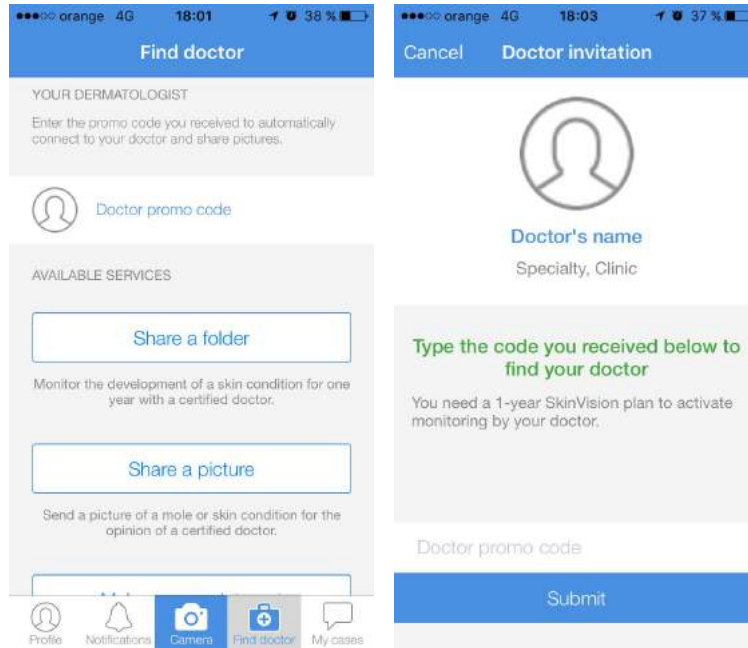
Press the 'Find Doctor' entry from the bottom menu to open the product list.
 Share Picture case type lasts for 15 days, after which they are automatically closed.
 Share Folder case type lasts for 12 months, after which they are automatically closed.
 Appointments will notify a doctor of your choosing and will serve as communication channel until you personally visit the doctor.

Appointments are free, while sharing a picture or folder requires payment, depending on each clinic's own prices.

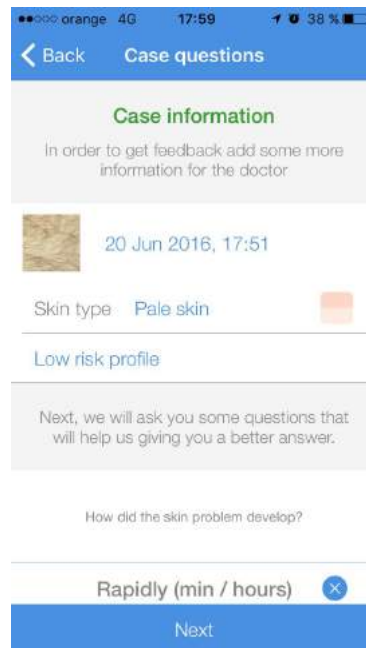



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3.9.2 If you have received a promo code from your doctor, you can insert the code by pressing the field above. This will let you share any folder or picture with your preferred doctor, for free, provided you have a 12-month active SkinVision subscription.

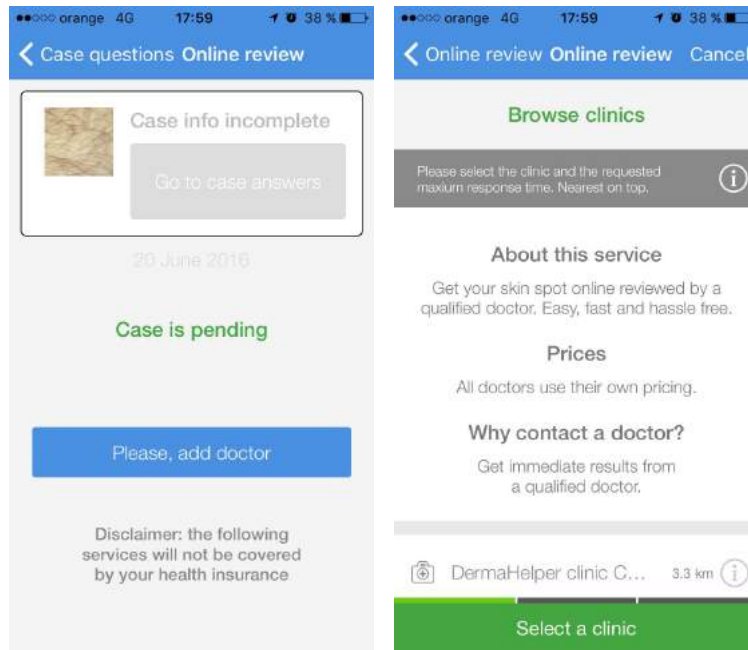


3.9.3 Select which service you want to use, after which you are asked to select the picture or folder where the case is about, your Skin Type and Risk Profile, and answer a few questions about the particular lesion.

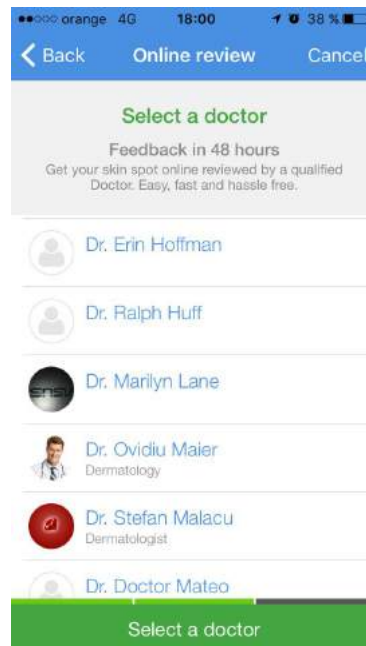



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3.9.4 Next, you will be shown a list of clinics from your country that have signed up with SkinVision.

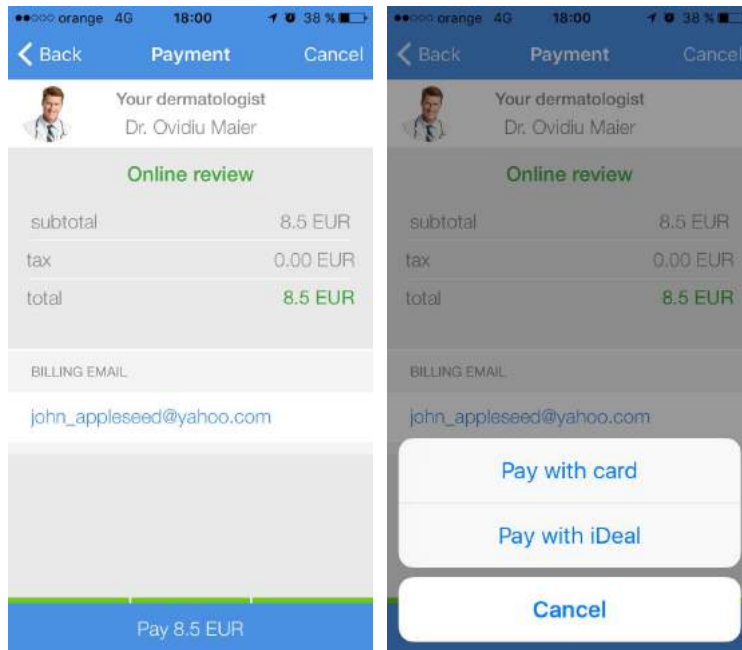


3.9.5 In the next step you will be asked to choose a doctor with whom you will share your concerns.




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3.9.6 The next screen shows you a review of what you have chosen, and how much it costs to start the case. Choose a method of payment to proceed, and complete the required fields.



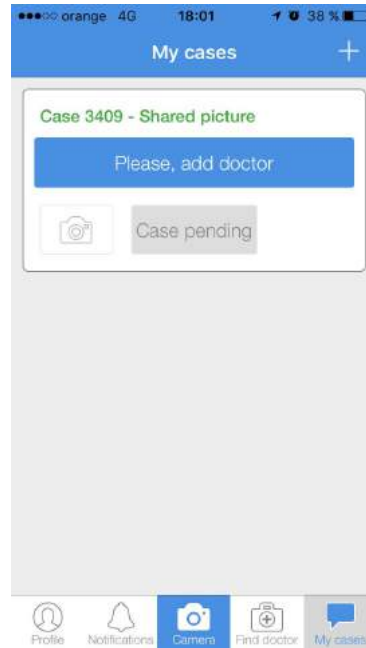
3.9.7 After the completion of the payment process you can start talking with your doctor.



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3.10 *Managing cases & appointments*

3.10.1 If you created a case, but have not added a doctor yet, the case card will ask you to add a doctor.

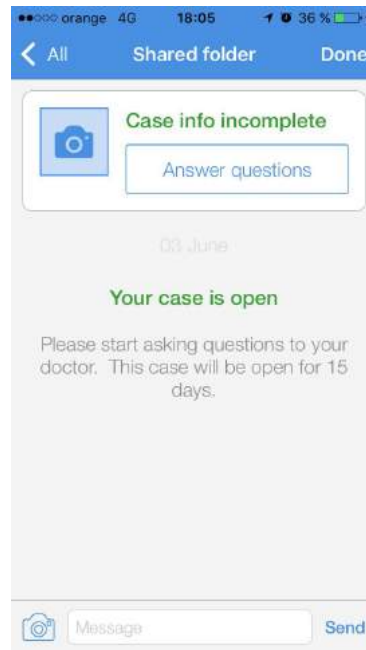


3.10.2 To send a message in a case, press the Open Case button and type a response in the text box at the bottom. To add a picture to a case, press the Camera button on the left, and take a new picture.



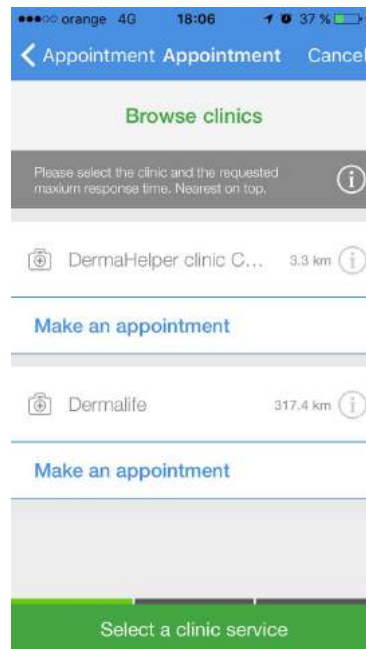
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3.10.3 If the case information is incomplete, press the 'Answer Questions' button to answer the questions.



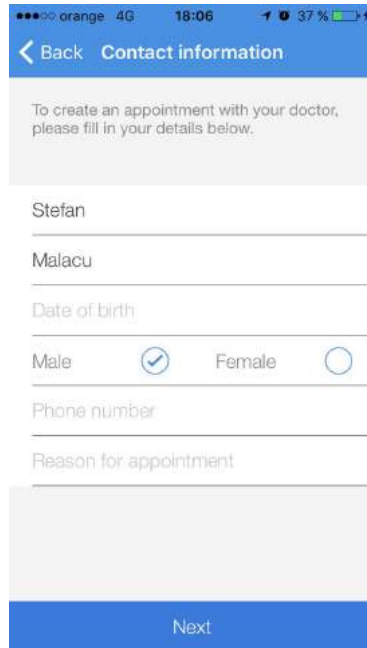
3.8 Making Appointments

3.11.1 To make an appointment, you will first need to select a clinic, and secondly select one of their doctors you would want to have an appointment with.



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3.11.2 In the next step your personal and contact information is required in order for doctors to know who is coming for a visit, why, and how they can be contacted.



orange 4G 18:06 37%

< Back Contact information

To create an appointment with your doctor, please fill in your details below.

Stefan

Malacu

Date of birth

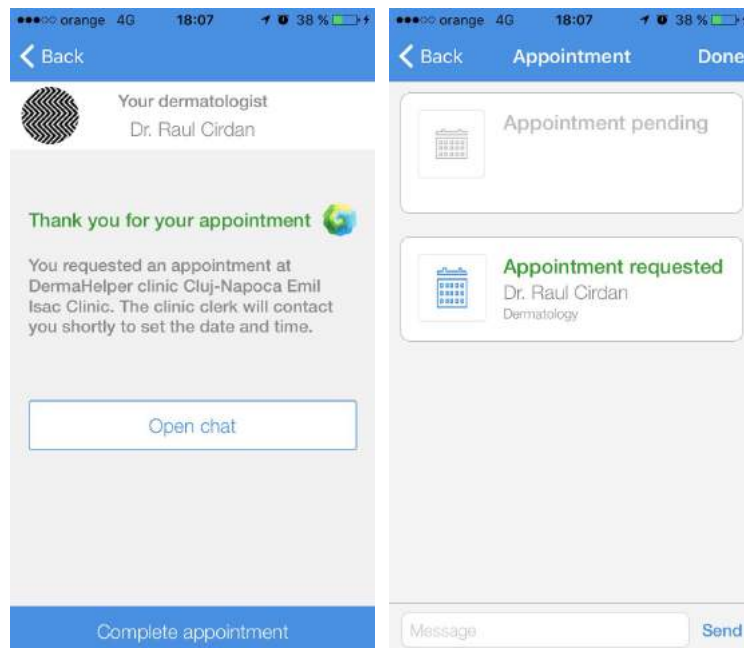
Male Female

Phone number

Reason for appointment

Next

3.11.3 After creating the appointment, the clinic clerk will ask you the date and time best suitable for your visit. After deciding on it, you will be reminded of the appointment as the date approaches.



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< Back

Your dermatologist
Dr. Raul Cirdan

Thank you for your appointment

You requested an appointment at DermaHelper clinic Cluj-Napoca Emil Isac Clinic. The clinic clerk will contact you shortly to set the date and time.

Open chat

Complete appointment


orange 4G 18:07 38%

< Back Appointment Done

Appointment pending

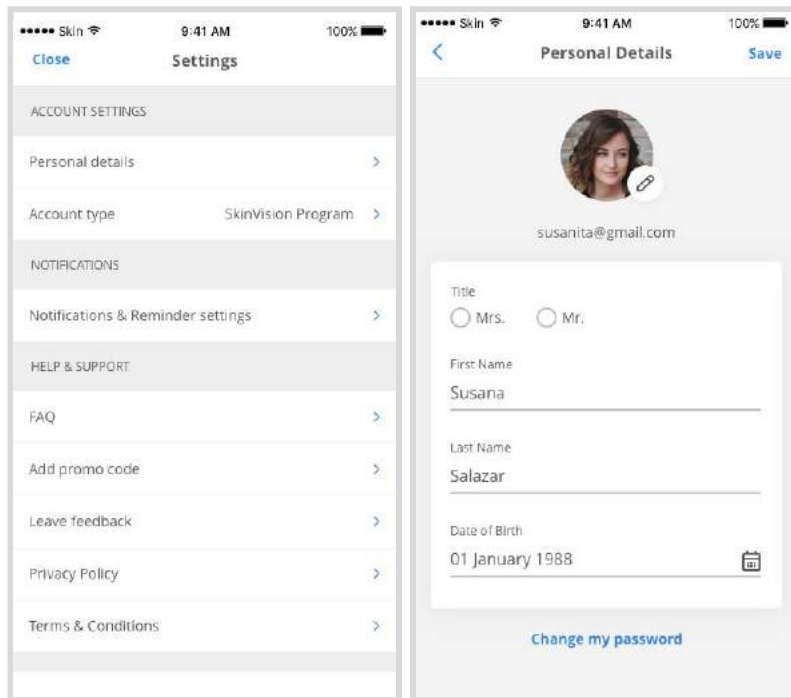
Appointment requested
Dr. Raul Cirdan
Dermatology

Message Send

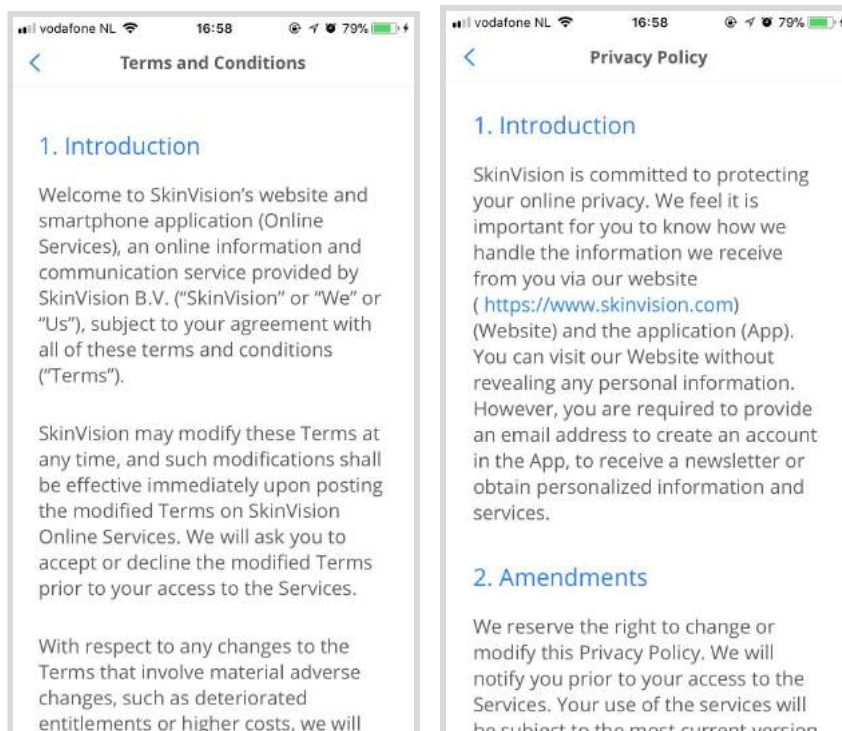
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3.12 Settings

In this screen you can review and edit your account information,

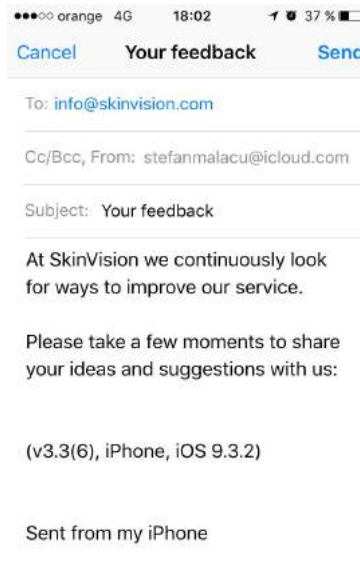


Press the 'Terms & Conditions' and 'Privacy Policy' buttons to review the respective documents.

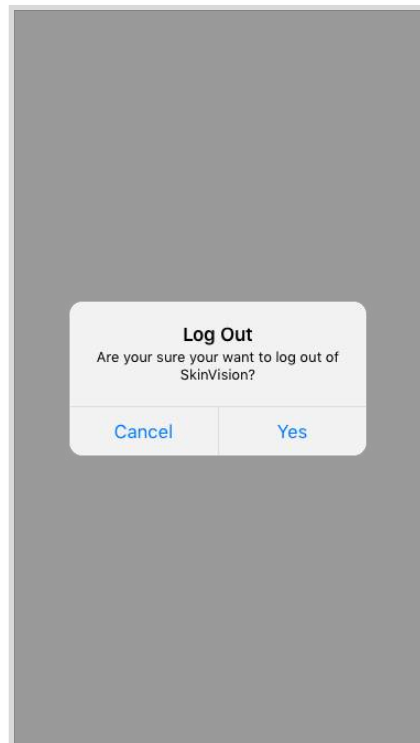



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Press the Ask us a question button to send SkinVision an inquiry.



3.13.6 Press Log out to end the session and remove access to your SkinVision account from your device.



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3.14 Error Messages

Function: To capture an image (mobile device level)

Failure Mode: Cannot capture the image

Effect of Failure: Image cannot be saved, shown to the user or forwarded for analysis; no result

Failure Cause: Cannot allocate memory at mobile device level

Proof of Risk Mastering: Informs user with message: “No image taken”

Function: Send image to backend (mobile device level)

Failure Mode: Image cannot be sent

Effect of Failure: No analysis result or image not stored in Archive

Failure Cause: No internet connection

Proof of Risk Mastering: Informs user with message: “No internet connection”

Function: Receive image (backend level)

Failure Mode: Image cannot be sent to server for analysis

Effect of Failure: Image cannot be analyzed

Failure Cause: Image cannot be parsed (arrived corrupted)

Proof of Risk Mastering: Informs user with message: “Image cannot be analyzed”

Function: Analyze image (backend level)

Failure Mode: Image cannot be analyzed


Effect of Failure: Image cannot be analyzed; no result is provided

Failure Cause: Low quality of image (low lighting or blurred image)

Proof of Risk Mastering: Inform user: “The image cannot be analyzed”

4 Warranty

You understand and agree that **SkinVision online services** and any services, content or information contained on or provided by **SkinVision online services** is provided on an „as is” basis. **SkinVision** does not make any express or implied warranties, representations or endorsements whatsoever (including without limitation warranties of title or noninfringement, or the implied warranties of merchantability or fitness for a particular purpose) with regard to the service or any merchandise, information or service provided through the service. In addition, SkinVision does not guarantee that use of SkinVision online services will be free from technological difficulties including, but not limited to, unavailability of information, downtime, service disruptions, viruses or worms and you understand that you are responsible for implementing sufficient procedures and checkpoints to satisfy your particular requirements for accuracy of data input and output.

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5 Legal Notices


5.1 Disclaimer

- a. The Online Services of SkinVision are being provided to monitor, track and understand your skin health. The Online Services are not to be used or relied on for any diagnostic or treatment purposes and they do not replace a visit to the doctor. Any reliance by you is at your own discretion and risk.
- b. The risk assessment tool within the app is provided to estimate the risk of an individual to develop melanoma (over time). It is highly recommended that you discuss your personal risk factors and results of your risk assessment with your doctor.
- c. SkinVision makes no representation or warranties relating to the information contained in our Online Services. We do not warrant that the medical information on the Online Services will be available, complete, completely accurate, up-to-date or not misleading.
- d. SkinVision is not involved in the conversations between you and the doctor and SkinVision does not refer you to or endorse or recommend particular doctors.
- e. SkinVision shall not be liable for any acts or omissions of doctors, content in communication, or the ability of doctor to answer questions.
- f. Notwithstanding the foregoing, SkinVision reserves the right, but is not obligated, to refuse to post or to remove any content and/or remove your access to the Service.
- g. We have no responsibility or liability for any kind of action that you do or do not take because of or despite of the information on the Online Services. If you are experiencing a medical emergency or you have any concern about your medical condition in any way you should seek immediate medical attention. You should not delay seeking medical advice, stop treatment, or disregard medical advice because of the information contained in the Online Services.

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- you do not use the materials in a way that suggests an association with SkinVision or an affiliated SkinVision entity. You understand and agree that title to these materials shall not pass to you or any other user.

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6 Manufacturer Contact Information



SkinVision B.V.

T.a.v. Dick Uyttewaal
Barbara Strozzilaan 201
1083 HN Amsterdam,
The Netherlands
Contact e-mail: info@skinvision.com