

SkinVision

Instructions for Use - English

SkinVision Service 6.0



Instructions for use are available in an electronic format



SkinVision B.V.

Kraanspoor 28
1033 SE Amsterdam
info@skinvision.com



This product complies with the relevant requirements of the EU Directive 93/42/EEC

INTENDED USE

The SkinVision Service is a software-only, over-the-counter (OTC), mobile medical application, which is intended for use on consumer mobile devices by laypeople.

The SkinVision Service allows users to take and submit photos of skin lesions for assessment, and gives a skin cancer risk indication associated with the specific lesion, detailing whether it is recommended to visit a specialized healthcare professional for further examination of the lesion, or to keep monitoring the lesion within the Standard Of Care.

The application also facilitates keeping track of skin lesions, and provides information on the photographed lesions that may be used when seeking professional healthcare advice.



The SkinVision Service augments already existing self-assessment techniques of skin lesions, and is not an alternative to healthcare professionals, who may however use the SkinVision Service.

The SkinVision Service is not intended for use on persons under the age of 18 years old (22 y.o. in the United States of America). The SkinVision Service does not diagnose skin cancer, does not provide any other diagnosis.

USING SKINVISION



Please note before you start

Do not use the app to take a photo of a skin spot that:

1. Is close in color with the surrounding skin, for example, a skin spot on (very) dark skin (type V and VI per the Fitzpatrick scale), white patch on fair skin, or on sunburnt skin,
2. is surrounded by multiple skin spots,
3. is surrounded by non-intact skin (e.g. open sores, ulcers, bleeding, scabs),
4. is under the nail,
5. is close to a (visible) area with scar(s),
6. contains foreign matter (e.g. marker, tattoo, sunscreen, skin cream, powder, etc.),
7. is covered by a significant amount of hair,
8. is on mucosal surfaces (e.g. lips, genitals),
9. is on or near a skinfold (e.g. eyelid, navel),
10. is not on human skin.

The SkinVision service is not intended to replace traditional methods for the evaluation of skin cancer risk level, does not give a diagnosis, and is not a substitute for visits to a healthcare professional.

The SkinVision Service is not intended for use on persons under the age of 18 years old (22 y.o. in the United States of America).



1. SkinVision download and account creation

- Download the SkinVision App from the App Store or Google Play Store on a compatible iOS or Android phone (For more information on supported devices, please visit skinvision.com/compatibility).
- Open the SkinVision App and follow the instructions in creating an account.

2. Performing a Smart Check

- Find an evenly lit place where you can make a Smart Check. Avoid direct light sources that may cause shadows on or around your skin spot.
- Open the SkinVision App and tap on the camera icon.
- You will be taken to a screen where you can map your skin spot by tapping anywhere on the picture of the body.
- Once you've tapped on the body to place a spot, a '+' icon will appear. You will be asked whether you want to add a new skin spot.
- After tapping 'Yes, check a new spot', a help screen to introduce you to the Smart Camera will open.
- Once you have read the guidance and watched the video, press 'Continue', the Smart Camera will open.
- Aim the Smart Camera at the spot on the skin you want to assess and wait for the camera to focus.
- To help focus the camera, adjust the distance of your phone between 4-8 inches (10-20 cm) from the skin spot until the blue ring appears on the screen. Refer to the in-camera feedback to understand which photo criteria need to be met.
- If you are unable to take a clear photo of your skin spot or if it is in a position that is difficult to reach by yourself we recommend asking another person (friend, family member) to take the photo for you or to see a healthcare professional.
- Once your Smart Photo has been taken, review the photo and confirm that this is a clear and focused image of the skin spot you want to have assessed. Otherwise, retake the photo.



- Indicate whether any symptoms are present regarding the spot on the skin (no symptoms, itching, bleeding, changing or infected). Multiple choices are allowed.
- You will receive a risk indication associated with the specific spot, detailing whether it is recommended to visit a specialized healthcare professional for further examination or to keep monitoring the spot.

	<p>In case of High risk</p>	<p>Make an appointment to see your doctor, preferably within the next 2 weeks so you can get a more in-depth examination of this skin spot.</p> <p>Stay calm. Remember that this recommendation does not mean you have skin cancer.</p>
	<p>In case of Low risk</p>	<p>Set a reminder to do a skin check within 3 months. Remember that some skin spots can change in a relatively short period of time.</p> <p>We recommend that you regularly check your skin spots for changes and seek medical advice if you have any concerns, and especially if it changes in color, size, shape and/or if it's itching or bleeding.</p>

3. Monitoring over time

- When finishing your Smart Check, you can set a reminder to check the skin spot in the future. Dermatologists recommend that you check your skin every three months.
- You can adjust the frequency and type of reminders and means of notification by tapping on the "Reminders" tab.
- Smart Checks that were made previously can be found by tapping on the skin spot in the "My body" screen.



4. Personal risk profile for skin cancer

- Select “Risk Profile” or “Skin Type” from “My body” and take the quiz to receive information on your personal risk for skin cancer based on your physique, lifestyle and medical history.
- You can receive a notification about the strength of the UV index in your local area. To do this first enable the app to access your location. You will then see an alert in the action bar when the UV index in your local area is high, or very high.

5. Healthcare professionals

- The SkinVision Service may be used by any person (therefore including healthcare professionals) within the provisions set forth in the intended use.
- Healthcare professionals should generate a healthcare PDF report and store this in the patient's file and subsequently delete photos taken after each consultation finishes.
- Ensure to keep a record that each patient agrees to Terms and Conditions and Data Privacy Policy.
- The SkinVision Service is not intended for population screening in the Netherlands.

PROBLEM SOLVING

If you encounter any problems during the use of the SkinVision Service, follow the instructions in the troubleshooting guide below or contact us at support@skinvision.com.

Problem	Solution
The Smart Camera does not detect the skin spot.	<ol style="list-style-type: none"> 1. Make sure that the view of the camera on the skin spot is not obstructed. 2. Center the camera on the skin spot so that the dot in the center of the camera interface turns green 3. Make sure that there is enough lighting at your location so that your skin (spot) is lit evenly.



Problem	Solution
The Smart Camera does not focus on the skin spot.	Adjust the distance of the camera to the skin spot to between 4-8 inches (10-20cm) and allow the camera to focus.



WARNING

1. Do not install or use the SkinVision App on a device with non-original iOS or Android ('jailbroken' or 'rooted') software.
2. Before using the SkinVision App, check that the camera lens is clean and not obstructed by anything. Wipe the lens carefully with a soft cloth if it is dirty.
3. Do not cover the flashlight source or the camera in any way while the photos are being captured.
4. Do not upload or transmit content of any type that may infringe or violate the rights of any party.
5. Do not disable, modify, "hack" or otherwise interfere with the proper functioning of this software.
6. In case multiple assessments of the same skin spot provide a different outcome, you shall visit a healthcare professional.

ADDITIONAL INFORMATION

For more detailed information, troubleshooting or technical information, please visit <https://www.skinvision.com/faq> or contact us at support@skinvision.com.

ABOUT SKINVISION






SkinVision B.V. has been certified by BSI to ISO 13485, ISO 27001 and NEN 7510 for information security and medical device quality management under certificate numbers MD 667168, ISC 340 and NEN 7510-082.



DISCLAIMER

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 inquiries 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.

SYMBOLS USED ON THE DEVICE

Symbol	Title of the symbol
	Consult Instructions for use
	Manufacturer
	Date of manufacture
	CE Mark
	Warning