



Instructions for Use - English

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. The SkinVision Service does not diagnose skin cancer, does not provide any other diagnosis.



USING SKINVISION SERVICE



Please note before you start

Do not use the app to take a photo of a skin spot or lesion 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), a 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.

If you fall into 1 or more of the following categories, you are considered to be at an elevated risk of developing skin cancer in your lifetime. Seek professional medical attention for any worrisome skin spots or lesions if you have:

1. Personal history of any skin cancer;
2. Family history of melanoma in a first-degree relative;
3. Red hair;
4. Immune suppression/compromise (e.g. organ transplant patients or patients using immunosuppressive



- medications, AIDS patients, or patients with a history of lymphoma);
5. Genetic or acquired susceptibility disorders such as photosensitivity, DNA-repair defects (a disease called xeroderma pigmentosum) , albinism, radiation exposure, or use of photosensitizing drugs.

The SkinVision Service is not intended for use on persons under the age of 18 years old.

1. SkinVision App 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](https://www.skinvision.com/compatibility)).
- Open the SkinVision App and follow the instructions in creating an account.

2. Performing a Smart Check photo

- Find an evenly lit place where you can take a Smart Check photo.
 - 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 a skin spot or lesion by tapping the body map icon in the same location as the area of the skin you want assessed.
- Once you've tapped on the body map icon, a '+' icon will appear. You will be asked whether you want to add a new skin spot photo or cancel and select again.
- After tapping 'Add spot', a help video will guide you through the best practices for taking a photo.
- Once you have read the guidance and watched the video, instructions listed here for reference: <https://www.skinvision.com/getting-started/>, press 'Continue' and your camera will open.
- Aim the 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.
- A photo will be automatically taken once 3 criteria have been met: "In focus", "Detected", and "Clear"
 - You will know these criteria have been met when a green checkmark '✓' appears below each photo criteria.
 - 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 consult a healthcare professional.
- Once your Smart Check 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. If symptoms are listed, the algorithm will recommend you visit a doctor.
- You will receive a risk indication associated with the specific skin spot or lesion, detailing whether it is recommended to visit a specialized healthcare professional, or to keep self-monitoring the spot.

	In case of High risk	Make an appointment to see your doctor, preferably within the next 4 weeks so you can get a more in-depth examination of this skin spot or lesion. This risk assessment is NOT a skin cancer diagnosis. However, it is an indication that certain elements of your skin spot photo match those of the skin cancer images in our database.
	In case of Low risk	Set a reminder to do a skin check within 3 months. Remember that some skin spots can



	<p>without listed symptoms</p>	<p>change in a relatively short period of time.</p>
	<p>In case of low risk and listed symptoms</p>	<p>SkinVision did not identify a match between the photo and high-risk skin cancer images in the database. However, because you indicated symptoms a follow up message will be sent to you in the coming days with a personalized recommendation.</p> <p>Warning signs that the skin spot or lesion may be skin cancer:</p> <ol style="list-style-type: none"> 1. Changing: a skin spot that changes in size (fastly growing), in color (especially getting darker or exhibiting multiple colors and shows shades of tan, brown, or black; even pink, blue or white) or shape (develops an odd, irregular shape). 2. Bleeding: a lesion that bleeds easily (several times) or crusts over. Those lesions can also appear as a non-healing sore or sore that heals and returns. 3. Itching: a spot or sore that continues to itch. 4. Infected: a lesion that develops an abnormal redness around the area that becomes tender and painful.
	<p>In case of quality check needed</p>	<p>The SkinVision algorithm has determined that an extra quality check is needed to provide you with the most accurate outcome.</p> <p>You will receive your final recommendation within 48 hours via the SkinVision app and</p>



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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 3 months.
 - You can adjust the frequency and type of reminders and means of notification by tapping on the “Reminders” tab.
- Photos that were previously submitted can be found by tapping on the skin spot in the “My body” tab in the bottom left corner of the screen.
 - You can download a PDF version of the submitted photo and associated risk assessment by clicking on the photo, selecting “see more details”, then select the “Share all” icon in the bottom right corner, and finally select the “Generate my report” button.
 - This feature allows users to take and save images of the same skin spot over time. The SkinVision Service algorithm does not analyze changes between photos and the photos cannot be overlaid for comparison.

4. Personal risk profile for skin cancer and environmental factors

- Select “Risk Profile” or “Skin Type” from the “My body” tab and answer the questionnaire to receive information on your personal risk for skin cancer based on your physique, lifestyle, and medical history.
 - Please note that these standalone features are for you to understand your skin health and in no way impact the algorithm outcome.
- 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.



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 The camera does not detect the skin spot or lesion.	Solution <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 or lesion 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 The camera does not focus on the skin spot.	Solution <p>Adjust the distance between the camera and the skin spot to 4-8 inches (10-20cm) to allow the camera to focus. You will know the camera is in focus when a green checkmark appears beneath the "In focus" section of the photo quality criteria. A photo will be automatically taken once 3 criteria have been met: "In focus", "Detected", and "Clear".</p>



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. Due to the functionality of the algorithm, in certain cases you may receive different risk assessment outcomes for different photos taken in rapid succession of the same skin spot. In such cases, err on the side of caution and always visit a healthcare professional.

Performance

The SkinVision Service algorithm can correctly detect the most common types of skin cancer 87-95% of the time (sensitivity). The specificity of SkinVision Service for clearly benign lesions, commonly known as spots that do not need a visit to the doctor, is 70-80%.¹

ABOUT SKINVISION

Skin Vision 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 **Skin Vision 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.

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SYMBOLS USED ON THE DEVICE

Symbol	Title of the symbol
	Consult Instructions for use
	Manufacturer
	Date of manufacture
	CE Mark
	UKCA Mark
	UK Responsible Person
	Australian Sponsor
	Warning

ADDITIONAL INFORMATION

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



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