



## Instructions for Use - English

<b>Current Revision</b>	1.6
<b>Replaces Version</b>	1.5
<b>Basic UDI</b>	872089231SV6.0G5
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### Note regarding availability of electronic Instructions for use:

The printable PDF version of Instructions for Use can be found on our website: <https://www.skinvision.com/instructions-for-use/>

This link provides access to the latest version of the IFU in electronic format (eIFU). All documents are stored in ".pdf" format to allow access with any standard PDF reader software and web browsers.

In order to know the correct version of the IFU, always select the IFU provided in the website. This is always kept up-to-date. In case you need to access an older version of the IFU, this can be accessed in the archived section of the webpage.

If you wish to have the IFU in paper format, you may request so by contacting us at [support@skinvision.com](mailto:support@skinvision.com). Please provide us your details and address where it shall be sent. We expect to deliver it to you within 7 business days. You shall not be charged for this.



## 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 consists of an assessment module that generates an immediate indication of risk for the most common types of skin cancer based on a picture of the skin lesion of concern, taken with the app on the mobile device.

Based on the assessment, the SkinVision Service provides a recommendation whether to continue monitoring or recommends to visit a health professional for a further review of the skin lesion.

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.

The SkinVision Service is not intended for use on people under the age of 18 years old. The SkinVision Service does not diagnose skin cancer, does not provide any other diagnosis.

**Indication for use:** The SkinVision Service generates an immediate indication of risk for the most common types of skin cancer based on a picture of a lesion on human skin.

## CLINICAL BENEFITS

SkinVision has the following clinical benefits:



1. SkinVision Service has the sensitivity and specificity better than self assessment or General Practitioners.
2. SkinVision Service helps to identify more cases of skin cancer compared to traditional methods and standard service.

## USING SKINVISION SERVICE

### Contraindications

It is not advised to 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, a white patch on fair skin, or on sunburnt skin,
2. Is on a darker skin types (IV, V and VI), due to camera limitations,
3. is surrounded by multiple skin spots (for example: a rash or an irritation on the skin's surface. It can look like a cluster of small red bumps, blotches, or reddened areas that may cause itching or burning.)
4. is surrounded by non-intact skin (e.g. open sores, ulcers, bleeding, scabs),
5. is under the nail,
6. is close to a (visible) area with scar(s),
7. contains foreign matter (e.g. marker, tattoo, sunscreen, skin cream, powder, etc.),
8. is covered by a significant amount of hair,
9. is on mucosal surfaces (e.g. lips, genitals),
10. is on or near a skinfold (e.g eyelid, navel),
11. is not on human skin.



## Please note before you start

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 device is highly accurate, correctly identifying over 90% of the three most common forms of skin cancer (sensitivity) which are Malignant Melanoma (MM), Squamous Cell Carcinoma (SCC) and Basal Cell Carcinoma (BCC). The specificity measured on SkinVision's population is 89%, that the SkinVision gives reassurance in 89% of the cases where the lesion is actually benign. While it's very reliable, it's important to note that it may not be flawless in every scenario. This means:

1. Occasionally, the app might not correctly identify a high risk (false negative). Regular check-ups and consultations remain essential to ensure timely care.
2. The app might indicate a *high risk* when there is none (false positive), which could lead to an extra visit to your healthcare professional. While this may be inconvenient, these visits serve as a precaution to keep you healthy.
3. Clinical studies have demonstrated the accuracy of the device. These studies showed that while the accuracy of the outcome may vary due to factors such as age and the location of the lesion, these variations remain within the acceptable range. In case of any doubts or concerns about the results, users are advised to consult a medical professional.
4. Please carefully read the recommendation provided by the app. If you have any doubts about the results, feel free to consult us for clarification.



5. If anything in the app's information seems unclear or off, don't hesitate to reach out to us. We're here to assist you or your healthcare professional in getting the right guidance and support.

Your health and well-being are our top priorities. If you have any concerns or questions about the app or its results, please contact us anytime.

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 people under the age of 18 years old.

## Device Requirements

***Please note:*** We further reserve the right to exclude certain devices from



*downloading the application from the Google Play Store or the Apple App Store.*

<b>Operating System</b>	<p>The App shall be installable on compatible mobile devices running:</p> <ol style="list-style-type: none"><li>1. Android 7.0 or higher.</li><li>2. iOS version 12.0 or higher.</li></ol>
<b>Hardware Requirements</b>	<p>The Service shall require a mobile device with:</p> <ol style="list-style-type: none"><li>1. At least 1 GB of available RAM,</li><li>2. A touch screen</li><li>3. The availability of a back-facing camera with a minimum video streaming resolution of 720p and autofocus support</li><li>4. A torch (continuous flashlight).</li><li>5. An active internet connection.</li></ol>
<b>Security requirements</b>	<ol style="list-style-type: none"><li>1. The application should not be installed or used on devices with modified operating systems, such as 'jailbroken' iOS or 'rooted' Android devices, to maintain security.</li><li>2. You are advised to turn on the biometric authorization in the app settings. When enabled, biometric or pin authentication is required to start the SkinVision application.</li></ol>



## WARNINGS

1. 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.
2. Do not cover the flashlight source or the camera in any way while the photos are being captured.
3. Do not upload or transmit content of any type that may infringe or violate the rights of any party.
4. Do not disable, modify, "hack" or otherwise interfere with the proper functioning of this software.
5. 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.

## 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 .
  - Android:
    - Go to the Play Store and search for the app.
    - In the search result tap on the SkinVision app.
    - Tap "Install".
    - When the installation is complete, you will see the app's icon on the home screen or in the app drawer of your mobile device which means the app is ready to be used.



- iOS:

- Go to the App Store and search for the app.
- In the search result, tap on the SkinVision app.
- Tap “GET” and then “INSTALL”.
- If prompted, sign in to the App Store to complete the installation.
- When the installation is complete, you will see the app’s icon on the home screen of your mobile device and the app is ready to be used.
- Open the SkinVision App and follow the instructions in creating an account.
- After an account is created, the app is ready to be used for checking your skin spot.

## 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.
- 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.

**If you have managed to clear all the steps above and have received a recommendation, then the app is working as per its intended use. In case you run into any errors, please refer to the "Problem Solving" chapter in this document or refer to the [FAQs](#) on our website. You can also reach out to us at [support@skinvision.com](mailto:support@skinvision.com).**

	<b>In case of High risk</b>	Make an appointment to see your doctor, preferably within the next 4 weeks so
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		<p>you can get a more in-depth examination of this skin spot or lesion.</p> <p><u>This risk assessment is NOT a skin cancer diagnosis.</u> However, it is an indication that certain elements of your skin spot photo match those of the skin cancer images in our database.</p>
	<b>In case of Low risk without listed symptoms</b>	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.



	<b>In case of low risk and listed symptoms</b>	<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"><li>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).</li><li>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.</li><li>3. Itching: a spot or sore that continues to itch.</li><li>4. Infected: a lesion that develops an abnormal redness around the area that becomes tender and painful.</li></ol>
	<b>In case of quality check needed</b>	<p>The SkinVision algorithm has determined that an extra quality check is needed to provide you with the most accurate outcome.</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](mailto:support@skinvision.com).

Problem	Solution
The camera does not detect the skin spot or lesion.	<ol style="list-style-type: none"><li>1. Make sure that the view of the camera on the skin spot is not obstructed.</li><li>2. Center the camera on the skin spot or lesion so that the dot in the center of the camera interface turns green.</li><li>3. Make sure that there is enough lighting at your location so that your skin (spot) is lit evenly.</li></ol>
The camera does not focus on the skin spot.	Adjust the distance between the camera and the skin spot to 4-8 inches (10-20 cm) 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".

## AI and Performance

The recommendations provided by the SkinVision Service are based on an algorithm that uses artificial intelligence (A.I.) to assess the risk of skin cancer. This algorithm operates as a statistical model, trained on an extensive collection of photos annotated by board-certified dermatologists. The SkinVision Service algorithm has a sensitivity of greater than 90% in the detection of the three most common types of skin cancer (MM, SCC and BCC) and a specificity of 89% on SkinVision's user population



**Quality Control:** In cases where the assessment of skin lesion pictures indicates risks of skin cancer, the pictures undergo an additional quality control process that includes an extra assessment by a panel of expert dermatologists.

## Incident Reporting

Any serious incident should be reported to the manufacturer and the competent authority of the EU member state where the user resides.

### What is a serious incident?

As per Regulation (EU) 2017/745 (EU Medical Device Regulations), a serious incident is defined as any incident that directly or indirectly led, might have led or might lead to any of the following:

1. the death of a user,
2. the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
3. a serious public health threat.

An incident can be reported to us via email: [regulatory@skinvision.com](mailto:regulatory@skinvision.com) and to the competent authority of the EU member state concerned.

A list of competent authorities by EU member states can be found at the following link:

[https://ec.europa.eu/health/document/download/c28e965a-3b7c-4a5b-a6ee-d1724d06f20d\\_en?filename=md\\_contact\\_points\\_of\\_national\\_authorities.pdf](https://ec.europa.eu/health/document/download/c28e965a-3b7c-4a5b-a6ee-d1724d06f20d_en?filename=md_contact_points_of_national_authorities.pdf)

Please use the above link to find the relevant competent authority for your country of residence and click on the link to their website to submit an incident report.



## Data Deletion

### How do I delete a photo?

In case you wish to delete a photo taken for an assessment in the past, please complete the following steps in the app:

- Open the SkinVision app
- Click on "My Body" tab
- Click on the icon  (list view)
- Choose the photo you want to delete from the list
- Click on the photo again
- Click on the bin icon on the top right corner
- Choose "Yes"
- Your photo is deleted.

### How do I delete my account?

We understand that there may come a time when you no longer feel the need for our service. In the interest of empowering all users in taking control of their data, we want to make deletion an easy process if you choose to do so:

You can delete your account by simply completing the following steps:

- Open the SkinVision app
- Click on 'Account' at the bottom right
- Scroll down and click on 'Delete account'
- Read the proposed information and click 'Confirm'
- Tick the 'I agree' box and click 'Delete my account'

Your account and associated data will now be deleted automatically.



## **What happens to your data after deletion?**

Some of your Personal Data (Personal information) including name, email, insurance number may be kept until the next billing cycle. This is for tax purposes.

However, your device details and IP address are anonymised so that there is no trace back to you personally.

Personal Health information including images, tags and recommendations are also completely anonymised after your account is deleted. As a medical device, we are required to keep this for audit trails.

If you have any questions related to this article, please contact our support team at [support@skinvision.com](mailto:support@skinvision.com).

## **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.



## SYMBOLS USED ON THE DEVICE

Symbol	Title of the symbol
	<b>Consult Instructions for use</b>
	<b>Manufacturer</b>
	<b>Date of manufacture</b>
	<b>CE Mark with reference number of the Notified body</b>
	<b>UK Responsible Person</b>
	<b>Australian Sponsor</b>
	<b>Warnings/Precautions</b>
	<b>Medical Device</b>
	<b>Unique Device Identifier (Basic UDI)</b>



## ADDITIONAL INFORMATION

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



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UK REP

### UK Responsible Person

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