

IVY AI SOLUTIONS · SCANSKINAI

Ivy AI Skin Illness Detection - Instructions for Use (IFU)

ScanSkinAI mobile / web workflow | Assistive screening and triage only - not a diagnosis

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Manufacturer	Ivy AI Solutions Limited
Product	ScanSkinAI - Ivy AI Skin Illness Detection Module

Important: ScanSkinAI is a screening and triage aid. It cannot rule in or rule out a medical diagnosis and must not be used to delay urgent or professional medical care.

1. Device Identification

Product / Medical Device Name	Ivy AI Skin Illness Detection Module
Trade Name	ScanSkinAI
Manufacturer	Ivy AI Solutions Limited, 71-75 Shelton Street, Covent Garden, London WC2H 9JQ, United Kingdom
Document Version	2.0
Software Configuration	V2.0 - three-module architecture
GMDN Code / Term	67021 - Home-use dermatological image-analysis software
UK Classification	General Medical Device - Class I (non-sterile, non-measuring)

2. Intended Purpose

ScanSkinAI analyses user-captured photographs of the skin to support screening and triage for skin conditions. It provides a structured assessment, condition or risk indicators, safety guidance and recommendations on when professional review may be appropriate. It is intended for use in non-emergency home or clinic environments.

ScanSkinAI does not provide a definitive diagnosis, does not prescribe treatment, does not control therapy or measure physiological parameters, and does not replace assessment by a qualified healthcare professional.

3. Intended Users and Use Environment

- Adults using the service for themselves.
- Carers assisting another person, with appropriate consent.
- Healthcare or wellness professionals using the software as an assistive screening/triage tool.
- Non-emergency home, clinic, pharmacy, workplace screening or other controlled environments with suitable lighting and internet access.

4. How the V2.0 Analysis Works

The user experience presents one integrated result. Internally, the current controlled configuration uses three coordinated AI modules:

Stage	What it does
1. LLM Triage	Performs initial visual/contextual triage and safety routing.
2. 77-Condition Classifier	Assesses the image against the defined 77-condition dermatological classifier taxonomy.
3. High-Risk Cancer Flag	Checks for high-risk indicators associated with melanoma, basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), using conservative escalation logic.

The total controlled condition coverage is 80 conditions. The LLM triage module is a processing and safety layer and is not counted as an additional condition.

5. Indications, Limitations and When Not to Use

- Use for a visible skin concern that can be photographed clearly with one primary area of interest in frame.
- Do not use as the sole basis for deciding whether a lesion or skin condition is benign, malignant or requires treatment.
- Do not use for emergency situations, severe allergic reactions, breathing difficulty, rapidly spreading swelling, uncontrolled bleeding, severe pain, or rapidly worsening illness. Seek urgent medical care instead.
- Do not rely on the service for mucosal surfaces, images dominated by tattoos/occlusion, or images where the relevant skin feature is not clearly visible.
- Performance depends on image quality, lighting, focus, skin visibility and the clinical similarity of different skin conditions.
- A low-risk or reassuring result does not exclude cancer or another clinically important condition.
- Children should not use the software independently; an appropriate adult should supervise and obtain any required consent.

6. Required Equipment

- A compatible smartphone, tablet or other camera-enabled device with a working camera.
- A stable internet connection.
- The ScanSkinAI application or authorised ScanSkinAI web / hosted scan interface.

7. Quick Start

1. Open ScanSkinAI using the authorised app, website or scan link and review the privacy information and consent requirements.
2. Select or confirm the body location where requested.
3. Prepare the skin area and use good, even lighting. Remove heavy cosmetics or anything that obscures the feature where practical.
4. Capture one clear image centred on the main area of concern, with a small margin of surrounding skin. Retake if the image is blurred, too dark, overexposed or obstructed.
5. Submit the image for analysis. If the quality or safety checks are not satisfied, follow the prompt to retake or seek professional review.
6. Review the result, including the condition/risk assessment, any high-risk flag, the plain-language explanation and the recommended next step.
7. Seek professional medical assessment whenever advised, when symptoms persist or worsen, or whenever you remain concerned regardless of the software result.

8. Image Capture Guidance

- Use natural light or a steady indoor light; avoid harsh glare and deep shadows.
- Clean the camera lens and hold the device steady.
- Keep the relevant skin feature in focus and large enough to assess while retaining some surrounding skin context.
- Avoid excessive digital zoom, beauty filters, image enhancement or screenshots where possible.
- Retake the image if the lesion is partly hidden by hair, clothing, jewellery, heavy cosmetics or strong reflections.

9. Understanding the Result

Result Element	Meaning
Condition / Findings	A screening-level description of the condition or visual pattern considered most relevant by the system. It is not a confirmed diagnosis.
Confidence / Risk Indicator	An estimate or qualitative indication of how strongly the image supports the screening output. It must be interpreted with the limitations of image-based analysis.

Result Element	Meaning
High-Risk Cancer Flag	A dedicated safety alert when suspicious features associated with melanoma, BCC or SCC are identified. A flag means prompt professional assessment is recommended; absence of a flag does not rule out cancer.
Recommendation	Plain-language next-step guidance such as retake/monitor, pharmacist/GP review, dermatology review, or urgent care depending on the detected risk and symptoms.

Do not delay care: If you are worried about a skin change, if the condition is worsening, or if symptoms are severe, seek professional assessment even if ScanSkinAI provides a low-risk or uncertain result.

10. High-Risk Cancer Safety Guidance

- The High-Risk Cancer Flag is designed as a conservative safety mechanism for melanoma, basal cell carcinoma and squamous cell carcinoma indicators.
- A high-risk flag is not a cancer diagnosis. It means the image contains features that warrant timely professional clinical assessment.
- Do not attempt to self-treat or remove a suspicious lesion based on the result.
- If a lesion is changing rapidly, bleeding repeatedly, ulcerating, painful, or otherwise concerning, arrange professional assessment even when no high-risk flag is shown.

11. Warnings and Contraindications

- This software does not provide a definitive medical diagnosis or treatment decision.
- Do not delay professional or emergency care because of a ScanSkinAI result.
- False positive, false negative, uncertain and visually confusable results can occur.
- Do not upload images containing unnecessary personally identifiable information.
- Do not use altered, filtered, heavily compressed or poor-quality images where the skin feature is not reliably visible.
- Results must be interpreted together with symptoms, history and clinical context by an appropriate healthcare professional when medical concern exists.

12. Data Protection and Privacy

- Images and associated data are protected using encryption in transit and at rest within the controlled service environment.
- Where the product offers optional image/history storage, use the available privacy settings according to your preference and applicable service terms.
- Refer to the current ScanSkinAI Privacy Policy and in-product notices for data processing, retention, deletion and data-subject rights.

13. Troubleshooting

Issue	Action
Upload fails	Check the internet connection, confirm the file is a supported image, and try again.
Image rejected / retake required	Improve lighting, clean the lens, steady the camera and ensure the main skin feature is visible and in focus.
No analysis / non-skin image message	Confirm that the submitted image clearly shows skin and one primary area of concern.

Issue	Action
Result seems inconsistent with symptoms	Do not rely on the software result. Seek professional clinical assessment.

14. Clinical Safety Notes

- Safety logic is designed to favour retake, deferral or referral when image quality or model confidence is insufficient.
- High-risk cancer handling is calibrated for conservative escalation rather than reassurance where suspicious features are present.
- Different dermatological conditions can look similar in a photograph; clinical examination, dermoscopy, pathology or other tests may be required for diagnosis.
- The Phase 1 clinical audit reported 98% clinically acceptable triage performance across 100 reviewed production cases; these data support assistive triage use and do not eliminate the possibility of individual errors.

15. United Kingdom Regulatory Notice

The UK registered device is a Class I General Medical Device under UK MDR 2002 and is associated with GMDN 67021 - Home-use dermatological image-analysis software. The intended use is assistive screening and triage, not standalone diagnosis.

16. Electronic Labelling and Versioning

- This IFU may be provided electronically within the ScanSkinAI application and/or on the ScanSkinAI website.
- The software version or release identifier is available within the application or service information area where applicable.
- Use only the current released version of the software and the current IFU supplied by Ivy AI Solutions Limited.

17. Manufacturer and Support

Manufacturer	Ivy AI Solutions Limited
Address	71-75 Shelton Street, Covent Garden, London WC2H 9JQ, United Kingdom
Support	info@ScanSkinAI.com
Website	www.scanskinai.com

Document Revision History

Version	Date	Change Summary
1.1	Nov 2025	Earlier mobile IFU; UK scope limited to cancer-suspicion triage and earlier GMDN wording.
2.0	31 Aug 2026	Updated GMDN term; aligned IFU to 80-condition screening/triage scope and current three-module architecture; added dedicated cancer-flag safety guidance and updated limitations/warnings.