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

Version 1.1 • Mobile app workflow • This software provides assistive screening/triage only — it does not diagnose.

1. Device identification

Product name: Ivy AI Skin Illness Detection Module (mobile app + cloud inference)

Manufacturer: Ivy AI Solutions Limited, 71–75 Shelton Street, Covent Garden, London WC2H 9JQ, United Kingdom

Software version: v1.0 (DINOv2-Base backbone)

2. Intended purpose

Standalone software that analyses user-captured smartphone photographs of skin lesions and returns a ranked risk/differential result with a recommendation to support clinician review and referral. The software is not intended to provide a diagnosis or treatment decision and does not control therapy or perform physiological measurement.

3. Intended users and environment

- Adults, carers, and healthcare professionals.
- Use in non-emergency settings (home or clinic).

4. Indications & limitations

- Single visible cutaneous lesion (e.g., mole, rash patch, ulcer).
- Not for emergency situations, bleeding or rapidly worsening conditions — seek urgent care.
- Not for mucosal surfaces (mouth, genital), nails with heavy polish, or tattoos covering the lesion.
- Performance depends on image quality and lighting; results are decision-support only.

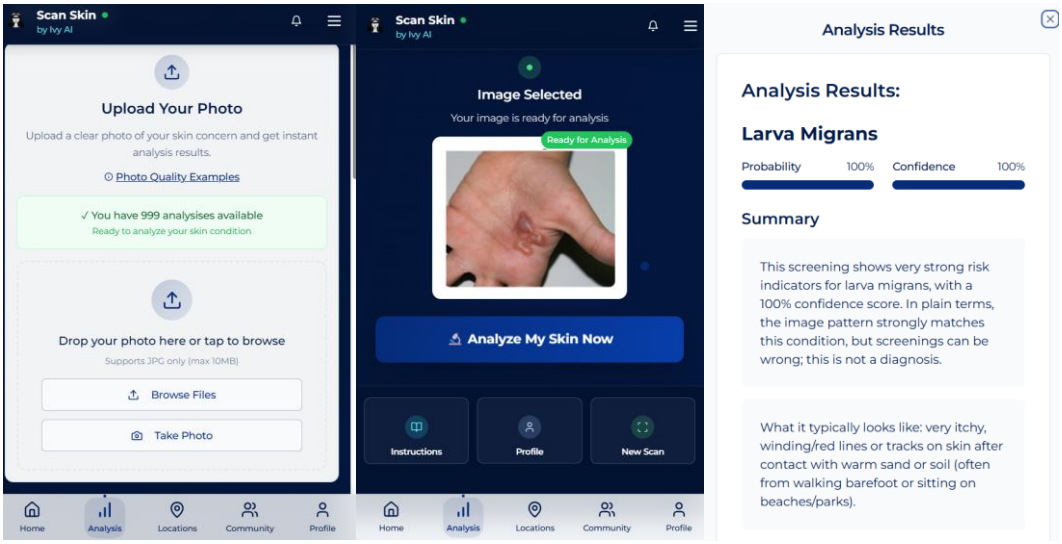
5. Required equipment

- A smartphone with a working camera and internet connection.
- The Ivy AI mobile app (ScanSkinAI).

6. Quick start — mobile workflow

1. Download the app: visit www.scanskinai.com and choose your mobile store.
2. Create your account: register and accept the privacy notice and consent.

3. Prepare the scene: clean the area; ensure good, even lighting; avoid heavy cosmetics; hold still.
4. Capture one clear photo of the suspicious lesion or mole. Take a second angle if possible.
5. Upload the photo in the app to run AI analysis.
6. Review the result page: ranked possible conditions with confidence and a plain-language recommendation (e.g., self-monitor, retake image, speak to pharmacist/GP/dermatologist, or urgent care).
7. Generate your PDF report from the result screen and save or share it with a clinician.
8. Follow the app guidance for when to seek professional assessment.



7. Image capture guidance

- Avoid harsh flash glare and strong shadows; use natural light or a steady lamp.
- Center the lesion with a small margin of surrounding skin.
- Keep the camera 10–20 cm from the skin; ensure the image is in focus.
- Retake if blurry, obscured, or overexposed.

8. Result interpretation

Your result includes three elements:

- **Findings** —brief summary of what the AI detected in the photo.
- **Recommendation** —simple, step-by-step advice for self-care you can try at home.
- **when to see a dermatologist**--- clear triggers and a timeframe for booking a specialist visit

Important: This is not a diagnosis. If in doubt or symptoms worsen, seek professional care regardless of the recommendation.

9. Warnings & contraindications

- This software does not provide a medical diagnosis or treatment decision.
- Do not delay professional care because of app results.
- Do not upload images that contain personally identifiable information.
- Not designed for children to use without adult supervision.

10. Data protection & privacy

- Images are encrypted in transit and at rest.
- You can choose not to store images after analysis; saved history is private to your account.
- See the in-app Privacy Policy for details on data processing, retention and your rights.

11. Troubleshooting

- Upload failed — check your internet connection and try again.
- Blurry results — retake with better lighting and steady hands; clean the lens.
- Model cannot analyse — ensure the image shows one primary skin lesion, not multiple or non-skin background.

12. Clinical safety notes

- Conservative thresholds prioritise sensitivity for suspicious patterns; uncertainty gating prompts retake or clinician review.
- Known confusions include visually similar pigmented lesions; the app will err on the side of referral when uncertain.

13. Market-specific notice (UK variant)

For the United Kingdom filing: the UK configuration supports cancer-suspicion triage only under the device category 'Skin cancer screening image-analysis software'. Non-cancer dermatology outputs are disabled in the UK build and are not claimed.

14. Electronic labelling & versioning

- The IFU is provided electronically within the app and on www.scanskinai.com.
- Software version is shown in the app's About screen; update via the app store.

15. Manufacturer & support

Ivy AI Solutions Limited • 71–75 Shelton Street, Covent Garden, London WC2H 9JQ, United Kingdom

Support: info@ScanSkinAI.com• www.scanskinai.com