ChatGPT

Android wound-healing measurement and tracking on Redmi Note 14 5G

Executive summary

A wound-tracking app on Redmi Note 14 5G can deliver clinically useful longitudinal metrics (area change, tissue/colour proportions, healing rate) **if** it treats imaging as a measurement system rather than "taking photos". The device's rear camera system (high-resolution main sensor with optical stabilisation) is capable of capturing consistent images suitable for 2D planimetry, but the main determinants of accuracy will be (a) **protocol** (distance, angle, lighting, scale marker placement) and (b) **calibration & QC** (fiducials, perspective correction, blur detection, and manual verification). [1]

Clinically accepted wound-area measurement methods span simple ruler estimates, contact/non-contact planimetry, calibrated digital photography, and 3D techniques. Ruler length×width methods are fast but systematically overestimate irregular wounds; digital planimetry with a robust scale strategy materially improves accuracy and precision, especially when using **two reference rulers/markers** to reduce bias from camera skew. [2]

Regulatory and ethical risk is dominated by: (1) whether the app's stated intended use makes it a regulated medical device (e.g., automated measurement or risk scoring used for clinical decisions), and (2) whether wound images and associated metadata are handled as sensitive health data with explicit consent, strong access controls, encryption, and auditable logs. HIPAA's technical safeguards and the GDPR/UK GDPR security expectations (e.g., encryption/pseudonymisation as appropriate to risk) provide a practical baseline; in Sri Lanka context, the Personal Data Protection Act also requires appropriate security measures and processing conditions. [3]

A pragmatic AI approach is a **segmentation-first pipeline** (wound boundary → calibrated area → optional tissue/colour proportions), with: lightweight U-Net-family models optimised for on-device inference; manual correction tools as a clinical safety backstop; and uncertainty estimation plus method-comparison statistics (e.g., Bland–Altman) to quantify agreement against an accepted reference process. [4]

Unspecified items that materially affect architecture and governance: the exact clinical workflow (who captures images, where, and under what infection-control constraints), number of users/devices, and deployment scale (single clinic offline vs. multi-clinic sync and analytics platform). These uncertainties should be treated as first-class requirements and explicitly documented in risk management and validation planning. [5]

Scope and assumptions

This report assumes the primary goal is **longitudinal wound monitoring** inside a clinic: repeated measurement of the same wound over days/weeks, with trends used to support (not replace) clinician judgement. That framing is consistent with how wound area reduction has been used as a predictor of healing in ulcer literature, but it does not automatically justify autonomous "diagnosis" or "treatment recommendation" claims. [6]

Where guidance differs by jurisdiction (US/EU/UK/Sri Lanka), the intent here is to surface common controls and evidence expectations rather than provide legal advice. Regulatory classification ultimately depends on *intended use*, claims, and workflow integration, which are not fully specified. [7]

Device capabilities and constraints of Redmi Note 14 5G

Camera, sensors, processing, storage, and what they mean for wound imaging

The official Redmi Note 14 5G specifications published by Xiaomi [8] indicate a rear triple-camera system with a high-resolution main camera and optical stabilisation, plus an ultrawide and macro camera. [9]

Key imaging-relevant details from official specs:

Component	Official spec (summary)	Imaging implication for wound measurement
Main rear camera	108MP, f/1.7, 1/1.67" sensor, 0.64μm pixels with 9-in-1 binning to 1.92μm; OIS; 6-element lens [9]	High detail and good low-light potential, but computational photography and auto-processing can alter colour/contrast; prefer controlled lighting and fixed capture settings where possible. OIS helps reduce motion blur (better edge consistency for segmentation). [10]
Ultrawide	8MP f/2.2 [9]	Generally **avoid** for measurement: wide-angle lenses have stronger distortion and perspective exaggeration unless rigorously calibrated and corrected. Better reserved for context photos (not area). [11]
Macro	2MP f/2.4 [9]	Low resolution; tends to be noisy and inconsistent for boundary delineation. Use main camera + minimum focus distance instead of macro lens for small wounds. [12]
Video	Up to 1080p at 30fps on rear; 1080p on front [13]	Video is not a substitute for calibrated stills. Still capture should be the primary measurement artefact. [14]
Sensors	Accelerometer, gyroscope, electronic compass, IR blaster, ambient light sensor, “virtual proximity sensor” [9]	Gyroscope + accelerometer can support **angle guidance** (keep camera normal to wound plane); ambient light sensor can prompt when illumination is too low/hot-spotted. No dedicated depth sensor is listed, limiting native 3D capture. [15]
SoC and compute	MediaTek [16] Dimensity 7025-Ultra (6nm), octa-core up to 2.5GHz, IMG BXM-8-256 GPU [9]	Adequate for on-device inference if models are lightweight (mobile encoder, int8 quantisation). Real-time overlays and QC checks are feasible if optimised. [17]

Component	Official spec (summary)	Imaging implication for wound measurement
RAM & storage	LPDDR4X + UFS 2.2; configurations include 6–12GB RAM and 128–512GB storage; microSD supported up to 1TB via shared SIM slot [9]	Storage is sufficient for local encrypted image archives, but **microSD introduces physical exfiltration risk**; prefer internal app-private storage with encryption and controlled export. [18]
OS	Xiaomi HyperOS [9]	OEM camera pipelines and background restrictions may affect determinism. Use platform APIs (CameraX) and in-app QC rather than assuming camera output is stable across updates. [19]

OS and Android constraints that affect clinical capture and privacy engineering

Camera capture should use **CameraX**, which is the recommended Jetpack library that provides consistent behaviour across devices for preview, image capture, and analysis pipelines. [20]

Modern Android storage is governed by **scoped storage**; sensitive clinical images should be saved in app-private storage (internal storage or app-specific external storage) rather than exposed public galleries, and exported only via explicit user action.

Two up-to-date platform constraints relevant to a medical imaging app:

- **Jetpack security-crypto deprecation**: Android's `security-crypto` / `security-crypto-ktx` libraries are deprecated with no further releases planned; implementations should rely on platform cryptography and direct Android Keystore use (or a maintained library such as Tink). [21]
- **NNAPI deprecation trajectory**: Android documentation indicates NNAPI is deprecated and focuses guidance on migrating workloads to other on-device execution paths (e.g., updated runtime approaches). This emphasises using supported inference stacks (e.g., TFLite delegates) rather than betting on NNAPI long-term. [22]

Clinically accepted wound measurement methods and accuracy trade-offs

Wound measurement methods trade off between speed, cost, infection-control practicality, and accuracy on irregular shapes and curved anatomy. A systematic review comparing wound measurement techniques highlights variability in accuracy, with 3D approaches often offering improved measurement capability (especially volume) at the cost of equipment and complexity, while 2D approaches are more accessible but sensitive to protocol. [23]

Method classes and practical accuracy considerations

Ruler-based (length × width) measurement is widely used due to simplicity, but it tends to overestimate area for irregular wounds because it uses bounding dimensions rather than the true outline. This is repeatedly documented in wound-measurement literature and is one reason planimetry is preferred when accuracy matters. [24]

Contact planimetry (tracing the wound perimeter on acetate/film and counting grid squares) is closer to "true outline" measurement but is slower and can be affected by wound curvature and contact/infection-control constraints. [25]

Digital photography with planimetry is the most practical non-contact path on a smartphone: segment the border on a calibrated image, then convert pixel area to cm². Accuracy hinges on a robust scale strategy and controlling camera angle: if the camera is not perpendicular, the reproduced area is affected (proportional to the cosine of the angle), and in practice you often do *not* know the exact angle well enough to compensate perfectly. [26]

Two-marker / two-ruler calibration is a crucial improvement: in an empirical evaluation, calibrating digital planimetry using two rulers (placed on opposite sides) substantially reduced measurement variability and improved accuracy compared with a single ruler, including when using smartphone cameras. [27]

3D measurement (structured light, stereo imaging, laser scanning, or photogrammetry) can better handle anatomical curvature and enable volume estimation, but feasibility on Redmi Note 14 5G is limited by lack of a listed depth sensor; implementing robust 3D often requires external hardware or multi-image reconstruction pipelines and more careful validation. [28]

Comparative table of clinically used approaches

Method	Typical workflow	Strengths	Main error sources	Fit for Redmi Note 14 5G
Ruler (L×W, rectangle/ellipse)	Measure max length + max width; compute rectangle or ellipse area [24]	Very fast, no software	Overestimation for irregular shapes; inter-rater variability; unclear boundary choices [24]	Useful only as a fallback or for rough triage; not ideal if you're building an "architecture and research specialist" measurement app. [29]
Contact planimetry (tracing)	Trace border on film and compute area by grid or digitiser [25]	More faithful to outline than L×W	Contact/infection-control; curved surfaces; manual tracing error [30]	Not phone-native; could be used as "reference method" for validation studies. [31]
Calibrated digital photography + 2D planimetry	Photo with scale marker; segment; pixel→cm² conversion [29]	Non-contact; scalable; supports audit trail	Camera tilt (cosine error), scale-marker misplacement, lighting/colour drift, lens distortion [32]	Best primary method for this device if paired with strong capture protocol and QC. [10]

Method	Typical workflow	Strengths	Main error sources	Fit for Redmi Note 14 5G
3D/stereo/ToF (area+volume)	Multi-view acquisition; reconstruct surface; compute area and/or volume [33]	Handles curvature; can estimate volume	Hardware and calibration complexity; reconstruction error; workflow friction [33]	“Optional advanced mode” (likely server-side photogrammetry) rather than default. [34]

Image capture protocol and measurement algorithms

Protocol for consistent, comparable wound images

A clinically defensible capture protocol must make bias visible and preventable. The protocol below operationalises what measurement studies show about **angle effects** and the benefits of **multi-marker calibration**. [35]

Environment and setup

- Use consistent lighting: avoid specular highlights (wet tissue) and mixed colour temperatures; if possible, use a repeatable light source/position. Lighting instability is a major driver of colour-analysis drift. [36]
- Use a neutral background where feasible, and avoid including faces/identifiers to reduce privacy exposure. [37]

Geometry control (distance + angle)

- Aim for the camera optical axis as close to **perpendicular** to the wound plane as possible. If off-angle, the projected area changes ~cos(θ), and in real use the angle is not reliably known for exact correction. [38]
- Use an on-screen “level” overlay (gyroscope-derived) and distance guidance (e.g., a standoff or “fill frame to this bounding box” rule) to standardise scale and sharpness. Device sensors support this. [15]

Scale and calibration marker strategy

- Prefer **two reference rulers/markers placed on opposite sides of the wound and in the same plane**. Empirically, two-ruler calibration improves precision multiple-fold and improves accuracy compared with one-ruler calibration, including for smartphone images. [27]
- If rulers are impractical, use a **printed fiducial** (e.g., ArUco or AprilTag) with known size; ensure it lies flat in the wound plane (or as close as possible). ArUco is designed for robust detection and pose estimation; AprilTag 3 is BSD-licensed and widely used for pose estimation. [39]
- For infection-control and workflow, consider disposable adhesive markers or markers printed on sterile-compatible material. (This is a workflow design decision; validation should reflect real clinic practice.) [40]

Camera settings

- Use the **main camera** for all quantitative captures. Avoid ultrawide and macro for measurements. [9]
- Lock focus and exposure once the wound and markers are in place; enforce minimum sharpness (blur detection) before accepting the image. CameraX supports capture + analysis pipelines required for this. [20]

Multi-angle capture (optional but valuable)

- Capture an orthogonal "measurement image" plus 1–2 oblique context images. Oblique views can help clinicians interpret undermining/tunnelling visually even if not used for area computation. [41]

Computing surface area from 2D images

Your 2D "surface area" measurement from a single photo is effectively **projected area** of the wound boundary on the imaging plane, scaled to real units using a marker. This is clinically useful for trend monitoring if the protocol is consistent, but it is not identical to true 3D surface area on curved anatomy. [42]

A robust algorithmic pipeline:

1. **Detect fiducials / rulers**
2. If using ArUco: detect marker corners; estimate pose; compute pixel-to-mm scaling and optionally a homography for rectification. OpenCV's ArUco module explicitly supports detection, pose estimation, and camera calibration. [43]
3. If using two rulers: detect endpoints/edges; compute pixel-per-cm from both sides and average (two-ruler calibration improves accuracy/precision vs single ruler). [27]
4. **Perspective correction (recommended)**
5. Use the marker corners to compute a homography that warps the wound plane to a canonical fronto-parallel view. This reduces angle-related distortion which otherwise follows a cosine relationship. [44]
6. **Wound segmentation → binary mask**
7. Produce a wound-border mask via AI segmentation plus optional manual correction (see AI section). [45]
8. **Area computation**
9. Pixel area: $A_{px} = \sum M$ where M is the binary mask.
10. Real area: $A_{mm^2} = A_{px} \times s_x \times s_y$. With a well-rectified plane, $s_x \approx s_y$ and $A_{cm^2} = A_{mm^2}/100$. This is the practical digital planimetry workflow studied in the literature. [46]
11. **QC gates**

12. Reject / warn if: fiducial not found; marker too small; glare hotspots; blur; insufficient illumination; angle beyond threshold; segmentation confidence low. Angle matters because the area scales with cosine when misaligned. [47]

Optional 3D approximations without a dedicated depth sensor

Because Redmi Note 14 5G does not list a ToF/LiDAR depth sensor, 3D estimation requires indirect methods:

- **Photogrammetry / structure-from-motion**: capture multiple views and reconstruct a mesh; then compute wound area on the mesh. This can approximate true surface area over curvature but adds workflow friction and computation. [48]
- **Learning-based monocular depth**: can support "rough" curvature correction, but is generally not a measurement-grade substitute without strong validation and may drift by skin tone, lighting, and wound type (ethical and safety concerns). [49]
- **Hybrid approach**: treat 3D as an "advanced research mode" for selected cases, not the default clinical production path, unless you can validate it against a known reference. A dedicated multimodal chronic wound dataset exists with photographs and 3D models, indicating the kind of ground truth you'd need for meaningful evaluation. [34]

Free and open-source toolchain with proposed AI approach

Library, tool, and model inventory

All items below are free; most are open-source with permissive licences (verify licence compatibility for your distribution model).

Pipeline stage	Free tools/libraries/ models	Why they fit this use case	Primary source
Android capture & camera pipeline	CameraX	Device-agnostic capture/analysis pipeline; supports image capture + analysis for QC overlays [20]	[50]
Image processing & calibration	OpenCV (incl. ArUco / ChArUco)	Marker detection, camera calibration concepts, homography/perspective correction; ArUco supports pose estimation [51]	[51]
Fiducials	AprilTag 3 (BSD-2)	Robust fiducial detection; BSD licence; useful alternative or complement to ArUco [52]	[52]
Baseline measurement reference	ImageJ / Fiji	Widely used scientific image analysis; Fiji distribution is open-source and heavily used in bioimage workflows	
Annotation tools	CVAT, Label Studio	Mature annotation platforms; support polygon masks; helpful for wound boundary/tissue labelling	

Pipeline stage	Free tools/libraries/ models	Why they fit this use case	Primary source
Core segmentation model family	U-Net variants	Biomedical segmentation baseline; many lightweight variants for mobile; strong boundary localisation [53]	[54]
Public wound segmentation datasets	FUSeg; DFU segmentation challenges; chronic wound multimodal DB	Pixel-wise annotated ulcer datasets exist; some are accessible via challenge mechanisms; multimodal DB includes 3D meshes [55]	[55]
Foundation segmentation models	Segment Anything (SAM) + MobileSAM	Useful for interactive segmentation / correction; MobileSAM reduces compute vs full SAM [56]	[56]
On-device inference runtime	TensorFlow Lite; ExecuTorch; ONNX Runtime (optional)	TFLite is a standard for Android inference; ExecuTorch is promoted for edge deployment; ONNX runtime is MIT-licensed and has mobile builds [57]	[57]
Charting & graphs	MPAndroidChart (Apache 2.0)	Mature charting library for time-series and grouped/stacked charts [58]	[58]
Local structured storage	Room	Standard Android persistence layer over SQLite; enables offline-first design [59]	[60]
Database encryption option	SQLCipher (community/ BSD-style via Guardian Project)	Encrypted SQLite-like DB; consider licence clarity and app size trade-off [61]	[61]
File/content export	Android PdfDocument	Free built-in PDF generation API for clinical reports [62]	[62]
Cryptography	Tink + Android Keystore	Open-source cryptographic APIs; integrates with Android Keystore; useful replacement path given Jetpack crypto deprecation [63]	[64]

Proposed AI approach

Target output variables

A clinically oriented measurement model should produce:

- **Wound boundary mask** (primary) → calibrated **area (cm^2)**. [65]
- Optional **tissue/colour proportions** (granulation / slough / eschar proxies), reported cautiously as “image-derived” features because colour varies strongly with lighting and camera post-processing. [66]

- **Uncertainty estimate** (per-pixel and per-area), used to trigger "manual review needed" rather than to mask failures. [67]

Model selection and deployment

A robust architecture for this device class is:

1. **Mobile segmentation model (production default)**
2. Encoder: lightweight (e.g., MobileNet/EfficientNet-like), decoder: U-Net style, output: wound mask. U-Net is a canonical biomedical segmentation architecture and remains a strong baseline. [53]
3. Export: quantised int8 model for on-device inference using TFLite delegates (CPU/GPU as available). [68]
4. **Interactive correction model (clinician-in-loop)**
5. Use SAM/MobileSAM-style prompted segmentation to refine boundaries, or provide a brush/polygon editor that writes back to the mask. MobileSAM is explicitly positioned as a "faster, smaller" SAM variant. [69]
6. **Server inference (optional, only if scale requires it)**
7. Use a server for heavier 3D reconstruction or ensemble inference. This should remain optional because server processing expands privacy and regulatory burden (data transfer, retention, cross-border processing). [70]

Training data sources and annotation strategy

Recommended public datasets (access conditions vary):

- **FUSeg**: reported to contain 1,210 pixel-wise annotated foot-ulcer images from 889 patients, designed as a benchmark for segmentation. [71]
- **DFU segmentation challenge datasets (DFUC/DFU challenges)**: large-scale annotated training sets exist, often accessible under licence agreements; challenge reports describe training sets with thousands of images and masks. [72]
- **Chronic wound multimodal database**: includes photographs plus 3D meshes and expert outlines; valuable for testing 3D ideas and cross-modality robustness. [34]
- **Medetec wound images**: free stock images across multiple wound types; potentially useful for pretraining classification/robustness but not a direct segmentation ground truth source and quality varies (older images, potential artefacts). Confirm usage rights for ML training within your distribution context. [73]

Annotation workflow using CVAT/Label Studio:

- Create polygon masks for wound border, plus optional sublabels (e.g., necrotic region).
- Use **inter-annotator agreement** checks on a subset to quantify ambiguity and establish a consensus protocol (important because wound borders are not always sharply defined). [31]

Transfer learning and domain adaptation

Given limited labelled local data, use transfer learning:

- Start from ImageNet-pretrained backbones; fine-tune on FUSeg/DFU datasets; then fine-tune on your clinic's images captured with your protocol. [74]
- Explicitly address skin-tone diversity and illumination variation; research notes that heterogeneous capture and skin-tone differences can degrade segmentation performance without targeted design and evaluation. [75]

Uncertainty quantification and failure detection

A practical uncertainty stack for segmentation:

- **Monte Carlo dropout** at inference (multiple stochastic forward passes) as a computationally feasible Bayesian approximation, as introduced in the dropout-as-Bayesian framework. [76]
- Compute pixel-wise variance maps; propagate to area uncertainty by sampling across mask realisations (report mean ± CI). This aligns with broader uncertainty-estimation practice in segmentation. [77]
- Track model calibration (e.g., Expected Calibration Error) when producing probabilities; calibration metrics are standard in modern neural network evaluation. [78]

Validation metrics and method-comparison statistics

Model/measurement performance should be expressed as:

- Segmentation: IoU, Dice (commonly used in segmentation benchmarks and challenge scoring). [79]
- Area accuracy: MAE in cm^2 and relative error (%), plus stratification by wound size (small wounds behave differently under rounding and scale errors). [27]
- Clinical measurement agreement: Bland–Altman analysis against a reference method is a standard method-comparison approach. [80]

Regulatory, privacy, and ethical considerations

Privacy and lawful basis: treating wound images as sensitive health data

Wound photographs are health data; if they include identifying context (face, tattoos, room identifiers) they become directly identifying personal data. Under GDPR, data concerning health is a special category with stricter processing requirements; GDPR also expects security measures appropriate to risk (including encryption/pseudonymisation as appropriate). [81]

For UK/EU practice, guidance from Information Commissioner's Office [82] emphasises that special category data processing requires a lawful basis and a condition for processing special category data (and robust security governance). [83]

In Sri Lanka, the Personal Data Protection Act (official text issued via Parliament of Sri Lanka [84] sources) includes obligations around security (integrity/confidentiality) and processing conditions; for a clinic app, this reinforces the need for explicit governance around consent, purpose limitation, retention, and safeguards. [85]

HIPAA-style safeguards as a practical security baseline

If the app is used in a HIPAA-covered environment, HIPAA's Security Rule establishes required administrative/physical/technical safeguards, and the technical safeguards section (45 CFR 164.312) requires measures for access control, audit controls, integrity, person/entity authentication, and transmission security. [86]

The US U.S. Department of Health and Human Services [87] guidance and the regulatory text make clear that protecting electronic health information in transmission and access logging are required design considerations. [86]

Medical device regulation and intended use risk

Software that performs automated measurement and is used for clinical management can be considered Software as a Medical Device depending on intended purpose and claims. Guidance from the International Medical Device Regulators Forum [88] and the U.S. Food and Drug Administration [89] illustrates that clinical evaluation, risk management, and evidence proportional to risk are central expectations for SaMD. [7]

A conservative strategy for early deployments is to frame outputs as **measurement support** (with manual confirmation) and avoid diagnostic claims ("infection detection", "treatment recommendation") until you have the dataset, clinical validation, and regulatory pathway to justify such features. [90]

Ethical issues specific to wound imaging AI

Key ethical risks and mitigations:

- **Bias and generalisation**: wound presentation varies by skin tone, lighting, and aetiology; models trained on limited datasets can fail silently. Incorporate diversity in local validation and track uncertainty as a safety trigger. [91]
- **Automation bias**: clinicians may over-trust "precise-looking" numbers. Countermeasure: always show overlays, confidence/quality flags, and require explicit confirmation for recorded measurements. [92]
- **Dignity and data minimisation**: avoid capturing identifiable anatomy unnecessarily; default to tight cropping with explicit clinician control and clear consent text. [37]

UI/UX blueprint, analytics, architecture, and implementation plan

Core workflows and screens

A professional clinical UX should prioritise speed, repeatability, and auditability.

Patient and case management

- **Clinician sign-in** (role-based): local passcode/biometric unlock + session timeout; optional multi-user roles (nurse, wound specialist, admin). [93]
- **Patient registration**: minimal identifiers by default (clinic MRN + initials or pseudonymous ID) to reduce risk; full identifiers only if explicitly required by workflow. [37]

- **Wound record creation**: location (body map), aetiology category (DFU/VLU/pressure injury/surgical), onset date, baseline notes. (These fields affect analytics and risk stratification.) [94]

Visit capture and measurement

- **Capture guidance screen**: live camera preview with overlays:
- "Level" indicator (gyroscope) to keep perpendicular. [15]
- Marker-detected bounding box; "move closer/farther" prompts; glare/blur warnings. [19]
- **Review screen**: show captured image + detected marker + auto boundary overlay; allow:
- quick accept, or
- "refine boundary" (brush/polygon/SAM prompt), then save. [56]
- **Clinical inputs**: dressing method (standardised list), exudate amount, odour, pain score, infection suspicion flag (manual), offloading/compression notes—kept as clinician observations, not automated diagnoses. [95]

Longitudinal review

- **Timeline**: scrollable visit cards with thumbnail + area + % change + "quality flag".
- **Compare mode**: pick two dates → show side-by-side photos; optionally overlay outlines after marker-based alignment (rectified plane makes alignment meaningful). [96]

Required graphs and a table of graph designs

MPAndroidChart supports line and bar charts suitable for these clinical analytics. [58]

Graph	Clinical question answered	Data inputs	Visual encoding recommendation
Days vs wound area	Is the wound shrinking, plateauing, or growing?	(date, area cm^2); optional confidence interval	Line chart with points; shaded CI band if uncertainty estimated; mark dressing changes as vertical annotations. [97]
Area vs dressing method	Which dressing approaches coincide with better area reduction?	(visit, area, dressing type)	Grouped bar (mean final area reduction by method) or stacked bar (counts by method + direction of change). Ensure sample size displayed to avoid false inference. [98]
Healing rate	Are we meeting expected trajectory?	area time series	Slope (Δcm^2/day) or % area reduction per week; show rolling window (e.g., 7-day). Wound area reduction is a documented healing predictor in ulcer studies. [6]
% change from baseline	Quick clinical judgement	baseline area + each follow-up	Line or bar of % change; highlight thresholds used in literature (e.g., early area reduction predictive signals) as reference lines. [6]

Graph	Clinical question answered	Data inputs	Visual encoding recommendation
Colour/ necrosis proportion	Is devitalised tissue decreasing?	tissue/colour segmentation per image	Stacked area chart over time showing % granulation vs slough vs eschar proxies; include QC warning when lighting conditions are inconsistent. [99]
Infection risk score (optional, caution)	Is there increased concern requiring review?	clinician-entered signs + trend features	If implemented, present as *risk flag* not diagnosis; explain components; show as categorical band (low/ medium/high) with audit trail. Regulatory risk is higher here. [100]

Data model diagram and storage schema

The data model should separate **identity**, **clinical artefacts**, and **derived measurements**. That supports privacy (pseudonymisation), reproducibility (keep original image), and model iteration (recompute derived measures).

```
erDiagram
  CLINICIAN ||--o{ VISIT : records
  PATIENT ||--o{ WOUND : has
  WOUND ||--o{ VISIT : assessed_in
  VISIT ||--o{ IMAGE_ASSET : captures
  IMAGE_ASSET ||--o{ MEASUREMENT : derives
  VISIT ||--o{ DRESSING_EVENT : applies
  PATIENT ||--o{ CONSENT : grants
  VISIT ||--o{ AUDIT_LOG : logs

  PATIENT {
    string patient_id
    string local_pseudonym
    string mrn_hash
    date   dob_optional
  }

  WOUND {
    string wound_id
    string patient_id
    string location_code
    string aetiology
    date   onset_date
  }

  VISIT {
    string visit_id
    string wound_id
    datetime captured_at
    string clinician_id
```

```
    string notes
  }

  IMAGE_ASSET {
    string image_id
    string visit_id
    string file_uri
    string capture_profile
    string marker_type
    boolean qc_pass
  }

  MEASUREMENT {
    string measurement_id
    string image_id
    float area_cm2
    float area_ci_low
    float area_ci_high
    float dice_if_gt_available
    string model_version
  }

  DRESSING_EVENT {
    string dressing_event_id
    string visit_id
    string dressing_type
    string adjuncts
  }

  CONSENT {
    string consent_id
    string patient_id
    datetime signed_at
    string scope
    datetime expires_at
  }

  AUDIT_LOG {
    string audit_id
    string visit_id
    datetime ts
    string action
    string actor_id
  }
```

Implementation note: store metadata in Room (offline-first) and store images in app-private storage; export via explicit workflow only. Room is the standard persistence abstraction on Android. [101]

Architecture flowchart

A modular design aligns with Android best practice and supports later scaling (optional sync, reprocessing, audits) without rewriting the app.

```
flowchart TD
  A[Capture Screen\nCameraX Preview] --> B[QC Module\nblur/glare/marker
checks]
  B -->|pass| C[Persist Original Image\napp-private storage]
  B -->|fail| A
  C --> D[Preprocess\nrectify + normalise]
  D --> E[Segmentation Inference\non-device model]
  E --> F[Manual Review & Edit\nbrush/polygon/SAM prompt]
  F --> G[Measurement Engine\narea + tissue ratios]
  G --> H[Local DB\nRoom + encrypted assets]
  H --> I[Analytics UI\ncharts + compare overlay]
  H --> J[Export\nCSV/PDF]
  H --> K[Optional Sync\nserver API]
```

This design explicitly preserves the original image, isolates derived measurements, and allows model upgrades to recompute measurements with version tracking—an evidence-friendly pattern for clinical software. [90]

Backup, export, and data-handling requirements

Because medical images are sensitive:

- **Backups**: default to encrypted, app-controlled backup packages (e.g., export bundle encrypted with a clinic key); avoid automatic copying into shared folders or removable microSD unless encrypted and policy-approved. [102]
- **Exports**:
- CSV: visits + measurements + dressing metadata (no images by default).
- PDF: summary report with selected images (cropped), area graph, % change, clinician notes—generated with PdfDocument. [62]
- **Encryption**: use platform cryptography and Keystore-managed keys; Jetpack `security-crypto` is deprecated and should not be relied on for long-term support. [103]

Step-by-step implementation blueprint with effort estimates

Milestone	Scope	Effort	Evidence/testing artefacts
Requirements + workflow mapping	Capture roles, infection-control constraints, consent flow, data retention, export needs	Medium	Written SOP draft; threat model; data dictionary aligned to workflow [104]
Imaging module MVP	CameraX capture, guidance overlays, QC checks, app-private storage	High	QC unit tests; device test matrix; sample image set with pass/fail labels [105]

Milestone	Scope	Effort	Evidence/testing artefacts
Calibration & rectification	Fiducial/ruler detection; homography rectification; two-ruler calibration option	High	Calibration accuracy report; synthetic tests; error vs angle tests (cosine effect) [32]
Baseline segmentation + manual editor	U-Net model + brush editor + outline overlay	High	Segmentation metrics (IoU/Dice) on public set; clinician usability feedback [45]
Measurement engine	Area cm^2; % change; healing rate; tissue/colour ratios (optional)	Medium	Method comparison vs reference (Bland–Altman); stratified error analysis by wound size [106]
Analytics UI	Timeline, compare mode, required graphs, filters by dressing	Medium	UI tests; chart correctness tests; clinician review sessions [58]
Security hardening	Role-based access, audit logs, encryption strategy using Keystore/Tink	High	Security test plan; penetration checklist; log review procedures [107]
Export & reporting	CSV/PDF exports with configurable de-identification	Medium	Export validation; PDF render tests; consent-based export restrictions [108]
Clinical validation study	Prospective or retrospective comparison against reference measurement method	High	Study protocol; ethics approval; Bland–Altman plots; inter-rater agreement results [80]

Clinical validation and research-grade testing plan

A credible validation plan should explicitly measure *agreement* and *repeatability*, not just ML metrics:

- **Reference method**: choose a practical reference such as contact planimetry or well-controlled digital planimetry with two-ruler calibration and expert annotation; two-ruler calibration has demonstrated improved accuracy/precision and provides a strong baseline for smartphone workflows. [27]
- **Method comparison**: Bland–Altman analysis (difference vs mean) is widely used for assessing agreement between clinical measurement methods. [80]
- **Repeatability**: same-user repeated captures under protocol; quantify within-subject variance; stratify by wound size because small wounds show more relative error sensitivity. [27]
- **Robustness**: evaluate across lighting conditions and skin tones; track failure cases with uncertainty flags and QC outcomes to ensure the app fails safely. [91]

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[1] [8] [9] [10] [12] [15] [82] REDMI Note 14 5G Specs
https://www.mi.com/global/product/redmi-note-14-5g/specs/

[2] [24] [29] [65] [88] Methods to assess area and volume of wounds - PMC
https://pmc.ncbi.nlm.nih.gov/articles/PMC7949796/?utm_source=chatgpt.com

[3] [93] [107] https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-164/subpart-C/section-164.312
https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-164/subpart-C/section-164.312

[4] [45] [53] [54] https://arxiv.org/abs/1505.04597
https://arxiv.org/abs/1505.04597

[5] https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/securityrule/techsafeguards.pdf
https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/securityrule/techsafeguards.pdf

[6] [97] [98] Percent change in wound area of diabetic foot ulcers over ...
https://pubmed.ncbi.nlm.nih.gov/12766127/?utm_source=chatgpt.com

[7] [90] [100] Summary of the HIPAA Security Rule
https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html?utm_source=chatgpt.com

[11] https://docs.opencv.org/4.x/da/d13/tutorial_aruco_calibration.html
https://docs.opencv.org/4.x/da/d13/tutorial_aruco_calibration.html

[13] All Specs, Features of Redmi Note 14 5G | Xiaomi Sri Lanka
https://www.mi.com/lk/product/redmi-note-14-5g/

[14] [26] [27] [32] [35] [38] [42] [44] [46] [47] [87] https://journals.plos.org/plosone/article/file?id=10.1371%2Fjournal.pone.0134622&type=printable
https://journals.plos.org/plosone/article/file?id=10.1371%2Fjournal.pone.0134622&type=printable

[16] [83] Special category data | ICO
https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/lawful-basis/a-guide-to-lawful-basis/special-category-data/?utm_source=chatgpt.com

[17] https://ai.google.dev/edge/mediapipe/solutions/guide
https://ai.google.dev/edge/mediapipe/solutions/guide

[18] [40] [85] Software as a Medical Device (SaMD): Clinical Evaluation
https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-170921-samd-n41-clinical-evaluation_1.pdf?utm_source=chatgpt.com

[19] [20] [50] [84] [105] https://developer.android.com/ndk/guides/neuralnetworks/migration-guide
https://developer.android.com/ndk/guides/neuralnetworks/migration-guide

[21] [89] https://developer.android.com/jetpack/androidx/releases/security
https://developer.android.com/jetpack/androidx/releases/security

[22] https://github.com/tensorflow/tensorflow/blob/master/tensorflow/lite/tools/delegates/README.md
https://github.com/tensorflow/tensorflow/blob/master/tensorflow/lite/tools/delegates/README.md

[23] [25] [28] [30] [41] [94] Comparison of Digital Planimetry and Ruler Methods for ...
https://www.mdpi.com/1648-9144/59/1/135?utm_source=chatgpt.com

[31] [80] [106] https://pubmed.ncbi.nlm.nih.gov/2868172/
https://pubmed.ncbi.nlm.nih.gov/2868172/

[33] [34] [48] https://www.sciencedirect.com/science/article/abs/pii/S0895611120301397
https://www.sciencedirect.com/science/article/abs/pii/S0895611120301397

[36] [95] Art. 9 GDPR – Processing of special categories of personal ...
https://gdpr-info.eu/art-9-gdpr/?utm_source=chatgpt.com

[37] [70] [81] [102] [104] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX%3A32016R0679
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX%3A32016R0679

[39] https://docs.opencv.org/3.4/d5/dae/tutorial_aruco_detection.html
https://docs.opencv.org/3.4/d5/dae/tutorial_aruco_detection.html

[43] [51] [96] https://docs.opencv.org/3.4/d9/d6a/group__aruco.html
https://docs.opencv.org/3.4/d9/d6a/group__aruco.html

[49] [77] https://www.sciencedirect.com/science/article/pii/S2950162823000036
https://www.sciencedirect.com/science/article/pii/S2950162823000036

[52] https://raw.githubusercontent.com/AprilRobotics/apriltag/master/LICENSE.md
https://raw.githubusercontent.com/AprilRobotics/apriltag/master/LICENSE.md

[55] [71] [79] https://www.mdpi.com/2078-2489/15/3/140
https://www.mdpi.com/2078-2489/15/3/140

[56] https://github.com/facebookresearch/segment-anything
https://github.com/facebookresearch/segment-anything

[57] [68] https://discuss.pytorch.org/t/pytorch-mobile-current-status/192040
https://discuss.pytorch.org/t/pytorch-mobile-current-status/192040

[58] https://github.com/PhilJay/MPAndroidChart
https://github.com/PhilJay/MPAndroidChart

[59] [60] [101] https://developer.android.com/training/data-storage/room
https://developer.android.com/training/data-storage/room

[61] https://guardianproject.info/code/sqlcipher/
https://guardianproject.info/code/sqlcipher/

[62] [108] https://developer.android.com/reference/android/graphics/pdf/PdfDocument
https://developer.android.com/reference/android/graphics/pdf/PdfDocument

[63] [64] https://developers.google.com/tink
https://developers.google.com/tink

[66] [99] https://arxiv.org/abs/2406.16012
https://arxiv.org/abs/2406.16012

[67] [76] [92] https://proceedings.mlr.press/v48/gal16.html
https://proceedings.mlr.press/v48/gal16.html

[69] https://github.com/ChaoningZhang/MobileSAM
https://github.com/ChaoningZhang/MobileSAM

[72] https://www.sciencedirect.com/science/article/pii/S1361841524000781
https://www.sciencedirect.com/science/article/pii/S1361841524000781

[73] https://www.medetec.co.uk/files/medetec-image-databases.html
https://www.medetec.co.uk/files/medetec-image-databases.html

[74] https://pmc.ncbi.nlm.nih.gov/articles/PMC7736585/
https://pmc.ncbi.nlm.nih.gov/articles/PMC7736585/

[75] [91] https://arxiv.org/html/2505.23392v1
https://arxiv.org/html/2505.23392v1

[78] https://proceedings.mlr.press/v70/guo17a/guo17a.pdf
https://proceedings.mlr.press/v70/guo17a/guo17a.pdf

[86] https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html
https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html

[103] https://developer.android.com/privacy-and-security/cryptography

https://developer.android.com/privacy-and-security/cryptography