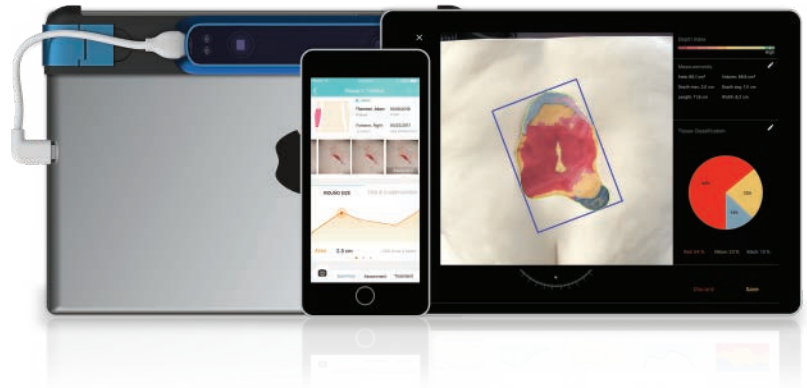
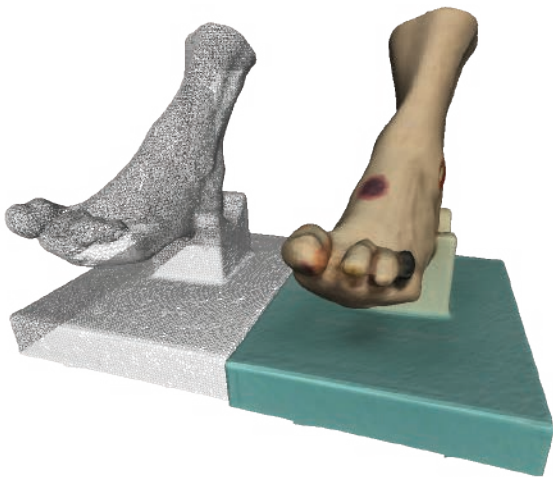


inSight® for Clinical Research

Collecting clear, high-quality data is critical to the success of any research study. The eKare inSight imaging and wound measurement system enables clinicians to securely capture wound measurement data and streamline data collection across study sites. eKare inSight is indicated for wound measurement and documentation for all external wound types.

Advanced Digital Wound Care

inSight combines the latest in computer vision, sensor technology and machine learning to enable clinicians to capture high-quality wound images and surface topography from a mobile device. Using these image input, the non-invasive solution instantly outputs measurements for area, length, width, and depth. The use of computer vision technology to measure the wound means data is available for review in real-time and helps minimize inaccuracies and subjectivity.



Accurate Data Collection Across Study Sites

inSight provides a scalable, competitively priced solution that collects data securely across study sites. eKare offers extensive support and services from study design through database closure. With inSight, your entire study team can seamlessly collect wound images and generate measurement data.

- eKare offers extensive support to Sponsor/CRO from study design through implementation
- Trained users at different sites use inSight to collect wound images and data.
- Independent wound readers can be trained and granted access to the system for real-time review.
- Subjects can be given prescription to directly capture and report wound images at home.
- inSight integrates with your Electronic Data Capture (EDC) system for seamless data acquisition and calculates measurements in real time.



Integration Capability

inSight integrates with your Electronic Data Capture (EDC) system and processes measurements in real-time. No more estimating wound size to determine subject eligibility.

Tried and True

inSight devices are deployed worldwide for dozens of clinical studies. From small investigator-initiated studies to pivotal Phase III studies and post-market studies, eKare has the expertise to get the cleanest data possible for your clinical trial.

Data Reliability

Using AI to identify and measure the wound area equates to improved consistency. The system has an inter-rater reliability of .99* and an intra-rater reliability of .99*.

Comprehensive Care

Viable for measuring all external wound types. inSight has been utilized in clinical trials involving the most prevalent skin/wound etiologies.

Easy Access

inSight's web-based portal complements use of the app. Users can login to review images and measurements, utilize data summary tools, manage their account, and more.

Endpoint Analysis

Data exported from the system is SAS and CDISC/CDASH compatible.

Regulatory Compliance

21 CFR Part 11 and HIPAA/GDPR compliant; FDA-accepted data reporting

eKare inSight® Measurement Modes

	2D	2D+
Technology	Digital Planimetry	Stereophotogrammetry
Reference Marker	Required	Not Required
Accuracy	Good (user dependent)	Excellent
Reliability	Good (user dependent)	Excellent
Compatible Hardware	Apple iPhone® and Android	Apple iPhones® (dual or triple lens camera)
Benefit	Easy to deploy, Improvement over manual measurement	High accuracy & reliability, estimates depth & volume, non-contact, consistent regardless of user experience/training
Recommended Use	Upgrade from manual measurement, streamline documentation	Inpatient, outpatient, post-acute, research

Testimonial

"eKare inSight allows for a seamless integration of accurate and reliable wound measurement and photography in a consolidated system."


- Dr. Paul J. Kim, Department of Plastic Surgery,
UT Southwestern Medical Center




*Based on independent validation studies. Figures not specifically cleared by the FDA.

Visit www.ekare.ai for publications on validation.

Customer Support

Call us at **(844) 443-5273** or email us at support@ekareinc.com

 **eKare Inc.**
3040 Williams Drive
Ste 610
Fairfax, VA 22031

 1-844-443-5273
 info@ekareinc.com
 www.ekare.ai



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