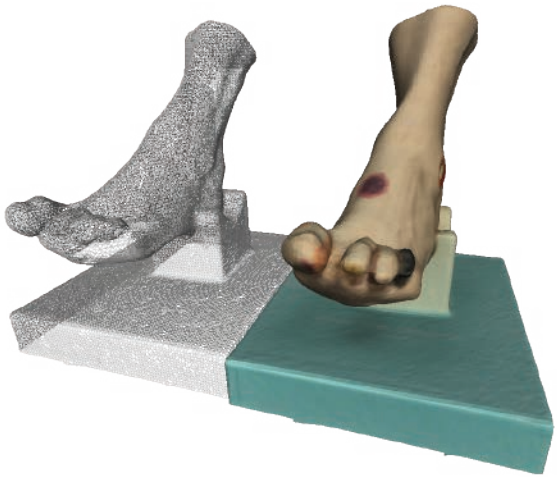
inSight® for Clinical Research

Collecting clear, high-quality data is critical to the success of any research study. The eKare inSight 3D imaging and wound measurement system enables clinicians to securely capture 3D 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 3D wound images and data from a mobile device. This non-invasive solution renders the wound bed in 3D and converts the data instantly into measurements for area, length, width, depth and volume. The use of Artificial Intelligence technology to measure the wound means data is available for review in real-time and helps control the subjectivity of wound measurement.



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 to Sponsor/CRO 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.

1-844-443-5273

www.ekare.ai

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.

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*.

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.

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.

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

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® 2D vs. 3D Measurements

	2D	3D
Technology	Digital Planimetry	3D Sensing (Structured Light)
Reference Marker	Required	Not Required
Accuracy	Good (user dependent)	Excellent
Reliability	Good (user dependent)	Excellent
Compatible Hardware	Apple iPad® and iPhone® (all models)	Apple iPad® (select models)
Benefit	Easy to deploy, Improvement over manual measurement	High accuracy & reliability, measure depth & volume, non-contact, consistent regardless of user experience/training
Recommended Use	Upgrade from manual measurement, streamline documentation, supplement to 3D measurement	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

eKare offers extensive support and services to Sponsor/CRO and study sites from study design through database closure.

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

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