

Advanced Wound Imaging & Analytics

Technical Fact Sheet

eKare inSight® Overview

- An integrated suite of applications to aid clinicians in wound measurement, wound documentation, telehealth and remote patient monitoring
- Real-time imaging feedback and automatic border delineation for fast and precise measurement
- Independently validated in both preclinical and clinical setting
 - Inter-rater reliability of 0.99* and intra-rater reliability of 0.99*
- FDA registered Class 1 Medical Device:
 - Registration 3012227854
- CE-marked: CE Certification 648302
- Regulatory compliance
 - 21 CFR Part 11
 - HIPAA-and EU/UK GDPR
 - Cyber Essentials Certification
 - Data Security and Protection Toolkit - Standards Met

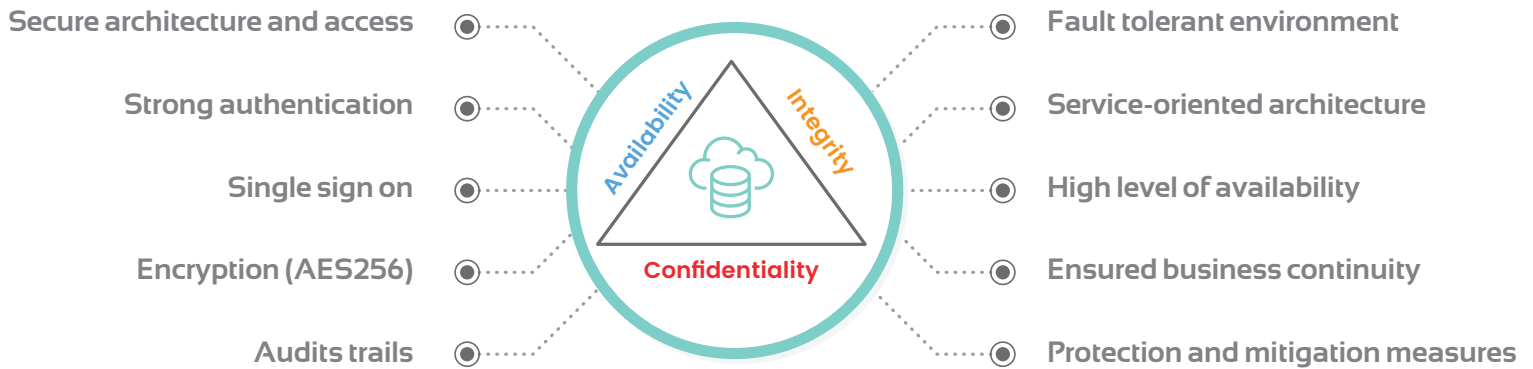


Security and Compliance

- Robust technical safeguards and standards for data capture, storage, and sharing
- Data transfers and storage are subject to multifactor security measures including encryption in transit and at rest, role-based access control, complete audit trails
- Audited data storage environment with certifications from accreditation bodies including BSI and HITRUST and feature a Service Level Agreement (SLA) of 99.95%
- Comprehensive user management, role-based access control, automatic user privilege assignment and revocation
- Each update is tested and validated by Quality Assurance per ISO 13485:2016 before release to ensure relevancy, timeliness, and consistency
- Easy to configure, granular administrative controls to implement site policies and procedures

Service Availability, Backup, and Recovery

- Multi-layered protection to ensure system and resources are available for continuous operations, while incurring minimal to no downtime
- Built with no single point of failure, offering complete redundancy on a secure distributed architecture that ensures 99.95% availability and durability
- eKare systems are deployed and managed in accordance with Multi-tier Cloud Security (MTCS) standards that ensure Scalability, Extensibility and Accuracy
- Streamlined detection, monitoring and management for fast issue detection and resolution
- Unlimited technical support 24 hours a day and 7 days a week



Integration

- Designed to be interoperable for effortless and secure exchange of data with and EDC or EHR/EMR
 - Published, ready to deploy APIs
 - Outbound and inbound integration capabilities
 - Maximum security with SMART on FHIR standards to ensure safe access to data
 - Pre-built integrations with leading platforms including Epic™, Cerner, Medidata Rave, SystemOne and other major EHR systems
 - Custom integration solutions based on industry best practices and standards on a wide range of technologies
- Epic is a registered trademark of Epic Systems Corporation.



Multi-platform data capture



HIPAA & GDPR-compliant data hosting



System integration into existing processes and workflow



Predictive and prescriptive analytical capabilities

Application Device Compatibility

The inSight app is available on both iOS and Android and the web portal is supported on all major browsers.

Compatibility	iOS 13.0 & up	Android 8.0 & up
Device	iPad, iPhone	All major brands
Web portal	Safari, Google Chrome, Internet Explorer, Microsoft Edge, Firefox	

Certifications & Compliance

