Healthy.io

Digital Wound Management

Technical Fact Sheet

Security and compliance

1. We have implemented a comprehensive risk-based security approach to all aspects of our business activities. Our security program is based on the NIST Cybersecurity Framework in conjunction with the ISO 27001 Information Security Management System standard and adjusted to comply with relevant cybersecurity and privacy laws and regulations.
   a. We are HIPAA compliant, covering both patients' rights for privacy and the secured mechanisms to protect it.
   b. We are ISO 27001 certified by an external party, certifying that we operate the company using a security-based approach.
   c. We are GDPR compliant, focusing on people's privacy rights and assuring that sensitive data is properly managed.

2. Our Quality Management System complies with FDA 21 CFR Part 820, EN ISO 13486:2016, and the EU Medical Device Directive 93/42/EEC.

3. Our infrastructure is hosted and operated over secured platforms while implementing OS hardening and restricted access as part of a defense-in-depth approach.

4. All data is encrypted at-rest and in-transit using strong encryption protocols.
   a. Data encrypted in-transit (HTTPS TLS1.2)
   b. Data encrypted at-rest (AES256).

5. We evaluate our products' security posture using industry-standard tools for scanning and manage to remediate high-risk vulnerabilities as fast as possible.

Service availability, backup, maintenance and recovery

1. Our platforms are highly available and support 99% uptime.

2. All of our data is hosted securely on Google Cloud Platform and is backed up daily.

3. We perform disaster recovery exercises several times a year and make sure our platforms can be restored if needed.

4. We have an effective incident response plan in place.

Integration

1. We offer comprehensive structured data integration allowing standard EMRs to consume all data collected in the observation and analysis phases. We support standard HL7 and FHIR data structures.

2. We support a single-sign-on using OAuth 2.0, SAML, ADFS, SMART on FHIR and similar technologies.

3. We allow an easy test-and-scale approach by providing an end to end system with a mobile app and a web-based portal, and supportive export of the visit summary as a user-friendly PDF export.
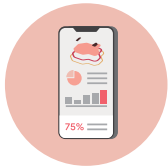
Application device compatibility

1. Our native application supports both iOS and Android.

2. Download the SPOT mobile app by visiting healthy.io/download/wound

The app supports devices that meet the following criteria:

iOS:

- Operating system: iOS 12 and above
- iPhone: 7 and above
- iPad: 5th generation and above
- iPad Mini: 4 and above
- iPad Air: 2 and above
- iPad Pro

Android:

- Operating system: Android 7.0
- Video capturing: 1080*1920, 30 fps
- RAM: 3 GB RAM
- Processor: 64 Bit
- Display size: 720*1280
- Additional features: Gyro

Web portal compatibility

Desktop

- Google Chrome
- Microsoft Edge
- Safari
- Firefox
- Internet Explorer (version 11)

Mobile

- Safari
- Google Chrome

AES 256 ENCRYPTION · HL7 FHIR · GDPR · SMART® · ISO 27001 Certified · ISO 13485:2016 · HIPAA COMPLIANT HIPAATraining.com · FDA Cleared & CE Marked

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