

DATA SECURITY AND ARCHITECTURE OVERVIEW.

COALA LIFE US

QUICK OVERVIEW

Where is the Coala-data stored?	Within the USA.
How is the data stored?	Securely and encrypted in Microsoft Azure SQL Datacenters.
What high-level data safety measures are the system?	Microsoft's data centers and services are certified according to ISO 27001, ISO 27018, SOC 1 and 2 security and audit standards. SSL login.
What are the medical device classifications and conformed standards of Coala?	<ul style="list-style-type: none">- FDA 510(k) and CE Class IIa- ISO 13485:2016- HIPAA compliant- Verified against IEC 60601-2-47, IEC 60601-2-27, IEC 60601-2-25 and ANSI/AAMI EC57 testing and performance standards



INTRODUCTION

The Coala Heart Monitor is a digital electrocardiogram (ECG) and heart sound recording system that can be used both by medical professionals and health conscious individuals in a home healthcare environment.

The Coala device is a small hand-held device with integrated stainless electrodes that is held against the chest for 30 seconds for simultaneous recordings of ECG and heart sounds through electrodes and a phonocardiograph membrane, following a 30 second measurement with fingers pressed against the electrodes.

The Coala App is installed in a smartphone is used to collect, view, save, listen to heart sounds and transmit recordings to the Coala Cloud server. The server provides automatic detection of cardiac rhythm deviations, stores all the recordings for review by a medical professional and handles the Coala account.

WHAT SECURITY MEASURES ARE IMPLEMENTED IN THE COALA-SYSTEM?

Coala Life protects the personal privacy and information in the best possible way in compliance with HIPAA, applicable laws and regulations on personal data protection, including the new GDPR legislation.

Coala Life collaborates with Microsoft to store and manage data in the Azure environment. For over 20 years, Microsoft has provided healthcare organizations with enterprise-oriented secure solutions. Coala Life has thus chosen not to build its own system, but instead collaborate with one of the global market leaders in the field to ensure secure and compliant storage and data management.

Microsoft's data centers and services are certified according to ISO 27001, ISO 27018, SOC 1 and 2 security and audit standards. Microsoft's cloud services are also designed to deliver reliability, accessibility and performance with at least 99.9% availability (so-called "uptime") and financially guaranteed service level agreements (SLAs).

- Secure Bluetooth connectivity from device to App
- Encrypted data transmission via Firewall to Microsoft Azure servers
- Data separated into different storage servers with encrypted 128-bit keys
- Secure login to Coala Care portal via SSL

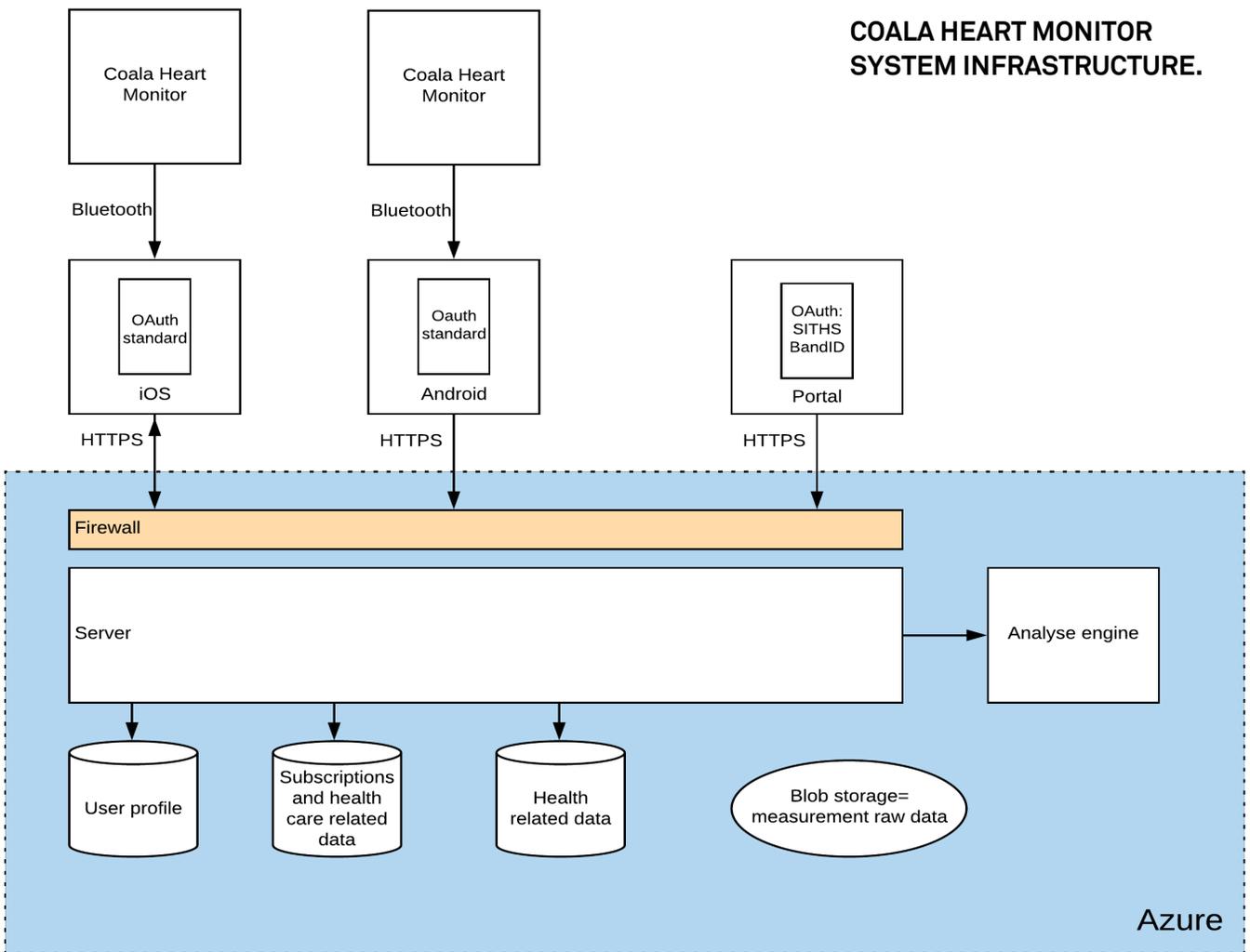
Physical security in the data centers consist of a long chain of security mechanisms that include 24-hour video surveillance and a very limited access where only necessary personnel are given access. For example, physical hard disks are destroyed in Microsoft's data centers to minimize all data breach risks.

Microsoft has 40 different FIPS 140-2 certificates for its encryption features. Standardized encryption algorithms and protocols are used to protect dormant data (i.e., data to be restored), as well as data transmitted.

WHERE ARE THE SERVERS AND DATA LOCATED?

All data centers used by Coala Life through its collaboration with Microsoft are located within the USA and form geographically separated pairs to ensure high availability, and to ensure delivery even in extraordinary situations such as natural disasters or war.

COALA HEART MONITOR SYSTEM INFRASTRUCTURE.



WHAT IS THE OVERALL INFRASTRUCTURE OF THE SYSTEM?

The infrastructure is based on the use of the latest and up-to-date security protocols. Data is transmitted securely over Bluetooth from the Coala device to the Coala App. Data is further transmitted encrypted via a Firewall to Azure datacenters for analysis and storage.

The user's identity is stored within the system. Authentication is handled by the Coala Cloud Service and provides a Json Web Token (JWT Bearer Token) that will be used in all communication with the backend. The JWT Bearer Token implementation follows the RFC 7519 standard. The Token is based on the symmetric HS256 algorithm using the keyed-hash message authentication code (HMAC) with a SSL certificate (SHA256 key).

WHAT DATA IS STORED?

The personal information that Coala Life handles includes name, e-mail address, heart data, such as ECG and heart sound, and any other personal information provided to us upon registering an account.

FOR HOW LONG DOES COALA LIFE STORE THE DATA?

Data of registered users are kept as long as the user is active and after that for a period of at least 12 months. Users can at any time unsubscribe and request deletion or extraction of data.

GENERAL PRODUCT SPECIFICATIONS

ECG and algorithms	Patent pending 2-lead ECG event monitor with resolution of 1000 Hz, 24 bit. 3 reusable, integrated stainless electrodes. Automatic detection and annotation tool for AF and normal.
Digital stethoscope	Patented piezo-membrane with frequency span 20 – 500 Hz. Synchronous recording with phonocardiographic (PCG) viewer.
Approvals and data management.	FDA 510(k) Rx cleared and CE Class IIa approved for home use. Microsoft Azure based, encrypted datacenters within the borders of EU and US – depending on area of usage. ISO 13485:2016 and HIPAA compliant. Verified against IEC 60601-2-47, IEC 60601-2-27, IEC 60601-2-25 and ANSI/AAMI EC57 testing and performance standards. Secure SSL login with SHA256 key.
Compatibility	Secure Bluetooth connection to most smartphones: iPhone 5 (iOS 8.x) and later models, and Android 4.4 (KitKat) and later models. Smartphone required.
Battery	Rechargeable, capacity of at least 40 recordings.

FOR MORE INFORMATION

Please contact Philip Siberg, President of Coala Life Inc, for further questions on data security.

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