



TITLE: SuperSonic MACH40 v2.X Security Statement	DOCUMENT # RD.DD.489	Rev. A
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SuperSonic MACH40 v2.X Security Statement

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1. Introduction

Hologic is a leading developer, manufacturer and supplier of premium diagnostics, medical imaging systems and surgical products dedicated to serving the healthcare needs of women. Ensuring the integrity of our systems and the business continuity of our customers is a top concern for Hologic.

1.1. Scope

This Security Statement applies to SuperSonic MACH40 version V2.X.

1.2. Audience

The intended audience includes the systems administrator, network administrator, and/or security personnel. The reader of this document should be familiar with operating systems, networking, and security of computer systems.

2. Cybersecurity documentation

2.1. Manufacturer Disclosure Statement for Medical Device Security

For many products, Hologic uses the Manufacturer Disclosure Statement for Medical Device Security (MDS2) to provide HIPAA-related security information about its products. The latest version of the SuperSonic MACH40 MDS2 is in the SuperSonic MACH40 Support section of the Hologic website.

2.2. Software BoM

A Software Bill of Material is available at the end of the SuperSonic MACH40 MDS2 document

3. Cybersecurity functions

3.1. User Authentication

User are logged in using the standard Pluggable Authentication Module (PAM). Applicative users are separated from Operating System user by storing applicative user information in a dedicated PostgreSQL database.

3.2. Emergency Access

An Emergency account is available to enable image acquisition even if an operator cannot login.

3.3. User Restriction

Each user is attributed a role (Admin, User, Emergency). Limitations are implemented based on this role to protect access to configuration and exams.

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3.4. Asset at rest Protection

Asset at rest are stored on an encrypted disk partition (using TPM 1.2).

3.5. Communication Encryption

DICOM communication are encrypted using DICOM TLS. The default profile for communication encryption is BCP 195 TLS Secure Transport Connection Profile

3.6. Automatic Logoff

SuperSonic MACH40 does not allow automatic logoff, but a session is automatically locked after a defined period of inactivity. A locked session can be unlocked by its user or may be closed to allow any other user (including emergency account) to create another exam.

3.7. Authorization

Based on the role they are assigned, user accounts may or may not allow access to the exams stored on the database or to configuration of cybersecurity features.

3.8. Configuration of Security Features

Access to security feature configuration is prohibited to any user not having the admin role

3.9. Personal Data De-Identification

DICOM objects are anonymized in accordance to the “basic profile” from PS3.15 Annex E Attribute Confidentiality Profiles.

3.10. Data Backup and Disaster Recovery

SuperSonic MACH40’s configuration and exam database can be backed up and recovered.

3.11. Physical Security

The system does not come with physical locks. Customers can restrict access to USB ports by applying physical locks.

3.12. Software Integrity

SuperSonic MACH40 use a custom OS based on the Debian 9 GNU/Linux distribution. All packages included in this distribution are digitally signed by Hologic SuperSonic to prevent installation of untrusted software.

3.13. Cybersecurity Product Upgrades

SuperSonic MACH40’s software can be updated remotely or by a technician on site. Upgrades are included in Service Packs (SP) updates.

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3.14. **Antivirus and Malware Detection / Protection**

SuperSonic MACH40 does not come with an antivirus and no additional software can be installed.

4. **Cybersecurity contact**

The following contact information can be used to report incidents, vulnerabilities or for general inquiries regarding cybersecurity:

cybersecurity@supersonicimagine.com

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