

TITLE: Aixplorer MACH20 and MACH30 V3.X Security Statement	DOCUMENT # RD.DD.534	Rev. A
		Page 1 sur / of 5

Date: Nov 2nd, 2020

Aixplorer MACH20 and MACH30 V3.x Security Statement

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TITLE: Aixplorer MACH20 and MACH30 V3.X Security Statement	DOCUMENT # RD.DD.534	Rev. A
		Page 2 sur / of 5

Table of content

1. Introduction	3
1.1. Scope	3
1.2. Audience.....	3
2. Cybersecurity documentation.....	3
2.1. Manufacturer Disclosure Statement for Medical Device Security	3
2.2. Software BoM	3
3. Cybersecurity functions.....	3
3.1. User Authentication.....	3
3.2. Emergency Access	3
3.3. User Restriction	3
3.4. Assets at rest Protection	4
3.5. Communication Encryption	4
3.6. Automatic Logoff	4
3.7. Authorization.....	4
3.8. Configuration of Security Features.....	4
3.9. Personal Data De-Identification.....	4
3.10. Data Backup and Disaster Recovery	4
3.11. Physical Security	4
3.12. Software Integrity	4
3.13. Cybersecurity Product Upgrades.....	4
3.14. Antivirus and Malware Detection / Protection	5
4. Cybersecurity contact.....	5

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TITLE: Aixplorer MACH20 and MACH30 V3.X Security Statement	DOCUMENT # RD.DD.534	Rev. A
		Page 3 sur / of 5

1. Introduction

SuperSonic Imagine is a developer, manufacturer and supplier of premium diagnostics ultrasound systems. Ensuring the integrity of our systems and the business continuity of our customers is a top concern for SuperSonic Imagine.

1.1. Scope

This Security Statement applies to Aixplorer MACH20 and MACH30 version V3.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, SuperSonic Imagine uses the Manufacturer Disclosure Statement for Medical Device Security (MDS2) to provide HIPAA-related security information about its products. The latest version of the Aixplorer MACH20 and MACH30 V3.X MDS2 is available upon request to your local contact.

2.2. Software BoM

A Software Bill of Material is available at the end of the Aixplorer MACH20 and MACH30 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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TITLE: Aixplorer MACH20 and MACH30 V3.X Security Statement	DOCUMENT # RD.DD.534	Rev. A
		Page 4 sur / of 5

3.4. Assets at rest Protection

Assets 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

Aixplorer MACH20 and MACH30 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

Aixplorer MACH20 and MACH30 '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

Aixplorer MACH20 and MACH30 use a custom OS based on the Debian 9 GNU/Linux distribution. All packages included in this distribution are digitally signed by SuperSonic to prevent installation of untrusted software.

3.13. Cybersecurity Product Upgrades

Aixplorer MACH20 and MACH30 's software can be updated remotely or by a technician on site. Upgrades are included in Service Packs (SP) updates.

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TITLE: Aixplorer MACH20 and MACH30 V3.X Security Statement	DOCUMENT # RD.DD.534	Rev. A
		Page 5 sur / of 5

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

Aixplorer MACH20 and MACH30 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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