



FIPS 140-2 Non-Proprietary Security Policy

---

FUJIFILM SONOSITE Cryptographic Module

FIPS 140-2 Level 1 Validation

Software Version: 1.0

Date: November 3rd, 2021



**Title:** FUJIFILM-SONOSITE Cryptographic Module Security Policy

**Date:** November 3<sup>rd</sup>, 2021

**Prepared By:** Acumen Security, LLC

Worldwide Headquarters:  
FUJIFILM SONOSITE, Inc.  
21919 30th Drive SE,  
Bothell, Washington 98021

Worldwide Inquiries:  
Phone: +1.425.951.1200  
Fax: +1.425.951.1201  
<https://www.sonosite.com/>

Copyright © 2021, FUJIFILM SONOSITE, Inc. All rights reserved. This document is provided for information purposes only and the contents hereof are subject to change without notice. This document is not warranted to be error-free, nor subject to any other warranties or conditions, whether expressed orally or implied in law, including implied warranties and conditions of merchantability or fitness for a particular purpose. FUJIFILM SONOSITE, Inc specifically disclaims any liability with respect to this document and no contractual obligations are formed either directly or indirectly by this document. This document may reproduced or distributed whole and intact including this copyright notice.

**Modification History**

Version	Date	Description
1.0	11/03/2021	Initial Release

**TABLE OF CONTENTS**

Section	Title	Page
1.	Introduction .....	1
2.	Ports and Interfaces.....	3
3.	Modes of Operation .....	4
3.1	Approved Mode .....	4
3.2	Non Approved But Allowed Services .....	6
3.3	Non-Approved Services.....	6
3.4	Critical Security Parameters and Public Keys.....	6
4.	Roles, Authentication and Services .....	10
5.	Self-Tests.....	12
6.	Operational Environment .....	14
7.	Mitigation of Other Attacks.....	15
Appendix A: Installation and Usage Guidance .....		16
References.....		17

**List of Tables**

Table 1: Security Level of Security Requirements .....	1
Table 2: Logical Interfaces .....	3
Table 3: FIPS Approved Cryptographic Functions.....	5
Table 4: Non-FIPS Approved But Allowed Cryptographic Functions .....	6
Table 5: Non-FIPS Approved Cryptographic Functions .....	6
Table 6: Critical Security Parameters .....	7
Table 7: Public Keys .....	7
Table 8 - DRBG Entropy Requirements .....	8
Table 9: Services and CSP Access .....	11
Table 10: Power On Self-Tests.....	12
Table 11: Conditional Self-Tests .....	13
Table 12: Tested Configurations.....	14
Table 13: Vendor Affirmed Configurations.....	14
Table 15: References .....	17

**List of Figures**

Figure 1: Module Block Diagram .....	2
--------------------------------------	---

## 1. Introduction

This document is the non-proprietary security policy for the FUJIFILM SONOSITE Cryptographic Module, hereafter referred to as the Module.

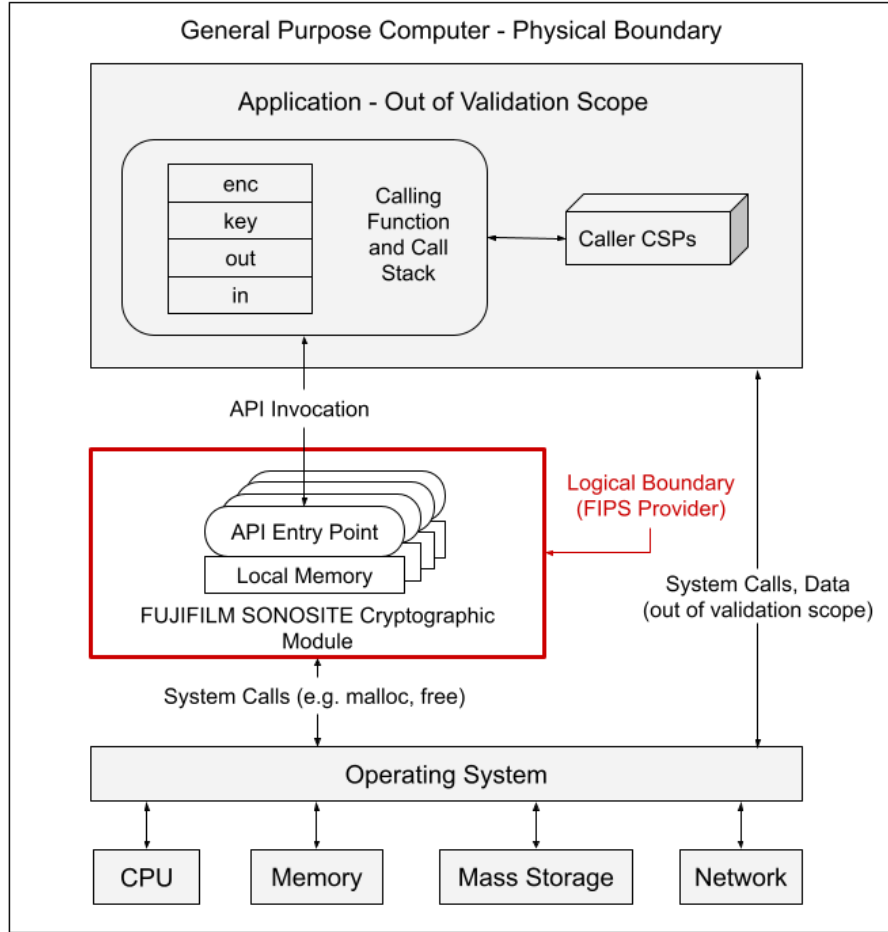
The Module is a software library providing a C language application program interface (API) for use by other processes that require cryptographic functionality. The Module is classified by FIPS 140-2 as a software module, multichip standalone module embodiment. The physical cryptographic boundary is the general-purpose computer on which the module is installed. The logical cryptographic boundary of the Module is the fipscanister object module, a single object module file named fipscanister.o. The Module performs no communications other than with the calling application (the process that invokes the Module services).

The FIPS 140-2 security levels for the Module are as follows:

Security Requirements Section	Level
Cryptographic Module Specification	1
Cryptographic Module Ports and Interfaces	1
Roles and Services and Authentication	2
Finite State Machine Model	1
Physical Security	N/A
Operational Environment	1
Cryptographic Key Management	1
EMI/EMC	1
Self-Tests	1
Design Assurance	3
Mitigation of Other Attacks	N/A

**Table 1: Security Level of Security Requirements**

The Module's software version for this validation is 1.0.



**Figure 1: Module Block Diagram**

## 2. Ports and Interfaces

The physical ports of the Module are the same as the computer system on which it is executing. The logical interface is a C language API.

Logical Interface Type	Description
Control Input	API entry point and corresponding stack parameters
Data Input	API entry point data input stack parameters
Status Output	API entry point return values and status stack parameters
Data Output	API Entry point data output stack parameters

**Table 2: Logical Interfaces**

As a software module, control of the physical ports is outside module scope. However, when the module is performing self-tests, or is in an error state, all output on the logical data output interface is inhibited. The module is single-threaded and in error scenarios returns only an error value (no data output is returned).

### 3. Modes of Operation

The Module supports FIPS 140-2 Approved, Allowed and Non-Approved algorithms in a single mixed mode of operation.

#### 3.1 Approved Mode

The Module supports the following services and algorithms in FIPS Approved Mode:

Function	Algorithm	Options	Cert #
Random Number Generation; symmetric key generation	[SP 800-90A] DRBG <sup>1</sup> Prediction resistance supported for all variations	<b>Hash_Based DRBG:</b> [ Prediction Resistance Tested: Enabled and Not Enabled (SHA-1 , SHA-224 , SHA-256 , SHA-384 , SHA-512 ) ] <b>HMAC_Based DRBG:</b> [ Prediction Resistance Tested: Enabled and Not Enabled (SHA-1 , SHA-224 , SHA-256 , SHA-384 , SHA-512 ) ] <b>CTR_DRBG:</b> [ Prediction Resistance Tested: Enabled and Not Enabled; BlockCipher_Use_df: ( AES-128 , AES-192 , AES-256 ) ] BlockCipher_No_df: ( AES-128 , AES-192 , AES-256 ) ]	A2040
Cryptographic Key Generation (CKG)	[SP 800-133] CKG		Vendor affirmed
Encryption, Decryption, and CMAC	[SP 800-67] [SP 800-38A]	3-Key TDES ECB, TCBC, TCFB, TOFB; CMAC generate and verify	A2040
	[FIPS 197] AES	128/ 192/256 ECB, CBC, OFB, CFB 1, CFB 8, CFB 128, CTR, XTS; CCM; GCM; CMAC generate and verify	A2040
	[SP 800-38B] CMAC		
	[SP 800-38C] CCM [SP 800-38D] GCM [SP 800-38E] XTS		
Message Digests	[FIPS 180-4]	SHA-1, SHA-2 (224, 256, 384, 512)	A2040
Keyed Hash	[FIPS 198] HMAC	SHA-1, SHA-2 (224, 256, 384, 512)	A2040
Digital Signature and Asymmetric Key Generation	[FIPS 186-2] RSA	SigGen9.31, SigGenPKCS1.5, SigGenPSS (4096 with all SHA-2 sizes) SigVer9.31, SigVerPKCS1.5, SigVerPSS (1024/1536/2048/3072/4096 with all SHA sizes)	A2040
	[FIPS 186-4] RSA	Key Gen, SigGen9.31, SigGenPKCS1.5, SigGenPSS, (2048/3072 with all SHA2 sizes)	A2040
	[FIPS 186-4] DSA	Key Pair Gen (2048/3072) PQG Gen, Sig Gen (2048/3072 with all SHA-2 sizes) PQG Ver, Sig Ver (1024/2048/3072 with all SHA sizes)	A2040
	[FIPS 186-4] ECDSA	Key Pair Gen: CURVES P-224 P-256 P-384 P-521 K-233 K-283 K-409	A2040

<sup>1</sup> For all DRBGs the "supported security strengths" is just the highest supported security strength per [SP800-90A] and [SP800-57].



Function	Algorithm	Options	Cert #
		K-571 B-233 B-283 B-409 B-571 (ExtraRandomBits TestingCandidates ) PKV: CURVES (ALL-P ALL-K ALL-B ) SigGen: CURVES P-224: (SHA-224, 256, 384, 512) P-256: (SHA-224, 256, 384, 512) P-384: (SHA-224, 256, 384, 512) P-521: (SHA-224,256, 384, 512) K-233: (SHA-224, 256, 384, 512) K-283: (SHA-224, 256, 384, 512) K-409: (SHA-224, 256, 384, 512) K-571: (SHA-224, 256, 384, 512) B-233: (SHA-224, 256, 384, 512) B-283: (SHA-224, 256, 384, 512) B-409: (SHA-224, 256, 384, 512) B-571: (SHA-224, 256, 384, 512) ) SigVer: CURVES P-192: (SHA-1, 224, 256, 384, 512) P-224: (SHA-1, 224, 256, 384, 512) P-256: (SHA-1, 224, 256, 384, 512) P-384: (SHA-1, 224, 256, 384, 512) P-521: (SHA-1, 224, 256, 384, 512) K-163: (SHA-1, 224, 256, 384, 512) K-233: (SHA-1, 224, 256, 384, 512) K-283: (SHA-1, 224, 256, 384, 512) K-409: (SHA-1, 224, 256, 384, 512) K-571: (SHA-1, 224, 256, 384, 512) B-163: (SHA-1, 224, 256, 384, 512) B-233: (SHA-1, 224, 256, 384, 512) B-283: (SHA-1, 224, 256, 384, 512) B-409: (SHA-1, 224, 256,384, 512) B-571: (SHA-1, 224, 256, 384, 512)	
KAS-SSC [X1] <sup>2</sup>	[SP 800-56Ar3]	Diffie-Hellman ≥ 2048 bits, ECDH B, K, and P curves ≥ 256 bit curves	Vendor affirmed

**Table 3: FIPS Approved Cryptographic Functions**

<sup>2</sup> In the approved mode, KAS-SSC can only be used in conjunction with an Approved KDF from SP 800-56C or SP 800-135

### 3.2 Non-Approved But Allowed Services

The Module supports the following non-approved but allowed services.

Category	Algorithm	Description
Key Encryption/Decryption	RSA	RSA may be used to perform key establishment with another module by securely exchanging symmetric encryption keys with another module

**Table 4: Non-FIPS Approved But Allowed Cryptographic Functions**

The module supports the following non-FIPS 140-2 approved but allowed algorithms:

- RSA (key wrapping; key establishment methodology provides between 112 and 256 bits of encryption strength; non-compliant less than 112 bits of encryption strength)

### 3.3 Non-Approved Services

The Module implements the following services which are Non-Approved per the SP 800131Ar1 transition:

Function	Algorithm	Options
Digital Signature and Asymmetric Key Generation	[FIPS 186-2] RSA	GenKey9.31, SigGen9.31, SigGenPKCS1.5, SigGenPSS (1024/1536 with all SHA sizes, 2048/3072/4096 with SHA1)
	[FIPS 186-2] DSA	PQG Gen, Key Pair Gen, Sig Gen (1024 with all SHA sizes, 2048/3072 with SHA1)
	[FIPS 186-4] DSA	PQG Gen, Key Pair Gen, Sig Gen (1024 with all SHA sizes, 2048/3072 with SHA-1)
	[FIPS 186-2] ECDSA	PKG: CURVES (P-192 K-163 B-163 ) SIG(gen): CURVES(P-192 P-224 P-256 P-384 P-521 K-163 K--233 K-283 K-409 K-571 B-163 B-233 B-283 B-409 B-571 )
	[FIPS 186-4] ECDSA	PKG: CURVES ( P-192 K-163 B-163 ) SigGen: CURVES (P-192: (SHA-1, 224, 256, 384, 512) P224:(SHA-1) P-256:(SHA-1) P-384: (SHA-1) P-521:(SHA-1) K-163: (SHA-1, 224, 256, 384, 512) K-233:(SHA-1) K-283:(SHA-1) K-409:(SHA-1) K-571:(SHA-1) B-163: (SHA-1, 224, 256, 384, 512) B-233:(SHA-1) B-283: (SHA-1) B-409:(SHA-1) B-571:(SHA-1) )
ECC CDH (KAS)	[SP 800-56Ar1] (§5.7.1.2)	B, K and P curves sizes 163 and 192

**Table 5: Non-FIPS Approved Cryptographic Functions**

These algorithms shall not be used when operating in the FIPS Approved mode of operation. Use of the non-conformant algorithms listed in Table 5 will place the module in a non-approved mode of operation.

### 3.4 Critical Security Parameters and Public Keys

All CSPs used by the Module are described in this section. All access to these CSPs by Module services are described in Section 4. The CSP names are generic, corresponding to API parameter data structures.

CSP Name	Description
RSA SGK	RSA (2048 to 15360 bits) signature generation key
RSA KDK	RSA (2048 to 16384 bits) key decryption (private key transport) key

CSP Name	Description
DSA SGK	[FIPS 186-4] DSA (2048/3072) signature generation key
DH Private	Diffie-Hellman $\geq$ 2048 private key agreement key
ECDSA SGK	ECDSA (All NIST defined B, K, and P curves except sizes 163 and 192) signature generation key
EC DH Private	EC DH (All NIST defined B, K, and P curves except sizes 163 and 192) private key agreement key.
AES EDK	AES (128/192/256) encrypt / decrypt key
AES CMAC	AES (128/192/256) CMAC generate / verify key
AES GCM <sup>3</sup>	AES (128/192/256) encrypt / decrypt / generate / verify key
AES XTS	AES (256/512) XTS encrypt / decrypt key
Triple-DES EDK	Triple-DES (3-Key) encrypt / decrypt key
Triple-DES CMAC	Triple-DES (3-Key) CMAC generate / verify key
HMAC Key	Keyed hash key (160/224/256/384/512)
Hash_DRBG CSPs	V (440/888 bits) and C (440/888 bits), entropy input (length dependent on security strength)
HMAC_DRBG CSPs	V (160/224/256/384/512 bits) and Key (160/224/256/384/512 bits), entropy input (length dependent on security strength)
CTR_DRBG CSPs	V (128 bits) and Key (AES 128/192/256), entropy input (length dependent on security strength)
CO-AD-Digest	Pre-calculated HMAC-SHA-1 digest used for Crypto Officer role authentication
User-AD-Digest	Pre-calculated HMAC-SHA-1 digest used for User role authentication

**Table 6: Critical Security Parameters**

Authentication data is loaded into the module during the module build process, performed by an authorized operator (Crypto Officer), and otherwise cannot be accessed.

The module does not output intermediate key generation values.

CSP Name	Description
RSA SVK	RSA (1024 to 16384 bits) signature verification public key
RSA KEK	RSA (2048 to 16384 bits) key encryption (public key transport) key
DSA SVK	[FIPS 186-4] DSA (2048/3072) signature verification key
ECDSA SVK	ECDSA (All NIST defined B, K and P curves) signature verification key
DH Public	Diffie-Hellman public key agreement key
EC DH Public	EC DH (All NIST defined B, K and P curves) public key agreement key

**Table 7: Public Keys**

<sup>3</sup> The module's IV is generated internally by the module's Approved DRBG. The DRBG seed is generated inside the module's physical boundary. The IV is 96-bits in length per NIST SP 800-38D, Section 8.2.2 and FIPS 140-2 IG A.5 scenario 2. The selection of the IV construction method is the responsibility of the user of this cryptographic module. In approved mode, users of the module must not utilize GCM with an externally generated IV. The only approved use of GCM is with TLS and with a randomly generated IV.

**For all CSPs and Public Keys:**

**Storage:** RAM, associated to entities by memory location. The Module stores DRBG state values for the lifetime of the DRBG instance. The module uses CSPs passed in by the calling application on the stack. The Module does not store any CSP persistently (beyond the lifetime of an API call), with the exception of DRBG state values used for the Modules' default key generation service.

**Generation:** The Module implements SP 800-90A compliant DRBG services for creation of symmetric keys, and for generation of DSA, elliptic curve, and RSA keys as shown in Table 3. The calling application is responsible for storage of generated keys returned by the module. For operation in the Approved mode, Module users (the calling applications) shall use entropy sources that contain at least 112 bits of entropy. To ensure full DRBG strength, the entropy sources must meet or exceed the security strengths shown in the table below:

DRBG Type	Underlying Algorithm	Minimum Seed Entropy
Hash_DRBG or HMAC_DRBG	SHA-1	128
	SHA-224	192
	SHA-256	256
	SHA-384	256
	SHA-512	256
CTR_DRBG	AES-128	128
	AES-192	192
	AES-256	256

**Table 8 - DRBG Entropy Requirements**

**Entry:** All CSPs enter the Module’s logical boundary in plaintext as API parameters, associated by memory location. However, none cross the physical boundary.

**Output:** The Module does not output CSPs, other than as explicit results of key generation services. However, none cross the physical boundary.

**Destruction:** Zeroization of sensitive data is performed automatically by API function calls for temporarily stored CSPs. In addition, the module provides functions to explicitly destroy CSPs related to random number generation services. The calling application is responsible for parameters passed in and out of the module.

Private and secret keys as well as seeds and entropy input are provided to the Module by the calling application, and are destroyed when released by the appropriate API function calls. Keys residing in internally allocated data structures (during the lifetime of an API call) can only be accessed using the Module defined API. The operating system protects memory and process space from unauthorized access. Only the calling application that creates or imports keys can use or export such keys. All API functions are executed by the invoking calling application in a non-overlapping sequence such that no two API functions will execute concurrently. An authorized application as user (Crypto Officer and User) has access to all key data generated during the operation of the Module.

**Use:** In the case of AES-GCM, the IV generation method is user selectable and the value can be computed in more than one manner.

Following RFC [5288](#) for TLS, the module ensures that it's strictly increasing and thus cannot repeat. When the IV exhausts the maximum number of possible values for a given session key, the first party, client or server, to encounter this condition may either trigger a handshake to establish a new encryption key in accordance with RFC [5246](#), or fail. In either case, the module prevents and IV duplication and thus enforces the security property.

In the event Module power is lost and restored the calling application must ensure that any AES-GCM keys used for encryption or decryption are redistributed.

The calling application shall ensure that the same Triple-DES key is not used to encrypt more than  $2^{16}$  64-bit blocks of data.

## 4. Roles, Authentication and Services

The Module implements the required User and Crypto Officer roles and requires authentication for those roles. Only one role may be active at a time and the Module does not allow concurrent operators. The User or Crypto Officer role is assumed by passing the appropriate password to the `FIPS_module_mode_set()` function. The password values may be specified at build time and must have a minimum length of 16 characters. Any attempt to authenticate with an invalid password will result in an immediate and permanent failure condition rendering the Module unable to enter the FIPS mode of operation, even with subsequent use of a correct password.

Authentication data is loaded into the Module during the Module build process, performed by the Crypto Officer, and otherwise cannot be accessed.

Since minimum password length is 16 characters, the probability of a random successful authentication attempt in one try is a maximum of  $1/256^{16}$ , or less than  $1/10^{38}$ . The Module permanently disables further authentication attempts after a single failure, so this probability is independent of time.

Both roles have access to all of the services provided by the Module.

- User Role (User): Loading the Module and calling any of the API functions.
- Crypto Officer Role (CO): Installation of the Module on the host computer system and calling of any API functions.

All services implemented by the Module are listed below, along with a description of service CSP access. The access types are determined as follows:

- Generate (G): Generates the Critical Security Parameter (CSP\_ using an approved Random Bit Generator
- Read (R): Export the CSP
- Write (W): Enter/establish and store a CSP
- Destroy (D): Overwrite the CSP
- Execute (E): Employ the CSP
- None: No access to CSP's

Service	Role	Description	Access Type
Initialize	User, CO	Module initialization. Does not access CSPs. CO-AD-Digest, User-AD-Digest	E
Self-test	User, CO	Perform self tests (FIPS_selftest).	None
Show status	User, CO	Functions that provide module status information: <ul style="list-style-type: none"> <li>• Version (as unsigned long or const char *)</li> <li>• FIPS Mode (Boolean)</li> </ul>	None
Zeroize	User, CO	Functions that destroy CSPs: fips_drbg_uninstantiate DRBG CSPs (Hash_DRBG CSPs, HMAC_DRBG CSPs, CTR_DRBG CSPs)  All other services automatically overwrite CSPs stored in allocated memory. Stack cleanup is the responsibility of the calling application.	D
Random number generation	User, CO	Used for random number and symmetric key generation. <ul style="list-style-type: none"> <li>• Seed or reseed a DRBG instance</li> <li>• Determine security strength of a DRBG instance</li> <li>• Obtain random data</li> </ul>	E

Service	Role	Description	Access Type
		Hash_DRBG CSPs, HMAC_DRBG CSPs, CTR_DRBG CSPs.	
Asymmetric Key Generation	User, CO	Used to generate DSA, ECDSA and RSA keys: RSA SGK, RSA SVK; DSA SGK, DSA SVK; ECDSA SGK, ECDSA SVK	G
Symmetric Encrypt/Decrypt	User, CO	Used to encrypt or decrypt data.  AES EDK, TRIPLE-DES EDK, AES GCM, AES XTS (passed in by the calling process).	E
Symmetric Digest	User, CO	Used to generate or verify data integrity with CMAC.  AES CMAC, TRIPLE-DES CMAC (passed in by the calling process)	E
Message Digest	User, CO	Used to generate a SHA-1 or SHA-2 message digest.	None
Keyed Hash	User, CO	Used to generate or verify data integrity with HMAC.  HMAC Key (passed in by the calling process).	E
Key Transport <sup>4</sup>	User, CO	Used to encrypt or decrypt a key value on behalf of the calling process (does not establish keys into the module).  RSA KDK, RSA KEK (passed in by the calling process).	E
Key Agreement	User, CO	Used to perform key agreement primitives on behalf of the calling process (does not establish keys into the module).  Diffie-Hellman/EC Diffie-Hellman Private, Diffie-Hellman/EC Diffie-Hellman Public (passed in by the calling process)	E
Digital Signature	User, CO	Used to generate or verify RSA, DSA or ECDSA digital signatures.  RSA SGK, RSA SVK; DSA SGK, DSA SVK; ECDSA SGK, ECDSA SVK (passed in by the calling process).	E
Utility	User, CO	Miscellaneous helper functions.	None

**Table 9: Services and CSP Access**

<sup>4</sup> "Key transport" can refer to a) moving keys in and out of the module, or b) the use of keys by an external application. The latter definition is the one that applies to the FUJIFILM SONOSITE Cryptographic Module

## 5. Self-Tests

The Module performs the self-tests listed below on invocation of “initialize” or “self-test”.

Algorithm	Type	Test Attributes
Software integrity	KAT	HMAC-SHA-1
HMAC	KAT	One KAT per SHA-1, SHA-224, SHA-256, SHA-384 and SHA-512 Per IG 9.3, this testing covers SHA POST requirements.
AES	KAT	Separate encrypt and decrypt, ECB mode, 128 bit key length
AES CCM	KAT	Separate encrypt and decrypt, 192 key length
AES GCM	KAT	Separate encrypt and decrypt, 256 key length
XTS-AES	KAT	128, 256 bit key sizes to support either the 256-bit key size (for XTS-AES-128) or the 512-bit key size (for XTS-AES-256)
AES CMAC	KAT	Sign and verify CBC mode, 128, 192, 256 key lengths
Triple-DES	KAT	Separate encrypt and decrypt, ECB mode, 3-Key
Triple-DES CMAC	KAT	CMAC generate and verify, CBC mode, 3-Key
RSA	KAT	Sign and verify using 2048 bit key, SHA-256, PKCS#1
DSA	PCT	Sign and verify using 2048 bit key, SHA-384
DRBG	KAT	CTR_DRBG: AES, 256 bit with and without derivation function HASH_DRBG: SHA256 HMAC_DRBG: SHA256
ECDSA	PCT	Key gen, sign, verify using P-224, K-233 and SHA-512.
ECC CDH	KAT	Shared secret calculation per SP 800-56A §5.7.1.2, IG 9.6

**Table 10: Power On Self-Tests**

The Module is installed using one of the set of instructions in Appendix A, as appropriate for the target system. The HMAC-SHA-1 of the Module distribution file as tested by the CMT Laboratory and listed in Appendix A is verified during installation of the Module file as described in Appendix A.

Per IG 9.10, the Module implements a default entry point and automatically runs the FIPS self-tests upon startup.

The module has a function called `FIPS_module_mode_set()` within the init code that is automatically set to enable “FIPS Mode” by default. When the Module is initialized, it will always run its power-on self-tests meeting the IG 9.10 requirement.

The module also has a Boolean check value to verify whether the module has run its power-on self-tests upon subsequent instantiations. If the module is determined to have already run its power-on self-tests, future instantiations will only run the power-up integrity test and not the full set of POST’s. If power is lost to the module, the Boolean check value “1” is zeroized and the module will run its power-up self-tests again to verify the correctness of the module operation. Upon successful completion of the POST’s, the Boolean check value is restored. This is consistent with the requirement described in IG 9.11.



The Module also implements the following conditional tests:

Algorithm	Test
DRBG	Tested as required by [SP80090A] Section 11
DRBG	FIPS 140-2 continuous test for stuck fault
NDRNG	FIPS 140-2 continuous test for NDRNG
DSA	Pairwise consistency test on each generation of a key pair
ECDSA	Pairwise consistency test on each generation of a key pair
RSA	Pairwise consistency test on each generation of a key pair

**Table 11: Conditional Self-Tests**

In the event of a DRBG self-test failure the calling application must un-instantiate and re-instantiate the DRBG per the requirements of [SP 800-90A]; this is not something the Module can do itself.

Pairwise consistency tests are performed for both possible modes of use, e.g. Sign/Verify and Encrypt/Decrypt.

## 6. Operational Environment

The tested operating systems segregate user processes into separate process spaces. Each process space is logically separated from all other processes by the operating system software and hardware. The Module functions entirely within the process space of the calling application, and implicitly satisfies the FIPS 140-2 requirement for a single user mode of operation.

### 6.1 Tested Configurations

The module was tested in the following configurations.

Version	Operating System	Hardware Platform and Processor	Optimizations Target
1.0	Android 9	Lantronix Open-Q 820 Development Kit with Qualcomm Snapdragon 821E	with PAA
1.0	Android 9	Lantronix Open-Q 820 Development Kit with Qualcomm Snapdragon 821E	without PAA

**Table 12: Tested Configurations**

### 6.2 Vendor Affirmed Configurations

The following platforms have not been tested as part of the FIPS 140-2 level 1 certification however FUJIFILM SONOSITE “vendor affirms” that these platforms are equivalent to the tested and validated platforms. Additionally, FUJIFILM SONOSITE affirms that the module will function the same way and provide the same security services on any of the systems listed below.

Operating Environment	Hardware
Android 10	Lantronix Open-Q 820 Development Kit with Qualcomm Snapdragon 821E

**Table 13: Vendor Affirmed Configurations**

## **7. Mitigation of Other Attacks**

The module is not designed to mitigate against attacks which are outside of the scope of FIPS 140-2.

## **Appendix A: Installation and Usage Guidance**

The FUJIFILM SONOSITE Cryptographic Module comes pre-installed and configured on the tested platform listed in Section 6.1. The module is intended only for use as configured by FUJIFILM SONOSITE on the listed platform. As FIPS mode is enabled by default, the administrator can verify FIPS mode is set by calling the `FIPS_module_mode()` function.

## References

The FIPS 140-2 standard, and information on the CMVP, can be found at <https://csrc.nist.gov/projects/cryptographic-module-validation-program> . More information describing the module can be found on the *FUJIFILM SONOSITE* web site at [www.sonosite.com](http://www.sonosite.com). This Security Policy contains non-proprietary information. All other documentation submitted for FIPS 140-2 conformance testing and validation is “FUJIFILM SONOSITE, Inc - Proprietary” and is releasable only under appropriate non-disclosure agreements.

Reference	Full Specification Name
[FIPS 140-2]	Security Requirements for Cryptographic modules, May 25, 2001
[FIPS 180-4]	Secure Hash Standard
[FIPS 186-4]	Digital Signature Standard
[FIPS 197]	Advanced Encryption Standard
[FIPS 198-1]	The Keyed Hash Message Authentication Code (HMAC)
[SP 800-38A]	Recommendation for Block Cipher Modes of Operation: Methods and Techniques
[SP 800-38B]	Recommendation for Block Cipher Modes of Operation: The CMAC Mode for Authentication
[SP 800-38C]	Recommendation for Block Cipher Modes of Operation: The CCM Mode for Authentication and Confidentiality
[SP 800-38D]	Recommendation for Block Cipher Modes of Operation: Galois/Counter Mode (GCM) and GMAC
[SP 800-56A]	Recommendation for Pair Wise Key Establishment Schemes Using Discrete Logarithm Cryptography
[SP 800-67R1]	Recommendation for the Triple Data Encryption Algorithm (TDEA) Block Cipher
[SP 800-89]	Recommendation for Obtaining Assurances for Digital Signature Applications
[SP 800-90A]	Recommendation for Random Number Generation Using Deterministic Random Bit Generators
[SP 800-131A]	Transitions: Recommendation for Transitioning the Use of Cryptographic Algorithms and Key Lengths

**Table 14: References**