

BUTTERFLY iQ3 MDS2

Manufacturer Disclosure Statement for Medical Device Security

| Question ID | Question | Response | Comment | IEC TR 80001-2-2:2012 | NIST SP 800-53 Rev. 4 | ISO 27002:2013 |
|-------------|--|--|---|---|-----------------------|----------------|
| DOC-1 | Manufacturer Name | Butterfly Network, Inc. | | | | |
| DOC-2 | Device Description | Handheld ultrasound and workflow management solution | | | | |
| DOC-3 | Device Model | iQ3 | | | | |
| DOC-4 | Document ID | 950-20050-00 Rev 01 - BNI-055 IQ3 MANUFACTURER DISCLOSURE STATEMENT FOR MEDICAL DEVICE SECURITY | | | | |
| DOC-5 | Manufacturer Contact Information | Technical Support https://support.butterflynetwork.com/ 855-296-6188 | | | | |
| DOC-6 | Intended use of device in network-connected environment: | Yes | Network connectivity is only required if saving images to the Butterfly Cloud, or to any connected hospital system. | | | |
| DOC-7 | Document Release Date | | 7/17/24 | | | |
| DOC-8 | Coordinated Vulnerability Disclosure: Does the manufacturer have a vulnerability disclosure program for this device? | Yes | | | | |
| DOC-9 | ISAO: Is the manufacturer part of an Information Sharing and Analysis Organization? | No | | | | |
| DOC-10 | Diagram: Is a network or data flow diagram available that indicates connections to other system components or expected external resources? | Yes | | https://manual.butterflynetwork.com/2Butterfly+Network+Technology+and+Security/White+Paper+950-20009-00+rev+E.pdf | | |
| DOC-11 | SaMD: Is the device Software as a Medical Device (i.e. softwareonly, no hardware)? | No | | https://manual.butterflynetwork.com/butterfly-iq-user-manual_rev-bi-en.pdf | | |
| DOC-11.1 | Does the SaMD contain an operating system? | N/A | | | | |
| DOC-11.2 | Does the SaMD rely on an owner/operator provided operating system? | N/A | | | | |
| DOC-11.3 | Is the SaMD hosted by the manufacturer? | N/A | | | | |
| DOC-11.4 | Is the SaMD hosted by the customer? | N/A | | | | |

| Question ID | MANAGEMENT OF PERSONALLY IDENTIFIABLE INFORMATION | Response | Comment | IEC TR 80001-2-2:2012 | NIST SP 800-53 Rev. 4 | ISO 27002:2013 |
|-------------|---|----------|---|-----------------------|-----------------------|----------------|
| MPII-1 | Can this device display, transmit, store, or modify personally identifiable information (e.g. electronic Protected Health Information (ePHI))? | Yes | | | AR-2 | A.15.1.4 |
| MPII-2 | Does the device maintain personally identifiable information? | No | | | AR-2 | A.15.1.4 |
| MPII-2.1 | Does the device maintain personally identifiable information temporarily in volatile memory (i.e., until cleared by power-off or reset)? | Yes | Ultrasound exams are briefly cached in the Butterfly iQ mobile app encrypted using AES 256-bit encryption until uploaded to the Butterfly Cloud. | | AR-2 | A.15.1.4 |
| MPII-2.2 | Does the device store personally identifiable information persistently on internal media? | No | | | | |
| MPII-2.3 | Is personally identifiable information preserved in the device's non-volatile memory until explicitly erased? | No | | | | |
| MPII-2.4 | Does the device store personally identifiable information in a database? | Yes | Butterfly mobile app can securely transmit data to the Butterfly Cloud where it is stored in a database long term. | | | |
| MPII-2.5 | Does the device allow configuration to automatically delete local personally identifiable information after it is stored to a long-term solution? | Yes | Local data is deleted once successfully received by the Butterfly Cloud. | | AR-2 | A.15.1.4 |
| MPII-2.6 | Does the device import/export personally identifiable information with other systems (e.g., a wearable monitoring device might export personally identifiable information to a server)? | Yes | Our Customers determine and control what Customer Data is uploaded to the Butterfly Cloud, but such data typically includes the patient's full name, DOB, gender, accession #, as well as the MRN scans captured through the iQ Device. It may also include the Customer's clinical notes on the patient and their scans. | | AR-2 | A.15.1.4 |
| MPII-2.7 | Does the device maintain personally identifiable information when powered off, or during power service interruptions? | Yes | Ultrasound exams not uploaded to the Butterfly Cloud will be maintained in the cache of the Butterfly iQ mobile app until uploaded to the Butterfly Cloud, or the user is logged out of the application. | | AR-2 | A.15.1.4 |
| MPII-2.8 | Does the device allow the internal media to be removed by a service technician (e.g., for separate destruction or customer retention)? | N/A | Internal media is part of the smart device being used in conjunction with the Butterfly iQ mobile app. No data is saved to the smart device's media. | | | |
| MPII-2.9 | Does the device allow personally identifiable information records be stored in a separate location from the device's operating system (i.e. secondary internal drive, alternate drive partition, or remote storage location)? | Yes | Butterfly mobile app can securely transmit data to the Butterfly Cloud where it is stored in a database long term. | | AR-2 | A.15.1.4 |
| MPII-3 | Does the device have mechanisms used for the transmitting/importing/exporting of personally identifiable information? | Yes | Data is transmitted to the Butterfly Cloud using HTTPS with TLSv1.2 and v1.3. Further, the TLSv1.2 and v1.3 ciphers supported by these endpoints are industry recommended ciphers such as ChaCha stream cipher and Poly1305 authenticator (CHACHA20 POLY1305) | | AR-2 | A.15.1.4 |
| MPII-3.1 | Does the device display personally identifiable information (e.g., video display, etc.)? | Yes | | | AR-2 | A.15.1.4 |
| MPII-3.2 | Does the device generate hardcopy reports or images containing personally identifiable information? | Yes | Butterfly Cloud has the ability to download a patient study as a PDF. | | AR-2 | A.15.1.4 |

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| MPII-3.3 | Does the device retrieve personally identifiable information from or record personally identifiable information to removable media (e.g., removable-HDD, USB memory, DVD-R/RW, CD-R/RW, tape, CF/SD card, memory stick, etc.)? | No | | | AR-2 | A.15.1.4 |
| MPII-3.4 | Does the device transmit/receive or import/export personally identifiable information via dedicated cable connection (e.g., RS232, RS-423, USB, FireWire, etc.)? | No | | | AR-2 | A.15.1.4 |
| MPII-3.5 | Does the device transmit/receive personally identifiable information via a wired network connection (e.g., RJ45, fiber optic, etc.)? | No | | | AR-2 | A.15.1.4 |
| MPII-3.6 | Does the device transmit/receive personally identifiable information via a wireless network connection (e.g., Wi-Fi, Bluetooth, NFC, infrared, cellular, etc.)? | Yes | Internet connectivity is required for access to hospital Modality Worklist, or to upload studies from the Butterfly IQ mobile app to the Butterfly Cloud. | | AR-2 | A.15.1.4 |
| MPII-3.7 | Does the device transmit/receive personally identifiable information over an external network (e.g., Internet)? | Yes | Data is transmitted to the Butterfly Cloud using HTTPS with TLSv1.2 and v1.3. Further, the TLSv1.2 and v1.3 ciphers supported by these endpoints are industry recommended ciphers such as ChaCha stream cipher and Poly1305 authenticator (CHACHA20 POLY1305). | | AR-2 | A.15.1.4 |
| MPII-3.8 | Does the device import personally identifiable information via scanning a document? | No | | | | |
| MPII-3.9 | Does the device transmit/receive personally identifiable information via a proprietary protocol? | No | | | | |
| MPII-3.10 | Does the device use any other mechanism to transmit, import or export personally identifiable information? | Yes | DICOM, HL7 or FHIR is used to send or receive data from connected hospital systems. | | AR-2 | A.15.1.4 |

AUTOMATIC LOGOFF (ALOF)

The device's ability to prevent access and misuse by unauthorized users if device is left idle for a period of time.

Response

Comment

| Question ID | | | | | | |
|-------------|--|-----|--|-------------------|-------|--------------------|
| ALOF-1 | Can the device be configured to force reauthorization of logged in user(s) after a predetermined length of inactivity (e.g., autologoff, session lock, password protected screen saver)? | Yes | Butterfly IQ mobile app session time-out is enabled through our MDM integration. | Section 5.1, ALOF | AC-12 | None |
| ALOF-2 | Is the length of inactivity time before auto-logout/screen lock user or administrator configurable? | Yes | | Section 5.1, ALOF | AC-11 | A.11.2.8, A.11.2.9 |

Question ID **AUDIT CONTROLS (AUDT)**

The ability to reliably audit activity on the device

Response

Comment

IEC TR 80001-2-2:2012

NIST SP 800-53 Rev. 4

ISO 27002:2013

| Question ID | | | | | | |
|-------------|--|-----|--|-------------------|------|---|
| AUDT-1 | Can the medical device create additional audit logs or reports beyond standard operating system logs? | Yes | Audit logs can be requested from Butterfly Technical Support. | Section 5.2, AUDT | AU-1 | A.5.1.1, A.5.1.2, A.6.1.1, A.12.1.1, A.18.1.1, A.18.2.2 |
| AUDT-1.1 | Does the audit log record a USER ID? | Yes | | | | |
| AUDT-1.2 | Does other personally identifiable information exist in the audit trail? | No | | Section 5.2, AUDT | AU-2 | None |
| AUDT-2 | Are events recorded in an audit log? If yes, indicate which of the following events are recorded in the audit log: | Yes | | Section 5.2, AUDT | AU-2 | None |
| AUDT-2.1 | Successful login/logout attempts? | Yes | | Section 5.2, AUDT | AU-2 | None |
| AUDT-2.2 | Unsuccessful login/logout attempts? | Yes | | Section 5.2, AUDT | AU-2 | None |
| AUDT-2.3 | Modification of user privileges? | No | | Section 5.2, AUDT | AU-2 | None |
| AUDT-2.4 | Creation/modification/deletion of users? | No | | Section 5.2, AUDT | AU-2 | None |
| AUDT-2.5 | Presentation of clinical or PII data (e.g. display, print)? | Yes | | Section 5.2, AUDT | AU-2 | None |
| AUDT-2.6 | Creation/modification/deletion of data? | Yes | | Section 5.2, AUDT | AU-2 | None |
| AUDT-2.7 | Import/export of data from removable media (e.g. USB drive, external hard drive, DVD)? | N/A | | Section 5.2, AUDT | AU-2 | None |
| AUDT-2.8 | Receipt/transmission of data or commands over a network or point-to-point connection? | Yes | | Section 5.2, AUDT | AU-2 | None |
| AUDT-2.8.1 | Remote or on-site support? | N/A | Butterfly Support is remote, however no remote access is needed by Butterfly Technical Support. | Section 5.2, AUDT | AU-2 | None |
| AUDT-2.8.2 | Application Programming Interface (API) and similar activity? | Yes | There are several internal only APIs used in the development of the Butterfly. There is no API available to customers. | Section 5.2, AUDT | AU-2 | None |
| AUDT-2.9 | Emergency access? | N/A | | Section 5.2, AUDT | AU-2 | None |
| AUDT-2.10 | Other events (e.g., software updates)? | N/A | | Section 5.2, AUDT | AU-2 | None |
| AUDT-2.11 | Is the audit capability documented in more detail? | No | | Section 5.2, AUDT | AU-2 | None |
| AUDT-3 | Can the owner/operator define or select which events are recorded in the audit log? | No | | Section 5.2, AUDT | AU-2 | None |
| AUDT-4 | Is a list of data attributes that are captured in the audit log for an event available? | Yes | All activities below are logged by User ID and date/time to the millisecond: Logon Failed login attempts Image create/view/modify/delete Modification of study details User account create/delete/modification Administrator changes | Section 5.2, AUDT | AU-2 | None |
| AUDT-4.1 | Does the audit log record date/time? | Yes | | Section 5.2, AUDT | AU-2 | None |
| AUDT-4.1.1 | Can date and time be synchronized by Network Time Protocol (NTP) or equivalent time source? | Yes | | Section 5.2, AUDT | AU-2 | None |
| AUDT-5 | Can audit log content be exported? | No | To request a customized audit log email butterfly support at support@butterflynetwork.com. | Section 5.2, AUDT | AU-2 | None |
| AUDT-5.1 | Via physical media? | No | | | | |
| AUDT-5.2 | Via IHE Audit Trail and Node Authentication (ATNA) profile to SIEM? | No | | | | |
| AUDT-5.3 | Via Other communications (e.g., external service device, mobile applications)? | No | | | | |

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|----------|--|-----|--|-------------------|------|------|
| AUDT-5.4 | Are audit logs encrypted in transit or on storage media? | N/A | | | | |
| AUDT-6 | Can audit logs be monitored/reviewed by owner/operator? | No | To request a customized audit log email butterfly support at support@butterflynetwork.com. | | | |
| AUDT-7 | Are audit logs protected from modification? | Yes | | Section 5.2, AUDT | AU-2 | None |
| AUDT-7.1 | Are audit logs protected from access? | Yes | | | | |
| AUDT-8 | Can audit logs be analyzed by the device? | No | | Section 5.2, AUDT | AU-2 | None |

| Question ID | AUTHORIZATION (AUTH) <i>The ability of the device to determine the authorization of users.</i> | Response | Comment | IEC TR 80001-2-2:2012 | NIST SP 800-53 Rev. 4 | ISO 27002:2013 |
|-------------|---|----------|---|-----------------------|-----------------------|----------------|
| AUTH-1 | Does the device prevent access to unauthorized users through user login requirements or other mechanism? | Yes | | Section 5.3, AUTH | IA-2 | A.9.2.1 |
| AUTH-1.1 | Can the device be configured to use federated credentials management of users for authorization (e.g., LDAP, OAuth)? | Yes | | Section 5.3, AUTH | IA-2 | A.9.2.1 |
| AUTH-1.2 | Can the customer push group policies to the device (e.g., Active Directory)? | No | | Section 5.3, AUTH | IA-2 | A.9.2.1 |
| AUTH-1.3 | Are any special groups, organizational units, or group policies required? | No | | Section 5.3, AUTH | IA-2 | A.9.2.1 |
| AUTH-2 | Can users be assigned different privilege levels based on 'role' (e.g. user, administrator, and/or service, etc.)? | Yes | Butterfly Access Roles allow administrators to control what actions a user can take within the Butterfly platform. Each user has one and only one Butterfly Access Role. Each user's Butterfly Access Role governs what they can do throughout the entire domain. | Section 5.3, AUTH | IA-2 | A.9.2.1 |
| AUTH-3 | Can the device owner/operator grant themselves unrestricted administrative privileges (e.g., access operating system or application via local root or administrator account)? | No | | Section 5.3, AUTH | IA-2 | A.9.2.1 |
| AUTH-4 | Does the device authorize or control all API access requests? | N/A | | Section 5.3, AUTH | IA-2 | A.9.2.1 |
| AUTH-5 | Does the device run in a restricted access mode, or 'kiosk mode', by default? | No | Butterfly IQ mobile app can be run in kiosk mode. | | | |

| Question ID | CYBERSECURITY PRODUCT UPGRADES (CSUP) <i>The ability of on-site service staff, remote service staff, or authorized customer staff to install/upgrade device's security patches.</i> | Response | Comment | IEC TR 80001-2-2:2012 | NIST SP 800-53 Rev. 4 | ISO 27002:2013 |
|-------------|---|----------|--|-----------------------|-----------------------|----------------|
| CSUP-1 | Does the device contain any software or firmware which may require security updates during its operational life, either from the device manufacturer or from a third-party manufacturer of the software/firmware? If no, answer "N/A" to questions in this section. | Yes | Butterfly Cloud is a SaaS with continuous delivery. Updates are deployed during periods of low cloud usage using non-breaking changes with no impact to the end user. Butterfly IQ mobile app and Butterfly IQ firmware updates and security patches are provided automatically using Over the Air (OTA) updates. Updates are not generally required, however, major updates, such as those affecting safety or data security, could be mandatory. For Enterprise customers, mobile app upgrades can also be pushed to end-users through MDM integration. Mobile devices, Server and Workstation maintenance, updates, patches, and anti-virus software are the responsibility of the customer. | | | |
| CSUP-2 | Does the device contain an Operating System? If yes, complete 2.1-2.4. | No | Mobile devices, Server and Workstation maintenance, updates, patches, and anti-virus software are the responsibility of the customer. | | | |
| CSUP-2.1 | Does the device documentation provide instructions for owner/operator installation of patches or software updates? | Yes | https://support.butterflynetwork.com/hc/en-us/articles/16906028518939-User-Manual | | | |
| CSUP-2.2 | Does the device require vendor or vendor-authorized service to install patches or software updates? | No | | | | |
| CSUP-2.3 | Does the device have the capability to receive remote installation of patches or software updates? | Yes | | | | |
| CSUP-2.4 | Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g., Microsoft) to be installed without approval from the manufacturer? | Yes | | | | |
| CSUP-3 | Does the device contain Drivers and Firmware? If yes, complete 3.1-3.4. | Yes | | | | |
| CSUP-3.1 | Does the device documentation provide instructions for owner/operator installation of patches or software updates? | Yes | https://support.butterflynetwork.com/hc/en-us/articles/16906028518939-User-Manual | | | |
| CSUP-3.2 | Does the device require vendor or vendor-authorized service to install patches or software updates? | No | | | | |
| CSUP-3.3 | Does the device have the capability to receive remote installation of patches or software updates? | Yes | | | | |
| CSUP-3.4 | Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g., Microsoft) to be installed without approval from the manufacturer? | Yes | | | | |
| CSUP-4 | Does the device contain Anti-Malware Software? If yes, complete 4.1-4.4. | No | | | | |
| CSUP-4.1 | Does the device documentation provide instructions for owner/operator installation of patches or software updates? | N/A | | | | |
| CSUP-4.2 | Does the device require vendor or vendor-authorized service to install patches or software updates? | N/A | | | | |
| CSUP-4.3 | Does the device have the capability to receive remote installation of patches or software updates? | N/A | | | | |
| CSUP-4.4 | Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g., Microsoft) to be installed without approval from the manufacturer? | N/A | | | | |
| CSUP-5 | Does the device contain Non-Operating System commercial off-the-shelf components? If yes, complete 5.1-5.4. | No | | | | |
| CSUP-5.1 | Does the device documentation provide instructions for owner/operator installation of patches or software updates? | N/A | | | | |

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| CSUP-5.2 | Does the device require vendor or vendor-authorized service to install patches or software updates? | N/A | | | | |
| CSUP-5.3 | Does the device have the capability to receive remote installation of patches or software updates? | N/A | | | | |
| CSUP-5.4 | Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g., Microsoft) to be installed without approval from the manufacturer? | N/A | | | | |
| CSUP-6 | Does the device contain other software components (e.g., asset management software, license management)? If yes, please provide details or reference in notes and complete 6.1-6.4. | No | | | | |
| CSUP-6.1 | Does the device documentation provide instructions for owner/operator installation of patches or software updates? | N/A | | | | |
| CSUP-6.2 | Does the device require vendor or vendor-authorized service to install patches or software updates? | N/A | | | | |
| CSUP-6.3 | Does the device have the capability to receive remote installation of patches or software updates? | N/A | | | | |
| CSUP-6.4 | Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g., Microsoft) to be installed without approval from the manufacturer? | N/A | | | | |
| CSUP-7 | Does the manufacturer notify the customer when updates are approved for installation? | Yes | Butterfly Cloud is a SaaS with continuous delivery. Updates are deployed during periods of low cloud usage using non-breaking changes with no impact to the end user. Butterfly iQ mobile app and Butterfly iQ firmware upgrades and security patches are provided automatically using Over the Air (OTA) updates. Updates are not generally required, however, major updates, such as those affecting safety or data security, could be mandatory. For Enterprise customers, mobile app upgrades can also be pushed to end-users through MDM integration. Mobile devices, Server and Workstation maintenance, updates, patches, and anti-virus software are the responsibility of the customer. | | | |
| CSUP-8 | Does the device perform automatic installation of software updates? | Yes | | | | |
| CSUP-9 | Does the manufacturer have an approved list of third-party software that can be installed on the device? | No | Mobile devices, Server and Workstation maintenance, updates, patches, and anti-virus software are the responsibility of the customer. | | | |
| CSUP-10 | Can the owner/operator install manufacturer-approved third party software on the device themselves? | N/A | | | | |
| CSUP-10.1 | Does the system have mechanisms in place to prevent installation of unapproved software? | N/A | | | | |
| CSUP-11 | Does the manufacturer have a process in place to assess device vulnerabilities and updates? | Yes | | | | |
| CSUP-11.1 | Does the manufacturer provide customers with review and approval status of updates? | No | Butterfly iQ mobile app and Butterfly iQ firmware upgrades and security patches are provided automatically using Over the Air (OTA) updates. Updates are not generally required, however, major updates, such as those affecting safety or data security, could be mandatory. | | | |
| CSUP-11.2 | Is there an update review cycle for the device? | No | Generally, updates are released through the App Store monthly. | | | |

| Question ID | HEALTH DATA DE-IDENTIFICATION (DIDT) <i>The ability of the device to directly remove information that allows identification of a person.</i> | Response | Comment | IEC TR 80001-2-2:2012 | NIST SP 800-53 Rev. 4 | ISO 27002:2013 |
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| DIDT-1 | Does the device provide an integral capability to de-identify personally identifiable information? | Yes | | Section 5.6, DIDT | None | ISO 27038 |
| DIDT-1.1 | Does the device support de-identification profiles that comply with the DICOM standard for de-identification? | Yes | | Section 5.6, DIDT | None | ISO 27038 |

| DATA BACKUP AND DISASTER RECOVERY (DTBK) <i>The ability to recover after damage or destruction of device data, hardware, software, or site configuration information.</i> | | | | | | |
|--|--|----------|---|-----------------------|-----------------------|----------------|
| Question ID | | Response | Comment | IEC TR 80001-2-2:2012 | NIST SP 800-53 Rev. 4 | ISO 27002:2013 |
| DTBK-1 | Does the device maintain long term primary storage of personally identifiable information / patient information (e.g. PACS)? | Yes | Butterfly Cloud can also be integrated with a hospital's PACS/VNA or EHR. | | | |
| DTBK-2 | Does the device have a "factory reset" function to restore the original device settings as provided by the manufacturer? | Yes | | Section 5.7, DTBK | CP-9 | A.12.3.1 |
| DTBK-3 | Does the device have an integral data backup capability to removable media? | No | | Section 5.7, DTBK | CP-9 | A.12.3.1 |
| DTBK-4 | Does the device have an integral data backup capability to remote storage? | Yes | Backups of all Butterfly Cloud system data are stored in Amazon Web Services. Backups are automatically performed daily and prior to application upgrades, but can also be performed on demand. The format of the backups are snapshots of the encrypted Amazon Elastic Block Store volume. Backups are maintained for 8 days prior to being deleted. Backups include, but are not limited to, RDS and K8s apps. For specific data center disaster recovery details, please refer to the AWS SOC III report. https://d1.awsstatic.com/whitepapers/compliance/AWS_SOC3.pdf | | | |
| DTBK-5 | Does the device have a backup capability for system configuration information, patch restoration, and software restoration? | No | | | | |
| DTBK-6 | Does the device provide the capability to check the integrity and authenticity of a backup? | Yes | Backups of all Butterfly Cloud system data are stored in Amazon Web Services. | Section 5.7, DTBK | CP-9 | A.12.3.1 |

| Question ID | EMERGENCY ACCESS (EMRG) <i>The ability of the device user to access personally identifiable information in case of a medical emergency situation that requires immediate access to stored personally identifiable information.</i> | Response | Comment | IEC TR 80001-2-2:2012 | NIST SP 800-53 Rev. 4 | ISO 27002:2013 |
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| EMRG-1 | Does the device incorporate an emergency access (i.e. "breakglass") feature? | No | | Section 5.8, EMRG | SI-17 | None |

| Question ID | HEALTH DATA INTEGRITY AND AUTHENTICITY (IGAU) <i>How the device ensures that the stored data on the device has not been altered or destroyed in a non-authorized manner and is from the originator.</i> | Response | Comment | IEC TR 80001-2-2:2012 | NIST SP 800-53 Rev. 4 | ISO 27002:2013 |
|-------------|--|----------|--|-----------------------|-----------------------|----------------|
| IGAU-1 | Does the device provide data integrity checking mechanisms of stored health data (e.g., hash or digital signature)? | Yes | From an App side, health data is retrieved, manipulated, and stored in the following manner: PHI of patients can be retrieved from the Butterfly Cloud only to populate a study's association. The cloud is the interface with the EMR systems and the mobile app cannot interface with them directly. Rather it retrieves it, leverages short term memory objects to show it, and discards any references that | Section 5.9, IGAU | SC-28 | A.18.1.3 |

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| | | | <p>are not used in conjunction with a study. The app does not manipulate the data in any way.</p> <p>If the healthcare professional is manually inputting the patient data, it is up to them to get the data properly inputted.</p> <p>When a study is performed and tied to a patient, that data is stored in a study reference in the local DB until it is uploaded to the cloud. Once uploaded, any reference locally is deleted predominately. While stored, all the PHI is encrypted.</p> <p>The app does pull down from the cloud a list of previously performed studies (archive list), but that is a read only operation.</p> <p>Hash values are used to associate various objects of a patient. Ex: when an image is captured or pulled down from the cloud in the archive, a hash value is used to associate the data object between the patient and the object. This ensures data integrity between the various health data elements and ensures they can connect back to the patient if all hash references are known.</p> | | | |
| IGAU-2 | Does the device provide error/failure protection and recovery mechanisms for stored health data (e.g., RAID-5)? | Yes | <p>If someone logs out, we alert them that their locally stored studies that have yet to sync to the cloud will be deleted premaritally.</p> <p>If a study fails to upload due to network connectivity or due to a partial upload, we do have failure scenarios that ensure it can continue to upload the next time it gets a stable connection.</p> <p>All data is encrypted at rest. For iOS, data is encrypted when the device is locked with a PIN code. On android, the data is protected until the application is opened.</p> | Section 5.9, IGAU | SC-28 | A.18.1.3 |

| Question ID | MALWARE DETECTION/PROTECTION (MLDP) <i>The ability of the device to effectively prevent, detect and remove malicious software (malware).</i> | Response | Comment | IEC TR 80001-2-2:2012 | NIST SP 800-53 Rev. 4 | ISO 27002:2013 |
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| MLDP-1 | Is the device capable of hosting executable software? | No | | Section 5.10, MLDP | | |
| MLDP-2 | Does the device support the use of anti-malware software (or other anti-malware mechanism)? Provide details or reference in notes. | Yes | Mobile devices, Server and Workstation maintenance, upgrades, patches, and anti-virus software are the responsibility of the customer. | Section 5.10, MLDP | SI-3 | A.12.2.1 |
| MLDP-2.1 | Does the device include anti-malware software by default? | No | Mobile devices, Server and Workstation maintenance, upgrades, patches, and anti-virus software are the responsibility of the customer. | Section 5.10, MLDP | CM-5 | A.9.2.3, A.9.4.5, A.12.1.2, A.12.1.4, A.12.5.1 |
| MLDP-2.2 | Does the device have anti-malware software available as an option? | No | | Section 5.10, MLDP | AU-6 | A.12.4.1, A.16.1.2, A.16.1.4 |
| MLDP-2.3 | Does the device documentation allow the owner/operator to install or update anti-malware software? | N/A | | Section 5.10, MLDP | CP-10 | A.17.1.2 |
| MLDP-2.4 | Can the device owner/operator independently (re-)configure antimalware settings? | Yes | | Section 5.10, MLDP | AU-2 | None |
| MLDP-2.5 | Does notification of malware detection occur in the device user interface? | No | | | | |
| MLDP-2.6 | Can only manufacturer-authorized persons repair systems when malware has been detected? | N/A | | | | |
| MLDP-2.7 | Are malware notifications written to a log? | N/A | | | | |
| MLDP-2.8 | Are there any restrictions on anti-malware (e.g., purchase, installation, configuration, scheduling)? | No | | | | |
| MLDP-3 | If the answer to MLDP-2 is NO, and anti-malware cannot be installed on the device, are other compensating controls in place or available? | N/A | | Section 5.10, MLDP | SI-2 | A.12.6.1, A.14.2.2, A.14.2.3, A.16.1.3 |
| MLDP-4 | Does the device employ application whitelisting that restricts the software and services that are permitted to be run on the device? | N/A | Butterfly Cloud applications are based on Amazon EKS. | Section 5.10, MLDP | SI-3 | A.12.2.1 |
| MLDP-5 | Does the device employ a host-based intrusion detection/prevention system? | Yes | Butterfly Cloud uses a hardened EKS base image with Rapid7 installed on it. | Section 5.10, MLDP | SI-4 | None |
| MLDP-5.1 | Can the host-based intrusion detection/prevention system be configured by the customer? | No | | Section 5.10, MLDP | CM-7 | A.12.5.1 |
| MLDP-5.2 | Can a host-based intrusion detection/prevention system be installed by the customer? | Yes | | Section 5.10, MLDP | | |

| Question ID | NODE AUTHENTICATION (NAUT) <i>The ability of the device to authenticate communication partners/nodes.</i> | Response | Comment | IEC TR 80001-2-2:2012 | NIST SP 800-53 Rev. 4 | ISO 27002:2013 |
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| NAUT-1 | Does the device provide/support any means of node authentication that assures both the sender and the recipient of data are known to each other and are authorized to receive transferred information (e.g. Web APIs, SMTP, SNMP)? | Yes | Data is transmitted to the Butterfly Cloud using HTTPS with TLSv1.2 and v1.3. Further, the TLSv1.2 and v1.3 ciphers supported by these endpoints are industry-recommended ciphers such as ChaCha stream cipher and Poly1305 authenticator (CHACHA20 POLY1305) | Section 5.11, NAUT | SC-23 | None |
| NAUT-2 | Are network access control mechanisms supported (E.g., does the device have an internal firewall, or use a network connection white list)? | Yes | Butterfly Cloud utilizes three firewalls. AWS Shield and CloudFrontend ModSecurity (firewall at the application level). Web application traffic is secured with TLS 1.3. Butterfly Network hosts all of its cloud compute resources on private-only EKS clusters. AWS WAF is also utilized. The Butterfly Cloud uses a multi-tenant cloud architecture that ensures data separation through organization specific metadata tags. | Section 5.11, NAUT | SC-7 | A.13.1.1, A.13.1.3, A.13.2.1, A.14.1.3 |
| NAUT-2.1 | Is the firewall ruleset documented and available for review? | No | These are reviewed by our 3rd party auditor. Report is available for review. | | | |
| NAUT-3 | Does the device use certificate-based network connection authentication? | Yes | Encryption keys are managed by AWS. AWS KMS (Key Management Services) is tightly integrated with the AWS product portfolio to provide leading security controls, auditing, management, and compliance for encryption keys. The service uses FIPS 140-2 validated hardware security modules (HSMs) to protect the confidentiality and integrity of the keys. TLS certificates expire every 90 days and are rotated beforehand. No Butterfly employees can access them directly by any means. Encryption keys are customer-specific for Butterfly Cloud-to-Customer network communications. iOS: File protection keys are stored in the escrow keybag, which is compatible with MDM syncing. When a passcode-locked device is first connected to iTunes, the user is prompted to enter a passcode. The device then creates an escrow keybag containing the same class keys used on the device, protected by a newly generated key. | | | |

| Question ID | CONNECTIVITY CAPABILITIES (CONN) | Response | Comment | IEC TR 80001-2-2:2012 | NIST SP 800-53 Rev. 4 | ISO 27002:2013 |
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Question ID

IEC TR 80001-2-2:2012

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ISO 27002:2013

All network and removable media connections must be considered in determining appropriate security controls. This section lists connectivity capabilities that may be present on the device.

| | | | | | | |
|------------|---|-----|--|--|--|--|
| CONN-1 | Does the device have hardware connectivity capabilities? | Yes | | | | |
| CONN-1.1 | Does the device support wireless connections? | No | | | | |
| CONN-1.1.1 | Does the device support Wi-Fi? | No | | | | |
| CONN-1.1.2 | Does the device support Bluetooth? | No | | | | |
| CONN-1.1.3 | Does the device support other wireless network connectivity (e.g. LTE, Zigbee, proprietary)? | No | | | | |
| CONN-1.1.4 | Does the device support other wireless connections (e.g., custom RF controls, wireless detectors)? | No | | | | |
| CONN-1.2 | Does the device support physical connections? | Yes | Butterfly iQ probes plug into a smart device using a lightning or USB-C cable. The security of the USB connection is managed by the underlying mobile operating system: Android or iOS. | | | |
| CONN-1.2.1 | Does the device have available RJ45 Ethernet ports? | No | | | | |
| CONN-1.2.2 | Does the device have available USB ports? | No | | | | |
| CONN-1.2.3 | Does the device require, use, or support removable memory devices? | No | | | | |
| CONN-1.2.4 | Does the device support other physical connectivity? | No | | | | |
| CONN-2 | Does the manufacturer provide a list of network ports and protocols that are used or may be used on the device? | Yes | HTTPS (port 443) outbound via mobile app for connectivity to the Cloud | | | |
| CONN-3 | Can the device communicate with other systems within the customer environment? | Yes | Butterfly Cloud can be integrated with the following: Patient Chart Imaging Archive SSO Workstations Smart devices | | | |
| CONN-4 | Can the device communicate with other systems external to the customer environment (e.g., a service host)? | Yes | Butterfly iQ mobile app securely connects to the Butterfly Cloud hosted in AWS. | | | |
| CONN-5 | Does the device make or receive API calls? | Yes | Butterfly iQ – Ultrasound Android and iOS mobile apps interact with our AWS GraphQL API. | | | |
| CONN-6 | Does the device require an internet connection for its intended use? | Yes | Butterfly iQ mobile app uses the smart device connectivity to communicate with Butterfly Cloud for data archive, patient data, new feature deployment, and user authorization. Internet connectivity is required at least every 30 days to ensure user authentication and firmware/software. Butterfly Cloud requires internet connectivity to access stored patient studies and is facilitated through a supported web browser. | | | |
| CONN-7 | Does the device support Transport Layer Security (TLS)? | Yes | Data is transmitted to the Butterfly Cloud using HTTPS with TLSv1.2 and v1.3. Further, the TLSv1.2 and v1.3 ciphers supported by these endpoints are industry recommended ciphers such as ChaCha stream cipher and Poly1305 authenticator (CHACHA20 POLY1305) TLS 1.2 and 1.3 | | | |
| CONN-7.1 | Is TLS configurable? | Yes | | | | |
| CONN-8 | Does the device provide operator control functionality from a separate device (e.g., telemedicine)? | Yes | Telemedicine is a feature of the Butterfly Platform and can be used between two authorized users of the same customer domain. | | | |

Question ID

PERSON AUTHENTICATION (PAUT)

The ability to configure the device to authenticate users.

Response

Comment

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| PAUT-1 | Does the device support and enforce unique IDs and passwords for all users and roles (including service accounts)? | Yes | | Section 5.12, PAUT | IA-2 | A.9.2.1 |
| PAUT-1.1 | Does the device enforce authentication of unique IDs and passwords for all users and roles (including service accounts)? | Yes | Enterprise memberships may be integrated with customer's SSO via SAML 2.0 to enforce authentication. | Section 5.12, PAUT | IA-2 | A.9.2.1 |
| PAUT-2 | Is the device configurable to authenticate users through an external authentication service (e.g., MS Active Directory, NDS, LDAP, OAuth, etc.)? | Yes | Enterprise memberships may be integrated with customer's SSO via SAML 2.0. | Section 5.12, PAUT | IA-5 | A.9.2.1 |
| PAUT-3 | Is the device configurable to lock out a user after a certain number of unsuccessful logon attempts? | Yes | Butterfly user ID's lock after 10 failed attempts. Alternatively, lock will follow your SSO rules. | Section 5.12, PAUT | IA-2 | A.9.2.1 |
| PAUT-4 | Are all default accounts (e.g., technician service accounts, administrator accounts) listed in the documentation? | N/A | No default accounts. | Section 5.12, PAUT | SA-4(5) | A.14.1.1, A.14.2.7, A.14.2.9, A.15.1.2 |
| PAUT-5 | Can all passwords be changed? | Yes | | Section 5.12, PAUT | | |
| PAUT-6 | Is the device configurable to enforce creation of user account passwords that meet established (organization specific) complexity rules? | Yes | Enterprise memberships may be integrated with customer's SSO via SAML 2.0 to meet complexity requirements. | Section 5.12, PAUT | IA-2 | A.9.2.1 |
| PAUT-7 | Does the device support account passwords that expire periodically? | N/A | There are no support accounts | | | |
| PAUT-8 | Does the device support multi-factor authentication? | Yes | Enterprise memberships may be integrated with customer's SSO via SAML 2.0 to meet MFA requirements. | | | |
| PAUT-9 | Does the device support single sign-on (SSO)? | Yes | | Section 5.12, PAUT | IA-2 | A.9.2.1 |
| PAUT-10 | Can user accounts be disabled/locked on the device? | Yes | | Section 5.12, PAUT | IA-2 | A.9.2.1 |
| PAUT-11 | Does the device support biometric controls? | No | | Section 5.12, PAUT | IA-2 | A.9.2.1 |
| PAUT-12 | Does the device support physical tokens (e.g. badge access)? | No | | | | |
| PAUT-13 | Does the device support group authentication (e.g. hospital teams)? | No | | | | |
| PAUT-14 | Does the application or device store or manage authentication credentials? | Yes | | | | |
| PAUT-14.1 | Are credentials stored using a secure method? | Yes | Passwords are hashed using Bcrypt. https://auth0.com/docs/authorize/database-connections/auth0-user-store | | | |

Question ID

PHYSICAL LOCKS (PLOC)

Physical locks can prevent unauthorized users with physical access to the device from compromising the integrity and confidentiality of personally identifiable information stored on the device or on removable media

Response

Comment

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| PLOK-1 | Is the device software only? If yes, answer "N/A" to remaining questions in this section. | No | | Section 5.13, PLOK | PE- 3(4) | A.11.1.1, A.11.1.2, A.11.1.3 |
| PLOK-2 | Are all device components maintaining personally identifiable information (other than removable media) physically secure (i.e., cannot remove without tools)? | Yes | | Section 5.13, PLOK | PE- 3(4) | A.11.1.1, A.11.1.2, A.11.1.3 |
| PLOK-3 | Are all device components maintaining personally identifiable information (other than removable media) physically secured behind an individually keyed locking device? | Yes | | Section 5.13, PLOK | PE- 3(4) | A.11.1.1, A.11.1.2, A.11.1.3 |
| PLOK-4 | Does the device have an option for the customer to attach a physical lock to restrict access to removable media? | N/A | There is no removable media | Section 5.13, PLOK | PE- 3(4) | A.11.1.1, A.11.1.2, A.11.1.3 |

Question ID **ROADMAP FOR THIRD PARTY COMPONENTS IN DEVICE LIFE CYCLE (RDMP)** **Response** **Comment** **IEC TR 80001-2-2:2012** **NIST SP 800-53 Rev. 4** **ISO 27002:2013**

Manufacturer's plans for security support of third-party components within the device's life cycle.

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| RDMP-1 | Was a secure software development process, such as ISO/IEC 27034 or IEC 62304, followed during product development? | Yes | Butterfly's Security Program utilizes industry leading, risk-based, frameworks and standards such as OWASP and AWS benchmarking best practices. Butterfly has a security team led by a Chief Information Security Officer (CISO) who is responsible for the development and maintenance of security policies, enforcing security operations and monitoring technical security within the company and associated third parties. Butterfly Network has documented policies and procedures in place regarding systems authentication, access, and security monitoring. These policies and procedures are reviewed by management annually. | Section 5.14, RDMP | CM-2 | None |
| RDMP-2 | Does the manufacturer evaluate third-party applications and software components included in the device for secure development practices? | Yes | | Section 5.14, RDMP | CM-8 | A.8.1.1, A.8.1.2 |
| RDMP-3 | Does the manufacturer maintain a web page or other source of information on software support dates and updates? | Yes | | Section 5.14, RDMP | CM-8 | A.8.1.1, A.8.1.2 |
| RDMP-4 | Does the manufacturer have a plan for managing third-party component end-of-life? | Yes | | Section 5.14, RDMP | CM-8 | A.8.1.1, A.8.1.2 |

SOFTWARE BILL OF MATERIALS (SBoM)

A Software Bill of Material (SBoM) lists all the software components that are incorporated into the device being described for the purpose of operational security planning by the healthcare delivery organization. This section supports controls in the RDMP section.

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| SBOM-1 | Is the SBoM for this product available? | Yes | Available under NDA. | | | |
| SBOM-2 | Does the SBoM follow a standard or common method in describing software components? | Yes | | | | |
| SBOM-2.1 | Are the software components identified? | Yes | | | | |
| SBOM-2.2 | Are the developers/manufacturers of the software components identified? | Yes | | | | |
| SBOM-2.3 | Are the major version numbers of the software components identified? | No | | | | |
| SBOM-2.4 | Are any additional descriptive elements identified? | Yes | | | | |
| SBOM-3 | Does the device include a command or process method available to generate a list of software components installed on the device? | No | | | | |
| SBOM-4 | Is there an update process for the SBoM? | Yes | | | | |

Question ID **SYSTEM AND APPLICATION HARDENING (SAHD)** **Response** **Comment** **IEC TR 80001-2-2:2012** **NIST SP 800-53 Rev. 4** **ISO 27002:2013**

The device's inherent resistance to cyber attacks and malware.

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| SAHD-1 | Is the device hardened in accordance with any industry standards? | Yes | | Section 5.15, SAHD | CM-7 | A.12.5.1* |
| SAHD-2 | Has the device received any cybersecurity certifications? | Yes | HIPAA and HITECH compliant GDPR Ready Freedom of Information and Protection of Privacy Act (FOIPPA) Ready Personal Information International Disclosure Protection Act (PIIDPA) Ready ISO 13485 | Section 5.15, SAHD | SA-12(10) | A.6.2.1, A.6.2.2, A.13.1.1, A.13.2.1, A.14.1.2/None A.14.2.7, A.15.1.1, A.15.1.2, A.15.1.3 |
| SAHD-3 | Does the device employ any mechanisms for software integrity checking | Yes | S3 is used for file storage and integrity monitoring https://docs.aws.amazon.com/AWSonS3/latest/userguide/s3-compliance.html | | | |
| SAHD-3.1 | Does the device employ any mechanism (e.g., release-specific hash key, checksums, digital signature, etc.) to ensure the installed software is manufacturer-authorized? | Yes | | | | |
| SAHD-3.2 | Does the device employ any mechanism (e.g., release-specific hash key, checksums, digital signature, etc.) to ensure the software updates are the manufacturer-authorized updates? | Yes | | Section 5.15, SAHD | CM-8 | A.8.1.1, A.8.1.2 |
| SAHD-4 | Can the owner/operator perform software integrity checks (i.e., verify that the system has not been modified or tampered with)? | No | | Section 5.15, SAHD | AC-3 | A.6.2.2, A.9.1.2, A.9.4.1, A.9.4.4, A.9.4.5, A.13.1.1, A.14.1.2, A.14.1.3, A.18.1.3 |
| SAHD-5 | Is the system configurable to allow the implementation of filelevel, No patient level, or other types of access controls? | No | | Section 5.15, SAHD | CM-7 | A.12.5.1* |
| SAHD-5.1 | Does the device provide role-based access controls? | Yes | Butterfly Access Roles allow administrators to control what actions a user can take within the Butterfly platform. Each user has one and only one Butterfly Access Role. Each user's Butterfly Access Role governs what they can do throughout the entire domain. | Section 5.15, SAHD | CM-7 | A.12.5.1* |
| SAHD-6 | Are any system or user accounts restricted or disabled by the manufacturer at system delivery? | Yes | | Section 5.15, SAHD | CM-8 | A.8.1.1, A.8.1.2 |
| SAHD-6.1 | Are any system or user accounts configurable by the end user after initial configuration? | No | | Section 5.15, SAHD | CM-7 | A.12.5.1* |
| SAHD-6.2 | Does this include restricting certain system or user accounts, such as service technicians, to least privileged access? | N/A | | Section 5.15, SAHD | CM-7 | A.12.5.1* |
| SAHD-7 | Are all shared resources (e.g., file shares) which are not required for the intended use of the device disabled? | Yes | | Section 5.15, SAHD | CM-7 | A.12.5.1* |
| SAHD-8 | Are all communication ports and protocols that are not required for the intended use of the device disabled? | Yes | | Section 5.15, SAHD | SA-18 | None |
| SAHD-9 | Are all services (e.g., telnet, file transfer protocol [FTP], internet information server [IIS], etc.) which are not required for the intended use of the device deleted/disabled? | Yes | | Section 5.15, SAHD | CM-6 | None |
| SAHD-10 | Are all applications (COTS applications as well as OS-included applications, e.g., MS Internet Explorer, etc.) which are not required for the intended use of the device deleted/disabled? | Yes | | Section 5.15, SAHD | SI-2 | A.12.6.1, A.14.2.2, A.14.2.3, A.16.1.3 |

| Question ID | | | | IEC TR 80001-2-2:2012 | NIST SP 800-53 Rev. 4 | ISO 27002:2013 |
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| SAHD-11 | Can the device prohibit boot from uncontrolled or removable media (i.e., a source other than an internal drive or memory component)? | Yes | | | | |
| SAHD-12 | Can unauthorized software or hardware be installed on the device without the use of physical tools? | No | | | | |
| SAHD-13 | Does the product documentation include information on operational network security scanning by users? | Yes | Mobile devices, Server and Workstation maintenance, upgrades, patches, and anti-virus software are the responsibility of the customer. | | | |
| SAHD-14 | Can the device be hardened beyond the default provided state? | No | | | | |
| SAHD-14.1 | Are instructions available from vendor for increased hardening? | N/A | | | | |
| SHAD-15 | Can the system prevent access to BIOS or other bootloaders during boot? | Yes | | | | |
| SAHD-16 | Have additional hardening methods not included in 2.3.19 been used to harden the device? | N/A | | | | |

| Question ID | SECURITY GUIDANCE (SGUD) | Response | Comment | IEC TR 80001-2-2:2012 | NIST SP 800-53 Rev. 4 | ISO 27002:2013 |
|-------------|---|----------|--|-----------------------|-----------------------|----------------|
| | <i>Availability of security guidance for operator and administrator of the device and manufacturer sales and service.</i> | | | | | |
| SGUD-1 | Does the device include security documentation for the owner/operator? | Yes | | | Section 5.16, SGUD | AT-2/PL-2 |
| SGUD-2 | Does the device have the capability, and provide instructions, for the permanent deletion of data from the device or media? | Yes | | | Section 5.16, SGUD | MP-6 |
| SGUD-3 | Are all access accounts documented? | N/A | All service accounts have been disabled. | | Section 5.16, SGUD | AC-6,IA-2 |
| SGUD-3.1 | Can the owner/operator manage password control for all accounts? | Yes | | | | |
| SGUD-4 | Does the product include documentation on recommended compensating controls for the device? | Yes | | | | |

| Question ID | HEALTH DATA STORAGE CONFIDENTIALITY (STCF) | Response | Comment | IEC TR 80001-2-2:2012 | NIST SP 800-53 Rev. 4 | ISO 27002:2013 |
|-------------|--|----------|---|-----------------------|-----------------------|----------------|
| | <i>The ability of the device to ensure unauthorized access does not compromise the integrity and confidentiality of personally identifiable information stored on the device or removable media.</i> | | | | | |
| STCF-1 | Can the device encrypt data at rest? | Yes | Data at rest is encrypted with AES 256-bit within the Butterfly IQ Android and iOS mobile app and on the AWS Butterfly Cloud. References: https://source.android.com/docs/security/features/encryption/file-based https://support.apple.com/ja-jp/security/data-protection-overview-spec626da8a/web https://docs.aws.amazon.com/whitepapers/latest/efs-encrypted-file-systems/encryption-of-data-at-rest.html | Section 5.17, STCF | SC-28 | A.8.2.3 |
| STCF-1.1 | Is all data encrypted or otherwise protected? | Yes | | | | |
| STCF-1.2 | Is the data encryption capability configured by default? | Yes | | | | |
| STCF-1.3 | Are instructions available to the customer to configure encryption? | No | | | | |
| STCF-2 | Can the encryption keys be changed or configured? | No | Encryption keys are managed by AWS. AWS KMS (Key Management Services) are tightly integrated with the AWS product portfolio to provide leading security controls, auditability, management and compliance for encryption keys. The service uses FIPS 140-2 validated hardware security modules (HSMs) to protect the confidentiality and integrity of the keys. TLS certificates expire every 90 days and are rotated before-hand. No Butterfly employees can access them directly by any means. Encryption keys are customer-specific for Butterfly Cloud-to-Customer network communications. | Section 5.17, STCF | SC-28 | A.8.2.3 |
| STCF-3 | Is the data stored in a database located on the device? | No | | | | |
| STCF-4 | Is the data stored in a database external to the device? | Yes | Butterfly Cloud | | | |

| Question ID | TRANSMISSION CONFIDENTIALITY (TXCF) | Response | Comment | IEC TR 80001-2-2:2012 | NIST SP 800-53 Rev. 4 | ISO 27002:2013 |
|-------------|--|----------|---|-----------------------|-----------------------|----------------|
| | <i>The ability of the device to ensure the confidentiality of transmitted personally identifiable information.</i> | | | | | |
| TXCF-1 | Can personally identifiable information be transmitted only via a point-to-point dedicated cable? | No | | | Section 5.18, TXCF | CM-7 |
| TXCF-2 | Is personally identifiable information encrypted prior to transmission via a network or removable media? | Yes | Data is transmitted to the Butterfly Cloud using HTTPS with TLSv1.2 and v1.3. Further, the TLSv1.2 and v1.3 ciphers supported by these endpoints are industry-recommended ciphers such as ChaCha stream cipher and Poly1305 authenticator (CHACHA20 POLY1305) | Section 5.18, TXCF | CM-7 | A.12.5.1 |
| TXCF-2.1 | If data is not encrypted by default, can the customer configure encryption options? | N/A | Data is encrypted by default. | | | |
| TXCF-3 | Is personally identifiable information transmission restricted to a fixed list of network destinations? | Yes | Butterfly IQ mobile app will only connect with the Butterfly Cloud. Additionally, the Butterfly Cloud can be pre-configured to send to hospital end points like PACS/VNA/EHR. | Section 5.18, TXCF | CM-7 | A.12.5.1 |
| TXCF-4 | Are connections limited to authenticated systems? | Yes | | Section 5.18, TXCF | CM-7 | A.12.5.1 |
| TXCF-5 | Are secure transmission methods supported/implemented (DICOM, HL7, IEEE 11073)? | Yes | Data is transmitted to the Butterfly Cloud using HTTPS with TLSv1.2 and v1.3. Further, the TLSv1.2 and v1.3 ciphers supported by these endpoints are industry-recommended ciphers such as ChaCha stream cipher and Poly1305 authenticator (CHACHA20 POLY1305). Additional transmission modes include DICOM-TLS and HL7. | | | |

| Question ID | TRANSMISSION INTEGRITY (TXIG) | Response | Comment | IEC TR 80001-2-2:2012 | NIST SP 800-53 Rev. 4 | ISO 27002:2013 |
|-------------|---|----------|---------|-----------------------|-----------------------|----------------|
| | <i>The ability of the device to ensure the integrity of transmitted data.</i> | | | | | |

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| TXIG-1 | Does the device support any mechanism (e.g., digital signatures) intended to ensure data is not modified during transmission? | Yes | Data is transmitted to the Butterfly Cloud using HTTPS with TLSv1.2 and v1.3. Further, the TLSv1.2 and v1.3 ciphers supported by these endpoints are industry-recommended ciphers such as ChaCha stream cipher and Poly1305 authenticator (CHACHA20 POLY1305) | Section 5.19, TXIG | SC-8 | A.8.2.3, A.13.1.1, A.13.2.1, A.13.2.3, A.14.1.2, A.14.1.3 |
| TXIG-2 | Does the device include multiple sub-components connected by external cables? | No | | | | |
| Question ID | REMOTE SERVICE (RMOT) <i>Remote service refers to all kinds of device maintenance activities performed by a service person via network or other remote connection.</i> | Response | Comment | IEC TR 80001-2-2:2012 | NIST SP 800-53 Rev. 4 | ISO 27002:2013 |
| RMOT-1 | Does the device permit remote service connections for device analysis or repair? | No | | | AC-17 | A.6.2.1, A.6.2.2, A.13.1.1, A.13.2.1, A.14.1.2 |
| RMOT-1.1 | Does the device allow the owner/operator to initiate remote service sessions for device analysis or repair? | No | | | | |
| RMOT-1.2 | Is there an indicator for an enabled and active remote session? | N/A | | | | |
| RMOT-1.3 | Can patient data be accessed or viewed from the device during the remote session? | N/A | | | AC-17 | A.6.2.1, A.6.2.2, A.13.1.1, A.13.2.1, A.14.1.2 |
| RMOT-2 | Does the device permit or use remote service connections for predictive maintenance data? | No | | | | |
| RMOT-3 | Does the device have any other remotely accessible functionality (e.g. software updates, remote training)? | No | | | | |