

Equipment Maintenance and Repair Service and Security Addendum

As part of the Terms and Conditions for Services Purchased this Equipment Maintenance and Repair Service and Security Addendum (this "Addendum") is hereby attached and incorporated herein.

A. Maintenance and Repair Service Requirements

The Contractor shall be responsible for adhering to the following requirements for maintenance and repair services provided under this Addendum.

1. Preventive Maintenance

- a. Preventive maintenance services shall be completed according to Joint Commission standards. A timetable of acceptable intervals has been provided in Table A below.

Table A: Preventive Maintenance Intervals

| Maintenance Frequency | Maintenance Window |
|-------------------------------|---|
| 3 years/36 months | Scheduled Maintenance Month +/- 45 days |
| Annual /12 month interval | Scheduled Maintenance Month +/- 30 days |
| Biannual/ 6 month interval | Scheduled Maintenance Month +/- 20 days |
| Quarterly/ Every three months | Scheduled Maintenance Month +/- 10 days |
| Weekly/Once per calendar week | Scheduled Maintenance week |

- b. St. Jude requires preventive maintenance schedules to follow manufacturer frequency requirements. The Contractor must comply with the manufacturer frequency for preventive maintenance service as a minimum requirement of the Agreement.
- c. The Contractor must provide preventive maintenance documents describing the actions required and the frequency of the actions to Biomedical Engineering through emailed documentation to bmeadministration@stjude.org.
- d. The Contractor must provide field service reports detailing services provided, parts exchanged, and Contractor personnel providing services on medical devices covered under the Agreement.
 - i. Field service reports must be sent to Biomedical Engineering through emailed documentation within ten (10) business days of services rendered. Documentation must be emailed to bmeadministration@stjude.org.

2. Repair Services

The Contractor is responsible for all required repairs to devices covered under the Agreement. A repair service will be required under the following conditions:

- a) Device issues reported by the end user relative to system output changes that directly affect the end user's ability to provide diagnosis or care to a patient, determine an outcome, document a result, or collect, store, or transfer data values.
- b) A device covered under this agreement is deemed unsafe for use due to evaluated physical failures or failure of internal parts.
- c) A device does not pass preventive maintenance inspection and requires corrective action resulting in parts or software replacements.

Repair services rendered under the Agreement must adhere to the following requirements:

- a) The Contractor must provide field service reports detailing services provided, parts exchanged, and Contractor personnel providing services on medical devices covered under the service agreement.

- aa. Field service reports must be sent to Biomedical Engineering through emailed documentation within ten (10) business days of services rendered. Documentation must be emailed to bmeadministration@stjude.org
- b) Field service personnel providing repair/maintenance services must provide certification of training demonstrating competence to service the equipment covered under the agreement.
 - aa. In order to satisfy this requirement, the Contractor can provide certifications or written documentation for service personnel competence to bmeadministration@stjude.org.
- c) Test equipment used in the repair, maintenance, or calibration of equipment covered under this agreement must be certified and maintained by the Contractor.
 - aa. Documentation of test equipment calibration and annual certifications must be provided to Biomedical Engineering at bmeadministration@stjude.org.
- d) Parts exchanged or repaired on medical devices covered under the service agreement must comply with parts recommended or purchased from the original equipment manufacturer.
 - aa. If the Contractor will be using parts not purchased from the original equipment manufacturer or a certified distributor, the Contractor must provide written documentation certifying the equivalence of the parts provided to the parts required by the original equipment manufacturer.
- e) If the Contractor determines that the medical equipment must be removed for offsite repair or maintenance, St. Jude must be informed prior to equipment removal. All data or configuration files specific to the institution must be removed from the device prior to offsite services.

B. Medical Device Information Security Service Guidelines

The following guidelines are applicable to services provided to medical devices during installation, maintenance, repair, and training as provided to St. Jude.

In accordance with the Agreement established, the Contractor shall consent to the following terms and conditions for reasonable conduct during services rendered to medical equipment:

1. The Contractor shall provide a detailed list of personnel providing services to medical equipment at St. Jude no later than thirty (30) days after notice of contract award or contract execution.
 - a. The Contractor shall agree to provide updates to the personnel authorization list as individuals are removed, added, or upon request of the medical facility.
 - b. The Contractor shall provide certification either through written notice or training certificates that the personnel providing services have completed courses covering the Health Insurance Portability and Accountability Act (HIPPA) and Information Security.
 - c. The Contractor shall not grant access to any company personnel not listed in the authorized users list provided to St. Jude. Any updates should be sent to bmeadministration@stjude.org
2. The Contractor shall only access systems, software, databases, and data which are authorized within the terms of the contract.
3. The Contractor shall not use non-St. Jude owned equipment with the purpose of storing, transferring, or processing PHI or PII.
4. The Contractor shall provide documentation of the most current antivirus scans and updates for any devices, expressly service laptops and removable media, not owned by St. Jude requiring connection in order to complete services.
5. The Contractor shall not use authorized access to override or disable security, technical, or management controls of medical devices or medical systems.
6. The Contractor shall not create/change device or system level passwords without written consent from St. Jude's BME department.
7. The Contractor shall not run, host, or setup an internet browser related to the access of medical systems or information systems covered under the Agreement.

8. The Contractor shall not connect to the St. Jude medical device network and an external network at the same time during service.
9. The Contractor shall only use antivirus, antispyware, and firewall intrusion protection software that has been authorized by St. Jude.
10. The Contractor shall not disable/degrade installed antivirus, antispyware, and firewall intrusion protection software of devices or systems expressly covered under the contractual agreement.
11. The Contractor shall preschedule the use, deployment, or application of patching services to software housed on equipment under the ownership of St. Jude as expressly covered under this Addendum.
12. If the Contractor determines that medical equipment must be removed for offsite repair or maintenance, St. Jude must be informed prior to equipment removal. All data or configuration files specific to St. Jude must be removed from the device prior to offsite services.
13. If the medical device connects with a dedicated workstation, tablet, or mobile device, the attached equipment must adhere to the St. Jude Information Security Addendum. All attached devices must be considered in patching and update actions performed by the Contractor.

C. Medical Device Patching and Software Update Requirements

The following medical device patching and software update requirements apply to medical equipment covered under the Agreement.

1. The Contractor is responsible for furnishing and applying software updates related to the operating system, application software, database software, and antivirus software of medical equipment covered under the service agreement as applicable.
 - a. Patching and updates shall be provided on a routine basis.
 - b. Patching and updates must be vetted by the original equipment manufacturer as compatible before application.
 - c. The Contractor shall provide a schedule to St. Jude detailing patch and update release dates. Application of patches and updates will be scheduled with St. Jude to minimize impact to clinical services.
2. The Contractor shall be responsible for the mitigation and response to vulnerabilities discovered on medical devices covered under this agreement.
 - a. Vulnerabilities may be reported through recalls, customer reported events, customer vulnerability scans, or notifications from the manufacturer related to voluntary disclosure.
 - b. Any actions taken by the Contractor to mitigate vulnerabilities must be certified by the system manufacturer as applicable and must not degrade the functions of the medical equipment.
3. All documentation related to device patching and software update actions must be submitted to Biomedical Engineering for review and approval prior to implementation at bmeadministration@stjude.org.