(September 2021)

PERFORMANCE CRITERIA
FOR

SECTION 27 52 13

PATIENT MONITORING AND TELEMETRY SYSTEM
09/21

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GENERAL
This Performance Criteria specifies the requirements for point of care systems.

1.1 REFERENCE

1.1.1 Unified Facilities Criteria (UFC)
Contractor must comply with the following:
- **A.** UFC 1-200-01 General Building Requirements
- **B.** UFC 1-200-02 High Performance and Sustainable Building Requirements
- **C.** UFC 3-120-10 Interior Design
- **D.** UFC 3-501-01 Electrical Engineering
- **E.** UFC 3-580-01 Telecom Building Cabling Systems Planning and Design
- **F.** UFC 4-010-06 Cybersecurity
- **G.** UFC 4-510-01 Military Medical Facilities

1.1.2 Military Standard
- **A.** MIL-STD 1691 Construction and Material Schedule for Medical, Dental, Veterinary and Medical Research Laboratories.

1.1.3 National Fire Protection Association (NFPA)
- **A.** NFPA 99 Healthcare Facilities Code

1.1.4 Military Health System Standards
- **A.** Reserved for future

1.1.5 Underwriters Laboratories (UL)
- **A.** UL 60601-1 Medical and Electrical Equipment, Part 1: General Requirements for Safety

1.1.6 International Electrotechnical Commission (IEC)
- **A.** IEC 60601 Medical Electrical Equipment and Systems

1.1.7 Food and Drug Administration

A. CFR Title 21, Chapter I

1.1.8 Defense Health Agency Standards

A. Building Control Systems Categorization Memorandum
B. Cyber Security Controls for Physically Isolated Systems
C. Cyber Security Controls for Medical Community of Interest (MEDCOI)

1.1.9 Department of Defense Standards

A. Department of Defense Instruction (DoDI) Number 8500.01
B. Department of Defense Instruction (DoDI) Number 8510.01
C. Department of Defense Instruction (DoDI) Number 8530.01

1.1.10 National Institute of Standards and Technology

A. NTEP Certificate of Conformance
B. NIST Handbook 44

1.1.11 Federal Communications Commission (FCC)

A. FCC Approved RF Communicating Device

1.1.12 Other Standards

A. Reserved for future

2.1 DESCRIPTION & MATERIALS

All requirements within the MIL-STD 1691 JSN descriptions must be met as well as the performance guidelines listed in the following descriptions.

2.1.1 General

A. Paints & finishes will be selected from the manufacturers' standard options for the specified model unless noted otherwise.
B. All product finishes must be capable of maintaining sheen and color through warranty period when using industry standard cleaning and disinfection solutions.
C. All display panel surfaces must maintain clarity through warranty period when using industry standard cleaning and disinfection solutions.
D. Electrified equipment must be UL listed and capable of 110/240 volts, 50/60 Hz, Autosensing, unless noted otherwise.
E. Provide cabling and other balance of system components in accordance with the manufacturer's recommendations and UFGS 27 10 00 – Building Telecommunications Cabling System.
F. System must not have an anticipated end of system support in the next 24 months. Systems being phased out are not acceptable.
G. All products that have interoperability capable hardware (i.e. internal storage, data transmission via wireless, Ethernet, LAN, or USB to PC or server connectivity) must meet Cybersecurity requirements in accordance with DoDI 8510.01 Risk Management Framework.
H. DoDI 8510.01 applies to all DoD IT (medical devices included) that receive, process, store, display, or transmit DoD information. These technologies are broadly grouped as DoD IS, platform IT (PIT), IT services, and IT products. This includes IT supporting research, development, test and evaluation (T&E), and DoD-controlled IT operated by a contractor or other entity on behalf of the DoD solutions.
I. System is required to interface and send data to the DoD approved Electronic Health Record (EHR).

2.1.2 Patient Monitoring and Telemetry

M4880 – Telemetry System, ECG, Ambulatory, Multi-Channel
M7806 – Telemetry System, ECG
M7807 – Monitor, 4 Channels, Telemetry, Bedside
M7818 – Monitor, Transport
M7820 – Monitor, Fetal, Bedside/Stand Alone
M7825 – Monitor, Central System, Fetal
M7845 – Monitor, Physiological, Bedside, 4 Channel

M7850 – Monitor, Physiological, Central, 8 Bed, Color
M7855 – Monitor, Physiological, Infant
M7865 – Monitor, Physiologic, Respiratory Gas
M7900 – Monitor, Anesthesia/Respiratory Gas
M7925 – Monitor, Blood Parameter

A. Display to be LED/LCD high contrast with continuous display of patient parameters. Display text must be readable in any ambient light level.
1. User configurable with up to eight (8) [___] pre-configured views, including split-screen views with real-time patient information.
2. Views configured based on care areas, patient, acuity, and environment.
3. Central Station to be comprised of two (2) [___] displays providing remote viewing of patient displays and alarms.
4. [Minimum [17 in.] [20 in.] [___] secondary display adjacent to central station with 250ms maximum display delay, connected via DVI-I.]

B. Patient parameters will include [ECG], [respiration and heart rates], [invasive/ non-invasive blood pressure], [body temperature and SpO2].
1. High resolution trends with 2-second viewing for beat-to-beat evaluation of bradycardia and apnea events, with Arrhythmia monitoring of up to 12-leads.
2. Scalable and interchangeable modules for specific monitoring needs.
3. [Wireless] [Hardwired] connectivity between patient monitor display and monitoring leads.
4. Operating temperature: [32° to 104° F (0° to 40° C)[[___].
5. Provides up to 96 hours of trends, with data resolution 30-second sampling.
6. Event storage to be provided for up to 150 events, 20-second strips, and all waveforms.

C. Central Station must be located at the Central Nurse Station within the main and secondary patient care areas, to be comprised of central workstation, display(s), and printer.
1. Central Station to provide historical data viewable for up to six (6) days post-discharge.
2. Provides up to 96 hours of trends, with data resolution 30-second sampling.
3. Event storage to be provided for up to 150 events, 20-second strips, and all waveforms, per patient station.
4. Central Station Printer connected [wirelessly] [hardwired] to Central Station.

D. Alarm notifications must have options using visual or auditory or both.

E. Unit to be table-top, wall mounted, or mobile. Mobile to be mounted on included mobile cart or trolley supplied by the manufacturer. Unit must have optional accessory brackets available for wall mounting.

F. Construction to be free of sharp edges, resistant to corrosion, and splash proof. External parts will allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or sterilizable if being reused.

G. Hardware to include wireless, Ethernet, and USB to PC connectivity for data transmission with connection/interface to EMR/EHR.
1. Hardwired data connections to be provided via Cat [5e] [6] [6a] cabling per UFGS 26 20 00 Interior Distribution System.
2. Mobile Telemetry requires a separate wireless LAN with connectivity to various departments within the facility (includes but not limited to Emergency Department, OR, Patient Rooms, etc.) Conduit, cabling, and WAPS will need to be installed by vendor to support system.

H. Power to be provided through battery during transportation. Include battery backup switch and low battery alert in case of power loss.

I. Provide documentation for each display, central station, monitoring equipment and leads which can be stored and accessed.

3.1 SUBMITTALS

3.1.1 Submittals required for government review

A. Submittal requirements are outlined in [Division 01] [PWS SOW] [___]

B. [Product Information must include manufacturer's installation instructions, sizing (including required clearance for access and maintenance), utility requirements, isometric drawings, tagged floorplans showing placement for count accountability and accessories/options/consumables lists.]

C. All submittals require Government approval prior to procurement. Submit all listed items herein, with information sufficient to show full compliance with the criteria. Submit all product selections for review and approval, including

but not limited to: materials, finishes, colors, options, accessories, and complimentary products. Provide for review all warranties and service contracts and any available extended warranty or service options.

D. Samples: Furnish material samples and full range of color selection options for all items that offer material and color selections.

E. Submit and highlight all applicable options for Government review for all items which optional accessories are provided.

F. [Joint Interoperability Test Command (JTIC) Approval Documentation.]

3.2 QUALITY ASSURANCE

3.2.1 Materials and Equipment

A. Materials and equipment must be standard products of a manufacturer regularly engaged in the manufacture of products which are of a similar material, design, and workmanship and are offered for sale on the commercial market through advertisements, manufacturer's catalogs, or sales brochures. The products must have been in commercial or industrial use under similar circumstances and of similar size for 2 years prior to selection for approval/procurement. Products must be supportable for at least three years after government acceptance.

3.2.2 Alternative Service Record

A. Products having less than a 2-year field service record will be acceptable if a certified record of the manufacturer's factory or laboratory tests demonstrating performance compliance is provided to the Contracting Officer.

3.2.3 Service Support

A. Equipment items must be supported by service organizations located near the equipment installation, able to service the equipment on a regular basis and respond to emergency calls throughout the warranty period.

3.2.4 Manufacturer's Nameplate

A. Each item of equipment must have an attached nameplate that is securely affixed in a conspicuous space. A nameplate listing only the name of the distributing agent is not acceptable. The nameplate must contain the following fields in English:

1. Manufacturer’s name and address
2. Model and Serial Number
3. Item’s utility ranges and/or capacities
4. Voltage, amperage, and applicable Underwriters Laboratory (UL) or Conformitè Europëenne (CE) rating if electrically powered
5. Date of manufacture

3.2.5 Factory Inspection

A. Arrange and perform all quality control and quality assurance inspections required by the technical sections of the criteria, unless otherwise specified. Report these inspections in the daily report to the Government inspector.

3.2.6 Product Qualifications

A. The products specified in the technical sections of this criteria establish standards for each item.

3.2.7 Design Parameters

A. It is not the intention of this Criteria to limit consideration to products of specific manufacturers. The product standards establish the characteristics for which submitted items of equipment will be reviewed and approved by the Government. Equipment furnished must meet each of the following parameters specified in the technical sections:

1. Size of equipment
2. Function of equipment
3. Standard and listed accessories and options
4. Equipment controls and performance of equipment
5. Construction of equipment
6. Finish

3.3 STANDARDS DEVIATIONS

3.3.1 Reporting and Submission for Approval

A. Submit for approval a record of deviations from the standards listed in section (3.2.7.A.) established for each specified product, before ordering equipment.

3.4 DELIVERY, STORAGE AND PROTECTION

3.4.1 Packaging and Transporting

A. Each unit of equipment must be placed in a substantial shipping container or crate for safe transportation to final destination. The shipping container or crate for heavy equipment must be on skid construction to facilitate handling by lift equipment.

3.4.2 Packing List

A. Clearly and legibly indicate on exterior of each container or crate the shipping address and a brief description of contents. Fasten to outside of container a packing list and complete instructions for uncrating equipment and setting it in place. Protect such information in a weatherproof envelope.

3.4.3 Protection

A. Properly protect all materials and equipment from injury and damage during storage, installation, and acceptance.

3.5 INSTALLATION, VERIFICATION AND ACCEPTANCE TESTING

3.5.1 Qualifications of Installers and Inspectors

A. If required by product warranty, use installers that are approved and licensed by the manufacturer. When required to complete installation, all electricians and plumbers used must be bonded and licensed in the project's jurisdiction.

B. [Company specializing in installing the products specified in this section must have a minimum 5 years of documented experience.]

C. [Company specializing in installing the products specified in this section must be within 200 miles or 4 hours travel time.]

3.5.2 Installation, Operation, Testing and Certification

A. Products must be delivered in manufacturer's original packaging with manufacturer's installation instructions. Include clearly marked project reference.

B. Prior to installation, thoroughly examine the equipment, materials, and components for both visual defects and conformance with criteria.

C. Install all equipment in compliance with manufacturer's written instructions and installation procedures.

D. After installation, the equipment must be inspected and tested under operating conditions. If the equipment fails an inspection or test, such defects/failures must be corrected. Upon correction of defects/failures, inspect and retest all affected functions related directly and indirectly to the defect or failure. Corrections, replacement, and retesting must be made at no additional expense to the Government.

E. Provide all items necessary to make equipment fully functional.

F. Provide appropriately trained personnel to energize, commission, inspect, electrical safety check, calibrate, certify, and provide all required technical testing for equipment and systems. Contractor must provide documentation, test reports and certification documentation attesting that the equipment is properly installed, functional, safe, calibrated, and ready for its intended use.

G. An equipment item will be considered defective if it cannot be made to meet all established criteria consistent with the activities listed in section (F).

H. Provide two sets of special tools, software, and any other item/s for each equipment [item] [item type] if required for maintenance and/or future reconfiguration of the item.

I. Contractor to supply all start-up supplies for medical equipment for a fully operational installation. Contractor must supply to the Government a listing of all needed supplies for ongoing equipment operation for each item of equipment requiring additional supplies for operation.

J. Engage a factory-authorized service representative to train Government's staff and maintenance personnel to adjust, operate, and maintain medical equipment.

K. [Confirm functionality of required interfaces to other systems and networks.]

3.6 WARRANTY

3.6.1 Minimum Requirements

A. Warranty requirements are outlined in [Division 01] [PWS SOW] [___].

B. [Provide manufacturer's written warranty for all items listed. Provide warranty for a minimum of (1) year against defects in materials and workmanship. Warranty must provide for material, labor and all associated replacement and/or repair costs required to provide for a fully operational equipment replacement or repair. Submit manufacturers and installers standard service contract beyond the warranty period for Government review. Warranty must be transferrable to the final owner without risk of being voided. All warranty certification and documentation must be provided to the final owner after date of acceptance.]

C. Provide routine warranty service in accordance with manufacturer's warranty requirements, for a period of [12 months (minimum)] [___] after the open for business date. Perform work during regular working hours. Perform service only by factory trained personnel. Maintain a maintenance log of all service orders performed during the warranty period.

3.7 OPERATIONS AND MAINTENANCE (O & M)

3.7.1 Provide the following to the final owner

A. Provide O & M data for all FFE-LVS as outlined in [Division 01] [PWS SOW] [___].

B. Upon completion of equipment installation, furnish [two (2)] copies of operators/service/maintenance manuals for each type of equipment which will require service or maintenance

C. Each manual must contain operating instructions and information required for performing periodic maintenance on the equipment. Each service manual must include an illustrated parts breakdown which identifies each part of the unit with manufacturer's part number, wiring diagrams, and a list of necessary service parts, tools, and equipment needed to support maintenance requirements.

D. Accessory Catalogs: Upon completion of the Project, furnish two copies of the manufacturer's catalogs containing optional accessory items available for all equipment relative to the procured equipment/system delivered herein.

E. Provide instruction video for cleaning and maintenance, when available.

F. Provide cleaning requirements for all items to prevent void of warranty.

G. [Provide contact information for Repair Technician or Emergency Repair Company]

H. Provide contact information to [Logistics, Pharmacy, Laboratory, and Biomedical Equipment Services.]

I. Train designated staff in the operation and maintenance of the provided equipment/system. Provide two training sessions for equipment/system users and two training sessions for maintenance personnel scheduled to accommodate shift work. [Provide training certificates that can be executed up to eleven months after the system is installed, in order to provide a refresher course for each group of trainees.] Provide DVD copy of the training with the O & M data.

--End of Section--