(September 2021)

PERFORMANCE CRITERIA
FOR

SECTION 11 72 13

EXAMINATION EQUIPMENT
09/21

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GENERAL
This Performance Criteria specifies the requirements for examination equipment.

[This section includes healthcare equipment in primarily outpatient settings. Refer to section 11 73 00 PATIENT CARE EQUIPMENT for healthcare equipment in primarily inpatient settings.]

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 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
- **B.** NFPA 101 Life Safety Code
- **C.** NFPA 260 Standard Methods of Tests and Classification System for Cigarette Ignition Resistance of Components of Upholstered Furniture
- **D.** NFPA 701 Standard Methods of Fire Tests for Flame Propagation of Textiles and Films

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

1.1.5 American Society for Testing and Materials (ASTM)
- **A.** ASTM 2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

B. ASTM E84 Standard Test Method for Surface Burning Characteristics of Building Materials

1.1.6 American National Standards Institute (ANSI)

A. ANSI S3.22 Specification of Hearing Aid Characteristics
B. ANSI S3.6 Specification for Audiometers
C. ANSI/AAMI EC11 Diagnostic Electrocardiographic Devices

1.1.7 Underwriters Laboratories (UL)

A. UL 60601-1 Medical and Electrical Equipment, Part 1: General Requirements for Safety

1.1.8 International Electrotechnical Commission (IEC)

A. IEC 60645-1 Electroacoustics – Audiometric Equipment – Part 1: Equipment for Pure Tone Audiometry
B. IEC 60601 Medical Electrical Equipment and Systems]

1.1.9 Food and Drug Administration

A. CFR Title 21, Chapter I

1.1.10 Occupational Safety and Health (OSHA)

A. OSHA 1910

1.1.11 Business & Institutional Furniture Manufacturers Association (BIFMA)

A. ANSI/BIFMA x5.6 - Panel Systems

1.1.12 International Organization for Standardization (ISO)

A. ISO 13485 Quality Management system for Medical Devices
B. ISO 26782 Anesthetic and Respiratory Equipment - Spirometers
C. ISO 23747 Anesthetic and Respiratory Equipment – Peak flow meters

1.1.13 Specialty Steel Industry of North America (SSINA)

A. Specifications for Stainless Steel - Designer Handbook
B. The Care and Cleaning of Stainless Steel - Designer Handbook

1.1.14 European Union (EU)

A. MDD 93/42/EEC Medical Devices Directive

1.1.15 American Thoracic and European Respiratory Societies

A. ATS/ERS Standards

1.1.16 American Academy of Sleep Medicine

A. AASM PSG Guidelines

1.1.17 Other Standards

A. CAL-117 (California Technical Bulletin 117-2013)
B. 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 here.

2.1.1 All JSN'S

A. Paints, fabrics, and finishes must be selected from the manufacturer's 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. All equipment that have components that are meant for reuse must be autoclavable or able to withstand industry standard cleaning and disinfection processes.
E. Electrified equipment must be UL listed and capable of 110-240 volts, 50/60 Hz, Autosensing, unless otherwise noted.
F. Casters provided must be designed for use on the installed floor finish.
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.

2.1.2 Audiology (Diagnostic)

A. Analyzers

M0015 – Tympanograph, w/X-Y Recorder
M0020 – Hearing Aid Analyzer
M0035 – Analyzer, Auditory, Evoked Potential
M0036 – Inner Ear (Cochlear) Analyzer, Screen

1. Display must be LCD/LED high contrast with continuous display of patient parameters. Display text must be readable in any ambient light level.
2. Hardware to include wireless, Ethernet, or USB to PC connectivity for data transmission.
3. Refer to MIL STD 1691 descriptions for specific performance requirements in this category.

B. Testing and Screening

M0005 – Audiometer, Screening, Group
M0025 – Audiometer, Diagnostic, Middle Ear, Impedance
M0030 – Audiometer, Diagnostic
M0031 – Screening Device, Newborn Hearing
M0040 – Booth, Audio, Single Wall, 1 Person

1. Display must be LCD/LED high contrast with continuous display of patient parameters. Display text must be readable in any ambient light level.
2. Hardware to include wireless, Ethernet, or USB to PC connectivity for data transmission.
3. Refer to MIL STD 1691 descriptions for specific performance requirements in this category.

2.1.3 Cardiology (Diagnostic)

M7705 – Electrocardiograph, 3 Channel Display/Printout
M7710 – Electrocardiograph, 12 Lead, Portable
M7715 – Electrocardiograph, Portable, Single Channel
M7735 – Recorder, ECG, Long Term, Portable, w/Case
M7740 – Recorder, Blood Pressure, Long Term, Portable
M7760 – Electrocardiograph, 3 Channel, CAPOC Compatible
M7770 – Computer, Holter Monitor Analysis System

A. Display msut be LCD/LED high contrast with continuous display of patient parameters. Display text must be readable in any ambient light level.
B. Alarm notification must have options using visual or auditory or both.
C. All patient connectors must be readily cleanable, reusable, and designed for attachment to disposable patient patches
D. Unit must be mounted on an included mobile cart or trolley supplied by the manufacturer. Unit must have optional accessory brackets available for wall mounting.
E. External parts must allow for disassembly for thorough cleaning and disinfection. All components contacting patient must be disposable.
F. Printer must be included integrated within unit or as separate standalone printer.
G. Hardware to include internal storage as well as expandable external storage of patient records and wireless, Ethernet, or USB to PC connectivity for data transmission options.

2.1.4 Cardiopulmonary (Diagnostic)

M0715 – Pulmonary Function Analyzer, Portable
M0720 – Analyzer, Pulmonary Function, w/Computer
M0730 – Cart, Metabolic

A. Display must be LCD/LED high contrast with continuous display of patient parameters. Display text must be readable in any ambient light level.
B. All patient connectors must be readily cleanable, reusable, and designed for attachment to disposable patient patches.
C. Unit must be mounted on an included mobile cart or trolley supplied by the manufacturer. Unit must have optional accessory brackets available for wall mounting.
D. External parts must allow for disassembly for thorough cleaning and disinfection. All components contacting patient must be disposable. Glass must be tempered security glass and metal parts must be aluminum alloy or similar.
E. Printer must be included integrated within unit or as separate standalone printer.
F. Hardware to include internal storage as well as expandable external storage of patient records and wireless, Ethernet, or USB to PC connectivity for data transmission options. Provide ability to interface with other PFT, CPET, nutrition, and sleep software systems.

2.1.5 Cardiopulmonary Spirometry (Diagnostic)

M0700 – Spirometer, Diagnostic
M0705 – Spirometer, Monitoring, Handheld
M0710 – Spirometer, Therapeutic

A. Display must be LCD/LED high contrast with continuous display of patient parameters. Display text must be readable in any ambient light level.
B. Mouthpieces must accept disposable mouthpieces in both adult and pediatric sizes. Reusable mouthpieces are acceptable if autoclavable for disinfection.
C. Unit must be tabletop style. Unit can be mobile and mounted on an included mobile cart or trolley supplied by the manufacturer.
D. External parts must allow for disassembly for thorough cleaning and disinfection. All components contacting patient must be disposable.
E. Printer must be integrated within unit or as separate standalone printer.
F. Hardware to include internal storage as well as expandable external storage of patient records and wireless, Ethernet, or USB to PC connectivity for data transmission options.

2.1.6 Gastro-Intestinal (Diagnostic)

M8665 – Analyzer, Hydrogen, Breath

A. Unit must be tabletop style. Unit can be mobile and mounted on an included mobile cart or trolley supplied by the manufacturer.
B. External parts must allow for disassembly for thorough cleaning and disinfection. All components contacting patient must be disposable.

2.1.7 Neurology (Diagnostic)

M7723 – Electroencephalograph, 32 Channel
M7725 – Electromyograph
M7730 – Electronystagmography w/Accessories
M7750 – Recorder, Sleep Study System, w/Pan Zoom Camera

A. Display must be LCD/LED high contrast with continuous display of patient parameters. Display text must be readable in any ambient light level.
B. Unit must be tabletop style. Unit can be mobile and mounted on an included mobile cart or trolley supplied by the manufacturer.
C. External parts must allow for disassembly for thorough cleaning and disinfection. All components contacting patient must be disposable.
D. Hardware to include internal storage as well as expandable external storage of patient records and wireless, Ethernet, or USB to PC connectivity for data transmission options.

2.1.8 Vascular (Diagnostic)

M0520 – Plethysmograph System, Vascular

A. Display must be LCD/LED high contrast with continuous display of patient parameters. Display text must be

readable in any ambient light level.

B. Unit can be portable or tabletop with options for mounting on IV stand, bed or cart.

C. External parts must allow for disassembly for thorough cleaning and disinfection. All components contacting patient may be disposable or easily disinfected if being reused.

D. Printer must be integrated within unit or as separate standalone printer with USB.

E. Hardware to include wireless, Ethernet, or USB to PC connectivity for data transmission.

M4105 – Stethoscope, Doppler

A. Display must be LCD/LED high contrast with continuous display of patient parameters. Display text must be readable in any ambient light level.

B. Unit must be portable [or tabletop] with options for mounting on IV stand, bed or cart.

C. Must have a built-in loudspeaker and output for headset or audio recording device.

D. Must have the ability to interchange probes.

2.1.9 Commode Chair (Support)

M4801 – Commode Chair

A. Must have a minimum tested weight capacity of 350 lbs [159 kg].

B. Frame must be aluminum or enamel/powder coated steel.

C. Seat height must be adjustable from 27 to 31 inches [69 to 79 cm].

D. Construction must be free of seams, resistant to corrosion, and allow for thorough cleaning and disinfection.

2.1.10 MRI Compatible (Support)

M4257 – Stand, IV, Adjustable, MRI Compatible

M8340 – Table, Utility, 3 Drawers w/Shelf, MRI Safe

M8827 – Table, Instrument, MRI Compatible

M8835 – Table, Utility 72" W, MRI Compatible

A. All materials must be non-ferrous and non-magnetic materials such as aluminum, stainless steel and plastic. Product must be labeled as safe for 3T MRI use in accordance to ASTM 2503.

B. Equipment must allow thorough cleaning and disinfection and be resistant to liquids.

2.1.11 Exam and Treatment Chairs & Tables (Treatment)

A. Manual Exam & Treatment Tables

M9020 – Table, Exam, Pediatric, With Scale

1. Must have a minimum weight capacity of 150 lbs [68 kg] at all adult tables.
2. Manually operated adjustable backrest must be provided.
3. Must have a retractable nonslip steel footstep.
4. Integral paper roll compartment must accept 21 x 3.5 inches [53 x 9 cm] standard roll size, 14 inch [36 cm] acceptable at pediatric tables.
5. At a minimum one convenience receptacle hospital grade 115 VAC, 5 amp must be provided.
6. Storage capacity within table base must be a minimum of 250 cu. in.
7. Stirrups multi positional, with lateral and length adjustment stowable within table.
8. A minimum of 2 inches [5.08 cm] of padding must be provided for patient's comfort.
9. Base must be 18 gauge steel with baked enamel, powder coat, or epoxy paint finish.
10. The optional accessories must be available:
    a). Exam light LED adjustable gooseneck with integral table mounting bracket.
    b). Patient assist rails in stainless or powder coated steel. Removable without tools.
    c). Accessory rails on both sides of table factory installed.
    d). Heated drawers.

B. Powered Exam & Treatment Chairs

M4910 – Chair, Exam, Vestibular

1. Must have a minimum weight capacity of 400 lbs [181 kg].
2. Powered lift, tilting, and footrest must be independently electronically controlled. With maximum 22 inch [56 cm] low access seating height.
3. At a minimum one convenience receptacle hospital grade 115 VAC, 5 amp must be provided.
4. A minimum of 2 inches [5.08 cm] of padding must be provided for patient's comfort.
5. Base must be [stainless steel] steel frame with baked enamel, powder coat, or epoxy paint finish.
6. The optional accessories must be available:

a). Integral paper roll compartment to accept 21" x 3.5" standard roll size.
b). Exam light LED adjustable gooseneck with integral table mounting bracket.
c). Hand and foot control capability.

C. Ultrasound Tables

M9005 – Table, Ultrasound, Mobile, General Purpose

M9006 – Table, Ultrasound, Mobile, Echocardiology

1. Table must have a minimum weight capacity of 500 lbs [227 kg].
2. Table must have a motorized height adjustment from 23 to 39 inches [58 to 99 cm] with open steel frame and individually locking wheels.
3. Must have an adjustable motorized tilt to the Fowler and Trendelenburg positions.
4. Must have an integral paper roll compartment to accept 21 x 3.5 inches [53 x 9 cm] standard roll size, 14 inch [36 cm] acceptable at pediatric tables.
5. Must have hand control of tables positioning.
6. Side rails, two patient restraints and arm board must be included.
7. A minimum of 2 inches [5.08 cm] of padding must be provided for patient's comfort.
8. Base must be [stainless steel] steel frame with baked enamel, powder coat, or epoxy paint finish.
9. The optional accessories must be available:
    a). Hand and foot control capability.
    b). Detachable IV Pole.
    c). Fluid containment.

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--