(September 2021)

PERFORMANCE CRITERIA

FOR

**SECTION 11 75 00**

**OPTICAL EQUIPMENT**

09/21

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**GENERAL**

This Performance Specificationspecifies the requirements for optical equipment.

**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 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

 **B.** FDA 86-8260 Compliance Guide for Laser Products

**1.1.8 Business & Institutional Furniture Manufacturers Association (BIFMA)**

**A.** BIFMA HCF 8.1 – Health Care Furniture Design – Guidelines for Cleanability

**B.** [BIFMA HCF 8.2 – Health Care Seating]

**1.1.9 Other Standards**

**A.** CAL-117 (California Technical Bulletin 117-2013)

**B.** Reserved for future

* 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 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 115 Volt 15 amp maximum unless noted otherwise.

**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 Optical Equipment (Diagnostic)**

 **A.** Vision Testing/Screening

 **M5500 – Autorefractor, Ophthalmic**

 **M5550 – Instrument, Ophthalmic, Multifunction**

1. Display must be LED/LCD high contrast with continued display of measured parameters readable in any ambient light level.

2. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.

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

4. Unit is a tabletop model consisting of a display monitor, adjustable chin rest/forehead rest, measuring head, height adjustable and joystick.

5. Features low contrast screening, accommodation testing and retro-illumination, visual acuity chart, subjective sphere refinement, multiple pupil zone imaging method, and Super Luminescent Diode (SLD).

6. Provide a fully automatic eye tracking system.

 **M5555 – Perimeter, Automated**

1. Display must be LED/LCD high contrast with continued display of measured parameters readable in any ambient light level.

2. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.

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

4. Unit has on screen display for rapid and accurate alignment of patient’s automatic pupil size measurement, seven different fixation aids, ergonomic chin rest, several threshold strategies, and high target intensity.

5. Must be able to detect visual field loss associated with the following ocular diseases: Cataract, glaucoma, myopia, optic nerve disease, diabetic retinopathy, corneal opacity, retinal vein occlusion, macular degeneration, vitreous opacity, epiretinal membrane, stroke, retinal detachment.

6. Must include age corrected test modes and blind spot monitor.

 **M5560 – Projector, Acuity w/Stand, Wall Mounted Screen**

 **M5561 – Tester, Visual Acuity, Cone Contrast**

 **M5562 – Tester, Visual Acuity, Video/Microprocessor Based**

 **M5570 – Armed Forces Vision Tester**

 **M5650 – Screener, Spot Vision, Pediatric**

1. Display must be LED/LCD high contrast with continued display of measured parameters readable in any ambient light level.

2. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.

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

4. Unit must include the following optotypes: Snellen Letters, Tumbling E, Landolt Rings, Numbers, HOTV, Crowding Bars, Children's charts, Red/Green Testing, ETDRs and Contrast Testing.

 **M5595 – Test Set, Vision, Worth Binocular**

1. 4-Dot flashlight with red/green glasses used for testing and training of fusion, suppression, and/or diplopia.

2. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.

 **M5599 – Phoropter**

 **M5600 – Unit, Exam, Eye, w/Motor Chair, Phoropter**

1. Display must be LED/LCD high contrast with continued display of measured parameters readable in any ambient light level.

2. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.

3. Chair upholstery fabric must be flame resistant, antistatic, impervious to fluids, and easily cleanable.

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

5. Unit has on screen display for rapid and accurate alignment of patient’s automatic pupil size measurement, seven different fixation aids, ergonomic chin rest, several threshold strategies, and high target intensity.

6. Unit must include multiple lenses, fully integrated Graphical User Interface (GUI), preconfigured workflows or individually configured. Compatible with Electronic Health Record (EHR).

7. Included with phoropter: +-.25 Flip Cylinder, +1.5 Retinoscopic lenses, face shields, reading rod with card holder.

 **M5705 – Gauge, Distance, Pupillary**

1. Display must be LED/LCD high contrast with continued display of measured parameters readable in any ambient light level.

2. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

3. Unit must be capable of measuring interpupillary distance and right/left pupil-to-nose distance.

 **M5710 – Mirror, Front Surface Reflector, Eye Exam**

1. Unit must include 12x12 inch framed mirror to display the Acuity System information to the patient in an eye exam/treatment room.

2. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

 **M5720 – Screen, Projection, Eye Exam**

1. Unit must include a screen, projector, and mirror to be used as a system for eye exam screening.

2. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

 **B.** Retinal Imaging

 **M5505 – Camera, Fundus, Flash, Automatic**

 **M5510 – Camera, Fundus, Digital**

 **M5551 – Tomography System, Optical Coherence (OCT)**

 **M5564 – Microscope, Specular**

 **M6045 – Corneal Topography Unit**

 **M6050 – Retinal Imaging System, Fluorescein/Indocyanine**

 **X2111 – Scanner System, Ophthalmic, Topographic**

1. Display must be LED/LCD high contrast with continued display of measured parameters readable in any ambient light level.

2. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.

3. Unit must consist of a digital imager, computer, monitor, chin rest, joystick and software to record, store, edit and print digital images

4. Unit must include digital filters Red free and Cobalt, Green and Red Channel.

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

 **C.** Lens Measurement

 **M5520 – Lensometer**

 **M5525 – Lensometer, Soft Contact**

 **M5565 – Radiuscope**

1. Display must be LED/LCD high contrast with continued display of measured parameters readable in any ambient light level.

2. Unit must include lamps, prism measuring lens marking device, cylinder axis wheel calibrated in two 180-degree segments and a green filter for tinted glass.

3. Unit must include inboard printer, UV Transmittance measurement, Green measurement Light Beam, Auto Focal Detection for singe and progressive lenses.

4. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.

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

 **D.** Corneal Testing/Measurement

 **M5530 – Lamp, Slit, w/Applanation Tonometer**

 **M5531 – Lamp, Slit, Photographic w/Tonometer**

1. The slit lamp is an ophthalmic instrument that emits a high intensity beam of light that can be focused and shined into the eye so that the interior (of the eye) can be examined.

2. The slit lamp must meet the following characteristics:

 a. Illumination Field Diameter: ø 8mm, 5mm, 3mm, 2mm, 1mm, 0.2mm.

 b. Slit Image rotatability: +/- 90°

 c. Swiveling of the slit illumination to the microscope axis: Horizontal +/- 90°, Vertical 0-20°

 d. Filters: Blue, red-free (green), grey (10%) and yellow

 e. Ocular magnification: 12.5x

 f. Stereo angle: 13° (convergent optics)

 g. Range adjusting eye pieces: +7 to – diopter

 h. Pupil distance: 52-78 mm

 i. Magnification changer: 6.3x, 10x, 16x, 25x, 40x

 j. Object field ø in mm: 32.0, 20.0, 12.7, 8.0, 5.1

 k. Zoom Capability: magnification can be continuously changed from 6 up to 40x

3. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.

 **M5535 – Ophthalmoscope, Binocular, Indirect**

1. Unit must consist of headband and crown, halogen quartz lamp or LED, multi-coated aspherical lenses, scleral depressor and mirror.

 2. Unit must include a control switch that regulates the illumination.

 **M5536 – Ophthalmoscope, Direct**

1. Unit must be a lightweight handheld instrument with rechargeable battery handle, mirror, forehead rest and lamp.

2. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

 **M5545 – Ophthalmoscope/Keratometer**

1. Unit must include a focusing system, engraved focusing scale, positive fixation for rapid measurements, center and peripheral corneal measurements scale with a range from 30D to 60D.

2. Unit must be capable of measuring corneal astigmatism.

3. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

 **M5574 – Biometer, IOL (Intra-Ocular Lens) Calculator**

1. The optical biometer must be able to function as a non-contact, optical low coherence reflectometer used for obtaining ocular measurements and preforming calculations to determine the correct power of an intraocular lens placed inside the eye after cataract surgery and the removal of the natural lens of the eye.

2. Must use built in IOL approved formulas for calculations of corneal measurement (for example: Barrett IOL).

3. Unit must deliver accurate axial length, lens thickness, and central corneal thickness information

3. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

 **M5575 – Tonometer, Noncontact**

1. Display must be LED/LCD high contrast with continued display of measured parameters readable in any ambient light level.

2. Unit must provide Intra Ocular Pressure (IOP) measurements used to determine the risk of glaucoma with a measurement range of 0-70 mmHg.

3. Unit must include the following features: continuous 360-degree streak rotation, external focusing sleeve, optics sealed within scope, and polarizing filter.

 **M5580 – Tonometer, Applanation**

1. Display must be LED/LCD high contrast with continued display of measured parameters readable in any ambient light level.

2. Unit must provide Intra Ocular Pressure (IOP) measurements used to determine the risk of glaucoma with a measurement range of 0-60 mmHg.

3. Unit must be capable of being used in conjunction with a slit lamp.

 **M5585 – Gonioscope, Lens, Contact**

1. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.

2. Unit must be capable of being used in conjunction with a slit lamp.

|  |
| --- |
| 3. Unit must provide 360-degree viewing of the anterior chamber.  |

 **M6040 – Pachymeter, Ultrasound, Corneal**

1. Unit must be a portable device capable of measuring corneal thickness accurately and quickly.

2. The item must have an LCD display to indicate the current measurement, average, and standard deviation of all measurements taken.

3. The item must measure in the range of 200 to 1100 microns, with an accuracy of +/- 5 microns and a resolution of 1 micron.

4. The item must provide audible feedback to indicate when each measurement is complete.

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

 **E.** Retinoscopy

 **M5605 – Retinoscope**

1. Unit must be a lightweight instrument with interchangeable heads, rechargeable battery handle, mirror, forehead rest and one lamp.

2. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.

3.Unit must include the following features; continuous 360-degree streak rotation, external focusing sleeve, optics sealed within scope, and polarizing filter.

 **M5606 – Electroretinographer**

1. Display must be LED/LCD high contrast with continued display of measured parameters readable in any ambient light level.

2. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.

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

 **M5700 – Frame Set, Lens Trial**

1. Set must consist of light weight and color-coded marked lenses, holding tray, and a complete assortment of other accessories.

2. Set must include features horizontal and vertical bridge adjustments with individual adjustments for temple length and angle.

3. Set must include (266) piece set including: sphere lenses concave and convex (0.25-20.00), cylinder lenses concave and convex (.25-6.00), prism lenses (0.5-10.00), accessory lenses (11 types).

 **M5715 – Prism Set, Square, w/Case**

1. Provide a prism set capable of aiding in the measurement of phoria deviations.

2. Set must include at a minimum the following diopters: 1/2, 1, 2, 4, 6, 8, 10, 15, 20, 25.

3. Set must include a carrying case.

**2.1.3 Stretchers/Patient Transport (Support)**

 **M4653 – Stretcher, Chair, Ophthalmic Surgical**

**A.** Stretchers must have adjustable height capabilities and include folding side rails for patient access with manual emergency release for resuscitation.

**B.** Stretchers must have the capability of accommodating a variety of accessories based on user requirements.

**C.** Base will include four antistatic casters with braking capability on each. Stretchers will have dual end brakes, steer control, and push handles.

**D.** Surfaces will be either stainless or enamel/powder coat steel construction. Construction must be free of sharp edges, non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Non-metal parts must be anti-static, antimicrobial, non-porous, and impervious to fluids.

**2.1.4 Furniture (Support)**

 **M5005 – Cabinet, Instrument, Lens Measuring**

 **M5010 – Desk, Fitting/Dispensing, Optical**

 **M5020 – Workbench, Fabrication/Maintenance**

 **M5025 – Table, Instrument, Ophthalmic, Adjustable**

 **M5027 – Table, Multiple Instrument, Ophthalmic**

**A.** Work surface must be plastic laminate, composite solid surface, or stainless steel.

**B.** Work surface edge must be vinyl on laminate tops, integral on solid surface, or integrated rolled edge on stainless steel tops.

**C.** Where applicable base storage must be customizable with various drawers’ bins and storage components.

**2.1.5 Optical Equipment (Support)**

 **A.** Optical Exam Support

 **M5540 – Power Supply, Ophthalmoscope**

1. Charger must be capable of accommodating 1 to 2 individual ophthalmoscope handles.

2. Construction must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

3. Unit must include an indicator for low battery life, charging or fully charged.

 **M5601 – Chair, Glide, Exam**

1. Must be compatible with the examination chair (M5600).

2. Unit must be capable of aiding the examination chair meet ADA requirements by allowing the chair to be pushed back so that a wheelchair can be placed in its position.

3. Must have a tapered track to allow doctor to get closer to patient without glide impeding access to patient.

 **M5730 – Stand, Instrument, Ophthalmic**

1.Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

2. Unit must provide a mounting post and power supply for ophthalmic equipment.

 **B.** Glasses/Lens Manufacturing

 **M5735 – Warmer, Spectacle, Plastic**

1. Unit must include an adjustable temperature control with a maximum temperature setting of 350 – 400 degrees.

2. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

3. Unit must have a recessed pan sealed in place so warming media (salt or glass bead) will not spill.

 **M6005 – Edger, Lens, Automatic Beveling**

 **M6015 – Generator, Lens**

 **M6020 – Polisher, Lens**

 **M6025 – Surfacer, Lens, Cylinder, 2 Spindle, Automatic**

 **M6035 – Tempering Unit, Heat Lens**

1. Display must be LED/LCD high contrast with continued display of measured parameters readable in any ambient light level.

2. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

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

4. Unit must be able to use all lens materials required for active duty readiness such as CR-39, Hi-Index, Trivex, and Polycarbonate.

**2.1.6 Optical Equipment (Treatment)**

 **A.** Glaucoma/Cataracts Treatment

 **M5514 – Laser, Ophthalmic, Semiconductor Diode**

 **M5515 – Laser System w/Slit Lamp or Ophthalmoscope**

 **M5517 – Laser, Photocoagulation, Dual Fiber, Ophthalmology**

 **M5519 – Laser, SLT (Selective Laser Trabeculoplasty)**

 **M5740 – System, Phacofragmentation**

1. Display must be LED/LCD high contrast with continued display of measured parameters readable in any ambient light level.

2. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

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

**B.** Refractive Surgery (PRK/LASIK)

 **M5518 – Laser, Corneal Surgery**

1. Display must be LED/LCD high contrast with continued display of measured parameters readable in any ambient light level.

2. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

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

4. All necessary operations before laser ablation, such as Torsion Error Detection (TED) alignment, magnification change, focus, illumination, eye tracking must be controllable by hand on user console.

4. Unit must have active tracking for eye movement and eye location verification.

5. Unit must fit through standard doorways and in small operating rooms.

**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--**