(September 2021)

PERFORMANCE CRITERIA
FOR

SECTION 11 73 00

PATIENT CARE EQUIPMENT
09/21

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GENERAL
This Performance Criteria specifies the requirements for patient care equipment.

[This section includes healthcare equipment in primarily inpatient settings. Refer to section 11 72 00 EXAMINATION AND TREATMENT EQUIPMENT for healthcare equipment in primarily outpatient 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 Underwriters Laboratories (UL)

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

1.1.7 International Electrotechnical Commission (IEC)

A. IEC 60601 Medical Electrical Equipment and Systems]

1.1.8 Food and Drug Administration

A. CFR Title 21, Chapter I

B. FDA Compressed Medical Gases Guideline

1.1.9 International Organization for Standardization (ISO)

A. ISO 5356 Anesthetic and Respiratory Equipment

B. ISO 8536 Infusion Equipment for Medical Use

C. ISO 10524-4 Pressure Regulators for Use With Medical Gases Part 4: Low Pressure Regulators

D. ISO 13485 Quality Management system for Medical Devices

E. ISO 15002 Flow-Metering Devices for Connection to Terminal Units of Medical Pipeline Systems

F. ISO 80601 Particular Requirements for Basic Safety and Essential Performance of Critical Care Ventilators

1.1.10 American Academy of Pediatrics

A. AAP Guidelines

1.1.11 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 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 Gastroenterology (Diagnostic)

M8500 – Nasopharyngoscope, Fiberoptic, Examination Only

M8501 – Nasopharyngoscope, Fiberoptic, Therapeutic
M8502 – Bronchoscope, Fiberoptic, Examination Only
M8503 – Bronchoscope, Fiberoptic, Therapeutic
M8504 – Bronchoscope, Video, Therapeutic
M8505 – Bronchoscope, Fiberoptic, Adult, Slim Casing
M8506 – Bronchoscope, Fiberoptic, Adult, Large Channel
M8507 – Bronchoscope, Fiberoptic, Pediatric
M8508 – Bronchoscope, Fiberoptic, Adult
M8509 – Bronchoscope, Fiberoptic, Video, Ultrasonic
M8511 – Colonoscope, Video, Therapeutic
M8512 – Duodenoscope, Video, w/Accessories
M8513 – Duodenoscope, Fiberoptic, Therapeutic
M8514 – Duodenoscope/Choledochoscope System, Mother/Daughter
M8515 – Gastroscope, Fiberoptic, Therapeutic
M8517 – Enteroscope, Fiberoptic, Therapeutic
M8518 – Gastroscope, Video, Therapeutic
M8519 – Enteroscope, Video, Therapeutic
M8520 – Laparoscope
M8545 – Sigmoidoscope, Fiberoptic, Therapeutic
M8546 – Sigmoidoscope, Video, Therapeutic
M8650 – System, Esophageal Motility Recording
M8655 – Recorder, Esophageal Motility, Ambulator

A. A rigid or flexible tube of various size which is passed into the digestive tract capable to provide a video image. Within the tube are the electronics necessary to capture HD video images.
B. Flexible scopes have a control section to control and maneuver the tip of the scope in a precise manner at varying degrees depending on anatomy explored.
C. Flexible scopes if specified, must have channels that permit the passage of devices to sample tissue, stop bleeding, or remove polyps.
D. Must be durable and safe for use for thousands of procedures and withstand the manufacturer recommended cleaning protocols, leak testing and the use of chemical disinfectants.

2.1.3 Modality/Integration Management Systems (Diagnostic)

M7765 – Computer Assisted Cardiology Management System
M7860 – Monitoring System, Cardiac Catheterization Lab
M8600 – Workstation, Endoscopy Video Documentation

A. Personal computer (PC) should match facility standard. Coordinate requirements with the Government.
B. Central server should match facility standard for reporting, network monitoring tools, etc. Coordinate requirements with the Government.
C. System must utilize the most current version of Windows Operating Systems for workstations and servers. Entire network must be capable of being supervised, monitored, patched, maintained, and life-cycled. Vendor must coordinate with Government to establish a plan of action for approval and dissemination of required Information Assurance Vulnerability Alert (IAVA) patches as well as software and security updates.
D. Systems must have flexibility to meet the scope and capacity needs for the identified facility based upon size, workload, and procedures performed.
E. Hardware to include wireless, Ethernet, or USB to PC connectivity for data transmission. Systems must be configured based on site specific requirements using manufacturers' standard software interface. System is to have capability to support connectivity to other manufacturers' external equipment.

2.1.4 Telehealth (Diagnostic/Support)

M0508 – Telemedicine Station, Mobile Cart

A. Mobile telemedicine station with modular design and flexibility to be further configured based on user needs.
B. Cart must have a computer, dual monitors, PTZ web camera, mouse, 2 locking drawers, keyboard, writing surface on locking casters.
C. Cart must have cable management system and battery back-up with long battery life.
D. Personal computer (PC) should match facility standard. Coordinate requirements with the Government.
E. Audio included via sound bar with active speakers.
F. System must utilize the most current version of Windows Operating System. Vendor must coordinate with

Government to establish a plan of action for approval and dissemination of required Information Assurance Vulnerability Alert (IAVA) patches as well as software and security updates.

G. Unit must be compatible with peripheral devices to assess patient vitals.

H. Hardware to include wireless, Ethernet, or USB to PC connectivity for data transmission. Systems must be configured based on site specific requirements using manufacturers' standard software interface. System is to have capability to support connectivity to other manufacturers' external equipment.

2.1.5 Scales (Diagnostic)

M4005 – Scale, In-Bed, 400 Pound Capacity

M4035 – Scale, Sling Type, Digital Read-Out

A. Display must be LED/LCD high contrast with text readable in any ambient light.

B. Functions to include weight recall, reweigh, and kg/lbs display.

C. Construction must be free of sharp edges, resistant to corrosion, and splash proof. External parts must allow for thorough cleaning and disinfection.

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

2.1.6 Urology (Diagnostic)

M4795 – Urinary Flow Metering System

M4800 – Urodynamic Measurement System w/Video

A. Display must be LED/LCD high contrast with text readable in any ambient light level.

B. Hardware to include wireless, Ethernet, or USB to PC connectivity for data transmission. Systems must be configured for use with manufacturers' standard software interface.

C. Unit must be portable and mounted on manufacturer supplied IV or mobile stand.

D. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. External 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.

2.1.7 Urology (Treatment)

M4805 – Lithotripter, Ultrasonic

A. System is comprised of a generator, footswitch, ergonomic hand piece, and a wide range of probes.

A. Control must be provided by foot pedal with a minimum 6 foot connection cable.

B. System must be dual energy and power output must be adjustable by the user.

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

2.1.8 Lifts (Support)

M8080 – Lift, Patient, Hydraulic, 350 Lb. Cap, Adj U-Base

M8085 – Lift, Patient, Electric, 600 Lb. Cap, Bariatric

A. Material must be steel. Finish must be enamel/powder coat, stainless, or chrome plated. Parts must allow for thorough cleaning and disinfection.

B. Safe working load of at least 350lbs for standard lifts, 600lbs for bariatric lifts.

C. Must have locking ball bearing casters.

D. If equipped to operate on rechargeable batteries, lifts must have power remaining indicator displayed.

E. Must include slings and accessories to accommodate different size patients and bed configurations.

2.1.9 Plumbing/Med Gas

A. Treatment

M0750 – Flowmeter, Air, Connect w/50 PSI Supply

M0755 – Flowmeter, Oxygen, Low Flow

M0760 – Proportioner (Blender), Oxygen/Air

M0765 – Regulator, Vacuum

1. If unit has display, it must be an LCD high contrast with text readable in any ambient light level or has a flow tube to display the desired settings/flow.
2. Configurable with fittings or adapters to connect to facility central pipeline system.
3. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. External

parts must allow for thorough cleaning and disinfection. All components contacting fluids or gases must be protected by a disposable cover or easily disinfected if being reused.

B. Support

M0615 – Oxygen Analyzer, Battery or Rechargeable

1. Unit must be battery operated with ability to replace or recharge batteries. Optional power adapter to extend battery life is preferable.
2. Display must be LED/LCD high contrast with text readable in any ambient light level.
3. Must have a high/low alarm system with visual and audible signals.
4. Must have a galvanic fuel cell as its sensing unit.
5. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. External parts must allow for thorough cleaning and disinfection. All components contacting fluids or gases must be protected by a disposable cover or easily disinfected if being reused.

M0770 – Cart, Cylinder-E, w/Du-O-Vac, Crash, MRI Compatible

1. System must include E cylinder, cart, cylinder wrench and regulator with 0-15 LPM flowmeter
2. MRI compatible product 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.
3. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. External parts must allow for thorough cleaning and disinfection. All components contacting fluids or gases must be protected by a disposable cover or easily disinfected if being reused.

2.1.10 Stretchers/Patient Transport; MRI Compatible (Support)

M4654 – Stretcher, Mobile, Trauma
M4655 – Stretcher, Mobile, CRS, 9 Position
M4656 – Stretcher, Mobile, CRS, Tapered Head Section
M4660 – Stretcher, Recovery, Labor
M4665 – Stretcher, Recovery, Surgical
X9705 – Stretcher, MRI Compatible

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

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

C. Surfaces may be 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.

D. Upholstery fabric must be flame resistant, antistatic, impervious to fluids, readily cleanable and removable from stretcher for easy cleaning

E. MRI compatible product 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.

2.1.11 Beds (Treatment)

A. Patient Beds

M7000 – Bed, Birthing, Electric
M7007 – Bed, Patient, Electric, Special Care
M7009 – Bed, Patient, Electric, Bariatric
M7010 – Bed, Patient, Electric

1. Provide a minimum tested weight capacity of 500 lbs [227 kg] for standard and 1000 lbs [454 kg] for bariatric.
2. Display must be LED/LCD high contrast with text readable in any ambient light level.
3. Beds must be mounted on four casters with braking on each caster and dual sided pedal control.
4. All bed movements must be motorized. Provide separate adjustable movement of head, torso, legs, and overall height. Include a manual emergency release for resuscitation.
5. Movements must be controlled on bed control panel and by remote control.
6. Construction must be free of sharp edges, non-porous, impervious to fluids, and resistant to corrosion. Non-metal parts must be anti-static, antimicrobial, non-porous, and impervious to fluids.
7. Beds to include manual battery backup in the case of power loss.
8. If mattress is included, upholstery fabric must be flame resistant, antistatic, impervious to fluids, readily

cleanable and removable from bed for easy cleaning.

B. Specialty Beds

M3010 – Bed, Air-Fluidized

M7005 – Bed, Hi-Low, Manual

M7006 – Bed, Electric, Sleep Study, Full Size

M7015 – Crib

1. Provide a minimum tested weight capacity of 400 lbs [181 kg] Pediatric cribs to have a minimum tested capacity of 200 lbs [91 kg].
2. Beds must be mounted on four casters with braking on each caster.
3. Provide independent adjustable movement of head, torso, legs, and overall height.
4. Movements must be manually controlled; if powered include bed control panel or remote control.
5. Construction must be free of sharp edges, non-porous, impervious to fluids, and resistant to corrosion. Non-metal parts must be anti-static, antimicrobial, non-porous, and impervious to fluids.
6. If mattress is included, upholstery fabric must be flame resistant, antistatic, impervious to fluids, readily cleanable and removable from bed for easy cleaning.

2.1.12 Beds (Support)

A. Bed Accessories (Safety/Patient Assist)

M3020 – Frame, Bed, Overhead, Balkan

M7020 – Top, Crib, Safety

1. Surfaces may be 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.

B. Mattress Hospital Grade

M3025 – Mattress, Pressure Reduction

M7025 – Mattress, Bed, Hospital

1. Provide a minimum tested weight capacity of 400 lbs [181 kg] Pediatric cribs to have a minimum tested capacity of 200 lbs [91 kg].
2. Upholstery must be flame resistant, antistatic, impervious to fluids, readily cleanable and removable from bed for easy cleaning.
3. Provide independent adjustable movement of head, torso, legs, and overall height.
4. Movements must be manually controlled; if powered include bed control panel or remote control.
5. Construction must be free of sharp edges, non-porous, impervious to fluids, and resistant to corrosion. Non-metal parts must be anti-static, antimicrobial, non-porous, and impervious to fluids.

2.1.13 Cardiology (Treatment)

A. Heart Pumps

M4806 – Controller, Heart Pump Catheter

M4809 – Heart / Lung Machine, Portable

1. Display must be LED/LCD high contrast with text 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. Include automatic battery backup in the case of power loss or need for patient transport.

B. Temporary Pacemakers

M4812 – Pacemaker, Single Chamber, External, Temporary

M4813 – Pacemaker, Dual Chamber, External, Temporary

1. Display must be LED/LCD high contrast with text 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. Lightweight and easy to configure and operate.
4. 15 day or longer battery life.

2.1.14 Cardiopulmonary (Treatment)

M0910 – Ventilator, High Frequency, Infant
M0915 – Ventilator, High Frequency, Adult
M0920 – Ventilator, High Frequency, Transport
M0925 – Ventilator, ICU, Adult
M0930 – Ventilator, ICU, Neonatal/Pediatric
M0935 – Ventilator, Portable
M0940 – Ventilator, Transport

A. Display must be LED/LCD high contrast with text readable in any ambient light level. Monitor must allow movement for easy viewing at multiple angles.
B. Alarm notifications must have options using visual or auditory or both.
C. 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.
D. Unit must be portable, mounted with universal clamp on an optional included mobile cart or trolley supplied by the manufacturer.
E. Provide functional capabilities to accommodate patients of all ages and body weights.
F. Include automatic battery backup and low battery alert in case of power loss.
G. Hardware to include wireless, Ethernet, or USB to PC connectivity for data transmission.

2.1.15 Cardiovascular (Treatment)

A. Varicose Vein Treatment

M4277 – Pump, Anesthesia, Tumescent

1. Display must be LED/LCD high contrast with text readable in any ambient light level. Monitor must allow movement for easy viewing at multiple angles.
2. Unit must be mobile and mounted on an optional mobile cart, trolley or bed hardware supplied by the manufacturer.
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.

B. Pneumatic Pumps (Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE) prevention)

M4280 – Pump, Pneumatic Stocking/Cuff

1. Display must be LED/LCD high contrast with text 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. Lightweight and easy to configure and operate.
4. Able to deliver compression to leg, foot, or both simultaneously.
5. Adjusts level and frequency of compression without nursing intervention.
6. Ability to run on battery power for a period of 6 – 8 hours depending upon sleeve configuration and sleeve application.
7. Unit must be mobile and mounted on an optional mobile cart, trolley or bed hardware supplied by the manufacturer.

C. Pneumatic Pumps (Tourniquet)

M4285 – Pump, Pneumatic Tourniquet

1. Display must be LED/LCD high contrast with text 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. Lightweight and easy to configure and operate.

2.1.16 Cryosurgery (Treatment)

M4825 – Cryosurgical Unit, Mobile

A. 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.
B. Controls either by hand or foot switch to deliver extreme cold treatment.

C. Tips must be autoclavable and/or disposable.

2.1.17 Renal Care/Dialysis

A. Renal Care (Treatment)

M1715 – Hemodialysis Unit, Hollow Fiber or Plate

M4820 – Hemodialysis Unit, Mbl, w/Reverse Osmosis System

M4860 – Peritoneal Dialysis Unit, Hollow

1. Display must be LED/LCD high contrast with text readable in any ambient light level.
2. Broad range of flow rates to individualize therapy based upon patient condition.
3. Simple controls to ensure ease of use and simplify user training.
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.

B. Renal Care (Support)

M4855 – Monitor, Renal Preservation

1. Display must be LED/LCD high contrast with text 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. Lightweight and easy to configure and operate.
4. Battery life must last at least 15 days or longer.

2.1.18 ENT (Treatment)

M4840 – ENT Unit, w/Air, Electric Power, Suction, Pressure

A. Base must be mobile with braking swivel casters. Stationary base must include toe kick.

B. Options for left or right hand use must be available.

C. Materials may include stainless or painted steel, aluminum, solid surface, or medical grade laminates.

D. 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.

2.1.19 Infusion (Treatment)

M4245 – Infuser, Rapid, Blood

M4250 – Pump, Syringe, Infusion

M4260 – Controller, Flow, Infusion, 5-60 DPM

M4265 – Pump, Volumetric, Infusion, Single Line

M4266 – Pump, Volumetric, Infusion, Multiple Line

M4268 – Pump, Volumetric, Infusion, Dual, MRI Compatible

M4275 – Pump, Continuous, Analgesia (PCA)

A. Display must be LED/LCD high contrast with text readable in any ambient light level.

B. Alarm notification must have options using visual, auditory or both for all parameters.

C. All patient connectors must be readily cleanable, reusable, and designed for attachment to disposable patient patches.

D. Unit must be portable with options for universal clamp onto IV stand or bed.

E. Provide functionality to accommodate patients of all ages and body weights. Provide programming of flow rates and capability to accept any kind of fluids as solutions or medications. Syringe pumps to accept commonly available size syringes from 1 to 60 ml and automatically detect the size.

F. Hardware to include wireless, Ethernet, or USB to PC connectivity for data transmission options. Systems must be configured for use with manufacturers' standard software interface.

G. Automatic battery backup is must be included as well as a low battery alarm.

H. 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.

I. MRI compatible products must use 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.

2.1.20 Lights (Treatment)

M8205 – Light, Infrared/Ultraviolet Combination
M8220 – Light, Infrared
M8225 – Light, Ultraviolet, Mobile

A. Light must be mobile and mounted on an included mobile cart or trolley supplied by the manufacturer.
B. Include height or lamp head adjustment on lights.
C. Construction must be free of sharp edges, non-porous, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

2.1.21 Neonatal (Treatment)

A. Incubators

M0805 – Incubator, Infant, ICU, Mobile/Transport
M0810 – Incubator, Infant, ICU, Mobile
M0815 – Incubator, Infant, Mobile, Isolation

1. Display must be LED/LCD high contrast with text readable in any ambient light level. Monitor must be located for easy viewing and access to the control panel.
2. Alarm notification must have options using visual, auditory or both for all parameters.
3. Unit must be mounted on four conductive casters with two brakes. Transport models must be available with a removable base.
4. Adjustability must include Trendelenburg, reverse Trendelenburg, and adjustable height.
5. Provide minimum temperature range control from 20 to 38 deg. C in increments of 0.1 deg. C. Accuracy must be within +-0.5 deg C. Provide controls for baby temperature, air temperature, servo humidity, oxygen input flow rate, respiratory rates [scale], and pressures.
5. Include integrated in-bed scale.
6. Upholstery must be flame resistant, antistatic, impervious to fluids, and readily cleanable. Upholstery must be removable for easy cleaning.
7. Power must be provided through battery during transportation. Include battery backup switch and low battery alert in case of power loss.
8. 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.

B. Warmers

M0800 – Warmer, Bassinet, Mobile, Neonatal
M0820 – Warmer, Infant, Mobile

1. Display must be LED/LCD high contrast with continuous display of patient parameters. Display text will be readable in any ambient light level.
2. Alarm notification must have options using visual or auditory or both for all parameters.
3. Unit must be mounted on four conductive casters with two brakes.
4. Adjustability must include adjustable height.
5. Provide heater minimum adjustment range from 0-100%. Provide minimum temperature range control from 34 to 37 deg. C in increments of 0.1 deg. C accurate to within +-0.5 deg C.
6. Mattress or pad must be flame resistant, antistatic, impervious to fluids, and readily cleanable. Mattress or pad must be removable for easy cleaning.
7. 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.
8. Integrated resuscitation unit must be provided with oxygen, air, vacuum and suction.

C. Lights

M0825 – Transilluminator, Neonatal
M8215 – Light, Phototherapy, Mobile
M8217 – Phototherapy Unit, Fiberoptic w/ Bili-Lite Pad

1. Include height adjustment on mobile stand or freely adjustable lamp head.
2. Light source may be halogen quartz, fluorescent, or LED producing daylight, cool white, blue or special blue color. Bulbs to produce wavelengths after filtering of 420-480 NM. Include UV filter shield under bulb.
3. Provide for automatic turn off after a set time length.
4. Construction must be free of sharp edges, non-porous, impervious to fluids, non-ferrous, and corrosion

resistant. Parts must allow for thorough cleaning and disinfection.

2.1.22 Nutrition (Treatment)

M2605 – Pump, Breast

A. Display must be LED/LCD high contrast with text readable in any ambient light level.

B. Vacuum setting range from 30 – 270 mmHg.

C. Collection bottle material must be suitable for refrigeration, freezing, and warming of breast milk.

D. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. External 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.

M4270 – Pump, Enteral Feeding

A. Display must be LED/LCD high contrast with text readable in any ambient light level.

B. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. External 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.

2.1.23 Otolaryngology (Treatment)

M8495 – Laryngoscope, Video Glidescope

A. Display must be LED/LCD high contrast with text readable in any ambient light level.

B. Dimmable LED light source must be included on the tip of the laryngoscope to allow for clear insertion of the endotracheal tube.

C. Unit must accept disposable and reusable blades in all sizes, designs, and lengths.

D. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. External 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.

E. Unit must be portable with optional hardware to mount on mobile stand.

F. Hardware to include connections for external monitor display of video and/or images.

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--