MILITARY SPECIFICATION

DEPLOYABLE MEDICAL SYSTEMS, GENERAL REQUIREMENTS FOR

This specification is approved for use by all Departments and Agencies of the Department of Defense.

1. SCOPE

1.1 Scope. This document covers general requirements for medical equipment used in DoD Deployable Medical Systems (DMS) and is intended to be used in conjunction with the detailed specification, purchase description or procurement document covering such additional requirements as are applicable to each equipment item.

2. APPLICABLE DOCUMENTS

2.1 Government documents.

2.1.1 Specifications and standards, and handbooks. The following specifications, standards, and handbooks form a part of this specification to the extent specified herein. Unless otherwise specified, the issues of these documents shall be those listed in the issue of the Department of Defense Index of Specifications and Standards (DODISS) and supplement thereto, cited in the solicitation.

Beneficial comments (recommendations, additions, deletions) and any pertinent data which may be of use in improving this document should be addressed to: Defense Personnel Support Center, Directorate of Medical Materiel, DPSC-RST, 2800 South 20th Street, Philadelphia, PA 19101, by using the self-addressed Standardization Document Improvement Proposal (DD Form 1426) appearing at the end of this document or by letter.

AMSC/NA FSC 65GP

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SPECIFICATIONS

FEDERAL

L-P-390	Plastic, Molding and Extrusion Material, Polyethelene and Copolymers (Low, Medium, and High Densities).
PPP-C-1752	Cushioning Material, Packaging, Unicellular Polyethelene Foam, Flexible.

MILITARY

MIL-M-7298	Manual, Technical, Commercial Equipment
MIL-P-26514	Polyurethane Foam, Rigid or Flexible, for Packaging
MIL-V-27166	Valve, Pressure Equalizing, Gaseous Products
MIL-C-46168	Coating, Aliphatic Polyurethane, Chemical Agent Resistant

STANDARDS

FEDERAL

FED-STD-101	Test Procedures for Packaging material.

MILITARY

MIL-STD-129	Marking for Shipment and Storage
MIL-STD-130	Identification Marking of U.S. Military Property
MIL-STD-1388	DOD Requirements for a Logistical Support Analysis Record.
MIL-STD-1472	Human Engineering Design Criteria for Military Systems, Equipment and Facilities
MIL-STD-1561	Provisioning Procedures, Uniform DoD

HANDBOOKS

MILITARY

MIL-HDBK-304	Package Cushioning Design

2.1.2 Other Government documents. The following other Government documents form a part of this specification to the extent specified herein. Unless otherwise specified, the issues shall be those in effect on the date of the solicitation.

DFARS 52,227-7013	Rights in Technical Data and Computer Software
NAT-STD 2905	Basic Voltage and Current Characteristics of Electromedical Equipment

2.2 Other publications. The following document(s) form a part of this specification to the extent specified herein. Unless otherwise specified, the issues of the documents which are DoD adopted shall be those listed in the issue of the DODISS specified in the solicitation. Unless otherwise specified, the issues of documents not listed in the DODISS shall be the issue of the nongovernment document which is current on the date of the solicitation.

NATIONAL FIRE PROTECTION ASSOCIATION (NFPA)

NFPA 70	National Electrical Code (specifically Article 517)
NFPA 99	Standard for Health Care Facilities

(Application for copies should be addressed to the National Fire Protection Association, Batterymarch Park, Quincy, MA 02269).

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Public Law 90-602 Radiation Control for Health and Safety Act - (Subchapter J of Title 21, The Code of Federal Regulations).

Federal Food, Drug and Cosmetic Act, as amended.

AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)

ANSI/AAMI ES1	Safe Current Limits for Electromedical Apparatus.

(Application for copies should be addressed to the American National Standards Institute, 1430 Broadway, New York, NY 10018).

UNDERWRITERS LABORATORIES

UL 544	Standard for Safety, Medical and Dental Equipment

(Application for copies should be addressed to Underwriters Laboratories, 333 Pfingsten Road, Northbrook, IL 60062).

(Industry association specifications and standards are generally available for reference from libraries. They are also distributed among technical groups and using Federal agencies).

2.3 Order of precedence. In the event of a conflict between the text of this specification and the references cited herein, the text of this specification shall take precedence. Nothing in this specification, however, shall supercede applicable laws and regulations unless a specific exemption has been obtained.

3. REQUIREMENTS

3.1 General. All equipment offered shall conform to the requirements specified herein and the manufacturers' commercial specifications, standards, and drawings.

3.1.1 Specification sheets. The individual item requirements shall be as specified herein and in accordance with the applicable specification sheets. In the event of any conflict between requirements of this specification and the specification sheets, the latter shall govern.

3.2 Characteristics.

3.2.1 Physical characteristics. The contractor shall provide the following information:

Electrical Characteristics of the Equipment Item Offered:

Required Nominal Voltage Range: _____V
Required Frequency: _____Hz
Wattage Used: _____watts
Line Current, Max: _____amps

NOTE: Horsepower ratings shall be converted to watts.

Nominal Weight and Volume of Equipment Item with Reuseable Container:

Weight: _____lbs
Cube: _____ft
Dimensions: _____inches (LxWxH)

NOTE: On large assemblies weight and volume shall be provided for each component.

Nominal Weight and Volume of Equipment Item without Reuseable Container:

Weight: _____ lbs
Cube: _____ ft
Dimensions: _____ inches (LxWxH)

NOTE: On large assemblies weight and volume shall be provided for each component.

Nominal Packed Shipping Weight and Volume of Each Shipping Container:

Weight: _____ lbs
Cube: _____ ft
Dimensions: _____ inches (LxWxH).

3.2.2 Storage characteristics. Item may be subjected to storage in an uncontrolled environment (temperature and humidity) for extended periods of time (e.g., 5 to 10 years). If the item can only be stored in a controlled environment, the contractor shall submit information with the bid/proposal which clearly explains the environmental limits within which the item shall be stored. The contractor shall provide a list of parts subject to deterioration during storage, (e.g., rubber goods, tubing, batteries), and maintenance/inspection schedules to prevent problems in operation after extended periods of storage.

3.2.2.1 Periodic inspection/maintenance. For items requiring periodic inspection/maintenance while in storage, the contractor shall provide detailed instructions delineating appropriate methods and procedures. In addition, the contractor shall provide a means to access the equipment/components without permanently destroying the packaging container (e.g., provide reusable shipping/storage containers). The cost of providing such packaging, if different from the usual method of shipping, will be separately identified in the bid/proposal. This will allow the Government to determine the cost effectiveness of this requirement versus the Government performing its own packaging for storage.

3.3 Design and construction. Shall be in accordance with the essential salient characteristics of the applicable specification sheet (see 3.1.1).

3.3.1 Electrical characteristics.

3.3.1.1 Alternating Current (AC) powered equipment.

3.3.1.1.1 Input power. AC equipment, as identified in the specification sheets shall be capable of operating from the following line sources: 110 volts, plus and minus 10 percent, and 230 volts, plus and minus 10 percent alternating current, multiple frequency, 50 and 60 Hz plus or minus 2 Hz.

Modifications to the offeror's standard commercial item which will allow operation on all the above voltage levels and 50/60 Hz may be acceptable.

The design modification may be integral to the equipment or may consist of a separate external equipment item(s). The conversion kit shall include adequate instructions for the Government to perform the modifications. Complex modifications requiring more than one manhour to accomplish are not acceptable.

3.3.1.1.2 Line sensing. Equipment which does not automatically permit operation on multi-voltage 50/60 Hz (either 110 or 220 volt) shall be set for Air Force 110 volt, 50 Hz, and Navy/Marines/Army 110 volt, 60 Hz.

3.3.1.1.3 Power line cord and plug. All medical equipment shall be supplied with a UL-approved three-wire ground line cord and a 110 volt green dot hospital grade male plug. Where a hospital grade plug is not available, a plug suitable for use in hospital environments shall be provided.

3.3.1.2 Direct Current (DC) powered equipment.

3.3.1.2.1 Input Power. DC equipment, as identified in the specification sheet, shall be capable of operating from the DC sources specified within the specification sheet.

Items offered which operate form both AC and DC power shall be capable of operating by AC power when the DC power source (battery(ies)) is removed from the equipment. The items shall also be capable of operating from the DC source(s) when the AC power source is removed from the equipment.

3.3.1.2.2 Power line cord and plug. The provisions of paragraph 3.3.1.1.3 are applicable when the equipment, as identified in the specification sheet (see 3.1.1) contains a battery charger.

3.3.2 Identification marking.

3.3.2.1 Nameplates and product marking. Unless otherwise specified in the applicable specification sheet, each unit shall have as a minimum the following information on one or more nameplates:

a. Name or Registered Trademark of the Manufacturer.
b. Type or Model Number.
c. Serial Number.
d. Electrical Characteristics.
e. National Stock Number (NSN).
f. Federal Supply Code For Manufacturers (FSCM).
g. Quarter and Year of Manufacture (3Q81 - Designates third quarter of 1981).

Nameplates shall be permanently and securely attached to the equipment. Adhesives shall not be used. Equipment shall be permanently and legibly marked in accordance with the general marking requirements of MIL-STD-130. The nameplate shall be located on an external equipment surface which is readily accessible.

3.3.3 Interchangeability. Parts having the same manufacturers part number shall be fully and functionally interchangeable. All major components of the assembled system having the same model number shall be physically and functionally interchangeable.

3.3.3.1 Engineering design changes. The contractor shall notify the provisioning activity of all changes whether of a production or modification type which are approved for incorporation into the end item furnished under the contract and which modify, add to, delete, or supersede parts in the end item or its supporting equipment. Requirements for Design Change Notices are described in the attached DD 1423, Contract Data Requirements List (CDRL) and DD 1664, Data Item Description (DID).

3.3.4 Safety. All items shall conform to the applicable requirements of a nationally recognized standard for the safety of medical equipment of the issue in effect on the date of solicitation. All items shall be approved as conforming to such a standard by an independent nationally recognized testing laboratory, as applicable. Items which fit into one or more of the general descriptions given in table I shall conform/comply to the indicated Health/Safety document.

Table I. General Health/Safety Requirements.

General Description	Applicable Documents
100 Devices used in Health Care Facilities	NFPA 99
101 Devices requiring contractor installation	NFPA 70 (Article 517)
102 Electronic devices generating radiation	Public Law 90-602 (Subchapter J of Title 21)
103 Devices subject to recall by FDA	Federal Food, Drug and Cosmetic Act section 518 (b)
104 All electromedical apparatus	ANSI/AAMI ES1

3.4 Documentation.

3.4.1 Operation, installation, and service/maintenance instructions. The contractor shall furnish manuals, handbooks, and/or brochures containing complete operation, installation, and service/maintenance instructions (including pictures or illustrations, as necessary) with complete schematics and wiring diagrams. The manual requirements and distribution are described in the attached DD Forms 1423, and DD forms 1664, (MIL-M-7298 is referenced as a guide for format only). The contractor shall also furnish one copy of training materials used to train field service engineers/technicians in the repair, installation, and maintenance of equipment offered in the bid/proposal. Training material requirements and distribution are described in the attached DD form 1423, and DD Form 1664. If the contractor has furnished an identical set of information to this address on a previous contract/purchase order, then the contractor will furnish a statement of such prior submission with the bid/proposal. Such a statement will include:

a. Date previously submitted.
b. Contract/purchase order number.
c. Equipment nomenclature.

3.4.2 Documentation reproduction. The contractor may be required to provide one (1) set of all documentation in reproducible format. The reproducibles shall be separately identified and priced on the bid/proposal.

3.5 Logistics.

3.5.1 Maintenance and supply. Initial operating supplies, spares, repair parts, special tools, and test equipment shall be shipped in the quantities identified below.

3.5.1.1 Repair parts support kit. See applicable specification sheet (see 3.1.1).

3.5.2 Support items technical documentation. The contractor must furnish technical documentation necessary to identify and determine the range and quantity of support items to be purchased with the end item as spares, repair parts, special tools, and test equipment in accordance with MIL-STD-1388 and MIL-STD-1561. The technical documentation requirements are described in the attached DD Form 1423 and DD Form 1664. The Government will review the technical documentation and identify those support items to be included in the repair parts support kit as well as determining the capability of the contractor to provide the required support.

3.6 Container characteristics

3.6.1 Medical items, and related accessories, will be packed in a reusable, rotationally molded, polyethylene, shipping and storage container or equal (e.g. fiberglass, plastic) container. Container shell material shall meet the requirements of Federal Specification L-P-390 for Type I, Class M, Grade II, polyethylene or equal. The container may be an integral part of the medical item design or may be separate item. If the container is not an integral part of the medical item, the container will be equipped with a cushioning and support system sufficient to protect the contents from damage in transit and storage due to vibration, shock, or compression.

3.6.2 Materials used in container design and construction shall be compatible with chemical agent decontamination or be painted with a chemical agent resistant aliphatic polyurethane coating per MIL-C-46168.

3.6.3 The container, whether integral to the medical item or not, shall be corrosion resistant, dustproof, moisture vapor proof, and provide protection to the contents from transit and storage damage due to vibration, shock, or compression. Compliance with requested characteristics shall be verified by techniques from applicable sections of Federal Standard 101.

3.6.4 The containers must provide the medical equipment storage and transport protection in environments where temperatures range from -40°C to +60°C (storage) and -30° to +50°C (transport) and relative humidity range from 0 to 95 percent (non-condensing).

3.6.5 The container shall be equipped with a closed loop gasket at the parting line closure. An automatic/manual pressure/vacuum relief valve per MIL-V-27166 (set at +/- 0.5 psig) shall be installed within a recessed area of the container wall. Seal shall be verified by pneumatic pressure technique of Federal Standard 101, Test Method Method 5009.

3.6.6 The container outer surfaces shall be self draining when stored in the normal upright shipping attitude.

3.6.7 The container shall have stainless steel, spring loaded, full-grip 90° stop handles (Nielson P/N H945-SS-SS-2-NALS-RG or equal), capable of being used by personnel wearing gloves or mittens. Inside dimension of the bail shall be 4.25 x 1.8 minimum. Quantity and placement of handles per MIL-STD-1472.

3.6.8 The container design shall include stainless steel quarter turn catches (Simmons P/N B1900-1144 or equal) to provide secure fastening of lid to container base.

3.6.9 Cushion and support system of the container shall provide adequate vibration, shock, and compression protection of the contents. Evidence of conformance shall be qualification of container through the rough handling tests of Federal Standard 101. If foam inserts are to be utilized, they shall be constructed of unicellular, polyethylene foam (color charcoal gray) conforming to PPP-C-1752 Type I, Class 2, or flexible polyurethane foam conforming to MIL-P-26514 Type I, Class 2, Grade C. Cushioning system shall be designed in accordance with MIL-HDBK-304.

3.6.10 Container identifications and markings shall be in accordance with MIL-STD-129 and MIL-STD-130 for medical materiel.

3.6.11 Catches and strikes shall be mechanically affixed to the container with stainless steel rivets and using molded-in steel inserts. Handles shall be installed using back-up plates and neoprene gaskets on both inside and outside surfaces. All hardware shall be recessed within the outer surface of the container.

3.6.12 The container must be resilient so as not to sustain permanent dents, even under severe impacts.

3.6.13 There shall be no nutrient materials used in the construction of the case which shall support fungal life.

3.6.14 The container shall be abrasion resistant. Color pigmentation shall be compounded throughout the container shell material.

3.6.15 Container material shall not require painting (other than chemical resistant coating, if required), but shall readily accept a variety of paints used to apply tactical identification markings.

3.6.16 Instructions and illustrative graphics shall be provided by the container to explain procedures for the packing and unpacking of medical items and accessories in and out of the container. These instructions shall be permanently mounted inside the container in such a manner as to preclude damage by the equipment stored and transported therein. Instructions and illustrative graphics shall be printed to be easily readable, and shall be laminated. Completed instructions and illustrative graphics shall be made available for review during the First Article Inspection.

3.6.17 The container shall be easily cleaned with solvents, solutions and mild detergents without adverse effect.

3.7 Installation and personnel training.

3.7.1 Installation. Unless otherwise specified in the applicable specification sheet (see 3.1.1), equipment items shall be government installed. If required, the contractor shall provide necessary installation guides and templates.

3.7.2 Training. Unless otherwise specified in the applicable specification sheet (see 3.1.1), personnel training is not required.

3.8 Workmanship. The equipment item, component parts, assemblies and associated fittings and accessories shall be processed in such a manner as to be uniform in quality and free from defects that will affect life, serviceability, or appearance, or may impair equipment performance.

4. QUALITY ASSURANCE PROVISIONS.

4.1 Contractor certification. The contractor shall certify that the product offered meets the salient characteristics of this description and the applicable specification sheet (see 3.1.1), and conforms to the producers' own drawings, specifications, standards, and quality assurance practices. The Government reserves the right to require proof of such conformance prior to first delivery and thereafter as may be otherwise provided for under the provisions of the contract.

4.2 Regulatory requirements.

4.2.1 Federal Food, Drug and Cosmetic Act. If the product covered by this document has been determined by the U. S. Food and Drug Administration to be under its jurisdiction, the offeror/contractor shall comply, and be responsible for compliance by its subcontractors/suppliers, with the requirements of the Federal Food, Drug and Cosmetic Act, as amended, and regulations promulgated thereunder. In addition, the offeror/contractor shall comply, and be responsible for compliance by its subcontractors/suppliers, with the requirements of all other applicable Federal, State, and local statutes, ordinances, and regulations.

4.2.2 Recovered materials. The offeror/contractor is encouraged to use recovered material in accordance with Public Law 94-580 to the maximum extent practical.

5. PACKAGING.

5.1 Preservation, packaging, and packing. Unless otherwise specified, preservation, packaging, and packing shall be to a degree of protection to preclude damage to containers and/or contents thereof under normal shipping conditions, handling, etc., involving shipment from the supply source to the receiving activity, plus reshipment from receiving activity, and shall conform to applicable carrier's rules and regulations. Intermediate and exterior package quantities shall be as specified in the contract and/or order.

5.2 Marking. Each unit package, intermediate package, and exterior container shall be marked in accordance with MIL-STD-129. In addition, each exterior container shall be marked with the following markings:

a. Manufacturer's Name.
b. Manufacturer's Part Number (P/N).
c. Federal Supply Code for Manufacturers (FSCM).
d. Type or Model Number.
e. Serial number.
f. Electrical Characteristics.
g. National Stock Number (NSN).
h. Date of Manufacture (quarter and year).
i. Index No. _____ (Legend to be marked on container, number will be assigned and applied to container at destination).
j. Special markings as required (see 5.4 of MIL-STD-129).

6. NOTES

6.1 Intended use. Equipment covered by this specification is intended for use in medical war readiness assemblages and DoD Deployable Medical Systems (see 3.1.1).

6.2 Ordering data.

6.2.1 Acquisition requirements. Acquisition documents should specify the following:

a. Title, number, and date of this specification.
b. Title, number, and date of the applicable specification sheet.
c. NSN (as applicable).
d. Quantity in intermediate package and exterior package, if required.

6.2.2 Data requirements. When this specification is used in an acquisition which incorporates a DD Form 1423, Contract Data Requirements List (CDRL), the data requirements shall be as specified by an approved Data Item Description (DID), DD Form 1664, and delivered in accordance with the approved CDRL incorporated into the contract. When the provisions of DFARS 52.227-7013 (n) (2) are invoked and the DD Form 1423 is not used, the data shall be delivered by the contractor in accordance with the contract or purchase order requirements.

6.3 Definitions.

6.3.1 Repair parts. Consumable bits and pieces, that is, individual parts on nonrepairable assemblies, required for the repair of spare parts or end items.

6.3.2 Spare parts. Repairable components or assemblies used for maintenance replacement purposes in major end items of equipment.

6.3.3 Special tools, special test equipment, and special support equipment. Those support items that have single/peculiar application to a specific end item.

6.3.4 Consumables. Those support items that are consumed in use or replaced frequently, that is, gels, chemicals, rubber goods, and electrodes that deteriorate during use.

6.4 Key word listing.

Medical equipment
Deployable Medical Systems
Medical Material

Custodians:

Army MD
Navy MS
Air Force 03

Review Activities:

Army MD
Navy MS
Air Force 03

User Activities

Army MD
Navy MS
Air Force 03

Preparing Activity:

DoD-MB

Agent:

DLA-DM

Project No. 65GP-0015
Location: DEPMEDS/H10-1a

INSTRUCTIONS: In a continuing effort to make our standardization documents better, the DoD provides this form for use in submitting comments and suggestions for improvements. All users of military standardization documents are invited to provide suggestions. This form may be detached, folded along the lines indicated, taped along the loose edge *(DO NOT STAPLE)*, and mailed. In block 5, be as specific as possible about particular problem areas such as wording which required interpretation, was too rigid, restrictive, loose, ambiguous, or was incompatible, and give proposed wording changes which would alleviate the problems. Enter in block 6 any remarks not related to a specific paragraph of the document. If block 7 is filled out, an acknowledgement will be mailed to you within 30 days to let you know that your comments were received and are being considered.

NOTE This form may not be used to request copies of documents, nor to request waivers, deviations, or clarification of specification requirements on current contracts. Comments submitted on this form do not constitute or imply authorization to waive any portion of the referenced document(s) or to amend contractual requirements.

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Philadelphia, PA 19101

STANDARDIZATION DOCUMENT IMPROVEMENT PROPOSAL

(See Instructions – Reverse Side)

1. DOCUMENT NUMBER	2. DOCUMENT TITLE
MIL-D-42048	Deployable Medical Systems, General Requirements for

3a. NAME OF SUBMITTING ORGANIZATION	4. TYPE OF ORGANIZATION *(Mark one)*
	☐ VENDOR
b. ADDRESS *(Street, City, State, ZIP Code)*	☐ USER
	☐ MANUFACTURER
	☐ OTHER *(Specify)* _____

5 PROBLEM AREAS

a. Paragraph Number and Wording

b. Recommended Wording

c. Reason/Rationale for Recommendation

6 REMARKS

7a. NAME OF SUBMITTER *(Last, First, MI)* – Optional	b. WORK TELEPHONE NUMBER *(Include Area Code)* – Optional
c. MAILING ADDRESS *(Street, City, State, ZIP Code)* – Optional	8. DATE OF SUBMISSION *(YYMMDD)*

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