

## TEMPERATURE MONITORING DEVICE

## 1. SCOPE

1.1 This Specification Sheet covers the requirements for various types and sizes of temperature monitoring devices.

1.2 Intended use. Temperature monitoring devices shall be suitable for use in the non-Radio Frequency Identification (RFID) shipment of medical materiel, pharmaceuticals, biologics, and specimens requiring a constant temperature range while intransit. They shall validate packaged temperatures throughout the shipping process and provide pertinent data to both customer and shipper to ensure material viability.

## 2. CLASSIFICATION

2.1 Temperature monitoring devices covered by this document shall be suitable for use in all non-RFID shipments requiring compliance with controlled room temperature, refrigerated, or frozen temperature requirements (including shipments requiring dry ice) while intransit.

## 3. SALIENT CHARACTERISTICS

3.1 Material. Units shall have a water-resistant casing, equivalent to Chimei Polylac ABS PA-757. Casing shall have a National Electrical Manufacturers Association (NEMA) rating of 6 (see 5.6.1).

3.2 Dimensions. In order to ensure adherence to Defense Logistics Agency (DLA) "Packaging Protocols for Medical Temperature Sensitive Products," unit dimensions shall allow the unit to fit into the smallest available Cargo Area Space (cubic inches): 10 3/4" L x 6 1/2" W x 4" H (see 7.2.1.1)

3.3 Design.

3.3.1 Shall be self-contained, non-RFID, non-Universal Serial Bus (USB), probeless, electronic monitors that are available in either single use or re-programmable forms. Only single use monitors shall be acceptable for dry ice shipments.

3.3.2 Shall be 3-point tested and traceable to National Institute of Standards and Technology (NIST) established standards (see 5.6.2).

3.3.3 Shall meet the following regulatory requirements:

3.3.3.1 Shall be certified in accordance with the ElectroMagnetic Compatibility (EMC) directive (see 5.6.3).

3.3.4 Shall have non-volatile 2K or 16K Electronically Erasable Programmable Read-Only Memory (EEPROM), or equivalent, options for memory.

3.3.5 Shall have a data storage capacity of a maximum 1920 or 16000 data points.

3.3.6 Shall have a 1 year run life/3.0 v lithium battery.

3.3.7 Shall have the ability to display data in both Celsius (C) and Fahrenheit (F), digitally through a Liquid Crystal Display (LCD).

3.3.8 Shall have the following operational ranges:

- Non dry-ice: an upper range of 70°C (158°F), and a lower range of -30°C (-22°F)
- Dry-ice: an upper range of 30°C (86°F), and a lower range of -80°C (-112°F)

3.3.9 Shall have customizable alarm settings that can either be pre-programmed or programmed on-site. These alarm settings shall be able to be set to a minimum of one of the following standard or dry-ice temperature ranges:

– Standard

2° to 8°C (36° to 46°F)

15° to 30°C (59° to 86°F)

-20° to 8°C (-4° to 46°F)

-20° to -10°C (-4° to 14°F)

– Dry ice

-80° to -15°C (-112° to 5°F)

-80° to 8°C (-112° to 46°F)

3.3.10 Shall have front face labels that meet the following criteria:

3.3.10.1 Shall be available in different colors, with the option to add colors at no additional cost on an as-needed basis. As a minimum, the following colors shall be available: orange, yellow, light blue, dark blue, white, and pink.

3.3.10.2 Shall have lines for documentation.

3.3.10.3 Shall display a unique alpha-numeric identifier on the device itself.

3.3.10.3.1 Shall have a removable adhesive tag, on top of the identifier on the device itself, displaying the unique alpha-numeric identifier as well

3.4 Function.

3.4.1 Units shall have the following temperature accuracy ranges:

+/- 1.1°C (34°F) from -30° to -1°C (-22° to 30°F)

+/- 0.22°C (33°F) from -1° to 10°C (30° to 50°F)

+/- 1.1°C (34°F) from 10° to 70°C (50° to 158°F)

+/- 1.7°C (35°F) from -80° to 30°C (112° to 36°F)

3.4.2 Shall have a temperature resolution of 0.1°C over the full temperature measurement range.

3.4.3 Shall have a data sampling interval programmable from 10 seconds up to a maximum of 2 hours for standard devices, and a maximum of 15min for dry ice devices.

3.4.4 Shall have a maximum recording period of 30 days.

3.4.5 Shall have a start-up delay that can be set at a minimum of 0 seconds, up to maximum 194 days for standard devices and a maximum of 10 days for dry ice devices.

3.4.6 Shall have a manual or automatic launch start up option.

3.4.7 Shall have the ability to display the following sets of data (in both Celsius and Fahrenheit):

- Start icon
- Stop icon
- Alarm icon
- Current temperature reading
- High temperature and time
- Low temperature and time
- Average temperature and time

3.4.8 Shall have the ability to create a marked event date stamp.

3.5 Instructions for use. Shall be supplied with detailed instructions for use.

3.6 Warranty. Shall have a minimum one-year limited warranty.

3.7 Hardware/Software requirements.

3.7.1 Shall be compatible with the Government's current hardware/software infrastructure (TempTale Manager Desktop (TTMD) Software and Interface Plus optical communications hardware). As an alternate, the Contractor shall provide the required number of hardware/software units to replace the current infrastructure, as determined by the Government.

3.7.2 Hardware shall be a non-USB connection device, or something comparable, that does not require a USB connection for installation or functionality.

### 3.8 Recycling.

3.8.1 Used monitors shall be recycled at no cost to the Government. All shipping costs incurred shall be paid by the contractor. The contractor shall develop a procedure including instructions/shipping information to return used monitors for recycling; a copy of the procedure shall be provided to the Government prior to award.

3.8.2 The contractor shall also provide a pre-paid pre-addressed shipping label with each monitor; as an alternate, the contractor may provide the complete address for return of the monitor, together with the name/account number of the carrier to be used.

3.9 Workmanship. Workmanship shall be first class throughout. The temperature monitoring device shall be free from defects which detract from its appearance or impair its serviceability.

## 4. REGULATORY REQUIREMENTS

4.1 Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder. 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 requirements of all other applicable Federal, State, and local statutes, ordinances, and regulations.

4.2 Recovered materials. The offeror/contractor is encouraged to use recovered materials in accordance with the Federal Acquisition Regulation (FAR) Subpart 23.403 to the maximum extent practical.

## 5. QUALITY ASSURANCE PROVISIONS

5.1 Product conformance. The products provided shall meet the salient characteristics of this specification sheet, conform to the producer's own drawings, specifications, standards, and quality assurance practices, and be the same product offered for sale in the commercial market. 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.

5.2 Bid sample. The company producing the item shall provide a sample of the item it is bidding on for evaluation to the contracting officer. The government technical evaluation team shall take appropriate action to determine if the sample provided meets the requirements of this specification. Pending approval of the bid sample, acquisition of materials, components, or commencement of production is at the sole risk of the contractor.

5.3 Inspection. Inspection, as used herein, is defined as examination, such as visual or auditory investigation without the use of special laboratory appliances or procedures.

5.4 Quality conformance inspection. Quality conformance inspection shall include the

examination and the review of contractor tests specified herein.

5.5 Certificates of quality. Certificates of quality, supplied by the manufacturer of the materials, may be furnished in lieu of actual performance of such testing by the contractor, provided lot identity has been maintained and can be demonstrated to the Government. The certificate shall include the name of the contractor, the contract number, the name of the manufacturer or supplier, the catalog number, the NSN (when applicable), the item identification, the name of the component/material, the lot number and the lot size.

5.6 Tests. Tests shall be conducted by the contractor to determine compliance with specification requirements. Testing results/documentation (or certificates of quality, as specified in 5.6) showing specification compliance in the following areas shall be submitted with the Bid Sample.

5.6.1 Shall be tested in accordance with applicable NEMA standards to insure the water- resistant casing of the unit has a NEMA rating of 6 (see 3.1).

5.6.2 Shall be 3-point tested in accordance with, and shall be traceable to, applicable NIST standards (see 3.3.2).

5.6.3 Shall be tested in accordance with the EMC directive (see 3.3.3.1).

5.7 Manufacturing facility. The contractor's manufacturing facility shall be ISO 9001:2000 certified. The Government reserves the right to require proof of such certification prior to first delivery and thereafter as may be otherwise provided for under the provisions of the contract.

5.8 Contractor certification. The contractor shall certify that the product offered meets the salient characteristics of this specification sheet and conforms to the producer's 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.

5.10 Metric products. Products manufactured to metric dimensions will be considered on an equal basis with those manufactured using inch-pound units. Dimensions and tolerances specified shall be converted using conversion tables contained in the latest revision of IEEE/ASTM SI-10. If a product is manufactured to metric dimensions and those dimensions exceed the tolerances specified in the inch-pound units, a request should be submitted to the contracting officer to determine if the product is acceptable. The contracting officer has the option of accepting or rejecting the product.

5.11 Packaging inspection. The inspection of the unit package, packing and marking for shipment and storage shall be in accordance with quality assurance provisions of the applicable container specification and marking requirements of MIL-STD-129.

5.12 Other quality assurance provisions. Shall meet all quality assurance provisions of the contract and/or purchase order.

## 6. PACKAGING

6.1 Packaging shall be in accordance with the requirements of ASTM D 3951 and as specified herein.

6.2 Preservation. Preservation shall be commercial.

6.2.1 Unit. Each (EA). One temperature monitoring device, as specified, constitutes one unit of issue. Each temperature monitoring device shall be packaged in a suitable, sealed commercial container. The following documentation shall accompany **each** temperature monitoring device:

6.2.1.1 National Institute of Standards and Technology (NIST) validation certificate (see 3.3.2).

6.2.1.2 Detailed instructions for use (see 3.5).

6.2.1.3 Instructions for return of used monitors for recycling (see 3.8).

6.2.2 Intermediate package. Intermediate package may be supplied at the option of the contractor.

6.3 Packing. Packing shall be commercial.

6.3.1 Exterior (shipping) container. Quantities of units to be supplied in the exterior (shipping) container shall be at the option of the contractor.

6.3.2 Unitization. Material shall be unitized as specified in the contract or order.

6.4 Marking.

6.4.1 Unit. Each unit shall be marked in accordance with commercial practice. Marking shall include the catalog number, National Stock Number (NSN), when applicable, and quantity and unit of issue.

6.4.2 Intermediate package (if supplied), exterior (shipping) container and unitized load. Each intermediate package (if supplied), exterior (shipping) container and unitized load shall be marked as specified in MIL-STD-129.

6.4.3 Warranty markings. In addition to marking as specified, warranty markings shall be applied to each container.

## 7. NOTES

7.1 Ordering data. Acquisition documents will specify the following:

- Title, number and date of this document.
- Catalog number and/or NSN (when applicable).

- Monitor type, label color, and pre-programming requirements (i.e. alarm settings, sampling interval, recording period, and start-up delay).

## 7.2 Sources of referenced documents.

### 7.2.1 Government documents.

7.2.1.1 For use in meeting salient characteristics, the following Regulation is available at <http://www.dsc.dla.mil/Offices/packaging/medical.asp>:

DLAR 4145.21 – Preparation of Medical Temperature-Sensitive Products  
Requiring Freeze or Refrigerated (Chill) Environments for Shipment

Attachment 1 – Packaging Protocols for Medical Temperature Sensitive Products  
Requiring Storage Temperatures between 2°C – 8°C (36°F – 46°F)