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MARCH 7, 1956

SUPERSEDING
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FEDERAL SPECIFICATION

INHALATOR, OXYGEN (DEMAND)

This specification was approved by the Commissioner, Federal Supply Service, General Services Administration, for the use of all Federal agencies.

1. SCOPE AND CLASSIFICATION

1.1 Scope. — This specification shall cover demand inhalators for the administration of 100 percent pure oxygen or prepared mixtures of oxygen and carbon dioxide or oxygen and helium.

1.2 Classification.

1.2.1 *Types and styles.*—The inhalators shall be of the following types and styles, as specified in the invitation for bid:

Type I.—Inhalator, single, one mask.
- Style A.—Inhalator for use with cylinder supplied oxygen, oxygen and carbon dioxide or oxygen and helium.
- Style B.—Inhalator for use with wall-outlet from central oxygen supply.

Type II.—Inhalator, multiple, two mask.
- Style A.—Inhalator for use with cylinder supplied oxygen, oxygen and carbon dioxide or oxygen and helium.

2. APPLICABLE SPECIFICATIONS, STANDARDS, AND OTHER PUBLICATIONS

2.1 Specifications.—There are no other specifications applicable to this specification.

2.2 Standards.—The following standard, of the issue in effect on date of invitation for bids, forms a part of this specification:

Federal Test Method Standard:

No. 601—Rubber: Sampling and Testing.

(Activities outside the Federal Government may obtain copies of Federal Specifications and Standards as outlined under General Information in the Index of Federal Specifications and Standards and at the prices indicated in the Index. The Index, which includes cumulative monthly supplements as issued, is for sale on a subscription basis by the Superintendent of Documents, U. S. Government Printing Office, Washington 25, D. C.

(Single copies of this specification and other product specifications required by activities outside the Federal Government for bidding purposes are available without charge at the General Services Administration Regional Offices in Boston, New York, Atlanta, Chicago, Kansas City, Mo., Dallas, Denver, San Francisco, Los Angeles, Seattle, and Washington, D. C.

(Federal Government activities may obtain copies of Federal Specifications and Standards and the Index of Federal Specifications and Standards from established distribution points in their agencies.)

2.3 Other publications.—The following publications of the issues in effect on date of invitation for bids, form a part of this specification:

Underwriters' Laboratories Inc., Standards:

Subject No. 404—Standard for High-Pressure Gas Gauges.

UL–407—Standard for High-Pressure Gas Manifolds.

UL–252–(c)—Standard for Pressure Regulators or Reducing Valves.

(Copies of Underwriters' Laboratories, Inc., Standards may be obtained from the Underwriters' Laboratories, Inc., 161 Sixth Avenue, New York 13, N. Y.; 207 East Ohio Street, Chicago 11, Ill.; or 1655 Scott Lane, Santa Clara, California.)

362248—56—No. 220

American Standards Association Publication:

B57.1–1953—Compressed Gas Cylinder Valve Outlet and Inlet Connections (CGA–V–1).

(Standards of the American Standards Association are published by the American Standards Association, 70 East Forty-fifth Street, New York 17, New York.)

3. REQUIREMENTS

3.1 Fire and casualty hazards.—The bidder shall submit to the contracting agency proof that the gas gauges, gas manifolds, pressure regulators and reducing valves he proposes to supply under this specification conform to the standards of Underwriters' Laboratories, Inc., as regards fire and casualty hazards. The label or listing of the Underwriters' Laboratories, Inc., will be accepted as evidence that the inhalators conform with this requirement. In lieu of the label or listing, the bidder may submit independent proof satisfactory to the contracting agency, that his inhalators conform to the published standards, including methods of test of the Underwriters' Laboratories, Inc. Compliance with the above requirements as regards fire and casualty hazards does not absolve the bidder from complete compliance with the other requirements of this specification in order to secure acceptance of his inhalators.

3.2 Materials. — All parts entering into the construction of any components of the inhalators covered by this specification shall be manufactured from materials which are entirely satisfactory for the purpose and of sufficient strength and durability to maintain operational efficiency for the life of the equipment.

3.3 Inhalator, demand oxygen, type I, style A.—The equipment consists of an oronasal mask connected through a flexible breathing tube to a "Demand type" oxygen flow control regulator which is connected through a pressure-reducing device to a source of compressed oxygen. The mask may be secured by means of the head straps furnished, or it may be held in place manually. No adjustments of pressure or flow shall be required.

3.3.1 *Mask.*—The mask shall be formed from flexible molded rubber, plastic, or other suitable material and shall be of such form that a comfortable fit is obtained when worn by a person of normal features. Each mask shall be equipped with a suitable head harness of elastic material for retaining the mask on the face.

3.3.1.1 *Exhalation valve.* — The mask shall be equipped with exhalation valve or valves which shall be normally closed to prevent inhalation of ambient air, but shall open to allow exhalation at a pressure of not more than 6 mm. of water and permit exhalation at the rate of 85 LPM at a pressure of not more than 25 mm. of water.

3.3.2 *Breathing tube.* — The breathing tube through which oxygen is conveyed to the mask shall be of the pleated extensible type, offering the greatest flexibility compatible with minimal resistance to flow. The tube shall have a normal length of not less than 27 inches. The breathing tube shall be secured to the mask and to the demand regulator by positive type clamps.

3.3.3 *Demand regulator.*—The demand regulator shall consist of a suitable casing or housing, an admission valve, a membraniform diaphragm with a suitable cover, and a safety valve in the breathing system. The admission valve shall be normally closed, allowing no flow of oxygen from the regulator except when the valve is actuated.

3.3.3.1 The membraniform diaphragm shall be formed of suitable flexible material of a type which will retain elasticity and flexibility and is not subjected to deterioration when exposed to oxygen or a mixture of oxygen, carbon dioxide, or oxygen and helium. The diaphragm shall be so disposed as to be responsive to any change of pressure within the mask. A reduction of pressure within the mask shall cause the diaphragm to move inward, thereby actuating the admission valve and allowing oxygen to flow to the mask. The magnitude of diaphragm movement shall be proportional to the reduction in pressure, so that the rate of flow of oxygen to the mask is controlled entirely by the depth of inspiration of the subject and the ventilation rate is governed by the natural respiratory rate and tidal volume of the subject. There must be no interference with,

nor any tendency to influence, the natural respiratory cycle. A reduction in pressure of less than 1 cm. H_2O below atmospheric shall be sufficient to actuate the admission valve initiating a flow of oxygen. A negative pressure of 1.3 cm. H_2O shall cause a flow of not less than 50 LPM. Immediately on cessation of inspiration, the diaphragm shall return to its normal position, the valve shall close, and the flow of oxygen cease. No positive pressure shall be required to stop the flow of oxygen.

3.3.3.2 *Auxiliary flow provision.*—An auxiliary flow device shall be incorporated into the demand regulator to be used whenever the use of oxygen under a slight positive pressure is indicated. The auxiliary flow control shall consist of a button on the demand regulator. Manual depression of the button shall cause a calibrated coil or leaf-spring to bear against the diaphragm, thereby opening the admission valve and allowing oxygen to flow until the pressure underneath the diaphragm is sufficient to overcome the resistance of the leaf-spring, at which time the admission valve will close and the flow of oxygen cease. The positive pressure transmitted to the mask shall not exceed the relief pressure of the mask exhalation valve. With the mask properly fitted to the patient's face, the flow of oxygen should cease on expiration. Releasing the auxiliary flow control button shall automatically restore the demand regulator performance as outlined in 3.3.3 and 3.3.3.1.

3.3.3.3 *Safety valve.* — A "Safety Valve" shall be mounted in the breathing system. This valve shall open if the pressure within the breathing system at any time becomes lower than 1.8 cm. H_2O below atmospheric. The opening of the valve shall admit ambient air to the mask. Thus, any failure of the oxygen supply will result only in the cessation of oxygen therapy and in a slight increase in inhalation resistance. This valve shall close instantly on cessation of inspiration and expired air shall be expelled through the mask exhalation valve or valves.

3.3.3.4 *Pressure reducing regulator.* — The pressure reducing regulator shall be of a single or multiple stage type as specified in the invitation for bids and be equipped with a cylinder pressure gauge calibrated from 0 to 3000 p.s.i. with a suitable means of relieving excessive pressure. The inlet of the regulator shall be equipped with a standard oxygen coupling, 0.903 inches 14 NGO—RH—EXT female thread, in accordance with Compressed Gas Association Standard No. 540 (ASA B57.1–1953). A renewable filter element comprising spun glass, sintered metal or other equivalent material shall be interposed between the coupling and the regulator. The outlet of the regulator shall be a standard oxygen connection.

3.3.4 *Oxygen-supply hose.*—If flexible breathing tube (3.3.2) is 6 feet or more in length, no oxygen-supply hose need be furnished. The oxygen-supply hose shall be of natural or synthetic rubber and shall be capable of withstanding a pressure of 150 p.s.i. The hose shall be of such length that in combination with the flexible breathing tube the total length of tubing between the oxygen cylinder and the face mask shall be not less than 6 feet. The hose shall be equipped with standard medical oxygen couplings $\frac{9}{16}$—18 thread, male on one end and female (swivel nut) on the other end.

3.4 Inhalator, demand, oxygen, type I, style B, wall-outlet type one mask.—Shall not include pressure reducing device referred to in paragraph 3.3; pressure reducing regulator referred to in 3.3.3.4 or oxygen-supply hose in paragraph 3.3.4. All other parts of equipment to be the same. Also in lieu of parts omitted above, furnish a suitable wall-outlet male fitting as described in 3.4.1.

3.4.1 *Oxygen-supply hose with wall-outlet fitting.*—The oxygen-supply hose shall be made of natural or synthetic rubber, reinforced to safely withstand an internal pressure of 150 p.s.i. and shall be not more than $\frac{5}{8}$ inch O.D. This hose shall be of such length that in combination with the flexible breathing tube, the total length of tubing between the oxygen connection and the facemask shall be not less than 6 feet. The hose shall be furnished with a standard male oxygen coupling $\frac{9}{16}$ inch, 18 threads per inch on one end. The opposite end of the demand regulator shall be fitted with a Connector, Quick, Cou-

pling, Female, and Valve Assembly, Oxygen, ordering office to specify make, style, and manufacturer's name of female and valve assembly installation on oxygen wall inlet.

3.5 Inhalator, demand oxygen type II.— The equipment shall consist of that described in 3.3 through 3.3.4 with a manifold, duplex adapter, and extra mask, breathing tube, and oxygen-supply hose.

3.5.1 *Manifold.* — The manifold shall be of such form and construction that the pressure reducing regulator may be attached thereto, and one or two standard medical oxygen cylinders of the size and style known as "Type D" may be connected and securely attached to the manifold. Check valves in the manifold shall permit either cylinder to be removed without loss of gas from the other cylinder. No tools shall be required to remove or install cylinders. A handle shall be incorporated to permit carrying the equipment.

3.5.2 *Duplex adapter.*—The duplex adapter shall comprise a tee-coupling having one $^{9}/_{16}$—18 female (swivel) nut and two $^{9}/_{16}$—18 male threaded connections, whereby two oxygen supply hoses and/or two demand regulators may be connected to one pressure reducing regulator.

3.6 Service data.—The contractor shall enclose with each unit two copies of one or more booklets which contain complete instructions for installation, operation, maintenance, and a list of spare parts. Each part other than common fasteners, etc., shall be identified by the manufacturer's part number.

3.7 Workmanship.—Workmanship shall be first class throughout. Regulators shall be free from defects which detract from their appearance or which may impair their serviceability.

4. SAMPLING, INSPECTION AND TEST PROCEDURES

4.1 Sampling. — Unless otherwise specified, samples shall be submitted in accordance with instructions furnished by the procuring activity.

4.2 Inspection. — Inspection may be made throughout the entire process of manufacture. The passing as satisfactory of any detail of construction or materials shall not relieve the contractor of responsibility for faulty workmanship or materials which may be discovered at any time prior to final acceptance. Final inspection of the finished article shall be made either at point of production or at point of delivery designated in the contract or purchase order of procuring agency. In case of factory inspection, every facility shall be afforded inspectors by the manufacturer, for the prosecution of their work.

4.3 Tests.

4.3.1 *Accelerated aging test.* — Accelerated aging test shall be conducted in accordance with Federal Test Method Standard No. 601, method 7001.

4.3.2 *Tensile strength test.*—Tensile strength shall be conducted in accordance with method specified in Federal Test Method Standard No. 601, method 4001.

4.3.3 *Rubber hydrocarbon by volume.*—Test for rubber hydrocarbon shall be conducted in accordance with Federal Test Method Standard No. 601, method 16111.

4.3.4 *General.* — Other material shall be tested to determine compliance with this specification.

5. PREPARATION FOR DELIVERY

5.1 Packaging.—Unless otherwise specified, commercial packages are acceptable.

5.2 Packing.—Unless otherwise specified, the inhalators shall be delivered in standard commercial containers so constructed as to permit acceptance by common or other carrier for safe transportation at the lowest rate to point of delivery.

5.3 Marking.

5.3.1 *Individual packages.*—Unless otherwise specified, each interior package shall be marked with the name of the material, the specification number, quantity contained therein, name of the manufacturer, and the number of the contract or order.

5.3.2 *Shipping containers.*—Unless otherwise specified, shipping containers shall be marked with name of item, type and style, as defined by the contract or order under which shipment is made, the name of the contractor and the number of the contract or order.

6. NOTES

6.1 Ordering data. — Invitations for bids should specify type and style and purchasers should exercise any desired options offered herein (see 1.2.1, 4.1, 5.1, 5.2 and 5.3).

6.2 It is believed that this specification adequately describes the characteristics necessary to secure the desired material, and that normally no samples will be required prior to award to determine conformance to the requirements of this specification. If, for any particular purpose, samples with bids are necessary, they should be specifically asked for in the invitation for bids, and the particular purpose to be served by the bid sample, should be definitely stated, the specification to apply in all other respects.

6.3 Federal specifications do not include all types, classes, grades, sizes, etc., of the commodities indicated by the titles of the specification, or which are commercially available, but are intended to cover the types, etc., which are suited for Federal Government requirements.

6.4 Transportation description.—Transportation description applicable to this item is:

Oxygen administering apparatus

Carload minimum weight 12,000 pounds, subject to Rule 34, Uniform Freight Classification.

Truckload minimum weight 12,000 pounds.

Patent notice.—When Government drawings, specifications, or other data are used for any purpose other than in connection with a definitely related Government procurement operation, the United States Government *thereby incurs no responsibility nor any obligation* whatsoever; and the fact that the Government may have formulated, furnished, or in any way supplied the said drawings, specifications, or other data, is not to be regarded by implication or otherwise as in any manner licensing the holder or any other person or corporation, or conveying any rights or permission to manufacture, use, or sell any patented invention that may in any way be related thereto.