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An American National Standard

Standard Specification for Medical and Surgical Suction and Drainage Systems¹

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This standard has been approved for use by agencies of the Department of Defense.

1. Scope

1.1 This specification describes minimum safety and performance requirements for medical and surgical suction and drainage apparatus.

1.2 This specification covers apparatus to be used for:

- 1.2.1 Oral, nasal, tracheal (ONT) suction,
- 1.2.2 Gastrointestinal drainage,
- 1.2.3 Pleural space and mediastinal drainage,
- 1.2.4 Closed wound drainage, and
- 1.2.5 Surgical suction (including uterine aspiration).

1.2.6 This specification also covers devices powered by centrally piped vacuum systems, compressed gases, electricity, and manual operation.

1.3 This specification does not cover the following:

- 1.3.1 Central vacuum pumps and piping systems of vehicles and buildings,
- 1.3.2 Catheters, tubes, drains, curettes, and suction tips inserted into the patient,
- 1.3.3 Syringes,
- 1.3.4 Breast pumps,
- 1.3.5 General dentistry suction equipment,
- 1.3.6 Waste gas scavenging systems,
- 1.3.7 Laboratory suction,
- 1.3.8 Fetal vacuum extractor or vacuum forceps with self-contained suction,
- 1.3.9 Autotransfusion,
- 1.3.10 Cardiopulmonary bypass pumps, and
- 1.3.11 Urinary drainage.

1.4 The following precautionary caveat pertains only to the test method portion, Section 5, of this specification: *This standard does not purport to address all of the safety problems, if any, associated with its use. It is the responsibility of the user of this standard to consult and establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.* See 5.3.3.

2. Terminology

2.1 Definitions of Terms Specific to This Standard:

¹ This specification is under the jurisdiction of ASTM Committee F29 on Anesthetic and Respiratory Equipment and is the direct responsibility of Subcommittee F29.17 on Medical Surgical Suction and Drainage.

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2.1.1 *aspiration*—the withdrawal, by means of suction, of fluids or friable tissue.

2.1.2 *collection vessel assembly*—a container whose primary function is to collect liquids.

2.1.3 *disclosure*—information on performance and test methods to be made available by manufacturers.

2.1.4 *drainage*—the removal of fluids from a body cavity or wound by a process utilizing gravity; drainage may be assisted by the application of vacuum.

2.1.5 *filter*—a device for reducing airborne particulate matter.

2.1.6 *flow-direction sensitivity*—performance is dependent on the direction of fluid flow.

2.1.7 *free air flow*—the flow of air into a vacuum source when its inlet is open to atmosphere.

2.1.8 *gastrointestinal drainage*—the removal of gastrointestinal contents, consisting of fluids and solid particles, by means of an indwelling tube which may be supplemented by gravity siphon or by vacuum.

2.1.9 *graduation indicators*—visible means of displaying measurement increments.

2.1.10 *inlet*—the port of a component into which fluid enters under use conditions.

2.1.11 *mediastinal drainage*—the removal of fluids from the mediastinum which may be supplemented by vacuum.

2.1.12 *outlet*—the port of a component from which fluid exits in normal use.

2.1.13 *patient connection*—the point at which the suction catheter, curette, or drainage tube inserted into the patient is attached to the suction system.

2.1.14 *pleural drainage*—the removal of fluids from the pleural space, maintaining a relatively constant partial vacuum within that space.

2.1.15 *regulator*—a device, which may be adjustable, that limits vacuum to a predetermined level.

2.1.16 *reprocessing*—preparation for reuse.

2.1.17 *shutoff mechanism*—a device designed to avoid overflow of suctioned material.

2.1.18 *stand-alone component*—a device which is not an integral part of any other component of the suction system.

2.1.19 *static vacuum*—the vacuum level without fluid movement.



2.1.20 *suction*—the removal of fluids or solids by the application of vacuum.

2.1.21 *suction system*—a series of components, devices, or assemblies which may include tubing, connectors, filters, collection vessels, shutoff mechanisms, regulators, portable pumps, safety overflow traps, and gages, beginning at the point of connection with the patient.

2.1.22 *vacuum*—a pressure less than atmospheric pressure.

2.1.23 *wound drainage*—the removal of fluids from a wound; removal may be supplemented by vacuum.

3. General Requirements

3.1 *Shutoff Mechanisms*—A suction or vacuum-assisted drainage system shall incorporate a shutoff mechanism which may stand alone or may be an integral part of a component of the system, unless the system is intended to continue operating after invasion or overflow of aspirated liquids and solids.

3.2 *Tubing Considerations*—Tubing used in suction and drainage systems should be kept as short as practical and should be arranged to minimize loops and drapes which can accumulate liquid and increase the potential for occlusion from pinching and kinks. Tubing diameter influences the total system resistance (see Appendix X1).

3.3 *Liquid Connections*—The connections which conduct liquids should be designed to minimize occlusion.

3.4 *Stand Alone Suction Tubing Connectors*:

3.4.1 *Lumen Size and Characteristics*—The size of stand alone suction tubing connector lumen chosen should not be less than 80 % of the nominal inside diameter of the suction tubing or 5 mm, whichever is greater. Internal passageways should be smooth. This requirement does not apply to wound and gastrointestinal drainage systems.

4. Performance Requirements

4.1 *Shutoff Mechanism Performance*—The shutoff mechanism shall not pass more than 5 mL of water distal to the shutoff mechanism. If the shutoff mechanism is integral to a collection vessel, it shall not activate before 90 % of the stated useable collection capacity of the system is reached.

4.2 *Electric Conductivity*—All components labeled conductive shall have a resistance not greater than 1 MΩ.

4.3 *System Performance*—When assembling the components of a suction or drainage system, the user should consider the flow resistance characteristics of the components in series and ensure that the system has the necessary performance characteristics for the suction procedure (see Appendix X2). The user should consider whether the system performance will be compromised by the use of a Y-piece or other multiport connector.

4.3.1 *Maximum Pleural Drainage System Pressure*—Pleural drainage systems shall not develop a pressure in excess of +10 cm H₂O at the patient inlet, at a flow of 10 L/min. If the pleural drainage system requires periodic adjustment to prevent intrapleural pressures above 10 cm H₂O, this shall be stated in the labeling.

4.3.2 *Leakage*—The leakage of a suction or drainage system is affected by the leaks of its components. Therefore, individual components shall not exceed their respective allow-

able leakage rates. Pumps and regulators are excluded (see 4.4 and 4.6.1.2).

4.3.3 *Resistance to Implosion*—If the collection vessel assembly will not resist loss of integrity and implosion at an applied vacuum of 690 mm Hg (27 in. Hg) for suction vessels, and at 200 cm H₂O (147 mm Hg) applied vacuum for pleural and mediastinal drainage vessels, labeling shall state the maximum vacuum the collection vessel assembly will withstand. This requirement does not apply to wound drainage.

4.4 *Vessel Air Leak Capacity*:

4.4.1 *Suction Collection Vessels*—The maximum leak rate of suction collection vessels shall be less than 10 bubbles in 10 s (approximately 13 mL/min) when exposed to a vacuum level of 300 mm Hg.

4.4.2 *Closed-Wound Drainage Vessels*—Closed-wound drainage vessels shall not lose more than 20 % of their maximum capacity after 2 h.

4.4.3 *Pleural Drainage Collection Vessels*—Pleural drainage collection vessels should not leak between the patient and the underwater seal (or one-way valve, if used).

4.5 *Indicator Performance*:

4.5.1 *Accuracy of Indicators*—Indicators shall be accurate to within ±10 % of full-scale calibration. The graduation increments of the indicator should not be less than the accuracy of the indicating device.

4.5.2 *Stability*—The regulator reading shall return to its original setting within ±10 % of full scale when the flow is cycled off and on.

4.6 *Tubing Performance*:

4.6.1 *If Connectors are Permanently Attached to Suction, Pleural, and Mediastinal Drainage Tubing*:

4.6.1.1 *Inside Diameter (ID)*—The smallest inside diameter of the connector shall not be less than 80 % of the nominal ID of the tubing, or 5 mm, whichever is greater.

4.6.1.2 *Integrity of Connector Attachment*—For connectors which are formed (molded) separately and subsequently attached to the tube, the bond shall be sufficiently strong to withstand a pull of 24.5 N (5.5 lbf) for 10 min and not exceed the leakage requirement of less than 10 bubbles in 10 s (approximately 13 mL/min) when exposed to a vacuum of 300 mm Hg. Tubing intended for use with drainage systems should not leak.

4.6.1.3 *Resistance to Collapse*—Tubing shall retain at least 50 % of its outside diameter throughout its length for at least 5 min when subjected to the disclosed vacuum (6.6.2).

4.6.1.4 *Connector Strength*—Connectors should resist collapse under normal use conditions.

4.6.2 *Flexibility*—Tubing should be flexible to permit bending and positioning and to reduce strain on connections.

4.6.3 *Translucency*—Tubing should be sufficiently translucent to permit observation of the contents.

4.7 *Filtering Device Performance (If used in a suction system)*:

4.7.1 *Filtering Device Integrity*—The filtering device shall maintain integrity of housing, if present, and filter medium when subjected to the flow and vacuum tests in 5.7.1.

5. Test Methods

5.1 *Shutoff Mechanism*—Connect the shutoff mechanism





the system in accordance with the manufacturer's instructions. Suction (draw) room temperature water into the system until the shutoff mechanism is activated. Measure the volume of water which passed the shutoff. Measure the volume collected in the vessel if the shut-off mechanism is an integral part of a vessel.

5.2 *Electric Conductivity*—Measure the electrical resistance of the component between inlet and outlet with an ohm meter. Resistance shall not be greater than 1 MΩ.

5.3 System Performance:

5.3.1 *Maximum Pleural Drainage System Pressure*—Attach the patient end of the pleural drainage system set up for normal operation in accordance with manufacturer's recommendations, to a pressure source adjusted to produce a flow of 10 L/min and measure the pressure at that point (Fig. 1).

5.3.1.1 *Reprocessing of Reuseable Components*—Reprocess the component as recommended and assure that the manufacturer's stated performance is not impaired. Check the labeling for conformance.

5.3.2 *Leakage*—The leakage of the system is affected by the leaks of its components. See 5.4 and 5.6.1.2.

5.3.3 *Resistance to Implosion*—Place the collection vessel in a protective enclosure, that is, a box, bag, etc. Attach a vacuum source to the collection vessel outlet and occlude all other collection vessel openings. Evacuate suction collection vessels to not less than 690 mm Hg (27 in. Hg) vacuum; pleural or mediastinal drainage collection vessels to 200 cm H₂O (147 mm Hg), or to the manufacturer's labeled maximum vacuum. Hold vacuum for 5 min. Release vacuum. Repeat cycle once (see Fig. 2). **Warning**—This test can be hazardous and proper care should be taken to protect personnel from possible flying debris.

5.3.3.1 *Graduation Indicator Accuracy*—The accuracy of the collection vessel graduation indicators shall be tested by filling the vessel with a premeasured amount of liquid and checking the volume indication to be within the disclosed accuracy.

5.4 Vessel Air Leak Capacity Tests:

5.4.1 *Suction Collection Vessels*—Set the regulator to 300 mm Hg. Open the valve and allow test component to reach the set vacuum. Close valve. Observe water bottle for bubbles. The test is passed if no more than 9 bubbles are observed in 10 s.

5.4.2 Closed-Wound Drainage Vessels:

5.4.2.1 Activate the vacuum in accordance with manufacturer's instructions.

5.4.2.2 Cap or plug all ports tightly.

5.4.2.3 Allow 2 h to elapse. Avoid excessive temperature fluctuations.

5.4.2.4 Place the unit in a water bath so that the patient port

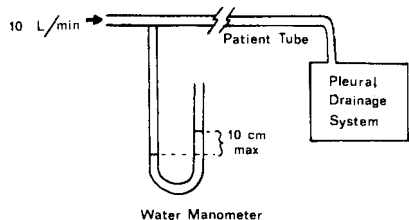


FIG. 1 Typical Test Setup for Evaluating Pleural Drainage System Performance

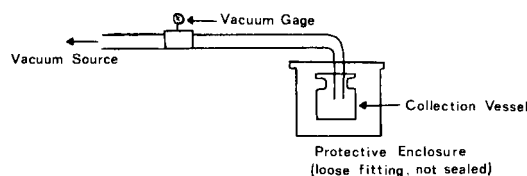


FIG. 2 Suction and Drainage Collection Vessel Assembly

is immersed approximately 2 cm deep.

5.4.2.5 Open the cap of the patient port and allow water to enter the vessel until the vacuum is spent.

5.4.2.6 Remove from bath and expel all the aspirated water into a graduated cylinder to measure the residual capacity.

5.4.2.7 Reactivate the vessel and seal all ports.

5.4.2.8 Repeat the residual capacity determination of the vessel immediately after activation. This is the maximum capacity.

5.4.2.9 The capacity remaining after 2 h (5.4.2.6) shall be at least 80 % of the maximum capacity (5.4.2.8).

5.5 Indicators and Suction Regulators:

5.5.1 *Accuracy of Indicators*—Check accuracy of the indicator against a mercury or water column as appropriate for the device.

5.5.2 *Stability*—Set regulator at 50 % of the maximum setting at any vacuum level with the inlet occluded. Open and close the inlet several times and observe that the vacuum indicator returns to the set value with ± 10 % of full-scale calibration.

5.5.3 *Vacuum Indicator (gauge)*—Check the markings for conformance.

5.5.4 *Vacuum Control Mechanism*—Attach the vacuum source, occlude inlet, and observe that adjusting the vacuum control mechanism in the indicated direction will change the level of vacuum in that direction.

5.5.5 *Operation and Repair Manual for Regulators*—Check the manual for conformance.

5.6 Tubing:

5.6.1 *Connectors Permanently Attached to Suction, Pleural, and Mediastinal Drainage Tubing:*

5.6.1.1 *Inside Diameter*—Direct measurement.

5.6.1.2 *Integrity of Connector Attachment*—Securely plug one end of the tube and attach the other connector to the set up of Fig. 3. Apply a 2.5-kg weight to the vertically suspended tube. After 10 min, with the weight attached, test for air leaks in accordance with the test in 5.4.

5.6.1.3 *Resistance to Collapse Under Vacuum*—At 20 to 25°C, uncoil the test specimen to its full length and plug one end to prevent any air flow through the tube. Attach a vacuum source to the other end of the tube and adjust the level of vacuum to the disclosed maximum (see Fig. 4). The specimen passes the test if the tube retains at least 50 % of the nominal diameter throughout its length for at least 5 min. The calculation of the degree of collapse may be determined by measurements performed on the outside diameter, as illustrated in Fig. 5.

5.7 Filtering Devices (If used in a suction system):

5.7.1 *Filtering Device Integrity*—Attach by tubing, the filtering device to a regulated vacuum source and occlude the inlet of the filtering device. Apply 300 mm Hg vacuum to