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Standard Performance and Safety Specification for Cryosurgical Medical Instruments[1]

This standard is issued under the fixed designation F 882; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

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

INTRODUCTION

This performance and safety specification was developed by Task Force F04.08 on Cryosurgical Medical Instruments.

This specification is intended to provide the user of Cryosurgical Medical Instruments with the assurance that the equipment will meet or exceed all safety and performance levels established by this document as claimed by the manufacturer. This is predicated on the requirements that the equipment is operated according to the manufacturer's recommendations.

Since, in the pursuit of improved health care and reduced medical costs, the medical industry is required to be innovative and dynamic, this standard must be capable of being upgraded in a swift and efficient manner. All inquiries regarding this standard should be addressed to: Committee F-4 Staff Manager, ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428.

1. Scope

1.1 This specification covers standards a manufacturer shall meet in the designing, manufacturing, testing, labeling, and documenting of cryosurgical medical instruments, but it is not to be construed as production methods, quality control techniques, or manufacturer's lot release criteria, or clinical recommendations.

1.2 This specification represents the best currently available test procedures at this time and is a minimum safety and performance standard.

1.3 This specification covers only those cryosurgical devices intended for use on humans or animals for therapeutic purposes. This specification assumes the user is well-trained in the procedures of cryosurgery and has the ability to determine if an abnormality is treatable by cryosurgery, particularly by the type of equipment to be used.

1.4 Cryosurgical medical instruments produce low temperatures either inside a cryoprobe or directly on the target tissue by the principle of Latent Heat of Vaporization or the Joule-Thompson Effect, or both. The cryogen may be transported from the source as a liquid or a gas. These systems may be closed or open depending on the application and cryogen. In the open cryotip system, the cryogen is applied directly to the target tissue, while in the closed cryotip system, the cryogen is applied indirectly and is exhausted away from the target area.

1.5 Cryosurgical medical instruments are used to produce cryonecrosis, inflammatory response, or cryoadhesion.

1.6 Monitoring the progress of treatment during application is sometimes very important. Such monitoring is done by accessories that indicate the temperature of the cryotip or the target area being frozen. The temperature of the tissue may be measured directly (for example, by a thermocouple). These accessories are also covered by this specification.

1.7 The following precautionary caveat pertains only to the Test Method portion, Sections 8-13, of this specification: *This standard may involve hazardous materials, operations, and equipment. This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ANSI Standard:*

ANSI B40.1-1974 Use and Installation of Pressure Gauges[2]

2.2 *ANSI/AAMI Document:*

ANSI/AAMI SCL 12/78[3]

2.3 *Canadian Standards Association (C.S.A.) Standard:*

C22.2-125 Electromedical Equipment 1973[4]

2.4 *International ElectroTechnical Commission (IEC) Document:*

[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.65 on Medical/Surgical Instruments.

Current edition approved Sept. 11, 1984. Published February 1985.

[2] Available from the American National Standards Institute, 1430 Broadway, New York, NY 10018.

[3] Available from the Association for the Advancement of Medical Instrumentation (AAMI). 1901 North Fort Myer Drive, Suite 602, Arlington, VA 22209.

[4] Available from the Canadian Standards Association (C.S.A), 173 Rexdale Blvd., Rexdale, Ontario M9W 1R3, Canada.

IEC 601-1 1977[5]

2.5 *Compressed Gas Association Document:*

CGA V-1 1977[6]

2.6 *FDA Document:*

21CFR801: Labeling Specifications[7]

2.7 *NBS Document:*

Table IPTS-68 NBS Monograph 125[8]

3. Terminology

3.1 *Definitions:*

3.1.1 *closed cryotip*—a hollow, closed end usually shaped to fit a particular anatomical site where the cryogen cools the external surface which is applied to the target tissue.

3.1.2 *closed cryotip reference temperature*—the average of the minimum/maximum cycle temperature variation at the end of the freeze cycle.

3.1.3 *compressed gas cylinder*—a container that is specifically designed to store a gas or liquid under elevated pressure conditions.

3.1.4 *compressed gas cylinder connector*—a device specifically designed to attach to a cylinder for proper and safe removal of its contents.

3.1.5 *cryoadhesion*—cryotip attachment to target tissue.

3.1.6 *cryogen*—a substance used to obtain reduced temperatures. Cryogens are usually classed by their boiling points. The most common cryogens and their respective boiling points are as follows:

Cryogen	Boiling Point at S.T.P., °C
Freon 12	−29.8
Freon 22	−49.8
Carbon Dioxide (CO_2)	−78.6
Nitrous Oxide (N_2O)	−88.5
Liquid Nitrogen (LN_2)	−195.8

3.1.7 *cryometer*—a device for measuring low temperature(s) when used with a temperature sensor such as a thermocouple.

3.1.8 *cryonecrosis*—destruction of tissue cells using a cryosystem.

3.1.9 *cryoprobe*—the instrument used to deliver the cryogen to the cryotip or open tip. For a cryotip, a cryoprobe also directs the cryogen away from the target tissue.

3.1.10 *cryosystem*—all parts of a system excluding the cryogen and its container, unless supplied by the manufacturer, that is designed to apply or use a cryogen.

3.1.11 *defrost*—the ability to return the cryotip to ambient temperature.

3.1.12 *Dewar*—a vacuum insulated container that is specifically designed to store a liquid cryogen.

3.1.13 *Dewar withdrawal device*—a device specifically designed to attach to a dewar for proper and safe removal of its contents.

3.1.14 *disposable*—any device which is designated to be discarded after use.

3.1.15 *inflammatory response*—irritation of tissue cells as a result of using a cryosystem.

3.1.16 *mechanical integrity*—the ability of all components of a cryosystem to withstand the pressures and temperatures that may be encountered during use as recommended by the manufacturer.

3.1.17 *open cryotip*—a device specifically designed to apply the cryogen directly to the target tissue.

3.1.18 *target tissue*—the specific anatomical area intended to be treated.

3.1.19 *thermal insulation*—a material or technique, or both, used to prevent unintended cryonecrosis, inflammatory responses, or cryoadhesion to nontarget tissue.

3.1.20 *thermocouple*—a junction of two dissimilar metals that produce an output voltage proportional to the temperature of the junction. When used in conjunction with a cryometer(s), the output is directly correlated to the temperature to which the sensing junction is exposed.

3.1.21 *tractive forge*—the cryoadhesive attraction between the cryotip and the target tissue.

3.1.22 *worst case conditions*—the maximum pressures or temperatures, or both, a cryosystem may encounter when used according to the manufacturer's instructions.

4. Conformance

4.1 Presently, this specification is voluntary and not mandated by law. A manufacturer may label his product as conforming to these standards only if the product indeed meets the requirements of this specification.

5. Cryosystem Performance and Reproducibility Requirements

5.1 The purpose of these requirements is to ensure that a cryosystem of the same design or accessories, or both, shall meet the minimum performance and reproducibility requirements as originally designed. The cryosystem and accessory requirements shall not vary from procedure to procedure provided they are used and maintained according to the manufacturer's recommendations.

5.2 *Closed Cryotip Temperature Reproducibility*:

5.2.1 Cryosystem requirements are divided into three primary categories in accordance with their clinical application: cryonecrosis, inflammatory response, and cryoadhesion. The manufacturer's test procedures must be categorized into these groups and tested accordingly.

5.2.2 All cryosystems manufactured with closed cryotips of the same model, temperature sensing or nontemperature sensing, shall meet the requirements of Table 1.

5.2.3 *Test Method*—See Section 11.

5.3 *Closed Cryotip Tractive Force*:

5.3.1 All cryosystems specifically designed for cryoadhesion shall be capable of attaching to, lifting, and holding a minimum weight of 60 g for a minimum of 45 s.

5.3.2 *Test Method*—See Section 12.

5.4 *Monitoring Devices*:

5.4.1 *Cryogen Monitors, Regulators, and Gages*—Cryogen monitors include any instrument, device, or accessory intended

[5] Available from the International Electro-Technical Commission (IEC), Committee 62D, Rue de Varembe, CH-1211, NIOSH, Geneva 20, Switzerland.

[6] Available from the Compressed Gas Association, 500 Fifth Ave., New York, NY 10036.

[7] Available from the Food and Drug Administration (FDA), Bureau of Medical Devices, 8757 Georgia Ave., Silver Spring, MD 20910.

[8] Available from the National Bureau of Standards-Monograph 125, Gaithersburg, MD 10877.

TABLE 1 Time and Temperature Requirements

Manufacturers Specified Intended Use	Freeze Mode Duration	Cryotip Temperature Reproducibility (°C)	
	Time per Cycle (s)	Range 0 to − 100°C	Range − 100.1 to − 200°C
Cryonecrosis	180	±5	±10
Inflammatory Response	30	±5	±10
Cryoadhesion	30	±10	±10

to display or control any cryogen parameter. The cryogen monitors include, but are not limited to, pressure gages, pressure regulators, flow gages, and flow regulators.

5.4.1.1 Pressure gages on all cryosystems shall meet or exceed the ANSI Specification B 40.1.

5.4.1.2 Cryogen monitors shall be compatible with the type of cryogen employed and be of such design and construction to display or control the cryogen safely.

5.4.1.3 The manufacturer shall assure the user that the safety, performance, and reproducibility of a cryosystem will be maintained at the maximum error points of the cryogen monitor(s). See disclosure requirement in 6.2.10.

5.4.2 *Temperature Monitors, Cryotip*—Temperature monitors include, but are not limited to: analog cryometers, digital cryometers, chart recorders. A thermocouple is most commonly used as the temperature sensor.

All cryotip temperature monitor(s) shall be representative of the temperature of the cryotip when tested using the simulated tissue model. The following requirements shall be applied to cryosystems containing cryotip temperature monitors:

Temperature	Range °C
0 to − 100	−100.1 to − 200
±5°	±10°C

5.4.3 *Temperature Monitors, Tissue Temperature*—All cryosystems of accessories with tissue temperature monitors that use an invasive on noninvasive technique to monitor actual tissue temperature shall adhere to the requirements listed in 5.4.2.

6. Disclosure, Labeling, and Documentation Requirements

6.1 These requirements are intended to ensure a manufacturers' written dissemination of all necessary information that allow a user to determine properly a cryosystem's (and its accessories) operation, application, and limitation. These disclosure, labeling, and documentation requirements also ensure clear identification of the product and make available all pertinent data a user may require. A manufacturer may label his product as conforming to this standard only if the product fulfills the requirements of this specification.

6.2 *Disclosures*—A manufacturer shall disclose each specification listed, where applicable.

6.2.1 *Warning Statement*—A manufacturer of a cryosystem shall provide a warning statement to inform the user where contact with the cryosystem may cause user/patient harm. This statement shall appear in the instrument's instruction manual and, if possible, on sections of the instrument that become 0°C or colder.

6.2.2 A cryosystem designed to spray a cryogen onto a target tissue must have a disclosure statement warning the user to provide adequate protection to himself and the patient due to excess or residual cryogen droplets or mist.

6.2.3 A disclosure statement shall be required that states the normal operating pressure at +20°C, the boiling point, and the type of cryogen for which the instrument is designed.

6.2.4 *Sterilization*—A disclosure statement that states exactly what items of the cryosystem and its accessories can be sterilized and the recommended sterilization procedures shall be included with each cryosystem.

6.2.5 *Presterilized Cryosystem*—A disclosure statement shall be included with each presterilized cryosystem. This statement shall include the following information: (*1*) the device is sterile, (*2*) the expiration date of sterilization, and (*3*) notes of caution concerning means of shipping, storage, and use of the instrument.

6.2.6 All a-c powered cryosystems and accessories shall be prominently labeled "Danger-Explosion Hazard. Do Not Use in Presence of Flammable Anesthetics".

6.2.7 *Tissue Temperature Monitors*—The following description and specifications shall be included in the disclosure statement for tissue temperature monitors.

6.2.7.1 Type of cryometer (analog, digital, recorder),

6.2.7.2 Temperature range: minimum to maximum,

6.2.7.3 Type of thermocouple (for example, Type "T"),

6.2.7.4 Temperature limits for storage, shipping, and operation, and

6.2.7.5 Power requirements.

6.2.8 *Cryogen Use, Handling, and Storage*—The manufacturer shall disclose all safety requirements for use, handling, and storage of cryogens as recommended by the cryogen supplier.

6.2.9 *Optimum Operating Pressure*—The optimum operating pressure for each open cryotip shall be disclosed to maximize control and where appropriate minimize liquid run off.

6.2.10 *Cryogen Containers*—The manufacturer shall recommend or supply containers designed for the specific cryogen employed.

6.2.11 *Cryogen Monitors, Regulators and Gages*—A disclosure statement is required stating the recommended operating pressures, the minimum and maximum pressure limits, the optimum cryogen flows, the pressure or flow gage accuracy, and the accuracy and reproducibility of all regulators used in a cryosystem or accessory, where applicable.

6.3 *Labeling*:

6.3.1 All labeling shall be of a size that is legible, in size and color dictated by FDA guidelines, durable to last the life of the cryosystem, and permanently attached so as not to be lost.

6.3.2 All cryosystems shall be labeled so as to contain the following information:

6.3.2.1 Model of cryosystem,

6.3.2.2 Manufacturer's or distributor's name and address,

6.3.2.3 Type(s) of cryogen(s) used,

6.3.2.4 Power requirements,

6.3.2.5 Additional items needed such as water, air, venting, etc.,

6.3.2.6 Serial number or lot and batch number, and

6.3.2.7 Operational instructions.

6.3.3 If labeling is not conducive to direct attachment to the cryosystem, then all information should be provided in the manufacturer's instruction manual or, for disposable cryosystems, the final packaging itself.

6.4 *Documentation*:

6.4.1 All cryosystems shall include instruction manuals.

6.4.2 All instruction manuals for cryosystems shall include the following information, where applicable.

A Brief Theory of Operation
Operating Instructions
Set up
Use
Dismantle
Calibrations
Intended Applications
6.4.2.1 *Specifications—Cryosystem and Cryogen*:
Size
Weight
Type(s) of Cryogen(s) Used
Minimum and Maximum Operation Pressure
Power Requirements
Temperature Control Description
Cryosystem and Cryoprobe Performance Check
Defrost Features
Temperature Sensor
Serviceable Parts
Manufacturer's Recommended Cryogen Containers
Thermal Insulation
Specifications - Cryogen Container
6.4.2.2 *Recommended Withdrawal Devices*:
Type(s) of Cryogen Employed
Size
Weight
Capacity
Static Hold Time: Container Only
Static Hold Time: Container and Withdrawal Device
Optimum and Maximum Operating Pressure
Rating on Pressure Limiting Device
Filling Directions
Serviceable Parts
6.4.3 *Servicing Instructions*:
Trouble-Shooting Chart
Cryogen Flow Chart
Electrical Schematics
User Serviceable Part Numbers
Preventive Maintenance Recommendations
Warranty Information
6.4.4 *Electrical and Cryogen Safety Instructions*:
User Related
Patient Related
6.4.5 *Available Accessories*.

7. Cryosystem Safety Requirements

7.1 These cryosystem safety requirements are intended to protect the user and patient from harm during the use and storage of the cryosystem.

7.2 *Mechanical Integrity*:

7.2.1 The purpose of this requirement is to ensure the user that the cryosystem is capable of withstanding the pressure and temperatures normally encountered during operation.

7.2.2 All related assemblies of new or repaired cryosystems must be able to withstand static overpressure of at least two times the normal operating pressure that the assembly shall encounter. The pressure normally encountered shall be calculated based on the following conditions:

7.2.2.1 A cryosystem that uses a cryogen regulated by the Compressed Gas Association (CGA) shall withstand two times the CGA designated pressure at standard temperature and pressure for that or those specific cryogens.

7.2.2.2 A cryosystem with a pressure limiting device shall withstand two times the pressure of the maximum rating of the device's set operating pressure.

7.2.2.3 A cryosystem without a pressure limiting device shall withstand two times the maximum pressure it can normally encounter under the worst case conditions, (for example, storage and shipping temperature) as specified by the manufacturer.

7.2.3 *Test Method*—See Section 9.

7.3 *Cryogen Exposure*:

7.3.1 The purpose of this requirement is to minimize direct user or patient contact or exposure to the cryogen or to excessive gas concentrations.

7.3.2 *Cryogen Exhaust*—All cryosystems are required to vent the exhausted cryogen in such a manner that the user or patient cannot come into contact with cryogen droplets or mist, or both, under normal operating conditions.

Exception—This requirement does not apply to those cryosystems that spray the cryogen directly onto the target tissue.

7.3.3 *Ambient Concentrations of Nitrous Oxide*—Ambient concentrations of nitrous oxide shall not exceed 25 ppm in accordance with the test procedure. (25 ppm is a recommended level as suggested by NIOSH 77-140. All nitrous oxide cryosystems shall be equipped with a gas collection system that can be conveniently routed for safe disposal. To minimize nitrous oxide exposure, the disposition of the gas collected and exhausted from the system is the responsibility of the user.)

7.3.4 *Test Method*—See Section 10.

7.4 *Thermal Insulation*:

7.4.1 The purpose of this requirement is to prevent accidental injury to both the user and the patient due to contact with the cold sections of a cryosystem.

7.4.2 Where feasible, the manufacturer is responsible for adequate insulation designed into the cryosystem to prevent accidental injury. See disclosure requirement in 6.2.1.

7.5 *Device Sterilization*:

7.5.1 The purpose of this requirement is to inform the user of sterilizing methods suitable for the cryosystem(s).

7.5.2 See disclosure requirement in 6.2.4.

7.6 *Safe Current Limits for Cryosystems*:

7.6.1 The purpose of this requirement is to protect the user or patient from electrical hazard.

7.6.2 All alternating-current (a-c) powered cryosystems shall meet at a minimum, the requirement in Table 2.

7.6.3 Refer to the IEC 601-1 for test procedures.

7.7 *Use in the Presence of Flammable Anesthetics*:

7.7.1 The purpose of this requirement is to eliminate the possibility of explosion due to the ignition of flammable

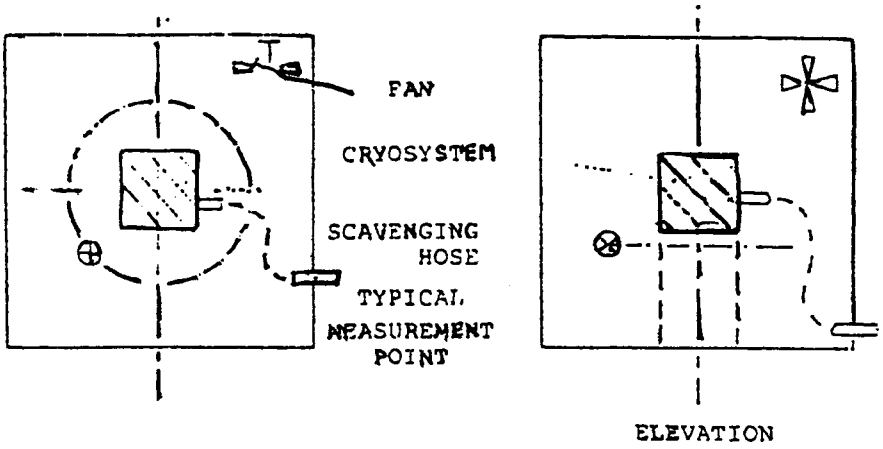


FIG. 1 Standard Test Room
1000 mL of distilled water at 30 ± 2°C. Brass weight: 60 g minimum.

TABLE 2 Maximum Leakage Current

Direction	Normal	Patient Connections Micro Amps (A/C)	Chassis/Enclosure Micro Amps (A/C)
		Heart	(Ground/Open)
Source	50	10	100
Sink	50	10	N/A

anesthetics by cryosystems.

7.7.2 All ac powered cryosystems and accessories shall be prominently labeled as described in 6.2.5.

7.8 *Cryogen Cylinder Connector(s)*—All cryosystems that use a cryogen regulated by the CGA, shall meet all the requirements of CGA V-1 1977.

TEST METHODS

8. Significance and Use

8.1 Sections 9-13 specify test methods for selecting, using, calibrating, controlling, and maintaining measurement standards and measuring devices used to determine conformance with this specification.

8.2 All measuring devices or systems shall be used in a manner which ensure that measurement uncertainty is known and is consistent with the required measurement capability. Measurement errors shall be recorded or, where possible, eliminated by calibration of the measuring device.

9. Test Method for Mechanical Integrity

9.1 *Apparatus*:

9.1.1 *Timing Device* (for example, clock).

9.1.2 *Hydraulic or Pneumatic Pressure Testing System*.

9.1.3 *Other Components*, to make the cryosystem functional in accordance with the manufacturer's operational instructions.

9.2 *Sampling*—For cryosystems of the same model, test and record five individual systems. For limited production, or for a unique cryosystem, test and record one unit.

9.3 *Procedure*:

9.3.1 Connect and operate the cryosystem as described in the manufacturer's operating instructions.

9.3.2 Thermally cycle the cryosystem in air under no load through five stimulated freezing modes of 3 min duration, followed by five defrost modes of 5 min each. For disposable cryosystems, one freeze defrost mode expending the total cryogen shall be sufficient prior to pressure test.

9.3.3 Begin timing once the cryosystem has stabilized at the coldest operating temperature in the freeze mode and at ambient temperature in the defrost mode.

9.3.4 Pressure test the item under investigation immediately following the thermal cycling. (See 7.2).

9.4 *Conformance*—Conformance with the requirements (7.2) shall be checked by inspection of the cryosystem or any of its components for absence of adverse effects such as bursting, rupturing, leaking, or other indications which compromise the integrity of the cryosystem.

10. Test Method for Determining Ambient Concentration of Nitrous Oxide

10.1 *Apparatus*:

10.1.1 *Standard Test Room*, as described in Fig. 1.

10.1.1.1 *Room Volume*, 1000 cubic feet maximum, nominally 10 by 10 by 10 ft.

10.1.1.2 *Ceiling Height*, 7 ft minimum.

10.1.1.3 *Fan Flowrate*, 500–600 cu. ft/min, fixed position household fan style to circulate air is required.

10.1.1.4 *Infrared Spectrophotometer.*[9]

10.2 *Sampling*—For a cryosystem of a similar design, test one cryosystem in accordance with 10.4. This cryosystem shall be a representative sample of a currently marketed production system.

10.3 *Preparation of Apparatus*:

10.3.1 Locate fan one foot from two walls and floor to the center of the fan. Make sure the flow is parallel to the wall and floor.

10.3.2 The room is to be leaktight with essentially zero room air changes.

10.3.3 Place the entire cryosystem including nitrous oxide cylinders in geometric center of room and confine about center as close as is practical.

10.3.4 Rout the scavenging hose out of the test room.

[9] A Wilks Miran 1A Infrared Spectrophotometer has been found satisfactory for this purpose.

Locate the sampling point at any point on a 3-ft radius from geometric center, 3 ft above floor level.

10.4 *Procedure*:

10.4.1 Position the cryosystem in the test room as specified in Fig. 1.

10.4.2 Turn on the circulating fan.

10.4.3 Zero and calibrate the spectrophotometer in accordance with the manufacturer's specification.

10.4.4 Monitor 12 data points at 1-min intervals. The total test for each cryosystem shall last 12 min.

10.4.5 Perform each test in accordance with the recommended operating procedure as specified in the cryosystem operational instructions.

10.4.6 Perform the test for two freeze modes of 3 min each, followed by two wait modes of 3 min each. The "wait" period shall consist of defrost, standby, or shut off modes in accordance with the manufacturer's recommended operating procedure.

10.4.7 To calculate the resultant ambient nitrous oxide concentration, average the readings from the 12 data points.

10.4.8 Vent the room of residual nitrous oxide gas prior to subsequent tests.

10.5 *Conformance*—Conformance with the requirements shall be checked by comparison of the calculated average nitrous oxide concentration with the maximum NIOSH recommended level of 25 ppm.

11. Test Method for Determining Closed Cryotip Temperature Reproducibility

11.1 *Apparatus*:

11.1.1 *Simulated Tissue Model*—The tissue model shall be 1000 mL of distilled water in a standard 1000-mL beaker. The water shall be maintained at 30 ± 2°C by a constant temperature bath. The water in the beaker shall not be circulated artificially during the actual test.

11.1.2 *Low Thermal Mass Thermocouple Sensor*.

11.1.3 *Temperature Indicator or Chart Recorder*.

11.1.4 *Other Components*, to make the cryosystem functional in accordance with the manufacturer's operational instructions.

11.2 *Sampling*:

11.2.1 For limited production of a unique cryosystem, perform and record a series of three freeze modes.

11.2.2 For cryosystems of the same model, test and record three individual systems.

11.2.3 Test in accordance with the requirements of Table 1.

11.3 *Procedure*:

11.3.1 Attach the thermocouple sensor to the therapeutic surface of the cryotip as determined by the manufacturer.

11.3.2 Immerse the closed cryotip into the simulated tissue model in a way which simulates the intended application as determined by the manufacturer.

11.3.3 Follow all parameters as described in the manufacturer's operational instructions to make the cryosystem functional.

11.3.4 Allow the cryotip to defrost between cycles.

11.3.5 Include disposable devices.

11.3.6 A precycle for the cryosystem to normalize operating conditions is permitted.

11.3.7 Calculate the reference temperature and limits of deviation from the recorded data.

11.4 *Conformance*—Conformance with the requirements (6.2.1) shall be checked by comparison of the deviation between the closed cryotip reference temperature and Table 1.

12. Tractive Force Test Method

12.1 *Apparatus*:

12.1.1 *Tractive Force Model*, as described in Fig. 2.

12.1.2 *Other Components*, to make the cryosystem functional in accordance with the manufacturer's operational instructions.

12.2 *Sampling*:

12.2.1 Test closed cryotips used for cryoadesion for tractive force. For limited production, or a unique cryosystem, perform and record a series of three cryoadhesion tests.

12.2.2 For cryosystems of the same model, test and record three individual cryosystems.

12.3 *Procedure*:

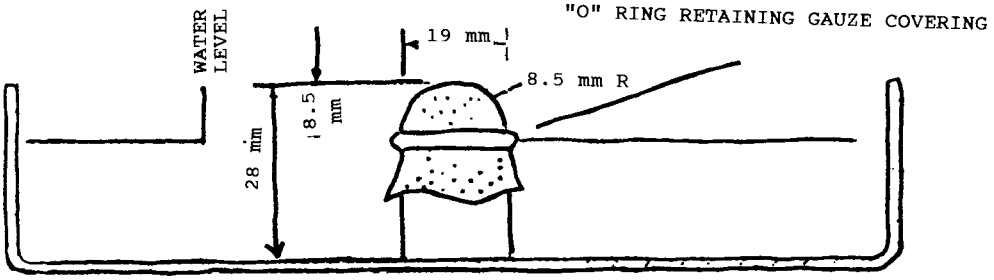
12.3.1 Place ambient temperature closed cryotip onto the top of the gauze covered weight.

12.3.2 Follow all normal operational procedures as described in the manufacturer's operational instructions.

12.3.3 Activate the cryosystem freeze mode.

12.3.4 When the cryotip has adhered sufficiently to the gauze, lift the weight out of the water, and hold for a minimum of 45 s.

12.4 *Conformance*—Conformance with the requirements (6.3) shall be attained by satisfactorily lifting and retaining the test weight.



NOTE 1—All dimensions given are minimum values.

FIG. 2 Tractive Force Model

13. Test Method for Determining the Accuracy of Temperature Monitors (Cryotip and Tissue)

13.1 *Thermocouple Type*.

13.2 *Apparatus*:

13.2.1 *Direct-Current (d-c) Millivolt Generator*, with an output source resistance equivalent to the thermocouple resistance as specified by the manufacturer and a suitable test lead.

13.2.2 A method of measuring ambient or reference junction temperature.

13.2.3 *Thermocouple Reference Tables*, based on IPTS-68, refer to NBS Monograph 125.

13.2.4 *Direct-Current (d-c) Millivoltmeter*, and a suitable test lead.

13.2.5 *Calibration Medium*, such as ice/ice water, liquid nitrous oxide, dry ice, or liquid nitrogen.

13.3 *Sampling*—Test any cryosystem or accessory containing a cryometer for accuracy of temperature indication. For cryosystems of the same model, test and record three individual monitoring systems. For limited production, or a unique cryosystem, test and record each monitoring system. Accuracy may be checked as a complete monitoring system or by summing the cumulative errors of the cryometer and thermocouple tested individually. Testing shall be in accordance with the requirements of 5.4.2 for any temperature within the noted range.

13.4 *Procedure*:

13.4.1 *Determination of Cryometer Accuracy*:

13.4.1.1 Connect the test apparatus to the cryometer. Ensure that there is temperature uniformity. The reference ambient temperature shall be displayed on the measuring device located adjacent to, and preferably in thermal contact with, the reference junction.

13.4.1.2 With zero dc millivolts inserted via the test lead, the cryometer shall display the actual ambient temperature ±5°C.

NOTE 1—The cryometer may be calibrated to precisely display at 0°C, the cryogen boiling point, or any other specific operating temperature relevant to the intended use.

13.4.1.3 From the thermocouple tables, calculate the d-c millivolts signal equivalent to the calibration temperature relative to the reference ambient temperature, for the thermocouple type specified by the manufacturer. With the calculated d-c input voltage applied, the cryometer shall display the calibration temperature. Record the temperature deviation between the calibration temperature and the displayed value.

13.4.2 *Determination of Thermocouple Accuracy*:

13.4.2.1 Connect the d-c millivoltmeter to measure the thermocouple emf. The reference ambient temperature shall be displayed on the measuring device located adjacent to, and preferably in contact with, the reference junction. Ensure that there is temperature uniformity.

13.4.2.2 Insert the thermocouple measuring junction into the calibration medium and allow the temperature to stabilize. Measure the thermocouple electromotive force (emf).

13.4.2.3 From the thermocouple reference tables, calculate the emf value of the reference ambient temperature for the thermocouple type specified by the manufacturer. Subtract the reference ambient temperature emf from the value measured with the thermocouple in the test medium.

13.4.2.4 Determine the measuring junction temperature from the resultant emf according to the thermocouple reference tables.

13.4.2.5 Record the temperature deviation between the calibration medium temperature and the determined value.

13.5 *Conformance*—Conformance with the requirements (6.4) shall be checked by test.