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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]

[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.

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2.4 *International ElectroTechnical Commission (IEC) Document:*

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] 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.

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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

5.4 *Monitoring Devices*:

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

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