Designation: F1719 – 96 (Reapproved 2008)

Standard Specification for Image-Interactive Stereotactic and Localization Systems[1]

This standard is issued under the fixed designation F1719; 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.

1. Scope

1.1 This specification covers the combined use of stereotactic instruments or systems with imaging techniques, to direct a diagnostic or therapeutic modality into a specific target within the brain, based on localization information derived from such imaging techniques.

1.2 For the purpose of this specification, a stereotactic instrument or system is a guiding, aiming, or viewing device used in human neurosurgery for the purpose of manually directing a system or treating modality to a specific point within the brain by radiographic, imaging, or other visualization or identification of landmarks or targets or lesions.

1.3 *Definition of Stereotactic Imaging Systems*—Types of imaging-guided systems all require three components: an imaging system, a stereotactic frame, or other physical device to identify the position of a point in space, and a method to relate image-generated coordinates to frame or device coordinates. See Performance Specification F1266. The imaging technique must reliably and reproducibly generate data concerning normal or abnormal anatomic structures, or both, that can interface with the coordinate system of the stereotactic frame or other stereotactic system. The imaging-guided systems must allow accurate direction of therapeutic, viewing or diagnostic modalities to a specific point or volume or along a specific trajectory within the brain or often accurate estimation of structure size and location allowing biopsy, resection, vaporization, implantation, aspiration, or other manipulation, or combination thereof. The standards of accuracy, reproducibility, and safety must be met for the imaging modality, the stereotactic system, and the method of interface between the two, and for the system as a whole. The mechanical parts of the imaging modality and the stereotactic system should be constructed to allow maximal interaction with minimal interference with each other, to minimize imaging artifact and distortion, and minimize potential contamination of the surgical field.

1.4 *General Types of Imaging that May Be Used With Stereotactic Systems*—Currently employed imaging modalities used in imaging-guided stereotactic systems include radiography, angiography, computed tomography, magnetic resonance imaging, ultrasound, biplane and multiplane digital subtraction angiography, and positron emission scanning. However, it is recognized that other modalities may be interfaced with currently available and future stereotactic systems and that new imaging modalities may evolve in the future. Standards for imaging devices will be dealt with in documents concerning such devices, and will not be addressed herein.

1.5 General types of diagnostic modalities include biopsy instruments, cannulas, endoscopes, electrodes, or other such instruments. Therapeutic modalities include, but are not limited to, heating, cooling, irradiation, laser, injection, tissue transplantation, mechanical or ultrasonic disruption, and any modality ordinarily used in cerebrospinal surgery.

1.6 *Probe*—Any system or modality directed by stereotactic techniques, including mechanical or other probe, a device that is inserted into the brain or points to a target, and stereotactically directed treatment or diagnostic modality.

NOTE 1—Examples presented throughout this specification are listed for clarity only; that does not imply that use should be restricted to the procedures or examples listed.

1.7 *Robot*—A power-driven servo-controlled system for controlling and advancing a probe according to a predetermined targeting program.

1.8 *Digitizer*—A device that is directed to indicate the position of a probe or point in stereotactic or other coordinates.

1.9 *Frameless System*—A system that does not require a stereotactic frame, that identifies and localizes a point or volume in space by means of data registration, and a method to relate that point or volume to its representation derived from an imaging system.

1.10 The values stated in SI units are to be regarded as the standard.

1.11 The following precautionary caveat pertains only to the test method portion, Section 3, of this specification: *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*

[1] This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.31 on Neurosurgical Standards.

Current edition approved Feb. 1, 2008. Published March 2008. Originally approved in 1996. Last previous edition approved in 2002 as F1719 – 96 (2002). DOI: 10.1520/F1719-96R08.

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 *ASTM Standards:*[2]

F1266 Performance Specification for Cerebral Stereotactic Instruments

3. Types of Imaging-Guided Stereotactic Systems

3.1 Any type of stereotactic apparatus may be adapted to imaging-guided stereotactic surgery. A stereotactic system can be based on one or more of the following concepts:

3.1.1 *Arc-Centered Type*—A target centered arc with rectilinear adjustments is constructed according to the spherical radius principle so that the target point lies at the center of an arc along which the probe holder moves, so that when a probe is inserted into the probe holder perpendicular to a tangent of the arc and for a distance equal to the radius of the arc, the tip of the probe arrives at a single point in space, that is, the stereotactic target.

3.1.2 *Rectilinear Type*—The rectilinear type provides individually for the longitudinal, transverse, and vertical movements of the probe holder or the patient, or both, perpendicular to or at an angle to the planes along which the probe holder is moved.

3.1.3 *Aiming Type of Stereotactic Apparatus*—A device that is referenced to a specific entry point so the probe can be pointed to the desired target point and then advanced to it.

3.1.4 *Multiple-Arc Type*—An arc system that is not target centered and is a system of interlocking arcs, pivots, or joints arranged so that the orientation of the probe is controlled and can be directed to the target by independent movement of the elements. As the depth of each target may be different relative to the arc system, means for determining target depth must be provided.

3.1.5 An articulated arm that allows accurate determination of the position in space of a probe or other device held by the arm. Such a system ordinarily is coupled with computer graphics to allow identification of the location of the probe in relation to the position of the head in space. By relating the position of the head and the graphic image, the position of the probe relative to the head or structures within the head can be demonstrated.

3.1.6 A probe whose position and movement in space can be detected, calibrated, and related to the position on the patient's head or intracranial target by a nonmechanical modality, such as infrared, visual light, sound, or ultrasound.

3.1.7 The above represents a general classification of current systems and does not preclude future developments. Any given system may represent any of the above types of stereotactic device or may be a combination of two or more systems.

3.2 *Image Interactive Localization Systems:*

3.2.1 Any type of stereotactic apparatus may be adapted to function as an image interactive localization system. For such to occur, it is necessary for the stereotactic apparatus to be equipped with a means for relating its location in three-dimensional space with the computerized image display system. These means of communication may include the following:

3.2.1.1 Optical encoders that record the amount of displacement on the set of coordinates axis and arcs that are used to position the probe of the stereotactic system.

3.2.1.2 Mechanical encoders that record the amount of displacement set on the coordinate axis and arcs that are used to position the probe of the stereotactic system.

3.2.1.3 Other means of recording the amount of displacement set on the coordinate axis and arcs that are used to position the probe of the stereotactic system.

3.2.2 Systems may be designed for image interactive localization that do not incorporate the stereotactic apparatus concepts discussed in 9.1.1. Regardless of whether these systems are framed-based, table-based or room-(space) based, they employ a means for generating a probe orientation in three-dimensional space that can be used by the computerized image display system. Intraoperative calibration of the system is desirable, and it should be incorporated where practical. Means for generating a probe orientation in three-dimensional space may include the following:

3.2.2.1 Multiple-degree-of-freedom "robotic" arms that use optical, mechanical, or other types of encoders to register the position/orientation of each joint. Calibration of the arm with respect to the known location of reference points in three-dimensional space is usually required.

3.2.2.2 Systems that use optical or sonic information to triangulate the location and orientation of the probe. Calibration of the system with respect to the known location of reference points in three-dimensional space is usually required.

3.2.2.3 Six-degree-of-freedom electromagnetic receiver/transmitters that may or may not require intraoperative calibration of the three-dimensional space.

3.2.2.4 Other alignment by means of generated information may be used by the computerized image display system, with or without three-dimensional space calibration.

3.2.3 The above represents a general classification of current systems or systems currently in development and does not preclude future development.

4. Applications of Imaging Techniques to Stereotactic Instruments

4.1 Some of the means used to relate an imaging system to stereotactic apparatus may be mated by:

4.1.1 Attaching the apparatus to the table during imaging and relating the position of the slice to fiducials on the apparatus,

4.1.2 Relating the height of the image to the stereotactic apparatus by attaching an indicator to the table, that can then be used as a phantom to adjust the apparatus,

4.1.3 Employing a translational imaging technique to relate the position of the image to the head or to the apparatus,

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

4.1.4 Including in the scanner plane markers or fiducials which can be used to calculate the position and inclination of the imaging slice,

4.1.5 Using three-dimensional computer reconstruction techniques to determine both the position of the target and the position of the apparatus, so these two positions might be correlated. Such techniques may make possible the visualization of the volume and shape of the target in space, so that each point in the entire target can be defined by stereotactic coordinates.

4.2 *Imaging Systems:*

4.2.1 The region of interest may either be constituted by abnormal structures (brain lesions) identified with imaging systems or normal anatomical structures (functional stereotaxis), or both, to which the sensitivity of the imaging technique should be addressed. In case of normal structures, the location may need the use of standard atlases or tables and the method of transposition and its accuracy should be addressed. Previously, the conversion of X-ray coordinates to stereotactic space was performed with manual triangulation. With the development of computed tomography and magnetic resonance imaging technology, most conversion is often now performed utilizing computer software.

4.2.2 The interface between imaging and stereotactic space may be performed by several methods; the identification of the location of normal structures within stereotactic space and then the use of standard atlases or other tables to define a given anatomical location, the identification of the relationship of normal and abnormal structures using an imaging technique with subsequent reconstruction of this relationship within the stereotactic system, digitization and conversion of analog imaging data to stereotactic space, and transformation of imaging data generated within the stereotactic system using manual transfer where indicated.

4.2.3 Imaging may be based on visualization in a slice, a reconstructed plane, or be represented by a volume, and the accuracy may vary depending of which system is used. The system should incorporate, wherever feasible, an alternate or back-up method to compensate for possible primary system failure or distortion. It is recognized that, in the future, changes are likely to occur in both imaging and technology and computer technology, and these standards should not be interpreted in such a manner as to impair development of new systems, as long as accuracy and safety requirements are met.

4.3 *Stereotactic Frame Requirements*—It should be possible to use the frame with an imaging system or systems for which it has been designed or adapted, as verified by the calibration considerations outlined in 4.3 and 4.4.

4.4 *Accuracy*—In addition to concerns of accuracy of each of the components of the stereotactic systems, enumerated in other sections of this specification, the components should interrelate in such a way that accuracy of the overall system is not compromised.

4.5 *Application Accuracy:*

4.5.1 Each system should include information from the manufacturer indicating the reproducible accuracy of the entire system in use for each imaging modality with which the system is to be used, how such accuracy was determined, and instructions so the surgeon might test the entire system to ensure that the indicated accuracy and degree of confidence has been preserved.

4.5.2 *MR-stereotactic Application Accuracy*—Since nonlinear distortion is an inherent property of magnetic resonance scanning, the surgeon should be aware of potential inaccuracies imposed in an individual case. Also, since accuracy of magnetic resonance imaging scanners varies from one scanner to another and from one technique to another, such user testing might demonstrate inaccuracies inherent in an individual MR-stereotactic system.

5. Anesthesia and Operating Room Safety

5.1 *Scope*—This specification is concerned with the definitions and standards that are required in the design of imaging-guided stereotactic systems to ensure patient and operating room personnel safety during the administration of anesthesia for imaging-guided stereotactic procedures.

5.2 *Definition*—For the purpose of this specification, general anesthesia may be defined as a state of altered consciousness occurring as a result of drug administration by intravenous, intramuscular, inhalational, or oral routes.

5.3 The choice of type of anesthesia (general versus monitored versus local) is the responsibility of the operating surgeon, with consultation with the anesthesiologist as indicated. The choice of anesthetic agent and means of administration is the responsibility of the anesthesiologist after consultation with the operating surgeon.

5.4 *General Requirements*—The standards for the use of anesthesthetics with imaging-guided stereotactic surgery are the same as indicated in Performance Specification F1266.

5.5 *Specific Requirements:*

5.5.1 *Disconnect System*—The mechanism to connect or rapidly disconnect the patient from that part of the imaging-guided stereotactic apparatus as may be necessary in an emergency must be easily accessible, quickly operative, and independent of electrical supply, as may be necessary to manage any untoward drug reaction, excess secretions to cardiopulmonary failure during either the imaging or surgical part of the procedure.

5.5.2 *Airway Maintenance*—The apparatus shall allow reasonable access to the head and neck for maintenance of an airway either by endotracheal tube, laryngeal mask airway, or suctioning.

5.5.3 *Other Monitoring*—The apparatus shall also be constructed to allow monitoring of vital signs including, but not limited to, blood pressure, electrocardiogram, and pulse oximetry, during the operative portion of the procedure, or any part of the procedure during which sedation or general anesthesia is employed.

5.5.4 If there is a significant risk of pressure on or burns to any part of the patient, warnings and instructions to avoid this should be included.

5.5.5 The device should allow changing of the position of the patient's head as necessary to gain access to carry out the planned procedure safely and address any emergencies that may arise.