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Standard Performance Specification for Cerebral Stereotactic Instruments¹

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1. Scope

1.1 This specification covers stereotactic instruments used by neurosurgeons to assist in the placement of probes, such as cannulae, needles, forceps, or electrodes or to direct radiation into brain regions or anatomical targets that are not visible on the surface. The general location of these regions is determined by measurements from landmarks visualized by X ray or other means, such measurements being based on atlases derived from anatomical studies and autopsy. Because of the anatomical variability, more precise location in any single patient may be determined by physiological responses in that patient. The degree of success in stereotactic surgery depends upon the experience of the surgeon as well as the precision of the stereotactic instrument. Nevertheless, minimum standards of accuracy for stereotactic instruments that are within the range of variability of human anatomy must be maintained.

1.2 For the purpose of this specification, a stereotactic instrument is a guiding device used in human neurosurgery for the purpose of directing an instrument or treating modality to a specific point within the brain by radiographic or other visualization of landmarks.

1.3 Stereotactic instruments must be constructed to afford the surgeon reliably reproducible accuracy in placing instruments into target areas. Proper positioning of the probe is often verified by X rays to control errors in calculation and to correct deflection of the probe during insertion. Physiological parameters may be used to further define the optimal target.

1.4 At the present time, stereotactic instruments are used most frequently, but not exclusively in the following operations. The list is presented only to present examples and should not be construed to restrict advances or developments of new procedures. For some applications it is not required to hit a point in space, but to hit a volume or make a lesion within a mass. For that purpose, devices other than those covered by this specification may be employed, but should be restricted to such uses:

- 1.4.1 Thalamotomy for parkinsonism and other types of tremor,
- 1.4.2 Electrode implantation for epilepsy,
- 1.4.3 Needle or magnetic insertion, or both, for aneurysm thrombosis,
- 1.4.4 Thalamic or subthalamic operations for dystonia,
- 1.4.5 Thalamic or subthalamic operations for involuntary movements such as chorea or hemiballismus,
- 1.4.6 Ablation of deep cerebellar nuclei for spasticity,
- 1.4.7 Cingulotomy and thalamic or subthalamic surgery for pain,
- 1.4.8 Mesencephalotomy or tractotomy for pain,
- 1.4.9 Ablations of subcortical temporal lobe structures for treatment of epilepsy,
- 1.4.10 Psychosurgical procedures,
- 1.4.11 Implantation of depth stimulating electrodes for pain,
- 1.4.12 Insertion of forceps or needle for obtaining biopsy specimens,
- 1.4.13 Foreign body removal,
- 1.4.14 Implantation of radioactive material, and
- 1.4.15 Biopsy or treatment of tumors.

1.5 *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 *NFPA Standard:*
[NFPA 99 Health Care Facilities Code \(56A and 76B-T\)](#)²
- 2.2 *UL Standard:*
[UL 544 Electrical, Medical, and Dental Equipment](#)³

3. Terminology

3.1 *Descriptions of Terms*—The following descriptions of terms are for the purposes of this specification only. Other nomenclature may be used throughout the literature and by various manufacturers:

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.

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² Available from National Fire Protection Association (NFPA), 1 Batterymarch Park, Quincy, MA 02169-7471, <http://www.nfpa.org>.

³ Available from Underwriters Laboratories (UL), 333 Pfingsten Rd., Northbrook, IL 60062-2096, <http://www.ul.com>.

3.1.1 *anatomical accuracy*—the reliability or accuracy with which the tip of a probe can be introduced into a given anatomical target. Because of anatomical variability, a given anatomical structure or anatomical target may vary relative to the position of the reference atlas position of that structure. Consequently, it is not possible to relate the reliability of a stereotactic apparatus to anatomical accuracy, but only to mechanical accuracy.

3.1.2 *anatomical target*—that anatomical structure within the central nervous system into which it is intended to insert a probe.

3.1.3 *anatomic variability*—a variation in position, size or configuration of an anatomical structure from one human brain to another.

3.1.4 *angular accuracy*—the accuracy to which the probe holder can be adjusted to a given angle from reference planes.

3.1.5 *angular scale*—the scale on the stereotactic apparatus which indicates at which angle the electrode probe holder directs a probe in relation to one or more reference planes of the coordinate system of the apparatus.

3.1.6 *atlas*—a topographical map of the brain or spinal cord based on autopsy studies, used to define the relationship between anatomical structures and landmarks, sometimes including information about the anatomical variability.

3.1.7 *direct visualization*—the visualization of an anatomical target by direct visual observation or roentgenographically with or without the assistance of air or contrast material.

3.1.8 *disconnect system*—a system to afford adequate access to the patient.

3.1.9 *electrode*—a probe usually insulated except for a specific portion or portions, commonly the end, which is stereotactically inserted into a desired anatomical target for the purpose of recording electrical activity, stimulating nervous tissue, producing a lesion in nervous tissue by passage of a direct or rapidly alternating electrical current, or measuring impedance.

3.1.10 *frame*—that part of the stereotactic apparatus which is attached to the skull.

3.1.11 *guide tube*—a tube through which an electrode or probe can be directed to a target. The tube imparts additional strength and less likelihood of deviation from a true trajectory. The guide tube can be attached to the electrode probe holder or stereotactic apparatus or attached to the electrode or insertional probe in a sleeve-like fashion.

3.1.12 *landmark*—a structure than can be visualized radiographically, with or without contrast material or air, from which measurements are made to define the position of the stereotactic target.

3.1.13 *linear accuracy*—the positioning accuracy of a linear movement of the probe holder in the direction of one or more of the reference planes of the stereotactic apparatus.

3.1.14 *linear scale*—the scale on the stereotactic apparatus which indicates linear movement of the electrode probe holder in relation to one or more of the reference planes, or a point within the coordinate system.

3.1.15 *mechanical accuracy*—the accuracy with which a stereotactic apparatus can bring the tip of a straight probe to a given coordinate within the stereotactic coordinate system.

3.1.16 *probe*—any type of long, thin device stereotactically inserted into a desired anatomical target. The most common type of probe is an electrode, but probes can also be cryoprobes, leukotomes, needles, biopsy devices, devices to insert radioactive or other material, magnetic probes, needles or injection devices, cannulae, forceps, and so forth.

3.1.17 *probe holder*—that part of the stereotactic apparatus that holds the electrode or probe. It is ordinarily attached to the frame either directly or indirectly, depending on the type of apparatus.

3.1.18 *simulated skull*—any device to which a stereotactic apparatus might be attached to simulate the stresses imparted to the apparatus when it is attached to the patient's skull. Because of the differences in how various stereotactic apparatus are attached to the skull, no universal simulated skull can be described.

3.1.19 *stereotactic apparatus*—any guiding device used in human neurosurgery for the purpose of directing a probe into the brain, under guidance of radiographic visualization of landmarks, direct radiographic visualization, or other means.

3.1.20 *stereotactic target*—that point in space, defined by the coordinate system of some types of stereotactic apparatus, to which it is desired to insert a probe.

3.1.21 *undamaged—in regard to electrodes*—not damaged to an extent where the electrical properties would be affected as to make an electrode unacceptable for clinical use.

4. Classification of Stereotactic Apparatus

4.1 Four basic types of stereotactic instruments, or a combination thereof are presently used and will be referred to herein as the arc (polar coordinate), rectilinear type, (c) aiming type, and (d) interlocking arc type. Types with comparable or greater accuracy should be recognized as they are developed.

4.1.1 *Arc Type*—The arc type apparatus 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 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, the center of the circle defined by the arc, that is, the stereotactic target. This occurs regardless of the position of the probe holder along the arc or the angle the arc subtends with the base of the apparatus. Generally, the apparatus is adjusted so that the stereotactic target point corresponds to the anatomical target point, so the probe might be introduced at any angle yet accurately find the stereotactic target.

4.1.2 *Rectilinear Type*—The rectilinear type provides individually for the longitudinal, transverse and vertical movements of the probe and probe holder. Ordinarily, a rectilinear stereotactic apparatus also provides for sagittal and transverse angle adjustment as well. Calculations can be made so the probe can be adjusted to the scales to aim and advance the probe to the desired target point along a predetermined trajectory.

4.1.3 *Aiming Type*—The aiming type of stereotactic apparatus is attached to a burr hole in the skull. The angles of insertion can be adjusted and the depth of insertion of the electrode or probe controlled so the probe can be pointed to the desired target point and then advanced to it.

5. Significance and Use

5.1 The purpose of a stereotactic apparatus is to guide the advance of an electrode or other probe accurately and in a controlled fashion to a given point in space, relative to the apparatus, to the stereotactic target. Thus, when the apparatus is attached to the skull, the electrode or probe can be advanced to a given geographical point within the cranial cavity, near the base of the skull or in the spinal canal.

5.1.1 As generally employed, the ventricles or cavities within the brain or other neurosurgical landmarks are identified roentgenographically by other means and, by consulting an atlas or other table, the mean distance and direction between the visualized landmark and a given anatomical target are measured. The electrode or probe is then inserted to the stereotactic target, that is, the point in space which is calculated from the distance and direction between the visualized landmark and the desired target in relation to the coordinate system of the stereotactic apparatus.

5.1.2 It is recognized that there is considerable anatomical variability in the size and shape of the central nervous system so that the target point that is identified from the atlas or table is only approximate. Usually, where possible, physiological verification may also be obtained. One must distinguish between the anatomical accuracy, which is inexact because of the variability of brains, and the mechanical accuracy, which is a function of the precision of the stereotactic instrument.

5.1.3 The requirements set forth herein are concerned only with the mechanical accuracy of stereotactic instruments. It is also recognized that once minimum standards for mechanical accuracy have been obtained, increased mechanical precision will not necessarily lead to increased anatomical precision.

6. Application

6.1 *Attachment to the Skull*—It is necessary to fix the stereotactic apparatus to the skull firmly in order to maintain an accurate relationship between the stereotactic apparatus and the skull. Those stereotactic apparatus which are attached to a platform or operating table shall provide for the rigid fixation of the skull to the apparatus or to the supporting platform. There shall be no visible movement of the frame of the apparatus in relation to the skull with the application of forces of magnitude and direction as would ordinarily be encountered during stereotactic surgery. Furthermore, fixation shall be secured enough to maintain mechanical accuracy. Design and construction of the apparatus shall be such that forces incidental to screwing its attachment pins into the skull do not distort the system to the extent of compromising its mechanical accuracy.

6.2 *Access for Radiology or Other Visualization*—Since the central nervous system landmarks are identified roentgenographically or by other means, the apparatus or that part of the apparatus from which movements are made, when properly

applied to the patient, shall be arranged in such a way that radiographs can be made in more than one plane or other visualization obtained. Means shall also be available to reposition the X-ray tubes accurately and conveniently. The stereotactic apparatus shall be constructed in such a way that no mechanical part interferes with X-ray, computerized tomography or other necessary visualization of landmarks during the part of the procedure when radiographs are being made.

6.3 *Accuracy of the Probe Placement*—The accuracy of placement in an anatomical target is dependent on anatomical variability which exceeds the mechanical inaccuracies of the stereotactic system. Nevertheless, specifications for mechanical precision, to a practical extent, are appropriate to obtain maximum target accuracy with an electrode or other probe. In general, the mechanical precision of a stereotactic apparatus should be sufficient to place a probe at a given point in space one half the diameter of the probe. Since most electrodes or probes are larger than 1.2 mm in diameter, a mechanical accuracy of 0.6 mm at the 99 % confidence level would ensure that a given point is generally included within the probe tract. Although probes less than 1.2 mm in diameter are sometimes employed, they are generally used for specialized purposes which require direct visualization of the target.

6.4 *Probe Holder*—The probe holder shall be designed so that it mechanically grasps the electrode or probe along sufficient length to prevent deviation, so the accuracy of the instrument is maintained, and so that its insulation is undamaged. A system to identify the appropriate target length of the electrode or probe, either on a depth scale or by a system preventing electrode overtravel shall be employed. If the procedure requires that the probe be advanced only to the target point, the system shall be designed so that the probe can be stopped accurately at the chosen target so that penetration beyond the target can be avoided. If the system is designed to advance the electrode along a calculated trajectory, a mechanical or other drive system shall be employed so that the millimetre-by-millimetre advance can be controlled.

6.5 *Adjustability of Probe Holder*—The apparatus shall be designed so that the probe holder may be locked at the proper angular scale or linear scale reading and can be moved in a controlled fashion along the appropriate scale, either by a continuous mechanical drive system, by a mechanical drive system in 1-mm steps or less, or manually. The system shall be free of binding. The system should be designed to allow clear and legible visibility by the operator performing the adjustments of the scale to which adjustments are being made.

6.6 *Linear Accuracy*—A mechanical linear accuracy one half the diameter of the probe or electrode is desired, but accuracy of greater than 0.6 mm at the 99 % confidence level is not required.

6.7 *Angular Accuracy*—A stereotactic device, such as the arc type, which requires only the advancement of the electrode probe tip to a specific target point regardless of the angle of insertion need not have an angular accuracy of greater than 1°.

6.7.1 A stereotactic device that uses a phantom target point shall have an angular accuracy that provides a mechanical accuracy of at least 0.6 mm for the whole system.