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Standard Performance Specification for Cerebral Stereotactic Instruments[1]

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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.

6.7.2 For repositioning without the use of the phantom, the angular accuracy of the apparatus shall be such that a probe of the length ordinarily used in stereotactic surgical procedures will fall within 0.6 mm of the intended stereotactic target coordinates at the 99 % confidence level. For example, if a stereotactic apparatus is designed for use with a probe 250 mm in length, an angular accuracy to introduce a given angle into a rectilinear system would be 0.256° or better. Less angular accuracy would be required to consistently fall within 0.6 mm of a point for an arc type stereotactic apparatus used with a probe of identical length.

7. Insertional Devices/Brain Instrument Interface

7.1 *Desirability for Intracranial Guiding*—When it is necessary to introduce a fine gage probe into central nervous tissue and thermal tissue resistance may cause a flimsy probe to deviate excessively, means shall be provided to increase probe rigidity to prevent deviation. Probe deviation may be prevented by stepped diameters along the shaft to increase rigidity or by introducing the probe through a rigid guide tube extended subdurally along the probe trajectory to a point beyond deflective tissue.

7.1.1 *Materials Used in Intracranial Guides*—Whether such guides are insulated or uninsulated shall be a matter of calculated design, and if insulated, the same criteria for electrode insulation shall apply. If uninsulated, the guide tube extension shall be grounded separately or through the electrode holder so as to prevent potentials being induced on it by its inherent or by other means, whereby such intermediate potentials might have effects which are clinically detectable or undesirable for recording purposes.

NOTE 1—Standards for electrodes and other probes will be dealt with in a separate document under the jurisdiction of a separate working group.

8. Calibration of Apparatus

8.1 *Test Probes*—A probe used in the calibration and recalibration of the apparatus shall consist of a steel rod no less than 1.5 mm or greater than 2.5 mm in diameter which will be straight to better than ½ mm. The dimensions of the test probe shall be similar to that of an electrode probe ordinarily used with the apparatus under test and shall be capable of being held securely by the electrode holder of that apparatus.

8.2 *Test Method*—The accuracy of an instrument shall be determined by the maximum error found in a significant number of tests performed by moving the probe time from any given starting position to any other predetermined position within the recommended working area for that instrument.

8.3 *Frame Distortion*—Frame accuracy of each type of apparatus shall be measured by the manufacturer on a suitable simulated skull or test phantom. The range of distortions which would be anticipated in normal use shall be included in the calibration measurement procedure unless a method is presented to eliminate such distortion effects.

8.4 *Recalibration*—A system shall be included, with appropriate instructions by the manufacturer, to make it possible for the operator to recalibrate the apparatus between cases or at any time there is likelihood that the apparatus may have become damaged or distorted. Such recalibration may involve either advancing a test probe to a simulated stereotactic target within the apparatus or the alignment of a test probe with specified reference lines defining reference planes or reference points.

9. Radiologic Safety Aspects

9.1 It is recognized that although roentgenographically is an indispensable part of many stereotactic procedures, the radiologic aspects concern separate equipment which is not part of the stereotactic frame. Refer to standards for intra-operative use of roentgenographic equipment for specific standards pertaining thereto.

9.2 *Safety*—Any stereotactic apparatus that requires the direct contact with a radiologic apparatus shall include provision for electrical safety, to ensure that the patient is protected from harmful current flow in the event of a short circuit or grounding failure of the radiologic equipment. The requirements and techniques of such provisions shall be clearly defined in the information supplied by the manufacturer.

9.2.1 *Radiologic Safety*—Standards for preventing overexposure of patient and personnel to harmful radiation during a stereotactic procedure are a function of safety procedures established for the use of radiologic equipment and consequently do not involve the manufacturer of stereotactic instruments. Nevertheless, it is recognized that those individuals qualified to use stereotactic equipment should likewise be knowledgeable about safe radiologic techniques with stereotactic procedures.

9.2.2 The stereotactic apparatus shall be constructed in a manner such that it does not interfere with alignment and use of radiologic equipment.

9.2.3 The stereotactic apparatus shall not include any component that would hinder X-ray visualization of anatomical structures of interest since this would necessitate the use of inordinately large doses of X rays to perform the studies necessary for precision and safety of the stereotactic operation.

10. Anesthesia and Operating Room Safety

10.1 *Scope*—This specification is concerned with the definitions and standards that are required in the manufacture of stereotactic instruments to ensure patient and operating room personnel safety during the administration of anesthesia for stereotactic surgery.

10.2 *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, inhalation or oral routes. However, most stereotactic surgery is performed with local anesthetic, the choice being the responsibility of the operating surgeon.

10.3 *General Requirements*—It is desirable to designate the operative area as a nonflammable anesthetizing location in accordance with NFPA Standard Nos. 56A and 76B-T both included in NFPA No. 99. To this end, appropriate signs shall be posted.

10.4 *Specific Requirements:*

10.4.1 *Disconnect System*—The mechanism to connect or rapidly disconnect the patient from that part of the 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 reactions from excess secretions to cardiopulmonary failure.

10.4.2 *Airway Maintenance*—The apparatus shall allot free access to the head and neck for maintenance of an airway either by endotracheal intubation or suctioning.

10.4.3 *Other Monitoring*—The apparatus shall also be constructed to allow monitoring of vital signs including blood pressure, electrocardiograms, and so forth.

10.4.4 *Avoidance of Facial Damage*—The apparatus shall be constructed to avoid undue pressure on the eyes, ears, or other susceptible areas of the skin.

10.4.5 *Electrical Safety*—The apparatus shall not interfere with the maintenance of electrical safety and electrical isolation as defined in governmental regulations.

11. Electrical Safety

11.1 *Scope*—This specification is concerned with the definitions and standards that are required to ensure operating room safety to prevent electrical shock to the patient or to the operating room personnel, and to prevent distressing secondary effects such as skin burns. It must be recognized that the stereotactic frame and the patient become part of an electrical circuit when an electrode is introduced into the body. When electrical devices other than those directly concerned with the conduct of the procedure are connected to the patient, it is mandatory that any electrical currents that can flow in the complex network, thereby created, be held to safe levels by adherence to the safety procedures used with those devices. Unless overall instrumentation standardization is set up, it must be assumed that a variety of grounded output or isolated output systems may be connected to the patient. It must be further assumed that attempts to apply a UL Standard 544 to the design of the stereotactic frame and its electrodes would make electrode systems so awkward and cumbersome as to preclude their use in the desired manner. Consequently, responsibility falls on the operator to use informed judgment in providing for all aspects of electrical safety since, by the very nature of the stereotactic apparatus, it is not possible to design sufficient safeguards for electrical safety into the apparatus.

11.2 *Reference Potential of the Frame:*

11.2.1 A common characteristic of almost all stereotactic frames is that they are fixed to the skull by pointed metallic screws or other metallic parts. Each screw may therefore be assumed to be in some degree of electrical contact with the patient, the contact impedance depending on several factors.

11.2.2 Ideally, the frame should be fabricated of materials and surface finishes which are conductors or which afford very low electrical resistance between the various parts, so that the frame can be considered as one piece electrically; accordingly, the frame also should be electrically bonded to the operating table or have a common ground, so that the patient could not contact metal parts which were not at the same potential as the stereotactic frame.

11.2.3 Although one might theoretically consider that frames made of surface treated aluminum might not have sufficient electrical contact between parts so that a small electrical potential might exist between the parts of the apparatus, current flow which might result from the discharge of these potentials are far from those parts of the body which would be adversely affected by brief flow of current at such levels. Indeed, historically the good safety record of surface coated aluminum stereotactic devices indicates that such construction is satisfactory from the standpoint of electrical safety.

11.3 *Electrode Systems*—The electrode should be electrically isolated from the stereotactic apparatus. Ordinarily, this is a function of the manufacture of the electrode. The electrical or grounding characteristics of the lesion generator are beyond the scope of this specification. Electrical hazards caused by spurious current pathways associated with electrical connections to auxiliary equipment can only be prevented by the precautions ordinarily employed in an operating room environment.

11.4 *Explosion Hazard*—To prevent explosion hazards, the usual precautions in the operating room must be taken. If possible, electrical ground connections between the stereotactic frame and auxiliary apparatus shall be made before the line cord is plugged into the explosion proof wall receptacle.

12. Sterilizability of Devices

12.1 *Scope*—This specification establishes requirements for sterilizability of stereotactic devices. Examples of devices included are the (*a*) arc type, (*b*) rectilinear type, and (*c*) the aiming type of stereotactic devices as described in 4.1. Excluded are insertional devices/brain instrument interface which will be included in a separate standard.

12.2 *Requirements:*

12.2.1 The patient-invasive components of the stereotactic apparatus must be sterilizable by an accepted procedure for sterilization of neurosurgical instruments.

12.2.2 If detached from the main apparatus during the sterilization procedure, it must be possible to reattach these patient invasive components to the apparatus with preservation of sterility.

12.2.3 The probe holder must satisfy the requirement of sterilizability by an accepted procedure for sterilization of surgical instruments.

12.2.4 If the design of the apparatus permits intraoperative adjustments of the probe holder, the apparatus design must reasonably permit the operator to make such adjustments while preserving the sterility of both the probe and the patient-invasive components.

13. Instructions and Warnings

13.1 *General*—Instructions to be included with every stereotactic apparatus sold by the manufacturer shall include the following information:

13.1.1 Description of the apparatus and nomenclature for the component parts.

13.1.2 Instructions or diagrams for a recommended method of positioning the patient's head or attachment of the apparatus to the patient's head.

13.1.3 Recommended procedure for positioning or changing position of the probe holder indicating a technique that is compatible with the design of the apparatus.

13.1.4 Instructions for a recommended technique for insertion of electrode or other probes into the probe holder to minimize risk to the straightness or insulation of the device.

13.1.5 Recommended procedure for repositioning the probe holder or the patient's head in order to properly adjust the instrument to aim the insertional device to the target.

13.1.6 Recommended procedure for aligning and taking X rays with safeguards to ensure the reproducibility of alignment and X ray safety, if appropriate.

13.1.7 Recommended procedure for rapidly disconnecting the patient from the apparatus for quick access to the head in the event of an emergency, if required by instrument design.

NOTE 2—It is recognized that there is no standard technique for the conduct of stereotactic surgery and that it is not appropriate for the manufacturer to dictate surgical procedures. Instructions should pertain only to matters regarding the design of the apparatus. It is recognized that the surgeon has the ultimate responsibility for the welfare of patients and that surgeons have a variety of surgical approaches. The manufacturer cannot include all possible acceptable techniques in any instructional manual, but should include a recommended technique and sufficient detail so that one familiar with stereotactic surgery might know how to use the specific stereotactic instrument, even if the operator has had not prior experience with it. It is recognized that the experience, training and innovation of the operator may lead him to use or develop a technique other than the single technique outlined in the instruction manual.

13.2 *Sterilizability:*

13.2.1 Instructions shall be included for the sterilization of necessary parts of the stereotactic apparatus using techniques ordinarily available in an operating suite. These instructions shall include any special requirements for cleaning, disassembling and reassembling, packaging requirements, or special handling of any parts of the apparatus if such a procedure does not conform to the usual techniques for sterilization of surgical instruments.

13.2.2 Any contraindications to sterilization of all or part of the stereotactic apparatus by the use of any standard sterilization technique shall be noted. For instance, it is not possible to sterilize some plastic parts by steam autoclave without distorting them.

13.3 *Hazards:*

13.3.1 Any reported hazards particular to a specific instrument shall be noted.

13.3.2 Hazards related to the attachment of the instrument to the skull shall be specifically noted.

13.4 *Calibration and Recalibration:*

13.4.1 Instructions for calibration, recalibration, or verification of the proper alignment of the stereotactic instrument shall be included. These should be sufficiently clear and concise so that a nurse or surgeon or one not familiar with engineering or mechanical testing can perform the testing procedure accurately.

13.4.2 A recommended schedule of recalibration shall be included to ensure that the apparatus maintains the mechanical accuracy defined above. This may involve testing of the procedure for alignment and configuration between or just prior to each stereotactic procedure and may be incorporated in the procedure for X ray alignment. Alternatively, it may be recommended at reasonable intervals depending upon the mechanical stability of each type of apparatus.

13.5 *Manufacturer's Warranty:*

13.5.1 The limits of the manufacturer's warranty shall be clearly specified in the information originally supplied with the stereotactic apparatus.

13.5.2 A source for service or repair of the apparatus shall be clearly indicated in the information supplied by the manufacturer.

13.5.3 Where appropriate, instructions for readjustments or repairs of the most common repairs that can be performed locally shall be included in the information originally supplied by the manufacturer.

13.6 *Serial Number*—Each apparatus shall be assigned a unique serial number by the manufacturer who will keep a record of the original owner. If information is received by the manufacturer of the transfer of the apparatus to new owner, it shall be incorporated in his records. If, at any time, the device is returned to the manufacturer for repairs, but proper repairs are not possible, the current owner shall be notified and this information shall be recorded by the manufacturer.

13.7 *Clinical Information*—It is not required that the manufacturer include information of a clinical nature with the apparatus, nor information concerning the physiologic recommendations for monitoring or anatomical variabilities.