BUREAU OF INDIAN STANDARDS

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कंप्यूटर-असिस्टेड सर्जिकल सिस्टम - सर्जिकल ईएनटी नेविगेशन सिस्टम सामान्य और सुरक्षा आवश्यकताएँ

Draft Indian Standard

Computer-Assisted Surgical Systems – Surgical ENT Navigation System General and Safety Requirements

[ICS 11.040.30]

Ear, Nose ,Throat, Head & Neck Surgery Instruments Sectional Committee, MHD 04	Last date for comments: **10 Aug 2024**

FOREWORD

(Formal clause will be added later)

This standard provides requirement and guidance for the ENT Navigation System. This device are primarily intended for the guidance for Ear, Nose , Throat navigation during the surgery . Mechanical and physical requirements , test methodology , technical specification and instructions are also mentioned in standard

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2: 2022 ‘Rules for rounding off numerical values (*second revision*)’. The number of significant places retained in the rounded-off value should be same as that of the specified value in this standard.

1. SCOPE

This standard specifies the general and safety requirements for **Surgical ENT Navigation Systems** used for precisely locating anatomical structure in open or percutaneous surgical ENT procedures with the help of trackable tools / instruments.

2. NORMATIVE REFERENCES

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IS No / other publications	*Title*
IS/ISO 13485 : 2016	Medical Devices — Quality Management Systems — Requirements for Regulatory Purposes (First Revision)
IS/ISO 14971 : 2019	Medical devices - Application of risk management to medical devices First Revision
IS/ISO 62304 : 2015	Medical device software - Software life cycle processes
IS 17922 (Part 1) : 2023/ IEC 62366-1: 2015 CSV	Medical Devices Part 1: Application of Usability Engineering
IS 17932 (Part 1) : 2023	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process (ISO 10993-1 : 2018, MOD)
IS/ISO 16142-1 : 2016	Medical Devices - Recognized Essential Principles of Safety and Performance of Medical Devices Part 1 General Essential Principles and Additional Specific Essential Principles for all Non-IVD Medical Devices and Guidance on the Selection of Standards
ASTM F 2554-18(Not adopted)	Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems

3. TERMINOLOGY

For the purpose of this standard, the following definitions are applied.

3.1. Computer Assisted Surgery (CAS): The use of computers to facilitate or enhance Surgical Procedures via the use of three-dimensional space tracking of objects.

3.2. Surgical ENT Navigation System: A device consisting of a computer with associated ENT software and a localizer that tracks reference elements attached to surgical instruments or implants as well as one or more dynamic reference bases attached to the therapeutic object. It provides real-time feedback of the performed action by visualizing it within the virtual environment.

3.3. Stereotaxic: Relating to or denoting techniques for surgical treatment or scientific investigation that permit the accurate positioning of probes inside the brain or other parts of the body.

3.4. Optical Navigation in Surgery: Optical Navigation Systems makes use of optical physics to measure the degree of the relative motion (both speed and magnitude) between a navigation device and the navigation surface. In which it detects the light from a reflective surface or trained patterns through a stereotaxic camera to measure the geometric location of various instruments.

3.5. Accuracy: the closeness of agreement between a measurement result and an accepted reference value. The term **accuracy**, when applied to a set of measurement results, involves a combination of a random component and of a common systematic error or bias component.

3.6. Fiducial: An artificial object (for example, screw or sphere) that is implanted into, or a feature created on, a therapeutic object prior to virtual object acquisition to facilitate registration.

3.7. Marker: A single 3-degree-of-freedom indicator on a reference element or dynamic reference base.

3.8. Registration: The determination of the transformation between the coordinate spaces of the therapeutic and virtual objects or between the coordinate spaces of two virtual objects. A registration is rigid if it consists only of rotations, translations, and scaling; it is non-rigid if it also comprises local or global distortions.

3.9. Tool calibration: The pre- or intraoperative determination of the location of points-of-interest on a navigated instrument (for example, its tip position, axis) in relation to a reference frame (for example, the attached reference element for a tracked instrument).

3.10. Tracker: A device that measures the spatial location and orientation of surgical instruments implants, or the therapeutic object that are instrumented with reference elements or a dynamic reference base respectively. A tracker may measure based on infrared light (see tracking, active and tracking, passive), ultrasound, electromagnetic fields, mechanical linkage, video streams, and so forth.

3.11. Tracking: Active, a tracking technology that uses markers that emit energy (for example, an infrared light-based tracking technology that uses pulsed LEDs as markers, ultrasound, electromagnetic fields, and so forth).

3.12. Tracking passive: A tracking technology that uses markers that absorb or reflect externally produced energy. (For example, a light-based tracking technology that uses reflective spheres or similar objects as markers). coordinate measuring machine (CMM), measuring system with the means to move a stylus and capability to determine spatial coordinates on a work piece surface.

3.13. ENT: ear, nose, and throat

4. General Requirements

4.1. Physical and Mechanical Requirements

4.1.1. The Surgical ENT Navigation System shall be designed and Developed with the material which are suitable for the particular use and shall be made and finished with the degree of uniformity and grade of workmanship fit for this particular system.

4.1.2. Attachments of plugs and harness, circuits, fuse holder, fuse, power cables & connectors, display, camera, etc. which are provided as a part of Surgical ENT Navigation System shall be chosen with respect to their suitability for the particular application and shall conform to appropriate Indian Standard. In case Indian standard is not available it will be agreed to between manufacturer and purchaser.

4.1.3. The enclosure shall be so formed and provided with barriers that the supporting surface will be protected against the short-circuit and damage to electrical components in the event of failure of the equipment.

4.1.4. The sheet metal employ as an enclosure for Surgical ENT Navigation System shall be of such thickness, or shall be formed or reinforced, that it's strength and rigidity should be not less than that of a flat steel sheet having an average thickness of 0.6mm.

4.1.5. An enclosure of material other than metal may be acceptable if it has been shown to have mechanical strength, resistance to impact, non-combustibility, and other properties suitable for the application.

4.1.6. Electrical Parts / Components of the Surgical ENT Navigation System shall be so located or enclosed that suitable protection against accidental contact with the live metal parts shall be provided.

4.1.7. The components like SMPS (Switch-Mode Power Supply), motherboard and other high voltage components shall be enclosed withing a metallic enclosure provided with means for earthing, if within an enclosure of suitable insulating material.

4.1.8. The enclosure of Surgical ENT Navigation System shall be of protection class IP 20 of IS: 2147. The equipment shall be constructed so as to prevent the penetration of foreign bodies which might adversely affect the safety of the equipment.

4.1.9. Equipment parts which move shall be arranged or protected against contact in such a manner that the operator / user is not endangered.

4.1.10. Protective casings, protection parts / components and the like shall have adequate mechanical strength. They shall not be removable without the aid of a tool, unless their removal is essential for proper use.

4.1.11. Surgical ENT Navigation System which in use, is placed on the floor and which, when overturned, may present a hazard for the user or surroundings, shall have adequate stability.

4.1.12. Surgical ENT Navigation System which may be adjusted to voltages range shall be built in such a manner that accidental changing of the voltage setting is impossible.

4.2. Radiation Protection:

4.2.1. The Surgical ENT Navigation System shall be conformed to all relevant requirements specified in IS 7064, for the protection of user and surroundings.

4.3. Corrosion Protection

4.3.1. The Surgical ENT Navigation System and its Instruments are subjected to spillage of liquid in normal use shall be constructed in such a manner to prevent from the corrosion and electrical insulation is not adversely affected by such spillage.

4.3.2. Surgical ENT Navigation System and its instruments which contain batteries shall be built in such a manner that the insulation is not adversely affected by leakage acid or alkali.

4.4. Surface and Edges

4.4.1. Surgical ENT Navigation System and its sub systems (Tools, Instruments) shall be designed in a way that their intended use should not lead to an unintentional injury to the user/ patient.

4.4.2. The surfaces of all the instruments shall not have cracks, pores, remainders of tooling agents and reactive material against the use environment.

4.5. Relative point to point accuracy (linear)

4.5.1. The Surgical ENT Navigation System shall provide the relative point to point accuracy with respect to its instruments and tracking technology (Optical, Electromagnetic or Manual).

4.5.2. The manufacturer of Surgical ENT Navigation System shall define a standardized reporting format, which includes definition of the coordinate systems to be used for reporting the measurements, and statistical measures (for example, mean, standard deviation, maximum error).

4.6. Visibility Range in Optical technology

4.6.1. The visibility range of the camera shall be defined. The variations and orientations required to be made in the trackable instruments, reference frames for effective use of equipment in the use environment.

4.7. Interference in Electromagnetic technology

4.7.1. The magnetic interference caused due to the other essential equipment in the use environment shall be noted and rectified with valid solutions and the variations found in accuracy of Surgical ENT Navigation System shall be determined and verified with its acceptance criteria.

4.8. Basic Safety and Essential Performance

4.8.1. The electrical safety of Surgical ENT Navigation System shall be complied with IEC 60601-1 and Electro 60601-1-2, 80601-2-77

4.9. Biological Compatibility

4.9.1. Materials used in the instruments which used in sterile environment and touch the patient shall be evaluated for biological compatibility in accordance with ISO 10993

4.10. Connectors

4.10.1. The manufacturer shall carry out risk management procedure accordance with ISO 14971 for the risk associated with connections / Integrations done to Surgical ENT Navigation System with other medical equipment's (Microscopes, Endoscopes) to consider the probability of misconnection of medical device intended for connection to other non-Surgical ENT Navigation System devices.

5. Practice

5.1. This practice provides recommendations for the collection, analysis, and presentation of data regarding the positional accuracy of surgical navigation and robotic positioning systems.

5.2. Data to be provided includes measured statistical distribution, maximum error, mean, and standard deviations, 5th and 95th percentiles of location and orientation accuracy.

5.3. This practice is for measuring accuracy of the tracking system (optical, magnetic, mechanical, and so forth) made under repeatable conditions. Subsequent standards will address the system along with any necessary imaging modality (fluoroscopy, computed tomography, magnetic resonance imaging, ultrasound, and so forth) for image-based systems, and the software for registering the images or the imageless data to the patient. Additional standards will also address task specific procedures and surgical applications (, tumor biopsy and/or resection, brain surgery (ENT approach), and so forth).

6. Apparatus

6.1. Standardized measurement object (phantom).

6.2. System to be evaluated, including tracking system, stylus, and associated required hardware and software. While the software may be custom written for the tasks

outlined in this practice it should use the same algorithms and methodologies being implemented in the commercial/clinical system to be assessed.

7. Technical Specifications

The manufacturer shall specify the technical specifications of the device which includes the following information.

i. Software specifications with versions
   a. Operating systems and ENT navigation software
   b. Security software
   c. Third party software

ii. Hardware Specifications
   a. Cart specifications
   b. Electrical hardware specifications
   c. Tools and instruments specifications (Specific designs as required by the ENT surgeries)
   d. Integrations with other medical/non-medical devices in the use environment

iii. Other Information
   a. Intended user types
   b. Use Environment
   c. Intended patient population
   d. Indications for use

8. Testing

8.1. General

All tests described in this document are type tests

8.2. Surface and Edges

The compliance of an instrument with the requirements of 4.2 shall be judged visually and subjectively, without magnifying aids and with sufficient illumination.

8.3. Relative Point to Point Accuracy

The accuracy of the system shall be determined by the use of industry defined procedure or phantom that test and provides the appropriate accuracy results to verify tools.

The accuracy shall be in accordance with ASTM F2554 - 22

8.4. Electromagnetic compatibility (EMC) and Interference in Electromagnetic technology

The manufacturer shall determine the electromagnetic interference in accordance with IEC 80601-2-30.

The manufacturer shall conduct the EMC testing of medical device in specified environment which is certified to do as per IEC 60601-1-2.

9. Marking

Each individual Surgical ENT Navigation System shall have the following minimum marking

i. Catalogue number and/or other mark sufficient to identify the instrument and its manufacturer
ii. Connections and related marking to identify and connect proper cables / connections
iii. All Instruments of Surgical ENT Navigation System shall have the Product / Device ID
iv. The manufacturer shall affix the Safety and caution related marking on the device

9.1. Marking legibility

The marking shall remain legible when the instruments are used, cleaned, disinfected, sterilized and stored in accordance with the manufacturer's instruction manual.

9.2. Marking exceptions

When marking on the instruments, detachable components and detachable semi-assembled components is impossible to achieve due to size or configuration, the required marking shall be part of the packaging or part of the accompanying instruction manual.

10. Instruction Manual

The manufacturer of the Surgical ENT Navigation System devices shall provide-the user with an instruction manual containing at least the following information:

i. a statement of the intended uses of the instrument;
ii. instructions on the functions and proper use of the instrument;
iii. annotated illustrations of the instruments as appropriate to permit the user to identify pertinent parts and characteristics of the instrument which are referenced in instruction manual
iv. identification and specifications of the instrument, including the following:
    a. manufacturers or distributor's name and address;
    b. instrument catalogue number and name;
    c. maximum working range and sterility of instruments
    d. remote controls and associated controllable portion positions available to the user;
    e. identification of any user-replaceable parts and instructions for their replacement

f. identification of any user-replaceable parts and instructions for their replacement
g. identification of where the user can obtain authorized service on the instrument;
h. identification of the accuracy of the instruments, procedure to verify the accuracy of the tools/ instruments and if required calibrate them for standard accuracy.

v. instructions as required for assembling the instrument for its intended uses, and for the disassembling of the instrument and reassembling after cleaning, disinfection and/or sterilization processes;
vi. precautions and instructions applicable for the intended uses of the instrument, including those related to electrical, electronic, electro-optical, electro-medical, or electro-acoustical apparatus intended to be used with the instrument and in conformance with IEC 60601-1-2:
    a. any available and unavailable liquids intended to be used with the Surgical ENT Navigation System instruments or device, e.g., cleansing medium, water etc. as well as any warnings concerning the usage of liquids not mentioned here;
    b. precautions for use in flammable atmospheres;
vii. inspection instructions to provide reasonable assurance that the instrument is in working order;
viii. instructions for the cleaning of reusable instruments and identification of any specific cleaning tools or equipment;
ix. instructions for the specific disinfection and sterilization environments which the equipment can survive
x. recommended procedures for the storage of the instrument prior to use and, for reusable instruments, between use.

11. Packaging

The manufacturer should package the instrument so as to protect the instrument from the adverse effects of storing and shipping environments.