Designation: F2554 – 22

Standard Practice for Measurement of Positional Accuracy of Computer-Assisted Surgical Systems[1]

This standard is issued under the fixed designation F2554; 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 document provides procedures for measurement and reporting of basic static performance of surgical navigation and/or robotic positioning devices under defined conditions. They can be performed on a subsystem (for example, tracking only) or a full computer-aided surgery system as would be used clinically. Testing a subsystem does not mean that the whole system has been tested. The functionality to be tested based on this practice is limited to the performance (accuracy in terms of bias and precision) of the system regarding point localization in space by means of a pointer. A point in space has no orientation; only multidimensional objects have orientation. Therefore, orientation of objects is not within the scope of this practice. However, in localizing a point the different orientations of the pointer can produce errors. These errors and the pointer orientation are within the scope of this practice. The aim is to provide a standardized measurement of performance variables by which end users can compare within a system (for example, with different reference elements or pointers) and between different systems (for example, from different manufacturers). Parameters to be evaluated include (based upon the features of the system being evaluated):

(1) Accuracy of a single point relative to a coordinate system.

(2) Sensitivity of tracking accuracy due to changes in pointer orientation.

(3) Relative point-to-point accuracy.

1.1.1 This method covers all configurations of the evaluated system as well as extreme placements across the measurement volume.

1.2 This practice defines a standardized reporting format, which includes definition of the coordinate systems to be used for reporting the measurements, and statistical measures (for example, mean, RMS, and maximum error).

1.3 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard, except for angular measurements, which may be reported in terms of radians or degrees.

1.4 *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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.5 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E456 Terminology Relating to Quality and Statistics

E2281 Practice for Process Capability and Performance Measurement

2.2 *Other References:*[3]

ISO 10360 Geometrical Product Specifications (GPS)—Acceptance and Reverification Tests for Coordinate Measuring Machines (CMM)

3. Terminology

3.1 *Definitions:*

3.1.1 *accuracy, n*—the closeness of agreement between a measurement result and an accepted reference value. **E456**

3.1.1.1 *Discussion*—In the context of this standard, with the definitions of bias and precision (see below), it can be considered that the accuracy of a measurement of a point will be subject to some bias error and some precision error.

3.1.2 *bias, n*—the difference between the expectation of the measurement results and an accepted reference value. **E456**

[1] This practice is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.38 on Computer Assisted Orthopaedic Surgical Systems.

Current edition approved Sept. 1, 2022. Published September 2022. Originally approved in 2010. Last previous edition approved in 2018 as F2554 – 18. DOI 10.1520/F2554-22.

[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.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

3.1.2.1 *Discussion*—In the context of this standard, bias represents the systematic error in a set of measurements of a target reference point making their average deviate from the actual reference point with a certain magnitude and direction.

3.1.3 *calibration, n*—the pre- or intraoperative registration of an item or device to its reference element.

3.1.4 *computer-assisted surgery (CAS), n*—the use of computers to facilitate or enhance surgical procedures via the use of three-dimensional space tracking of objects.

3.1.5 *coordinate measuring machine (CMM), n*—measuring system with the means to move a stylus and capability to determine spatial coordinates on a work piece surface. **ISO 10360-1**

3.1.6 *degree of freedom (DOF), n*—set of independent displacements that specify completely the displaced or deformed position of the body or system.

3.1.7 *dynamic reference base, n*—the coordinate system of a reference element used for the tracking of other therapeutic objects.

3.1.8 *fiducial, n*—an artificial item (for example, a screw or a sphere) rigidly attached to a therapeutic object to facilitate its calibration.

3.1.9 *ground truth, n*—short name for the accepted reference value (see 3.1.1).

3.1.10 *marker, n*—a single 3-degree-of-freedom indicator on a reference element or dynamic reference base.

3.1.11 *maximum error, n*—the largest distance between any measured point and its ground truth for any trial during a testing procedure.

3.1.12 *mean, n*—of a population, u, average or expected value of a characteristic in a population; of a sample, x, sum of the observed values in the sample divided by the sample size. **E456**

3.1.13 *measurement range, n*—the interval of allowed values for a specific degree of freedom while performing the practice.

3.1.14 *measurement volume, n*—measuring range of a tracker, stated as simultaneous limits on all spatial coordinates measured by the tracker. **ISO 10360-1**

3.1.15 *navigation system, n*—a set of devices consisting of a computer, its associated software, and a tracker capturing the reference elements within the measurement volume. This system provides real-time feedback of the state of the surgical scene under operation.

3.1.16 *phantom, n*—standardized measurement object. See Appendix X1 for details regarding the design of the phantom used in this practice.

3.1.17 *pointer, n*—the device offered by the evaluated system to point and locate a position on any object including anatomical landmarks. The pointer is the whole device, including the stylus-like tip all the way to any reference element used to track it in space.

3.1.18 *precision, n*—the closeness of agreement between independent measurement results obtained under stipulated conditions. **E456**

3.1.18.1 *Discussion*—In the context of this standard, precision represents scatter of a set of measurements of a point.

3.1.19 *range, R, n*—the largest observation minus the smallest observation in a set of values or observations. **E456, E2281**

3.1.20 *reference element, n*—an artificial item composed of rigidly bound markers in a unique and asymmetrical pattern recognizable by the tracker. While being rigidly attached to a therapeutic object, the position and orientation of the reference element can be used to determine those of the therapeutic object after its calibration.

3.1.21 *registration, n*—the determination of the spatial relationship between the referential frames of two coordinate systems. This may occur between two reference elements or between the fiducials and a reference element of a therapeutic object. The registration is rigid if it consists only of rotations and translations (six degrees of freedom) and non-rigid if it also comprises scaling and/or local or global distortions (seven degrees of freedom and more).

3.1.22 *repeatability, n*—precision under repeatability conditions. **E456**

3.1.23 *reproducibility, n*—precision under reproducibility conditions. **E456**

3.1.24 *robotic positioning system, n*—use of an active mechanical (mechatronic) device to position an instrument guide at a specified location in 3D space (up to six degrees of freedom).

3.1.25 *root mean square (RMS), n*—means of estimation of the scatter of a set of values, which consists of the square root of the average of the squared values.

3.1.26 *therapeutic object, n*—a surgical item or a part of the patient.

3.1.27 *tracker, n*—a device that detects and locates fiducials and markers in its measurement volume. This can be achieved by mechanical linkage or by analyzing signals of various types (visible or infrared light, electromagnetic field, or ultrasound).

4. Summary of Practice

4.1 This practice provides recommendations for the collection, analysis, and presentation of data regarding the positional accuracy (in terms of bias and precision) of surgical navigation and robotic positioning systems under repeatable conditions.

4.2 Data to be reported consists of all measurements, their corresponding errors if applicable, their statistical analysis, the test conditions, and the system conditions.

5. Significance and Use

5.1 The purpose of this practice is to provide data that can be used for evaluation of the accuracy of different CAS systems.

5.2 The use of surgical navigation and robotic positioning systems is becoming increasingly common. In order to make informed decisions about the suitability of such systems for a given procedure, their accuracy capability needs to be evaluated under clinical application and compared to the requirements. As the performance of a whole system is constrained by