



Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems¹

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1. Scope

1.1 This practice addresses the techniques of measurement and reporting of basic static performance (accuracy, repeatability, and so forth) of surgical navigation and/or robotic positioning devices under defined conditions. The scope covers the tracking subsystem, testing only in this practice the accuracy and repeatability of the system to locate individual points in space. A point in space has no orientation; only multi-dimensional 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 localization tool can produce errors. These errors and the orientation of the localization tool 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 (for example, different fixed reference frames or stylus tools) and between (for example, different manufacturers) different systems. Parameters to be evaluated include (based upon the features of the system being evaluated):

- (1) Location of a point relative to a coordinate system.
- (2) Relative point to point accuracy (linear).
- (3) Repeatability of coordinates of a single point.
- (4) For an optically based system, the range of visible orientations of the reference frames or tools.
- (5) This method covers all configurations of tool arrays in the system.

1.2 The system as defined in this practice includes only the tracking subsystem (optical, magnetic, mechanical, and so forth) stylus, computer, and necessary hardware and software. As such, this practice incorporates tests that can be applied to a prescribed phantom model in a laboratory or controlled setting.

1.3 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, standard deviation, maximum error).

1.4 This practice will serve as the basis for subsequent standards for specific tasks (cutting, drilling, milling, reaming, biopsy needle placement, and so forth) and surgical applications.

1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.6 *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 ASTM Standards:²

E456 Terminology Relating to Quality and Statistics

E2281 Practice for Process and Measurement Capability Indices

2.2 Other References:

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

3. Terminology

3.1 Definition of Terms Specific to Accuracy Reporting:

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

3.1.1.1 *Discussion*—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.

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

3.1.2.1 *Discussion*—Bias is the total systematic error as contrasted to random error. There may be one or more systematic error components contributing to the bias. A larger

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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.