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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 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.

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systematic difference from the accepted reference value is reflected by a larger bias value.

3.1.3 *maximum error, n*—the largest distance between any measured point and its corresponding reference position (for example, as measured by CMM) for any trial during a testing procedure.

3.1.4 *mean, n*—the arithmetic mean (or simply the mean) of a list of numbers is the sum of all the members of the list divided by the number of items in the list. If one particular number occurs more times than others in the list, it is called a mode. The arithmetic mean is what students are taught very early to call the "average". If the list is a statistical population, then the mean of that population is called a population mean. If the list is a statistical sample, we call the resulting statistic a sample mean.

3.1.5 *measurement range, n*—see *measurement volume*.

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

3.1.6.1 *Discussion*—Precision depends on random errors and does not relate to the true value or the specified value. The measure of precision usually is expressed in terms of imprecision and computed as a standard deviation of the test results. The standard deviation is expressed as:

$$S = \sqrt{\frac{\sum_{i=1}^{N}\left(X_i - \bar{X}\right)^2}{N-1}}$$

Less precision is reflected by a larger standard deviation. "Independent test results" means results obtained in a manner not influenced by any previous result on the same or similar test object. Quantitative measure of precision depends critically on the stipulated conditions. Repeatability and reproducibility conditions are particular sets of extreme stipulated conditions.

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

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

3.1.8.1 *Discussion*—Repeatability is one of the concepts or categories of the precision of a test method. Measures of repeatability defined in this compilation are repeatability, standard deviation, and repeatability limit.

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

3.1.9.1 *Discussion*—Ability of a test or experiment to be accurately reproduced, or replicated.

3.1.10 *resolution, n—of a device/sensor*, the smallest change the device or sensor can detect in the quantity that it is measuring. The resolution is related to the precision with which the measurement is made.

3.1.11 *standard deviation, n*—the most usual measure of the dispersion of observed values or results expressed as the positive square root of the variance. **E456**

3.1.12 *variance, n—of a random variable*, measure of its statistical dispersion, indicating how its possible values are spread around the expected value. Where the expected value shows the location of the distribution, the variance indicates the scale of the values. A more understandable measure is the square root of the variance, called the standard deviation.

3.2 *Definition of Terms Specific to Surgical Navigation and Robotic Positioning Systems:*

3.2.1 *data integrity, n*—condition in which data is identically maintained during any operation, such as transfer, storage, and retrieval.

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

3.2.3 *dynamic reference base, n*—a reference element that is intraoperatively attached to a therapeutic object and allows tracking that object. It defines the local coordinate system of the therapeutic object.

3.2.4 *fiducial, n*—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.

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

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

3.2.7 *navigation system, n*—a device consisting of a computer with associated 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.

3.2.8 *reference element, n*—a device attached to surgical instruments and implants and other devices that enables determination of position and orientation in 3d space (up to 6 degrees of freedom) of these by means of a tracker. It defines the local coordinate system of this instrument or implant.

3.2.9 *referencing, n*—tracking of a therapeutic object by means of a dynamic reference base.

3.2.10 *registration, n*—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.

3.2.11 *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 6 degrees of freedom).

3.2.12 *stylus, n*—a mechanical device consisting of a stylus tip and a shaft. The stylus tip is the physical element that establishes the contact with the workpiece. **ISO 10360-1**

3.2.13 *tool calibration, n*—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).

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3.2.14 *tracker, n*—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.

3.2.15 *tracking, active, n*—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).

3.2.16 *tracking, passive, n*—a tracking technology that uses markers that absorb or reflect externally produced energy. (for example, an light based tracking technology that uses reflective spheres or similar objects as markers).

3.3 *Others:*

3.3.1 *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.

3.3.2 *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**

3.3.3 *phantom, n*—standardized measurement object. See Appendix X1 for recommendations regarding phantom design. Specific points referenced in this practice are with regards to the recommended phantom design in Appendix X1.

4. Summary of Practice

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

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

4.3 This practice provides protocols (Section 8) 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 (joint arthroplasty, osteotomy, tumor biopsy and/or resection, laproscopy, pedicle screw insertion, brain surgery, and so forth).

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 and requires a degree of trust by the user that the data provided by the system meets necessary accuracy requirements. In order to evaluate the potential use of these systems, and to make informed decisions about suitability of a system for a given procedure, objective performance data of such systems are necessary. While the end user will ultimately want to know the accuracy parameters of a system under clinical application, the first step must be to characterize the digitization accuracy of the tracking subsystem in a controlled environment under controlled conditions.

5.3 In order to make comparisons within and between systems, a standardized way of measuring and reporting accuracy is needed. Parameters such as coordinate system, units of measure, terminology, and operational conditions must be standardized.

6. Apparatus

6.1 Standardized measurement object (phantom). See X1.1.

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. Hazards

7.1 None.

8. Procedure

8.1 A standardized measurement object (phantom) measured with a CMM or similar measurement device calibrated to a traceable standard, will be used to evaluate the accuracy of the tracking subsystem. The resolution of this measurement device will determine the significant digits that can be reported in the results See Appendix X1 for phantom recommendations. The accuracy of the measurement device must be at least 4×, and preferably 10×, as accurate as the anticipated accuracy to be reported.

8.2 Rigid attachment of a dynamic reference base to the phantom is to be performed according to navigation system manufacturer's recommendations. Once testing has begun, the dynamic reference base should not be repositioned relative to the phantom. Note that some systems, such as Robotic Positioning Systems, may not use a dynamic reference base. Measured points should be expressed in the coordinate system defined by the dynamic reference base where applicable.

8.3 *Test Conditions:*

8.3.1 Test conditions (temperature, humidity, and so forth) should be recorded and reported (Section 9). Known potential sources of interference should be replicated by simulating as realistic an environment comparable to the operating room conditions (for example, infrared noise and reflections for optical systems, large metal objects for electromagnetic systems, and so forth).

8.3.2 *System Conditions*—Any changes to standard system (tool or stylus configuration, and so forth) configuration must

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be reported (Section 9). Specific details of the phantom to be used, with particular regard to the divot geometry (see Fig. X1.2).

8.3.3 Single point measurements to quantify accuracy of single points and effect of tool orientation. A single calibration point on the phantom will be digitized using the specifically designated and identified device (stylus, pointer, and so forth) specified by the Navigation and/or Robotic System manufacturer. Data will be collected by software on the Navigation and/or Robotic System. The measurement shall consist of an appropriate sample size, with a minimum of six independent trials performed at a single point (#20 Fig. X1.4) on the phantom. All measured tool tip positions shall be averaged to obtain the average tool tip position. The difference between each measured tip position and this average shall be computed. The mean, maximum error and standard deviation of these calculated differences shall be reported. Optionally, this computation can also be performed for each of the 3 substeps below (that is, compute mean, maximum, and standard deviation of the calculated differences for just the data obtained in step 8.3.4, 8.3.7).

8.3.4 The purpose of this step is to evaluate whether accuracy of the coordinates measured at the tip of the tool is affected by the angle of rotation of the tool about its axis. At point number 20 (Fig. X1.4), start with the tool's reference element perpendicular to the relevant face of the phantom and rotate tool about its axis 360°. Data should be collected at approximately 15°(±5°) increments. Data to be reported include the angles at which data integrity is lost and regained, if applicable, as well as the coordinates of the tip of the tool at each 15° measurement.

8.3.5 The purpose of this step is to evaluate whether accuracy of the coordinates measured at the tip of the tool is affected by the angular position in the plane perpendicular to the camera or detection device of the CAS Using the protractor scale on the phantom at point number 20 (Fig. X1.4), imagine a plane approximately perpendicular to the face along the 90°–270° axis, lean the tool's reference element back and forth along that plane. There must be a minimum of 6 approximately equally (±5°) spaced measurements over the measurement range. Record the angle of rotation of the tool and the coordinates of the tip.

8.3.6 The purpose of this step is to evaluate whether accuracy of the coordinates measured at the tip of the tool is affected by the angular position in the plane parallel to the camera or detection device of the CAS. Using the protractor scale on the phantom at point number 20 (Fig. X1.4), imagine a plane approximately perpendicular to the face along the 0°–180° axis, lean the reference element back and forth along that plane. There must be a minimum of 6 approximately equally (±5°) spaced measurements over the measurement range. Record the angle of rotation of the tool and the coordinates of the tip.

8.3.6.1 *Distance Measurement between Points*—The purpose of this step is to determine the accuracy of measuring the distances between various points. For each pair of points, the distance error shall be computed as the difference between the measured distance and the known distance (i.e., distance error = measured distance – known distance). Maximum, minimum, mean, and standard deviations of error of the distances, and the distance ranges, will be calculated and reported.

8.3.7 In each trial, the tester locates the individual marked points on the phantom following the navigation system manufacturer's instructions for obtaining point data. Note that the manufacturer instructions (including tool orientation) may require collection of only a single data point or they may require a pivot motion to allow multiple readings to be averaged. Points should be digitized in the specified order (see Appendix X1). The test report should note whether or not all points were digitized with similar (within approximately 10°) orientation. Measurements should be reported in units of millimeters. The data from this step addresses the data needs for the 2nd goal.

8.4 Repeat steps 8.1 through all steps in 8.3 in different phantom orientations and positions within the measurable volume (with all systems). For optical systems, one orientation perpendicular to the image plane, and one at the maximum rotation allowed by the tracking device and/or dynamic referencing device will be tested at each position. Positions will include the center of the measurement volume, as well as three extreme positions of the measurable volume (for optical systems—two (orthogonal directions) in the image plane and one perpendicular to the image plane). Present results as mean, standard deviation, max, for each position and orientation.

8.5 If the system has different reference frame array configurations then steps 8.1 through 8.3 should be repeated for each different array that is attached to the phantom in combination with a point localizing tool array.

9. Report

9.1 Report characteristics of phantom and calibration, including divot geometry.

9.2 Location of phantom for each step in Section 8.

9.3 The report should include:

9.3.1 Coordinates and location of all points measured with appropriate units,

9.3.2 Maximum error,

9.3.3 Mean of errors,

9.3.4 Standard deviation of all errors, and

9.3.5 Temperature, humidity, lighting, interference sources.

10. Precision and Bias

10.1 As with any measurement system, uncertainties and errors will be present. A Coordinate Measuring Machine (CMM) or other traceable measurement device of suitable precision will be used as the "gold standard" reference, but these devices have finite accuracy. Manufacturer claimed accuracies of 0.25 mm or better for most CMM exceed the expected accuracies of surgical navigation systems by several times. The accuracy of the particular system to be used can be evaluated by measuring the standardized calibration object.

11. Keywords

11.1 computer assisted surgery; computer navigation; imageless guided surgery; infrared tracking system; optical tracking

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APPENDIX

(Nonmandatory Information)

X1. PHANTOM

X1.1 A standardized measurement object (phantom) following the general design contained herein will be used in applying this practice. While each group executing this practice is free to construct their own phantom (or purchase one from a 3rd party) each individual phantom must be measured with a CMM or similar measurement device traceable to NIST, FDA, EU, and ISO standards. The phantom will be used to evaluate the accuracy of the tracking subsystem. This object will have forty-seven marked points arrayed at known locations on the surface (coming in from multiple angles; dependency on tracking device). Points 1 and 19 will be arranged in such a way as to establish the *x*-axis of a Cartesian coordinate system. Points 1 and 18 will be arranged in such a way as to establish the *y*-axis of a Cartesian coordinate system, ensuring perpendicularity to the *x*-axis. The intersection of these lines will establish the origin of the coordinate system. The cross-product of the *x* and *y* axes will define the *z*-axis. Include machined faces or slots at 6 unique orientations. Include threaded holes for interface of adapter for dynamic reference frame attachment.

X1.2 *Material Recommendations* —Each group applying this practice is free to manufacture the phantom out of a material of their choosing. If such material is not dimensionally stable then it should be calibrated under similar conditions those in which it will be used.

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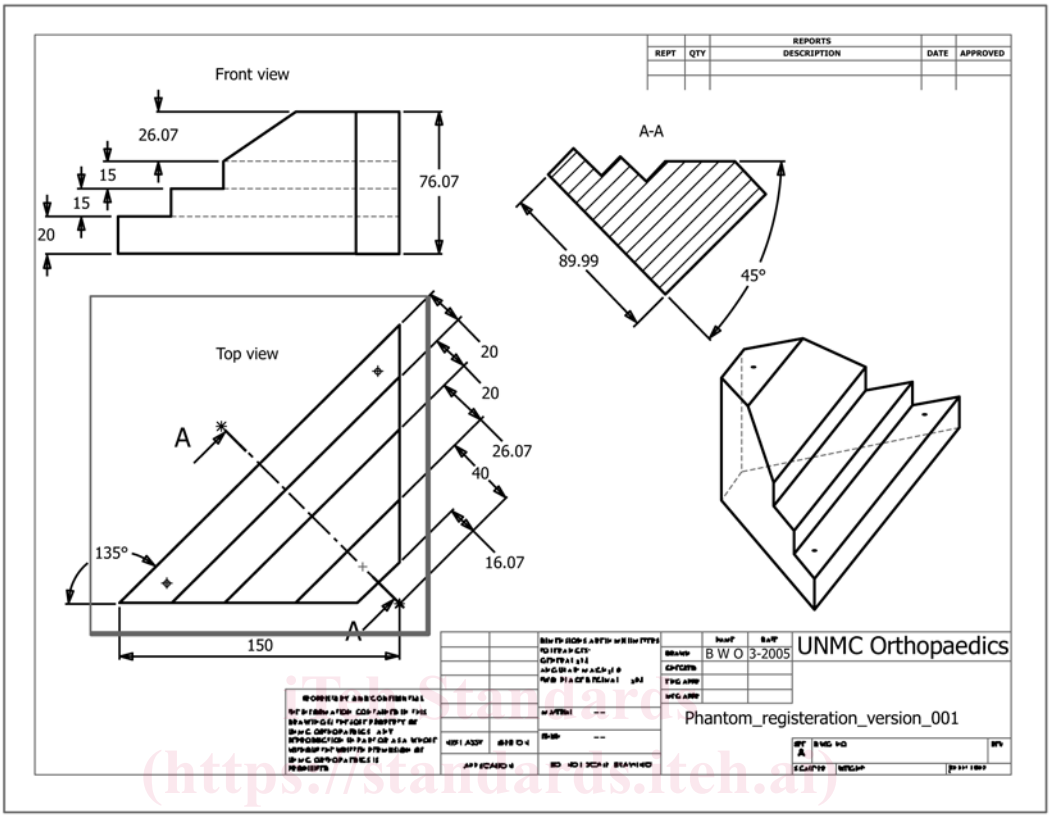

FIG. X1.1 Blueprint of Phantom

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