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Designation: F3107 – 14

# Standard Test Method for Measuring Accuracy after Mechanical Disturbances on Reference Frames of Computer Assisted Surgery Systems[1]

This standard is issued under the fixed designation F3107; 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 standard will measure the effects on the accuracy of computer assisted surgery (CAS) systems of the environmental influences caused by equipment utilized for bone preparation during the intended clinical application for the system. The environmental vibration effect covered in this standard will include mechanical vibration from: Cutting saw (sagittal or reciprocating), Burrs, drills and impact loading. The change in accuracy from detaching and re-attaching, or disturbing a restrained connection that does not by design require repeating the registration process of a reference base will also be measured.

1.2 It should be noted that one system may need to undergo multiple iterations (one for each clinical application) of this standard to document its accuracy during different clinical applications since each procedure may have different exposure to outside forces given the surgical procedure variability from one procedure to the next.

1.3 All units of measure will be reported as millimeters for this standard.

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 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

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

F2554 Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems

2.2 *ISO Standard:*[3]

ISO 10360 Geometrical Product Specifications (GPS) — Acceptance and re-verification 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 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 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**

[1] This test method 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 Dec. 1, 2014. Published January 2015. DOI: 10.1520/F3107-14.

[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.

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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.

3.1.6.2 *Discussion*—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 measures of precision depend 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 devise/sensor*, smallest change it 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 *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.

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

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

3.2.4 *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.

3.2.5 *fiducial, n*—an artificial object (e.g., screw or sphere) that is implanted into, or a feature created on, a therapeutic object prior to virtual object acquisition to facilitate registration.

3.2.6 *marker, n*—a single indicator on a reference element or dynamic reference base where a collection of these indicators are utilized to define an object, tool or reference frame in space.

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

3.2.8 *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.

3.2.9 *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.

3.2.10 *reference point, n*—a designated point on the phantom or sawbone used to repeat measures and to make comparisons to after each trial is performed within the standard.

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

3.2.12 *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.

3.2.13 *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).

3.2.14 *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**

3.2.15 *tool calibration, n*—the pre- or intraoperative determination of the location of points-of-interest on a navigated instrument (e.g., its tip position, axis) in relation to a reference frame (e.g., the attached reference element for a tracked instrument).

3.2.16 *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, etc.

3.2.17 *tracking, active, n*—a tracking technology that uses markers that emit energy (e.g., an infrared light based tracking technology that uses pulsed LEDs as markers, ultrasound, electromagnetic fields, etc.).

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

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