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**

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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.

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

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).

4. Summary of Test Method

4.1 *Reference Base Attachment Tolerance*—This portion of the standard will evaluate the robustness of the reference base and tracking array attachment to outside forces and repeated use in an environment and application that is clinically relevant to their intended use. These forces will simulate operating room incidental contacts from end users and assistants. The results will allow comparison of the stability and repeatability of the tolerances and strength of the reference base attachment of the markers used for the CAS system. Utilization of a phantom will be used as described in F2554-10 for attachment of the reference base in a clinically applicable manner to the intended use of the CAS system being tested.

4.2 The second portion of this standard will entail testing typical situations in the operating room that occur during a surgical procedure that can impact the accuracy of the CAS system that involves a computer marker attachment to a bony landmark. This portion of the standard will involve attachment of a reference base to the chosen model according to manufacturer's guidelines and performing procedures using a material of similar density and mechanical property of the applicable bony anatomical region being tested. Measurement of a marked point on the chosen test specimen which will be repeated with a pointing device to a set of six points on the test specimen with removal of the tracking array from the reference base, reattachment and repeat. This procedure will be repeated for sagittal saw, drilling and impaction procedures. Above completed for a minimum of 6 trials with the mean, STD, and 95% confidence interval calculated and tabulated.

5. Significance and Use

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

5.2 The use of CAS systems and robotic tracking 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 point 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 Fig. 1.

6.2 System to be evaluated, including tracking system, stylus or any pointing device, and associated required hardware and software. While the software may be custom written for the tasks outlined in this standard it should use exactly the same

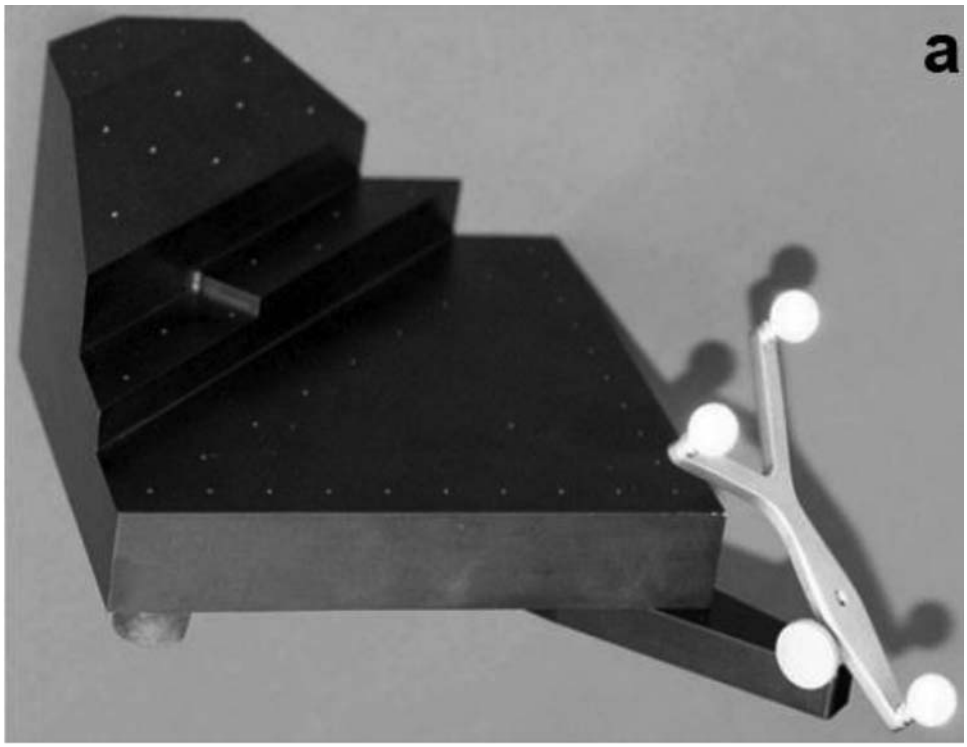

FIG. 1 Phantom

algorithms and methodologies being implemented in the commercial/clinical system to be assessed under this standard.

6.3 A chosen biomechanical test specimen that is anchored or rigidly fixed to the phantom and placed on a table will be utilized. A standard reference base attachment and manufacturer application tools will be utilized during the procedure. See Fig. 1.

7. Hazards

7.1 The hazards from performing the standard are from handling the instruments and from the saw and drill bits. No human or biological tissues are utilized so no biohazard exists.

8. Procedure—Reference Base Attachment Test

8.1 Complete steps 8.1 to 8.33 in F2554-10 utilizing the phantom described in Appendix A2 but with utilizing one determined point on the phantom. Note that the reference base must be part of the CAS system being tested (those typical of tracking bony reference landmarks and instruments) and attached to the phantom. It cannot be a permanent part of the phantom and must include a reference base attachment for the active or passive markers. If the array is not detachable from the reference base then it is left alone for all tests in this standard.

8.2 Measure the chosen point on the phantom for a baseline comparison. Next, detach the reference base from the phantom completely, reattach and then perform a measurement on the same point of the phantom as in 8.1.1. Steps 8.1.1–8.1.2 will be completed 6 times with the same point registered and the Mean, STD, 95% confidence interval, standard error, range and maximum error for each Cartesian measure (x, y, and z).

8.3 The same steps above will then be performed with a spring scale attached to the reference base. Apply a 10 N force on the attached spring scale in a perpendicular to the nominal axis of the reference base at a distance of 1 cm from the bony surface. Record the locations of the same 6 designated points, and compare those locations to the previous corresponding measured locations. Determine to the scalar distance This will be repeated for 20N and 30N and the mean, standard deviation and 95% confidence interval recorded for each trial (0 N, 10 N, 20 N and 30 N).

8.4 *Applied Clinical Tasks:*

8.4.1 The CAS system should be setup around a table within the recommended distance away from the detection camera according to the CAS specifications. The CAS system should be setup to perform the simulated surgical procedure that is being tested. The chosen test specimen is then rigidly attached to the table at the discretion of the person performing the test, but.in a consistent manner throughout each trial. If the system requires certain registration landmarks and indirect registration points (e.g., center of the femoral head) then the test specimen preparation and setup must include those joints (e.g., the hip joint and the ankle joint for total knee arthroplasty procedure). If necessary, the use of simulated bony landmarks is acceptable as long as they are within the applicable region of interest. The reference base should be attached at the anatomical location recommended for the system being tested.

8.4.2 A point on the test specimen will be marked with a 1.2 mm drill bit in a unicortical fashion at three points along varying aspects of the circumference of the specimen or the bony region chosen for the application tested and should not be colinear. If the CAS system tool has a larger tip than 1.2 mm then you may select a larger drill bit size for this step. These points will be utilized as the points to be measured and compared throughout the standard (these will serve as the defined “Reference Points”). Each of these points should be located a minimum of 10cm from the reference base attachment.

8.4.3 A sagittal saw cut at either end of the test specimen will then be performed and the reference points digitized for comparison. A sagittal saw cut will then be repeated on the same test specimen for a minimum of 6 trials. The sequential bone cuts should be of a sufficient thickness to allow for 6 complete passes with the sagittal saw through the entire test specimen utilized.

8.4.4 A 2.5 mm drill bit will then be utilized to perform a drill hole through the entire thickness of the test specimen. After the drill hole has been completed the reference points will be digitized for comparison. This will be repeated for a minimum of 6 drill holes through the entire test specimen.

8.4.5 Tolerance to the effects of burring the test specimen will also be tested in a similar manner. A 5 mm round type cortical burr tip will be utilized at an RPM of chosen speed typical for operating room tasks. Six burr holes will be placed at a minimum depth of 5mm and the reference points digitized after each burr hole is made and recorded for comparison.

8.4.6 Impaction testing: placing an intramedullary rod or other impaction device onto or into the chosen test specimen a 0.25 kg weight is then dropped from a distance of one foot from the residual metaphysis or applicable region of the sawbone. After a 0.25 kg weight will be dropped from a height of 1 foot onto the metaphyseal end of the sawbone the reference points will be digitized. This will be repeated at a minimum of six times.

9. Report

9.1 The report should include for each section in Section 8:

9.1.1 Test specimen and anatomical type,

9.1.2 Fixation method to fix synthetic bone model to the table (Medium size synthetic bone if possible),

9.1.3 Describe the reference base attachment location diagrammatically,

9.1.4 Specific reference frame coordinates labeled diagrammatically,

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

9.1.6 Distance measure to the reference point for each task performed,

9.1.7 Maximum error,

9.1.8 Mean for each step with 95% confidence intervals,

9.1.9 Standard deviation,

9.1.10 Precision,

9.1.11 Range, and

9.1.12 Temperature and humidity.

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. Using a standard type of bone model to mimic bony applications although may introduce small amounts of bias into the system it serves as a relatively consistent variable. The procedure as described is the start of task oriented testing method designed to measure the additive effects of surgical operating room tasks on the robustness of the reference frame attachments and cumulative accuracy of the system.

11. Keywords

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

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