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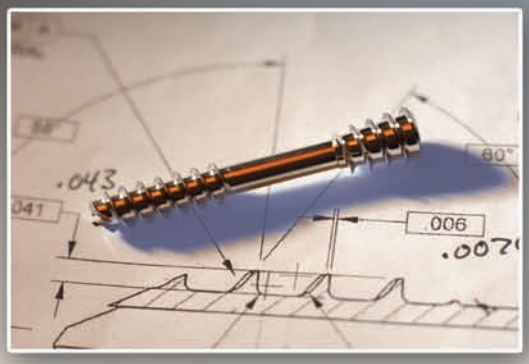

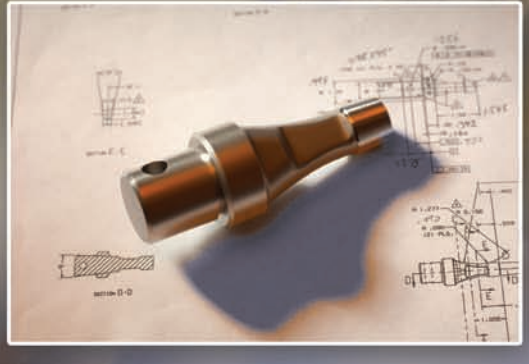

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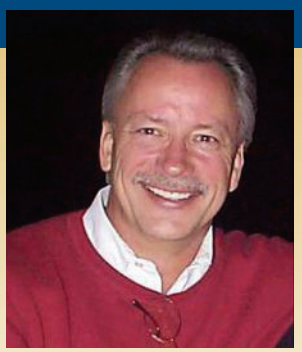

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Software Validation Considerations within Medical Companies per "FDA 21 CFR PART 11"

One critical challenge facing today's medical OEMs and suppliers is validating analytical software used for determining compliance to mechanical drawings for components and assemblies. This article will make visible some of the risks and limitations in current software validation and provide direction to simplify future validation initiatives. This information will aid individuals chartered with the responsibility to ensure the analytical software used at their company and throughout their supplier base meets validation criteria intended to be in compliance with the FDA 21 CFR PART 11.

Compliance to "FDA 21 CFR PART 11"

Part 11 requires medical device manufacturers, biotech companies, biologics developers and other FDA-regulated industries, with some specific exceptions, to *implement controls, including audits, system validations, audit trails, electronic signatures and documentation for software and systems involved in processing electronic data that are (a) required to be maintained by FDA's predicate rules or (b) used to demonstrate compliance to a predicate rule.*

Requirements to meet Part 11 are not defined clearly as there are so many different levels of software to consider. Analytical software used to determine if mechanical components comply with stated engineering requirements must comply with the only mathematical standard in the world supporting compliance to the ASME Y14.5M-1994 Standard—which is ASME Y14.5.1M-1994. In other words, all analytical software used for determining compliance to mechanical engineering drawings that state compliance to ASME Y14.5M-1994 must be validated per the ASME Y14.5.1-1994 Standard.

Major medical OEMs such as Medtronic (in its CRDM and Neurological Divisions) have aggressively analyzed the broad array of analytical software used for determining compliance to the Y14.5/Y14.5.1 Standards. The result of this aggressive analysis has influenced specific mathematical test cases to be developed to determine limitations with most analytical software.

Risk to Medical Industry

Medical components are increasing in complex surface geometries and decreasing feature tolerances. Both of these factors are driving the need for unprecedented precision in product design definition. Precision Geometric Dimensioning & Tolerancing (GD&T) has been identified as the key solution for dimensioning and tolerancing practices for mechanical and electro-mechanical components and assemblies. This increased complexity makes it mandatory for components and assemblies to be analyzed with higher precision measurement devices and validated software that ensures sound mathematical definition and traceability to the applicable dimensioning and tolerancing standards. Without utilizing mathematically validated software, the medical industry is at a high risk of increased development cycles, component and product failures and compromised product reliability.

Precision GD&T and Requirements for Software Validation

The precision language of Dimensioning & Tolerancing is explicitly defined in the ASME Y14.5M-1994 Standard on Dimensioning and Tolerancing, and is mathematically complimented by the ASME Y14.5.1M-1994 Standard on Mathematical Definition of Dimensioning and Tolerancing Principles. Both of these Standards form the basis for a precise definition of complex surface geometries and should be the basis for mathematical analysis using validated software intended to be in compliance with FDA 21 CFR PART 11.

Exhibit 1 is an engineering drawing from Pioneer Surgical Technology. It depicts profile tolerancing of all 3D surfaces being defined with explicit profile of a surface callouts. Validating software used for determining compliance to critical engineering requirements such as these and other precision GD&T and measurement requirements are essential for proving compliance to medical devices.

Exhibit 2 is an engineering drawing example depicting profile tolerancing of all 3D surfaces being fully defined with three explicit profiles of surface callouts per the ASME Y14.41-2003 Standard.

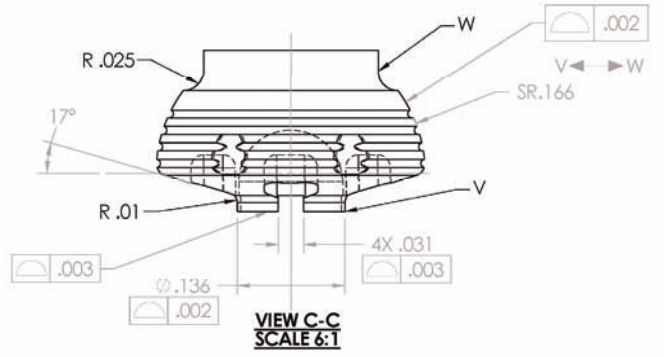
Exhibit 3 is a non-orthopaedic engineering drawing depicting profile tolerancing of all external 3D surfaces defined with profile of a surface callouts that are in relationship to the datum reference frame, which allows mobility of the Profile Tolerance zone in relationship to datum simulators. Many medical companies have multiple divisions that not only encompass orthopaedic products, but also other major medical components and assemblies. Ensuring that analytical software is capable of proving compliance to these critical requirements is not insignificant. It requires aggressive software validation criteria to be established to ensure the medical components being produced will truly comply with all of their stated requirements.

Limitations in Most Analytical Software

Most companies with advanced metrology needs have, over a period of years, purchased a broad range of coordinate measuring machines (CMMs). Each machine comes with its own unique analytical software package requiring installation, upgrades and licenses. Unfortunately, this array of analytical software can evaluate the same data sets and derive completely different results. The majority of software does not have the ability to ensure full compliance to the ASME Y14.5.1M-1994 Standard. This problem is magnified when different users, even within the same department, can take the same measured data set, imbed it into multiple analytical software programs and derive completely different results. The real danger is that all of these results can be repeatably and reproducibly incorrect.

These results will not be made visible in most medical OEMs and suppliers. In most cases, good measurement is limited to determining if measured results satisfy a "Gage Repeatability and Reproducibility" study (GR&R). The analyzed results from any CMM software can be "Repeatable and Reproducible" (R&R) and not even be compliant with the stated engineering requirement per the ASME Y14.5/Y14.5.1 Standards.

Exhibit 1: 3D Engineering Drawing Example per ASME Y14.5M-1994 (all dimensions are basic)



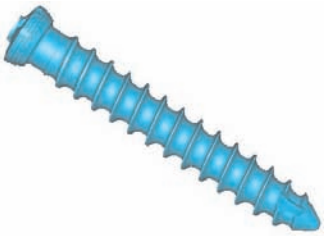


Exhibit 2: 3D Engineering Drawing Example per ASME Y14.41-2003

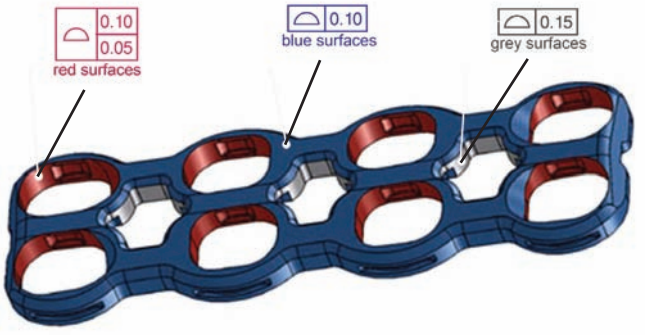
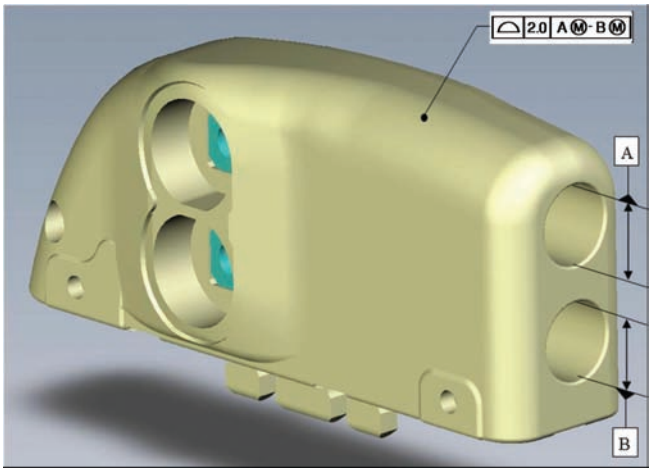


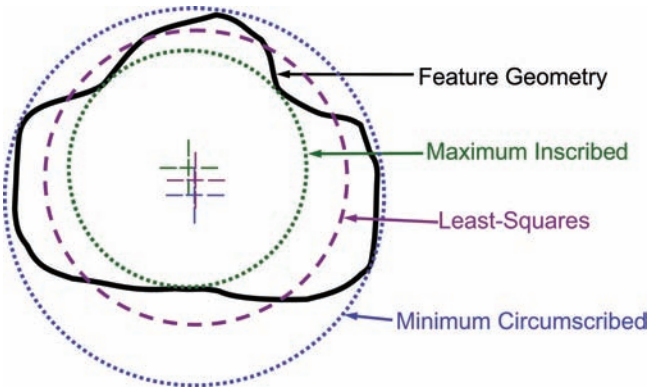
Exhibit 3: 3D Engineering Drawing Example per ASME Y14.5M-1994 with Complex Requirement



Software Validation Considerations... continued from page 27

Exhibit 4 is a simple example for the measurement of a cylindrical feature of size for its actual mating size and location of the axis of the actual mating envelope. The majority of software default to least squares fitting to determine the features size as well as the location of its axis in both the X and Y direction. Using least-squares analysis, commonly referred to as Best-Fit analysis or an averaging result, to derive all three measurements will conclude with the incorrect results per the ASME Y14.5M-1994 Standard. These results can be repeatably and reproducibly incorrect. The correct results would require analysis of the largest inscribed cylinder or the smallest circumscribed cylinder depending on the feature being an internal or external feature and the considered feature modifier applied by the designer. While the majority of software have the fundamental ability to apply maximum inscribed and smallest circumscribed algorithms, in most cases the metrologists at OEMs and Suppliers are not incorporating these fundamental algorithms and are not even aware of the broader limitations of the analytical software.

Exhibit 4: Analysis of a Cylindrical Feature of Size



OEMs and suppliers already know when this is occurring, as one of two scenarios results. Measurement data can look good: it complies with specification requirements, but the parts do not work or fit properly; or measurement data can look bad: it does not comply with specification requirements, but the parts actually do work. The implications to statistical data analysis on medical components and assemblies are disturbing and place product reliability at risk. It is common throughout industry for OEMs to request statistical data from suppliers and use this data to evaluate the supplier's process capability. This can take the form of capability indices such as Cpk, which is analyzed using measurement results. A major implication to valid statistical data is valid measurement results, which in the majority of cases are incorrect.

Certificate of Software Compliance by National Laboratory

Some OEMs and suppliers consider their software validated if it comes with a certificate of compliance from a national laboratory such as the National Institute of Standards and Technology (NIST) in the U.S. or the Physikalisch Technische Bundesanstalt (PTB) in Germany. Many are unaware that, at NIST and PTB, the critical element of these certificates--algorithm testing--is restricted to the basic form elements: straight line, plane, circle, cylinder, cone and sphere. In addition, reference results are calculated using the Gaussian method of least squares, usually referred to as best-fitting algorithms, which fundamentally means averaging algorithms. These fitting algorithms do not comply with the ASME Y14.5.1 Standard. It is also critical to understand that the individuals from NIST and PTB are involved with further development of testing per the Y14.5.1 Standard. These limitations are forcing medical OEMs to develop their own mathematical data sets to prove compliance to the more challenging requirements of the ASME Y14.5.1-1994 Standard.

Expectation of Compliance to Engineering Requirements

Medical devices will be produced and shipped with confidence once it is known that they, in fact, meet the stated requirements. This means that measured results must confidently ensure that the resulting values prove conformance to requirements with a low enough "Measurement Uncertainty." This is not possible given the current GR&R criteria and acceptance criteria defined within companies. Current criteria does not include truncating, or guard banding, the tolerance based on the magnitude of measurement uncertainty as defined in the ASME B89.7.3.1-2001 Standard on "Considering Measurement Uncertainty in Determining Conformance to Specifications."

Future Direction of Analytical Software - a Better use of CMM Data Points

Historically, metrologists have found the measurement of complex surface profiles too challenging due to CMM software limitations. Today, profile tolerancing is considered one of the simplest ways to analyze complex surface geometries—so long as the users have the applicable software.

SmartProfile™ analytical software by Kotem Technologies, for example, has been mathematically validated to generated data sets specifically targeted at validating proof of compliance to the ASME Y14.5.1M-1994 Standard, and is now used by many medical companies to ensure proof of compliance with the stated engineering standard. SmartProfile defaults to using optimization algorithms to help ensure optimized results per the Standard.

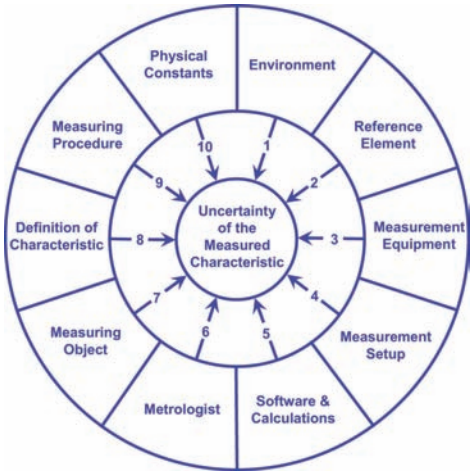
It quickly communicates compliance or non-compliance to the specified tolerance, and the output values are what the metrologists and engineers use to determine compliance vs. non-compliance as well as inputs into any level of statistical analysis. SmartProfile provides additional information tremendously valuable to manufacturing and engineering functions, as it graphically represents absolute deviations showing the total range of results. This level of information allows manufacturing engineers to immediately see root-cause effects resulting from the manufacturing process and provides indications on how to optimize the process to achieve better results.

SmartProfile may solve or significantly reduce the software validation effort on every metrology software package. Many companies are not capable of analyzing results to the ASME Y14.5.1 Math Standard. This allows validation to one software package that can be used no matter what CMM they have. The value of CMMs is that they collect measured points by single sensor and multi-sensors such as tactile, vision, laser, white light and other technologies to optimally capture the measured point arrays. But all of their various software can provide different results. A better solution is to use the CMM to simply collect data points or a point cloud and then import it into SmartProfile for final analysis. Supplier Engineers, Development Engineers and others can simply request the measured point array from the metrologist and analyze results in minutes rather than rely on confusing inspection reports.

The Wheel of Uncertainty

Many error sources must be considered by the metrologist when measuring parts. Exhibit 5 illustrates a wheel of uncertainty contributors which depicts categories of inherent error sources that should be a minimum consideration by the metrologist. One of these key error sources is Software and Calculations. It is very easy to have measured results that are repeatably and reproducibly incorrect, as uncorrected biases are easily induced that can be many times larger than the repeatability and reproducibility numbers initially recognized by the metrologist.

Exhibit 5: Wheel of Uncertainty Contributors



It is essential for everyone to understand that all task-specific measurements will result in some level of uncertainty. However, it is critical that the metrologist or the individual doing to analysis uses the fitting algorithm that provides minimal uncertainty as a ratio to the specification tolerance. A very significant error that is not usually addressed is biases caused by softwares that are not capable of some of the more complex geometric requirements.

Test Criteria for Compliance to Engineering Requirements

Stated Compliance to the engineering requirements as defined per the ASME Y14.5 and Y14.5.1 Standards and therefore FDA 21 CFR PART 11 require compliance with the following "Test Criteria."

1. **Size**, which is defined as having two parts based on "Limits of Size" criteria defined in section 2.3 of the Y14.5.1 Standard. This requires compliance to both the "Actual Local Size" and "Actual Mating Size."
2. **Datums** which are based on criteria defined in section 4.3 of the Y14.5.1 Standard, which requires:
    a. Datum "Features of Size at RFS" (Regardless of Feature Size) to be simulated as "Actual Mating Envelopes."
    b. Datum "Features of Size at MMC (Maximum Material Condition) or LMC (Least Material Condition)" to be simulated as "Virtual Conditions."
    c. "Multiple Features of Size" defined as a "Single Datum" to be "Simulated as Patterns" based on "Actual Mating Envelopes" (RFS) or "Virtual Conditions" (MMC or LMC).
3. **Position** Tolerances which are based on criteria defined in section 5 of the Y14.5.1 Standard, which requires:
    a. Analysis of axes based on "Actual Mating Envelope" principle.
    b. Analysis of "Bonus Tolerance" based on applicable features defined at MMC or LMC.
    c. Analysis of "Simultaneous Requirement" which requires all features to simultaneously be within their respective tolerances when the feature control frames have the same datum, in the same sequence with the same datum feature modifiers.
    d. Analysis of Single-Segment vs. Composite Feature Control Frames.

Software Validation Considerations... continued from page 29

4. **Profile** Tolerances which are based on criteria defined in section 6.5 of the Y14.5.1 Standard, which requires:
    a. Minimum Zone fitting algorithms are used.
    b. Profile results must always look for the smallest possible deviation of the actual geometry (worst case measured point) from nominal geometry, ideally a CAD model that can be compared to the profile tolerancing in the feature control frame.
    c. Must ensure "Simultaneous Requirements" are being met, which requires all features to simultaneously be within their respective tolerances when the feature control frames (Single-Segment) "have the same datum, in the same sequence with the same datum feature modifiers."
5. **Revision** changes of software must be validated to original "Test Criteria" for continued "*Proof of Compliance*" to ensure ongoing integrity of measured results and conformance to requirements.

Conclusion

Proof of compliance to precision requirements defined on mechanical drawings by design engineers on all mechanical components and assemblies are essential to ensuring functional intent within stated requirements. Miniaturization of medical components and significant reduction in feature tolerances make it mandatory for components and assemblies to be analyzed with validated software, such as SmartProfile, that proves compliance to all stated requirements of the ASME Y14.5M-1994 and ASME Y14.5.1M-1994 standards. Only in so doing can medical device manufacturers meet not only the requirements, but the technically correct interpretation of FDA 21 CFR PART 11.

A Customer and Supplier Partnership in Precision Tolerancing and Validation of Analytical Software

A commitment to precision tolerancing and validation of analytical software is a true partnership between an OEM and their suppliers. Here are some tips on how you can be sure both parties are committed to achieving optimum goals:

- Are designers precisely defining complex surface geometries using precision GD&T?
- Are OEMs and suppliers investing and standardizing in precision measurement equipment and validated software needed to analyze complex geometries with low measurement uncertainty?
- Are OEMs and suppliers jointly working on proof of compliance for all analytical software used for determining compliance to stated engineering requirements?
- Has there been fundamental to advanced training in profile and position tolerancing per the ASME Y14.5 Standard?

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Dr. Hetland has 30+ years experience in the Medical, Disc-Drive, Aerospace, Defense and Commercial industries with extensive expertise in the mechanical and precision engineering fields as an engineer, consultant, educator and author. He has extensive technical society affiliation and is recognized worldwide as chairman and member of U.S. committees as well as a U.S. representative on international standards development in the areas of dimensional tolerancing, physical metrology, statistical tolerancing and uncertainty analysis with emphasis in the sub-micrometer regime.

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