Industrial Metrology
for Medical Products and Devices

Strategies, Automation,
FDA and MDR conformity

Summarized by

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Measurement is knowledge
Georg Simon Ohm (1789-1854)

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Oberkochen, November 2019
Dr. Robert Roithmeier and Michael Wieler

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1 Introduction

The world of medical technologies is fascinating. Cardiac implants make weak hearts return to their rhythm. Endoprosthetics make disordered joints move without pain. Modern implants and aids make deaf ears hear. New procedures and devices in medical technology improve quality of life and often even save and preserve lives.[1]

Miniaturization and precision

This medical progress is associated with innovative product developments in medical technology, e.g. for different implants and instruments. The international developments are also characterized by increasing miniaturization and precision. Accordingly, there are increasing demands on the geometric and surface characteristics of these potentially complex form elements. Consequently, the need for highly accurate tests for the verification of these characteristics is rapidly increasing.

ZEISS – an optical company that has achieved top performance in optics and research for more than 170 years – successfully and reliably faces these challenges. Being a leading manufacturer of medical, measurement, and testing technology, ZEISS delivers a high level of know-how in the industrial production of medical devices and products. To this end, metrological solutions and their applications for medical technology are explained (Chapter 2).

[1] see [MedTech 2010].

100% check

According to the relevant product liability laws, the manufacturers are liable for any damage caused by a product launched on the market. Therefore, the particularly sensitive medical and pharmaceutical sector often requires comprehensive quality controls (100% serial tests). The corresponding solutions are shown in Chapter 3.

Reliability of test results

But how reliable are the measuring results of quality control? To obtain really **reliable** test results, the measurement strategy, measuring machine and measurement environment must be checked for uncertainty influences and the quality of the measuring results must be evaluated. The required procedures are described in detail in Chapter 4.

FDA, MDR

The advanced requirements for medical devices and products due to e.g. MDR[2] and FDA[3] regulations place high demands on the metrology used and the electronic documentation of measuring results. For more details, please refer to Chapter 5. The appendix contains easy-to-use checklists relating to the rules according to 21 CFR Part 11.

Figure 1: Metrology and medical technology at ZEISS

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2 Medical Device Regulation (EU ordinance)

3 Food & Drug Administration (US health authority)

Summary

Development in medical technology is in full swing and progress advances rapidly. Highly precise measurements of the geometry and surface, wear and defects, FDA-proof measurement and documentation processes and fully automated 100% controls make their contribution to the "revolution of medical technology in the 21st century" [quotation from MEDTECH 2010].

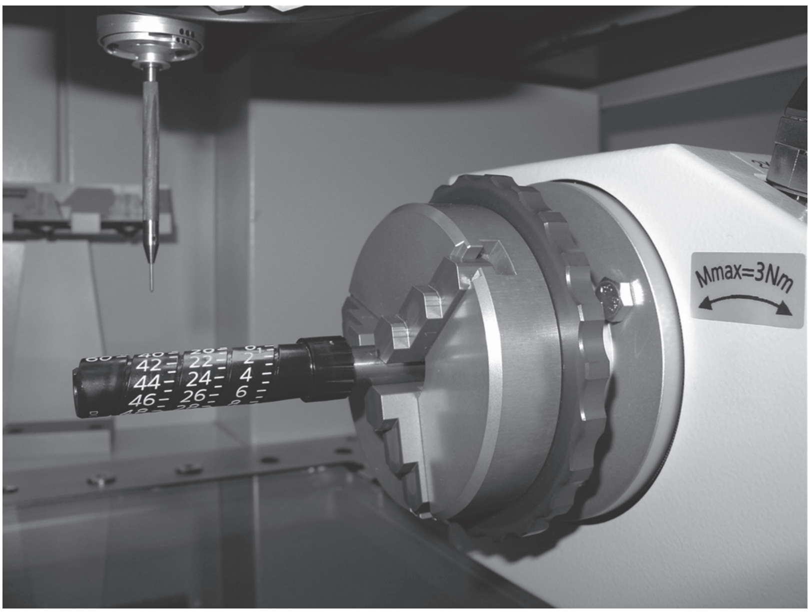
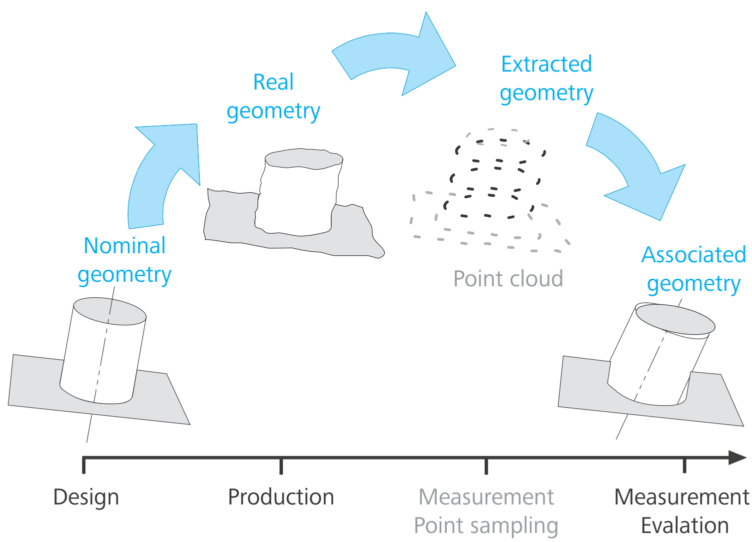


Figure 2: InsulinPen on O-INSPECT multisensor coordinate measuring machine

1.1 Coordinate metrology

Most of the quality-relevant geometric product characteristics can be measured by means of coordinate metrology. For measurements in coordinate metrology, the coordinates of individual points on the surface of a workpiece are determined by a measuring system. This procedure is called coordinate measurement. The result of a coordinate measurement is a "point cloud" which describes the actual form of the workpiece. These points are used to determine the actual values of the characteristics of the product. During the subsequent evaluation, they are linked to form geometric information ("associated geometry"); see Figure 3.

Figure 3: Principle of coordinate metrology



Almost all workpieces, including those with complex geometric characteristics, can be measured with high precision by means of coordinate metrology. For workpieces with narrow tolerances, which become more and more complex due to modern production technologies, coordinate measuring machines (CMM) often provide the only way to measure the shapes of such workpieces with the required accuracy. The increasing use of coordinate metrology is based on a number of advantages:

- High universality and flexibility
- High degree of automation
- High Precision
- Integration in the production environment
- Connection to the meter standard
- Online documentation of measuring results
- Coupling with SPC[4] and CAQ[5]
- Closing production-oriented quality control loops

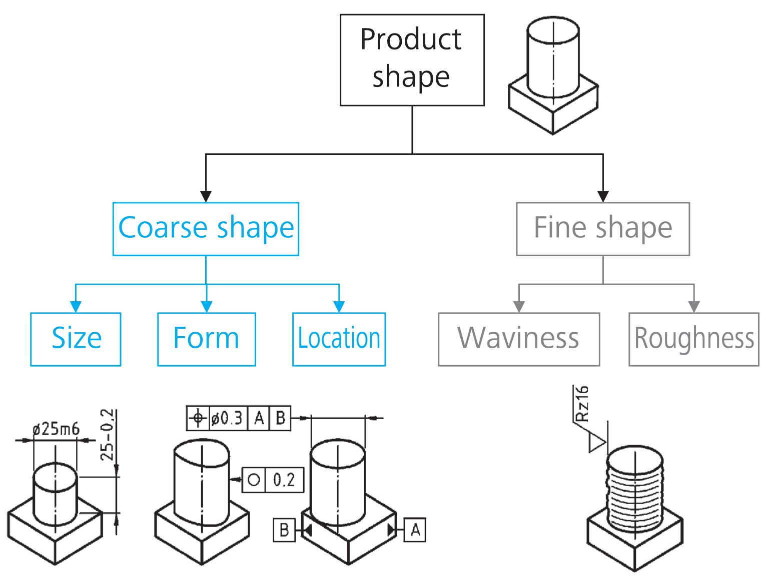


Figure 4: Measuring jobs for coordinate measuring machines

[4] Statistical Process Control

[5] Computer Aided Quality

Different designs and versions of coordinate measuring machines for a wide range of applications are available (Figure 5).

Figure 5: Coordinate measuring machine designs (examples)

Other methods of coordinate metrology such as computer tomography (Figure 6), are also based on this principle. Tomography is a radiographic technique utilizing X-ray beams. Radiography generates a gray scale pattern on the detector of the tomography system whose gray scale values largely depend on the geometry (material thickness) as well as on the density and absorption characteristics of the test object. In computer tomography, the object to be measured is penetrated by radiation from several directions. The superposition of the "projected" radiation patterns thus generated makes it possible to reconstruct the test object. One of the results of this reconstruction is a model of the product surface that can be used for the determination of geometric product characteristics [Imkamp 2006].

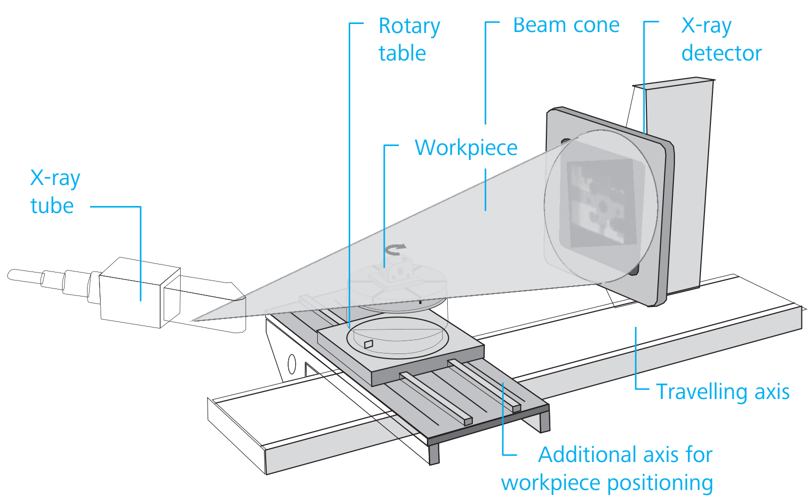


Figure 6: Computer tomography for coordinate measurement