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Information technology — Medical image-based modelling for 3D printing —

Part 1: General requirements

Technologies de l'information — Modélisation médicale à base d'images pour l'impression 3D —

Partie 1: Exigences générales

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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This document was prepared by Joint Technical Committee ISO/IEC JTC 1, *Information technology*.

A list of all parts in the ISO/IEC 3532 series can be found on the ISO and IEC websites.

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Introduction

This document was developed in response to the need for customization of 3D scanning and 3D printing technology within the medical industry, which can be achieved by taking full advantage of information and communication technology (ICT).

This document addresses the overview of medical image processing and requirements for image-based modelling. 3D printing technology has caused a revolution in health care delivery. New classes of medical devices embody the true meaning of personalized medicine. Medical device designers and practitioners are able to practically and efficiently create devices that were very difficult or impossible to create before. In addition to using 3D printing technology to create standard medical devices with features like intricate lattice structures, clinicians and engineers work in conjunction to produce what are known as patient-specific devices or patient-matched devices. These are medical devices designed to fit a specific patient's anatomy, typically using medical imaging from that patient. Anatomically matched devices have very complex geometrical contours and shapes. Several challenges exist in the design process between the input data and the final device design. Most of these steps definitely depend on software-based management of medical images.

Overall, the world revenue from 3D printing technology in the healthcare industry is expected to grow exponentially, yet very few guides exist for 3D printing for medical practice. Medical images from the human body are different from solid objects due to the non-geometric nature of the human body. To perform 3D printing for medical practice, an accurate and consistent approach for image processing and data creation from medical images is needed. Standardization for 3D printing processes in medicine is urgently required for education, diagnosis, neurosurgical treatment, developing simulation models, medical equipment (including surgical guides) and surgical implantable devices in the clinical fields. Regulatory bodies from several countries (US, Republic of Korea, etc.) have already published their own guidelines for approval. However, those guidelines are not specifically designed for 3D printing technology.

Applications of 3D printing in medicine are thriving, and include surgical simulation models, surgical guides, educational models, surgical implants, etc. Those which are manufactured by 3D printing technology require patient- and/or procedure-specific data (e.g. planned surgical technique and others) and medical image data acquisition processing. Most of the processing of medical images for 3D printing medical devices is software-based. In order to accurately and consistently visualize human body anatomy, appropriate software-based modelling for 3D printing is needed. This document provides requirements for software-based medical image processing for the purpose of producing 3D models for 3D printing. Valuable information related to optimized medical image data for additive manufacturing can be found in ISO/ASTM TR 52916.

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Part 1: General requirements

1 Scope

This document specifies the requirements for medical image-based modelling for 3D printing for medical applications. It concerns accurate 3D data modelling in the medical field using medical image data generated from computed tomography (CT) devices. It also specifies the principal considerations for the general procedures of medical image-based modelling. It excludes soft tissue modelling from magnetic resonance image (MRI).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 2382, *Information technology — Vocabulary*

ISO/ASTM 52900, *Additive manufacturing — General principles — Fundamentals and Vocabulary*