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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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Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms, definitions and abbreviated terms	1
3.1 Terms and definitions.....	1
3.2 Abbreviated terms.....	4
4 Overview of image processing for the medical industry	5
4.1 Process flow.....	5
4.1.1 3D printing process for medical applications.....	5
4.1.2 Explanation of a typical use case (cranial implant case).....	5
5 General requirements	6
6 Requirements of data processing	7
6.1 Medical image data flow.....	7
6.2 Medical image acquisition/computed tomography scan.....	8
6.3 Segmentation.....	9
6.4 3D reconstruction and visualization.....	11
6.5 Calibration and validation of 2D and 3D conversion.....	12
6.6 File format.....	13
Annex A (informative) Reporting	14
Bibliography	15

Foreword

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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.