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

Part 2: Segmentation

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

Partie 2: Segmentation

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Contents

Page

Foreword

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Introduction

This document was developed in response to the need for customization of 3D printing technology in the medical industry through the use of information and communication technology (ICT).

There are many points where the existing standards for additive manufacturing (AM) do not match the requirements of the medical industry. From medical images to 3D printing, medical device development is quite a complex journey with complicated management of multiple pieces of software.

With the emerging market for medical 3D printed parts, there are many points requiring standardization.

There is currently no standardized process for the creation of protocols and validation procedures to ensure that medical imaging data can be consistently and accurately transformed into a 3D printed object.

For medical 3D printing, segmentation techniques should be optimized and combined according to the characteristics of the medical images and corresponding body parts to get an optimal 3D model.

In particular, during medical image segmentation, identification of the pixels of organs or lesions from raw data such as computed tomography (CT) or magnetic resonance (MR) images, is one of the most challenging analysis tasks.

For example, segmentation of the orbital bone is necessary for orbital wall reconstruction in cranio-maxillofacial surgery to support the eye globe position and restore the volume and shape of the orbit. However, orbital bone segmentation is challenging as the orbital bone is composed of cortical bone with a high intensity value, and trabecular and thin bone with low intensity values, similar to soft tissue.

The human bone is delineated and extracted by segmentation techniques, and a 3D skeletal model is built from this segmentation. The minimization of errors during segmentation of relevant body parts of interest is critical. As there are several known critical issues for this segmentation, a verification process is made before proceeding.

Not only single segmentation techniques but also combinations of those techniques should be adopted for accurate extraction of a target body part. However, this process depends heavily on the operator. For minimization of errors during this job, operators should know which segmentation technique is most used in their imaging software and possess the necessary skills for that technique.

Thresholding techniques which are provided by a default Hounsfield unit (HU) range do not completely recover true bony structure.[1] An operator should typically adjust the extent of the segmentation manually. The problem is usually under-segmentation. However, over-segmentation will also be problematic for further designing processes, especially for surgical implants. Various techniques have been suggested to reduce human error and improve performance and consistency for segmentation issues.[2]

This document proposes a standardized process for the optimization of segmentation.

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

Part 2: Segmentation

1 Scope

This document provides an overview of the segmentation process for medical image-based modelling of human bone. This document specifies a standardized process to improve the performance of human bone segmentation.

This document is also applicable to medical 3D printing systems that include medical 3D modelling capabilities.

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 15708-1, *Non-destructive testing — Radiation methods for computed tomography — Part 1: Terminology*

ISO/IEC 2382, *Information technology — Vocabulary*

ISO/ASTM 52950, *Additive manufacturing — General principles — Overview of data processing*