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Information technology —Medical image-based modelling for 3D printing – Part 1: General requirements

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

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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.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html and www.iec.ch/national-committees.

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, Korea, Repulic 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 booming, such as 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 of 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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Information ~~Technology —~~technology — Medical ~~Image-Based Modelling~~image-based modelling for 3D printing~~-~~ — Part 1: General ~~Requirements~~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~~:2015~~, *Information technology — Vocabulary*

ISO/ASTM~~/~~ 52900~~:2021~~, *Additive manufacturing — General principles — Fundamentals and Vocabulary*

3 Terms, definitions and abbreviated terms

For the purposes of this document, the terms and definitions given in ISO/IEC 2382~~:2015~~, ISO/ASTM 52900~~:2021,~~ and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

~~3.1~~ 3.1 Terms and definitions

3.1.1
image acquisition
scanning of the structure of interest using computed tomography (CT), magnetic resonance imaging or other three-dimensional imaging technology

~~[SOURCE: ISO 21227-1:2003(en), 3.4]~~

3.1.2
slice distance
slice spacing
distance between the centre of the slices, which is calculated by the difference in the slice locations of two adjacent slices

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3.1.3
hard tissue
tissue which is mineralized and has a firm intercellular matrix (such as bone, tooth enamel, dentin and cementum)

3.1.4
soft tissue
tissue that connects, supports or surrounds other structures and organs of the body, excluding *hard tissue* (3.1.3)

3.1.5
solid organ
organ which has firm tissue consistency such as the heart, kidney, liver, lungs, and pancreas, etc., excluding hollow organs (such as the organs of the gastrointestinal tract) and tissue with liquid consistency (such as blood)

3.1.6
pixel
picture element
smallest two-dimensional element of a display image that can be independently assigned attributes such as color and intensity

[SOURCE: ISO/IEC 2382:2015, 13.03.08]2125999, modified — Notes to entry have been removed.]

3.1.7
voxel
volume element
smallest three-dimensional element in volume or volumetric (solid) modeling that can be independently assigned attributes such as colour and intensity

[SOURCE: ISO/IEC 2382:2015, 13.03.09]2126000, modified — Notes to entry have been removed; "solid" has been replaced by "volume or volumetric (solid)".]

3.1.8
vector data
vector image
vector model
digital description of 2D image or 3D model stored as a series of points and mathematical functions to describe the geometric figure

[SOURCE: ISO 12651-1:2012, 4.139, modified — "3D model" has been added, points"image" has been replaced by "vertices"]"2D image or 3D model".]

3.1.9
raster data
raster image
raster model
bitmap data
bitmap image
bitmap model
2D image or 3D model data formed by a set of *picture elements* (3.1.6) or *volume elements* (3.1.7) arranged in a grid pattern

[SOURCE: ISO 12651-1:2012, 4.18, modified — "3D model" and "volume elements" has been added]

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3.1.10
volume model
solid model
three-dimensional geometric model which deals with the solid characteristics of an object in order to represent its internal structure as well as its external shapes

Note 1 to entry: ~~Solid modeling;~~See ISO/IEC 2382 for definitions of volume modeling~~: terms~~ and ~~definition standardized by ISO/IEC [ISO/IEC 2382-13:1996; ISO/IEC 2382-24:1995].~~solid modeling.

Note 2 to entry: Volume model can be represented with *raster model* (3.1.9) or *vector model*~~.~~ (3.1.8).

3.1.11
surface model
boundary model
data set of a model which represents the surfaces of objects

Note 1 to entry: See ISO/IEC 2382 for definitions of surfacing~~;~~ and surface modeling~~: terms and definition standardized by ISO/IEC [ISO/IEC 2382-13:1996; ISO/IEC 2382-24:1995]~~.

3.1.12
facet model
faceted model
surface model (3.1.11) of which surfaces consist of group of polygons

Note 1 to entry: A triangle is widely used as a polygon.

3.1.13
segmentation
process of separating the objects of interest from their surroundings

Note 1 to entry: Segmentation can be applicable to 2D, 3D, raster or *vector data*~~.~~ (3.1.8).

3.1.14
3D visualization
presentation intended for human viewing of a scene on a flat display surface, using graphics techniques to convey depth information and knowledge of the arrangement and shapes of the visualized scene in a three-dimensional space

Note 1 to entry: The graphics techniques can include use of perspective, occlusion, stereoscopy, lighting and environmental effects, and ability to navigate the viewpoint to alternate positions and orientations.

3.1.15
3D modelling
activity intended to create a digital representation of the form and arrangement of one or more 3D objects in a three-dimensional space.

Note 1 to entry: 3D ~~Models may~~models can contain geometric information such as mesh vertices, appearance, lighting, and animation information. The created representation is a prerequisite to creating a *3D visualization* (3.1.14) of the modelled objects.

3.1.16
maximum intensity projection
MIP

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scientific visualization method for 3D data that projects in the visualization plane the voxels with maximum intensity that fall in the way of parallel rays traced from the viewpoint to the plane of projection.

3.1.17
minimum intensity projection
MinIP
data visualization method that enables detection of low-density structures in a given volume.

Note 1 to entry: The algorithm uses all the data in a volume of interest to generate a single two-dimensional image. In other words, it consists of projecting the voxel with the lowest attenuation value on every view throughout the volume onto a 2D image.

3.1.18
Hounsfield Valuevalue
Hounsfield Unitunit
an integer representing the intensity of the image at each image point ([*pixel*) (3.1.6)] which originates from the x-ray scanning process and in turn represents the image intensity which in turn depends on the density of the tissue at that location.

Note 1 to entry: Hounsfield values rise monotonically with tissue density but are not linearly proportional to density.

Note 2 to entry: The highest range of biological tissue Hounsfield values is for cortical bone, and they can go even higher for image artefacts such as metallic implants, metallic sections of a hospital bed included in the image, etc.

3.1.19
multiplanar reformation
MPR
two-dimensional reformatted images that are reconstructed secondarily in arbitrary planes from the stack of axial image data.

Note 1 to entry: Multiplanar reformation (MPR) allows images to be created from the original axial plane in either the coronal, sagittal, or oblique plane.

3.1.20
volume rendering
set of techniques used to display a 2D projection of a 3D discretely sampled data set, typically a 3D scalar field

3.2 3.2 Abbreviated terms

2D	two-dimensional
3D	three-dimensional
AM	additive manufacturing
AMF	additive manufacturing file format
ANN	artificial neural network
CAD	computer aided design
CT	computed tomography

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DICOM	digital imaging and communications in medicine
HU	Hounsfield unit
PACS	picture archiving communication system
QC	quality control
ROI	region of interest
STL	stereolithography
SVM	support vector machine

4 Overview of image processing for the medical industry

~~4.1~~ 4.1 Process flow

~~4.1.1~~ 4.1.1 3D printing process for medical applications

In general, the medical 3D printing processing flow can be divided into eight phases, as shown in Figure 1.

1) Image acquisition phase

In the image acquisition phase, medical images are acquired from medical imaging devices such as CT.

2) Segmentation phase

In the segmentation phase, the acquired medical images are segmented to fit the design purpose and are processed to be divided (segmented) to extract a subset that would represent the part(s) of the anatomy under consideration.

3) 3D modelling phase

In the 3D modelling phase, the segmented data representing the human tissue is converted (reconstructed) into a 3D model optimized for 3D printing.

4) 3D printing phase

In the 3D printing phase, 3D printing is performed using the 3D model designed. For this phase 3D model is processed for 3D printing by slicing, assigning build parameters, being oriented and placed within the build space, and can have support structures generated.

5) Post-processing phase

In the post-processing phase, the 3D printed part is post-processed to become fit for actual medical use.

6) Quality control (QC) phase

In the QC phase, the 3D printed part is finally verified to meet all requirements (user/design/quality/risk).

7) Clinical application and review phase

In the clinical application and review phase, the 3D printed part is reviewed as applicable to clinical application by the healthcare practitioner.

8) Post-market phase

In the post-marketing stage, the 3D printed part is managed based on the post-sale market management policy according to product life cycle issues such as tracking management/recall.

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