SLOVENSKI STANDARD
kSIST-TP FprCEN ISO/ASTM TR 52916:2021

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Aditivna proizvodnja za medicino - Formati datotek - Optimizirani medicinski slikovni posnetki (ISO/ASTM DTR 52916:2021)

Additive manufacturing for medical - Data - Optimized medical image data (ISO/ASTM DTR 52916:2021)

Additive Fertigung - Datenformate - Normspezifikation für optimierte medizinische Bilddaten (ISO/ASTM DTR 52916:2021)

Fabrication additive dans le secteur médical - Données - Données d'images médicales optimisées (ISO/ASTM DTR 52916:2021)

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TECHNICAL REPORT

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Additive manufacturing for medical — Data — Optimized medical image data

Fabrication additive dans le secteur médical — Données — Données d'images médicales optimisées

PROOF/ÉPREUVE

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by ISO/TC 261, *Additive manufacturing*, in cooperation with ASTM Committee F42, *Additive Manufacturing Technologies*, on the basis of a partnership agreement between ISO and ASTM International with the aim to create a common set of ISO/ASTM standards on additive manufacturing. and in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 438, *Additive manufacturing,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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.

Introduction

This document has been developed in close cooperation of ISO/TC 261 and ASTM F 42 on basis of a partnership agreement between ISO and ASTM international with the aim to create a common set of ISO/ASTM standards on additive manufacturing.

Digital imaging and communications in medicine (DICOM) image files cannot be used directly for 3D printing; further steps are necessary to make them readable by additive manufacturing system. In particular, as the thickness of the computed tomography slice increases, there is a problem that the error in 3D reconstruction of the anatomical structure increases. Therefore, the focus of this technical report is to automatically reconfigure the slice interval through the application of isotropic conversion technology to utilize the existing dicom file and visualization and editing software as it is. In addition, in order to present a method for optimized medical image data for additive manufacturing, tomography metadata without compression is used by editing and processing the output format file without loss in the AM equipment system, or tomography within the maximum allowable range of radiation. Consider reducing the spacing of slices as much as possible and increasing the resolution per image as much as possible.

This document benefits from the direction of development and high quality additive manufacturing output through the technical optimization of medical imaging for additive manufacturing: medical academics, clinic and industry fields for AM like as anatomical measurements, 3D analysis, finite element analysis and surgical planning or simulation, patient-specific implant and device design. There are many affected stakeholder like as medical AM system manufacturer, AM feedstock manufacturer, AM feedstock supplier and vendor, medical AM hardware manufacturer, medical AM software manufacturer, medical AM system manufacturer, medical AM platform manufacturer, AM based medical device manufacturer, medical 3D scanning and digitizing device manufacturer, surgical simulation AM model manufacturer, AM surgical implant manufacturer, AM surgical guide manufacturer, AM physical model for clinical education and diagnostic treatment, disposable medical AM consumable devices.

Additive manufacturing for medical — Data — Optimized medical image data

1 Scope

This document includes the creation of optimized data for medical additive manufacturing (MAM). These data are generated from static modalities, such as magnetic resonance imaging (MRI), computed tomography (CT). This document addresses improved medical image data, and medical image data acquisition processing and optimization approaches for accurate solid medical models, based on real human and animal data.

Solid medical models are generally created from stacked 2D images output from medical imaging systems. The accuracy of the final model depends on the resolution and accuracy of the original image data. The main factors influencing accuracy are the resolution of the image, the amount of image noise, the contrast between the tissues of interest and artefacts inherent in the imaging system.

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/ASTM 52900, *Additive manufacturing — General principles — Terminology*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/ASTM 52900 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
CT
computed tomography
computed axial tomography
radiographic scanning technique that uses a number of CT projections of an object at different angles in order to allow calculation of a CT image

[SOURCE: ISO 15708-1:2017, 3.7]

3.2
MRI
magnetic resonance image
imaging technique that uses static and time varying magnetic fields to provide images of tissue by the magnetic resonance of nuclei

[SOURCE: ISO 14630:2012, 3.5]

3.3
polygon
planar surface defined by one exterior boundary and by zero or more interior boundaries

Note 1 to entry: Each interior boundary describes a hole in the surface.

Note 2 to entry: A single or group of polygons can be used to define a treatment zone.

[SOURCE: ISO 11783-10:2015, 3.13]

3.4
reconstruction
process of transforming a set of CT projections into a CT image

[SOURCE: ISO 15708-1:2017, 3.25]

3.5
rendering
action of transforming from a scene description to a specific output description/device

[SOURCE: ISO 19262:2015, 3.213]

3.6
ROI
region of interest, sub-volume within an object or a CT image

[SOURCE: ISO 15708-1:2017, 3.26]

3.7
segmentation
method which partitions a surface or volume into distinct regions

[SOURCE: SOURCE: ISO 25178-2:2012, 3.3.6, modified — ISO 25178-2:2012 had "scale-limited surface" in the definition.]

3.8
volume data
data of a volume in a 3D space

Note 1 to entry: The description can be performed on the basis of density differences inside the three-dimensional space.

[SOURCE: ISO 18739:2016, 3.1.42]

3.9
voxel
volume pixel
three-dimensional cuboid representing the minimum unit comprising a three-dimensional image

[SOURCE: ISO/TR 16379:2014, 2.17, modified — "volume pixel" has been added as a second term.]

3.10
2D
geometry in a xy-plane, where all the geometry's points have only x and y coordinates

[SOURCE: ISO 14649-10:2004, 3.1]

3.11
DICOM
digital imaging and communications in medicine
international standard for medical images and related information

Note 1 to entry: It defines the formats for medical images that can be exchanged with the data and quality necessary for clinical use.

Note 2 to entry: The Medical Imaging Technology Association (MITA), a division of NEMA, serves as the DICOM Secretariat. The current DICOM standard may be found at: https://www.dicomstandard.org/current.

4 Medical images generation for AM

4.1 General medical image data generation

The start for image generation is to collect raw image data. This collects raw information about the inside of the human body and becomes the basic object of all subsequent image processing tasks. In the end, regardless of the image format, the data collection process detects physical factors, pre-processes the collected signals and then digitizes them (see Figure 1).

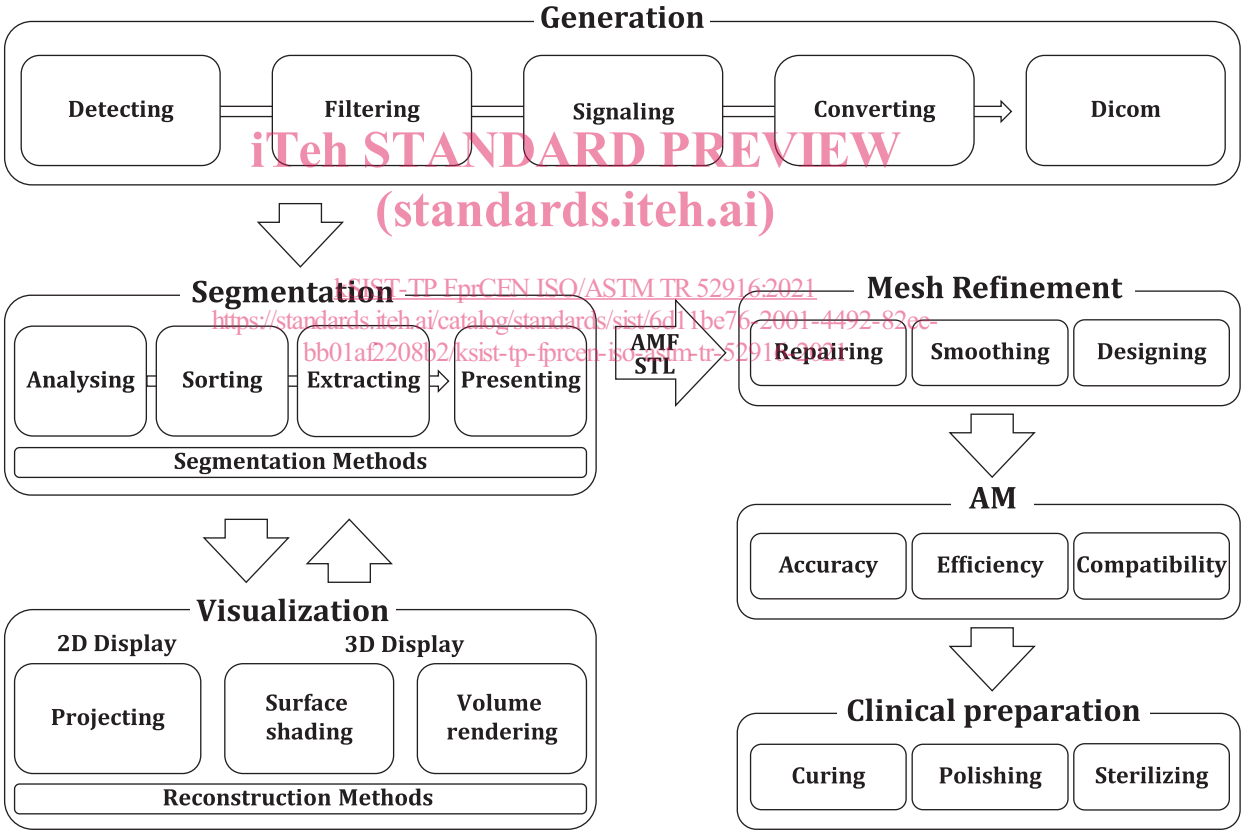

Figure 1 — Process from medical image to medical additive manufacturing

4.2 General error occurrence steps in medical images generation

With gradual technological advancement, many solutions for medical additive manufacturing are emerging. However, research into the cause for resolving errors in medical additive manufacturing output is still ongoing. The cause of additive manufacturing accuracy error occurs in the process of converting the raw data to medical images and the process of converting 3D model data. Error generation factors that occur during this conversion process are described in 4.3 for the most common tomography systems.

Additional errors may be generated by the process of converting DICOM or PACS data to the computational formats used within segmentation editing software and saving the STL 3D mesh format for use in additive manufacturing systems. When saving a customized STL file, all meta data that defined colour, material, surface textures are lost. The lack of accuracy and precision for 3D data from the scan systems, editing and modelling software can reduce the quality of an additive manufactured medical device.

NOTE 1 There can be other factors in creating errors when utilizing other image capture modalities, such as ultrasound, digital microscopy, etc. not covered in 4.3.

4.3 Medical image extraction

4.3.1 Introduction of medical image extraction

The quality of a medical image depends on the degree to which the microscopic structure of the human body can be accurately represented. According to the needs of the medical professional who requested the tomography, the layer spacing between the cross-sectional images is adjusted and photographed. Based on the captured meta data, reconstruction through 3D visualization is performed to extract the data of the region of interest. In this process, the medical imaging tomography technology, imaging conditions, and data conversion process will continue to affect the medical additive manufacturing output resolution.

4.3.2 CT image error generation factors

CT modality images use absorption coefficient parameters that visualize the density of an image. The contrast of hard tissue is more clearly expressed than soft tissue. Since sequential image layers are output as a series, 3D reconstruction is possible. The important factors that determine the image quality are the accuracy of the CT reduction coefficient, which expresses the degree of attenuation of a substance, noise, uniformity, spatial resolution, contrast resolution, and radiation dose. It is recommended that the patient's exposure dose is small, but it is very difficult to control the exposure dose and image quality because it is directly related to image noise and density resolution. Adjustment of radiation dose for each body part according to the patient's condition follows the clinical experience and medical recommendations of the radiologist. This is an external factor that affects the medical image data homogeneity.

— CT matrix size: The digital medical image is stored as 2D pixels, and each pixel is converted into the number of bits matched by the number of gray levels and represented. The CT image size depends on the anatomy being examined. Typically, CT images have a matrix size of 512 pixels × 512 pixels × 8 bytes (12 bits), and gray levels range from 512 pixels (28 bits) to 4 096 pixels (212 bits). A single CT section requires 512 pixels × 512 pixels × 2 bytes = 524,288 bytes of storage on the computer.

— CT reduction coefficient: The tissue weighting factor (W_T) is a relative measure of the risk of stochastic effects that might result from irradiation of that specific tissue. It accounts for the variable radiosensitivities of organs and tissues in the body to ionizing radiation. To calculate the effective dose, the individual organ equivalent dose values are multiplied by the respective tissue weighting factor and the products added. The sum of the weighting factors is 1.

— Based on the values of tissue weighting factors, tissues are grouped into following to assess the carcinogenic risk:

high risk (W_T = 0,12): stomach, colon, lung, red bone marrow;

moderate risk (W_T = 0,05): urinary bladder, oesophagus, breast, liver, thyroid;

low risk (W_T = 0,01): bone surface, skin.

— Spatial resolution: Ability to image small objects that have high subject contrast, CT has moderate spatial resolution 20 lp/cm.

