TECHNICAL REPORT

ISO/ASTM TR 52916

First edition

Additive manufacturing for medical — Data — Optimized medical image data

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

PROOF/ÉPREUVE

Reference number
ISO/ASTM TR 52916:2021(E)

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Published in Switzerland

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Foreword

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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).

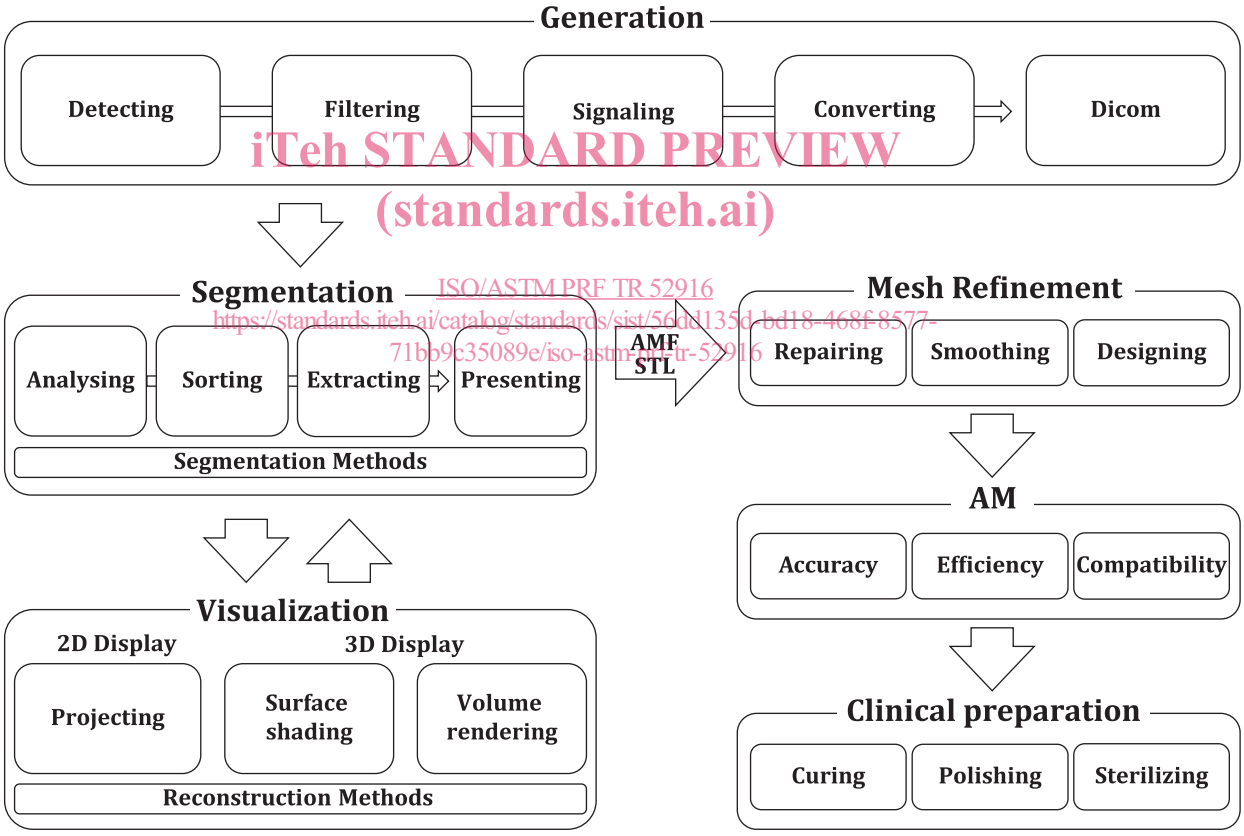

Figure 1 — Process from medical image to medical additive manufacturing

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.

— Contrast resolution: Ability to distinguish between and image similar tissues, CT has excellent low contrast detectability 0,25 % to 0,5 % difference in tissue attenuation.

4.3.3 MRI Image error generation factors

MRI uses a magnetic field that is harmless to the human body and radio frequency, which is non-ionizing radiation. The principle is to image the density and physicochemical properties of the atomic nucleus by causing nuclear magnetic resonance phenomenon in the atomic nucleus inside the human body. The advantage and difference are that it has several imaging parameters compared to CT. Four factors, such as the density of the hydrogen atom nucleus, T1 relaxation time, T2 relaxation time, and blood flow, are important parameters that determine the shading of the image. However, not only the distribution of the hydrogen atom nucleus, but also the molecular state of the contained tissue or the physical state of the image varies. The MRI image looks at the distribution of spin density and is further affected by the T1 T2 relaxation time associated with the NMR (Nuclear Magnetic Resonance) phenomenon. However, due to parameter elements for each MRI device, standard parameter settings are different for each MRI imaging personnel and are external factors affecting image data homogeneity.

MRI image quality depends on resolution (matrix, field of view, slice thickness), signal noise ratio, contrast, artefacts. Especially contrast depends on the MRI scan parameter.

MRI resolution is the size of an individual pixel, the smaller it is, the higher the resolution. The MRI matrix size is the number of pixels in the images. To improve the MRI resolution, increase the matrix, decrease the FOV, and decrease the slice thickness.

In the field of orthopedic surgery, MRI scan parameters are applied in the following ranges of maximum and minimum values of FOV, slice thickness, interslice gap, and matrix size.

Table 1 — Musculoskeletal MRI scan parameters

Parameters	Scan section					
	Shoulder	Elbow	Wrist	Hip	Knee	Ankle
Field of view (cm)	≥16	10 to 16	6 to 12	16 to 20	≥16	≥14
Slice thickness (mm)	≥3	3 to 4	≥3	3 to 4	≥3	≥3
Slice gap (%)	≥10	≥33	≥33	≥33	≥10	≥10
Matrix size (pixel)	≤ 256 × 192	≤ 256 × 256	≤ 256 × 192	≤ 512 × 384	≤ 256 × 192	≤ 256 × 192

— Signal noise ratio: The signal noise ratio is a measure that compares the level of a desired signal to the level of background noise. For data acquired through magnetic resonance imaging, this quantification is typically used to allow comparison between imaging hardware, imaging protocols and acquisition sequences. In this context, the signal noise ratio is conceptualised by comparing the signal of the MRI image to the background noise of the image. Mathematically, the signal noise ratio is the quotient of the signal intensity measured in a region of interest and the standard deviation of the signal intensity in a region outside the anatomy of the object being imaged or the standard deviation from the noise distribution when known. For example, field of view, scan parameters, magnetic field strength and slice thickness, the signal noise ratio of MRI images can be increased because these parameters influence the background noise.

— Image contrast: The repetition time (TR) and Echo time (TE) are basic pulse sequence parameters and stand for ‘repetition time’ and ‘echo time’ respectively. They are typically measured in milliseconds (ms). The echo time represents the time from the centre of the RF-pulse to the centre of the echo. For pulse sequences with multiple echoes between each RF pulse, several echo times may be defined and are commonly noted TE1, TE2, TE3, etc. The repetition time (TR) is the length of time between corresponding consecutive points on a repeating series of pulses and echoes.

Variations in the value of TR and TE have an important effect on the control of image contrast characteristics. Short values of TR (less than e.g. 1 000 ms) and TE (less than e.g. 25 ms) are common in images exhibiting T1 contrast. Long values of TR (greater than e.g. 1 500 ms) and TE (greater than e.g. 60 ms) are common in images exhibiting T2 contrast. Middle TR values (e.g. from 1 000 ms to 1 500 ms) and middle TE values (e.g. from 25 ms to 60 ms) are common for density weighted contrast.

— Artifacts: Most common MRI artifacts were movement, Gibb's, metal and slice overlap artifacts.

— Movement artifact correction: Breath holding, sedation, anesthesia, electrocardiographic trigger, spatial RF pre-saturation, flow compensation.

— Gibb's Artifact (truncation, ringing, spectral leakage artifacts) correction: Softening filters, larger acquisition matrix, smaller FOV.

— Slice overlap Artifact correction: Avoid sharp angle changes between slice groups, increase a gap between slices, apply different storage processes for images.

5 Image segmentation

5.1 Introduction of segmentation

Image segmentation is the process of partitioning an image into multiple labelled regions locating objects and boundaries in images. It can be used to create patient-specific, highly accurate computer models of organs and tissue. There are a number of image segmentation techniques, which each have advantages and disadvantages, but there is no single segmentation technique which is suitable for all images and applications. Basic segmentation approaches rely on the principle that each tissue type has a characteristic range of pixel intensities. Hence, it is possible to distinguish between tissues and identify boundaries.

Image segmentation refers to a process of grouping connected pixels having similar characteristics among pixels constituting a given whole image. However, despite the many image processing methods, there are not many differences in the image attribute information values of the anatomical human structures, so there are many results that appear to be unclear or disconnected. If a modification is made to improve image quality, data corruption problems occur. In the end, it is necessary to improve the segmentation algorithm that can extract all ROI (Region of Interest) boundaries.

5.2 Segmentation techniques

In the 2D medical image, the region of interest needs to be accurately divided so that the desired region of interest can be 3D visualized. As a measure of image segmentation grouping, feature elements such as contrast, colour components, edges, texture, motion, and depth information are used. Many types of segmentation algorithms are applied based on these indicators, and the image segmentation methods. Thresholding-based algorithms, clustering-based algorithms, region-based algorithms, and level-set-based algorithms are representative.

5.2.1 Thresholding algorithm

It is a method to divide into a thresholding range using a histogram. In this case, when a characteristic of a pixel is a pixel value, a set of pixels with a result of 1 is called an object, and a set of results with a result of 0 is called a binary image partitioning method. After determining the general threshold values for bones and muscles, segments of all pixels larger or smaller are divided into groups, and segments are sequentially processed. However, if there is no spatial characteristic of the image to make the noise stronger, there is a method of segmentation using information associated with the local intensity.

5.2.2 Region growing algorithm

The region growing segmentation is a method of finally dividing the entire image by gradually integrating and growing regions with the same characteristics from adjacent small regions. This is an

