



BSI Standards Publication

Additive manufacturing for medical — Data — Optimized medical image data

National foreword

This Published Document is the UK implementation of CEN ISO/ASTM/TR 52916:2022. It is identical to ISO/ASTM TR 52916:2022.

The UK participation in its preparation was entrusted to Technical Committee AMT/8, Additive manufacturing.

A list of organizations represented on this committee can be obtained on request to its committee manager.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

This publication is not to be regarded as a British Standard.

© The British Standards Institution 2022
Published by BSI Standards Limited 2022

ISBN 978 0 539 21286 0

ICS 25.030

Compliance with a Published Document cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 August 2022.

Amendments/corrigenda issued since publication

Date	Text affected
<hr/>	

English Version

Additive manufacturing for medical - Data - Optimized
medical image data (ISO/ASTM TR 52916:2022)

Fabrication additive dans le secteur médical - Données
- Données d'images médicales optimisées (ISO/ASTM
TR 52916:2022)

Additive Fertigung - Datenformate - Normspezifikation
für optimierte medizinische Bilddaten (ISO/ASTM TR
52916:2022)

This Technical Report was approved by CEN on 18 January 2022. It has been drawn up by the Technical Committee CEN/TC 438.

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 09 March 2022.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

This document (CEN ISO/ASTM/TR 52916:2022) has been prepared by Technical Committee ISO/TC 261 "Additive manufacturing" in collaboration with Technical Committee CEN/TC 438 "Additive Manufacturing" the secretariat of which is held by AFNOR.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

Endorsement notice

The text of ISO/ASTM TR 52916:2022 has been approved by CEN as CEN ISO/ASTM/TR 52916:2022 without any modification.

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Medical images generation for AM	3
4.1 General medical image data generation	3
4.2 General error occurrence steps in medical images generation	3
4.3 Medical image extraction	4
4.3.1 Introduction of medical image extraction	4
4.3.2 CT image error generation factors	4
4.3.3 MRI Image error generation factors	5
5 Image segmentation	6
5.1 Introduction of segmentation	6
5.2 Segmentation techniques	6
5.2.1 Thresholding algorithm	6
5.2.2 Region growing algorithm	6
5.2.3 Morphological image algorithm	7
5.2.4 Level-set algorithm	7
5.2.5 Other partial segmentation algorithm	7
6 Reconstruction	7
6.1 Introduction of reconstruction	7
6.2 Reconstruction process	7
7 Smoothing	8
7.1 Marching cubes	8
7.2 Mesh smoothing	8
8 3D visualization method	8
8.1 Surface rendering	8
8.1.1 Introduction of surface shaded rendering	8
8.1.2 Surface shaded rendering feature	9
8.2 Volume rendering	9
8.2.1 Introduction of volume rendering	9
8.2.2 Volume rendering feature	9
8.2.3 Ray casting techniques	9
8.2.4 3D texture mapping techniques	9
9 Additional processing for additive manufacturing	10
10 Methods	10
10.1 Image isotropic conversion	10
10.2 Image enhancement	11
10.3 Image segmentation	12
11 Minimizing error of software and equipment	14
11.1 Introduction of software and equipment error	14
11.2 Software error	14
11.2.1 Background	14
11.2.2 Verification method using main inflection	14
11.2.3 Improving accuracy and precision	14
11.3 Equipment error	15
11.3.1 Background	15
11.3.2 Standard computational mesh model data creation for an evaluation method	15

11.4 Tolerance error situations..... 15

Annex A (informative) Medical CAD for additive manufacturing tolerance..... 16

Bibliography..... 24

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 — Fundamentals and vocabulary*

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](#)).

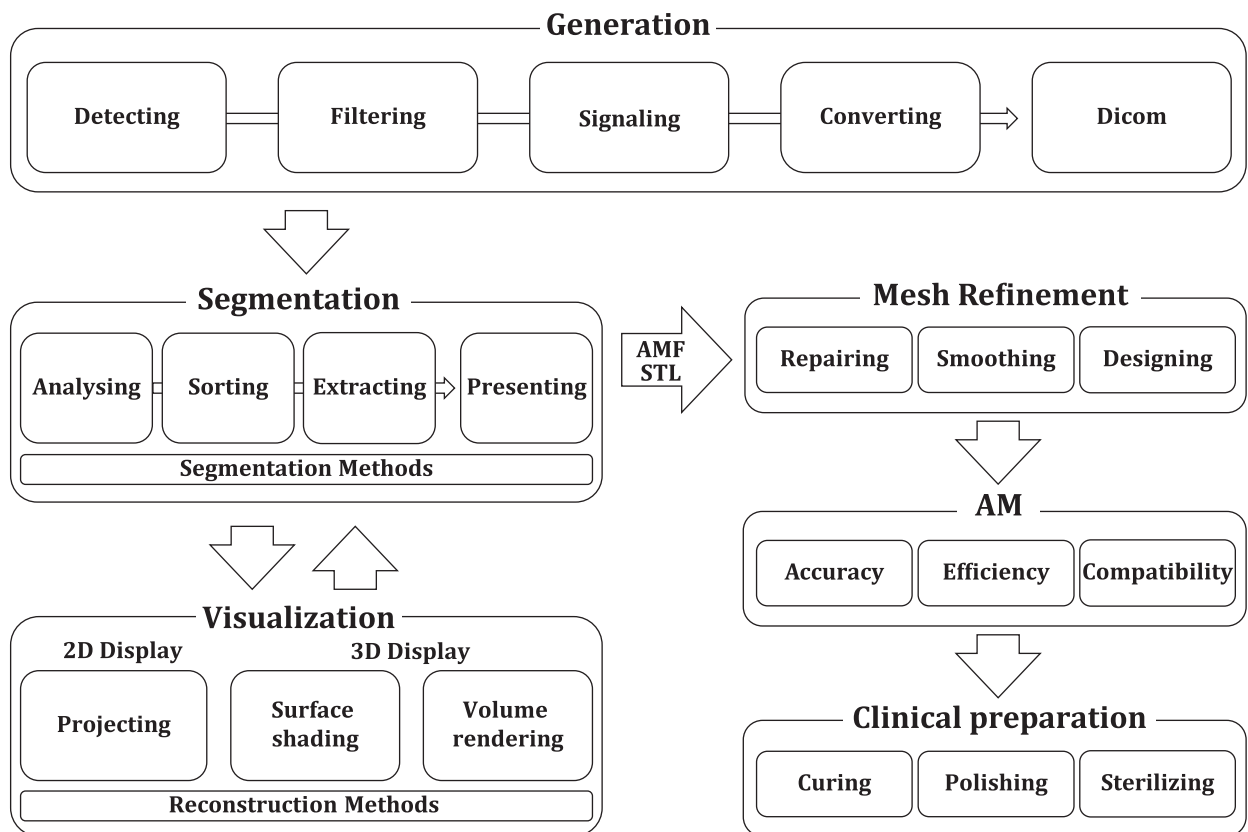


Figure 1 — Process from medical image to medical additive manufacturing

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.