ISO/IEC FDIS 3532-2:2023(E)

2023-05-15

ISO/IEC JTC 1

Secretariat: ANSI

Date: 2023-11-13

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

Part 2: Segmentation

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

Partie 2: Segmentation

iTeh Standards
(https://standards.iteh.ai)
Document Preview

ISO/IEC FDIS 3532-2
https://standards.iteh.ai/catalog/standards/sist/c47163ff-792e-49a1-b03e-4c8118846661/iso-iec-fdis-3532-2

FDIS stage

Edited DIS - MUST BE USED

© ISO/IEC 2023

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11

Fax: +41 22 749 09 47

EmailE-mail: copyright@iso.org
Website: www.iso.orgwww.iso.org

Published in Switzerland

iTeh Standards
(https://standards.iteh.ai)
Document Preview

ISO/IEC FDIS 3532-2
https://standards.iteh.ai/catalog/standards/sist/c47163ff-792e-49a1-b03e-4c8118846661/iso-iec-fdis-3532-2

ii © ISO/IEC 2023 – All rights reserved

Edited DIS - MUST BE USED

Contents

1 Scope 1
2 Normative references 1
3 Terms and definitions 1
4 Abbreviations 2
5 Objective of segmentation 4
5.1 Background 4
5.2 Related works 4
6 Overall segmentation process 5
6.1 General 5
6.2 Step1: data preparation 5
6.3 Step2: preprocessing for segmentation 5
6.4 Step3: annotation 5
6.5 Step4: selection of segmentation network model 5
6.6 Step5: performance evaluation 5
6.7 Step6: model deployment and running 6
6.8 Step7: post-processing for segmentation 6
7 Data preparation 6
7.1 General 6
7.2 Medical image 6
7.2.1 General 6
7.2.2 CT scan 6
7.2.3 MRI scan 6
7.3 Preparation steps 6
7.3.1 General 6
7.3.2 Image acquisition 7
7.3.3 Image reconstruction 7
8 Preprocessing for segmentation 7
8.1 General 7
8.2 Intensity normalization 7
8.3 Spacing normalization 8
9 Annotation 8
9.1 Data labeling 8
9.2 Pre-processing for annotation 9
9.3 Dataset management (training and testing) 9
9.4 Augmentation 10
10 Selection of network model 10

iTeh Standards
(https://standards.iteh.ai)
Document Preview
ISO/IEC FDIS 3532-2
https://standards.iteh.ai/catalog/standards/sist/c47163ff-792e-49a1-b03e-4c8118846661/iso-iec-fdis-3532-2

© ISO/IEC 2023 – All rights reserved

© ISO/IEC 2023 – All rights reserved
iii

Edited DIS - MUST BE USED

10.1 General 10
10.2 Input patch 10
11 Evaluation 11
11.1 General 11
11.2 Evaluation metrics 11
11.3 Evaluation procedure 12
12 Deployment and running 12
13 Post-processing for segmentation 13
Annex A (informative) CT scanning conditions for orbital bone segmentation 15
Annex B (informative) Characteristics of orbital bone segmentation from CT 16
Annex C (informative) Deep learning techniques 18
Annex D (informative) Considerations for overall segmentation performance 19
Bibliography 24

iTeh Standards
(https://standards.iteh.ai)
Document Preview
ISO/IEC FDIS 3532-2
https://standards.iteh.ai/catalog/standards/sist/c47163ff-792e-49a1-b03e-4c8118846661/iso-iec-fdis-3532-2

© ISO/IEC 2023 – All rights reserved

iv
© ISO/IEC 2023 – All rights reserved
Edited DIS - MUST BE USED

Contents

Foreword vii
Introduction viii
Part 2: Segmentation 1
1 Scope 1
2 Normative references 1
3 Terms and definitions 1
4 Abbreviated terms 3
5 Objective of segmentation 4
5.1 Background 4
5.2 Types of segmentation methods 4
6 Overall segmentation process 4
6.1 General 4
6.2 Step 1: data preparation 5
6.3 Step 2: preprocessing for segmentation 5
6.4 Step 3: annotation 6
6.5 Step 4: selection of segmentation network model 6
6.6 Step 5: performance evaluation 6
6.7 Step 6: model deployment and running 6
6.8 Step 7: post-processing for segmentation 6
7 Data preparation 6
7.1 General 6
7.2 Medical image 6
7.2.1 General 6
7.2.2 CT scan 6
7.2.3 MR image 7
7.3 Preparation steps 7
7.3.1 General 7
7.3.2 Image acquisition 7
7.3.3 Image reconstruction 7
8 Preprocessing for segmentation 8
8.1 General 8
8.2 Intensity normalization 8
8.3 Spacing normalization 9
9 Annotation 10
9.1 Data labelling 10
9.2 Preprocessing for annotation 11

iTeh Standards
(https://standards.iteh.ai)
Document Preview
ISO/IEC FDIS 3532-2
https://standards.iteh.ai/catalog/standards/sist/c47163ff-792e-49a1-b03e-4c8118846661/iso-iec-fdis-3532-2

© ISO/IEC 2023 – All rights reserved

© ISO/IEC 2023 – All rights reserved

Edited DIS - MUST BE USED

9.3 Dataset management (training and testing) 11
9.4 Augmentation 12
10 Selection of network model 12
10.1 General 12
10.2 Input patch 13
11 Evaluation 13
11.1 General 13
11.2 Evaluation metrics 14
11.3 Evaluation procedure 16
12 Deployment and running 16
13 Post-processing for segmentation 16
Annex A (informative) CT scanning conditions for orbital bone segmentation 17
Annex B (informative) Characteristics of orbital bone segmentation from CT 18
Annex C (informative) Deep learning techniques 21
Annex D (informative) Considerations for overall segmentation performance 23
D.1 Overview 23
D.2 Data preparation 24
D.3 Multi-grey-level FCN-based segmentation and mask integration 25
D.4 Experimental plan 26
D.5 Quantitative evaluation 27
D.6 Qualitative evaluation 27
Bibliography 30

iTeh Standards
(https://standards.iteh.ai)
Document Preview
ISO/IEC FDIS 3532-2
https://standards.iteh.ai/catalog/standards/sist/c47163ff-792e-49a1-b03e-4c8118846661/iso-iec-fdis-3532-2

© ISO/IEC 2023 – All rights reserved

© ISO/IEC 2023 – All rights reserved
Edited DIS - MUST BE USED

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.

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 document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directiveswww.iso.org/directives or www.iec.ch/members_experts/refdocs).

Attention is drawnISO and IEC draw attention to the possibility that some of the elementsimplementation of this document may beinvolve the subjectuse of (a) patent(s). ISO and IEC take no position concerning the evidence, validity or applicability of any claimed patent rights. in respect thereof. As of the date of publication of this document, ISO and IEC had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents and https://patents.iec.ch. ISO and IEC 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) or the IEC list of patent declarations received (see https://patents.iec.ch).

iTeh Standards
(https://standards.iteh.ai)
Document Preview

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.htmlwww.iso.org/iso/foreword.html. In the IEC, see www.iec.ch/understanding-standardswww.iec.ch/understanding-standards.

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-committeeswww.iso.org/members.html and www.iec.ch/national-committees.

© ISO/IEC 2023 – All rights reserved

© ISO/IEC 2023 – All rights reserved

Edited DIS - MUST BE USED

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 Manufacturingadditive 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 Tomographycomputed tomography (CT) or Magnetic Resonancemagnetic resonance (MR) images, is one of the most challenging tasks in medical image 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, the 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 heavilyonheavily on the operator. For minimization of errors during this job, operators should know which segmentation technique areis most used in their imaging software and possess the necessary skills for that technique.

Thresholding techniques which are provided by a default Hounsfield Unitunit (HU) range do not completely recover true bony structure.[1].[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 the human error and improve performance as well asand consistency for the segmentation issues.[2].[2]

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

© ISO/IEC 2023 – All rights reserved

viii
© ISO/IEC 2023 – All rights reserved
Edited DIS - MUST BE USED

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

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

ISO/IEC 2382, *Information technology — Vocabulary*

iTeh Standards (https://standards.iteh.ai) Document Preview
ISO/IEC FDIS 3532-2
https://standards.iteh.ai/catalog/standards/sist/c47163ff-792e-49a1-b03e-4c8118846661/iso-iec-fdis-3532-2

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/ASTM 52950, ISO 15708-1, ISO/IEC 2382 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/obphttps://www.iso.org/obp

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

3.1
image acquisition
scanning of the structure of interest using computed tomography (CT), magnetic resonance (MR) imaging or other three-dimensional imaging technology

3.2
image annotation
process of attaching labels to an image

© ISO/IEC 2023 – All rights reserved

3.3
label
classifying phrase or name applied to a target

3.4
learning
<machine learning> process by which a biological or an automatic system gains knowledge or skills that it may use to improve its performance

[SOURCE: ISO/IEC 2382:2015, 2122966], modified — Notes to entry have been removed.]

3.5
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.

[SOURCE:ISO/IEC 2382:2015, 2121945, modified]

3.6
ground-truth label
correct answer of the training set for segmentation based on supervised learning

3.7
region of interest
ROI
specified boundary as defined in the image

iTeh Standards
(https://standards.iteh.ai)
Document Preview

3.8
data normalization
changing of the values of numeric columns in the dataset to use a common scale, without distorting differences in the ranges of values.

ISO/IEC FDIS 3532-2
https://standards.iteh.ai/catalog/standards/sist/c47163ff-792e-49a1-b03e-4c8118846661/iso-iec-fdis-3532-2

3.9
machine learning
ML
process of optimizing model parameters through computational techniques, such that the model's behaviour reflects the data or experience

[SOURCE: ISO/IEC 22989:2022, 3.3.5]

3.10
labeled data
group of data that have been tagged with one or more labels

3.11
hyperparameter
characteristic of a machine learning algorithm that affects its learning process

Note 1 to entry: Hyperparameters are selected prior to training and can be used in processes to help estimate model parameters.

© ISO/IEC 2023 – All rights reserved

© ISO/IEC 2023 – All rights reserved

Note 2 to entry: Examples of hyperparameters include number of network layers, width of each layer, type of activation function, optimization method, learning rate for neural networks; the choice of kernel function in a support vector machine; number of leaves or depth of a tree; the K for K-means clustering; the maximum number of iterations of the expectation maximization algorithm; the number of Gaussians in a Gaussian Mixture Modelmixture.

[SOURCE: ISO/IEC 22989:2022, 3.3.4]

3.12
Medicalmedical image
Typetype of images generated by medical imaging devices

4 Abbreviated terms

AI	artificial intelligence
AIM	annotation and image markup
CAD	computer-aided diagnosis
CCL	connected component labelling
~~CCL~~	~~connected component labeling~~
CNN	convolutional neural network
~~CRF~~	~~conditional random field~~
CRF	conditional random field
CT	computed tomography
DICOM	digital imaging and communications in medicine
DL	deep learning
DSC	dice similarity coefficient
FCN	fully convonlutional network
FOV	field of view
~~FN~~	~~false negative~~
FN	false negative
FP	false positive
HU	Hounsfield unit
~~HU~~	~~hounsfield units~~
IoU	intersection over union
MIoU	mean intersection over union
ML	machine learning
MR	magnetic resonance
~~MR~~	~~magnetic resonance~~
MRI	magnetic resonance imaging
NIfTI	neuroimaging informatics technology initiative
PET	positron emission tomography
SPECT	single-photon emission computerized tomography
TN	true negative
TP	true positive
US	ultrasonography

iTeh Standards
(https://standards.iteh.ai)
Document Preview
ISO/IEC FDIS 3532-2
https://standards.iteh.ai/catalog/standards/sist/c47163ff-792e-49a1-b03e-4c8118846661/iso-iec-fdis-3532-2

5 Objective of segmentation

5.1 Background

The purpose of segmentation is to extract a specific region or organ from a patient's CT/~~MRI~~MR medical image and use it to create a 3D model.

Segmentation is the process of partitioning an image into different meaningful segments. For medical images, segmentation techniques should be optimized and combined according to the characteristics of image aquisition modalities and body parts to get an ideal 3D visualization. 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 anatomy is critical.

Modelling for medical 3D printing requires optimized segmentation to provide ~~a~~ better overlaying and matching processes for human tissues and organs. However, most of the commercially available image software cannot segment human bone effectively.

For improved medical image based 3D modeling, formalization and standardization of these procedures is required.

5.2 Types of segmentation methods

Several methods have been investigated that segment human bone from CT images ~~[18][19][22][23].~~ [18][19][22][23]

Semi-automatic segmentation: Thresholding is the simplest method of image segmentation, and thresholding can be used to create binary images. This method replaces each pixel in an image with an object pixel if the pixel intensity is greater than a specific human bone threshold value, or replaces it with a background pixel if the pixel intensity is less than a specific human bone threshold value.

Deformable model ~~-~~-based segmenation: Deformable models are curves or surfaces for segmentation in the image domain, which deform under the influence of internal and external forces to delineate the object boundaries. The internal forces are defined such that they preserve the shape smoothness of the model, while the external forces are defined by the image features to drive the model toward the desired region boundary. By constraining extracted boundaries to be smooth and incorporating other prior information about the shape, deformable models offer robustness to both image noise and boundary gaps~~[35,36].~~ [35][36] However, there is a limit due to the difficulty of segmentation at the weak object boundary of a thin bone with a low intensity value similar to soft tissue.

CNN (~~Convolutional Neural Network)~~ convolutional neural network)-based segmentation: The FCN (fully convolutional network) is a network that does not contain any dense layers. Instead, it contains 1x1 convolutions that perform the task of fully connected layers. The U-Net network, which is commonly used for medical image segmentation, is based on a fully convolutional network and consists of a contracting path and an expansive path, which gives it the U-shaped architecture.

6 Overall segmentation process

6.1 General

The overall segmentation process consists of seven steps in total, as described in ~~subclauses 6.2~~6.2 to ~~6.8. Figure 1~~6.8. Figure 1 shows the overall process flow of segmentation, where ~~number~~the numbers in parenthesis refer to clauses of this document.

 ~~© ISO/IEC 2023 – All rights reserved~~

 © ISO/IEC 2023 – All rights reserved