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Standard**

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**Information technology — 3D
printing and scanning — Data
standard operating procedure
(SOP)**

*Technologies de l'information — Impression et numérisation 3D
— Mode opératoire normalisé (SOP) pour les données*

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Foreword

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This document was prepared by Joint Technical Committee ISO/IEC JTC 1, *Information technology*.

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 quality management needs of 3D printing and scanning technology, with the aim of taking full advantage of information and communication technology (ICT) in this context.

However, there is currently no standardized evaluation procedure for the process of turning scanned data into consistent and accurate 3D printed objects, making continuous quality assessment and improvement activities impossible. Issues with precision evaluation and inaccurate modelling from 3D scanned data exist, but no agreed standard specifies practically acceptable measurement accuracy or an evaluation process.

Artificial intelligence/machine learning (AI/ML) technology can be used for generating and optimizing 3D models from 3D scanned data, particularly for enhancing design accuracy and efficiency. For the training data of an ML-based model, the collection of as much data as possible (big data) is considered to improve the performance of the model. However, it is not practical to use big data as test data. Therefore, minimal requirements are necessary for achieving rigorous and comprehensive evaluation.

In this context, this document describes the standard operating procedure (SOP) and necessary requirements for curation and quality control of test data for evaluation of modelling from 3D scanned data.

Information technology — 3D printing and scanning — Data standard operating procedure (SOP)

1 Scope

This document describes a standard operating procedure (SOP) for the curation and quality control of test data, consisting of 3D scanned data and its corresponding label data, for the evaluation of modelling from 3D scanned data.

This document classifies the main task phases and defines the required tasks in each phase of the 3D scanned and labelled data SOP.

This document defines essential requirements for test data for evaluating modelling from 3D scanned data and describes how to verify conformance to these requirements.

2 Normative references

There are no normative references in this document.

Bibliography

- [1] ISO 15378:2017, *Primary packaging materials for medicinal products — Particular requirements for the application of ISO 9001:2015, with reference to good manufacturing practice (GMP)*
- [2] ISO/IEC/IEEE 15939:2017, *Systems and software engineering — Measurement process*
- [3] ISO/IEC 25000:2014, *Systems and software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Guide to SQuaRE*
- [4] ISO/IEC JTC 1-N13604, *Study Group Report on 3D Printing and Scanning*
- [5] IEEE 610.12-1990, *IEEE Standard Glossary of Software Engineering Terminology — Description*
- [6] Statistical considerations for testing an AI algorithm used for prescreening lung CT images. *Contemporary clinical trials communications* 16 (2019): 100434
- [7] Preparing imaging data for machine learning. *Radiology* (2020) 295.1: 4-15
- [8] Machine learning and data mining. *Communications of the ACM* 42.11 (1999): 30-36
- [9] Reporting guidelines for clinical trial reports for interventions involving artificial intelligence: the CONSORT-AI extension. *bmj* 370 (2020)
- [10] Image quality assessment: from error visibility to structural similarity. *IEEE transactions on image processing* (200) 13: 600-612
- [11] Image information and visual quality. *IEEE Transactions on image processing* (2006) 15: 430-444