JTC 1 Opening remarks

Tony Holland

About JTC 1

Joint Technical Committee of IEC and ISO

- "Standardization in the field of Information Technology"
- Consistent IT deliverables across IEC and ISO
- Building blocks for global markets that respond to the needs of businesses, consumers, governments, other organizations

40 P-members and 62 O-members

Organized in 23 Subcommittees and 5 JTC 1 Working Groups

More than 4500 active participants currently developing around 500 standards; more than 3300 published

JTC 1 Focus

Horizontal by design, JTC 1 develops information technology standards that are applicable across domains

- Emphasis on initiating new areas of work at the right time, delivering high quality standards that respond to market trends
- Track record of acceptance by global markets

Work together with other IEC and ISO TCs and other organizations that are utilizing information technology to develop domain-specific standards

- More than 400 liaisons (JTC 1 and its SCs)
- 18 approved submitters of Publicly Available Specifications
- Emphasis on effective cooperation/collaboration

Technical areas

- Coded character sets
- Telecommunications and information exchange between systems
- Software and systems engineering
- Cards and security devices for personal identification
- Programming languages
- Digitally recorded media
- Computer graphics, image processing
- Interconnection of IT equipment (home electronics)
- IT security techniques
- Office equipment (printing)
- Coding of audio, picture, multimedia (JPEG, MPEG)
- Automatic ID and data capture (RFID)
- Data management
- Document description, processing
- User interfaces
- IT for learning, education, training
- Biometrics
- Cloud computing
- IT Sustainability
- IT governance
- Internet of Things and Digital Twin
- Artificial Intelligence
- IT for smart cities
- 3D printing and scanning
- Trustworthiness
- Quantum Information Technology
- Brain-Computer Interface

ISO/IEC JTC 1

JTC1info.org

www.jtc1info.org JTC1News@gmail.com

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3D Printing Standardization for Medical Devices

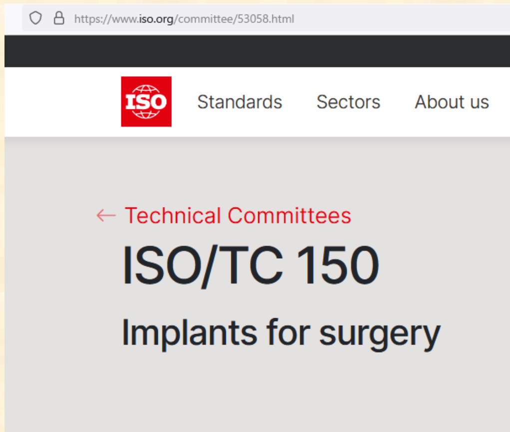
Kohei MURASE

ISO/TC150 JWG1

Center for Industry-University Collaboration,

Graduate School of Engineering Science, Osaka University

JAPAN



OSAKA UNIVERSITY

3D Printing and Scanning (ISO/IEC JTC 1/WG 12 - Online Workshop)

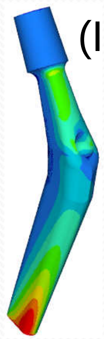
2023-Dec.12

My profile

- Graduate School of Engineering Science. **Osaka University**
  - Special Appoint Professor, **Center for Industry-University Collaboration**,
  - Computational Engineering Laboratory for **Medical Instruments and Devices**,
  - Member of JSME, JSCB
- Convener of Joint ISO/TC150(Implant for Surgery) – 261(Additive Manufacturing)

  ‘**Additive manufacturing in surgical implant applications**’ (TC150 JWG1)
- Liaison Officer between ISO/TC106 (Dentistry) and ISO/TC206 (Fine Ceramics) :

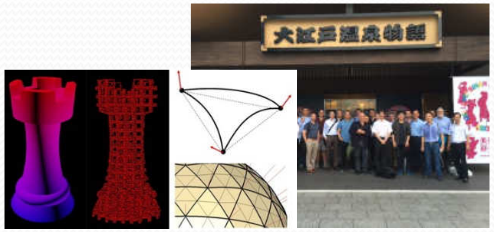
ISO /TC150
(Implant for Surgery)



2

Osaka University

ISO /TC261
(Additive Manufacturing)



TECHNICAL COMMITTEES

ISO/TC 150

Implants for surgery

- Est.1971.
- Standardization in the field of
  - implants for surgery and their required instrumentation,
  - covering terminology,
  - specifications and methods of tests for all types of implants, and for the materials both basic and composite used in their manufacture and application.

175	49	24
Published ISO standards *	ISO standards under development *	Participating members
of which 17 under the direct responsibility of ISO/TC 150	of which 4 under the direct responsibility of ISO/TC 150	

- ISO/TC 106 (Dentistry)
- ISO/TC 150 (Implants for surgery)
- ISO/TC 194 (Biological and clinical evaluation of medical devices)
- ISO/TC 198 (Sterilization of health care products)
- ISO/TC 210 (Quality management and corresponding general aspects for medical devices)
- ISO/TC 261 (Additive manufacturing)
- ISO/TC 276 (Biotechnology)
- ASTM F04 (Medical devices)
- ASTM F42 (Additive manufacturing)

and JTC 1/WG 12 !!

Today's Topics

- Needs in Orthopaedics with AM (Additive Manufacturing = 3D printing) standardization.
- Introduction of ISO TC 150/JWG1 (Joint Working group with ISO TC261)
- Scope and currently work in TC150/JWG1 - 'Additive manufacturing in surgical implant applications'

Artificial joint replacement (in Asia)

- Reported by Japanese Society for *Replacement Arthroplasty*
  - 22,935 cases* for Hip joint replacement a year,
  - 25,892 cases* for Knee joint replacement a year,
  - About 130 cases a day !
- 3 times increasing for 5 years (2012 to 2017)
- Increasing "revision surgery"
- Increasing a variety of replacement
  - Spine, Shoulder, etc…
- Patient-Specified-Instrument (PSI : Custom-made)

Additive Manufacturing is the ***key*** of medical devices.

What's required in International standard?

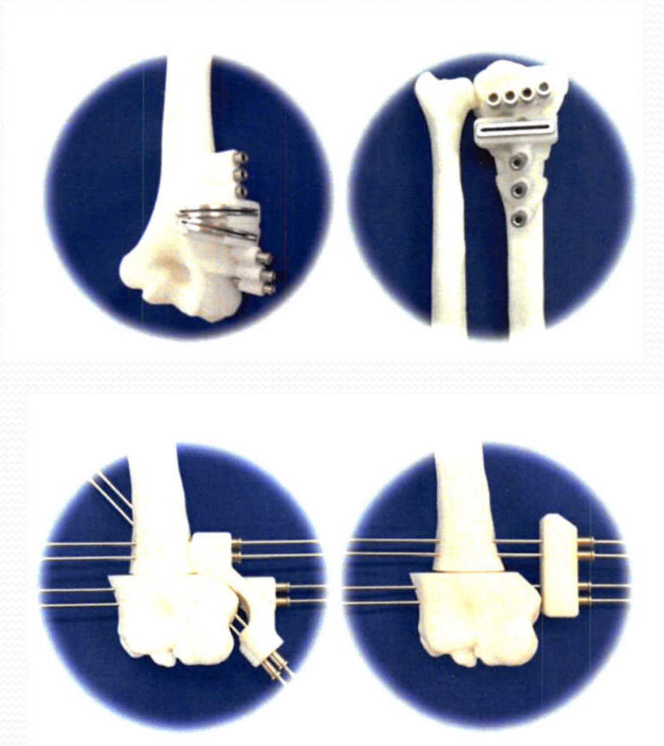
- After Medical operation, Medical implants **works for 15~20 years**.
- $=5\times10^{6}\sim2\times10^{7}$cycle works **under 200～2,300N**

  (3~5 times of bodyweight)
- **Mechanical strength is very important for medical implants**

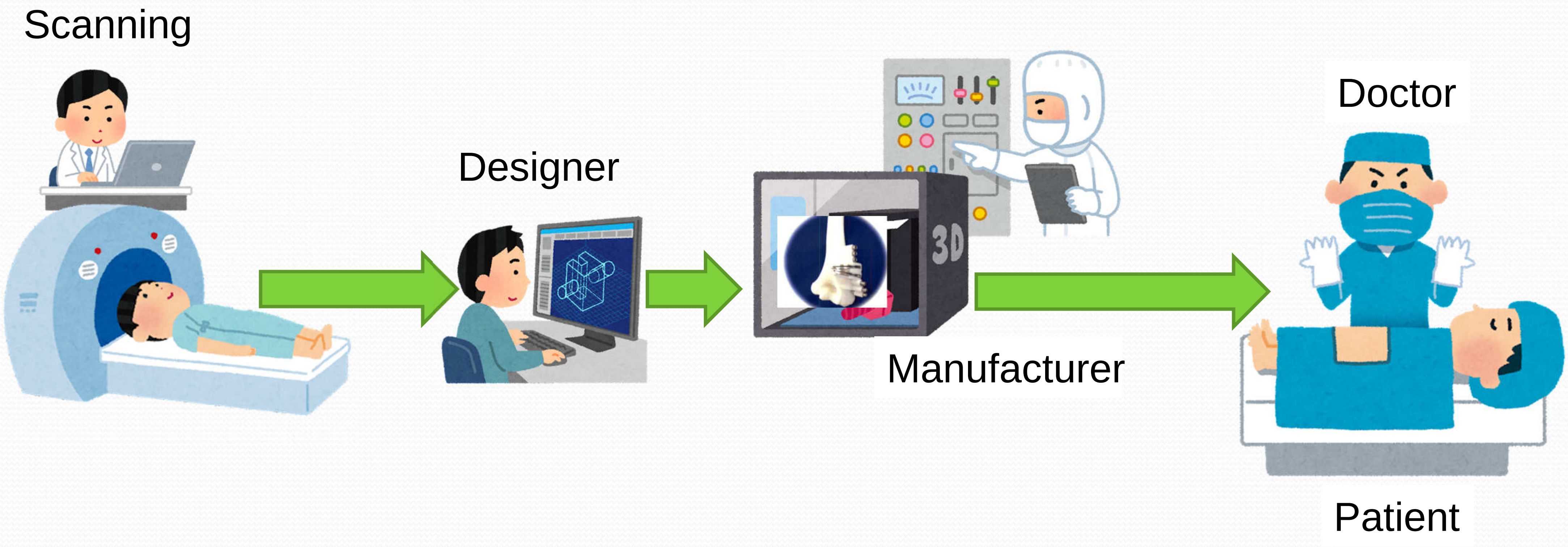
- Medical implants in human body **needs** mechanical **durability**.
- We need the **'Golden methods'** to estimate the performance of each devices. = **International Standard**

Surgical Guides

- Effective instruments for “quickly” / “accurate” operations.
- Potential for use in minor areas (ankle / shoulder)



Who is Stakeholder ?



- To standardization, which categories do we belong to?

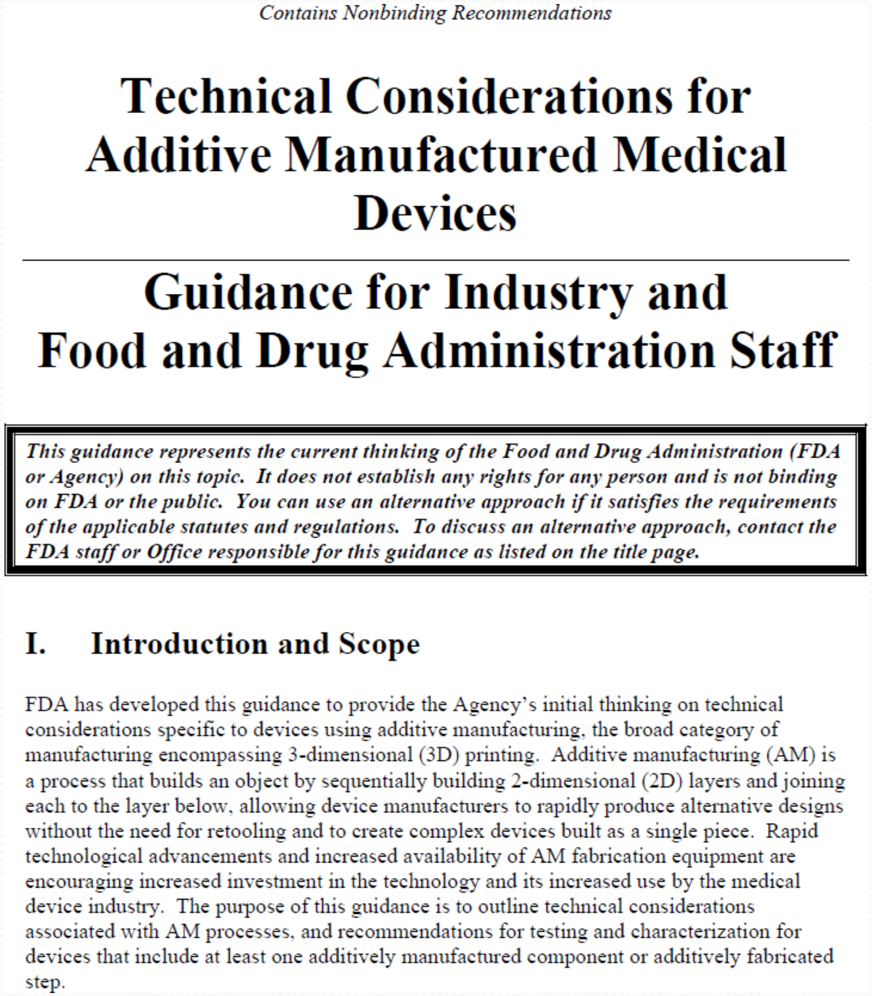
ISO/TC150 JWG1

		2023-01-17 (14)	2023-02-08 (19)	2023-03-22 (14)	2023-05-08 (13)	2023-07-12 (9)
Member from	Australia		1	1	1	
	Brazil	1	1	1		1
	France	1			1	1
	Germany	3	2	6	3	1
	Italy		1	1	1	
	Japan	1	1	2	2	
	Republic of Korea	2			2	1
	United Kingdom	1	1			1
	United state	5	2	2	3	4
Stakeholder	(A) Industry and commerce: Manufacturers, Suppliers, Trade associations	6	4	5	4	3
	(B) Government: Government organizations, Regulatory authorities	3	3	2	3	3
	(C)Consumers: Patients, Healthcare centers, Surgeons					
	(D) Labour: Trade unions, Employees.					
	(E) Academic and research bodies: Academic and research communities.	2	1	3	3	2
	(F) Standards application: Testing facilities, Accreditation bodies.	3	1	4	3	2
	(G)Non-governmental organization; Government independent organizations.					

- Convenor:
  - Kohei Murase (TC150)
  - Lim Wonbong (TC261)
- Manager :

  Klaus Zeier (DIN)

Considerations for medical AM implants



Contains Nonbinding Recommendations

Technical Considerations for Additive Manufactured Medical Devices

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction and Scope

FDA has developed this guidance to provide the Agency's initial thinking on technical considerations specific to devices using additive manufacturing, the broad category of manufacturing encompassing 3-dimensional (3D) printing. Additive manufacturing (AM) is a process that builds an object by sequentially building 2-dimensional (2D) layers and joining each to the layer below, allowing device manufacturers to rapidly produce alternative designs without the need for retooling and to create complex devices built as a single piece. Rapid technological advancements and increased availability of AM fabrication equipment are encouraging increased investment in the technology and its increased use by the medical device industry. The purpose of this guidance is to outline technical considerations associated with AM processes, and recommendations for testing and characterization for devices that include at least one additively manufactured component or additively fabricated step.

- In 2017, FDA(U.S.) announced 'Technical consideration for AM Medical Devices'
  - https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM499809.pdf
- For Medical use, we have to pass the (Very severed)certifications from each country.

Scope of ISO/TC150 JWG1 (9 items)

1. Qualifications of machine operators of AM Machines used in surgical implant applications

   e.g., *powder bed fusion, stereolithography, fused filament fabrication, liquid-based extrusion machines*,

2. Calibration, Validation and Re-validation for acceptance of AM Machines used in surgical implant applications,

   e.g., *powder bed fusion, stereolithography, fused filament fabrication, liquid-based extrusion machines*,

Scope of JWG1 (cont.)

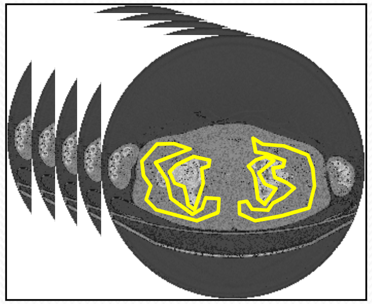
6. Physical and mechanical test methods or considerations to address risks associated with AM of surgical implants,
7. Addressing each of the above items also in the use or incorporation of biological, cellular, or tissue-based products in AM.
8. Biological considerations of final devices taking into account *manufacturing residues, cleanliness, sterilization, biocompatibility*
9. Labeling considerations

- Data Format, Security, Voxel modeling, etc.

Scope of JWG1 (cont.)

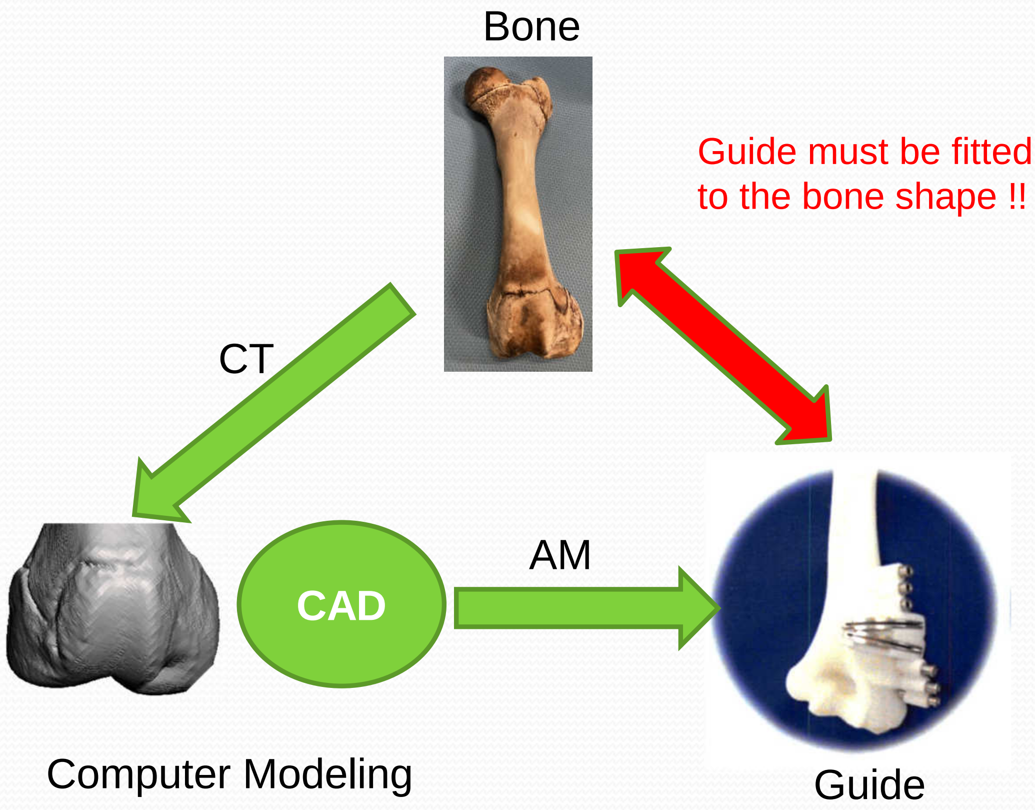
3. Specifications for materials used in AM of surgical implant applications,
   - e.g., *virgin and reused powders/starting materials,*

4. Process specifications and quality considerations
   - including, e.g., *design (standard or patient-matched from* ***medical imaging*** *), software workflow, printing/build, and post-printing/build validation,*



5. Identification of risks
   - including, e.g., *variability in quality, geometry, surface finish, tolerances, microstructure, chemistry,*

To estimate 3D quality of 'real' product…



- Resolution of CT image
- Slice thickness
- X-ray Strength (kV)
- Specification of AM machine.
- Material specification
- Necessarily of metal-use for hole and cutting space.
- Posture during Scanning
- …

Currently work in JWG1

- Identified gaps with respect to AM in existing implant specific standards.

- Provide a list of references to existing / currently developed relevant standard documents in TC150, TC261, ASTM F04 and F42

  - JWG1 is working on ISO/CD 5092, “Additive manufacturing for medical – General principles – Additive manufacturing of non-active implants”.
  - The RoV and comments of ISO/CD 5092 received on 2023-11-03 and the next meeting will be held on January 2024.
  - We request participate **you** to discuss AM for medical use!!

Summary

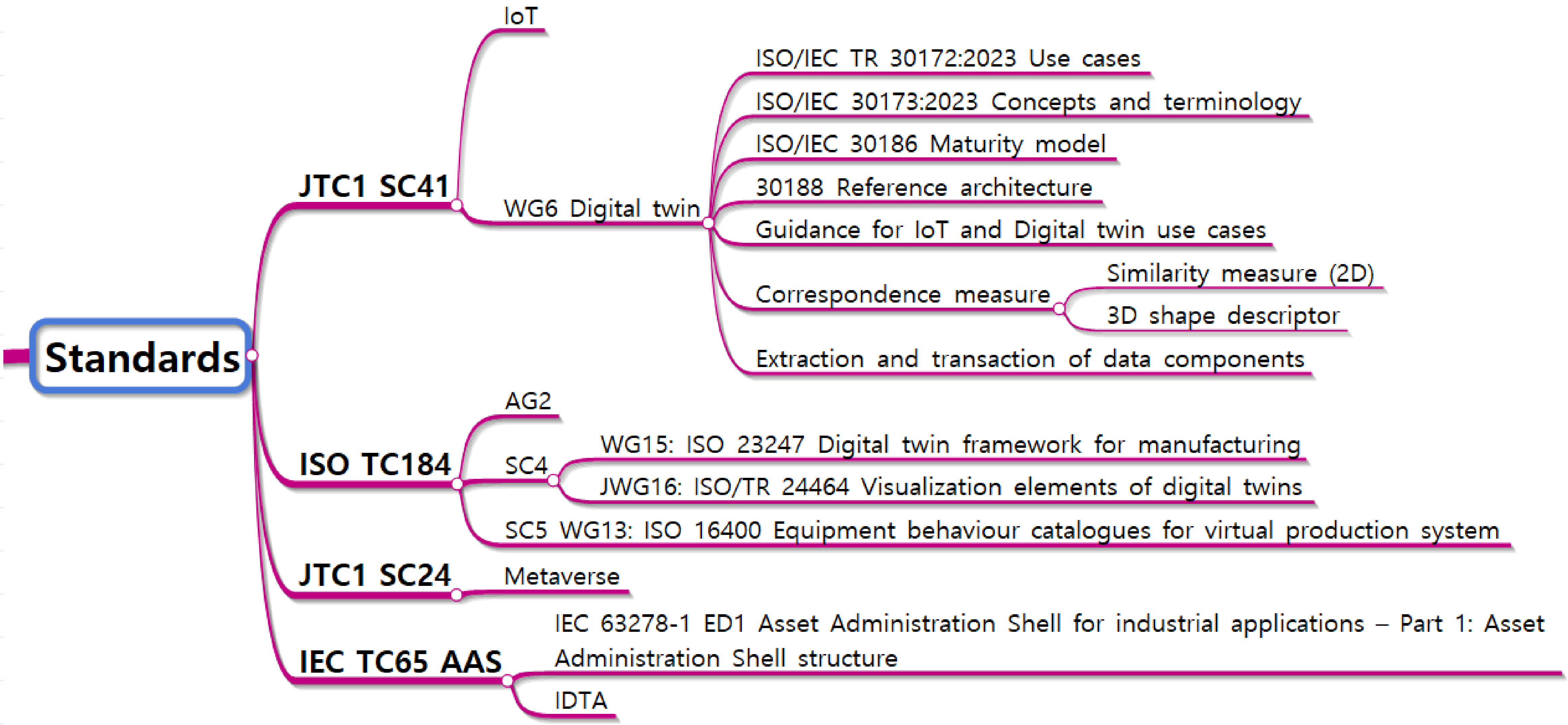
- **Additive Manufacturing (3D Printing and Scanning)** is powerful tool to develop the future medical devices (=Patient-Specified Instruments : PSI).
- In medical application of AM, It is important to **establish the international standards** for
  - Modeling,
  - Measurement (Scanning) ,
  - Material constitution , etc …

  Collaborate with many other fields (categories).

- Collaborations of AM & computer modeling will grow up to ease / agree with orthpaedics.

Thank you for your attention!
murase.kohei.es@osaka-u.ac.jp

Digital Twin projects around ISO/ TC184/ SC4/ JWG16


Standards
JTC1 SC41
IoT
WG6 Digital twin
ISO/IEC TR 30172:2023 Use cases
ISO/IEC 30173:2023 Concepts and terminology
ISO/IEC 30186 Maturity model
30188 Reference architecture
Guidance for IoT and Digital twin use cases
Correspondence measure
Similarity measure (2D)
3D shape descriptor
Extraction and transaction of data components
ISO TC184
AG2
SC4
WG15: ISO 23247 Digital twin framework for manufacturing
JWG16: ISO/TR 24464 Visualization elements of digital twins
SC5 WG13: ISO 16400 Equipment behaviour catalogues for virtual production system
JTC1 SC24
Metaverse
IEC TC65 AAS
IEC 63278-1 ED1 Asset Administration Shell for industrial applications – Part 1: Asset Administration Shell structure
IDTA

Standards About us News Taking part Store EN MENU

ISO/IEC JTC 1

ISO/IEC JTC 1/SC 41

Internet of things and digital twin

ABOUT

QUICK LINKS

Undergoing Projects in WG6:

- ISO/IEC WD 30186 Digital twin – Maturity model and guidance for a maturity assessment
- ISO/IEC WD 30188 Digital Twin - Reference Architecture
- PWI JTC1-SC41-6 Guidance for IoT and Digital Twin use cases
- PWI TR JTC1-SC41-11 Digital Twin - Correspondence measure of DTw twinning
- PWI TR JTC1-SC41-16 Digital Twin – Extraction and transactions of data components

Published;
ISO/IEC TR 30172:2023 Internet of things (IoT) - Digital twin - Use cases
ISO/IEC 30173:2023 Digital twin - Concepts and terminology

Korea STEP Center KSTEP

Standards About us News Taking part Store

← ICS

ISO/IEC AWI 30173

Digital twin — Concepts and terminology

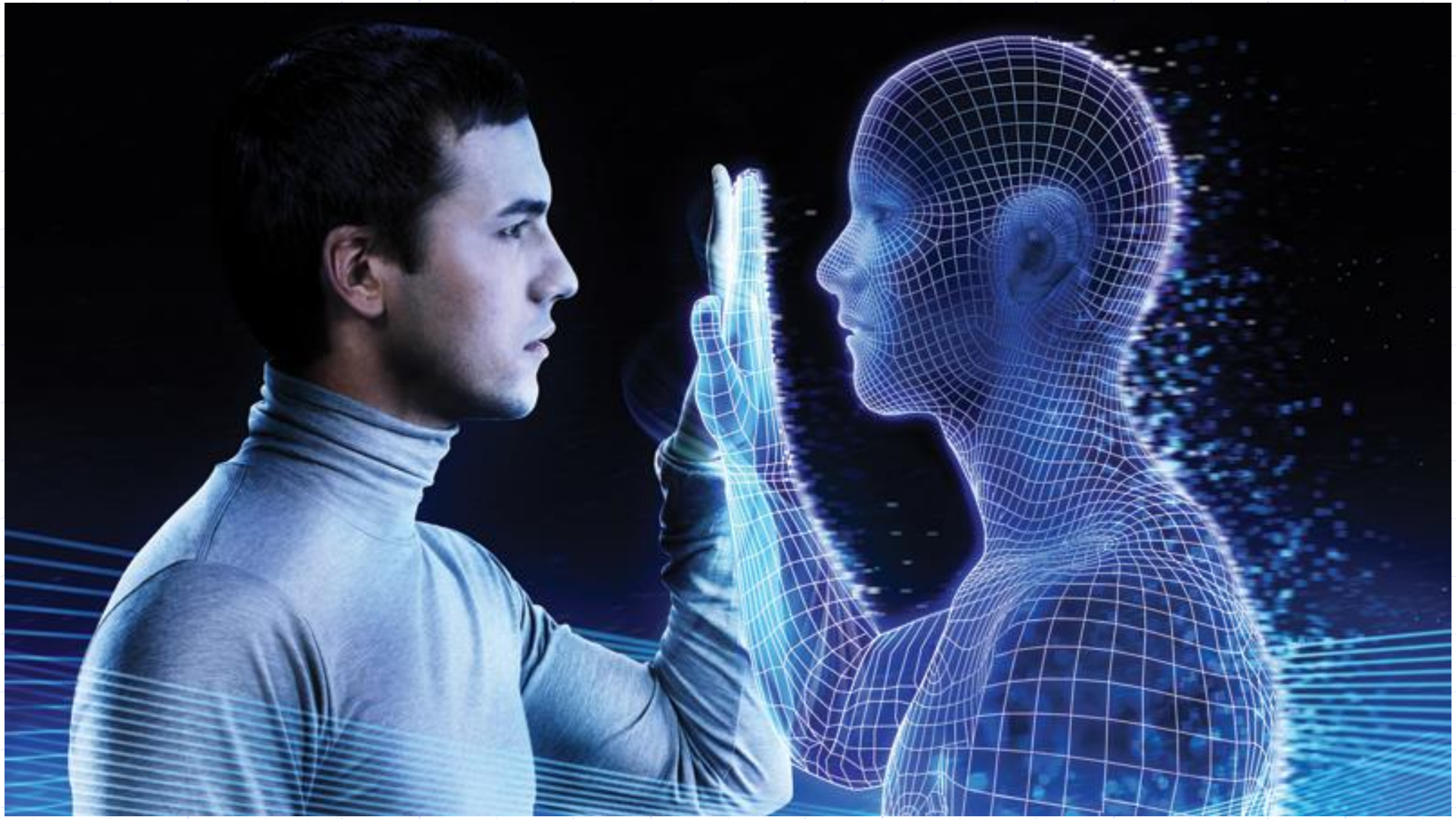
General information

Status : Under development

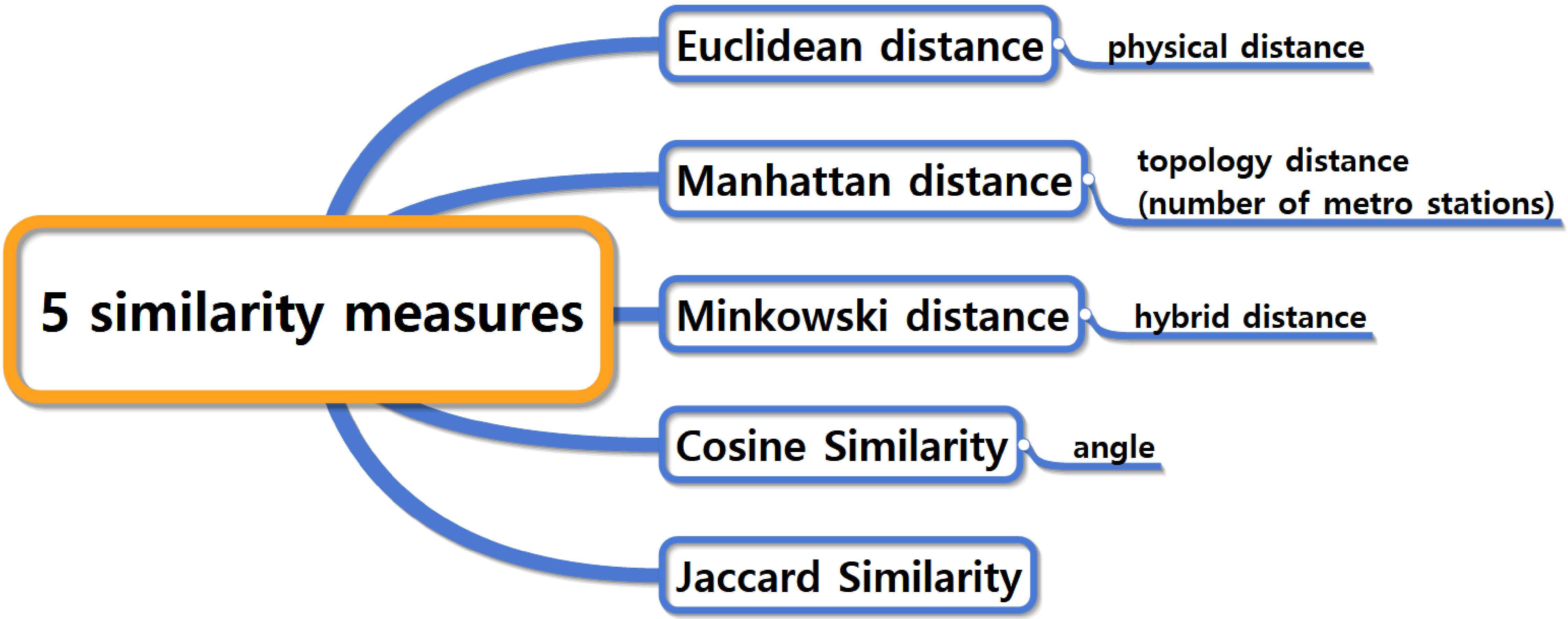
Edition : 1

Technical Committee : ISO/IEC JTC 1/SC 41 Internet of things and digital twin

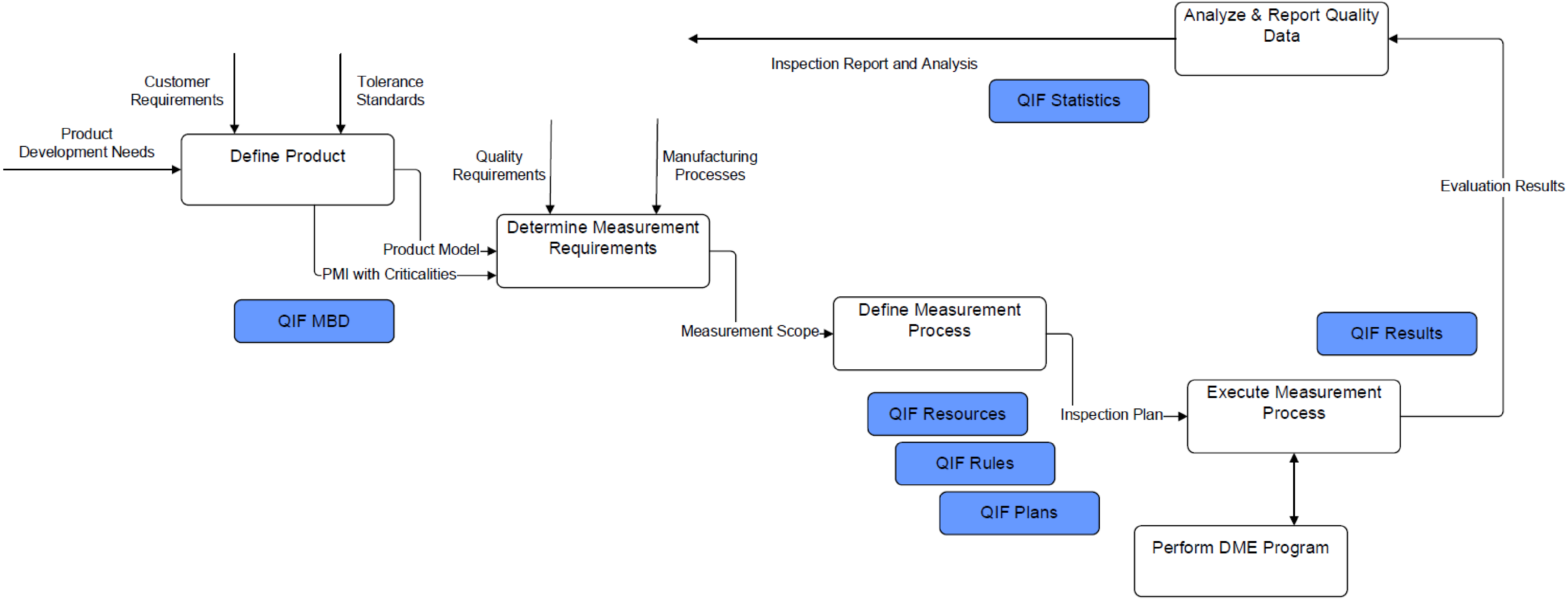
Differentiate human twins?
Correspondence measure



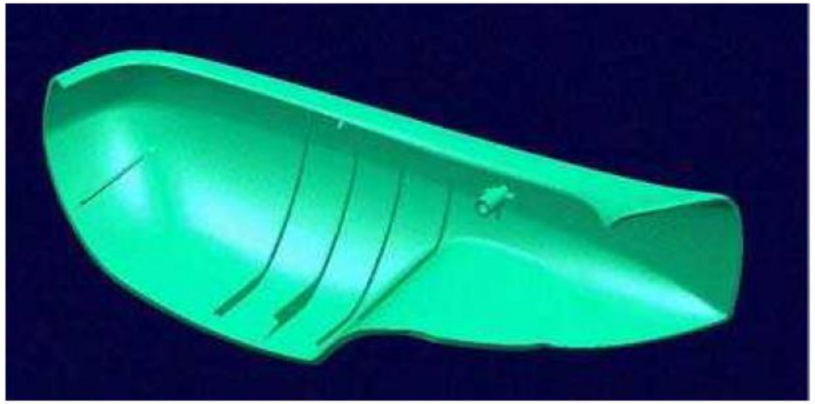
https://cmte.ieee.org/futuredirections/2017/09/27/can-we-have-a-digital-twin/

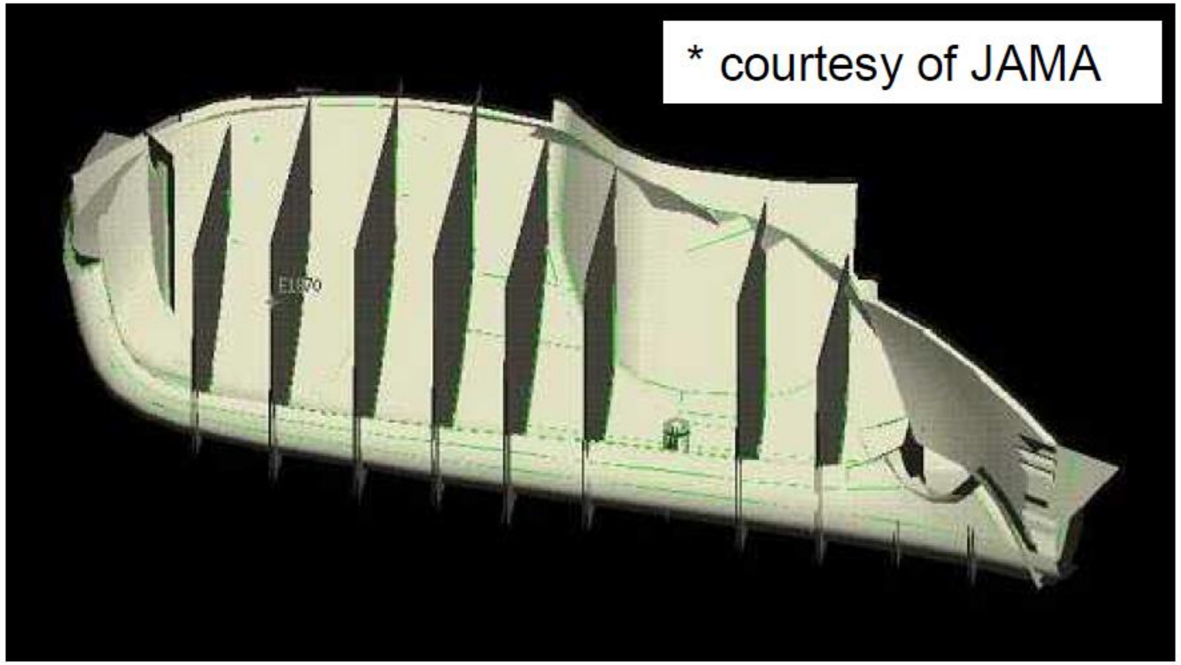


https://dataaspirant.com/five-most-popular-similarity-measures-implementation-in-python/

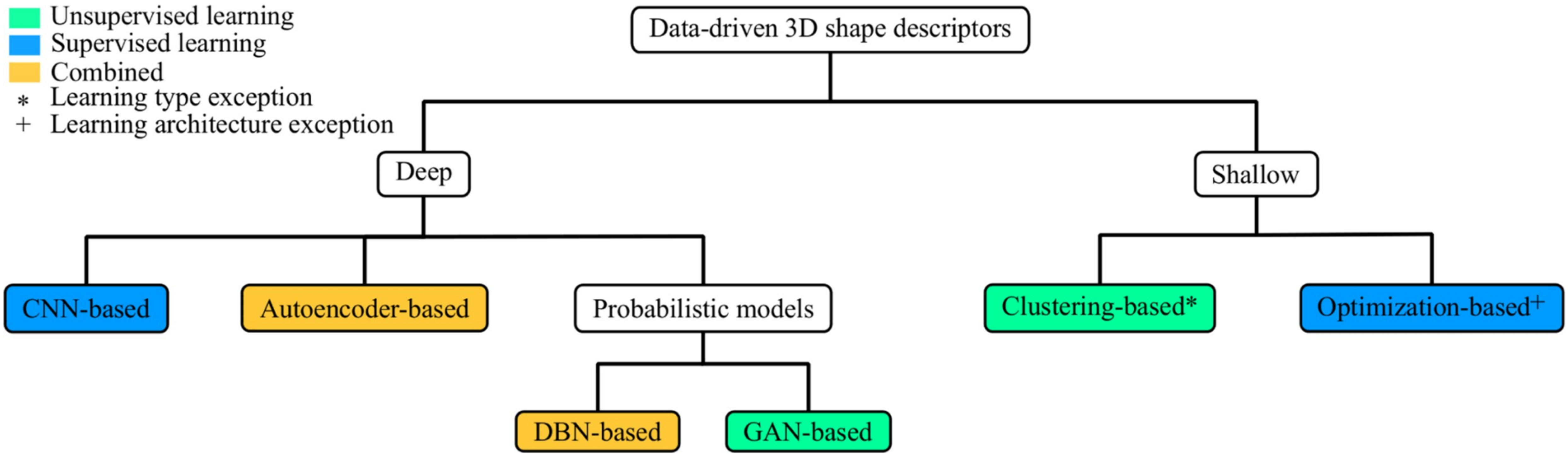


Integrated metrology process with QIF standard

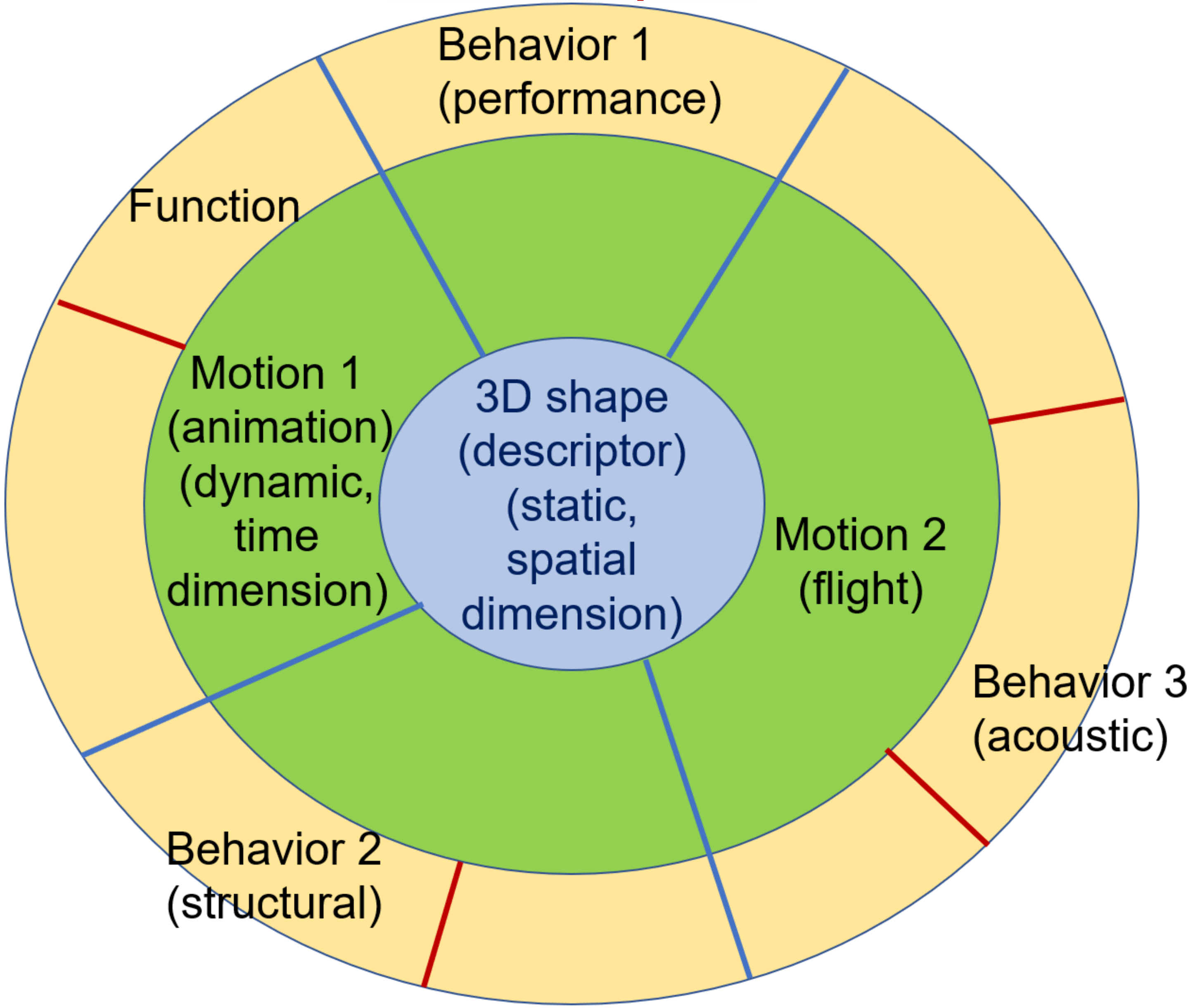


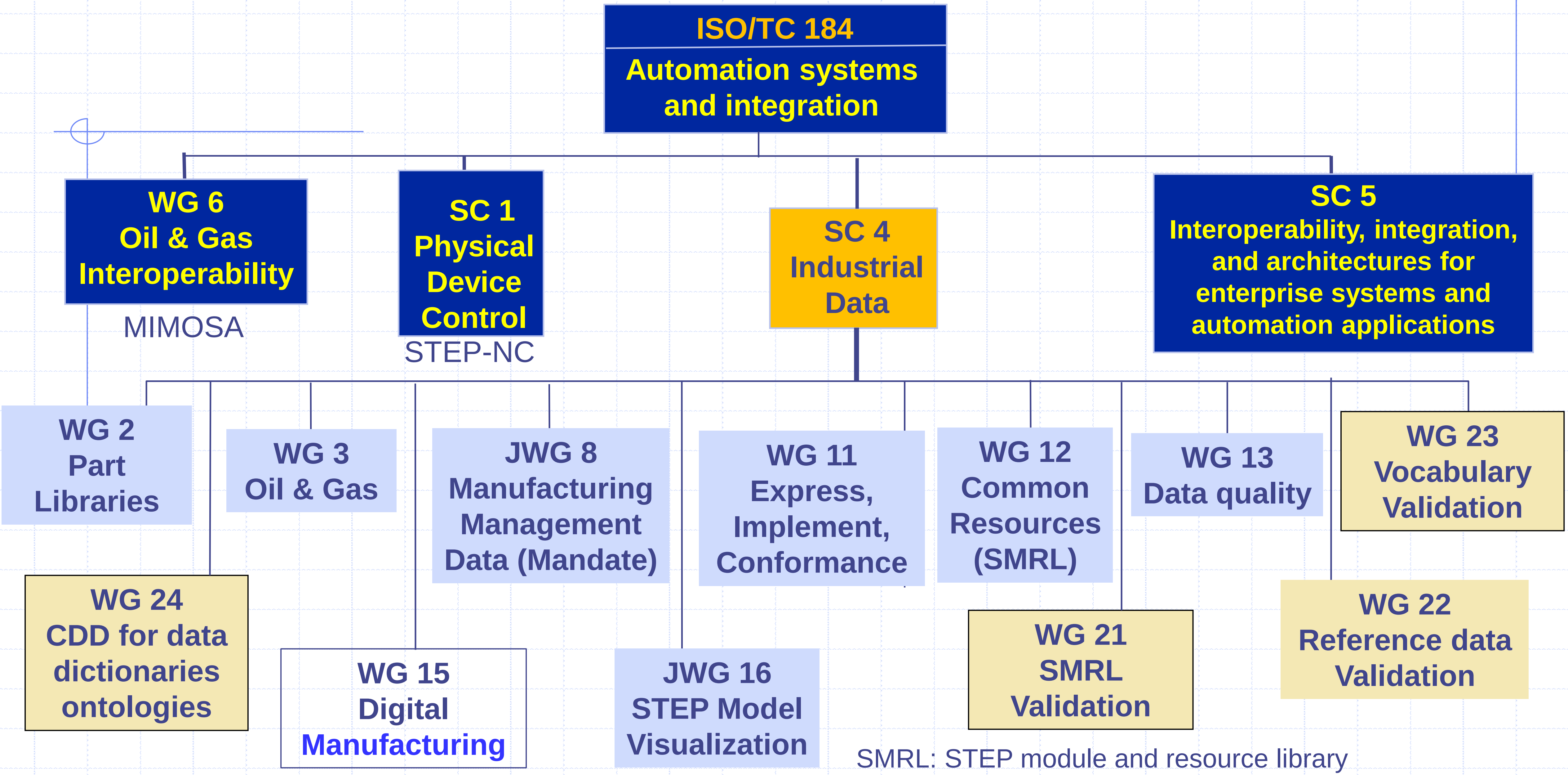


Unwanted surface gaps of CAD models (PDQ)


Unsupervised learning
Supervised learning
Combined
* Learning type exception
+ Learning architecture exception
Data-driven 3D shape descriptors
Deep
Shallow
CNN-based
Autoencoder-based
Probabilistic models
DBN-based
GAN-based
Clustering-based*
Optimization-based+

Onion model of correspondence measure





ISO/TC 184
Automation systems and integration
WG 6
Oil & Gas Interoperability
MIMOSA
SC 1
Physical Device Control
STEP-NC
SC 4
Industrial Data
SC 5
Interoperability, integration, and architectures for enterprise systems and automation applications
WG 2
Part Libraries
WG 3
Oil & Gas
JWG 8
Manufacturing Management Data (Mandate)
WG 11
Express, Implement, Conformance
WG 12
Common Resources (SMRL)
WG 13
Data quality
WG 23
Vocabulary Validation
WG 24
CDD for data dictionaries ontologies
WG 15
Digital Manufacturing
JWG 16
STEP Model Visualization
WG 21
SMRL Validation
WG 22
Reference data Validation
SMRL: STEP module and resource library

ISO/TC 184

Automation systems and integration

About

Secretariat: AFNOR

Committee Manager: Mr Skander Ben Yahia

Chairperson (until end 2023): M Patrick Lamboley

ISO Technical Programme Manager [TPM]: Ms Laura Mathew
ISO Editorial Manager [EM]: Ms Claudia Lueje

Creation date: 1983

Structure Liaisons Meetings

Reference ↑	Title
ISO/TC 184/SC 1	Industrial cyber and physical device control
ISO/TC 184/SC 4	Industrial data
ISO/TC 184/SC 5	Interoperability, integration, and architectures for enterprise systems and automation applications
ISO/TC 184/AG 2 ⓘ	Digital Twin

KSTEP Korea STEP Center

Published on 10 November 2020

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Ed.2 is in ballot process 2023

ICS › 25 › 25.040 › 25.040.40

ISO/TR 24464:2020

Automation systems and integration — Industrial data — Visualization elements of digital twins

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← ICS ← 25 ← 25.040 ← 25.040.40

ISO/TC184/SC4/WG15
ETRI

ISO 23247-1:2021

Automation systems and integration — Digital twin framework for manufacturing — Part 1: Overview and general principles

Abstract

Preview

This document provides an overview and general principles of a digital twin framework for manufacturing including:

— terms and definitions;

— requirements of the digital twin framework for manufacturing.

Buy this standard

Format	Language
PDF + ePub	English
Paper	English

TC184 WG15

Digital Twin Framework for Manufacturing ISO 23247

- Part 1 — Overview
- Part 2 — Reference Architecture
- Part 3 — Data examples
- Part 4 — Network protocols

ISO/AWI 23247-5 Digital twin framework for manufacturing
Part 5: Digital thread for digital twin
ISO/AWI 23247-6 Digital twin framework for manufacturing
Part 6: Digital twin composition

ISO TC/184/SC5/WG13: EBC

ISO 16400 – Equipment behavior catalogues for virtual production system

- Part1: Overview
- Part2: Formal description of catalogue template
- Part3: Guideline for construction of equipment instance model
- Part4: Application method
- Part5: Integration of EBC templates in production system design & operation
- Part6: An EBC enhanced with machine learning techniques

JTC 1/SC 24 Standards and Projects for the Metaverse

ISO/IEC Workshop: Standards for the Metaverse

2023-06-26

Myeong Won Lee, JTC 1/SC 24 Chair

INFORMATION TECHNOLOGY STANDARDS

https://www.iec.ch/system/files/2023-06/presentations_0.pdf

TC 65 Industrial-process measurement, control and automation

Detail

Committee	Working Groups	Project Leader	Current Status	Frcst Pub Date	Stability Date
TC 65	WG 24	Mr Michael Hoffmeister	BPUB	2024-01	2026

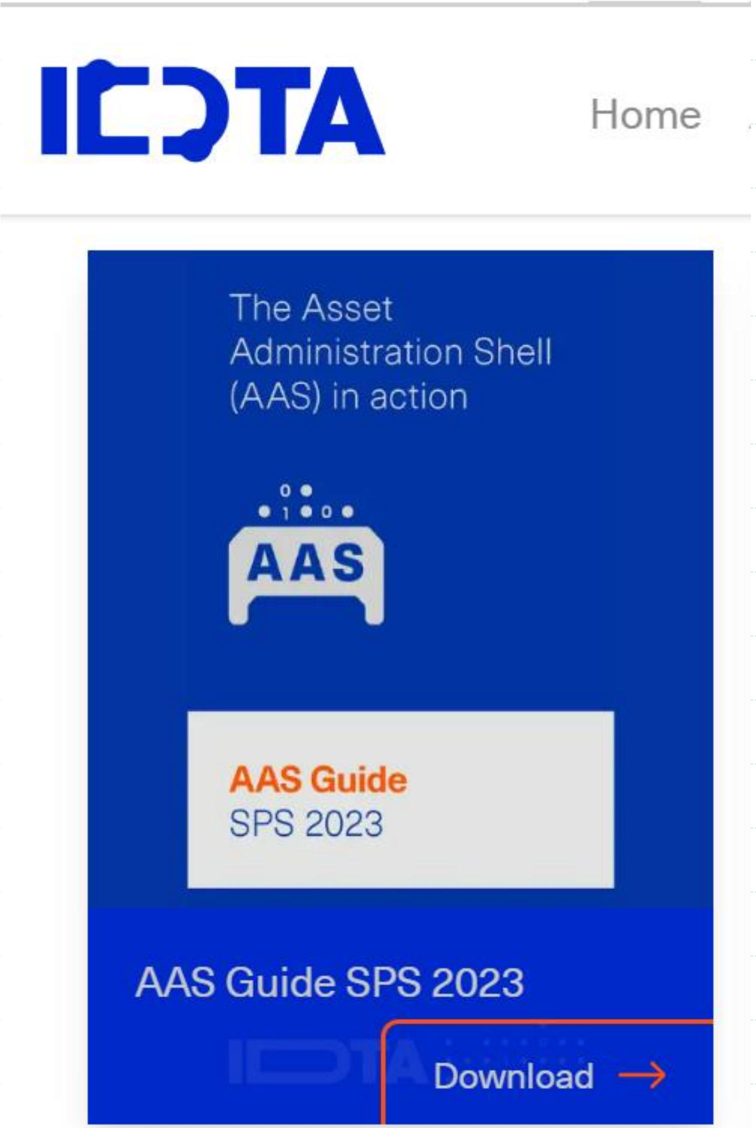
History

Project

IEC 63278-1 ED1

Asset Administration Shell for industrial applications – Part 1: Asset Administration Shell structure

Related documents:
SMB/7507A/INF
428 kB



https://industrialdigitaltwin.org/en/content-hub/downloads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dhanyavadagalu
shukriya
mercé
мерси
তোমাকে ধন্যবাদ
감사합니다
xièxie
merci

Soonhung Han (韓淳興)

- Current
  - iCAD laboratory, Mechanical and Ocean Systems engineering, KAIST, https://sites.google.com/view/icadlab/home
  - Korea STEP center: ISO standard for exchange of engineering design www.kstep.or.kr
  - Convener of JWG16 of ISO/TC184/SC4, https://committee.iso.org/home/tc184sc4
  - ICT convergence network: Industry 4.0 in Korea, https://kicon.org/
- Study
  - PhD in Ship CAD, University of Michigan, USA
  - MS in Ship Design, Newcastle upon Tyne, UK
  - Naval Architecture, Seoul National University, Korea
- Work
  - Ship and ocean research institute, www.kriso.re.kr
  - Society of CAD/CAM Engineers (Korea) www.cde.or.kr
  - Start up www.PartDB.com
  - Design committee for ships and ocean plants (Korea)
  - Society for e-business studies (Korea)

ISO/TC 106/SG 9
Scanning & 3D Printing on Digital Dentistry

12th, Dec. 2023

Seoul National University
School of Dentistry

WG 3 ILT project leader
WG 7 Secretary

Prof. Ji-Man Park

ISO

MEETING SCHEDULE

ISO/TC 106 MEETING - Milan, ITALY September 16-21, 2018

Meeting Registration - ISO Meetings at https://sd.iso.org/meetings/51714 (login required)

TC/SC/WG	Title	Mon Sep 17 AM	Mon Sep 17 PM	Tues Sep 18 AM	Tues Sep 18 PM	Wed Sep 19 AM	Wed Sep 19 PM	Thurs Sep 20 AM	Thurs Sep 20 PM	Fri Sep 21 AM	Meeting Time	Meeting Room
TC106 - Plenary	Dentistry									X	9:00 – 12:00	
TC 106/WG 10	Biological evaluation						X				13:00 – 17:00	
SC1 - Plenary	Filling and restorative materials								X		13:00 – 15:00	
SC1/WG 2	Endodontic materials		X								13:00 – 17:00	
SC1/WG 7	Dental amalgam	X									9:30 – 12:30	
SC1/WG 9	Polymer based restorative materials				X						13:00 – 17:00	
SC1/WG 10	Dental luting cements, bases and liners						X				13:00 – 17:00	
SC1/WG 15	Orthodontic products			X							8:30 – 10:30	
SC1/WG 17	Orthodontic anchors			X							10:30 – 12:30	
SC2 - Plenary	Prosthodontic materials							X			10:30-12:30	
SC2/WG 1	Dental ceramics	X									8:00 – 12:00	
SC2/WG 8	Color stability test methods			X							8:00 – 12:00	
SC2/WG 7	Impression materials						X				13:00 – 17:00	
SC2/WG 11	Corrosion test methods					X					8:00 – 12:00	
SC2/WG 14	Dental brazing materials						X				13:00 – 15:00	
SC2/WG 16	Polymer veneering and die materials				X						13:00 – 17:00	
SC2/WG 18	Dental waxes				X						13:00 – 17:00	
SC2/WG 20	Artificial teeth			X							8:00 – 12:00	
SC2/WG 22	Magnetic attachments					X					10:30 – 12:30	
SC2/WG 23	Chairside denture base relining materials		X								13:00 – 17:00	
SC3 - Plenary	Terminology							X			9:00-11:00	
SC3/WG 1	Harmonization of dental codes and abbreviations			X							8:00 – 12:00	
SC3/WG 2	Dental vocabulary (Revision of ISO 1942 and thematic coding of its terms)				X						14:00 – 17:00	
SC3/WG 5	Terminology for forensic odontology data	X	X								9:00 – 17:00	
SC4 - Plenary	Dental instruments							X			9:00-11:00	
SC4/WG 1	Rotary instruments			X							8:00 – 12:00	
SC4/WG 7	Dental handpieces	X	X								9:30 – 17:30	
SC4/WG 8	Dental hand instruments	X	X								9:00 – 17:00	
SC4/WG 9	Endodontic instruments					X	X				9:00 – 17:00	
SC4/WG 10	Dental injection systems					X					8:30 – 10:30	
SC4/WG 12	Implant instruments				X						14:00 – 16:00	
SC4/WG 14	Materials for dental instruments						X				13:00 – 17:00	
SC6 - Plenary	Dental equipment								X		13:00-15:00	
SC6/WG 1	Dental operating light					X	X				9:00 – 17:00	
SC6/WG 2	Dental patient chair and dental unit			X	X						9:30 – 17:30	
SC6/WG 5	Amalgamators, dispensers and capsules		X								13:00 – 17:00	
SC6/WG 7	Powered polymerization activators				X						13:00 – 17:00	
SC6/WG 8	Suction equipment	X	X								9:30 – 17:30	
SC7 - Plenary	Oral care products								X		13:00-15:00	
SC7/WG 1	Manual toothbrushes					X					10:30 – 12:30	
SC7/WG 2	Powered oral hygiene devices											
SC7/WG 3	Oral rinses			X							8:00 – 10:30	
SC7/WG 5	Dentifrice			X							10:30 – 12:30	
SC7/WG 7	Dental bleaching products	X									8:00 – 12:00	
SC7/WG 8	Fluoride varnishes						X				13:00 – 17:00	
SC7/WG 9	Denture adhesives				X						14:00 – 17:00	
SC7/WG 10	Analytical methods for oral care products		X								14:00 – 17:00	

*SC5/WG 5 invites SC2/WG 1 members to a meeting
**CAG Meeting on Thursday is a tentative meeting, if required

ISO

MEETING S

ISO/TC 106 MEETING - Milan, ITALY Septembe

Meeting Registration - ISO Meetings at https://sd.iso.org/meetings/51714 (login required)

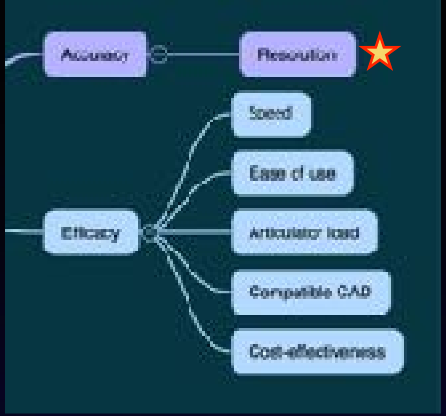
TC/SC/WG	Title	Mon Sep 17 AM	Mon Sep 17 PM	Tues Sep 18 AM	Tues Sep 18 PM	Wed Sep 19 AM	Wed Sep 19 PM	Thurs Sep 20 AM	Thurs Sep 20 PM	Fri Sep 21 AM	Meeting Time
SC 8 - Plenary	Dental implants							X			9:00-12:00
SC 8/WG 1	Implantable materials			X							8:00 – 10:00
JOINT SC1/WG17 - SC8/WG1	Orthodontic anchors & Implantable materials			X							10:30 – 12:30
SC 8/WG 3	Content of technical files	X									8:00 – 12:00
SC 8/WG 4	Mechanical testing		X								13:00 – 17:00
SC 8/WG 6	Pre-clinical performance requirements				X						13:00 – 17:00
SC 8/WG 7	Evaluation of Connective Interfaces of Dental Implant Assemblies					X					8:00 – 12:00
SC 9 - Plenary	Dental CAD/CAM systems							X			8:00-10:00
SC 9/WG 2	Terminology	X									8:00 – 10:00
SC 9/WG 3	Digitizing devices			X							8:00 – 12:00
SC 9/WG 4	Interoperability					X					10:30 – 12:30
SC 9/WG 5	Machined devices		X								13:00 – 17:00
SC 9/WG 6	Machinable blanks				X						13:00 – 17:00
CAG	Chairman's Advisory Group (CAG		X						X**		17:00-19:00

*SC 9/WG 6 invites SC 2/WG 1 members to a meeting
**CAG Meeting on Thursday is a tentative meeting, if required

Working group 3

Digitizing devices

Accuracy specification based on ISO 12836



Documented Scan accuracy (ISO 12836)

Know your investment - tested against ISO 12836 standard

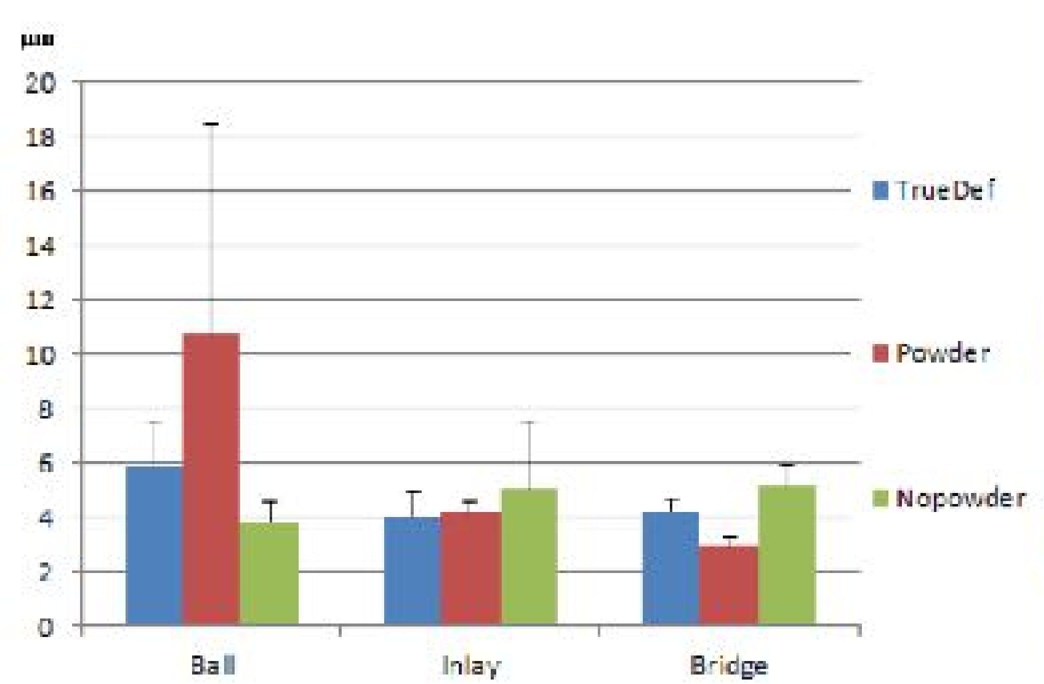
Users should understand accuracy measurement methods behind the manufacturer's claims. 3Shape measures and documents accuracy for all scanners using ISO 12836 standards and dedicated implant bar validation objects.

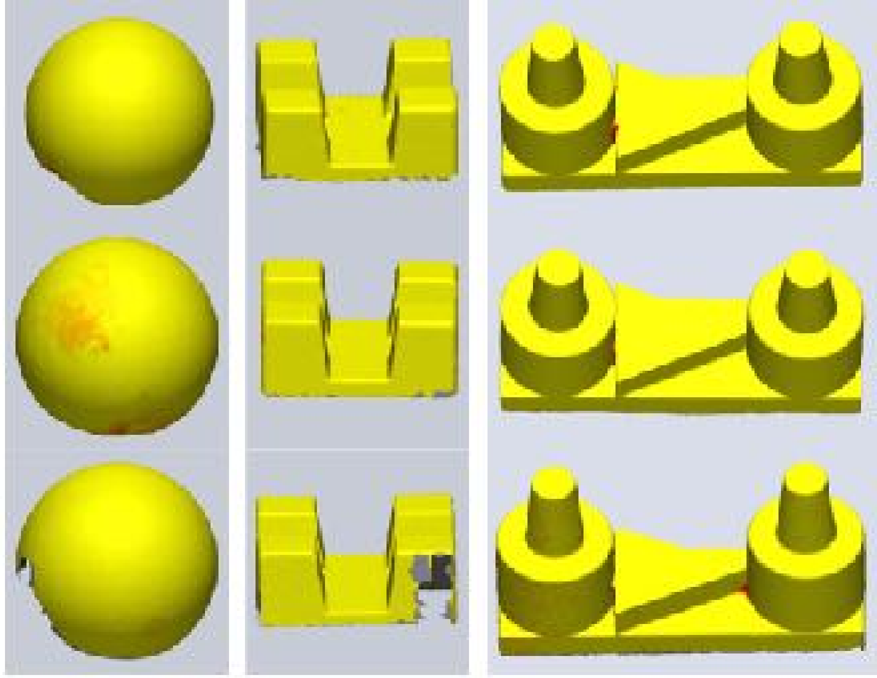
from Medit

NEW Documented 5 micron accuracy (ISO 12836)

4 x 5.0 MP cameras, high quality mechanics and calibration algorithms.

from 3shape





Materials and Methods

List	Item	Abbreviation
Scanner model	IDENTICA Hybrid	ID
	CS3500	CS
	TRIOS3	TR
	EzScan	EZ
Material of test specimen	Resin for 3D Printing	3D
	Improved Stone	IS
Surface treatment of test specimen	No treatment	NO
	Powder	PO
	Sandblast	SB
Shape of test specimen	Crown form of ANSI/ADA 132 Standard	#1
	Inlay form of ANSI/ADA 132 Standard	#2
	Inlay form of ISO 12836 Standard	#3
	Bridge form of ISO 12836 Standard	#4

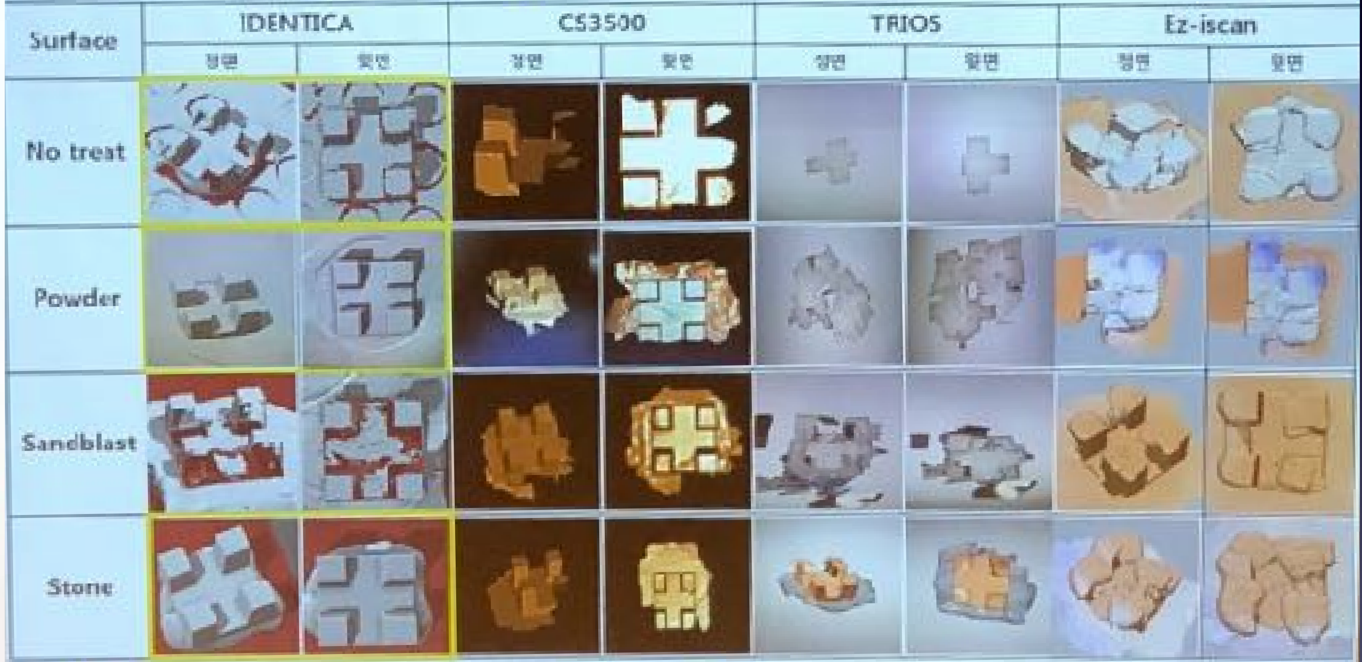
Ex) TRIOS3로 찍은 표면 처리하지 않은 경석고 ISO12836 인레이 모델 → TR-IS-NO-#3

◆ 구강스캐너로 얻은 표준모델 이미지 재현율 등급

Level	Reproductibility	Explanatory note
A	100 %	스캔이미지가 거의 완벽한 형태를 표현하는 경우
B	75 %	절반 이상 표현하지만 비어있거나 중첩되는 형상이 있는 경우
C	50 %	절반 이하로 표현되거나 제대로 된 형상을 표현하지 못하는 경우

Results

◆ ISO 12836 인레이 표준 시편(#3)

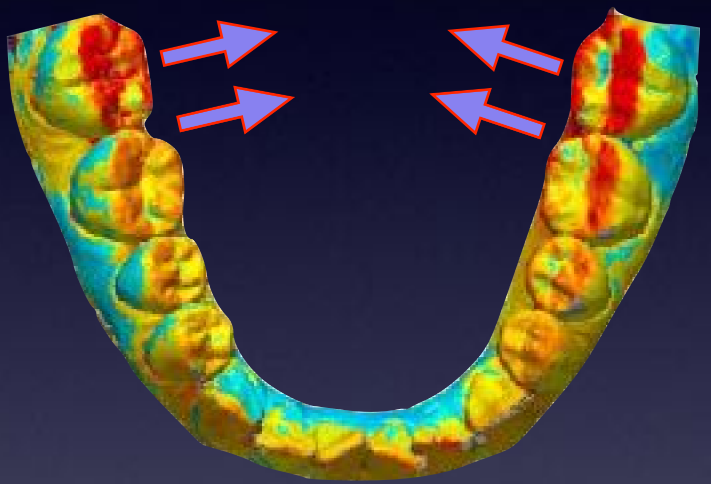


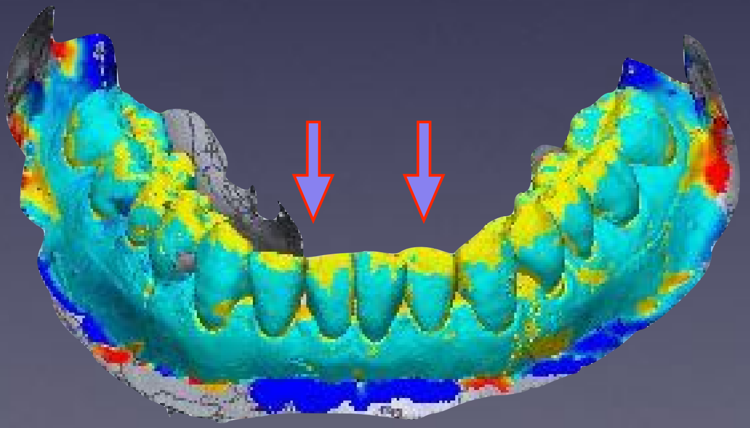
A : ID-3D-NO-#3, ID-3D-PO-#3, ID-IS-NO-#3

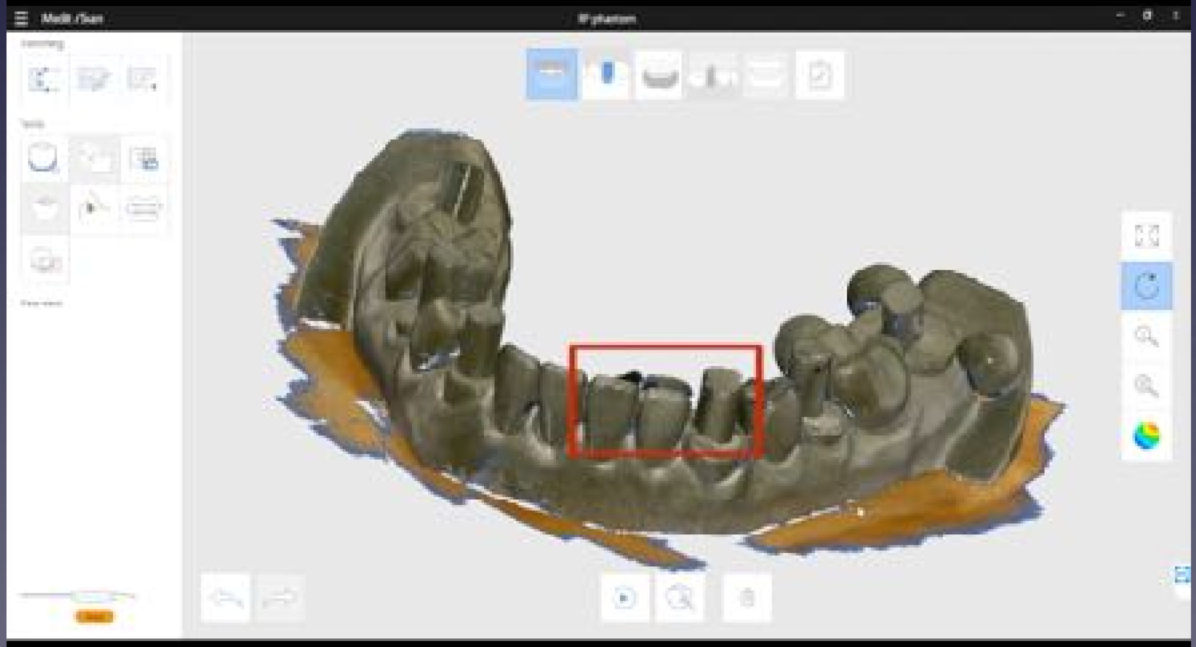
B : CS-3D-NO-#3, CS-3D-PO-#3, ID-3D-SB-#3, CS-3D-SB-#3, CS-IS-NO-#3, TR-IS-NO-#3, EZ-3D-SB-#3

C : TR-3D-NO-#3, TR-3D-PO-#3, TR-3D-SB-#3, EZ-3D-NO-#3, EZ-3D-PO-#3, EZ-3D-IS-#3

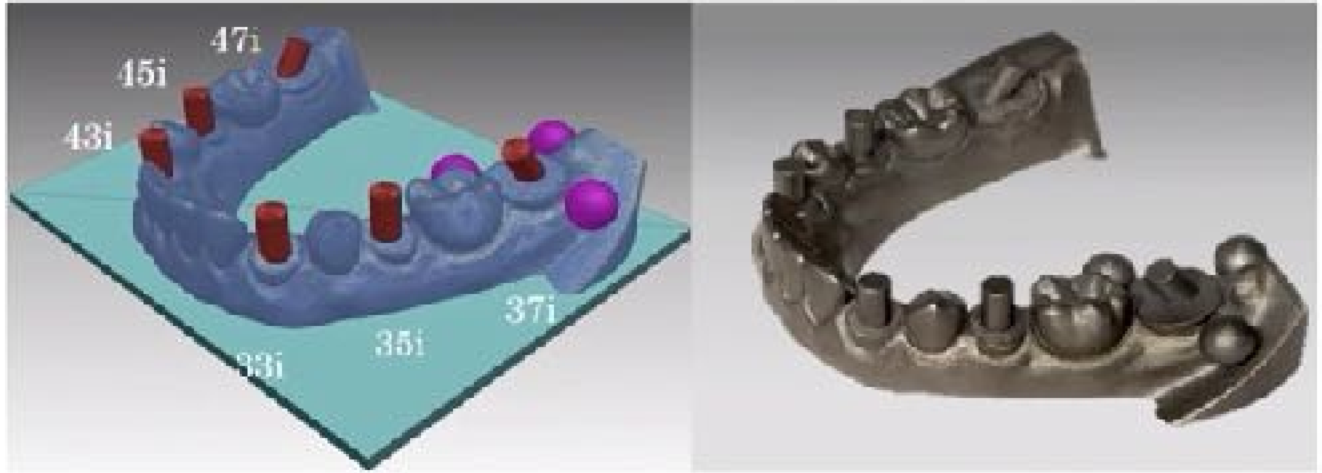
Consideration for intraoral scanner
: Arch distortion

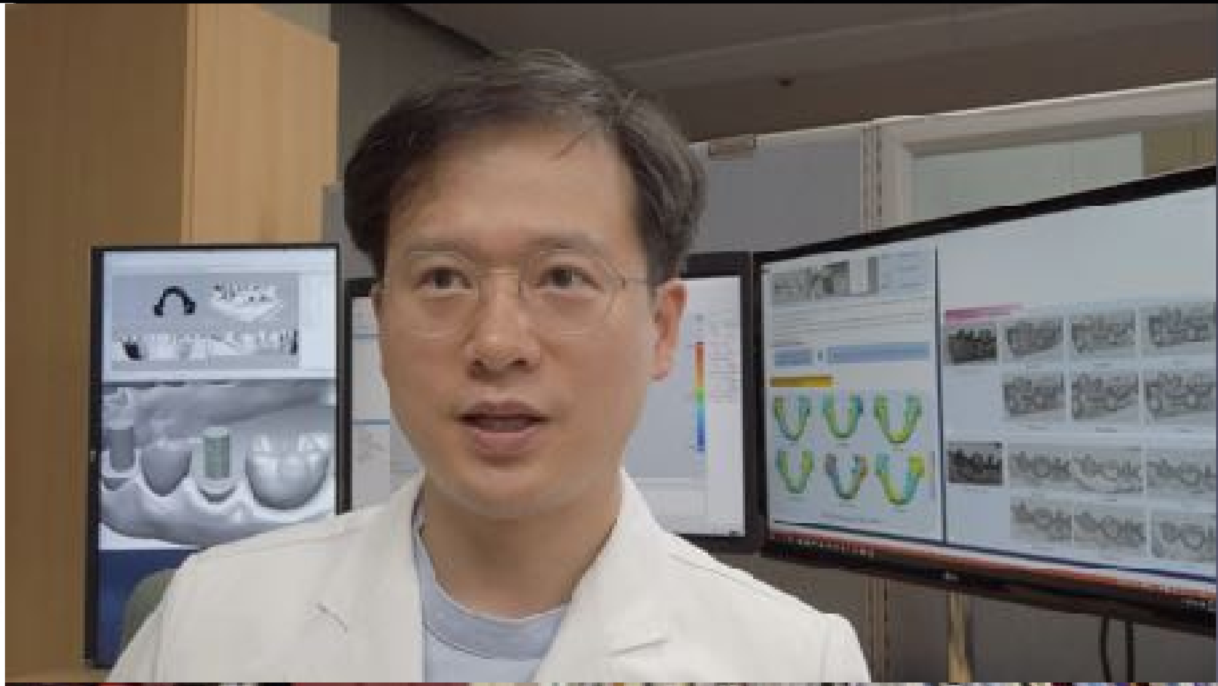


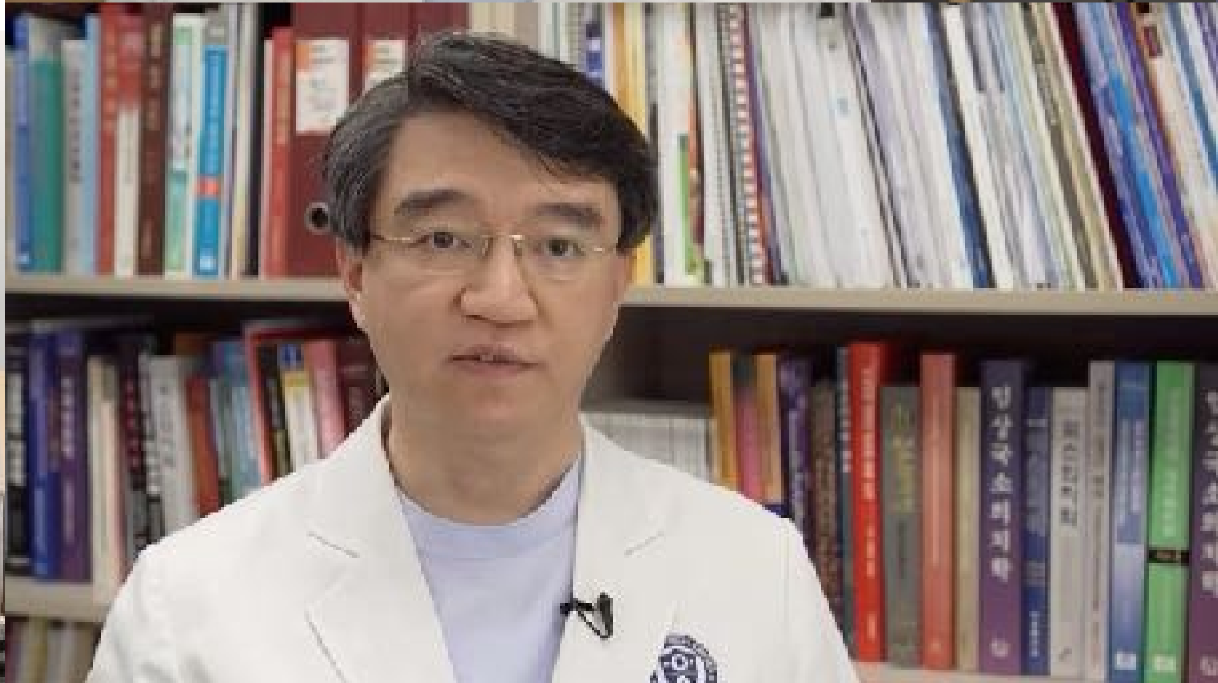




Park JM, Shim JS. Measuring the Complete-arch Distortion of an Optical Dental Impression. J Vis Exp 2019 May;(147).

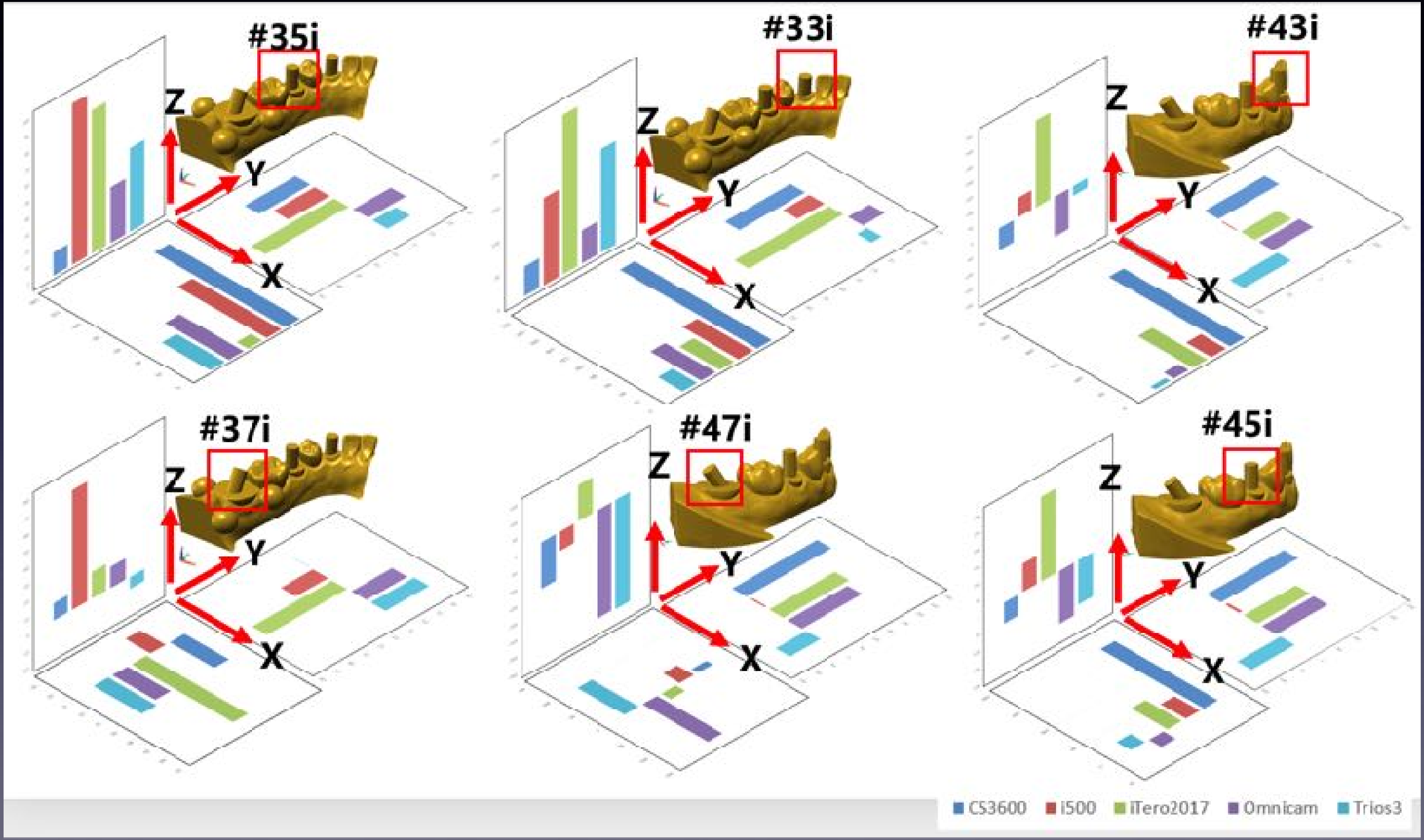






Test methods are developed & introduced

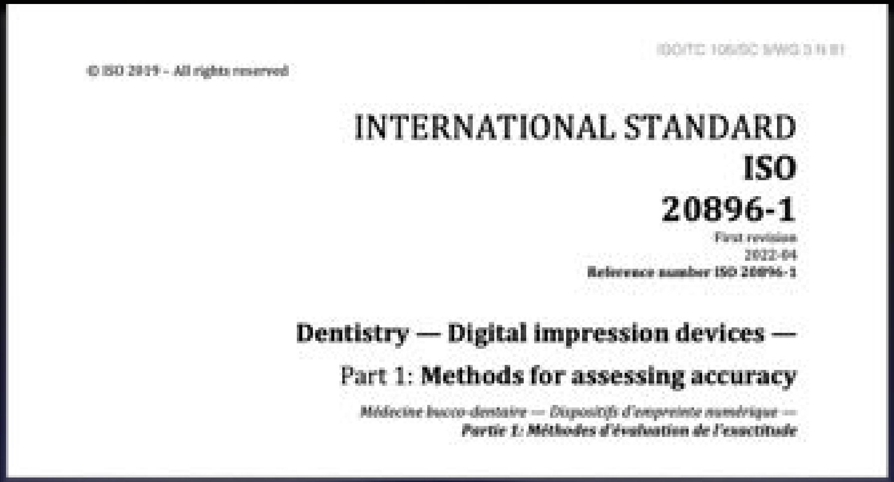
Park JM, Shim JS. Measuring the Complete-arch Distortion of an Optical Dental Impression. J Vis Exp 2019 May;(147).



Intraoral scanners introduced at IDS 2019

IOS Brand	Manufacturer	Special feature	Demo with Human or Model	Arch Distortion	Scan speed	Wand size & weight
Aoralscan	Shining 3D	Newcomer (Nothing special)	Model	4	4	3
Condor	Condor	Smallest scanner tip	Human	4	4	1
CS3700	Carestream	Ergonomic design/ Shade matching algorithm	Human	2	2	3
Emerald S	Planmeca	Small scanner tip/ Transillumination tip	Human	3	3	2
i500	Medit	Subgingival margin - Add impression scan	Human	1	1	3
iTero Element 5D	Align Technology	NIRI(Near-infrared Imaging) proximal caries detection without Transillumination tip	Model	1	2	5
KaVo X Pro	KaVo	Newcomer (Nothing special)	Model	3	3	2
Primescan	Dentsply Sirona	Improved speed/Wide monitor/Touchpad	Human	1	1	4
Trios 4	3shape	Surface caries detection / Transillumination tip	Human	1	1	3
V-IOS	VOCO	Subsurface scanning (Digital Holography)	Not yet introduced	No information	5	5
Virtuo Vivo	Dental Wings	Small wand(Pen-grip)/ Wide window	Human	3	2	1

*The smaller the number, the higher the performance.



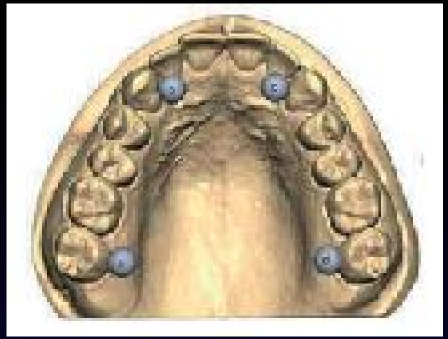
INTERNATIONAL STANDARD
ISO
20896-1

First revision
2022-04
Reference number ISO 20896-1

Dentistry — Digital impression devices —
Part 1: Methods for assessing accuracy

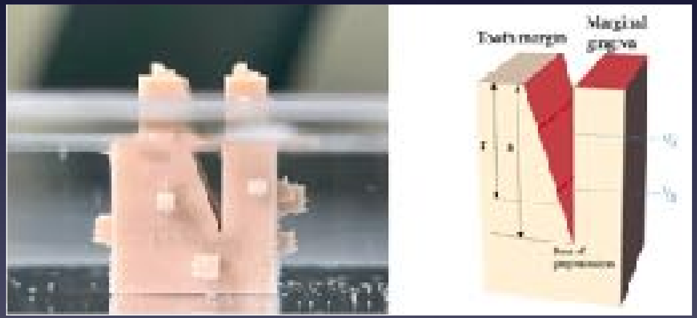
Médecine bucco-dentaire — Dispositifs d'empreinte numérique —
Partie 1: Méthodes d'évaluation de l'exactitude

Annex A (Full arch)

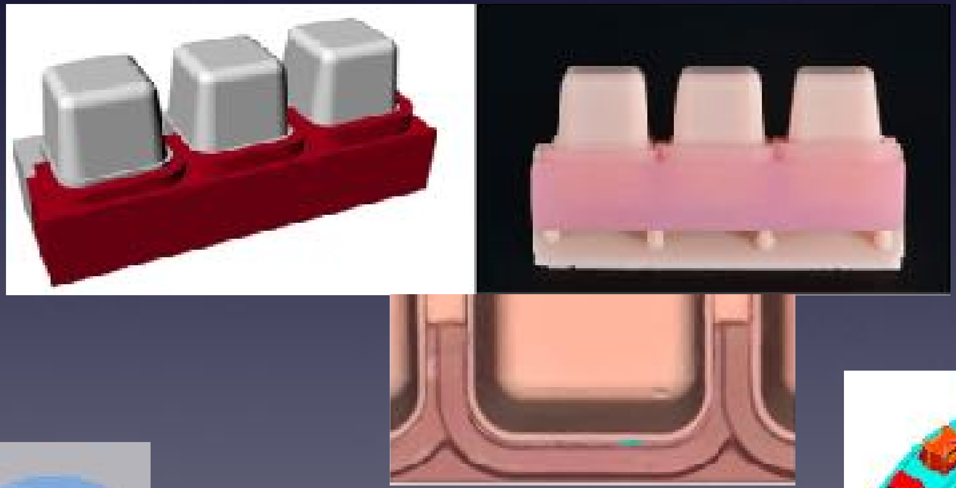


Annex B (Long edentulous ridge)

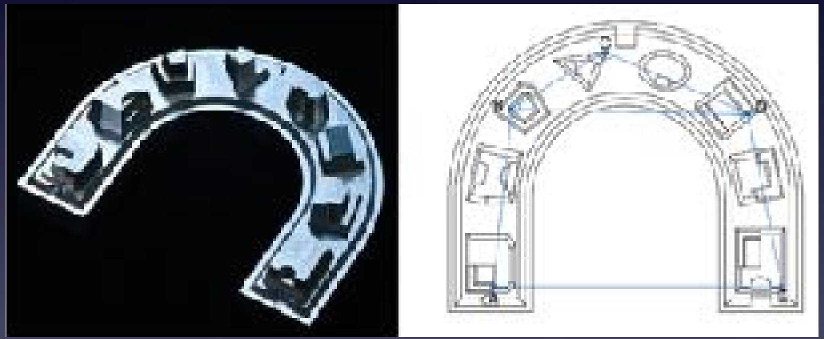
Annex C (Margin w/ sulcular fluid)



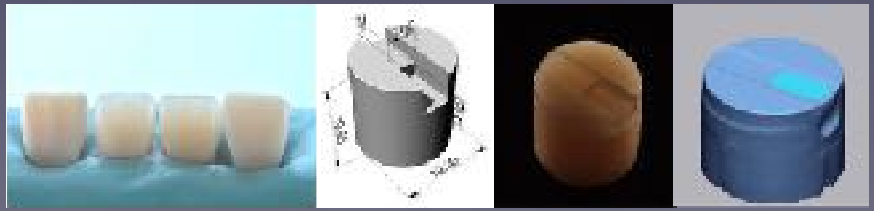
Annex E (Margin line)



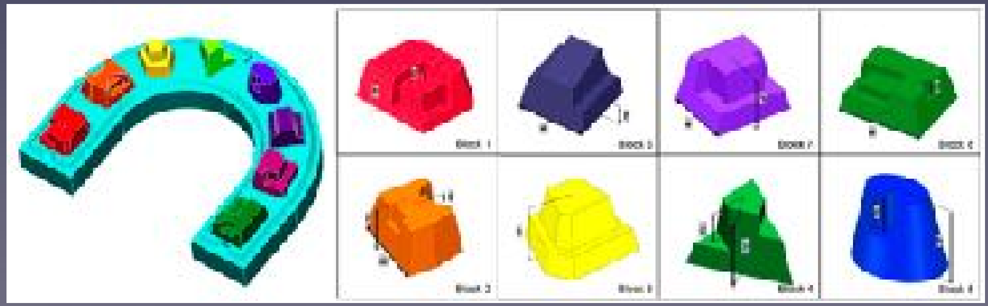
Annex F (Arch distortion)



Annex D (Translucent tooth surface)



Annex G (Inlay,onlay,crown preparation)



ILT Protocol circulation (Feb 2023)

Protocol of ILT for ISO WD 20896-1 (Ed 2)

I. Background

This protocol is prepared for an inter-laboratory (ILT) test for test methods specified in ISO WD 20896-1 (Ed 2), Dentistry — Digital impression devices — Part 1: Methods for assessing accuracy. For the Annexes B to G, the testing procedures have been improved from the procedures described in Annex B to G of ISO WD 20896-1 (Ed 2) based on the results of TC 106/SC 9/WG 3 meeting held in Berlin.

NOTE 1 ILT project manager can loan the metal test object of Annexes F and G on request of the participating laboratory, requiring them to be returned at the end of the ILT. Also, the test object of Annex B to E will be provided on request.

NOTE 2 The STL files used for test methods mentioned in Annexes B to G are based on the data of the ILT project manager and will be supplied centrally.

II. Test Method Procedures

1 Long edentulous ridge of Annex B

1.1 General

This test evaluates the distortion that occurs during scanning a long edentulous model with an intraoral scanner (IOS). Phantom was fabricated by attaching four spheres for distortion evaluation to the long edentulous model [MIS2017-L-HD-HM-32; Nissin dental products inc.] and scanned with a desktop scanner (T500; Medit). The scanned STL file was 3D printed (Form 3; Formlabs) using resin (Gray V4; Formlabs) with a layer thickness of 50 um. Reference data should be obtained by scanning the test object using a desktop scanner with minimal distortion. For distortion evaluation, the centers of each sphere are used as measurement points, and the distances between them are evaluated as the measured values.

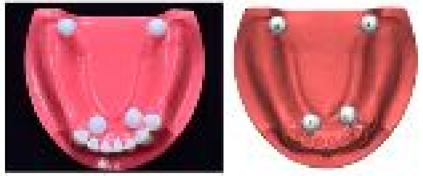


Figure 1 — A complete arch test object showing the placement and the sequential designation of four gauge balls. Points a, b, c, and d designate gauge balls.

obtain an intersecting section line (Fig. 7B). Evaluate the polygons forming the margin line on the abutment scan data. Compared to the reference margin line obtained by sectioning the area clearly distinguished by the edge of the polygon shall be left. However, the indefinite margin that appears as a polygon face and differs from the reference margin line shall be deleted (Fig. 7C). Using the 'Section' command, section the margin line the same way as before for the modified abutment scan data where unclear margin polygons are deleted. At this time, only the clear margin line shall be obtained as curves. Calculate the clear margin line's total length by summing the curves' lengths. As a result, the whole length of the abutment margin, which is composed only of polygons with properly formed margin lines, is measured (Fig. 7D). The reference length shall be obtained by measuring the margin line length in the same way as above on the CAD reference data (Fig. 7E).

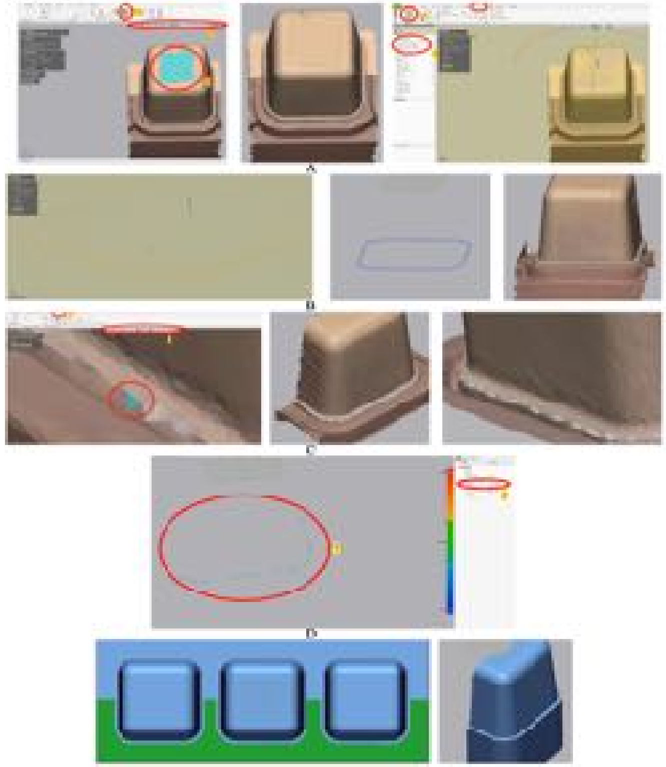


Table 5.2 Contents of test report for Annex F (Part 2. Measurement result)

	Unit: mm	r	t	ΔR_t	ΔR_p
Tested IOS: XXXX					
1	AE				
2	BD				
3	CB				
4	CD				
5	EA				
6	DE				
7	∠ACE				
8	∠CBA				
9	∠CDE				
10	A-EDB				
11	E-ABD				
Tested IOS: xxxx					
1	AE				
2	BD				
3	CB				
4	CD				
5	EA				
6	DE				
7	∠ACE				
8	∠CBA				
9	∠CDE				
10	A-EDB				
11	E-ABD				
Tested IOS:					
	...				
	...				

r : The standard reference value (mm)
m : average value of IOS measured (mm)
p : Standard deviation of IOS measured (mm)
t : Trueness of IOS measured (mm)
$t = m - r$ (mm)
ΔR_t : Relative Error_Trueness %)
$\Delta R_t = \left|\frac{t}{r}\right| \times 100$ (%)
ΔR_p : Relative Error_Precision %)
$\Delta R_p = \left|\frac{p}{r}\right| \times 100$ (%)

Example)

	Unit: mm	r	t	ΔR_t	ΔR_p
Tested IOS: CEREC Omnicam					
1	AE	44.6202	0.2448	0.5486	0.4013
2	BD	36.5568	-1.1948	3.2684	[illegible]
3	CB	17.6303	-1.1417	6.4760	0.1258
4	CD	23.8710	-1.2665	5.3018	0.0184
5	EA	27.6097	-0.0610	0.2211	0.1525
6	DE	27.2177	0.7376	2.7100	0.0869
7	∠ACE	62.4357	1.5445	2.4737	0.0612
8	∠CBA	124.1056	0.6981	0.5625	0.3873
9	∠CDE	125.4121	-0.6598	0.5261	0.0368

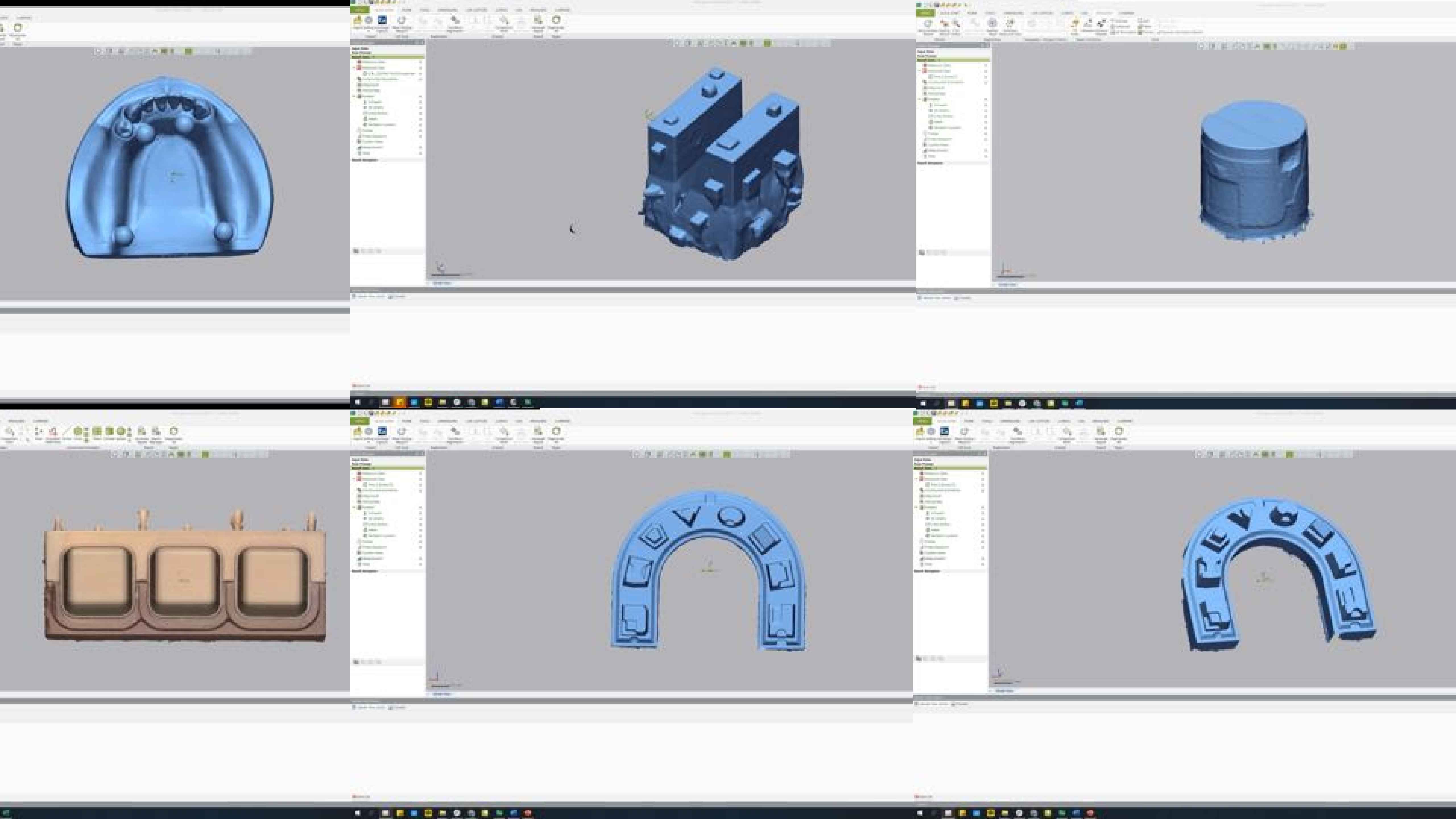
Delivery of test objects (Feb-Mar 2023)

Delivery of test objects (Feb-Mar 2023)

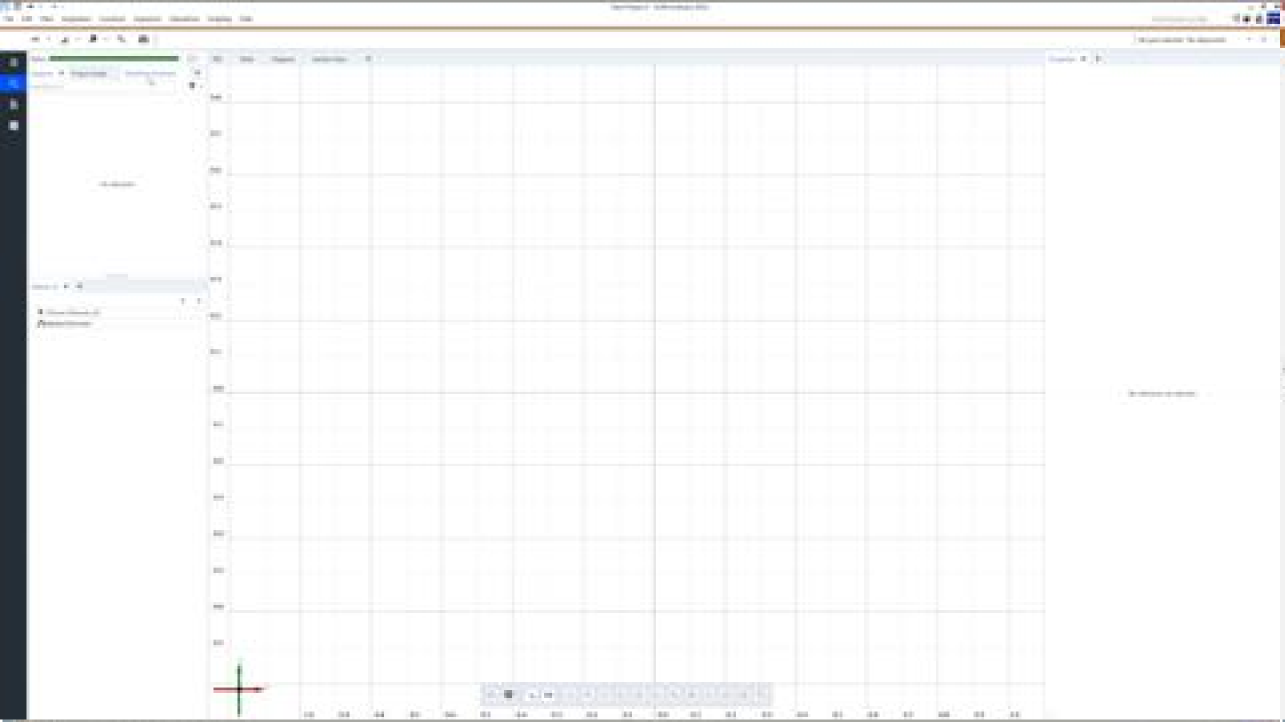
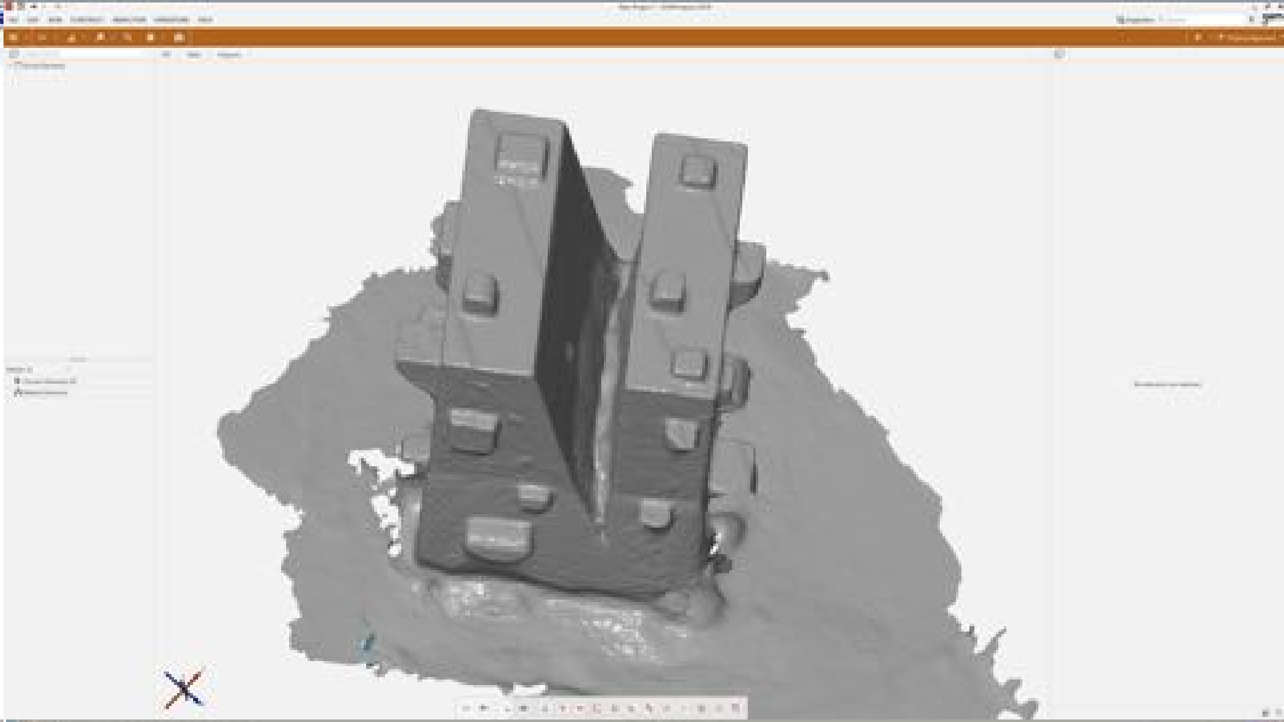
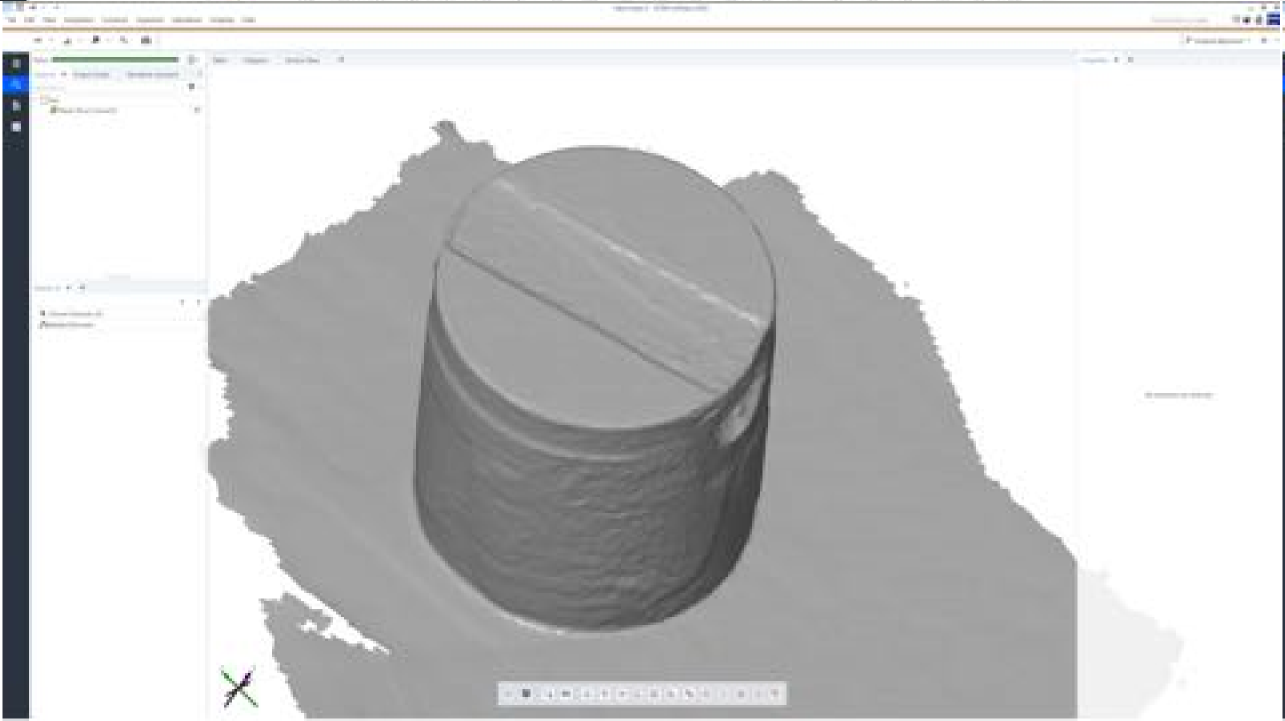
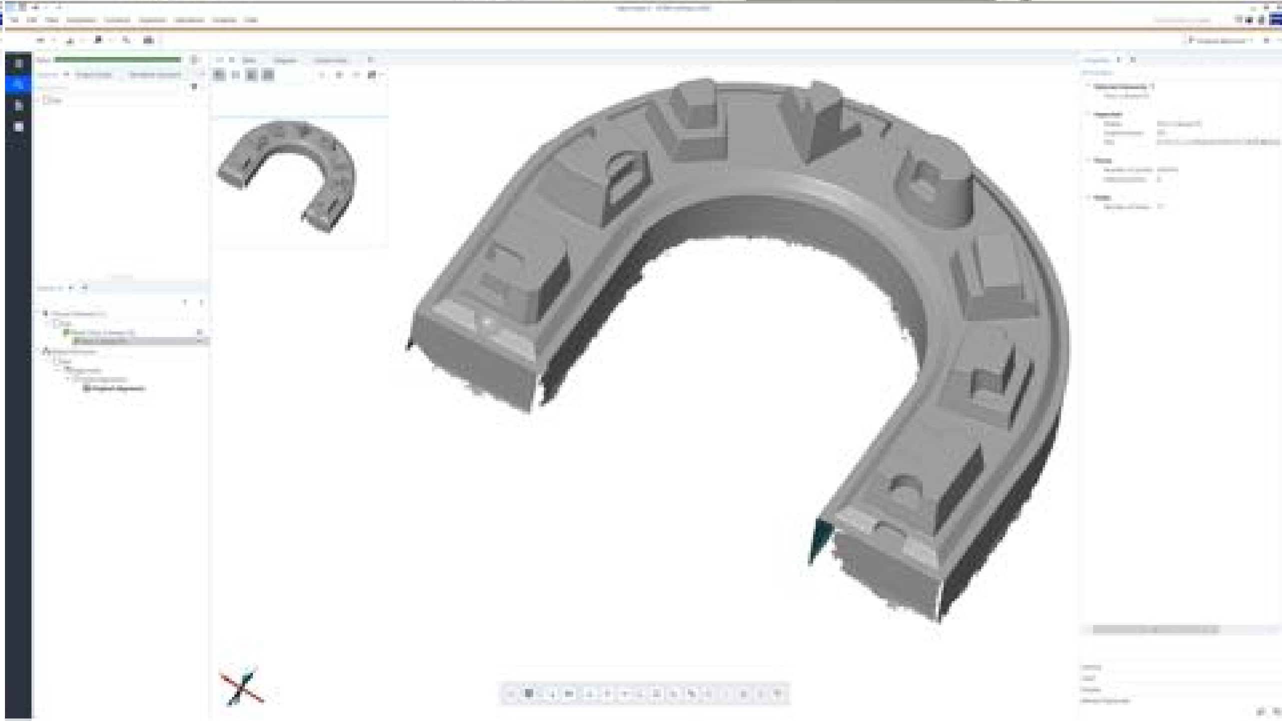
Hands-on videos for scanning

Hands-on videos for measurement

(Geomagic Control X)

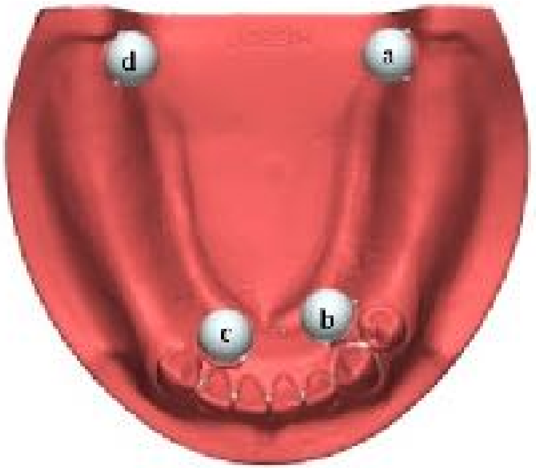


Hands-on videos for measurement
(Gom Inspect)

Annex B (Long edentulous ridge)

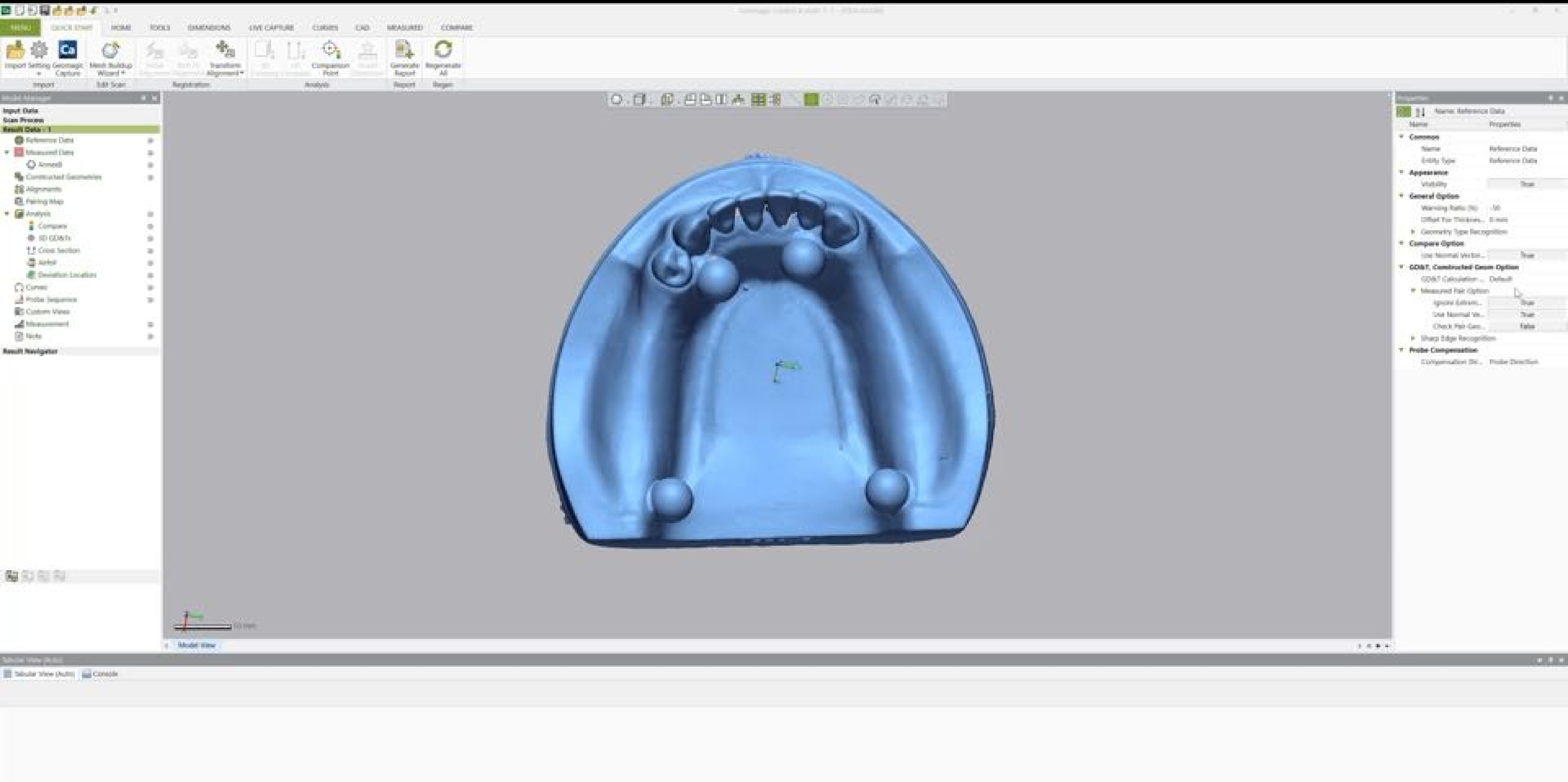
Measurement



Measurement software
: Geomagic Control X or GOM Inspect

Four measurement points (a, b, c, d)
: reverse engineered at sphere centers

1		distance from a to b
2		distance from b to c
3		distance from c to d
4		distance from d to a
5		distance from a to c
6		distance from b to d
7	a to	distance between point a and a plane defined by the three points b, c, and d
8	d to	distance between point d and a plane defined by the three points a, b, and c



How-to-measure Video (Annex B)

Comments from Participants

Comments

1. Sphere Geometry Issues: Data Excludes Problematic Areas at Sphere Bottom (UK)

   : Complete Sphere Scanning with each Scanner’s Full Functionality

2. Scanning Issues with Primescan: Difficulty Scanning Test Object (Japan)

   : Primescan’s Robust AI Requires Complete Data for Scanning

   : For Better Recognition, Scan Along Buccal Side of Alveolar Ridge (Canine to Molar Area)

3. Color & Recognition Issues with Primescan: Dark Color Causes Scanning Issues (Japan)

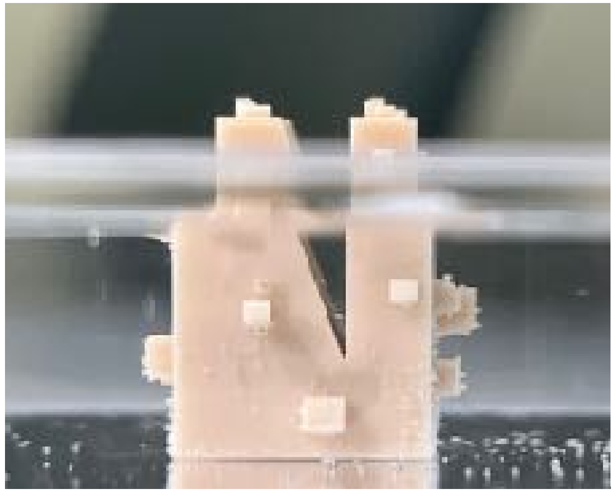
   : Scan Initiated when a Skin-colored Object (Finger) was Included

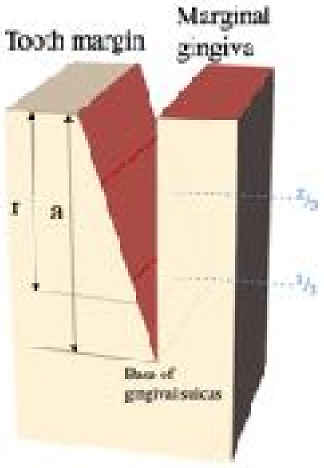
   : Scan Continued even After Removing Finger

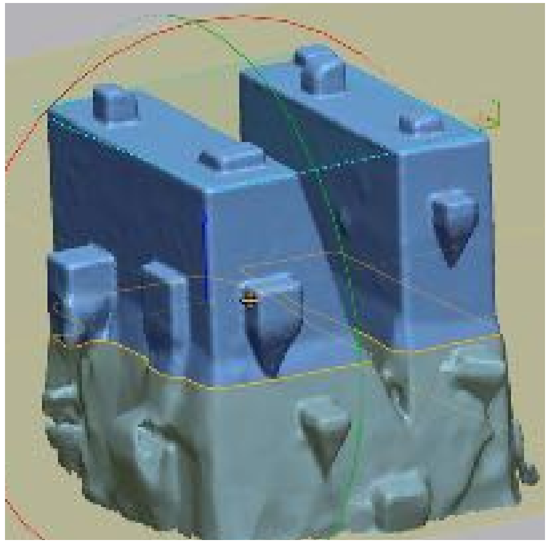
   : Primescan's performance issues, Not solely due to Color, But also its Strong AI algorithms in Edentulous Areas

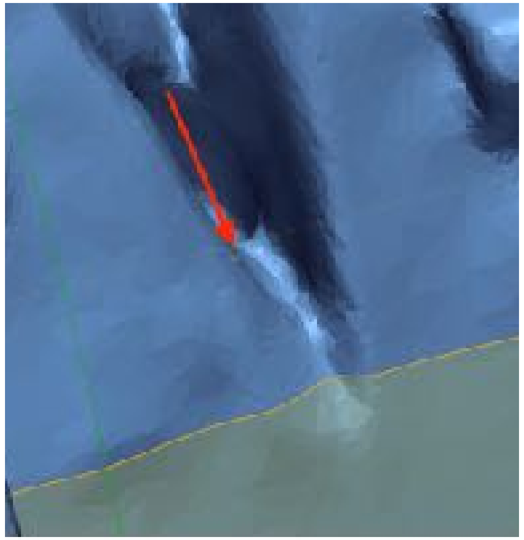
Annex C (Margin with sulcular fluid)

Measurement





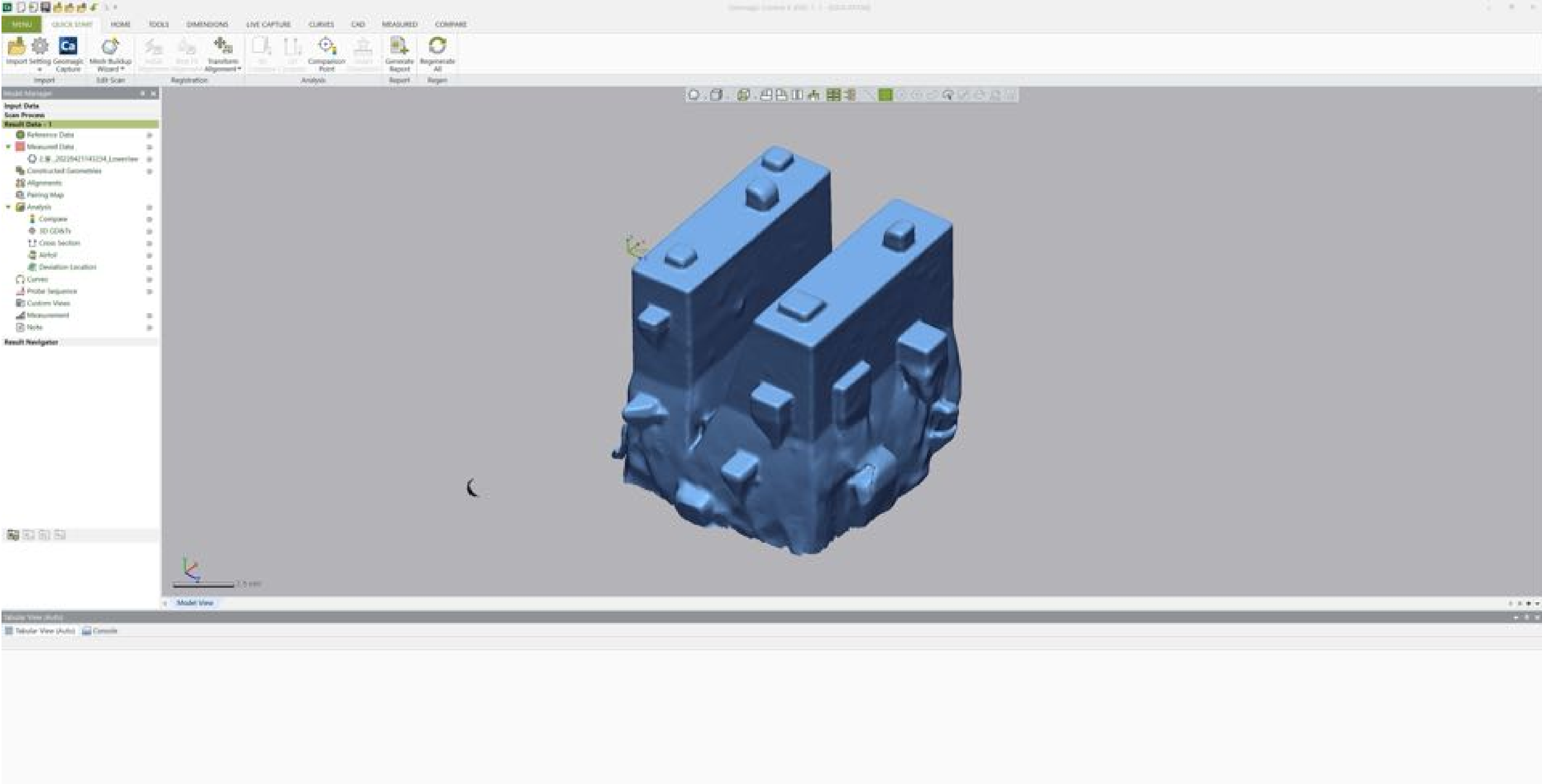




Measuring Liquid Distortion:
1. SW: Geomagic Control X or GOM Inspect
2. Determine depth from top to deepest sulcus.
3. Create section lines from top plane in scan data.
4. Gradually lower section plane, until the lowest point (red arrow)
5. Measure shortest distance from point to top plane.

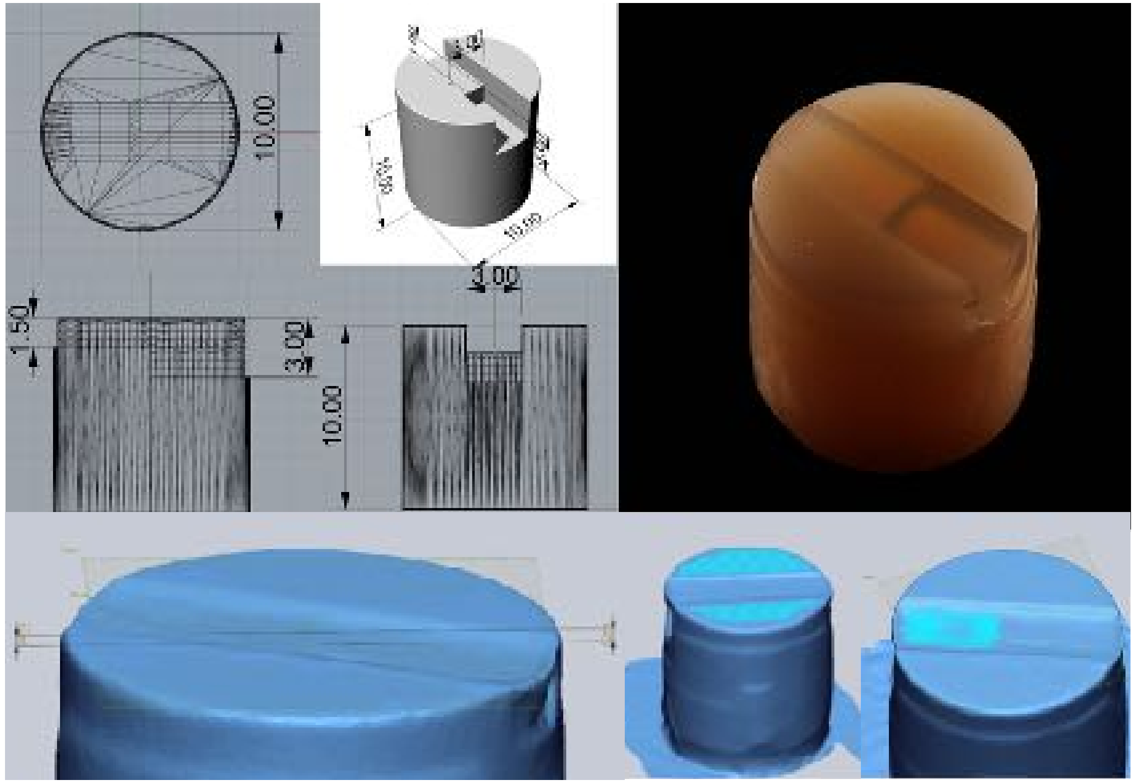
Key measurement items

1	Arid	distance between the deepest point and top plane without artificial saliva
2	Wet 1/3	distance between the deepest point and top plane when 1/3 submerged in artificial saliva
3	Wet 2/3	distance between the deepest point and top plane when 2/3 submerged in artificial saliva



How-to-measure Video (Annex C)

Annex D (Translucency)



Distortion Measurement Method:

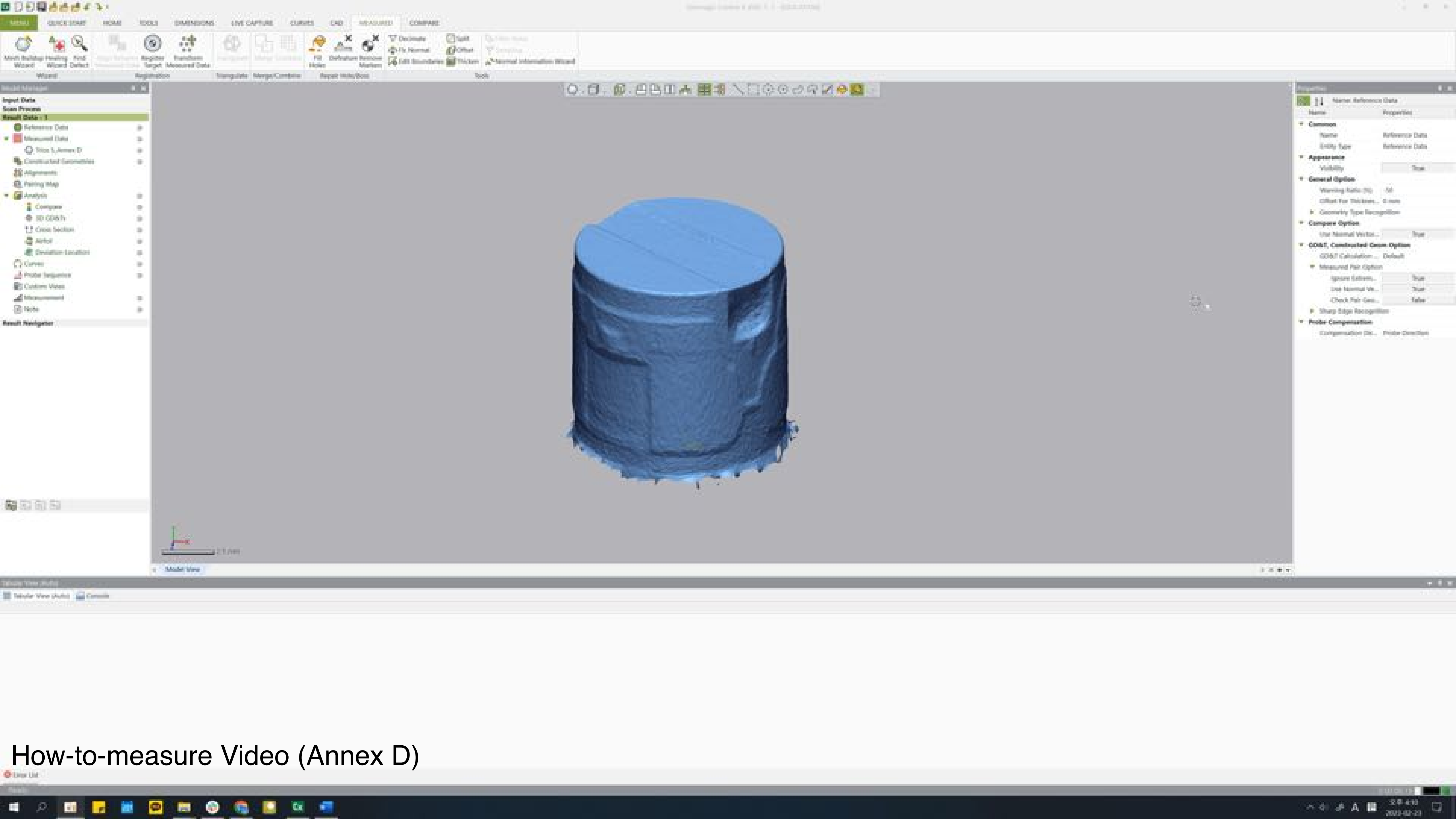
- SW: Geomagic Control X or GOM Inspect
- Measure distortion of two conditions (h1, h2)
- Simulate difference between IOS scan data and actual surface position

Translucent Tooth Surface Measurement Process:

- Select mesh on top face of translucent layer.
- Create reverse-engineered dentin surface plane.
- Form body part surface with 1.5 mm deep translucent resin.
- Measure distance between created planes to calculate height difference between simulated enamel-dentin and dentin-only part.
- Repeat process for incisal part with 3 mm deep translucent resin

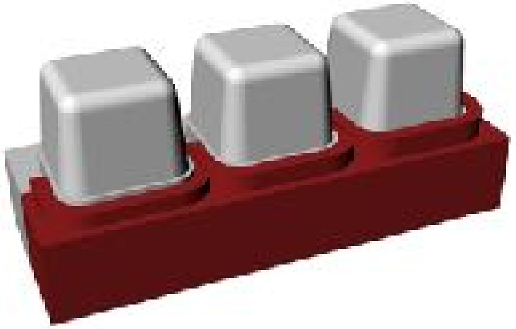
Key measurement items

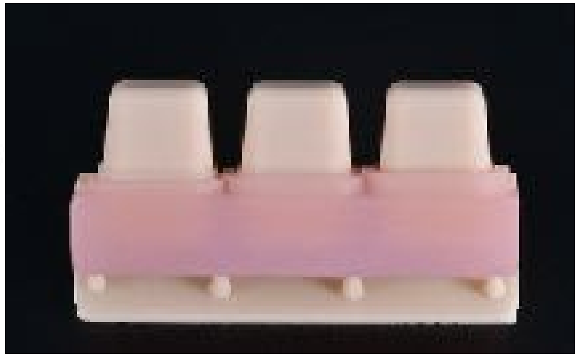
1	h1	Displacement at body part (dentin/ enamel): 1.5 mm deep translucent resin on the upper step
2	h2	Displacement at incisal part (enamel): 3 mm deep translucent resin on the lower step



How-to-measure Video (Annex D)

Annex E (Margin line)

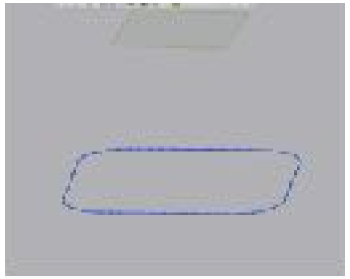




- SW: Geomagic Control X or GOM Inspect

Key measurement items

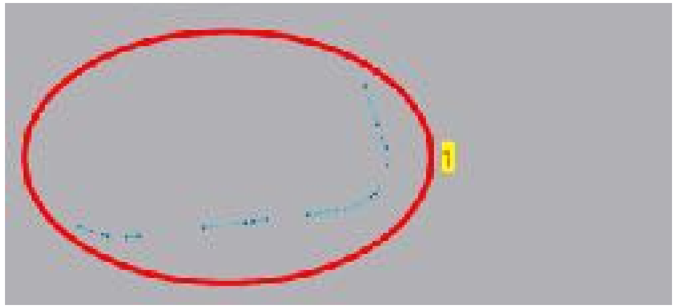
1	m_{su}	Sum of clearly discernable margin line length at supra-gingival margin tooth
2	m_{eq}	Sum of clearly discernable margin line length at equi-gingival margin tooth
3	m_{sb}	Sum of clearly discernable margin line length at sub-gingival margin tooth



Create line at margin level

Delete polygon if margin line encroaches certain portion

Keep polygon if margin line & polygon outer edge line overlaps



Measure total length of kept margin with remaining poly-gons

How-to-measure Video (Annex E)

Comments from Participants

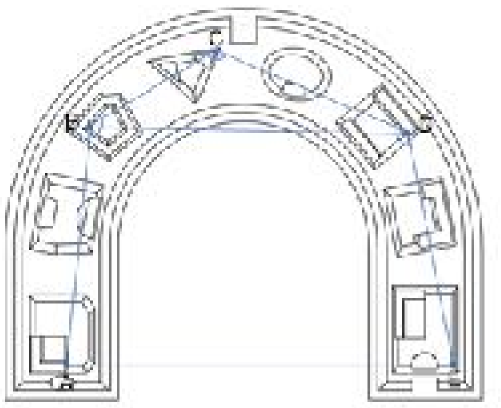
Comments (HongKong U)

1. Subjective Judgement in Measuring 'Sharp and Identifiable Margins' Causes Inconsistency

→ Developing Automation Software with Clear Margin Criteria

Fig. 37 Measurement of the total length of sharp and identifiable margins by evaluation of polygons forming the margin line in the 3D model. In the above example, the portion of the margins in red circle was left because it could be clearly distinguished by the edge of the polygon, while the portion of the margins in yellow circle was deleted because it appeared as a polygon face. The distinguishment between these two involved subjective judgements and was disputable.

Annex F (Arch distortion)

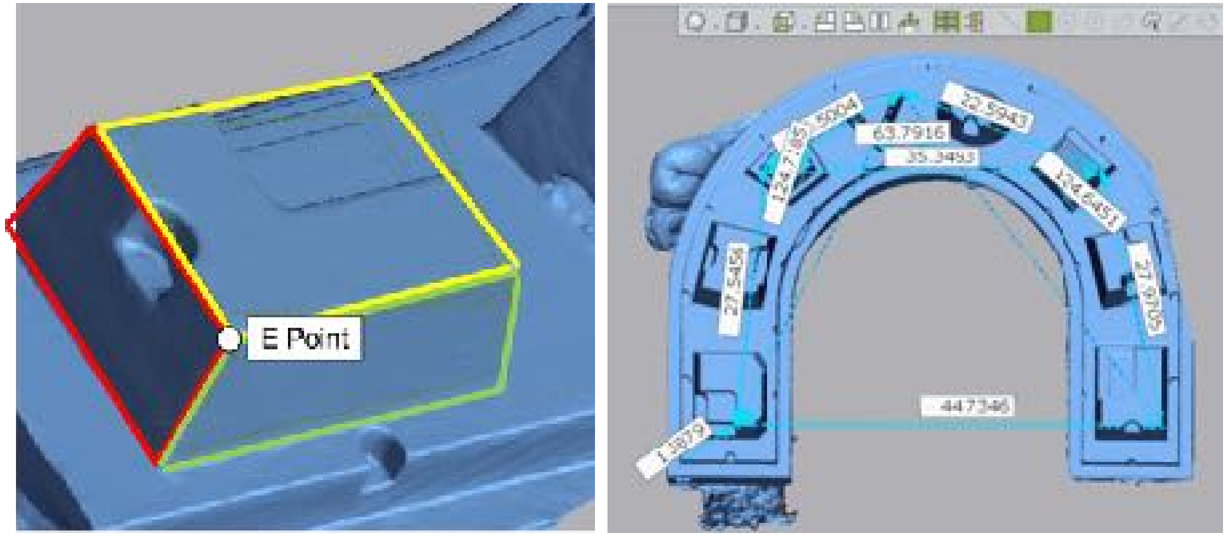


Measurement

The amount of distortion shall be measured using industrial 3D analysis software, such as Geomagic Control X. Five measurement points (A, B, C, D, and E) shall be created. The following are the measurement items;

Horizontal	**Angular**	
posterior inter-block width	∠ACE	total arch convergence angle
anterior inter-block width	∠CBA	Lt. anterior convergence angle
Lt. anterior circumferential length	∠CDE	Rt. anterior convergence angle
Rt. anterior circumferential length	**Distortion**	
Lt. posterior circumferential length	A-	Lt. vertical distortion
Rt. posterior circumferential length	E-	Rt. vertical distortion

Annex F (Arch distortion)

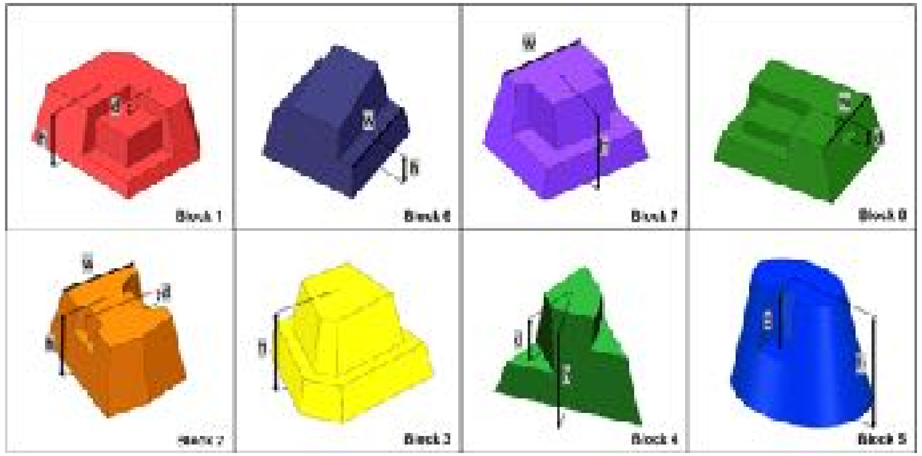


Five points of test object are reverse-engineered by intersecting planes that make up the corners.
Examples of distances and angulations that need to be measured.

Method

Three planes forming the corners corresponding to points shall be obtained by reverse-engineering and intersecting the three planes to set the measurement points. The perpendicular distance of the posterior reference points at either side from the plane shall be defined by the rest of the three reference points.

Annex G (Inlay, onlay, and crown preparation)

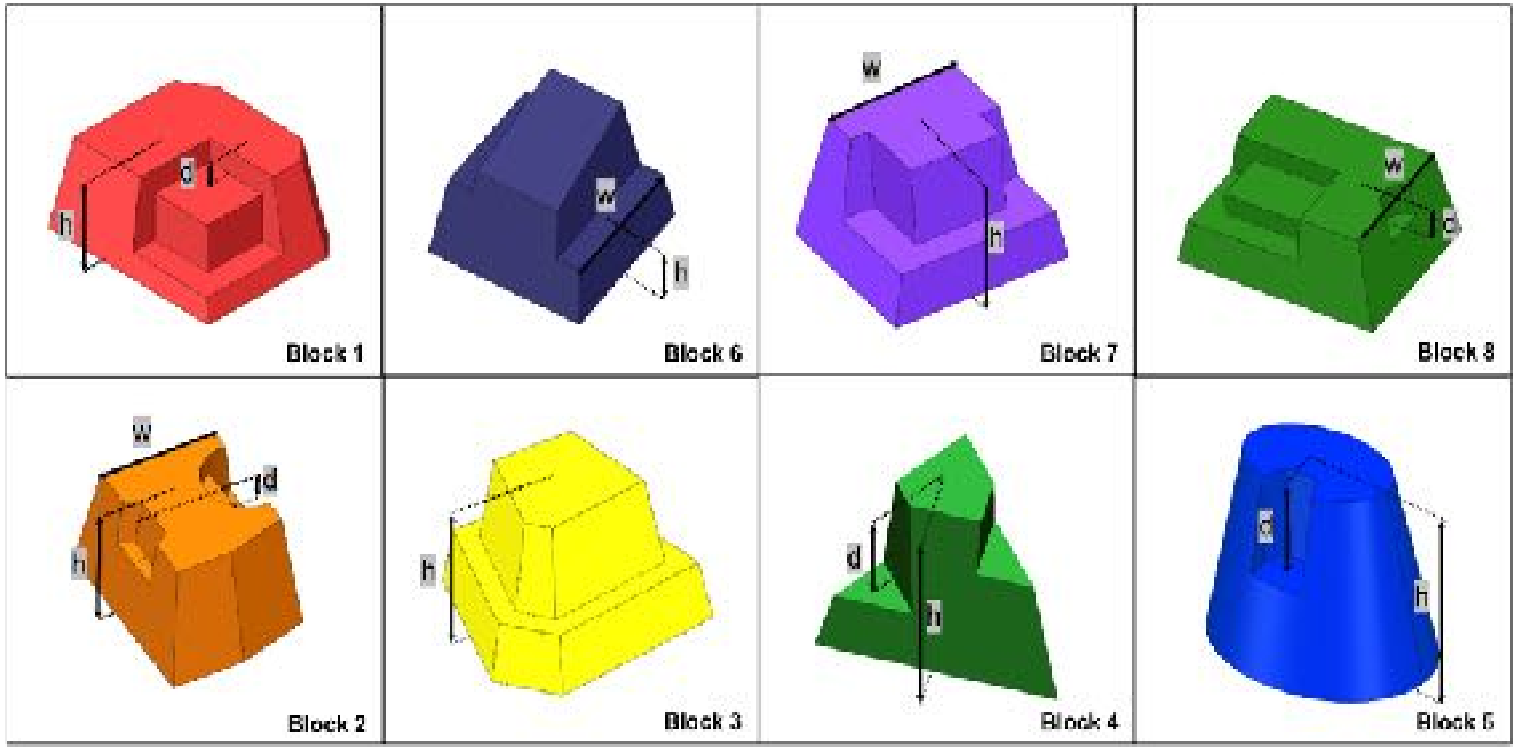


Measurement

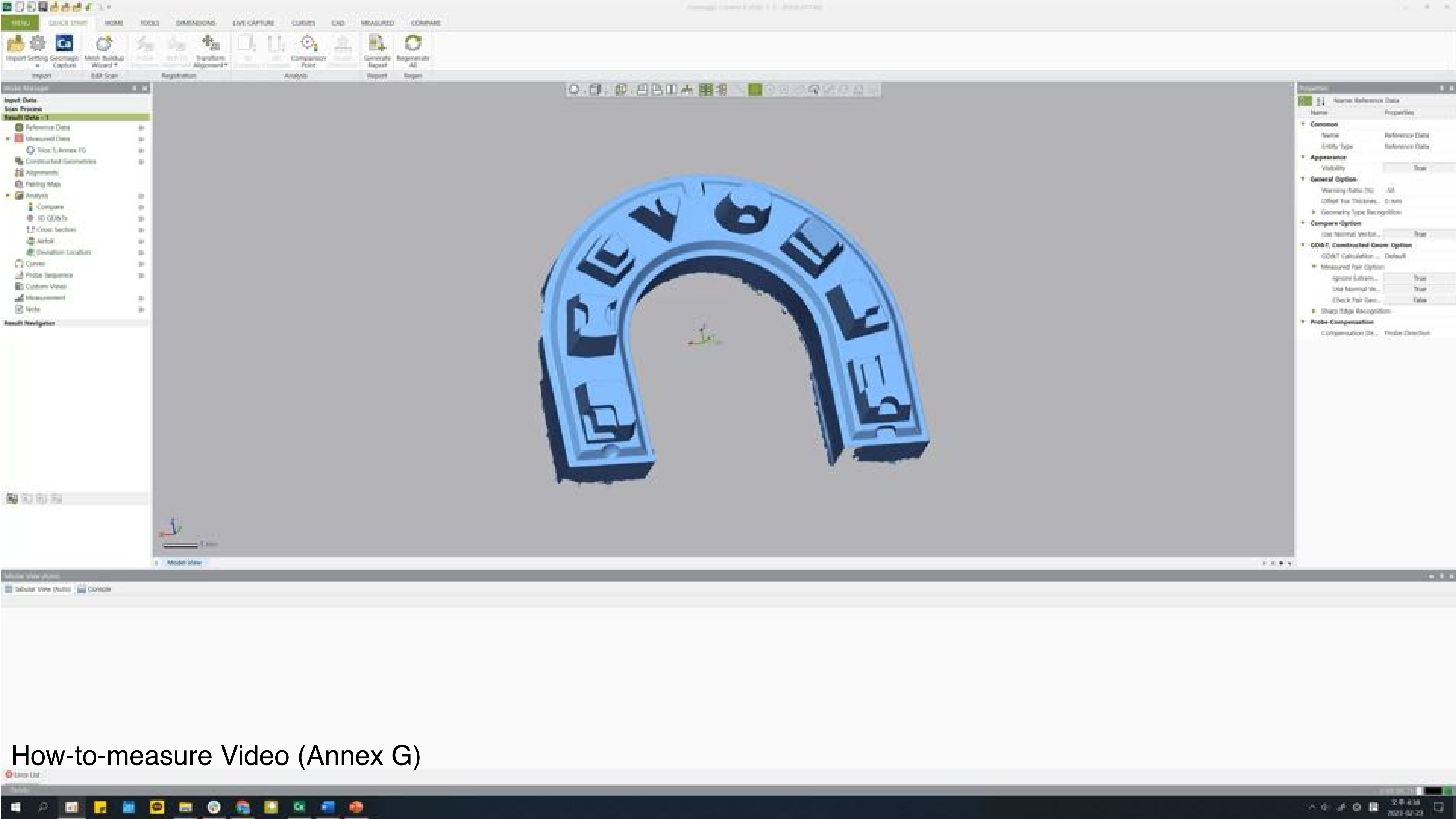
The amount of distortion is measured using industrial 3D analysis software, such as Geomagic Control X. The following are the measurement items;

Inlay		Crown	
h1	height of block 1	**h2**	height of block 2
d1	onlay floor depth of block 1	**w2**	buccolingual width of block 2
w6	mesiodistal width of block 6	**d2**	lingual inlay base depth of block 2
h6	buccal base height of block 6	**h3**	height of block 3
h7	height of block 7	**h4**	height of block 4
w7	mesiodistal width of block 7	**d4**	recess depth of block 4
w8	buccolingual width of block 8	**h5**	height of block 5
d8	distal groove depth of block 8	**d5**	groove depth of block 5

Annex G (Inlay, onlay, and crown preparation)



Method
For height, measure the height of the plane at the base of the test object and the top plane of each block. For depth, measure the depth from each block's top plane to the other planes of the block. For width, measure each block's mesiodistal width or buccal lingual width.



How-to-measure Video (Annex G)

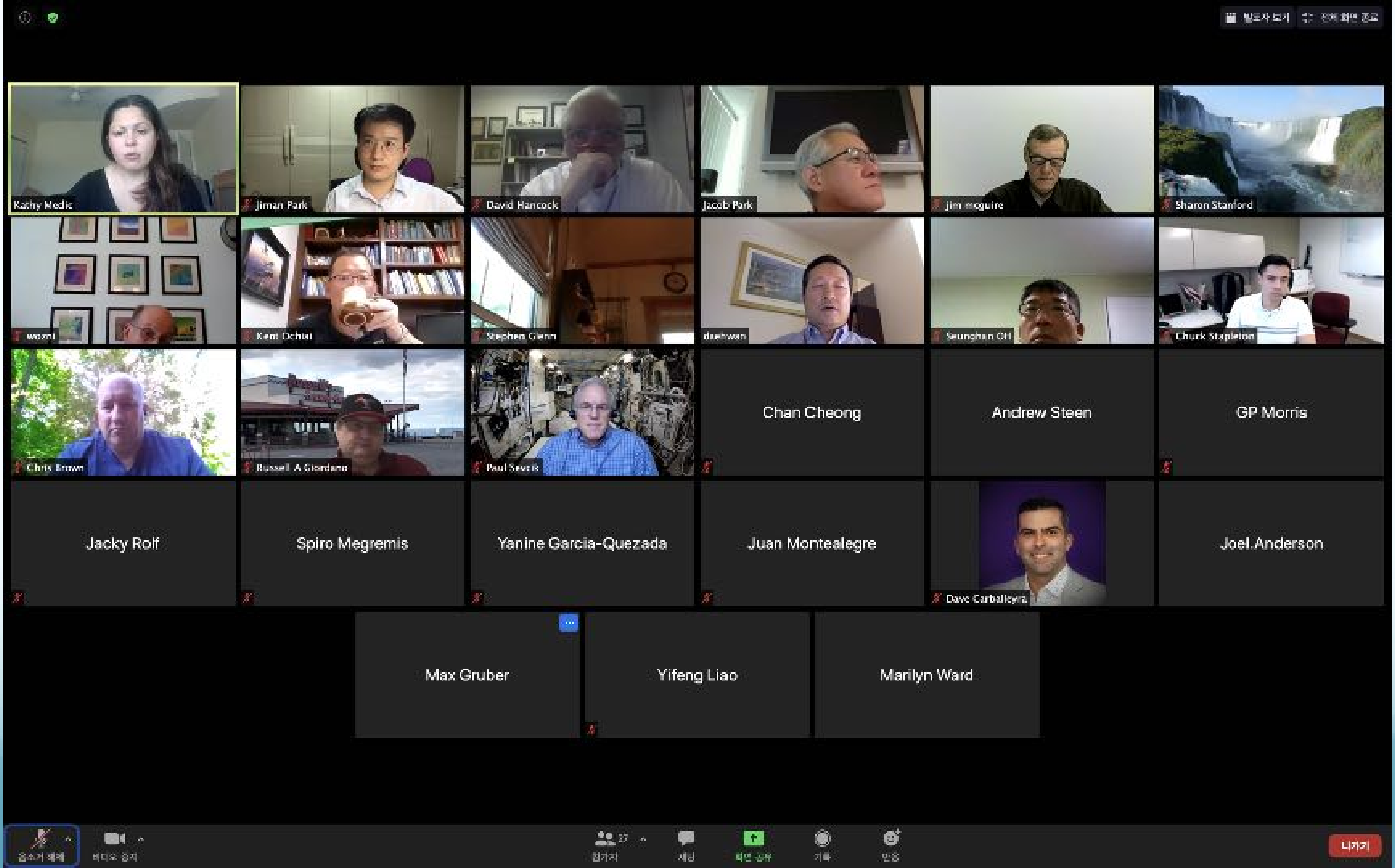
Working group 7

Additive manufacturing

ISO TC 106 SC9/WG7
Virtual meeting 2020

Daehwan Shin, Ph.D.
Ji-Man Park, Ph.D.

ISO - DTR 5015
Dentistry – Accuracy of CAD/CAM 3D printed dental products


Kathy Medic
Jiman Park
David Hancock
Jacob Park
jim mcguire
Sharon Stanford
Stephen Glenn
daehwan
Seunghan OH
Chuck Stapleton
Chris Brown
Russell A Giordano
Chan Cheong
Andrew Steen
GP Morris
Jacky Rolf
Spiro Megremis
Yanine Garcia-Quezada
Juan Montealegre
Dave Carballeyra
Joel.Anderson
Max Gruber
Yifeng Liao
Marilyn Ward


Numerous dental 3D printers are introduced




Dental 3D printing materials are also competitively introduced.

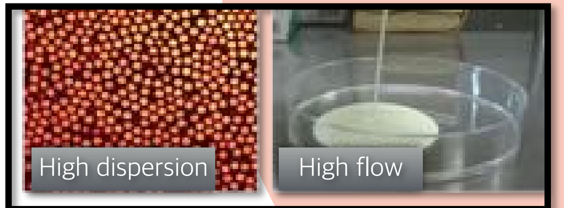

Polyjet
Stratasys
Temporary restoration
Model
Orthodontic appliance
Objet Eden260VS
Objet30 OrthoDesk
Objet Eden500V for Dental
Best speed and throughput for large labs
WDM
Stratasys
Metal coping Wax
FrameWorx
CrownWorx
Highest precision crown and bridge wax-ups
SLA
Metal coping Wax
Orthodontic appliance
DLP
envisionTEC
Temporary restoration
Metal coping Wax
Model
Orthodontic appliance
Surgical template
PBF
Metal coping
CONCEPTLASER
eos

Importance of co-work between Material & Device parts

Material

Device

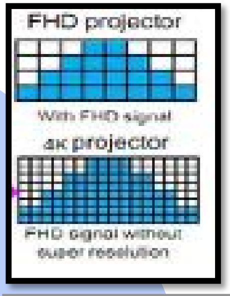
Refinement of filler particle size, dispersion of particles

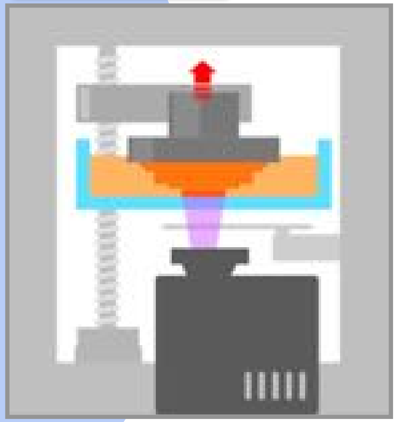


Dispersion state
Particle size

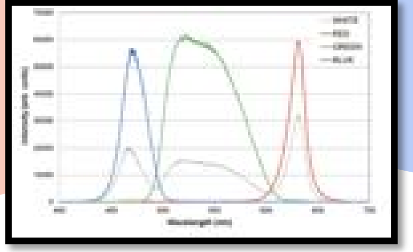
Reflection rate
Wavelength
Curing time
Viscosity
Light source power

Pixel size
Axis movement



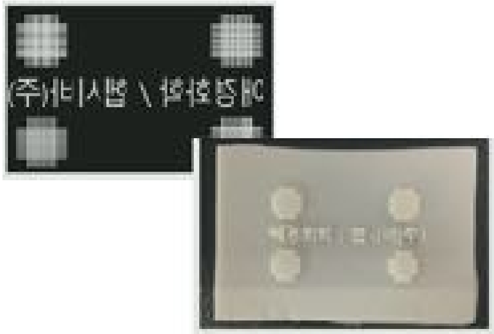
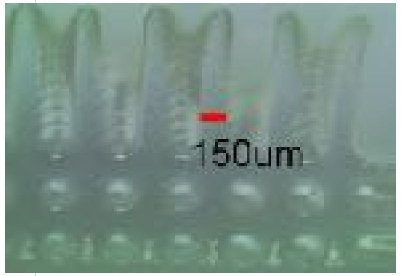


Maximizing light sensitivity
Development of high dispersion material technology
Increase of interlayer bonding power



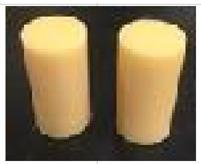
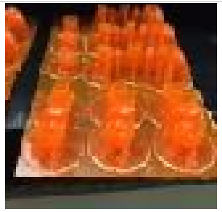
light source spectrum analysis
Optimal wavelength selection
Speed up material supply
Securing large area uniformity through pixel stitching

Physical property measurement of printed products according to printing conditions

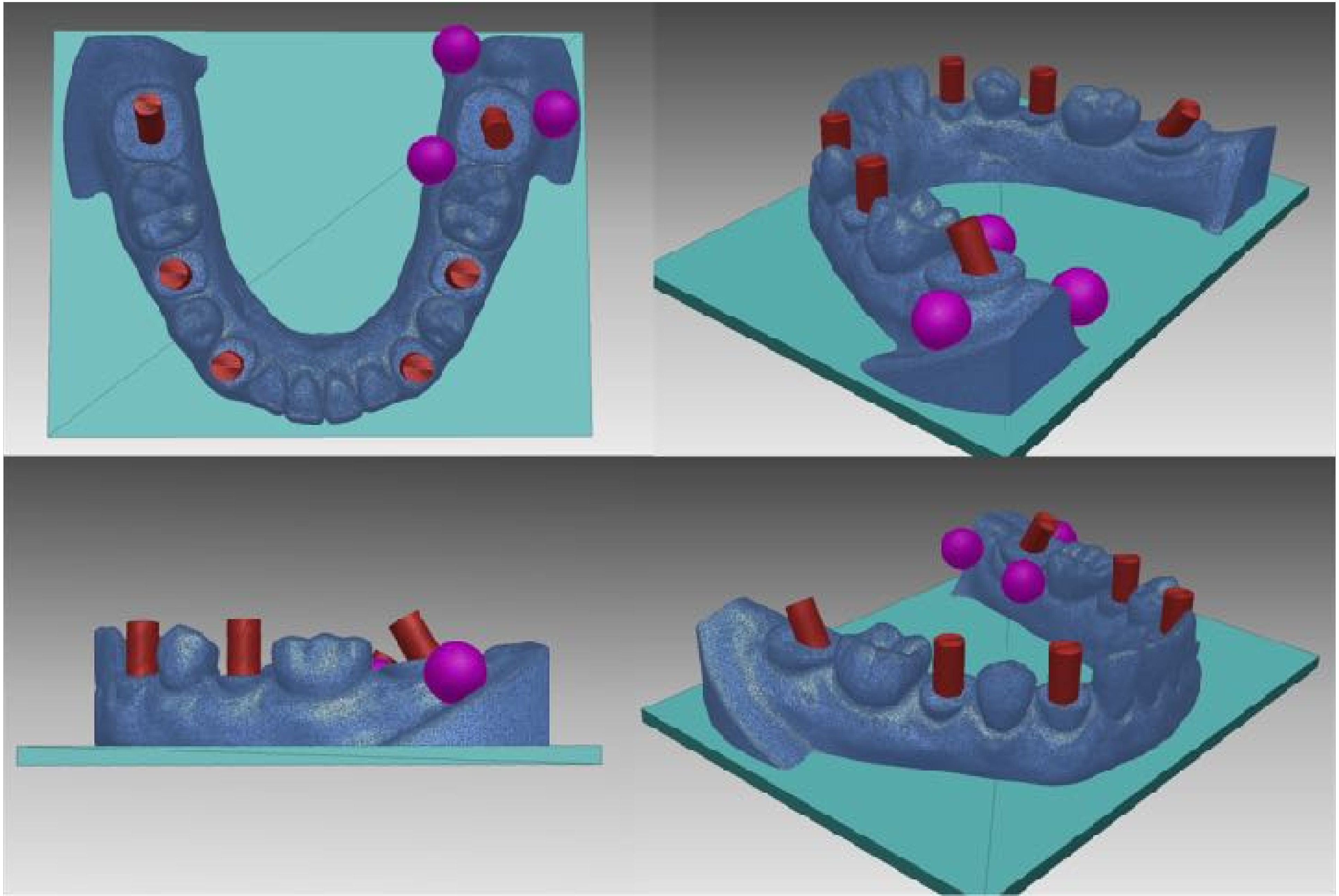
Verification drawing for printing condition	Microscopic image
	
[Printing condition] Line width : 50,100,150,170 um Layer Thickness : 50,100um Expose time : 4~10sec UV Power : 10~60	Confirm printing condition by line width discrimination performance

-Printing grid patterns of various line widths

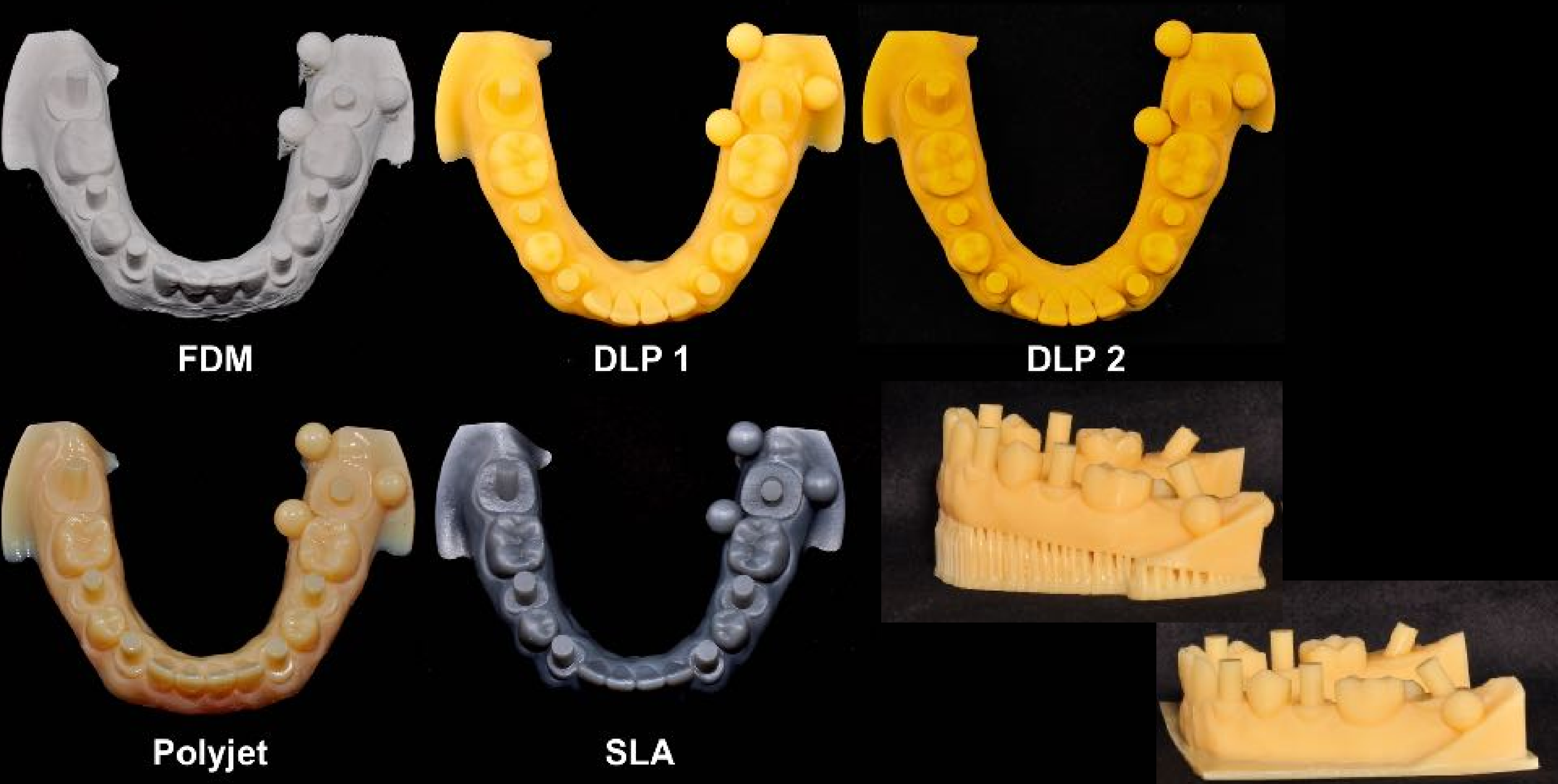
-Check the expose time that shows optimal line width

Standard specimen specification			
			
Vickers ha spe 15 X 15 (ISO		al strength ent specimen X 80 mm O 178)	Casting patter (ISO 15854)

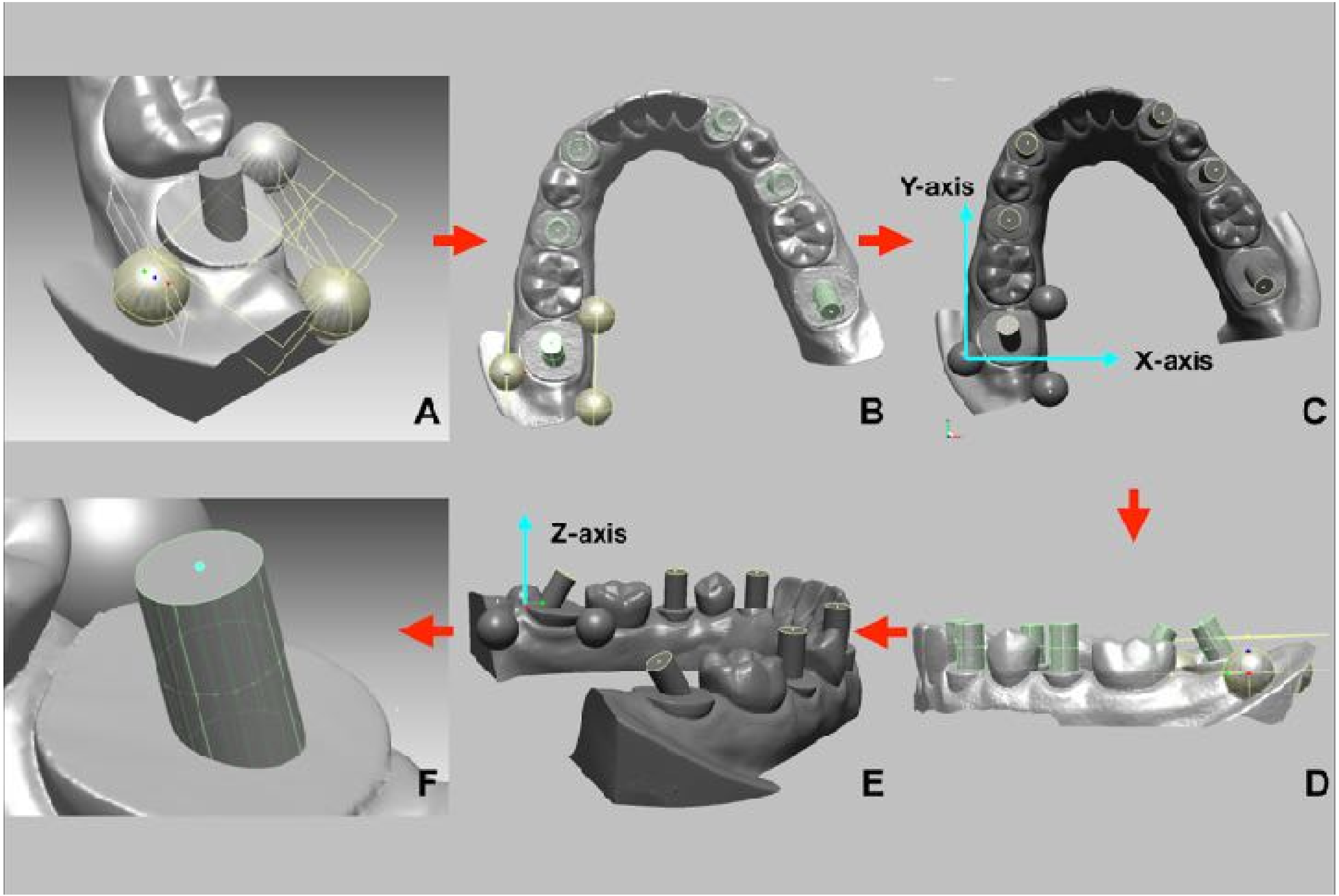
Design of reference data



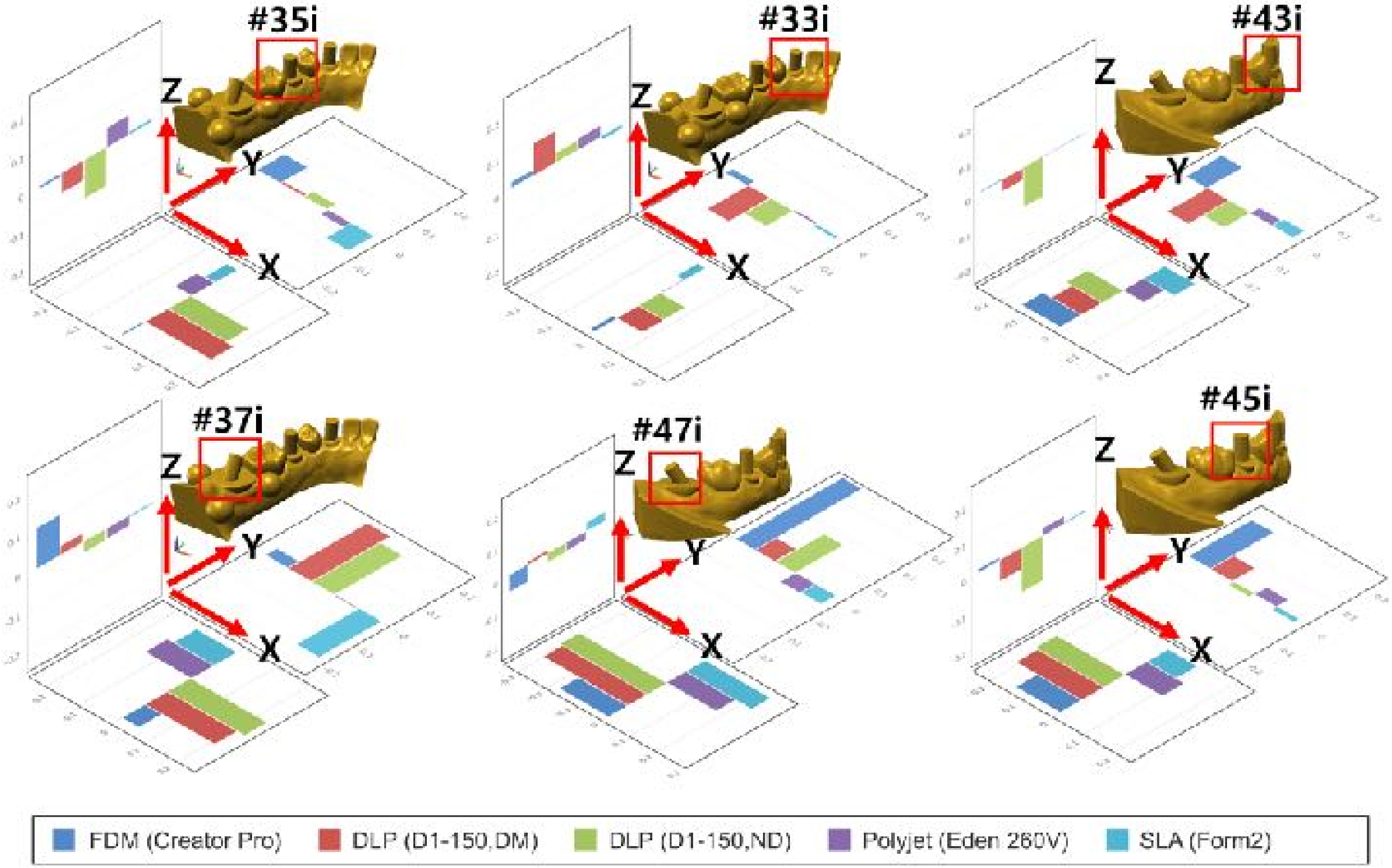
3D printed models



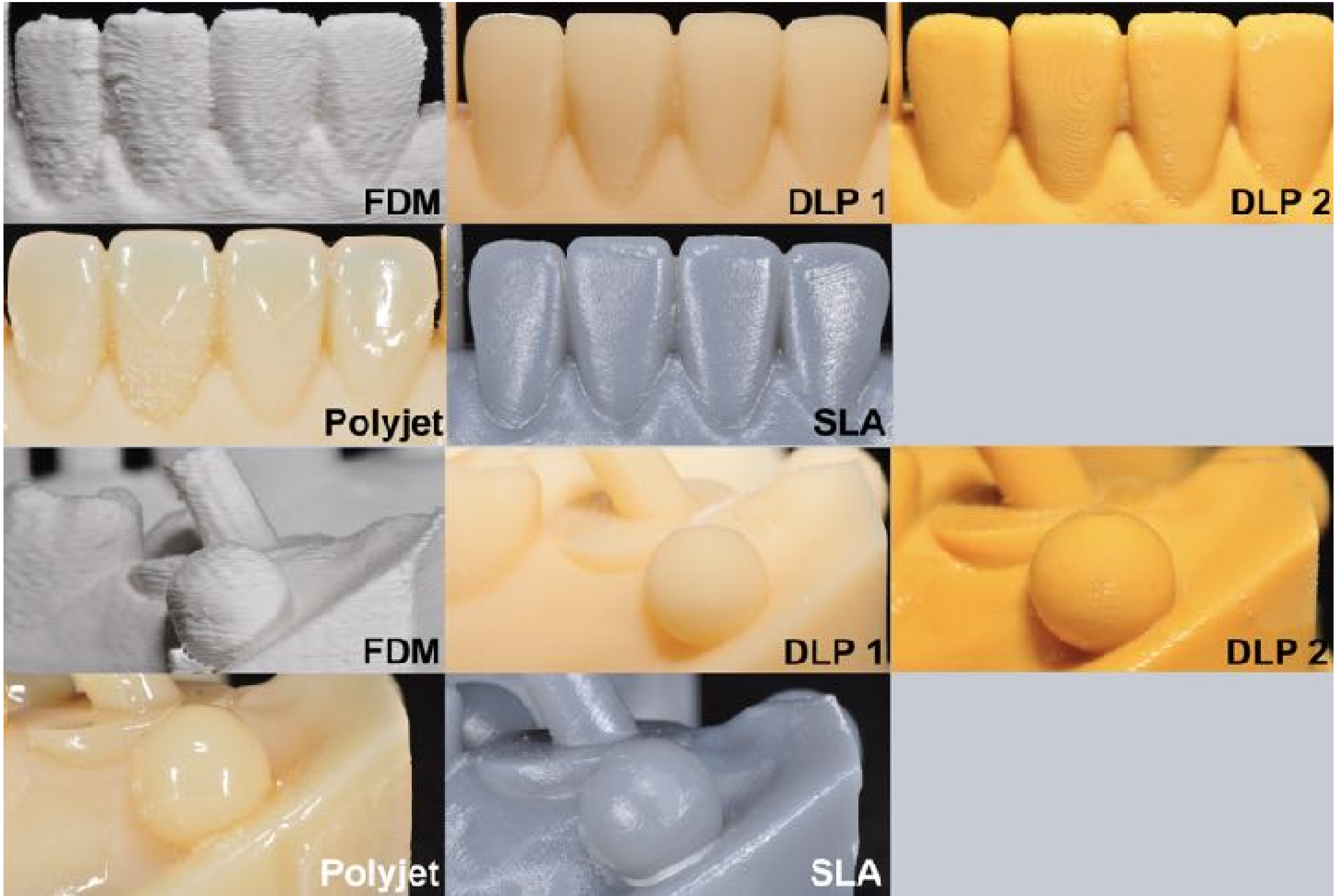
Measurement protocol



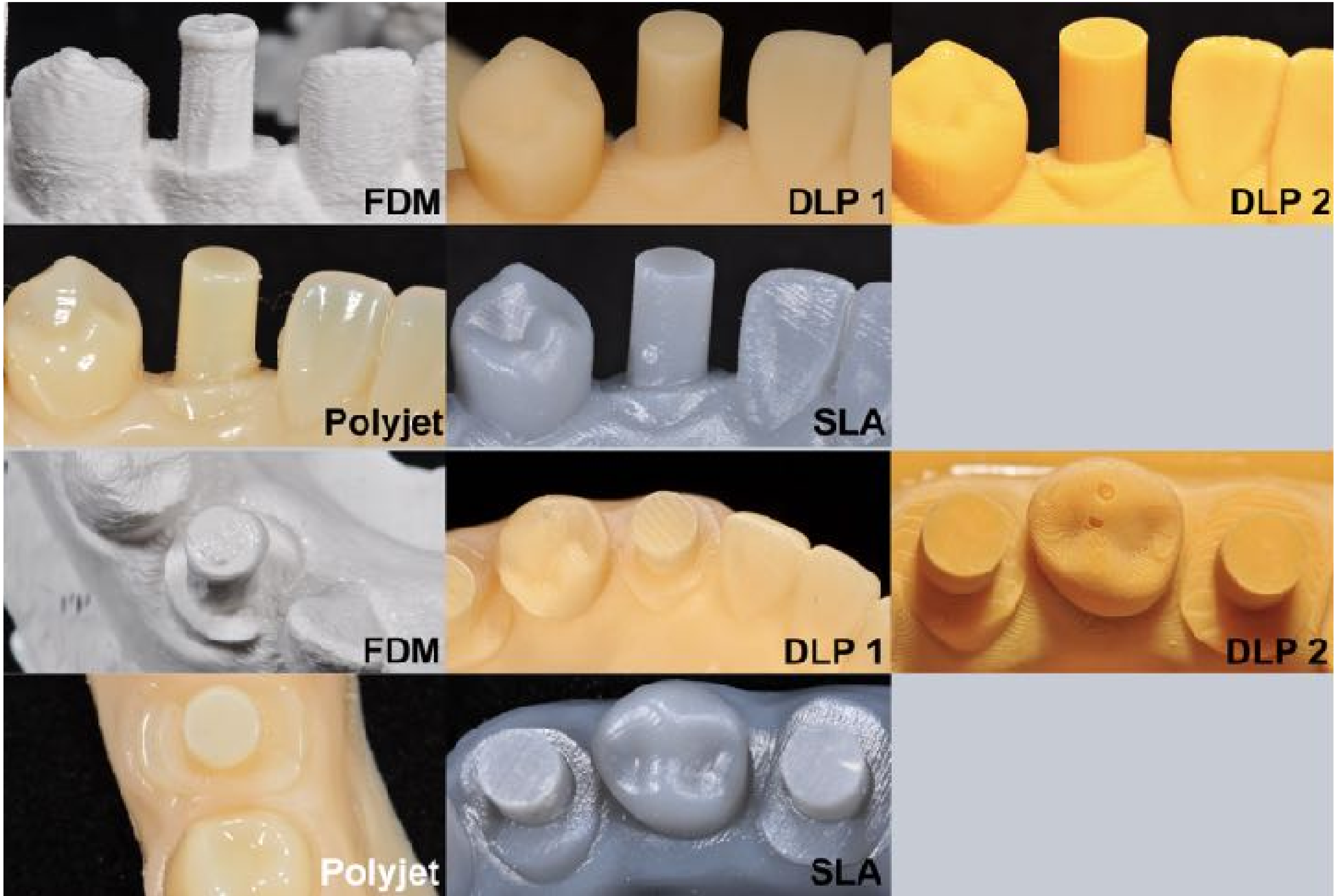
Result of coordinate study



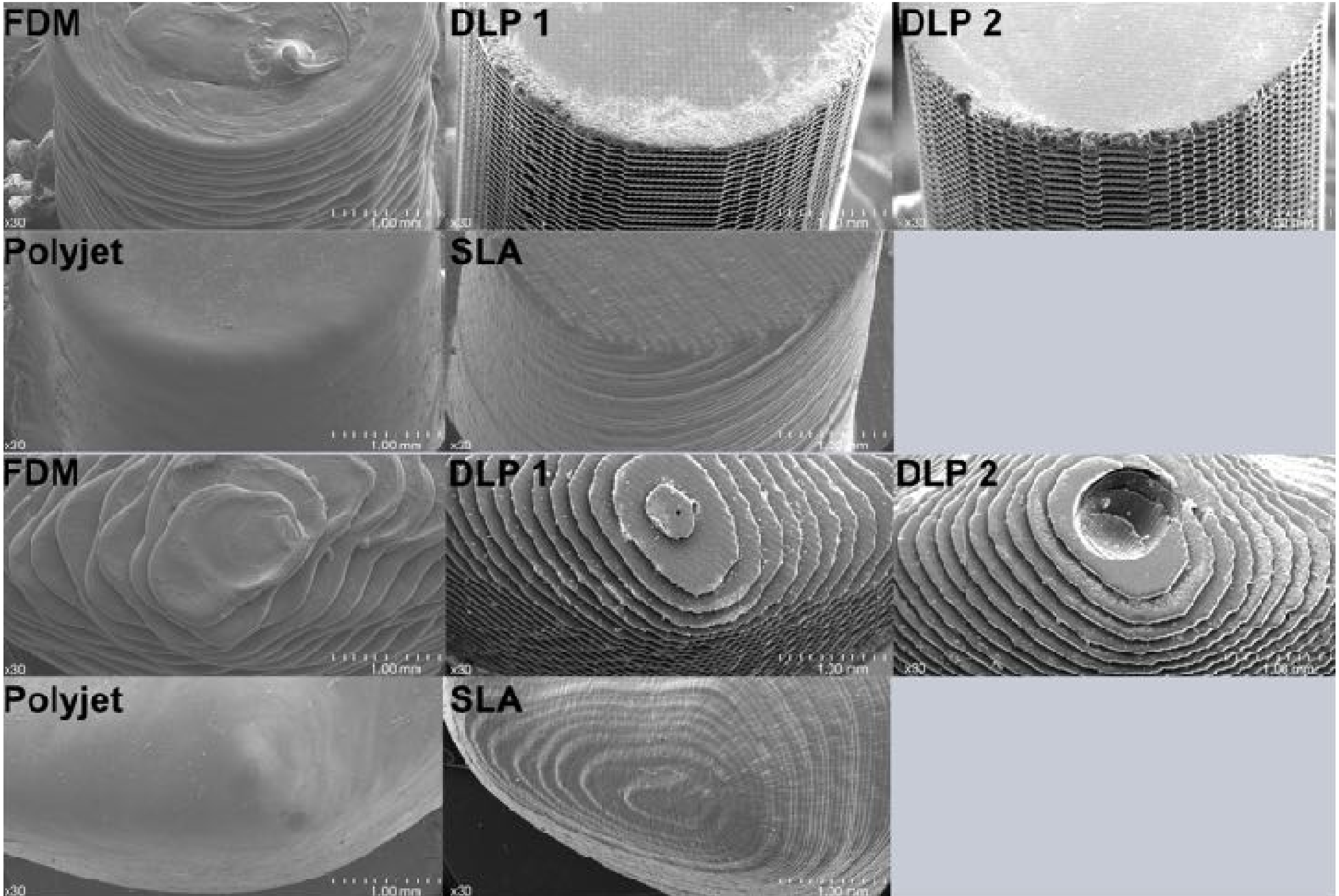
Surface texture of 3D printed models



Surface texture of 3D printed models

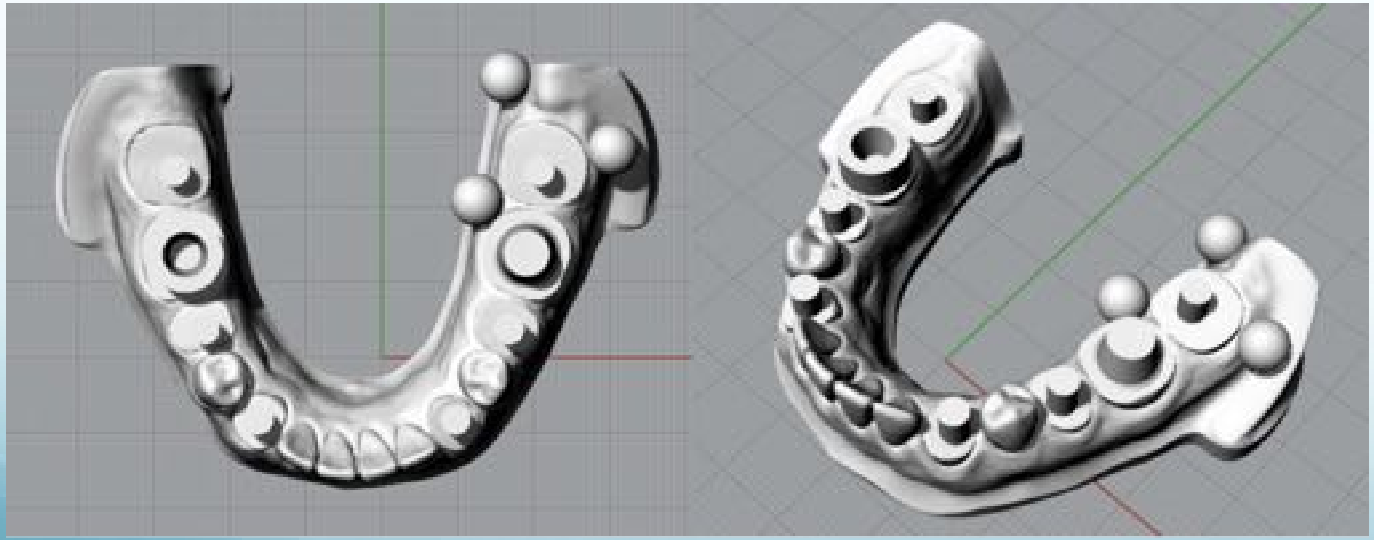


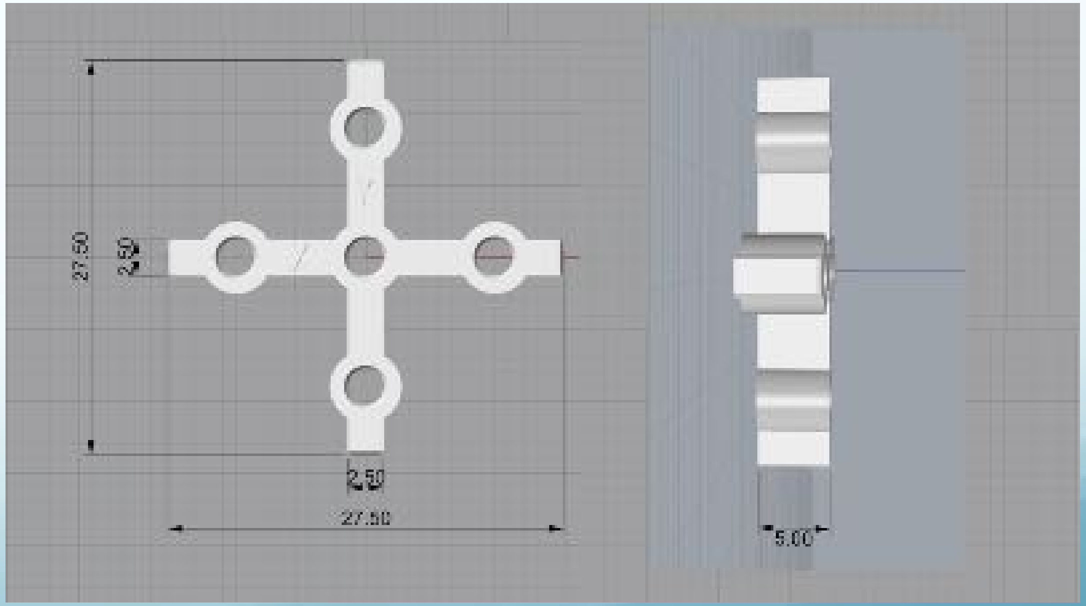
SEM comparison of 3D printed models



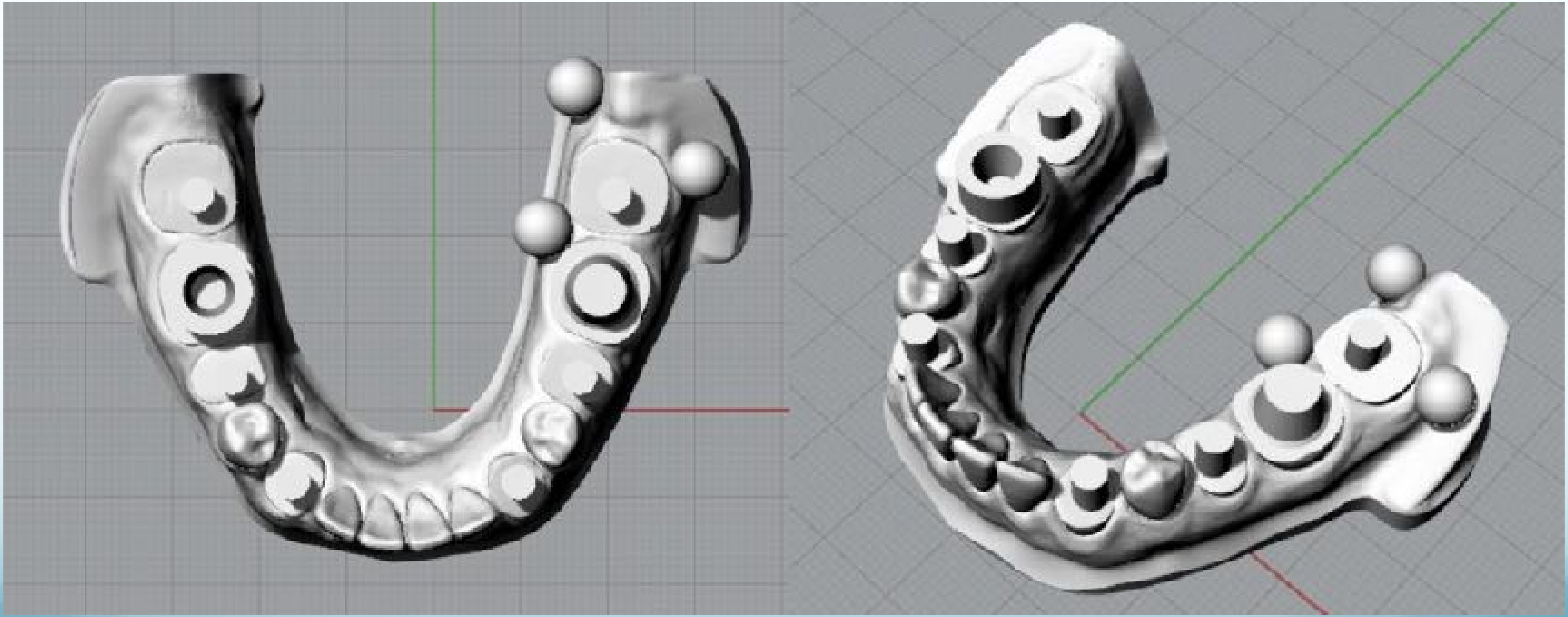
Test Objects

- Test object one: All-in-one specimen (crown/inlay/long distance evaluation)
- Test object two: Cross model with drill sleeves

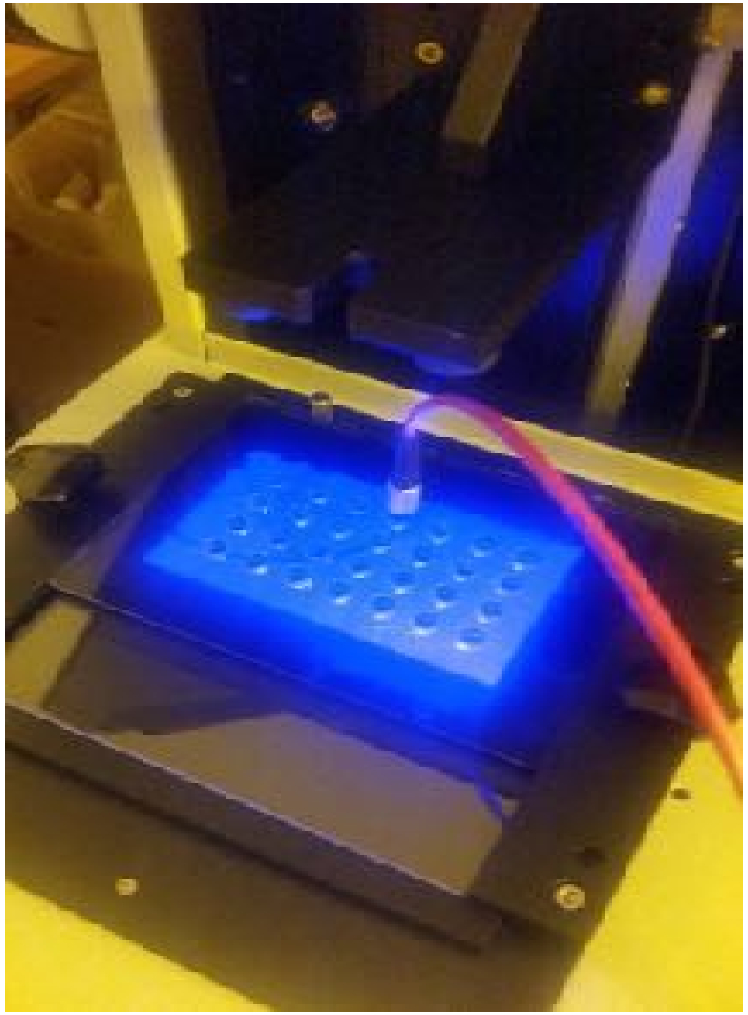


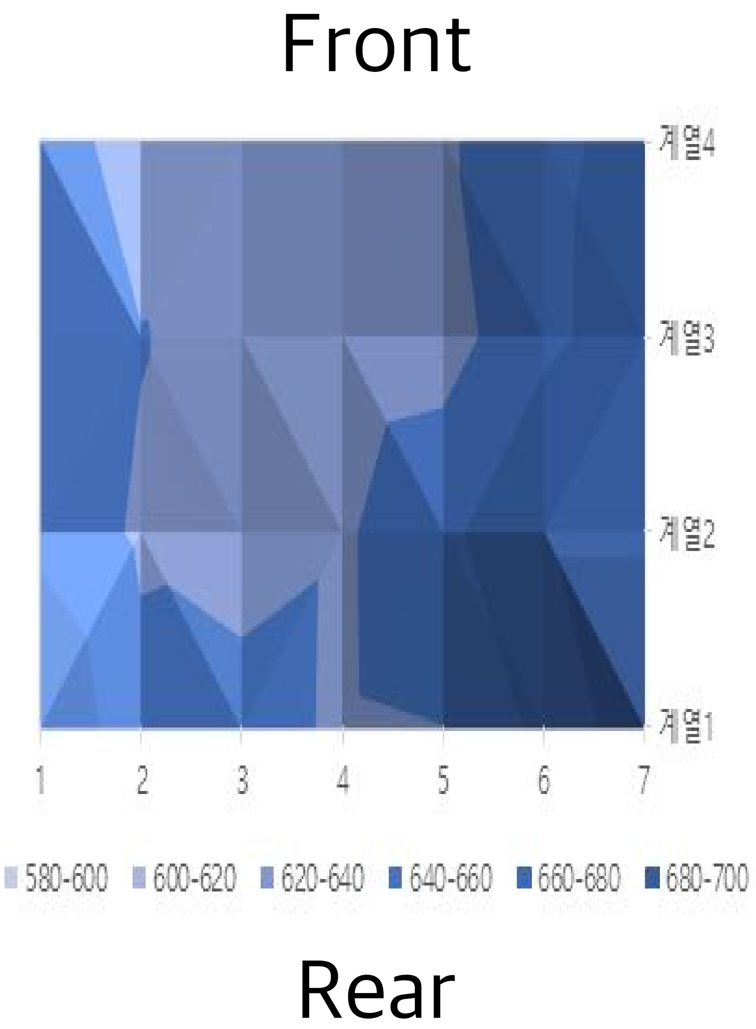


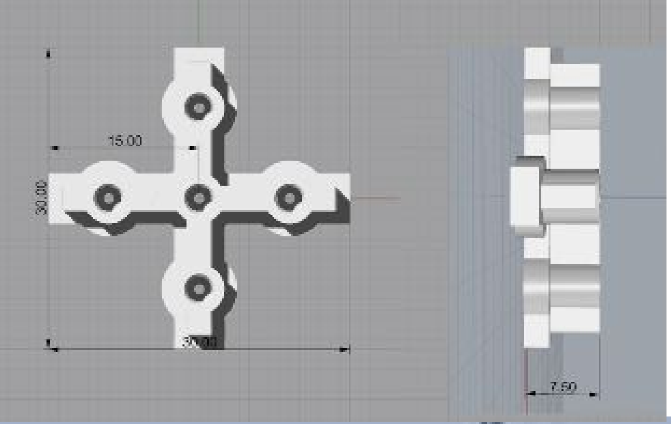
Test object one: The six-cylinder specimen for long distance evaluation



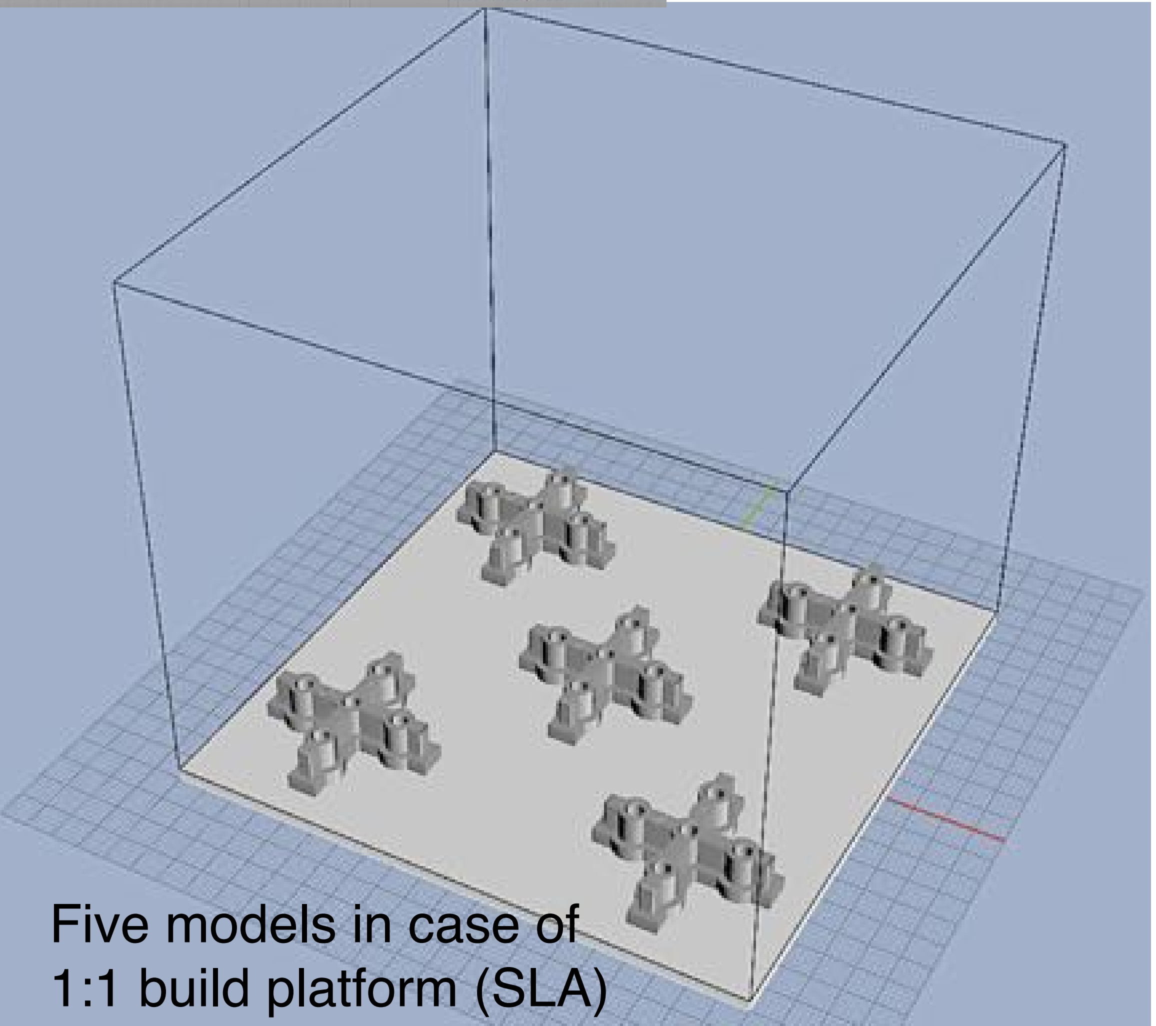
Importance of evaluating light uniformity of vat





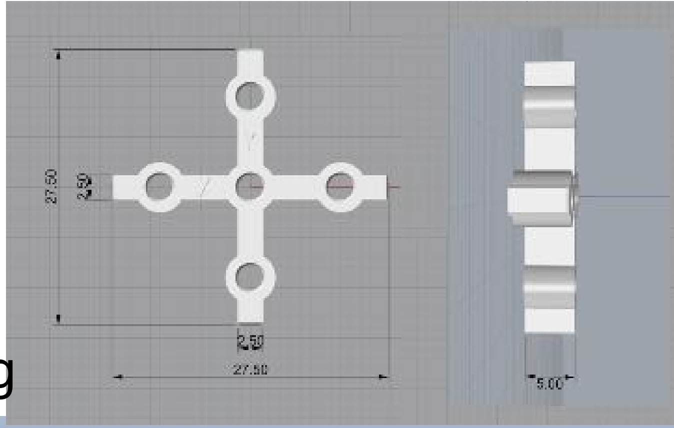


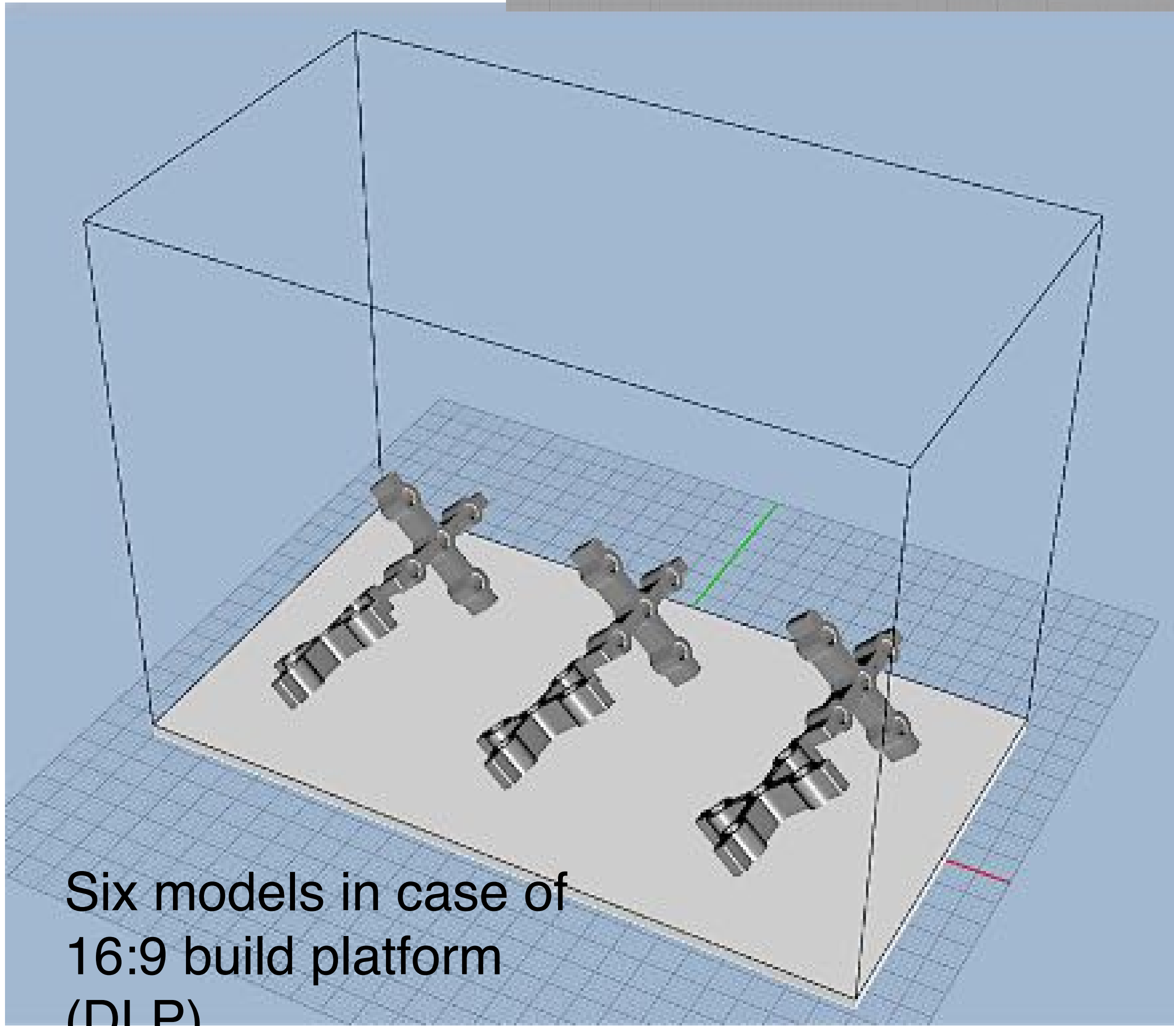
Cross with base
- horizontal setting



Five models in case of
1:1 build platform (SLA)

Cross without base
- 45 degrees setting

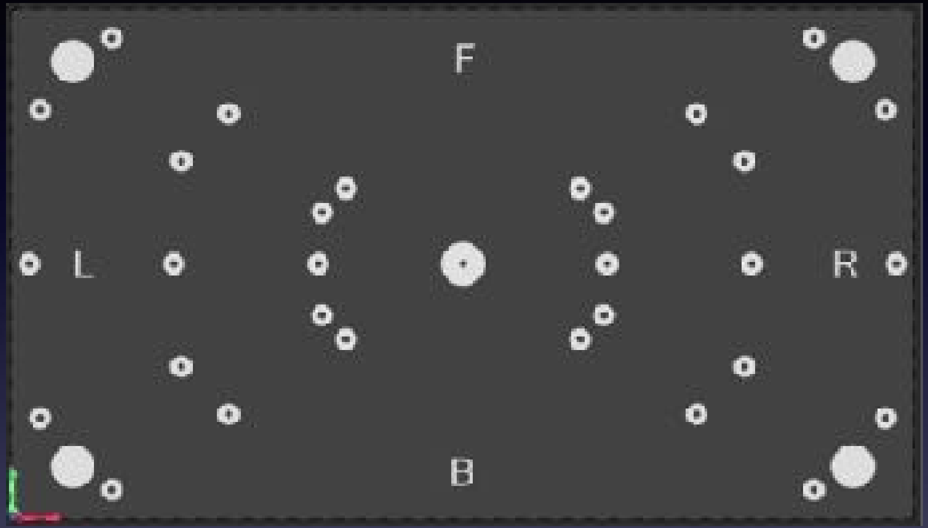


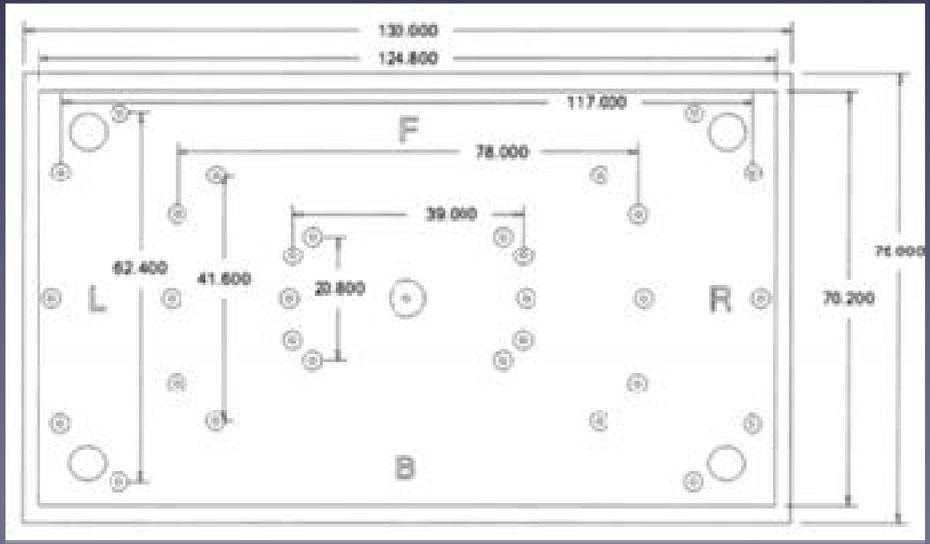


Six models in case of
16:9 build platform
(DLP)

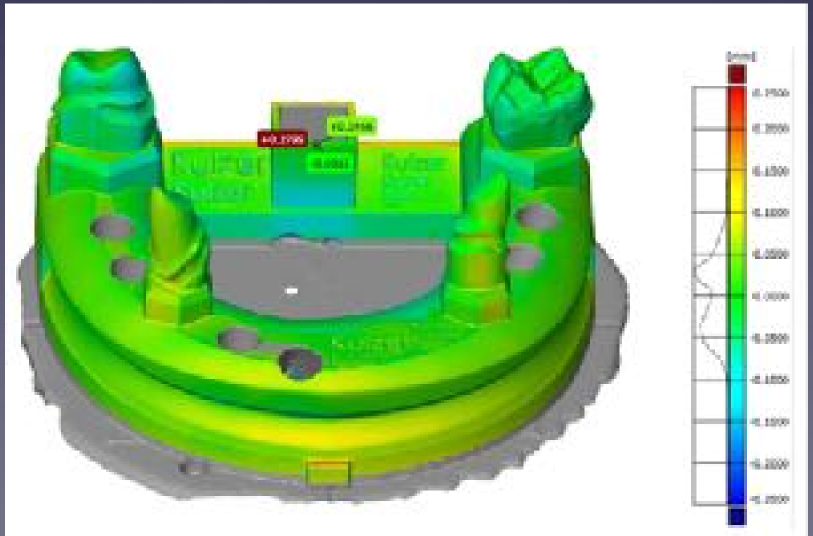
Opinions from Japan

Accuracy Validation Print



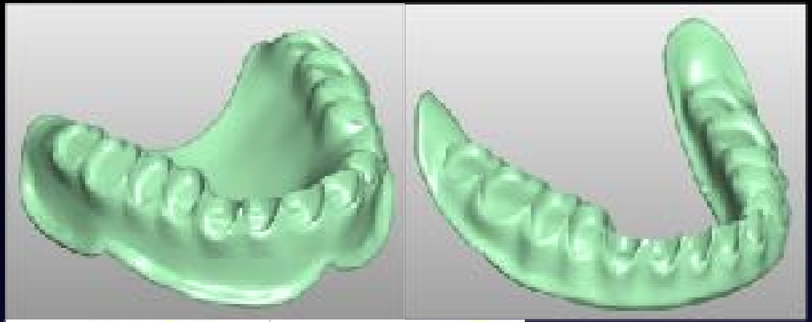


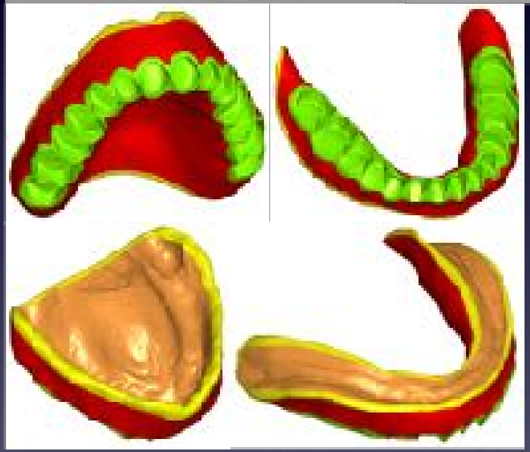
Benchmark print



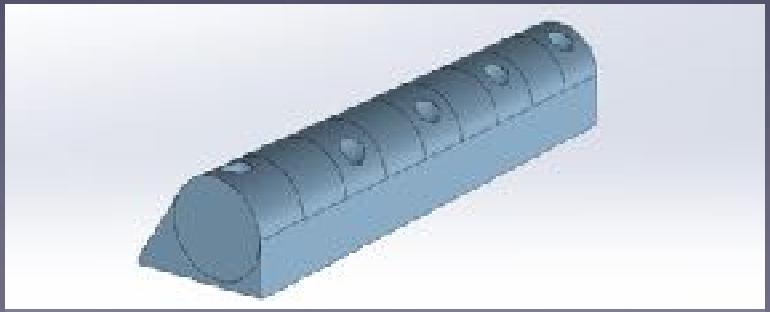
Opinions from Germany

Denture base



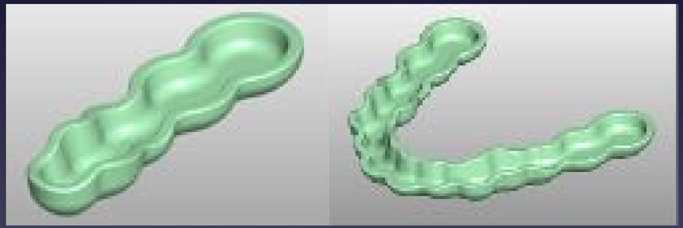


Model with fixed angles



Drill sleeves

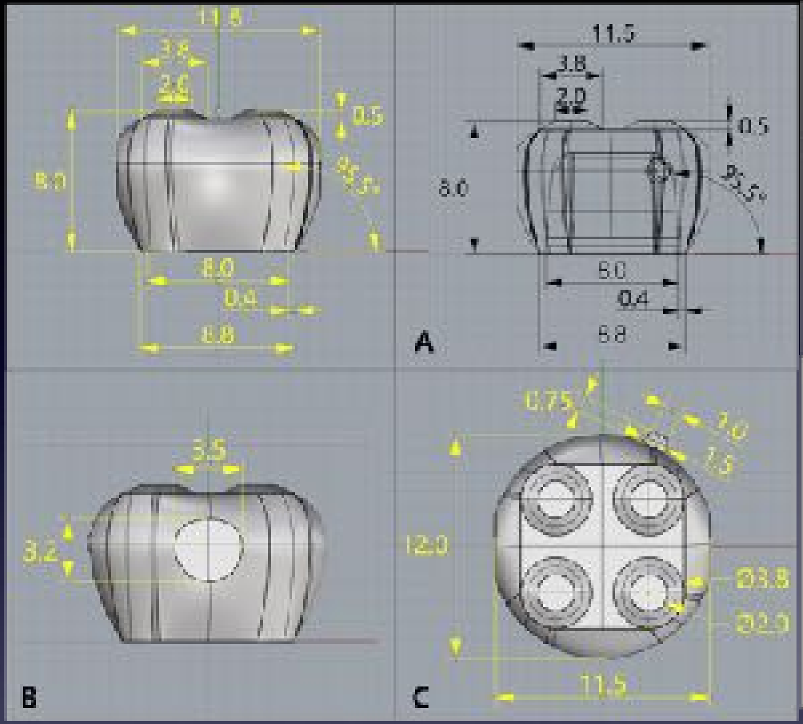
Splints



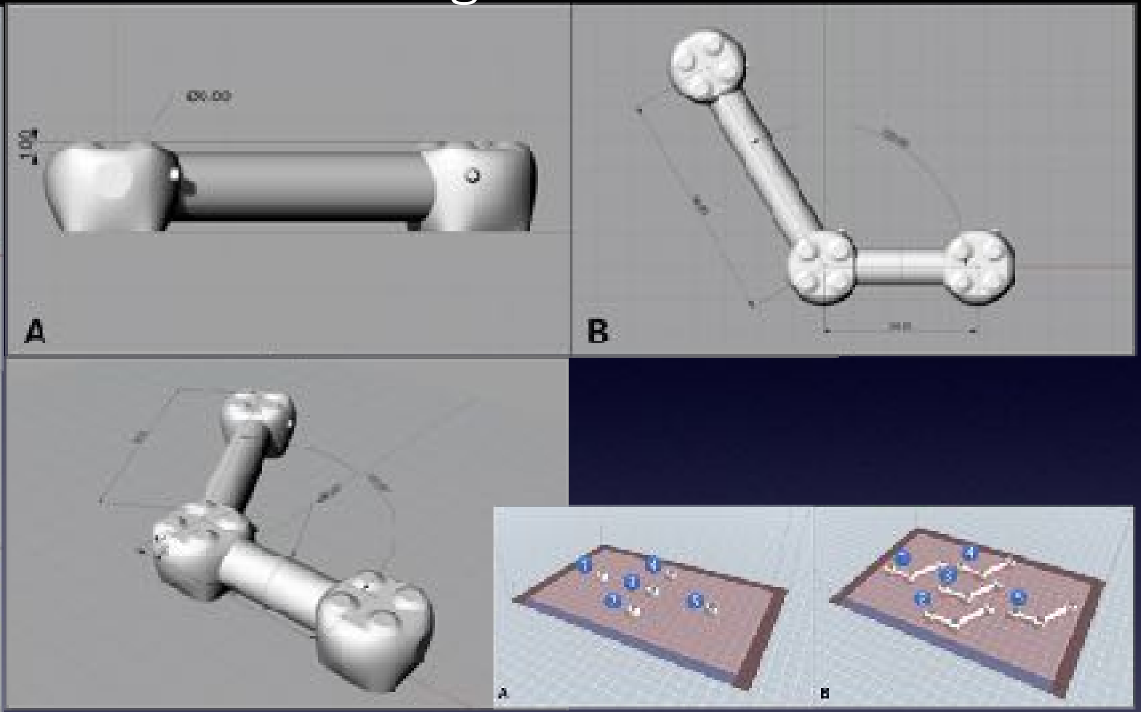
Impression tray
Bracket positioner
Crown & bridge (w/ different wall thickness)
Inlay & onlay
Dental cast
Aligner

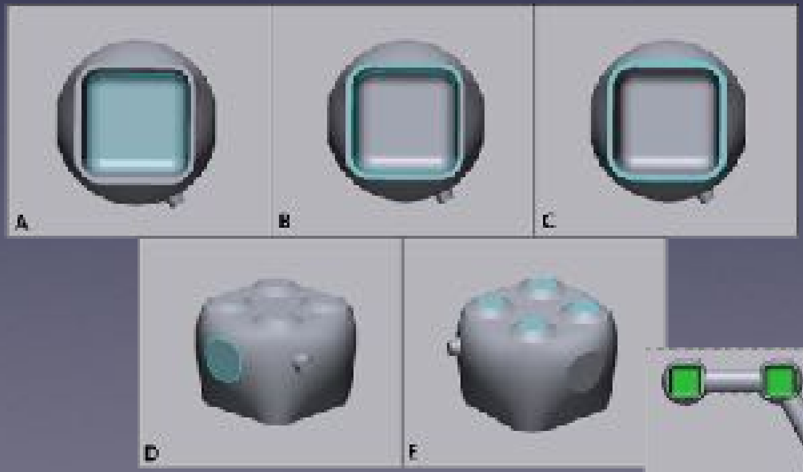
Opinions from Korea

Crown restoration



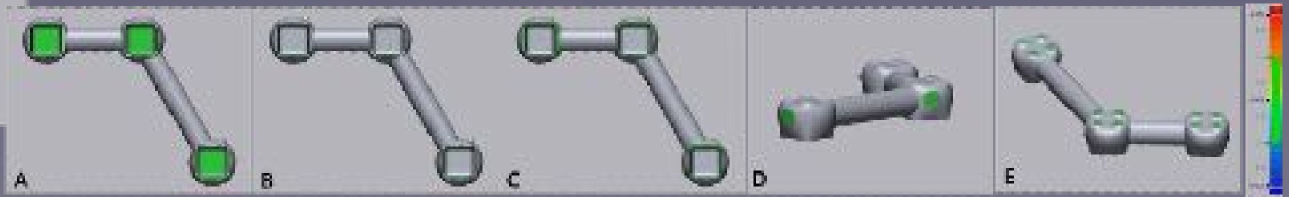
Bridge restoration

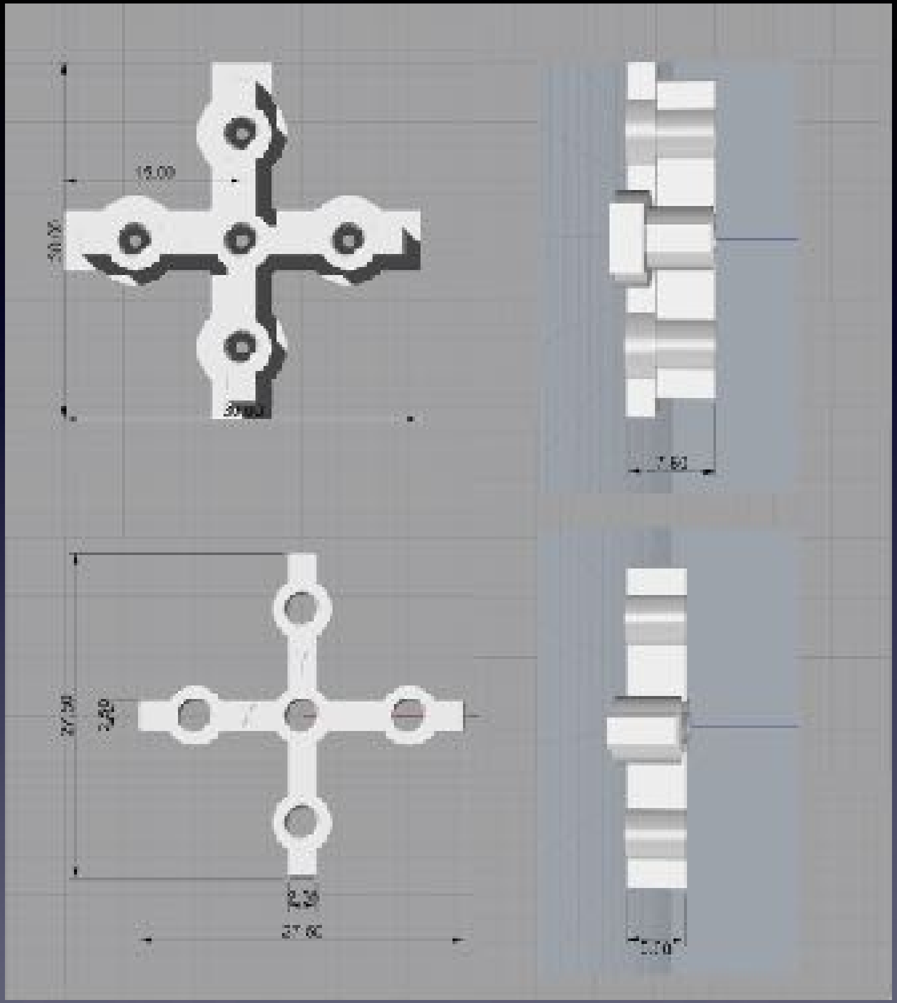


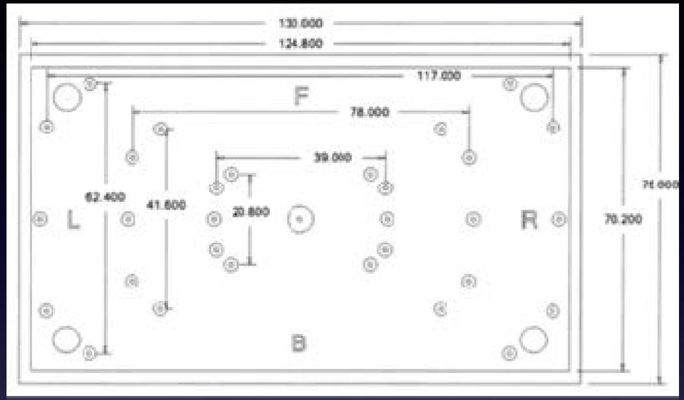


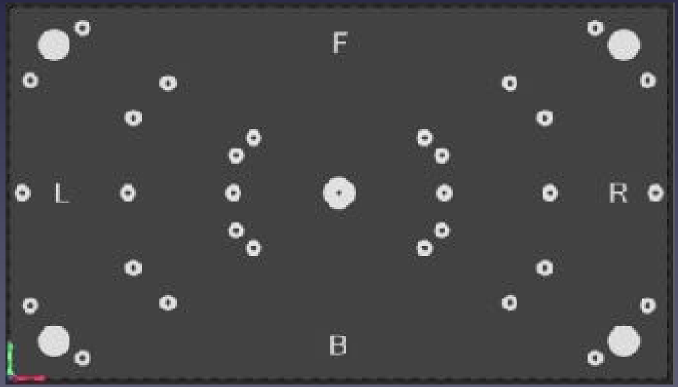
Measurement areas

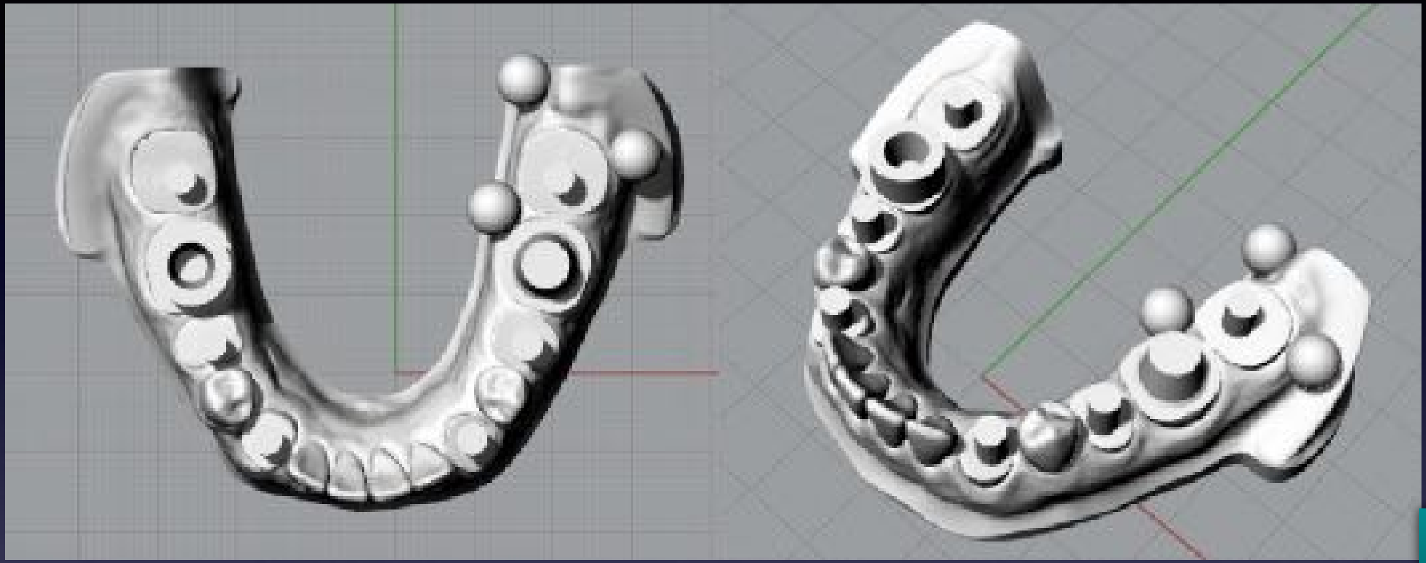
A: intaglio occlusal
B: intaglio lateral
C: margin
D: external lateral
E: external occlusal

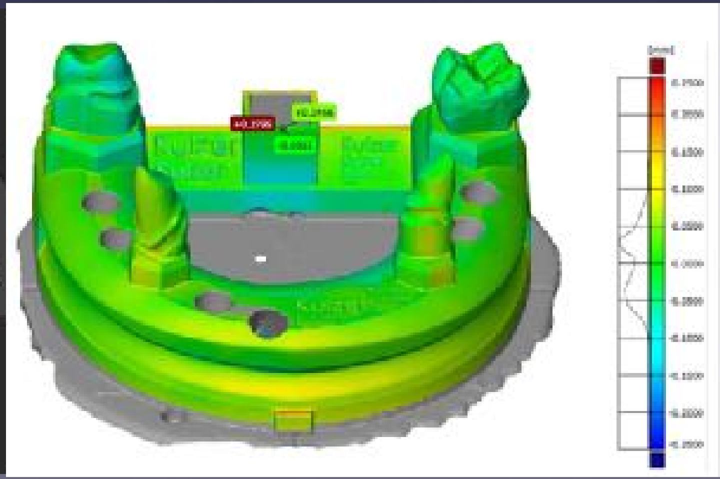


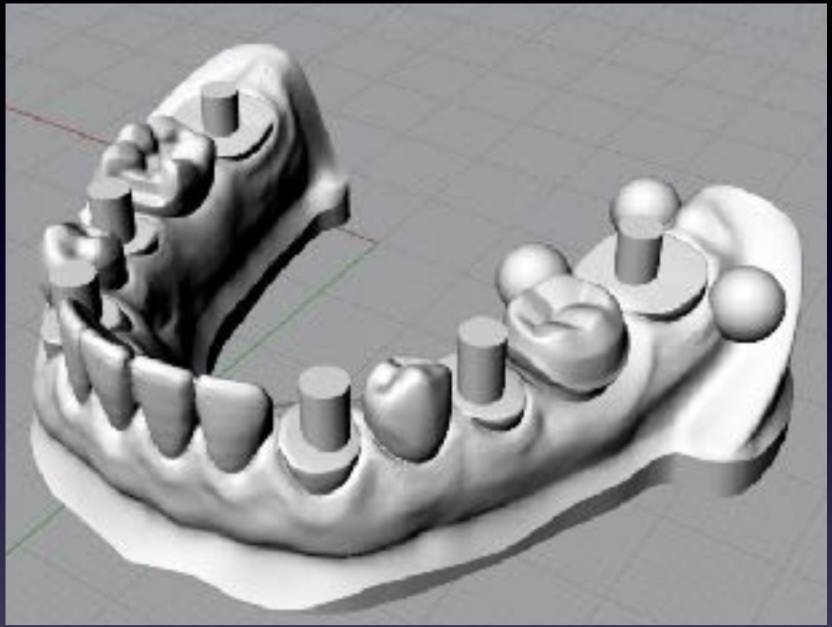

15.00
27.60

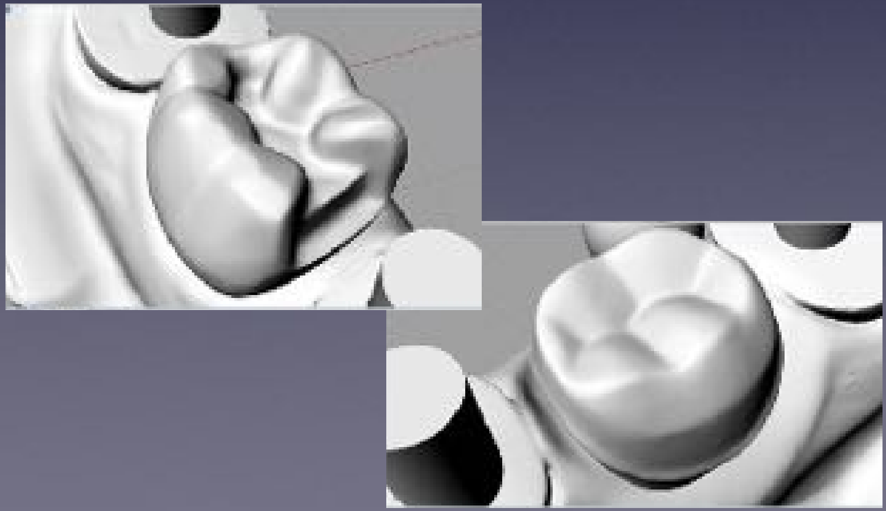

130.000
124.800
117.000
F
78.000
39.000
62.400
41.600
20.800
L
R
70.200
B


F
L
R
B









Technical report —> Technical specification (Berlin 2022)
DTS discussed & began ILT (Sydney 2023)

ISO/TC 106/SC 9/WG 7 **N 29**

Date: 2023 XX XX

ISO WD DTS 5105

ISO TC 106/SC 9/WG 7

Secretariat: JISC

Dentistry — Accuracy of CAD/CAM Additive Manufactured Dental Products - Part 1: Polymeric Materials with Vat Photopolymerization Technology

WD stage

Warning for WDs and CDs

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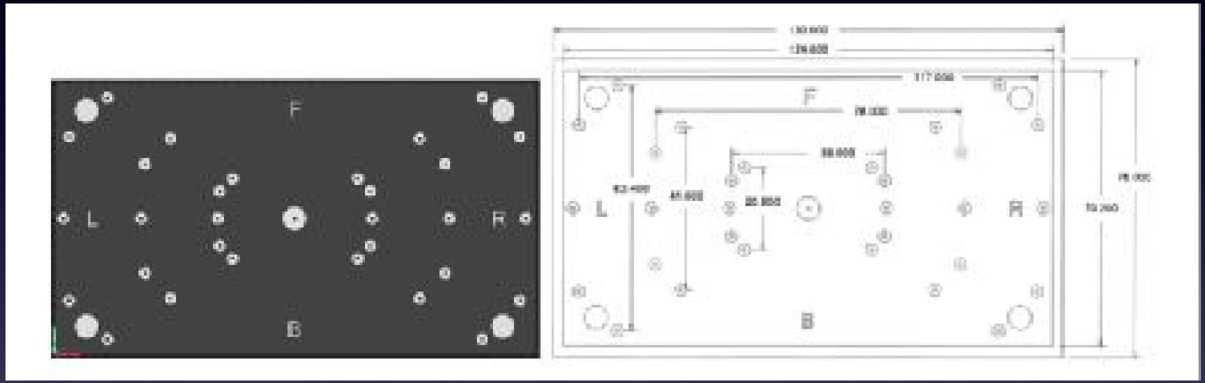
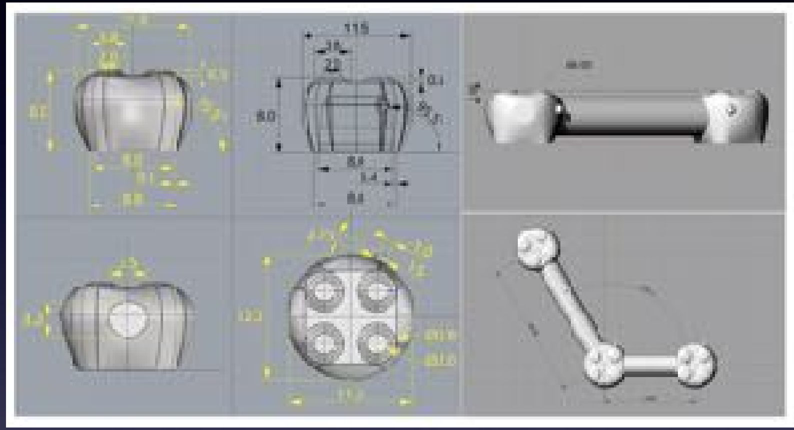
Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Test objects of DTS 5105 (Under ILT project, Project leader: Park JM)

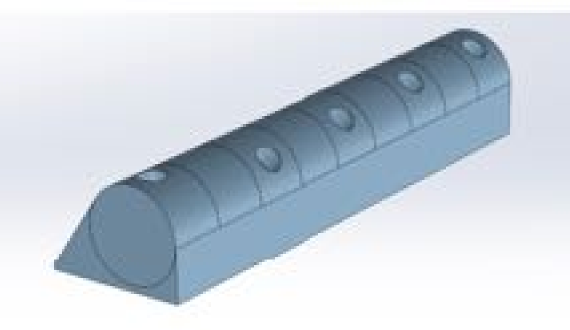
(Annex A) Accuracy validation specimen



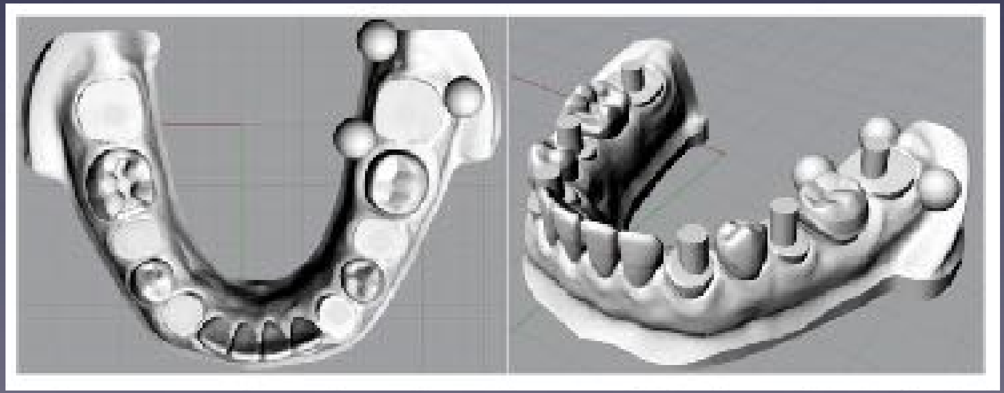
(Annex B) Complete-arch dental model with single inlay and crown dies



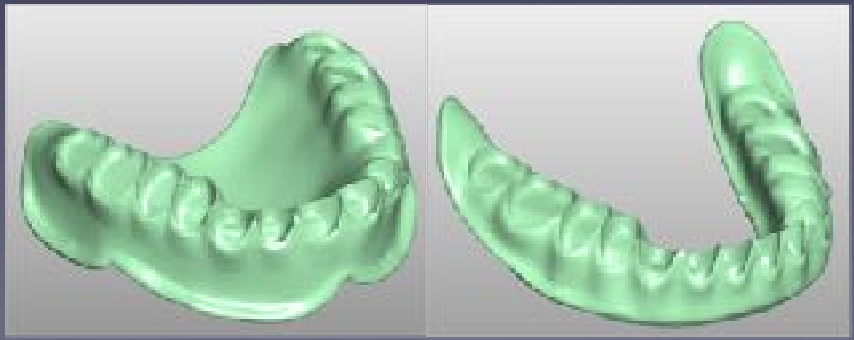
(Annex C) Drill sleeve model with fixed angles



(Annex D) Crown and bridge restorations



(Annex E) Full denture



Thank you for your attention!

IEC Systems Committee
on
Bio-digital Convergence
(IEC SyC BDC)

v 1.0

https://horizons.gc.ca/en/2022/05/31/biodigital-today-and-tomorrow/

François Coallier,PhD, P.Eng.
IEC SyC BDC Chair
ISO/IEC JTC 1/SC 41 Chair

ISO/IEC JTC 1/WG 12
Workshop
2023-12-12

International
Electrotechnical
Commission

Mandate of the SYC on Bio-digital convergence

Systems level standardization activities in the domain of bio-digital convergence for the IEC, including ISO/IEC JTC 1.

- Facilitate outreach and influence the work on bio-digital convergence with ISO, other SDOs, and industry consortia, in collaboration with relevant IEC entities and thus facilitate the advancement and coordination of bio-digital convergence standardization.

- Identify and assess potential new forthcoming bio-digital convergence topics and problematics that may become relevant to IEC activities and recommend to the SMB an appropriate course of action to meet the needs of the global community.

https://www.iec.ch/dyn/www/f?p=103:186:401031034592075::::FSP_ORG_ID,FSP_LANG_ID:49793,25

Bio-digital Convergence

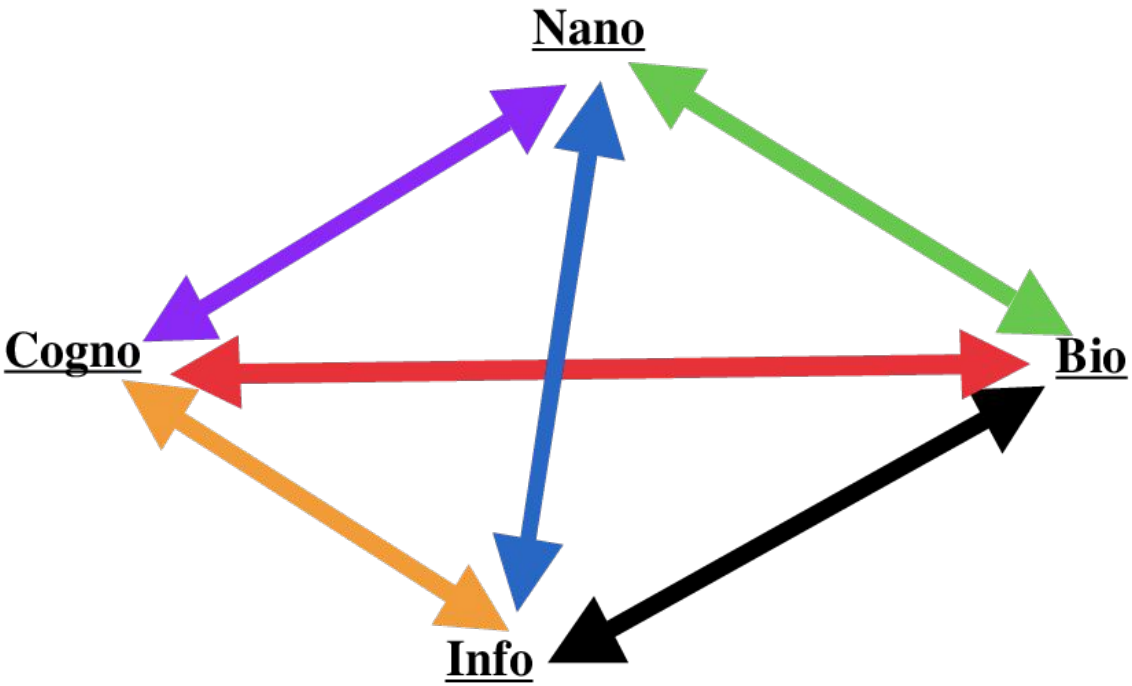
convergence of engineering, nanotechnology, biotechnology, information technology and cognitive science

Note 1 to entry: convergence means the creative union of sciences, technologies, engineering and peoples, focused on mutual benefit; this is a process requiring increasing integration across traditionally separate disciplines, areas of relevance, and across multiple levels of abstraction and organization.

[SOURCE: Modified from: *M. C. Roco, W. S. Bainbridge, B. Tonn, and G. Whitesides, Eds., Convergence of Knowledge, Technology and Society: Beyond Convergence of Nano-Bio-Info-Cognitive Technologies. Cham: Springer International Publishing, 2013. doi: 10.1007/978-3-319-02204-8.*]

Bio-digital Convergence -

a ~20 years old concept!

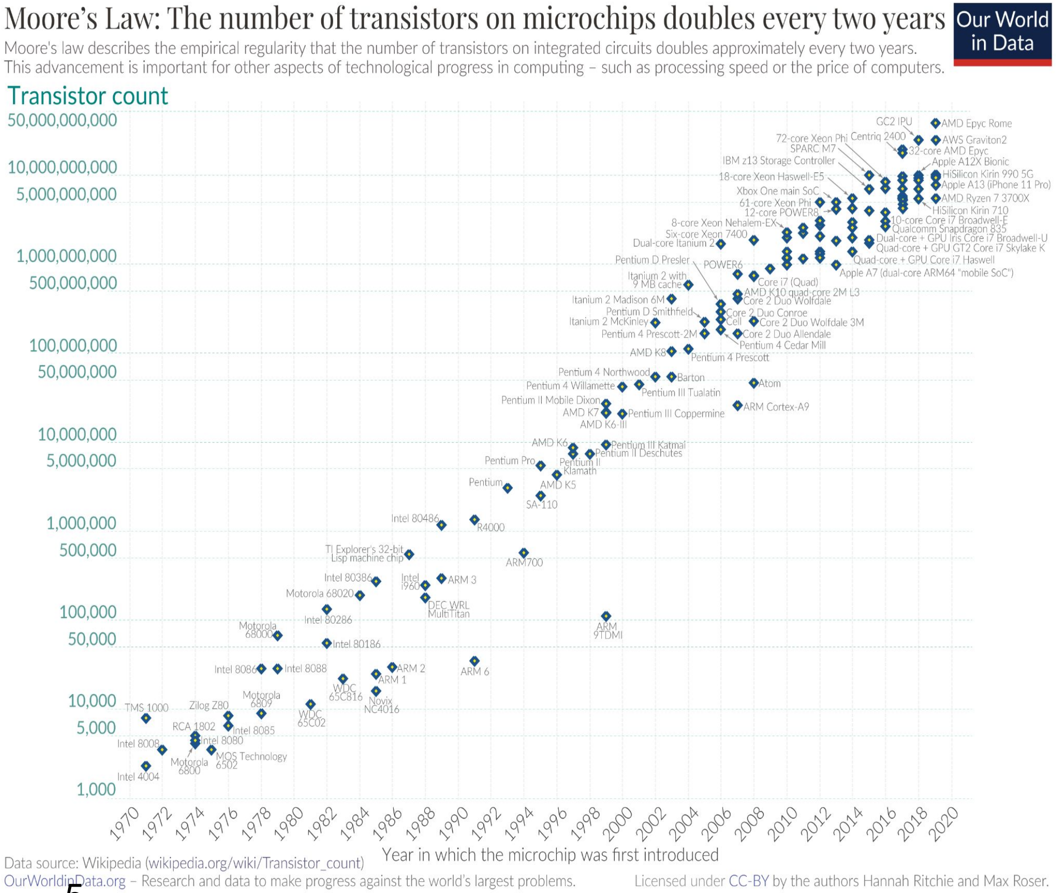


In the context of BioDigital convergence,
'The phrase "convergent technologies" refers to the synergistic combination of four major "NBIC"(Nano-Bio-Info-Cogno) provinces of science and technology, each of which is currently progressing at a rapid rate: (a) nanoscience and nanotechnology; (b) biotechnology and biomedicine, including genetic engineering; (c) information technology, including advanced computing and communications; and, (d) cognitive science, including cognitive neuroscience.' [1]

[1] Roco, Mihail & Bainbridge, William (**2003**). Converging Technologies for Improving Human Performance.
https://www.researchgate.net/publication/252444145_Converging_Technologies_for_Improving_Human_Performance
Also in DOI：10.1007/978-94-017-0359-8

IT has changed a lot in the last 20 years

https://en.wikipedia.org/wiki/Moore%27s_law



https://techcrunch.com/2023/06/05/apple-announces-the-m2-ultra-with-up-to-192gb-of-memory/

Reverse Engineering of Life

Living Systems:

Descriptive:

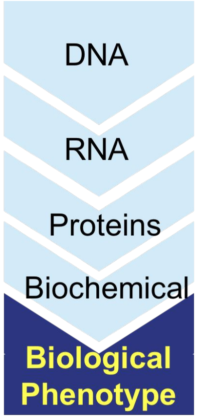
- Genomics
- Transcriptomics
- Proteomics
- Metabolomics
- Epigenetics
- Microbiomics

Systems integration

- Metagenomics
- Physiology

'Life-cyle'

- Epigenetics
- Developmental biology
- Evolution



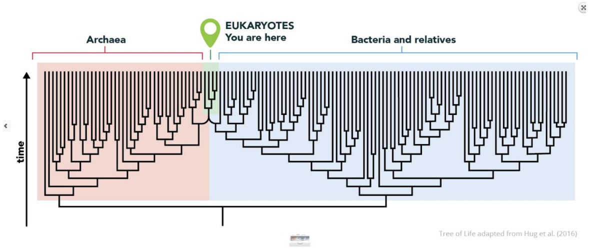
Genomics

Transcriptomics

Proteomics

Metabolomics

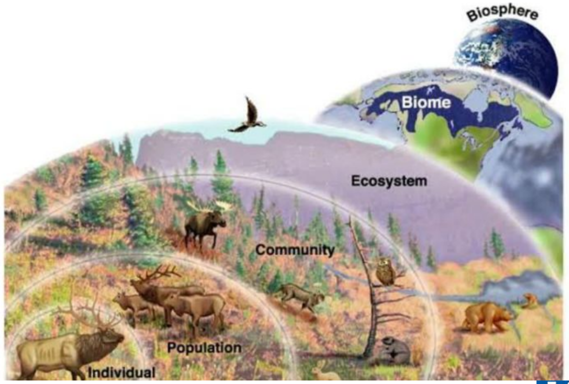
https://en.wikipedia.org/wiki/Metabolomics



https://evolution.berkeley.edu/evolution-101/

Environment and biologic system of systems:

- Metagenomics
- Exposomics
- Ecosystems
- Ecosystem Evolution
- Gaia



https://civilaspirant.in/levels-of-organisation-in-ecology/

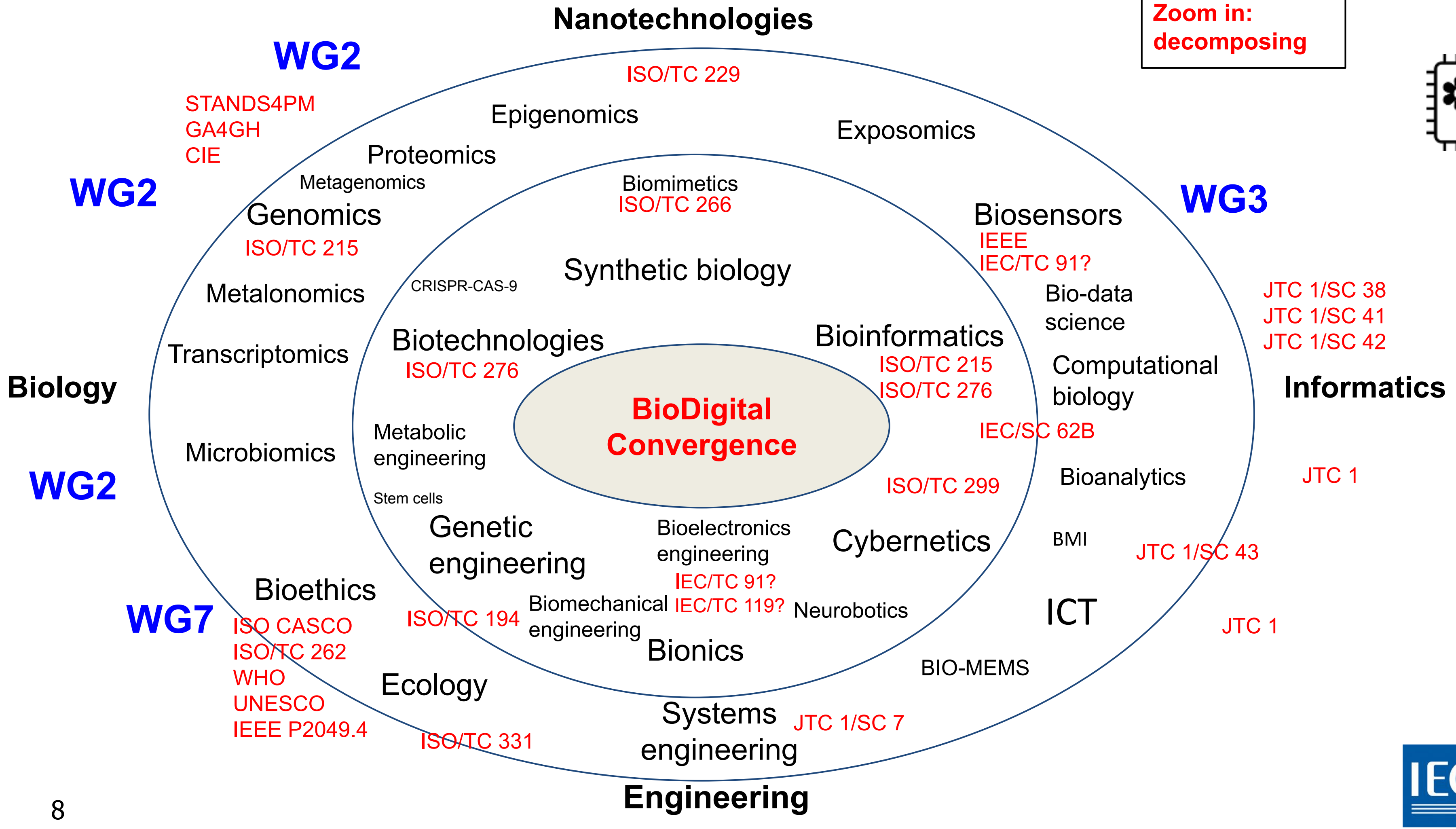
How much information?

<u>For a human</u>

- Genome: ~3x10^9 base pairs, ~700 MB of very complex programming - <u>need a cellular factory to 'decode' and additional 'instructions' to 'execute'</u>
  ~22 000 genes
  - *+ mitochondrial DNA (~17 000 base pairs)*
- Proteome: ~20 000 proteins (encoded in about 1% of the human genome)
- Metabolome: ~+110 000 molecules
- Microbiome: ~+316 000 000 genes.

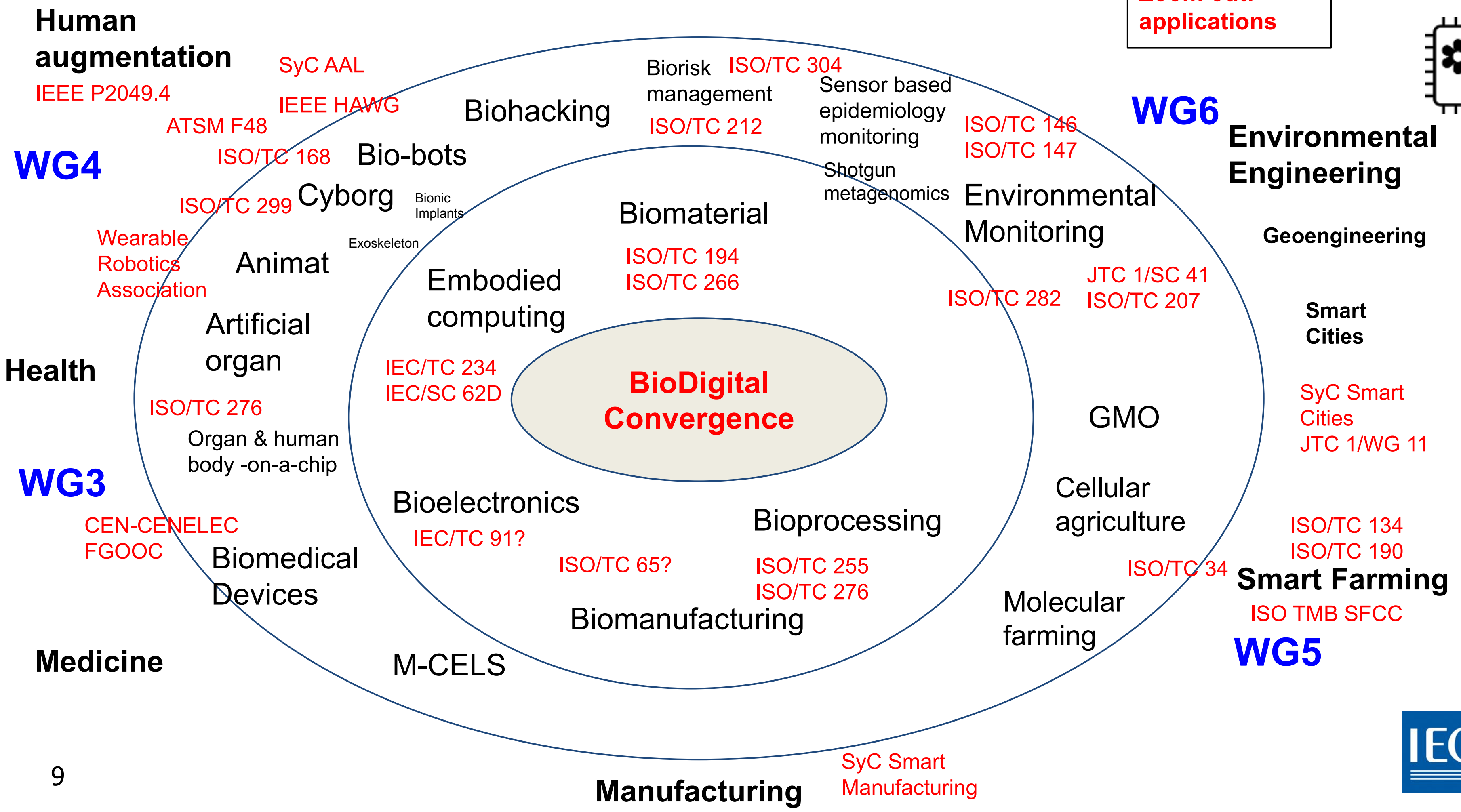
http://biosoft.kaist.ac.kr/

Zoom in: decomposing



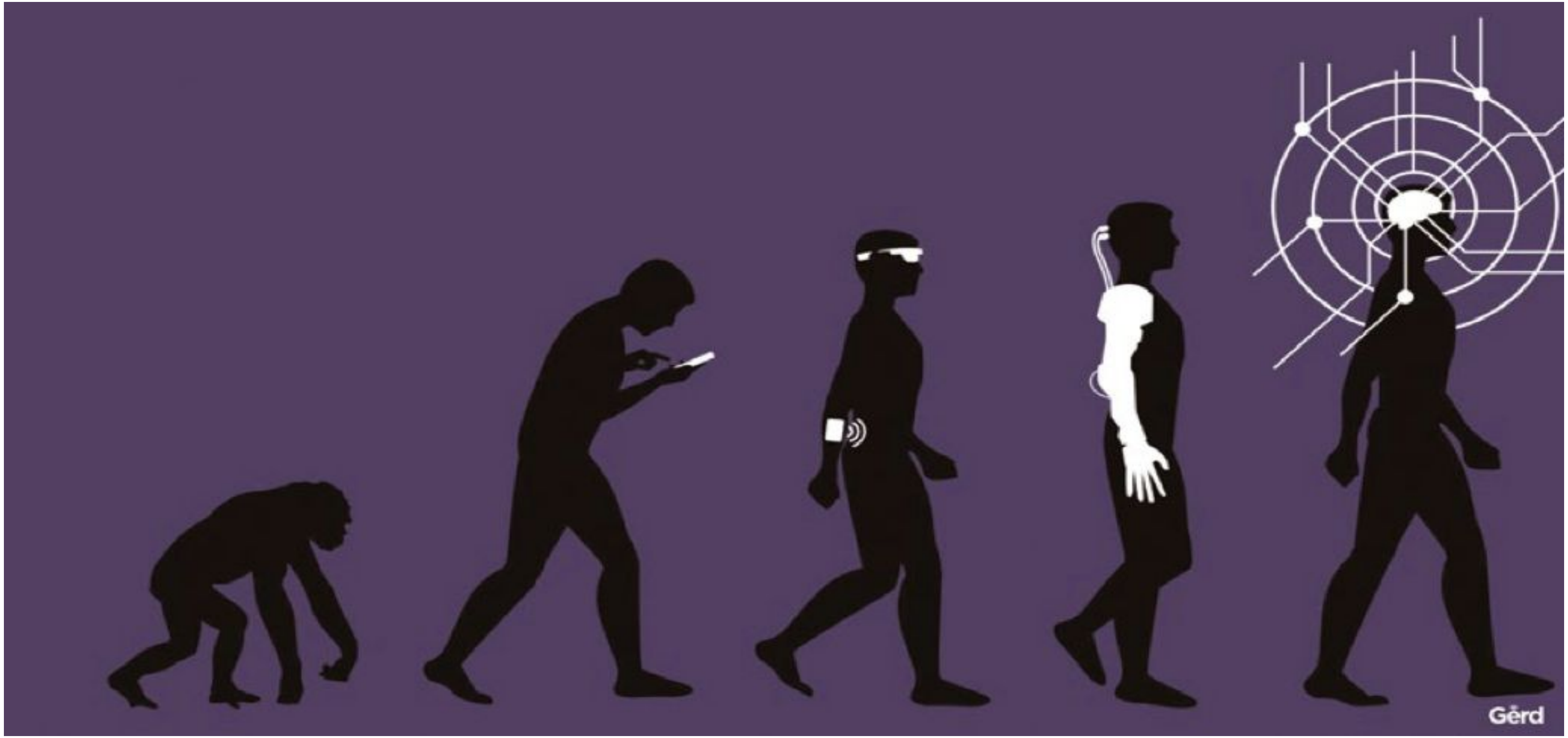
IEC, 2023, BioDigital Convergence Standardization Opportunities - Final report of the IEC Systems Evaluation Group 12 - BioDigital Convergence, in press. [Internet]. International Electrotechnical Commission; 2023. Available from: https://www.iec.ch/basecamp

Zoom out: applications



IEC, 2023, BioDigital Convergence Standardization Opportunities - Final report of the IEC Systems Evaluation Group 12 - BioDigital Convergence, in press. [Internet]. International Electrotechnical Commission; 2023. Available from: https://www.iec.ch/basecamp

Human Augmentation Technologies

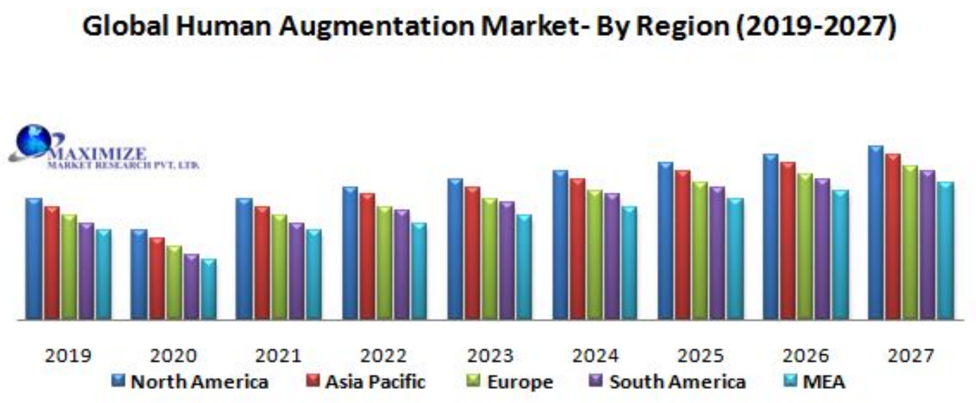


Modified from: Human Augmentation - The Dawn of a New Paradigm, A strategic implication project, UK Ministry of Defence (MOD), May 2021, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/986301/Human_Augmentation_SIP_access2.pdf

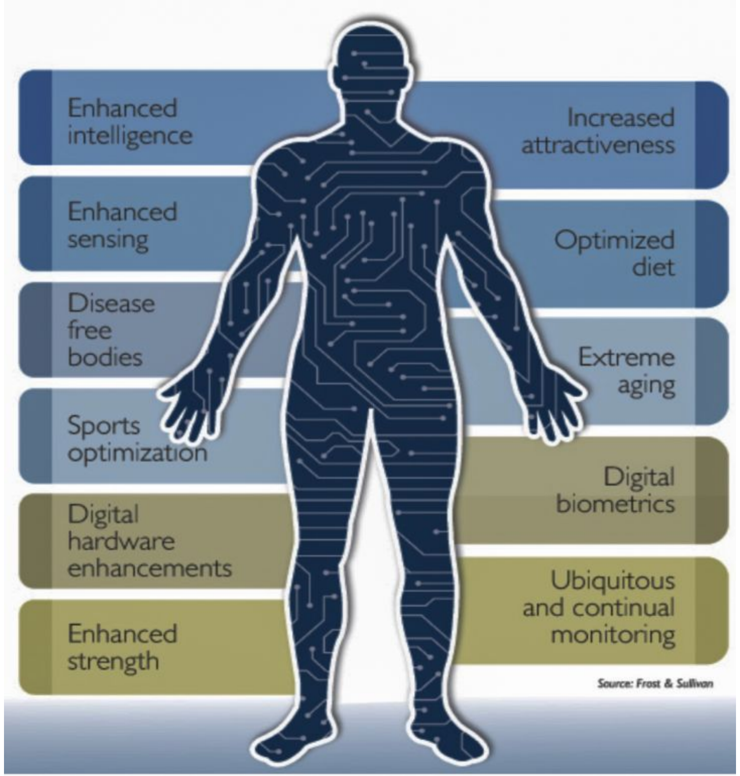
Human Augmentation Technologies

Phase 1. Recovering, repairing the existing impaired human physiological functions. Most assistive technologies in this phase, e.g., rehabilitation exoskeleton, focuses on rehabilitation scenarios in hospitals and at home.
Phase 2. Replicating, substituting human functions and organs. Power augmentation Exoskeletons (rehabilitation exoskeleton excluded) and artificial organs are common examples at Phase 2. External devices that supplement the daily life living, e.g., smart watches and VR glasses, are also considered as typical use cases.
Phase 3. Enhancing, outperforming human capabilities. Applications aiming at exceeding human abilities are performed using emerging technologies from biomechanical engineering to genetic engineering

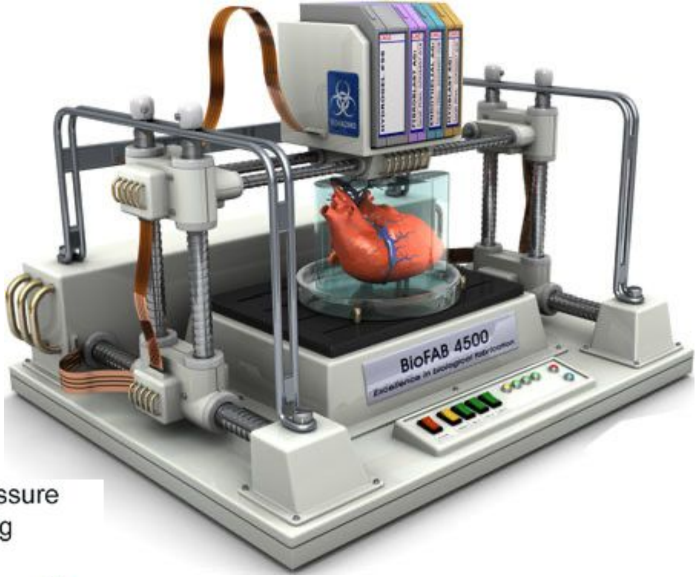
Source: Preliminary findings of IEC SEG 12/WG4

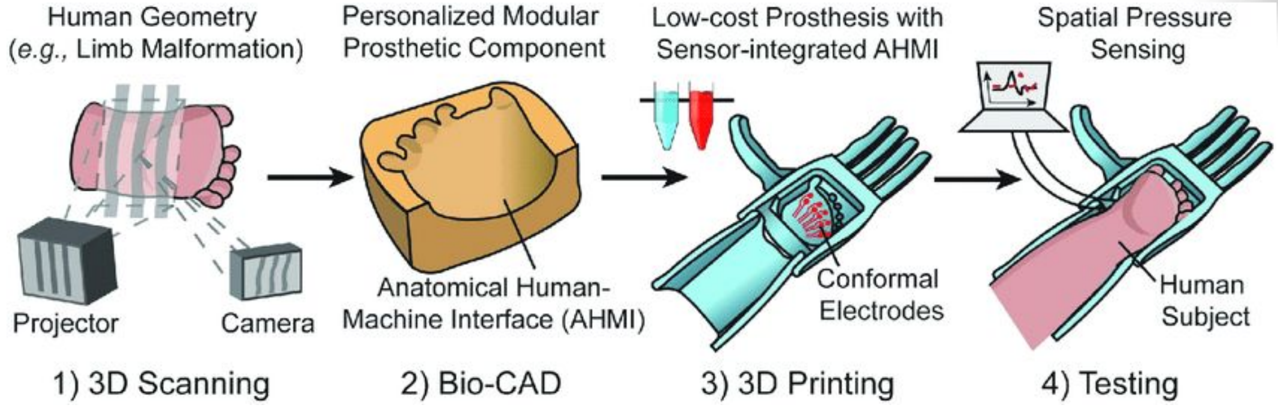


https://www.maximizemarketresearch.com/market-report/global-human-augmentation-market/66366/



https://cmte.ieee.org/futuredirections/2018/08/09/transhumanism-evolving-the-human-body-ii/

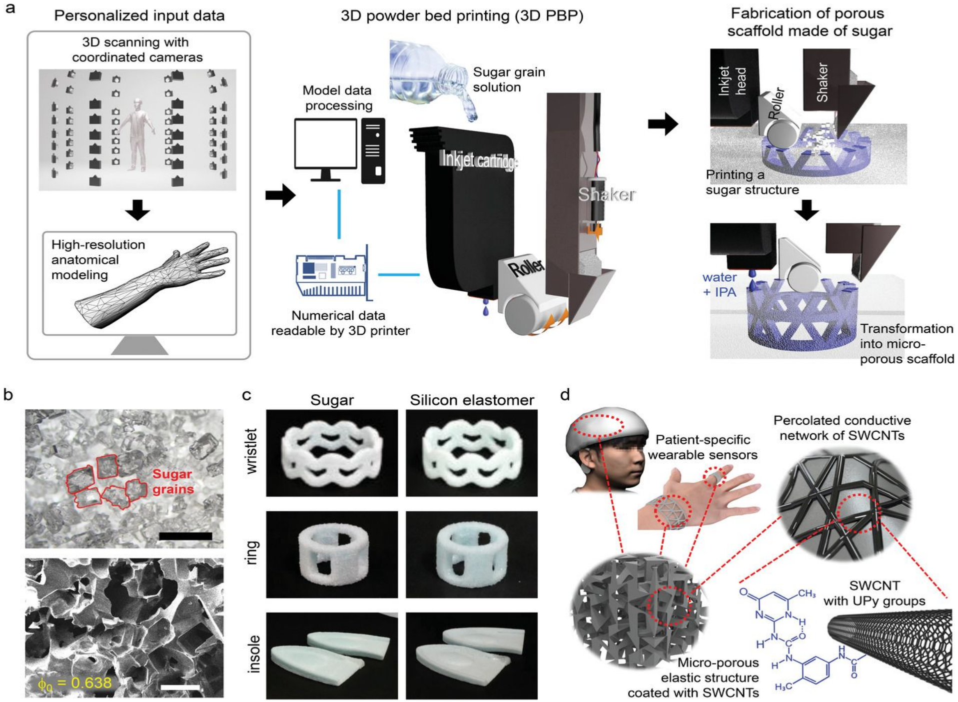




http://3dprintingireland.com/portfolio/pharmaceutical-medical/attachment/scanmain/

Ozbolat, Ibrahim & Yu, Yin. (2013). Bioprinting Toward Organ Fabrication: Challenges and Future Trends. IEEE Transactions on Biomedical Engineering. 10.1109/TBME.2013.2243912.

Tong, Yuxin & Kucukdeger, Ezgi & Halper, Justin & Cesewski, Ellen & Karakozoff, Elena & Haring, Alexander & McIlvain, David & Singh, Manjot & Khandelwal, Nikita & Meholic, Alex & Laheri, Sahil & Sharma, Akshay & Johnson, Blake. (2019). Low-cost sensor-integrated 3D-printed personalized prosthetic hands for children with amniotic band syndrome: A case study in sensing pressure distribution on an anatomical human-machine interface (AHMI) using 3D-printed conformal electrode arrays. PLOS ONE. 14. e0214120. 10.1371/journal.pone.0214120.

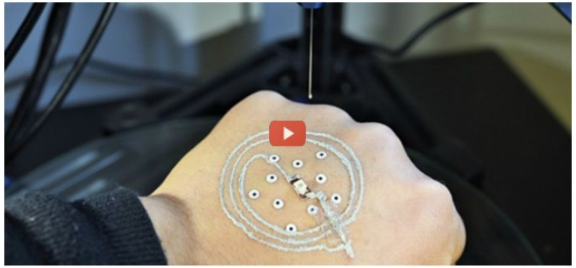


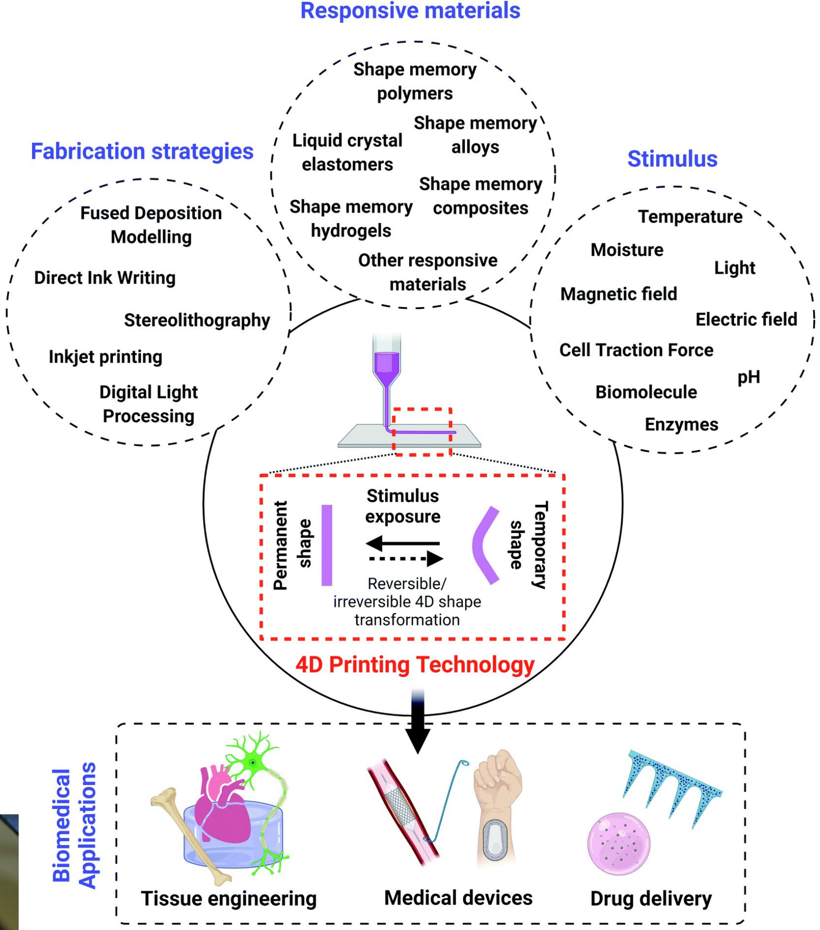
3D printing the wearable sensors. Image via SKKU.

https://3dprintingindustry.com/news/korean-researchers-3d-print-highly-sensitive-wearable-biosensors-172043/

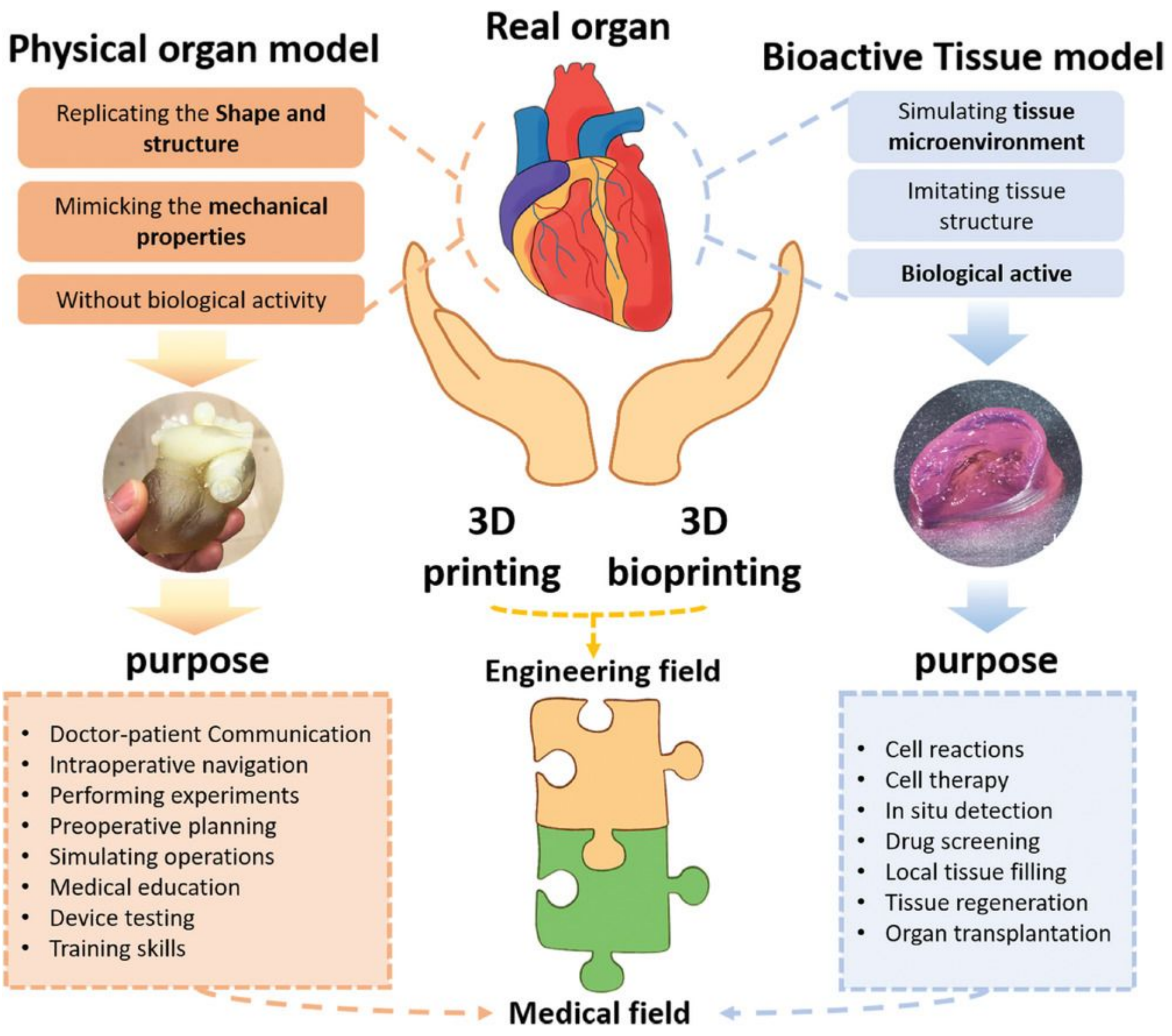
3D Printing Electronics and Sensors Directly on Skin [video]

by Bruce Brown | May 23, 2018 | Enabling Tech, General News | 0 comments

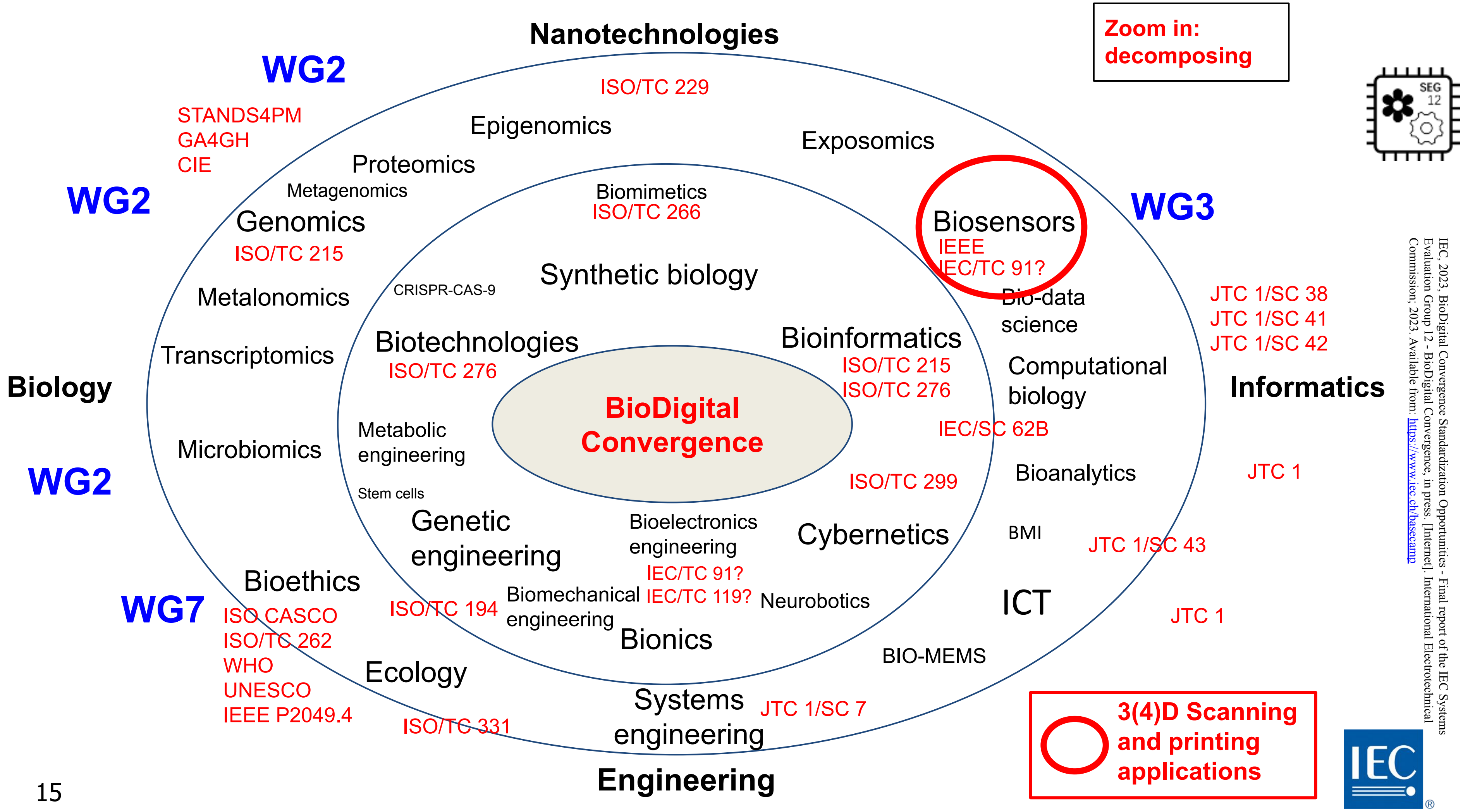




https://doi.org/10.1039/D1TB01335A

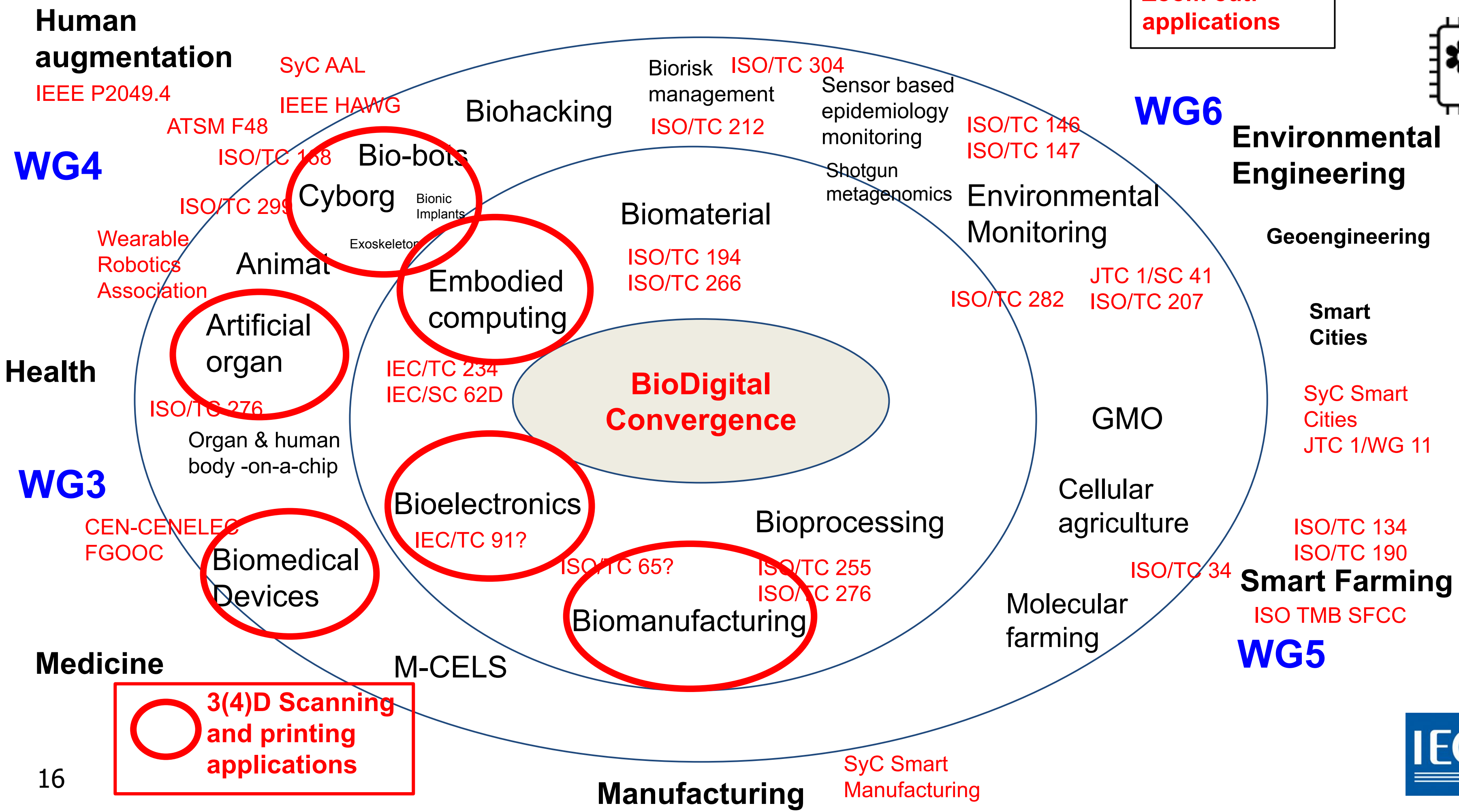


https://en.wikipedia.org/wiki/3D_bioprinting



IEC, 2023, BioDigital Convergence Standardization Opportunities - Final report of the IEC Systems Evaluation Group 12 - BioDigital Convergence, in press. [Internet]. International Electrotechnical Commission; 2023. Available from: https://www.iec.ch/basecamp

Zoom out: applications



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History and Status of the SyC BDC

Precursor - Standards Exploratory Group (SEG) 12:

- Created in April 2021
- 7 Working Groups, 125 members
- Report issued to SMB in May 2023
- Technical Report to be published IQ2024

SyC BDC

- Created at the October 2023 IEC SMB Meeting
- Chair and Secretariat assigned
- Kick-Off Plenary in April 2024
- SMB resolution inviting ISO for collaboration through a possible joint structure

SEG 12 Structure & Topics

- WG1 - Communications, Synthesis and Edition of Report
- WG2 - Reverse Engineering of Living Systems
- WG3 - Life systems and Bioengineering
- WG4 - Human Augmentation Technologies
- WG5 - Agricultural Bioengineering
- WG6 - Environmental Bioengineering
- WG7 - Biodigital Social, Risks and Ethical Aspects
- AG8 - Convener Advisory Group

SyC BDC

As an IEC systems committee, the SyC BDC can have:

- Vice- chair(s) (See 1.8.2 of the IEC Supplement)
- Working groups (Cannot develop standards unless a project is specifically authorized by the SMB)
- Joint Working Groups, Joint Project Teams (with IEC or ISO TCs or SCs)
- Registered (R) Members (Essentially enhanced liaisons with IEC or ISO TCs or SCs as well as other Standards Developing Organizations - SDOs)
- Pool(s) of Experts (from NBs and R Members)
- Open Forum(s) - open (like a SEG) to any self-nominated experts
- Advisory Groups

For more details, see https://syc-se.iec.ch/home/what-a-system-committee-does/ and Annex SO of the IEC Supplement.

SyC BDC - Future plans (chair's view)

- Kick-off Plenary (virtual) in April 2024
- Agree on a initial structure
- Review and implement SEG 12 recommendations to the SMB
- As requested by the SMB, come with recommendations for a course of action on ethical issues
- Do whatever is necessary to initiate standardization activities (with IEC and ISO TCs) identified by IEC / SEG 12. This includes the draft bio-digital vocabulary elaborated by SEG 12
- etc…

SyC BDC - how to participate

- Nomination through a National Body
- Nomination through future liaisons or ‘R’ liaisons
- Joining (a) future(s) open forum(s)

Thank You

https://horizons.gc.ca/en/2020/02/11/exploring-biodigital-convergence/

Brief Introduction of JTC 1/WG 12 3D Printing and Scanning

JTC 1/WG 12 workshop, virtual

(2023-12-12, 1100-1400 UTC)

Kyu Won Shim, MD, PhD

Convenor of JTC 1/WG 12

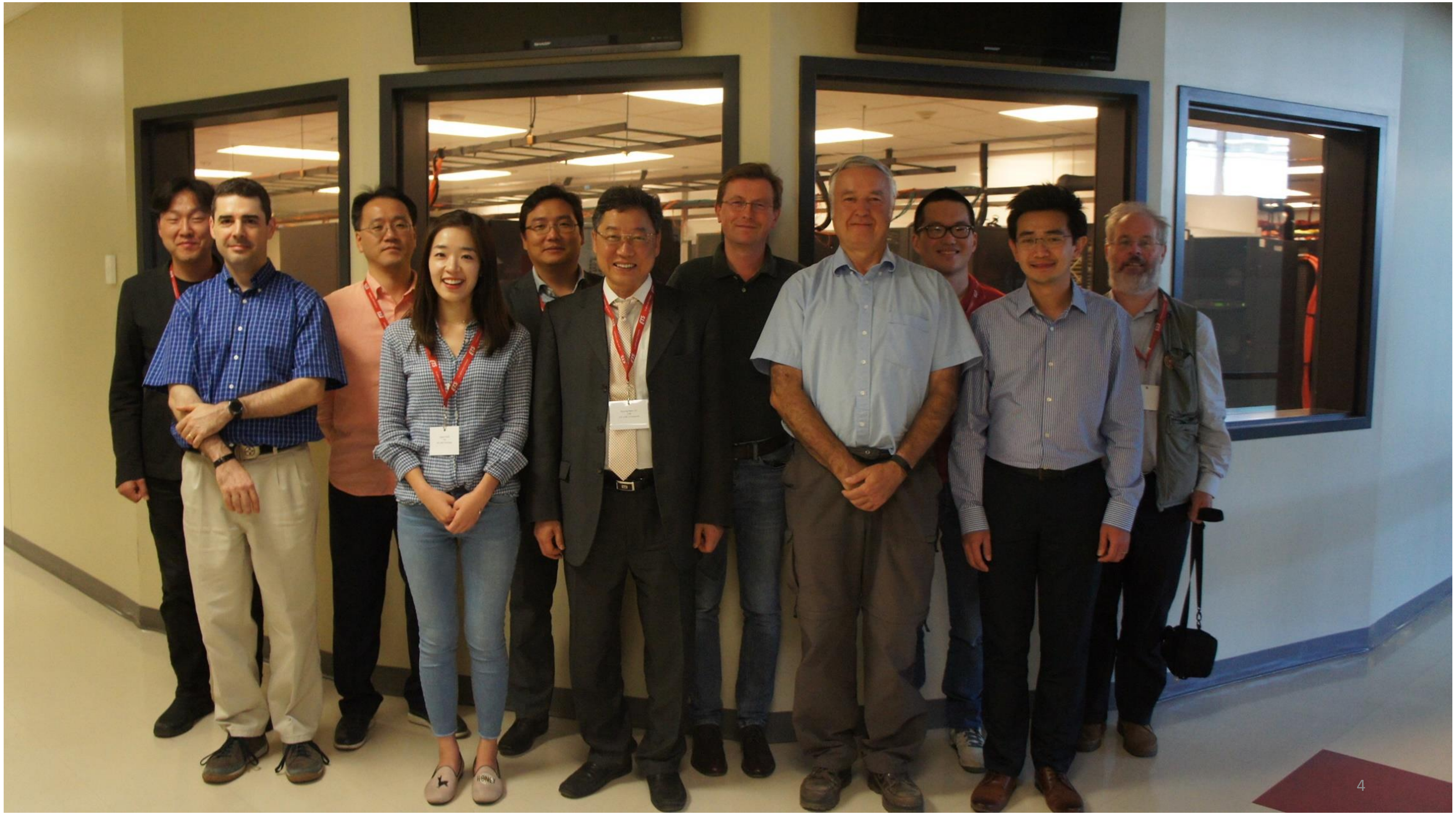
Co-convenor of JTC 1/WG 12/AHG 3 3D scanning

Status of JTC 1/ WG 12

- **Established at**
  - the 32nd JTC 1 Plenary in Vladivostok, Russia in 2017 conditionally
- **Activated from**
  - 2018-08-15 with the approval of NP 23510
- **Officers**
  - WG 12 Convenor: Prof. Kyu-Won Shim
  - WG 12 Secretary: Ms. Yaeseul Park
- **Members**
  - 74 members from 11 NBs, 5 Liaisons and SIF facilitator (December 2023)

F2F Seoul Meeting for ISO/IEC JTC 1 Study Group on 3D Printing and Scanning, May 24 to 26, 2017

F2F Montreal Meeting for ISO/IEC JTC 1 Study Group on 3D Printing and Scanning, Ecole de technologie superieure, Department of Software and IT Engineering, August 29 to 31, 2017



Terms of Reference

- Serve as a focus of and proponent for the JTC 1 standardization program on 3D Printing and Scanning
- Develop ICT related foundational standards for 3D Printing and Scanning upon which other standards can be developed
- Develop other 3D Printing and Scanning standards that are built upon the foundational standards when relevant ISO and IEC committees that could address these standards do not exist or are unable to develop them
- Identify gaps and opportunities in 3D Printing and Scanning standardization
- Develop and maintain liaisons with all relevant ISO and IEC committees as well as with external organizations that have interests in 3D Printing and Scanning
- Engage with 3D Printing and Scanning communities to raise awareness of JTC 1 standardization efforts and provide an open platform for discussion and further cooperation
- Develop and maintain a list of existing 3D Printing and Scanning standards produced and standards development projects underway in ISO TCs, IEC TCs and JTC 1

Members

No.	National Body	Number of Experts	Role
1	Australia	1	Committee Member
2	China	6	
3	Canada	1	
4	France	3	
5	Germany	1	
6	India	1	
7	Israel	5	
8	Italy	1	
9	Japan	5	
10	Korea	26	
11	Luxembourg	1	
12	Nigeria	1	
13	UK	2	
Total		53	

- **Subgroups (2)**
  - AHG 1 on 4D Printing
  - AHG 3 on 3D scanning for 3D printing

- **Liaisons**
  - ISO/TC 106, 150, 171/SC 2, 184/SC 1 and SC 4, 215, 261
  - JTC 1/SC 24, 29 and 42
  - Khronos Group

- **Collaborate with other committees**
  - JTC 1/SC 41, ISO/TC 184/SC 4/JWG 16, IEC SyC Bio-Digital convergence and ISO/IEC JSEG 15 etc.

AHG 1 on 4D Printing

JTC 1/WG 12 agrees to reconstitute AHG 1 on 4D Printing with the following

Terms of Reference:

1) Continue to update the description of key concepts and terminology related to 4D Printing.

2) Assess the current state of standardization activities relevant to 4D Printing in other relevant ISO and IEC TCs, in other SDOs and in consortia.

3) Identify and propose how JTC 1 could address ICT standardization needs of 4D Printing.

4) Provide a progress report to the 11th JTC 1/WG 12 Meeting including recommendations for further study and/or potential NWIPs.

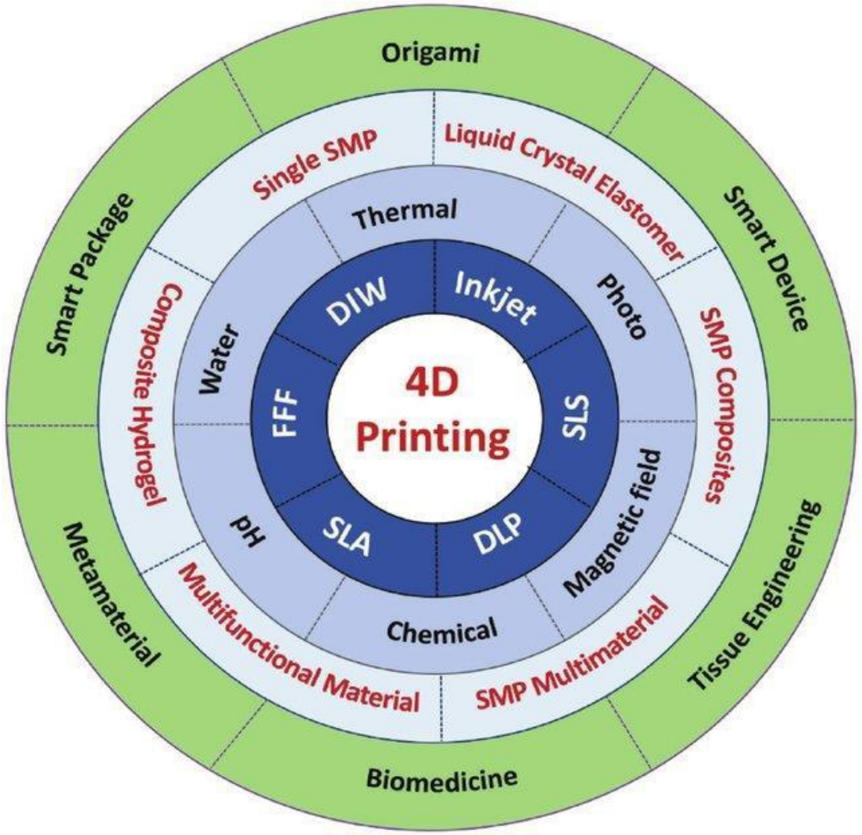
Membership in the AHG 1 is open to:

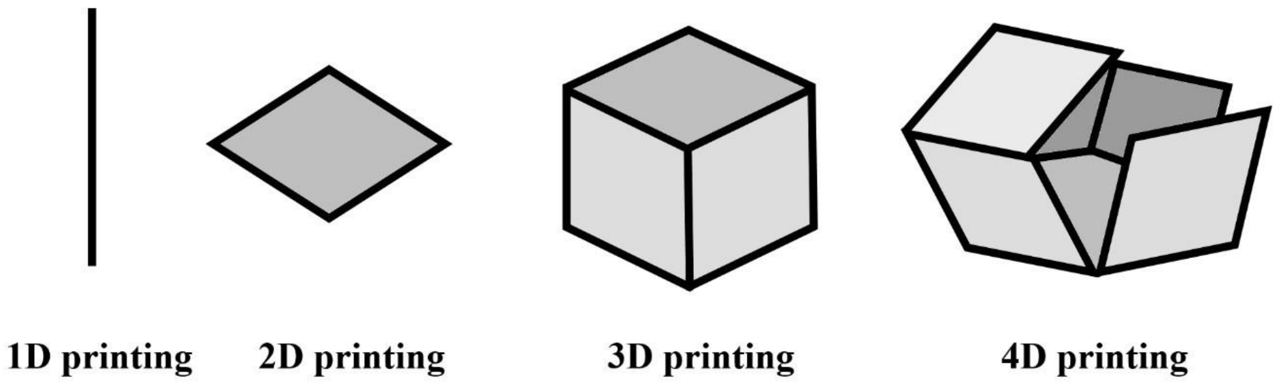
- JTC 1/WG 12 registered experts and Category C liaisons with JTC 1/WG 12;
- Appointed experts from JTC 1/SCs, JTC 1/WGs, relevant ISO and IEC TCs;
- Invited standards setting organizations that are engaged in 4D Printing standardization

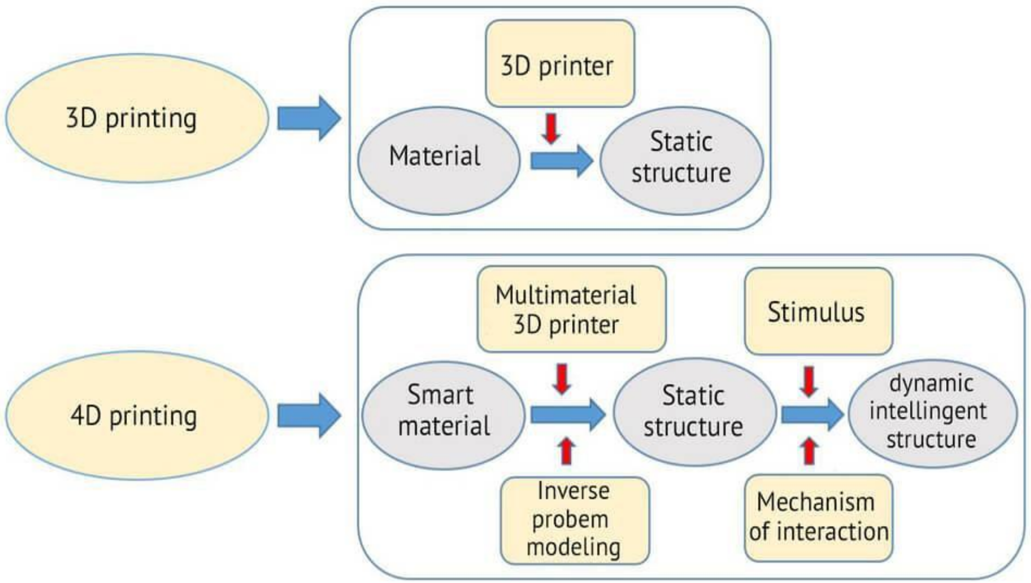
as approved by the AHG.

JTC 1/WG 12 reappoints Mr. Adin Stern (IS) as the Convenor with the following membership: Prof. François Coallier (CA), Dr. Byoung Nam Lee (KR), Mr. Dongyub Lee (KR), Prof. Hwanyong Lee (KR), Prof. Jumyung Um (KR), Dr. Atsuhiko Onuma (JP), Prof. Kyu-won Shim (KR), and Prof. Yonghui Liu (CN).

JTC 1/WG 12 requests the AHG 1 Convenor to report the AHG 1 activity no later than 2024-01-15.


4D Printing
DIW
Inkjet
SLS
DLP
SLA
FFF
Thermal
Photo
Magnetic field
Chemical
pH
Water
Single SMP
Liquid Crystal Elastomer
SMP Composites
SMP Multimaterial
Multifunctional Material
Composite Hydrogel
Origami
Smart Device
Tissue Engineering
Biomedicine
Metamaterial
Smart Package


1D printing
2D printing
3D printing
4D printing


3D printing
3D printer
Material
Static structure
4D printing
Multimaterial 3D printer
Stimulus
Smart material
Static structure
dynamic intelligent structure
Inverse probem modeling
Mechanism of interaction

AHG 3 on 3D Scanning for 3D printing

JTC 1/WG 12 agrees to reconstitute AHG 3 on 3D scanning for 3D printing with the following

Terms of Reference:

1) Investigate current market and technical status related to 3D scanning for 3D printing.

2) Investigate and assess the current status of standardization activities relevant to 3D scanning in other relevant ISO and IEC TCs, in other SDOs, and in consortia.

3) Investigate the future impact of new ICT technology (e.g. digital twin, metaverse) to JTC 1 with 3D scanning for 3D printing.

4) Provide gap analysis for standardization opportunities related to 3D scanning for 3D printing.

5) Identify and propose how JTC 1 could address ICT standardization needs of 3D scanning for 3D printing.

6) Propose, if appropriate, new work items related to 3D scanning and 3D replications (onestop continuous processing that started from 3D scanning to 3D printing).

7) Provide a progress report to the 12th JTC 1/WG 12 Meeting including recommendations for further study and/or potential NWIPs.

Membership in the AHG 3 is open to:

- JTC 1/WG 12 registered experts and Category C liaisons with JTC 1/WG 12;
- Appointed experts from JTC 1/SCs, JTC 1/WGs, relevant ISO and IEC TCs;

JTC 1/WG 12 reappoints Prof. Kyu-won Shim (KR) and Dr. Jason Dowling (AU) as the Co-Convenors with the following membership: Dr. Byoung Nam Lee (KR), Mr. Jonghong Jeon (KR), Mr. Dongyub Lee (KR), Prof. Hwanyong Lee (KR, JTC 1/SC 24 and Khronos Group), Prof. Jumyung Um (KR, ISO/TC 184), Prof. Ji-Man Park (KR, ISO/TC 106), Mr. Yusuke Yasuda (JP), Adin Stern (IS), and Prof. Yonghui Liu (CN).

JTC 1/WG 12 requests the AHG 3 Co-Convenors to report the AHG 3 activity no later than 2024-01-15.

ICT Aspects of 3D Scanning

7.1 Data acquisition: 3D scanners use various technologies such as structured light, laser, or stereo vision to capture the surface geometry of an object or a person. The data captured by the scanner is typically stored in a digital format and can be processed, analyzed, and transmitted using ICT.

7.2 Data processing: After data acquisition, the raw data is typically processed using specialized software to create a 3D model. This process involves a variety of tasks such as data alignment, registration, and meshing.

7.3 Data storage and management: The 3D models generated by scanning process can be large and complex, so they require efficient storage and management. Cloud-based storage and remote access solutions can be used to store and share 3D models, enabling collaboration among multiple users.

7.4 Data visualization: 3D models can be visualized using specialized software, and can be used to generate 2D images, animations, and interactive simulations. This can be done locally or remotely and can be accessed by multiple users.

7.5 Remote access and control: With advancements in ICT, it is possible to remotely control and operate 3D scanners and software, enabling remote data acquisition and processing. This can be useful for applications such as telemedicine or remote monitoring.

Pertinent Standardization activities

10.1 General

		Description
1. Object	1.1 Target object	What is the target object for scanning? (e.g: human body, car, building, city ...)
2. Acquisition methods	2.1 Scanning device	What is the name of the scanning device? (e.g: CT, MRI, intra oral scanner ...)
	2.2 Distance	Scanning distance (e.g.: contact, short-range, mid-range, long-range...)
	2.3 Device Type	Scanning device type (e.g: fixed, handheld, ...)
	2.4 Scan style	3D scanning method (e.g: LASER triangulation, Structured light, Photogrammetry, Contact-based, LASER pulse-based, ...)
	2.5 Raw Data	Raw data format or type

3. Segmentation	3.1 Segmentation required	Dose it require a segmentation technique? If yes, what kind of segmentation techniques are required?
4. 3D model generation	4.1 3D reconstruction	What 3D (object) reconstruction methods are used? (e.g. from point clouds, models, a set of 2D slices, laser scans, photographs ...)
	4.2 3D representation	What 3D representation methods are used? (e.g.: Raw data(point cloud, range image, polygon soup), Solids (Voxels, BSP tree, CSG, Sweep), Surfaces (Mesh, Subdivision, Parametric, Implicit), High-level structures (Scene graph, Skeleton, Application specific))
	4.3 Format	What kind of 3D model format is used?
	4.4 Compression	Is standardized compression technology used?
5. Application	5.1 Registration	Are registration techniques used?
	5.2 Size/Scale	What is the size and scale level?
	5.3 Error range	What is the acceptable range of error?
	5.4 Level of Details	What is the acceptable range of error?
	5.5 Application	Application category (e.g.: space experiments, construction industry and civil engineering, design process, entertainment, 3D photography, Law enforcement, reverse engineering, real estate, virtual/remote tourism, cultural heritage, Medical CAD/CAM, quality assurance and industrial metrology....)
6. Standardization	6.1 Related Standards	List of related standards (finished and under development)

Liaisons

Organization/Committee	Description
ISO/TC 106	Dentistry
ISO/TC 150	AM in surgical implant applications
ISO/TC 171/SC 2	Document file formats, EDMS systems and authenticity of information
ISO/TC 215	Health informatics
ISO/TC 261	Additive Manufacturing
ISO/TC 184/SC 1	Automation systems and integration – physical device control
ISO/TC 184/SC 4	Automation systems and integration – industrial data
ISO/IEC JTC 1/SC 24	Computer graphics, image processing and environmental data representation
ISO/IEC JTC 1/SC 29	Coding of audio, picture, multimedia and hypermedia information
ISO/IEC JTC 1/SC 42	Artificial intelligence
Khronos Group	3D graphics, Virtual and Augmented Reality, Parallel Computing, Machine Learning, and Vision Processing

Current Activities

Projects

- **Published Standards (2)**

  - **ISO/IEC 23510:2021**, Information technology — 3D printing and scanning — Framework for an Additive Manufacturing Service Platform (AMSP)
  - **ISO/IEC 3532-1:2023**, Information technology — Medical image-based modelling for 3D printing — Part 1: General requirements

- **Under development (5)**

  - **ISO/IEC FDIS 3532-2**, Information technology — Medical image-based modelling for 3D printing — Part 2: Segmentation
  - **ISO/IEC CD 8801**, Information Technology — 3D Printing and Scanning — 3D scanned and labeled data Standard Operating Procedure (SOP) for evaluation of modelling from 3D scanned data
  - **ISO/IEC CD 8803**, Information Technology — 3D Printing and Scanning — accuracy and precision evaluation process for modeling from 3D scanned data
  - **ISO/IEC CD 16466**, Information Technology — 3D Printing and scanning — Assessment methods of 3D scanned data for 3D printing model
  - **ISO/IEC AWI 23955**, Information Technology — 3D Printing and scanning — Technical requirements for product data protection of Additive Manufacturing Service Platform (AMSP)

ISO/IEC 23510:2021, Information technology — 3D printing and scanning — Framework for an Additive Manufacturing Service Platform (AMSP)

Contents

Page

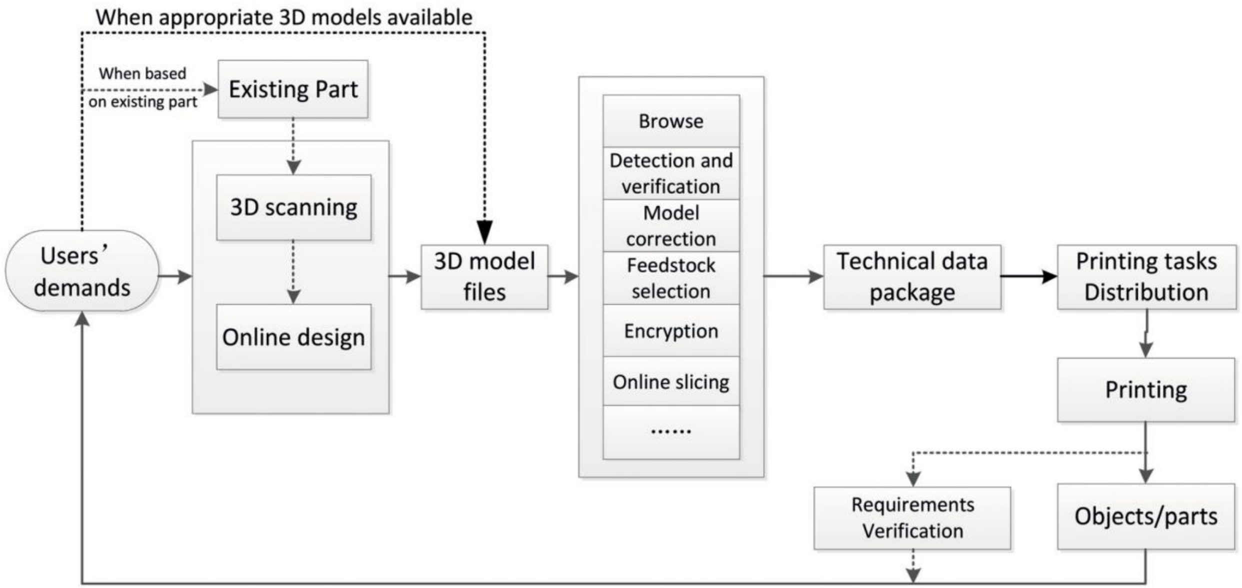
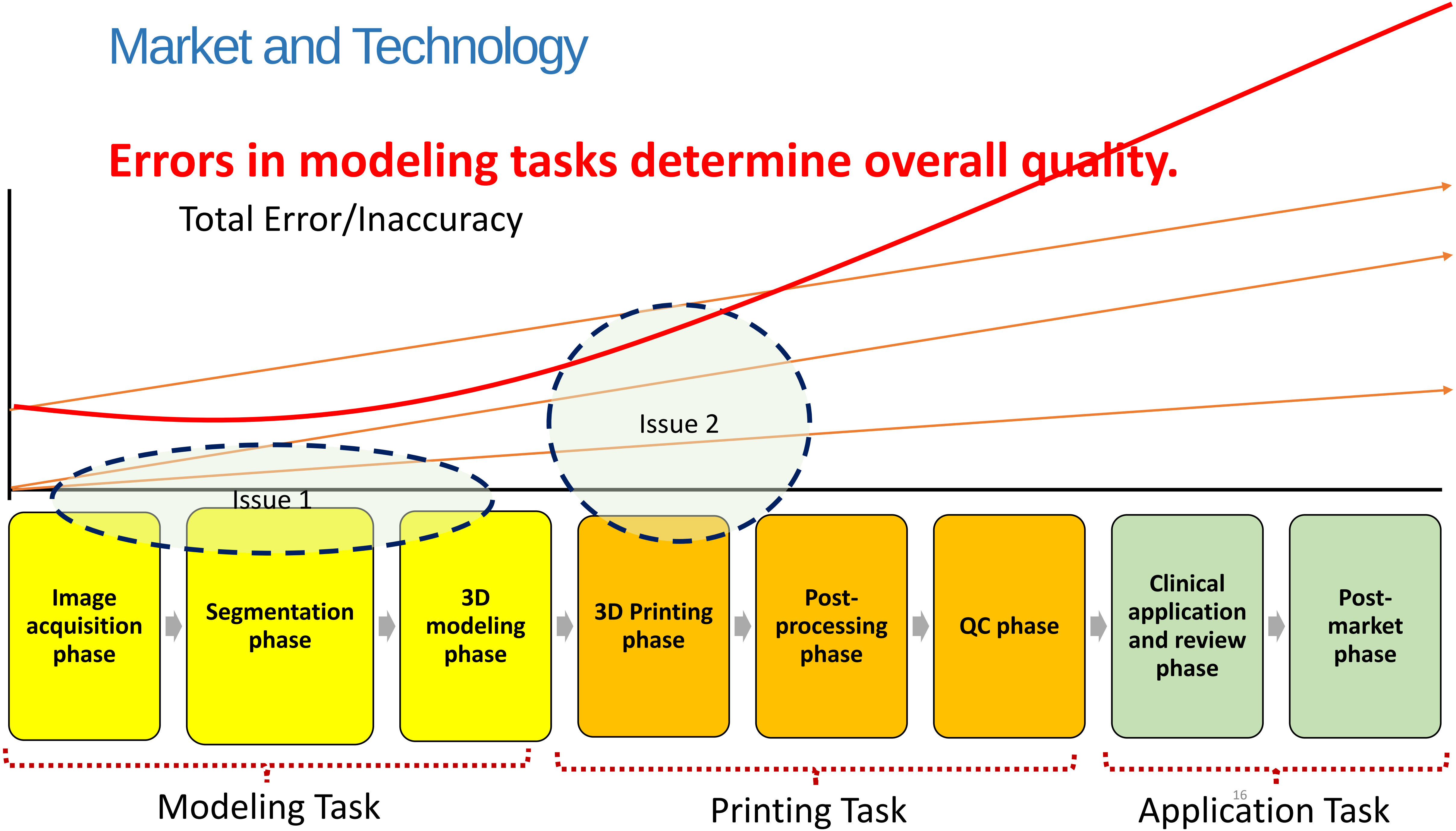


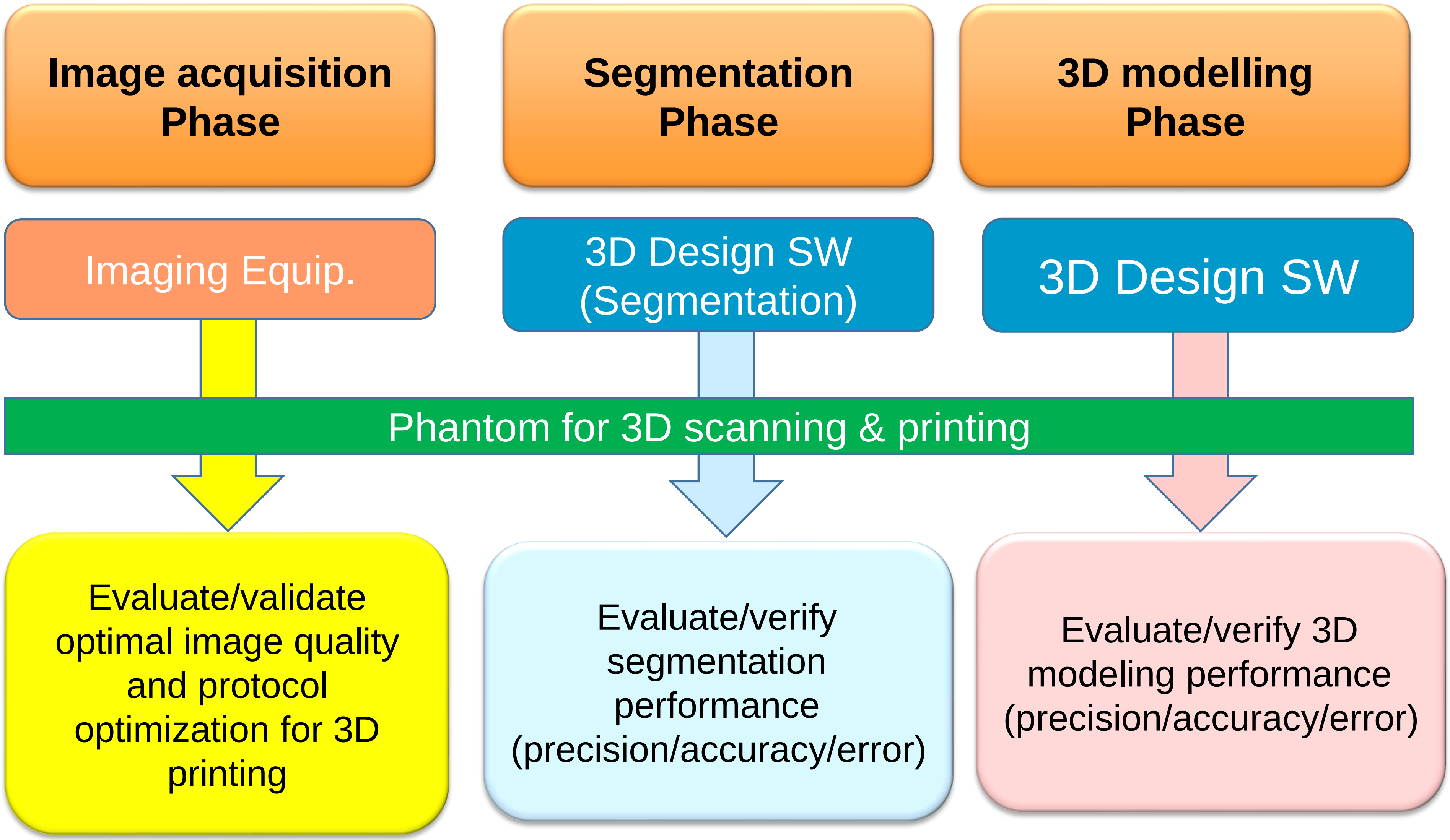
Figure 2 — Typical workflow of an AMSP

Market and Technology

Errors in modeling tasks determine overall quality.



Scope of Items



ISO/IEC CD 8801

IEC

ed.1 - id.84597 ISO/IEC JTC 1/WG 12 30.20

Title

en fr

en Information Technology — 3D Printing and Scanning-- 3D scanned and labeled data Standard Operating Procedure (SOP) for evaluation of modelling from 3D scanned data

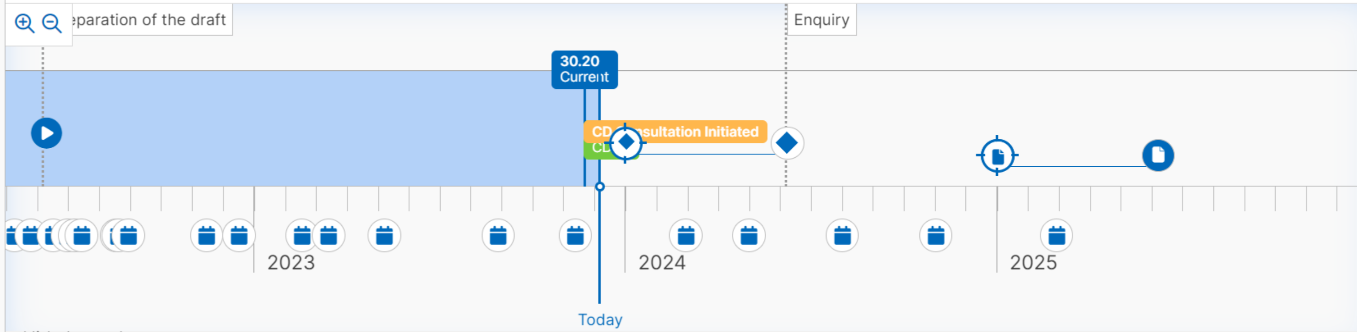
fr Titre manque

Scope

en

Timeline

Registration date	Timeframe	Time since registration	In stage	STATUS
2022-06-08	36 months	18 months	30.20 for 15 days	en CD consultation initiated



Hide legend

- Project approved (clock starts)
- Meeting
- Past period
- Critical period

	Target/Critical	Limit/Critical
Publication		
DIS		
Stage		

Stage

Stage	Version	Description	Go to draft	Target date	Limit date	Started	Status
30.00	1	Committee draft (CD) registered				2023-11-22	Closed
30.20	**1**	**CD study/ballot initiated**				**2023-11-23**	**Current**
30.60	1	Close of voting/comment period					Awaiting
30.92	1	CD referred back to Working Group					Awaiting

Scope

- This document describes a standard operating procedure (SOP) of a test data for the evaluation of modelling from 3D scanned data. And the test data consists of 3D scanned data and its corresponding label data
- This document classifies the main task phases and defines the required tasks in each phase on 3D scanned and labeled data SOP
- This document defines essential requirements of test data for evaluating modelling from 3D scanned data and describing how to check them.

Ballots

Type	Version	Started	End date	Status	Result
CD	1	2023-11-23	2024-01-18	OPEN	
NP	1	2022-02-08	2022-05-03	CLOSED	-

Responsibilities

Project Leader
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Committee Manager
Rajchel Lisa Mrs.

Secretariat
ANSI

Convenor
Shim Kyu-Won Prof.

ISO Technical Programme Manager (TPM)
Dryden Andrew Mr.
Dutnall Stephen Mr

ISO Editorial Programme Manager (EPM)
Reid-Jamond Alison Ms

ISO/IEC CD 8803

IEC

ed.1 - id.84598 ISO/IEC JTC 1/WG 12 30.20

Title

en fr

en Information Technology — 3D Printing and Scanning — accuracy and precision evaluation process for modeling from 3D scanned data

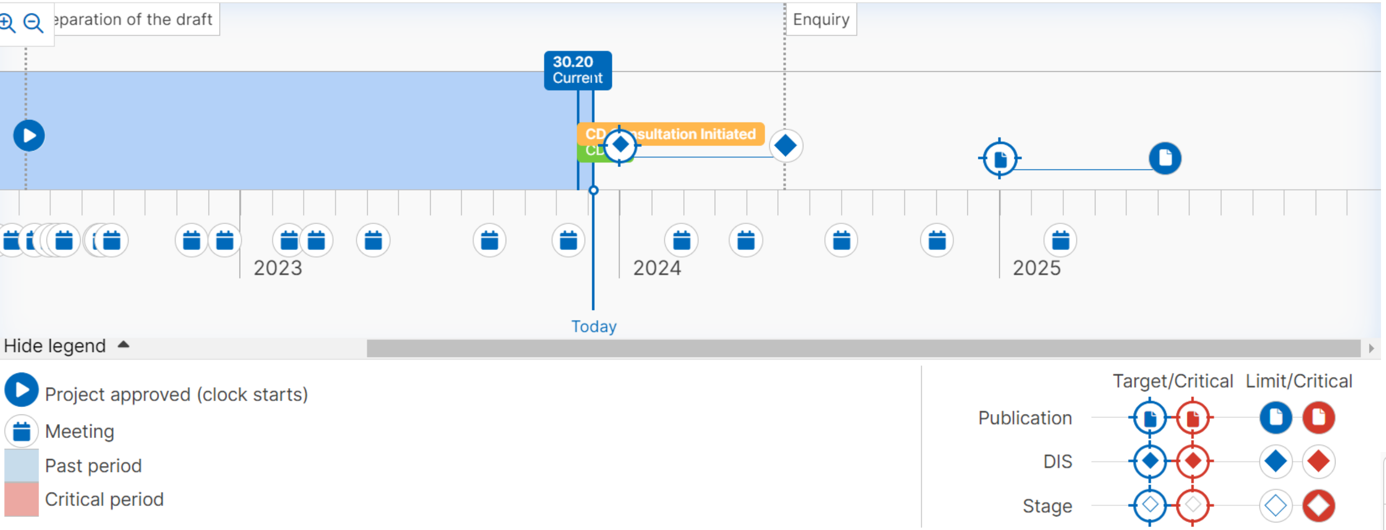
fr Titre manque

Scope

en

Timeline

Registration date	Timeframe	Time since registration	In stage	STATUS
2022-06-09	36 months	17 months	30.20 for 15 days	en CD consultation initiated



Stage

Stage	Version	Description	Go to draft	Target date	Limit date	Started	Status
30.00	1	Committee draft (CD) registered				2023-11-22	Closed
30.20	**1**	**CD study/ballot initiated**				**2023-11-23**	**Current**
30.60	1	Close of voting/comment period					Awaiting
30.92	1	CD referred back to Working Group					Awaiting

Scope

- This document defines a standardized accuracy and precision evaluation process for modelling from 3D scanned data. The set of processes, activities and tasks described in this document provides a common framework for evaluating quality factors such as accuracy and precision for the modelling from 3D scanned data.
- This document is not intended to evaluate the 3D printed product itself.

Ballots

Type	Version	Started	End date	Status	Result
CD	1	2023-11-23	2024-01-18	OPEN	
NP	1	2022-02-08	2022-05-03	CLOSED	-

Responsibilities

Project Leader
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ISO Editorial Programme Manager (EPM)
Reid-Jamond Alison Ms

ISO/IEC CD 16466

IEC

ed.1 - id.84599 ISO/IEC JTC 1/WG 12 30.20

Title

en fr

en Information Technology — 3D Printing and scanning — Assessment methods of 3D scanned data for 3D printing model

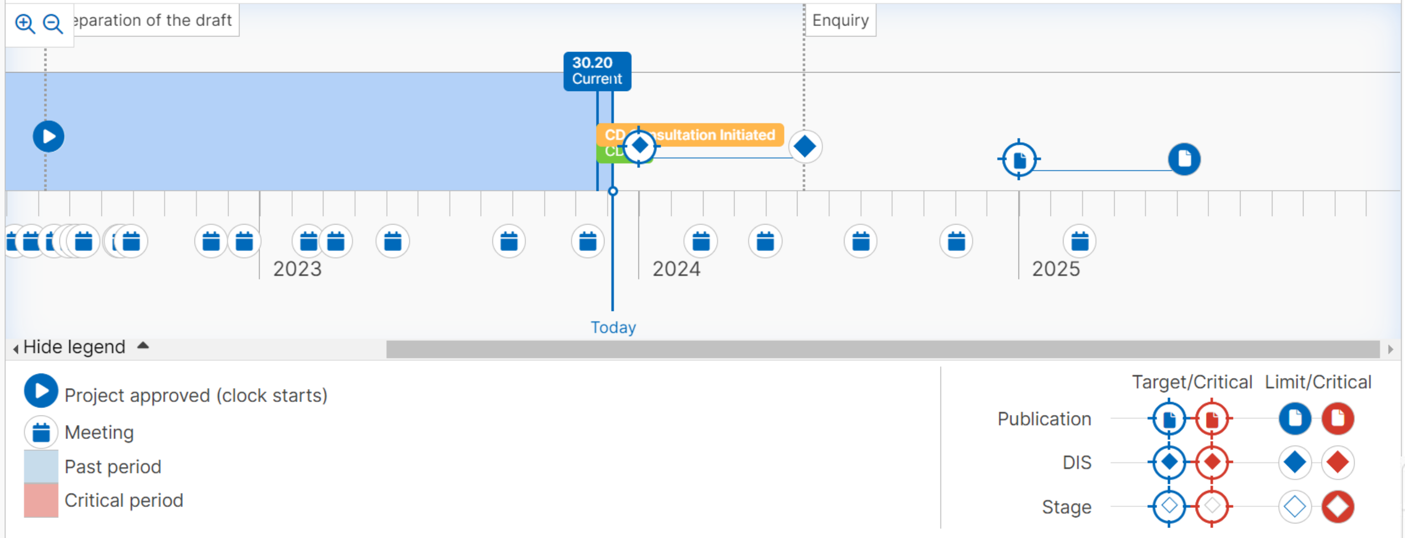
fr Titre manque

Scope

en

Timeline

Registration date	Timeframe	Time since registration	In stage	STATUS
2022-06-09	36 months	17 months	30.20 for 15 days	en CD consultation initiated



Stage

Stage	Version	Description	Go to draft	Target date	Limit date	Started	Status
30.00	1	Committee draft (CD) registered				2023-11-22	Closed
30.20	**1**	**CD study/ballot initiated**				**2023-11-23**	**Current**
30.60	1	Close of voting/comment period					Awaiting
30.92	1	CD referred back to Working Group					Awaiting

Scope

- This document specifies the assessment methods of 3D scanned data for 3D printing model for the accuracy and precision in the total 3D printing life cycle.
- This document focusses mainly on 3D scanned data from computed tomography. Computed tomography can acquire the informations of internal structures, regional density, orientation and/or alignment of scanning objects as well as shape and appearance.
- This document is not intended to evaluate the 3D printed product itself.

Ballots

Type	Version	Started	End date	Status	Result
CD	1	2023-11-23	2024-01-18	OPEN	
NP	1	2022-02-08	2022-05-03	CLOSED	-

Responsibilities

Project Leader
Shim Kyu-Won Prof.

Committee Manager
Rajchel Lisa Mrs.

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Convenor
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ISO Technical Programme Manager (TPM)
Dryden Andrew Mr.
Dutnall Stephen Mr

ISO Editorial Programme Manager (EPM)
Reid-Jamond Alison Ms

Meeting Records

- Study Group

The 1st SG 3 F2F Meeting was held in May 24-26, 2017 in Seoul, Korea

The 2nd SG 3 F2F Meeting was held in August 29-31, 2017 in Montreal, Canada

- Working Group

The 1st WG 12 F2F Meeting was held in October 15-17, 2018 in Seoul, Korea

The 2nd WG 12 F2F Meeting was held in February 26-28, 2019 in New York, United State

The 3rd WG 12 F2F Meeting was held in August 27-29, 2019 in Dublin, Ireland

The 4th WG 12 Meeting was held with hybid mode of F2F and Virtual in March 3-5, 2020 in New York, United State (COVID-19 Pandemic)

The 5th WG 12 Meeting was held fully virtually in August 25-27, 2020

The 6th WG 12 Meeting was held fully virtually in March 8-12, 2021

The 7th WG 12 Meeting was held fully virtually in August 16-20, 2021

The 8th WG 12 Meeting was held fully virtually in February 14-17, 2022

The 9th WG 12 Meeting was held fully virtually in August 29-September 1, 2022

The 10th WG 12 F2F Meeting was held with remote participants in March 14-16, 2023 in Tel Aviv, Israel

The 11th WG 12 F2F Meeting was held with remote participants in August 29-September 1, 2023 in Seoul, Korea

The 1st F2F Meeting for ISO/IEC JTC 1/WG12 in Seoul Korea (15-17 October, 2018)

Current Activities

Meetings

2nd NY, USA

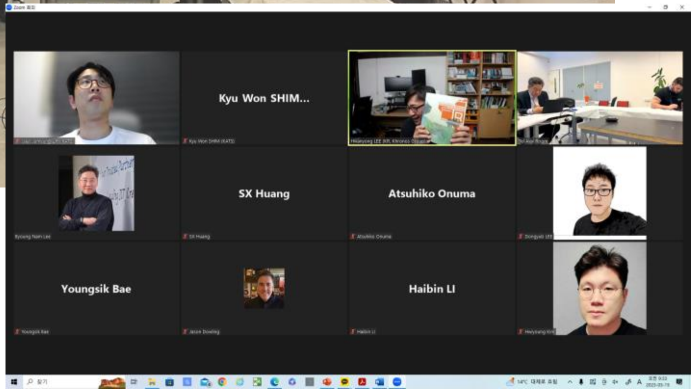
3rd Dublin, Ireland

2020. 03 4th NY, USA -> COVID-19 Pandemic

Current Activities

Meetings

- March 2023
  - 10th WG 12 F2F Meeting
  - Tel Aviv, Israel
- August 2023
  - 11th WG 12 F2F Meeting
  - Seoul, Korea
- March 2024
  - 12th WG 12 F2F meeting
  - Sydney, Australia
- August 2024
  - 13th WG 12 F2F meeting
  - TBD, China



JTC 1/AG 21 or "JTC1 strategic direction,“

- the strategic direction and operational structure of JTC 1.
- addressing future environmental changes and adapting JTC 1's operations accordingly.

ISO IEC

ISO/IEC JTC 1/AG 21 **N 87**

ISO/IEC JTC 1/AG 21 "JTC1 strategic direction"
Convenorship: **AFNOR**
Convenor: **Bensalem Norbert M.**

Revised SC 41 Chair Contribution - AG21 JTC 1 Modeling v1.2

Document type	Related content	Document date	Expected action
Meeting / Working documents for discussion	Meeting: VIRTUAL 29 Jun 2023	2023-06-14	COMMENT/REPLY by 2023-06-29

Replaces: N 86 SC 41 Chair Contribution - AG21 JTC 1 Modeling v1.0

ISO/IEC JTC 1 **N 16484**

ISO/IEC JTC 1 "Information technology"
Secretariat: **ANSI**
Committee manager: **Rajchel Lisa Mrs.**

AG 21 Interim Report

Document type	Related content	Document date	Expected action
Project / Other	Meeting: Berlin (Germany) 13 Nov 2023	2023-09-21	**COMMENT/REPLY** by 2023-10-16

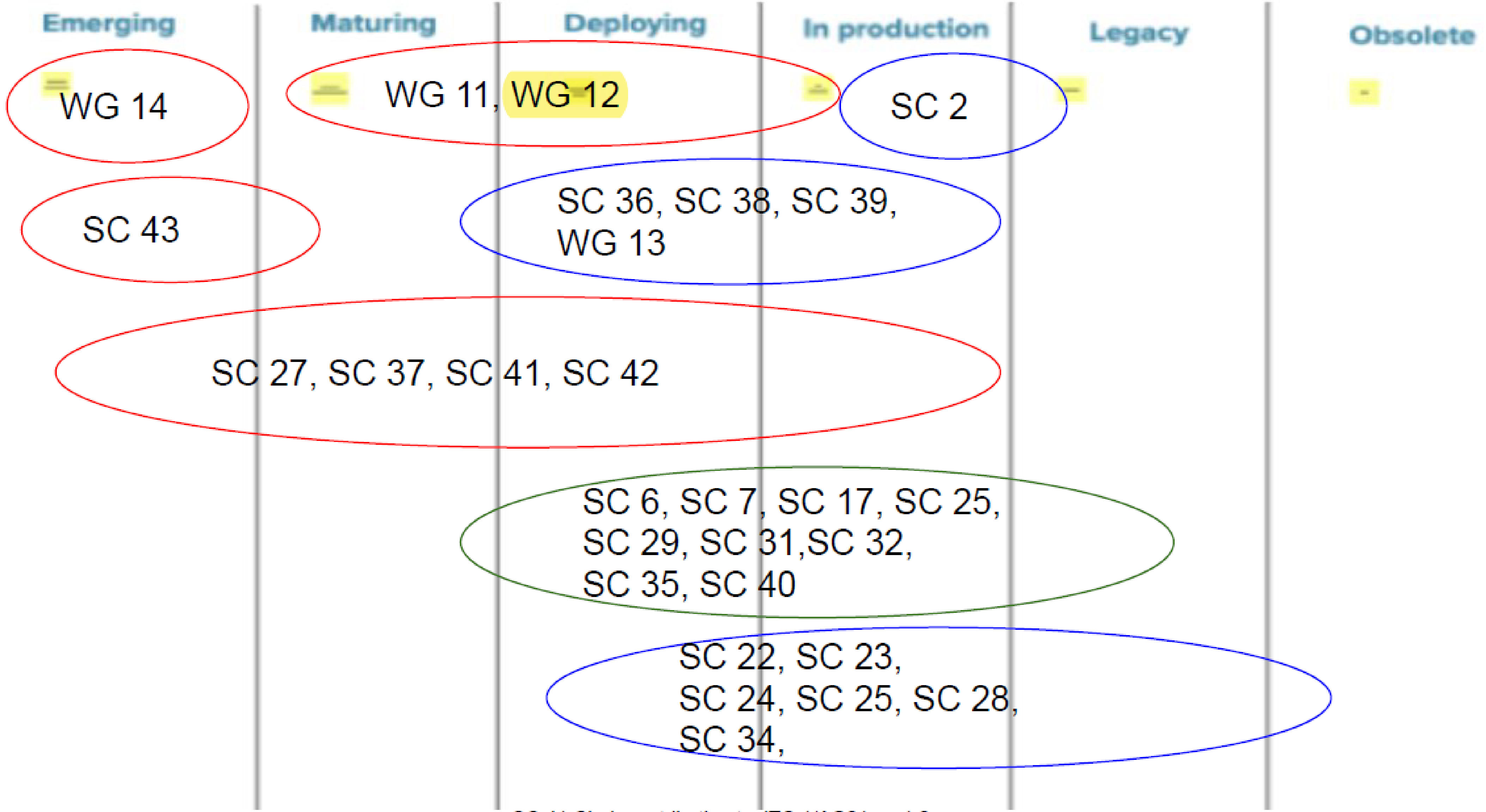
Description

This document is circulated for review and consideration at the November 2023 JTC 1 Plenary.

JTC 1 entities by technical areas (1)

Technical Areas	ISO/IEC JTC 1 (Information Technology) Subcommittees and Working Groups
Application Domains Technologies & IT Integration	SC 27 - Information security, cybersecurity and privacy protection (JWG 6) SC 36 - Learning Technology SC 41 – Internet of Things and Digital Twin (WG 5 , WG 7, JWG 17, JWG 24, JWG3) SC42 - Artificial Intelligence (JWG 3)
Cultural and Linguistic Adaptability and User Interfaces	SC 02 - Coded Character Sets SC 22/WG 20 – Internationalization SC 35 - User Interfaces
Data Capture and Identification Systems	SC 17 - Cards and Personal Identification SC 31 - Automatic Identification and Data Capture Techniques
Data Management and Governance	SC 32 - Data Management and Interchange SC 42 - Artificial Intelligence (WG2) SC 40 – IT Governance and IT Management (ISO/IEC 38505-2 & 3) SC 07 - Software and System Engineering (ISO/IEC 25012)
Document Description Languages	SC 34 - Document Description and Processing Languages
Information Interchange Media	SC 23 - Optical Disk Cartridges for Information Interchange
Multimedia and Synthesis	SC 24 - Computer Graphics and Image Processing SC 29 - Coding of Audio, Picture, and Multimedia and Hypermedia Information WG12 - 3D Scanning and Printing SC 41 – Internet of Things and Digital Twin (WG6)

JTC 1 entities technology maturity map



JTC 1 entities sectors stakeholders

Application sectors facing

Formal cooperative work with non-IT sectors entities: SC 27, SC 41, SC 42, JTC 1 (WG 11), SC 25.

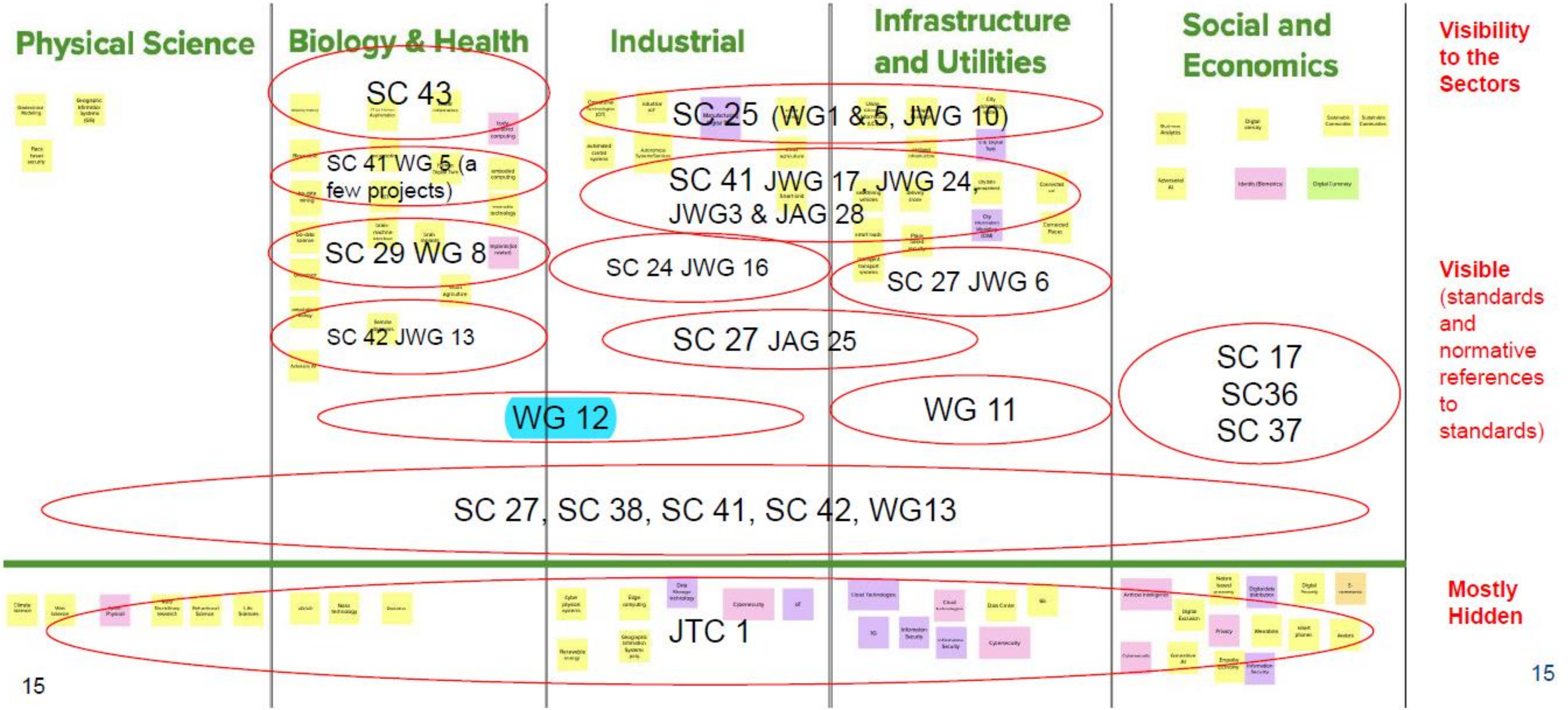
SC 36, SC 7, SC 17, SC 31, SC 35, SC 37, SC 38, WG12, WG 13.

SC 24, SC 27, SC 43, SC 28, SC 40.

SC 2, SC 6, SC 22, SC 23, SC 29, SC 32, SC 34, SC 39, WG 14.

IT sector facing

JTC 1 entities non-IT sectors mapping



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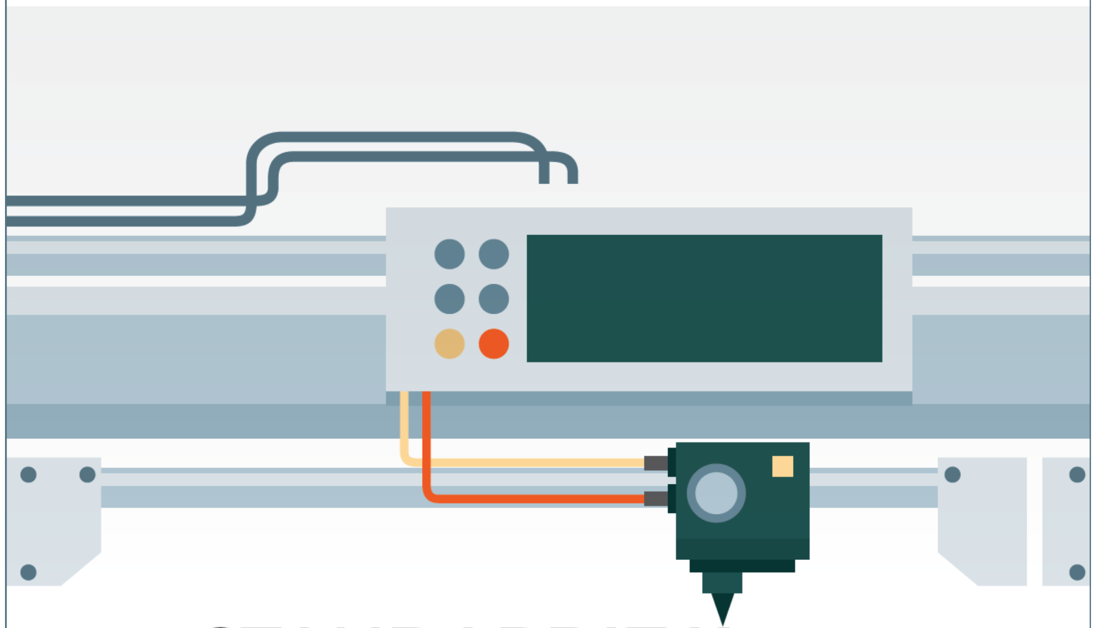
America Makes ANSI



STANDARDIZATION ROADMAP FOR ADDITIVE MANUFACTURING

Version 3.0 | July 2023

Prepared by the America Makes & ANSI Additive Manufacturing Standardization Collaborative (AMSC)

U.S. Army Combat Capabilities Development Command (DEVCOM) Armaments Center	Peter Canales, Ryan Carpenter, Erin Hardmeyer, Elias Jelis, John LaBar, Mishail Sharma
U.S. Army DEVCOM Army Research Laboratory	Matthew Feurer, William Lum, Wayne Ziegler[3]
U.S. Army DEVCOM Ground Vehicle Systems Center (GVSC)	Aaron LaLonde, Eric Niemasz
U.S. Department of Defense (DoD) Defense Advanced Research Projects Agency (DARPA)	Andrew Detor
U.S. Department of Defense (DoD) Defense Innovation Unit (DIU)	Travis DeMeester, Joel Van Brunt
U.S. Department of Defense (DoD) Defense Logistics Agency (DLA)	Jesse Chambers,[3] Tony Delgado, Kyle Hedrick
U.S. Department of Defense (DoD) DLA Aviation	David Anderegg, Jorge Bentacourt, Matthew Borsinger
U.S. Department of Defense (DoD) Manufacturing Technology (Man Tech) Program	Brett Conner, Tracy Frost
U.S. Department of Energy (DOE)	Blake Marshall[3]
U.S. Food and Drug Administration (FDA)	James Coburn,[3] Matthew Di Prima, Xiaofei Liu, Kirstie Snodderly[3]
U.S. Marine Corps	Bill Baker
U.S. Marine Corps Advanced Manufacturing Operation Cell (AMOC)	Douglas McCue
U.S. Navy	Ling Xu, Molly Zantow
U.S. Nuclear Regulatory Commission (NRC)	Amy Hull, Shah Malik
University of Louisville	Li Yang
University of North Dakota	Surojit Gupta
Vibrant Corporation	Eric Biedermann
Victrex	Silvia Berretta, Patrick Clemensen, Robert McKay, Michael Wallick
Virginia Commonwealth University	Barbara Boyan
Volume Graphics GmbH	Philip Sperling
Weatherford	Robert Badrak
Wentworth Institute of Technology	Serdar Tumkor
Wichita State University, National Institute for Aviation Research (NIAR)	Rachael Andrulonis,[4] Mark Shaw
Wohlers Associates, powered by ASTM International	Shane Collins[4]
Xerox	Farhan Khan
Yonsei University, Seoul, Korea	Kyu Won Shim

2.3.3.7.2 Data Output from Imaging Sources

Patient-specific data can be acquired by a variety of medical imaging modalities, including CT scan, MRI, and ultrasound. The Digital Imaging and Communications in Medicine (DICOM) standard is overseen by the Medical Imaging & Technology Alliance (MITA), a division of the National Electrical Manufacturers Association (NEMA). The DICOM standard applies to communication and management of medical imaging information and related data. The standard facilitates interoperability of medical imaging equipment by specifying protocols for network communication, syntax and semantics of commands, media storage, and file format structure. DICOM is the standard used by all manufacturers of X-ray, CT scan, and MRI imaging equipment. However, the ability to capture radiological output data varies depending on the manufacturer.

Published Standards, etc.

- 3D Manufacturing Format (3MF)
- ISO/ASTM 52915:2020, Specification for additive manufacturing file format (AMF) Version 1.2
- ISO/ASTM TR 52916:2022, Additive manufacturing for medical — Data — Optimized medical image data
- ISO/IEC 3532-1, Information technology – Medical image-based modelling for 3D Printing – Part 1: General requirements

In-Development Standards

- ISO/IEC CD 8803, Information Technology — 3D Printing and Scanning — Accuracy and precision evaluation process for modeling from 3D scanned data (ISO/IEC JTC 1)
- ISO/IEC AWI 16466, Information Technology — 3D Printing and Scanning — Assessment methods of 3D scanned data for 3D printing model (ISO/IEC JTC 1)
- ISO/IEC DIS 3532-2, Information technology – Medical image-based modelling for 3D Printing – Part 2: Segmentation (ISO/IEC JTC 1)

2.3.3.7.3 Data Acquisition for 3D Modeling: Imaging Protocols

The issue here is multifold:

- Diagnostic CT and MRI image data is routinely acquired for the CAD file or modelling application used to create the 3D file for use in the additive manufacturing process. However, the metadata that describes the accuracy, precision, and quality of the source files may not meet the needs of 3D printed patient-matched medical devices.
- Different imaging equipment has different installed protocols and many patient-matched medical device manufacturers require specialized protocols.
- There is a clinical balance between image quality and patient exposure.

Published Standards

- ISO/ASTM TR 52916:2022, Additive manufacturing for medical — Data — Optimized medical image data
- ISO/IEC 3532-1, Information technology – Medical image-based modelling for 3D Printing – Part 1: General requirements

In-Development Standards

- ISO/IEC DIS 3532-2, Information technology – Medical image-based modelling for 3D Printing – Part 2: Segmentation (ISO/IEC JTC 1)

2.3.3.7.13 Quality, Verification, and Validation of Medical Product 3D Models

3D models are typically created for a region of interest (ROI). Image processing therefore entails functions such as data segmentation (determining ROI), deleting (eliminating artifacts, noise, and non-ROIs), smoothening, texturing (better visualization, surface finishing), and reducing post-processing time. Models are transferred back and forth between image processing and graphic software to create the best model.

Published Standards

- ISO/IEC 3532-1, Information technology – Medical image-based modelling for 3D Printing – Part 1: General requirements

In-Development Standards

- ISO/IEC CD 8803, Information Technology — 3D Printing and Scanning — Accuracy and precision evaluation process for modeling from 3D scanned data (ISO/IEC JTC 1)
- ISO/IEC AWI 16466, Information Technology — 3D Printing and Scanning — Assessment methods of 3D scanned data for 3D printing model (ISO/IEC JTC 1)
- ISO/IEC DIS 3532-2, Information technology – Medical image-based modelling for 3D Printing – Part 2: Segmentation (ISO/IEC JTC 1)

2.4.3.2 3D Image Quality Indicators (IQI)

Published Standards

- ASME B89.4.23: 2020, X-Ray Computed Tomography (CT) Performance Evaluation provides guidance for performance evaluation for users of the machine to assess.
- ASTM E1695–20e1 Standard Test Method for Measurement of Computed Tomography (CT) System Performance)
- ASTM E1441-19: Standard Guide for Computed Tomography (CT)

In-Development Standards

- ASTM WK84836 New Practice for Standard Practice for Visual Determination of Computed Tomography (CT) Image Quality (in development in E07.01)
- ISO/IEC CD 8803, Information Technology — 3D Printing and Scanning — Accuracy and precision evaluation process for modeling from 3D scanned data (ISO/IEC JTC 1)
- ISO/IEC AWI 16466, Information Technology — 3D Printing and Scanning — Assessment methods of 3D scanned data for 3D printing model (ISO/IEC JTC 1)

2.6 Data

2.6.1 Introduction

As a digital production process, the formatting, extraction, transfer, integration, security and interoperability of data is critical along the entire additive manufacturing value chain. Data will impact the design, testing, validation, qualification, and quality assurance of parts and systems in nearly all industry sectors. Standards which support data management will help inform decision making in AM production. The following links provide more background regarding how data and data management support AM:

- Data Driven Decision Support for Additive Manufacturing
- A Collaborative Data Management System for Additive Manufacturing[45]

standards, for example under ASTM F42.08 and in cooperation with ISO have published ISO/ASTM 52950:2021, Additive manufacturing -- General principles -- Overview of data processing. This section may also include domain specific data needs, such as:

- ISO/IEC 3532-1, Information technology – Medical image-based modelling for 3D Printing – Part 1: General requirements (ISO/IEC JTC 1) deals with image data processing throughout the full lifecycle of 3D printing.
- ISO/IEC 27000:2018, Information technology — Security techniques — Information security management systems — Overview and vocabulary

2.6.9.2 Medical AM Quality Management Systems

The FDA is proposing to expand regulation of hospitals and other "point of care" medical facilities conducting additive manufacturing of medical devices to include individual, patient specific medical devices. This will require point of care facilities to comply with FDA guidance governing manufactured medical devices. A critical requirement within this regulatory "framework" is the creation and use of a quality management system (QMS) that will facilitate validation of each medical device's quality by the

Published Standards

- ISO/ASTM TR 52916:2022, Additive manufacturing for medical — Data — Optimized medical image data
- ISO/ASTM 52915:2020, Specification for additive manufacturing file format (AMF) Version 1.2
- ISO/IEC 3532-1, Information technology – Medical image-based modelling for 3D Printing – Part 1: General requirements

In-Development Standards

- IEEE P3333.2.3™, Standard for Three-Dimensional (3D) Medical Data Management
- ISO/IEC CD 8803, Information Technology — 3D Printing and Scanning — Accuracy and precision evaluation process for modeling from 3D scanned data (ISO/IEC JTC 1/WG12)
- ISO/IEC AWI 16466, Information Technology — 3D Printing and Scanning — Assessment methods of 3D scanned data for 3D printing model (ISO/IEC JTC 1/WG12)
- ISO/IEC DIS 3532-2, Information technology – Medical image-based modelling for 3D Printing – Part 2: Segmentation (ISO/IEC JTC 1/WG12)

Challenges and Opportunities

3D Printing and 3D Scanning are two distinct industries with significant overlap.

These industries are growing rapidly, are being utilized in an increasing array of applications, and are facing many significant challenges.

There is a risk that a large number of collaborator/partners in the same industry can act as a competitor in some situation. It is necessary to communicate and discuss closely at all times so that the cooperative relationship is maintained well.

- ISO/TC 261/WG 4 addresses ‘Data and design’, it does not fully cater to ICT standards.
- ISO/TC 150/JWG 1 focuses on medical 3D printing, but it does not encompass the ICT perspective of data processing and the implant design process itself.

Maintaining a healthy relationship with both ISO/TC 150/JWG 1 and ISO/TC 261, despite their competitive and cooperative dynamics, is indeed crucial.

We should carry out 'open communication, mutual respect, collaboration, conflict resolution and shared goals'.

Many existing groups are already working on underlying technologies and standards, which will provide an opportunity to work closely together to accomplish the needs of the industry and the start-up.

Plan and Strategy

3D Printing and 3D Scanning are inherently cyber-physical systems.

As such, many standardization opportunities cannot be addressed from a strictly ICT point-of-view.

Collaboration with other standards bodies with complementary areas of expertise will be required in many cases. For each opportunity, the following approaches will be considered:

1. If the standardization opportunity is clearly a foundational ICT enabler for 3D printing or 3D scanning, then WG 12 will take the initiative and lead in developing that standard. Examples include but are not limited to underlying broadly applicable file formats, protocols, or cyber-security mechanisms.

2. If the standardization opportunity requires both ICT expertise and domain expertise in another area, then WG 12 will investigate collaborative development opportunities with other entities within ISO and/or IEC, and externally with other appropriate standards bodies. Examples include but are not limited to, specific applications of file formats and protocols, information management policies, data quality standards.

For those 3D printing and scanning related standardization activities with significant ICT concerns currently underway, WG 12 will seek a collaborative arrangement with the standards bodies responsible for the work.

ISO/IEC 3532 series

JTC 1/WG 12 workshop, virtual (2023-12-12, 1100-1400 UTC)

Kyu-Won Shim, MD, PhD.

Convenor of JTC 1/WG 12

Project leader of ISO/IEC 3532-1:2023, ISO/IEC CD 16466

ISO/IEC 3532-1:2023

IEC

ed.1 - id.79624 ISO/IEC JTC 1/WG 12 60.60

Edition date 2023-06

Title

en fr

en Information technology — Medical image-based modelling for 3D printing — Part 1: General requirements
fr Technologies de l'information — Modélisation médicale à base d'images pour l'impression 3D — Partie 1: Exigences générales

Scope

en

Timeline

Development Published

In stage
60.60
for 4 months 12 days

STATUS
en Document published

Stage

Stage	Version	Description	Edit draft	Target date	Limit date	Started	Status
60.00	1	International Standard under publication				2023-04-20	Closed
60.60	**1**	**International Standard published**		**2023-06-09**	**2023-08-24**	**2023-06-09**	**Current**
90.20	1	International Standard under periodical review		2028-04-15			Awaiting
90.60	1	Close of review		2028-09-02			Awaiting

Show all stages

Ballots

Type	Version	Started	End date	Status	Result
FDIS	1	2023-02-22	2023-04-20	CLOSED	Approved
DIS	1	2021-11-18	2022-02-20	CLOSED	Approved
CD		2021-04-01	2021-05-28	CLOSED	-
CD	1	2020-09-16	2020-11-12	CLOSED	-
NP	1	2019-10-03	2019-12-26	CLOSED	-

Responsibilities

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ISO/IEC FDIS 3532-2

IEC

ed.1 - id.79625 ISO/IEC JTC 1/WG 12 50.20

Title

en fr

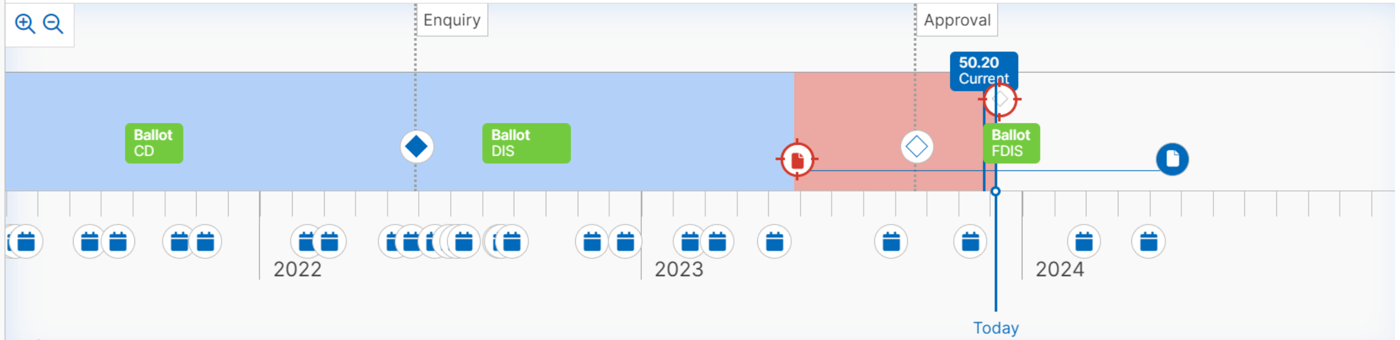
en Information technology — Medical image-based modelling for 3D printing — Part 2: Segmentation

fr Technologies de l'information — Modélisation médicale à base d'images pour l'impression 3D — Partie 2: Segmentation

Scope

Timeline

Registration date	Timeframe	Time since registration	In stage
2020-08-24	57 months	39 months	50.20 for 11 days



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Project approved (clock starts)

Meeting

Past period

Critical period

	Target/Critical	Limit/Critical
Publication		
DIS		
Stage		

Stage

Stage	Version	Description	Go to draft	Target date	Limit date	Started	Status
50.00	1	Final text received or FDIS registered for formal approval		2023-02-16		2023-09-22	Closed
50.20	**1**	**Proof sent to Secretariat or FDIS ballot initiated: 2 months**		**2023-11-27**		**2023-11-27**	**Current**
50.60	1	Close of voting -- Proof returned by Secretariat		2024-01-22			Awaiting
60.60	1	International Standard published		2023-05-30	2024-05-24		Awaiting

Ballots

Type	Version	Started	End date	Status	Result
FDIS	1	2023-11-27	2024-01-22	OPEN	
DIS	1	2022-08-04	2022-10-28	CLOSED	Approved
CD	1	2021-08-26	2021-10-21	CLOSED	-
NP	1	2019-10-03	2019-12-26	CLOSED	-

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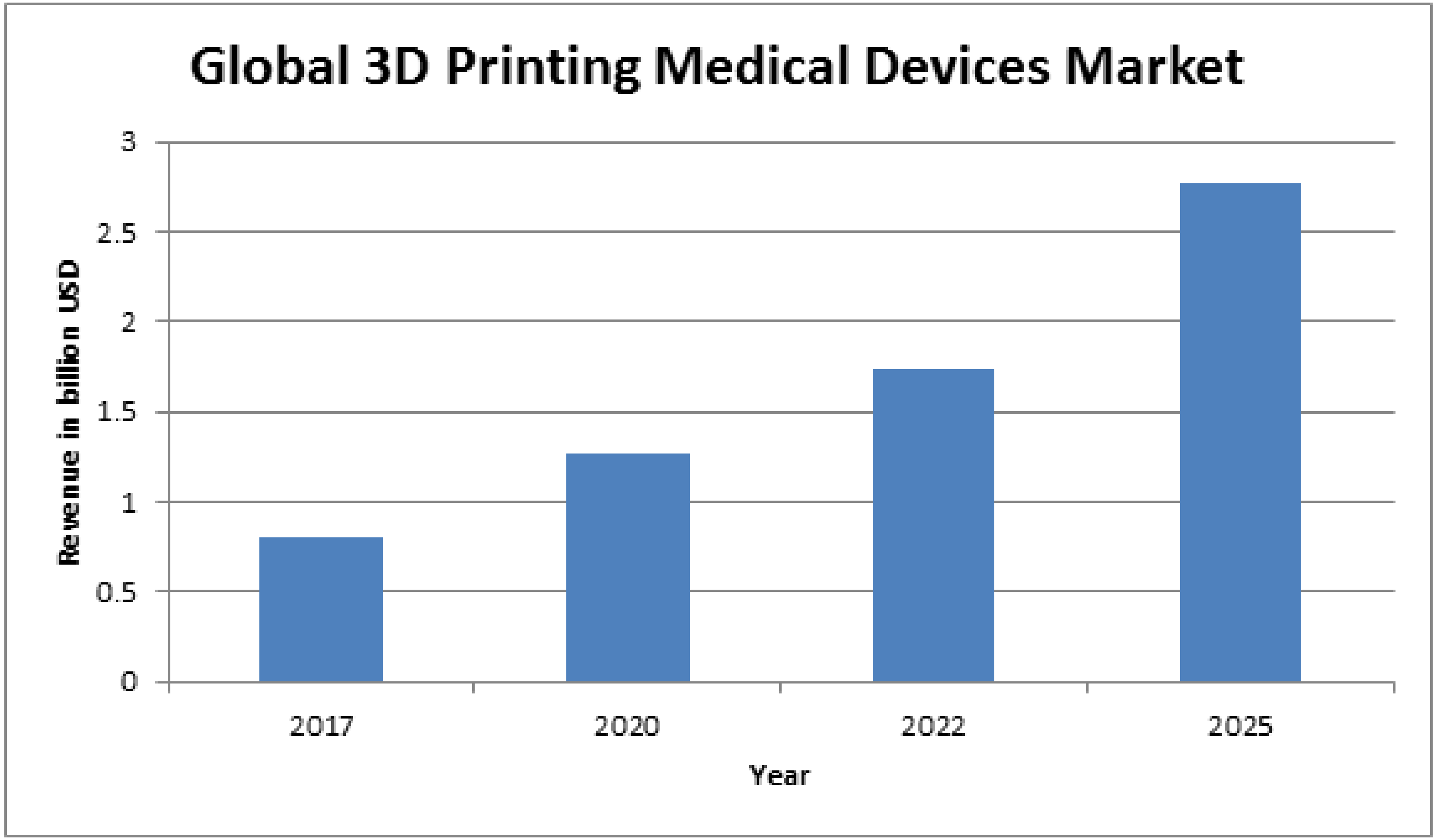
ISO Editorial Programme Manager (EPM)
Reid-Jamond Alison Ms

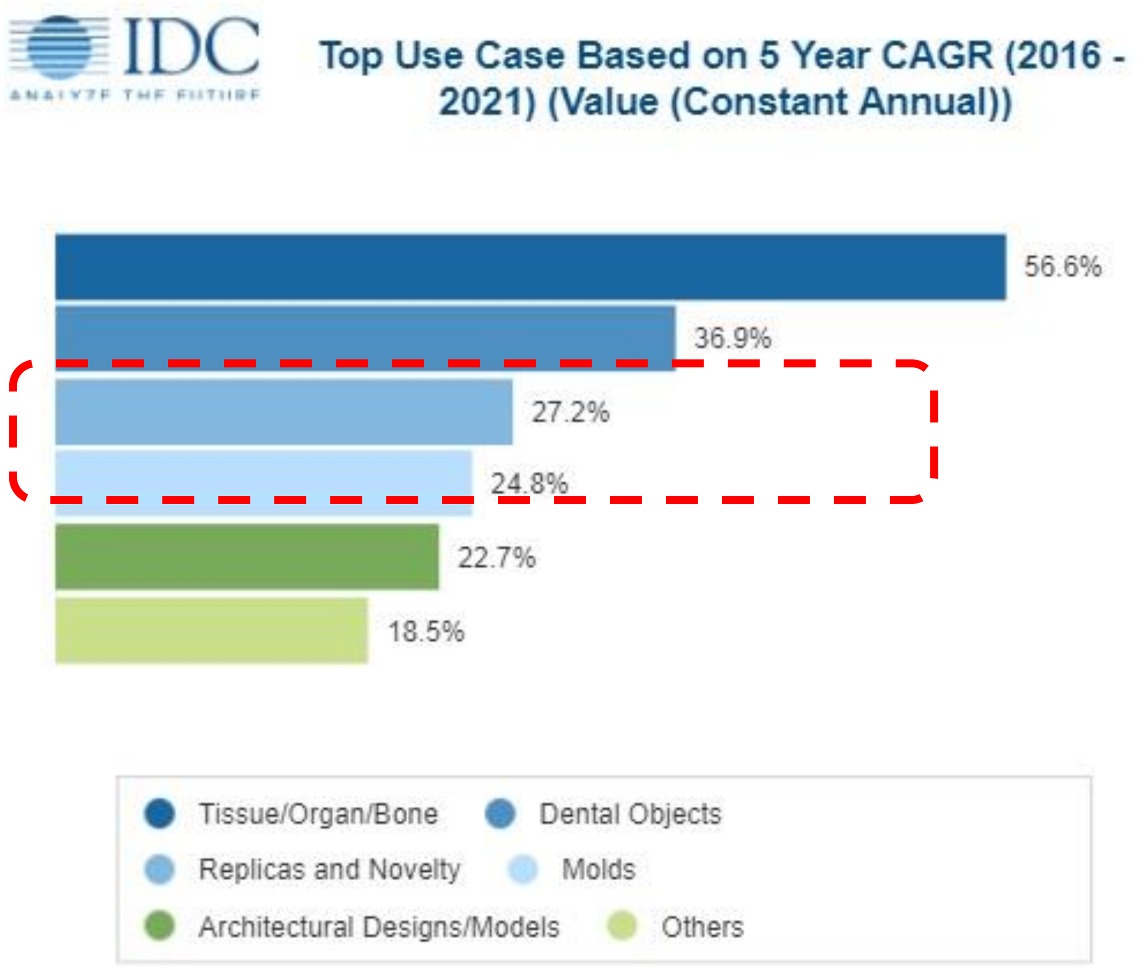
Market and Technology

- **3D Printing Medical Devices Market** is estimated to reach $2.77 billion by 2025; growing at a CAGR of 16.8% between 2017 and 2025. (@profsharemarketresearch)



Market and Technology

- By 2021, IDC expects worldwide spending to be nearly $20.0 billion with a five-year compound annual growth rate (CAGR) of 20.5%.
- **The two use cases of 3D printing** that will see the fastest spending growth – **tissue/organ/bone** (56.6% CAGR) and **dental objects** (36.9% CAGR) – will also be driven by healthcare provider spending.



Source: IDC Worldwide Semiannual 3D Printing Spending Guide, 2017H1

F2F Seoul Meeting for ISO/IEC JTC 1 Study Group on 3D Printing and Scanning, 24 ~ 26 May, 2017

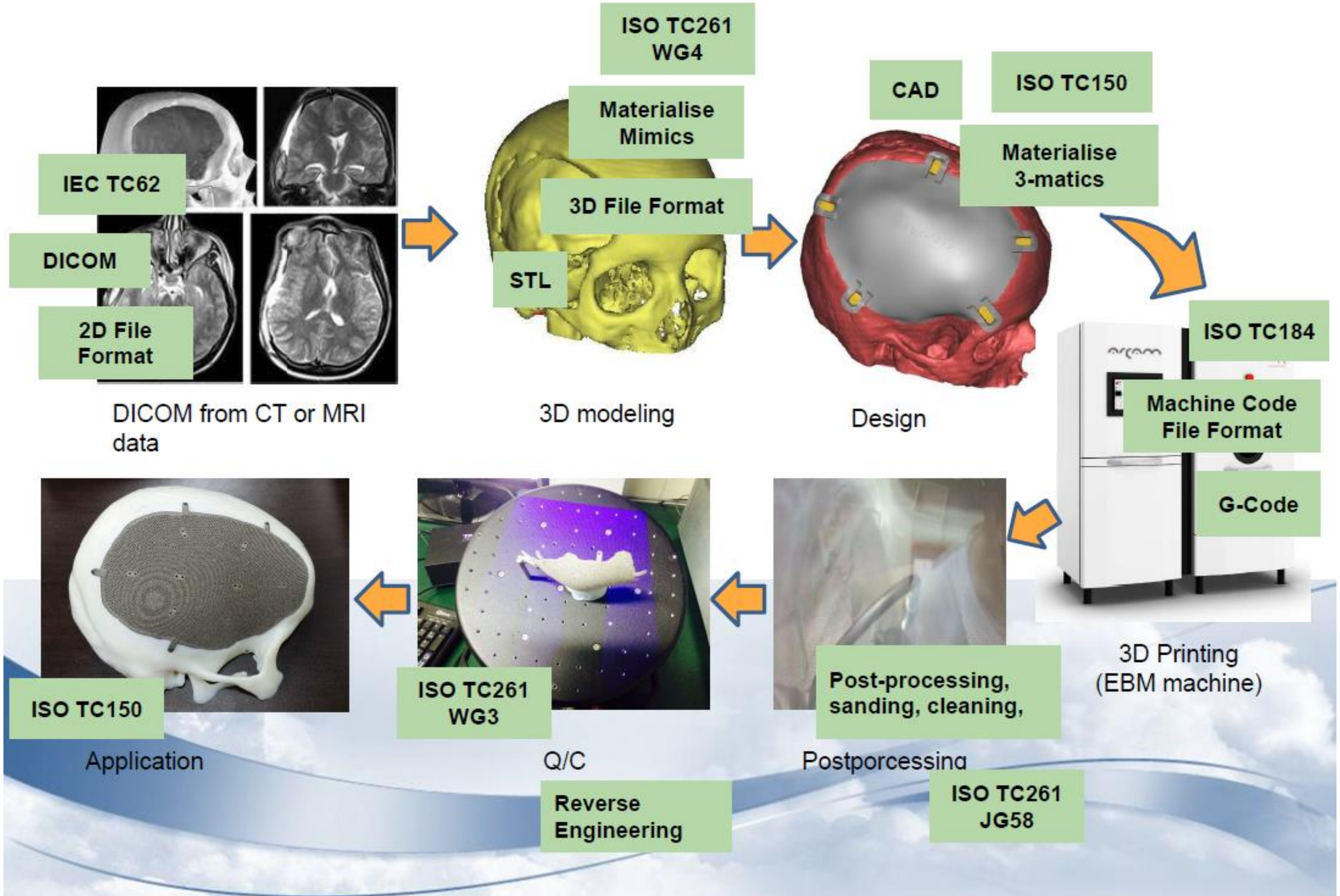
ISO | IEC

ISO/IEC JTC 1/SG 3 **N 30**

ISO/IEC JTC 1/SG 3 3D Printing and scanning Convenorship: KATS (Korea, Republic of)

Document type:	Other document (Open)
Title:	Wrap-up report for cranial implant
Status:	
Date of document:	2017-05-26
Source:	Leader of Editing group 2
Expected action:	INFO
Email of convenor:	b.n.lee@etri.re.kr
Committee URL:	http://isotc.iso.org/livelink/livelink/open/jtc1sg3

3D implant Workflow

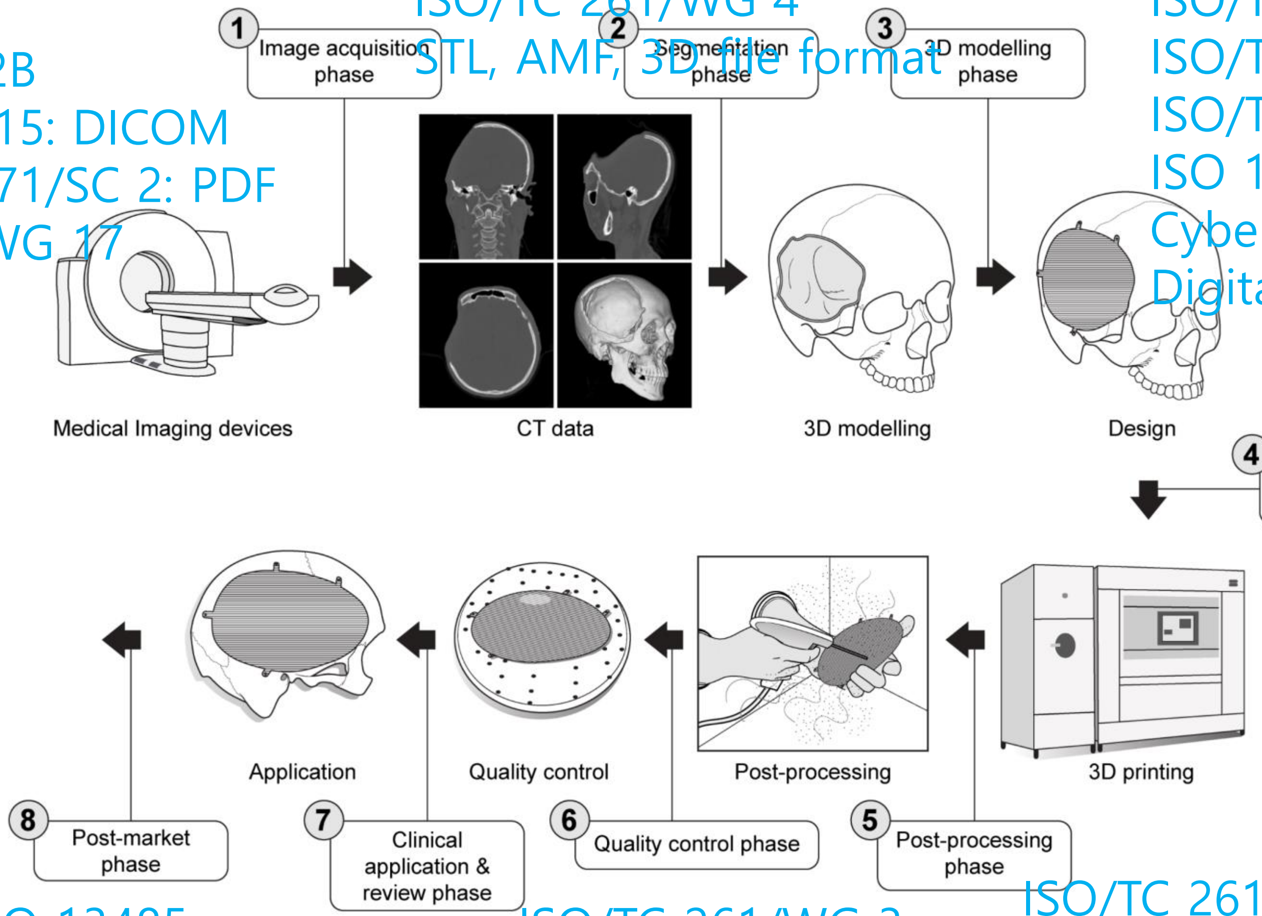


ISO/IEC 23510 AMSP

ISO/IEC FDIS 3532-2
ISO/IEC CD 8803, 8801, 16466
JTC 1/SC 41 Digital twin
JTC 1/SC 24 Computer graphics
JTC 1/SC 42 AI
ISO/TC 261/WG 4
STL, AMF, 3D file format

JTC 1/SC 24
IEC TC 62D
IEC SEG 12 BioDigital convergence
JTC 1/SC 7 Software
ISO/TC 150/JWG 1
ISO/TC 106
ISO/TC 184, ISO/TC 184/SC 4,
ISO/TC 184/SC 4/WG 15
ISO 10303-21: STEP, STEP-NC
Cyber-physical control
Digital manufacturing

IEC TC 62B
ISO/TC 215: DICOM
ISO/TC 171/SC 2: PDF
DICOM WG 17



ISO/TC 261
ISO/TC 184/SC 4
ASTM F42
Cyber-physical control
Machine control
G-code

ISO/TC 261/WG 2/JG 58, ISO/ASTM 52908

ISO/TC 261/WG 3
Reverse engineering
NDT, DICONDE

ISO 13485
ISO/TC 150/JWG 1
ISO CD 5092

Contents

Page

1 Scope

This document specifies the requirements for medical image-based modelling for 3D printing for medical applications. It concerns accurate 3D data modelling in the medical field using medical image data generated from computed tomography (CT) devices. It also specifies the principal considerations for the general procedures of medical image-based modelling. It excludes soft tissue modelling from magnetic resonance image (MRI).

: ISO/IEC 3532-1:2023 touching on CT Scan Data through to image optimization, and with the Point Cloud XYZ format and DICOM data.

ISO/IEC 3532-1:2023 is applicable to NDT or related technology based on CT.

4 Overview of image processing for the medical industry

4.1 Process flow

4.1.1 3D printing process for medical applications

In general, the medical 3D printing processing flow can be divided into eight phases, as shown in Figure 1.

1) **Image acquisition phase**

In the image acquisition phase, medical images are acquired from medical imaging devices such as CT.

2) **Segmentation phase**

In the segmentation phase, the acquired medical images are segmented to fit the design purpose and are processed to be divided (segmented) to extract a subset that would represent the part(s) of the anatomy under consideration.

3) **3D modelling phase**

In the 3D modelling phase, the segmented data representing the human tissue is converted (reconstructed) into a 3D model optimized for 3D printing.

4) **3D printing phase**

In the 3D printing phase, 3D printing is performed using the 3D model designed. For this phase 3D model is processed for 3D printing by slicing, assigning build parameters, being oriented and placed within the build space, and can have support structures generated.

5) **Post-processing phase**

In the post-processing phase, the 3D printed part is post-processed to become fit for actual medical use.

6) **Quality control (QC) phase**

In the QC phase, the 3D printed part is finally verified to meet all requirements (user/design/quality/risk).

7) **Clinical application and review phase**

In the clinical application and review phase, the 3D printed part is reviewed as applicable to clinical application by the healthcare practitioner.

8) **Post-market phase**

In the post-marketing stage, the 3D printed part is managed based on the post-sale market management policy according to product life cycle issues such as tracking management/recall.

F2F Seoul Meeting for ISO/IEC JTC 1 Study Group on 3D Printing and Scanning, 24 ~ 26 May, 2017

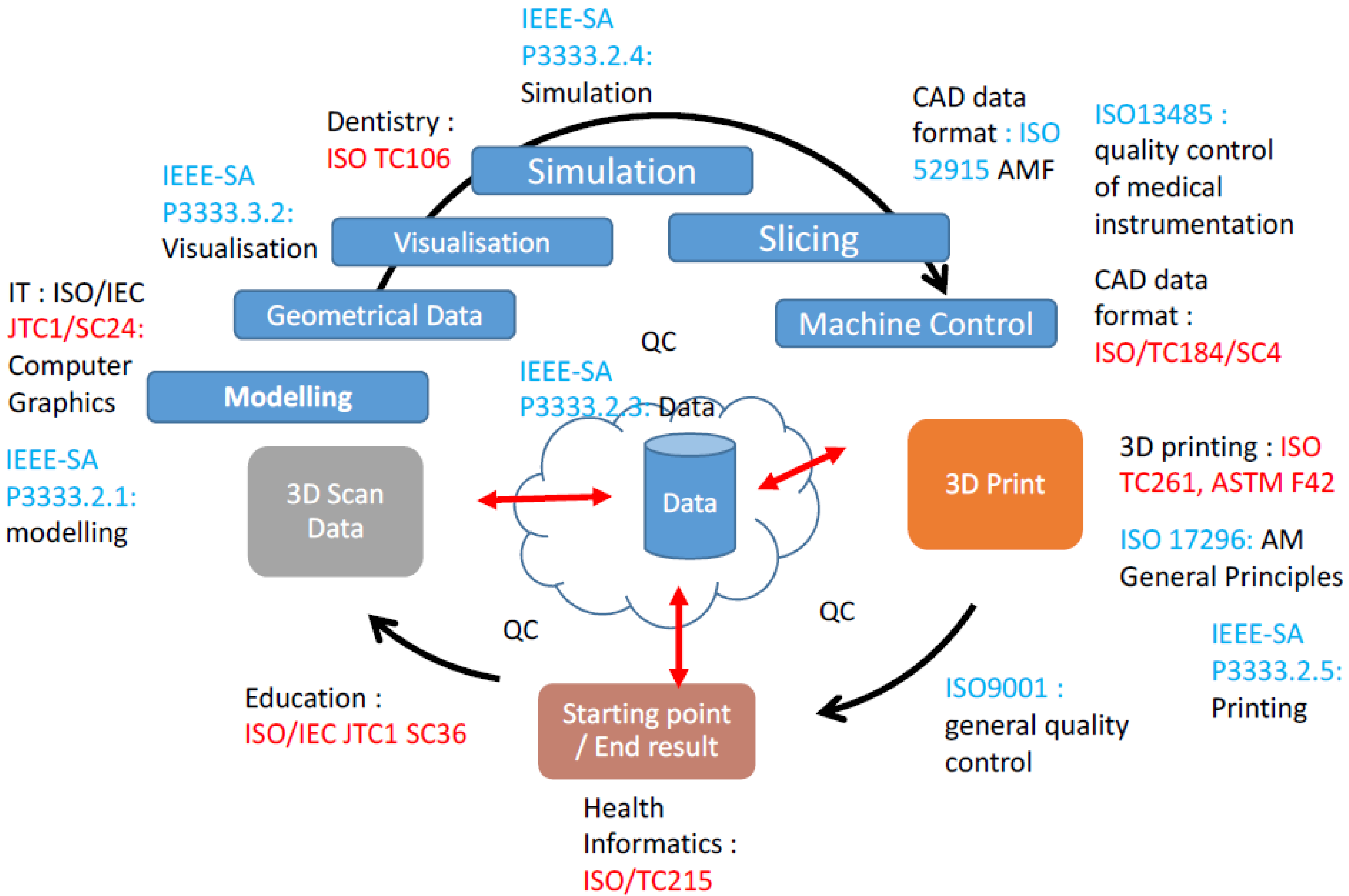
ISO/IEC JTC 1/SG 3 **N 31**

ISO/IEC JTC 1/SG 3 3D Printing and scanning Convenorship: KATS (Korea, Republic of)

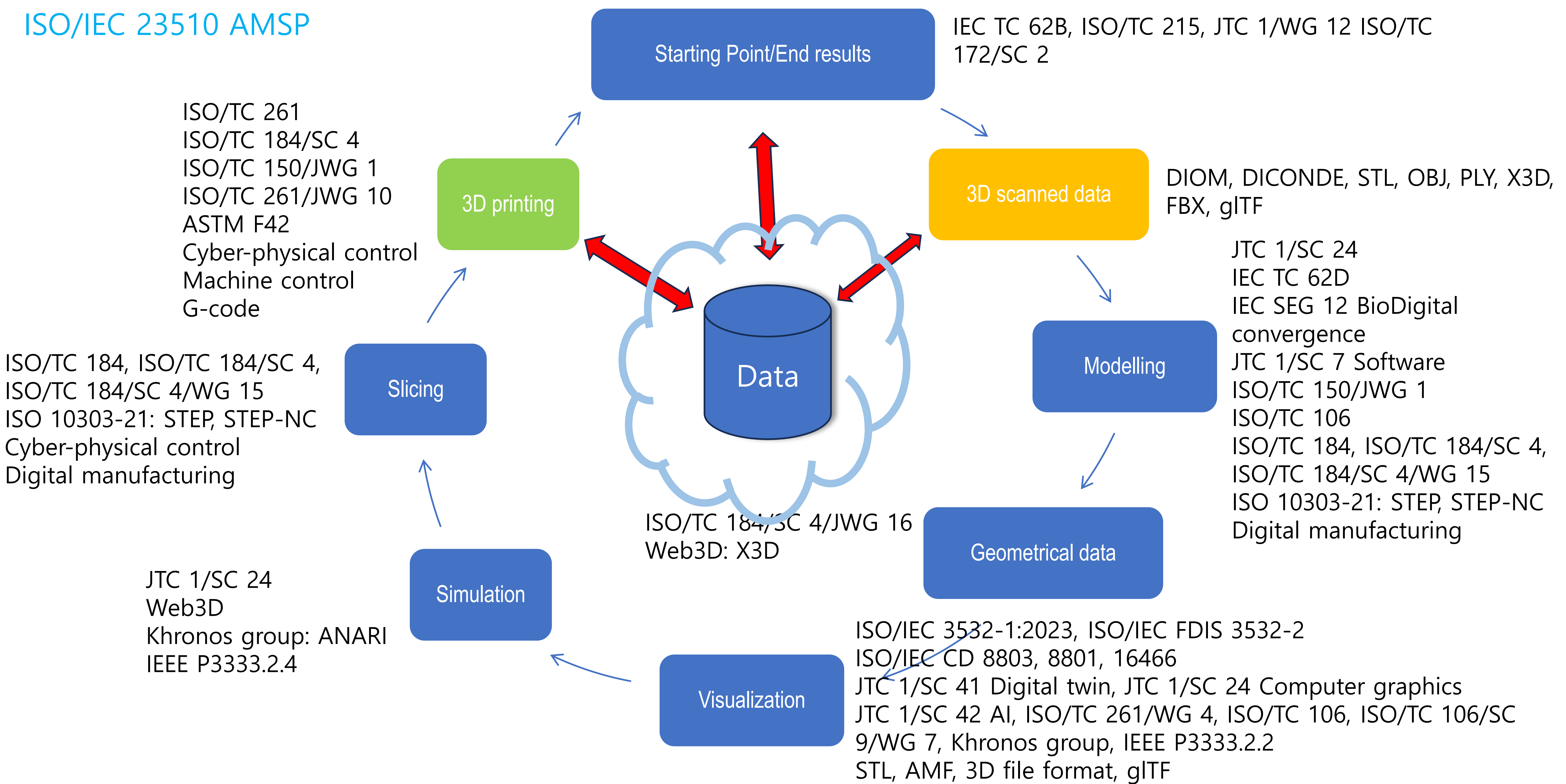
Document type:	Other document (Open)
Title:	Wrap-up report for IEEE 3D Based Medical Application and 3D Printing and Digital Dental Clinic
Status:	
Date of document:	2017-05-26
Source:	Leaders of Editing Group 1 and 3
Expected action:	INFO
Email of convenor:	b.n.lee@etri.re.kr
Committee URL:	http://isotc.iso.org/livelink/livelink/open/jtc1sg3

ISO/IEC JTC1-SG3

Proposed Generic Workflow View for 3D Printing and Scanning Processes

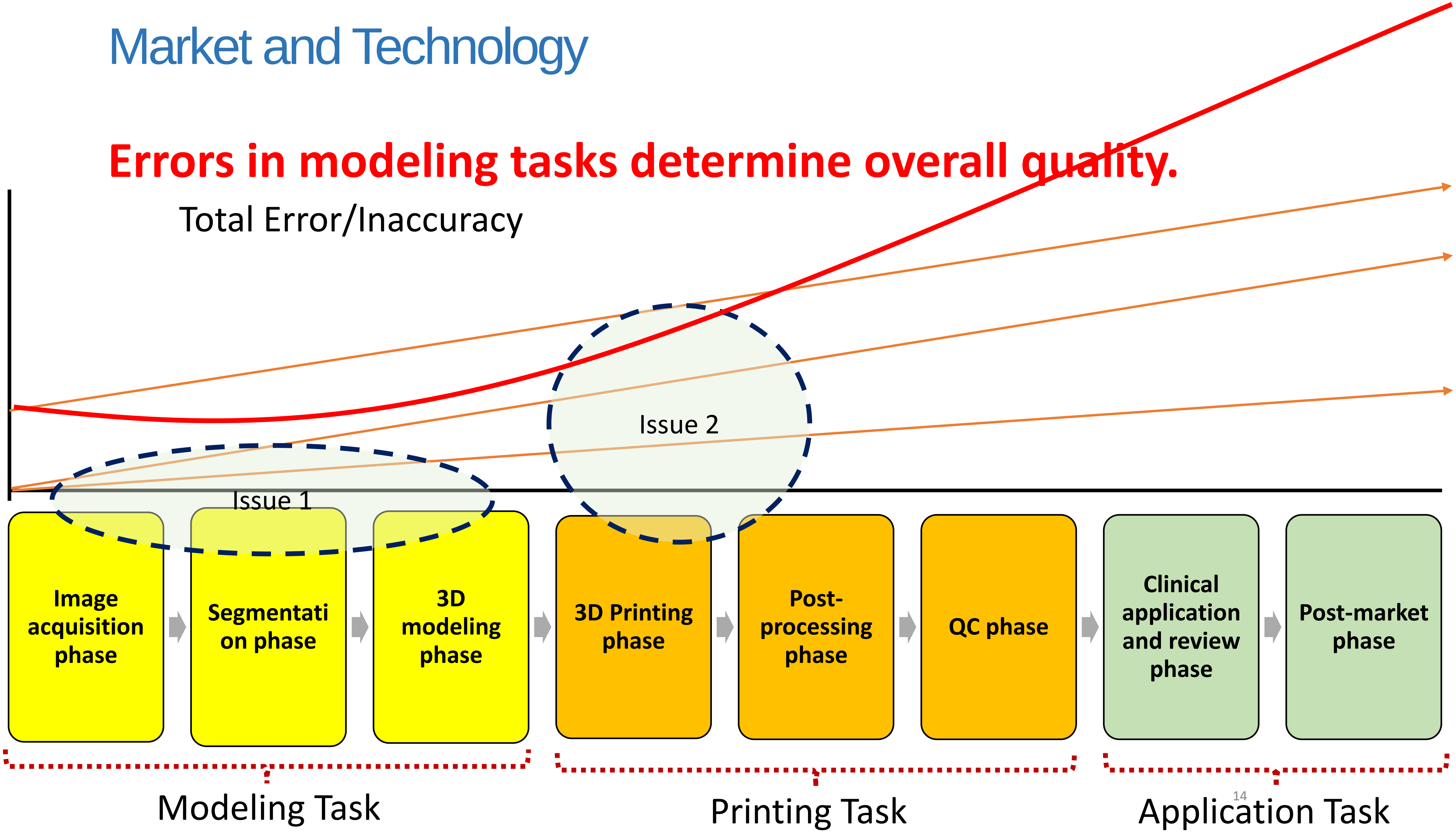


Proposed Generic Workflow View for 3D Printing and Scanning Processes V2.0



Market and Technology

Errors in modeling tasks determine overall quality.



ISO/IEC FDIS 3532-2

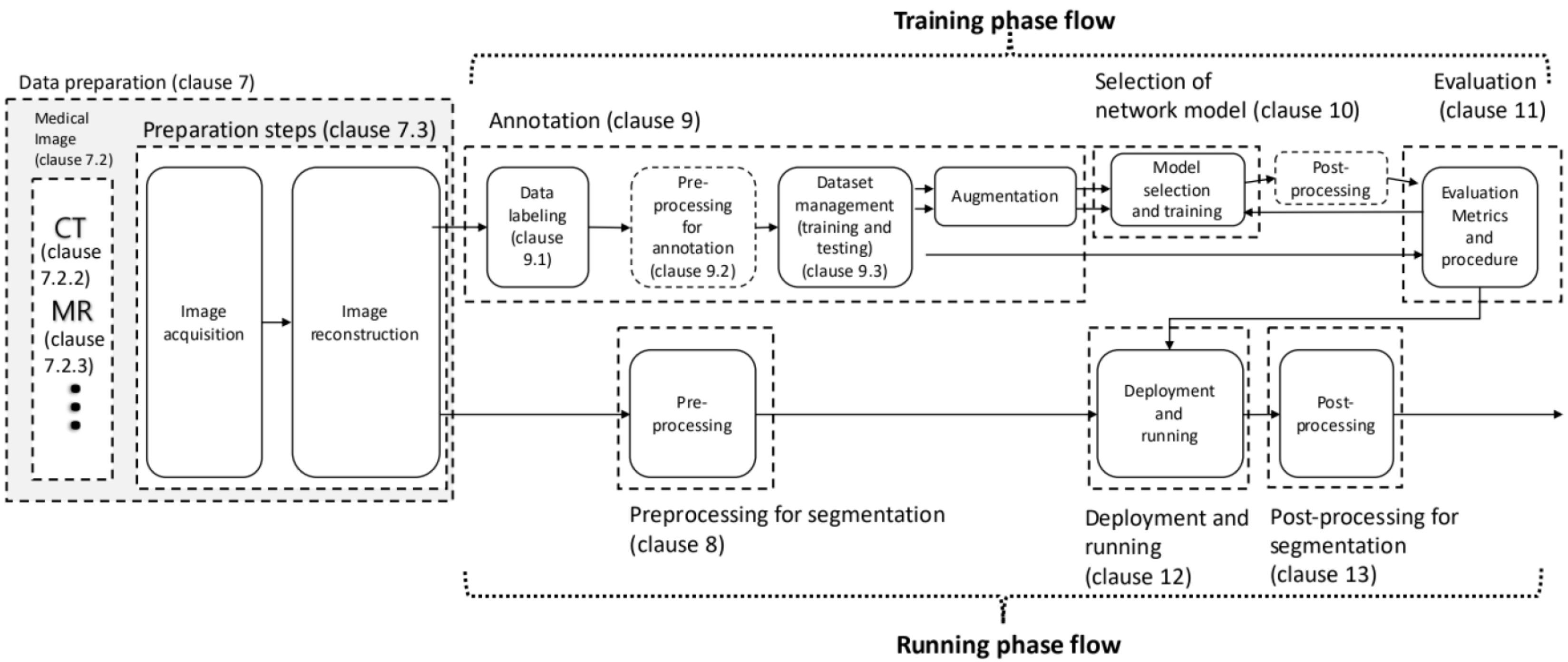


Figure 1 — overall process flow of segmentation

Annex A
(informative)

CT scanning conditions for orbital bone segmentation

High-quality CT scanning is one of the key preconditions in obtaining accurate human bone segmentation. Table A.1 shows the CT scanning parameters and conditions for segmentation of the orbital bone and how to acquire the medical image data. These CT scan conditions are the minimum recommendations considered for the most difficult orbital bone segmentation and, in the cases of other human bones. can be adjusted to appropriate values.

Table A.1 — CT scanning conditions (minimum recommendations)

Term		Condition
Basic conditions	Region of interest	For orbital bone, the whole head can be scanned, and an optimal ROI can be extracted ‘from 1 cm above the supraorbital foramen to infraorbital foramen’.
	Bony position	Supine position
	Image resolution	At least 512 × 512
Scanning conidtions	Tube voltage	80 kV to 120 kV (100 kV recommended)
	Tube current	250 mA to 400 mA (CT-AEC recommended)
	Scan slice thickness	Below 1,0 mm
	Scan (rotation) time	0,5 s to 1,5 s
Reconstructing conditions	FOV	100 mm to 150 mm
	Slice thickness	Below 1,25 mm
	Slice spacing	Below 1,0 mm
	Reconstruction kernel	Standard
	Output format	DICOM (Digital Imaging and Communications in Medicine) format, as most medical 3D modeling software is compatible with the DICOM format.

NOTE ISO 19233-1 recommends CT scanning conditions for the orthopedic joint prosthesis [21].

Medical Applications of Additive Manufacturing/3D Printing

	General	Anatomical Modeling	Surgical Planning	Personalized/Precision Prosthetics	Permanent Implants	Active & Wearable Devices	Bioprinting/Tissue Fabrication
Brief Description	Non-personalized, instruments or prototypes	Patient-matched anatomical models from medical imaging studies (CT/MRI)	Templates, guides, and models after preparing a patient-specific surgical plan in a software environment (The 3D printed items are brought into operating room.)	Patient-matched prosthetics or orthotics	"Off-the-shelf" (Ability to create fine details easily, such as porous structures/surfaces) and patient-matched implants	Devices that include electronics or other active element	3D printing of materials that incorporate living cells or of living cells
Examples of What is 3D Printed	• Simple instruments: plastic or metal • Specialized metal/other instruments for hospital/surgical use (e.g. plate bending) • Testing pieces built with new materials • Prototypes for iterative design process	• Models for surgical preparation, training, and simulation (e.g. pediatric cardio, conjoined twins) • Models for teaching or training purposes ("off-the-shelf" models) • Models for communicating with patient, parents, and colleagues (e.g. scoliosis model) • Simulation/Demo models to test fit and fixation of a device (e.g. stent deployment, implant sizing)	• Guides that mark without cutting or injection; Examples: a. Surgical marking guide b. Implant placement guides (i.e. guiding placement of "off-the-shelf" total joint replacement components for total hip, knee and shoulder surgery) c. Radiation shields d. Imaging frames • Cutting/Drilling guides for surgical injection/instrumentation; Examples: a. Guiding osteotomies in the bone b. Surgical saw guide c. Surgical drill guide	• Patient-Matched Prosthetics/ Orthotics a. Direct Contact with Non-Mucosal Surface (e.g. glasses, body braces, hearing aids, casts, prosthetic limbs and attachments, etc.) b. Direct Contact with Mucosal Surface (i.e. dental and orthodontic applications) • Assistive device	• Serialized Implants a. Metallic Implants (e.g. titanium, titanium alloys, cobalt chrome alloy) b. PEEK/PEKK Implants c. Temporary or Permanent Implants • Patient-Matched Reconstructive Implants a. Small Quantity Cases (e.g. limb salvage, oncology cases) b. "Everyday" types of implants (e.g. knee replacements) c. Temporary (or Removable) Implants (i.e. nasal stents) a. Permanent Implants: Non-Dissolvable (e.g. knee/bone implants) or Dissolvable Implants (e.g. tracheal implant)	• Wearable sensors • Lab on a chip • Microfluidics • Electronics for active devices	• Tissues or scaffolds used for regenerative engineering, drug delivery, drug discovery, toxicology, tissue engineering, etc. • Organ on a chip • Tissue and bone scaffolds
Where	All	All, with emphasis on point-of-care	All	All	Service and device manufacturers	All	Point-of-Care
Technology	- 3D Printing - Materials	- 3D Printing/Additive Manufacturing - Image Processing Software - Materials	- 3D Printing - Biocompatibility - Design Software - Materials - Surgical Planning Software - Templating	- 3D Printing - Design Software - Digitizing Anatomy - Manufacturing Workflows - Materials - Scanning	- Additive Manufacturing (DMLS, EBM, SLS) - Materials	- 3D Printing - Materials - Telemetrics	- 3D Printing - Materials
Standards	- Aging - Cleaning and Sterilization - Material Properties - Re-Use	- Cleaning and Sterilization - Color - Imaging - Material Properties			- Cleaning and Sterilization - Material Properties - Porous Material Evaluation		
Issues of Importance	- Material Properties - Repetitive Use - Foreseeable Misuse (e.g. device which was designed as a holding aid is bent or stuck with a mallet during use, or)	- Automation of Software - Biocompatibility - Cleaning and Sterilization - Model Accuracy - Multi-Materials - Point of Care Issues	- Biocompatibility (including the debris from drilling/cutting) - Efficiency - Foreseeable Misuse - Proving it Matters (Reimbursement)	- Automation of Design - Biocompatibility - Build Orientation - Foreseeable Misuse - Model Accuracy - Part Strength - Secondary Post Processing - Shelf Life - Workflows and Efficiency	- Biocompatibility - Build Orientation - Cleaning and Sterilization (including cleaning pores) - Part Strength - Point of Care Issues - Process Control - Secondary Post-Processing - Shelf Life - Speed and Relation to Cost - Validations - Verification and Inspection		- Biocompatibility - Cell Survival - Materials - Point of Care Issues - Sterility

The role of JTC 1/WG 12

- This utilization of 3D printing in the medical field has led to numerous advancements, including the production of customized medical devices, surgical models, prosthetics, and even tissue and organ printing.
- These technologies have the potential to revolutionize healthcare by enabling personalized treatments and improving patient outcomes.
- "Medical applications of 3D printing" refers to the extensive use of 3D printing technology in the field of healthcare and medicine. The market share for these applications is substantial, accounting for over 35-45% of the overall market.
- Therefore, it is crucial to explore common technological elements that can be applied from an Information and Communication Technology (ICT) perspective.
- Furthermore, any technology standards derived from this exploration should be designed to be applicable in both medical and non-medical contexts, as suggested by JTC 1/AG 21.

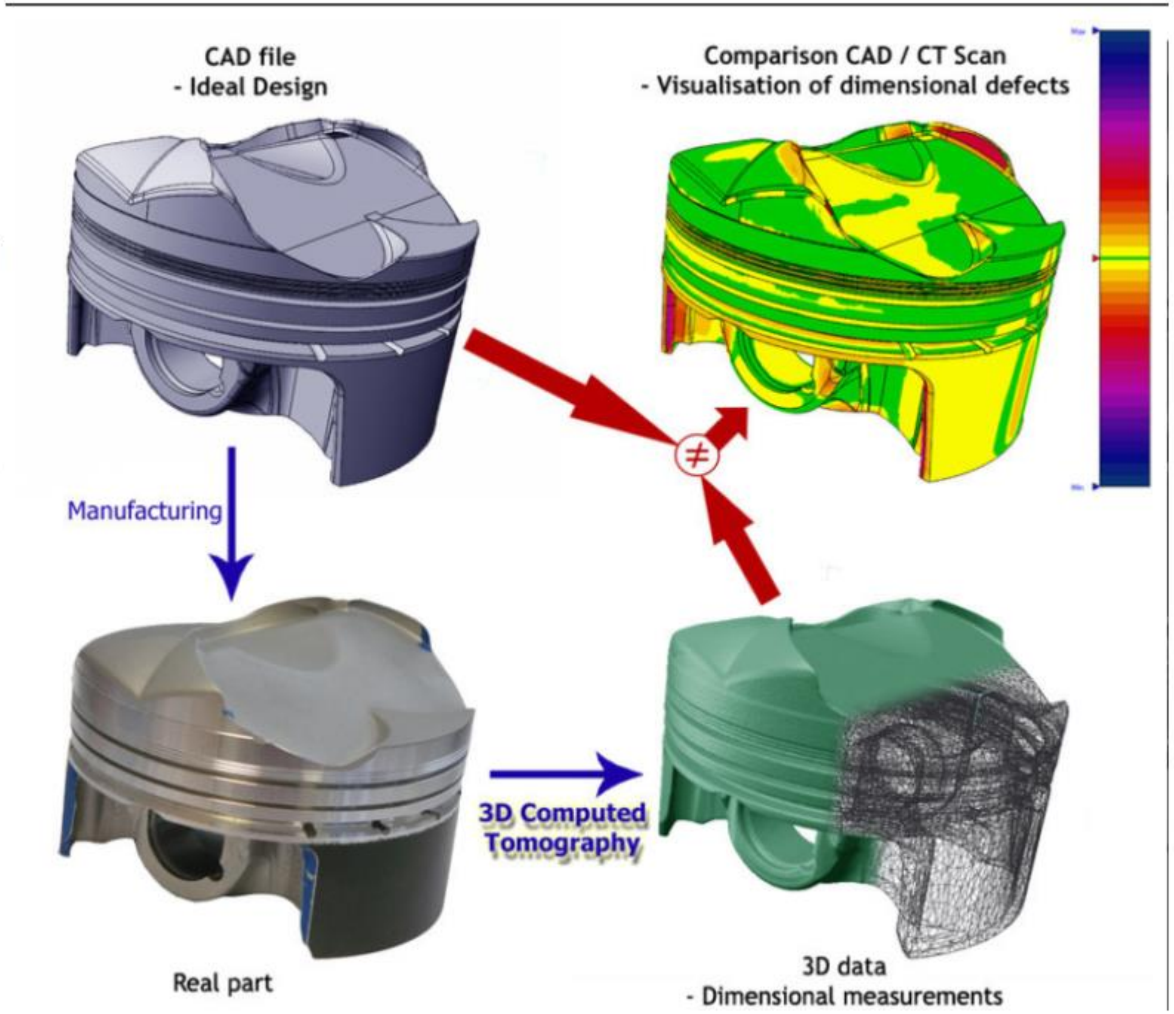
The role of JTC 1/WG 12

- JTC 1/AG 21 is known for its role in standardizing 3D printing and scanning across various fields in a horizontal and versatile manner. The specific group responsible for this role is “JTC 1/WG 12," which promotes international standardization for 3D printing and scanning, defines standardized procedures and terminology, and supports the broader utilization of 3D printing and scanning technology across various application areas.
- From an ICT perspective, ISO/IEC 3532-1:2023 outlines the process of creating the most commonly used 3D model, a standard deemed essential for 3D printing.
- ISO/IEC 3532 series were designed to include horizontal details about the needs of each related TCs since JTC 1/SG 3, with the concept and basic needs originating from the medical industry.

Nondestructive, 3D Scanning of Internal and External Geometries

Benefits of CT Scanning:

- Non-destructive inspection of your parts; line of sight or visual access to any surface is not required for CT scanning, yet 100% of the surface data is captured Your object, material or system will not be compromised or impaired, so its future usefulness is kept intact
- CT Scanning can provide accuracy on small parts of +/-0.010mm andon larger parts of +/-0.025mm (depending on size of part)
- Parts with small, complex, and fine geometry from the medical and electronics industries benefit especially from this technology, since they are very difficult to measure using even the most advanced, laser-based scanning or CMM technologies
- Customizable two- and three-dimensional inspections of small- to medium-sized objects generate 3D XYZ scan data in standard file format outputs for inspection and reverse engineering applications.
- CT scanning helps you capture all surfaces, both external and internal, of complex and free-form parts without damage to the object.



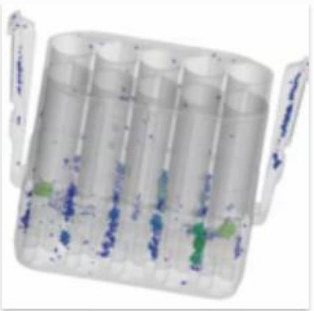
[Nondestructive, 3D Scanning of Internal and External Geometries | Laser Design]

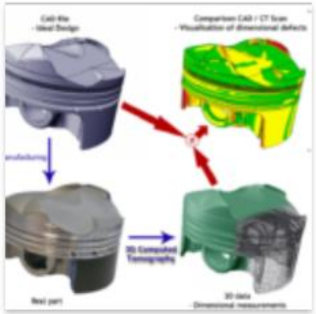
Nondestructive, 3D Scanning of Internal and External Geometries

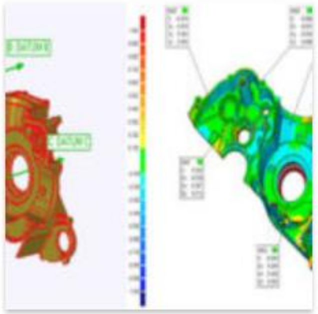
[Nondestructive, 3D Scanning of Internal and External Geometries | Laser Design]

CT Scanning Photo Gallery

The Laser Design 3D Scanning Team has been busy! Besides a busy lab (that is also ITAR certified) we've also been to the World Trade Center, the new U.S. Bank Stadium, Space Needle, Miami Airport, ships in Korea, the Mirage volcano and more! We have the experience and know-how to tackle your next project whether it's a small hearing aid or an entire ship! Check out our gallery of CT scanned photos.

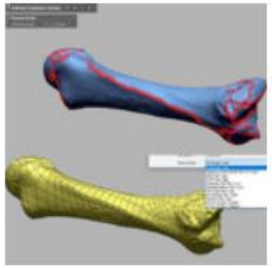






Nondestructive, 3D Scanning of Internal and External Geometries

CTScanning Case Studies

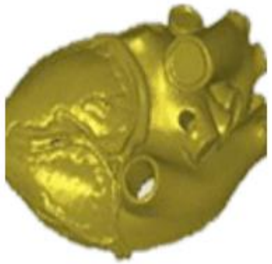


4 Easy Steps to NURBS Surface Modeling in Geomagic Design X

Case Study – Using EasyTom CT Scanner and Volume Graphics Analysis Software for Defect Detection

Case Study – CT Scanning Baseballs

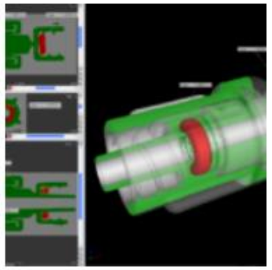
Merit Medical Gains R&D Efficiencies with 3D Scanning



Just what the Doctor Ordered: Innovative Medical Applications of Non-Contact 3D Scanning

Verifying Assemblies Using CT Scans and Geomagic

Laser Design adds EasyTom Industrial CT Scanner to Services Division



Application Story – Medical Device 3D CT Scanning

[Nondestructive, 3D Scanning of Internal and External Geometries | Laser Design]

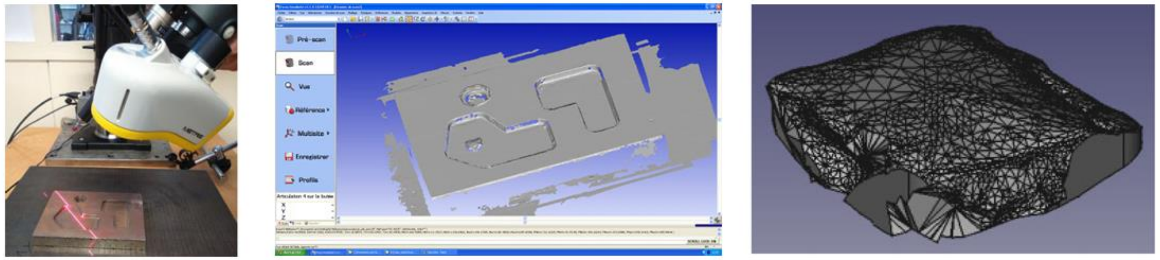
Nondestructive, 3D Scanning of Internal and External Geometries

- CT scanner captures all surfaces, both external and internal, of complex free-form parts and assemblies without harming the object. Parts made of plastic, ceramics or composite materials, as well as magnesium, aluminum and steel, can be measured and efficiently evaluated. A very long service life is enabled by the open X-ray tube technology and it has a measurement range of 11.8" x 13.8" (300 mm x 350 mm). The CT system can also be equipped with a higher resolution detector to make very fine part structures visible, and the enlarged detailed view can be measured with extremely high accuracy.
- Processing the CT scan data through Volume Graphics, the 3D model is then loaded into Geomagic Qualify where the assembly is compared to either original CAD design data or to scan data of another known working product. Geomagic Qualify quickly and automatically measures and assesses deviations between the new scan data and the comparison assembly model, making measurement on known tolerances, identifying deviations in the assembly based on unanticipated forces between parts. Geomagic Qualify then automatically produces a custom report for the production engineers in PDF, so it can be viewed by all concerned parties.

Nondestructive, 3D Scanning of Internal and External Geometries | Laser Design

Part Repair, Remanufacturing

(a) Building whole shape (b) Removing all bosses (c) Adding bosses by laser cladding



(a) Laser scanner inspecting a pocket (b) Image processing of scanned data (c) Extraction of broken part

This use of additive manufacturing is interesting for several reasons.

1. Material is added to an existing part rather than to a base plate or table.
2. The build direction may well not be constant.
3. The material added may not be in planar sections – Directed Energy Deposition (DED) has been proposed for the repair of turbine blade edges, for example.

The same technique may also be used to add manufacturing features where, say, milling cannot be used because there is no tool access.

The most important knowledge for this case comes from accurate scanning of the broken shape including very small complex geometry and balancing the ratio between the shape removed before 3D printing and the shape filled by the 3D printing process.

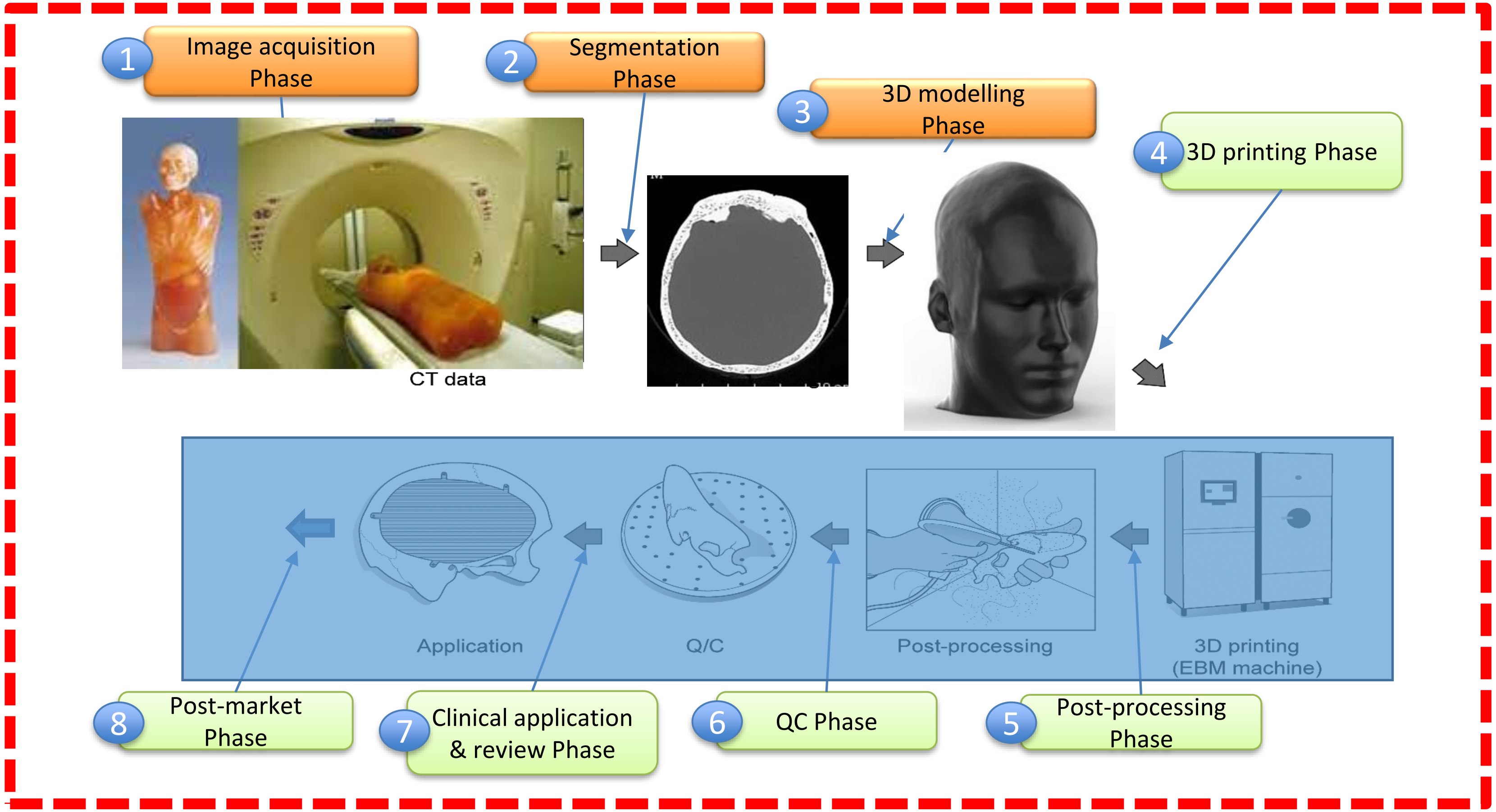
The International Journal of Advanced Manufacturing Technology volume 88, pages1215–1230 (2017)

Needs for the New Standard

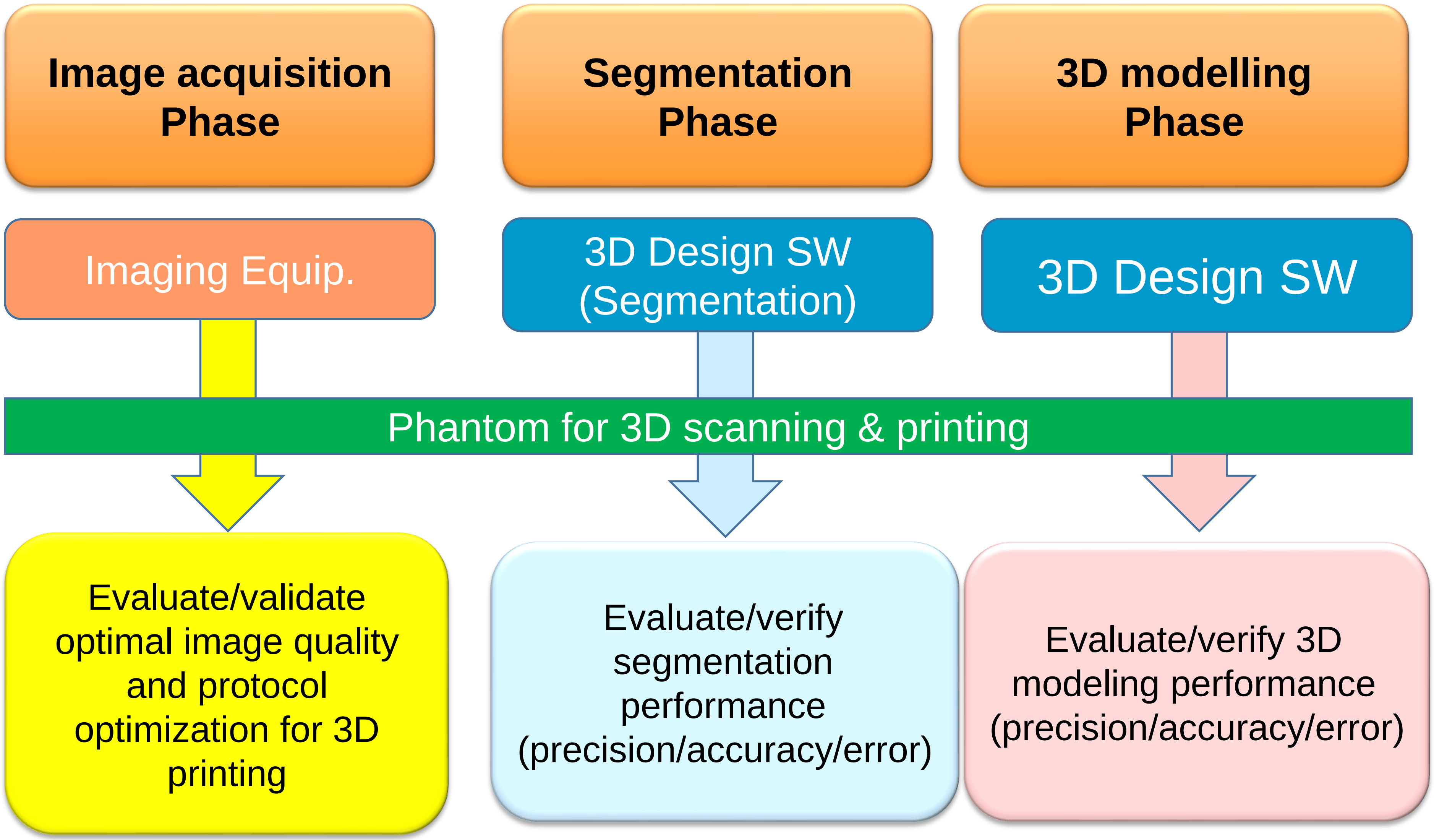
- Information technology — 3D Printing and Scanning — Image-Based Modelling from 3D scanned Data
  - ISO/IEC 3532-1 : General Requirement
  - ISO/IEC 3532-2 : Segmentation
  - ISO/IEC 8803 : Accuracy and precision evaluation process for modeling from 3D scanned data
  - ISO/IEC 16466 : Assessment methods of 3D scanned data for 3D printing model
  - ISO/IEC 8801: 3D scanned and labeled data Standard Operating Procedure (SOP) for evaluation of modelling from 3D scanned data
  - NWIP : Phantom-based evaluation methods for 3D printing modeling software

Scope of NWIP

- Defines **Phantom-based assessment procedure of 3D Modeling Software for 3D Printing** in the Total 3D Printing Life cycle, and especially focuses on the image-based modelling of 3D scanned data from CT scanner, industrial and medical.



Scope of NWIP



ISO/IEC JTC 1 - N:####(X)

ISO/IEC JTC 1

Secretariat: ANSI

Information Technology — 3D Printing and Scanning — Phantom-based evaluation methods for 3D printing modeling software

Contents

1. Scope

- This document defines the test procedure and test methods for the accuracy and precision evaluation of 3D modeling software used for 3D printing parts/devices using well-designed phantom.
- This document is not intended to evaluate the 3D printed product itself.

reviewed and refined to ensure that it meets the necessary standards and specifications.

5 Phantom Design Requirements

5.1 General

The requirements for the design of the well-designed phantom used in the accuracy and precision evaluation of the 3D modeling software, including material requirements, size and shape requirements, and any other relevant physical characteristics.

Unlike conventional 3D printing, architectural 3D printing models buildings and structures from design images. Design images have errors due to resolution, image noise, etc. when acquired, and have difficulty in accurately representing the boundaries of buildings and structures with complex geometric shapes due to resolution limitations. In particular, the dome area has structural features such as curves, curved surfaces, small sizes, and thin parts, and is composed of different materials and colors, making it difficult to segment images due to the limitations of design images. Due to the inaccurate information of the design image, it is difficult to verify whether the result of the modeling process, which proceeds through image acquisition, segmentation, STL file conversion, architectural design, etc., is accurate with the original design. To verify and correct the modeling process, a phantom that can measure and compare evaluations is required. The architectural phantom should reflect the geometric characteristics of the design being simulated and provide spatial (3D) information for verifying the accuracy and precision of the results of the modeling process.

5.2 Requirements

5.2.1 It shall reflect the physical characteristics (such as specific dimensions and characteristic shapes, RGB values of the constituent materials in design images, etc.) of the items and structural target parts of the customized products.

5.2.2 It shall distinguish between the customized target region of interest (ROI) and non-region of interest (non-ROI).

5.2.3 It shall describe the design, production material, and production method of the phantom.

6 Assessment Procedure

6.1 General

The procedure for the accuracy and precision evaluation of the 3D modeling software, including the steps involved in preparing the well-designed phantom, using the 3D modeling software to create a 3D model of the phantom, and measuring the accuracy and precision of the 3D model using the well-designed phantom.

- Prepare the basics required for the test
- Set the software to be tested to the optimal environment according to the manufacturer's recommendations

6.2 Assessment Procedures

6.2.1 Retrieving the test phantom CT data corresponding to the phantom elements specified in Annex B from the 3D modeling software

6.2.2 Segmentation function accuracy/precision test

6.2.2.1 Split the CT phantom into individual components using segmentation in 3D modeling software.

6.2.2.2 Select the key test measurement locations specified in Annex A for each segmented assessment target

6.2.2.3 Measure the length, height, angle, and radius of each major test measurement position using the measurement function provided by the 3D modeling software.

6.2.2.4 Record the measurements obtained from the 3D modeling software in the test results table.

6.2.2.5 Compare the measurements obtained from the 3D modeling software with the values in the measurement

phantom reference table.

6.2.2.6 Calculate the mean absolute difference (MAD), mean square error (MSE), and mean square root error (RMSE) between measurements obtained from the 3D modeling software and measurements obtained from the measurement tool.

6.2.2.7 Evaluate the comparison results and determine the accuracy and precision of the segmentation capabilities of the 3D modeling software.

6.2.3 3D reconstruction functional accuracy/precision test

6.2.3.1 Use 3D reconstruction capabilities in 3D modeling software to organize segmented data into 3D models.

6.2.3.2 For 3D models reconstructed from 3D models, select the key test measurement locations specified in Annex A for each assessment target.

6.2.3.3 Measure the length, height, angle, and radius of each major test measurement position using the measurement function provided by the 3D modeling software.

6.2.3.4 Record the measurements obtained from the 3D modeling software in the test results table.

6.2.3.5 Compare the measurements obtained from the 3D modeling software with the values in the measurement phantom reference table.

6.2.3.6 Calculate the mean absolute difference (MAD), mean square error (MSE), and mean square root error (RMSE) between measurements obtained from the 3D modeling software and measurements obtained from the measurement tool.

6.2.3.7 Evaluate the comparison results and determine the accuracy and precision of the 3D reconstruction capabilities of the 3D modeling software.

7 Precision/accuracy test methods for Modeling software using phantoms

The methods used to evaluate the precision and accuracy of 3D modeling software using phantoms, including the measurement metrics used to quantify precision and accuracy.

7.1 General

The software test method using phantom will have the following advantages compared to the test method using actual human tissue.

7.1.1 Standardization

Phantoms provide standardized and well-defined reference objects that can be used to evaluate the accuracy and precision of 3D modeling software, so that standardized phantoms can objectively compare evaluation results between different software programs.

7.1.2 Objectivity

Because the phantom is designed to have precisely measured physical properties based on quantified values, it can provide an objective means of evaluating the accuracy and precision of 3D modeling software and 3D printing quality in a consistent and repeatable manner.

7.1.3 Realism

Phantom can be designed to closely mimic real objects (such as bones and organs) in terms of physical characteristics and geometry, and this sense of reality allows quality to be evaluated by reflecting practical issues encountered in 3D modeling software or 3D printing environments.

7.1.4 Repeatability

Phantom can be used to evaluate the quality of 3D modeling software and 3D printing by running multiple times under different conditions with different workers, which can be used to evaluate repeatability and reproducibility.

7.1.5 Cost-effectiveness

When compared to other methods, using a phantom can save time and reduce overall trial costs because it can be

Q & A

shimkyuwon@yuhs.ac

Introduction to Additive Manufacturing Service Platform (AMSP)

12 Dec. 2023，Online Workshop

Prof. Yonghui Liu, Member of ISO/IEC WG12, and SAC/TC 562
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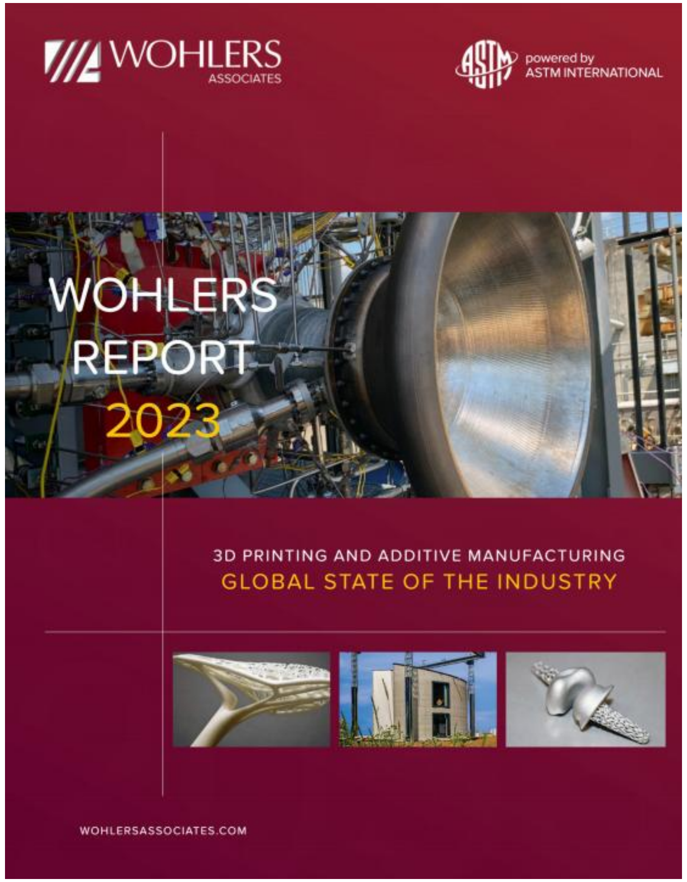
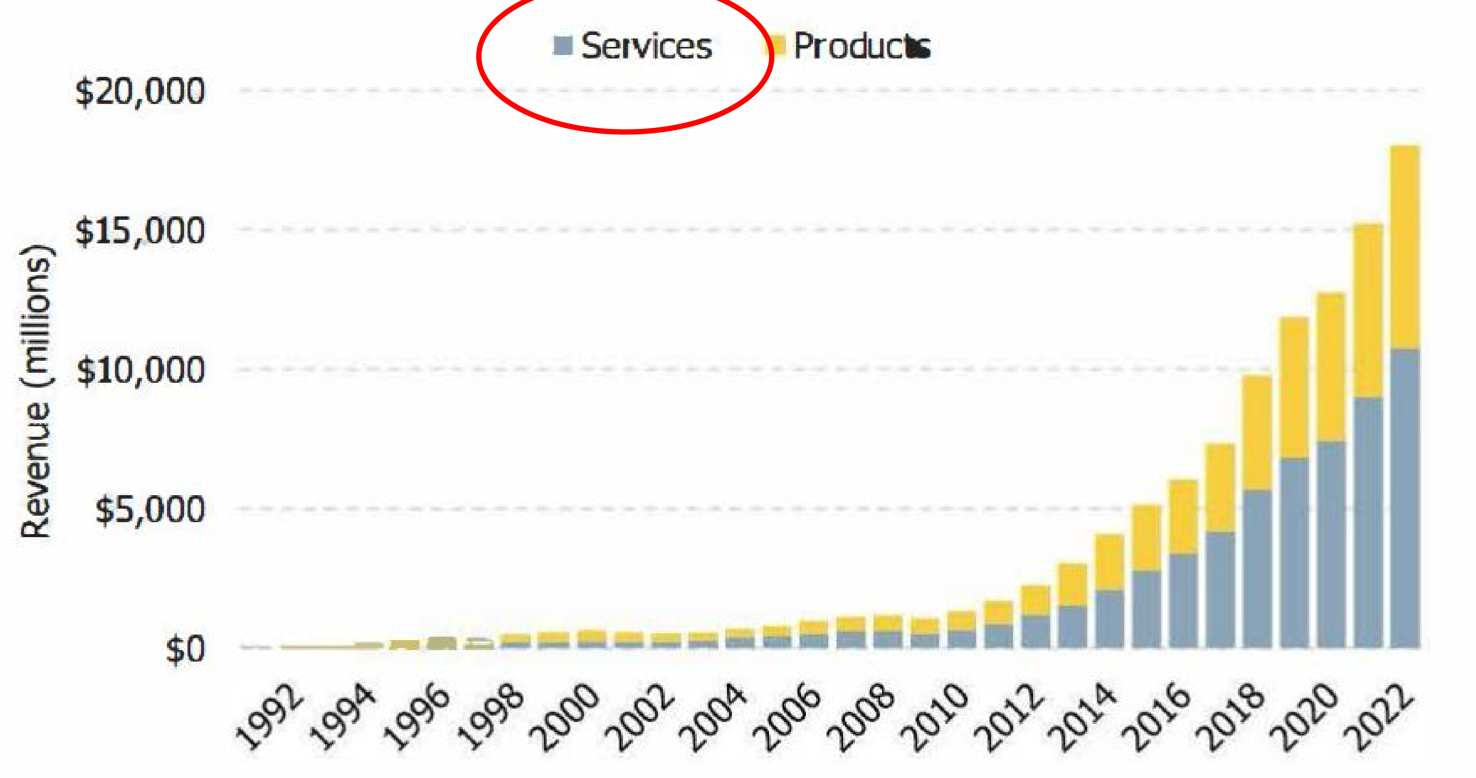
Ocean University of China/ShanDong CharmRay Laser Technology Co.,Ltd
No.238, Songling Road, Laoshan District Qingdao, China

Contents

Market and Technology

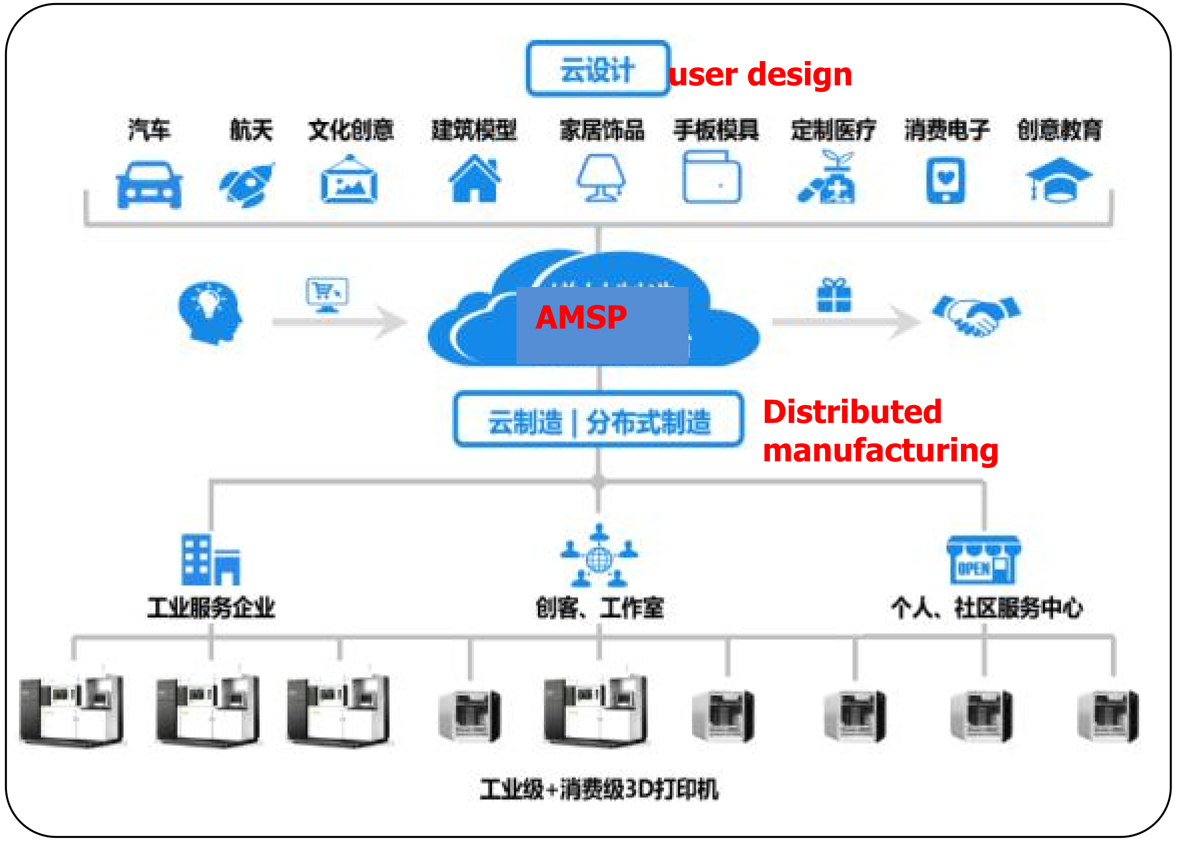


(Source: Wohlers Report 2023)



- **Worldwide revenues from AM products and services were about $18.027 billion in 2022, with an increase of 18.3%. 1)Revenues from AM products were $7.289 billion, with an increase of 17%. 2)Revenues from AM services were $10.738 billion (about 60%), with an increase of 19.1%.**

What is an AMSP?



AMSP = 3D Printing + ICT！

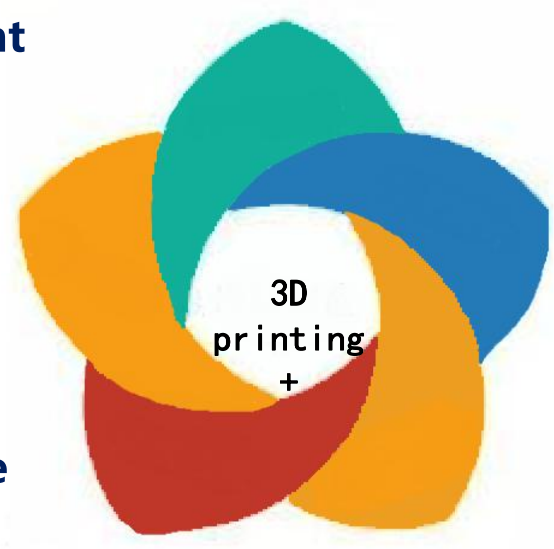
- Additive Manufacturing Service Platform (AMSP) uses additive manufacturing technology and information technology to provide services according to users' requirements.

What is an AMSP?

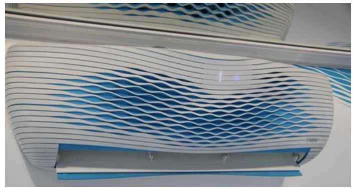
- AMSP can satisfy different 3D printing needs from different fields through the Internet very easily, especailly those who do not have 3D printers or cannot design.

➢ Personalization

➢ Lightweight design



➢ Home appliances



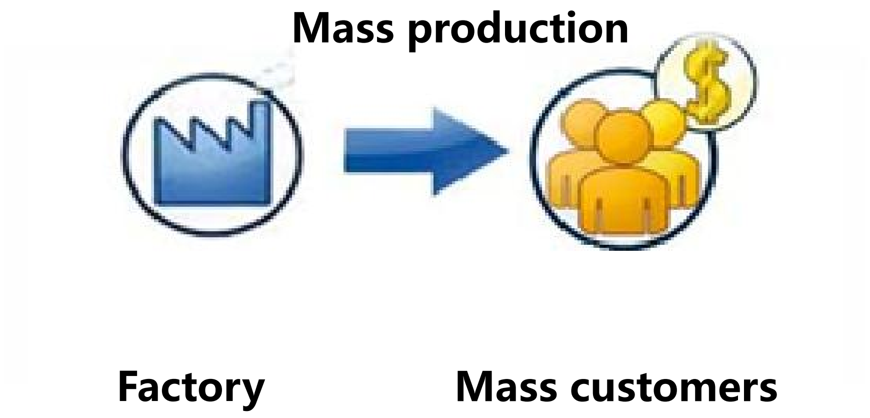
➢ Architecture

Application of AMSPs

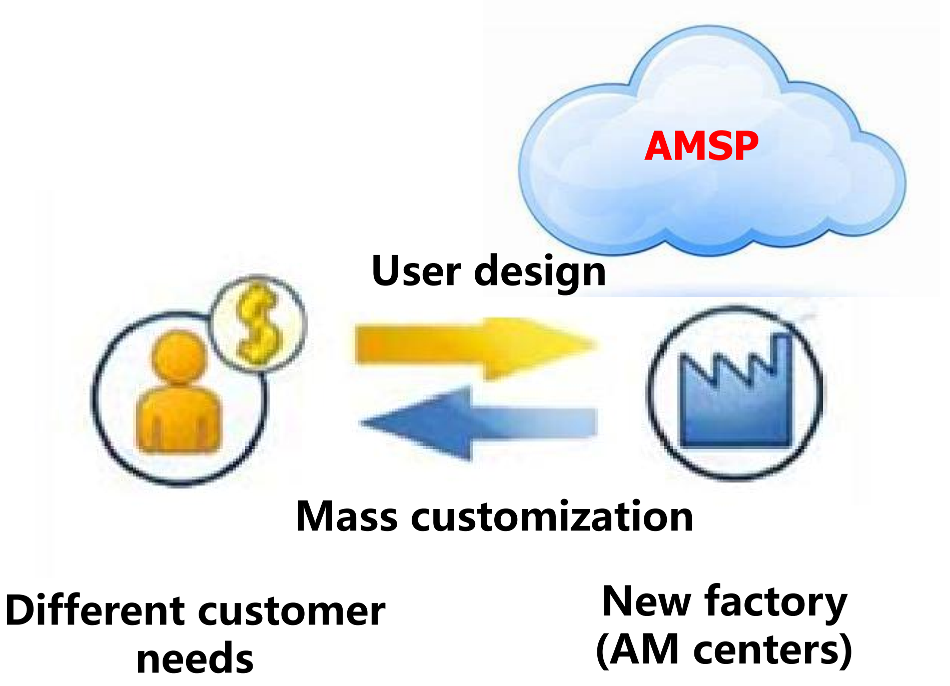
➢ Medical

What is an AMSP?

- **AMSP has created a new business model and also brought about the need for standardization.**



a) Traditional business model



b) New business model based on AMSPs

What is an AMSP?

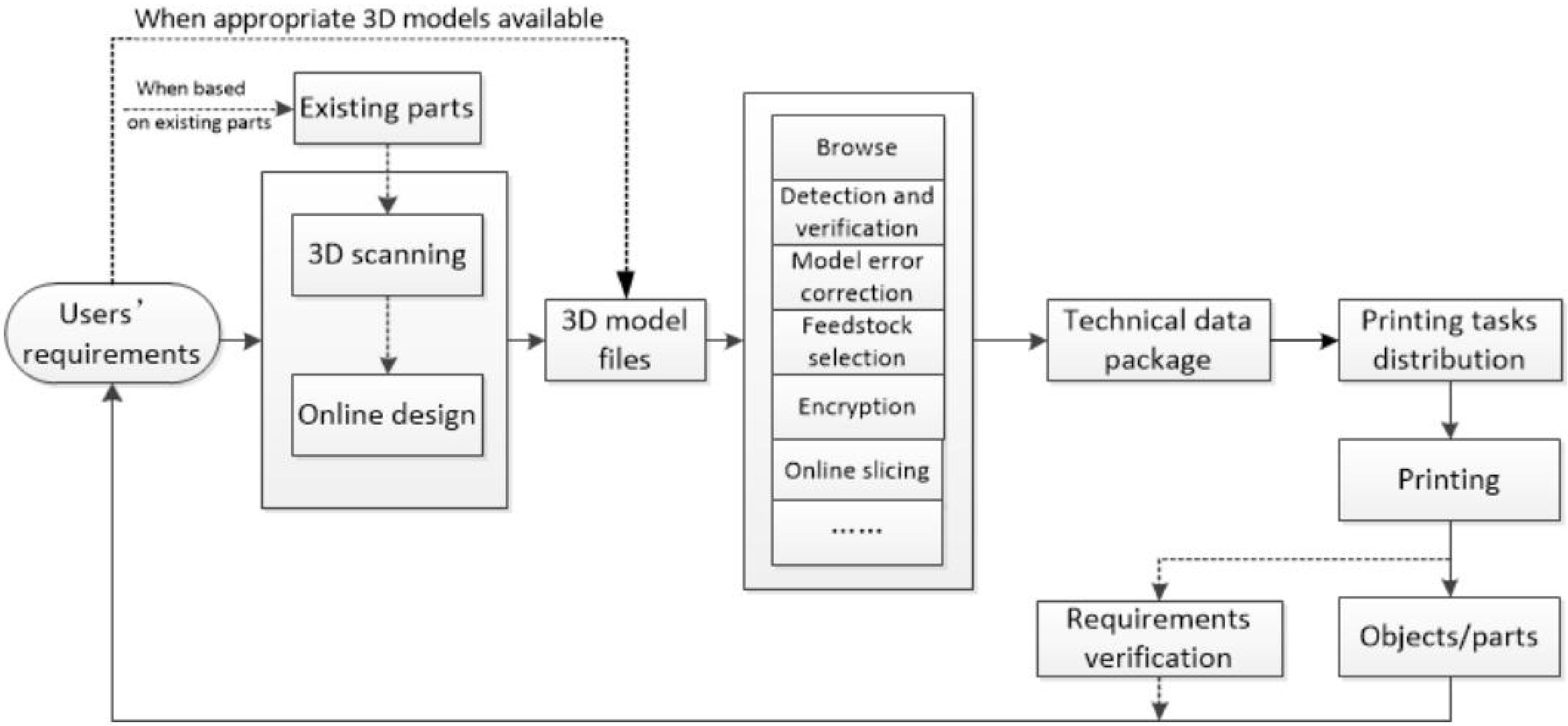


Figure 1 — Typical AMSP workflow

What is an AMSP?

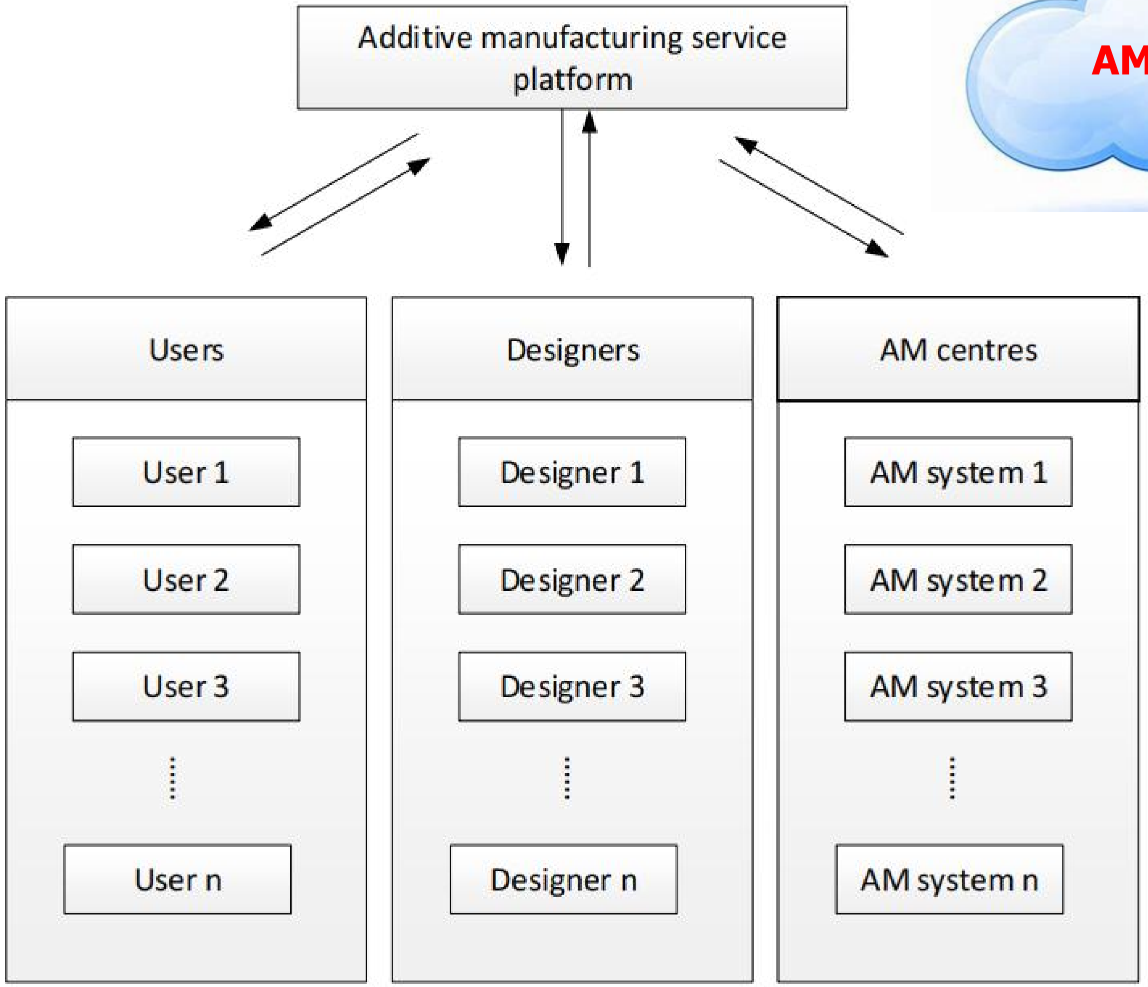
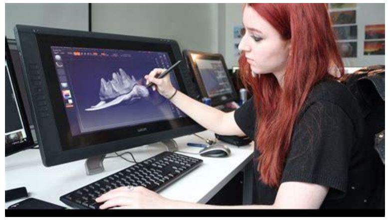


Figure 2 — Interaction among stakeholders including an AMSP, users, designers and AM centres



Needs for the Standards(1) ISO/IEC 23510

- In October, 2021， the first AMSP standard, ISO/IEC 23510： 2021 Information technology — 3D printing and scanning — Framework for an Additive Manufacturing Service Platform (AMSP) proposed was successfully published.

Needs for the Standards(2) NP 23955

- **Based on ISO/IEC 23510, a new draft standard related to AMSP entitled *Information technology — 3D Printing and Scanning — Technical requirements for product data protection of Additive Manufacturing Service Platform (AMSP)* is proposed in 2022.**

ISO/IEC 23510:2021(E)

Table 1 *(continued)*

	Resource layer	Technical support layer	Engine layer	Platform integration operating environment layer	Tool layer	Access layer	User layer
Security management	x			x			
Operation monitoring	x	x	x	x	x		

7 Considerations

7.1 Copyright protection

An AMSP allows users to upload or create personalized 3D models online in a convenient manner. The data of 3D models is usually easily spread or stolen illegally through the transmitting procedure over the internet. Meanwhile, 3D models are also easily printed without permission, which can cause a loss to the designer or model provider. Therefore, the data security of the 3D model during the data storage, transmission and printing are ensured and the intellectual property of designers and model providers needs to be protected.

7.2 Quality inspection

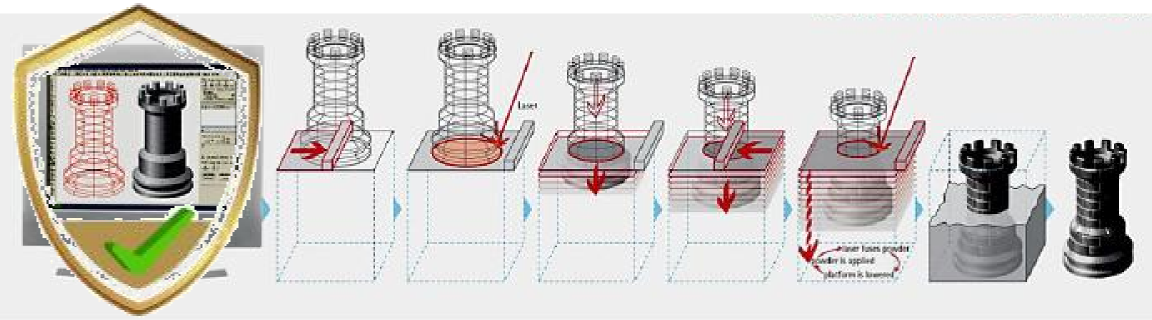
The performance requirements and inspection methods of the final objects/parts delivered to the user from the AMSP should meet the requirements of ISO 17296-3 and ISO/ASTM 52901.

7.1 Copyright protection

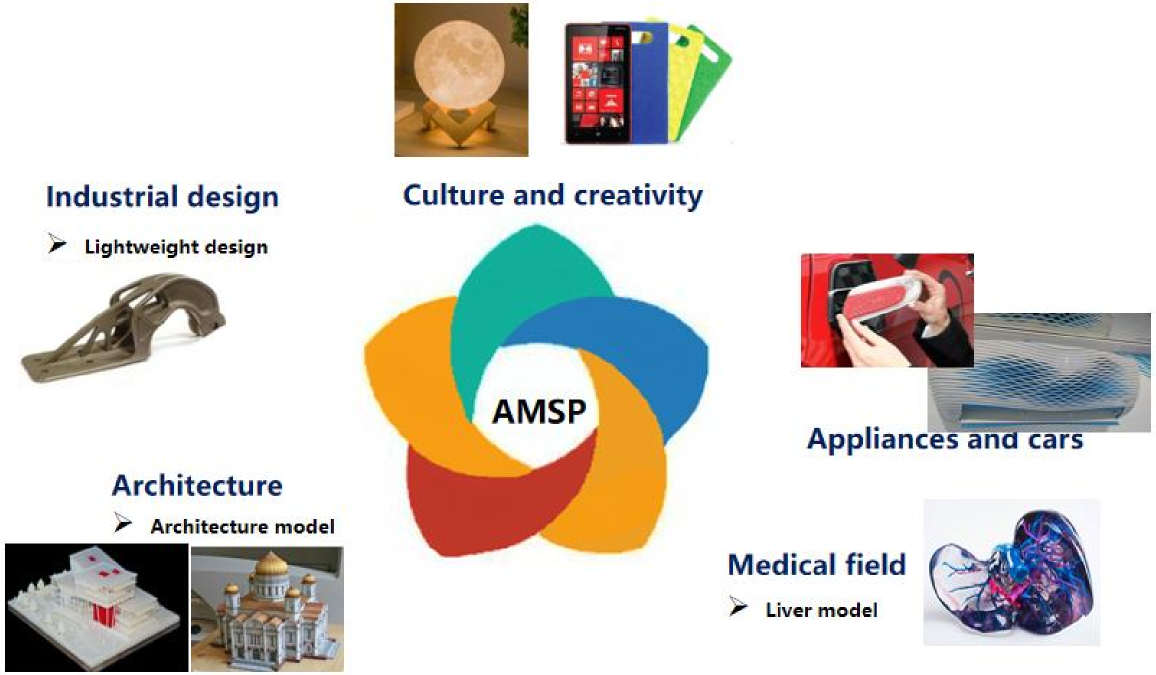
An AMSP allows users to upload or create personalized 3D models online in a convenient manner. The data of 3D models is usually easily spread or stolen illegally through the transmitting procedure over the internet. Meanwhile, 3D models are also easily printed without permission, which can cause a loss to the designer or model provider. Therefore, the data security of the 3D model during the data storage, transmission and printing are ensured and the intellectual property of designers and model providers needs to be protected.

Needs for the Standards (2) NP 23955

- 3D design model is the core of additive manufacturing for the application of 3D printing on an AMSP, which embodies the great efforts and wisdom of a designer.
- However, many AMSPs lack the mechanism of product data information protection, limiting the commercialization of excellent design works combined with additive manufacturing technology.
- According to statistics, about 80% of designers are not willing to share their designs on an AMSP for fear of theft.



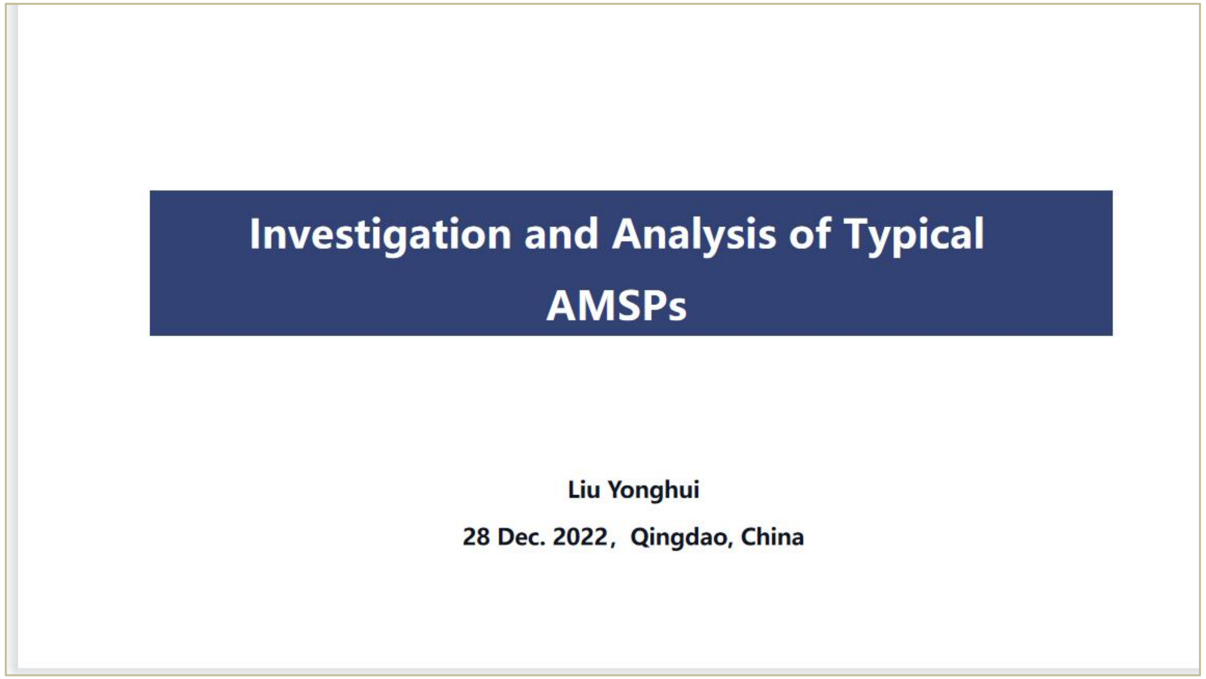
3D design model is the core of additive manufacturing

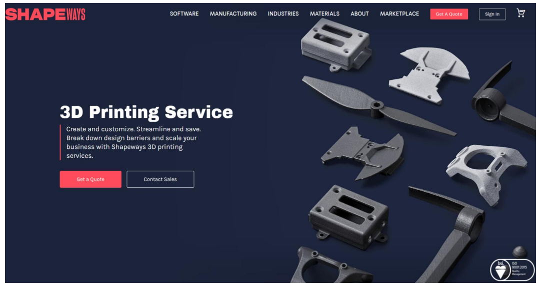


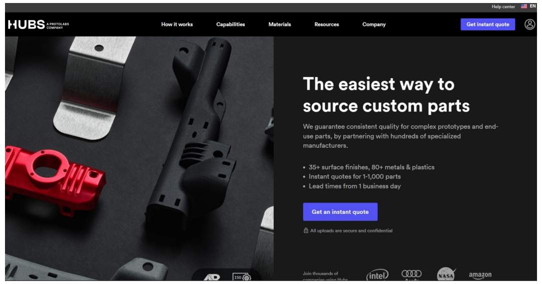
Needs for the Standards (3) ... ...

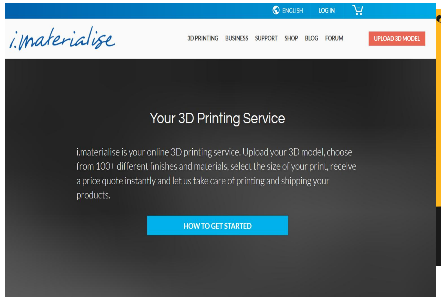
- **Open application program interface requirements for AMSP**

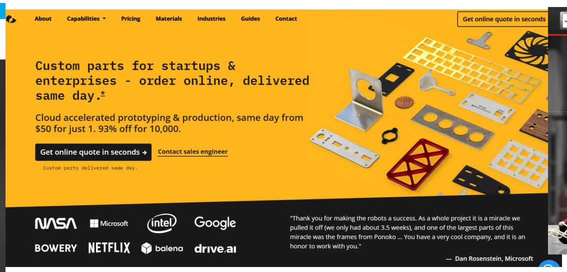
Investigation and Analysis of Typical AMSPs

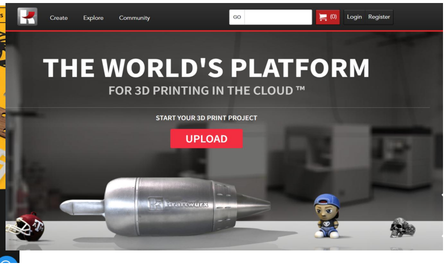












Introdution to NP23955

☐ Title

Technical requirements for product data protection of Additive Manufacturing Service Platform (AMSP)

☐ Purpose and justification of the proposal

① This standard was developed in response to the needs of product data protection so as to promote the mass customization of additive manufacturing technology by taking full advantage of information and communication technology (ICT).

② This standard can protect the product data information of designers and stimulate their innovation enthusiasm.

③ Moreover, it can provide guidance for the establishment and operation of an AMSP, and promote the healthy development of the new industry of providing additive manufacturing services by AMSP.

Introdution to NP23955

☐ Normative references

- ISO/ASTM 52900, Additive Manufacturing — General Principles — Fundamentals and vocabulary
- ISO/ASTM 52901, Additive manufacturing — General principles — Requirements for purchased AM parts
- ISO/IEC 23510: 2021, Information technology- 3D Printing and Scanning-Framework for Additive Manufacturing Service Platform (AMSP)
- ISO/IEC 27001, Information security management
- ISO/IEC 27017:2015, Information technology — Security techniques — Code of practice for information security controls based on ISO/IEC 27002 for cloud services
- ISO/IEC 29151:2017, Information technology — Security techniques — Code of practice for personally identifiable information protection

Introdution to NP23955

□ Terms and definitions (which can be cited)

- additive manufacturing service platform
  AMSP

- user

- designer

- additive manufacturing centre
  AM centre

Introdution to NP23955

□ Terms and definitions (which are new)

● product data information on AMSP

information related to 3D model that can be processed by the application software of AMSP in the process of providing additive manufacturing products and relevant services.

● provider of 3D model

individual or organization that provides 3D model data to AMSP and has the ownership of 3D model data or obtains partial or all of rights and interests after being legally authorized by the owners of 3D design data, mainly including users and designers.

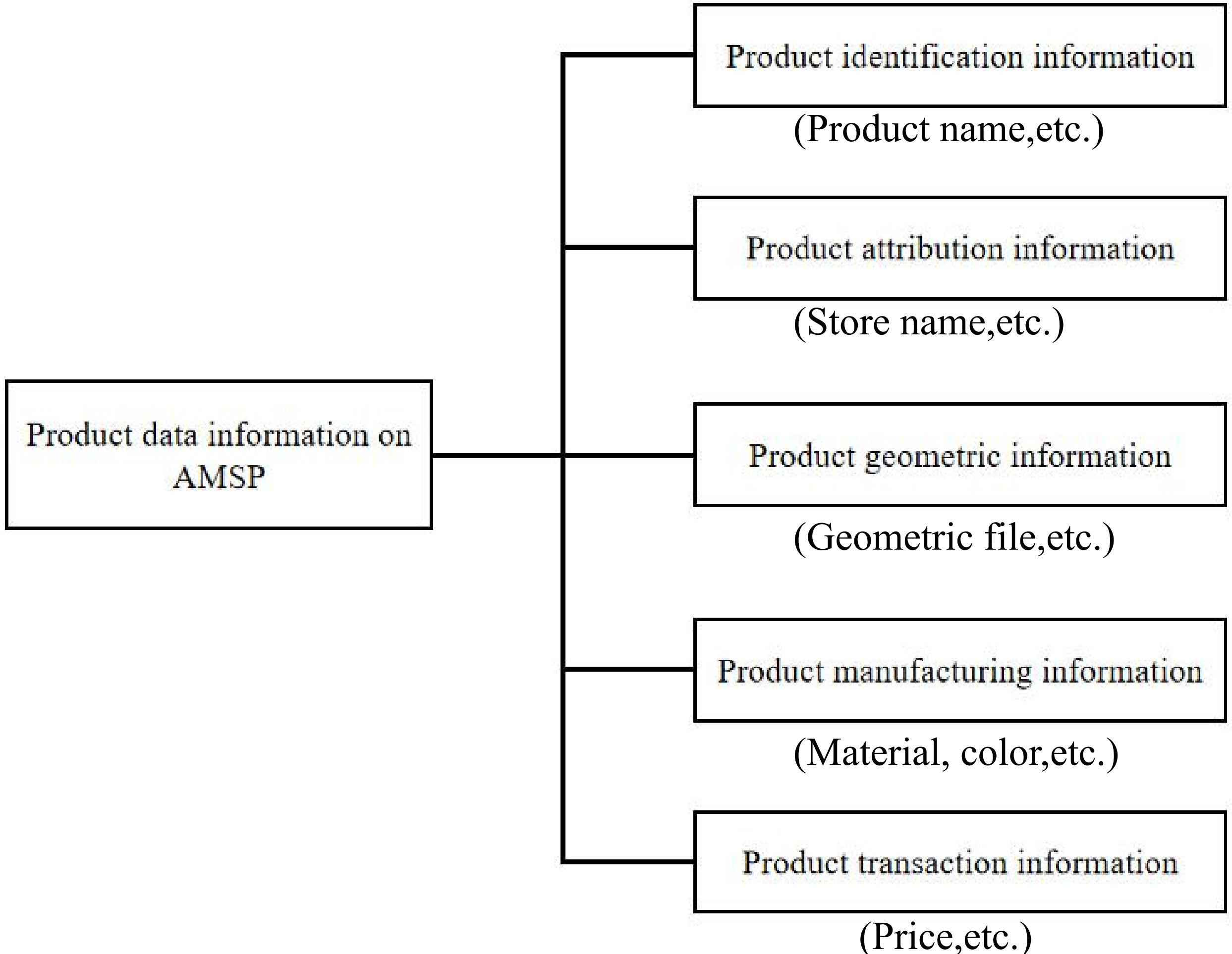
● receiver of 3D model

individual or organization that receives 3D model data from AMSP for the manufacturing purposes, usually referring to AM centres.

Introdution to NP23955

◻ Classification of product data information on AMSP

Figure 2 Categories of product data information on AMSP



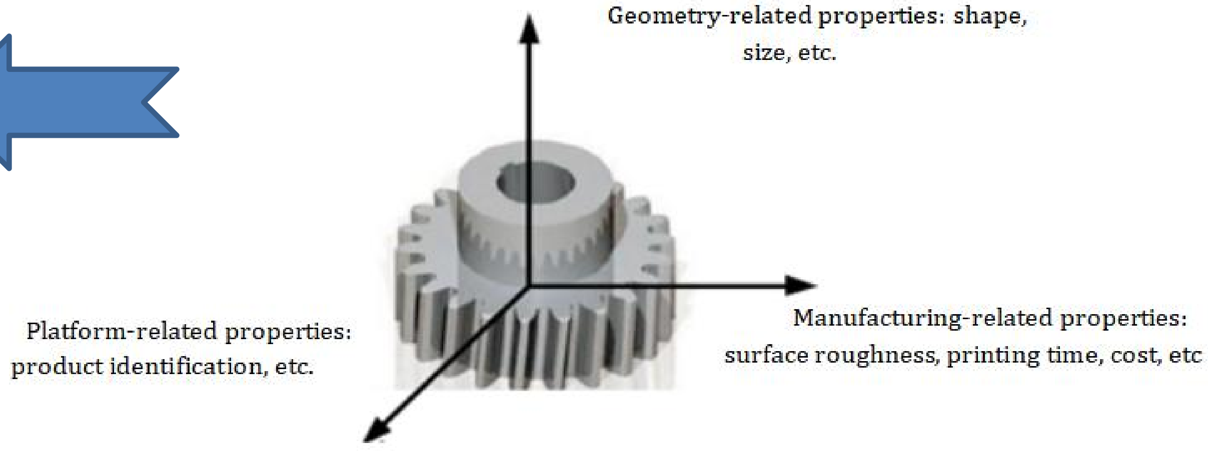
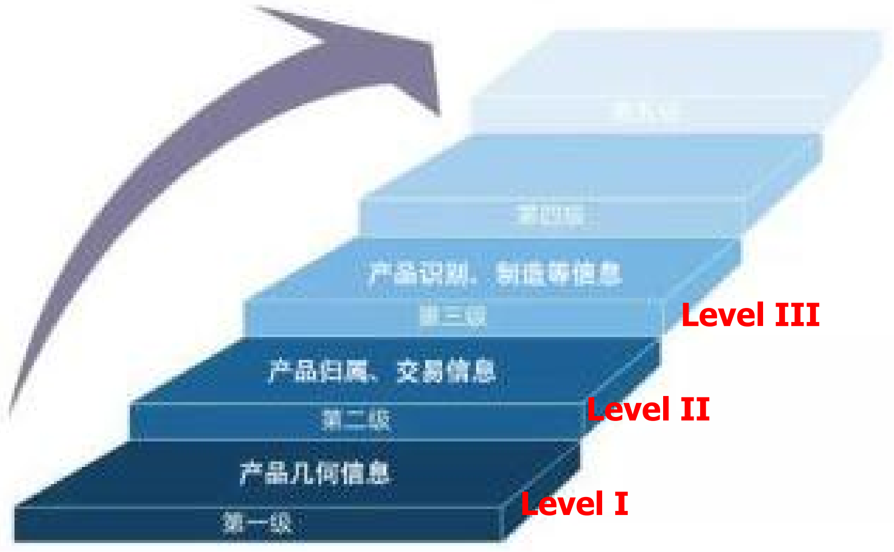


Figure 1 — Property types of a product on AMSP

Introdution to NP23955

☐ Protection for different categories of product data informations

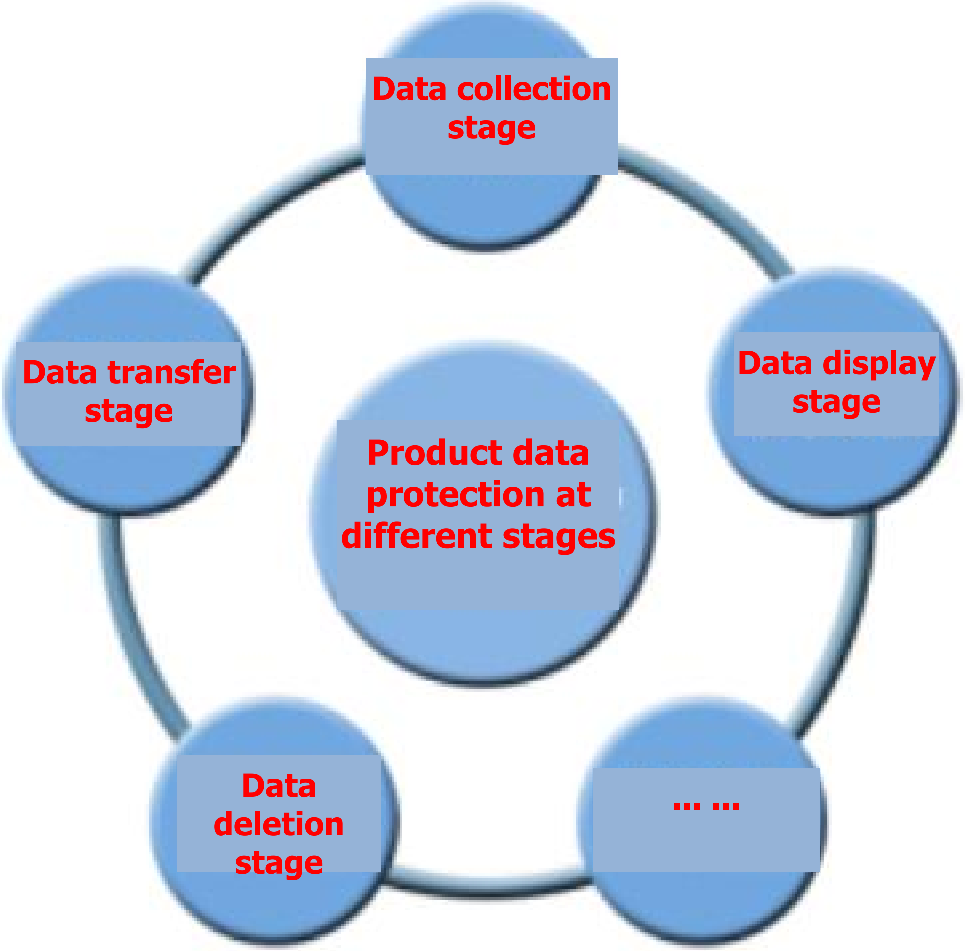
Categories	Main contents	Protection level
Product identification information	Product name, trademark and/or brand, product type, product description, etc.	Level III
Product attribution information	Uploader and/or designer (or design owner), etc.	Level II
Product attribution information	Store name	Level III
Product geometric information	Product shape, size, geometric file and format type, sliced file and format type, etc.	Level I
Product manufacturing information	Manufacturing materials, manufacturing process and/or equipment, product color, post-processing (like surface roughness), etc.	Level III
Product transaction information	Product quotation, lead time, delivery method, etc.	Level III
	Quantity of purchased products, transaction value, etc.	Level II



- According to the importance of different categories of product data information, three protection levels can be divided, which are level I, level II and level III.
- Level I is the strictest protection level.

Introdution to NP23955

□ Technical requirements for product data information protection at different stages



- The processing of product data information on AMSP mainly invloves four stages, i.e. data collection, data display, data transfer and data deletion, and the protection of product data information should be carried out throughout all the four stages.

Introdution to NP23955

□ Responsibilities and obligations assumed by different entities

All stakeholders including 3D model providers, 3D model receivers and AMSPs have the responsibilities and obligations to protect product data information

- Responsibilities and obligations of 3D model providers
- Responsibilities and obligations of 3D model receivers
- Responsibilities and obligations of AMSPs

Plan of NP 23955

- The voting process has fininshed before 2023-11-07
- Proposed Standard Development Track: 36months
- Proposed date for first meeting: 2024-01-05
- Proposed TARGET dates for key milestones
- Circulation of 1st Working Draft (if any) to experts: 2024-06-15
- Committee Draft consultation (if any): 2024-11-15
- DIS submission*: 2025-07-15
- Publication*: 2026-08-15

We need the participation from YOU!

Thank you!

Your advices are highly appreciated

12 Dec. 2023， Online Workshop

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glTF for 3D Scan Data Format

Hwanyong Lee, Ajou University
Member of Korean National Body of JTC 1/WG 12
Liaison Representative of WG12-Khronos Group

Contents

glTF 2.0 Scene Description Structure

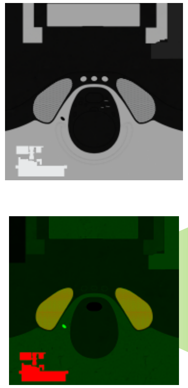
.gltf (JSON)

Node hierarchy, PBR material textures, cameras

.bin
Geometry: vertices and indices
Animation: key-frames
Skins: inverse-bind matrices

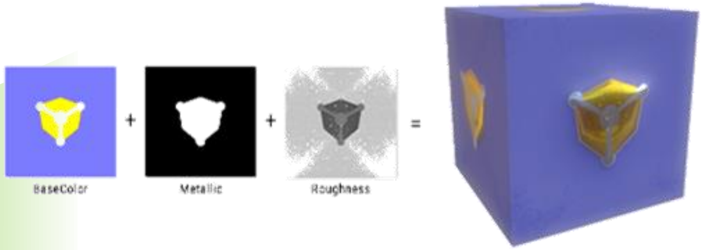
.png
.jpg
.ktx2
Textures

Geometry

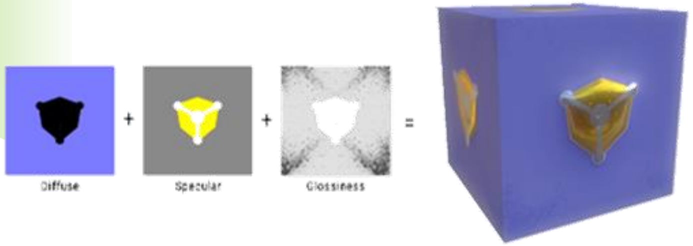


Texture based
PBR materials

Mandatory Metallic-Roughness Materials

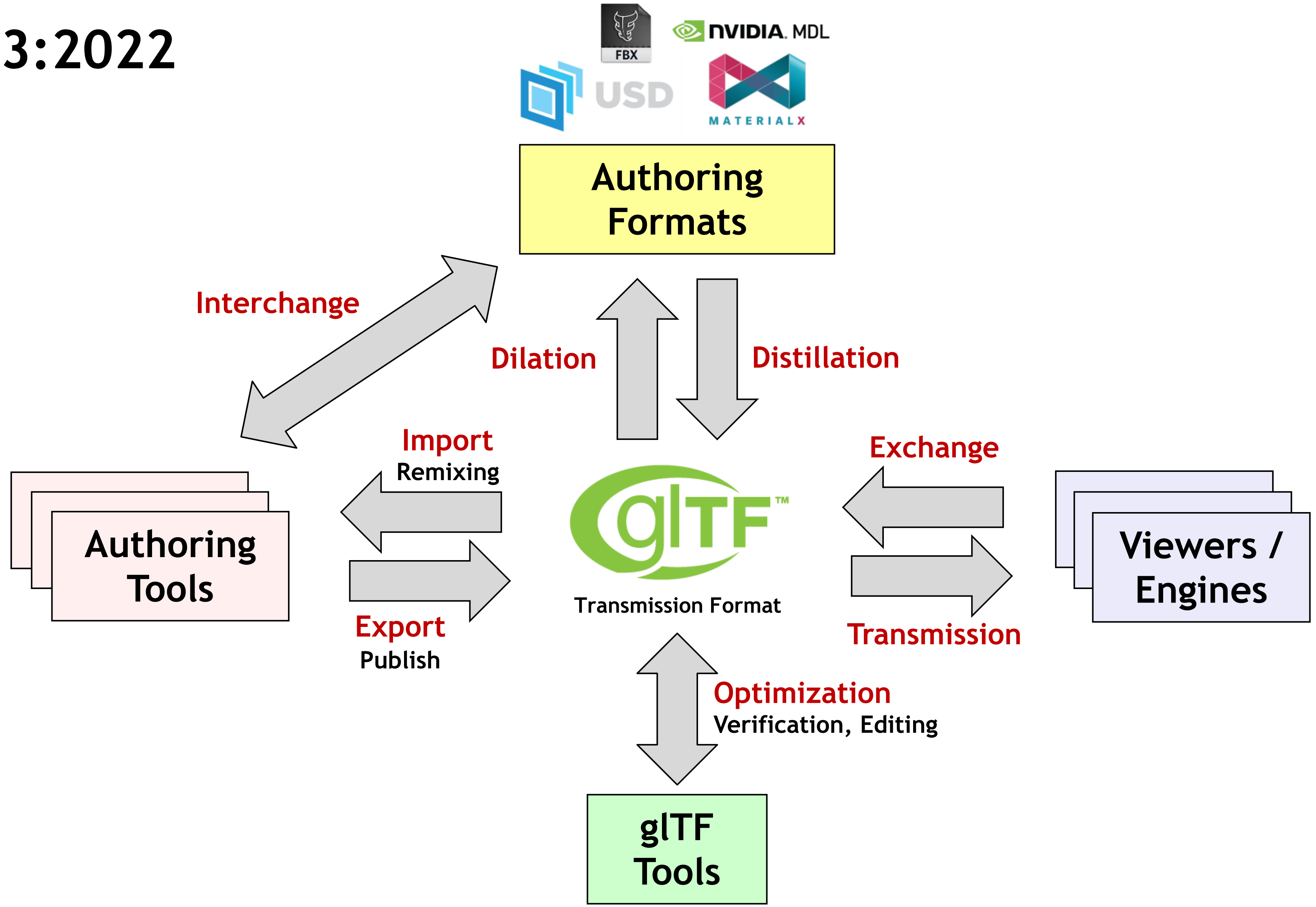


Optional Specular-Glossiness Materials



glTF

- ISO/IEC 12113:2022



glTF - The JPEG of 3D!

Audio	Video	Images	3D
MP3	H.264	JPEG	glTF™
napster	YouTube™	facebook	New market opportunities for 3D content creation and deployment!

glTF spec development
on open GitHub - get involved!
https://github.com/KhronosGroup/glTF

glTF™

Compact to Transmit ✓
Simple and Fast to Load ✓
Describes Full Scenes ✓
Runtime Neutral ✓
Open and Extensible ✓

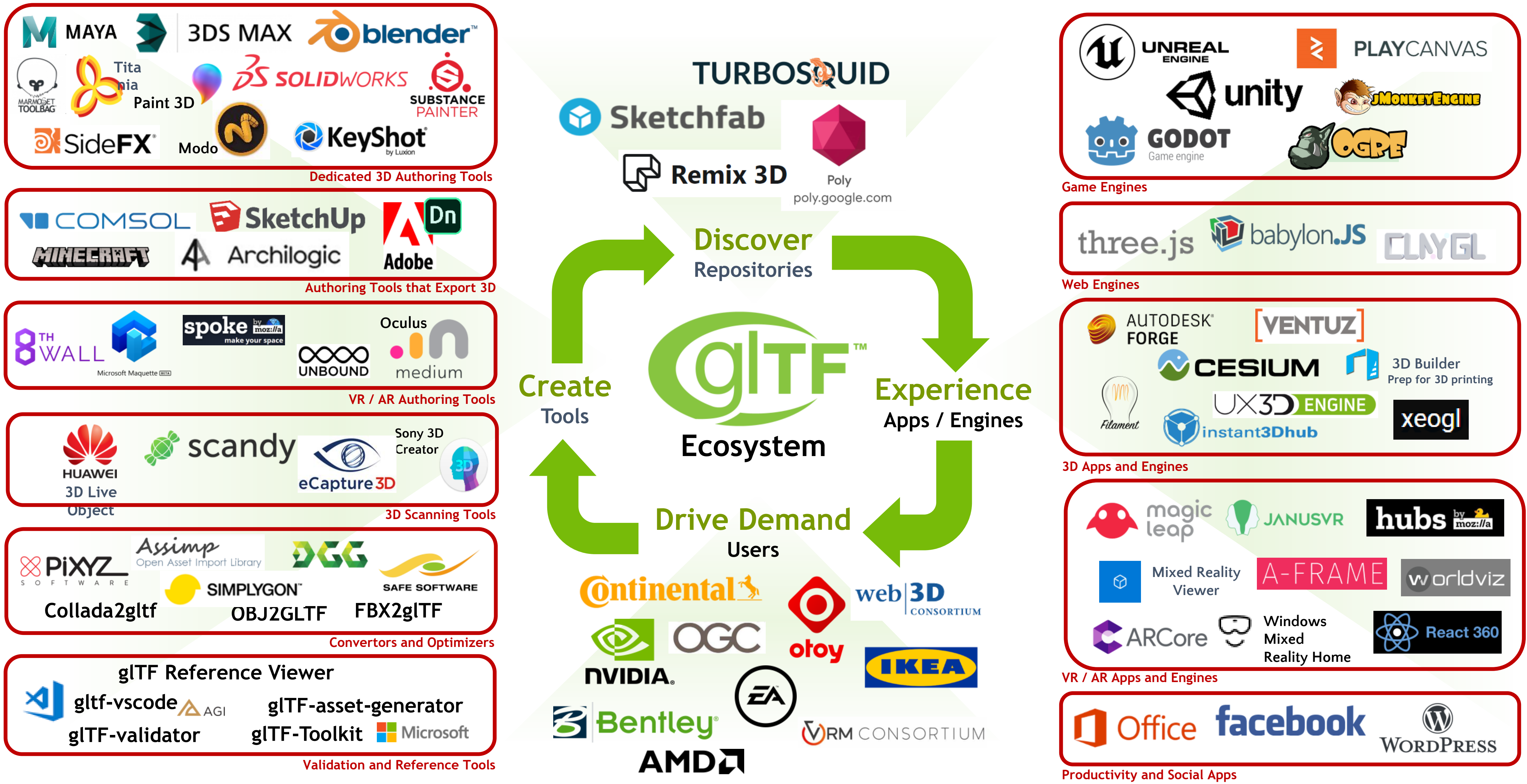
Efficient, reliable transmission
Bring 3D assets into 1000s of apps and engines

glTF™
WebGL™

glTF 1.0 - December 2015
Primarily for WebGL
Uses GLSL for materials

WebGL™ DirectX 12 Vulkan.

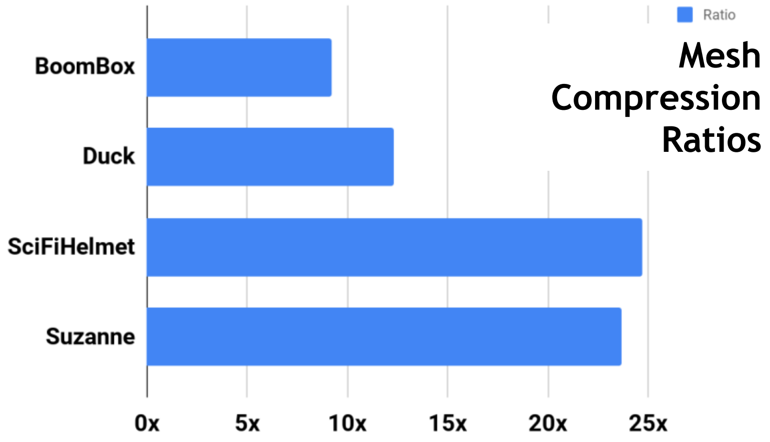
glTF 2.0 - June 2017
Native AND Web APIs
Physically Based Rendering
Metallic-Roughness and Specular-Glossiness



MAYA
3DS MAX
blender
MARMOSET TOOLBAG
Tita nia
Paint 3D
SOLIDWORKS
SUBSTANCE PAINTER
SideFX
Modo
KeyShot
by Luxion
Dedicated 3D Authoring Tools
COMSOL
SketchUp
Dn
Adobe
MINECRAFT
Archilogic
Authoring Tools that Export 3D
8TH WALL
Microsoft Maquette BETA
spoke by mozilla
make your space
Oculus
UNBOUND
medium
VR / AR Authoring Tools
HUAWEI
3D Live Object
scandy
eCapture3D
Sony 3D Creator
3D Scanning Tools
PiXYZ SOFTWARE
Assimp
Open Asset Import Library
DGG
SIMPLYGON
SAFE SOFTWARE
Collada2gltf
OBJ2GLTF
FBX2glTF
Convertors and Optimizers
glTF Reference Viewer
gltf-vscode
AGI
glTF-asset-generator
glTF-validator
glTF-Toolkit
Microsoft
Validation and Reference Tools
TURBOSQUID
Sketchfab
Poly
poly.google.com
Remix 3D
Discover
Repositories
Create
Tools
glTF™
Ecosystem
Experience
Apps / Engines
Drive Demand
Users
Continental
otoy
web3D CONSORTIUM
NVIDIA
OGC
IKEA
EA
Bentley
AMD
VRM CONSORTIUM
UNREAL ENGINE
PLAYCANVAS
unity
JMONKEYENGINE
GODOT
Game engine
OGRE
Game Engines
three.js
babylon.JS
CLAYGL
Web Engines
AUTODESK FORGE
VENTUZ
CESIUM
3D Builder
Prep for 3D printing
Filament
UX3D ENGINE
instant3Dhub
xeogl
3D Apps and Engines
magic leap
JANUSVR
hubs by mozilla
Mixed Reality Viewer
A-FRAME
worldviz
ARCore
Windows Mixed Reality Home
React 360
VR / AR Apps and Engines
Office
facebook
WordPress
Productivity and Social Apps

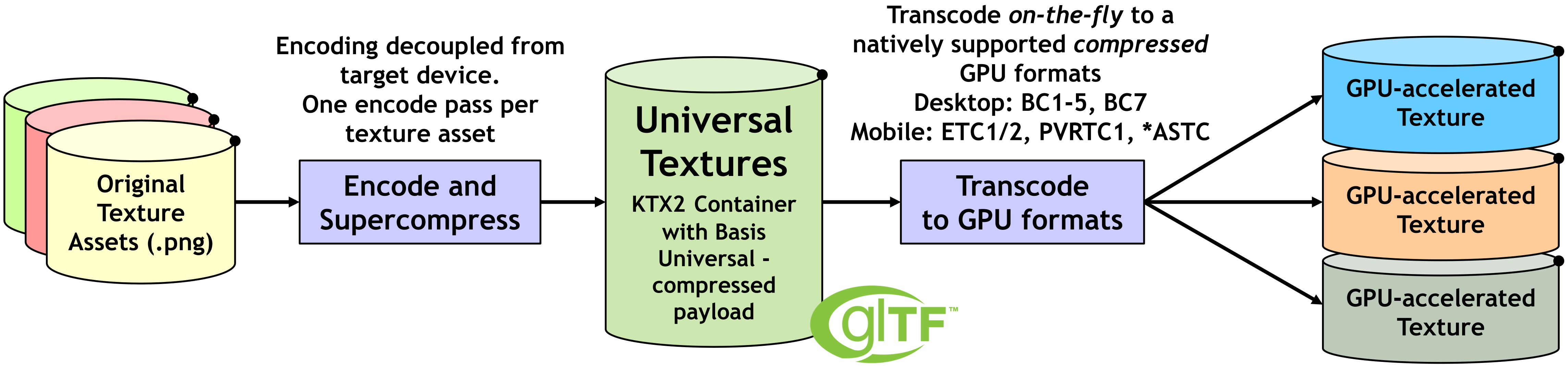
Draco glTF Mesh Compression Extension

- **Library for compressing and decompressing 3D geometric meshes and point clouds**
  - Draco designed and built for compression efficiency and speed - great fit with glTF!
  - https://github.com/google/draco
- **Draco glTF extension launched in February 2018**
  - https://github.com/KhronosGroup/glTF/blob/master/extensions/2.0/Khronos/KHR_draco_mesh_compression/README.md
- **Google has released Draco encoders and decoders in open source**
  - C++ source code encoder to compress 3D data
  - C++ and JavaScript decoders for the encoded data
  - https://github.com/google/draco/tree/gltf_2.0_draco_extension
- **glTF/Draco compression already in use**
  - Blender, three.js, BABYLON.JS, Adobe Dimension, glTF pipeline, FBX2glTF, AMD Compressonator and glTF sample models



Universal Textures for glTF

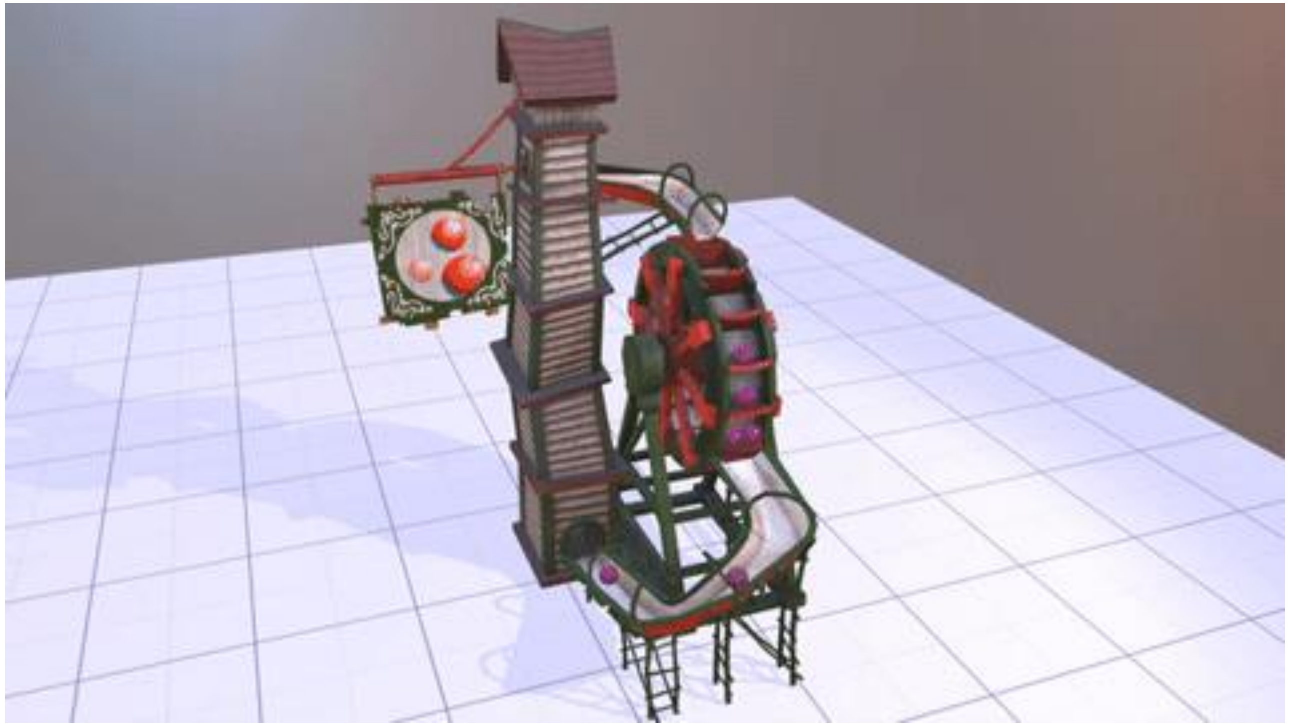
- **Fragmentation of GPU texture formats is significant issue for developers**
  - Binomial's 'Basis Universal' technology enables JPEG-sized texture assets
  - Transcodable on-the-fly to natively supported compressed GPU formats
- **glTF Universal Texture extension uses KTX2 as a flexible container**
  - Precisely defined specification for consistent, cross-vendor generation and validation
  - Can contain wide range of texture formats used in Vulkan/DirectX/Metal
  - Supports streaming and full random access to MIP levels
  - Subset of full KTX2 - mandating supercompressed textures using Basis Universal technology



*ASTC support in development

Physics

- Collision geometry
- Motions
- Materials
- Joints
- Filters



PBR in glTF

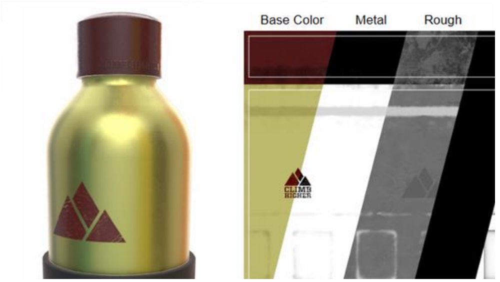
Clearcoat

Volume

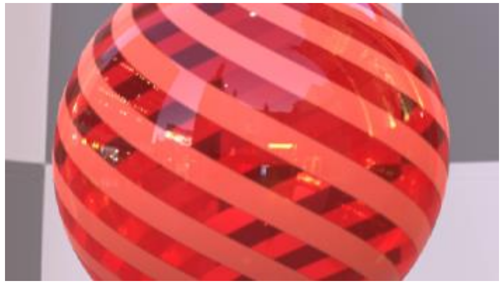
Sheen

Index of Refraction

Metal / Rough



Transmission



Specular

Geospatial

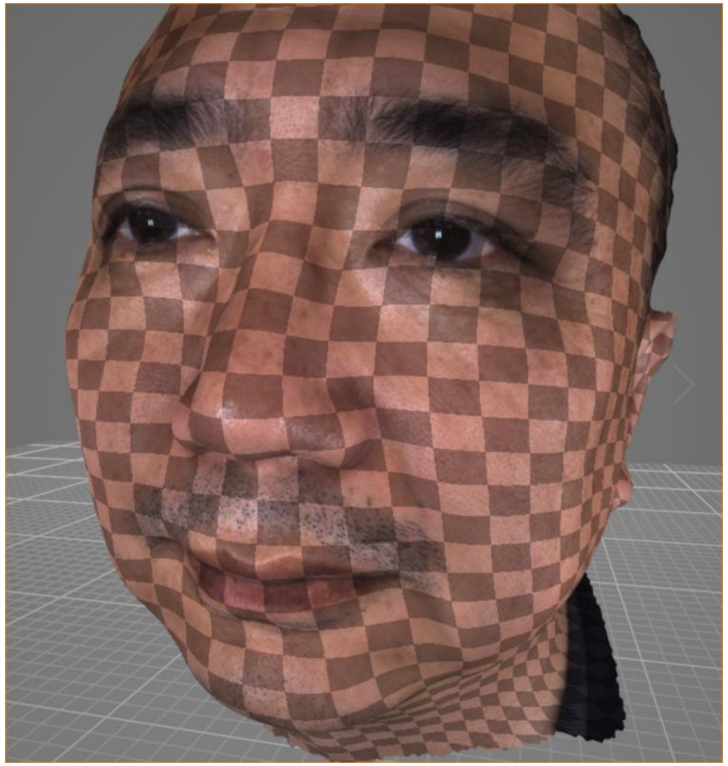
Expand the capabilities of glTF and related technologies to better address the needs and requirements for transmission and display of 3D models, scenes, and interfaces for geospatial applications.

- Liaison with Open Geospatial Consortium (OGC)
- Very large data sets
- Specialized data handling (Heirarchical Level of Detail - HLOD)

3D Scanning Data Format Based on glTF

3D Scanned Data

Geometry : Vertex and Mesh



Texture Mapping : UV Coords

Textures : Materials

glTF 2.0 Scene Description Structure

.gltf (JSON)

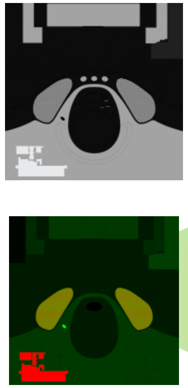
Node hierarchy, PBR material textures, cameras

.bin

Geometry: vertices and indices
Animation: key-frames
Skins: inverse-bind matrices

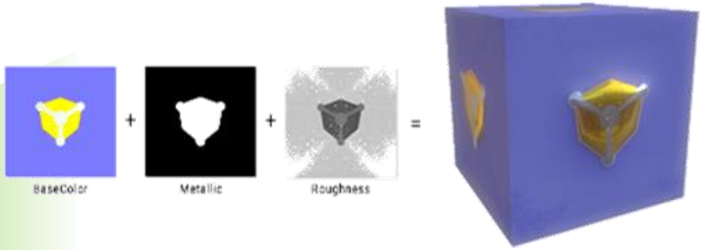
.png
.jpg
.ktx2
Textures

Geometry

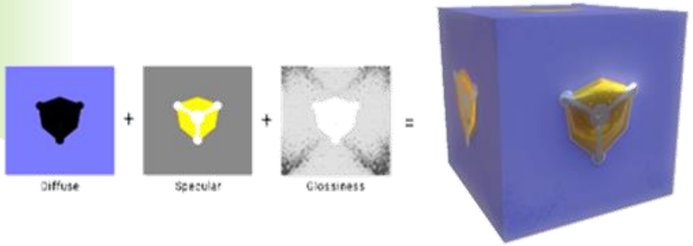


Texture based PBR materials

Mandatory Metallic-Roughness Materials



Optional Specular-Glossiness Materials



Why glTF for 3D Scanning

- **Efficiency - Directly import/export 3D asset for GPU**
  - No need to conversion - binary data of Geometry, Image (Texture)
  - GPU import / export tools available with open source

- **Usefulness**
  - Asset can be used in tremendous tools for editing, visualization, compression, metaverse and commerce etc.
  - Annotation (PDF), Presentation (MS PowerPoint), Documentation (MS Word), Rich Media (MPEG)

- **It is an international standard!**
  - ISO/IEC 12113:2022
  - Can be used as a reference standard

Thank you

Hwanyong Lee, Ajou University

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Proposal for NWIP overview and vocabulary for 3D scanned data

JTC1 WG12 Online workshop, 2023-12-09
Korean experts

Presenter: Prof. Jumyung UM
JTC1 WG12 & ISO TC184 SC1
Kyung Hee University

Contents

- **Motivation**
  ① Advanced features
  ② Advanced scanning technology
  ③ Advanced visualization method

- **Use cases**
  ① Legacy methods
  ② Quality control
  ③ Reverse engineering
  ④ Robot programming
  ⑤ Digital factory
  ⑥ Construction yards
  ⑦ Retail applications
  ⑧ Medical applications

- **Working draft**
  ① Introduction
  ② Scope
  ③ Related standards
  ④ General procedure
  ⑤ Table of Contents
  ⑥ Plan

- **QnA**

- modern 3D scanner have advanced features
  - What is Base Color, F0, Normal, Metalness, Roughness and Scattering?
  - Who can define them precisely ?

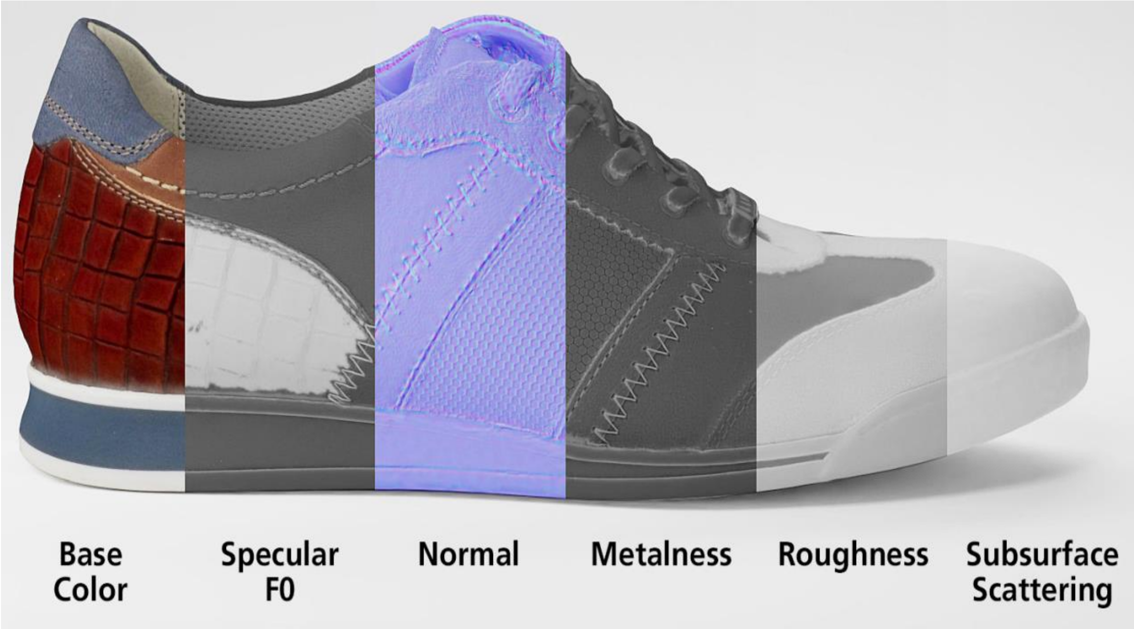
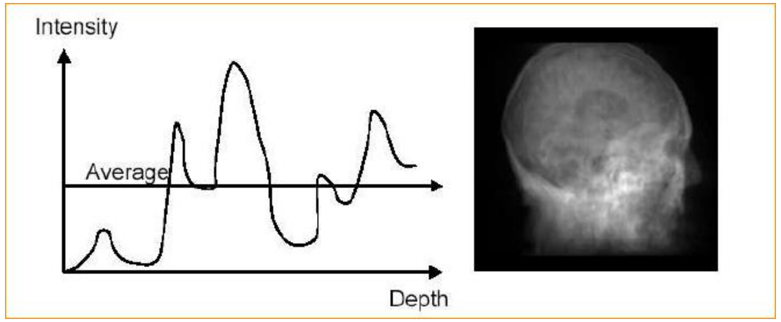
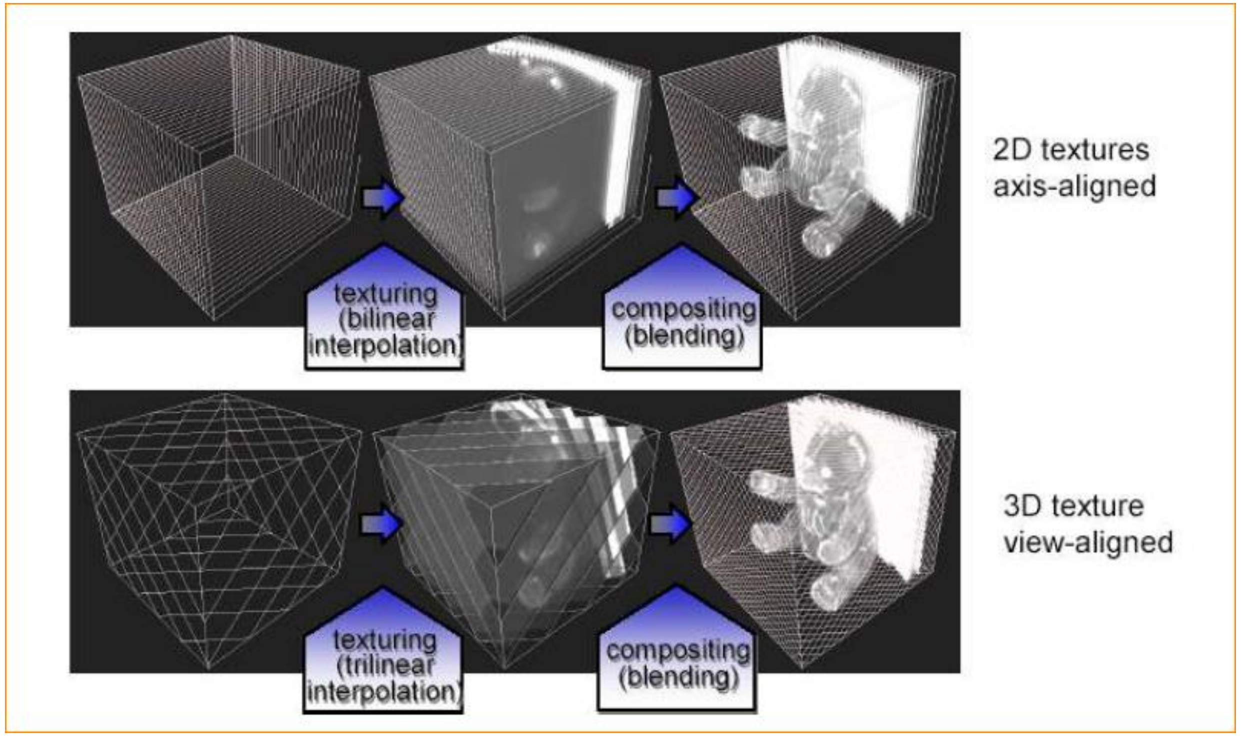


Image courtesy from DGG and ZEISS

- How can we evaluate 3D scanned quality?
  - Can we separate skin color and shadow?
  - Resolutions of color and geometry.

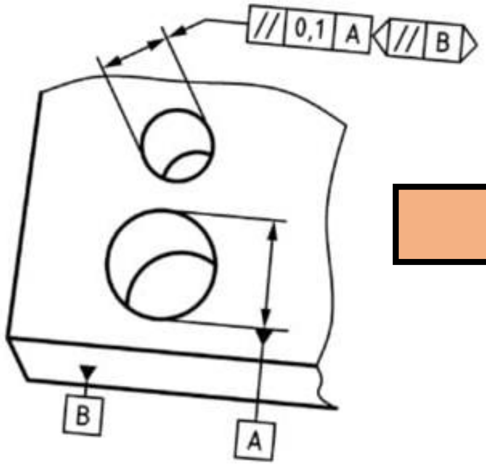
- New visualization methods for 3D scanned images are feasible
  - for instance, Direct Volume Rendering - rendering without iso-surface detection
  - need definition
    - drawing params
    - technical features

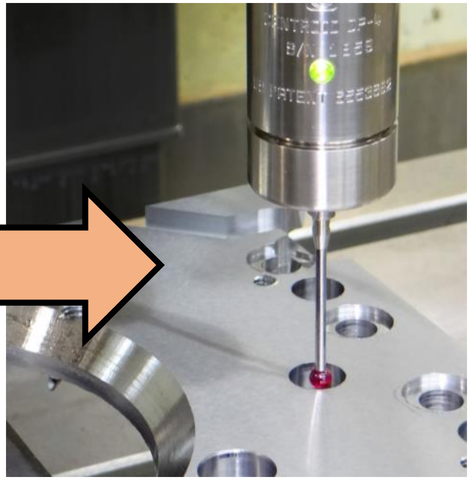




Use cases > Legacy methods of traditional manufacturing

Source: ISO 1011





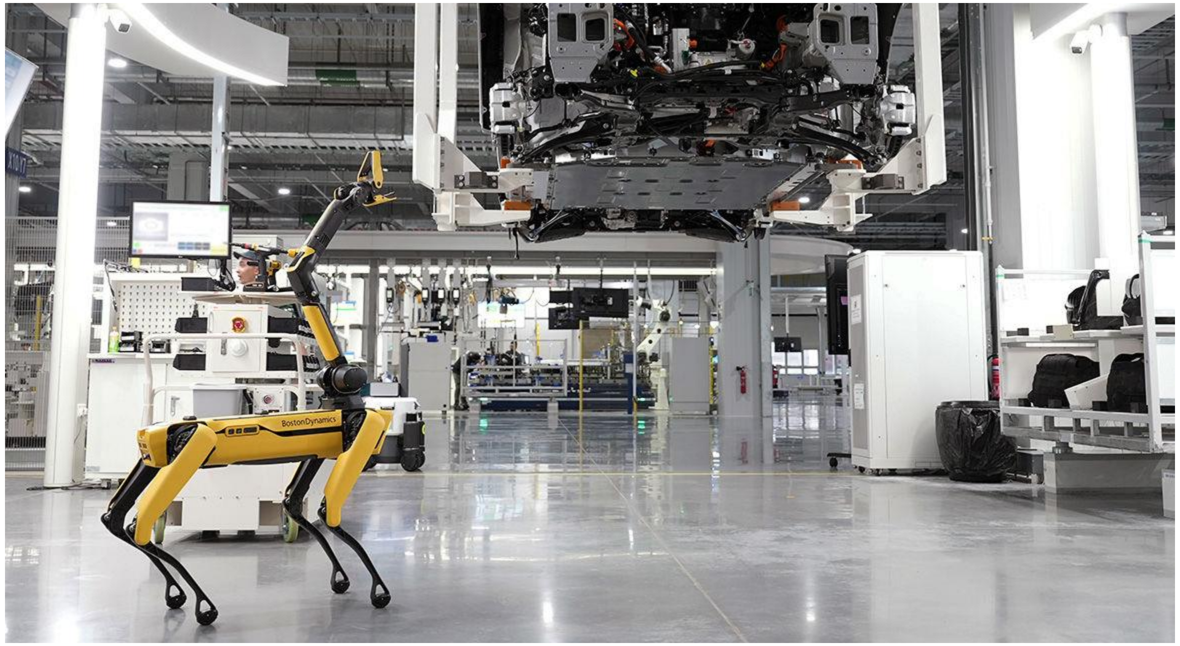
Touch probing : GD&T measurement of machining parts

- **Legacy metrology and inspection processes are using touch probing to measure selected points on the surface of final products**
- **Limitations: Single point measurement, Part accessibility, Surface finish sensitivity, Material compatibility, Tool deflection**

➔ 3D scanning method

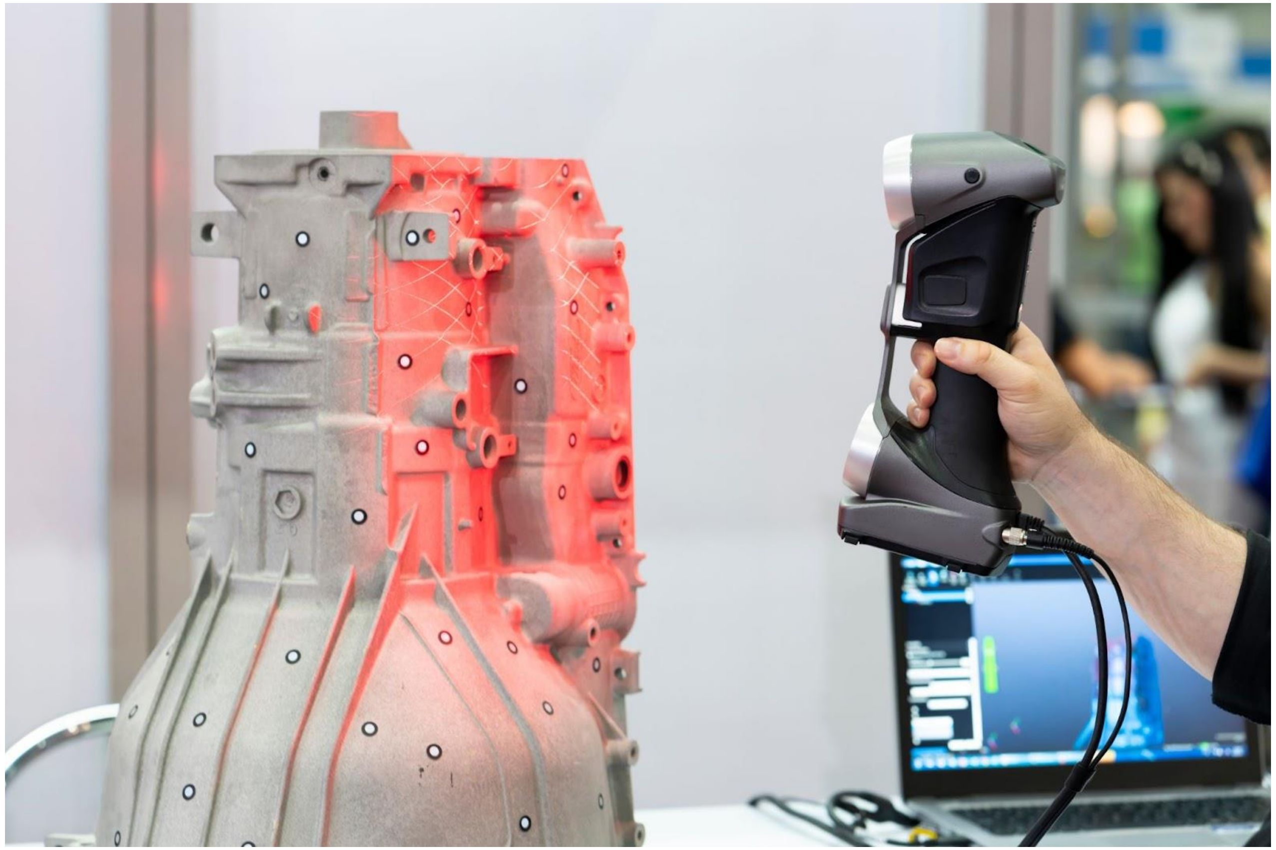
Use cases > Quality control

Source: https://www.hyundai.com/worldwide/en/company/newsroom/detail/0000000363



- **Advanced assembly factories are employing new quality control methods of welding surface with whole plates by using 3D scanning**
- **There is use cases of mobile robots inspecting assembly results visually by using 3D camera attached in the end of its head.**

Use cases > Reverse engineering

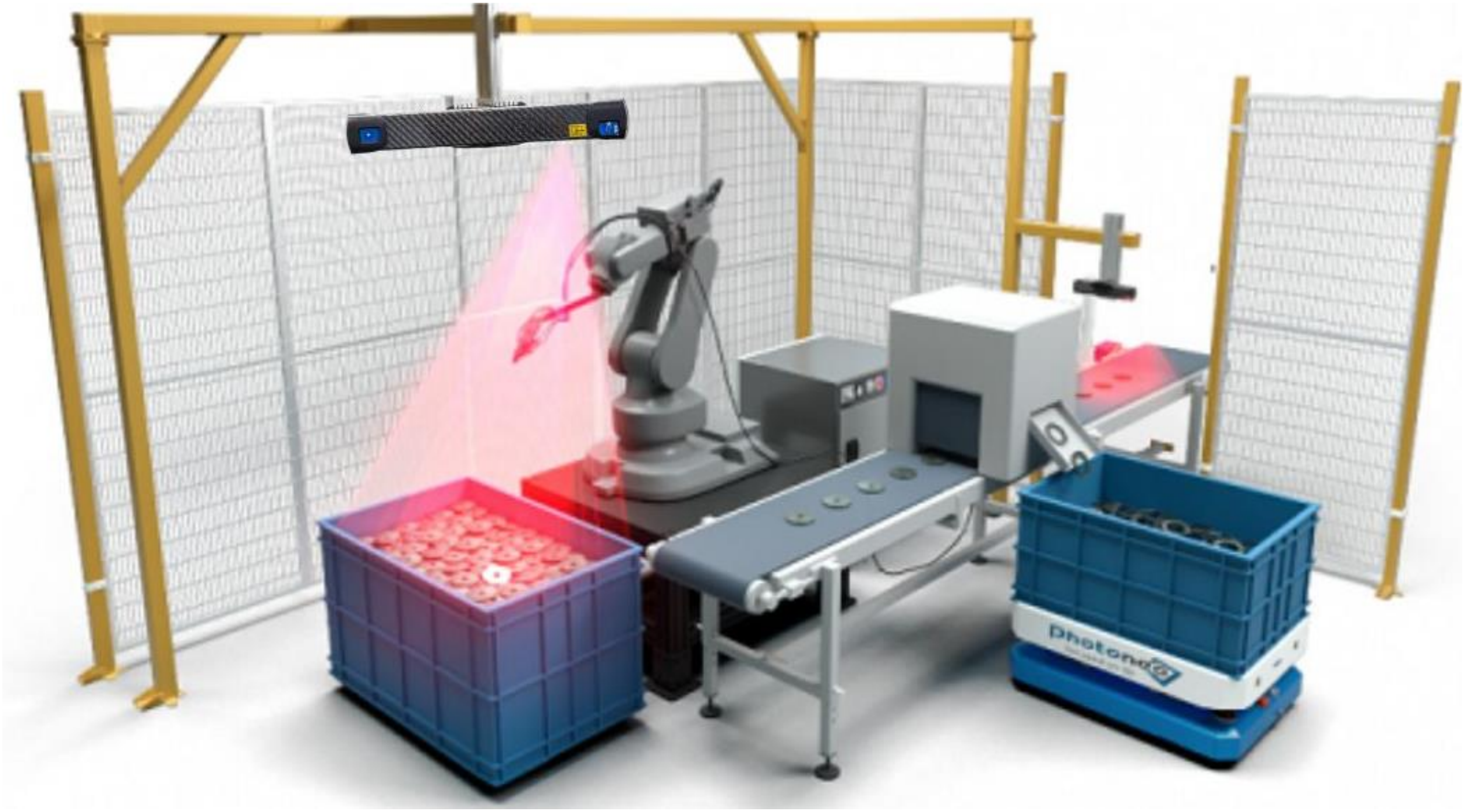


- **“Overhaul and Repair” is evolving by using 3D scanning technologies. Dense scanning data and Deep learning methods let the process enhance the speed and the accuracy.**
- **By comparing scanned data with the original shape, repair process optimizes the time and cost .**
- **Various 3D scanning methods are used. In particular, metal parts are more challenging but new technologies overcome the limitation.**

Source : https://www.fictiv.com/articles/tips-for-3d-scanning-to-cnc-machine-repair-and-overhaul-parts

Use cases > Factory safety > Robot programming

- Since collaborative robots (Cobots) are introduced in shop floors, Camera sensors are widely used to recognize positions of parts as well as to detect possible hazardous situation such as collision with human operators.
- Legacy robot programming is off-line way, but Cobot control requires for synchronizing with 3D scanning data during the robot are running.



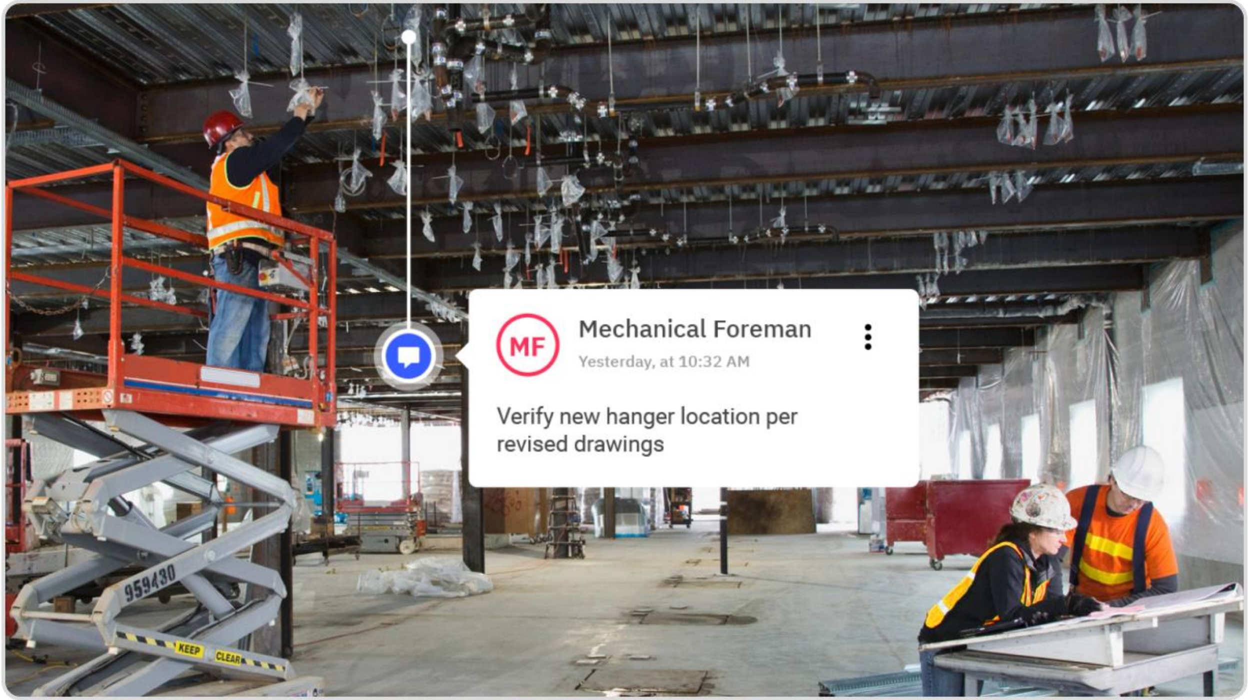
Source: https://www.sodavision.com/product/photoneo-bin-picking-studio-with-phoxi-3d-scanner-m/

Use cases > Factory safety > Digital factory

- Building digital twin of factories give the opportunities of asset management, layout planning, Safety analysis, Training operators, Real-time monitoring, etc.
- In essence, 3D scanning data forms the foundation for creating detailed and accurate digital twins of factory environments, enabling a wide range of applications.

Use cases > Civil applications > Construction yards

Source: https://matterport.com/ko/industries/architects-engineering-construction



- **Leveraging 3D scanning data in constructing digital twins of construction yards significantly improves safety measures by providing simulations, real-time monitoring, training opportunities, and proactive hazard identification and mitigation strategies.**

- **Visualizing Safety Protocols, Emergency routes, Worker monitoring and tracking, Dynamic Safety Assessment, Collaborative Safety Planning, etc**

Use cases > Retail applications

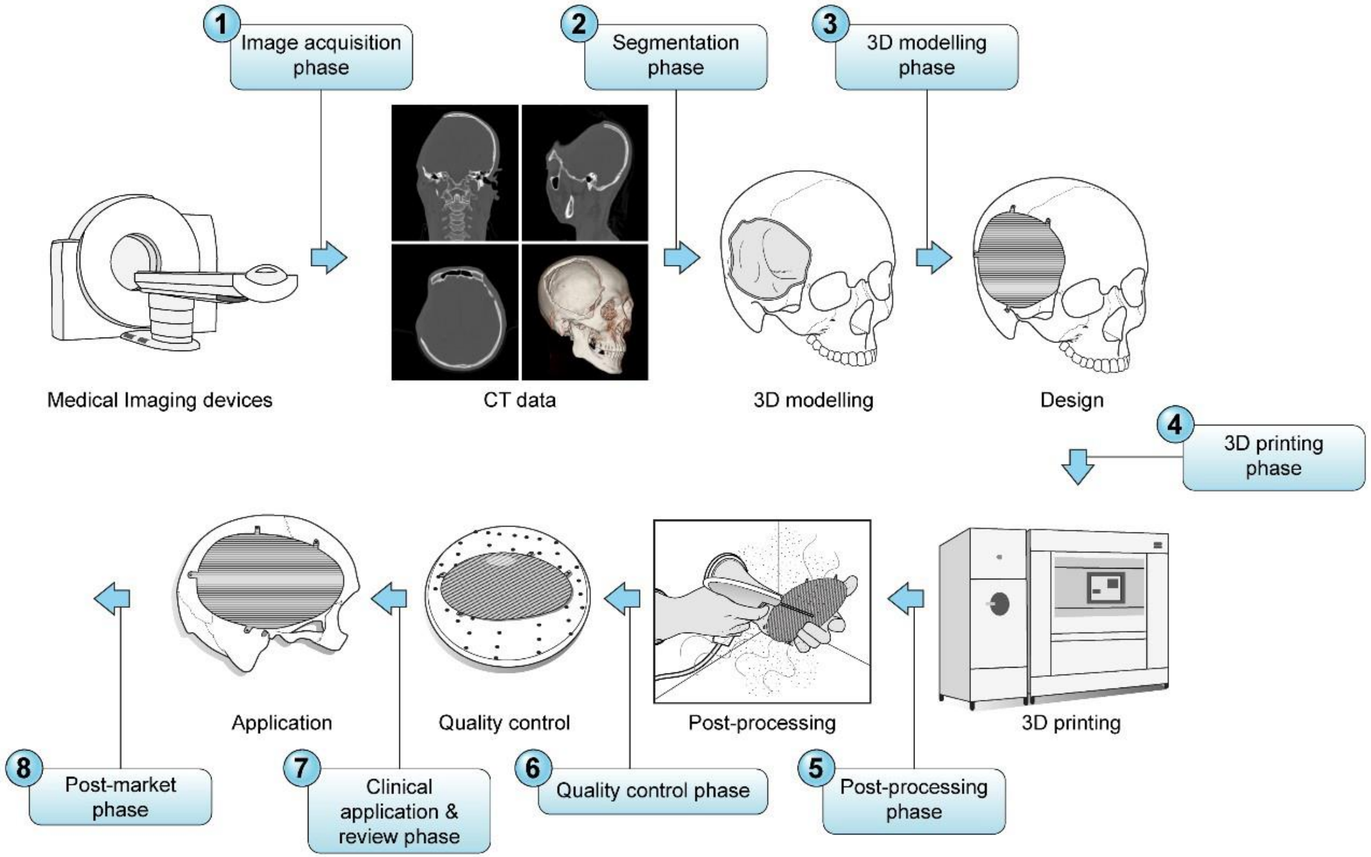
- **3D scanning is a widely used solution in various industries, including fashion, retail, and retail. It allows for accurate body measurements for tailored apparel and allows shoppers to try on new clothes using their 3D avatars. Virtual fitting rooms also provide new opportunities for in-store and online shopping, allowing customers to view results in 360 degrees.**

https://www.iphone3dscanner.com/solutions

Use cases > Medical applications

- 3D scanning technology plays a pivotal role in improving patient care by enabling personalized treatments, precise surgical planning, enhanced medical education, and the development of innovative medical devices and interventions

- WG12 is standardizing a data procedure of Medical Image-Based Modelling as ISO/IEC 3532-1.



Source : ISO/IEC 3532-1 CD version

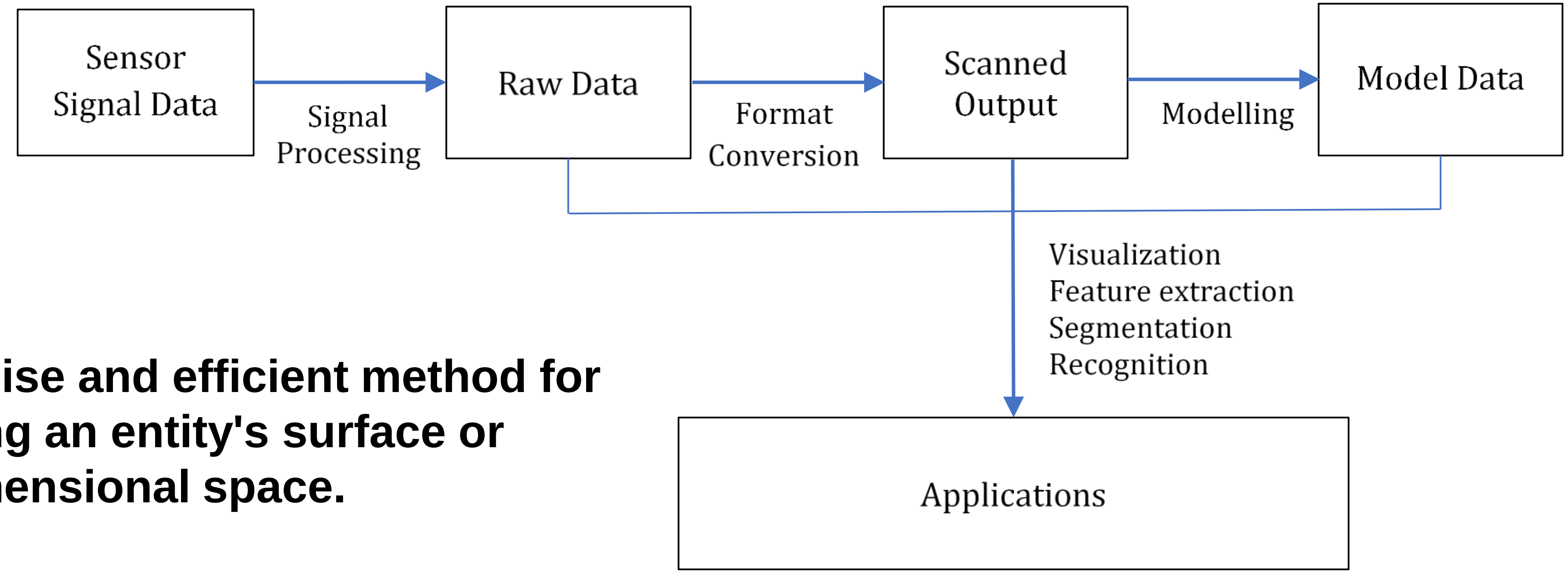
- **This document provides an overview of 3D printing and scanning along with a set of terms and definitions. The purpose of this document is to provide foundational standards for better understanding and for developing key ideas and practices on the Information and Communication Technology (ICT) aspect of 3D printing and scanning.**

- **This document places an emphasis on the ICT aspects of terms used for 3D scanning. It clarifies and enhances definitions for generic workflows for 3D printing and scanning to emphasize the ICT perspective that aligns with the work scope of JTC 1. The definitions include terms related to 3D scanning devices, data, process, and its applications.**

- **This document provides an overview of the ICT aspects of 3D scanning and its applications along with a set of terms and definitions.**
- **This document also related with the following processes: visualization, machining, inspection, product design, reverse engineering, and 3D printing.**
- **New terms from the future work within ISO/IEC JTC 1/WG 12 will be included in upcoming amendments of this document.**

Working draft > Related standards

Title	Group	Link
ISO/IEC 23510:2021 - Information technology — 3D printing and scanning — Framework for an Additive Manufacturing Service Platform (AMSP)	ISO/IEC JTC 1 - Information technology	https://www.iso.org/standard/75842.html
ISO 10303-242:2022 Industrial automation systems and integration — Product data representation and exchange — Part 242: Application protocol: Managed model-based 3D engineering	ISO/TC 184/SC 4 Industrial data	https://www.iso.org/standard/84667.html
ISO 10303-42:2022 Industrial automation systems and integration — Product data representation and exchange — Part 42: Integrated generic resource: Geometric and topological representation	ISO/TC 184/SC 4 Industrial data	https://www.iso.org/standard/84672.html
ISO 10303-46:2022 Industrial automation systems and integration — Product data representation and exchange — Part 46: Integrated generic resource: Visual presentation	ISO/TC 184/SC 4 Industrial data	https://www.iso.org/standard/84676.html
ISO 14649-10:2004 Industrial automation systems and integration — Physical device control — Data model for computerized numerical controllers — Part 10: General process data	ISO/TC 184/SC 1 Industrial cyber and physical device control	https://www.iso.org/standard/40895.html
ISO/IEC 12113:2022 - Information technology — Runtime 3D asset delivery format — Khronos glTF™ 2.0	ISO/IEC JTC1 & Khronos group	https://www.iso.org/standard/83990.html



3D scanning is a precise and efficient method for accurately determining an entity's surface or volume in a three-dimensional space.

It captures real-world information, aiding in visualization and measurement, and can be utilized for comparative analysis or design changes in new products.

Working draft > Plan

- terms used in 3D asset scanning, manipulation and visualization.
- no redundant definition!
- only new terms and difference usage in 3D asset (not listed in ISO terminologies)
- terms and overview for evaluation of 3D scanning and 3D asset manipulation and visulisation

- Schedule - In the end of 2023 - NWIP and first draft will be provided by KNB

Thank You

ISO/IEC JTC1/WG12
AHG 3 on 3D Scanning for 3D Printing

12th Dec 2023: 3D Scanning for 3D Printing Webinar

Jason Dowling, Ph.D.
Principal Research Scientist, CSIRO
Brisbane, Australia

Jason.Dowling@csiro.au

AHG 3 3D SCANNING FOR 3D PRINTING: TERMS OF REFERENCE

01

Investigate current market and technology status related to 3D scanning for 3D printing

02

Investigate/assess status of relevant standardization activities in other ISO/IEC TCs; SDOs, and consortia

03

Investigate future impact of new ICT technology (e.g. digital twin, metaverse) to JTC1.

04

Provide gap analysis for standardization opportunities

05

Identify and propose how JTC 1 could address ICT standardization needs

06

Propose, if appropriate, new work items related to 3D scanning and 3D replications

AHG 3 HISTORY

- **16 Jun 2022**: 1ST JTC 1/WG 12 AHG 3 MEETING VIRTUAL. 15 PARTICIPANTS, 2.5 HOURS (N520)
- **7 Jul 2022**: 2ND JTC 1/WG 12 AHG 3 MEETING VIRTUAL. 8 PARTICIPANTS; 2 HOURS
- **31 Aug 2022**: 3RD JTC 1/WG 12 AHG 3 MEETING VIRTUAL
- **16 Feb 2023**: 4TH JTC 1/WG 12 AHG 3 MEETING ON 3D SCANNING FOR 3D PRINTING, VIRTUAL 4 PARTICIPANTS; 1HOUR 45 MINUTES.
- **14 Mar 2023**: 5TH JTC 1/WG 12 AHG 3 MEETING TEL AVIV, ISRAEL F2F MEETING WITH REMOTE PARTICIPATION.

AHG3 CURRENT MEMBERSHIP

- Prof. Kyu won Shim (KR) (Co- Convenor)
- A/Prof Jason Dowling (AU) (Co- Convenor)
- Dr. Byoung Nam Lee (KR)
- Mr. Jonghong Jeon (KR)
- Mr. Dongyub Lee (KR)
- Prof. Hwanyong Lee (KR, JTC 1/SC 24)
- Prof. Jumyung Um (KR, ISO/TC 184)
- Prof. Ji-Man Park (KR, ISO/TC 106)
- Mr. Yusuke Yasuda (JP)
- Adin Stern (IS)
- Prof. Yonghui Liu (CN)

HIGH LEVEL ICT ASPECTS OF 3D SCANNING

Data acquisition (structured light, laser, stereo vision, etc)

Data processing (data alignment, registration, meshing, etc)

Data storage and management (3D models require efficient storage and management)

Data visualization (generate 2D images, animation, interactive simulations, etc)

Remote access and control of 3D scanners (eg. remote monitoring)

SAMPLE 3D SCANNING APPLICATIONS

Cultural heritage

Construction industry and civil engineering

Engineering design process

Entertainment

3D photography

Law enforcement

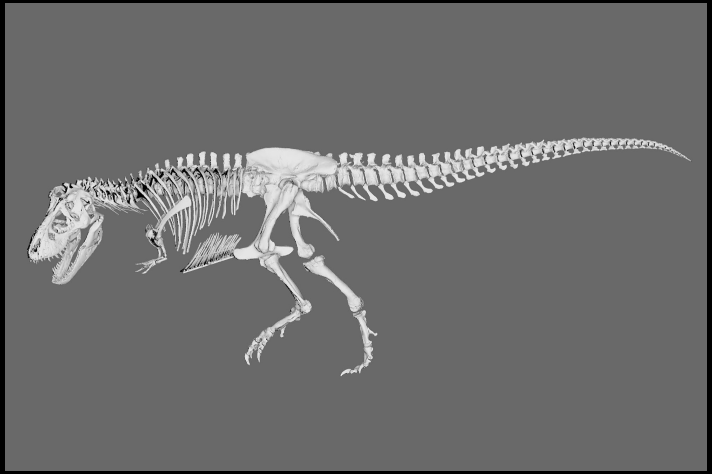
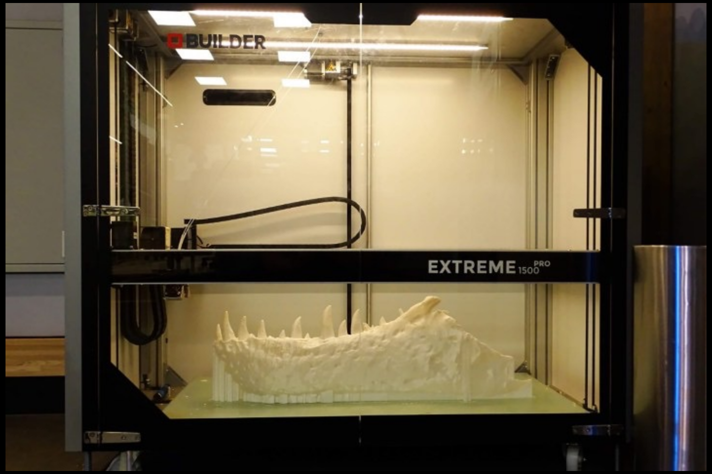
Reverse engineering

Real estate

Virtual remote tourism

Circumvention of shipping costs and tariffs

Medical

Above: Artec handheld scanned tyrannosaurus rex in the Netherlands; modelled and printed in Nagasaki, Japan.

https://www.digitaltrends.com/computing/3d-printed-t-rex-skeleton/

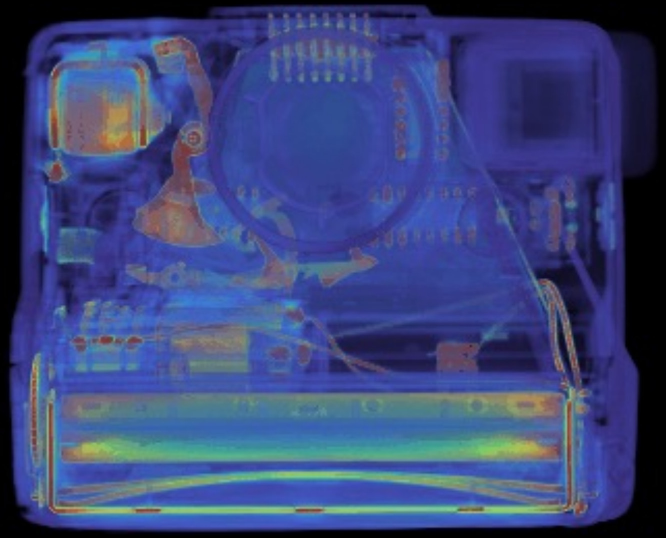
APPLICATIONS: CULTURAL HERITAGE

- Recording and preserving historical sites and artifacts
- Restoration and conservation
- Archaeology
- Digital preservation
- Education

APPLICATIONS: ENGINEERING DESIGN PROCESS


Neptune 3D CT scan of Moka Express Coffee maker.
https://www.scanofthemonth.com/scans/coffee

1. 3D scanning of object
2. Data processing (e.g., convert point cloud to mesh)
3. Design (import mesh into CAD or BIM software)
4. Simulation and analysis (in virtual environment)
5. Fabrication (3D print, CNC machining, etc.)
6. Inspection (Compare 3D scan result with original design)

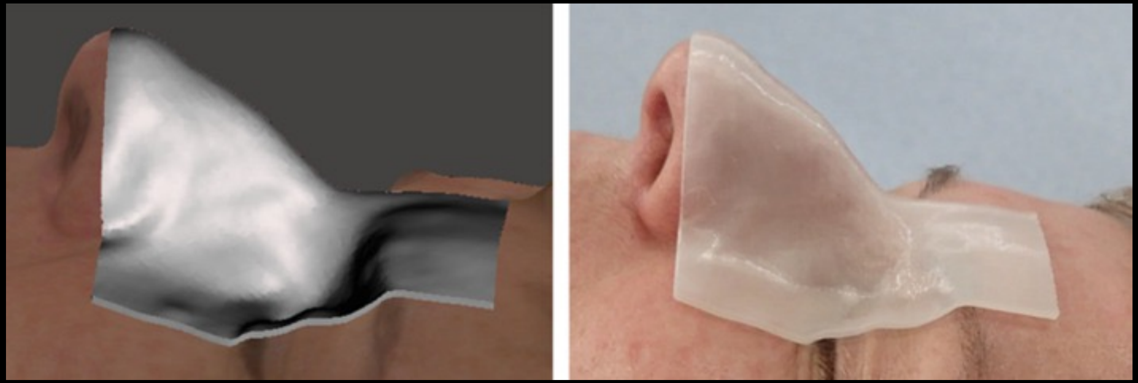



https://www.theverge.com/2023/3/18/23640484/lumafield-neptune-ct-scanner-3d-x-ray-hands-on-interview

APPLICATIONS: MEDICAL

- 3D scanning (e.g. CT and MRI) can acquire data for detailed digital models of human anatomy, which can be used in medical research and education, as well as in the planning of surgeries.

- 3D scans of a patient's external surface can be acquired through 3D scanning technologies



Scanned (Artec Leo); Modelled (Autodesk Meshmixer); and 3D printed (Ender 5) bolus for radiation therapy treatment.

Crowe, S., et al. Evaluation of optical 3D scanning system for radiotherapy use. J Med Radiat Sci. 69 (2021) 218– 226.

EMERGING TECHNOLOGIES

Handheld 3D scanning: quickly and easily capture 3D data of objects and environments. Lightweight, portable and easy to use

Multi-modal 3D scanning: Combines different 3D scanning technologies, such as laser scanning and photogrammetry, to capture data from different perspectives and in different lighting conditions

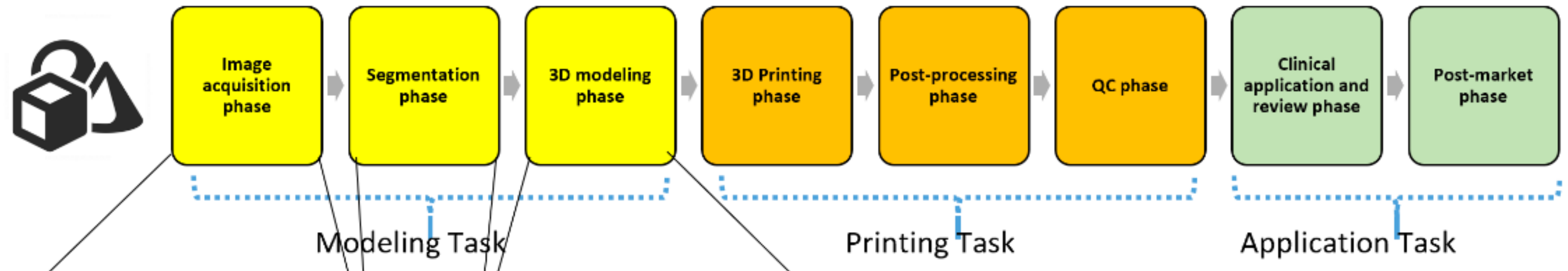
Active illumination 3D scanning: uses structured light or laser to project a pattern of light onto an object, and then captures the deformation of the pattern using a camera. Can improve the accuracy and resolution of 3D scanning in certain situations

Deep learning for 3D scanning: Use deep learning techniques to improve the quality of 3D scans by making the process more automated, faster, and more accurate

Mobile 3D scanning: Uses a combination of 3D scanning, GPS and computer vision to capture 3D data while moving. Useful for mapping and surveying large areas, such as cities, mines or archaeological sites

Terrestrial Laser Scanners: Uses lasers to scan a wide area quickly and accurately, and can be used for large-scale mapping and surveying, such as for construction and civil engineering projects; and digital twins

STANDARDIZATION ACTIVITIES: GAP ANALYSIS



		1. Object	2. Acquisition methods					3. Segmentation	4. 3D model generation				5. Application					6. Standardization
	SDOs	1.1 Target object	2.1 Scaning device	2.2 Distance	2.3 Device Type	2.4 Scan style	2.5 Raw Data	3.1 Segmentation required	4.1 3D reconstruction	4.2 3D representation	4.3 Format	4.4 Compression	5.1 Registration	5.2 Size/Scale	5.3 Error range	5.4 Level of Details	5.5 Application	6.1 Related Standards
1	ISO/IEC JTC 1/WG 12 (3D Printing and scanning)		CT, MRI					Y										
2	ISO/TC 106 (Dentistry)																	
3	ISO/TC 184 (Automation systems and integration)																	
4	ISO/TC 150/WG 14 (Implants for surgery)																	
5	ISO/IEC JTC 1/SC 24 (Computer graphics)																	
6	ISO/IEC JTC 1/SC 41 (Internet of things and digital twin)																	
7	ISO/TC 159 (Ergonomics)																	
8	Khronos Group																	
9	ISO/TC 133 (Clothing sizing systems)																	
10	ASTM Committee E57 on 3D Imaging System																	
11	OGC point cloud																	
12	MPEG point cloud compression																	
13	IEEE SA 3D Body Processing																	
14	Misc																	

AHG3 REQUEST

AHG 3 wants to focus on opportunities for horizontal standardization which align with other ISO/IEC committees

Membership in the AHG 3 is open to:

- JTC 1/WG 12 registered experts and Category C liaisons with JTC 1/WG 12
- Appointed experts from JTC 1/SCs, JTC 1/WGs, relevant ISO and IEC TCs

We welcome more diverse active membership from a wide range of application domains

ISO/IEC JTC1/WG12
AHG 3 on 3D Scanning for 3D Printing

12th Dec 2023: 3D Scanning for 3D Printing Webinar

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