

AI Algorithmic Auditing and Dataset Testing (AA&DT) for the Medical Imaging Industry

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Agenda

- 1 What is AI AA&DT?
- 2 Relationship between AA&DT and other forms of AI assessment, including the EU AI Act
- 3 Benefits of a voluntary AA&DT
- 4 Examples from the Medical Imaging Industry
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What is AI AA&DT?





Poll question





Supplying your Models and Datasets

Your models and datasets will be uploaded, stored and deleted securely

- BSI offer a secure upload service via our portal or SFTP
- Your dataset and model are temporarily stored during the assessment on secure servers, based in the EU
- Following the assessment your dataset and model will be securely deleted, with a deletion certificate

bsi



Supported AI workflows

BSI supports common AI workflows, is expanding the supported range, and would like to hear of your needs and feedback

- BSI currently supports AI workflows including classification, object detection and semantic segmentation
- Additional workflows are under development, including biometric identification and verification
- Please speak with us to discuss your needs



Supported AI metrics

BSI supports common metrics appropriate to supported AI workflows, based on international AI standards

- Supported metrics are derived from ISO/IEC standards including:
 - ISO/IEC 4213:2022 (Classification Performance)
 - ISO/IEC 24027:2021 (Bias and Fairness)
 - ISO/IEC 24029-1:2021 (Robustness)
 - ISO/IEC 3532-2:2024 (Segmentation Performance)
- Includes common metrics for classification, object detection and segmentation workflows, e.g.
 - Confusion matrices, accuracy, precision, recall, sensitivity, specificity, F1, ROC curves...

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0.5

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0.2

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06

coitive Rate

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0.8

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• Dice coefficient, Hausdorff distance...





Supported dataset and model formats

BSI supports common dataset and model formats, model-neutral formats, and model-free assessments

- Tabular CSV, parquet
- Image JPG, PNG, DICOM 2D/3D, NIFTI
- Docker, Python code, common model formats such as PyTorch, TensorFlow/Keras, scikit-learn, XGBoost
- Precomputed predictions no model supplied, just model predictions





Poll question





Relationship between AA&DT and other forms of AI assessment

A voluntary AA&DT can help prepare for a conformity assessment under the EU AI Act

- After the transition period for the EU AI Act, any provider or deployer of high-risk AI systems in the EU market will be required to undergo a third-party conformity assessment
- AA&DT can be complementary to other forms of voluntary assessment, such as certification against ISO 42001 (AI management systems)
- This assessment may involve verifying that datasets and algorithms conform to harmonised state of the art standards
 43.

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	ANNEX VII
	Conformity based on an assessment of the quality management system and an assessment of the technical documentation
.3.	The technical documentation shall be examined by the notified body. Where relevant, and limited to what is necessary to fulfil its tasks, the notified body shall be granted full access to the training, validation, and testing data sets used, including, where appropriate and subject to security safeguards, through API or other relevant technical means and tools enabling remote access.
.4.	In examining the technical documentation, the notified body may require that the provider supply further evidence or carry out further tests so as to enable a proper assessment of the conformity of the AI system with the requirements set out in Chapter III, Section 2. Where the notified body is not satisfied with the tests carried out by the provider, the notified body shall itself directly carry out adequate tests, as appropriate.
.5.	Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Chapter III, Section 2, after all other reasonable means to verify conformity have been exhausted and have proven to be insufficient, and upon a reasoned request, the notified body shall also be granted access to the training and trained models of the AI system, including its relevant parameters. Such access shall be subject to existing Union law on the protection of intellectual property and trade secrets.



Benefits of a voluntary AA&DT

A voluntary AA&DT demonstrates confidence in your AI systems

- The AA&DT deliverable confirms that:
 - Your models and datasets have been assessed by independent, third-party experts, using extensively validated methods based on ISO standards
 - The values of the performance metrics that you are calculating internally have been verified
- The Confirmation Letter can:
 - Supply confidence to your customers or to your investors
 - Supply confidence to your internal AI development teams in their processes

Confirmatio	By Royal
Commatio	
Artificial Intelligence Algori	thm Auditing and Dataset Testing Document number
This is to confirm that:	Company Name Company Address
AI Model(s) under test: Released on	Insert filename(s) and version. Insert AI model release date.
AI Dataset(s) under test:	Insert filename(s) and version
Declared Metrics for Assessment:	Insert filename(s) with version
Reference Number:	BSI-AADT-XXXXX
have had their reported metrics and t for those metrics listed in:	heir values assessed and validated for compliance against the requirement
 ISO/IEC TR 24027:2021 – Bia 	is in AI systems and AI aided decision making
 Clauses X 	
 ISO/IEC TS 4213:2022 – Asse 	essment of machine learning classification performance
 Clauses Y 	
 ISO/IEC TR 24029-1:2021 – A 	Assessment of the robustness of neural networks - Part 1: Overview
 Clauses Z 	L G TO
This Confirmation Letter is provided v metrics which have been tested. Th unconfirmed, in which case the value d	with Test Report Reference Number which details the full list of declar ese declared metrics have been classified as either confirmed correct etermined through testing has been provided.
For and on behalf of BSI:	Graeme Tunbridge, Senior Vice President Global Regulatory & Quality, Regulatory Services
Assessment completion date: <xx< td=""><td>wy-mm-dd> Report: <smo>/ <www.mm-dd></www.mm-dd></smo></td></xx<>	wy-mm-dd> Report: <smo>/ <www.mm-dd></www.mm-dd></smo>
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Poll question





Medical Imaging Use Case

Background: An Asia-based startup company, designing an AI system to segment and classify retinal pathologies

- Approaching investors for additional funding to position their system in the EU
- Datasets from Asian and EU populations

Insight: AA&DT verifies the performance of their AI system, including parity across populations

Value: Confirmation Letter can demonstrate confidence to investors and customers, and AA&DT can prepare for a conformity assessment under the EU AI Act





Medical Imaging Use Case 2

Background: A US manufacturer of an AI system to detect forms of cardiac arrhythmia

- Expanding the range of supported implantable devices
- Concerned about performance with signal degradations e.g. gain, noise

Insight: AA&DT verifies the performance of their AI system, including parity across supported devices and robustness to perturbed input signals

Value: Confirmation Letter can demonstrate confidence in supported devices, and AA&DT can prepare for a conformity assessment under the EU AI Act





Medical Imaging Use Case 3

Background: A manufacturer of an AI system to identify early signs of breast cancer from histopathology slides

- Introducing a new version of their AI system soon
- Regularly updating libraries/dependencies

Insight: AA&DT verifies the performance of their AI system across software versions during the change process

Value: AA&DT can be used periodically as part of an MLOps process to verify performance across versions





Summary

A voluntary AA&DT with BSI:

- Involves sharing a copy of your datasets and models with BSI so that we can verify performance – including bias and robustness – using standards-based metrics
- Can help you prepare for a conformity assessment under the EU AI Act
- Can demonstrate confidence in your AI system to your customers, your investors, and your internal development teams





Q&A







Thank you for attending!

