CHAI Applied Model Card

Name: BriefCase-Triage for Aortic Dissection **Developer:** Aidoc	**Inquires or to report an issue:** www.aidoc.com/contact-support/ or email:info@aidoc.com
Release Stage: FDA Cleared, Commercial (K222329) **Release Date:** September 2022 **Version:** AD-01 **Global Availability:** US, EU (CE Marked), UK (UKCA Marked), Canada (MDEL), Australia (ARTG), New Zealand, Israel (AMAR), UAE and South Africa. **Regulatory Approval:** Please find attached the AD-01 510(k) summary.	
Summary: The Aortic Dissection solution is a radiological computer-aided triage and notification software indicated for use in the analysis of CT exams with contrast (CTA and CT with contrast) that include the chest in adults or transitional adolescents aged 18 and older. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communicating suspected positive cases of aortic dissection (AD) pathology. BriefCase uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings on a standalone application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device. The results of BriefCase are intended to be used in conjunction with other patient information and based on the user's professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.	**Uses and Directions:** • **Intended use and workflow:** The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communicating suspected positive cases of aortic dissection (AD) pathology. • **Primary intended users:** The Aortic Dissection solution is intended to be used by appropriately trained medical specialists. Appropriately trained medical specialists for Aortic Dissection are emergency physicians, radiologists, cardiologists, and interventional radiologists. • **How to use:** The user is presented with notification for cases with suspected findings. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The results of the Aortic Dissection solution are intended to be used in conjunction with other patient information and based on their professional judgment, to assist with triage/prioritization of medical images. • **Targeted patient population:** patients Adults or transitional adolescents aged 18 and older. • **Cautioned out-of-scope settings and use cases:** Notifications include compressed preview images that are meant for informational purposes only and not

Keywords: None	intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device. Only for use in workflow triage, and only for use by appropriately trained medical specialists. Please refer to BriefCase-Triage User Guide (UG0009) for further information on warnings and precautions.

Warnings

- **Known risks and limitations:** Notified clinicians are responsible for viewing full images per the standard of care. Please refer to BriefCase-Triage User Guide (UG0009), label, and additional tutorial materials provided by the company for further information on risks and limitations.
- **Known biases or ethical considerations:** None
- **Clinical risk level:** Low, Class II (FDA) / IIa (EU)

Trust Ingredients

AI System Facts:

- **Outcome(s) and output(s):** Binary notification of suspected Aortic Dissection cases. The desktop application feed displays incoming suspect cases. Hovering over the feed pops up a compressed, unannotated image that is captioned "not for diagnostic use." The radiologist prioritizes cases based on this additional info and reads the case as per standard of care.
- **Model type:** Custom-built 3D deep convolutional neural network.
- **Foundation models used in application:** N/A
- **Input data source:** The BriefCase-Triage imaging AI solutions are trained, tuned, and validated using diverse data sets. Specifically, Aidoc works with DICOM images, which capture anatomical and physiological data from medical imaging technologies like CT scans and X-rays. These data sets are sourced from a wide range of institutions, including community hospitals, academic centers, teleradiology providers, private clinics, and imaging centers across various global regions (e.g., east and west US, central US, EU, and other parts of the world).
- **Output/Input data type:** Real World Digital imaging and communications in medicine (DICOM) images.

  Inclusion criteria: Scans performed on adults/transitional adolescents ≥ 18 years of age. CT exams with contrast (CTA and CTwith contrast) that include the chest. Slice thickness 0.5 mm - 5.0 mm

  Exclusion Criteria: All studies that are technically inadequate, such as severe metal artifacts, or inadequate field of view.

  Output: Binary notification of suspected cases of malpositioned Aortic Dissection.

- **Development data characterization:** The Aortic Dissection model has been trained, tuned, and validated on over 10,000 scans. The training and validation populations consist of a wide range of institutions and patient settings, including academic centers, community hospitals, teleradiology providers, private imaging centers, and clinics worldwide

(specifically East, West, and Center of US, EU, Middle East, Oceania, Latin America and far east).

Analyzed data included key demographic elements such as age, gender, comorbidities, geographical location, patient settings, reason for exam, and technological characteristics (e.g., equipment manufacturer, slice thickness, and modality model distribution).

The time frame for the data used for the initial and retrained model construction and validation is 2020-2025.

- **Bias mitigation approaches:** Aidoc's AI solutions undergo rigorous training, validation, and monitoring to ensure robust and equitable performance across diverse patient populations. Bias mitigation and advancing care equity are highly prioritized throughout the design and development of Aidoc solutions, while working within the known constraints of limited accessibility to certain data elements.

  Recognizing these constraints, Aidoc creates proxies to effectively mitigate risks associated with the absence of certain demographic details, when applicable.

  Specifically, race, ethnicity, language, sexual orientation, gender identity, social determinants of health data, and health status assessment data are not accessible as part of the DICOM image.

  To address potential biases, Aidoc employs diverse data sets from a wide range of institutions and patient settings, including academic centers, community hospitals, teleradiology providers, private imaging centers, and clinics worldwide (specifically East, West, and Center of US, EU, Middle East, Oceania, Latin America and far east).

  Aidoc validates and measures the AI model across subpopulations to ensure a normal and predictable performance on them.

  Additionally, key demographic elements are analyzed such as age, gender, comorbidities, geographical location, patient settings, reason for exam, and technological characteristics (e.g., equipment manufacturer, slice thickness, and modality model distribution);

  Furthermore, Aidoc conducts multiple retraining throughout the lifecycle of each AI module to ensure increased generalizability across all the aforementioned parameters. While the exact size of Aidoc's training data sets is proprietary, over the model lifecycle, they may include up to millions of DICOM studies.

- **Ongoing Maintenance:** Aidoc's quality management system is ISO 13485 MDSAP and EU MDR certified, and 21 CFR Part 820 compliant, requiring structured and validated installation, servicing, and Post-Market Surveillance (PMS) activities.

  Specifically, Aidoc's PMS plan outlines the systematic collection and analysis of data regarding the device's safety and performance throughout its lifecycle.

  Data analysis methods, both qualitative and quantitative, are applied to the collected data. The results are documented in a PMS report and in a Periodic Safety Update Report (PSUR). In addition, Aidoc implements site-specific controls, ensuring high standards are consistently maintained across all operational locations. The current Coronary Artery Calcification model represents the first FDA clearance for Coronary Artery Calcification at

Aidoc. Aidoc periodically retrains the algorithm on additional data and subjects the retrained versions to the required regulatory review and controls.

An expanded dataset enhances the model's generalization capabilities and potentially elevates the product's performance (improved or non-inferior to the previously cleared device's Time-to-Notification and/or AUC). The inclusion of data from a broader and more diverse array of sources enhances the model's ability to perform effectively across a wider range of clinical and technical settings, particularly if any real-world data changes or if any data was underrepresented in the original dataset.

Continuous monitoring: As detailed in the previous answer, Aidoc has robust monitoring systems in place to track the AI performance and identify any emerging issues, such as AI drift. In addition, regular audits and assessments ensure the model continues to deliver fair and accurate prioritizations.

Furthermore, Aidoc remains committed to ongoing research and development to refine the AI and address any safety concerns that may arise. The Aidoc AI Monitoring team monitors algorithm performance 24/7 for the purpose of mitigating AI drift. The team monitors and considers aspects such as alert correctness, the timeliness of data available, data completeness, slice thickness, series correctness and relevancy, contrast phase, algorithm specificity, and algorithmic positive ratio.

- **Security and compliance environment practices or accreditations:** Aidoc's products are structured based on international quality, privacy, and security standards and frameworks, including ISO 13485, ISO 27001, ISO 27017, ISO 27018, ISO 27799, SOC 2 Type 2, Cyber Essentials, and C5. Aidoc follows a systematic approach, integrating these frameworks into Aidoc's Information Security Management System (ISMS) to ensure a holistic and proactive risk management strategy.

  Aidoc's risk management program involves regular risk assessments, leveraging common methodologies, to identify, evaluate, and prioritize risks. Continuous monitoring, periodic audits, and assessments contribute to the dynamic nature of Aidoc's risk management program, allowing us to adapt to evolving threats and vulnerabilities. Aidoc regularly monitors its server's logs for unusual activity and implements intrusion detection and prevention systems, paying attention to unusual or suspicious activities such as unexpected errors, system slowdowns, or strange user access patterns. Furthermore, Aidoc conducts multiple retraining throughout the lifecycle of each AI module.

  Additionally, Aidoc's Governance, Risk, and Compliance (GRC) Program is responsible for enterprise oversight and direction for all security governance activities; governance for risk-related activities including Risk Identification, Management, Mitigation, and Remediation, and Risk Assessments; and responsibility for the planning, execution, and adherence with Aidoc Security Policies and Procedures, legal, regulatory, and contractual requirements.

- **Transparency, Intelligibility, and Accountability mechanisms:** The company ensures Transparency, Intelligibility, and Accountability in Aidoc's medical devices via its product design and its Quality Management System (QMS). Some examples include (non-exhaustive list):
  - Explainability and transparency features by design;
  - Reporting and feedback mechanism directly via the device's UI and additional communication in different platforms;

- User guide, labeling, and additional tutorial materials are available electronically at all times via the user community;
- Robust user training.

Transparency Information:

- **Funding source of the technical implementation:** Aidoc's model creation is self-funded.
- **3rd Party Information:** N/A
- **Stakeholders consulted during design of intervention (e.g. patients, providers):** Physicians, health system administrators, and patient groups were engaged in the development of the model

Key Metrics

<table>
<tr><th colspan="2">Usefulness, Usability, and Efficacy</th><th colspan="2">Fairness and Equity</th><th colspan="2">Safety and Reliability</th></tr>
<tr><td colspan="2">Goal of metric: Evaluate the software's performance in providing estimated coronary artery calcification detection category from non-cardiac-gated NCCT images that include the heart in 433 cases from 6 US-based clinical sites.</td><td colspan="2">Goal of metric: Evaluate for differences in performance (agreement) based on available socio-demographic variables of age, location and gender.</td><td colspan="2">Goal of metric: To show an agreement between the ground truth compared to the algorithm output by ordinal measurment category</td></tr>
<tr><td>Result: The algorithm performance showed that the overall agreement between the ground truth and algorithm across estimated CAC scores was 87.1%. Because the overall agreement estimate was up to the prespecified performance goal, the study's primary endpoint was achieved.</td><td>Interpretation: Primary endpoints were agreement between the ground truth and algorithm across estimated CAC scores which was 87.1%</td><td>Result: The mean age of patients whose scans were reviewed for BriefCase-Quantific ation for Coronary Artery Calcification (CAC) was 67.4 years, with a standard deviation of 12.8 years. Gender distribution was 50% male, and 50% female.</td><td>Interpretation: Device performance did not meaningfully interact with location, gender or age (Race distribution for sample was unavailable).</td><td>Result: The overall agreement estimate was up to the prespecified performance goal across all individual categories, the study's secondary endpoint was achieved.</td><td>Interpretation: The algorithm performance between the ground truth and algorithm, in individual categories, was as follows: very low = 95.1%; low = 81.3%; medium = 81.5%; and high =89.3% . Because the overall agreement estimate was up to the prespecified performance goal across all individual categories, the study's secondary endpoint was achieved.</td></tr>
<tr><td colspan="2">Test Type: Retrospective, blinded, multicenter study.</td><td colspan="2">Test Type: Retrospective, blinded, multicenter study</td><td colspan="2">Test Type: Retrospective, blinded, multicenter study</td></tr>
<tr><td colspan="2">Testing Data Description: The mean age of patients whose scans were reviewed for BriefCase-Quantification for Coronary Artery</td><td colspan="2">Testing Data Description: Same study as Usefulness, Usability, and Efficacy section.</td><td colspan="2">Testing Data Description: Same study as Usefulness, Usability, and Efficacy section.</td></tr>
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Calcification (CAC) was 67.4 years, with a standard deviation of 12.8 years. Gender distribution was 50% male, and 50% female Race distribution within the study data patient population was unavailable. None of the potential covariates demonstrated statistical significance, thus, device performance did not meaningfully interact with location, gender or age.		
Validation Process and Justification: Methods used are described in the 510(k) summary.	**Validation Process and Justification:** Link to Methods Description	**Validation Process and Justification:** Link to Methods Description AiDoc develops software within a Design Control process that is aligned with FDA 21 CFR Part 820 and ISO 62304 Medical device software - Software life cycle processes.

Resources

- **Evalation References:** Please reference our clinical compendium.
- **Clinical Trial:** N/A
- **Peer Reviewed Publication(s):** Aidoc's clinical compendium with 100+ Peer-reviewed publications or abstract/conference presentations are available at the following link.
- **Reimbursement Status:** N/A
- **Patient consent or disclosure required or suggested:** N/A

References
