CHAI Applied Model Card

<table>
<tr><td>Name: BriefCase-Triage for Intracranial Hemorrhage (ICH)
Developer: Aidoc</td><td>Inquires or to report an issue:
Demetri.g@aidoc.com +1 321-243-1594</td></tr>
<tr><td colspan="2">Release Stage: FDA Cleared Commercial
Release Date: May 2022
Version: V2
Global Availability: CE Marked, UKCA, Canada, Australia, New Zealand, Israel, UAE and South Africa
Regulatory Approval: N/A</td></tr>
<tr><td>Summary: The ICH solution is a radiological computer aided triage and notification software indicated for use in the analysis of non-enhanced head CT images in adults aged 18 and older. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communication of suspected positive findings of Intracranial hemorrhage (ICH) pathologies. The ICH solution uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings on a standalone desktop application in parallel to the ongoing standard of care image interpretation. 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 ICH 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. Notified clinicians are responsible for viewing full images per the standard of care.

Keywords: None</td><td>Uses and Directions:
Intended use and workflow: for use in the analysis of non-enhanced head CT images in adults aged 18 and older.
Primary intended users: The BriefCase-Triage is intended to be used by appropriately trained medical specialist
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 ICH 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 18 and over with non-contrast head CTs.
Cautioned out-of-scope settings and use cases: Only for use in workflow triage, and only for use by appropriately trained medical specialists.</td></tr>
<tr><td colspan="2">Warnings</td></tr>
<tr><td colspan="2">Known risks and limitations: The results of Aidoc's solutions are intended to be used in conjunction with other patient information and based on professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care. For false positives, it might take the radiologist additional time to read the scan. For false negatives, it also might take additional time reducing the</td></tr>
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radiologists' efficiency. Non-availability might do so as well if the radiologists are accustomed to having the Aidoc solution.
- **Known biases or ethical considerations:** None
- **Clinical risk level:** Low

Trust Ingredients

AI System Facts:

- **Outcome(s) and output(s):** 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" and is displayed as a preview function. The radiologist prioritizes cases based on this additional info and reads the case as per standard of care. Output: Binary prediction of suspected ICH cases.
- **Model type:** Custom-built 3D deep convolutional neural network. Output: Binary prediction of suspected ICH cases.
- **Foundation models used in application:** N/A
- **Input data source:** Our imaging AI solutions are trained, tuned, and validated using diverse data sets. Specifically, we work 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). The names of our partners are proprietary and confidential information.
- **Output/Input data type:** Input: Digital imaging and communications in medicine (DICOM) images.
- **Development data characterization:** The ICH model has been trained, tuned, and validated on over 10,000 scans. Each image processing algorithm was trained on images of the specific pathology it is intended to analyze. As is customary in the field of machine learning, deep learning algorithm development consisted of training on manually labeled ("tagged") images. The sites from which images were obtained were from diverse geographies within the USA, as well as diverse settings including urban and rural, academic medical centers and community hospitals, etc. This was done to ensure the data cover the diversity of the US population to support the generalizability of the algorithm. Additionally, we conduct research and validations with most of our customer sites to evaluate model performance and provide data to the sites for publication and research purposes. The time frame for the data used for the initial and retrained model construction and validation is 2015-2022, with most cases from 2021-2022.
- **Bias mitigation approaches:** At Aidoc, we take bias mitigation seriously, building AI solutions that advance care equity while working within the known constraints of limited accessibility to certain data elements. Our commitment is driven by the understanding that there is a risk of AI solutions underperforming for populations that may need them the most. With this in mind, we approach the development of our imaging AI solutions with diligence and responsibility, rigorously training, validating, and monitoring our models to ensure robust and equitable performance across diverse patient populations.

  Given that some of the aforementioned factors are not accessible to us, we take a two-fold approach: (1) maximizing what can be achieved with the data we have by analyzing 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); and (2) creating proxies that allow us to effectively mitigate risks associated with the absence of certain demographic details. We address potential biases by employing 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). We validate and measure the AI across subpopulations to ensure a normal and predictable performance on them.

When it comes to addressing disability, our training and validation data encompass a broad range of ages, and health statuses. This ensures that our models are well-equipped to handle diverse health conditions, further supporting equitable care for individuals with disabilities. Notably, FDA has accepted and validated this approach across Aidoc's FDA-cleared devices.

As part of our commitment to continuous improvement, Aidoc conducts multiple retrainings throughout the lifecycle of each AI module to ensure increased generalizability across all the aforementioned parameters. While the exact size of our training data sets is proprietary, they may include up to hundreds of thousands of DICOM studies in a product lifecycle.

- **Ongoing Maintenance:** The current ICH model is the second FDA clearance for ICH at Aidoc. Aidoc constantly trains the algorithm on Additional Data and passes the retrained versions to FDA's review. An expanded dataset enhances the model's generalization capabilities and potentially elevates the product's performance (improved or non-inferior to 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 changes to real-world data were made or if any data was underrepresented in the original dataset.

  Continuous monitoring: 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. We have robust monitoring systems in place to track the AI's performance and identify any emerging issues like AI drift and bias creep. Regular audits and assessments ensure the model continues to deliver fair and accurate prioritizations. We remain committed to ongoing research and development to refine the AI and address any ethical concerns that may arise.

  Aidoc quality management system is ISO 13485 certified, and 21 CFR Part 820 compliant.

  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 includes 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.

- **Security and compliance environment practices or accreditations:** The Aidoc aiOS is structured based on international standards and frameworks, including ISO 27001, ISO 27017, ISO 27018, and SOC 2 Type 2. We follow a systematic approach, integrating these frameworks into our Information Security Management System (ISMS) to ensure a holistic and proactive risk management strategy. Our 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 our risk management program, allowing us to adapt to evolving threats and vulnerabilities.
- **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), by providing users with:
  - User guide and labeling and additional tutorial materials;
  - Robust user training;

- Explainability and transparency by design;
- Reporting and feedback mechanism directly via the device's UI and additional communication in different platforms.

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

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<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 identifying non-contrast head CT images containing intracranial hemorrhage (ICH) in 220 cases from 5 US-based clinical sites.</td><td colspan="2">Goal of metric: Evaluate for differences in performance (sensitivity & specificity) based on available socio-demographic variables of age, location and gender.</td><td colspan="2">Goal of metric: The time-to-notification metric observed for the BriefCase software in the five medical centers was compared to the equivalent metric of prior predicate devices.</td></tr>
<tr><td>Result: Sensitivity was 96.15% (95% CI: 90.44%, 98.94%) and specificity was 94.83% (95% CI: 89.08%, 98.08%).</td><td>Interpretation: Primary endpoints of sensitivity and specificity with an 80% performance goal were met. Secondary endpoints were BriefCase time-to-notification compared to the predicate device, Positive Predictive Value (PPV), Negative Predictive Value (NPV), Positive Likelihood Ratio (PLR), and Negative Likelihood Ratio (NLR).</td><td>Result: No statistically significant interaction between performance and age, gender, or location.</td><td>Interpretation: Race distribution for sample was unavailable. Device performance did not meaningfully interact with location, gender or age.</td><td>Result: Mean Time to Notification (sec) Predicate K203505 = 267.6, 95% CI = 246.0-289.5. Mean Time to Notification (sec) Briefcase = 33.5, 95% CI = 30.9-36.1</td><td>Interpretation: The time-to-notification results obtained for the subject BriefCase device showed improvement with regard to time savings to the standard of care review.</td></tr>
<tr><td colspan="2">Test Type: Aidoc conducted a 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 in the study was 65.1 years, with standard deviation of 18.8 years. Gender distribution was 49.8% male, and 50.2% female. Race distribution within the study data patient population was unavailable. None of the potential</td><td colspan="2">Testing Data Description: The mean age of patients whose scans were reviewed in the study was 65.1 years, with standard deviation of 18.8 years. Gender distribution was 49.8% male, and 50.2% female. Race distribution within the study data patient population was unavailable.</td><td colspan="2">Testing Data Description: The BriefCase time-to-notification includes the time to get the DICOM exam, de-identify it, upload it to the cloud, analyze and send a notification on a positive suspect case back to the desktop application. The BriefCase time-to-notification was measured for all</td></tr>
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covariates demonstrated statistical significance, thus, device performance did not meaningfully interact with location, gender or age.		True Positive cases (i.e., identified as positive both by the reviewers as well as the BriefCase device).
Validation Process and Justification: Link to Methods Description	**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
