## Executive Summary (Oral Presentation Recap)

* **Technology Name**: Aidoc’s Stroke Package
* **Type**: AI-powered diagnostic tool for acute stroke detection
* **Manufacturer**: Aidoc Medical Ltd.
* **Intended Use**: Detection and prioritization of acute intracranial hemorrhage (ICH) and large/medium vessel occlusion (LVO/MEVO) in CT scans
* **Target Population**: Patients with suspected stroke, particularly in emergency settings
* **Users**: Radiologists and emergency physicians
* **Environment**: Emergency departments and radiology units
* **Algorithm Performance**: High sensitivity (89-95%), specificity (94-99%), and accuracy (93-98%) for ICH detection [1-3].
* **Clinical Impact**: Reduced time to diagnosis and treatment, decreased hospital length of stay, improved patient outcomes [4-6].
* **Regulatory Approvals**: FDA-cleared, CE-marked and ISO 13485:2016 certification.

## Introduction

Aidoc’s Stroke Package is an AI-powered diagnostic tool providing real-time analysis and alerts to enhance the detection and prioritization of acute intracranial hemorrhage (ICH) and large/medium vessel occlusion (LVO/MEVO) in CT scans. The device consists of the following three modules: (1) Aidoc Hospital Server (AHS/Orchestrator) for image acquisition; (2) Aidoc Cloud Server (ACS) for image processing; and (3) Aidoc Desktop Application for workflow integration.

## PART 1: Technology Description and Use

### Intended Use

Aidoc’s Stroke Package is primarily deployed in emergency departments and radiology units to enhance the workflow of stroke diagnosis. The tool is designed to quickly detect and prioritize cases of ICH, LVO, and MEVO in patients presenting with suspected stroke symptoms. By seamlessly integrating with existing hospital imaging systems, such as PACS (Picture Archiving and Communication System) and RIS (Radiology Information System), facilitates the prompt identification of critical cases. Aidoc’s AI modules, including those used in the Stroke Package, have received FDA clearance, CE marked, and ISO 13485:2016 certification.

### AI Technology Description

The technology underlying Aidoc’s Stroke Package is a sophisticated deep learning framework, utilizing a two-stage convolutional neural network (CNN) design to analyse CT images. [5]. The initial stage of this system employs a 3D CNN, which has been trained extensively on a vast and varied dataset of CT scans sourced from different imaging centres globally. This first stage of the network focuses on generating a 3D segmentation map, that identifies and highlights areas within the brain that may require further scrutiny. Following this, the second stage of the network takes over, categorizing the highlighted regions as either indicative of a pathology or normal, relying on a combination of the deep learning features identified by the first stage and conventional image analysis techniques. Upon detecting a potential issue, the system promptly notifies radiologists, enabling them to prioritize these flagged cases for immediate review and potential intervention.

### Competing/Comparable Technologies

Many other AI solutions for stroke diagnosis exist. In 2022, Wardlaw’s team provide a detailed evaluation and comparison of various commercially available AI software for stroke detection (Table 1) [5]. They are focusing particularly on the three most popular and most cited competing commercial products: Brainomix, RapidAI, and Viz.ai.

ASPECTS has been integrated into the AI software of 7 out of 18 companies that currently offer commercial solutions for stroke imaging. However, ASPECTS has its limitations, such as its lack of independence as an outcome predictor and variability in cut points and validity. Some companies, like Brainomix, NICO.Lab, RapidAI, and Viz.ai, offer comprehensive AI packages that handle a range of imaging types—non-enhanced CT, angiography, and perfusion imaging—all within a single workflow. Others, including Aidoc, Avicenna, and Circle Neurovascular Imaging, focus on combining non-enhanced CT and angiographic imaging in their assessments. Additionally, there are other companies that concentrate on specific aspects of ischemic or hemorrhagic stroke.

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Wardlaw’s team undertook a review of the published literature on Brainomix, RapidAI, and Vizai (Table 2). This review involved analysing published literature, which was updated with information from PubMed searches for company and software names, as well as data from the vendors' websites. The studies ideally involving more than 100 patients, to provide reliable statistics.

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## PART 2: Technology Assessment

### Algorithm Performance

Aidoc’s Stroke Package has been evaluated through some studies across multiple institutions and patient populations, demonstrating its effectiveness in accurately detecting and prioritizing cases of intracranial hemorrhage (ICH) and large/medium vessel occlusion (LVO/MEVO). However, it’s important to note that some of the evaluations come from conference proceedings rather than peer-reviewed journal articles.

In a study presented at the SPIE Medical Imaging conference in 2019 [1], the performance of Aidoc’s convolutional neural network (CNN) for detecting intracranial bleeds, particularly acute ICH, on non-contrast head CT scans was assessed. The study reported that the algorithm’s achieved a sensitivity of approximately 95% and around 98% specificity. Most of false negatives were small hemorrhages that did not require urgent intervention, However, the missed identification of certain critical signs, such as the hyperdense middle cerebral artery (MCA) sign, which can indicate an acute thrombus requiring emergent intervention, highlights areas where the algorithm could be further improved. Moreover, the overall accuracy was around 98%, showcasing the CNN’s reliable performance in clinical settings. Although the results were promising, it is important to recognize that the study was presented at a conference and, as such, may not have undergone the rigorous peer-review process typically associated with journal publications.

Another study, presented by Raskin et al. at the Israel Radiological Association Annual Meeting in 2018 [2], presented results of Aidoc’s algorithm in detecting pathological intracranial hyperdense lesions. Conducted at Sheba Medical Center, this study analysed a total of 160 cases and reported that Aidoc’s AI achieved a sensitivity of 91.1% (CI: 0.76 - 0.98%, P < 0.05), with a specificity of 97.6% (CI: 0.93 - 0.99%, P < 0.05) and accuracy was at around 96.2% (CI: 0.92 - 0.98%, P < 0.05). These metrics revealed that Aidoc’s AI demonstrated a notable performance in identifying ICH in clinical environments. Similarly, the previous study, this one was also presented at a conference and is not a peer-reviewed journal article, which suggests that the findings should be interpreted with some caution.

A more comprehensive evaluation of Aidoc’s algorithm was published in the journal Neuroradiology by Ginat in 2020 [3]. This peer-reviewed study analysed the performance of Aidoc’s deep learning software in flagging head CT scans for acute intracranial hemorrhage. The study involved a large dataset of 2,011 NCCT scans and reported a sensitivity of 88.7%, specificity of 94.2%, and an overall accuracy of 93.4% in detecting and prioritizing acute intracranial hemorrhage (ICH) across a wide range of hemorrhage types, including subdural, epidural, and intraparenchymal hemorrhages. Additionally, Ginat’s research reported a positive predictive value (PPV) of 73.7% and a negative predictive value (NPV) of 97.7%, underscores the reliability in real-world medical practice. The study’s peer-reviewed status lends further credibility to these findings. Moreover, the accuracy of ICH detection was slightly higher in emergency settings compared to inpatient settings (96.5% vs. 89.4%). This insight of the performance variations across different patient visit locations might help optimise AI-driven clinical workflows.

### Expected Clinical Utility

The expected clinical utility of Aidoc’s Stroke Package is grounded in its received multiple FDA clearances. Each FDA submission includes detailed performance metrics. The expected clinical utility of Aidoc’s Stroke Package includes:

* Improved Diagnostic Accuracy

For instance, the FDA approval (K180647) for Aidoc’s non-enhanced head CT and CTA images used in detecting suspected Intracranial Hemorrhage (ICH) showed a sensitivity of 93.6% and a specificity of 92.3% across 198 cases from three clinical sites. Another significant approval (K192383), related to head CTA images for detecting Large Vessel Occlusion (LVO) pathologies, demonstrated a sensitivity of 88.8% and a specificity of 87.2% in 383 cases from three U.S.-based clinical sites. These metrics indicate that the AI is well-suited for identifying critical stroke-related conditions that require immediate intervention.

* Faster Clinical Workflow

The time-to-notification metrics reported in the FDA submissions underline the potential utility of Aidoc’s Stroke Package in expediting clinical workflows. For instance, the mean time-to-notification for ICH was 3.9 minutes (95% CI: 3.7-4.1) (K190072); for LVO was 3.8 minutes (95% CI: 3.6-4.0) (K192383) for brain aneurysm (BA) was 4.2 minutes (95% CI: 3.9-4.5) (K213721); for vessel occlusion (VO) was VO was 2.23 minutes (95% CI: 2.22-2.23) (K220709), all significantly shorter than standard of care times.

* Resource Optimization

By reliably flagging only the most critical cases, Aidoc’s AI can help optimize the use of medical resources, ensuring that radiologists and clinicians focus their attention on the patients who need it most.

For detailed performance data and a comprehensive list of FDA-approved AI/ML-enabled devices related to Aidoc, please refer to the attached Excel file named FDA.xlsx.

### Human Factors Analysis

Aidoc’s integration into radiology workflows is designed to minimize use errors and reduce missed diagnoses, particularly during high-volume periods or off-hours. The AI system automatically detects and flags critical cases, allowing radiologists to prioritize the most urgent scans and improve overall diagnostic accuracy.[3, 7].

A study involving 4,946 head CT scans across 18 hospitals between May and September 2020 demonstrated the effectiveness of this approach [7]. Discrepancies between the AI analysis and the initial radiology reports were thoroughly reviewed by a blinded neuroradiologist, providing an additional layer of validation and quality control. The AI’s automatic detection and alerting mechanisms significantly reduce the likelihood of missed diagnoses, especially during high-volume periods or off-hours when radiologist availability may be limited. By flagging and prioritizing critical cases, Aidoc’s system allows radiologists to focus on the most urgent scans first, ensuring that patients with life-threatening conditions receive timely attention.

Moreover, the study highlights the AI's ability to act as a reliable second reader, cross-checking initial radiology reports and identifying discrepancies that may have been missed during the first review. This feature enhancing diagnostic confidence and reducing the likelihood of errors during high workload periods.

### Clinical Impact

The clinical utility of Aidoc’s Stroke Package is substantial, as evidenced by improved turnaround times, reduced hospital stays, decreased mortality rates, and better neurological outcomes. These benefits highlight the tool’s value in enhancing patient care, particularly in urgent, high-stakes environments. As enhancing the speed and accuracy of detection is crucial, where timely intervention can greatly influence patient outcomes of stroke [8].

* Enhanced Diagnostic Workflow and Efficiency

One of the compelling aspects of Aidoc’s utility is impact on radiology study turnaround time (TAT). A randomized clinical trial involving 620 non-contrast head CT cases demonstrated that the use of Aidoc’s AI for detecting intracranial hemorrhage (ICH) significantly reduced TAT [4]. Flagged cases were reported much faster than non-flagged cases, with average TATs of 73 minutes for flagged cases compared to 132 minutes for non-flagged cases (p < 0.05). The overall sensitivity, specificity, and accuracy across all cases were 95.0%, 96.7%, and 96.4%, respectively. This reduction in TAT enables quicker decision-making and more timely therapeutic interventions, which are crucial for improving outcomes in stroke patients.

* Improvement in Patient Outcomes

The clinical utility of Aidoc’s AI extends beyond just speed. Its integration into clinical workflows has also led to a significant reduction in all-cause mortality rates. A retrospective cohort study conducted at a Level 1 trauma centre found that, after one year of implementing Aidoc’s AI for ICH detection, there was a substantial reduction in 30-day and 120-day all-cause mortality rates among stroke patients. Specifically, the 30-day mortality rate decreased from 27.7% pre-AI to 17.5% post-AI (CI: 0.29 - 0.79p = 0.004), and the 120-day mortality rate dropped from 31.8% to 21.7% (CI: 0.37 - 0.91 p = 0.017) [6]. These results underscore the life-saving potential of AI when integrated into clinical practice.

Additionally, the study also reported an improvement in the Modified Rankin Scale (mRS) for neurological disability at discharge, which decreased from 3.2 pre-AI implementation to 2.8 post-AI (p = 0.044) [6]. This metric indicates not only survival but also the quality of life, suggesting that patients are more likely to recover with fewer disabilities when Aidoc’s AI is used as part of their care.

* Economic Impact and Resource Optimization

Moreover, the implementation of Aidoc’s Stroke Package has been associated with a significant decrease in hospital length of stay for patients with ICH. A study reported an 1.30 days (11.9%) reduction in hospital length of stay, which translates into both better patient outcomes and more efficient use of healthcare resources [9]. This reduction not only helps patients recover more quickly but also alleviates the burden on hospital facilities. It is important to note that this study was supported by Aidoc, as the article processing fee was provided by the company. While this does not necessarily undermine the validity of the findings, it is a factor to consider when interpreting the results.

The Aidoc has ability to integrate seamlessly with existing hospital systems, such as PACS and RIS, ensures that its implementation does not require significant additional investment or disruption to current practices. Combined with the AI operating system integrate and orchestrate multiple AI solutions (from other vendors). This ease of integration makes it a scalable solution that can be deployed across various healthcare settings, from small community hospitals to large academic medical centres and covering a variety of radiology subspecialties and imaging enhancements.

## Conclusion

The integration of machine learning (ML) and deep learning algorithms in stroke imaging, highlights the broader impact of AI. ML algorithms, like those utilized by Aidoc, are instrumental in optimizing clinical workflows by reducing scan times, improving image quality, and facilitating early triage. In particular, it has shown promise in reducing diagnostic errors and improving the accuracy of stroke detection in high-pressure environments. In the near future, these AI tools will probably play a larger role in disease identification and treatment determinations [10].

## Reference:

1. P, O., et al. *The utility of deep learning: evaluation of a convolutional neural network for detection of intracranial bleeds on non-contrast head computed tomography studies*. in *SPIE*. 2019.

2. Raskin, D., et al. *Preliminary Results of AIDOC’s Deep Learning Algorithm Detection Accuracy for Pathological Intracranial Hyperdense Lesions*. in *Israel Radiological Association Annual Meeting*. 2018. Sheba Medical Center.

3. Ginat, D.T., *Analysis of head CT scans flagged by deep learning software for acute intracranial haemorrhage.* Neuroradiology, 2020. **62**(3): p. 7.

4. Wismüller, A. and L. Stockmaster, *A Prospective Randomized Clinical Trial for Measuring Radiology Study Reporting Time on Artificial Intelligence-Based Detection of Intracranial Hemorrhage in Emergent Care Head CT*, in *Medical Imaging 2020: Biomedical Applications in Molecular, Structural, and Functional Imaging*, A. Krol and B.S. Gimi, Editors. 2020, arXiv.org: Ithaca: Cornell University Library.

5. Wardlaw, J.M., et al., *Accuracy of Automated Computer-Aided Diagnosis for Stroke Imaging: A Critical Evaluation of Current Evidence.* Stroke (1970), 2022. **53**(7): p. 11.

6. Kotovich, D., et al., *The impact on clinical outcomes after 1 year of implementation of an artificial intelligence solution for the detection of intracranial hemorrhage.* International journal of emergency medicine, 2023. **16**(1): p. 9.

7. Kundisch, A., et al., *Deep learning algorithm in detecting intracranial hemorrhages on emergency computed tomographies.* PloS one, 2021. **16**(11): p. 18.

8. Saver, J.L., et al., *Time to Treatment With Endovascular Thrombectomy and Outcomes From Ischemic Stroke: A Meta-analysis.* JAMA, 2016. **316**(12): p. 10.

9. Petry, M., et al., *Decreased Hospital Length of Stay for ICH and PE after Adoption of an Artificial Intelligence-Augmented Radiological Worklist Triage System.* Radiology research and practice, 2022. **2022**: p. 7.

10. Sheth, S.A., et al., *Machine learning and acute stroke imaging.* Journal of neurointerventional surgery, 2023. **15**(2): p. 5.