annalise

Annalise Triage

Performance Guide

US

English (US)

Annalise Triage

OPT-PRM-105 v1

This guide is applicable to Annalise Backend version **3.3**

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℞ Only

Overview

Overview

This document outlines the performance of the Annalise Triage device.

The performance results contained in this document are based on the dataset used by Annalise.ai to evaluate the device.

Differences in demographics, imaging equipment, image quality or other variables may result in changes in performance.

For general user information refer to the *Annalise Triage User Guide*.

Symbol glossary

Definitions of symbols that may appear on the device or in the related documentation are listed below.

Symbol	Information
	Manufacturer
	Prescription only
	Indicates a warning or caution
	Medical device

Standalone performance evaluation

Overview

A standalone performance evaluation of the device was performed on a test dataset of chest X-ray cases obtained from four sites in the United States.

Ground truth interpretations

The reference standard ('ground truth') for the test dataset was determined by two ground truthers, with a third ground truth radiologist used in the event of disagreement. All ground truthers were US board-certified radiologists with a thoracic sub-speciality.

The device performed inference on the test dataset and the results were compared with the ground truth interpretations to evaluate the standalone performance of the device for each finding:

Chest X-ray (CXR)	CT brain (CTB)
• pleural effusion • pneumoperitoneum • pneumothorax • tension pneumothorax • vertebral compression fracture	• acute subdural/epidural hematoma • acute subarachnoid hemorrhage • intra-axial hemorrhage • intraventricular hemorrhage

Performance was measured in terms of detection accuracy as Area Under the Receiver-Operating Characteristic Curve (AUC), and sensitivity and specificity.

The results of these standalone performance evaluations are summarized in the following pages.

Detected accuracy as Area Under the Curve (AUC)

The AUC and distribution of ground truth positive/negative cases is outlined below.

For CTB findings, AUC was evaluated at two slice thickness ranges for each finding.

CXR

Finding	Positive cases	Negative cases	AUC (95% CI)
Pleural effusion	481	505	0.980 (0.972-0.986)
Pneumoperitoneum	101	182	0.969 (0.924-0.996)
Pneumothorax	413	536	0.979 (0.970-0.986)
Tension pneumothorax	123	290	0.988 (0.981-0.993)
Vertebral compression fracture	272	317	0.954 (0.939-0.968)

CTB

Finding	Slice thickness range	Positive cases	Negative cases	AUC (95% CI)
Acute subarachnoid hemorrhage	≤1.5mm	147 (63.4%)	85 (36.6%)	0.993 (0.985-0.998)
	>1.5mm & ≤5.0mm	182 (63.4%)	105 (36.6%)	0.967 (0.946-0.983)
Acute subdural/epidural hematoma	≤1.5mm	303 (75.6%)	98 (24.4%)	0.972 (0.957-0.984)
	>1.5mm & ≤5.0mm	397 (74.6%)	135 (25.4%)	0.942 (0.921-0.959)
Intra-axial hemorrhage	≤1.5mm	480 (68.4%)	222 (31.6%)	0.968 (0.954-0.978)
	>1.5mm & ≤5.0mm	587 (67.1%)	288 (32.9%)	0.965 (0.952-0.976)
Intraventricular hemorrhage	≤1.5mm	73 (48.7%)	77 (51.3%)	0.986 (0.968-0.997)
	>1.5mm & ≤5.0mm	91 (49.5%)	93 (50.5%)	0.983 (0.966-0.994)

Sensitivity and specificity by operating point

Sensitivity and specificity were evaluated at a range of operating points for each finding.

A default operating point configuration is provided as part of an organization's initial installation. The organization may select a different operating point from the range of points validated during the device's standalone performance evaluations. Different operating points may be selected for each finding based on the following considerations:

- prevalence of disease in the population
- significance of false positives and false negatives, and
- criticality of the clinical condition.

Changes in configuration to apply these operating points can only be made in consultation with Annalise.ai.

The following tables outline the results for sensitivity and specificity at each operating point.

CXR

Finding	Operating point	Sensitivity (%)	Specificity (%)
Pleural effusion	0.2302	96.0 (94.2,97.7)	88.3 (85.3,91.1)
	0.2990	93.8 (91.5,95.8)	91.7 (89.3,94.1)
	0.4355	86.3 (83.0,89.4)	95.6 (93.7,97.2)
Pneumoperitoneum	0.0322	90.1 (84.2,95.0)	87.4 (82.4,92.3)
	0.0484	86.1 (79.2,92.1)	89.6 (85.2,94.0)
	0.2266	82.2 (75.2,89.1)	96.2 (93.4,98.9)
Pneumothorax	0.082358398	93.9 (91.8,96.1)	92.2 (89.9,94.4)
	0.03583958	96.6 (94.7,98.3)	84.1 (82.1,87.1)
	0.179978475	89.1 (86.2,92.0)	95.7 (94.0,97.4)
Tension pneumothorax	0.078706875	94.3 (90.2,98.4)	95.8 (94.3,97.1)
	0.051158268	95.9 (91.9,99.2)	94.9 (93.3,96.4)
	0.164259434	83.7 (76.4,90.2)	97.8 (96.7,98.7)
Vertebral compression fracture	0.3849	89.3 (85.7, 93.0)	89.0 (85.8,92.1)
	0.4834	85.3 (80.9, 89.3)	90.9 (87.7,94.0)

Sensitivity and specificity by operating point *(cont.)*

CTB

Finding	Slice thickness range	Operating point	Sensitivity (95% CI)	Specificity (95% CI)
Acute subarachnoid hemorrhage	≤1.5mm	0.014372	98.0 (95.2, 100.0)	89.4 (82.4, 95.3)
		0.060162	93.9 (89.8, 97.3)	96.5 (91.8, 100.0)
		0.082652	89.8 (85.0, 94.6)	100.0 (100.0, 100.0)
	>1.5mm & ≤5.0mm	0.020255	90.7 (86.3, 95.1)	92.4 (86.7, 97.1)
		0.030010	87.4 (82.4, 91.8)	96.2 (92.4, 99.0)
Acute subdural/epidural hematoma	≤1.5mm	0.060177	91.4 (88.1, 94.4)	86.7 (79.6, 92.9)
		0.101143	89.1 (85.5, 92.4)	94.9 (89.8, 99.0)
		0.135700	86.5 (82.5, 90.1)	96.9 (92.9, 100.0)
	>1.5mm & ≤5.0mm	0.060177	82.4 (78.6, 86.1)	89.6 (83.7, 94.8)
Intra-axial hemorrhage	≤1.5mm	0.322700	93.1 (90.8, 95.2)	85.6 (81.1, 89.6)
	>1.5mm & ≤5.0mm	0.203600	93.4 (91.3, 95.1)	85.1 (80.9, 88.9)
		0.322700	90.3 (87.9, 92.5)	90.3 (86.8, 93.8)
Intraventricular hemorrhage	≤1.5mm	0.015487	95.9 (90.4, 100.0)	90.9 (84.4, 97.4)
		0.051859	90.4 (83.6, 97.3)	97.4 (93.5, 100.0)
	>1.5mm & ≤5.0mm	0.008430	95.6 (91.2, 98.9)	86.0 (78.5, 92.5)
		0.015487	92.3 (86.8, 96.7)	89.2 (82.8, 94.6)
		0.051859	87.9 (80.2, 94.5)	97.8 (94.6, 100.)

Subgroup analysis: Sensitivity and specificity

Subgroup analysis

The test dataset included a range of patient demographics and imaging equipment manufacturers. Subgroup analysis was performed for the following:

- patient age
- patient gender
- patient race
- equipment manufacturer
- presence of co-existing findings or abnormalities
- presence of specific co-existing findings or abnormalities (intra-axial hemorrhage only)
- acute subdural/epidural hematoma location
- series thickness for slice thickness range >1.5mm to ≤5mm

Detection accuracy for each sub-group is summarized in each of the following tables.

Patient age

The following tables outline the sensitivity and specificity for each finding by operating point and patient age.

CXR

Finding	Operating point	Patient age	Sensitivity (%)	Specificity (%)
Pleural effusion	0.2302	≤ 65 years	97.4 (94.7,99.3)	91.3 (87.9,94.3)
		> 65 years	95.5 (93.0,97.6)	85.1 (80.5,89.6)
	0.2990	≤ 65 years	93.4 (88.7,97.4)	92.4 (89.0,95.5)
		> 65 years	93.9 (91.2,96.4)	90.9 (87.1,94.2)
	0.4355	≤ 65 years	87.4 (82.1,92.1)	97.3 (95.1,99.2)
		> 65 years	85.8 (81.8,89.4)	91.3 (87.9,94.3)
Pneumoperitoneum	0.0322	≤ 65 years	90.0 (80.0,98.0)	88.9 (82.2,95.6
		> 65 years	90.2 (80.4,98.0)	85.9 (78.3,92.4)
	0.0484	≤ 65 years	90.0 (80.0,98.0)	91.1 (84.4,96.7)
		> 65 years	82.4 (70.6,92.2)	88.0 (81.5,94.6)
	0.2266	≤ 65 years	86.0 (76.0,94.0)	95.6 (91.1,98.9)
		> 65 years	78.4 (66.7,90.2)	96.7 (92.4,100.0)
Vertebral compression fracture	0.3849	≤ 65 years	84.6 (75.0,94.2)	93.7 (89.7,97.1)
		> 65 years	90.5 (86.4,94.1)	83.1 (76.8,88.7)
	0.4834	≤ 65 years	78.8 (67.3,88.5)	95.4 (92.0,98.3)
		> 65 years	86.8 (82.3,90.9)	85.2 (78.9,90.8)

Patient age *(cont.)*

CXR

Finding	Patient age	AUC (95% CI)
Pneumothorax	≤ 65 years	0.982 (0.971, 0.990)
	> 65 years	0.976 (0.961, 0.988)
Tension Pneumothorax	≤ 65 years	0.988 (0.977, 0.995)
	> 65 years	0.989 (0.981, 0.995)

Patient age *(cont.)*

CTB

Finding	Slice thickness range	Operating point	Patient age	Sensitivity (95% CI)	Specificity (95% CI)
Acute subarachnoid hemorrhage	≤1.5mm	0.014372	≤65 years	100.0 (100.0,100.0)	87.8 (79.6,95.9)
			>65 years	97.2 (93.5,100.0	91.7 (83.3,100.0)
		0.060162	≤65 years	95.0 (87.5,100.0)	93.9 (85.7,100.0)
			>65 years	93.5 (88.8,97.2)	100.0 (100.0,100.0)
		0.082652	≤65 years	95.0 (87.5,100.0)	100.0 (100.0,100.0)
			>65 years	87.9 (81.3,93.5)	100.0 (100.0,100.0)
	>1.5mm & ≤5.0mm	0.020255	≤65 years	94.3 (86.8,100.0)	91.1 (82.1,98.2)
			>65 years	89.1 (83.7,94.6)	93.9 (85.7,100.0)
		0.030010	≤65 years	90.6 (81.1,96.2)	96.4 (91.1,100.0)
			>65 years	86.0 (79.8,91.5)	95.9 (89.8,100.0)
Acute subdural/epidural hematoma	≤1.5mm	0.060177	≤65 years	90.7 (85.2,95.4)	92.7 (82.9,100.0)
			>65 years	91.8 (87.7,95.4)	82.5 (71.9,91.2)
		0.101143	≤65 years	86.1 (79.6,92.6)	100.0 (100.0,100.0)
			>65 years	90.8 (86.7,94.9)	91.2 (82.5,98.2)
		0.135700	≤65 years	80.6 (73.1,87.0)	100.0 (100.0,100.0)
			>65 years	89.7 (85.1,93.8)	94.7 (87.7,100.0)
	>1.5mm & ≤5.0mm	0.060177	≤65 years	77.1 (69.4,84.0)	93.1 (86.2,98.3)
			>65 years	85.4 (81.0,89.3)	87.0 (77.9,93.5)

Patient age *(cont.)*

CTB

Finding	Slice thickness range	Operating point	Patient age	Sensitivity (95% CI)	Specificity (95% CI)
Intra-axial hemorrhage	≤1.5mm	0.322700	≤65 years	91.7 (87.5,95.3)	88.8 (82.7,94.9)
			>65 years	94.1 (91.3,96.5)	83.1 (76.6,89.5)
	>1.5mm & ≤5.0mm	0.203600	≤65 years	93.8 (90.2,96.9)	85.2 (78.7,91.8)
			>65 years	93.1 (90.4,95.6)	84.9 (79.5,90.4)
		0.322700	≤65 years	90.6 (86.6,94.2)	90.2 (84.4,95.1)
			>65 years	90.1 (86.8,93.1)	90.4 (85.5,94.6)
Intraventricular hemorrhage	≤1.5mm	0.015487	≤65 years	95.8 (87.5,100.0)	100.0 (100.0,100.0)
			>65 years	95.9 (89.8,100.0)	85.1 (74.5,93.6)
		0.051859	≤65 years	87.5 (75.0,100.0)	100.0 (100.0,100.0)
			>65 years	91.8 (83.7,98.0)	95.7 (89.4,100.0)
	>1.5mm & ≤5.0mm	0.008430	≤65 years	96.7 (90.0,100.0)	89.5 (78.9,97.4)
			>65 years	95.1 (88.5,100.0)	83.6 (72.7,92.7)
		0.015487	≤65 years	96.7 (90.0,100.0)	94.7 (86.8,100.0)
			>65 years	90.2 (82.0,96.7)	85.5 (76.4,94.5)
		0.051859	≤65 years	86.7 (73.3,96.7)	100.0 (100.0,100.0)
			>65 years	88.5 (80.3,96.7)	96.4 (90.9,100.0)

Patient gender

The following tables outline the sensitivity and specificity for each finding by operating point and patient gender.

CXR

Finding	Operating point	Patient gender	Sensitivity (%)	Specificity (%)
Pleural effusion	0.2302	Female	96.0 (93.3,98.2)	89.0 (85.0,92.9)
		Male	96.1 (93.4,98.4)	87.6 (83.7,91.6)
	0.2990	Female	93.7 (90.6,96.9)	92.5 (89.4,95.7)
		Male	93.8 (90.7,96.5)	90.8 (87.3,94.4)
	0.4355	Female	85.2 (80.3,89.7)	94.9 (92.1,97.3)
		Male	87.2 (82.9,91.1)	96.4 (94.0,98.4)
Pneumoperitoneum	0.0322	Female	87.5 (77.1,95.8)	91.1 (85.6,96.7)
		Male	92.5 (84.9,98.1)	83.7 (76.1,91.3)
	0.0484	Female	83.3 (72.9,93.8)	91.1 (85.6,96.7)
		Male	88.7 (79.2,96.2)	88.0 (81.5,94.6)
	0.2266	Female	79.2 (66.7,89.6)	95.6 (91.1,98.9)
		Male	84.9 (75.5,94.3)	96.7 (92.4,100.0)
Vertebral compression fracture	0.3849	Female	91.6 (87.1,95.5)	89.9 (85.2,94.1)
		Male	85.1 (77.7,91.5)	87.8 (82.4,92.6)
	0.4834	Female	88.8 (83.7,93.3)	91.7 (87.6,95.9)
		Male	78.7 (70.2,86.2)	89.9 (84.5,94.6)

Patient gender *(cont.)*

CXR

Finding	Patient gender	AUC (95% CI)
Pneumothorax	Female	0.978 (0.961, 0.989)
	Male	0.980 (0.969, 0.988)
Tension Pneumothorax	Female	0.990 (0.978, 0.997)
	Male	0.987 (0.979, 0.993)

Patient gender *(cont.)*

CTB

Finding	Slice thickness range	Operating point	Gender	Sensitivity (95% CI)	Specificity (95% CI)
Acute subarachnoid hemorrhage	≤1.5mm	0.014372	Female	97.7 (94.2,100.0)	88.6 (77.1,97.1)
			Male	98.4 (95.1,100.0)	90.0 (82.0,98.0)
		0.060162	Female	93.0 (87.2,97.7)	97.1 (91.4,100.0)
			Male	95.1 (88.5,100.0)	96.0 (90.0,100.0)
		0.082652	Female	88.4 (80.2,94.2)	100.0 (100.0,100.0)
			Male	91.8 (83.6,98.4)	100.0 (100.0,100.0)
	>1.5mm & ≤5.0mm	0.020255	Female	88.5 (81.2,94.8)	93.9 (85.7,100.0)
			Male	93.0 (87.2,97.7)	91.1 (82.1,98.2)
		0.030010	Female	84.4 (76.0,90.6)	95.9 (89.8,100.0)
			Male	90.7 (83.7,96.5)	96.4 (91.1,100.0)
Acute subdural/epidural hematoma	≤1.5mm	0.060177	Female	88.5 (83.2,93.9)	86.5 (76.9,94.2)
			Male	93.6 (89.5,97.1)	87.0 (76.1,95.7)
		0.101143	Female	86.3 (80.2,91.6)	94.2 (88.5,100.0)
			Male	91.3 (86.6,95.3)	95.7 (89.1,100.0)
		0.135700	Female	84.7 (77.9,90.8)	96.2 (90.4,100.0)
			Male	87.8 (83.1,92.4)	97.8 (93.5,100.0)
	>1.5mm & ≤5.0mm	0.060177	Female	80.2 (73.8,86.0)	91.0 (83.6,97.0)
			Male	84.0 (79.1,88.4)	88.2 (80.9,95.6)

Patient gender *(cont.)*

CTB

Finding	Slice thickness range	Operating point	Gender	Sensitivity (95% CI)	Specificity (95% CI)
Intra-axial hemorrhage	≤1.5mm	0.322700	Female	92.5 (88.8,95.8)	88.7 (82.6,93.9)
			Male	93.6 (90.6,96.2)	82.2 (74.8,88.8)
	>1.5mm & ≤5.0mm	0.203600	Female	93.0 (89.9,96.1)	86.2 (80.3,91.4)
			Male	93.6 (90.9,96.0)	83.8 (77.2,89.7)
		0.322700	Female	90.3 (86.4,93.8)	89.5 (84.2,94.1)
			Male	90.3 (86.9,93.3)	91.2 (86.0,95.6)
Intraventricular hemorrhage	≤1.5mm	0.015487	Female	100.0 (100.0,100.0)	94.4 (86.1,100.0)
			Male	90.9 (78.8,100.0)	87.8 (78.0,97.6)
		0.051859	Female	97.5 (92.5,100.0)	100.0 (100.0,100.0)
			Male	81.8 (66.7,93.9)	95.1 (87.8,100.0)
	>1.5mm & ≤5.0mm	0.008430	Female	100.0 (100.0,100.0)	88.6 (79.5,97.7)
			Male	91.1 (82.2,97.8)	83.7 (73.5,91.8)
		0.015487	Female	95.7 (89.1,100.0)	90.9 (81.8,97.7)
			Male	88.9 (80.0,97.8)	87.8 (77.6,95.9)
		0.051859	Female	91.3 (82.6,97.8)	100.0 (100.0,100.0)
			Male	84.4 (73.3,93.3)	95.9 (89.8,100.0)

Patient race

The following tables outline the sensitivity and specificity for each finding by patient race subgroup.

The analysis was performed using one representative operating point at the slice thickness range of ≤1.5mm grouped by the following race subgroups:

- White or Caucasian
- Other (includes American Indian or Alaskan Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, Other, Two or more races), and
- Unknown (includes Declined or Unavailable).

This analysis suggests that the device performance is not distinctly different between race subgroups.

CTB

Finding	Slice thickness range	Operating point	Race	Sensitivity (95% CI)	Specificity (95% CI)
Acute subarachnoid hemorrhage	≤1.5mm	0.060162	White or Caucasian	93.3 (88.3,97.5)	96.8 (92.1,100.0)
			Other	100.0 (100.0,100.0)	93.8 (81.2,100.0)
			Unknown	90.0 (70.0,100.0)	100.0 (100.0,100.0)
Acute subdural/epidural hematoma	≤1.5mm	0.060177	White or Caucasian	90.8 (87.0,94.5)	85.7 (77.1,92.9)
			Other	92.2 (84.3,98.0)	87.5 (70.8,100.0)
			Unknown	100.0 (100.0,100.0)	100.0 (100.0,100.0)
Intra-axial hemorrhage	≤1.5mm	0.322700	White or Caucasian	93.1 (90.6,95.6)	85.2 (80.1,90.3)
			Other	92.9 (87.8,98.0)	88.9 (77.8,97.2)
			Unknown	95.0 (85.0,100.0)	80.0 (50.0,100.0)
Intraventricular hemorrhage	≤1.5mm	0.015487	White or Caucasian	98.2 (94.7,100.0)	93.3 (86.7,98.3)
			Other	85.7 (64.3,100.0)	80.0 (60.0,100.0)
			Unknown	100.0 (100.0,100.0)	100.0 (100.0,100.0)

Equipment manufacturer

The following tables outline the sensitivity and specificity for each finding by operating point and equipment manufacturer.

CXR

Finding	Operating point	Manufacturer	Sensitivity (%)	Specificity (%)
Pleural effusion	0.2302	Agfa	92.9 (87.5,97.3)	91.1 (85.1,96.0)
		Carestream	100.0 (100.0,100.0)	90.2 (80.5,97.6)
		Fujifilm	96.1 (90.8,100.0)	95.1 (90.2,98.8)
		GE Healthcare	100.0 (100.0,100.0)	94.7 (84.2,100.0)
		Kodak	100.0 (100.0,100.0)	87.5 (75.0,100.0)
		Konica Minolta	95.2 (90.4,99.0)	82.7 (74.7,90.7)
		McKesson	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		Multiple	94.1 (85.3,100.0)	78.3 (60.9,95.7)
		Philips	100.0 (100.0,100.0)	79.3 (69.0,89.7)
		Siemens	96.2 (88.5,100.0)	90.4 (82.7,98.1)
		Unknown	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		Varian	100.0 (100.0,100.0)	76.9 (53.8,100.0)

Equipment manufacturer *(cont.)*

CXR

Finding	Operating point	Manufacturer	Sensitivity (%)	Specificity (%)
Pleural effusion *(cont.)*	0.2990	Agfa	91.1 (85.7,95.5)	96.0 (92.1,99.0)
		Carestream	96.3 (88.9,100.0)	97.6 (92.7,100.0)
		Fujifilm	94.7 (89.5,98.7)	98.8 (96.3,100.0)
		GE Healthcare	100.0 (100.0,100.0)	94.7 (84.2,100.0)
		Kodak	100.0 (100.0,100.0)	91.7 (79.2,100.0)
		Konica Minolta	92.3 (87.5,97.1)	84.0 (76.0,92.0)
		McKesson	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		Multiple	94.1 (85.3,100.0)	82.6 (65.2,95.7)
		Philips	98.3 (94.8,100.0)	82.8 (72.4,91.4)
		Siemens	92.3 (80.8,100.0)	92.3 (84.6,98.1)
		Unknown	91.7 (75.0,100.0)	100.0 (100.0,100.0)
		Varian	92.3 (76.9,100.0)	76.9 (53.8,100.0)

Equipment manufacturer *(cont.)*

CXR

Finding	Operating point	Manufacturer	Sensitivity (%)	Specificity (%)
Pleural effusion *(cont.)*	0.4355	Agfa	86.6 (80.4,92.0)	99.0 (97.0,100.0)
		Carestream	81.5 (66.7,96.3)	97.6 (92.7,100.0)
		Fujifilm	88.2 (80.3,94.7)	100.0 (100.0,100.0)
		GE Healthcare	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		Kodak	100.0 (100.0,100.0)	91.7 (79.2,100.0)
		Konica Minolta	78.8 (71.2,86.5)	90.7 (84.0,97.3)
		McKesson	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		Multiple	82.4 (67.6,94.1)	95.7 (87.0,100.0)
		Philips	98.3 (94.8,100.0)	89.7 (81.0,96.6)
		Siemens	88.5 (73.1,100.0)	96.2 (90.4,100.0)
		Unknown	75.0 (50.0,100.0)	100.0 (100.0,100.0)
		Varian	84.6 (61.5,100.0)	84.6 (61.5,100.0)

Equipment manufacturer *(cont.)*

CXR

Finding	Operating point	Manufacturer	Sensitivity (%)	Specificity (%)
Pneumoperitoneum	0.0322	Agfa	84.8 (72.7,93.9)	84.4 (75.0,92.2)
		Carestream	93.5 (83.9,100.0)	90.4 (80.8,98.1)
		Fujifilm	85.7 (64.3,100.0)	82.8 (69.0,96.6
		GE Healthcare	-	-
		Kodak	-	-
		Konica Minolta	92.3 (76.9,100.0)	93.3 (80.0,100.0)
		McKesson	-	-
		Multiple	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		Philips	100.0 (100.0,100.0)	83.3 (58.3,100.0)
		Siemens	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		Unknown	-	-
		Varian	-	100.0 (100.0,100.0)

Equipment manufacturer *(cont.)*

CXR

Finding	Operating point	Manufacturer	Sensitivity (%)	Specificity (%)
Pneumoperitoneum *(cont.)*	0.0484	Agfa	78.8 (63.6,90.9)	87.5 (79.6,95.3)
		Carestream	87.1 (74.2,96.8)	92.3 (84.6,98.1)
		Fujifilm	85.7 (64.3,100.0)	82.8 (69.0,96.6)
		GE Healthcare	-	-
		Kodak	-	-
		Konica Minolta	92.3 (76.9,100.0)	93.3 (80.0,100.0)
		McKesson	-	-
		Multiple	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		Philips	100.0 (100.0,100.0)	91.7 (75.0,100.0)
		Siemens	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		Unknown	-	-
		Varian	-	100.0 (100.0,100.0)

Equipment manufacturer *(cont.)*

CXR

Finding	Operating point	Manufacturer	Sensitivity (%)	Specificity (%)
Pneumoperitoneum *(cont.)*	0.2266	Agfa	72.7 (57.6,87.9)	95.3 (89.1,100.0)
		Carestream	83.9 (71.0,96.8)	94.2 (86.5,100.0)
		Fujifilm	85.7 (64.3,100.0)	96.6 (89.7,100.0)
		GE Healthcare	-	-
		Kodak	-	-
		Konica Minolta	84.6 (61.5,100.0)	100.0 (100.0,100.0)
		McKesson	-	-
		Multiple	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		Philips	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		Siemens	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		Unknown	-	-
		Varian	-	100.0 (100.0,100.0)

Equipment manufacturer *(cont.)*

CXR

Finding	Operating point	Manufacturer	Sensitivity (%)	Specificity (%)
Vertebral compression fracture	0.3849	Agfa	76.2 (57.1,95.2)	86.2 (72.4,96.6)
		Carestream	100.0 (100.0,100.0)	90.0 (75.0,100.0)
		Fujifilm	87.0 (78.3,94.2)	84.9 (76.7,93.2)
		GE Healthcare	75.0 (25.0,100.0)	100.0 (100.0,100.0)
		Kodak	89.5 (73.7,100.0)	88.9 (72.2,100.0)
		Konica Minolta	-	-
		McKesson	-	-
		Multiple	96.7 (90.0,100.0)	87.5 (74.9,100.0)
		Philips	97.3 (91.9,100.0)	91.5 (83.0,97.9)
		Siemens	88.0 (76.0,100.0)	92.3 (82.1,100.0)
		Unknown	89.5 (73.7,100.0)	80.0 (60.0,95.0)
		Varian	86.5 (75.7,97.3)	95.3 (88.4,100.0)

Equipment manufacturer *(cont.)*

CXR

Finding	Operating point	Manufacturer	Sensitivity (%)	Specificity (%)
Vertebral compression fracture *(cont).*	0.4834	Agfa	66.7 (47.6,85.7)	93.1 (82.8,100.0)
		Carestream	100.0 (100.0,100.0)	95.0 (85.0,100.0)
		Fujifilm	82.6 (73.9,91.3)	86.3 (78.1,93.2)
		GE Healthcare	75.0 (25.0,100.0)	100.0 (100.0,100.0)
		Kodak	89.5 (73.7,100.0)	88.9 (72.2,100.0)
		Konica Minolta	-	-
		McKesson	-	-
		Multiple	93.3 (83.3,100.0)	87.5 (74.9,100.0)
		Philips	94.6 (86.5,100.0)	93.6 (85.1,100.0)
		Siemens	88.0 (76.0,100.0)	92.3 (82.1,100.0)
		Unknown	89.5 (73.7,100.0)	85.0 (70.0,100.0)
		Varian	75.7 (62.2,89.2)	95.3 (88.4,100.0)

Equipment manufacturer *(cont.)*

CXR

Finding	Manufacturer	AUC (95% CI)
Pneumothorax	Agfa	0.973 (0.956, 0.986)
	Carestream	0.988 (0.96, 1.000)
	Fujifilm	0.998 (0.992, 1.000)
	GE Healthcare	1.000 (1.000, 1.000)
	Kodak	0.881 (0.607, 1.000)
	Konica Minolta	0.973 (0.943, 0.993)
	McKesson	1.000 (1.000, 1.000)
	Philips	0.987 (0.967, 0.999)
	Siemens	1.000 (1.000, 1.000)
	Unknown	1.000 (1.0, 1.000)
	Varian	0.990 (0.956, 1.000)

Equipment manufacturer *(cont.)*

CXR

Finding	Manufacturer	AUC (95% CI)
Tension pneumothorax	Agfa	0.983 (0.969, 0.992)
	Carestream	1.000 (0.975, 1.000)
	Fujifilm	0.991 (0.968, 1.000)
	GE Healthcare	-
	Kodak	-
	Konica Minolta	0.998 (0.990, 1.000)
	McKesson	0.997 (0.969, 1.000)
	Philips	1.000 (0.987, 1.000)
	Siemens	1.000 (1.000, 1.000)
	Unknown	-
	Varian	0.970 (0.890, 1.000)

Equipment manufacturer *(cont.)*

The following tables outline the sensitivity and specificity for each finding by operating point and equipment manufacturer.

Standalone performance evaluation of the device was performed on datasets with the majority of subgroup representation of studies acquired using GE Healthcare, Siemens and Toshiba CT scanners.

Use of this device with other CT scanner manufacturers may result in differences in performance.

CTB

Finding	Slice thickness range	Operating point	Manufacturer	Sensitivity (95% CI)	Specificity (95% CI)
Acute subarachnoid hemorrhage	≤1.5mm	0.014372	GE Healthcare	100.0 (100.0,100.0)	94.1 (85.3,100.0)
			NeuroLogica	-	100.0 (100.0,100.0)
			Philips	-	-
			Siemens	96.8 (92.5,100.0)	86.0 (76.0,94.0)
			Toshiba	-	-
		0.060162	GE Healthcare	94.4 (87.0,100.0)	94.1 (85.3,100.0)
			NeuroLogica	-	100.0 (100.0,100.0)
			Philips	-	-
			Siemens	93.5 (88.2,97.8)	98.0 (94.0,100.0)
			Toshiba	-	-
		0.082652	GE Healthcare	90.7 (81.5,98.1)	100.0 (100.0,100.0)
			NeuroLogica	-	100.0 (100.0,100.0)
			Philips	-	-
			Siemens	89.2 (82.8,95.7)	100.0 (100.0,100.0)
			Toshiba	-	-

Equipment manufacturer *(cont.)*

CTB

Finding	Slice thickness range	Operating point	Manufacturer	Sensitivity (95% CI)	Specificity (95% CI)
Acute subarachnoid hemorrhage *(cont.)*	>1.5mm & ≤5.0mm	0.020255	GE Healthcare	91.8 (83.7,98.0)	90.9 (81.8,100.0)
			NeuroLogica	-	100.0 (100.0,100.0)
			Philips	-	-
			Siemens	88.3 (81.9,94.7)	92.0 (84.0,98.0)
			Toshiba	94.9 (87.2,100.0)	95.2 (85.7,100.0)
		0.030010	GE Healthcare	89.8 (81.6,98.0)	97.0 (90.9,100.0)
			NeuroLogica	-	100.0 (100.0,100.0)
			Philips	-	-
			Siemens	84.0 (76.6,91.5)	96.0 (90.0,100.0)
			Toshiba	92.3 (82.1,100.0)	95.2 (85.7,100.0)

Equipment manufacturer *(cont.)*

CTB

Finding	Slice thickness range	Operating point	Manufacturer	Sensitivity (95% CI)	Specificity (95% CI)
Acute subdural/epidural hematoma	≤1.5mm	0.060177	GE Healthcare	95.0 (91.0,99.0)	87.5 (75.0,96.9)
			NeuroLogica	100.0 (100.0,100.0)	-
			Philips	100.0 (100.0,100.0)	-
			Siemens	89.5 (85.0,93.5)	86.2 (76.9,93.8)
			Toshiba	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		0.101143	GE Healthcare	93.0 (88.0,97.0)	96.9 (90.6,100.0)
			NeuroLogica	100.0 (100.0,100.0)	-
			Philips	100.0 (100.0,100.0)	-
			Siemens	87.0 (82.0,91.5)	93.8 (87.7,98.5)
			Toshiba	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		0.135700	GE Healthcare	93.0 (88.0,97.0)	100.0 (100.0,100.0)
			NeuroLogica	100.0 (100.0,100.0)	-
			Philips	100.0 (100.0,100.0)	-
			Siemens	83.0 (78.0,88.0)	95.4 (89.2,100.0)
			Toshiba	100.0 (100.0,100.0)	100.0 (100.0,100.0)

Equipment manufacturer *(cont.)*

CTB

Finding	Slice thickness range	Operating point	Manufacturer	Sensitivity (95% CI)	Specificity (95% CI)
Acute subdural/epidural hematoma *(cont.)*	>1.5mm & ≤5.0mm	0.060177	GE Healthcare	84.8 (78.6,91.1)	90.5 (81.0,97.6)
			NeuroLogica	100.0 (100.0,100.0)	0.0 (0.0,0.0)
			Philips	100.0 (100.0,100.0)	-
			Siemens	81.2 (75.6,86.8)	93.8 (87.5,98.4)
			Toshiba	81.2 (72.9,89.4)	82.1 (67.9,96.4)

Equipment manufacturer *(cont.)*

CTB

Finding	Slice thickness range	Operating point	Manufacturer	Sensitivity (95% CI)	Specificity (95% CI)
Intra-axial hemorrhage	≤1.5mm	0.322700	GE Healthcare	94.3 (89.6,98.1)	84.7 (74.6,93.2)
			NeuroLogica	100.0 (100.0,100.0)	-
			Philips	100.0 (100.0,100.0)	-
			Siemens	92.7 (90.0,95.4)	85.8 (80.2,91.4)
			Toshiba	100.0 (100.0,100.0)	100.0 (100.0,100.0)
	>1.5mm & ≤5.0mm	0.203600	GE Healthcare	93.5 (89.7,96.7)	83.8 (76.8,90.9)
			NeuroLogica	50.0 (0.0,100.0)	-
			Philips	100.0 (100.0,100.0)	-
			Siemens	93.2 (90.4,95.6)	86.1 (80.4,91.1)
			Toshiba	97.1 (88.2,100.0)	83.9 (71.0,96.8)
		0.322700	GE Healthcare	87.0 (82.1,91.8)	90.9 (84.8,96.0)
			NeuroLogica	50.0 (0.0,100.0)	-
			Philips	100.0 (100.0,100.0)	-
			Siemens	91.8 (89.1,94.3)	89.9 (85.4,94.3)
			Toshiba	94.1 (85.3,100.0)	90.3 (80.6,100.0)

Equipment manufacturer *(cont.)*

CTB

Finding	Slice thickness range	Operating point	Manufacturer	Sensitivity (95% CI)	Specificity (95% CI)
Intraventricular hemorrhage	≤1.5mm	0.015487	GE Healthcare	95.8 (87.5,100.0)	91.7 (79.2,100.0)
			NeuroLogica	100.0 (100.0,100.0)	100.0 (100.0,100.0)
			Philips	-	-
			Siemens	95.8 (89.6,100.0)	90.4 (82.7,98.1)
			Toshiba	-	-
		0.051859	GE Healthcare	91.7 (79.2,100.0)	95.8 (87.5,100.0)
			NeuroLogica	0.0 (0.0,0.0)	100.0 (100.0,100.0)
			Philips	-	-
			Siemens	91.7 (83.3,97.9)	98.1 (94.2,100.0)
			Toshiba	-	-

Equipment manufacturer *(cont.)*

CTB

Finding	Slice thickness range	Operating point	Manufacturer	Sensitivity (95% CI)	Specificity (95% CI)
Intraventricular hemorrhage *(cont.)*	>1.5mm & ≤5.0mm	0.008430	GE Healthcare	91.7 (79.2,100.0)	95.7 (87.0,100.0)
			NeuroLogica	100.0 (100.0,100.0)	100.0 (100.0,100.0)
			Philips	-	-
			Siemens	95.8 (89.6,100.0)	79.2 (66.7,89.6)
			Toshiba	100.0 (100.0,100.0)	90.5 (76.2,100.0)
		0.015487	GE Healthcare	87.5 (75.0,100.0)	95.7 (87.0,100.0)
			NeuroLogica	100.0 (100.0,100.0)	100.0 (100.0,100.0)
			Philips	-	-
			Siemens	91.7 (83.3,97.9)	85.4 (75.0,93.8)
			Toshiba	100.0 (100.0,100.0)	90.5 (76.2,100.0)
		0.051859	GE Healthcare	83.3 (66.7,95.8)	100.0 (100.0,100.0)
			NeuroLogica	100.0 (100.0,100.0)	100.0 (100.0,100.0)
			Philips	-	-
			Siemens	85.4 (75.0,95.8)	97.9 (93.8,100.0)
			Toshiba	100.0 (100.0,100.0)	95.2 (85.7,100.0)

Equipment manufacturer: Outside US (OUS) data analysis

The following tables outline the sensitivity and specificity for each finding by operating point and equipment manufacturer.

Additional analysis was conducted with GE, Philips, Siemens and Toshiba CT scanners on a dataset ≤ 1.5mm slice thickness sourced from Australia.

CTB

Finding	Slice thickness range	Operating point	Manufacturer	Sensitivity (95% CI)	Specificity (95% CI)
Acute subarachnoid hemorrhage	≤1.5mm	0.014372	GE Healthcare	97.5 (91.7, 100.0)	76.6 (73.4, 79.8)
			Philips	90.9 (76.9, 100.0)	79.8 (75.7, 83.7)
			Siemens	100.0 (100.0, 100.0)	68.3 (63.5, 73.0)
			Toshiba	98.2 (93.9, 100.0)	81.3 (79.1, 83.5)
		0.060162	GE Healthcare	90.0 (79.5, 97.7)	88.9 (86.4, 91.2)
			Philips	90.9 (76.9, 100.0)	92.6 (89.8, 95.1)
			Siemens	97.0 (90.0, 100.0)	85.3 (81.6, 88.8)
			Toshiba	92.8 (85.2, 98.4)	92.4 (90.9, 93.9)
		0.082652	GE Healthcare	90.0 (79.5, 97.7)	90.8 (88.5, 92.9)
			Philips	90.9 (76.9, 100.0)	94.1 (91.6, 96.3)
			Siemens	97.0 (90.0, 100.0)	88.3 (85.0, 91.5)
			Toshiba	92.8 (85.2, 98.4)	93.6 (92.1, 95.0)

Equipment manufacturer: Outside US (OUS) data analysis *(cont.)*

CTB

Finding	Slice thickness range	Operating point	Manufacturer	Sensitivity (95% CI)	Specificity (95% CI)
Acute subdural/epidural hematoma	≤1.5mm	0.030172	GE Healthcare	96.1 (89.8, 100.0)	84.7 (82.0, 87.3)
			Philips	100 (100.0, 100.0)	89.7 (86.5, 92.6)
			Siemens	95.9 (89.5, 100.0)	79.1 (74.9, 83.3)
			Toshiba	96.1 (89.8, 100.0)	84.7 (82.0, 87.3)
		0.060177	GE Healthcare	90.2 (81.1, 97.8)	88.7 (86.3, 91.0)
			Philips	100 (100.0, 100.0)	92.8 (90.1, 95.3)
			Siemens	93.8 (86.3, 100.0)	85.9 (82.2, 89.5)
			Toshiba	94.9 (88.5, 100.0	93.1 (91.7, 94.6)
		0.101143	GE Healthcare	88.3 (78.6, 96.2)	92 (89.9, 94.0)
			Philips	96.2 (87.0, 100.0)	94.1 (91.6, 96.3)
			Siemens	89.6 (80.0, 97.7)	89 (85.7, 92.1)
			Toshiba	93.2 (86.1, 98.5)	94.6 (93.3, 95.9)
		0.135700	GE Healthcare	88.3 (78.6, 96.2)	93.6 (91.7, 95.4)
			Philips	96.2 (87.0, 100.0)	95.9 (93.8, 97.7)
			Siemens	89.6 (80.0, 97.7)	90.7 (87.6, 93.6)
			Toshiba	91.5 (83.6, 98.1)	95.2 (94.0, 96.4)

Equipment manufacturer: Outside US (OUS) data analysis *(cont.)*

CTB

Finding	Slice thickness range	Operating point	Manufacturer	Sensitivity (95% CI)	Specificity (95% CI)
Intra-axial hemorrhage	≤1.5mm	0.1498	GE Healthcare	85.9 (78.0, 92.9)	92.6 (90.5, 94.7)
			Philips	78.1 (62.5, 92.0)	89.5 (86.3, 92.4)
			Siemens	93 (85.7, 98.4)	89.6 (86.2, 92.7)
			Toshiba	87.3 (81.3, 92.7)	93.5 (92.1, 94.9)
		0.2036	GE Healthcare	84.7 (76.7, 92.0)	94.8 (93.0, 96.5)
			Philips	78.1 (62.5, 92.0)	90.8 (87.7, 93.5)
			Siemens	91.2 (83.1, 98.1)	91.3 (88.2, 94.2)
			Toshiba	84.9 (78.5, 90.9)	94.9 (93.6, 96.1)
		0.322700	GE Healthcare	77.7 (68.4, 86.1)	96.7 (95.2, 98.0)
			Philips	68.6 (51.6, 84.6)	94.5 (92.1, 96.7)
			Siemens	84.2 (74.0, 93.2)	95.3 (92.9, 97.4)
			Toshiba	77 (69.4, 84.1)	97.1 (96.1, 98.0)

Equipment manufacturer: Outside US (OUS) data analysis *(cont.)*

CTB

Finding	Slice thickness range	Operating point	Manufacturer	Sensitivity (95% CI)	Specificity (95% CI)
Intraventricular hemorrhage	≤1.5mm	0.00843	GE Healthcare	100 (100.0, 100.0)	78.3 (75.2, 81.3)
			Philips	94 (80.0, 100.0)	84.1 (80.4, 87.7)
			Siemens	100 (100.0, 100.0)	71.6 (67.1, 76.1)
			Toshiba	100 (100.0, 100.0)	83.1 (81.0, 85.2)
		0.015487	GE Healthcare	100 (100.0, 100.0)	86.8 (84.3, 89.3)
			Philips	88.2 (69.6, 100.0)	89.6 (86.5, 92.6)
			Siemens	100 (100.0, 100.0)	83.2 (79.4, 86.9)
			Toshiba	100 (100.0, 100.0)	88 (86.1, 89.8)
		0.051859	GE Healthcare	90.9 (80.0, 100.0)	94.4 (92.6, 96.0)
			Philips	88.2 (69.6, 100.0)	97.5 (95.8, 98.9)
			Siemens	100 (100.0, 100.0)	93.6 (91.0, 95.9)
			Toshiba	100 (100.0, 100.0)	95 (93.8, 96.2)

Presence of co-existing findings or abnormalities

The following tables outline the sensitivity and specificity for each finding by operating point and the presence of co-existing findings or abnormalities.

CTB

Finding	Slice thickness range	Operating point	Co-finding	Sensitivity (95% CI)	Specificity (95% CI)
Acute subarachnoid hemorrhage	≤1.5mm	0.014372	Any finding	98.3 (95.7,100.0)	78.8 (63.6,90.9)
			No additional findings	96.8 (90.3,100.0)	96.2 (90.4,100.0)
		0.060162	Any finding	96.6 (93.1,99.1)	93.9 (84.8,100.0)
			No additional findings	83.9 (71.0,96.8)	98.1 (94.2,100.0)
		0.082652	Any finding	91.4 (86.2,96.6)	100.0 (100.0,100.0)
			No additional findings	83.9 (71.0,96.8)	100.0 (100.0,100.0)
	>1.5mm & ≤5.0mm	0.020255	Any finding	92.4 (87.6,96.6)	86.4 (75.0,95.5)
			No additional findings	83.8 (70.3,94.6)	96.7 (91.8,100.0)
		0.030010	Any finding	89.7 (84.1,94.5)	93.2 (84.1,100.0)
			No additional findings	78.4 (64.9,91.9)	98.4 (95.1,100.0

Presence of co-existing findings or abnormalities *(cont.)*

CTB

Finding	Slice thickness range	Operating point	Co-finding	Sensitivity (95% CI)	Specificity (95% CI)
Acute subdural/epidural hematoma	≤1.5mm	0.060177	Any finding	93.5 (89.8,96.8)	80.9 (70.2,91.5)
			No additional findings	86.2 (79.3,93.1)	92.2 (84.3,98.0)
		0.101143	Any finding	90.3 (86.6,94.0)	93.6 (85.1,100.0)
			No additional findings	86.2 (79.3,93.1)	96.1 (90.2,100.0)
		0.135700	Any finding	87.0 (82.4,91.2)	95.7 (89.4,100.0)
			No additional findings	85.1 (77.0,92.0)	98.0 (94.1,100.0)
	>1.5mm & ≤5.0mm	0.060177	Any finding	85.0 (80.6,89.0)	85.7 (76.2,93.7)
			No additional findings	76.6 (69.4,83.9)	93.1 (87.5,98.6)
Intra-axial hemorrhage	≤1.5mm	0.322700	Any finding	93.7 (91.4,95.8)	77.5 (70.3,84.8)
			No additional findings	40.0 (0.0,80.0)	98.8 (96.4,100.0)
	>1.5mm & ≤5.0mm	0.203600	Any finding	93.9 (91.9,95.8)	76.5 (69.9,82.5)
			No additional findings	55.6 (22.2,88.9)	100.0 (100.0,100.0)
		0.322700	Any finding	91.3 (89.1,93.6)	84.7 (79.2,89.6)
			No additional findings	22.2 (0.0,55.6)	100.0 (100.0,100.0)

Presence of co-existing findings or abnormalities *(cont.)*

CTB

Finding	Slice thickness range	Operating point	Co-finding	Sensitivity (95% CI)	Specificity (95% CI)
Intraventricular hemorrhage	≤1.5mm	0.015487	Any finding	95.8 (90.3,100.0)	83.3 (71.4,92.9)
			No additional findings	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		0.051859	Any finding	90.3 (83.3,95.8)	95.2 (88.1,100.0)
			No additional findings	100.0 (100.0,100.0)	100.0 (100.0,100.0)
	>1.5mm & ≤5.0mm	0.008430	Any finding	95.5 (91.0,98.9)	75.0 (63.5,86.5)
			No additional findings	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		0.015487	Any finding	92.1 (86.5,97.8)	80.8 (69.2,90.4)
			No additional findings	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		0.051859	Any finding	87.6 (80.9,94.4)	96.2 (90.4,100.0)
			No additional findings	100.0 (100.0,100.0)	100.0(100.0,100.0)

Presence of specific co-existing findings or abnormalities for intra-axial hemorrhage

The following tables outline the sensitivity and specificity by operating point and the presence of co-existing findings or abnormalities for intra-axial hemorrhage.

CTB

Finding	Slice thickness range	Operating point	Co-existing findings or anomalies	Absent/ present	Sensitivity (95% CI)	Specificity (95% CI)
Intra-axial hemorrhage	≤1.5mm	0.322700	Intracranial hemorrhage	Absent	87.6 (82.2,92.3)	97.7 (95.4,99.4)
				Present	96.1 (93.9,98.1)	42.9 (28.6,57.1)*
			Fracture including calvarial/skull base/facial	Absent	92.7 (90.2,95.0)	86.3 (81.5,91.0)
				Present	97.5 (92.5,100.0)	72.7 (45.5,100.0)
			Parenchymal abnormality including ischemia/ mass/cyst/ encephalomalacia	Absent	94.6 (92.1,96.9)	85.6 (79.6,90.4)
				Present	89.0 (83.5,94.5)	85.5 (74.5,94.5)
			Parenchymal atrophy (excluding age-expected atrophy)	Absent	93.6 (91.0,96.0)	85.2 (79.6,90.1)
				Present	91.3 (85.4,96.1)	86.7 (78.3,95.0)
			Edema including transependymal/ vasogenic	Absent	71.1 (57.8,84.4)	89.0 (85.0,93.0)
				Present	95.4 (93.3,97.2)	54.5 (31.8,72.7)
			Hydrocephalus including obstructive/non-obstructive	Absent	93.0 (90.5,95.2)	87.2 (82.5,91.5)
				Present	93.9 (89.0,98.8)	54.5 (27.3,81.8)

*Specificity may be reduced for intra-axial hemorrhage in the presence of other intracranial hemorrhage findings.

Presence of specific co-existing findings or abnormalities for intra-axial hemorrhage *(cont.)*

CTB

Finding	Slice thickness range	Operating point	Co-existing findings or anomalies	Absent/ present	Sensitivity (95% CI)	Specificity (95% CI)
Intra-axial hemorrhage *(cont.)*	≤1.5mm *(cont.)*	0.322700	Ventricular drain including extraventricular drain, ventriculoperitoneal shunt	Absent	93.2 (90.7,95.4)	85.3 (80.2,89.9)
				Present	92.3 (80.8,100.0)	100.0 (100.0,100.0)
			Other evidence of intracranial surgery	Absent	92.7 (90.0,95.1)	85.9 (81.1,90.3)
				Present	95.8 (90.1,100.0)	81.2 (62.5,100.0)
			Metallic artifact overlapping region of interest	Absent	93.4 (90.9,95.7)	85.8 (80.9,90.2)
				Present	89.7 (79.5,97.4)	83.3 (66.7,100.0)
			Motion artifact overlapping region of interest	Absent	93.5 (91.2,95.9)	85.6 (80.8,89.9)
				Present	89.1 (80.4,97.8)	85.7 (64.3,100.0)

Presence of specific co-existing findings or abnormalities for intra-axial hemorrhage *(cont.)*

CTB

Finding	Slice thickness range	Operating point	Co-existing findings or anomalies	Absent/ present	Sensitivity (95% CI)	Specificity (95% CI)
Intra-axial hemorrhage *(cont.)*	>1.5mm & ≤5.0mm	0.203600	Intracranial hemorrhage	Absent	88.0 (83.4,92.2)	98.2 (96.3,99.5)
				Present	96.5 (94.6,98.4)	45.1 (33.8,56.3)*
			Fracture including calvarial/skull base/facial	Absent	93.1 (90.9,95.2)	86.4 (82.0,90.4)
				Present	95.7 (89.4,100.0)	62.5 (37.5,87.5)
			Parenchymal abnormality including ischemia/ mass/cyst/ encephalomalacia	Absent	94.5 (92.2,96.3)	87.8 (83.3,91.9)
				Present	90.2 (85.6,94.8)	76.1 (65.7,85.1)
			Parenchymal atrophy (excluding age-expected atrophy)	Absent	93.8 (91.6,96.0)	83.9 (79.0,88.8)
				Present	91.8 (87.3,96.3)	88.0 (80.7,94.0)
			Edema including transependymal/ vasogenic	Absent	77.4 (66.1,87.1)	89.0 (85.2,92.8)
				Present	95.2 (93.3,97.0)	41.7 (20.8,62.5)
			Hydrocephalus including obstructive/non-obstructive	Absent	92.9 (90.6,95.1)	85.8 (81.7,89.8)
				Present	95.8 (91.7,99.0)	71.4 (50.0,92.9)

*Specificity may be reduced for intra-axial hemorrhage in the presence of other intracranial hemorrhage findings.

Presence of specific co-existing findings or abnormalities for intra-axial hemorrhage *(cont.)*

CTB

Finding	Slice thickness range	Operating point	Co-existing findings or anomalies	Absent/ present	Sensitivity (95% CI)	Specificity (95% CI)
Intra-axial hemorrhage *(cont.)*	>1.5mm & ≤5.0mm *(cont.)*	0.203600	Ventricular drain including extraventricular drain, ventriculoperitoneal shunt	Absent	93.4 (91.4,95.5)	84.8 (80.5,88.7)
				Present	93.1 (82.8,100.0)	100.0 (100.0,100.0)
			Other evidence of intracranial surgery	Absent	93.0 (90.6,94.9)	85.6 (81.2,89.7)
				Present	95.9 (90.5,100.0)	76.5 (52.9,94.1)
			Metallic artifact overlapping region of interest	Absent	93.6 (91.6,95.6)	85.3 (80.9,89.7)
				Present	90.2 (80.5,97.6)	81.2 (62.5,100.0)
			Motion artifact overlapping region of interest	Absent	93.0 (90.8,95.1)	84.3 (79.9,88.3)
				Present	96.4 (90.9,100.0)	100.0 (100.0,100.0)

Presence of specific co-existing findings or abnormalities for intra-axial hemorrhage *(cont.)*

CTB

Finding	Slice thickness range	Operating point	Co-existing findings or anomalies	Absent/ present	Sensitivity (95% CI)	Specificity (95% CI)
Intra-axial hemorrhage *(cont.)*	>1.5mm & ≤5.0mm *(cont.)*	0.322700	Intracranial hemorrhage	Absent	83.4 (78.3,88.5)	99.1 (97.7,100.0)
				Present	94.3 (91.9,96.5)	63.4 (52.1,74.6)*
			Fracture including calvarial/skull base/facial	Absent	89.8 (87.2,92.2)	90.8 (87.1,94.1)
				Present	95.7 (89.4,100.0)	81.2 (62.5,100.0)
			Parenchymal abnormality including ischemia/ mass/cyst/ encephalomalacia	Absent	91.9 (89.4,94.2)	92.3 (88.7,95.5)
				Present	85.6 (79.7,90.8)	83.6 (74.6,92.5)
			Parenchymal atrophy (excluding age-expected atrophy)	Absent	91.2 (88.5,93.6)	88.8 (84.4,93.2)
				Present	87.3 (81.3,92.5)	94.0 (88.0,98.8)
			Edema including transependymal/ vasogenic	Absent	64.5 (53.2,75.8)	93.9 (90.9,96.6)
				Present	93.3 (91.0,95.4)	50.0 (29.2,70.8)
			Hydrocephalus including obstructive/non-obstructive	Absent	89.6 (86.8,92.3)	91.2 (87.6,94.2)
				Present	93.8 (88.5,97.9)	71.4 (50.0,92.9)

*Specificity may be reduced for intra-axial hemorrhage in the presence of other intracranial hemorrhage findings.

Presence of specific co-existing findings or abnormalities for intra-axial hemorrhage *(cont.)*

CTB

Finding	Slice thickness range	Operating point	Co-existing findings or anomalies	Absent/ present	Sensitivity (95% CI)	Specificity (95% CI)
Intra-axial hemorrhage *(cont.)*	>1.5mm & ≤5.0mm *(cont.)*	0.322700	Ventricular drain including extraventricular drain, ventriculoperitoneal shunt	Absent	90.7 (88.4,93.2)	90.1 (86.5,93.3)
				Present	82.8 (69.0,96.6)	100.0 (100.0,100.0)
			Other evidence of intracranial surgery	Absent	89.7 (87.1,92.2)	91.1 (87.8,94.1)
				Present	94.6 (89.2,98.6)	76.5 (52.9,94.1)
			Metallic artifact overlapping region of interest	Absent	90.7 (88.1,93.0)	89.7 (85.7,93.4)
				Present	85.4 (75.5,95.1)	100.0 (100.0,100.0)
			Motion artifact overlapping region of interest	Absent	90.0 (87.6,92.5)	89.8 (85.8,93.4)
				Present	92.7 (85.5,98.2)	100.0 (100.0,100.0)

Acute subdural/epidural hematoma location

The following table outlines the sensitivity for each finding by operating point and acute subdural/epidural hematoma subgroup location.

CTB

Finding	Slice thickness range	Operating point	Subgroup	Sensitivity (95% CI)
Acute subdural/epidural hematoma	≤1.5mm	0.060177	Epidural	94.7 (82.4,100.0)
			Subdural	90.5 (86.7,94.0)
			Subdural and epidural	96.8 (89.7,100.0)
		0.101143	Epidural	94.7 (82.4,100.0)
			Subdural	87.7 (83.7,91.6)
			Subdural and epidural	96.8 (89.7,100.0)
		0.135700	Epidural	84.2 (66.6,100.0)
			Subdural	86.2 (81.9,90.2)
			Subdural and epidural	90.3 (79.2,100.0)
	>1.5mm & ≤5.0mm	0.060177	Epidural	80.0 (64.0,95.5)
			Subdural	80.8 (76.6,85.0)
			Subdural and epidural	97.4 (91.7,100.0)

Series thickness for slice thickness range >1.5mm to ≤5mm

The following table outlines the sensitivity and specificity for each finding by operating point and series thickness range.

CTB

Finding	Operating point	Slice thickness range	Sensitivity (95% CI)	Specificity (95% CI)
Acute subarachnoid hemorrhage	0.020255	>1.5 to ≤3.5 mm series	98.2 (94.5,100.0)	93.5 (83.9,100.0)
		>3.5 to ≤5 mm series	87.4 (81.1,92.9)	91.9 (85.1,97.3)
	0.030010	>1.5 to ≤3.5 mm series	96.4 (90.9,100.0)	96.8 (90.3,100.0)
		>3.5 to ≤5 mm series	83.5 (77.2,89.8)	95.9 (90.5,100.0)
Acute subdural/epidural hematoma	0.060177	>1.5 to ≤3.5 mm series	93.1 (88.2,97.1)	89.7 (79.5,97.4)
		>3.5 to ≤5 mm series	78.6 (73.9,83.1)	89.6 (83.3,94.8)
Intra-axial hemorrhage	0.322700	>1.5 to ≤3.5 mm series	95.5 (92.6,97.9)	88.8 (81.6,94.9)
		>3.5 to ≤5 mm series	86.7 (82.9,90.1)	91.1 (86.8,94.7)
	0.203600	>1.5 to ≤3.5 mm series	97.9 (95.9,99.6)	81.6 (74.5,88.8)
		>3.5 to ≤5 mm series	90.1 (86.9,92.8)	86.8 (81.6,91.6)
Intraventricular hemorrhage	0.015487	>1.5 to ≤3.5 mm series	92.9 (82.1,100.0)	83.3 (66.7,95.8)
		>3.5 to ≤5 mm series	92.1 (85.7,98.4)	91.3 (84.1,97.1)
	0.051859	>1.5 to ≤3.5 mm series	92.9 (82.1,100.0)	95.8 (87.5,100.0)
		>3.5 to ≤5 mm series	85.7 (77.8,93.7)	98.6 (95.7,100.0)
	0.008430	>1.5 to ≤3.5 mm series	96.4 (89.3,100.0)	83.3 (66.7,95.8)
		>3.5 to ≤5 mm series	95.2 (88.9,100.0)	87.0 (78.3,94.2)

Subgroup analysis: Distribution

Subgroup analysis	Test datasets included a range of patient demographics. Distribution subgroup analysis was performed for the following: • patient ethnicity • patient race • presence of co-existing findings or abnormalities Detection accuracy for each sub-group is summarized in each of the following tables.

Patient ethnicity

The following tables outline the distribution for each finding by patient ethnicity subgroup.

CTB

Finding	Slice thickness range	Subgroup	**Total** (N=232)
Acute subarachnoid hemorrhage	≤1.5mm	Hispanic	18 (7.8%)
		Not Hispanic	195 (84.1%)
		Prefer not to say/Decline	2 (0.9%)
		Unavailable	17 (7.3%)

Finding	Slice thickness range	Subgroup	**Total** (N=287)
Acute subarachnoid hemorrhage	>1.5mm & ≤5.0mm	Hispanic	17 (5.9%)
		Not Hispanic	249 (86.8%)
		Prefer not to say/Decline	2 (0.7%)
		Unavailable	19 (6.6%)

Patient ethnicity *(cont.)*

CTB

Finding	Slice thickness range	Subgroup	**Total** (N=401)
Acute subdural/epidural hematoma	≤1.5mm	Hispanic	42 (10.5%)
		Not Hispanic	337 (84.0%)
		Prefer not to say/Decline	0 (0.0%)
		Unavailable	22 (5.5%)

Finding	Slice thickness range	Subgroup	**Total** (N=532)
Acute subdural/epidural hematoma	>1.5mm & ≤5.0mm	Hispanic	51 (9.6%)
		Not Hispanic	458 (86.1%)
		Prefer not to say/Decline	0 (0.0%)
		Unavailable	23 (4.3%)

Patient ethnicity *(cont.)*

CTB

Finding	Slice thickness range	Subgroup	**Total** (N=702)
Intra-axial hemorrhage	≤1.5mm	Hispanic	57 (8.1%)
		Not Hispanic	602 (85.8%)
		Prefer not to say/Decline	3 (0.4%)
		Unavailable	40 (5.7%)

Finding	Slice thickness range	Subgroup	**Total** (N=875)
Intra-axial hemorrhage	>1.5mm & ≤5.0mm	Hispanic	68 (7.8%)
		Not Hispanic	757 (86.5%)
		Prefer not to say/Decline	4 (0.5%)
		Unavailable	46 (5.3%)

Patient ethnicity
(cont.)

CTB

Finding	**Slice thickness range**	**Subgroup**	**Total** (N=150)
Intraventricular hemorrhage	≤1.5mm	Hispanic	17 (11.3%)
		Not Hispanic	129 (86.0%)
		Prefer not to say/Decline	1 (0.7%)
		Unavailable	3 (2.0%)

Finding	**Slice thickness range**	**Subgroup**	**Total** (N=184)
Intraventricular hemorrhage	>1.5mm & ≤5.0mm	Hispanic	16 (8.7%)
		Not Hispanic	162 (88.0%)
		Prefer not to say/Decline	1 (0.5%)
		Unavailable	5 (2.7%)

Patient race

The following tables outline the distribution for each finding by patient race subgroup.

CTB

Finding	Slice thickness range	Race	**Total** (N=232)	**Hispanic ethnicity** (N=18)
Acute subarachnoid hemorrhage	≤1.5mm	American Indian or Alaska Native	1 (0.4%)	0 (0.0%)
		Asian	12 (5.2%)	0 (0.0%)
		Black or African America	6 (2.6%)	1 (5.6%)
		Native Hawaiian or Other Pacific Islander	0 (0.0%)	0 (0.0%)
		White or Caucasian	183 (78.9%)	5 (27.8%)
		Other	12 (5.2%)	7 (38.9%)
		2 or more races	2 (0.9%)	1 (5.6%)
		Declined	2 (0.9%)	0 (0.0%)
		Unavailable	14 (6.0%)	4 (22.2%)

Patient race *(cont.)*

CTB

Finding	Slice thickness range	Race	**Total** (N=287)	**Hispanic ethnicity** (N=17)
Acute subarachnoid hemorrhage	>1.5mm & ≤5.0mm	American Indian or Alaska Native	2 (0.7%)	0 (0.0%)
		Asian	12 (4.2%)	0 (0.0%)
		Black or African America	9 (3.1%)	1 (5.9%)
		Native Hawaiian or Other Pacific Islander	0 (0.0%)	0 (0.0%)
		White or Caucasian	230 (80.1%)	4 (23.5%)
		Other	12 (4.2%)	7 (41.2%)
		2 or more races	4 (1.4%)	1 (5.9%)
		Declined	3 (1.0%)	0 (0.0%)
		Unavailable	15 (5.2%)	4 (23.5%)

Patient race *(cont.)*

CTB

Finding	Slice thickness range	Race	**Total** (N=401)	**Hispanic ethnicity** (N=42)
Acute subdural/epidural hematoma	≤1.5mm	American Indian or Alaska Native	0 (0.0%)	0 (0.0%)
		Asian	20 (5.0%)	0 (0.0%)
		Black or African America	25 (6.2%)	2 (4.8%)
		Native Hawaiian or Other Pacific Islander	0 (0.0%)	0 (0.0%)
		White or Caucasian	308 (76.8%)	14 (33.3%)
		Other	26 (6.5%)	20 (47.6%)
		2 or more races	4 (1.0%)	2 (4.8%)
		Declined	2 (0.5%)	1 (2.4%)
		Unavailable	16 (4.0%)	3 (7.1%)

Patient race *(cont.)*

CTB

Finding	Slice thickness range	Race	**Total** (N=532)	**Hispanic ethnicity** (N=51)
Acute subdural/epidural hematoma	>1.5mm & ≤5.0mm	American Indian or Alaska Native	0 (0.0%)	0 (0.0%)
		Asian	21 (3.9%)	0 (0.0%)
		Black or African America	27 (5.1%)	2 (3.9%)
		Native Hawaiian or Other Pacific Islander	0 (0.0%)	0 (0.0%)
		White or Caucasian	423 (79.5%)	16 (31.4%)
		Other	33 (6.2%)	26 (51.0%)
		2 or more races	8 (1.5%)	3 (5.9%)
		Declined	3 (0.6%)	1 (2.0%)
		Unavailable	17 (3.2%)	3 (5.9%)

Patient race *(cont.)*

CTB

Finding	Slice thickness range	Race	**Total** (N=702)	**Hispanic ethnicity** (N=57)
Intra-axial hemorrhage	≤1.5mm	American Indian or Alaska Native	0 (0.0%)	0 (0.0%)
		Asian	46 (6.6%)	0 (0.0%)
		Black or African America	42 (6.0%)	4 (7.0%)
		Native Hawaiian or Other Pacific Islander	1 (0.1%)	1 (1.8%)
		White or Caucasian	538 (76.6%)	13 (22.8%)
		Other	39 (5.6%)	33 (57.9%)
		2 or more races	6 (0.9%)	2 (3.5%)
		Declined	4 (0.6%)	0 (0.0%)
		Unavailable	26 (3.7%)	4 (7.0%)

Patient race *(cont.)*

CTB

Finding	Slice thickness range	Race	**Total** (N=875)	**Hispanic ethnicity** (N=68)
Intra-axial hemorrhage	>1.5mm & ≤5.0mm	American Indian or Alaska Native	1 (0.1%)	0 (0.0%)
		Asian	50 (5.7%)	0 (0.0%)
		Black or African America	51 (5.8%)	5 (7.4%)
		Native Hawaiian or Other Pacific Islander	2 (0.2%)	1 (1.5%)
		White or Caucasian	687 (78.5%)	19 (27.9%)
		Other	42 (4.8%)	36 (52.9%)
		2 or more races	8 (0.9%)	3 (4.4%)
		Declined	4 (0.5%)	0 (0.0%)
		Unavailable	30 (3.4%)	4 (5.9%)

Patient race *(cont.)*

CTB

Finding	Slice thickness range	Race	**Total** (N=150)	**Hispanic ethnicity** (N=17)
Intraventricular hemorrhage	≤1.5mm	American Indian or Alaska Native	0 (0.0%)	0 (0.0%)
		Asian	4 (2.7%)	0 (0.0%)
		Black or African America	16 (10.7%)	3 (17.6%)
		Native Hawaiian or Other Pacific Islander	0 (0.0%)	0 (0.0%)
		White or Caucasian	117 (78.0%)	5 (29.4%)
		Other	8 (5.3%)	7 (41.2%)
		2 or more races	1 (0.7%)	0 (0.0%)
		Declined	1 (0.7%)	0 (0.0%)
		Unavailable	3 (2.0%)	2 (11.8%)

Patient race *(cont.)*

CTB

Finding	Slice thickness range	Race	Total (N=184)	Hispanic ethnicity (N=16)
Intraventricular hemorrhage	>1.5mm & ≤5.0mm	American Indian or Alaska Native	0 (0.0%)	0 (0.0%)
		Asian	4 (2.2%)	0 (0.0%)
		Black or African America	16 (8.7%)	3 (18.8%)
		Native Hawaiian or Other Pacific Islander	0 (0.0%)	0 (0.0%)
		White or Caucasian	151 (82.1%)	5 (31.2%)
		Other	7 (3.8%)	6 (37.5%)
		2 or more races	0 (0.0%)	0 (0.0%)
		Declined	1 (0.5%)	0 (0.0%)
		Unavailable	5 (2.7%)	2 (12.5%)

Presence of co-existing findings or abnormalities

The following tables outline the presence of co-existing findings or abnormalities by slice thickness range for each finding.

CTB

Finding	Slice thickness range	Subgroup	Ground truth positive (N = 147)	Ground truth negative (N = 85)	Total (N = 232)
Acute subarachnoid hemorrhage	≤1.5mm	Intracranial hemorrhage	96 (65.3%)	5 (5.9%)	101 (43.5%)
		Fracture including calvarial/ skull base/facial	27 (18.4%)	1 (1.2%)	28 (12.1%)
		Parenchymal abnormality including ischemia/mass/cyst/ encephalomalacia	70 (47.6%)	20 (23.5%)	90 (38.8%)
		Parenchymal atrophy (excluding age-expected atrophy)	6 (4.1%)	2 (2.4%)	8 (3.4%)
		Edema including transependymal/vasogenic	50 (34.0%)	6 (7.1%)	56 (24.1%)
		Hydrocephalus including obstructive/non-obstructive	17 (11.6%)	5 (5.9%)	22 (9.5%)
		Ventricular drain including extraventricular drain, ventriculoperitoneal shunt	5 (3.4%)	5 (5.9%)	10 (4.3%)
		Other evidence of intracranial surgery	11 (7.5%)	4 (4.7%)	15 (6.5%)
		Metallic artifact overlapping region of interest	5 (3.4%)	5 (5.9%)	10 (4.3%)
		Motion artifact overlapping region of interest	9 (6.1%)	7 (8.2%)	16 (6.9%)
		Any finding	116 (78.9%)	33 (38.8%)	149 (64.2%)

Presence of co-existing findings or abnormalities *(cont.)*

CTB

Finding	Slice thickness range	Subgroup	Ground truth positive (N = 182)	Ground truth negative (N = 105)	Total (N = 287)
Acute subarachnoid hemorrhage *(cont.)*	>1.5mm & ≤5.0mm	Intracranial hemorrhage	123 (67.6%)	6 (5.7%)	129 (44.9%)
		Fracture including calvarial/ skull base/facial	31 (17.0%)	1 (1.0%)	32 (11.1%)
		Parenchymal abnormality including ischemia/mass/cyst/ encephalomalacia	82 (45.1%)	26 (24.8%)	108 (37.6%)
		Parenchymal atrophy (excluding age-expected atrophy)	9 (4.9%)	5 (4.8%)	14 (4.9%)
		Edema including transependymal/vasogenic	56 (30.8%)	7 (6.7%)	63 (22.0%)
		Hydrocephalus including obstructive/non-obstructive	18 (9.9%)	6 (5.7%)	24 (8.4%)
		Ventricular drain including extraventricular drain, ventriculoperitoneal shunt	5 (2.7%)	5 (4.8%)	10 (3.5%)
		Other evidence of intracranial surgery	14 (7.7%)	7 (6.7%)	21 (7.3%)
		Metallic artifact overlapping region of interest	6 (3.3%)	7 (6.7%)	13 (4.5%)
		Motion artifact overlapping region of interest	11 (6.0%)	8 (7.6%)	19 (6.6%)
		Any finding	145 (79.7%)	44 (41.9%)	189 (65.9%)

Presence of co-existing findings or abnormalities *(cont.)*

CTB

Finding	Slice thickness range	Subgroup	Ground truth positive (N = 303)	Ground truth negative (N = 98)	Total (N = 401)
Acute subdural/epidural hematoma	≤1.5mm	Intracranial hemorrhage	131 (43.2%)	10 (10.2%)	141 (35.2%)
		Fracture including calvarial/ skull base/facial	56 (18.5%)	2 (2.0%)	58 (14.5%)
		Parenchymal abnormality including ischemia/mass/cyst/ encephalomalacia	114 (37.6%)	32 (32.7%)	146 (36.4%)
		Parenchymal atrophy (excluding age-expected atrophy)	7 (2.3%)	7 (7.1%)	14 (3.5%)
		Edema including transependymal/vasogenic	72 (23.8%)	7 (7.1%)	79 (19.7%)
		Hydrocephalus including obstructive/non-obstructive	27 (8.9%)	6 (6.1%)	33 (8.2%)
		Ventricular drain including extraventricular drain, ventriculoperitoneal shunt	15 (5.0%)	4 (4.1%)	19 (4.7%)
		Other evidence of intracranial surgery	53 (17.5%)	6 (6.1%)	59 (14.7%)
		Metallic artifact overlapping region of interest	11 (3.6%)	2 (2.0%)	13 (3.2%)
		Motion artifact overlapping region of interest	32 (10.6%)	9 (9.2%)	41 (10.2%)
		Any finding	216 (71.3%)	47 (48.0%)	263 (65.6%)

Presence of co-existing findings or abnormalities *(cont.)*

CTB

Finding	Slice thickness range	Subgroup	Ground truth positive (N = 397)	Ground truth negative (N = 135)	Total (N = 532)
Acute subdural/epidural hematoma *(cont.)*	>1.5mm & ≤5.0mm	Intracranial hemorrhage	171 (43.1%)	16 (11.9%)	187 (35.2%)
		Fracture including calvarial/ skull base/facial	74 (18.6%)	2 (1.5%)	76 (14.3%)
		Parenchymal abnormality including ischemia/mass/cyst/ encephalomalacia	154 (38.8%)	45 (33.3%)	199 (37.4%)
		Parenchymal atrophy (excluding age-expected atrophy)	12 (3.0%)	7 (5.2%)	19 (3.6%)
		Edema including transependymal/vasogenic	96 (24.2%)	9 (6.7%)	105 (19.7%)
		Hydrocephalus including obstructive/non-obstructive	34 (8.6%)	6 (4.4%)	40 (7.5%)
		Ventricular drain including extraventricular drain, ventriculoperitoneal shunt	17 (4.3%)	5 (3.7%)	22 (4.1%)
		Other evidence of intracranial surgery	65 (16.4%)	11 (8.1%)	76 (14.3%)
		Metallic artifact overlapping region of interest	13 (3.3%)	3 (2.2%)	16 (3.0%)
		Motion artifact overlapping region of interest	30 (7.6%)	11 (8.1%)	41 (7.7%)
		Any finding	273 (68.8%)	63 (46.7%)	336 (63.2%)

Presence of co-existing findings or abnormalities *(cont.)*

CTB

Finding	Slice thickness range	Subgroup	Ground truth positive (N = 480)	Ground truth negative (N = 222)	Total (N = 702)
Intra-axial hemorrhage	≤1.5mm	Intracranial hemorrhage	311 (64.8%)	49 (22.1%)	360 (51.3%)
		Fracture including calvarial/ skull base/facial	40 (8.3%)	11 (5.0%)	51 (7.3%)
		Parenchymal abnormality including ischemia/mass/cyst/ encephalomalacia	127 (26.5%)	55 (24.8%)	182 (25.9%)
		Parenchymal atrophy (excluding age-expected atrophy)	103 (21.5%)	60 (27.0%)	163 (23.2%)
		Edema including transependymal/vasogenic	435 (90.6%)	22 (9.9%)	457 (65.1%)
		Hydrocephalus including obstructive/non-obstructive	82 (17.1%)	11 (5.0%)	93 (13.2%)
		Ventricular drain including extraventricular drain, ventriculoperitoneal shunt	26 (5.4%)	5 (2.3%)	31 (4.4%)
		Other evidence of intracranial surgery	71 (14.8%)	16 (7.2%)	87 (12.4%)
		Metallic artifact overlapping region of interest	39 (8.1%)	18 (8.1%)	57 (8.1%)
		Motion artifact overlapping region of interest	46 (9.6%)	14 (6.3%)	60 (8.5%)
		Any finding	475 (99.0%)	138 (62.2%)	613 (87.3%)

Presence of co-existing findings or abnormalities *(cont.)*

CTB

Finding	Slice thickness range	Subgroup	Ground truth positive (N = 587)	Ground truth negative (N = 288)	Total (N = 875)
Intra-axial hemorrhage *(cont.)*	>1.5mm & ≤5.0mm	Intracranial hemorrhage	370 (63.0%)	71 (24.7%)	441 (50.4%)
		Fracture including calvarial/ skull base/facial	47 (8.0%)	16 (5.6%)	63 (7.2%)
		Parenchymal abnormality including ischemia/mass/cyst/ encephalomalacia	153 (26.1%)	67 (23.3%)	220 (25.1%)
		Parenchymal atrophy (excluding age-expected atrophy)	134 (22.8%)	83 (28.8%)	217 (24.8%)
		Edema including transependymal/vasogenic	525 (89.4%)	24 (8.3%)	549 (62.7%)
		Hydrocephalus including obstructive/non-obstructive	96 (16.4%)	14 (4.9%)	110 (12.6%)
		Ventricular drain including extraventricular drain, ventriculoperitoneal shunt	29 (4.9%)	6 (2.1%)	35 (4.0%)
		Other evidence of intracranial surgery	74 (12.6%)	17 (5.9%)	91 (10.4%)
		Metallic artifact overlapping region of interest	41 (7.0%)	16 (5.6%)	57 (6.5%)
		Motion artifact overlapping region of interest	55 (9.4%)	14 (4.9%)	69 (7.9%)
		Any finding	578 (98.5%)	183 (63.5%)	761 (87.0%)

Presence of co-existing findings or abnormalities *(cont.)*

CTB

Finding	Slice thickness range	Subgroup	Ground truth positive (N = 73)	Ground truth negative (N = 77)	Total (N = 150)
Intraventricular hemorrhage	≤1.5mm	Intracranial hemorrhage	64 (87.7%)	11 (14.3%)	75 (50.0%)
		Fracture including calvarial/ skull base/facial	6 (8.2%)	2 (2.6%)	8 (5.3%)
		Parenchymal abnormality including ischemia/mass/cyst/ encephalomalacia	64 (87.7%)	27 (35.1%)	91 (60.7%)
		Parenchymal atrophy (excluding age-expected atrophy)	1 (1.4%)	2 (2.6%)	3 (2.0%)
		Edema including transependymal/vasogenic	57 (78.1%)	11 (14.3%)	68 (45.3%)
		Hydrocephalus including obstructive/non-obstructive	31 (42.5%)	3 (3.9%)	34 (22.7%)
		Ventricular drain including extraventricular drain, ventriculoperitoneal shunt	8 (11.0%)	2 (2.6%)	10 (6.7%)
		Other evidence of intracranial surgery	13 (17.8%)	11 (14.3%)	24 (16.0%)
		Metallic artifact overlapping region of interest	1 (1.4%)	2 (2.6%)	3 (2.0%)
		Motion artifact overlapping region of interest	4 (5.5%)	2 (2.6%)	6 (4.0%)
		Any finding	72 (98.6%)	42 (54.5%)	114 (76.0%)

Presence of co-existing findings or abnormalities *(cont.)*

CTB

Finding	Slice thickness range	Subgroup	Ground truth positive (N = 91)	Ground truth negative (N = 93)	Total (N = 184)
Intraventricular hemorrhage *(cont.)*	>1.5mm & ≤5.0mm	Intracranial hemorrhage	80 (87.9%)	15 (16.1%)	95 (51.6%)
		Fracture including calvarial/ skull base/facial	6 (6.6%)	3 (3.2%)	9 (4.9%)
		Parenchymal abnormality including ischemia/mass/cyst/ encephalomalacia	80 (87.9%)	33 (35.5%)	113 (61.4%)
		Parenchymal atrophy (excluding age-expected atrophy)	1 (1.1%)	4 (4.3%)	5 (2.7%)
		Edema including transependymal/vasogenic	71 (78.0%)	12 (12.9%)	83 (45.1%)
		Hydrocephalus including obstructive/non-obstructive	39 (42.9%)	3 (3.2%)	42 (22.8%)
		Ventricular drain including extraventricular drain, ventriculoperitoneal shunt	9 (9.9%)	2 (2.2%)	11 (6.0%)
		Other evidence of intracranial surgery	15 (16.5%)	12 (12.9%)	27 (14.7%)
		Metallic artifact overlapping region of interest	1 (1.1%)	2 (2.2%)	3 (1.6%)
		Motion artifact overlapping region of interest	4 (4.4%)	2 (2.2%)	6 (3.3%)
		Any finding	89 (97.8%)	52 (55.9%)	141 (76.6%)

Triage effectiveness

Triage turnaround time

Triage turnaround time is defined as the time taken for the device to process and package the chest X-ray or brain CT study, perform model inference, process inference results, package them as a triage payload and transmit the triage payload to the relevant customer platform.

Assessing triage effectiveness

Triage turnaround time of the device was assessed using validation datasets of cases positive for each finding eligible for prioritization, as shown in the table below.

These cases were collected from multiple data sources spanning a variety of geographical locations, patient demographics and technical characteristics.

Algorithm speed: CXR

Finding	No. of cases	Mean (sec)	Std deviation
Pleural effusion	482	24.8	±8.4
Pneumoperitoneum	53	22.6	±10.6
Pneumothorax*	621	20.57	±0.67
Tension pneumothorax*			
Vertebral compression fracture	245	30.0	±4.7

*These findings were calculated together.

Algorithm speed: CTB

Finding	No. of cases	Mean (sec)	Std deviation
Acute subarachnoid hemorrhage*	n = 277	81.6	10.8
Acute subdural/epidural hematoma*			
Intra-axial hemorrhage*			
Vertebral compression fracture*			

*These findings were calculated together.

Support and feedback

Support and feedback

Refer to the following table for support and feedback details:

Support type	Details
Professional services, technical support, product feedback and complaints	Email *support@annalise.ai* Any serious incidents related to Annalise Triage should be reported to Annalise.ai and the competent authority or regulatory authority in which the user and/or patient is established.
Product user, performance and administration guides	Check our website: *annalise.ai/guides*

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