annalise

Annalise Triage

Performance Guide

US

English (US)

Annalise Triage

OPT-PRM-105 v2

This guide is applicable to Release 3.4 which includes:

- Annalise Viewer version 3.4
- Annalise Backend version 3.4
- Annalise Integration Adapter version 3.4

Annalise Backend version **3.4**

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℞ Only

Introduction

Guide details

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

Background

Overview

A standalone performance evaluation of the device was performed on a test dataset of cases obtained within the United States (chest X-ray cases were obtained from four sites and brain CT cases were obtained from five sites).

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 for chest x-ray evaluations and a neuroradiology sub-speciality for CT brain evaluations.

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	• acute subarachnoid hemorrhage
• pneumoperitoneum	• acute subdural/epidural hematoma
• pneumothorax	• intra-axial hemorrhage
• tension pneumothorax	• intraventricular hemorrhage
• vertebral compression fracture	• mass effect
	• obstructive hydrocephalus*
	• vasogenic edema

*The device does not differentiate between acute, subacute or chronic.

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.

Note: During the obstructive hydrocephalus standalone performance evaluation which had a total test dataset of size of n=175 for slice thickness ≤1.5mm and n=191 for slice thickness >1.5mm to ≤5.0mm, a subset of cases (n=4 for slice thickness ≤1.5mm and n=6 for slice thickness >1.5mm and ≤5.0mm) were incorrectly filtered out by the device prior to clinical AI model inference.

As a result, no performance result for these cases could be obtained and the cases were excluded from the following analyses.

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 ethnicity (distribution)
- patient race (including distribution)
- equipment manufacturer
- series thickness for CTB findings
- presence of co-existing findings or abnormalities (including distribution)
- presence of specific co-existing findings or abnormalities (intra-axial hemorrhage only)
- acute subdural/epidural hematoma location
- presence of mimics for obstructive hydrocephalus

Detected accuracy as sensitivity and specificity for each sub-group is summarized in each of the following tables.

Additional information

The following additional information is helpful for interpreting results.

Finding/s	Additional information
Pleural effusion	• specificity may be reduced in the presence of scarring and/or pleural thickening • standalone performance evaluation was performed on a dataset that included supine and erect positioning • use of this device with prone positioning may result in differences in performance
Pneumoperitoneum	• standalone performance evaluation was performed on a dataset that included supine and erect positioning where most cases were of unilateral right-sided and bilateral pneumoperitoneum • use of this device with prone positioning and for unilateral left-sided pneumoperitoneum may result in differences in performance
Vertebral compression fracture	• standalone performance evaluation was performed on a dataset that included only erect positioning • use of this device with supine positioning may result in differences in performance

A. Detected accuracy as Area Under the Curve (AUC)

Overview

The AUC and distribution of ground truth positive/negative cases is outlined on the following pages.

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

Table A.CXR.1: Detected accuracy as Area Under the Curve (AUC)

Finding	Positive cases	Negative cases	AUC (95% CI)
Pleural effusion	481	505	0.980 (0.972-0.986)
Pneumoperitoneum	101	182	0.969 (0.950-0.984)
Pneumothorax	413	536	0.979 (0.970-0.986)
Tension pneumothorax	123	826	0.988 (0.981-0.993)
Vertebral compression fracture	272	317	0.954 (0.939-0.968)

Table A.CTB.1: Detected accuracy as Area Under the Curve (AUC)

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)
Mass effect	≤1.5mm	493 (78.8%)	133 (21.2%)	0.987 (0.979-0.993)
	>1.5mm & ≤5.0mm	594 (78.0%)	168 (22.0%)	0.983 (0.974-0.991)
Obstructive hydrocephalus	≤1.5mm	75 (42.9%)	100 (57.1%)	0.988 (0.972-0.998)
	>1.5mm & ≤5.0mm	84 (44.0%)	107 (56.0%)	0.987 (0.969-0.997)
Vasogenic edema	≤1.5mm	60 (35.9%)	107 (64.1%)	0.981 (0.961-0.993)
	>1.5mm & ≤5.0mm	99 (33.8%)	194 (66.2%)	0.988 (0.977-0.996)

B. Sensitivity and specificity

Overview

Sensitivity and specificity were evaluated at a range of operating points for each finding. For CTB, these were evaluated at two slice thickness ranges.

An operating point configuration is provided as part of the organization's initial installation. An organization may select a different operating point from the range of points validated during the device's standalone performance evaluation.

Different operating points may be selected for each finding for an organization 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.

Sensitivity and specificity results are shown as follows:

- CXR: at each operating point
- CTB: at each operating point and each slice thickness range

Table B.CXR.1: Sensitivity and specificity by operating point

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)

Table B.CTB.1: Sensitivity and specificity by operating point

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.)

Table B.CTB.1: Sensitivity and specificity by operating point (cont.)

Finding	Slice thickness range	Operating point	Sensitivity (95% CI)	Specificity (95% CI)
Mass effect	≤1.5mm	0.160195	97.0 (95.3,98.4)	88.7 (83.5,94.0)
		0.221484	96.6 (94.9,98.2)	89.5 (84.2,94.0)
	>1.5mm & ≤5.0mm	0.120944	96.8 (95.3,98.1)	89.3 (84.5, 93.5)
		0.160195	95.3 (93.6, 97.0)	92.9 (88.7, 96.4)
Obstructive hydrocephalus	≤1.5mm	0.149943	97.3 (93.3,100.0)	94.0 (89.0,98.0)
		0.185900	94.7 (89.3,98.7)	95.0 (90.0,99.0)
		0.281473	92.0 (85.3,97.3)	97.0 (93.0,100.0)
	>1.5mm & ≤5.0mm	0.100591	97.6 (94.0,100.0)	95.3 (90.7,99.1)
		0.149943	95.2 (90.5,98.8)	95.3 (90.7,99.1)
		0.185900	94.0 (89.3,98.8)	95.3 (90.7,99.1)
		0.281473	88.1 (81.0,94.0)	95.3 (90.7,99.1)
Vasogenic edema	≤1.5mm	0.060584	91.7 (85.0,98.3)	89.7 (83.2,95.3)
		0.094076	90.0 (81.7,96.7)	90.7 (85.0,96.3)
		0.145352	90.0 (81.7,96.7)	93.5 (88.8,97.2)
	>1.5mm & ≤5.0mm	0.060584	94.9 (89.9,99.0)	93.3 (89.7,96.4)
		0.094076	93.9 (88.9,98.0)	94.3 (90.7,97.4)
		0.145352	90.9 (84.8,96.0)	95.4 (92.3,97.9)
		0.261255	89.9 (83.8,94.9)	97.4 (94.8,99.5)

C. Subgroup analysis: Patient age

Overview

The following tables outline patient age (younger to midlife adults aged ≤65 years vs elderly adults age >65 years) by sensitivity and specificity.

Table C.CXR.1: Patient age – sensitivity and specificity

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)	93.8 (90.5,96.7)
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)

Table C.CXR.1: Patient age – sensitivity and specificity (cont.)

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)

Table C.CTB.1: Patient age – sensitivity and specificity

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)

Table C.CTB.1: Patient age – sensitivity and specificity (cont.)

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)

Table C.CTB.1: Patient age – sensitivity and specificity (cont.)

Finding	Slice thickness range	Operating point	Patient age	Sensitivity (95% CI)	Specificity (95% CI)
Mass effect	≤1.5mm	0.160195	≤65 years	97.5 (94.9,99.5)	91.7 (83.3,97.9)
			>65 years	96.6 (94.6,98.6)	87.1 (80.0,94.1)
		0.221484	≤65 years	97.5 (94.9,99.5)	91.7 (83.3,97.9)
			>65 years	95.9 (93.6,98.0)	88.2 (81.2,94.1)
	>1.5mm & ≤5.0mm	0.120944	≤65 years	97.1 (95.1,98.8)	94.1 (88.2,98.5)
			>65 years	96.6 (94.6,98.3)	86.0 (80.0,92.0)
		0.160195	≤65 years	95.5 (92.6,98.0)	97.1 (92.6,100.0)
			>65 years	95.1 (92.9,97.1)	90.0 (84.0,95.0)

Table C.CTB.1: Patient age – sensitivity and specificity (cont.)

Finding	Slice thickness range	Operating point	Patient age	Sensitivity (95% CI)	Specificity (95% CI)
Obstructive hydrocephalus	≤1.5mm	0.149943	≤65 years	95.3 (88.4,100.0)	91.8 (83.7,98.0)
			>65 years	100.0 (100.0,100.0)	96.1 (90.2,100.0)
		0.185900	≤65 years	93.0 (83.7,100.0)	91.8 (83.7,98.0)
			>65 years	96.9 (90.6,100.0)	98.0 (94.1,100.0)
		0.281473	≤65 years	93.0 (83.7,100.0)	95.9 (89.8,100.0)
			>65 years	90.6 (78.1,100.0)	98.0 (94.1,100.0)
	>1.5mm & ≤5.0mm	0.100591	≤65 years	97.8 (93.5,100.0)	92.3 (84.6,98.1)
			>65 years	97.4 (92.1,100.0)	98.2 (94.5,100.0)
		0.149943	≤65 years	95.7 (89.1,100.0)	92.3 (84.6,98.1)
			>65 years	94.7 (86.8,100.0)	98.2 (94.5,100.0)
		0.185900	≤65 years	93.5 (84.8,100.0)	92.3 (84.6,98.1)
			>65 years	94.7 (86.8,100.0)	98.2 (94.5,100.0)
		0.281473	≤65 years	91.3 (82.6,97.8)	92.3 (84.6,98.1)
			>65 years	84.2 (73.7,94.7)	98.2 (94.5,100.0)

Table C.CTB.1: Patient age – sensitivity and specificity (cont.)

Finding	Slice thickness range	Operating point	Patient age	Sensitivity (95% CI)	Specificity (95% CI)
Vasogenic edema	≤1.5mm	0.060584	≤65 years	92.0 (80.0,100.0)	84.3 (74.5,94.1)
			>65 years	91.4 (80.0,100.0)	94.6 (87.5,100.0)
		0.094076	≤65 years	88.0 (76.0,100.0)	86.3 (76.5,94.1)
			>65 years	91.4 (80.0,100.0)	94.6 (87.5,100.0)
		0.145352	≤65 years	88.0 (76.0,100.0)	90.2 (82.4,98.0)
			>65 years	91.4 (80.0,100.0)	96.4 (91.1,100.0)
	>1.5mm & ≤5.0mm	0.060584	≤65 years	95.0 (87.5,100.0)	90.8 (83.9,96.6)
			>65 years	94.9 (88.1,100.0)	95.3 (91.6,99.1)
		0.094076	≤65 years	92.5 (82.5,100.0)	93.1 (87.4,97.7)
			>65 years	94.9 (88.1,100.0)	95.3 (91.6,99.1)
		0.145352	≤65 years	90.0 (80.0,97.5)	94.3 (89.7,98.9)
			>65 years	91.5 (83.1,98.3)	96.3 (92.5,99.1)
		0.261255	≤65 years	87.5 (77.5,97.5)	96.6 (92.0,100.0)
			>65 years	91.5 (83.1,98.3)	98.1 (95.3,100.0)

D. Subgroup analysis: Patient gender

Overview

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

Table D.CXR.1: Patient gender– sensitivity and specificity

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)

Table D.CXR.1: Patient gender– sensitivity and specificity (cont.)

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)

Table D.CTB.1: Patient gender– sensitivity and specificity

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)

Table D.CTB.1: Patient gender– sensitivity and specificity (cont.)

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)

Table D.CTB.1: Patient gender– sensitivity and specificity (cont.)

Finding	Slice thickness range	Operating point	Gender	Sensitivity (95% CI)	Specificity (95% CI)
Mass effect	≤1.5mm	0.160195	Female	98.3 (96.6,99.6)	90.8 (83.1,96.9)
			Male	95.7 (93.0,98.0)	86.8 (77.9,94.1)
		0.221484	Female	97.5 (95.4,99.2)	90.8 (83.1,96.9)
			Male	95.7 (93.0,98.0)	88.2 (79.4,95.6)
	>1.5mm & ≤5.0mm	0.120944	Female	96.7 (94.5,98.5)	85.9 (78.2,93.6)
			Male	96.9 (94.7,98.8)	92.2 (86.7,96.7)
		0.160195	Female	94.5 (91.5,97.1)	89.7 (82.1,96.2)
			Male	96.0 (93.8,98.1)	95.6 (91.1,98.9)

Table D.CTB.1: Patient gender– sensitivity and specificity (cont.)

Finding	Slice thickness range	Operating point	Gender	Sensitivity (95% CI)	Specificity (95% CI)
Obstructive hydrocephalus	≤1.5mm	0.149943	Female	95.5 (88.6,100.0)	92.6 (85.2,98.1)
			Male	100.0 (100.0,100.0)	95.7 (89.1,100.0)
		0.185900	Female	90.9 (81.8,97.7)	94.4 (88.9,100.0)
			Male	100.0 (100.0,100.0)	95.7 (89.1,100.0)
		0.281473	Female	86.4 (75.0,95.5)	96.3 (90.7,100.0)
			Male	100.0 (100.0,100.0)	97.8 (93.5,100.0)
	>1.5mm & ≤5.0mm	0.100591	Female	96.0 (90.0,100.0)	94.5 (87.3,100.0)
			Male	100.0 (100.0,100.0)	96.2 (90.4,100.0)
		0.149943	Female	92.0 (84.0,98.0)	94.5 (87.3,100.0)
			Male	100.0 (100.0,100.0)	96.2 (90.4,100.0)
		0.185900	Female	90.0 (82.0,98.0)	94.5 (87.3,100.0)
			Male	100.0 (100.0,100.0)	96.2 (90.4,100.0)
		0.281473	Female	84.0 (74.0,94.0)	94.5 (87.3,100.0)
			Male	94.1 (85.3,100.0)	96.2 (90.4,100.0)

Table D.CTB.1: Patient gender– sensitivity and specificity (cont.)

Finding	Slice thickness range	Operating point	Gender	Sensitivity (95% CI)	Specificity (95% CI)
Vasogenic edema	≤1.5mm	0.060584	Female	92.9 (82.1,100.0)	89.8 (81.6,98.0)
			Male	90.6 (78.1,100.0)	89.7 (81.0,96.6)
		0.094076	Female	92.9 (82.1,100.0)	89.8 (81.6,98.0)
			Male	87.5 (75.0,96.9)	91.4 (84.5,98.3)
		0.145352	Female	92.9 (82.1,100.0)	93.9 (85.7,100.0)
			Male	87.5 (75.0,96.9)	93.1 (86.2,98.3)
	>1.5mm & ≤5.0mm	0.060584	Female	97.8 (93.3,100.0)	94.0 (89.0,98.0)
			Male	92.6 (85.2,98.1)	92.6 (87.2,97.9)
		0.094076	Female	97.8 (93.3,100.0)	95.0 (90.0,99.0)
			Male	90.7 (83.3,98.1)	93.6 (88.3,97.9)
		0.145352	Female	95.6 (88.9,100.0)	95.0 (90.0,99.0)
			Male	87.0 (77.8,96.3)	95.7 (91.5,98.9)
		0.261255	Female	95.6 (88.9,100.0)	97.0 (93.0,100.0)
			Male	85.2 (75.9,94.4)	97.9 (94.7,100.0)

E. Subgroup analysis: Patient race and ethnicity

Overview

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

Table E.CTB.1: Patient race – sensitivity and specificity

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)
	>1.5mm & ≤5.0mm	0.060162	White or Caucasian	81.9 (75.8,87.2)	97.5 (93.8,100.0)
			Other	90.9 (77.3,100.0)	100.0 (100.0,100.0)
			Unknown	90.9 (72.7,100.0)	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)
	>1.5mm & ≤5.0mm	0.060177	White or Caucasian	81.9 (77.9,86.0)	88.2 (81.4,94.1)
			Other	81.7 (71.7,90.0)	93.1 (82.8,100.0)
			Unknown	93.8 (81.2,100.0)	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)
	>1.5mm & ≤5.0mm	0.322700	White or Caucasian	89.8 (87.2,92.5)	91.1 (86.8,94.5)
			Other	91.2 (85.0,96.5)	92.7 (85.4,100.0)
			Unknown	95.5 (86.4,100.0)	66.7 (41.7,91.7)

Table E.CTB.1: Patient race – sensitivity and specificity (cont.)

Finding	Slice thickness range	Operating point	Race	Sensitivity (95% CI)	Specificity (95% CI)
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)
	>1.5mm & ≤5.0mm	0.015487	White or Caucasian	93.1 (86.1,98.6)	89.9 (83.5,96.2)
			Other	86.7 (66.7,100.0)	83.3 (58.3,100.0)
			Unknown	100.0 (100.0,100.0)	100.0 (100.0,100.0)

Table E.CTB.1: Patient race – sensitivity and specificity (cont.)

Finding	Slice thickness range	Operating point	Race	Sensitivity (95% CI)	Specificity (95% CI)
Mass effect	≤1.5mm	0.160195	White or Caucasian	96.7 (94.9,98.5)	87.5 (80.8,93.3)
			Other	97.5 (93.8,100.0)	95.8 (87.5,100.0)
			Unknown	100.0 (100.0,100.0)	80.0 (40.0,100.0)
	>1.5mm & ≤5.0mm	0.160195	White or Caucasian	94.8 (92.8,96.7)	92.1 (87.1,95.7)
			Other	97.8 (94.6,100.0)	100.0 (100.0,100.0)
			Unknown	94.4 (83.3,100.0)	80.0 (40.0,100.0)
Obstructive hydrocephalus	≤1.5mm	0.149943	White or Caucasian	96.5 (91.2,100.0)	94.8 (89.6,98.7)
			Other	100.0 (100.0,100.0)	94.1 (82.4,100.0)
			Unknown	100.0 (100.0,100.0)	83.3 (50.0,100.0)
	>1.5mm & ≤5.0mm	0.149943	White or Caucasian	93.8 (87.7,98.5)	96.3 (91.5,100.0)
			Other	100.0 (100.0,100.0)	94.7 (84.2,100.0)
			Unknown	100.0 (100.0,100.0)	83.3 (50.0,100.0)
Vasogenic edema	≤1.5mm	0.094076	White or Caucasian	93.5 (84.8,100.0)	89.0 (81.7,95.1)
			Other	75.0 (50.0,100.0)	94.7 (84.2,100.0)
			Unknown	100.0 (100.0,100.0)	100.0 (100.0,100.0)
	>1.5mm & ≤5.0mm	0.094076	White or Caucasian	96.2 (92.4,100.0)	93.5 (89.0,97.4)
			Other	82.4 (58.8,100.0)	96.9 (90.6,100.0)
			Unknown	100.0 (100.0,100.0)	100.0 (100.0,100.0)

Table E.CTB.2: Patient race – distribution

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%)

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%)

Table E.CTB.2: Patient race – distribution (cont.)

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%)

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%)

Table E.CTB.2: Patient race – distribution (cont.)

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%)

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%)

Table E.CTB.2: Patient race – distribution (cont.)

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%)

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%)

Table E.CTB.2: Patient race – distribution (cont.)

Finding	Slice thickness range	Race	**Total** (N=626)	**Hispanic ethnicity** (N=50)
Mass effect	≤1.5mm	American Indian or Alaska Native	0 (0.0%)	0 (0.0%)
		Asian	22 (3.5%)	0 (0.0%)
		Black or African America	46 (7.3%)	4 (8.0%)
		Native Hawaiian or Other Pacific Islander	0 (0.0%)	0 (0.0%)
		White or Caucasian	498 (79.6%)	19 (38.0%)
		Other	32 (5.1%)	24 (48.0%)
		2 or more races	5 (0.8%)	2 (4.0%)
		Declined	3 (0.5%)	0 (0.0%)
		Unavailable	20 (3.2%)	1 (2.0%)

Finding	Slice thickness range	Race	**Total** (N=762)	**Hispanic ethnicity** (N=51)
Mass effect	>1.5mm & ≤5.0mm	American Indian or Alaska Native	0 (0.0%)	0 (0.0%)
		Asian	29 (3.8%)	0 (0.0%)
		Black or African America	46 (6.0%)	4 (7.8%)
		Native Hawaiian or Other Pacific Islander	0 (0.0%)	0 (0.0%)
		White or Caucasian	623 (81.8%)	19 (37.3%)
		Other	34 (4.5%)	25 (49.0%)
		2 or more races	7 (0.9%)	2 (3.9%)
		Declined	3 (0.4%)	0 (0.0%)
		Unavailable	20 (2.6%)	1 (2.0%)

Table E.CTB.2: Patient race – distribution (cont.)

Finding	Slice thickness range	Race	**Total** (N=175)	**Hispanic ethnicity** (N=17)
Obstructive hydrocephalus	≤1.5mm	American Indian or Alaska Native	0 (0.0%)	0 (0.0%)
		Asian	6 (3.4%)	0 (0.0%)
		Black or African America	12 (6.9%)	0 (0.0%)
		Native Hawaiian or Other Pacific Islander	1 (0.6%)	0 (0.0%)
		White or Caucasian	134 (76.6%)	5 (29.4%)
		Other	11 (6.3%)	9 (52.9%)
		2 or more races	2 (1.1%)	2 (11.8%)
		Declined	2 (1.1%)	0 (0.0%)
		Unavailable	7 (4.0%)	1 (5.9%)

Finding	Slice thickness range	Race	**Total** (N=191)	**Hispanic ethnicity** (N=17)
Obstructive hydrocephalus	>1.5mm & ≤5.0mm	American Indian or Alaska Native	0 (0.0%)	0 (0.0%)
		Asian	7 (3.7%)	0 (0.0%)
		Black or African America	14 (7.3%)	0 (0.0%)
		Native Hawaiian or Other Pacific Islander	1 (0.5%)	0 (0.0%)
		White or Caucasian	147 (77.0%)	5 (29.4%)
		Other	11 (5.8%)	9 (52.9%)
		2 or more races	2 (1.0%)	2 (11.8%)
		Declined	2 (1.0%)	0 (0.0%)
		Unavailable	7 (3.7%)	1 (5.9%)

Table E.CTB.2: Patient race – distribution (cont.)

Finding	Slice thickness range	Race	**Total** (N=167)	**Hispanic ethnicity** (N=10)
Vasogenic edema	≤1.5mm	American Indian or Alaska Native	0 (0.0%)	0 (0.0%)
		Asian	11 (6.6%)	0 (0.0%)
		Black or African America	10 (6.0%)	0 (0.0%)
		Native Hawaiian or Other Pacific Islander	0 (0.0%)	0 (0.0%)
		White or Caucasian	128 (76.6%)	2 (20.0%)
		Other	9 (5.4%)	7 (70.0%)
		2 or more races	1 (0.6%)	0 (0.0%)
		Declined	1 (0.6%)	0 (0.0%)
		Unavailable	7 (4.2%)	1 (10.0%)

Finding	Slice thickness range	Race	**Total** (N=293)	**Hispanic ethnicity** (N=20)
Vasogenic edema	>1.5mm & ≤5.0mm	American Indian or Alaska Native	0 (0.0%)	0 (0.0%)
		Asian	14 (4.8%)	0 (0.0%)
		Black or African America	18 (6.1%)	1 (5.0%)
		Native Hawaiian or Other Pacific Islander	0 (0.0%)	0 (0.0%)
		White or Caucasian	234 (79.9%)	6 (30.0%)
		Other	13 (4.4%)	10 (50.0%)
		2 or more races	4 (1.4%)	1 (5.0%)
		Declined	1 (0.3%)	0 (0.0%)
		Unavailable	9 (3.1%)	2 (10.0%)

Table E.CTB.3: Patient ethnicity – distribution

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%)

Table E.CTB.3: Patient ethnicity – distribution (cont.)

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%)

Table E.CTB.3: Patient ethnicity – distribution (cont.)

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%)

Table E.CTB.3: Patient ethnicity – distribution (cont.)

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%)

Table E.CTB.3: Patient ethnicity – distribution (cont.)

Finding	Slice thickness range	Subgroup	**Total** (N=626)
Mass effect	≤1.5mm	Hispanic	50 (8.0%)
		Not Hispanic	533 (85.1%)
		Prefer not to say/Decline	3 (0.5%)
		Unavailable	40 (6.4%)

Finding	Slice thickness range	Subgroup	**Total** (N=762)
Mass effect	>1.5mm & ≤5.0mm	Hispanic	51 (6.7%)
		Not Hispanic	669 (87.8%)
		Prefer not to say/Decline	4 (0.5%)
		Unavailable	38 (5.0%)

Table E.CTB.3: Patient ethnicity – distribution (cont.)

Finding	Slice thickness range	Subgroup	**Total** (N=175)
Obstructive hydrocephalus	≤1.5mm	Hispanic	17 (9.7%)
		Not Hispanic	142 (81.1%)
		Prefer not to say/Decline	0 (0.0%)
		Unavailable	16 (9.1%)

Finding	Slice thickness range	Subgroup	**Total** (N=191)
Obstructive hydrocephalus	>1.5mm & ≤5.0mm	Hispanic	17 (8.9%)
		Not Hispanic	157 (82.2%)
		Prefer not to say/Decline	0 (0.0%)
		Unavailable	17 (8.9%)

Table E.CTB.3: Patient ethnicity – distribution (cont.)

Finding	Slice thickness range	Subgroup	**Total** (N=167)
Vasogenic edema	≤1.5mm	Hispanic	10 (6.0%)
		Not Hispanic	151 (90.4%)
		Prefer not to say/Decline	0 (0.0%)
		Unavailable	6 (3.6%)

Finding	Slice thickness range	Subgroup	**Total** (N=293)
Vasogenic edema	>1.5mm & ≤5.0mm	Hispanic	20 (6.8%)
		Not Hispanic	264 (90.1%)
		Prefer not to say/Decline	1 (0.3%)
		Unavailable	8 (2.7%)

F. Subgroup analysis: Equipment manufacturer

Overview

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

Additional information

The following additional information relates to the findings listed below:

Finding/s	Additional information
Mass effect and vasogenic edema	• 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
Acute subarachnoid hemorrhage, acute subdural/epidural hematoma, intra-axial hemorrhage and intraventricular hemorrhage	• 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 • Additional analysis was conducted with GE, Philips, Siemens and Toshiba CT scanners on a dataset ≤ 1.5mm slice thickness sourced from Australia.
Obstructive hydrocephalus	• Standalone performance evaluation of the device was performed on datasets with the majority of subgroup representation of studies acquired using GE Healthcare and Siemens CT scanners. • Use of this device with other CT scanner manufacturers may result in differences in performance • Additional analysis was conducted with GE, Philips, Siemens and Toshiba CT scanners on a dataset ≤ 1.5mm slice thickness sourced from Australia.

Table F.CXR.1: Equipment manufacturer– sensitivity and specificity

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)
		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)
		Varian	100.0 (100.0,100.0)	76.9 (53.8,100.0)
		Multiple	94.1 (85.3,100.0)	78.3 (60.9,95.7)
		Unknown	100.0 (100.0,100.0)	100.0 (100.0,100.0)

Table F.CXR.1: Equipment manufacturer– sensitivity and specificity (cont.)

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)
		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)
		Varian	92.3 (76.9,100.0)	76.9 (53.8,100.0)
		Multiple	94.1 (85.3,100.0)	82.6 (65.2,95.7)
		Unknown	91.7 (75.0,100.0)	100.0 (100.0,100.0)

Table F.CXR.1: Equipment manufacturer– sensitivity and specificity (cont.)

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)
		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)
		Varian	84.6 (61.5,100.0)	84.6 (61.5,100.0)
		Multiple	82.4 (67.6,94.1)	95.7 (87.0,100.0)
		Unknown	75.0 (50.0,100.0)	100.0 (100.0,100.0)

Table F.CXR.1: Equipment manufacturer– sensitivity and specificity (cont.)

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)
		Konica Minolta	92.3 (76.9,100.0)	93.3 (80.0,100.0)
		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)
		Varian	-	100.0 (100.0,100.0)
		Multiple	100.0 (100.0,100.0)	100.0 (100.0,100.0)
	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)
		Konica Minolta	92.3 (76.9,100.0)	93.3 (80.0,100.0)
		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)
		Varian	-	100.0 (100.0,100.0)
		Multiple	100.0 (100.0,100.0)	100.0 (100.0,100.0)

Table F.CXR.1: Equipment manufacturer– sensitivity and specificity (cont.)

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)
		Konica Minolta	84.6 (61.5,100.0)	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)
		Varian	-	100.0 (100.0,100.0)
		Multiple	100.0 (100.0,100.0)	100.0 (100.0,100.0)

Table F.CXR.1: Equipment manufacturer– sensitivity and specificity (cont.)

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)
		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)
		Varian	86.5 (75.7,97.3)	95.3 (88.4,100.0)
		Multiple	96.7 (90.0,100.0)	87.5 (74.9,100.0)
		Unknown	89.5 (73.7,100.0)	80.0 (60.0,95.0)
	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)
		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)
		Varian	75.7 (62.2,89.2)	95.3 (88.4,100.0)
		Multiple	93.3 (83.3,100.0)	87.5 (74.9,100.0)
		Unknown	89.5 (73.7,100.0)	85.0 (70.0,100.0)

Table F.CXR.1: Equipment manufacturer– sensitivity and specificity (cont.)

Finding	Manufacturer	AUC (95% CI)
Pneumothorax	Agfa	0.973 (0.956, 0.986)
	Carestream	0.988 (0.961, 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)
	Varian	0.990 (0.956, 1.000)
	Unknown	1.000 (1.0, 1.000)
Tension pneumothorax	Agfa	0.983 (0.969, 0.992)
	Carestream	1.000 (0.975, 1.000)
	Fujifilm	0.991 (0.968, 1.000)
	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)
	Varian	0.970 (0.890, 1.000)

Table F.CTB.1: Equipment manufacturer– sensitivity and specificity

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)
			Siemens	96.8 (92.5,100.0)	86.0 (76.0,94.0)
		0.060162	GE Healthcare	94.4 (87.0,100.0)	94.1 (85.3,100.0)
			NeuroLogica	-	100.0 (100.0,100.0)
			Siemens	93.5 (88.2,97.8)	98.0 (94.0,100.0)
		0.082652	GE Healthcare	90.7 (81.5,98.1)	100.0 (100.0,100.0)
			NeuroLogica	-	100.0 (100.0,100.0)
			Siemens	89.2 (82.8,95.7)	100.0 (100.0,100.0)
	>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)
			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)
			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)

Table F.CTB.1: Equipment manufacturer– sensitivity and specificity (cont.)

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)
	>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)

Table F.CTB.1: Equipment manufacturer– sensitivity and specificity (cont.)

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)

Table F.CTB.1: Equipment manufacturer– sensitivity and specificity (cont.)

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)
			Siemens	95.8 (89.6,100.0)	90.4 (82.7,98.1)
		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)
			Siemens	91.7 (83.3,97.9)	98.1 (94.2,100.0)
	>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)
			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)
			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)
			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)

Table F.CTB.1: Equipment manufacturer– sensitivity and specificity (cont.)

Finding	Slice thickness range	Operating point	Manufacturer	Sensitivity (95% CI)	Specificity (95% CI)
Mass effect	≤1.5mm	0.160195	GE Healthcare	97.1 (94.3,99.4)	83.7 (72.1,93.0)
			NeuroLogica	100.0 (100.0,100.0)	-
			Philips	83.3 (50.0,100.0)	-
			Siemens	97.4 (95.4,99.0)	91.1 (84.4,96.7)
			Toshiba	75.0 (0.0,100.0)	-
		0.221484	GE Healthcare	96.0 (93.1,98.3)	86.0 (74.4,95.3)
			NeuroLogica	100.0 (100.0,100.0)	-
			Philips	83.3 (50.0,100.0)	-
			Siemens	97.4 (95.4,99.0)	91.1 (84.4,96.7)
			Toshiba	75.0 (0.0,100.0)	-
	>1.5mm & ≤5.0mm	0.120944	GE Healthcare	96.6 (93.7,98.9)	82.5 (70.0,92.5)
			NeuroLogica	100.0 (100.0,100.0)	-
			Philips	83.3 (42.9,100.0)	-
			Siemens	97.2 (95.1,99.0)	92.0 (85.1,96.6)
			Toshiba	96.7 (93.4,99.2)	90.2 (80.5,97.6)
		0.160195	GE Healthcare	94.9 (91.4,97.7)	90.0 (80.0,97.5)
			NeuroLogica	100.0 (100.0,100.0)	-
			Philips	83.3 (42.9,100.0)	-
			Siemens	95.5 (93.1,97.6)	94.3 (88.5,98.9)
			Toshiba	95.9 (91.8,99.2)	92.7 (85.3,100.0)

Table F.CTB.1: Equipment manufacturer– sensitivity and specificity (cont.)

Finding	Slice thickness range	Operating point	Manufacturer	Sensitivity (95% CI)	Specificity (95% CI)
Obstructive hydrocephalus	≤1.5mm	0.149943	GE Healthcare	100.0 (100.0,100.0)	84.2 (68.4,100.0)
			Siemens	96.9 (92.3,100.0)	96.2 (91.0,100.0)
		0.185900	GE Healthcare	100.0 (100.0,100.0)	84.2 (68.4,100.0)
			Siemens	93.8 (87.7,98.5)	97.4 (93.6,100.0)
		0.281473	GE Healthcare	100.0 (100.0,100.0)	94.7 (84.2,100.0)
			Siemens	90.8 (83.1,96.9)	97.4 (93.6,100.0)
	>1.5mm & ≤5.0mm	0.100591	GE Healthcare	100.0 (100.0,100.0)	87.5 (75.0,100.0)
			Siemens	96.9 (92.3,100.0)	97.5 (93.7,100.0)
		0.149943	GE Healthcare	100.0 (100.0,100.0)	87.5 (75.0,100.0)
			Siemens	95.4 (89.2,100.0)	97.5 (93.7,100.0)
		0.185900	GE Healthcare	100.0 (100.0,100.0)	87.5 (75.0,100.0)
			Siemens	93.8 (87.7,98.5)	97.5 (93.7,100.0)
		0.281473	GE Healthcare	93.3 (80.0,100.0)	87.5 (75.0,100.0)
			Siemens	87.7 (80.0,95.4)	97.5 (93.7,100.0)

Table F.CTB.1: Equipment manufacturer– sensitivity and specificity (cont.)

Finding	Slice thickness range	Operating point	Manufacturer	Sensitivity (95% CI)	Specificity (95% CI)
Vasogenic edema	≤1.5mm	0.060584	GE Healthcare	71.4 (42.9,100.0)	91.7 (75.0,100.0)
			NeuroLogica	100.0 (100.0,100.0)	50.0 (0.0,100.0)
			Siemens	94.2 (86.5,100.0)	91.2 (84.6,96.7)
		0.094076	GE Healthcare	71.4 (42.9,100.0)	91.7 (75.0,100.0)
			NeuroLogica	100.0 (100.0,100.0)	75.0 (25.0,100.0)
			Siemens	92.3 (84.6,98.1)	91.2 (84.6,96.7)
		0.145352	GE Healthcare	71.4 (42.9,100.0)	91.7 (75.0,100.0)
			NeuroLogica	100.0 (100.0,100.0)	100.0 (100.0,100.0)
			Siemens	92.3 (84.6,98.1)	93.4 (87.9,97.8)

Table F.CTB.1: Equipment manufacturer– sensitivity and specificity (cont.)

Finding	Slice thickness range	Operating point	Manufacturer	Sensitivity (95% CI)	Specificity (95% CI)
Vasogenic edema *(cont.)*	>1.5mm & ≤5.0mm	0.060584	GE Healthcare	89.3 (78.6,100.0)	98.0 (94.1,100.0)
			NeuroLogica	100.0 (100.0,100.0)	60.0 (20.0,100.0)
			Siemens	96.2 (90.6,100.0)	90.5 (84.2,95.8)
			Toshiba	100.0 (100.0,100.0)	97.7 (93.0,100.0)
		0.094076	GE Healthcare	89.3 (78.6,100.0)	98.0 (94.1,100.0)
			NeuroLogica	100.0 (100.0,100.0)	80.0 (40.0,100.0)
			Siemens	94.3 (86.8,100.0)	91.6 (85.3,96.8)
			Toshiba	100.0 (100.0,100.0)	97.7 (93.0,100.0)
		0.145352	GE Healthcare	89.3 (78.6,100.0)	98.0 (94.1,100.0)
			NeuroLogica	100.0 (100.0,100.0)	80.0 (40.0,100.0)
			Siemens	90.6 (81.1,98.1)	92.6 (87.4,97.9)
			Toshiba	94.1 (82.4,100.0)	100.0 (100.0,100.0)
		0.261255	GE Healthcare	85.7 (71.4,96.4)	100.0 (100.0,100.0)
			NeuroLogica	100.0 (100.0,100.0)	80.0 (40.0,100.0)
			Siemens	90.6 (81.1,98.1)	95.8 (91.6,98.9)
			Toshiba	94.1 (82.4,100.0)	100.0 (100.0,100.0)

Table F.CTB.2: Equipment manufacturer– Outside US (OUS) data analysis

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)

Table F.CTB.2: Equipment manufacturer– Outside US (OUS) data analysis (cont.)

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	100.0 (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	100.0 (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)	92.0 (89.9, 94.0)
			Philips	96.2 (87.0, 100.0)	94.1 (91.6, 96.3)
			Siemens	89.6 (80.0, 97.7)	89.0 (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)

Table F.CTB.2: Equipment manufacturer– Outside US (OUS) data analysis (cont.)

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	93.0 (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	77.0 (69.4, 84.1)	97.1 (96.1, 98.0)

Table F.CTB.2: Equipment manufacturer– Outside US (OUS) data analysis (cont.)

Finding	Slice thickness range	Operating point	Manufacturer	Sensitivity (95% CI)	Specificity (95% CI)
Intraventricular hemorrhage	≤1.5mm	0.00843	GE Healthcare	100.0 (100.0, 100.0)	78.3 (75.2, 81.3)
			Philips	94.0 (80.0, 100.0)	84.1 (80.4, 87.7)
			Siemens	100.0 (100.0, 100.0)	71.6 (67.1, 76.1)
			Toshiba	100.0 (100.0, 100.0)	83.1 (81.0, 85.2)
		0.015487	GE Healthcare	100.0 (100.0, 100.0)	86.8 (84.3, 89.3)
			Philips	88.2 (69.6, 100.0)	89.6 (86.5, 92.6)
			Siemens	100.0 (100.0, 100.0)	83.2 (79.4, 86.9)
			Toshiba	100.0 (100.0, 100.0)	88.0 (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	100.0 (100.0, 100.0)	93.6 (91.0, 95.9)
			Toshiba	100.0 (100.0, 100.0)	95.0 (93.8, 96.2)

Table F.CTB.2: Equipment manufacturer– Outside US (OUS) data analysis (cont.)

Finding	Slice thickness range	Operating point	Manufacturer	Sensitivity (95% CI)	Specificity (95% CI)
Obstructive hydrocephalus	≤1.5mm	0.100591	GE Healthcare	97.0 (90.0 100.0)	90.3 (88.1, 92.4)
			Philips	88.4 (71.4, 100.0)	92.9 (90.3, 95.3)
			Siemens	100.0 (100.0, 100.0)	89.7 (86.5, 92.6)
			Toshiba	88.4 (75.0, 100.0)	91.7 (90.1, 93.2)
		0.149943	GE Healthcare	97.0 (90.0, 100.0)	94.0 (92.3, 95.8)
			Philips	82.6 (61.9, 100.0)	94.2 (91.8, 96.4)
			Siemens	87.4 (68.7, 100.0)	92.5 (89.8, 95.0)
			Toshiba	88.4 (75.0,100.0)	93.7 (92.4,95.0)
		0.185900	GE Healthcare	97.0 (90.0, 100.0)	95.2 (93.6, 96.7)
			Philips	82.6 (61.9, 100.0)	95.2 (93.0, 97.2)
			Siemens	87.4 (68.7, 100.0)	93.3 (90.7, 95.7)
			Toshiba	80.7 (64.0, 95.2)	95.0 (93.7, 96.1)
		0.281473	GE Healthcare	97.0 (90.0, 100.0)	97.2 (96.0, 98.4)
			Philips	70.8 (47.1, 92.3)	97.5 (95.8, 98.9)
			Siemens	74.8 (50.0, 94.4)	95.4 (93.2, 97.4)
			Toshiba	76.8 (59.3, 92.3)	96.7 (95.7, 97.7)

G. Subgroup analysis: Series slice thickness for CTB findings

Overview

The following table outlines the sensitivity and specificity for each CTB finding by operating point and >1.5mm to ≤5mm slice thickness range.

Table G.CTB.1: Series thickness for slice thickness range >1.5mm to ≤5mm

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)

Table G.CTB.1: Series thickness for slice thickness range >1.5mm to ≤5mm (cont.)

Finding	Operating point	Slice thickness range	Sensitivity (95% CI)	Specificity (95% CI)
Mass effect	0.120944	>1.5 to ≤3.5 mm series	98.5 (96.4,100.0)	88.4 (79.1,97.7)
		>3.5 to ≤5 mm series	96.0 (94.0,98.0)	89.6 (84.0,94.4)
	0.160195	>1.5 to ≤3.5 mm series	97.9 (95.9,100.0)	90.7 (81.4,97.7)
		>3.5 to ≤5 mm series	94.0 (91.5,96.2)	93.6 (88.8,97.6)
Obstructive hydrocephalus	0.100591	>1.5 to ≤3.5 mm series	97.9 (93.8,100.0)	96.0 (90.0,100.0)
		>3.5 to ≤5 mm series	97.2 (91.7,100.0)	94.7 (89.4,100.0)
	0.149943	>1.5 to ≤3.5 mm series	95.8 (89.6,100.0)	96.0 (90.0,100.0)
		>3.5 to ≤5 mm series	94.4 (86.1,100.0)	94.7 (89.4,100.0)
	0.185900	>1.5 to ≤3.5 mm series	93.8 (85.4,100.0)	96.0 (90.0,100.0)
		>3.5 to ≤5 mm series	94.4 (86.1,100.0)	94.7 (89.4,100.0)
	0.281473	>1.5 to ≤3.5 mm series	85.4 (75.0,93.8)	96.0 (90.0,100.0)
		>3.5 to ≤5 mm series	91.7 (80.6,100.0)	94.7 (89.4,100.0)
Vasogenic edema	0.060584	>1.5 to ≤3.5 mm series	95.0 (87.5,100.0)	90.9 (84.4,96.1)
		>3.5 to ≤5 mm series	94.9 (89.8,100.0)	94.9 (90.6,98.3)
	0.094076	>1.5 to ≤3.5 mm series	95.0 (87.5,100.0)	92.2 (85.7,97.4)
		>3.5 to ≤5 mm series	93.2 (86.4,98.3)	95.7 (91.5,99.1)
	0.145352	>1.5 to ≤3.5 mm series	95.0 (87.5,100.0)	93.5 (88.3,98.7)
		>3.5 to ≤5 mm series	88.1 (79.7,94.9)	96.6 (93.2,99.1)
	0.261255	>1.5 to ≤3.5 mm series	95.0 (87.5,100.0)	97.4 (93.5,100.0)
		>3.5 to ≤5 mm series	86.4 (77.9,94.9)	97.4 (94.0,100.0)

H. Subgroup analysis: Presence of co-existing findings or abnormalities

Overview

The following tables outline:

- the sensitivity and specificity for each finding by operating point and the presence of co-existing findings or abnormalities
- the presence of co-existing findings or abnormalities by slice thickness range for each finding*
- the sensitivity and specificity by operating point and the presence of co-existing findings or abnormalities for intra-axial hemorrhage

*Note: 'Any finding' means that one or more of the co-existing findings or abnormalities listed in the table is present.

Table H.CTB.1: Presence of co-existing findings or abnormalities – sensitivity and specificity

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)

Table H.CTB.1: Presence of co-existing findings or abnormalities – sensitivity and specificity (cont.)

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)

Table H.CTB.1: Presence of co-existing findings or abnormalities – sensitivity and specificity (cont.)

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)

Table H.CTB.1: Presence of co-existing findings or abnormalities – sensitivity and specificity (cont.)

Finding	Slice thickness range	Operating point	Co-finding	Sensitivity (95% CI)	Specificity (95% CI)
Mass effect	≤1.5mm	0.160195	Any finding	97.3 (95.8,98.5)	75.0 (62.5,85.7)
			No additional findings	88.2 (70.6,100.0)	98.7 (96.1,100.0)
		0.221484	Any finding	97.1 (95.4,98.5)	76.8 (66.1,87.5)
			No additional findings	82.4 (64.7,100.0)	98.7 (96.1,100.0)
	>1.5mm & ≤5.0mm	0.120944	Any finding	97.2 (95.8,98.4)	76.8 (66.7,85.5)
			No additional findings	86.4 (68.2,100.0)	98.0 (94.9,100.0)
		0.160195	Any finding	95.8 (94.1,97.4)	82.6 (73.9,91.3)
			No additional findings	81.8 (63.6,95.5)	100.0 (100.0,100.0)

Table H.CTB.1: Presence of co-existing findings or abnormalities – sensitivity and specificity (cont.)

Finding	Slice thickness range	Operating point	Co-finding	Sensitivity (95% CI)	Specificity (95% CI)
Obstructive hydrocephalus	≤1.5mm	0.149943	Any finding	97.3 (93.3,100.0)	89.7 (81.0,96.6)
			No additional findings	-	100.0 (100.0,100.0)
		0.185900	Any finding	94.7 (89.3,98.7)	91.4 (82.8,98.3)
			No additional findings	-	100.0 (100.0,100.0)
		0.281473	Any finding	92.0 (85.3,97.3)	94.8 (87.9,100.0)
			No additional findings	-	100.0 (100.0,100.0)
	>1.5mm & ≤5.0mm	0.100591	Any finding	97.6 (94.0,100.0)	91.7 (85.0,98.3)
			No additional findings	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		0.149943	Any finding	95.2 (90.4,98.8)	91.7 (85.0,98.3)
			No additional findings	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		0.185900	Any finding	94.0 (88.0,98.8)	91.7 (85.0,98.3)
			No additional findings	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		0.281473	Any finding	88.0 (80.7,94.0)	91.7 (85.0,98.3)
			No additional findings	100.0 (100.0,100.0)	100.0 (100.0,100.0)

Table H.CTB.1: Presence of co-existing findings or abnormalities – sensitivity and specificity (cont.)

Finding	Slice thickness range	Operating point	Co-finding	Sensitivity (95% CI)	Specificity (95% CI)
Vasogenic edema	≤1.5mm	0.060584	Any finding	91.5 (84.7,98.3)	80.0 (68.0,90.0)
			No additional findings	100.0 (100.0,100.0)	98.2 (94.7,100.0)
		0.094076	Any finding	89.8 (81.4,96.6)	82.0 (72.0,92.0)
			No additional findings	100.0 (100.0,100.0)	98.2 (94.7,100.0)
		0.145352	Any finding	89.8 (81.4,96.6)	86.0 (76.0,94.0)
			No additional findings	100.0 (100.0,100.0)	100.0 (100.0,100.0)
	>1.5mm & ≤5.0mm	0.060584	Any finding	94.8 (89.7,99.0)	80.6 (70.1,89.6)
			No additional findings	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		0.094076	Any finding	93.8 (88.7,97.9)	83.6 (74.6,92.5)
			No additional findings	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		0.145352	Any finding	90.7 (84.5,95.9)	86.6 (77.6,94.0)
			No additional findings	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		0.261255	Any finding	89.7 (83.5,94.8)	92.5 (85.1,98.5)
			No additional findings	100.0 (100.0,100.0)	100.0 (100.0,100.0)

Table H.CTB.2: Presence of co-existing findings or abnormalities – distribution

Finding	Slice thickness range	Subgroup	Ground truth positive (N = 147)	Ground truth negative (N = 85)	Total (N = 232)
Acute subarachnoid hemorrhage	≤1.5mm	Other 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%)

Table H.CTB.2: Presence of co-existing findings or abnormalities – distribution (cont.)

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	Other 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%)

Table H.CTB.2: Presence of co-existing findings or abnormalities – distribution (cont.)

Finding	Slice thickness range	Subgroup	Ground truth positive (N = 303)	Ground truth negative (N = 98)	Total (N = 401)
Acute subdural/epidural hematoma	≤1.5mm	Other 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%)

Table H.CTB.2: Presence of co-existing findings or abnormalities – distribution (cont.)

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	Other 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%)

Table H.CTB.2: Presence of co-existing findings or abnormalities – distribution (cont.)

Finding	Slice thickness range	Subgroup	Ground truth positive (N = 480)	Ground truth negative (N = 222)	Total (N = 702)
Intra-axial hemorrhage	≤1.5mm	Other 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%)

Table H.CTB.2: Presence of co-existing findings or abnormalities – distribution (cont.)

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	Other 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%)

Table H.CTB.2: Presence of co-existing findings or abnormalities – distribution (cont.)

Finding	Slice thickness range	Subgroup	Ground truth positive (N = 73)	Ground truth negative (N = 77)	Total (N = 150)
Intraventricular hemorrhage	≤1.5mm	Other 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%)

Table H.CTB.2: Presence of co-existing findings or abnormalities – distribution (cont.)

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	Other 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%)

Table H.CTB.2: Presence of co-existing findings or abnormalities – distribution (cont.)

Finding	Slice thickness range	Subgroup	Ground truth positive (N = 493)	Ground truth negative (N = 133)	Total (N = 626)
Mass effect	≤1.5mm	Intracranial hemorrhage	320 (64.9%)	6 (4.5%)	326 (52.1%)
		Fracture including calvarial/ skull base/facial	10 (2.0%)	1 (0.8%)	11 (1.8%)
		Parenchymal abnormality including ischemia/mass/cyst/ encephalomalacia	317 (64.3%	32 (24.1%)	349 (55.8%)
		Parenchymal atrophy (excluding age-expected atrophy)	8 (1.6%	4 (3.0%)	12 (1.9%)
		Edema including transependymal/vasogenic	318 (64.5%)	5 (3.8%)	323 (51.6%)
		Hydrocephalus including obstructive/non-obstructive	79 (16.0%)	5 (3.8%)	84 (13.4%)
		Ventricular drain including extraventricular drain, ventriculoperitoneal shunt	18 (3.7%)	1 (0.8%)	19 (3.0%)
		Other evidence of intracranial surgery	92 (18.7%)	3 (2.3%)	95 (15.2%)
		Metallic artifact overlapping region of interest	28 (5.7%)	7 (5.3%)	35 (5.6%)
		Motion artifact overlapping region of interest	45 (9.1%)	5 (3.8%)	50 (8.0%)
		Any finding	476 (96.6%)	56 (42.1%)	532 (85.0%)

Table H.CTB.2: Presence of co-existing findings or abnormalities – distribution (cont.)

Finding	Slice thickness range	Subgroup	Ground truth positive (N = 594)	Ground truth negative (N = 168)	Total (N = 762)
Mass effect *(cont.)*	>1.5mm & ≤5.0mm	Intracranial hemorrhage	366 (61.6%)	10 (6.0%)	376 (49.3%)
		Fracture including calvarial/ skull base/facial	12 (2.0%)	1 (0.6%)	13 (1.7%)
		Parenchymal abnormality including ischemia/mass/cyst/ encephalomalacia	389 (65.5%)	39 (23.2%)	428 (56.2%)
		Parenchymal atrophy (excluding age-expected atrophy)	8 (1.3%)	5 (3.0%)	13 (1.7%)
		Edema including transependymal/vasogenic	391 (65.8%)	8 (4.8%)	399 (52.4%)
		Hydrocephalus including obstructive/non-obstructive	96 (16.2%)	8 (4.8%)	104 (13.6%)
		Ventricular drain including extraventricular drain, ventriculoperitoneal shunt	21 (3.5%)	2 (1.2%)	23 (3.0%)
		Other evidence of intracranial surgery	110 (18.5%)	4 (2.4%)	114 (15.0%)
		Metallic artifact overlapping region of interest	26 (4.4%)	8 (4.8%)	34 (4.5%
		Motion artifact overlapping region of interest	46 (7.7%)	8 (4.8%)	54 (7.1%)
		Any finding	572 (96.3%)	69 (41.1%)	641 (84.1%)

Table H.CTB.2: Presence of co-existing findings or abnormalities – distribution (cont.)

Finding	Slice thickness range	Subgroup	Ground truth positive (N = 75)	Ground truth negative (N = 100)	Total (N = 175)
Obstructive hydrocephalus	≤1.5mm	Intracranial hemorrhage	51 (68.0%)	32 (32.0%)	83 (47.4%)
		Fracture including calvarial/ skull base/facial	0 (0.0%)	2 (2.0%)	2 (1.1%)
		Parenchymal abnormality including ischemia/mass/cyst/ encephalomalacia	70 (93.3%	40 (40.0%)	110 (62.9%)
		Parenchymal atrophy (excluding age-expected atrophy)	0 (0.0%)	2 (2.0%)	2 (1.1%)
		Edema including transependymal/vasogenic	71 (94.7%)	22 (22.0%)	93 (53.1%)
		Non-obstructive hydrocephalus	0 (0.0%)	5 (5.0%)	5 (2.9%)
		Ventricular drain including extraventricular drain, ventriculoperitoneal shunt	13 (17.3%)	4 (4.0%)	17 (9.7%)
		Other evidence of intracranial surgery	23 (30.7%)	12 (12.0%)	35 (20.0%)
		Metallic artifact overlapping region of interest	2 (2.7%)	3 (3.0%)	5 (2.9%)
		Motion artifact overlapping region of interest	2 (2.7%)	2 (2.0%)	4 (2.3%)
		Any finding	75 (100.0%)	58 (58.0%)	133 (76.0%)

Table H.CTB.2: Presence of co-existing findings or abnormalities – distribution (cont.)

Finding	Slice thickness range	Subgroup	Ground truth positive (N = 84)	Ground truth negative (N = 107)	Total (N = 191)
Obstructive hydrocephalus *(cont.)*	>1.5mm & ≤5.0mm	Intracranial hemorrhage	58 (69.0%)	33 (30.8%)	91 (47.6%)
		Fracture including calvarial/ skull base/facial	0 (0.0%)	2 (1.9%)	2 (1.0%)
		Parenchymal abnormality including ischemia/mass/cyst/ encephalomalacia	78 (92.9%)	40 (37.4%)	118 (61.8%)
		Parenchymal atrophy (excluding age-expected atrophy)	0 (0.0%)	2 (1.9%)	2 (1.0%)
		Edema including transependymal/vasogenic	79 (94.0%)	21 (19.6%)	100 (52.4%)
		Non-obstructive hydrocephalus	0 (0.0%)	5 (4.7%)	5 (2.6%)
		Ventricular drain including extraventricular drain, ventriculoperitoneal shunt	14 (16.7%)	4 (3.7%)	18 (9.4%)
		Other evidence of intracranial surgery	23 (27.4%)	11 (10.3%)	34 (17.8%)
		Metallic artifact overlapping region of interest	2 (2.4%)	3 (2.8%)	5 (2.6%)
		Motion artifact overlapping region of interest	4 (4.8%)	3 (2.8%)	7 (3.7%)
		Any finding	83 (98.8%)	60 (56.1%)	143 (74.9%)

Table H.CTB.2: Presence of co-existing findings or abnormalities – distribution (cont.)

Finding	Slice thickness range	Subgroup	Ground truth positive (N = 60)	Ground truth negative (N = 107)	Total (N = 167)
Vasogenic edema	≤1.5mm	Intracranial hemorrhage	43 (71.7%)	10 (9.3%)	53 (31.7%)
		Fracture including calvarial/ skull base/facial	1 (1.7%)	1 (0.9%)	2 (1.2%)
		Parenchymal abnormality including ischemia/mass/cyst/ encephalomalacia	56 (93.3%)	27 (25.2%)	83 (49.7%)
		Parenchymal atrophy (excluding age-expected atrophy)	0 (0.0%)	3 (2.8%)	3 (1.8%)
		Edema including transependymal	5 (8.3%)	8 (7.5%)	13 (7.8%)
		Hydrocephalus including obstructive/non-obstructive	13 (21.7%)	9 (8.4%)	22 (13.2%)
		Ventricular drain including extraventricular drain, ventriculoperitoneal shunt	7 (11.7%)	4 (3.7%)	11 (6.6%)
		Other evidence of intracranial surgery	18 (30.0%)	5 (4.7%)	23 (13.8%)
		Metallic artifact overlapping region of interest	2 (3.3%)	0 (0.0%)	2 (1.2%)
		Motion artifact overlapping region of interest	6 (10.0%)	8 (7.5%)	14 (8.4%)
		Any finding	59 (98.3%)	50 (46.7%)	109 (65.3%)

Table H.CTB.2: Presence of co-existing findings or abnormalities – distribution (cont.)

Finding	Slice thickness range	Subgroup	Ground truth positive (N = 99)	Ground truth negative (N = 194)	Total (N = 293)
Vasogenic edema *(cont.)*	>1.5mm & ≤5.0mm	Intracranial hemorrhage	59 (59.6%)	14 (7.2%)	73 (24.9%)
		Fracture including calvarial/ skull base/facial	1 (1.0%)	2 (1.0%)	3 (1.0%)
		Parenchymal abnormality including ischemia/mass/cyst/ encephalomalacia	93 (93.9%)	36 (18.6%)	129 (44.0%)
		Parenchymal atrophy (excluding age-expected atrophy)	0 (0.0%)	4 (2.1%)	4 (1.4%)
		Edema including transependymal	8 (8.1%)	11 (5.7%)	19 (6.5%)
		Hydrocephalus including obstructive/non-obstructive	23 (23.2%)	12 (6.2%)	35 (11.9%)
		Ventricular drain including extraventricular drain, ventriculoperitoneal shunt	7 (7.1%)	5 (2.6%)	12 (4.1%)
		Other evidence of intracranial surgery	21 (21.2%)	6 (3.1%)	27 (9.2%)
		Metallic artifact overlapping region of interest	2 (2.0%)	0 (0.0%)	2 (0.7%)
		Motion artifact overlapping region of interest	6 (6.1%)	11 (5.7%)	17 (5.8%)
		Any finding	97 (98.0%)	67 (34.5%)	164 (56.0%)

Table H.CTB.3: Presence of specific co-existing findings or abnormalities for intra-axial hemorrhage

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	Other 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.

Table H.CTB.3: Presence of specific co-existing findings or abnormalities for intra-axial hemorrhage (cont.)

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)

Table H.CTB.3: Presence of specific co-existing findings or abnormalities for intra-axial hemorrhage (cont.)

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	Other 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.

Table H.CTB.3: Presence of specific co-existing findings or abnormalities for intra-axial hemorrhage (cont.)

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)

Table H.CTB.3: Presence of specific co-existing findings or abnormalities for intra-axial hemorrhage (cont.)

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	Other 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.

Table H.CTB.3: Presence of specific co-existing findings or abnormalities for intra-axial hemorrhage (cont.)

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)

I. Subgroup analysis: Other

Overview

Other subgroup analysis was performed including:

- the sensitivity for each finding by operating point and acute subdural/epidural hematoma subgroup location
- the sensitivity and specificity by operating point for the presence of mimics for obstructive hydrocephalus*

*Note: Parenchymal atrophy (excluding age-expected atrophy), non-obstructive hydrocephalus, age ≥75 years and ≥80 years may mimic the appearance of obstructive hydrocephalus due to enlargement of ventricles.

Table I.CTB.1: Acute subdural/epidural hematoma location

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)

Table I.CTB.2: Presence of mimics for obstructive hydrocephalus- sensitivity and specificity

Finding	Slice thickness range	Operating point	Mimic subgroup	Absent/ present	n	Sensitivity (95% CI)	Specificity (95% CI)
Obstructive hydrocephalus	≤1.5mm	0.149943	Parenchymal atrophy (excluding age-expected atrophy)	Absent	173	97.3 (93.3,100.0)	93.9 (88.8,98.0)
				Present	2	-	100.0 (100.0,100.0)
			Non-obstructive hydrocephalus	Absent	170	97.3 (93.3,100.0)	94.7 (89.5,98.9)
				Present	5	-	80.0 (40.0,100.0)
			Age ≥ 75 years	Absent	129	96.6 (91.4,100.0)	93.0 (87.3,98.6)
				Present	46	100.0 (100.0,100.0)	96.6 (89.7,100.0)
			Age ≥ 80 years	Absent	150	96.9 (92.3,100.0)	92.9 (87.1,97.6)
				Present	25	100.0 (100.0,100.0)	100.0 (100.0,100.0)
			Any mimic	Absent	146	96.6 (91.4,100.0)	94.0 (88.1,98.5)
				Present	29	100.0 (100.0,100.0)	93.9 (84.8,100.0)

Table I.CTB.2: Presence of mimics for obstructive hydrocephalus- sensitivity and specificity (cont.)

Finding	Slice thickness range	Operating point	Mimic subgroup	Absent/ present	n	Sensitivity (95% CI)	Specificity (95% CI)
Obstructive hydrocephalus *(cont.)*	≤1.5mm *(cont.)*	0.185900	Parenchymal atrophy (excluding age-expected atrophy)	Absent	173	94.7 (89.3,98.7)	94.9 (90.8,99.0)
				Present	2	-	100.0 (100.0,100.0)
			Non-obstructive hydrocephalus	Absent	170	94.7 (89.3,98.7)	95.8 (91.6,98.9)
				Present	5	-	80.0 (40.0,100.0)
			Age ≥ 75 years	Absent	129	93.1 (86.2,98.3)	94.4 (88.7,98.6)
				Present	46	100.0 (100.0,100.0)	96.6 (89.7,100.0)
			Age ≥ 80 years	Absent	150	93.8 (87.7,98.5)	94.1 (89.4,98.8)
				Present	25	100.0 (100.0,100.0)	100.0 (100.0,100.0)
			Any mimic	Absent	146	93.1 (86.2,98.3)	95.5 (89.6,100.0)
				Present	29	100.0 (100.0,100.0)	93.9 (84.8,100.0)

Table I.CTB.2: Presence of mimics for obstructive hydrocephalus- sensitivity and specificity (cont.)

Finding	Slice thickness range	Operating point	Mimic subgroup	Absent/ present	n	Sensitivity (95% CI)	Specificity (95% CI)
Obstructive hydrocephalus *(cont.)*	≤1.5mm *(cont.)*	0.281473	Parenchymal atrophy (excluding age-expected atrophy)	Absent	173	92.0 (85.3,97.3)	96.9 (93.9,100.0)
				Present	2	-	100.0 (100.0,100.0)
			Non-obstructive hydrocephalus	Absent	170	92.0 (85.3,97.3)	97.9 (94.7,100.0)
				Present	5	-	80.0 (40.0,100.0)
			Age ≥ 75 years	Absent	129	91.4 (84.5,98.3)	97.2 (93.0,100.0)
				Present	46	94.1 (82.4,100.0	96.6 (89.7,100.0)
			Age ≥ 80 years	Absent	150	90.8 (83.1,96.9)	96.5 (91.8,100.0)
				Present	25	100.0 (100.0,100.0)	100.0 (100.0,100.0)
			Any mimic	Absent	146	91.4 (82.8,98.3)	98.5 (95.5,100.0)
				Present	29	94.1 (82.4,100.0)	93.9 (84.8,100.0)

Table I.CTB.2: Presence of mimics for obstructive hydrocephalus- sensitivity and specificity (cont.)

Finding	Slice thickness range	Operating point	Mimic subgroup	Absent/ present	n	Sensitivity (95% CI)	Specificity (95% CI)
Obstructive hydrocephalus *(cont.)*	>1.5mm & ≤5.0mm	0.100591	Parenchymal atrophy (excluding age-expected atrophy)	Absent	189	97.6 (94.0,100.0)	95.2 (90.5,99.0)
				Present	2	-	100.0 (100.0,100.0)
			Non-obstructive hydrocephalus	Absent	186	97.6 (94.0,100.0)	96.1 (92.2,99.0)
				Present	5	-	80.0 (33.3,100.0)
			Age ≥ 75 years	Absent	140	96.9 (92.2,100.0)	94.7 (89.5,98.7)
				Present	51	100.0 (100.0,100.0)	96.8 (90.3,100.0)
			Age ≥ 80 years	Absent	163	97.2 (93.1,100.0)	94.5 (89.0,98.9)
				Present	28	100.0 (100.0,100.0)	100.0 (100.0,100.0)
			Any mimic	Absent	136	96.9 (92.2,100.0)	95.8 (90.3,100.0)
				Present	55	100.0 (100.0,100.0)	94.3 (85.7,100.0)

Table I.CTB.2: Presence of mimics for obstructive hydrocephalus- sensitivity and specificity (cont.)

Finding	Slice thickness range	Operating point	Mimic subgroup	Absent/ present	n	Sensitivity (95% CI)	Specificity (95% CI)
Obstructive hydrocephalus *(cont.)*	>1.5mm & ≤5.0mm *(cont.)*	0.149943	Parenchymal atrophy (excluding age-expected atrophy)	Absent	189	95.2 (90.5,98.8)	95.2 (90.5,99.0)
				Present	2	-	100.0 (100.0,100.0)
			Non-obstructive hydrocephalus	Absent	186	95.2 (90.5,98.8)	96.1 (92.2,99.0)
				Present	5	-	80.0 (33.3,100.0)
			Age ≥ 75 years	Absent	140	93.8 (87.5,98.4)	94.7 (89.5,98.7)
				Present	51	100.0 (100.0,100.0)	96.8 (90.3,100.0)
			Age ≥ 80 years	Absent	163	94.4 (88.9,98.6)	94.5 (89.0,98.9)
				Present	28	100.0 (100.0,100.0)	100.0 (100.0,100.0)
			Any mimic	Absent	136	93.8 (87.5,98.4)	95.8 (90.3,100.0)
				Present	55	100.0 (100.0,100.0)	94.3 (85.7,100.0)

Table I.CTB.2: Presence of mimics for obstructive hydrocephalus- sensitivity and specificity (cont.)

Finding	Slice thickness range	Operating point	Mimic subgroup	Absent/ present	n	Sensitivity (95% CI)	Specificity (95% CI)
Obstructive hydrocephalus *(cont.)*	>1.5mm & ≤5.0mm *(cont.)*	0.185900	Parenchymal atrophy (excluding age-expected atrophy)	Absent	189	94.0 (88.1,98.8)	95.2 (90.5,99.0)
				Present	2	-	100.0 (100.0,100.0)
			Non-obstructive hydrocephalus	Absent	186	94.0 (88.1,98.8)	96.1 (92.2,99.0)
				Present	5	-	80.0 (33.3,100.0)
			Age ≥ 75 years	Absent	140	92.2 (84.4,98.4)	94.7 (89.5,98.7)
				Present	51	100.0 (100.0,100.0)	96.8 (90.3,100.0)
			Age ≥ 80 years	Absent	163	93.1 (87.5,98.6)	94.5 (89.0,98.9)
				Present	28	100.0 (100.0,100.0)	100.0 (100.0,100.0)
			Any mimic	Absent	136	92.2 (84.4,98.4)	95.8 (90.3,100.0)
				Present	55	100.0 (100.0,100.0)	94.3 (85.7,100.0)

Table I.CTB.2: Presence of mimics for obstructive hydrocephalus- sensitivity and specificity (cont.)

Finding	Slice thickness range	Operating point	Mimic subgroup	Absent/ present	n	Sensitivity (95% CI)	Specificity (95% CI)
Obstructive hydrocephalus *(cont.)*	>1.5mm & ≤5.0mm *(cont.)*	0.281473	Parenchymal atrophy (excluding age-expected atrophy)	Absent	189	88.1 (81.0,94.1)	95.2 (90.5,99.0)
				Present	2	-	100.0 (100.0,100.0)
			Non-obstructive hydrocephalus	Absent	186	88.1 (81.0,94.1)	96.1 (92.2,99.0)
				Present	5	-	80.0 (33.3,100.0)
			Age ≥ 75 years	Absent	140	89.1 (81.2,95.3)	94.7 (89.5,98.7)
				Present	51	85.0 (70.0,100.0)	96.8 (90.3,100.0)
			Age ≥ 80 years	Absent	163	87.5 (79.2,94.4)	94.5 (89.0,98.9)
				Present	28	91.7 (75.0,100.0)	100.0 (100.0,100.0)
			Any mimic	Absent	136	89.1 (81.2,95.3)	95.8 (90.3,100.0)
				Present	55	85.0 (70.0,100.0)	94.3 (85.7,100.0)

Triage effectiveness performance

J. Triage effectiveness

Overview

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.

Table J.CXR.1: Algorithm speed

	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.

Table J.CTB.1: Algorithm speed

	No. of cases	Mean (sec)	Std deviation
Acute subarachnoid hemorrhage*****	n = 277	81.6	10.8
Acute subdural/epidural hematoma*****			
Intra-axial hemorrhage*****			
Intra-ventricular hemorrhage*			
Mass effect*****			
Obstructive hydrocephalus*****			
Vasogenic edema*****			

*****These findings were calculated together.

Support

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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