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Annalise Enterprise

Performance Guide

US

English (US)

Annalise Enterprise

Product version: **3.2**

Date of issue: **2023-05**

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℞ Only

Overview

Overview

This document outlines the performance of the Annalise Enterprise 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 Enterprise User Guide*.

Symbol glossary

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

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

Standalone performance evaluation

Overview

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

Ground truth interpretations

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

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

- pneumothorax
- tension pneumothorax
- pleural effusion
- pneumoperitoneum
- vertebral compression fracture

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

The results of this standalone performance evaluation are summarised in the following pages.

Detected accuracy as Area Under the Curve (AUC)

AUC was evaluated at a range of operating points at two slice thickness ranges for this finding.

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

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

Sensitivity and specificity

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

A default operating point configuration is provided as part of the organisation's initial installation. An organisation 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 organisation 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.

Results for sensitivity and specificity at each operating point are shown in each of the following tables.

Subgroup analysis

The test dataset included a range of patient demographics and imaging equipment manufacturers. Subgroup analysis was performed for patient gender, patient age, and equipment manufacturer.

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

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)

Patient age

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

Patient age (cont.)

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

Patient gender

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

Patient gender (cont.)

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)

Manufacturer

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

continued

Manufacturer (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)
		Multiple	94.1 (85.3,100.0)	82.6 (65.2,95.7)
		Philips	98.3 (94.8,100.0)	82.8 (72.4,91.4)
		Siemens	92.3 (80.8,100.0)	92.3 (84.6,98.1)
		Unknown	91.7 (75.0,100.0)	100.0 (100.0,100.0)
		Varian	92.3 (76.9,100.0)	76.9 (53.8,100.0)

continued

Manufacturer (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)
		Multiple	82.4 (67.6,94.1)	95.7 (87.0,100.0)
		Philips	98.3 (94.8,100.0)	89.7 (81.0,96.6)
		Siemens	88.5 (73.1,100.0)	96.2 (90.4,100.0)
		Unknown	75.0 (50.0,100.0)	100.0 (100.0,100.0)
		Varian	84.6 (61.5,100.0)	84.6 (61.5,100.0)

continued

Manufacturer (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
		GE Healthcare	-	-
		Kodak	-	-
		Konica Minolta	92.3 (76.9,100.0)	93.3 (80.0,100.0)
		McKesson	-	-
		Multiple	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		Philips	100.0 (100.0,100.0)	83.3 (58.3,100.0)
		Siemens	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		Unknown	-	-
		Varian	-	100.0 (100.0,100.0)

continued

Manufacturer (cont.)

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

continued

Manufacturer (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)
		GE Healthcare	-	-
		Kodak	-	-
		Konica Minolta	84.6 (61.5,100.0)	100.0 (100.0,100.0)
		McKesson	-	-
		Multiple	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		Philips	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		Siemens	100.0 (100.0,100.0)	100.0 (100.0,100.0)
		Unknown	-	-
		Varian	-	100.0 (100.0,100.0)

continued

Manufacturer (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)
		Konica Minolta	-	-
		McKesson	-	-
		Multiple	96.7 (90.0,100.0)	87.5 (74.9,100.0)
		Philips	97.3 (91.9,100.0)	91.5 (83.0,97.9)
		Siemens	88.0 (76.0,100.0)	92.3 (82.1,100.0)
		Unknown	89.5 (73.7,100.0)	80.0 (60.0,95.0)
Vertebral compression fracture	0.4834	Agfa	66.7 (47.6,85.7)	93.1 (82.8,100.0)
		Carestream	100.0 (100.0,100.0)	95.0 (85.0,100.0)
		Fujifilm	82.6 (73.9,91.3)	86.3 (78.1,93.2)
		GE Healthcare	75.0 (25.0,100.0)	100.0 (100.0,100.0)
		Kodak	89.5 (73.7,100.0)	88.9 (72.2,100.0)
		Konica Minolta	-	-
		McKesson	-	-
		Multiple	93.3 (83.3,100.0)	87.5 (74.9,100.0)
		Philips	94.6 (86.5,100.0)	93.6 (85.1,100.0)
		Siemens	88.0 (76.0,100.0)	92.3 (82.1,100.0)
		Unknown	89.5 (73.7,100.0)	85.0 (70.0,100.0)

Manufacturer (cont.)

Finding	Manufacturer	AUC (95% CI)
Pneumothorax	Agfa	0.973 (0.956, 0.986)
	Carestream	0.988 (0.96, 1.000)
	Fujifilm	0.998 (0.992, 1.000)
	GE Healthcare	1.000 (1.000, 1.000)
	Kodak	0.881 (0.607, 1.000)
	Konica Minolta	0.973 (0.943, 0.993)
	McKesson	1.000 (1.000, 1.000)
	Philips	0.987 (0.967, 0.999)
	Siemens	1.000 (1.000, 1.000)
	Unknown	1.000 (1.0, 1.000)
	Varian	0.990 (0.956, 1.000)
Tension pneumothorax	Agfa	0.983 (0.969, 0.992)
	Carestream	1.000 (0.975, 1.000)
	Fujifilm	0.991 (0.968, 1.000)
	GE Healthcare	-
	Kodak	-
	Konica Minolta	0.998 (0.990, 1.000)
	McKesson	0.997 (0.969, 1.000)
	Philips	1.000 (0.987, 1.000)
	Siemens	1.000 (1.000, 1.000)
	Unknown	-
	Varian	0.970 (0.890, 1.000)

Triage effectiveness

Triage turnaround time

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

Assessing triage effectiveness

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

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

Algorithm speed

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

*These findings were calculated together.

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 Enterprise 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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OPT-PRM-105 Ver.0