annalise

Annalise CXR Edge

Performance Guide

English

Annalise CXR Edge

Fujifilm

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MD

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Import License Number: IMP/MD/2023/000218

Contents

1. Performance

This document provides product performance information pertaining to Annalise CXR Edge. For general user information please refer to the User Guide which can be found at Annalise.ai/guides.

The following table includes all supported findings for Annalise CXR Edge, presented in alphabetical order. Each row shows the finding name and the Area Under Curve (AUC).AUC indicates the probability by which the algorithm can correctly identify a finding.

These performance results are based on the data set that Annalise.ai has used to evaluate the product. Information about this dataset can be found in Section 3. Differences in demographics, imaging equipment or other variables may result in changes in performance.

2. AUC by Findings

Finding Name	AUC
Abdominal clips	0.9163
Acute clavicle fracture	0.9381
Acute humerus fracture	0.9672
Acute rib fracture	0.9399
Airway stent	0.9274
Aortic arch calcification	0.9698
Aortic stent	0.966
Atelectasis	0.871
Axillary clips	0.9929
Biliary stent	0.9774
Breast implant	0.9836
Bronchiectasis	0.9114
Calcified axillary nodes	0.9549
Calcified granuloma (< 5mm)	0.9179
Calcified hilar lymphadenopathy	0.8412
Calcified mass (> 5mm)	0.9379
Calcified neck nodes	0.9196
Calcified pleural plaques	0.9735
Cardiac valve prosthesis	0.9843
Cervical flexion	0.9883
Chest incompletely imaged	0.9546
Chronic clavicle fracture	0.9442
Chronic rib fracture	0.9277
Chronic humerus fracture	0.9849
Clavicle fixation	0.9905
Clavicle lesion	0.9585
Coronary stent	0.8582
Diaphragmatic elevation	0.9243
Diaphragmatic eventration	0.9778
Diffuse airspace opacity	0.9189
Diffuse nodular / miliary lesions	0.976
Diffuse pleural thickening	0.9584
Distended bowel	0.973
Effusions	0.9552
Electronic cardiac devices	0.9992
Emphysema	0.9498
Focal airspace opacity	0.8474
Gallstones	0.7985
Gastric band	0.9417
Hilar lymphadenopathy	0.9242

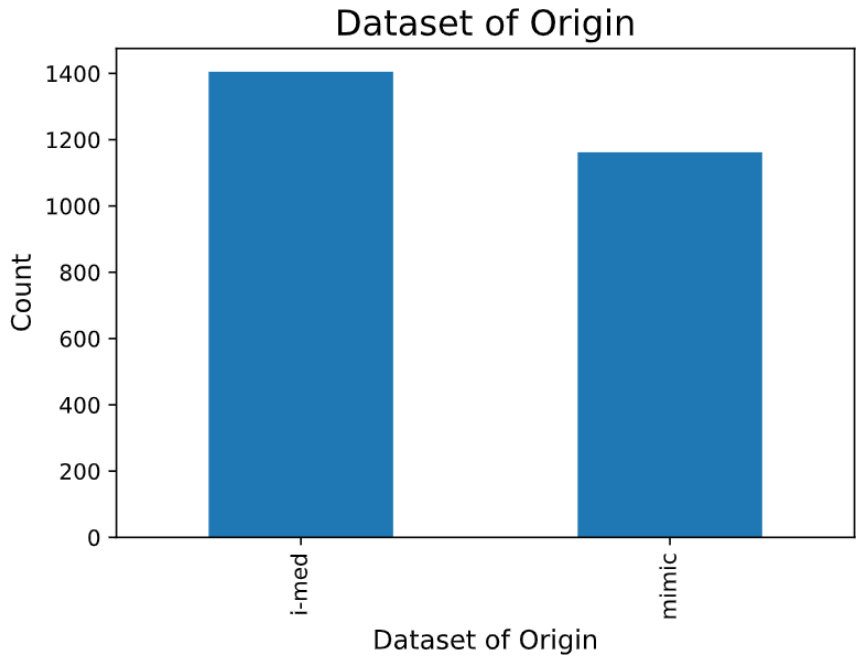
Humeral lesion	0.9686
Hyperinflation	0.9596
Image obscured	0.899
In position Central Line (CVC)	0.9942
In position Endotracheal tube (ETT)	0.9982
In position Nasogastric tube (NGT)	0.9981
In position pulmonary arterial catheter (PAC)	0.9983
Intercostal drain	0.9935
Internal foreign body	0.9304
Interstitial Thickening	0.9177
Lung collapse	0.9962
Lung sutures	0.949
Mastectomy	0.9498
Mediastinal clips	0.9835
Mediastinal Mass	0.9234
Neck clips	0.974
Nipple shadow	0.9388
Oesophageal stent	0.972
Overexposed	0.8319
Patient rotation	0.8987
Peribronchial cuffing	0.8175
Pericardial fat pad	0.9152
Pleural mass	0.9442
Pneumomediastinum	0.96
Pneumothorax	0.9915
Post resection volume loss	0.9748
Pulmonary artery enlargement	0.9174
Rib fixation	0.9871
Rib lesion	0.9624
Rib resection	0.9719
Rotator cuff anchor	0.9996
Scapular fracture	0.9169
Scapular lesion	0.9425
Scoliosis	0.94
Segmental collapse	0.9001
Shoulder arthritis	0.9806
Shoulder dislocation	0.9558
Shoulder fixation	0.9997
Shoulder replacement	1
Soft Tissue Lung Nodule	0.9098
Spinal fixation	0.9844
Sternotomy wires	0.9997
Subcutaneous emphysema	0.9909

Subdiaphragmatic gas	0.9711
Suboptimal central line (CVC)	0.9678
Suboptimal endotracheal tube (ETT)	0.9925
Suboptimal gastric band	0.986
Suboptimal Nasogastric tube (NGT)	0.9818
Suboptimal pulmonary arterial catheter (PAC)	0.9929
Tracheal deviation	0.9374
Underexposed	0.9236
Underinflation	0.9678
Unfolded aorta	0.8897
Widened aortic contour	0.9709
Widened cardiac silhouette	0.9453

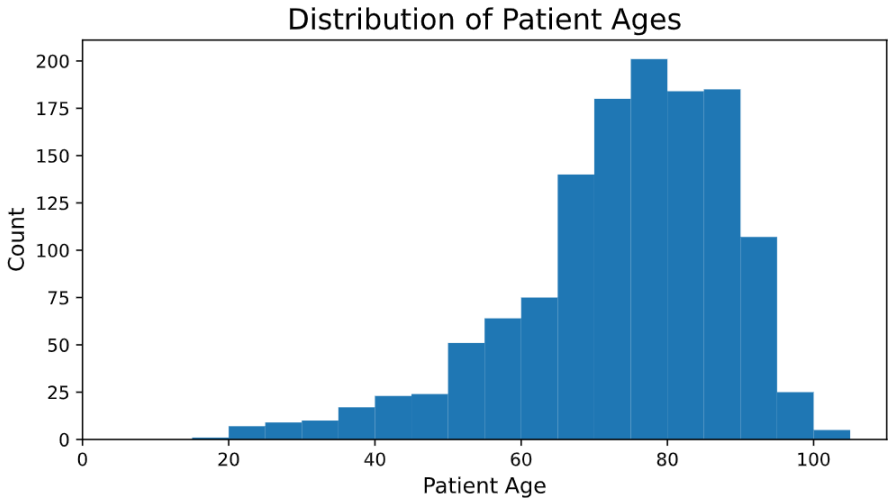
3. Model Validation Dataset Characteristics

The Annalise CXR Edge product is validated on over 2,500 studies acquired from clinics across Australia and the United States of America.

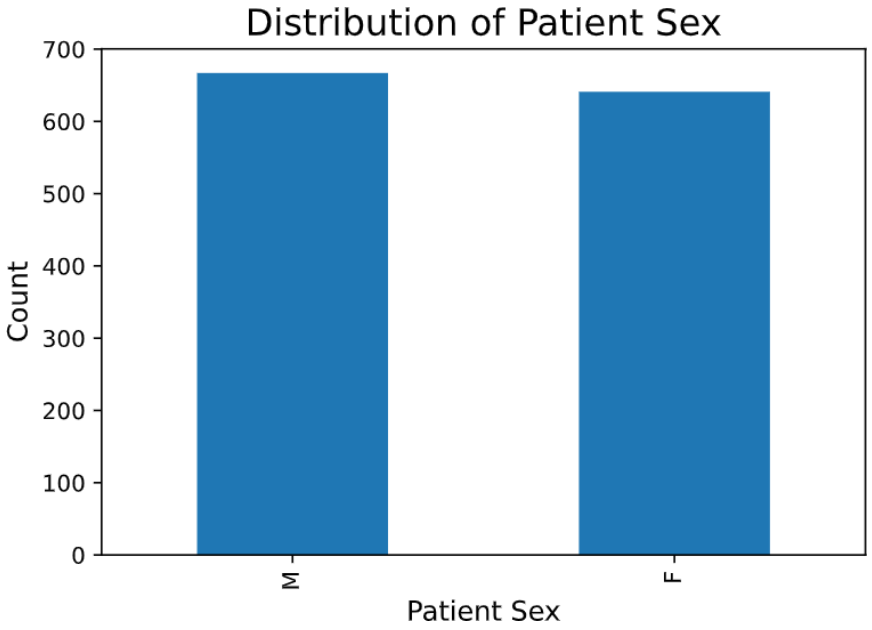
3.1 Dataset of Origin



3.2 Patient Age

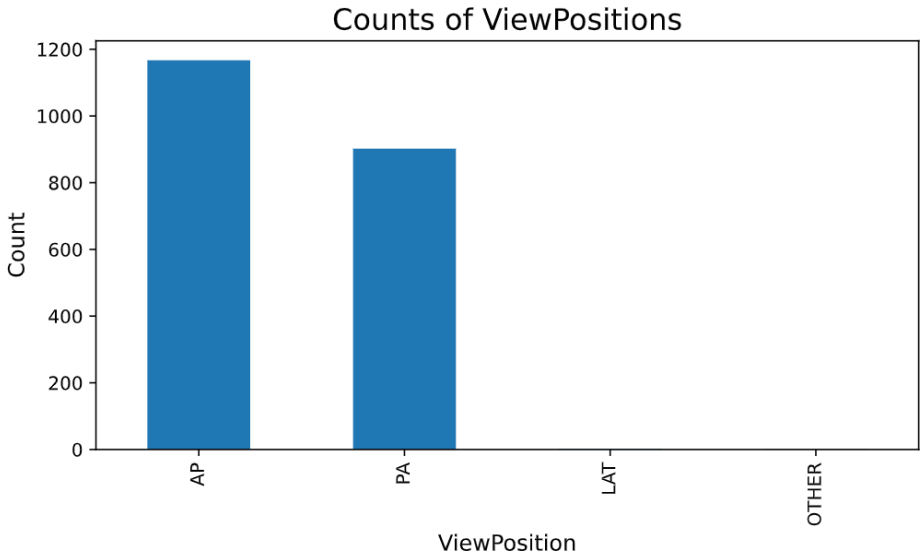


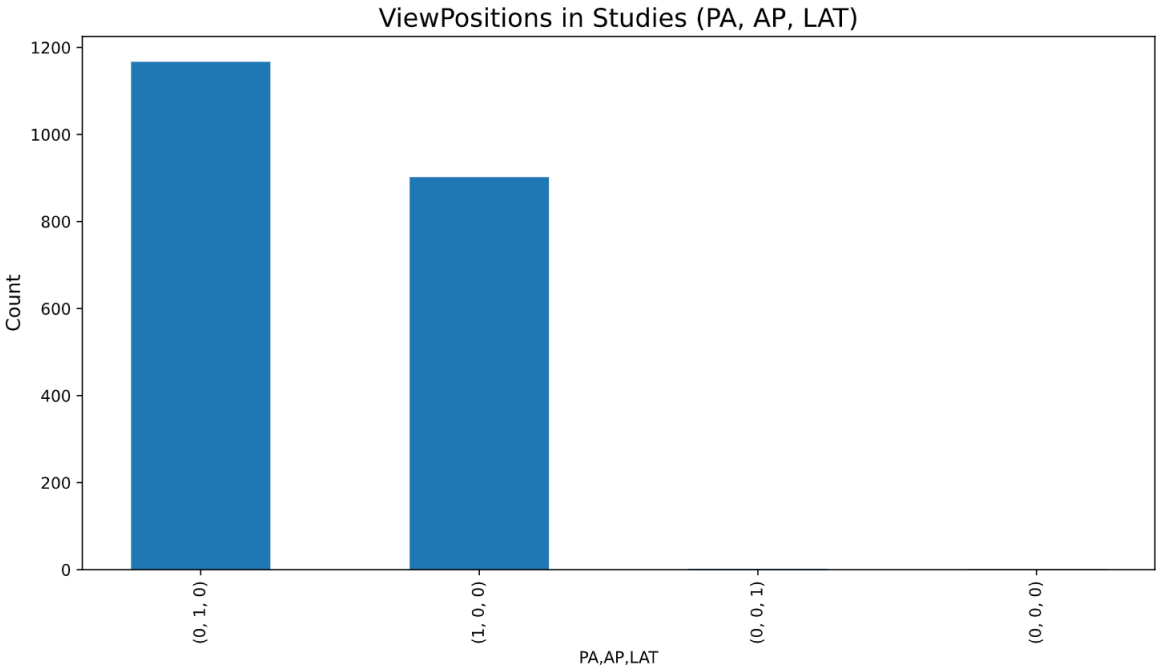
3.3 Patient Sex



3.4 View Position Characteristics

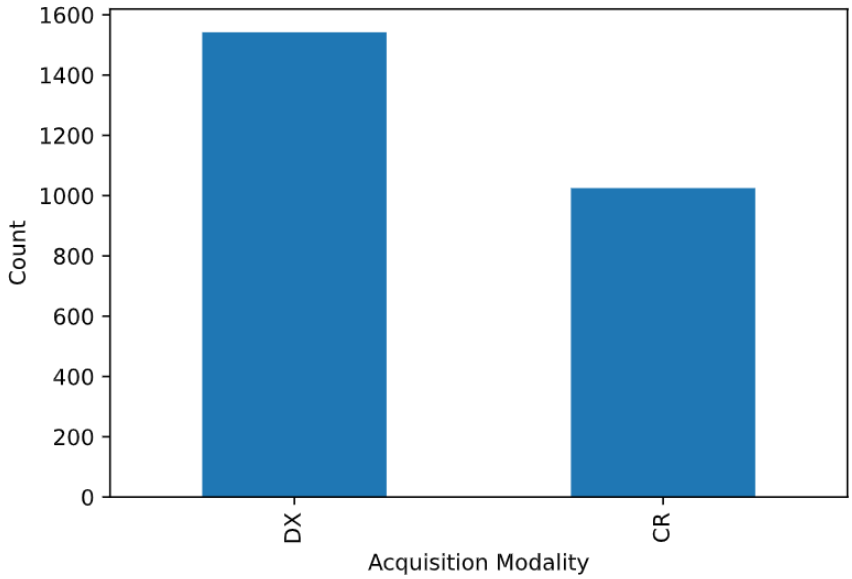
The Annalise CXR Edge product is designed to utilize frontal views only, and performance has been measured on manually verified frontal views




ViewPositions in Studies (PA, AP, LAT)
Count
1200
1000
800
600
400
200
0
(0, 1, 0)
(1, 0, 0)
(0, 0, 1)
(0, 0, 0)
PA,AP,LAT

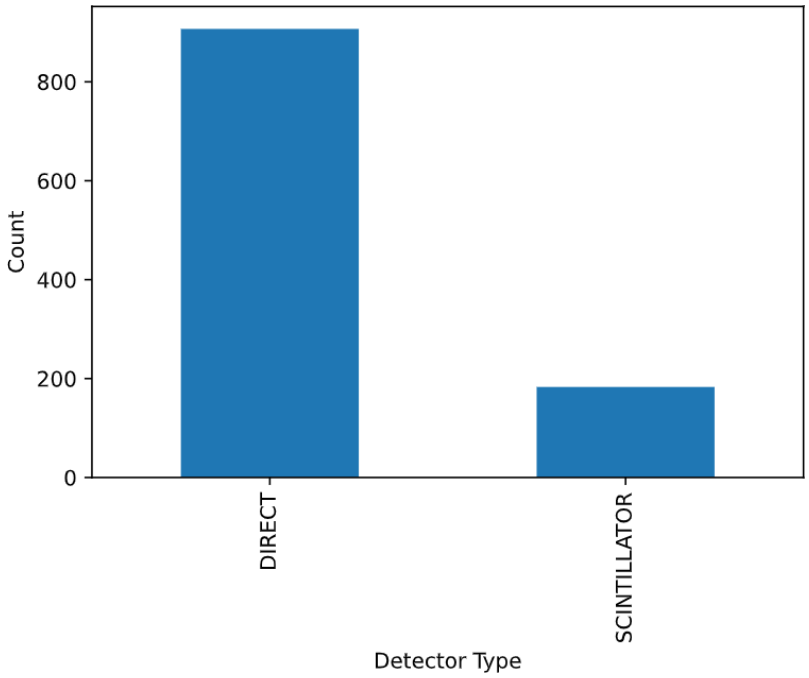
4. Acquisition Modality of Images

The Acquisition Modality is an important marker of image quality. Computed Radiography (CR) is an older technology which records information on a phosphor cassette prior to digitization while Digital Radiography (DX) records and digitizes information at the detector, leading to improved spatial resolution. Decreased spatial resolution may lead to difficulty in distinguishing fine detail on X-rays such as rib fractures or lung nodules.

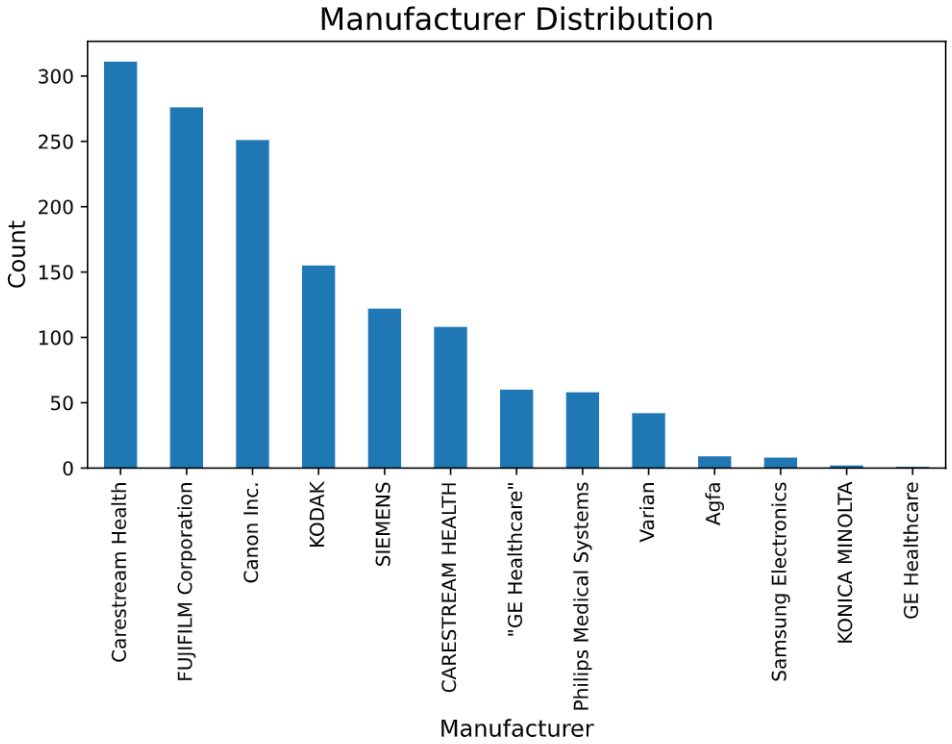


5. Detector Type

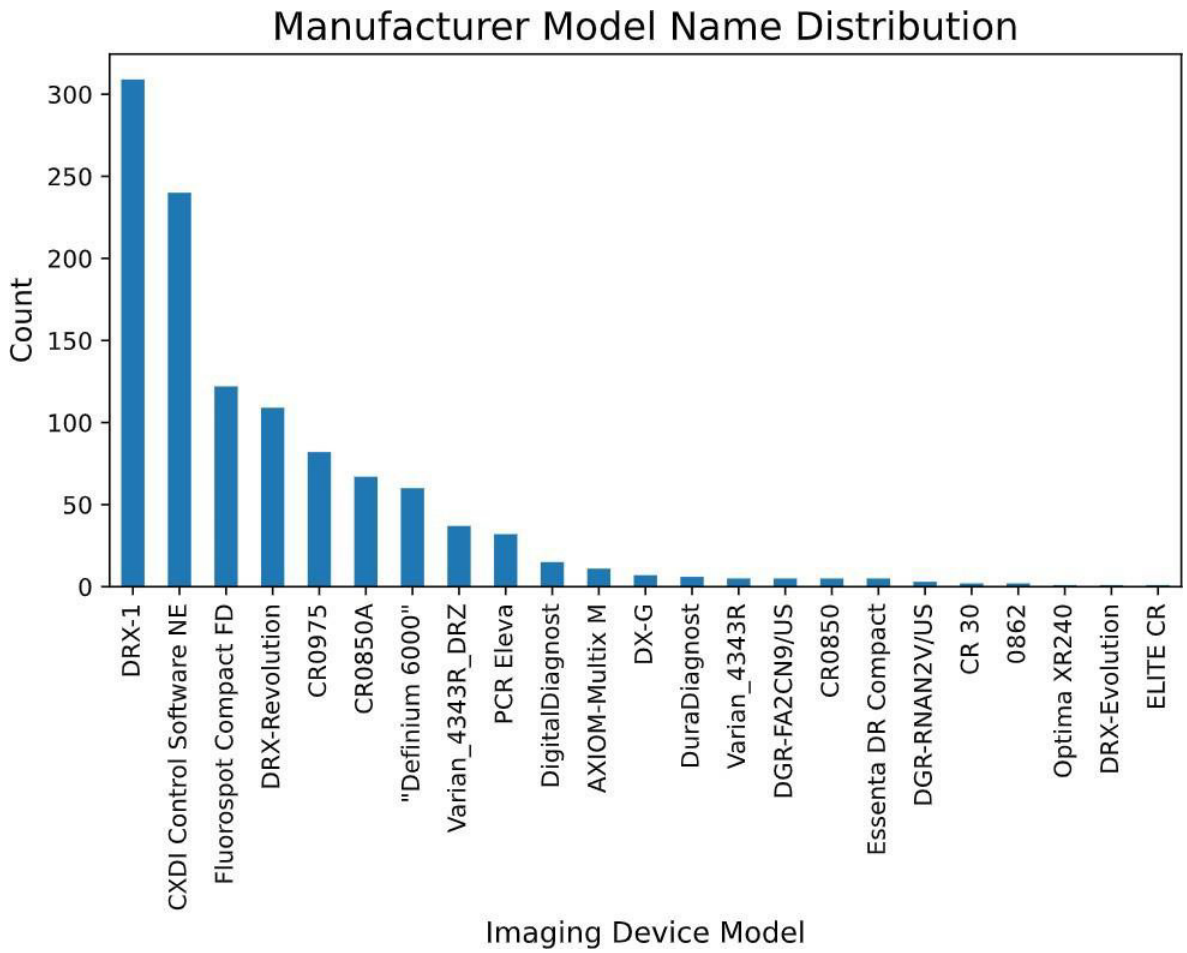
When Digital Radiography is used, the type of detector also changes the image quality. Scintillator detectors are older technologies which convert X-ray photons to visible photons via scintillation crystals while Direct detectors detect X-ray photons without an intermediate step. Direct detectors tend to have improved modulation transfer function and spatial resolution. Decreased spatial resolution may lead to difficulty in distinguishing fine detail on X-rays such as rib fractures or lung nodules.



6. Imaging Device Manufacturers



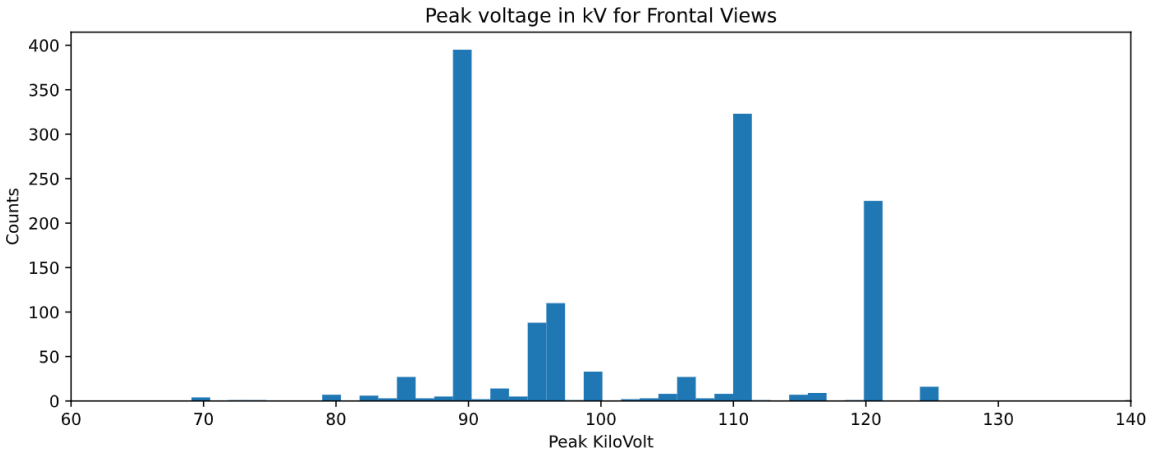
7. Image Device Model



8. Distribution of Peak kV

The Peak KV is selected by the radiographer at the time of imaging and can affect image quality. With automatic exposure control in most systems, higher KVP leads to more x-rays passing through the body and reaching the detector, reducing dose but also reducing contrast resolution. Lower KVP improves contrast resolution but increases dose to the patient. Too high KVP may lead to difficulty in distinguishing low contrast structures like lung opacities.

The Annalise CXR Edge product is designed to utilize frontal views only, and performance has been measured on manually verified frontal views. Therefore no data is available for lateral views.



9. Distribution of Exposure in uAs

The exposure in micro-ampere-seconds is the total output of the X-ray tube and is usually automatically controlled through the use of Automatic Exposure Control, which aims to maintain image quality while reducing exposure as low as reasonably achievable. Hence, lateral views where there is more tissue for the X-ray photons to pass through will require more exposure. Changing the exposure manually will change the Exposure Index and Deviation Index

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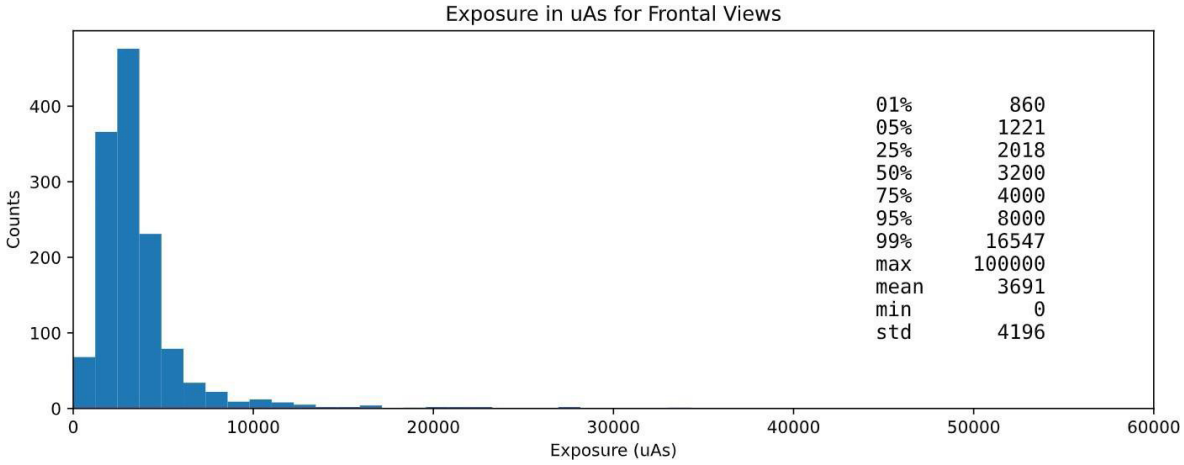


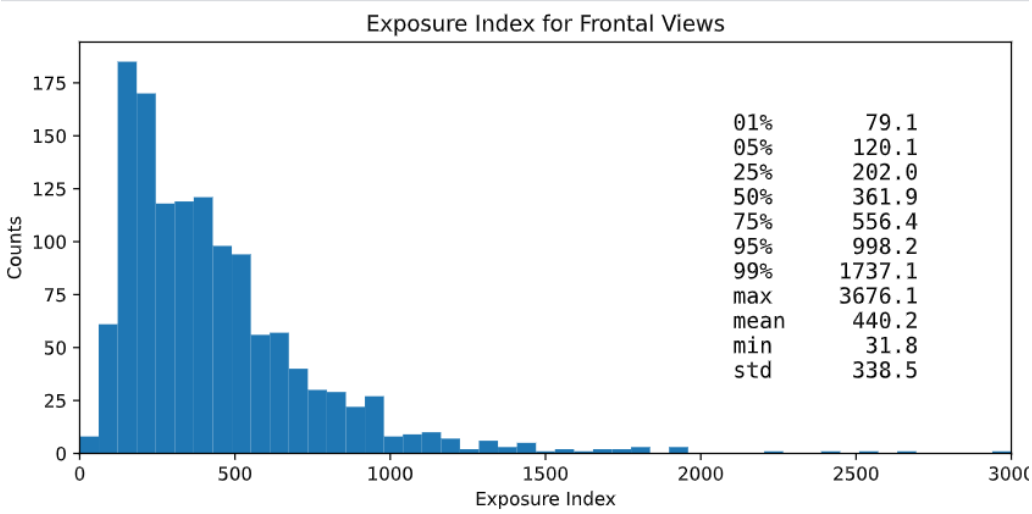
10. Radiograph Quality Indices

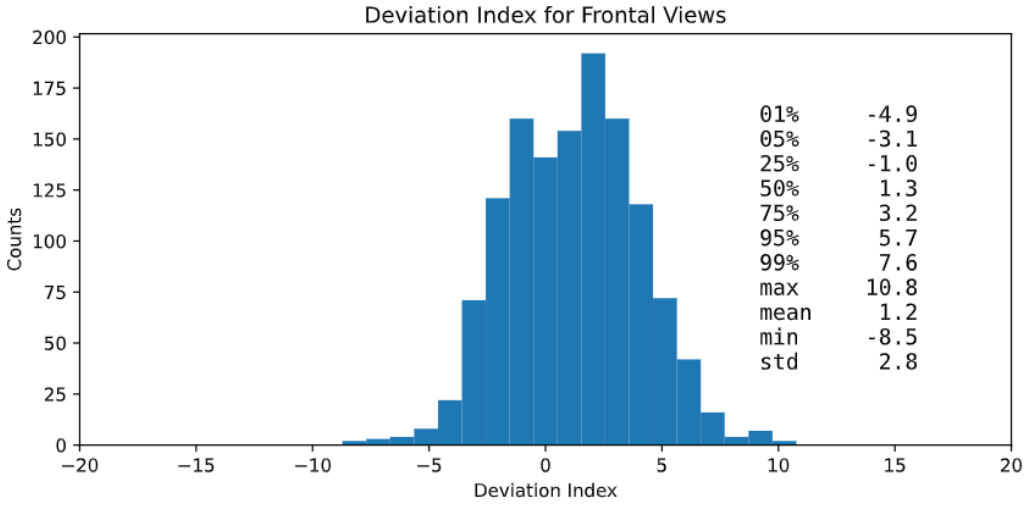
The exposure index is a measure of the incident radiation on the detector plate. When automatic exposure control is used, this should be roughly similar within the same exam type (e.g. frontal chest radiographs) as AEC aims to maintain exposure at a target exposure index

The deviation index is a logarithmic measure of the difference between the target exposure index and the actual target exposure. High deviation index indicates overexposure while low deviation index indicates underexposure (likely to cause the image to appear more white than necessary)

Different EIs and DIs may lead to difficulty in visualizing structures with poor contrast resolution such as lung opacities.

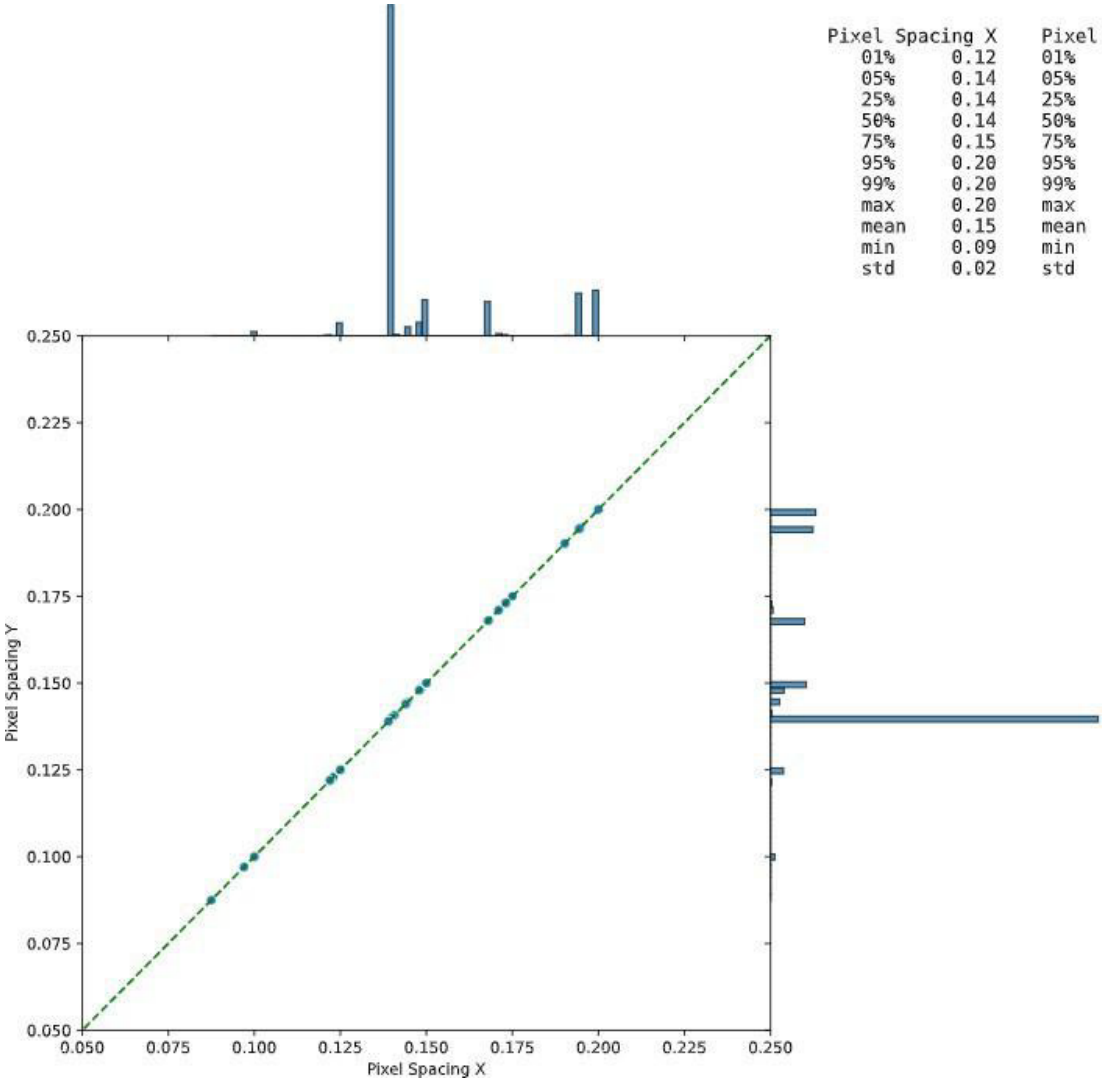
The Annalise CXR Edge product is designed to utilize frontal views only, and performance has been measured on manually verified frontal views. Therefore no data is available for lateral views.


Exposure Index for Frontal Views
Counts
Exposure Index
01% 79.1
05% 120.1
25% 202.0
50% 361.9
75% 556.4
95% 998.2
99% 1737.1
max 3676.1
mean 440.2
min 31.8
std 338.5


Deviation Index for Frontal Views
Counts
Deviation Index
01% -4.9
05% -3.1
25% -1.0
50% 1.3
75% 3.2
95% 5.7
99% 7.6
max 10.8
mean 1.2
min -8.5
std 2.8

11. Pixel Spacing Values

Pixel spacing is the measure of the physical distance between each recorded pixel on the detector. It is not adjusted for geometric magnification. Higher pixel spacing values typically indicate improved spatial resolution unless post-processing has been applied to the image. Decreased spatial resolution may lead to difficulty in distinguishing fine detail on X-rays such as rib fractures or lung nodules.



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

Symbol glossary

Definitions of symbols that may appear on the Annalise CXR Edge product or in the related documentation are listed below.

Symbol	Information
	CE labelling in accordance with EC directive
	Manufacturer
	European Authorised Representative
	Indicates a warning or caution
	Read the instructions for use
	Medical Device

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