annalise

Annalise Enterprise

Performance Guide

English

Annalise Enterprise

OPT-PRM-029 v4

This guide is applicable to Release 3.3 and Release 3.4.

Release 3.3 includes:

- Annalise Viewer version 3.4
- Annalise Backend version 3.3
- Annalise Integration Adapter version 3.3

Release 3.4 includes:

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

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Product use

Intended purpose

Annalise Enterprise is a medical device intended to assist clinicians with the interpretation of radiological imaging studies and provide notification of suspected findings.

Indications for use

Annalise Enterprise identifies suspected findings in:

- digitised (CR) or digital (DX) chest X-ray studies taken in the anterior-posterior (AP) or posterior-anterior (PA) and optionally lateral (LAT) orientations of adult patients
- non-contrast brain CT scans (brain kernel) of adult patients

For chest X-ray (CXR), the device improves the detection of radiological findings visible on chest X-rays. For CT Brain (CTB), the device improves the detection of radiological findings visible on non-contrast CT brain scans.

The device identifies 124 CXR findings and 130 CTB findings.

The device is used on a PC workstation in conjunction with a medical imaging viewer (i.e. PACS system).

The device may also be configured to provide input to worklist software to assist with notification and triaging. The device identifies studies with selected findings and communicates these studies to the worklist software which enables triaging of the worklist and notification.

Intended user

The device is intended to be used by trained clinicians who are qualified to interpret chest X-rays and/or CT scans as part of their scope of practice.

Intended patient population

The intended population is:

- CXR: Patients who are 16 years or older
- CTB: Patients who are 18 years or older

Contraindications

The device:

- is not intended to provide direct diagnosis
- is not to be used on patients under the age of 16 years for CXR and under the age of 18 years for CTB
- does not enable an increase in the clinician's scope of practice

WARNING

Qualified clinicians who interpret chest X-rays and or brain CT scans as part of their scope of practice hold ultimate responsibility for interpreting studies.

The clinician must review the Annalise Enterprise output concurrently with the original chest X-ray images or brain CT scan and all other relevant clinical information before making their clinical decisions.

Installation and system requirements

Refer to the *Annalise Enterprise Administration Guide* for details about system requirements and installation.

Annalise Enterprise performance

Overview

This document outlines the product performance of Annalise Enterprise.

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

AUC by findings (CXR)

The following tables include all supported findings for Annalise Enterprise (CXR) in alphabetical order. Each row displays both the finding name and the area under the curve (AUC) mean.

These performance results are based on the dataset used by Annalise.ai to evaluate the product. Differences in transfer syntax, demographics, imaging equipment or other variables may result in changes in performance.

CXR findings

Finding	AUC
Abdominal clips	0.978
Acute clavicle fracture	0.960
Acute humerus fracture	0.974
Acute rib fracture	0.969
Airway stent	0.966
Aortic arch calcification	0.976
Aortic stent	0.994
Atelectasis	0.882
Axillary clips	0.997
Basal interstitial thickening	0.887
Biliary stent	0.999
Breast implant	0.996
Bronchiectasis	0.928
Calcified axillary nodes	0.978
Calcified granuloma (< 5mm)	0.930
Calcified hilar lymphadenopathy	0.891
Calcified mass (> 5mm)	0.953
Calcified neck nodes	0.932
Calcified pleural plaques	0.981
Cardiac valve prosthesis	0.997
Cavitating mass with content	0.971

continued

CXR findings (cont.)

Finding	AUC
Cavitating mass(es)	0.928
Cervical flexion	0.992
Chronic clavicle fracture	0.963
Chronic humerus fracture	0.988
Chronic rib fracture	0.948
Clavicle fixation	0.997
Clavicle lesion	0.966
Coronary stent	0.966
Diaphragmatic elevation	0.934
Diaphragmatic eventration	0.983
Diffuse airspace opacity	0.979
Diffuse bullae	0.969
Diffuse fibrotic volume loss	0.960
Diffuse interstitial thickening	0.938
Diffuse lower airspace opacity	0.933
Diffuse nodular/miliary lesions	0.979
Diffuse pleural thickening	0.963
Diffuse spinal osteophytes	0.987
Diffuse upper airspace opacity	0.978
Distended bowel	0.979
Electronic cardiac devices	1.000
Focal airspace opacity	0.852
Gallstones	0.871
Gastric band	0.974
Hiatus hernia	0.991
Hilar lymphadenopathy	0.937
Humeral lesion	0.976
Hyperinflation	0.965
Image obscured	0.937
In position central line (CVC)	0.995
In position endotracheal tube (ETT)	0.997
In position nasogastric tube (NGT)	0.997
In position pulmonary arterial catheter (PAC)	0.992
Incompletely imaged chest	0.981

continued

CXR findings (cont.)

Finding	AUC
Inferior mediastinal mass	0.969
Intercostal drain	0.997
Internal foreign body	0.933
Kyphosis	0.976
Loculated effusion	0.952
Lower zone bullae	0.954
Lower zone fibrotic volume loss	0.923
Lung collapse	0.997
Lung sutures	0.966
Mastectomy	0.962
Mediastinal clips	0.993
Multifocal airspace opacity	0.896
Multiple masses or nodules	0.957
Neck clips	0.987
Nipple shadow	0.971
Oesophageal stent	0.998
Osteopaenia	0.955
Overexposed	0.917
Patient rotation	0.910
Pectus carinatum	0.900
Pectus excavatum	0.994
Peribronchial cuffing	0.836
Pericardial fat pad	0.926
Perihilar airspace opacity	0.943
Pleural mass	0.949
Pneumomediastinum	0.969
Post resection volume loss	0.980
Pulmonary artery enlargement	0.942
Pulmonary congestion	0.926
Reduced lung markings	0.955
Rib fixation	0.991
Rib lesion	0.971
Rib resection	0.986
Rotator cuff anchor	1.000

continued

CXR findings (cont.)

Finding	AUC
Scapular fracture	0.942
Scapular lesion	0.951
Scoliosis	0.954
Segmental collapse	0.911
Shoulder arthritis	0.983
Shoulder dislocation	0.966
Shoulder fixation	0.997
Shoulder replacement	1.000
Simple effusion	0.951
Simple pneumothorax	0.980
Solitary lung mass	0.946
Solitary lung nodule	0.897
Spinal arthritis	0.938
Spinal fixation	0.999
Spinal lesion	0.971
Spinal wedge fracture	0.967
Sternotomy wires	1.000
Subcutaneous emphysema	0.997
Subdiaphragmatic gas	0.996
Suboptimal central line (CVC)	0.975
Suboptimal gastric band	0.997
Suboptimal nasogastric tube (NGT)	0.985
Suboptimal endotracheal tube (ETT)	0.995
Suboptimal pulmonary arterial catheter (PAC)	0.993
Superior mediastinal mass	0.952
Tension pneumothorax	0.997
Tracheal deviation	0.951
Underexposed	0.946
Underinflation	0.973
Unfolded aorta	0.896
Upper interstitial thickening	0.900
Upper zone bullae	0.964
Upper zone fibrotic volume loss	0.976
Widened aortic contour	0.981
Widened cardiac silhouette	0.951

AUC by findings (CTB)

The following tables include all supported findings for Annalise Enterprise (CTB) in alphabetical order. Each row displays both the finding name and the area under the curve (AUC) mean.

These performance results are based on the dataset used by Annalise.ai to evaluate the product. Differences in transfer syntax, demographics, imaging equipment or other variables may result in changes in performance.

CTB findings

Finding	AUC
Abnormal prominent vessels	0.847
Acute brainstem infarct	0.830
Acute cerebellar infarct	0.925
Acute cerebral infarct	0.923
Acute haemorrhagic infarct	0.987
Acute infarct petechial haemorrhage	0.963
Acute intraparenchymal haemorrhage	0.985
Acute lacunar infarct	0.840
Acute on chronic subdural haematoma	0.993
Acute peripheral infarct	0.888
Acute subdural/extradural haematoma	0.974
Acute watershed infarct	0.920
Aggressive bone lesion	0.886
Aggressive extra-axial mass of soft tissue	0.979
Aggressive meningeal thickening	0.913
Aggressive skin lesion	0.970
Air fluid level paranasal sinuses	0.948
Aneurysm	0.815
Aneurysm coils	0.998
Arachnoid cyst	0.963
Basal ganglia and dentate calcification	0.970
Cerebellar atrophy	0.922
Cerebral atrophy	0.884
Cerebral convexity subarachnoid haemorrhage	0.966
Chiari malformation	0.985
Chronic globe abnormality	0.927
Chronic or fungal sinusitis	0.969
Chronic subdural haematoma	0.980

continued

CTB findings (cont.)

Finding	AUC
Cochlear implant	1.000
Colloid cyst	0.998
Colpocephaly	0.991
Communicating hydrocephalus/NPH	0.974
Corpus callosum agenesis/hypogenesis	0.987
Cortical laminar necrosis	0.941
Cortical or leptomeningeal calcification	0.958
Craniotomy extra-axial collection	0.988
Craniotomy/cranioplasty/craniectomy	0.994
Deep brain stimulation electrodes	1.000
Deep white or grey matter infarct	0.949
Diffuse hypoxic-ischaemic encephalopathy	0.988
Dilated superior opthalmic vein	0.885
Disappearing basal ganglia sign	0.958
Dural calcification	0.948
Effacement of basal cisterns	0.971
Empty sella	0.950
Encephalomalacia	0.961
Entrapment of lateral ventricle	0.981
Erosion of bone in tympanic cavity	0.988
Exophthalmos	0.970
Expanded pituitary fossa	0.983
Extracranial herniation	0.953
Extracranial Ventricular Drain (EVD)	0.994
Extradural haematoma	0.937
Face and neck haematomas	0.962
Focal intra-axial calcification	0.904
Foreign body face and neck	0.906
Foreign body orbit	0.908
Foreign body scalp	0.848
Fourth ventricular effacement	0.979
Fracture of calvarium	0.960
Fracture of skull base	0.948
Fracture paranasal sinuses/facial bones	0.935

continued

CTB findings (cont.)

Finding	AUC
Generalised calvarial thickening	0.975
Haemorrhagic contusion	0.980
Haemorrhagic lesion in sella	0.899
Hyperdense artery in anterior circulation	0.956
Hyperostosis frontalis	0.987
Hypopneumatised mastoid	0.978
Insular ribbon sign	0.960
Intraaxial lesion calcification	0.978
Intraaxial lesion complex cyst	0.932
Intraaxial lesion haemorrhage	0.975
Intraaxial lesion heterogeneous	0.979
Intraaxial lesion hyperdense	0.961
Intraaxial lesion hypodense	0.928
Intraaxial lesion isodense	0.917
Intra-ocular silicone	0.998
Intra-ventricular haemorrhage	0.992
Left/right ventricular effacement	0.978
Mastoid opacification	0.907
Mastoidectomy	0.997
Meningioma with hyperostosis of adjacent calvarium	0.960
Metallic artefact	0.969
Midline shift	0.980
Movement artefact	0.901
Mucosal thickening	0.918
Non-aggressive extra-axial mass containing calcification	0.934
Non-aggressive extra-axial mass without calcification or fat	0.843
Non-aggressive skin lesion	0.870
Obstructive hydrocephalus	0.981
Old lacunar infarct	0.915
Opacity in tympanic cavity	0.987
Orbital fat stranding	0.954
Orbital mass benign	0.905
Orbital mass inflammatory or malignant	0.967
Osteoma	0.864

continued

CTB findings (cont.)

Finding	AUC
Parotid lesion	0.843
Perimesencephalic/aneurysmal subarachnoid haemorrhage	0.987
Petrous bone fracture	0.935
Pineal mass or complex cyst	0.842
Pneumocephalus	0.940
Prominent perivascular spaces	0.873
Prosthetic globe	0.996
Resection cavity	0.981
Scalp haematomas	0.963
Sella or suprasellar cyst, mass, or cystic mass	0.965
Simple pineal cyst	0.938
Sino-nasal, oral, mandibular, and maxillofacial surgery	0.905
Sinus soft tissue density lesion	0.930
Small vessel ischaemic disease	0.938
Soft tissue mass in the neck	0.906
Striatocapsular slit-like chronic hemorrhage	0.971
Subacute intraparenchymal haemorrhage	0.925
Subacute subdural haematoma	0.979
Subcutaneous emphysema	0.936
Subependymal calcification or nodules	0.864
Sulcal effacement	0.965
Temporomandibular joint arthritis	0.852
Temporomandibular joint dislocation	0.969
Third ventricular effacement	0.984
Tonsillar herniation	0.993
Transependymal oedema	0.981
Transphenoidal surgery	0.957
Uncal herniation	0.993
Vascular clips	0.984
Vasogenic oedema	0.977
Ventricular cyst/xanthogranulomatous change	0.871
Ventricular mass	0.821
Ventriculoperitoneal (VP) Shunt	0.998
Vitreous haemorrhage	0.974

Model validation dataset characteristics

Dataset characteristics (CXR)

The Annalise Enterprise product is validated on over 2,500 studies (both lossless transfer syntax and lossy transfer syntax) acquired from clinics across Australia and the United States of America.

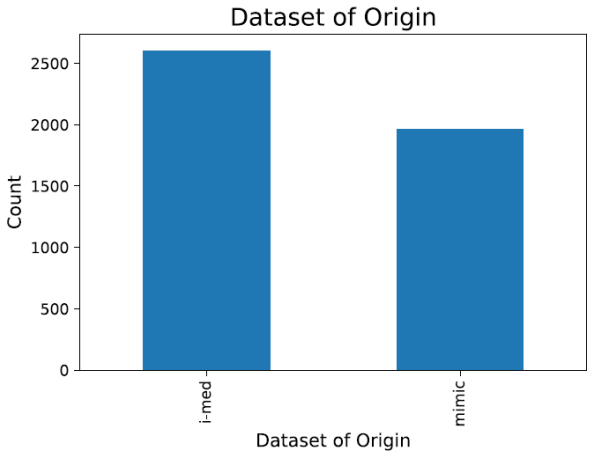
Demographics of the overall test dataset:

Demographics	Details
Patients	2,285
Studies	Lossless: 2,557 Lossy: 2,559
Images	4,566
Patient sex	Male: 29% Female: 28% Unknown: 43%*
Mean age	74 years (standard deviation 15 years)*
View position	Posterior-anterior (PA): 25.6% (1,170/4,566 images) Anterior-posterior (AP): 31.4% (1,432/4,566 images) Optionally lateral (LAT): 20.2% (921/4,566 images) Other: 0.3% (13/4,566 images)

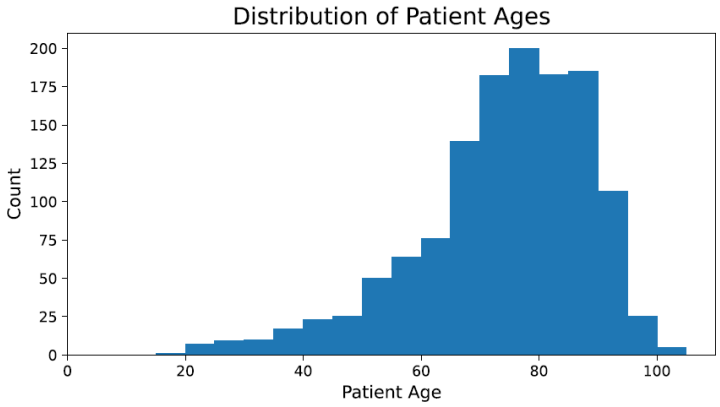
*As MIMIC-CXR does not provide sex or age information, data for this is incomplete.

Dataset of origin

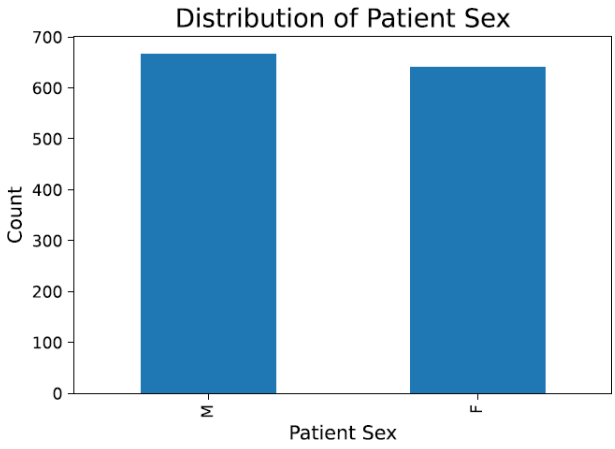
Dataset of origin of images were obtained from I-MED and the publicly available MIMIC dataset.



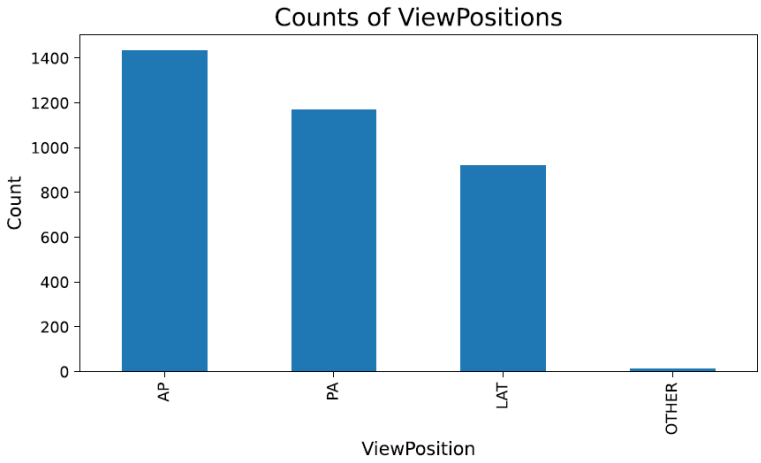
Patient age

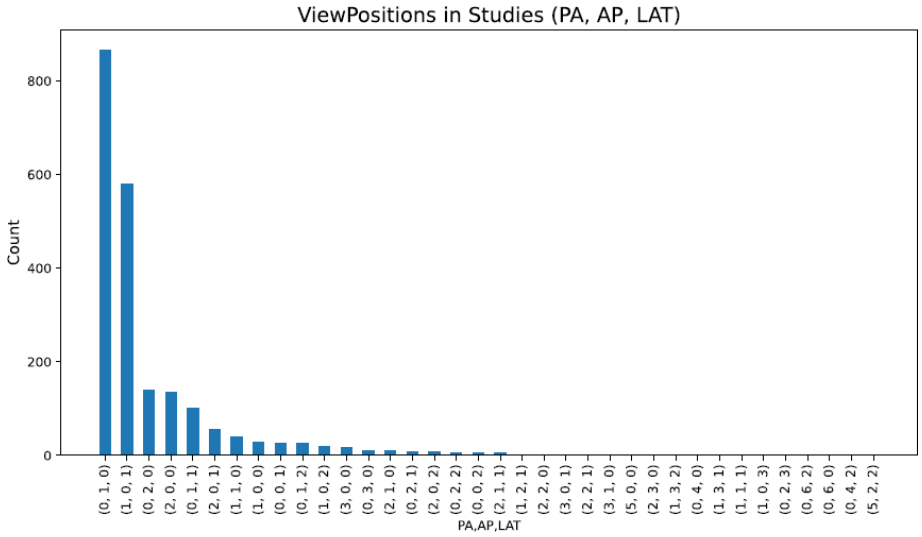


Patient sex



View/position characteristics





Dataset characteristics (CTB)

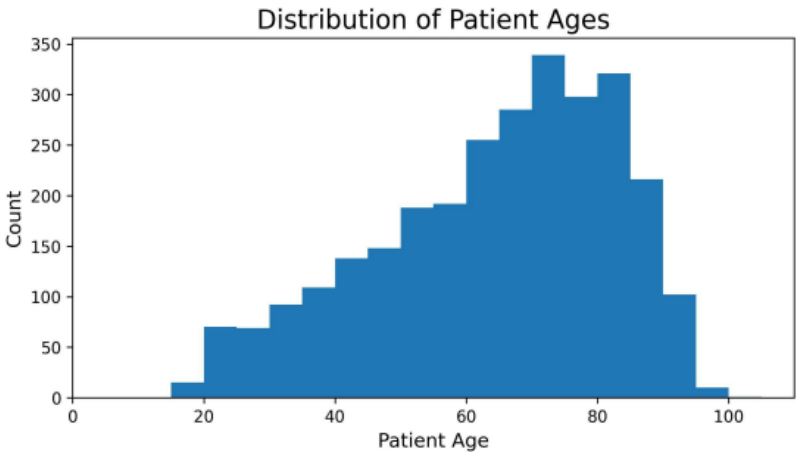
The Annalise Enterprise product is validated on over 2,500 studies (lossless transfer syntax) acquired from a single Australian source (I-MED Radiology Network Limited).

Demographics of the overall test dataset:

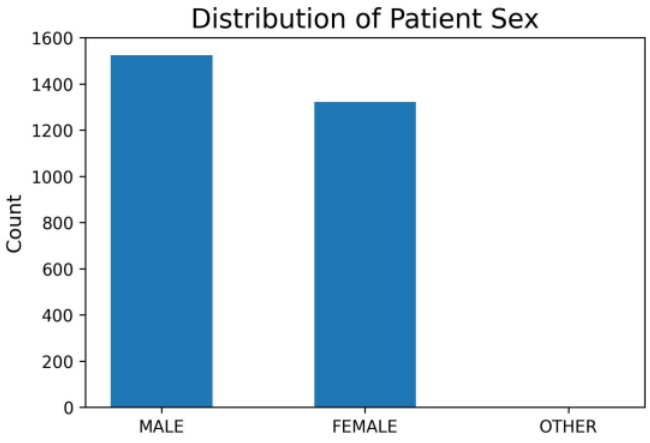
Demographics	Details
Patients	2,419*
Studies	2,848
Patient sex	Male: 1,292/2,419 (53.4%) Female: 1,125/2,419 (46.5%) Unknown: 2/2,419 (0.1%)
Mean age	63.9 years (standard deviation 18.2)

*From a single Australian source: I-MED Radiology Network Limited.

Patient age



Patient sex



Acquisition modality of images (CXR)

Overview

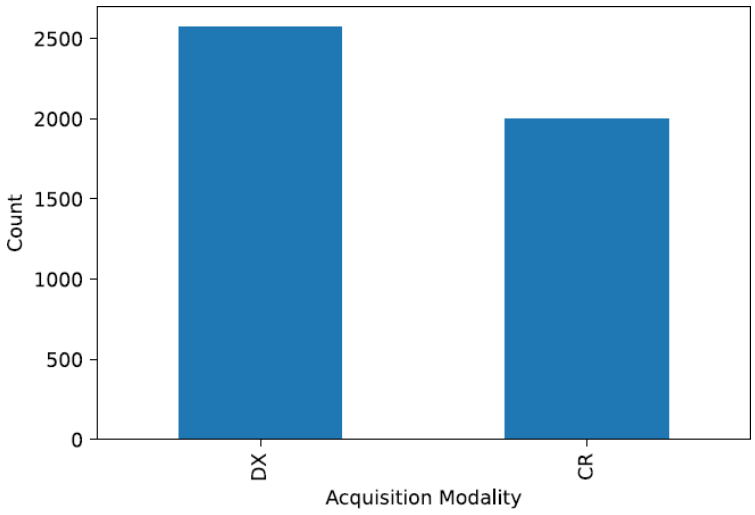
The Acquisition Modality is an important marker of image quality.

Computed Radiography (CR) is an older technology which records information on a phosphor cassette prior to digitisation, while Digital Radiography (DX) records and digitises 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).

Acquisition modality

The following graph displays the distribution of acquisition modalities:



Imaging device

Overview

This section outlines the distribution characteristics of:

- detector type (CXR)
- imaging device manufacturers (CXR and CTB)
- imaging device models (CXR and CTB)

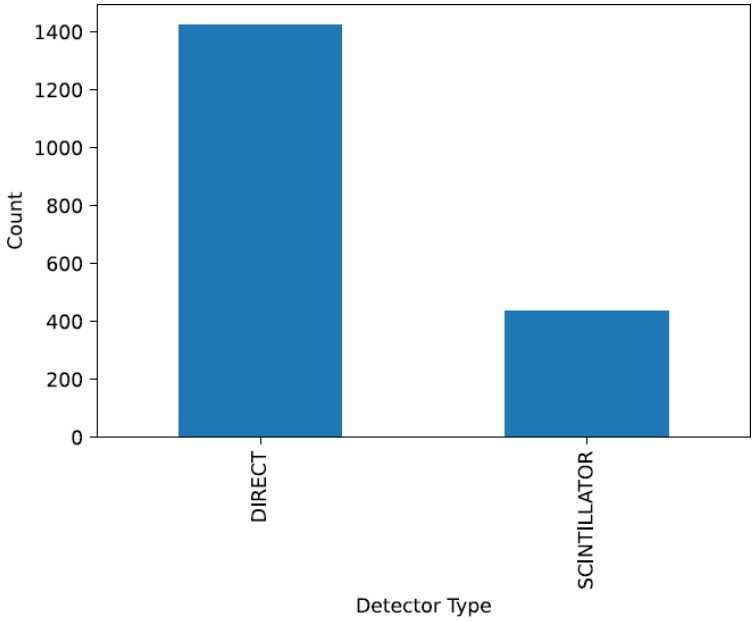
Detector type (CXR)

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.

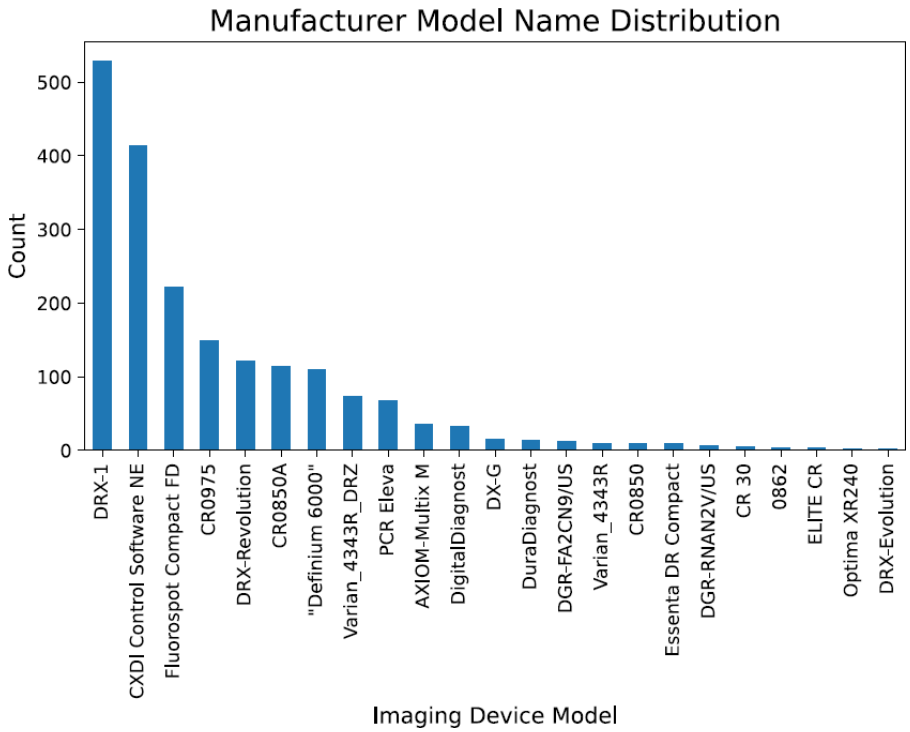
Direct detectors tend to have improved modulation transfer function and spatial resolution. Decreased spatial resolution may lead to difficulty in distinguishing fine detail on X-rays (such as rib fractures or lung nodules).

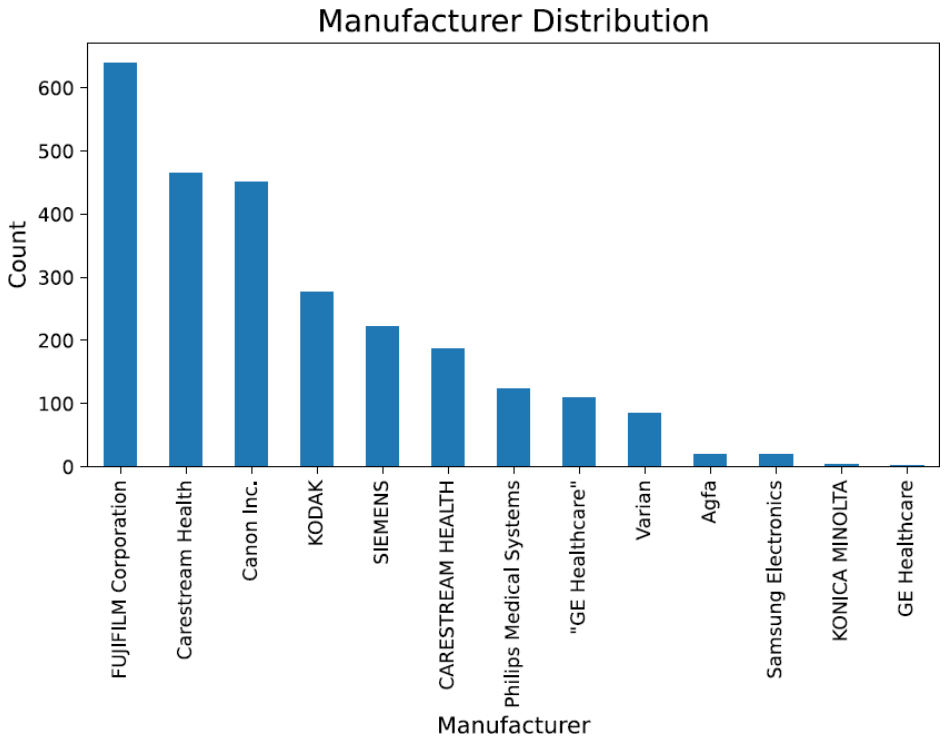
The following graph displays the distribution of detector types of radiographs:



Imaging device models and manufacturers (CXR)

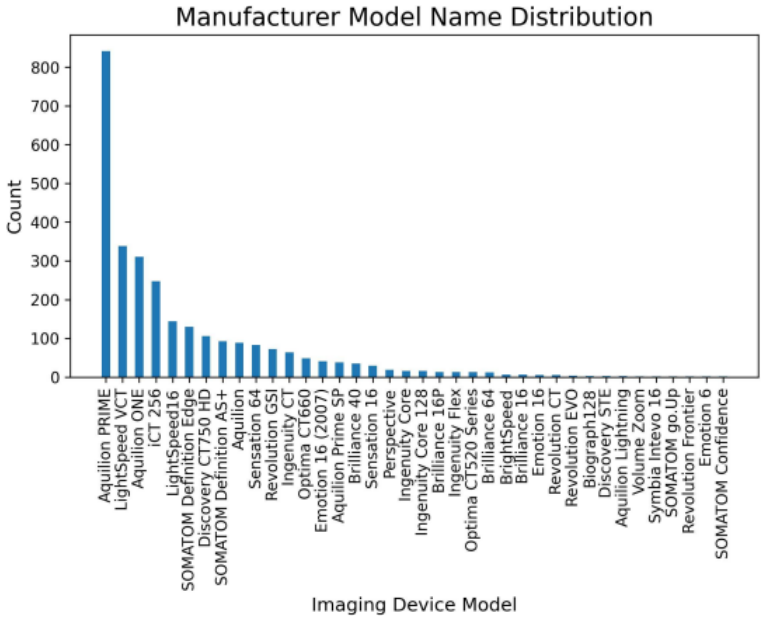
The following graphs display the distribution of CXR imaging device models and manufacturers:

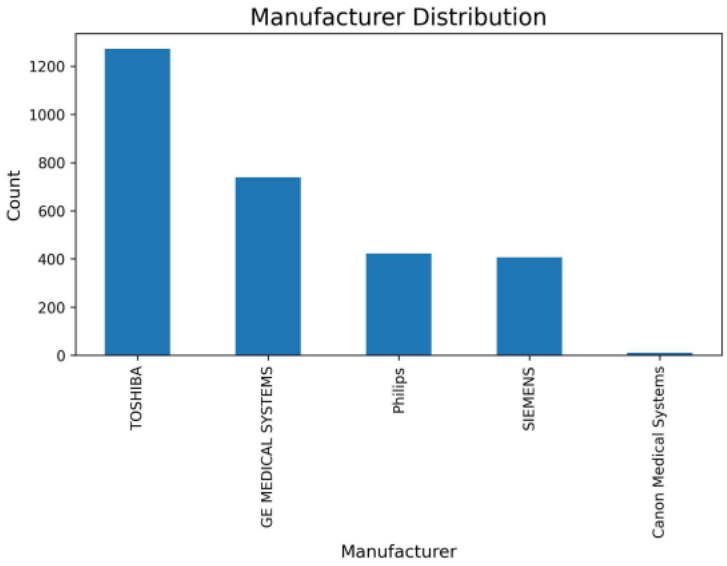




Imaging device models and manufacturers (CTB)

The following graphs display the distribution of CTB imaging device models and manufacturers:





Distribution of peak kV (CXR)

Overview

The peak kilovolt (KVP) is selected by the radiographer at the time of imaging and can affect image quality.

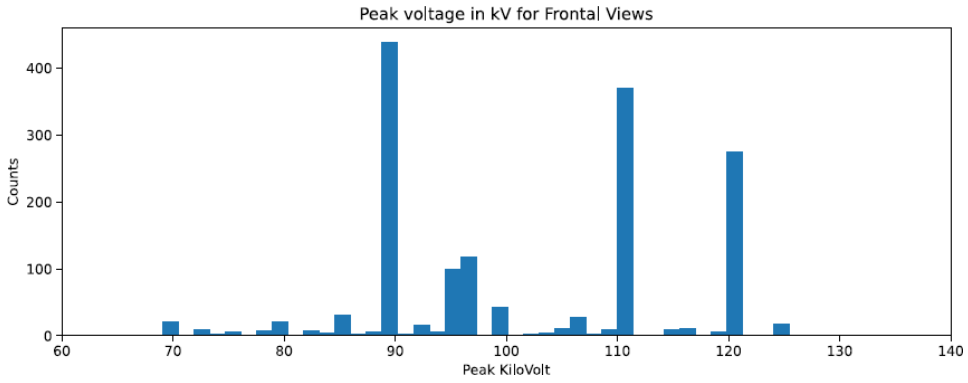
With automatic exposure control in most systems, higher KVP leads to more X-rays passing through the body and reaching the detector, reducing dose but also reducing contrast resolution.

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.

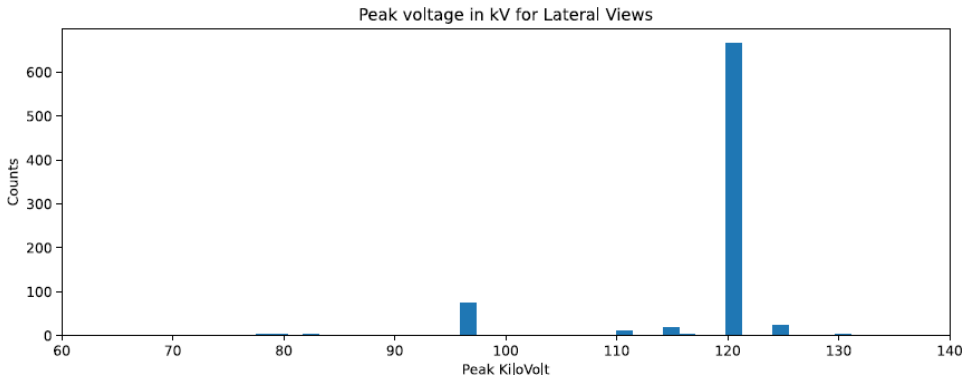
Results

The following graphs display the peak voltage in kV for frontal and lateral views:

Frontal views



Lateral views



Distribution of exposure in uAs (CXR)

Overview

The exposure in micro-ampere-seconds (uAs) is the total output of the X-ray tube and is usually automatically controlled by using automatic exposure control. This aims to maintain image quality while reducing exposure as low as reasonably achievable.

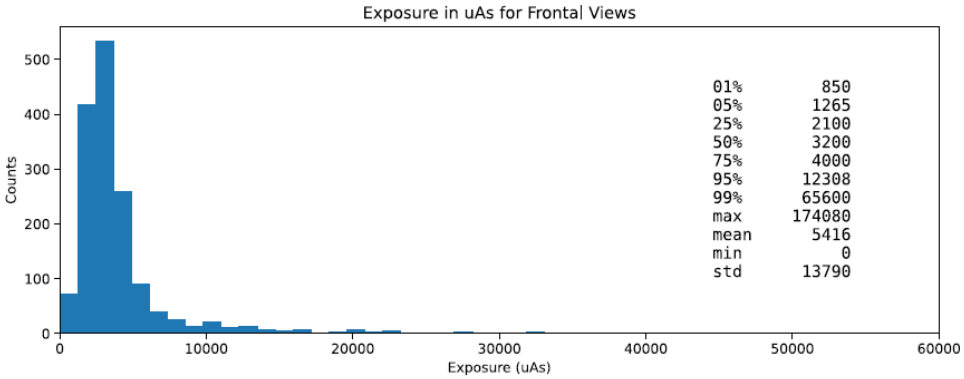
Therefore, lateral views will require more exposure where there is more tissue for the X-ray photons to pass through.

Changing the exposure manually will change the Exposure Index (EI) and Deviation Index (DI).

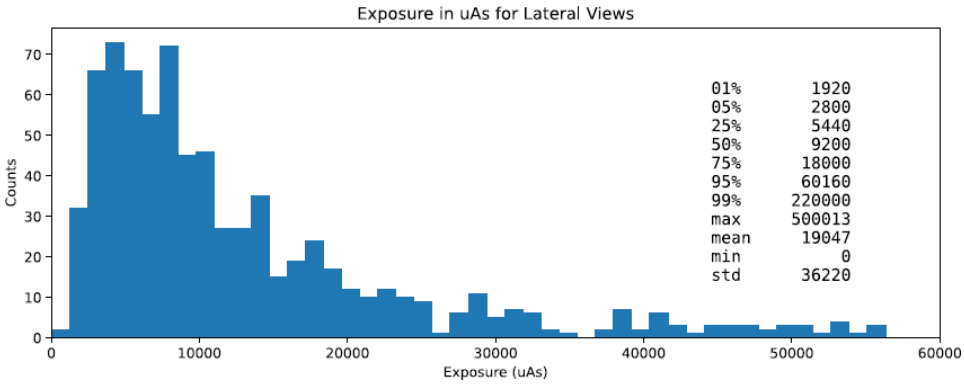
Results

The following graphs display the exposure in uAs for frontal and lateral views:

Frontal views



Lateral views



Radiograph quality indices (CXR)

Overview

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

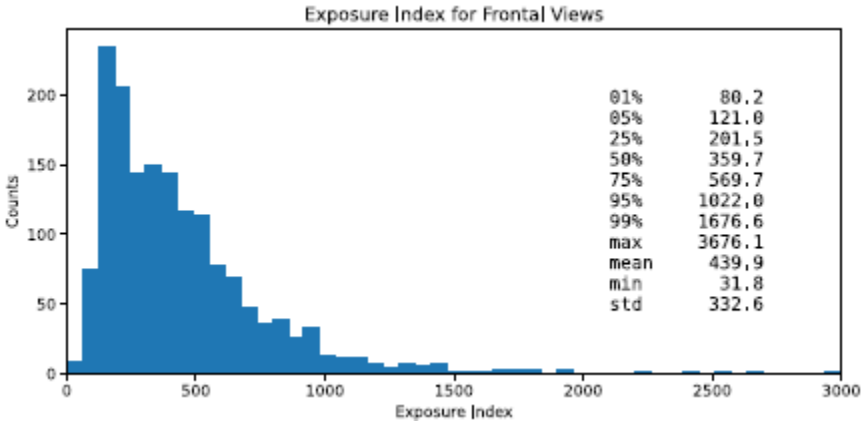
The Deviation Index (DI) is a logarithmic measure of the difference between the target exposure index and the actual target exposure. High deviation index indicates overexposure while low deviation index indicates underexposure (likely to cause the image to appear more white than necessary).

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

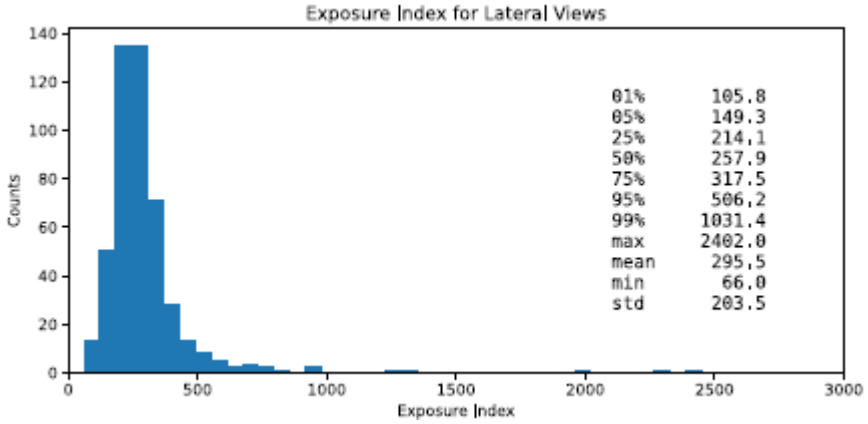
Results

The following graphs display the exposure index for frontal and lateral views and the deviation index for frontal and lateral views:

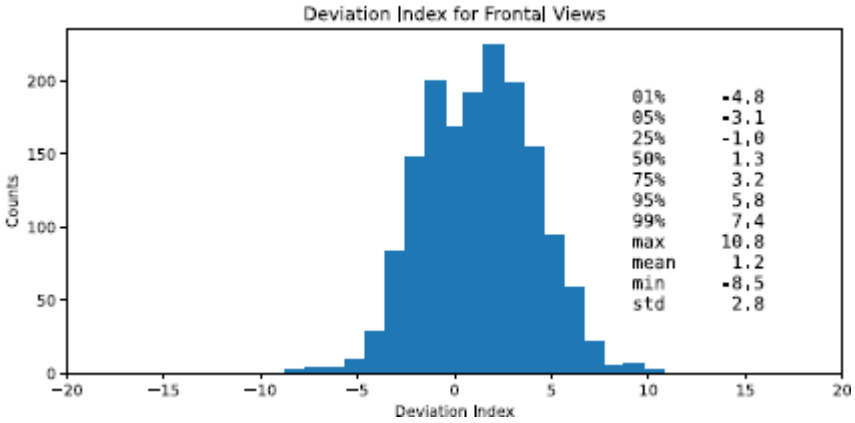
Exposure index for frontal views



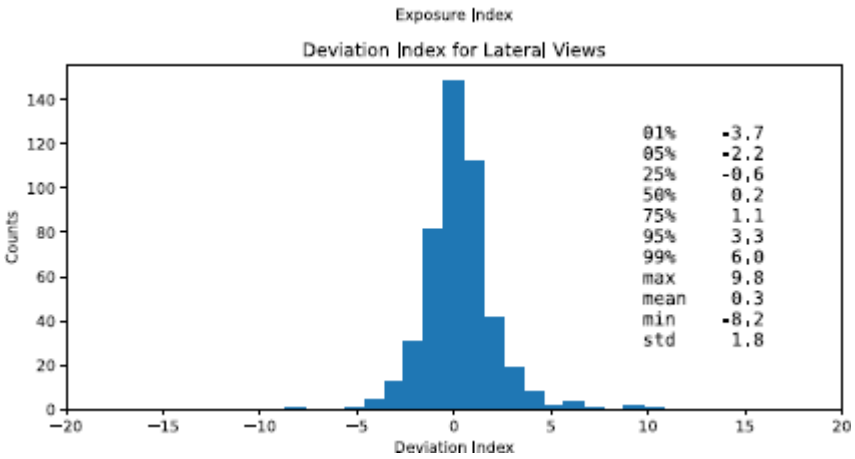
Exposure index for lateral views



Deviation index for frontal views



Deviation index for lateral views



Pixel spacing values

Overview

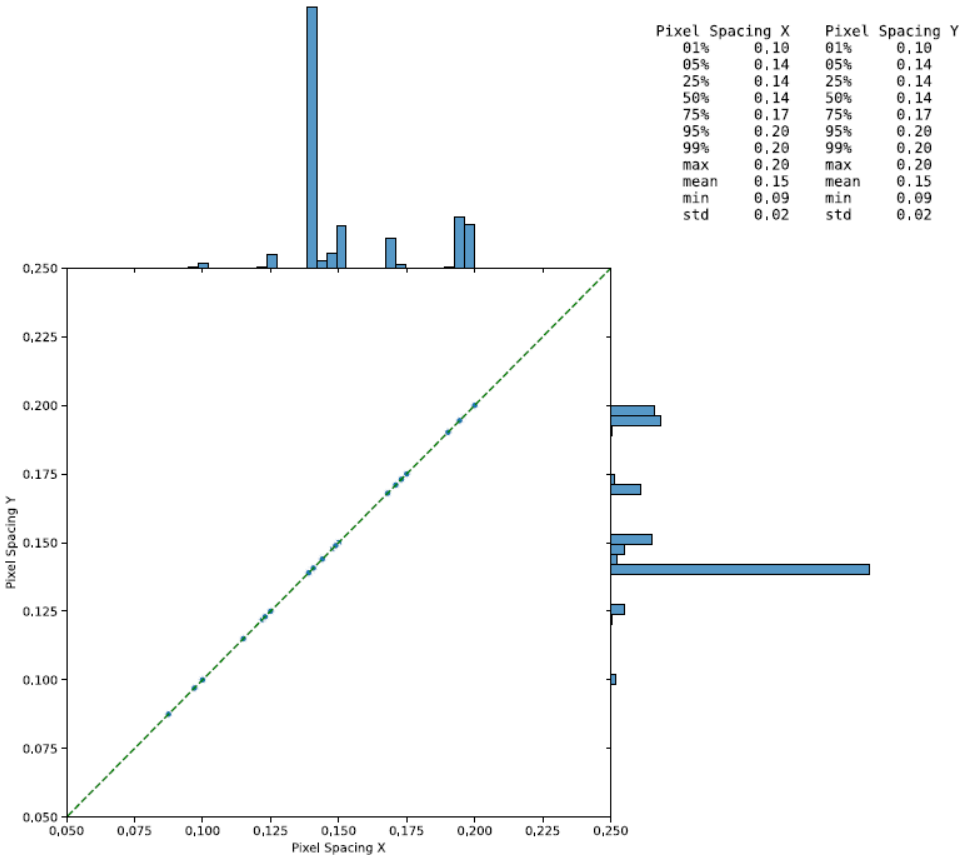
Pixel spacing is the measure of the physical distance between each recorded pixel on the detector. It is not adjusted for geometric magnification.

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) and CT scans (such as subtle bleeds and fractures).

Pixel spacing values (CXR)

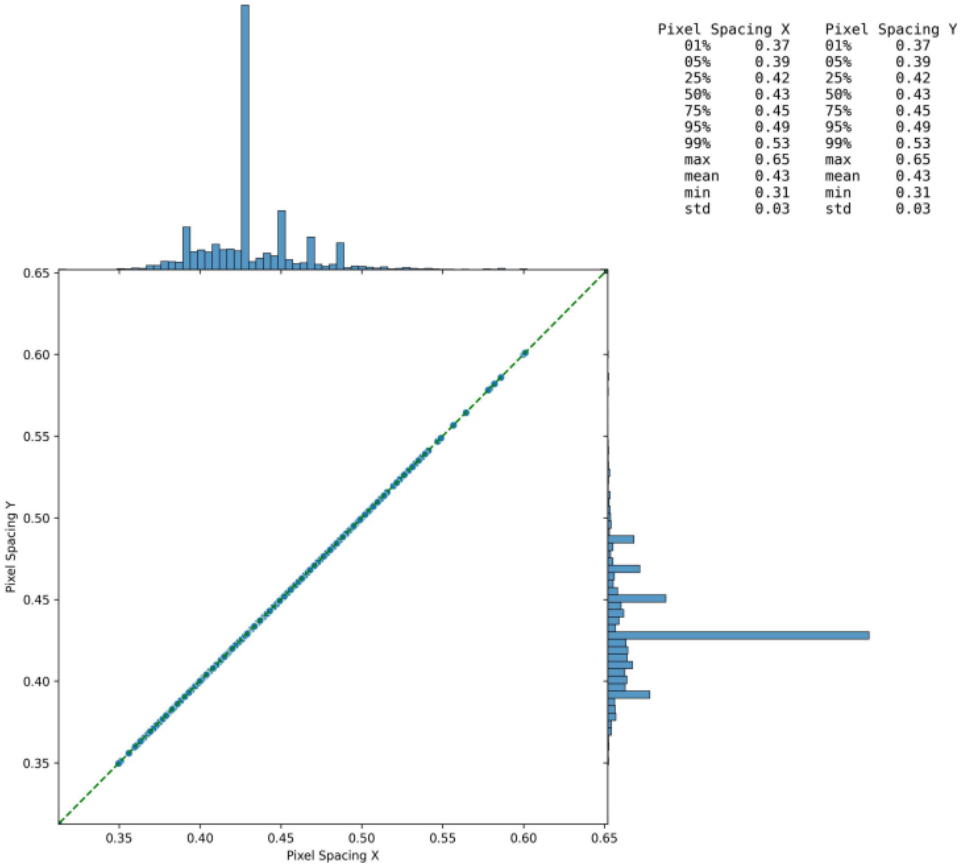
The following graph displays the pixel spacing values for cases in the dataset:



Pixel spacing values (CTB)

Distribution of pixel spacing ranged from 0.65 mm (max) to 0.31 mm (min) with a mean of 0.43 mm across all images (standard deviation 0.03).

The following graph displays the pixel spacing values for the cases in the dataset:



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*

Symbol glossary

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

Symbol	Information
CE 2797	CE labelling
UK CA	UK Conformity Assessed marking
	Manufacturer
EC REP	European Authorised Representative
CH REP	Swiss Authorised Representative
	Indicates a warning or caution
	Read the instructions for use
MD	Medical Device

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