

Anritsu



Pharmaceutical X-ray Inspection System

KXE7510DGEKE

World-leading quality assurance

Opaque aluminum foil packaging materials are increasingly being used to maintain the quality of pharmaceutical products.

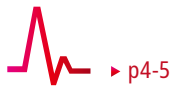
This makes it difficult for visual systems to detect product defects like missing or chipped tablets and sealing faults.

Anritsu's pharmaceutical x-ray system penetrates foil to uncover critical product faults that otherwise can pass through undetected and reach consumers.



**Pharmaceutical
X-ray Inspection System**
KXE7510DGEKE

Provide Solutions on the Spot
High Sensitivity,
High Stability



► p4-5

FDA 21 CFR Part 11
Compliance



► p6

Intuitive System Setup,
Simple Operation

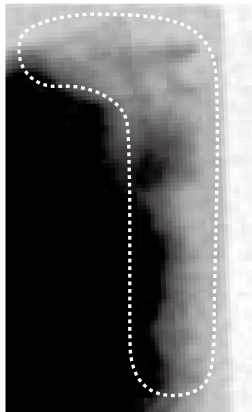


► p7

High sensitivity and high stability



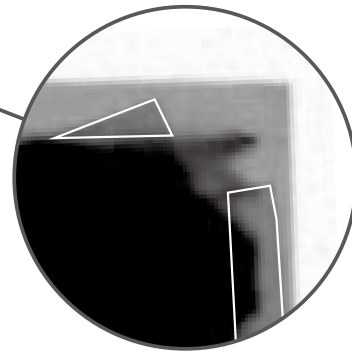
The Anritsu Pharmaceutical X-ray Inspection System is equipped with a new x-ray unit optimized for thin product inspection. The system contributes to quality stabilization with significantly improved x-ray image quality and reduced quality variance, which often occurs in visual and hand inspections.



Conventional models



New model



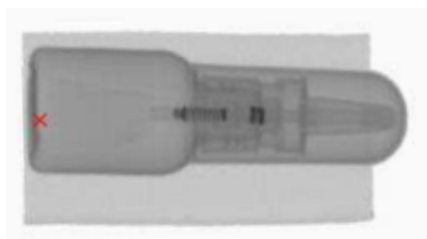
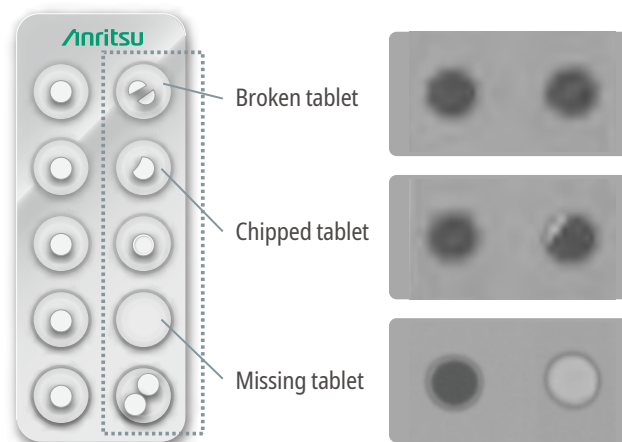
Our unique technology minimizes x-ray leakage so that a product with a height of 10 mm or less can be conveyed without touching the leakage prevention curtain, which reduces false rejects caused by product jams or the disturbance of product orientation during conveyance. It also ensures that defective products are properly rejected at the correct timing.



The system performs a variety of product integrity checks

The Pharmaceutical X-ray Inspection System can verify product integrity while simultaneously inspecting for contaminants.

Shape Inspection / Missing Product Detection

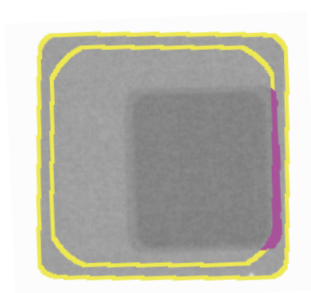


Missing straw inside a spray container



Broken syringe needle

Package Check



Transdermal patches



Facial treatment mask



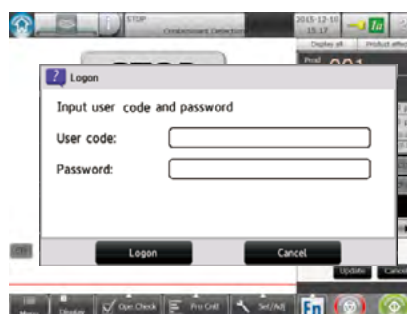
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Supporting FDA 21 CFR Part 11 (Optional)

The Anritsu Pharmaceutical X-ray Inspection System complies with FDA 21 CFR Part 11, including eligibility user authentication, audit trails, and data encryption/decryption.

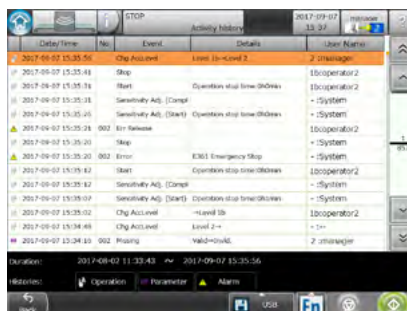
Eligibility authentication (User management)

Access level can be individually set for each user to prevent unauthorized operations and potential operator mistakes.



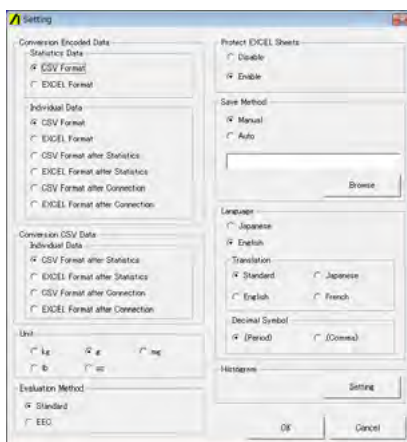
Audit trail

The history of operations and actions related to production and results of operation check are internally recorded. The data can be used to monitor fraudulent activity and analyze the cause of such activity.



Data encryption and decryption

Various data can be easily transmitted, including audit trail statistics and parameters.



Intuitive system setup and simple operation

No blind spot design prevents contamination

The conveyor belts and rollers including the front cover and x-ray leakage prevention curtains can be easily removed or attached without tools for easy cleaning and maintenance. The design with no blind spot prevents statistical discrepancies and contamination due to improper conveyance and products falling off the line.



Easily configure the system to achieve high sensitivity and low false rejects

Product Registration Navigation simplifies parameter setting procedures with step-by-step illustrated instructions. No fine adjustment is required, making it easier for anyone to set up the system with the optimum use.

A simple product setup minimizes the time needed to register a new product, reducing the operator's workload.

Effect of X-ray exposure on the pharmaceutical products

It is your responsibility to check and ensure that you comply with all applicable laws and regulations of your country or region regarding the effect of x-ray exposure on pharmaceutical products. Anritsu conducted a research with the Nagoya City University about the effect of x-rays on the pharmaceutical quality of drug tablets and found that exposure to x-rays did not affect pharmaceutical quality of the drug content.

We exposed commercially available non-steroidal anti-inflammatory drugs (acetaminophen, loxoprofen and mefenamic acid) to x-rays of various doses from 0.34 mGy to 300 Gy, and evaluated the quality of the tablets using pharmaceutical tests. We found the samples exposed to x-rays exhibited almost the same profile in the tests as control samples (0 Gy). We also investigated the influences of heat and humidity on drug tablets after x-ray exposure, and confirmed that the combination of x-ray exposure with accelerated temperature and humidity tests (40°C, relative humidity 75%) also did not affect the pharmaceutical quality.

Anritsu Industrial Solutions Co., Ltd. (former company name) and Drug Delivery and Nano Pharmaceutics, Graduate School of Pharmaceutical Sciences, Nagoya City University (Drug Development and Industrial Pharmacy, 2015; 41(6): 953-958).

Anritsu safety mechanism

Safety in design

Anritsu believes customer safety is of utmost importance.

The Anritsu x-ray system incorporates seven safety design features to ensure safe operation.



Safety management

X-ray Inspection System has been designed to fully satisfy the safe operation. However, to ensure even higher safety, use the safety procedures outlined below.

1. Periodic measurement and recording of x-ray leakage data
Please make a maintenance contract including X-ray leakage measurement.
2. Management of operator working hours
3. Additional safety measures
Covers may need to be mounted on upstream and downstream conveyors instead of the shield curtains, depending on the shape, weight, and package of products.
4. No disassembly or modification
NEVER modify or disassemble the main unit, covers, x-ray leakage prevention curtains, safety covers, safety interlocks, etc., otherwise the x-ray leak-proof design may no longer be functional.

X-ray radiation safety

Safety of inspected products

According to the World Health Organization (WHO), "irradiation of any food commodity up to an overall average dose of 10 kGy presents no toxicological hazard and introduces no special nutritional or microbiological problems." *

The maximum dose of x-ray radiation to the products moving through Anritsu x-ray inspection systems is 2.0 mGy, which is 5 million times lower than the WHO threshold.

*Wholesomeness of Irradiated Food: Report of a Joint FAO/IAEA/WHO Expert Committee, 1980

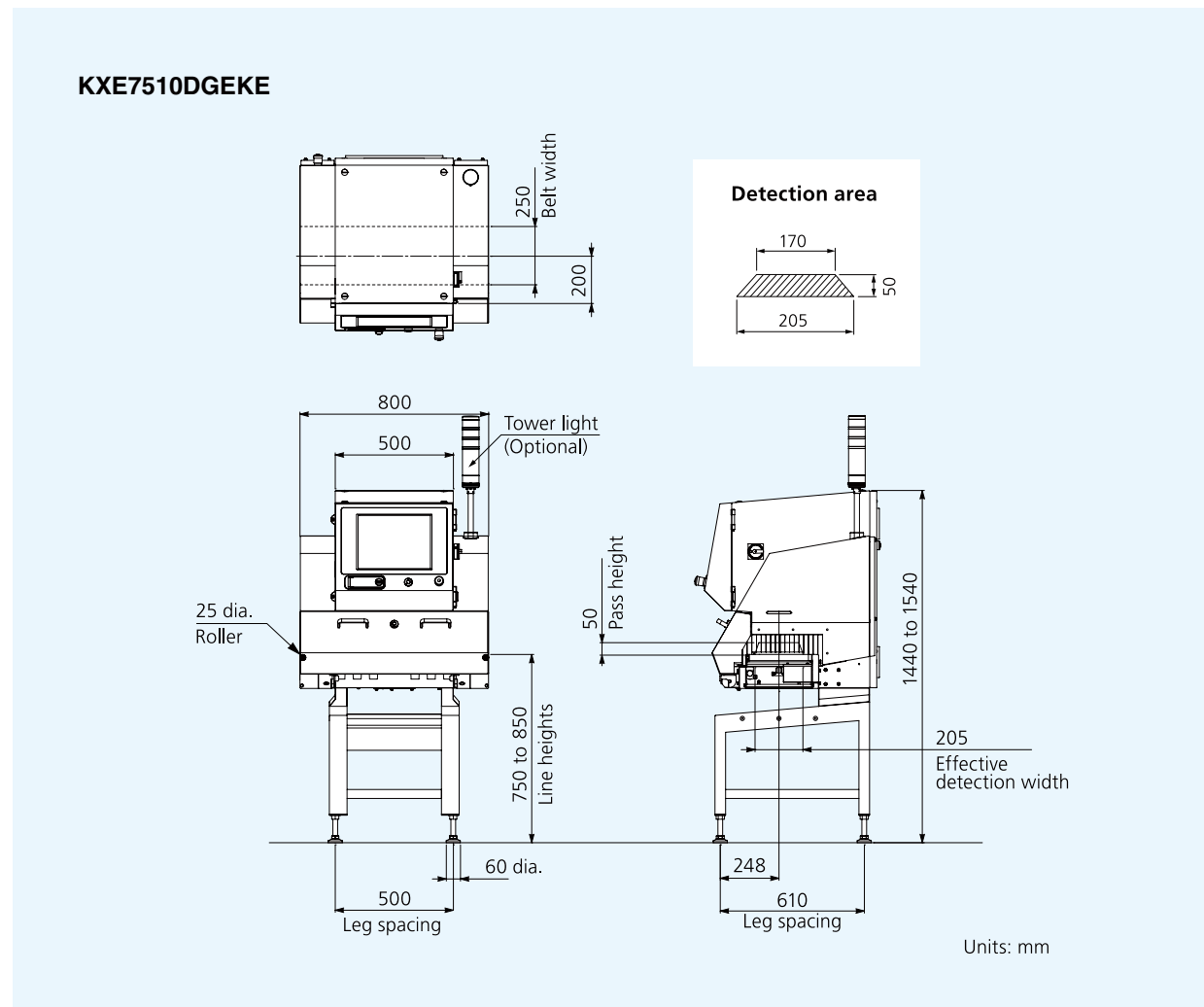
Safety of humans

The average U.S resident receives a total radiation dose of 6.2 mSv/year (620 mRem). About one third (2.4 mSv / 240 mRem) of that annual radiation derives from natural sources like the sun and soil. The rest comes from manmade sources like medical procedures (a typical chest x-ray generates about 0.1 mSv / 10mRem) or air travel (a round trip flight from New York to Tokyo is about 0.2 mSv / 20 mRem).

Throughout the world, most governments consider 20–50 mSv/year (2,000–5,000 mRem) to be safe for occupational workers. Anritsu cabinet x-rays are engineered to meet some of the strictest emission standards in the world. A typical Anritsu x-ray solution is designed for maximum dosage of 2.0 mSv/year (200 mRem) This is based on the improbable scenario of a worker continually being 2 inches (5.08 cm) from the x-ray machine 2,000 hours/year (40 hours/week × 50 weeks). For typical work environments, the actual radiation dose from the cabinet x-ray to the worker is negligible.

Note: Please follow the local laws and regulations regarding the installation and use of the x-ray inspection systems.

External Dimensions



Specifications



Model	KXE7510DGEKE
Safety	X-ray leakage maximum 1.0 μ Sv/h or less, prevention of x-ray leakage by safety devices, lead-free shield curtains with a 10 mm clearance from the conveyor surface as standard
Display	15-inch color TFT LCD
Operation method	Touch panel (with touch buzzer)
Detection area ^{1, 2}	Maximum width 205 mm, Maximum height 50 mm
Belt width	250 mm
Preset memory	200
Belt speed ³ / Maximum product weight ⁴	10 to 90 m/min, maximum 2 kg
Power requirements ⁵	100 Vac to 240 Vac, single phase, 50/60 Hz, 1.0 kVA or less
Mass ⁶	230 kg
Environmental conditions	Temperature: 0°C to 35°C, Relative humidity: 30% to 85%, non-condensing
Protection class	IP40
Exterior	Stainless steel (SUS304)

1 : The product size should fall below the detection area.

2 : The entrance and exit may require covers depending on the length of a product.

3 : Variable depending on Product No.

4 : Sum total of product weight on the conveyor.

5 : Allowable power fluctuation range is $\pm 10\%$.

6 : Mass without option.

Pharmaceutical Quality Assurance based on GMP

We offer a wide range of inspection solutions including dynamic weighing, contaminant and shape detection for the pharmaceutical manufacturing and packaging process.

Filling control/Weight check

Seal check/Missing tablet check



Tablets



Capsules



Sachets / Sticks



Tubes



Bottles / Cans

Pharmaceutical
Metal Detector



Capsule Checkwigher



Built-In Multi-Lane
Weighing System



Multi-Lane
Checkweigher



Aerosol Inhaler
Checkweigher



Small Bottle
Checkweigher



*Non-conforming to CE marking

*Non-conforming to CE marking

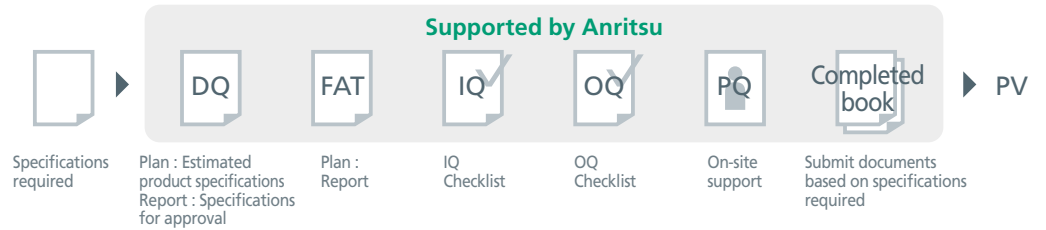


Pharmaceutical
X-ray Inspection
System



Supporting CSV guidelines : Validation support

Anritsu also provides IQ/OQ checklists and on-site support during PQ process.



Missing Blister pack check



Missing insert check (magnetic ink)



Missing pack check



Missing carton check



SSV-h Series Checkweigher conforming to CFR 21 Part 11



*MID approval

M Series Metal Detector



*Non-conforming to CE marking

SSV-h Series Checkweigher



*MID approval

Case Checkweigher



*Non-conforming to CE marking

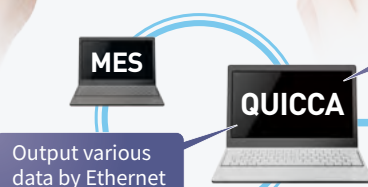
Quicca Pharma

Overall Quality Management and Control System for Pharmaceutical

Support making good use of data by various CFR 21 Part 11 complied functions.

Delivering Data Integrity as specified by CFR 21 Part 11 by utilizing the data from the machine connected to the network.

- User Authentication Management
All user access is managed centrally.
- Audit Trail
The history of operations and actions related to production and results of operation check are recorded and displayed in list-view style for easy and quick view.
- Production Analysis
Production progress monitor and Overall Equipment Effectiveness (OEE) can be viewed in real time.
- Quality Analysis
Statistic data and individual data are recorded via Ethernet.

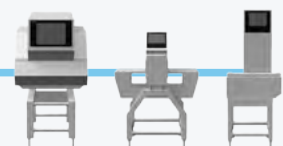


Display each data with different statistic method as your preference.

Ethernet

« Inspection results

Various inspection machines





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- To ensure proper operation, read the Operation Manual before using the machine.
- In addition to daily inspection, a full maintenance inspection should be completed annually.

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