

# 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 to detect, whether by visual or camera inspection, product defects such as missing or chipped tablets and products caught in sealed parts.

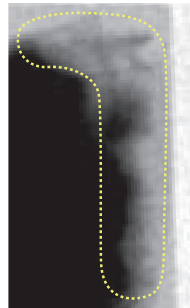
Anritsu developed an x-ray inspection system designed specifically for pharmaceutical products. Its unique x-ray control technology enables pharmaceutical manufacturers to inspect transdermal patches caught in sealed areas and broken or missing pieces of orally-disintegrating tablets that were previously undetectable.





## High sensitivity and high stability

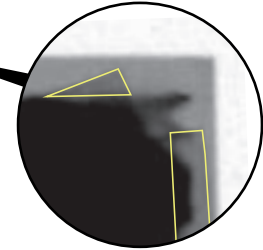
The Anritsu Pharmaceutical X-ray Inspection System is equipped with a new X-ray unit most suitable for the inspection of thin products, which easily transmit x-rays. With significantly improved X-ray image quality and reduced variation in quality, which occurs in visual and tactile inspections, the system contributes to quality stabilization.



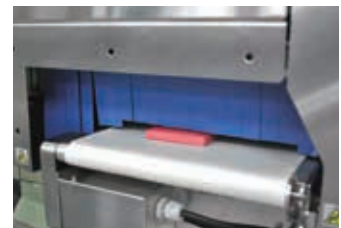
Conventional models



New model



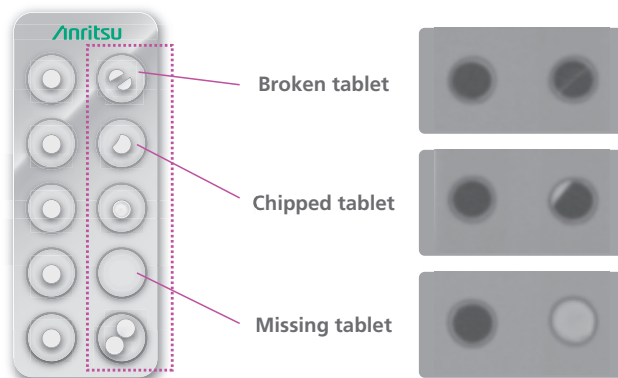
Our unique technology minimizes x-ray leakage so that a product with a height of 10mm or less can be conveyed without touching the leakage prevention curtain, which reduces the problem with false rejects caused by product jam or the disturbance of product orientation during conveyance. It also ensures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



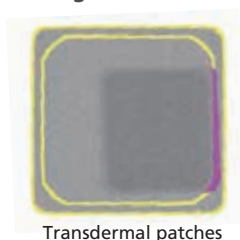
## The system performs a variety of product integrity checks

The Anritsu Pharmaceutical X-ray Inspection System provides not only contaminant detection but also product verification simultaneously. Products in various types of retail packaging can be inspected for shape, count, and package check.

### ● Shape Inspection / Missing Product Detection



### ● Package Check



Transdermal patches



Facial treatment mask



Liniments

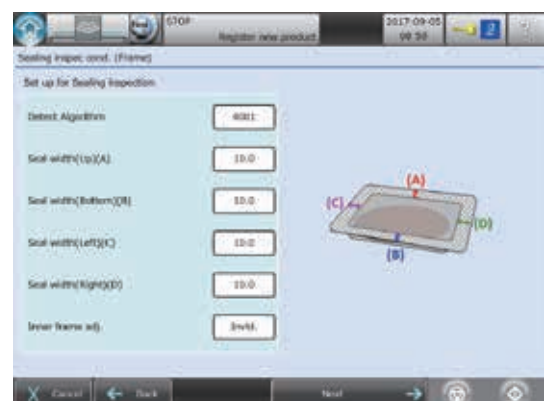


## Setting the system with ease

**Anyone can easily set the system to achieve high sensitivity.**

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 the system with the optimum use.

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



# Supporting FDA 21 CFR Part 11

The KXE7510DGEKE model corresponds FDA 21 CFR Part 11 regulation with Eligibility authentication, Audit trail, Data encryption and decryption which all deliver a piece of mind to processors in the pharmaceutical industries.

## 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, 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 including statistical and parameter data from Audit trail can be easily transmitted.



## 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.







# 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.

### Emergency stop switch

Cuts power to x-ray and drive circuits, stops the conveyor and x-ray radiation

### X-ray ON/OFF key

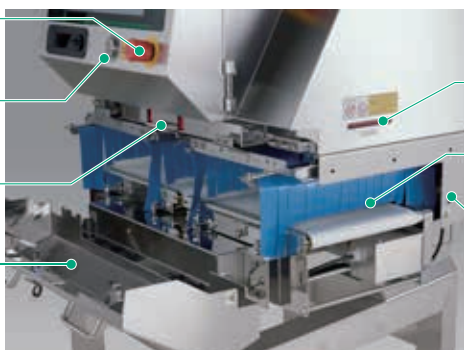
Turning the key to OFF stops x-ray radiation completely

### X-ray shield cover open/close sensor

Opening the cover stops x-ray radiation completely

### X-ray shield cover

Opened/Closed using x-ray irradiation ON/OFF key. Opening the cover stops x-ray radiation due to the x-ray shield cover open/close sensor



### X-ray irradiation display

The lamp is lit during x-ray radiation

### Leakage prevention curtain

Prevents x-ray leakage

### Hand insertion sensor

Interrupting the sensor for a certain period of time stops x-ray radiation

## 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

### 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.

### 2 Management of operator working hours

### 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.

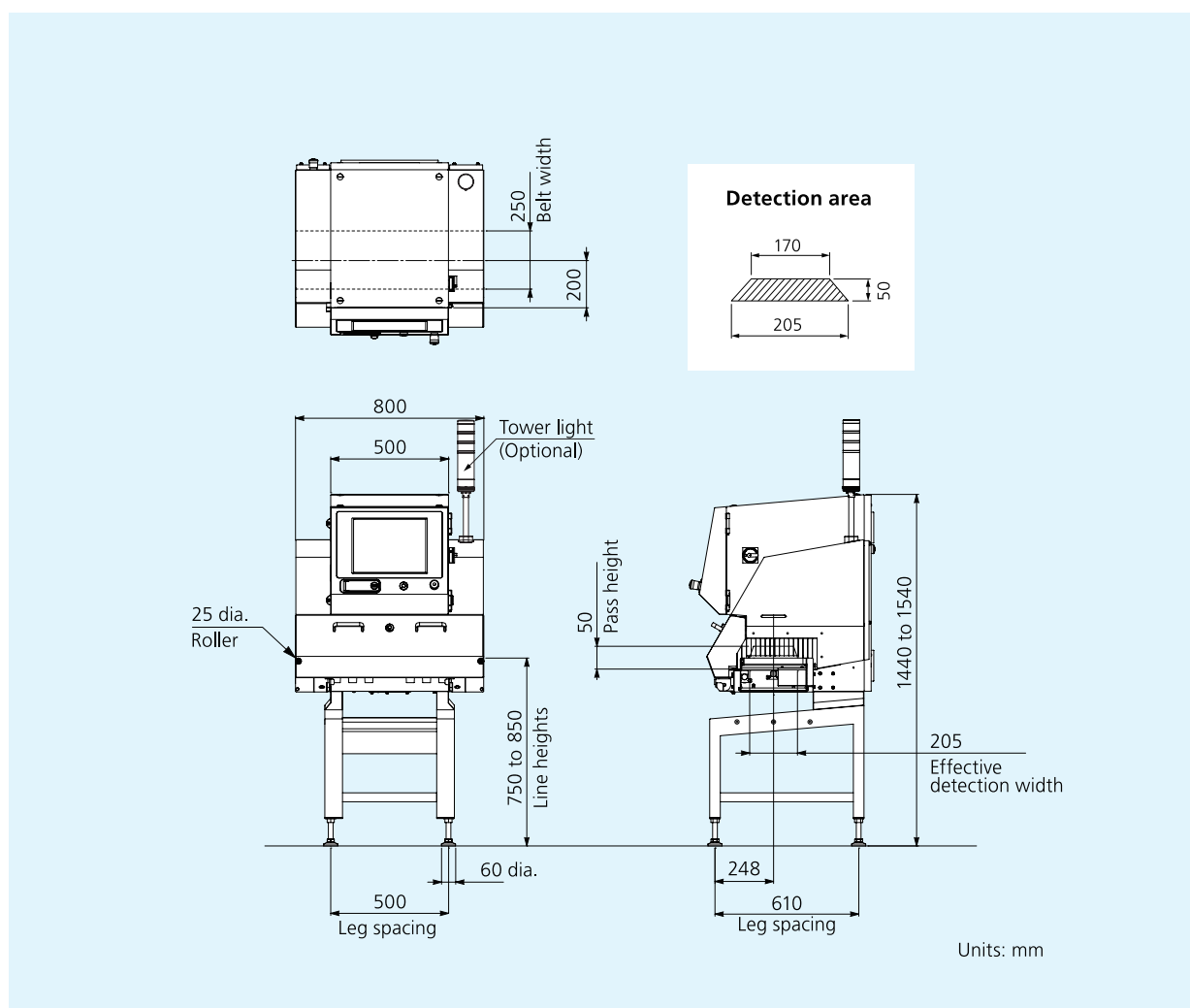
## Safety of inspected products

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. For more details, refer to the full report at <http://informahealthcare.com/ddi>

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

## External Dimensions



## Specifications



Model	KXE7510DGEKE
Safety	X-ray leakage maximum 1.0 $\mu$ 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 <sup>1,2</sup>	Maximum width 205 mm, Maximum height 50 mm
Belt width	250 mm
Preset memory	200
Belt speed <sup>3</sup> / Maximum product weight <sup>4</sup>	10 to 90 m/min, maximum 2 kg
Power requirements <sup>5</sup>	100 Vac to 240 Vac, single phase, 50/60 Hz, 1.0 kVA or less
Mass <sup>6</sup>	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  $\pm 10\%$ .

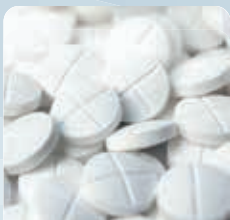
6 : Mass without option.

# Pharmaceutical Quality Assurance based on GMP

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

## Filling control/Weight check

## Seal check/Missing tablet check



Tablets



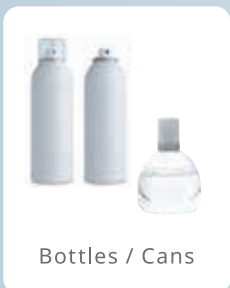
Capsules



Sachets / Sticks



Tubes



Bottles / Cans

Pharmaceutical  
Metal Detector



Capsule Checkweigher



Built-In Multi-Lane  
Weighing System



Multi-Lane  
Checkweigher



Aerosol Inhaler  
Checkweigher



Small Bottle  
Checkweigher



\*Non-conforming to CE marking

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\*Non-conforming to CE marking

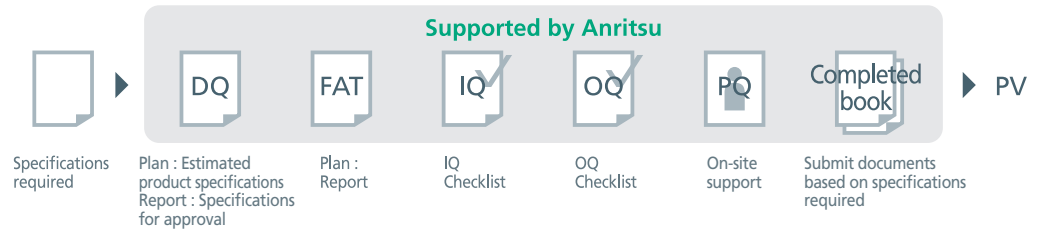
Pharmaceutical  
X-ray Inspection  
System





Supporting CSV guidelines :  
**Validation support**

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



**Missing blister pack check**



SSV-h Series Checkweigher conforming to CFR 21 Part 11



\*MID approval

**Missing insert check (magnetic ink)**



M Series Metal Detector



\*Non-conforming to CE marking

**Missing pack check**



SSV-h Series Checkweigher



\*MID approval

**Missing carton check**



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.

- **Eligibility Authentication (User 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.
- **Data for Quality**  
Statistic data and individual data are recorded via Ethernet.



MES

QUICCA

Output various data by 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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