

Seidenader X-Ray Module to inspect where you cannot see

Seidenader and Dylog, the largest manufacturer for X-ray inspection modules, have closed an agreement for international cooperation in the pharmaceutical industry. Seidenader is integrating Dylog's inspection modules either into dedicated machine platforms or into Seidenader's range of automatic inspection machines. This combines the experience of two market leaders to the advantage of our customers.

Areas of Applications:

Particle inspection in powders and lyophilized products

Detection of particles in non transparent products has been a challenge ever since. X-ray inspection allows the reliable detection of dense particles like glass and metals.

Particle inspection in emulsions and suspensions

Liquids which are intransparent can only be inspected for particles which are visible to operators or cameras if they touch the inside wall of the container. X-ray can detect glass chips and metal pieces in liquids even if they are not readily visible from the outside.

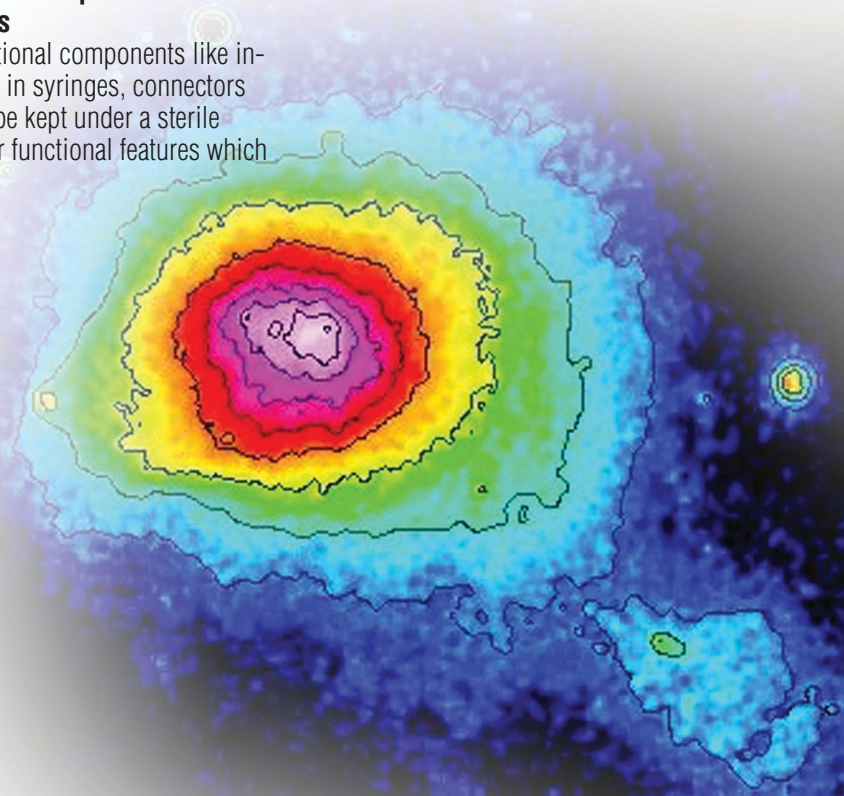
Components under plastic or rubber covers

Important functional components like injection needles in syringes, connectors which have to be kept under a sterile cover and other functional features which

are not open for camera or operator inspection can be inspected for presence, proper orientation and breakage.

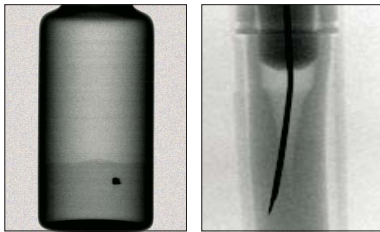
Advantages

- Full inspection of intransparent liquids, powders and lyophilized products
- Elimination of manual shaking and handling of vials and bottles
- Documentation of all inspections by generating images of defects
- Fully embedded in Seidenader inspection machine PLC and HMI structure



Function

1. Products are passing the X-ray head in a defined position in a special guide system from top and bottom.
2. X-ray penetrates the powder, dense objects block rays.
3. The X-ray signal is received and converted into a digital image.
4. The image is analyzed by a vision processing tool.
5. Pass/fail signals are sent to PLC which is tracking each product and activates a reject gate.

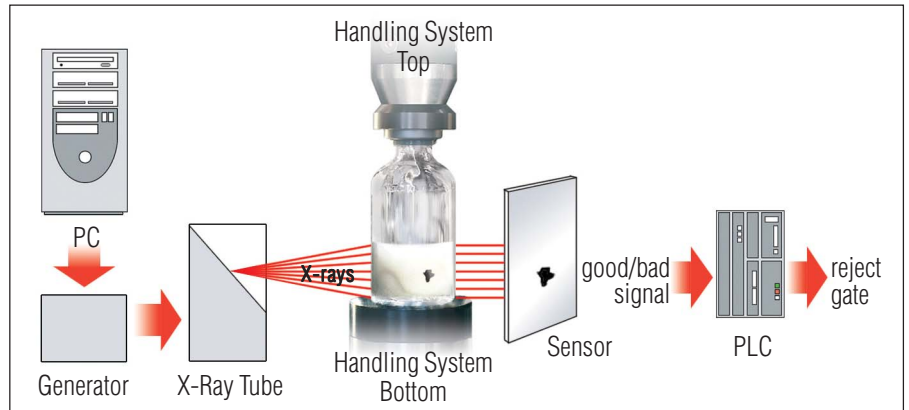


Particle in Iyo cake

Bent needle

Case Studies - History

- 1996 Seidenader have performed feasibility studies to use X-ray to detect particles in insulin.
- 2000 Seidenader have presented a concept to inspect emulsion products using X-ray, in co-operation with the University of Erlangen.
- 2003 Seidenader and a major French pharmaceutical manufacturer have made tests with X-ray to inspect syringe needles covered by plastic shields.
- 2004 Seidenader have made tests to check the profile of syringe needles covered by rubber covers for a German manufacturer of glass syringes.
- 2006 Seidenader in cooperation with Dylog present an inspection module to detect particles in powder filled and lyophilized products.



Technical Data **DYLOG X-Ray Module**

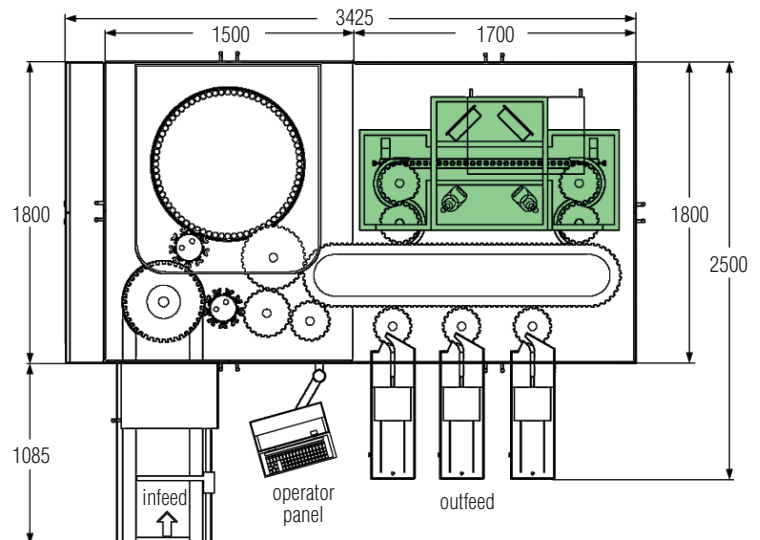
Typical exposure: - for particle inspection 25 μ Sv, for needle inspection less
- exposure time less than 200 ms at 300 inspections/min

For comparison: intercontinental flight 40-90 μ Sv cosmic radiation, 1/2 year storage about 750 μ Sv natural radiation

Throughput rate: up to 400 inspections/min depending on application

Dimensions depending on application

Design: integrated design complies with current GMP recommendations, OSHA regulations, CE requirements, EN 60204-1 and 21 CFR part 11

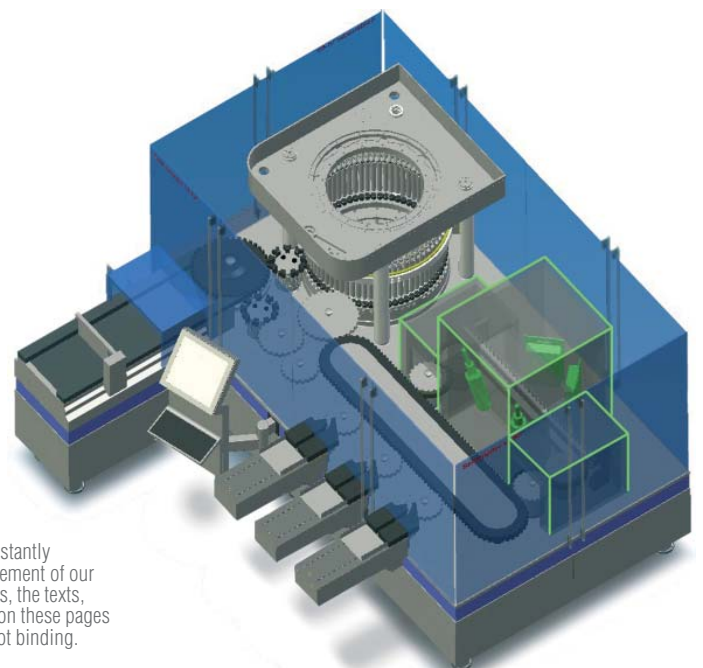


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