Examining X-Ray Technology

Ray Spurgeon
Eriez

Use X-ray inspection to see whether your product is contaminant-free and packaged properly.

X-ray technology plays an important role in the inspection of food, pharmaceutical, chemical and other packaged products. For example, in food production, X-ray inspection systems help ensure product purity and package integrity by reliably identifying foreign objects, scanning for broken products, detecting package voids, confirming fill levels, inspecting mass, and analyzing fat content.

This article discusses cabinet X-ray systems — what they are, how they work, what they can (and cannot) do, and safety considerations related to their use.

As shown in Figure 1, the heart of a cabinet X-ray system is an X-ray generator and detector array installed in an enclosure designed to minimize X-ray emissions. The cabinet also prevents access to the interior of the enclosure. In addition, today's state-of-the-art X-ray machines employ sophisticated algorithms for optimal detection. Other features include external USB connectors for communication and troubleshooting. Cabinet X-ray machines can be installed on conveyer lines that move packaged products or bulk materials, or on pipelines (Figure 2).

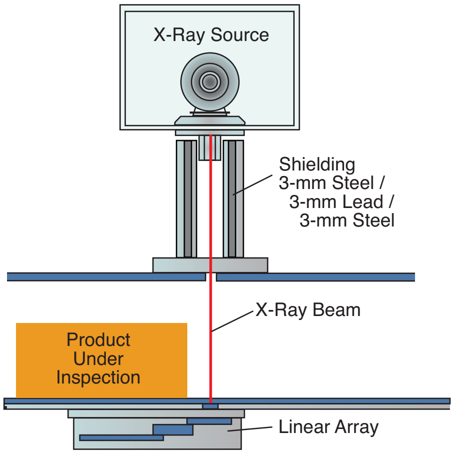
Most cabinet X-ray systems operate at very low energy levels (from 50 to 70 keV) to improve equipment longevity and provide the highest-resolution image. Higher energy can burn through small foreign objects that may be present. When the product is dense, (*e.g.*, a block of cheese), higher-energy (120 keV) systems are warranted to enable the photons to better penetrate the product.

The high-voltage tanks used in cabinet X-ray machines need to be kept cool to ensure the longevity of the tubes contained within. This can be achieved by submerging the X-ray tubes in oil and providing an external fan, or using a pump to circulate oil through a radiator. The radiator system adds to the cost, but such systems are completely sealed and are suitable for use in dusty or wash-down environments.

Alternatively, a simple, low-cost approach to cooling is an exhaust fan mounted on the cabinet. However, this method cannot be used in dusty or wash-down environments. An intermediate choice is a vortex cooler. These coolers are mounted on top of the cabinet and are completely sealed, so the system can be used in a wash-down environment. The disadvantage of this design is a higher initial cost as well as higher operating costs for compressed air.

X-ray vision in action

A cabinet X-ray machine uses low-energy radiation to penetrate the product, enabling the adaptive algorithm to automatically reject off-specification product. As shown in Figure 3,



■ Figure 1. The heart of a cabinet X-ray inspection system is the X-ray source and the detector array. These are contained in an enclosure designed to minimize radiation emissions.

X-rays are channeled into a thin fan-shaped beam that is collimated (*i.e.,* aligned) to scan the product on a belt or in a pipeline. The collimated fan beam is directed toward the detector (a silicon array of photodiodes) as the conveyed material passes through the assembly.

When the product moves through the beam, a gray-scale image is generated (Figure 4). Each image is made up of pixels, each of which is assigned a value ranging from 0 for black (the densest portions of the product) to 255 for white (least dense). The arrow in Figure 4a points to a pixel with a gray-scale value of 150.

■ Figure 2. Cabinet X-ray systems can be used to inspect products passing through on a conveyor (left) or in a pipeline (right).

Algorithms use the pixels' gray-scale values to create a histogram that depicts the number of pixels of each value. In Figure 4b, 19 pixels have a value of 255, one has a value of 240, four 215, and so on, down to the pixel with a value of 69 representing the densest area of the product.

Most contaminants, such as metal, glass or stone, are denser than the product being scanned. Here, a small (approximately 1.5-mm-dia.) piece of glass (the red dot) contaminates the product; its gray-scale value is 6. This is well below the 69–255 range that has been established as normal for the product. The system's software interprets the out-of-range value as an anomaly and sends a signal that triggers the automatic rejection of off-spec product.

Liquid emulsions and slurries in pipelines can be scanned in a similar manner. The system will detect small variations in product density that indicate contamination or deviation from accepted specifications. This activates a three-way ball valve, providing precise rejection of the impurity.

A cabinet X-ray system enables a manufacturer running thousands of packages or pounds of product through the process to check for contamination, as well as for:

• *absence* — by measuring the gray-scale differences in the X-ray image, the technology can determine if any product is missing from a package (Figure 5)

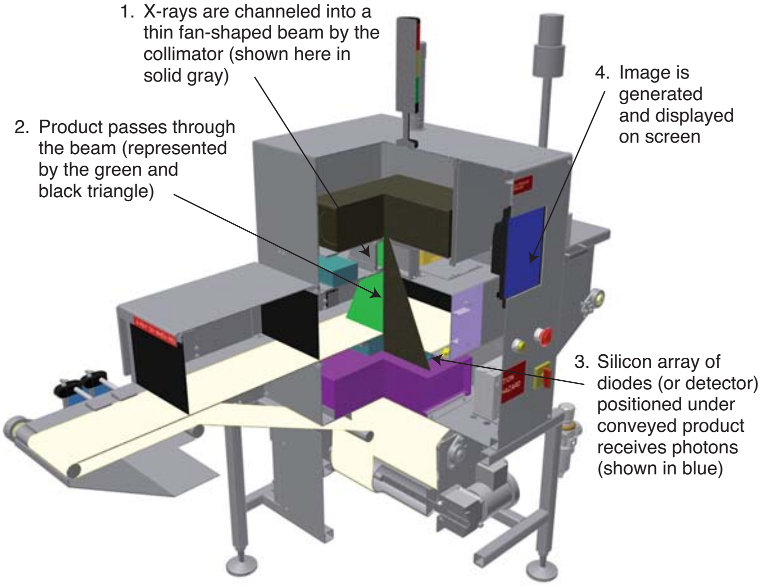
• *damage* — a gray-scale algorithm can be designed to measure crushed or damaged product, which cannot be detected by weight measurements, as those would yield the same results for good product and bad product (Figure 6)

• *amount* — the machine can count the items in a package and reject those that do not have the correct number (Figure 7)

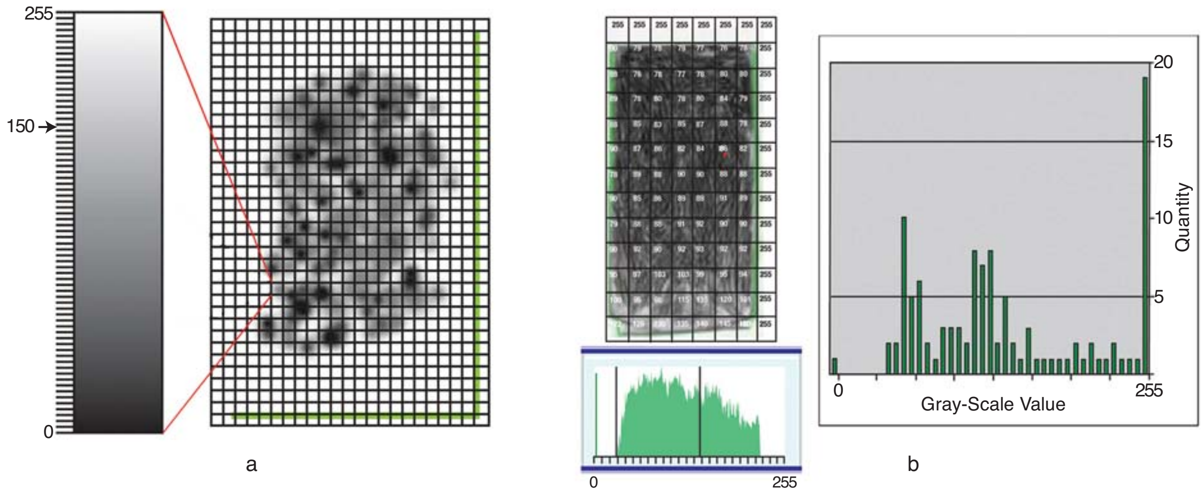
• *accompanying materials* — if the package should contain a leaflet (*e.g.,* instructions), the machine can determine whether the leaflet has been included and verify that it is in the proper position (Figure 8).

Contaminant detection

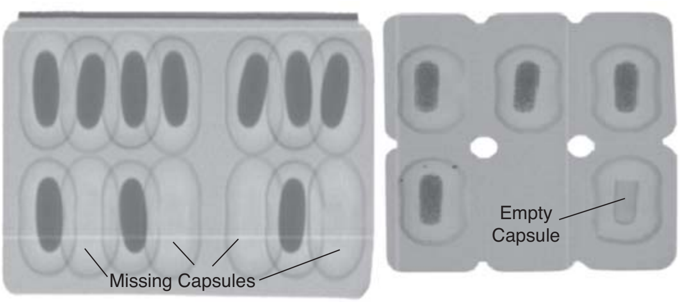
An important function of cabinet X-ray systems is contaminant detection. An X-ray machine will detect foreign objects, such as metal slivers introduced by broken dies on tablet press machines. Contaminants can be revealed in several ways, including gray-scale images as discussed earlier or by atomic weight.



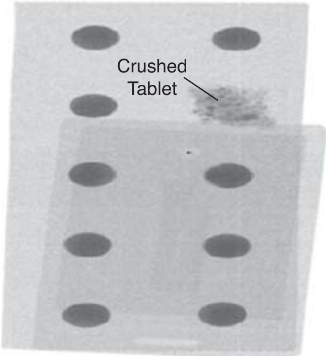
■ Figure 3. X-rays are generated in a tube and channeled into a fan-shaped beam that passes through the product to the detector.



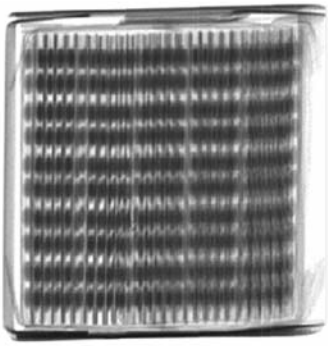
■ Figure 4. Each pixel in the X-ray image of a product is assigned a gray-scale value of 0 to 255, then a histogram displaying the number of pixels of each gray-scale value is created.



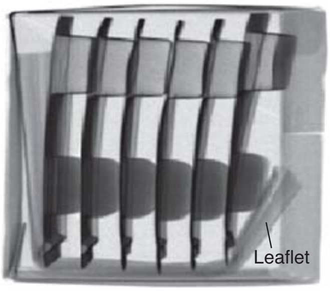
■ Figure 5. Using gray-scale analysis, X-ray inspection can easily detect if any capsules are missing (left) or empty (right).



■ Figure 6. Mass analysis would indicate the presence of the correct number of tablets, but would not be able to determine that one of the tablets is crushed. The gray-scale histogram produced by a cabinet X-ray system would identify this anomaly.



■ Figure 7. The number of items in a package can be confirmed.



■ Figure 8 (right). X-ray analysis confirms that the patient-instruction leaflet is present in this medication package.

For instance, food and pharmaceuticals are primarily composed of carbon, hydrogen and oxygen atoms. Metal, glass and calcified bone are detectable contaminants because they have atomic numbers higher than those of the base materials being scanned.

Conventional metal detectors can be affected by improper conveyor design, foil packaging, liquids, conductive products, and ambient noise; these do not affect X-ray machines. Many foods and pharmaceuticals are sold in foil packaging, which renders a metal detector impractical; however, an X-ray system can be an effective method for inspecting these types of products.

X-ray technology does not detect every kind of contaminant. For example, it cannot detect certain types of plastic, hair, insects or wood, as these have similar atomic makeup and little gray-scale difference.

Safety

Before discussing X-ray safety, it is important to understand some key terminology:

• *Exposure vs. dose*. *Exposure* is the amount of ionizing radiation that strikes living or inanimate material. *Dose* is the quantity of radiation or energy absorbed. Dose may refer to either the *absorbed dose,* which is the amount of energy deposited per unit mass, or the *equivalent dose,* which is the absorbed dose adjusted for the relative biological effect of the type of radiation being measured.

• *Roentgen* (R) is a unit of exposure of ionizing radiation; it indicates the strength of the ionizing radiation. One Roentgen is the amount of X-ray needed to produce ions carrying one electrostatic unit of electrical charge in one cubic centimeter of dry air under standard atmospheric conditions.

• *Roentgen absorbed dose* (rad) is the basic unit of absorbed radiation dose. A dose of one rad to an object means that each gram of the object received 100 ergs of energy, *i.e.*, 1 rad = 100 ergs/g.

• *Roentgen equivalent man* (rem) is the basic unit of equivalent dose; it relates the absorbed dose in human tissue to the biological effect of the radiation. Not all radiation has the same biological effect, even for the same amount of absorbed dose.

X-ray emissions are measured in milliroentgen (mR). An emission of 1 mR results in a dose of approximately 1 millirem (mrem).

The U.S. Food and Drug Administration (FDA) has set a maximum exposure limit for emissions from cabinet X-ray machines at 0.5 mR/h at any point 5 cm from the external surface of the device (21 CFR 1020.40). Most cabinet X-ray machines emit at levels that are well below this. At this low level, most states do not require operating personnel to wear personal monitoring devices.

To put this into perspective, when flying in a commercial airplane at altitudes of 30,000–40,000 ft, one is exposed to about 3–4 mR/h from cosmic radiation. Other sources of naturally occurring radiation are certain rock or clay deposits containing elements radon, uranium or thorium. Man-made sources of radiation include airport, medical and dental X-rays, projection television sets, and tobacco, most of which have emission levels that far exceed the levels emitted from cabinet X-ray machines.

Objects scanned by a cabinet X-ray machines typically receive a radiation dose of 1 millirad (mrad) or less. The minimum radiation dose used for food preservation or pathogen destruction is 30,000 rad. Thus, when used properly, X-ray systems will not degrade or irradiate products.

The design and construction of X-ray systems are regulated by the FDA's Center for Devices and Radiological Health (CDRH). Section 40 ("Cabinet X-ray Systems") of 21 CFR 1020, "Performance Standards for Ionizing Radiation Emitting Products," requires many safety features (Figure 9). Steel covers and curtains, which serve as shielding and prevent virtually all radiation from exiting the system enclosure, must be present. In addition, doors must be equipped with safety interlocks, which disconnect power to the X-ray generator if they are opened; as a failsafe mechanism, the interlocks have two circuits passing though them. High-visibility light towers are required to indicate when X-rays are being generated. Finally, emergency stop buttons, accessible from both sides of the machine, and a keyed lock-out switch to disable the system add another layer of safety.

■ Figure 9. FDA standards require X-ray equipment to include numerous safety features.

X-ray equipment must be registered according to state and local regulations. Companies that use a cabinet X-ray system must develop a safety audit program, operating and emergency procedures, and an employee training program. A radiation safety officer or other "responsible person" (as defined in the standard) must be designated, and some states require records of operating personnel exposure to be kept.

Choosing an X-ray inspection system

To determine whether a cabinet X-ray system is right for your application, it is important to thoroughly understand the technology's capabilities and limitations as discussed here.

Consider product testing, which many manufacturers offer to customers at no charge. By supplying the X-ray manufacturer with samples of your products, you can find out what the machines can actually do for you. It is also advantageous to have the manufacturer conduct a plant survey to understand the full scope of the application.

To make a good selection, the following factors (among others) should be considered: whether the product is packaged in foil; the amount of available floor space; the types of foreign objects that may be expected; and price.

Most manufacturers offer a range of systems at various costs to handle diverse applications. The prices of cabinet X-ray systems range from approximately $50,000 to more than $100,000. Actual costs depend on the unique needs of the process and the configuration of the system. CEP

RAY SPURGEON, JR., is Product Manager – Inspection Systems for Eriez Magnetics (2200 Asbury Rd., Erie PA 16506; Phone: (814) 835-6298; E-mail: rspurgeon@eriez.com), where he oversees all aspects of the X-ray division, including applications, FDA and regulatory compliance, technical presentations, and sales representative training. Since 1995, he has served in various capacities in this division, including assistant product manager and technical sales representative. He has had numerous white papers published on food safety and foreign object detection. He attended Penn State Behrend College, Gannon Univ., and Edinboro Univ., where he studied industrial management, and sales and marketing. He also completed radiation safety courses with the Radiation Safety Academy.