Helping keep pharmaceuticals safe: metal detection overview and guidelines

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Using metal detection as a means of identifying foreign object contamination has been prevalent in the food industry for decades. Metal detection traditionally has been the first line of defense to identify the presence of ferrous, non-ferrous, or stainless steel contaminants in food products before they have the chance to leave the processing plant.

Although in use for tablets and capsules by the pharmaceutical industry for 40 years, the application of metal detection at other points in the production process has not been widespread. One of the main reasons is that the most common forms of drug packaging—blisters, vials and plastic bottles—typically incorporate a foil component making metal detection quite challenging, if not impractical.

However, since pharmaceutical manufacturing is not immune to metal-object contamination, it is important to discuss ways to effectively incorporate metal detection into the production or packaging processes when practicable.

Figure 1 — The Thermo Scientific APEX 500 Rx pharmaceutical metal detection system showing detail of the rejection system. The system is placed at the outlet of the tablet press, deduster, or capsule filler. Every product coming off the production line passes through its aperture and is metal detected.

Possible sources of metal contamination

Metal contaminants typically come from one of four sources:

1. Raw ingredients: metal chips and flakes from pipes, cargo tanks, bins, etc.
2. Machinery: parts not properly tightened, decaying molds, machine aging, two parts rubbing together, vibration, etc.
3. People: accidental or intentional actions
4. Environmental: plant construction, building failure, HVAC system

Since metal is prevalent on any automated production line, there is always the possibility of contamination occurring.

In pharmaceutical processing facilities, possible contamination gateways include raw ingredients, during the mixing process, and in the tablet pressing and capsule forming and filling stages. In short, at any point in the production process prior to package sealing.

With lines operating at fast speeds and machine parts in repetitive motion, often vibrating, it is possible for a small metal component to become dislodged and unintentionally find its way into the product. The contaminants can vary from small screws, washers to metal shavings and thin wires.

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Metal detection in the pharmaceutical industry

A broad range of pharmaceutical products are suitable for metal detector inspection. These include solids, powders, liquids and gels.

Pharmaceutical companies have been utilizing metal detectors immediately after a tablet presses for nearly four decades, while metal detectors have been used after dedusters for about 15 years.

Metal detectors designed specifically for these types of applications are capable of detecting magnetic or conductive metals as small as a 0.3-mm diameter sphere. Operating at speeds up to 500,000 tablets or capsules per hour, far exceeding the capabilities of the naked eye, a metal detector can play an important role in removing products with contaminants before they get to the packaging operation.

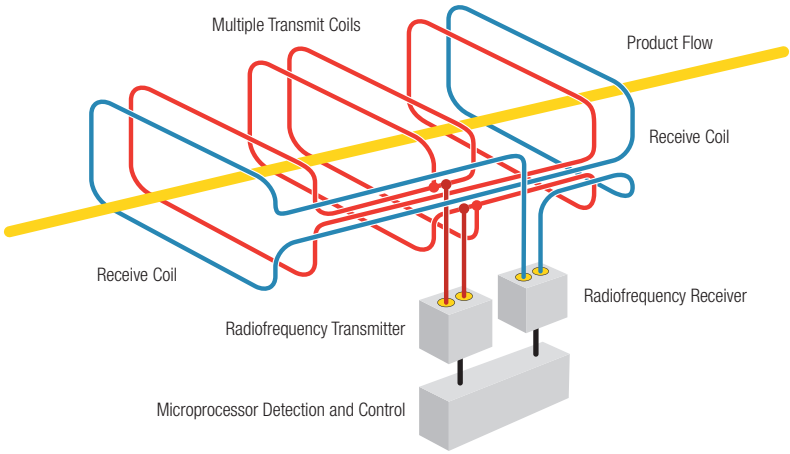

Figure 2 — Multicoil architecture in a metal detector results in higher sensitivity.

On plastic bottle packaging lines, metal detection, if performed at all, has typically been done prior to the capper and induction sealer. This is because most metal detectors are not able to perform the inspection after the foil seal is adhered to the bottle. The inspection is therefore performed with no cap on the bottle, thus providing the possibility of a metal contaminant entering the bottle after these two machines.

There have been recent advancements in metal detection technology that now permit bottles with foil seals to be tested after the induction sealer. This provides a true, end-of-line, final inspection for metal contaminants. The size of contaminants that can be detected are dependent on the bottle and foil size, foil thickness and position of the product inside the metal detector.

How metal detectors work

A typical metal detector contains a transmitter antenna that sends out a radio frequency signal ranging from 300 kHz to 1 MHz *(see Figure 1)*. Two receiver antennas sit on each side of the transmitter at equal distance from the transmitter. When the system is balanced and there is nothing magnetic or conductive inside the metal detector aperture, the difference between the two signals is zero, signifying that no metal is present.

Table 1 — Typical detectable metal diameter by aperture size.

Contaminant Type	Aperture Size		
	100 mm x 25 mm	100 mm x 35 mm	100 mm x 50 mm
Ferrous Metal	0.30 mm	0.35 mm	0.40 mm
Non-Ferrous Metal	0.30 mm	0.35 mm	0.40 mm
Non-Magnetic Stainless Steel	0.50 mm	0.55 mm	0.60 mm

When metal is present and traveling through the detector, a detectable imbalance is created. The accurate performance of this system depends on three factors:

- The closeness of the metal that is being detected to the antennas or coils (i.e., the aperture or opening size)
- The effectiveness of the fields created by the transmitter (i.e., the transmitter-antenna design)
- The signal frequency used (the higher the frequency, the better the detection of conductive, nonmagnetic metals).

The receivers' signals are digitized and analyzed by a digital-signal processor (DSP) that filters the signals. The DSP uses signal-processing algorithms to increase the probability of an accurate detection. The signals have two components: one is magnetic (X), and one is conductive (R). These components enable the system to detect metal foreign objects that are mainly conductive and have a small amount of magnetism such as in 316-alloy stainless steel.

As a result, detection of conductive metal objects relies on a different signal analysis than a ferrous- (iron) containing metal. Most metals exhibit both magnetic and conductive behaviors; these behaviors can change with the size of the metal.

In some applications, the ability of the system to ignore the signals that can be caused by the uncontaminated product passing through the metal detector is crucial. For example, some products may have a chemical composition that appears to be slightly magnetic or conductive to the metal-detector fields. This type of product effect can be ignored by the system by first learning the magnitude of the product's X and R signals.

During production, the system creates a region where any combination of X and R signals with the same ratio and similar magnitude are thereby ignored. This process, called phasing, is typically only required in pharmaceutical applications using products that have high concentrations of iron or other metallic elements.

One new technology is the inclusion of multicoil arrangements in metal detectors to improve the signal obtained by the receiver. Compared with a single transmitter with two receivers, multicoil arrangements can improve detection performance of the instrument (as measured by the detectable metal diameter) by up to 20%.

Electromagnetic field simulation software can be used to optimize the number and placement of such coils or antennas, which make it easier to detect smaller metal foreign objects without seeing higher levels of false rejections *(see Figure 2)*.

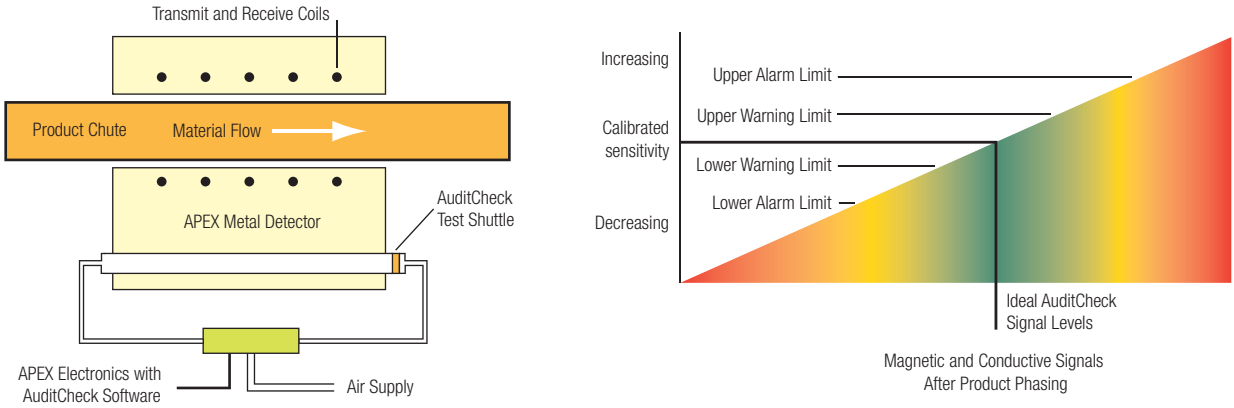

Figure 3 — Thermo Scientific AuditCheck block diagrams. The diagram on the left is a side view of the metal detector, displaying where the product and AuditCheck device passes through the electromagnetic field. The diagram on the right shows how the magnetic (X) and conductive (R) signals are calibrated with the AuditCheck system, and how warning and alarm limits are set.

Selecting a detection system

There are many criteria to consider when evaluating metal-detection systems for tablet or capsule production. Perhaps the most important is the system's sensitivity (i.e., how small a metal fragment can be detected). Prior to packaging, the typical sensitivity range for pharmaceutical tablet and capsule applications is less than 0.5 mm. Another factor is how immune the system is to outside influences, such as vibration and electromagnetic noise, which can cause false rejects *(see Table 1)*.

When selecting the size of the system's aperture, one should consider performance as well as throughput and size to avoid product jams during production.

Sensitivity

One subtle, but important, factor to consider when evaluating different systems is what, if any, effect a product might have on the equipment. Most tablets and capsules "look" like dry products to the metal detector, but it is possible that they may trigger a false reject if they contain significant concentrations of metal elements such as iron.

If a false reject continually occurs, the detector's operating threshold can be desensitized, but this change may reduce the system's performance. Therefore, before making a selection it is important to test the system on all of the pharmaceutical products that may be run through it. This will help to determine how the system will perform in a production setting.

Table 2 — Key criteria for selecting a pharmaceutical metal detection system.

Criteria	Primary Questions to Address
Failsafe operation	Does the system reject all products and alert the operator if a system fault occurs (i.e., loss of power, electronics failure, or software error)?
Flexible mobile operation	Can the system be easily moved in and out of production? Can it be adjusted easily for use with tablet presses and capsule fillers?
Handling effect on the product	Does the system affect products passing through it? If so, is the effect minimal (i.e., cosmetic)?
Product auditing capability	How easy is it to periodically pass sample contaminants through the system to check for detection sensitivity?
Contaminated product notification and contaminant	If a contaminated product is detected, how is the operator notified?
Software ease of use and security	How difficult is it to set up the system's software? How often must this be done? Can the software be password protected from inadvertant changes by the operator?
Ease of cleaning	Can the system be easily disassembled, cleaned, and reassembled? Are the primary parts in contact with the product approved by the U.S. FDA? Is the system rated for full IP65 (i.e., the intellectual protection rating for dust and water (washdown), if required by your cleaning process?
Availability of validaion documentation	Are installation, operational, and performance qualification documentation available for the system, and if so, what does it include?
Design quality	Was the system built using good-manufacturing-practice principles and is the design robust?
Application flexibility	What configuration options are available (e.g., finish, material handling, custom configurations) and do they meet your company's needs?
Total cost of ownership	What typical maintenance is required and how much does the maintenance cost per year?

Once it is determined that a system can detect the smallest fragments of metal possible with no chance of false rejection, there are additional aspects to consider. Table 2 provides a list of key questions to ask when evaluating a system.

Quality control

Another key consideration is how the detection system is audited. Typically, manufacturers audit detection systems every one-to two hours during production to check for detection sensitivity *(see Table 1)*. Most of these audits involve simple pass/fail checks.

An additional automatic early-warning system has been developed that can be set to periodically (i.e., based on user-defined preferences) pass a metal piece through the detector's fields to measure the two primary X and R signals previously defined *(see Figure 3)*. These signals are calibrated during set-up, and any changes from the expected values can generate warnings or alarms to the user.

An early warning allows the user to take immediate action such as cleaning the detector of foreign material or adjusting the detection threshold. As a result, production volume and time can be maximized. In addition, the automation of the audit can help to reduce labor resources.

Operation and deployment

After selecting and implementing a new or upgraded metal-detection system, a short on-line trial test is advised to further determine how the system will perform during production. In addition to the criteria outlined in Table 2, one should consider the following:

1. Did the system reliably detect the metal sizes and types in question?
2. Were there false rejects and, if so, why? Can they be avoided or minimized?
3. Did the system jam?
4. Can the system be adjusted easily to the production process with no loss of material?
5. Was set-up easy and how much operator intervention is needed to run the system?
6. How is the system audited and documented?
7. Can the system be cleaned easily? Can it be disassembled and reassembled quickly?
8. Did the system produce any errors? If so, how did it react?
9. Does the vendor offer a complete validation package?

Conclusion

Equipment manufacturers continue to develop metal object detection systems which offer improved performance and ease-of-use. With more pressure being placed on pharmaceutical companies to make sure that consumer safety is not compromised by adulterated products, it is incumbent upon manufacturers to make sure preventative processes are in place.

Small incidents can cost millions of dollars and lead to total business disruption. How much are you willing to risk? Weigh this against the total cost of ownership for the metal detection system including installation, training, maintenance, repairs and the cost of downtime.

Selecting a metal detection system requires a trial-and-error approach that takes into consideration sensitivity, ease-of-use and audit ability. Once implemented on a production scale, a metal-detection system can help to maximize product safety and quality.

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If you would like to get more information on how we can assist you with your product inspection requirements, please contact us at +1 (800) 227-8891 or sales.packaging.us@thermofisher.com.

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