High-Stability and High-Sensitivity Metal Detection using M6-h Series Metal Detector for Medical Drugs

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[Summary] We have developed a new M6-h series metal detector for inspecting medical-drug tablets and capsules based on the concept of easy operability with high stability and high sensitivity by anyone. This metal detector inherits the same digital signal processing and high stability/high sensitivity/easy usability of its predecessor metal detector in the same series for foodstuffs, while also achieving even better sensitivity and adding a new built-in validation function. It can detect metal test pieces with a volume ratio of about 30% smaller than can be detected by the metal detector for foodstuffs in the same series.

1 Introduction

Globalization of the medical drugs market has led to procurement of raw materials from diverse sources to assure steady supply. In particular, the number of raw materials procured from newly industrializing economies is increasing due to lower manufacturing costs, causing problems with lower product quality resulting from contaminants due to lower quality awareness and management standards compared to more advanced economies. Moreover, with the recent increasing use of fast-dissolving tablets that disintegrate rapidly in the mouth there have been more cases where overlooked product contaminants have been released from the tablet in the mouth. Consequently, more thorough contaminant inspection is required to prevent the risk of patients discovering contaminants in his or her mouth.

In the medical drugs market, when a contaminant is discovered, the entire preceding and succeeding lots are also discarded, causing not only huge financial loss but also a damaged product image. As a result, makers of medical drugs are implementing stricter quality control.

Tablet and capsule production lines use metal detectors to improve product quality by thoroughly examining products for contaminants. These detectors are centered around the tablet and capsule filling machines where there is a higher risk of metal contaminants entering the product, and they are used as dedicated machines testing exclusively for metal contamination. This type of metal detector must be able to detect the finest metal contaminants as tablets and capsules drop through the detector.

To meet these requirements, we have developed a new metal detector based on the concepts of having excellent detection sensitivity and validation functions required by the medical drugs market as well as ease of use. Facilities for manufacturing medical drugs require improved countermeasures against problems, such as vibration and static electric charges, demanding high stability and sensitivity. In addition, monitoring and validation functions must also be incorporated to assure maintenance of the highest stability and sensitivity during production runs to prevent unforeseen misoperation and drops in sensitivity. Moreover, the developed metal detector has high operability and usability leveraging our 40 years of experience in developing metal detectors for inspecting foodstuffs.

This article introduces our development of the M6-h series (Figure 1) of metal detectors for medical drugs with high stability, high sensitivity, and easy usability based on the M6-h metal detector for inspecting foodstuffs.

Figure 1 External View of M6-h Series Metal Detector for Medical Drugs

2 Metal Detectors

2.1 What is a Metal Detector?

A metal detector is composed of a metal-detecting sensor at the detector opening, a conveyor for carrying products to be inspected, a indicator for controlling the overall machinery and displaying detection results, and a rejector for rejecting contaminated products in accordance with the detection results. Figure 2 shows the structure of the developed metal detector for medical drugs using a conveyor chute with a pitch difference.

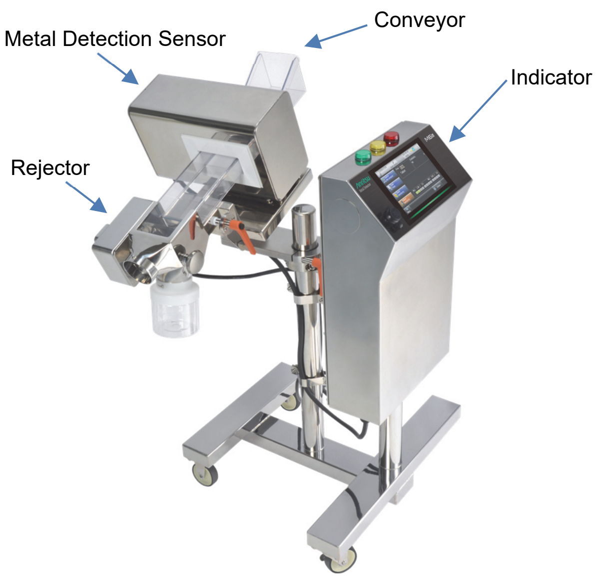


Figure 2 Structure of Metal Detector

The metal-detection sensor detects changes in the magnetic field caused by the passage of products. When the value exceeds some threshold, the respective product causing the field change is evaluated as a metal-contaminated no good (NG) product. Since even normal uncontaminated products can cause magnetic-field changes due to composition, temperature, conveyance conditions, etc., the detected signal for each inspected product has some degree of randomness. As an example, Figure 3 shows the detected-signal randomness of 10 inspected products. Since the detected signal for some uncontaminated (Pass) products is in the yellow range, to prevent excessive mis-identification of Pass products as NG products, it is necessary to allow some margin for the NG evaluation threshold. For high-sensitivity metal-contaminant detection, it is necessary to either amplify the contaminant signal value or decrease the inspected product signal.

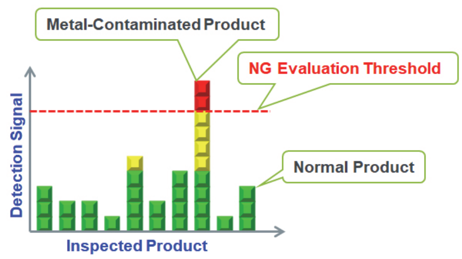


Figure 3 Metal Detector Sensing Image

2.2 Principles of Metal Detector Sensor

2.2.1 Basic Principles of Metal Detector

This section explains the basic principles of the coaxial alternating current (ac) metal-detection sensor used by this metal detector. This sensor is composed of one transmitter coil for generating an ac-magnetic field sandwiched between two differentially connected receiver coils, all of which are wound coaxially and orthogonally to the conveyance direction of inspected products (Figure 4).

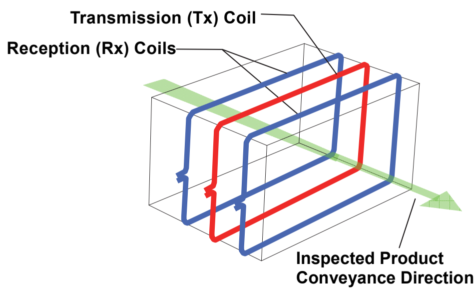


Figure 4 Detection Head Coil

Figure 5 (a) shows the balanced equal conditions of the magnetic flux between the transmitter coil and the two receiver coils when no metal-contaminated inspected product is passing through the sensor, causing no induced voltage in the receiver coils.

Figure 5 (b) shows the conditions when a product containing a ferrous metal, such as iron, passes through the metal sensor; the magnetic flux is drawn to the metal contaminant, causing the balanced flux at the two receiver coils to collapse; the larger the magnetic field generated by the transmitter coil, the bigger the flux balance collapse as the metal-contaminant size increases. Similarly, Figure 5 (c) shows the conditions when the inspected product includes a non-magnetic contaminant, such as stainless steel (SUS); in this case, the magnetic flux is repelled by the contaminant and the balance is distorted to the opposite side from the contaminant. As the field strength generated by the transmitter coil increases, the magnetic frequency increases and the loss of balance becomes larger as the non-magnetic contaminant size increases.

Since the metal detector detects the size of the imbalance, detection of small contaminants is more difficult.

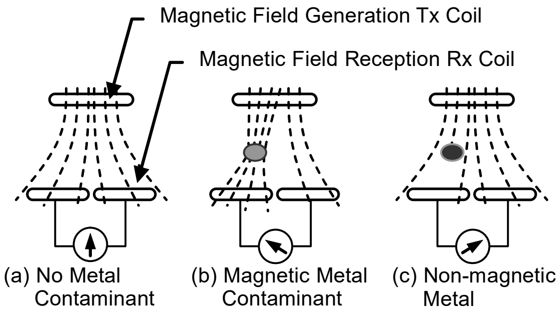


Figure 5 Magnetic and Non-Magnetic Metals in AC Magnetic Field

2.2.2 Detector and Metal Contaminant Properties

Inspected products, such as medical drugs and health foods, include various components, such as minerals like iron and salts as well as herbal ingredients and crude drugs all of which can have an impact on the metal-detector sensor magnetic field. When the inspected product contains a lot of herbal and mineral ingredients, since the detection sensitivity might be reduced due to the large impact on the sensor, the metal detector signal processing settings must be adjusted to optimize sensitivity.

3 Development Concept and Implementation

3.1 Concept of M6-h Series Medical Drugs Metal Detector

When starting development of a metal detector for medical drugs based on a metal detector for foodstuffs, the following important issues were considered taking the needs of the medical and healthfood markets into account.

(1) Implement high stability, high sensitivity, and easy analysis functions
- No misdetection in production environment
- Industry-leading metal-contaminant detection sensitivity
- Magnetic field component analysis

(2) Support easy usability and maintenance
- Eliminate complex operations and settings
- Immediate use after power-on
- Tool-free disassembly/assembly for daily cleaning of parts in contact with inspected product

(3) Support validation
- Constant monitoring of detector internal status
- Self-diagnosis of metal-detector performance
- Constant monitoring of rejector operation

3.1.1 Implementing High Stability and High Sensitivity

(1) Environmental Noise Tolerance

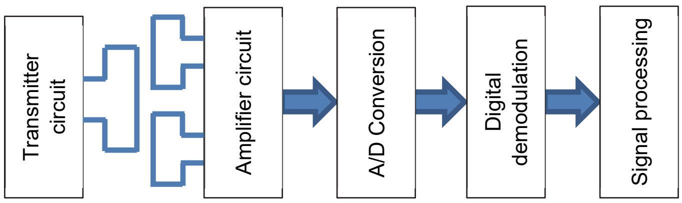
In the following types of noisy production environments, metal detectors have problems such as misdetection of Pass products as metal-contaminated NG products.

- Environments with high-frequency noise emitted by machines containing inverters, machines using large currents such as electric motors switching on and off, and fluorescent tubes
- Environments with mechanical noise from production-line equipment, such as tablet presses and capsule fillers

Since receiver-coil signals of metal-detector sensors are easily influenced by even the smallest environmental noise, in the M6-h series, the receiver signal is digitized prior to signal processing, such as modulation processing, to separate the inspected-product signal, contaminant signal, and environmental noise by implementing various data signal processings under different conditions to strengthen noise tolerance.

(2) High-Sensitivity Sensor and Signal Processing

As well as using a high-sensitivity sensor with several times better performance than the M6-h series for foodstuffs plus signal processing, both high sensitivity and high speeds were achieved for application to contaminant inspection of tablets and capsules for medical drugs and health foods by reducing the inspected-product signal and increasing the signal-processing speed.



(3) Metal Detector Contaminant Analysis Function

When a metal detector discovers metal contaminants in products at a medical-drug manufacturing facility, the composition of the contaminant is investigated by destructive testing using specialized examination equipment, which can take time before results are available. If the contaminant can be characterized quickly, the source can be identified faster, helping reduce production-line downtime. Consequently, we added a component analysis function to this metal detector (Figure 6) to identify the contaminant from the degree of magnetic properties by using previously described signal processing and signal vector data. As a result, contaminants can be easily characterized as magnetic or non-magnetic simply by passing known metal-contaminated NG products through the detector.

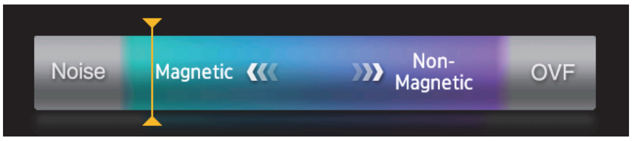


Figure 6 Component Analysis Screen

3.1.2 Easy Usability and Maintenance

(1) No Complex Operations and Settings

Conventional metal detectors required implementation of automatic settings matching the inspected product. This auto-setting was performed by training by passing inspected products through the metal detector to “learn” the product characteristics. Since this metal detector is targeted at markets for medical drugs and health foods, this metal detector can be used without the need for auto-setting and other complex adjustments by presetting factors related to detection sensitivity. However, for medical drugs and health foods including components (such as iron salts) that make accurate contaminant detection difficult, the optimum settings can be auto-adjusted simply by passing an inspected product once through the detector.

(2) Temperature Stabilization using Reduced Power Consumption Circuit Design

The signal-processing board built into the metal-detector sensor uses an efficient circuit design to cut power consumption by 25% over conventional detectors. Additionally, temperature stability is improved using a feedback circuit design that tracks temperature change. Starting work immediately after power-on with requiring warm-up cuts setup time before starting production.

(3) Tool-free Maintenance

To reduce the risk of contamination at a medical-drug production site, only specified and managed tools can be brought on-site. In addition to prevent contaminant ingress, parts of the production line coming into contact with the product must be cleaned every day to prevent biological contamination.

This metal detector uses handle mechanisms (Figure 7) to adjust parts in contact with product, chute angles, etc., for tool-free disassembly/assembly and adjustment. Additionally, the disassembly/assembly and adjustment handles are color-coded for intuitive use by operators.

Figure 7 Assembly/Disassembly Handle

3.1.3 Validation Confirmation

Medical drug production sites require thorough quality control and faulty metal detector operation must be prevented at all times. Consequently, this metal detector has the following functions to assure correct operation.

(1) Metal Detector Internal Status Fault Monitoring

The internal mechanical status of the metal detector is monitored continuously by the detector itself and if a fault is discovered, it is indicated by the error notification function. Additionally, for maintenance, the status of each unit and current values can be confirmed at the display. Figure 8 shows an image of the monitoring status for each unit.

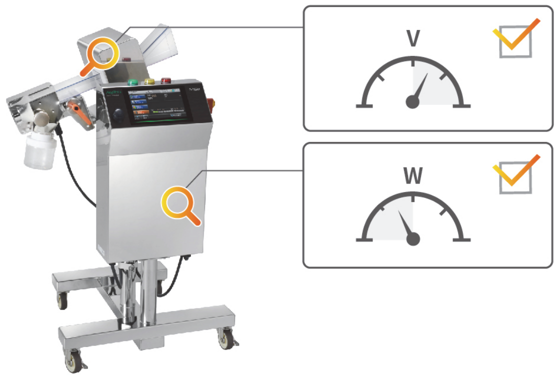


Figure 8 Internal Status Fault Monitoring

(2) Self Diagnostics

Generally, metal detectors can confirm whether the detection performance is being maintained by passing contaminant test pieces through the detector. However, this confirmation method requires stopping the production line so that the operator can feed the metal contaminants test pieces through the detector, which causes issues with wasted time and effort. Consequently, this metal detector has an added detection self-diagnostic function for confirming that the detection sensitivity is maintained without needing to pass test pieces through the detector. It generates an NG signal simulating changes in the magnetic field within the detector to confirm that the detection sensitivity is maintained based on the change amount (Figure 9). The self-diagnostic function runs when the detector is powered-on to notify any detected abnormalities. Furthermore, the self-diagnostic function can also be run at any required time.

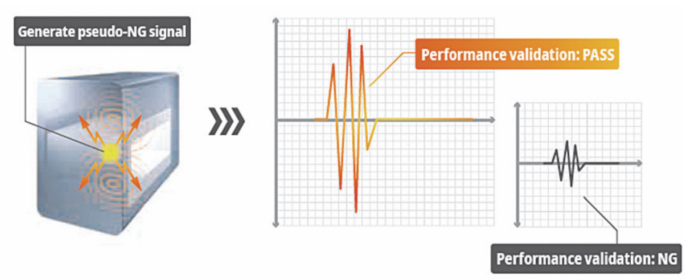


Figure 9 Self-Diagnostics

(3) Rejector Operation Monitoring

A position sensor built into the rejector mechanism monitors the rejector gate position continually. If an inspected product is caught between the rejector and gate to cause a gap as a result of abnormal positioning, there is a risk of metal-contaminated products passing through this gap. Consequently, the rejector position sensor continually confirms that the evaluation condition and rejector gate position are matched; if there is a mismatch, an error notification is issued. Furthermore, errors are also notified if there is a mistake in installing a rejector gate or in the rejector cable connections, or if a part, such as an actuator, is in poor condition. When an error is notified, the failsafe gate position is to reject all products as NG.

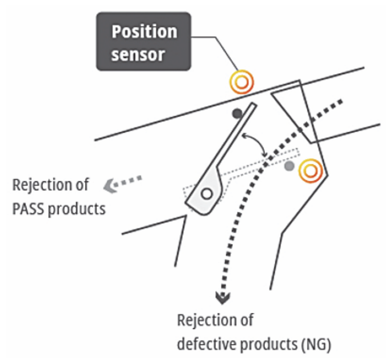


Figure 10 Rejector Position Sensor

4 Detected-Product Sensitivity Test

The key function of a metal detector is to reliably detect contaminants in actual products with high sensitivity. Table 1 lists detection data comparing test-piece sensitivity of the metal detectors for medical drugs and the M6-h series for foodstuffs. The results confirm that the metal detector for medical drugs can detect test pieces with a 30% smaller volume ratio than the metal detector for foodstuffs.

Table 1 Detection Sensitivity Comparison with Metal Detector for Foodstuff Inspection

Inspected product	Contaminant	Medical Drugs Metal Detector (KDS1004PSW)	Foodstuffs Metal Detector (KDS2105ABW)	Volume Ratio
Cold Medication	Fe	ϕ0.25 mm	ϕ0.4 mm	× 0.39
	Non-Fe*	ϕ0.3 mm	ϕ0.4 mm	× 0.56
	SUS316	ϕ0.4 mm	ϕ0.7 mm	× 0.33
Health Foods Containing Herbal Remedies	Fe	ϕ0.3 mm	ϕ0.5 mm	× 0.36
	Non-Fe*	ϕ0.3 mm	ϕ0.5 mm	× 0.36
	SUS316	ϕ0.45 mm	ϕ0.8 mm	× 0.32

* Non-Fe means non-ferrous brass. Since brass is commonly used for food manufacturing equipment and appliances, it is commonly chosen as a standard along with Fe and SUS316 for measuring sensitivity.

5 Key Specifications

Table 2 lists the main specifications of the M6-h series of metal detectors for medical drugs inspection.

Table 2 Main Specifications of M6-h Series Medical Drugs Metal Detector

Model		KDS1004PSW	KDS0902PSW
Opening Internal Dia.		100 × 40 mm	90 × 25 mm
Chute Internal Dia.		86 × 31 mm	76 × 16 mm
Chute Angle		20° to 45°	
Detection Sensitivity	Fe Spheres	ϕ0.25 mm	ϕ0.22 mm
	Non-Fe Spheres	ϕ0.3 mm	ϕ0.25 mm
	SUS316 Spheres	ϕ0.4 mm	ϕ0.37 mm
At Metal Detection		Rejection and Warning	
Waterproof Standard		IP65	
Power		100 to 240 Vac +10%/−15% Single phase 50/60 Hz 120 VA, Peak current 50 A (typ.) (20 ms max.)	
Mass		55 kg	

6 Conclusions

We have developed the M6-h series of high-sensitivity metal detectors incorporating validation and component analysis functions for inspecting medical drugs. This article describes the easy tool-free assembly/disassembly design to improve use of convenience and simple operability.

We are continuing with development of detection methods and sensors for detecting metals with even higher sensitivity and stability to support provision of stable and safe food and medical products while offering detectors matching users' requirements.

References

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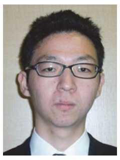

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