

# ETW

## Optical inspection for Quality Assurance in the Pharmaceutical, Cosmetics and Food Industries

### Inspection of Stoppers for Vials

Today producers need to fulfill extensive quality assurance requirements for their manufactured parts. The inspection and documentation demands in the pharmaceutical, cosmetic and food industry may often be the most severe. A common requirement here are reliable and flexible non-contact optical inspections that can easily be adapted to different products. In this article a camera control system is described that verifies the correct position of stoppers in vials in a star wheel as required by GMP Annex 1-121.

Requirements for inspection devices vary. Even if the inspection is simply to determine whether something is 'good' or 'bad', some applications require a large number of additional qualifications from the test system. Vision specialists, ETW Wollmershäuser GmbH, based in Wolpertshausen, Germany, offer a camera inspection system designed to meet the highest requirements of the pharmaceutical industry.

The items inspected are examined and evaluated from two sides by two scalable cameras. To ensure this CrossCAM system offers maximum flexibility, ETW Wollmershäuser GmbH are working with automation experts Omron, whose extensive image data processing portfolio enables the inspection system to be precisely tailored to customer requirements.

### Additional qualifications are essential

In areas subject to special requirements for cleanliness and hygiene, a simple inspection system would not be sufficient. In addition to the actual measuring task, it is essential that the working environment is taken into consideration for this type of application. The food industry requires a material suitable for use with food products, which can also withstand frequent cleaning, whilst the demands increase for materials used in clean rooms in the pharmaceutical industry. Therefore the universal inspection system supplied had to meet the highest of requirements.

The CrossCAM system consists of a stainless steel housing made from 1.4404 steel with protection category IP65 suitable for an isolator (a special clean room for pharmaceutical filling operations). The geometry of the housing, with its robust, three millimeter thick glass panels, not only takes into account the requirements of the camera inside and the LED lighting, but also fulfills other constraints. The housing meets all hygienic design requirements, enabling easy cleaning. In order to create a laminar flow environment—a uniform air flow from top to bottom that removes particles and bacteria—the housing (figure 1) is designed to largely eliminate turbulence in the airflow. A stainless steel mirror at the very bottom plus a red

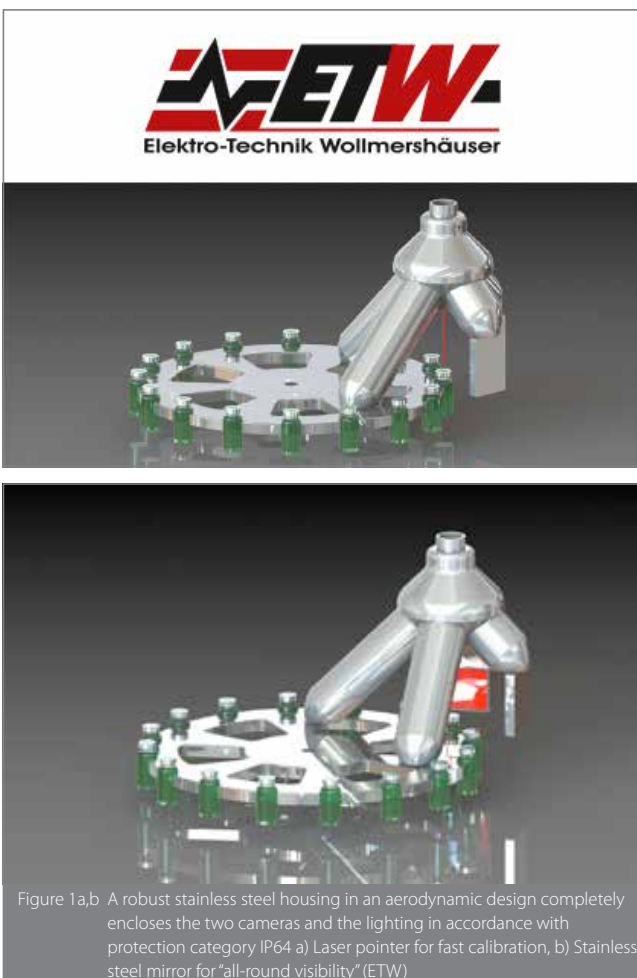


Figure 1a,b A robust stainless steel housing in an aerodynamic design completely encloses the two cameras and the lighting in accordance with protection category IP64 a) Laser pointer for fast calibration, b) Stainless steel mirror for "all-round visibility" (ETW)

light that provides background lighting, allows measurements to be taken just above a star wheel or a linear conveyor belt. This provides the user with flexibility in choosing the vials, bottles, flasks or other containers that are used.

### Practical added value

The system uses two cameras positioned at right angles to one another using the backlight of a stainless steel mirror. The test specimens are located in the focal point of the lens, allowing them to be inspected precisely (figure 2). To allow the entire lens to be calibrated quickly and so that the calibration can also be validated, an additional laser pointer with crosshairs is located inside the central axis of the housing. If the cross is projected centrally onto the stopper, the system is adjusted optimally. This also means that the compact inspection unit (227 x 285 x 185 mm) can easily be retrofitted into existing facilities with all common transport systems as no complex adjustments are necessary. Thanks to the scalable design, the customer only has to pay for the equipment required for the specific application. The plug-and-play system, including documentation (IQ, OQ), is also available with an FDA CFR21 part 11 compliant-ready software package and can display the results via 12.1, 15 or 19-inch TFT touch screens, web servers or .Net Framework. The image resolution needed for the stopper inspection makes the 2-megapixel camera the preferred choice though other resolutions are available for special applications.

### A choice of camera technology

The stainless steel housing of the CrossCAM system forms a universal outer shell, so that the inner components—the camera, controller and lighting—can be selected according to the individual customer requirements. The Omron FH image processing system (figure 3) is also suitable for demanding tasks such as stopper inspections and is specifically designed for seamless interaction with PLC, motion controllers and robotic systems and thus facilitate integration into new systems or retrofitting onto existing systems. The powerful image processor guarantees the fastest image evaluation possible and therefore facilitates high system throughput. Components include an Intel i7 multi-core processor and fast EtherCAT communication, which only takes around one eighth of the time when compared to conventional communication standards. As a result, up to eight high-resolution cameras can be connected. This allows, as in this application with two cameras, fast and parallel evaluation of recordings and an overall assessment of the stopper fit. The result can be transferred to a machine controller in an EtherCAT communication cycle of only 500 µs. The user-independent calibration accuracy simplifies certification in demanding applications.

FH series high-speed cameras are available in monochrome or color versions. The resolution ranges from 640H x 480V with 0.3 megapixels and 2040H x 1088V and 2 megapixels, to 5 megapixels at 2040 x 2048 (H x V). The frame rate of the cameras is 308 fps or 3.3 ms for the FH-SM and FH-SC models and 219 fps or 4.6 ms for the FH-SM/SC 02 and FH-SM/SC04 models (figure 4). This provides cost-effective solutions, perfect for simple tasks, while also ensuring that even the slightest deviation can be detected so that demanding inspection tasks can be performed reliably.



Figure 2 Test recording of stopper inspection; the correct fit is important (ETW)

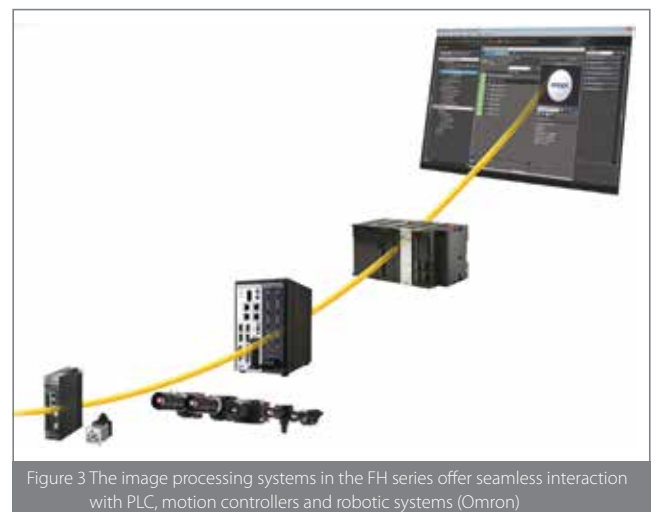


Figure 3 The image processing systems in the FH series offer seamless interaction with PLC, motion controllers and robotic systems (Omron)

### About ETW Wollmershäuser GmbH

ETW Wollmershäuser GmbH, based in Wolpertshausen in the German state of Baden-Wuerttemberg, specializes in the fields of control technology, cabling and industrial electronics. With 28 employees, the company implements new systems and system conversions in a range of industries — from the pharmaceuticals industry to air and space travel. The German company's portfolio also includes its own products, such as engine controllers, camera housings and oscillating conveyor control devices. One example of an innovation developed in-house is the company's stainless steel backlight with genuine glass front. It generates homogenous light and can be cleaned with high pressure/steam rays in line with protection category IP69K, meaning the lighting system can be used in the foodstuff or pharmaceutical industries.