

Application Report – Track-and-trace based on image processing: Improved safety

## On the safe side

Counterfeit pharmaceutical products are booming – and cause not only severe damage to the pharmaceutical industry but also are a high risk for patients. Therefore, full traceability is a prerequisite to ensure transparency throughout the entire supply chain. Track-and-trace systems based on image processing like serialization modules by ISW (Industrielle Sensorysysteme Wichmann GmbH) provide decisive benefits in fulfilling the increasingly high demands on quality and safety in the industry.

By 2018 at the latest, pharmaceutical manufacturers will face the need to ensure product traceability in compliance to standards, regulations and applicable law. Serialization experts like ISW are in high demand when it comes to user-specific solutions for non-contact quality control systems. For more than 20 years, ISW has been active in the pharmaceutical industry where their track-and-trace systems have been experiencing a two-digit growth rate. “We have been keeping pace with this market trend with own product developments like PALC”, explains Mr. Stefan Tukac, authorized officer at ISW, and further adds: “PALC is the abbreviation for Package Aggregation Line Controller Unit. This module enables inline integration in any packaging line for serialization of pharmaceutical products.”

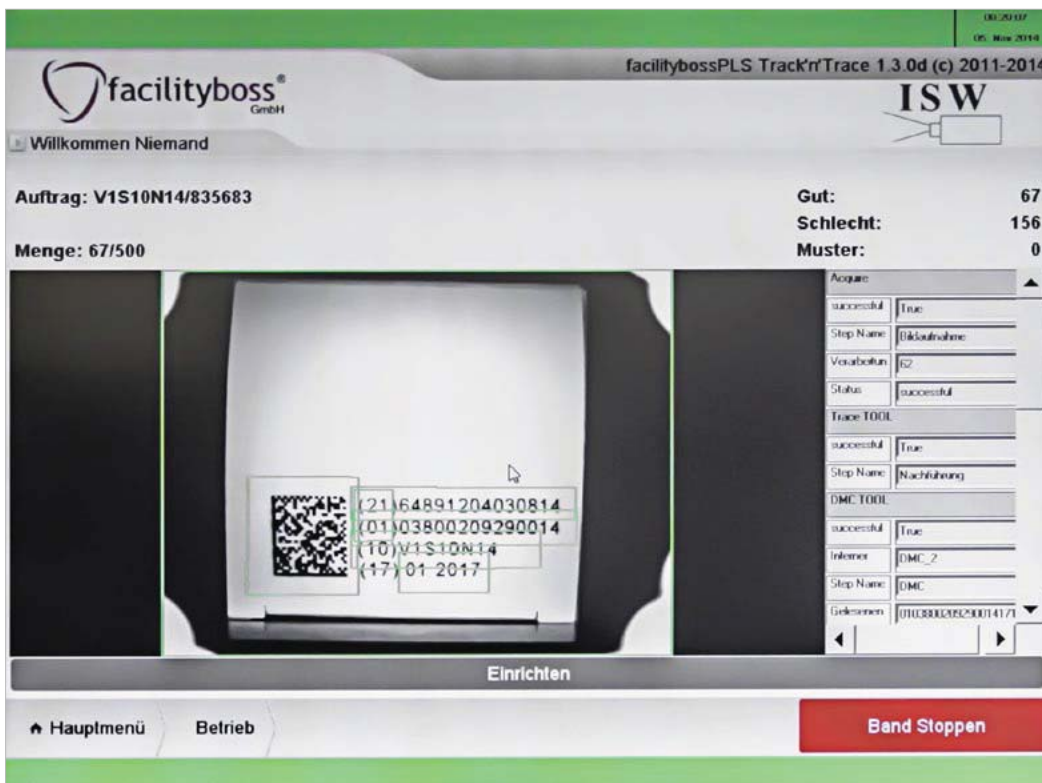
### Image processing is capable of a lot more

Within the packaging line, PALC is supplied with drug packages by the infeed system. “In the feeding process, the boxes are imprinted according to the respective requirements to ensure unambiguous identification and traceability by various encodings with human-readable characters. Quality control and evaluation come in the next step.” Mr. Tukac outlines the operating principle. For their image processing-based system, ISW relies on high-resolution images supplied by a Baumer TX Series GigE camera. Both 1D and 2D codes as well as graphics like logos and human-readable characters can be verified for correctness and quality. “Any non-compliant product is sorted out straight away in order to prevent faulty packages from being fed into the downstream processing machine”, explains Mr. Tukac. With their 2 megapixel resolution, the cameras provide up to 7 fps and

are ideal to map even the finest detail of divergence at high speed. Speeds of up to 30 meters per minute allow for serialization of up to 400 packages per minute, dependent on size and the relevant marking requirements. Through versatile configuration options, conveyor belts adapt to PALC serialization with packaging sizes up to 30 cm in width and 1.5 to 13 cm in height. The benefits of image processing-based systems are obvious: “Unlike mere code scanning, image processing can do a lot more: reading and verification of human-readable characters (OCR/OCV) while verifying in parallel the allover print quality.



PALC is designed for serialization of drug packages. The development concept focused on high performance and convenient implementation; combined with user-friendliness and a modular product platform to comply with different levels of periphery. In the track-and-trace process, faulty products are ejected into a locked container by a compressed air jet while simultaneously being logged into the system.



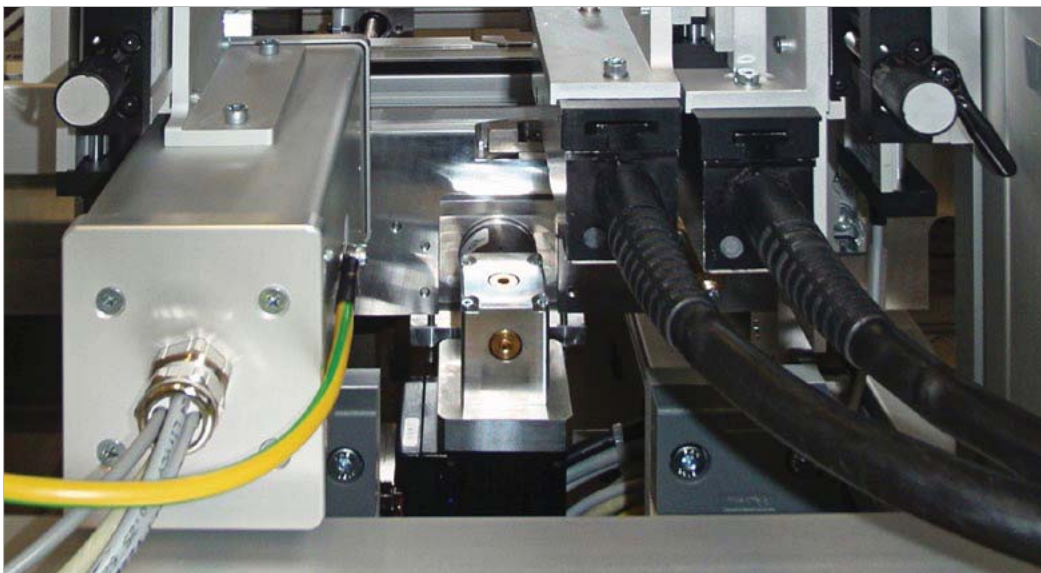
Calibration of the overall system, for example conveyor speed, is via the intuitive HMI which is easy to operate even in complex parameterization. During operation, the monitor shows at the left the current image together with the respective image processing tool and related parameters at the right.

What good is the best code when it is illegible and therefore couldn't be tracked?" argues Mr. Tukac. Success is proving ISW right: So far, 16 systems have been deployed worldwide by numerous pharmaceutical manufacturers – and demand is increasing. ISW's reliance on Baumer cameras is due to the outstanding quality of both image and product. "Besides performance, component reliability is a crucial factor. At present, more than 300 systems with Baumer TX cameras are installed in the field. The failure rate is less than 1% – so

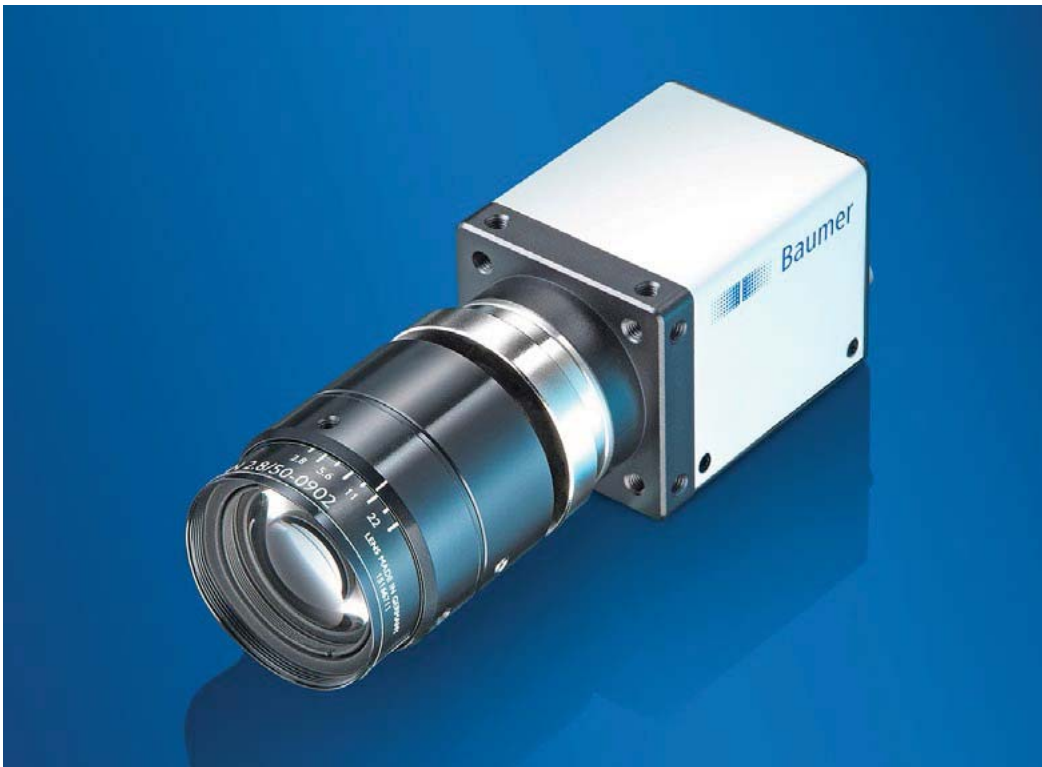
we have the easy choice when it comes to new systems like PALC", explains Mr. Tukac.

#### Full flexibility in every respect

At the international level, there are many stringent requirements on product marking and track-and-trace, as for example directive 2011/62/EU which applies within the European Community. "There are many international regulations to eliminate counterfeit pharmaceuticals, and we know the requirements. PALC as an automated, universal



The high-performance printing system and camera unit is the heart of PALC. It can be attached to each side of the conveyor and can be adjusted to package size in both height and distance. A specialized IP 54 housing protects the camera and lens from soiling.  
Photo: ISW



Baumer TX series cameras are available in more than 100 models with resolutions starting at 5 megapixel and 210 fps to master virtually any application across varied industries.

modular track-and-trace system has got what it takes to match individual requirements with highest flexibility", Tukac says. Whether it comes to integration and positioning of different printing systems, user-configurable database interface, adjusting capabilities to match conveying height or enhanced functionalities such as tamper-proof protection control – PALC will master most diverse customer-specific needs. ISW also provides companies with small-batch production and small-sized packaging lines with a specialized solution: A mobile system to serialize folding box cuts in offline mode. "Since many of our customers use

both system variants, we attach great importance to a uniform operating and HMI concept in all our systems. This allows for hassle-free conversions without facing the operator with too much of a rethink process", says Mr. Tukac and further explains: "Our systems are ultra-flexible, ensure quick installation and implementation and in the same way can be quickly repositioned between the packaging lines."



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