

Press Release

Packaging and pharmaceutical safety at ACHEMA 2024

Innovative inspection technologies for quality and process control in the production and filling of pharmaceutical primary packaging will be the focus of attention at the HEUFT stand C57 in Hall 3.1 of the Frankfurt exhibition grounds from 10 to 16 June.

In addition to the HEUFT *Syringer*, which uses pulsed X-ray technology and smart X-ray image processing to realise a precise inspection of pre-fillable syringes during their production and packaging, a new combination of seamless optical inspection and precise high-voltage leak testing of blow-fill-seal ampoules will be causing quite a stir.

In co-operation with Nikka Densok LTD from Japan, HEUFT SYSTEMTECHNIK GMBH is now offering it as a joint complete solution for the quality and integrity assurance of practical primary packaging materials for liquid preparations such as small volume parenterals (SVP) or ophthalmic products.

The HEUFT *spotter*^{II} *BFSB* is the first choice for ensuring this in the blow-fill-seal process of infusion bottles. Just like the HEUFT *spotter*^{II} *BFSA* for the aforementioned ampoule inspection it realises a complete optical inspection of all containers in an efficient straight run and simultaneously checks their tightness.

The trade fair highlights also include the Multi Colour Image Processing developed and manufactured in-house for more reliable detection during the in-line inspection of pharmaceutical primary packaging materials.

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Bundled expertise for flawless BFS ampoules

HEUFT and Nikka Densok are presenting a joint solution for a comprehensive quality inspection in the blow-fill-seal process for ampoules at ACHEMA.

When it comes to the optical quality inspection of each individual primary packaging material, the German company HEUFT SYSTEMTECHNIK GMBH already has 45 years of expertise. The same applies to Nikka Densok LTD from Japan, a pioneer in the field of high-voltage leak testing. The two leading suppliers have combined their expertise in order to realise both in the quality testing of blow-fill-seal ampoules:

The new combination of HEUFT *spotter*^{II} *BFSA* and the pinhole inspector of the HDI series from Nikka Densok enables what Annex 1 of the Good Manufacturing Practices (GMP) has stipulated since August 2023 – 100 per cent container closure integrity testing (CCIT).

From foreign particles in the ampoule to deformed closures, black spots and inclusions to damage, cracks and leaks, it detects everything that threatens packaging and drug safety in the blow-fill-seal process of liquid preparations such as small volume parenterals (SVP) or eye drops.

Visually perceptible defects are identified during the full-coverage inspection of the bundled ampoule strips with the HEUFT *spotter*^{II} *BFSA*. The Pinhole Inspector from Nikka Densok takes over the high-voltage detection of micro-leaks.

The two technology leaders can now provide their customers in the pharmaceutical industry with a joint complete solution. In addition to cosmetic defects, it identifies all critical defects that can occur in the blow-fill-seal process of ampoule cards.

The innovative combination of the HEUFT *spotter*^{II} *BFSA* and the

pinhole inspector from Nikka Densok's HDI series will be exhibited for the first time at ACHEMA – at the HEUFT stand 3.1 / C57 on the Frankfurt exhibition grounds.

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Flawless BFS ampoules

Specially developed for the one hundred percent complete inspection of blow-fill-seal ampoule strips filled with small volume parenterals (SVP) and other liquid preparations, the straight HEUFT *spotter*^{II} BFS achieves full coverage – and thanks to the newly integrated Multi Colour Image Processing (MCIP) even greater detection accuracy.

With adaptive lighting as well as smart optomechanics, image filtering and subtraction the HEUFT *spotter*^{II} BFS realises a complete all-round inspection of every single aseptically produced and filled primary packaging material. It identifies deformations, missing or surplus packaging components, contamination, leaks, scratches, cracks, grooves and inclusions in the material of the polypropylene or polyethylene containers just as reliably as filling quantity and colour deviations of the products and foreign objects inside them.

The latest HEUFT *reflexx*^{A.I.} cameras and the new, already tried and tested MCIP significantly increase the detection accuracy. This is because different lighting scenarios in different colours can now be smartly combined and offset against each other at each individual detection station. From one and the same perspective, the ampoule strips can be inspected in multiple colours in both incident and transmitted light, for example, while conserving components and resources.

And not just top-down and bottom-up. For full coverage the compact HEUFT *spotter*^{II} BFS also realises a complete optical inspection of the sidewalls and caps of each individual ampoule in efficient linear operation. The transport belt, which clamps the ampoule strips and guides them straight through the device, is therefore specially designed to alternate: In the infed, they are gripped at the top in order to inspect the entire lower part right down to the base edge and then at the bottom

in the outfeed, so that the entire upper half is covered right up to the caps.

Intelligent optical technologies and the smart HEUFT *reflexx*^{A.I.} image processing ensure full detection reliability. Inverted evaluation images, for example, make black spots and other inclusions throughout the SVP container material clearly recognisable as white dots on a black background.

Adapted to their specific characteristics and all possible critical defects, the innovative MCIP puts the primary packaging material in the right coloured light to reliably find even the smallest foreign particles in the ampoule and clearly distinguish them from harmless deviations. Even if they are located in the filling line area, which is difficult to see.

Based on the current HEUFT *SPECTRUM*^{II} platform the linear compact system not only achieves the necessary precision for tracking, inline inspection of up to 30,000 blow-fill-seal ampoules per hour and reliable fault rejection with a wide variety of rejection systems but also a fully automatic adjustment of the trigger photocells, cameras, lighting units and transport belts to different container sizes. Programme and format changes can be carried out without tools and without any human intervention. The audiovisual HEUFT *NaVi* user guidance system ensures simple, error-free operation.

With user-related access rights and detailed audit trail documentation of all operating and process information, the HEUFT *spotter*^{II} *BFS*A fulfils the 21 CFR Part 11 requirements of the FDA. A connection to higher-level databases and MES systems enables the real-time transfer of batch and production data. There is a network connection to the HEUFT *TeleService* for secure remote diagnosis and maintenance. The system, which has already been tried and tested in practice, consistently fulfils the basic GMP and GAMP5 requirements for the 100% complete inspection of bundled ampoule strips.

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Safe blow-fill-seal infusion bottles

With Multi Colour Image Processing (MCIP) the HEUFT *spotter*^{II} BFSB now achieves a significant increase in precision in the one hundred percent complete inspection of blow-fill-seal infusion bottles – and at the same time checks their tightness in order to detect even the smallest leaks.

MCIP also puts blow-fill-seal infusion bottles in the right light to highlight impurities, product faults and packaging defects even more clearly. Thanks to smart multi-colour illumination, optomechanics, image filtering, subtraction and processing, which are tailored to different defect categories, the HEUFT *spotter*^{II} BFSB achieves complete precision in the full-coverage inline inspection of every product. In the same operation it can also detect a drop in internal pressure caused by leaks and thus detect and reject leaking infusion bottles.

Directly integrated into the intelligent HEUFT *reflexx*^{A.I.} camera developed and manufactured in-house, MCIP combines different illumination principles at a single inspection station. As each type of illumination is carried out in a different colour, the information obtained can be spectrally separated from each other so that the most diverse characteristics and properties can be clearly worked out from just one single image thanks to smart, pixel-precise calculation of the individual colour channels.

From black spots in the material of the 100, 250, 500 or even 1,000 millilitre packaging for large volume parenteral products (LVP) or the smallest foreign particles in the product: critical defects can be found even better and distinguished from harmless deviations. The same applies to scratches, cracks and leaks, among other things.

The additional integrity check and leak test provides even more safety. For this purpose, the containers are guided in a belt drive that exerts a precisely definable force on them. Special sensors measure their

internal pressure twice so that a drop in pressure caused by leaks can be reliably identified, regardless of the electrical conductivity of the product inside. Clamped in this way, the infusion containers "float" above the optical module for base inspection in the centre of the device so that this area can be completely inspected without any gaps in order to identify defects, foreign particles and defective bottle hangers, among other things, with unrivalled reliability using MCIP.

The modules for optical 360° cap and sidewall inspection, which also detect torn sealing films, deformed or misaligned cap toggles and underfilling or overfilling, are located in the inlet and outlet, where the blow-fill-seal infusion bottles are not yet or no longer transported in the belt drive. This means that their full volume is covered without any blind areas.

Based on the current HEUFT *SPECTRUM II* platform the linear feeder not only achieves the highest precision in container tracking, in-line inspection and fault rejection with a wide variety of rejection systems but also a fully automatic adjustment of the trigger photocells, cameras, lighting units and transport belts to different sizes of blow-fill-seal infusion bottles. Programme and format changes can be carried out without tools and completely without human intervention.

The first HEUFT *spotter II BFSB* systems installed inspect up to 12,000 infusion bottles per hour. The audiovisual HEUFT *NaVi* user guidance system ensures simple, error-free operation. With user-related access rights and detailed audit trail documentation of all operating and process information, the modular system fulfils the 21 CFR Part 11 requirements of the FDA.

A connection to higher-level databases and MES systems enables the real-time transfer of batch and production data. There is a network connection to HEUFT *TeleService* for secure remote diagnosis and maintenance. The HEUFT *spotter II BFSB* with newly integrated MCIP thus fulfils the basic GMP and GAMP5 requirements.

Press Release

Colourful image processing

Self-invented and already tried and tested in practice: HEUFT's innovative MCIP image processing solution puts products to be inspected and pharmaceutical primary packaging materials in the right light in a resource-saving manner.

Every product has specific characteristics that need to be taken into account during inspection. This applies in particular to primary containers used by the pharmaceutical industry with their wide range of different materials and formats. It is therefore a challenge to optimise image processing to suit both their typical characteristics and the defects that absolutely must be detected. And to do this as cost-effectively as possible, saving time, energy and space, with less effort, equipment and components.

The Multi Colour Image Processing (MCIP) developed by HEUFT masters these challenges – thanks to an innovative combination of universally controllable lighting scenarios in different colours with image processing algorithms matched to them.

Originally developed for HEUFT *spotter*^{II} BFS devices for the 100% all-round inspection and integrity check of filled blow-fill-seal ampoule strips and infusion bottles, the innovative process has already proven its impressive detection accuracy in various customer systems and is now also being integrated into other in-line inspection systems for the pharmaceutical industry in order to optimally present a wide variety of containers.

Directly integrated into the intelligent HEUFT *reflexx*^{A.I.} camera, MCIP combines different illumination principles such as bright and dark field illumination in incident and transmitted light at just one single inspection station. Each type of illumination used is designed in a different colour so that the resulting information can be spectrally separated from one another as it progresses.

A wide variety of features and properties can be extracted from just one single image by appropriately calculating the individual colour channels. Where previously transmitted and reflected light applications were only possible with several cameras at different positions from different perspectives, this can now all be done in a resource-saving and space-saving manner with just one detection unit: the HEUFT *reflexx* ^{A.I.} camera obtains all the information at once on the spot and offsets it with pixel accuracy so that it can be correlated much better in order to identify critical defects even more clearly.

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Safe to use pre-fillable syringes

One hundred per cent pulsed X-ray inspection instead of random visual checks: the HEUFT *Syringer* examines every single injection instrument and makes the previously invisible visible. This protects patient safety and protects against wasted packaging and medication.

The EU GMP Annex 1, which came into force in August last year, already stipulates a 100 per cent inspection of each individual filled syringe. This is not yet required during the assembly and packaging of the practical disposable injection instruments. But it is definitely advisable for in-process control (IPC). And already possible:

Instead of just random checks, the HEUFT *Syringer* carries out a continuous quality inspection of each individual pre-fillable syringe in order to visualise critical faults which often occur during the last assembly step, the fitting of the needle shield, and which remain hidden to conventional camera technology: Deformed or crookedly positioned needles in the needle shield and punctured soft or rigid needle shields (SNS / RNS), which threaten the sterility of the packaging and the microbial purity of its future contents.

For the syringe manufacturer, the timely identification of these critical defects guarantees higher production quality. For the pharmaceutical manufacturer, it offers effective protection against costly packaging and drug wastage: Affected disposable syringes are not only discovered and disposed of when the high-priced preparation is already contained, but are withdrawn from circulation long before they are filled.

The pulsed X-ray technology exclusively available from HEUFT makes it possible for the first time to detect the angle of the needle and punctures. Two X-ray images of each prefillable syringe are stereoscopically combined. Even at high speeds, the images remain high-resolution and free of motion blur. For even greater detection

accuracy the intelligent HEUFT *reflexx* ^{A.I.} real-time image processing system denoises and analyses them in order to clearly identify and characterise a wide variety of features. Each individual feature serves as a reference so that the relative position of the injection needle to the centre axis of the syringe body and also to the outer edges of the needle guard can be precisely determined during needle angle detection.

The slim module can completely replace optical detection units for checking the presence of the needle guard. As it even identifies perforated protective bonnets, the fault is recognised in every case. As an alternative to direct integration into pre-fillable syringe processing machines, the HEUFT *Syringer* is also available as a stand-alone unit. With tamper-proof access rights, a complete audit trail protocol and batch balancing including counter statistics it complies with the FDA specifications of 21 CFR Part 11. The HEUFT *PROFILER* realises the recording, network-based transmission and long-term archiving of operating and batch data, test protocols and detection images. Documentation and validation obligations in accordance with GMP and GAMP5 are reliably fulfilled.

As a fundamental component of quality management, the HEUFT *Syringer* not only enriches the IPC with new inspection approaches and detection options, but also Good Manufacturing Practices in the production of pre-fillable syringes as a whole: instead of random checks of a few, a 100% X-ray inspection is carried out on every single one of them. This makes an important contribution to patient safety and against senseless waste of packaging and medicines.

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Advanced X-ray technology

HEUFT has consistently further developed its unique X-ray technology with new tubes, generators, high-voltage components and the right expertise. This further increases the detection accuracy and availability and reduces the Total Cost of Ownership (TCO).

Full precision with minimal radiation! This has characterised the pulsed X-ray technology exclusively available from HEUFT for the gentle and precise detection of foreign objects, product faults and packaging defects right from the start. New X-ray components developed in-house now further increase the detection and operational reliability of radiometric inline quality inspection.

Since HEUFT developed it and brought it onto the market in 1998, the patented pulsed X-ray has scored points above all with its extremely short exposure time for significantly clearer detection images. Because an X-ray flash of no more than one millisecond is only emitted at the moment when something really needs to be checked, there is no motion blurring. In conventional line scanning with uninterrupted X-ray radiation, this makes it difficult to recognise objects, especially in high-speed lines. In contrast, pulsed X-ray inspection of up to 1,200 products per minute virtually freezes the product flow: streaks and blurred areas cannot occur in the first place. And no radiation is emitted for up to 99 per cent of the operating time!

If it does, the intensity of an X-ray pulse of just 0.000015 Gray is a full 600 million times below the limit value up to which the World Health Organisation (WHO) considers the irradiation of food to be harmless. The maximum radiation energy is 90 kilo-electron volts. And at 0.01 microsievert, the respective radiation dose is only a hundredth of what conventional X-ray scanners emit on average. For medical X-rays, it is even 900 times higher.

New X-ray tubes, generators and high-voltage components developed in-house, combined with optimised image converter technology, increase coverage, sensitivity, detection and operational reliability! Each individual X-ray pulse now penetrates significantly larger packaging volumes and product quantities than before. Depending on the application, the size of reliably recognisable foreign objects and defects is halved.

At the same time, the lifetime is increased. And before important components can fail completely, the user is informed in good time so that there is still enough time for preventive maintenance. Essential X-ray components are even integrated redundantly – should one fail, the other takes over immediately to avoid unplanned production interruptions.

Whether during the pipeline inspection of still unpackaged product mass or during the precise examination of pre-fillable syringes: The advanced pulsed X-ray therefore not only increases detection accuracy, but also operational reliability – and sustainably reduces TCO.

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Company profile: HEUFT is SYSTEMTECHNIK

Quality, safety, efficiency: this is what matters when filling and packaging pharmaceuticals, beverages and food! Modular quality control and inspection systems from HEUFT SYSTEMTECHNIK GMBH realise these key factors effectively and simply. With maximum productivity, they ensure that only flawless products reach the market.

Unique camera, X-ray and image processing technologies for precise empty and full container inspection and smart tools for container flow optimisation, production data acquisition and performance analysis ensure sustainable product quality and line efficiency!

A consistent modular principle with a cross-system control unit for a wide range of technologies, processes and modules generates the right automation solution for every application with a high degree of component harmonisation.

Anyone who decides in favour of a user-friendly HEUFT system can rely on a high level of operational reliability. With long-term availability of spare parts and 24/7 service availability, competent support is always guaranteed. This concept keeps the globally operating company on a dynamic growth course. The number of employees has long since exceeded the 1,000 mark. The company's own sites in 18 different countries and a close-knit network of service centres on all five continents satisfy the high demand for HEUFT systems manufactured exclusively in Germany.

The result: greater safety, quality and efficiency in the filling and packaging of pharmaceuticals, food and beverages. HEUFT knows how!

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Fact Sheet

Company:	HEUFT SYSTEMTECHNIK GMBH
Management:	Alexandra Heuft, Bastian Heuft, Bernhard Heuft, Dr Thomas Jahnen, Thomas Holzberger
Company headquarter:	Burgbrohl, Rhineland-Palatinate, Germany
Other locations:	Argentina, Australia, Brazil, China, Denmark, France, Great Britain, Hong Kong, India, Italy, Mexico, Netherlands, Austria, Russia, Spain, Thailand, USA
Foundation:	01.04.1979
Employees:	over 1,000 in the HEUFT Group
Industry:	Special machine construction
Product range:	inspection, quality control, labelling, rejection, transport and IT systems for the pharmaceutical, food and beverage industries
Applications:	empty container inspection, container sorting, fill management, full container inspection, foreign object detection, rejection systems, transport optimisation, conveyor control, labelling technology, full container inspection, code reading, label inspection, closure inspection, production data acquisition, line analysis
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