SAFE
SERIALISATION
LABELLING
AUTOMATION

SERIALISATION AND AGGREGATION SYSTEMS

TURNKEY SOLUTIONS.
MORE THAN JUST
COMPLIANCE.

SAFE
SERIALISATION
LABELLING
AUTOMATION

- EXPERIENCED IN ALL INDUSTRIES

CONTENTS

We, b+b Automations- und Steuerungstechnik GmbH, develop complete solutions in the fields of labelling, automation, serialisation and aggregation. Legal requirements as well as your wishes and needs are the focus here. In addition to our industry-specific standard systems, we offer complete solutions and project the necessary hardware and software modules for your application. For this purpose we integrate components from well-known partners in the fields of printing, sensoring and vision technology. Our serialisation and aggregation systems are characterized by quality, modularity, user-friendliness and durability.

MORE THAN JUST COMPLIANCE

Pharmaceutical packaging and its labelling and marking are subject to high legal requirements in order to guarantee the safety of the patient. Therefore, the requirements in the pharmaceutical industry are higher than in any other industry.

In addition to our standard systems, we offer customer-specific hardware solutions and the necessary software modules for implementing the requirements for serialisation (also in combination with labelling systems) and aggregation (Track & Trace), which go far beyond the usual compliance requirements.

We have got the right solution according to your needs - no matter whether it is the serialisation of small or large batches.

All systems are equipped with a b+b LineManager, which intuitively guides the operating personnel through the processing of the production order. An uninterruptible power supply unit (UPS) prevents data loss in the event of an unexpected power failure. All systems are equipped with a properly sized touch panel HMI. Every system fulfils the FDA requirement 21 CFR Part 11 (Audit Trail) and has the function for “RE-WORK mode” and the possibility to take samples at any time.

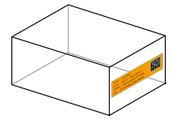
All models shown here can be upgraded with modules such as

- Fully automatic / semi-automatic / manual labelling
- Additional printing unit(s)
- Additional vision inspection
- Infeed and outfeed buffers etc.

SERIALISATION SYSTEMS

LSS-PVeco > SERIALISATION OFFLINE [filled boxes]

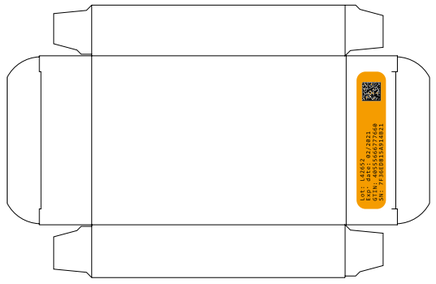
The LSS-PV model was developed to serialize small product batches cost-effectively and according to the requirements of country-specific FMD guidelines. The products are fed manually.
A transport system with product carriers guarantees a precise and continuously accurate alignment of the products. After the printing process performed by a thermal inkjet printing system (TIJ), the print data is inspected.
If the inspection result is positive, the products are either collected on the collection table at the outfeed of the system or glide over an optionally available transfer plate into an outer shipping case. Defective products are reliably separated from the GOOD products by the product reject station.
This process is verified twice in the PLC.



HSF > SERIALISATION OFFLINE [flat boxes]

This powerful HSF friction feeder is the optimal solution when empty folding boxes have to be marked with variable data offline from the production line. The modular design of the system enables an easy integration of the desired marking technology.

The HSF separates the folding boxes from the stack in the infeed magazine. The cartons are guided to the printing station by two parallel running belt conveyors. Print information could be e.g. serialisation data in the form of bar codes or data matrix codes and text. Depending on requirements, thermal inkjet, laser coders or label print- and apply systems can be used (also in combination).



The printed data is inspected and verified by an integrated vision system. The b+b Linemanager recognized all 21CFR Part 11 data for each serial number and is able to report this back to the Siteserver system (e.g. b+b Siteserver)

Folding boxes inspected by the camera as unusable are automatically rejected by a rejection unit. A shingling conveyor belt takes over the finished boxes and can group them for manual pick up.

The performance of the system is adjustable between 10 and 30 m/minute. The HSF is easy to operate and uncomplicated to handle via the Touchpanel HMI. The system can be moved during multiple production line (lockable castors). As an option we supply the system with a labelling module (vignettes).

Model	Products	
HSF-PV eco	Boxes	up to 60 products/min
HSF-PV 350	Boxes (max. width 350 mm)	up to 100 products/min
HSF-PV 400	Boxes (max. width 400 mm)	up to 100 products/min
HSF-PV 450	Boxes (max. width 450 mm)	up to 100 products/min

HSS > SERIALISATION INLINE [filled boxes]

Due to increasing product counterfeiting, many manufacturers are forced to make their products tamper-proof and counterfeit-proof. There are legal requirements for this in many countries. For this task we have developed our model series HSS. The system enables single-sided and/or double-sided printing and print data verification of pharmaceutical cartons and is designed to fulfil all current and future serialisation requirements.

During development, great attention was paid to protecting the packaging and the format range of the products to be processed.

In the basic version, cartons with format widths (in running direction) of 50 mm to 250 mm can be serialized at a speed of up to 350 folding cartons/minute. Models for processing wider folding boxes are based on the same system concept.

A b+b LineManager controlled via a 15“ Multitouch HMI is used to operate the system. As an alternative to the HSS model series, we offer the TE-PV model of the TE model series in order to implement both serialisation and tamper evident labelling in a combined system.

The system is also equipped with a product reject station with counterchecking to reliably remove and collect products that are marked as faulty in the shift register (standard) from the process.

Model	Products	
HSS-PV	Boxes (1-sided serialisation)	up to 350 products/min
HSS-PV-2S	Boxes (2-sided serialisation)	up to 350 products/min
TE-PV	Boxes (1-sided serialisation and seal labelling on both sides)	up to 300 products/min
TE-PV-2S	Boxes (2-sided serialisation and seal labelling on both sides)	up to 300 products/min

VRM > SERIALISATION INLINE [vials, cylindrical products]

To serialize vials and other cylindrical products, we rely on the proven quality and reliability of our labelers. In order to achieve the best possible grading of the serialisation barcodes, we integrate thermal transfer printer or marking laser units directly on the label applicator. The vision system immediately inspects the print data after the printing process. If the inspection shows a negative result, we optionally offer a label reject station which automatically removes the label from the process and therefore does not waste a „good product“.

Both the vision system and the print engine are fully integrated in the touch panel HMI. Shift registers in the label applicator as well as in the complete system enable product and label tracking through the complete system.

Possible options:

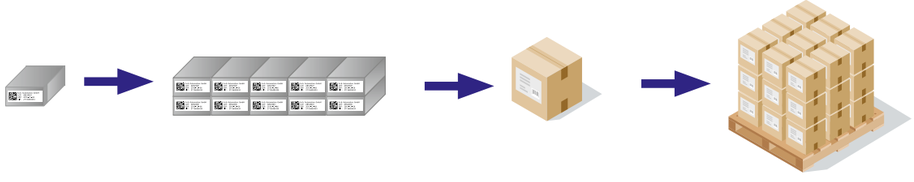
- „Fallen bottle“ sensor
- Antistatic product cleaning before the labelling process
- Label presence check
- Product reject station with counter control and collection box
- Infeed and outfeed buffer tables/infeed and outfeed turntables with tray infeed and outfeed plates
- Automatic tray loading station

Model	**Products**	
VRM-DS-PV	Vials, cylindrical products	up to 60 products/min
VRM-RB-PV	Vials, cylindrical products	up to 250 products/min
VRM-DSRB-PV	Vials, cylindrical products	up to 60 products/min

WE OFFER

- PROJECT MANAGEMENT
- TURNKEY SOLUTIONS
- ON CONTACT PERSON FOR ALL PROJECT PHASES
- INDUSTRY-SPECIFIC DOCUMENTATION
- SERVICE LEVEL AGREEMENTS / AFTER SALES SERVICE
- CUSTOMER-SPECIFIC SPECIAL SOLUTIONS DESPITE STANDARDIZATION

AGGREGATION AND SERIALISATION SYSTEMS



Our hybrid systems are used for serialisation and aggregation. Both are carried out in one system. Often only small batches of certain products are serialized, which must be aggregated depending on the target market. All systems are available with 1 to n aggregation levels or can be expanded.

LSS-PV-AG > SERIALISATION OFFLINE | AGGREGATION OFFLINE eco

As with the MS-PV-AG model, the products are fed manually by the operator. Product carriers and adjustable guide rails ensure a stable product transport. As soon as the thermal inkjet printer has printed the serialisation data, the integrated vision system checks that the data is correct. If an error is detected (e.g. insufficient grading), the product is removed from the process and fed to a lockable collection box.

It is not taken into account during the formation of the aggregation pedigree and is ejected and marked in the shift register as soon as the error is detected.

As soon as the filling quantity per carton is reached according to the specified packing scheme, the system automatically generates a serialized label for the shipping carton. It is applied manually by the operator and confirmed by a handheld scanner that the aggregation label has been applied.
Depending on the number of products in the shipping carton and the number of aggregation levels, approx. 15 to 20 products/min can be serialized here.

Model	Products
LSS-PV-AG-C	Serialisation of boxes and one-stage aggregation in carton
LSS-PV-AG-CP	Serialisation of boxes | aggregation in carton | aggregation carton of pallets (two level)

MS-PV-AG > SERIALISATION OFFLINE | AGGREGATION OFFLINE

This workstation enables the manual serialisation of drug packages and their aggregation into shipping cases. For this purpose, each individual box is first printed with order-related serialisation data by a thermal inkjet printing system as it passes by and then manually placed in a shipping carton. As soon as it is filled, the downstream thermal transfer label printer creates an individual serialisation label. The correct print data and print quality are permanently monitored by a vision system.

The operator places the medicine products to be serialized on a reference edge at the infeed. As soon as the thermal inkjet printer has printed the serialisation data, the integrated vision system checks that the data is correct. If an error is detected (e.g. insufficient grading), the product stops at a certain position marked by red LEDs. The removal of the rejected product must be confirmed by pressing a button on the HMI. This is to ensure that only GOOD products with correct serial numbers are placed in the shipping case. When the filling quantity per carton is reached according to the specified packing scheme, the system automatically generates a serialized label for the shipping case. It is applied manually by the operator and the application is verified by the handheldscanner.

Depending on the number of products in the shipping case and the number of aggregation levels, approx. 10 to 12 products/min can be serialized here.

Model	Products
MS-PV-AG-C	Serialisation of boxes and one-level aggregation in carton
MS-PV-AG-CP	Serialisation of boxes | aggregation in carton | aggregation carton of pallets (two level)

AGGREGATION SYSTEMS

STS-T > AGGREGATION OFFLINE | AGGREGATION INLINE

The STS-T series is based on high-resolution image chips and is available with resolutions of 12, 20 or 30 megapixels. With the real-time autofocus, any number of barcodes, even if they vary greatly in height, can be easily and reliably captured without mechanical or manual adjustment.

For this reason, the system also finds its place in the incoming goods department of large pharmacies or re-importers (in entrance module mode). The field of view of 600 mm in width and 400 mm in depth is marked on the base frame. The shipping cases can have a height of up to 380 mm.

Model	**Products**	
STS-T-1C20	approx. 300 barcodes per image	Working range 600 (W) x 400 (D) x 380 mm (H)
STS-T 1C12	approx. 200 barcodes per image	Working range 490 (W) x 360 (D) x 200 mm (H)

Both model variants are available as OEM variants for integration into casepackers.

STS-B > AGGREGATION OFFLINE

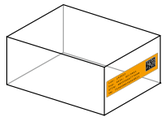
The STS-B was developed for the simple aggregation of pharmaceutical packs into a bundle. For this purpose, the barcodes of serialized products are captured from below by the vision system through a scratch-resistant glass plate. The distance between camera and barcode therefore always remains the same. The maximum working surface is 420 mm (W) x 300 mm (D).

The device is available in 3 variants:

Modell	**Products**
STS-B-B	Aggregation boxes to bundle
STS-B-C	Aggregatio boxes in shipping cases
STS-B-CP	Aggregationboxes in shipping cases | hipping cases of pallets

The detected serial numbers are marked in green so that they are easy for the operators to understand. Depending on the configuration, the system can compare the recorded serial numbers with the default values of the L3 installation. Particular attention was paid to user guidance (workflow) in order to achieve maximum process reliability. In order to completely fill the carton layer(s) or spaces, barcodes that cannot be placed with the barcode facing upwards due to their orientation can be manually added in each layer by the integrated handheld scanner to complete the respective layer or carton.

MAT-CP > AGGREGATION MANUAL



The MAT model series serves as a mobile terminal for all aspects of aggregation and rework. Aggregation and rework can take place over several levels.

The devices are available in the following expansion stages:

Model	Products
MAT-C	Manual aggregation and rework station (1 level) (boxes – shipping cases)
MAT-P	Manual aggregation and rework station (1 level) (shipping cases – pallets)
MAT-CP	Manual aggregation and rework station (2 level) (boxes – shipping cases – pallets)

SOFTWARE

Although the above-mentioned systems communicate with other Level 3 solutions, we offer our b+b Siteserver, a modular and at any time flexibly expandable Level 3 solution. This can be extended by a multitude of additional modules in order to handle your processes as a brand owner, contract manufacturer, logistics service provider or re-importer far beyond the legal requirements.

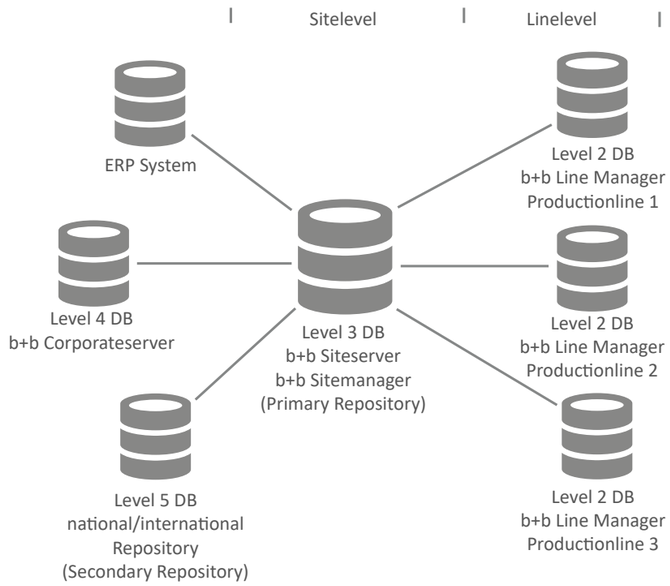
A large selection of interfaces to gateway providers, machine manufacturers, ERP and WMS systems have already been implemented. Our modular software concept enables us to quickly adapt to the requirements of different national and international laws and guidelines and guarantees you a project and processes „without headaches“.

Our standard modules at a glance:

Manufacturing
b+b Siteserver*
b+b SiteManager*
b+b Workorder Label Module
b+b Code Check Module
b+b Repack Module (re-importer)
b+b Aggregation Module

Goods receipt (re-importer/warehouse):
b+b Entrance Module (manual)
b+b Entrance Line Module (mechanically)

Warehousing/Goods issue:
b+b Storage List Module
b+b Packing List Module



A small excerpt of the connections to the authority databases of and to the b+b site server:

- EMVS Direct (European Hub)
- EMVS Web Gateway (European Hub)
- Securpharm System (Germany)
- AMVS System (Austria)
- BPOM System (Indonesia)
- SFDA System (Saudi-Arabia)
- CRPT System (Russia)
- NGDA System (Germany)

b+b Automations- und Steuerungstechnik GmbH

Beerfelden Site I · Dieselstrasse 18 · Airlenbach Site II · Eichenstrasse 38a · 64760 Oberzent (Germany)

phone: +49 (0) 6068 9310-0 · fax: +49 (0) 6068 9310-8990

info@bb-automation.com · www.bb-automation.com

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