Print and Verification, Secure and Straightforward All-in-one Solution

PV650C

HSA SYSTEMS
A UNIQUE IMPRINT

Pack Handling Unit for Pharmaceutical Folded Cartons

Key Benefits
PV650C Pack Handling Unit

- Smooth and stable package handling system

- High quality print due to top-bottom synchronized transport guides

- The machine is prepared for printing on front and the back simultaneously (optional)

- Adjustable conveyor speed

- Integrated ejection control system

- Tool and format-free batch change

- Machine design in stainless steel and transparent polycarbonate

- Easy maintenance access to all machine parts via large top cover and removable back cover

Design, print, verify and control the machine from one interface

Key Benefits
HSAJET® Print & Verify System

- Complete machine controlled by HSAJET® software and hardware

- The unit enables the pharmaceutical company to comply with GAMP and 21 CFR part 11 and other regulatory requirements

- Print and verification in accordance with ISO15415 and ISO15416 and other industrial standards

- The most compact and maintenance friendly system in the market

HSAJET® Pack Handling Unit

The HSAJET® solution is a stand-alone pack handling system for marking applications on folded cartons.
The design of a continuous top-bottom belt conveyance system ensures accurate transport of products, providing optimal conditions for high quality printing.
The use of qualified components allows fast integration into existing line equipment.
The basic machine is prepared for 2-side installation of the HSAJET® HP TIJ 2.5 printhead and camera.

Turnkey Solution

The combination of the HSAJET® software and the pack handling machine results in a compact overall solution for trouble-free print and verification of a folded carton in a pharmaceutical production.
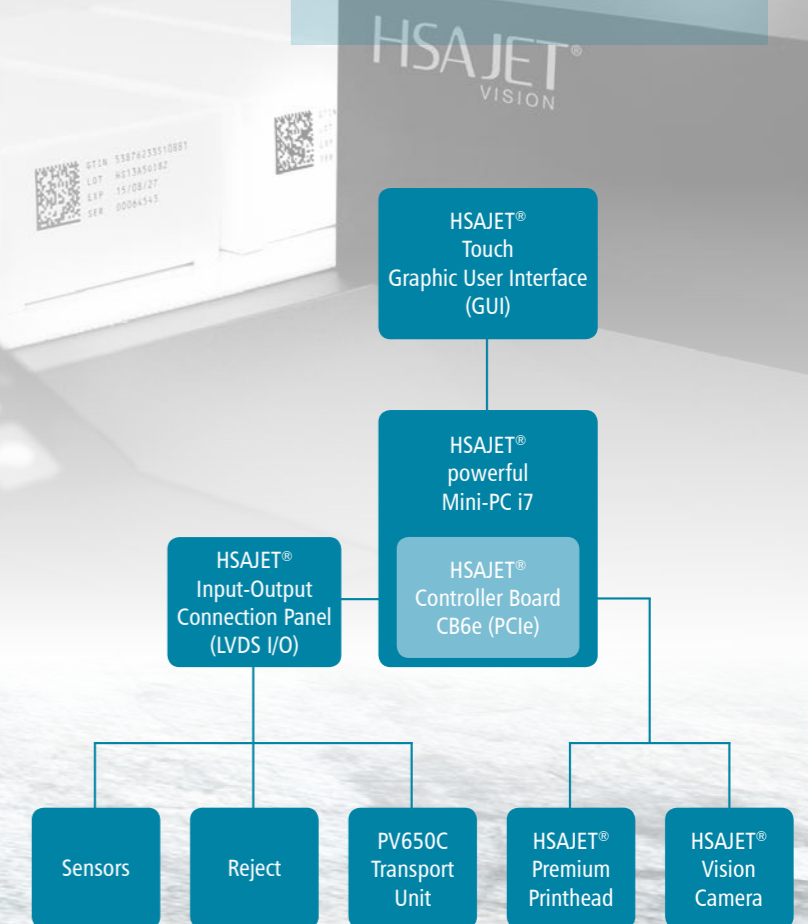
HSAJET® Print and Verification

The HSAJET® Print and Verification system is the control centre of the machine, utilizing a touch screen to provide design of jobs, control of print, verification and eject, and interfacing to other associated equipment.

HSAJET®
Touch
Graphic User Interface
(GUI)

HSAJET®
powerful
Mini-PC i7

HSAJET®
Input-Output
Connection Panel
(LVDS I/O)

HSAJET®
Controller Board
CB6e (PCIe)

Sensors | Reject | PV650C Transport Unit | HSAJET® Premium Printhead | HSAJET® Vision Camera

Main power On/Off, Fuse and Main power connections are found on right side of the machine.

User-friendly machine operation, printer and vision via one central 15" touch screen

Transparent top cover and safety guard.

Beacon
(optional)

Safety switch will stop the machine if cover is opened during production.

Reject bin, with lock, for rejected items.

Stainless steel cabinet
with safety locker for controller

Air inlet, as well as Up-stream/Down-stream connection is easily accessible

The Connection Panel is built into the cabinet. All in- and outputs are distributed internally and externally from here.

Height adjustable supports

Small footprint only 66 x 64 cm

PC On, Emergency Stop and Reset buttons are placed on front of the machine.

Belt speed 60 m/min (standard speed)

Model for higher speeds available

Tool and format-free batch change

Throughput +500 cartons/min

Throughput depends on product size and nature
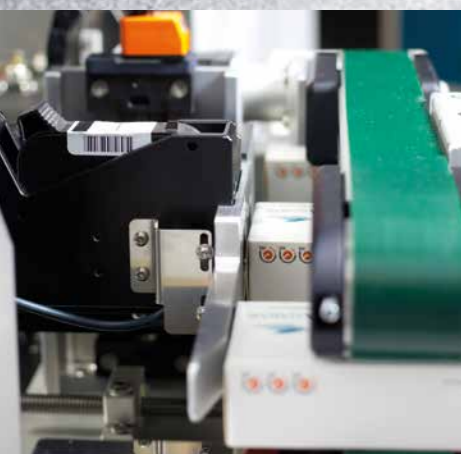
Camera and printhead on common height adjustable bracket.

Integrated ejection control system with eject verification sensor.

The top belt is height adjustable from 10 to 75 mm. Synchronized carton guide between top and bottom belts.

Accept verification sensor.

Sideguide

sideways adjustment from 40 to 210 mm

Vision Inspection Camera: Code verification and grading.

Robust mounting base

Blow-out Reject. The catch tray guides rejected cartons into the bin.

HSASYSTEMS
A UNIQUE IMPRINT

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A UNIQUE IMPRINT

The software is designed to be intuitive for the operator, simplifying the task of handling a complete print and verification system

From the touch interface both print, vision and machine controlling are handled

Multi-lingual interface

Wizard-based job creation

Real-time production and verification status

SOFTWARE

A number of features have been included to provide a self-explanatory user interface

- Easy and intuitive system operation with wizard based job creation
- Automatic creation of human readable application identifiers
- Visual level of information kept to "what is necessary" for the operator
- Automatic preparation of vision control. No teaching needed
- Process control function for system proof

Machine control
The speed synchronisation between the top and bottom belts is done through the software and no manual settings are required.

Access control
The software is protected by a customizable user level access control, preventing unauthorized access. Double password protects sensitive functionalities.

Extensive access and logging for added security
Multi-level access control of unlimited number of users.
System shut-down upon consecutive failed access attempts.

Job wizard
The wizard provides trouble-free creation of datamatrix codes that follow the GS1 structure.
Even complex jobs with multiple application identifiers are easily created. Human readable text is automatically created and positioned on the layout.

Job selection and execution
Print jobs are stored in a job library featuring a folder structure and "quick search" function for easy access.
In production mode information on current status is provided by the software regularly.

Remote controlling via XML
Connection of databases for serialisation is an intuitive and trouble-free task.
Our XML-based remote controlling protocol provides added flexibility for integration purposes, such as connection for track and trace solutions.

USER INTERFACE

Display
15" Touch monitor adjustable in X-Y-Z positions.

Software
HSAJET® multi-lingual software for Printing, Grading and HMI (PGH).

EXTENSIVE LOG

Full Audit Trail
The software features a full audit trail. All data related to the actual printing and verification is logged and time stamped.

- System events, such as emergency switch activation and safety doors being opened, are logged and time stamped

- All printed information is provided with quality grade and verification status
- Images of all rejected items are stored for later review
- Creation of jobs, operator intervention and any changes made in the software are logged and time stamped

SQL database
The logs are stored using the built-in SQL database for later review or proof. The data can be exported or printed. Access to all functions is protected by user level control.

HSA SYSTEMS
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> The system is equipped with a top and bottom belt for smooth transport of the products. The two belts accurately keep the cartons in position to ensure a high print quality
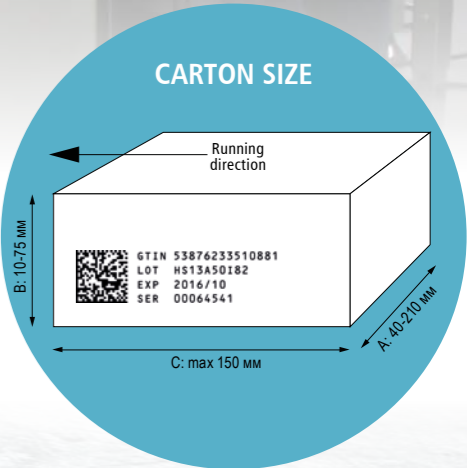
IMPRINT

Technology
HSAJET® Premium printheads
HP TIJ 2.5 technology

Print dimension
Height up to 25.4 mm (1")
Length up to 145 mm (5.7")

Print features
1D code
2D code
Human readable
Date
Time
Counter
Bitmaps
Freely created text
Serialisation (via database connectivity)

PRINTING SYSTEM

Technology
HSAJET® Premium printheads
HP TIJ 2.5 technology

Print height
12.7-25.4 mm (½"-1") 1 or 2 pens

Resolution
Up to 600 dpi

Print distance
0.5-5.0 mm dependent on ink and speed, typically 0.5-2.0 mm (nozzle to print surface).

Ink supply
HP45 ink cartridges, dye and pigmented, water or solvent based inks.

Printhead features, e.g.
Purge and ink reset buttons.

LED indication for cartridge detection and low ink.

Cartridge detect switch.

System controller
Mini-PC cabinet
Intel® Core i7 processor
SSD hard drive for maximum processing power and reliability.
I/O LVDS connection panel

The printing features of the controller are provided by the HSAJET®, PCI Express based, CB6e card which acts as the interface between the controller, printhead, camera and the I/O connection panel.

PRODUCTION

Print position
Print on back
Print on front (optional)

Carton size (max)
A: 40-210 mm (leading edge)
B: 10-75 mm (height)
C: Max. 150 mm (printed side)

1) The actual throughput is dependent on the distance between products, and surface, stability and rigidity of the carton.

Throughput
300[1] units/min (average sized product)
480[1] units/min (special product size and machine configuration)

Precise position control
Synchronized top and bottom belts and sensors ensure that the exact position is known during the carton's travel along the conveyor.

If a carton is incorrectly positioned, the conveyor stops.

CARTON SIZE

Running direction

B: 10-75 мм
C: max 150 мм
A: 40-210 мм

GTIN 53876233510881
LOT HS13A50I82
EXP 2016/10
SER 00064541

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HSASYSTEMS
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VERIFICATION & GRADING

Verification
Verification of printed text, 1D, 2D code.

Grading
Quality of 1D/2D code is determined with grade level between F and A (0-4).
Quality of Unicode text is determined with a font-based reference scheme and grade level between 0 and 100.

Qualification of printed items
In accordance with industrial standards, ISO/IEC 15415 and 15416.

Datamatrix standard
According to GS1 and ISO/IEC 16022

Barcode standard
PIATS code based on Code 128C according to ISO/IEC 15417

Text standard
OCR-B font (possible to use other fonts)

COMPLIANCE

GAMP
The system is made following the guidelines, enabling the customer to comply with GAMP.

21 CFR Part 11
The system is made following the guidelines, enabling the customer to comply with 21 CFR Part 11.

CONTROLS & SYSTEM MONITORING

System management
All settings and control of print, vision and machine interface are carried out via HSAJET® software.

Access control
User level access control with 6 user groups.
Unlimited number of users can be created.
Administrator managed access definition.
Time limited access definition with automatic expiry.

Interlocking
Queue control management with four sensors for carton location tracking.
Carton length verification.
Rejection verification.
Up-stream/down-stream verification (like cartonator and bundler).
Cartridge absent/present verification.
No-gap between boxes detection.

Warnings in software
A message will notify the user when an error or other incidents occurs such as;
Low ink level in cartridge(s).
Device not ready.
Cartridge not inserted.
Up-stream/down-stream not ready.
Top cover open.
Air pressure below required level (optional).
The system will automatically stop after multiple consecutive errors.

VISION SYSTEM

Camera
HSAJET® VS2

Resolution
1280 x 1024 px

Inspection area
55 x 45 mm standard

Light
Integrated light.
Shielding against stray light with diffuser for glossy substrates.

VALIDATION PACKAGE (optional)

DQ, IQ and OQ validation package available.
The validation package is a generic series of documents and templates, which can be edited to meet specific customer requirements in following the GAMP guidelines.

The validation pack includes
• Design Qualification (DQ) with functional specification
• Installation Qualification (IQ)
• Operational Qualification (OQ) with template test schematics

COMPLIANCE

Protection class
IP54

Complies to
CE directives

MECHANICAL

Dimensions
Length: 664 mm
Width: 640 mm
Height: 1015 mm
Height adjust: ±50 mm

Working height
870 mm ±50 mm

Weight
90 kg (approx.)

Top and Bottom drives
Synchronised stepper motors

Belt dimensions
Bottom (length): 646 mm
Top (length):   360 mm
Width: 40 mm

Belt speed
5-60 m/min

Running direction
Left to right

Cabinet
Brushed stainless steel with key locked space for controller and reject bin.

Top cover
Transparent polycarbonate.
Cover equipped with safeguard switch to stop the machine if opened during production.

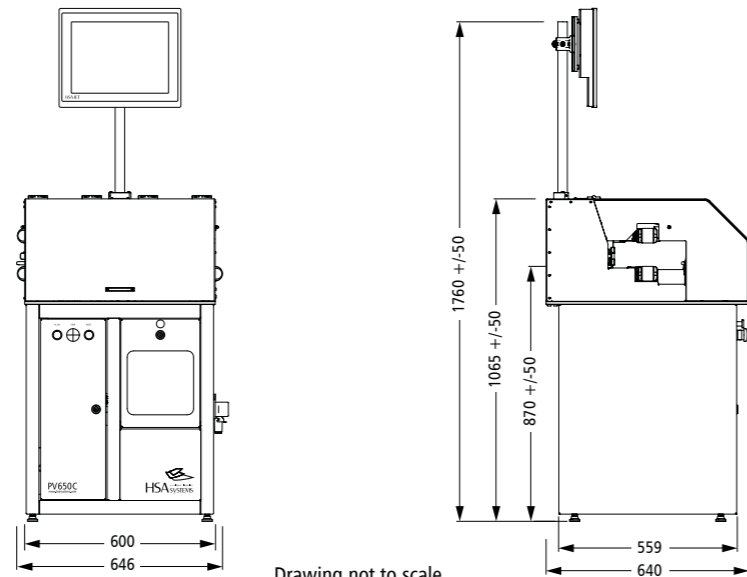**Brackets and Supports**
Stainless steel.
Anodised aluminium.

Printhead & Camera mountings
Integrated common height adjustable bracket for printhead and camera for correct positioning.
Mountkit for front mounting.

Format adjustment
Tool free adjustment. Reproducible by digital display at the spindle.

Drawing not to scale

600
646

1760 +/-50
1065 +/-50
870 +/-50

559
640

ELECTRICAL

Electrical connection
Main switch (lockable)
Industrial power cable

Voltage (1 phase):	230 VAC	110 VAC
Frequency:	50 Hz	60 Hz
Power consumption:	690 W	690 W
Fuse:	3.0 A	6.0 A

Power backup
Uninterruptible Power Supply (UPS) for shutting down system properly in case of unexpected power disruption (optional).

Electrical panel
PC On, Emergency Stop and Reset buttons.

Emergency operation
Switch on front panel.
Hardware controlled emergency stop function.

PNEUMATIC

Air pressure
8 bar main supply (min 6 bar required).

Reject system
Air pressure blow-out for cartons up to 250 g.
Pneumatic push out device available for products >250 g (optional).

CONNECTIONS

External connections
Main power
Air pressure

Upstream/Downstream machine control signals for interaction with other machines.

Product position sensors
for print, camera, reject and accept
Omron E3Z-LS83-2M (3 pcs)
Omron E3Z-T81 (1 pc)

Input / Output
I/O Connection Panel (LVDS) with 40 inputs and 32 outputs.

Verification log file
Error log file
System log file

ACCESSORIES & OPTIONS

Beacon
3-colour beacon for display of current status.

Front print kit
Kit for mounting of printhead and camera on operator's side.

Pneumatic reject
Push out device.

Glossary

2D Datamatrix
Compared to Barcodes, this is a 2-dimensional matrix code made from black and white modules. The code is typically used for pharmaceutical cartons. Compared to conventional barcodes, the density of information is much higher.

FDA
United States Food and Drug Administration.

CFR 21 part 11
Part of the Title 21 of the code of Federal Regulations where the United Stated Food and Drug Administration (FDA) describes how to handle electronic documents so they will be considered valid when submitted to the Food and Drug Administration.

DPI
When talking about inkjet, the word DPI is often used as an synonym for resolution. The DPI is Dots per Inch, representing how many dots of ink are being provided within a given area.

ECC200
One of the most common versions of how to code a Datamatrix, providing a high degree of error correction.

ePedigree
System created by the FDA, for providing information about pharmaceutical products through the supply chain. Part of the ePedigree is that individual cartons are being serialised with unique data.

FMD
The EU Directive on Falsified Medicines Act (FMD) is the European method for preventing falsified drugs entering the supply chains. Part of the FMD is a unique traceable serialisation of individual pharmaceutical cartons.

GAMP
GAMP is an acronym of Good Automated Manufacturing Practice. This is a set of guide lines and procedures that helps ensure that pharmaceutical products have the required quality. One of the core principles of GAMP is that quality cannot be determined from a batch of products but must be built into each stage of the manufacturing process.

GS1
GS1 is an international not-for-profit association with members in over 100 countries. The GS1 system of standards is the most widely used supply chain standards system in the world. It is used to identify the purpose and nature of barcode content.

GTIN
The GTIN is the acronym for Global Trade Item Number. GTIN can be used by a company to uniquely identify all of its trade items. GTIN defines trade items as products or services that are priced, ordered or invoiced at any point in the supply chain.

HMI
HMI is the Human Machine Interface. This is the interface between the operator and the controller.

Identifier
Within the GS1 system, a digit is used as identifier for identifying the type of content of the data which follows. This way, electronic systems can tell apart a product number (GTIN) from an expiry date or a serial number. The identifier system is strictly defined by the GS1 organisations.

IEC
International Standards and Conformity Assessment for all electrical, electronic and related technologies.

ISO
International Organization for Standardization. ISO International Standards ensure that products and services are safe, reliable and of good quality. For business, they are strategic tools that reduce costs by minimizing waste and errors, and increasing productivity. They help companies to access new markets, level the playing field for developing countries and facilitate free and fair global trade.

Linear barcodes
A barcode is a machine-readable representation of data. Typically, a barcode is comprised from a number of vertical lines with a specific distance between each line. The thickness of the lines varies. Linear barcodes are often referred to as 1D codes, as they can only be read across the lines.

PIATS
This is the Chinese equvilant to the European FMD. PIATS is short for Product Identification and Tracking System, and requires pharmaceutical cartons to be serialised.

PIC/S
Pharmaceutical Inspection Co-operation Scheme.

RFID
Radio Frequency Identification is a method for wireless reception of data from an RFID tag. This is typically used for automated data capture and tracking of a product.

TIJ 2.5
Term for Thermal Inkjet 2.5 developed by Hewlett-Packard.

All-in-one Solution