

PAGOpharma
**The new standard
for labelling systems
in the pharmaceutical
industry**



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C O N T E N T S

PAGO is a byword for secure pharmaceutical labelling

Decades of experience

Pago is an experienced specialist in self-adhesive labelling for perfect, high-quality solutions and maximum labelling security. Pago is also a general supplier because its interest is always in the entire labelling process. From labels with their specific material and adhesive properties through printing to the labelling machine. From product decoration via identification to process control. We have developed our expertise over decades and laid the groundwork for our leading position today in innovation and system expertise.

International synergies

Closer integration of markets and uniform standards in the global village confront us with new challenges every day. From the outset, Pago has kept ahead of the trend. Our international structure of the group of companies provides a stable basis for this purpose. We have used that advantage to harmonise criteria profiles at an early date and find innovative solutions that give our customers an edge on markets which are becoming tighter as they become more competitive.

In pharmaceutical labelling, where national security requirements have traditionally been high, finding answers for the new international standards as they develop has become important. Multilevel answers which fit the bill – to satisfy maximum requirements and provide an economical solution for specific individual tasks.

Innovation based on partnership

Close contact with our pharmaceutical customers made us aware of the special background conditions at an early stage, the emphasis being on absolute security, continuous control, verifiable identification, high labelling accuracy and the specific innovative properties, which labels on pharmaceutical substances must satisfy. We have learnt from experience, accepted suggestions, thought them through and developed new concepts with our customers.

The PAGO PharmaTeam

Today, this special know-how is combined in the Pharma Team at Pago – a highly creative competence centre which finds far-sighted solutions for your particular applications.



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Labelling you can trust – innovative concepts for tomorrow's safety standards



PAGOpharma

PAGOpharma – the security breakthrough

The Pharma Team at PAGO has followed this approach to develop its basic PAGO Pharma standard. It provides important features for the right labelling technology.

- Complete construction of machines in V2A high-grade steel, protection housings in breakage-proof polycarbonate.
- Easy cleaning due to cables sheltered by protective conduits, covered screw heads and emergency stop switches mounted in a remote position.
- High standard of programming security:
 - Fail-safe for reliable detection of sensor errors
 - Positive logic to OK the product only after all the relevant features have been confirmed
- Validated software with ongoing amendments to meet GAMP 4 requirements.
- Equipment with the latest automatic labelling devices suitable for pharmaceutical products in Pagomat 6 series.

- Basic safety devices are already fitted as standard:
 - Roll end detection and advance warning
 - Label presence check with pneumatic ejection and shaft

Full provision for efficient validation

In addition, all PAGO systems built to the Pagopharma standard have been specially developed to satisfy pharmaceutical criteria. Production is based on the secure foundation of the GAMP 4 and GMP principles.

The basic package has CE/ISO certification; full machine documentation is supplied comprising the user manual and a one or two day functional test with the presence of the customer on our premises (FAT, Factory Acceptance Test).

General compliance with 21 CFR Part 11 makes optional equipment of our machines to satisfy this standard straightforward. Efficient and time-saving validation is ensured from the outset by these principles.

Exacting tasks...

Labelling and identification of pharmaceutical products are tasks which involve the need to satisfy stringent standards. Statutory rules and standards are tending to increase rather than decrease as progress towards standardisation continues. The highest standard as the lowest common denominator is often regarded as a solution, but frequently by passes the real needs and economic realities.

...call for carefully thought out solutions

PAGO therefore offers a multistage concept for perfect integration of the labelling process into your production line as the right response to the need for security and cleanness in fine chemical and pharmaceutical labelling tasks. Our aim is to provide the right level of security for your particular pharmaceutical task – designed to satisfy your specific needs and all the relevant criteria in an economically viable manner.

PAGO represents a decisive step forwards

The modular thinking behind the Pagopharma concept brings benefits going beyond user-orientated perfect implementation of our labelling technology in your production system.

With the add-on functions and units needed for your labelling process, it also permits customised economical solutions which remain open to future modifications and extensions.

PAGOpharma has the options you need

Pagopharma labelling systems readily permit the optional incorporation of all kinds of identification technologies from hot embossing through thermal printing to an impression check with coloured mark reader. Test devices, such as a pharmaceutical code reader, monitoring cameras or product discharge by router or conveyor belt can be fitted as required. PAGO PMC (Pharma Management Centre) and PAGO LSO (Label Sort Out) additionally increase security for control or protection against incorrect labelling.

21 CFR Part 11 Preparation

Wherever new demands are placed on the pharmaceutical industry, we make our contribution to professional implementation of standards in efficient and economical solutions.

Pagopharma supplies basic machines and attached extension stages including a full-scale labelling technology module (21 Part 11 ready) which satisfies all the relevant criteria to permit 21 CFR Part 11 Compliance for your whole system.

Two great benefits of PAGOPharma: better service – greater security

The increasing demand for complete packages for reliable, smooth and time-saving implementation of our labelling systems into the environment of pharmaceutical production lines is satisfied by our multistage customer-orientated service concept. Two differentiated add-on stages extend our Pagopharma standard offer.

PAGOPharma +

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Over and above the basic Pagopharma standard, the Pagopharma+ standard ensures full validation of the Pago system and Change Control according to GAMP 4.

As well as the project plan, the validation documents include functional specification (FS), installation qualification (IQ) and

operational qualification (OQ/ function test).

Throughout its life cycle, your project is handled by an expert project manager from the Pago Pharma Team, who has been specially trained to satisfy pharmaceutical needs and criteria and is your direct contact person at all times.

PAGOPharma ++

PAGOPharma ++

As a further extension stage, Pagopharma++ gives on site installation support and a two-day accompanied commissioning or factory acceptance by the project manager and a specialised technician from our Pharma Team.

During this attendance, we provide one day's professional training for your qualified staff, based on a defined training plan which is also part of the documentation.

Following an agreed period, subsequent training for your technicians is provided on site on two further days, including further machine verifications as part of the Pagopharma++ package.

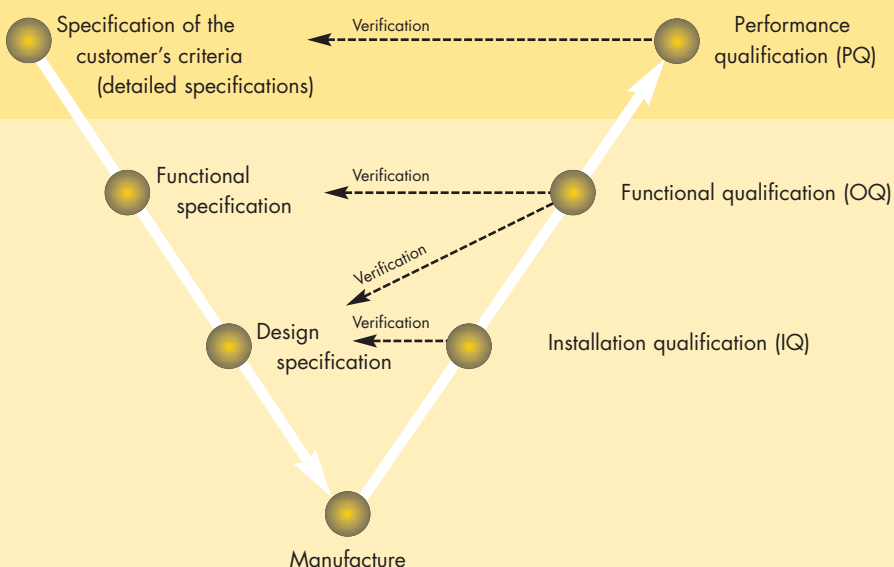
Our contribution to smooth integration into your system

System expertise for pharmaceutical labelling means competence for smooth and economical integration of the labelling process into the customer's specific environment – to comply with your particular criteria and security standards.

Let us discuss the best concept to solve your particular labelling task.

PAGO < > CUSTOMER

Validation to PAGOPharma+ (GAMP 4) standard



If Pagopharma+ is chosen, the acceptance test on our premises (FAT, Factory Acceptance Test) is a three to four day sequence with direct advice from the project manager.



Reliable expertise

Pago Systems satisfy EU directives. Pago benefits from DIN EN ISO 9001 certification. We provide dependable service!



Everything under control – the guarantees of process and product security



A sharp eye
Optional camera monitoring (top) or code reader as part of the Pagopharma standard – only the latest verification technology is used in Pagopharma systems.

When verification is essential

To guarantee maximum product dependability which the pharmaceutical industry requires in respect of the labelling process, all Pagopharma systems have complete verification devices.

1 Label presence check and ejector station

Luminescence scanners check for the presence of labels in the production run. When an initial monitoring function reports an error, the product concerned is discharged by an electro-pneumatic system. Confirmed security is ensured by a second check on ejection.



Highly precise stable adjusting devices with precise adjustment scales permit simple and accurate setting of all the units.



Sophisticated control security

The sophisticated Pagopharma security concept is already embodied in the user-orientated standard control. Its fail-safe programming guarantees detection

of defective sensor signals so making incorrect labelling impossible. The positive logic concept only approves the labelled product if all the test parameters have been positively resolved.



PAGO Pharma Management Center

As an option, all Pagopharma systems can be equipped with a PAGO PMC main central control. This permits convenient equipment operation via a single unit and combines all the intelligent assemblies such as the monitoring, identification and safety devices. Your database and online support permit very simple product conversion. In addition, improved diagnostics are provided with the possibility of online assistance.

Specialised security: options

Individual security measures must always be taken to satisfy the highly specific security criteria applicable to pharmaceutical products. We offer various options for this purpose, with smooth integration into the overall line control.

2 Code monitoring

The extended dispensing device of the automatic Pagomat labelling units is fitted as standard with a Pharmacode monitoring reader/detection system. This initiates immediate tracing/rejection if a fault is detected or activates label sort out (optional).

3 Individual product identification

Variable high quality imprints can be applied using a thermal printer (as illustrated) or hot foil embosser in the ongoing labelling process to mark the products with codes, information or batch numbers. The units used by us for this purpose are integrated as standard with all the relevant parameters into the facility security monitoring.

4 Monitoring cameras

For opto-electronic detection of all kinds of product features, various recording systems are available on request.

5 Colour cap check

Colour sensors check at the machine infeed whether the infusion bottles have the right colour coding. Depending on whether the colour cap, the knurled ring or printed information is to be checked – the product can only pass the labelling test as fault free when the signals from all the verification devices have been positively confirmed.



6 Precaution against incorrect labelling: the Label Sort Out System PAGO LSO

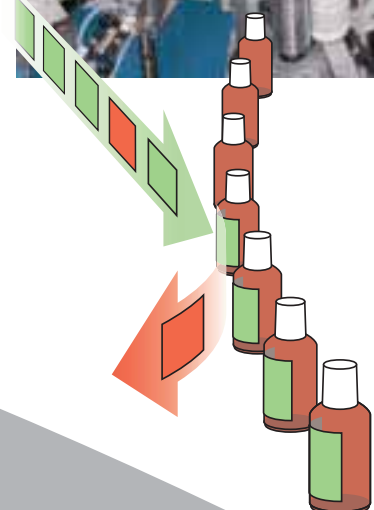
Defective labels previously necessitated cost-intensive product follow-up, ejection and special treatment of the product.

Pago LSO prevents labels detected as being defective from reaching the product. They are automatically rejected from the process and collected separately.

Label errors detected by the code check and batch print monitoring units on the dispenser tongue result are followed by targeted disposal of the label.

As soon as the defective label reaches a dispensing position, it is rejected and removed via a take-up roll. The unlabelled product is returned to the labelling system after a short stop or ejected in the case of a linear production system. No unlabelled bottles reach the line delivery end.

However, for security reasons, a label presence check with an ejector station is generally fitted.



In conjunction with the appropriate monitoring devices and computer links, PAGO PMC naturally also satisfies standard 21 CFR Part 11 in respect of verified user management and recording of modifications (audit trail).

PAGO System 214/221

Labelling of pharmaceutical vignettes and tamper evidence labels for folding boxes



The PAGO System 214/221 is a labelling system which applies vignettes and tamper evidence labels to the pharmaceutical products. Proper labelling is checked directly. Defective labelling is immediately recognised and the corresponding products rejected.

Consistent accuracy

The aligning system on the machine entry side ensures precise alignment of the folding boxes on the conveyor belt. Side belts and an upper retaining belt guarantee safe guidance for labelling purposes. The central transport unit drive ensures absolute synchronisation. This enables the label position on the product to be precisely defined and reproduced.

Dead accurate – 300 times a minute

The high performance Pagomat 6 automatic labelling machine applies 300 labels per minute in conjunction with the aligning station. Without the aligning station up to 400 labels can be applied each minute.

The PAGO System 214/221 is a multi-purpose machine combining vignette labelling with tamper evidence labelling on both sides. The vignettes are applied to the top of the folding box. The tamper evidence labels are dispensed at the side and deflected over the folding box edge.

Monitored security

All labelling processes can be reliably checked by an intelligent monitoring station. Faults are detected immediately and the products concerned removed through

the ejector station. The ejection check completes the pharma security concept and ensures the presence of a continuous verification chain.

Product-specific identification

The PAGO System 214/221 satisfies all special pharmaceutical requirements. Code readers to check the vignette codes on the dispenser tongue can be fitted as options together with thermal printers or hot foil embossing devices. Codes, information or batch identifications can be printed or checked before the labelling process. An additional camera can read comparative data or check for presence of labels as required. The labelling capacity is adapted to the required performance range.

Simple operation

The PAGO System 214/221 is fitted with a clear and convenient control and automatic pre-warning of approaching label roll end. Optionally, a PAGO PMC control with touch screen panel can be fitted.

Compact modular structure

The PAGO System 214/221 has a modular design for box handover and attachment of further components (such as a protective housing). Its compact structure supports smooth integration into the production line.





Precise alignment

The products are aligned precisely in the side conveyor belt in feed.



Light barrier fork

...for precise label scanning in the high performance range.



Vignette application

Up to 300 vignettes per minute can be accurately positioned on the folding box.



Notes on standard equipment of the Pagopharma machines and the many available options will be found on pages 4 to 7.

Tamper evidence labelling

(left fig.) The labels are dispensed on both sides and deflected to the box edges. Sensors check proper application.

Comparison check (center fig.)

A camera on the discharge side reads the data on the applied vignette for reconciliation with the database.

Ejection station (right fig.)

Products with defective labelling are detected immediately and separated in the ejector station.



PAGO System 610 Pharma

Maximum precision and versatility – all-round labelling with the rotary star system



All-round or front/back labelling with a precise visual gap

The PAGO System 610 Pharma is suitable for all kinds of applications and can also handle multiple Pagoinforoll wrapped labels.

Precise axial alignment

The perfect all-round labelling of cylindrical products on fast-running production lines is a technical challenge. Especially when double labels (two labels per product) or target labels (to be placed at a particular position on the product) are needed. PAGO system 610 Pharma handles these labelling needs easily with its rotary star system. The stable three-point product support during labelling guarantees optimum precision without spiral effects and a perfect label fit.

Fast peripheral labelling

is generally effected by the PAGO System 610 Pharma in high performance mode using a wrapper strip. The peripheral area can be labelled partially or with an accurate visual gap or overlapping alignment with the edges.

For difficult special tasks

Special requirements such as double labelling with front and back labels (arranged alternately on the roll, including the possibility of different label lengths) or wrapped labelling with multi-layer information labels, can be handled perfectly by the PAGO System 610 Pharma – depending on the needs in an operating cycle in conjunction with a driven press down roll or in continuous mode with the wrapper strip.

Stable structure and plenty of room for options - PAGOmat Pharma

The Pagomat System 610 Pharma with the Pagomat Pharma is ideal for stringent identification and monitoring requirements with its innovative drive technology and an extended dispenser tag. Ample space is available for the attachment of label presence checks, thermal printers or hot foil embossers, batch pressure and pharma code check. Perfectly precise imprint of variable information is therefore assured. For the application of multilayer PAGO media labels or PAGO inforoll wrapped labels, the Pagomat Pharma can be ideally equipped. Maximum labelling accuracy is guaranteed by the highly stable double suspension for the base plate.



PAGOmat Pharma

Robust labelling technology for tough use in continuous high performance production: the Pagomat Pharma combines this basic virtue of our automatic labelling machines with a highly vibration-resistant double suspension and a very long dispensing tongue. Ample space is available on this machine for the various identification and monitoring devices as well as the automatic label sort out.



Top performance of all components

Pago System 610 Pharma sets the pace with its capacity of up to 350 articles per minute in continuous operating mode. Even in the cycled mode for double or target labelling, up to 100 pieces per minute can be handled. The machine is infinitely variable from zero to the maximum speed with automatic speed adjustment for all the functional assemblies.

Short reset times and simple format change

The modular design and convenient assemblies ensure flexibility and short set-up and adjustment times. For format conversion, the rotary star is simply changed without a tool using its three-star handle.

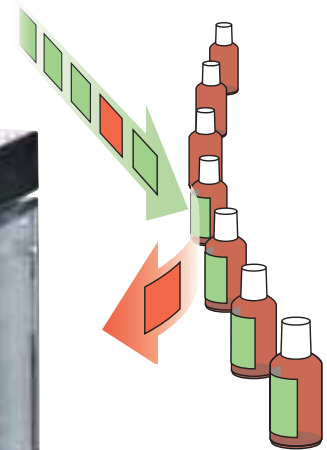
Label Sort Out – for additional security and economy

As an option, an LSO system protects the passing containers against expensive labelling errors. Only labels which have been checked and found to be correct reach the bottle.

Defective labels are registered by the monitoring devices on the dispenser tongue, followed up carefully and disposed of or dispensed at the extremity on a separate take-up roller. The otherwise usual complex recording and isolation when faults occur is unnecessary.



Only a very short production delay occurs without unlabelled or defectively labelled bottles occurring. A label presence check with a discharge station on the machine delivery side is, however, advisable for security reasons.

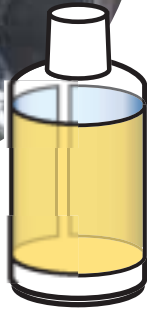


Details of the standard equipment of Pagopharma machines and the various options will be found on pages 4 to 7.

PAGO System 560 Pharma

Efficiency and economy –

all-round labelling with wrapper strip



The PAGO System 560 Pharma combines convincing flexibility with universal use. It provides a technologically secure basis for fast and economical labelling of all kinds of cylindrical plastic and glass packages.

Reliable technology

All the functional and auxiliary assemblies are mounted on the base plate in a clear layout for easy use. The assembly device to mount the Pagomat automatic labeller has a strong double tubular design. Height adjustment is effected by means of a spindle with a hand wheel. A digital positioning display facilitates adjustment and reproduction of the values. The PAGO System 560 Pharma is infinitely adjustable. The conveyor belt, isolating screw and wrapper strip are centrally driven.

Powerful in every respect

For continuous operation or in the high performance mode with labelling capacities of up to 300 per minute!

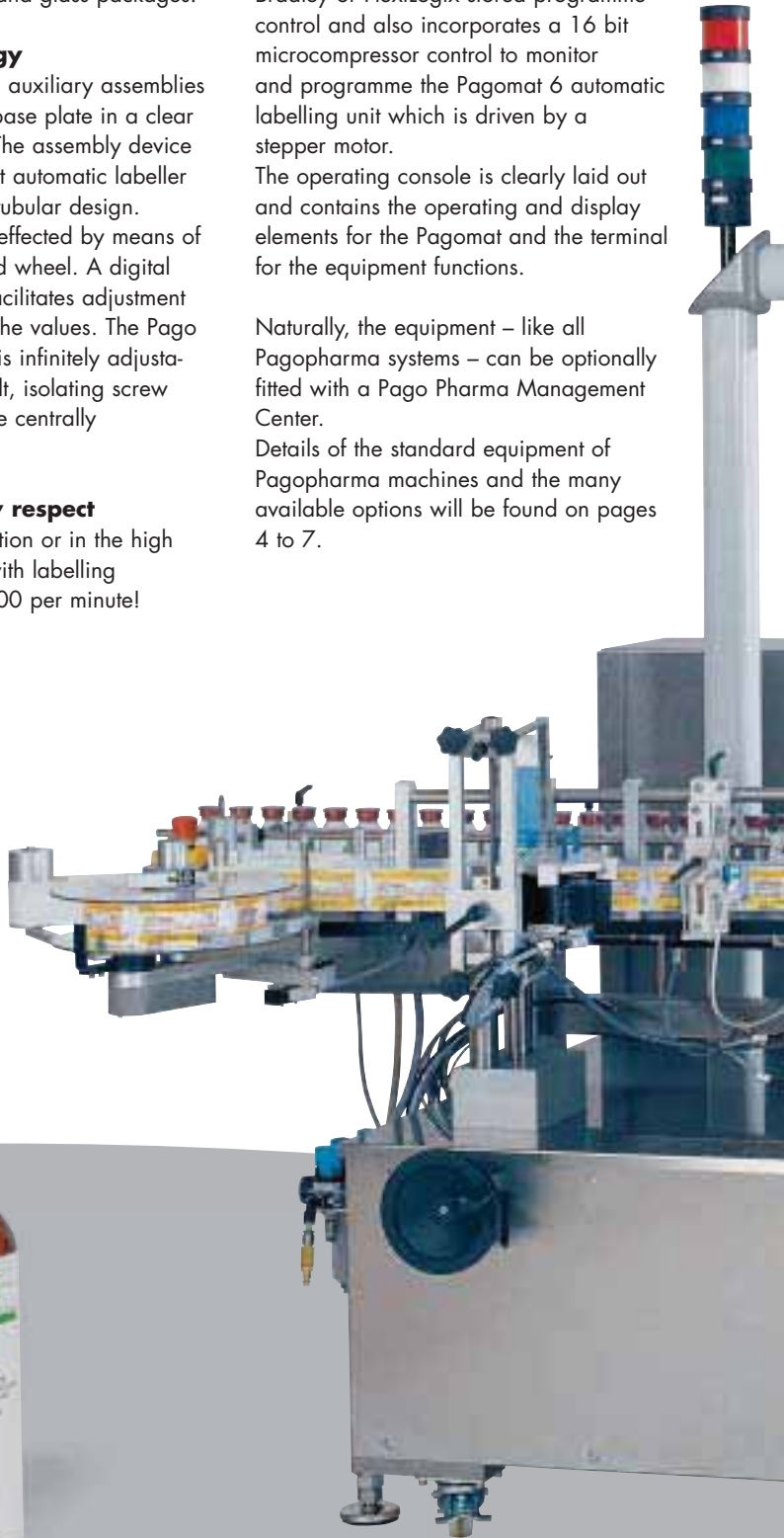
Control and operation

Like all the PAGO systems, the PAGO System 560 Pharma in its standard version is equipped with a Siemens S 7, Allen-Bradley or FlexiLogix stored programme control and also incorporates a 16 bit microcompressor control to monitor and programme the Pagomat 6 automatic labelling unit which is driven by a stepper motor.

The operating console is clearly laid out and contains the operating and display elements for the Pagomat and the terminal for the equipment functions.

Naturally, the equipment – like all Pagopharma systems – can be optionally fitted with a PAGO Pharma Management Center.

Details of the standard equipment of Pagopharma machines and the many available options will be found on pages 4 to 7.



Precise identification

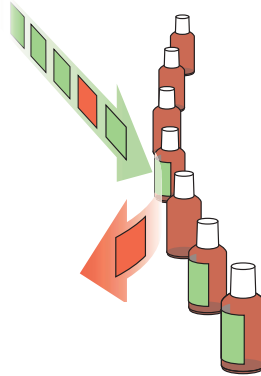
To print individual product data, all kinds of hot foil embossers or thermal printers are available. All production-relevant properties such as temperature etc are monitored.

Simple and easy product change

Pago System 560 Pharma offers extreme flexibility in respect of the choice or change of products to be labelled as the screw is the only format element that has to be changed.

Ejector station

Unlabelled or defective products are eliminated from the production process by an electropneumatic ejector unit.



PAGO Label Sort Out

For linear running systems, like the Pago System 560 Pharma, an effective and economical prevention of incorrect labelling is available as an option in the shape of the label sort out technique. Defective labels are already detected on the dispensing tongue of the Pagomat, followed through to the end of the tongue and dispensed and disposed of on a separate take-up roller. They do not reach the product. The unlabelled product is detected by the subsequent label presence check and eliminated at the ejector station. Production remains uninterrupted.



Details of the standard equipment of the Pagopharma machines and the many available options will be found on pages 4 to 7.

PAGO System 520 C Pharma

Precise front and back labelling of shaped bottles on linear machines



With its sophisticated linear technology and modular design, the PAGO System 520 C Pharma is ideal for perfect labelling of shaped bottles. Its development was based on our extensive experience in the highly demanding cosmetic industry. The simple change of the few format pieces without the use of special tools makes this equipment a flexible multipurpose solution.

Precise separation and alignment

Product separation is effected behind a blocking zone by means of an isolating screw with indexing designed for the particular labelling task. The robust structure swivels and allows fast exchange for product changes. The product alignment for precise labelling is effected by means of eccentric jaws which act on both sides and follow the linear product flow.

250 accurate labels per minute

With this high capacity and constant high delivery quality, the PAGO System 520 C Pharma sets new standards.

For precise labelling, perfect product fixing by AIR-PRESS-Technology together with stable, precise and rapid change assembly devices set the standard. The robust automatic labelling unit in the Pagomat 6 series is your guarantee of perfect label application.

Special requirements

The machine also permits accurate labelling of shaped containers with complex product shapes. In such cases, the labels are additionally set to the correct position by means of an optional post-printing station. Various additional assemblies are available for this purpose depending on the particular task and are synchronised with the machine running. The application of multilayer Pagomedia labels or Outserts and three-sided labelling across the corners are possible.





Perfect control and continuous monitoring

The PAGO System 520 C Pharma also permits the integration of all pharmaceutically relevant monitoring and coding devices. All the current monitoring systems using cameras for testing the imprint, presence and positions of the labels through to print quantity sensors and print mark checkers are available as options. We integrate the

monitoring units and with the optional PAGO Pharma Management Center create the high level control for perfect overview, continuous security and guaranteed ejection of defective products.

Pharma Management Center PAGO PMC

With its combination of all the intelligent assemblies in a central operating unit, PAGO PMC makes the labelling process control extremely simple, even with the most stringent monitoring requirements. 21 CFR Part 11 requirements are satisfied and can be easily achieved in combination with the necessary monitoring and computer units. With the database and online support, product conversions are easily implemented by PAGO PMC.



For reliable seating: eccentric post-printing station

Special labelling materials or product forms frequently require additional label dimension checks. The eccentric post-printing station with shaped jaws for the specific products is an optional extra assembly supplied for this purpose.



Fast product change

PAGO PMC with its memory functions and the tool-free exchange of the small number of format parts create flexibility for fast product changes. Only the isolating screw and the shaped jaws of the alignment station and possibly the optional post-printing station need replacement.



Details of the standard equipment of Pagopharma machines and the many options will be found on pages 4 to 7.

Incorporation of the PAGOmat into your production line

Attached automatic devices like the Pagomat 6HS offer an efficient and economical possibility of effecting price sticker labelling directly in the discharge belts of the cardboard box preparation machines on pharmaceutical production lines. The high performance labelling machine adjusts automatically to every cardboard box machine. The electrical lift column ensures ultra-simple operation and height adjustment.

Our automatic attached units can of course be fitted with optional monitoring devices. The intelligent control concept guarantees ideal communication with previous and subsequent equipment.

The installation length of the automatic attached unit is generally immaterial and its modular design makes for perfect solutions even when space is at a premium.



PAGOmat 6 For economical in line labelling



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