



SEPHA
working together

ACHIEVING EXCELLENCE
IN PHARMACEUTICAL
ENGINEERING



SEPHA

working together ... *with pharmaceutical manufacturers, R&D laboratories, contract packers and dispensing pharmacies*

working together ... *to improve the quality assurance of packaging processes, improve efficiencies and reduce waste*

QUICK GUIDE

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Sepha has been designing innovative products in the specialised field of pharmaceutical blister packaging since 1980, including the pioneering work on the first commercially available automated deblistering equipment.

The SEPHA name is now associated with quality machinery in the field of R&D blister packaging, product recovery and, more recently, for technological breakthroughs in non-destructive leak testing.

about us

SEPHA has extensive technical expertise within the pharmaceutical industry. Our close working relationships with a large number of the top global pharmaceutical manufacturers and dispensaries enable us to work with them to develop solutions which reduce downtime, improve process efficiencies and increase quality.

All SEPHA's products are designed, developed and manufactured in-house to ensure the highest standards of quality. Our innovative designs are covered by patents, registered designs, or copyrights.

We support our customers in meeting the stringent demands placed upon them by the highly competitive and regulated pharmaceutical markets. SEPHA endeavours to develop lasting partnerships with all of our customers, irrespective of their location across the world, and in many cases have become regarded as a natural extension of their R&D, production and packaging departments.

“ Our philosophy is to develop equipment that is simple for non-skilled users; equipment that saves time and money; and equipment that solves problems, not creates them. ”





SEPHA

Our EZ BLISTER range of blister packing machines offers flexibility by producing extremely high quality blister packs from a wide variety of packaging materials.

Ideal for small batches of pharmaceutical, medical or nutraceutical products from tablets and capsules to ampoules and medical devices, the EZ Blister range is economical, time efficient and suitable for:

- clinical trials and stability studies
- package development
- marketing samples
- low volume production eg. of specialist drugs

The compact and easy to use models provide a 3-in-1 operational flexibility and combine the convenience of a lab-scale machine with the capability of a full sized production machine.

BLISTER PACKING

Control your schedule

Why wait until your Production Department can fit your small R&D batches into their busy schedule? EZ Blister gives your lab total control, so clinical trials and stability studies are completed on time and to budget. Every day saved in R&D is a day when a new product can make extra profits on the marketplace. Your blister packing department also benefits as they will not have to clean and set-up large scale packaging equipment for small batches.

Flexibility

With the capability to handle all thermoform and cold-form materials the EZ Blister offers high quality packs for all requirements including child-resistant/peelable, sachets, and monitored unit dose packs.

Repeatable results

Programme bespoke settings for temperature, air pressure and dwell time through the electronically monitored controls or use the EZ Blister pre-set limits for easy operation.

For more information about R&D blister packing visit www.sepha.com

SEPHA

EZBLISTER PHARMACEUTICAL

EZBLISTER GENERAL PURPOSE

Laboratory blister packer for clinical trial batches with a choice of two machine construction finishes to suit your factory environment.

FEATURES

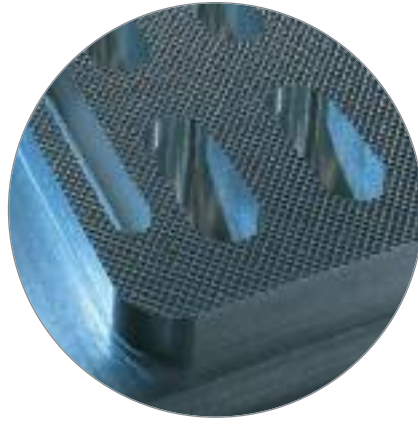
- Forms from the roll or from cut pieces
- Quick release, tool-less changeover of size parts (Patented) in 2 minutes
- Fast set-up
- Easy to use - no specialist knowledge required
- Compact design - saves space in the laboratory
- Mobile - easily wheeled from one room to another
- Fast cleaning - stainless steel, fully cGMP
- Optional sealing under vacuum or inert gas

▼ EZBLISTER PHARMACEUTICAL



▼ EZBLISTER GENERAL PURPOSE





MACHINE OPERATION

The EZ Blister machines have a 3-in-1 operational flexibility:

- 1. Forming** - Trays are formed automatically from the roll, advanced and separated manually or with optional cutting device.
- 2. Sealing** - The formed trays are sealed and batch code embossed automatically using pre-cut lidding foil.
- 3. Perforating and Cutting** - The sealed trays are cut and perforated automatically to produce the finished packs.

TOOLING

A set of custom tooling is required for each different type of blister pack. Sepha offers customers a free blister design service.

TECHNICAL SPECIFICATION

OPERATION	Semi-automatic	
CONSTRUCTION	Pharmaceutical Model: General Purpose Model:	Stainless Steel (Grade 316) Powder-coated Steel
FORMAT DIMENSIONS	Format Area: Max. Draw Depth: Max. Foil Width: Max. Foil Roll Diameter: Core Diameter:	190 x 130mm (7.5 x 5") PVC: 15 - 25mm (0.6 - 0.9") Alu/Alu: 8 - 12mm (0.3 - 0.5") 165mm (6.5") 400mm (16") 35 - 85mm (1.4 - 3.3")
CONTROLS	Temperature: Pressure: Timers: Counter:	0 - 200°C 15.75kN 0 - 9.99 sec 0 - 999 cycles
POWER SUPPLIES	Electrical: Air Pressure: Air Consumption:	110/230V single phase 6A 6 Bar 14.5 litres/stroke at max. speed
OPERATING SPEED	Approx. 12 cycles per minute for any single operation	
MACHINE DIMENSIONS	750 (W) x 830 (L) x 1355 (H) mm (30 x 33 x 53")	
MACHINE WEIGHT	200kg (440lbs) / Shipping Weight: 300kg (660lbs)	
TOOLING CHANGEOVER	2 - 3 minutes	

As EZ Blister offers many of the features found on larger, fully automatic blister packers, R&D laboratories can confidently produce small batches of the highest quality





SEPHA

Our LEAK TESTING range of machines offers state-of-the-art non-contact scanning technology at an affordable price.

With the ability to handle pharmaceutical or medical blisters, sachets, pouches and bags, our scanning machines offer a non-destructive alternative to other messy tests on the market.

The clean and dry process allows samples which pass the test to be replaced in the packaging line reducing waste.

LEAK TESTING

Why test blister packs for leaks?

Testing is vital to ensure drug stability through protection from moisture, air and bacteria. Leak testing also minimises reject blisters and reduces deblistering and excess waste disposal. Performing leak testing before stability studies will confirm that all results apply to blisters which are known to be properly sealed.

Fully validated results

With a reliable validation process as standard, operator subjective judgments and errors are avoided.

Accurate and clear readings

While other tests can only detect holes above 50 microns, our detection technology tests for leaks as small as 7 microns and identifies the precise pocket or pack that is leaking. Detailed results are then available for analysis.

To compare various leak testing methods visit www.sepha.com

SEPHA BLISTERSCAN

Non-destructive leak testing for blister packs utilising state-of-the-art non-contact scanning technology at an affordable price. The perfect alternative to the messy Blue Dye test.

FEATURES

- Detects leaks as small as 7µm in individual blister pockets
- Non-destructive clean and dry process so packaging and its contents are not damaged. Fewer samples are destroyed - less waste generated
- Fully validatable - faults identified by machine not operator removing subjectivity. Comprehensive GMP or GAMP validation documents available
- Full web testing, with no limit on number of pockets
- Can be set to operate at same rejection level as Blue Dye Test (30-50µm)
- Fast, semi-automatic set-up with self-testing mechanism to verify the functionality of the sensor each time
- Automatic sampling and statistical testing
- Test data can be automatically collected, printed and stored or downloaded for post-test analysis. Results stored for 10 years min.
- Innovative product recognition feature means product-specific test data is stored automatically in pre-designated file locations
- Easy calibration using tool supplied. Select calibration options through the touch screen display

▼ BLISTERSCAN



TEST METHOD

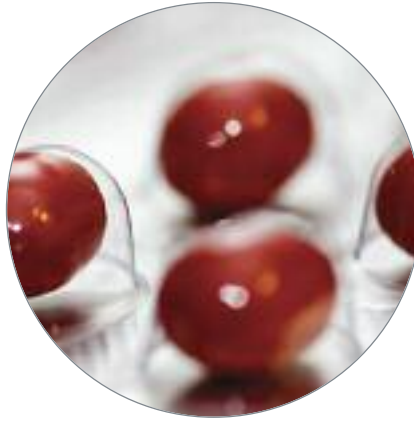
A beam of light scans the individual pockets before and after applying a vacuum. After a set dwell time the blister pockets are scanned again. A Pass or Fail result is given based on a comparison of the 'before' and 'after' readings against a predetermined leakage acceptance level. From the results, a correlation with the hole size can be made.

Trace the source of a leak

BlisterScan instantly pinpoints the location of a faulty pocket seal. Further graphical analysis is provided for each individual blister pocket. This improves your blister packing process by enabling engineers to trace and identify the source of a leak, according to current PAT (Process Analytical Technology) thinking.

The BlisterScan screen shows a pass (green) or fail (red) result for each blister pocket and also indicates the absence of a blister pack (black).





MACHINE OPERATION

No specialist knowledge or training is required:

1. Custom tooling is inserted into the tooling holder and is automatically scanned as soon as the drawer is closed. BlisterScan automatically selects the correct test method and displays pre-determined information (e.g. Nest Number, Product Name, Test Method, Date and Time).
2. Operator fills in the relevant batch data via the touch screen and keyboard.
3. The drawer is opened and the blister pack is placed onto the plate.
4. The drawer is closed to seal the test chamber. The operator presses the START button on the touch screen.
5. A Pass or Fail result is indicated immediately on completion of the scans (approx. 2 minutes after the start).

LOW COST TOOLING

Test method development, and two low-cost custom-made plates, are required for each different blister format.

TECHNICAL SPECIFICATION

BLISTER WEB	Up to 320mm width (13")	Up to 150mm length (6")
TEST CYCLE TIME	1 - 6 mins	
MEASUREMENT RANGES	Down to hole size of less than 7 microns	
TOOLING CHANGEOVER	Approx. 30 seconds	
CONFIGURATION OPTIONS	DVD Ethernet	CD-ROM drive 2 x USB
POWER SUPPLIES	Electrical: Air:	110/230V AC Single Phase 6 Bar
USER INTERFACES HARDWARE	VGA LCD MMI colour wide angle touch screen display with virtual instruments. Integral QWERTY keyboard. Printer	
SOFTWARE	System can be run in compliance with 21 CFR Part 11	
CONSTRUCTION	Stainless Steel (Grade 316L)	
MACHINE DIMENSIONS	630 (W) x 770 (L) x 1600 (H) mm (25 x 30 x 63")	
MACHINE WEIGHT	125kg (275lbs) / Shipping Weight: 300kg (660lbs)	
WARRANTY	Supplied with a 12 month warranty. After this period we recommend the customer takes out a Service Agreement.	

SEPHA Leak Test Service gives customers a 'snap-shot' of the quality of their current stability batches. The test data results are returned in graphical and tabular form for analysis

SEPHA PAKSCAN

Non-destructive leak testing for pouches, sachets and other flexible packs (non-porous materials) which contain dry powder or a solid component with a head space inside the packs.

FEATURES

- **Non-destructive test reduces waste costs**
Tested samples can be replaced in the packaging line as they are not damaged during the test process. This test is clean and dry, unlike the Methylene Blue Dye method, therefore PakScan generates less waste and reduces associated waste disposal costs.
- **Test multiple packs simultaneously**
PakScan inspects up to 4 large sachets simultaneously, each pack measuring up to 250mm x 80mm x 20mm. This speeds up testing and offers a more representative view of the entire production web. The machine can be customised for smaller or larger format areas or to accommodate users' specific sample size requirements.
- **Identifies leaks from 10µm**
PakScan identifies leaks in individual packs as small as 10µm, depending on the pack size and format. The system can also be pre-programmed at the same rejection levels as the Blue Dye Test (usually 30-50µm), if required.
- **Fully validatable system**
PakScan test results are generated automatically based on the pre-programmed test method used for each pack. As operator subjectivity is removed, the system can be validated. Complete GMP or GAMP validation documents are available.
- **Clear result indicator screen**
Intact pouches show a green 'Pass' result and leaking pouches show a red 'Fail' results.

▼ PAKSCAN



Pack 1	Pack 2	Pack 3	Pack 4
PASS	GROSS FAIL	UPPER GROSS FAIL	UPPER GROSS FAIL
Gross Force 2261 g	Gross Force -2 g	Gross Force 5079 g	Gross Force 5633 g
Force Decay -2 g	Force Decay -12 g	Force Decay 214 g	Force Decay 118 g



MACHINE OPERATION

Sample packs are loaded into a custom designed product nest and the test chamber lid is closed. There are then 4 key test phases:

- 1. Evacuation Phase** - A pre-determined level of vacuum is applied to generate an expansive force which is monitored throughout the test cycle.
- 2. Stabilisation Phase** - Following evacuation of the vacuum, a stabilisation phase allows the air temperature to normalise.
- 3. Decay Test Phase** - The decay test phase measures any reduction in head space pressure. If the expansive force decays by more than a set amount the pack will be classed as a failure.
- 4. Gross Hole Identification Phase** - At the end of the decay phase, if the reactive force is less than the pre-determined level in the test method, a pack will be classed as a gross leak failure.

TECHNICAL SPECIFICATION

OPERATION	Semi-automatic	
CONSTRUCTION	All product contact areas constructed from Stainless Steel (Grade 316)	
PACK TYPE	Sachets, pouches, bags, MAPs - in flexible and non-porous materials	
PACK DIMENSIONS	250 x 80 x 20mm (10 x 3 x 0.8") per pack	
POWER SUPPLIES	Electrical:	110/230V 1kva Single Phase
	Air:	6 Bar
OPERATING SPEED	Up to 4 cycles per minute	
SOFTWARE	System can be run in compliance with 21 CFR Part 11	
MACHINE DIMENSIONS	650 (W) x 750 (L) x 1660 (H) mm (25 x 30 x 65")	
MACHINE WEIGHT	150kg (330lbs) / Shipping Weight: 180kg (400lbs)	
TOOLING CHANGEOVER	Approx. 3 minutes A different product nest is required for each product to be tested	

A touch screen user interface monitors the PakScan progress through a virtual instrument panel





SEPHA

Our comprehensive PRESS-OUT range of deblistering machines enables the safe recovery of valuable product from all types of rejected blister packs.

Over 15 million hours of reliable, fast, hygienic and cost-saving operations worldwide are achieved from our deblistering solutions. That is why the top pharmaceutical companies choose SEPHA Press-Out.

All models in the Press-Out range allow rapid changeover and minimum downtime with maximum hygiene and efficiency. Using minimal pressure to extract tablets and capsules ensures that foil pieces do not detach from the blisters and prevents product damage during the deblistering process. SEPHA has products suitable for push-thru blisters as well as child resistant or peelable blisters.

DEBLISTERING

Why recover product from blister packs?

Blister packs are rejected because of: empty pockets; incorrect product; incorrect batch coding; leak test failure; and inventory changes. The recovered product can immediately be repackaged increasing production yields.

Reduce waste disposal costs

It is generally less expensive to dispose of empty blisters than filled ones, so it makes sense to separate active product from waste packaging before disposal.

Environmental Policy

Deblistering can help to meet legislative requirements whilst minimising the impact of manufacturing processes on the environment.

Inventory Management

Manage fluctuating market demands and organise inventory efficiently by emptying existing blister stocks and repacking products into alternative formats.

Increase staff motivation

Emptying blisters by hand is tedious and repetitive. Mechanical deblistering prevents sore or cut fingers, and reduces the risk of RSI or Carpal Tunnel Syndrome.

For more detailed information on the benefits of deblistering visit www.sepha.com

SEPHA

PRESSOUT

MANUAL / MANUAL WIDE

PRESSOUT

SEMI-AUTOMATIC

Portable manual and semi-automatic deblistering machines for recovering tablets and capsules from push-thru blisters with in-line layout. Manual Wide and Semi-Automatic models also handle diagonal / offset layouts.

FEATURES

- Portable
- No air supplies needed
- Non-slip safety pads
- Fully cGMP and easily cleaned
- Single change part
- Handles PVC/alu as well as alu/alu blisters
- Flexible - can be adjusted quickly to suit any push-thru blister pack
- Easy to use - no specialist skills needed
- Product recovered cleanly and hygienically
- Ideal for small batches
- Affordable

▼ **PRESSOUT**
MANUAL



▼ **PRESSOUT**
MANUAL WIDE



▼ **PRESSOUT**
SEMI-AUTOMATIC





PRESSOUT MANUAL / MANUAL WIDE

MACHINE OPERATION

Blister packs are manually fed through a set of rollers by turning a handle. The tablets or capsules are simultaneously removed from the blister pack and separated from the waste packaging.

MANUAL MODEL - In-line layout blister packs only

MANUAL WIDE MODEL - Handles blister packs with Diagonal / Offset layout as well as the more traditional 'In-line' design.

TOOLING

The single set of tooling is fully adjustable. A simple settings scale is printed on the platen plate for fast set-up within 1-2 minutes. Training takes less than 15 minutes.

PRESSOUT SEMI-AUTOMATIC

MACHINE OPERATION

Single blister packs are automatically fed through a set of rollers. The tablets or capsules are simultaneously removed from the blister pack and separated from the waste packaging.

This machine uses the same patented deblistering mechanism as the Press-Out Manual Wide, but is driven by an electrical motor which runs continuously, providing an automated feed which increases the deblistering rate to 40 blisters per minute.

TOOLING

The single set of tooling is fully adjustable. A simple settings scale is printed on the platen plate for fast set-up within 1-2 minutes. Training takes less than 15 minutes.

TECHNICAL SPECIFICATION

		MANUAL	MANUAL WIDE	SEMI-AUTOMATIC
OPERATION		Manual	Manual	Semi-Automatic
BLISTER TYPE		Push-thru	Push-thru	Push-thru
BLISTER LAYOUT		In-line	In-line and Diagonal / Offset	In-line and Diagonal / Offset
FORMAT	Width	120mm (4.7")	170mm (6.7")	170mm (6.7")
DIMENSIONS	Length	Unlimited	Unlimited	Unlimited
CONSTRUCTION		All product contact areas constructed from Stainless Steel (Grade 316) and ABS Food Grade		
POWER SUPPLIES		None required	None required	Electricity: Single Phase 110/230V
OPERATING SPEED		Up to 20 blisters per minute	Up to 20 blisters per minute	Up to 40 blisters per minute
MACHINE	Width	200mm (8")	380mm (15")	365mm (14.4")
DIMENSIONS	Length	300mm (12")	295mm (12")	340mm (13.4")
	Height	200mm (8")	230mm (9")	250mm (9.8")
MACHINE WEIGHT		6.5kg (15lbs)	8kg (18lbs)	16kg (35lbs)
SHIPPING WEIGHT		8.5kg (19lbs)	11.5kg (25lbs)	28kg (61lbs)
TOOLING CHANGEOVER		3 minutes	3 minutes	3 minutes

SEPHA PRESSOUT

AUTOMATIC

Deblistering machine for recovering tablets and capsules from push-thru and multi-product blisters with in-line and offset layouts. Suitable for medium to large batches.

FEATURES

- Automatic feed
- Easy to use with no specialist skills required
- User interface with fault indicators
- Variable speed up to 60 blisters per minute
- Handles PVC/alu as well as alu/alu blisters
- No air supplies needed
- Low-cost tooling, fast turnaround
- Fully cGMP
- Pack counter
- Sensors to prevent magazine operating when empty
- Easy cleaning
- Low maintenance

▼ PRESSOUT AUTOMATIC





MACHINE OPERATION

The speed of the machine operation can be varied to a maximum of 60 blisters per minute.

1. Blister packs are fed automatically from the magazine stack through a set of rollers.
2. The tablets or capsules are gently eased out of the blister and are collected separately from the waste packaging.

TOOLING

Custom tooling is required for each different blister pack size. Format changeover, which does not require tools, is fast and easy.

TECHNICAL SPECIFICATION

OPERATION		Automatic
BLISTER TYPE		Push-thru and Multi-product
FORMAT DIMENSIONS	Width	120mm (4.7")
	Length	105mm (4.1")
CONSTRUCTION		All product contact areas constructed from Stainless Steel (Grade 316) and ABS Food Grade
POWER SUPPLIES		Electricity: Single Phase 110/230V
OPERATING SPEED		Up to 60 blisters per minute
MACHINE DIMENSIONS	Width	620mm (24.4")
	Length	620mm (24.4")
	Height	1170mm (46")
MACHINE WEIGHT		50kg (110lbs)
SHIPPING WEIGHT		85kg (187lbs)
TOOLING CHANGEOVER		1 - 2 minutes

State-of-the-art
deblistering solution for
the pharmaceutical
industry with unrivalled
recovery rates, flexibility
and speed

SEPHA

PRESSOUT

MINI UNIVERSAL

PRESSOUT

UNIVERSAL

Ideal for valuable product with a unique gentle action for fragile tablets and capsules. Suitable for all blister materials including heavy gauge alu/alu and paper-backed materials.

FEATURES

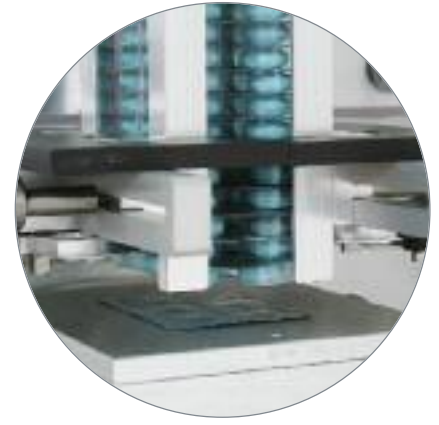
- Variable speed control
- Fully cGMP
- Open construction - total access for easy and fast cleaning
- Maintenance-free
- Tool-less changeover
- Jam-free operation

▼ **PRESSOUT**
MINI UNIVERSAL



▼ **PRESSOUT**
UNIVERSAL





PRESSOUT MINI UNIVERSAL

A highly flexible and compact, semi-automatic solution for emptying small batches of blister packs of all types including child resistant.

MACHINE OPERATION

Blister packs are placed manually into the pack holder. The pack holder is pushed in and a partial cut is made in the lidding foil around each blister pocket. The contents of the blisters are then emptied gently and separated from the waste packaging.

TOOLING

Only 2 single custom plates are needed for each different blister pack format. Changeover is completely tool-less and takes less than 1 minute.

PRESSOUT UNIVERSAL

The state-of-the-art deblistering solution for the pharmaceutical industry because of its flexibility, speed and unrivalled recovery rates.

MACHINE OPERATION

Blister packs are fed automatically from the magazine stack to a cutting station. A cut is made in the lidding material around the base of the blister pocket. The tablets or capsules are gently eased out of the blisters and collected separately from the waste packaging.

TOOLING

Custom tooling is supplied for each different pack size with fast delivery times.


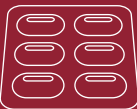


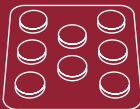



TECHNICAL SPECIFICATION

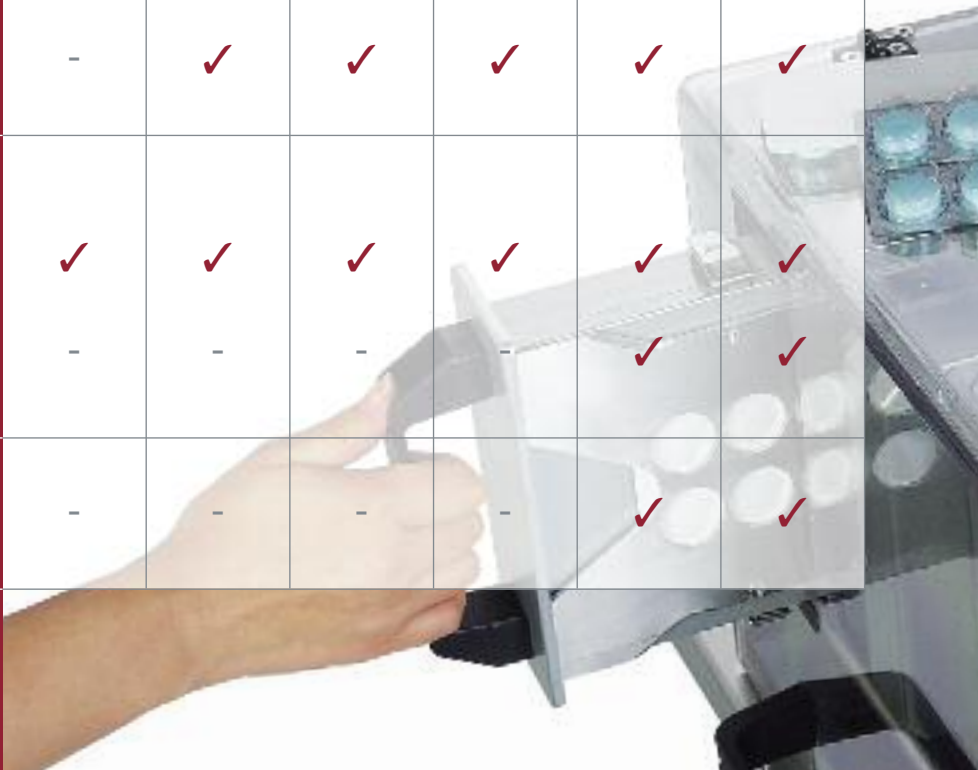
		MINI UNIVERSAL	UNIVERSAL
OPERATION		Semi-Automatic	Automatic
BLISTER TYPE		Push-thru and Child-resistant / Peelable / Multi-product	
BLISTER LAYOUT		All	All
FORMAT	Width	160mm (6.3")	160mm (6.3")
DIMENSIONS	Length	140mm (5.5")	140mm (5.5")
CONSTRUCTION		All product contact areas constructed from Stainless Steel (Grade 316) and ABS Food Grade	
POWER SUPPLIES		Electricity: Single Phase 110/230V Air Supply: 6 Bar	
OPERATING SPEED		Up to 20 blisters per minute	Up to 50 blisters per minute
MACHINE	Width	620mm (24")	650mm (25.5")
DIMENSIONS	Length	620mm (24")	1200mm (47")
	Height	1325mm (52")	1300mm (51")
MACHINE WEIGHT		80kg (176lbs)	270kg (594lbs)
SHIPPING WEIGHT		150kg (330lbs)	350kg (770lbs)
TOOLING CHANGEOVER		1 minute	5 minutes

The user-friendly Universal model is also ideally suited for singularising Hospital Unit Dose blisters

WHICH PRESS-OUT?

QUICK REFERENCE TABLE

BLISTER PACK TYPE (Perforated and Unperforated)	PRESS-OUT MANUAL	PRESS-OUT MANUAL WIDE	PRESS-OUT SEMI- AUTOMATIC	PRESS-OUT AUTOMATIC	PRESS-OUT UNIVERSAL MINI	PRESS-OUT UNIVERSAL
PUSH-THRU						
PVC/Alu	✓	✓	✓	✓	✓	✓
PVDC/Alu	✓	✓	✓	✓	✓	✓
PP/Alu	✓	✓	✓	✓	✓	✓
ACLAR/Alu	✓	✓	✓	✓	✓	✓
						
Alu/Alu	✓	✓	✓	✓	✓	✓
						
CHILD-RESISTANT						
Push-Thru	✓	✓	✓	✓	✓	✓
						
Peelable	-	-	-	-	✓	✓
						
DIAGONAL / OFFSET	-	✓	✓	✓	✓	✓
						
MULTI-PRODUCT						
In-line	✓	✓	✓	✓	✓	✓
						
Staggered	-	-	-	-	✓	✓
						
CIRCULAR	-	-	-	-	✓	✓
						





SEPHA

SUPPORT

We want you to feel confident about choosing Sepha as part of your pharmaceutical packaging solution. That's why we offer great service and support for the life of your machine from purchase to servicing requirements.

Installation

All machines are supplied with comprehensive documentation and an Instruction Manual. We also provide on-site training or a demonstration video.

Validation

If required, validation assistance can be given in the form of protocols to be completed by the end user.

Technical & Customer Support Services

Experienced staff are available at all times to provide a high level of support and advice on a wide range of technical and pharmaceutical processing and production issues.

Maintenance-Free Operation

SEPHA EZ Blister and Press-Out machines are virtually maintenance-free, requiring only cleaning. All parts to be cleaned are easily removed from the unit and can be thoroughly washed in hot water and dried at elevated temperatures.

Warranty

All machines and component parts are supplied with a 12 month warranty (including labour) applicable from date of installation. This excludes normal wear and tear or loss of parts.

All SEPHA products are covered by patents, registered trade marks or copyrights.

All SEPHA machines conform to CE certification requirements.

SEPHA
working together

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