

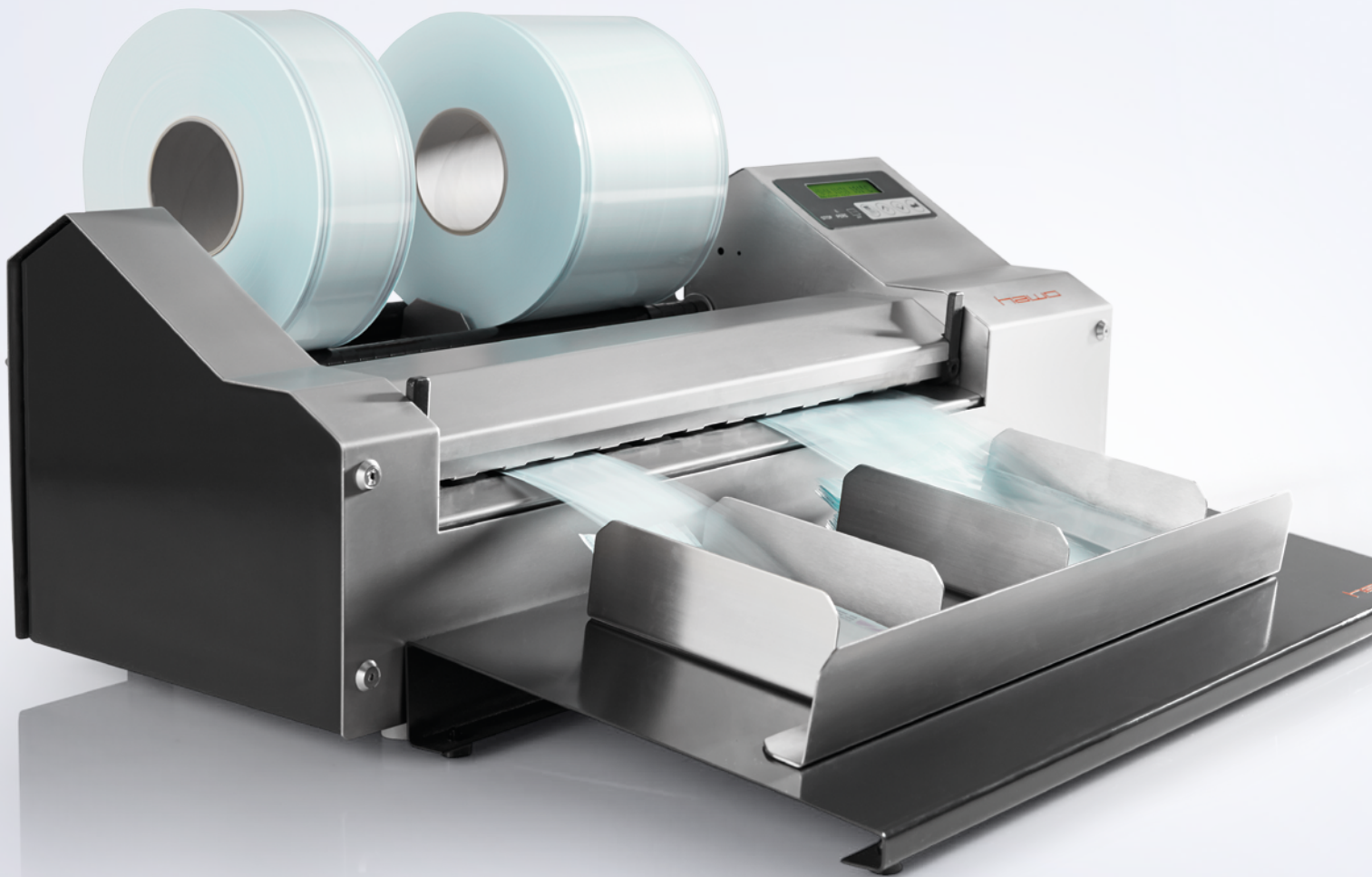
hm 8000 AS/AS-V SealCut

POUCHMAKING MACHINE FOR
THE AUTOMATIC PRODUCTION OF
FLAT AND GUSSETED POUCHES.



hm 8000 AS/AS-V SealCut

TO DELIVER MAXIMUM FLEXIBILITY AND COST-EFFECTIVENESS, HAWO HAS DEVELOPED A FULLY AUTOMATIC POUCHMAKING MACHINE, KNOWN AS THE hm 8000 AS/AS-V SealCut (V=VALIDATABLE). THIS INNOVATIVE MACHINE COMBINES A FILM REEL DISPENSER AND A HEAT SEALER TO AUTOMATICALLY PRODUCED STERILE GOODS POUCHES FROM STANDARD REELS IN THE REQUIRED QUANTITY AND LENGTH. THE MATERIAL CONSUMPTION IS KEPT TO A MINIMUM, SINCE THE POUCH LENGTH CAN BE DETERMINED ON A CUSTOMISED BASIS. WITH AN OUTPUT OF UP TO 5,000 BAGS PER HOUR AND COMPACT DIMENSIONS, THIS MACHINE IS AT THE TOP OF ITS DEVICE CLASS.¹

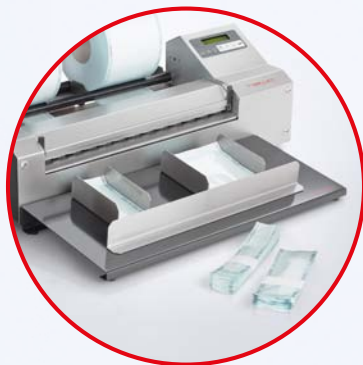


¹ Based on 6 reels, sealing time 1.5 sec., pouch length 100 mm / 4 in

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**Sealing of pre-formed
sterile barrier systems**



**Optional sorting module
hm 8000 SD**

hm 8000 AS/AS-V SealCut (V=validatable)

Regardless of whether flat or gusseted reels made from paper/ plastic or Tyvek®/plastic are used, the material consumption is kept to a minimum, since the pouch length can be determined on a customised basis. The small footprint of 74 cm / 29 in and the fact that no inlet or outlet area is required on either side means that the device can be used in even the smallest of spaces.

HIGH PRODUCTIVITY.

The high production rate, which results from up to 14 cycles per minute (over 800 cycles per hour), allows film pouches to be produced cost-effectively. The extremely wide reel holder can support up to six reels of film, all of which can be used simultaneously. The machine can therefore produce up to 5,000 pouches an hour¹. In seal-only mode, the pre-made pouches are conveniently sealed after filling.

hm 8000 SD – OPTIONAL SORTING MODULE.

Another of the device's advantages is its ability to sort the pouches. The hm 8000 AS/AS-V SealCut can sort the finished pouches by size, conveniently remove them, finish them, bag them or shrink-wrap them. You also have the option of adding an hm 8000 SD sorting module to the device.

FUNCTIONALITY.

Operation and configuration are performed either via the integrated keypad or optionally using the innovative hawo IntelligentScan system. Different formulars can therefore be pre-programmed and changed with just a 'scan' (e.g. pouch length 30 cm / 12 in, sealing temperature 190 °C / 375 °F, sealing time 2 sec.).

An optional label printer can be connected for labelling and documentation purposes. The devices can also be connected to existing batch documentation systems using standard RS 232, USB and Ethernet interfaces.

The following processing modes can be set:

- > **production mode:** Pouch sealed on 3 sides are produced completely automatically.
- > **seal only mode:** Pre-produced pouches can be sealed on the fourth side after filling.
- > **cutting mode:** Pouches are precut and not sealed.

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VALIDATION.

ISO 11607-2 and the new international ISO/TS 16775 guidance document explicitly require validated packaging processes. Heat sealers must therefore be able to control and monitor critical process parameters. According to ISO/TS 16775 these are:

- > sealing temperature
- > contact pressure and
- > sealing time (dwell)

In the event of a deviation from the preset value (e.g. 190 °C / 375 °F), the device must be switched off and/or the enduser alerted. The hm 8000 AS-V controls and monitors the critical process parameters.

The hm 8000 AS-V also features the option of recording critical process parameters on a USB stick. The requirement of routine documentation of the critical parameters according to EN ISO 11607-2 can therefore be easily satisfied.



ERGONOMICS.

Work processes in the preparation of instruments should be as simple and comfortable as possible. That's why the unit is aligned for the ideal utilization of the work area. Maintenance is reduced to a minimum; worn parts are easily replaceable. The low energy consumption of just 200 watts highlights the excellent economy of the hm 8000 AS/AS-V SealCut pouchmaking machine (hawo GreenTek).



SERVICES.

Regular maintenance can extend the life of your product. That is why we and our authorized service partners offer maintenance (ServiSeal), calibration (CaliSeal) and validation service in accordance with EN ISO 11607-2 for sealers with validatable process (ValiSeal) as well as a seal seam strength test in accordance with EN 868-5 just from one source.

For more information visit www.hawo.com/service



hm 8000 AS**hm 8000 AS-V****PERFORMANCE FEATURES**

Productivity	up to 14 cycles/min (>840 Cycles/hour) depending on the pre-adjusted sealing time 5,000 pouches/hour ¹	up to 14 cycles/min (>840 Cycles/hour) depending on the pre-adjusted sealing time 5,000 pouches/hour ¹
Adjustment quantity of pouches	1 - 500 pouches	1 - 500 pouches
Adjustment pouch lengths	100 - 1,000 mm / 4 - 40 in	100 - 1,000 mm / 4 - 40 in
Width of seal seam and cutting lengths, roll holder	420 mm 16.5 in	420 mm 16.5 in

RANCHE OF USE AND CERTIFICATION

Especially suitable for use in	medical practice hospital and medical industry	medical practice hospital and medical industry
CE signed	x	x
GS-certified (tested safety)	x	x
Conformity ISO 11607-2		x
Conformity ISO/TS 16775		x
GreenTek	x	x

POWER SUPPLY DATA

Mains connection	100 - 240 V, 50/60 Hz	100 - 240 V, 50/60 Hz
Power	200 W	200 W

MECHANICAL DATA

Dimension w x d x h	740 x 355 x 240 mm 29.1 x 14 x 9.5 in	740 x 355 x 240 mm 29.1 x 14 x 9.5 in
Stainless steel AISI 304 casing cover	x	x
Weight	29 kg (64 lbs)	29 kg (64 lbs)
Seal seam	12 mm / 0.5 in ²	12 mm / 0.5 in ²
Distance to medical device (ISO/TS 16775)	30 mm / 1.2 in	30 mm / 1.2 in
Reel holder (incl. 2 reel fixation sets hm 8000 RF)	x	x

SEALING MATERIALS

Sealable pouches and reels in accordance with ISO 11607-1 (Paper/Plastic according to EN 868-5 and Paper/Tyvek ^{®3} , according to EN 868-9 ⁴	x	x
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ELECTRONIC FEATURES

Microprocessor controlled	x	x
LCD-Display	x	x

OPERATION AND COMMUNICATION

Interface USB A/B, RS 232, Ethernet connection	x	x
hawa IntelligentScan ⁵	x	x

PROCESS PARAMETERS

Sealing temperature	max. 200 °C / 390 °F (monitored)	max. 200 °C / 390 °F (monitored)
Contact pressure	fix	fix (monitored)
Sealing time (dwell)	0.5 - 10.0 s	0.5-5 s (monitored)
Overheating protection	x	x

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² also as ripped seam on request³ Tyvek[®] is a reg. Trademark of E.I. du Pont Nemours⁴ different sealable pouches and reels on request⁵ optional scanner needed

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hm 8000 AS

hm 8000 AS-V

CONTROL FUNCTION IN ACCORDANCE WITH ISO 11607-2 and ISO/TS 16775

Sealing process	automatic/reproducible	automatic/reproducible
Validatable process		x
Switch-off tolerance +/- 5°C (ISO/TS 16775)	x	x
Alarm and machine stop in case the monitored parameters exceed predetermined limits	x	x

ACCESSORIES

hawo USB-stick for process documentation	x	x
hawo IntelligentScan barcode scanner (with HS 980 BR software for generating barcode lists)	x	x
ValiPrint barcode printer	x	x
Sorting unit hm 8000 SD	x	x
Reel holder fixation set hm 8000 RF (2 fixing units in one set)	x	x
Banding machine hm 8000 BM	x	x
Seal Check med indicator strips	x	x
hawo InkTest dye penetration test (ISO 11607-1, Annex B (ASTM F 1929))	x	x

Seal Check med Seal Check HDPE⁶ hawo InkTest

FOR THE ROUTINE MONITORING OF THE SEALING SEAMS.

hawo offers two testing systems for the routine testing of the sealing seam as well as to carry out an Operational Qualification (OQ) and Performance Qualification (PQ) during the validation process. hawo sealing devices with hawo IntelligentScan automatically activate the test-mode by scanning the printed barcodes.

> **hawo Seal Check:** The Seal Check med (paper/plastic pouches and reels) and Seal Check HDPE⁶ (Tyvek®/plastic pouches and reels) make deviations visible in the indicator field of the Seal Check.

> **hawo InkTest:** The standardized dye penetration test for testing the seal integrity in accordance with ISO 11607-1, Annex B (ASTM F1929), is distinguished by its simple handling and provides objective results. For this purpose a special test is applied with a pipette into the pouch or reel. Defects (e.g. channels) are immediately visible.

⁶ Not suitable for coated Tyvek®.



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