1250 DC-V/hm 880 DC-V

ROTARY SEALERS WITH PRINTER (VALIDATABLE PROCESS IN ACCORDANCE WITH ISO 11607-2)



GENERATION PRO

THE HM 850 DC-V AND HM 880 DC-V GENERATION PRO ROTARY SEALING DEVICES WITH INTEGRATED PRINTER ARE THE ANSWER TO PROFESSIONAL REQUIREMENTS IN HOSPITALS AND THE MEDICAL INDUSTRY. THE PROCESS IS VALIDATABLE IN ACCORDANCE WITH ISO 11607-2. ROBUST AND BUILT FOR MAXIMUM COMFORT AS USUAL, THE DESIGN EMPHASIZES THE INTRINSIC VALUES OF THESE DEVICES: MAXIMUM PERFORMANCE AND SPEED, AUTOMATIC RECORDING AND DOCUMENTATION OF ALL RELEVANT DATA, SEAMLESS INTEGRATION INTO EXISTING INFRASTRUCTURES AND VERY EASY TO USE HANDLING THANKS TO THE SUCCESSFUL hawo IntelligentScan™ TECHNOLOGY (HM 880 DC-V) MAKES THE EQUIPMENT A RELIABLE PARTNER FOR STERILE GOODS PACKAGING.





SAFE, GUARANTEED: VALIDATION OF SEALING PROCESSES.

The proper hygiene as a prerequisite for the safety of doctors and patients is at the forefront of all considerations. The decisive factor is the automatic process control. The ultimate goal for packing systems for medical products in hospitals and the medical industry that are sterilised in the final packaging is the maintenance of sterility from the aseptic presentation until the point of use. Only validated processes in accordance with the international packaging standard ISO 11607-2 and the therefrom resulting "Guideline for the validation of the sealing process" from the WFHSS are expressly recommended for the packing of medical instruments. ^{1/2} During validation, the sealing device is first installed and connected to the power supply (Installation Qualification IQ). Second: Set the optimal sealing temperature (Operational Qualification OQ). And third: Check, if the sealing seams are strong enough – even after sterilization (Performance Qualification PQ).

Sealing devices must meet the following validation requirements:

- > monitoring the critical process parameters and
- > warn the user in case of deviation from preset values.

The hawo GENERATION PRO sealing devices meet these requirements. During the sealing process, the critical parameters sealing temperature and contact pressure are automatically monitored (hm 880 DC-V: also sealing speed). If one of the parameters deviates from preset values, the devices warn the user acoustically and stop the sealing process. Both sealers possess a PC interface (RS232) for process and batch documentation (hm 880 DC-V: also Ethernet and USB). The sealing devices guarantee efficient and reproducible packing, especially for large volumes of instruments.

EASY-OPERATION SEALING EQUIPMENT: hawo IntelligentScan®.

The sealers hm 850 DC-V and hm 880 DC-V sealers have the new, clearly laid out keyboard display. Through this central control unit, all instrument functions and settings are clearly laid out for the user. The hm 880 DC-V can also be easily operated and configurated via an optional hm 780 BR barcode scanner and the accompanying hs 780 BR PC software. Using the PC software, all device configurations, printer data and entire printer configurations for individual packaging materials can be entered centrally and output as a barcode list on a standard printer in just one operation. The scanner reads the bar code lists with the relevant packaging information and automatically assigns them to the appropriate device function.

¹ Also applies to sealable pouches and reels, wrapping sheets and containers.

² Available in German, English and French for free at www.hawo.com

hm 850 DC-V/hm 880 DC-V

The validatable rotary sealers are used for the automatic closing of seal-able pouches and reels (Sterile Barrier Systems SBS) in hospitals (CSSD) and the medical industry. Our successful classic model hm 850 DC-V was revised in details and adapted to the current design. The brand new hm 880 DC-V includes all hawo top technologies and sets the benchmark in its class.



INTEGRATED PRINTER WITH FontMatic[™] (hm 880 DC-V)

The hm 850 DC-V and hm 880 DC-V can print all normatively requested information directly onto the packaging during the sealing process (symbols according to EN 980). Thanks to the patented FontMatic™ technology the hm 880 DC-V automatically recognises the width of the sealing material and adjusts the font size to the available space. Printing over the edges is a thing of the past.

- > Identification of manufacturer or personel number
- > Product information³
- > Packaging time and date, expiry date
- > Batch data, lot number or serial number
- > Piece counter
- > Designation "sterile" and sterilization type (e.g. steam, plasma)
- > Amount
- > Arbitrary texts³

FLEXIBILITY

The hawoflex™ sealing system accommodates every material – even gusseted pouches and reels. Therefore a flawless, full-area sealing seam can also be achieved with materials of varying thickness. The unique design of the hawoflex™ sealing seam guarantees an optimal sealing security and seal seam strength. The hm 850 DC-V and hm 880 DC-V are appropriate for the following packaging materials:⁴

- > Sealable pouches and reels according to EN 868-4:2009, EN 868-5:2009 and EN ISO 11607-1:2009
- > HDPE (Tyvek®)
- > Aluminum-laminate film

ERGONOMICS AND MAINTENANCE

Work processes in the preparation of instruments should be as simple and comfortable as possible. That is why the unit is designed for the ideal utilization of the work area. Maintenance is reduced to a minimum; worn parts are easily replaceable. The ink ribbon change is simply carried out from the front of the device.



³ hm 880 DC-V: Using hawo IntelligentScan™ this information can be created as a barcode list read directly via scanner. Optional barcode scanner hm 780 BR required.

⁴ Inappropriate for thermoplastic films (PE, PP, PVC). Tyvek® is a registered trademark of E.I. du Pont de Nemours.

250 DC-V/hm 880 DC-V

	hm 880 DC-V	hm 850 DC-V
RANGE OF USE AND CERTIFICATIONS		
Especially suitable for use in	hospital and medical industry	hospital and medical industry
CE sign	X	x
GS-certified GS-certified	X	x
Conformity ISO 11607-2	х	х
Conformity DIN 58953-7:2010	х	x
Conformity WFHSS-Guideline	х	х
POWER SUPPLY AND MECHANICAL DATA		
Mains connection / mains frequency	100-240 V / 50/60 Hz	100/115/230 V / 50/60 Hz
Power ⁵	400 W	400 W
Dimensions w x d x h (incl. infeed section)	710 x 260 x 240 mm	710 x 260 x 240 mm
Weight	21 kg	23 kg
Casing cover	Stainless steel AISI 304	Stainless steel AISI 304
Sealing system	hawoflex®	hawoflex®
Sealing distance from edge	0-35 mm	0-35 mm
Seal seam width	12 mm	12 mm
Distance to medical product (DIN 58953-7)	> 30 mm	> 30 mm
Device protect (in-feed guard)	х	х
Reverse Feed	Х	Х
SEALING MATERIALS		D
Sealable pouches and reels according to EN 868-4:2009/EN 868-5:2009	Paper pouches/transparent pouches/paper/film and Tyvek®/film reels (also with side gusset)	Paper pouches/transparent pouches/paper/film and Tyvek®/film reels (also with side gusset)
Aluminium-laminate film	х	х
ELECTRONIC FEATURES AND COMMUNICATION		
Control	Microprocessor	Microprocessor
Parameter settings remain even after a power failure (Autosafe)	X	х
Automatic start of motor by photocell	X	х
Automatic update of date and time even when device is switched off	х	Х
Display and keypad	2-lined LCD / Membrane keypad	2-lined LCD / Membrane keypad
PC interface (for process and batch documentation systems)	RS 232, Ethernet and USB	RS 232
hawo IntelligentScan®	X ⁶	
GreenTek®	Motor stop after 30 sec / Stand-by after 10-120 min	Motor stop after 30 sec / Stand-by after 10-120 min
Piece counter and operating time	х	Х
CONTROL FUNCTIONS IN ACCORDANCE WITH ISO 11607-2		
Sealing process	automatic/reproducible	automatic/reproducible
Validatable process (ISO 11607-2)	X	X
Process parameter monitored:	(000 00)	(000 00)
Sealing temperature	x (max. 220 °C)	x (max. 220 °C)
Contact pressure Sealing speed (dwell)	x (100 N)	x (100 N) – (10 m/min, not monitored)
Switch-off tolerance ± 5°C (DIN 58953-7:2010)	x (10 m/min) x	- (10 m/min, not monitorea)
Switch-off tolerance adjustable	± 2-5 °C	± 2-5 °C
Alert and motor stop in case the monitored parameters		
exceed predetermined limits	X	X
Printout of process parameters (Seal Check-function)	х	х
PRINTER FUNCTIONS WITH INTEGRATED PRINTER		
Display of printer data with running function in display	х	х
Printout Communication of the	single line	single line
FontMatic™ (automatic adjustment of type size to film width)	X	
ACCESSORIES		
Mobile process documentation hawo ht 180 PT-USB	X	Х
IntelligentScan™ barcode scanner hm 780 BR (with hs 780 BR software for generating bar code lists)	X	
ht Seal Check med und ht Seal Check HDPE indicator strips	х	х
Seal Check reference card	х	х

 $^{^{\}rm 5}$ Values can vary during heating-up period. \mid $^{\rm 6}$ Optional scanner needed.



hawotest ht 180 PT-USB



PROCESS DOCUMENTATION.

Following the requirements set out in ISO 11607-2, the routine monitoring and documentation of the process parameters can be carried out with the help of a USB stick and the hawo ht 180 PT USB storage unit. The process protocols can then be called up, digitally signed and archived on a PC.

hawotest Seal Check med/Seal Check HDPE



FOR ROUTINE MONITORING OF THE SEALING SEAMS.

The hawotest seal indicators Seal Check med (sealable paper/film pouches and reels) and Seal Check HDPE (sealable Tyvek®/film pouches and reels) make it easy to check the seal seam quality properties and carry out an Operational Qualification (OQ) in accordance with ISO 11607-2. Thanks to the Seal Check indicators, deviations become visible on the indicator area of the SEAL CHECK. The new Seal Check med and Seal Check HDPE indicators have a printed barcode. Once the hm 780 BR barcode scanner reads the printed barcode, the device with IntelligentScan™ automatically activates the Seal Check mode (hm 880 DC-V).



SERVICE.

It is our claim that our sealing devices always meet your requirements. Thanks to our world wide service partners, we offer you a wide range of services. The following fall under the process validation:

- > Issuing of calibration certificates for the parameters relevant to the
- > Tensile seal strength tests in accordance with EN 868-5:2009/ASTM F88 as part of the routine tests in the Performance Qualification (PQ)
- > Validation consultation
- > Service-Hotline: Please contact our Service-Team. Call +49 6261 9770-31.











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