hm 850 DC-V / hm 880 DC-V

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

GENERATION PRO

hawomed

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 MONITORING OF THE CRITICAL PROCESS PARAMETERS SEAMLESS INTEGRATION INTO TRACKING SYSTEMS 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 PACKAGING.

The figure shows the sealing device with accessories. Roll conveyor, tray (not shown) and the hm 850K are optionally available.

THE PRO CLASS.

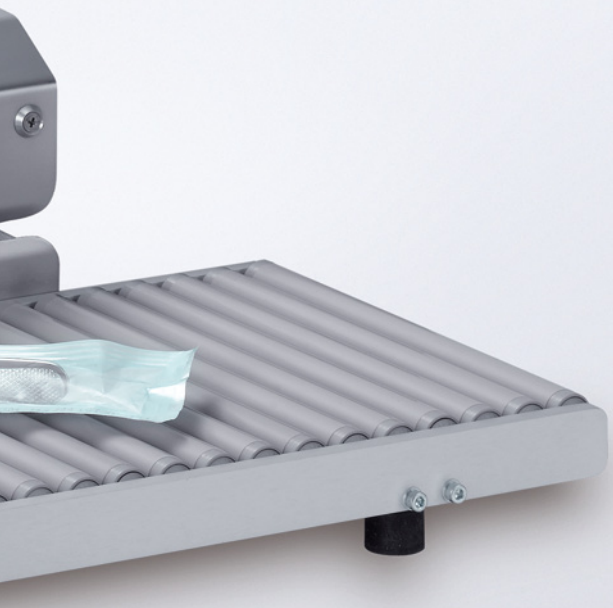
The validatable rotary sealers are used for the automatic closing of sealable pouches and reels (Sterile Barrier Systems SBS) in hospitals (CSSD) and the medical industry. Our successful classic model hm 850 DC-V was updated and changed to the current design. The hm 880 DC-V includes all hawo top technologies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

◀**Font**Matic▶

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 personnel number*
> *Product information*[1]
> *Packaging time and date, expiry date*
> *Batch data, lot number or serial number*
> *Piece counter*
> *hm 880 DC-V: Designation "sterile" and sterilization type (e.g. steam, plasma)*
> *hm 880 DC-V: Amount*
> *Arbitrary texts*[1]



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:[2]

> *All sealable pouches and reels according ISO 11607-1 (e.g. medical grade paper, Tyvek®, nonwoven, etc.)*
> *Gussetted pouches and reels*
> *Aluminum-laminate film*

ERGONOMICS AND MAINTENANCE.

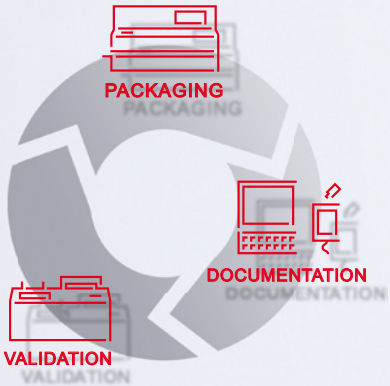
Work processes in the preparation of instruments should be as simple and comfortable as possible. That is why the unit is designed for the ideal utilization of the work area. Maintenance is reduced to a minimum; worn parts are easily replaceable. The ink ribbon change is simply carried out from the front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

[1] 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.
[2] Not suitable for thermoplastic films (PE, PP, PVC).
Tyvek® is a registered trademark of E.I. du Pont de Nemours.

hm 850 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	x	x
Conformity DIN 58953-7:2010	x	x
Conformity ISO/DTS 16775[5]	x	x
Conformity ISO 11607-2	x	x
POWER SUPPLY AND MECHANICAL DATA		
Mains connection / mains frequency	100-240 V / 50/60 Hz	100/115/230 V / 50/60 Hz
Power[6]	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 protection (insert guard)	x	x
Reverse feed	x	x
SEALING MATERIALS		
All sealable gussetted pouches and reels according ISO 11607-1 (e.g. medical grade paper, Tyvek®, nonwoven, etc.)	x	x
Aluminium-laminate film	x	x
ELECTRONIC FEATURES AND COMMUNICATION		
Control	Microprocessor	Microprocessor
Parameter settings remain even after a power failure (Autosafe)	x	x
Automatic start of motor by photocell	x	x
Automatic update of date and time even when device is switched off	x	x
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[7]	
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	x	x
CONTROL FUNCTIONS IN ACCORDANCE WITH ISO 11607-2		
Sealing process	automatic/reproducible	automatic/reproducible
Validatable process (ISO 11607-2)	x	x
Process parameter monitored:		
Sealing temperature	x (max. 220 °C)	x (max. 220 °C)
Contact pressure	x (100 N)	x (100 N)
Sealing speed (dwell)	x (10 m/min)	– (10 m/min, not monitored)
Switch-off tolerance ± 5°C (DIN 58953-7:2010)	x	x
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)	x	x
PRINTER FUNCTIONS WITH INTEGRATED PRINTER		
Display of printer data with running function in display	x	x
Printout	single line	single line
FontMatic (automatic adjustment of font size to film width)	x	
ACCESSORIES		
Mobile process documentation hawo ht 180 PT-USB	x	x
hawo 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	x	x
Seal Check reference card	x	x

[5] ISO Technical Specification: Packaging for terminally sterilized medical devices – Guidance on the application of ISO 11607-1 and ISO 11607-2.
[6] Values can vary during heating-up period. | [7] Optional scanner needed.



SAFE PACKAGING.

The correct reprocessing process of medical devices consists of the steps of washing & disinfection, packaging and sterilisation. The instruments can only be called sterilised when they are packaged before the sterilisation. The single-use (!) packaging, made from laminated poly film and a porous material (Tyvek® or medical grade paper) is permeable for the sterilisation medium (e. g. steam, plasma, Formaldehyde FO or Ethylenoxide ETO), but not for bacteria or microorganisms. Only by following this reprocessing sequence (see illustration left) and by using professional heat sealers to seal the instruments as well as professional packaging material can the sterility up to the point of use as well as the aseptic presentation of the instrument be guaranteed. Medical devices delivered in a sterile state should be packed to ensure that they remain sterile until the point of use. The validation of packaging processes is crucial to ensure that sterile barrier system integrity is attained and will remain so until opened by the users. The international packaging standard ISO 11607-2 as well as the Technical Specification draft ISO/DTS 16775[1] explains how packaging processes should be validated. The international packaging validation guideline[1] gives guidance how to validate the packaging processes.[2/3]

Sealing devices must meet the following validation requirements to fulfil the requirements of ISO 11607-2:

> *Monitoring the critical process parameters and*

> *Warn the user in case of deviation from preset values.*

The sealing devices hm 850 DC-V and hm 880 DC-V meet these requirements. During the sealing process, the critical parameters sealing temperature and contact pressure are continously 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 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] Packaging for terminally sterilized medical devices – Guidance on the application of ISO 11607-1 and ISO 11607-2 (under development)

[2] Also applies to sealable pouches and reels, wrapping sheets and containers.

[3] Available free of charge in German, English and French at www.hawo.com

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.

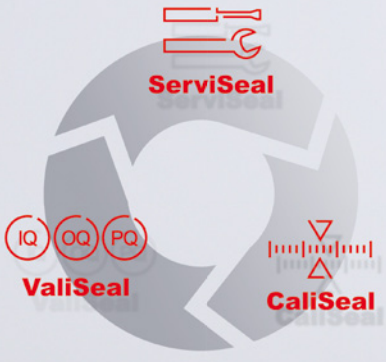
Seal Check med | Seal Check HDPE | hawo InkTest

FOR 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 onprinted barcodes.

> **hawo Seal Check:** The Seal Check med (paper/film pouches and reels) and Seal Check HDPE (Tyvek®/film pouches and reels) make deviations visible on 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 ink is given with a pipette into the pouch or reel. Defects (e.g. channels) become immediately visible.



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 process*
> *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.*

Subject to technical alterations
11/2012 | 9.344.083 | Printed in Germany
11/2012 | 500 | www.wolf-corporate.de

hawo GmbH
Obere Au 2-4
74847 Obrigheim/Germany
T +49 (0) 6261 / 9770-0
F +49 (0) 6261 / 9770-69
info@hawo.com
www.hawo.com