

hm 460 AS-V/hm 660 AS-V

Microprocessor-controlled impulse sealers
for the packaging of sealable pouches and reels (SBS)
(Validatable process in accordance with EN ISO 11607-2)

HAWO

hawomed

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Microprocessor-controlled impulse sealers for the packaging of sealable pouches and reels (SBS)

(The devices conform to the requirements of EN ISO 11607-2 and DIN 58953-7)

The highest goal of every packaging system for medical devices, which are terminally sterilized, is the assurance of sterility until the products are used on the patient.

Validation

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 of sterile medical devices.

The new standard stipulates a packaging process that can be validated and is reproducible. For the sealing of a preformed sterile barrier system (SBS), e.g. sealable pouches and reels, only those processes that can be validated in accordance with EN ISO 11607-2 are recommended. The standard additionally requires that the critical process parameters (here: temperature, contact pressure and sealing time) are monitored and routinely documented. A warning system and machine stop must be activated in the event that critical process parameters exceed predetermined limits.

EN ISO 11607-2 conformity

- Internal monitoring of the critical process parameters (temperature, contact pressure and sealing time)
- Warning system and machine stop in case the critical parameters exceed predetermined limits
- Integration with external instrument management systems e.g., hawotest ht 180 PT-USB

The devices thereby fulfill all necessary requirements for process validation in accordance with EN ISO 11607-2 as well as the therefrom resulting specifications of the German Society for Sterile Supply DGSV detailed in the 'Guideline for the Validation of the Sealing Process'.¹

The hm 460 AS-V and hm 660 AS-V devices are appropriate for the following packaging materials (not suitable for gusseted pouches):

- Sealable pouches and reels according to EN 868-5 and EN ISO 11607-1
- HDPE materials (Tyvek™)
- Thermoplastic foil (e.g., PE, PP, PVC)

Simple data input and programming

The clear keyboard of the hm 460 AS-V and hm 660 AS-V devices makes menu navigation and data input exceptionally simple. Information is clearly and precisely presented on the well laid out, 2-line LCD display.

Documentation of the critical process parameters

The critical process parameters of temperature, contact pressure and sealing time are monitored directly by the devices. For long-term documentation the devices are compatible with additional systems:

1. ht 180 PT-USB

The hawotest-device ht 180 PT-USB is a mobile process documentation system. It automatically receives the critical process parameters as well as further relevant protocol data (date/time, machine number, personnel number, etc.). The data is then saved on a USB

stick and transferred to a PC. The data is archived by means of a digitally signed and coded PDF document directly on the PC.

2. hm 455 C 3-channel curve tracer

For visual display and documentation of the critical process parameters temperature, contact pressure and sealing time.

Standard conformity

- Quality management system in accordance with ISO 9001:2000 (QM certificate)
- Fulfillment of the requirements of the DGSV Guideline for the Validation of the Sealing Process
- Included declarations of conformity:
 - CE
 - EN ISO 11607-2:2006

Security

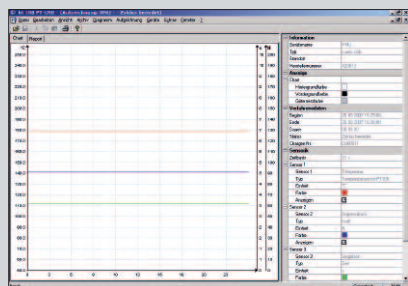
- **Autosave:** Parameter settings remain even after a power failure
- **Proven Safety:** GS-certified safety by German test institution

Additional Functions:

- 2-line back-lit LCD display
- Integrated clock
- Multiple language menu navigation
- RS 232 interface for bi-directional communication (USB optional)
- Operating time
- Piece counter (absolute and with reset function)
- Locking of data input through password service

Service

- Issuance of a calibration certificate for process-decisive parameters (optional)
- Seal seam strength tests in accordance with EN 868-5 within validation (optional)



hm 460/660 AS-V



¹ According to the standard, validation must be carried out by the user in the installation location. The new guideline of the German Society for Sterile Supply (DGSV) for the Validation of the Sealing Process in accordance with EN ISO 11607-2 offers practical assistance ([www.dgsv-ev.de / download](http://www.dgsv-ev.de/download): www.hawo.com).

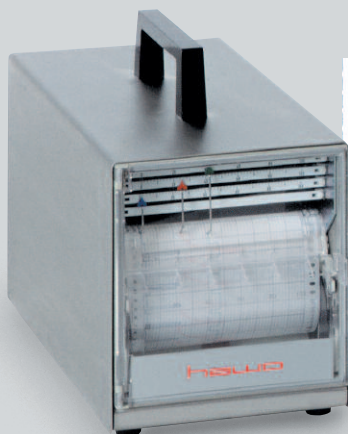
Installation requirements:
The cross-section for the supply line of the outlet used must be a minimum of 2.5 mm² and be insured with security automatic circuit breaker 16A, characteristic curve K (G).

Technical Data

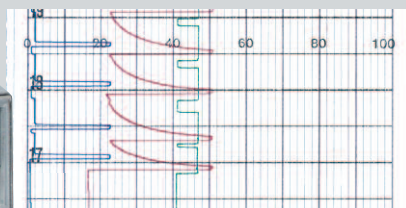
	hm 460 AS-V	hm 660 AS-V
Type of device	Impulse sealer	
Control	Microprocessor	
Process cycle	automatic/reproducible	
Sealing time	0 – 9,9 sec sealing time	
Sealing temperature	max. 300°C (572°F)	
Cooling temperature	> 40% –100% of adjusted sealing temperature	
Film width (reels)	max. 360 mm (max. 14.2 in.)	max. 540 mm (max. 21.3 in.)
Film width (pouches)	450 mm (17.7 in.)	630 mm (24.8 in.)
Seal seam width	8 mm (0.3 in.)	
Mains connection	230 V, 50/60 Hz, supply line cross-section at least 2,5 mm ² (0.1 in. ²)	
Fuse protection	16 A, characteristic curve K (G)	
Critical parameters (monitored)	Temperature (variable) Sealing time (variable) Contact pressure	
Interface	RS 232(USB optional)/connection of curve tracer or ht 180 PT-USB	
Power	2800 VA (only during the sealing process)	
Dimensions l x w x h	520 x 330 x 220 mm (20.5 x 13.0 x 8.7 in.)	700 x 330 x 220 mm (27.6 x 13.0 x 8.7 in.)
Weight	approx. 25 kg (55.3 lb.)	approx. 26 kg (57.8 lb.)
Casing cover	Stainless steel AISI 304	
Casing base	Metal, powder-coated	

Accessories

3-channel curve tracer	hm 455 C
Process documentation system	ht 180 PT-USB
Storage tray	hm 450 T / hm 630 T



hm 455 C: 3-channel curve tracer



Laterally structured service elements with back-lit LCD display



hawomed

Sealing devices and accessories for sterile goods packaging in clinics, central sterilization departments (CSSD) and the medical industry



hawotest

Testing systems for the validation (Operational and Performance Qualification) of heat sealing processes



hawodent

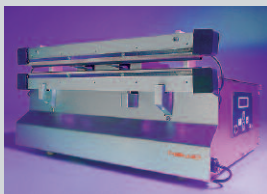
Sealing devices and accessories for sterile goods packaging in dentists' and doctors' surgeries

See also: www.generationeasy.com



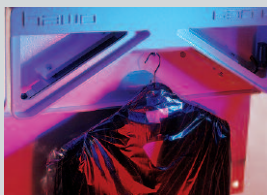
hawoplast

Plastic film welding devices for industrial packaging



hawovac

Vacuum impulse sealers for industrial and medical packaging



hawopack

Packaging machines for clothes and linen for laundries, dry cleaners and the fashion industry

Subject to technical alterations

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hawo

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